Comparison of two different skin preparation strategies for open cardiac surgery

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Abstract
Introduction: Surgical site infection (SSI) is a serious complication after cardiac surgery; skin preparation is an important step in the prevention of wound contamination with skin flora. In this study, two different skin preparation strategies (standard povidone iodine cleaning plus plain adhesive drape and microbial sealant (InteguSeal, Kimberly-Clark Health Care, Roswell, GA, USA) were compared in cardiac surgery patients.
Methodology: This prospective study included 96 cardiac surgery patients randomized to either a standard plain adhesive drape (28 patients, control group) or a microbial sealant (68 patients, study group). Bacterial isolates were obtained from the wounds in the operating room before the skin incision and after the surgical procedure had ended.
Results: Microorganisms were isolated from 38 patients (39.6%) in the study population. Twenty-seven of these patients were from the microbial sealant group and 11 were from the plain adhesive drape group. No postoperative wound infection was encountered in either group.
No statistically significant differences between the two groups regarding the number of patients with microorganism isolation (p = 0.974) or postoperative leukocyte counts and neutrophil granulocyte percentages were observed.
Conclusions: Regarding SSI after cardiac surgery, microbial sealant is equivalent to the standard skin preparation strategy applied with povidone iodine cleaning and a plain adhesive drape.

Key words: heart surgery; surgical drape; surgical wound infection


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Introduction
Surgical site infection (SSI) is a serious complication after cardiac surgery [1]. Sternal wound infections can vary from superficial to deep infections. Incidences range between 2% and 6% for superficial and between 0.45% and 5% for deep sternal wound infections [1-3]. The mortality rates for patients with deep sternal infections ranged between 10% and 47% in various studies [4-6]. Long-term survival is also worse for patients with deep sternal infections and mediastinitis [1,4]. Sternal wound infections lead to substantial increases in morbidity and thus result in increased lengths of stay, increased costs, and re-admissions [7,8]. In addition to a cumbersome reoperative process, patients are exposed to significant impairment in physical and mental health after an SSI [9,10].

Risk factors for sternal infection have long been identified in various studies [1-7]. Obesity, diabetes mellitus, duration of surgery and cardiopulmonary bypass (CPB), poor NYHA functional class, prior heart surgery, presence of comorbid conditions, poor hemostasis at the time of closure, chronic obstructive pulmonary disease (COPD), smoking, preoperative length of hospital stay, intra-aortic balloon counterpulsation (IABP), peripheral artery disease (PDH), and blood transfusions are among these factors [1-6]. The concentration and virulence of the pathogens, which are mainly endogenous skin flora, and the host’s natural defense operate together based on these risk factors.

In addition to general preventive measures such as administering appropriate antibiotic prophylaxis, minimizing local injury through surgery, and optimizing host defenses through better management of the patient in the perioperative period, attempts at reducing bacterial contamination of the surgical site have also been practiced in order to prevent SSI [11-14]. Different preoperative antiseptic showers, hair removal devices for the surgical site, various adhesive
barrier drapes – either plain or impregnated with povidone iodine – have been studied [15-21]. A microbial sealant (InteguSeal, Kimberly-Clark Health Care, Roswell, GA, USA) containing cyanoacrylate for immobilization of the skin flora during surgical procedures has been used in various studies with different results [22-25]. In a prospective randomized controlled study, we compared our routine skin preparation strategy (plain adhesive drape) with this microbial sealant in 102 patients.

**Methodology**

**Patients**

One hundred two patients undergoing coronary artery bypass grafting (CABG) or valve or congenital heart surgeries between January 2009 and March 2010 were enrolled in the study. Patients with prior cardiac surgery, any infection, skin lesions on the surgical site, and morbid obesity (body mass index > 35) were excluded from the study. Emergent cases and patients with an anesthesia risk score (ASA) score of more than 3 were also excluded, as they constitute a higher risk group for SSI mortality. Another reason for the exclusion of emergent cases is that before an emergent operation, it may not be possible to diagnose and treat an infection, which is an exclusion criteria of the study. Patients requiring postoperative surgical exploration were also excluded from the study because the routine antibiotic prophylaxis is changed (addition of a single dose of vancomycin – 1 gram intravenously) in these patients. Two patients from the control group were explored due to bleeding and excluded. Four patients allocated to the plain adhesive drape group were excluded from the study due to bacterial isolation from the baseline skin culture taken before the skin incision in the operating room, leaving 28 patients in the control group.

All patients received standard perioperative care and all operative procedures were performed by the same staff surgeon group. White blood cell (WBC) neutrophil granulocyte counts and percentages were obtained from the patients preoperatively, on the first, second, third, and fifth postoperative days. For the WBC counts, the above-normal value was 9,700 neutral cells/µL and neutrophil percentages above 78.4%.

