Predictors of surgical site infection following adult cardiac surgery at the Jewish General Hospital: A cohort study

Victoria C. Allen

Department of Epidemiology, Biostatistics, and Occupational Health
McGill University, Montreal
June 2014

A thesis submitted to McGill University in partial fulfilment of the requirements of the degree of Master of Science

ABSTRACT

Background

Surgical site infections (SSI) are the second most common cause of nosocomial infections and thus constitute a major concern to hospitals. SSIs of the sternal and graft site wounds following cardiac surgery are associated with increases in hospitalisation costs, length of in-hospital stays, and mortality.

Objective

To identify modifiable risk factors for the development of SSIs within up to one year of surgery following invasive cardiac surgery at the Jewish General Hospital in Montreal (JGH), Quebec. SSIs of interest include both sternal wound infections (SWIs) and leg incision infections (LIIs).

Methods

Using the Quebec Registry in Adult Cardiac Surgery (QRACS), the cohort of all patients undergoing cardiac surgery at the JGH between 1 April 2011 and 31 October 2013 was identified. Outcomes of interest included all surgical site infections identified in the QRACS during a maximum of one year of follow-up, with particular attention paid to SWIs and LIIs. Survival analysis using the Cox proportional hazards model was used to estimate the hazard ratios (HRs) of SSI associated with pre- and intraoperative risk factors. The Kaplan-Meier method for survival data was employed to estimate cumulative incidence of sternal and leg SSIs.

Results

The cohort included 1,210 patients who were on average 67 years old at the time of surgery and 72.1% were male. SWIs constituted 77.9% of all SSI and LIIs 22.1%. In multivariate analysis, failing to remove hair from surgical sites prior to surgery (HR: 2.30, 95% CI: 1.18-4.48), surgeon B (HR: 1.87, 95% CI: 1.08-3.23), and use of immunosuppressants/steroids (HR: 3.20, 95% CI: 1.36-7.54) were significantly associated with all varieties of infection. In addition, use of α-blockers (HR: 3.62, 95% CI: 1.39-9.48) and immunosuppressants/steroids (HR: 9.40, 95% CI: 2.65-33.42) were associated specifically with SWI and LII, respectively.

Conclusion

Patients with the identified modifiable risk factors should be monitored closely. The usefulness of the QRACS in monitoring SSIs was demonstrated.

Keywords

Surgical site infections (SSI), Cardiac surgery, Sternal wound infections (SWI), Quebec Registry in Adult Cardiac Surgery (QRACS)

RÉSUMÉ

Problématique

En tant qu'infection nosocomiale, les infections du site opératoire (ISO) constituent un souci majeur des hôpitaux. À la suite de la chirurgie cardiaque, les ISO des sites sternal ou de la greffe sont associées aux augmentations des frais hospitaliers, aux durées du séjour à l'hôpital et à la mortalité.

Objectif

Identifier les facteurs de risque modifiables liés aux ISO dans l'année suivant une chirurgie cardiaque envahissante à l'Hôpital général juif (HGJ) de Montréal. Les ISO d'intérêt incluent les infections de la plaie sternale et les infections de la plaie de jambe.

Patients et méthodes

Utilisant des données du Quebec Registry in Adult Cardiac Surgery (QRACS), une cohorte de tous les patients recevant une chirurgie cardiaque à l'HGJ entre le 1er avril 2011 et le 31 octobre 2013 a été constituée. Pendant un maximum d'une année de suivi, toutes les ISO identifiées dans le QRACS, plus particulièrement les infections de la plaie sternale et les infections de la plaie de jambe, représentaient nos variables d'intérêt. Pour calculer les rapports de risque (RR) et leurs intervalles de confiance (IC) des ISO associés avec les facteurs de risque préopératoires et périopératoires, l'analyse de survie avec la régression de Cox fut utilisée. L'estimateur de Kaplan-Meier pour l'analyse de survie fut employé pour estimer la fréquence cumulative des ISO des sites sternal ou de la jambe.

Résultats

La cohorte était constituée de 1.210 patients dont 75 ont développé une ISO. L'âge moyen était 67 ans et 72,1% des patients étaient mâles. Les infections de la plaie sternale représentaient 77,9% de toutes les ISO et les infections de la plaie de jambe 22,1%. Dans les analyses multivariées, ne pas raser les poils du site opératoire avant la chirurgie (RR : 2,30; IC 95% : 1,18-4,48), le chirurgien B (RR : 1,87; IC 95% : 1,08-3,23) et l'utilisation des immunosuppresseurs/stéroïdes (RR : 3,20; IC 95% : 1,36-7,54) étaient associés avec toutes les

ISO. En outre, l'utilisation des alpha-bloquants (RR : 3,62; IC 95% : 1,39-9,48) et l'utilisation des immunosuppresseurs/stéroïdes (RR : 9,40; IC 95% : 2,65-32,42) étaient associées aux infections de la plaie sternale et infections de la plaie de jambe (respectivement).

Conclusion

Une attention particulière devrait être portée aux patients qui ont les facteurs de risque identifiés. L'utilité du QRACS pour la surveillance d'ISO fut démontrée.

Mots clés

Infections du site opératoire (ISO), Chirurgie cardiaque, Infection de la plaie sternale, Quebec Registry in Adult Cardiac Surgery (QRACS)

ACKNOWLEDGEMENTS

I would like to extend my heartfelt gratitude to the many people who contributed to the successful completion of this Master's thesis:

Drs. Samy Suissa and Paul Brassard, my supervisors, for their ideas, encouragement, counsel, patience, and attentiveness to detail. Both helped foster an appreciation for meticulous work, which will serve me well for the rest of my life.

The incredibly knowledgeable professors and teaching assistants in the department of Epidemiology, Biostatistics, and Occupational Health for the training and support they provided at McGill University. They helped me establish the necessary foundation to succeed in my research endeavours through countless hours of dedicated instruction.

The exceptionally erudite biostatisticians at the Lady Davis Institute for Medical Research, especially Valérie Patenaude, for their boundless insight and advice.

The cardiac surgical staff at the Jewish General Hospital, particularly Dr. Jean-François Morin, who initially proposed this project, and Dr. Yves Langlois, who introduced me to the Quebec Registry in Adult Cardiac Surgery and permitted me the amazing experience of witnessing a coronary artery bypass graft surgery firsthand. This incident really helped put my work into perspective and renewed my admiration not only for the fragility of human life, but the remarkable advancements of medical science as well.

The Jewish General Hospital staff, including the dedicated Sybile Germain and Claire Deland, who maintain the databanks I required for this thesis: my work would have been impossible without them.

The administrative staff of the Centre for Clinical Epidemiology and McGill's department of Epidemiology, Biostatistics, and Occupational Health for their tireless efforts to keep our institutions running. I am particularly grateful to Diane Gaudreau, whose resourcefulness has proved singularly valuable on innumerable occasions.

My friends, new and old, who provide support, amusement, and affection with equal regularity.

My family, whose profound love and encouragement have been consistent all of these years. I am forever indebted to you all.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

Tables

Figures

LIST OF ABBREVIATIONS

ACC	American College of Cardiology
ACCVTQ	Association des chirurgiens cardiovasculaires et thoraciques du Québec
ACE	Angiotensin-Converting-Enzyme inhibitor
ASA	AcetylSalicylic Acid
BMI	Body Mass Index
CABG	Coronary Artery Bypass Grafts
CDC	(U.S. American) Centers for Disease Control and Prevention
COD	Cause Of Death
COPD	Chronic Obstructive Pulmonary Disease
CPB	Cardio-Pulmonary Bypass
CVA	CerebroVascular Accident
DOB	Date Of Birth
(D)SWI	(Deep) Sternal Wound Infection
H2RA	H2-receptor antagonist
IABP	Intra-Aortic Balloon Pump
ICU	Intensive Care Unit
JGH	Jewish General Hospital
LII	Leg Incision Infection
LV	Left Ventricle/Ventricular
LVEF	Left Ventricular Ejection Fractions
MHICC	Montreal Heart Institute Co-ordinating Centre
MI	Myocardial Infarction (heart attack)
MRSA	Methicillin-Resistant *Staphylococcus Aureus*
NSAID	Non-Steroidal Anti-Inflammatory Drug
Opera	Opera Surgical Management System
OR	Operating Room
PPI	Proton Pump Inhibitor
QRACS	Quebec Registry in Adult Cardiac Surgery
RF	Risk Factor

SSI	Surgical Site Infection
STS	Society of Thoracic Surgeons
TAVR	Transcatheter Aortic Valve Replacement
TIA	Transient Ischemic Attack

1 INTRODUCTION

SSIs are the second most common cause of nosocomial infection.[1] At the JGH in Montreal, approximately 400 adult cardiac surgeries are performed each year, and an average of 7.0% of cardiac surgery patients will contract one or more SSI within one year of surgery. SSI of the sternal and graft wound sites following cardiac surgery are associated with increases in hospitalisation expenses, length of in-hospital stays, and death.[1]

Reported characteristics predisposing CABG patients to SSIs at healthcare facilities around the world are diverse and frequently contradictory. Pre-existing medical conditions such as diabetes (45.4%), congestive heart failure (40.5%), and obesity (23.9%) have been found in disproportionate rates in individuals who develop SSIs.[2] Obesity in particular has been identified as a risk factor for SSIs in many different studies.[3-7]

Since 2009, the JGH has recorded extensive information on its cardiac surgery patients in the QRACS. The databank was created to facilitate province-wide evaluations and inter-facility contrasts concerning quality of patient care and specific outcomes after cardiac interventions.[8] The QRACS was conceived with a specific goal in mind: to develop a risk model which would gauge the role of individual variables on carefully defined outcomes, assist surgeons in counselling patients on the best course of treatment, and assess the quality of healthcare provided in participating institutions.[9]

While the global data on SSI risk factors is extensive, the QRACS data unique to the JGH has not yet been analysed and so site-specific potential mechanisms for infection have never been investigated. Further, there is important inconsistency in the literature regarding the significance of the various factors alleged to predispose SSIs after cardiac surgery. The QRACS contains diverse details over a comparatively long follow-up period, including (coded) surgeon identity and patient drug use prior to surgery, factors that have been hitherto largely unexplored in the existing literature.

The importance of SSIs to healthcare systems worldwide and the survival of individual patients is undeniable, as is the need for further research into modifiable risk factors. Currently, the JGH has not maximised the potential of several years' worth of data recorded in the QRACS. Appropriate analysis of its contents would prove valuable to the hospital's efforts to stem nosocomial infection rates and reduce patient mortality following cardiac surgery.

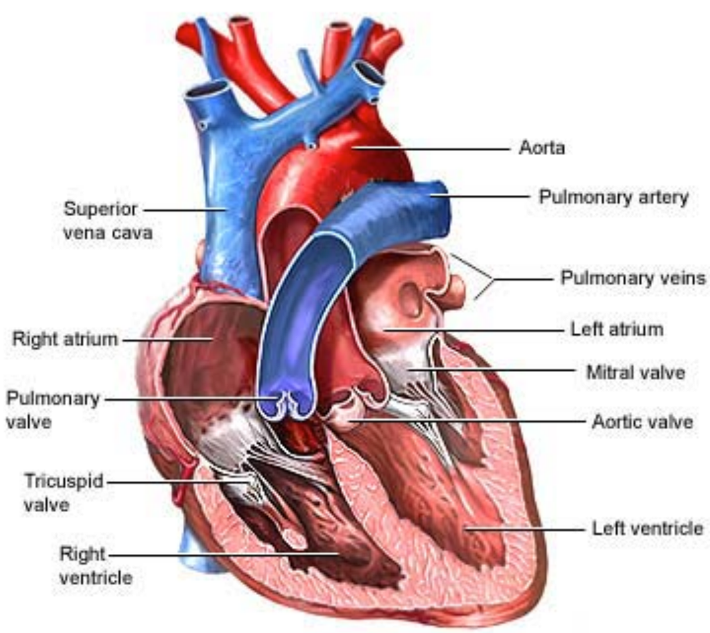
2 LITERATURE REVIEW

2.1 CARDIAC SURGERY

Cardiac surgery is a term encompassing all forms of surgery concerning the heart or large vessels that bring blood to and from the heart. These vessels include the aorta, the inferior and superior venae cavae, and the pulmonary arteries and veins (see Figure 2.1). The most common indications for cardiac surgery are ischemic heart disease (usually due to atherosclerosis of the coronary arteries), congenital heart disease, or valvular heart disease (congenital or acquired).

To address ischemic heart disease and acquired valvular heart disease, there are two main forms of surgery that are performed: coronary artery bypass grafts and valve replacement surgery.

Figure 2.1: The human heart[10]



2.1.2 Coronary Artery Bypass Grafts (CABGs)

CABG is a surgical procedure most often conducted to mitigate chest pain due to a restriction of oxygenated blood supply (ischemia) to heart tissue. The intent of the surgery is to improve blood flow to ischemic areas of the heart by bypassing occluded blood vessels with grafts. A majority of patients undergoing CABG receive saphenous vein grafts, but approximately 40% also have an internal mammary artery graft.[11]

According to the American College of Cardiology (ACC), indications for CABG include disease of the left main coronary artery, disease of all three coronary vessels (left anterior descending artery, left circumflex artery, and right coronary artery), or widespread disease that cannot be treated with percutaneous coronary intervention. Low ejection fraction and diabetes mellitus can be unique high-risk indications for CABG.[12]

Established procedures prior to first incision for CABG surgery include a chlorhexidene shower the night before surgery, the removal of chest hair the morning of surgery, a one-minute povidone/iodine skin scrub, and use of povidone/iodine solution at the skin site(s).[13] Prophylactic intravenous antibiotic treatment with cefazolin, vancomycin, ceftriaxone, or a combination of the three is dispensed 30-120 minutes before incision and can be administered intraoperatively in the event of prolonged procedure.[13] It is continued postoperatively until the thoracostomy tubes are removed.[2] Reducing perioperative trauma, blood perfusate, pressure limited distension techniques, and gentle management of grafts are integral to the endothelial integrity of the graft material.[11]

2.1.3 Valve Replacement

Valve replacement surgery is a general term that refers to any one of four surgical procedures in which one or more heart valves are replaced with either an artificial heart valve or a bioprosthesis. These procedures include aortic valve replacement, mitral valve replacement, pulmonary valve replacement, or tricuspid valve replacement (see Figure 2.1). Valve replacement surgery can be conducted in a variety of ways: minimally invasive cardiac surgery, minimally invasive catheter-based aortic valve replacement surgery, or open-heart surgery.

According to the ACC, there are varying classifications of severity of adult valve disease. Left-sided valve disease is divided into four possible problems: aortic stenosis, mitral stenosis, aortic regurgitation, and mitral regurgitation. These complications can be graded as mild, moderate, or severe depending on individual indication criteria.[14]

There are a variety of valve replacement procedures, defined by the replacement material (mechanical or biological) and the surgical methodology (surgical, minimally invasive, and non-surgical). Mechanical valves are made from inorganic materials, such as carbon, ceramics, metals, and plastics.[15] Biological valves, conversely, can be adapted from pig valves or bovine pericardial engineered valves (called xenographs), donated human heart tissues (an allograft or homograft), or the patient’s own tissues (an autograft).[15]

In a conventional surgical procedure on the heart, the breastbone is separated laterally and the entire chest is opened (sternotomy). Minimally invasive valve replacement surgery, also referred to as endoscopic or robotic heart surgery, involves the insertion of long-handled instruments through four small thoracic incisions.[15] The surgeon carries out the procedure while observing the manipulation of the surgical tools through projection from an endoscopic video camera onto a monitor. Non-surgical valve replacement requires catheter insertion into the femoral or brachial artery, and navigation of the catheter through the blood vessels and into the heart. The artificial valve can thus be inserted with considerably less risk than more invasive procedures; this methodology is often reserved for aortic valve replacement and is commonly referred to as TAVR (transcatheter aortic valve replacement).[16]

One to two weeks before surgery, smoking patients are usually asked to cease their tobacco intake as this can be a factor in blood clotting and breathing problems during the procedure. Patients are expected to fast starting the night before any form of heart valve replacement surgery; also during the night prior to surgery, patients undergo skin disinfection. On the day of surgery, the surgical site is washed and scrubbed with an antiseptic cleanser. Any chest hair is trimmed.[15] The surgery itself is carried out under a general anaesthetic, and except for during TAVR, patients are connected to a heart-lung machine. The procedure usually takes anywhere between two and four hours and is often followed by about a week of hospital care. Recovery is typically faster in non-surgical patients.[15]

Death associated with valve replacement within the first three postoperative months is an adverse outcome linked to a variety of factors, including but not limited to higher New York Heart Association functional class, increased urea concentration, longer duration of CABG, nonuse of allograft valve, and prosthetic valve endocarditis (as well as its infection status; death rates are lower in those who have healed).[17] Death beyond three months has been linked with age at time of operation and *Staphylococcus aureus* (*S. aureus*) infection.[17] Minimally invasive cardiac valve surgery has been found to improve patient satisfaction and decrease requirement for post-rehabilitation services.[18]

2.2 SURGICAL SITE INFECTIONS

Surgical site infections (SSI) are the second most common cause of nosocomial infection and thus constitute a major concern to hospitals.[1] In cardiac surgery patients, SSIs of the sternal wound can manifest as various subsets of SSI including: superficial SSI (affecting the skin, subcutaneous tissue, and pectoralis fascia only), deep sternal wound infection (DSWI, affects presternal tissue and may involve sternal osteomyelitis), sternal osteomyelitis (infection of the bone and/or marrow), mediastinitis (infection of presternal tissue, sternal osteomyelitis, possible mediastinal sepsis), and endocarditis (inflammation of the endocardium) (see Table 2.1).[3 19 20] Patients who undergo minimally invasive surgeries are less likely to develop antibodies to enteric Gram-negative bacilli, indicating an overall decreased exposure to bacterial pathogens and susceptibility to infection.[21]

