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Reevaluating Surgical Antibiotic Prophylaxis in Pediatric Pyloromyotomy: Insights From the NSQIP-Pediatric Database

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ABSTRACT

Background: Pyloromyotomy is a clean surgical procedure with a low risk of surgical site infections (SSIs). Despite this, surgical antibiotic prophylaxis (SAP) is often administered, raising concerns about unnecessary antibiotic exposure and antimicrobial resistance. This study aims to evaluate whether SAP reduces SSI rates in infants undergoing pyloromyotomy for hypertrophic pyloric stenosis and to propose a guideline for selective SAP omission.
Methods: This retrospective cohort study analyzed data from the National Surgical Quality Improvement Program-Pediatric database. Infants undergoing pyloromyotomy between January 1, 2021 and December 31, 2023 were included. The primary outcome was the occurrence of SSIs within 30 days postoperatively. Secondary outcomes included stratified rates of superficial, deep incisional, and organ/space SSIs.
Results: Among 4917 infants (age <1 year; 84.26 % male), 49.48 % received SAP. Additionally, 81 patients (1.65 %) received post-operative antibiotics beyond the intraoperative period. The overall SSI rate was 1.42 %, primarily comprised of superficial SSIs. There was no significant difference in SSI rates between infants receiving SAP (1.15 %) and those not receiving SAP (1.69 %) ($p = 0.110$). The rate of unplanned readmission and unplanned return to the operating room within 30 days was 2.44 % and 1.04 %, respectively, with no significant difference between those who received post-operative antibiotics and those who did not ($p > 0.2$ for both comparisons).
Conclusions: Routine SAP administration in pyloromyotomy is unnecessary given the low risk of SSIs. SAP in ASA Class I or II infants undergoing isolated pyloromyotomy without mucosal perforation, immune-compromising conditions, infections, or trauma should be omitted. These findings support efforts to optimize antibiotic stewardship in pediatric surgical practice.
Type of Study: Original Research Article.
Level of Evidence: III.

1. Introduction

Pyloromyotomy, the standard surgical treatment for hypertrophic pyloric stenosis in infants, is considered a clean surgical procedure with a low inherent risk of surgical site infections (SSIs), provided there is no mucosal violation or perforation during the procedure [1]. Despite this classification, the use of surgical antibiotic prophylaxis (SAP) for this procedure remains a contentious issue. Balancing the benefits of infection prevention with the potential drawbacks of unnecessary antibiotic use, such as antimicrobial resistance and increased healthcare costs, can be challenging. However, determining whether SAP is warranted in procedures like pyloromyotomy is critical for optimizing patient outcomes and supporting antimicrobial stewardship efforts.

Evidence regarding the efficacy of SAP in preventing SSIs for clean surgical procedures in children, and for pyloromyotomies specifically, is inconsistent [2–10]. A systematic review and meta-analysis by Nthumba et al. highlighted that SAP does not significantly reduce SSI rates in clean pediatric surgical procedures, questioning its necessity in such contexts [2]. Furthermore, the inherent low risk of SSIs in procedures classified as wound class I (clean) as is typically the case for pyloromyotomy, suggests that routine SAP may not be beneficial in these cases [11]. However,

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some studies suggest that SAP may have a role in specific circumstances. For example, studies on other clean surgical procedures, such as inguinal hernia, have shown conflicting results regarding SAP effectiveness, with some indicating a potential reduction in SSIs, particularly in institutions with higher baseline SSI rates [12]. These inconsistencies and gaps in evidence, particularly from large-scale pediatric databases, continue to limit clear recommendations on SAP use for clean surgeries, leading to inconsistent practice patterns. A study using National Surgical Quality Improvement Program-Pediatric (NSQIP-P) data found that SAP administration remained prevalent across multiple pediatric clean surgeries, even in cases where clear evidence of benefit was lacking, suggesting that many clinicians continue to use SAP despite limited supporting data [13]. In the context of increasing global concerns over antibiotic resistance, understanding the role of SAP in low-risk surgeries is imperative [14,15].

