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Comparison of complications of distal hypospadias repair with and without the use of postoperative prophylactic IV antibiotics: A randomized controlled trial

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Abstract

Objective

To compare the outcome of distal hypospadias repair in terms of complication rates in paediatric patients with and without the use of prophylactic antibiotics.

Study Design:

Randomized controlled trial

Place and Duration:

This randomized controlled trial was conducted at King Edward Medical University/Mayo Hospital, Lahore, between September 2024 and May 2025.

Methods

Sixty male patients, aged up to 12 years, undergoing tabularised incised plate urethroplasty with stent placement were randomly assigned into two equal groups. Group A received postoperative IV antibiotics (co-amoxiclav and amikacin), while Group B did not. All patients received preoperative IV ceftriaxone. Outcomes assessed included urinary tract infection (UTI), surgical site infection (SSI), wound dehiscence, meatal stenosis, and urethrocutaneous fistula (UCF) at discharge, 15 days, and 30 days postoperatively. The data was analysed using spss and chi square tests applied.

Results

Infection-related complications (UTI and SSI) were observed in 5(2 + 3)/30 patients (16.7%) in Group A compared to 5(1 + 4)/30 (16.7%) in Group B ($p > 0.99$). Rates of UCF were equal in both groups (6.7%), while meatal stenosis occurred in 1/30 (3.3%) in Group A and 2/30 (6.67%) in Group B ($p > 0.99$). Overall complication rates were similar in Group A 8/30 (26.6%) as compared to 9/30 (30%) in Group B.

Conclusion

Routine postoperative IV antibiotics did not significantly reduce overall complication rates in distal hypospadias repair, though a reduction in infection-related complications was observed. These findings suggest that while antibiotics may provide some protection against infection, careful surgical technique and individualized care remain central to optimizing outcomes. Larger multicentre trials are needed to guide future recommendations.

Introduction

Hypospadias is a common congenital condition, where the urethral opening is located on the underside of the phallus in a male rather than at the tip[1,2], affecting 3–5 male infants in 1000 births[1]. Surgical repair is often required to achieve optimal urinary and sexual function, as well as desirable visually appealing outcomes[3]. Distal hypospadias is one of the most observed types. Although various surgical techniques exist, most surgeons use a urinary catheter during the initial postop period[4]. Despite advancements in surgical techniques, postoperative complications such as wound infection and dehiscence, bleeding, fistula and long-term complications such as fistula, chordee or stricture remain a significant concern impacting patient outcomes and quality of life[4,5].

One of the debated aspects in the postoperative management of hypospadias repair is the use of prophylactic intravenous (IV) antibiotics. While some clinicians advocate for their use to prevent infections and other complications, others question their necessity due to potential side effects and the risk of antibiotic resistance[6,7,9]. The recent Centres for Disease Control clinical practice guideline strongly advise against the use of additional prophylactic antimicrobials for clean and clean-contaminated surgeries after the surgical incision is closed in the operating room, despite the presence of drains[8]. Although, the American Urological Association recommends antibiotic prophylaxis for patients undergoing surgeries involving stent placement. However, this recommendation is limited and does not specifically address the use of antibiotics for hypospadias repair with a stent in place[10,11].

In contrast to adult procedures, the guidelines or protocols for postoperative antibiotic use in many paediatric surgeries, including hypospadias repair, are not standardized. Currently, there is no well defined practice or clinical guideline to guide clinicians on postoperative antibiotic prophylaxis for patients undergoing hypospadias repair[6,12]. This randomized controlled trial aims to compare the complications associated with distal hypospadias repair with and without the use of postop prophylactic IV antimicrobials. This study seeks to provide evidence based guidance on the optimal postoperative management strategy for patients undergoing distal hypospadias repair. The findings of this research could have significant implications for clinical practice, potentially leading to improved patient care and resource utilization.

Methods

This randomized control trial was conducted from September 2024 to May 2025 following the authorization by the College of Physicians and Surgeons Pakistan (CPSP) ref no: CPSP/REU/PSG-2022-066-561, ethical approval from Institutional Review Board King Edward Medical University ref number 581/RC/KEMU and trial registration with Australian New Zealand Clinical Trial Registry, registration number ACTRN12625000915459, dated 22-08-2025. 60 patients undergoing urethroplasty for distal penile hypospadias were recruited from the Department of Paediatric Surgery, King Edward Medical University (KEMU)/Mayo Hospital, Lahore. Patients of male gender of ages up to 12 years presenting to

