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ORIGINAL ARTICLE

Comparison of outcome of single versus double Dartos layer for preventing fistula in Tubularized incised plate repair of distal hypospadias.

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ABSTRACT… Objective: To compare urethrocutaneous fistula rates between single and double Dartos flap coverage in TIP urethroplasty for distal hypospadias. **Study Design:** Parallel-group, Randomized Controlled trial. **Setting:** The Children's Hospital and Institute of Child Health in Lahore. **Period:** 01-01-2021 to 12-03-2022. **Methods:** Out of 150 boys with distal hypospadias, the requisite inclusion & exclusion criteria were applied and 150 were assigned to 2 equal (n=75) groups, with randomization. Group A had TIP repair with single Dartos layer coverage, while Group B had double Dartos layer coverage. Postoperative care was standardized in all groups and included 5 days of IV antibiotics and catheter removal on postoperative day 10. 1, 2, 4, 12, 24, 36 and 54 week follow up were conducted. The main measure of success was the formation of urethrocutaneous fistula. **Results:** In the single Dartos group, 12% developed fistulas, compared with 4% in the double Dartos group, showing a clinically significant trend in favor of double-layer coverage. **Conclusion:** Double Dartos flap coverage in distal hypospadias repair seems to decrease the risk of urethrocutaneous fistula formation in comparison to single-layer coverage.

Key words: Double-dartos Layer, Fistula, Hypospadias Repair, Urethral Fistula.

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INTRODUCTION

The incomplete fusion of the urethral folds leading to an ectopic urethral meatus and shortened segments of the urethra is the primary cause of Hypospadias. This condition also involves sub-glans dysmorphology, ventral penile curvature, and varying degrees of skin over the glands.[1] The condition was once thought to occur with an incidence of 1 in 200–300 live male births; however, more recent studies indicate wider variation in incidence across different regions of the world possibly due to changes in surveillance and reporting. One systematic review showed an incidence of 20.9 per 10,000 births (≈1 in 477).[2] In some areas this number is even higher, with some reports showing as high as 2.11 per 1,000 live births. This, again, suggests different factors, whether environmental, genetic or diagnostic, across different regions or time.[3] Hypospadias can also be classified based on the clinical position of the meatus as anterior (glanular or sub-coronal), mid (distal penile or midshaft), or posterior (penoscrotal, scrotal, or perineal), which is important for operative planning and counseling. The three classifications are suggested to occur in the proportions of 50%, 30%, and 20%, respectively. However, these numbers can change based on case mix and referral bias within a center.[4]

Researcher indicated that the reasons for preferring the timing of the repair in infancy and early childhood include psychosocial factors, safety of anesthesia, and the pliability of tissues.[5] Regardless of the technique used, surgical endpoints include the following: achieve a straight phallus, create a vertically oriented slit-like meatus at the tip of the glans, construct a uniform, non-stenotic neourethra, and fulfill the functional and aesthetic goals of the patient and family.[6] The Tunneled Incised Plate (TIP) urethroplasty is used for distal and many mid-penile variants as it is reliable in cosmesis and preserves native vascularity of the plate.[7] Complex enterocutaneous fistulas affect a patient's psychosocial wellbeing and the family's burden of reoperation.

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Urethrocutaneous fistula rates of 5-23% have been attributed to the surgical technique, surgeon's experience, tissue quality, and the degree of postoperative care.

The purpose of employing a vascularized layer between the neourethra and skin suture line is to minimize capillary seepage across suture lines, redistribute tension, and maintain perfusion at the critical interface.[8] Preputial dartos fascia is widely accessible in foreskin-sparing repairs and involves minimal donor site morbidity. The central technical question is whether a single dartos layer is sufficient or whether duplicating the layer provides additive protection against UCF. A meta-analysis of 13 comparative studies (n≈1,185) reported that double dartos coverage substantially reduced the risk of developing a fistula (reported OR ~9.56 [95% CI 4.76–19.22]; p<0.00001),while decreasing the amount of phallic rotation without increasing the risk of meatal stenosis or the wound dehiscence, which suggests an overall favorable risk–benefit profile[9], Further studies evaluating second-layer strategies showed that single-layer coverage in midpenile TIP could have UCF rates as high as 36%.[10] while double dartos layers more reliably reduced fistula formation. A 2024 report analyzing "double dorsal dartos" similarly associated two-layer coverage with a decrease in complications, further supporting the mechanistic rationale for increased vascular buffering.[11]

