REVISTA DE EPIDEMIOLOGIA E CONTROLE DE INFECÇÃO

RECI

2025

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

VOLUME 15

ISSN 2238-3360 | ANO XV - VOLUME 15 - NÚMERO 1 - 2025

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

Revista de Epidemiologia e Controle de Infecção

ISSN 2238-3360

Elaboração, veiculação e informações: *Núcleo de Epidemiologia do Hospital Santa Cruz*
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PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

Revista de Epidemiologia e Controle de Infecção

ISSN 2238-3360

R454 Revista de epidemiologia e controle de infecção [recurso eletrônico] / Núcleo Hospitalar de Epidemiologia do Hospital Santa Cruz, Programa de Pós Graduação em Promoção da Saúde.
Vol. 15, n. 1 (2025) Jan./Mar. - Santa Cruz do Sul: EDUNISC, 2025.

Dados eletrônicos.
Modo de acesso: World Wide Web: <http://www.unisc.br/edunisc>
Trimestral
eISSN 2238-3360

Temas: 1. Epidemiologia - Periódicos. 2. Microbiologia - Periódicos.
3. Doenças transmissíveis - Periódicos.
I. Núcleo Hospitalar de Epidemiologia do Hospital Santa Cruz. II. Título.

CDD: 614.405

Catalogação: Bibliotecária Jorcenita Alves Vieira CRB – 10/1319

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

Revista de Epidemiologia e Controle de Infecção

ISSN 2238-3360

Sumário

Artigo Original

Artigo de Revisão

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ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Nurses' knowledge about safety in the clinical management of patients with influenza: a cross-sectional study

Conhecimento de enfermeiros sobre a segurança no manejo clínico de pacientes com influenza: estudo transversal

Conocimientos del enfermero sobre seguridad en el manejo clínico de pacientes con influenza: estudio transversal

Site doi: https://doi.org/10.17058/reci.v15i1.19391

Submitted: 04/30/2024
Accepted: 11/07/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: to assess nurses' knowledge profile about the indications for the clinical management of *influenza*. **Methods:** descriptive cross-sectional study, carried out in October 2019. Sociodemographic and clinical variables were assessed of 53 nurses, compared using descriptive and univariate statistics. **Results:** nurses reported that returning to the health service to review the clinical condition is not an indication for the clinical management of patients with *influenza*-like syndrome (IS) with risk factors for complications (10; 19.0%). The indigenous population living in villages (3; 6.0%) and individuals under 19 years of age, in prolonged use of acetylsalicylic acid (36; 68.0%), are not/do not know that they are considered risk factors for complications. The use of symptomatic medications (5; 9.0%), the use of oseltamivir phosphate (16; 30.0%) and returning to the health service for review of the clinical condition (12; 23.0%) are not indications for the clinical management of patients with IS, without risk factors for complications, as well as the use of oxygen therapy, continuous monitoring and hospital admission if there are signs of worsening, including $SatO_2$ <95% (3; 6.0%), the use of oseltamivir phosphate (3; 6.0%), the performance of a radiological examination (1; 2.0%) and the control of hyperthermia with paracetamol (4; 7.0%) are not/do not know that they are indications for the clinical management of pregnant/postpartum women. **Conclusion:** nurses' knowledge is satisfactory, but there are doubts regarding the care of more specific patients, such as pregnant and postpartum women as well as the risk factors or conditions for complications.

Keywords: *Knowledge. Human Influenza. Nurse.*

RESUMO

Justificativa e Objetivos: avaliar o perfil de conhecimento de enfermeiros sobre as indicações para o manejo clínico da *influenza*. **Métodos:** estudo transversal descritivo, realizado em outubro de 2019. Foram avaliadas variáveis sociodemográficas e clínicas de 53 enfermeiros, comparadas através de estatística descritiva e univariada. **Resultados**: enfermeiros referiram que retornar ao serviço de saúde para revisão do quadro clínico não é uma indicação para o manejo clínico de pacientes com síndrome gripal (SG), com fatores de risco para complicações (10; 19,0%). População indígena aldeada (3; 6,0%) e indivíduos menores de 19 anos de idade, em uso prolongado de ácido acetilsalicílico (36; 68,0%), não são/não sabem que são considerados fatores de risco para complicações. O uso de medicamentos sintomáticos (5; 9,0%), o uso de fosfato de oseltamivir (16; 30,0%) e retornar ao serviço de saúde para revisão do quadro clínico (12; 23,0%) não são indicações para o manejo clínico do paciente com SG, sem fatores de risco para complicações, assim como o uso de oxigenoterapia, monitorização contínua e internação hospitalar se houver sinais de agravamento, incluindo $SatO_2$<95% (3; 6,0%), o uso de fosfato de oseltamivir (3; 6,0%), a realização de exame radiológico (1; 2,0%) e o controle de hipertermia com paracetamol (4; 7,0%) não são/não sabem que são indicações para o manejo clínico de gestantes/puérperas. **Conclusão**: o conhecimento dos enfermeiros é satisfatório, porém há dúvidas com relação ao cuidado de pacientes mais específicos, como grávidas e puérperas, bem como sobre os fatores ou condições de risco para complicações.

Descritores: *Conhecimento. Influenza Humana. Enfermeiro.*

RESUMEN

Justificación y Objetivos: evaluar el perfil de conocimiento de los enfermeros sobre las indicaciones para el manejo clínico de la *influenza*. **Métodos**: estudio descriptivo transversal, realizado en octubre de 2019. Variables sociodemográficas y clínicas. Fueron evaluados 53 enfermeros, comparados mediante estadística descriptiva y univariada. **Resultados:** los enfermeros informaron que regresar al servicio de salud para revisar el cuadro clínico no es una indicación para el manejo clínico de pacientes con síndrome gripal (SG), con factores de riesgo para complicaciones (10; 19,0%). La población indígena de las aldeas (3; 6,0%) y los individuos menores de 19 años, en uso prolongado de ácido acetilsalicílico (36; 68,0%), no saben/no saben que se consideran factores de riesgo de complicaciones. El uso de medicamentos sintomáticos (5; 9,0%), el uso de fosfato de oseltamivir (16; 30,0%) y el regreso al servicio de salud para revisar el cuadro clínico (12; 23,0%) no son indicaciones para el manejo clínico de pacientes con SG, sin factores de riesgo de complicaciones, así como el uso de oxigenoterapia, monitorización continua e ingreso hospitalario si existen signos de empeoramiento, incluyendo $SatO_2$<95% (3; 6,0%), el uso de fosfato de oseltamivir (3; 6,0%), la realización de exámenes radiológicos (1; 2,0%) y el control de la hipertermia con paracetamol (4; 7,0%) no son/no saben que son indicaciones para el manejo clínico de mujeres embarazadas/posparto. **Conclusión:** el conocimiento de las enfermeras es satisfactorio, sin embargo, existen dudas respecto de la atención de pacientes más específicos, como las mujeres embarazadas y puérperas, así como los factores o condiciones de riesgo para complicaciones.

Palabras Clave: *Conocimiento. Gripe humana. Enfermero.*

INTRODUCTION

Respiratory diseases are the second leading cause of hospital admissions and the third leading cause of death worldwide, affecting 10% to 20% of the world's population.[1] Among them, *influenza* is present with its complications and evolution to severe forms, being considered, in the ranking, the first in number of hospital admissions, causing deaths and high costs to health services.[2] And subtype A is responsible for the occurrence of most epidemics worldwide.[3]

Influenza is an acute viral infectious disease of the respiratory system, which is highly transmissible and globally distributed, and has a self-limiting course. However, when severe forms manifest, it causes rapid and fatal death, especially in individuals who present risk factors or conditions for complications from the infection.[3] The *influenza* virus, called *Myxovirus influenzae*, branches into types A, B and C, and only types A and B show clinical relevance in humans, being correlated with outbreaks and epidemics of respiratory origin.[4]

The most common complications of the *influenza* virus are *influenza*-like syndrome (IS), which consists of cases of people with fever, accompanied by cough and/or sore throat, with symptoms beginning in the last seven days, and severe acute respiratory syndrome (SARS), which is characterized by cases of people of any age, with IS, who present dyspnea or oxygen saturation (SpO_2) <95%, in room air, signs of respiratory distress and increased respiratory rate, according to age, and hypotension, in relation to frequent blood pressure, before the onset of symptoms.[3]

Surveillance of *influenza* and other respiratory viruses in Brazil consists of sentinel surveillance of IS and surveillance of SARS in hospitalized patients and deaths from SARS. Its objective is to monitor cases of IS due to respiratory viruses of public health importance in selected health units, called sentinel units, so that they serve as an early warning to the surveillance system.[5]

Worldwide, it is estimated that one billion cases of *influenza* occur annually, with three to five million cases of severe illness, with mortality ranging from 290,000 to 650,000 due to complications related to the disease.[6] In Brazil, in 2024, up to epidemiological week (EW) number 37, 61,124 cases of SARS were reported, with identification of respiratory viruses, 27% of which were *influenza* viruses, with 22% of deaths.[7] In Ceará, up to EW 15 of 2024, it is shown that the *influenza* A virus was detected in 1,631 (46.8%) samples. Of these, 275 (16.9%) were subtyped, with a predominance of H1N1 in 172 (62.5%). A total of 2,268 cases of SARS were also confirmed in the state.[8]

At a national level, care for patients with *influenza* must currently be provided in accordance with the *Influenza* Management and Treatment Guide, which aims to guide therapeutic conduct for *influenza*, as well as intra- and extra-hospital control measures.[5]

Knowing and assessing nurses' knowledge profile on the clinical management of patients with *influenza* will involve local, state and federal municipal managers, together with health professionals from each region of the country, to create ongoing and permanent educational strategies, through training on the use of *influenza* management and treatment guides, seeking to minimize errors resulting from unsafe care, as well as complications and injuries resulting from the disease. Thus, the study aims to assess nurses' knowledge profile regarding the indications for the clinical management of *influenza*.

METHODS

This is a descriptive cross-sectional study carried out in Basic Health Units (BHU), Emergency Care Unit, polyclinic and municipal hospital, located in the municipality of Quixadá, in the state of Ceará, with approximately 80,600 inhabitants. The report was guided by the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement.[9]

The study population consisted of 70 nurses, with the sample consisting of nurses working in the city's health services. Nurses who had been working for more than three months in these locations were included. Nurses who were on maternity leave, vacation or away from work for some other reason during the data collection period were excluded, totaling 53 nurses.

The data were collected in October 2019, using a questionnaire-type instrument, prepared based on the Ministry of Health's 2017 *Influenza* Treatment Protocol.[10] The questionnaire has 11 items.

To collect data, daily visits were made to services, from Monday to Friday, approaching nurses, before or after their care activities, without interfering in care routine. At this time, the purpose of the study and its objective were presented to participants, explaining the importance of the Informed Consent Form. After a participant signed, the questionnaire was given to the participant to complete.

The data were tabulated in a spreadsheet created in Microsoft Excel by the researcher himself, based on the variables in the questionnaire. They were then subjected to statistical analysis using EPI INFO 7.0, generating percentage frequencies, which were displayed in tables and later interpreted and discussed in conjunction with the bibliography on the subject.

The research was designed in compliance with the ethical aspects recommended in Resolutions 466/12 and 518/2018 of the Brazilian National Health Council, which regulate research with human beings, and was approved under Opinion 3,660,758 and Certificate of

Presentation for Ethical Consideration 23697019.7.0000.5046, on 10/24/2019.

RESULTS

The sociodemographic characterization of the 53 nurses participating in the research showed that the majority were women (49; 92.4%), aged between 31 and 59 years old (47; 88.8%), married/stable union (32; 60.0%), working at the BHU (18; 34.0%) (Table 1).

Table 1. Sociodemographic characterization of nurses in health services of Quixadá, Ceará. Quixadá, Ceará, Brazil, 2019.

Variables	N=53 (%)
Sex	
Male	04 (7.6)
Female	49 (92.4)
Age group	
18-30 years	05 (9.4)
31-59 years	47 (88.8)
>=60 years	01 (1.8)
Marital status	
Single	21 (40.0)
Married/stable union	32 (60.0)
Health service	
Basic Health Unit	18 (34.0)
Emergency Care Unit	16 (30.0)
Polyclinic	03 (6.0)
Municipal hospital	16 (30.0)

The analysis of the distribution of indications for the clinical management of patients with IS who present risk factors for complications revealed that all nurses demonstrated knowledge about the importance of the use of symptomatic medications, adequate hydration and oseltamivir phosphate, with 100% agreement on each of these measures (53; 100.0%). Furthermore, 81% of nurses (43) indicated the need to return to the health service to review patients' clinical condition, while 19% (10) did not mention this recommendation (Table 2).

Table 2. Distribution of indications for clinical management of patients with *influenza*-like illness, with risk factors for complications, according to nurses' knowledge. Quixadá, Ceará, Brazil, 2019.

Variables	N=53 (%)
Symptomatic medications	
Yes	53 (100.0)
Hydration	
Yes	53 (100.0)
No	
Does not know	
Oseltamivir phosphate	53 (100.0)
Yes	
Returning to the health service to review the clinical condition	
Yes	43 (81.0)
No	10 (19.0)

The distribution of conditions and risk factors for complications, according to nurses' knowledge, indicated unanimous agreement (53;100%) in several categories, including pregnant women at any gestational age, postpartum women up to two weeks postpartum, adults aged 60 or over, children under five years old and individuals with conditions such as lung diseases, tuberculosis, cardiovascular diseases, nephropathies, liver diseases, hematological diseases, metabolic disorders, neurological disorders, immunosuppression, neoplasms, HIV/Aids, among others, in addition to obesity.

A significant number of nurses (50;94%) also recognized the indigenous population living in villages or with difficult access as a risk group. However, a relevant portion (36;68%) is unaware that individuals under 19 years of age who are taking acetylsalicylic acid (ASA) for a long time are at risk of complications, which highlights an important gap in knowledge (Table 3).

Table 3. Distribution of condition(s) and risk factor(s) for *influenza* complications according to nurses' knowledge. Quixadá, Ceará, Brazil, 2019.

Variables	N=53 (%)
Pregnant women at any gestational age	53 (100.0)
Yes	
Women who have given birth up to two weeks after giving birth	53 (100.0)
Yes	
Adults ≥ 60 years	53 (100.0)
Yes	
Children <5 years	53 (100.0)
Yes	
Indigenous population living in villages or with difficult access	50 (94.0)
Yes	03 (6.0)
Does not know	
Individuals under 19 years of age using acetylsalicylic acid for a long time	11 (21.0)
Yes	36 (68.0)
No	06 (11.0)
Does not know	
Individuals with lung disease, tuberculosis of all forms, cardiovascular disease, nephropathy, liver disease, hematological diseases, metabolic disorders, neurological and developmental disorders that may compromise respiratory function or increase the risk of aspiration, immunosuppression associated with medications, neoplasms, HIV/AIDS or others, obesity	53 (100.0)
Yes	

In relation to the distribution of indications for clinical management of patients with IS, without risk factors for complications, the results were heterogeneous. All nurses reported the indication of hydration (53; 100.0%), while 48 (91.0%) mentioned the use of symptomatic medications, 36 (68.0%), the use of oseltamivir phosphate, and 41 (77.0%) advised returning to the health service to review the clinical condition (Table 4).

Table 4. Distribution of indications for clinical management of patients with *influenza*-like illness, without risk factors for complications, according to nurses' knowledge. Quixadá, Ceará, Brazil, 2019.

Variables	N=53 (%)
Symptomatic medications	48 (91.0)
Yes	05 (9.0)
No	
Hydration	53 (100.0)
Yes	
Oseltamivir phosphate	36 (68.0)
Yes	16 (30.0)
No	01 (2.0)
Does not know	
Returning to the health service to review the clinical condition	41 (77.0)
Yes	12 (23.0)
No	

The distribution of indications for the clinical management of pregnant and postpartum women, according to nurses' knowledge, identified that all refer to: complete physical examination with measurement of vital signs (53; 100.0%); observing warning signs in

pregnant women with respiratory rate values >20 rpm or heart rate >100 bpm% (53; 100.0%); and precautions with newborns in the postpartum period (53; 100.0%) (Table 5).

Table 5. Distribution of indications for clinical management of pregnant and postpartum women according to nurses' knowledge. Quixadá, Ceará, Brazil, 2019.

Variables	N=53 (%)
Complete physical examination with measurement of vital signs	
Yes	53 (100)
Observing warning signs in pregnant women with respiratory rate values >20 rpm or heart rate >100 bpm%	
Yes	53 (100)
Oxygen therapy, continuous monitoring and hospital admission if there are signs of worsening, including $SatO_2$<95%	
Yes	50 (94.0)
No	03 (6.0)
Oseltamivir phosphate	
Yes	49 (92.0)
No	01 (2.0)
Does not know	03 (6.0)
Radiological examination	
Yes	52 (98.0)
No	01 (2.0)
Controlling hyperthermia with paracetamol	
Yes	47 (89.0)
No	04 (7.0)
Does not know	02 (4.0)
Precautions for newborns in the postpartum period	
Yes	53 (100.0)

All nurses are aware of the indications for clinical management of patients with SARS, such as: hospital admission; intravenous hydration; oxygen therapy; maintaining clinical monitoring; measuring vital signs; oseltamivir phosphate; collecting respiratory secretion samples for laboratory testing; and indications for hospitalization of patients with *influenza* in the Intensive Care Unit (ICU), such as: persistent hemodynamic instability; signs and symptoms of respiratory failure, including hypoxemia requiring oxygen supplementation to maintain arterial oxygen saturation above 90%; and progression to other organ dysfunctions, such as acute renal failure and neurological dysfunction.

As for the problems and failures in implementing clinical management based on the 2017 *Influenza* Treatment Protocol, all reported a lack of training on the use of the protocol (53; 100.0%), and more than 50% reported a lack of knowledge about the disease (34; 64.0%), lack of knowledge about the protocol (37; 70.0%) and lack of training by the municipality (45; 85.0%).

DISCUSSION

The study describes the knowledge of 53 nurses about the indications for the clinical management of patients with *influenza*, a seasonal infection that causes significant morbidity and mortality and economic losses, worldwide and every year, requiring targeted and quality care for patients at different levels of care.[11]

Regarding the disease clinical management, it is known that all patients with IS and with conditions and risk factors for complications should be advised to return to the health service for a review of clinical condition, where they should be reassessed in relation to the criteria for SARS or other signs of worsening. It can be seen, therefore, that the professionals investigated had good knowledge regarding many care measures; in this item, however, the health team needs to know that the importance of returning to the health service to reassess the health status is an essential step in the clinical management of the disease of patients with IS and risk factors for complications.[5]

The study showed that, in the sample analyzed, there are nurses who are unaware that indigenous populations living in villages or with difficult access constitute one of the risk factors for complications from *influenza*. However, Ordinance 2,436 of September 21, 2017, which approves the Brazilian National Primary Care Policy, considers that it is a common responsibility of all members of teams working in Primary Health Care, such as nurses, to be responsible for monitoring the population involved, meeting the needs for preventive care and seeking comprehensiveness in the provision of services.[12-13]

Another variable that deserves attention, as it presented a result that differs from what is recommended in the literature, is that individuals under 19 years of age, in prolonged use of ASA, is also not a risk factor for complications from *influenza*. In this context, it is worth mentioning that, since 1980, the Food and Drug Administration and the Centers for Disease Control and Prevention recommend that aspirin should not be used to treat acute febrile viral illnesses in children and adolescents under 19 years of age, as its use may cause Reye's syndrome, which is a rare but life-threatening acute non-inflammatory encephalopathy with fatty liver failure.[14-15]

Regarding the indications for clinical management of patients with IS without risk factors for complications, a significant percentage of nurses report that the use of oseltamivir phosphate is not recommended. It is known that oseltamivir phosphate has extensive evidence supporting its safe and effective use in the treatment and prevention of *influenza* in older adults, including those with complicated infections or who reside in Nursing Homes, requiring only dose adjustments in renal patients.[16] Furthermore, its prescription, in addition to symptomatic medications and hydration, should be considered based on clinical judgment, preferably in the first 48 hours after the onset of the disease.[5]

During pregnancy, extending into the puerperal phase, physiological changes occur, including changes in cellular immunity, increased heart rate and systolic volume, and increased oxygen consumption, which leads to cautious care by nurses when pregnant and postpartum women are affected by *influenza*. It is a cause for concern that, in this study, some nurses reported not knowing important indications when

approaching this population.[17-18] However, ideally, these professionals, in their services, should promote efforts to improve vaccination coverage, through informative conversations with patients, which could protect mothers and their babies against serious respiratory diseases.[19]

Regarding the care of patients with *influenza* that progress to SARS, characterized by symptoms of high fever, cough and dyspnea, accompanied by increased respiratory rate, hypotension in relation to patients' usual blood pressure, and, often, lack of smell, taste and appetite, it is known that the recognition of these signs of severity by nurses is essential, in order to carry out the appropriate indications in the clinical management of these patients, as seen in the results of this research, as this is one of the most worrying manifestations among respiratory infections in humans.[5, 20]

Turning to indications for patients with *influenza* who should be admitted to the ICU, research, which sought to analyze a large cohort of patients hospitalized, in this context, for severe *influenza*, over ten years, showed that overall mortality was 25.1%. The predominant clinical presentation was specific lung involvement, which rapidly required mechanical ventilation and often progressed to acute respiratory distress syndrome. Therefore, timely admission to the ICU is recommended as early as possible in cases of respiratory failure in order to allow effective intensive care, which was known to all nurses working in the health services studied.[21]

Finally, regarding the problems and failures in implementing clinical management based on the 2017 *Influenza* Treatment Protocol, alarming data were found in the research regarding nurses' lack of knowledge about *influenza* and the protocol for managing it clinically, as well as the result of a study that sought to understand the dynamics of knowledge, attitudes and practices of health professionals related to *influenza*, suggesting political implications and advocating the review of national strategies to strengthen the training of health professionals on a disease that has been present in Brazil since the last century, and which has a large increase in the number of cases each year.[22]

Furthermore, the report of the municipality's lack of training on the disease and the use of the treatment protocol is quite concerning, considering that *influenza* continues to cause up to five million cases of serious illness resulting in 500,000 deaths worldwide.[23] However, in Brazil, the Brazilian National Policy for Continuing Education seeks to transform health work, with the aim of encouraging critical, reflective, committed and technically efficient action, and respect for regional characteristics and specific training needs of professionals working in health services, for the transformation of health practices towards meeting the fundamental principles of the Brazilian Health System, based on local reality and collective analysis of work processes. It is clear that it is the role of health managers and professionals to seek to improve health practices to the detriment of offering quality care.[24]

Finally, each year, changes in the viral involvement profile of different types of diseases may reflect the effect of different variants, which implies the relevance of knowledge by nurses as well as by all health professionals about the clinical management not only of *influenza*, but of several other viral infections, based on the recommendations of official guidelines and protocols of national and international government agencies, in order to offer safe care to patients.[25]

The study's limitations included the lack of availability and lack of interest of most professionals in answering the questionnaire, as many reported not feeling confident enough to answer, mainly due to a lack of knowledge about the protocol and even about the disease. Many nurses also stated that there were no cases of *influenza* in their services.

In conclusion, the study achieved its objective by assessing nurses' knowledge profile regarding the indications for clinical management of *influenza*. The results demonstrate that, although nurses have a good level of knowledge in most of the areas assessed, some important gaps were identified.

It is suggested that municipal health departments carry out more frequent training in relation to the entire context surrounding the disease, since it is a pathology that affects people worldwide every year.

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All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Campos RKGG, Pinheiro AB, Maniva SJCF, Benevides JL, Holanda RE. Nurses' knowledge about safety in the clinical management of patients with influenza: a cross-sectional study. Rev Epidemiol Control Infect [Internet]. 2025 Jan. 4;15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19391

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Construction and validity of a bundle to prevent skin infections due to burns: a methodological study

Construção e validação de bundle para prevenção de infecção de pele por queimaduras: estudo metodológico
Construcción y validación de un paquete para prevenir infecciones de la piel por quemaduras: estudio metodológico

Site doi: https://doi.org/10.17058/reci.v15i1.19599

Submitted: 07/10/2024
Accepted: 11/22/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: skin infections can occur in burn patients due to the loss of the main protective and immunological barrier. Although there are general protocols for treating burns and preventing infection, few are suitable exclusively for children and adolescents. Aiming to prevent and improve routine care, this study aimed to build and validate a bundle for the management and prevention of skin infections due to burns in children and adolescents. **Methods:** a methodological study developed at a Burn Treatment Center in northern Paraná from March 2021 to December 2023. The research was developed in three phases, theoretical, empirical and analytical, through statistical analysis in the Statistical Package for the Social Sciences. **Results:** bundle content validity was performed by seven professionals who were experts in the subject. Regarding the bundle content validity, there was 100% agreement among all participants regarding the dimensions assessed: objectivity; layout; simplicity; clarity; relevance; variety; breadth; credibility; and balance. The Content Validity Index was used to verify the bundle content validity. Of the nine items in validity with judges, the Content Validity Index was equal to 1.0. In accordance with the results and minimal suggestions in the bundle, only one round of validity with judges was carried out. **Conclusion:** the bundle was validated to support the treatment of severe burns given the complexity of careful and multidisciplinary management.

Keywords: *Burn Units. Hospital Infection Control Program. Patient Care Bundles. Burns.*

RESUMO

Justificativa e Objetivos: infecções de pele podem ocorrer em pacientes com queimaduras devido à perda da principal barreira protetora e imunológica. Apesar de existir protocolos gerais para tratamento de queimaduras e prevenção de infecção, poucos são adequados exclusivamente para crianças e adolescentes. Visando prevenir e aprimorar a rotina na assistência, o objetivo do estudo foi construir e validar um *bundle* para o manejo e prevenção de infecção de pele por queimaduras em crianças e adolescentes. **Métodos:** estudo metodológico desenvolvido em um Centro de Tratamento de Queimados no norte do Paraná de março de 2021 a dezembro de 2023. A pesquisa foi desenvolvida em três fases, teórica, empírica e analítica, mediante análise estatística no *Statistical Package for the Social Sciences*. **Resultados:** a validação de conteúdo do *bundle* foi realizada por sete profissionais *experts* na temática. Quanto à validade de conteúdo do *bundle*, houve uma concordância de 100% entre todos os participantes diante das dimensões avaliadas: objetividade; *layout*; simplicidade; clareza; relevância; variedade; amplitude; credibilidade; e equilíbrio. Para a verificação da validade de conteúdo do *bundle*, foi utilizado o Índice de Validade de Conteúdo. Dos nove itens na validação com os juízes, o Índice de Validade de Conteúdo foi igual a 1,0. Em conformidade com os resultados e mínimas sugestões no *bundle*, foi decorrida apenas uma rodada na validação com os juízes. **Conclusão:** o *bundle* foi validado para subsidiar o tratamento de queimaduras grave devido à complexidade do manejo cuidadoso e multidisciplinar.

Descritores: *Unidades de Queimados. Programa de Controle de Infecção Hospitalar. Pacotes de Assistência ao Paciente. Queimaduras.*

RESUMEN

Justificación y Objetivos: las infecciones de la piel pueden ocurrir en pacientes con quemaduras debido a la pérdida de la principal barrera protectora e inmunológica. Aunque existen protocolos generales para tratar quemaduras y prevenir infecciones, pocos son adecuados exclusivamente para niños y adolescentes. Con el objetivo de prevenir y mejorar la atención de rutina, el objetivo del estudio fue construir y validar un paquete de medidas para el manejo y la prevención de la infección de la piel por quemaduras en niños y adolescentes. **Métodos:** estudio metodológico desarrollado en un Centro de Tratamiento de Quemados del norte de Paraná de marzo de 2021 a diciembre de 2023. La investigación se desarrolló en tres fases, teórica, empírica y analítica, mediante análisis estadístico en el *Statistical Package for the Social Sciences*. **Resultados:** la validación de contenido del paquete fue realizada por siete profesionales expertos en el tema. En cuanto a la validez de contenido del paquete, hubo 100% de acuerdo entre todos los participantes respecto de las dimensiones evaluadas: objetividad; disposición; sencillez; claridad; pertinencia; variedad; amplitud; credibilidad; y equilibrio. Para comprobar la validez del contenido del paquete, se utilizó el Índice de Validez del Contenido. De los nueve ítems validados con los jueces, el Índice de Validez de Contenido fue igual a 1,0. De acuerdo con los resultados y las sugerencias mínimas del paquete, solo se realizó una ronda de validación con los jueces. **Conclusión:** el paquete fue validado para apoyar el tratamiento de quemaduras graves dada la complejidad del manejo cuidadoso y multidisciplinario.

Palabras Clave: *Unidades de Quemados. Programa de Control de Infecciones Hospitalarias. Paquetes de Atención al Paciente. Quemaduras.*

INTRODUCTION

According to the World Health Organization, burns are considered the fourth most common type of trauma in the world. They constitute a major global health concern, significantly impacting the affected population's quality of life, affecting all age groups, and can cause minor, serious injuries and death.[1]

Most of the burns reported in Brazil occurred in the victim's home, with half of them involving children. According to data from the Brazilian Health System Department of Information Technology[2], between September 2020 and August 2021, there were more than 9,000 hospitalizations of newborns, children and adolescents who were victims of burns.[2] The most affected age group was 1 to 4 years.[2] It is estimated that approximately 1 million Brazilians suffer burn accidents annually. Of these cases, approximately 100,000 require hospitalization and approximately 2,500 result in death.[3]

Those who suffer extensive and severe burn injuries require intensive care and are often admitted to Burn Treatment Centers (BTCs) for prolonged hospital stays.[4-5]

Thus, the need to develop simplified protocols and packages of measures, based on high-standard evidence literature, is essential to guide and improve professional practice and, consequently, improve care, given the positive impacts on care contributing to the improvement of care provided.[6-7]

As a result, in the mid-2000s, in the United States of America, standardized bundles emerged, with the aim of implementing protocols for the prevention of infection, aiming to improve care and hospitalized individuals' quality of life.[8]

Therefore, to facilitate the teaching-learning process, the use of educational technologies is essential to raise awareness and encourage new evidence-based practices in the construction of knowledge, in addition to enabling decision-making. Such educational tools can be booklets, folders, pamphlets, leaflets and manuals, serving as a guide for health promotion.[9]

In Brazil, this topic is considered relatively recent and some hospital units are still in the process of implementation. Although studies present some conducts, there is still no systematic evidence in literature of bundles regarding the prevention and management of infection in skin lesions due to burns in children and adolescents.

This age group undoubtedly presents unique challenges due to their thinner skin and still developing immune system, as well as the specialized center where this study was conducted, not having a bundle for children and adolescents with burns. Thus, the importance of its construction and validity is justified. Therefore, the construction and validity of a specific bundle for burns in pediatrics are essential to ensure the best adherence of professionals.

Considering the importance of preventing and managing infection in burn skin injuries in children and adolescents to aid daily practice and improve the quality of care provided, the question is: is the construction of a bundle valid and feasible for implementation in a specialized center to improve care planning and promote benefits in the therapeutic process? Therefore, this study aimed to construct and validate a bundle for the management and prevention of burn skin infections for children and adolescents.

METHODS

This is a methodological study developed in a specialized center in a public tertiary university hospital, in the northern region of the state of Paraná, from March 2021 to December 2023.

This study was conducted at a referral hospital in the northern region of Paraná that provides specialized care to children, adolescents, adults and elderly victims of first- to third-degree burns. This unit has been in existence for over 15 years, with capacity for ten ward beds, six Intensive Care Unit (ICU) beds, a balneotherapy room, two surgical rooms, an outpatient clinic (Emergency Care) and a hyperbaric oxygen therapy room.

The research was developed in three phases: (a) theoretical phase consisting of literature review, prototype construction, layout development, design and texts; (b) empirical phase consisting of a dialogued expository class and bundle assessment by professionals working in care and experts in the area; (c) analytical phase consisting of the application of statistical analysis.

Theoretical phase: the first phase was carried out from March to June 2021. The following descriptors (DeCS/MeSH) were used for literature review: "Burn Units", "Hospital Infection Control Program", "Patient Care Bundles" and "Burns", combined with the Boolean operator AND. Original studies, systematic reviews, open access, published between 2010 and 2023 were included, with the aim of covering the most recent studies in the area of interest, in the Virtual Health Library, Scientific Electronic Library Online and Latin American and Caribbean Literature in Health Sciences databases. Gray literature was also used, consisting of manuals and protocols on healthcare-related infections from the Ministry of Health and the Brazilian Burn Society. Duplicate studies were excluded. The instrument was constructed in a diagram, in which each structured figure has the main aspects and relevant content to guide decision-making in clinical practice.

Empirical phase: in the second phase, the sample of professionals was intentionally selected, with the following inclusion criteria: being a professional

working at BTC for more than one year in the categories: nursing technicians, nurses and physiotherapists. It should be noted that the bundle is applicable to children ≤ 12 years of age and adolescents (between 12 and 18 years of age).

Subsequently, participants were approached through successive conversations with the team involved and professionals who were experts in the area. The invitation was made in person by the main researcher and explained their participation in the research, the research objectives and methods, guaranteeing anonymity through the signing of the Informed Consent Form. After that, professionals were scheduled for classes according to their availability during the morning, afternoon and evening work shifts.

To assist in the bundle construction and improvement, the researcher held a 30- to 40-minute lecture to guide the team during each work shift. Afterwards, a questionnaire with two open-ended questions was applied for participants to describe the skin infection prevention measures carried out in the sector and what other measures would be feasible to implement.

After analyzing the feasibility, available literature and meetings with experts, considering the exchange of knowledge, five measures were defined to compose the bundle, namely: 1 – Room cleaning twice a day, a terminal cleaning when the room is unoccupied or weekly in prolonged hospitalizations; 2 - Strict hand hygiene; 3 - Use of personal protective equipment; 4 - Early excision and grafting of full-thickness burns; 5- Use of topical antimicrobial dressings.

Throughout the period of the dialogued intervention, participants were free to contribute to discussions on the topic, integrating knowledge and perspectives permeating exchange of knowledge. The entire process of construction and elaboration took place between April and August 2022.

Data collection and expert participation took place in an online round. The link was sent via WhatsApp®, using the Google Forms® electronic tool, and the bundle was attached to the questionnaire, which included data related to expert characterization (age, gender, current occupation, professional category, time since graduation, title and time working in the burns area) and the Content Validity Instrument, composed of 9 items that assessed objectivity, layout, simplicity, clarity, relevance, variety, breadth, credibility and balance. Each item contained affirmative sentences on a 5-point Likert scale and, after reading the material and assessing the bundle, judges could assess the item as (5) totally agree, (4) partially agree, (3) neither agree nor disagree, (2) partially disagree and (1) totally disagree. Judges were instructed to justify the scores 1, 2 and 3. This assessment and validity phase took place in December 2023.

Analytical phase: data organization and analysis were performed using the Statistical Package for the Social Sciences version 19. To characterize professionals, descriptive analysis was used, available in numbers and percentages, and judges were characterized. A descriptive data analysis was performed, with the calculation of absolute and relative frequencies. To verify the bundle content validity, the Content Validity Index (CVI) was used, with the calculation of the Item-Level Content Validity Index for each item of the instrument and the overall CVI. The bundle was considered valid when each item obtained a CVI equal to or greater than 0.80.

This study was conducted in accordance with the recommendations set out in Resolution 466/2012 of the Brazilian National Health Council. The study is part of a research project entitled "*Avaliação das infecções relacionadas à assistência à saúde em crianças e adolescentes*", approved by the *Universidade Estadual de Londrina* Research Ethics Committee on April 26, 2020, under Opinion 3.991.033 and Certificate of Presentation for Ethical Consideration 28068119.6.0000.5231.

RESULTS

The theoretical phase allowed for a literature review, which enabled the bundle construction, and after consensus meetings with the entire BTC team, in the empirical phase, the intervention was carried out through a dialogued class with the participation of 53 professionals. However, of these, 30 met the inclusion criteria for the protocol elaboration, being 18 nursing technicians (60%), seven nurses (23.3%) and five physiotherapists (16.7%), with an average age of 44.5 years. As for the most frequent qualification was higher education (40%), followed by specialization (23.3%), technical education (16.7%) and master's and doctoral degrees (10%). Concerning the time of professional experience in the research sector, 53.3% had 11 to 15 years, 26.7%, 1 to 5 years, and 20%, 6 to 10 years.

The content was structured based on scientific evidence, practical experience of the researcher, healthcare professionals and experts, all working in the research scenario, considering the individual needs and distinct specificities of children and adolescents who are victims of burn injuries. The material was developed by the researcher using the Microsoft PowerPoint - Microsoft 365® program to create illustrations and a textual diagram structured in topics (Figure 1).

After the construction and intervention were completed, banners containing the bundle were created and installed in the different BTC units (ward, ICU, balneotherapy and surgical rooms) for access and visibility by the entire team. The same printed material contained a QR Code so that the protocol could be

circulated both among the BTC team and in the scientific community, configuring itself as a safe and effective tool for multidisciplinary assistance to individuals who are victims of burns (Figure 2).

It is important to emphasize that the bundle was presented to all healthcare professionals involved in the study so that the protocol's relevance and usefulness could be emphasized and, consequently, implemented through continuous adherence through team collaboration and involvement working at the BTC.

After the theoretical and empirical phase, the final version of the bundle for management and prevention of skin infection due to burns for children and adolescents was created, consisting of five measures:

1) Room cleaning twice a day, a terminal cleaning when the room is unoccupied or weekly in prolonged hospitalizations

Critical areas are where there is an increased risk of infection transmission, where immunocompromised patients are found:[10-11]

- BTC;
- ICU;
- Operating Room.

2) Strict hand hygiene

In critical areas such as units with immunocompromised patients, the hands of healthcare professionals can be colonized by pathogenic microorganisms.[12]

- Rubbing antiseptic on hands: 20 to 30 seconds;
- Hand hygiene with soap and water: 40 to 60 seconds;
- Antiseptic hand hygiene: 40 to 60 seconds;
- Surgical antisepsis or preoperative hand preparation:

3 to 5 minutes – first surgery;
2 to 3 minutes – subsequent surgeries.

3) Use of personal protective equipment

Personal protective equipment is one of the measures in the prevention and control of infections in sectors that care for critical patients with bacterial resistance due to the high frequency of antibiotic use and disruption of the tissue barrier.[13]

4) Early excision and grafting of full-thickness burns

Excision and closure of deep wounds help prevent sepsis, decrease systemic inflammation, and speed healing. The wound may be covered with:[14]

- Autograft,
- Allograft;
- Synthetic substitute fabric.

5) Use of topical antimicrobial dressings

- Protect the damaged epithelium;
- Minimize bacterial and fungal colonization;
- Provide immobilization to maintain the appropriate functional position;
- Be occlusive to minimize heat loss and cold aggression;
- Provide comfort to the painful wound.[15]

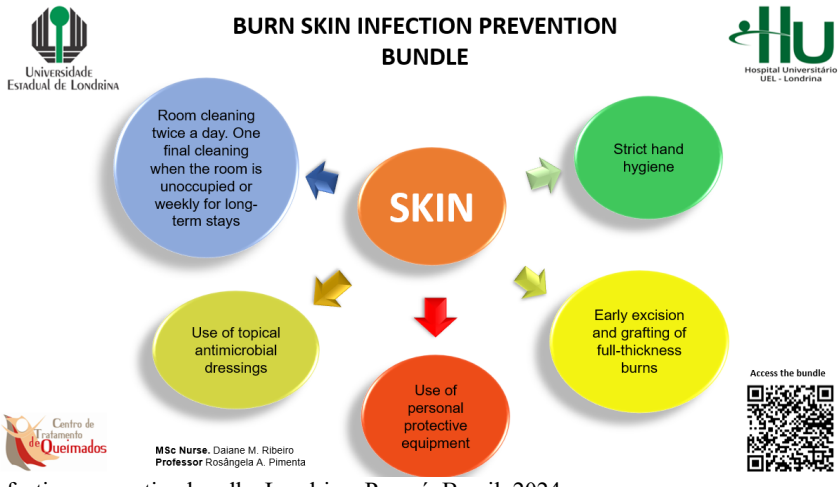

Figure 1. Burn skin infection prevention bundle. Londrina, Paraná, Brazil, 2024.

Figure 2. Bundle installed in the Burn Treatment Center units (ward, Intensive Care Unit, balneotherapy and surgical rooms). Londrina, Paraná, Brazil, 2024.

Also in the empirical phase, the bundle underwent content validity by seven professionals considered experts on the subject, including one physician (14.3%), three nurses (42.8%) and three physiotherapists (42.8%), with an average age of 44.5 years. As for qualifications, four had master's degree and three had doctoral degree.

In relation to professional time at the research site, 42.9% had 6 to 9 years, and 57.1% had ≥10 years, with 57.1% working in management, 28.6% in care, and 14.3% in care and management simultaneously. Regarding training time, 85.7% had ≥20 years.

As for the bundle's content validity, there was 100% agreement among all participants regarding the dimensions assessed: objectivity; layout; simplicity; clarity; relevance; variety; breadth; credibility; and balance. The CVI of the nine items in validity with judges was equal to 1.0. In accordance with the results and the minimum suggestions in the bundle, only one round of validity with experts was carried out.

Experts' suggestions referred to adjustments in the text, in the simplicity item, replacing the term "skin" with "injury, burn or lesion". The suggestion was not accepted, since the protocol addresses burn injuries to the skin, considering that the skin is the site of infection and other terms are defined as trauma. Furthermore, in the clarity item, it was requested that the action verb be in the infinitive to intensify the instruction. The suggestion was not accepted, considering that the protocol is intended to guide and direct care practice, aiming to list subsidies for the prevention of infection and not to establish conduct.

Furthermore, it was suggested in the variety item that the types of antimicrobial dressings and their respective change times could be exemplified. In accordance with the other items, this was not accepted, as the study sector already has a protocol of recommendations for covering injuries according to the type of burns.

It is worth noting that experts' suggestions did not invalidate the protocol already assessed and validated. From the same point of view, interviewees showed good acceptance of the instrument due to the topic, which promotes quality of care with better benefits, ensuring patient safety.

As a result, the bundle validity protocol Item-Level Content Validity Index showed a maximum agreement of 1.0 among all judges/experts, in the nine dimensions, namely objectivity, layout, simplicity, clarity, relevance, variety, breadth, credibility and balance.

DISCUSSION

Burn patients are exposed to organic changes that make them vulnerable to infectious conditions, increasing their susceptibility to infection due to trauma, such as the breakdown of the protective barrier, the skin, which becomes a predisposing factor for microbial colonization and growth. Moreover, prolonged hospitalization and invasive procedures intensify systemic inflammation. Thus, morbidity is high and alarming, with sepsis being the main cause of death.[16] In view of this, care for critically ill burn patients and prevention of infection are of utmost importance for their outcome; therefore, knowledge of the signs and symptoms of infection is essential for a good prognosis.[17-18]

In this sense, it is essential to clean the wound by applying dressings to burn injuries, thus stimulating the healing process and preventing infection associated with the injury. To achieve these goals, dressing technologies that individualize care must be used.[19]

In view of this, the appropriate management of burn victims, combined with the application of specific protocols and ongoing training of the multidisciplinary team, underpins a fundamental strategy for preventing infections.[20] It is important to highlight that the available studies were conducted mostly with adult patients, highlighting a gap in research aimed at the child and adolescent population.

From the same point of view, literature expresses that bundles have been widely applied in the standardization of protocols as a crucial strategy to improve quality of care and prevention of infections in burn patients in contemporary times.[21]

Thus, there is evidence that healthcare professionals can contribute to validity processes of materials as resources in health education as a pertinent point in the teaching-learning process, especially in therapeutic mediation. Furthermore, the bundle enriches knowledge, improves attitudes, skills and autonomy, encouraging adherence to essential treatments, according to the findings.[22]

Therefore, the instrument validity process demonstrates in practice that the material produced may be capable of improving clinical practice and allowing the target audience to be presented with material that has relevant, clear, understandable content and is based on scientific evidence.[23]

As a result, item construction and content validity, the first stage, were carried out based on the theoretical basis of the construct, involving the definition of properties, the determination of the dimensionality of attributes and the elaboration of constitutive and operational definitions. In the second stage, data collection was carried out to assess the properties and applicability of the instrument. Finally, the third stage consisted of the execution of analytical procedures.

The instrument was constructed based on behavioral criteria, with objectivity, simplicity, relevance in content, accuracy and variety, transmitting credibility and clarity in the information provided, presenting

breadth on the topic exposed, balance between the content cited and the definition of the instrument.[24]

Thus, the protocol emerges as a fundamental instrument to guide clinical practice, by offering objective and accessible information as a therapeutic tool endorsed as a safe and effective resource. In addition, it is recommended to be used by the multidisciplinary team in specialized centers as a teaching-learning resource, providing continuous updating in health practices according to innovations in the theoretical, methodological, scientific and technological fields, consequently, significantly collaborating with improvement and qualification of care.

Furthermore, new studies can be produced from the application of the bundle in the BTC of the aforementioned institution and in others, which will presumably enable new and valuable contributions to the topic of treatment, also benefiting adult patients with burn injuries.

It is worth noting that, due to the implementation, an institutional protocol was created for the management and prevention of skin infections due to burns in children and adolescents. A WebQuest will be developed in order to assist daily practice, improve the quality of care provided based on evidence and encourage teaching and learning in pedagogical practice as a strategy, recognizing the knowledge that exists in everyday life and strengthening the development of the work process.

A limitation of this study is the fact that it was developed at a local level and was not applied in other units for comparison purposes. Another point is the need for continued assessment and adherence to the bundle by professionals, as well as ongoing health education by the hospital, since the intervention was carried out to begin the implementation process for research purposes. It is also worth emphasizing that there are still few literary findings regarding the use of the bundle as a preventive measure for skin infection due to burns in specialized treatment centers.

It was concluded that the research provided the construction and validity of a bundle for the prevention of skin infections due to burns, developed in collaboration with judges who are experts in the subject. It is expected that the bundle will be used as an educational tool, contributing to the strengthening of health education in several BTCs, including for the adult population. The implementation of educational interventions for health promotion requires specific practices adapted to the needs and particularities of each individual. The bundle construction is valid as a teaching-learning tool to develop educational actions in healthcare practice focused on the subject, since it obtained agreement from all judges regarding objectivity, layout, simplicity, clarity, relevance, variety, breadth, credibility and balance. Therefore, by validating the protocol as an educational strategy in health, it was able to facilitate motivation and understanding, in addition to supporting the management in treatment of children and adolescents who are victims of burns.

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AUTHORS' CONTRIBUTIONS

Daiane Mendes Ribeiro: Data conception and design or analysis and interpretation; Article writing or critically reviewing the relevant intellectual content; Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the work. **Lucas Benedito Fogaça Rabito:** Data conception and design or analysis and interpretation; Article writing or critically reviewing the relevant intellectual content; Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the work. **Susany Franciely Pimenta:** Data analysis and interpretation; Article writing or critically reviewing the relevant intellectual content; Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the work. **Gilselena Kerbauy Lopes:** Article writing or critically reviewing the relevant intellectual content; Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the work. **Jaqueline Dario Capobiango:** Article writing or critically reviewing the relevant intellectual content; Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the work. **Rosângela Aparecida Pimenta:** Data conception and design or analysis and interpretation; Article writing or critically reviewing the relevant intellectual content; Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the work.

All authors have approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Ribeiro DM, Rabito LBF, Pimenta SF, Lopes GK, Capobiango JD, Pimenta RA. Construction and validity of a bundle to prevent skin infections due to burns: a methodological study. Rev Epidemiol Control Infect [Internet]. 2025 Feb. 16;15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19599

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

SARS-CoV-2 seroprevalence among adults in the cities of Mariana and Ouro Preto, Minas Gerais, Brazil

Soroprevalência do SARS-CoV-2 em adultos nas cidades de Mariana e Ouro Preto, Minas Gerais, Brasil

Seroprevalencia del SRAS-CoV-2 en adultos en las ciudades de Mariana y Ouro Preto, Minas Gerais, Brasil

Site doi: https://doi.org/10.17058/reci.v15i1.19515

Submitted: 06/14/2024
Accepted: 12/11/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: At the beginning of the Covid-19 pandemic, the absence of a national protocol for epidemiological surveillance and control hindered the understanding of the true prevalence of Covid-19 in Brazil. This study aimed to estimate the anti-SARS-CoV-2 antibodies prevalence and describe the serological profile according to socioeconomic, geographic, and health characteristics in Mariana and Ouro Preto municipalities, Minas Gerais. **Methods:** A cross-sectional population-based serological survey was conducted with 1,762 adults from October to December 2020. A qualitative immunochromatographic rapid test assessed infection; georeferencing and statistical inference analyses were performed. **Results:** The infection prevalence was 5.2%. Multivariate analysis revealed that lower per capita family income (≤ 0.5 minimum wage) (OR: 3.63; 95% CI: 1.70–7.76), higher density of occupants per room (≥ 1.0) (OR: 0.42; 95% CI: 0.23–0.76), and previous contact with suspected or confirmed cases of Covid-19 (OR: 2.58; 95% CI: 1.16–5.73) were significantly associated with seropositivity. Seropositive individuals reported higher frequencies of fatigue (14.8%), dyspnea (9.3%), ageusia (9.3%), and anosmia (8.8%), in addition to lower educational performance (p=0.024), lower per capita family income (p=0.018), and a greater number of comorbidities (p=0.041). A heterogenous geographic distribution was observed, with concentrations in census sectors with average incomes of one to three minimum wages. **Conclusion:** The study highlights a heterogeneous distribution of SARS-CoV-2 infections, with seropositive individuals predominantly coming from lower socioeconomic segments and presenting greater health vulnerabilities. These findings emphasize the need for targeted public health strategies and interventions to improve disease surveillance and mitigate health disparities in similar contexts.

Keywords: *Coronavirus infections. Sero-epidemiological studies. Socioeconomic factors.*

RESUMO

Justificativa e Objetivos: No início da pandemia, a ausência de um protocolo nacional de vigilância e controle epidemiológico dificultou a compreensão da verdadeira prevalência da Covid-19 no Brasil. Este estudo teve como objetivo estimar a prevalência de anticorpos anti-SARS-CoV-2 e descrever o perfil sorológico de acordo com as características socioeconômicas, geográficas e de saúde das cidades de Mariana e Ouro Preto, Minas Gerais. **Métodos:** Uma pesquisa sorológica transversal de base populacional foi realizada com 1.762 adultos, entre outubro e dezembro de 2020. Um teste rápido imunocromatográfico qualitativo foi usado para avaliar a infecção; foram realizadas análises de georreferenciamento e inferência estatística. **Resultados:** A prevalência de infecção foi de 5,2%. A análise multivariada revelou que a menor renda familiar per capita (≤ 0,5 salário mínimo) (OR: 3,63; IC95%: 1,70-7,76), a maior densidade de ocupantes por quarto (> 1,0) (OR: 0,42; IC95%: 0,23–0,76) e o contato prévio com casos suspeitos ou confirmados de Covid-19 (OR: 2,58; IC95%: 1,16-5,73) foram significativamente associados à soropositividade. Os indivíduos soropositivos relataram frequências mais altas de fadiga (14,8%), dispneia (9,3%), ageusia (9,3%) e anosmia (8,8%), além de menor escolaridade (p=0,024), menor renda familiar per capita (p=0,018) e maior número de comorbidades (p=0,041). Foi observada uma distribuição geográfica heterogênea, com concentrações em setores censitários com renda média de um a três salários mínimos. **Conclusões:** O estudo destaca uma distribuição heterogênea da infecção por SARS-CoV-2, com indivíduos soropositivos predominantemente de segmentos socioeconômicos mais baixos e apresentando maiores vulnerabilidades de saúde. Esses achados enfatizam a necessidade de estratégias e intervenções de saúde pública direcionadas para melhorar a vigilância de doenças e mitigar as disparidades de saúde em contextos semelhantes.

Descritores: *Infecções por coronavírus. Estudos soroepidemiológicos. Fatores socioeconômicos.*

RESUMEN

Justificación y Objetivos: Al inicio de la pandemia, la ausencia de un protocolo nacional de vigilancia epidemiológica y control complicó la comprensión de la verdadera prevalencia del Covid-19 en Brasil. Este estudio tuvo como objetivo estimar la prevalencia de anticuerpos anti-SARS-CoV-2 y describir el perfil serológico de acuerdo con las características socioeconómicas, geográficas y sanitarias de las ciudades de Mariana y Ouro Preto, Minas Gerais. **Métodos:** Se realizó una encuesta serológica transversal de base poblacional con 1.762 adultos entre octubre y diciembre de 2020. Se utilizó una prueba rápida inmunocromatográfica cualitativa para evaluar la infección; se realizaron análisis de georreferenciación e inferencia estadística. **Resultados:** La prevalencia de la infección fue del 5,2%. El análisis multivariante reveló que los menores ingresos familiares per cápita (≤ 0,5 salario mínimo) (OR: 3,63; IC95%: 1,70-7,76), la mayor densidad de ocupantes por habitación (> 1,0) (OR: 0,42; IC95%: 0,23–0,76) y el contacto previo con casos sospechosos o confirmados de Covid-19 (OR: 2,58; IC 95%: 1,16-5,73) se asociaron significativamente con la seropositividad. Los individuos seropositivos informaron de una mayor frecuencia de fatiga (14,8%), disnea (9,3%), ageusia (9,3%) y anosmia (8,8%), además de un menor nivel educativo (p=0,024), una menor renta familiar per cápita (p=0,018) y un mayor número de comorbilidades (p=0,041). Se observó una distribución geográfica heterogénea, con concentraciones en sectores censales con ingresos medios de uno a tres salarios mínimos. **Conclusiones:** El estudio destaca una distribución heterogénea de la infección por SRAS-CoV-2, con predominio de individuos seropositivos de los segmentos socioeconómicos más bajos y que presentan mayores vulnerabilidades sanitarias. Estos hallazgos subrayan la necesidad de estrategias e intervenciones de salud pública específicas para mejorar la vigilancia de la enfermedad y mitigar las disparidades sanitarias en contextos similares.

Palabras Clave: *Infecciones por coronavirus. Estudios seroepidemiológicos. Factores socioeconómicos*

INTRODUCTION

At the beginning of the Covid-19 pandemic, the lack of a national protocol for epidemiological surveillance, disease control, or mitigation hindered the understanding of the true prevalence of coronavirus disease (Covid-19) throughout Brazil. The high number of cases and deaths revealed significant transmission patterns of severe acute respiratory syndrome coronavirus (SARS-CoV-2), the etiological agent of Covid-19. Failures in control measures increased the vulnerability of the Brazilian population to infection.[1]

Notably, Brazil has reported more than 22.1 million positive cases of Covid-19and confirmed more than 616,600 deaths from the disease by the beginning of the second week of December 2021; it is believed that the records do not reflect the true extent of SARS-CoV-2 infection.[2] In addition to the country's low testing rates, the literature suggests that many infected people remain asymptomatic or manifest mild symptoms and therefore do not have laboratory confirmation of infection.[3]

Population-based surveys are essential for visualizing the epidemiological scenario, as they contribute to understanding the dynamics of virus transmission and disease evolution, supporting the implementation of public health policies.[1,4] There are few studies with this design focused on estimating the frequency of infected individuals in the Brazilian population.[5] Until September 2020, only two studies had estimated the profile of infection by SARS-CoV-2 in Brazil using household surveys. One of them, nationwide, investigated individuals living in 133 cities; the other described the seropositivity profile in the city of São Paulo.[1,6]

In Minas Gerais, the epidemiological bulletins available from the State Health Department indicated the record of 295,169 cases until September 2020, with a considerable increase in the number of unconfirmed suspected cases. This scenario evidenced the need and relevance of implementing strategies to improve the diagnosis of SARS-CoV-2 infection in municipalities and contribute to the knowledge of the prevalence of infection, supporting decision-making in the field of prevention and healthcare for the population exposed to the virus.[7]

Related to what was discussed above, the hypothesis adopted is that the population's sociodemographic, social vulnerability and health characteristics could be associated with seropositivity for SARS-CoV-2, assuming that individuals under greater socioeconomic and health vulnerability would have a higher seroprevalence of anti-SARS-CoV-2 antibodies.

This study aimed to estimate the anti-SARS-CoV-2 antibodies prevalence and describe the serological profile according to socioeconomic, geographic, and health characteristics in the cities of Mariana and Ouro Preto, Minas Gerais.

METHODS

Study design and setting

This is a descriptive study, based on primary data from a sero-epidemiological survey conducted in the cities of Mariana and Ouro Preto, from October to December 2020.

