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Original Article

Evaluation of therapeutic vancomycin monitoring in patients with and without hemodialysis in a medium-sized hospital in Southern Brazil

Experiência de monitoramento terapêutico da vancomicina em pacientes com e sem hemodiálise em um hospital de médio porte no Sul do Brasil

Experiencia de seguimiento terapéutico de vancomicina en pacientes con y sin hemodiálises en un hospital de mediano porte del Sur de Brasil

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ABSTRACT

Background and Objectives: Vancomycin is a glycopeptide antibiotic widely used in hospital settings for the treatment of severe infections caused by resistant Gram-positive bacteria, particularly methicillin-resistant *Staphylococcus aureus* (MRSA). Due to its narrow therapeutic window and high interindividual pharmacokinetic variability, therapeutic drug monitoring (TDM) is essential to ensure effective and safe therapy. The purpose of this study was to evaluate local practices for TDM of vancomycin in a medium-sized hospital in southern Brazil by comparing patients with and without hemodialysis, identifying failures in achieving therapeutic levels. **Methods:** This retrospective study was conducted between September 2023 and September 2024 in a medium-sized hospital in Southern Brazil. Local TDM practices for vancomycin were evaluated, focusing on patients with and without the need for intermittent hemodialysis. **Results:** Thirty-three adult inpatients were included and categorized into four groups based on dialysis status and whether vancomycin levels were monitored. Among the 19 patients who underwent TDM, only six achieved therapeutic concentrations (15–20 mg/L). Notably, all patients in the hemodialysis monitoring group (HDV) presented supratherapeutic levels at first measurement (mean: 33.7 mg/L). In the non-dialysis monitored group (NDV), high variability in initial serum concentrations was observed (mean: 26.3 mg/L; CV: 40%). **Conclusion:** These findings support the urgent implementation of structured TDM workflows led by clinical pharmacists, integrated into electronic medical records, and supported by pharmacokinetic modeling and clinical decision tools. Institutional adoption of AUC/MIC-based monitoring, pharmacist-led interventions, and multidisciplinary education are critical to ensure the rational and safe use of vancomycin.

Keywords: *Renal Dialysis. Therapeutic index. Drug. Vancomycin.*

RESUMO

Justificativa e Objetivos: A vancomicina é um antibiótico glicopeptídico amplamente utilizado em ambientes hospitalares para o tratamento de infecções graves causadas por bactérias Gram-positivas resistentes, especialmente *Staphylococcus aureus* resistente à meticilina (MRSA). Devido à sua estreita janela terapêutica e à elevada variabilidade farmacocinética interindividual, o monitoramento terapêutico de fármacos (MTF) é essencial para garantir eficácia e segurança. Avaliar as práticas locais de MTF da vancomicina em um hospital de médio porte do sul do Brasil, comparando pacientes com e sem necessidade de hemodiálise e identificando falhas na obtenção de níveis terapêuticos. **Métodos:** Estudo retrospectivo realizado entre outubro de 2023 e outubro de 2024, envolvendo pacientes adultos internados e tratados com vancomicina. Os participantes foram categorizados em quatro grupos conforme o status dialítico e a realização do MTF. **Resultados:** Foram incluídos 33 pacientes, dos quais 19 realizaram MTF; apenas seis atingiram concentrações terapêuticas (15–20 mg/L) em algum momento do tratamento. Todos os pacientes do grupo hemodiálise com monitoramento (HDV) apresentaram níveis supraterapêuticos na primeira mensuração (média: 33,7 mg/L), revelando falhas críticas nas estratégias empíricas de dosagem. No grupo sem diálise com monitoramento (NDV), observou-se elevada variabilidade nas concentrações iniciais (média: 26,3 mg/L; CV: 40%), e poucos alcançaram a exposição ideal. **Conclusão:** Os resultados evidenciam deficiências no manejo da vancomicina, especialmente pela dependência de dosagens empíricas e do monitoramento baseado apenas em concentrações de vale. A implementação de fluxos estruturados de MTF, conduzidos por farmacêuticos clínicos e baseados em AUC/MIC, integrados ao prontuário eletrônico, é fundamental para otimizar a terapia e reduzir a toxicidade.

