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Original Article

Flowchart for the management of *Clostridium difficile* infection in intensive care settings: a validation study

Fluxograma para manejo da infecção por Clostridium difficile em ambiente de cuidado intensivo: um estudo de validação
Flujograma para el manejo de la infección por Clostridium difficile en entornos de cuidados intensivos: un estudio de validación

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ABSTRACT

Background and Objectives: Despite the clinical relevance of *Clostridium difficile* infection, difficulties in diagnosis and appropriate management remain frequent, especially in intensive care settings. The absence of standardized protocols compromises decision-making and patient safety. Furthermore, there are gaps in the training of professionals regarding the identification and handling of cases. In this context, the development of an evidence-based flowchart emerges as an essential strategy to guide healthcare practice, promote consistent approaches, and enhance the quality of care provided to critically ill patients affected by this infection. Therefore, the objective was to develop and validate a flowchart for the management of diarrheal syndromes caused by Clostridium difficile in the ICU. **Methods:** Methodological study conducted at a University Hospital, carried out in three phases: literature review for the development of the evidence-based flowchart, validation of the instrument by expert professionals, and statistical analysis of the data. The study complied with ethical standards. **Results:** The resulting flowchart was validated by the experts, achieving 100% agreement after two consultation rounds. The instrument proved to be suitable for guiding the management of patients infected with *Clostridium difficile* in the ICU, offering a clear, objective, and relevant structure. **Conclusion:** The developed and validated flowchart is a valuable tool for clinical practice in the ICU, promoting effective and standardized care for patients with *Clostridium difficile* infection. Its application may reduce discrepancies in diagnosis and treatment, ensuring safety and efficiency in the care of critically ill patients through a uniform and effective approach.

Keywords: *Clostridium difficile. Intensive Care Units. Workflow. Nursing.*

RESUMO

Justificativa e Objetivos: Apesar da relevância clínica da infecção por *Clostridium difficile*, ainda são frequentes as dificuldades no diagnóstico e no manejo adequado, especialmente em ambientes de terapia intensiva. A ausência de protocolos padronizados compromete a tomada de decisão e a segurança do paciente. Além disso, há lacunas na formação dos profissionais quanto à identificação e à condução dos casos. Nesse contexto, a construção de um fluxograma baseado em evidências surge como estratégia essencial para orientar a prática assistencial, promover condutas uniformes e qualificar o cuidado prestado a pacientes críticos acometidos por essa infecção. Portanto, objetivou-se construir e validar um fluxograma para o manejo de síndromes diarreicas causadas por *Clostridium difficile* na UTI. **Métodos:** Estudo metodológico, de abordagem quantitativa e delineamento transversal, realizado em um Hospital Universitário, conduzido em três fases: revisão da literatura para o desenvolvimento do fluxograma fundamentado em evidências, validação do instrumento por profissionais *experts* utilizando a Técnica *Delphi* e análise estatística dos dados. **Resultados:** O fluxograma resultante foi validado pelos *experts*, obtendo 100% de concordância após duas rodadas de consulta. O instrumento demonstrou ser adequado para orientar o manejo de pacientes infectados por *Clostridium difficile* na UTI, oferecendo uma estrutura clara, objetiva e relevante. **Conclusão:** O fluxograma construído e validado é uma ferramenta valiosa para a prática clínica na UTI, promovendo assistência eficaz e padronizada aos pacientes com infecção por *Clostridium difficile*. Sua aplicação pode reduzir divergências no diagnóstico e no tratamento, garantindo segurança e eficiência no cuidado aos pacientes críticos por meio de uma abordagem uniforme e eficaz.

Descritores: *Clostridium difficile. Unidades de Terapia Intensiva. Fluxo de Trabalho. Enfermagem.*

