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ANALYSIS OF A PREEMPTIVE ANTIBIOTIC THERAPY PROTOCOL IN INSTRUMENTED SPINAL ARTHRODESIS

ANÁLISE DE UM PROTOCOLO DE TERAPIA ANTIBIÓTICA PREEMPTIVA EM ARTRODESES INSTRUMENTADAS DA COLUNA VERTEBRAL

ANÁLISIS DE UN PROTOCOLO DE ANTIBIOTICOTERAPIA PREEMPTIVA EN ARTRODESIS INSTRUMENTADAS DE COLUMNA VERTEBRAL

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ABSTRACT

Objective: To describe the clinical profile and postoperative outcomes of patients undergoing instrumented spinal arthrodesis under a preemptive antibiotic therapy protocol with vancomycin and ciprofloxacin. Methods: A retrospective, consecutive, and single-center case series was conducted involving 88 patients operated on between January 2021 and December 2022. The protocol consisted of intravenous vancomycin (1 g) and ciprofloxacin (400 mg) administered 60 minutes before incision, with postoperative maintenance for five days. The minimum clinical follow-up was 24 months. Results: The mean age was 45.2 years, with a male predominance (60.2%). Trauma was the most frequent surgical indication (38.9%), followed by neoplasms (25%). The overall arthrodesis infection rate was 4.5% (4/88 patients), with 75% of these cases occurring in patients with oncological etiology. Only one adverse event (1.1%) related to vancomycin was recorded. Conclusions: The preemptive antibiotic therapy protocol showed favorable infection rates (4.5%) and good pharmacological tolerability in the studied sample, suggesting it is a viable strategy for high-complexity spine surgeries. ***Level of Evidence IV; Case series.***

Keywords: Spine; Spinal Fusion; Surgical Wound Infection; Disease Prevention; Vancomycin; Ciprofloxacin.

RESUMO

Objetivo: Descrever o perfil clínico e a evolução pós-operatória de pacientes submetidos à artrodese da coluna vertebral instrumentada sob um protocolo de terapia antibiótica preemptiva com vancomicina e ciprofloxacino. Métodos: Foi realizada uma série de casos retrospectiva, consecutiva e unicêntrica envolvendo 88 pacientes operados entre janeiro de 2021 e dezembro de 2022. O protocolo consistiu na administração de vancomicina (1 g) e ciprofloxacino (400 mg) intravenosos 60 minutos antes da incisão, com manutenção pós-operatória por cinco dias. O seguimento clínico mínimo foi de 24 meses. Resultados: A idade média foi de 45,2 anos, com predominância do sexo masculino (60,2%). O trauma foi a indicação cirúrgica mais frequente (38,9%), seguido por neoplasias (25%). A taxa global de infecção da artrodese foi de 4,5% (4/88 pacientes), sendo que 75% desses casos ocorreram em pacientes com etiologia oncológica. Registrou-se apenas um evento adverso (1,1%) relacionado à vancomicina. Conclusões: O protocolo de terapia antibiótica preemptiva apresentou taxas de infecção favoráveis (4,5%) e boa tolerabilidade farmacológica na amostra estudada, sugerindo ser uma estratégia viável para cirurgias de coluna de alta complexidade. ***Nível de Evidência IV; Série de casos.***

Descritores: *Coluna Vertebral; Fusão Vertebral; Infecção da Ferida Operatória; Profilaxia; Vancomicina; Ciprofloxacino.*

