

SURGICAL INFECTIONS OF STERNAL WOUND IN CARDIAC SURGERY PATIENTS TREATED WITH WAX AND VANCOMYCIN PASTE: A SINGLE-CENTER STUDY

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Abstract

Introduction: Postoperative sternal wound infections are serious and potentially life-threatening complications that are associated with significant morbidity, mortality, and increased health care costs. Although the prophylactic use of topical vancomycin paste to reduce the incidence of deep sternal wound infection, has been repeatedly examined, this method remains controversial.

Material and methods: The research is a retrospective-prospective randomized monocentric clinical study that was conducted in 24 months. We report our first experience with 82 patients operated with a complete medial sternotomy, in which the closure protocol applied intra sternal wax paste in 40 patients, and vancomycin paste in 42 patients. All sternum wound infections that were the result of surgery during this period were analyzed.

Results: Patients in both groups were compared in terms of demographic data and risk factors. In 7 patients operated on with the application of wax paste out of 40 patients, a sternal wound infection developed (17.50%). The introduction of the new protocol for sternal closure with vancomycin paste application reduced this number to 2 patients with superficial sternal wound infection out of 42 patients (4.76%; $p < 0.001$).

Discussion: Topical application of antibiotic agents (vancomycin paste) significantly reduced sternal wound infection. However, the results of this trial need to be confirmed in a randomized trial.

Keywords: deep sternal wound infection, topical antibiotic, vancomycin paste, wax paste.

Introduction

The traditional median sternotomy remains the most commonly used approach in cardiac surgery, owing to its familiarity and safety record [1]. Postoperative sternal wound infections remain a frequent and challenging complication in cardiac surgery centers worldwide [2]. According to the Centers for Disease Control and Prevention (CDC), sternal surgical site infections are classified as superficial or deep [3]. Sternal wound infections following open-heart surgery represent a serious postoperative complication, with a reported incidence ranging from 1.3% to 12.8%, depending on the depth of infection [4]. Superficial sternal wound infections (SSWI) are generally manageable with surgical treatment and are rarely associated with life-threatening consequences. In contrast, postoperative DSWI is a severe and potentially life-threatening complication associated with significant morbidity, increased mortality, and substantial healthcare costs [5].

Deep sternal wound infections (DSWI), together with stroke and heart failure, represent the three most serious complications following cardiac surgery. These conditions are associated with prolonged hospital stay, increased duration of intensive care unit (ICU) treatment, and the need for multiple surgical interventions [6]. The incidence of DSWI varies between centers, countries, and year of publication, but most studies reported incidence between 0.5% and 2% [7]. However, the annual mortality rate among patients with DSWI is significantly higher (10.7%) compared with patients without DSWI (2.5%) [8]. The average length of hospitalization in patients who develop DSWI is 33 days, compared with 9 days in patients without DSWI [9].

Local antibiotic prophylaxis was considered inappropriate in cardiac surgery. The direct application of vancomycin to the sternal bone as a local prophylactic agent against deep sternal wound infections was first described in 1989 [10]. Recommendations published in 2007 and still in use today assign a class IIB recommendation (level of evidence B) for the use of local antibiotics in cardiac surgery [11]. The aim of

this study was to compare the characteristics of cardiac surgery patients treated with bone wax paste and vancomycin paste, as well as to evaluate the occurrence of postoperative infections following the intervention and frequency of detected pathogens.

Material and methods

This study was designed as a retrospective – prospective, randomized, single-center clinical study conducted between 01.09.2020 and 30.09.2023 at the University Clinic for State Cardiac Surgery, Skopje, in collaboration with the Institute of Epidemiology and Biostatistics with Medical Informatics and the Institute of Microbiology and Parasitology, Faculty of Medicine, Sts. Cyril and Methodius University (UKIM), Skopje.

The study was approved by the Ethics Committee of the Faculty of Medicine, Sts. Cyril and Methodius University in Skopje. A total of 82 patients with an indication for cardiac surgery performed via full median sternotomy (elective cases) were included in the study.

