

A Comparative Study of Polydioxanone (PDS) and Polyglactin (Vicryl) in Hypospadias Repair

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Abstract

Background: Hypospadias is a fairly common problem, and it is the most common genital congenital anomaly. **Objective:** This study was carried out to compare polyglactin and polydioxanone in hypospadias repair by assessing the rate of complications, especially urethrocutaneous fistula (UCF) formation. **Patients and Methods:** This is a prospective observational cross-sectional hospital-based study 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. All patients were operated by the same surgeon. **Results:** 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. **Conclusion:** Polydioxanone (PDS) is satisfactory in hypospadias repair as it is associated with better outcome, especially UCF, which is most common and most difficult to treat complication.

Keywords: Hypospadias, meatal stenosis, polydioxanone, polyglactin, urethrocutaneous fistula

INTRODUCTION

Hypospadias is one of the most common congenital anomalies in males, and the most common congenital penile abnormality, representing a spectrum of deficiency of penile development in which the fusion of the urethral folds is incomplete, so the urethral meatus terminates on the ventral surface of the penis proximal to the normal position, anywhere from glans to perineum. It occurs in approximately 1 in 150–1 in 300 males.^[1] The term hypospadias is derived from the Greek. Hypo means under and spadon means a rent or a fissure.^[2] Different classifications have been described, most surgeons use the one proposed by Barcat and modified by Duckett, which describes the location of the meatus after correction of any associated chordee, anterior (glanular and subcoronal), middle (distal penile, mid-shaft and proximal penile) and posterior (penoscrotal, scrotal and perineal).^[1] Surgical reconstruction is the only therapeutic option for hypospadias. The primary

objectives of the reconstruction are to create a vertically slit orthotopic meatus, straighten the penis by correction of chordee if present and establish good cosmetic results that include a conically shaped glans. Other important aspects for the reconstruction are to avoid shortening the penis and optimal skin coverage that excludes the use of scrotal skin for coverage of the penis.^[3] 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. The choice of suture material is related to complication rate although there is (currently) no consensus about the best suture material to use. Ideally, the sutures used for urethroplasty should be absorbable while maintaining

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sufficient mechanical strength to support the wounds until they are self-supporting and able to resist urinary flow. In hypospadias surgery, non-absorbable sutures are not used, because of the risk of stone formation when it comes in contact with the urine.^[2]

PATIENTS AND METHODS

A prospective observational cross-sectional hospital-based comparative study was conducted in Ribat University Hospital, Department of Paediatric Surgery, over 1½ years from June 2015 to November 2016. Patients were operated by the same surgeon and followed for 6 months postoperatively. It included all the paediatric patients who presented with hypospadias, treated surgically, agreed to participate in the study and followed for 6 months postoperatively during the study period. A non-probability consecutive sampling with total coverage during the study period was done, and the total number of samples during the study period was allocated randomly in two groups according to the type of the suture used in repairing the hypospadias. In Group A, polyglactin (Vicryl) was used, and polydioxanone (PDS) was used in Group B. Data were collected using a constructed structure pre-tested questionnaire. The questionnaire was revised by three senior surgeons pre-tested in five conveniently selected patients. Questionnaires were filled using face-to-face interview and clinical examination pre- and postoperatively. Patients were followed up for a period of 6 months as routine patients were kept in the hospital for 5 days. In the 5th post-operative day, dressing was removed. They attended the outpatient clinic at the 10th post-operative day for removal of the catheter. Then, they were given appointments at 3 weeks and 2 and 6 months after the operation. During the visits, the patients were examined regarding urinary flow and for complications. The examinations of the surgical results focused on function, cosmetic appearance and complications such as fistulas, strictures, ruptures, post-operative infections, haematomas or bleeding, malfunctioning of catheters and urinary retention. Some patients who developed stenosis were scheduled for urethral dilatation sessions, tailored by their treating surgeon. Study variables included general demographic data, family history, time of diagnosis, presentation, type of hypospadias, associated chordee, other associated anomalies, circumcision, age at time of surgery, type of surgery, number of stages of surgery, type of suture material, period of catheterisation, hospital stay and post-operative complications.

