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Diagnostic Accuracy of Uroflowmetry for Urethral Strictures in Pediatric Hypospadias: TIP vs. Non-TIP Outcomes

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Abstract:
Introduction: To evaluate the diagnostic accuracy of uroflowmetry in detecting pediatric urethral strictures following Tubularized Incised-Plate (TIP) and non-TIP urethroplasty.
Materials and Methods: A retrospective cohort study was conducted on children who underwent primary hypospadias repairs from June 2016 to June 2023 at our institution. Patients were categorized into the TIP and the non-TIP groups. Urethral calibration and uroflowmetry were used to evaluate urethral patency following urethroplasty. Data on demographic characteristics, perioperative information, uroflowmetry results, urethral calibration outcomes, and postoperative complications were collected. The relationship between calibration and uroflowmetry and the diagnostic accuracy of uroflowmetry for urethral strictures were analyzed.
Results: A total of 62 cases were included, with 38 in the TIP group and 24 in the non-TIP group. Ten patients were diagnosed with urethral strictures. The maximum urinary flow rate (Qmax) exhibited a higher area under the curve (AUC) than the average urinary flow rate (Qave) in both the TIP and non-TIP groups. The Qmax in the non-TIP group demonstrated a higher AUC than in the TIP group (non-TIP: AUC=0.94, Cut-off=6.65 ml/s, sensitivity=100%, specificity=81.0%; TIP: AUC=0.80, Cut-off=5.75 ml/s, sensitivity=100%, specificity=58.1%). A significant quadratic correlation was found between Qmax and urethral calibration (non-TIP: C2=14.72*Qmax, R2=0.96; TIP: C2=14.76*Qmax, R2=0.88). The Qmax nomogram interval ≤ -3 standard deviation was a significant predictor for non-TIP urethral strictures (Kappa=0.70).
Conclusions: Uroflowmetry, particularly Qmax, shows promise as a non-invasive screening tool for detecting urethral strictures after hypospadias repair, with high diagnostic accuracy in non-TIP cases but limited utility in TIP cases.

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Introduction

Urethral stricture is a common complication following hypospadias repairs, posing significant management challenges and the risk of multiple reoperations[1]. Long-standing urethral strictures can lead to urinary retention, urinary tract infections, bladder dysfunction, and in severe cases, renal damage. In a minority of pediatric patients, urethral stricture may even results in erectile dysfunction[2]. Current diagnostic methods, such as retrograde urethrography and cystoscopy, are considered the gold standard for diagnosing urethral strictures[3, 4]. Urethral calibration is also a relatively straightforward method for diagnosing strictures and can be performed on an outpatient basis[5]. Sometimes, these invasive procedures need to be done under anesthesia, and may cause pain or other potential complications. Therefore, there is a need to explore non-invasive methods to reduce post-examination complications, minimize pain, and improve examination cooperation in pediatric patients.

Uroflowmetry records the volume of urine and the duration of micturition through electronic devices, providing the maximum urinary flow rate (Qmax) and the average urinary flow rate (Qave)[6]. It is the best non-invasive urodynamic examination for detecting lower urinary tract obstruction[7]. However, the results of uroflowmetry do not always match the actual presence of urethral stricture in some patients[8, 9], which limits its diagnostic utility in cases with suspicious urethral stricture. In clinical practice, further invasive examinations are still needed to confirm the presence of true urethral stricture in patients whose uroflowmetry suggests possible stricture. Moreover, current evidence is insufficient to recommend a specific cut-off value for Qmax or Qave to determine the appropriateness of treatment.

Low urinary flow rates are common after hypospadias repair, especially following tubularized incised plate (TIP) urethroplasty. Previous studies and clinical experience suggest that the diagnostic accuracy of uroflowmetry may vary between TIP and non-TIP patients[10, 11]. TIP urethroplasty utilizes only the urethral plate, while non-TIP procedures may involve the foreskin or other tissues. These differences and biological variations between tissues may affect postoperative urination, urethral compliance, and scar formation. Therefore, this study compares the diagnostic performance of uroflowmetry for urethral stricture in TIP and non-TIP patients using urethral calibration as the reference standard, and explores the potential quantitative relationship between uroflowmetry and urethral calibration.

