

Comparative Study between Early and Delayed Removal of Urethral Stent after Tubularised Incised Plate Urethroplasty in Distal Hypospadias

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Abstract

Background: The use of urethral stent is very popular in hypospadias repair in order to permit the repair to be water tight, immobilize the suture line, tamponade any hemorrhage and avoid the risk of urinary retention. However, some pediatric surgeons don't prefer to leave urethral stents for long time, and remove it early to avoid complications such as inflicting pain, bladder spasm and infection.

Aim of Study: This study aimed to compare the early and delayed removal of urethral stent in the repair of distal hypospadias regarding hospital stay and the incidence of postoperative complications.

Patients and Methods: This is a prospective randomized controlled study performed from May 2019 to January 2022. It included 42 patients with distal hypospadias repaired by the tubularized incised plate technique. They were divided randomly into 2 groups; where the urethral catheters were assessed for early removal after 48 hours in group A, and they were removed on the 5th postoperative day in group B. Both groups were compared regarding the hospital stay and the incidence of postoperative complications.

Results: Early removal of the urethral stent was feasible in 84% of cases, whereas it was delayed to the 5th postoperative day because of oedema in 3 cases and hematoma in 1 case. Postoperative hospital stay was significantly shorter in group A cases with a mean of 3.74 days versus 5.86 days in group B (p -value <0.001). Postoperative complications were comparable in both groups with overall complications rate of 28.6% and 23.8% in group A and B respectively ($p=0.726$). Fistula and glans dehiscence were the commonest postoperative complications; fistula was reported in 2 cases in group A and 3 cases in group B, while glans dehiscence was reported in 2 cases in group A versus a single case in group B. There were no sta-

tistically significant differences between both groups regarding each type of complications ($p>0.05$).

Conclusion: Early removal of urethral stent after repair of distal hypospadias is applicable in the majority of cases with significantly shorter hospital stay and without increase in the incidence of postoperative complications.

Key Words: Hypospadias – Urethral stent – Early removal – Hospital stay – Fistula.

Introduction

HYPOSPADIAS is a common congenital anomaly affecting about 1/300 live male births, in which the urethral meatus is located on the ventral surface of the penis, at any point from the glans to the perineum [1]. Tubularized incised plate (TIP) urethroplasty is the most popular surgical technique performed for repair of distal hypospadias [2]. Urethral stents are used by the majority of surgeons after hypospadias repair aiming to protect the repair and prevent possible postoperative complications as urinary retention, fistula and neourethral stricture [3-5]. Nevertheless, several stent related problems were reported such as bladder spasm and hematuria, moreover stents could be blocked, kinked, migrated, or accidentally dislodged [4,6]. Accordingly, many authors recommended earlier removal of stents or even stent free repair with many comparative studies performed to compare the outcome of this policy versus the traditional trend of stent removal after 5-10 days [7-9]. Yet, the debate about the optimum time for stent removal after hypospadias repair remains unresolved. This study aims to study the feasibility of early catheter removal after distal hypospadias repair and compare the postoperative outcome after early and delayed stent removal regarding hospital stay and the incidence of postoperative complications.

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Patients and Methods

This is a prospective randomized controlled trial including 42 cases of distal hypospadias. It was conducted in the Pediatric Surgery Department at Mansoura University Children Hospital in the period between May 2019 and January 2022.

A priori analysis using G-power was done to estimate the study sample size. A power of 84%, type I error of 0.05 and effect size of 60% yielded sample size of 42 cases (21 cases per group) [10].

All male patients diagnosed as distal hypospadias, aged between 6 and 72 months, and underwent Tubularized Incised Plate (TIP) operation for hypospadias repair, were eligible to be included in the study. Patients with proximal hypospadias or severe chordee, those corrected by techniques other than TIP, redo cases, patients with associated complex anomalies, and patients whom parents refused to participate in the study were excluded.

Selected cases were randomized into two groups by sealed envelope method; group A for patients subjected to early catheter removal, whereas the removal of catheter was delayed in group B. Each group included 21 cases, yet 10 additional envelopes were prepared for each group to replace the excluded cases. Patients' parents or legal guardians signed an informed consent to be included in the study. The Institutional Review Board approved the study protocol and consent form (Code: MS.19.06.682).

Tubularized incised plate urethroplasty, as it was described by Snodgrass (1994), was performed for repair of hypospadias in all cases included in the study.

