Published in final edited form as:

Ann Thorac Surg. 2014 September ; 98(3): 927–933. doi:10.1016/j.athoracsur.2014.04.090.

Implementing a standardized perioperative antibiotic prophylaxis protocol for neonates undergoing cardiac surgery

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Abstract

Background—A lack of perioperative antibiotic prophylaxis guidelines for neonates undergoing cardiac surgery has resulted in a wide variation in practice. We sought to: **1)** determine the safety of a perioperative antibiotic prophylaxis protocol for neonatal cardiac surgery as measured by surgical site infections (SSIs) rates before and after implementation of the protocol and **2)** evaluate compliance with selected process measures for perioperative antibiotic prophylaxis.

Methods—This quasi-experimental study included all cardiac procedures performed on neonates from July 2009 to June 2012 at a single center. An interdisciplinary task force developed a standardized perioperative antibiotic prophylaxis protocol in the fourth quarter of 2010. SSI rates were compared in the pre-intervention (July 2009 to December 2010) versus the post-intervention periods (January 2011 to June 2012). Compliance with process measures (appropriate drug, dose, timing, and discontinuation of perioperative antibiotic prophylaxis) was compared in the two periods.

Results—During the study period, 283 cardiac procedures were performed. SSI rates were similar in the pre- and post-intervention periods (6.21 vs. 5.80 per 100 procedures respectively). Compliance with the four process measures significantly improved post-intervention.

Conclusions—Restricting the duration of perioperative antibiotic prophylaxis after neonatal cardiac surgery to 48 hours in neonates with a closed sternum and to 24 hours after sternal closure was safe and did not increase the rate of SSIs. Compliance with selected process measures

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improved in the post-intervention period. Additional multicenter studies are needed to develop national guidelines for perioperative prophylaxis for this population.

Keywords

Antibiotics; antifungals; antiviral agents; Perioperative care; Neonate; Wound infection

Introduction

Surgical site infections (SSIs) are a serious health complication after operative procedures and are associated with increased mortality and healthcare costs [1]. SSI rates after pediatric cardiac surgery range from 2.3 to 9.9% [2–7]. Thus, prevention of SSIs is a quality improvement metric for healthcare organizations, state and federal regulatory bodies [8–14]. The Joint Commission has made the reduction of SSIs and implementation of evidence-based practices for prevention of SSIs, including appropriate use of perioperative prophylaxis, a national patient safety goal for 2013 [8]. Several national organizations including the Society of Thoracic Surgeons (STS), the Centers for Disease Control and Prevention (CDC), American Society of Health-System Pharmacists (ASHP), the Surgical Infection Society (SIS), the Infectious Diseases Society of America (IDSA) and the Society for Health Care Epidemiology of America (SHEA) have developed guidelines for perioperative antibiotic prophylaxis after cardiac surgery [9–14].

However, current guidelines are largely restricted to adult populations as few studies describe the efficacy of perioperative antibiotic prophylaxis for children [11]. Thus, pediatric recommendations are largely based on expert opinion and from data extrapolated from adult patients [11]. As a result, there is wide variation in practice across pediatric cardiac centers; several different prophylactic antibiotic regimens are followed and for varying durations [15–21]. Despite lack of evidence of clinical benefit, extended antibiotic prophylaxis until removal of thoracotomy tubes or invasive lines remain common practices in pediatric populations [3,15–21].

The Surgical Infection Prevention Project (SIP) was introduced in 2002 as a quality improvement initiative to promote optimal use of perioperative antibiotic prophylaxis [10]. The SIP adopted three process of care measures to reduce SSIs: selection of appropriate antibiotic consistent with published guidelines, administration of parenteral antimicrobial prophylaxis within 60 minutes prior to skin incision and discontinuation of antimicrobial prophylaxis within 24 hours of surgery and within 48 hours for cardiac surgery to reduce SSI. These evidence-based recommendations have been incorporated into the broader Surgical Care Improvement Project (SCIP), and adopted by the Joint Commission and other national quality improvement forums [10].

To date, evidence-based recommendations are unavailable for perioperative antibiotic prophylaxis for neonates who undergo cardiac surgery. We hypothesized that limiting prophylaxis to 48 hours as recommended for adult cardiac surgical patients would be safe in neonates. We present a protocol, developed at our institution by an interdisciplinary task force, for perioperative antibiotic prophylaxis for neonatal cardiac surgery. A quasi-experimental study of all neonates who underwent cardiac surgery was conducted with the

following objectives: **1)** determine the safety of a perioperative antibiotic prophylaxis protocol for neonatal cardiac surgery as measured by SSI rates before and after implementation of the protocol and **2)** evaluate compliance with selected process measures for perioperative antibiotic prophylaxis.

