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The Simple Two-Layered And The Triple-Layered (Pants Over-Vest) Repair For Denovo Fistula Post Hypospadias, A Randomized Controlled Trial

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Abstract: Purpose: To compare the success rate of the simple two-layered "Goldstein and Hensle techniques" and the triple-layered 'pants-over-vest' repair for denovo fistula post hypospadias repair.

Patients and Methods: A randomized controlled trial was carried out for denovo post hypospadias fistula. Inclusion criteria were patients with age ≥ 6 months and all repairs were done at least after 6 months from the primary repair. Patients will be allocated into 2 groups, patients will undergo simple two-layered closure (Group 1), while in Group II; patients will undergo triple-layered double flap closure, the pants-over-vest repair. The primary outcome is success which defined as no fistula recurrence within 6 months post the repair. All patients were followed up at 1,3, and 6 months. The function assessment was done for successful cases in both groups either voiding or cosmetic outcomes.

Results; A total 91 patients met the inclusion criteria between November 2021 to December 2023. Patients were grouped according to fistula site to distal (85%) and proximal (15%). Fistula was characterized according to size (>2mm and <2mm) and number (single and more than one). The overall success rate was 62.5% in simple two-layered repair versus 82.5% in triple-layered with significant difference (p>0.039) during follow up. No patients had any major complications during the early or delayed postoperative periods. There was no impaction on success rate regarding the age of patients, fistula characters, and duration to fistula repair. The majority of patients in both groups were satisfied with micturition in more than 90%. PVR in all cases is insignificant. The PPPS showed no significant difference between the two groups in terms of total score (p>0.95).

Conclusions: The triple-layered repair technique was better than the simple repair technique regarding recurrent fistula formation with comparable high satisfaction in functional and cosmetic outcomes. The significant success rate in the repair with the addition of a waterproofing layer recommended that rather than being saved for later use, this interposition layer should be used as soon as possible to reduce a recurrence.

Keywords: Hypospadias, urethrocutaneos fistula, waterproofing layers, durham pants-over-vest.

Introduction

In the field of Pediatric Urology, Hypospadias shows the highest prevalence among urologic congenital anomalies, having a global incremental rising trend over the years, Egypt has a high prevalence trend for hypospadias (>50/10,000 total births) **(1).**

There are various methods for hypospadias repair all of them are around to have cosmetically acceptable shaft with normally located meatus, together with straight penis and straight stream **(2)**.

Complications in the repair of hypospadias surgery persist despite progress. The most common adverse effect of surgery for treating hypospadias is urethracutaneous fistula (UCF) **(3).**

Due to their frequent recurrence and likelihood to demand many surgeries in a single patient, UCF continue to be a distressing complication for both surgeons and patients **(4)**. Depending on the degree of hypospadias, various approaches, and the skill of the operating surgeon, incidence of UCF is reported be variable from 0 to 30% **(5).** It might be an indicator for another problem, like urethral diverticulum or stricture **(6).**

Even yet, many of the fundamentals of the perfect restoration method have been made clear. Currently, it is thought to be necessary to perform fine tissue handling, invert the mucosa after cutting the epithelialized portion of the fistula, perform a repair at multiple layers using properly vascularized tissues, avoid using non-absorbable suture materials and overlapping sutures, perform a tension-free closure, with the use of optical magnification, and perform needle-point cautery for hemostasis **(7)**. Still, no single repair method has proven to be generally successful.

Numerous variables impact the outcome of repair, including the state of tissues, the length of time the operation lasted, the surgeon's prior experience with fistula repair, the material of suture utilized, and their level of expertise **(8)**. Size (less than 5 mm and greater than 5 mm) and whether the fistula is single or multiple can be used to classify the fistula.

It is recommended that the UCF be repaired a minimum of six months following the initial procedure, due to the approximate six-month duration needed for skin vascularization and resolving inflammation **(9).**

In 1981, Goldstein and Hensle proposed a simplified technique of UCF repair with a success rate of 100 % **(10)**. The use of different types of well-vascularized tissue as the second interposition layer became popularized later on as a layered or multilayer repair technique. The success rate of this technique varied in different series of studies.