Descritores: *Diálise renal. Índice terapêutico. Medicamento. Vancomicina.*

RESUMEN

Justificación y Objetivos: La vancomicina es un antibiótico glucopéptido ampliamente utilizado en hospitales para el tratamiento de infecciones graves causadas por bacterias Gram positivas resistentes, especialmente *Staphylococcus aureus* resistente a la meticilina (MRSA). Debido a su estrecho margen terapéutico y alta variabilidad farmacocinética interindividual, el monitoreo terapéutico de fármacos (MTF) es esencial para garantizar eficacia y seguridad. Evaluar las prácticas locales de MTF de vancomicina en un hospital de mediano porte del sur de Brasil, comparando pacientes con y sin hemodiálisis e identificando fallas en la obtención de niveles terapéuticos. **Métodos:** Estudio retrospectivo realizado entre octubre de 2023 y octubre de 2024 en pacientes adultos hospitalizados y tratados con vancomicina. Los pacientes fueron clasificados en cuatro grupos según la condición dialítica y la realización del MTF. **Resultados:** Se incluyeron 33 pacientes; 19 se sometieron a MTF, pero solo seis alcanzaron concentraciones terapéuticas (15–20 mg/L) en algún momento del tratamiento. Todos los pacientes del grupo con hemodiálisis y monitoreo (HDV) presentaron niveles supraterapéuticos en la primera medición (media: 33,7 mg/L), revelando fallas en las estrategias empíricas de dosificación. En el grupo sin diálisis con monitoreo (NDV) se observó una alta variabilidad en las concentraciones iniciales (media: 26,3 mg/L; CV: 40%), con pocos pacientes que lograron la exposición óptima. **Conclusión:** Los resultados evidencian deficiencias importantes en el manejo de la vancomicina, especialmente la dependencia de dosis empíricas y del monitoreo basado solo en niveles valle. La implementación de flujos estructurados de MTF dirigidos por farmacéuticos clínicos y basados en AUC/MIC, integrados al registro electrónico, es esencial para optimizar la terapia y reducir la toxicidad.

Palabras Clave: *Hemodiálisis. Monitorización terapéutica. Fármacos. Vancomicina.*

INTRODUCTION

Vancomycin is a glycopeptide antibiotic widely used in hospital settings, primarily for the treatment of severe infections caused by resistant Gram-positive bacteria, particularly methicillin-resistant *Staphylococcus aureus* (MRSA).[1] The therapeutic efficacy of vancomycin comes from its ability to inhibit bacterial cell wall synthesis, rendering it particularly relevant in the management of conditions such as endocarditis, nosocomial pneumonia, osteomyelitis, meningitis, and device-associated bloodstream infections.[2] However, due to its narrow therapeutic window, the safe and effective administration of vancomycin is contingent upon maintaining adequate serum exposure to avoid the risk of serious adverse events, including nephrotoxicity and ototoxicity.[3]

Vancomycin has a predominantly extracellular distribution pattern, high molecular weight, limited tissue penetration, and almost solely renal clearance.[4] In individuals with intact renal function, vancomycin has a half-life of 6 to 12 hours, but in those with renal failure or undergoing intermittent hemodialysis, it may exceed 100 hours, rendering empiric dosing risky.[4,5] Minor fluctuations in renal function or dialysis frequency can significantly impact plasma concentrations, leading to underdosing and consequent therapeutic failure or overdosing with the associated toxicity risks.[3,4]

In hemodialysis patients, the challenges multiply. Vancomycin is partially removed during dialysis, but this removal is variable and depends on factors such as membrane type, blood flow, session duration, and dosing interval.[9,19] Standardized regimens, such as fixed doses after dialysis sessions, are common, but often result in over- or underexposure, as they do not consider individual pharmacokinetics or accumulation over time.[9,19] Similarly, in non-dialysis patients with impaired renal function, variations in serum levels can occur unpredictably, especially in acute conditions.[20]

Due to these pharmacokinetic characteristics, close therapeutic drug monitoring (TDM) is essential to ensure the safe and effective administration of vancomycin, particularly in vulnerable patient populations, such as those with renal impairment or undergoing hemodialysis.[6–9]

In recent years, there have been significant advances in the analysis and clinical application of vancomycin serum concentrations.[10] Improved laboratory methods, such as high-performance liquid chromatography and mass spectrometry, provide greater precision, sensitivity and speed in detecting vancomycin serum levels.[8,10,11] Additionally, the development of population pharmacokinetic models and Bayesian software has facilitated the estimation of the area under the curve (AUC) from one or two serum samples, optimizing the clinical utility of these data.[8,12] This modern approach, which combines pharmacometrics with clinical decision support technology, enables more individualized dosage adjustments. Such innovations have contributed to making TDM more effective, practical and accessible, even though their implementation is far from universal.