**Perioperative care**

Hair removal was routinely performed with a clipper at 10 p.m. for the next day’s morning cases and at 6 a.m. on the same day for afternoon cases. After hair removal, patients were showered with soap only.

All operating rooms had laminar flow ventilation with HEPA filtration. Cardiopulmonary bypass with moderate hypothermia and the same blood cardioplegia methods were applied to all patients in the study. Blood glucose levels were monitored regularly and kept below 180 mg/dL with insulin infusion during the perioperative period. All patients received antimicrobial prophylaxis (cephazoline – 1 gram intravenously) before the first incision and afterwards until all chest tubes were withdrawn. The incisions were protected with sterile dressings for three days postoperatively.

**Skin preparation**

For all patients, a 10% povidone-iodine solution was applied as paint completely covering the surgical field and allowed to dry before either the standard plain adhesive drape (plain adhesive drape group, n = 68) or the microbial sealant (microbial sealant group [control group], n = 28) was applied.

**Microbiological methods**

Baseline skin cultures were obtained using a cotton swab from a rectangular area of 1.5×10 cm – corresponding to the area of an index finger – from the skin adjacent (right side) to the planned midline incision of the anterior chest before application of the drape or the sealant. If contamination (even one colony) occurred in the baselines cultures, the patient was excluded from the study. Immediately prior to sternal wiring and closure of the wound, cultures were obtained again from the same area corresponding to the previously cultured site. Any microorganism isolation was considered important. Isolates were identified in the microbiology laboratory using routine microbiological diagnostic procedures.

**Follow-up**

Patients were followed up for six months postoperatively for detection of any sternal wound infection. Patients’ names were checked against the hospital’s infection control committee’s records.

**Statistical analysis**

SPSS version 16.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Continuous variables were expressed as mean and ± standard deviation. Categorical variables were expressed as percentage. Categorical variables were analyzed using the χ² test and Fisher’s exact test. Continuous variables were analyzed using the t-test or Mann Whitney-U when
appropriate. All p values less than 0.05 were considered statistically significant.

**Results**

The mean operation time was 187.4±69.7 minutes for all patients. Sixty-four patients (66.7%) underwent a CABG procedure, twenty-four patients underwent valve replacements, seven patients underwent congenital heart operations, and a single patient underwent CABG and valve replacement surgery. A single mortality occurred postoperatively on the second day in the congenital heart disease group. Exploration for bleeding was required in two patients postoperatively and, as the routine antibiotic prophylaxis was changed (addition of single dose of vancomycin – 1 gram intravenously), these patients were excluded from the study.

Each groups’ preoperative characteristics were comparable except for the length of operation; this was significantly longer in the plain adhesive drape group (Table 1).

Microorganisms were isolated from 38 patients (39.6%). Twenty-seven of these patients were from the microbial sealant group (39.7%) and 11 (39.3%) were from the plain adhesive drape group with no significant difference in the number of patients with microorganism isolation (p > 0.05, Table 2). Isolated microorganisms were methicillin-sensitive coagulase negative *Staphylococcus epidermidis* in most patients (35 patients; 92.2%). *Staphylococcus epidermidis* was identified in one patient (2.6%), *Staphylococcus aureus* in another patient (2.6%), and *Acinetobacter baumannii* was identified in one patient (2.6%). The last two patients had been hospitalized in the coronary intensive care unit for 6 and 10 days, respectively, before the operation; after careful follow-up with no change in the antibiotic prophylaxis, both patients progressed without any evidence of clinical infection. WBC values returned to baseline on the second and fifth postoperative days, respectively.

Mean values of white blood cell counts, neutrophil counts, and neutrophil granulocyte percentages showed no differences between the two groups (p > 0.05, Table 2). After an expected rise in the WBC on the first to third postoperative days, 82.4% of the microbial sealant and 92.9% of the plain adhesive sealant patients reached normal limits on the fifth postoperative day, with no significant difference between the two groups (p > 0.05). There was also no significant difference between the two groups in terms of patients with elevated neutrophil counts and percentages on the fifth postoperative day (22.1% versus 21.4% for neutrophil counts and 20.6% versus 14.3% for neutrophil percentages for the sealant and control groups, respectively; p > 0.05).

Mediastinitis or SSI did not occur in any of the patients. Sternal dehiscence was observed in one male patient with CABG in the microbial sealant group. During reoperation when the sternum was reapproximated, no evidence of infection based on clinical, hematological, or microbiological observations was evident.

There was no statistically significant difference between patients with (38 patients) or without (58 patients) microorganism isolation with respect to presence of diabetes mellitus and length of operation (p > 0.05).