Materials and Methods

Study Design

This study is a retrospective cohort study. Data were collected retrospectively from consecutive patients who underwent primary hypospadias repairs at our center from June 2016 to June 2023. Patients were divided into TIP and non-TIP groups based on their primary surgical techniques. This study complied with all principles and regulations of the Helsinki Declaration and was approved by the Ethics Committee of our hospital, with the ethical number 2024-IRB-0262-P-01.

The inclusion criteria were as follows: (1) Primary hypospadias; (2) age < 18 years old; (3) the non-TIP group included patients who underwent one-stage and staged Duckett, Duckett + Duplay procedure, Onlay, and Mathieu procedures, and the TIP group consisted of patients who only underwent TIP procedure; (4) the availability of both urethral calibration data and uroflowmetry data within one month before calibration postoperatively; (5) follow-up > 12 months. Exclusion criteria were: (1) Uroflowmetry data with a voided volume of less than 50 mL; (2) urethral dilation, cystoscopy, or catheterization were performed within one month prior to uroflowmetry; (3) patients with concomitant posterior urethral valves or neurogenic bladder.

Surgical techniques nuances

The surgeries were all performed by doctors with more than 10 years of rich experience in hypospadias surgery. The materials for urethroplasty vary considerably among different hypospadias repair techniques. In the TIP or Duplay procedures, the native urethral plate is used as the urethroplasty material. By contrast, the Duckett procedure utilizes a vascular pedicled prepuce, and the Onlay or Mathieu procedures incorporate a combination of the native urethral plate and the prepuce. The severity of hypospadias cases suitable for different surgical techniques differs significantly. The one-stage or staged Duckett, or Duckett + Duplay procedure, is generally indicated for proximal hypospadias or those accompanied by severe chordee. Conversely, the TIP, Onlay, and Mathieu procedures are commonly used for mid or distal hypospadias. Moreover, the development state of the urethral plate plays a vital role in determining the appropriate surgical approach. The TIP procedure relies on a well-developed urethral plate. In contrast, the Onlay and Mathieu procedures show greater adaptability to cases with suboptimal urethral plate development.

Calibration and Uroflowmetry

Calibration could be conducted on an outpatient basis without anesthesia when there was a parental request or suspicion of urethral stricture. It could also be conducted under anesthesia during surgeries for associated conditions not requiring urethral reconstruction, such as prepuce epidermoid cysts, hydrocele, and undescended testes. Urethral calibration was performed by surgeons experienced in hypospadias repairs. The calibration value (C) was defined as the largest size of the urethral sound that could be inserted without significant resistance, breakthrough feeling, or causing noticeable pain for outpatients. Urethral stricture was defined as a calibration value less than 8Fr (< 1 year), less than 10Fr (1 to pre-puberty), and less than 12Fr (post-puberty)[12, 13]. Uroflowmetry was performed by trained professionals using a uroflowmeter (Medical Measurement Systems, Netherlands) in patients without untreated postoperative urethral fistulas or dehiscence. The assessment included maximum urinary flow rate (Qmax), average urinary flow rate (Qave), and Siroky nomogram intervals. Collecting data on demographic information, surgical techniques, uroflowmetry results, urethral calibration outcomes, and postoperative complications.

Sample Size

In this retrospective cohort study, participants were divided into two groups: the urethral calibration group and the uroflowmetry group, with urethral stricture serving as the primary outcome measure. The diagnostic difference between the two groups for urethral stricture is 10%, with a standard deviation of uroflowmetry being 4. Assuming a two-sided alpha of 0.05 (one-sided 0.025), a power of 0.9 (1-beta), and a non-inferiority margin of 4, and referring to the method by Chow et al.[10], the calculated sample size for the urethral calibration group is 23 cases, and for the uroflowmetry group is 23 cases. Considering a 10% loss to follow-up and refusal rate, a minimum of 26 cases per group is required.

