

TO COMPARE RESULTS OF VICRYL 6-0 SUTURE VS PDS 6-0 SUTURE IN TUBULARIZED INCISED PLATE URETHROPLASTY IN DISTAL TO MID PENILE HYPOSPADIAS

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ABSTRACT:

Background: Hypospadias is considered the second most common congenital disorder in male offsprings worldwide after cryptorchidism, but the most common penile congenital malformation. Although usually successful, hypospadias surgery may result in a number of complications. The selection of suture material is an essential component of hypospadias correction, since it greatly influences the efficacy and longevity of the surgical result.

Methods: The present observational comparative study was conducted in the Department of Pediatrics and General Surgery at SGRD Charitable Hospital, a tertiary care hospital, Amritsar, Punjab on 60 children ranging between ≥ 6 months to 5 years of age with clinical diagnosis of distal and mid penile hypospadias, who were divided into 2 groups - A and B - of 30 each and underwent Tubularized incised plate (TIP) urethroplasty with Vicryl and Polydioxanone (PDS) suture, respectively during the period from January,2023 to March,2024. Data regarding the chief complaints, local examination, post-operative complications and urethral dilatation were recorded and findings were analyzed.

Results: Out of the 60 cases, frequency of urethrocutaneous fistula (UCF) was significantly higher in Group A on post-operative day (POD) 10 (26.67%) and 15th day after discharge (16.67%), urethral stricture was an another significantly correlated post-operative outcome on 30th day after discharge(23.33%). There was significant difference in thinning of stream of urine after the removal of infant feeding tube (IFT) on POD 10 between Group A and Group B patients with p-value=0.038, denoting increased risk with the use of Vicryl 6-0 suture. Follow up urethral dilatation was required comparatively more in Group A patients (60%).

Conclusions: PDS 6-0 suture is comparatively better in hypospadias repair as it is associated with fewer post-operative complications especially urethrocutaneous fistula which is commonest and most difficult to treat complication. PDS 6-0 suture reduced the prevalence of thin urinary stream and requirement of post-operative urethral dilatation.

Keywords: Hypospadias, Vicryl, PDS, TIP Urethroplasty, Urethrocutaneous fistula

INTRODUCTION:

Hypospadias is considered the second most common congenital disorder in male offsprings worldwide, but the most common penile congenital malformation, affecting nearly 1 in 200-300 live births.

Hypospadias occurs due to failure of the normal development of the urethra, foreskin and anterior aspect of penis. It is therefore characterized as an association of three anomalies of penis :(1) an abnormal opening of urethral meatus that may be located anywhere from the ventral/anterior aspect of the glans penis to the perineum (2) an abnormal ventral curvature of penis (chordee) and (3) an abnormal distribution of foreskin with a “hood” present dorsally and deficient foreskin ventrally.¹

Hypospadias is commonly classified into three types based on the different locations of urethral opening: Distal, midshaft and proximal hypospadias. Distal hypospadias is a common finding in the Western world, whereas in Asia proximal forms are more prevalent.

Cryptorchidism (7% to 9%) and inguinal hernia or hydrocele (9% to 16%) are the commonly associated anomalies with hypospadias.

The precise cause of hypospadias is multifactorial and not completely understood. Research suggests that genetic factors play a significant role, as there is a higher prevalence among male relatives and identical twins.

Hypospadias can affect urinary function, leading to difficulties in directing the urine stream. Additionally, chordee which may become more pronounced during erections and potentially impact sexual function later in life.

Diagnosis of hypospadias typically occurs shortly after birth during a routine physical examination. The mainstay of treatment is surgical correction. The optimal timing for surgery usually ranges from 6 to 18 months of age to minimize psychological trauma and facilitate healing.² There are over 250 methods of surgical procedures of hypospadias described in the literature, which indicates that the ‘hypospadiologists’ are still looking for the ideal technique.³ In this study, we aim to focus on Tubularized Incised Plate (TIP) urethroplasty for distal and mid penile hypospadias.

Hypospadias repair, while generally successful, can be related to a variety of complications. UCF is the most common and most difficult to treat complication of hypospadias repair. Other complications may include bleeding, wound dehiscence, persistent chordee, urethral stricture and meatal stenosis.

