Predicting cardiac surgical site infection: Development and validation of the B-SIR tool

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Abstract

Objective: To develop and validate a new risk tool (Barts Surgical Infection Risk (B-SIR)) to predict surgical site infection (SSI) risk after all types of adult cardiac surgery, and compare its predictive ability against existing (but procedure specific) tools: Brompton-Harefield Infection Score (BHIS), Australian Clinical Risk Index (ACRI), National Nosocomial Infection Surveillance (NNIS).

Design: Single-centre retrospective analysis of prospectively collected data.

Patients and Setting: Data from 2,449 patients undergoing cardiac surgery between January 2016 and December 2017 from one European tertiary centre were included.

Methods: Thirty-four variables associated with SSI risk after cardiac surgery, identified from the literature, were collated from three local databases. Independent predictors were identified using stepwise multivariate logistic regression. Bootstrap resampling was conducted to validate the model. Hosmer-Lemeshow goodness of fit test was performed to assess calibration of scores. A p-value of <0.05 was considered statistically significant for all analyses.

Results: The B-SIR model was constructed from six independent predictors (female gender, body mass index (BMI) >35, diabetes, left ventricular ejection fraction (LVEF) <45%, peripheral vascular disease (PVD) and operation type, and the risk estimates were derived. The Receiver Operating Characteristics curve for B-SIR was 0.679, vs 0.603 for BHIS, 0.618 for ACRI and 0.482 for the NNIS tool.

Conclusion: B-SIR provides greater predictive power of SSI risk after cardiac surgery compared with existing tools in our population. Further studies are needed to validate B-SIR on other cardiac populations and specific cardiac patient groups.

1. Introduction

Surgical site infections (SSI) are serious complications accounting for 20% of all the healthcare-associated infections[1] and are considered the second most frequent type of hospital-acquired infection (HAI) in Europe and the United States.[2] Although SSIs are among the most preventable HAIs,[3] they represent a significant burden in terms of morbidity, mortality and additional costs to health care system. In cardiac surgery, approximately 3.6% of the patients who have heart operation experience an SSI.[10] Although the mortality related to SSI is only about 1.6%,[11] the mean additional hospital LOS can be up to 12 days[12] which results in extra hospital cost of €9444 per SSI-infected patient.[11] The most important part of the economic burden due to SSI after cardiac surgery are the indirect costs due to patients' temporary or permanent incapacity to work, income lost by family members, forgone leisure time, travel and home care costs, which can account up to eight times the direct costs of SSI.[12] Thus, efforts in understanding and modifying risk factors to reduce SSI are imperative.

Although there are existing SSI risk stratification tools for cardiac patients, they have several limitations. For example, the National Nosocomial Infection Score (NNIS) risk index categorises patients according to their infections in terms of American Association of Anaesthesiologists (ASA) score, wound type and duration of surgery. Since most of the patients who undergo cardiac surgery have ASA scores greater than three and clean wounds, this index only dichotomised patients on the basis of the procedure duration,[13] which is not sufficient. Since then, new methods of predicting and stratifying SSI risks in cardiac populations have been developed including the Australian Clinical Risk Index (ACRI)[14] and Brompton and Harefield Infection Score (BHIS).[15] They both have good predictive power in comparison with the NNIS risk index,[14-15] but both were developed in only coronary artery bypass graft (CABG) patients and it is unclear whether they can be applied to other cardiac

surgery patient groups. At our centre, we conduct a wide range of cardiac surgeries and require SSI risk prediction to inform these patient groups. By giving the patients more insights on their risk, patients will be empowered to take part in the decision making. Shared decision making has been proven to improve motivation for therapy adherence and lifestyle change (Rosselo et al) Previous study also demonstrated that implementation of risk prediction tool facilitated clinicians in becoming more aware of the outcomes, more informed of the risk factors and have a more positive attitude toward preemptive management. (Kappenn et al 2016) Further, it has been recognised that risk profile assessment may vary according to each institution's patient population.[16] Thus, we sought to develop and validate a new score based on our population and to compare its predictive ability with existing cardiac risk scores.