A simple layered closure with or with no trans-positional skin flap is effective in 71% of repairs. The fistula's tract is outlined and its exterior rim and the adjacent tissue are entirely dissected down to fresh tissue. Inversion of the tract is then performed by keeping absorbable sutures outside the urethra and turning the edges intraluminal. Additional layers of adjacent subcutaneous tissue and skin are generously mobilized to help buttress the area **(11).**

The success rate at the first attempt of a triple-layered double-flap closure, the 'pants-over-vest' repair, covering the simple closure of the fistula with two overlapping cutaneous flaps, one of which was 94% versus 74% for simple closure. At the second attempt it was 100% for the layered repair versus 80% for simple closure **(12).**

In addition to the retrospective nature and heterogeneous fistula characteristics of the studies comparing fistula repair quality, the retrieved data revealed that the techniques utilized varied over time. Therefore, a prospective study is required to assess fistula repair techniques.

Patients and methods:

Study design:

A randomized controlled clinical trial

Target population:

In Mansoura urology and nephrology center-Paediatric division, children with denovo post hypospadias fistula whom will be scheduled for repair will be assessed. Legible subjects fulfilling inclusion criteria will be included in a randomized clinical trial and their parents will be asked to sign an informed consent form according to Good Clinical Practice and the Declaration of Helsinki.

Duration of study: November 2021 to December 2023

Inclusion criteria:

1) Age ≥ 6 months

2) Urethral rest ≥ 6 months' post fistula diagnosis

Exclusion criteria:

1) Patient with Glanular and Coronal fistula site.

2) Uncorrected meatal stenosis.

Patients' allocation:

All patients underwent thorough history and physical examination with respect to age, duration from primary surgery, number, site, size of the fistula, and the condition of the surrounding skin. All repairs were done at least after 6 months from the primary hypospadias surgery. Patients received induction dose of 1st generation cephalosporin followed by oral antibiotics for 10 days in the postoperative period and were operated under general anesthesia.

Randomization: The randomization process was carried out using closed envelope technique in a 1:1 ratio. Patients were assigned to the study groups on the day of surgery.

All patients will be initially examined properly intraoperative to assess the pliability of penile skin. Site, size and number of fistulas were identified by inserting lignocaine jelly through the meatus using nozzle of the syringe. After induction, meatal stenosis and distal urethral obstruction were ruled out by passing infant feeding tube.

Patients will be allocated into 2 groups. In the 1st one, patients will undergo fistula simple two-layered closure. The margins of each fistula will excised and the fistula closed taking care to invert the fistula edge into the urethral lumen with an additional layers of adjacent subcutaneous tissue according to Goldstein and Hensle technique (Group I), while in the 2nd group (Group II); patients will undergo triple-layered double flap closure, the pants-over-vest repair, covering the simple closure of the fistula with two overlapping flaps, one of which was deprived of the external skin layer.

STEPS (Group II):

1. Circumferential incision around fistula and 2 flaps were marked with marker.

2. Exterior rim of fistula is dissected to fresh tissue all around.
3. Lateral flaps were mobilized and fistula was closed with polydioxanone or Vicryl 6-0 over 6/8 Fr infant feeding tube.
4. One flap was de-epithelialized.
5. The de-epithelialized flap was sutured over the fistula repair underneath the opposite layer.
6. Second skin flap was used to cover the repair in a vest-over-pant fashion allowing for a multilayer closure without overlapping suture line.

In both groups the repair was done by the same skilled surgeon (defined as 2 years post fellowship training) and by 6/0 absorbable sutures (vicryl). The catheter was maintained for 10 days after surgery in both groups with no other diversion was used and cuban dressing for 3 days.

STUDY OUTCOMES AND MEASURES:

I. The primary outcome: fistula repair success will be recorded.
Success was defined as no fistula recurrence within 6 months post the repair.
Follow up: all patients were followed up by clinical examination and history taking assessing force and caliber of urinary stream from normal meatus, urine leak from any site other than normal meatus, and chordee. Evaluation was done at 1,3, and 6 months.
II. The secondary outcome: assess functional (voiding and cosmetic) outcome.

