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ORIGINAL ARTICLE

Impact of the implementation of an interdisciplinary infection control program to prevent surgical wound infection in pediatric heart surgery

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Abstract Surgical site infection (SSI) remains a major source of morbidity, mortality, and increased health care costs in children undergoing heart surgery. The aim of this study was to assess the effectiveness of an intervention program designed to reduce the high incidence of SSI observed at our center in pediatric patients. An interdisciplinary infection control program including pre-, intra-, and postoperative measures was introduced for children undergoing heart surgery with cardiopulmonary bypass. We conducted a quasi-experimental interventional study comparing a pre-intervention cohort (June 2009 to March 2010) and a post-intervention cohort (July 2011 to July 2012). A significant drop in SSI incidence from 10.9 % (95 % CI 4.7–18.8) to 1.92 % (95 % CI 0.4–5.52) was observed. Variables significantly associated with infection risk were median age (14 days in infected vs 2.3 years in non-infected patients; $p<0.01$), hospitalization unit (10.3 % SSI cumulative incidence in the neonatal intensive care unit vs 0 cases in the pediatric intensive care unit; $p<0.01$), and median preoperative hospital stay (14 days in infected vs 1 day in non-infected patients; $p=0.03$).

Conclusions: The implementation of a new intervention program was associated with an 82 % (95 % CI 34–94) reduction in SSI incidence in children undergoing heart surgery at our center.

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What is known:

• *Surgical site infection (SSI) is associated with significant morbidity and mortality following pediatric cardiac surgery.*
• *Younger patients and longer cardiopulmonary bypass times are associated with higher SSI rates.*

What is New:

• *Comprehensive infection control program including preoperative, intraoperative and postoperative nonpharmacologic measures is a key factor for the prevention of SSI.*
• *A significant reduction in SSI rates can be achieve despite a narrower-spectrum antibiotic usage.*

Keywords Surgical site infection · Heart surgery · Prophylaxis · Congenital heart defects

Introduction

Surgical site infection (SSI) is associated with significant morbidity and mortality following pediatric heart surgery [7, 11, 17, 19, 21, 24]. Infection rates range from 0.5 to 7 % [1, 2, 7, 10, 11, 17, 19, 21, 24]. Several risk factors have been proposed, including age under 1 month, surgery duration, prolonged extracorporeal circulation time, delayed sternal closure, profuse postoperative bleeding, and persistent low cardiac output [7, 14, 17, 21, 22, 24]. Microorganisms causing SSI are predominantly Gram-positive, mainly skin colonizers such as *Staphylococcus aureus* and *Staphylococcus epidermidis*, while Gram-negative bacilli and fungi are less frequently involved [7, 10, 11, 17, 21].

Although international consensus guidelines for the prevention of SSI in pediatric heart surgery have been published [3, 20, 23], the range of antibiotic regimens used and their duration vary widely [1, 4, 6, 12, 18]. Moreover, no conclusive data exist regarding the appropriate antibiotic usage and duration in specific situations such as delayed sternal closure in children.

At our center, the hospital-acquired infection surveillance program includes periodic monitoring of surgical infections. Between June 2009 and March 2010, a SSI cumulative incidence over 10 % was observed in pediatric heart surgery. An intervention program based on existing recommendations and available scientific evidence was introduced in order to prevent further cases and to optimize non-pharmacologic strategies and the use of antibiotic prophylaxis.

The purpose of this study was to analyze the results obtained following the implementation of the program, and to describe the risks factors for SSI.

Patients and methods

A quasi-experimental study was conducted to analyze the impact of a comprehensive infection control program to reduce the incidence of SSI in children undergoing pediatric heart surgery. A pre-intervention cohort (June 2009 to March 2010) was analyzed retrospectively and compared with a post-intervention cohort conducted prospectively (July 2011 to July 2012).

The surveillance program for nosocomial infections is an integral part of the health care quality program at our center and waives individual informed consent for the practice of surveillance, prevention, and control activities. The study was reviewed and approved by the institutional review board.

Study population and inclusion criteria

At our center, the postoperative care of children after heart surgery is undertaken in two structurally distinct units: a 45-bed neonatal intensive care unit (NICU) for infants under 1 month of age on admission, and a 16-bed pediatric intensive care unit (PICU) for patients from 1 month to 16 years of age.

