

COMPARISON BETWEEN URETHROPLASTY WITH AND WITHOUT STENT FOR HYPOSPADIAS IN TERMS OF POSTOPERATIVE URETHROCUTANEOUS FISTULA FORMATION

Naveed Ahmed, Iftikhar Ahmed, Omar Fraz, C. Aqeel Safdar, Mudasir Saleem, Safdar Hussain Awan, Javad Yousaf*

Pak Emirates Military Hospital/National University of Medical Sciences (NUMS) Rawalpindi Pakistan, *Army Medical College/National University of Medical Sciences (NUMS) Rawalpindi Pakistan

ABSTRACT

Objective: To compare the urethroplasty with and without stent for hypospadias in terms of frequency of postoperative urethrocutaneous fistula formation.

Study Design: Randomized controlled trial.

Place and Duration of Study: Department of Pediatric Surgery, Pak Emirates Military Hospital Rawalpindi, from Jan 2015 to Dec 2017.

Patients and Methods: A total of 260 patients with diagnosis of hypospadias were selected from outpatient department after confirming their diagnosis by taking a detailed history and performing thorough clinical examination. Patients were divided randomly into two groups, group A and group B via lottery method. In group A, urethroplasty was done by using a stent while in group B, urethroplasty was done without a stent although stent was used in this group as a template preoperatively to form a neo urethra and then removed after 24 hours. The 6-8 FR nasogastric tube was used as stent. The follow up was after 2, 6 and 12 weeks to see the fistula formation in both types of procedures. All the data was recorded on the specially designed proforma attached as annexure A. Data was analyzed using SPSS version 22.

Results: The overall incidence of urethrocutaneous fistula was 21 (8%) out of the total study population. In group-A there were 18 (13%) cases who developed fistula and in group-B 3 (2%) cases developed fistula. There was significantly higher no of cases in group-A, who developed fistula as compared to group-B, p -value = 0.001.

Conclusion: Stents are routinely used in many centres after urethroplasty for hypospadias repair leading to higher incidence of urethrocutaneous fistula. If urethroplasty is done meticulously, stentless surgery may produce fewer fistulas.

Keywords: Fistula, Hypospadias, Stent, Urethroplasty.

This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

INTRODUCTION

Hypospadias is one of the most common congenital anomalies, occurring in approximately 1 in 250 newborns or 1 in 125 live male births¹. It can be defined as arrest in normal development of the urethra, foreskin and ventral aspect of the penis. This arrest in normal development results in a congenital condition in which the urethral opening lies on the ventral surface of the penis. This anomaly has a great deal of impact both socially and psychologically both on parents and the patient later in life. If left untreated, the patients with proximal hypospadias have to sit

down to void and also they tend to shun the intimate relationships². Moreover, understanding of this anomaly dates back to Greek culture with high appreciation of the goddess Hermaphrodite whose statues reflect hypospadiac genitalia. The treatment of hypospadias has also evolved from amputation of the distal curved portion by Alexandrian surgeons to the present day modern techniques. It occurs embryologically during the urethral development at about 8th to 20th weeks of gestation. The cause is not known but many factors are thought to contribute like hormone receptor impairment, genetic impairment, enzyme defects, maternal factors like age and primiparity or paternal factors like abnormalities of scrotum or testes, low spermatozoa motility and abnormal sperm morphology and even

Correspondence: Dr Naveed Ahmed, Pediatric Surgery Dept, Pak Emirates Military Hospital Rawalpindi Pakistan

