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Comparison of Polyglactin (Vicryl) Versus Polydioxanone (PDS) Suture in Sub-Coronal Hypospadias Repair in Terms of Urethrocutaneous Fistula Development

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ABSTRACT

Background: Delayable absorbable sutures like polydioxanone may reduce urethrocutaneous fistula, but some surgeons warn that they could cause urethral stricture due to long-term tissue irritation. Various surgical techniques have evolved to manage this anomaly, but little research exists on the Pakistan Health sector's comparison of polyglactin (VICRYL) versus polydioxanone (PDS) sutures in pediatric hypospadias repair. **Objective:** The purpose of this study is to compare the Polyglactin (VICRYL) versus Polydioxanone (PDS) suture in hypospadias repair regarding the frequency of urethrocutaneous fistula development. **Study Design:** Randomized controlled trial. **Settings:** Department of Pediatric Surgery, Allied Hospital, Faisalabad Pakistan. **Duration:** 8th July 2023 to 7th July 2024. **Methods:** 150 male patients aged 1 to 5 years with sub-coronal hypospadias. Patients with previous hypospadias repair, pre-surgical testosterone stimulation, or other urogenital anomalies were excluded. Patients were divided into two groups: VICRYL (Polyglactin5/0 sutures) and PDS (Polydioxanone5/0 sutures) for urethroplasty. Postoperative assessment focused on the development of urethrocutaneous fistula, confirmed through clinical examination during follow-up. **Results:** In this study, urethrocutaneous fistula was found in 24.0% of patients in group V (Polyglactin (VICRYL)) and in 10.67% of patients in group P (Polydioxanone (PDS) suture) (p-value = 0.031). **Conclusion:** This study concluded that the frequency of urethrocutaneous fistula development is less with Polydioxanone suture in hypospadias repair as compared to Polyglactin suture.

Keywords: *Hypospadias, Polydioxanone (PDS) suture, Polyglactin suture, Urethrocutaneous fistula.*

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INTRODUCTION

Hypospadias is a common congenital anomaly with an incidence of 0.4-8.2 per 1000 live births and is the second most common congenital disorder after cryptorchidism in boys.[1] Hypospadias is classified by level of urethral opening into anterior hypospadias (glanular, coronal, and subcoronal), which comprises of 50% patients, middle hypospadias (distal penile, midshaft, and proximal penile), which comprises of 30% cases, and posterior hypospadias (penoscrotal, scrotal, and perineal), which comprises of 20% cases.[2] It can be associated with inguinal hernia (with or without hydrocele), undescended testicles, penile torsion, orthopedic, and cardiovascular defects. More than 200 methods have been described for hypospadias repair. The objective is to make a straight penis, slit like meatal opening at the tip of the glans, a urethra of satisfactory length and calibre, balanced appearance of glans and penile shaft, a projectile stream, normalization of erections, and, in this manner, making the child confident. To accomplish these objectives, procedures such as meatoplasty, glanuloplasty, orthoplasty, urethroplasty, and scrotoplasty should be performed, and skin coverage should be provided. Urethrocutaneous fistula (UCF) is the most prevalent complication after hypospadias repair surgery.[3]

Many factors contribute to fistula formation, including the gentle tissue handling, precise hemostasis, use of magnification, and meticulous subcuticular suturing without any tension.[4] Some authors suggest that Urethrocutaneous fistula may be reduced by using delayed absorbable sutures like polydioxanone (PDS); however, some surgeons recommend that delayed absorbable sutures might cause urethral stricture due to long-term tissue irritation. Different surgical techniques have evolved through the years to manage this anomaly.[5] Both rapid absorbable sutures, polyglactin (Vicryl), and delayed absorbable sutures, polydioxanone (PDS), are used in hypospadias repair based on the surgeon's preference.[6] The major complications in hypospadias repair are:

urethrocutaneous fistula, urethral stricture, meatal stenosis, wound infection, and breakdown of repair. Urethrocutaneous fistulas following hypospadias repair are one of the most common surgical complications.[7]

Alaraby *et al* (2021) conducted a study to compare polyglactin and polydioxanone in hypospadias repair by assessing the rate of urethrocutaneous fistula (UCF) formation in two groups. Tubularized incised plate urethroplasty was done in 31.4%. 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 (25.45%) and 10% patients in Group B. Polydioxanone (PDS) is satisfactory in hypospadias repair as it is associated with better outcome, especially urethrocutaneous fistula, which is most common and most challenging to treat complication.[1]

The least amount of published research work has been available pertinent to the Pakistan Health sector, evaluating the outcome of comparison of polyglactin (VICRYL) versus polydioxanone (PDS) suture in sub-coronal hypospadias repair in terms of urethrocutaneous fistula development in the pediatric age group of up to 5 years. The suture with the fewest complications will be suggested for future use and might become the suture of choice.