All pediatric patients undergoing heart surgery with cardiopulmonary bypass via median sternotomy during both study periods were included. Patients who died during surgery or within 24 h from non-infectious causes and those requiring postoperative mechanical circulatory support or heart transplantation were excluded. Patients undergoing more than one surgery during admission were also excluded from the analysis. Patients were closely monitored for SSI during admission and up to 90-days post-surgery.

Comprehensive infection control program

The infection control team alerted clinicians to the high SSI rates in pediatric heart surgery at our center. Consequently, staff from different medical departments, including cardiac surgeons, pediatric cardiologists, neonatologists, pediatric intensivists, pediatric infectologists, epidemiologists, and infection-control nurses met to draw up a comprehensive infection control program to include preoperative, intraoperative, and postoperative non-pharmacologic measures along with appropriate antibiotic prophylaxis based on institutional epidemiological data (Table 1).

Prior to the implementation of this new intervention program, no consensus regarding antibiotic prophylaxis or institutional guidelines for prevention of SSI in pediatric patients existed at our center. Furthermore, the antibiotic prophylaxis policies differed from the NICU to the PICU for patients with delayed chest closure. The most common antibiotic regimens were (1) cefazolin initiated intraoperatively and for 24 h in patients undergoing chest closure immediately after heart surgery, and (2) vancomycin and piperacillin/tazobactam in PICU and cefazolin in NICU in patients with delayed chest closure, with no homogeneous duration.

Table 1 Summary of measures covered by the intervention program

1. Non-pharmacologic measures
   Preoperative
   - Bathing or showering with 4 % chlorhexidine soap 2 h prior to surgery
   - Change clothing and bed sheets after bathing
   - If hair has to be removed, use electric clippers with a single-use head on the day of surgery

   Intraoperative
   - Operating room used exclusively for clean surgery
   - Daily review of the operating room air-conditioning
   - Ensure doors are closed throughout surgery
   - Antiseptic skin preparation with 2 % alcoholic chlorhexidine solution
   - Change of surgical gloves after sternotomy and before skin suturing
   - Checklist for compliance of the above measures

   Postoperative
   - Keep first dressing of the wound in place for at least the first 48 h
   - If transthoracic echocardiography is required, use aseptic technique with sterile ultrasound probe cover kits
2. Antibiotic prophylaxis[a]
   Surgery with sternal closure in the operating room
   - Cefazolin[b] iv 25 mg/kg every 6 h for 24 h[c]

   Surgery with delayed sternal closure
   - Cefazolin[b] iv 25 mg/kg every 6 h+aztreonam[d] iv 50 mg/kg every 8 h until 24 h after sternal closure

[a] First dose of prophylactic antibiotic to be administered in the hour prior to surgical incision. In patients with antibiotics before surgery, the same antibiotic regimen will be applied throughout the postoperative period, always covering Gram-positive cocci and Gram-negative bacilli

[b] Patients with beta-lactam allergy or colonization with methicillin-resistant *Staphylococcus aureus*, vancomycin iv 10 mg/kg every 8 h replaces cefazolin. Should renal failure occur, the antibiotic dose will be adjusted according to the estimated glomerular filtration rate [16]

[c] In surgeries lasting more than 3 h, a repeat dose of the antibiotic should be administered for every 500 ml of cardiopulmonary bypass perfusion

[d] Aztreonam was added because of several infections by Gram-negative bacilli (some of them resistant to conventional aminoglycosides) in surgery with delayed sternal closure in the pre-intervention study, particularly in neonates, and because of its low nephrotoxicity [16]

Study variables

The following data were collected: (1) patient characteristics (gender, age, type of heart disease, number of previous surgeries, presence of associated extracardiac anomalies), (2) surgery characteristics (Aristotle's complexity score [13], surgery duration, extracorporeal circulation duration, timing of sternal closure), (3) perioperative variables (postsurgical unit [PICU or NICU], antibiotic use prior to surgery, type of antibiotic prophylaxis used, duration of pleuromediastinal drainage, open chest duration, length of PICU, NICU, and hospital stay), (4) infection-related variables (superficial or deep infection and isolated microorganisms), and (5) protocol compliance (using a checklist of measures described in Table 1).