paediatric surgery department with distal penile hypospadias. Patients with re do urethroplasty, malnourished, comorbidities i.e. liver disease, TB and immunodeficient patients were not included. A sample size of 60 patients (30 in each group) was estimated using 80% power of the test and 95% confidence interval (CI). Patients were enrolled using a probability simple random sampling technique. Written informed consent was obtained from all patients' parents/guardians. The initial data was recorded using a predesigned research proforma. All surgical procedures were performed under general anaesthesia. Preop antibiotic prophylaxis included intravenous Ceftriaxone 25mg/kg before induction of anaesthesia. Patients were allocated into two equal groups (1:1 ratio) using random allocation software. Group A received post operative prophylactic antibiotics and Group B did not. The assignment sequence was concealed in pre-sealed numbered opaque envelopes to ensure blinding. Each envelope contained the group assignment for each individual patient. Tabularised incised plate urethroplasty with stent placement was done in patients with distal penile hypospadias. Vicryl 5 – 0 suture was utilized for tube formation and closure of the wounds for every patient. All surgeries were performed by senior registrar or consultant surgeon. Post operatively in Group A, prophylactic antibiotics were given which were inj co-amoxiclav 30mg/kg three times a day and inj Amikacin 7.5mg/kg twice a day via intravenous route for 5 days till stent removal. In Group B, no prophylactic antibiotics were given. During postoperative period, the wound was examined daily for signs of urinary tract infection (UTI), wound infection and dehiscence till the time of stent removal, then at 15th post operative day and then at day 30 on follow-up. Assessment was done clinically, and wound culture and urine cultures were also taken. Patients were also assessed for late complications like meatal stenosis and urethrocutaneous fistula (UCF) on 15th and 30th day. Patients who developed infective complications if present in the group not taking antibiotics were reevaluated and appropriate antibiotics and wound care was given. Data analysis was conducted using SPSS version 23.0. Quantitative variables were reported as mean and standard deviation (SD) while qualitative variables presented as frequency and percentage. Both groups were compared for UTI, wound infection, wound dehiscence, meatal stenosis and UCF using Chi Square Test and Fisher's Exact Test, p-value ≤ 0.05 was considered as significant.

Results

A total of 60 patients were recruited for this study and randomized into two groups. Group A had 30 patients who received post operative prophylactic antibiotics and group B had 30 patients who did not receive post operative prophylactic antibiotic. The mean age in group A was 5.93 years SD 3.7 comparable to the mean age of group B that was 6.17 SD 3.72. The mean hospital stay period in group A and B was 5.93 SD 0.83 and 5.97 SD 0.81 days respectively. In group A there were 2/30 coronal, 23/30 sub coronal and 5/30 distal penile hypospadias whereas in group B there were 2/30 glanular, 13/30 sub coronal and 15/30 distal penile hypospadias.

Urinary tract infection (UTI) was documented in 2 out of 30 patients (6.67%) in the antibiotic group A whereas 1 in 30 patients (3.33%) had UTI in the no antibiotic group B (RR = 0.50; 95% CI: 0.05–5.23). Surgical site infection SSI was 3 out of 30 (10%) in the group receiving antibiotic prophylaxis, whereas 4 out of 30 (13.3%) patients in non-prophylaxis group developed SSI (RR = 0.75; 95% CI: 0.18–3.07). For

both these infection related complications, SSI and UTI combined, 5 out of 30 in group A and 5 out of 30 in group B, the p value is > 0.05, this shows that using antibiotics had no significant effect in reducing the risk of infection related complications. (Table 1)

Table 1
Infection related outcomes (UTI and SSI)

Complication	Group A (Antibiotics) (n = 30)	Group B (No antibiotics) (n = 30)	Relative Risk	p-value [1]
UTI	2 (6.67%)	1 (3.33%)	0.5	> 0.99
SSI	3 (10%)	4 (13.3%)	0.75	> 0.99
[1] *p-value was calculated using Fisher Exact Test*				
Urethrocutaneous fistula (UCF) was seen in 2 out of 30 cases (6.67%) in group A and 2 out of 30 (6.67%) in group B (RR = 1.00; 95% CI: 0.15–6.64). Meatal stenosis was reported in 1 out of 30 cases (3.33%) in group A and 2 out of 30 (6.67%) cases in group B, (RR = 2.00; 95% CI: 0.19–20.90). No wound dehiscence was reported in any of the cases. The overall wound related complications included UCF and meatal stenosis were 3 out of 30 (10%) and 4 out of 30 (13.3%) in group A and B respectively with an insignificant p value of > 0.05. (Table 2)				

Table 2
Wound related outcomes (UCF and Meatal stenosis)