**Discussion**

Surgical site infection is a rare but potentially hazardous morbidity following cardiac surgery. Various approaches must be considered perioperatively to prevent SSI in cardiac surgery. Preoperative interventions include screening for *S. aureus* colonization, proper preparation of the patient for surgery, preoperative antiseptic showering, and proper hair removal techniques, especially with clippers [16-18]. Intraoperative management strategies to prevent SSI include strict adherence to the rules of sterilization, appropriate prophylactic antibiotic administration, shorter operation times, strict glycemic control, and minimization of electrocautery and bone wax usage [12-14]. However, despite of all these measures, SSI can still be encountered.

Skin preparation for surgery is one of the key elements to prevent postoperative infections. Skin preparation with topical iodine or chlorhexidine solutions is an almost universal procedure in most surgical clinics [15,16]. There are few reports in the literature regarding different surgical drapes for cardiac surgery [20-21]. Iodophor-impregnated drapes were found to be more resistant to bacterial contamination from the skin in microbiological and clinical grounds. However, they were less cost-effective when factors other than materials were compared [21]. Regarding disposable and traditional cotton gowns, Moylan et al. reported that the likelihood of wound infection was two-and-a-half times higher with cotton gowns compared to disposable gowns and the drape system in clean general surgical procedures [22].
### Table 1. Demographic characteristics of the patients

<table>
<thead>
<tr>
<th>Features</th>
<th>Microbial sealant (n = 68)</th>
<th>Plastic adhesive drape (n = 28)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>51.32 ± 16.52</td>
<td>48.61 ± 17.59</td>
<td>0.12</td>
</tr>
<tr>
<td>Gender (%)</td>
<td></td>
<td></td>
<td>0.77</td>
</tr>
<tr>
<td>Female</td>
<td>24 (35.3%)</td>
<td>9 (32.1%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>44 (64.7%)</td>
<td>19 (67.9%)</td>
<td></td>
</tr>
<tr>
<td>DM (%)</td>
<td>24 (35.3%)</td>
<td>12 (42.9%)</td>
<td>0.49</td>
</tr>
<tr>
<td>HT (%)</td>
<td>19 (27.9%)</td>
<td>10 (35.7%)</td>
<td>0.45</td>
</tr>
<tr>
<td>COPD (%)</td>
<td>13 (19.1%)</td>
<td>6 (21.4%)</td>
<td>0.80</td>
</tr>
<tr>
<td>Preop WBC</td>
<td>7784.4 ± 1958.2</td>
<td>8420.4 ± 1731.1</td>
<td>0.14</td>
</tr>
<tr>
<td>Preop neut count</td>
<td>4827.7 ± 1506.5</td>
<td>5382.1 ± 1409.3</td>
<td>0.10</td>
</tr>
<tr>
<td>Preop neut (%)</td>
<td>61.2 ± 7.5</td>
<td>62.3 ± 8.3</td>
<td>0.45</td>
</tr>
<tr>
<td>Type of operation (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CABG</td>
<td>47 (69.1%)</td>
<td>18 (64.3%)</td>
<td></td>
</tr>
<tr>
<td>Valve</td>
<td>16 (23.5%)</td>
<td>8 (28.6%)</td>
<td>0.87</td>
</tr>
<tr>
<td>Congenital</td>
<td>5 (7.4%)</td>
<td>2 (7.1%)</td>
<td></td>
</tr>
<tr>
<td>Length of operation (min)</td>
<td>178.13 ± 63.64</td>
<td>209.64 ± 79.29</td>
<td>0.044</td>
</tr>
</tbody>
</table>

DM: diabetes mellitus; HT: hypertension; COPD: chronic obstructive pulmonary disease; Preop WBC: preoperative white blood cell count; Preop neut count: preoperative neutrophil count; Preop neut (%): preoperative neutrophil percentage; CABG: coronary artery bypass grafting