Material and Methods

Study design, site, and subjects

We performed a quasi-experimental study of neonates who underwent cardiac surgery from July 1, 2009 to June 30, 2012 at our tertiary care academic center in New York City. Some subjects were previously included in a study of risk factors for SSIs [22]. SSIs were compared in the pre-intervention (July 1, 2009 to December 31, 2010) and post-intervention periods (January 1, 2011 to June 30, 2012). Included subjects were neonates $\geq$ 30 days of age who underwent cardiac surgery and received pre- and postoperative care in the cardiac section of the neonatal intensive care unit (NICU). Excluded neonates were premature (<37 completed weeks of gestation) infants who underwent ligation of the ductus arteriosus only, in whom insertion of a permanent pacemaker was the only procedure performed (as the perioperative prophylaxis regimen is different), and who died within 24 hours after surgery. The institutional review board for Columbia University Medical Center approved this study with a waiver of informed consent.

Perioperative Antimicrobial Prophylaxis Regimen

In the fourth quarter of 2010, after reviewing existing evidence, an interdisciplinary task force developed a consensus-based protocol for perioperative antibiotic prophylaxis for neonatal cardiac surgery. The task force included representatives from Pediatric Cardiothoracic surgery, Pediatric Cardiology, Neonatology, Pediatric Infectious Disease, Infection Prevention and Control, and Anesthesiology. The perioperative prophylaxis recommendations included the use of the appropriate antimicrobial agent, dose, timing of preoperative dose, intraoperative re-dosing (if relevant), and discontinuation (Table 1). After receiving institutional approval, the protocol was implemented on January 1, 2011. During the implementation period, the task force met quarterly and SSI rates and compliance with the prophylaxis recommendations data were shared.

During the pre-intervention period, the perioperative antimicrobial prophylaxis regimen was similar to that followed during the post-intervention period with three exceptions. **1)** For neonates who underwent lateral thoracotomy or median sternotomy whose sternal wound was closed in the operating room, cefazolin was continued until all chest tubes were removed. **2)** For neonates whose sternal wound was left open, vancomycin and gentamicin were provided until sternal closure after which cefazolin was provided until all chest tubes were removed. **3)** Prescriber audit and feedback of perioperative prophylaxis parameters were not performed.

Process of care measures

The interdisciplinary task force adopted four process of care measures to assess compliance with the standardized protocol in the areas of correct drug, dose, timing and discontinuation:

Correct Drug: As per protocol (Table 1).

Correct Dose for Cefazolin or Vancomycin: $\pm 10\%$ of recommended dose (Table 1).

Correct timing:

Preoperative- As per protocol (Table 1).

Intraoperative re-dosing- Cefazolin re-dosing should be initiated 4 hours $\pm$ 30 minutes from previous dose or 8 hours $\pm$ 30 minutes from previous dose if vancomycin is used.

Postoperative: As per protocol (Table 1).

Correct discontinuation: As per protocol (Table 1).

Case definitions

The task force performed active surveillance for SSIs pre- and post-intervention. The Center for Disease Control and Prevention National Healthcare Surveillance Network (NHSN) definition for SSI was used [23]. Patients were followed for SSI for 90 days after the surgical procedure. The Pediatric Infection Prevention and Control, NICU, and cardiothoracic surgery teams detected potential SSIs. A member of the cardiac surgical team adjudicated cases (RC). If a patient had more than one surgical procedure, the SSI was attributed to the most recent procedure unless the procedure was performed secondary to infection, e.g., debridement.

Data Collection

The following data were collected from each patient's electronic medical record (EMR) by a single investigator (MM): age at time of initial surgery, sex, weight, gestational age, Risk Adjustment in Congenital Heart Surgery (RACHS-1) category, compliance with the four process measures for appropriate perioperative antibiotic prophylaxis, and SSI microbiology results, when available. The RACHS-1 groups cardiac surgical procedures with similar operative mortality rates into 6 categories with group 1 procedures carrying the lowest risk and group 6 procedures, the highest risk of mortality [24].

Statistical Methods

Descriptive analyses were completed to determine the incidence of SSI and compliance with the perioperative antibiotic prophylaxis guidelines. To ensure the comparability of the patient population in the pre- and post-intervention periods, characteristics of included neonates undergoing surgery during these two time periods were compared. For continuous and categorical characteristics, t-test and Chi square tests were used to test for statistical significance, respectively. The proportions of appropriate perioperative antibiotic prophylaxis and the rate of SSI before and after protocol implementation were compared using Chi square test. Differences were considered significant for p-value ≤ 0.05 . Statistical analyses were conducted using SAS (9.2 for Windows, SAS Institute, Inc., Cary, NC).

