Early-onset of deep sternal wound infection after cardiac surgery is associated with decreased survival: A propensity weighted analysis

Ramsey Elsayed[1,2], Joseph N. Carey[2], Robbin Cohen[2], Mark Barr[2], Craig Baker[2], Vaughn Starnes[2], and Michael Bowdish[2]

[1]University of Southern California (USC)
[2]University of Southern California Keck School of Medicine

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Abstract

Objectives: To compare outcomes after the development of early ([?]30 days) versus delayed (>30 days) deep sternal wound infection (DSWI) after cardiac surgery. Methods: Between 2005 and 2016, 64 patients were treated surgically for DSWI following cardiac surgery. Thirty-three developed early DSWI, while 31 developed late DSWI. Mean follow up was 34.1 ± 32.3 months. Results: Survival for the entire cohort at 1, 3, and 5 years was 93.9, 85.1, and 80.8%, respectively. DSWI diagnosed early and attempted medical management were strongly associated with overall mortality (hazard ratio (HR), 25.0 and 9.9; 95% confidence intervals (CI), 1.18-528 and 1.28-76.5; p-value 0.04 and 0.04, respectively). Survival was 88.1, 77.0, 70.6 and 100, 94.0 and 94.0% at 1,3, and 5 years in the early and late DSWI groups, respectively (Log-rank = 0.074). Those diagnosed early were more likely to have a positive wound culture (odds ratio (OR), 0.06, 95% CI 0.01-0.69, p=0.024) and diagnosed late were more likely to be female (OR 8.75, 95% CI 2.0-38.4, p=0.004) and require an urgent DSWI procedure (OR 9.25, 95% CI 1.86-45.9, p=0.007). Both early diagnosis of DSWI and initial attempted medial management were strongly associated with mortality (hazard ratio 7.48, 95% CI 1.38-40.4, p=0.019 and hazard ratio 7.76, 95% CI 1.67-35.9, p=0.009, respectively). Conclusions: Early aggressive surgical therapy for deep sternal wound infection after cardiac surgery results in excellent outcomes. Those diagnosed with DSWI early and have failed initial medical management have increased mortality.

Introduction

The historical incidence of deep sternal wound infection (DSWI) after sternotomy for cardiac surgery ranges between 0.2 and 8%, with most recent estimates demonstrating a persistent risk despite implementation of quality improvement initiatives of 1-2%[1-4]. Although relatively uncommon, this complication is associated with increased duration of hospital stay or readmission, mortality, significant morbidity and costs[5,6].

Management options for deep sternal wound infection are typically individualized based on the extent of infection, offending organisms, and clinical status of the patient. Treatment can include combinations of antibiotic therapy, wound debridement, negative pressure wound therapy, partial or total sternal resection, and soft tissue flap reconstruction[7-11]. The optimal treatment for these infections remains controversial and highly individualized based on surgeon and treatment center[7]. Although a multitude of risk factors for deep sternal wound infection have been identified, the timing of onset of infection as a risk factor for mortality is not well characterized. The present study examined outcomes for deep sternal wound infection after cardiac surgery based on the time of onset.

Materials and Methods

Patient Selection, data collection, and endpoints

This was a systematic retrospective cohort study of consecutive patients undergoing surgical management of deep sternal wound infection following cardiac surgery between January 2006 and December 2016. The Institutional Review Board of the University of Southern California Health Sciences Campus approved this study (HS-17-00053) and waived the requirement for patient consent.

Patients were treated for DSWI at a single center (Keck Hospital of USC), however, patients transferred from other institutions were included. All patients were required to have undergone cardiac surgery via a full sternotomy. Partial sternotomies, other less invasive approaches, and sternotomies for non-cardiac surgery were not included. No time limit was placed on the interval between previous sternotomy and diagnosis of deep sternal wound infection. Patients with sterile sternal wound dehiscence who only required sternal rewiring were excluded. The follow-up period closed April 30th, 2017.