Table 2.1: Summary of incidence and outcomes of assorted SSIs related to cardiac surgery, in order of incidence magnitude

SSI Classification	Incidence (% all applicable surgery patients, approximate)	Case Fatality (% affected patients, approximate)
Medaistinitis	0.4-1.7[13 22 23]	7.2-25.1[24 25]
DSWI	0.4-4.6[13 22-24 26]	10.0-40.0[2]
Osteomyelitis	0.4-5.0[27]	rare
Superficial sternal wound	0.4-6.4[13 22-24]	33.0[28]
Endocarditis	2.0[29]	56.0[29]
Aortic graft	2.0[30]	90.0[30]
Valve surgery, pacemaker-defibrillator, vascular grafts	4.0-9.5[30 31]	22.0-86.0[29]
Leg wound	8.0-32.6[32]	rare

2.2.2 Risk Factors for SSIs

Median sternotomy is the preferred means of access to the heart for CABG and valve replacement, and is one of the most commonly used incisions in cardiac surgery. Nonetheless, it remains a cause of SSIs, mechanical instability, and dehiscence.[26] Extensive literature exists concerning SSIs following cardiac surgery. A majority of studies reviewed indicate few significant risk factors (two to three per study), although the factors identified as significant can vary substantially between subjects. Reported characteristics predisposing CABG patients to SSIs are diverse and frequently contradictory. A study of 1,554 cardiothoracic surgical patients conducted at Barnes-Jewish Hospital, a teaching hospital and level I trauma centre in Missouri with surgical scope comparable to the JGH (a teaching hospital and level II trauma centre), on the epidemiology of chest and leg wound infections following CABG concluded that behaviours such as smoking (49.7%) and pre-existing medical conditions such as diabetes (45.4%), congestive heart failure (40.5%), and obesity (23.9%) were present in disproportionate rates in individuals who develop SSIs.[2] Similarly, a history of infections (11%) including urinary tract infections, pneumonia, primary bacteraemia, and purulent phlebitis was found to be more common in SSI cases. The study concluded that female sex, diabetes, and prolonged surgery were statistically significantly associated with multiple infections.[2]

Host factors believed to predispose patients to SSIs following CABG surgery have been investigated at length and, depending on the study, may include: advanced age, COPD, diabetes mellitus, male sex, obesity, preoperative hospital stays longer than five days, prolonged mechanical ventilation, smoking, use of internal mammary artery grafts, and use of steroids.[23 33] Obesity specifically has been identified as a risk factor for SSI in many different studies.[3-7] However, at least one study concluded that neither sex nor obesity was a proven risk factor for SSIs.[26] The significance of previous sternotomy as a risk factor for SSIs has also been questioned in some studies despite opposing findings elsewhere.[26] Adverse outcomes associated with CABG (mortality, peri- or postoperative cerebrovascular accidents, postoperative bleeding, and sternal wound infection) have been found to be two to three times higher in obese patients.[34] Possible justification for this includes ineffective prophylactic antibiotic dose, adipose tissue as substrate for infection, difficulties harvesting grafts, and complications in skin preparation.[35] Obesity, previous surgery, and diabetes are associated with increase in SWI and bacteraemia following CABG surgery.[36]

Surgical risk factors for SSIs include duration of bypass, extensive electrocautery, intra-aortic balloon pumping (IABP), post-operative bleeding, reoperation, shaving with razors, sternal rewiring, use of bone wax, and ventilation time.[3 30 37 38] Generally, the greater the number of risk factors harboured by an individual, the greater the rates of SSIs.[39]

Several studies by Furnary *et al*. have investigated the relationship of diabetes mellitus and SSIs following CABG surgery.[40] They contend that diabetes does not actually alter a patient's likelihood of developing a SSI but rather, diabetes is an indication of the true risk factor: blood glucose level. Reducing blood glucose levels in diabetic patients has been found to lower the incidence of wound complications after CABG.[40] Hyperglycaemia in the first postoperative day is associated with adverse outcomes in diabetic patients following CABG.[41] Sixteen percent of people undergoing CABG in Canada are diabetic; in-hospital mortality rate is approximately 4% and rates of nonfatal cardiovascular events and SSIs are around 21%.[41]

According to a Belgian study, patients randomized to intensive blood glucose control during CABG had 34% lower mortality and 46% fewer septic complications compared to patients whose blood glucose levels were managed in the conventional manner.[41] Use of perioperative intravenous insulin infusion in diabetics undergoing CABG was found to significantly decrease SWI rates and its associated costs.[40]

Red blood cell (RBC) transfusion after cardiac surgery is associated with increased mortality, morbidity, and cost.[42] RBC transfusion is independently associated with higher incidence of bacterial infections post-CABG.[43]

There is considerable overlap between risk factors for infection following valve replacement and aortocoronary bypass operations. Univariate analysis indicated blood transfusions greater than 2,500 mL, duration of cardiopulmonary bypass, duration of operation, IABP use, and reoperation are associated with severe infection post valve replacement surgery.[31 44] It has been hypothesised that contamination and tissue trauma over the course of an operation are the most significant factors provoking infections following aortocoronary bypass surgery. Concerning cardiac valve replacement, however, host resistance weakened by the severity of the underlying disease appears to be a more important predictor.[31]

Some studies indicate that specific infection control interventions (e.g. quotidian assessment of wounds, culture of all suspect wounds, 30-day outpatient clinic follow-up) can reduce SSI rates by as much as 50%.[45 46] Further, one study showed that the presence of preoperative enteric Gram negative bacilli antibodies are significantly protective against postoperative infection as well as fever in the first 24 hours after operation.[21] It is inferred that enteric Gram negative bacilli, endotoxin, or some other constituent of the bacteria is involved in the onset of postoperative fever. Another study, which involved preoperative administering of antibodies to enteric Gram negative bacilli (notably antiendotoxin), indicated a significant protective effect against Gram negative infection.[47] Other studies indicate the beneficial effects of Gram negative bacilli antibodies may be due to antiendotoxins rather than the antibodies.[48]

As summarised by Roy, “Prevention of SSI after cardiac surgery has become an important component of quality assurance and hospital cost containment; yet, with the amalgam of studies published, it is hard to delineate which risk factors for SSI are most important and where infection control practitioners and surgeons can intervene.”[3]

2.2.3 Microbiology of SSIs

The Barnes-Jewish Hospital study found that, in pure culture, one third of chest wound infections were caused by *S. aureus* (including MRSA), with the remainder accounted for by coagulase-negative staphylococci (35.6%), enterobacriaceae (20%), yeast species (6.7%), *Enterococcus* species (2.2%), and other species (2.2%) (all diagnoses were confirmed with immediate bedside examination, review of medical records, and consultation of the National Nosocomial Infection Surveillance System).[2 49] One study found that nearly 86% of all *S. aureus* isolates from SSIs were methicillin-resistant.[50] Another concluded 46.4% of mediastinitis in infections in open-heart surgery patients could be attributed to *S. aureus*, 21.4% to *Pseudomonas*, and 17.9% to *Klebsiella*. Cultures came back negative in 14.3% of infection cases.[26] The primary infectious agents in SSIs may vary by geographical location and institution, depending on the overall presence of particular bacteria in the immediate populations.

Both patient and healthcare worker nasal carriage of *Staphylococcus spp.* has been linked to SSIs in CABG surgery patients.[51 52]

2.2.4 Treatment of SSIs

There are two main ways to treat SSIs: medical therapy and surgical therapy. Concerning surgical implants, the variety of antibiotic prescribed is of extreme importance. Infections with an unknown microbiologic cause are best treated with antibiotics that are effective against methicillin-resistant staphylococci (e.g. vancomycin).[30 53] Combination antibiotic therapy is best used when infected implants is retained or the response to single antimicrobial agents is deficient.[30] On the occasion of implant replacement, antibiotic coverage should ideally include treatment effective against the organisms isolated during the first surgery. If the new implant is introduced to a severely infected area, long-term antibiotic therapy is required.[30]

In cases of surgical therapeutic responses to SSIs, resolution of the infection is likely to necessitate the removal of the implants affected by especially virulent organisms like *S. aureus* and candida.[30] In the event of a nonresponsive result to antimicrobial therapy, the infected implant and all of its components should be removed. Replacement of the surgical implant should only occur once clinical and microbiologic evidence of absence of infection has been secured.[30]

2.2.5 Economics of SSIs

SSIs following CABG surgery are associated with significant increases in hospitalisation costs, length of in-hospital stays, and mortality.[54-56] These issues are likely precipitated by flap closure of the chest, prolonged antibiotic use, readmission, and sternal debridement, which are all associated with SSI individually.[37 57 58] According to analysis of U.S. American data published in 2000, patients who were diagnosed with SSIs had a mortality rate 21% higher than those who did not develop a SSI, accumulated an average of 20 additional hospital days, and incurred $20,012 in added costs in the first postoperative year. Costs related to CABG patients who perish subsequent to the diagnosis of SSIs are roughly $60,546 more than infected patients who survive.[54] This is likely an underestimate of the costs associated with SSIs as the figure only includes direct expenses and neglects indirect costs.

2.3 LACUNAE

According to Marggraf *et al.*, contemporary organization of algorithms concerning SSIs following cardiac surgery has not elicited a significant effect on the incidence of and mortality from SSIs.[23] Further, there is definite discrepancy in the literature regarding the significance of the myriad characteristics suspected to be predisposing qualities to SSIs following CABG. Most studies have not taken into account skill and methodological differences between attending surgeons and other surgical staff, and the literature concerning the impact of pharmaceutical use of any kind (e.g. NSAIDs, statins, steroids) for any duration prior to cardiac surgery is limited.

Study cohorts have been derived from single and multiple sites in diverse settings (type of health care facility, country of origin, etc.), with large variations in sample size;[26 55 59-61] although some studies reflect institutions comparable to the JGH, the scope of variables under investigation in these situations is limited.[2 5 36] While the Society of Thoracic Surgeons (STS) National Cardiac Database in the United States of America is comparable to the QRACS in purpose and has been used to establish clinical predictors of major infections after cardiac surgery, it is not maintained in-house and it is only updated semiannually.[25] In fact, most studies concerning SSI risk factors following cardiac surgery do not make use of universal, regulated databanks like the STS National Cardiac Database, which is a leader in real-time data collection and makes use of data worksheets developed in tandem by the STS Quality, Research, and Patient Safety Department staff; data managers; and surgeons.[62] More than 3,000 surgeons currently contribute to the STS National Cardiac Database, which undergoes quarterly performance outcomes reports, analyses major outcomes of process-of-care measures, and develops risk profiles of patients compared to national standards.[62] Furthermore, follow-up time in the QRACS is often limited to the length of in-hospital stays, which can lead to misclassification of noncases because of informative censoring. Analytic techniques vary significantly between studies and can be limited to univariate analyses and logistic regression; [25 55] most studies focus on preoperative risk factors while a minority attempt to describe time trends in infection rates and the microorganisms responsible for reported SSIs as well.[2] Studies scrutinizing drug use usually focus on antibacterial prophylaxis instead of the impact of preoperative use of other pharmaceuticals in the time period immediately preceding surgery.[13 63 64] Confounding remains an issue, in large part due to the limited scope of variables collected in surveys and databanks intended for studies. In all, data unique to the JGH have not yet been analysed to investigate potential site-specific mechanisms for infection in a context where data on longer follow-up are available.

2.4 STUDY SIGNIFICANCE

Results from this study can prove significant on micro and macro scales.

2.4.2 Micro Significance

At the local level, it is anticipated that the JGH will benefit enormously from the identification of hospital-specific risk factors for infection post-cardiac surgery. After significant risk factors have been identified, rules and regulations can be customized or developed to address the hospital's unique needs as identified through analysis of the data, with the ultimate goal of reducing rates of SSIs following CABG and valve replacement surgeries. The ideal outcome of such policy improvement would be a significantly reduced rate of SSIs in cardiac patients and consequent reduced rates in patient mortality and hospital expenditure in the treatment of infections.

An assessment of the strengths and weaknesses of the QRACS will also prove useful for future studies using the registry and may help improve its organisational convenience and accessibility.

2.4.3 Macro Significance

The data obtained and interpreted from this study can prove instrumental in the development of a generalised risk stratification model for cardiac surgery patients. To better the generalisability of such a model, the current study can be used to provide a framework for more extensive studies at the provincial, national, and international levels.

2.5 RESEARCH QUESTION

What pre- and intraoperative patient factors are independently and significantly associated with the risk of surgical site infection in patients recovering from invasive (i.e. requiring sternotomy) cardiac surgery at the Jewish General Hospital?

2.6 OBJECTIVES

2.6.2 Primary Objective

The primary objective of this study is to identify predominantly modifiable internal and external risk factors for the development of SSIs within up to one year of surgery following invasive cardiac surgery (i.e. involving sternotomy) at the JGH. SSIs of interest include both SWI as well as infection of secondary surgical sites (e.g. leg graft sites).

2.6.2.3 Specific Primary Objectives

1. To determine the utility of the Quebec Registry in Adult Cardiac Surgery (QRACS) databank to epidemiological studies such as this one.
2. To describe SSI trends at the JGH (location in the body, primary infectious agents, etc.) as well as trends in cause of death (COD; causes and time trends).
3. To establish which pre- and intraoperative patient internal and external factors significantly raise or diminish the risk of SSIs in patients recovering from invasive cardiac surgery.
4. To establish whether there is a correlation between postoperative patient internal and external factors associated with SSIs in patients recovering from invasive cardiac surgery.
5. To determine whether there is a statistically significant difference in covariate distribution between individuals who develop SSIs within up to one year of surgery and individuals who do not develop SSIs.

6. To attempt to merge the QRACS and JGH-specific Opera Surgical Management System (Opera) databanks into one cohesive and comprehensive databank.

2.6.3 Secondary Objective

To propose potential interventions or modifications to the current surgical methodology in order to reduce the risk of patient SSIs at the JGH based on the conclusions of the previous objectives.

3 METHODS

3.1 OVERVIEW OF THE STUDY DESIGN

A retrospective cohort study will be conducted using data collected on adult patients undergoing cardiac surgery at Sir Mortimer B. Davis Jewish General Hospital in Montreal, Quebec, between 1 April 2011 and 31 October 2013. The primary data source, the province-wide QRACS, will provide information on over 250 variables, of which 26 will be selected to identify predictors of the risk of SSIs. An attempt to supplement the QRACS data with data from the JGH's own Opera Surgical Management System will be made.

3.2 DATA SOURCES

The JGH is a teaching hospital associated with McGill University, which provides general and specialised care to the people of Montreal. Each year, teams in the hospital's cardiac surgery department perform surgical cardiac interventions on approximately 400 individuals. For the majority (66%) of the 2,188 individuals who underwent cardiac surgery from 1 April 2011 to 31 October 2013, interventions included CABG and valve replacement/repair surgeries. Data concerning each operation are stored in two databanks maintained by the hospital.

3.2.2 Quebec Registry in Adult Cardiac Surgery[65]

In 2004, the Association des chirurgiens cardiovasculaires et thoraciques du Québec (ACCVTQ) decided to develop and install a prospective, uniform databank in all adult cardiac centres in Quebec. The databank was designed to enable province-wide evaluations and inter-facility contrasts.[8] As it was the ACCVTQ's goal to provide data for clinical studies, the databank was designed to have clear variables and a well-defined outcome of interest. From the inception of the QRACS, the ACCVTQ had a clear use for the data in mind: to develop a risk model which would assess the role of certain variables on outcomes, help surgeons advise patients on the best course of treatment, and assess the quality of healthcare providers.[9]

The QRACS is currently used in the following regions of Quebec: Capitale Nationale, Estrie, Montréal, and Saguenay. The institutions linked to the databank in each of these regions include: L'Institut universitaire de cardiologie et de pneumologie de Québec (Capitale Nationale); Le Centre hospitalier universitaire de Sherbrooke at Hôpital Fleurimont (Estrie);

L'Hôpital Sacre Cœur de Montréal, L'Institut de cardiologie de Montréal, Le Centre hospitalier de l'Université de Montréal at Hôtel Dieu, Le Centre universitaire de santé McGill at Royal Victoria Hospital, and Sir Mortimer B. Davis JGH (Montreal); and Le Centre de santé et de services sociaux de Chicoutimi (Saguenay).

Since 2009, the JGH has recorded extensive information on its cardiac surgery patients in the QRACS. The QRACS data starting from 2011 onward is most reliable, as variables were still being modified as late as the end of 2010, and some data were incomplete in the first two years of operation. Since 2011, the databank infrastructure has not changed. Designated healthcare professionals in the JGH's cardiac surgery department enter data into the QRACS. Data quality review, including ongoing verification, end-study audit, and critical variables review are all part of the MHICC's role in maintenance of the QRACS.

Every patient in the QRACS is assigned a study-specific number. Other unique patient identifiers include date of birth (DOB) and health insurance number.

The data amassed in the QRACS is divided into nine categories: preoperative diagnostics, preoperative anaesthesia, perfusion, perioperative data, perioperative anaesthesia, postoperative data, physiotherapy, infections, and systematic monitoring. Between these nine categories, there are over 250 different potential variables with a variety of possible answer formats (yes/no, selection from provided options, numerical entry, descriptive entry).

