



# The use of protocolised care bundle to prevent paediatric cardiac surgical site infection in resource-limited setting

## Original Article

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### Abstract

**Objective:** Surgical site infection is an important concern due to its association with morbidity and mortality after paediatric cardiac surgery. The aim of this study was to present our approach and experience in the utilisation of a modified care bundle in a recently established paediatric cardiac surgical unit in the low-income region of Turkey. **Methods:** Between 2019 and 2021, we identified children who underwent cardiac surgical procedures and retrospectively collected relevant demographic data, disease characteristics, operational data, Risk Adjustment For Congenital Heart Surgery (RACHS-1) scores, and post-operative factors such as morbidities, mortality, critical care, and in-hospital stay lengths. Surgical site infections and late infections were scanned. **Results:** Ninety-six patients (49 males, 47 females) underwent a total of 127 surgical procedures during the study period. Overall adherence to the protocol was 94%, 100%, and 96% in the pre-operative, intra-operative, and post-operative periods, respectively. There was no reported surgical site infection, and no late infection was encountered throughout the follow-up period. **Conclusions:** We conclude that a low rate of surgical site infection, or even a rate of nil, is attainable through the utilisation of locally standardised guidelines for its prevention.

Surgical site infection is a major concern due to its association with morbidity and mortality after paediatric cardiac surgery.<sup>1,2</sup> There have been reports of surgical site infections rates from 1.5% to 7.5%, as high as 15–30% in patients with delayed sternal closure; the percentage may be higher in newly established units of developing countries because most data are not audited.<sup>3,4</sup> The negative impact is related not only to increased mortality rates but also to morbidity caused by increased antibiotic use and prolonged stay in the ICU. Locally, surgical site infections result in cellulitis, abscess development, sternal osteomyelitis, and further wound breakdown, whereas systemically they might advance to bacteraemia with the possibility of sepsis and additional haemodynamic instability.<sup>1–4</sup>

It is known that comprehensive infection control regimens, including non-pharmacologic pre-operative, intra-operative, and post-operative procedures, are critical in avoiding surgical site infection.<sup>4,5</sup> Given the significant morbidity and mortality associated with surgical site infections in patients after paediatric cardiac surgery, significant quality improvement efforts have been implemented to reduce these events. Following the implementation of surgical site infection preventive strategies, the incidence of both surgical site infections has decreased considerably. This strategy has resulted in lower surgical site infection rates and better patient outcomes.<sup>6–9</sup>

The lack of data on risk factors for surgical site infection and prevention strategies in children made it necessary for organisations to develop interventions and bundles based on data extrapolated mostly from adult studies. In this article, our aim is to present our approach and experience in the utilisation of a modified care bundle in a recently established paediatric cardiac surgical unit in the low-income region of Turkey.

## Materials and methods

### Cohort

Between 2019 and 2020, 96 children underwent a total of 127 surgical procedures in a recently established paediatric cardiac surgical unit in Turkey's far east, where gross domestic product per capita is the lowest according to Turkish Statistical Institute data [10]. Elective patients were hospitalised in the dedicated paediatric cardiology and cardiac surgery ward. After the operation, patients were admitted to the general paediatric ICU with the exception of neonatal patients, in which off-pump neonatal cases were admitted to the neonatal ICU. Informed consent was obtained for all procedures.

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Preoperative	Intraoperative	Postoperative
Soap & water bath night before surgery.	Timing of preoperative antibiotics. Cephalosporin or single-shot bolus medications given 60 minutes prior to skin incision.	Daily postoperative CHG wipe.
Pre-op bath with 2% with emphasis on anterior thorax.	CHG used for skin preparation for children >1,500 g	Daily postoperative linen change and minimize sternotomy exposure to home blankets.
Place child in clean hospital gown after CHG bath.		Dressing removed within 48 hours of procedure using aseptic technique and covering incision site when at risk for contamination.
		Echocardiograms performed in sterile fashion.
		Appropriate documentation of state of wound (photo if needed)
		Postoperative antibiotic continued at appropriate time and dose for 72 hours, continued if chest open.
		Chest tube drain sites covered with occlusive dressing.