Deep sternal wound infection was defined according to the mediastinitis category as reported in the Centers for Disease Control and Prevention Guidelines[12]. The diagnosis of deep sternal wound infection required one of the following: positive cultures from the mediastinal area, evidence of infection during surgical exploration, or one of the following signs or symptoms with no other recognized cause: fever, chest pain or sternal instability, and either purulent drainage from the mediastinal area, positive cultures in blood or the mediastinal area, or mediastinal widening on chest x-ray[12].

The cohort was divided into two groups based on the timing of onset of deep sternal wound infection after the index cardiac procedure. An early infection was defined as those occurring less than 30 days from the index procedure, while a late infection was defined as those occurring greater than or equal to 30 days from the index procedure.

Patient baseline demographics, operative characteristics for the index cardiac procedure and all procedures related to the DSWI, and perioperative outcomes were identified through the USC Cardiothoracic Surgery Database and The Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database. All medical records from our electronic medical record were reviewed. Mortality was confirmed through clinical follow-up, direct patient (or family) or direct provider contact. Follow-up was 100% complete. The primary endpoint was mortality.

Management Approach

Once a diagnosis of DSWI is suspected, broad spectrum antibiotics were started and a CT of the chest obtained. Fluid resuscitation, nutritional evaluation, and cardiac optimization were instituted prior to aggressive and prompt surgical debridement. Initial exploration, drainage and irrigation of the mediastinum were followed by radical debridement of all devitalized tissue and removal of sternal wires and plates. Cultures were routinely obtained. Sternectomy was aggressively performed for severe infections. Depending on the extent of the infection and the patients clinical condition, staged debridement with open chest or negative pressure suction was considered versus immediate flap coverage. Those with overt sepsis, clinical instability, or extensive infection were typically treated with staged negative pressure wound therapy. Aggressive nutritional replacement was instituted, with enteral feeding if necessary. Once stabilized, and the debridement completed, soft tissue coverage was performed by our plastic surgeons. The extent of flap coverage was dependent on the extent of the debridement and included pectoralis myocutaneous advancement, pectoralis rotation, and omental flaps. Omental flaps were often selected in the case of mediastinal grafts or extensive dead space. Skin grafts and free flaps were considered in patients with inadequate skin coverage.

Statistical Analysis

Data analyses were performed using SAS 9.4 software (SAS institute, Cary, NC). Figures of odds and hazard ratios were prepared using Prism 7 (GraphPad Software, Inc., La Jolla, CA, USA). Data are presented for the overall cohort, and the two groups stratified by timing of onset of deep sternal wound infection after index cardiac procedure. Categorical data were summarized as the number and percentage of patients. For continuous data, the mean value and standard deviations were reported for normally distributed data while the median value and interquartile ranges were reported for non-normally distributed data. Continuous variables were compared between the two groups using either Student's t-test or the Wilcoxon rank sum test, depending on data normality. Categorical variables were compared using the chi square or Fisher's exact test, depending on expected values. Unadjusted survival was assessed by Kaplan-Meier methods for the overall cohort and various strata. Between strata comparisons were made by log-rank. Multivariable Cox proportional hazard modeling was used to model predictors of death in the overall cohort.

Multivariable logistic regression was performed to determine which preoperative variables were predictive of onset of DSWI within 30 days of index cardiac procedure. Early onset DSWI was modeled as the dependent variable and the following independent variables were included in the model based on univariate analysis, the medical literature, and biologic plausibility: sex, smoking (yes vs. no), previous cardiac surgery to the index operation for the DSWI (yes vs. no), positive wound culture at time of initial DSWI operation (yes vs. no), and urgency of initial DSWI operation (yes vs. no). The C-statistic and Hosmer-Lemeshow goodness-of-fit test were reported for the model.

To estimate the impact of timing of onset of deep sternal wound infection after cardiac surgery on subsequent mortality, the multivariable regression model was used to calculate a subject's propensity for having an early onset DSWI. Propensity scores were then entered into a separate Cox proportional hazard regression model to calculate adjusted hazard ratios for estimates of mortality.

