

Comparison of Outcome of Autologous Platelet Rich Plasma Membrane Plus Dartos Flap Versus Simple Dartos Flap In Hypospadias Surgery

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Abstract

Objective: To compare the outcome of application of autologous platelet-rich plasma membrane layer and dartos fascial flap versus only dartos fascial flap in mid and distal penile hypospadias surgery.

Material and Methods: This randomized controlled trial (NCT06275646) was conducted at Pediatric General surgical department, the Children's hospital and the University of Child health, Lahore for the period of 12 months. Non probability, purposive sampling was used for data collection and randomization was done to assign the treatment. Total of 220 patients fulfilling the selection criteria were admitted after taking an informed consent. Cases were randomly divided into two groups A and B using random generator of Excel program. In group-A, dartos flap and Platelet Rich Plasma (PRP) membrane layer was applied and in group-B, only a preputial dartos fascial flap was applied.

Results: The mean age of all cases was 5.86 ± 3.10 years, while the mean age in group-A and group-B was 5.78 ± 3.13 years and 5.95 ± 3.08 respectively, with non-significant p-value > 0.05 . The mean hospital stay was statistically same in group-A (6.67 ± 2.80 days) as compared to group-B (7.34 ± 2.79 days), p-value 0.08 (i.e. > 0.05). The mean time for urethral stent removal was statistically same in group-A (9.31 ± 3.08 days) as compared to group-B (9.81 ± 2.81 days), p-value 0.21 (i.e. > 0.05). In group-A and group-B, 32 (29.1%) cases and 43 (39.1%) cases had complications respectively (infection, urethrocutaneous fistula, glans dehiscence, Meatal stenosis). The complications rate was statistically same in both groups, p-value > 0.05 .

Conclusion: It is concluded that patients who received dartos flap and PRP membrane coverage had less incidence of urethrocutaneous fistula as compared to cases received a preputial dartos flap only. Other complications were statistically same in both study groups.

Keywords: Mid penile hypospadias, distal penile hypospadias, surgery, dartos flap and PRP membrane, preputial dartos flap, complications.

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Introduction

Hypospadias is most common congenital condition of phallus in which the opening of urethra present

on the ventral aspect of phallus anywhere proximal to its actual location.¹ The incidence of hypospadias ranged from 0.6/10,000 births to 464/10,000 births¹. Patients with hypospadias are usually referred for surgery during early childhood or infancy.²

Hypospadias repair surgery has been progressed steadily over recent years.³ However, the results of hypospadias repair are still mostly unfavorable with reported complications rate as high as approximately 50% or above.^{1,4} The commonest complications following hypospadias surgery usually accompany with urethral fistulas, followed by stenosis of meatus, stricture of urethra, formation

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of urethral diverticulum, dehiscence of glans, and cosmetically unfavorable outcomes necessitating redo surgeries.⁵

Modern surgical interventions claim that it is now accessible to make a functionally and cosmetically acceptable phallus. Assessment of outcomes include: rate of complications (such as wound infection, glans dehiscence, Urethrocutaneous fistula (UCF) and meatal stenosis), cosmetic penile appearance, functional ability (urination, sexual intercourse), and psychological issues like improvement in value of life and psychosexual life of patient.

Various types of techniques for urethroplasty has been evolved for example simple tubularization of the urethral plate, giving incision in midline of urethral plate and formation of Tubularized incised plate (TIP), use of adjacent preputial skin flaps as covering layer, different types of skin grafts, grafts from buccal mucosa, and mobilized flaps enriched with vascular supply (mostly involving the inner preputial skin).⁶ Methods of providing vascularized tissue coverage to neo-urethra include application of dartos fascia, tunica vaginalis, de-epithelized skin, and corpus spongiosum.⁷ Recently it is reported that platelet rich plasma membrane has the capability to minimize post-operative complications occurring after repair of hypospadias, especially post-operative infection & urethrocutaneous fistula formation by improving wound healing with help of platelets themselves and platelet derived growth factors present in Platelet Rich Plasma (PRP). In this study, UCF occurred in 10% of patients and infection in 5% of patients using PRP material as compared to patients in which repair was done without the PRP, in which fistula rate was 25% and infection rate was 35%.

Another study reported that UCF developed in 2(6%) in total 33 cases when autologous PRP membrane was used as an alternative covering layer in repair of hypospadias. No complications were reported in relation to the sampling of blood. No statistically significant difference was observed between study and the control group (undertaking the same surgery, but with different mean). Another comparative study showed complications and outcome rate of application of PRP layer versus dartos flap layer only during primary surgery of distal hypospadias. They reported 12 (13.3%) complications in group A (in which TIP urethroplasty done with PRP membrane was applied), and 24 (26.7%) patients had complications in group B (dartos flap only as second layer). Urethrocutaneous fistula after primary Snodgrass repair was seen in 9(10%) patients in A group, and in

