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Vancomycin Paste does not Reduce the Incidence of Deep Sternal Wound Infection after Cardiac Surgery

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Abstract

Background—Deep sternal wound infection (DSWI) is a devastating complication that increases morbidity and mortality in cardiac surgery patients. Vancomycin is often administered intravenously for antibiotic prophylaxis in cardiac surgery. Many cardiac surgeons also apply vancomycin paste topically to the sternal edges. We examined the effect of vancomycin paste upon the incidence of DSWI in patients undergoing elective cardiac surgery.

Methods—We performed a single institution, retrospective medical record review of all patients from 2003 to 2015 who underwent CABG, valve or CABG/valve surgery. We derived the Society for Thoracic Surgeons (STS) DSWI risk index for each patient and performed a systematic review of operative, pharmacy, microbiology and discharge records to identify patients that developed DSWI. Multivariate analyses were used to identify predictors of DSWI in this cohort and to quantify the effect of vancomycin paste.

Results—14,492 patients were examined, of whom 136 patients developed DSWI, resulting in an overall incidence of 0.9%. After multivariate analysis, body mass index, NYHA class and STS DSWI risk index remained statistically significant and associated with DSWI. Although the incidence of DSWI decreased over time, the use of vancomycin paste was not associated with a reduced incidence of DSWI.

Conclusions—There was a marked decrease in the incidence of DSWI over the study period, concurrent with institutional implementation of revised STS antibiotic dosing guidelines in 2007 and other strategies. However, the application of vancomycin paste to the sternal edges of patients undergoing cardiac surgery was not associated with a reduced risk of DSWI.

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Sternal wound infection is a rare but serious event after cardiac surgery (1, 2). Surgical site infection (SSI) accounts for 14%–16% of all nosocomial infections in hospitalized patients (3). SSIs are associated with increased morbidity and mortality due to prolonged hospitalization, extended antibiotic administration and additional surgical interventions. Furthermore, it has been estimated that patients with sternal wound infections, total perioperative costs are up to 2.8 times greater than patients with an uncomplicated post-operative course (1).

Over the past several decades there has been a substantial focus on infection control with several quality improvement and patient safety protocols being implemented in an attempt to minimize the occurrence of SSI (4). In 2007, the Society of Thoracic Surgeons (STS) recommended the addition of a glycopeptide, vancomycin, to standard beta-lactam coverage in patients with a high risk of staphylococcal infection undergoing cardiac surgery (5). In addition to routinely administered intravenous antibiotics, vancomycin paste applied directly to the sternal edges following sternotomy, has been used as an adjunct to further reduce the incidence of DSWI. There have been a limited number of studies to date that investigate whether the application of vancomycin paste reduces the incidence of sternal wound infection (6–8).

We hypothesized that the use of vancomycin paste is associated with a reduced frequency of DSWI. To explore this hypothesis, we investigated the incidence of DSWI at our institution in patients undergoing cardiac surgery with sternotomy over a twelve-year period, to determine whether the application of vancomycin paste is associated with the prevention of DSWI.

PATIENTS AND METHODS

Patient Populations

From the medical records of an urban Massachusetts Hospital (Brigham and Women's Hospital, Boston, MA) and with Institutional Review Board approval, all adults (≥ 18 years) undergoing primary and reoperation CABG, valve or valve/CABG only surgery between 01/01/2003 – 06/30/2015 were identified. Text searches and individual review of the local STS database, discharge summaries, surgical records, microbiology reports and transthoracic and transesophageal echocardiogram reports were reviewed. Patients with previous history of infective endocarditis, congenital heart disease other than bicuspid aortic valve, ventricular assist devices and cardiac transplant were excluded from further analysis. Long-term mortality data were obtained from routine institutional follow-up protocols, from our internal research data repository, and the Massachusetts Department of Public Health and the U.S. Social Security Death Indices.