Results

Overall cohort

A total of 64 patients with a deep sternal wound infection after a previous cardiac procedure were identified during the study period. Baseline and index operative, and operative characteristics of the DSWI procedures are shown in **Tables 1, 2, and 3** . In general, the overall cohort was predominantly older men (mean 60 ± 12 years) who were borderline obese (30.2 ± 7.1 kg/m^2), hypertensive, diabetic, and had coronary artery disease. Almost half were transferred to our center from another institution for management of the DSWI after a cardiac procedure elsewhere. The most common index cardiac procedure was a coronary artery bypass grafting, followed by a valve repair or replacement. DSWI after an aortic procedure or ventricular assist device were less common in this cohort.

The median time to diagnosis of DSWI was 30 days (Interquartile Range (IQR) 13.5 – 67 days). Positive wound cultures were documented in 54 (84%) with Gram-positive organisms being the most common. Twenty-one (33%) patients had an attempt at medical management with antibiotics alone, however, all eventually underwent surgical therapy as per study design. A total of 135 operative procedures for treatment of the DSWI were performed on these 64 patients. Surgical management was debridement and wound therapy alone in 13 (20%), while 51 (80%) underwent flap coverage as either a primary or secondary procedure.

Mean follow up was 34.1 ± 32.3 months. Overall survival was 93.9, 85.1, and 80.8% at 1, 3, and 5 years respectively (**Figure 1**). Univariate Cox proportional hazard modelling showed only a history of hypertension was associated with overall mortality (hazard ratio (HR), 0.21, 95% confidence intervals, 0.05-0.96, p=0.44, see Supplemental Table 1). A multivariable model of mortality with those variables with univariate p valves <0.2 (infection diagnosed more than 30 days after index operation, male gender, history of hypertension, and attempted medical management) showed infection diagnosed within 30 day of index cardiac procedure and attempted initial medical management were strongly associate with overall mortality (hazard ratios 25.0 and 9.9, respectively), while the absence of hypertension was protective (hazard ratio 0.10, **Table 4)** .

Comparison of cohorts based on timing of DSWI diagnosis

As time of diagnosis of the DSWI in relation to the index procedure was significant for mortality on adjusted multivariable Cox proportional hazard modeling, we divided the cohort into two groups: those in which the diagnosis of DSWI was made within 30 days of the index cardiac procedures (33 patients, early onset), and those in which it was made 30 days or more after the index cardiac procedure (31 patient, late onset).

Baseline and index operative, and operative characteristics of the DSWI procedures of the two cohorts are shown in **Tables 1, 2, and 3** . Those with early diagnosis of DSWI were less likely to be female, more likely to be smokers, and more likely to have an elevated glycated hemoglobin. The early DSWI group also had longer lengths of stay after the index hospital procedure.

The median time to infection was 14 days in the early onset group and 76 days in the late onset group. Fifty-four patients (84%) had positive wound cultures, and a positive wound culture was more common in the early DSWI group. Types of organisms did not differ between groups. Equal numbers of patients had an initial attempt at medical management, however all eventually underwent surgical therapy as per study design. The initial DSWI operation was performed urgently after diagnosis more commonly in the late diagnosis group, and electively in the early group. Initial flap coverage was performed in similar numbers of in the early diagnosis group, while delayed flap coverage was more common in the delayed infection group.

Mean follow up was slightly longer in the late DSWI group (32.0±28.6 versus 36.1±35.8 months, p=0.03). Overall survival was 88.1, 77.0, 70.6 and 100, 94.0 and 94.0% at 1,3, and 5 years in the early and late DSWI groups, respectively (Log-rank = 0.074).