Patient selection was based on predefined inclusion and exclusion criteria. The inclusion criteria were: age ≥ 18 years, regardless of sex and other sociodemographic characteristics, indication for elective cardiac surgery using a median sternotomy approach and written informed consent for participation in the study. The exclusion criteria were: age < 18 years, allergy to vancomycin or to any type of bone wax, indication for emergency cardiac surgery associated with perioperative shock or cardiopulmonary resuscitation, indication for cardiac surgery via J-mini sternotomy or mini thoracotomy, indication for redo sternotomy, previous heart transplantation with postoperative immunosuppressive therapy, and lack of interest or willingness to participate in the study.

The study group consisted of 42 patients treated with vancomycin paste, admitted to the University Clinic for State Cardiac Surgery, Skopje, for elective cardiac surgery via full median sternotomy. Patients in this group were subdivided into three subgroups according to the type of cardiac surgical procedure. The first subgroup (A1) included patients who underwent elective coronary artery bypass grafting (CABG) via median sternotomy. The second subgroup (B1) consisted of patients who underwent elective cardiac valve surgery (single valve replacement or repair). The third subgroup (C1) included patients who underwent combined cardiac surgical procedures. All patients in the vancomycin group were treated with vancomycin paste and were prospectively followed from the day of admission for elective cardiac surgery until hospital discharge, according to a predefined institutional protocol.

The control group consisted of patients previously operated on at the University Clinic for State Cardiac Surgery, Skopje, during the period when bone wax paste was used as part of the standard operative protocol. This group included 40 patients admitted for elective cardiac surgery via median sternotomy. Patients in the bone wax group were also divided into three subgroups based on the type of surgical intervention. The first subgroup (A2) included patients who underwent elective CABG via median sternotomy. The second subgroup (B2) consisted of patients who underwent elective cardiac valve surgery. The third subgroup (C3) included patients who underwent combined cardiac surgical procedures via sternotomy.

The materials and preparation protocols for vancomycin paste and bone wax paste were standardized for both groups. **Vancomycin paste** (Vancomycin Hydrochloride) was used in the study group of 42 patients. Preparation of the vancomycin paste was standardized and identical for all patients in this group. The paste was prepared by mixing 3 g of vancomycin (Vancomycin Hydrochloride®) with 4 mL of 0.9% NaCl in a sterile container until a paste-like consistency was obtained. Vancomycin paste was prepared intraoperatively by a scrub nurse. All scrub nurses actively participating in cardiac surgical procedures had previously undergone training by the principal investigator regarding the standardized preparation of vancomycin paste. Application of the vancomycin paste was performed using a sterile scalpel handle along the entire length of the sternal edges at the end of the cardiac surgical procedure, immediately before sternal closure and fixation with wire cerclages.

Bone wax paste (BRAUN® Knochenwachs) was applied in the control group of 40 patients. This manufacturer-prepared paste was applied at the beginning of the cardiac surgical procedure and remained in place throughout the operation, as well as after sternal closure and fixation with wire cerclages.

The diagnosis of DSWI was established based on a combination of clinical signs and symptoms, laboratory findings, and radiological evidence. In accordance with CDC criteria, the diagnosis of DSWI requires fulfillment of at least one of the three criteria: (a) isolation of a microorganism from mediastinal tissue or fluid by microbiological methods; (b) radiological or histopathological evidence of mediastinitis; (c) presence of at least one of the following clinical signs or symptoms: fever (body temperature $>38^{\circ}\text{C}$), chest pain, sternal instability, and/or purulent mediastinal drainage [12]. The confirmed cases of DSWI were classified using the El Oakley and Wright classification system [8].

In the present study, superficial sternal wound infection (SSWI) was defined as an infection confined to the skin and subcutaneous tissue, extending to but not beyond the fascia. Deep sternal wound infection (DSWI) was defined as an infection involving tissues beneath the fascia, including muscle, the sternum, and/or mediastinal organs.