1. The urinary voiding outcome was assessed by: Uroflowmetry**:** After toilet training, *Q-max* (was considered normal if <25th percentile, as equivocally obstructed when in the 5th-25th percentile, and obstructed if >5th percentile) and Voided volume were estimated.
2. Cosmetic assessment: was evaluated using the following two questionnaires, The Pediatric Penile Perception Score **(PPPS)** will be completed by parents to evaluate their perception of the cosmetic outcomes with regard to meatus, glans, straightness of erection skin and general appearance.

STATISTICAL ANALYSIS

Data were entered and statistically analyzed using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA, version 26). Independent sample t-test, Mann Whitney test or $\chi 2$ (chi-squared) test, were used for comparison between groups, as appropriate. "P-value ≤0.05" was considered to be statistically significant.
Calculation of the sample size: Using G* power programme and chi-square test based on effect sample size of 0.3, assuming type I statistical error 5% and type II statistical error of 20%, to obtain a power of 80% and based upon difference of about 30% between both techniques in **(13, 14)** and increase 10% as drop out, so the total sample size will be 91 patients.

COMPLIANCE WITH ETHICAL STANDARDS

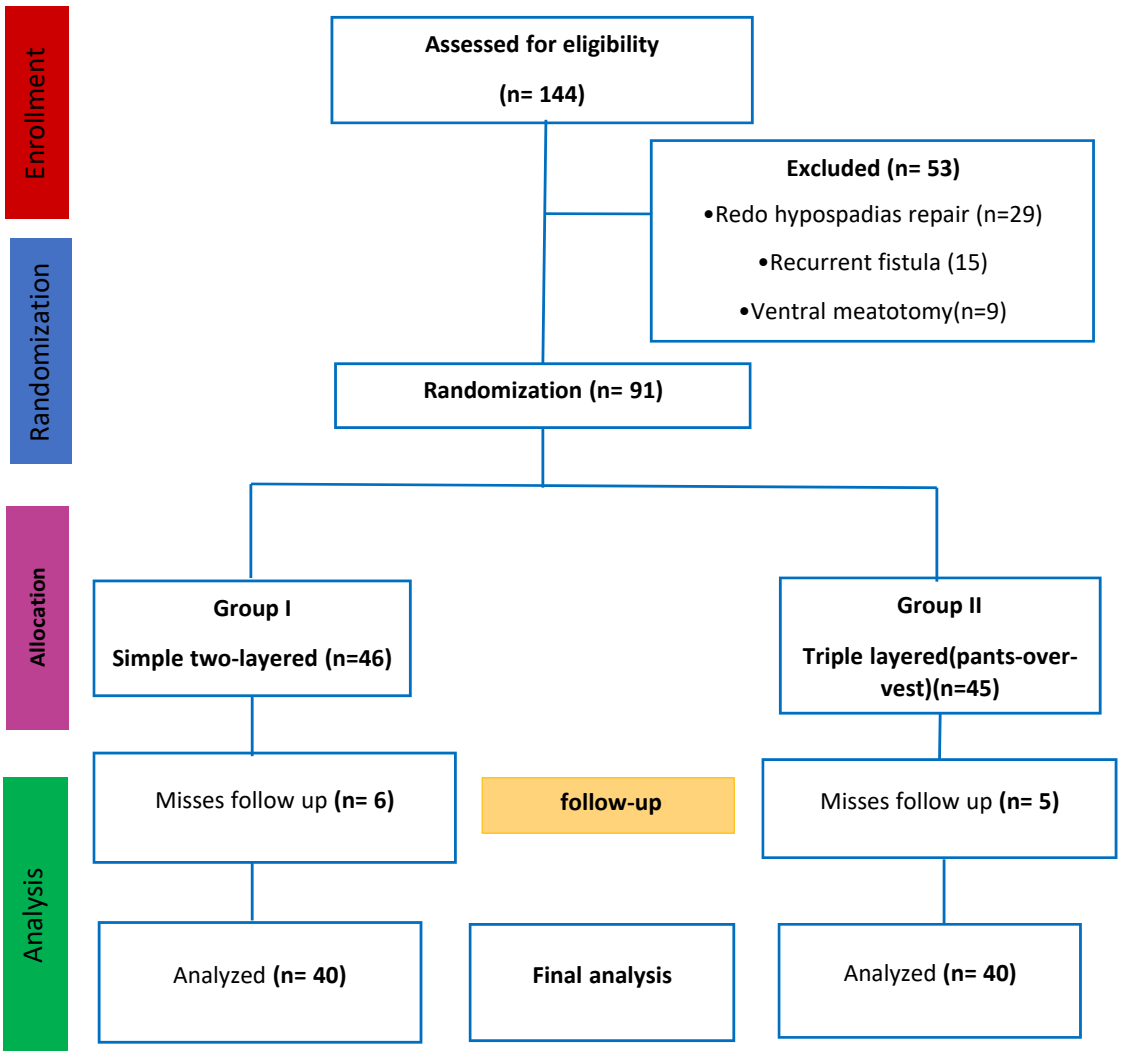
Conflict of interest: The authors declare that they have no conflict of interest.
Human and animal rights. All procedures in this study involving human participants were in accordance with the 1964 Helsinki Declaration and its later amendments.