2. Methods

2.1. Research ethics and governance

Ethics approval was received from NHS Research Ethics Committee (REC, reference 18/WA/0159) and Confidentiality Advisory Group (CAG, reference 18/CAG/0080) for using existing patient data for research purposes without explicit patient consent. The study was conducted in accordance with the General Data Protection Regulation 2018[17] and the Declaration of Helsinki of 2013.[18]

2.2. Participants

All consecutive patients undergoing coronary artery bypass graft (CABG) surgery and/or cardiac valve surgery in a single tertiary centre, one of the largest cardiac hospitals in Europe, between January 2016–December 2017 were eligible for inclusion. Excluded patients were those aged ≤18 years at the time of surgery, had grown-up congenital heart disease related

surgery, with concurrent aortovascular surgery, had ventricular-assist device, haemolung, impellar, extracorporeal membrane oxygenator before and/or after cardiac surgery and had an open-chest immediately after surgery. The Centre for Disease Control and Prevention's definition was used for SSI after cardiac surgery.[19]

2.3. Identification of variables associated with SSI risk after cardiac surgery

Forty-five variables were identified following a systematic literature search of CINAHL, Embase and Medline databases using the following search terms: risk factors, surgical site infection, cardiac surgery. All variables, except four (steroid use, preoperative HbA1c level, cerebrovascular accident (CVA) and congestive heart failure), were routinely collected locally and matched the definition of the national data reporting. However, seven variables were further excluded (endocarditis, prolonged mechanical ventilation, creatinine level prior to surgery and transfusion of packed red blood cells (pRBC) and platelet both within 24 hours and within 3 days postoperatively) due to considerable proportions (17.7-81.5%) of missing data. Thus, a total of 34 variables were included in the data analysis and were categorised into preoperative, intra-operative/surgical and postoperative variables.

2.4. Data collection and linkage

Prospectively collected local data which is collected for mandatory submission to national databases was obtained from our local Intensive Care National Audit and Research Centre (ICNARC), National Institute of Cardiovascular Outcomes Research (NICOR) and Public Health of England (PHE) Surgical Site Infection Surveillance databases. Data quality was assessed for accuracy, completeness and reliability and medical notes (electronic and hard copies) were accessed where data was missing or deemed to be inaccurate.

Data from the three databases were matched and linked in a stepwise fashion using medical record number (MRN), date of birth (DOB) and date of surgery. Patients who could not be matched were excluded. Once data linkage was complete, a unique identifier using a six-digit code was assigned, and all personally identifiable information was removed immediately.

2.5. Statistical methods

A sample size of 2000 patients was expected, based on the number of surgeries undertaken at the centre from 2016 to 2017. Assuming an SSI rate of 3.8% based on the national average, this sample size will give 80% power at the 5% significance level to detect a 0.33 standard deviation difference between those with and without SSI for any continuous variable. For categorical variables with prevalence ranging from 10-90%, detectable odds ratios for this sample size will lie between 1.8 and 2.4.

Previous studies have found the area under the curve (AUC) from receiver operating characteristic (ROC) curve to be approximately 0.7 for BHIS and ACRI.[14-15] If the correlation for Barts Surgical Infection Risk (B-SIR) score with the established BHIS and ACRI scores lies between 0.9 and 0.5, the detectable effect size for 80% power at the 5% significance level will range from a ROC area of > 0.747 (correlation=0.9) to >0.799 (correlation=0.5) for the new score. MedCalc version 18 software was utilised for power analysis.

Patient characteristics were defined and then stratified into two groups based on the presence or absence of SSI. The descriptive data was presented as mean ± standard deviation for continuous variables and as number and percentage (%) for categorical variables. Differences between the two groups were compared using univariate logistic regression.

A complete case analysis was utilised first, followed by sensitivity analysis using multiple imputation as a method to assess the impact of missing data on the included variables.

Univariate binary logistic regression analysis was performed to identify the univariate predictors of SSI and the corresponding odds ratio (OR) and its 95% confidence interval (CI). Forward stepwise multivariate binary logistic regression analysis was subsequently performed to identify the significant independent predictors (OR and 95% CI) of SSI. For all regression analyses, the referent category was assigned to the one that conferred the least risk of SSI.