Definition of surgical site infection

Superficial SSI was defined, according to the National Healthcare Safety Network definitions [5], as the presence of clinical signs or symptoms of infection (purulent drainage from the superficial incision; and/or organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision; and/or diagnosis of a superficial incisional SSI by the surgeon or attending physician) that involves only skin and subcutaneous tissue of the incision. Deep incisional SSI was defined as the presence of clinical signs or symptoms of infection (purulent drainage from the deep incision; and/or a deep incision that spontaneously dehisces or is deliberately opened by a surgeon; and/or an abscess or other evidence of infection involving the deep incision that is detected on direct examination, during invasive procedure or by histopathologic examination or imaging test) that involves deep soft tissues of the incision. There was a RN that ascertained the diagnosis of SSI in both periods.

Statistics

The cumulative incidence of SSI with its corresponding 95 % confidence interval (95 % CI) was calculated as the proportion of patients within the whole operated cohort who developed SSI. Results were compared with those obtained in the pre-intervention period. Comparability of both cohorts (pre- and post-intervention) was assessed by the appropriate statistical tests.

A descriptive analysis was made using proportions for categorical variables and median and range for quantitative variables. Data from infected and non-infected patients were compared. Pearson's chi-square test or Fisher's exact test were used to analyze the association between categorical variables and the presence of SSI. Non-parametric Mann–Whitney U test was applied to analyze the association between continuous variables and the presence of SSI. A p value <0.05 was considered statistically significant. The SPSS 15.0 statistical software (SPSS Inc., Chicago, Illinois, US) was used for statistical analyses. Infection rates pre- and post-implementation of the intervention program were compared using Fisher's two-tailed exact test with the WINPEPI program (version 1.31 © J.H. Abramson).

Results

Pre-intervention cohort

During this 10-month period (June 2009–March 2010), 64 patients were included. Characteristics of the pre-intervention cohort are shown in Table 2. SSI developed in

Table 2 Patient's characteristics during pre- and post-intervention periods

Variable	2009–2010	2011–2012	*p*
Number of patients	64	156	
Age (days)	268 (2–6057)	784 (0–5533)	0.41
Aristotle score	7 (3–11)	7 (3–14.5)	0.77
Cardiopulmonary bypass time (minutes)	125 (40–730)	113 (25–478)	<0.01
Duration of surgery (minutes)	340 (118–1260)	335 (85–985)	0.8
Gender			
Male	28 (43.8)	92 (59.0)	0.05
Female	36 (56.2)	64 (41.0)	
Hospitalization unit			
PICU	45 (70.3)	127 (81.4)	0.07
NICU	19 (29.7)	29 (18.6)	
Compliance of the protocol		156 (100)	

Quantitative (median; range), categorical (*N*; %)

seven patients (three deep and four superficial sternal site infections) (Table 3). The SSI cumulative incidence was 10.9 % (95 % CI 4.7–18.8) (2.1 % in PICU and 33.3 % in NICU). No SSI-associated deaths occurred during this period.

Post-intervention cohort

One hundred fifty-six patients were included from June 2011 to June 2012 following implementation of the new intervention program, with 100 % rate of compliance. Characteristics of the cohort are presented in Table 2. SSI developed in three patients (one deep and two superficial sternal site infections) (Table 3). The SSI cumulative incidence was 1.92 % (95 % CI 0.4–5.52). No SSI-associated deaths occurred during this period.

Patients from pre- and post-intervention cohorts were similar in clinical and demographic variables, except for sex distribution and cardiopulmonary bypass time (125 vs 113 min, respectively; $p<0.01$) (Table 2).

An 82 % (95 % CI 34–95) reduction in SSI cumulative incidence was observed. All reported SWI infections in the post-intervention period occurred in the NICU.

