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Efficacy of additional tunica vaginalis flap coverage for protecting against urethrocutaneous fistulas in tubularized incised plate urethroplasty: A prospective, randomized controlled trial

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Purpose: We compared the protective effect of additional tunica vaginalis flap coverage combined with a dartos flap against ure-throcutaneous fistulas in tubularized incised plate (TIP) urethroplasty in a randomized controlled trial.

Materials and Methods: This prospective, randomized controlled trial in a single tertiary center enrolled 50 patients in whom it was feasible to perform single TIP urethroplasty between 2016 and 2017. Consecutive children were randomly allocated to study group A (additional tunica vaginalis flap coverage, n=25) or control group B (dartos-only coverage, n=25). All patients were examined in the outpatient clinic at 1, 3, 12, and 24 months. Postoperative cosmetic outcomes were evaluated by surgeons and parents using the Pediatric Penile Perception Scale questionnaire.

Results: In group B, 1 of 25 patients (4.0%) developed an urethrocutaneous fistula within 12 months. An additional two cases of fistula were found in all proximal-type hypospadias patients at 24 months in the same group without statistical significance (p=0.07). The penile cosmetic satisfaction rate was not significantly different between the groups according to scores on the Pediatric Penile Perception Scale.

Conclusions: Our randomized controlled trial did not show a significant decrease in the incidence of or a significant slowing of the progression of postoperative fistulas after TIP urethroplasty by the use of additional tunica vaginalis coverage. A tunica vaginalis flap is not routinely recommended but could have a selective role in proximal-type TIP urethroplasty with deficient dartos and subcutaneous tissue to cover the neourethra.

Keywords: Hypospadias; Surgical flaps; Urethra; Urinary fistula

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INTRODUCTION

Since its introduction for hypospadias surgery, tubular-

ized incised plate (TIP) urethroplasty has been popularized and applied worldwide [1]. The incidence of complications varies according to the severity of hypospadias [2]. Of the

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complications, urethrocutaneous fistula and meatal stenosis occur frequently [2,3]. Several methods have been used to prevent complications in TIP procedures. Dartos or tunica vaginalis flaps have been developed as well-vascularized tissue with good surgical outcomes during urethroplasty [4]. Tunica vaginalis flaps have been introduced as a feasible second-layer coverage in hypospadias, and retrospective studies have reported better outcomes than for dartos flaps [5]. Similar results have been shown since Snodgrass first reported the use of tunica vaginalis flaps to reduce the incidence of fistulas in 1995 [6-8]. However, these studies were not randomized controlled trials and did not consider the type of hypospadias. Only one randomized controlled trial in 2018 compared tunica vaginalis and preputial dartos flaps [9]. That trial showed a comparable result of tunica vaginalis as a vascular cover in TIP urethroplasty with a patient cohort of 40. Is there an additional benefit to preventing fistula if we use the tunica vaginalis in the TIP procedure? In most cases, would it be enough to cover the neourethra with the dartos layer and subcutaneous tissue? Our study began with this doubt. As experienced surgeons, the authors believed that enhancement of the dartos layer coverage would result in a lower incidence of fistulas without the use of additional T vaginalis and would not affect surgical outcomes.

Our prospective randomized controlled trial was designed to evaluate the usefulness and additional protective effect of a tunica vaginalis flap during TIP urethroplasty against fistulas. We hypothesized that additional tunica vaginalis flap coverage combined with a dartos flap would protect against urethrocutaneous fistulas comparable to dartos-only layer coverage during TIP urethroplasty. The primary goal of the study was an additional reduction in the rate of fistula by use of the tunica vaginalis flap compared with dartos-only coverage. A secondary goal of our study was to assess the feasibility and safety of the use of a tunica vaginalis flap during TIP urethroplasty.

MATERIALS AND METHODS

1. Patients and study design

Our study protocol was approved by the Institutional Review Board of Asan Medical Center (approval number: 2016-0586).

