



Original Article

Feeding tube or Foley catheter for urethral drainage in hypospadias repair: A randomized controlled trial

Jaraspong Vuthiwong¹, Phitsanu Mahawong¹, Wilaiwan Chongruksut²

¹Division of Urology, Department of Surgery, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand.

²Research Unit, Department of Surgery, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand.

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Abstract

Objective: To compare the early complications occurring between indwelling use of a feeding tube and Foley catheter for urethral drainage after hypospadias repair.

Material and Method: Sixty boys with proximal or distal hypospadias were included in this prospective study. The patients were randomly divided into 2 groups. In group I a feeding tube was used as a urethral stent and in group II a Foley catheter was used. All patients underwent hypospadias repair by the same surgeon using the bilateral external skin tube (BEST) technique. The patients were followed up at 1-month after surgery for clinical evaluation.

Result: There were no statistically significant differences between group I and group II in catheter obstruction, kinking, dislodgment, bladder spasm, hematuria, urinary tract infection, and pain score. At the 1-month follow-up, there were no statistically significant differences between the groups in urethrocutaneous fistula, glans dehiscence, repair breakdown, flap necrosis, hematoma, and wound infection. Five patients in group I (16%) and 1 patient (3%) in group II had catheter dislodgment ($p=0.19$). Seven patients in group I (23%) and 3 patients (10%) in group II had bladder spasm ($p=0.30$).

Conclusion: The use of a Foley catheter appears to lead to lower bladder spasm and catheter dislodgment rates than the use of a feeding tube. A larger sample size is required for a future randomized controlled study in order to add weight to these findings.

Corresponding author: Phitsanu Mahawong, Associate Professor of Urology

Address: Division of Urology, Department of Surgery, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand

E-mail: mahawongp1@gmail.com

Introduction

Hypospadias is a developmental anomaly characterized by a urethral meatus that opens onto the ventral surface of the penis, proximal to the end of the glans. The meatus may be located anywhere along the shaft of the penis, from the glans to the perineum^[1]. It is one of the most common male urogenital deformities, but the precise etiology is still undefined. The incidence of hypospadias is reported to be 1 in 300 male births and increasing^[2]. The only treatment for hypospadias to date is surgical. A modern repair is usually performed in a single stage procedure^[1]. Surgical reconstructive repair of the hypospadias is a challenge. The principal goals of this surgery are better functional outcomes and good cosmetic results.

A number of complications, including urethrocutaneous fistula, meatal stenosis, urethral diverticulum and wound dehiscence, have been reported as a result of the different techniques of hypospadias repair^[3-6]. Therefore, besides the surgical technique used for hypospadias repair, other factors affecting the outcome of hypospadias repair may exist. Some of these factors, including the use of a urethral stent, have important roles. However, the exact roles of these factors in the successful outcome of hypospadias repair are yet to be determined^[7].

To date, there is still disagreement over the need for urine diversion after hypospadias repair for a period of time^[8]. Although many pediatric urologists prefer urinary diversion, there is still controversy regarding its type and duration. While there is little scientific evidence to support one approach over another, most surgeons advocate leaving a bladder catheter in place for a duration of 7-10 days^[9]. Significant morbidity has been associated with urethral stents, including infection, catheter blockage, bladder spasm, and migration. Furthermore, indwelling catheters require special care in order to avoid accidental forcible slippage or inadvertent pressure on the neourethra^[10].

The feeding tubes used for this function are made of polyurethane. The disadvantages associated with the use of a feeding tube are catheter dislodgement and catheter knotting. The incidence of feeding tube knotting is 2 in 1000000 patients^[11]. The Foley catheter is made of natural rubber latex or silicone latex. It has two parts: the tube and balloon. The diameter of the balloon is greater than the tube by 1-2 millimeters. After inflation and deflation of the balloon, a cuffing effect may occur which leads to difficulties in the removal of the catheter and is traumatic to the neourethra^[12]. Some pediatric urologists prefer to use a feeding tube instead of a Foley catheter due to the tube's greater durability, availability, and cost effectiveness.

There is currently no ideal urethral stent for hypospadias repair. Pediatric urologists choose stents according to their personal preferences^[13]. The literature on the use of a urethral stent in hypospadias repair is controversial, and there is a distinct lack of any randomized trial. Therefore, the present prospective, randomized, controlled study was designed to compare the impact of a feeding tube and a Foley catheter on early complications after hypospadias repair.

Material and Method

The study included all children with hypospadias who were suitable candidates for hypospadias repair between August 2015 and December 2017 who were treated by a single surgeon (PM). Hypospadias repair was performed in a single stage procedure with the bilateral external skin tube (BEST) technique. BEST repair comprises: degloving of the penile skin, release of subcutaneous tissue, preparation of bilateral external foreskin flaps, cutting of the urethral plate at the subcoronal level, midline incision of the glans, development of the glans wings, creation of a neourethral plate, tubularization of the neourethra, development of the meatus and glans, and covering of the penile shaft skin using the button hole technique.