Mariana and Ouro Preto are neighbor municipalities of the Inconfidentes micro-region, located in the central macro-region of the state of Minas Gerais, with estimated populations of 61,288 and 74,558 residents, respectively. The main economic activities are the extraction of iron ore, tourism, services, and the federal higher educational institutions located in the cities, which generate high population mobility due to workers' and students' daily commute.[8]

Participants

It was considered eligible for this study individuals living in permanent households at the headquarters of the cities, aged 18 years or older. It was excluded individuals who, at the time of data collection, were in isolation/quarantine due to Covid-19; those who presented loss of cognitive function, were referred by family members or had difficulty understanding the questionnaire during the initial evaluation; individuals whose blood samples could not be collected due to difficulties in venous access and those who were not at home at the time the team visited.

To select participants, it was adopted conglomerate sampling in three stages: by census sector (considering the number of households and the average income of each sector, according to data from the Brazilian Institute of Geography and Statistics (IBGE); by household (selected from a systematic sampling); by resident (randomly selected via a drawing application). For each city, four strata were defined, according to the average nominal monthly income of the head of the household, available in the 2010 census, to ensure the representativeness of the different socioeconomic levels in the sample.

Variables

The variables included in this survey were as follows: SARS-CoV-2 infection—defined by the presence or absence of antibodies in the immunochromatographic rapid test, without distinction between immunoglobulin class (IgM or IgG) and classified as seropositive or seronegative; demographic and socioeconomic variables: sex (female or male); the age group (18–34 years, 35–59 years, 60 years or older); self-reported race/skin color (black, white, mixed-race, yellow, or indigenous); marital status (single, married/in a stable

union, separated/divorced, or widowed); education (complete or incomplete elementary school, complete or incomplete high school, higher education and/or graduate school); family income—minimum wage of R$1,045.00 (< 1 minimum wage, from 1 to 3 minimum wages, ≥ 4 minimum wages); per capita family income—minimum wage (≤ 0.5 minimum wages, > 0.5 minimum wages); density of residents per room (≤ 1.0 residents or > 1.0 residents); prior contact with suspected or confirmed cases of Covid-19 (no or yes); prior SARS-CoV-2 testing (no or yes); self-assessment of health (good, very good, regular, poor, or very poor); characteristic clinical symptoms of Covid-19 in the 15 days before the study, evaluated individually (feverish sensation, sore throat, cough, dyspnea, diarrhea, anosmia, ageusia, fatigue, skin patches); presence of comorbidities (none; 1–2; ≥ 3).

Data collection

The household survey was composed of three moments of data collection in each city, from October to December 2020, with an interval of 21 days between each collection, due to the incubation period of the virus (Mariana: October 16 to 18; November 06 to 08 and November 27 to 29; Ouro Preto: October 30 to November 01; November 20 to 22 and December 11 to 13). The collections were performed on weekends (Friday, Saturday, and Sunday), to enable the participation of residents who worked during the week. In the previous week, the research team carried out the enrollment of households in the pre-selected census sectors.

The selection of census sectors, included in each stage of the survey, considered the number of households and the average income, according to IBGE data, ensuring the representativeness of different socioeconomic strata (<1 minimum wage, from 1 to 3 minimum wages, ≥4 minimum wages) in the final sample. A total of 14,078 and 17,753 households were considered, distributed across 49 and 36 eligible census sectors in Mariana and Ouro Preto, respectively. To select the number of households, we initially enrolled the selected census sectors, counting the number of households in each sector. After this inventory, the household selection interval (k) was calculated, according to the equation: k = Ni / (xi/ni), in which Ni = total number of households in the census sector; xi = sample size; ni = number of households to be selected in the census sector.

Data collection was performed during face-to-face interviews at home, using an electronic questionnaire.[9] Data Goal® software (Data Goal Startup, Belo Horizonte, Minas Gerais, Brazil) was used to apply the questionnaire and collect longitude and latitude of the interviewee's home.

Participant's blood was collected for testing for anti-SARS-CoV-2 antibodies after the interview via peripheral venous access, performed by trained phlebotomists, using a 7.5 mL S-Monovette® serum gel tube (SARSTEDT AG & Co. KG., Nümbrecht, Germany). After blood centrifugation, serological analysis was performed using the non-differentiated qualitative immunochromatographic method for antibodies (IgG and IgM) anti-coronavirus 2 (One Step Covid 2019® test, Guangzhou Wondfo Biotech, China), following the manufacturer's guidelines.[9]

The data collected in the Data Goal application was exported to a single spreadsheet in Office Excel® software (Microsoft Corporation, Redmond, Washington, USA) and underwent consolidation and subsequent consistency analysis.

Bias control

To control possible biases, the interviewers were trained in the use of the digital questionnaire and how to approach the interviewees. In addition, sample selection was randomized; collection was done on weekends to increase the participation of workers; losses were controlled by the collection team coordinators, using printed spreadsheets; the online questionnaire was used to avoid errors and missing data; investigation was done using serum samples, increasing the sensitivity of the test and ensuring greater accuracy.

Sample size

For sample size calculation, each city was considered separately, using information from the 2010 demographic census. It was adopted a 95% confidence level, an estimate of infection that ranged from 3% to 10% according to the moment of the survey, and a design effect equal to 1.5.9 To calculate the sample size, it was used the OpenEpi tool (https://www.openepi.com/Menu/OE_Menu.htm), which estimated a minimum of 732 interviews for each city, to which it was added a percentage of 20% of recomposition for losses due to refusals, absence of the randomly selected resident, and the possibility of closed households during the visit, totaling the need to randomly select, in each city, 879 individuals for the study.

Statistical analysis

Descriptive and statistical inference analyses were performed considering the complex sample design, using the svy command of the Stata® software, version 16.1 (Stata Corp, College Station, TX, USA). Data were presented as percentages and confidence intervals (95% CI), considering the total sample and the distribution in the two cities. Pearson's Chi-squared test was used to compare the frequency of Covid-19 clinical symptoms and the distribution of sociodemographic, social vulnerability, and health characteristics of study

participants between positive and negative for anti-SARS-CoV-2 antibodies, with a 5% significance level.

Geographic analyses were performed by georeferencing the investigated households, using version 2.10.1 of QGIS (Open Source Geospatial Foundation, Beaverton, Oregon, USA), an open-source geographic information system, which enabled the preparation of thematic maps relating income and the distribution of positive cases of SARS-CoV-2 infection. For income categorization, income ranges were adopted, calculated from the data obtained in the interview, to identify which socioeconomic level presented the highest percentage of positive cases.

In addition to the analyses, it was carried out weighted logistic regression to adjust the model to the complex sample design. The variables included in the multivariate model were selected based on biological plausibility and univariate analysis, considering those with a p-value < 0.20 as the initial criterion. The variables were then gradually removed from the model using the stepwise backward method, until all the remaining variables had a p-value < 0.05. Although the density of occupants per room variable did not meet the $p < 0.20$ criterion in the univariate analysis, we chose to include it in the multivariate model due to its epidemiological importance, previously described in the literature, as a relevant fator in household transmission of SARS-CoV-2. It was assessed the collinearity between the variables in the model using the variance inflation fator (VIF). The results indicated the absence of significant collinearity, with VIF < 10 for all the variables included in the model.

Ethical issues

In compliance with current ethical aspects regarding research involving human beings (Resolution 466/2012 of the Brazilian National Health Council), the study was approved by the Universidade Federal de Minas Gerais (UFMG) Research Ethics Committee, under CAAE no. 32815620.0.1001.5149 and Opinion no. 4,292,475.

RESULTS

A total of 5,279 households were approached, 2,536 (48.0%) from Mariana and 2,743 (52.0%) from Ouro Preto. Of the total, 1,912 (36.1%) households were closed (967 in Mariana, and 945 in Ouro Preto); in 1,079 (20.3%), residents refused to participate (560 in Mariana, and 519 in Ouro Preto); in 499 (9.4%), the selected resident was absent (232 in Mariana, and 267 in Ouro Preto); and in 1,789 (33.8%), residents agreed to participate in the study, 27 (0.4%) were excluded due to incomplete interviews. In the end, 1,762 individuals were evaluated, of which 764 (43.4%) were from Mariana and 998 (56.6%) from Ouro Preto.

Regarding the sociodemographic characteristics of the study participants, considering both cities, it was observed a predominance of women (51.9%), aged 35 to 59 years old (47.2%), unmarried individuals (53.2%), black or mixed-race (67.9%), with more than nine years of schooling (68.8%), and with a per capita family income of ≤ 0.5 minimum wage (60.6%). There was a significant difference in the distribution of the education and density of occupant per room variables, which showed a higher number of people with higher education in the city of Ouro Preto. Regarding the other variables, there were no significant differences between the two cities (Table 1).

Table 1. Distribution of sociodemographic characteristics of the study participants, in Mariana and Ouro Preto, Minas Gerais, October to December 2020.

Parameter	Total[a] (n=1.762)	Mariana[a] (n=764)	Ouro Preto[a] (n=998)	p-value[b]
Sex				0.892
Female	51.9 (44.8;59.0)	51.3 (37.0;65.5)	52.4 (47.0;57.8)	
Male	48.1 (41.0;55.2)	48.7 (34.5;63.0)	47.6 (42.2;53.0)	
Age group (years)				
18-34	34.0 (30.5;37.6)	29.0 (22.5;36.5)	37.2 (32.1;42.6)	0.118
35-59	47.2 (43.1;51.4)	55.6 (43.7;66.9)	51.4 (46.4;56.3)	
60 or more	18.8 (16.0;21.9)	15.4 (10.3;22.5)	11.4 (8.5;15.3)	
Marital status				
Married/stable union	33.6 (29.3;38.1)	29.0 (22.5;36.5)	37.2 (32.1;42.6)	0.212
Single	53.2 (47.2;59.2)	55.6 (43.7;66.9)	51.4 (46.4;56.3)	
Separated/divorced or widowed	13.2 (10.3;16.8)	15.4 (10.3;22.5)	11.4 (8.5;15.3)	
Race/skin color				
White	26.1 (22.1;30.7)	22.0 (14.8;31.5)	28.5 (22.9;34.9)	
Black	21.5 (17.7;25.8)	23.1 (14.4;34.9)	18.9 (14.8;23.7)	0.577
Brown	46.4 (37.3;50.1)	49.1 (36.3;62.1)	47.0 (42.3;51.7)	
Yellow or indigenous	6.0 (4.8;9.0)	5.7 (3.0;10.6)	5.6 (4.3;7.3)	
Education				
Elementary school complete or incomplete	31.2 (26.7;36.0)	37.9 (30.6;45.9)	25.8 (21.5;30.6)	
High school complete or incomplete	59.7 (55.8;63.6)	57.2 (49.8;64.2)	61.8 (57.9;65.6)	**0.002**
Higher and/or post-graduate education	9.1 (6.6;12.3)	4.9 (2.6;9.0)	12.4 (8.9;17.0)	
Family income per capita				
>0.5 minimum wage	39.4 (34.3;44.6)	35.7 (28.8;43.2)	42.6 (35.5;49.9)	0.183
≤ 0.5 minimum wage	60.6 (55.4;65.6)	64.3 (56.8;71.2)	57.4 (50.1;64.5)	
Density of occupant per room				**0.036**
≤ 1.0	42.1 (36.2;48.3)	34.8 (25.1;46.0)	48;0 (42.7;53.3)	
> 1.0	57.9 (51.7-63.8)	65.2 (54.0;74.9)	52.0 (46.7;57.3)	

Legend: a) data shown as percentages and 95% confidence intervals; b) Pearson's chi-square test.

Anti-SARS-CoV-2 antibodies prevalence in the total sample was 5.2% (95% CI 3.8;7.0). The presence of at least one characteristic clinical symptom in the 15 days preceding the blood sample collection was reported by 29.9% (95% CI 25.1;34.9) of participants, and 27.7% (95% CI 23.4;32.5) of the seronegative individuals reported the presence of some Covid-19 characteristic symptom. In contrast, 43.6% (95% CI 28.1;60.3) of seropositive individuals reported the presence of these symptoms (p=0.034) (data not shown). The most frequent clinical symptoms among seropositive individuals were: fatigue (14.8%), dyspnea (9.3%), ageusia (9.3%), and anosmia (8.8%) (Table 2).

Table 2. Frequency of clinical symptoms of Covid-19 according to SARS-CoV-2 infection, in Mariana and Ouro Preto, Minas Gerais, October to December 2020.

Symptom	Seropositive % (95% CI)[a]	Seronegative % (95% CI)[a]	p-value[b]
Feverish sensation	1.2 (0.7;2.2)	2.8 (0.8;9.1)	0.131
Sore throat	5.7 (1.6;17.9)	4.8 (3.6;6.5)	0.803
Coughing	19.6 (8.0;40.9)	16.2 (12.6;20.6)	0.613
Dyspnea	9.3 (3.8;21.0)	4.0 (2.7;6.2)	**0.047**
Diarrhea	4.4 (1.8;10.2)	4.9 (3.2;7.3)	0.805
Anosmia	8.8 (4.2;17.5)	2.4 (1.3;3.5)	**0.001**
Ageusia	9.3 (4.0;20.3)	1.4 (0.7;2.9)	**<0.001**
Fatigue	14.8 (6.0;32.4)	5.1 (3.6;7.1)	**0.027**
Skin blemishes	1.9 (0.2;1.2)	1.2 (0.7;2.0)	0.676

Legend: a) 95% CI: 95% confidence interval; b) Pearson's Chi-squared test.

It was found a higher prevalence of seropositive individuals with low education (p=0.024), per capita income below 0.5 minimum wage (p=0.018), density of occupant per room lower than 1.0 (p=0.018) and with three or more comorbidities (p=0.041) (Table 3).

Table 3. Sociodemographic, social vulnerability and health characteristics of study participants, according to serological profile, in Mariana and Ouro Preto, Minas Gerais, October to December 2020.

Parameter	Seropositives % (95%CI)[a]	Seronegatives % (95%CI)[a]	p-value[b]
Sex			0.149
Female	6.3 (4.4;9.0)	93.7 (91.0;95.6)	
Male	4.0 (2.4;6.5)	96.0 (93.4;97.6)	
Age group (years)			0.164
18-34	4.3 (2.6;6.7)	95.7 (93.3;97.3)	
35-59	4.5 (2.8;7.2)	95.5 (92.7;97.2)	
60 or more	8.6 (4.3;16.2)	91.4 (83.8;95.6)	
Marital status			0.486
Married/stable union	3.7 (2.3;6.3)	96.3 (96.4;97.7)	
Single	5.8 (3.2;10.5)	94.2 (89.5;96.8)	
Separated/divorced or widowed	6.0 (3.5;10.0)	94.0 (90.0;96.5)	
Race/skin color	2.8 (7.4;9.6)	97.2 (90.4;99.3)	
White			0.839
Black	5.5 (3.7;8.1)	94.5 (91.9;96.3)	
Brown	4.7 (2.9;7.6)	95.3 (92.4;97.1)	
Yellow or indigenous	6.1 (2.0;17.0)	93.9 (83.0;98.0)	
Education			**0.024**
Elementary school complete or incomplete	7.9 (4.6;3.3)	92.1 (86.7;95.4)	
High school complete or incomplete	4.0 (2.6;6.0)	96.0 (94.0;97.4)	
Higher and/or post-graduate education	2.5 (1.2;5.1)	97.5 (94.8;98.8)	
Family income per capita			**0.018**
>0.5 minimum wage	3.1 (1.9;5.0)	96.9 (94.9;98.1)	
≤ 0.5 minimum wage	6.4 (4.3;9.4)	93.6 (90.5;95.7)	
Density of occupant per room			**0.018**
≤ 1.0	7.4 (5.0;10.7)	92.6 (94.3;97.7)	
> 1.0	3.6 (2.3;5.7)	96.4 (89.3;95.0)	
Prior contact with suspected or confirmed case of Covid-19			0.136
No	4.3 (3.1;6.0)	95.7 (94.0;96.9)	
Yes, with a suspected or confirmed case	7.0 (4.0;12.1)	93.0 (87.9;96.0)	
Prior testing for SARS-CoV-2			0.356
Yes	3.9 (2.0;0.7)	96.1 (92.7;98.0)	
No	5.5 (3.9;7.8)	94.5 (92.2;96.1)	
Self-assessment of health			0.236
Good/very good	4.5 (3.1;9.7)	95.5 (93.5;97.0)	
Fair/bad/very bad	7.4 (3.7;14.1)	92.6 (85.9;92.2)	
Presence of comorbidities			**0.041**
None	4.0 (2.5;6.7)	96.0 (93.3;97.5)	
1-2	4.5 (2.8;7.2)	95.5 (92.8;97.2)	
≥ 3	11.5 (5.3;22.9)	88.5 (93.0;96.2)	

Legend: a) 95% CI: 95% confidence interval; b) Pearson's Chi-squared test

The geographical distribution of the percentages of seropositive individuals by income was heterogeneous within each city, with a higher frequency in census sectors where the average income ranged from one to three minimum wages, similar to Mariana and Ouro Preto (Figure 1).

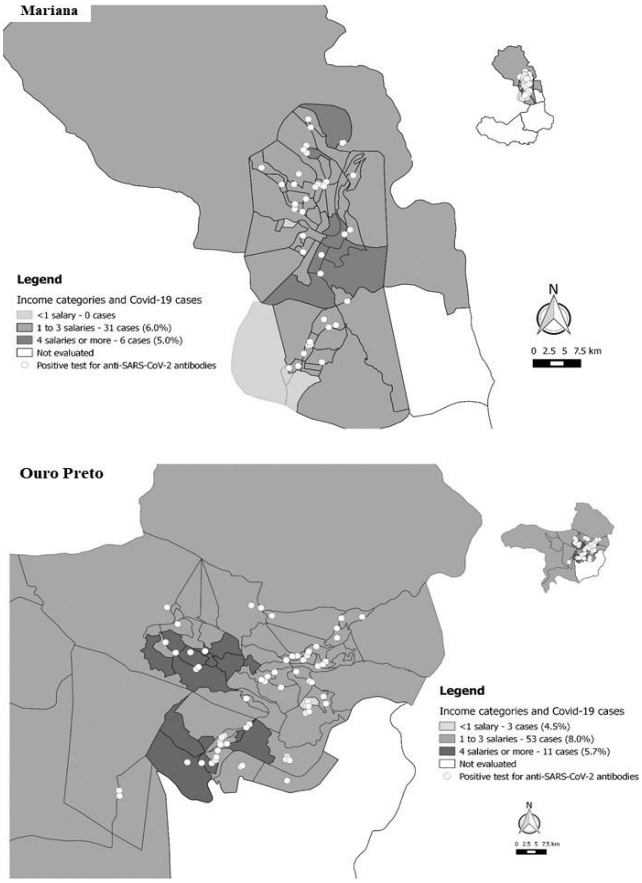

Figure 1. Spatial distribution of the percentages of positive cases for anti-SARS-CoV-2 antibodies by census sector and income bracket in Mariana and Ouro Preto, Minas Gerais, from October to December 2020. *The percentages indicated on the maps represent the proportion of positive cases within each specific income bracket (<1 minimum wage, 1 to 3 minimum wages, 4 salaries or more), in relation to the total number of individuals tested in that same income bracket.*

In the multivariate analysis, conducted by weighted logistic regression, it was found that those in the extremes of the education spectrum (elementary school and higher education) were associated with a greater chance of testing positive for anti-SARS-CoV-2 antibodies compared to those with complete or incomplete high school education. Per capita family income above 0.5 minimum wage was shown to be a protective factor for infection, reducing the chance of testing positive (OR: 0.27; 95% CI: 0.13–0.59; p=0.001) compared to those with income less than or equal to 0.5 minimum wage. Similarly, the density of occupants per room ≥ 0.5 remained associated with a lower chance of infection (OR: 0.47; 95% CI: 0.23–0.97; p=0.043), which may reflect specific characteristics of the analyzed population and the pattern of household transmission in the region. Finally, previous contact with suspected or confirmed cases of Covid-19 was associated with a greater chance of testing positive for anti-SARS-CoV-2 antibodies (OR: 2.58; 95% CI: 1.16–5.73; p=0.020).

Table 4. Associated factors with Covid-19 seropositivity in a multivariate model, in Mariana and Ouro Preto, Minas Gerais, October to December 2020.

Parameter	Univariate OR	p-value	Multivariate OR	p-value
Education				
High school complete or incomplete	1.00		1.00	
Elementary school complete or incomplete	2.14 (1.01-4.53)	**0.047**	2.56 (1.01-5.03)	**0.046**
Higher and/or post-graduate education	1.78 (0.75-4.23)	0.186	3.30 (1.18-9.27)	**0.024**
Family income per capita				
>0.5 minimum wage	1.00		1.00	
≤ 0.5 minimum wage	0.42 (0.22-0.82)	**0.011**	0.27 (0.13-0.59)	**0.001**
Density of occupant per room				
≤ 1.0	1.00		1.00	
> 1.0	0.47 (0.25-0.89)	**0.020**	0.41 (0.23-0.76)	**0.005**
Prior contact with suspected or confirmed case of Covid-19				
No	1.00		1.00	
Yes, with a suspected or confirmed case	1.71 (0.86-3.39)	0.123	2.58 (1.16-5.73)	**0.020**

The multivariate analysis was conducted using a weighted logistic regression model. Variables were selected based on biological plausibility and an initial p-value < 0.20 in univariate analysis, with stepwise backward elimination until all variables in the final model presented p < 0.05. Despite not meeting the initial p-value criterion, density of occupants per room was included in the multivariate model due to its epidemiological importance in household Covid-19 transmission. The model was adjusted for sex and age, and collinearity was assessed using the Variance Inflation Factor (VIF), with no collinearity detected (VIF < 10).

DISCUSSION

Anti-SARS-CoV-2 antibodies prevalence was 5.2% and the main symptoms reported were fatigue, dyspnea, ageusia, and anosmia. Seropositive individuals were less educated, their per capita income was ≤ 0.5 minimum wage, had three or more comorbidities, and resided in census sectors with average middle income (one to three minimum wages).

The study evaluated a representative probabilistic sample of the two cities, enabling the results to be generalized to adults living in their urban areas. Moreover, it provides estimates of the prevalence of SARS-CoV-2 infection in a period not well explored by household surveys.[1,6,10]

The prevalence of infection in Mariana and Ouro Preto, from October to December 2020, was higher than the values found for the Southeast region (less than 1%), in the national survey conducted in 133 municipalities, in May and June 2020.[1] This difference is possibly due to the period of investigation and the pandemic period in the region, a finding that is supported by the survey conducted in the city of São Paulo, in late September 2020, which showed a prevalence of infection close to 14%.[6]

The lower percentage of seropositive individuals who reported the absence of symptoms in the 15 days before the interview, as indicated in this study, corroborates the results of the national survey conducted by Menezes et al.,[11] which found less than 1% of asymptomatic individuals tested positive. These findings show that most individuals with antibodies against SARS-CoV-2 had mild symptoms.[11]

The relationship between the positive serological profile and the main symptoms reported is described in the literature, which indicates the predominance of ageusia and anosmia in mild cases of the disease, and

dyspnea as the main symptom among severe cases that can evolve to death.[12,13] In an European multicenter cohort study, it was observed that more than 85% of the participants had ageusia and/or anosmia, symptoms that showed high specificity when included as screening criteria for the diagnosis of Covid-19.[14]

Because they did not meet the criteria for testing and continued in contact with other people, seropositive individuals who showed no symptoms may have influenced the dynamics of infection transmission in Mariana and Ouro Preto. However, it has been reported that the viral load of these individuals is similar to that of symptomatic individuals, making them potential silent disseminators of the disease.[15] In this context, the results of this study support the need for and importance of adopting mass testing of the population to detect asymptomatic positive cases or those with mild symptoms of the disease.

The relationship between the infection and the low education level and socioeconomic status found in the Mariana and Ouro Preto population suggests that there possibly were difficulties in implementing prevention and control measures for Covid-19 in this population. The difficulty of leaving home for work and the limitation in understanding the high risk of getting sick compromises the adherence to measures that prevent the spread of the virus. According to data from the United Kingdom on Covid-19 control actions, income is a determining factor for adherence to social distancing measures, and people with lower income are three times less likely to perform social isolation.[16] In Brazil, a study of Covid-19 seroprevalence in blood donors in the state of Rio de Janeiro observed that the lower the level of education, the greater the chance of testing positive for the disease.[17]

In Mariana and Ouro Preto, three or more comorbidities were observed among individuals with anti-SARS-CoV-2 antibodies. This result is different from that observed in the national survey, which found no difference in the prevalence of infection between individuals with and without chronic diseases.[18] However, the national data show that 43% of the individuals with comorbidities had similar sociodemographic characteristics to the individuals seropositive for SARS-CoV-2 in Mariana and Ouro Preto (women, white or mixed-race skin, low education, and lower socioeconomic status). The literature shows that aging and the consequent increase in comorbidities enhance the severity of Covid-19 and the risk of death from the disease.[19-21]

The heterogeneous distribution of cases of SARS-CoV-2 infection in the cities of Mariana and Ouro Preto is consistent with projections of the transmission of Covid-19 in intra-urban space. These projections indicate that the dispersion of coronavirus-2 was initiated in regions of higher income and extended to less developed regions, in which territorial use and social conditions can be propelling factors for the spread of the virus.[22] The spread of the disease to areas of greater vulnerability potentially compromises the quality of life and health conditions of the population,[23] especially in the context of restriction of circulation necessary to control the SARS-CoV-2 spread. This profile of case distribution , which starts in higher-income areas and spreads to less developed areas, emphasizes that the disease is socially determined,[4] as is the case with other diseases, such as HIV infection.[24]

This study has limitations due to the restriction of the sample to two medium-sized Brazilian cities, which represent only 12.2% of Brazilian municipalities, as well as the exclusion of residents from the rural areas of the municipalities. This geographic limitation reduces the generalizability of the results to other regions of Brazil, especially to rural areas and more populated urban centers. Additionally, the lack of temporal comparisons limits the ability to observe changes in seroprevalence over different phases of the pandemic, such as before and after the vaccination campaigns. Another limitation is the use of rapid serological tests, which, although widely used during the pandemic, are subject to lower sensitivity and specificity compared to other diagnostic methods, such as RT-PCR.[25] This reliance on rapid tests may have affected the accuracy of seroprevalence estimates, potentially underestimating or overestimating the true prevalence of anti-SARS-CoV-2 antibodies in the population. However, the results play an important role in providing information on the socio-economic and health impacts on the population resulting from social distancing. From a social perspective, this study allowed us to expand the offer of Covid-19 testing to the population of the cities of Mariana and Ouro Preto, contributing to public management with disease monitoring at a time when Brazil was experiencing the beginning of the increase in cases, which culminated in the peak of transmission throughout the national territory in 2021, transforming the country into one of the largest centers of dissemination of Covid-19 worldwide.

Results showed that the seroprevalence of SARS-CoV-2 infection in Mariana and Ouro Preto was higher than that found in cities in the Southeast region in the first semester of 2020 (May to June) and lower than that observed in a city in the Northeast before the study (July to August). Despite the heterogeneous distribution of individuals with anti-SARS-CoV-2 antibodies in the two cities, the results indicate that they mostly belong to social segments with lower income, which shows a profile of socioeconomic vulnerability in the infected group. These results emphasized the importance of epidemiological surveys for monitoring highly transmissible diseases, such as Covid-19, and suggest that health surveillance actions and strategies for coping

with the disease should consider the characteristics of the population.

Future research should expand the scope of the study to include other geographic areas, especially rural regions and larger urban centers, as well as conduct longitudinal analyses to explore temporal variations in seroprevalence and the impact of vaccination campaigns. Such studies would provide a more comprehensive understanding of the socio-demographic and geographic disparities associated with SARS-CoV-2 infection and strengthen public health policies aimed at reducing vulnerabilities in different population groups.

ACKNOWLEDGEMENTS

The authors acknowledge the Federal University of Ouro Preto (UFOP) and the Nutrition and Public Health Research Group (GPENSC) for their support and incentive. And also the support of the Municipal Health Secretariats of the municipalities evaluated in the study.

FINANCIAL SUPPORT

This study was supported by Coordenação de Aperfeiçoamento de Pessoal de Nível Superior-Brazil (CAPES) [nº 88887.504994/2020-00] and finance code 001 for PhD student scholarship.

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AUTHORS' CONTRIBUTIONS

Adriana Lúcia Meireles contributed to project administration and supervision, interpretation of results, review and final approval of the version to be published. **Ana Maria Sampaio Rocha** contributed to bibliographical research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions and final approval of the version to be published. **Bárbara dos Santos Simões** contributed to bibliographical research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions and final approval of the version to be published. **Luciano Garcia Lourenção** contributed to data collection, article writing, review and final approval of the version to be published. **Luiz Antônio Alves de Menezes-Júnior** contributed to data collection, statistics, interpretation and description of results, preparation of tables, review and final approval of the version to be published. **Irene Carolina Sousa Justiniano** contributed to data collection, interpretation and description of results, discussion, conclusion and final approval of the version to be published. **Hillary Nascimento Coletro** contributed to data collection, interpretation and description of results, discussion, conclusion and final approval of the version to be published. **Samara Silva de Moura** contributed to data collection, interpretation and description of results, discussion, conclusion and final approval of the version to be published. **Amanda Popolino Diniz** contributed to data collection, interpretation and description of results, discussion, conclusion and final approval of the version to be published. **Thaís da Silva Sabião** contributed to data collection, interpretation and description of results, discussion, conclusion and final approval of the version to be published. **Aline Priscila Batista** contributed to data collection, processing in the laboratory and final approval of the version to be published. **Nara Nunes Lage** contributed to data collection, processing in the laboratory and final approval of the version to be published. **Keila Furbino Barbosa** contributed to data collection, processing in the laboratory and final approval of the version to be published. **Cássio Zumerle Masioli** contributed to data collection, processing in the laboratory and final approval of the version to be published. **Carolina Ali Santos** contributed to data collection, supporting patients' medical treatment and final approval of the version to be published. **Márcio Antônio Moreira Galvão** contributed to data collection and final approval of the version to be published. **Raquel de Deus Mendonça** contributed to interpretation and description of results, discussion, conclusion and final approval of the version to be published. **George Luiz Lins Machado-Coelho** contributed to project administration and supervision, interpretation of results, review and final approval of the version to be published.

All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Meireles AL, Rocha AMS, Simões BS, Lourenção LG, de Menezes-Júnior LAA, Justiniano ICS, Coletro HN, de Moura SS, Diniz AP, Sabião TS, Batista AP, Lage NN, Barbosa KF, Masioli CZ, Santos CA, Galvão MAM, Mendonça RD, Machado-Coelho GLL. SARS-CoV-2 seroprevalence among adults in the cities of Mariana and Ouro Preto, Minas Gerais, Brazil. Rev Epidemiol Control Infect [Internet]. 2025 Feb. 16;15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19515

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Surgical site infection incidence rate related to quality indicators

Taxa de incidência de infecção de sítio cirúrgico relacionada a indicadores de qualidade
Tasa de incidencia de infección del sitio quirúrgico relacionada con indicadores de calidad

Site doi: https://doi.org/10.17058/reci.v15i1.19503

Submitted: 06/10/2024
Accepted: 12/11/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: it is important to measure and relate theory and practice applied in the workplace through health quality indicators such as adequate care for surgical patients and prevention of future infections. This study aimed to analyze quality indicators related to the prevention of surgical site infections in a teaching hospital. **Methods:** a cross-sectional, analytical, prospective and quantitative study, with a theoretical basis in triad structure, process and outcome. It was carried out in the surgical center of a public, university hospital in southern Brazil, linked to the Brazilian Health System. The study sample included the surgical teams and the surgical center of the study hospital, and its composition was given based on the inclusion criteria, such as surgery performed during the daytime period (from 07:00 to 19:00), from Monday to Friday, on an elective basis, during a period of three months, in 2022 (September to November). **Results:** there were 283 elective surgical procedures, with emphasis on procedures performed without breaking the aseptic technique of the surgical field reported in the transoperative record (97.53%; 276). The surgical center studied presented an operational structure that was incomplete in accordance with the recommended safe practice standards. The sample identified 22.30% (63) of patients with surgical site infection. **Conclusion:** the analysis of indicators demonstrated the need to adapt items related to structure and process (adequate antiseptic dispenser and taps operated without manual contact), in addition to reviewing standard operational protocols.

Keywords: *Surgical Wound Infection. Quality Indicators, Health Care. Perioperative Nursing. Patient Safety.*

RESUMO

Justificativa e Objetivos: é importante mensurar e relacionar a teoria e a prática aplicada no ambiente de trabalho através de indicadores de qualidade em saúde como uma assistência adequada ao paciente cirúrgico e prevenção de futuras infecções. O objetivo deste estudo foi analisar os indicadores de qualidade relacionados à prevenção da infecção de sítio cirúrgico de um hospital de ensino. **Métodos:** estudo transversal, analítico, prospectivo e quantitativo, com embasamento teórico na tríade de estrutura, processo e resultado. Foi realizado no centro cirúrgico de um hospital público, universitário, do Sul do Brasil, vinculado ao Sistema Único de Saúde. A amostra do estudo incluiu as equipes cirúrgicas e o centro cirúrgico do hospital de estudo, e sua composição foi dada com base nos critérios de inclusão, como cirurgia realizada durante o período diurno (das 07:00 às 19:00), de segunda a sexta-feira, com caráter eletivo, durante um período de três meses, no ano de 2022 (setembro a novembro). **Resultados:** foram 283 procedimentos cirúrgicos eletivos, com destaque para procedimentos realizados sem quebra de técnica asséptica do campo operatório relatada em ficha transoperatória (97,53%; 276). O centro cirúrgico estudado apresentou uma estrutura operacional incompleta aos padrões de práticas seguras recomendadas. A amostra identificou 22,30% (63) dos pacientes com infecção de sítio cirúrgico. **Conclusão:** a análise dos indicadores demonstrou a necessidade de adequação de itens relacionados à estrutura e processo (dispensador de antisséptico adequado e torneiras acionadas sem contato manual), além da revisão de protocolos operacionais padrão.

Descritores: *Infecção de Ferida Operatória. Indicadores de Qualidade em Assistência à Saúde. Enfermagem Perioperatória. Segurança do Paciente.*

RESUMEN

Justificación y Objetivos: es importante medir y relacionar la teoría y la práctica aplicadas en el lugar de trabajo a través de indicadores de calidad de la salud como la atención adecuada a los pacientes quirúrgicos y la prevención de futuras infecciones. El objetivo de este estudio fue analizar los indicadores de calidad relacionados con la prevención de infecciones del sitio quirúrgico en un hospital universitario. **Métodos:** estudio transversal, analítico, prospectivo y cuantitativo, con fundamento teórico en la tríada de estructura, proceso y resultado. Se realizó en el centro quirúrgico de un hospital universitario público del Sur de Brasil, vinculado al Sistema Único de Salud. La muestra del estudio incluyó a los equipos quirúrgicos y al centro quirúrgico del hospital del estudio, y su composición se basó en criterios de inclusión, como cirugía realizada en el período diurno (de 7:00 a 19:00 horas), de lunes a viernes, con carácter electivo, durante un período de tres meses, en 2022 (septiembre a noviembre). **Resultados:** hubo 283 procedimientos quirúrgicos electivos, con énfasis en los procedimientos realizados sin romper la técnica aséptica en el campo operatorio reportados en el registro intraoperatorio (97,53%; 276). El centro quirúrgico estudiado presentó una estructura operativa incompleta con los estándares de prácticas seguras recomendados. La muestra identificó el 22,30% (63) de pacientes con infecciones del sitio quirúrgico. **Conclusiones:** el análisis de los indicadores demostró la necesidad de adecuar elementos relacionados con la estructura y el proceso (dispensador de antiséptico adecuado y grifos operados sin contacto manual), además de revisar los protocolos operativos estándar.

Palabras Clave: *Infección de la Herida Quirúrgica. Indicadores de Calidad de la Atención de Salud. Enfermería Perioperatoria. Seguridad del Paciente.*

INTRODUCTION

The surgical center (SC) is a complex hospital sector that is susceptible to the occurrence of several adverse events, where low tolerance for these errors will influence the safety and satisfaction of patients and employees and the sector's cost-benefit. In this regard, the relevance of efficient management and administration is essential for the development of the work process.[1]

Quality indicators (QIs) are tools for measuring the classification of service quality, and involve the application of actions to the quality of care provided to surgical patients.[2] These tools can be analyzed based on the theory that defends quality components in healthcare, supported by three pillars, such as structure, process and outcome. Structure is related to the facilities of the hospital building and the attributes of the professionals involved in the care analyzed; process is linked to the workflow, decontamination of materials and how the professionals themselves are acting; thus, both are directly proportional to the third pillar: outcome. The third pillar expresses the measures implemented based on the reflection and profile of the population studied.[3]

QIs are quantitative measures to reassess, replan and reorganize service activities, contributing to control and decision-making, in addition to sustaining the quality of the service provided and understanding complex phenomena in the work process.[4] Within the management tools that guide the path to excellence in care, QIs comprise the way in which healthcare professionals analyze an activity, monitor aspects related to a given reality and assess what happens to patients, indicating the efficiency and effectiveness of processes and organizational outcomes.[5]

One of the key indicators linked to the SC flow is surgical site infections (SSIs). SSIs are infections related to surgical procedures, with or without implant placement, in inpatients and outpatients.[6] Infections can be characterized by incision, tissue, organ or manipulated space, with diagnosis up to 30 days after the surgical procedure, or up to one year, in the case of prosthesis implantation.[7] Furthermore, SSIs can also be caused by individuals' own microbiota, due to the incidence of antimicrobial use that patients undergo, bacterial selection, local colonization and fungi present.[6]

SSI is identified through the depth reached, being classified as superficial infection, that which reaches subcutaneous tissue from the first day to the 30th day after the procedure, presenting purulent drainage, positive culture and phlogistic sign, and deep infection, identified up to 90 days after the surgical act, having purulent drainage, fever greater than 38 ºC, abscess or dehiscence of the surgical wound and infection of cavities or organs, resulting in positive culture, abscess, possible reoperation and anatomopathological examination.[8]

Each year, SSIs threaten the lives of millions of patients around the world and are a major contributor to the spread of bacterial resistance. In low- and middle-income countries, about 11% of patients develop infections after surgical procedures. In Africa, up to 20% of women who undergo cesarean sections develop wound infections, which harm their health and make it difficult to care for their newborns. However, SSIs do not only affect developing countries; in the United States, for example, these infections result in more than 400,000 extra days of hospitalization and an additional cost of about $900 million per year.[9]

In Brazil, SSIs account for approximately 14% to 16% of infections found in hospitalized patients.[6] Of all healthcare-associated infections, SSIs account for 31% and are associated with a mortality rate of 3%, with 75% of deaths resulting from surgical procedures. Even with such percentages, these infections can be avoided in up to 60% of cases through the application of preventive and control interventions.[10]

The present study is justified by the importance of assessing and analyzing the context of where and how SSI occurs, broadening the focus of the discussion of the topic. The triad of QIs helps in the analysis of the relationship between theory and practice applied in the work environment through health indicators, creating more precise parameters for the prevention of infections.[3] This study aimed to analyze the QIs related to the prevention of SSI in a teaching hospital, presented by the Brazilian National Health Regulatory Agency (In Portuguese, *Agência Nacional de Vigilância Sanitária* - ANVISA), based on the triad structure, process and outcome.

METHODS

The research is a cross-sectional, prospective study with a quantitative approach. It was carried out in the SC of a large public university hospital in southern Brazil, linked to the Brazilian Health System (In Portuguese, *Sistema Único de Saúde* - SUS). This hospital is a reference center for trauma and orthopedics, emergency care, organ harvesting and removal center, and video-assisted surgeries, among others.

The SC has seven operating rooms, one of which is specifically for urgent and emergency surgeries. It serves several specialties, operating 24 hours a day, performing an average of 500 surgeries per month at the time the data was collected. Its staff consists of nurses, nursing technicians and assistants as well as operational assistants and administrative technicians.

The convenience sample included patient surgeries performed at the teaching hospital, and its composition

was based on the following inclusion criteria: primary surgical procedure; surgeries of various surgical specialties, with open and videolaparoscopic techniques performed at the institution; and surgeries performed during the daytime (from 7:00 am to 7:00 pm), from Monday to Friday, on an elective basis, during a three-month period in 2022 (September, October and November). Exclusion criteria were emergency surgeries, surgical re-intervention and patients who died after the surgical procedure. To assess the structure and process QIs related to the development of SSIs, the surgical team components were assessed: medical team (surgeon and anesthesiologist) and nursing team (nursing technician or nurse with the role of SC circulator and scrub nurse). Inclusion criteria for these groups are being scheduled to work in the operating room selected for the study or being part of the team that will perform patients' procedure.

The data collected and analyzed refer to general characteristics of surgical anesthetic procedures, such as surgical specialty, classification of surgery according to contamination potential (clean, potentially contaminated, contaminated and infected), size of surgery (size I, II, III, IV) and type of anesthesia (general and regional).

The variables defined in structure and process indicators were based on criteria presented in an ANVISA manual.[6] The criteria presented in the manual are based on the structure, process and outcome triad, as detailed below:

The variables of structure indicators were one circulating staff for each room, adequate provision of antiseptic for surgical hand antisepsis, and an autonomous mechanism for keeping doors closed.

The process indicator variables were preoperative risk factors, such as preoperative hospitalization time, surgical field antisepsis with appropriate solution and administration of antibiotic prophylaxis up to one hour before surgical incision. Intraoperative risk factors were number of surgical boxes with inspection record (zebra-striped tape and integrators according to the type of box and packaging, presence of dirt, residues, humidity and expiration date), correct aseptic technique, disinfection time and donning of professionals. Postoperative risk factor was duration of antibiotic prophylaxis.

The outcome indicator variable was the incidence rate calculation performed per procedure for reporting purposes.

Dependent variables were structure, process and outcome indicators. Independent variables were anesthetic-surgical data.

For data collection, based on the daily surgical schedule, patients with surgery scheduled as the first in the morning and the first in the afternoon who were waiting for the procedure in the pre-anesthesia room were approached. Daily quantity was verified according to the demand for the times (from 07:00 to 09:00 and from 13:00 to 15:00). These times were selected for large procedures that used the entire period, and in order to have significant demand for data collection and full observation of the procedure, this process was stipulated. The researcher presented the objective of the research to patients and their companions, in order to clarify the study and request the signing of the Informed Consent Form, which was submitted to the Research Ethics Committee linked to the institution where data collection took place, in accordance with Resolution 466/2012 of the Brazilian National Health Council, under registration Certificate of Presentation for Ethical Consideration 03477018.2.0000.5231 and favorable Opinion 5,069,973, with approval date on October 28, 2021. After acceptance, clinical and surgical information was collected from these patients using a pre-structured script, with part of the information provided by the patients themselves and part through their medical records.

The assessment of the structure and process QIs related to SSI was carried out through observation and recording of the surgical environment, surgical team and their work process during the procedures of patients mentioned above. The outcome indicator assessment was carried out after tabulating the data and calculating the incidence rate of SSI.

The data collection instrument consisted of two sections. In the first, data characterizing the surgical procedures were recorded. In the second section, data for analysis of structure and process indicators were recorded. The data were entered, standardized and analyzed using IBM SPSS software. A simple descriptive frequency analysis was performed for the categorical variables, and an analysis of central tendency (mean and median) and variability (standard deviation) was performed for the numerical variables. Frequencies are presented in contingency tables, and to verify whether the assumptions of association and dependence between QI variables and the result of the development of the SSI rate are met, the chi-square test was used.

To identify frequencies greater than five in each row of the table and the presence of violated assumptions (more than 20% of values less than 5) in the chi-square test, Fisher's exact test was performed. For ordinal categorical variables (preoperative hospitalization time), the Mann-Whitney test was used, in which it was possible to assess whether there is a difference in the parameters between individuals who had and did not have infection.

To calculate the compliance indexes of selected practices, formulas recommended in the operational constructs of these indicators were used, through their arrangement in numerators and denominators. Denominators correspond to the total of practices

assessed, and numerators, to the total of practices assessed that obtained compliance. To calculate compliance indexes, the equations of general compliance and of each assessed component were used. For the significance, a significance interval of 5% was adopted in this work. The results presented p-values less than 5%, considered significant, and p-value less than 0.1% (<0.001***).

RESULTS

A total of 283 elective surgical anesthetic procedures were assessed, classified according to surgical specialty: clinical, contamination potential, surgical size and type of anesthesia. The sample characteristics are presented below (Table 1).

Table 1. Distribution of sample characteristics according to the development of surgical site infection. Londrina, Paraná, Brazil, 2022.

Characteristic	General N	With infection N (%)	Without infection N (%)	p-value
Surgical-clinical specialty (n=283)				
Bucomaxillofacial	19	5 (26.32)	14 (73.68)	0.567b
Head and neck surgery	10	2 (20)	8 (80)	
Digestive system surgery	26	5 (19.23)	21 (80.77)	
Ophthalmic surgery	18	4 (22.22)	14 (77.78)	
Plastic surgery	3	2 (66.67)	1 (33.33)	
Thoracic surgery	5	-	5 (100)	
Vascular surgery	13	1 (7.69)	12 (92.31)	
Gynecology and obstetrics	13	4 (30.77)	9 (69.23)	
Neurosurgery	13	2 (15.38)	11 (84.62)	
Orthopedics	91	18 (19.78)	73 (80.22)	
ENT	17	3 (17.65)	14 (82.35)	
General surgery	2	-	2 (100)	
Urology	53	17 (32.08)	36 (67.92)	
Potential of contamination (n=283)				
Clean	135	27 (20)	108 (80)	0.449b
Potentially contaminated	142	36 (25.35)	106 (74.65)	
Contaminated	1	-	1 (100)	
Infected	5	-	5 (100)	
Size of surgery (n=283)				
Size I	140	33 (52.38)	107 (48.64)	0.361d (r=-0.05)
Size II	110	26 (41.27)	84 (38.18)	
Size III	22	3 (4.76)	19 (8.64)	
Size IV	11	1 (1.59)	10 (4.55)	
Anesthesia (n=283)				
Regional	176	45 (25.57)	131 (74.43)	
General	107	18 (16.82)	89 (83.18)	0.117a (v=0.1)
Preoperative hospitalization time (n=283)				
Not reported	115	-	-	0.540d (r=-0.04)
Up to one day	101	40 (64.52)	61 (57.55)	
One day	15	3 (4.84)	12 (11.32)	
One day to three days	11	4 (6.45)	7 (6.6)	
More than three days	41	15 (24.19)	26 (24.53)	
Surgical field antisepsis with appropriate solution (n=283)				
Adequate	281	61 (21.71)	220 (78.29)	0.049b
Inadequate	2	2 (100)	-	
Antibiotic prophylaxis performed up to 1 hour before incision (n=283)				
Adequate	12	6 (50)	6 (50)	
Inadequate	271	57 (21.03)	214 (78.97)	0.029b
Number of surgical boxes with inspection record (n=283)				
Adequate	283	63 (22.3)	220 (77.7)	
Inadequate	-	-	-	
Correct aseptic technique of the surgical field (n=283)				
Yes	276	61 (22.1)	215 (77.9)	0.654b
No	7	2 (28.57)	5 (71.43)	
Hand disinfection time for professionals (n=283)				
More than 60 seconds	228	32 (14.04)	196 (85.96)	<0.001***a (v=0.4)
From 40 to 60 seconds	55	31 (56.36)	24 (43.64)	
Complete donning of professionals (private, disposable cap, mask, closed shoes, goggles) (n=283)				
Adequate	11	7 (63.64)	4 (36.36)	0.003b
Inadequate	272	45 (24.19)	141 (75.81)	

Tests performed to achieve the result: chi-square (marked by the letter "a"); Fisher's exact test (marked by the letter "b"); Mann-Whitney (marked by the letter "d"); Odds Ratio (OR - marked by the letter "r"); Cramer's V (marked by the letter "v").

It was identified that 22.30% (63) of patients presented SSI, being detailed according to the distribution of characteristics (Table 1).

To identify the p-value between the variables (clinical, surgical classification, surgical field antisepsis with appropriate solution, antibiotic prophylaxis performed up to 1 hour before incision and correct aseptic

technique of the surgical field), Fisher's exact test (marked by the letter "b") in the table was used. This test was selected because it is the most appropriate for calculating the probability of independence between the variables. The association between SSI and such variables accepts evidence of the hypothesis of association from the test. Also, statistically, no evidence was found through the Mann-Whitney test (marked by the letter "d") in the table, to reject differences between the distributions of preoperative hospitalization time in relation to the development of SSI, thus reporting an effect size in which, the further from 0, the greater the association effect.

As for complete donning (private, disposable cap, mask, closed shoes and goggles), it was observed that the choice of clothing was linked to professionals' preference and not to a standard operational protocol of the institution. The result presented of 96.11% (272), inadequate, shows that the professionals paid attention to the minimum donning (apron and sterile gloves, mask and cap) for the execution of the surgical procedure.

For the p-value of the anesthesia and donning variables, the chi-square test of independence (marked by the letter "a") was performed, which followed the calculations (x^2 (1) = 2.46 p = 0.117), (x^2 (1) = 0.87 p = 0.352) and (x^2 (1) = 0 p = 1). No evidence of an association between any of them and SSIs was found. The variable hand disinfection time for professionals was also calculated by the chi-square test of independence, which showed an association with infection (x2 (1) = 43.46 p = <0.001***). With this, the Odds Ratio (OR) was calculated, which compares the chance of infection in operations with a degerming time of 40 to 60 seconds (31/24 = 1.29) and the chance of the same outcome in the group in which degerming was performed for more than 60 seconds (32/196 = 0.16). Thus, OR = 7.91 (95% CI = (4.13; 15.17)) indicates a 7.91 times greater chance of infection in the 40 to 60 seconds group than in the more than 60 seconds group.

In relation to the effect size in part of variables in SSIs, Cramer's V was calculated, which is classified as negligible, small, medium and large. In the anesthesia variable (v=0.1), the effect is considered small, and in the hand disinfection time for professionals variable (v=0.4), the effect is considered medium.

The SC assessment revealed an operational structure that partially meets the recommended standards for surgical practices. Each surgical room is attended by a dedicated circulating nurse and an anesthetist, who are checked according to the daily schedule. In addition, there is one washing station for every two surgical rooms, but the adequate provision of antiseptic for surgical antisepsis was identified as a failure, as there are no taps that can be operated without contact with the hands. The existence of a written cleaning routine for the sector and environmental signage standards for restricting the movement of people in the sector were also observed as points for preventing SSI. However, aspects that require adjustments were highlighted for both structure and process indicators, to adapt to current contamination prevention compliance standards, which require attention and possible improvements (Tables 2 and 3).

Table 2. Compliance of structure indicators related to infection according to the Brazilian National Health Regulatory Agency manual. Londrina, Paraná, Brazil, 2022.

Indicator	Situation
One circulating person for each room	Adequate
Adequate provision of antiseptic for surgical hand antisepsis	Inadequate
Antiseptic dispensers and taps operated without contact with hands	Inadequate
Autonomous mechanism for keeping doors closed	Inadequate

Table 3. Compliance of process indicators related to infection according to the Brazilian National Health Regulatory Agency manual. Londrina, Paraná, Brazil, 2022.

Variable	N (%)
Surgical field antisepsis (n=283)	
Adequate	281 (99.29)
Inadequate	2 (0.71)
Antibiotic prophylaxis performed up to 1 hour before incision (n=283)	
Adequate	12 (4.24)
Inadequate	271 (95.76)
Surgical box inspection (n=283)	
Adequate	283 (100)
Inadequate	-
Correct aseptic technique of the surgical field (n=283)	
Adequate (yes)	276 (97.53)
Inadequate (no)	7 (2.47)
Hand disinfection time for professionals (n=283)	
Adequate (more than 60 seconds)	228 (80.57)
Inadequate (from 40 to 60 seconds)	55 (19.43)
Complete donning (private, disposable cap, mask, closed shoes, goggles) (n=283)	
Adequate	11 (3.89)
Inadequate	272 (96.11)

DISCUSSION

The assessment of indicators is a daily challenge, and the triad focuses on these three pillars (structure, process and outcome) for good service management. The influence of the quality of healthcare integrates central concepts to measure and improve quality in health, classifying important types of information that can be obtained in order to infer whether quality of care is adequate and provides ideal assistance in patient care.[11,12]

The results of structure indicators revealed an operational structure partially adequate for resolving the quality work process, highlighting the need for improvements within the sector, such as switching to taps operated without contact with the hands and adequate dispensing of antiseptic for surgical hand antisepsis. A study in Pernambuco presented the use of indicators as a measure of quality in patient care, in addition to showing that adequate physical structure allows for patient isolation, adequate location and a sufficient number of sinks for hand hygiene. The

institution must provide adequate and sufficient personal protective equipment, and offer a good quality environment to professionals. In the current research, it was observed that the physical structure has a probability of spreading the infection, does not contribute to good practices according to the ANVISA manual and favors the spread of infection from person to person.[6-13]

In relation to the autonomous mechanism for keeping doors closed, it was observed that, in the institution where this study was conducted, the reality is that doors swing in the internal corridors and sliding doors in the external corridors of the surgical sector, without the existence of automatic technologies. In other studies, it is pointed out that the building infrastructure is essential for the spread or not of infectious agents and the relationship between the flow of people in the sector influences cross-contamination. The exchange of air flow from the opening and closing of a door and the number of times this occurs during the procedure drive the transport of infectious agents by the movement of air.[14,15]

The process QIs identified in the study focus on professionals' preparation to perform the surgical procedure. The outcomes observed through the environment at the study institution present the profile of a teaching hospital, where the occurrence of students, interns and residents is constant, and the assiduous preparation to work in the SC requires updated standard operating protocols.[16] Two significant variables observed in the study were the correct performance of the aseptic technique of the surgical field and the hand disinfection time for professionals. The first showed that the transfer of how to perform the correct asepsis technique is between chief surgeons and their resident assistants. This method is in accordance with the culture of daily practice and with what was seen in the undergraduate course. The recognition of a documented manual to perform the standard correct technique within the institution was observed in an absence.[12]

The second variable also identified an essential result regarding the disinfection of professionals' hands, showing that there is a 7.91 times greater chance of infection in the 40 to 60 seconds group than in the more than 60 seconds group. A study conducted in Porto Alegre, RS, in a public teaching hospital, showed similar results regarding time. This study shows a general average of professionals with 72 seconds of disinfection, which is significant for the institution's infection rate. The outcome impacts the discussion on the reduction of bacterial counts of professionals' own microbiota, arguing that if the longer time is followed, there is a greater probability of bacterial reduction during the surgical procedure compared to degerming in a shorter time and influences it as a method of preventing SSI.[17]

The current study also presents results regarding the classification of the potential for contamination of surgeries in relation to the risk factors for the development of SSI, due to the profile of the institution and the convenience sample observed. The procedures classified as potentially contaminated surgeries and clean surgeries resulted in a higher prevalence of SSI. The average of the two scored approximately 80% of classifications with development of SSI. In comparison with two other recent studies with profiles similar to this research, of university teaching and with full service to the SUS, the incidence of SSI rates, this being the outcome indicator in the triad, are close to that found in outcomes, ranging from 18% to 20%.[16,17]

Another point observed in the institution's surgical block that complements quality management and that was identified in the study variables is the number of surgical boxes with inspection record with a result of 100% in the sample. This demonstrated the consequence of traceability coming from the sterilization material center and how its connection in the surgical process is essential, mainly in the prevention of SSI. It was analyzed that the registration and monitoring of materials are done with computerized barcode technology, and all the inspected tests that come inside the boxes by professionals during surgery are recorded in the sector's system that contributes to quality traceability.[12-18]

The application of packages of measures measured by QIs to prevent post-surgical infections brings positive results for both the institution and the patients, resulting in reduced length of hospital stay and cost of stay for these patients.[19,20] The analysis of QIs in this research demonstrated the weaknesses and need to redefine goals of adequacy for items related to both the structure and the process, and also drew attention to the review of standard operating protocols for the prevention of SSI development, identification of previous adverse events, attention to the importance of qualified care and safety of surgical patients.

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AUTHORS' CONTRIBUTIONS

Beatriz Zago Lupepsa, Gabriela Encarnação Leandro and Cibele Cristina Tramontini contributed to the conception, bibliographic research, article design, manuscript writing, statistics, data analysis and interpretation, description of results, preparation of tables and conclusions. **Helenize Ferreira Lima Leachi and Marília Ferrari Conchon** contributed to manuscript writing, article planning and design, article review and final approval.