Between June 2016 and December 2017, a prospective and randomized controlled trial was conducted in 50 patients who underwent TIP urethroplasty in a single tertiary center. Eligible patients who met the inclusion criteria were randomly assigned to two groups on the basis of secondlayer coverage. Group A received additional tunica vaginalis flap coverage, and group B (control group) received dartos flap-only coverage during TIP urethroplasty. Pediatric hypospadias patients suitable for the TIP procedure were included, whereas patients who underwent scrotal or testicular surgery for any reason were excluded. The primary purpose was to compare the success rate and incidence of complications between the groups.

2. Randomization procedure

Subjects who were informed about the study and agreed to participate were assigned a clinical study subject identification code in the order in which they signed the clinical study consent form. Patients were allocated into two groups

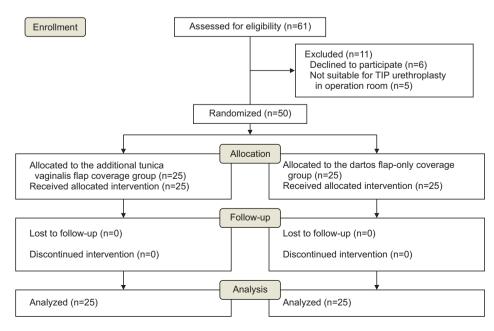


Fig. 1. CONSORT 2010 flow diagram of patient recruitment and follow-up. TIP, tubularized incised plate.



according to secondary urethral covering technique, with 25 patients each receiving additional tunica vaginalis flap or dartos-only coverage (Fig. 1). Randomization sequences were generated in a 1:1 allocation ratio using random blocks of 4 and 6 via SAS (version 9.1; SAS Institute, Cary, NC, USA). The random numbers were assigned to the patients by using the Interactive Web-Based Response System (IWRS).

3. Hypospadiac surgical procedure

All procedures were performed with the patients under general anesthesia. Glans width, stretched penile length, and urethral plate width of the longest diameter of the penis were measured intraoperatively by use of calipers and a ruler [10]. After the penile skin was degloved, the chordee was intraoperatively corrected via dorsal albuginea plication (3-0 prolene) if the penile curvature was over 20 degrees as measured with a protractor. The urethral plate was incised from the hypospadiac meatus to the glans penis with the Snodgrass method and then tubularized over a Nelaton catheter (8-French) with a polyglactin 910 (6.0 Vicryl; Ethicon) subcuticular continuous suture.

In all patients, a glans wing was made and glandular

urethra formation was performed. A number 11 blade was used to manipulate a glans wing up to half of the glans. Dissection was done with micro-scissors until the corpus cavernosum was revealed to ensure sufficient glans wing width. The neourethra suture was finished up to the glans level. Glans fusion was performed using polyglactin 910 sutures (6.0 Vicryl). In the dartos-only coverage group, the neourethra was covered by the dartos tissue near the neourethra (Fig. 2B). The tissue was sutured with polyglactin 910 sutures (6.0 Vicryl) without tension. In all patients, coverage over the neourethral suture line was made by using a dartos layer. Also, de-epithelized subcutaneous tissue was used to additionally cover the neourethra during Byar's flap transposition in patients with an eligible preputial skin.

Harvesting for the additional tunica vaginalis flap coverage was performed on the relatively larger scrotum with hydrocele because it was easy to handle; otherwise, a left-side testicular vaginalis was preferred. A rectangular-shaped tunica vaginalis was harvested from the dorsal part of the vaginalis using micro-scissors. The flap was 5 mm in width and the length was sufficient to cover the neourethra (Fig. 3A). The distal end of the flap was not inserted below the

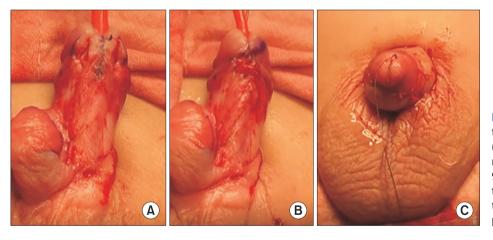


Fig. 2. Dartos flap-only coverage during tubularized incised plate urethroplasty. (A) Subcuticular suture was used for neourethra formation with polyglactin 910 sutures (6.0 Vicryl; Ethicon). (B) Dartos tissue was covered on the neourethra without tension. (C) Immediate postoperative photography.