In group A, each patient was evaluated 48 hours after the operation and the catheter was removed if there were no signs of complications, nevertheless if there were oedema or hematoma, the catheter removal was postponed till the 5th postoperative day, and this patient was excluded from evaluation of the postoperative outcome. However, the percentage of failure of early removal of the catheter was calculated among group A cases. On the other hand, in group B patients, the urinary catheter was left to be removed in the 5th postoperative day. If the catheter removed earlier due to slippage or blockage the incident was reported and the case was excluded. Other stent related problems as bladder spasm were reported in the included cases and compared in both groups.

Patients were discharged after passing a urinary stream from the neomeatus. Hospital stay from operation to discharge was reported for each case and was compared between both groups. Patients were followed-up at the outpatient clinic weekly during the first 6 weeks and then monthly for 6 months. If

there were any complications, follow-up visits were more frequent and at shorter intervals.

On follow-up visits, patients were evaluated for reporting any postoperative complications. Urinary retention or difficulty in micturition were reported depending on parent's history combined with clinical examination. Meatal stenosis and urethral stricture were evaluated by assessing the urine flow during micturition and by calibration after two weeks by Nelaton's catheters 6 Fr and/or 8 Fr according to the age of the patient. Breakdown of the repair or urethro-cutaneous fistula could be detected by clinical examination. Patients in both groups were compared regarding the incidence of each of the previously mentioned complications.

IBM's SPSS statistics (Statistical Package for the Social Sciences) for windows (version 25) was used for statistical analysis of the collected data. Shapiro-Wilk test was used to check the normality of the data distribution. Normally distributed continuous variables were expressed as mean \pm SD while categorical variables and the abnormally distributed continuous ones were expressed as median and inter-quartile range or number and percentage (as appropriate). Student *t*-test and Mann-Whitney test were used for normally and abnormally distributed continuous data respectively. Chi square test was used for categorical data. *p* (probability) value <0.05 was considered statistically significant.

Results

The age of the patients at time of hypospadias repair ranged from 11 to 34 months, with a mean age of 20.86 ± 13.324 months in group A versus 22.86 ± 11.573 months in Group B, and there was no statistically significant difference between the two groups ($p=0.606$). Preoperative evaluation of the included patients indicated that the commonest position of the urinary meatus was distal penile in both groups (10 patients in each group). By comparing both groups the position of urinary meatus was comparable with no statistically significant difference ($p=0.509$). Urethral plate width was narrow in three patients in group A and four patients in group B, with no statistically significant difference between both groups ($p=0.679$). There were no statistically significant differences between the two groups for any of the parameters of preoperative examination indicating that both groups are matched.

Early catheter removal was feasible in 84% of patients in group A (21 out of 25 patients). In 4 cases, catheter removal was postponed to the 5th day, because of oedema in 3 cases and hematoma in one (Photos 1-3). Though these four cases passed without postoperative complications, they were excluded from the evaluation of postoperative outcome. On the other hand, 3 cases were excluded in group B, two of them because of early slippage of the catheter and one case was allocated in group B by

randomization after the required number of patients was fulfilled in this group. Accordingly, allocation of patients in both groups was continued till the number of patients was 21 in each group.



Photo (1): Favorable postoperative condition before early catheter removal.



Photo (2): Failed early catheter removal due to postoperative oedema.



Photo (3): Failed early catheter removal due to postoperative hematoma.

The postoperative hospital stay was significantly shorter in group A, with the mean length of hospital stay was 3.47 ± 0.717 days, versus 5.86 ± 0.854 days in Group B ($p < 0.001$) (Fig. 1).

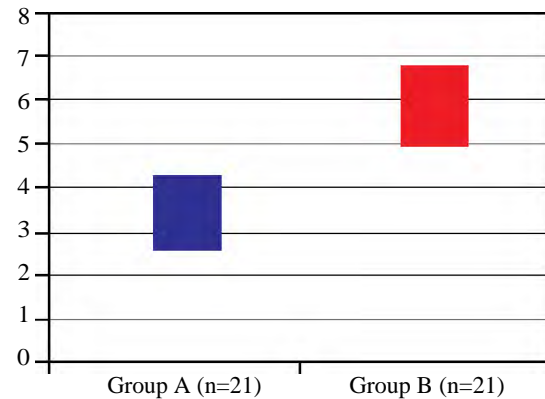


Fig. (1): Length of postoperative hospital stay in both groups.

