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Original Research

Use of platelet rich plasma gel in preventing healing complications of tubularised incised plate urethroplasty in children with distal and mid-penile hypospadias — A randomized clinical trial

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Keywords
Bio-adjuvant; Children; Hypospadias objective scoring evaluation; Platelet rich plasma; Snodgrass urethroplasty; Urethrocutaneous fistula

Abbreviations
PRP, Platelet Rich Plasma; HOSE, Hypospadias Objective Scoring Evaluation; PRF, Platelet Rich Fibrin; GMS Score, Glans, Meatus, Shaft Score; TIP, Tubularised Incised Plate

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Summary

Introduction
Hypospadias is a common congenital disorder of the male external genitalia which is repaired surgically. Platelet rich plasma (PRP) gel formed by centrifugation of autologous blood has been shown to promote wound healing and has previously been used as a covering layer in hypospadias repair.

Objective
Objective comparison of the occurrence of urethrocutaneous fistula and overall cosmetic appearance after PRP gel application on children with mid and distal penile hypospadias.

Study design
A two arm parallel design randomised controlled trial was performed on 50 children (age <14 years) with distal or mid penile hypospadias at a tertiary care centre in India from July 2024 to July 2025. We compared the patients who underwent Tubularised Incised Plate urethroplasty with PRP gel application (Study Group) to those who underwent standard tubularised incised plate urethroplasty (Control Group).

Results
We noted a comparable preoperative Glans, Meatus and Shaft score between the groups (7.1 v/s 6.7, $p = 0.25$). Urethrocutaneous fistula had lower occurrence in the study group (8/25 v/s 12/25, $p = 0.25$). Post operative Hypospadias Objective Scoring Evaluation (HOSE) scores at 1 and 3 months were significantly different between the study and control groups respectively (14.4 v/s 12.6, $p = 0.001$; 14 v/s 11.7, $p < 0.001$)

Discussion & conclusion
Utilization of platelet rich plasma gel in anterior hypospadias repair is safe and may have a role in reducing the occurrence of urethrocutaneous fistula and improving the overall cosmetic appearance. Its use may be extended to posterior hypospadias and compared to tissue flaps like tunica vaginalis in future studies.

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Introduction

Hypospadias is the second most common congenital defect of the genitourinary system in boys [1]. It presents with a hooded prepuce, abnormal ventral chordee and ventrally located urethral meatus. Functional problems range from a misdirected stream of urine to psychosexual disturbance [2]. Most of the cases require surgical repair by multiple defined techniques. Most common complication of hypospadias repair is formation of a urethrocutaneous fistula [3,4]. Over the years, it has become the bench mark for comparing the success of hypospadias repair. Various technical modifications have been devised to reduce the occurrence of this complication.

Platelet rich plasma (PRP) gel is a platelet concentrate formed by centrifugation of whole blood. It promotes wound healing by acting as a scaffold for red blood cells and fibrin [5,6]. It also contains growth factors and cytokines which promote angiogenesis [7]. The vascular channel development in the hypospadias genitalia is abnormal [8]. Moreover, certain growth factor pathways (Fibroblast Growth Factors 8 and 10) are consistently abnormal in the embryogenesis of hypospadias [9]. Hence there is a growing interest in the utilisation of PRP derivatives during hypospadias surgery. Along these lines, we designed a randomised controlled trial to use PRP gel as a covering layer to decrease healing complications of primary hypospadias repair.

Materials and method

Study design and patients

A prospective, parallel design, participant and outcome assessor blinded, randomised controlled trial was conducted at the Department of Paediatric Surgery in a Tertiary Care Centre, India from July 2024 to July 2025. 50 children with Age <14 years with Primary Distal and Mid penile Hypospadias were randomized (Block randomization — www.sealedenvelope.com) into 2 groups after taking consent. The study was approved by the Institutional Ethics Committee and Research Division. The trial was registered with the Clinical Trial Registry of India with Reference number — CTRI/2024/07/069879. CONSORT Checklist and Flow Chart were completed as detailed in Supplementary Material.

