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Comparison between Stented and Non Stented TIP Urethroplasty for Distal Hypospadius

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Abstract: Background: Hypospadias is a condition where the meatus is situated along the underside of the penis instead of the normal position at its tip. **Aim of the Work:** To compare the outcome of stented versus non stented repair in TIP urethroplasty operation for distal hypospadius as regards cosmetic outcome and complications rate e.g. fistula, disruption and infection. **Patients and Methods:** This is a randomized control study to assess the outcome of TIP repair of distal hypospadias with or without stents as regarding surgical outcomes. This study was conducted at (pediatric surgery department), Ain Shams University Hospitals. Approval of the Ethical Committee and informed consent from all participants were obtained. This study was conducted over a period of 6 months. **Results:** This study is an effort to find out the effects of urethral stenting on complication rate in distal hypospadias repair but it was seen that there was no difference in post-operative fistula rates in unstented and stented patients in distal hypospadias surgery, but at the same time there was no difference in post-operative stay between the two groups. **Conclusion:** Repair with stents or without stents did not affect the outcome of hypospadias repair in terms of fistula formation or postoperative stay.

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1. Introduction

The meatus is most often found near the end of the penis ("distal" position). Hypospadias is the second most common birth defect in males, potentially affecting both urinary and sexual function of the penis. Surgical treatment is necessary, and more than 300 operation techniques have been described for primary hypospadias. The objective of all of procedures is the formation of a functionally normal urethra and a cosmetically acceptable penis [(1)].

Snodgrass described the tubularized incised plate (TIP) hypospadias repair in 1994 as a mean to widen and improve mobilization of the urethral plate when performing a Thiersch-Duplay urethroplasty [(2)].

The TIP repair is a reliable method for treating both distal and proximal hypospadias and is suitable for both primary and re-operated cases with accepted low rate of complications [(3)].

Significantly better outcome is achieved with distal hypospadias, covering the neourethra by the mobilized corpus spongiosum (spongioplasty) or by a flap [(3)].

There is little long-term data available for any of the operations of hypospadias in common use today. Throughout the history of hypospadias repair continued evolution of techniques has often resulted in new operations being applied and then discarded before long-term results are determined. Furthermore, most operations are performed in the first year of life, and it is not reasonable to expect data to be available on more than a sampling of these patients after they complete puberty [(1)].

Many authors stated that urine diversion after hypospadias repair maintain the site of anastomosis dry and reduce postoperative complications such as fistula formation, meatal stenosis, hematoma formation, flap necrosis, persistent chordee. McCormack et al 3 stated that urinary diversion after hypospadias repair has no proven beneficial effect on surgical outcome but it prolongs the hospital stay of corrected patients. Further studies have found that urethral drainage by catheter or stent does not reduce the risk of postoperative complications after hypospadias repair such as fistula formation. The role of stent and the duration of stenting in TIP repair of distal hypospadias are highly debated with no clear guidelines. This study is an effort to find out the effects of urethral stenting on complication rate in TIP repair of distal hypospadias as regard cosmetic

satisfaction and postoperative complications [2].

Aim of the Work

This study aims to compare the outcome of stented versus non stented repair in TIP urethroplasty operation for distal hypospadius as regards cosmetic outcome and complications rate e.g. fistula, disruption and infection.

2. Patients and Methods

Type of Study:

Randomized control study to assess the outcome of TIP repair of distal hypospadias with or without stents as regarding surgical outcomes.

Study Setting:

This study was conducted at (pediatric surgery department), Ain Shams University Hospitals. Approval of the Ethical Committee and informed consent from all participants were obtained.

Study Period:

Our study was conducted over a period of 6 months.

Study Population

Inclusion Criteria:

All male patients, irrespective of their age, with distal hypospadias.

Exclusion Criteria:

All patients with previous hypospadias surgery were excluded

Sampling Method:

Simple random sampling

Sample Size:

The required sample size has estimated to be 10 patients who undergo TIP repair of distal hypospadias with stenting and 10 patients underwent repair without stenting.

Ethical Considerations:

Informed consent:

Informed consent from patients care giver who are invited to participate in the research.

Confidentiality:

All patients data are confidential and they were not mentioned by name at any published paper. Patients have the right to refuse joining the research or withdraw at any time without affecting their chances to recieve the traditional therapy at anytime.

Study Tools, Procedures, Interventions:

All patients included in the study were candidates for:

Clinical assessment

- Careful history taking as regard abnormal urination, familial pattern of hypospadias, any past medical history or comorbidity.
- General condition assessment.
- Local genital examination as regard meatal location, glans configuration, skin coverage, and chordee according to GMS SCORE.