The incidence of postoperative complications was comparable in both groups with overall complications rate of 28.6% and 23.8% in group A and B respectively ($p = 0.726$). Fistula, meatal stenosis, and glans dehiscence were the commonest postoperative complications; fistula was reported in 2 cases in group A and 3 cases in group B, while both meatal stenosis and glans dehiscence was reported in 2 cases in group A versus a single case in group B. There were no statistically significant differences between both groups regarding each type of complications ($p > 0.05$) (Table 1). Early catheter removal in group A was complicated by difficult micturition in 2 patients only. Both were improved gradually with time and none of them needed urinary diversion or re-catheterization. Though no difficulty in micturition was reported among patients in group B, there is still no statistically significant difference on comparison ($p = 0.147$). On the other hand, two cases in group B complained from bladder spasm that required anticholinergic drugs to relieve pain with no statistical significance despite the absence of this complaint in the other group.

Table (1): Postoperative complications in both groups.

	Group A (n=21)	Group B (n=21)	Odds ratio	<i>P</i>
Overall complications	6 (28.6%)	5 (23.8%)	0.78	0.726
Infection	0 (0.0%)	1 (4.8%)	2.05	0.311
Fistula	2 (9.5%)	3 (14.3%)	1.58	0.634
Glans dehiscence	2 (9.5%)	1 (4.8%)	0.48	0.549
Urethral stricture	0 (0.0%)	0 (0.0%)	1	1
Meatal stenosis	2 (9.5%)	1 (4.8%)	0.48	0.549
Difficult mictrition	2 (9.5%)	0 (0.0%)	2.11	0.147
Bladder spasm	0 (0.0%)	2 (9.5%)	2.11	0.147

Discussion

Ureteral catheters are widely left after hypospadias repair either by introducing the catheter inside the bladder or just as ureteral stents with the tip of the catheter distal to the external sphincter [11]. Urethral stents were thought for long time to make the repair water tight, stabilize the suture line, tamponade any hemorrhage and avoid urine retention or difficulty in micturition in the early postoperative period [5,12]. However, studies in animal models proved that catheters are not necessary for normal epithelization of the constructed neourethra [13].

The current study examined the feasibility of early catheter removal within 2 days after hypospadias repair, considering postoperative significant oedema or hematoma as indications for delaying catheter removal. Accordingly, catheters could be removed early in the majority of cases (84%). This agrees with many studies that reported effective early stent removal or even stent free repairs [7,14,15]. Nevertheless, there were no clear data in these studies explaining whether the catheters were still removed early or not in situations of postoperative oedema or hematoma.

Some authors reported that early catheter removal was complicated by acute postoperative urine retention with a statistical significance [16-18]. However, in the present study two patients only complained from difficulty in micturition after early catheter removal with no significant difference in comparison with patients where the catheter removal was delayed, and this agrees with the results reported by Kumar and Ram Dhayal, [9] where urine retention was reported in 12.5% of patients after early catheter removal versus 0% after delayed removal ($p=0.045$). On the other hand, delayed catheter removal was reported to be complicated by bladder spasm in significant number of patients reaching up to 47.8% in stented group versus 8.5% in unstented group [17]. In the present study, bladder spasm was reported in only 9.5% of cases in the group of delayed stent removal with no statistically significant difference although it was not reported in the other group. Similarly, El-Hawy et al., [8] reported bladder spasm in 9% of stented patients with no significant difference.

In the present study, early catheter removal was associated with a statistically significant shorter hospital stay, with a mean of 3.47 ± 0.717 days versus 5.86 ± 0.854 days after delayed catheter removal ($p < 0.001$). Similarly, Scarpa et al. [15] reported that the median length of hospital stay was 7 days in group A patients who removed the catheter after 6 days versus 3 days in group B with catheter removal immediately after the operation ($p=0.000$).

In this study, early catheter removal was not associated with increased incidence of postoperative complications with comparable incidences of

urethrocutaneous fistula, meatal stenosis and glans dehiscence in both groups. This agrees with Kumar and Ram Dhayal [9], who removed the catheter before 5 days or less in group A and after more than 5 days in group B. They reported urethrocutaneous fistula in 6.3% in group A versus 6.7% in group B ($p=0.94$), meatal stenosis in 9.4% and 6.7% respectively ($p=0.696$), and stricture in 3.1% versus 0% ($p=0.32$). Similarly, Burki et al. [19] compared postoperative complications after unstented repair versus stented repair where the catheter was removed after 7 days. In this study there were higher incidence of meatal stenosis in the unstented patients (5.8% versus 0%) ($p=0.06$). Yet, the incidences of fistula and glans dehiscence were comparable (15.5% versus 19.1% and 7.8% versus 4.2% respectively), with no reported cases with postoperative stricture similar to our study.