Fig. 3. Additional tunica vaginalis flap coverage during tubularized incised plate urethroplasty. (A) Tunica vaginalis flap was designed with rectangular shape. (B) Tunica vaginalis flap was applied on the neourethra. (C) Immediate postoperative photography.



glans because the glans can become too tight with the import of additional tissue, possibly causing glans dehiscence. The graft was placed by using an interrupted suture over the neourethra (Fig. 3B). Thereafter, tension-free interrupted sutures were made on the penile shaft in more than 6 points with polyglactin 910 sutures (6.0 Vicryl). Byar's flap was taken and the ventral portion of the penis was covered. The penile degloved skin was sutured with polyglactin 910 sutures (5.0 Vicryl; Ethicon) with meticulous tension-free suturing. A 6-French Urocare® balloon catheter was inserted in all patients.

The penis was kept secured with DuoDERM Extra Thin dressing (ConvaTec). The dressing was sandwiched; i.e., the penis was placed between two gauze pieces and secured over the anterior abdominal wall with compression film (Tegaderm Diamond Pattern Film Dressing 1686; 3M) applied over the gauze. A double diaper was used to protect the surgical site from urine contamination by positioning a urethral catheter tip between the two diapers. In cases of toilet-trained boys, the urine bag was connected to the urethral catheter. An open dressing was performed on the third postoperative day and the thin dressing was removed on the fifth postoperative day. In cases of stool contamination, the dressing was replaced directly. The indwelling urethral catheter was maintained for 7 to 9 days during hospitalization (7 days for distal, 8 days for mid penile, and 9 days for proximal hypospadias patients). The patients were planned to be discharged on the seventh to ninth days after the operation.

4. Assessment of outcomes

Early complications were evaluated during admission. Minor complications such as hematomas and swelling were checked every morning and problems that could occur during the hospital stay were recorded. Patients were instructed to visit at 1, 3, and 12 months postoperatively for evaluation of fistulas, meatal stenosis, urethral strictures, and cosmetic results. Additional outpatient follow-up at 24 months was performed to check for suspected fistulas or if other major problems were detected. The patients' guardians were asked to assess their satisfaction with the cosmetic outcome of urethroplasty in response to the Pediatric Penile Perception Scale (PPPS) [11]. During the follow-up visits at 1, 3, and 12 months, the urologist completed the PPPS questionnaire. Finally, we tested the statistical concordance of the PPPS scores between the surgeon and the parents.

5. Statistical methods

Continuous variables are expressed as medians or means± standard deviations. Categorical variables are expressed as percentages. Data analysis was performed by using IBM SPSS Statistics for Windows, version 19.0 (IBM Corp., Armonk, NY, USA). All p-values less than 0.05 were considered statistically significant. Categorical variables were compared by chi-square test and continuous variables were tested by independent t-test.

RESULTS

The preoperative baseline demographics and intraoperative findings of the patients are presented in Table 1. A total of 50 patients were enrolled and randomly assigned to a study group. There were no significant differences in the age distribution or incidence of hypospadias between the two groups. The median ages at the time of the surgical procedures were 14 (range: 8-95) and 11 (range: 8-25) months in groups A and B, respectively. The severity of hypospadias showed similar distribution patterns in both groups. The additional tunica vaginalis coverage group included six patients (24.0%) with distal penile hypospadias, five (20.0%) with mid penile hypospadias, seven (28.0%) with proximal penile hypospadias, four (16.0%) with penoscrotal hypospadias, and three (12.0%) with scrotal hypospadias. The dartos-only coverage group included five patients (20.0%) with distal penile hypospadias, six (24.0%) with mid penile hypospadias, seven (28.0%) with proximal penile hypospadias, six (24.0%) with penoscrotal hypospadias, and one (4.0%) with scrotal hypospadias. Combined cryptorchidism and penoscrotal transposition were observed in two (8.0%) patients in each group, which were corrected at the time of operation. Penisrelated parameters such as stretched penile length, glans width, and penile curvature did not differ significantly between the groups. Mean operative time was 113±26 minutes in the additional tunica vaginalis coverage group and 95±21 minutes in the dartos-only coverage group (p=0.012). Admission durations were 9.1 and 8.6 days in the tunica vaginalis and dartos-only coverage groups, respectively, without significant difference.