This study aims to address the current gaps in the literature by reviewing the use of SAP in patients undergoing pyloromyotomy using data from NSQIP-P. Specifically, the objectives are to (1) quantify the use of SAP for pyloromyotomy in a contemporary cohort and (2) assess whether SAP administration is associated with reduced SSI rates after pyloromyotomy. By focusing on SAP practices and their relationship to outcomes in a pediatric surgical population, this research seeks to provide insights that can inform clinical guidelines and optimize the balance between effective infection prevention and responsible antibiotic use in pediatric surgery.

2. Methods

2.1. Study design

This retrospective study utilized data from the NSQIP-Pediatric database, a nationally validated and risk-adjusted registry from the American College of Surgeons that collects data on surgical outcomes from participating institutions. The database was queried to identify infants (age <1 year) who underwent pyloromyotomy for the treatment of hypertrophic pyloric stenosis between January 1, 2021, and December 31, 2023. Patients were identified using Current Procedural Terminology (CPT) codes 43520 and 43659 (for open and laparoscopic pyloromyotomy, respectively).

Recent updates to the NSQIP database have included new variables specifically capturing the administration of SAP, enabling a more detailed examination of SAP practices and their relationship to surgical site infection outcomes. Patients with missing data on antibiotic prophylaxis were excluded from the study. In addition, patients undergoing additional procedures, as marked by CPT codes listed as “other” or “concurrent” procedures, were excluded from the study.

2.2. Study population

Patient demographics, clinical characteristics, and surgical outcomes were extracted from the database. Demographic variables included age, sex, and race, while clinical variables included wound classification, ASA classification, inpatient versus outpatient status, and the use of SAP, including the continuation of antibiotics post-operatively. Postoperative outcomes assessed were the occurrence of superficial incisional SSIs, deep incisional SSIs, and organ/space SSIs, incidence of *Clostridium difficile* infection, as well as unplanned readmissions and returns to the operating room (OR) within 30 days post-operatively.

2.3. Statistical analyses

Descriptive statistics were calculated to summarize the patient population and outcomes. Continuous variables, such as age, were reported using means, medians, and interquartile ranges, while categorical variables, including SAP usage, were presented as frequencies and percentages. Comparative analyses between those who did and did not receive SAP were performed using Chi-square tests and Fisher's exact tests for categorical data and Wilcoxon rank-sum tests for continuous variables. Those who received post-operative antibiotics were further compared to those who did not receive post-operative antibiotics to assess whether the post-operative antibiotics may have been indicated due to a surgical complication such as mucosal perforation. A multivariable logistic regression analysis adjusting for ASA classification, wound classification, and surgical approach (laparoscopic vs open) was used to further examine possible association between SAP use and SSI occurrence.

The CPT code typically utilized for laparoscopic pyloromyotomy is notably broad (“unlisted laparoscopic procedure performed on the stomach”). Given that the code could be used for other procedures, a sensitivity analysis was performed including only those patients whose surgical encounter was assigned a primary International Classification of Diseases (ICD-10) diagnosis code specific to pyloric stenosis. A p-value of <0.05 was considered statistically significant. All statistical analyses were performed using Statistical Analysis Software version 9.4.

3. Results

3.1. Study population

A total of 4917 infants who underwent pyloromyotomy for hypertrophic pyloric stenosis were included in the analysis (Table 1). Of these, 62.74 % (n = 3085) were classified as open pyloromyotomy, and 37.26 % (n = 1832) were classified as laparoscopic pyloromyotomy. The cohort was predominantly male (n = 4143, 84.26 %) and White (n = 3220, 65.49 %). The majority of patients were classified as ASA Class II (n = 3717, 75.59 %), indicating mild systemic disease, while 24.41 % (n = 1200) were classified as ASA Class I (normal/healthy). Most cases were classified as clean (n = 3651, 74.25 %), and the remaining 25.75 % were classified as clean-contaminated (n = 1266). The majority of cases were performed in an inpatient encounter (n = 4297, 87.39 %), with only 12.61 % (n = 620) classified as outpatient procedures.

