Original Article

Risk of Glans Dehiscence Associated with Vascular Flap Coverage of the Glanular Neourethra during Primary Urethroplasty: A Randomised Controlled Trial

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Abstract

Background: Hypospadias is one of the common congenital anomalies of male genitalia. Although over 300 different operative techniques have been described, post-operative complications are still common, of which glans dehiscence (GD) is the most severe complication requiring redo urethroplasty. Some surgeons use the vascular flap to cover the glanular part of the neourethra to prevent GD, but there are controversies regarding its usefulness. There is a paucity in the literature, about articles evaluating the risk of GD associated with vascular flap coverage of the glanular neourethra during primary urethroplasty. **Materials and Methods:** We planned a single-blinded, parallel-design, randomised controlled trial involving 56 cases of hypospadias treated with single-stage urethroplasty amongst the admitted cases of hypospadias for primary urethroplasty in the Department of Paediatric Surgery, AIIMS, Bhubaneswar, from November 2017 to December 2019 as an M.Ch. thesis project. This was approved by the Institutional Ethics Committee and enrolled in the national registry of clinical trial. 28 patients were randomised into Group A (without flap coverage of the glanular part of the neourethra) and 28 patients were randomised into Group B (with flap coverage of the glanular neourethra). **Results:** Only 2 (7.1%) cases amongst the Group A patients developed GD, while 9 (32.1%) cases of Group B had GD ($P = 0.013$). **Conclusions:** Extending the vascular flap coverage up to the glanular part of the neourethra till the neo-meatus during primary urethroplasty is significantly associated with GD.

Keywords: Glans dehiscence, hypospadias, single-stage urethroplasty, Snodgrass urethroplasty, vascular flap

Introduction

Hypospadias is a spectrum of disorder. This is a Greek word; 'hypo' means under, and 'spadias' means to tear off.[1] It is the second-most common birth anomaly, affecting 1 in every 200–300 males.[2] Meatal location and ventral curvature are the two major variables determining the severity of hypospadias. It ranges from a glanular meatus and no curvature to those with a perineal meatus and curvature of >90° potentially impacting the urinary and sexual functions.[3] Although more than 300 techniques have been described for correction of this anomaly, currently tubularised incised plate (TIP) urethroplasty is the most frequently performed technique for single-stage primary hypospadias repair.[4] This technique was first described by Snodgrass for correction of distal penile hypospadias.[5] Its indications were subsequently extended for mid-shaft and proximal penile hypospadias with no or minimal curvature (<30°).[6]

Despite advances in surgical techniques, still a number of patients experience complications; out of which urethrocutaneous fistula (UCF), meatal stenosis, glans dehiscence (GD) and urethral stricture are common.[7] Complete GD is a discouraging and unexpected complication after hypospadias surgery and one wonders about unidentified factors that may have a role during the healing process. The main indication for reoperation in hypospadias patients is persistent hypospadias from GD.[8,9]

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GD is defined as loss of glans wings approximation after hypospadias repair.[10] Snodgrass *et al*., from their retrospective data review of 641 consecutive patients of TIP urethroplasty, reported an overall incidence of GD in 5% of patients.[10] GD occurred in 4% of distal penile hypospadias, 2% cases of midshaft hypospadias and 15% cases of proximal hypospadias.[10] However, according to Babu and Chakravarthi, the incidence of GD amounts to around 25%.[11] The actual incidence worldwide may be even higher than what is reported. This may be attributed to many surgeons at various meetings worldwide, not recognising or disregarding this complication, especially after proximal repairs.[12] The introduction of a vascular flap of tissue as a protective layer (barrier flap) between the neourethra and the skin avoids suture line superimposition and reduces fistula occurrence, thus overall complication rate.[12] Commonly used protective layers are spongiosum tissue, dartos fascia, tunica vaginalis testis (TVT), pedicled external spermatic fascia and adipose tissue from scrotum. Out of these, the dartos fascia has been preferred for distal penile hypospadias and TVT for proximal penile hypospadias repair.[4]

A potential worry with burying the flap under the glans during glansplasty is the risk of glanular dehiscence due to the increased bulk and tension on the glans closure.[13]

We hypothesise that covering the glanular neourethra with a vascular flap increases the bulk of reconstituted glans and causes tension in suture lines after glansplasty. This, in turn, might be responsible for the increased incidence of GD. We conducted this study to evaluate the risk of GD associated with vascular flap coverage of the glanular neourethra during primary urethroplasty in comparison to those undergoing the same procedure without flap coverage of the glanular neourethra.