No wound infection or glans dehiscence was noted during regular follow-ups in any patients (Table 2). No scrotal hematoma or testicular complications occurred in the additional tunica vaginalis coverage group. In the dartos-only coverage group, 1 of 25 patients (4.0%) developed a urethrocutaneous fistula at 12 months. This patient underwent TIP urethroplasty for penoscrotal hypospadias having 30° penile curvature. A fistula developed at the penoscrotal junction at 12 months of follow-up. After the patient was observed for a while, he underwent fistula repair and meatoplasty for a mild meatal stenosis at 16 months postoperatively.



Table 1. Baseline characteristics and intraoperative finding of patients who underwent additional tunica vaginalis flap coverage compared with dartos-only coverage during TIP urethroplasty

Variable	Additional tunica vaginalis flap coverage group (n=25)	Dartos-only coverage group (n=25)	p-value
Median age at surgery (mo)	14 (8–95)	11 (8–25)	
Hypospadias type			
Distal penile	6 (24.0)	5 (20.0)	
Mid penile	5 (20.0)	6 (24.0)	
Proximal penile	7 (28.0)	7 (28.0)	
Penoscrotal	4 (16.0)	6 (24.0)	
Scrotal	3 (12.0)	1 (4.0)	
Combined hydrocele	2 (8.0)	1 (4.0)	
Combined cryptorchidism	2 (8.0)	2 (8.0)	
Combined PST	3 (12.0)	3 (12.0)	
Intraoperative findings			
Stretched penile length (mm)	38.6±11.7	37.1±9.4	0.616
Glans width (mm)	12.3±2.5	12.7±2.2	0.576
Urethral plate width (mm)	4.2±1.6	4.4±1.5	0.546
Curvature (°)	29.2±17.3	25.2±15.8	0.398
Neourethral length (mm)	20.6±8.8	17.6±6.4	0.175
Total anesthetic time (min)	155±27	137±22	0.016
Operative time (min)	113±26	95±21	0.012
Admission (d)	9.1±1.3	8.6±1.1	0.157

Values are presented as median (range), number (%), or mean±standard deviation.

TIP, tubularized incised plate; PST, penoscrotal transposition.

Table 2. Complications and PPPS scores of patients who underwent additional tunica vaginalis flap coverage compared with dartos-only coverage during TIP urethroplasty

Variable	Additional tunica vaginalis flap coverage group (n=25)	Dartos-only coverage group (n=25)	p-value
Complications			
Fistula	0 (0.0)	1 (4.0)	0.322
Meatal stenosis	0 (0.0)	1 (4.0)	0.322
Glans dehiscence	0 (0.0)	0 (0.0)	
Skin necrosis	0 (0.0)	0 (0.0)	
Scrotal hematoma	0 (0.0)	0 (0.0)	
PPPS score at 1 mo			
Surgeon	12.72±1.88	13.24±1.76	0.318
Parent	9.92±2.59	10.7±2.47	0.270
PPPS score at 3 mo			
Surgeon	12.60±2.06	13.20±1.80	0.279
Parent	9.80±2.40	10.52±2.65	0.319
PPPS score at 12 mo			
Surgeon	12.72±2.07	13.40±1.55	0.196
Parent	9.60±3.23	10.48±2.60	0.294
Follow-up (mo)	15.0±5.7	15.7±6.0	0.683

Values are presented as number (%) or mean±standard deviation. PPPS, Pediatric Penile Perception Scale; TIP, tubularized incised plate.

After a follow-up period of 12 months, we noticed two cases of fistula in the proximal-type hypospadias patients at 24 months. All three patients had received dartos-only coverage. The second patient, with proximal penile hypospadias (urethroplasty at 14 months of his age), underwent repair after confirmation of a midshaft fistula at 22 months postoperatively. The last patient, with penoscrotal hypospadias (urethroplasty at 19 months of his age), had a proximal penile shaft fistula at 24 months after surgery. He had a ventral curvature of approximately 30 degrees (severe). He underwent fistula repair surgery postoperatively at 27 months. There was no significant difference between the two groups (p=0.074).

The mean PPPS score evaluated by the surgeon was always higher than that of the parents. The mean scores of each group showed no significant difference between surgeons and parents for all three separate PPPS evaluations.

