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Surgical site infection related to use of elastomeric pumps in pectus excavatum repair. Lessons learned from root cause analysis

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ABSTRACT

Background: Pectus excavatum repair (PEX) is among the most painful thoracic procedures performed. Continuous peripheral nerve blockade (CPNB) is known to be efficacious in optimizing pain control while limiting narcotic use in adult thoracic procedures. It was introduced in May 2015 as a bridge to oral pain control in children undergoing PEX. Consequently, the surgical site infection (SSI) rate increased from 2.7% to 27.7%.
Methods: SSI surveillance followed national guidelines. The abrupt increase prompted root cause analysis and cessation of CPNB use. A dynamic systems model of SSI in PEX was developed. Statistical analysis compared SSI outcomes with and without CPNB.
Results: From May 2015 to June 2015, 21 PEX were performed; 11 with CPNB. 6 SSIs were observed. Use of CPNB significantly ($p = 0.008$) increased SSI incidence. Haller index, number of bars, usage of Fiberwire®, methicillin resistant *S. aureus* colonization and length of stay did not differ. Root cause analysis revealed the proximity of CPNB catheters to the wound, the use of CPNB with implanted hardware and a delayed utilization of CPNB catheters to be of concern.
Conclusion: Introduction of CPNB coincided with a significant increase in SSI. Further study is needed to assess the safety of CPNB in pediatric PEX.
Level of evidence: Level III treatment study.

Pectus excavatum (PE) can severely affect both cardiac and pulmonary function, limiting exercise tolerance [1,2]. This, alongside secondary psychosocial considerations, prompts the need for surgical intervention [1]. Repair is commonly achieved by the minimally invasive implantation of an elevating contoured stainless steel bar, known as the *Nuss procedure* [3]. Nuss repair is one most painful procedures performed by pediatric surgeons, as evidenced by a high and prolonged need for postoperative epidural and narcotic use [4]. Pain management in this patient population has been referred to as the critical component of postoperative care [4] and considerable efforts have been undertaken to reduce postoperative analgesic requirements, specifically, opioid use. While epidural analgesia is widely used following pectus excavatum repair (PEX) [1], it may increase cost, invasiveness and procedural risk [5,6]. In addition, pain control during transition from epidural to oral analgesia is a challenge faced by our team.

Continuous delivery of a local anesthetic near a peripheral nerve or surgical site can enhance postoperative analgesia and may provide a bridge to oral analgesia [1]. An elastomeric pain pump is a system by which the patient receives a portable reservoir from which local anesthetic is infused directly into the tissues at a continuous rate. Continuous peripheral nerve blockade (CPNB) via an elastomeric pump is increasingly being utilized to improve pain control following surgery. Meta-analysis data of randomized controlled trials has found CPNB to be safe and efficacious in controlling postoperative pain and limiting narcotic use while reducing the length of stay in adults in a variety of surgical settings [7]. Current pediatric experience with these appliances is limited, but both the feasibility [8] and the efficacy of CPNB in reducing postoperative pain and narcotic use in pediatric populations have been reported [9,10]. We introduced elastomeric pumps into our practice at Cincinnati Children's Hospital Medical Center (CCHMC) to enhance postoperative pain control in PEX. However, following elastomeric pump introduction, we noted an abrupt increase in postoperative surgical site infections (SSI). We describe our detailed analysis of the outbreak and its potential causes.

1. Methods

The Nuss procedure is performed by two dedicated surgeons at our institution. Surgical techniques are similar among the partners who have been in practice together for >10 years. Both follow a

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Table 1
Surgical site infection prevention bundle.

		SSI bundle active during analyzed period	Elastomeric pump SSI bundle active during analyzed period	Revised SSI bundle starting July 2015
Preoperative preparation	MRSA negative	Wash chest and body with chlorhexidine wash the evening and the morning prior to the procedure	Wash chest and body with chlorhexidine wash the evening and the morning prior to the procedure	Wash chest and body with chlorhexidine wash the evening and the morning prior to the procedure
	MRSA positive	Wash chest and body with chlorhexidine wash for 7 days prior to the procedure including the evening and the morning prior Twice daily muciprocin swabs to nose for 7 days prior to the procedure	Wash chest and body with chlorhexidine wash for 7 days prior to the procedure including the evening and the morning prior Twice daily muciprocin swabs to nose for 7 days prior to the procedure	Wash chest and body with chlorhexidine wash for 7 days prior to the procedure including the evening and the morning prior Twice daily muciprocin swabs to nose for 7 days prior to the procedure
Intraoperative measures		Skin preparation with chlorhexidine gluconate No shaving, hair clipping if appropriate Antibiotic within 30 min prior to incision Intraoperative antibiotic re-dosing Q3h Betadine wound irrigation	Skin preparation with chlorhexidine gluconate No shaving, hair clipping if appropriate Antibiotic within 30 min prior to incision Intraoperative antibiotic re-dosing Q3h Saline locking of elastomeric pain catheter Betadine wound irrigation	Skin preparation with chlorhexidine gluconate No shaving, hair clipping if appropriate Antibiotic within 30 min prior to incision Intraoperative antibiotic re-dosing Q3h Vancomycin powder applied to wound before closure
Antibiotic coverage	Standard	1 intraoperative and 3 postoperative doses of cefazolin	1 intraoperative and 3 postoperative doses of cefazolin	1 intraoperative and 3 postoperative doses of cefazolin
	Penicillin allergy	1 intraoperative and 3 postoperative doses of clindamycin	1 intraoperative and 3 postoperative doses of clindamycin	1 intraoperative and 3 postoperative doses of clindamycin
	MRSA positive	1 intraoperative dose of vancomycin and 3 postoperative doses of cefazolin	1 intraoperative dose of vancomycin and 3 postoperative doses of cefazolin	1 intraoperative dose of vancomycin and 3 postoperative doses of cefazolin
Postoperative measures		Occlusive wound dressing for 48 h	Occlusive dressings while catheter inserted	O2 supplementation per nasal canula for the first postoperative 4 h Occlusive wound dressing 48 h Washing of the chest and wounds with soap and water at 48 h