Sample size calculation and groups

Sample Size was calculated as 41 patients per group (82 total) using G*Power Software (Version 3.1.9.7). Assuming effect size of 0.6, Power of 0.80 (1-β), α error probability of 0.05. We further conducted a comprehensive power analysis with levels (85%, 90%, and 95%) and varying effect sizes (0.5, 0.6, and 0.7); and determined that effect size of 0.6 and a power level of 80% align with our research objectives and enable us to attain our desired sample size. All recruitments into the study had to be done by July 2025 as the primary investigator had a limited course duration. Hence, only 50 participants could be enrolled with complete follow up details. Both group patients were operated using standard TIP technique with additional application of PRP gel over urethroplasty in the Study group.

Objectives and outcome measures

The study was done to evaluate the effect of Platelet Rich Plasma Gel (covering layer) on post operative healing complications of urethroplasty. Primary outcome — Proportion of Urethrocutaneous Fistula; Secondary outcomes — HOSE Score [10])

Study procedure

All patients (n = 54) meeting inclusion criteria were approached by the primary investigator (who was unaware of the allocation sequence) and 50 were enrolled after due consent. 4 patients were excluded (2 = exclusion criteria, 1 = did not consent, 1 = discharged pre-surgery citing personal concerns). Demographic data and clinical examination findings were noted preoperatively. Their allocation into either group was concealed by using Sequentially Numbered Opaque Sealed Envelopes (generated using www.sealedenvelope.com by the Department Clerk) and decided just prior to induction of anaesthesia.

After induction of anaesthesia, clinical examination was done under anaesthesia and a Glans-Meatus-Shaft [11] (GMS) score was calculated. Depending on the allotted group, patient's blood sample was used for PRP Gel Preparation and a Tubularised Incised Plate [12] (TIP) Urethroplasty with or without PRP Gel application was performed over a 6Fr feeding tube stent. All surgeries were performed by a single paediatric surgeon with ten years of experience in the subject. The feeding tube was removed on post op day 7. Patients were then followed up in the outpatient clinic at 1 and 3 months where HOSE score was assessed by a single senior resident.

PRP gel preparation

This was performed by the Transfusion Medicine Team using a laminar flow chamber and a Centrifuge (Remi R-4C, Remi Lab World, India) under sterile precautions. 12 ml of whole blood (9 ml in EDTA vial and 3 ml in plain vial) was used (Fig. 1A). The 9 ml tubes underwent 1st low spin cycle at 150G (soft spin cycle at 1400) for 5 min (Fig. 1B). The translucent upper platelet layer underwent a second (high spin cycle at 3400) to yield platelet poor and rich plasma (upper 2/3 and lower 1/3 respectively) (Fig. 1C). The 3 ml blood in the plain vacutainer tube was allowed to clot and then spun at high-speed spin cycle at 3400 to yield a thrombin rich supernatant (Fig. 1D). The Platelet Rich Plasma gel was prepared by combining 3 ml of PRP with 1 ml of thrombin rich supernatant with 1 ml of calcium gluconate in a sterile vacutainer tube for 5 min (Fig. 1E). This PRP which was a gel was grasped with forceps and layered out on a sterile gauze and sized to requirement (Fig. 1F).

Surgical technique

Urethral plate was marked and measured. Complete degloving of penile skin was done. Glans wings were raised.