RESUMEN

Justificación y Objetivos: A pesar de la relevancia clínica de la infección por *Clostridium difficile*, aún son frecuentes las dificultades en el diagnóstico y el manejo adecuado, especialmente en entornos de cuidados intensivos. La ausencia de protocolos estandarizados compromete la toma de decisiones y la seguridad del paciente. Además, existen lagunas en la formación de los profesionales en cuanto a la identificación y el manejo de los casos. En este contexto, la construcción de un diagrama de flujo basado en evidencias surge como una estrategia esencial para orientar la práctica asistencial, promover conductas uniformes y mejorar la calidad del cuidado brindado a los pacientes críticos afectados por esta infección. Por lo tanto, se objetivó construir y validar un diagrama de flujo para el manejo de los síndromes diarreicos causados por *Clostridium difficile* en la UCI. **Métodos:** Estudio metodológico realizado en un Hospital Universitario, conducido en tres fases: revisión de la literatura para el desarrollo del diagrama de flujo basado en evidencias científicas, validación del instrumento por profesionales expertos y análisis estadístico de los datos. El estudio cumplió con las normas éticas. **Resultados:** El diagrama de flujo resultante fue validado por los expertos, obteniendo un 100% de concordancia tras dos rondas de consulta. El instrumento demostró ser adecuado para orientar el manejo de pacientes infectados por *Clostridium difficile* en la UCI, ofreciendo una estructura clara, objetiva y pertinente. **Conclusión:** El diagrama de flujo construido y validado es una herramienta valiosa para la práctica clínica en la UCI, promoviendo una atención eficaz y estandarizada a los pacientes con infección por *Clostridium difficile*. Su aplicación puede reducir las discrepancias en el diagnóstico y tratamiento, garantizando seguridad y eficiencia en el cuidado de pacientes críticos mediante un enfoque uniforme y eficaz.

Palabras Clave: *Clostridium difficile. Unidades de Cuidados Intensivos. Flujo de Trabajo. Enfermería.*

INTRODUCTION

Intensive care units (ICU) are hospital environments that demand highly complex care. These highly prepared places care for long-term patients in an acute or critical state of organic dysfunctions who face the imminent possibility of death or loss of one or more physiological functions.

In 2020, the Brazilian Association of Intensive Care Medicine mapped the care capacity of ICUs in the country, totaling 45,848 beds (following the guidelines of the World Health Organization and the Brazilian Ministry of Health, which determine an ideal ratio of one to three beds for every 10,000 inhabitants)—22,844 in the Brazilian Unified Health System and 23,004 in the private sector. The Brazilian Southeast stands out as the region with the largest number of beds: just over 24,000.[1,2]

Patients in this sector need uninterrupted medical and nursing assistance, specialized teams, and a large technological apparatus. Observing the scenario of ICUs (structural situation, long hospital stays, and the conditions of those admitted) shows that their patients often suffer from several complications during their stay.

Health care-associated infections constitute one of the complications in intensive care patients. These adverse events are defined as infections that affect individuals undergoing hospitalization or care procedures in hospitals or in outpatient care. They are considered one of the most important public health problems worldwide, greatly impacting hospital mortality, costs, and length of stay. The most frequent health care-associated infections in intensive care refer to multidrug-resistant microorganism colonies, i.e., microorganisms that can resist at least one potentially effective antimicrobial agent in three or more classes, a relevant clinical challenge due to its therapeutic limitations.[3]

Clostridium difficile (CD), a multidrug-resistant microorganism, can cause healthcare-associated infections. A recent study has highlighted this pathogen as the main causative agent of antibiotic-associated diarrhea in the world, accounting for 20% of all cases in hospitalized patients. It configures one of the most important complications in the health environment, being easily disseminated and difficult to eradicate in hospitals.[4]

This gram-positive, anaerobic, and sporulating bacillus lies in the intestinal microbiota of humans in its latent form. However, in patients under antimicrobials, the pathogen sporulates and spreads across patients' intestines to defend itself from pharmacological aggressions. Such spores can resist thermal and chemical attacks (including stomach acid), remaining viable for months.[5]

Transmitted via the fecal-oral route, its spores are released via feces in the hands of patients and healthcare providers, medical devices, and other utensils and technological devices in ICUs. In addition to being intrinsically related to antibiotic therapy, the use of proton pump inhibitors and histamine H2 may also contribute to the development and dissemination of CD.[6]

CD infections have a high mortality rate and recurrence frequency. Such recurrence can lead patients to depend on the continuous use of antimicrobials, which negatively impacts their quality of life and favors the perpetuation of a cycle of infection since antibiotic therapy is an important risk factor for CD infection[7].