Brief description of the standardized infection prevention bundle used for pectus excavatum repair prior to and following the recent rise in surgical site infections.

comprehensive approach to prevent surgical site infection implemented in 2012, as summarized in Table 1. After introducing the option of placing elastomeric pumps to patients and their families in May 2015, surgical placement of the elastomeric pumps was performed following a standard protocol according to manufacturer's instructions. we adopted the technique described by a high volume surgical practice emphasizing inserting the catheter away from the incision sites and directing the catheters posteriorly and away from the bar implants. A manufacturer representative was present in the operating theater for all cases in which elastomeric pumps were implanted. In brief, following bar placement silver-coated wound catheters were introduced before closure of the surgical wounds by removing 5–10 cm of the Ioban® covering of the chest surrounding the surgical wounds. Next, on either side, a tunneler was introduced approximately 5–10 cm inferior and posterior to the thoracic incisions and tunneled upwards, taking care to stay a minimum of 5 cm from the postero-lateral wound edges. Through this, the saline-primed wound catheters were threaded and the tunneler was removed. Next, the surgical wounds were closed as per standard technique with Vicryl suture, Steristrips® and Tegaderm®. The wound catheter was then fixed to the thoracic wall with Dermabond® and Tegaderm® placed under sterile conditions. SSI surveillance is conducted by our institution's infection control program according to national guidelines and definitions [11,12]. For the purposes of our investigation, we extended the post-procedure surveillance period from 30 to 60 days. Infection preventionist notification of a positive culture in a postoperative patient prompted an initial investigation to determine if the case met SSI criteria. When an increase over baseline was noted, an initial review of SSIs following PEX found that each infected patient had an elastomeric pump placed, and their use was suspended. We then began a detailed review of the cases, including hypothesis generation for SSI cause, group discussion, and in depth retrospective chart and microbiological result review. In addition, SSI bundle adherence was tracked.

We ran two separate comparisons of the data: one comparing patients who did to those who did not have an elastomeric pump, and another of patients with to those without an SSI. A comparison between patient with elastomeric pumps with and without an SSI was attempted, but was found to be underpowered for valid statistical analysis. Statistical analysis was performed using Mann–Whitney *U* and Fisher exact test, as appropriate, using the Vassarstats freeware [13].

2. Results

In May and June of 2015, 21 PEX were performed, among which six (28.5%) SSIs occurred. Of the 21 PEX patients, 11 used elastomeric catheters for postoperative pain management. All six SSIs occurred among the 11 elastomeric pump patients. Wound cultures were positive in 4 of the 6; 2 grew *Staphylococcus epidermidis*, 1 methicillin sensitive *Staphylococcus aureus*, and 1 *Pseudomonas aeruginosa*. No polymicrobial infections occurred. Cultures from the remaining two patients had no growth. Microbiological testing of the lot of implanted catheters was not retrospectively performed. Surgical site infections presented with increased and prolonged postoperative pain, fever, itching, wound breakdown and skin rashes. The mean time to postoperative presentation was 28 days (range 11–52 days). Four patients required readmission, two of whom required surgical wound exploration and one required negative pressure wound therapy. No patients required removal of the implanted hardware. Culture specific or empiric antibiotic therapy was prescribed and followed clinically and with serial serum inflammatory markers.

Patients who had an elastomeric pump did not differ by mean Haller index, number of bars placed, usage of Fiberwire®, preoperative methicillin resistant *S.aureus* colonization, perioperative antibiotic therapy or postoperative length of stay (LOS). However, patients who had an elastomeric pump showed preponderance to being male and were on average 2 years older than those that did not have an elastomeric pump (Table 2). Subjective comparison of elastomeric pump patients with and without SSI showed no striking differences (Table 3).

3. Discussion

Infection control is a critical component of any operation where foreign material is implanted because of the increased risk of SSI. Reported SSI rates following Nuss PEX range from 1.5% to 6.9% [14–16]. From