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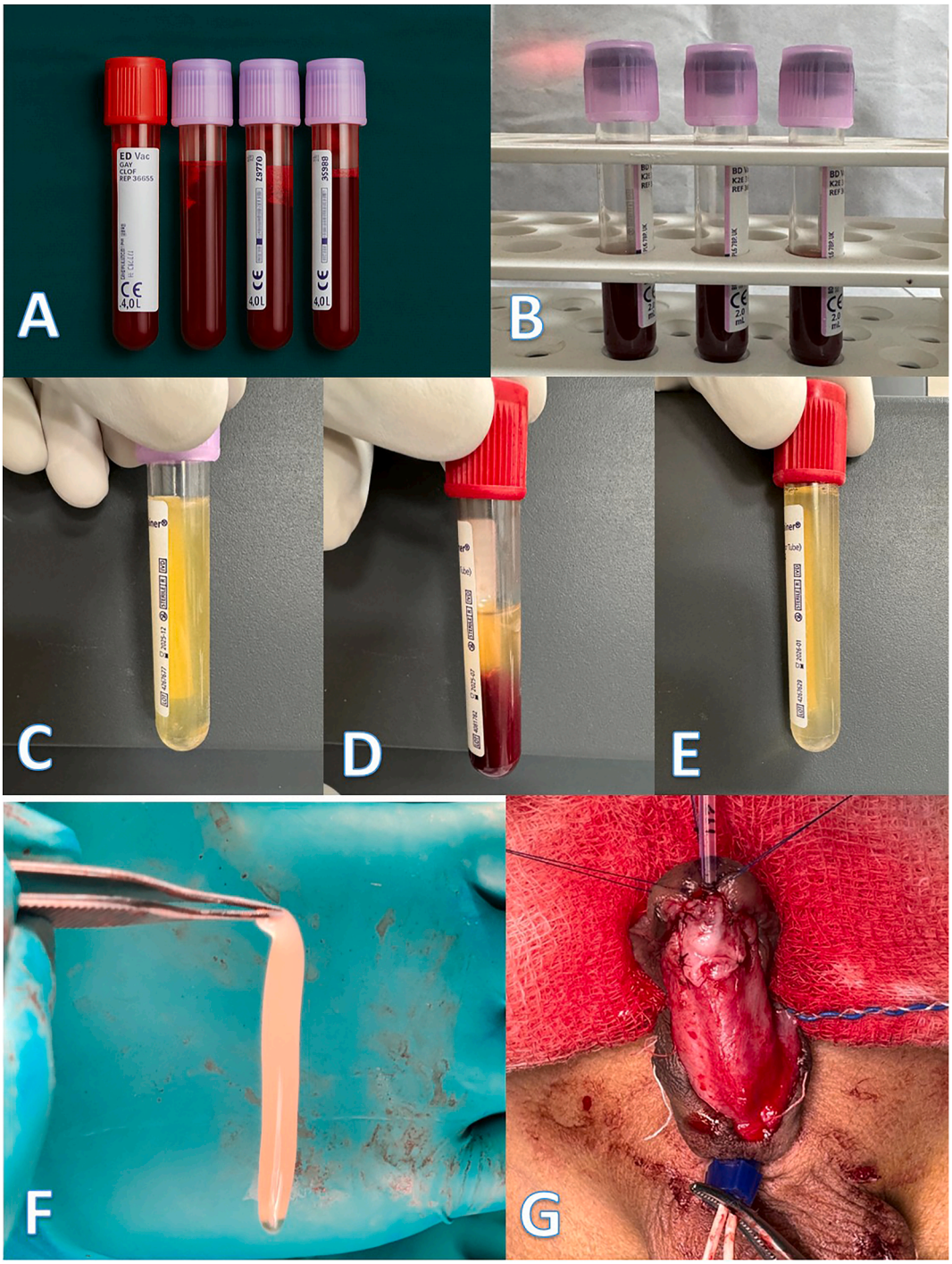


Fig. 1 Preparation and Application of PRP Gel. (A) Collection of Sample, (B) After soft spin of 9 ml sample, (C) Plasma with platelets ready for hard spin, (D) 3 ml plain sample after hard spin to separate thrombin, (E) Formed PRP gel after combining Platelet rich plasma with thrombin and calcium gluconate, (F) Extracted PRP Gel which is trimmed to requirement and (G) Applied and fixed PRP over urethroplasty.

Midline incision was made over the native urethral plate and it was Tubularised over a 6Fr Infant Feeding Tube using 6-0 Polyglactin 910 continuous sutures. The covering layer over this was decided as per the allotment protocol. All study group patients underwent PRP gel application followed by spongioplasty. The platelet gel was secured using 6-0 Polyglactin 910 interrupted sutures (Fig. 1G). Patients in the control group underwent urethroplasty followed by spongioplasty. Skin management was done with dorsal skin flaps rotated ventrally in both groups. A gauze and Tegaderm dressing was done. The dressing was removed on post-op day 4 and the feeding tube on day 7.

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Data collection and statistical analysis

All Data was collected using Google forms and the Google Sheets so formed were cleaned, organised and imported into Jamovi Software (Version 2.6.26) for analysis. Normal distribution of data was checked using the Shapiro–Wilk Test and Q–Q Plots. Descriptive statistics were used for all demographic data and to define the comparability of Study and Control groups. Proportion of Urethrocutaneous fistula between groups were analysed using the Chi Square Test. Between the study and Control groups, HOSE Scores at 1 month and 3 months were compared using independent sample T-test.