This infection shows wide global dissemination, being the most common among nosocomial infections in hospitals and causing most gastrointestinal tract infections. Its release of toxins can cause manifestations ranging from mild diarrhea to severe and potentially fatal pseudomembranous colitis[8].

The United States Centers for Disease Control and Prevention have estimated that one in five patients will have a recurrence of CD infection within a month of diagnosis. It also points out that one in 11 people over the age of 65 will die because of such infections.[9] During the last three decades, CD has increased in incidence and severity throughout the world. Patients who develop it endure longer hospital stays; higher medical care costs and recurrence of hospital admissions, possibility of recurrence of the disease, and high mortality.[10]

Although a pathogen of great microbiological importance due to its consequences to patients, Brazil has scarce data on CD infections, which may be directly related to underreporting due to lack of diagnosis since testing is expensive and often unavailable in health institutions.

Moreover, managing CD infections also offers challenges. A study with intensive care professionals found great disagreement or little knowledge related to the diagnosis and treatment of diarrheal conditions due to CD. It highlighted the lack of consensus regarding the understanding of the causes of the incidence, the establishment of the diagnosis, and the management of patients with diarrhea.[11]

Considering the medical and epidemiological importance of CD and its consequences and the evident difficulty healthcare providers face to identify, diagnose, and manage infections, this study aims to construct and validate a flowchart for the management of diarrheal syndromes due to CD in the intensive care unit of a regional university hospital in northwestern Paraná. This research sought to answer the following guiding question: "What would a flowchart for professionals working in ICUs on managing diarrheal syndromes due to CD would look like?"

METHODS

This methodological study with a quantitative approach and cross-sectional design constructed and validated a flowchart to manage adult patients infected with CD who were admitted to the chosen ICU. From the beginning of August to December 2022, this research was developed in three stages: a theoretical one consisting of an exploratory literature review, layout elaboration, design, and texts; an empirical one, which consisted of the evaluation of the flowchart by expert professionals via judge content validation.[12]

The Delphi Technique was used in the validation process. It consists of a structured method to seek consensus among a group of experts on a topic via systematic rounds of evaluation and feedback, ensuring the anonymity and reliability of the collected opinions.[13] The analytical phase consisted of statistical analyses of the data.

Research Scenario

This study was developed at a regional university hospital in northwestern Paraná. An adult ICU with eight beds and clinical, surgical, and traumatological care was chosen as the research scenario. The hospital has 130 beds in sectors such as medical clinic; surgical clinic; emergency care; wards, semi-intensive; and adult, general, and pediatric ICUs. GSUS (an electronic medical record system) is used in the hospital. It includes patients' medical and socioeconomic information and tools that help and standardize care.

Flowchart Development

Theoretical phase: the first phase (an exploratory literature review) was carried out from August to September 2022 by two reviewers using the following health descriptors (Decs/Mesh): "Clostridium difficile," AND "Unidade de Terapia Intensiva," AND "fluxo de trabalho," AND "Enfermagem" on the databases of the journal portal Brazilian Federal Agency for Support and Evaluation of Graduate Education, accessed via Comunidade Acadêmica Federada.

The following were chosen as inclusion criteria: open access systematic reviews and original studies that were published from 2018 to 2022 (to encompass the most recent knowledge in the area of interest) and the gray literature (Brazilian Ministry of Health manuals).

The exclusion criteria were chosen to maintain the focus, practical relevance, and scientific rigor of the review. Duplicates, articles outside the established time frame, those unavailable in full, lacking peer reviews, focusing on pediatric or neonatal populations (since this study focused on an adult ICU), with inadequate methodology or lack of clarity in their results, and on CD outside hospitals or that failed to directly address clinical management, diagnosis, or care flow were excluded. Studies in languages different to those known by the reviewers (Portuguese, English, or Spanish) were also disregarded to ensure data analysis and extraction fidelity. These criteria retrieved content that effectively contributed to the construction of a practical and applicable flowchart based on consistent evidence.

In total, 20 documents were analyzed, serving as the foundation for the main addressed aspects, relevant content, and synthesis for the flowchart. The flowchart consisted of rectangles, squares, and arrows. Each shape has its meaning within the flow, guiding professionals in decision-making.

In the second empirical phase, the expert professionals were personally and individually invited to this study by the main researcher in their work environment, at which point the objectives of this study and the importance of the technical contribution of each specialist were detailed. The objectives and methods of participation in this research were shared, and a pilot of the flowchart was presented in this process.