12(13.3%) patients in B group. Partial or complete dehiscence of glans seen in 1.1% of patients in A group, and in 4.4% of patients in B group. In A group no patient had a superficial wound infection, as compared to B group in which 6.7% of patients had wound infection. One patient (1.1%) of urethral stricture and meatal stenosis was observed in both groups, both were conservatively managed by regular dilatation of meatus and urethra weekly for 2 to 3 months.⁸

Material & Methods

This randomized control trial (NCT06275646) was conducted at Pediatric Surgery Department, The Children's Hospital and University of Child Health Sciences, Lahore. After approval from the ethical review committee of the hospital, patients (Age 6 months to 12 years) with mid, distal penile or sub coronal hypospadias having minimal chordae (less than 20) were included in the study. Patients having proximal hypospadias, moderate to severe chordae, previously operated cases, a preoperative androgens treatment (for example in penoscrotal hypospadias and small sized phallus) were excluded from study. The study was carried out between 1st September 2021 to 30th August 2022.

A total of 220 patients (110 in each group) fulfilling the selection criteria were admitted after taking an informed consent. Patient's demographic data includes name, age and contact details were obtained. Patients were divided randomly into two groups, A and B using ballooning method. In group-A, a dartos flap and PRP layer was applied and in group B patients, only the preputial dartos flap layer was applied. Whereas PRP membrane was prepared at the time of surgery, a 2.5 × 1.5cm PRP layer was made from 8-10 cc of whole blood of patient with doubled centrifugation of sample for about 15-20 minutes at 2500 -3000 RPM. In the operation theatre, 2 to 3 drops of calcium chlorate added in coagulum, and incubation of sample was done for 2-3 minutes at 37°C until a bright red to whitish layer was formed at the middle of tube. The centrifuged blood was then separated into three layers, depending on its density: the red blood cells in bottom layer; the PRP membrane, (approximately 1-1.5ml) enriched with white blood cells and platelets in middle layer; and the platelet-poor plasma in top layer. After extracting from the tube, the clot was separated from the RBCs, and gently pressed between two saline soaked gauzes to form a thin membrane. All patients were operated through the Snodgrass technique with a suitable sized catheter (NG8-10Fr). Neo-urethra was formed by continuous layer with absorb-

able suture sized 7/0 or 6/0, followed by second covering layer with dartos fascia by interrupted absorbable sutures. After that a thin PRP layer was applied between dartos and skin. Closure was done with absorbable suture followed by antiseptic dressing. The dressing changed on the fourth postoperative day and wound examined. The catheter was kept in placed for 10–12 days for urine drainage, and after removing the catheter, wound and stream of urine was observed in patients of both groups. Surgical team of same level did all surgical procedures to reduce the risk of biasness.

Data was entered and analyzed through SPSS -24. Quantitative variable like age was presented as mean \pm S.D. The qualitative data like gender and complications such as wound infection, glans dehiscence, urethrocutaneous fistula and meatal stenosis was presented as percentage and frequency. Chi-square test was applied to compare complication such as (wound infection, glans dehiscence, urethrocutaneous fistula and meatal stenosis) in both study groups. P value equal to or less than 0.05 was considered as significant.

Results

The mean age of all cases was 5.86 ± 3.10 years, while the mean age in group-A and group-B was 5.78 ± 3.13 years and 5.95 ± 3.08 respectively, with nonsignificant p-value > 0.05 . The mean hospital stay was statistically same in group A (6.67 ± 2.80 days) as compared to group-B (7.34 ± 2.79 days), p-value 0.08 (i.e. > 0.05). The mean time for urethral stent removal was statistically

Table 1: Comparison of Complications in both study groups

	Study groups		Total	
	Group-A	Group-B		
Complications	Yes	32(29.1%)	43(39.1%)	75(34.1%)
	No	78(70.9%)	67(60.9%)	145(65.9%)
Total		110(100%)	110(100%)	220(100%)

Chi-square = 2.45, p-value = 0.118 (significant)

Table 2: Comparison of Wound infection at 2 week, 4 weeks, 12 weeks in both study groups

Wound infection		Study groups		Chi-square	p-value
		Group-A	Group-B		
At 2 weeks	Yes	15(13.6%)	18(16.4%)	19.04	0.015
	No	95(86.4%)	92(83.6%)		
At 4 weeks	Yes	3(2.7%)	3(2.7%)	0.00	1
	No	107(97.3%)	107(97.3%)		
At 12 weeks	Yes	0(0%)	0(0%)	--	--
	No	110(100%)	110(100%)		

Chi-square = 2.45, p-value = 0.118 (significant)

Table 3: Comparison of Glans Dehiscence, Urethrocutaneous Fistula and Meatal stenosis at 2nd weeks

Types of complications		Study groups		Chi-square	p-value
		Group-A	Group-B		
Glans Dehiscence	Yes	3(2.7%)	5(4.5%)	0.519	0.471
	No	107(97.3%)	105(95.5%)		
Urethrocutaneous Fistula	Yes	24(21.8%)	38(34.5%)	4.40	0.036
	No	86(78.2%)	72(65.5%)		
Meatal stenosis	Yes	1(0.9%)	2(1.8%)	0.56	0.5
	No	109(99.1%)	108(98.2%)		

same in group-A (9.31 ± 3.08 days) as compared to group-B (9.81 ± 2.81 days), p-value 0.21 (i.e. > 0.05).