From this study it can be concluded that early catheter removal after hypospadias repair is feasible in the majority of cases of distal hypospadias with significantly shorter hospital stay and without increase in the incidence of postoperative complications. However, further studies on larger number of cases are required to develop conclusions solid enough to change the popular practice.

References

- 1- HOROWITZ M. and SALZHAUER E.: The 'learning curve' in hypospadias surgery. *BJU Int.*, 97: 593-596, 2006. Doi: 10.1111/j.1464-410X.2006.06001.x.
- 2- SNODGRASS W.: Tubularized incised plate urethroplasty in distal hypospadias. *J. Urol.*, 151 (2): 464-465, 1994.
- 3- ADRA I.S. and MAHMUTOĞLU M.: Urethral catheterization in hypospadias surgery: Should the device enter the bladder or be made a urethral stent? *J. Pediatr. Surg.*, 36: 1829-1831, 2001.
- 4- ASLAN A.R., YUCEBAŞ E., TEKIN A., SENGÖR F. and KOGAN B.A.: Short-term catheterization after TIP repair in distal hypospadias: Who are the best candidates? *Pediatr. Surg. Int.*, 23: 265-269, 2007.
- 5- RADWAN M., SOLIMAN M.G., TAWFIK A., ABO-ELEEN M. and EL-BENDAY M.: Does the type of urinary diversion affect the result of distal hypospadias repair? A prospective randomized trial. *Ther. Adv. Urol.*, 4: 161-165, 2012.
- 6- CHALMERS D.J., SIPRASKY G.I., WIEDEL C.A. and WILCOX D.T.: Distal hypospadias repair in infants without a postoperative stent. *Pediatr. Surg. Int.*, 31: 287-290, 2015.
- 7- XU N., XUE X.Y., WEI Y., LI X.D., ZHENG Q.S., JIANG T. and HUANG J.B.: Outcome analysis of tubularized incised plate repair in hypospadias: Is a catheter necessary? *Urol. Int.*, 90 (3): 354-357, 2013. Doi: 10.1159/000347127.
- 8- EL-HAWY M.A., ALI M.M., ABDELHAMID A.M., FAWZY A.M., HUSSEIN A. and ELSHARKAWY M.M.: Long term outcome of non-stented tubularized incised

- plate urethroplasty for distal hypospadias repair: A complication analysis. *Cent European J. Urol.*, 74: 595-600, 2021. Doi: 10.5173/ceju.2021.R1.0063
- 9- KUMAR A. and RAM DHAYAL I.: A comparative study on the outcomes of hypospadias surgery following early versus late bladder catheter removal. *Cureus*, 14 (6): e26104, 2022. Doi: 10.7759/cureus.26104.
 - 10- FAUL F., ERDFELDER E., LANG A.G. and BUCHNER A.: G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, 39: 175-191, 2007. doi: 10.3758/bf03193146.
 - 11- DEMIRBILEK S. and ATAYURT H.F.: One-stage hypospadias repair with stent or suprapubic repair with stent or suprapubic diversion: Which is better? *J. Pediatr. Surg.*, 32: 1711-1712, 1997.
 - 12- OSTERLING J.E., GEARHART J.P. and JEFFS R.D.: Urinary diversion in hypospadias surgery. *Urology*, 29: 513-516, 1987.
 - 13- HAFEZ A.T., HERZ D., BAGLI D., SMITH C.R., MCLORIE G. and KHOURY A.E.: Healing of unstented tubularized incised plate urethroplasty: An experimental study in a rabbit model. *BUJ Int.*, 91: 84-88, 2003.
 - 14- BUSON H., SMILEY D., REINBERG Y. and GONZALEZ R.: Distal hypospadias repair without stents: Is it better? *J. Urol.*, 151 (4): 1059-1060, 1994. Doi: 10.1016/s0022-5347(17)35180-7.
 - 15- SCARPA M.G., PERIN G., DI GRAZIA M., CODRICH D., PEDERIVA F., GUIDA E., LEMBO M.A., GIANNOTTA A. and SCHLEEF J.: Surgery for distal hypospadias: What about the catheter? *La Pediatria Medica e Chirurgica*, 39: 145-148, 2017.
 - 16- EL-SHERBINY M.T.: Tubularized incised plate repair of distal hypospadias in toilet-trained children: Should a stent be left? *BJU Int.*, 92: 1003-1005, 2003.
 - 17- EL-KARAMANY T.M., AL-ADL A.M., OMAR R.G., ABDEL AAL A.M., ELDAKHAKHNY A.S. and ABDELBAKI S.A.: Critical analysis of stented and unstented tubularized incised plate urethroplasty through a prospective randomized study and assessment of factors influencing the functional and cosmetic outcomes. *Urology*, 107: 202-208, 2017.
 - 18- NAVEED A., IFTIKHAR A. and FRAZ O.: Comparison between urethroplasty with and without stent for hypospadias in terms of postoperative urethrocutaneous fistula formation. *Pak Armed Forces Med. J.*, 68: 1511-1516, 2018.
 - 19- BURKI A., AL HAMS W., NAZER A., MOJALLID A., ABASHER A., JAMALALAIL Y., AL MODHEM F. and AL SHAMMARI A.: Outcome of stented versus unstented mid-shaft to distal hypospadias repair. *Urology Annals*, 14 (2): 147-151, 2022.