METHODS

This randomized controlled trial was conducted at the Department of Pediatric Surgery, Allied Hospital, Faisalabad, over a period of one year. This study was started after approval from the Ethical Review Committee of FMU, Faisalabad vide letter no. 48.ERC/FMU/2022-23/292 dated 08-07-2023. The sample size was calculated using the WHO sample size calculator with a level of significance of 5%, power of study at 80%, and anticipated proportions of 25.45% and 10%, resulting in a total of 150 patients, with 75 in each group.[1] A non-probability, consecutive sampling technique was employed. Male patients aged 1 to 5 years with clinically confirmed sub-coronal hypospadias were included in the study. Exclusion criteria were previous hypospadias repairs, pre-surgical testosterone stimulation, hypospadias of positions other than sub-coronal, and other urogenital anomalies, including chordee, ambiguous genitalia, or intersex conditions. The patients fulfilling the inclusion criteria were enrolled, and informed consent was taken.

Children were divided into two groups based on a computer-generated random number table. Group V was the VICRYL group in which Polyglactin (5/0) was used. Group P was the PDS group in which Polydioxanone (5/0) was used. Tubularized incised plate (TIP) urethroplasty was used as the standard operating procedure. Tubularized incised plate (TIP) urethroplasty is a surgical technique described for the correction of distal hypospadias by tubularizing the urethral plate. A deep longitudinal incision is given on the plate, which allows tabularization without the need for additional flaps. Data was collected using a structured proforma. Patients were followed up for 6 months, as routine patients were kept in the hospital for 5 days. On the 5th postoperative day, the dressing was removed. Patients attended the outpatient clinic on the 10th postoperative day for removal of the catheter. They were given appointments at 3 weeks, 2 months, and 4 months after the operation. The examinations of the surgical results were focused on Urethrocutaneous fistula development and were confirmed on clinical examination. During the visits, the patients were examined clinically regarding urethrocutaneous fistula formation, in which there was more than one urinary stream, i.e., one from the meatus and one from the abnormal opening.

The data was entered and analyzed in SPSS version 25. Quantitative variables such as the age of the patient and the age at diagnosis of hypospadias were presented as mean and SD. Qualitative variables such as family history and urethrocutaneous fistula development were measured by using frequency and percentage. The chi-square test was used to compare the urethrocutaneous fistula between the two groups. Effect modifiers like age, age at diagnosis, and family history were controlled by stratification. Post-stratification chi–square test was applied to see their effect on the outcome. A p-value less than or equal to 0.05 was considered significant.

RESULTS

Age range in this study was from 1 to 5 years, with a mean age of 3.04 ± 1.16 years. The mean age of patients in group V was 3.04 ± 1.16 years, and in group P was 3.04 ± 1.17 years. The majority of the patients, 96 (64.0%), were between 1 and 3 years of age, as shown in Table 1. Mean age at diagnosis was 3.04 ± 1.16 years (Table 2). Distribution of patients according to family history of hypospadias is shown in Table 3. In my study, urethrocutaneous fistula in group V (Polyglactin (VICRYL 5/0)) was found in 24.0% of patients, and group P (Polydioxanone (PDS 5/0) suture) was 10.67% (p-value = 0.031), as shown in Table 4.

Stratification of urethrocutaneous fistula according to age of patients, age at diagnosis, and family history of hypospadias is shown in Tables 5, 6 & 7, respectively.