Vancomycin dosing adjustments have traditionally been guided by serum concentrations, with target values between 15 and 20 mg/L for severe infections, like endocarditis and MRSA pneumonia.[5,13] This range has been widely adopted due to its practicality and the indirect correlation with clinical efficacy.[14] Trough measurement performed shortly before the next dose administration, representing the lowest plasma concentration, is used as a surrogate for total drug exposure, although it does not directly reflect the AUC. Thus, the reliance on trough levels alone, without considering individual pharmacokinetic factors, can lead to suboptimal dosing and subtherapeutic or supratherapeutic concentrations.[14,15] Newer guidelines recommend using the AUC as the preferred parameter for vancomycin monitoring, as it provides a more comprehensive assessment of the patient exposure and correlation with both efficacy and safety.[15] The implementation of AUC-based monitoring, often facilitated by Bayesian software, can enable more personalized dosing adjustments and improved patient outcomes, but its implementation remains limited in some healthcare settings.

This study aimed to evaluate the TDM practices for vancomycin in a medium-sized hospital in Southern Brazil by comparing patients undergoing hemodialysis with those not requiring renal replacement therapy. The analysis focused on determining the proportion of patients who achieved therapeutic serum concentrations, and identifying deficiencies in dosing strategies and monitoring procedures with the goal of informing improvements in the safety and effectiveness of vancomycin therapy.

METHODS

This retrospective observational study investigated patterns of vancomycin TDM in hospitalized patients with and without the need for intermittent hemodialysis. The analysis focused on serum vancomycin concentrations, their alignment with therapeutic targets, and the effectiveness of TDM practices in routine clinical care.

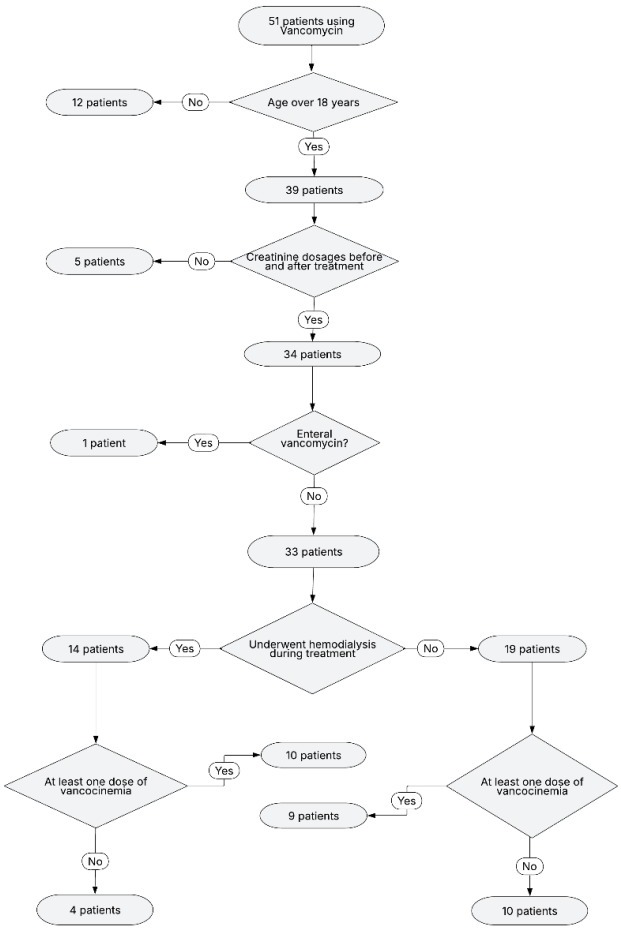

Figure 1. Distribution of patients according to hemodialysis status and implementation of therapeutic drug monitoring (TDM) for vancomycin in a medium-sized hospital in Southern Brazil, September 2023 to September 2024.

This was a single-center, retrospective, observational study conducted at a tertiary care hospital in Southern Brazil between September 2023 and September 2024. The hospital serves as a referral center for a regional population of approximately 150,000 inhabitants and features 149 inpatient beds, including 20 adult Intensive Care Unit (ICU) beds and 10 neonatal ICU beds. Its structure encompasses surgical and obstetric centers, medical and pediatric wards, and multidisciplinary residency programs, reflecting its role as a key healthcare provider in the region.