**Figure 1.** Modified care bundle to prevent SSI after paediatric cardiovascular surgery.

CHG = chlorhexidine gluconate.

We retrospectively collected relevant demographic data, disease characteristics, operational data, Risk Adjustment For Congenital Heart Surgery (RACHS-1) scores, and post-operative factors such as morbidities, mortality, critical care, and in-hospital stay lengths. Surgical site infections were epidemiologically diagnosed using the Centers for Disease Control and Prevention criteria. Infection definitions were divided into three types: superficial, deep, and organ/space. Superficial incisional was defined as surgical site infection affecting the skin and subcutaneous tissue. These infections might show localised signs such as redness, pain, heat, or swelling at the site of the incision or by the drainage of pus. Deep incisional was defined as surgical site infection affecting the fascial and muscle layers. These infections can be detected by the presence of pus or an abscess, fever with tenderness of the wound, or a separation of the edges of the incision exposing the deeper tissues. Organ or space infection was defined as surgical site infection, which involves any part other than the incision that is opened or manipulated during the surgical procedure, for example, a joint or the peritoneum. These infections can be suspected by the drainage of pus or the formation of an abscess detected by histopathological or radiological examination or during re-operation.

#### Modified protocol for the prevention of SSI

Following a comprehensive review of the current literature about the topic, we adopted two care bundles involving paediatric cardiac surgical patients only. We chose those protocols as they both showed statistically significant decrease in the rate of surgical site infections after protocol implementation and specific interventions included in those studies were easily applicable in our unit.

Woodward et al<sup>8</sup> described protocol interventions for sternal wound infection used in nine paediatric cardiac centres in the United States of America. Pre-operative, intra-operative, and post-operative interventions were part of the protocol. They achieved

91.3% compliance, with a 1.5% rate of sternal wound infection, down from 1.9% before the protocol.

A Stanford group study focused on the post-operative drivers of surgical site infection and proposed 11 post-operative elements with the goal of developing a standard practice to consistently reduce the risk of surgical site infection in post-operative paediatric cardiac patients. With a compliance rate of 95%, they were able to reduce the surgical site infection rate from 3.4 to 0.9 per 100 surgeries.<sup>9</sup>

Following a thorough examination of both protocols, we established a modified protocol in lieu of our institutional resources and the socio-economic status of the region. In the protocol, we used the template given by Woodward et al<sup>8</sup>, which divided the protocol into three parts: pre-operative, intra-operative, and post-operative. We included all elements reported in their article. Stanford group's care bundle primarily focused on post-operative variables. Thus, we added different post-operative elements to our template. Finally, we ended up with modified care bundle including interventions in pre-operative, intra-operative, and post-operative periods (Fig. 1).

At all stages, the protocol was strictly monitored and team members were encouraged to follow all interventions. Monthly regular educational sessions were organised with a major two-day meeting with all members of the team before the implementation of the protocol. Chart documentation was added to medical records for surveillance, which was done by the staff nurse of the paediatric cardiac surgical ward. That chart included all protocol elements with check marking boxes on the side and attached to the patient's file to be controlled with the time-out chart in the operating room. To educate the families of the patients, the bedside nurses served as the primary liaison. We used nurse quality rounds to track intervention adherence in real time with formal checklists. The interventions took effect in July 2019, with the first patient being operated on in the unit.

### Data presentation

Statistical analysis was performed using Jamovi Version 2.3.18.0 (Jamovi Projects). Continuous data descriptive statistics were presented as median and inter-quartile range.

