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Comparative study between polydioxanone 6.0 and polyglactin 6.0 suture material in distal hypospadias repair

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Abstract

Background: Despite advancements in several procedures and suture materials and the proposal of new ones, hypospadias repair problems must be decreased. Urethrocutaneous fistulas, the most prevalent consequence, are used to assess therapy effectiveness. A prospective comparison study of hypospadias children examined how suturing material affected treatment outcome. The study aims to compare Polydioxanone 6.0 and Polyglactin 6.0 suture materials in distal hypospadias repair using the T.I.P. technique, focusing on post-operative complications like wound infection, edema, glans dehiscence, fistula, urethral stricture, and meatal stenosis.

Method: Between November 2018 and November 2019, 43 boys with distal hypospadias underwent T.I.P. technique repair at Ghazi AL Hariri Hospital and Nursing Home Hospital. They were divided into two groups: Group A (23 patients) used Polydioxanone for urethroplasty, and Group B (20 patients) used Polyglactin. Exclusions were mid/proximal hypospadias, previous repair failures, second-stage hypospadias, and over 30-degrees curvature. Follow-ups at 14 days, 1 month, 3 months, 6 months, and 1 year focused on complications like wound infection, edema, glans dehiscence, fistula, urethral stricture, and meatal stenosis. Results: In the study, Group A (mean age 4.74 ± 2.598 years) experienced higher edema (30.43%) compared to Group B (mean age 4.80 ± 2.526 years) with 5.00% at 2 weeks, a statistically significant difference favoring Polyglactin (p-value 0.0325). Similarly, Group A had a higher incidence of post-operative wound infection (30.43%) at 6 months compared to Group B (5.00%), also significant in favor of Polyglactin (p-value 0.0325). However, there were no statistically significant differences between the groups in other post-operative complications like glans dehiscence, fistula, urethral stricture, and meatal stenosis.

Conclusion: Both suture materials can be used in the repair of distal hypospadias by tubularized incised plate technique (T.I.P.) without significant difference in complications, in favor of polyglactin 6.0 suture material with long term results.

Keywords: Hypospadias, suture materials, polydioxanone, polyglactin

Introduction

Hypospadias, a common congenital penile malformation, affects 1 in 300 male neonates, with 70-80% having a distal urethral opening near the glans ^[1]. Diagnosis is typically made in newborns, often identified by an incompletely developed dorsal foreskin. Ventral curvature, a significant issue especially in proximal cases, can lead to sexual dysfunction in adulthood ^[1]. Various surgical techniques aim to reconstruct a normal-functioning and normal-appearing penis ^[2]. Embryologically, genitalia in both sexes are initially identical, undergoing differentiation by the 9th week. In males, the genital tubercle elongates under androgen influence, forming the penis and scrotum. Failure of this process results in hypospadias, completed by 14 weeks of gestation ^[3]. The etiology of hypospadias is multifaceted, involving endocrine, genetic, environmental, and maternal factors ^[4]. Hypospadias severity is traditionally classified by the urethral meatus location, but this oversimplification can underestimate complexity in some cases ^[5]. Diagnosis is usually made postnatally, though prenatal ultrasound techniques are improving ^[6]. Preoperative evaluation includes history, physical examination, and assessment for associated anomalies like cryptorchidism or inguinal hernia. Severe cases may require genetic and endocrine work-up to exclude intersexuality ^[7]. Preoperative androgen therapy, though widely practiced, lacks conclusive evidence for improving outcomes ^[8]. The optimal timing for hypospadias surgery is typically between 6 and 18 months, with some evidence suggesting

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increased complication rates if performed after 6 months or 1 year [9]. The Glans Meatus and Penile Shaft (GMS) score, assessing glans and urethral plate quality, meatus location, and penile curvature, helps stratify severity and predict complication risks [10]. Various surgical procedures are available, with no single technique being superior [11]. The TIP procedure is preferred for distal hypospadias with adequate urethral plate and ventral tissue, offering reliability and a low complication rate [12]. Other techniques include the Meatal Advancement and Glanuloplasty (MAGPI) and Tubularized Incised Plate repair (TIP) [13]. Suture material has evolved significantly, impacting hypospadias surgery outcomes. Historically, materials ranged from animal intestine to synthetic absorbables like polyglactin and Polydioxanone [14]. The ideal suture should balance tensile strength, handling ease, minimal tissue reaction, infection resistance, and appropriate biodegradation [15]. Polyglactin acid sutures like Polyglactin 910 (Vicryl) are synthetic, braided, and absorb by hydrolysis, maintaining strength for a suitable duration before absorption [16]. Polydioxanone (PDS) is a monofilament polymer with prolonged tensile strength, used primarily for tendon repair due to its low tissue reactivity and slower degradation [17]. Choosing the right suture material involves considering factors like tensile strength duration, potential risk of fistula formation, and wound dehiscence prevention [18]. Complications of TIP repair can include meatal stenosis, fistula, glans dehiscence, urethral stricture, infections, and breakdown of urethral repair [19]. Aim of the study is to compare the outcome of hypospadias repair between (Polydioxanone 6.0 and polyglactin 6.0) suture material when used in the repair of distal hypospadias by using T.I.P technique in early and long-term complications.

