POST CARDIAC SURGERY STERNAL WOUND SEPSIS BURDEN, RISK FACTORS AND OUTCOMES AT RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL, CAPE TOWN, SOUTH AFRICA: A FIVE-YEAR EXPERIENCE

BY

FEFEKAZI MPISANE

STUDENT NO: MPSJEN001

SUBMITTED TO THE UNIVERSITY OF CAPE TOWN

IN FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE

OF MASTERS OF MEDICINE

(MINI-DISSERTATION)

IN THE FACULTY OF HEALTH SCIENCES

Date of submission: 25/08/2020

SUPERVISORS:

1. Professor L. Zühlke

Department of Paediatrics and Child Health, Red Cross War Memorial Children's Hospital, ICH Building Room 2.17, Rondebosch 7700 , Cape Town, South Africa. Tel: 021 650 2373

2. Dr. A. Brooks

Chris Barnard Division of Cardiothoracic Surgery, Groote Schuur Hospital, Observatory 7925, Cape Town, South Africa.
Tel: 021 404 5017

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DECLARATION

I, Fefekazi Mpisane, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Date: 22 /04 / 2020

ACKNOWLEDGEMENTS AND CONTRIBUTIONS

It is not by my own intelligence that this project became a success , it is by grace bestowed upon me by my Lord and saviour Jesus Christ. I have taken time and effort into accomplishing the research project but would not have done any of it without the hands that have been stretched to me.

Many thanks to the RCWMCH medical records staff who assisted with locating and providing patients' medical files for data extraction. I would also like to acknowledge and thank the quality assurance nursing staff who shared their experiences of rolling out and implementing the SWPB at RCWMCH

I would like to extend a sincere gratitude to my project supervisor Prof Liesl Zühlke whose contribution in stimulating suggestions and assisted me to coordinate the project. She supervised data collection, reviewed and revised the manuscript and mostly invested her full effort in guiding me in achieving the goal. For her inspirational guidance in making sure that this project is not only finished but also a great success and source of information for the coming generation. My deepest appreciation goes to Dr Andre Brooks for providing feedback on the development of the actual protocol and ensuring that all cases were captured, recorded during data collection and also assisted in reviewing the protocol and manuscript .

Further on I would like to also thank Ms Perkins who made a contribution by creating data collection forms and obtaining HREC approval. Throughout the study, she assisted with logistics for collecting and capturing data. Ms Perkins also proofread and edited the manuscript before submission. I would like to send many thanks to Mr Basera for assisting in making my concept into understandable numbers by conducting statistical analysis after having extrapolated the data, he also assisted with proofreading and revising the statistical results.

Last but not least, my most sincere gratitude goes to my husband Dr Zimasa Jama who has given me tremendous support since the beginning of the project, all his guidance with developing and editing this project hasn't gone unnoticed. Thank you for allowing me to use our family time for the project. It is all worth it at the end.

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

07 November 2017

HREC REF: 777/2017

A/Prof L Zuhlke
Division of Paediatric Cardiology
ICH Building, Room 2.17
Red Cross War Memorial Children's Hospital
Rondebosch

Dear A/Prof Zuhlke

PROJECT TITLE: POST CARDIAC SURGERY STERNAL WOUND SEPSIS BURDEN, RISK FACTORS AND OUTCOMES AT RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL, CAPE TOWN, SOUTH AFRICA: A FIVE-YEAR EXPERIENCE (MMeD-candidate: Dr F Mpisane)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 November 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr F Mpisane will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

HREC 742/2017

LIST OF ABBREVIATIONS AND ACRONYMS

ASA score	American Society of Anaesthesiology
CHD	Congenital Heart Disease
DSC	Delayed sternal closure
DSWI	Deep Sternal Wound Infection
ECMO	Extracorporeal membrane oxygenation
IQIC	International Quality Improvement Collaborative
PICU	Paediatric intensive care unit
PRIM score	Paediatric Risk of Mortality score
RCWMCH	Red Cross War Memorial Children's Hospital
SWPB	Sternal wound prevention bundle
SSWI	Superficial sternal wound infection
SCIP	Surgical Care Improvement Project

ABSTRACT

Purpose

Sternal wound infection (SWI) is associated with significant morbidity and mortality in post-operative cardiac patients. We aimed to describe the burden, risk factors and outcomes of SWI in post-operative paediatric cardiac patients at a tertiary children's hospital.

Methods

We conducted a retrospective record review of cardiac surgeries via median sternotomy over a five-year period to identify cases of SWI.

Results

Between 2012-16, 1319 patients underwent median sternotomy. Thirty-four (2.6%) patients developed SWI; eighteen (1.4%) patients developed deep sternal wound infection (DSWI), and sixteen (1.2%) developed superficial sternal wound infections (SSWI). Twenty-two (1.6%) of SWIs were apparent within a week post-surgery before discharge, the remaining were re-admitted post-discharge. Seven (0.5%) patients died from complications.

Conclusion

Significant morbidity was associated with SWI. Furthermore, with a mortality rate of 20 % in the case of DSWI. We strongly support quality improvement procedures such as the Sternal Wound Prevention Bundle (SWPB) that was introduced in late 2014. However, the rate of SWI implies that ongoing monitoring and evaluation of the SWPB is necessary and more stringent adherence to the protocol may result in better outcomes.