Results:

Patients were recruited for participation in the study between November 2021 to December 2023. Out of 144 post hypospadias fistula patients enlisted for repair, 91 patients met the inclusion criteria and were eligible to take part in the study. Other 53 patients, redo repair of hypospadias was done for 29 cases and 9 patients underwent ventral meatotomy only.

Subjects' allocation and study's flowchart:

46 patients underwent the simple two-layered closure (Group I) and the other 45 patients underwent the triple layered, pants-over-vest, technique (Group II) as shown in CONSORT flowchart (Fig. 1).



(Figure 1): CONSORT flow chart for study participants

Baseline patients' demographics and clinical characteristics:

The median age for all groups at time of fistula repair was 7 years with range (3-21), the median age for group 1 was 8y and that of group II was 6y. Mean patients' Body mass index (BMI) at time of surgery was 17.71 ± 3.3 and 17.6 ± 3.4 in group I and Group II respectively.

Patients were grouped according to site of fistula to distal one including distal and mid penile position which is 68 (85%) patients and only 12 (15%) patients as proximal group. Fistula was characterized according to size (>2mm and <2mm; table 1) and number (single and more than one; table 1). The majority of fistula size was less than 2mm (93.8%) and single opening in (88.8%) in both groups.

Table 1: Baseline patients' demographics and clinical characteristics:

Patients characteristics	All groups (N=80)	Simple (N=40)	Triple (N=40)
AGE Median (Range)	7 (3-21)	8(3-17)	6(3-21)
BMI Mean (±SD)	17.67 =3.38	17.71=3.36	17.63=3.44
Fistula position %			
Distal	68(85%)	34(85%)	34(85%)
Proximal	12 (15%)	6 (15%)	6 (15%)
Fistula number %			
1	71(88.8%)	35(87.5%)	36(90%)
<1	9(11.2%)	5(12.5%)	4(10%)
Fistula size %			
>2mm	75(93.8%)	38(95%)	37(92.5%)
<2mm	5(6.2%)	2(5%)	3(7.5%)
Primary repair %			
MAGPI	6(7.5%)	3(7.5%)	3(7.5%)
MATHIEU	7(8.8%)	3(7.5%)	4(10%)
TIP	60(75%)	30(75%)	30(75%)
PROXIMAL	7(8.8%)	4(10%)	3(7.5%)
Duration to repair median (range)	22.5(6-60)	23(10-60)	19.5(6-60)

All repairs were done at least after 6 months from the primary repair with median 22.5 m (6-60), 23m (10-60) and 19.5m (6-60) in all groups, group 1and Group II respectively. The primary procedure for hypospadias was done in Mansoura urology and nephrology center in 68 cases (85%), and 12 cases were referred from elsewhere to our hospital, as it is tertiary referral center. The majority of primary procedure either done in our center or elsewhere (by history) were post-tubularized incised plate (TIP) repair in 60 cases (75%).