Statistical Analysis

Data analysis was conducted using SPSS 26.0 and R 4.4.0. Non-normally distributed continuous variables were expressed as median with interquartile range (IQR), and comparisons between groups were made using the Mann-Whitney test. Categorical variables were expressed as frequencies and percentages, and comparisons between groups were made using chi-square tests, Kappa tests, or Fisher's exact tests. Missing values were replaced with the median. The Receiver Operating Characteristic (ROC) curve was used to evaluate the diagnostic efficacy of uroflowmetry for urethral stricture, with the Youden index used to set the optimal cut-off value. Curve regression was used to investigate the correlation between uroflowmetry and urethral calibration. A *P*-value of less than 0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 62 children were included in the study (**Figure 1**), with 38 in the TIP group and 24 in the non-TIP group, followed up for a median of 4.00 years (IQR 3.00-6.75). The median Qmax was 5.50 (IQR 3.50-7.50) ml/s in the TIP groups and 8.70 (IQR 6.60-10.62) ml/s in the non-TIP groups, showing a statistically significant difference between the two groups (P=0.003). The median urethral calibration was 10.00 (IQR 9.25-11.00) Fr in the TIP group and 11.00 (IQR 10.00-13.00) Fr in the non-TIP group, also showing a statistically significant difference (P=0.021). Ten children were diagnosed with urethral strictures. Baseline characteristics are presented in **Table 1**.

Diagnostic Accuracy of Qmax and Qave for Urethral Stricture

ROC analysis was used to assess the diagnostic accuracy of Qmax and Qave for urethral strictures (**Supplements S1**). In the non-TIP group, the area under the curve (AUC) for Qmax was 0.94 (Cut-off=6.65 ml/s, sensitivity=100%, specificity=81.0%), higher than that of Qave with 0.91 (Cut-off=4.95 ml/s, sensitivity=100%, specificity=71.4%). In the TIP group, the AUC for Qmax was 0.80 (Cut-off=5.75 ml/s, sensitivity=100%, specificity=58.1%), higher than that of Qave with 0.70 (Cut-off=3.20 ml/s, sensitivity=71.4%, specificity=67.7%).

Diagnostic Accuracy of Uroflowmetry Nomogram Intervals for Urethral Stricture

Uroflowmetry Siroky nomogram intervals Qmax ≤ -3 standard deviation (SD), Qmax < -2SD, Qave ≤ -3SD, and Qave < -2SD were used to perform Kappa consistency tests for the diagnosis of urethral stricture. In the non-TIP group, the Qmax nomogram interval ≤ -3 SD showed good consistency for the diagnosis of urethral stricture (Kappa=0.70), with the ROC curve showing an AUC of 0.95 (Cut-off=0.5, sensitivity=100%, specificity=91.0%) (**Supplements S1**). In contrast, the intervals Qmax < -2 SD, Qave ≤ -3SD, and Qave < -2SD showed poor consistency for the diagnosis of urethral stricture (Kappa=0.29, 0.00, and 0.50, respectively). In the TIP group, the intervals Qmax ≤ -3SD, Qmax < -2SD, Qave ≤ -3SD, and Qave < -2SD also showed poor consistency for the diagnosis of urethral stricture (Kappa=0.37, 0.13, -0.18, and 0.08, respectively).

Relationship Between Uroflowmetry and Urethral Calibration

Curve regression analysis was used to examine the relationship between uroflowmetry and urethral calibration (**Supplements S2**). In the non-TIP group, a strong quadratic correlation was found between urethral calibration and Qmax (C^2=14.72*Qmax, R^2=0.96, P<0.001), which was superior to the correlation in the TIP group (C^2=14.76*Qmax, R^2=0.88, P<0.001). Similarly, in the non-TIP group, a strong quadratic correlation was found between urethral calibration and Qave (C^2=23.92*Qave, R^2=0.96, P<0.001), which was superior to the correlation in the TIP group (C^2=23.21*Qave, R^2=0.87, P<0.001).

Discussion

This study evaluates the diagnostic accuracy of uroflowmetry in detecting urethral strictures following hypospadias repair in children. By comparing uroflowmetry results with urethral calibration, we found that uroflowmetry, particularly Qmax, can effectively indicate the presence of urethral strictures in non-TIP patients. For non-TIP patients with a urine flow rate lower than 6.65 ml/s, the presence of urethral stricture should be considered. The diagnostic accuracy of urethral stricture is superior when the nomogram interval is less than -3SD compared to -2SD. The use of the formula C^2=14.72*Qmax allows for the non-invasive estimation of urethral calibration. The diagnostic significance of uroflowmetry for urethral strictures in TIP patients is limited, yet it still holds considerable value for screening purposes. In summary, uroflowmetry can serve as a routine follow-up procedure after hypospadias surgery to aid in the detection of urethral strictures.