Complication	Group A (Antibiotics) (n = 30)	Group B (No antibiotics) (n = 30)	Relative Risk	p-value[2]
Urethrocutaneous fistula (UCF)	2 (6.7%)	2 (6.7%)	1	> 0.99
Meatal stenosis	1(3.3%)	2 (6.67%)	2	> 0.99
[2] *p-value was calculated using Fisher Exact Test*				

These results suggest no statistically significant difference in outcome rates between groups receiving postoperative antibiotics versus no postoperative antibiotics. However, clinically we can see that there was some advantage of giving postoperative prophylactic antibiotics in term of infection related outcomes. (Fig. 1)

Discussion

The management of distal hypospadias has advanced significantly in recent years, with modern surgical techniques providing better cosmetic and functional outcomes. Nevertheless, postoperative complications such as wound infection, dehiscence, and urethrocutaneous fistula remain a concern for both surgeons and families, often influencing long-term satisfaction with the repair[4,5]. One of the most debated issues in postoperative care is the use of prophylactic antibiotics, particularly when a urethral stent is placed[6,7].

In this randomized controlled trial, we observed no significant difference in early postoperative complication rates between children who received intravenous antibiotics and those who did not. These findings align with recent systematic reviews, including the work of Chua et al., which demonstrated that routine antibiotic prophylaxis in stented distal hypospadias repair offers little to no reduction in infection-related complications[1,14]. Our findings are consistent with the recent double blinded placebo controlled randomised trial of MA Faasse et al., which concluded that the use of prophylactic antibiotics following stented mid-to-distal hypospadias repair yielded no significant difference in the rates of infection or urethroplasty complications compared to placebo[15]. This reinforces the compelling data questioning the utility of antibiotics in such cases[6,7,12].

Broader surgical guidelines also support these findings. The Centres for Disease Control and Prevention (CDC) guidelines advocate against postoperative antibiotics for clean or clean-contaminated surgeries subsequent to wound closure, regardless of drain or catheter placement[8]. Even though the American Urological Association suggests prophylaxis for procedures involving stents, these recommendations are not specific to hypospadias and are based more on expert consensus than on paediatric evidence[10]. Our results suggest that in the setting of distal hypospadias repair, routine postoperative IV antibiotics may not provide additional clinical benefit.

The potential harms of unnecessary antibiotic exposure must also be considered. Overuse of antibiotics is a well-recognized driver of antimicrobial resistance[9,11], which carries profound long-term implications for both individuals and public health. In addition, unnecessary antibiotic use may expose children to avoidable drug-related side effects. As emphasized by Kanaroglou and others, the relatively low risk of infection in hypospadias repair does not justify the broader medical costs of antibiotic overuse[7].

It is also important to highlight that complications following hypospadias surgery are often influenced more by surgical factors than by infection. As Bhat and Mandal noted, issues such as fistula formation and wound dehiscence are frequently related to technical aspects, tissue handling, and vascularity rather than infection alone[5]. This underscores the importance of surgical precision and attentive postoperative care in improving outcomes, rather than reliance on antibiotics.

Our findings support a shift toward a more selective approach in prescribing antibiotics after hypospadias repair. While withholding postoperative prophylaxis appears safe in most cases, individual patient factors such as immunocompromised status, previous urinary infections, or complex anatomy should still guide clinical judgment. Future large-scale, multicentre studies with longer follow-up are needed to further validate these results and assess their implications for late complications such as urethral stricture or fistula formation.

In conclusion, this trial suggests that routine postoperative IV antibiotics in distal hypospadias repair with stent placement do not reduce early complication rates. These results add to the growing evidence base advocating for more judicious antibiotic use in paediatric urology[1,6,7,12], aligning with global efforts to combat antibiotic resistance and optimize resource utilization in surgical practice.

Conclusion

Routine postoperative IV antibiotics did not significantly reduce the overall complication rate following distal hypospadias repair. However, they were highly effective at preventing infection-related complications. The primary, long-term morbidity, urethrocutaneous fistula (UCF), was unaffected. This suggests that non-infectious factors are the main drivers of surgical failure. We conclude that routine IV prophylaxis cannot be universally recommended. Focus should remain on meticulous surgical technique and individualized care. Larger trials are needed to define specific patient groups who might benefit from this antibiotic regimen.

Declarations

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

During the preparation of this work the author used ChatGPT in order to get assistance in writing. After using this tool/service, the author reviewed and edited the content as needed and takes full responsibility for the content of the publication.

Consent to participate

and publish: Informed written consent taken from the participants of the study.