CHAPTER : 2

POST CARDIAC SURGERY STERNAL WOUND SEPSIS BURDEN, RISK FACTORS AND OUTCOMES AT RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL, CAPE TOWN, SOUTH AFRICA: A FIVE-YEAR EXPERIENCE

F Mpisane[1], A Brooks [2], S Perkins[1], W Basera[3], L J Zühlke [1,4,]

Department of Paediatrics and Child Health, Red Cross War Memorial Children's Hospital, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa

1. Chris Barnard Division of Cardiothoracic Surgery, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa
2. School of Public Health and Family Medicine, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa
3. Division of Cardiology, Department of Medicine, Groote Schuur Hospital, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa
4. Division of Paediatric Cardiology, Department of Paediatrics and Child Health, Red Cross War Memorial Children's Hospital, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa

Corresponding Author:

Professor Liesl Zühlke

Department of Paediatrics and Child Health, Red Cross War Memorial Children's Hospital

Department of Medicine, Groote Schuur Hospital

ICH Building Room 2.17

Rondebosch 7700

Faculty of Health Sciences, University of Cape Town

Cape Town, South Africa

Phone: 021 650 2373

Fax: None

E-mail: Liesl.zuhlke@uct.ac.za

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INTRODUCTION

Sternal wound infection (SWI) is an important complication of sternotomy post-cardiac surgery in adults and children and is associated with significant mortality and morbidity. It is classified into superficial and deep sternal wound infections according to the US Centers for Disease Control and Prevention (CDC). [1, 2] Superficial sternal wound infection (SSWI) is defined as an infection that occurs within 30 days of surgery and involves only the skin or subcutaneous tissue at the incision site. [3]

Additionally, a superficial infection must meet one of the following criteria:1) purulent drainage; 2) organisms isolated from an aseptically obtained culture of fluid or tissue; 3) pain or tenderness; 4) localized swelling, redness or heat; and 5) a superficial incision deliberately opened by surgeon that is culture-positive or not cultured. [1, 2]

Deep sternal wound infection (DSWI) is defined as an infection that occurs within 30-days after surgery if there is no implant in situ. An implant includes any non-human foreign body that is permanently placed in a patient, including screws, mesh, and/or wires that are left permanently (this includes prosthetic valves, bovine valves etc.) or within one year if the implant has been left in place. DSWI involves tissues or spaces beneath the subcutaneous tissues and meets at least one of the following criteria: 1) an infective organism isolated from culture of mediastinal tissue or fluid; 2) evidence of mediastinitis seen during the operation; 3) chest pain; 4) sternal instability; or 5) fever (>38°C). In addition, it includes any purulent discharge from the mediastinum or an organism isolated from blood or drainage culture of the mediastinal area; abscess or other evidence of infection involving the deep incision found on direct examination, during reoperation or by histopathologic or radiologic examination and/or spontaneous incisional dehiscence. [1, 2]

Paediatric cardiac infections have a reported incidence as high as 15-30%. [4-7] Studies from Europe and the United States reported an incidence of SSWI between 0.5-8% with an associated morbidity and mortality rate ranging from 0.5-9%. [8-10] DSWI has an incidence of 1-5%. [11] The overall worldwide incidence of SWI is reported to be between 0.5 and 7.5%. [12-16]

The most common pathogens implicated in sternal wound sepsis are *Staphylococcus aureus*, coagulase-negative *Staphylococcus*, *Pseudomonas aeruginosa*, and *Salmonella* species. [17] Different studies have reported various risk factors for the development of sternal wound infection post-cardiac surgery. These include bypass time of longer than one-hour, significant post-operative bleeding and a low cardiac output state persisting for more than 24-hours post-operatively. [17, 18] Post-operative stay of more than 12 days in a paediatric intensive care unit (PICU) increases the risk of SWI significantly. [17] Pollock et al [19] reported an association between SWI occurrence and high Paediatric Risk of Mortality (PRIM) score. Mehta et al [20] showed that younger age, underlying disease and higher American Society of Anaesthesiology (ASA) score were risk factors for infection, while Allpress et al [21] determined that age less than 1-month and longer surgical time were risk factors. Furthermore, a multicentre study described post-operative inotropic support as an independent risk factor. [22] Moreover, Delgado-Corcoran et al [23] reported the presence of genetic abnormalities, pre-operative hospitalization, ventilator support, extracorporeal membrane oxygenation (ECMO) use, and delayed sternal closure (DSC) are risk factors of surgical site infections (SSIs) in children.

Despite these findings that SWI causes significant mortality and morbidity in both children and adults post cardiac surgery, there are no national guidelines in South Africa to help surgical programs reduce infection rates.

Several international programs have been described with reduction of SWIs as a primary goal. In response to inconsistent compliance with infection prevention measures in the US, the Centers for Medicare and Medicaid Services and the US CDC developed the Surgical Care Improvement Project (SCIP) in 2002. [24] This project was developed to standardize practice to reduce the risk of surgical infection and increase compliance to infection prevention measures.

Most of the SCIP initiative measures applied to the peri-operative period. However, little substantial improvement in SSI rates in adults at US Veteran's Administration Hospitals were seen despite adherence to the SCIP measures after a decade. [25] Further programmes included the development of a sternal wound prevention bundle (SWPB) in 2012. The implementation and use of an SWPB in paediatric cardiac patients recently demonstrated both a standardisation of peri-operative care and a significant reduction in SWI rates in patients with DSC. [23]

The Chris Barnard Division of Cardiothoracic Surgery at the University of Cape Town, based at Red Cross War Memorial Children's Hospital (RCWMCH), operates on ~300 paediatric patients per year and experiences a regular occurrence of SWIs. The Division recently joined the International Quality Improvement Collaborative (IQIC) for Congenital Heart Surgery in Developing World Countries which provides benchmarking data for health care professionals and guides quality improvement efforts. The goal of the IQIC is to decrease morbidity and mortality rates at participating sites and to demonstrate continuous improvement in quality.[26]

One of the key variables of interest of the IQIC is SWI. Apart from early informal review prior to establishing wound care bundles, the incidence and outcomes of SWI at RCWMCH had not been systematically interrogated.