Preoperative Investigations:

Routine preoperative investigations as CBC, kidney and liver functions, chest x ray, urine tests.

Surgical intervention:

Either stented or non stented hypospadias repair.

Operative details:

Patients included in the study was divided into two groups; first group, which represent patients with stented TIP repair of distal hypospadias, and second group, which represent patients with non stented TIP repair of distal hypospadias.

Specific instruments and materials used for hypospadias repair include: • Optical magnification (loupes); • Marking pen; • 0.5 Castro-Viejo forceps; • Castro-Viejo needle driver; • 69 Beaver scalpel; • Tenotomy scissors; •nilaton catheter • 6–0 vicryl sutures; • 1: 1000 and 1: 100 000 noradrenaline patient is positioned supine for surgery nerve block is given before beginning. A 6–0 vicryl sutures is place into the glans. The initial skin incision depends upon whether the family prefers circumcision or foreskin reconstruction. Longitudinal incisions are made along the visible junction of the glans wings to the urethral plate. Midline incision of the urethral plate by counter-traction maintained by the surgeon and assistant along opposite margins of the plate. Using tenotomy scissors, the relaxing incision is made from within the meatus to the tip of the urethral plate. It should not be carried further distally into the glans. The depth of incision depends upon whether the plate is grooved or relatively flat, but in all cases extends down to near the corpora cavernosa.

Nelaton catheter is passed into the bladder and secured to the glans traction suture. Then the urethral plate is tubularized beginning at the neomeatus, using 6–0 vicryl sutures. The first suture is placed through the epithelium at a point just distal to the midglans so that the meatus has an oval, not rounded, configuration. Tubularization is completed with a running two-layer subepithelial closure, turning all epithelium into the neourethral lumen.

A dartos pedicle flap is dissected from the preputial hood and dorsal shaft skin in patients undergoing circumcision, then button-holed and transposed ventrally to cover the entire neourethra.

Glansplasty with a 6–0 vicryl suture through the epithelium at the desired point for the ventral lip of the meatus. A second 6–0 suture is placed subepithelially in this same location to further buttress the neomeatus and hopefully prevent partial dehiscence. The remainder of glans approximation is then done using interrupted 6–0 vicryl subepithelial sutures proximally to the corona.

Skin closure

A Tegoderm dressing is applied and the stent is left open dripping into a diaper.

Follow up:

All the patients were followed up postoperatively for length of hospital stay, Cosmetic outcome according to HOPE score, and surgical complications whether acute or chronic. Acute complications include bleeding, hematoma, edema, infection, wound dehiscence, skin or flap necrosis, fistula, penile torsion, inadvertent removal of urethral stent and bladder spasm. Chronic complications include skin irregularities, flap or skin necrosis, fistula, stenosis, residual chordae and balanitis.

Statistical Analysis

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The distribution of quantitative data was tested by Kolmogorov-Smirnov test of normality. So, the quantitative data were presented as mean, standard deviations and ranges when parametric. Also qualitative variables were presented as number and percentages.

The comparison between groups regarding qualitative data was done by using **Chi-square test** and/or **Fisher exact test** when the expected count in any cell found less than 5.

The comparison between two independent groups with quantitative data and parametric distribution was done by using **Independent t-test**

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:

- P-value > 0.05: Non significant (NS)
- P-value < 0.05: Significant (S)
- P-value < 0.01: Highly significant (HS)

3. Results

Table (1) shows that there was no statistically significant difference found between non stented and stented groups regarding age and type of hypospadias with p-value = 0.540 and 0.361.

Table (1): Comparison between non stented group and stented group regarding age and type of hypospadias

		Non stented No. = 10	Stented No. = 10	Test value	P-value	Sig.
Age	Median (IQR)	22 (12 – 36)	30 (18 – 36)	-0.612ǂ	0.540	NS
	Range	10 – 80	10 – 60			
Type of hypospadias	Coronal	5 (50.0%)	7 (70.0%)	0.833*	0.361	NS
	Distal penile	5 (50.0%)	3 (30.0%)			

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test; ǂ: Mann Whitney test

Table (2) shows that there was no statistically significant difference found between non stented and stented groups regarding operative time and blood loss with p-value = 0.929 and 0.531 respectively.

Table (2): Comparison between non stented group and stented group regarding operative time and blood loss

		Non stented No. = 10	Stented No. = 10	Test value•	P-value	Sig.
Operative time	Mean±SD	75.00 ± 10.27	74.50 ± 14.03	0.091	0.929	NS
	Range	60 – 90	50 – 100			
Blood loss	Mean±SD	23.50 ± 13.34	20.00 ± 11.06	0.639	0.531	NS
	Range	15 – 60	5 – 40			

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
•: Independent t-test

Table (3) shows that there was no statistically significant difference found between non stented and stented groups regarding glans length, glans width and GMS score with p-value = 0.224, 0.512 and 1.000 respectively.