Results

During the study period, 305 neonates underwent 317 cardiac surgical procedures of which 34 were excluded (Figure 1). In the final analysis, 283 procedures were included: 145 pre-intervention and 138 post-intervention. Overall, the study population was similar during the pre- and post-intervention periods (Table 2). However, significantly more complex surgeries were performed during the post-intervention period ($p=0.02$).

Incidence of SSI during pre- and post- intervention periods

During the study period, 17 SSIs (6.00 SSI per 100 procedures) were diagnosed; 14 were superficial and 3 were deep incisional SSIs. The rate of SSI was similar in the pre- and post-intervention periods (6.21 vs. 5.80 per 100 procedures, respectively, $p=0.88$). The median number of days to SSI was 20.0 (range 4–49 days) and did not differ significantly between the pre- and post-intervention periods ($p = 0.53$).

Pathogens causing SSI

Methicillin-susceptible *Staphylococcus aureus* (MSSA) was the most common pathogen during both study periods. MSSA caused 67% of SSI in the pre-intervention period and 38% of SSI during the post-intervention period ($p=0.35$).

Compliance with perioperative antibiotic prophylaxis process measures

The most common deficiencies noted during the pre-intervention period were (Table 3): **1)** 20% of patients did not receive antibiotics within 60 minutes of skin incision, **2)** 84% of patients had inadequate postoperative dosing, and **3)** 27% of eligible patients did not receive intraoperative re-dosing. As the duration of antibiotic prophylaxis was governed by the presence of chest tubes in the pre-intervention period, as expected, only 38% of subjects had antibiotics discontinued within 48 hours of surgery or within 24 hours of chest closure.

During the postoperative period, compliance with the 4 process of care indicators significantly improved and generally exceeded 90% (Table 3). However, postoperative drug dosing remained suboptimal; only 65% of subjects received the recommended dose and under-dosing of cefazolin was the most common deficiency (range 5–26 mg/kg). Compliance with appropriate antibiotic prophylaxis was similar among subjects with and without SSIs (Table 4).

Comment

To our knowledge, this is the first study to investigate the impact of a standardized perioperative antibiotic prophylaxis protocol for neonatal cardiac surgery. We focused on neonates because they are at greater risk for SSIs than older children and adults [2,4,7]. Furthermore, no recommendations exist for perioperative antibiotic prophylaxis after neonatal cardiac surgery. The ASHP Report offers recommendations for cardiac surgical antibiotic prophylaxis for adults and children older than 1 year of age, but do not include neonates and younger infants [11].

We confirmed our hypothesis that adult guidelines were safe to use in neonates. Limiting the duration of perioperative antibiotic prophylaxis to 48 hours in neonates with a closed sternum did not increase SSI rates in our study. The 6% rate of SSI in our study population is within the range reported in other studies; however, those studies also included older children [2–7]. Our results are similar to studies of adult and pediatric cardiac surgical patients wherein no incremental benefit was noted for extending prophylaxis beyond 48 hours or until chest tubes or invasive catheters and vascular lines were removed [18,25]. However, our findings differed from those reported by Maher wherein limiting prophylaxis to 48 hours increased the rate of SSI in pediatric cardiac surgical patients compared to when guided by the presence of thoracotomy tubes and vascular catheters [20].

Recommendations for perioperative prophylaxis have been proposed by several national organizations, including the STS, and all discourage the extended use of antibiotic prophylaxis [11–13]. Prolonged antibiotic administration carries the hazard of promoting growth of resistant bacterial strains or yeast and/or developing *Clostridium difficile* colitis or other toxicities without substantially decreasing infectious risk [11,13,18,25]. However, surveys of practice have revealed that prolonged antibiotic prophylaxis is common practice in pediatric cardiac surgery; 40% of surgeons continued antibiotic prophylaxis beyond 24–48 hours after surgery and 30% of centers continued prophylaxis until chest tube removal [15–17]. We speculate several reasons why caregivers are reluctant to limit perioperative antibiotic prophylaxis duration. Most neonatal cardiac surgeries are performed on cardiopulmonary bypass, which has detrimental effects on cellular and humoral response [26]. Furthermore, the mortality rate is greatly increased in patients who develop organ space SSIs [27]. Invasive devices do increase the risk of healthcare-associated infections but there is no evidence that perioperative prophylaxis reduces this risk.