One crucial aspect of hypospadias repair is the choice of suture material, which plays a significant role in the success and durability of the surgical outcome. Among the various options available, Vicryl (polyglactin) and PDS (polydioxanone) sutures are commonly used absorbable sutures with distinct characteristics and properties.

This observational comparative study aims to provide the considerations surrounding the use of Vicryl versus PDS sutures in hypospadias repair for patients with distal and mid penile hypospadias in the age group of ≥ 6 months to 5 years undergoing TIP urethroplasty performed by the same surgeon .

Aim: To compare results of Vicryl 6-0 suture vs PDS 6-0 suture in Tubularized Incised Plate Urethroplasty in distal to mid penile hypospadias.

Objectives of the Study:

1. To evaluate the result of Vicryl 6-0 suture in Tubularized Incised Plate Urethroplasty.
2. To evaluate the result of PDS 6-0 suture in Tubularized Incised Plate Urethroplasty.
3. To compare post-operative outcomes of vicryl 6-0 suture vs PDS 6-0 suture in Tubularized Incised Plate Urethroplasty in distal to mid penile hypospadias.

Inclusion criteria:

1. Patients presenting with distal to mid penile hypospadias ≥ 6 months to 5 years of age.

Exclusion criteria:

1. Patients presenting with distal to mid penile hypospadias < 6 months of age and > 5 years of age.
2. Patients presenting with proximal hypospadias (Peno-scrotal, scrotal and perineal hypospadias).
3. Operated cases of distal to mid penile hypospadias.

Material and Methods:

The present observational comparative study was conducted in the Department of Pediatrics and General Surgery at SGRD Charitable Hospital, a tertiary care hospital, Amritsar, Punjab during the period from January,2023 to March,2024 on 60 patients fulfilling the inclusion criteria who were randomized using Open Epi software to create 2 groups. Patients were allocated group A/B. Group A underwent Tubularized Incised Plate Urethroplasty using Vicryl 6-0 sutures and Group B underwent Tubularized Incised Plate Urethroplasty using PDS 6-0 sutures. Data regarding the chief complaints, local examination, post-operative

complications and urethral dilatation were recorded in a Microsoft excel spread sheet and analysed using SPSS software version 26. Improvement in symptoms were compared on post-operative day 5, post-operative day 10 and on follow up on 15th day and 30th day after being discharged from hospital.

RESULTS:

1. URETHROCUTANEOUS FISTULA

UCF is one of the most frequently seen complications of hypospadias surgery requiring reoperation. It remains a significant challenge for pediatric surgeons despite the advances in surgical techniques. UCF is usually confirmed on physical examination.

TABLE 1: DISTRIBUTION OF HYPOSPADIAS PATIENTS WITH UCF ON POST OPERATIVE DAY 10 AFTER IFT REMOVAL

UCF ON POD 10	VICRYL		PDS	
	No.	%age	No.	%age
ABSENT	22	73.33	28	93.33
PRESENT	8	26.67	2	6.67
TOTAL	30	100.00	30	100.00
p-value	X ² : 4.320; df:1; p=0.037			

Amongst a total of 60 patients with hypospadias post TIP urethroplasty, it was observed that 10 patients developed UCF on POD 10 after IFT removal, out of which 8 patients belonged to Group A (Patient undergoing TIP urethroplasty with Vicryl 6-0 suture) and 2 patients belonged to Group B (Patient undergoing TIP urethroplasty with PDS 6-0 suture) (p-value=0.037), as depicted in Table 1.

TABLE 2: DISTRIBUTION OF HYPOSPADIAS PATIENTS WITH UCF ON 15th DAY AFTER DISCHARGE ON FOLLOW UP

UCF ON 15 th DAY AFTER DISCHARGE ON FOLLOW UP	VICRYL		PDS	
	No.	%age	No.	%age
ABSENT	25	83.33	30	100.00
PRESENT	5	16.67	0	0.00
TOTAL	30	100.00	30	100.00
p-value	X ² : 5.455; df:1; p=0.019			

As shown in Table 2, the number of patients in Group A who acquired UCF on the 15th day after discharge on follow-up was 5 with no new instances recorded in Group B.