All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Lupepsa BZ, Leandro GE, Leachi HFL, Conchon MF, Tramontini CC. Surgical site infection incidence rate related to quality indicators. Rev Epidemiol Control Infect [Internet]. 2025 Mar. 25;15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19503

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Profile of antimicrobial use in burn patients admitted to an intensive care unit

Perfil de utilização de antimicrobianos em pacientes queimados internados em unidade de terapia intensiva
Perfil del uso de antimicrobianos em pacientes quemados ingressados em uma unidad de cuidados intensivos

Site doi: https://doi.org/10.17058/reci.v15i1.19488

Submitted: 06/03/2024
Accepted: 12/11/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: After extensive burns, infections are a major cause of death. This study aimed to identify bacterial infections and antimicrobial consumption in burn patients admitted to an intensive care unit (ICU). **Methods:** A retrospective observational study was conducted at a public trauma referral hospital in 2022. Data were obtained from patient medical records. Antimicrobials were classified following the Anatomical Therapeutic Chemical (ATC) system, and the amount administered was expressed in Defined Daily Dose per thousand patient-days (DDD/1000). **Results:** A total of 64 burn patients were hospitalized during the period, 75% of them were male, aged 18 to 83 years. The main cause of hospitalization were fires (45%), with the mortality outcome observed in 25% of cases. Bacterial infections were present in 73.4% and fungal infections in 4.7% of cases. In total, 263 microorganisms were isolated, including Gram-negative bacteria (n=183), Gram-positive bacteria (n=73), and fungi (n=7). A total of 15 different antimicrobials were used, totaling 13,060 units dispensed. The total antimicrobial consumption during the study period was 1,111.20 DDD/1000, with the most used antimicrobials being meropenem (281.0 DDD/1000), oxacillin (250.5 DDD/1000), polymyxin B (1.8 DDD/1000), and vancomycin (178.0 DDD/1000). **Conclusion:** Bacterial infections show a high incidence among critical burn patients. The use of broad-spectrum antimicrobials, such as meropenem and vancomycin, may be related to the infection profile of these ICU patients.

Keywords: *Burns. Bacterial Infections and Mycoses. Anti-Infective Agents. Burn Units.*

RESUMO

Justificativa e Objetivos: Após queimaduras extensas, as infecções são uma causa de morte importante. O objetivo deste estudo foi identificar as infecções bacterianas e o consumo de antimicrobianos em pacientes queimados internados em uma Unidade de Terapia Intensiva (UTI). **Métodos:** Estudo observacional retrospectivo desenvolvido em um hospital público referência em trauma no ano de 2022. Os dados foram obtidos do prontuário do paciente. Os antimicrobianos foram classificados de acordo com a *Anatomical Therapeutic Chemical* (ATC) e a quantidade utilizada expressa em Dose Diária Definida por mil pacientes-dia (DDD-1000). **Resultados:** Internaram por queimaduras no período, 64 pacientes, 75% do sexo masculino, com idade entre 18 e 83 anos, fogo (45%) foi a principal causa de internação e o desfecho óbito foi observado em 25% dos casos. A incidência de infecções bacterianas foi de 73,4% e de infecções fúngicas de 4,7%. Foram isolados 263 microrganismos, Gram-negativos (n=183), Gram-positivos (n=73) e fungos (n=7). Foram utilizados 15 diferentes antimicrobianos, totalizando 13.060 unidades dispensadas. O consumo total de antimicrobianos no período foi de 1.111,20 DDD-1000, sendo os mais utilizados meropenem (281,0), oxacilina (250,5), polimixina B (1,8) e vancomicina (178,0). **Conclusão:** Infecções bacterianas são de alta incidência em pacientes queimados críticos. A utilização de antimicrobianos de amplo espectro como meropenem e vancomicina podem estar relacionados ao perfil de infecção desses pacientes em UTI.

Descritores: *Queimaduras. Infecções Bacterianas e Fúngicas. Agentes Antimicrobianos. Unidades de Queimados.*

RESUMEN

Justificación y Objetivos: Después de quemaduras extensas, las infecciones son una causa importante de muerte. El objetivo de este estudio fue identificar las infecciones bacterianas y el consumo de antimicrobianos en pacientes quemados ingresados en una unidad de Cuidados Intensivos (UCI). **Métodos:** Estudio observacional retrospectivo desarrollado en un hospital público de referencia de traumatología en el año 2022. Los datos se obtuvieron de la historia clínica del paciente. Los antimicrobianos se clasificaron según la Química Terapéutica Anatómica (ATC) y la cantidad utilizada expresamente en Dosis Diaria Definida por mil días-paciente (DDD-1000). **Resultados:** 64 pacientes fueron hospitalizados por quemaduras durante el período, 75% del sexo masculino, con edades entre 18 y 83 años, el fuego (45%) fue la principal causa de hospitalización y el desenlace se observó en el 25% de los casos. La infección por infecciones bacterianas fue del 73,4% y por infecciones fúngicas del 4,7%. Se aislaron 263 microorganismos, Gram negativos (n=183), Gram positivos (n=73) y hongos (n=7). Se utilizaron 15 antimicrobianos diferentes, totalizando 13.060 unidades dispensadas. El consumo total de antimicrobianos en el período fue de 1.111,20 DDD-1000, siendo los más utilizados meropenem (281,0), oxacilina (250,5), polimixina B (1,8) y vancomicina (178,0). **Conclusión:** Las infecciones bacterianas tienen una alta incidencia en pacientes críticos quemados. El uso de antimicrobianos de amplio espectro, como meropenem y vancomicina, puede estar relacionado con el perfil de infección de estos pacientes de la UCI.

Palabras Clave: *Quemaduras. Infecciones Bacterianas y Micosis. Antiinfecciosos. Unidades de Quemados.*

INTRODUCTION

Burns are skin injuries resulting from exposure to thermal, chemical, or electrical energy agents, capable of producing excessive heat that damages body tissues and leads to cell death.[1,2,3] Burns are classified into first, second, and third degrees based on the depth of skin damage. The severity of a burn is determined by evaluating its depth, size of the body surface, and region affected. Moreover, the extent of the burn, along with depth, inhalation injury, and other factors, will determine the patient's severity status and therapeutic approaches. Burns also cause significant systemic changes, such as hypermetabolic and inflammatory response, with impact on the patient's general clinical condition.[1,2,3]

Globally, the World Health Organization (WHO) estimates that 11 million burn injuries occur every year, with 180,000 being fatal.[1] The incidence of these events varies across regions,[1] with 90% of mortality occurring in low- and middle-income countries.[4] In the United States, in 2016, approximately 486,000 patients were treated for burns, and approximately 40,000 required hospitalization.[5]

In Brazil, according to the Brazilian Ministry of Health, via the Hospital Information System of the Unified Health System (SIH/SUS), in 2022, 3,836 hospitalizations were recorded due to burns, representing 0.28% of all hospitalizations registered that year.[6]

Infections are the leading cause of death after extensive burns, with burn patients suffering from infections showing double the mortality rate compared to those who are not infected.[5,7] Damage to the integrity of the skin's protective barrier increases the risk of invasion of pathogenic microorganisms that can cause infections.[7] Other factors involved in the infection process in burn patients include inhalation injuries, endotracheal intubation, central venous access, arterial lines, urinary catheters, surgical procedures, and prolonged hospitalization. Moreover, systemic changes in burn patients also impact the immune system, further increasing susceptibility to infections.[1,7,8] The most common infections in burn patients are pneumonia, bloodstream infections, and wound infections.[9]

Prevention and early diagnosis of sepsis are essential in the care of burn patients. Prevention can be achieved via antimicrobial dressings, surgical intervention with early grafting, and nutritional support. However, there is no evidence of effectiveness in administering systemic antimicrobials preventively.[7] Antimicrobial resistance increases morbidity, mortality, and length of hospital stay, while also hindering the prevention of infections in patients undergoing multiple procedures and reducing therapeutic options for treating infections caused by some microorganisms. Furthermore, antimicrobial resistance increases healthcare costs for both public and private/supplementary systems, as well as for society.[10]

In 2021, it is estimated that 4.71 million deaths were associated with bacterial resistance worldwide. Among Gram-negative bacteria, resistance to carbapenems stood out compared to other classes of antimicrobials, with these infections totaling 1.03 million associated deaths.[11]

Given the above, this study aimed to identify bacterial infections and antimicrobial consumption in burn patients admitted to a burn/trauma intensive care unit (ICU).

METHODS

This work followed an observational design with retrospective data collection and was conducted in a reference ICU for the treatment of burn patients, with 10 beds, at a public hospital in the south of Brazil. This unit receives patients from various municipalities statewide and also operates as a backup for other trauma cases. In this study, all patients hospitalized for burns from January to December 2022 were included. Patients hospitalized for other causes were excluded.

The data were obtained via the SIH/SUS, specifically from the Medical Records, Laboratory, and Pharmacy modules, and were compiled into an Excel spreadsheet for analysis. The Medical Records module covers the patient evolution by both the medical and multidisciplinary team perspective, so the information is presented in a complementary way. The Laboratory module provides access to laboratory test results, including cultures and antibiograms. The Pharmacy module provides access to data on medications dispensed by the hospitalization unit. Burn cause was classified at the time of admission following the SIS/SUS categories, including chemical agent, electric current, explosive, fire, or liquids. Data on patient's age, sex, cause of burn, length of stay, burned body surface, outcome, microorganisms identified in culture tests, and the dose and type of antimicrobials used.

The antimicrobials used during the period were grouped following the third level of the Anatomical Therapeutic Chemical (ATC) classification, corresponding to the pharmacological subgroup, then further categorized following the fifth level, corresponding to the specific chemical substance.

The amount of antibacterial used, in grams, was divided by the corresponding Defined Daily Dose (DDD), which represents the assumed average maintenance dose per day for a medication used for its main indication in adults weighing 70 kg, despite not necessarily reflecting the recommended or prescribed daily dose.[12] Then, the number of patient-days was used as the denominator to estimate the density or consumption rate per patient-day. This consumption

density was multiplied by 1,000, transforming into density or consumption rate per thousand patient-days (DDD/1000). The DDD patient-day data is a measure that enables comparisons of medication consumption between studies.[13]

The data were compiled into Excel spreadsheets, analyzed using descriptive statistics, and presented via absolute and relative frequencies.

The research was conducted following the required ethical standards, in accordance with Resolutions 466/2012, 510/2016 and 580/2018, of the Brazilian Ministry of Health. The project was approved by the Research Ethics Committee, CAAE 62935722.1.0000.5338 under opinion 5801905, on December 8, 2022.

RESULTS

During 2022, 197 patients were admitted to the ICU, 64 (34%) due to burns. Most burn patients were male (75%), with a median age of 43 years, ranging from 18 to 83 years. The major cause of burns was fire (45.31%), and death occurred in 25% of cases (Table 1).

Table 1. Characteristics and outcomes of burn patients admitted to a burn/trauma ICU (Porto Alegre, ICU, 2022, n=64).

Parameter	Outcome				
	Discharge on request N (%)	Discharge N (%)	Death N (%)	Transfer N (%)	Total N (%)
Sex					
Female	0	11 (17.2)	3 (4.7)	2 (3.1)	16 (25.0)
Male	2 (3.1)	28 (43.8)	13 (20.3)	5 (7.8)	48 (75.0)
Age group (years)					
15 to 40	2 (3.1)	20 (31.3)	5 (7.8)	4 (6.3)	31 (48.4)
41 to 60	0	15 (23.4)	7 (10.9)	1 (1.6)	23 (35.9)
More than 60	0	4 (6.3)	4 (6.3)	2 (3.1)	10 (15.6)
Cause of burn					
Chemical agent	0	6 (9.4)	3 (4.7)	1 (1.6)	10 (15.6)
Electrical current	0	6 (9.4)	1 (1.6)	0	7 (10.9)
Explosive	1 (1.6)	4 (6.3)	1 (1.6)	1 (1.6)	7 (10.9)
Fire	0	17 (26.6)	10 (15.6)	2 (3.1)	29 (45.3)
Liquids	1 (1.6)	6 (9.4)	1 (1.6)	3 (4.7)	11 (17.2)
Days in ICU					
Up to 10	0	15 (23.4)	8 (12.5)	0	23 (35.9)
11 to 30	2 (3.1)	13 (20.3)	8 (12.5)	3 (4.7)	26 (40.6)
31 to 90	0	9 (14.1)	0	1 (1.6)	10 (15.6)
More than 90	0	2 (3.1)	0	3 (4.7)	5 (7.8)
Body surface area (%)					
Up to 20	2 (3.1)	20 (31.3)	2 (3.1)	2 (3.1)	26 (40.6)
20 to 40	0	15 (23.4)	5 (7.8)	3 (4.7)	23 (35.9)
More than 40	0	4 (6.3)	9 (14.1)	2 (3.1)	15 (23.4)
Not informed	0	1 (1.6)	0	0	1 (1.6)
Total	2 (3.1)	39 (61.0.)	16 (25.0)	7 (10.9)	64 (100.0)

The average length of stay in the ICU was 30.2 days, and total hospitalization was 46.7 days. The incidence rate of bacterial and fungal infections in critically ill burn patients was 73.4% and 4.7%, respectively. Of the 64 patients, 50 (78.1%) received antibiotics and 47 (73.4%) had positive culture results.

In total, 15 different antimicrobials were used, totaling 13,060 units dispensed. The total consumption of antimicrobials during the period was 1,111.60 DDD/1000 patient-days. Meropenem, oxacillin, polymyxin B, and vancomycin were the antimicrobials with the highest DDD/1000 (Table 2).

Table 2. Units consumed and defined daily dose of antimicrobials used in burn patients admitted to a burn/trauma ICU in 2022.

ATC	Antimicrobials	DDD/1000	Consumed units
Other antimicrobials		**361.9**	**3,720**
J01XB02	Polymyxin B 500.000 UI vial	183.9	1,624
J01XA01	Vancomycin 500 mg vial	178.0	2,096
Beta-lactams, penicillins		**346.6**	**3,811**
J01CF04	Oxacillin 500 mg vial	250.5	2,950
J01CR05	Piperacillin 4 g + Tazobactam 500 vial	49.3	508
J01CR02	Amoxicillin 1 g + Clavulanate 200 mg vial	28.5	21
J01CR01	Sulbactam 1 g + Ampicillin 2 g vial	18.8	332
Other beta-lactams		**335.7**	**5,268**
J01DH02	Meropenem 500 mg vial	281.0	4,963
J01DE01	Cefepime 2 g vial	39.9	235
J01DB04	Cefazolin 1 g vial	9.0	8
J01DD02	Ceftazidime 1 g vial	4.8	56
J01DD04	Ceftriaxone 1 g vial	1.0	6
Aminoglycosides		**32.7**	**108**
J01GB03	Gentamicin 80 mg/2 mL ampoule	16.9	15
J01GB06	Amikacin 500 mg/2 mL ampoule	15.8	93
Quinolones		**23.4**	**147**
J01MA12	Levofloxacin 500 mg/100 mL bag	14.6	43
J01MA02	Ciprofloxacin 200 mg/100 mL bag	8.8	104
Macrolides, streptogramins, and lincosamides		**11.3**	**6**
J01FA10	Azithromycin 500 mg vial	6.8	2
J01FF01	Clindamycin 600 mg/4mL ampoule	4.5	4
Total		**1,111.6**	**13,060**

The microorganisms were isolated and identified via cultures of material collected from the respiratory system (tracheal aspirate, sputum, pleural fluid), bloodstream cultures, and urinary system. These tests were requested in order to confirm or reject the diagnosis of an infectious condition associated with devices in ICU patients on mechanical ventilation, with tracheostomy, central and/or peripheral venous line, and indwelling bladder catheters.

A total of 263 microorganisms were isolated, Gram-negative (69.6%), Gram-positive (27.7%), and fungi (2.7%). A single patient could have more than one pathogen identified in more than one collection site. The fungus *Candida* sp. was identified in seven samples, with three from the respiratory system and four from the urinary system (Figure 1).

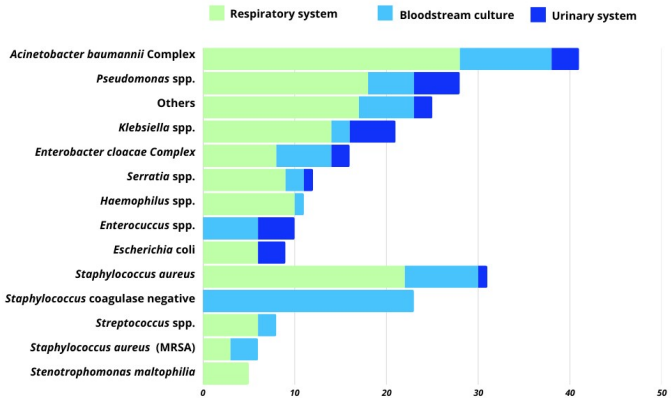

Figure 1. Gram-positive and Gram-negative microorganisms identified by collection site in burn patients admitted to a burn/trauma intensive care unit in 2022.

DISCUSSION

In this study, the incidence rate of bacterial infections in critically ill burn patients was high (almost a third of patients) and resulted in the use of 15 different

antimicrobials, with a greater frequency of broad-spectrum antimicrobials such as meropenem and vancomycin. The average age of patients admitted to the ICU was 43 years, mostly males, and a higher prevalence of burns caused by fire, a profile consistent with both international and national studies.[14,15,16]

The average length of ICU stay was 30.2 days, similar to the findings of a study conducted with 711 patients admitted from 2011 to 2020 in Lisbon, Portugal, in which the average was 29 days. The factors that prolonged hospital stay included burn severity, the number of surgeries, the time elapsed until the first surgery, hematological and biochemical laboratory parameters during hospitalization, and the presence and number of documented infections.[17] On the other hand, a study conducted in Goiânia, state of Goiás reported an average ICU stay of 14.73 days.[14] A review study covering 54,397 burn patients showed a trend towards a positive association between infection and longer hospital stay.[9]

In this context, 62.5% of patients were discharged, whereas 25% had a fatal outcome. Other studies indicated a mortality rate of around 10%.[14,15] A retrospective study conducted at a university hospital in the city of Uberaba, state of Minas Gerais, with 168 burn patients hospitalized from January 2013 to January 2019, found a positive relationship between mortality and incidence of infections, as well as burned body surface, number of accesses used, and hospital expenses. The mortality rate was 7.73%, similar to that found in this study.[18]

We highlight that severe burn injuries are traumatic and physically debilitating, impacting almost all body systems and leading to significant morbidity and mortality.[1] Burn patients are vulnerable to infections, making the rational use of antimicrobials essential in the prevention of the development of bacterial resistance in the hospital setting. Patients with severe burns commonly require prolonged hospitalization, urinary and arterial catheters, central lines, orotracheal intubation, and/or other procedures that also increase the risk of contamination. Moreover, the use of broad-spectrum antimicrobial therapy is an important factor in the development of infections caused by resistant agents.[17]

We found a 73.4% incidence of bacterial infections in critically ill burn patients, with 47.5% in the respiratory system, 28.1% in the bloodstream, and 11.4% in the urinary system. We found no records of skin infections related to burns. A review study found that the main infections in burn patients include pneumonia,[5,8] bloodstream infections, and those in burned areas.[9] The formation of biofilm on catheters plays an important role in infections, as bacteria are in a protected environment, with proximity that enables the exchange of genetic material, thus facilitating the occurrence of phenotypic changes and the production of virulence factors.[19]

Among the 263 microorganisms isolated, 69.6% were Gram-negative and 27.7% were Gram-positive, a result similar to the review study by Braga and collaborators, which evaluated the main pathogens causing infections in burn patients and found a frequency of Gram-positive and Gram-negative bacteria ranging from 21.8% to 24% and from 70.3 to 78%, respectively.[20]

The results regarding Gram-negative bacteria are in line with the findings by Troche-Zaracho and collaborators (2017), who found *Pseudomonas aeruginosa* (37%), *Acinetobacter* spp. (26%), and *Klebsiella* spp. (18%) as the most prevalent strains.[16] A study involving patients in a trauma ICU (without burns), showed a bacteriological profile similar to that found in the burn/trauma ICU in Porto Alegre, state of Rio Grande do Sul, with 75% of the bacteria isolated being Gram-negative and 25% Gram-positive, in line with our results and with the hospital bacteriological profiles found in the literature.[21]

The risk of infections caused by multidrug-resistant microorganisms increases with the length of hospital stay in burn patients. In the first days of post-burn hospitalization, more susceptible Gram-positive microorganisms predominate, while later more resistant Gram-negative microorganisms are found.[5,8]

A study evaluated 200 burn patients at a hospital in Italy, and the cumulative prevalence of infections was 27% on the 7th day and 43.8% on the 28th day. Skin and soft tissue infections (32%) were the most common. The most prevalent infections included carbapenem-resistant *Acinetobacter baumannii* (28%), *P. aeruginosa* (26%), and *Staphylococcus aureus* (MRSA) (25%). The presence of a central line was associated with a higher infection rate, while surgical treatment acted as a protective factor.[22]

Regarding fungal infections, *Candida* sp. was identified in seven samples, three of which came from the respiratory system and four from the urinary system. *Candida* sp is the main fungus found in burn wounds and represents a significant risk only when it invades certain tissues or the bloodstream, considerably increasing lethality rates. The incidence of this pathogen increases with prolonged hospitalization, especially if it exceeds three weeks, due to the routine antimicrobial use and the presence of extensive lesions not covered by grafts.[19]

It is crucial that antimicrobials are prescribed only when there is a clear clinical indication, administered at the appropriate dose, and for an appropriate period, following the institutional protocols. Moreover, they should be chosen based on the sensitivity of the bacteria causing the infection and monitored for the development of adverse effects.[13]

Regarding the use of antimicrobials, the total consumption during the analyzed period was 1,111.6 DDD/1000, significantly higher than that found in a study conducted at the National Burn Center of Paraguay, which showed an antimicrobial consumption of 78.4 DDD/100 bed-days.[16]

In this study, meropenem, oxacillin, polymyxin B, and vancomycin were the most frequently used antimicrobials. In the study by Troche-Zaracho and collaborattors (2017), ceftazidime was the most used drug, and among the most consumed classes of antimicrobials were "Other antibacterials" (36.19 DDD/100 patient-days), followed by "Beta-lactams and penicillins" (34.66 DDD/100 patient-days),[16] showing a similar profile to that found in our study.

The class of "Other antibacterials," represented by the drugs vancomycin and polymyxin B, showed the highest consumption (32.5% of the total). Vancomycin is the first choice for empirical treatment when MRSA infection is suspected, particularly in regions with a high prevalence of methicillin-resistant *S. aureus* isolates and in patients known to be colonized by MRSA.[23] However, the bacterial profile in this study pointed that only 2.3% of the samples were infected with MRSA.

Moreover, vancomycin is generally used as part of combined treatments in cases of infections caused by multidrug-resistant Gram-negative bacteria, including *P. aeruginosa* and *A. baumannii*.[22] The indication of the drug is in line with the bacterial profile identified in this study. However, consumption was found to be disproportional when related to the low prevalence of cultures with MRSA. Some factors such as surgical prophylaxis with vancomycin and a longer time until de-escalation may have contributed to the high rate of use of this medication.

Regarding the "Beta-lactams of the penicillin class," oxacillin was the most used, showing a good safety and efficacy profile considering the assessment of susceptibility to methicillin. Moreover, oxacillin shows good tissue penetration and is one of the drugs of choice in cases of *S. methicillin-sensitive aureus* (MSSA). In a study conducted at a general ICU, which analyzed antimicrobial consumption over five years, there was a large variation in oxacillin consumption over the period. However, a tendency towards an increase in MRSA was found among the isolates of Gram-positive microorganisms, along with an increase in the consumption of vancomycin and a decrease in oxacillin. Overall, the study pointed a decrease in the consumption of medications with a more selective action against Gram-positive microorganisms and an increase in medications with a selective profile for Gram-negative or broad-spectrum microorganisms.[24]

Meropenem is a broad-spectrum antimicrobial and accounted for 38% of the total antimicrobials dispensed. A systematic review and meta-analysis sought to identify potential modifiable risk factors for colonization or infection by multidrug-resistant Gram-negative microorganisms in severely burned patients. Previous exposure to extended-spectrum cephalosporins and carbapenems, as well as the use of urinary and arterial catheters, were found to pose a greater risk of infection or colonization by these microorganisms.[25]

The use of broad-spectrum drugs, such as meropenem and vancomycin, is associated with the infection profile typically found in the ICU setting. The choice of empirical antibiotics in severely burned patients requires a proactive approach by the multidisciplinary infection control team,[5,8] which is in line with the recommendations of the Brazilian National Plan for Antimicrobial Resistance Prevention and Control in Health Services, which considers interaction between prescribers, clinical analysis laboratories, and clinical pharmacy services to be essential. This interaction enables monitoring of therapy results, as well as directing treatment time and de-escalation of antimicrobials used. Joint actions allow improving patient outcomes and reducing hospital costs.[13]

This study shows limitations, including its retrospective nature, with data collected from medical records, which may be incomplete or inaccurate. For this reason, the data analyzed are associated with information on antimicrobial consumption and test results, which are generally good quality data.

The estimation of DDD/1000 is an antimicrobial consumption data that enables monitoring trends in consumption patterns over time and facilitates comparisons within the same institution and/or other hospitals. However, the tool shows limitations, as it does not analyze the adequacy of antimicrobial indications or treatment time.[12,13,21]

On the other hand, the present study provided a comprehensive overview of the epidemiology and treatment of patients with severe burns in a burn/trauma ICU. The results revealed a significant number of bacterial infections. Understanding the local microbiological profile is important for selecting antimicrobial therapies, thus leading to better patient outcomes.

The results of this study can also encourage the development of a management program for the use of antimicrobials in the institution, that is, a set of actions aimed at controlling the use of antimicrobial medications in the service, including pharmacovigilance.

Further studies can be developed seeking to elucidate the associations between the variables analyzed, in addition to deepening the investigation into the microbiological profile and the prescription of antimicrobials in burn patients. Moreover, economic

analyses can be conducted on the use of antimicrobials and other medications used in the care of burn patients.

Understanding microbiological and microbial resistance profiles, along with treatment practices in burn patients, can support the clinical management of the medications used. The rational use of antimicrobials is essential for improving clinical outcomes and addressing the challenges inherent in treating patients with severe burns in hospital settings.

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AUTHORS' CONTRIBUTIONS

Tasiana Aylen Cervellera Simonetti contributed to the bibliographic research, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Matheus William Becker** contributed to project management, writing of methodology, discussion, interpretation and description of results, conclusions, review and statistics. **Carine Raquel Blatt** contributed to writing the abstract, methodology, interpretation and description of results, conclusions, review and statistics. **Karin Hepp Schwambach** contributed to project management, bibliographic research, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, conclusions, review and statistics.

All authors have approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Simonetti TAC, Becker MW, Blatt CR, Schwambach KH. Profile of antimicrobial use in burn patients admitted to an intensive care unit . Rev Epidemiol Control Infect [Internet]. 2025 Feb. 16; 15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19488

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Epidemiological profile of sepsis in a high-complexity hospital in northwest Paraná

Perfil epidemiológico de sepse em um hospital de alta complexidade do noroeste do Paraná
Perfil epidemiológico de la sepsise nun hospital de alta complejidad del noroeste de Paraná

Site doi: https://doi.org/10.17058/reci.v15i1.19482

Submitted: 05/28/2024
Accepted: 11/22/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: Sepsis constitutes a major cause of global morbidity and mortality with exorbitant costs. It is necessary to relate the patients' sociodemographic profile with sepsis diagnosis in order to understand the specific characteristics and outcomes and to provide information for the development of clinical protocols that positively impact prognoses. **Methods:** This cross-sectional, retrospective, and quantitative study with a documentary research collected data from January to December 2023. Data were analyzed on R (version R-4.3.0) with inferential statistics and association testing. The Fisher's exact test was used to assess variable relationships, with a 5% significance level. **Results:** Of the total 320 records, 76.6% (n=245) of patients died and 23.4% (n=75) were discharged. Patients aged over 60 years had a higher risk of infection and unfavorable outcomes. Regarding infection site, death was related to pulmonary (60.4%) and abdominal infections (13.1%). The analysis of the correlation between length of stay and mortality showed a higher incidence of unfavorable outcomes within the first seven days (40.0%). **Conclusion**: This study showed the relationship between sociodemographic profile and outcomes related to sepsis and septic shock in line with the Brazilian context and adding information that enables the development of a sepsis management protocol to reduce mortality.

Keywords: *Epidemiology. Hospitalization. Mortality. Sepsis*.

RESUMO

Justificativa e Objetivos: A sepse é uma grande causa de morbimortalidade global com custos extremamente elevados, para contribuir com informações para o desenvolvimento de protocolos clínicos se faz necessário relacionar o perfil sociodemográfico dos pacientes com diagnóstico de sepse e conhecer as especificidades e os desfechos apresentados. **Métodos:** Trata-se de uma pesquisa transversal, retrospectiva e documental de abordagem quantitativa, com universo amostral de pacientes adultos internados com diagnóstico de sepse de janeiro a dezembro de 2023. Os dados foram analisados no software R (versão R- 4.3.0) com estatística inferencial e teste de associação. Para relacionar as variáveis foi realizado o teste Exato de Fisher, com o nível de significância de 5%. **Resultados:** Do total de 320 prontuários, verificou-se que 76,6% (n = 245) dos pacientes evoluíram a óbito e 23,4% (n = 75) receberam alta. Pacientes com idade superior a 60 anos apresentaram maior risco de adquirir uma infecção e ter evolução desfavorável. Em relação ao foco da infecção, detectou-se que o desfecho de óbito está mais relacionado com a infecção pulmonar (60,4%) e abdominal (13,1%). A correlação entre o tempo de internamento e o óbito determinou que o desfecho desfavorável é maior no período de até 7 dias (40,0%). **Conclusão:** Este estudo mostrou a relação entre o perfil sociodemográfico com os desfechos relacionados com a sepse e o choque séptico, sendo condizente com o cenário brasileiro e contribuindo com informações que possibilitem o desenvolvimento de um protocolo de gerenciamento da sepse para a redução da mortalidade.

Descritores: *Epidemiologia. Hospitalização. Mortalidade. Sepse.*

RESUMEN

Justificación y Objetivos: La sepsis es una de las principales causas de morbimortalidad en el mundo, con costos extremadamente elevados, por lo cual con el fin de contribuir con información para el desarrollo de protocolos clínicos es necesario relacionar el perfil sociodemográfico de los pacientes con diagnóstico de sepsis y comprender las especificidades y los desenlaces presentados. **Métodos:** Se trata de una investigación transversal, retrospectiva y documental con enfoque cuantitativo, en la cual se contó con la participación de pacientes adultos, hospitalizados con diagnóstico de sepsis de enero a diciembre de 2023. Los datos se analizaron en el software R (versión R- 4.3.0) utilizando estadística inferencial y pruebas de asociación. Para relacionar las variables se realizó la prueba Exacta de Fisher, con un nivel de significancia del 5%. **Resultados:** Del total de 320 registros, se verificó que el 76,6% (n=245) de los pacientes fallecieron y que el 23,4% (n=75) fueron dados de alta. Los pacientes mayores de 60 años presentaron un mayor riesgo de adquirir una infección y tener un resultado desfavorable. En cuanto al foco de la infección, se detectó que el desenlace de fallecimiento estuvo relacionado con la infección pulmonar (60,4%) y abdominal (13,1%). El análisis de la correlación entre la duración de la estancia hospitalaria y la mortalidad reveló una mayor incidencia de resultados desfavorables en los primeros 7 días (40,0%). **Conclusión:** Este estudio mostró la relación entre el perfil sociodemográfico y los desenlaces relacionados con la sepsis y el choque séptico, por lo cual estuvo coherente con el contexto brasileño y aportó información para el desarrollo de un protocolo de manejo de la sepsis con el fin de reducir de la mortalidad por esta afección.

Palabras Clave: *Epidemiología. Hospitalización. Mortalidad. Sepsis.*

INTRODUCTION

Sepsis constitutes a major cause of global morbidity and mortality. In 2017, 48.9 million cases and 11.0 million deaths were recorded, representing 19.7% of deaths worldwide.[1] It is also considered a main cause of hospital mortality, surpassing the death rates for myocardial infarction and cancer. The Covid-19 pandemic has further aggravated this problem in healthcare facilities.[2]

A multicenter study conducted by the Latin-American Sepsis Institute (ILAS) entitled *Sepsis PREvalence Assessment Database* (SPREADs) evaluated sepsis incidence and mortality in 227 randomized intensive care units in Brazil, finding an average of approximately 30% of ICU beds occupied by patients with sepsis or septic shock and a lethality rate around 55%.[3]

Sepsis can vary according to age group, sex, and region analyzed, as places with lower sociodemographic indices have higher incidence and mortality. [1] Thus, updates on the epidemiological profile are fundamental to direct fighting programs and prevent involvement. These measures must be implemented and monitored mainly in the hospital environment since this setting has a high development of this disease, with higher mortality rates than community-acquired sepsis.[4, 5]

Furthermore, sepsis-related costs are extremely high.[6] In Brazil, a case of sepsis can cost up to US$ 9,632.00 with a daily average of US$ 934.00, and the median daily cost for non-surviving patients is significantly higher than that of survivors.[7] From 2010 to 2019, the state of Paraná recorded 27,516 deaths, showing a coefficient of 24.8 per 100,000 inhabitants, data that represent patients treated by the Brazilian Unified Health System (SUS).[3]

Given the above, this study describes the sociodemographic profile of patients diagnosed with sepsis in order to understand the specificities and outcomes presented, and to contribute with information for developing clinical protocols that can reduce mortality.

METHODS

This is a quantitative cross-sectional, observational, retrospective and documentary study conducted in a high-complexity hospital in northwest Paraná. It was conducted at the Sarandi Metropolitan Health Care Network, a tertiary hospital in northwest Paraná that provides 204 beds, 42 of which are divided into three Adult Intensive Care Units and is a reference center for neurocritical and polytraumatized patients. ICD-10 code A41 was used for data search and collection on records from the Infection Control Service and the electronic medical records made available by the Medical and Statistical Archive Service (SAME) regarding the population admitted to the institution from January to December 2023. Sociodemographic profile data (sex, age group, race/ethnicity, origin, occupation, inflammatory site, and length of hospital stay) were collected using a specific form. These data were collected from patients over 15 years old with records of sepsis or septic shock diagnosis at this hospital.

Data were stored and organized in Microsoft Office Excel spreadsheets and analyzed using the R software (version R-4.3.0). For this purpose, an inferential statistic was considered with p-value calculation and association test. Tables were constructed to describe patient sociodemographic profile and show the diagnosis characterization. Relationship between personal and diagnostic variables were estimated by Fisher's exact test which analyzes the relationship between two qualitative variables. Significance level was set at 5%.

The research was authorized by the Research Ethics Committee (COPEP) of the State University of Maringá, as recommended by Resolution 466/12 by opinion No. 6,014,607. Protocol No. CAAE 66526722.5.0000.0104.

RESULTS

A total of 320 medical records related to ICD-10 code A41 were selected, 54.1% of which were male patients and 45.9% female. Table 1 shows that community-based infection and healthcare-related infection (HRI) have a higher occurrence in males. However, statistical analysis indicates that they are independent. Regarding age group, most patients were over 60 years old (67.2%). The remaining patients were divided into different age ranges. For infections, both community infections (found on admission) and HRI, the most affected age group was also those over 60, corresponding to 69.2% and 57.4%, respectively. This association was statistically significant with a p-value of 0.0041 (Table 1).

Table 1. Sociodemographic profile regarding infection origin presented by patients treated at a tertiary and philanthropic hospital in northwest Paraná from January to December 2023.

Sociodemographic profile	Community (%)	HRIs (%)	Total (%)	P-value
Sex				
Female	125 (47.0)	22 (40.7)	147 (45.9)	0.4552
Male	141 (53.0)	32 (59.3)	173 (54.1)	
Age group				
15 to 30 years	12 (4.5)	7 (13.0)	19 (5.9)	
31 to 45 years	19 (7.1)	9 (16.7)	28 (8.8)	
46 to 60 years	51 (19.2)	7 (13.0)	58 (18.1)	0.0041*
61 to 75 years	83 (31.2)	20 (37.0)	103 (32.2)	
Over 75	101 (38.0)	11 (20.4)	112 (35.0)	
Ethnicity/Race				
White	168 (63.2)	37 (68.5)	205 (64.1)	
Mixed-race	83 (31.2)	16 (29.6)	99 (30.9)	0.8223
Black	10 (3.8)	1 (1.9)	11 (3.4)	
Asian	5 (1.9)	0 (0.0)	5 (1.6)	
Origin				
Maringá	50 (18.8)	13 (24.1)	63 (19.7)	
Sarandi	107 (40.2)	9 (16.7)	116 (36.3)	
Other municipalities of the 15th Regional	82 (30.8)	17 (31.5)	99 (30.9)	0.0004*
Other Regionals	27 (10.2)	15 (27.8)	42 (13.1)	

As for race/ethnicity, most patients were white (64.1%), followed by mixed-race (30.9%), black (3.4%) and Asian (1.6%) individuals. Statistical analysis using this variable and community and HRI sepsis showed that this association can be ruled out based on the p-value = 0.8223. Most patients came from the municipality of Sarandi (36.3%), followed by those from other 15th Regional Health Region municipalities (30.9%), Maringá (19.7%) and patients from municipalities of other health regions (13.1%). Association test of origin and infection resulted in a p-value of 0.0004, indicating a correlation between these variables (Table 1).

There were 245 deaths and 75 discharge processes, with no association between sex and outcome (discharge or death) (p-value = 0.3573). Among patients over 60, 52.0% were discharged and 71.9% of those who remained hospitalized died. Association test between age group and outcome resulted in a p-value of 0.0002, i.e., the age group is related to the patient's outcome, especially in case of death (Table 2).

Table 2. Sociodemographic profile regarding the outcome of patients treated at a tertiary and philanthropic hospital in northwest Paraná from January to December 2023.

Sociodemographic profile	Discharge (%)	Death (%)	Total (%)	P-value
Sex				
Female	38 (50.7)	109 (44.5)	147 (45.9)	0.3573
Male	37 (49.3)	136 (55.5)	173 (54.1)	
Age group				
15 to 30 years	10 (13.3)	9 (3.7)	19 (5.9)	
31 to 45 years	14 (18.7)	14 (5.7)	28 (8.8)	
46 to 60 years	12 (16.0)	46 (18.8)	58 (18.1)	0.0002*
61 to 75 years	20 (26.7)	83 (33.9)	103 (32.2)	
Over 75	19 (25.3)	93 (38.0)	112 (35.0)	
Origin				
Maringá	15 (20.0)	48 (19.6)	63 (19.7)	
Sarandi	33 (44.0)	83 (33.9)	116 (36.3)	
Other municipalities of the 15th Regional	18 (24.0)	81 (33.1)	99 (30.9)	0.3593
Other Regionals	9 (12.0)	33 (13.5)	42 (13.1)	
Occupation				
Non EAP	46 (61.3)	182 (74.3)	228 (71.3)	0.0406*
EAP	29 (38.7)	63 (25.7)	92 (28.8)	

Legend: EAP: Economically active person.

Note that 44.0% of the discharged patients and 33.9% of those who died were from the municipality of Sarandi. However, the association test between origin and outcome was not significant (p-value = 0.3593). As for occupation, discharge occurred in 38.7% of Economically Active (EA) patients and in 61.3% of non-EA individuals, i.e., homemakers, retirees/pensioners, students, among others. Death occurred in 74.3% of non-EA patients and 25.7% of EA. Association test between occupation and outcome was significant (p-value = 0.0406) (Table 2).

Among the discharged patients, 81.3% were diagnosed with community-acquired infection and 18.7% with HRIs. Of those who died, 83.7% were diagnosed with community-acquired infection and 16.3% with HRIs. Statistical analysis found no correlation between the type of infection and outcome (p-value = 0.6026). Table 3 summarizes the relationship between outcome, infection site, and length of hospital stay.

Table 3. Analysis of outcome in relationship to infection site and the length of hospital stay of patients treated at a tertiary and philanthropic hospital in northwest Paraná from January 2023 to December 2023.

Diagnosis	Discharge (%)	Death (%)	Total (%)	P-value
Type of infection				
Community	61 (81.3)	205 (83.7)	266 (83.1)	0.6026
HRIs	14 (18.7)	40 (16.3)	54 (16.9)	
Site				
Abdominal	6 (8.0)	32 (13.1)	38 (11.9)	
Cutaneous	3 (4.0)	19 (7.8)	22 (6.9)	
Soft parts	0 (0.0)	1 (0.4)	1 (0.3)	
Pulmonary	39 (52.0)	148 (60.4)	187 (58.4)	0.0241*
Urinary tract	23 (30.7)	31 (12.7)	54 (16.9)	
Two sites**	4 (5.3)	12 (4.9)	16 (5.0)	
Unspecified	0 (0.0)	2 (0.8)	2 (0.6)	
Length of hospital stay				
0 to 7 days	16 (21.3)	98 (40.0)	114 (35.6)	
8 to 15 days	19 (25.3)	64 (26.1)	83 (25.9)	
Up to 1 month	15 (20.0)	46 (18.8)	61 (19.1)	0.0014*
Up to 3 months	19 (25.3)	33 (13.5)	52 (16.3)	
More than 3 months	6 (8.0)	4 (1.6)	10 (3.1)	

As for the correlation between infection site and discharged patients, 52.0% had pulmonary site-related sepsis and 30.7%, urinary tract-related. Regarding the outcome death, pulmonary site was also observed in greater proportion (60.4%), followed by abdominal (13.1%) and urinary tract (12.7%). Association test between infection site and patient outcome showed a significant relationship with p-value = 0.0241. For discharged patients, the proportion was similar between the time ranges of 1 day to 3 months. Of the patients who died, 40% were hospitalized up to 7 days, 26.1% up to 15 days, 18.8% up to 1 month, 13.5% up to 3 months and 1.6% more than 3 months. Association between length of hospital stay and outcome was confirmed with p-value = 0.0014 (Table 3).

DISCUSSION

A study conducted in the Brazilian territory shows that sepsis incidence in the Southeast stands out due to the State of Minas Gerais, which had the highest coefficient of hospitalizations with 81.3 cases per 1000 patients/day (95% CI 80.0–82.5). As for mortality, the Northeast had a PCA of 17.8 (95%CI 14.5–21.2) from 2010 to 2016.[8]

Statistical analysis found that patients over 60 years are more likely to acquire an infection with evolution to sepsis, showing that the older the age (> 60 years), the greater the probability of death. This finding corroborates other studies which verified that this condition mainly affects older adults, a population more vulnerable to infectious agents and consequent development of inflammatory processes that may be related to physiological changes inherent to the ageing process which increases the risk of death.[9,10,11,12]

Regarding sex, a small difference was observed between the percentage values of sepsis occurrence and/or septic shock for male patients compared with female patients. Similar situation was described in two studies which obtained information from the Ministry of Health's SUS Department of Informatics (DATASUS). These studies highlight that male individuals pay less care and attention to their health compared with women and thus may present greater occurrence of sepsis.[13,14] However, research conducted from January 2017 to March 2018 in a university hospital in southern India showed a higher occurrence for women.[15]

Given this context, new studies should focus on the possible difference related to sepsis development, establishing a relationship between the biological differences between sexes to justify a sex-based prevalence in relation to hospitalizations due to sepsis.

As for the occupation of patients affected by sepsis, non-EA patients may be correlated with age, since 71.3% of patients are retired/pensioners, among others. Hence, they are close to or over 60 years old.

Hospitalized patients who self-declared their race/ethnicity were mostly white (64.1%) which concurs with the study by Belo et al., who analyzed the epidemiological aspects of sepsis and mortality in Brazil.[16] The 2022 IBGE Census also corroborates this study and highlights that Paraná has approximately 64% of if its population self-declared white.[17]

Correlation between outcome (discharge/death) and the infectious site was significant, and here patient death was related especially with pulmonary and abdominal site-relate infection. Some authors have reported the prevalence of pulmonary site-related sepsis,[13,18] whereas others reported the prevalence of abdominal site-related sepsis. A study conducted in Rio Branco from March 2016 to February 2018 found that patients with abdominal sepsis died, were over 60 years and presented septic shock.[19]

A global study covering 42 countries observed that ICU patients with intra-abdominal infection and age over 60 years had an association with the outcome death, and that patients over 80 years presented the worst prognosis associated with comorbidities and general disease severity.[20]

Moreover, the shorter the hospitalization time, the greater the probability of death. This association might be related to the patient's clinical condition at time of hospitalization, in which many patients already present alterations in vital organs and end up evolving to an unfavorable outcome, as described by Arvaniti et al.[20]

Still regarding the outcome (discharge/death), some authors have described that patients with septic shock are more likely to die compared with patients diagnosed with sepsis. Additionally, this outcome is also related to patient comorbidities and age, concurring with the present results and with those described by Arvatini et al. and Gorordo-Delsol et al.[20, 21]

In short, our findings showed the relationship between the sociodemographic profile and the outcomes related to sepsis and septic shock, corroborating the statistical accuracy presented by the Brazilian scenario. Importantly, as the search for care records used the ICD-10 code A41, some medical records may have been overlooked since they indicated infection with sepsis criteria but lacked the ICD code. To mitigate this fact, data collection should take place during patient hospitalization so that any absent information can be obtained from the care team.

This study investigated the relationships between the sociodemographic profile of patients with sepsis and septic shock with outcomes (discharge/death) who were treated at a tertiary and philanthropic hospital in northwest Paraná. Our results concur with the Brazilian scenario and contribute with useful information that enables developing a sepsis management protocol aimed at standardizing conducts and reducing mortality.

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AUTHORS' CONTRIBUTIONS

Patrícia Junglos contributed to the bibliographic research, writing of the abstract, introduction, methodology, discussion, interpretation, conclusions. **PhD Prof. Edilson Nobuyoshi Kaneshima** contributed to project management, bibliographic research, methodology, discussion and review.

All authors have approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Junglos P, Kaneshima EN. Epidemiological profile of sepsis in a high-complexity hospital in northwest Paraná. Rev Epidemiol Control Infect [Internet]. 2025 Jan. 21;15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19482

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Association of biological factors, social determinants of health, and hospitalization with mortality due to SARS/Covid-19

Associação de fatores biológicos, determinantes sociais de saúde e hospitalização com a mortalidade devido a SRAG/Covid-19

Asociación de factores biológicos, determinantes sociales de la salud y hospitalización con mortalidad por SRAS/Covid-19

Site doi: https://doi.org/10.17058/reci.v15i1.19438

Submitted: 05/09/2024
Accepted: 10/18/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: To study the factors related to mortality in patients with severe acute respiratory syndrome (SARS) in order to understand the dynamics of transmission, health care delivery, and the epidemiological profile of patients upon the demographic, economic and health care diversity found in Brazil. The present study seeks to evaluate the association of sociodemographic, clinical and hospitalization variables with mortality among hospitalized patients with SARS by Covid-19 between the 14th and 39th epidemiological weeks of 2021 in Ituiutaba-MG. **Methods:** Cross-sectional study with on-site review of SARS notifications, diagnostic examinations, and death certificates of SARS-CoV-2 cases. Prevalence ratio was estimated using Poisson regression. **Results:** Out of 8,770 cases confirmed, 592 notifications were evaluated from April 4th to October 2nd, 2021. Fewer years of education, vaccination with two doses and need for invasive ventilation were associated with mortality. The risk of death increased with every year of life (PR=1.03; 95%CI 1.02-1.04), the presence of chronic disease (PR=1.55; 95%CI 1.1-2.18), and ICU hospitalization (PR= 3.49 95%CI 2.7-4.54). **Conclusion:** In addition to age, pre-existing clinical conditions and ICU hospitalization contribute to mortality.

Keywords: *Severe acute respiratory syndrome. Mortality registries. Covid-19 vaccines. Comorbidity. Covid-19 Testing.*

RESUMO

Justificativa e Objetivos: Investigar os fatores relacionados com a mortalidade em pacientes com síndrome respiratória aguda grave (SRAG), a fim de compreender as dinâmicas de transmissão, oferta de serviços de saúde e o perfil epidemiológico dos pacientes mediante a diversidade populacional, econômica e de assistência em saúde encontradas no Brasil. O presente estudo busca avaliar a associação de variáveis sociodemográficas, clínicas e de hospitalização em pacientes com por Covid-19 com a mortalidade entre a 14ª e 39ª semana epidemiológica de 2021 em Ituiutaba-MG. **Métodos:** Estudo transversal com consulta local de notificações de SRAG, de diagnóstico e certidão de óbito. Razões de prevalência foram estimadas por regressão de Poisson. **Resultados:** Dos 8.770 casos confirmados, 592 notificações foram avaliadas entre 4 de abril a 2 de outubro de 2021. Poucos anos de estudo, vacinados com duas doses e necessidade de ventilação invasiva foram associadas ao óbito. O risco de morte aumentou a cada ano de vida (RP=1,03; IC95% 1,02-1,04), na presença de doença crônica (RP=1,55; IC95% 1,1-2,18), e para os hospitalizados na UTI (RP= 3,49 IC95% 2,7-4,54). **Conclusão:** Além da idade, as condições clínicas preexistentes e a internação em UTI são contributivas para o óbito.

Descritores: *Síndrome respiratória aguda grave. Registros de mortalidade. Vacinas contra Covid-19. Comorbidade. Teste para Covid-19.*

RESUMEN

Justificación y Objetivos: Investigar los factores relacionados con la mortalidad en pacientes con el síndrome respiratorio agudo severo (SRAS), a fin de comprender las dinámicas de transmisión, la oferta de servicios sanitarios y el perfil epidemiológico de los pacientes mediante la diversidad de población, económica y de asistencia en salud encontradas en Brasil. El presente estudio busca evaluar la asociación de variables sociodemográficas, clínicas y de hospitalización de individuos con síndrome respiratorio agudo severo por Covid-19 con la mortalidad entre la semana epidemiológica 14 y 39 del año 2021 em Ituiutaba-MG. **Métodos:** Estudio transversal, con consulta local de notificaciones de SRAS, de diagnóstico y certificado de defunción. Las razones de prevalencia se estimaron mediante regresión de Poisson. **Resultados:** De los 8.770 casos confirmados, se evaluaron 592 notificaciones entre abril y octubre del 2021. Los menores años de escolaridad, la vacunación con dúas doses, y el uso de ventilación invasiva se asociaron con la muerte. El riesgo de muerte aumentó con cada año de vida (RP=1,03; IC95% 1,02-1,04), en presencia de enfermedad crónica (RP=1,55; IC95% 1,1-2,18), y en pacientes hospitalizados en UCI (RP= 3,49; IC95% 2,7-4,54). **Conclusiones:** Además de la edad, las condiciones clínicas preexistentes, el ingreso en UCI contribuyen a la muerte.

Palabras Clave: *Síndrome respiratorio agudo severo. Registros de mortalidad. Vacunas contra la Covid-19. Comorbilidad. Prueba de Covid-19.*

INTRODUCTION

SARS-CoV-2 is a respiratory virus that can lead infected patients to develop severe acute respiratory syndrome (SARS).[1] Clinical manifestations include flu syndrome along with other symptoms such as dyspnea or respiratory distress, low oxygen saturation, chest pain, progressive respiratory difficulties, and acute respiratory distress syndrome.[1] The Covid-19 symptomatology varies widely, ranging from asymptomatic cases to those that evolve with severe complications that lead to death.[1]

The first case of corona virus disease (Covid-19) in Brazil was confirmed on February 25, 2020.[2] But the country currently records more than 38 million accumulated cases, approximately 710 thousand deaths,[3] and a monovalent vaccinal coverage of 83% (□169 million) with two doses, and 51% (□103 million) with three doses as of January 29, 2024.[4]

The decline in deaths caused by Covid-19 has been propelled by vaccinating the elderly,[5] which now extends to the administration of booster vaccine doses.[6] Nevertheless, the potential of the disease increasing morbidity and mortality rates is still high.[7]

Since September 15, 2021, the Ministry of Health adopted the administration of a booster dose for elderly people aged 70 and above who had completed their primary vaccination schedule. Other groups have subsequently been included according to their risk of exposure to the virus, risk of complications, and death.[6] Surveillance of Covid-19 remains continuous, especially due to the potential emergence of new variants and outbreaks. Moreover, monitoring the disease is crucial for individuals who are more susceptible to infections and complications, even if they are vaccinated.[7]

In addition to the disease's general clinical characteristics, today the scientific literature discusses post-Covid-19 symptoms, sequels, and comorbidities.[8,9] Previous studies have shown that age,[10,11] being male, and having comorbidities, especially cardiovascular diseases, diabetes, kidney, and chronic respiratory diseases[10,12,13] are some of the risk factors that influence gravity and mortality of SARS-CoV-2 patients.

Therefore, investigations about the factors associated with hospitalization and mortality in SARS-CoV-2 patients based on the different economical, historical-cultural and healthcare coverage aspects of the regions in a developing country contributes to the development of programs, policies, and health actions to face epidemics. Thus, this study aims to evaluate the association of sociodemographic, clinical and hospitalization variables with mortality among hospitalized patients with SARS.

METHODS

Study design and data collection

This is a cross-sectional study conducted at the Municipal Health Secretariat (Secretaria Municipal de Saúde) in Ituiutaba, Minas Gerais State, between April 4th and October 2nd, 2021. All the SARS notification forms, diagnostic tests for Covid-19, and death certificates were reviewed.

Data collection at the Municipal Health Secretariat was conducted manually by reviewing every SARS occurrence in every hospital of the city, the *Unidade de Pronto Atendimento/UPA* (Health Center Emergency Room) of Ituiutaba, the Hospital *São José da Sociedade de São Vicente de Paulo*, the Hospital *Nossa Senhora da Abadia* and the Hospital *São Joaquim*, totalizing four hospitals. The investigators were trained to conduct a proper data collection from the forms, death certificates and exams. The record and the number of Covid-19 vaccination doses were confirmed by consulting the Data System (Sistema de Informação) of the National Vaccination Program (Programa Nacional de Imunizações).

Participants and inclusion criteria

This study included a non-probabilistic sample of hospitalized individuals diagnosed with SARS caused by SARS-CoV-2 from both public and private healthcare services of Ituiutaba-MG. The exclusion criteria were applied to notifications with critical absence of identification, clinical and case outcome data and/or without diagnostic examination.

Investigated variables

The covariables assessed were: (1) sociodemographic characteristics (age, sex, race, and years of education); (2) clinical (vaccination scheme, symptoms of SARS, and pre-existing chronic diseases); and (3) hospitalization (total days of hospital stay, days of treatment in the intensive care unit (ICU), need of ICU, and invasive support ventilation). The rapid test diagnosis, serologic and molecular tests were used as evidence of a positive result for SARS-CoV-2 infection and to confirm the cases of SARS registered in the notification sheets. Additionally, the death certificates were used to confirm Covid-19 deaths and for *causa mortis* collection.

Statistical methods

Descriptive statistics of the variables were obtained, and the prevalence of each covariable was calculated. The normality of the data was assessed by Shapiro-Wilk test, and data was presented in the median and interquartile range for data with non-normal distribution. To identify the factors associated with mortality, the group with outcome "discharged" was

compared to "death". Categorical covariables were associated with the outcome variable (hospital discharge or non-survived) and were analyzed by the chi-square test of Pearson. For continuous variables with non-normal distribution, the differences were identified with the Mann-Whitney *U* test. Poisson regression analysis was used by adopting the prevalence ratio (PR) with robust variance and the respective 95% confidence interval (CI). The analysis was performed in two stages, the first with a bivariate-unadjusted model and the second with a multivariate-adjusted model. After the bivariate analysis, the covariables were assessed based on the presence of multicollinearity for metric and categorical variables, adopting the Spearman correlation and the value of contingency coefficient, respectively. Multicollinearity was assumed when the coefficients were above 0.6. The variables that presented $p<0.05$ in the bivariate model were included in the adjusted model, remaining those with $p<0.03$. Data analysis was performed with JAMOVI (V2.4.8).

Ethics

The research was conducted in accordance with the ethical standards required from Resolutions 466/2012, 510/2016 and 580/2018, from the Brazilian Ministry of Health. The study protocol was submitted to the unified Brazilian platform for registration of research involving human beings (*Plataforma Brasil*) and approved by the Ethics Committee of the Federal University of Uberlândia in June 2022 (CAAE 56051721.2.0000.5152; CEP/UFU n. 5.448.555/2022).

RESULTS

The initial sample comprised 673 notifications of SARS. After the exclusion of forms which did not present identification, clinical, and case outcome data, the analytic sample comprised 592 individuals (age 59.4±16.9; women 46.6%). The participants excluded presented similar observed frequencies for sex and mean age (age 61.5±14.6; women 44.4%).

