Triclosan-Coated Sutures for the Reduction of Sternal Wound Infections: Economic Considerations

Tatjana Fleck, MD, Reinhard Moidl, MD, Alexander Blacky, MD, Michael Fleck, MS, Ernst Wolner, MD, Martin Grabenwoger, MD, and Wilfried Wisser, MD

Department of Cardiothoracic Surgery, AKH Vienna, Medical University of Vienna, Department of Cardiothoracic and Vascular Surgery, KH Hietzing, and Department of Infection Control, Medical University of Vienna, Vienna, Austria

Background. Sternal wound infections are a major complication after cardiac surgery in terms of morbidity and cost increase. To decrease the incidence of infection, we evaluated triclosan-coated sutures for the closure of the sternal incision, as it is known that most of the surgical site infections are related to the incision site.

Methods. From May to December 2005, a total of 479 patients underwent a cardiac surgical procedure. From those, 103 patients were closed with triclosan-coated suture material (cost per patient \$30 [in United States dollars]), whereas the remaining 376 patients had their incision closed with noncoated sutures (cost per patient \$21).

Results. During the study period, 24 patients had superficial (n = 10) or deep (n = 14) sternal wound

infections (cost per patient \$11,200). All those patients were closed with conventional suture material. In the triclosan group, no wound infection or dehiscence was observed during hospital stay and follow-up visits.

Conclusions. Triclosan-coated sutures might be valuable in the reduction of sternal wound infections and avoid the suture being a risk factor for surgical site infections. The increased cost of the coated suture material has to be weighed against the enormous cost of sternal wound infections caused directly by the cost of care as well as indirectly through the loss of economic productivity.

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Sternal wound infections are a major cause of morbidity and mortality after cardiac surgery. Although the frequency of sternal infection is reported to be low, between 0.7% and 3.3%, the costs associated with multiple procedures and increased hospital stay should not be underestimated [1, 2]. The causes of infection are mainly related to the location of the incision and the risk of wound contamination [3]. The specific difficulties associated with sternal wounds relate to the endogenous sources of infection as nasal carriage of *Staphylococcus aureus*, vomit, and pulmonary secretions. Exogenous sources of infection are related to tracheal intubation, monitoring wires, catheters, and pacing wires [4, 5].

The current Centers for Disease Control (CDC) guidelines recommend the wound to be covered for 24 to 48 hours after surgery. At this time, a fibrin scab seals the wound and thereby prevents the admission of bacteria [3]. Several studies have been conducted to evaluate the effectiveness of certain dressings, but unfortunately owing to the lack of empirical evidence, a high variability exists in the type of dressing used [6].

Triclosan (5-chloro-2 (2,4-dichlorophenoxyphenol) is a broad-spectrum biocide that has been used for more than 30 years in various products such as toothpaste and soaps. In the beginning the mode of action was supposed

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Address correspondence to Dr Fleck, Department of Cardiothoracic Surgery, AKH Vienna, Leitstelle 20A, Währinger Gürtel 18-20, Vienna, 1090, Austria; e-mail: tatjana.fleck@meduniwien.ac.at.

to be through nonspecific disruption of the bacterial cell membrane [7]. Newer studies, however, revealed that the target of triclosan is the Fab I gene, which blocks bacterial fatty acid synthesis (particularly the enzyme enoyl-acyl carrier protein reductase [ENR]) [8, 9].

The aim of our study was to evaluate whether the incidence of sternal wound infection can be reduced when triclosan-coated sutures are used for sternal wound closure and the impact on the overall costs and the costs associated with sternal wound infections.

Material and Methods

Patients

From May to December 2005, a total of 479 patients underwent a cardiac surgical procedure. Of those, 376 patients had a conventional wound closure, and 103 patients underwent wound closure with triclosan-coated sutures. This retrospective study was approved by the Institutional Ethics Board, and informed consent was obtained from each patient at the time of operation.

Preoperative characteristics of the patients are comparable and are given in Table 1. Patients were randomly selected into one group, so that all surgeons had patients with conventional closure and triclosan-coated sutures. They were not blinded to the closure method used, as they could tell by the different sutures used, but usually did know only that the sutures were new but not that they were antibacterial coated.