RESULTS

The mean age in Group A was 5.7 ± 4.3 years and 5.1 ± 3.9 years in Group B. A family history was found in 13.7%. The chief presenting symptoms were as follows: abnormal stream of urine and abnormal penile shape with the percentage of 57.1% and 56.2%, respectively. The percentage of coronal was 23.8%, glanular 22.9%, distal penile 20%, mid or proximal penile 15.2%, scrotal 13.3% and perineal 4.8%. Chordee was found in 76.2%, undescended testis in 13.3% and inguinal

Table 1: Complications following hypospadias repair among each group

Complications	Group A, n (%)	Group B, n (%)	Total, n (%)	P
Fistula	14 (13.3)	5 (04.8)	19 (18.1)	0.012
Oedema	0	11 (19.2)	11 (19.2)	0.001
Stenosis	9 (08.6)	2 (3.6)	11 (19.2)	0.016
Infection	2 (01.9)	2 (01.9)	4 (03.8)	0.650
Bleeding	0	4 (03.8)	4 (03.8)	0.120

Table 2: Suture material and outcome of surgery in patients operated for hypospadias

Outcome	Group A, n (%)	Group B, n (%)	Total, n (%)
Successful	33 (66.0)	49 (89.1)	82 (78.1)
Complication	17 (34.0)	6 (10.9)	23 (21.9)
Total	50 (100.0)	55 (100.0)	105 (100.0)

$P=0.004$

hernia in 1%. The percentage of patients who were circumcised before surgery was 5.7%. Single-stage repair was performed in 79.3% and multistage repair performed in 20.7%. Meatal advancement and glanuloplasty incorporated (MAGPI) operation was done in 47.6%, tubularized incised plate urethroplasty (TIP) in (31.4%), Thiersch-Duplay in 20% and Mathieu's repair in 1%. The mean period of catheterisation was 6.6 ± 2.5 days, and the mean hospital stay was 6.1 ± 1.2 days. The complication rate was 34% in Group A and 10.9% in Group B. The most frequent complication was urethrocutaneous fistula (UCF), as 19 patients (18.1%) of all the study subjects 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.

DISCUSSION

The complications which were encountered in this study are bleeding, oedema, infection, UCF and stenosis [Table 1]. The overall rate of complications was 21.9% in both the groups. In Group A, the complication rate was 34%, while it was 10.9% in Group B [Table 2]. Our results came in favour of using PDS in repair; on looking to the type of hypospadias, in Group B, it is noticeable that the percentage of proximal, scrotal and perineal (38.2%) is more in comparison to Group A (28%), and this arguably puts Group B at a higher risk of complications as the primary position of the meatus is one of the major determinants of the outcome.^[2] UCF was the most frequent complication in both groups. It was observed in 19 patients in both groups combined accounting for 18.1% of all study subjects. Most of them were in Group A (14 patients) and 5 patients in Group B. This result came in concordance with national, regional and international studies, as the reported incidence of UCF ranged from 0% to 30%.^[4] We found two local studies: the first one showed a rate of 16.1% (was done in patients with distal hypospadias), and in the other one,

Table 3: The effect of chordee, stages of surgery, type of surgery and post-operative complications on urethrocutaneous fistula formation following hypospadias repair

Variables	Urethrocutaneous fistula		Total, n (%)	P
	No (n=86), n (%)	Yes (n=19), n (%)		
Chordee				
Absent	22 (25.6)	3 (15.8)	25 (23.8)	0.280
Present	64 (74.4)	16 (84.2)	80 (76.2)	
Stages of surgery				
One stage	69 (80.2)	5 (26.3)	74 (70.5)	0.000
Multistage	17 (19.8)	14 (73.7)	31 (29.5)	
Type of surgery				
MAGPI	48 (55.8)	2 (10.5)	50 (47.6)	0.003
TIP	22 (25.6)	11 (57.9)	33 (31.4)	
Mathieu	1 (1.2)	0	1 (1.0)	
Thiersch-Duplay	15 (17.4)	6 (31.6)	21 (20.0)	
Post-operative bleeding				
Absent	82 (95.3)	19 (100.0)	101 (96.2)	0.440
Present	4 (4.7)	0	4 (3.8)	
Post-operative oedema				
Absent	76 (88.4)	18 (94.7)	94 (89.5)	0.370
Present	10 (11.6)	1 (5.3)	11 (10.5)	
Post-operative wound infection				
Absent	84 (97.7)	17 (89.5)	101 (96.2)	0.150
Present	2 (2.3)	2 (10.5)	4 (3.8)	
Post-operative meatal stenosis				
Absent	81 (94.2)	13 (68.4)	94 (89.5)	0.004
Present	5 (5.8)	6 (31.6)	11 (10.5)	