No guidelines exist for antibiotic prophylaxis for patients who have an open sternum postoperatively. Hence, different antibiotic regimens are used and often for extended durations [15–20]. Our study did not find a difference in SSI rates in neonates in the pre- and post intervention periods.

To date, most studies in children have focused on the duration of antibiotic prophylaxis after cardiac surgery, rather than the selection, timing and dosing of prophylaxis. We chose to expand the process measures because adherence to appropriate timing and agent has reduced SSIs in adult populations [28–30]. During the pre-intervention period only 80% of neonates who underwent surgery received antibiotic prophylaxis within 60 minutes of skin incision. Furthermore, about 25% of neonates who were candidates for re-dosing did not receive an additional dose of antibiotics in the operating room. We also found that despite quarterly audits and feedback to key stakeholders including the cardiothoracic surgical team, neonatal cardiac care team, and anesthesiologists, postoperative dosing of cefazolin remained suboptimal in the post-intervention period, as infants were frequently under-dosed. We speculate that a default dosing recommendation in our electronic medical record or the use of an incorrect weight for dose calculations by providers likely contributed to suboptimal dosing.

Several methods including hospital collaboratives, electronic medical records, and order sets have been employed to improve SIP performance measures in adult surgical patients [29,30]. Our study confirms the importance of antibiotic stewardship programs and dedicated interdisciplinary task forces in improving adherence to these process measures. Periodic audits, feedback and education to prescribers and key stakeholders significantly improved the selection, dosing and timing and discontinuation of prophylactic antibiotics in our study.

Despite improved adherence to perioperative antibiotic prophylaxis measures in the post-intervention period, a statistically significant decline in SSI rate was not noted in our study, although a higher proportion of complex cases were performed. Studies evaluating the effectiveness of SIP process measures on reducing SSI rates in adult surgical patients have generated conflicting results [30–32]. While some studies have shown a decline in SSI rates with improved adherence to process measures, others have not demonstrated a similar benefit [30–32]. Factors other than appropriate delivery of perioperative antibiotic prophylaxis may also influence SSI rates including hospital case volume, case-mix index, surgical skill, working environment, and overall quality of care [31,32].

Our study did not find significant differences in rates of compliance with any of the four process measures between neonates who developed SSI and those who did not develop SSI. These results appear to contradict our earlier finding that incorrect timing of preoperative antibiotic prophylaxis was a risk factor for SSI following cardiac surgery [22]. We speculate that several differences in study design may account for these divergent findings. The previous study was conducted between January 2010 and December 2011, included all infants younger than 1 year of age, and analyzed outcomes following 552 procedures. Thus, the sample size of the current study may have been too small to detect an association between incorrect preoperative timing of prophylactic antibiotic and SSI. It is also possible that factors other than appropriate perioperative prophylaxis influence SSI rates in neonates.

There are several limitations to this study. This is a single center study with a unique, cardiac NICU and thus, the findings may not be generalizable to other pediatric cardiac ICUs in which care is offered to older children in the same unit. Although the proportion of patients who received appropriate perioperative antibiotic prophylaxis increased significantly during the post-intervention period, the decline in the incidence of SSI during this period was not statistically significant. The sample size may be too small and/or the study period may be too short to see a statistically significant decrease in the rate of SSI. Furthermore, SSI may have not been reported if patients presented to other institutions.

In conclusion, this study demonstrates that limiting the duration of perioperative antibiotic prophylaxis for neonatal cardiac surgery to 48 hours if the sternum is closed or to 24 hours after sternal closure is safe as determined by SSI rates. Additional multicenter studies are needed to develop national guidelines for perioperative prophylaxis for this population. The implementation of the consensus protocol with feedback resulted in significant improvements in the delivery of perioperative antibiotic prophylaxis in four process measures including appropriate drug selection and dosing, timely administration and discontinuation. However, deficiencies in postoperative dosing persisted in the post-

intervention period. Further research is needed to determine the association between each of the perioperative antibiotic prophylaxis process of care measures and the occurrence of SSI.

Acknowledgments

This work was supported, in part, by the National Institute for Nursing Research – National Institute of Health (R01 NR010821) to LS.

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Figure 1.

Above figure describes a flow diagram of patient population and procedures.

