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Original Article

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ABSTRACT

Objective: To determine the frequency of surgical site infections in pediatric patients undergoing elective inguinal surgeries with and without post-operative antibiotic prophylaxis.

Methods: This randomized controlled trial was conducted at the Department of Pediatric Surgery, Fatima Memorial Hospital, Shadman, Lahore, over six months. A total of 88 children aged 2–7 years undergoing elective inguinal herniotomy or orchidopexy were randomized into two groups of 44 each. All patients received a single pre-operative dose of intravenous Ceftriaxone (50 mg/kg). Group A received additional post-operative oral antibiotics (Amoxicillin-Clavulanic acid for five days), while Group B received no post-operative antibiotics. Patients were followed for 30 days post-operatively, and surgical wounds were assessed for signs of infection. Data were analyzed using SPSS version 25, with a p-value < 0.05 considered statistically significant.

Results: The overall incidence of SSI was 5.7% (5 out of 88). Group A had 2 cases (4.5%) of SSI, while Group B had 3 cases (6.8%), a difference that was not statistically significant ($p = 0.64$). All infections were superficial and managed conservatively. No significant difference was found in hospital stay or severity of infections between the two groups.

Conclusion: Routine post-operative antibiotic prophylaxis does not significantly reduce the risk of surgical site infections in clean elective pediatric inguinal surgeries. Judicious use of antibiotics is recommended to reduce the risk of antimicrobial resistance without compromising patient safety.

Keywords: Surgical Site Infection, Pediatric Surgery, Inguinal Hernia, Orchidopexy, Antibiotics, Prophylaxis, Randomized Controlled Trial.

1. INTRODUCTION

Surgical site infections (SSIs) remain one of the most common healthcare-associated infections, contributing significantly to postoperative morbidity, prolonged hospital stays, and increased healthcare costs, particularly in low- and middle-income countries (1, 2). In pediatric surgical practice, inguinal procedures such as herniotomy and orchidopexy are among the most frequently performed operations. These are classified as "clean" surgeries, with inherently low risks of postoperative infection (3, 4). However, the role of prophylactic antibiotics in such cases has been a matter of ongoing debate.

While antibiotic prophylaxis is routinely administered in many surgical procedures to prevent SSIs, its use in clean elective surgeries, including inguinal hernia repair and orchidopexy, is controversial. Several guidelines, including those from the Centers for Disease Control and Prevention (CDC), advise against routine antibiotic prophylaxis in clean surgeries, emphasizing the need to avoid unnecessary antibiotic use to curb the development of antimicrobial resistance (5, 6). Nonetheless, some surgeons continue to administer antibiotics post-operatively, influenced by concerns about potential SSIs and variations in institutional protocols (7).

The global rise in antimicrobial resistance highlights the importance of rational antibiotic use, particularly in pediatric populations, who are more vulnerable to the adverse effects of antibiotics (8). Overuse of antibiotics not only contributes to the emergence of resistant organisms but also exposes patients to unnecessary risks, including allergic reactions, gastrointestinal disturbances, and changes in normal microbial flora (9).

Previous studies evaluating the necessity of perioperative antibiotic prophylaxis in pediatric inguinal surgeries have shown mixed results. Some randomized controlled trials have demonstrated no significant benefit of prophylactic antibiotics in preventing SSIs in clean pediatric surgical cases (10, 11), while others have recommended their selective use in high-risk populations (12).

Given this background, the current randomized controlled trial was designed to assess the frequency of surgical site infections in children undergoing elective inguinal surgeries with and without the administration of post-operative antibiotics. The aim was to determine whether routine post-operative antibiotic prophylaxis provides any significant benefit in preventing SSIs in this population, thereby guiding rational antibiotic stewardship in pediatric surgical practice.