Table 1: Age distribution for both groups (n=150)

Age (years)	Group V (n=75)		Group P (n=75)		Total (n=150)	
	No. of patients	%	No. of patients	%	No. of patients	%
1-3	49	65.33%	47	62.67%	96	64.0%
4-5	26	34.67%	28	37.33%	54	36.0%
Mean ± SD	**3.04 ± 1.16**		**3.04 ± 1.17**		**3.04 ± 1.16**	

Table 2: Distribution of patients according to age at diagnosis (n=150)

Age (years)	Group V (n=75)		Group P (n=75)		Total (n=150)	
	No. of patients	%	No. of patients	%	No. of patients	%
1-3	49	65.33%	47	62.67%	96	64.0%
4-5	26	34.67%	28	37.33%	54	36.0%
Mean ± SD	**3.04 ± 1.16**		**3.04 ± 1.17**		**3.04 ± 1.16**	

Table 3: Distribution of patients according to family history of hypospadias

Family history	Group V (n=75)		Group P (n=75)		Total (n=150)	
	Frequency	%	Frequency	age	Frequency	%
Yes	09	12.0%	10	13.33%	19	12.67%
No	66	88.0%	65	86.67%	131	87.33%

Table 4: Comparison of the Polyglactin (VICRYL) versus Polydioxanone (PDS) suture in hypospadias repair regarding frequency of urethrocutaneous fistula development

	Group V (n=75)		Group P (n=75)		p-value
	Yes	No	Yes	No	
Urethrocutaneous fistula	18 (24.0%)	57 (76.0%)	08 (10.67%)	67 (89.33%)	**0.031**

Table 5: Stratification of urethrocutaneous fistula according to age of patients

Age of patients (years)	Group V (n=75) urethrocutaneous fistula		Group P (n=75) urethrocutaneous fistula		P-value
	Yes	No	Yes	No	
1-3	16 (32.65%)	33 (67.35%)	06 (12.77%)	41 (87.23%)	**0.020**
4-5	02 (7.69%)	24 (92.31%)	02 (7.14%)	26 (92.86%)	**0.939**

Table 6: Stratification of urethrocutaneous fistula according to age at diagnosis

Age of patients (years)	Group V (n=75) urethrocutaneous fistula		Group P (n=75) urethrocutaneous fistula		P-value
	Yes	No	Yes	No	
1-3	16 (32.65%)	33 (67.35%)	06 (12.77%)	41 (87.23%)	**0.020**
4-5	02 (7.69%)	24 (92.31%)	02 (7.14%)	26 (92.86%)	**0.939**

Table 7: Stratification of urethrocutaneous fistula according to family history of hypospadias

Family history	Group V (n=75) urethrocutaneous fistula		Group P (n=75) urethrocutaneous fistula		P-value
	Yes	No	Yes	No	
Yes	02 (22.22%)	07 (77.78%)	02 (20.0%)	08 (80.0%)	**0.906**
No	16 (24.24%)	50 (75.76%)	06 (9.23%)	59 (90.77%)	**0.022**

DISCUSSION

Hypospadias is a common congenital anomaly affecting about 0.7% of newborns worldwide.[8,9] The fact that over 300 methods have been tried throughout history for the repair of this anomaly only serves to prove that the search for the ideal method of repair is still being carried out. For the past few decades, the most popular procedures have been the tubularized incised plate urethroplasty (Snodgrass technique), mainly employed for distal hypospadias, and the 2-stage Bracka repair used for the proximal varieties 10. Within this context, Urethrocutaneous fistula (UCF) continues to be a common and frustrating complication after hypospadias repair. [10,11]

The reported incidence of fistula formation varies greatly from 0.48% to 44%.[12] However, in general practice, it is our observation that the incidence is more towards the higher side. Many factors are thought to contribute to fistula formation. Amongst the various guidelines about the repair technique, there is consensus regarding the gentle tissue handling, precise hemostasis, use of magnification, and meticulous subcuticular suturing without any tension.[13] There are, however, many controversies too, such as the use of stents, types of dressings, and which suture material to use. We aimed to address the last question in this study and focused on the two most commonly used suture materials worldwide, polyglactin 910 and polydioxanone. There are numerous studies about suture material and how it behaves in living tissue or on exposure to human urine.[14] Some have compared different sutures used with different techniques.[14]

We conducted this study to compare the frequency of urethrocutaneous fistula development between Polyglactin (VICRYL) and Polydioxanone (PDS) sutures in hypospadias repair. In my research, urethrocutaneous fistula was found in 24.0% of patients in group V (Polyglactin (VICRYL)) and in 10.67% of patients in group P (Polydioxanone (PDS) suture) (p-value = 0.031). Alaraby *et al*. (2021) conducted a study to compare polyglactin and polydioxanone in hypospadias repair by assessing the rate of urethrocutaneous fistula (UCF) formation in two groups. Tubularized incised plate urethroplasty was done in 31.4%. 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 (25.45%), and 10% patients in Group B. Polydioxanone (PDS) is satisfactory in hypospadias repair as it is associated with better outcome, especially Urethrocutaneous fistula, which is most common and most challenging to treat complication.[15]