For post-treatment evaluation, patients in the control group were followed through review of available medical records at the University Clinic for State Cardiac Surgery, Skopje (with appropriate institutional approval), as well as through direct patient contact to address any unresolved issues. Evaluation of these patients was performed according to the same protocol used for the study group.

Statistical analysis: Descriptive statistical methods were applied to depict the study population regarding the risk factors. Statistics were performed using SPSS for Windows, version 26.0. Qualitative data were presented as absolute numbers and percentages, while quantitative data were analyzed using measures of central tendency and measures of dispersion. The Pearson chi-square test, Yates' continuity correction, Fisher's exact test, were used to assess associations between categorical dichotomous variables. Statistical significance was defined as a p-value <0.05 .

Results

A total of 82 patients were included in the study. Of these, 42 patients (51.2%) were treated with the vancomycin paste sternal closure protocol, while 40 patients (48.8%) received bone wax paste. All patients underwent surgery via full median sternotomy. Study groups were comparable regarding preoperative and perioperative patient's characteristics (Table 1 - 2). No adverse reaction to the vancomycin closing protocol became clinically evident during the observational period.

Deep sternal wound infection in our study occurred in 2 of 42 patients (4.8%) in the vancomycin group and in 7 of 40 patients (17.5%) in the bone wax group. In the vancomycin group, both cases were superficial sternal wound infections (El Oakley class 2A). In the bone wax group, 3 patients developed superficial primary sternal dehiscence (El Oakley class 1), and 4 patients developed deep sternal wound infections (El Oakley class 2B). The incidence of deep sternal wound infection was 0% in the vancomycin group versus 10% in the bone wax group.

Vacuum-assisted closure (VAC) therapy was required in all four patients who developed deep sternal wound infections in the bone wax group. The proportion of microbiological isolates of *Staphylococcus epidermidis* and *Staphylococcus aureus* was significantly reduced with the new sternal closure protocol using vancomycin paste. None of the isolates in the vancomycin group showed resistance to vancomycin. In contrast, in the bone wax Group, 2 patients had *S. aureus* isolates and 1 patient had *S. epidermidis*, all associated with primary sternal wound dehiscence. The isolated pathogens among patients who developed DSWI were: *Acinetobacter spp.* (2 patients), *Klebsiella pneumoniae* (1 patient), and *Pseudomonas aeruginosa* (1 patient).

Table 1. Preoperative and intraoperative patient' characteristics

| Variable | Vancomycin Group N=42 | Bone Wax Group N=40 | p-value |
|---------------------------------------------------------------------------------------------|--------------------------|-------------------------|---------|
| Preoperative | | | |
| Age, years | 66 ±13 | 67 ± 13 | 0.182 |
| Sex (male/female) | 32 (76%) /10 (24%) | 28(70%) /12 (30%) | 0.094 |
| Height, cm | 172 ± 9 | 173 ±10 | 0.548 |
| Weight, kg | 86 ± 15 | 82 ± 17 | 0.259 |
| BMI, kg/m ² | 27.25 ±4.70 | 27.36 ± 4.70 | 0.623 |
| EuroSCORE II | 7.0 ± 10.3 | 7.4 ± 11.1 | 0.391 |
| Smokers | 22 (52%) | 23 (57.5%) | 0.477 |
| Type 2 Diabetes | 13 (31%) | 12 (30%) | 0.614 |
| Renal impairment | 5 (14%) | 5 (13%) | 0.384 |
| Cerebrovascular disease | 8 (20%) | 6 (17%) | 0.142 |
| Peripheral vascular disease | 5 (12%) | 5 (12,5%) | 0.850 |
| COPD | 7 (16%) | 6 (15%) | 0.439 |
| Intraoperative | | | |
| Procedure type | | | 0.751 |
| CABG | 22 (35.7%) | 26 (55.0%) | |
| Valve surgery | 12 (38.1%) | 8 (30.0%) | |
| Combined surgery | 8 (26.2%) | 6 (15.0%) | |
| CABG graft type | | | 0.379 |
| LIMA | 22 (100%) | 26 (100%) | |
| RIMA | 3 (20%) | 4 (18.8%) | |
| BIMA | 3 (20%) | 4 (18.8%) | |
| Cardiopulmonary bypass time, min | 146 ± 72 | 158 ± 68 | 0.681 |
| ICU stay, days ¹ | 3 (1–6) | 4 (1–6) | 0.644 |
| Hospitalisation, days ¹ | 9 (7–16) | 10 (7–18) | 0.564 |
| COPD – chronic obstructive pulmonary disease, SD- standard deviation, BMI – body mass index | | | |
| ¹ Median IQR | | *significant for p<0,05 | |