3.2. Surgical antibiotic prophylaxis

Approximately half of the patients (n = 2433, 49.48 %) received surgical antibiotic prophylaxis (SAP), while 50.52 % (n = 2484) did not (Table 1). SAP was more commonly used for open pyloromyotomy compared to laparoscopic pyloromyotomy (53.65 % vs 42.47 % $p < 0.001$). In addition, SAP was more commonly administered to patients who were ASA Class I compared to ASA Class II (52.00 % vs 48.67 %, $p = 0.045$). Those classified as clean-contaminated were more likely to receive SAP than patients who were classified as clean (57.50 % vs 46.70 %, $p < 0.001$). SAP use was similar between procedures coded as inpatient (n = 2143, 49.87 %) and outpatient (n = 290, 46.77 %). Of those who received SAP, 81 patients (3.33 %) received antibiotics beyond the intra-operative period. Of those who received post-operative antibiotics, just 2 patients had any documented infection development. The median time to the last dose of antibiotics for patients who were continued on post-operative antibiotics was 20.65 h (IQR: 13.17, 25). There

Table 1
Descriptive characteristics of the entire cohort.

Characteristic	Overall n = 4917	SAP n = 2433	No SAP n = 2484	p-value
Procedure type (CPT)				
Open pyloromyotomy (43520)	3085 (62.74 %)	1655 (53.65 %)	1430 (46.35 %)	<0.001
Laparoscopic pyloromyotomy (43659)	1832 (37.26 %)	778 (42.47 %)	1054 (57.53 %)	
Sex				
Female	774 (15.74 %)	386 (49.87 %)	388 (50.13 %)	0.813
Male	4143 (84.26 %)	2047 (49.41 %)	2096 (50.59 %)	
Race				
White	3220 (65.49 %)	1549 (48.11 %)	1671 (51.89 %)	0.025
Unknown/Not reported	1050 (21.35 %)	562 (53.52 %)	488 (48.48 %)	
Black or African American	335 (6.81 %)	165 (49.25 %)	170 (50.75 %)	
Other	312 (6.03 %)	157 (50.32 %)	155 (49.68 %)	
ASA classification				
ASA 1 – Normal/Healthy	1200 (24.41 %)	624 (52.00 %)	576 (48.00 %)	0.045
ASA 2 – Mild systemic disease	3717 (75.59 %)	1809 (48.67 %)	1908 (51.33 %)	
Wound classification				
I - clean	3651 (74.25 %)	1705 (46.70 %)	1946 (53.30 %)	<0.0001
II – Clean-contaminated	1266 (25.75 %)	728 (57.50 %)	538 (42.50 %)	
Inpatient/Outpatient				
Inpatient	4297 (87.39 %)	2143 (49.87 %)	2154 (50.13 %)	0.149
Outpatient	620 (12.61 %)	290 (46.77 %)	330 (53.523 %)	

were no instances of *Clostridium difficile* infection in the entire cohort.

3.3. Surgical site infections & unplanned returns

The overall incidence of SSIs was low across the cohort at 1.42 % (n = 70) (Table 2). Superficial incisional SSIs occurred in 1.16 % of cases (n = 57), while deep incisional SSIs and organ/space SSIs were observed in 0.08 % (n = 4) and 0.18 % (n = 9) of cases, respectively.

Despite differences in SAP utilization, there were no significant differences in SSI rates across surgical approach, ASA classification, or wound classification. Open procedures had a superficial SSI rate of 1.17 % (n = 36), while laparoscopic procedures had a similar rate of 1.15 % (n = 21) (p > 0.99). Deep SSI was rare, with 3 cases (0.01 %) in open procedures and 1 case (0.05 %) in laparoscopic procedures (p > 0.99). Organ/space SSI occurred in 0.23 % (n = 7) of open procedures and 0.11 % (n = 2) of laparoscopic procedures (p = 0.5).