Results

50 patients were randomised into study and control group. Normal distribution of data was noted across patient age, GMS score, HOSE score at 1 and 3 months($p = 0.133$ and $p = 0.06$).All patients were accounted for at the end of the study with complete follow up of 3 months as expected. All 50 patients have been analysed to arrive at the results.

Demographic data

Mean age across both groups was 5.8 ± 2.2 years (range 3–12 years) and 5.6 ± 2.3 years (range 3–11 years), in study and control groups respectively. Preoperative GMS Scores were comparable at 7.2 ± 1.2, and 6.7 ± 1.7, in study and control groups respectively ($p = 0.25$). Patient platelet counts; Stretched Penile Length and Penile Circumference were also documented (Table 1).

Urethrocutaneous fistula

Urethrocutaneous Fistula was identified by clinical examination along with examination of urinary stream. At one month of follow up, 8/25 patients developed urethrocutaneous fistula in the Study group and 12/25 patients had a similar outcome in the control group ($p = 0.25$). At 3 months follow up, 1 more patient in the Study group and 2 in the Control group was noted to have a Urethrocutaneous Fistula ($p = 0.16$) (Fig. 2).

Overall appearance

Mean Composite HOSE score was 14.4 ± 1.5 and 12.6 ± 2 (CI 95%) at 1 month post operatively in Study and Control Group respectively ($p = 0.001$). At 3 months, a similar finding was noted (14 ± 1.5 v/s 11.7 ± 2.2, CI 95%, $p < 0.001$) (Fig. 3). A subgroup analysis of study and control group HOSE at 1 month (without fistula score component) revealed composite scores of 10.7 ± 1.2 and 9.1 ± 1.7 ($p < 0.001$) and at 3 months 10.4 ± 1.2 and 8.4 ± 1.7 ($p < 0.001$)

Discussion

Our study is a parallel arm, randomized controlled trial of 50 patients to evaluate the outcomes of using a PRP gel in hypospadias repair. Preoperative demographic variables were comparable. We prefer to operate hypospadias at ages more than 3 years as the child is easier to manage at this age. Preoperative GMS Score was also checked for all patients. It takes into account the glans configuration, meatal location, and degree of penile curvature, providing a unified score that reflects the overall anatomical complexity. With mean scores of 7.2 in the Study Group and 6.7 in the Control Group ($p = 0.25$), we could conclusively say that both groups have comparable preoperative characteristics. Among the previously published similar studies [13–15], we were unable to find a preoperative objective assessment between Study and Control groups to ensure comparability.

Surgical correction of hypospadias aims to restore urinary function, cosmetic appearance as well as sexual function. One of the most frequently encountered and challenging complications is urethrocutaneous fistula (urethro-cutaneous fistula), with reported incidence ranging from 5% to 30%, depending on the severity of the hypospadias and the surgical method used [12,16]. Various strategies have been explored to improve healing and reduce complication rates, including the use of interposition tissue layers like foreskin flaps [17], Dartos flap [18], Tunica Vaginalis [19,20] and adjunctive therapies like fibrin glue [13,21].

PRP use has been investigated in hypospadias repair, yielding favorable results in lowering postoperative complications. In research conducted by Eryilmaz et al., children receiving PRP exhibited reduced rates of urethral fistulas, stenosis, and infections compared to those in the control group [14]. Mahmoud et al. recorded fewer complications in patients treated with PRP, such as urethrocutaneous fistula and urethral stricture, indicating its potential to enhance surgical outcomes in hypospadias repairs [13].

In our study, at one-month post-operatively, the proportion of patients with urethro-cutaneous fistula was more in the control group ($n = 12$) as compared to the Study group ($n = 8$). At 3 months post-operatively, similar findings were

Table 1 Baseline demographic and clinical characteristics for each group.

	Study group (n = 25)	Control group (n = 25)	P
Age (in years)	5.80	5.64	0.70
Weight (in Kg)	20.88	18.72	0.28
GMS score	7.16	6.68	0.25
Platelet count (in lakhs)	3.60	3.06	0.09
Stretched penile length (in cm)	4.40	4.38	0.97
Penile circumference (in cm)	4.15	4.04	0.69

$P < 0.05$ is significant.