Propensity analysis and adjusted outcomes by cohorts of timing of DSWI diagnosis

Given the significant differences in baseline characteristics between the early and late diagnosis groups, five baseline variables were used to create a logistic regression model for selection to an early or late diagnosis of DSWI. **Figure 3** shows the results of the logistic regression model predicting selection to the early or late diagnosis of DSWI group. Those more likely to be in the early diagnosis group were those with positive wound cultures (odds ratio 0.06, 95% CI 0.01-0.69, p=0.24) and those more likely to be in the late diagnosis group were females (OR 8.75, 95% CI 2.0-38.4, p=0.004) and those requiring urgent DSWI procedures (OR 9.25, 95% CI 1.86-45.9, p=0.007). The area under the receiver operator curve (c-statistic) was 0.84 and the Hosmer-Lemeshow goodness-of-fit test was not statistically significant (p=0.62), suggesting good model discrimination and limited collinearity and interactions **(Supplemental Figure 1)** .

Propensity score adjusted multivariable Cox proportional hazard regression outcomes for mortality are shown in **Figure 4** . Early diagnosis of DSWI and initial attempted medical management were both strongly associated with increased mortality (hazard ratio 7.48, 95% CI 1.38-40.4, p=0.019 and hazard ratio 7.76, 95% CI 1.67-35.9, p=0.009, respectively). This was independent of initial operation (flap or negative pressure wound therapy) or whether any flap was eventually performed.

Conclusions

Deep sternal wound infection (DSWI) after cardiac surgery is known to be associated with an increased length of stay, readmission and mortality. Perrault et. al. recently reported outcomes in 5,198 patients enrolled in a prospective study evaluating infections after cardiac surgery and their effect on readmissions and mortality for up to 65 days after cardiac surgery. The cumulative incidence of DSWI (termed mediastinitis in this report) was 0.79% and the median time to diagnosis of infection was 20.6 days. Readmission rates and mortality were five times higher in the mediastinal infection group.

Admitting that DSWI occurs and has been relatively resistant to quality improvement initiatives, we sought to examine outcomes after treatment for DSWI after cardiac surgery. The main findings of our study are that overall survival with our surgical approach to these infections is relatively good, and that those diagnosed with DSWI early and those who have failed initial medical management have increased mortality. As a tertiary referral center, almost half of the subjects in the study were transferred to our institution after their index cardiac surgical procedure and our general management approach is to be surgically aggressive with these infections given the known increased mortality risk in this population.

The overall survival in this cohort of patients was 93% and 81% at 1 and 5 years, suggesting that our operative approach results in acceptable outcomes. These findings of survival after treatment of DSWI are consistent with other reports. Jones et. al. reported a 8.1% 20 years mortality rate in 409 patients undergoing flap coverage of DSWI[11], while Baillot et. al. reported a 15 years review of 88% three years survival of

124 patients undergoing primary negative pressure wound therapy as treatment for DSWI[10]. Others have reported similar results with a variety of treatment modalities[8,13-16].

Risk factors for increased mortality after development of a DSWI in the overall cohort included early diagnosis of DSWI (within 30 days of index cardiac procedure) and attempted medical management. The significant finding of attempted medical management is not entirely surprising given that by study design we only included those patients who had undergone surgical procedures for the DSWI. Therefore, we do not know the true risk of failed medical management of DSWI at our institution as patients managed successfully with medical therapy alone, are not included in this analysis.

The role of timing of diagnosis of DSWI was investigated further by comparing outcomes in those diagnosed early (<30 days) and late ([?]30 days) with DSWI after index cardiac procedure. Those with an early diagnosis of DSWI were more likely to be male, more likely to be smokers, and more likely to have elevated glycated hemoglobin levels. After developing propensity scores from a multivariable logistic model to predict differences in baseline characteristics between the two group, male sex, smoking and a positive wound culture were significantly more common in the early diagnosis group. Propensity adjusted Cox proportional hazard modeling demonstrated that early diagnosis of DSWI and an initial attempt at medical management were strongly associated with mortality (hazard ratio 7.48, 95% CI 1.38-40.4, p=0.019 and hazard ratio 7.76, 95% CI 1.67-35.9, p=0.009, respectively), and that this effect was independent of the initial operation (flap or negative pressure wound therapy) or whether any flap was eventually performed.