3. URETHRAL STRICTURE

TABLE 3: DISTRIBUTION OF HYPOSPADIAS PATIENTS WITH URETHRAL STRICTURE ON 30TH DAY AFTER DISCHARGE ON FOLLOW UP

URETHRAL STRICTURE ON 30 TH DAY AFTER DISCHARGE ON FOLLOW UP	VICRYL		PDS	
	No.	%age	No.	%age
ABSENT	23	76.67	29	96.67
PRESENT	7	23.33	1	3.33
TOTAL	30	100.00	30	100.00
p-value	X ² : 5.192; df:1; p=0.022			

Amongst total of 60 patients, 8 patients developed urethral stricture on 30th day after discharge on follow up out of which 7 belonged to Group A (Patients who underwent TIP urethroplasty with Vicryl 6-0 suture) and 1 belonged to Group B (Patients who underwent TIP urethroplasty with PDS 6-0 suture) (p-value=0.022), as represented in Table 3.

4. STREAM OF URINE AFTER IFT REMOVAL:

IFT is removed on POD 10 after removing the dressing following which patient should pass urine with a well formed stream or else there maybe thinning of the stream of urine.

TABLE 4: STREAM OF URINE AFTER IFT REMOVAL IN PATIENTS WHO UNDERWENT TIP URETHROPLASTY WITH VICRYL V/S PDS SUTURE

STREAM OF URINE AFTER IFT REMOVAL	VICRYL		PDS	
	No.	%age	No.	%age
NORMAL	22	73.33	28	93.33
THIN STREAM	8	26.67	2	6.67
TOTAL	30	100.00	30	100.00
p-value	X ² : 4.320; df:1; p=0.038			

Table 4 shows that out of total 60 patients, 8 patients who had undergone TIP urethroplasty with vicryl 6-0 suture developed thin urinary stream after removing IFT whereas only 2 patients who had undergone TIP urethroplasty with PDS 6-0 suture had similar complaint (p-value=0.038).

5. FOLLOW UP URETHRAL DILATATION:

Urethral dilatation is the ideal first line treatment for patients presenting with meatal stenosis and urethral stricture post TIP urethroplasty.

TABLE 5: FOLLOW UP URETHRAL DILATATION IN HYPOSPADIAS PATIENTS POST TIP URETHROPLASTY

FOLLOW UP URETHRAL DILATATION	VICRYL		PDS	
	No.	%age	No.	%age
DONE	18	60.00	5	16.67
NOT DONE	12	40.00	25	83.33
Total	30	100.00	30	100.00
p-value	X ² : 11.915; df:1; p=0.001			

Table 5 shows that of the 60 patients in this study, 18 patients in Group A (Patients who underwent TIP urethroplasty with Vicryl 6-0 suture) and 5 in Group B (Patients who underwent TIP urethroplasty with PDS 6-0 suture) needed dilatation (p-value=0.001).

DISCUSSION:

In this observational comparative study, Vicryl 6-0 and PDS 6-0 suture were used for TIP urethroplasty in patients with distal to mid penile hypospadias; and compared the outcomes of two sutures in terms of post-operative complications, symptoms and need for follow up urethral dilatation at the time intervals of POD 5, POD 10, 15th day after discharge on follow up and 30th day after discharge on follow up. The post-operative complications estimated were bleeding, UCF, wound dehiscence, meatal stenosis and urethral stricture.

Alaraby SO et al.⁴ conducted a comparative study of Polydioxanone (PDS) and Polyglactin (Vicryl) in hypospadias repair. This was carried out at the Department of Paediatric Surgery, Ribat University Hospital, from June 2015 to November 2016. In Group A, there were 55 patients who underwent repair using polyglactin, and in Group B, there were 50 patients who underwent repair using polydioxanone. The mean age of Group A was 5.7 ± 4.3 years and 5.1 ± 3.9 years in Group B. Meatal advancement and glanuloplasty incorporated operation was done in 47.6%, Tubularized incised plate urethroplasty in (31.4%), Theirsch-Duplay in 20% and Mathieu's repair in 1%. The complication rate was 34% in Group A and 10.9% in Group B. The most frequent complication was UCF, as 19 patients (18.1%) of the study candidates developed UCF; most of them were in Group A (14 patients) and 5 patients in Group B. Another significant complication was meatal stenosis, which occurred in 11 patients (10.5%): 9 in Group A and 2 in Group B. Regarding oedema and bleeding, they occurred only in Group B, with the percentage of 10.5% and 3.8%, respectively. Bleeding was more in Group B, but it was not of statistical significance as $P = 0.12$ (Fisher's exact test). This study concluded Polydioxanone (PDS) is satisfactory in hypospadias repair as it is associated with better outcome especially urethrocutaneous fistula which is commonest and most difficult to treat complication. Factors that affected UCF formation are the type of hypospadias, type of repair, stages of repair, type of suture material, and meatal stenosis.