Bootstrap resampling was conducted to internally validate the model using 1000 random draws from the total sample size. Hosmer-Lemeshow goodness of fit test was performed to assess calibration of the scores. For this test, a p-value that was not statistically significant ($p>0.05$) was considered to indicate a reasonable model fit. The B-SIR tool was then developed using bias corrected coefficients from the model as weights. SSI risk estimates were also calculated based on the methods used in the Framingham model.[20]

The area under the ROC curve was utilised as measure of discrimination. Further internal validation was undertaken by dividing the population into two random samples. A score was developed from the initial sample and compared its predictive performance as measured by the AUC in the second sample. All statistical analyses were conducted using IBM SPSS statistical package version 25. A p-value of <0.05 was considered statistically significant for all analyses.

3. Results

3.1. Participants

A total of 3885 patients underwent cardiac surgery during the study period, of which 3634 (93.5%) were linked across all three databases (NICOR, ICNARC and PHE). The majority of the unmatched patients (n=251, 6.5%) had undergone cardiac surgery as a complication of highly specialized procedures such as trans-catheter aortic valve implantation, percutaneous

coronary interventions, cardiac catheterization, implantation of permanent pacemaker and others (n=172; 68%) and thus were non-eligible for this study. All non-matched patients were excluded with a further 445 (12%) patients excluded as they did not meet one or more of the study's eligibility criteria mostly due to concurrent aortovascular surgery (41.6%) and repair of congenital heart problem (29.4%). This resulted in 3189 patients being included in the univariate analysis. Patient demographics are reported in Table 1. In total, seven hundred-forty patients had at least one missing risk variable and were excluded from the multivariate analysis. Thus, the final multivariate model was conducted on 2449 patients (out of 3189 eligible patients, 77%) with complete data. Multiple imputation results, however, confirmed that the missing data did not introduced any bias to the result.

3.2. B-SIR model development

Univariate analysis

Overall, 341 (10.7%) patients experienced an SSI. As highlighted in Table 1, those who developed an SSI were more likely to be female (31.9% SSI vs 24.2% non-SSI, p=0.002), have a BMI >30 (45% vs 32.3%, p<0.001), diabetic (46.8% vs 30.5%, p< 0.001), had a history of PVD (24.4% vs 5.3%, p<0.001) and hypertension (89.9% vs 82.6%, p=0.001) and with LVEF <45% (24.4% vs 17.1%, p=0.001). They were also likely to have coronary artery bypass graft (CABG) with and without valve surgery (85% vs 66.3%, p<0.001), done as an urgent operation (29.3% vs 23.9%, p=0.027), utilised an internal mammary artery (IMA) (75.1% vs 62.2%, p<0.001) and less likely to have a valve implant (32.7% vs 44.8%, p<0.001).

Multivariate analysis

BMI >35 (OR= 2.365, 95% CI, p<0.001), female gender (OR=1.722, 95% CI, p<0.001), a history of diabetes (OR=1.500, 95% CI, p = 0.001), the presence of PVD (OR=1.73, 95% CI,

p=0.007), a LVEF <45% (OR=1.446, 95% CI, p=0.012) and the type of operation (OR=5.442, 95% CI, p< 0.001) were identified as independent predictors of SSI (Table 2).

Final B-SIR model

Following the bootstrap resampling, the bias corrected coefficients were derived, which were used as weights for the calculation of B-SIR scores and rounded to the nearest integer. A point score for each independently predicted variable was derived (Appendix A) and presented in Table 3.

Comparison of risk prediction of B-SIR, BHIS, ACRI and NNIS tools

Area under the ROC curve (AUC) for B-SIR tool is 0.679 (0.649-0.710), versus 0.603 (0.570-0.637) for BHIS, 0.618 (0.585-0.652) for ACRI and 0.482 (0.449-0.515) for NNIS risk index (Figure 1). B-SIR differed significantly from all three existing tools (p<0.001). Further, it has a higher discriminatory ability in detecting the risk of SSI after cardiac surgery in this study cohort. The internal validation conducted on the split random samples further confirms a good discriminatory power of the B-SIR model (1st sample AUC = 0.685; 2nd sample AUC = 0.668). Finally, Hosmer-Lemeshow test showed a score of 0.497 indicating a reasonable model fit of the B-SIR tool.