The instrument was then evaluated by the participants according to their convenience and preference. The sample of professionals was intentionally chosen according to the following inclusion criteria: being a health professional with complete tertiary education who worked in an ICU and having completed a PhD in the area for at least one year.

The expert professionals in this research were selected by convenience considering their extensive clinical and managerial experience in adult and general ICUs in the chosen hospital and their availability to participate in this study. The following professionals were chosen: a physician (the clinical director of the adult ICU) and two nurses (the general nurse directors of the adult and general ICUs). All professionals had worked in the sector for an average of 22 years, having completed their PhD more than three years ago. The three evaluators participated in the two flowchart evaluation rounds.

Experts participated in two content validation rounds. Each participant was given an evaluation questionnaire with nine items on aspects such as "objectivity, layout, simplicity, clarity, relevance, variety, breadth, credibility, and balance."[14] Responses were recorded on a five-point Likert scale. The professionals were asked to justify "1," "2," and "3."

In the first phase of evaluation, the experts proposed adjustments to the text (especially regarding clarity) to avoid any ambiguity that could affect teams' decision-making. They also suggested simplifying the used terms to make the content more accessible and understandable for everyone. All suggestions were incorporated, and the evaluation questionnaire was sent back to the experts for a second round.

Analytical phase: in the third and final phase, judges' content validity index (CVI) was analyzed as it

measures the proportion of judges in agreement on the aspects of the instrument. The CVI enabled the individual analysis of each item (I-CVI) in the first phase and of the whole scale later (S-CVI). As before, a one-to-five Likert scale was used. Its scores were calculated by adding the agreement of the items that experts marked as “4” or “5.” Items that received scores “1” “2” or “3” were reviewed or eliminated. The ideal values for the I-CVI and S-CVI were to total at least 0.78 0.80, respectively.[12]

The Fleiss’ Kappa statistical test was also applied to calibrate the agreement of three or more experts on the flowchart variables. Its values ranged from −1 to +1; the higher the value, the stronger the agreement.[15]

After the experts’ validation, the flowchart was shared with the entire team of the adult ICU, during which the professionals approved the use of the flowchart and suggested that it be incorporated as part of the industry-standard operating protocol.

This study met the established ethical requirements. It was submitted to and approved by the Research Ethics Committee of the institution involved. All participants voluntarily consented to this research, signing an informed consent form in two copies. This study complied with all ethical recommendations in CNS resolution 674/2022 and was submitted to the Ethics Committee, approved on October 28, 2022, and certified (CAAE: 61738922.8.0000.0104) under no. 5.718.969.

RESULTS

The flowchart was developed based on scientific evidence, considering evaluators’ opinion and knowledge and the individual needs and particularities of patients with CD. The final version of the flowchart incorporates all the adjustments and contributions from the experts during validation (Figure 1).