Prior to joining IQIC, our institution used several surgical modalities for treating SWI. These include a closed-suction antibiotic catheter irrigation system, vacuum-assisted closure, sternal exploration, surgical debridement, and rewiring of the sternum. Post-operatively, if any clinical evidence of SWI is detected, empiric second-line broad-spectrum antibiotics are initiated as per hospital nosocomial protocol. Broad-spectrum coverage is targeted at methicillin-resistant gram-positive and gram-negative organisms. Once the organism has been confirmed, either on blood or tissue specimen (obtained in theatre or tissue swab at bedside), sensitivity guided therapy is initiated and continued for a minimum of 4 weeks and 6-weeks maximum if a DSWI diagnosis has been confirmed. The hospital's infectious disease team is consulted for appropriate antibiotics and duration of treatment.

Management of wounds includes dressing with Primapore® dressing and the wound is reviewed on day two or three post-surgery. Sternal sutures are subcutaneous and therefore are not removed. SSWIs are cleaned or explored and vacuum dressings applied in the first instance. DSWIs are aggressively debrided in theatre and vacuum dressings are applied. Further, a follow up "re-look" in theatre as required and vacuum dressing is continued until the wound is ready for secondary closure.

An SWPB was introduced at RCWMH in September 2014. Before implementation, staff members underwent in-service training. Challenges encountered included shortages of linen, stock-outs of intranasal mupirocin, revisions to an existing checklist, and revisiting the data recording and collection process.

Figure 3 outlines the introduced pre-operative skin preparation procedure in detail.
The SWPB included pre-, intra- and post-operative measures. Pre-operatively, skin preparation included a full body wash and administration of prophylactic antibiotics 30-60 minutes prior to incision.

Intra-operatively, the quality of surgical drapes was improved and surgical mask requirements were re-enforced; Post-operatively, prevention focused on wound dressing using SOPs, caring for the echo probe used in ICU post-operatively, line care, urine catheter care and lastly, monitoring of serum blood glucose. The theatre preparation SOP (Pre-operative SOP, Figure 2) was replaced with a surgical site infection compliance checklist.

In 2017, SWI-prevention efforts were renewed with the aim of reviewing and assessing risk factors, with the placement of a full-time nursing sister dedicated to this task, secondary to joining IQIC.

This study aimed to describe the burden, associated risk factors and outcomes of sternal wound sepsis in post-operative paediatric cardiac patients at the RCWMCH.

METHODS

We conducted a retrospective medical record review of cardiac surgeries over five years from 1 January 2012 to 31 December 2016 at RCWMCH to identify all cases of SWI. Data were collected from the following sources: 1) cardiac surgical database; 2) cardiothoracic surgical case notes; 3) infection control database; and 4) National Health Laboratory Services (NHLS). All paediatric patients, regardless of age, who underwent cardiac surgery at RCWMCH via sternotomy approach during the study period were included and all patients who underwent thoracic surgery for non-cardiac conditions and cardiac surgeries other than sternotomy approach were excluded.

Ethics approval for the study (HREC 777/2017) was obtained from the University of Cape Town Human Research Ethics Committee with a waiver of parental consent. A REDCap™ database hosted on a UCT-secured server was used for recording and managing data.

Data Collection

Medical records were reviewed for each patient and subject identification numbers were assigned in lieu of actual names for data collection. Outcome variables were grouped as demographics, surgery, culture isolates, and morbidity and mortality. Demographic data included sex, age, genetic abnormalities and the type of congenital heart disease. Surgery variables were length of bypass and cross-clamp times, number of postoperative ICU days, inotropic support, antibiotic and ventilation duration. Culture isolates focused on the number of positive isolates and the most common pathogen isolated. Outcomes included morbidity and mortality.

Data analysis

Stata 16[27] was used for data analysis. The incidence of DWSI and SSWI among all identified cardiac surgical patients is presented as percentages and as per 1000 population with 95% confidence intervals (95% CI). Continuous variables are expressed as means with standard deviations (mean ±SD) or medians with interquartile ranges [median (IQR)] depending on normality of the data, while categorical variables are expressed as frequencies and percentages. Group differences in categorical variables were tested using Fisher exact tests since group numbers were small and the large number assumption for chi-square tests did not apply. Student t-tests or Mann Whitney tests were applied to test associations between continuous variables and the wound type/mortality outcome depending on normality.
The value for statistical significance was set at p-value=0.05.

RESULTS

The demographic, clinical presentation, type of surgery, wound features and microbiological culture variables are presented in Tables l - V stratified by type of wound infection viz deep or superficial. Data by mortality are presented in Table Vl and Figure 6.

A total of 1669 paediatric patients underwent cardiac surgery during the study period. Of those, 1319 (79%) had median sternotomies while 350 (21%) were performed via other approaches (left posterolateral thoracotomy, right posterolateral thoracotomy, left anterior thoracotomy, right anterior thoracotomy) and were thus excluded. Thirty-four patients (2.6%), or 0.04 per 1000 population with a 95% confidence interval (0.02-0.49), developed sternal wound sepsis. Eighteen of these patients developed DSWI while 16 developed SSWI. Twenty-two of the 34 patients developed SWI during hospitalization post-cardiac surgery while the rest developed wound infection post-discharge and were readmitted for treatment.

A total (1.6%) of the patients who developed SWI post-surgery showed symptoms within one week (before day 7), and the rest developed SWI in the second week (after day 7) post-surgery. Only one patient had a total erosion of sternum due to multiple debridement (Figure 5). Seven patients died from complications of SWI; four of these patients had DSWI and three had SSWI. Those who developed DSWI were older at 8.1 months [IQR: 0.5-22.7] as opposed to those with SSWI 1.1 months [IQR: 0.3-6.1]. There was no significant difference in age, sex and genetic defects associated with the development of either SSWI or DSWI (Table l).

Twenty-three of those with SWI (67.7%) had cyanotic congenital heart disease and majority of these patients developed DSWI (72.2%). Chromosomal abnormalities were found in four (11.7%) patients in this cohort, of which three (8.8%) were trisomy 21 and one (2.9%) had confirmed chromosome 22q deletion syndrome.