The QRACS has as outcome a variety of possible infections, categorised into two sections: general and postoperative infection. Screening practices and measures taken to prevent infection prior to surgery are recorded here, as are diagnoses of infection and treatment. The systematic monitoring section, which also contains outcome data, is broken down into the following constituents: renal conditions, complications within hospitalization, complications within 30 days post-operation, and complications at one year.

3.2.3 The Opera Surgical Management System (Opera)

Since 2000, hospital-specific details on surgical patient conditions are available through the JGH's Opera Surgical Management System (frequently shortened to Opera), provided by CHCA Computer Systems Incorporated. This system is updated throughout each patient's stay at the JGH. Every surgical patient is assigned a unique unit number, which serves as a primary identification element. The primary unit is in turn linked to the patients' file number; full name;

diagnostic indication for surgery; and extensive details concerning their surgical procedure, from the time anaesthesia is first administered to the time they exit the operating room. Comprehensive lists of attending surgical staff are also included in Opera.

All forms of surgical interventions taking place at the JGH are monitored through Opera, but this study's exposures of interest are the procedures that involve median sternotomy (primarily CABGs and valve replacement/repair, but also Bentall procedures, plication of ascending aorta, re-exploration for mediastinal bleeding, resection atrial myxoma, thrombectomy/thromboendarterectomy of the pulmonary artery, and reoperation). Any interventions falling outside of this specification will not be considered in statistical analysis.

The variables recorded for each patient are extensive, and include: the date of operation, the date the patient was admitted to hospital, the type of admission to hospital (inpatient, outpatient day surgery, or same-day surgery), type of anaesthetic (general; local, IV standby, or IV block; or any combination of the local and IV variants), the time anaesthetic was started, the time anaesthetic was stopped, the total time the patient was under anaesthetic, the specific variety of cardiac intervention, incision time, time of last stitch, the duration of the intervention, the OR in which the intervention took place, the time the patient entered the OR, the time the patient left the OR, extra time spent in the OR, the total duration of the patient's stay in the OR, the state in which the patient arrived, the recovery room, the surgeon, the speciality of the surgeon, the sector where the operation took place (surgery or cath lab), the operatory technique, the anaesthesiologist, preoperative diagnosis, postoperative diagnosis, service received, service point (operating theatre), localisation (corporeal site and side), patient sex, and responsibility of payment.

3.2.4 Common Variables in the QRACS and Opera

Patient variables common to both the QRACS and Opera include date of admission, date of surgery, time of first incision (unreliable), sex, and time of last stitch (unreliable). Primary analyses found both time of first incision and last stitch to be highly variable between the two data sources; they proved entirely ineffective as a data linkage variable and thus will not be used. Instead, referring back to patient files (using the file numbers recorded in Opera) will allow patient dates of birth to be matched with Opera entries. This thus provides Opera with another very specific patient identifier found in the QRACS. The three common variables upon which matching will be based between the two data sources are therefore: DOB, date of surgery, and sex.

3.3 STUDY DESIGN

A retrospective cohort study will be conducted.

3.3.2 Study Setting and Data Source

The primary source of data is the QRACS, and initial analyses will be carried out using this databank exclusively. As a secondary concern and in order to establish a comprehensive databank that includes all of the variables of interest, the QRACS and Opera will be merged. In view of the fact that these databanks are anonymised, this amalgamation will be based on three identifiers: date of birth, date of surgery, and sex. Comparison of the date of admission will be used to resolve any instances of ambiguity between matches.

3.3.3 Cohort Definition

For the analyses involving the QRACS exclusively, all patients registered in the databank with surgery dates between 1 April 2011 and 31 October 2013 (inclusive) will comprise the study cohort. All patients will be followed for up to one year after their cardiac surgery date.

For the analyses involving the QRACS and Opera, all patients registered in both databanks with surgery dates between 1 April 2011 and 31 October (inclusive) will comprise the study cohort. During the time frame of interest, there may be unequal numbers of patients in the QRACS and Opera databanks. In the event that either databank has duplicate entries, the first entry will be used and a variable added to indicate whether the patient experienced reoperation, based on their duplicate entries. Any remaining patients who cannot be matched between Opera and the QRACS will not be included in the merged databank.

3.3.4 Predictor Variables of Interest

The variables under investigation in this study have been identified based on the particular concerns of the JGH's surgical staff as well as the most agreed upon predictors of SSIs in the existing literature. Some are hospital-specific (e.g. the surgeon performing the operation) while others are more general (e.g. whether a patient has COPD). The most valuable variables in the QRACS are therefore those that reflect the surgical staff's interests and have a substantial completion rate (over 70%).

Preoperative variables of interest include the location from which the patient arrives prior to surgery (i.e. from home vs. hospital), waiting time at the JGH, factors predisposing SSIs (e.g. age, BMI), whether the patient showered the night before or the day of the surgery, when hair removal was carried out, and the time between prophylactic antibiotic treatment and the first incision.

Intraoperative variables of interest include time of antibiotic commencement, whether the surgery was carried out in the morning or the afternoon, the patients' preoperative status (i.e. whether the surgery was elective or urgent), duration of the surgery, whether talon clips were used, whether the harvesting of the saphenous vein was endoscopic or open, and the type of surgery (one vs. two mammaries).

Lastly, the postoperative variables under investigation in this study include use of blood transfusions in the seven days following surgery, whether the patients experienced fluid overload within the first 24 hours post operation, duration of mechanical ventilation (based on first recorded intubation and extubation), length of stay in the ICU, use of IABP and/or presence of low cardiac output syndrome, and whether the patient was diagnosed with a neurological complication within one month of the surgery.

3.3.5 Sample Size and Detectable Relative Risk

As indicated by the literature review and by the hospital's own surgeons, there are many prevalent identified risk factors (e.g. obesity, diabetes, age) for SSIs. Table 3.1 displays the minimum detectable relative risks that can be observed for risk factors with varied prevalence (10-50%) given a sample size of 1,000, 95% confidence, and 80% or 90% power.

Table 3.1: Minimum detectable relative risk for risk factors of SSI (in bold)

Population 1,000		95% Confidence
RF* Distribution	90% Power	80% Power
10:90	**1.56**	**1.47**

* Risk factor

20:80	**1.41**	**1.35**
30:70	**1.36**	**1.31**
40:60	**1.34**	**1.29**
50:50	**1.34**	**1.29**

3.3.6 Measurement of Outcome

The principal outcome for this study is sternal SSI within up to one year of surgery. The definition of SSI is derived from the QRACS which in turn refers to the Centers for Disease Control and Prevention definition: "…[A]n infection that occurs after surgery in the part of the body where the surgery took place. Surgical site infections can sometimes be superficial infections involving the skin only. Other surgical site infections are more serious and can involve tissues under the skin, organs, or implanted material."[66]

3.3.7 Study Period

The sample consists of all patients in the databank undergoing cardiac surgery during the two-and-a-half year period between 1 April 2011 and 31 October 2013.

3.3.8 Blinding

Databank-specific identification numbers guard all patient identities once patient names are omitted/excluded from Opera. Cardiac surgeon identities are coded as 1, 2, or 3 in the QRACS, and have been recoded here as letters A, B, or C (not necessarily in that order). The primary researcher has no personal connection with the surgical department's patients and does not interact with patients in any form pre-, intra-, or postoperation. Further, the cardiac surgeons performing the surgical interventions are not involved in the diagnosis of SSIs in the patients, which is based on maintenance by post-operative care professionals of a SSI surveillance sheet (based on CDC definitions for SSIs), progress notes, ostomy/skin care nurse observations, and/or CT scan reports. Identification of infectious agents is made possible through microorganism culture growths, although a positive culture is not mandatory for a diagnosis (e.g. CDC diagnosis of mediastinitis requires that only one of the following criteria is met: isolation of organism from mediastinal tissue or fluid sample; evidence of mediastinitis seen during operation/in histopathological examination; or fever over 38ºC, chest pain, or sternal instability).[67] This study is therefore blinded.

3.3.9 Data Collection and Variables

Data collection has already occurred as this study relies on pre-existing databanks. In the QRACS alone, there are some 250 variables for each patient with varying degrees of completeness. In the event of a successful merger between the QRACS and Opera, an additional 38 variables (with some overlap in content) for each patient will be available.

3.4 DATA MANAGEMENT AND ANALYSIS

Data will be analysed using SAS 9.3 statistical software. The incidence rates of sternal SSIs at thirty days and one year and their corresponding 95% confidence intervals (CIs) will be calculated using methods for Poisson data. The cumulative incidence of sternal SSI will be estimated using life tables, and the Kaplan-Meier method for survival data will assess mortality trends. Survival analysis using the Cox proportional hazards model will be used to estimate the hazard ratio of SSIs and 95% CI associated with pre- and intraoperative risk factors as well as postoperative correlations.

3.5 ETHICS

Ethics approval was obtained for this study and the use of Opera data from the JGH's Research Ethics Committee (Appendix, section 8.1). Use of the QRACS data was approved by the ACCVTQ (Appendix, section 8.2).

4 ANALYSIS

4.1 DATA CLEANING OVERVIEWS

Neither the QRACS nor Opera were immediately useable for this analysis in their raw extracted forms. Several data cleaning measures were taken to produce data sets appropriate for this project.

4.1.2 The QRACS Cleaning

The data extracted from the QRACS contained information on all patients who had been entered into the databank since its inception. This thus meant that there were several years' worth of superfluous information; all patients who had an executed surgery date outside of the range of interest (i.e. April 2011 to October 2013 inclusive) for this study were therefore methodically excluded. The dates of operation for 41 patients were not available and these patients were not retained in the QRACS after cleaning. Due to the unreliability of the "age" variable, a new age variable was created based on the patients' DOBs and executed surgery dates. Due to computer error, all patients born before 1 January 1930 were recorded as having DOBs in the 2000s (e.g. a patient born in 1925 was recorded as having a birthday in 2025). This was manually corrected. Patients with duration of surgery values that were impossible (i.e. negative hours) were removed. The resulting dataset included 1,117 patients, for each of whom 250 variables were measured (see Figure 4.1-i).

4.1.3 Opera Cleaning

The data extraction procedure for Opera was much more efficient compared to the QRACS data regarding dates and allowed for selection based on specific variable values; only patients who had an executed surgery date inside the range of interest were included. However, the variety of surgeries present in the Opera data was highly variable due to an apparent large margin of entry error. Therefore, the "service" (i.e. the variety of intervention performed) and "secteur" (i.e. where the intervention was performed) were used to identify non-cardiac and non-surgical interventions. Only patients whose "service" variable had a value of "cardiac" and whose "secteur" variable had a value of "surgery" were retained in Opera after cleaning. The resulting dataset consisted of 1,391 patients for each of whom 37 variables were measured.

4.2 MERGING

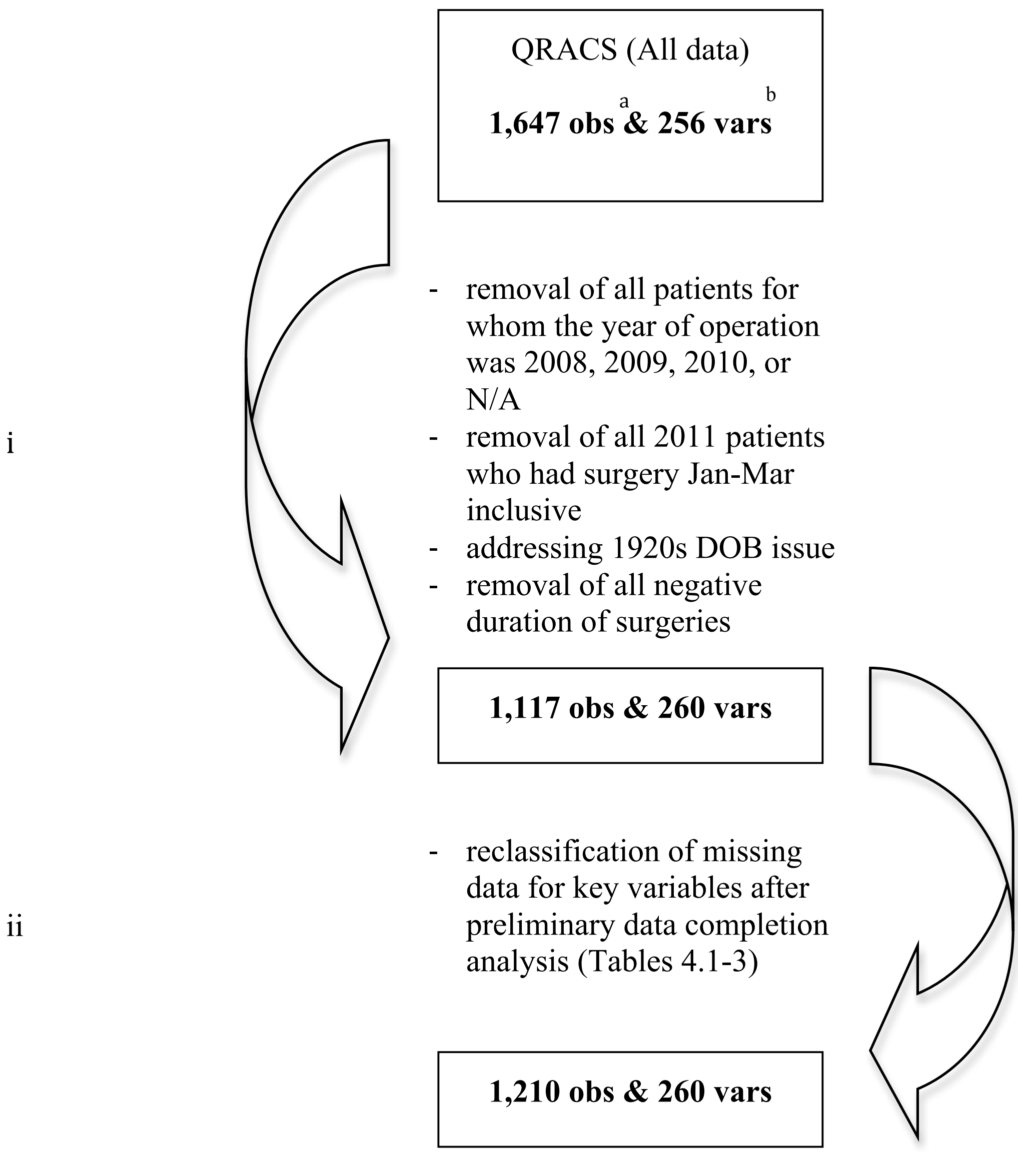
Based on the common variables DOB, date of surgery, and sex, SAS 9.3 statistical software was used to attempt merging the QRACS and Opera data. During this process, it became evident that the date of surgery variable was systematically different between the two databanks. After excluding date of surgery from the merging criteria, still no successful matches were made between the QRACS and Opera. Any combination of the three initial matching variables yielded no matches despite consistent formatting. The possibility of using either only sex or DOB as matching criteria was discarded due to the complete lack of confidence that would accompany any resulting matches (see Appendix, section 8.3).

Due to a lack of confidence in any sort of merger as well as its lack of match success, a successful merger of the QRACS and Opera databanks into one cohesive and comprehensive databank with at least 80% success was not accomplished. Consequently, the QRACS data exclusively will be used to realise the primary and secondary objectives, notably, which pre- and intraoperative patient internal and external factors significantly raise the risk of SSIs in patients recovering from invasive cardiac surgery.

4.3 THE QRACS CHARACTERISTICS

Of the 250 variables initially present in the QRACS, approximately 60% have completion rates greater than or equal to 90%. These well-documented variables constitute basic and universal characteristics, such as patient health and physical profiles (e.g. DOB, BMI existing medical conditions, sex), established SSI risk factors (e.g. diabetes, number of diseased vessels in the heart), clerical data (e.g. date of admission, surgery, and discharge/death; whether of home or hospital origin), and surgical details (e.g. incision time, duration of surgery, use of IABP, date/time of intubation and extubation). Overall, 68% of the data has a completion rate of 75% or greater. The variables with lower completion rates are most often related to the more nuanced aspects of surgery and drug therapy and the resultant complications, most of which are exceedingly rare.

Figure 4.1: Flow chart of steps taken to clean the QRACS



4.3.2 Pre-, Intra-, and Postoperative Patient Characteristics

Table 4.1 gives a generalised profile of all of the patients in the QRACS relevant to this study with respect to the variables of interest identified in section 3.3.4, while Tables 4.2 and 4.3 provide information on the intraoperative and postoperative variables of interest, respectively.

---

[a] observations (cardiac surgery patients)
[b] variables

Counts are presented for categorical variables whereas means and standard deviations are calculated for continuous variables.