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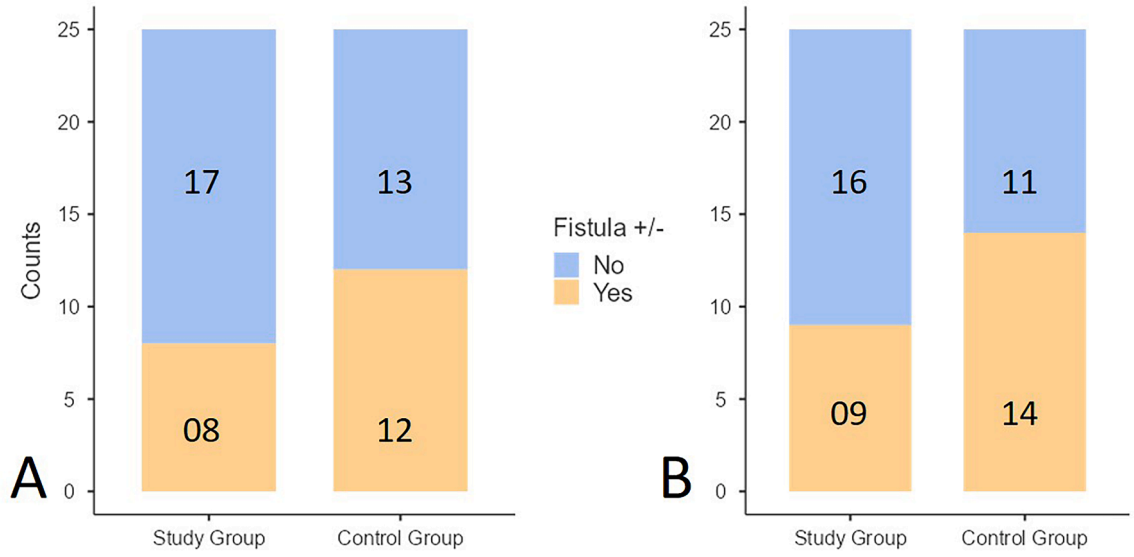


Fig. 2 Proportion of patients with Urethro-cutaneous fistula in Study and Control group at 1 month (Panel A) and 3 month (Panel B) follow up.

noted with one more urethro-cutaneous fistula in the Study Group and two in the control group. Mahmoud et al. conducted a randomized trial on 180 boys using PRP covering and noted a similar outcome. While in their study, 9 patients with PRP application developed urethro-cutaneous fistula, 12 patients had this outcome in the Control group ($p = 0.642$). Another well-structured randomized trial from Turkey noted 2/20 urethro-cutaneous fistula in PRP cases while normal repair cases had 5/20 urethro-cutaneous fistula ($p = >0.05$) [14]. In a recent Prospective Randomized study from Egypt a decrease in incidence of urethro-cutaneous fistula was noted in patients with Platelet Rich Fibrin application as compared to a Dartos flap (1/22 v/s 4/22, $p = 0.48$) [15]. Another study from Egypt documented more incidence of urethro-cutaneous fistula in the Platelet Rich Fibrin gel group as compared to the Dartos flap group (4/30 vs 3/30, $p = 0.69$) [22].

Post operative evaluation with HOSE Score at 1 month and 3 months showed a significant difference in mean scores (14.4 v/s 12.3 at 1 month, 14.1 v/s 11.6 at 3 months, p value < 0.001). Very few previous studies have objectively defined postoperative appearance of the penis after application of PRP gel. A total score of $\geq$14 has been suggested as acceptable standard [10]. The largest study with a sample size of 180 patients used a simple evaluation by parents into good, acceptable, bad or indifferent with almost comparable results in both groups (73% v/s 69% good) [13]. A higher HOSE score suggest a cosmetically better appearance and may be linked to higher self-confidence and quality of life [2].

A Systematic Review conducted by Borkar et al. to analyze the effect of Platelet Rich Concentrates on various outcome variables of hypospadias repair included 4 studies with a pooled analysis of about 350 patients [13,14,23—25].