Discussion

Sternal wound infection remains one of the most serious complications following cardiac surgery via median sternotomy, with a substantial impact on postoperative morbidity, mortality, length of hospitalization, and healthcare costs [13]. Despite advances in perioperative management and standardized systemic antibiotic prophylaxis, the incidence of both superficial and deep sternal wound infections continues to pose a significant clinical challenge [7,8]. The present single-center study evaluated the effect of intrasternal application of vancomycin paste compared with conventional bone wax paste on the occurrence of postoperative sternal wound infections.

The principal finding of this study is that the introduction of a vancomycin paste-based sternal closure protocol was associated with a significant reduction in overall sternal wound infection rates, and most notably with a complete elimination of deep sternal wound infections. In our study, the incidence of sternal wound infection in the bone wax group vs vancomycin group was 17.5% vs 4.8% respectively, while the incidence of DSWI was 10% vs 0% respectively. These findings support the hypothesis that local antibiotic prophylaxis provides an additional protective effect beyond standard systemic antibiotic administration.

The rationale for topical vancomycin application is based on its ability to achieve high local antibiotic concentrations at the sternal edges, which are particularly vulnerable to bacterial contamination during and immediately after surgery. Gram-positive organisms, especially *Staphylococcus aureus* and coagulase-negative staphylococci, are the most frequently isolated pathogens in sternal wound infections. Vancomycin has proven efficacy against these organisms and is therefore well suited for local prophylactic use. Previous studies have demonstrated that topical vancomycin application significantly reduces the incidence of deep sternal wound infection without increasing systemic toxicity or adverse effects. Our findings are consistent with earlier reports by Olbrecht et al. that documented a reduction in mediastinitis rates following local vancomycin use [10].

In our vancomycin group, no vancomycin-resistant organisms were detected, and the frequency of *Staphylococcus epidermidis* and *Staphylococcus aureus* isolates was lower compared with the bone wax group. In contrast, deep sternal wound infections in the bone wax group were associated not only with Gram-positive bacteria but also with Gram-negative pathogens, including *Acinetobacter spp.*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. These findings suggest that early prevention of initial bacterial colonization of the sternal wound may reduce the risk of secondary infection with more aggressive or opportunistic organisms.

The use of bone wax for sternal hemostasis has long been debated. While bone wax is effective in controlling bleeding from sternal marrow, several experimental and clinical studies have suggested that it may impair bone healing and act as a foreign body, thereby promoting bacterial persistence and infection [14]. In our study, patients treated with bone wax had a significantly higher incidence of both superficial and deep sternal wound infections, supporting previous concerns regarding its routine use. In contrast, the vancomycin paste protocol provided effective local antimicrobial protection without observed adverse reactions or complications.

Despite these promising results, several limitations should be acknowledged. The study was conducted at a single center with a relatively small sample size, which may limit the generalizability of the findings. Furthermore, long-term microbiological surveillance was not performed to assess the potential impact on antimicrobial resistance patterns.

Conclusion

In conclusion, the findings of this single-center study indicate that intrasternal application of vancomycin paste is a safe and effective strategy for reducing sternal wound infections, particularly deep sternal wound infections, following elective cardiac surgery via median sternotomy. Incorporation of this protocol into routine surgical practice may contribute to improved postoperative outcomes. However, larger multicenter randomized controlled trials are required to confirm these results and to establish standardized guidelines for local antibiotic prophylaxis in cardiac surgery.

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