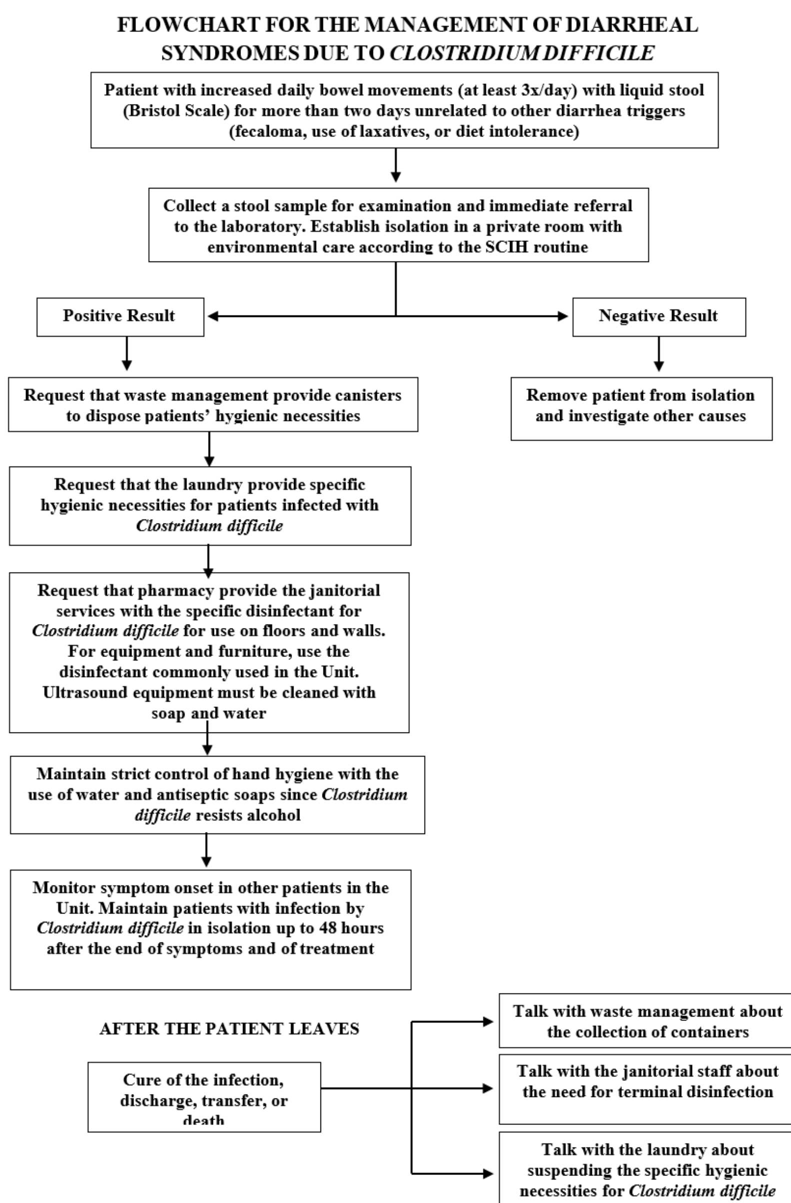

Figure 1. Flowchart to manage patients with *Clostridium difficile* in ICUs. 2023 Maringá, PR, Brazil.

The CVI totaled 0.66 in the first stage of evaluation. Participants received the instrument and the initiative of its creation well, deeming its content innovative given the scarcity of studies on CD infection management. They also highlighted the importance of establishing this material in the unit based on previous experiences since professionals (especially night shift workers) face difficulties in starting the management of patients with CD infections.

In the evaluation of the flowchart, participants suggested changes to the following aspects: clarity, amplitude, and simplicity. Volunteers asked for a definition of patients infected by CD, the specification of the disinfectant to clean infected patients' accommodations, and the time patients should remain in isolation. This research accepted the requests regarding these aspects to facilitate the understanding of the professionals who would use the instrument and to avoid doubts in decision-making.

During the evaluation of the instrument, one judge suggested that the Bristol Scale be attached to the flowchart as it illustrates seven types of stool shapes and indicates the speed of intestinal transit, which has fundamental importance in diagnosis and therapeutic monitoring due to its highly reliable intestine health assessment. This study attached the scale to the flowchart to avoid divergences regarding the definition of patients with CD considering feces consistency, an aspect that causes great disagreement, even in the literature.[16]

With the Bristol Scale attached and the suggestions accepted, the second round of the evaluation forwarded the instrument to the experts. The dimensions objectivity, layout, simplicity, clarity, relevance, credibility, and balance of the flowchart content validation instrument obtained S-CVI/UA (universal agreement). The amplitude criterion totaled 0.88. Regarding the calibration of the agreement between the evaluators, the Kappa index for all items equaled +1 (Table 1).

Table 1. Content validity index of the management flowchart for patients hospitalized in ICUs with *Clostridium difficile*. 2023 Maringá, PR, Brazil.

Dimensions	I-IVC*	Fleiss' Kappa
Objectivity	1	+1
Layout	1	+1
Simplicity	1	+1
Clarity	1	+1
Relevance	1	+1
Variety	1	+1
Amplitude	0.88	0
Credibility	1	+1
Balance	1	+1

Abbreviation: *CVI = content validity index.