The incidence of superficial incisional SSI was 1.33 % (n = 16) in ASA 1 patients and 1.10 % (n = 41) in ASA 2 patients (p = 0.54). Deep incisional SSI occurred in 0.08 % of patients in both groups, with a p-value of >0.99. Similarly, organ/space SSI was reported in 0.25 % (n = 3) of ASA 1 patients and 0.16 % (n = 6) of ASA 2 patients (p = 0.46).

The rate of superficial incisional SSI for clean procedures was 1.12 % (n = 41) and 1.26 % (n = 16) in clean-contaminated procedures (p = 0.69). Deep SSI occurred in 0.11 % of clean procedures (n = 4), and there were 0 cases in clean-contaminated procedures (p = 0.58). Organ/space SSI occurred in 0.19 % of clean cases (n = 7) and 0.16 % of clean-contaminated cases (n = 2) (p > 0.99).

There was no significant unadjusted difference in incidence of overall SSI between those who did and did not receive SAP (1.15 % vs. 1.69 %, p = 0.110) (Table 2). Likewise, there were no significant differences observed in the specific rates of superficial, deep incisional, or organ/space SSIs between the those who did and did not receive SAP. After adjusting for ASA classification, wound classification, and surgical approach, the odds of SSI was similar regardless of SAP utilization (adjusted odds ratio 0.66, 95 % CI 0.41–1.07, p = 0.093).

Overall, 120 patients (2.44 %) experienced unplanned readmissions within 30 days, and 51 patients (1.04 %) had an unplanned return to the OR (Table 2). There were no significant differences in either unplanned readmission rates or return to OR between those who did and did not receive SAP.

Patients who received post-operative antibiotics, all of whom had received SAP, had similar readmission rates and return to OR rates compared to those who did not receive post-operative antibiotics (p-value = 0.458) (Table 3). However, the length of hospital stay was notably longer in patients who received post-operative antibiotics (p < 0.001).

With regard to the sensitivity analysis, 98.47 % of the cohort had an ICD-10 diagnosis code for pyloric stenosis. The remaining 1.53 % had a variety of more generic ICD-10 diagnosis codes largely consistent with pyloric stenosis presentation (most commonly vomiting and failure to thrive). Within the 98.47 % who had an ICD-10 diagnosis code for pyloric stenosis, utilization of SAP was still high (49.30 %) and similar to the main cohort. Inferences regarding the lack of association between SAP and outcomes were unchanged in the sensitivity analysis. Specifically, there were no differences in SSI, readmission, or return to OR between those who did and did not receive SAP.

4. Discussion

This study found a persistently high use of SAP among infants undergoing pyloromyotomy from 2021 to 2023. The overall

Table 2
Comparison between SAP groups.

Outcome	Overall n = 4917	SAP n = 2433	No SAP n = 2484	p-value
Any infection	70 (1.42 %)	28 (1.15 %)	42 (1.69 %)	0.110
Superficial SSI	57 (1.16 %)	21 (0.86 %)	36 (1.45 %)	0.055
Deep incisional SSI	4 (0.08 %)	2 (0.08 %)	2 (0.08)	0.983
Organ space SSI	9 (0.18 %)	5 (0.21 %)	4 (0.16 %)	0.715
Unplanned readmission	120 (2.44 %)	64 (2.63 %)	56 (2.25 %)	0.393
Return to OR	51 (1.04 %)	26 (1.07 %)	25 (1.01 %)	0.830

Table 3
Comparison between those who did and did not receive post-operative antibiotics.