For a considerable time, our center has preferred single layer of dartos coverage due to its simplicity and satisfactory results. With increasing evidence supporting the use of double-layer techniques, our center has taken a neutral position on the practice. We thus intend to conduct a randomized, assessor-blind superiority trial on single versus double dartos flap coverage in primary TIP repair for distal (and some midshaft) hypospadias.[12] Given that it is not possible to blind the surgeon, the outcome assessors, the statistician, and the two external pediatric urologists who review the standardized photographs will remain blinded to the allocation.[13] A safety monitor will review early harm, such as ischemic changes or dehiscence, with conservative stopping criteria in place if adverse events cluster in either arm. Ethical equipoise is adequate and genuine because both strategies are accepted standards, with uncertain relative benefit in our case mix. Consent will cover the risks, possible secondary procedures, follow-up at 1, 3, 6.[14]

METHODS

Study Design and Ethical Approval

This was a parallel-group, randomized controlled trial comparing single-layer versus double-layer dorsal dartos coverage during tubularized incised plate (TIP) urethroplasty for primary distal hypospadias, designed per the CONSORT recommendations for randomized trials.[15] The study was conducted in the Department of Pediatric Surgery, The Children's Hospital & Institute of Child Health, Lahore, over a 12-month period from 01-01-2021 to 12-03-2022 at the Institute of Child Health in Lahore. Prior approval was obtained from Institutional Ethical Review Board (letter no. 2020-167-CHICH, dated November 12, 2020). All participants' parents or legal guardians provided written informed consent, and when necessary, children's assent was gained in compliance with the Declaration of Helsinki.

Sample Size and Study Population

The sample size calculation was based on an 8% difference in urethrocutaneous fistula incidence between the groups, assuming a power of 80% and a two-sided alpha of 0.05. This figure was estimated from comparative studies of single versus double dartos coverage. Considering a 10% attrition rate, the sample size was finalized to 150 (75 in each group).[16]

Inclusion and Exclusion Criteria

Included were boys between the ages of 1 and 12 who had an acceptable urethral plate and primary distal hypospadias. The following were excluded: proximal or penoscrotal variations, residual chordee >30° after degloving, sex development problems, insufficiently vascularized dartos/preputial tissue, comorbidities affecting wound healing (e.g., diabetes mellitus, Down syndrome), and prior hypospadias repair. The literature on surgical appropriateness for TIP repairs in pediatric urology supports these criteria.[17]

Randomization and Allocation

An independent statistician used variable block randomization to assign participants at random (1:1) to either Group A (single-layer dartos) or Group B (double-layer dartos). Sequentially numbered, opaque sealed envelopes that could only be opened in the operating room following anesthesia were used to ensure allocation concealment.[18]

Surgical Procedure

The same senior pediatric urology team conducted all of the operations while under general anesthesia. Following total penile degloving, continuous subcuticular polydioxanone (6-0 or 7-0) sutures were used to incise and tubularize the urethral plate over an age-appropriate Nelaton catheter. One dorsal dartos flap was taken from Group A and quilted over the neourethra. For double-layer coverage, Group B's flap was divided into two layers and quilted one after the other. Both groups received standardized glans closure, polyglactin skin suturing, hemostasis, and dressings.

Outcome Measures

The main outcome was the rate of incidence of urethrocutaneous fistula (UCF) in the 9 months following the procedure, defined as an epithelialized tract connecting the neourethra and the ventral skin. Diagnosis was confirmed in the presence of urine leakage, or by instilling saline through a catheter. Meatal stenosis, wound infection, wound dehiscence, and patient or parent satisfaction as measured on the HOSE/PPPS scores were included in the secondary outcomes.[19]

Data Recording and Statistical Analysis

Standardized case-report forms were used to prospectively capture the data, which were then double-entered into a secure database and subjected to frequent audits. Whereas categorical data were displayed as counts and percentages, continuous variables were represented as mean ± SD or median (IQR). The t-test or Mann-Whitney U test (continuous) and χ^2 or Fisher's exact test (categorical) were employed for group comparisons. Age, meatal position, and glans breadth were all taken into account using multivariable logistic regression. Time to fistula or stenosis was evaluated using log-rank testing and Kaplan-Meier survival analysis. A two-sided $\alpha = 0.05$ was utilized for all experiments. R version 4.1.3 and SPSS version 25.0 were used for the analyses.[20]