Early onset infection was more common in male patients, smokers, and those with a positive wound culture while female sex and the requirement of an urgent operation was more common in late onset infection. After adjusting for differences between both groups, those with early onset deep sternal wound infection had higher mortality, likely reflecting a greater degree of aggressiveness of these infections.

These findings support our general philosophy that early aggressive treatment of these infections is optimal. The results suggest that those with early onset infections would perhaps benefit from early aggressive surgical management of DSWI. This general approach is also advocated by others, as Sears et. al. recently demonstrated in a national database study that delayed flap closure for DSWI is associated with increased mortality[8].

Limitations to our study should be acknowledged. First, the retrospective nature of the study limits the ability to draw conclusions regarding causality. Second, our study might be underpowered to draw definitive conclusions. Lastly, the timing and surgical approach undertaken are not standardized and are subject to surgeon preference, reflecting daily clinical practice.

In summary, these results suggest that the early onset of DSWI is associated with increased mortality and that a high index of suspicion, early diagnosis, and aggressive treatment of this devastating complication after cardiac surgery can results in improved outcomes.

Figure Legends

Figure 1 . Kaplan-Meier survival analysis of entire cohort with a deep sternal wound infection with 95% confidence banks.

Figure 2. Kaplan-Meier survival analysis after deep sternal wound infection, stratified by time of onset after cardiac surgery, (<31 days, solid line) versus late (>30 days, dashed line).

Figure 3. Forest plot of multivariable logistic regression model of late (>30 days) or early ([?] 30 days) onset of deep sternal wound infection after cardiac surgery. Odds ratio (OR) > 1.0 favors late infection (bars represent 95% confidence intervals).

Figure 4. Forest plot of propensity adjusted multivariable analysis of mortality. Hazard ratio (HR >1.0 associated with increased mortality (bars represent 95% confidence intervals). Abbreviations: NPWT = negative pressure wound therapy.

Table 1. Baseline characteristics of overall cohort and comparison of early versus late DSWI strata[1]

	Overall (N=64)	Early DSWI (N=33)	Late DSWI (N=31)	Odds Ratio	95
Demographics					
Age (years)	60.3 ± 12	61.6 ± 10.3	59 ± 13.6	—[2]	—
Female	23 (36)	7 (11)	16 (25)	3.96	1.3
Body mass index (kg/m^2)	30.2 ± 7.1	30.7 ± 6	29.7 ± 8	—[1]	—
Comorbidities					
Hypertension	50 (78)	25 (76)	25 (81)	1.33	0.4
Diabetes mellitus	33 (52)	17 (52)	16 (52)	1.00	0.3
Coronary artery disease	44 (69)	23 (70)	21 (68)	0.91	0.3
Congestive heart failure	12 (19)	4 (12)	8 (26)	2.52	0.6
Hyperlipidemia	27 (44)	13 (41)	14 (47)	1.27	0.4
End-stage renal disease	14 (22)	9 (27)	5 (16)	0.51	0.1
Smoking history	20 (31)	14 (42)	6 (19)	0.32	0.1
Anemia	45 (71)	25 (76)	20 (67)	0.64	0.2
Immunosuppression	34 (53)	19 (58)	15 (48)	0.69	0.2
Reoperative sternotomy	11 (17)	3 (9)	8 (26)	3.47	0.8
Hemodynamic instability	16 (25)	8 (24)	8 (256)	1.08	0.3
Glycated hemoglobin	6.5 (5.7, 7.4)	6.9 (6.4, 7.5)	5.6 (5.2, 6.5)	—[2]	—
Preoperative ejection fraction	55 (43, 65)	55 (50, 65)	55 (35, 63)	—[2]	—
Transfer from outside hospital	30 (47)	13 (20)	17 (27)	1.86	0.6

[1] Values are n (%), mean (standard deviation), or median (interquartile range). Odds ratios and 95% confidence intervals are also reported for categorical comparisons between strata.