2. METHODOLOGY

This randomized controlled trial was conducted at the Department of Pediatric Surgery, Fatima Memorial Hospital, Shadman, Lahore, over a period of six months, following approval from the Institutional Review Board. The study aimed to evaluate the frequency of surgical site infections (SSI) in children undergoing elective inguinal surgeries with and without post-operative antibiotic prophylaxis. A total of 88 pediatric patients were enrolled through non-probability consecutive sampling. Children aged between 2 and 7 years who were scheduled for elective clean inguinal surgeries, including herniotomy and orchidopexy, were included in the study. Eligible participants had an American Society of Anesthesiologists (ASA) physical status classification of I or II, and informed written consent was obtained from their parents or legal guardians prior to enrollment.

Patients were excluded if they were immunocompromised, had an existing infection at or near the surgical site, required

emergency surgery, had a known allergy to the antibiotics used in the study, or had received systemic antibiotics within the seven days preceding surgery. After applying the inclusion and exclusion criteria, participants were randomized into two equal groups using a computer-generated randomization table. Group allocation was concealed in sealed opaque envelopes, which were opened immediately before surgery. Group A (n = 44) received post-operative antibiotic prophylaxis, while Group B (n = 44) did not receive post-operative antibiotics. All surgeries were performed by consultant pediatric surgeons under standardized aseptic conditions.

Pre-operative skin preparation was carried out using povidone-iodine solution, followed by sterile draping. A standard surgical technique was used for both herniotomy and orchidopexy procedures. All patients in both groups received a single pre-operative dose of intravenous Ceftriaxone (50 mg/kg) administered within 30 minutes prior to skin incision, as per the institutional protocol. In addition, patients in Group A received post-operative oral antibiotics—specifically Amoxicillin-Clavulanic acid at a dose of 25 mg/kg/day in divided doses for five days. Group B did not receive any further antibiotics unless there was clinical evidence of a surgical site infection.

The primary outcome of the study was the incidence of surgical site infection within 30 days of surgery. SSIs were classified according to the Centers for Disease Control and Prevention (CDC) criteria as superficial incisional, deep incisional, or organ/space infections. Secondary outcomes included the severity of infection, duration of hospital stay, and any need for additional interventions. Follow-up evaluations were conducted on post-operative days 3, 7, 14, and 30 by a surgeon who was blinded to the group allocations. During each follow-up, the surgical wound was assessed for signs of infection, including redness, swelling, discharge, tenderness, or wound dehiscence. If infection was suspected, a wound swab was taken for culture and sensitivity testing. Demographic data, surgical details, the occurrence and classification of SSI, length of hospital stay, and complications were recorded using a structured proforma. Confidentiality was maintained by anonymizing patient information. Data analysis was carried out using IBM SPSS Statistics version 25. Quantitative variables such as age, duration of surgery, and hospital stay were presented as mean ± standard deviation, while qualitative variables such as gender, type of surgery, and occurrence of SSI were expressed as frequencies and percentages. The chi-square test was used for the comparison of categorical variables, and independent sample t-tests were used for continuous variables. A p-value of less than 0.05 was considered statistically significant.

3. RESULTS

A total of eighty-eight pediatric patients undergoing elective inguinal surgeries were enrolled in this randomized controlled trial. The participants were randomly assigned into two equal groups: Group A (n = 44), who received post-operative antibiotic prophylaxis, and Group B (n = 44), who did not receive post-operative antibiotics. The baseline characteristics of the two groups were comparable. The mean age of the participants was 4.5 ± 1.6 years, with ages ranging from 2 to 7 years. There were 54 males (61.4%) and 34 females (38.6%), with no statistically significant difference in gender distribution between the two groups. Similarly, the types of surgical procedures were evenly distributed, with herniotomy and orchidopexy being performed at similar rates in both groups ($p > 0.05$).