MAGPI: Meatal advancement and glanuloplasty incorporated, TIP: Tubularized incised plate

the rate was 14.4%.^[5,6] In a study done at Egypt in 2011, the UCF rate was around 13%,^[7] and in another regional study in Saudi Arabia in 2011, the UCF rate was approximately 10%.^[8] Internationally, the rate of UCF was comparable to our results; for example, in a Korean study, UCF complicated 21.4% of the cases,^[9] and another study in the UK by Smith *et al.* showed a UCF rate of 9% [Table 3].^[10]

The type of hypospadias was statistically significant ($P = 0.001$, Chi-square test) factor in UCF formation, as 74.5% of the patients with UCF had proximal hypospadias. The two available local studies did not examine the type of hypospadias as a risk factor for UCF formation; however, most of the international studies mentioned it as a risk factor for UCF like Sung Kwang Chung study in Korea.^[9] Another study by Huang came with a contradicting result as they concluded that the type of hypospadias is not a risk factor for UCF.^[11]

Another significant complication was meatal stenosis, which occurred in 11 patients (10.5%): 9 in Group A and 2 in Group B. All patients were managed successfully with urethral dilatation.

About 18% of the patients in Group A developed meatal stenosis compared to only 3.6% in Group B; again, this result was statistically significant ($P = 0.016$, Chi-square test) and in favour of PDS. In a study done at the Kingdom of Saudi Arabia, the incidence of meatal stenosis was 3.1% which is far less if we compared it to the overall incidence of meatal

stenosis (both the groups), but if we took in consideration that they only used PDS in the repair, we will find that their result is comparable to ours.^[12] In one of our local studies, 8.9% of the study candidates developed meatal stenosis,^[6] and the other local study showed a little bit lower incidence of meatal stenosis (6.3%).^[5] Regarding oedema and bleeding, they occurred only in Group B, with the percentage of 10.5% and 3.8%, respectively. The occurrence of oedema was higher in Group B and statistically significant with $P = 0.001$ (Fisher's exact test), but it was not clinically significant as the outcome in Group B was much better. Bleeding was more in Group B, but it was not of statistical significance as $P = 0.12$ (Fisher's exact test). We could not compare our incidence of bleeding to other studies because the incidence of bleeding following hypospadias surgery is not clearly recorded in the literature. The incidence of oedema mentioned in the literature is about 11.11%, but in most, it did not affect the outcome of the operation.^[13] Wound infection affected both the groups equally, with 2 patients in each group (3.8%); obviously, there was no correlation between the type of suture and the occurrence of wound infection ($P = 0.65$). There are two studies comparing polyglactin and polydioxanone in hypospadias repair, but none of the patients developed post-operative wound infection.^[14,15] As mentioned above, the outcome was better in Group B, as the complication rate was only 10.9% compared to 34% in Group A. All studied complications were less in group B except for bleeding and oedema. Although bleeding and oedema were

more in group B this had no clinical significance reflected on the overall outcome. The percentage of proximal hypospadias was more in Group B which renders it at a higher risk for complications, and this once again proves the superiority of PDS in hypospadias repair. On reviewing the literature for studies comparing different types of suture materials in hypospadias repair, we found no consensus about the ideal type of suture. 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 with 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 utilising polydioxanone (PDS) suture material in urethroplasties.^[15] 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]

There are multiple factors incriminated in the aetiology of UCF following hypospadias repair. In our study, we observed suture material, age at time of operation, presence of chordee, type of hypospadias, type of repair, stages of repair, post-operative bleeding, post-operative wound infection, post-operative oedema, period of catheterisation and period of post-operative hospital stay as possible risk factors for UCF.

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 done by Yildiz *et al.* to study the age of patients as a risk factor for UCF in hypospadias surgery, the risk was higher in older patients.^[19] Another Italian study had also suggested that the age of the patient is a risk factor for developing complications, especially UCF.^[11] Only 3 (15.8%) of the patients who developed UCF did not have chordee compared to 16 (84.2%) patients who had chordee and developed UCF. However, this was not statically significant relation ($P = 0.28$), because 64 (74.4%) patients with chordee did not develop UCF. We could not find other studies addressing the relation between chordee and UCF. The type of hypospadias was one of the major determinants for the development of UCF ($P = 0.001$). More proximal forms were associated with higher rates of the development of UCF. Our result came in concordance with international

