Efficacy of topical vancomycin application in cardiac surgery to reduce deep sternal wound infection: a randomised control trial at tertiary cardiac care hospital

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ABSTRACT

Background: Mediastinitis is lethal complication and a challenge in post cardiac surgery patients. We aim at evaluation of topical vancomycin by applying it at sternal edge in prevention of deep sternal wound infection.

Methods: The vancomycin group had local application of vancomycin paste prepared by mixing 1gm of powder in 3 ml of normal saline and stirred until paste was formed. The control group had reinforced closure technique without vancomycin paste application. All cases were followed up for symptoms and signs of sternal wound infection during hospital stay and uptil 1 month.

Results: There was increase incidence of wound infection with control group as compared to vancomycin group, there were no wound infection in patients of vancomycin group.

Conclusions: Application of topical vancomycin significantly reduces post-sternotomy wound infection and prevents deep mediastinitis.

Keywords: Mediastinitis, Topical Vancomycin, Sternotomy

INTRODUCTION

The incidence of sternal wound infections has decreased to 1% to 4% of all cardiac surgical patients, but they are associated with increased morbidity and mortality.1-3 Sternal wound infections prolong hospital stay, several methods have been successful in decreasing the incidence of sternal wound infections. These include the use of prophylactic antibiotics, glycemic control with intravenous insulin infusions and the avoidance of bone wax is used routinely.4,5 These therapies have decreased, but have not eliminated sternal wound infections. Tissue perfusion is impaired in patients with diabetes and atherosclerosis, who are common in cardiac surgery. Median sternotomy has been the preferred way to gain access to mediastinum. The procedure is quick and efficient but has two major complications: sternal infection (1-3% of patients) and non-union (2-8% of patients).6 SWI is one of the most dangerous complications after cardiac surgery, it may lead to serious morbidities and even mortality.7 According to El Okaley classification, sternal complications are categorized as follows:non-infected dehiscence (El Oakley class-1), SWI without sternal dehiscence (El Oakley class- 2A) and DSWI with or without sternal dehiscence (El Oakley class-2B).8 Prevention of SWI by the use of prophylactic systemic or local antibiotics is widely applied in cardiac surgery centres. Topical application combines the benefit of higher effective concentration at the sternum, and minimal side effects.9 The topical application of vancomycin into the sternal bone was first reported in 1989 to protect against deep sternal wound infection.10 Vancomycin is one of the most efficiently used local antibiotic for SWI prevention. It is a potent bactericidal glycopeptide antibiotic against methicillin resistant
*Staphylococcus aureus* (MRSA) and methicillin resistant coagulase negative *Staphylococcus species.* Studies have shown that topical antibiotics, used in a dry or powdered form, achieve much higher local wound concentrations than are possible with systemic antibiotics and that this high concentration persists for several hours after the closure of the wound. Vander Salm and colleagues found that using topical vancomycin resulted in a significant decrease in sternal wound infections in patients undergoing cardiac surgical procedures. This study was therefore aimed at evaluation of topical vancomycin by applying it at sternal edge in prevention of deep sternal wound infection.

**METHODS**

This was randomised control trial conducted at Seth GS Medical College and KEM Hospital. A total of 100 consecutive patients undergoing cardiac surgery were taken from November 2020 to October 2021 were included in the study. After the Institutional Review Board approval, an informed and written consent was obtained from all the participants.

**Inclusion criteria**

Inclusion criteria for current study are—patients with HTN, DM, obesity, elderly, COPD, patient undergoing median sternotomy, patient with LIMA harvesting, long CPB and long operation time, exploration for bleeding and long ICU and hospital stay.

**Exclusion criteria**

Exclusion criteria for current study are; patients undergoing thoracotomy and immunocompromised states.

**Preoperative preparations**

Routine preparation was done including full history taking, clinical examination, full laboratory and radiological investigations including coronary angiography, echocardiography and plain chest X-ray. Careful glycemic control for the diabetic patients according to guidelines to keep blood sugar less than 180 mg/dl. All measures advised by guidelines for prevention of surgical site infection were applied. All patients had received perioperative antibiotics, comprising of ceftriazone (1 g intravenously IV on induction of anesthesia. The IV antibiotics were continued postoperatively after surgery.