Materials and Methods

We planned a single-blinded, parallel-design, randomised controlled trial amongst the admitted cases of hypospadias for primary urethroplasty in the Department of Paediatric Surgery, AIIMS, Bhubaneswar, from November 2017 to December 2019. This study was approved by the Institutional Ethics Committee as an M.Ch. thesis project and registered in the Clinical Trial Registry of India (CTRI/2018/01/011304).

All cases of hypospadias for primary urethroplasty (including distal penile, mid penile and proximal penile hypospadias without chordee) and good urethral plate scheduled for TIP as per our institutional protocol were included in this study. Those unwilling to participate were excluded from this study.

Patients were admitted, and a routine pre-operative workup was done. Pre-anaesthetic evaluation and fitness for surgery were taken. Parental counselling about the disease process, type of surgery and risk and complications associated with surgery was done. After obtaining written and informed consent from parents and assent from patients (>9 years of age), they were assigned with a serial number for enrolment in this study. This number was strictly according to the chronology of admission. They were randomised into two groups (Group A and Group B) based on a previously determined computer-generated table of random numbers with a sealed opaque envelope technique [Flow Chart 1]. In Group A patients, there was no flap coverage of the glanular neourethra. Only the proximal neourethra up to the corona was covered with a vascular flap. In Group B patients, the entire neourethra, including the glanular neourethra up to the glanular recess, was covered with a vascular flap. All patients were operated by the standard and reproducible urethroplasty technique of TIP as per our institutional protocol. The surgeries were carried out by five faculties of the department with more than 5 years of post-degree experience operated as per the standard guidelines, with assistance from trainees.

Method of urethroplasty

The glans width at the level of the corona and the width of the urethral plate were measured with a calliper. The penis was degloved, and a U-shaped incision was made along the lateral margins of the urethral plate. The glans wings were raised up to 90° in all cases for a tension-free glans closure. A relaxing incision was done in the midline of the urethral plate. Urethral stents depending on the age of the child are used for tubularisation of the urethral plate with 6-0 absorbable suture material in a continuous fashion. As per the local tissue availability, dartos flap or spongiosa flap or tunica vaginalis flap was used as a protective layer of cover over the tubularised neourethra.

According to the computer-generated table of random numbers with a sealed opaque envelope technique, the glanular part of the neourethra was either covered with a vascular flap up to the tip of neo-meatus (Group B) or remained uncovered (Group A). Glans wings were then approximated with 5-0 absorbable suture material in the inner layer and 6-0 absorbable suture material in the outer layer in all cases. Post-glansplasty glans width at the corona was measured with a calliper. Degloved penile skin was re-approximated with 5-0 absorbable suture material. A stent was fixed to the glans with a 4-0 Prolene stitch. Antiseptic (Neosporin) ointment was used over the wound, and adhesive compression dressing was done. This standard and reproducible surgical technique of TIP urethroplasty as per our institutional protocol was followed by all five faculties in all the cases. Patients were followed up to 6 months postoperatively to document complications.

Sample size calculation

Power analysis for the Chi-square test was conducted in G*power version 3.1.9.7., Heinrich Heine University, Dusseldorf[14] to determine a sufficient sample size using an alpha of 0.05, a power of 0.95, an effect size of 0.5 (large effect size) using Cohen's convention and two tails. There was an equal allocation of participants into each group. Based on the aforementioned assumptions, the desired sample size was calculated; (χ^2 tests, goodness-of-fit tests, contingency tables, effect size $w = 0.5$, α err prob = 0.05, power [1− β err prob]

= 0.95, Df = 1, non-centrality parameter λ = 13.0000000 and critical χ^2 = 3.8414588 implying a total sample size of 56 with actual power of the study being 0.95). Thus, the minimum sample size for each arm was 28.

Statistical analysis

Data were coded and recorded in MS Excel spreadsheet program. The SPSS v23, (2021) IBM corporation, USA was used for data analysis. Descriptive statistics was elaborated in the form of means/standard deviations, frequencies and percentages. Data were presented in a graphical manner wherever appropriate for data visualisation using histograms. In case the expected frequency in the contingency tables was found to be <5 for >25% of the cells, Fisher's exact test was used. Statistical significance will be kept at $P < 0.05$.