Outcomes	Overall, n = 4917	Post-Operative Antibiotic[a], n = 81	No Post-Operative Antibiotic[b], n = 4836	p-value
Unplanned readmission (N, %)	120 (2.44 %)	3 (2.50 %)	78 (1.63 %)	0.458
Return to OR (N, %)	51 (1.04 %)	2 (2.47 %)	49 (1.01 %)	0.200
LOS (Median, IQR), n = 4908	2.0 (2.0, 3.0)	2.0 (1.0, 2.0)	1.0 (1.0, 2.0)	<0.001

[a] All patients who received post-operative antibiotics also received pre-operative antibiotic prophylaxis.
[b] Some received pre-operative antibiotic prophylaxis and some did not.

incidence of SSI after pyloromyotomy was quite low and similar between those who did and did not receive SAP. These findings further support that SAP does not significantly reduce the already low rates of SSIs in pediatric pyloromyotomy, a finding that aligns with the broader literature on clean surgical procedures. Notably, this study is the first to evaluate these outcomes using the NSQIP-Pediatric database, enabled by the recent addition of new variables specifically capturing surgical antibiotic prophylaxis practices, offering a large-scale, nationally representative analysis of real-world practices. These findings should prompt a critical reassessment of routine SAP use in this population, particularly in light of the growing emphasis on antimicrobial stewardship.

Pyloromyotomy is widely recognized as a clean procedure with minimal infection risk, attributed to its limited incision depth and absence of contamination-prone anatomical sites [3,4]. The low SSI rates observed in this study, both superficial and deep, highlight the minimal risk of infection associated with pyloromyotomy and are consistent with previous reports for similar surgeries [2–4,7,8,10,11]. Existing evidence further demonstrates that clean surgical procedures in children generally experience low infection rates, often irrespective of SAP use [2]. This concordance underscores the limited utility of SAP in pyloromyotomy, highlighting the potential risks of antibiotic administration in relation to limited or no benefit. Despite this finding, our analysis revealed that approximately 50 % of patients undergoing pyloromyotomy still receive antibiotic prophylaxis in recent years among the hospitals participating in NSQIP-Pediatric. Importantly, over 3 % of patients receiving SAP had antibiotics continued post-operatively as well, with no differences noted in unplanned readmissions or returns to the OR. These findings reflect significant variability in SAP use, consistent with previous studies, and emphasize the need for standardized guidelines to optimize antibiotic use and reduce unnecessary variation in clinical practice.

Antibiotic stewardship is particularly critical in pediatric populations, especially for infants under one year of age undergoing procedures like pyloromyotomy. Unnecessary antibiotic exposure in this vulnerable population can disrupt the developing microbiota, potentially leading to long-term health consequences such as metabolic and immune dysfunction [16,17]. Infants are also more susceptible to adverse reactions, including allergies and gastrointestinal disturbances [18]. Additionally, inappropriate antibiotic use accelerates the emergence of multidrug-resistant pathogens, complicating future treatment options. In light of these risks and the findings of this study, routine SAP for low-risk procedures like pyloromyotomy does not align with evidence-based stewardship principles.

We acknowledge that the continued use of SAP for pyloromyotomy is likely related to concern regarding the risk of mucosal perforation, in which case SAP would theoretically be beneficial to decrease infection risk. However, the risk of mucosal perforation is generally low (<2 % in most studies) [19,20]. We could not directly determine which if any patients had mucosal perforation in this study. However, very few patients (<2 % overall) in this study received post-operative antibiotics, which would be likely in cases of mucosal perforation, and those who did receive post-operative antibiotics did not have notably different outcomes. In addition, we excluded any patients who had an “other” or “concurrent” procedure listed, such as if a duodenal or gastric repair had been required at the time of pyloromyotomy. We therefore believe that the results of this study are applicable to patients *without* mucosal perforation. In the rare cases when mucosal perforation is noted (making the case no longer “clean”), providing a dose of antibiotics is certainly reasonable.