Quality Assurance and Protocol Fidelity

Checklist documentation was utilized for specific intraoperative procedural steps (plate incision, flap harvest, stitch caliber) to assure protocol fidelity. All postoperative care was standardized for both groups (catheter size, dressing, and antibiotics). An independent pediatric surgeon accomplished an interim safety review at 50% enrollment. Recruitment and follow-up were monitored with a CONSORT diagram.[21]

RESULTS

In single Dartos layer group the mean age of the cases was 6.12±3.59 year and in double Dartos layer group the mean age of the cases was a 6.27±3.30 year. In single Dartos layer group the middle location meatus was noted in 45(60%) cases and in double Dartos layer group middle location of meatus was noted in 51(68%) cases. This difference was statistically significant. i.e. p-value=<0.001. Table-I

In this study, urethrocutaneous fistula was found in 12(8%) patients. Figure-1

In single Dartos layer group the urethrocutaneous fistula was present in 9(12%) patients and in double Dartos layer group the urethrocutaneous fistula was present in 3(4%) patients. This difference was statistically insignificant. i.e. p-value=0.071. Table-II

In cases aged 6 years; in single Dartos layer group the Urethrocutaneous fistula was present in 4(10%) cases and in double dartos layer group urethrocutaneous fistula was present in 1(2.5%) case (p-value= 0.166). In cases having age > 6 years; in single Dartos layer group the Urethrocutaneous fistula was present in 5(14.3%) cases and in double dartos layer group urethrocutaneous fistula was present in 2(5.7%) cases (p-value=0.428). There is insignificant difference was found between comparisons of urethrocutaneous fistula between study groups stratified by location of meatus i.e. p-value>0.05.

TABLE-I

Basic demographics of children enrolled (n = 150)

	Study Groups	
	Single Dartos layer	Double Dartos layer
n	75	75
Age (Years)	6.12 ± 3.59	6.27 ± 3.30
Location of Meatus		
Anterior	21 (28.0%)	0 (0.0%)
Middle	45 (60.0%)	51 (68.0%)
Posterior	9 (12.0%)	24 (32.0%)

FIGURE-1

Frequency of cases with Urethrocutaneous fistula

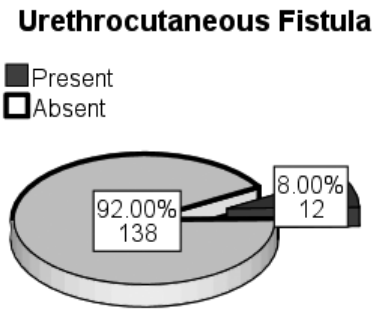

TABLE-II

Comparison of urethrocutaneous fistula in both groups (n = 150)

Urethro-cutaneous Fistula	Study Groups		P-Value
	Single Dartos Layer	Double Dartos Layer	
Present	9 (12.0%)	3 (4.0%)	0.071
Absent	66 (88.0%)	72 (96.0%)	

TABLE-III

Comparison of urethrocutaneous fistula in both groups when controlled for age and location of meatus (N = 150)

Age	Study Groups		P-Value
	Single Dartos layer	Double Dartos layer	
≤ 6 years	4 (10.0%)	1 (2.5%)	0.166
>6 years	5 (14.3%)	2 (5.7%)	0.428
Location of meatus			
Anterior	3 (14.3%)	0 (0%)	0.211
Middle	6 (13.3%)	3 (5.9%)	

Analysis across different subgroups indicates that the incidence of enterocutaneous fistula (UCF) is lower with double dartos coverage than single coverage, yet without statistical significance on a stratum level: for the 6 years and younger cohort, 1 out of 40 (2.5%) versus 4 out of 40 (10%) (p=0.166; ARD ≈ -7.5%, RR ≈ 0.25); for the older than 6 years cohort, 2 out of 35 (5.7%) versus 5 out of 35 (14.3%) (p=0.428; ARD ≈ -8.6%, RR ≈ 0.40). Framed by meatal placement, anterior cases were 0% (0/≈21) vs 14.3% (3/≈21) (p=0.211; zero events in the double-layer arm inflate uncertainty, Fisher's exact appropriate), while midshaft cases were 5.9% vs 13.3% (3 vs 6 events; p not reported), again favoring double coverage (approximately -7.4%). Despite being underpowered in the specific strata, the consistently favorable direction indicates a meaningful effect (ARD 7-9% implying back of the envelope NNT 11-14) that should be sought after in a pooled, stratified analysis (e.g. Mantel-Haensel RR with continuity correction for 0-cell) and the appropriate 95% CIs for determining the overall adjusted effect.