Table 4.1: Preoperative patient characteristics and risk factors

Preoperative Factor	Count (%[c]) or mean ± sd	N & (%) Data Completeness
Age	67.2 ± 10.5	1082 (96.9)
Sex (male)	805 (72.1)	1117 (100)
Smoking		1068 (95.6)
Active (≤2 months)	240 (22.5)	
Ceased (2<10 years)	52 (4.9)	
No (≥10 years)	776 (72.7)	
BMI (kg/m^2)		1068 (95.6)
Underweight	10 (0.9)	
Normal	283 (26.5)	
Overweight	447 (41.9)	
Obese	328 (30.7)	
Patient source		1117 (100)
Cardiology unit	246 (22.0)	
Cath lab	14 (1.3)	
Emergency	22 (2.0)	
Home	392 (35.1)	
ICU	3 (0.3)	
Other	440 (39.4)	
Waiting time (days)	6.94 ± 37.6	1065 (95.3)
Cardiac insufficiency	129 (12.2)	1058 (94.7)
COPD	136 (12.7)	1069 (95.7)
Diabetes	353 (33.0)	1071 (95.9)
Dialysis dependency (peritoneal/haemo)	16 (1.5)	1069 (95.7)
Lower limb arterial disease	69 (6.4)	1070 (95.8)
LVEF		1065 (95.3)
≥50%	758 (71.2)	
30% - <50%	235 (22.1)	
<30%	72 (6.8)	
# diseased vessels	2.04 ± 1.23	1066 (95.4)
Parsonnet score		217 (19.4)
1-20	95 (43.8)	
21-40	90 (41.5)	
41-60	21 (9.7)	
61-80	7 (3.2)	
81-101	4 (1.8)	

[c] i.e. percentage of all completed patient data (N) for the given variable

Chlorhexedine shower		927 (83.0)
Before shaving	854 (92.1)	
After shaving	3 (0.3)	
N/A	67 (7.2)	
Unknown	3 (0.3)	
Shaving		1117 (100)
Clipper, <2h pre-op	77 (6.9)	
Clipper, >2h pre-op	764 (68.4)	
Hand, <2h pre-op	1 (0.1)	
No	77 (6.9)	
Unknown	198 (17.7)	
Time between antibiotic prophylaxis & first incision (minutes)	112.9 ± 1529.9	1062 (95.1)

Note that the preoperative patient characteristics variables experience overall completion rates of at least 90% except for the Parsonnet score (completion rate of 19.43%) and the information concerning the chronology of chlorhexedine shower (completion rate of 82.81%) in the preoperative preparation process. Due to the Parsonnet score variable's exceedingly low completion rate, it will be removed from further data analysis.

A significant portion of adult cardiac surgery patients was forwarded to the JGH for surgery from other institutions (39.4%). More than half of the patients either came to the JGH directly from home or were already checked into the JGH's cardiology unit (57.1%). The catheterization laboratory, emergency room, and ICU accounted for the few other patients (together, these sources accounted for 3.5% of all patients). The catheterization laboratory, emergency room, and ICU patients (all probably extremely urgent cases) will therefore be compressed into the other category in the interest of efficiency.

On average, patients waited just under a week in hospital before they underwent surgery. They began antibiotic prophylaxis at a mean of just under two hours before first incision. Most patients (68.4%) had hair at their surgical sites removed using clippers at a time more than two hours before first incision. As patients whose surgical sites were shaved by hand were an extreme minority, this category will be consolidated with the unknown category under the heading of unknown. Chlorhexedine showers most often took place before shaving. As the after shaving and unknown categories of chlorhexedine showers have very low counts, they will be combined with the N/A category to create a new category: other.

The mean age of cardiac surgery patients was 67 years, and just over 72% of them were male. Diabetes, COPD, and cardiac insufficiency were relatively common conditions in the population, with nearly one-third living with diabetes and over one tenth suffering from COPD and/or cardiac insufficiency. Patients had an average BMI of 28.1, classed as overweight; a majority were either overweight or obese. As the underweight category has so few counts (10), it will be combined with the normal BMI category to form a new category: “not overweight”. A minority of patients were dialysis-dependent and/or diagnosed with lower limb arterial disease. Most patients (67.9%) had a LVEF greater than or equal to 50%. They had, on average, 2.04 diseased vessels identified prior to surgery.

In order to allow for the use of standard techniques for complete data, reclassification methods will be employed for missing data. The data will be entered into the original extraction of the QRACS, rather than the cohort of 1,117 patients. This is because some of the data being reclassified concerns the variables on which exclusion from the cohort was based; reclassifying in the original QRACS extraction may lead to more serviceable variables. For continuous variables, the average will be reclassified. For the smoking variable, missing values will be replaced with “No (≥10 years)”; missing BMI values will be replaced with “not overweight”; missing source values will be replaced with “other”; missing LVEF values will be replaced with “≥50%”; and missing data on the time of chlorhexedine shower will be replaced with “other”.

Table 4.2: Intraoperative risk factors

Intraoperative Factor	Count (%) or mean ± sd	N & (%) Data Completeness
Use of prophylactic antibiotic?		1071 (95.9)
Yes	1069 (99.8)	
No	2 (0.2)	
Type of prophylactic antibiotic		1070 (95.79)
Cefazolin	915 (85.5)	
Vancomycin	85 (7.9)	
Vancomycin & Gentamicin	36 (3.4)	
Other	35 (3.3)	
Surgery time of day		1117 (100)
AM	749 (67.1)	
PM	368 (32.9)	
Surgeon		1085 (97.1)

A	372 (34.3)	
B	382 (35.2)	
C	331 (30.5)	
Status pre-op		1066 (95.4)
Elective	373 (35.0)	
Urgent (same hospital stay)	629 (59.0)	
Extreme urgency (<6h)	64 (6.0)	
Total duration of surgery (minutes)	247.0 ± 653.6	1117 (100)
Clips		1115 (99.8)
Arm	4 (0.4)	
Leg	13 (1.2)	
Sternum	2 (0.2)	
None	1096 (98.3)	
Saphenous vein harvesting		
Endoscopic	756 (87.1)	868 (77.7)
Other	112 (12.9)	
Mammary arteries		
Left	693 (62.0)	
Right	12 (1.1)	1117 (100)
Left & right	89 (8.0)	
None	67 (6.0)	
Unknown	256 (22.9)	

Like the preoperative characteristics variables, the intraoperative characteristics variables have high completion rates. Only the variable concerning saphenous vein harvesting, which had a completion rate of 77.7%, had a completion rate less than 90%.

Most cardiac surgeries performed at the JGH between April 2011 and October 2013 inclusive were for urgent cases (56.3% of all patients), meaning that the surgery was carried out during the same hospital stay for which they were initially admitted. About one-third presented for elective surgery, whereas a minority (5.7% of all patients) had extremely urgent cases for which they underwent surgery within six hours of being admitted to the JGH. Over two-thirds of surgeries were carried out in the morning (i.e. had a morning starting time, although lengthy procedures may have carried on into the afternoon). Each of the three cardiac surgeons at the JGH accounted for approximately one-third of interventions, with Surgeon B accounting for slightly more (34.2%) and Surgeon C accounting for slightly fewer (29.6%). Surgeries lasted, on average, just over four hours.

A majority of patients (95.7% of all patients) were administered prophylactic antibiotics. The most common prophylactic regime involved cefazolin (in 81.9% of patients), or vancomycin on its own (7.6%) or in combination with gentamicin (3.2%). Even taking into account the missing data, more than two-thirds of cardiac surgery patients underwent endoscopic saphenous vein harvesting; open harvesting was only used in 2.8% of all cases, and 7.3% were recorded as not undergoing saphenous vein harvesting. In most patients, one or more mammary arteries were used as a conduit, with only the left mammary artery being the most frequent conduit (in 62% of patients). The use of surgical clips to close the skin was rather uncommon, with their use recorded in only 1.7% of patients.

Reclassification will be used: for prophylactic antibiotic use, missing values will be replaced with "no"; for type of prophylactic antibiotic, "other" will replace missing values; for missing surgeon data, the new category "unknown" will be created; for status pre-op, missing values will be replaced with "elective"; for clips, missing values will be replaced with "none"; and saphenous vein harvesting will be replaced with "none" for missing values. Missing values for continuous variables will be replaced with the mean.

Table 4.3: Postoperative characteristics

Postoperative Factor	Count or mean ± sd	N & (%) Data Completeness
Maximum bleeding at time of mediastinal drains removal (cc)	1317.9 ± 1223.9	860 (77.0)
Fluid overload	40 (10.5)	381 (34.1)
Duration of mechanical ventilation (minutes)	139.9 ± 1821.7	848 (75.9)
Length of stay ICU (days)	9.80 ± 43.1	886 (79.3)
IABP use		1099 (98.4)
Yes, pre-op	53 (4.8)	
Yes, intra-op	25 (2.3)	
Yes, post-op	1 (0.1)	
No	1020 (92.8)	
Neurological complications within 30 days		558 (50.0)
None	469 (84.1)	
Delirium/confusion (may include CVA or TIA)	56 (4.6)	
Other	33 (5.9)	

Postoperative risk factors were less diligently recorded compared to preoperative patient characteristics and intraoperative risk factors. Only data pertaining to IABP use was recorded with greater than 90% regularity; of the remaining postoperative risk factors, their completion ranged from 34.1% (fluid overload) to 79.3% (length of stay in the ICU).

Problems such as fluid overload and assorted neurological complications were relatively rare, with fluid overload occurring in only 3.3% of all patients and any variety of neurological complication occurring in 7.4% of all patients. The most common complication was delirium/confusion (including CVA or TIA), which was experienced by 4.6% of all patients. Average maximum postoperative bleeding was 1,318cc, and the mean duration of mechanical ventilation, calculated from the intubation time and first extubation time variables, was roughly two hours and twenty minutes. Patients stayed an average of nearly ten days in the ICU following their surgeries, and IABP was used in only a minority (7.1%) of patients.

Missing data will be supplemented using reclassification: for fluid overload, IABP use, and neurological complications within 30 days, "no" will replace missing values. Missing or unknown values for continuous variables will be replaced with the mean.

4.3.3 Collinearity and Strength of Association Assessment

The strength of association between continuous variables was carried out using Pearson correlation coefficients; of length of stay in the ICU, maximum bleeding volume, patient age, time between commencement of antibacterial prophylaxis and first incision, total duration of mechanical ventilation, total duration of surgery, and waiting time, only the waiting time and length of stay in the ICU variables were found to be even remotely correlated. With a Pearson correlation coefficient of -0.84, the two variables have a relatively strong negative correlation; that is, as the number of days a patient waits in hospital prior to their surgery increases, the number of days they spend in the ICU following their surgery decreases.

The associations between categorical variables were assessed using chi-squared analyses. Due to the relative sparseness of the distribution of some variables, there were no strong associations amongst categorical variables.

4.3.4 Outcomes

Once reclassification of missing data was completed, data on 1,210 patients remained for analysis (see Figure 4.1-ii).

There are a great number of possible outcome variables in the QRACS with varying degrees of data completion. Infections of the arm, leg, thoracotomy, resternotomy, or sternal incisions within one month of surgery as well as specific implants are all possible outcomes identified in the QRACS. The SSIs of any kind variable itself has a completion percentage of 83.6%, of which 8.5% indicate development of a SSI (7.1% of all patients when missing values are interpreted as no infection). These infections occurred despite antibacterial prophylaxis (in 95.7% of patients) and preoperative topical decolonisation (in 82.3% of patients).

The site of sternal incision is by far the most frequent site of surgical site infection with nearly four fifths of all identified SSIs occurring at this location (sternotomy was employed as the primary approach in 96.0% of surgeries). The site of saphenous vein harvesting was the second most frequent location for SSIs, with just over one fifth of identified SSIs arising in the leg. Resternotomy incision (a rare variety of incision, as only one patient underwent a resternotomy) SSI was reported only once. SSIs at the arm incision location was also exceedingly infrequent. Although no definitive data was available on the prevalence of arm incisions in general, it is a relatively unusual procedure for the identified cardiac surgery procedures. No infections of the thoracotomy incision were reported. Like resternotomy, thoracotomy was rarely the approach selected for the intervention; only six thoractotomy procedures were recorded in the databank (i.e. 0.5% of all procedures). No infections of any implants within one year of cardiac surgery were reported. All variables that contained outcome information on individual SSIs (i.e. leg, arm, thoracotomy, resternotomy, and sternal incisions and implant ≤ 12 months) had very low completion rates at 7.2%. The all locations variable had a completion rate of 83.6%.

Table 4.4: All SSI outcome variables of interest, max one-year post-op

Location of SSI	Count	N Eligible Patients	% SSI in Eligible Patients	% SSI in All (1210) Patients	% All Infections[d]
Leg incision[e]	19	992	1.9	1.6	22.1

[d] Based on total of 86 cases identified

Arm incision[f]	2	4	50.0	0.2	2.3
Implant ≤ 12 months[g]	-	271	-	-	-
Thoracotomy incision[h]	-	6	-	-	-
Resternotomy incision[i]	1	3	33.3	0.1	1.2
Sternal Incision[j]	67	1105	6.1	5.5	77.9
All locations	86[k]	1210	7.1	7.1	100

Four patients who were diagnosed with a leg incision SSI were also diagnosed with a sternal incision SSI; thus 21% of leg incision cases were part of a multiple diagnosis. The arm incision SSI was a unique diagnosis. While the date of diagnosis of the resternotomy incision SSI is unknown, it occurred in a patient who was also diagnosed with a sternal incision SSI. Thus 7.5% (5/67) of sternal incision SSIs were part of a multiple diagnosis.

Table 4.5: Type of sternal SSIs

Type of Sternal SSIs	Count (% All Sternal SSIs)
Superficial	34 (50.8)
Mediastinitis	2 (3.0)
Deep	31 (46.3)
Total	67 (100.0)

[e] Of a total of 920 patients who were recorded as having usable saphenous veins prior to surgery
[f] Of 4 patients on whom clips were used; there are no other indicator variables for procedures involving arm incisions. This infection rate is thus probably an overestimation.
[g] Of a total 271 Bentall procedures and valve replacements (CarboMedics Mechanical, porcine, pericardial Magna, Medtronic Freestyle, Medtronic Mosaic, On-X Mechanical, resuspension with pericardial Magna, St. Jude Mechanical, and valve sparing); data was missing on 721 patients
[h] Of a total 6 patients who are recorded as undergoing a direct thoracotomy, mini direct thoracotomy, or a mini videoscopic thoracotomy as the surgical approach
[i] Of a total 3 reoperations for repair of late sternal dehiscence (same incision); 2 within 30 days and 1 within 12 months
[j] Of a total 1094 who are known to have had a sternal closure (and thus must have underwent a sternal incision); data were missing for the variable for 23 patients
[k] Note that due to 3 patients developing more than one infection, there are 3 cases unaccounted for in the QRACS's "all locations" variable; the "Frequency" column sum is 89

Of the 67 sternal incision SSIs identified, there were three different classifications of infection: superficial, mediastinitis, and DSWI. The most frequent variety of sternal incision SSI was superficial, at a count of 34 diagnoses (51%). DSWIs were the second most frequent, accounting for 31 diagnoses (46%), while the least frequently diagnosed condition was mediastinitis, at a count of 2 patients (3%).

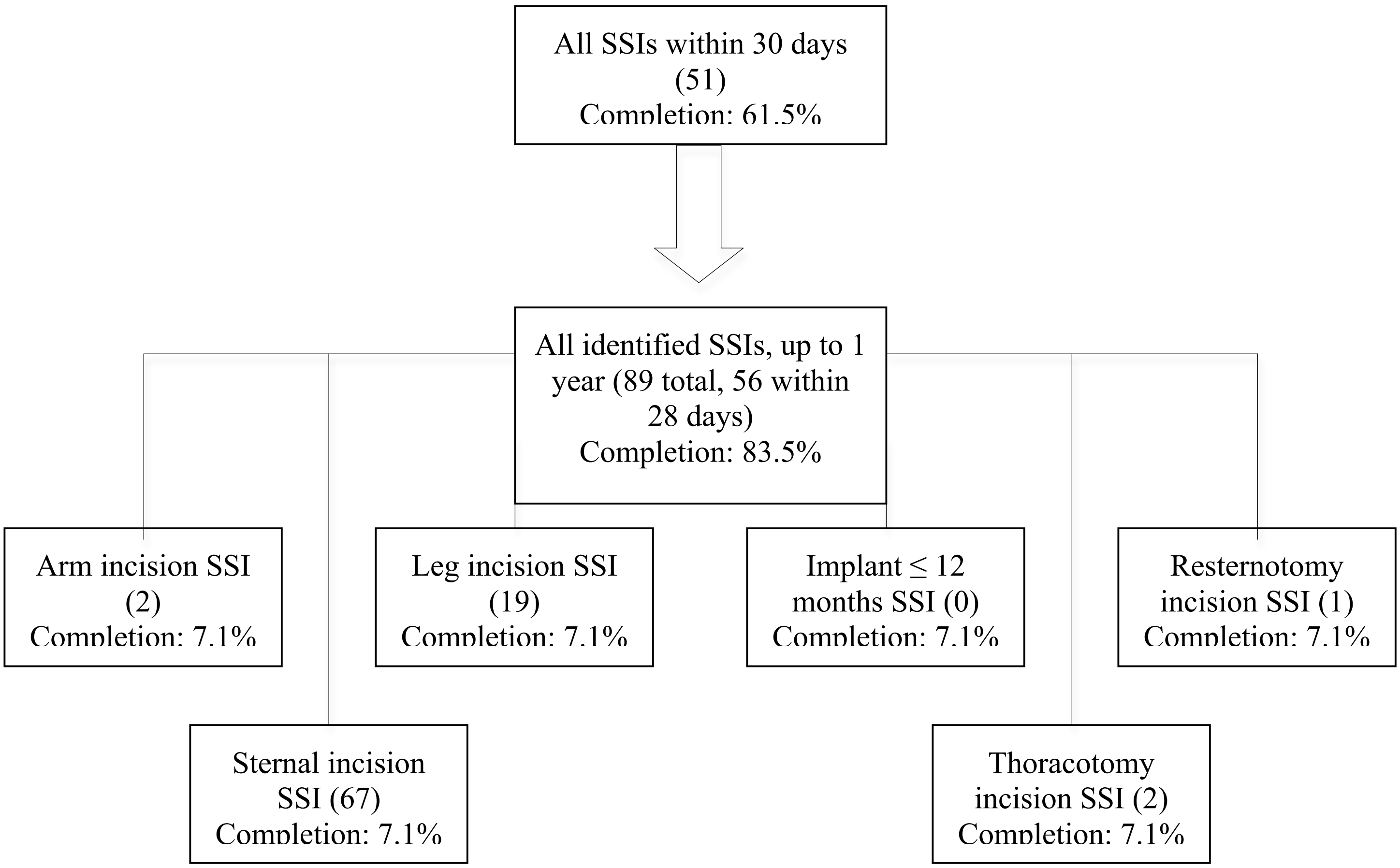
Data reliability and quality in the QRACS is questionable due to a number of inconsistencies. For example, the time span of variables pertaining to SSIs of various locations was not explicitly apparent; although a total of 89 different SSIs were identified in the variables recording SSI data (all of which had very low completion rates at 7.1%, save the overall SSIs variable, which had a completion rate of 83.6%) and 56 occurred within 28 days of surgery, only 51 infections were identified in a variable purported to record information on all infections identified within 30 days of a given patient's operation (see Figure 4.2, next page). This case of missing cases is not easily corrected by assuming the missing 38 cases of infection occurred within 12 months of the surgery occurring, as only two cases of infection within one year of the surgical intervention are currently identified in the system. There are thus internal inconsistencies, or at least a lack of clarity regarding criteria for given outcomes in the QRACS.