From April to October, the health services of Ituiutaba-MG received 32,036 notifications, of which 8,770 patients (27.4%) were positive for Covid-19. According to the initial screening of the SARS notifications, approximately 7.7% (n=673) of the positive cases for Covid-19 sought medical care. Using the eligibility criteria of this study, the sample was composed of 592 individuals (6.8%). Most of the diagnosis were done through antigen tests (n=379; 64%) followed by reverse transcription polymerase chain reaction (RT-PCR) (n=144; 24.3%).

Two hundred and eleven (35.6%) patients with SARS who received hospital care (64.4%; n=381) died from Covid-19. From these individuals, older patients (>60 years) with fewer years of education (≤ 5 years of education or illiterate), those vaccinated with two doses and those with preexisting noncommunicable diseases (NCDs), such as cardiovascular disease (CVD) and/or diabetes mellitus (DM), as well as those with pneumopathy, who received care in an intensive care unit (ICU) and required invasive ventilation were significantly associated with death. According to the data, the symptoms of SARS included respiratory distress, dyspnea, and loss of smell and taste (Table 1).

The frequency of patients who died and were admitted to the ICU was higher among those aged 40-59 (n=50; 24.5%) and 60-79 (n=60; 29.4%), followed by patients aged 80 or above (n=32; 15.7%), compared to the younger age group of 20-39 (n=5; 2.4%).

The comorbidities most frequently registered were CVD (50.6%), 31.3% (n=164) corresponding to systemic arterial hypertension, and DM (23.3%), whilst 16% had both CVD and DM. Low oxygen saturation (87.6%) and dyspnea (82.9%) were the symptoms most frequently reported, followed by respiratory distress (67.1%), cough (64.5%), fatigue (40.1%), and fever (38.5%) (Table 1).

Table 1. Characteristics of the population treated in the health service, Ituiutaba, MG, 2021.

Variables	Hospital discharge N (%)	Non-survived N (%)	Total N (%)	*p*-value
Sociodemographic				
Age (years)	52 (22)[c]	67 (24)[c]		<0.01 †
< 20	7 (1.8)	0 (0)	7 (1.2)	<0.01*
20-39	75 (19.7)	6 (2.8)	81 (13.7)	
40-59	177 (46.5)	65 (30.8)	242 (40.9)	
60-79	92 (24.1)	82 (38.9)	174 (29.4)	
≥80	30 (7.9)	58 (27.5)	88 (14.9)	
Sex				
Male	204 (53.5)	112 (53.1)	316 (53.4)	0.914
Female	177 (46.5)	99 (46.9)	276 (46.6)	
Race[a]				
White	194 (54.2)	127 (60.2)	321 (56.4)	0.189
Non-white	164 (45.8)	84 (39.8)	248 (43.6)	
Schooling level[a]				
Illiterate	10 (4.3)	21 (10.8)	31 (7.3)	<0.01*
≤5 years of study	66 (28.6)	91 (46.9)	157 (36.9)	
>6 and ≤12 years of study	126 (54.5)	71 (36.6)	197 (46.4)	
>12 year of study	29 (12.6)	11 (5.7)	40 (9.4)	
Clinical characteristics				
Vaccination scheme[a]				
Complete (2 doses)	64 (16.8)	84 (40)	148 (25)	<0.01*
Incomplete	67 (17.6)	48 (22.9)	115 (19.5)	
Unvaccinated	250 (65.6)	78 (37.1)	328 (55.5)	
Symptoms[a]				
Respiratory distress	240 (63.2)	155 (74.2)	395 (67.1)	0.007*
Diarrhea	62 (16.3)	30 (14.4)	92 (15.6)	0.530
Dyspnea	306 (80.5)	182 (87.1)	488 (82.9)	0.043*
Abdominal pain	31 (8.2)	11 (5.3)	42 (7.1)	0.191
Sore throat	63 (16.6)	28 (13.4)	91 (15.4)	0.307
Fatigue	143 (37.6)	93 (44.5)	236 (40.1)	0.104
Fever	151 (39.7)	76 (36.4)	227 (38.5)	0.421
Loss of smell	43 (11.3)	8 (3.8)	51 (8.7)	0.002*
Loss of taste	63 (16.6)	14 (6.7)	77 (13.1)	0.001*
Saturation (less that <95%)	326 (85.8)	190 (90.9)	516 (87.6)	0.071
Cough	252 (66.3)	128 (61.2)	380 (64.5)	0.218
Vomiting	33 (8.7)	19 (9.1)	52 (8.8)	0.868
Morbidity[a]				
NCDs	196 (60.3)	159 (79.9)	355 (67.7)	<0.01*
CVD	145 (44.6)	120 (60.3)	265 (50.6)	<0.01*
DM	60 (18.5)	62 (31.2)	122 (23.3)	<0.01*
Pneumopathy	7 (2.2)	11 (5.5)	18 (3.4)	0.04*
Obesity	35 (10.8)	29 (14.6)	64 (12.2)	0.197
CVD and DM	40 (12.3)	44 (22.1)	84 (16)	<0.01*
Hospital care[a]				
Infirmary	333 (89.8)	57 (27.9)	390 (67.8)	<0.01*
ICU[b]	38 (10.2)	147 (72.1)	185 (32.2)	
Hospitalization in ICU (days)	0 (0)[c]	4 (11)[c]		<0.01†
Ventilation support[a]				
Non-invasive	308 (91.9)	141 (69.8)	449 (83.6)	<0.01*
Invasive	8 (2.4)	60 (29.7)	68 (12.7)	<0.01*
Total time of hospitalization (days)	5 (8)[c]	10 (12)[c]		<0.01†

Legend: *Pearson´s $\chi 2$ test; †Mann-whitney´s Test. Abbreviations: IC95%: confidence interval; NCDs: noncommunicable diseases; DM: diabetes *mellitus;* CVD: Cardiovascular disease; ICU: intensive care unit. [a]Relative and percentage frequency includes the number of observations without "not reported/missing values" for self-reported

data. [b]The variables under ICU represent patients who received treatment in the hospital and were also admitted to the ICU. [c]Data is presented as median, interquartile range (IQR).

Only the correlation coefficients of the variables DCV and DM, infirmary and non-invasive ventilation exceeded the contingency coefficient (≥0.6). Therefore, they were not considered in the Poisson regression models because they could reduce predictive power. The association of independent variables in the bivariate analysis showed that the factors significantly associated with the outcome death were age, educational level lower than twelve years, vaccination scheme, self-reported symptoms of respiratory distress, dyspnea, loss of smell or taste, self-reported morbidity of CVD, DM, pneumopathy, hospitalization in ICU and use of invasive respiratory support, and total hospitalization time and time spent in the ICU (Table 2).

Older age, pre-existing NCDs, loss of taste and the need for intensive care during hospitalization were the main variables associated with mortality in the adjusted model for patients with SARS-CoV-2 (Table 2). The probability of death increases by 3% for each year of life (PR adjusted[2]= 1.03; 95%CI 1.015-1.035). The symptom loss of taste (PR adjusted[2]= 0.54 95%CI 0.36-0.78) and self-reported CVD (PR adjusted[2]= 0.73 95%CI 0.56-0.96) were less frequent in patients who died. However, the registration of some self-reported NCDs was more frequent in patients who died (PR adjusted[2]= 1.55; 95%CI 1.1-2.18) than those who were discharged from the hospital. ICU hospitalization was around 3.5 times more common in individuals who succumbed to Covid-19 (PR adjusted[2]= 3.49, 95%CI 2.7-4.54) compared to those who were discharged from the hospital. The absence of information for independent variables was as follows: 23 for race, 167 for education level, 1 for vaccination, 3 for symptoms, 68 for morbidity, 17 for hospitalization, and 53 for ventilation support.

Table 2. Poisson regression for clinical, sociodemographic, and hospitalization variables and mortality by Covid-19.

Variables	Crude PR (95%CI)	*p*-value	PR adjusted[1]* (95%CI)	*p*-value
Sociodemographic				
Age (years)	1.03 (1.023-1.036)	**<0.01**	1.03 (1.015-1.035)	**<0.01***
Race				
White	1.00		-	-
Non-white	0.86 (0.69-1.06)	0.165	-	-
Schooling level				
Illiterate	1.00		1.00	
≤ 5 years of education	0.86 (0.61-1.23)	0.385	0.78 (0.56-1.11)	0.151
>6 and ≤ 12 years of education	0.53 (0.38-0.77)	**<0.01**	0.81 (0.57-1.18)	0.258
> 12 years of education	0.41 (0.23-0.69)	**<0.01**	0.67 (0.39-1.12)	0.137
Clinical variables				
Vaccination scheme				
Unvaccinated	1.00		1.00	
Incomplete	1.76 (1.31-2.34)	**<0.01**	1.01 (0.77-1.31)	0.958
Complete (2 doses)	2.39 (1.86-3.06)	**<0.01**	0.84 (0.60-1.16)	0.283
Symptoms				
Dyspnea				
No	1.00		1.00	
Yes	1.4 (1.02-1.96)	**0.037**	1.26 (0.92-1.74)	0.163
Respiratory distress				
No	1.00		1.00	
Yes	1.41 (1.1-1.82)	**<0.01**	1.01 (0.8-1.28)	0.941
Saturation (less that <95%)				
No	1.00		-	-
Yes	1.42 (0.99-2.11)	0.074	-	-
Fatigue				
No	1.00		-	
Yes	1.2 (0.96-1.49)	0.105	-	-
Loss of smell				
No	1.00		1.00	
Yes	0.42 (0.22-0.71)	**<0.01**	0.78 (0.46-1.27)	0.349
Loss of taste				
No	1.00		1.00	
Yes	0.48 (0.3-0.72)	**<0.01**	0.54 (0.36-0.78)	**<0.01***
Morbidity				
NCDs				
No	1.00		1.00	
Yes	1.89 (1.45-2.51)	**<0.01**	1.55 (1.1-2.18)	**0.012***
CVD				
No	1.00		1.00	
Yes	1.48 (1.19-1.86)	**<0.01**	0.73 (0.56-0.96)	**0.024***
DM				
No	1.00		1.00	
Yes	1.49 (1.17-1.88)	**<0.01**	1.03 (0.82-1.29)	0.818
Pneumopathy				
No	1.00		1.00	
Yes	1.64 (0.98-2.58)	**0.043**	0.99 (0.59-1.58)	0.979
Obesity				
No	1.00		-	-
Yes	1.23 (0.89-1.66)	0.199	-	-
Hospital care				
ICU[a]				
No	1.00		1.00	
Yes	5.44 (4.27-6.99)	**<0.01**	3.49 (2.7-4.54)	**<0.01***
Hospitalization in ICU (days)	1.03 (1.03-1.04)	**<0.01**	1.01 (0.99-1.02)	0.744
Invasive ventilation support				
No	1.00		1.00	
Yes	2.91 (2.29-3.69)	**<0.01**	1.18 (0.94-1.49)	0.158
Total time of hospitalization (days)	1.02 (1.02-1.03)	**<0.01**	1.0 (0.98-1.01)	0.416

Legend: IC95%: confidence interval; PR: prevalence ratio; NCDs: noncommunicable diseases; DM: diabetes mellitus; CVD: Cardiovascular disease; ICU: intensive care unit. *[1]Model I – all values adjusted for all variables included in the models. [a]The variables under ICU represent patients who received treatment in the hospital and were also admitted to the ICU.

The *causa mortis* most frequently registered on death certificates were cardiorespiratory arrest (n=46; 21.8%), severe acute respiratory syndrome/SARS (n=37; 17.6%), acute respiratory failure (n=63; 29.8%), septic shock (n=19; 9%), sepsis (n=12, 5.2%) and multiple organ failure (n=8; 3.8%). Furthermore, there were reports of chronic/acute kidney insufficiency (n=24; 11.4%), bacterial pneumonia (n=2; 0.9%), Covid-19 pneumonia (n=50; 23.7%) or both (n=2; 0.9%), and unspecified (n=52; 26.6%), such as underlying conditions (Table S1).

DISCUSSION

The main findings of this study show that age, self-reported chronic disease, loss of taste, CVD, and requirement of ICU were associated with non-survival patients. The second wave of Covid-19 cases, probably the longest and most lethal, occurred between

November 2020 and April 2021. In this study, it was not possible to collect genomic data to further differentiate variants. However, the infections registered are attributed to P.1 and P.2 Gamma variants,[12,14] which had a significant effect on mortality[14] and hospitalization rates during the second wave.[12]

The outcome death was more frequent among the patients with two doses of the vaccine than among those who were not vaccinated or had an incomplete vaccination schedule. Another study identified a higher lethality rate among individuals who received two doses[13] of the vaccine, similar to the findings of our study. The improvement of the vaccine coverage varied across the country, and only 50% of the population of the southeastern region had been vaccinated by the 38th epidemiological week of 2021.[14] In addition to vaccine coverage, other factors helped to explain the profile of severe cases and mortality, including older age and the influence of senescence,[10,11] low education,[12] the presence of DCV,[12,13] DM, pneumopathy and longer periods of hospitalization.[8] However, a previous study found that the death probability of individuals who received a post-Omicron booster vaccine dose was lower (-9.3%).[13]

The vaccine against Covid-19 is still the main measure against SARS-CoV-2 infection, hospitalization, and death, and also reduces adverse events associated with the disease.[15] A recent consortium[15] showed that vaccination deficit was associated with a high risk of serious outcomes due to SARS-CoV-2 infection in the age group 16-74 years of age, being 1.26 for the deficit for one dose, 1.88 for two doses, and 1.5 for three doses. The risk is even higher for those over 75 years of age.

The prevalence of chronic diseases increases with aging. Studies show that the risk of mortality increases with comorbidities, including cardiovascular and diabetes diseases.[12,16] The results show a lower prevalence of CVD for the group with outcome death, although the prevalence of some NCD was 55% more frequent for the same group. Investigation into medical records and self-referred variables may contain memory bias, and the report's quality depends on the accuracy of the notification by the health professional. A report[17] indicated that hypertension (32%), diabetes *mellitus* (18%), and CVD (20%) are some of the main morbidities among Covid-19 cases in Latin America. Moreover, this study revealed that the severity of Covid-19 is proportionally higher for those who have multiple comorbidities.[17]

Hypertension is strongly associated with the burden of CVD and early mortality,[18] and its prevalence has been lower in high-income countries than in low and middle-income countries.[19] Evidence shows that the mortality risk associated with Covid-19 is higher with DM, hypertension, and CVD.[20,21] In Latin American countries, the proportion of deaths in patients with Covid-19 is higher among those with chronic kidney and hepatic disease. However, there is no variation[17] under other conditions such as DM and CVD (55%).

Despite the quality of the notifications, as well as the absence of data regarding the SARS-CoV-2 variants, the results are consistent in indicating that older age and the presence of comorbidities help explain mortality. Moreover, this data once again reinforces how important it is to administer booster doses to prevent severe cases and death.

Hypoxemia, acute respiratory distress syndrome (ARDS), metabolic acidosis, coagulopathy, and septic shock can lead to vital organ dysfunction.[7] Reports of cardiac insufficiency, septic shock, and respiratory insufficiency are among the several complications reported in non-survival Covid-19 patients. An analysis involving 19,014 Covid-19 patients and 4,655 non-survivors revealed that pre-existing health conditions were associated with complications, showing that age, comorbidities, and DM were factors associated with respiratory insufficiency. Age, comorbidities, and cardiovascular and cerebrovascular diseases were associated with cardiac insufficiency. Septic shock is associated with factors such as DM, comorbidities, age, hypertension, and cardiovascular diseases.[18]

The profile of the individuals evaluated aligns with the recognized pattern of severe infections, as evidenced in their clinical history, revealing the presence of comorbidities such as hypertension, cardiopathy, and obesity. The data also indicates that respiratory complications and septicemia are reported causes of death; scenarios in which respiratory insufficiency is often managed with mechanical ventilation.[7,20] In this regard, deaths attributed to Covid-19 often have contributory implications that stem from pre-existing health conditions.

Both hospital admission[16] and the length of stay[12] are important factors that influence patient prognosis. The survival rate of women aged 65 or older with a stay that exceeds 11 days was reduced by 50%.[10] The results indicate that the mean hospitalization duration for non-survival individuals was 10 days. Additionally, the diagnosis plays a crucial role in determining the need for hospital care. A study revealed that 14% of 6,068 hospitalized patients developed symptoms after admission with most patients being hospitalized following the onset of symptoms.[22] In Brazil, individuals predominantly sought hospital care after symptoms appeared, suggesting an infection.

The results revealed that most diagnosis were made using antigen tests. A study conducted in Brazilian capitals and in Brasília reported inadequacies between the onset of the symptoms and the diagnostic testing using antigen tests, and that only 32% of the tests were conducted within an appropriate timeframe (mean: 5.9-13.9 days). In other words, more than 50% of the tests

were performed outside the recommended time frame.[23,24] Therefore, the predominance of this diagnostic approach as the first line may be limited[25] due to factors that include an increased exposure time to infection without access to healthcare.

Data from a cohort conducted by Danaché et al. (2022)[16] with 827 patients showed that the longest interval (>6 days) between the symptom onset and hospital admission occurred among adult individuals (median: 69; IQR 54-78 years), as well as a higher frequency of admission in the ICU, indicating that age, individual risk perception, and morbidity profile influenced healthcare-seeking behavior.

Moreover, data from Covid-19 cases reported by *SIVEP-gripe* revealed 245,304 (17%) ICU hospitalizations during both the first and the second wave, with the majority of the admissions to the ICU (n=130,286) in the latter. Additionally, 83,781 deaths were reported.[12] Compared to the first wave, ICU hospitalization among younger individuals and the need for ventilatory support were more frequent during the second wave. A study estimated an odds ratio of 2.9-13.9 times for ICU admission among individuals aged 40-59 years, 60-79 years and 80 years or older with the P.1 variant.[25]

Furthermore, cases of hospitalization due to SARS, probably more severe and symptomatic, were gathered by excluding the assessment of positive Covid-19 cases that did not require hospitalization. Nonetheless, the data shows a trend that is consistent with findings reported by other studies.[12,13,18,21] Overall, it encompasses sociodemographic characteristics, clinical aspects, and risk factors for Covid-19 mortality that reflect the reality of medium-sized cities in Brazil and other developing countries.

This study has a limitation regarding the intragroup behavior of hospitalized patients during the pandemic period, attributed to the analysis of raw data due to the quality of the Covid-19 case notifications and the absence of functional hospital systems aligned with the national notification system. Clinical information was frequently incomplete, resulting in the exclusion of certain variables from this study, which potentially introduced bias due to the sample's reduced representativeness. The adjusted analysis aimed to mitigate this effect, however, it may not have elucidated differences between the groups evaluated. Hence, this limitation constrained the ability to fully elucidate certain aspects of the patients' clinical progression. Collaborations between different research groups that conduct studies in locus is a relevant strategy to overcome the inherent limitations regarding the quality of the data since larger samples have the potential to reveal subtle differences hidden in small studies. Data collected by electronic surveillance systems are also affected by limited data integrity and database feeding strategies, therefore, standardized data collection carried out by trained researchers, consulting documents that validate the information present in the notifications, brings the panorama raised by the studies closer to regional realities.

This study evaluated a series of notifications and death certificates from hospitalized patients with SARS on-site. The evaluation of clinical and sociodemographic data revealed that severe patients who died were older, had fewer years of education, had comorbidities, required ICU, and mechanical ventilation. With an adjusted model, this study noticed that mortality among hospitalized patients increases with age and among those also hospitalized in the ICU with chronic diseases. We hope that this study will strengthen the evidence regarding the profile of hospitalized patients with Covid-19, contributing to the creation of new public policies that deal satisfactorily with the logistical challenges of infectious diseases with pandemic potential. Finally, we reinforce the importance of health professional's effort toward the correct notifications, aiming to qualify the actions of the epidemiological surveillance.

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AUTHORS' CONTRIBUTIONS

Victor Antonio Ferreira Freire contributed to the bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Gustavo Siconello dos Santos** contributed to the bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Morun Bernardino Neto** contributed to the interpretation and description of results, review and statistics. **Luciana Karen Calábria** contributed to the project administration, bibliographic research, methodology, discussion, interpretation and description of results, conclusions and review. **Alexandre Azenha Alves de Rezende** contributed to the project administration, bibliographic research, methodology, discussion, interpretation and description of results, conclusions and review.

All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its version and integrity.

Please cite this article as: Freire VAF, dos Santos GS, Neto MB, Calábria LK, de Rezende AAA. Association of biological factors, social determinants of health, and hospitalization with mortality due to SARS/Covid-19. Rev Epidemiol Control Infect [Internet]. 2025 Jan. 7;15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19438

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

Revista de Epidemiologia e Controle de Infecção

ISSN 2238-3360

Original Article

Investigation of the Covid-19 outbreak in a prison unit: health surveillance actions

Investigação de surto de Covid-19 em unidade prisional: ações de vigilância em saúde
Investigación del brote de Covid-19 en una unidad penitenciaria: acciones de vigilancia

Site doi: https://doi.org/10.17058/reci.v15i1.19419

Submitted: 05/02/2024
Accepted: 12/11/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: the population deprived of liberty is classified as vulnerable to contagion by Covid-19, living in environments susceptible to the spread of infections. Given this, it was proposed to describe the Covid-19 outbreak in a prison unit and analyze health surveillance actions to control it. **Methods:** this is a mixed, quantitative and qualitative study of a Covid-19 outbreak that occurred between July and September 2020 in a Remand Center. Secondary data from suspected cases of Covid-19 were used, and in the qualitative analysis, interviews were carried out with five healthcare professionals. **Results:** 640 suspected cases of Covid-19 were registered; 477 (74.5%) cases were confirmed for Covid-19; and only 91 (14.2%) of cases showed characteristic symptoms. They all evolved into healing. Screening symptomatic people, isolation cells, suspension of visits and mass testing were strategies listed to control the outbreak. **Conclusion:** the population deprived of liberty is vulnerable to respiratory diseases due to the overcrowded context in which they live.

Keywords: *Disease Outbreaks. Prisons. Prisoners. Coronavirus Infections.*

RESUMO

Justificativa e Objetivos: a população privada de liberdade é classificada como vulnerável à infecção pela Covid-19, pois vive em ambientes suscetíveis à disseminação de infecções. Diante disso, propôs-se descrever o surto de Covid-19 em unidade prisional e analisar as ações de vigilância em saúde para o seu controle. **Métodos:** trata-se de estudo misto, de caráter quantitativo e qualitativo, de surto de Covid-19 ocorrido entre julho e setembro de 2020 em Centro de Detenção Provisória. Utilizaram-se dados secundários de casos suspeitos da Covid-19, e na análise qualitativa, foram realizadas entrevistas com cinco profissionais de saúde. **Resultados:** foram registrados 640 casos suspeitos de Covid-19; 477 (74,5%) casos foram confirmados para Covid-19; e somente 91 (14,2%) dos casos apresentaram sintomas característicos. Todos evoluíram para cura. Rastreio de sintomáticos, celas de isolamento, suspensão de visitas e testagem em massa foram estratégias elencadas para o controle do surto. **Conclusão:** a população privada de liberdade é vulnerável a doenças respiratórias devido ao contexto de superlotação em que vivem.

Descritores: *Surto de Doenças. Prisões. Prisioneiros. Infecções por Coronavírus.*

RESUMEN

Justificación y Objetivo: la población privada de libertad se clasifica como vulnerable al contagio por Covid-19, al vivir en ambientes susceptibles a la propagación de infecciones. Ante esto, se propuso describir el brote de Covid-19 en una unidad penitenciaria y analizar acciones de vigilancia sanitaria para controlarlo. **Métodos:** se trata de un estudio mixto, cuantitativo y cualitativo de un brote de Covid-19 ocurrido entre julio y septiembre de 2020 en un Centro de Detención Provisional. Se utilizaron datos secundarios de casos sospechosos de Covid-19, y en el análisis cualitativo, se realizaron entrevistas a cinco profesionales de la salud. **Resultados:** se registraron 640 casos sospechosos de Covid-19; 477 (74,5%) casos fueron confirmados para Covid-19; y sólo 91 (14,2%) de los casos presentaron síntomas característicos. Todos ellos evolucionaron hacia la curación. El cribado de personas sintomáticas, el aislamiento en celdas, la suspensión de visitas y los test masivos fueron estrategias enumeradas para controlar el brote. **Conclusión:** la población privada de la libertad es vulnerable a padecer enfermedades respiratorias debido al contexto de hacinamiento en el que vive.

Palabras Clave: *Brotes de Enfermidades. Prisiones. Prisioneros. Infecciones por Coronavírus.*

INTRODUCTION

Coronavirus infection (Covid-19), caused by the SARS-CoV-2 virus, declared a pandemic by the World Health Organization (WHO), continues to be a major health concern. Around 676 million cases and 6.8 million deaths have been reported as of August 2023.[1] The population deprived of liberty (PDL) is classified as vulnerable to Covid-19 infection, as they live in environments susceptible to the spread of infection.[2,3]

Preventing Covid-19 in prison units (PUs) is a challenge due to population density, difficulties in accessing facilities and hygiene supplies as well as limited space for isolation and quarantine to ensure the PDL safety.[4,5] In an attempt to control the spread of infection in the PDL, Brazil adopted measures recommended by the WHO.[6]

Due to the complex situation of Covid-19, PDL presented a high burden of the disease.[7] In a systematic review carried out in 2022, a prevalence of 24% was reported in PDL.[8] In a prevalence study carried out in the state of Espírito Santo, 31.6% of Covid-19 cases were reported in PDL.[9] In this context, prison health and security teams had to reorganize work processes to deal with the disease as well as carry out actions in conjunction with the health surveillance service to minimize the impact of Covid-19 transmission among the PDL.

Intersectoral collaboration between prison teams and health surveillance are essential for early detection and control of disease transmission in prisons. Understanding the aspects of Covid-19 in prisons and its real impact on healthcare services' routine and prison security is essential to predict improvements in the disease prevention process and propose appropriate actions. Therefore, this study aimed to describe the Covid-19 outbreak in prisons and analyze health surveillance actions for its control.

METHODS

This is a mixed study of a quantitative and qualitative nature to address the aspects of the Covid-19 outbreak that occurred between July and September 2020 in a Remand Center (RC) located in the municipality of São Mateus, in the north of the state of Espírito Santo.

The study was divided into two stages. In the first stage, a descriptive study of the Covid-19 outbreak in the RC was carried out using secondary data from the compulsory notification information system for diseases in the municipality of São Mateus. All notification forms that were made between July and September 2020 and had the RC of São Mateus as the notifying health facility were included.

To describe the outbreak, we used the variables from the Covid-19 suspected case notification form, which were: age; race/skin color (black, yellow, white, indigenous, and unknown); clinical signs and symptoms (fever, difficulty breathing, cough, nasal congestion, runny nose, sore throat, diarrhea, headache, weakness, loss of smell, loss of taste); comorbidities and risk factors (chronic lung disease, chronic cardiovascular disease, diabetes mellitus, and HIV infection); results of specific tests for Covid-19 (positive and negative for rapid serological immunochromatographic test (RT) and reverse transcription-polymerase chain reaction (RT-PCRT); and outcome of suspected case and evolution (cure, death, discarded).

For the second stage, a qualitative study was carried out with professionals who worked in health surveillance at the Superintendence of the Northern Region of Health and professionals from epidemiological surveillance in the municipality of São Mateus. To participate in the study, workers had to have worked on actions during the Covid-19 outbreak at RC. The interviews were audio-recorded with a voice recorder and deleted after data transcription, which were stored in a Microsoft Word® ".doc" file.

A semi-structured interview script was used, consisting of two parts: the first contained sociodemographic information, and the second was represented by guiding questions organized into chunks, namely: understanding of the process of requesting to act within the RC; understanding of the process of acting within the RC; coping, control and prevention actions; intervening factors for acting within the RC.

The interviews were conducted individually in a private room and lasted a maximum of 45 minutes. No criteria were established for closing the interviews. Participant anonymity and confidentiality were preserved by coding statements, using the letters "HP" for healthcare professionals, followed by a sequential Arabic number for each interview. All health workers interviewed signed the Informed Consent Form.

Quantitative data analyses were performed using the software Epi Info™ statistical version 7.4.2. Relative and absolute frequencies were calculated for qualitative variables, and mean and standard deviation were calculated for quantitative variables. A histogram graph was created based on the date of onset of symptoms or the date of test collection for asymptomatic cases. The graph was created using Microsoft Office Excel® 2019.

For qualitative data analysis, the software *Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires* (IRAMUTEQ) version 0.7 alpha 2.3.3.1 was used. This software performs analysis on text *corpora* through the Descending Hierarchical Classification (DHC) method, which grouped the segments of workers' speeches into classes by similar excerpts.[10] Based on the DHC, thematic content analysis was performed, including material exploration, which aims to transform the raw data to reach the core of

understanding of the text, and treatment of results, in which the author makes inferences and interpretations.

The study was approved by the ethics committee of *Centro Universitário Norte do Espírito Santo, Universidade Federal do Espírito Santo*, under Opinion 5.738.429/2022.

RESULTS

Characterization of the Covid-19 outbreak in the prison unit

Between June and September 2020, 640 reports of suspected cases of Covid-19 were made among the RC PDL. Figure 1 shows the distribution of confirmed cases of Covid-19 based on the date of onset of symptoms or the date of collection of specific tests for Covid-19 in the asymptomatic PDL. After the first confirmed case on July 18, 2020, confirmed cases began to increase, with a peak of confirmed cases on August 8, 2020, registering 378 confirmed cases. Soon after, there was a decline in cases, with the last one on September 1, 2020.

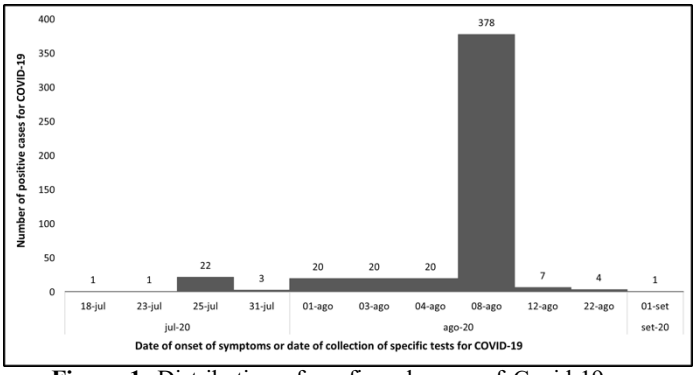

Figure 1. Distribution of confirmed cases of Covid-19 over time from the date of onset of symptoms or the date of collection of specific tests for Covid-19 in the prison population. São Mateus, ES, Brazil, 2020 (N=477)

The sociodemographic profile and distribution of comorbidities and risk factors among the PDL of the RC show that, in relation to race, 267 (41.7%) declared themselves as black (black and brown). The mean age was 28.2 (±8.7) years. Among the comorbidities, 32 people had chronic cardiovascular disease; five had a diagnosis of HIV; five had a diagnosis of chronic lung disease; and two had diabetes mellitus (Table 1).

Table 1. Characterization of the sociodemographic profile and distribution of comorbidities/risk factors presented by the population deprived of liberty participating in the study. São Mateus, ES, Brazil, 2020 (N=640).

Variable	N (%)
Race	
Black*	267 (41.72)
Yellow	187 (29.22)
White	60 (9.38)
Indigenous	1 (0.16)
Ignored	125 (19.53)
Mean age (SD)	28.2 (±8.7)
Chronic lung disease	10 (1.56)
Chronic cardiovascular disease	32 (5.0)
Diabetes mellitus	2 (0.31)
HIV infection	5 (0.78)

Legend: SD - standard deviation; *considers the values reported for the black and brown population deprived of liberty according to the IBGE classification.

In relation to the distribution of signs and symptoms of Covid-19 presented by the RC PDL and the results of specific tests, it was observed that 91 (14.2%) presented symptoms suggestive of Covid-19 in the last 14 days referring to the date of notification. The most frequent symptoms were fever (13.28%), headache (10.94%), runny nose (7.81%) and cough (7.34%). On the other hand, 549 (85.7%) of the PDL did not present signs and symptoms suggestive of Covid-19 (Table 2).

Table 2. Distribution of Covid-19 symptoms and distribution of laboratory data of the prison population participating in the study. São Mateus, ES, Brazil, 2020 (n=640).

Variable	N (%)
Presence of signs and symptoms in the last 14 days	
Yes	91 (14.22)
No	549 (85.78)
Fever	85 (13.28)
Difficulty breathing	5 (0.78)
Cough	47 (7.34)
Nasal or conjunctival congestion	14 (2.19)
Runny nose	50 (7.81)
Sore throat	37 (5.78)
Diarrhea	14 (2.19)
Nausea/vomiting	1 (0.16)
Headache	70 (10.94)
Weakness	33 (5.16)
Loss of smell	8 (1.25)
Loss of taste	3 (0.47)
Rapid test sample collected*	534 (83.44)
Rapid test result*	
Positive	58 (10.86)
Negative	476 (89.14)
Collected RT-PCR sample	582 (90.94)
RT-PCR result	
Positive	419 (71.99)
Negative	159 (27.32)
Inconclusive	4 (0.69)
Confirmed for Covid-19	477 (74.53)
Evolution	
Cure	477 (74.53)
Discarded cases	163 (25.47)

Legend: RT-PCR - reverse transcription polymerase chain reaction test; *rapid immunochromatographic serological test.

When analyzing laboratory data, it was identified that 534 (83.4%) underwent RT, of which 58 (10.8%) had a positive result. A total of 582 (90.9%) RT-PCR sample collections were performed in the PDL with negative RT, of which 419 (71.9%) had a positive result for Covid-19. There was confirmation of 477 (74.5%) cases of Covid-19 in the PU and, of these, all evolved to the clinical outcome of cure (Table 2).

Health surveillance actions to control Covid-19 in the prison unit

Five healthcare professionals participated in the interview. Regarding the characterization of classes, four categories were identified, described below:

Class 1. Establish an action plan and interprofessional relationship between teams for Covid-19 contingency

The lack of protocols and contingency plans for the spread of the SARS-CoV-2 virus was evident in healthcare professionals' statements. It was expected that, at the beginning of a pandemic scenario, there would still be gaps in the construction of protocols for the conduct to be taken.

> *"During the outbreak, there was no contingency plan... until now, there was no contingency plan for prison health with Covid". HP3*

However, efforts by professionals to build solutions to the problem to be faced were observed with the meetings held, in order to build an action plan for the control of Covid-19 in the PU that involved all security professionals and health surveillance professionals.

> *"We held meetings with the responsible parties, and we drew up a work plan of what was going to be done in relation to the outbreak". HP4*

Class 2. Changes in the prison system routine to monitor and organize disease prevention

It was possible to observe, in professionals' speeches, the need for changes in the institutional routine, as well as the performance of tasks and processes to be able to monitor new cases of the disease among the PDL and prevent the proliferation of the virus.

> *"We implemented a new routine; if a new inmate arrived, he would be kept in an isolated cell and would only enter his own cell if he took the test." HP3*
>
> *"We suggested that sunbathing be separate, that all areas be disinfected." HP4*
>
> *"And also measures for entering the RC. So, we implemented a barrier at the RC door". HP3*

It is possible to verify that, based on the signs of Covid-19 infection, the PU drew up strategic plans to separate the PDL, considering spaces, such as cells and wings, in order to promote the necessary isolation.

> *"We made a technical visit to understand and be able to guide the entire process". HP2*
>
> *"In one of the meetings with the technical team, we even discussed the structure of the cells, the number of cells to be able to move them". HP2*
>
> *"The PDL was constantly monitoring them. To prevent the situation from getting worse, everyone who tested positive was kept in one cell". HP2*

Class 3. Strategies applied in the prison unit to contain the virus

Concern for the PDL's health was the driving force that led professionals to outline strategies to contain the virus, such as dividing the PDL into blocks and separate times for sunbathing.

> *"We considered the dirty area and the clean area. So, in the dirty area, which would be block A or B, were the positive PDL. In the clean area, were those who were not positive. And we also had cell freezing [...] if there was a positive person in that cell, that person was isolated and that cell was frozen. No one could enter and no one could leave." HP1*
>
> *"It was also recommended that all those who were not infected should take their daily sunbath before those who were infected. So, we had to separate two sunbath times so that they would not be together". HP3*

Class 4. Covid-19 screening strategy for the prison population

In their statements, healthcare professionals report the testing process for everyone at the PDL. The statements highlight the process of reporting those tested for Covid-19 in e-SUS Health Surveillance during the pandemic. The difficulty of reporting quickly was also clear, given the high occurrence of cases of the disease.

> *"The epidemiological surveillance team was the one who made [the notification] during the outbreak." HP3*
>
> *"When you collect an RT-PCR sample, I also need to enter it into the LACEN laboratory management system. While we were there collecting, here in the epidemiological surveillance, there were people notifying and entering these tests into the GAL". HP3*

The statements also provide an insight into the emergence of the first people who presented suspected Covid-19, and highlight the importance of the process of monitoring suspected cases carried out by health

surveillance to carry out a rapid response to public health events.

> *"I realized that we tested positive for one person, one inmate, and then I realized that from one, the next week we already had five, two days later we already had ten, I don't remember the exact numbers. I was alerted, because in less than a week, we were testing positive very quickly...". HP3*

Professionals highlight the organization and process of carrying out tests to screen for Covid-19. As a limitation, they highlight the adaptation to the collection environment, how to ensure everyone's safety in this process, as well as the limitations of the tests used, being the serological ones and only later the RT-PCR ones.

> *"We used the yard itself. Five people would come down from a cell, an entire cell would be opened, and then the entire cell, which had around five to seven people, would sit on plastic chairs. The security chiefs and prison officers would position the PDL, and after that, we would collect it and bring it to storage, because it was placed in the technical box. [...] we would collect it and release it to return to the cell [...] and while they were going through the other staircase at the end of the wing, there was already another cell going down at the beginning of the wing. So, we always created this flow so that they wouldn't cross paths either". HP3*
>
> *"What we did first was the rapid serological test [...] at that time, we didn't have a vaccine, we didn't have antibody production yet, so we could use the rapid serological test and that's what we had. [...] for the negative ones, we did the RT-PCR". HP4*

DISCUSSION

We found a high rate of SARS-CoV-2 infection among PDL with rapid transmission of the virus within the prison system. In Brazil, a cross-sectional study conducted in four prisons found a seroprevalence for SARS-CoV-2 of 81.1%.[11] In the state of Espírito Santo, the prevalence among PDL was 31.64%, with emphasis on the North region, which presented 43.7% prevalence.[9] The differences found in the studies may be related to the structure of the PU healthcare services in the different regions, which may affect the early detection of symptoms and delay in diagnosis, affecting the spread of the disease.

Monitoring people with respiratory symptoms is essential in the health surveillance process at the PU. Early identification of symptomatic people triggers preventive actions, such as the use of masks and isolation in specific cells. It was from monitoring notifications of suspected cases of Covid-19 that the epidemiological surveillance service raised the hypothesis of a possible outbreak among the PDL, triggering actions to control the disease. The PDL presented several symptoms, the most prevalent being fever, headache, runny nose, cough and sore throat. The symptoms are inherent to the fact that the respiratory system is the most commonly affected by Covid-19.[12-15] However, a quantity of PDL greater than the PU's capacity may provide incipient monitoring, creating a favorable scenario for the spread of Covid-19.

A mass testing strategy used in 16 PUs in the United States reported a prevalence of 86.8% of SARS-CoV-2 among the PDL, with a reduction in the emergence of new cases in the PU.[4] We observed that the strategy of testing all PDL patients rapidly increased the positivity rate, but then presented a decrease in positive cases, remaining at zero, suggesting a good strategy for controlling the disease. Considering that one of the main objectives of health surveillance is disease control actions, this action was effective in identifying new cases and acting to contain the spread of Covid-19 in the PU.

Not only testing everyone, but also testing the PDL made it possible to reduce cases and control the outbreak in the PU. Measures such as screening for respiratory symptoms, dividing the PDL into symptomatic or asymptomatic blocks, isolation cells, suspension of visits, among others, were essential for controlling Covid-19. The pandemic required changes to PU's routine.[16,17] The pandemic scenario was challenging for PU professionals, given the need to deal with something new, with the creation of new protocols without compromising the PDL safety and health,[16] with interprofessional interaction between safety professionals and health surveillance professionals being the key point for controlling Covid-19 in the PU.[18]

Prison conditions are conducive to the spread of SARS-CoV-2. [19] Although these conditions are favorable for the introduction and spread of respiratory diseases, there are few reports on the transmission dynamics and impact of Covid-19 in prisons. [20-21] In an investigation of a Covid-19 outbreak in a prison in the Brazilian capital, no statistical association was found between overcrowding or sleeping location and the presence of SARS-CoV-2 antibodies.[11]

There are several possibilities for SARS-CoV-2 to enter the PU.[22,23] One of the ways of entering is through the external environment, through visitors and professionals who work inside the PU.[23-24] With the introduction of SARS-CoV-2 inside the PU, its transmission is extremely fast, which responds to a peak in cases.[25] A systematic approach study assessed the risk of SARS-CoV-2 transmission in different environments,

describing that a detainee infected with SARS-CoV-2 has a 60% chance of infecting another within the same cell, which may justify the speed of Covid-19 transmission in the PU.[26]

Professionals were concerned about the worsening of PDL with a diagnosis of Covid-19, which may require hospitalization and risk of death. At the beginning of the Covid-19 pandemic, little was known about clinical management and factors associated with death and hospitalization, so there was greater concern for the most vulnerable populations. Studies have already described a higher risk of hospitalization and death from Covid-19 in PDL when compared to the general population.[27-29] However, in our study, no people were found in the PDL who required hospitalization and had a fatal outcome, which may be a result of early management and monitoring, and interprofessional partnership with health surveillance.

This study highlights the interprofessional actions listed to contain a Covid-19 outbreak in a public health unit that contribute to the process of preventing the disease and proposing appropriate actions for possible new outbreaks and pandemics. However, it is necessary to highlight its limitations. Since this is a secondary data analysis, the lack of complete information in the notification forms or incorrect filling of information in the information system may have influenced the results. However, since this was a major Covid-19 outbreak, the data were revisited by the health surveillance team, validating the information.

In conclusion, the data led to the understanding that the PDL is vulnerable to rapid transmission of respiratory diseases due to the context in which these people live. Health surveillance strategies for the rapid identification of introduction of pathogens into the PU and blocking transmission are essential factors to prevent the massive spread of the communicable disease. Structuring health surveillance services and qualifying their organizational process is essential for the prevention and control of future outbreaks.

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AUTHORS' CONTRIBUTIONS

Carlos Alves Pessoa contributed to bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **João Paulo Cola** contributed to bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Thiago Nascimento do Prado** contributed to bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Letícya Dos Santos Almeida Negri** contributed to bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Heleticia Scabelo Galavote** contributed to bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics.

All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Pessoa CA, Cola JP, do Prado TN, Negri LSA, Galavote HS. Investigation of the Covid-19 outbreak in a prison unit: health surveillance actions. Rev Epidemiol Control Infect [Internet]. 2025 Jan.28; 15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19419

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Clinical-epidemiological profile and outcome of patients with Covid-19 in the second wave of the pandemic in Paraná, Brazil

Perfil clínico-epidemiológico e desfecho de pacientes com Covid-19 na segunda onda da pandemia no Paraná, Brasil
Perfil clínico-epidemiológico y evolución de los pacientes con Covid-19 en la segunda ola de la pandemia en Paraná, Brasil

Site doi: https://doi.org/10.17058/reci.v15i1.19162

Submitted: 02/15/2024
Accepted: 11/07/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: knowing the characteristics of patients who were hospitalized due to Covid-19 provides support to healthcare professionals and managers in the construction of strategies to reduce vulnerability and suffering from complications of this disease. Therefore, the objective was to describe the clinical-epidemiological profile and identify outcomes in patients with Covid -19 in the second wave of the pandemic in a public hospital in northern Paraná, Brazil. **Methods:** a sectional and analytical study with 1,467 adult patients admitted and hospitalized with a confirmed diagnosis of Covid-19, according to records from the epidemiology center, Medical Archive and Statistics Service and patients' electronic medical record, from January 1 to March 31 2021, in a hospital in the city of Londrina, Paraná, Brazil. **Results:** it was found that the majority of those infected were male, white, married, aged ≤64, and lived in the city of Londrina. When identifying the outcomes, it was evident that there were more discharges when compared to deaths and transfers. The main signs and symptoms described in the medical records were respiratory, however, the signs and symptoms that were associated with mortality were desaturation, tachypnea, and respiratory effort. **Conclusion:** the results indicated that the majority of those infected were male, aged up to 64 years, with mortality being more frequent among elderly patients and those with comorbidities, mainly pulmonary and nephrological. The research also highlighted that severe respiratory symptoms, such as desaturation and tachypnea, were associated with a higher risk of death.

Keywords: *Covid-19. Covid-19 Pandemic. Epidemiological Profile. SARS-CoV-2.*

RESUMO

Justificativa e Objetivo: conhecer as características dos pacientes que foram internados por Covid-19 disponibiliza subsídios aos profissionais de saúde e gestores na construção de estratégias para reduzir vulnerabilidade e acometimento por complicações dessa doença. Logo, objetivou-se descrever o perfil clínico-epidemiológico e identificar os desfechos em pacientes com Covid-19 na segunda onda da pandemia em hospital público do norte do Paraná, Brasil. **Métodos:** estudo seccional e analítico, com 1.467 pacientes adultos admitidos e internados com diagnóstico confirmado de Covid-19, conforme registros do núcleo de epidemiologia, Serviço de Arquivo Médico e Estatística e prontuário eletrônico do paciente, no período de 01 de janeiro a 31 de março de 2021, em hospital no município de Londrina, Paraná, Brasil. **Resultados:** constatou-se que a maioria dos infectados era do sexo masculino, de cor branca, casada, com idade ≤64 e pertencia ao município de Londrina. Ao identificar os desfechos, evidenciou-se que houve mais altas quando comparada com óbitos e transferências. Os principais sinais e sintomas descritos nos prontuários foram respiratórios, contudo os sinais e sintomas que foram associados à mortalidade foram dessaturação, taquipneia e esforço respiratório. **Conclusão:** os resultados indicaram que a maioria dos infectados era homem, com idade até 64 anos, sendo a mortalidade mais frequente entre pacientes idosos e aqueles com comorbidades, principalmente pulmonares e nefrológicas. A pesquisa também destacou que sintomas respiratórios graves, como dessaturação e taquipneia, estavam associados a maior risco de óbito.

Descritores: *Covid-19. Pandemia por Covid-19. Perfil Epidemiológico. SARS-CoV-2.*

RESUMEN

Justificación y Objetivo: conocer las características de los pacientes que fueron hospitalizados a causa de Covid-19 brinda apoyo a los profesionales y gestores de la salud en la construcción de estrategias para reducir la vulnerabilidad y el padecimiento de las complicaciones de esta enfermedad. Por lo tanto, el objetivo fue describir el perfil clínico-epidemiológico e identificar resultados en pacientes con Covid-19 en la segunda ola de la pandemia en un hospital público del norte de Paraná, Brasil. **Métodos:** estudio seccional y analítico, con 1.467 pacientes adultos ingresados y hospitalizados con diagnóstico confirmado de Covid-19, según registros del centro de epidemiología, Servicio de Archivo y Estadística Médica y la historia clínica electrónica del paciente, del 1 de enero al 31 de marzo de 2021, en un hospital de la ciudad de Londrina, Paraná, Brasil. **Resultados:** se constató que la mayoría de los infectados eran hombres, blancos, casados, con edad ≤64 años y pertenecían al municipio de Londrina. Al identificar los resultados, se evidenció que hubo más altas que muertes y traslados. Los principales signos y síntomas descritos en las historias clínicas fueron respiratorios, pero los signos y síntomas que se asociaron con la mortalidad fueron desaturación, taquipnea y esfuerzo respiratorio. **Conclusión:** los resultados indicaron que la mayoría de los infectados fueron hombres, con edades hasta 64 años, siendo la mortalidad más frecuente entre los pacientes ancianos y con comorbilidades, principalmente pulmonares y nefrológicas. La investigación también destacó que los síntomas respiratorios graves, como la desaturación y la taquipnea, se asociaron con un mayor riesgo de muerte.

Palabras Clave: *Covid-19. Pandemia de Covid-19. Perfil Epidemiológico. SARS-CoV-2.*

INTRODUCTION

The pandemic caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has exposed the importance of global health. On January 30, 2020, the World Health Organization declared and emphasized that the outbreak of the new coronavirus constituted a Public Health Emergency of International Concern.[1] This virus began in the city of Wuhan, Hubei province, in the People's Republic of China, and spread rapidly to other countries, causing a crisis in the global health system.[2]

In mid-March 2020, community transmission of Coronavirus Disease 2019 (Covid-19) was declared throughout the national territory.[3] Since the beginning of the pandemic in Brazil, until October 26, 2022, there have been more than 34 million cases and 687,907 deaths, being considered one of the countries with the highest number of deaths in the world, and in Londrina there were until October 21, 2022, 148,994 cases and 2,617 deaths.[4-6]

The second wave of the pandemic began to manifest itself clearly in several countries. In Brazil, the second wave, longer and more lethal, occurred between November 8, 2020 and April 10, 2021, which ended with three times as many deaths.[7] In 2021, with the alarming increase, the measures were only tightened when the number of cases and deaths had already reached very high levels.[8]

With the exponential rise in the number of people infected and killed by SARS-CoV-2 in Brazil, public and private hospitals in the country experienced situations of overcrowding, shortages of medications used to intubate and/or sedate patients, associated with waiting lists for highly complex beds in Intensive Care Units (ICUs).[9,10] It is known that mortality from Covid-19 can be nine times higher among people with some chronic disease, when compared to patients without pre-existing pathologies.[11]

Studies carried out at the beginning of the pandemic emphasized the need to pay attention to patients with comorbidities in Covid-19 treatment, since patients who become seriously ill have evidence of underlying diseases, such as cardiovascular diseases, liver diseases, kidney diseases or malignant tumors.[12-14] These patients usually died due to exacerbation of their underlying diseases.

In a retrospective, multicenter cohort study conducted at a hospital in Wuhan, China, of the 191 patients who were included in the study, 137 were discharged and 54 died in hospitals, of which 91 (48%) had comorbidities, including hypertension, diabetes mellitus, and coronary heart disease.[14]

It is known that there is a gap in the clinical-epidemiological profile of patients affected by Covid-19 in the second wave of the pandemic. In this regard, the analysis of patient characteristics and clinical outcomes in the second wave contributes to identifying risk factors, vulnerabilities and changes in disease behavior that can guide future public health policies and management strategies in possible new waves or other health emergencies.

Based on this premise, knowing the characteristics of patients who were hospitalized for Covid-19 provides support for healthcare professionals and managers in developing strategies to reduce vulnerability and incidence of complications from this disease. Therefore, the following research question emerged: what are the clinical-epidemiological characteristics and outcomes of patients with Covid-19 in the second wave of the pandemic? Therefore, the objective was to describe the clinical-epidemiological profile and identify the outcomes in patients with Covid-19 in the second wave of the pandemic in a public hospital in northern Paraná, Brazil.

METHODS

This is a sectional and analytical study that followed the Strengthening the Reporting of Observational Studies in Epidemiology recommendations.[15] The study population consisted of 1,467 adult participants with Covid-19, admitted to a public hospital in northern Paraná, from January 1 to March 31, 2021. The present study was carried out at the university hospital (UH), a supplementary body of the *Universidade Estadual de Londrina* (UEL). Since the beginning of the pandemic, UEL-UH has been part of the Sentinel Hospital Network, according to the Brazilian National Health Regulatory Agency, and is a tertiary reference for the care of moderate and severe cases of Covid-19.

Participant data were obtained from records in medical records available at the Medical Archive and Statistics Service (In Portuguese, *Serviço de Arquivo Médico e Estatística* - SAME), Internal Epidemiology Center (In Portuguese, *Núcleo Interno de Epidemiologia* - NIE), Electronic Patient Record in MedView software, consolidated through an instrument designed by the researchers and transcribed in the Microsoft Excel 97® program. It is also worth noting that there was no need for an Informed Consent Form, since the data were obtained indirectly; however, a Confidentiality and Confidentiality Agreement was used.

Inclusion criteria comprised hospitalized adult patients, aged ≥18 years, with a confirmed diagnosis of Covid-19 and a positive result for real-time reverse transcriptase polymerase chain reaction for SARS-CoV-2 in respiratory samples (nasopharyngeal and/or oropharyngeal swab).[3] Exclusion criteria comprised incomplete medical records and patients suspected of having Covid-19 who did not have a confirmed diagnosis during hospitalization.

The data from medical records were completed by healthcare professionals from the aforementioned institution who provided direct care to patients. This information was forwarded by SAME and NIE, and the missing data were collected from medical records and recorded in the instrument designed and previously tested by the research team, composed of a nursing resident, a doctoral degree holder and a doctoral student in nursing. Data collection took place from January to March 2022.

The instrument included several variables, highlighting sociodemographic characteristics, clinical conditions such as previous symptoms, comorbidities, risk factors and disease outcome. The hospitalization outcome was defined as discharge, transfer and death, as defined in the electronic medical record system itself. Independent variables of social characterization were sex (male and female), age (≤64 and ≥65 years), race (yellow, white, brown/black), marital status (married, single, widowed, divorced and not informed) and origin (Londrina or another city). The variable education level was not used due to the lack of its respective record.

Categorical variables were analyzed descriptively using absolute and relative frequency, while continuous age was assessed using mean and standard deviation. The association between clinical outcome and exposure variables was verified using the chi-square test to compare frequency and odds ratio. For data that did not follow a normal distribution, the Kolmogorov-Smirnov test and Bonferroni post-test were used.

Variables related to symptoms, comorbidities and risk factors that presented statistical significance in bivariate analysis were subjected to multinomial regression adjusted for sex, age (continuous) and municipality of origin, in addition to the other variables in the chunk. A significance level of 5% was adopted. The Statistical Package for the Social Sciences for Windows® software was used for data analysis.

The research was based on standards and guidelines that regulate research involving human beings according to Resolutions 466/2012 and 510/2016 of the Brazilian National Health Council. The study was approved on April 25, 2022 by the UEL Research Ethics Committee, under Opinion 5.365.229 and Certificate of Presentation for Ethical Consideration 56710722.9.0000.5231, authorized by the institution.

RESULTS

Between January and March 2021, 1,476 patients diagnosed with Covid-19 were admitted to the study site. Of these, nine were excluded based on established criteria (four had incomplete medical records and five had no confirmation of the Covid-19 test).

Considering clinical-epidemiological characteristics, it was observed that most cases occurred in males (811; 55.3%), aged ≤64 (806; 54.9%), white (1,199; 81.7%), married (686; 46.8%) and residents of Londrina (762; 51.9%). When assessing the outcome characteristics, the analyses showed that there were higher rates (783; 53.4%) in relation to deaths and transfers (Table 1).

Table 1. Sociodemographic data of patients hospitalized (n=1,467) for Covid-19 according to sociodemographic characteristics in a public hospital. Londrina, Paraná, Brazil, 2022

Variables, n (%)	Total	Outcome			p-value**
		Death	Transfer	High*	
Sex					**0.004**
Male	811 (55.3%)	297 (36.7%)	113 (13.9%)	401 (49.4%)	
Female	656 (44.7%)	197 (30.0%)	77 (11.7%)	382 (58.3%)	
Age (in years)					**<0.001**
≤64	806 (54.9%)	190 (23.6%)	97 (12.0%)	519 (64.4%)	
≥65	661 (45.1%)	304 (46.0%)	93 (14.1%)	264 (39.9%)	
Race					0.240
White	1199 (81.7%)	404 (33.7%)	158 (13.2%)	637 (53.1%)	
Brown or black	161 (11.0%)	53 (32.9%)	18 (11.2%)	90 (55.9%)	
Yellow	26 (1.8%)	10 (38.5%)	7 (26.9%)	9 (34.6%)	
Data not provided	81 (5.5%)	27 (33.3%)	7 (8.6%)	47 (58.1%)	
Marital status					0.179
Married	686 (46.8%)	229 (33.4%)	83 (12.1%)	374 (54.5%)	
Single	229 (15.6%)	81 (35.4%)	27 (11.8%)	121 (52.8%)	
Widowed	112 (7.6%)	45 (40.2%)	12 (10.7%)	55 (49.1%)	
Divorced	71 (4.8%)	27 (38.0%)	15 (21.1%)	29 (40.9%)	
Other	369 (25.2%)	112 (30.4%)	53 (14.3%)	204 (55.3%)	
Municipality of origin					**<0.001**
Londrina	762 (51.9%)	227 (29.8%)	133 (17.4)	402 (52.8)	
Another municipality	705 (48.1%)	367 (37.9%)	57 (8.1)	381 (54.0)	
Total	**1467 (100%)**	**494 (33.6%)**	**190 (13.0%)**	**783 (53.4%)**	

Legend: X = mean; SD = standard deviation; *discharge by cure, discharge on request and discharge by evasion; ** chi-square test.