In the diagnosis of urethral strictures, methods like retrograde urethrography, cystoscopy, urethral calibration, and uroflowmetry are commonly used[11]. Visual methods such as retrograde urethrography and cystoscopy show stricture details but have low patient compliance (54.4%)[14]. Urethral calibration, using a sound to measure urethral circumference, is a simple diagnostic method for urethral strictures that can be performed in an outpatient setting. Campbell[7] and Snodgrass[15] suggest that calibration < 8Fr with urination symptoms indicates stricture. However, some researchers find it hard to differentiate calibration from dilation due to potential stricture dilation during the procedure[16]. Therefore, the current study defines calibration as the maximum size of sound entering without significant resistance, breakthrough sensation, or severe pain for outpatients. Considering the convenience of clinical application, urethral calibration was chosen as the main diagnostic method, with only a few patients undergoing retrograde urethrography and cystoscopy (not included in the data).

Uroflowmetry is being investigated as an independent diagnostic tool for urethral stricture. Erickson et al.[17] demonstrated that reduced uroflowmetry accompanied by urinary symptoms has 99% sensitivity and 98% specificity for diagnosing urethral strictures. Yanagi et al.[18] showed the effectiveness of uroflowmetry in predicting the anatomical success of urethroplasty, with positive predictive values of 86% for Qmax and 87% for ΔQ (Qmax -

Qave). Considering that ΔQ may reflect urinary flow obstruction[19], the current study included ΔQ in analyses, finding it not more accurate than Qmax, as detailed in **Supplements S3 and S4**. Lambert et al.[20] established a predictive model for adult urethral strictures, using the formula (1.675Ln[Qmax] - 4.360Sqrt[ΔQ] + 4.146) to score patients, distinguishing healthy individuals from those with urethral strictures. These studies highlight uroflowmetry's value, but most were on adults, and pediatric data is lacking. Unlike adults, where posterior strictures are common, children mostly have anterior strictures post-hypospadias surgery[21]. This study proposed a non-invasive formula using Qmax for pediatric strictures, which holds practical significance for clinical application.

The results of this study indicate that in the non-TIP group, both Qmax and Qave have high sensitivity and specificity in diagnosing urethral strictures, with Qmax showing superior performance. Boroda et al.[22] propose that the repaired hypospadias urethra, especially those with longer tube lengths, may not behave like a standard rigid tube, which could affect Qmax more significantly than Qave. Furthermore, our study indicates that the urinary flow rate nomogram interval of less than -2SD does not effectively reflect the presence of urethral stricture. This is likely because the standards for obstructive urination established from adult studies are not applicable to children. A threshold of ≤ -3SD can effectively reflect urethral stricture in children who have undergone non-TIP surgical techniques. This is important because children have smaller bladders and urethras, leading to lower flow rates compared to adults. Additionally, structural abnormalities are inherent in hypospadias cases in children. Therefore, using a threshold of ≤ -3SD offers greater diagnostic accuracy and sensitivity for urethral stricture compared to the < -2SD.

The correlation between uroflowmetry and urethral calibration in TIP patients is not as good as in non-TIP patients, which may be related to the "gourd-shaped" configuration of the urethra[23] or decreased urethral compliance[10] following TIP surgery. Due to possible structural and/or functional abnormalities of the urethral corpus spongiosum in children with hypospadias, the spongiosum is limited in expansion during urination, leading to low uroflow rates. Nonetheless, such abnormalities do not impact the outcomes of urethral calibration assessments. While uroflowmetry's diagnostic value is limited, its 100% sensitivity and non-invasive nature offer significant screening value. And long-term observational studies have demonstrated a substantial increase in uroflowmetry values during puberty for TIP patients. Consequently, the uroflowmetry and urethral calibration of TIP patients may become more aligned after puberty, which requires further follow-up studies to validate[11, 24].

This study has several limitations. Firstly, as a retrospective study, the long follow-up period and the fact that some patients were followed up locally led to missing data. The use of median values to replace missing data may introduce information bias. Secondly, uroflowmetry results can be affected by the volume of urine voided, making it difficult to standardize the voided volume, which may impact the results. However, this study analyzed the uroflowmetry nomogram intervals to minimize the influence of voided volume on uroflowmetry results. Thirdly, urethral calibration is not a routine examination for patients with normal urine flow and urine flow rate, leading to a lack of a large amount of normal urethral data and causing selection bias. Lastly, this study is based on a single center with a small sample size, and it did not grade the severity of urethral strictures, which limits the generalizability of the findings. Therefore, future multicenter, large-sample, prospective cohort studies are needed to further validate our findings and refine the diagnostic thresholds of uroflowmetry for urethral strictures of varying severities.

