

Three Week or One Week Bladder Catheterization in Reducing Urethrocutaneous Fistula for Hypospadias Repair: A Randomized Controlled Trial

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ABSTRACT

Introduction

Surgical correction is the only treatment for hypospadias. Complication rate is usually high. Indwelling catheter is kept postoperatively for urinary diversion and proper healing. There is no consensus regarding the duration of catheterization. This study was conducted to compare urethrocutaneous fistula (UCF) rate between one and three weeks of catheterization.

Methods

This study was a randomized control trial, conducted at Tribhuvan University Teaching Hospital, Kathmandu, Nepal. All children undergoing urethroplasty for hypospadias were randomized into two groups. After surgery, urinary catheter was kept for one and three weeks in group 1 and group 2 respectively. Occurrence of UCF and other complications were noted and compared between the groups.

Results

A total of 32 patients were randomized into 2 groups having 16 in each group. Fourteen (43.8%) developed UCF. In one week group, 8 (50%) and in three week group 6(37.5%) developed UCF. It was not statistically different ($p = 0.48$). Occurrence of UCF was not different in different age of children, type of hypospadias and single or staged procedure. Meatal stenosis was not different in both groups.

Conclusion

Incidence of UCF was not different in one week or three week of urinary catheterization after surgery for hypospadias.

Keywords

Catheter duration, hypospadias surgery, meatal stenosis, urethrocutaneous fistula

INTRODUCTION

Hypospadias is a developmental anomaly of male genitalia characterized by urethral meatus that opens onto the ventral surface of penis. Meatus may be located anywhere along the shaft of penis, from glans to perineum. Surgical correction is the only treatment of choice.¹ Urethroplasty is required to restore normal function and appearance of penis. Basic goal of hypospadias correction are : position of meatus at glans, voiding in an upstanding position, proper voiding stream, and normal straight penile appearance that can lead to normal erection and normal coitus.¹

A variety of surgical techniques are described in literature and none of them are without complications. Urethrocutaneous fistula (UCF) is the most common complication after hypospadias repair.² Many surgeons prefer urinary diversion after hypospadias repair to prevent UCF. There is no consensus regarding type and duration of urinary diversion.¹ With little evidences, most surgeons prefer urethral catheterization for duration of 7-10 days. But some literature suggest to keep urinary diversion for a longer period of time up to 3 weeks.³

The physiological study of urethral wound suggests that phases of wound healing are similar with dermal healing. The duration of phases is longer in comparison to dermal healing.⁴ This theory can be applied to justify longer duration of catheterization. This study was conducted to determine if 3 week catheterization reduces the incidence of UCF formation after hypospadias repair.

METHODS

This study was a randomized controlled trial conducted in Pediatric Surgery Unit of Department of General Surgery and Department of Urology of Tribhuvan University Teaching Hospital from November 2018 to November 2019.

All children below 16 years of age with diagnosis of hypospadias that underwent urethroplasty were included in the study. All types of repair including single stage urethroplasty or final urethroplasty of 2-staged surgery were included. First surgery of 2-staged surgery, cripple hypospadias, surgery for UCF, and repair with buccal mucosa were excluded from the study.

This Study was approved by ethical board from Institutional Review Committee (IRC), Institute of Medicine, Tribhubvan University with reference number: 435/(6-11)E2/075/076. Informed consent was taken from parents or legal guardians. Patients were randomized to 1:1 ratio by computer generated random sampling method into two groups; group 1 for one week catheterization and group 2 for three week catheterization.

All surgery was performed by faculty surgeons of pediatric surgery and urology. Polygalactin suture of size 6/0 was used for urethroplasty. Neo-urethra was created over 6 or 8 FG polyvinyl chloride enteric feeding tube, that was left indwelling in bladder for urinary diversion and fixed on glans using non absorbable suture (Polypropylene 6-0). Post operatively dressing was applied around penis and