4.3.4.2 Infectious Agents

A majority of the bacteria responsible for the SSIs in Table 4.4 were identified through cultures in the JGH's laboratories. Screening for *S. aureus* bacteria was carried out prior to surgery for all but six patients (0.6%). In 96.5% of instances, the results came back negative; 1.8% were identified as positive with resistant strains and 1.0% were indentified as positive with sensitive strains. Coagulase-negative *S. aureus* was the bacteria the most commonly responsible for SSIs, identified as the primary infectious agent for 52.8% of all SSIs. *Pseudomonas aeruginosa* was the second most prevalent primary identified cause of SSIs, with 5.6% of cases caused by the pathogen. Other bacteria (*Corynebacterium spp*., *Escherichia coli*, *Klebsiella spp*., *Proteus spp*., *Pseudomonas spp*., and *S. aureus*) and fungi (*Candida spp*.) were responsible for 14.6% of cases, while 20.2% of SSIs did not have a corresponding pathogen identified. Other unspecified pathogens were identified as the primary causative pathogen in 4.5% of cases (see Table 4.5). Although the data in Table 4.5 lists only the primary identified pathogen in cases of

SSI, more often than not two or more pathogens were identified in culture for a given patient with a SSI.

Figure 4.2: Completion rates of related and identified SSI variables



4.3.4.3 Prior Recent Drug Exposure

The QRACS had several variables designed to collect data on patients' pharmaceutical use within seven days prior to their surgeries (see Table 4.6). The rates of completion of these variables are high; all have data on at least 90% of patients. A majority of patients were on ASA (54.3%), β-blockers (62.2%), PPIs (76.3%), and/or statins (82.6%). ACE inhibitors (49.4%), calcium channel blockers (22.2%), diuretics (31.5%), oral hypoglycaemic agents (24.3%), and Plavix (24.9%) were also relatively frequently used, with at least one-fifth of patients using them in the week prior to their surgeries.

4.3.4.4 Mortality

Mortality as an outcome was measured in the QRACS as two variables, one concerning 30-day follow-up and the other regarding 12-month follow-up (see Tables 4.7 and 4.8). The completion rates of these variables are, like the other outcome variables, quite low (50.0% and 0.5%, respectively). The exceedingly low completion rate of 12-month CODs is in part related to the impossibility of data completion given the study's time window; any mortalities occurring after 31 October 2012 would not have had the opportunity to be entered at the time of data extraction. Immediate CODs and, if relevant, accompanying complications/secondary CODs were recorded for all identified mortalities.

4.3.5 Yearly Rates of Infection

The incidence rate of infections per year (i.e. the number of infections per patient per year) are displayed in Table 4.10. These were calculated in order to reflect the rate of infections per operation on a yearly basis while accounting for the fact that 2013 was incomplete at the time of data harvesting (the end of October 2013).

The lowest proportion of infections at the JGH from 2011-2013 was experienced in 2013, at a rate of 4.2 infections per year, while the highest rates of SSIs during the study time period occurred during 2012, with rates of infection exceeding 10%.

Using Poisson methods,[68] with 2011 as the reference year, it was found there was a statistically significant increase in diagnosis of infection rates for 2012 (1.75, 95% CI: 1.06, 2.90). There was no statistically significant difference between 2013 and 2011 (0.63, 95% CI: 0.32, 1.23). These estimates controlled for the fact that a patient diagnosed in one year may have underwent surgery in the previous year, and the pre- and intraoperative surgical conditions to which they were subjected do not reflect those of the year of diagnosis.

Table 4.6: Bacteria causing SSIs

Primary Bacterium[1]	Leg Incision Frequency	Arm Incision Frequency	Implant ≤ 12 Months Frequency	Thoracotomy Incision Frequency	Resternotomy Incision Frequency	Sternal Incision Frequency	All Locations Frequency	% All Infections
Candida spp.	1	-	-	-	-	1	2	2.2
Corynebacterium spp.	-	-	-	-	-	1	1	1.1
Escherichia coli	2	-	-	-	-	1	3	3.4
Klebsiella spp.	-	-	-	-	-	2	2	2.2
Proteus spp.	-	-	-	-	-	1	1	1.1
Pseudomonas aeruginosa	3	-	-	-	-	2	5	5.6
Pseudomonas spp.	-	-	-	-	-	2	2	2.2
Staphylococcus aureus	2	-	-	-	-	2	4	4.5
Staphylococcus negative coagulase	7	-	-	-	-	40	47	52.8
Unknown	2	2	-	-	1	13	18	20.2
Other	2	-	-	-	-	2	4	4.5
Total	19	2	-	-	1	67	89	100

[1] A majority of cultures contained 2-3 bacteria; only the primary agent is identified here

Table 4.7: Medication taken within 7 days prior to surgery

Drug	Count (%)	N & (%) Data Completeness
α-blockers	24 (2.25)	1068 (95.61)
Acetylsalicylic acid (ASA)	574 (54.30)	1057 (94.63)
Angiotensin-converting-enzyme inhibitors (ACE)	528 (49.44)	1068 (95.61)
Anti GIIb/IIIa inhibitors	6 (0.56)	1068 (95.61)
β-blockers	664 (62.17)	1068 (95.61)
Bronchodilators	128 (11.99)	1068 (95.61)
Calcium channel blockers	237 (22.17)	1069 (95.70)
Diuretics	337 (31.52)	1069 (95.70)
H_2-receptor antagonist (H2RA)	4 (0.38)	1047 (93.73)
Immunosuppressants/steroids	30 (2.81)	1068 (95.61)
Insulin	102 (9.54)	1069 (95.70)
Intropes	9 (0.84)	1069 (95.70)
Nitro IV	66 (6.17)	1069 (95.70)
Non-steroidal anti-inflammatory drugs (NSAIDs)	5 (0.48)	1047 (93.73)
Oral hypoglycaemic agent	260 (24.32)	1069 (95.70)
Plavix	256 (23.95)	1069 (95.70)
Proton pump inhibitors (PPIs)	815 (76.31)	1068 (95.61)
Statins	883 (82.60)	1069 (95.70)
Vasopressors	18 (1.68)	1069 (95.70)

Reclassification will be used to supplement the missing data. For all drugs, “0” will indicate non-use and will replace missing data.

Table 4.8: Causes of 30-day mortality

Primary COD	Count (%)	N & (%) Data Completeness	% All 30-day Mortality
Cardiac		558 (50.0)	
Arrhythmia	1 (0.2)		3.7
Ischemia	1 (0.2)		3.7
Low output	7 (1.3)		25.9
Valvular	1 (0.2)		3.7
Gastrointestinal	3 (0.5)	558 (50.0)	11.1
Haemorrhage	1 (0.2)	558 (50.0)	3.7
Multi-organ failure	1 (0.2)	558 (50.0)	3.7
Neurological	1 (0.2)	558 (50.0)	3.7
Pulmonary	3 (0.5)	558 (50.0)	11.1
Renal	1 (0.2)	558 (50.0)	3.7
Other	7 (1.3)	558 (50.0)	25.9

All causes	27 (4.8)	558 (50.0)	100

Using reclassification methods, a value of no outcome will replace all missing data.

Table 4.9: Causes of 12-month morality[m]

Primary COD	Count	N & (%) Data Completeness	% All 30-day Mortality
Cardiac		5 (0.5)	
Low output	1 (20.0)		50.0
Pulmonary	1 (20.0)	5 (0.5)	50.0
All causes	2 (40.0)	5 (0.5)	100

Using reclassification methods, a value of no outcome will replace all missing data.

Table 4.10: Yearly proportion of infections

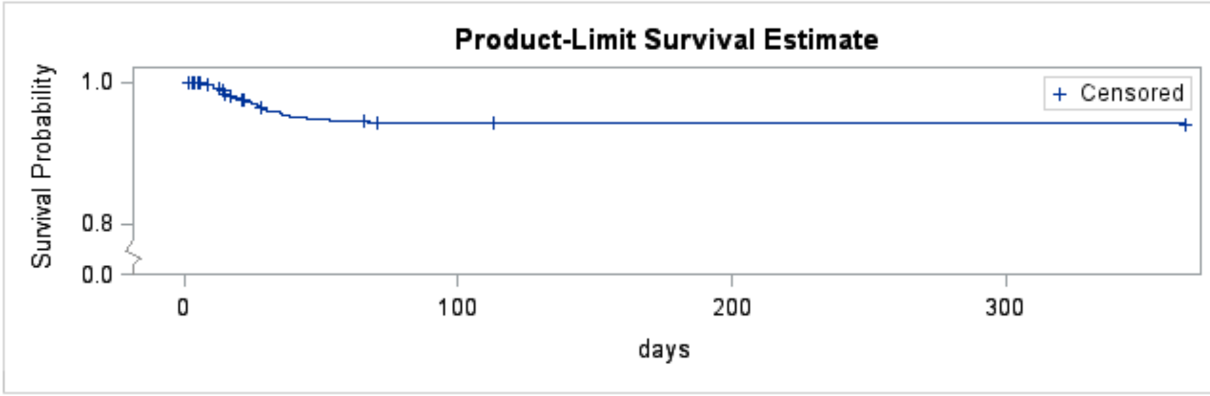
Year of Surgery	# Surgeries	# SSI Diagnoses	Rate of Infections (# Per Year)
2011	375	25	6.7
2012	440	45	10.2
2013	354	15	4.2
Unknown	41	4	9.8
Total	1210	85	7.0

4.4 SURVIVAL ANALYSIS

The Kaplan-Meier method was employed thrice to perform survival analysis on the QRACS data, where the outcomes of interest were any SSIs, sternal SSIs, and leg SSIs. The method estimated the time to SSI event distribution and the 30-day and 12-month mortality. The follow-up period from the date of surgery was a maximum of one year (see Figure 4.2). If a patient developed more than one SSI, the date of the first to occur was taken if they were diagnosed on different dates. For the analysis of survival within patients who developed a SSI, when patients with more than one SSI diagnosis occurred on the same date, the more severe class of SSI (i.e. sternal) was used to reference the illness.

[m] Note that surgeries that occurred after 31 October 2012 have not yet experienced one year of follow-up

Figure 4.2: Kaplan-Meier curve of time to SSI detection (censored=fatality or end of year-long follow-up)



4.4.2 Time to Infection

All SSIs of any kind were diagnosed between 7 and 159 days following surgery. Survival from any SSI (i.e. not experiencing a SSI of any kind) was 93.0% (see Table 4.11). Survival from sternal SSI was 94.3% (see Table 4.12). Overall survival from leg SSIs was 98.4% (see Table 4.13). Mortality rates were low enough to be negligible for these life table analyses. A clear majority of cases of sternal SSI were diagnosed within one month of the executed cardiac surgery date; of 67 diagnoses, 44 occurred within 28 days of surgery. On average, all cases of SSI occurred within one month. Leg SSIs tended to be diagnosed earlier than sternal SSIs by an average of just over one week. Table 4.13 shows time to infection data for all SSIs, sternal SSI, and leg SSI.

Table 4.11: Life table for any SSI diagnosis within up to one year of cardiac surgery at the JGH

Days	Number at Risk	SSIs in Interval	Risk of SSI	Survival Probability	Cumulative Survival Probability
0-7	1210	2	0.00165	0.99835	0.99835
8-14	1208	22	0.01821	0.98179	0.98014
15-21	1186	14	0.01180	0.98820	0.96834
22-28	1172	18	0.01536	0.98464	0.95298
29-35	1154	15	0.01300	0.98700	0.93998
36-42	1139	3	0.00263	0.99737	0.93735
43-49	1136	2	0.00176	0.99824	0.93559
50-70	1134	4	0.00353	0.99647	0.93206
71-365	1130	2	0.00177	0.99823	0.93029

Table 4.12: Life table for sternal incision SSI diagnosis within up to one year of cardiac surgery at the JGH

Days	Number at Risk	Sternal Incision SSIs in Interval	Risk of SSI	Survival Probability	Cumulative Survival Probability
0-7	1210	2	0.00165	0.99835	0.99835
8-14	1208	16	0.01324	0.98676	0.98511
15-21	1192	11	0.00923	0.99077	0.97588
22-28	1181	15	0.01270	0.98730	0.96318
29-35	1166	11	0.00943	0.99057	0.95375
36-42	1155	3	0.00260	0.99740	0.95115
43-49	1152	2	0.00174	0.99826	0.94941
50-70	1150	4	0.00348	0.99652	0.94593
71-365	1146	3	0.00262	0.99738	0.94331

Table 4.13: Life table for leg incision SSI diagnosis within up to one year of cardiac surgery at the JGH

Days	Number at Risk	Leg Incision SSIs in Interval	Risk of SSI	Survival Probability	Cumulative Survival Probability
0-7	1210	0	0	1	1
8-14	1210	6	0.00496	0.99504	0.99504
15-21	1204	4	0.00332	0.99668	0.99172
22-28	1200	5	0.00417	0.99583	0.98755
29-35	1195	3	0.00251	0.99749	0.98504
36-42	1192	1	0.00084	0.99916	0.98420
43-49	1191	0	0	1	0.98420
50-70	1191	0	0	1	0.98420
71-365	1191	0	0	1	0.98420

Mortalities followed a similar trend to SSIs, with virtually all (90%) occurring within the 70 days immediately following surgery. Thirty-one patients were recorded to have passed away within 365 days of their surgery; overall survival for patients within one year of surgery was thus 97.4% (censorship unrelated to fatality occurred at the 365 days post-surgery mark). Deaths occurred at an average of 27 (± 7.8) days following surgery. There was one fatality within 30 days of the operation for which a date was not specified; it was simply listed as “neurological”. Due to the confidentiality complications inherent to confirming the exact date of death for this patient, this death was treated as occurring 29 days after the operation for the purposes of our analysis.

Table 4.14: Time to infection for all SSIs of interest

Aspect	All SSIs	Sternal SSIs	Leg SSIs
Days to infection mean ± sd	26.3 ± 2.3	27.7 ± 2.8	20.3 ± 1.8

4.4.3 Univariate Proportional Hazards Modelling

Hazard rates, literally the probability of a given outcome per unit of time of items under investigation, or the rate of transition out of a current state, are used here as ratios (HRs) to determine the relative effect of the identified patient characteristics and risk factors for outcomes of any SSIs, sternal SSIs, or leg SSIs. Their significance to developing a proportional hazards model is here determined by their 95% CI; if it does not straddle 1 (i.e. null effect), it can either have a negative (HR<1, indicating it does not encourage the outcome) or a positive (HR>1, indicating it encourages the outcome) effect. For variables where the HRs' 95% CIs include 1, the significance of the variable cannot be discerned based on the current data. Tables 4.14 to 4.16 present the hazard ratios for all variables of interest specified in section 3.2.2. HRs and 95% CIs for given pharmaceuticals are presented in Table 4.17.

If a patient developed more than one SSI, the date of the first to occur was taken if they were diagnosed on different dates. When they were diagnosed on the same date, the more severe class of SSI (i.e. sternal) was used to reference the illness. For two cases, the date was not given and therefore it was excluded from the HR analysis. Variables identified as statistically significant in the univariate analyses become the variables for which the multivariate analysis model is adjusted. The purpose of the adjusted HR is to establish which risk factors are positively or negatively associated with the SSI outcome possibilities when controlling for crudely ascertained risk factors.