دراسة مقارنة بين الإزالة المبكرة والمتأخرة لدعامة مجرى البول بعد إجراء عملية الشق الانبوبي لإصلاح قصور الإحليل السفلى الطرفى فى قناة مجرى البول

يعد الإحليل السفلى هو ثانى أكثر العيوب الخلقية شيوعاً فى الجهاز التناسلى الذكري، ويؤثر على واحد من كل ٢٥٠ ذكرًا عند الولادة.

يعتبر الشق الانبوبي حاليًا أكثر الأساليب استخدامًا على نطاق واسع لعلاج الإحليل السفلى لأنه يوفر نتائج وظيفية وتجميلية ممتازة. يعد الناسور أحد أكثر المضاعفات شيوعًا، وتعد الدعامة مهمة للسماح بإغلاق مجرى الماء، وتثبيت الخياطة، وسد أى نزيف وتجنب خطر احتباس البول. والوقت الأمثل لإزالة دعامة مجرى البول بعد الجراحة لا يزال محل خلاف فى الأبحاث المختلفة .

الهدف من العمل: كان الهدف من الدراسة الحالية هو المقارنة بين الإزالة المبكرة والمتأخرة لدعامة مجرى البول لإصلاح الإحليل السفلى فيما يتعلق بفترة البقاء بالمستشفى و حدوث مضاعفات مثل الناسور واحتباس البول وضيق قناة مجرى البول.

تصميم الدراسة: هذه الدراسة تم إجراؤها على ما مجموعه ٤٢ حالة من الإحليل السفلى البعيد والتي أجريت فى قسم جراحة الأطفال بمستشفى جامعة المنصورة فى الفترة من مايو ٢٠١٩ إلى مايو ٢٠٢٠ . وتم تقسيم الحالات عشوائياً إلى مجموعتين. بالنسبة للمجموعة أ تم تقييم الحالات بعد إجراء الجراحة بيومين لإمكانية إزالة الدعامة مبكراً فى حال عدم وجود تورم شديد أو تجمع دموى، فى حين تمت إزالة الدعامة فى اليوم الخامس بعد الجراحة بالنسبة لحالات المجموعة ب.

كشفت الدراسة الحالية عن النتائج التالية:

- لم يكن هناك فروق ذات دلالة إحصائية بين المجموعات فيما يتعلق بالعمر.
- لا توجد فروق ذات دلالة إحصائية بين المجموعتين فيما يتعلق بجميع معايير الفحص قبل الجراحة.
- الإزالة المبكرة لدعامة مجرى البول كانت ممكنة فى ٨٤٪ من الحالات فى المجموعة أ.
- ارتبطت المجموعة ب بزيادة كبيرة فى مدة الإقامة فى المستشفى .
- لم يكن هناك فروق ذات دلالة إحصائية بين المجموعتين فيما يتعلق بجميع المضاعفات.
- لا توجد فروق ذات دلالة إحصائية بين المجموعتين فيما يتعلق بصعوبة التبول أو احتباس البول بعد إزالة الدعامة بعد الجراحة.

الاستنتاج: يبدو أن الإزالة المبكرة والمتأخرة لدعامة مجرى البول فى إصلاح الإحليل السفلى متقاربة بين المجموعتين فيما يتعلق بمضاعفات ما بعد الجراحة وأعراض صعوبة التبول بالإضافة إلى النتائج التجميلية. ومع ذلك، زادت مدة الإقامة فى المستشفى بشكل ملحوظ فى المجموعة ب.

القيود: على الرغم من النتيجة الواعدة للدراسة الحالية، إلا أن صغر عدد الحالات لا يزال هو القيد الرئيسى.

التوصيات: يجب إجراء مزيد من الدراسات على عدد أكبر من الحالات.