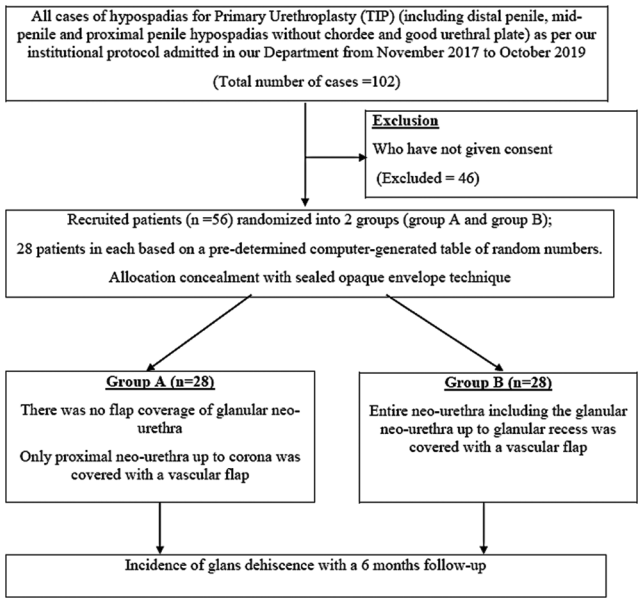
Continuous variables were represented as mean ± standard deviation and categorical variables as percentages. Fisher's exact test was used for categorical variables. We considered $P < 0.05$ as significant.

Results

During the study period, 102 patients were assessed. Forty-six cases did not give consent and were excluded from the study [Flow Chart 1]. The remaining 56 cases (28 in each group) were included in this study. All patients were followed up for 6 months. There was no dropout. The data were collected, and the results were analysed.

Age distribution

Most of our patients (52%) were in the 1–5 years (pre-school) age group, followed by the 6–10 years age group (45%). Only 2 (3%) patients were more than 10 years old but had not attained puberty. In Group A, 12 patients were in the 1–5 years age group, 14 patients were in the 6–10 years of age group and two patients were in the more than 10 years of age group (not attained puberty). In Group B, 17 patients were in the 1–5 years age group, 11 patients were in the 6–10 years age group and no patient was in more than 10 years age group. The mean age was 5.3 years with a standard deviation of 2.41 years. However, there was no statistically significant difference in group-wise age distribution of these patients.



Flow Chart 1: Work plan of management

Type of hypospadias

Most of our cases were distal penile hypospadias, followed by mid-penile hypospadias. Out of 56 cases, distal penile hypospadias were 30 (53%), mid-penile hypospadias were 18 cases (32%) and proximal penile hypospadias were 8 (15%). There was also no significant difference in group-wise distribution [Table 1].

Pre-operative glans width

In our study, in Group A, glans diameter >14 mm was present in 22 patients, and <14 mm glans width was found in six cases. In Group B, 26 cases had a glans width >14 mm, and in two cases, the glans width was <14 mm [Figure 1]. The mean glans diameter was 10.385 ± 1.08 mm. There was also no significant difference in group-wise distribution.

Type of vascular flap

Selection of vascular flap coverage as a protective layer on urethroplasty was done according to the availability of local tissue. Dartos flap as a secondary cover over the neourethra was done in 46 cases, while spongiosa coverage was done in three cases. TVT flap was used in seven cases. Amongst the dartos flap, 24 cases were in Group A, and 22 cases were in Group B. Amongst the patients with TVT flap, only two cases were in Group A and five cases were in Group B.

We have done spongiosum coverage of the neourethra in three cases, out of which two cases were in Group A, while only one case was in Group B. Flap coverage was evenly distributed in both groups, and there was no statistically significant difference in the distribution.

Group-wise glans dehiscence after urethroplasty

In Group A patients, only 2 (7.1%) cases had GD, while 9 (32.1%) cases of Group B had GD post-urethroplasty [Table 2].

Table 1: Group-wise distribution of type of hypospadias

Type of hypospadias	Total (*n*)	Group A	Group B
Distal penile hypospadias	30	16	14
Mid-penile hypospadias	18	9	9
Proximal penile hypospadias	8	3	5
Total	56	28	28