Email: amcolian22@gmail.com

Received: 11 Jun 2018; revised received: 25 Aug 2018; accepted: 27 Aug 2018

reduced levels of the placental hormone human chorionic gonadotropin (hCG) may play a role³. The abnormal urethral opening can be as far back as scrotum or perineum. It is the 2nd most common urogenital birth abnormality in boys, the commonest being the undescended testis. It is associated with the other penile deformities like ventral shortening and curvature called chordee⁴. Some scrotal abnormalities like prepenile scrotal transposition is also associated with proximal types of hypospadias⁵. Although classifying hypospadias is not necessarily useful in determining surgical approach, the meatal position can be anterior (distal) that includes glanular, coronal or subcoronal, mid penile and posterior (proximal) that includes posterior penile, penoscrotal, scrotal or perineal. The subcoronal is the most common position. Proximal cases are considered severe as they are associated with severe chordee and other abnormalities like prepenile scrotum, disorders of sexual differentiation, undescended testes or inguinal hernia. Distal hypospadias are more common as they account for approximately 60% to 65% of cases, 20% to 30% are midpenile, and 10% to 15% are proximal⁶. The treatment of hypospadias is only surgical and the goal of treatment is to get reasonable cosmetic and functional results and also to address the psychological aspects to alleviate the anxiety of the patient and parents. Surgical treatment involves correction of chordee that is confirmed by artificial erection and urethroplasty with orthotopic meatus. The timing of surgery is of paramount importance because delaying surgery waiting for penile growth is considered unnecessary and potentially emotionally harmful also. Children become increasingly sensitive to hospitalization after 18 months of age and are phallic aware from the age of 2 years. Hence the aim should be to complete the surgery by the age of 2 years. Sometimes pre-treatment with topical or systemic testosterone is also initiated in order to achieve adequate length of the penile shaft but its use is debateable⁷. In severe cases with very small penis like partial androgen insensitivity syndrome presurgical test-

osterone stimulation can be useful. Depending on location of hypospadias the various surgical procedures are used. The tubularized incised plate repair (TIP) is most commonly used for both distal and mid shaft hypospadias. For proximal hypospadias, the two stage procedure (Bracka) is used which involves grafting using the foreskin followed by urethroplasty⁸. After the urethroplasty the urinary diversion is used to permit the repair to be water tight, immobilize the suture line and provide patient comfort⁹. Urethroplasty using a stent is a common practice. Stent can be either a Foley catheter or a feeding tube¹⁰. Generally feeding tube is preferred over Foley catheter because it causes less bladder spasm and has less chances of blockage. Aim of the stent is firstly to construct the neourethra over it while using it as a template and secondly to prevent the suture line from leakage and to keep it water tight which will eventually help in preventing postoperative urethrocutaneous fistula formation in which case patient passes stream of urine from line of repair instead of meatus, which is a known complication of hypospadias repair. However, use of stent after urethroplasty is associated with complications like urinary tract infections, bladder spasm and prolonged hospital stay besides becoming blocked frequently. To avoid such complications stentless urethroplasty can be performed in which case the neourethra is constructed over a stent while using it as a template but at the end of the procedure the stent is removed so that the patient voids from the neourethra. The rationale of our study was that urethral stent after urethroplasty for hypospadias has increased rate of fistula formation in early postoperative period as compared to stentless urethroplasty. The objective of the study was to compare the urethroplasty with and without stent for hypospadias in terms of frequency of postoperative urethrocutaneous fistula formation.

PATIENTS AND METHODS

It was a randomized controlled trial carried out at department of Pediatric Surgery, Pak Emirates Military Hospital, Rawalpindi over a

period of 3 years from January 2015 to December 2017. Patients were selected by non probability consecutive sampling. Patients undergoing urethroplasty for distal and mid penile hypospadias, between 1 to 12 years of age were included in the study. Patients with proximal hypospadias, with previous history of any failed urethroplasty or undergoing staged repair were excluded from the study.

A total of 260 patients with diagnosis of mid penile and distal hypospadias were selected from outpatient department and included in the study after permission from the hospital ethical committee. Parents of the patients were counselled in detail. Preoperative workup included full blood count and hepatitis profile of the patients. Patients were divided randomly into two groups, A and B, via lottery method. In group A the stent urethroplasty was performed while in group B stentless urethroplasty was performed. The 6-8 FR nasogastric tube was used as a stent, depending upon the age of the patient. All surgical procedures were done under general anesthesia after seeking written informed consent from the parents. The procedure was standardized as the urethroplasty was performed by a consultant paediatric surgeon. Injection Cefuroxime was administered according to weight of the patient (50 to 100 mg/kg) at the time of induction. Line of incision was marked after anesthesia. For haemostasis, 0.5% Lignocaine with 1: 200,000 adrenaline (5 to 7 mg/kg body weight) was infiltrated in the line of incision. Repairs were performed in 3 layers. In all patients, Polydioxanone 6/0 was used for first and second layers however, Polyglactin 5/0 was used to close the skin in interrupted fashion i.e. third layer. The first layer was closed in an interrupted fashion however, second layer was closed in continuous fashion. All the patients were given same standard postoperative treatment in the form of antibiotic and analgesia i.e. Injection Cefuroxime 50 to 100 mg/kg and Injection Nalbuphine 0.1mg/kg respectively. The patients were discharged on 2nd postoperative day with stentless urethroplasty and 7th post-