Table 1. Preoperative Characteristics of the Two Groups

	Triclosan n = 103	Conventional $n = 376$	<i>p</i> Value Univariate ANOVA
Age, years, mean	58.9 ± 20.7 (6–90)	67 ± 13.2 (23–94)	0.004
Male	65	331	1.00
Female	38	154	0.99
Body mass index >30	10 (10%)	30 (8%)	0.698
COPD	15 (14%)	36 (10%)	0.673
Diabetes mellitus	18 (17%)	39 (11%)	0.415
Preoperative renal impairment	10 (10%)	33 (9%)	0.495
EuroSCORE, mean (SD)	6.5 (0–16)	6.1 (0–19)	0.819
NNIS risk score 0	35%	25%	0.998
NNIS risk score 1	32%	50%	0.999
NNIS risk score 2	23%	20%	0.996
NNIS risk score 3	10%	5%	0.979

ANOVA = analysis of variance; COPD = chronic obstructive pulmonary disease; EuroSCORE = European System for Cardiac Operative Risk Evaluation; NNIS = National Nosocomial Infections Surveillance System; SD = standard deviation.

The National Nosocomial Infections Surveillance System (NNIS) risk score [10] was used for classification of the patients in terms of risk for the development of a surgical site infection, as an NNIS risk score of 2 or greater is associated with an increased risk for sternal wound infection.

Routine antibiotic prophylaxis consisted of cefazoline 4 g intravenously 30 minutes before skin incision and at the end of cardiopulmonary bypass in both groups. All sternal and wound closures were performed by the attending surgeon.

Technique of Sternal Closure Triclosan Group

After closing the sternal bone with steel wires, the sternal fascia was closed with interrupted 2-0 Vicryl Plus antibacterial sutures (Vicryl Plus Antibacterial [Ethicon, Sommerville, New Jersey]). Thereafter the subcutaneous tissue was closed with 2-0 Vicryl Plus antibacterial in a continuous fashion. The skin was closed with 3-0 Vicryl Plus antibacterial intracutaneous or after the fashion of Donatti in redo cases or patients with diabetes mellitus.

Technique of Sternal Closure Conventional Group

After closing the sternum in the same manner as above, the fascia was closed with interrupted sutures of 2-0 Vicryl Plus. Thereafter, the subcutaneous tissue was sutured continuously with 2-0 Dexon (US Surgical, Norwalk, Connecticut), and the skin was closed with 4-0 Maxon (US Surgical) intracutaneously. For redo cases or for patients with diabetes mellitus, 3-0 Dafilon (Aesulap, Center Valley, PA) was used for the skin and sutured after Donatti.

Outcome Measures, CDC Criteria

Patients were daily inspected by skilled nurse personal for any wound discharge, exudates, wound integrity, and signs of inflammation. In case of a suspect wound, swabs for cultures were taken, and a cardiac surgeon was called for evaluation and potential surgical revision. After discharge, all patients were seen in the outpatient department 2 weeks and 8 weeks after surgery. In the meantime, the patients were in a rehabilitation centre. In case of a wound infection detected there, the patients were sent to our center for inspection. Follow-up was 100% complete and was on average 7.6 months (range, 2 to 15).

Data Analysis

The SPSS Sigma Stat Version 3-1 software (SPSS, Chicago, Illinois) was used for data analysis. Results are given as mean and standard deviation. A Pearson correlation was done to match the two groups. Comparsions between patient groups were done with the Mann-Whitney U test or the Student t test, depending on the normality of the data. Univariate analysis and multivariate logistic regression analyses were used to determine predictors for risk of sternal wound infection. Variables showing a trend toward statistical significance (p < 0.30) were further evaluated in multivariate analysis. A value of p less than 0.05 was considered significant.

Table 2. Postoperative Characteristics of the Two Groups

	Triclosan n = 103	Conventional n = 376	p ValueUnivariateANOVA
Redo	21 (20%)	57 (15%)	0.040
CABG	29 (28%)	195 (52%)	
Valve	37 (36%)	85 (23%)	
CABG; valve	23 (23%)	53 (14%)	
Other	14 (14%)	43 (11%)	
Cardiopulmonary bypass time	109.1 ± 90	111.2 ± 89	0.338
Antic cross-clamp time	71 ± 40	65 ± 33	0.04
Wound infection 2A	0	10 (2.6%)	0.008
Wound infection 2B	0	14 (3.7%)	

ANOVA = analysis of variance; CABG = coronary artery bypass graft surgery.