Table-1: Demographics

Parameter	Group A (n=44)	Group B (n=44)	p-value
Mean Age (years)	4.6 ± 1.5	4.4 ± 1.7	0.68
Gender (M/F)	28 / 16	26 / 18	0.65
Type of Surgery	Herniotomy: 24 (54.5%) Orchidopexy: 20 (45.5%)	Herniotomy: 23 (52.3%) Orchidopexy: 21 (47.7%)	0.83

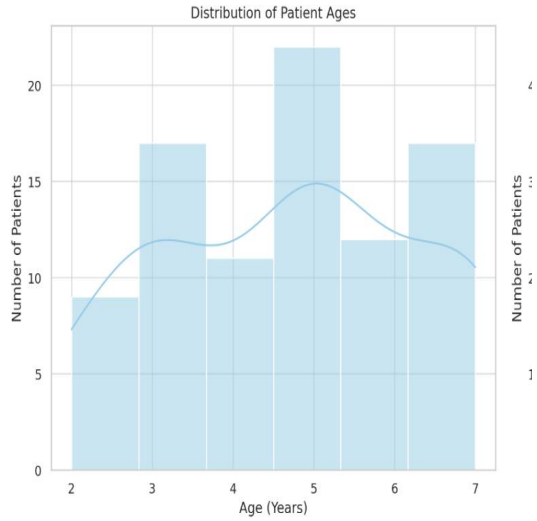

Figure:1

Outcome	Group A (n=44)	Group B (n=44)	p-value
SSI Incidence (%)	2 (4.5%)	3 (6.8%)	0.64
Relative Risk (RR)	Reference	1.5	-
95% Confidence Interval	-	0.25 – 8.87	-

Table-2:Outcomes

In terms of surgical site infections, Group A, which received post-operative antibiotics, had 2 cases of SSI (4.5%), whereas Group B, which did not receive post-operative antibiotics, had 3 cases of SSI (6.8%). Statistical analysis revealed that this difference was not significant (p = 0.64). The calculated relative risk of developing SSI in the no-antibiotic group was 1.5, with a 95% confidence interval ranging from 0.25 to 8.87, indicating no substantial increase in infection risk in the absence of post-operative antibiotic prophylaxis.

Regarding the severity of infections, in Group A, one infection was classified as mild and one as severe. In Group B, two infections were mild and one was severe. All SSIs were superficial and successfully managed with wound care and oral antibiotics. No patients required surgical re-intervention or hospital readmission due to infection-related complications.

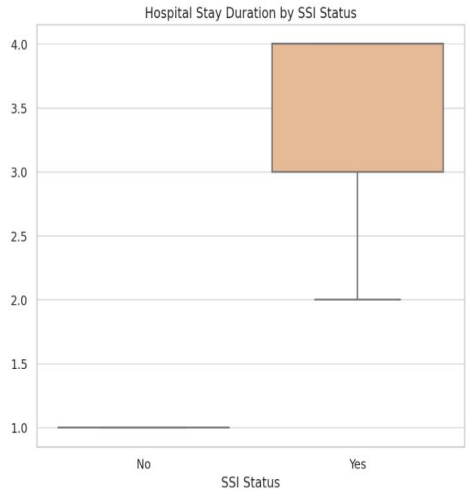

Figure: 2

The length of hospital stay was also analyzed. The median duration for patients without SSI was one day in both groups. However, those who developed SSIs experienced prolonged hospital stays ranging from three to four days. Despite this, there was no statistically significant difference in the overall hospital stay duration between Group A and Group B (p = 0.71).

Graphical representation of the data further illustrated these findings. A histogram demonstrated a uniform distribution of patient ages across both groups. A bar chart comparing SSI cases highlighted the minimal difference in infection rates between groups. A

box plot of hospital stay duration showed a slightly longer stay for patients with SSIs, regardless of group allocation. Additionally, a pie chart of SSI status indicated that 94.3% of all patients did not develop an infection, while 5.7% experienced SSIs.

4. DISCUSSION

Surgical site infections (SSIs) in children undergoing inguinal surgeries are a significant concern in pediatric surgical practice, with implications for morbidity, mortality, and healthcare costs. The incidence of SSIs varies based on numerous factors, including the use of prophylactic antibiotics, underlying health conditions of the children, and surgical techniques employed. Studies have reported varying rates of SSI and highlighted the complexities involved in determining the necessity and efficacy of antibiotic prophylaxis for preventing these infections. The prevalence of SSIs following inguinal surgeries in pediatric patients is well-documented, with surgical site infection being the predominant complication in these settings. For instance, Vaze et al. reported a study demonstrating a lack of significant evidence supporting prophylactic antibiotics due to varying outcomes across patient demographics and clinical presentations (13).