The overall success rate was 62.5% in simple two-layered repair versus 82.5% in triple-layered, pants-over-vest, technique with statistical significant difference (p>0.039) during follow up with maximum 6 months; table 2. No patients had any major complications during the early or delayed postoperative periods. There was no impaction on success rate regarding the age of patients [when categorized to preschool (>6y) and postschool age], fistula characters, and duration to fistula repair.

Table 2: primary end point.

	SIMPLE (40)	TRIPLE (40)	P VALUE
SUCCESS	25(62.5%)	33(82.5%)	0.039
FAILURE	15(37.5%)	7(17.5%)	

**Categorical variables (Chi square test); significant p < 0.05

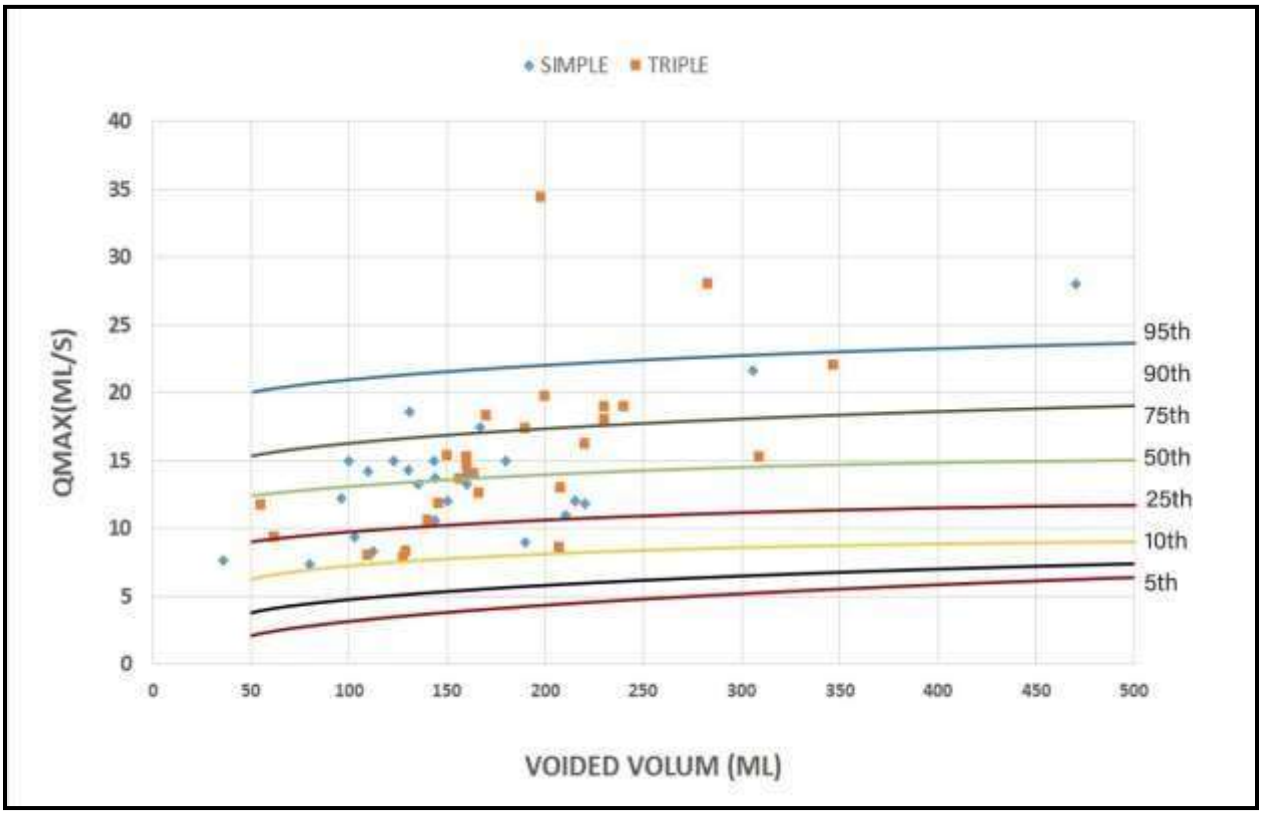
The function assessment of successful cases in both groups either voiding or cosmetic outcomes.