Results

Incidence of Wound Infections

During the study, sternal wound infection developed in 24 patients (Table 2). The infection was further classified into superficial or deep after the Oakley classification [11], which resulted in 10 2A infections (superficial) and 14 2B infections (deep, with involvement of the sternal bone). The associated NNIS risk score was 0 in 10 patients, 1 in 7 patients, 2 in 5 patients, and 3 in 2 patients.

Infection beginning was after a mean 11.7 ± 6.7 days (range, 5 to 25). All patients with wound infections had a conventional wound closure, whereas patients closed with triclosan-coated sutures showed no signs of wound dehiscence or infection during the study period (univariate analysis of variance, p = 0.008). Mean follow-up was 7.6 months (range, 2 to 15). The most common isolated bacteria were *Staphyloccus aureus* (n = 9) and *S epidermidis* (n = 8), followed by methicillin-resistant *S aureus* (MRSA [n = 3]) and *Enterococcus faecalis* (n = 4).

Costs of Suture Material

The costs of our previously used suture material (Vicryl Plus, Dexon, and Maxon) are \$21 (in United States

Table 3. Cost of Sternal Wound Infection

Table 5. Cost of Sternal vvound Infection				
	Cost (US Dollars)			
Costs of sternal wound infection				
VAC rent	\$58 per day			
Total costs VAC therapy	\$800			
Operating costs for VAC implantation and VAC change	\$2,600			
Hospital stay approximately 13 days prolonged: 600×13	\$7,800			
Total cost of a sternal wound infection	\$11,200			
Estimated costs for the entire study group				
Operating cost	\$3,700			
Intensive care unit stay (1 day)	\$3,500			
Hospital stay (7 days)	\$4,200			
Suture material				
Conventional	\$21			
Triclosan coated	\$30			
Total				
Conventional	\$11,421			
Triclosan coated	\$11,430			
Total costs of 103 study patients	\$1,177,290			
Patient with sternal wound infection \$11,200 + \$11,400	\$22,600			
For the 24 patients	\$542,400			
Estimated costs of a 12 month period (example, Jan-Dec 2005)				
1,100 cardiopulmonary bypass cases	\$12,563,000			
Total costs of sternal wound closure in 1,100 patients	\$23,100			
Costs with the triclosan-coated sutures	\$33,000			
Forty patients sustained a sternal wound infection	\$448,000			

VAC = vacuum-assisted closure.

dollars) per patient and of the Vicryl Plus antibacterial-coated material, \$30 per patient. In summary, the Vicryl Plus antibacterial-coated material increases the cost per patient as much as \$9.

Costs of Sternal Wound Infection

All costs are estimated and are given in Table 3. Currently, our management of patients with sternal wound infections consists of surgical debridement, application of the vacuum-assisted closure (VAC) system (KCI, San Antonio, Texas), and secondary closure of the wound or plastic reconstruction with muscle flaps, depending on the integrity and involvement of the sternal bone [12]. The costs for a sternal wound infection was therefore calculated as follows: VAC rent, \$58 per day (approximately 10 days and 3 dressing changes are necessary until the infection resolved, and the wound is ready for definitive therapy); total costs VAC therapy, \$800 (VAC rent and usable material); operating costs for VAC implantation and VAC change (done in the operating room under general anesthesia), \$2,600; hospital stay approximately 13 days prolonged, $$600 \times 13 = $7,800$. Total cost of a sternal wound infection, \$11,200.

Estimated costs for the entire study group and the estimated costs of a 12-month period (for example, January to December 2005) are given in Table 3.

The costs of a patient with sternal wound infection is \$11,200 plus the costs of the normal stay (\$11,400), resulting in a total cost of \$22,600. Total costs of sternal wound closure in 1,100 patients can be estimated as \$23,100. When we calculate the increase of costs with the triclosan-coated sutures, we have an increased cost for suture material of \$9,900 per year. Calculated on 1,100 patients per year, the total costs of sternal wound closure would rise to \$33,000. However, during the same period (12 months, January to December 2005), a total of 40 patients sustained a sternal wound infection, which resulted in an increase in cost of \$448,000. In an optimistic case, if we can achieve a reduction of sternal wound infections of 50% (20 cases), that would result in a decrease of costs of \$224,000 minus \$9,900, or \$214,100.

Results of Statistical Analysis

Statistical analysis was performed to evaluate the differences between groups in terms of risk factors for sternal wound infection. Factors analyzed were age, redo surgery, the presence of chronic obstructive pulmonary disease, chronic renal failure, diabetes mellitus, body mass index greater than 30, EuroSCORE (European System for Cardiac Operative Risk Evaluation), extracorporeal circulation time, aortic cross-clamp time, intensive care unit stay, and intubation time.