Shirazi *et al*.[16] investigated the outcome of hypospadias repair based on the suture materials in a study conducted on animals. They found better outcomes in the Monocryl and PDS groups. A higher percentage of vessel density and a higher volume of the urethral lumen in the PDS group may explain the lower complications in their study. This aligns with the results of the present study. The nature of PDS suture, which is a long-term absorbable suture with a less inflammatory response in comparison to the Vicryl suture, can explain this significant difference.

Ulman *et al*. carried out a study to evaluate the effect of suturing technique and material on complication rate, and their result was comparable to ours. They divided the patients into two groups. In Group I, neourethra was constructed using 6/0 polyglactin (Vicryl), and in Group II, 7/0 Polydioxanone (PDS) was used in the urethral anastomosis. Patients were followed up from 6 to 12 months. Urethral or meatal stenosis was not observed in any patient (contradicting our results). There was no infectious complication. The UCF rate was significantly higher in Group I (16.6%) compared to Group II (4.9%) (P <

0.01). They concluded that the complication rate following hypospadias repair can be reduced by the use of a subcutaneous suture technique utilizing polydioxanone (PDS) suture material in urethroplasties. Another study that supports the use of PDS in urethroplasty was done by Arslan *et al*. in Turkey; they compared PDS with polyglactin.[16] The same result was found by Serhan, who compared different suture materials in hypospadias repair and reported the superiority of PDS.[17] We found one study with contradicting results, as they recommended precluding the use of PDS in urethroplasty due to its delayed absorption; however, this recommendation was only in small calibre urethroplasties.[18]

Disandro and Palmer compared rapidly absorbable sutures with PDS suture and showed a higher incidence rate of urethral stricture in the latter group. However, they did not find any significant difference in postoperative fistula formation based on the suture material. In their study, different surgical methods were used, while we used the same surgical method for all patients.[19] This may be the reason for the discrepancy. Another study performed by Guarino *et al*. revealed no association between the suture material and the development of post-urethroplasty fistula, wound dehiscence, and infection in children with distal hypospadias. The reason for the difference may be that they only investigated the patients with distal hypospadias, which is known for the least postoperative complication formation of another hypospadias type.[20]

It is widely known that the younger the patient, the better the outcome (determined mainly by UCF formation), but in our study, the mean age of the two groups was close; that is why there was no statistical difference in the UCF formation between the two groups (P = 0.15). In a study by Yildiz *et al*., the age of patients was identified as a risk factor for UCF in hypospadias surgery, with a higher risk observed in older patients.[21] Another Italian study had also suggested that the age of the patient is a risk factor for developing complications, especially UCF.[22]

CONCLUSION

This study concluded that the frequency of urethrocutaneous fistula development is less with Polydioxanone (PDS) suture in hypospadias repair as compared to Polyglactin (VICRYL) suture. We recommend that Polydioxanone (PDS) suture be used routinely in every hypospadias repair patient to reduce the incidence of urethrocutaneous fistulas, which in turn will reduce the morbidity of these patients.

LIMITATIONS

The present study was conducted with a limited sample size from a single surgical center, which may affect the generalizability of the findings. The follow-up period was relatively short, restricting long-term evaluation of complications such as meatal stenosis and cosmetic outcomes. Surgeon experience, although standardized as much as possible, may have introduced performance bias. Moreover, other variables influencing fistula formation – such as tissue handling, suture tension, and infection control – were not quantitatively assessed.

SUGGESTIONS / RECOMMENDATIONS

Future research should include multicenter randomized controlled trials with larger sample sizes and longer follow-up durations to validate these findings. Objective scoring systems for cosmetic and functional outcomes should be incorporated. Comparative studies assessing additional absorbable suture materials or novel bioabsorbable options may help identify the optimal choice for urethral reconstruction. Evaluating cost-effectiveness and patient satisfaction could further guide clinical practice.

CONFLICT OF INTEREST / DISCLOSURE

The authors declare no conflict of interest related to this study.

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