All patients who received vancomycin during hospitalization were included. Vancomycin therapy initiation and dosing were determined by each attending physician's clinical judgment, based on infection status, comorbidities, and therapeutic needs. The initial cohort consisted of 51 individuals sequentially evaluated for age, availability of creatinine measurements before and after therapy, and route of vancomycin administration. Patients younger than 18 years, without complete renal function data, and those who received enteral vancomycin were excluded. The remaining patients were stratified based on whether they underwent hemodialysis during treatment. Within each stratum, individuals were further categorized according to exposure to at least one dose of vancomycin or not, resulting in the final analytical groups. Four groups were formed based on the need for renal replacement therapy and whether vancomycin serum levels were measured, as follows: HDV (hemodialysis patients with vancomycin monitoring), HDNV (hemodialysis patients without vancomycin monitoring), NDV (non-dialysis patients with vancomycin monitoring), and NDNV (non-dialysis patients without vancomycin monitoring) (Figure 1).

Data were collected from the Tasy® electronic medical record system, including age, sex, duration of vancomycin therapy, and the dates and values of vancomycin serum concentrations. Serum levels were obtained immediately before the third or fourth dose. For patients undergoing intermittent hemodialysis, pre-dialysis serum levels should be collected three to four days after the first vancomycin dose. Serum levels were classified as subtherapeutic (<15 mg/L), therapeutic (15–20 mg/L), or supratherapeutic (>20 mg/L). Descriptive statistics included means, standard deviations, value ranges, and coefficients of variation.

For each patient group, mean values, standard deviations, ranges, and coefficients of variation were calculated to assess variability and distribution patterns. The analysis also compared initial and subsequent vancomycin concentrations to determine the proportion of patients who achieved therapeutic targets during treatment.

This study was approved by the Human Research Ethics Committee of the Federal University of Santa Catarina (Protocol Number 6.818.378). This was a retrospective study using data from electronic medical records, therefore, direct data collection from patients was not needed.

RESULTS

The final sample included 33 patients. Table 1 describes the composition and characteristics of each group (Table 1).

Table 1. Distribution of patients according to group and performance of vancomycin therapeutic drug monitoring (TDM) in a medium-sized hospital in Southern Brazil, September 2023 to September 2024.

Group	Description	N (%)	Sex Male (%)	Average age (years)	Average days of therapy (days)
HDV	Hemodialysis + vancomycin monitoring	10 (30.3%)	40%	60.9	6.5
HDNV	Hemodialysis without vancomycin monitoring	4 (12.1%)	25%	58.25	10.75
NDV	Non-dialysis + vancomycin monitoring	9 (27.3%)	55,5%	57.4	20
NDNV	Non-dialysis without vancomycin monitoring	10 (30.3%)	40%	62	7.4

Among the 33 patients included in this study, only six reached therapeutic vancomycin levels at any point during therapy, while an additional six patients presented baseline concentrations already within the desired range (Figure 2).

In the HDV group, all patients presented supratherapeutic concentrations at the first measurement, with a mean of 33.7 mg/L and values ranging from 22.6 to 64.5 mg/L. Seven patients had vancomycin levels exceeding 30 mg/L. The coefficient of variation was 29%, suggesting some homogeneity among cases, though consistently above the desired range. During treatment, only three patients in the HDV group achieved therapeutic levels at any point (Table 2).

Table 2. Results of the first vancomycin serum concentration measurement according to patient group, in a medium-sized hospital in Southern Brazil, September 2023 to September 2024.

Group	N	Average (mg/L)	SD	CV (%)	15–20 mg/L	<15 mg/L	>20 mg/L
HDV	10	33.7	9.7	29	0%	0%	100%
NDV	9	26.3	10.5	40	33.3%	22.2%	44.4%

In the NDV group, the first serum measurement yielded a mean concentration of 26.3 mg/L, with a broad range from 9.2 to 54.7 mg/L and a coefficient of variation of 40%. This wide variability reflects the clinical heterogeneity within the group. At baseline, three patients had vancomycin concentrations within the target range (15–20 mg/L), two presented subtherapeutic levels, and four exhibited supratherapeutic levels. Despite monitoring, only four patients in this group achieved therapeutic concentrations during treatment.

However, dosing-related issues were common, since nine patients were initially overdosed with serum levels well above the recommended threshold, while two were underdosed. The combined mean of the first measured serum concentrations in the monitored cohort was approximately 29.6 mg/L, substantially higher than the recommended therapeutic range of 15 to 20 mg/L.