Table 2: Fisher's exact test for statistical analysis

Group-wise distribution (*n*)	Group A (*n*=28)	Group B (*n*=28)	*P*
GD	2	9	0.013

GD: Glans dehiscence

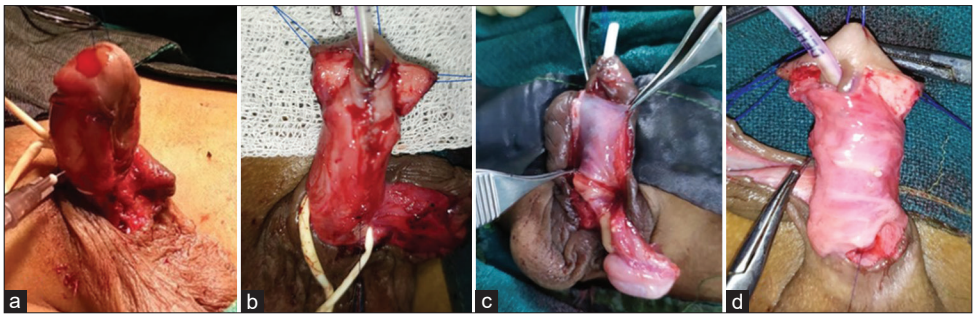


Figure 1: (a and b – Method of urethroplasty) – (a) Degloving + chordee testing, (b) urethroplasty with open glans; (c and d) – (c) Group A – no vascular flap cover of the glanular neourethra, (d) Group B – vascular flap cover of the glanular neourethra

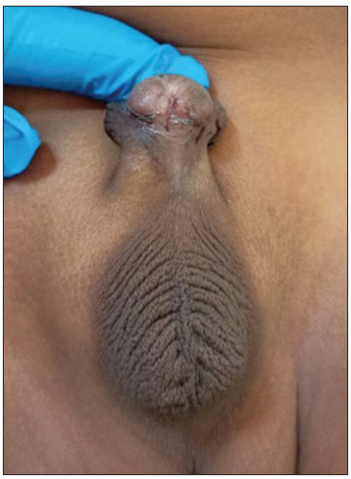


Figure 2: Post-operative glans dehiscence

We have represented the data on the incidence of GD in two operative groups in a 2 × 2 contingency table, and Fisher's exact test was performed to detect the difference between the two groups. The results from Fisher's exact test showed $P = 0.013$ which is statistically significant. The relative risk is equal to 0.42 with a 95% confidence interval; 0.204–0.871. From the above results, it was evident that the incidence of GD in no flap cover group (Group A) is lower and was statistically significant.

Dartos flap coverage on distal penile hypospadias and glans dehiscence

We have done dartos flap coverage of neourethra in distal penile hypospadias in 26 cases, out of which 15 cases were in Group A, while 11 cases were in Group B. There was no GD in Group A cases and six cases developed GD in Group B patients in the post-operative follow-up period.

We have represented the data on the incidence of GD in two operative groups in a 2 × 2 contingency table, and the Fisher exact test was performed to detect the difference between the two groups. The results from the Fisher exact test showed $P = 0.019$. From the above results, it was evident that the incidence of GD in no flap coverage group (Group A) is lower and was statistically significant with dartos flap coverage in distal penile hypospadias [Table 3].

Table 3: Fisher's exact test for statistical analysis for dartos flap in distal penile hypospadias

Group-wise distribution (*n*)	Group A (*n*=15)	Group B (*n*=11)	*P*
GD	0	6	0.019

GD: Glans dehiscence

Pre-operative glans diameter versus glans dehiscence

In our study, GD was observed in two cases in Group A with a glans diameter >14 mm, whereas in the same group, no GD was seen with a glans diameter <14 mm. In Group B, GD was observed in seven cases of glans width >14 mm and in two cases with glans width <14 mm.

Post-glansplasty glans diameter versus glans dehiscence

There was no GD observed in Group A cases with glans diameter >14 mm, whereas in the same group, two cases had GD with glans diameter <14 mm. In Group B, GD was observed in six cases of glans width >14 mm and in three cases with glans width <14 mm.

Logistic regression was done, and it was found that there was no association between the incidence of complications and glans diameter. The odds ratio of the absence of complications is 0.364–1.105 ($P = 0.108$) [Figure 2].

Maximal versus minimal glans width impacting the outcome

Based on our study, we did not find the glans diameter as the single most important prognostic factor affecting the outcome.

Discussion

The surgical repair of hypospadias in childhood is often associated with post-operative complications involving the external urinary meatus (stenosis and retrusive meatus), the urethra (stricture, fistula and diverticulum), the corpora cavernosa (penile curvature, torsion or deformity), the preputial skin or the genitalia. These complications may involve a single compartment of the male genitalia (urethra, corpora cavernosa, glans or penile or scrotal skin), or a combination of them. The most severe complication of urethroplasty is GD which often requires a redo urethroplasty. Considerations for the correction

of GD are similar to those for distal hypospadias (splaying, deviation of urinary stream and unsightly glans appearance).[15] Snodgrass *et al*., from their retrospective data review of 641 consecutive patients of TIP urethroplasty, reported an overall incidence of GD in 5% of patients.[10]

Snodgrass *et al*., in their study of glans size as an independent risk factor for urethroplasty complications after hypospadias repair in 400 patients, stated that glans size is the single most important factor affecting complications of hypospadias surgery.[16] They had a GD of 10% in patients with glans diameter <14 mm while around 4% in patients with glans diameter >14 mm.[16] However, in our study, we did not find any correlation between the glans diameter and GD. This might be due to the small sample size of 56 patients in our study and the fact of pre-operative testosterone use in a few cases to increase the glans diameter artificially.