Table 2. Index operative procedure and outcomes for overall cohort and comparison of early versus late DSWI strata

	Overall (N=64)	Early DSWI (N=33)	Late DSWI (N=31)	Odds Rat
Index cardiac surgery procedure				
Coronary artery bypass grafting	37 (58)	22 (67)	15 (48)	0.46
Valve repair or replacement	15 (23)	8 (24)	7 (23)	0.91
Aortic procedure	9 (14)	3 (9)	6 (19)	2.40
Ventricular assist device	3 (5)	0 (0)	3 (10)	—[2]
Outcomes for index procedure				
Length of stay (days)	14.5 (8, 26.5)	19 (12, 32)	10 (6, 17)	—[3]
Intensive care length of stay (days)	4 (0, 12)	4 (1, 15)	3.5 (0, 11)	—[3]
Time to infection (days)	30 (13.5, 67)	14 (10, 19)	76 (37, 238)	—[3]
Long-Term Outcomes				
Follow-up (months)	34.1 ± 32.3	32.0 ± 28.6	36.1 ± 35.8	—[3]
Mortality	7 (11)	6 (18)	1 (2)	0.15

Table 3. Microbiological and operative characteristics of DSWI procedures for overall cohort and comparison of early versus late DSWI strata

	Overall (N=64)	Early DSWI (N=33)	Late DSWI (N=31)	Odds Ratio	95% CI	p-value
Wound culture	54 (84)	32 (97)	27 (71)	0.19	0.04-0.96	0.04
Gram Positive	37 (69)	22 (59)	15 (41)	0.47	0.17-1.29	0.14
Gram Negative	12 (22)	5 (23)	7 (77)	1.63	0.46-5.8	0.44
Gram Positive and Negative	3 (6)	2 (67)	1 (33)	0.52	0.04-6.00	1.00
Other	2 (4)	2 (100)	0	0.94	0.86-1.02	0.49
Timing of DSWI procedure						
Urgent (< 24 hours of diagnosis of DSWI)	20 (31)	6 (18)	14 (45)	3.70	1.19-11.5	0.03
Elective ([?] 24 hours of diagnosis of DSWI)	44 (69)	27 (82)	17 (55)	0.27	0.08-0.83	0.02
Initial Attempt at Medical Manage- ment	21 (33%)	10 (30)	11(35)	1.27	0.44-3.60	0.66
Requirement of a soft tissue flap	51 (80)	31 (61)	20 (39)	0.60	0.22-1.65	0.33
Initial	23 (45)	13 (57)	10 (43)	0.84	0.27-2.58	0.76
Delayed	28 (55)	17 (61)	11 (39)	0.84	0.27-2.58	0.76

Table 4. Propensity score adjusted multivariate Cox-proportional hazard model of preoperative risk factors for mortality in overall cohort of DSWI patients

	Hazard Ratio	95% Confidence Interval	p-value
Variable			
Infection within 30 days of index cardiac procedure	25.0	1.18-528	0.039
Gender (male)	1.60	0.13-19.7	0.72
Hypertension (no)	0.10	0.13-0.75	0.03
Attempted initial medical management	9.88	1.28-76.5	0.03

Table Legends

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Table 2. Index operative procedure and outcomes for overall cohort and comparison of early versus late DSWI strata

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Author Contributions:

Concept/design: RE, JC, RC, MLB, VS, MEB

Data collection: RE, AH, AA

Data analysis/interpretation: RE, MEB

Drafting article: RE, RC, MB, MEB

Critical revision of article: RE, MEB

Approval of article: RE, RC, MLB, VS, MEB

Statistics: RE, MEB

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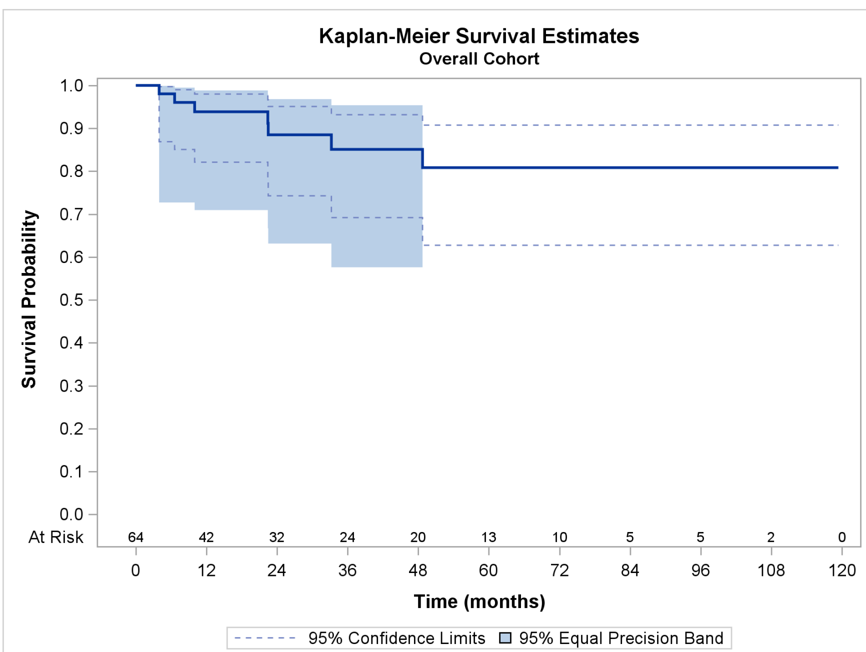
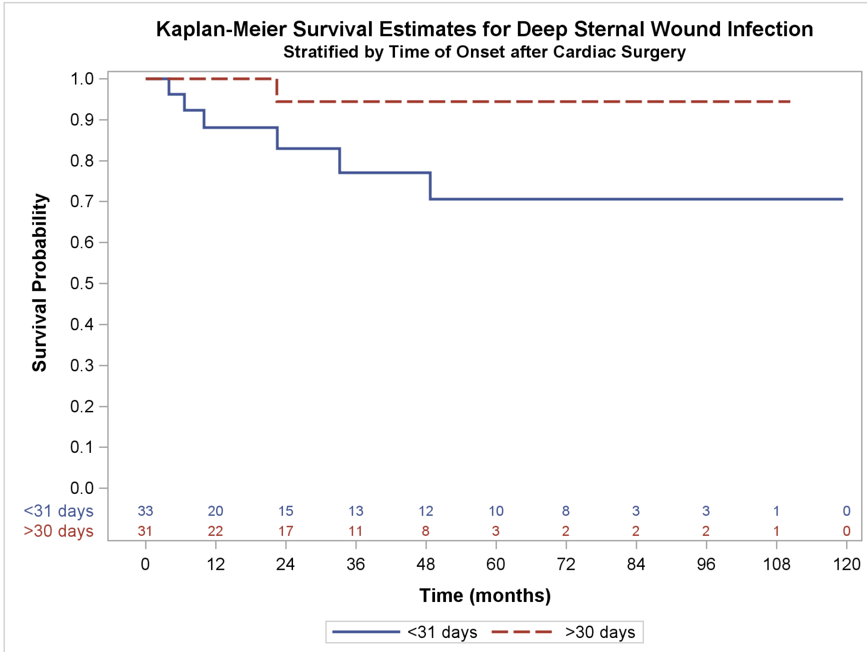
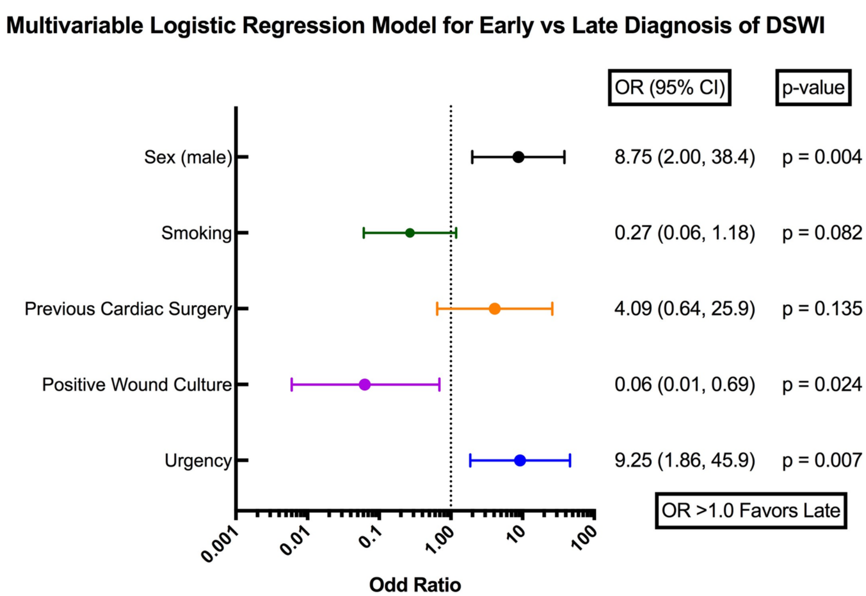
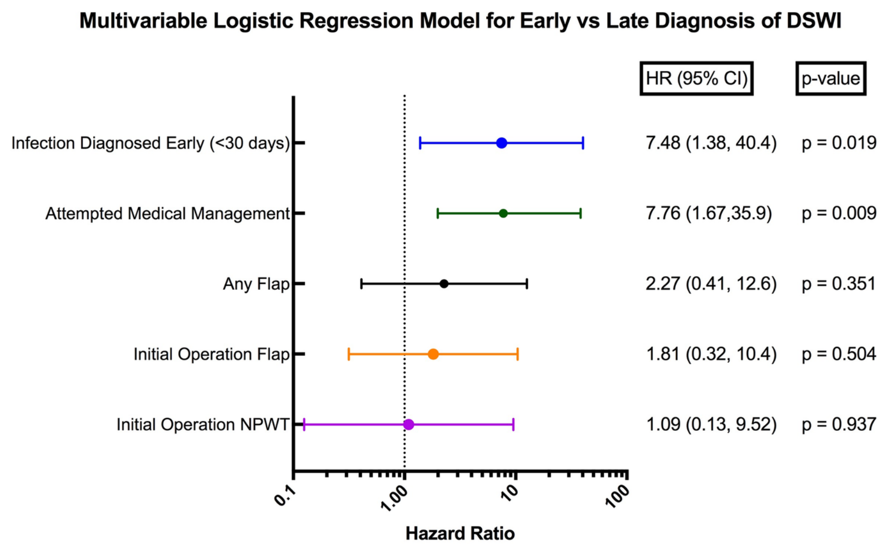