The continued use of SAP could also be related to a persistent lack of understanding regarding whether or not SAP is in fact indicated for an uncomplicated pyloromyotomy. The fact that approximately 25 % of the procedures in this study were classified as clean-contaminated, which we suspect were largely classified as so incorrectly, supports the potential for persistent misunderstanding regarding wound classification and SAP for pyloromyotomy. The utilization of SAP was notably higher in those classified as clean-contaminated, without any differences in SSI rates between the wound classification groups.

Recent research utilizing the NSQIP – Surgical Antibiotic Prophylaxis database has evaluated SAP practices in other pediatric surgeries, providing a strong foundation for this study [5,21,22]. The NSQIP database's standardized, risk-adjusted data collection allows for robust assessments of surgical outcomes and highlights gaps in adherence to evidence-based practices. Building on prior studies, the present analysis demonstrates the lack of benefit from routine SAP in pyloromyotomy and reinforces the importance of aligning clinical practices with current guidelines. These findings contribute to the broader goal of supporting data-driven approaches to antimicrobial stewardship in pediatric surgery.

While the NSQIP-Pediatric database provides standardized and risk-adjusted data, it does not capture specific variables such as surgeon-specific practices, procedural nuances, or hospital-level policies, all of which could influence SSI rates. It is therefore unclear whether the use of SAP is concentrated among a small number of centers or surgeons or is distributed more randomly across all centers and surgeons. Additionally, the database does not account for factors like preoperative skin preparation methods or intraoperative environmental controls, which may independently affect infection risk.

The NSQIP-Pediatric database also has the potential for coding errors. For example, we suspect the percentage of open pyloromyotomies (63 %) is a significant overestimate in this study given the lack of a specific CPT code for laparoscopic pyloromyotomy, which may prompt some to simply use the open pyloromyotomy code rather than the “unlisted laparoscopic procedure on the stomach” code. Given the absence of a specific CPT code for laparoscopic pyloromyotomy and the potential that we could have inadvertently included patients having unlisted gastric procedures for other diagnoses, we performed a sensitivity analysis including only patients with a diagnosis code for pyloric stenosis (98.5 % of the study population), and inferences were unchanged. Finally, NSQIP is limited also in the inability to determine precise reasons for readmission and reoperation, to differentiate between true same-day discharges and short observation stays (more likely for pyloric stenosis) within those classified as outpatient procedures, and to assess longer-term outcomes beyond the 30-day post-operative period, which could overlook delayed infections or complications related to SAP.

Taking into account our findings and study limitations, we suggest the following guideline for patients undergoing pyloromyotomy for hypertrophic pyloric stenosis: SAP can be safely omitted in patients undergoing either open or laparoscopic pyloromyotomy who are classified as ASA Class I or II. This recommendation would apply to isolated procedures performed as inpatient or outpatient procedures for patients without immune-compromising comorbidities, a history of prior SSIs, or other complicating factors such as mucosal perforation. We believe that such a guideline would reduce unnecessary antibiotic use while still ensuring safe and effective surgical care. Future efforts should focus on dissemination and implementation strategies, including leveraging platforms like NSQIP-Pediatric to track SAP use as a quality metric and support hospital-level antibiotic stewardship initiatives for low-risk procedures such as pyloromyotomy.

In conclusion, the findings of this study suggest that SAP for pediatric pyloromyotomy, despite use in nearly 50 % of cases, is unnecessary. Infants undergoing pyloromyotomy, a clean procedure with a low risk of SSIs, do not significantly benefit from SAP use, aligning with recommendations to avoid prophylactic antibiotics in uncomplicated clean surgeries. This study further supports efforts to discontinue routine use of SAP in this patient population to minimize avoidable risks, such as adverse drug reactions and antimicrobial resistance, while ensuring safer, more cost-effective care. These results highlight the need to update clinical guidelines to omit SAP in pyloromyotomy, supporting global efforts to promote antimicrobial stewardship.

Declaration of Generative AI and AI-assisted technologies in the writing process

Generative artificial intelligence of AI-assisted technologies were not used in the writing process.

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Conflict of interest

None.

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