In present study of 60 hypospadias patients within the age group of 6 months to 5 years patients were randomized into two groups, Group A and Group B of 30 each. Group A patients underwent TIP urethroplasty with Vicryl 6-0 suture and Group B patients underwent TIP urethroplasty with PDS 6-0 suture. It was observed that the mean age group in this study was 22.60 ± 12.25 months in Group A patients and 20.30 ± 13.92 in Group B patients. The most frequent complication was UCF, 10 patients developed UCF on POD 10 after IFT removal, out of which 8 patients belonged to Group A (26.67%) and 2 patients belonged to Group B (6.67%) which was statistically significant with p value of 0.037. Bleeding occurred in 1 patient each in Group A and B on POD 5, but it was not of statistical significance. Whereas there was no episode of bleeding in both the groups on POD 10. On the other hand, meatal stenosis occurred only in 1 patient in Group B on 15th day after discharge, and in 4 and 2 patients in Group A and Group B, respectively on 30th day after discharge on follow up which was also not of statistical significance with p-value of 0.389.

In order to evaluate the risk factors for the development of urethrocutaneous fistula following hypospadias correction, Chung et al.⁵ carried out a retrospective study at the Department of Urology, Kyungpook National University School of Medicine, Daegu, Korea, from January 1990 to May 2010. 294 patients who were monitored for more than six months were included in this study. 63 patients (21.4%) of the 294 children who had hypospadias correction developed urethrocutaneous fistulas following the procedure. The sutures utilized in the correction of hypospadias were polydioxanone (PDS), chromicized catgut (Chromic catgut), and polyglactin 910 (Vicryl). Depending on the kind of suture material used, the incidence rates of urethrocutaneous fistula were 20.0%, 24.3%, and 24.0%, respectively.

Shehata and Hashish⁶ directed a study at Department of Pediatric Surgery, Tanta University Hospital, Tanta, Egypt in 2011 for the management of post hypospadias urethral fistula which showed that the fistula formation rate was significantly higher in the group of patients where neourethra was constructed using 6/0 polyglactine (Vicryl) (16.6 %) compared to group of patients in which 7/0 polydioxanone (PDS) was used in the urethral anastomosis with fistula rate of 4.9 %.

In the present investigation, following IFT removal, 8 patients from Group A (26.67%) and 2 patients from Group B (6.67%) acquired UCF on POD 10, which was statistically significant with a p value of 0.037. On the 15th and 30th day following discharge, there were 5 and 1 patients in group A who acquired UCF, respectively, while no new instances were reported in group B on the same dates. As a result, group A's UCF rate on the 15th day following discharge likewise exhibited a statistically significant p value of 0.019. Thus, there was a clear relationship between UCF formation and the type of suture employed.

DiSandro and Palmer⁷ from the Department of Urology, University of California, Davis, School of Medicine, Sacramento, USA conducted a study in July, 2014 to evaluate the stricture incidence related to suture material in hypospadias surgery. During a 7-year period (2014 to 2020), 117 boys aged 5 to 124 months (mean, 14) underwent surgical correction of hypospadias. The urethral anastomoses were performed with chromic sutures (n = 15), with

polydioxanone (PDS) between (n = 46), and with polyglycolic acid (PgA) (n = 56). In the chromic/PgA group, 6.8% had strictures, compared with 23.6% of the PDS group (P < .02). There was significant difference in the incidence of postoperative urethral strictures between the two groups.