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Author Contribution

MRW: Conceptualization; Methodology; Formal analysis; Writing – original draft; Writing – review & editing.BF: Conceptualization; Methodology; Supervision; Formal analysis; Writing – original draft; Writing – review & editing.KB: Supervision; Writing – original draft; Writing – review & editing.ZZ: Formal analysis; Data curation; Writing – review & editing.BS: Formal analysis; Writing – review & editing.SN: Investigation; Writing – review & editing.SSHZ: Writing – review & editing, Tables

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16. CONSORT Flow Diagram

Figures

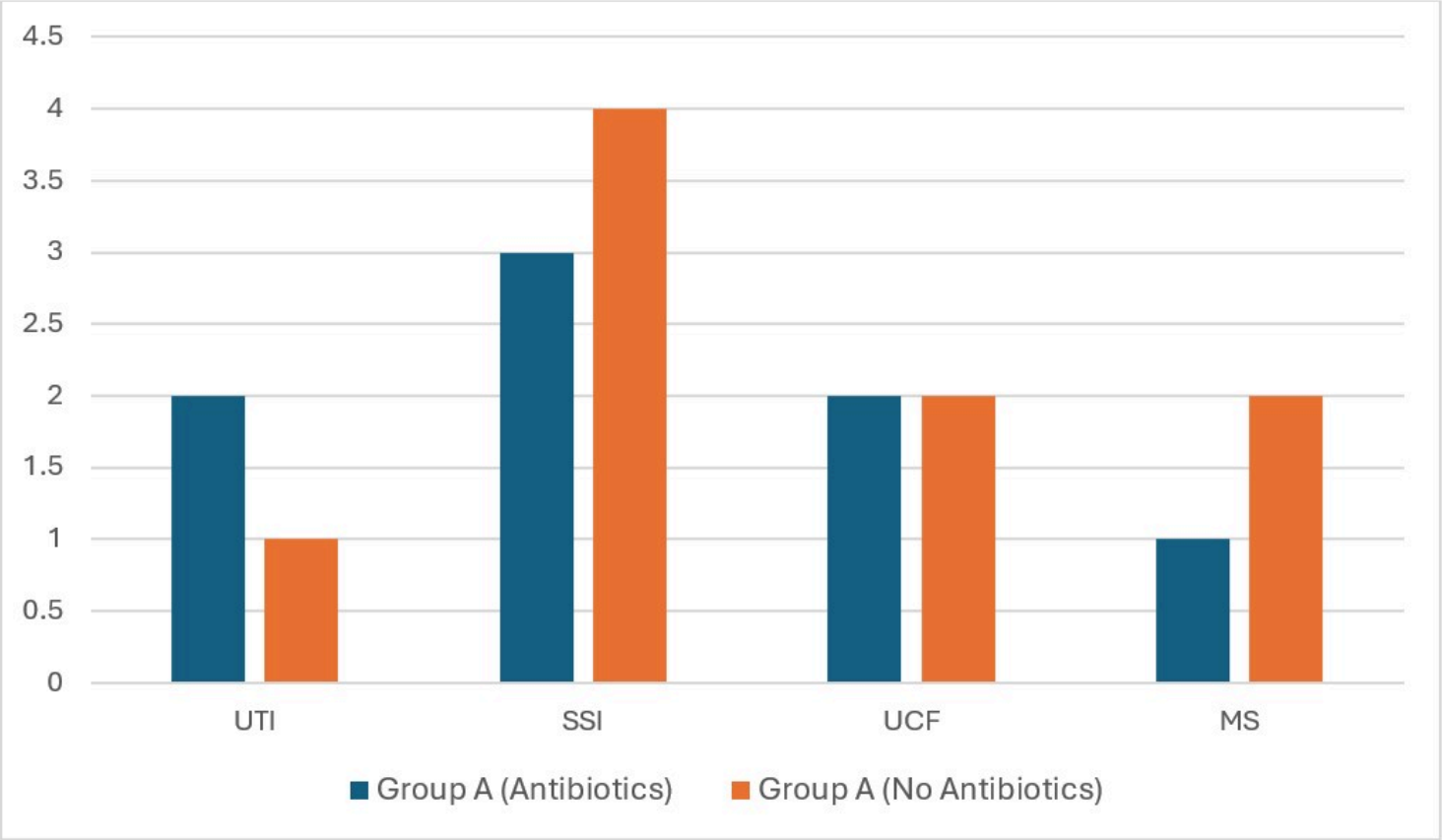


Figure 1

Complication percentage in Group A (with antibiotics-blue) and Group B (without antibiotics-orange)

Supplementary Files

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- 1.jpg