Conclusions

Uroflowmetry, particularly Qmax, shows promise as a non-invasive screening tool for detecting urethral strictures after hypospadias repair, with high diagnostic accuracy in non-TIP cases but limited utility in TIP cases. Further multicenter prospective studies are needed to validate these findings, refine diagnostic thresholds, and integrate uroflowmetry into standardized pediatric follow-up protocols.

Author contributions

W.R.: Concept and design, methodology, data verification, statistical analysis, revision of the manuscript, and funding acquisition. H.L.: Concept and design, methodology, data collection, statistical analysis, and manuscript drafting. J.Z.: Concept and design, methodology, data collection, revision of the manuscript, and critical appraisal of the manuscript. Q.H.: Methodology, statistical analysis, revision, and critical appraisal of the manuscript. F.Y.: Reviewed proposal, statistical analysis, revision, and critical appraisal of the manuscript. L.H.: Reviewed proposal, revision, and critical appraisal of the manuscript. G.C.: Concept and design, methodology, project administration, revision, and critical appraisal of the manuscript. Y.Y.: Concept and design, methodology, project administration, revision, final approval of the version to be published.

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Data availability

Data are available upon request.

Conflict of interest

None.

Consent for publication

This is a retrospective cohort study using an anonymized dataset, which was approved by the Ethics Committee of our hospital (2024-IRB-0262-P-01).

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Figure 1. Flowchart.

Table 1. Baseline characteristics.

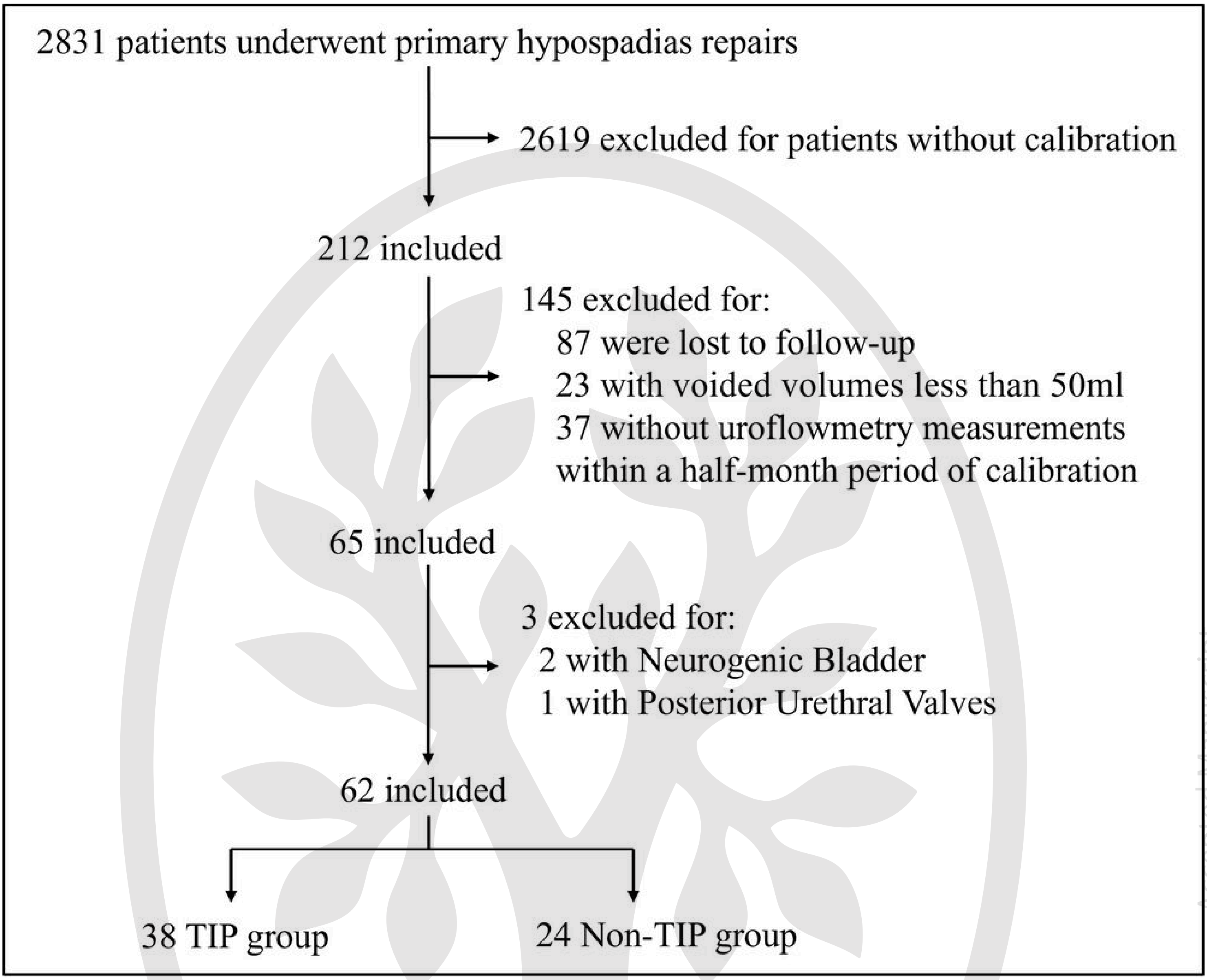
Variables	Total (n = 62)	TIP (n = 38)	Non-TIP (n = 24)	Statistic	*P*-value
Surgical information					
Age at Surgery (months), M (Q_1, Q_3)	15.00 (9.00, 31.50)	14.50 (8.25, 36.25)	15.00 (10.00, 23.00)	Z = -0.06	0.949
Glans Diameter (mm), M (Q_1, Q_3)	14.00 (13.00, 15.00)	14.00 (13.00, 16.50)	13.25 (13.00, 14.00)	Z = -1.33	0.182
Degloved Curvature, M (Q_1, Q_3)	20.00 (5.00, 45.00)	15.00 (2.50, 20.00)	60.00 (45.00, 90.00)	Z = -4.97	**< 0.001**
Urethral Plate Width (mm), M (Q_1, Q_3)	4.00 (2.50, 5.00)	4.00 (2.75, 5.00)	2.50 (2.00, 4.50)	Z = -0.95	0.345
Meatus Location#, n (%)				-	**0.006**
Proximal	18 (32.73)	7 (18.92)	11 (61.11)		
Midshaft	30 (54.55)	25 (67.57)	5 (27.78)		
Distal	7 (12.73)	5 (13.51)	2 (11.11)		
Surgical techniques, n (%)				-	-
TIP	38 (61.29)	-	-		
Non-TIP	24 (38.71)	-	-		
One-stage Duckett	11 (45.83)	-	-		