We utilized variables from the STS database to determine the STS-derived estimated risk index of DSWI in our patient population (9–12). We also collected demographic, pharmacy, microbiology and operative records to identify which patients received vancomycin paste and to obtain additional covariates. Vancomycin paste was only prepared by mixing 5 or 10 grams of powdered vancomycin with a small amount of sterile water. This paste was applied directly to the sternal edges at the beginning and the end of the case in an effort to reduce

bone marrow bleeding. All diagnoses of DSWI were reconfirmed by independent manual chart review by two investigators.

Definitions

We defined DSWI as an infection involving the muscle, bone and/or mediastinum that occurred within 90 days of surgery, required operative intervention (incision and drainage or re-exploration), had positive cultures if obtained and the patient was not previously on antibiotics at the time of sampling, and received antibiotic treatment beyond routine perioperative prophylaxis (13). This definition is consistent with the STS database classification of post-operative deep sternal infection with the caveat that we specified a 90-day time period from initial surgery compared to the STS definition that utilizes a 30-day time period (13, 14). Bedside procedures were not included as part of the definition of DSWIs as they usually reflected only superficial infection.

Patient variables analyzed included age, gender, race, weight, body mass index (BMI), NYHA Class, presence of diabetes, baseline creatinine, dialysis, peripheral artery disease, previous myocardial infarction, operation type, intra-aortic balloon pump (IABP) and bypass time. These variables were defined in strict accordance to the STS Adult Cardiac Database Data Specifications (14). We also examined the effect of the attending Surgeon and the year of operation to identify institutional factors that increased the risk of DSWI.

Statistical Methods

Categorical variables were summarized by frequency and analyzed by $\chi 2$ and Fisher Exact tests. Comparisons of potential clinical predictors of DSWI, including age, estimated STS DSWI risk, vancomycin paste use and surgeon, amongst others against the occurrence of DSWI were performed. Variables associated with DSWI or the use of vancomycin paste (p value < 0.1), were entered into a backward stepwise logistic regression model. Variables with $p < 0.05$ were retained while forcing age, STS DSWI risk and the use of vancomycin paste into the model. Model fit was assessed using the log-likelihood goodness of fit test. Statistical significance was assigned for two-tailed p values less than 0.05. Statistical analysis was performed with JMP version 12.0 (SAS Institute, Cary, NC).

RESULTS

Of the 14,492 patients identified, DSWI occurred in 136 patients (0.9%). Demographic and patient characteristics of the study population are summarized in Table 1. The median calculated STS DSWI risk for the study population was 0.34% (95% CI 0.12 – 0.92%). Vancomycin paste use generally increased over the study period (Table 1). In addition, there were statistically significant differences in use of vancomycin paste by age, gender, race, BMI and other patient and operative characteristics. Without accounting for confounding factors, patients receiving vancomycin paste were not less likely to suffer from DSWI than those that did not receive vancomycin paste (0.8% vs. 1.0%, P=0.10). DSWI occurred at a median of 17 days (10–90% range 6 – 68 days) with 32% of DSWIs occurring more than 30 days after surgery (Figure 1).

Patients who suffered a DSWI had higher BMI, worse NYHA class, and were more likely to have diabetes, chronic lung, renal and peripheral artery disease with a higher median calculated STS DSWI risk (0.54%; 95% CI 0.16 – 1.5%) than patients who did not suffer a DSWI (0.33%; 95% CI 0.11 – 0.90%; P<0.0001, Table 2). They were more likely to undergo urgent and CABG surgery with longer operative times. Patients with a DSWI had increased mortality over the following one (16.9% vs. 6.1%; P<0.0001) and five years (30.2% vs. 15%; P<0.0001). DSWI incidence was not associated with attending surgeon.

As both vancomycin use and DSWI varied by year and several other variables, we constructed a multivariable logistic regression model of DSWI. We forced the use of vancomycin paste into a multivariable model (Table 3) and after stringent multivariate analysis, year of operation, BMI >30 kg/m2, NYHA class IV and STS DSWI risk index remained associated with the development of DSWI, while vancomycin paste application was not (OR = 1.2; 95% CI 0.79 – 1.82; P=0.40). Model fit assessed using the likelihood ratio goodness of fit test indicated good model fit ($\chi 2$ =111.6 P=0.76, Table 3).