Risk factor analysis

Risk factor analysis is shown in Table 4. Children who developed SSI were younger [14 days (5–14) vs 2.3 years (0–15) ($p<0.01$)], had longer preoperative hospital stay [14 days (5–14) vs 1 (0–351) (p:0.03)], and all were in the NICU (Table 4). Length of hospital and postoperative intensive care unit stays was significantly longer for SSI cases [55 days (25–69) vs 13 (2–375) (p:0.07)] and [20 days (1–43) vs 4 (1–61) (p:0.07)], respectively. Since all infected patients were neonates and patient age determines the type of intensive care unit and overall

Table 3 Description of patients with surgical site infection

Period	Case	Age	Gender	Unit	Diagnosis	Infection type	Delayed sternal closure	Microorganism isolated
2009–2010	1	9 days	Male	NICU	TGA	Deep	Yes	*Enterococcus faecalis* *Staphylococcus epidermidis*
	2	4 days	Female	NICU	TGA	Superficial	No	Negative culture
	3	9 days	Male	NICU	TGA	Superficial	Yes	*Enterococcus faecium*
	4	2 months	Female	NICU	VSD	Superficial	No	Negative culture
	5	6 days	Male	NICU	TGA	Superficial	No	*Staphylococcus epidermidis*
	6	2 months	Female	PICU	VSD	Deep	No	*Staphylococcus aureus* sensitive to methicillin *Klebsiella oxytoca*
	7	2 months	Female	NICU	TGA	Deep	Yes	*Escherichia coli*
2011–2012	1	14 days	Female	NICU	Hypoplastic aortic arch with VSD	Superficial	No	Gram stain: Gram-positive cocci Negative culture
	2	14 days	Male	NICU	Pulmonary atresia with VSD	Deep	No	*Staphylococcus aureus* sensitive to methicillin
	3	5 days	Male	NICU	TGA	Superficial	Yes	*Staphylococcus epidermidis*

Table 4 Characteristics of patients included in the study. Analysis of risk factors associated with surgical site infection

Variable	All	Infected	Non-infected	*p*
Number of patients	220	10	210	
Age	25.5 months (0–181)	7.5 days (0–105)	27 months (0–181)	0.014
Aristotle score	7 (3–14.5)	10 (6–11)	7 (3–14.5)	0.015
Cardiopulmonary bypass time (minutes)	118 (25–730)	193 (104–730)	115 (25–478)	0.016
Duration of surgery (minutes)	337 (85–1260)	270 (170–1260)	340 (85–985)	0.691
Preoperative stay (days)	1 (0–351)	11 (2–62)	1 (0–351)	<0.0001
Gender (*N*, %)				
Male	120 (54.5)	5 (4.2)	115 (95.8)	0.77
Female	100 (45.5)	5 (5)	95 (95)	
Hospitalization unit (*N*, %)				
PICU	172 (78.2)	1 (0.6)	171 (99.4)	<0.0001
NICU	48 (21.8)	9 (18.8)	39 (81.2)	
Delayed sternal closure				
Yes	35 (16.4)	4 (11.4)	31 (88.6)	0.062
No	178 (83.6)	6 (3.4)	172 (96.6)	
Time with chest tubes (days)	2 (1–29)	3 (2–8)	2 (1–29)	0.47

Quantitative (median; range), categorical (*N*; %)

length of hospital stay, these two variables were analyzed separately in the neonatal group. No significant differences were observed between infected and non-infected patients.

Discussion

The incidence of SSI in children and neonates undergoing heart surgery at our center prior to implementation of the intervention program was higher than that reported in the literature [1, 2, 7, 10, 11, 17, 19, 21, 24]. Studies on this issue in pediatric patients are scant. Nateghian et al. [17] reported an SSI cumulative incidence of 3.4 %, lower than the 7.5 % described by Pollock et al. [19] and the 5 % by Mehta et al. [15]. More recently, lower incidences have been reported in the literature (0.0–1.8 %) [9, 11, 25]. After implementation of our interdisciplinary infection control program, an 82 % reduction was achieved in the SSI cumulative incidence. Costello et al. [6] reported a drop from 3 to 2 % in the incidence of SSI with an intervention program which, as in our case, involved a multidisciplinary effort with special emphasis on maintaining surgical site asepsis before, during, and after surgery. This aspect is important since the majority of publications focus on which prophylactic antibiotic regimen should be prescribed and tend to obviate non-pharmacologic preventive measures [1, 7, 10, 11, 17, 19, 21, 24].