**Study groups**

100 patients scheduled for cardiac surgery majority CABGs and Valve surgeries, were randomly allocated in two groups A and B. Patients in group A (n=50) had reinforced closure technique without vancomycin paste application and patients in group B (n=50) vancomycin group had local application of vancomycin paste

**Techniques**

All patients had classic median sternotomy followed by On Pump technique for various cardiac cases. Harvesting: LIMA (for CABG cases) and saphenous vein graft were harvested. On-pump technique: techniques of sternotomy closure: the sternum was routinely closed with figure of eight technique using sternal wires. Vancomycin group: it was prepared by mixing 1000 mg of powder in 5 ml of normal saline and stirred until paste was formed. All patients had classic median sternotomy followed by on pump technique for various cardiac cases. Harvesting of LIMA and saphenous vein grafts (for CABG cases). Cases were carried out using on-pump technique then sternum was closed with figure of eight technique using sternal wires. In vancomycin group paste was prepared by mixing 1000mg of powder in 5 ml of normal saline and stirred until paste was formed and was applied. The incidence of deep sternal wound infection was evaluated during hospital stay and up till 1 month duration of discharge from hospital. Major risk factors like diabetes mellitus (DM), smoking, and operation time were also taken in to consideration for their implications in the outcome with the use of topical antimicrobial.

**Statistical analysis**

Data are presented as absolute values, percentages, and the mean standard deviation. The Fisher exact test and c2 test were used to test statistical significance for the incidence of sternal wound infections between the groups. Analyses were performed using SAS version 9.2 software (SAS Institute, Inc, Cary, NC).

**RESULTS**

All the parameters like age, obesity, diabetes mellitus, hypertension, CVD, smoking, hypoprotinemia were compared between control group and vancomycin group but it was not statistically significant. There was no significant relation between occurrence of SWI in patients of both studied groups and their preoperative, intra operative and post operative characteristics as shown in (Table 1-3).

There was no statistically significant difference among both studied groups regarding intraoperative data (p>0.05). There was non-significant difference regarding the ICU data in both studied groups (p>0.05). Vancomycin group patients had slightly shorter hospitals stay, in comparison to control group. However, it did not reveal statistical significance (Table 3). There is a statistically significant increased prevalence of superficial sternotomy infection with purulent discharge amongst control group patients (20% versus 4% of vancomycin group patients). There was no case of late sternal dehiscence with deep mediastinitis in any of the group (Table 4).
Table 1: Various parameters comparisons between both the groups.

| Variables               | Control group N=50 Frequency (%) | Vancomycin group N=50 Frequency (%) | Chi square test | P value |
|-------------------------|----------------------------------|-----------------------------------|----------------|---------|
| Age (years), mean±SD    | 45.36±13.768                     | 48.34±15.124                     | 1.03 (t test)  | 0.30 NS |
| Sex                     |                                  |                                   |                |         |
| Male                    | 32 (64)                          | 30 (60)                           | 5.223          | 0.22    |
| Female                  | 18 (36)                          | 20 (40)                           |                |         |
| Obesity                 | 7 (14)                           | 9 (18)                            | 0.4            | 0.69    |
| DM                      | 18 (36)                          | 16 (32)                           | 0.157          | 0.211   |
| HTN                     | 20 (40)                          | 18 (36)                           | 0.903          | 0.57    |
| Renal impairment        | 6 (12)                           | 3 (6)                             | 0.24           | 0.24    |
| CVD                     | 9 (18)                           | 6 (12)                            | 0.78           | 0.63    |
| Previous heart surgery  | 2 (4)                            | 2 (4)                             | 0.88           | 0.8     |
| Emergency surgery       | 2 (4)                            | 2 (4)                             | 0.88           | 0.98    |
| Hypoprotinemia          | 7 (14)                           | 9 (18)                            | 0.43           | 0.37    |
| Smoker                  | 4 (8)                            | 2 (4)                             | 0.24           | 0.81    |

Table 2: Intra operative comparisons between both the groups.