During follow-up in Group A on the 15th day following discharge, urethral stricture was identified in only 1 patient in the current study. At the follow-up, 8 patients—7 from Group A (23.33%) and 1 from Group B (3.33%)—developed urethral strictures on the 30th day following discharge. This difference was statistically significant, with a p value of 0.022, and it is consistent with the results of the previously described study.

A study conducted in 2013 by Kerstein et al.⁸ at the Royal Free London NHS Foundation Trust Hospital, London, UK's Department of Plastic and Reconstructive Surgery, investigated the impact of up to 27 days of storage in human urine on 6/0 gauge Vicryl, Vicryl Rapide, Monocryl and polydioxanone (PDS) sutures. Urine exposure caused wound dehiscence and decreased all evaluated suture materials' tensile and breaking strengths. PDS showed the highest degree of resiliency. The weakest suture, Vicryl Rapide, entirely broke down by day 6. The degradation patterns of Vicryl and Monocryl were similar, although Vicryl held onto its tensile strength for a longer period of time. Out of the four suture materials evaluated, Vicryl appeared to have the best properties for urethroplasty, according to the study's findings.

However, out of 30 patients in this trial, wound dehiscence on POD 5 and POD 10 was observed in 1 and 2 patients, respectively, after TIP urethroplasty with Vicryl 6-0 suture. No wound dehiscence occurred in any of the 30 patients who underwent TIP urethroplasty with PDS 6-0 suture on POD 5 or POD 10. Consequently, no obvious relationship was found between the type of suture material used and wound dehiscence.

CONCLUSIONS:

The majority of the hypospadias patients presented in the age group of 12-24 months (36.67%) followed by 6-12 months of age (25%). 85% of the hypospadias patients belonged to rural areas implicating the role of possible poor maternal health to the etiology of hypospadias. Amongst 60 hypospadias patients, 30% had mid penile hypospadias whereas 70% presented with distal penile hypospadias.

Thin urinary stream was the 2nd most common chief complaint (41.67%) after passing of urine from abnormal site (100%). Downward bend of penis (31.67%) was among the other chief complaints. Hooded prepuce (65%), conical glans (96.67%) and chordee (55%) were the commonly associated findings on local examination.

Stretched penile length (SPL) of majority of the hypospadias patients was ≥ 4 cm (51.67%).

There was no significant association of cryptorchidism and inguinal hernia or hydrocele with hypospadias.

Bleeding was not a significant post-operative complication in either Group A or Group B on POD 5 and POD 10 indicating that the type of suture material did not play any role in post-operative bleeding after TIP urethroplasty in distal to mid penile hypospadias.

Frequency of UCF was significantly higher in hypospadias patients who underwent TIP urethroplasty with Vicryl 6-0 suture than with PDS 6-0 suture on POD 10 (26.67%) and 15th day after discharge (16.67%) with p-value=0.037 and 0.019, respectively. Many studies agreed with this study, as there was a direct correlation between the type of suture material used and post-operative UCF formation.

The type of suture material used did not have any significant association with increasing the risk of wound dehiscence and meatal stenosis postoperatively.

However, urethral stricture was an another significantly correlated post-operative outcome on 30th day after discharge in hypospadias patients who underwent TIP urethroplasty with Vicryl 6-0 suture (23.33%) with p-value=0.022.

There was significant difference in thinning of stream of urine after the removal of IFT on POD 10 between Group A and Group B patients with p-value=0.038, denoting increased risk with the use of Vicryl 6-0 suture.

Follow up urethral dilatation was required in 60% of the patients in Group A compared to only 16.67% of the patients in Group B postoperatively and showed significant difference with p-value=0.001. Most of the patients who underwent urethral dilatation had complaint of thin urinary stream due to urethral stricture or meatal stenosis.

Therefore, it has been concluded that Polydioxanone (PDS) 6-0 suture is comparatively better in hypospadias repair as it is associated with fewer post-operative complications especially urethrocutaneous fistula which is commonest and most difficult to treat complication. Better outcome in terms of other post-operative complications such as urethral stricture was exhibited compared to Vicryl 6-0 suture. PDS 6-0 suture reduced the prevalence of thin urinary stream and requirement of post-operative urethral dilatation.

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