operative day with stent urethroplasty after removing the stent. The follow up was after 2, 6 and 12 weeks to see the fistula formation in both types of procedures. All the data was recorded on the specially designed proforma attached as annexure A.

Data was analyzed using SPSS version 22. The variables to be analyzed were quantitative data like age and qualitative data like fistula formation. Mean and standard deviation were calculated for quantitative data. Frequency and percentage was used for analysis of qualitative data. Frequency of fistula formation was compared between two groups by using Chi square test. Effect modifiers like age was controlled by stratification. A p -value ≤ 0.05 was considered to be significant.

RESULTS

The mean age of patients was 7.21 ± 3.21 years with minimum and maximum age as 1 and 12 years respectively. In group-A and group-B the mean age was 6.98 ± 3.21 years and 7.44 ± 3.21 years respectively.

In group-A 29 (22%) patients had coronal, 67 (52%) had subcoronal and 34 (26%) had mid-penile hypospadias. In group-B 17 (13%) patients had coronal, 76 (58%) had subcoronal and 37 (29%) had midpenile hypospadias (table-I).

In group-A and group-B there were 18 (13.8%) patients and 3 (2.3%) patients respectively who developed fistula. There was significantly higher no of patients in group-A who developed fistula as compared to group-B, p -value = 0.001 (table-II).

In group-A, out of 18 patients who developed fistula, 11 patients had subcoronal hypospadias, 5 had midpenile and 2 patients had coronal hypospadias.

In group-B, out of 3 patients who developed fistula, 2 patients had subcoronal hypospadias, and 1 patient had coronal hypospadias.

When data was stratified for age (1-6 years and 7-12 years) we found significantly higher no of cases in group-A who developed fistula as

compared to group-B in either age group, *p*-value <0.05 (table-III).

DISCUSSION

This study provided us a chance to compare the urethroplasty with or without stent in hypospadias and look for postoperative fistula formation that is the most feared complication for any surgeon. In this study the age range was very

Hypospadias is regarded as quite common birth defect that affects 0.2-1% of male newborns¹¹. The exact cause of hypospadias remains unknown. Multiple factors can be implied in the causation of this abnormality like environmental, endocrine and genetic factors. These factors lead to the abnormal penile development resulting in displacement of the

Table-I: Comparison of two groups in terms of location of hypospadias.

	Group A	Group B
Coronal	29 (22%)	17 (13%)
Subcoronal	67 (52%)	76 (58%)
Midpenile	34 (26%)	37 (29%)
Total	130	130

Table-II: Comparison of fistula formation in both study groups.

		Study groups		Total
		Group-A	Group-A	
Fistula formation	Yes	18 13.8%	3 2.3%	21 8.1%
	No	112 86.2%	127 97.7%	239 91.9%
Total		130 100.0%	130 100.0%	260 100.0%

p-value = 0.001

Table-III: Comparison of fistula formation in both study groups with respect to age groups.

Age groups	Fistula formation	Study groups		<i>p</i> -value
		Group-A	Group-B	
1-6 years	Yes	9 16.7%	2 3.9%	0.033
	No	45 83.3%	49 96.1%	
7-12 years	Yes	9 11.8%	1 1.3%	0.007
	No	67 88.2%	78 98.7%	

wide i.e. 1 to 12 years however the ideal age to treat this anomaly is 18 to 24 months. The reason behind the late presentation in our society is firstly the strong social and cultural beliefs due to which the parents do not bring the child to the surgeon during the initial years of his life and secondly the majority of the population resides in the rural areas with less per capita income resulting in delayed or no presentation to the surgeon. There is also lack of awareness about the disease amongst the general practitioner that leads to late referral to the tertiary care facility.

urethral meatus proximal to its physiological position along the penile shaft, perineum or scrotum¹².