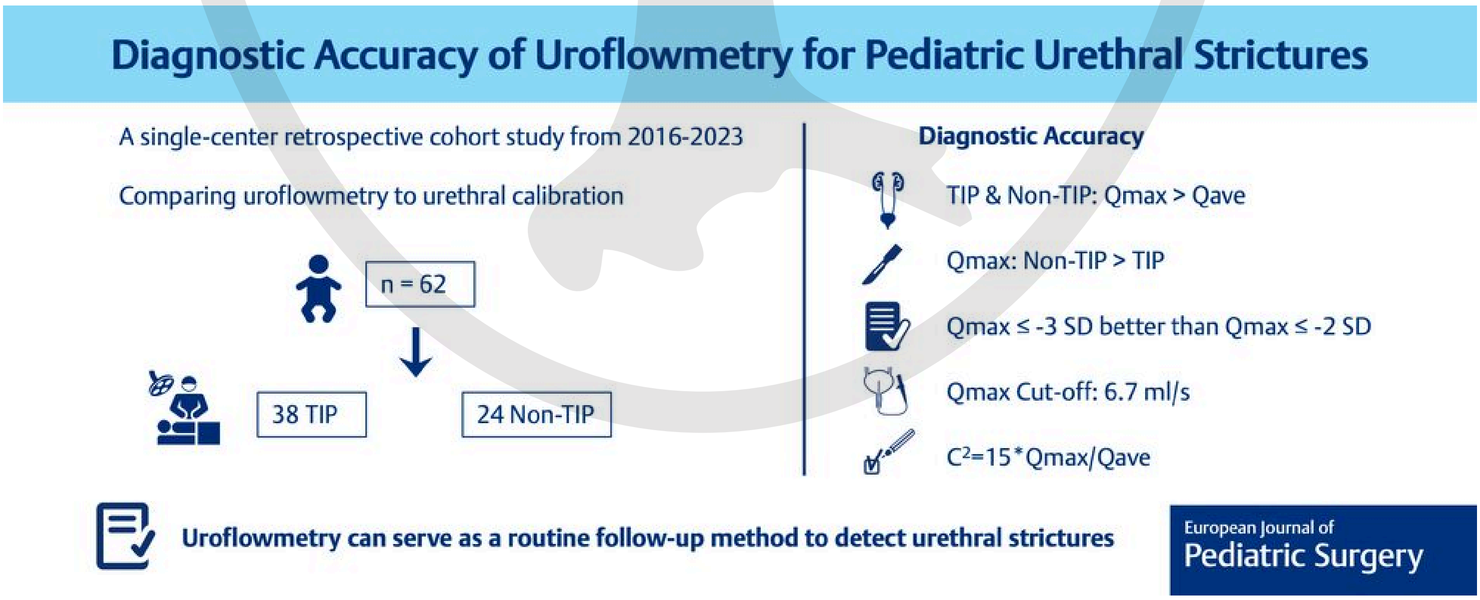
Staged Duckett	6 (25.00)	-	-		
Duckett and Duplay	5 (20.83)	-	-		
Onlay	1 (4.17)	-	-		
Mathieu	1 (4.17)	-	-		
Reconstruction Length (mm), M (Q_1, Q_3)	25.00 (18.00, 40.00)	20.00 (15.00, 25.00)	40.00 (36.50, 46.25)	Z = -5.42	**< 0.001**
Uroflowmetry					
Age at Uroflowmetry (years), M (Q_1, Q_3)	4.00 (3.00, 6.75)	4.50 (3.00, 6.75)	4.00 (3.00, 5.50)	Z = -0.30	0.764
Qmax, M (Q_1, Q_3)	6.60 (4.78, 9.50)	5.50 (3.50, 7.50)	8.70 (6.60, 10.62)	Z = -2.92	**0.003**
Qave, M (Q_1, Q_3)	4.50 (3.10, 5.80)	4.05 (2.50, 4.68)	5.55 (4.45, 6.45)	Z = -3.22	**0.001**
Calibration					
Calibration, M (Q_1, Q_3)	10.00 (10.00, 12.00)	10.00 (9.25, 11.75)	11.00 (10.00, 13.00)	Z = -2.06	**0.040**
Age at Calibration (years), M (Q_1, Q_3)	4.00 (2.00, 6.00)	5.00 (3.00, 6.75)	3.00 (2.00, 5.00)	Z = -1.34	0.180
Post-operative complications					