Voiding assessment

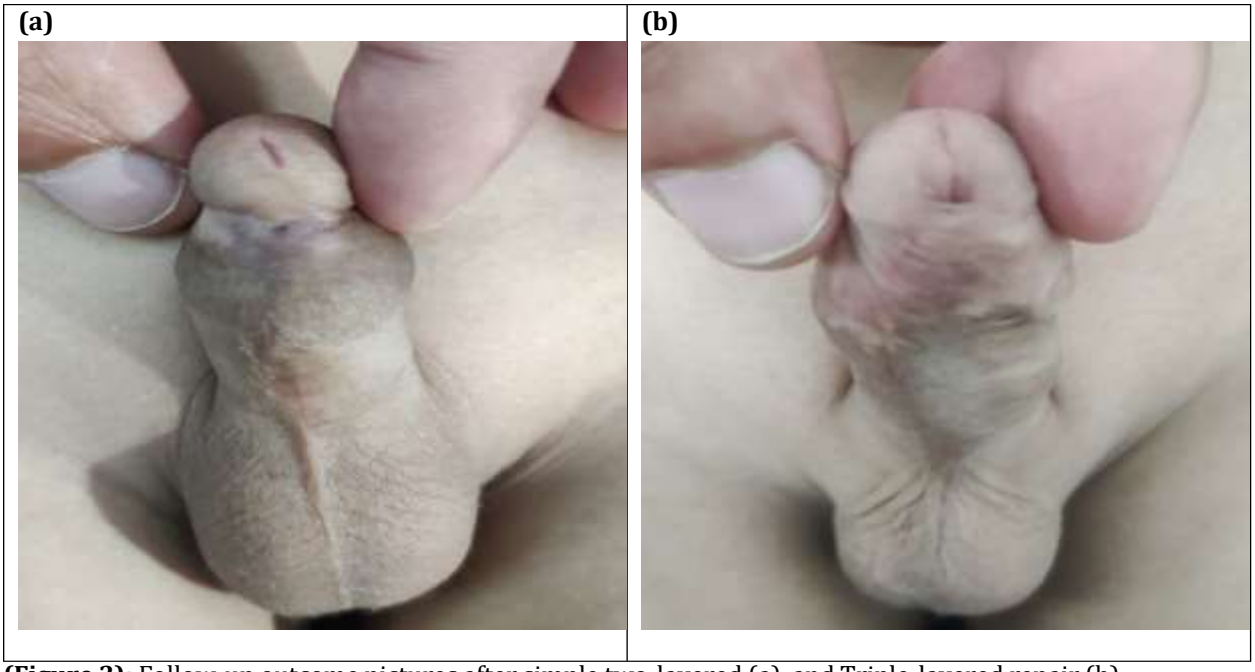
We assessed the voiding function during follow up visit by asking about satisfaction, straining, streaming, spraying, and post voiding dribbling. The majority of patients in both groups were satisfied with micturition in more than 90%.

Uroflowmetry was done for all cases in both groups with success fistula repair, maximal flow rates (Q-max) were plotted against the voided volume on a recently published nomogram for age-matched children

(15). All cases have normal flow pattern (above <25th percentile) (fig.2). Post Voiding Residual (PVR) was estimated and all cases have insignificant PVR.



(Figure 2): Q-max versus voided volume



(Figure 3): Follow-up outcome pictures after simple two-layered (a), and Triple-layered repair (b).

Cosmetic assessment

There no special tool critically evaluates cosmetic outcome, we use The Pediatric Penile Perception Score (PPPS) which is the newest objective assessment tool, which seems to be the most reliable instrument to assess penile self-perception in children after hypospadias with more concern on the shape of skin and general appearance of the penis.

In our study, comparing two techniques in fistula repair, the majority of patients expressed a high satisfaction for every single item of the penile perception scale especially, in appearance of skin with no significant difference between the two groups in terms of total score as in table 3.