Table ll describes the surgical caseload in detail. Most cases were elective (73.5%), the mean bypass and cross-clamp times were 131.4 minutes [±SD73.9] and 83.2 minutes [±SD 49.4] respectively. Most patients 32/34 (94%) needed post-operative inotropic support with adrenaline for a median duration of 1.8 days. All patients were ventilated post-operatively according to cardiac intensive care protocols with a median time of 61.4 hours [IQR: 29-146]. This excluded patients with missing data. Intensive care unit (ICU) stay was 7.1 days [IQR: 3.6-16.1], and six (17.7%) patients had DSC. None of these indices was statistically significant in either of the DSWI or SSWI groups. However, trends were noted when comparing DSWI with SSWI variables.

DSWI patients had prolonged duration of ICU stay and mechanical ventilation time when compared to SSWI with a median ICU stay of 8.6 days versus 3.9 days for SSWI. DSWI patients had an average ventilation duration of 107.8 versus 58 hours for SSWI. DSWI patients had a shorter mean duration between antibiotics administration to incision time of 57.1 minutes compared to those with SSWI of 81.7 minutes [SD±35.5], p 0.03.
Table lll illustrates the distribution of DSWI and SSWI features. All patients who met criteria for SSWI presented differently. Purulent drainage and localised swelling were the most common presentations, 56% and 50% respectively. The two major features present in all DSWI patients were purulent drainage (77.8%) and spontaneous dehiscence (61.1%).

Osteomyelitis was noted in three (16.7%) DSWI patients. One patient had a total erosion of sternum due to multiple debridement.

Twenty-two children (64%) had positive identifiable cultures and 12 children (35%) were culture-negative but met the criteria for SWI. The most common pathogens isolated were methicillin-resistant *S. aureus* (MRSA) followed by Coagulase-negative *S. aureus, Klebsiella* pneumonia, *P. aeruginosa* and *enterococcus* species. Three unusual organisms (*Candida albicans*, *Acinetobacter baumannii* and *Proteus mirabilis*) were identified in two DSWI patients. No unusual organisms were identified in the SSWI group.

As illustrated in Table V, the median duration of antibiotic use was 12.5 days (IQR [7-40]). Although not statistically significant (p=0.89), patients with DSWI required more treatments in theatre than those with SWI. The duration of treatment for DSWI was a maximum of 48 days with antimicrobials and a maximum of 21 days for SSWI.

The infection control team's assessment of weekly compliance with the overall SSI bundle from January 2015 to August 2017 is illustrated in Figure 4. Of the 34 patients included in our study, 15 patients' medical records contained only the pre-operative SOP. However, these patients were treated before the SWPB checklist was implemented. Another 16 patient records, both before and after the implementation of the checklist, contained neither the pre-operative SOP nor the new SWPB checklist. Three folders were incomplete and therefore no assessment of these elements could be made.

Table IV shows the pathogens found that are in keeping with the literature (Staphylococcal, Klebsiella and Pseudomonas infections). We observed a difference in the pathogens causing infections where more unusual pathogens (*Candida albicans*, *Acinetobacter*, and *Proteus*)

were identified, however, *Staphylococcus aureus* was still the most common pathogen causing infection.

Of the seven (20%) patients who died from SSI complications, four had DSWI and three had SSWI. Tables Vl (a-c) outline the comparisons between these patients and the majority who survived. Of the four patients with DSWI, three had emergency surgery for complex cyanotic CHD and four had elective surgery. Three were re-admitted from home with overwhelming septicaemia as a complication of SWI, four developed SWI post-operatively as inpatients by day-14 post-surgery. Two of the three patients who were re-admitted had a previous SWI diagnosed before discharge. They received antibiotics and multiple theatre debridement treatments prior to discharge and had been deemed sepsis-free and fit for discharge. The third patient had no SWI complications noted prior to discharge.

Five patients died from septicaemia secondary to SWI; two patients died from overwhelming septicaemia secondary to pneumonia. One of the latter died from hypoxia secondary to carbapenem-resistant *Klebsiella* pneumonia on a background of severe chronic lung disease and the other had severe adenovirus pneumonia. However, both these patients had been treated for SWIs a month prior.

DISCUSSION

Overall, SWI in post-operative paediatric cardiac patients at our institution was associated with significant morbidity and mortality. Our cohort had an incidence of DSWI of 1.4 which is similar to reported worldwide values of 1-5%. [(11)] We noted that younger age was not a significant risk factor,

but there was a trend towards DSWI developing in the older age group of 11.5 months [interquartile range [IQR, 0.6-19.5 months].

Although some studies showed that the presence of genetic abnormalities was a risk factor for SSWIs, our findings indicate that genetic abnormalities and DSC were not risk factors in our context as only four of the twenty patients had chromosomal abnormalities and/or DSC.

Most of our patients required ventilatory support post-operatively. A median bypass time of 140 minutes in all patients who had SSWI was noted. This is in keeping with the literature suggesting that bypass time of longer than one-hour; significant post-operative bleeding; and a low cardiac output state persisting for more than 24-hours post-operatively are risk factors for development of SSWIs. [17, 18]

We identified unusual organisms, not typical of the organisms identified in the review of the literature. Although our patients had some typical organisms, in three cases we isolated *Candida albicans*, *Acinetobacter* and *Proteus* organisms, which are different from the previous studies. All these patients with unusual organisms had DSWI.