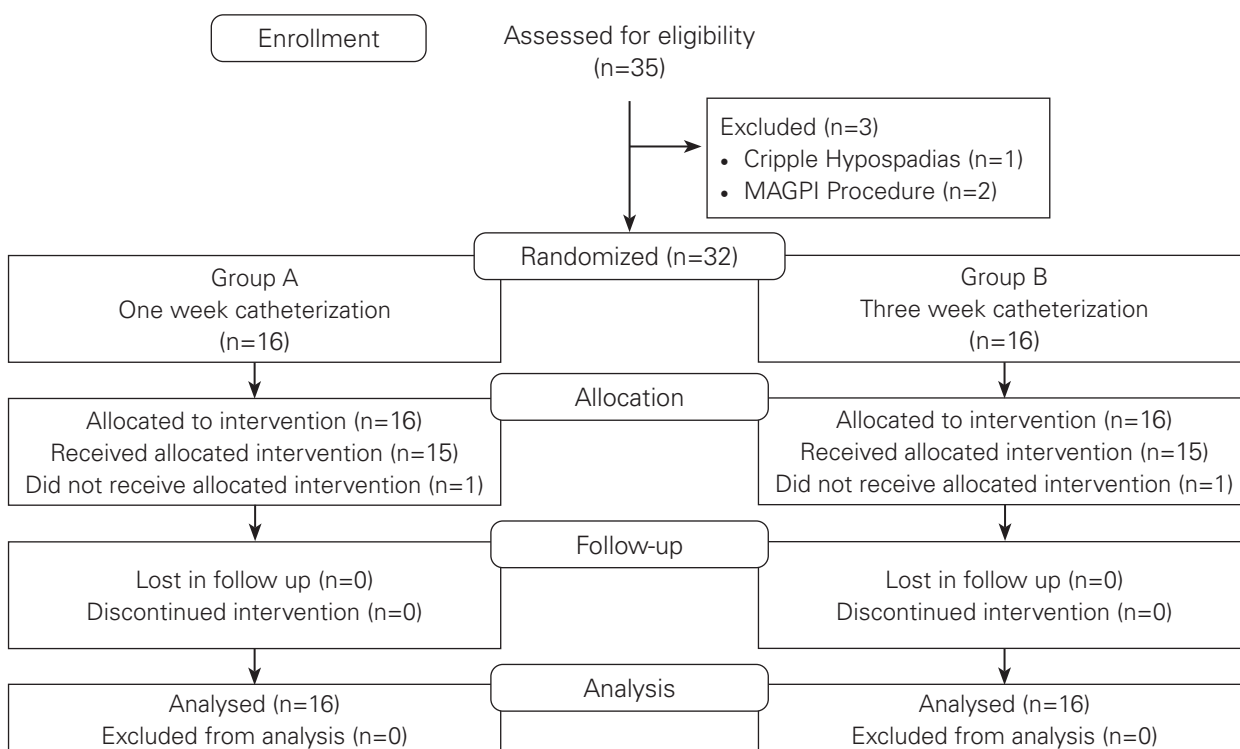


Figure 1. CONSORT flow diagram

removed on 3rd POD. Patients were discharged on post operative day 5 unless contraindicated.

Randomization was done at the end of surgery and the patients were divided into group 1 and 2. Patients on group 1 were followed up on post operative day 7 and catheter was removed. Patients on group 2 were followed up on 21 post operative day or earlier if they have complications. Catheter was removed on 21st post operative day in group 2 patients. All cases were followed up to 30th POD for occurrence of urethra-cutaneous fistula and other complications.

Demography, different clinical profiles and complications were compared between the two groups. Chi square test or Fischer exact test was used for categorical variables; student t-test was used for continuous variable. Data was analyzed using the IBM SPSS Statistics software version 24.0 and p value <0.05 was considered as statistically significant.

RESULTS

During the study period, 35 children underwent urethroplasty for hypospadias. Three patients were excluded from the study because one was cripple hypospadias and two undergone meatal advancement and glanuloplasty (MAGPI) procedure. The remaining 32 children were randomized into two groups having 16 in each group. Consolidated standards of reporting trials (CONSORT) flow chart is explained in Figure 1.

Mean age of the patients was 103±28 months. Twelve (38%) were distal, 12 (38%) were mid penile and 8 (24%) were proximal type. Single stage urethroplasty was done in 19 (59%) patients. The demographic patterns in both groups are explained in Table 1. Age, hypospadias type and stage of surgery were similar in the 2 groups.

Total of 14 (43.8%) patients developed UCF in the study period of 30 days. Fistula was noted in 9

Table 2. Comparison of UCF different age groups, types of hypospadias and stage of surgery

Characteristics	No.	1 week group (n=8)	3 weeks group (n=6)	p value
Age (months)	14	103±21	92±32	
Age group (years)				
1-5	3	2	1	0.3
5-10	4	1	3	
>10	7	5	2	
Hypospadias type				
Distal	5	4	1	0.25
Mid	5	3	2	
Proximal	4	1	3	
Stage of surgery				
Single stage	7	3	4	0.28
Final of 2 stage	7	5	2	

(60%) within 1 week after surgery. In 'One week group' 8 (50%) patients developed UCF and in 'Three week group' 6 (37.5%) patients developed UCF. The difference was not statistical difference (p = 0.48, OR = 0.6, CI 95%= (0.147 - 2.455))

There was not statistical difference of occurrence of UCF with different age group, first or second stage of surgery and types of hypospadias with respect to one or three week group (Table 2).

Irrespective of duration of catheter, occurrence of UCF was also not significant in age group, types of hypospadias and stage of surgery (Table 3).

Regarding other complications, meatal stenosis was observed in 2 patients of 'one week group' only. Urinary tract infection, glans disruption, persistence of ventral curvatures were not found in the study.

Catheterization was prolonged in one patient in one

Table 1. Demographics of patients in two groups (n=32)

Characteristics	Number	1 week group (n=16)	3 weeks group (n=16)
Age (months)	32	112±24	88±27
Hypospadias type			
Distal	12	5	7
Mid	12	8	4
Proximal	8	3	5
Stage of surgery			
Single stage	19	8	11
Final of 2 stage	13	8	5

Table 3. Comparison of various factors in occurrence of UCF (n=14)

Characteristics	Number	p value
Age group (years)		
< 1 yr	0	0.72
1-5	3	
5-10	4	
>10	7	
Hypospadias type		
Distal	5	0.34
Mid	5	
Proximal	4	
Stage of surgery		
Primary	7	0.43
Reoperation	7	

week group. Similarly catheter was self removed on day 12 on three week group. Analysis of the patients was done as per 'intention to treat'. Both patients did not develop UCF.