Discussion

In general, postoperative urinary diversion, wound care, and dressings have helped to ease postoperative care without compromising outcomes of surgery. Traditionally, a variety of urinary diversion methods has been used in hypospadias repair to maintain patency of neourethra and to keep urine away from wound thereby reducing the possible complications.⁹ In their study, mean age at operation was 2.45 years (range: 1–4 years). One more study was done in 180 boys (age range 12–65 months).⁸ In current study, cases of 2–12 years were taken, with mean age of 5.86 ± 3.10 years.

Alternatively, some reports also suggest that urethroplasty without stenting excludes the problems of bladder spasm and discomfort during removal of stent without increasing rate of complications.¹⁰ In current study in group-A and group-B, 32(29.1%) cases and 43(39.1%) cases had complications respectively, the complications rate was statistically same in both groups, with p-value greater than 0.05. In our study till 2nd week of follow up 3(2.7%) cases in group-A and 5(4.5%) cases in group-B had Glans dehiscence, with no statistical difference, p-value was > 0.05 .

Recently a study was done on 180 boys (ranging from 12–65 months) in which they were divided randomly into two groups. In A group, TIP urethroplasty done with PRP layer and in B group, dartos fascial flap was used. They reported that there was statistically significant difference in the complications rate between both groups. A total of 36(20%) patients had complications in both groups. The authors reported that 12 (13.3%) patients had complications in A group as compared to B group in which 24 (26.7%) patients had complications. They concluded that PRP membrane might be used as substitute layer for repair of distal hypospadias, particularly when a healthy layer is absent.⁸ While in current study

we found similar complications rate, overall infection rate was same but according to Southampton criteria Group-A was relatively better. Another study reported that the Platelet rich fibrin patch can be an efficient and safe covering method in repair of hypospadias. This procedure can be used as an additional approach to cover the neo-urethra for hypospadias repair, especially when the healthy tissue is not available as coverage layer. This, in turn can reduce the incidence of post-operative complications.¹¹ In current study, in group-A and group-B there were 1(0.9%) and 2(1.8%) cases who had meatal stenosis, p-value > 0.05. These findings are similar to another study that reported that only one case (1.1%) of urethral stricture and meatal stenosis was reported in each group, all of which were conservatively managed by regular weekly dilatation of meatus and urethra for two to three months.⁸

The commonest complication occurring after repair of hypospadias is urethrocutaneous fistula (UCF) with an incidence fluctuating from 4 to 28%. One of the most important procedures used to reduce the possibility of fistula formation is application of an intermediate layer between the neo-urethra and the skin. Dartos flap and PRP coverage are among several techniques which are gaining fame.

In study done in 2019, in which 180 patients were divided into two groups randomly. In A group TIP urethroplasty done with PRP layer and in B group dartos flap was used. Glans dehiscence occurred in 1(1.1%) patient in A group, and 4(4.4%) patients in B group. Urethrocutaneous fistula was reported in 9(10%) patients in A group, and 12 (13.3%) patients in B group. No case of superficial wound infection reported in group A, compared with group B in which six patients had wound infection (Mahmoud et al., 2019).⁸ A study was planned by Guinot and colleagues to evaluate the, safety, feasibility, and efficacy of autologous PRF membrane in hypospadias surgery. They reported that UCF occurred in 2/33(6.1%) patients when autologous PRF membrane used as coverage in hypospadias surgery. The median follow-up of patients was 8 months (range from, 6–18 months). It was a descriptive study with no comparison.¹⁰ A local study reported that among 88 cases treated with autologous platelet rich plasma patch, urethrocutaneous fistula was developed in 11.36% of the cases. In our study, the UCF rate was 21.8% and 34.5% in group A and B respectively with p-value < 0.05.

In current study, in group-A and group-B there were 1(0.9%) and 2(1.8%) cases who had meatal stenosis, p-value > 0.05. These findings are similar to another

study that reported that only one case (1.1%) of urethral stricture and meatal stenosis was recorded in both groups.⁸

In a recent study comparison of autologous PRP material plus dartos flap vs only dartos flap in mid penile hypospadias surgery was compared. In patient group using PRP, infection occurred in 5% and fistula in 10% of patients. While in group without using PRP infection occurred in 35% and fistula in 25% of patients.⁵ In our study, infection occurred in 13.6% and fistula in 21.8% of patients with using PRP membrane, while in group without using PRP, infection occurred in 16.4% and fistula in 34.5% of patients.

Conclusion

It is concluded that patients who received dartos flap and PRP membrane coverage had less incidence of urethrocutaneous fistula as compared to cases who received a preputial dartos flap only. Other complications were statistically same in both study groups. Hence in future dartos flap and PRP membrane coverage should be encouraged to apply for mid penile and distal hypospadias surgery to achieve better outcomes.

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