### Table 2. Postoperative variables

<table>
<thead>
<tr>
<th>Features</th>
<th>Microbial sealant (n = 68)</th>
<th>Plastic adhesive drape (n = 28)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microorganism isolation</td>
<td>27 (39.7%)</td>
<td>11 (39.3%)</td>
<td>0.97</td>
</tr>
<tr>
<td>WBC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PO1</td>
<td>10877.1 ± 2722.1</td>
<td>10877.1 ± 2778.3</td>
<td>0.14</td>
</tr>
<tr>
<td>PO2</td>
<td>11905.9 ± 4108.1</td>
<td>11570.5 ± 3757.2</td>
<td>0.74</td>
</tr>
<tr>
<td>PO3</td>
<td>11547.5 ± 4492.3</td>
<td>10988.1 ± 3258.4</td>
<td>0.66</td>
</tr>
<tr>
<td>PO5</td>
<td>9388.4 ± 3042.8</td>
<td>8979.6 ± 2405.8</td>
<td>0.53</td>
</tr>
<tr>
<td>Neutrophil counts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PO1</td>
<td>9486.7 ± 2467.5</td>
<td>9780.0 ± 2529.6</td>
<td>0.61</td>
</tr>
<tr>
<td>PO2</td>
<td>9783.2 ± 3650.9</td>
<td>9803.5 ± 3499.9</td>
<td>0.82</td>
</tr>
<tr>
<td>PO3</td>
<td>9437.0 ± 4302.5</td>
<td>8708.8 ± 3937.2</td>
<td>0.56</td>
</tr>
<tr>
<td>PO5</td>
<td>6341.2 ± 3006.5</td>
<td>6074.6 ± 2549.8</td>
<td>0.86</td>
</tr>
<tr>
<td>Neutrophil %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PO1</td>
<td>86.6 ± 4.4</td>
<td>84.5 ± 7.0</td>
<td>0.25</td>
</tr>
<tr>
<td>PO2</td>
<td>81.3 ± 6.0</td>
<td>80.8 ± 8.1</td>
<td>0.76</td>
</tr>
<tr>
<td>PO3</td>
<td>80.6 ± 9.2</td>
<td>76.8 ± 13.1</td>
<td>0.23</td>
</tr>
<tr>
<td>PO5</td>
<td>64.6 ± 11.0</td>
<td>64.9 ± 11.1</td>
<td>0.89</td>
</tr>
<tr>
<td>Mediastinitis</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Mortality</td>
<td>0 (0%)</td>
<td>1 (3.6%)</td>
<td>0.12</td>
</tr>
</tbody>
</table>

WBC: white blood cell count; PO1-5: first, second, third, and fifth postoperative days; Neutrophil count: neutrophil granulocytes count; Neutrophil %: neutrophil granulocyte percentage
An antimicrobial skin sealant with cyanoacrylate has been evaluated in some studies [23-26]. In a randomized controlled study, a significant risk reduction for SSI with sealant was observed when compared to iodine-based skin preparations; this effect was more pronounced in obese patients [23]. In another study, a lower incidence of SSI was reported for the antimicrobial skin sealant group even though the combined operative risk score for SSI was significantly higher in that group [24]. However, some studies are in conflict with these reports. Waldow et al., for example, monitored a large group of patients (n = 983) and reported that there was no influence of antimicrobial skin sealant on the prevention of mediastinitis after cardiac surgery [25]. Similarly, Dohmen et al. did not find a significant difference between antimicrobial skin sealant and commonly used skin preparation systems, although a trend for SSI reduction was demonstrated [26]. In our study, a significant reduction in the microbiological skin contamination was also not observed with the use of microbial sealant compared to a plain adhesive drape. We also did not observe mediastinitis in any patient in our study population. In accordance with the clinical results, WBC neutrophil counts and percentages were not different between the two groups postoperatively.

Some limitations of our study include the relatively low number of patients enrolled, especially in the plain adhesive drape group. Another drawback of the study is the difference in the length of the operative procedures between the two groups. Although not consistent in every report, operation length was reported to be a risk factor for SSI or mediastinitis in some studies [4]. Part of the criticism of this study might be about the method of obtaining skin cultures. The cotton swab might inhibit recovery of specific bacterial species; therefore, a Dacron or rayon swab or special nylon filters could have been used. However, these methods were not available and we did not intend to make a quantitative analysis regarding number of isolated colonies. It could be better to enroll only patients with valve operations in the study, as internal mammary artery (IMA) harvesting in coronary artery bypass operations may predispose the patients to mediastinal infections. However, as bilateral IMA harvesting has a stronger risk for postoperative mediastinitis than does single internal thoracic artery (ITA) grafting, only patients with single ITA grafting were enrolled in the study. The patients were comparable in all aspects except for the different operation times.

An important observation worth mentioning from this study is the lifting of the plain adhesive drape from the wound edge towards the end of the surgery. This is commonly encountered with most adhesive drapes and may be due to perspiration during rewarming, trauma of the retractors, or the aqueous solutions used to paint the surgical site as mentioned in a previous study [27]. Although a comparison of this disadvantage was not specifically performed in this study, we observed that the skin in the sealant group was dry, with the cyanoacrylate film barrier still intact. We speculate that as there was neither inferiority nor superiority of the cyanoacrylate film barrier, studies regarding cost effectiveness of the product may be needed to determine whether this method of preventing SSIs should be universally adopted.

Surgical site infection is certainly a major complication after cardiac surgery; the risks should be minimized during procedure. Although the newly introduced drape techniques are attractive to clinicians, results with higher numbers of patients should be established and cost analysis studies should be performed to determine realistic outcomes.

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