Discussion

Despite the extensive efforts made to identify risk factors associated with SSI after CABG, relatively little has been done to determine the risk factors associated with SSI after cardiac surgery in other cardiac surgery populations. At our centre, we conduct a wide range of cardiac surgeries and require SSI risk prediction to inform these patient groups. Thus, we used local prospectively collected existing data from three databases (NICOR, ICNARC and

PHE) to determine the significant predictors of SSI after cardiac surgery, to explore the predictive power of existing validated risk tools and develop a model that will improve the prediction of SSI in our patient population. While we found the ACRI and BHIS models demonstrated good predictive power of SSI development, we concurred with other studies identifying that NNIS is a poor predictor of SSI after cardiac surgery.[13 21] Both the ACRI and BHIS models were validated in procedure-specific populations (valve[21] and CABG,[22] respectively) which may be why they performed less well than the B-SIR tool which was developed specifically to include patients undergoing various forms of cardiac surgery. This can also suggests that risk profile assessment varies based on the institutions' patient population as previously identified. [16]

Interestingly, we identified having CABG alone increases the risk of developing SSI in this study cohort. This finding is important as this tool explores the effect of the type of cardiac surgery on the SSI risk. Both ACRI and BHIS utilized CABG patients only in their tool development.[14-15] This risk could be related to the incidences of donor leg SSIs associated with CABG. Previous report indicates that impaired healing of the leg harvesting site occurs in 44% of the patients, [23] which makes leg SSI as the leading cause of readmission after bypass surgery.[24] Hence, particular attention should be given by clinicians to the surgical technique used to harvest the vein grafts and the postoperative wound care in this particular group of patients. We also found that that preoperative risks may be more important than intraoperative and postoperative risk factors, contrary to the findings of other research.[25-26] This indicates that high-risks patients may be identifiable before surgery and that some of these risks are potentially modifiable. Patients' understanding of their risks could support them to take a more active role in effectively managing or reducing chronic condition such as diabetes and obesity. For example, patients could be involved more closely in attempts to

reduce weight and improve blood sugar control prior to surgery to reduce their risks of SSI. This would be particularly useful for elective cardiac procedures planned for obese patients with stable cardiac disease, where there is a time window available prior to surgery. Hence, utilization of the B-SIR tool can potentially aid patient selection, counselling and development of targeted interventions for the prevention of SSI. However, in contrast with previous reports,[27-28] we found that the use of an IMA is a protective factor against SSI. The use of IMA is a well-established risk factor for delayed wound healing after CABG since it deprives the sternum of vascular flow to the anterior chest wall.[27] Our different result could be due to an unexpected increase of SSI in valvular patients at one point during the study period creating an imbalance in the dataset. We further explored this and the B-SIR predictive power remained exactly the same when we tested the model without this variable.

Strengths and limitations

This study has several strengths. First, the B-SIR model was developed to include all types of SSI (sternal and/or leg, superficial or deep). Previous studies highlight how the same risk factors predict basically all types of SSI complicating CABG surgery.[14 26] There is little evidence specific to SSI in valvular surgery but we felt that the same risk factors would probably affect this group of patients. By considering all types of SSI, the inherent problem of wound misclassification bias for cardiac surgery patients- where some deep or organ space SSI were considered as superficial SSI, would potentially be prevented. Secondly, the total number of SSI cases in this study is relatively high (n=341). Although this could be due to multifactorial reasons, it enhances the study's ability to identify associations with a large number of variables which strengthens its generalizability on our patient population. Finally, we have utilized a more robust procedure of deriving the B-SIR score using the bias corrected coefficients from the model as weights, which is considered as the only algebraically correct approach of calculating risk scores.[29]