### Results

Ninety-six patients (49 males, 47 females) underwent a total of 127 paediatric cardiovascular procedures during the study period. Patient pre-operative, intra-operative, and post-operative variables are given in Table 1. The mean age at the time of operation was  $1.25 \pm 2.7$  years (range: 1 day–17 years). The mean weight at the time of operation was  $6.46 \pm 7.5$  kg (range: 680 g–50 kg). Forty-six operations (36%) were performed during the neonatal period, while 87 operations (69%) were performed during their infancy period. There were 15 delayed sternal closures. Most of the operations were classified as RACHS categories 1 and 2, 33% and 31%, respectively. Sixty-eight percent of patients required foreign material placement for the surgical procedure. Early mortality was 7.2% (7 patients) with RACHS categories 4 and 6. All deaths were related to low cardiac output. No late mortality was observed during the follow-up of mean  $2.65 \pm 0.23$  years.

With the use of the bundle, no surgical site infection was encountered, including patients with delayed sternal closure. Furthermore, we have not encountered any delayed presentation of surgical site infection within the follow-up period of almost 3 years. Overall protocol adherence was 94%, 100%, and 96% in the pre-operative, intra-operative, and post-operative periods, respectively.

### Discussion

After paediatric cardiac surgery, surgical site infection is a potentially life-threatening complication that can develop. Surgical site infections can result in extended hospital stays, higher medical expenses, morbidities, and even mortality.<sup>4,6,11,12</sup> Infection rates are higher in developing countries, in newly established units, and in ICUs.<sup>3,6,7</sup> Identifying patients at risk for surgical site infection is essential to reduce post-operative morbidity and death. Multiple studies identify several risk factors for surgical site infection after paediatric cardiac surgery. Younger patients and longer cardiac bypass periods are associated with higher surgical site infection rates.<sup>10,11</sup> Complex procedures and previous cardiothoracic surgery are also risk factors. Other risk factors are as follows: longer post-operative stay, presence of catheter-associated urinary tract infection, presence of ventilator-associated pneumonia, presence of invasive medical device, comorbid conditions such as cardiac disease and brain tumour, and pre-operative colonisation with staphylococci.<sup>11–13</sup> These risk factors for surgical site infection in poor healthcare settings in low-income countries are comparable to those discovered after paediatric heart surgery in high-income countries.<sup>3</sup>

Allied health personnel play an important role in reducing the risk of surgical site infection, although they frequently do not receive the appropriate training.<sup>14,15</sup> Therefore, a comprehensive infection control programme that includes non-pharmacologic pre-operative, intra-operative, and post-operative measures is essential for the prevention of surgical site infection. The perfect adherence to surgical site infection prevention bundles was associated with a decrease in the risk of post-operative

**Table 1.** Pre-, intra-, and post-operative variables of patients.

Pre-operative variables	
Age	
≤ 30 days	37 (39)
31 days–1 year	36 (38)
≥ 1 year	23 (23)
Sex	
Male	49 (51)
Female	47 (49)
Weight	
≤ 2.4 kg	19 (20)
2.5–4.9 kg	43 (45)
5–9.9 kg	20 (20)
≥ 10 kg	14 (15)
Pre-operative inpatient	68 (71)
Pre-operative infection	15 (16)
Pre-operative ventilation	35 (36)
Underlying condition	
Cyanotic	36 (38)
Acyanotic	60 (63)
Univentricular	26 (27)
Biventricular	70 (73)
Genetic abnormalities	22 (23)
Previous sternotomy	18 (19)
Intra-operative variables	
Bypass time (min)	98.06 ± 56.6
Cross clamp time (min)	39.7 ± 24.1
Circulatory arrest use	6 (6)
Transthoracic lines use	118 (93)
Foreign materials placed	65 (68)
Sternum left open	15 (16)
Emergency: elective	48:48 (50:50)
RACHS categories	
1	42 (33)
2	40 (31)
3	14 (11)
4	19 (15)
5	0 (0)
6	12 (10)
Post-operative variables	
Post-operative TPN use	16 (17)
Inotropic score (mean ± std)	11.3 ± 11.2
Mechanical ventilation (hours) (mean ± std)	5.4 ± 14.4
PICU stay (days) (mean ± std)	10.6 ± 17.7

infections.<sup>7,14,16</sup> The advantage of employing a bundled strategy is that it involves implementing multiple evidence-based interventions at the same time, which can be more successful than implementing individual interventions separately. Healthcare professionals can target several components of care that contribute to infection risk and improve overall adherence to infection control measures by coordinating interventions. Furthermore, a bundled strategy can aid in standardisation of treatment between different providers and institutions, perhaps leading to more consistent and effective infection prevention procedures.<sup>17,18</sup>