Participating in IQIC now provides a formalised method for documenting wound sepsis and pre-operative status of patients, and facilitates more stringent record-keeping of treatment regimens in hopes of gaining new insights and a more accurate reflection of our patients.[26]

The current guidelines for surgical antimicrobial prophylaxis recommends incision time to take place within 60 minutes of administration of the antibiotics. [28] More evidence shows that prophylactic antibiotics administered after skin incision or more than 60 minutes before skin incision reduces the effectiveness of antibiotics.[28] However, these recommendations are not based on randomized trials, systematic reviews and/or meta-analyses.[28]

Overall, there is some evidence suggesting that surgical antimicrobial prophylaxis administration of more than 120 minutes prior to incision increases the risk of SSI compared to administration within 120 minutes. [28] It is not possible to establish the precise optimal timing within the 120-minute interval. [28] No significant difference was found between different time intervals within the 120-minute period, for example, within 120-60 minutes prior to incision versus within the 60-0 minute period prior to incision, or within 60-30 minutes prior to incision versus within 30-0 minutes prior to incision. [29]

The current practice at RCWMCH is administration of cefazolin 30 minutes prior to incision, then every eight hours for the first 24 hours. Our study found a mean time of 81.7 minutes in the SSWI group – longer than the recommended 60-minute minimum. Despite the increased mean time, no association was found between this time period and the development of SSWI. We, therefore, suggest a more stringent application of the timing of the intravenous antibiotics and review of future cases. Our study results show no difference in the total number of theatre treatments received between the two groups.

As discussed, the SWPB for SSIs at RCWMCH was established in September 2014 - midway through the review period of this study – and encountered several challenges. We found no documentation of the SSI Compliance Checklist or pre-operative SOP in 16 of the patients' records retrieved for our study. Of note, this included 12 patients following the implementation of the SWPB. This was attributed to a lack of continuity and availability of staff.

Figure 4 shows the overall weekly assessment of compliance to the SWPB. From January 2016,116 compliance checklists were completed for the year. However, none of this documentation was found in the medical records of the patients identified for this review.

In the initial stages, the SWPB was rolled out as a trial and there was no strict, formal handover procedure for the completed checklist forms thus accounting for the missing documentation.

Study Limitations

Inherent to a retrospective study, limitations include missing data in the medical records, inaccurate information, and the lack of information regarding mortality and morbidity for these patients after discharge. Most information about the process and challenges encountered during the implementation of the SWPB was not readily available. There was no long-term follow-up as the study is limited to 5 years. Of interest would have been an assessment of our post-discharge, recurrence of SWI, and the physical and psychological effects of SWI.

Implications for future research and clinical practice

In conducting this study, we have created a database that can be used for a prospective registry of sternal wound infections in our patient population. This would allow for better documentation of risk factors, outcomes and preventative measures and would allow us to add variables such as ECMO and ASA. The results of this study have reinforced improved quality practices: the use of echo sleeves has been implemented in the theatre, patients with any symptoms of SWI are now being flagged early, and the use of SWPB checklists is instituted immediately post-operatively in ICU.

As this is the first study to review the risk factors and burden of SWI before and since the implementation of the SWPB, it provides the opportunity to evaluate the outcomes of the bundle.

The incidence of SWI in our institution is comparable to the global literature but carries significant morbidity. In addition, DSWI carries a mortality rate of 20%. Our institution strongly supports the quality improvement procedures such as the SWPB implemented in late 2014. However, the rate of SWI implies ongoing monitoring and evaluation of the SWPB is necessary and more stringent adherence to the protocol may result in better outcome.

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FIGURES

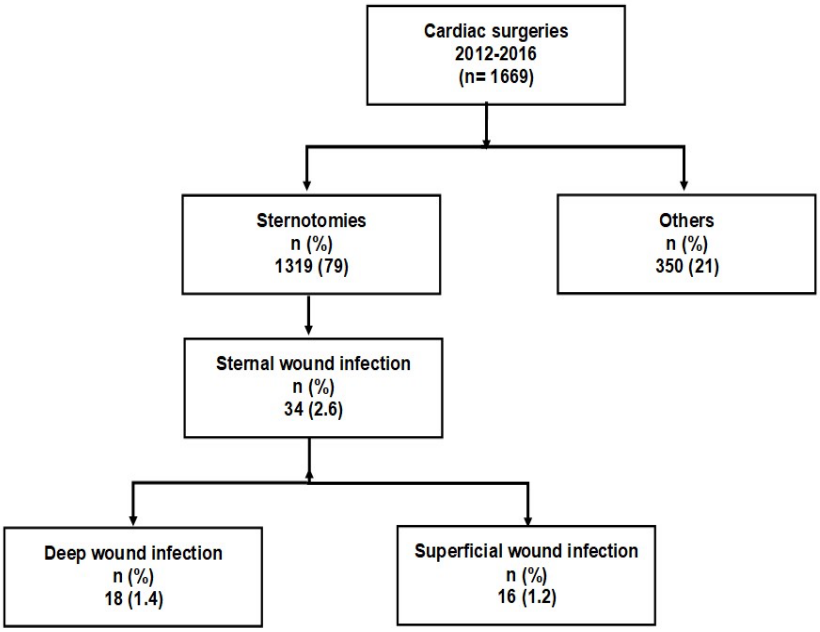

Figure 1: Outline to assess eligibility for enrolment
Others (left posterolateral thoracotomy, right posterolateral thoracotomy, left anterior thoracotomy, right anterior thoracotomy), n = number, % = percent

Standard operational procedure	Date: Time:	Date: Time:
Bed/cot/incubator clean and covered with clean hospital linen.		
Finger and toenails are short and clean. Nail polish removed.		
Hair and scalp washed with Bioscrub, thoroughly rinsed off and dried properly.		
Bioscrub was lathered on skin using a disposable wash cloth.		
Patient was washed in circular movements from face downward.		
Patient is well washed under armpits, behind the ears, between toes and fingers and around the groin area.		
Patient was thoroughly rinsed off in shower, with shower head or in basin with clean water.		
Patient properly dried with a clean hospital towel.		
Patient dressed in clean theatre gown.		
Signature		

FIGURE 2: Pre-op surgical checklist.