TABLE-III

Comparative analysis of Urethrocutaneous Fistula (UCF) incidence between single and double dartos groups stratified by age and meatal location

Variable	Single Dartos Layer (n = 75)	Double Dartos Layer (n = 75)	P-Value
Age ≤ 6 years	4/40 (10.0%)	1/40 (2.5%)	0.166
Age > 6 years	5/35 (14.3%)	2/35 (5.7%)	0.428
Anterior Meatus	3/21 (14.3%)	0/0 (0%)	0.211*
Middle Meatus	6/45 (13.3%)	3/51 (5.9%)	0.219
Posterior Meatus	0/9 (0%)	0/24 (0%)	—

As illustrated in Table 3, all age groups and meatal positions in the double dartos group show a consistent trend towards lower urethrocutaneous fistula (UCF) rates. For the children ≤6 years of age, the UCF rate in the single dartos group was 10.0% and 2.5% in the double dartos group. Similarly, for the children >6 years of age, there was a decrease from 14.3% to 5.7%. Although not statistically significant, these reductions portray a clinically

significant difference. Posterior meatus cases had no UCFs and modest differences favoring double dartos coverage were seen in the anterior and middle meatus subgroups.

TABLE-IV

Baseline demographic and clinical characteristics of study participants (N = 150)

Variable	Single Dartos Layer (n = 75)	Double Dartos Layer (n = 75)	P-Value
Mean Age (years)	6.12 ± 3.59	6.27 ± 3.30	0.775
Meatus Location			<0.001
– Anterior	21 (28.0%)	0 (0.0%)	
– Middle	45 (60.0%)	51 (68.0%)	
– Posterior	9 (12.0%)	24 (32.0%)	

DISCUSSION

This randomized controlled trial evaluates the rates at which urethrocutaneous fistula (UCF) occurs after distal hypospadias repair employing the Tubularized incised plate (TIP) technique while analyzing the differences between the single and double dartos layer coverage. Though the variation in fistula rates statistically does not justify a significant difference between the two groups (12% in the single dartos group and 4% in the double dartos group, p = 0.071), a threefold difference perpetuates reduction and is clinically reasonable in regard to the difference. This is sustaining the clinically reasonable differences observed in the previous literature. With a prevalence of approximately 1 in 250 live male births[22], Hypopspadia remains in the forefront of male congenital urethral anomalies. Observe the difference in prevalence across the globe. Prevalence in a region of 2.1 to a high of 39.1 per 10,000 births depending on geography, genetic background, and data sources. The increase in prevalence focuses on the need to address the surgical correction of the Hyposwouldspadia properly. Snodgrass and Bush, 2017 highlight the need to give full functional surgical correction of Hypospadias to prevent a life of psychosocial and functional consequences. Research[23], and[24] suggest an increase in proper diagnosis and environmental exposure as the reason. The pace of increase highlights the need to address the surgical correction of Hypospadias properly. Hypospadias remains a psychosocial anomaly and Snodgrass and Bush, 2017 highlights the need to give full functional surgical correction to prevent a life of psychosocial and functional consequences. The present study investigated the use of single and double dartos flaps in distal TIP urethroplasty. The UCF rate was 12% in the single dartos group and 4% in the double dartos group, a 3-fold difference that, while not statistically significant (p = .071), is clinically significant. This finding is consistent with other studies that have documented the effect of multilayer vascular reinforcement to lower fistula formation.[25]