Methods

This prospective comparative study, conducted at Ghazi AL Hariri Hospital for Surgical Specialties and Nursing Home Hospital in Medical City from November 2018 to November 2019, involved 43 patients undergoing hypospadias repair using the Tubularized Incised Plate (T.I.P.) technique. The patients were divided into two groups: Group A (23 patients) used Polydioxanone for urethroplasty, and Group B (20 patients) used Polyglactin. They were evaluated at five intervals post-operatively: 14 days, 4 weeks, 3 months, 6 months, and 12 months.

Inclusion and Exclusion Criteria

The study included patients undergoing single-stage repair for distal hypospadias with chordee less than 30 degrees post-degloving. It excluded those with proximal and mid-shaft hypospadias, redo surgeries, and chordee exceeding 30 degrees post-degloving.

Preoperative Evaluation

Participants underwent comprehensive preoperative evaluations, including blood tests, renal function tests, urinalysis, and imaging, to ensure suitability for surgery. Informed consent was obtained from the patients' families. Preoperative antibiotics were administered according to weight.

Surgical Technique

Surgeries were performed under general anesthesia. Key steps included glans traction with a 3-0 silk suture, careful skin incision to preserve inner prepuce, penis degloving, glans wings dissection, and midline incision of the urethral plate. The urethral plate was tubularized using Polydioxanone in Group A and Polyglactin in Group B, with different knotting techniques due to material properties. A dartos pedicle flap was dissected for coverage, and glansplasty and skin closure were performed with the same suture material used in urethroplasty. Postoperative care involved dressing maintenance, antibiotic therapy, and Foley's catheter management.

Postoperative Care

Patients received ongoing wound care with Fucidin cream and dressings. They were discharged on day 3 with instructions for home care, including wound bathing and cream application. Foley's catheters were removed on day 10, followed by wound assessment for infection or dehiscence.

Post-operative Evaluation and Follow-up

Follow-up visits at Ghazi Al-Hariri Hospital were scheduled for 2 weeks, 1 month, 3 months, 6 months, and 1-year post-surgery. Physical examinations focused on complications such as edema, wound infection, fistula, glans dehiscence, urethral stricture, and meatal stenosis.

Ethical Considerations

The study was approved by the hospital administration, and written informed consent was obtained from the patients' families.

Statistical Analysis

Data were processed using Microsoft Office 2016 and analyzed with SPSS version 25. The analysis included mean, standard deviation, ranges, frequencies, percentages, and chi-square tests to explore the relationship between the groups. A p-value of ≤ 0.05 was used to determine significance.

Results

A total of 43 cases were enrolled in this study, 23 patients were undergone repair by using Polydioxanone as suture material and were classified as group A, 20 patients were undergone repair by using polyglactin as suture material and were classified as group B all patients managed in one-stage repair using tubularized incised plate technique. The mean and standard deviation of age in group A was (4.74±2.59) years and in group B was (4.80±2.52) years. As shown in fig 1.

All patients had been seen in 5 different intervals from the first postoperative day (2 weeks, 4 weeks, 3 months, 6 months, 1 year) and examined for post-operative (edema, wound infection, glans dehiscence, fistula, urethral stricture and meatal stenosis). At 2 weeks, the edema was more in group A (7 of 23) patients (30.43%) while in group B (1 of 20) patients (5.00%). this result statistically was significant in favor of polyglactin the p value was (0.0325). Follow up at 1 month and 3 months did not show significant difference statistically between the two groups the p value (0.1140) and (0.6351) respectively. As showed in table 1.