Table 4.15: Crude HRs of preoperative risk factors[o]

Preoperative Factor	HR All SSIs (95% CI)	HR Sternal Incision SSIs (95% CI)	HR Leg Incision SSIs (95% CI)
Age (10 years)	0.94 (0.76, 1.15)	0.92 (0.73, 1.14)	0.84 (0.55, 1.28)
Sex (female)	0.94 (0.58, 1.54)	0.87 (0.50, 1.51)	0.99 (0.35, 2.78)
Smoking			
No (≥10 years)*	1	1	1
Active (≤2 months)	0.78 (0.45, 1.37)	0.84 (0.46, 1.54)	1.03 (0.34, 3.17)

[o] Asterisk denotes the reference group for categorical variables

Ceased (2<10 years)	0.75 (0.24, 2.40)	0.61 (0.15, 2.52)	1.24 (0.16, 9.45)
BMI (kg/m^2)			
Not overweight*	1	1	1
Overweight	0.95 (0.55, 1.62)	1.16 (0.63, 2.12)	0.56 (0.15, 2.09)
Obese	1.23 (0.71, 2.14)	1.31 (0.69, 2.46)	1.82 (0.61, 5.43)
Patient source			
Cardiology unit	1.09 (0.63, 1.87)	1.14 (0.62, 2.09)	1.04 (0.29, 3.69)
Home*	1	1	1
Other	0.77 (0.46, 1.27)	0.85 (0.48, 1.48)	1.17 (0.41, 3.39)
Waiting time (days)	1.00 (0.98, 1.01)	1.00 (0.98, 1.01)	0.99 (0.95, 1.03)
Cardiac insufficiency	1.41 (0.77, 2.60)	1.44 (0.74, 2.82)	1.64 (0.48, 5.67)
COPD	1.32 (0.71, 2.43)	1.35 (0.69, 2.64)	1.51 (0.44, 5.20)
Diabetes	1.71 (1.11, 2.66)	1.86 (1.15, 3.01)	1.81 (0.72, 4.59)
Dialysis dependency	1.09 (0.15, 7.84)	1.35 (0.19, 9.74)	-[p]
Lower limb arterial disease	2.27 (1.17, 4.40)	2.20 (1.05, 4.60)	3.16 (0.92, 10.93)
LVEF			
≥50%*	1	1	1
30% - <50%	0.90 (0.52, 1.53)	0.82 (0.44, 1.50)	1.46 (0.51, 4.19)
<30%	0.76 (0.28, 2.08)	0.68 (0.21, 2.17)	2.12 (0.47, 9.54)
# diseased vessels	1.20 (0.99, 1.47)	1.16 (0.94, 1.44)	1.72 (0.98, 3.02)
Chlorhexedine shower			
Before shaving*	1	1	1
Other	0.95 (0.57, 1.59)	1.08 (0.62, 1.87)	0.63 (0.18, 2.17)
Shaving			
Clipper, >2h pre-op*	1	1	1
Clipper, <2h pre-op	0.81 (0.33, 2.03)	1.07 (0.42, 2.71)	-
No	2.08 (1.09, 3.98)	2.77 (1.43, 5.38)	-
Unknown	0.73 (0.38, 1.40)	0.79 (0.39, 1.62)	0.73 (0.21, 2.54)
Time between antibiotic prophylaxis & first incision (hours)			
1*	1	1	1
2	1.57 (0.95, 2.60)	1.66 (0.96, 2.88)	1.83 (0.64, 5.05)
3+	-	-	-

Diabetes, lower limb arterial disease and not shaving the chest area prior to surgery are significant predictors of all SSIs and sternal SSIs.

[p] An HR value of "–" indicates no event occurred in the group for this category

Table 4.16: Crude HRs of intraoperative risk factors

Intraoperative Factor	HR All SSIs (95% CI)	HR Sternal Incision SSIs (95% CI)	HR Leg Incision SSIs (95% CI)
Prophylactic antibiotic	1.07 (0.34, 3.40)	1.33 (0.33, 5.44)	0.69 (0.09, 5.21)
Type of prophylactic antibiotic			
Cefazolin*	1	1	1
Vancomycin	1.06 (0.46, 2.43)	1.34 (0.58, 3.11)	0.80 (0.11, 6.02)
Vancomycin & Gentamicin	1.12 (0.35, 3.57)	1.43 (0.45, 4.57)	1.72 (0.23, 13.01)
Other	0.85 (0.34, 2.11)	0.86 (0.31, 2.36)	0.77 (0.10, 5.83)
Surgery time of day (PM)	1.35 (0.87, 2.11)	1.36 (0.83, 2.21)	0.99 (0.37, 2.64)
Surgeon			
A*	1	1	1
B	1.89 (1.10, 3.25)	2.34 (1.25, 4.38)	0.86 (0.31, 2.36)
C	1.38 (0.76, 2.50)	1.65 (0.83, 3.26)	0.43 (0.11, 1.60)
Unknown	-	-	-
Status pre-op			
Elective*	1	1	1
Urgent	1.00 (0.63, 1.58)	1.08 (0.65, 1.81)	1.16 (0.43, 3.15)
Extreme urgency	1.04 (0.40, 2.68)	1.37 (0.52, 3.60)	1.03 (0.12, 8.52
Total duration of surgery (hours)			
2*	1	1	1
3	1.34 (0.18, 9.95)	1.06 (0.14, 8.02)	-
4	1.48 (0.20, 10.83)	1.38 (0.19, 10.16)	-
5	1.40 (0.19, 10.26)	1.02 (0.14, 7.55)	-
Clips			
None*	1	1	1
Arm	-	-	-
Leg	-	-	-
Sternum	-	-	-
Saphenous vein harvesting			
No*	1	1	1
Endoscopic	1.18 (0.71, 1.96)	1.32 (0.74, 2.36)	1.97 (0.57, 6.85)
Other	0.82 (0.33, 2.05)	0.92 (0.33, 2.53)	0.92 (0.10, 8.84)
Mammary arteries			
None*	1	1	1
Left	0.53 (0.26, 1.08)	0.49 (0.23, 1.04)	1.34 (0.18, 10.22)
Right	1.31 (0.28, 6.05)	0.69 (0.09, 5.54)	5.85 (0.37, 93.51)
Left & right	0.34 (0.11, 1.11)	0.39 (0.12, 1.28)	-
Unknown	0.48 (0.22, 1.06)	0.40 (0.17, 0.95)	0.66 (0.07, 6.33)

Amongst intraoperative risk factors, only surgeon B was found to have a significant relationship with the outcome of all SSIs and sternal incision SSIs.

Table 4.17: Crude HRs of postoperative risk factors

Postoperative Factor	HR All SSIs (95% CI)	HR Sternal Incision SSIs (95% CI)	HR Leg Incision SSIs (95% CI)
Maximum bleeding at time of mediastinal drains removal (cc.)			
0-1,000*	1	1	1
1,001-2,000	0.71 (0.45, 1.12)	0.76 (0.46, 1.26)	0.96 (0.36, 2.56)
2,001-3,000	0.55 (0.17, 1.78)	0.70 (0.22, 2.29)	-
3,001-4,000	0.58 (0.14, 2.41)	0.37 (0.05, 2.68)	1.62 (0.20, 12.95)
4,000+	0.58 (0.14, 2.37)	0.74 (0.18, 3.06)	1.59 (0.20, 12.74)
Fluid overload	2.73 (1.26, 5.91)	2.29 (0.92, 5.69)	3.56 (0.82, 15.49)
Duration of mechanical ventilation (minutes)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
Length of stay ICU (days)	1.00 (1.00, 1.01)	1.00 (0.99, 1.01)	1.00 (0.99, 1.02)
IABP use			
No*	1	1	1
Yes, pre-op	0.48 (0.12, 1.94)	0.59 (0.14, 2.40)	-
Yes, intra-op	1.78 (0.56, 5.66)	1.45 (0.36, 5.94)	2.66 (0.35, 19.95)
Yes, post-op	-	-	-
Neurological complications within 30 days			
None*	1	1	1
Delirium/confusion (may include CVA or TIA)	1.08 (0.40, 2.97)	0.98 (0.31, 3.11)	1.33 (0.18, 10.07)
Other	1.82 (0.67, 4.99)	1.06 (0.26, 4.32)	4.54 (1.04, 19.85)

Fluid overload was positively associated with the outcome of any sort of SSI, while unspecified (other) forms of neurological complications were associated specifically with leg incision SSIs.

The patient characteristics and risk factors identified as having a significant positive effect on developing any of the outcomes will be accounted for in an adjusted proportional hazards model.

4.18: Crude HRs of drug use in the week prior to surgery

Drug	HR All SSIs (95% CI)	HR Sternal Incision SSIs (95% CI)	HR Leg Incision SSIs (95% CI)
α-blockers	3.37 (1.36, 8.33)	4.14 (1.66, 10.30)	2.90 (0.39, 21.80)
ASA	2.21 (1.07, 4.58)	1.75 (0.84, 3.66)	4.00 (0.53, 30.08)
ACE	1.16 (0.75, 1.79)	1.29 (0.80, 2.09)	0.70 (2.7, 1.80)
Anti GIIb/IIIa inhibitors	1.53 (0.21, 11.01)	-	7.40 (0.99, 55.57)
β-blockers	1.01 (0.65, 1.58)	0.95 (0.58, 1.54)	1.07 (0.41, 2.75)
Bronchodilators	1.18 (0.61, 2.29)	1.15 (0.55, 2.41)	1.67 (0.49, 5.78)
Calcium channel blockers	1.02 (0.60, 1.72)	1.14 (0.65, 2.00)	0.45 (0.10, 1.96)
Diuretics	1.67 (1.07, 2.59)	1.89 (1.16, 3.06)	1.55 (0.60, 4.00)
H2RA	-	-	-
Immunosuppressants/ steroids	2.88 (1.26, 6.62)	1.63 (0.52, 5.22)	7.09 (2.05, 24.48)
Insulin	2.41 (1.38, 4.22)	2.58 (1.41, 4.72)	2.08 (0.60, 7.17)
Intropes	-	-	-
Nitro IV	1.28 (0.56, 2.93)	1.30 (0.52, 3.24)	0.93 (0.12, 7.01)
NSAIDs	3.31 (0.46, 23.79)	4.09 (0.57, 29.48)	-
Oral hypoglycaemic agent	1.29 (0.79, 2.09)	1.28 (0.75, 2.20)	1.34 (0.48, 3.76)
Plavix	0.82 (0.48, 1.41)	0.84 (0.46, 1.51)	0.39 (0.09, 1.71)
PPIs	1.51 (0.87, 2.61)	1.39 (0.77, 2.50)	0.72 (0.27, 1.92)
Statins	1.72 (0.91, 3.24)	1.35 (0.71, 2.57)	2.11 (0.49, 9.17)
Vasopressors	1.86 (0.46, 7.55)	2.28 (0.56, 9.33)	4.37 (0.58, 32.81)

Several pharmaceuticals were found to have a statistically significant influence on the outcomes of interest; α-blockers were associated with increased risk of all SSIs and specifically sternal incision SSIs, ASA was associated with increased risk of all SSIs, anti GIIb/IIIa inhibitors were associated with leg incision SSIs, diuretics were associated with all and sternal incision SSIs, immunosuppressants/steroids indicate higher risk of all and leg incision SSIs, and insulin was associated with incidence of all and sternal incision SSIs.

4.4.4 Variable Selection for AIC-based Multivariate Analysis

In the pre-surgery shaving variable, the category of hand shaving had only one patient. This category was thus deleted, and constituted missing data for the variable. The variable containing information on the timing of the chlorhexedine shower was similarly dispersed, with only two patients receiving the shower after shaving and two more patients with an undetermined timing. These two categories were therefore abolished and their component patients added to the missing data category for the variable.

Several categories in the neurological complications variable were collapsed in order to preserve statistical power and to focus on the conditions deemed most relevant by the JGH's surgical staff.

Variables that were deemed insignificant through the initial univariate analysis were not included in the multivariate analysis. However, once preliminary multivariate models were established, all variables excluded based on the univariate analyses were re-entered and then removed one by one to see whether they became significant in the presence of the other variables. Using this method, if a variable was found to be significant, it was later added to a final version of the multivariate model. The relevance of variables depends on the outcome under investigation; all locations SSIs, sternal incision SSIs, and leg incision SSIs. For the all locations SSIs, the following variables were retained: lower limb arterial disease, chorhexedine shower, shaving, and surgeon; and α-blocker, diuretic, and immunosuppressants/steroid use within seven days prior to surgery. For sternal incision SSIs, lower limb arterial disease, chlorhexedine shower, and shaving were included. Lastly, for leg incision SSIs, lower limb artieral disease and anti GIIb/IIIa inhibitors and immunosuppressants/steroid during the week before surgery were maintained.

The multivariate analyses concerning postoperative risk factors were carried out separately from the preoperative, intraoperative, and drug use risk factors analyses, as their eligibility occurred after baseline (and there were no dates of measurement/diagnosis available for postoperative variables) and thus the causal directionality between the purported risk factors and the outcomes of interest could not be discerned.

Fundamental covariates including age, sex, and BMI, which are generally unanimously regarded as identified risk factors for SSIs, will be maintained in the models.

4.4.5 Multivariate Proportional Hazards Modelling

As the postoperative risk factors identified in Table 4.3 can occur after the executed surgery date (e.g. fluid overload and neurological complications could be diagnosed in the days and weeks following surgery, rather than the day of), the postoperative risk factors were analysed separately from the preoperative, intraoperative and drug use risk factors.

Table 4.19: Adjusted HRs of preoperative, intraoperative, and drug use risk factors for all SSIs

Risk Factor	HR All SSIs (95% CI)[q]
Diabetes	1.15 (0.67, 2.00)
Lower limb arterial disease	0.65 (0.32, 1.32)
Shaving	
Clipper, <2h pre-op	0.73 (0.29, 1.84)
Clipper, >2h pre-op*	1
No	2.30 (1.18, 4.48)
Unknown	0.80 (0.41, 1.54)
Surgeon	
A*	1
B	1.87 (1.08, 3.23)
C	1.29 (0.71, 2.36)
α-blockers	3.17 (1.23, 8.18)
ASA	1.98 (0.94, 4.18)
Diuretics	1.33 (0.83, 2.13)
Immunosuppressants/steroids	3.20 (1.36, 7.54)
Insulin	1.60 (0.82, 3.14)

Failing to shave the surgical sites before operation, surgeon B, and use of α-blockers and immunosuppressants/steroids in the seven days prior to surgery are statistically significantly related to developing all varieties of SSIs.

After all variables deemed insignificant through univariate analyses were added separately to and then removed from the model, it was found that no other preoperative, intraoperative, or drug use risk factors became statistically significant in the multivariate model.

Table 4.20: Adjusted HRs of preoperative, intraoperative, and drug use risk factors for sternal incision SSIs

Risk Factor	HR Sternal Incision SSIs (95% CI)[r]
Diabetes	1.29 (0.70, 2.34)
Lower limb arterial disease	0.61 (0.28, 1.33)
Shaving	
Clipper, <2h pre-op	1.01 (0.40, 2.57)
Clipper, >2h pre-op*	1
No	2.81 (1.42, 5.58)
Unknown	0.85 (0.41, 1.76)
Surgeon:	
A*	1

[q] Adjusted for age, sex, and BMI
[r] Adjusted for age, sex, and BMI

B	2.28 (1.21, 4.28)
C	1.55 (0.78, 3.08)
α-blockers	3.62 (1.39, 9.48)
Diuretics	1.46 (0.87, 2.44)
Insulin	1.73 (0.84, 3.55)

Surgeon B was found to be associated with increased risk of developing a sternal incision SSIs following surgery, compared to Surgeons A and C. Not shaving surgical sites prior to operation and use of α-blockers in the seven days prior to surgery were also found to be associated with an increased risk of developing sternal incision SSIs.

After all variables deemed insignificant through univariate analyses were added separately to and then removed from the model, it was found that no other preoperative, intraoperative, or drug use risk factors became statistically significant.

Table 4.21: Adjusted HRs of preoperative, intraoperative, and drug use risk factors for leg incision SSIs

Risk Factor	HR Leg Incision SSIs (95% CI)[s]
Immunosuppressants/steroids	9.40 (2.65, 33.42)

Use of immunosuppressants/steroids within one week of surgery was associated with a statistically significant increase in the HR of leg incision SSIs.

After all variables deemed insignificant through univariate analyses were added separately to and then removed from the model, it was found that anti GIIb/IIIa inhibitors became statistically significant in the presence of immunosuppressant/steroid use. It was therefore added to the preoperative, intraoperative, and drug use risk factors for leg incision SSIs model (see Table 4.21).

Table 4.22: Adjusted HRs of preoperative, intraoperative, and drug use risk factors for leg incision SSIs with Anti GIIb/IIIa

Risk Factor	HR Leg Incision SSIs (95% CI)[s]
Anti GIIb/IIIa inhibitors	10.50 (1.34, 82.09)
Immunosuppressants/steroids	10.03 (2.80, 35.90)

[s] Adjusted for age, sex, and BMI
[s] Adjusted for age, sex, and BMI

Table 4.23: Adjusted HRs of postoperative characteristics for all SSIs

Risk Factor	HR All SSIs (95% CI)[t]
Fluid overload	2.83 (1.29, 6.17)

Fluid overload was associated with a statistically significant augmentation in the HR of all SSIs occurring in patients who underwent surgery. As the date of diagnosis of fluid overload is not provided in the QRACS, the directionality of causation between fluid overload and all SSIs cannot be discerned.

After all variables deemed insignificant through univariate analyses were added separately to and then removed from the model, it was found that no other postoperative characteristics became statistically significant.

No significant associations were identified for postoperative characteristics and sternal or leg incision SSIs in univariate analysis.

[t] Adjusted for age, sex, and BMI

5 DISCUSSION

5.1 OVERVIEW

The primary objective of this study, to identify predominantly modifiable internal and external risk factors for the development of SSIs within one year of surgery following invasive cardiac surgery (i.e. involving sternotomy) at the JGH, was achieved.

Description of SSI trends at the JGH as well as trends in COD (causes as well as time to death) were achieved, producing detailed profiles on yearly rates of infection, SSI location in the body, type of sternal SSIs (between superficial, mediastinitis, and deep), primary infectious agents, time to infection, and survival analyses.

Pre- and intraoperative patient internal and external factors independently and significantly raising the risk of SSIs in patients recovering from invasive cardiac surgery were determined using Cox proportional models. Likewise, correlations between postoperative patient factors and the occurrence of SSIs were assessed. Ultimately, it was established that there is a statistically significant difference in covariate distribution between individuals who develop SSIs within one year of surgery and individuals who do not develop SSIs.