Pre-operatively – nursing staff to complete		Intra-operatively – anaesthetist to complete			Pre-operatively – ICU nursing staff to complete		
Ward:	Time and date				Time of second antibiotic dose given?		
Time and date that the patient received the first wash according to the SOP	.....	Antibiotic used	Time given			Ward: ..... Day 1	
Time and date the second wash done according to the SOP	.....	Was the prescrub done?	YES	NO	Did the dressing meet the criteria to be changed?	YES	NO
		Skin was cleaned with chlorhexidine?	YES	NO	Was the dressing changed?	YES	NO
		Was the neck and sternum dry before it was draped?	YES	NO	Highest glucose reading on ABG over last 24 hours?	.....mmol/L	
		Was lobane applied prior to incision?	YES	NO	Can any of the invasive lines be removed?	YES	NO
		Time of incision	.....		Were the lines removed within 4 hours of decision?	YES	NO
		Was an echo done?	YES	NO	Can the urinary catheter be removed?	YES	NO
		What type of echo?			Was urinary catheter removed within 3 hours of decision?	YES	NO
		Was the sternum closed?	YES	NO	Was an echo done?	YES	NO
		If left open, what dressing was applied?			If an echo was done was the echo probe used according the SOP?	YES	NO
		.....			Date and time the drains were removed?	.....	

FIGURE 3: Surgical site infection compliance checklist.

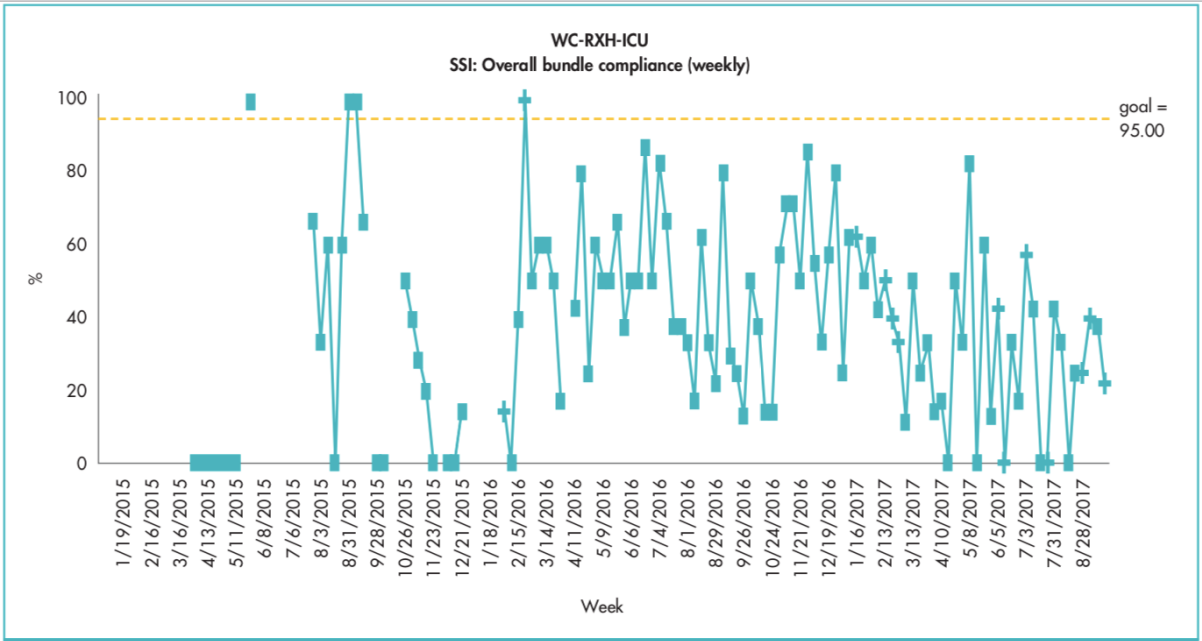

FIGURE 4: Weekly compliance review

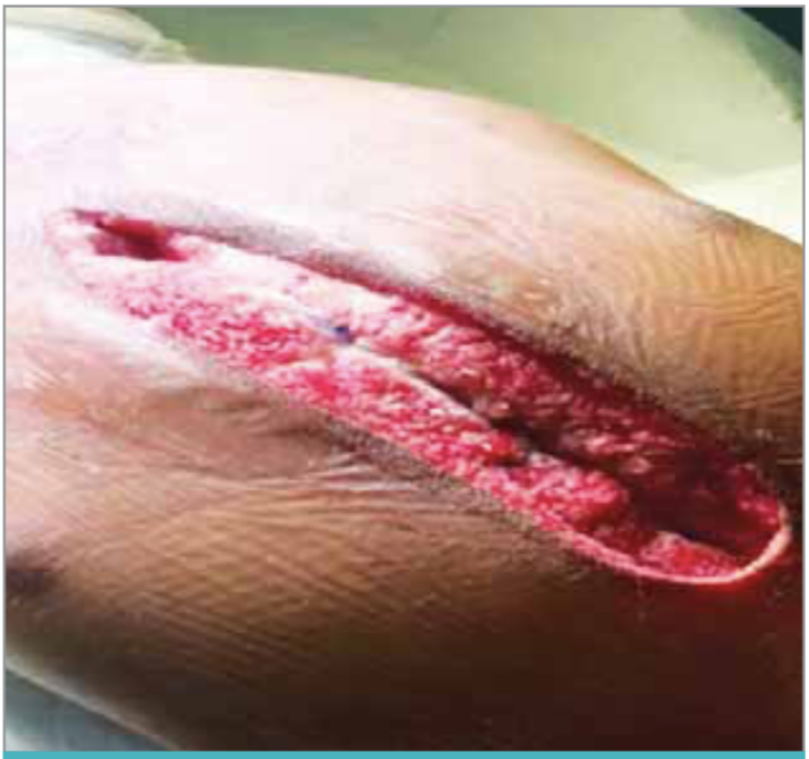

FIGURE 5: Deep sternal wound infection patient post-debridement.