DISCUSSION

Patients admitted to hospitals often suffer from complications during their stay, the most common of which being health care-associated infections, of which those by CD occur the most. This pathogen of great medical and epidemiological importance severely damages patients. These microorganisms have shown an increase in worldwide incidence and antibiotic therapy resistance, including to broad-spectrum antimicrobials, being easily disseminated and difficult to eradicate.[17]

In health service routines, especially those with critical patients, professionals often face complex situations, hindering quick and objective decisions to solve problems. A team's lack of preparation regarding the definition of diarrhea, identification of patients affected by the disease, and lack of consensus in determining treatment is one of the challenging aspect. The healthcare team should be well-prepared, supported, and guided in decision-making, especially when there are no supervision of the sector.[18]

During the last three decades, CD has increased in incidence and severity in many countries, increasing hospital stays, medical care costs, hospital admission and disease recurrence, and mortality.[19] Given such data, the experts accepted the flowchart very well as it may prevent and even solve incidences and outbreaks of CD infection.

Although this pathogen greatly impacts health, Brazil has neither much data on CD infections nor updated studies on treating, preventing, and controlling its infections. Such shortage may be related to the high cost of diagnosis and of treating patients due to the need for special materials, hygienic incineration, and intense antibiotic therapy (which most pathogens can resist). Such facts may justify the underreporting of cases.[20-21]

This evinces the need for efficient practical guide for such situations, one that avoids varying interpretations or doubts during its reading. Constructing a flowchart for health services can offer a clear view of the needs of the flow of care during patient stay, positively contributing to the administrative and organizational process.[22]

Building a flowchart requires a consistent and quality theoretical foundation, which was achieved by this study as its final product presents objectivity, good layout, simple and clear information, and relevant and reliable scientific content that conveys credibility to the information and offers great potential to positively impact care practice and quality of care.

The limitations of this study include it having been carried out in a single unit, hindering comparisons. It also only reflects participants' practices and perspectives. The small number of specialists (n=3) was an intentional methodological choice based on the clinical and managerial expertise of the professionals in

the research scenario, being in accordance with the minimum acceptable to calculate the CVI and Fleiss' Kappa. However, flowcharts accessibly and concretely standardize the daily routine of the sector**.** Moreover, this study was limited to the construction and validation of the content of the flowchart.

Despite its limitations, such as its inclusion of a single intensive care unit (restricting the generalization of its results), this research highlights the importance of building instruments that standardize and instruct patient care. Mitigating the possible risks due to the implementation of the flowchart or its inappropriate use will require strategies such as rigorous validation by specialists with extensive experience in the area, the incorporation of suggestions that increased instrument clarity and objectivity, and the presentation of the material to the multiprofessional team for alignment and training. Future studies should assess the practical application of the instrument in a clinical environment to evaluate its impact on the standardization of care and health indicators.

The rigorous validation of the instrument by the experts (evinced by the favorable CVI and the positive Kappa index) attests to its adequacy and structure to meet sector needs. Its applicability is of great importance, especially due to the scarcity of studies on the standardization of care for patients with CD in ICUs.

The divergences in information on CD management show significant medical and epidemiological impacts on the treatment of critically ill patients, reinforcing the relevance of this instrument as a guide for clinical practice. Ensuring the sustainability and effectiveness of the flowchart requires continuous training of professionals, monitoring its use in the daily life of units, and carrying out periodic reviews based on the most current evidence. Such actions ensure that the instrument will safely and effectively guide practice, minimizing misinterpretations and promoting evidence-based clinical decisions.

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AUTHORS' CONTRIBUTIONS

Maiara Basseto Sena 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. **Endric Passos Matos** contributed to project management, bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, conclusions, review, and statistics. **Felipe Fabbri** contributed to the writing of the abstract, methodology, interpretation of results, conclusions, review, and statistics. **Nathalie Campana de Souza** contributed to the writing of the abstract, review, and statistics. **Lucas Benedito Fogaça Rabito** contributed to project management, fund acquisition, literature research, review, and statistics. **Samira Goldberg Rego Barbosa** contributed to project management, bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, conclusions, review, and statistics. **Silvia Maria do Santos Saalfeld** contributed to project management, fund acquisition, literature research, review, and statistics. **Maria Fernanda do Prado Tostes** contributed to project management, bibliographic research, abstract writing, introduction, methodology, discussion, interpretation and description of results, conclusions, review, and statistics. **Rafaely de Cassia Nogueira Sanches** contributed to project management, bibliographic research, abstract writing, 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.

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