The main signs and symptoms described in medical records were respiratory, such as desaturation (640; 43.6%) and dyspnea (594; 40.5%), followed by cough (362; 24.7%), fever (245; 16.7%) and asthenia (153; 10.4%) (Table 2).

Table 2. Signs and symptoms associated with outcome in hospitalized patients (n=1,467) with Covid-19 according to symptoms in a public hospital. Londrina, Paraná, Brazil, 2022

Variables, n (%)	Total	Death	Transfer	Discharge*	p-value**
Desaturation					**0.003**
Yes	640 (43.6%)	225 (35.2%)	101 (15.7%)	314 (49.1%)	
No	827 (56.4%)	269 (32.5%)	89 (10.8%)	469 (56.7%)	
Dyspnea					**0.001**
Yes	594 (40.5%)	178 (30.0%)	98 (16.5%)	318 (53.5%)	
No	873 (59.5%)	316 (36.2%)	92 (10.5%)	465 (53.3%)	
Cough					**0.003**
Yes	362 (24.7%)	98 (27.1%)	59 (16.3%)	205 (56.6%)	
No	1105 (75.3%)	396 (35.8%)	131 (11.9%)	578 (52.3%)	
Fever					0.407
Yes	245 (16.7%)	71 (29.0%)	32 (13.0%)	142 (58.0%)	
No	1221 (83.3%)	423 (34.6%)	158 (12.9%)	641 (52.5%)	
Asthenia					0.224
Yes	153 (10.4%)	42 (27.5%)	21 (13.7%)	90 (58.8%)	
No	1314 (89.6%)	452 (34.4%)	169 (12.9%)	693 (52.7%)	
Myalgia					**<0.001**
Yes	147 (10.0%)	27 (18.4%)	35 (23.8%)	85 (57.8%)	
No	1320 (90.0%)	467 (35.4%)	155 (11.7%)	698 (52.9%)	
Headache					**0.002**
Yes	123 (8.4%)	24 (19.5%)	20 (16.3%)	79 (64.2%)	
No	1344 (91.6%)	470 (35.0%)	170 (12.6%)	704 (52.4%)	
Tachypnea					**0.001**
Yes	104 (7.1%)	47 (45.2%)	20 (19.2%)	37 (35.6%)	
No	1363 (92.9%)	447 (32.8%)	170 (12.5%)	746 (54.7%)	
Respiratory effort					**0.007**
Yes	100 (6.8%)	47 (47.0%)	14 (14.0%)	39 (39.0%)	
No	1367 (93.2%)	447 (32.7)	176 (12.9%)	744 (54.4%)	
Hyporexia					**0.027**
Yes	62 (4.2%)	18 (29.0%)	15 (24.2%)	29 (46.8%)	
No	1411 (96.2%)	483 (34.2%)	179 (12.7%)	749 (53.1%)	
Lack of appetite					**0.038**
Yes	54 (3.7%)	12 (22.2%)	4 (7.4%)	38 (70.4%)	
No	1413 (96.3%)	482 (34.1%)	186 (13.2%)	745 (52.7%)	
Nausea					**0.005**
Yes	56 (3.8%)	8 (14.3%)	7 (12.5%)	41 (73.2%)	
No	1411 (96.2%)	486 (34.4%)	183 (13.0%)	742 (52.6%)	
Ageusia					**0.040**
Yes	40 (2.7%)	7 (17.5%)	9 (22.5%)	24 (60.0%)	
No	1427 (97.3%)	487 (34.1%)	181 (12.7%)	759 (53.2%)	
Others*					0.090
Yes	326 (22.2%)	126 (38.7%)	37 (11.3%)	163 (50.0%)	
No	1141 (77.8%)	368 (32.3%)	153 (13.4%)	620 (54.3%)	
Total	**1467 (100%)**	**494 (33.6%)**	**190 (13.0%)**	**783 (53.4%)**	

Legend: **discharge due to cure, discharge on request and discharge due to evasion; **chi-square test; *others <100: diarrhea, emesis, chest pain, anosmia, prostration and odynophagia.

After adjustments for the main symptoms described, it was found that patients who presented tachypnea (OR: 1.71; 95% CI: 1.02-2.85; p: 0.042), respiratory effort (OR: 1.98; 95% CI: 1.20-3.27; p: 0.007) and desaturation (OR: 1.35; 95% CI: 0.98-1.83; p: 0.063) were more likely to die in relation to other symptoms. Those who presented hyporexia (OR: 1.91; 95% CI: 0.95-3.84; p: 0.071), myalgia (OR: 1.83; 95% CI: 1.12-3.00; p: 0.016) and tachypnea (OR: 1.77; 95% CI: 0.95-3.31; p: 0.073) were more likely to be transferred to another service due to the need for lower complexity beds, because they were patients with limited therapeutic support, post-Covid patients with significant sequelae and need for prolonged hospitalization, and because of the location of family members for monitoring (Table 3).

Table 3. Risk of symptoms related to the outcome of death and transfer in patients with Covid-19 (n=1,467). Londrina, Paraná, Brazil, 2022

	Death			Transfer		
Presence of	**Odds Ratio***	**95% CI**	**p-value****	**Odds Ratio***	**95% CI**	**p-value****
Desaturation	1.35	0.98-1.83	0.063	1.17	0.79-1.74	0.435
Dyspnea	0.78	0.57-1.06	0.117	1.24	0.83-1.84	0.297
Cough	0.74	0.53-1.03	0.070	0.93	0.62-1.38	0.705
Myalgia	0.68	0.41-1.13	0.137	1.83	1.12-3.00	0.016
Headache	0.76	0.44-1.30	0.314	0.92	0.51-1.65	0.772
Tachypnea	1.71	1.02-2.85	0.042	1.77	0.95-3.31	0.073
Respiratory effort	1.98	1.20-3.27	0.007	1.29	0.66-2.54	0.454
Hyporexia	1.16	0.60-2.24	0.654	1.91	0.95-3.84	0.071
Inappetence	0.45	0.22-0.92	0.028	0.33	0.11-0.96	0.042
Nausea	0.47	0.21-1.06	0.070	0.69	0.29-1.64	0.398
Ageusia	0.51	0.21-1.27	0.150	1.32	0.56-3.09	0.526

Legend: *model adjusted for sex, age (continuous), municipality of origin, desaturation, dyspnea, cough, myalgia, headache, tachypnea, respiratory effort, hyporexia, loss of appetite, nausea and ageusia; CI – Confidence Interval.

Of the total number of patients treated at the hospital, approximately 1,008 (69.7%) had some type of previous comorbidity and 439 (30.3%) did not. Of the patients who had some comorbidity, 494 (36.3%) died.

It is worth noting that 593 (57.5%) had two or more comorbidities. Of these, 224 (37.8%) died; 78 (13.1%) were transferred; and 291 (49.1%) were discharged. The main diseases were cardiovascular (795; 54.2%), endocrine (484; 33.0%), neurological (191; 13.0%), pulmonary (116; 7.9%), renal (63; 4.3%) and gastrointestinal (38; 2.6%) (Table 4).

Table 4. Outcomes of patients hospitalized (n=1,467) for Covid-19 according to comorbidities in a public hospital in Londrina. Londrina, Paraná, Brazil, 2022

Variables, n (%)	**Total**	**Death**	**Transfer**	**Discharge***	**p-value****
Cardiovascular					**<0.001**
Yes	795 (54.2%)	302 (38.0%)	111 (14.0%)	382 (48.0%)	
No	672 (45.8%)	192 (28.6%)	79 (11.7%)	401 (59.7%)	
Endocrine					0.330
Yes	484 (33.0%)	172 (35.5%)	67 (13.8%)	245 (50.7%)	
No	983 (67.0%)	322 (32.8%)	123 (12.5%)	538 (54.7%)	
Neurological					0.815
Yes	191 (13.0%)	65 (34.0%)	22 (11.5%)	104 (54.5%)	
No	1275 (87.0%)	429 (33.6%)	168 (13.2%)	678 (53.2%)	
Pulmonary					**0.002**
Yes	116 (7.9%)	56 (48.3%)	11 (9.5%)	49 (42.2%)	
No	1351 (92.1%)	438 (32.4%)	179 (13.2%)	734 (54.4%)	
Renal					**0.028**
Yes	63 (4.3%)	31 (49.2%)	6 (9.5%)	26 (41.3%)	
No	1404 (95.7%)	463 (33.0%)	184 (13.1%)	757 (53.9%)	
Gastrointestinal					0.996
Yes	38 (2.6%)	13 (34.2%)	5 (13.2%)	20 (52.6%)	
No	1429 (97.4%)	481 (33.7%)	185 (12.9%)	763 (53.4%)	
Total	**1467 (100%)**	**494 (33.6%)**	**190 (13.0%)**	**783 (53.4%)**	

Legend: **discharge by cure, discharge on request and discharge by evasion; **chi-square test.

As for the presence of risk factors, 449 (30.6%) had at least one risk factor and 1,018 (69.4%) did not. Of these, 148 (33.0%) died; 62 (13.8%) were transferred; and 239 (53.2%) were discharged. The main risk factors were obesity (227; 15.5%), smoking (55; 3.7%), alcoholism (30; 2%), being a former smoker (183; 12.5%) and being a former alcoholic (21; 1.4%).

The chance of death in the population ≥65 years old was higher in relation to those under 64 years old. Those who had some nephrological (OR: 1.55; 95% CI: 0.86-2.79; p: 0.144) and pulmonary (OR: 1.53; 95% CI: 0.98-2.40; p: 0.064) comorbidity had a greater chance of dying (Table 5).

Table 5. Association of the presence of comorbidities with the outcome of death and transfer in patients with Covid-19 (n=1,467). Londrina, Paraná, Brazil, 2022

	Death			Transfer		
Comorbidities	**Odds Ratio***	**95% CI**	**p-value****	**Odds Ratio***	**95% CI**	**p-value****
Presence of comorbidity	0.89	0.59-1.33	0.568	0.68	0.39-1.18	0.166
Cardiovascular	1.10	0.77-1.57	0.592	1.49	0.89-2.50	0.122
Pulmonary	1.53	0.98-2.40	0.064	0.84	0.42-1.70	0.631
Nephrological	1.55	0.86-2.79	0.144	0.83	0.33-2.10	0.693

Legend: *model adjusted for sex, age (continuous), municipality of origin, presence of cardiovascular, pulmonary and nephrological comorbidity; CI - Confidence Interval.

DISCUSSION

According to the Government of the State of Paraná (2021), more than 15 thousand people were treated during the new coronavirus pandemic at UEL-UH and around 33% required hospitalization in high complexity beds, 96 in wards, 106 in adult ICU and 11 in pediatric ICU, receiving the mark of one of the main treatment and rehabilitation centers against Covid-19 in the State.[16]

This study portrayed the first months of the second wave of the Covid-19 pandemic, in order to explore the clinical and epidemiological characteristics and outcomes in a referral hospital for this disease in the city of Londrina. The pandemic had already affected and led to the death of many people around the world, and in Brazil, not unlike other countries, the pandemic gained strength with each passing day and showed no signs of remission.

The sociodemographic profile showed that the majority of patients infected with Covid-19 in the second wave were male, married, white, aged ≤64, and residents of Londrina. A multicenter international study conducted in the first wave of the pandemic revealed that the predominance of infected patients supports this study, which was male and white, but it differs in the age variable, with the most affected being older, 50-74 years old, with a median of 59 years.[17] A large national study also showed a higher frequency of infections in patients over 60 years old, male, with an equal

percentage for white and black/brown people.[18]

When assessing the characteristics with the outcome, the analyses showed that there were more discharges when compared with deaths and transfers, supporting the findings of a national study, where general hospital mortality was lower than the other outcomes.[18]

A variety of symptoms can be presented by patients with Covid-19, from mild complaints, such as fever and cough, to more severe symptoms associated with dyspnea, as presented in this study.[19] According to the Pan American Health Organization and the Ministry of Health (MoH), milder symptoms include fever, fatigue, dry cough, loss of taste or smell, nasal congestion, sore throat, headache, myalgia, nausea, vomiting, among others. Severe symptoms include dyspnea, loss of appetite, confusion, persistent pain or pressure in the chest and hyperthermia.[20-21]

This study showed a higher frequency of symptoms related to the respiratory system, with desaturation (35.2%), tachypnea (45.2%) and respiratory effort (47.0%) having significance regarding the outcome of death in relation to the other signs and symptoms. Findings from a retrospective cohort study conducted in New York revealed that, among the factors associated with hospital mortality, tachypnea and peripheral oxygen saturation below 92% increased the risk of in-hospital mortality, in agreement with the present study.[17]

The MoH considers the elderly, pregnant and postpartum women, children, and people with risk factors or chronic conditions, regardless of age, such as smokers and/or ex-smokers, hypertensive patients, cardiomyopathies of different etiologies, diabetics, obese patients, chronic kidney disease, among others, to be at risk for developing severe forms of Covid-19.[22] The results of this study showed that 57.5% of hospitalized patients had two or more comorbidities, with emphasis on cardiovascular, endocrine, neurological, and pulmonary diseases. The mortality rate in this study was 33.6%, in which older adults with comorbidities, especially pulmonary and renal, had a higher chance of death.

A cohort study carried out in Acre in 2020, which aimed to analyze risk factors for death in individuals with Covid-19, showed that the presence of cardiovascular and endocrine diseases was a characteristic associated with death from Covid-19, showing a difference with this study in which the Odds Ratio of death was higher in patients with pulmonary and nephrological comorbidities.[23] However, another study carried out in southern Brazil identified the prevalence of cardiovascular, pulmonary and endocrine diseases, confirming the findings of this study.[24]

As a limitation of this study, the lack of the variable education level was considered due to the absence of its respective record. This data is of utmost importance, since having a high level of education influences the lower probability of having diseases, such as cardiovascular, endocrine, pulmonary and nephrological.[25] Another limitation was working with data from medical records, which, in turn, are limited to access to the internet and because their collection is only in-hospital. On the other hand, the advantage is to bring more agility, security and loyalty to their clinic.

In short, the research conducted addressed the second wave of the Covid-19 pandemic and its implications in a referral hospital in northern Paraná, highlighting the sociodemographic and clinical characteristics of hospitalized patients. The results indicated that the majority of infected individuals were men, aged up to 64 years, with mortality being more frequent among elderly patients and those with comorbidities, mainly pulmonary and nephrological. The research also highlighted that severe respiratory symptoms, such as desaturation and tachypnea, were associated with a higher risk of death. It is concluded that the second wave of Covid-19 was as devastating as the first wave, but there was a change in the age profile of those infected. These findings contribute to understanding the evolution of Covid-19 and reinforce the need for intervention strategies aimed at the most vulnerable groups, especially those with multiple comorbidities. Therefore, this and future studies will make it possible to highlight the profile of patients affected by Covid-19 and will help in facing major pandemics such as this one. It is suggested that studies be carried out that incorporate, for instance, the impact of vaccination on the various outcomes of the disease, in order to confirm the effectiveness of vaccines as well as the reduction in mortality in patients with Covid-19 and associated factors.

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AUTHORS' CONTRIBUTIONS

Lucas Benedito Fogaça Rabito: Data conception and design or analysis and interpretation; Article writing or critical review of relevant intellectual content; Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the work. **Bruna Daniella de Sousa de Lima**: Writing the article or critically reviewing it for relevant intellectual content; Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the work. **Thamyris Lucimar Pastorini Gonçalves**: Writing the article or critically reviewing it for relevant intellectual content; Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the work. **Gabriel Guembarski Flavio**: Writing the article or critically reviewing the relevant intellectual content; Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the work. **Márcia Eiko Karino**: Final approval of the version to be published; Being responsible for all aspects of the work in ensuring the accuracy and integrity of any part of the

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All authors have approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Rabito LBF, de Lima BDS, Gonçalves TLP, Flavio GG, Karino ME, da Rocha AF, Menolli GA, Cristina MCN. Clinical-epidemiological profile and outcome of patients with Covid-19 in the second wave of the pandemic in Paraná, Brazil. Rev Epidemiol Control Infect [Internet]. 2025 Feb. 16; 15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19162

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Impact of the Covid-19 pandemic on schistosomiasis control in an endemic region of the Northeastern Brazil, 2020-2021

Impacto da pandemia de Covid-19 no controle da esquistossomose em região endêmica do nordeste brasileiro, 2020-2021

Impacto de la pandemia de Covid-19 en el control de la esquistosomiasis en región endémica del noreste de Brasil, 2020-2021

Site doi: https://doi.org/10.17058/reci.v15i1.19373

Submitted: 04/24/2024
Accepted: 11/22/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: The Covid-19 pandemic has affected the fight against neglected diseases worldwide, including schistosomiasis. In the Brazilian context, schistosomiasis is an endemic disease with an impact mainly in the Northeastern region. Here, this study aims to analyze the impact of the Covid-19 pandemic on the epidemiological indicators of the Schistosomiasis Control Program (PCE) in an endemic area in the Northeast Brazil in 2020 and 2021. **Methods:** This is a population-based ecological study conducted in the State of Pernambuco, based on data from the PCE. Data was extracted from the Schistosomiasis Control Program Information System (SISPCE). The following indicators were analyzed: population reached, number of tests performed, positivity rate, and percentage of people treated. Percentage change was used to compare the observed value to the expected value, according to the pre-pandemic period (2015-2019). **Results:** There was a decrease in the population reached (71.3% in 2020 and 64.1% in 2021). The tests performed decreased from 73.8% in 2020 to 66.5% in 2021. The State positivity rate for schistosomiasis decreased by 32.8% in 2020 and 6.4% in 2021. The rate of treated individuals increased by 5.8% in 2020 and decreased by 25.1% in 2021. **Conclusion:** The schistosomiasis control program in Pernambuco was affected by the Covid-19 pandemic, as observed in the variations of the variables analyzed. It is recommended that this program be strengthened to ensure active investigation, epidemiological surveillance, diagnosis and treatment of schistosomiasis in the study area.

Keywords: *Covid-19. Neglected diseases. Public health surveillance. Schistosomiasis.*

RESUMO

Justificativa e Objetivos: A pandemia da Covid-19 comprometeu o enfrentamento das doenças negligenciadas em todo mundo, dentre as quais está a Esquistossomose. No contexto brasileiro, esta é uma doença endêmica, com impacto predominantemente na região nordeste. Aqui, objetivou-se analisar o impacto da pandemia da Covid-19 em indicadores epidemiológicos do Programa de Controle de Esquistossomose (PCE) em área endêmica no Nordeste do Brasil nos anos de 2020 e 2021. **Métodos:** Trata-se de um estudo ecológico de base populacional, realizado no estado de Pernambuco, baseado nos dados do PCE. Os dados foram extraídos do Sistema de Informação do Programa de Controle da Esquistossomose (SISPCE). Os seguintes indicadores foram analisados: população assistida, número de exames realizados, taxa de positividade e proporção de indivíduos tratados. Utilizou o percentual de mudança para a comparação do valor observado com o valor esperado, de acordo com o período pré-pandemia (2015-2019). **Resultados:** Observou-se redução na população assistida (71,3% em 2020 e 64,1% em 2021). Os exames realizados apresentaram declínio de 73,8% em 2020 e 66,5% em 2021. A taxa de positividade estadual para esquistossomose reduziu 32,8% em 2020 e 6,4% em 2021. Houve um aumento na taxa de indivíduos tratados de 5,8% em 2020 e um declínio de 25,1% em 2021. **Conclusão:** O programa de controle da esquistossomose de Pernambuco foi impactado pela pandemia da Covid-19, conforme observado nas variações das variáveis analisadas. Recomenda-se fortalecer esse programa, visando garantir as ações de busca ativa, monitoramento epidemiológico, diagnóstico e tratamento da esquistossomose na área de estudo.

Descritores: *Covid-19. Doenças negligenciadas. Esquistossomose. Vigilância em saúde pública.*

RESUMEN

Justificación y Objetivos: La pandemia de Covid-19 ha afectado la lucha contra las enfermedades negligenciadas en todo el mundo, incluida la esquistosomiasis. En el contexto brasileño, la esquistosomiasis es una enfermedad endémica con un impacto principalmente en la región noreste. Aquí, nuestro objetivo fue analizar el impacto de la pandemia de Covid-19 en los indicadores epidemiológicos del Programa de Control de Esquistosomiasis (PCE) en un área endémica del noreste de Brasil en 2020 y 2021. **Métodos:** Este es un estudio ecológico basado en la población realizado en el estado de Pernambuco, basado en datos del PCE. Los datos se extrajeron del Sistema de Información del Programa de Control de Esquistosomiasis (SISPCE). Se analizaron los siguientes indicadores: población atendida, número de pruebas realizadas, tasa de positividad y porcentaje de personas tratadas. Se utilizó el cambio porcentual para comparar el valor observado con el valor esperado, de acuerdo con el período prepandemia (2015-2019). **Resultados:** Hubo una disminución en la población atendida (71,3% en 2020 y 64,1% en 2021). El número de pruebas realizadas disminuyó del 73,8% en 2020 al 66,5% en 2021. La tasa de positividad estatal para la esquistosomiasis disminuyó un 32,8% en 2020 y un 6,4% en 2021. La tasa de individuos tratados aumentó un 5,8% en 2020 y disminuyó un 25,1% en 2021. **Conclusión:** El programa de control de esquistosomiasis en Pernambuco se vio afectado por la pandemia de Covid-19, como se observó en las variaciones de las variables analizadas. Se recomienda fortalecer este programa para garantizar la investigación activa, la vigilancia epidemiológica, el diagnóstico y el tratamiento de la esquistosomiasis en el área de estudio.

Palabras Clave: *Covid-19. Enfermedades desatendidas. Esquistosomiasis. Vigilancia en salud pública.*

INTRODUCTION

Schistosomiasis is a parasitic disease that is endemic in 78 countries.[1] It is one of the most common neglected diseases in the world, mainly in poor areas without access to potable water and basic sanitation.[1,2] It can present in a variety of clinical forms, ranging from asymptomatic to severe and potentially fatal. The magnitude of the number of cases, combined with the severity of the clinical forms, keeps schistosomiasis as a public health problem in many places.[1]

Worldwide, the African continent is the most affected, with approximately 230 million cases per year. On the American continent, there are approximately 2.3 million cases per year. Among these countries, Brazil is the most affected, with an estimated 2.1 million cases per year.[3] In addition, *Schistosoma mansoni* is the only species that causes schistosomiasis in South and Central America.[4] In Brazil, schistosomiasis occurs in all five regions, although it is more prevalent in the northeast.[5] Of the nine States in the Northeast, six are endemic: Alagoas, Bahia, Pernambuco, Rio Grande do Norte, Paraíba, and Sergipe.[5] In the State of Pernambuco, there are six areas considered endemic, located in the eastern part of the State.[6] The high incidence in these areas reflects the social nature of the disease, which more severely affects communities with limited sanitation infrastructure and restricted access to clean water, increasing the vulnerability of the populations exposed.[1,6]

The Covid-19 pandemic has overwhelmed health systems around the world, with significant socioeconomic impacts on the various components of these systems.[9,10] As a result, many health services, such as screening and early diagnosis, immunization programs, epidemiologic surveillance, emergency services, health education, and vector control, have been compromised.[9] This setback has affected the diagnosis and treatment of many neglected diseases, such as dengue,[11] tuberculosis,[9] and schistosomiasis.[12]

Based on the above, this study aims to analyze the impact of the Covid-19 pandemic on the epidemiological indicators of the Schistosomiasis Control Program (PCE, acronym in Portuguese) in an endemic area of Northeastern Brazil in 2020 and 2021.

METHODS

Study design and area

This is a population-based ecological study conducted in the State of Pernambuco, Brazil. The State is politically divided into 184 municipalities and the island of Fernando de Noronha, covering an area of approximately 98,000 km^2. It had an estimated population of 10 million inhabitants in 2021. It is characterized by social inequalities, with 51% of the population living in poverty.[13] There are 12 regions of health, six of which are considered endemic.[6] Regions I, II, III, IV, V and XII correspond to Recife, Limoeiro, Palmares, Caruaru, Garanhuns and Goiana, respectively.[14] (Figure 1).

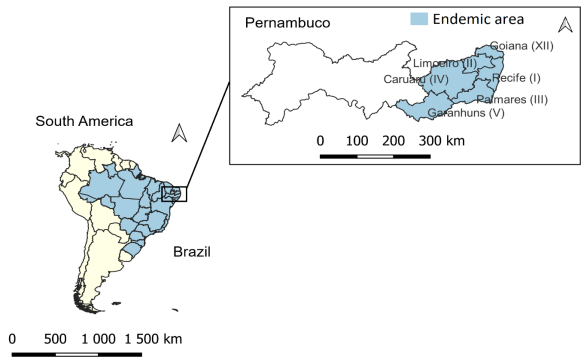

Figure 1. Location of the study area. Pernambuco, Brasil.

Population and study period

The Schistosomiasis Control Program (PCE) contains statistical data related to the population residing in endemic areas for the disease. The population analyzed in the study is from the six endemic regions for schistosomiasis in the State of Pernambuco. The study was conducted with schistosomiasis cases reported between 2020 and 2021. The pre-pandemic period (2015-2019) was extracted from the same database and served as a comparison parameter, as it has been used in other studies. [9, 11] The data collection period was November and December 2023.

Epidemiological indicators from PCE that were analyzed:

1. Population served in the study years: refers to the number of people who received the container for collecting material for examination.
2. Number of examinations performed in the study years: refers to the number of people examined (coproscopy).
3. Positivity rate in the study years: refers to the number of people in whom *Schistosoma mansoni* eggs were identified during the examination.
4. Percentage of people treated: refers to the number of people treated for schistosomiasis among those who tested positive by coproscopy.

Selection criteria

All cases of schistosomiasis diagnosed in the period from 2020 to 2021 were included. Cases that were closed as diagnostic errors were excluded.

Data source

The data was extracted from the Information System of the Schistosomiasis Control Program (SISPCE) from Pernambuco State Health Department (SES/PE) and available at the Department of Information Technology of the Unified Health System (DATASUS).

(http://tabnet.datasus.gov.br/cgi/deftohtm.exe?sinan/pce/cnv/pcebr.def)

The Schistosomiasis Control Program (PCE) was implemented in Brazil in 1975 as the Special Schistosomiasis Control Program (PECE) and was renamed the PCE in the 1980s.[14] The program has the potential to implement measures to control and minimize the spread of the disease, such as the distribution of diagnostic kits and drugs provided by the Ministry of Health for the diagnosis and treatment of all diagnosed positive cases to municipalities.[15, 16]

Impact of the COVID-19 pandemic on the PCE

To measure the impact of the COVID-19 pandemic on the indicators analyzed, the pre-pandemic period (2015-2019) was considered to calculate the expected value for the years 2020 and 2021. These expected values were compared with the observed values, using the following equations:

Impact in 2020:

$$Percentage\ change = \frac{observed\ indicator\ (2020) - expected\ indicator\ (mean\ 2015-2019)}{observed\ indicator\ (mean\ 2015-2019)}$$

Impact in 2021:

$$Percentage\ change = \frac{observed\ indicator\ (2021) - expected\ indicator\ (mean\ 2015-2019)}{observed\ indicator\ (mean\ 2015-2019)}$$

Where: 1- The event analyzed is the proportion of positive schistosomiasis cases; 2- The expected value for the year is calculated considering the last five years before the start of the pandemic, as recommended. This model has been used in other studies.[17] Results were presented in absolute numbers and proportions. These analyses were performed using Excel spreadsheets (Microsoft®) and Qgis (version 2.14.11, Open Source Geospatial Foundation (OSGeo), Beaverton, OR, USA).

Ethical aspects

The study used publicly available secondary data and therefore did not require the approval of a research ethics committee. In accordance with the required ethical standards - Resolutions 466/2012, 510/2016, and 580/2018 of the Ministry of Health.

RESULTS

In the pre-pandemic period, the annual average number of people served in the six health regions studied was 270,239. In 2020, this number decreased to 77,428 (a 71.3% decrease compared to the expected number). A decrease was observed in all regions, with the largest decrease in the Recife region (-87.5%). In 2021, there was an increase in the population served compared to 2020 (19,488 more people). However, when considering the expected value (average of the five years before the pandemic), the decrease was still significant (a 64.1% reduction compared to the expected value) (Figure 2 A and B).

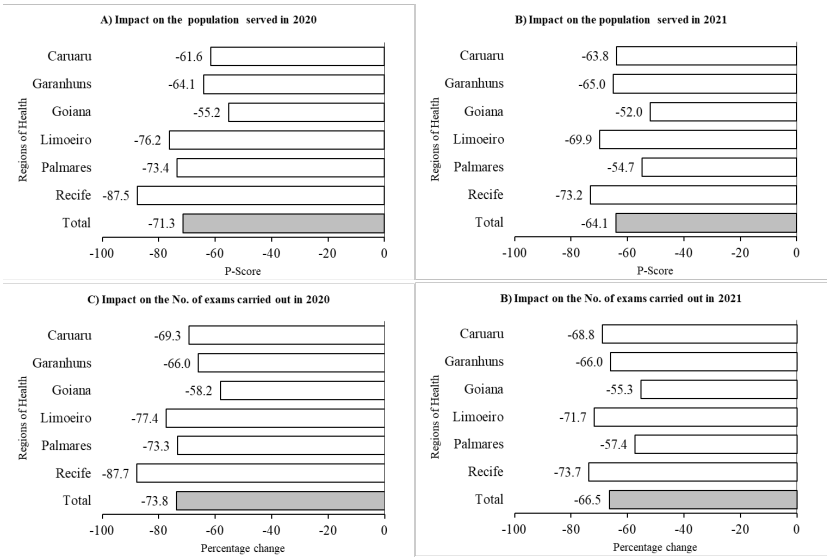

Figure 2. Percentage change in the population served and number of tests in 2020 and 2021 by the Schistosomiasis Control Program in Pernambuco, Brazil.

A similar trend was seen in the number of tests performed. The pre-pandemic average was 192,032 tests per year. In 2020, there was a decrease of 73.8%, meaning that 141,676 tests were not performed. In 2021, although 13,985 more tests were performed than in 2020, there was a 66.5% reduction (127,691 fewer tests) compared with the pre-pandemic average (Figure 2 C and D).

The statewide positivity rate was 2.5% in the pre-pandemic period, with the highest rate in the Palmares region (5.4%) and the lowest in Caruaru (0.5%) (Figure 3 A). In 2020, the State's positivity rate decreased to 1.7 (-32%), with the largest decrease in the Garanhuns region (-45.7%) (Figure 3 B). In 2021, the positivity rate increased to 2.3%, although it remained 6.4% below the expected rate (2.5%) (Figure 3 C). In addition, the Recife region showed a positive variation in the rate in the two years evaluated (6.1% in 2020 and 29.8% in

2021) and Garanhuns showed a positive variation in 2021 (53.3%) (Figure 3 B and C).

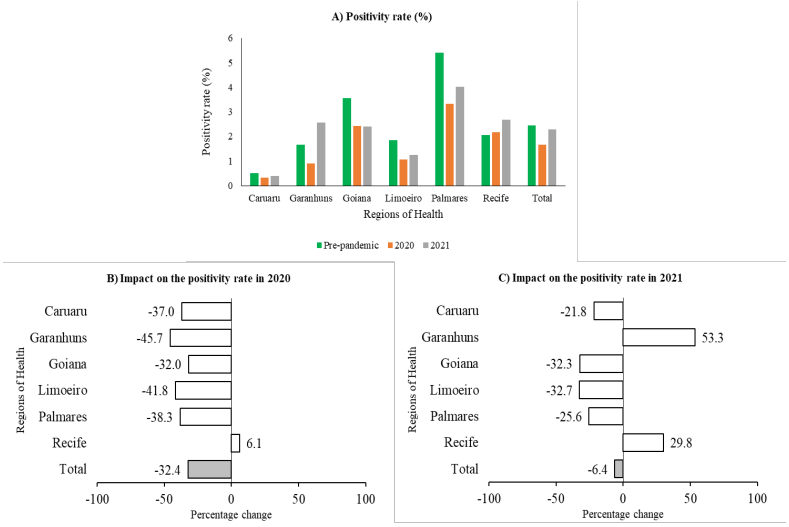

Figure 3. Percentage change in the positivity rate in tests conducted by the Schistosomiasis Control Program in 2020 and 2021 in Pernambuco, Brazil.

The State rate of individuals treated was 66% in the pre-pandemic period, with the highest rate in the Garanhuns region (84.6%) and the lowest in Recife (61.1%) (Figure 4 A). In 2020, the rate of individuals treated increased by 5.8% (from 66% to 69.9%) compared to the pre-pandemic period, although heterogeneously among regions (Figure 4 B). In 2021, the treatment rate decreased by 25.1% (from 66% to 49.4%). In addition, the regions of Palmares and Recife showed a positive change in the rate in 2020 (17.5% and 3.3%, respectively) (Figure 4 B). All other regions showed a decrease in both years analyzed (Figure 4 B and C).

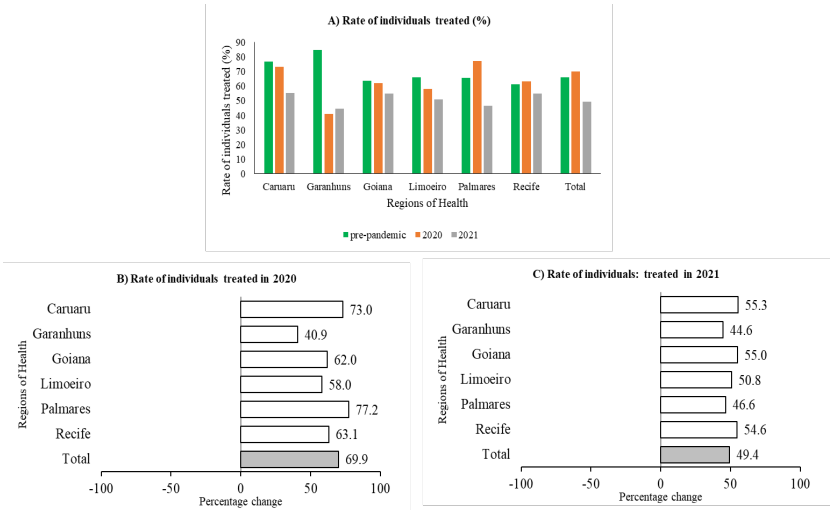

Figure 4. Percentage change in the rate of individuals treated in 2020 and 2021 by the Schistosomiasis Control Program in Pernambuco, Brazil.

DISCUSSION

This study analyzed the impact of the Covid-19 pandemic on the epidemiological indicators of the Schistosomiasis Control Program (PCE, *acronym in Portuguese*) in an endemic area of Northeastern Brazil. The results showed a significant impact on the population served, the number of tests performed, the positivity rate, and the population treated for schistosomiasis.

According to the Ministry of Health, approximately 1.5 million people in Brazil are exposed to schistosomiasis.[18] Brazilian public policy includes strategies to control this disease, such as parasitological testing of feces to identify infected individuals, followed by treatment with appropriate drugs, as well as the use of molluscicides to control the snail and interrupt transmission in natural and artificial breeding sites.[19]

In 2020 and 2021, health systems around the world were directly or indirectly affected by the measures adopted to control the Covid-19 pandemic.[20, 21] The measures adopted to reduce transmission, such as social distancing and reduced access to health services, combined with the fear of part of the population of contracting the infection during the pandemic led to a significant reduction in activities related to research,

detection, and treatment of neglected tropical diseases in Brazil.[12, 20, 21]

In Brazil, as in other countries, clinical suspicions and notifications of diseases such as visceral leishmaniasis,[22] leptospirosis,[22] malaria,[22] and schistosomiasis have decreased. Because of the Covid-19 pandemic, the reach of health services has been compromised, which has contributed to a decrease in the number of notifications and confirmed cases of endemic diseases and, consequently, an increase in the case fatality rate.[5, 22]

A study conducted in another schistosomiasis-endemic area in the Northeast showed that in 2021, there was a 19% decrease in the rate of schistosomiasis in the population analyzed compared to 2019. In that year, only 29.9% of people who needed treatment for the disease were reached, and 43.3% of children with an indication for preventive chemotherapy were treated.[12] It was then observed that PEC activities continuity was affected by the Covid-19 pandemic, causing a reduction in testing, thus reducing the case numbers of the disease, which masked the severity, especially in endemic areas.[1, 12, 17]

When evaluating the expansion of schistosomiasis treatment coverage in municipalities located in endemic regions of the State, Pernambuco's Annual Management Report (RAG) for 2021 noted low coverage, which was attributed to the redirection of PCE professionals to Covid-19 activities.[5] A similar situation was observed in the State of Alagoas, where there was a significant decrease in the number of people served.[12]

Because of the consequences of the Covid-19 pandemic, the fight against schistosomiasis requires vigorous action to strengthen the Brazilian health system to ensure timely notification, epidemiologic surveillance, diagnosis, and treatment of the disease.[23] In addition, key control strategies must be implemented, including health education, mass drug administration, intermediate host control strategies, and the implementation of basic sanitation measures.[24]

Despite all the care taken, this study has limitations, including the fact that it is a population-based ecological study based on secondary data in the public domain. This data is subject to the quality of surveillance services, especially in smaller communities. In addition, the pandemic itself had an impact on these surveillance services and consequently on the quality of the data obtained.

In conclusion, the Covid-19 pandemic has had an impact on the Schistosomiasis Control Program in the State of Pernambuco, with a decrease in the following indicators: population served, rate of tests performed and State positivity rate, especially in 2020. It is recommended that the PCE be strengthened to expand the epidemiological surveillance of the disease, as well as actions that allow early diagnosis and timely treatment of the disease.

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AUTHORS' CONTRIBUTIONS

Elisangela Cordeiro Alves contributed to the literature search, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Havandécio Rodrigues de Matos Júnior** contributed to the writing of the abstract, methodology, interpretation of results, conclusions, review and statistics. **Vanessa Dias Amorim** contributed to the writing of the abstract, methodology, interpretation of results, conclusions, review and statistics. **Rodrigo Feliciano do Carmo** contributed to the project administration, literature search, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, conclusions, review and statistics. **Carlos Dornels Freire de Souza** contributed to the project administration, literature search, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, conclusions, review and statistics.

All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Alves EC, Júnior HRM, Amorim VD, do Carmo RD, de Souza CDF. Impact of the Covid-19 pandemic on schistosomiasis control in an endemic region of the Northeastern Brazil, 2020-2021. Rev Epidemiol Control Infect [Internet]. 2025 Jan.28; 15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19373

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Self-efficacy in hand hygiene and glove use among nurses during the Covid-19 pandemic

Autoeficácia da higienização das mãos e uso de luvas entre a enfermagem durante a pandemia do Covid-19
Autoeficacia en higiene de manos y uso de guantes entre enfermeras durante la pandemia de Covid-19

Site doi: https://doi.org/10.17058/reci.v15i1.19372

Submitted: 04/23/2024
Accepted: 12/11/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: The global spread of SARS-CoV-2 led to the Covid-19 pandemic, necessitating preventive measures, especially hand hygiene and the use of gloves. Given the high transmissibility of the virus, nursing, being at the frontline, faced enormous pressure. The objectives of the study were: a) to assess the frequency of nursing professionals with self-efficacy in hand hygiene and glove use during the pandemic across the five regions of Brazil; b) to compare self-efficacy scores among the regions; and c) to analyze the association between sociodemographic characteristics and the level of self-efficacy. **Methods:** This is a retrospective observational study conducted between November 2020 and December 2021, with a sample of 493 nursing professionals (assistants, technicians, and nurses) from the five regions of Brazil who responded to the questionnaire "Self-Efficacy of Health Professionals: Hand Hygiene and Glove Use." **Results:** Of the participants, 72.5% were nurses, 75.8% were female, 21.3% were aged between 18 and 24 years, and 50.4% had postgraduate degrees (master's and/or doctorate). Most professionals exhibited high self-efficacy in hand hygiene and glove use (≥ 60%). No significant differences were found in self-efficacy scores among the regions of Brazil, nor was there an association between self-efficacy and sociodemographic characteristics. **Conclusion:** The results obtained during the Covid-19 pandemic constitute an important health management tool useful for identifying gaps in knowledge, skills, and engagement in infection control management.

Keywords: *Health professionals. SARS-CoV-2. Infection control. Health knowledge. Nursing education.*

RESUMO

Justificativa e Objetivos: A propagação global do SARS-CoV-2 levou à pandemia de Covid-19, demandando medidas preventivas, especialmente a higienização das mãos e o uso de luvas. Diante da alta transmissibilidade do vírus, a enfermagem, atuando na linha de frente, enfrentou enorme pressão. Os objetivos do estudo foram: a) avaliar a frequência de profissionais de enfermagem com autoeficácia na higienização das mãos e uso de luvas durante a pandemia nas cinco regiões do Brasil; b) comparar os escores de autoeficácia entre as regiões; e c) analisar a associação entre características sociodemográficas e o nível de autoeficácia. **Métodos:** Estudo observacional retrospectivo realizado entre novembro de 2020 e dezembro de 2021, com uma amostra de 493 profissionais de enfermagem (auxiliares, técnicos e enfermeiros) das cinco regiões do Brasil, que responderam ao questionário "Autoeficácia dos Profissionais de Saúde: Higiene das Mãos e Uso de Luvas". **Resultado:** Dos participantes, 72,5% eram enfermeiros, 75,8% do sexo feminino, 21,3% tinham entre 18 e 24 anos, e 50,4% possuíam pós-graduação (mestrado e/ou doutorado). A maioria dos profissionais apresentou alto nível de autoeficácia na higienização das mãos e uso de luvas (≥ 60%). Não foram encontradas diferenças significativas nos escores de autoeficácia entre as regiões do Brasil, nem associação entre autoeficácia e características sociodemográficas. **Conclusão:** Os resultados obtidos durante a pandemia de Covid-19 constituem uma importante ferramenta de gestão em saúde, útil para identificar lacunas no conhecimento, habilidades e envolvimento na gestão do controle de infecções.

Descritores: *Profissionais de saúde. SARS-CoV-2. Controle de infecção. Conhecimento em saúde. Educação em enfermagem.*

RESUMEN

Justificación y Objetivos: La propagación global del SARS-CoV-2 condujo a la pandemia de Covid-19, lo que requirió medidas preventivas, especialmente la higiene de manos y el uso de guantes. Dada la alta transmisibilidad del virus, la enfermería, que se encuentra en la primera línea, enfrentó una enorme presión. Los objetivos del estudio fueron: a) evaluar la frecuencia de profesionales de enfermería con autoeficacia en la higiene de manos y el uso de guantes durante la pandemia en las cinco regiones de Brasil; b) comparar las puntuaciones de autoeficacia entre las regiones; y c) analizar la asociación entre las características sociodemográficas y el nivel de autoeficacia. **Métodos:** Se trata de un estudio observacional retrospectivo realizado entre noviembre de 2020 y diciembre de 2021, con una muestra de 493 profesionales de enfermería (auxiliares, técnicos y enfermeros) de las cinco regiones de Brasil, quienes respondieron al cuestionario "Autoeficacia de los Profesionales de Salud: Higiene de Manos y Uso de Guantes." **Resultados:** De los participantes, el 72,5% eran enfermeros, el 75,8% eran mujeres, el 21,3% tenían entre 18 y 24 años, y el 50,4% tenían estudios de posgrado (maestría y/o doctorado). La mayoría de los profesionales presentaron un alto nivel de autoeficacia en la higiene de manos y el uso de guantes (≥ 60%). No se encontraron diferencias significativas en las puntuaciones de autoeficacia entre las regiones de Brasil, ni asociación entre la autoeficacia y las características sociodemográficas. **Conclusión:** Los resultados obtenidos durante la pandemia de Covid-19 constituyen una herramienta importante de gestión en salud, útil para identificar lagunas en el conocimiento, las habilidades y el compromiso en la gestión del control de infecciones.

Palabras Clave: *Profesionales de la salud. SARS-CoV-2. Control de infección. Conocimiento en Salud. Educación en enfermería.*

INTRODUCTION

In December 2019, in the city of Wuhan, China, a new coronavirus was identified, later named Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2),[1] which spread globally through the Coronavirus Disease 2019 and was responsible for the onset of the Covid-19 pandemic.[2] In the epidemiological scope, the virus has a high rate of transmissibility through direct contact, droplets, or aerosol. Virus survival time on environmental surfaces is variable, depending on the type of surface, temperature, air humidity, and virus strain. The virus can survive on innate objects and remain viable for 72 hours.[3] When considering these aspects, world governments, including Brazil, stipulated prevention measures for the entire population, with emphasis on hand sanitation. Self-efficacy is a proven determinant in carrying out prevention protocols, especially in relation to hand hygiene and the use of procedure gloves.[4] Due to the characteristics of the virus, it is essential to assess the quality of the preventive measures carried out by nursing professionals who provide care to patients confirmed and/or suspected of having Covid-19.

In addition to being standard precautionary measures for preventing the transmission of SARS-CoV-2,[3] hand hygiene, and the use of gloves enable a safe provision of care for patients and medical professionals.[5] According to Regulatory Standard 32 (NR 32), the use of gloves does not replace the hand hygiene process. Hand hygiene is a key factor in reducing the risk of other infections among healthcare professionals and patients.[6]

With the onset of the Covid-19 pandemic, infection rates became increasingly high. Consequently, there was a substantial increase in the use of health services by the population, especially in the hospital environment.[7] Around the world, nursing staff were under constant pressure, being on the front lines of care.[8] These professionals had to adapt suddenly, faced with scarce information about clinical aspects of the disease, new clinical protocols, routines, and norms, and the use of specific and insufficient personal protective equipment, compounded by insufficient nurses for the care demand.[9] In addition, the role of these workers requires professional experience and, above all, confidence to identify and treat patients with Covid-19[8] quickly.

Self-efficacy refers to the idea that a subject has about their capacity to perform a task and depends on their confidence level.[12] Note that a high sense of efficacy in a specific domain does not mean high self-efficacy in others. In this sense, the most apparent reasons for self-efficacy (direct experience, vicarious experience, social or verbal persuasions, and physical and emotional states) are estimated basic information in data communication that increase or decrease people's confidence about their own skills.[10]

The concept of self-efficacy is considered beneficial for exploring this subject, as it pertains to an individual's belief in their ability to perform specific tasks successfully. While this ability is subjective, it can be assessed using a measurement tool. Previously, there was no evidence in the scientific literature of a validated instrument that simultaneously measured the self-efficacy of health professionals in practicing hand hygiene and using gloves.[10] Checking the critical points and failures performed by health professionals in the scope of patient care is paramount for improving and developing preventive measures. The existing literature emphasizes that the procedure for hand hygiene and the use of gloves is strongly related to clinical practice, determining the commitment of the health system and professionals to improve the current situation, together with behavioral changes regarding the use of gloves.[11] There is a wide literature on hand hygiene. Still, there is a lack of scientific evidence regarding the use of validated instruments to verify the self-efficacy of health professionals for assistance and performance.[10]

Self-efficacy is an important mediator between knowledge and behavior, and low self-efficacy can present difficulties in complying with recommendations.[12] It is essential to be evaluated, which becomes even more important in critical moments, like a pandemic. Self-efficacy may imply the behavior of the nursing professionals, as well as the quality of hand hygiene and use of gloves. Therefore, the present study considers the work conditions during the Covid-19 pandemic and the importance of self-efficacy in safety protocols. In view of the above, the objectives of the study were: a) to evaluate the frequency of nursing professionals who have self-efficacy in hand hygiene and use of gloves during the Covid-19 pandemic in the five regions of Brazil; b) to compare the self-efficacy total score among the regions; and c) to assess the association of sociodemographic characteristics of the participants with the level of self-efficacy.

METHODS

This is a retrospective observational study,[13] which used the Reporting of Observational Studies in Epidemiology (STROBE) and Checklist for Reporting Results of Internet E-Surveys (CHERRIES) checklist for its development.

The sample consisted of 493 nursing professionals (assistants, nursing technicians, and nurses) working in nursing care in five different regions of Brazil (South, Southeast, Midwest, North, and Northeast). Recruitment of participants took place online between November 2020 and December 2021 and was carried out voluntarily through social networks such as Facebook®, Instagram®, Linkedin®, and WhatsApp®. The researcher identified himself and presented details of the research, making a brief report of the objectives, risks,

and contributions to the performance of nursing practice. The invitation was posted weekly and had access to the five regions of Brazil.

The sample size was defined by convenience, being the maximum number of participants accepted to participate in the research in the thirteen months of recruitment. The sociodemographic characteristics of the participants are sex (male or female), age grouping (18 to 24; 25 to 29; 30 to 39; 40 to 49; 50 to 59 years old), education level (Elementary School, 3rd Cycle of Basic Education (9th year); High School or Secondary School; Graduate - Bachelor's; Postgraduate, Master's or Doctorate Degree), professional category (Nurse; Nursing technician; Nursing assistant), how many nursing work places (1 to 3), institution (General; University; District; Emergency Room; Long Stay Institution; Basic Health Unit; Home Care; Obstetrics; Paediatrics; Surgical Clinic; Outpatient), nature of institution (Public; Private; Public and Private), length of nursing experience (less than 1 year; between 1 to 2; between 3 to 4; between 5 to 6; between 7 to 8; between 9 to 10; between 11 to 15; between 16 to 20; between 21 to 30; over 31 years), and region of Brazil (South, Southeast, Midwest, North and Northeast).

The inclusion criteria were nursing professionals aged ≥ 18 years old who worked in care during the Covid-19 pandemic at the time of data collection. To create the structured form and the participant's responses, the free Google forms® tool was used. It should be noted that to avoid duplicate responses, it was necessary to record the e-mail address. The instrument used for data collection, entitled "Questionnaire of self-efficacy of health professionals for hand hygiene and use of gloves," was developed and validated by Pereira et al. (2022). It was used to measure health professionals' self-efficacy for hand hygiene and use of gloves. The self-efficacy questionnaire consists of 19 items, with a continuous response scale ranging from 0 to 100 points. The final score varies between 0 and 1900 points, with the highest score corresponding to greater self-efficacy.[15]

Two independent researchers double-checked and coded the results to reduce possible coding errors. In the descriptive stage, the categorical data were submitted to absolute (n) and relative (%) frequency analysis. The data normal distribution of the variable final score of the questionnaire was obtained using the Kolmogorov-Smirnov (total sample and for each region, except South, Midwest, and North) and Shapiro-Wilk (South, Midwest, and North regions) tests. The Kruskal-Wallis test was used to compare the final score among the regions. Arbitrarily, we set the cutoff points for having self-efficacy and not having self-efficacy at ≥ 1800 and ≤ 1790 points, respectively. We used the Chi-square or Fisher's exact test to assess the association between nurse professionals who have self-efficacy and those who do not have sociodemographic characteristics for the total sample and in each region. The data were analyzed using the Statistical Package for Social Sciences (SPSS), version 23, with the significance level set at $\alpha = 5\%$.

This research was approved by the Ethics and Research Committee of the University of São Paulo at Ribeirão Preto School of Nursing (CEP-EERP/USP), under CAAE n° 38623520.6.0000.5393, and followed the guidelines that regulate research involving Human Beings, according to Resolution CNS 466/12 of the National Health Council.[14]

RESULTS

The total sample consisted of 493 nursing professionals, of which 358 were nurses (72.5%), 374 (75.8%) were female, 105 (21.3%) aged between 18 and 24 years, and 249 (50.4%) had a postgraduate degree (master's and/or doctoral level). Notably, the majority worked in private hospitals, 245 (49.6%), while only 44 (8.9%) worked in general hospitals. As for the time of performance as a nursing professional, 118 (23.9%) had been performing nursing services for less than a year. About the country's five regions, our sample enrolled a greater number of participants in the Southeast region (82%) and a smaller number in the South region (5%). Still, the demographic results of all regions followed a similar pattern of frequency (Table 1).

Table 1. Distribution of participants (total and by region) according to sociodemographic characteristics. Brazil, 2022.

Variables	Total N (%)	South N (%)	Southeast N (%)	Midwest N (%)	North N (%)	Northeast N (%)
Sex						
Female	374 (75.8)	20 (80)	297 (74.6)	22 (78.6)	3 (60)	32 (86.5)
Male	119 (24.2)	5 (20)	101 (25.4)	6 (21.4)	2 (40)	5 (13.5)
Age Grouping						
18 to 24	105 (21.3)	7 (28)	89 (22.4)	3 (10.7)	1 (20)	5 (13,5)
25 to 29	109 (22.2)	5 (20)	82 (20.6)	10 (35.7)	0	12 (32.4)
30 to 39	157 (31.8)	7 (28)	127 (31.9)	11 (39.3)	1 (20)	11 (29.7)
40 to 49	100 (20.2)	5 (20)	85 (21.4)	3 (10.7)	2 (40)	5 (13.5)
50 to 59	22 (4.5)	1 (4)	15 (3.8)	1 (3.6)	1 (20)	4 (10.8)
Education Level						
Elementary School, 3rd Cycle of Basic Education (9th year)	2 (0.4)	0	2 (0.5)	0	0	0
High School or Secondary School	94 (19)	12 (48)	71 (17.8)	3 (10.7)	2 (40)	6 (1.2)
Higher Education, Bachelor's	148 (30)	3 (12)	128 (32.2)	7 (25)	1 (20)	9 (24.3)
Postgraduate, Master's or Doctorate Degree	249 (50.4)	10 (40)	197 (49.5)	18 (64.3)	2 (40)	22 (59.5)
Profession						
Nurse	358 (72.5)	10 (40)	291 (73.1)	24 (85.7)	2 (40)	31 (83.8)
Nursing technician	110 (22.3)	15 (60)	82 (20.6)	4 (14.3)	3 (60)	6 (16.2)
Nursing Assistant	25 (5.4)	0	25 (6.3)	0	0	0
In how many nursing workplaces						
1	392 (79.4)	20 (80)	318 (79.9)	22 (78.6)	5 (100)	27 (73)
2	81 (16.4)	4 (16)	66 (16.6)	5 (17.9)	0	6 (16.2)
3	20 (4)	1 (4)	14 (3.5)	1 (3.6)	0	4 (10.8)
Institution						
General	219 (44.3)	7 (28)	180 (45.2)	10 (35.7)	3 (60)	19 (51.4)
University	44 (8,9)	2 (8)	38 (9.5)	0	0	4 (10.8)
District	3 (0,6)	0	2 (0.5)	1(3,6)	0	0
Emergency Room	45 (9,1)	1 (4)	40 (10.1)	2 (7.1)	0	2 (5.4)
Long Stay Institution	24 (4,9)	2 (8)	18 (4.5)	2 (7.1)	0	2 (5.4)
Basic health Unit	29 (5.9)	4 (16)	16(4)	2 (7.1)	1 (20)	6 (16.2)
Home care	47 (9.5)	49 (16)	34 (8.5)	6 (21.4)	1 (20)	2 (5.4)
Obstetrics	11 (2.2)	3	6 (1.5)	1 (3.6)	0	1 (2.7)
Paediatrics	14 (2.8)	2	9 (2.3)	2 (7.1)	0	1 (2.7)
Surgical Clinic	25 (5.1)	0	24 (6)	1 (3.6)	0	0
Outpatient	32 (6.5)	0	31 (7.8)	1 (3.6)	0	0
Nature of the institution						
Public	195 (39.5)	9 (36)	156 (39.2)	8 (28.6)	3 (60)	19 (51.4)
Private	245 (49.6)	9 (36)	204 (51.3)	17 (60.7)	2 (40)	13 (35.1)
Public, private	53 (10.7)	7 (28)	38 (9.5)	3 (10.7)	0	5 (13.5)
How long have you been performing nursing services?						
Less than 1 year	118 (23.9)	1 (4)	95 (23.9)	9 (32.1)	1 (20)	12 (32.4)
Between 1 to 2 years	75 (15.2)	4 (16)	61 (15.3)	4 (14.3)	0	6 (16.2)
Between 3 to 4 years	60 (12.1)	6 (24)	44 (11.1)	7 (25)	0	3 (8.1)
Between 5 to 6 years	34 (6.9)	2 (8)	29 (7.3)	0	0	3 (8.1)
Between 7 to 8 years	34 (6.9)	2 (8)	27 (6.8)	3 (10.7)	0	2 (5.4)
Between 9 to 10 years	43 (8.7)	1 (4)	38 (9.5)	2 (7.1)	0	1 (2.7)
Between 11 to 15 years	45 (9.1)	5 (20)	35 (8.8)	1 (3.6)	1 (20)	3 (8.1)
Between 16 to 20 years	42 (8.5)	3 (12)	36 (9)	0	2 (40)	1 (2.7)
Between 21 to 30 years	40 (8.1)	1 (4)	31 (7.8)	2 (7.1)	0	6 (16.2)
Over 31 years	2 (0.4)	0	2 (0.4)	0	0	0

We observed the frequency of nursing professionals who have self-efficacy. For the total sample, 60.4% of nursing professionals have self-efficacy. In all regions, the frequency was higher than 50% (Figure 1).