COMMENT

We tested the hypothesis that the application of vancomycin paste to sternal edges after sternotomy reduced the incidence of DSWI in cardiac surgery patients. The main finding of this study is that vancomycin paste did not reduce the incidence of DSWI after accounting for STS DSWI risk index and other covariates. These findings are in contradistinction to prior literature, including a randomized, but unblinded trial of vancomycin paste in 416 patients undergoing cardiac surgery where a reduction in DSWI was reported (8). Further, a single surgeon case series using historical controls, observed a lower incidence of DSWI after the use of vancomycin in a calcium-thrombin, and platelet-rich plasma vehicle (6). In a case series of 532 low DSWI-risk patients undergoing coronary artery bypass grafting were subjected to several changes in clinical practice thought to reduce DSWI risk, along with use of vancomycin paste, and did not observe any DSWI (7). An additional case series of 1,020 patients, all receiving vancomycin paste, observed an incidence of DSWI of 0.45%, but failed to reference any control group (15). Comparison of our study with this prior literature reveals several factors that may cause these differences. These include smaller comparison groups, failure to adjust for important covariates, different follow-up periods and the use of different substrate preparations of vancomycin paste.

Our study also has limitations that may importantly impact its findings. We performed a single center, retrospective review and had limited data on specifics about administration of systemic perioperative antibiotics. The frequency of DSWI declined over the study period with a notable decrease in the incidence between 2009 and 2010 (1.5% to 0.7%), probably due to implementation of updated STS antibiotic prophylaxis guidelines for cardiac surgery (5) and quality improvement campaigns for appropriate and timely administration of perioperative antibiotics, adoption of perioperative glucose management protocols (16), and patient-specific sternal closure techniques including double wires and sternal bands (17, 18). In addition, not all surgeons used vancomycin paste and there were changes in practice of the study period; however, we did not observe a relationship between individual surgeon and incidence of DSWI.

There are known risk factors for DSWI including diabetes, renal failure and other measures of clinical state. To account for these important covariates, we used the local STS database to determine the calculated STS DSWI risk for each patient (10–12), observing the STS DSWI risk to be significantly higher in patients that developed DSWI. As the DSWI risk index was developed from data prior to the 2007 STS antibiotic prophylaxis guidelines (5), we examined the value of including other potential covariates upon improvement in multivariate model performance for DSWI. After multivariate analysis including age and STS DSWI risk index, two risk factors, BMI and NYHA class, retained significance despite being accounted for in the STS DSWI risk index. This observation suggests that development of a new STS DSWI risk index utilizing data from after the publication of the STS DSWI risk index is warranted.

The STS defines DSWI by the occurrence within a 30-day post-operative time period (13). In the absence of implanted material the CDC also defines DSWI as infection occurring within 30 days after the operation; however, if an implant, including sternal wires, is in place then CDC definition extends this period to one year (4). The STS does not make a distinction regarding placement of an implant or not. Because we observed 32% of DSWI occurring more than 30 days after surgery, we extended our definition to 90 days post-operatively. Nine additional patients suffered sternal wound infection between 90–365 days postoperatively, but were not classified as DSWI. We believe that consideration should be made to extend the definition of DSWI to 90 days post-operatively to better capture the true incidence of DSWI and that concordance between the STS and CDC definitions is desirable.

In summary, our results demonstrate that the application of vancomycin paste does not reduce the frequency of DSWI. It is possible that vancomycin in a biologically degradable substrate may provide benefit for prevention of DSWI by allowing more effective delivery of vancomycin. Further, although the use of vancomycin paste is not supported for the prevention of DSWI, it may still be a useful adjunct to reduce bleeding. Although DSWI is a rare event, it has a profound impact on morbidity, mortality and overall cost. Further prospective, randomized and blinded trials will be necessary to identify whether certain high-risk populations, such as those with obesity, diabetes, renal insufficiency or advanced heart failure would benefit from vancomycin paste application or adjusted antibiotic dosing regimens during CPB. These trials should consider the substrate used for delivery of vancomycin.