Treatment of hypospadias is surgical correction only. After surgical repair, the aim is to have a straight penile shaft with correction of chordee, orthotopic meatus, good urinary stream, acceptable cosmesis, self-confidence of the child and to alleviate the anxiety of the parents. Choice of procedure to correct hypospadias depends on the location of the abnormal opening such as for distal hypospadias are incised plate urethroplasty

and glans approximation procedures whereas for proximal hypospadias is extended incised plate urethroplasty or staged repair using various flaps and graft techniques depending upon the experience of the operator. Results are better while using flap urethroplasty as compared to graft urethroplasty¹³. Hypospadias is a type of disorder that always poses a great challenge to the treating surgeons because there are number of procedures that can be performed depending upon the experience and preference of the surgeon¹⁴⁻¹⁶. Diversion of urine after hypospadias repair is a controversial issue as different opinions prevail among surgeons. Options can be suprapubic diversion or transurethral drainage in order to avoid leakage of urine from the suture line which is actually the most common complication. Transurethral drainage is also done in two different ways. Few surgeons prefer to place it in the bladder and others go to place the stent in the urethra just distal to the external sphincter^{17,18}. The advantage of placing the stent just distal to the bladder neck is that it causes less bladder spasm and bladder irritation. Mostly the surgeons agree on diverting the urine after hypospadias repair but two things always remain debateable i.e. duration of diversion and type of diversion, the options being: suprapubic diversion¹⁹, urethral stent (below the external sphincter of the bladder), or transurethral bladder catheter²⁰. But still many surgeons go against the urinary diversion keeping in view the complications associated with it²¹. A study conducted by Radwan *et al* in 2012 reported that postoperative fistula formation after urethroplasty with and without stent was 12.7% and 3.2% respectively (p -value <0.05)¹⁹. In our study, we found that in group-A and group-B there were 18 (13.8%) patients and 3 (2.3%) patients who developed fistula respectively. There was significantly higher no of cases in group-A who developed fistula as compared to group-B, p -value =0.001. That is almost similar statistics. Likewise another study performed by Chalmers *et al* in 2015 in which 110 patients were included who underwent urethroplasty also

favoured stentless repair that was associated with less complications as compared to repair with stent²². However, in this study only the patients upto one year of age with subcoronal hypospadias were included whereas in our study the age range was very wide and midpenile anomalies were also included. However, the followup period in both the studies was up to 3 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. These results are in total contradiction to our results. 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. No such research data is available in Pakistan so it would help us to manage the patients of hypospadias more effectively by reducing the stent related complications and thereby decreasing the morbidity. Moreover, it will also help us to reduce the cost of the treatment in our resource constraint country because it will significantly reduce the duration of hospital stay and also it is readily acceptable for the parents.

CONCLUSION

Hypospadias undoubtedly pose a great challenge both for the treating surgeon as well as the parents. Urethrocutaneous fistula formation is

the most common complication and is higher in cases with stent urethroplasty as compared to those with urethroplasty without stent. In future, cases of hypospadias can be managed without stent and further stent related complications can be reduced.

CONFLICT OF INTEREST

The author has no conflict of interest to be declared by any author.