Regarding antibiotic prophylaxis, while some centers use monotherapy with cefazolin in surgery with delayed sternal closure [1], we decided to add aztreonam owing to the presence of Gram-negative bacilli causing SSI in neonates during the pre-intervention period. No microorganism resistant to the antibiotic prophylaxis used was isolated in any of the three patients who developed SSI in the post-intervention cohort. Medical treatment was started at the first signs of infection in all three cases and only one patient required surgical debridement. The evolution of all three patients was satisfactory.

A national survey conducted by our group and including practices from 15 Spanish hospitals performing pediatric and neonatal heart surgery revealed significant variability in antibiotic prophylaxis use [12]. In surgery with sternal closure in the operating room, all pediatric centers surveyed used a first- or second-generation cephalosporin for 12 to 72 h, while five different antibiotic prophylaxis regimens were used in neonates. Eight of the 13 hospitals performing delayed sternal closure in high-risk patients maintained the same antibiotic regimen as in surgery with non-delayed sternal closure. The five remaining centers used two antibiotics or one with a broader spectrum: vancomycin at two centers and gentamycin, vancomycin-gentamycin, and cefazolin-aztreonam in the rest.

With respect to the duration of antibiotic prophylaxis, the majority of centers advocate maintaining the prophylaxis until pleuromediastinal drains have been withdrawn [1]. Nevertheless, the Working Group of the American Society of Thoracic Surgeons indicate that there is no scientific evidence, in adult heart surgery, that maintaining antibiotic prophylaxis until chest drains are removed reduces the risk of infectious complications [8]. In the present study, drainage duration was not associated with a greater risk of SSI.

In accordance with the literature, all children in our series who developed SSI were neonates and all were hospitalized in the NICU. It is postulated that neonates are at a higher risk owing to their immature immune system [6]; therefore, differences observed between SSI percentages in the PICU and NICU in our study may have been age-related. The small sample size of neonates included in the study does not permit deeper analyses of the influence of age and other variables. Nevertheless, these differences might also be related to the intrinsic differences between units in terms of structure and personnel. All these factors require more analyses to further reduce the SSI incidence at our institution.

Tabbutt et al. [24] and Maher et al. [14] associated delayed sternal closure with a greater risk of SSI. In our study, no significant differences were detected in SSI frequency between groups, although the sample size of our work was smaller.

It should be pointed out that the two cohorts differed in number (64 pre-intervention vs 156 post-intervention). This difference may be due mainly to a shorter study period and more stringent restriction of the number of elective surgeries following an institutional cost-saving policy during the summer months in the pre-intervention period. Nevertheless, the baseline characteristics of the two cohorts were similar except for a shorter duration of cardiopulmonary bypass time in the post-intervention period, and for a greater number of neonatal patients in the pre-intervention cohort in comparison with the post-intervention cohort (29.7 vs 18.6 %).

Some limitations related to the design of the study must be taken into account. Retrospective data collection in the pre-intervention cohort may generate information bias. However, we believe that if it exists, it does not affect the main variables under study since they were well recorded in the electronic medical records of the patients and in their corresponding surgical records. On the other hand, the design of the study was not aimed at evaluating risk factors of SSI. This could explain, in addition to possible insufficient sample size, the difficulty in detecting significant associations. However, the calculated statistical power was 77 %, which is close to the 80–90 % usually required in medical research. The low number of SSI detected in the post-intervention cohort impeded the construction of multivariate models for the analysis of risk factors for infection. Another limitation is that this is a single institutional study.

In summary, the implementation of a comprehensive intervention program at our center contributed to reducing SSI incidence in pediatric heart surgery. As neonates have the highest risk, specific prophylactic strategies should be devised for this age group. Continuous surveillance and interdisciplinary work will be paramount to control SSI incidence in the neonatal age group.

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Authors Contribution **Jaume Izquierdo-Blasco:** Study conception and design, Acquisition of data, Analysis and interpretation of data and Drafting of manuscript; **Pere Soler-Palacín** and **Joan Sanchez-de-Toledo:** Study conception and design, Analysis and interpretation of data, Drafting of manuscript and Critical revision of the manuscript; **Magda Campins-Martí:** Study conception and design, Analysis and interpretation of data, Statistical analysis and Critical revision of the manuscript; **Raúl Abella, Ferran Gran, Joan Balcells, Rosario Nuño** and **Felix Castillo:** Revision of the manuscript

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