Table 3: Pediatric penile perception score:

	Simple (N=25)	**Triple (N=33)**	**Total**
PPPS 1. Shape of Meatus			
Very satisfied	20(80%)	26(78.8%)	46
Satisfied	5(20%)	7(21.2%)	12
Dissatisfied	--	--	--
Very dissatisfied	--	--	--
PPPS 2. Shape of glans			
Very satisfied	23(92%)	29(87.9%)	51
Satisfied	2(8%)	4(12.1%)	7
Dissatisfied	--	--	--
Very dissatisfied	--	--	--
PPPS 3. Shape of skin			
Very satisfied	13(52%)	18(54.5%)	31
Satisfied	10(40%)	12(36.4%)	22
Dissatisfied	2(8%)	3(9.1%)	**5**
Very dissatisfied	--	--	--
PPPS 4. Penile length			
Very satisfied	22(88%)	28(84.8%)	50
Satisfied	3(12%)	5(15.2%)	8
Dissatisfied	--	--	--
Very dissatisfied	--	--	--
PPPS 5. General appearance			
Very satisfied	14(56%)	20(60.6%)	34
Satisfied	9(36%)	10(30.3%)	19
Dissatisfied	2(8%)	3(9.1%)	**5**
Very dissatisfied	--	--	--

	SIMPLE	**TRIPLE**	**P VALUE**
Total score mean(±SD)	13.52(2)	13.48(2.2)	0.95

*Continuous variables (independent t-test); significant $p < 0.05$

Discussion:

Development of urethrocutaneous fistula after corrective surgery for hypospadias remains one of the most important complications **(9).** There is no perfect technique for repair of urethrocutaneous fistula as in hypospadias. Factors affecting the result are various like the condition of local tissues, duration of the surgery, previous hypospadias repair technique, type of suture material, and experience of the surgeon **(8)**.

Tissue ischemia, distal obstruction of the neourethra, and postoperative infection are considered the main factors in UCF development after hypospadias surgery. However, the frequency of fistula formation has decreased due to surgeon experience, improvement in operative technique, use of appropriate suture materials and instruments, and coverage of the neourethra with well-vascularized tissue. Also, the suture lines should not overlap each other, and a dartos facial flap should be used between the suture lines to improve surgical outcomes **(9)**.

Repair of urethrocutaneous fistula should be done at least 6 months after primary procedure, as the time required for skin vascularization and resolution of inflammation around the fistula is around 6 months **(9)**. In our series, all cases were operated at least 6 months after primary procedure.

Under general anesthesia site, size, number of fistulas, and status of the surrounding skin can be meticulously examined and distal obstruction ruled out by inserting feeding tube in all cases **(3)**. Distal obstruction must be ruled out by cystoscopy, retrograde urethrography, or urethral calibration.

Intra-operative calibration is of paramount importance in cases where passage of feeding tube failed. In our series, obstruction was ruled out by inserting lignocaine jelly through the meatus using nozzle of the syringe. After induction, meatal stenosis and distal urethral obstruction were ruled out by passing infant feeding tube.

Meticulous penile examination is mandatory to assess the status of local tissue and to design the management plan. The number of fistulas was confirmed in various series by insertion of catheter or nozzle of syringe filled with diluted povidone-iodine into the urethral meatus and injection of betadine into the urethra, which helps in identifying any additional fistula and tracing the fistulous tract **(9)**. In our series, we used lignocaine jelly for detection of additional fistulas in all cases. In cases with multiple fistulas adjacent to each other, all are joined and made into single fistula.

The use of a microscope or loupe for magnification is now considered mandatory in hypospadias and other reconstructive surgeries. However, we did not use that in all of our procedures due to technical limitations.

The utility of interposing additional layers of tissues between the urethral repair and the penile skin in an attempt to 'waterproof' the UCF repair and to prevent overlapping suture lines has been widely accepted as an integral component in the management of UCF **(16)**. The different water proofing layers used in various series were de-epithelialized skin, tunica vaginalis, dartos flap, dorsal subcutaneous preputial flap, and external spermatic fascia. However, the utility and advantage of one over the other have not been established till date.