RESUMEN

Objetivo: Describir el perfil clínico y la evolución posoperatoria de pacientes sometidos a artrodesis de columna vertebral instrumentada bajo un protocolo de terapia antibiótica preemptiva con vancomicina y ciprofloxacino. Métodos: Se realizó una serie de casos retrospectiva, consecutiva y unicéntrica que incluyó a 88 pacientes operados entre enero de 2021 y diciembre de 2022. El protocolo consistió en la administración de vancomicina (1 g) y ciprofloxacino (400 mg) intravenosos 60 minutos antes de la incisión, con mantenimiento posoperatorio durante cinco días. El seguimiento clínico mínimo fue de 24 meses. Resultados: La edad media fue de 45,2 años, con predominio del sexo masculino (60,2%). El trauma fue la indicación quirúrgica más frecuente (38,9%), seguido de las neoplasias (25%). La tasa global de infección de la artrodesis fue del 4,5% (4/88 pacientes), ocurriendo el 75% de estos casos en pacientes con etiología oncológica. Se registró solo un evento adverso (1,1%) relacionado con la vancomicina. Conclusiones: El protocolo de terapia antibiótica preemptiva presentó tasas de infección favorables (4,5%) y buena tolerabilidad farmacológica en la muestra estudiada, lo que sugiere que es una estrategia viable para cirugías de columna de alta complejidad. ***Nivel de Evidencia IV; Serie de casos.***

Descriptores: *Columna Vertebral; Fusión Vertebral; Infección de la Herida Quirúrgica; Prevención de Enfermedades; Vancomicina; Ciprofloxacino.*

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INTRODUCTION

Arthrodesis infection is one of the most costly complications in spinal surgery, with an incidence ranging from 0.5% to 12%, depending on the complexity of the procedure[1,2]. This complication is directly associated with increased morbidity, prolonged hospitalization, and elevated hospital costs[3]. Identifying risk factors—related to the patient (modifiable, such as obesity and diabetes, or non-modifiable, such as age) and the procedure—is essential to mitigate these outcomes[4-6].

Staphylococcus aureus remains a frequent etiological agent in infections associated with spinal surgeries[7]. This scenario supports the recommendation of guidelines for the use of cefazolin as standard prophylaxis[8]. However, the failure of standard prophylaxis may relate to the involvement of resistant microorganisms and the presence of gram-negative bacilli, especially in larger instrumented surgeries[9,10].

The inadequacy of traditional antimicrobial coverage has driven the investigation of combined regimens and strategies targeted at higher-risk populations[11,12]. Unlike standard prophylaxis, the extended regimen with the combination of vancomycin and ciprofloxacin for five days is characterized as preemptive antibiotic therapy, aiming to early interrupt a possible subclinical infection in high microbiological risk scenarios.

Despite clinical plausibility, the prolonged use of broad-spectrum antibiotics requires caution due to the risk of toxicity and selection of bacterial resistance[8]. The literature lacks robust comparative analyses on the clinical profile of patients undergoing this specific regimen compared to standard prophylaxis.

The present study aims to describe the clinical profile and postoperative evolution of patients undergoing vertebral instrumentation under a preemptive antibiotic therapy protocol with vancomycin and ciprofloxacin.

From a conceptual standpoint, this strategy is characterized as preemptive antibiotic therapy, seeking not only to prevent intraoperative bacterial inoculation but also to early interrupt a possible subclinical infection already in progress in a high microbiological risk scenario.

METHODS

Study Design

A series of retrospective, consecutive, and unicentric cases was conducted, involving patients who underwent instrumented spinal surgeries between January 2021 and December 2022. The study was approved by the Research Ethics Committee of the Irmandade da Santa Casa de Misericórdia de São Paulo (CAAE: 79302224.5.0000.5479) and followed the guidelines of the PROCESS 2023 checklist. The minimum clinical follow-up adopted for inclusion in the efficacy analysis was 2 years (24 months) or until the outcome of death.

All participants signed the Informed Consent Form (ICF) after approval by the Research Ethics Committee.

Participants and Eligibility

Patients of both sexes, without age restriction, who underwent instrumentation of the cervical, thoracic, and/or lumbosacral spine were included. The fundamental inclusion criterion was the use of the institutional protocol for preemptive antibiotic therapy consisting of the combination of vancomycin and ciprofloxacin. Patients with open fractures, previous infections, those who were not subjected to the placement of synthetic material, or those who did not consent to the review of the clinical record during the perioperative period were excluded.