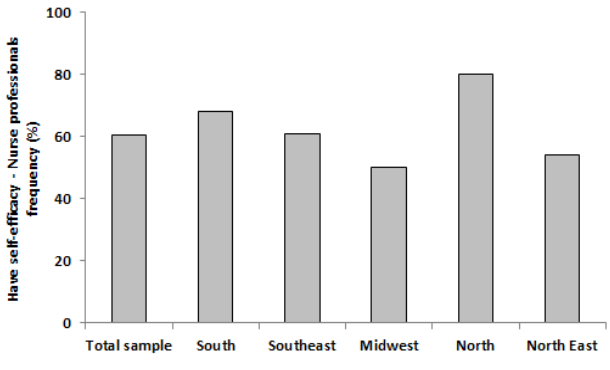

Figure 1. Frequency of nurse professionals who have self-efficacy in the total sample and from the five regions of Brazil. Brazil, 2022.

The comparison of the total self-efficacy score (median values, p 25th and p 75th) among nursing professionals from the five regions of Brazil. As our data (specifically self-efficacy) did not show a normal distribution, and after the Kruskal-Wallis test, we did not observe a statistically significant difference in the total self-efficacy score among nursing professionals from the five regions (H = 2.626; p = 0.622) (Figure 2).

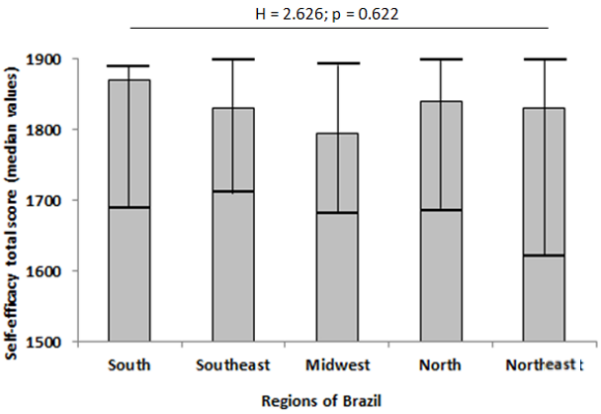

Figure 2. Comparison of self-efficacy total score among nurse professionals from the five regions of Brazil. Brazil, 2022.

In the appendix, the table describes the frequency of responses for each question to the Self-Efficacy Questionnaire of nursing professionals about hand hygiene and the use of gloves in the total sample and the five regions of the country. We observed that the frequency of answers for the scale/score "10 – very confident" was higher in all questions.

We did not find an association between nurse professionals who have or do not have self-efficacy (≥ 1800 and ≤ 1790 points, respectively) and sociodemographic characteristics in the total sample and for each region ($p > 0.05$).

DISCUSSION

In the study, we noted that the developmental element of self-efficacy can play an important role in adherence to hand hygiene; that is, the experience of high self-efficacy determines adherence. Most (60%) of the nurse professionals in our study demonstrated a high level of self-efficacy; no differences were found for the self-efficacy total score among the regions, and no association was found between this result and the sociodemographic characteristics. Among the nursing professionals included in the study, nurses between 30 and 39 years old with a postgraduate degree were predominant. This result aligns with the literature, as nurses found high self-efficacy levels. At the same time, other professionals on the team, nursing technicians and assistants, and midwives showed lower levels, showing that studies increase adherence to hand hygiene and the use of gloves.[15]

The study demonstrates that health professionals understand different levels of self-efficacy corresponding to their own conclusions about their capacities. The adherence of health professionals to hand hygiene practices can be low, even in the face of quality infrastructure and supplies. Self-efficacy needs both abilities and individual and institutional attempts to increase the potentiality to exercise specific conduct, which is an important facilitator between understanding and comportment.[10]

The experience of persons has a positive effect on self-efficacy. In addition, health professionals' knowledge is one of the main factors in individual security and containment of Covid-19. A study supports the positive mediating effect of Covid-19 associated with health professionals' knowledge related to self-efficacy.[16] This study reveals that health professionals who contributed to instruction on managing Covid-19 had much greater self-efficacy than their inexperienced colleagues.

A study conducted before the pandemic showed low adherence by health professionals to recommendations for hand hygiene, the use of gloves and aprons, engagement in activities with a higher risk of transmitting infection, and a high workload.[17,18,19,21] During the pandemic, hand hygiene was emphasized, which may have resulted in higher compliance rates. However, 11 (2.2%) nursing professionals showed a disincentive to perform hand hygiene due to the time this practice requires. It is possible that when feeling discouraged, these nurses omit or improperly perform hand hygiene, which implies low self-efficacy.[10]

Nurses provide direct assistance to patients for the duration of their illness, are involved in improving the quality of care and patient safety, and are positively at the van of interventions related to hand hygiene. As much as the practice of hand hygiene is an easy behavior, the defiance of routine application lies in the complication involved in this procedure. In this context, using multimodal strategies to improve adherence is not sufficient. Approaches should be part of the practice of health professionals, with continuous supervising and assessment. In addition, the challenges that health organizations face about the convenience of inputs and staff dimensioning are highlighted. Self-efficacy of health professionals represents a health management tool useful to identifying gaps in knowledge, skills and engagement in carrying out good health practices. Hand hygiene is crucial in the management of infection control. This study showed hand hygiene as one of the best means to contain contamination during the Covid-19 pandemic.[10] It is important to emphasize that the concern with infectious diseases must be constant. During post-pandemic periods, health professionals and the entire community must be encouraged to practice good hand hygiene. It is worth noting that the hygiene

measures due to Covid-19 have decreased the frequency of infections.[20]

There is a stringent need for future investigations established by constructing and validating instruments for measuring self-efficacy in various communities of health professionals despite the difficulty of measuring such constructs.[8] Thus, it will be likely to design interventions with intellectual, behavioural, educational and institutional resources. Some limitations were due to the cross-sectional study design, which does not allow monitoring of the subjects. Additionally, data was self-reported through an online survey instrument, which may have affected the heterogeneity in the recognition of the regions. Highlighting that, although the sample is not representative, it offers an initial insight into how these aspects may be reflected in different regions and states. This suggests the need to conduct similar studies with more comprehensive and representative samples in this context. The results of this study encourage the evaluation of behaviours, attitudes and responsibilities of health professionals in the management of infectious disease transmission. Completely even though hand hygiene is an easy attitude, the challenge to enhancing adherence levels lies in the difficulty of creating this procedure procedure. In this context, using certain multimodal strategies to improve adherence is insufficient. Strategies to enhance adherence to hand hygiene and the use of gloves should be components of the practice of health professionals, with constant checking and evaluation.

We concluded that most nursing professionals have high self-efficacy and use of gloves. No differences were observed about self-efficacy total score among the regions of Brazil. Additionally, no association was found between self-efficacy and sociodemographic characteristics. This insight acquired during the Covid-19 pandemic represents a health management tool, useful to identify gaps in knowledge, ability and engagement in managing infection control.

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AUTHORS' CONTRIBUTIONS

Daniella Corrêa Cordeiro contributed to project administration, literature search, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review, statistics, and final approval of the version to be published. **Jéssica Fernanda Corrêa Cordeiro** contributed to project administration, literature search, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review, statistics and final approval of the version to be published. **Ludmila Albano de Felice Gomes** contributed to the literature search, abstract writing, discussion, interpretation and description of results, conclusions, review, and final approval of the version to be published. **Tatiana Areas da Cruz** contributed to project administration, review, and final approval of the version to be published. **Marilia Duarte Valim** contributed to project administration, review and final approval of the version to be published. Denise de Andrade contributed to project administration and supervision, interpretation of results, review, and final approval of the version to be published. **André Pereira dos Santos** contributed to the project administration, bibliographic research, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review, statistics, and final approval of the version to be published.

All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Cordeiro DC, Cordeiro JFC, Gomes LAF, da Cruz TA, Valim MD, de Andrade D, dos Santos AP. Self-efficacy in hand hygiene and glove use among nurses during the COVID-19 pandemic. Rev Epidemiol Control Infect [Internet]. 2025 Mar.4; 15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19372

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Hand hygiene and mask use during the Covid-19 pandemic: analysis of agreement among primary care professionals

Higienização das mãos e uso de máscara na pandemia de Covid-19: análise de concordância entre profissionais da atenção primária

Higiene de manos y uso de mascarilla durante la pandemia de Covid-19: análisis de acuerdo entre profesionales de atención primaria

Site doi: https://doi.org/10.17058/reci.v15i1.19366

Submitted: 04/21/2024
Accepted: 11/22/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objective: the Covid-19 virus is transmitted through direct or indirect contact with respiratory droplets or secretions from infected individuals. Measures such as hand hygiene and mask use are effective in preventing and controlling Covid-19 infection. The objective is to analyze the agreement on correct hand hygiene and the appropriate use of surgical masks among Primary Health Care professionals during Covid-19. **Methods:** a cross-sectional study conducted in Brazil, in a virtual environment, between August 2020 and March 2021. To respond to the research objective, 29 physicians, 29 nurses and 29 nursing technicians participated. The validated instrument "EPI-APS Covid-19" was used for data collection. The agreement analysis of the responses was performed in the Statistical Package for the Social Sciences using the Kappa coefficient. **Results:** the frequency of correct hand hygiene and mask use was low among professionals. Nursing technicians were the ones who showed the highest frequency of correct hand hygiene and adequate use of surgical mask compared to nurses and physicians. There was fair agreement between nurses and physicians regarding hand hygiene. There was substantial agreement between nurses and nursing technicians and between nurses and physicians, and moderate agreement between nursing technicians and physicians regarding mask use. **Conclusion:** the results highlight the need to implement and strengthen actions related to best hand hygiene practices and mask use by Primary Health Care professionals.

Keywords: *Covid-19. Primary Health Care. Hand Desinfection. Personal Protective Equipment. Severe Acute Respiratory Syndrome Coronavirus 2.*

RESUMO

Justificativa e Objetivo: a transmissão do vírus da Covid-19 se dá por contato direto ou indireto com gotículas respiratórias ou secreções de indivíduos infectados. Medidas como higienização das mãos e uso de máscaras são efetivas na prevenção e controle de infecção por Covid-19. Tem-se como objetivo analisar a concordância da higienização correta das mãos e do uso adequado de máscaras cirúrgicas entre profissionais da Atenção Primária à Saúde durante a Covid-19. **Métodos:** estudo transversal, realizado no Brasil, em ambiente virtual, entre agosto de 2020 e março de 2021. Para responder ao objetivo da pesquisa, participaram 29 médicos, 29 enfermeiros e 29 técnicos de enfermagem. Utilizou-se o instrumento validado "EPI-APS Covid-19" para a coleta de dados. A análise de concordância das respostas foi realizada no *Statistical Package for the Social Sciences* por meio do coeficiente Kappa. **Resultados:** a frequência de higienização correta das mãos e uso de máscara foi baixa entre os profissionais. Os técnicos de enfermagem foram os que apresentaram maior frequência de higienização correta das mãos e uso adequado de máscara cirúrgica em comparação aos enfermeiros e médicos. Houve concordância regular entre os enfermeiros e médicos em relação à higienização das mãos. Houve concordância substancial entre enfermeiros e técnicos de enfermagem e entre enfermeiros e médicos, e moderada entre técnicos de enfermagem e médicos em relação ao uso de máscara. **Conclusão:** os resultados evidenciam a necessidade de implementação e fortalecimento de ações relacionadas a melhores práticas de higienização das mãos e uso de máscara pelos profissionais da Atenção Primária à Saúde.

Descritores: *Covid-19. Atenção Primária à Saúde. Higienização das Mãos. Equipamento de Proteção Individual. Coronavírus da Síndrome Respiratória Aguda Grave 2.*

RESUMEN

Justificación y Objetivo: el virus Covid-19 se transmite por contacto directo o indirecto con gotitas o secreciones respiratorias de personas infectadas. Medidas como la higiene de manos y el uso de mascarillas son efectivas para prevenir y controlar la infección por Covid-19. El objetivo es analizar el acuerdo sobre la correcta higiene de manos y el uso adecuado de mascarillas quirúrgicas entre los profesionales de Atención Primaria de Salud durante la Covid-19. **Métodos:** estudio transversal, realizado en Brasil, en ambiente virtual, entre agosto de 2020 y marzo de 2021. Para responder al objetivo de la investigación, participaron 29 médicos, 29 enfermeros y 29 técnicos de enfermería. Para la recolección de datos se utilizó el instrumento validado "EPI-APS Covid-19". El análisis de concordancia de las respuestas se realizó en el *Statistical Package for the Social Sciences* utilizando el coeficiente Kappa. **Resultados:** la frecuencia de correcta higiene de manos y uso de mascarilla fue baja entre los profesionales. Los técnicos de enfermería fueron quienes mostraron una mayor frecuencia de correcta higiene de manos y uso adecuado de mascarillas quirúrgicas en comparación con enfermeras y médicos. Hubo un acuerdo regular entre enfermeras y médicos sobre la higiene de manos. Hubo acuerdo sustancial entre enfermeras y técnicos de enfermería y entre enfermeras y médicos, y acuerdo moderado entre técnicos de enfermería y médicos respecto al uso de mascarilla. **Conclusión:** los resultados resaltan la necesidad de implementar y fortalecer acciones relacionadas con las mejores prácticas de higiene de manos y uso de mascarillas por parte de los profesionales de la Atención Primaria de Salud.

Palabras Clave: *Covid-19. Atención Primaria de Salud. Desinfección de las Manos. Equipo de protección Personal. Síndrome Respiratorio Agudo Severo Coronavirus 2.*

INTRODUCTION

The modes of transmission of SARS-CoV-2 (Severe Acute Respiratory Syndrome-Coronavirus-2) occur through contact with contaminated surfaces and/or people, droplets, aerosols and bodily fluids.[1] In this pandemic context, healthcare professionals, when providing direct care to suspected and confirmed patients,[2] need to adhere to personal protective equipment (PPE) use, such as surgical masks and hand hygiene (HH).[3] Standard precautions (SP) are fundamental measures for the safety of healthcare professionals, and should be used in care and assistance of all patients.[4]

According to the Brazilian National Health Regulatory Agency and the Pan American Health Organization, HH is an essential action for the prevention of all healthcare-associated infections (HAIs), including Covid-19.[4,5,6] HH is considered one of the most effective practices in preventing and controlling infection, as it aims to eliminate transient microbiota.[7] However, a study showed that HH is neglected by health workers in developed and developing countries, where the compliance rate for this measure was less than 20%.[8] Low adherence to HH is due to the culture of non-hygiene at all times during care.[9,10]

Surgical mask use during the Covid-19 pandemic, since they are effective in reducing contamination,[11,12] was recommended for carrying out procedures that generate droplets, in order to guarantee the protection and safety of professionals and users.[3] However, this PPE quickly loses its effectiveness (around four hours) due to humidity.[13] Furthermore, the incorrect use of PPE is still a worrying reality in healthcare services, compromising the safety and effectiveness of protective measures.[9]

Considering the above, in order to combat Covid-19, it was necessary to reinforce awareness among all professional categories regarding HH and surgical mask use to ensure adherence to these practices by the team, in order to minimize the risk of illness.[3,7,9] Therefore, the study aimed to analyze the agreement on correct HH and the adequate use of surgical masks among Primary Health Care (PHC) professionals during Covid-19.

METHODS

This is a cross-sectional study carried out in all PHC units in Brazil between August 2020 and March 2021. This study is linked to the research "*Uso de Equipamentos de Proteção Individual pelos profissionais de saúde no combate a Covid-19 – EPICOVID-19 Brasil*". The presentation of results followed the STrengthening the Reporting of OBservational studies in Epidemiology and CHEcklist for Reporting Results of Internet E-Surveys guidelines.

For the present study, the target population was all professionals in PHC units in Brazil (dentist, nurse, physiotherapist, speech therapist, nutritionist, pharmacist, social worker, psychologist, nursing assistant, nursing technician, physician, community worker, receptionist, technical administrative assistant, oral health technician and public health agent).[14]

The research was conducted in a virtual environment, using the free KoboToolbox platform. Various means of communication were used for dissemination, such as email, telephone contact and social media.[14] After accepting the Informed Consent Form, access to the questionnaire was made available online.

For this study, only physicians, nurses, and nursing technicians were included. At the end of data collection, 29 physicians, 57 nurses, and 29 nursing technicians participated. To compose the sample for this study, the number of physicians and nursing technicians determined the sample size of nursing professionals. The 29 nurses selected were randomly selected through an online draw among those who voluntarily agreed to participate in the research.

For data collection, the validated instrument EPI-APS Covid-19 was used. The questions related to PPE use were organized into eight domains after psychometric validation and exploratory factor analysis, namely: 1 - disposable cap or hat; 2 - gloves; 3 - behavior and safety; 4 - N95 mask; 5 - HH; 6 - disposable apron or gown; 7 - disposable surgical mask; and 8 - glasses or personal protective mask.[15]

Domains 5 and 7 were used in this study, and their respective questions were: how often do you sanitize your hands before touching a user? How often do you sanitize your hands after risk of exposure to bodily fluids (e.g., saliva, phlegm, blood, urine)? How often do you sanitize your hands after touching a user? How often do you sanitize your hands after touching environments/surfaces/surroundings close to the user? In the last six months, how often have you reused a disposable mask in the PHC service where you work? Do you place the mask carefully to cover your mouth and nose, minimizing gaps between your face and the mask as much as possible? Do you remove the mask using the appropriate technique (i.e., not touching the front, but removing the tie or knot at the back, or pulling on the elastic that sits over the ears)?

The items were answered using a four-point Likert scale "never", "rarely", "almost always" and "always", which were recoded dichotomously to define the score, namely: "no" (assigned the value of 0 points) for "never", "rarely" and "almost always"; and "yes" (assigned the value of 1 point) for "always". Correct HH and adequate use of surgical masks were considered to be the achievement of all points assessed in each domain, i.e., four points in the HH domain and three points in the disposable surgical mask domain.

After collection, the data were exported to Microsoft Office Excel® for database assessment and organization and, later, to the Statistical Package for the Social Sciences® version 21.0 for statistical analysis.

The Kappa coefficient was used to assess the agreement on the proper use of surgical masks and correct HH between physicians, nurses, and nursing technicians working in PHC. The agreement on the responses to items and domains was analyzed. The following parameters were considered to interpret the results: values above 0.80, almost perfect agreement; between 0.61 and 0.80, substantial agreement; between 0.41 and 0.60, moderate agreement; between 0.21 and 0.40, regular agreement; and below 0.21, slight agreement.[16]

The research was approved by the *Universidade Federal de Juiz de Fora* Research Ethics Committee on May 25, 2022, under Opinion 5.429.839, in accordance with Resolution 466/12, and Certificate of Presentation for Ethical Consideration 30933220.7.0000.5147, in 2020.

RESULTS

A total of 87 professionals participated in the study, including 29 nurses, 29 nursing technicians and 29 physicians. The mean age observed was 37.08 years, with a standard deviation of ± 9.9, with the predominant age range being 19 to 36 years (49; 56.3%). Females were more prevalent (70; 80.5%). Most participants reported having a partner (54; 62.1%), and the Southeast region was predominant among participants (57; 65.5%) (data not shown in the table).

The frequency of correct HH and the appropriate use of surgical masks were low among professionals. Nursing technicians were those who presented a higher frequency of correct HH and appropriate use of surgical masks compared to nurses and physicians (Table 1).

Table 1. Frequency of correct hand hygiene and adequate use of surgical masks between nurses, nursing technicians and physicians in all federative units of Brazil, 2021.

Domain	Nurses N (%)	Nursing technicians N (%)	Physicians N (%)
Hand hygiene			
Yes	11 (37.9)	15 (51.7)	9 (31.0)
No	18 (62.1)	14 (48.3)	20 (69.0)
Total	29 (100%)	29 (100%)	29 (100%)
Surgical mask			
Yes	3 (11.5%)	18 (78.3)	8 (36.4)
No	23 (88.5)	5 (21.7)	14 (63.6)
Total	26 (100%)	23 (100%)	22 (100%)

Agreement between nurses, nursing technicians and physicians regarding the HH and mask use domains was verified using the Kappa coefficient. The aim was to understand whether there was agreement on the best practices reported by participants in this study, with the achievement of the total number of points being assessed in each domain. Regarding the HH domain, fair and significant agreement was identified between nurses and physicians (Kappa = 0.39; p=0.03) (Table 2). Considering that HH is an essential measure for controlling HAIs, the moderate agreement indicates the need for interventions in order to improve adherence to HH among healthcare professionals.

Table 2. Agreement analysis related to the hand hygiene domain between nurses, physicians and nursing technicians (n=29) in all federative units of Brazil, 2021.

	Professional category		Hand hygiene domain: Physicians Yes	Physicians No	Nursing technicians Yes	Nursing technicians No
Hand hygiene domain	Nurses	Yes	6	5	7	4
		No	3	15	7	11
		Kappa (p)	0.39 (0.03)		0.24 (0.20)	
	Nursing technicians	Yes	5	9	-	-
		No	4	11	-	-
		Kappa (p)	0.09 (0.60)		-	

Agreement related to the mask use domain between nurses and nursing technicians was substantial (Kappa = 0.83; p<0.0001), and between nurses and physicians (Kappa = 0.49; p=0.01) and nursing technicians and physicians was moderate (Kappa = 0.43; p=0.05) (Table 3). The findings of this analysis show a more uniform behavior of adherence to mask use among nursing team professionals. Mask use during the Covid-19 pandemic was an essential measure to ensure the safety of workers in the care context. The almost perfect agreement among nursing team professionals indicates the concern of workers with their own safety and the provision of safe and quality care.

Table 3. Agreement analysis related to the domain use of surgical masks between nurses, physicians and nursing technicians (n=29) in all federative units of Brazil, 2021.

	Professional category		Surgical mask domain: Physician Yes	Physician No	Nursing technician Yes	Nursing technician No
Surgical mask use domain	Nurse	Yes	3	0	3	0
		No	4	13	1	16
		Kappa (p)	0.49 (0.01)		0.83 (<0.001)	
	Nursing technician	Yes	4	1	-	-
		No	4	10	-	-
		Kappa (p)	0.43 (0.05)		-	

Regarding the agreement between the answers to the questions that make up the HH domain, agreement was only evidenced for "How often do you sanitize your hands before touching a user?", being almost perfect between nurses and physicians (Kappa = 0.92; p<0.0001), and moderate between nurses and nursing technicians (Kappa = 0.53; p=0.001) and between nursing technicians and physicians (Kappa = 0.59; p<0.0001). HH before contacting a user confirms healthcare professionals' concern in providing safe and qualified care in the context of the Covid-19 pandemic. In relation to the agreement among the answers that

make up the surgical mask domain between nurses, physicians and nursing technicians, no significant results were found.

DISCUSSION

This study presents an analysis of the agreement on correct HH and the appropriate use of surgical masks between physicians, nurses, and nursing technicians who worked in PHC services during Covid-19. Therefore, given the risk of contamination between professionals and those who provide care in PHC,[3] adherence to SP by all during care is essential.[4,18]

In a Chinese study carried out in 2020, physicians and nurses who treated patients with Covid-19 were assessed, and physicians were found to have a higher risk of infection due to their longer contact with patients.[19] In research carried out in Brazil on the profile of deaths among healthcare professionals, the medical category surpassed the category of nurses, technicians and assistants.[20]

The study revealed that nursing technicians reported a higher frequency of HH and mask use compared to physicians and nurses. These results support data from a cross-sectional study conducted in Brazil in 2022, in a private hospital, which analyzed the team's adherence to HH practice. The categories of the aforementioned study also included nursing technicians, nurses, and physicians. Higher adherence was reported by nurses, and physicians had lower adherence.[9]

It is noteworthy that, although nurses and nursing technicians are part of the same professional category, the greater frequency of HH and mask use by nursing technicians may be related to the greater performance of procedures involving blood and other body fluids by this group of professionals, since, due to their role as team leaders, nurses are more focused on supervising these activities.[21]

Low adherence to HH by healthcare professionals may be linked to several factors, such as work overload, skin irritation, infrastructure, replacement of HH by gloves, knowledge gaps, forgetfulness and lack of supplies,[9] and may also be attributed to the lack of incentive from managers to practice HH.[9] Therefore, it is necessary to implement actions for professionals, in order to remedy deficiencies with regard to HH.[9]

In a literature review carried out in 2021, which verified adherence to HH by healthcare professionals, it was observed that medical professionals and nurses performed HH more frequently during the pandemic period, mainly after assisting patients.[22] In this same study, nursing technicians were less adept at this practice. This situation is a warning, since these professionals deal with these patients in a comprehensive manner and for a longer period of time. When observing professionals as a whole, the frequency of HH increased during the pandemic. Therefore, it is essential to promote educational activities in order to encourage practice.[22]

In this scenario, HH and mask use help reduce contamination by Covid-19 and also contribute to the prevention of HAIs.[3,9,11] For this to happen, it is essential that such practices are followed by everyone.[4] Mask use can promote collective and personal protection in the fight against the pandemic and other infectious diseases.[12]

In this study, the appropriate use of masks was higher among nursing technicians. In a study conducted in Brazil on mask use among healthcare professionals, nursing technicians obtained a higher score than nurses regarding mask use.[23] This result may be linked to the fact that nursing technicians provide direct care to patients, thus spending a long time close to them. This result shows that mask use is valued by this category.[23] However, guidance on the proper use and handling of masks should be provided to all healthcare workers.[20]

When it comes to the medical category in this study, they had less adherence to the use of this PPE. In a cross-sectional study carried out in Brazil with medical professionals, nurses and nursing technicians, mask use was attributed mainly to the perception of the severity of the disease, but also to the perception of protection of this PPE against infection.[11] Therefore, masks are effective physical barriers in limiting short-range transmission through direct or indirect contact and droplet dispersion.[11] According to Technical Note 04/20, updated on 03/31/2023, from the Brazilian National Health Regulatory Agency, mask use is recommended by all professionals in healthcare services. Furthermore, the note describes that masks should be used in contact with patients who are positive or suspected of having Covid-19 and in all situations in which the use of this PPE is necessary.[3]

The research has limitations related mainly to the low number of participants, which may have been influenced by the fact that data collection was carried out virtually, despite all efforts to ensure methodological rigor.[14] Regarding data collection in virtual format, it is pertinent to mention the possibility that participants provided answers that do not reflect what actually happens in their daily work routine.

Despite this, the study presents relevant contributions to scientific knowledge in health and nursing. Among them, it is worth noting the agreement between the professional categories of nursing technicians, nurses, and physicians who reported HH and mask use during the Covid-19 pandemic. Moreover, the results highlighted the need to strengthen SP use in the service as well as promote HH and mask use at all times of care to prevent HAIs. Furthermore, there is a need for health courses to reinforce teaching on PPE use and HH, with

greater awareness of these actions among medical students.

Therefore, it is recommended that professionals adopt ongoing education on the risks inherent to HAIs, in order to increase adherence and implementation of training activities on HH and mask use for different professional categories.

Thus, the study showed that, among the participating professionals, physicians and nurses were those who presented the lowest frequency of correct HH, as well as not using masks correctly and that the category with the best adherence to SP were nursing technicians.

It is important to reiterate that the recommendations for adherence to mask use and the performance of HH must be followed in the health sector by all professional categories and that promotion and strategies at all levels of healthcare are essential in order to guarantee the safety of professionals and users. It is suggested that new research be developed with a quantitative and qualitative approach on adherence to HH and the appropriate use of masks in different professional categories in the health context, with the aim of contributing to adherence of practices to prevent HAIs.

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AUTHORS' CONTRIBUTIONS

Kelly Aline Rodrigues Costa contributed to bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Ana Paula Mendes Carvalho** contributed to abstract writing, methodology, interpretation of results, conclusions, review and statistics. **Camila Cristina Gregório de Assis** contributed to abstract writing, methodology, interpretation of results, conclusions, review and statistics. **Herica Silva Dutra** contributed to project management, bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, conclusions, review and statistics. **Fernanda Moura Lanza** contributed to project management, bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, conclusions, review and statistics. **Angélica da Conceição Oliveira Coelho** contributed to project administration, fund acquisition, literature search, abstract writing, introduction, methodology, discussion, interpretation and description of results, conclusions, review, and statistics.

All authors have approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Costa KAR, Carvalho APM, Assis CCG, Dutra HS, Lanza FM, Coelho ACO. Hand hygiene and use of a mask: analysis of agreement among primary care professionals . Rev Epidemiol Control Infect [Internet]. 2025 Feb. 16;15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19366

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

RECI Revista de Epidemiologia e Controle de Infecção

ISSN 2238-3360

Original Article

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Prevalência do anticorpo para Hepatite C e comportamentos de risco em usuários de Unidades Básicas de Saúde de uma pequena cidade do Semiárido brasileiro

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Site doi: https://doi.org/10.17058/reci.v15i1.19314

Submitted: 04/11/2024
Accepted: 10/18/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: Hepatitis C virus (HCV) infection is a relevant public health problem due to its prevalence and possible progression to cirrhosis and hepatocellular carcinoma. Although the use of direct-acting antivirals has decreased the incidence in recent years, identifying those infected remains a challenge for the elimination of HCV by 2030. The objective of this study was to estimate the prevalence of HCV antibody (anti-HCV), and describe the sociodemographic and behavioral risk factors associated with HCV infection in individuals in a small town in the Brazilian semi-arid region. **Methods:** Following a non-random sampling procedure, a cross-sectional study of 800 individuals in the waiting rooms of Basic Health Units (BHU) was conducted. After formal consent, a rapid screen test for anti-HCV (Immunochromatography)was carried out, and a questionnaire was applied to collect sociodemographic, clinical and risk behavior data. **Results:** Five tests were positive (0.62%; 95%CI 0.2 – 1.4%), four women and one man. All were over 60 years old (mean age of 69.4) and some risk behaviors in the past, use of glass syringes, surgery, or blood transfusion, were statistically associated with HCV exposure. **Conclusion:** In this study, a low prevalence of anti-HCV was observed, close to that estimated in recent studies. The antibody was more frequently positive in older individuals, aged over 60 years, who reported risky past behavior. Greater attention should be given to these individuals.

Keywords: *Hepatitis C Antibody. Basic Health Care. Outpatient. Prevalence. Risk behaviors.*

RESUMO

Justificativa e Objetivos: A infecção pelo vírus da hepatite C (HCV) é um relevante problema de saúde pública devido à sua prevalência e possível progressão para cirrose e carcinoma hepatocelular. Mesmo com a diminuição da incidência nos últimos anos, devido ao uso dos novos antivirais, a identificação dos infectados continua sendo um desafio para a eliminação do HCV até 2030. O objetivo deste estudo foi estimar a prevalência do anticorpo contra o HCV (anti-HCV) e descrever os fatores sociodemográficos e comportamentais de risco associados à infecção pelo HCV em indivíduos em uma pequena cidade no semiárido brasileiro. **Métodos:** Após procedimento de amostragem não aleatória, um estudo transversal foi realizado com 800 indivíduos em salas de espera de Unidades Básicas de Saúde (UBS). Após consentimento formal, foi realizado teste rápido de triagem para o anti-HCV (imunocromatografia) e aplicado questionário para coleta de dados sociodemográficos, clínicos e de comportamento de risco. **Resultados:** Cinco testes foram positivos (0,62%, IC95% 0,2 – 1,4%), sendo quatro mulheres e um homem. Todos tinham mais de 60 anos (média de 69,4 anos) e comportamentos de risco no passado, uso de seringas de vidro, cirurgia ou transfusão de sangue, os quais foram estatisticamente associadas à exposição ao HCV. **Conclusão:** Neste estudo, observou-se baixa prevalência do anti-HCV, próxima às estimativas em estudos recentes. O anticorpo foi mais frequentemente positivo nos indivíduos mais velhos, acima de 60 anos, e que relataram comportamento de risco no passado, sugerindo a necessidade de maior atenção para esta população.

Descritores: *Anticorpo para hepatite C, Atenção Primária, Unidades Básicas de Saúde, Prevalência, Comportamento de risco.*

RESUMEN

Justificativa y Objetivos: La infección por el virus de la hepatitis C (VHC) es un problema relevante de salud pública debido a su prevalencia y posible progresión a cirrosis y carcinoma hepatocelular. Aunque el uso de antivirales de acción directa ha disminuido la incidencia en los últimos años, la identificación de los infectados sigue siendo un desafío para la eliminación del VHC en 2030. El objetivo de este estudio fue estimar la prevalencia de anticuerpos contra el VHC (anti-VHC) y describir los factores de riesgo sociodemográficos y comportamentales asociados a la infección por VHC en individuos de una pequeña ciudad (Arcoverde) de la región semiárida brasileña. **Método:** Después de un procedimiento de muestreo no aleatorio, se realizó un estudio transversal con 800 individuos en salas de espera de las Unidades Básicas de Salud (UBS). Después del consentimiento formal, se realizó una prueba rápida de tamizaje anti-VHC (inmunocromatografía) y se aplicó un cuestionario para recoger datos sociodemográficos, clínicos y de conductas de riesgo. **Resultados:** Cinco pruebas fueron positivas (0,62%, IC95% 0,2 – 1,4%), cuatro mujeres y un hombre. Todos tenían más de 60 años (edad media de 69,4 años) y algunas conductas de riesgo en el pasado, uso de jeringas de vidrio, cirugía o transfusión de sangre, se asociaron estadísticamente con la exposición al VHC. **Conclusión:** En este estudio se observó una baja prevalencia de anti-VHC, cercana a la estimada en estudios recientes. El anticuerpo fue más frecuentemente positivo en las personas mayores de 60 años que reportaron conductas de riesgo en el pasado. Se debe prestar mayor atención a estos individuos.

Palabras Clave: *Anticuerpos contra la hepatitis C. Atención Primaria de Salud. Centro de Salud. Prevalencia. Conductas de riesgo.*

INTRODUCTION

Hepatitis C virus (HCV) infection is a relevant public health problem, as it is one of the main causes of cirrhosis and hepatocellular carcinoma in the world.[1-3] The occurrence of HCV has been declining in recent years, with an estimated global prevalence of around 0.7% of the world's population, corresponding to approximately 50 million people infected with HCV in 2022. However, only 20% of them are aware of their condition.[1-3] The use of direct-acting antivirals since 2014 has certainly revolutionized hepatitis C treatment by providing high cure rates, few side effects and reducing the occurrence of this infection in recent years.[1-3]

Although prevalence studies are still scarce, Brazil is currently considered a country of low endemicity for HCV infection.[4] Most research on the prevalence of viral hepatitis B and C conducted in Brazil have evaluated viral markers in blood donors or addressed specific groups at greater contamination risk, such as chronic kidney disease patients on hemodialysis, sex workers and the penitentiary population, for example.[5-9]

The first broader Brazilian study on the prevalence of viral hepatitis in the general population was conducted in São Paulo city around 25 years ago, involving 1,059 individuals. The prevalence of anti-HCV was 1.42%, with an increase *pari passu* with age progression, reaching 3.8% in individuals between 50 and 59 years old.[10] Subsequently, the HCV infection rate of 1.38% was described in a study carried out in the late 2000s in the set of capitals of each macro-region of Brazil and in the Federal District.[11]

Data from the literature on the prevalence and risk factors involved in HCV transmission, especially in small cities in more remote regions, need to be better elucidated. Additionally, Brazil is one of the signatory countries of the World Health Organization (WHO) targets to eliminate viral hepatitis by the year 2030.[4] The WHO has launched a proposal to reduce new infections by hepatotropic viruses by 60% and the mortality related to them by 95% in the next few years.[12] The Brazilian Hepatitis C Elimination Plan involving Tripartite Commission (represented by the Brazilian Federal, State, and Municipal governments) was approved in October 2017, and aims to achieve this goal by expanding access to prevention, diagnosis, and treatment of HCV.[4,13]

Given this scenario, the aim of this study is to estimate the prevalence of antibodies against HCV in users of Basic Health Units in a small town (Arcoverde city) in the Brazilian semi-arid region, describing the sociodemographic profile and risk behaviors.

METHODS

This is a cross-sectional study of 800 adult outpatients of both genders conducted between July 2022 and March 2023. Participants were selected in a non-probabilistic way by slice through voluntary agreement. A slice was established for each of the Basic Health Units of 80 individuals in 10 different basic health units in a way that encompassed all areas of the urban region of Arcoverde city.

The municipality of Arcoverde occupies a total area of 344 km^2, with an urban area covering 13.4 km^2. This town has a population of 77,586 inhabitants, of which approximately 90% live in urban areas. It is considered a small town located in the semi-arid region in the state of Pernambuco, Northeast Brazil. Twenty-three out of its 25 Basic Health Units are in the urban area and two in the rural area.[14] Ten units located in the urban area were chosen to carry out the study, according to the distribution of the units by neighborhoods in order to cover all regions of the urban center. As the municipality does not have a map with the spatial distribution of each unit, an image taken from Google Maps was used, highlighting the unit. The city was divided into four quadrants that display the distribution of the units.

Considering a prevalence (p) of HCV infection in the order of 2.0% with a margin of error (d) of 1.0% and a reliability of 95% ($Z_{alfa/2}$ = 1,96), and applying the formula $n = [z^2 \times p \times (1 - p)]/d^2$ for infinite population, the minimum sample size was 745 sample units. To correct the sample for possible losses, a correction factor of 5% [100/ (100 – 95)] was applied, making a total of 785 individuals.[15]

Individuals who accessed the units for routine consultations or other reasons were recruited by open invitation in the waiting rooms of the 10 units through voluntary agreement, establishing a slice for each Basic Health Units of 80 individuals. Individuals under 18 years or those with a diagnosed cognitive disorder described in medical records that impaired them from understanding and answering the questionnaire were excluded.

For anti-HCV antibody assessment, the rapid test from the ABON HCV kit was employed by lateral flow immunochromatography, which allows the qualitative detection of the anti-HCV antibody in 50 microliters of whole blood obtained by finger stick. The outcome of interest was the presence or absence of HCV exposure. In a reserved room in the Basic Health Units, after signing the free and informed consent form and performing the rapid test, the patients answered the sociodemographic (gender, color, education), clinical and risk behavior (use of glass syringes, blood transfusion, surgery, use of illicit drugs, presence of tattoo, piercing, hemodialysis, transplant) questionnaire,

and these were considered as independent variables. Additional information about treatment against HCV and negative HCV-RNA detection test data were obtained at the aforementioned Treatment Centers. Then, 20 minutes after testing, the participants were informed about the result. The positive cases were referred to the specialized medical service from the Municipality to confirm the result and learn applicable conduct.

Quantitative continuous variables were described as mean ± standard deviation. An approximation of the binomial distribution to the normal distribution was performed for percentages using the 95% confidence interval. Means between groups were compared by Student's t-test for independent samples. The percentages or frequencies were compared by Fisher's exact test and linear trend chi-square test. A significance level of 5% was adopted.

This study complied with the ethical precepts of Resolution 466/12 of the National Health Council of Brazil and was approved by the Research Ethics Committee of the Universidade Federal de Pernambuco under Certificate of Presentation for Ethical Consideration 55342422.3.0000.5208 and opinion. No. 5.236.629 (Approved on March 21, 2022).

RESULTS

In waiting rooms, 800 individuals were tested, of which 636 (79.5%) were female and 164 (20.5%) male (p= 0.684). The age of participants ranged between 18 and 88 years, mean of 46.8 ± 15.8 years. The mean age for females was 46.1 years and for males 49.2 years.

The rapid test for anti-HCV detection was positive in five individuals (0.62%; 95%CI 0.2 – 1.4%), four women and one man. Four out of the five positive tests reported previous treatment against HCV and had negative HCV-RNA detection test. These data were obtained at the aforementioned Treatment Centers, upon confirmation of the sustained virological response. The only individual with positive result for anti-HCV antibody who did not report previous treatment was referred to the specialized medical service.

In the sociodemographic profile, the mean age of the five positive cases for anti-HCV stands out, 69.4 ± 6.7 years, which was much greater than the mean age of the negative cases, 46.7 ± 15.7 years (p= 0.001). All positive cases were over 60 years of age (Table 1).

Table 1. Sociodemographic characteristics of the 800 outpatients evaluated in the waiting rooms of 10 Basic Health Units, according to the presence/absence of anti-HCV antibody. Arcoverde, Pernambuco, Northeast Brazil, 2023.

Variable	Anti-HCV [+] N (%)	Anti-HCV [-] N (%)	p-value
Gender			0.684*
Male	1(20)	163(20.5)	-
Female	49(80)	632 (79.5)	-
Mean age (years)	69.4±6.7	46.7±15.7	0.001**
Color			0.650***
White	19(20)	213(28.2)	-
Brown	4(80)	448(59.3)	-
Black	0	88(11)	-
Yellow	0	46(5.7)	-
Education			0.862***
0 years	0	34(4.2)	-
1-5 years	3(60)	392(49.3)	-
High school	1(20)	285(35.8)	-
University education	1(20)	74(9.3)	-
Postgraduate education	0	10(1.2)	-

Legend: *Fisher's exact test. ** Unpaired student's t-test. *** Linear trend chi-squared

Among the risk behaviors of the 800 outpatients evaluated, note that all five anti-HCV positive cases had at least one of the following three risk factors due to parenteral exposure, e.g., use of glass syringes (p = 0.001), blood transfusion (p = 0.001) or surgery (p = 0.001) in the past, more frequently than negative cases (Table 2). None of the positive cases reported the use of illicit drugs, tattoos, or piercings.

Table 2. Risk behaviors in 800 adult outpatients evaluated in the waiting rooms of 10 Basic Health Units, according to the presence/absence of anti-HCV antibodies. Arcoverde, Pernambuco, Northeast Brazil, 2023.

Variable	Anti-HCV [+] N(%)	Anti-HCV [-] N(%)	p-value *
Use of glass syringe	3(60)	251(31.5)	**0.001**
Use of illicit drugs	0	14(1.7)	-
Presence of tattoo and/or piercing	0	150(18.8)	-
Blood transfusion	2(40)	78(9.8)	0.000
Hemodialysis	1(20)	2(0.02)	-
Surgery	4(80)	495(62.2)	**0.001**
Transplant	0	3(0.03)	-

Legend: *Fisher's exact test.

DISCUSSION

This was the first study to assess the occurrence of anti-HCV antibody in individuals in Arcoverde, a municipality in the Brazilian semi-arid region in the state of Pernambuco, revealing a prevalence of 0.62% (95%CI 0.2 – 1.4%). These results align with the latest estimates by the Brazilian Ministry of Health of around 0.53%, corresponding to about 1,091,000 individuals with positive anti-HCV in Brazil in 2016.[4] These figures correspond to about half of the estimates for the 1990s and 2000s.[10,11] Greater control in blood banks, the use of disposable syringes and needles, as well as the use of antivirals were certainly responsible for the reduced occurrence of this infection in the last 30 years.[1] Furthermore, these initial studies, although population-based with household data collection, were conducted in the most populous capitals of the country and did not

involve cities with lower population density, as in the present study. Our study was carried out with sample data from outpatients selected in waiting rooms for medical appointments of the basic health service in a municipality with less than 80,000 inhabitants in the semi-arid region of the state of Pernambuco.

Additionally, another population-based study carried out in Cavunge, a small town in the semi-arid region of the state of Bahia, involving approximately 75% of the population of the municipality of 2,000 inhabitants, found positivity for anti-HCV antibody in six out of 1,536 individuals (0.4%) tested.[16] Interestingly, this study from Bahia found only one of the six patients with viremia, but there were no reports of previous treatments against HCV. It is plausible to assume that the five patients with negative HCV-RNA achieved spontaneous cure or may have showed false-positive results for anti-HCV antibody. The mean age of individuals from the Bahia study was low, which may have favored the spontaneous cure of HCV infection in the younger ones.

A study with a very similar design to ours was developed at the University Hospital in São Paulo [UNIFESP] with 606 adult patients over 45 years old, half of whom came from the outpatient clinics and half from the Emergency service. Four anti-HCV positive cases were detected (0.66%), and all had viremia and reported risky behavior. Note that this study involved older patients and no differences between gender were observed.[17] This prevalence was very similar to that observed in the Arcoverde city, and greater attention should be paid to the detection of anti-HCV in older adults.

In another study carried out at a Basic Health Unit in São José dos Pinhais, state of Paraná, 13 positive cases for the rapid test for anti-HCV were found in a sample of 5,017 individuals, i.e., a prevalence of 0.30% (95%CI: 0.12% – 0.40%).[12] As in our sample, most individuals selected in the waiting rooms of the Basic Health Units in Paraná were female. The predominance of females in outpatient clinics has been described by other authors.[17] One of the explanations for the divergence between the male and female sex may be women's greater concern about their health and their more frequent search for medical care.

Unlike our study, where four out the five anti-HCV positive cases were among females (80%), in the study in São José dos Pinhais, most positive cases were among males (0.57%).[18] This gender discrepancy between the positive cases of the two studies may be explained by the smaller size of our sample, since estimated assessment by the Brazilian Ministry of Health describe a predominance of anti-HCV positive test in males.[4] In addition, it is already known that the predominance of females observed in the sample is explained by the higher demand of females in basic health units.

Regarding age distribution, in the Paraná survey, no differences were observed between mean ages of positive and negative cases. However, in our study, positive cases had a higher mean age (69.4 years) than negative (46.81 years). Time series studies show that individuals born in the three decades after World War II, between 1945 and 1975, called baby boomers, have a higher prevalence of HCV infection.[19] These individuals are presently over 50 years old and report a history of blood transfusion and use of non-disposable syringes or needles before the availability of anti-HCV tests.[19]

In our study, all cases with positive tests were over 60 years old and reported using non-disposable syringes, and having transfusions and surgeries in the past, possibly before the 1990s. However, none of the five anti-HCV positive cases reported other risk behaviors, such as illicit drugs, tattoos, or piercings, which reinforces the hypothesis of contamination through parenteral exposure in the past.

In addition, a few years ago, 97 former soccer players from the 1960s and 1970s were screened in the state of Pernambuco. Seven individuals (7.2%) were positive for anti-HCV, and the univariate analysis associated the infection with a history of transfusions, surgeries and use of vitamin complexes with non-disposable syringes. However, in the multivariate analysis to neutralize potential confounders, only the use of glass syringes remained an independent predictor for anti-HCV positivity ($p = 0.001$).[20]

A more recent study carried out in Minas Gerais, Southeast Brazil, involving 24,085 individuals, found 184 (0.76%) positive cases for anti-HCV, approximately 80.0% of those infected were born between the 1950s and 1980s and reported sharing needles or having tattoos and piercings.[21] Recent North American data suggest a bimodal incidence in age distribution of HCV infection, with peaks below 40 years attributed to the use of illicit injectable drugs, tattoos or piercings, and above 50 years (baby boomers) to blood transfusions and non-disposable syringe sharing.[1]

The main limitation of our study may have been the place where participants were recruited, i. e., the waiting rooms of Basic Health Units. Many of these individuals could attend these health units to control chronic diseases, such as arterial hypertension, diabetes mellitus or dyslipidemia, which eventually may have overestimated the prevalence of anti-HCV in this sample. Hence, patients with these diseases attend health services and undergo medical examinations, providing a greater risk of contamination. On the other hand, the lower representation of males in the sample may have led to a lower prevalence of positive anti-HCV antibody, since studies generally associate a higher risk of HCV contamination to males.[4] Moreover,

the inclusion criterion of 18 years old or over may have underestimated the prevalence of positive results for anti-HCV antibody in this screening. If the age limit for inclusion in the study protocol had been above 50 years, probably the antibody positivity might have been higher. However, the objective of the study was to enroll the entire adult population of the municipality in a small town in the Brazilian semi-arid region to evaluate the sharing of syringes and needles, and having tattoos and piercings in younger people as well.

In conclusion, a low prevalence of HVC exposure was observed in this study, although close to that which has been estimated in recent studies in Brazil, with antibody positivity more frequent in older people and who reported past risky behaviors.[16,17,21] Data may contribute to the development of policies for tracking and diagnosing HCV infection, as well as increasing access to treatment, with a view to eliminating this viral agent, including small municipalities in remote regions of Brazil by 2030. Therefore, in smaller municipalities, greater attention should be given to older adults (baby boomers) since the use of illicit drugs, tattoos, and piercings is rarely reported in these locations.

ACKNOWLEDGEMENT

We thank the Secretaria Estadual de Saúde de Pernambuco for making the tests available.

FINANCIAL SUPPORT

This study was supported by Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES).

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AUTHORS' CONTRIBUTIONS

Maria Tereza Estevam Vaz contributed to the bibliographic research, execution of the research with the performance of the tests, writing of the abstract, introduction, methodology, discussion, interpretation and description of the results, preparation of tables, conclusions, review and statistics. **Lílian Rose Maia Gomes de Araújo** contributed to the bibliographic research, writing of the abstract, introduction, methodology, discussion, interpretation and description of the results, preparation of tables, conclusions, review and statistics. **Andrea Batista Dória** contributed to the project administration, bibliographic research, writing of the abstract, introduction, methodology, discussion, interpretation and description of the results, conclusions, review and statistics. Relevant critical review of the intellectual content. **Norma Arteiro Filgueira** contributed to the writing of the abstract, methodology, interpretation of the results, conclusions, review and statistics. Relevant critical review of the intellectual content. **Paula Carolina Valença Silva** contributed to the writing of the abstract, review and statistics. Relevant critical review of the intellectual content. **Alcides da Silva Diniz** contributed to the writing of the abstract, review and statistics. Relevant critical review of the intellectual content. **Ana Lúcia Coutinho Domingues contributed** to the writing of the abstract, review and statistics. Critical review of the relevant intellectual content. Final approval of the version to be published. **Edmundo Pessoa Lopes** contributed to the project administration, bibliographic research, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, conclusions, review and statistics. Critical review of the relevant intellectual content. Final approval of the version to be published.

All authors have approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Vaz MTE, Filgueira NAF, Silva PCV, Diniz AS, de Araújo LRMG, Dória AB, Domingues ALC, Lopes EP. Prevalence of antibodies against HCV and risk behaviors in Basic Health Units users in a small town in the Brazilian semi-arid region. Rev Epidemiol Control Infect [Internet]. 2025 Jan. 28; 15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19314

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

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Site doi: https://doi.org/10.17058/reci.v15i1.19282

Submitted: 01/04/2024
Accepted: 11/07/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: The Antimicrobial Stewardship Program has shown satisfactory results in fighting antimicrobial resistance. Despite this, the program does not seem to be consolidated in Brazilian hospitals, which requires an understanding of the factors interfering in its consolidation according to the pharmacists' perspective. No validated tool was found in the literature to meet this objective. The objective of this study was to develop and test a tool for assessing the Antimicrobial Stewardship Program and the obstacles to its implementation in Brazilian hospitals from the perspective of pharmacists. **Methods:** The tool was developed based on literature searches and experiences in clinical practice. Content validation was carried out by a panel of experts, and semantic validation was done by the target audience. The Validity and Content Index (IVC/Ave) and the Suitability Assessment of Materials (SAM) were used in the data analysis, requiring an IVC/Ave > 90% and SAM > 80% to validate the tool. **Results:** In its final version, which contained 62 items, an IVC/Ave > 90% was found for all attributes evaluated, and the average SAM was 82%. **Conclusion:** The tool proved to be suitable for the purpose that led to its development, presenting itself as innovative, accessible, low-cost, and easy to apply by researchers.

Keywords: *Antimicrobial Stewardship. Drug Resistance, Microbial. Pharmacists. Hospitals. Anti-Bacterial Agents.*

RESUMO

Justificativa e Objetivos: O Programa de Gerenciamento de Antimicrobiano tem apresentado resultados satisfatórios no combate à resistência antimicrobiana. Apesar disso, o programa não parece estar consolidado nos hospitais brasileiros, o que exige a compreensão dos fatores que interferem na sua consolidação de acordo com a perspectiva dos farmacêuticos. Nenhuma ferramenta validada foi encontrada na literatura para atender a esse objetivo. Assim, o objetivo deste estudo foi construir e validar uma ferramenta para avaliar, na perspectiva dos farmacêuticos, o Programa de Gerenciamento de Antimicrobianos e as barreiras para sua implementação em hospitais brasileiros. **Métodos:** A ferramenta foi desenvolvida com base em pesquisas bibliográficas e experiências na prática clínica. A validação de conteúdo foi realizada por um painel de especialistas e a validação semântica foi feita pelo público-alvo. Na análise dos dados foram utilizados o Índice de Validade e Conteúdo (IVC/Ave) e a Avaliação de Adequação dos Materiais (SAM), sendo necessário IVC/Ave > 90% e SAM > 80% para validação do instrumento. **Resultados:** Em sua versão final, que continha 62 itens, foi encontrado IVC/Ave > 90% para todos os atributos avaliados, e o SAM médio foi de 82%. **Conclusão:** Assim, a ferramenta mostrou-se adequada à finalidade que motivou o seu desenvolvimento, apresentando-se como inovadora, acessível, de baixo custo e de fácil aplicação pelos pesquisadores.

Descritores: *Gestão de Antimicrobianos. Resistência Microbiana a Medicamentos. Farmacêuticos. Hospitais. Antibacterianos.*

RESUMEN

Justificación y Objetivos: El Programa de Administración de Antimicrobianos ha mostrado resultados satisfactorios en la lucha contra la resistencia a los antimicrobianos. Pese a ello, el programa no parece estar consolidado en los hospitales brasileños, lo que requiere comprender los factores que interfieren en su consolidación según la perspectiva de los farmacéuticos. No se encontró ninguna herramienta validada en la literatura para cumplir con este objetivo. Así, el objetivo de este estudio fue construir y validar una herramienta para evaluar, desde la perspectiva de los farmacéuticos, el Programa de Administración de Antimicrobianos y las barreras para su implementación en los hospitales brasileños. **Métodos:** La herramienta fue desarrollada con base en búsquedas bibliográficas y experiencias en la práctica clínica. La validación de contenido fue realizada por un panel de expertos y la validación semántica fue realizada por el público objetivo. En el análisis de datos se utilizó el Índice de Validez y Contenido (IVC/Ave) y la Evaluación de Idoneidad de Materiales (SAM), requiriéndose un IVC/Ave > 90% y SAM > 80% para validar la herramienta. **Resultados:** En su versión final, que contuvo 62 ítems, se encontró un IVC/Ave > 90% para todos los atributos evaluados y la SAM promedio fue de 82%. **Conclusión:** Así, la herramienta demostró ser adecuada para el propósito que motivó su desarrollo, presentándose como innovadora, accesible, de bajo costo y fácil de aplicar por los investigadores.