| Variables               | Control group N=50 Frequency (%) | Vancomycin group N=50 Frequency (%) | Chi square test | P value |
|-------------------------|----------------------------------|-----------------------------------|----------------|---------|
| Type of surgery         |                                  |                                   |                |         |
| CABG                    | 16 (32)                          | 14 (28)                           | 2.7            | 0.03    |
| Valve                   | 24 (48)                          | 25 (50)                           |                |         |
| CABG+valve              | 1 (2)                            | 2 (4)                             |                |         |
| Others                  | 9 (18)                           | 9 (18)                            |                |         |
| LIMA harvesting         | 17 (34)                          | 16 (32)                           | 1.31           | 0.51    |
| Redo surgery            | 2 (4)                            | 2 (4)                             | 0.76           | 0.92    |
| Total operative time (minutes) |                            |                                   |                |         |
| <180                    | 26 (52)                          | 29 (58)                           | 0.38           | 0.53    |
| >180                    | 24 (48)                          | 25 (42)                           |                |         |
| Open chest              | 0                                | 0                                 |                |         |
| Re-exploration          | 3 (6)                            | 3 (6)                             | 0.2            | 0.65    |

Table 3: Post operative comparison between both the groups.

| Variables               | Control group N=50 Frequency (%) | Vancomycin group N=50 Frequency (%) | Chi square test | P value |
|-------------------------|----------------------------------|-----------------------------------|----------------|---------|
| ICU stay (days)         |                                  |                                   |                |         |
| <3                      | 16 (32)                          | 14 (28)                           | 2.7            | 0.03    |
| >3                      | 24 (48)                          | 25 (50)                           |                |         |
| Mechanical ventilation  | 6.86±8.6                         | 6.78±7.5                          | 71.52          | 0.07    |
| Total hospital period (days) |                                 |                                   |                |         |
| <10                     | 36 (62)                          | 06 (12)                           | 0.38           | 0.53    |
| >10                     | 06 (12)                          | 02 (4)                            |                |         |
| Open chest              | 0                                | 0                                 |                |         |
| Mortality               | 3 (6)                            | 1 (2)                             | 0.23           | 0.63    |

DISCUSSION

Surgical wound infection represents the most frequent and most expensive complication after routine cardiac surgical procedures using median sternotomy as standard incision. Sternal wound infection is associated with an increased early and late mortality, morbidity and reoperation rate. Even in the current era, hospital mortality for deep sternal wound infection with or without mediastinitis is as high as 14% to 49%.
This novel sternal wound closure technique reduced postoperative wound infections in patients undergoing cardiac surgery through median sternotomy. The present bundle of measures proved to be effective in a large, multicentre, international group of patients, independent of the local hygiene culture as well as the educational status of the participating experts. The elimination of sternal wound infections has not been achieved by using expensive infrastructural measures, but by the consequent incorporation of several individual measures into a stable, multimodality protocol. Cardiac surgery performed during the COVID-19 pandemic will force the surgeons to operate in certain circumstances. Strict guidelines will decrease postoperative infections, reduce complications, and improve survival if it is followed properly. In our study, we tried to evaluate the safety and efficacy of local sternal vancomycin application in prevention of sternal wound infection in cardiac surgery patients. Multiple studies evaluated the effect of intraoperative variables on poststernotomy mediastinitis. They had found that long ischemic time, long cardiopulmonary bypass time, and long operation time are risk factors for poststernotomy wound infection. Additionally, authors found that prolonged ventilation time and ICU stay duration are risk factors for poststernotomy infections. Lu et al suggested that re-exploration for bleeding have been associated with sternal wound infections. Presence of two or more risk factors for infection was found to carry more risk for poststernotomy infection in our control group.

Jadhao et al found that vancomycin paste application over sternal edges is an effective method in prevention of sternal wound infection. The use of local vancomycin paste application is recommended especially in patients with co morbidities like diabetes mellitus and obesity. Additionally, Lazar et al found that topical sternal vancomycin application with perioperative antibiotics administration and strict glycemic control decreased rate of infection in postcardiac surgery patients. Results of our study showed that in the vancomycin group, poststernotomy superficial infections were in the form of superficial serous discharge. Frequent sterile dressing and thoracic support vest was enough for management.

Neither late sternal dehiscence nor deep mediastinitis was detected on follow up. Results of our study proved that topical sternal vancomycin paste is effective in prevention of post sternotomy deep mediastinitis and superficial infected discharge. There was no renal complication recorded with the used dose of vancomycin in the local vancomycin paste.

**Limitations**

This study has its limitations of small sample size, furthermore, surgical technique may vary between surgeons and change over time.

**CONCLUSION**

Application of topical vancomycin significantly reduces poststernotomy wound infection and prevents deep mediastinitis.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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