Antibiotic Therapy Protocol

The preemptive regimen consisted of the administration of vancomycin (1 g, intravenous) and ciprofloxacin (400 mg, intravenous), both 60 minutes before incision, with intraoperative reinforcement at 12 hours. Postoperative maintenance was continued with the same doses of both drugs every 12 hours, totaling 5 days of treatment.

Data Collection and Variables

Data were extracted from electronic medical records and included: demographic data (age, sex), comorbidities (diabetes, smoking, and oncological status), etiology of the condition that necessitated surgery (trauma, tumor, degenerative, or deformity), and length of hospitalization.

Outcomes

The primary outcome was the incidence of infection of the spinal fusion up to 2 years postoperatively, defined according to CDC (Centers for Disease Control and Prevention) criteria. Secondary outcomes included: adverse reactions to the antimicrobial regimen (nephrotoxicity, allergic reactions), need for reoperation due to mechanical or infectious causes, and microbiological isolation in cases of positive culture.

Statistical Analysis

Descriptive statistical analysis was performed. Continuous variables were presented as mean and standard deviation (or median and interquartile range, depending on normality). Categorical variables were expressed in absolute (n) and relative (%) frequency. The infection rate was calculated based on the total treated sample.

RESULTS

A total of 88 consecutive patients who underwent instrumental spinal surgery under the preemptive antibiotic therapy protocol with vancomycin and ciprofloxacin were included and analyzed. The study population exhibited demographic heterogeneity, with a mean age of 45.2 ± 18.4 years (ranging from 9 to 81 years). There was a predominance of the male sex (60.2%), and traumatic etiology was the most frequent surgical indication (38.9%), followed by neoplastic conditions, of which 81.8% were metastatic. The average length of hospitalization was 21 days. The most prevalent comorbidity was systemic arterial hypertension (SAH), present in 17% of the patients. (Tables 1 and 2)

Table 1. Baseline demographic and clinical characteristics of the sample (n=88). † Comorbidities are not mutually exclusive (one patient may have more than one). Data expressed in n (%). Percentages rounded to the nearest whole number.

Variable	n (%)
Sex	
Male	53 (60)
Female	35 (40)
Age Group	
< 18 years	13 (15)
18–60 years	53 (60)
> 60 years old	22 (25)
Comorbidities	
Smoking†	6 (7)
Diabetes mellitus†	3 (3)
Systemic arterial hypertension†	15 (17)

Table 2. Etiology (diagnosis at admission) of the sample (n=88). Data expressed in n (%). Percentages rounded to the nearest whole number. Mutually exclusive etiology categories (total n=88). * Percentages calculated within the Tumor group (n=22).

Etiology	n (%)
Trauma (fractures)	35 (40)
Tumor	22 (25)
└ Primary*	4 (18)
└ Metastatic*	18 (82)
Degenerative (hernia/stenosis/ spondylolisthesis)	8 (9)
Deformities	23 (26)

All patients completed the preemptive antibiotic therapy protocol with vancomycin and ciprofloxacin. The most common outcome observed was infection of the arthrodesis within 2 years, at 4.5% (4/88 patients). Three deaths (3.4%) were also recorded during the study follow-up. (Table 3)

The subgroup analysis revealed a predominance of oncological etiology in infectious risk: 75% (3/4) of arthrodesis infection cases occurred in patients operated on for tumors (metastasis or multiple myeloma). Only one case of infection was recorded in the trauma group, and none in the degenerative pathology or deformity groups.

Regarding pharmacological safety, the regimen was well-tolerated. There was only 1 adverse event (1.1%) characterized by hypersensitivity reaction to vancomycin (red man syndrome), with erythema on the face and neck during the infusion. The condition was reversed with antihistamines and a reduction in the infusion rate, without the need to suspend the protocol. The reoperation rate for mechanical (non-infectious) causes, such as implant failure or residual compression, was 4.5% (4 cases).

Two cases were also recorded in which the infection of the arthrodesis occurred more than 30 days after the surgical procedure, characterizing late infection. (Table 4)

Table 3. Outcomes in follow-up (n=88). Data expressed in n (%). Percentages rounded to the nearest whole number.