The two final specific primary objectives outlined in section 2.6.2.3 were unable to be explored due to the inter-databank unreliability regarding the QRACS and Opera; there was virtually no overlap between the variables present in the QRACS and in Opera. Indeed, the data extracted from each databank for the same time period appears to concern two entirely separate populations. This phenomenon may be attributable to systematic variability in the variables common to both databanks. Due to the 0% merger rate between the QRACS and Opera based on sex and DOB, the utility of the Opera databank—which contains no information on any of this study's potential outcome variables—compared to the QRACS could not be gauged.

The study's secondary objective, to propose interventions or modifications to the current surgical methodology in order to reduce the risk of patient SSIs at the JGH based on the conclusions of the study's primary objectives is discussed in section 5.3.2 and 5.3.3.

5.1.2 The QRACS Utility

Some difficulties were encountered regarding internal inconsistencies and missing data in the QRACS. Rates of completion were particularly low for variables related to the one year follow up in patients who did not experience an outcome, indicating a need for more effective follow up methods. Lack of clarity of the scope of some variables led to scepticism concerning their reliability.

Relating to the variables of interest identified for this study, the QRACS data appeared to be more relevant and extensive upon greater exploration compared to when taken at face value. Although it required an in-depth, rigorous perusal of the 250 variables initially recorded in the QRACS, the data present yielded more than was initially anticipated. This was due in part to the nonlinear fashion in which data was entered; for example, for the single variable concerning SSIs, the diagnosis, date of diagnosis, causative pathogen identified, and, in some cases, the antibiotic prescribed to treat the infection, were identified in the same cell for any given infection. It was therefore a matter of manually separating out the four different variables sharing a single label in order to expose the vastly dissimilar and valuable variables hidden behind a single title. In the future, a method that splits possible responses to a given variable into separate cells, so that each cell is responsible for one variety of response, would lend itself to easier data manipulation and fewer opportunities for human error. Barring this, the creation of new, more specific variables for the variables currently responsible for multiple varieties of responses would facilitate more efficient and reliable manipulation of data by omitting the manual separation phase.

Maintenance of the QRACS appears to be an ongoing issue. Although a majority of the core variables of interest in this study had high completion rates, some, including various outcome variables, had completion rates lower than 10%. This appeared to be a matter of failing to update the outcome variables for those who did not immediately experience a conclusion of interest (i.e. infection); however, it is not safe to assume this is the case, although a systematic method of yearlong follow-up is apparently absent. Similarly, unusual procedures or prescriptions for which there was an entire variable (often yes/no) created had very low completion rates.

5.1.3 Opera Utility

The variables recorded in Opera were of little interest for this study. Completion rates were particularly sparse for choice variables, such as those relating to the operative techniques, localisation of surgical efforts, and the state in which the patient arrived in hospital; some had rates as low as 0%. The failure of the system to record any recognisable outcome variable save a postoperative diagnosis of the patients' conditions, severely limits its research utility in general when compared to the QRACS, while the unreliability of notably the date of surgery, time of first incision, and sex variables (the reliability of other variables inherent to the system were unable to be assessed over the course of this study) was noted early in this study. Although the system has extensive internal data, such as the identities of the attending surgeons; anaesthesiologist; type of anaesthesia; variety of intervention; dates and times concerning commencement and finish of the interventions; and preoperative and postoperative diagnoses, the databank is too limited in scope to be of especial significance on its own.

Regarding the interests of this study, successfully combining the QRACS and Opera would not have led to any noteworthy contributions (save indicators of OR location within the JGH). As to the variables identified by the JGH's surgical staff as factors of curiosity, the data in Opera would have contributed little more to what the QRACS had to offer.

5.2 MAJOR FINDINGS

5.2.2 Patient Profile

Most cardiac surgery patients at the JGH were male; the average patient age was 67 years. A clear majority (73%) were non-smokers; many were overweight (42%), and nearly a third of all patients (31%) were obese. Patients had varying rates of comorbidities such as cardiac insufficiency (12%), COPD (13%), and lower limb arterial disease (6%), and most had healthy LVEFs (72% had LVEFs ≥50%).

Almost all patients (99.8%) were prescribed prophylactic antibiotics—usually cefazolin (86%)—prior to surgery, and two thirds (67%) of surgeries were carried out in the morning. The JGH's three cardiac surgeons split responsibilities almost equally, with Surgeon B completing a few more (35.2%) and Surgeon C completing fewer (30.5%). Most surgeries (59%) were urgent and lasted just over four hours on average.

Drug use in the week leading up to surgery was varied, although a majority of patients were on ASA, PPIs, and/or statins.

5.2.3 Outcomes

Eighty-nine unique SSIs were identified in the QRACS in a total of 86 patients for an overall infection rate of 7%. This rate is lower than reported by Gaspard *et al*. (8.4%) at the McGill University Health Centre, but higher than rates described in other settings (see section 1.3).[69] Most infections were of the sternal incision (78%), of which there was a near-even split between superficial (51%) and deep (46%) sternal SSIs. The next most frequent SSI was of the leg incision (22%), which occurred in the same patients as three sternal SSIs. The bacteria most commonly identified in cultures of the recognized SSIs were coagulase-negative *Staphylococci* (53%), although a large proportion (20%) of cases did not have an identified causative agent. Various other bacteria and fungi accounted nearly equally (1-6%) to the identified infectious agents.

Twenty-nine deaths occurred in the cohort during the study period; the most common CODs were attributed to cardiac and unspecified causes, and most of these (93%) occurred within 30 days of the dead patients' executed surgery dates.

Rates of infection varied by year, with the highest rate of infection (10.2%) occurring in 2012 and the lowest occurring in 2013 (4.2%), and did not follow a discernable linear time trend.

5.2.4 Survival Analysis

Most infections (68.3%) occurred within 28 days of surgery, with an average of 26 days for all SSIs, 28 days for sternal SSIs, and 20 days for leg SSIs. Sternal SSIs and leg SSIs had similar time to infection trends (66% and 79%, respectively). Likewise, most patient mortalities occurred during the month directly subsequent to surgery; 83% (24/29) occurred within 30 days of the executed surgery date, and all patient mortalities occurred within 157 days.

5.2.5 Inter-variable Associations

According to Pearson correlation coefficients for continuous variables, a correlation between the number of days a patient spends at the JGH prior to surgery and the number of days they spend in the ICU subsequent to surgery was recognised. If length of stay in the ICU is an indication of the rate of healing or prevalence and/or severity of surgical complications (including infections), the data indicate that a longer time spent in hospital prior to the surgery date is associated with fewer issues after surgery. It is important to consider, however, that the longer stay in hospital prior to surgery may well be a marker of lower cardiac disease severity; thus, it may be that the urgent and emergency surgery cases are more likely to experience complications than elective ones (a form of confounding). The relative strength of this association may itself be affected by greater opportunity for in-hospital bacterial colonization in elective cases.

5.2.6 Pre- and Intraoperative Risk Factors

Multivariate analysis yielding adjusted HRs of preoperative (including drug use) and intraoperative factors for all SSIs indicates that not removing hair from surgical sites prior to surgery, Surgeon B, and use of α-blockers and immunosuppressants/steroids are all significantly and independently associated with an SSI outcome. Not shaving, Surgeon B, and α-blockers were also associated with sternal SSIs, just as immunosuppressant/steroid and anti GIIb/IIIa inhibitor use was associated with leg SSIs. The finding of null results for such risk factors as age, sex, BMI, smoking, and diabetes is counter to the findings of many other studies (see section 2.2.2).

There are several possible logical explanations for these observations; firstly, hair removal with clippers is generally common practice prior to cardiac surgery, as it is widely believed to decrease postoperative SSI rates. The anticipated reduction in SSIs with hair removal (with clippers as opposed to shaving razors) is often attributed with establishing a sterile skin surface prior to incision.[70] The patients of Surgeon B, who performed more surgeries compared to Surgeon A and C, had higher rates of identified SSIs compared to those of Surgeons A and C (1.7%, 3.4%, and 2.0% for A, B, and C, respectively). This could be due to a variety of different reasons, as Surgeon B may operate on more severe cases (i.e. Surgeon B could be a proxy for types of patients at greater baseline risk of SSI, colinearity between Surgeon B and lack of shaving or α–blocker use), leading to a confounding of the association between Surgeon B and the outcomes of interest. Although there is little data linking use of α-blockers to developing SSIs, use of immunosuppressants has been associated with higher rates of SSIs and other infections in patients following surgery.[71 72] Immunosuppression has been found to mask inflammatory responses to infection, thus rendering early detection of infection more difficult and increasing the likelihood of severity and/or exacerbation.[72] Steroid use has had contradictory results when its association with SSI has been assessed; it has been confirmed and excluded as a predictor of SSIs.[67 73-75] However, given the immunosuppressive qualities of immunosuppressants and steroids, it is logical that rates of SSIs are greater in patients with a recent history of their use.

Although they were not established as statistically significant predictors of SSIs, there were several variables that indicated dose-response trends in the univariate analysis. For example, HR of sternal incision SSIs was found to increase with increasing BMI; advanced age was related to a higher HR of all and sternal SSIs; HR of leg incision SSIs increased with decreasing LVEF; as time between antibiotic prophylaxis and first incision increased, so too did the HR of all, sternal, and leg SSIs; extremely urgent preoperative status was associated with higher HR for all and sternal incision SSIs relative to urgent preoperative status, which in turn was higher than elective preoperative status; and increasing duration of surgery was associated with increasing HR for all SSIs.

5.2.7 Postoperative Associations

Due to date unavailability for postoperative characteristics, the direction of association—if any—for postoperative associations with SSI outcomes cannot be assessed. A significant association between fluid overload and all SSIs was established. No associations between postoperative characteristics under investigation in this study and sternal or leg SSIs were found. Whether there are mechanisms in common between a SSI outcome and fluid overload is not immediately apparent.

5.2.8 The QRACS-Opera Merger

Merging the QRACS and Opera databanks proved an exceptionally challenging, and, ultimately, impossible task. Firstly, there were few variables common to both databanks on which patients could be matched, and many that were common to both proved to be highly variable between them. Ultimately, DOBs were added to Opera after requesting them from hospital administration. This exercise was particularly time consuming and resulted in three data transfers (from patient files to hospital administration to researcher) and thus the reliability of this variable is questionable. An attempt at merging based on DOB yielded low matching rates. When DOB was combined with a second variable between date of surgery and sex, no matches were possible. Secondly, the dates of surgery were highly varied between the two databanks, with most dates appearing more or fewer times in one compared to the other. Lastly, sex ratios differed between databanks, meaning that even binary categorical variables were unreliable. The possibility of ineffectual and unequal extraction methods yielding entirely disparate populations cannot be excluded.

5.3 PROPOSALS

Based on the conclusions outlined in sections 5.1 to 5.3.9, several potential interventions or modifications to the current surgical methodology in order to reduce the risk of patient SSIs at the JGH have been developed. Further, suggestions for increasing the utility of the QRACS and Opera are put forward.

5.3.2 Potential Modifications

All identified pre- and intraoperative significant risk factors are modifiable. Therefore, recommendations based on the adjusted HRs of significant risk factors for all, sternal, and leg SSIs would include the removal of hair using clippers from all surgical sites for all patients and close monitoring of patients exposed to α-blocker and immunosuppressant/steroid use in the time period immediately preceding surgery. Concerning Surgeon B's role as a potentially modifiable risk factor, a more in-depth analysis of potential confounding factors (e.g. patient age, BMI, and severity; surgical team; preferred surgical methodology) in the relationship between the surgeon and the outcome must be assessed.

Postoperative characteristics associated with various SSIs (e.g. fluid overload and neurological complications) warrant further examination in order to determine a direction of potential causality and the possible mechanisms for the associations.

The QRACS and Opera databanks themselves have potential to be very valuable research tools. However, amelioration of data quality, completeness, and accessibility is required to maximise their potential. Development of more constructive variables in Opera, and the elimination of redundancies between the QRACS and Opera are time- and cost-saving possibilities the JGH may want to consider.

5.3.3 Potential Interventions

Several categorical variables, although ultimately determined to be statistically insignificant, demonstrated dose-response trends. For example, being overweight or obese is associated with a higher HR of sternal incision SSIs, likely related to the increased relative amount of tissue susceptible to developing an infection; it may therefore be recommendable for elective surgery patients to lose weight prior to undergoing surgery if the impact of this risk factor proves reversible.

5.4 LIMITATIONS

Initially, there were hopes that certain factors, including the impact (if any) of the OR in which the surgeries were carried out, could be assessed. However, due to the unsuccessful merger of the QRACS with Opera, these Opera-specific variables could not be studied in relation to the outcomes of interest (which were, in turn, confined to the QRACS).

Problems of accuracy of SSIs diagnosis or precision of SSIs diagnosis and patient mortality dates are another limitation of this study, particularly as the year-long follow-up is sparse in patients who did not develop an outcome of interest. Further, the relatively small sample size resulting from the QRACS data extraction and cleaning means that variability, bias, and power are issues of concern. Although the results yielded by the study are applicable to the JGH, they lack generalisability to the municipal, provincial, national, and international levels due to the specificity of the study population and its conditions.

There was insufficient data to fully assess the possibility of confounding regarding the statistically significant HR outcomes for Surgeon B. Further, as with the other statistically significant associations observed in this study, it is possible this association could be attributed to random error in the relatively small sample. More extensive studies with larger populations would prove valuable in ascertaining a closer estimation of reality concerning statistically significant associations between pre-, intra-, and postoperative factors and SSI outcomes. Validation of the QRACS (especially for diagnosis-related variables) is another important data quality-related consideration. A random sample data quality check of the QRACS based on a different existing hospital enterprise system would assist in the evaluation of data quality in the QRACS and provide an indication of why the QRACS and Opera databanks could not be merged (i.e. the QRACS- versus Opera-related issues).

Strengths of this study include its use of a regulated databank intended specifically for studies of exactly this variety. Assessment of the significance of patient drug use prior to surgery, including bacterial prophylaxis as well as various pharmaceuticals prescribed at least one week prior to surgery for pre-existing conditions, is another asset. The relatively uncommon examination of preoperative pharmaceutical use proved fruitful: immunosuppressant/steroid use was identified as a risk factor for all and leg incision SSIs and α-blocker use was identified as a risk factor for all and sternal SSIs. Immunosuppressant/steroid use as a risk factor for SSIs is a logically sound finding and consistent with the limited existing literature on the topic. Use of α-blockers and anti GIIb/IIIa inhibitor as risk factors for all and sternal and leg incision SSIs, respectively, constitutes seemingly unique findings; its introduction here can open dialogue and encourage research on the novel subject.

A prolonged follow-up period (up to one year) reduces the likelihood of misclassification of noncases because of informative censoring. In addition, there was no opportunity for selection bias as all patients in the QRACS for the given time period were included in the study. While information bias is a potential issue, its magnitude was tempered by the QRACS's stringent variable definitions and data entry criteria and the in-house maintenance of the databank at the JGH.

6 CONCLUSION

Several statistically significant modifiable pre- and intraoperative SSI risk factors were identified, and tentative suggestions regarding how to address them have been made. The results obtained in this study can provide an introduction to necessary research and discourse to improve surgical patient care and maximize service delivery. Important future research should address the discrepancies between the findings of this study and those of the prevailing literature within the unique context of the JGH.

7 REFERENCES

1. Bratzler DW, Houck PM. Antimicrobial prophylaxis for surgery: an advisory statement from the National Surgical Infection Prevention Project. Clin Infect Dis 2004;**38**(12):1706-15.
2. L'Ecuyer PB, Murphy D, Little JR, et al. The epidemiology of chest and leg wound infections following cardiothoracic surgery. Clin Infect Dis 1996;**22**(3):424-9.
3. Roy MC. Surgical-site infections after coronary artery bypass graft surgery: discriminating site-specific risk factors to improve prevention efforts. Infection control and hospital epidemiology : the official journal of the Society of Hospital Epidemiologists of America 1998;**19**(4):229-33.
4. Simchen E, Shapiro M, Marin G, et al. Risk factors for post-operative wound infection in cardiac surgery patients. Infection control : IC 1983;**4**(4):215-20.
5. Nagachinta T, Stephens M, Reitz B, et al. Risk factors for surgical-wound infection following cardiac surgery. The Journal of infectious diseases 1987;**156**(6):967-73.
6. Loop FD, Lytle BW, Cosgrove DM, et al. J. Maxwell Chamberlain memorial paper. Sternal wound complications after isolated coronary artery bypass grafting: early and late mortality, morbidity, and cost of care. The Annals of thoracic surgery 1990;**49**(2):179-86; discussion 86-7.
7. Lilienfeld DE, Vlahov D, Tenney JH, et al. Obesity and diabetes as risk factors for postoperative wound infections after cardiac surgery. American journal of infection control 1988;**16**(1):3-6.
8. Jewish General Hospital. 2010-2011 Achievements. Secondary 2010-2011 Achievements 2012. http://www.jghfoundation.org/sections/campatwork1011.html.
9. Association des chirurgiens cardiovasculaires et thoraciques du Québec. Quebec Registry in Adult Cardiac Surgery (QRACS) Operational Protocol and Development of a Risk Model, 2013.
10. Education ADAM. Heart valves anterior view. Secondary Heart valves anterior view 2013. http://medicalimages.allrefer.com/large/heart-valves-anterior-view.jpg.
11. Cameron EW, Walker WS. Coronary artery bypass surgery. BMJ 1990;**300**(6734):1219-20.
12. Eagle KA, Guyton RA, Davidoff R. et al. ACC/AHA 2004 guideline update for coronary artery bypass graft surgery: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Update the 1999 Guidelines for Coronary Artery Bypass Graft Surgery). Circulation 2004;**110**(14):e340-437.
13. Harbarth S, Samore MH, Lichtenberg D, et al. Prolonged antibiotic prophylaxis after cardiovascular surgery and its effect on surgical site infections and antimicrobial resistance. Circulation 2000;**101**(25):2916-21.
14. Bonow RO, Carabello BA, Chatterjee K, et al. 2008 Focused update incorporated into the ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease): endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. Circulation 2008;**118**(15):e523-661.
15. Heart and Stroke Foundation. Heart DIsease - Heart valve surgery: repair and replacement. Secondary Heart DIsease - Heart valve surgery: repair and replacement August 2012.

http://www.heartandstroke.on.ca/site/c.pvI3IeNWJwE/b.4010283/k.BCFD/Heart_Disease__Heart_valve_surgery_repair_and_replacement.htm.