Kaplan-Meier Survival Estimates for Deep Sternal Wound Infection
Stratified by Time of Onset after Cardiac Surgery
Survival Probability
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
<31 days 33 20 15 13 12 10 8 3 3 1 0
>30 days 31 22 17 11 8 3 2 2 2 1 0
0 12 24 36 48 60 72 84 96 108 120
Time (months)
<31 days
>30 days



Multivariable Logistic Regression Model for Early vs Late Diagnosis of DSWI
OR (95% CI)
p-value
Sex (male)
8.75 (2.00, 38.4)
p = 0.004
Smoking
0.27 (0.06, 1.18)
p = 0.082
Previous Cardiac Surgery
4.09 (0.64, 25.9)
p = 0.135
Positive Wound Culture
0.06 (0.01, 0.69)
p = 0.024
Urgency
9.25 (1.86, 45.9)
p = 0.007
OR >1.0 Favors Late
0.001
0.01
0.1
1.00
10
100
Odd Ratio


Multivariable Logistic Regression Model for Early vs Late Diagnosis of DSWI
HR (95% CI)
p-value
Infection Diagnosed Early (<30 days)
7.48 (1.38, 40.4)
p = 0.019
Attempted Medical Management
7.76 (1.67,35.9)
p = 0.009
Any Flap
2.27 (0.41, 12.6)
p = 0.351
Initial Operation Flap
1.81 (0.32, 10.4)
p = 0.504
Initial Operation NPWT
1.09 (0.13, 9.52)
p = 0.937
0.1
1.00
10
100
Hazard Ratio