Outcome	n (%)	Detailing
Infection of the arthrodesis	4 (5)	-
Reoperation (Non-infectious causes)	4 (5)	Neurological deterioration, implant removal, aseptic discitis/failure.
Adverse Reactions to Antibiotics	1 (1)	Allergic reaction to Vancomycin (ID 09).
Deaths (within a 2-year period)	3 (3)	Associated with the progression of oncological disease and/or systemic complications.

Table 4. Characteristics of arthrodesis infection cases and outcomes (n=4).

Case	Etiology	Microbiology	Outcome
1	Trauma	Polymicrobial	Healed after cleaning
2	Tumor	*S. aureus* + *K. pneumoniae*	Death
3	Tumor	A. baumannii	Death
4	Tumor	Staphylococcus sp.	Healed after cleaning

DISCUSSION

Infection of the arthrodesis remains one of the most relevant complications in instrumented spinal surgery, especially in high-risk populations. In this study, the clinical profile and postoperative evolution of patients subjected to a preemptive antibiotic therapy protocol with vancomycin and ciprofloxacin were evaluated, observing an overall arthrodesis infection rate within the range described in the literature during follow-up of up to two years[4-6].

Another relevant finding was the association with etiology: most infections occurred in patients with oncological disease. This result is consistent with previous studies that identify metastatic disease as an independent risk factor for infection after spinal surgery[13,14].

The microbiological analysis revealed diversity among Gram-positive and Gram-negative pathogens, including polymicrobial infections. These findings are in line with a series that describes a trend towards microbiological diversification in infections associated with spinal surgery[9,10]. Such a finding reinforces the importance of recognizing the local microbiological spectrum when defining antimicrobial strategies in higher-risk patients.

Regarding safety, a low frequency of adverse events related to vancomycin was observed, with no nephrotoxicity in the sample. Red man syndrome is a reaction described during infusion and generally responds to measures such as reducing the rate and antihistamines[15]. However, it should be considered that the evaluated regimen uses a duration longer than recommended in surgical prophylaxis guidelines and in part of the literature, which advocates shorter regimens (ideally up to 24 hours) to reduce the risk of resistance and adverse effects[8,16].

The occurrence of late infections (after 30 days) was observed, a phenomenon described in instrumented surgeries and associated, among other factors, with biofilm formation and subacute clinical presentation[17-19].

A strong point is the two-year follow-up, with microbiological identification and homogeneity of the protocol, allowing for a detailed description of the outcomes. Among the limitations are the observational design without a control group, the sample size, and the heterogeneity of surgical indications, which restrict causal inferences and generalization.

CONCLUSIONS

The protocol for preemptive antibiotic therapy with vancomycin and ciprofloxacin in instrumented spinal fusions has proven to be a viable strategy, with favorable fusion infection rates and a good pharmacological safety profile in the analyzed sample. In accordance with the descriptive nature of the study, the findings provide a basis for future prospective and comparative investigations that may support clinical recommendations for high-complexity populations.

CONFLICT OF INTEREST

All authors declare no potential conflict of interest related to this article.

CONTRIBUTIONS OF THE AUTHORS

LTYT: Methodology and Research; CMP: Research and Writing – Original Draft; SLCK: Data Curation and Research; MWWC: Validation and Writing – Review and Editing; SL: Resources and Writing – Review and Editing; GJTFC: Resources and Formal Analysis; MRGM: Supervision and Formal Analysis; GA: Supervision and Validation; CMFS: Supervision and Project Management; BRR: Data Curation and Formal Analysis; TFTMN: Data curation and Formal Analysis; BF: Data curation and Formal Analysis; GDCDS: Data curation and Research; FEA: Data curation and Research; XMC: Data curation and Research; BJS: Data curation and Research; RGD: Data curation and Research; MR: Supervision and Conceptualization.

DATA AVAILABILITY DECLARATION

The underlying contents of the research text are contained in the manuscript.

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