ABBREVIATIONS

BMI	Body Mass Index
CDC	Center for Disease Control and Prevention
CPB	Cardiopulmonary bypass
DSWI	Deep Sternal Wound Infection
IABP	Intra-aortic balloon pump
MIC	Minimum Inhibitory Concentration

NYHA	New York Heart Association
SSI	Surgical Site Infection
STS	Society for Thoracic Surgeons

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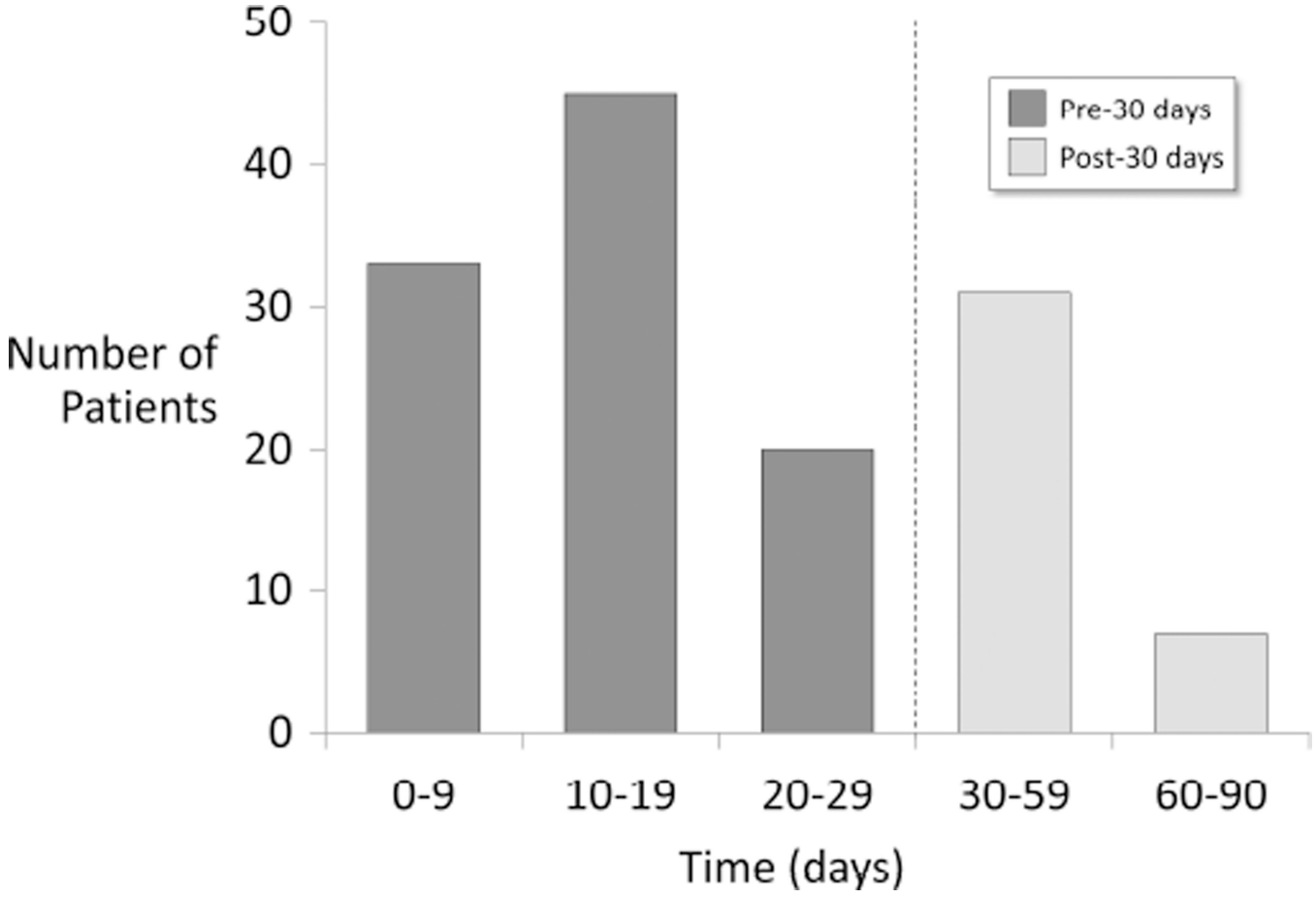