Palabras Clave: *Programas de Optimización del Uso de los Antimicrobianos. Resistencia Microbiana a los Medicamentos. Farmacéuticos. Hospitales. Antibacterianos.*

INTRODUCTION

Antimicrobials are considered to be the second most consumed class of drugs in hospital settings, accounting for around 20% to 50% of hospital spending on drugs.[1] These drugs have revolutionized healthcare by enabling the treatment of serious, life-threatening infections. The Covid-19 pandemic has worsened the already existing global antimicrobial resistance crisis by increasing the use of antimicrobials to treat the disease, in addition to aggravating the lack of adequate management in infection control practices in health care facilities due to overcrowding of health care facilities and extensive use of these drugs to treat secondary bacterial infections. Furthermore, indiscriminate use has also been identified as one of the main causes of the development of antimicrobial resistance.[2-4]

Antimicrobial resistance is a natural genetic phenomenon of microorganisms, in which genes encode proteins capable of protecting microorganisms from the action of antimicrobials, rendering them ineffective.[5] Thus, available antimicrobials are no longer effective and threaten the lives of patients who are susceptible to bacterial infections, such as transplant patients, those who are undergoing chemotherapy, and those who are in ICUs. Antimicrobial resistance thus favors an imbalance in the economy by reducing the productivity of individuals and increasing health costs. In this scenario, a study indicates that antimicrobial resistance will cause 10 million deaths per year on a global scale by 2050 without effective actions to control this phenomenon.[6]

This has challenged the scientific community to seek strategies to combat antimicrobial resistance. The concept of the Antimicrobial Stewardship Program (ASP) was first adopted in the USA in 1997 and refers to a program aimed at preventing antimicrobial resistance in hospitals through coordinated interventions to improve and measure the use of antimicrobials, promoting the optimization of therapy, cost reduction, and patient safety.[7]

In this context, clinical guidelines from countries such as Brazil, the United States, Australia, and France advocate for the participation of pharmacists in the ASP due to the important role they play in the program's activities.[8-10] An American study found that the ASP contributed to better outcomes in the treatment of hospitalized patients, minimized antimicrobial resistance, and reduced healthcare costs.[10] Another study, also conducted in the USA, showed a significant reduction in the consumption of fluoroquinolones, clindamycin, and ampicillin/sulbactam after the implementation of the ASP.[9,10] In both studies, pharmacists were actively involved in implementing and carrying out the actions inherent in the ASP. Despite this, barriers to pharmacists' work have been noted in different studies, limiting the benefits of the ASP in countries such as the USA, Australia, France, and Nigeria. In Nigeria, the barriers include a lack of training in ASP and insufficient support from hospital administrators. In France and Australia, lack of time and the significant volume of non-clinical activities are considered obstacles. In the United States, the lack of standardized treatment guidelines for infections is also a barrier.[9-11] In Brazil, there is a clear need to improve the elements of the ASP and define the responsibilities of the actions to optimize the management of the program. However, the factors that hinder the consolidation of the ASP have not yet been fully identified from the pharmacists' perspective, and there is a need to update the understanding of the facilitators and barriers affecting decision-making.[12]

Considering the unquestionable importance of the ASP, the regional differences of the program around the world, and the leading role of the pharmacist in the program's operational team, it is essential to better understand the reality of the ASP in Brazil and identify the reasons that interfere with its implementation in Brazilian hospitals from the perspective of these professionals. However, after a systematic search in the literature, no validated instruments were found to measure the perspective of pharmacists in relation to the ASP in hospitals and identify barriers to its consolidation. Therefore, the construction and validation of a data collection tool became necessary.

Questionnaires are self-administered tools in which respondents read the questions and provide written answers.[13] They are considered an integral part of clinical practice, with growing interest from researchers due to their extensive applicability and robust scientific results. They also influence the formulation of health programs and institutional policies.[14] However, it is known that there are significant differences in people's abilities to read, write, and comprehend, which can limit the application of questionnaires in research. It is worth noting that the ability to understand is not always associated only with specific groups such as children and the elderly, as functional illiteracy affects people from different social classes, age groups, and educational levels.[13,24] Thus, researchers emphasize that assessment tools only have the validity and reliability to produce accurate results if they are validated using appropriate methodologies that avoid language barriers in written communication and content flaws.[14,15]

Therefore, this study aimed to develop and validate a tool to evaluate the Antimicrobial Stewardship Program and the barriers to its implementation in Brazilian hospitals from the perspective of pharmacists.

METHODS

Type of Survey

This is a methodological study. This study design is constantly applied in the development of new tools and consists of three stages: 1) Development, production and construction of tools; 2) Validation of tools; 3) Application of tools.[13]

Development, production, and construction of the data collection tool

At the beginning of the study, a literature search was conducted to determine if a validated tool for assessing pharmacists' perspectives on Antimicrobial Stewardship and the barriers to its implementation in Brazilian hospitals existed. The search was performed in June 2021 across the PubMed, LILACS, and SciELO databases using the Health Sciences Descriptors (DeCS) "Antimicrobial Stewardship," "Drug Resistance, Microbial," and "Pharmacists," combined with the Boolean operator AND. Grey literature was also searched using Google Scholar®. The searches included studies published within the five years preceding the start of this research (October 2016 to June 2021) to ensure that the information was up-to-date and aligned with the guidelines for combating antimicrobial resistance from the World Health Assembly in Geneva, which took place in 2015. As a result, the references found did not identify a tool to evaluate the ASP and the barriers to its implementation, leading to the decision to develop a tool for data collection.

The tool was developed based on the literature, the list of essential elements of the Antimicrobial Stewardship Program,[16] and the researchers' clinical experience. In developing the tool, as recommended in the literature, clear and understandable language appropriate to the target audience and the research objectives was used, along with technical terms suited to the study population's knowledge level.[17] Furthermore, during the development of the tool, the formatting style, title, filling instructions, domain measured, and scores were considered when defining the structure and sequence of the items, in order to make them less exhaustive and more interesting, applying a logical sequence, which increased the specificity of the tool.[14] In order to facilitate availability and access, the tool was built using the *Google Forms*® survey manager.

The tool contained multiple-choice questions, short-answer questions, dichotomous questions, and questions with Likert-type measurement scales. The Likert-type scale is widely used to measure attitudes, skills, and qualities. It is simple, ordinal, and was expressed in the tool to indicate the degree of confidence in developing skills and qualities in performing activities, the degree of impact on barriers perceived to the participation in program management, and the degree of pharmacist's participation in the program according to the statements in the header.[13]

It was decided to remove the central alternatives, i.e., neutral points such as "neither agree nor disagree", because they represent a possible lack of opinion and make it difficult for respondents to understand. This practice has also been supported by some authors due to ambiguous interpretation by researchers.[18]

Data collection tool validation

Once built, following the recommendations of the literature, the tool was subjected to a validation process encompassing content validity (to check the suitability of the items in relation to the domains of the construct) and semantic validation (to check comprehensibility by the population under study).[14,15,18,19]

Content validation

The validation of content measures the extent to which the data collection tool achieves its intended purpose, and involves quantitative and qualitative aspects.[18] It can also be understood as an assessment.[14] For the selection of evaluators, some selection criteria are suggested, including clinical experience in the area of the tool, research and publications on the subject, mastery of the concepts involved and methodological knowledge about the construction of tools. In addition, when selecting evaluators, it is recommended to analyze the characteristics of the tool in order to direct it to those who have the appropriate knowledge to evaluate it, as well as checking the training, professional qualifications, and availability of those who will take part in this stage of the validation.[18] As for the number of evaluators, it is recommended that validation be carried out by a minimum of three and a maximum of 10 experts. As a result, seven expert evaluators with the following inclusion criteria were invited: areas of pharmaceutical assistance, hospital pharmacy, clinical pharmacy and Hospital Infection Control Committee (HICC) to form a committee to assess the tool's characteristics. An intentional non-probabilistic sample was used in accordance with the eligibility criteria described above.[18]

In the first phase, an e-mail was sent to the seven experts with the invitation letter in Portable Document Format (PDF), outlining the objective and justification for the study. The body of the e-mail contained a brief explanation of the study and a link to the evaluation tool in Google Forms® format. It is worth noting that only after accepting participation by signing an Informed Consent Form (ICF) the evaluators were given access to the evaluation itself. The response time was set at seven days.

The data collection tool was sent to the evaluators for evaluation, accompanied by a brief introduction to the study, an ICF, and instructions for evaluating the tool. A

reminder was sent via WhatsApp® the following day. The criteria used to evaluate the attributes of each item in the tool were representativeness, clarity, objectivity, precision, and relevance. The scores were calculated using a Likert scale.

Additionally, a space was provided for the experts to suggest improvements. A general evaluation of the data collection tool was available at the end of the document to assess the comprehensiveness of the tool, i.e., to analyze the need to include or exclude any items.

The items were analyzed by calculating the Validity and Content Index (VCI), which measures the percentage of evaluators who agree with certain aspects and items in the tool.[17,18] This analysis consists of applying a four-point Likert scale. There are several options for the four-point Likert scale found in the literature and they depend on the objectives of each study. In this study, the following scale was adopted: 1 = strongly agree, 2 = agree, 3 = disagree and 4 = strongly disagree.[18]

At first, the IVC at item level (IVC-I) was used with a cut-off point equal to 1.0 or 100% for individual item evaluation (modifications and deletions of items) because it was a new tool. The choice of IVC-I was also justified by the number of evaluators (n=4), since the literature recommends IVC-I equal to 1 when there are five or fewer evaluators. The IVC was also calculated at scale level according to the mean (IVC/AVE) to assess the attributes representativeness, clarity, objectivity, precision and relevance, with a cut-off standard of 0.90.[13,14,18,19]

Semantic validation

Semantic validation was conducted to verify the suitability of the data collection tool for the study population, with the inclusion criteria being Brazilian hospital pharmacists. In this process, recommendations for developing technological products were followed. According to the literature, 6 to 20 participants are sufficient. However, considering the possibility of losses or refusals, 22 pharmacists were invited using the snowball sampling technique. This technique is frequently used in virtual research, where the researcher sends an invitation to their contacts, who then recommend new potential participants, and so on, until the minimum number of participants required by the literature is reached.[20]

The main purpose of the data collection tool, made available to the participants by email, was to assess the suitability of the material, analyze the degree of understanding and the need for modifications. The tool was evaluated only once after the semantic validation participant agreed to the ICF. Preliminary information was also provided on how to complete the document correctly, and the deadline for returning the completed form was limited to 15 days. Reminders were sent to participants every five days by the researchers.

The Suitability Assessment of Materials (SAM) checklist, already validated for use in Brazil, was used to measure the results of the pharmacists' analysis at this stage. This checklist is made up of six sections (content, text comprehension, illustration, presentation, motivation and cultural adaptation) totaling 22 factors with a scoring scale of 0 to 2, where 2 = excellent, 1 = adequate, 0 = not adequate and N/A if the factor cannot be assessed, totaling up to 44 points. When interpreting the results to check the suitability of the material for the target audience in percentages, the SAM is classified as superior when the result is 100%, adequate when it is 80% to 99.9% and inadequate or not acceptable when it is less than 80%.[15,21]

Statistical analysis

In addition to calculating IVC-I, IVC/AVE and SAM, the profile of the participants in the validation processes was analyzed using descriptive statistics. Categorical quantitative variables were analyzed using absolute frequency, relative frequency and median.

The research was conducted in accordance with the required ethical standards (MS Resolutions 466/2012 - 510/2016 - 580/2018) and the study was approved on February 11, 2022 by the Ethics Committee of the Federal University of Alfenas (UNIFAL-MG) under protocol number 5.239.322 and CAAE 52933621.2.0000.5142.

RESULTS

The data collection tool in its final version contained 62 questions (Figure 1) organized into six sections: i) Demographic data; ii) Workplace; iii) Confidence in the performance of activities; iv) Barriers perceived to participation in program management; v) Essential elements of the program; and vi) Pharmacist participation in the ASP (Supplementary Material A).

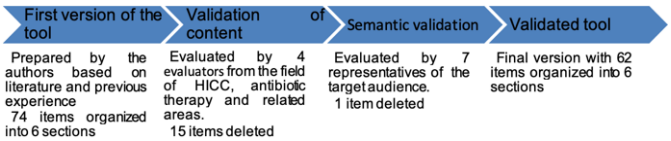

Figure 1. Products obtained at each stage of the validation process of the data collection tool built by the authors.

Data Collection Tool Validation

Content Validation

After the deadline set for sending the content validation evaluations had passed, a response was received. As a result, a new contact was made by sending an email to seven experts, followed by a WhatsApp® message the following day to confirm the email had been received. A reminder email was also sent on the fifth day, and three more responses were

received. As a result, a total of four evaluators took part in this validation stage.

After evaluation by the evaluators, the subjects were characterized, and the IVC-I and IVC-S/Ave were calculated. Modifications were made and the tool was revised so that it contained 67 items and was sent for a second evaluation. After this new evaluation, the IVC-I and IVC-S/Ave were calculated again according to tables 1 and 2. Based on the suggestions of the evaluators, further changes were made. The resulting version was sent for semantic validation. All the changes are described in Supplementary Material B.

The evaluators were mostly men (75%, N=3) with a mean age of 36 years (IQR=12.5; Max=46 years; Min=32 years). It was also found that 3 of the evaluators had master's degrees in a variety of fields but related to antibiotic therapy. All had more than six years of training, and the majority (75%, N=3) worked in public hospitals.

Table 1. Validity and Content Index at item level (IVC-I) obtained in the first and second evaluations of the tool by the evaluators.

Attributes	A1	Type of modification	Attributes	A2	Type of modification	IVC-I
Representativeness (N=74)	0	No modification	Representativeness (N=67)	0	No modification	0.25
	1	Modification		1	Modification	0.5
	27	Modification		8	Modification	0.75
	0	Exclusion		1	Exclusion	0.75
	46	No modification		57	No modification	1.0
Clarity (N=74)	3	Modification	Clarity (N=67)	0	Modification	0.25
	1	Exclusion		-	-	0.25
	10	Modification		2	Modification	0.5
	22	Modification		9	Modification	0.75
	3	Exclusion		-	-	0.75
	35	No modification		56	No modification	1.0
Objectivity (N=74)	0	No modification	Objectivity (N=67)	0	No modification	0.25
	2	Modification		1	Modification	0.5
	-	-		1	Exclusion	0.5
	10	Modification		8	Modification	0.75
	5	Exclusion		-	-	0.75
	57	No modification		57	No modification	1.0
Precision (N=74)	1	Modification	Precision (N=67)	0	Modification	0.25
	4	Modification		4	Modification	0.5
	-	-		1	Exclusion	0.5
	14	Modification		6	Modification	0.75
	5	Exclusion		1	Exclusion	0.75
	50	No modification		55	-	1.00
Relevance (N=74)	1	Modification	Relevance (N=67)	0	Modification	0.25
	1	Modification		2	Modification	0.5
	-	-		1	Exclusion	0.5
	18	Modification		6	Modification	0.75
	3	Exclusion		1	Exclusion	0.75
	51	No modification		57	No modification	1.0

Key: A1: Number of items changed in the 1st stage of validation, A2: Number of items changed in the 2nd stage of validation, IVC-I: Validity and Content Index at item level.

Table 2. Validity and Content Index according to the scale of the first and second stage of validation.

Attributes	IVC-S/Ave$_1$	IVC-S/Ave$_1$ (%)	IVC-S/Ave$_2$	IVC-S/Ave$_2$ (%)
Representativeness	0.90	90	0.94	94
Clarity	0.81	81	0.96	96
Objectivity	0.94	94	0.96	96
Precision	0.90	90	0.94	94
Relevance	0.90	90	0.94	94

Key: IVC-S/Ave1: Validity and Content Index according to the scale of the first stage of validation; IVC-S/Ave2: Validity and Content Index according to the scale of the second stage of validation.

Semantic validation

After the deadline set for sending the semantic validation evaluations, the tool was sent to 22 pharmacists, since the literature recommended six to 20 participants. Seven responses were obtained. As the number of respondents was in line with the literature, the SAM calculation was carried out (Table 3).

The participants in the semantic validation were mostly women (N=6; 85.7%) with a mean age of 39 years (IQR=11, Max=45 years; Min=30 years). It was also found that all of them worked in hospital pharmacies and the majority (N=4; 57.2%) in private hospitals.

Table 3. Calculation of the Suitability Assessment of Materials for the participants in the semantic validation.

Participants	SAM	SAM (%)
Participant 1	1.00	100
Participant 2	0.50	50
Participant 3	1.00	100
Participant 4	0.50	50
Participant 5	0.95	95
Participant 6	0.77	77
Participant 7	1.00	100
Average	0.82 (0.21)	82

Key: SAM: Suitability Assessment of Materials.

DISCUSSION

When building and validating a data collection tool in the health sector, it contributes to both clinical and scientific practice, as these tools are relevant in the formulation of health programs and public policies.[14] However, it is important to recognize that the development and validation of new tools are complex tasks that necessitate the consideration of cultural, economic, technological, and educational factors that are appropriate for the target audience and the country in which the tools are intended to be used.[14,22]

Technological products, such as data collection tools, are only valid if they are capable of accurately assessing their intended objective rather than an unrelated construct. Additionally, the process of validating technological products is a form of psychometrics that has been adapted to meet the need to validate other types of products, with an emphasis on their content. However, changes in the study population and the mode of application can influence the psychometric properties, making it necessary to perform a specific validation of the tool that takes these aspects into account.[14,23]

Moreover, it is important to note that even though the target audience for this study consists of individuals with university degrees, this does not exclude the possibility that some may experience functional illiteracy— the inability to interpret and understand texts, ideas, and perform simple mathematical calculations, despite being able to read. This issue affects individuals regardless of their education level or socioeconomic status. According to the Functional

Literacy Indicator (INAF), approximately 29% of the Brazilian population is affected by this problem, which justifies the semantic validation of the tool developed by the researchers.[24]

The IVC-I and IVC/Ave obtained attested to the validity of the content which proved to be relevant in measuring complex psychosocial traits, and the SAM attested to the semantic suitability in relation to the target audience.[13,15] In addition, it was observed that the use of WhatsApp® throughout the validation stages positively helped to clarify any doubts the participants had in real time and helped to bring them closer to the researchers.[25] In addition, it was found that the number of participants was positively influenced by WhatsApp® messages and reminders sent on the second contact of the content validation, thus reaching the minimum number of judges recommended in the literature for this type of validation. The use of Google Forms® platform was also noteworthy as a facilitator in the validation process, which, as well as being free, allowed the data to be exported to Microsoft Excel®.

Thus, the tool, after validation, proved to be both innovative and pertinent, as there is no known validated tool in Portuguese that is suitable for the purpose of the study and the target population. This validation makes it possible to use the tool in robust studies that seek to make significant contributions to the social, economic, and environmental aspects related to pharmacists' perceptions of Antimicrobial Stewardship Programs (ASP).[14] Its use as an online data collection strategy will also allow for economy, practicality, and logistical feasibility in future studies, especially when conducting surveys at times when social contact should be avoided.

Despite these benefits observed in the use of the technology during the development of the study, communication facilities in the digital universe favored an increase in the number of surveys carried out remotely during the Covid-19 pandemic and the overload of participation in surveys, which may have contributed to the absenteeism of professionals in the semantic validation stage. Other possible factors affecting absenteeism are also attributed to this period, such as the increase in electronic fraud, which may have led to a fear of clicking on the link to fill in the data collection tool, and the work overload caused by Covid-19. It should be noted that the target audience for the semantic validation was made up of professionals working on the so-called 'front line' during the pandemic. Despite these limitations, the tool has been validated and is capable of meeting the objectives for which it was designed.

In conclusion, the data collection tool developed has been validated and is compatible with the cultural, economic, technological, and educational characteristics of the target audience. It is anticipated that this tool will contribute to future studies aimed at assessing the perspective of pharmacists on ASP in Brazilian hospitals and identifying the barriers to its implementation.

ACKNOWLEDGMENTS

This study was carried out with the support of the Coordination for the Improvement of Higher Education Personnel - Brazil (CAPES) - Funding Code 001.

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AUTHORS' CONTRIBUTIONS

Jéssica Daniel Martins da Silva contributed to the literature search, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Carla Speroni Ceron** contributed to the project administration, literature search, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, conclusions, review and statistics. **Lucas Borges Pereira** contributed to the writing of the abstract, methodology, interpretation of results, conclusions, review and statistics. **Karina Dal Sasso Mendes** contributed to the writing of the abstract, methodology, interpretation of results, conclusions, review and statistics. **Tiago Marques dos Reis** contributed to the project administration, literature search, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, conclusions, review and statistics.

All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Martins J, Dal Sasso K, Pereira LB, Ceron CS, dos Reis TM. The Antimicrobial Stewardship Program: validation of a tool to assess pharmacists' perceptions. Rev Epidemiol Control Infect [Internet]. 2025 Jan. 21;15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19282

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Original Article

Practice of surgical hand antisepsis in a university hospital: an observational prevalence study

Prática da antissepsia cirúrgica das mãos em um hospital universitário: estudo de prevalência observacional

Práctica de la antisepsia quirúrgica de manos en un hospital universitario: estudio observacional de prevalencia

Site doi: https://doi.org/10.17058/reci.v15i1.19191

Submitted: 02/26/2024
Accepted: 11/07/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: surgical hand antisepsis is an essential measure in surgical site infection prevention, with the aim of reducing and eliminating the microbial load on the skin of professionals participating in surgical procedures. However, studies have shown that the surgical team has neglected this practice. In this context, the research aimed to assess the practice of hand surgical antisepsis among members of the surgical team of a teaching hospital. **Methods:** an observational, descriptive, quantitative study, conducted from September 20 to October 20, 2023. The data were transcribed in a spreadsheet, tabulated and analyzed by means of absolute and relative frequency. **Results:** a total of 238 surgical antisepsis were observed in the hands. In 100% of the practices, professionals did not use adornments; rubbing of the hands up to the elbow occurred in 96.22%; keeping the hands above the elbow occurred in 80.25%; rinsing in full running water occurred in 78.57%; and rinsing in a single direction occurred in 83.19%. However, the time used to perform the technique was adequate in 12.74% of observations for the first shift surgery and, in 23.53%, for the second. The overall adequacy of the practice was 9.31% and 17.65% for the first and second antisepsis of the shift, respectively. **Conclusion:** the research revealed deficiencies mainly in the time dedicated to practice, low general adequacy in the practice of surgical antisepsis of the hands, the hospital role as an educational institution in multiprofessional training in health.

Keywords: *Antisepsis. Hand Hygiene. Surgical Wound Infection. Infection Control.*

RESUMO

Justificativa e Objetivos: a antissepsia cirúrgica das mãos é medida essencial na prevenção de infecção de sítio cirúrgico, tendo como finalidade a redução e eliminação da carga microbiana na pele dos profissionais que participam de procedimentos cirúrgicos. Contudo, estudos têm evidenciado que a equipe cirúrgica tem negligenciado esta prática. Neste contexto, o objetivo da pesquisa foi avaliar a prática da antissepsia cirúrgica das mãos entre os membros da equipe cirúrgica de um hospital de ensino. **Métodos:** estudo observacional, descritivo, de abordagem quantitativa, realizado no período de 20 de setembro a 20 de outubro de 2023. Os dados foram transcritos em planilha, tabulados e analisados por meio de frequência absoluta e relativa. **Resultados:** foram observadas 238 antissepsias cirúrgicas das mãos. Em 100% das práticas, os profissionais não utilizaram adornos; a fricção das mãos até o cotovelo ocorreu em 96,22%; a manutenção das mãos acima do cotovelo ocorreu em 80,25%; o enxague em água corrente total ocorreu em 78,57%; e o enxágue em uma única direção ocorreu em 83,19%. Contudo, o tempo utilizado na realização da técnica foi adequado em 12,74% das observações para a primeira cirurgia do turno e, em 23,53%, para a segunda. A adequação geral da prática foi de 9,31% e 17,65% para a primeira e segunda antissepsia do turno, respectivamente. **Conclusão**: a pesquisa revelou deficiências, principalmente no tempo dedicado à realização da prática, adequação geral baixa na prática de antissepsia cirúrgica das mãos, resultado preocupante considerando o papel do hospital como instituição de ensino na formação multiprofissional na área da saúde.

Descritores: *Antissepsia. Higiene das Mãos. Infecção da Ferida Cirúrgica. Controle de Infecção.*

RESUMEN

Justificación y Objetivos: la antisepsia quirúrgica de la mano es una medida esencial en la prevención de la infección del sitio quirúrgico, con el objetivo de reducir y eliminar la carga microbiana en la piel de los profesionales que participan en los procedimientos quirúrgicos. Sin embargo, los estudios han demostrado que el equipo quirúrgico ha descuidado esta práctica. En este contexto, el objetivo de la investigación fue evaluar la práctica de la antisepsia quirúrgica de la mano entre miembros del equipo quirúrgico de un hospital docente. **Métodos:** estudio observacional, descriptivo, cuantitativo, realizado en el período del 20 de septiembre al 20 de octubre de 2023. Los datos fueron transcritos en hoja de cálculo, tabulados y analizados por medio de frecuencia absoluta y relativa. **Resultados:** se observaron 238 antisepsias quirúrgicas en las manos. En el 100% de las consultas los profesionales no utilizaron adornos; la fricción de las manos al codo ocurrió en el 96,22%; mantener las manos por encima del codo ocurrió en el 80,25%; el enjuague total con agua corriente ocurrió en el 78,57%; y el enjuague en una sola dirección ocurrió en el 83,19%. Sin embargo, el tiempo empleado para realizar la técnica fue adecuado en el 12,74% de las observaciones para la primera cirugía del turno y, en el 23,53%, para la segunda. La adecuación general de la práctica fue de 9,31% y 17,65% para la primera y segunda antisepsia del turno, respectivamente. **Conclusiones:** la investigación reveló deficiencias, principalmente en el tiempo dedicado a la práctica, baja adecuación general en la práctica de la antisepsia quirúrgica de las manos, el papel del hospital como institución de enseñanza en formación multiprofesional en el área de la salud.

Palabras Clave: *Antisepsia. Higiene de las Manos. Infección de la Herida Quirúrgica. Control de Infecciones.*

INTRODUCTION

Healthcare-associated infections (HAIs) are considered a serious public health problem worldwide and are among the most frequent adverse events occurring in health services.[1]

In Brazil, surgical site infection (SSI) is one of the main HAIs, ranking third among infections present in hospital services. It represents one of the most common complications in patients undergoing surgical procedures, occurring in the postoperative period in approximately 3% to 20% of surgeries performed.[2]

Although there have been advances in practices to control these infections, including improvements in surgical room ventilation, modernization of sterilization methods, improvement of surgical techniques and the availability of antibiotic prophylaxis, SSIs continue to significantly impact patients' health, contributing substantially to their morbidity and mortality, in addition to prolonging hospitalization and increasing the costs of additional treatments and interventions.[3]

The development of SSI depends on several factors, such as those related to the patients' immune system, the presence of a foreign body, the degree of contamination of the surgery, the indiscriminate use of antibiotic prophylaxis and the presence of bacteria inoculated at the site during the surgical procedure.[4]

One of the main ways in which microorganisms are transmitted to patients is through the hands of healthcare professionals during the care provided, as these become a reservoir for various pathogens that can be transmitted to patients.[5]

Hand hygiene (HH) is considered one of the pillars of infection prevention and control, and is one of the most important standard precaution strategies available in health care settings. It is widely recognized as the most effective, easy-to-implement, and cost-effective measure for preventing HAIs and reducing the spread of pathogens in health care settings.[5-6]

Aiming to promote adherence to HH practices, the World Health Organization (WHO) instituted, in 2009, the multimodal strategy, composed of five complementary and interdependent components, namely: system change; professional education and training; assessment and feedback; workplace reminders; and a favorable institutional safety climate. It was suggested with the purpose of increasing immediate compliance and cultivating a long-term cultural change, promoting safer health environments.[7]

HH techniques are categorized according to their intended purpose, including simple sanitation, antiseptic sanitation, antiseptic rubbing, and surgical antisepsis or preoperative preparation. The effectiveness of HH is intrinsically linked to the duration and technique employed during the procedure, highlighting the importance of rigorous practices to ensure maximum protection against the spread of pathogens.[6]

When it comes to preventing SSI, despite the causes being multifactorial, adequate surgical hand antisepsis is a fundamental stage, being one of the preoperative control measures listed by the Brazilian National Health Regulatory Agency (In Portuguese, *Agência Nacional de Vigilância Sanitária* - ANVISA) and strongly suggested by other organizations and societies, such as the WHO, Ministry of Health and Centers for Disease Control and Prevention.[1-3]

Surgical hand antisepsis aims to eliminate transient microbiota, reduce resident microbiota on the hands and forearms, and provide a residual effect on the skin of professionals participating in surgical procedures.[2]

Upon entering the Nursing Residency Program, Specialty in Health Surveillance and Infection Control, working and developing practices in various sectors of the study hospital, during the stay in the Hospital Infection Control Service (HICS), there has been growing concern regarding the practice of HH, including surgical antisepsis, given that this practice plays a crucial role in preventing HAIs, contributing significantly to patient safety and surgical procedures.

Although it is a very important procedure, studies have shown that the surgical team often does not perform it properly, whether in terms of the time spent or the technique used during the procedure.[8-9] Additionally, at the study institution, SSIs accounted for 19% of infections in 2022.

Therefore, given the relevance of this procedure in preventing SSI, the guiding question of this research is: how is surgical hand antisepsis performed by professionals working in a surgical environment? In this context, the study had the general objective of assessing the practice of surgical hand antisepsis among members of the surgical team of a teaching hospital. The specific objectives are to assess compliance in the stages of surgical hand antisepsis and to analyze compliance of the time in performing surgical hand antisepsis in the first and second/other surgical procedures.

METHODS

This is an observational, cross-sectional, descriptive study with a quantitative approach, carried out from September 20 to October 20, 2023, at the institution's Operating Room (OR). The study was carried out in a teaching hospital, located in the state of Paraná, which has 330 beds, according to the Brazilian National Registry of Health Establishments. It is currently a reference for emergency care, traumatology, orthopedics, neurosurgery, obstetrics, high-risk neonatology and rehabilitation of craniofacial anomalies, playing a fundamental role in providing

specialized health services to the community in 25 municipalities.

The institution's OR consists of six surgical rooms designed to perform procedures of various sizes and specialties. In order to ensure maximum safety and asepsis, the lavatories have an automated activation system (pedal and sensor), providing a contactless approach and reducing possible sources of contamination. Additionally, the institution has disposable brushes impregnated with antiseptic degerming for performing surgical hand antisepsis.

The study population consisted of surgeons, residents, medical students and surgical technicians who participated directly in the surgical procedure by convenience sampling. It is worth noting that professionals may have been observed on more than one occasion, due to their participation in several surgical procedures performed during the data collection period.

Observations were carried out "*in loco*", with the presence of the observer – a resident whose field of activity included the sector where the practices were monitored. This role, related to hospital infection control, allowed the observer to be regularly present in the environment, which facilitated the study without professionals realizing that they were being observed, specifically for the research. In this way, the observer's familiarity with the sector and their active role within the team created a natural context for data collection, ensuring that the observed practices reflected professionals' everyday and spontaneous actions, minimizing possible changes in behavior related to the awareness of being monitored.

For the first surgical antisepsis of the shift, a time of three to five minutes was considered adequate. For subsequent surgical antisepsis in the shift, a time of two to three minutes was considered adequate, as established by the institution's Standard Operating Protocol (SOP). It is worth noting that, according to ANVISA, for the second surgical antisepsis, a time of two to three minutes is considered adequate, as long as it is performed within one hour of the first antisepsis.[2]

The instrument for data collection and observations were based on the instructions of the Multimodal Strategy, contained in the WHO Manual for Observers, considering that, to date, there is no form with specific guidelines for evaluating surgical hand antisepsis.

According to the manual, the most accurate way to study HH practice is through direct observation of health professionals during their work routine, as it allows us to identify behaviors, assess lessons learned and remaining failures as well as help determine the most appropriate interventions for the promotion, instruction and training of this practice.[10]

The data collection instrument was designed considering the following variables: date; professional category; shift surgery; use of ornaments (ring, bracelet, watch); use of a brush impregnated with antiseptic; degerming agent used (Chlorhexidine 2% or Polyvinylpyrrolidone-iodine (PVP-I). To assess the general adequacy of the surgical hand antisepsis practice, the following were considered: not using adornments, rubbing the hand antisepsis agent up to the elbow, keeping the hands above the elbow, rinsing in running water, rinsing in a single direction and technique duration within the recommended time.

The collected data were transcribed into a Microsoft Office Excel® spreadsheet, tabulated and analyzed using absolute (n) and relative (%) frequencies. The results were organized and presented in the form of tables. This study is part of a larger project, submitted and approved by the Research Ethics Committee on September 6, 2023, under Opinion 6,287,135 and Certificate of Presentation for Ethical Consideration 72943723.5.0000.0107, respecting the ethical principles for research involving human beings recommended by Resolution 466/2012 of the Brazilian National Health Council.

RESULTS

There were 238 opportunities observed for the practice of surgical hand antisepsis performed by the team during the study period, 51 (21.43%) by surgeons, 125 (52.52%) by medical residents, 33 (13.87%) by medical students, and 29 (12.18%) by surgical instrument technicians.

Table 1. Characteristics involving the practice of surgical hand antisepsis according to the observed variable. Cascavel, Paraná, Brazil, September to October 2023.

Variables observed	N (%)
Use of ornaments (ring, bracelet, watch)	
Yes	0
No	238 (100)
Use of sponge impregnated with antiseptic	
Yes	238 (100)
No	0
Degerming agent used	
Chlorhexidine 2%	224 (94,12)
PVP-I	14 (5.88)
Rubbing the hand degerming agent up to the elbow	
Yes	229 (96.22)
No	9 (3.78)
Keeping hands above the elbow	
Yes	191 (80.25)
No	47 (19.75)
Rinse thoroughly in running water	
Yes	187 (78.57)
No	51 (21.43)
Rinse in one direction, towards the nails, hands to elbows	
Yes	198 (83.19)
No	40 (16.81)

Legend: Polyvinylpyrrolidone-iodine (PVP-I).

According to the data in Table 1, it was found that, during the practice of surgical hand antisepsis, none of

the professionals analyzed were using adornments. Rubbing of the hands up to the elbow was performed in 96.22% of antisepsis procedures, while keeping the hands above the elbow was observed in 80.25%. Rinsing in running water occurred in 78.57%, and rinsing in a single direction was adopted in 83.19% of the practices performed.

However, the surgical hand antisepsis time was timed and considered adequate in 12.74% of observations made for surgical antisepsis of the first surgical procedure and in 23.53% for the second surgical antisepsis of the shift (Table 2).

Table 2. Time spent on surgical hand antisepsis by professionals according to shift surgery. Cascavel, Paraná, Brazil, September to October 2023.

Surgical hand antisepsis time	1st shift surgery N (%)	2nd shift surgery N (%)
< 30 seconds	0	2 (5.88)
30 to 59 seconds	29 (14.22)	7 (20.59)
1:00 to 1:29 minutes	54 (26.47)	8 (23.53)
1:30 to 1:59 minutes	48 (23.53)	9 (26.47)
2:00 to 2:29 minutes	31 (15.20)	5 (14.71)
2:30 to 2:59 minutes	16 (7.84)	3 (8.82)
3:00 to 3:59 minutes	20 (9.80)	0
> 4 minutes	6 (2.94)	0
Total	204 (100)	34 (100)

In the first shift surgical antisepsis, the minimum time recorded was 31 seconds, with a maximum time of 06:08 minutes and an average of 02:53 minutes. In the second shift surgical antisepsis, the minimum time recorded was 28 seconds, with a maximum time of 02:55 minutes and an average of 01:31 minutes.

When analyzing all stages of surgical hand antisepsis, the results showed compliance of only 9.31% in the first antisepsis of the shift and 17.65% in the second, which highlights the lack of adherence to the institutionalized SOP and/or lack of updates of this practice that permeates the surgical teams' actions (Table 3).

Table 3. Compliance at all stages assessed according to shift surgery. Cascavel, Paraná, Brazil, September to October 2023.

Compliance at all stages assessed	1st shift surgery N (%)	2nd shift surgery N (%)
Yes	19 (9.31)	6 (17.65)
No	185 (90.69)	28 (82.35)
Total	204 (100)	34 (100)

DISCUSSION

The presence of microorganisms on the hands of the surgical team represents a potential risk of infection if these microorganisms penetrate the surgical site. Therefore, surgical hand antisepsis is routinely performed before invasive procedures, aiming to reduce the microbial load present, minimizing the risk of releasing bacteria into the operating field, even when barrier mechanisms are violated, such as tears or perforations in the gloves, and, consequently, reducing the risk of SSI.[11-12]

A recent study investigated the presence of microorganisms on the hands of surgeons, revealing a high incidence at two important moments: before surgical hand antisepsis (100%) and after this procedure (27.5%). This finding highlights the potential for transmission of microorganisms that can cause infections in hospitalized patients in different care settings. Transmission frequently occurs through the hands of health professionals, especially when hygiene is not performed at the recommended times and in an adequate manner.[12]

The surgical hand antisepsis procedure using a sterile sponge impregnated with antiseptic antigerm is based on wetting the hands, forearms and elbows, pressing the soft spongy part against the skin, spreading the antiseptic all over, cleaning the nails with the bristles of the brush and rubbing the hands (palm, back, interdigital spaces, sides), arm and forearm up to the elbow for at least three to five minutes. It is important to always keep the hands above the elbows to avoid recontamination of the hands through water/soap on the forearms and elbows.[2]

The technique is repeated on the opposite limb, followed by rinsing under running water, in the direction of the nails, hands and elbows, ensuring that all product residue is removed.[2]

As important as the technique itself are some recommendations related to the removal of adornments from the hands and arms (such as rings, bracelets, watches), the prohibition of artificial nails, keeping nails short and clean, and taking precautions against using brushes directly on the skin.[2]

The removal of adornments is recommended, especially in activities that require sterile technique, considering that their use can alter the microbiota of professionals' hands and make it difficult to effectively remove microorganisms that may remain under the adornments or in their irregularities, when present.[11,13-14]

In the case of long nails, in addition to presenting a greater microbial load in the subungual spaces, there is an increased probability of tearing gloves, in the same way that can occur with the use of rings, compromising the effectiveness of the protective barrier.[13-14] Therefore, it is recommended that nails do not exceed two millimeters in length.[13]

In this study, the results showed strict compliance by the surgical team due to the total absence of adornments in all observations, data that support the findings of another study, which identified complete adherence by the surgical team to the absence of adornments during surgical hand antisepsis, which emphasizes the team's commitment to preventing potential associated risks.[8]

All participants used disposable sponges for hand antisepsis, most of which were impregnated with 2%

Chlorhexidine, according to the institutional SOP. In addition to this antiseptic agent, the hospital where the study was conducted also provided a sponge impregnated with PVP-I, which would be an alternative in the absence of chlorhexidine. These products are indicated for hand antisepsis when there is a need to reduce microbial flora, as is the case in surgeries.[13]

The use of brushes directly on the skin is not recommended, due to the risk of causing damage to the skin layers and exposing bacteria present in deeper regions of the skin. However, if use is unavoidable, it is recommended that such brushes be sterile and for single use and used only to remove dirt from the nails.[2,13]

The recommendation to follow the unidirectional direction during rinsing is an important stage, as failure to do so may lead to the return of microorganisms to the hands, which are the most frequent contact areas in the surgical field. Moreover, inadequate rinsing may leave traces of the antiseptic agent, increasing the risk of adverse skin reactions and skin sensitization.

ANVISA recommends the use of alcohol-based products (ABP) together with antiseptic degerming agents for surgical hand antisepsis.[2] However, at the time of this study, this method has not yet been standardized. A study that evaluated the effectiveness of PBA in microbial reduction during surgical hand antisepsis showed a reduction in bacterial count in most cases, when analyzing the technique in less than and more than 90 seconds, and in techniques performed in more than 180 seconds, all samples showed a reduction in bacterial count.[15]

In another national study that investigated the acceptability of surgical professionals regarding the use of alcoholic solution for surgical hand antisepsis compared to antiseptic degerming agents (PVP-I and Chlorhexidine 2%), more than 70% of participants expressed a preference for the alcoholic solution, attributed to its pleasant texture, color and odor, as well as its less drying effect on the skin. Furthermore, professionals highlighted the more pleasant application of alcoholic solution, resulting in greater overall satisfaction with the product, and it is an alternative to consider in the practice of surgical hand antisepsis.[16]

The issue of time dedicated to surgical hand antisepsis is an important point that deserves further analysis. This finding, revealed by the observation that less than 13% of professionals completed the procedure, in the first shift surgery, within the time recommended by the institutional SOP, reveals a significant gap in compliance with recommended practices. It is important to highlight that the sector does not have well-positioned clocks near the hand antisepsis areas, visible to professionals' 'eyes', only on nearby walls (at a high level). This lack of timers or clocks can contribute to the difficulty in adequately monitoring the time dedicated to the procedure, further compromising compliance with established guidelines.

The time required for surgical hand antisepsis may be directly related to the effectiveness in reducing microorganisms present on the hands of healthcare professionals. Thus, the variation in the times observed not only reflects the effectiveness of the process, but also has implications for patient safety.

In recent research, multivariate statistical analysis revealed that brushing for two minutes increases the risk of contamination by 12 times when compared to longer durations.[11] Furthermore, even after surgical hand antisepsis, different species of microorganisms were identified on surgeons' hands, such as *Staphylococcus warneri*, *Staphylococcus capitis*, *Staphylococcus hominis*, *Staphylococcus hemolyticus*, *Micrococcus luteus* and *Stenotrophomonas maltophilia*, showing that surgeons' hands represent a considerable source of potentially infectious microorganisms.[12]

Other similar studies, focusing on unsatisfactory adherence by the surgical team in relation to the time and technique of surgical hand antisepsis, corroborate the findings of this study. In a previous study, only 16% of surgeons adequately followed the recommended technique and time for surgical hand antisepsis.[8] Another study observed complete adherence to the entire technique in only 18% of observations.[9]

Among the barriers that impede adherence to surgical antisepsis, the above study identified the lack of familiarity with the appropriate technique, the absence of managerial supervision, monitoring and the lack of direct practical training.[9] These results emphasize the need to address these issues to improve surgical antisepsis practice and, consequently, reduce the risks associated with the transmission of microorganisms.

Unlike the results found in previous studies, a study conducted at a university hospital in Madrid revealed remarkable compliance with surgical hand antisepsis practices during the period analyzed. The overall adequacy of the practice was 80.5%. The authors highlighted the timer as a facilitating element for adherence to the WHO protocol, since 25.8% of professionals assessed used this resource. It is noteworthy that this group showed 96.8% adherence to the recommended time for surgical hand antisepsis.[17]

In another study, researchers sought to achieve 100% adherence to surgical hand antisepsis. Interventions such as video demonstration, personal instruction by a consultant, and individual coaching were implemented to improve adherence. The 100% goal was achieved after six trials. Personal instruction emerged as the most effective intervention, and handwashing technique was the criterion that required the most attempts to correct.[18]

It is worth reflecting that achieving 100% adherence is not only a challenge, but also a journey that requires a holistic, adaptive and people-centered approach. In this

context, the lack of a compliance indicator becomes not only a gap in measuring the effectiveness of the process, but also highlights the urgent need to establish a reliable instrument to monitor and evaluate compliance with the practice of surgical hand antisepsis.

The results of this research highlighted that rubbing the hands up to the elbow, keeping the hands above the elbow, and rinsing in running water in a total and unidirectional manner were, in most cases, performed adequately. However, deficiencies persist in the execution of this procedure, especially with regard to the time dedicated to its completion.

These data reflect a worrying reality, especially considering that the hospital in question plays a crucial role in health professional training as an educational institution as well as a reference hospital in the region for various specialties and complexities. Every professional who enters the institution goes through a period of 'welcoming' at the institution, during which various sectors present their practices and protocols. The HICS addresses several topics related to HH, however surgical hand antisepsis is not specifically addressed in this training. This gap highlights the need for more focused training on surgical antisepsis that could be implemented during the induction period.

Another point to be mentioned is that no easily accessible and visible manuals or posters were identified in the workplaces, especially in the lavatories, regarding surgical hand antisepsis procedures. The absence of informative visual materials in these spaces may compromise correct adherence to protocols and reduce professionals' awareness of recommended practices. Implementing posters in strategic areas would be a simple but effective measure to reinforce institutional guidelines and promote compliance with antisepsis procedures.

Therefore, the implementation of continuous training, monitoring the performance of the technique and maintaining updated protocols in accordance with national guidelines and easily accessible emerge as essential measures to leverage the improvement of the processes carried out, ensuring that professionals are always up to date and prepared to follow the recommended protocols.

It is essential to undertake efforts to identify and implement teaching and ongoing supervision approaches that ensure not only the adoption but also the maintenance of high standards of surgical hand antisepsis by professionals.

Such actions aim not only to ensure patient safety, reducing the risks of HAIs, but also to contribute to training professionals who are more aware and adherent to good practices, essential in all patient care environments, consolidating ethical and moral commitment and co-responsibility in the context of evidence-based practices focused on human beings.

There is a possibility of the Hawthorne effect as a limitation of this study, in which health professionals may modify their behavior when they know they are being observed. This may distort actual surgical hand antisepsis practices, potentially influencing the outcome of the study.[19] Furthermore, it is relevant to mention the scarcity of studies on the subject, highlighting the need for additional research to strengthen the knowledge base in this field of study.

Adopting monitoring of this practice can provide insights into the consistency of practice over time and identify necessary interventions. This approach is essential to improve internal policies, training and protocols, resulting in tangible benefits for patient safety and the adequacy of practices carried out, aiming at HAI prevention and control.

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AUTHORS' CONTRIBUTIONS

Beatriz Talluly Bespalhok contributed to bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Débora Cristina Ignácio Alves** contributed to bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Fabiana Gonçalves de Oliveira Azevedo Matos** contributed to abstract review and writing, introduction, methodology, discussion, results and conclusions. **Lara Adrianne Garcia Paiano da Silva** contributed to abstract review and writing, introduction, methodology, discussion, results and conclusions.

All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

Please cite this article as: Bespalhok BT, Alves DCI, Matos FGOA, da Silva LAGP. Prática da antissepsia cirúrgica das mãos em um hospital universitário: estudo de prevalência observacional. Rev Epidemiol Control Infect [Internet]. 13º de janeiro de 2025;15(1). Disponível em: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19191

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Review Article

Impact of the use of macrolide antibiotics on bacterial resistance in non-fibrocystic bronchiectasis: a systematic review

Impacto do uso de antibiótico macrolídeos na resistência bacteriana em bronquiectasias não fibrocísticas: revisão sistemática

Impacto del uso de antibióticos macrólidos sobre la resistencia bacteriana en las bronquiectasias no fibroquísticas: revisión sistemática

Site doi: https://doi.org/10.17058/reci.v15i1.19905

Submitted: 09/24/2024
Accepted: 12/11/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: bronchiectasis is a chronic respiratory disease characterized by irreversible bronchial wall dilation, mucociliary dysfunction, persistent cough, productive sputum and recurrent infections. The use of antibiotics is an essential part of the treatment of non-cystic fibrosis bronchiectasis, with macrolides being commonly used due to their anti-inflammatory properties and effectiveness in neutrophilic diseases. However, the frequent use of macrolides is concerning due to their potential to induce antimicrobial resistance. In this regard, this article assessed the impact of macrolide antibiotic therapy in non-cystic fibrosis bronchiectasis on the emergence of bacterial resistance. **Methods:** this is a descriptive systematic review, carried out in the PubMed, LILACS and SciELO databases, including all articles published until August 2020 that were available in Portuguese, English and/or Spanish, using the keywords "antimicrobial resistance" and "bronchiectasis". On the other hand, reviews, opinion articles and editorials were excluded as well as those works that did not investigate bacterial resistance, especially to macrolide antibiotics. **Results:** the review found five studies, all carried out between 2008 and 2016 in Australia, New Zealand and the Netherlands, that assessed the effects of macrolides in children and adults with bronchiectasis. Four were controlled clinical trials and one was a prospective cohort study. Although studies have shown that macrolides were effective in reducing exacerbations and improving lung function, they have also reported the development of macrolide resistance in some cases. This article emphasizes the need for cautious use of macrolides in the treatment of bronchiectasis unrelated to cystic fibrosis due to the potential for antimicrobial resistance.

Keywords: *Bronchiectasis. Drug Resistance, Microbial. Antimicrobials. Azithromycin.*

RESUMO

Justificativa e Objetivos: a bronquiectasia é uma doença respiratória crônica caracterizada por dilatação irreversível da parede brônquica, disfunção mucociliar, tosse persistente, expectoração produtiva e infecções recorrentes. O uso de antibióticos é parte essencial do tratamento de bronquiectasias não fibrose cística, sendo os macrolídeos comumente utilizados devido às suas propriedades anti-inflamatórias e eficácia nas doenças neutrofílicas. No entanto, o uso frequente de macrolídeos é preocupante, devido ao seu potencial em induzir resistência antimicrobiana. Nesse sentido, este artigo avaliou o impacto da antibioticoterapia macrolídeo em bronquiectasias não fibrose cística no surgimento de resistência bacteriana. **Métodos:** trata-se de revisão sistemática descritiva realizada nas bases de dados PubMed, LILACS e SciELO, incluindo todos os artigos publicados até agosto de 2020 que estivessem disponíveis em português, inglês e/ou espanhol, encontrados pelas palavras-chave "resistência antimicrobiana" e "bronquiectasia". Por outro lado, foram excluídos revisões, artigos de opinião e editoriais, e aqueles trabalhos que não investigaram a resistência bacteriana, especialmente a antibióticos macrolídeos. **Resultados:** a revisão encontrou cinco estudos, todos realizados entre 2008 e 2016 na Austrália, Nova Zelândia e Países Baixos, que avaliaram os efeitos dos macrolídeos em crianças e adultos com bronquiectasias. Quatro eram ensaios clínicos controlados e um era estudo de coorte prospectivo. Embora os estudos tenham demonstrado que os macrolídeos foram eficazes na redução das exacerbações e na melhoria da função pulmonar, também relataram o desenvolvimento de resistência aos macrolídeos em alguns casos. Este artigo enfatiza a necessidade do uso cauteloso de macrolídeos no tratamento de bronquiectasias não relacionadas à fibrose cística devido ao potencial de resistência antimicrobiana.

Descritores: *Bronquiectasia. Resistência Microbiana a Antibióticos. Antimicrobianos. Azitromicina.*

RESUMEN

Justificación y Objetivos: las bronquiectasias son una enfermedad respiratoria crónica caracterizada por dilatación irreversible de la pared bronquial, disfunción mucociliar, tos persistente, esputo productivo e infecciones recurrentes. El uso de antibióticos es una parte esencial del tratamiento de las bronquiectasias por fibrosis no quística, siendo habitual el uso de macrólidos por sus propiedades antiinflamatorias y su eficacia en las enfermedades neutrofílicas. Sin embargo, el uso frecuente de macrólidos es preocupante debido a su potencial para inducir resistencia a los antimicrobianos. En este sentido, este artículo evaluó el impacto de la terapia con antibióticos macrólidos en las bronquiectasias por fibrosis no quística sobre la aparición de resistencia bacteriana. **Métodos:** se trata de una revisión sistemática descriptiva, realizada en las bases de datos PubMed, LILACS y SciELO, que incluye todos los artículos publicados hasta agosto de 2020 que estaban disponibles en portugués, inglés y/o español, encontrados por las palabras clave "resistencia a los antimicrobianos" y "bronquiectasias". Por otro lado, se excluyeron revisiones, artículos de opinión y editoriales, y aquellos trabajos que no investigaran la resistencia bacteriana, especialmente a los antibióticos macrólidos. **Resultados:** la revisión encontró cinco estudios, todos realizados entre 2008 y 2016 en Australia, Nueva Zelanda y Países Bajos, que evaluaron los efectos de los macrólidos en niños y adultos con bronquiectasias. Cuatro fueron ensayos clínicos controlados y uno fue un estudio de cohorte prospectivo. Aunque los estudios han demostrado que los macrólidos fueron eficaces para reducir las exacerbaciones y mejorar la función pulmonar, también han informado el desarrollo de resistencia a los macrólidos en algunos casos. Este artículo enfatiza la necesidad de un uso cauteloso de macrólidos en el tratamiento de bronquiectasias no relacionadas con la fibrosis quística debido al potencial de resistencia a los antimicrobianos.

Palabras Clave: *Bronquiectasias. Farmacoresistencia Microbiana. Antimicrobiano. Azitromicina.*

INTRODUCTION

Bronchiectasis is a chronic and disabling lung disease marked by bronchial wall permanent and abnormal expansions. This condition results in compromised function of mucociliary clearance mechanisms, leading to a persistent cough, copious mucus production, and frequent respiratory infections. In addition to making breathing difficult, bronchiectasis can cause fatigue, chest pain and significantly reduce patients' quality of life.[1-2] It can be caused by various etiologies, such as autoimmune diseases (rheumatoid arthritis and Sjögren's syndrome), severe infections (tuberculosis and bacterial pneumonia), genetic abnormalities (cystic fibrosis and primary ciliary dyskinesia) and acquired diseases.[3]

The use of antibiotics is an important part of the treatment for non-fibrocystic bronchiectasis.[3] Several classes of antibiotics and formulations tested have already established their role in providing clinical benefits, especially in patients with an exacerbator profile.[3] An exacerbator profile is defined as a worsening of respiratory symptoms treated with oral or intravenous antibiotics.[4] Macrolides are widely used antibiotics in the treatment of bronchiectasis due to their ease of administration, anti-inflammatory properties, and efficacy in cystic fibrosis and other neutrophilic diseases.[4] Moreover, macrolides have the advantages of high plasma concentration, long half-life, and broad antimicrobial spectrum.[4] All of this provides justification for this class of antibiotics to be used as maintenance therapy in patients with non-fibrocystic bronchiectasis and for prevention of exacerbations.[5] Macrolides inhibit protein production by reversibly binding to the 50S ribosomal subunit of susceptible microorganisms, blocking mRNA translation without interfering with nucleic acid synthesis. However, the widespread use of these antibiotics has inevitably led to the spread of resistant strains.[6] The two most common mechanisms of resistance are excretion of the drug from the cell and modification of the drug target site. Resistance can occur in long-term treatment prescriptions, especially in chronic diseases such as cystic fibrosis and bronchiectasis, where frequent and continuous use of macrolides can select resistant strains.[4] Developing more details about these mechanisms and the clinical conditions under which resistance is most likely helps to elucidate the complexity of the problem and the need for appropriate management strategies to prevent antimicrobial resistance. [4,6]

Currently, antimicrobial resistance is considered a global threat to health and development according to the World Health Organization (WHO).[8] Accordingly, it is known that this phenomenon leads to increased costs and overload of health systems, since patients infected with resistant pathogens are hospitalized for longer and use more expensive drugs.[9-10] Recently, due to the Covid-19 pandemic, many antibiotics have been prescribed, without taking into account the potential for increased antimicrobial resistance, which generates a global scenario of uncertainty regarding the future effectiveness of the antibiotics that exist today.[8] Therefore, this article aimed to assess the impact of antibiotic therapy with macrolides in non-fibrocystic bronchiectasis on the emergence of bacterial resistance through a systematic review.

METHODS

Experimental design and selection criteria

This is a descriptive systematic review that adopted the Preferred Items of Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Therefore, the following items were considered: eligibility criteria; exclusion criteria**;** information source and search strategy; selection of studies; and data collection.

Eligibility and exclusion criteria

In this study, were defined as eligibility criteria: i) experimental articles dealing with non-cystic fibrous bronchiectasis, regardless of the age group; ii) articles showing results regarding antimicrobial resistance to macrolides; iii) articles available in Portuguese, English and/or Spanish published until August 2020 in the PubMed, LILACS and SciELO databases. Reviews, editorials and personal views as well as articles not available in full and/or that did not address macrolide resistance involving patients with non-cystic fibrosis bronchiectasis were excluded.

Article search and selection strategies

Study selection, data collection, risk of bias in individual studies were carried out during the period from July to August 2020. Through the keywords "antimicrobial resistance" and "bronchiectasis", using the Boolean operator "AND". So, 295 articles were found; among these, 47 were selected for full reading (by two researchers, independently, reducing the risk of bias) based on the title. However, 42 articles were discarded due to eligibility criteria, resulting in five articles for analysis (Figure 1).

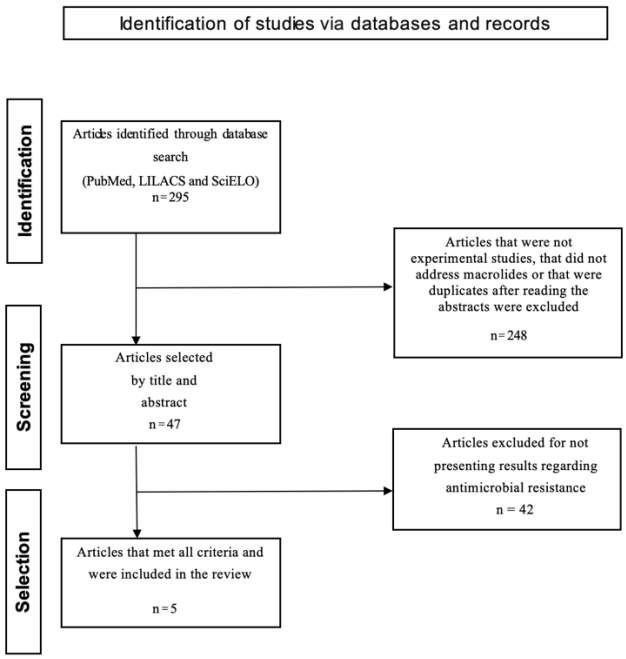

Figure 1. Identification of studies via databases and records.