16. Lasalandra M. Nonsurgical Option Now Available for Aortic Valve Replacement. Secondary Nonsurgical Option Now Available for Aortic Valve Replacement 2013. http://www.bidmc.org/YourHealth/HealthNotes/KeepingYourHeartHealthy/DidYouKnow/NonsurgicalValveOption.aspx.
17. McGiffin DC, Galbraith AJ, McLachlan GJ, et al. Aortic valve infection. Risk factors for death and recurrent endocarditis after aortic valve replacement. J Thorac Cardiovasc Surg 1992;**104**(2):511-20.
18. Cohn LH, Adams DH, Couper GS, et al. Minimally invasive cardiac valve surgery improves patient satisfaction while reducing costs of cardiac valve replacement and repair. Ann Surg 1997;**226**(4):421-6; discussion 27-8.
19. El Oakley RM, Wright JE. Postoperative mediastinitis: classification and management. The Annals of thoracic surgery 1996;**61**:1030-6.
20. Singh K, Anderson E, Harper JG. Overview and management of sternal wound infection. Semin Plast Surg 2011;**25**(1):25-33.
21. Freeman R, Gould FK. Prevention of fever and gram negative infection after open heart surgery by antiendotoxin. Thorax 1985;**40**(11):846-8.
22. Auerbach A. Prevention of surgical site infections. In: Sojanoa KG Duncan BW, McDonald KM, et al., ed. Making health care safer: a critical analysis of patient safety practices. Rockville, MD: Agency for Healthcare Research and Quality, 2001:221-44.
23. Marggraf G, Splittgerber FH, Knox M, et al. Mediastinitis after cardiac surgery--epidemiology and current treatment. The European journal of surgery Supplement : = Acta chirurgica Supplement 1999(584):12-6.
24. Ridderstolpe L, Gill H, Granfeldt H, Ahlfeldt H, Rutberg H. Superficial and deep sternal wound complications: incidence, risk factors and mortality. Eur J Cardiothorac Surg 2001;**20**(6):1168-75.
25. Fowler VG, O'Brien SM, Muhlbaier LH, Corey RC, Ferguson TB, Peterson ED. D. Clinical predictors of major infections after cardiac surgery. Circulation 2005;**112**:I-358-I-65.
26. Gwely N, Khalaf S, Maaty R, et al. Deep medial sternotomy wound infection after open heart surgery. Egypt J Surg 2001;**20**(4):742-48.
27. Strecker T, Rösch J, Horch RE, Weyand M, Kneser U. Sternal wound infections following cardiac surgery: risk factor analysis and interdisciplinary treatment. Heart Surgery Forum 2007;**10**(5):367-71.
28. Sofer D, Gurevitch J, Shapira I, Paz Y, Matsa M, Kramer A, Mohr R. Sternal wound infections in patients after coronary artery bypass grafting using bilateral skeletonized internal mammary arteries. Ann Surg 1999;**229**(4):585-90.
29. Wilson WR, Jaumin PM, Danielson GK, et al. Prosthetic valve endocarditis. Ann Intern Med 1975;**82**(6):751-6.
30. Darouiche RO. Treatment of infections associated with surgical implants. The New England journal of medicine 2004;**350**(14):1422-9.
31. Miholic J, Hudec M, Domanig E, et al. Risk factors for severe bacterial infections after valve replacement and aortocoronary bypass operations: analysis of 246 cases by logistic regression. The Annals of thoracic surgery 1985;**40**(3):224-8.
32. Biancari F, Tiozzo V. Staples versus sutures for closing leg wounds after vein graft harvesting for coronary artery bypass surgery. Cochrane Database Syst Rev 2010;**12**(5).

33. Slaughter MS, Olson MM, Lee JT, Jr., et al. A fifteen-year wound surveillance study after coronary artery bypass. The Annals of thoracic surgery 1993;**56**(5):1063-8.
34. Birkmeyer NJ, Charlesworth DC, Hernandez F, et al. Obesity and risk of adverse outcomes associated with coronary artery bypass surgery. Northern New England Cardiovascular Disease Study Group. Circulation 1998;**97**(17):1689-94.
35. Vuorisalo S, Haukipuro K, Pokela R, et al. Risk features for surgical-site infections in coronary artery bypass surgery. Infection control and hospital epidemiology : the official journal of the Society of Hospital Epidemiologists of America 1998;**19**(4):240-7.
36. Spelman DW, Russo P, Harrington G, et al. Risk factors for surgical wound infection and bacteraemia following coronary artery bypass surgery. Aust N Z J Surg 2000;**70**(1):47-51.
37. Lazar HL, Fitzgerald C, Gross S, et al. Determinants of length of stay after coronary artery bypass graft surgery. Circulation 1995;**92**(9 Suppl):II20-4.
38. Zacharias A, Habib RH. Factors predisposing to median sternotomy complications. Deep vs superficial infection. Chest 1996;**110**(5):1173-8.
39. National Nosocomial Infections Surveillance (NNIS) report, data summary from October 1986-April 1996, issued May 1996. A report from the National Nosocomial Infections Surveillance (NNIS) System. American journal of infection control 1996;**24**(5):380-8.
40. Furnary AP, Zerr KJ, Grunkemeier GL, et al. Continuous intravenous insulin infusion reduces the incidence of deep sternal wound infection in diabetic patients after cardiac surgical procedures. The Annals of thoracic surgery 1999;**67**(2):352-60; discussion 60-2.
41. McAlister FA, Man J, Bistritz L, et al. Diabetes and coronary artery bypass surgery: an examination of perioperative glycemic control and outcomes. Diabetes Care 2003;**26**(5):1518-24.
42. Reeves BC, Murphy GJ. Increased mortality, morbidity, and cost associated with red blood cell transfusion after cardiac surgery. Curr Opin Anaesthesiol 2008;**21**(5):669-73.
43. Chelemer SB, Prato BS, Cox PM, Jr., et al. Association of bacterial infection and red blood cell transfusion after coronary artery bypass surgery. The Annals of thoracic surgery 2002;**73**(1):138-42.
44. Miholic J, Hiertz H, Hudec M, et al. Fever, leucocytosis and infection after open heart surgery. A log-linear regression analysis of 115 cases. The Thoracic and cardiovascular surgeon 1984;**32**(1):45-8.
45. McConkey SJ, L'Ecuyer PB, Murphy DM, et al. Results of a comprehensive infection control program for reducing surgical-site infections in coronary artery bypass surgery: further data from the authors. Infection control and hospital epidemiology : the official journal of the Society of Hospital Epidemiologists of America 1999;**20**(12):791-2.
46. Olson M, O'Connor M, Schwartz ML. Surgical wound infections: A 5-year prospective study of 20,193 wounds at the Minneapolis VA Medical Center. Ann Surg 1984;**199**(3):253-9.
47. Braude AI, Ziegler EJ, Douglas H, et al. Antibody to cell wall glycolipid of Gram-negative bacteria: induction of immunity to bacteremia and endotoxemia. The Journal of infectious diseases 1977;**136 Suppl**:S167-73.
48. McCabe WR, Greely A, DiGenio T, Johns MA. Humoral immunity to type-specific and cross-reactive antigens of Gram negative bacilli. The Journal of infectious diseases 1973;**128**:S284-9.
49. Softah A, Hendry P, Masters RG, et al. Wound infection in cardiac surgery. Ann Saudi Med 2002;**22**(1-2):105-7.

50. Lepelletier D, Perron S, Bizouarn P, et al. Surgical-site infection after cardiac surgery: incidence, microbiology, and risk factors. Infection control and hospital epidemiology : the official journal of the Society of Hospital Epidemiologists of America 2005;**26**(5):466-72.
51. Kluytmans JA, Mouton JW, Ijzerman EP, et al. Nasal carriage of Staphylococcus aureus as a major risk factor for wound infections after cardiac surgery. The Journal of infectious diseases 1995;**171**(1):216-9.
52. Kluytmans JA, Mouton JW, VandenBergh MF, et al. Reduction of surgical-site infections in cardiothoracic surgery by elimination of nasal carriage of Staphylococcus aureus. Infection control and hospital epidemiology : the official journal of the Society of Hospital Epidemiologists of America 1996;**17**(12):780-5.
53. Brenner GM, Stevens CW. *Pharmacology*. 3rd ed. Philadelphia, PA: Saunders Elsevier, 2010.
54. Hollenbeak CS, Murphy DM, Koenig S, et al. The clinical and economic impact of deep chest surgical site infections following coronary artery bypass graft surgery. Chest 2000;**118**(2):397-402.
55. Lu JC, Grayson AD, Jha P, et al. Risk factors for sternal wound infection and mid-term survival following coronary artery bypass surgery. Eur J Cardiothorac Surg 2003;**23**(6):943-9.
56. Jenney AW, Harrington GA, Russo PL, et al. Cost of surgical site infections following coronary artery bypass surgery. ANZ J Surg 2001;**71**(11):662-4.
57. Gaynes R, Marosok R, Mowry-Hanley J, et al. Mediastinitis following coronary artery bypass surgery: a 3-year review. The Journal of infectious diseases 1991;**163**(1):117-21.
58. Kollef MH, Sharpless L, Vlasnik J, et al. The impact of nosocomial infections on patient outcomes following cardiac surgery. Chest 1997;**112**(3):666-75.
59. Levi N, Olsen PS. Primary closure of deep sternal wound infection following open heart surgery: A safe operation? J Cardiovasc Surg 2000;**41**(2):241-5.
60. Verkkala K, Järvinen A. Mediastinal infection following open-heart surgery. Scand J Thor Cardiovasc Surg 1986;**20**:203-7.
61. Leal-Noval SR, Rincón-Ferrari MD, García-Curiel A, Herruzo-Avilés A, Camacho-Laraña P, Garnacho-Montero J, Amaya-Villar R. Transfusion of blood components and postoperative infection in patients undergoing cardiac surgery. Chest 2001;**119**(5):1461-8.
62. Society of Thoracic Surgeons. Data Collection. Secondary Data Collection 2014. http://www.sts.org/sts-national-database/database-managers/adult-cardiac-surgery-database/data-collection.
63. Vuorisalo S, Poekla R, Syrjälä H. Comparison of vancomycin and cefuroxime for infection prophylaxis in coronary artery bypass surgery. Infection control and hospital epidemiology : the official journal of the Society of Hospital Epidemiologists of America 1998;**19**(4):234-9.
64. Classen DC, Evans RS, Pestotnik SL, Horn SD, Menlove RL, Burke JP. The timing of prophylactic administration of antibiotics and the risk of surgical-wound infection. New Engl J Med 1992;**326**(5):281-6.
65. Association des chirurgiens cardiovasculaires et thoraciques du Québec. Appendix E: Booklet of Definition of Terms for the Quebec Registry for Adult Cardiac Surgery: ADCCETD, 2013:38.
66. Centers for Disease Control and Prevention. Surgical Site Infection. Secondary Surgical Site Infection 17 May 2012. http://www.cdc.gov/hai/ssi/ssi.html.

67. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection. Infection control : IC 1999;**20**(4):250-80.
68. University of Massachusetts. The Poisson Distribution. Secondary The Poisson Distribution 2007. http://www.umass.edu/wsp/resources/poisson/.
69. Gaspard F, Brassard P, Alam T, Robineau C, Page C, Dell'Aniello S, de Varennes B. Impact of an antimicrobial dressing in reducing surgical site infections in cardiac surgery patients. Wounds 2013;**25**(7):178-85.
70. Reichman DE, Greenberg JA. Reducing surgical site infections: A review. Rev Obstet Gynecol 2009;**2**(4):212-21.
71. Dantas SR, Kuboyama RH, Mazzali M, Moretti ML. Nosocomial infections in renal transplant patients: risk factors and treatment implications associated with urinary tract and surgical site infections. J Hosp Infect 2006;**63**(2):117-23.
72. Hollenbeak CS, Alfrey EJ, Souba WW. The effect of surgical site infections on outcomes and resource utilization after liver transplantation. Surgery 2001;**130**(2):388-95.
73. Malone DL, Genuit T, Tracy JK, Gannon C, Napolitano LM. Surgical site infections: Reanalysis of risk factors. J Surg Res 2002;**103**(1):89-95.
74. Gil-Egea MJ, Pi-Sunyer MT, Verdaguer A, Sanz F, Sitges-Serra A, Eleizegui LT. Surgical wound infections: Prospective study of 4,485 clean wounds. Infection control : IC 1987;**8**(7):277-80.
75. Slaughter MS, Olson MM, Lee JT Jr, Ward HB. A fifteen-year wound surveillance study after coronary artery bypass. The Annals of thoracic surgery 1993;**56**(5):1063-8.

8 APPENDIX

8.1 OPERA ETHICS APPROVAL

Hôpital général juif
Jewish General Hospital

BUREAU D'ÉTHIQUE DE LA RECHERCHE
RESEARCH ETHICS OFFICE

Vasiliki Bessy Bitzas, N, PhD(C), CHPCN(C).
Chair, Research Ethics Committee
Bureau / Room: A-925
Tel: 514-340-8222 x 2445
Fax: 514-340-7951
Email: bbitzas@jgh.mcgill.ca
Website : jgh.ca/rec

October 28, 2013

Dr. Samy Suissa
Department of Epidemiology
Jewish General Hospital

SUBJECT: **Retrospective Chart Review CR 13-73** "Predictors of surgical site infection following adult cardiac surgery at the Jewish General Hospital"

Dear Dr. Suissa,

Subsequent to the receipt and review of the above-mentioned project, please be advised that your request for permission to extract data from the Opera System (approximately 10,400 patients) at the Jewish General Hospital as part of your clinical research project is granted.

It is our understanding that the purpose of this chart review is to identify characteristics predisposing adult cardiac surgery patients to surgical site infections. The data extraction will be done by Ms. Victoria Allen. The data extracted will be coded and kept on the servers of the Center of Clinical Epidemiology with its own access card which is limited to IT personnel only for a period of one year. No contact will be made with patients at any time during this retrospective chart review.

For your information, the above-mentioned protocol will be presented for corroborative approval at the next meeting of the Research Ethics Committee to be held on November 15, 2013.

This approval is for the period of one year at which point you must request permission once again.

Sincerely,

Vasiliki Bessy Bitzas, N, PhD(C), CHPCN(C)
Chair, Research Ethics Committee

Joseph Portnoy, MD
Director of Professional Services

VBB/lm

8.2 THE QRACS ETHICS APPROVAL

Hôpital général juif
Jewish General Hospital

Montréal, November 8, 2013

The research and Ethic committee
The Jewish General Hospital

Re: Access to the Quebec registry of adult Cardiac Surgery (QRACS)
Mrs. Victoria Allen

As principal administrator of the QRACS, it is my pleasure to confirm that Mrs. Victoria Allen has received a license giving her access to the QRACS data. The type of license she received provides her with the ability to read and extract date from all the sections of the database pertinent to the Jewish General Hospital. Access to these data is essential for the completion of her thesis project and any subsequent publications. After signing a confidentiality agreement form, Mrs. Allen received a unique username and confidential password. This access is valid for a period of one year renewable upon request.

Sincerely,

Yves Langlois, MD
President, scientific committee
Quebec registry for Adult Cardiac Surgery

YVES LANGLOIS, M.D., F.R.C.S.(C)

DIVISION DE CHIRURGIE CARDIAQUE A-520
Professeur Adjoint De Chirurgie

CARDIAC SURGERY DIVISION A-520
Associate professor of surgery

ylanglois@jgh.mcgill.ca
T 514 340 8222 x5598
F 514 340 7561

3755, chemin de la Côte-Ste-Catherine Road
Montréal (Québec) H3T 1E2
www.jgh.ca

HÔPITAL D'ENSEIGNEMENT DE L'UNIVERSITÉ MCGILL | A MCGILL UNIVERSITY TEACHING HOSPITAL

8.3 THE QRACS-OPERA MERGER STEPS

Figure 8.1: Flow chart of steps taken to clean data and attempt the QRACS-Opera merger

Opera (Apr 2011-Oct 2013 inclusive)

2,346 obs & 36 vars

- addition of DOB variable
- removal of all patients for whom "service" variable did not have a value of "cardiac"
- removal of all patients for whom "secteur" variable did not have value of "surgery"

1,391 obs & 37 vars

QRACS (All data)

1,647 obs & 256 vars

- removal of all patients for whom the year of operation was 2008, 2009, 2010, or N/A
- removal of all 2011 patients who had surgery Jan-Mar inclusive
- addressing 1920s DOB issue
- removal of all negative duration of surgeries

1,117 obs & 260 vars

- merger based on any combination of DOB, date of surgery, and sex variables

0 obs & 296 vars
(0% of QRACS patients successfully matched with Opera patients)