The mean age of the conventional group was significantly higher than in the Triclsoan group (p < 0.05), The aortic cross clamp times were longer in the triclosan group as in the conventional group (p = 0.04) which might be based on the fact that the numeber of redo surgery was higher in this group, but this did not reach statistical significance. All other variables did show significant differences between the two groups. In multivar-

iate logistic regression analysis (variables used: age, redo surgery, aortic cross-clamp time, presence of infection), only the use of conventional sutures and redo surgery emerged as risk factor for the development of a sternal wound infection (p < 0.001) (Table 2).

Comment

In 1990, Loop and colleagues [13] published in the Maxwell Chamberlain memorial paper the costs of care of sternal wound complications after isolated coronary artery bypass surgery. They concluded that the costs of sternal wound infections are estimated to be 2.8 times higher than a normal postoperative course in cardiac surgical patients [13]. Several studies have examined potential risk factors, further classified into patient related, environmental related and treatment related, for the development of a sternal wound infections. In a recent study, Ridderstolpe and colleagues [2] identified the following as risk factors: age more than 75 years, obesity, cigarette smoking, insulin-dependent diabetes mellitus, bilateral use of internal mammary artery, prolonged ventilator support, and a New York Heart Association score higher than 3.

As a result of increasing cost awareness in conjunction with limited resources, it has become important to optimize and assure quality of surgical procedures [14–17]. On the other hand, the patients of today are more debilitated and often have to undergo combined procedures, which often require an increased use of resources and prolonged intensive care unit stay [18]. Nilsson and colleagues [19] recently showed that the total costs are significantly correlated with the EuroSCORE. These findings are in accordance with our own observation, that our overall mean EuroSCORE increased from mean 3 to 6,5 during the last 2 years. However, with an increased usage of resources and associated cost increase, we were able to maintain our overall mortality rate.

Sternal wound complications are relatively uncommon, with an average incidence of 3% at our department, but have a major impact on cost of care. Especially patients with a NNIS score of 2 or greater are at increased for the development of a surgical site infection. In our study cohort, 33% of the triclosan group and 25% of the conventional group had NNIS score of 2 or 3.

In addition to optimum treatment of these infections, we are trying to evaluate the risk factors and to optimize interventions such as careful patient preparation, meticulous surgical technique, aseptic technique, and attention to details such as multiple glove changes to decrease or even prevent this cost-intensive complication.

Most of the surgical site infections are related to the incision site; therefore, the infection is in close contact to the suture material. Already in 1957 Elek and Conen [24] observed that in the presence of suture material, fewer colony-forming units were required to produce surgical infection [24]. Hence, to exclude the sutures as being a risk factor, coated sutures have been invented.

Triclosan, a widely used antibacterial agent, possesses potent activity against the most common bacteria respon-

sible for postoperative sternal wound infections [20, 21]. As triclosan is an antiseptic and not an antibiotic, the risk of resistance is very low [20]. An assessment of triclosan susceptibility in MRSA and S epidermidis showed its effectiveness even for these bacteria [22]. Recent studies indicated an efficacy in prevention of wound infections in animal models of general surgery [23]. With the introduction of triclosan-coated sutures in post-cardiac surgery wound closure, we attempt to overcome first, the suture as a risk factor for infection, and second, to prevent the wound from contamination during the first 10 days after surgery, when 90% of wound infections develop. Another advantage of this locally administered antiseptic is that it can overcome the problem of substance distribution with the commonly administered single shot. The problem with perioperative antibiotic prophylaxis is that the need for hemostasis perfusion is markedly reduced in the sternal wound, and therefore the necessary tissue concentration of antibiotic needed for optimum efficacy is seldom reached.

Regarding the cost efficacy, this preliminary study shows a moderate decrease in overall infections costs, but this finding needs confirmation by a larger collective. The increased cost of \$9 per patient through the use of the triclosan-coated sutures is negligible if even one sternal wound infection can be prevented (cost, \$11,200). We therefore conclude that the use of triclosan-coated sutures in cardiac surgery might be a valuable approach for avoiding the suture as being a risk factor and prevent the wound form being contaminated.

We are aware of the study limitations, namely, the small sample size, which might compromise the results owing to the lack of statistical power. We are currently performing a large series to allow us to firm these preliminary results.

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