Figure 1.
Time of onset of deep sternal would infection over the 90-day postoperative period.

Table 1

Demographics of study population categorized by use of vancomycin paste.

		Study population (N=14,492)	Vancomycin Paste Used (N=4,997)	Vancomycin Paste Not Used (N=9,495)	P Value *
Demographics					
Age					
	< 40	409 (2.8%)	130 (2.6%)	279 (2.9%)	0.028
	40–49	1024 (7.1%)	318 (6.4%)	706 (7.4%)	
	50–59	2573 (17.8%)	852 (17.0%)	1721 (18.1%)	
	60–69	3854 (26.6%)	1354 (27.1%)	2500 (26.3%)	
	70–79	4261 (29.4%)	1522 (30.5%)	2739 (28.9%)	
	>=80	2371 (16.4%)	821 (16.4%)	1550 (16.3%)	
Year					
	2003–2004	2323 (16.0%)	46 (0.9%)	2277 (24.0%)	<0.0001
	2005–2006	2403 (16.6%)	689 (13.8%)	1714 (18.1%)	
	2007–2008	2307 (15.9%)	849 (17.0%)	1458 (15.4%)	
	2009–2010	2380 (16.4%)	737 (14.7%)	1643 (17.3%)	
	2011–2012	2224 (15.3%)	1184 (23.7%)	1040 (10.9%)	
	2013–2015	2855 (19.7%)	1492 (29.9%)	1363 (14.3%)	
Gender (Female)		4981 (34.4%)	1800 (36.0%)	3181 (33.5%)	0.002
Race (Caucasian)		13689 (94.4%)	4757 (95.2%)	8932 (94.1%)	0.011
Height (cm)			170 (155–183)	173 (157–183)	0.0001
Weight (kg)		82 (60–107)	82 (60–107)	81 (60–107)	0.043
BMI (kg/m2)		27 (22–36)	28 (22–36)	27 (22–36)	<0.001
BMI >30 kg/m2		4542 (31%)	1666 (33.3%)	2876 (30.3%)	0.0002
Medical History					
Diabetes		3849 (26.6%)	1356 (27.1%)	2493 (26.3%)	0.25
Hypertension		10336 (71.3%)	3680 (73.6%)	6656 (70.1%)	<0.0001
Chronic lung disease		2068 (14.3%)	756 (15.1%)	1312 (13.2%)	0.033
Creatinine (mg/dL)		1.0 (0.7 – 1.5)	1.0 (0.7 – 1.5)	1.0 (0.7 – 1.5)	0.13
Creatinine > 1.5mg/dL		1328 (9.2%)	428 (8.6%)	900 (9.5%)	0.07