DISCUSSION

Hypospadias is the second most common urogenital congenital malformation in males.⁵ The aim of urethroplasty is to provide satisfactory cosmetic and functional results.¹ Despite the better understanding of pathology and improved surgical techniques, postoperative complications still occur. Urethrocutaneous fistula, tube dehiscence, meatal stenosis and buried penis are the most common complications of urethroplasty.⁶

In this study the incidence of UCF is 43.75%. This incidence of UCF is higher than that reported in many studies ranging from 0 to 30%.¹ Similarly high incidence of UCF have been reported by Tim Jumbi et al.⁷ Some of the reasons for higher UCF rates in our study could be explained by higher percentage of patients of age >10 years (50%), reoperation surgery (50%) and proximal hypospadias (29%) which are all considered to be high risk factors for UCF by various studies.¹

Indwelling bladder catheter after surgery helps to divert the urine freely and allows healing properly. Common side effect is having bladder spasms owing to irritation of the detrusor by the tip of the catheter. In order to avoid patient discomfort, some surgeons prefer placing a urethral "stent" where the tip is placed just below the external urinary sphincter. However, the main disadvantage of this method is voiding difficulty. On the other hand, a randomized controlled trial by Arda et al, no case of bladder spasm was found in their bladder catheter group and found that urethral stenting not only leads to significant patient irritability and voiding difficulty.⁸

Duration of catheter is also debatable in literature. A longer duration of catheter up to 3 weeks can improve healing. It can be explained by the physiology of urethral wound healing that duration of each phase of wound healing in urothelium is extended for a longer period when compared to that of dermatology.⁴ Bluestein et al found that even by day-21 postoperatively, the sutured repair still presented with a desmoplastic and inflammatory response.⁹

In this study, incidence of UCF was not found to be statistically significant between 1 week and 3 week catheter duration groups ($p= 0.48$). In a study by Paul Daher et al, complications including UCF was significantly more with 1 week catheter duration than 3 week catheter duration ($p<0.05$). Fistula rate was 17.89% and 5.32% in 1 week and 3 week catheterization respectively.¹ In other study done

by Muhamed et al, UCF was 52.5%, 20% and 15% in patients when catheter was removed in 24 hrs of surgery, within 7-10 days and in three weeks respectively. It was significantly different between three groups ($p < 0.001$).¹⁰

Incidence of UCF was higher in proximal hypospadias (50%) than distal (41.7%) and mid-shaft hypospadias (41.7%). But it was not significant among various hypospadias types ($p= 0.43$). Paul Daher et al had similar conclusion that severity of hypospadias did not have an impact on post-operative complications including UCF.³ Chung et al study showed that the risk of developing urethrocutaneous fistula after hypospadias repair is associated with the location of hypospadias (more proximal-type hypospadias) with incidence rate were 10.3%, 33.8% , and 48.9% for distal, middle, and proximal hypospadias, respectively ($p<0.001$).¹¹

In this study incidence of UCF was not found to be different between various age groups ($p= 0.72$). This finding is consistent with Weber et al.¹² They showed that surgical outcome and complications were not different between before or after 18 months of age for urethroplasty. This did not provide evidence to support recommendations concerning the ideal age for hypospadias repair. In another study by Turan Yildiz et al, UCF was higher in the 10-14 year-old group ($p < 0.05$).¹³ The current expert recommendation is better to perform surgery of the male genitalia between 6 month and 18 month of age.¹⁴ This recommendation is based on surgical and anaesthetic considerations and the psychology of child.¹⁵

In this study incidence of UCF was not different between primary surgery and second stage surgery ($p=0.34$). Repeat hypospadias repairs are more prone to develop UCF than primary cases.¹⁶ Snodgrass W et al showed that single re-operative hypospadias urethroplasty has double the risk for additional complications, which increases to 40% with three or more re-operations.¹⁷

Incidence of meatal stenosis ranges 8–11%.^{7,10} In this study the incidence of meatal stenosis was 6.25% . Lower incidence in this study could be due to shorter period of 3 weeks follow up. Median time for diagnosis of meatal stenosis is 6 months.¹⁸

Meatal stenosis was not different between 1 week and 3 week catheter duration groups ($p=0.14$). This finding was consistent with Daher et al.³ In other study done by Muhamed et al, meatal stenosis was 40%, 15% and 2.5% with catheter removed at different post operative time of 24 hrs, 7-10 days and three weeks respectively.¹⁰

CONCLUSION

Duration of indwelling catheterization after hypospadias repair does not have significant impact

on minimizing UCF and meatal stenosis. Occurrence of UCF is not affected by age of surgery, types of hypospadias and single or second staged surgery for hypospadias.

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CONFLICT OF INTEREST

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