Table 1

Protocol for perioperative antibiotic prophylaxis for neonatal cardiac surgery and Process of care measures

Surgical approach, open or closed sternum	Pre and intraoperative antibiotic prophylaxis	Postoperative antibiotic prophylaxis	Duration of antibiotic prophylaxis
Cardiac surgery via lateral thoracotomy or median sternotomy, closed sternum	Cefazolin: 30 mg/kg/dose Given in the OR ^a within 60 minutes prior to skin incision. - Repeat dose in 4 hours if surgical procedure exceeds 4 hours. Use Vancomycin 15 mg/kg/dose (Administer up to 120 minutes prior to skin incision) if known colonization/infection with MRSA ^b	Cefazolin: 30 mg/kg/dose 7 days old: q 12 hours >7 days old: q 8 hours Use Vancomycin 15 mg/kg/dose 7 days old: q 12 hours >7 days old: q 8 hours if known colonization/infection with MRSA.	Discontinue antibiotics 48 hours after surgery end time.
Cardiac surgery, open sternum	Cefazolin 30 mg/kg/dose Given in the OR within 60 minutes prior to skin incision - Repeat dose in 4 hours if surgical procedure exceeds 4 hours. Use Vancomycin 15 mg/kg/dose (Administer up to 120 minutes prior to skin incision) if known colonization/infection with MRSA.	Vancomycin: 15 mg/kg/dose 7 days old: q 12 hours >7 days old: q 8 hours AND Gentamicin All ages: 4 mg q 24 hours	Discontinue antibiotics 24 hours after sternal closure

Abbreviations used in table: a: OR – operating room, b: MRSA - methicillin resistant *Staphylococcus aureus*.

Table 2

Characteristics of neonates who underwent cardiac surgery in the pre and post- intervention periods

Characteristic	Pre-intervention Period N = 145 (%)	Post-intervention Period N=138 (%)	Chi Sq/T Test	P-value
Male	80 (55)	76 (55)	0.0003	0.99
Mean age (days) at surgery, std dev.	13.7±23.3	11.6±15.3	-0.89	0.38
Mean birth weight (Kg) std dev.	3.16±0.6	3.07±0.62	-1.20	0.23
Premature, <37 weeks	21 (14)	12 (9)	2.30	0.13
White Race	62 (43)	59 (43)	0.00	1.00
RACHS-1 ^a category >3	56 (39)	73 (53)	5.81	0.02

^aRACHS-1: Risk Adjustment in Congenital Heart Surgery

Table 3

Comparison of perioperative antibiotic prophylaxis compliance process measures in the pre and post-intervention periods.

Performance measure	Pre-intervention Period N = 145 (%)	Post-intervention Period N = 138 (%)	P-value	OR	OR CIs
Perioperative prophylaxis given					
Preoperative	138 (95)	137 (99)	0.07	0.14	0.02, 1.19
Intraoperative re-dosing, n=131	44/60 (73)	70/71 (99)	<0.01	0.04	0.01, 0.31
Postoperative	141 (97)	136 (99)	0.68	0.52	0.09, 2.88
Correct Drug					
Preoperative	132 (96)	134 (98)	0.50	0.49	0.12, 2.01
Postoperative	124 (88)	133 (98)	<0.01	0.16	0.05, 0.58
Correct Dose					
Preoperative	115 (87)	124 (93)	0.14	0.55	0.24, 1.24
Postoperative	20 (16)	86 (65)	<0.01	0.11	0.06, 0.19
Correct Timing					
Preoperative	106 (80)	132 (99)	<0.01	0.06	0.01, 0.27
Intraoperative	39 (89)	66 (94)	0.30	0.47	0.12, 1.87
Correct Discontinuation	47 (38)	126 (95)	<0.01	0.03	0.01, 0.08

Table 4

Perioperative antibiotic prophylaxis process measures and SSI

Parameter	SSI N = 17 (%)	No SSI N = 266 (%)	P-value	OR	OR CI ₉₅
Antibiotics given					
Preoperative	16 (94)	259 (97)	0.39	0.43	0.05, 3.73
Intraoperative, n=131	7/9(78)	107/122 (88)	0.24	0.49	0.09, 2.59
Postoperative	17 (100)	260 (98)	0.69	-	-
Correct Drug					
Preoperative	16 (100)	250 (97)	0.58	-	-
Postoperative	16 (94)	241 (93)	0.38	1.26	0.16, 10.03
Correct Dose					
Preoperative	15 (94)	224 (90)	0.33	0.57	0.07, 4.53
Postoperative	6 (38)	100 (41)	0.20	0.85	0.30, 2.40
Correct Timing					
Preoperative	13 (81)	225 (90)	0.23	2.08	0.55, 7.79
Intraoperative	7 (100)	98 (92)	0.55	-	-
Correct Discontinuation	12 (75)	161 (67)	0.18	1.49	0.47, 4.77