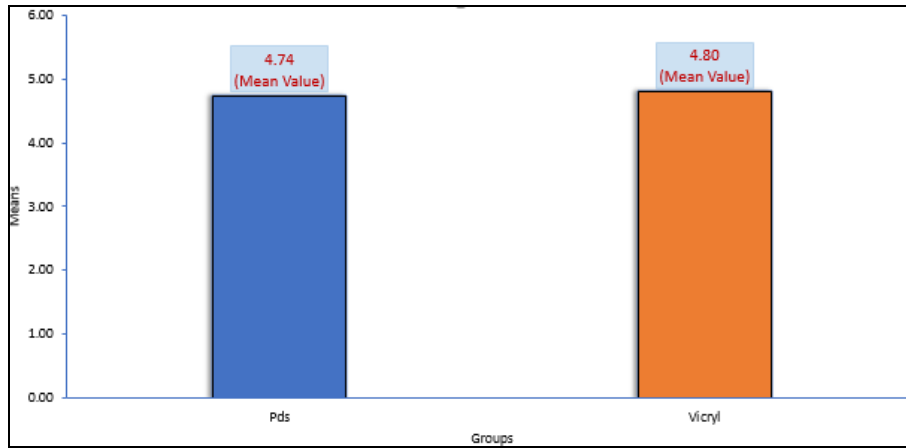


Fig 1: Mean Age value of the studied patients

Table 1: The results of post-operative edema

Suture type		PDS		Vicryl		P value
2 weeks	Yes	7	30.43%	1	5.00%	0.0325
	No	16	69.57%	19	95.00%	
4 weeks	Yes	5	21.74%	1	5.00%	0.1140
	No	18	78.26%	19	95.00%	
3 months	Yes	2	8.70%	1	5.00%	0.6351
	No	21	91.30%	19	95.00%	
6 months	Yes	0	0.00%	0	0.00%	0.6
	No	23	100%	20	100%	
1 year	Yes	0	0.00%	0	0.00%	0.6
	No	23	100%	20	100%	

While post-operative wound infection in 2 weeks in group A was (1 of 23) patients (4.35%) while in group B was (1 of 20 patients) (5.00%) this was statistically non-significant p value (0.9193). Only was significant statistically in 6 months follow up by granuloma formation in group A (7 of 23) patients (30.43%) while in group B (1 of 20) patients (5.00%) by p value (0.0325) in favor of polyglactin. As showed in table 2.

Table 2: Results of post-operative wound infection

Suture type		PDS		Vicryl		P value
2 weeks	Yes	1	4.35%	1	5.00%	0.9193
	No	22	95.65%	19	95.00%	
4 weeks	Yes	1	4.35%	1	5.00%	0.9193
	No	22	95.65%	19	95.00%	
3 months	Yes	2	8.70%	1	5.00%	0.6351
	No	21	91.30%	19	95.00%	
6 months	Yes	7	30.43%	1	5.00%	0.0325
	No	16	69.57%	19	95.00%	
1 year	Yes	0	0.00%	0	0.00%	
	No	23	100%	20	100%	

While fistula formation in 2 weeks in group A was (1 of 23) patients (4.35%) and in group B was (2 of 20) patient (10.0%) and reaching in 1 year in group A was (2 of 23) patients (8.70%) while in group B was (3 of 20) patients (15.00%). In favor of

Polydioxanone but not reaching statistically significance p value (0.5201). As showed in table 3.

Table 3: Results of postoperative fistula

Suture type		PDS		Vicryl		P value
2 weeks	Yes	1	4.35%	2	10.00%	0.468
	No	22	95.65%	18	90.00%	
4 weeks	Yes	1	4.35%	2	10.00%	0.468
	No	22	95.65%	18	90.00%	
3 months	Yes	2	8.70%	3	15.00%	0.5201
	No	21	91.30%	17	85.00%	
6 months	Yes	2	8.70%	3	15.00%	0.5201
	No	21	91.30%	17	85.00%	
1 year	Yes	2	8.70%	3	15.00%	0.5201
	No	21	91.30%	17	85.00%	

Glans dehiscence in 2 weeks follow up in group A was (2 of 23) patients (8.70%) and in group B was (1 of 20) patient (5.00%) in favor of polyglactin still not reaching statistically significant p value (0.6352). As showed in table 4.

Table 4: Results of post-operative glans dehiscence

Suture type		PDS		Vicryl		P value
2 weeks	Yes	2	8.70%	1	5.00%	0.6352
	No	21	91.30%	19	95.00%	
4 weeks	Yes	2	8.70%	1	5.00%	0.6352
	No	21	91.30%	19	95.00%	
3 months	Yes	2	8.70%	1	5.00%	0.6352
	No	21	91.30%	19	95.00%	
6 months	Yes	2	8.70%	1	5.00%	0.6352
	No	21	91.30%	19	95.00%	
1 year	Yes	2	8.70%	1	5.00%	0.6352
	No	21	91.30%	19	95.00%	

About urethral stricture in 1 year in group A was (1 of 23) patients (4.35%) while in group B was (1 of 20) patients (5.00%) in favor of Polydioxanone but it's still statistically insignificant p value (0.9193). As showed in table 5.