DISCUSSION

Tunica vaginalis flaps are used for penoscrotal surgery because they have the advantage of using a pedicle with good vascularity. For hypospadias repair, tunica vaginalis flaps can be effectively used in recurrent fistulas [12,13].



They can also be used to restore a ruptured testis, to repair tissue damage due to testicular torsion, and to repair epispadias. The vaginalis flap was initially used for fistula correction and showed good resolution for fistula repair [14,15]. Its thin, elastic, expandable, and highly vascularized properties mean that tunica vaginalis coverage is easily applied to TIP urethroplasty [16].

A meta-analysis by Pfistermuller et al. [2] reported a fistula incidence of only 5.7% in 3,621 cases of primary distal TIP urethroplasty. Given the low incidence of fistulas, a tunica vaginalis flap is not usually recommended for distal TIP repairs. Among 625 proximal-type TIP repairs, 12% had to undergo repeat surgery for complications [2]. Of the 16.7% of complicated cases involving meatal stenosis, fistula, and stricture, 10% had fistulas. The type of hypospadias (proximal vs. distal) is considered a risk factor for the development of urethrocutaneous fistula [17].

The results of our study demonstrated the absence of fistulas in the additional tunica vaginalis flap coverage group and a fistula incidence of 1 of 25 (4.0%) in the dartos flap-only coverage group. The primary proposed benefit of a tunica vaginalis flap is a reduction in fistulas. However, our study did not show a statistically significant effect compared with dartos-only coverage during TIP urethroplasty over 1 year of follow-up. Delayed fistula formation developed in two more patients in the dartos-only group during further follow-up (24 months) without a significant difference.

If dartos tissue is sufficient, the incidence of fistula would be expected to be low and there would be no significant effect on the surgical outcome even without the use of additional tunica vaginalis routinely. Consequently, routine use is not recommended. However, when follow-up over 1 year tends to reduce fistula incidence, it is concluded that selective application of tunica vaginalis may be useful if tissue is lacking to cover the neourethra suture line in proximaltype hypospadias. Tunica vaginalis can reduce the occurrence of fistulas by forming a thick layer of subcutaneous tissue in the suture line. In proximal-type hypospadias, the length of the neourethra is longer, resulting in a higher risk for fistulas than with the distal type. A tight suture covering with insufficient dartos tissue on the neourethra has a high possibility for skin devascularization [18,19].

Several retrospective studies have been conducted about tunica vaginalis flap coverage during urethroplasty. Chatterjee et al. [20] investigated 20 patients treated with the dartos flap alone and 29 patients treated with a tunica vaginalis flap and reported better outcomes in the tunica vaginalis flap group. Snow et al. [6] observed a fistula occurrence rate of 9% for the use of tunica vaginalis flaps with a microscope in various types of urethroplasty, with no significant side effects in the ipsilateral testicle or penis. Tavakkoli Tabassi and Mohammadi [21] performed tunica vaginalis flap coverage as the second layer in 33 patients with hypospadias during TIP urethroplasty, reporting one case of fistula during a 2-year follow-up.

Our randomized controlled study has a few limitations. First, we enrolled all types of hypospadias showing various rates of fistula occurrence. Different rates of fistula occurrence have been reported according to the severity of hypospadias. For this reason, further studies are warranted with eligible criteria including specific site of hypospadias. such as penile or proximal, during patient allocation, Second, the number of patients would have needed to have been greater for the findings to be statistically significant. Given the optimal sample size estimation for the study, the lack of a statistically significant effect may have been due to the small number of patients, even with the additional followup until 24 months. Additionally, even though the questionnaire given to parents was easy to understand, the PPPS is not validated for use in Korean, which is a drawback of our study.

CONCLUSIONS

Our randomized controlled trial did not show a significant decrease in the incidence of or slow the progression of postoperative fistulas after TIP urethroplasty using tunica vaginalis additional coverage. Given the low incidence of fistula formation in TIP urethroplasty with dartos flap coverage, the tunica vaginalis flap is not routinely recommended. However, the tunica vaginalis flap could have a selective role in proximal-type TIP urethroplasty with deficient dartos and subcutaneous tissue to cover the neourethra.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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