Despite these strengths, there are three main limitations of this study. First, SSIs detected from primary admissions to patients' discharge from the hospital were all included. This could lead to a potential over-estimating of SSI due to the patients' interpretation of reporting an SSI. However, this would lead to a more conservative result which we believe would likely not have biased our result. Enhanced surveillance within the primary care, perhaps through the implementation of telemedicine, may assist in more accurate SSI community assessment in the future. Secondly, the B-SIR tool was validated internally; hence, its applicability to other cardiac populations in other healthcare settings is unknown. Therefore, further work to externally validate the B-SIR tool, both nationally and internationally, is currently being explored. Finally, we were not able to include all variables identified as associated with SSI risk after cardiac surgery in our analysis, as they are not included in our routinely available datasets. These included steroid use, prolonged mechanical ventilation, history of endocarditis and HbA1C level. Exploration of the impact of these factors on SSI development is recommended. Although we have evaluated the effect of blood transfusion, our sample is under powered to explore this and thus, additional investigation could be undertaken to explore the effect of these factors.

In conclusion, the B-SIR model improves the predictive ability to assess risk of SSI after cardiac surgery compared with the BHIS, ACRI and NNIS risk index. Further validation study is recommended to assess its predictive power in other settings and patient groups.

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Tables and Figures

Table 1 Patients' Demographics

Variables	Without SSI (n = 2848) [a] Frequency (%) / Mean ± SD	With SSI (n = 341) [a] Frequency (%) / Mean ± SD	Odds ratio	95% CI Lower	95% CI Upper	p value
Age	65.03 ± 12.58	65.22 ± 10.34	1.001	0.992	1.010	0.793
BMI : 30 – 34.9	681 (24.4)	95 (28.5)	1.438	1.105	1.870	0.007
≥35	220 (7.9)	55 (16.5)	2.577	1.848	3.592	0.000
Gender: Female	686 (24.2)	108 (31.9)	1.467	1.149	1.872	0.002
Smoker: Yes	1329 (46.7)	170 (49.9)	1.136	0.908	1.423	0.265
Diabetes: Yes	844 (30.5)	155 (46.8)	2.003	1.591	2.523	0.000
COPD: Yes	168 (6.2)	26 (8.0)	1.303	0.848	2.003	0.228
Renal failure: Yes	139 (5.0)	24 (7.2)	1.496	0.955	2.343	0.079
Critical pre-op status: Yes	59 (2.1)	11 (3.3)	1.558	0.810	2.996	0.184
LVEF: < 45%	477 (17.1)	81 (24.4)	1.560	1.192	2.042	0.001
PVD: Yes	143 (5.3)	81 (24.4)	2.431	1.672	3.535	0.000
HTN: Yes	2210 (82.6)	293 (89.9)	1.872	1.289	2.720	0.001
Cardiogenic shock: Yes	21 (0.8)	3 (0.9)	1.175	0.348	3.960	0.795
Pre-operative Inotropic/ vasopressor use: Yes	26 (1.0)	2 (0.6)	0.631	0.149	2.669	0.531

Ventilated pre-operatively: Yes	34 (1.2)	2 (0.6)	0.493	0.118	2.061	0.333
Previous cardiac surgery: Yes	124 (4.4)	10 (2.9)	0.664	0.345	1.277	0.219
Dependency: Partially dependent Fully dependent	24 (0.9) 2 (0.1)	1 (0.3) 1 (0.3)	0.348 4.175	0.047 0.378	2.580 46.172	0.302 0.244
ASA score	3.06 ± 0.37	3.07 ± 0.31	1.114	0.840	1.477	0.455
Use of IMA: 1 or 2	1763 (62.2)	253 (75.1)	1.828	1.412	2.367	0.000
Intraoperative IABP use: Yes	27 (1.0)	2 (0.6)	0.611	0.145	2.582	0.503
Urgency of surgery: Urgent	680 (23.9)	100 (29.3)	1.323	1.032	1.696	0.027
Prolonged operation: >300 mins	358 (12.6)	33 (9.7)	0.743	0.510	1.082	0.121
Cardiopulmonary bypass: Yes	2683 (94.8)	316 (93.8)	0.830	0.518	1.330	0.439
Bypass time	102.05 ± 105.7	101.25 ± 51.16	1.000	0.999	1.001	0.892
Cross clamp time	69.79 ± 39.13	67.83 ± 36.50	0.999	0.996	1.002	0.402
Cardioplegia: Yes	2383 (84.5)	289 (86.3)	1.155	0.832	1.602	0.389
Type of operation: CABG CABG + valve surgery	1551 (54.5) 337 (11.8)	239 (70.0) 51 (15.0)	2.901 2.849	2.121 1.895	3.966 4.282	0.000 0.000
Use of implant: Yes	1270 (44.8)	102 (30.0)	0.601	0.473	0.763	0.000
Intraoperative Inotropic/ vasopressor use: Yes	227 (8.4)	19 (5.8)	0.673	0.415	1.091	0.108
Operation performed by: Specialist Registrar	1810 (66.7)	222 (67.7)	0.957	0.749	1.223	0.725
Closure performed by: Specialist Registrar	362 (12.9)	49 (14.7)	0.859	0.622	1.186	0.355