Table 5: Results of post-operative urethral stricture

Suture type		PDS		Vicryl		P value
2 weeks	Yes	0	0.00%	0	0.00%	
	No	23	100%	20	100%	
4 weeks	Yes	0	0.00%	0	0.00%	
	No	23	100%	20	100%	
3 months	Yes	1	4.35%	1	5.00%	0.9193
	No	22	95.65%	19	95.00%	
6 months	Yes	1	4.35%	1	5.00%	0.9193
	No	22	95.65%	19	95.00%	

	No	22	95.65%	19	95.00%	
1 year	Yes	1	4.35%	1	5.00%	0.9193

About meatal stenosis was in 1 year follow up in group A was (1 of 23) patients (4.35%) and in other hand group B was (2 of 20) patients (10.00%) in favor of Polydioxanone still not reaching statistically significance p value (0.4680). As showed in table 6.

Table 6: Postoperative meatal stenosis results.

Suture type	PDS		Vicryl		P value
	Yes	No	Yes	No	
2 weeks	0	0.00%	0	0.00%	
	23	100.00%	20	100.00%	
4 weeks	0	0.00%	0	0.00%	
	23	100.00%	20	100.00%	
3 months	1	4.35%	1	5.00%	0.9193
	22	95.65%	19	95.00%	
6 months	1	4.35%	2	10.00%	0.4680
	22	95.65%	18	90.00%	
1 year	1	4.35%	2	10.00%	0.4680
	22	95.65%	18	90.00%	

Discussions

In this study, we compared the outcomes of urethroplasty in children with distal hypospadias using two different suture materials: Polydioxanone (Group A) and Polyglactin (Group B). The study focused on various post-operative complications, including fistula, glans dehiscence, meatal stenosis, urethral stricture, wound infection, and edema, over a 12-month follow-up period. Suture Material Properties: Polyglactin is known for its faster absorption rate, while Polydioxanone has a slower rate of absorption. This difference in tensile strength loss and absorption time is crucial in the healing process and may influence post-operative complications. Major Complications: The study found no significant difference between the two groups in terms of major complications like fistula, glans dehiscence, meatal stenosis, and urethral stricture. However, minor complications such as post-operative edema and granuloma formation showed significant differences, favoring the Polyglactin group. Fistula Rates: Overall fistula rate was 11.6%. Group A (Polydioxanone) had a lower fistula rate (4.35%) compared to Group B (Polyglactin) at 10.0% one month post-operatively. This finding aligns with studies by Ulman *et al.* [20] and Uygur *et al.* [21], which also reported higher fistula rates in Polyglactin groups. Conversely, Guarino *et al.* [18] found a lower fistula rate in Polyglactin users, indicating variability in outcomes. Glans Dehiscence: The overall rate of partial glans dehiscence was 6.9%, with no statistically significant difference between the groups, similar to findings by Guarino *et al.* [18]. Wound Infection: Acute wound infection rates at two weeks were similar between the groups, but a significant difference emerged at 6 months due to granuloma formation, favoring the Polyglactin group. This is in line with Guarino *et al.* [18], but contrasted by an experimental study on baboons by Bartone *et al.* [22], which suggested detrimental effects of long-lasting sutures like Polydioxanone. Edema: Post-operative edema at two weeks was significantly higher in Group A (Polydioxanone), potentially due to a greater inflammatory reaction against this suture material, as described by Molea *et al.* [23]. Urethral Stricture: The overall stricture rate was 4.6%, with no significant difference between the groups, corroborated by Cimador *et al.* [24] who reported similar stricture rates for both suture materials. Meatal Stenosis: The overall rate of meatal stenosis was 6.00%, slightly favoring Group A (Polydioxanone), but this difference was not statistically significant. Studies by Leclair *et al.* [25] and

Akbiyik *et al.* [26] also reported comparable rates of stenosis with both suture materials.

Conclusion

The study concluded that there are no significant long-term differences between Polydioxanone and Polyglactin suture materials in major complications like urethrocutaneous fistula, partial glans dehiscence, urethral stricture, and meatal stenosis in distal hypospadias repair. However, Polyglactin showed a favorable outcome in minor complications such as post-operative edema and granuloma formation, likely due to Polydioxanone's longer absorption time and greater inflammatory response. Both sutures are deemed suitable for use in tubularized incised plate hypospadias repair.

Conflict of Interest

Not available

Financial Support

Not available

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