Urethral Fistula, n (%)				χ^2 = 0.08	0.773
No	35 (56.45)	22 (57.89)	13 (54.17)		
Yes	27 (43.55)	16 (42.11)	11 (45.83)		
Urethral Diverticulum, n (%)				χ^2 = 3.69	0.055
No	56 (90.32)	37 (97.37)	19 (79.17)		
Yes	6 (9.68)	1 (2.63)	5 (20.83)		
Residual Curve, n (%)				-	1.000
No	60 (96.77)	37 (97.37)	23 (95.83)		
Yes	2 (3.23)	1 (2.63)	1 (4.17)		

Z: Mann-Whitney test, χ^2: Chi-square test, -: Fisher exact, [#] Only 55 cases reported the meatus location.

Qmax: maximum urinary flow rate, Qave, average urinary flow rate, TIP: Tubularized Incised-Plate, M: Median, Q_1: 1st Quartile, Q_3: 3st Quartile


2831 patients underwent primary hypospadias repairs
2619 excluded for patients without calibration
212 included
145 excluded for:
87 were lost to follow-up
23 with voided volumes less than 50ml
37 without uroflowmetry measurements within a half-month period of calibration
65 included
3 excluded for:
2 with Neurogenic Bladder
1 with Posterior Urethral Valves
62 included
38 TIP group
24 Non-TIP group


Diagnostic Accuracy of Uroflowmetry for Pediatric Urethral Strictures
A single-center retrospective cohort study from 2016-2023
Comparing uroflowmetry to urethral calibration
n = 62
38 TIP
24 Non-TIP
Diagnostic Accuracy
TIP & Non-TIP: Qmax > Qave
Qmax: Non-TIP > TIP
Qmax ≤ -3 SD better than Qmax ≤ -2 SD
Qmax Cut-off: 6.7 ml/s
C²=15*Qmax/Qave
Uroflowmetry can serve as a routine follow-up method to detect urethral strictures
European Journal of Pediatric Surgery