Table (3): Comparison between non stented group and stented group regarding glans length, glans width and GMS score

		Non stented No. = 10	Stented No. = 10	Test value	P-value	Sig.
Glans length	Mean±SD Range	11.80 ± 3.58 8 – 20	10.00 ± 2.75 6 – 15	1.260	0.224	NS
Glans width	Mean±SD Range	10.20 ± 2.94 6 – 15	9.20 ± 3.71 5 – 16	0.669	0.512	NS
GMS score	Mean±SD Range	5.70 ± 0.95 4 – 7	5.70 ± 0.82 4 – 7	0.000	1.000	NS

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test; •: Independent t-test

Table (4) shows that there was no statistically significant difference found between non stented and stented groups regarding size of needle, time of tourniquet, urethral plate width and hope score with p-value = 0.060, 0.400, 0.492 and 0.424 respectively.

Table (4): Comparison between non stented group and stented group regarding size of needle, time of tourniquet, urethral plate width and hope score

		Non stented No. = 10	Stented No. = 10	Test value	P-value	Sig.
Type of suture	Vicryl	10 (100.0%)	10 (100.0%)	NA	NA	NA
Size of needle	6-0 5-0 & 6-0	3 (30.0%) 7 (70.0%)	0 (0.0%) 10 (100.0%)	3.529	0.060	NS
Time of tourniquet	Mean±SD Range	24.50 ± 4.97 20 – 35	22.50 ± 5.40 15 – 30	0.862	0.400	NS
Dressing	Vaseline gauze & gauze	10 (100.0%)	10 (100.0%)	NA	NA	NA
Urethral plate width	Mean±SD Range	4.80 ± 1.14 3 – 7	5.10 ± 0.74 4 – 6	-0.701	0.492	NS
HOPE score	Mean±SD Range	7.20 ± 1.01 5.5 – 9	7.60 ± 1.17 5 – 9	-0.818	0.424	NS

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test; •: Independent t-test

Table (5) shows that there was no statistically significant difference found between non stented and stented groups regarding fistula, hematoma, infection and meatal stenosis with p-value = 0.606, 0.305, 0.264 and 0.305 respectively.

Table (5): Comparison between non stented group and stented group regarding postoperative complications

		Non stented		Stented		Test value*	P-value	Sig.
		No.	%	No.	%			
Fistula	No Yes	7 3	70.0% 30.0%	8 2	80.0% 20.0%	0.267	0.606	NS
Disruption	No Yes	10 0	100.0% 0.0%	10 0	100.0% 0.0%	NA	NA	NA
Hematoma	No Yes	9 1	90.0% 10.0%	10 0	100.0% 0.0%	1.053	0.305	NS
Infection	No Yes	9 1	90.0% 10.0%	7 3	70.0% 30.0%	1.250	0.264	NS
Meatal stenosis	No Yes	10 0	100.0% 0.0%	9 1	90.0% 10.0%	1.053	0.305	NS

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test

Table (6): Complications after surgery in the two groups

Complications	Group A N (%)	Group B N (%)	P value
Early complications			
Wound infection	3	2	
Urinary tract infection	3	2	
Bladder spasms	0	0	
Urinary retention	0	1	
Urinary extravasation	0	0	
Late complications			
Fistula	2	3	
Metal stenosis	1	1	
Urethral stricture	0	0	-

4. Discussion

The main objective of any hypospadias repair is to have a functionally and cosmetically normal penis. Even in the hands of most experienced surgeons, hypospadias repair is associated with a number of complications ranging from urethrocutaneous fistula to the disruption of neourethra requiring reoperation of the different single stage hypospadias repairs. Urethrocutaneous fistula is the most common complication and shows an incidence of 5%-44% [(4)]. There are many causes of fistula formation such as infection, ischemia, poor tissue healing, distal obstruction, and lack of surgical expertise [(5)]. Many modifications have been introduced to decrease incidence of fistula, and no one of them is considered the best one. Buson et al. reported higher complication rates (18.9% non-stented vs. 4.6% stented repair) and the overall incidence of discomfort, including bladder spasms, dysuria, retention, extravasation and requirement for meatal dilatation, were significantly lower in stented patients than in unstented patients. The authors advocated the use of a urethral catheter or stent in hypospadias repair. The use of a catheter can reduce the incidence of fistula formation while adding only minimal morbidity.