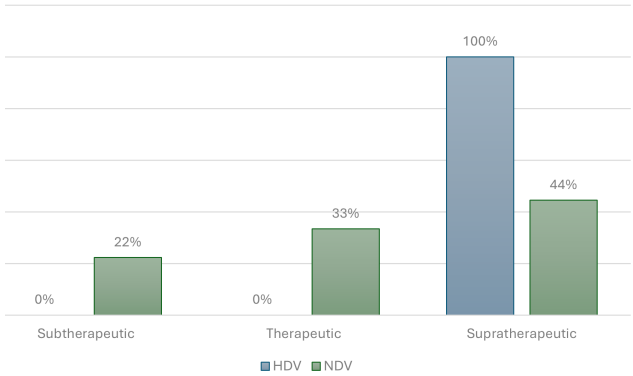

Figure 2. Classification of initial vancomycin serum concentrations according to therapeutic range in a medium-sized hospital in Southern Brazil, September 2023 to September 2024.

DISCUSSION

The universal overdosing observed in the HDV group underscores the limitation of fixed dosing regimens that fail to consider important factors, such as the type of dialysis membrane, duration of the hemodialysis session, or the individual pharmacokinetics of each patient. The fact that 100% of patients in this group had serum concentrations above 20 mg/L, with an average of 33.7 mg/L, highlights this issue. Even with the implementation of vancomycin TDM in this group, the rate of correction to the therapeutic range throughout treatment was only 30%.

In the NDV group, the wide variability in vancomycin levels reflects the clinical heterogeneity among patients that did not require hemodialysis. Same results were observed in the international literature, even when applying the updated 2020 guidelines. Frequent dose adjustments were necessary and maintaining the therapeutic range remained challenging in septic patients on hemodialysis.[23]

Although the rate of achieving the therapeutic range was higher than that observed in the HDV group, it was still unsatisfactory, demonstrating that TDM alone was not sufficient to ensure adequate vancomycin exposure in this population.

A recent study has highlighted key limitations in conventional vancomycin TDM. According to the authors, the use of fixed-dose regimens in patients undergoing hemodialysis often results in drug overexposure, even when vancomycin levels are measured, if those measurements are not actively used to guide dose adjustments.[7] Literature consistently supports the need for the adoption of structured pharmacokinetic models and the active involvement of trained clinical pharmacists. Without these components, TDM loses much of its effectiveness in optimizing vancomycin therapy.[24,25]

Therapeutic drug monitoring should not be regarded as an isolated laboratory test, but rather as an integrated therapeutic process encompassing timely sample collection, expert interpretation of results, and the prompt implementation of clinical interventions.[16,23] Protocols based on estimated AUC, supported by software or simplified pharmacokinetic models, are feasible and can be implemented in resource-limited hospital settings.[17,21] Even more critical is the presence of a dedicated clinical pharmacist to effectively lead this process, ensuring the optimization of vancomycin therapy.[24,26]

The present study revealed significant challenges in the use of vancomycin in patients with and without renal dysfunction, resulting in suboptimal rates of

therapeutic exposure, even among those undergoing monitoring. Only 6 out of 19 monitored patients achieved adequate vancomycin exposure. Notably, most hemodialysis patients began treatment with evident overdosing, reflecting major deficiencies in prescribing practices and therapeutic oversight. This scenario increases the risk of adverse events, prolonged hospitalization, and treatment failure. Therefore, it is imperative to establish an institutional workflow for vancomycin TDM led by clinical pharmacists and integrated into the electronic medical record system.

The implementation of AUC/Minimal Inhibition Concentration (AUC/MIC) - based protocols, systematic integration of clinical pharmacists into therapeutic decision-making, and ongoing team education are essential steps to address this gap. While vancomycin remains an effective agent, its clinical usefulness requires precision, which is achievable only through the integration of clinical data, pharmacokinetic parameters, and collaborative efforts among pharmacy, medical, and laboratory teams. Thus, the safe and rational use of vancomycin must be regarded as a fundamental standard of care, not an optional practice.

This study has several inherent limitations. First, its single-center, retrospective design restricts the generalizability of the findings, as clinical practices, patient characteristics, and monitoring routines may differ substantially across institutions. Second, the relatively small sample size, particularly within the hemodialysis subgroup, limits statistical power and reduces the ability to detect more subtle patterns in vancomycin monitoring. These constraints highlight the need for larger, prospective, and multicenter investigations to strengthen the evidence base surrounding vancomycin therapeutic monitoring in diverse clinical settings.

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AUTHORS' CONTRIBUTIONS

Guilherme Felipe Raimundo contributed to bibliographic research, writing the abstract, introduction, methodology, discussion, interpretation and description of results, preparation of tables, conclusions, review and statistics. **Helena Iturvides Cimarosti** contributed to project management, bibliographic research, writing the abstract, introduction, methodology, conclusions, review and statistics. **José Elias Amaral** contributed to the bibliographic research, writing the abstract, introduction, 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 accuracy and integrity.

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