	Study population (N=14,492)	Vancomycin Paste Used (N=4,997)	Vancomycin Paste Not Used (N=9,495)	P Value *
Preoperative dialysis	199 (1.4%)	77 (1.5%)	122 (1.3%)	0.21
Postoperative renal failure	877 (6.1%)	272 (5.4%)	605 (6.4%)	0.025
Peripheral Artery Disease	1898 (13.1%)	615 (12.3%)	1283 (13.5%)	0.040
Previous MI	3537 (24.4%)	1229 (24.6%)	2308 (24.3%)	0.70
Prior cardiac surgery	1296 (8.9%)	457 (9.1%)	839 (8.8%)	0.54
NYHA Class				
I	2374 (16.4%)	708 (14.6%)	1666 (17.5%)	<0.0001
II	6868 (47.4%)	2487 (49.8%)	4381 (46.1%)	
III	4634 (32.0%	1640 (32.8%)	2994 (31.6%)	
IV	616 (4.3%)	162 (3.2%)	454 (4.8%)	
STS DSWI Risk Index (%)	0.34% (0.12% – 0.92%)	0.33% (0.11% – 0.92%)	0.34% (0.11% – 0.90%)	0.020
STS DSWI Risk Index (%)				
<0.5%	9983 (68.9%)	3394 (67.9%)	6585 (69.3%)	0.16
0.5 – 1.0%	3383 (23%)	1189 (23.8%)	2189 (23.1%)	
>1.0%	1136 (8%)	414 (8.3%)	721 (7.6%)	
Operation				
Operative status				
Elective	9601 (66.3%)	3435 (68.8%)	6166 (64.9%)	<0.0001
Urgent	4480 (30.9%)	1395 (27.9%)	3085 (32.5%)	
Emergent or salvage	411 (2.8%)	167 (3.3%)	244 (2.6%)	
Operation type	879 (6.1%)			
CABG	5304 (36.6%)	1809 (36.2%)	3495 (36.8%)	0.085
Valve	6404 (44.2%)	2178 (43.6%)	4226 (44.5%)	
CABG/Valve	2784 (19.2%)	1010 (20.2%)	1774 (18.7%)	
IABP	783 (5.4%)	251 (5.0%)	534 (5.6%)	0.13
Bypass Time (min.)	119 (71–221)	126 (72–234)	116 (71–214)	<0.0001
Bypass time				
<120 min	6808 (50.0%)	2129 (45.1%)	4682 (53%)	<0.0001
120 – 180 min	4247 (31.3%)	1531 (32.4%)	2719 (31%)	

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	Study population (N=14,492)	Vancomycin Paste Used (N=4,997)	Vancomycin Paste Not Used (N=9,495)	P Value *
>180 min	2556 (18.8%)	1060 (22.5%)	1498 (17%)	
Open chest	147 (1.0%)	58 (1.2%)	89 (0.9%)	0.21
Outcomes				
DSWI (outcome)	136 (0.9%)	38 (0.8%)	98 (1.0%)	0.10
Mortality				
0–5 days	166 (1.1%)	57 (1.1%)	109 (1.1%)	0.97
0–1 year	897 (6.2%)	314 (6.3%)	584 (6.2%)	0.75
0–5 years	2197 (15.2%)	707 (14.2%)	1490 (15.7%)	0.013

Confidence intervals are 10^{th} and 90^{th} percentiles.

* Comparison of patients who received vancomycin paste and those who did not.

Table 2

Demographics of study population categorized by occurrence of DSWI.