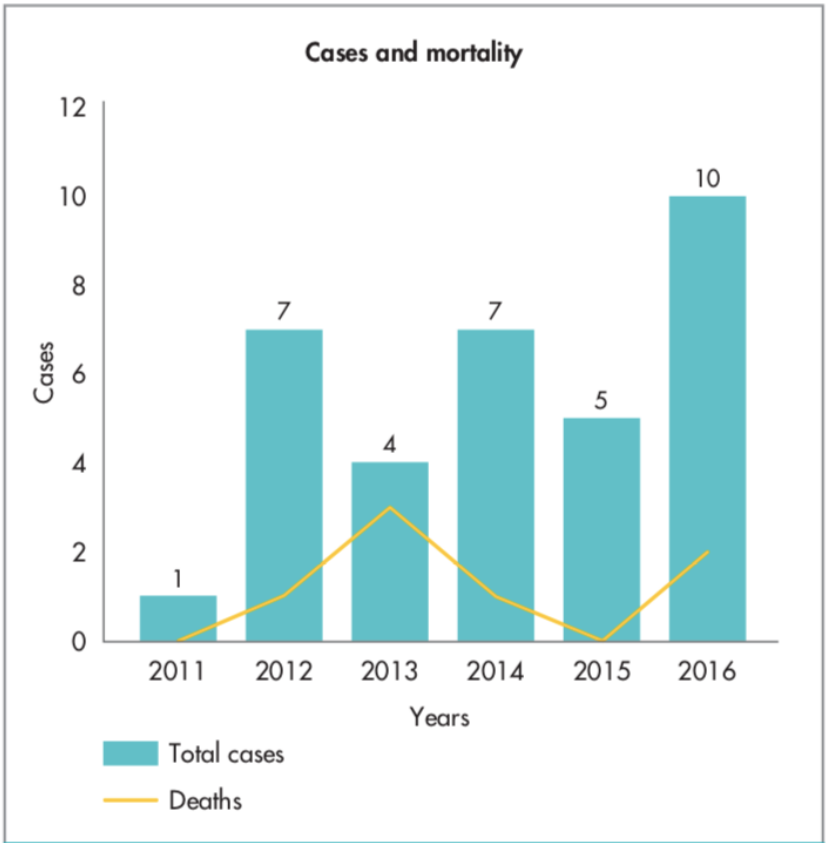

FIGURE 6: Deaths and total cases per year

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TABLES

TABLE I: Patient demographics – 3 folders had missing data.

Characteristic	Total n=34	Deep wound n=18	Superficial n=16	p-value
Age at surgery in months, median (IQR)	2.9 (0.8 - 12.0)	8.4 (0.6 - 22.5)	1.3 (0.8 - 5.5)	0.16
Sex, n (%) Male Female	 18/33 (54.6) 15/33 (45.6)	 8/17 (47.1) 9/17 (52.9)	 10/16 (62.5) 6/16 (37.5)	0.37
Previous surgery, n (%)	4 (15)	2 (11.1)	2 (12.5)	0.90
Type of surgery, n (%) Emergency Elective	 9 (26.5) 25 (73.5)	 4 (22.2) 14 (77.8)	 5 (31.3) 11 (68.8)	0.55
Congenital heart disease, n (%) Cyanotic Acyanotic	 23 (67.7) 11 (32.3)	 13 (72.2) 5 (27.8)	 10 (62.5) 6 (37.5)	0.70
Genetic associations, n (%) 22q microdeletion Trisomy	 1 (2.9) 3 (8.8)	 1 (5.6) 2 (11.1)	 0 1 (6.3)	 0.34 0.62

TABLE II: Surgery variables – 3 folders had missing data.

Characteristic	Total n=34	Deep wound n=18	Superficial n=16	p-value
Type of surgery, n (%) Emergency Elective	 9 (26.5) 25 (73.5)	 4 (22.2) 14 (77.8)	 5 (31.3) 11 (68.8)	0.55
Antibiotic admission to prior incision (mins), mean (±SD)	68.1 (31)	57.1 (22.2)	81.7 (35.5)	0.03
Incision time (mins), median (IQR)	195 (150 - 305)	251 (135 - 325.5)	175 (150 - 285)	0.33
Bypass duration (mins), mean (±SD)	131.4 (73.9)	146.3 (76.7)	109.2 (67.2)	0.23
Cross clamp duration (mins), mean (±SD)	83.2 (49.4)	81.5 (46.5)	85.5 (55.3)	0.84
Ventilation duration (hours), median (IQR)	61.4 (29 - 146)	107.8 (48 - 150.8)	58 (26.3 - 127.9)	0.42
Delayed sternal closure, n (%)	6 (17.7)	4 (22.2)	2 (12.5)	0.46

TABLE III: Sternal wound infection characteristics.

Characteristic	Deep wound n=18	Superficial n=16
Superficial wound features		
Pain and tenderness, n (%)		5 (31.3)
Localised swelling, n (%)		8 (50)
Redness or heat, n (%)		7 (43.8)
Purulent drainage, n (%)		9 (56.3)
Deep wound features		
Spontaneous incisional dehiscence, n (%)	11 (61.1)	
Serosanguineous drainage, n (%)	3 (16.7)	
Purulent drainage, n (%)	14 (77.8)	
Osteomyelitis, n (%)	3 (16.7)	
Mediastinitis, n (%)	3 (16.7)	
Widespread cellulitis, n (%)	3 (16.7)	

TABLE IV: Blood culture isolates.