The inclusion criteria were boys aged 6 months to 14 years who required a primary repair in all types of hypospadias. The exclusion criteria were patients with associated bladder abnormalities, undescended testes, presence of a hydrocele, or an inguinal hernia. Parents of the patients who qualified for this study based on the inclusion/exclusion criteria were given a registration form explaining the research and treatment procedures, as well as information on the advantages, disadvantages, and potential complications of each treatment. If the parents of the patients had any questions, they were free to ask the physicians about any details.

Patients were randomized into 2 groups by block of four randomization. In group I an infant feeding tube was used (Romsons, Nunhai, India) as a urethral stent (30 children) and in group II a Foley catheter was used (Tyco healthcare, Kangar, Malaysia) (30 children) (Figure 1). In both groups the size of the catheter depended on the size of the

urethra. In group I, a feeding tube no.6 or 8 Fr was passed into the bladder and secured to the glans with stay sutures and adhesive banding. In group II, the Foley catheter was inflated 3 ml. The catheter was connected to a collecting urinary bag.

The early postoperative evaluation included observation for catheter obstruction, kinking, knotting, dislodgment, bladder spasm, hematuria, and UTI. Pain score was recorded on postoperative days 1, 3, and 7. The urethral catheters were left for 1-10 days depending on the type of hypospadias. This decision was made by a clinician. Patients were then examined at the end of the first month for catheter may-related complications. Urethrocutaneous fistula, glans dehiscence, repair breakdown, flap necrosis, hematoma and wound infection were evaluated at the follow-up. Fisher's exact test (two-tail) was used to compare categorical data. Student's T-test was used to compare continuous variables, with $P < 0.05$ considered to indicate statistical significance.

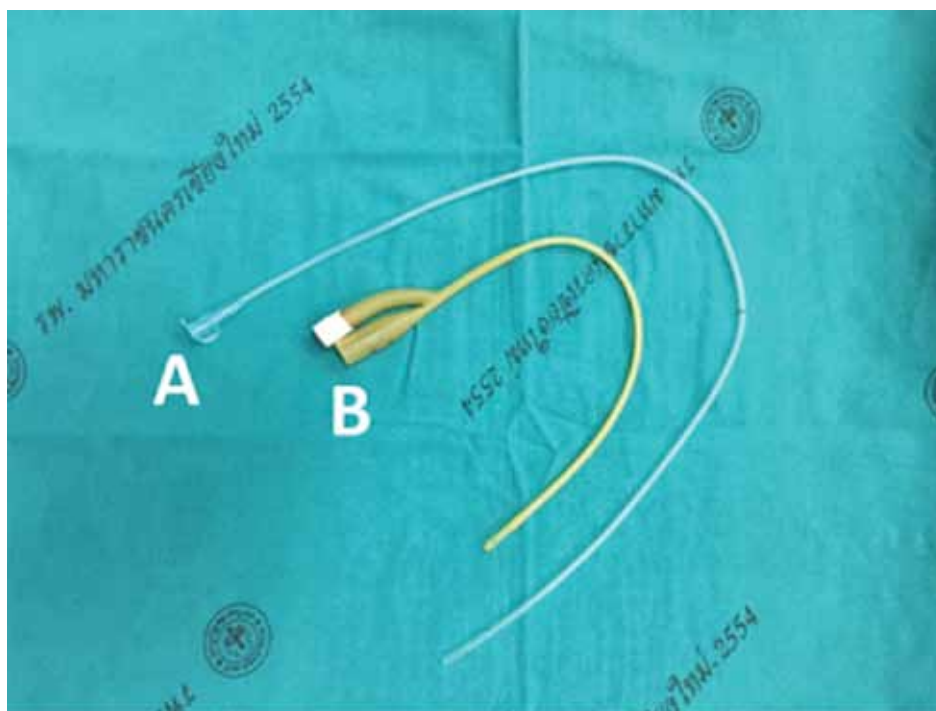


Figure 1 A. Infant feeding tube (8 Fr), B. Foley catheter (8 Fr).

Result

During the study period, a total of 60 patients underwent hypospadias repair and were divided into 2 groups according to the type of urethral catheter: the feeding tube group or group I (30 patients) and the Foley catheter group or group II (30 patients). Demographic data are presented in Table 1. Median age at hypospadias repair was 45.9 months old in group I and 45.2 months old in group II ($p=0.950$). In group I, the types of hypospadias were middle (53%) and posterior (47%). This was in contrast to group II in which the types of hypospadias were anterior (20%), middle (56%) and posterior (24%). There was no difference in size of catheter and catheter duration between the two groups, $p=1.000$ and $p=0.420$, respectively.