We used the de-epithelialized skin flap (pants-over-vest technique as described by Durham Smith) **(17)** as a waterproofing layer in patients who had healthy vascular, pliable surrounding skin without distal urethral/meatal obstruction and chordee. We compare this technique for urethrocutaneous fistula with simple two-layered using ventral dartos fascia which is widely applicable in clinical practice.

De-epithelialized skin flap (pants-over-vest repair) is done in group II cases. Urethra should be closed over feeding tube of size 6/8 Fr as per the caliber of urethra, using 6-0 Vicryl in continuous fashion by inverting the edges of urethra. A catheter one size smaller than urethral lumen should be selected to permit voiding around

the tube if tube becomes blocked or bladder spasm occurs. Time period of feeding tube/ catheter is variable in various series from 4 to 10 days **(9)**. In our series, the catheter was kept for 10 days in both groups.

All patients were followed up by clinical examination and history taking assessing force and caliber of urinary stream from normal meatus, urine leak from any site other than normal meatus, and chordee. Evaluation was done on weekly basis for 1 month, monthly basis for 1 year, and then yearly for next 5 years **(9)** . In our series, we also follow up our patient assessing the recurrence rate after one, three and six months.

The recurrence rate was 37.5%, 17.5% with simple two-layered and triple-layered techniques, respectively. This is in agreement with previously reported data on the effectiveness of multiple layers in preventing fistulae after urethroplasty **(18, 19).** However, the success rate of the simple repair technique, which is 62.5% in our study, contrasted with the first report of Goldstein and Hensle, who reported complete success with the same technique **(10)**.

In recent systematic review and meta-analysis, the success rates associated with different techniques were calculated and compared **(16)**. The cumulative success of using skin-based flaps in included studies (272 cases in 8 studies) is 87.5% which is slightly high compared with our result. There are possible reasons to justify such differences, e.g., patient selection, the fact that the surgeries were not done by one surgeon with variable experience and the technique is not widely applicable in our center.

Cimador et. al. reported the success rate at the first attempt of a triple-layered double-flap closure, the 'pants over-vest' repair, was 94% versus 74% for simple closure **(12).** Another study, comparing the recurrent fistula formation rate in forty UCF cases which was much higher in simple repair 30% than in layered repair 5% **(20)**.

Elbakry reports the outcome of managing urethrocutaneous fistula after hypospadias repair over 10 years, Simple closure was successful in 30 of 42 small fistulae (71%) and Rotational and advancement skin flaps were successful in 13 of 15 large fistulae (86%) **(13)**.

There are many studies evaluate the Durham Smith technique, Venkat et al. reported the success rate of 100% and concluded, Durham Smith vest-over-pant technique is a simple solution for complex problem (post-hypospadias surgery penile fistulas) in properly selected patients **(14)**. Availability of good, vascular, non-scarred, pliable surrounding skin and non-overlapping suture line is the key to success.

Recently, there is increased interest about the perception of the cosmetic outcomes and the psychological effects of hypospadias surgeries in our children. The main problems in cosmetic and functional outcomes are often subjective and variable between patients, parents, and doctors. So, we believed that a self-assessment questionnaire may be a good tool to provoke reliable answers.

In our work, we have used the PPPS, the first tool that was available to assess the surgical outcome and self-perception after hypospadias surgery and aimed to assess the improvement in psychosexual well-being and quality of life in children and adolescents with hypospadias surgeries **(21)**.

The limitation of our study was the shorter follow-up period, technical difficulties which is not widely applicable, not use of magnification loupe and the surgeries were performed by multiple surgeon with variable expertise.

The advantage of our study is that it was a randomized controlled trial with a large sample size and the variables were well-matched, including the similar population.

Conclusion:

The triple-layered repair technique was better than the simple repair technique regarding recurrent fistula formation with comparable highly satisfied in functional and cosmetic outcomes. The significant success rate in the repair with the addition of a waterproofing layer recommended that rather than being saved for later use, this interposition layer should be used as soon as possible to reduce a recurrence.

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