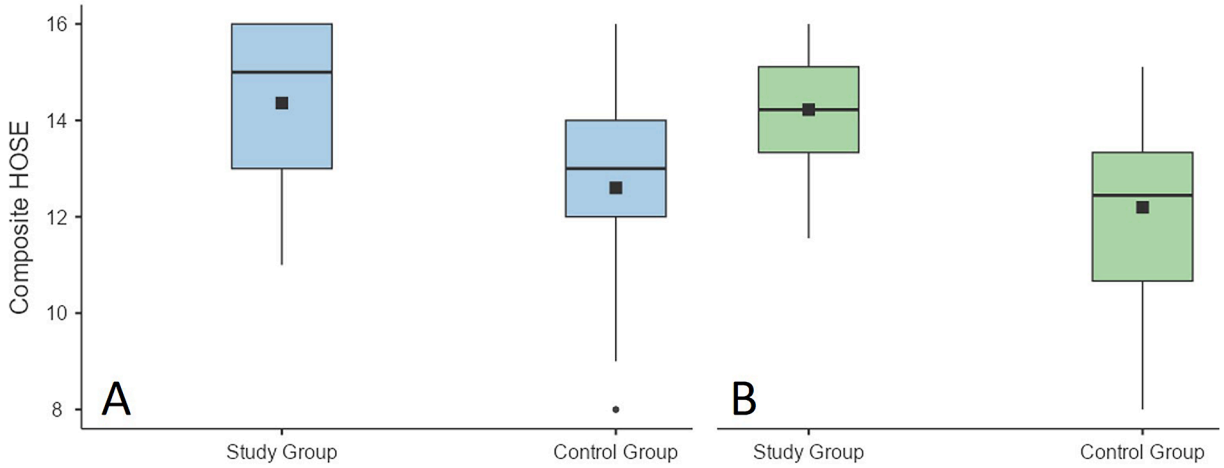


Fig. 3 Box and Whisker plot of HOSE (Hypospadias Objective Scoring Evaluation) at 1 month (Panel A) and 3 months post-operatively (Panel B).

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The authors noted no difference in the pooled outcome analysis when comparing complications of urethrocutaneous fistula, meatal stenosis, glans dehiscence and wound infection between Study and Control groups. Although the analysis appears majorly influenced by the outcomes from a single study which represents more than half of the total sample size (180/350) [13].

Few other bio-adjuvants have also been tried for prevention of urethrocutaneous fistula. Recent review articles have documented the various available biological adjuvant coverings for primary and redo hypospadias repair [26—28]. Other available Adjuvants include Tissue Glues/Sealants like Fibrin glue, Cyanoacrylate glue, Bioglue and Acellular Dermal Matrices which may be Autologous, Allogenic or Xenogeneic [28].

Our study has certain limitations. First, our relatively small sample may increase risk of type II errors, reduced statistical power, vulnerability to outliers and generalizability issues. Second, the follow-up duration was brief. Thus, additional research with long-term follow-up is required to uncover any late complications like stenosis, cosmetic issues or even urethrocutaneous fistula. Third, the study did not evaluate the efficacy of using the PRP gel in comparison to different flap like Dartos or Tunica Vaginalis. Fourth, the rates of fistula formation are high across our entire cohort. A deeper retrospective analysis is required to ascertain our institutional baseline. Fifth, the study was conducted at a single center, therefore, multicenter studies are planned to gather more information and provide more accurate results.

Conclusion

In our randomized clinical trial with a short follow-up, we noted a lower proportion of urethrocutaneous fistula in the Study group and a significant difference in the overall appearance at follow up using an objective, validated and simple HOSE Score. While, PRP gel may have a role in preventing healing complications of anterior hypospadias repair, larger studies with long follow up would be able to substantiate these claims.

Ethical approval

This research was approved by the Institutional Ethical Committee and was registered as a Clinical Trial with CTRI, India.

Consent

Consent was taken from the parents before enrollment of each patient and separate consent for surgery and anesthesia were also taken.

Generative AI

Generative AI and AI-assisted technologies were NOT used in the preparation of this work.

Funding source

This research did not receive and funding from any sources.

Conflict of interest

All authors declare that no conflict of interest were present that could inappropriately influence or bias their work.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jpurol.2026.106173.

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