REFERENCES

- Manson JM, Carr MC. Molecular epidemiology of hypospadias: review of genetic and environmental risk factors. *Birth Defects Res A Clin Mol Teratol* 2003; 67: 825-36.
- Schlomer B, Breyer B, Copp H, Baskin L, DiSandro M. Do adult men with untreated hypospadias have adverse outcomes? A pilot study using a social media advertised survey. *J Pediatr Urol* 2014; 10: 672-9.
- Spivey A. Tracking down a cause for hypospadias: placental malfunction may contribute. *Environ Health Perspect* 2008; 116: A350.
- Van HJR, Horst LL. Hypospadias, all there is to know. *Eur J Pediatr* 2017; 176: 435-41.
- Straub J, Karl A, Tritschler S, Lellig K, Apfelbeck M, Stief C, et al. Management der Hypospadias. *MMW-Fortschr Med* 2016; 158: 62-5.
- Soomro N, Neal D. Treatment of hypospadias: An update of current practice. *Hosp Med* 1998; 59: 553-6.
- Kaya C, Radmayr C. The role of pre-operative androgen stimulation in hypospadias surgery. *Transl Androl Urol* 2014; 3: 340-6.
- Faure A, Bouty A, Nyo YL, O'Brien M, Heloury Y. Two-stage graft urethroplasty for proximal and complicated hypospadias in children: A retrospective study. *J Pediatr Urol* 2016; 12: 286.
- Viseshsindh W. Factors affecting results of hypospadias repair: single technique and surgeon. *J Med Assoc Thai* 2014; 97: 694-8.
- Xie QG, Su C, Li ZQ, Li SS, Xu Z, Sun JJ, et al. Foley catheter versus urethral stent plus gastric tube for urine drainage following urethroplasty. *Zhonghua Nan Ke Xue* 2014; 20: 439-41.
- Toppari J, Virtanen HE, Main KM, Skakkebaek NE. Cryptorchidism and hypospadias as a sign of testicular dysgenesis syndrome (TDS): environmental connection. *Birth Defects Research Part A: Clinical and Molecular Teratology* 2010; 88: 910-9.
- Kraft KH, Shukla AR, Canning DA. Hypospadias. *Urologic Clinics of North America* 2010; 37: 167-81.
- Powell CR, McAleer I, Alagiri M, Kaplan GW. Comparison of flaps versus grafts in proximal hypospadias surgery. *J Urol* 2000; 163: 1286-9.
- Springer A, Krois W, Horcher E. Trends in Hypospadias Surgery: Results of a Worldwide Survey. *European Urology* 2011; 60: 1184-9.
- Mundy AR, Andrich DE. Urethral strictures. *BJU international* 2011; 107: 6-26.
- Wehbi E, Patel P, Kanaroglou N, Tam S, Weber B, Lorenzo A, et al. Urinary tract abnormalities in boys with recurrent urinary tract infections after hypospadias repair. *BJU international* 2014; 113: 304-8.
- Amin MS, Waseem A, Amr A, Salah M. Urinary Drainage after Hypospadias Repair: Urethral Stent or Bladder Catheter. *Ann Pediatr* 2009; 5: 101-3.
- Farrell MR, Sherer BA, Levine LA. Visual internal urethrotomy with intralesional mitomycin C and short-term clean intermittent catheterization for the management of recurrent urethral strictures and bladder neck contractures. *Urology* 2015; 85: 1494-500.
- Radwan M, Soliman MG, Tawfik A, Abo-Elenen M, El-Benday M. Does the type of urinary diversion affect the result of distal hypospadias repair? A prospective randomized trial. *Ther Adv Urol* 2012; 4: 161-5.
- Arda IS, Mahmutoglu M. Urethral catheterization in hypospadias surgery: Should the device enter the bladder or be made a urethral stent? *J Pediatr Surg* 2001; 36: 1829-31.
- Bernie JE, Alagiri M. Tubeless Barcat: a patient-friendly hypospadias procedure. *Urology* 2003; 61: 1230-2.
- Chalmers DJ, Siparsky GL, Wiedel CA, Wilcox DT. Distal hypospadias repair in infants without a postoperative stent. *Pediatr Surg Int* 2015; 31: 287-90.
- Lin N, Qiu J, Wu Y, Lin Z, Cao L. Three different strategies of urine drainage following hypospadias surgery: Clinical nursing and observation. *Zhonghua nan ke xue* 2015; 21: 153-6.
- Buson H, Smiley D, Reinberg Y, Gonzalez R. Distal hypospadias repair without stents: is it better? *J Urol* 1994; 151: 1059-60.