		DSWI (N=136)	No DSWI (N=14,356)	P Value
Demographics				
Age				
	< 40	1 (0.7%)	408 (2.8%)	0.50
	40–49	10 (7.4%)	1014 (7.1%)	
	50–59	28 (20.6%)	2545 (17.7%)	
	60–69	35 (25.7%)	3819 (26.6%)	
	70–79	43 (31.6%)	4218 (29.4%)	
	>=80	19 (14.0%)	2352 (16.4%)	
Year				
	2003–2004	45 (33.1%)	2278 (15.9%)	<0.0001
	2005–2006	27 (19.9%)	2376 (16.5%)	
	2007–2008	23 (16.9%)	2284 (15.9%)	
	2009–2010	26 (19.1%)	2354 (16.4%)	
	2011–2012	8 (5.9%)	2216 (15.4%)	
	2013–2015	7 (5.2%)	2848 (19.8%)	
Gender (Female)		45 (33.0%)	4936 (34.4%)	0.75
Race (Caucasian)		129 (94.9%)	13560 (94.5%)	0.63
Height (cm)		173 (155–183)	173 (157–183)	0.92
Weight (kg)		88 (63–110)	81 (60–107)	0.0008
BMI (kg/m2)		30 (22–39)	27 (22–36)	0.0034
BMI >30 kg/m2		65 (47.8%)	4477 (31.2%)	<0.0001
Medical History				
Diabetes		57 (40.4%)	3792 (26.4%)	0.0001
Hypertension		103 (75.7%)	10233 (71.2%)	0.25
Chronic lung disease		28 (20.6%)	2040 (14.2%)	0.045
Creatinine (mg/dL)		1.1 (0.8 – 1.8)	1.0 (0.7 – 1.5)	0.050
Creatinine > 1.5mg/dL		21 (15.4%)	1307 (9.1%)	0.019
Preoperative dialysis		6 (4.4%)	193 (1.3%)	0.015
Postoperative renal failure		10 (7.4%)	867 (6.0%)	0.53
Peripheral artery disease		26 (19.1%)	1872 (13.0%)	0.048
Previous MI		47 (34.6%)	3490 (24.3%)	0.008
Prior cardiac surgery		13 (9.6%)	1283 (8.9%)	0.80
NYHA Class				
	I	25 (18.4%)	2349 (16.3%)	0.002
	II	54 (39.7%)	6814 (47.6%)	
	III	41 (30.2%)	4593 (32.0%)	
	IV	16 (11.8%)	600 (4.2%)	
STS DSWI Risk Index (%)		0.54% (0.16% – 1.5%)	0.33% (0.11% – 0.90%)	<0.0001

	DSWI (N=136)	No DSWI (N=14,356)	P Value
STS DSWI Risk Index (%)			
<0.5%	62 (45.6%)	9917 (69.1%)	<0.0001
0.5 – 1.0%	50 (36.8%)	3328 (23.2%)	
>1.0%	24 (17.7%)	1111 (7.7%)	
Operation			
Operative status			
Elective	70 (51.5%)	9531 (66.4%)	
Urgent	56 (41.2%)	4424 (30.8%)	0.0008
Emergent or salvage	10 (6.9%)	401 (2.8%)	
Operation type:			
CABG	65 (47.8%)	5239 (36.4%)	
Valve	35 (25.7%)	6369 (19.4%)	<0.0001
CABG/Valve	36 (26.5%)	2748 (44.3%)	
IABP	17 (2.2%)	768 (5.3%)	0.0008
Bypass Time (min.)	130 (81–255)	119 (71–220)	0.016
Bypass time			
<120 min	49 (39.5%)	6759 (50.1%)	0.056
120 – 240 min	45 (36.3%)	4202 (31.2%)	
>240 min	30 (24.2%)	2526 (18.7%)	
Open chest after surgery	2 (1.5%)	145 (1.0%)	0.62
Vancomycin Paste Use	38 (27.9%)	4959 (34.5%)	0.10
Outcomes			
Mortality			
0–5 days	0 (0%)	166 (1.2%)	0.07
0–1 year	23 (16.9%)	874 (6.1%)	<0.0001
0–5 years	41 (30.2%)	2156 (15.0%)	<0.0001

Table 3

Multivariate model of deep sternal wound infection (N=14,492; AUC=0.731). Log likelihood goodness of fit testing yielded P=0.76 indicating good model fit.

		OR	95% CI	Multivariate model P value
Year				
	2003–2004	1		
	2005–2006	0.56	(0.34 – 0.93)	
	2007–2008	0.49	(0.29 – 0.84)	<0.0001
	2009–2010	0.56	(0.34 – 0.94)	
	2011–2012	0.18	(0.08 – 0.41)	
	2013–2015	0.12	(0.05 – 0.28)	
BMI > 30 kg/m2		1.72	(1.21 – 2.46)	0.003
NYHA Class IV		1.85	(1.08 – 3.18)	0.026
STS DSWI Risk Index (%)				
	< 0.5%	1		
	0.5–1.0%	1.96	(1.33 – 2.88)	0.0002
	> 1.0%	2.48	(1.51 – 4.10)	
Vancomycin Paste Use		1.20	(0.79 – 1.82)	0.40