As a newly established paediatric cardiac surgical unit in the lowest per capita income region of Turkey, we foresaw several inherent risk factors for surgical site infection. First, the new centre was in the lowest-income region of Turkey where resources are limited. Second, there was no dedicated paediatric cardiac ICU for patients post-operatively. Although there is no direct evidence on whether surgical site infection after paediatric cardiac surgery is higher in newly established centres, specialised paediatric cardiac intensive care is crucial for the management of critically ill patients with CHD, and the quality of care provided by specialised nursing staff and age-appropriate medical equipment is important for patient outcomes. For these reasons, we implemented a bundle to prevent surgical site infections. We believe that this methodical approach will be advantageous not just in institutions with low resources but also in advanced centres with abundant medical supplies.

Although previous studies have used interventions focused on different stages to minimise surgical site infection in paediatric cardiac patients, we believe that a comprehensive care bundle including pre-operative, intra-operative, and post-operative interventions would have better efficiency. To effectively apply the care bundle, a multi-disciplinary group was formed to determine critical elements of the pre-, intra-, and post-operative phases. Due to the lack of research on this topic of time, our team conducted an exhaustive review of the relevant literature, maintained communication with affiliated institutions, and sought the advice of clinical professionals. As a result, we modified two previously published care bundles in accordance with socio-economic, cultural, and local variables of the region. To promote strict adherence, regular staff education sessions were organised, and compliance was continuously monitored. We believe that all these interventions motivate the team and a high compliance rate similar to the literature was achieved. Although compliance was high during the data collection period, it was not 100% pre-operatively and post-operatively. Probably multiple factors contributed to these differences between the bundle protocol and the actual practice. Possibly, some non-compliance is attributable to patient or parent disobedience with pre-operative recommendations. As a result, with the implementation of a comprehensive care bundle, we managed to achieve a zero surgical site infection rate during the hospitalisation period of patients in our unit. International Quality Improvement Collaborative data on post-operative infection in developing world congenital heart surgery programmes, which covered 28 locations in 17 developing nations, indicated a surgical site infection incidence of 2.1%.<sup>3</sup> Considering the limited resources of a newly created facility, the surgical difficulty of the cases, and the relatively young age of the patients included in this study, we believe that our outcome is exceptional. Follow-up for late infection is especially important for patients with synthetic implants. There was no late infection in the cohort during the follow-up period, despite 68% of patients required foreign material placed in the surgery.

Several obstacles arose during the implementation of this protocol. First, 'cultural transformation' was the most difficult one.

Since no equivalent procedure had been introduced at the hospital prior to ours, team members were first hesitant. However, consistent instructional activities and positive feedback along the process enhanced the team's awareness and motivation. Second, the surgical complexity exceeded our expectations as a newly established centre. Nevertheless, we were able to adhere to the protocol. To overcome these hurdles, a team approach was implemented at every stage of the study, and every member of the team worked diligently to accomplish the desired outcome. Nursing personnel in the ward and operation room were vital to the protocol.

There were several limitations of this study. First, it is a single centre and an observational nature. Second, there is no patient cohort where this bundle was not used and there was no surgical site infection seen to define risk factors. Third, there was no historic surgical site infection data to compare results after the implementation of this protocol. Fourth, it is impossible to determine whether some interventions contributed more to the results than others. Fifth, we do not know whether this protocol positively or negatively affected the rate of other hospital-acquired infections as we do not have a relevant data about that. Lastly, there may have been unmeasured confounders, such as product changes, that could have contributed to the results. However, we strongly believe that the use of a standard protocol-based approach for all patients with a high compliance rate is fundamental in reducing surgical infections.

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**Competing interests.** None.

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