El-Sherbiny showed that the absence of catheter in toilet-trained children was associated with a 24% rate of urinary retention, and a high reoperation rate. These studies indicate that an indwelling catheter is a reasonable option in toilet-trained children. However, reports have also shown that unstented TIP repair has a faster rate of healing. The stent is not necessary for the normal epithelialization of urethral reconstruction postoperatively and urine flow might be responsible for keeping the healing edges of the plate separate during urothelial regeneration. Almodhen et al. argued that a non-stented technique for hypospadias repair simplifies postoperative care and obviates the need for antibiotics and anticholinergics. In a retrospective study comparing stented versus unstented TIP repair, Leclair et al. reported no difference in the outcomes with regard to the use of stents. Turial et al. reported their experiences with TIP repair without placement of a postoperative urethral stent in 41 cases. They concluded that non-stented TIP repair for distal and mid-shaft penile hypospadias does not increase early or late postoperative complication rates and unstented repair results in higher patient comfort.

The role of stenting in hypospadias surgery has been debated in recent times. First the transition from bladder drainage catheter to urethral splent was done by Pike et al. in 1991 who said that these reduce post-operative stay and minimal short term complications. Then even the role of these urethral stents was debated as various studies done not using stents in various procedures for distal hypospadias. McCormack et al. did unstented Mathieu repair and found no difference in complication rates and reduced postoperative stay. However Buson et al. did a similar study and concluded that stent placement is advantageous for the outcome of Mathieu operation.

Hakim et al. also did a study comparing stented and unstented Mathieu repair and found no difference in fistula rates in the 2 groups. Thus 3 different studies have shown 3 different results with respect to a particular procedure.

From our study, we noted that the absence of a postoperative urethral catheter was not associated with excessive immediate morbidity. Urinary retention is not common and subsequent management is not difficult. The incidence of urinary retention in our series was much lower than the previous report of El-Sherbiny, and was similar to that observed in boys after routine circumcision. In the non-catheter group, only one patient had postoperative urinary retention and presented with palpable bladder and pain. One patient required catheterization and none underwent cystostomy. A s 2% lidocaine hydrochloride gel was used for lubrication and anesthesia, catheterizations were well tolerated by the patients. This could be attributed to good lubrication and the graduated depth of the central relaxing incision, being shallower proximally, and thus preventing the creation of a false passage by the catheter. However, children with urinary retention did not later develop urethral complications. We have noticed that when this surgery was performed before toilet-training age, urinary retention was rare. The possible mechanism is that the automatic bladder activity during this period makes the child unable to restrain from voiding and decreases the risk of postoperative urinary retention. On the other hand, in the non-catheter group an adjunctive penile block with 2% lidocaine instead of caudal or epidural analgesia was used. This technique could greatly decrease the incidence of urinary retention. The incidence of bladder spasms was significantly reduced in the non-catheter group compared with the indwelling catheter group. In the non-catheter group, none of the patients required treatment with oxybutynin because of bladder spasms. In addition, non-catheter patients experienced subjective improvement in comfort. On the contrary, most of the patients who received a catheter were more irritable until the catheter was removed. There was no increased incidence of urethral stricture or meatal stenosis without a catheter. The incidence of late complications, including urethrocutaneous fistula, urethral stricture and meatal stenosis, was not significantly different for the non-catheter group compared with the indwelling catheter group.

However, in the previous studies only the patients upto one year of age and midpenile hypospadias were included whereas in our study the age range was very wide and midpenile anomalies were not included. However, the follow up period in both the studies was up to 6 months. As it was mentioned initially that to use or not to use the stent for urethroplasty is debateable amongst different centres and different surgeons so there are studies which strongly favour the use of stent for urethroplasty such as one study performed by Lin et al in 2015 reported the statistics that showed that complication rate of urethroplasty without stent is more as compared to urethroplasty with stent23. Likewise another study performed in 1994, the fistula formation was seen in 4.6% cases who underwent urethroplasty with stent and 18.9% in those without stent24. Hence whether to use the stent or not is still an open question and it depends upon many factors like available tissue, tension in the repair, type of anomaly, suture selection and most importantly the experience and preference of the surgeon because some surgeons favour to perform urethroplasty in interrupted fashion while others prefer to do it in continuous fashion. Definitely with the input from more centres and surgeons, a consensus can be drawn about the management of this common disorder. Overall, our data indicate that successful TIP repair is independent of the use of a urethral catheter and the noncatheter procedure resulted in higher patient comfort. In conclusion, non-catheter TIP repair is feasible, and based on an objective assessment in our cohort, suggests that good outcomes can be achieved with minimal complications, particularly in patients with primary distal and mid-shaft repairs. There was no increased risk of fistula, meatal stenosis, or urethral stricture formation with the non-catheter repair.

Conclusion

Repair with stents or without stents did not affect the outcome of hypospadias repair in terms of fistula formation or postoperative stay.

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