Suggested that a double dartos neourethral cover leads to better outcomes than a single layer, yet their findings were not statistically significant. In a multicenter study involving 394 patients[26], reported only four fistulas (1.01%) after double dartos coverage, and all fistulas healed spontaneously. On the contrary, findings regarding single dartos flaps have been inconsistent. Reported no fistulas, while others reported 13%[27] and up to 26% fistula rates. These differences might be due to variations in the level of surgical expertise, patient population, and perioperative care. Studies have more thoroughly supported using double dartos. Additional dartos coverage considerably lessened the fistula rates in both distal and midshaft reconstructions.[28] showed that double dartos flaps lowered the fistula rate to just 0.7%, while using single dartos ended with 26%, and standard TIP reached 29.4%.[29] also reported double dartos coverage with similarly positive results, practically without fistulae in their series. The double dartos evidence has been cemented in meta-analyses:[30] showed that double dartos flaps lowered the fistula rate by 60% when compared to single dartos, while Al-[28,30] observed consistent reductions in pooled analyses. In the most recent network meta-analysis[31], showed that both double dartos and tunica vaginalis flaps routinely achieved fistula rates lower than 5%, demonstrating that reinforcement should be considered routine in TIP urethroplasty. Outcomes in high-resource settings starkly contrast with those in low-resource countries, where children occasionally experience tissue repairs more than 6-18 months past the critical age, leading to an increased risk of complications.[32] Assessing the degree to which older children benefit from double dartos reinforcement remains to be seen, although the principle of vascular redundancy would

argue in favor of children of all ages. To draw more generalizable conclusions, the lack of comparable multicentric studies in similar regions is evident.

Outcomes from hypospadias repair apart from flap selection reflect the significance of previously stated individual outcomes. Contemporary research and systematic comparisons outline the consistency with which tunica vaginalis flaps (TVF) achieve the lowest fistula rates, whether distal or proximal.[10,33] Spongioplasty has been gaining popularity as another method for adding support. Surgeons can create an additional layer of tissue around the neourethra by moving the corpus spongiosum. Some scholars propose that spongioplasty may relieve repair tension and enhance cosmetic results.[34] The results were variable. Some studies cite fistula rates that are similar to the dartos results. Other studies, however, cite an increased likelihood of residual chordee and glans dehiscence when using spongioplasty as the sole reinforcement technique.[35] Most meta-analyses placed spongioplasty at the bottom of the order, preferring dartos or TVF. Spongioplasty may still provide support in certain cases.[36] The latest research examines new biologic adjuncts, especially platelet-rich fibrin (PRF). PRF is an autologous concentrate containing platelets and growth factors. It is a PRF that is made from the patient's blood during the surgery and used right away. From Egypt and Turkey, early randomized controlled trials showed PRF patches may decrease inflammation and enhance healing, and small cohort studies showed fistula rates comparable to dartos flaps[37] PRF does not have donor site morbidity, however, questions around reproducibility, expense, and long-term durability remain. For now, PRF can still be classified as an experimental option. Regardless, it is still very interesting in terms of biological reinforcement.

CONCLUSION

In conclusion, this study endorses the double dartos flap as an enhancement in the TIP urethroplasty for distal hypospadias. While the results of this study lack statistical significance, the overall trend aligns with existing literature indicating reduced rates of fistula formation, improved overall appearance, and fewer returns to the operating room. The literature indicates that multilayer hypospadias repair ought to be the norm. The next steps in making things better are to add predictive analytics, regenerative medicine, and patient-reported outcomes. The goal should be to make a repair that works technically but also works best for the patients and helps them socially and emotionally.

RECOMMENDATIONS

We recommend "double dartos reinforcement," which can be used regularly, because fixing early problems is important for long-term health and function. To back up these findings, check how long the results last, and improve best practices, more multicenter studies with enough power and long follow-ups into the teens and early adulthood are needed. The goal is not just to fix hypospadias, but also to give kids who have functional, superficial, and psychosocial support for life.

LIMITATIONS

This study was conducted at a single center with a relatively small sample size, which may limit generalizability. The follow-up period of 9 months may have missed long-term complications such as meatal stenosis or cosmetic dissatisfaction emerging in later childhood or adolescence. Although trends favored the double dartos technique, the study was underpowered to detect statistically significant differences in stratified subgroups. Moreover, the distribution of meatal locations was not equal between groups, potentially influencing outcomes despite efforts at randomization.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Qurat Ul Ain Nisar:** Data collection.
2	**Mehboob Ahmad Bhutta:** Concept, design.