Several techniques of providing vascularised soft-tissue cover to the neourethra have been described. They include de-epithelialised skin, corpus spongiosum, dartos fascia and TVT.[17-23] Preputial skin is usually used as a covering flap of the neourethra; however, this may result in penile torsion and devascularisation of the preputial skin that is often used in reconstruction of the penile skin.[24] In our study, we used dartos or spongiosa or TVT flap as per the local tissue availability.

In a study of 172 patients by Yiğiter *et al*., fistula was detected in 0.7% of those who had the TIP with interposition of double dartos flaps, in 29.4% of those with no interposition of covering flap and in 26% with single dartos flap.[25] However, Snodgrass *et al*. reported no difference in fistula rates with or without a barrier flap.[10] There are no studies available in literature comparing the type of vascular flap and the incidence of GD. In our study, we did not find any statistical difference in the nature of vascular flaps impacting GD.

Snodgrass *et al*.,[6] in their retrospective case review analysis, have shown that the risk of GD was not affected by age at surgery, pre-operative testosterone use or glansplasty sutures used.[2] In our study, the surgery was performed by faculty with adequate experience and as per the standard and reproducible institutional protocol. Snodgrass *et al*. reported that the risk of GD after TIP repair was 3.6-fold greater in patients with proximal hypospadias compared with distal hypospadias, although the same surgeon used the same sutures and suturing methods.[10] We have selected our cases for primary urethroplasty in those patients of hypospadias with no or minimal chordee and good urethral plate.[6]

There are some data available in the literature related to the risk of GD with flap coverage of the glanular neourethra in the form of opinions and case reports/series.[16,17] However, there is no randomised controlled trial available in the literature on the risk associated with vascular flap coverage on the glanular part of the neourethra. Elbakry argued that the dartos flap interposition might hinder a tension-free closure of the glans flaps during glansplasty and increase the risk of glanular dehiscence following urethroplasty.[13] Kureel *et al*.[17] reported double dorsal dartos flap coverage of the neourethra as an effective method to reduce the fistulous complication rate following distal hypospadias repair.[17] They have opined the need for a larger comparative study to evaluate conventional neourethral coverage with 'limited' neourethral coverage.[26] These findings of Snodgrass *et al.* and Elbakry *et al*.[12,13] indicated that vascular flap covering of the glanular part of the neourethra is not an absolute requirement to avoid fistula formation after TIP repair, and perfection of all other technical steps is mandatory.

Abolyosr,[27] in his series of 156 cases of Snodgrass repair, stated that a well-vascularised double-layered dartos flap is a good choice for preventing UCF formation. However, as per our experience for the same, we felt that the glans become bulky thus compromising the vascularity of the tissue. The glans being highly vascular may not warrant a need of another vascular flap for the neourethra.

In our study, we found that extending the vascular flap coverage up to the glanular part of the neourethra till the neo-meatus during primary urethroplasty is significantly associated with post-operative GD.

Strength of our study

There are so many studies available in the literature on hypospadias surgery regarding the use of vascular flap covers of the neourethra to prevent suture line superimposition and decrease post-operative complications. Few opinions are available in the literature on the usefulness of flap coverage of the glanular part of the neourethra and associated complications of urethroplasty like GD. Our study is a single-blinded, parallel-designed randomised controlled clinical trial, and no other similar study has been reported in the literature to date to the best of our knowledge.

Limitations of our study

We had a small sample size in this study. Bias from the involvement of multiple surgeons in the treatment of these patients might affect the outcomes of the study. However, surgical principles were standardised and followed as per protocol by all the surgeons involved in the treatment of these patients. Bias may also arise from the inclusion of different spectra of hypospadias in this study, but we have used only those cases with minimal chordees.

Conclusions and Recommendations

We would like to conclude that extending the vascular flap coverage up to the glanular part of the neourethra till the neo-meatus does not decrease the GD, but it adds to the bulk of tissue around the glanular part of the neourethra resulting in a tight ischaemic glansplasty which might be responsible for the increased incidence of complications. We recommend the extension of the vascularised flap only up to the corona as a protective cover in urethroplasty to avoid any suture line superimposition. Further research in this area can be done with a large sample size and/or multi-institutional involvement.

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Conflicts of interest
There are no conflicts of interest.

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