studies; Chung *et al.* reported that the risk of developing UCF after hypospadias repair is associated with the location of hypospadias (more proximal-type hypospadias).^[9] Another study carried out in the USA concluded the same outcome.^[20] As stated earlier, there are over 250 procedures for hypospadias repair, and the type of repair should be tailored according to each patient and the experience of the hypospadiologist. In our study, 50 patients underwent MAGPI operation (47.6%), 33 patients (31.4%) underwent TIP urethroplasty, 22 patients (20%) underwent Thiersch-Duplay repair and one patient (1%) underwent Mathieu's repair. The relation between the type of repair and UCF was found to be statistically significant ($P = 0.003$). The highest percentage of UCF was in patients who underwent TIP repair (57.9%), followed by Thiersch-Duplay (31.6%) and then MAGPI (10.5%), and the least was Mathieu's repair with 0%. TIP and Thiersch-Duplay were mostly used in patients with proximal hypospadias, and this explains why the UCF rate was higher when compared to MAGPI which is done only in distal hypospadias; this has resulted in a statistical bias in favour of MAGPI operation. Regarding Mathieu's repair, we excluded it from the comparison as it was only done in one patient. According to our result, Thiersch-Duplay repair had a better outcome in terms of less UCF when compared to TIP urethroplasty, but our result is contradicting with many studies; Zeytun *et al.* conducted a study to investigate the results of hypospadias surgery including MAGPI, TIP, Mathieu's repair and Mathieu and 'V' incision sutured, and they believe that TIP urethroplasty should be preferred for primary and recurrent hypospadias cases without chordee or with minimal chordee and with a normal urethral plate due to its lower complication rate and its satisfactory cosmetic appearance.^[20] Generally speaking, all distal forms of hypospadias can be repaired successfully in one-stage procedure, and only a small proportion of patients suffering from proximal hypospadias require a multistage repair. In our study, all the patients with distal hypospadias underwent a single-stage repair, and most of the patients with proximal hypospadias underwent a multistage repair.^[15] The percentage of patients who developed UCF was significantly higher in patients who underwent multistage surgery (73.7%) when compared to one-stage surgery (26.3%); this was found to be statistically significant ($P = 0.001$). However, all the patients who underwent multistage surgery were suffering from severe forms of hypospadias which puts them at a higher risk of UCF. In a meta-analysis carried out in Egypt, they reported that the complication rate of single-stage repair and multistage is 8%–61.5% and 15%–70%, respectively, and both techniques showed a similar pattern of post-operative complications in the form of fistula, meatal stenosis, partial glans dehiscence and urethral diverticulum.^[15] Post-operative bleeding did not affect the occurrence of UCF, as none of the patients who developed UCF suffered from post-operative bleeding ($P = 0.44$). We could not find other studies on the relation between bleeding and UCF formation among the patients who developed UCF (19 patients), and only two patients had post-operative wound infection; this was not statistically significant ($P = 0.15$).

However, it is believed that infection predisposes to UCF as mentioned in a paper done to study the acute post-operative complications of hypospadias.^[21] Post-operative oedema did not affect the occurrence of UCF, as only one (5.3%) of the patients who suffered oedema developed UCF ($P = 0.37$). We could not find studies specifically addressing the link between UCF and post-operative oedema, but in a study done by Kundra *et al.* in 2012, it demonstrated an association between the use of caudal epidural blocks and fistula formation. This finding was attributed to penile engorgement, a known consequence of caudal epidural blocks. These investigators theorised that increased penile oedema could result in poor tissue healing and formation of UCF.^[22] In our study, we noticed that meatal stenosis had significantly affected the development of UCF ($P = 0.004$). Six (31.6%) of the patients who had UCF had meatal stenosis as well. Many studies agreed with our result, for example, a study done by Hadidi *et al.* who found that 7.4% of the patients with UCF had meatal stenosis and they concluded that every patient with UCF should be examined for meatal stenosis.^[2] In our study duration of catheterization was not a risk factor for UCF formation ($P=0.31$). Our result contradicted with a study carried out in Iran which linked UCF formation to longer duration of catheterization post-surgery.^[23] In another study done at Cairo University, the role of stenting and catheterisation has been evaluated. The study included 100 patients divided randomly into a silicone stent group and a no stenting group. Although the difference was not statistically significant, the incidence of complications and fistula formation was higher in the stented group.^[2]

CONCLUSION

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.

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Conflicts of interest

There are no conflicts of interest.

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