Characteristic	Total n=34	Deep wound n=18	Superficial n=16	p-value
No of cultures, n(%)				
0	12 (35.3)	5 (27.8)	7 (43.8)	0.30
1	14 (41.2)	10 (55.6)	4 (25.0)	
2	4 (11.8)	1 (5.6)	3 (18.8)	
3	3 (8.8)	1 (5.6)	2 (12.5)	
4	1 (2.9)	1 (5.6)	0	
Culture isolate, n (%)				
Klebsiella	6 (17.6)	4 (22.2)	2 (12.5)	0.46
Pseudomonas	3 (8.8)	2 (11.1)	1 (6.3)	0.62
Staphylococcus	21 (61.7)	8 (44.4)	13 (81.3)	0.03
S. aureus (Coag. Neg)	2 (5.9)	2 (11.1)	0	0.17
Enterococcus	2 (5.9)	1 (5.6)	1 (6.3)	0.93
Antibiotic days, median (IQR)	12.5 (7 - 40)	9 (6 - 35)	17.5 (9 - 42)	0.08

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TABLE V: Morbidity and mortality outcomes.

Characteristic	Total n=34	Deep wound n=18	Superficial n=16	p-value
ICU duration (days), median (IQR)	7.1 (3.6 - 16.1)	8.6 (5.2 - 16.1)	3.9 (2.9 - 17.2)	0.29
Antibiotic days, median (IQR)	12.5 (7 - 40)	9 (6 - 35)	17.5 (9 - 42)	0.08
Number of treatments, median (IQR)	2.0 (1.0 - 4.0)	2.5 (1.0 - 3.0)	2 (1.0 - 4.0)	0.89
Length of hospital stay (days), median IIQR)	28.5 (2 - 42)	29 (22 - 49)	27.5 (16.5 - 41)	0.78
Death, n (%)	7 (20.6)	4 (22.2)	3 (18.8)	0.80

TABLE VI a: Baseline characteristics stratified by mortality - patient demographics by mortality.

Patient demographics				
Characteristic	**Total n=34**	**Dead n=7**	**Alive n=27**	**p-value**
Age at surgery in months, median (IQR)	2.9 (0.8 - 2.0)	3.5 (0.3 - 24.7)	2.4 (0.8 - 12.0)	0.80
Type of surgery, n (%)				
Emergency	9 (26.5)	2 (28.6)	7 (25.9)	1.00
Elective	25 (73.5)	5 (71.4)	20 (74.1)	
Congenital Heart Disease, n (%)				
Cyanotic	23 (67.7)	5 (71.4)	18 (66.7)	0.81
Acyanotic	11 (32.3)	2 (28.6)	9 (33.3)	

TABLE VI b: Baseline characteristics stratified by mortality - surgery variables by mortality.

Surgery variables				
Characteristic	**Total n=34**	**Dead n=7**	**Alive n=27**	**p-value**
Genetic associations, n (%) 22q microdeletion	1 (2.9)	1 (14.3)	0	0.05
Delayed sternal closure, n (%)	6 (17.7)	3 (42.9)	3 (11.1)	0.05
Antibiotic admission to prior incision (mins), mean (±SD)	68.1 (31)	56.6 (24.2)	70.5 (32.1)	0.37
Bypass duration (mins), mean (±SD)	131.4 (73.9)	106 (90.5)	137.8 (70.5)	0.40
Cross clamp duration (mins), mean (±SD)	83.2 (49.4)	46.4 (62.0)	92 (43.1)	0.06
ICU duration (days), median (IQR)	7.1 (3.6 - 16.1)	16.7 (5.9 - 29.2)	5.5 (3.0 - 11.0)	0.05
Ventilation duration (hours), median (IQR)	61.4 (29 - 146)	54.9 (48 - 107.5)	94.2 (26.3 - 162.6)	0.69
Adrenaline, n (%)	29 (85.3)	6 (85.7)	23 (85.2)	0.97
Adrenaline duration (days), median (IQR)	1.8 (1.0 - 2.5)	2.6 (1.8 - 3.1)	1.4 (1.0 - 2.2)	0.04
Length of hospital stay (days), median (IQR)	28.5 (22 - 42)	49 (31 - 356)	25 (19 - 40)	0.03

TABLE VI c: Baseline characteristics stratified by mortality - wound features by mortality.

Deep wound features				
Characteristic	**Total n=34**	**Dead n=7**	**Alive n=27**	**p-value**
Spontaneous incisional dehiscence, n (%)	11 (32.4)	1 (14.3)	10 (37.0)	0.25
Serosanguineous drainage, n (%)	3 (8.8)	1 (14.3)	2 (7.4)	0.57
Purulent drainage, n (%)	14 (41.2)	2 (28.6)	12 (44.4)	0.45
Osteomyelitis, n (%)	3 (8.8)	0	3 (11.1)	0.36
Mediastinitis, n (%)	3 (8.8)	2 (28.6)	1 (3.7)	0.04
Widespread cellulitis, n (%)	3 (8.8)	1 (14.3)	2 (7.4)	0.57
Antibiotic days, median (IQR)	12.5 (7 - 40)	12 (8 - 30)	14 (7 - 42)	0.67
Number of treatments, median (IQR)	2.0 (1.0 - 4.0)	3.0 (1.0 - 4.0)	2 (1.0 - 4.0)	0.98

APPENDICES

REVIEWERS' COMMENTS

Reviewers 1 and 2 :
Accepted the manuscript with the following comments
"The introduction and results are comprehensive but succinct and do not need to be altered."

Reviewer 3:

1. Introduction: Paragraph 5: "Post-operative stays of more than 12 days in a paediatric intensive care unit (PICU) were associated with all types of infection. [17]" This sentence does not make complete sense and perhaps can be rewritten.

2. Please use 'vacuum dressings' rather than "vac dressings"

3. The introduction and results sections can be shortened.

4. Please provide full references for reference 28 and 29.

All the comments were addressed and corrected prior to publishing.

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