Specifically, this study explored various patient factors impacting infection risk, such as age, surgical time, and surgical approach, which aligns with findings from other studies indicating that SSIs are commonly seen in such surgical procedures (14). Moreover, Emeka noted that surgical site infection is notably prevalent following groin surgeries, underlining the critical need for understanding the epidemiology of these infections to develop effective prevention strategies (15). A thorough analysis of surgical outcomes can show that while some patients experienced SSIs, others exhibited a lower incidence, suggesting that distinguishing risk factors can guide prophylactic strategies more judiciously (16). As inferred from Ibrahim et al., variations in surgical techniques lead to differing SSI rates. In their study, 9.27% of patients experienced surgical site infections post-inguinal herniotomy, signifying a call for adherence to strict surgical guidelines and possibly reconsideration of prophylactic antibiotic use (16).

The literature indicates that antibiotic prophylaxis can significantly lower the risk of SSIs in certain surgical contexts. A meta-analysis by Yan et al. supports the idea that appropriate use of antibiotics results in lower infection rates in various surgical procedures, although the efficacy depends on procedural classification and the specific risks associated with the surgery (17). This is aligned with findings by Napar et al., who reported comparable SSI rates in pediatric surgery without prophylactic antibiotics, suggesting that not all clean procedures necessitate antibiotic use as our study suggested. Overall, the question of whether routine antibiotic prophylaxis is required remains contentious, as evidenced by exploration of different perspectives in pediatric surgical practices. The balance between the benefits and risks of antibiotic use must be carefully managed to avoid unnecessary antibiotic exposure or the development of resistance (18,19). Studies have shown that while prophylaxis can significantly reduce SSIs, outdated practices may lead to increased resistance and adverse effects on population health (20,21).

Beyond the logistical aspects of antibiotic prophylaxis, the impact on healthcare outcomes must also be evaluated. As articulated by Halawi et al., SSIs constitute a considerable percentage of hospital-acquired infections, placing a significant burden on healthcare systems worldwide (21). Effective infection control measures, therefore, should not only consider antibiotic use but also incorporate comprehensive surgical protocols,

including proper sterilization techniques and patient management strategies (22,23).

The data presented in the literature indicates that various risk factors for SSIs must be meticulously analyzed to provide tailored and effective prophylactic strategies. Yoesoef et al. highlighted that the incidence rate of SSIs can vary significantly between different studies, emphasizing the necessity for consistent surveillance and data collection practices to inform best practices (24).

A standardized approach in evaluating the need for prophylactic antibiotics in pediatric surgeries could refine surgical outcomes further and lower the prevalence of SSIs. In conclusion, while the surgical community continues to grapple with the appropriate use of antibiotic prophylaxis in pediatric inguinal surgeries, the available data suggests a nuanced approach that factors in individual patient risk profiles, surgical techniques, and institutional protocols. Future studies must further investigate the long-term impacts of antibiotic use on surgical outcomes and broader public health implications, particularly concerning antibiotic resistance and patient safety. A multidisciplinary approach integrating insights from pediatric infectious disease specialists, surgeons, and epidemiologists may ultimately prove the most effective in combatting the incidence of surgical site infections in children undergoing inguinal surgeries.

5. CONCLUSION

This randomized controlled trial demonstrated that there was no statistically significant difference in the incidence of surgical site infections between children who received post-operative antibiotics and those who did not, following elective clean inguinal surgeries. The findings suggest that routine post-operative antibiotic prophylaxis may not be necessary in such procedures, provided that standard aseptic surgical techniques and appropriate pre-operative antibiotic prophylaxis are adhered to. Eliminating unnecessary post-operative antibiotic use can contribute to reducing the risk of antimicrobial resistance, minimizing medication-related side effects, and lowering healthcare costs. Based on these results, we recommend a more judicious approach to post-operative antibiotic administration in pediatric clean surgeries.

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