Postoperative IABP use: Yes	56 (2.0)	2 (0.6)	0.296	0.072	1.219	0.092
Postoperative Inotropic / vasopressor use: Yes	1914 (68.8)	219 (66.2)	0.888	0.697	1.130	0.334
Return to theatre: Yes	111 (4.0)	11 (3.3)	0.827	0.441	1.554	0.556
Haemofiltration: Yes	129 (4.6)	12 (3.6)	0.774	0.424	1.414	0.405

BMI – body mass index; COPD - chronic obstructive pulmonary disease; LVEF - left ventricular ejection fraction; PVD - peripheral vascular disease; HTN - hypertension; ASA - American Society of Anaesthesiologists; IMA - internal mammary artery; IABP- intraaortic balloon pump; CABG – coronary artery bypass graft

Table 2 Independent risk factors for SSI identified with logistic regression analysis

Variable	Odds ratio	95% CI		p value
		Lower	Upper	
BMI: 30 – 34.9	1.309	0.990	1.730	0.059
≥35	2.365	1.665	3.359	0.000
Gender: Female	1.722	1.310	2.262	0.000
Diabetes: Yes	1.500	1.169	1.926	0.001
LVEF : < 45%	1.446	1.086	1.924	0.012
PVD: Yes	1.730	1.158	2.585	0.007
Operation Type: CABG	5.442	3.138	9.439	0.000
CABG + valve surgery	4.104	2.401	7.016	0.000

BMI – body mass index; LVEF - left ventricular ejection fraction; PVD - peripheral vascular disease; CABG – coronary artery bypass graft

Table 3 B-SIR tool to predict SSI after cardiac surgery

Risk Factors		Point Scores	B-SIR Score	SSI risk (%)
BMI	≥ 35	2	0	2.80
Gender	Female	1	1	4.76
Diabetic		1	2	7.96
LVEF	< 45%	1	3	13.01
PVD		1	4	20.55
Operation type	CABG	3	5	30.91
	CABG + valve	3	6	43.63
			7	57.24
			8	69.84
			9	80.02

BMI - body mass index, LVEF - left ventricular ejection fraction, PVD - peripheral vascular disease, CABG – coronary artery bypass graft

Figure 1. Comparison of the predictive power of B-SIR model and the NNIS, ACRI and BHIS models in predicting surgical site infection (SSI) on the sample population after cardiac surgery

NNIS - National Nosocomial Infection Score; ACRI - Australian Clinical Risk Index; BHIS-Brompton and Harefield Infection Score; B-SIR – Barts Surgical Infection Risk

Appendix A Calculation of Point Scores and Risk Estimates

1. Point scores were derived using the formula:

point score = bias corrected coefficient of each variable / constant [a]

where constant is the difference in the risk between men and women equivalent to 0.548.

2. SSI risk estimates were calculated based on the methods used in the Framingham model. The risk estimates were derived by:

   (a) calculating BX = constant [a] + (point score x 0.548)

   where BX is the dependent variable (SSI) and the constant from the model is -

3.544 (Table 3)

(b) converting this (BX) to a probability using the formula: $P = 1 / [1 + \exp(-BX)]$

[a] The constant was included in the calculation of the risk estimates so that it will allow the conversion of the scores back to a probability and therefore, the risk associated with each category of score can be presented. For both formulas, the gender effect was utilised for the constant instead of the age effect, which was used in the Framingham model, because age was not found to be a significant predictor of SSI in this study.