Catheter related complications are recorded in Table 2. Two patients in both groups (6%) had

a catheter obstruction. Two patients in group I (6%) had catheter kinking. Five patients in group I (16%) had catheter dislodgment and 1 patient (3%) in group II had catheter dislodgment ($p=0.190$). Seven patients from group I (23%) had bladder spasm and 3 patients (10%) from group II had bladder spasm ($p=0.300$). Only 1 patient in group I had a urinary tract infection. Pain scores on postoperative days 1, 3, and 7 were 5, 2.8, and 1.5 respectively in group I. Pain scores on postoperative days 1, 3, and 7 were 4.5, 2.1, and 0.6 in group II.

At the 1-month follow-up, 5 patients (16%) in group I had a fistula compared with 6 patients (20%) in group II. One patient in group II had glans dehiscence. Two patients in group I had wound hematoma. Two patients in group I had wound infection compared with 1 patient in group II (Table 3).

Table 1. Demographic data of the patients in the study

Demographic data	Feeding tube (Group I)	Foley catheter (Group II)	P-value
Number of patients (N)	30	30	1.000
Mean age (months)	45.9	45.2	0.950
Types of hypospadias (N)			0.015
- Anterior	0	6	
- Middle	16	17	
- Posterior	14	7	
Mean catheter size (Fr)	6.8	6.8	1.000
Mean tourniquet time (minutes)	27.13	25.06	0.227
Mean operative time (minutes)	179.0	166.8	0.137
Mean catheter time (days)	8.60	7.26	0.028
Catheter duration (N)			0.424
- Less than 1 week	15	23	
- One week or more	15	7	
Mean postoperative hospital stay (days)	10.2	9.0	0.061

**Table 2.** Catheter related complications

Complications and pain score	Feeding tube (Group I)	Foley catheter (Group II)	P-value
Catheter problems (N)			
- Obstruction	2	2	1.000
- Kinking	2	0	0.490
- Knotting	0	0	1.000
- Dislodgement	5	1	0.195
Bladder spasm (N)	7	3	0.299
Hematuria (N)	0	0	1.000
Urinary tract infection (N)	1	0	1.000
Mean pain score on postoperative day 1	5.1	4.5	0.368
Mean pain score on postoperative day 3	2.8	2.1	0.217
Mean pain score on postoperative day 7	1.5	0.6	0.017

Table 3. Catheter may-related complications

Complications	Feeding tube Group I (N)	Foley catheter Group II (N)	P-value
Urethrocutaneous fistula	5	6	0.748
Glans dehiscence	0	1	0.492
Repair breakdown	0	0	1.000
Flap necrosis	0	0	1.000
Hematoma	2	0	0.490
Wound infection	2	1	1.000

Discussion

Modern hypospadias repair involves a single stage procedure with the aim of providing satisfactory functional and cosmetic results. Despite advances in surgical techniques, postoperative complications

still occur. Complete dehiscence, urethrocutaneous fistula, and meatal stenosis are the most common complications, and typically develop within 6 months postoperatively. The incidence of urethrocutaneous fistula after hypospadias repair ranges from 0 to 30%^[13].

Although many factors have been found to affect the occurrence of complications, there is still much debate regarding the impact of the role of urinary diversion and urethral stenting on this issue. Buson et al. found that patients in whom urinary diversion was used had a lower rate of complications compared to those who did not have urinary diversion (18.9% vs 4.6%)^[14]. Minevich et al. reported on a single-institution experience of 201 stented Mathieu hypospadias repairs: the total reoperation rate was minimal (1.5%) and compared favorably with the unstented repairs. From the current study, the authors think that urethral stenting decreased the risk of fistula formation while adding only minimal morbidity^[15].

While placing a catheter inside the bladder helps divert the urine freely, a common side effect is bladder spasms owing to irritation of the detrusor by the tip of the catheter. However, these symptoms typically resolve following the administration of anticholinergic medication. Savas et al. found that bladder spasms occurred in 25% (12 from 49 patients) of cases of hypospadias repair when a feeding tube was used as a urethral stent^[16]. In our study, the rate of bladder spasm (23%) from the use of a feeding tube was similar to that reported by Savas et al. We found that the use of a Foley catheter instead of a feeding tube could reduce bladder spasms to only 10%. Amin et al. also found that the incidence of catheter dislodgment was 20% when a feeding tube was used as a urethral stent^[17]. In our study, the rate of catheter dislodgment in the cases where a feeding tube was used was 16%, but only 1 patient in the Foley catheter group had catheter dislodgment because of spontaneous perforation of the catheter balloon.

The present study was not without limitations. First, the small sample size may have caused the differences to not be statistically significant. Second, there were differences in the types of hypospadias and mean catheter time between the groups. Third, absence of a very long-term follow-up after hypospadias

repair as most of the complications would usually occur in the first 6 months postoperatively.

Conclusion

Use of a Foley catheter seems to result in a lower incidence of bladder spasm and catheter dislodgment when compared to a feeding tube. A larger sample size is required for a future randomized controlled study.

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Conflict of interest

The authors report no conflicts of interest in this work.

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