RESULTS AND DISCUSSION

Among the five selected studies, four were placebo-controlled clinical studies and a prospective cohort study.[9–13] Three studies assessed the effects of macrolides in children.[11–13] All clinical trials, in turn, were conducted between 2008 and 2016 involving the population of Australia, New Zealand and the Netherlands. Important information about these studies is shown in the following table (Table 1).

Table 1. Clinical and prospective cohort studies evaluating the effects of macrolides in children and adults in Australia, New Zealand and the Netherlands (2008-2016).

Authors	Experimental design	Methods	Main results
Serisier *et al*. (2013)	Placebo-controlled clinical trial from 2008 to 2011 at an Australian university hospital	Oral erythromycin (400 mg, twice daily) or placebo	Oropharyngeal swab: erythromycin increased the proportion of macrolide-resistant commensal *Streptococcus*
Altenburg *et al*. (2013)	Placebo-controlled clinical trial in 14 hospitals in the Netherlands between 2008 and 2010	Oral azithromycin (250 mg, once a day) or placebo	Sputum sample: 88% of pathogens became resistant to macrolides in the azithromycin group, compared to 26% of pathogens in the placebo group
Valery *et al*. (2013)	Placebo-controlled clinical trial between 2008 and 2010 in Australia and New Zealand	Oral azithromycin (30 mg/kg, maximum of 600 mg) or placebo for 12 to 24 months	Nasal swab: increased carriage of azithromycin-resistant bacteria in the azithromycin group (7-fold higher odds)
Goyal *et al*. (2018)	Placebo-controlled clinical trial in Australia and New Zealand from 2012 to 2016	Azithromycin (5 mg/kg) or amoxicillin (22.5 mg/kg twice daily) for 21 days	29% in the amoxicillin group and 80% in the azithromycin group carried azithromycin-resistant organisms
Hare *et al*. (2013)	Prospective cohort study in Australia and Alaska from 2004 to 2008	Indigenous children from Australia (n = 79) and Alaska (n = 41) divided according to the use of azithromycin: no azithromycin in the 2-weeks preceding swab collection at any of the study visits; Azi-Infrequent - azithromycin preceding 1–50% of study visits; and Azi-Frequent - azithromycin preceding >50% of study visits	Nasopharyngeal swab: macrolide resistance was higher in Australia, and frequent use of azithromycin coincided with increased carriage of macrolide-resistant *S. pneumoniae*, *H. influenzae* and *S. aureus*

Legend:* *H. influenzae: Haemophilus influenzae; S. aureus: Staphylococcus aureus.*

Only one study assessed the emergence of erythromycin-resistant commensal *Streptococcus* in an oropharyngeal sample ($p<0.001$). All others focused on azithromycin as the macrolide of choice, demonstrating a significant relationship between different administration protocols of this antimicrobial and the increase in resistant microorganisms in sputum and nasopharynx samples. Thus, through an oropharyngeal smear for *Streptococcus* culture and macrolide sensitivity test, it was possible to show that the use of erythromycin significantly increased the proportion of *Streptococcus* resistant to macrolides (27.7% vs 0.04% or placebo; $p < 0.001$).[22]

Despite the increase in resistant pathogens, the use of erythromycin reduced the number of exacerbations (76 exacerbations per year for the erythromycin group *vs* 114 for the placebo group; $p = 0.003$).[11] This study emphasized the need to assess both the advantages and disadvantages of using this treatment. Although it may improve quality of life by reducing exacerbations, on the other hand, it may induce the emergence of resistant bacteria.[11] The resistance hypothesis suggests that while erythromycin has clinical benefits, continuous use may lead to the selection of resistant microorganisms. Bacteria exposed to antibiotics on a sublethal level may develop resistance mechanisms such as altering the antibiotic's target, activating the drug's enzyme, or altering the flow channels. While erythromicin may alleviate symptoms and improve patients' quality of life, indiscriminate use may contribute to a larger public health issue: the spread of drug-resistant pathogens.

On the other hand, in 2013, Altenburg *et al*. found comparable resistance patterns between groups (35% macrolide resistance among patients in the azithromycin group *vs* 27.5% in patients in the placebo group). However, during treatment, among patients receiving azithromycin, 88% of microorganisms became resistant to macrolides, compared to 26% in the placebo group ($p = 0.001$). Among the most frequently isolated microorganisms, *Haemophilus influenzae, Streptococcus pneumoniae, Staphylococcus aureus, Moraxella catarrhalis* and *Haemophilus parainfluenzae* stand out, which together comprised 87% of the total number of pathogens, 75% of which were tested for resistance to macrolides.[11] In addition to the bronchiectasis, this class of antimicrobial agents has also been recommended as the first line for the treatment of community-acquired pneumonia, which may impact the emergence of resistant microorganisms (commensals or pathogens) not only in exacerbation episodes in patients with non-cystic fibrosis bronchiectasis, but also in other infectious episodes that affect this group of patients. Therefore, it is indicated that the use of macrolides as maintenance therapy occurs only in those patients who have three or more annual exacerbations.

Regarding the action of azithromycin in reducing pulmonary exacerbations, a multicenter, double-blind, randomized controlled trial conducted in Australia demonstrated that the group that received azithromycin was less prone to pulmonary exacerbations.[13] However, the chances of boosting bacterial resistance to azithromycin were seven times greater in the azithromycin-treated group than in the control group.

Valery *et al*. raised concerns about the long-term use of azithromycin in indigenous children with bronchiectasis unrelated to cystic fibrosis or chronic pulmonary. The prolonged use of azithromycin for patients with chronic lung diseases should be carefully considered, because, despite its advantages of improving lung function and decreasing disease exacerbations, it may lead to negative outcomes, associated with adverse effects such as hearing impairment, and the emergence of bacterial resistance in isolates from treated patients, which, in addition to decreasing bacterial colonization (of pathogenic microorganisms or microbiota), may impact the restriction of antibiotic use in future infectious processes. The study found that the possibility of bacterial resistance to azithromycin compromises treatment efficacy and can lead to more difficult-to-treat infections. Continuous use of azithromycin leads to the selection of resistant bacteria, which is exacerbated by mechanisms such as ribosome modification. As a result, it is critical to balance its use with microbiological surveillance and alternative strategies, such as antibacterial rotation cycles and antimicrobial management programs. At the same time, only two of the 12 children participating in the study who were identified as colonized with azithromycin-resistant *S. pneumoniae* at the last study visit already had colonization with this resistant microorganism at the beginning of the study (both in the azithromycin group), allowing to hypothesize that the continuous use of this macrolide (azithromycin - 30 mg/kg once a week for up to 24 months) may have been the booster of the resistance that emerged in these isolates at the end of the assessments.[13]

Considering the potential of antimicrobial agents in reducing exacerbations and their possible intervention in the emergence of resistant pathogens, a clinical trial carried out between 2012 and 2016, in three Australian hospitals and one New Zealand hospital, compared the daily oral use for 21 days of azithromycin and amoxicillin-clavulanate. All exacerbations resolved by day 21 of treatment in 77.3% of children receiving amoxicillin-clavulanate and 76.8% of those receiving azithromycin. Furthermore, the median time to resolution of exacerbations was four days shorter in the amoxicillin-clavulanate group than in the azithromycin group. Thus, it is evident that the macrolide does not play a fundamental and irreplaceable role in reducing the number and duration of exacerbations.[14]

Also, considering the exposure of colonizers to antimicrobial agents, the authors highlighted the identification of 74 pathogens in the nasal swabs of individuals recruited for the study, namely *H. influenzae, S. pneumoniae, M. catarrhalis* and *Staphylococcus aureus*. The bacteriological profile of nasal swabs, including carriage of azithromycin-resistant organisms, was similar in both treatment groups at the onset of an exacerbation. Of the children whose swabs still contained pathogens on day 21, 4/14 (29%) in the amoxicillin-clavulanate group and 8/10 (80%) who received azithromycin carried azithromycin-resistant organisms. Even though the profile of azithromycin-resistant *S. aureus* isolates in both treatment groups did not change over the study period, bacterial resistance was more common in the group that used azithromycin.[14]

The authors propose that macrolides have been used to treat other community-acquired infectious processes, which would support the presence of resistant respiratory bacterial pathogens at the beginning of the study.[14] Specifically regarding azithromycin-resistant *S. aureus*, it should also be highlighted that these microorganisms remain resistant even after antibiotic therapy is discontinued. In addition to this, studies indicate the presence of resistant *S. aureus* in local and invasive infections among indigenous children as a whole.

In a prospective cohort study, it was reported that many physicians in Australia routinely prescribe azithromycin (often long-term) to children with bronchiectasis, while in Alaska this practice is uncommon, because macrolide resistance was significantly higher in Australian children compared to those from Alaska.[15] They hypothesized that the two populations would differ in their nasopharyngeal transport of potential respiratory bacterial pathogens and antibiotic resistance genes in these microorganisms. They suspect that because of variations in how antibiotics are prescribed (e.g., frequency, duration, and choice of antibiotic), the two populations may have significant differences in both colonization by respiratory pathogens and the prevalence of resistant bacterial strains. [15]

About a quarter of the children involved in the study had respiratory exacerbations, and both those in Alaska and Australia had *Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis* and *Staphylococcus aureus* colonizing their nasopharynx. On the other hand, unlike the results found in relation to colonization by *S. pneumoniae* which remained stable over time, Alaska and Australia differed in terms of persistence with decline among carriers of *M. catarrhalis* in Alaska children and *H. influenzae* in

Australian children.[15] The authors are comparing the differences in the persistence of colonization by different respiratory pathogens among children in Alaska and Australia across time. The researchers found that whereas *S. pneumoniae* (a common respiratory pathogen) remained stable in both populations, there were notable differences in the persistence of other pathogens. In Alaska, *M. catarrhalis* colonization decreased over time, while in Australia, *H. influenzae* colonization decreased among children. This difference may reflect differences in environmental, genetic, immune, or health practices between the two populations, affecting these pathogens' ability to remain in the respiratory tract over time.[15]

Therefore, in order to investigate the cumulative effect of repeated and prolonged exposure to long-term azithromycin on bacterial transport and resistance, Australian children were divided into three groups based on the frequency of azithromycin use during the study period (no use, use for up to half of the assessment time, use for more than 50% of study visits).[15] Thus, none of the assessed microorganisms showed resistance to beta-lactams, but resistance to macrolides in carriers of *S. pneumoniae* and *S. aureus* was significantly higher in Australian children compared to those from Alaska. This suggests that antibiotic prescribing practices, health policies, or other regional factors may have contributed to a greater selective pressure that favors the development of macrolide resistance in Australian children. All *H. influenzae* isolates from Alaskan children and 80% of Australian children were susceptible to macrolides, with resistance to isolates of *S. pneumoniae*, *H. influenzae*, and *S. aureus* tending to be higher in the group that used azithromycin frequently. However, *S. pneumoniae* resistance increased throughout the study, regardless of the type of exposure to azithromycin.[15] As a result, the authors suggest that bacterial resistance is being influenced by both antibacterial use and other epidemiological dynamics.

Thus, all studies report a significant increase in resistant microorganisms compared to the placebo group when at least one macrolide was administered (the ones used in these studies being azithromycin and erythromycin), mainly related to gram-positive pathogens, as in the case of *Staphylococcus aureus* and *Streptococcus pneumoniae.*[11,15]

This scenario has often been reported for the control of exacerbations in other diseases, such as what has been pointed out since the onset of Covid-19, in which the use of azithromycin and ceftriaxone was reported in over 68% of individuals.[14] In addition, the lack of clear evidence for the beneficial effects of macrolide use both in the pandemic and in bronchiectasis has already been frequently documented by health teams. [17-18]

The increase in macrolide-resistant *S. pneumoniae* was present in two studies [13,15], further highlighting the possible unexpected and undesirable effects of using these antimicrobial agents, including the fact that they are often recommended as first-line agents for the treatment of community-acquired pneumonia (CAP). Thus, macrolide resistance may be a potential cause of treatment failure in patients with CAP.[13,15] Resistance to macrolides in CAP, as described in the articles, occurred due to frequent and inadequate use of these antibiotics, which promoted the selection of resistant bacteria. This resistance compromises treatment efficacy and increases the risk of therapeutic failure and clinical complications.

Azithromycin is the most prescribed macrolide in clinical practice, and its longer half-life favors the dosage (3 times a week).[19] According to the Brazilian consensus on non-cystic fibrosis bronchiectasis, the use of azithromycin is indicated through continued therapy of 6-12 months for patients with bronchiectasis and at least two exacerbations per year, or those with a history of severe exacerbation, primary or secondary immunodeficiency, excluding patients with active infection by non-tuberculous mycobacteria.[3]

On the other hand, these therapeutic practices provide long periods of subinhibitory concentrations that increase the risk of developing antimicrobial resistance by modulating the expression of virulence and pathogenicity genes as well as efflux pumps, especially in gram positives. Moreover, the emergence of resistant strains increases the risk of its transmission to other individuals in the community. [13,19-22]

Therefore, the clinical benefits need to be balanced against the risk of antimicrobial resistance, since the macrolide will not always be the best option as a rescue antimicrobial in exacerbation crises, and the increase in microbial resistance will lead to greater morbidity and mortality of the community as a whole, especially in risk groups, such as children and adults, who have been the main individuals referred in studies of bronchiectasis.[5,14]

Even with the worrying situation of the emergence of microbial resistance, which according to government agencies will be the next global epidemic, there have been few studies involving this topic, especially in patients with bronchiectasis, where the infection still appears to be only yet another event in the vicious cycle of the disease. Therefore, one of the main limitations found in this review was, in addition to the lack of studies, the lack of articles highlighting the resistance associated with the prophylactic or therapeutic use of macrolides in recent years. Therefore, the urgent need to assess patients' clinical conditions and their prognostic outcomes beyond the underlying chronic disease is evident.

The medical community needs to develop an approach to the treatment of non-fibrocystic bronchiectasis that

takes into account not only the immediate benefits to individuals, but also the risks to the wider community, and prognostic outcomes that do not involve recurrent infections with impossibility of cure.[22]

CONCLUSION

Bronchiectasis causes bronchial wall dilation and mucociliary dysfunction, leading to recurrent infections, cough, and sputum. Macrolides are effective antibiotics in the treatment of non-fibrocystic bronchiectasis, but their frequent use can lead to antimicrobial resistance. Studies conducted in Australia, New Zealand and the Netherlands between 2008 and 2016 found that macrolides, particularly azithromycin, can increase the emergence of resistant microorganisms. Therefore, careful monitoring is required when using macrolides to treat non-cystic fibrous bronchiectasis.

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AUTHORS' CONTRIBUTIONS

Nadine Kinetz Funck contribuiu para a pesquisa bibliográfica, redação do resumo, introdução, metodologia, discussão, interpretação e descrição dos resultados, elaboração de tabelas, conclusões e revisão. **Marcelle Oliveira Garcia** contribuiu com revisão crítica relevante do conteúdo intelectual, correção e aprovação final da versão a ser publicada. **Daniel Wenceslau Votto Olmedo** contribuiu na análise e interpretação dos dados. **Daniela Fernandes Ramos** foi responsável por todos os aspectos do trabalho na garantia da exatidão e integridade de qualquer parte da obra.

Todos os autores aprovaram a versão final a ser publicada e são responsáveis por todos os aspectos do trabalho, incluindo a garantia de sua precisão e integridade.

Please cite this article as: Funck NK, Garcia MO, Olmedo DWV, Ramos DF. Impact of the use of macrolide antibiotics on bacterial resistance in non-fibrocystic bronchiectasis: a systematic review. Rev Epidemiol Control Infect [Internet]. 2025 Feb. 16;15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19905

PUBLICAÇÃO OFICIAL DO NÚCLEO HOSPITALAR DE EPIDEMIOLOGIA DO HOSPITAL SANTA CRUZ E PROGRAMA DE PÓS GRADUAÇÃO EM PROMOÇÃO DA SAÚDE - DEPARTAMENTO DE BIOLOGIA E FARMÁCIA DA UNISC

ISSN 2238-3360

Revista de Epidemiologia e Controle de Infecção

Review Article

The use of machine learning methods for computed tomography image classification in the Covid-19 pandemic: a review

O uso de métodos de aprendizado de máquina para classificação de imagens de tomografia computadorizada na pandemia da Covid-19: uma revisão

El uso de métodos de aprendizaje de máquina para clasificación de imágenes de tomografía computarizada en la pandemia de Covid-19: una revisión

Site doi: https://doi.org/10.17058/reci.v15i1.19227

Submitted: 03/12/2024
Accepted: 11/22/2024
Available online: 03/25/2025

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ABSTRACT

Background and Objectives: Covid-19 has been declared a pandemic by the World Health Organization, representing a major challenge worldwide. An early diagnosis method for Covid-19 is based on CT scans, which can be analyzed using artificial intelligence to save medical, logistical, and human resources. Therefore, this study aimed to present the current state of the art in the application of machine learning to classify computed tomography images in the Covid-19 pandemic. **Content:** The review briefly describes the types of machine learning methods for Covid-19 detection, the stages of deep learning model construction (segmentation, augmentation), and selected aspects of explainable artificial intelligence. Finally, the application results are discussed and the most common performance indicators for individual models are given. **Conclusion:** Models and algorithms developed during the peak of the Covid-19 pandemic can be reused in the event of future outbreaks of this or similar infectious diseases.

Keywords: *Covid-19. Tomography, X-Ray Computed. Machine Learning. Deep Learning. Neural Networks, Computer.*

RESUMO

Justificativa e Objetivos: A Covid-19 foi declarada uma pandemia pela Organização Mundial da Saúde, representando um grande desafio em todo o mundo. Um método de diagnóstico precoce da Covid-19 é baseado em tomografias computadorizadas, que podem ser analisadas usando inteligência artificial para economizar recursos médicos, logísticos e humanos. Portanto, o objetivo deste estudo foi apresentar o atual estado da arte na aplicação do aprendizado de máquina para classificar imagens de tomografia computadorizada na pandemia de Covid-19. **Conteúdo:** A revisão descreve brevemente os tipos de métodos de aprendizado de máquina para detecção de Covid-19, os estágios de construção do modelo de aprendizagem profunda (segmentação, aumento) e aspectos selecionados da inteligência artificial explicável. Finalmente, os resultados da aplicação são discutidos e os indicadores de desempenho mais comuns para modelos individuais são dados. **Conclusão:** Modelos e algoritmos desenvolvidos durante o pico da pandemia de Covid-19 podem ser reusados no caso de futuros surtos desta ou doenças infecciosas semelhantes.

Descritores: *Covid-19. Tomografia Computadorizada, Raios X. Aprendizado de Máquina. Aprendizado Profundo. Redes Neurais de Computação.*

RESUMEN

Justificación y Objetivos: La Organización Mundial de la Salud ha declarado que la Covid-19 es una pandemia, lo que ha planteó un gran desafío a nivel mundial. Un método de diagnóstico precoz para Covid-19 se basa en tomografías computarizadas, que pueden analizarse mediante inteligencia artificial para ahorrar recursos médicos, logísticos y humanos. Por lo tanto, el objetivo de este estudio fue presentar el estado actual del arte en la aplicación del aprendizaje automático para clasificar imágenes de tomografía computarizada en la pandemia de Covid-19. **Contenido:** La revisión describe brevemente los tipos de métodos de aprendizaje automático para la detección de Covid-19, las etapas de construcción del modelo de aprendizaje profundo (segmentación, aumento) y aspectos seleccionados de la inteligencia artificial explicable. Finalmente, se discuten los resultados de la aplicación y se presentan los indicadores de rendimiento más comunes para modelos individuales. **Conclusión:** Los modelos y algoritmos desarrollados durante el pico de la pandemia de Covid-19 pueden reutilizarse en caso de futuros brotes de esta o de enfermedades infecciosas similares.

Palabras Clave: *Covid-19. Tomografía Computarizada, Rayos X. Aprendizaje Automático. Aprendizaje Profundo. Redes Neurales de la Computación.*

INTRODUCTION

The first human cases of coronavirus disease 19 (Covid-19) were reported in Wuhan City, China, in December 2019.[1-3] The Covid-19 pandemic was declared on March 11, 2020, by the World Health Organization.[4,5] As of November 1, 2023, 771,548,954 cases and 6,974,460 deaths have been confirmed, ranking Covid-19 fifth among the deadliest epidemics and pandemics in history.[4]

Widely accepted management strategies to restrict the spread of Covid-19 have included lockdowns, travel restrictions, quarantines, social distancing, isolation, infection control measures, and vaccination.[5-7] Different drug types have also been developed and many substances with other indications have been "repurposed" to treat patients with Covid-19.[4] However, the emergence of new worrying variants has become a major problem in the efficient prevention and treatment of the infection.[8] SARS-CoV-2 may cause no symptoms, only mild symptoms such as cramps and fever, or serious complications such as shortness of breath and kidney failure.[3] The risk of severe disease is also higher for older people and for those with underlying conditions, such as diabetes and cancer.[2]

Real-time reverse transcription-polymerase chain reaction (rRT-PCR) is currently the diagnostic gold standard used to confirm Covid-19 infection.[8,9] However, the method is expensive, laborious, time-consuming, requires well-trained personnel to perform sophisticated procedures, and has a relatively low positive detection rate in the early stage.[1,10-15] Furthermore, new genetic variants of SARS-CoV-2 may lead to false-negative results.[16] An early diagnostic method for Covid-19 is based on computed tomography (CT) scans,[1,5,6,10,11,13,17,18] which provide a higher sensitivity rate (88-98%) than RT-PCR (59-71%).[19] Compared with X rays, CT generates more detailed cross-sectional images without tissue overlap, has higher sensitivity and specificity, and can distinguish between Covid-19 and other conditions, such as pneumonia.[2,8,9,12,16] Indeed, CT provides 3D examinations of organs from multiple angles and allows the severity of the infection to be assessed.[6] Three main types of Covid-19-related irregularities have been identified on lung CT images: ground-glass opacification, consolidation, and pleural effusion.[1,9,11,12] To further improve CT analysis, artificial intelligence (AI) can be used,[1,12,20] saving time as well as medical, logistical and human resources,[2,3,8,11] facilitating the detection, classification, diagnosis, segmentation, prediction, and improvement of image quality.[5,20,21]

Therefore, our study aimed to present the current state of the art in the application of machine learning to classify computed tomography images in the Covid-19 period.

METHODS

This narrative review was conducted to assess the literature with a focus on machine learning methods and their use to classify CT images during the Covid-19 pandemic, not to answer a specific research question. This review gathered a group of literature articles on the above-mentioned topic in a qualitative manner. In addition, a quantitative analysis of the literature or its quality was not the main aim of this study. The selection of articles was based on the following inclusion and exclusion criteria.

Eligibility criteria

Only full-text articles on applying machine learning methods to Covid-19 detection based on CT scans were included. The selected articles were published in English between January 1, 2021, and December 31, 2023.

Exclusion criteria

Preprints, conference abstracts, books, book chapters, notes, technical reports, as well as studies not addressing the scientific knowledge about applying machine learning methods to detect Covid-19 based on CT scans were excluded.

Information source and search strategy

The following query was used for searching PubMed (November 24th, 2023): machine learning AND computed tomography AND image classification AND Covid-19.

Selection of studies

Articles that appeared to meet the inclusion criteria were selected for full reading to determine their eligibility. Supplementary articles were included after checking their reference lists.

Data collection

The initial number of articles was 213 but it was reduced to 60 after applying exclusion criteria. The thorough reading and critical evaluation of article content resulted in the selection of the 40 most relevant articles (Figure 1).

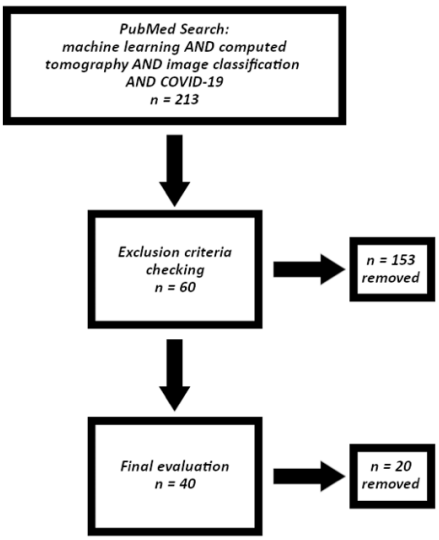

Figure 1. The procedure of article selection (studies from around the world, 2019-2023.

RESULTS

Segmentation and augmentation

Among the five models (U-Net, LinkNet, R2U-Net, Attention U-Net, and U-Net++),[12] the highest values were achieved by LinkNet for Dice coefficient (DC) and intersection over union (IoU) for lung segmentation (0.980 and 0.967, respectively), whereas R2U-Net showed the lowest values (0.962 and 0.928, respectively).[9] The lung area was also segmented from the small cohort of CT images with BCDU-Net,[22] which was inspired by U-Net and involved bi-directional convolutional long short-term memory (ConvLSTM) with densely connected convolutions.[23] In other studies, candidate infected regions were segmented from pulmonary CT images, using a 3D deep learning (DL) model (region proposal network)[14] or Visual Basic NET (VB-Net), followed by various classification methods [convolutional neural networks (CNN) and inception network or random forest (RF)].[13] The authors developed a VB-Net algorithm, which combined the V-Net model with the bottleneck layer, thus integrating the fine-grained Covid-19 image features, reducing the number of feature mapping channels, and effectively increasing the convolution speed. Dynamic fusion segmentation network (DFSN) is another image segmentation method,[18] whose IoU and DC values were 0.800 and 0.530, respectively. The first component of this system automatically segmented infection-related pixels and served as the backbone to extract dynamically selected pixel-level information, which was used to make a final diagnosis. Other authors used a semi-supervised lung infection segmentation deep network (Inf-Net) for chest CT images, including a parallel partial decoder to aggregate high-level features.[10,24] They obtained a slightly lower accuracy for non-infected CT regions and applied an additional classifier to improve the overall model performance.

Lung-lesion maps were obtained from input images processed by different segmentation networks (U-net, DRUNET, FCN, SegNet, and DeepLabv3).[5,25] Pre-trained 2D UNet,[26] unsupervised lung segmentation (Shift3D),[27] entire-lung segmentation (followed by resizing, bin discretization, and radiomic feature extraction),[28] k-means clustering with gray level co-occurrence matrices (for extracting regions of interest and textural features),[29] and a segmentation network within the DL framework (for segmenting lung and lesion areas, thus extracting spatiotemporal information from multiple CT scans to perform auxiliary diagnosis) were also used for image segmentation. In another study,[30,31] over-segmentation mean shift was followed by a superpixel-simple linear iterative clustering algorithm for pulmonary parenchyma segmentation. Each superpixel cluster was described according to its position, grey intensity, second-order texture, and spatial-context-saliency features. Subsequently, the watershed segmentation was applied to the mean-shift clusters to identify ground-glass opacity and pulmonary infiltrates only in the pulmonary parenchyma segmentation-indicated zones. Application of the EfficientNet and EfficientDet networks yielded DC values of 0.980 and 0.730 for lung and Covid-19 segmentation, respectively, whereas a DC of 0.590 was reported for a Unet-like architecture with backbone residual network (ResNet-34).[19,32] Finally, a DC of 0.575 was obtained using a weakly-supervised method based on a generative adversarial network (GAN),[33] whereas a multitask model outperformed individual segmentation models for the joint segmentation of pulmonary lesions.[34]

To prevent overfitting, data augmentation and transfer learning (TL) can be used. The former includes translation, horizontal (and vertical) flipping, and random rotation to enhance the accuracy of model prediction.[5] Augmentation may reduce class imbalance or data scarcity problems.[5,10] Some authors applied facile image transformation (scaling, rotation, and flipping) resources to increase the number of records, whereas others improved the representational learning capability by distortion, painting, and perspective transformation. Finally, GAN was used in two studies on data augmentation.[3,9,33,35,36] The first one involved GAN hyperparameter tuning with the whale optimization algorithm to avoid overfitting and instability, whereas the second one used image-level labels to generate normal-looking CT slices (from those with Covid-19 lesions), whose reality was improved with a feature match strategy.

Classification

An open-source framework consisting of several DL algorithms differentiated Covid-19 from community-acquired pneumonia and other lung diseases.[22] It could

deal with heterogeneous data and small sample sizes irrespective of the CT image source. To increase accuracy and decrease logarithmic loss and testing time, another study used augmented data to train CNN and ConvLSTM-based DL models. They were compared with traditional machine learning (ML) models [support vector machines (SVM) and k-nearest neighbors (k-NN)], and their performance was lower.[3] Covid-19 probability was also predicted using a weakly supervised DL model based on 3D CT volumes from the segmented 3D lung regions.[26] Lung lesions were determined from activation regions in a classification network and unsupervised connected components.

An infection size-aware RF automatically rated patients into classes with the different lesion ranges using the thin-section CT image records for Covid-19 and community-acquired pneumonia.[13] Model performance was further increased by including radiomic features. Another method distinguished Covid-19 from common pneumonia based on lung vessel morphology.[9] It used maximum intensity projection to indicate small-density changes in CT scans, thus accurately reflecting blood vessel condition and calcification of their walls. The applied capsule network used the DenseNet-121 feature extractor and outperformed ResNet-50 and Inception-V3. Community-acquired pneumonia and other non-pneumonic images were also analyzed with a 2D CNN (COVNet), which extracted visual features from volumetric chest CT scans.[23] Input CT slices were fed to a pre-trained ResNet50 to obtain features, which were then combined and processed by a fully connected layer. To increase the contrast between the local lesion regions and the abdominal cavity, another deep CNN-based classification algorithm performed convolution and deconvolution operations.[11] Moreover, discrimination between image types was improved with middle-level features, and they were classified in each channel using a modified open-source Covid-CT dataset.

One of the DL architectures (ResNet-18) distinguished among Covid-19, influenza, and normal subjects.[14] Segmented images were categorized with their corresponding confidence scores using a location-attention classification model. Another ResNet-18 architecture was trained on a large CT dataset for differentiating Covid-19 and other types of viral pneumonia.[25] This system involved segmentation, classification, and quantitative measurements. However, it required manually segmented images and multi-modal data that were difficult to obtain. Covid-19 was also differentiated from common pneumonia and healthy subjects by using a dynamic transfer-learning classification network in which dynamically selected pixel-level information was used for the final diagnosis.[18]

Features extracted by several CNN models (AlexNet, ResNet18, ResNet50, Inceptionv3, Densenet201, Inceptionresnetv2, MobileNetv2, GoogleNet) from the images stored in the Covid-19 Radiography Database were fed to the traditional ML models [SVM, k-NN, naïve Bayes (NB) and decision trees (DT)]. Their hyperparameters were determined with Bayesian optimization.[5] A pretrained InceptionV3 model was also developed for feature extraction and classification using the SARS-CoV-2 CT-Scan dataset.[36] Four different data [University of Texas (Southwestern Medical Center), China Consortium of Chest CT Image Investigation (CC-CCII), Covid-CT set, and MosMedData] sources were used for training DL models. Their best performance was obtained with multiple 3D CT datasets whose classification accuracy decreased when evaluated on an external set without lung field segmentation.[35] In another study,[12] datasets of Covid-19 were distinguished from those of community-acquired pneumonia with a pipeline (including a capsule network with the DenseNet121 block) consisting of four connected modules for lesion slice selection and slice- and patient-level prediction.

A multitask learning framework (involving task prioritization, convergence acceleration, and joint learning performance improvement) automatically classified CT images into Covid-19 positive or negative cases using a random-weighted loss function.[27] Covid-19 was detected with 3D CNN and an auxiliary feed-forward ANN based on chest CT scans and RT-PCR results. Clinical metadata also helped with distinguishing between Covid-19 and other viral pneumonia in a patient-level method (including InceptionResnetV2), which aggregated chest CT volumes into 2D representations.[34] A combination of features from chest CT volumes improved model performance compared with clinical data alone. Other DL models (AlexNet, ResNet50, and SqueezeNet) were also compared with the traditional ML ones (NB, bagging, and Reptree). They classified CT images into two categories (Covid and non-Covid),[29] whereas a custom 3D CNN trained on the CT scans from patients with suspected or known Covid-19 assigned images to three groups (Covid-19, other type of pulmonary infection or lack of infection signs).[32] More classes (severe-, moderate-, mild-, and non-pneumonic patients) were included in a multinomial logistic regression model, which was trained on the CT radiomic features selected by two feature selection algorithms (RF and multivariate adaptive regression splines).[28]

Automatic systems trained on multiple Covid-19 CT images were developed for Covid-19 detection (using spatiotemporal information fusion) or identification of ground-glass opacity, and pulmonary infiltrates to

assess disease progression during the patient's follow-up assessment and evaluation.[30,31] Differently, thousands of labeled CT images were used for a Covid-19 decision support and segmentation system (involving the EfficientNet and EfficientDet networks), which rejected non-related images using a header analysis and classifiers.[19]

Performance indicators for the models included in this review presented different values (for studies with two or more models, only that with the maximum sensitivity is mentioned) (Table 1).

Table 1. Performance indicators for Covid-19 detection models (studies from around the world, 2019-2023).

Author	Country	Objectives	Methods	Main results	Se (Re)	Sp	PPV (Pr)	NPV	Acc	F1	MCC	AUC
Sedik *et al.* (2020)[3]	Egypt	To improve the learnability of CNN and the convolutional long short-term memory-based DL models and increase the accuracy of COVID-19 detection.	Two data-augmentation techniques based on simple image transformations and generative adversarial networks.	Acc, logarithmic loss, and testing time were improved relative to DL models without data augmentation; an increased Acc (4-11%) was observed between data-augmented DL models and other investigated ML techniques.	0.997	0.987	0.987	0.997	1.000	0.990	0.984	0.990
Aslan *et al.* (2022)[5]	Turkey	To classify CT chest images from the COVID-19 Radiography Database and determine hyperparameters of ML algorithms.	Automatic lung segmentation with ANN; data augmentation, feature extraction with CNN, classification with support vector machines, k-nearest neighbors, naive Bayes, and decision trees; hyperparameter determination with Bayesian optimization.	DenseNet201 model and support vector machines showed the best predictive performance.	0.964	0.981	0.964	-	0.963	0.945	0.964	-
Wu *et al.* (2023)[9]	China	To accurately and automatically distinguish between COVID-19 and CAP using DL.	A DL method was based on maximum-intensity projection images (obtained from CT scans); they served as inputs into a capsule network trained and validated on 333 and 3581 CT scans, respectively.	LinkNet achieved the highest DC; the capsule network with the DenseNet-121 feature extractor outperformed ResNet-50 and Inception-V3; Acc decreased to 0.857 and 0.818 without maximum-intensity projection or capsule network, respectively; Acc of 0.961, 0.997, and 0.949 were achieved on the external validation datasets; Se was higher than or comparable to other state-of-the-art methods.	0.971	0.968	0.971	-	0.970	-	-	0.986
Qi *et al.* (2022)[12]	China	To improve existing ML methods for distinguishing between COVID-19 and CAP based on CT images.	A fully automatic DL pipeline comprising four connected modules (for lung segmentation, slice selection, and slice- and patient-level prediction) was trained and tested on 326 CT scans; its generalization capability was evaluated on a public dataset of 110 patients.	LinkNet exhibited the largest IoU and DC; the capsule network with ResNet50 achieved an Acc of 0.925 and AUC of 0.933 in the selection of slices with lesions; the capsule network with DenseNet121 showed an Acc of 0.971 and AUC of 0.992 for slice-level prediction; Acc of 1.000 was obtained for patient-level prediction.	0.997	0.966	0.965	-	0.981	-	-	0.983
Shi *et al.* (2021)[13]	China	To rapidly and accurately screen patients with COVID-19 and CAP using ML.	COVID-19 (1658) and CAP (1027) patients underwent thin-section CT; segmentation of infection and lung fields were used to extract location-specific features; a random forest categorized patients with different ranges of infected lesion sizes and classified them within each group.	Large performance margins were achieved against comparison methods, especially for medium infection size (0.01% to 10%); the inclusion of radiomic features slightly improved classification results.	0.907	0.833	-	-	0.879	-	-	0.942

Author	Country	Objectives	Methods	Main results	Se (Re)	Sp	PPV (Pr)	NPV	Acc	F1	MCC	AUC
Xu *et al.* (2020)[14]	China	To establish an early screening model for distinguishing COVID-19 from influenza-A viral pneumonia and healthy cases based on pulmonary CT images and DL.	Different numbers of samples were used for COVID-19 (219), influenza-A viral pneumonia (224), and healthy subjects (175); infection regions were determined using a 3D DL model; separated images were categorized with the corresponding confidence scores using a location-attention classification model; infection types and confidence scores were calculated using the noisy-OR Bayesian function.	The overall Acc on the benchmark dataset was 86.7% for all CT cases taken together.	0.900	-	0.931	-	0.867	0.915	-	-
Zhang *et al.* (2022)[18]	China, UK, Belgium	To automatically segment lesions from CT images and distinguish COVID-19 in common pneumonia patients and healthy subjects.	A dynamic fusion segmentation network segmented infection-related pixels and aggregated low-level features that were fused to model multi-scale semantic information; COVID-19 patients were identified with a dynamic transfer-learning classification network.	Two models achieved state-of-the-art performance in segmentation and classification tasks.	0.980	-	0.820	-	0.770	-	-	-
Carmo *et al.* (2021)[19]	Brazil	To develop and deploy a COVID-19 decision support and segmentation system based on CT and X-ray images.	EfficientNet and EfficientDet segmented and classified images in a real-time scalable manner in communication with a Picture Archiving and Communication System; non-related images were rejected using header analysis and classifiers.	Acc values of 0.94 and 0.98 were achieved for CT and X-ray classification, respectively, whereas those DC for lung and COVID-19 segmentation were 0.98 and 0.73, respectively; the median response times were 7 s for X-ray and 4 min for CT.	0.953	-	0.905	-	0.944	0.928	-	0.979
Shiri *et al.* (2021)[20]	Iran, Switzerland, Canada, The Netherlands, Denmark	To develop prognostic survival models for COVID-19 patients using clinical data and lung and/or lesion radiomic features extracted from chest CT images.	Survival modeling was based on radiomic features and clinical data (separately or in combination); the maximum-relevance minimum-redundancy method and XGBoost were used for feature selection and classification.	Cancer comorbidity, consciousness level, and radiological score were highly correlated with survival; oxygen saturation and blood urea nitrogen were important clinical features; small-area high-gray-level emphasis and high-gray level-zone emphasis from gray-level size-zone matrix, run-length non-uniformity from gray-level run-length matrix, and high-gray-level-zone emphasis from gray-level size-zone matrix yielded the highest predictive performance; the most accurate prognostic model included combined lung, lesion, and clinical features.	0.880	0.890	-	-	0.880	-	-	0.950
Javaheri *et al.* (2021)[22]	Iran, USA, Canada, Vietnam	To enhance the Acc of CT image-based COVID-19 recognition.	CovidCTNet (an open-source framework) differentiated COVID-19 from CAP and other lung diseases.	CovidCTNet increased the Acc of CT image-based COVID-19 detection to 95% compared with radiologist evaluation (70%) and was independent of the CT imaging hardware.	0.909	1.000	-	-	0.933	-	-	0.940
Li *et al.* (2020)[23]	China	To develop a fully automatic framework for COVID-19 detection using chest CT scans.	COVID-19 detection neural network (COVNet) extracted visual features from 4352 volumetric chest CT scans obtained from 3322 patients.	COVNet showed a high predictive performance on the independent test set.	0.900	0.960	-	-	-	-	-	0.960

Author	Country	Objectives	Methods	Main results	Se (Re)	Sp	PPV (Pr)	NPV	Acc	F1	MCC	AUC
Zhang *et al.* (2020)[25]	China	To develop an AI system for diagnosing COVID-19 pneumonia and differentiating it from other common types of pneumonia and normal controls.	AI system identified clinical markers correlated with COVID-19 lesion properties and provided accurate clinical prognosis together with clinical data.	Globally available AI systems showed high predictive performance.	0.949	0.911	-	-	0.925	-	-	0.980
Wang *et al.* (2020)[26]	China	To develop a DL-based model for automatic COVID-19 diagnosis based on chest CT images.	A weakly-supervised DL framework used 3D CT volumes for COVID-19 classification and lesion localization; the UNet-segmented 3D lung regions were fed into a 3D DL network; CT volumes were used for training (499) and testing (131).	The algorithm took only 1.93 s to process a single patient's CT volume; the weakly-supervised DL model could accurately predict COVID-19 without lesion annotation.	0.907	0.911	0.840	0.982	0.901	-	-	0.959
Bao *et al.* (2022)[27]	China, Australia	To develop an end-to-end multitask learning framework (COVID-MTL) capable of automated and simultaneous detection and severity assessment of COVID-19.	COVID-MTL learned different COVID-19 tasks in parallel through the random-weighted loss function; the 3D real-time augmentation algorithm (Shift3D) introduced space variances for 3D CNN components; MTL accelerated convergence and improved joint learning performance compared to single-task models; COVID-MTL was trained on 930 CT scans and tested on 399 cases.	COVID-MTL achieved high performance in the detection of COVID-19 against radiology and nucleic acid tests, outperforming other state-of-the-art models; COVID-MTL yielded AUC of 0.800 and 0.813 for classifying control and/or suspected, mild and/or regular, and severe and/or critically-ill cases.	0.902	-	0.912	-	0.902	0.905	-	0.939
Guhan *et al.* (2022)[29]	India, Saudi Arabia	To segment the CT images using k-means clustering, extract textural features using gray level co-occurrence matrix, and classify CT scans using ML.	One hundred COVID-19 and non-COVID-19 images were segmented and classified with naive Bayes, bagging, and REPTree; pre-trained AlexNet, ResNet50, and SqueezeNet were used for predictive performance comparison.	Naive Bayes and ResNet50 achieved the highest Acc (97.0% and 99.0%, respectively).	0.990	-	0.980	-	0.991	-	-	0.990
Li *et al.* (2021)[30]	China	To automatically detect COVID-19 based on spatiotemporal information fusion.	The spatiotemporal information features of multiple CT scans were extracted using a segmentation network to perform auxiliary diagnosis.	High predictive performance was achieved in the classification of COVID-19 and non-COVID-19 CT scans; each scan took about 30 s for detection.	0.953	-	0.967	-	0.944	0.960	-	0.946
Tello-Mijares *et al.* (2021)[31]	Mexico	To automatically identify ground-glass opacity and pulmonary infiltrates in CT images from COVID-19 patients and assess disease progression during the patient's follow-up evaluation.	Oversegmentation mean-shift followed by superpixel-simple linear iterative clustering was applied to COVID-19 CT images for pulmonary parenchyma segmentation.	Pulmonary parenchyma identification had a precision and recall of over 92.0% on twofold cross-validation; pulmonary infiltrate identification for ground-glass opacity showed a precision and recall of 96.0%.	0.968	-	0.967	-	-	0.967	-	0.983
Topff *et al.* (2023)[32]	The Netherlands, Spain, Belgium	To develop a DL-based clinical decision support system for the automatic diagnosis of COVID-19 on chest CT scans and construct a complementary segmentation tool for assessing the extent of lung involvement and measuring disease severity.	Data annotation was performed by 34 radiologists and/or radiology residents including quality control measures; 2,802 CT scans were ranked with a multi-class classification model created using a 3D CNN; an UNET-like architecture with a backbone Residual Network (ResNet-34) was selected for image segmentation.	The diagnostic multiclassification model yielded high micro-average and macro-average values for AUC (0.93 and 0.91, respectively) on the external test dataset; the segmentation performance was moderate (DC=0.59).	0.870	0.940	0.950	0.830	0.900	-	-	0.830

Author	Country	Objectives	Methods	Main results	Se (Re)	Sp	PPV (Pr)	NPV	Acc	F1	MCC	AUC
Yang *et al.* (2021)[33]	China, Taiwan	To localize COVID-19 lesions with a weakly-supervised method based on a generative adversarial network using only image-level labels.	A generative adversarial network-based framework generated normal-looking CT slices from CT slices with COVID-19 lesions; a feature match strategy improved the quality of generated images; the localization map of lesions was obtained by subtracting the output image from its corresponding input image; a diagnostic system with improved classification Acc was obtained by adding a classifier branch to the generative adversarial network-based framework.	The weakly-supervised learning method obtained a DC of 0.575 and exceeded other widely used weakly-supervised object localization approaches; its performance was similar to that of fully supervised learning methods in the COVID-19 lesion segmentation task (DC of 0.575); the common severity cohort had the largest sample size as well as the highest visual score.	0.647	0.929	-	-	0.884	0.640	-	0.883
Ortiz *et al.* (2022)[34]	USA	To assess the value of aggregated chest CT data for COVID-19 prognosis compared to clinical metadata alone.	A patient-level algorithm aggregated chest CT volumes into 2D representations that were integrated with clinical metadata to distinguish COVID-19 patients from healthy participants and patients with other viral pneumonia; the multitask segmentation approach was compared to combining feature-agnostic volumetric CT classification feature maps with clinical metadata for predicting mortality.	A multitask model for joint segmentation of different classes of pulmonary lesions present in COVID-19-infected lungs outperformed individual segmentation models for each task; a combination of features derived from chest CT volumes improved AUC values to 0.80 from 0.52 obtained by using only patients' clinical data.	0.590	-	0.690	-	0.920	0.750	-	0.810
Goel *et al.* (2021)[36]	India, Australia, Korea	To generate CT images using a generative adversarial network and optimize its hyperparameters using the whale optimization algorithm.	The method was tested with different classification and meta-heuristic algorithms using the SARS-CoV-2 CT-Scan dataset, consisting of COVID-19 and non-COVID-19 images.	The performance of the optimized model was better than that of other state-of-the-art methods.	0.998	0.978	0.978	0.998	0.992	0.988	-	-

Abbreviations: Acc: accuracy; ANN: artificial neural network; AUC: area under the curve; CAP: community-acquired pneumonia; CNN: convolutional neural network; CT: computed tomography; DC: Dice coefficient; DL: deep learning; F1: F1-score; IoU: intersection over union; MCC: Matthew correlation coefficient; ML: machine learning; NPV: negative predictive value; PPV (Pr): positive predictive value (precision); Se (Re): sensitivity (recall); Sp: specificity.

DISCUSSION

Types of methods

Machine learning, which belongs to the AI domain, can generally be divided into "traditional methods" and deep learning (both of which can be applied for pattern recognition, regression, or classification).[18] The difference lies in the way images are pre-processed, among other things. Whereas the first group relies on expert-derived inputs (such as the average greyscale) that require human involvement, the second uses the whole images as inputs and extracts the features by itself.[5-7,10,11,16,21] It can be successfully used for medical-related imaging tasks, such as image preprocessing, registration, detection, and segmentation.[6] In the context of Covid-19, DL has been applied at the molecular (*e.g.*, protein structure prediction), patient (*e.g.*, medical imaging for diagnosis), and population (*e.g.*, epidemiology) scales.[18] Deep learning, as a data-driven approach, performs classification based on the image features learned by a model during the training stage.[6,8]

It usually involves the type of artificial neural network (ANN), also called convolutional neural network (CNN). They have gained much popularity due to their higher performance in automatic disease detection tasks.[5,6,11,16] Other DL methods include recurrent neural networks, deep belief networks, and reinforcement learning.[10] One of the CNN architectures (named AlexNet, with fully supervised learning) achieved excellent performance on highly challenging datasets. It was the winner of the ImageNet Large Scale Visual Recognition Challenge (ILSVRC) in 2012.[6,16] A wide range of ANN settings and training skills (ReLU, dropout, pooling, and local response normalization) enabled more effective CNN training and better performance.[6,37] It has been used in many studies on

Covid-19 detection that mainly differed in the feature selection method and training of multiple classifiers. Since AlexNet was created, more advanced pre-trained networks based on this architecture (VGG, GoogLeNet, ResNet, DenseNet, MobileNet, SqueezeNet, and Network in Network) have been applied to Covid-19 detection.[5,7,16] Visual Geometry Group, which is simple in architecture but effective in performance, was the winner of the ILSVRC challenge in 2014.[6] ResNet and DenseNet both use residual blocks and skip connections to make image-level classification. They also employ attention mechanisms, multi-view presentation learning, and semi-supervision because high-level features tend to lose details of the input image and the above-mentioned methods may fail in complex imaging data.[18]

Pretrained networks can be reused in the process called transfer learning (TL).[10] The trained model can be transferred to a new one, for which additional training data may be provided and in which modified neural layers can be incorporated.[16] After automatic feature extraction (using TL with pre-trained models or custom CNN developed from scratch), ML methods (such as k-NN, SVM, DT, or NB) can be used to classify these features as Covid-19 or non-Covid-19 (e.g., normal or viral pneumonia).[5,6]

Deep learning stages

The DL algorithm may include several steps, such as pre-processing, segmentation, feature extraction, classification, performance evaluation, and explainable model prediction.[6,10] Preprocessing is the first stage in CT image analysis, for which different techniques are used. In preprocessing, raw images are converted into an appropriate format for further analysis. Medical images collected from different devices can vary in size, slice thickness, and the number of scans (*e.g.*, 60-70 in CT).[2,6] During preprocessing, resizing, normalization, and sometimes conversion from RGB to grayscale are performed.[16] In addition, the voxel dimension is resampled to account for the variation across datasets (resampling to an isomorphic resolution). Images are also improved with smoothing to increase the signal-to-noise ratio.

Segmentation is the next step of image preprocessing, for which a full CNN and its variants have been used.[1,6] An image that shows only the lungs is more appropriate for infection detection. This is probably because it prevents the model from focusing on unwanted targets like bone and soft tissue.[8] To achieve this, the lung region must be segmented from the raw image, which enables a more successful diagnosis. The lung area of the original image is cut by the segmentation process.[5] Sometimes, pixel values are also limited to obtain a proper range of Hounsfield units in the lung image.[6] In segmentation, underused multi-scale context information, high variance in texture, size and position of infected regions, and small inter-class variance of lesions are potential challenges.[18] Manual lung segmentation is laborious, tedious, time-consuming, and heavily depends on the radiologists' knowledge and experience.[6] However, DL-based segmentation techniques can automatically identify infected regions, thus allowing rapid screening of Covid-19 images. Classic U-Net, UNet++, and VB-Net are the popular segmentation methods.[2,6,10]

Of all DL models, U-Net is the most famous architecture for segmentation, whose results may also be affected by image type. For example, two different segmentation approaches were used for the NIFTI and DICOM CT lung images as no method works for all image formats.[8]

Dice coefficient (DC) and intersection over union (IoU) are the two common measures for evaluating segmentation effectiveness.[18] The first one is defined as:[38]

$$DC = \frac{2|A \cap B|}{|A|+|B|},$$

where A is a set that represents the ground truth and B represents the computed segmentation.

IoU, also known as the Jaccard index, is the most commonly used metric for comparing the similarity between two arbitrary shapes.[39] It encodes the shape properties of the objects under comparison into the region property and calculates a normalized measure with a focus on their areas (or volumes). It is given by the following formula:

$$IoU = \frac{|A \cap B|}{|A \cup B|}.$$

After segmentation, augmentation is employed to increase the segmented image count, thus providing data diversity.[5,16] Rotation, shifting in the width and height dimensions, shearing, zooming, flipping in the horizontal and vertical axes, and brightness changing can be used for this purpose.[10]

Explainable artificial intelligence

Deep learning black-box models provide no evidence of correctly extracted features. On the other hand, explainable AI is an emerging field that assigns certain values to image regions leading to the predicted outcome. Thus, radiologists can locate abnormalities in the lungs and have an insight into the important areas responsible for image classification.[6] According to some authors,[21] CT was the second most common (20.0%) image modality coupled with explainable AI, although other studies reported a combined application to CT and X rays. It should be noted that the performance of Covid-19 detection models can be further improved by incorporating both kinds of images (chest X-ray or CT).[6] Explainable AI has most often been applied to lung examination and used different publicly available data repositories of CT images for Covid-19 diagnosis

(Kaggle, Signal Processing Grand Challenge on Covid-19 dataset, Covidx CT, Covidx CT-2A & Covidx CT-2B, CC-CCII, MosMedData, Covid-Ctset, LTRC dataset, CT Chest Images Dataset from Mendeley, Covid pandemic, iRoads, Caltech-256, and Caltech-101). The availability of such repositories was the main reason for the advancement of Covid-19 studies among those using explainable AI.

Supervised vs. unsupervised learning

Further division of ML is based on the role of a "teacher" or "trainer": in supervised learning, a loss function is optimized considering predicted labels and ground truth requiring manual annotation; in unsupervised learning, data patterns are found automatically using clustering.[2] To achieve the best performance, all ML methods must be configured before the training process using hyperparameter optimization.[5,16] Hyperparameters differ from model parameters: the former (such as the number of ANN layers, size, shape, type, number of neurons, intermediate processing elements, etc.) are calculated before the training phase, whereas the latter (such as weights) are optimized during learning. There are several ways to set the hyperparameters and different strategies can be adopted (including a manual one). Many algorithms, such as Bayesian optimization, grid search, swarm optimization (e.g., Sparrow optimization algorithm), etc., can be used to search the optimal hyperparameter.[16]

Performance indicators

The most frequently reported model performance indicators are as follows: sensitivity (or recall; Se), specificity (Sp), accuracy (Acc), positive predictive value (or precision; PPV), negative predictive value (NPV), F-measure (F1), Matthews correlation coefficient (MCC), and area under the curve (AUC).[2,8,16] They are expressed by the following equations:[6,9-12,40]

$$Se = \frac{TP}{TP+FN}, Sp = \frac{TN}{TN+FP}, PPV = \frac{TP}{TP+FP}, NPV = \frac{TN}{TN+FN}, Acc = \frac{TP+TN}{TP+TN+FP+FN},$$

$$F_1 = 2\frac{PPV \cdot Se}{PPV+Se}, MCC = \frac{TN \cdot TP - FN \cdot FP}{\sqrt{(TP+FP)(TP+FN)(TN+FP)(TN+FN)}},$$

where *TP*, *TN*, *FP*, and *FN* are the numbers of true positives, true negatives, false positives, and false negatives, respectively. Area under the curve (AUC) is the area under the receiver operating characteristic curve (Figure 2).

To evaluate the performance of a model, the dataset is usually divided into a training, validation, and test set. Training data are used to develop a model, whereas the learning process and model quality are assessed by monitoring overfitting or underfitting on the validation set. The model is finally evaluated on an independent test set, assuming that the input features are similar to those learned in the training set.[6] K-fold cross-validation is an alternative approach to model testing.[10]

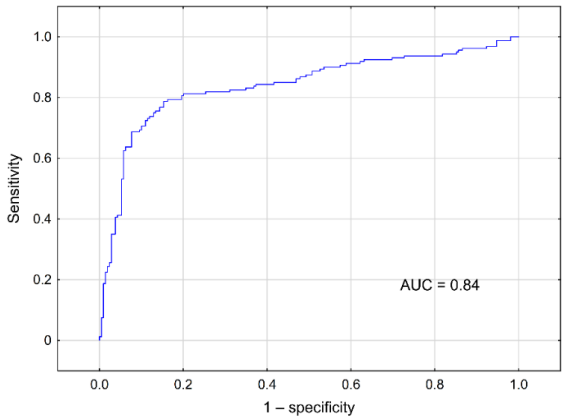

Figure 2. An example of a receiver operating characteristic (ROC) curve (studies from around the world, 2019-2023); AUC: area under the curve.

Finally, some limitations of the present study must be mentioned. The first limitation of this review is the total number of references (40) that were finally included in the text. The second limitation, which is also a drawback, is the use of only one database (PubMed) for article search. However, the inclusion of additional literature sources would have increased the number of references even further. Therefore, a final representative subset of original studies and review articles was selected from the largest biomedical bibliographic database in the world.

CONCLUSION

Most studies on the use of artificial intelligence for Covid-19 diagnosis involved deep learning and feature extraction methods. Segmentation and augmentation were also frequently applied to improve model performance and overcome data scarcity. More extensive data sets and standardized modeling procedures, including an objective evaluation of model predictive capabilities, will be required in the future to introduce these methods into the common clinical practice. Models developed during the peak of the Covid-19 pandemic can be reused in future outbreaks of other similar diseases.

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AUTHORS' CONTRIBUTIONS

Daniel Zaborski and **Jacek Sieredziński** contributed to the literature search, writing of the abstract, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review, and statistics.

All authors have approved the final version to be published, being responsible for all aspects of the work and ensuring its accuracy and integrity.

Please cite this article as: Sieredzinski J, Zaborski D. The use of machine learning methods for computed tomography image classification in the Covid-19 pandemic: a review. Rev Epidemiol Control Infect [Internet]. 2025 Feb. 16;15(1). Available from: https://online.unisc.br/seer/index.php/epidemiologia/article/view/19227