

Original Research Article

Prospective comparative study of hypospadias surgical repair with and without the use of fibrin sealant

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ABSTRACT

Background: Hypospadias is the most common congenital malformation of the penis, affecting about 4-6 males per 1000 male births, and ranging in severity from a urethral meatus that is slightly off-center to a meatus in the perineal area. The aim of this study was to evaluate whether the application of fibrin sealant over the suture lines of neo-urethra reduces complications and improve overall outcome in children hypospadias repair.^{1,2}

Methods: It was a prospective comparative study conducted in a tertiary care center (Department of pediatric surgery - Menoufia University), we included the patients age more than 6 months and less than 4 years presented with hypospadias to our department in this study. A total 30 patients of coronal, sub coronal, mid shaft hypospadias and distal hypospadias were studied and were divided into two groups, group (A) 15 cases and group (B) 15 cases. All patients underwent a tabularized incised plate (TIP) repair with a Dartos vascularized pedicle flap to cover the neo-urethra. In group (B) a thin layer of fibrin sealant applied over the suture line of neo-urethra but no sealant was used in group (A).

Results: Postoperative surgical complications: urethra cutaneous fistula, flap dehiscence, flap necrosis and urethral stricture were recorded. Urethrocutaneous fistula flap dehiscence and flap necrosis were lower in group (B) patients. There was no significant difference in postoperative urethral stricture between two groups.

Conclusions: Use of fibrin sealant in hypospadias repair is safe and can reduce complications.

Keywords: Hypospadias, Fibrin sealant, TIP, Urethra cutaneous fistula, Fibrogloo

INTRODUCTION

Hypospadias is the most common congenital malformation of the penis, and it is considered by some to be a mild form of 46XY disorders of sex development, affecting about 4-6 males per 1000 male births, and ranging in severity from a urethral meatus that is slightly off-center to a meatus in the perineal area due to incomplete closure of the penile structures during embryogenesis.^{1,2} Over the past three decades its prevalence may have increased due to changes in reporting of mild cases and/or increased survival of low birth weight infants due to improved neonatal care.⁽¹⁾

Elastosonography has showed markedly altered anatomy in hpospadiac penis in the form of stiffer and less elastic corpus spongiosum (and penis) as well as less developed corpora cavernosa.³ The aim of this study was to evaluate whether the application of fibrin sealant over the suture lines of neo-urethra reduces complications and improve overall outcome in children hypospadias repair.

METHODS

It was a prospective comparative study conducted in a tertiary care center (Department of pediatric surgery - Menoufia University), we included the patients age more

than 6 months and less than 4 years presented with hypospadias to our department in this study. A total 30 patients of coronal, sub coronal, mid shaft hypospadias and distal hypospadias were studied from March 2018 to September 2018.



Figure 1: Tip repair.

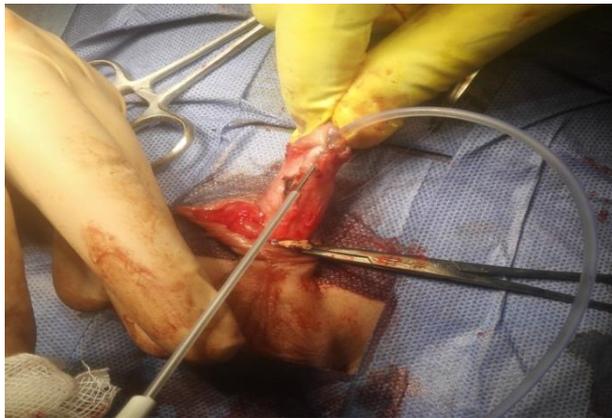


Figure 2: TIP repair with fibrogloo application.

On admission detail, history and examination included lower urinary tract symptoms, the location of urethral meatus, presence or absence of ventral chordee. The patients then divided into two groups: Group (A):

includes 15 patients will be managed by TIP repair only (Figure 1), Group (B): includes 15 Patients will be managed by TIP repair with fibrin sealant application (Figure 2); the operations will be done under general anesthesia. The two groups will be followed up for four weeks postoperative which is the end point of the study and will be compared according to: Urethrocutaneous fistula, wound edema and dehiscence flap necrosis, urethral stents problems and urethral strictures. All patients underwent a tabularized incised plate (tip) repair. Surgical correction of chordee was done by degloving of penis. The neo-urethra was created by developing suture layers of the 5.0 polydioxanone running suture followed by the second layer of the interrupted vicryl 5.0. In group (B) a thin layer of fibrin sealant (fibrogloo manufactured by Cairo Medical Central Blood Bank) applied over the second layer of suture line but no sealant was used in group (A). In all patients of both the groups, Dartos vascularized pedicle flap was used to cover the neo-urethra, A Silastic 10Fr catheter was left for a period of 5 days in all patients, follow-up for four weeks. Continuous data were expressed as mean (\pm SD). Comparative analyses between groups were done by Chi-square test, Mann-Whitney U test and Independent t-test.

RESULTS

Demographic data, original meatus location, the presence of chordee, age in months, weight and HB% were similar in both groups with the (A) group had a lower Mann Whitney test value and non-significant p value 0.678, according to meatal opening site before chordee release the (B) group had a higher chi-square test value and a very low p value of 0.137 but still non-significant and group (B) had a higher Mann Whitney test for both hemoglobin concentration and children weight mean values and a non-significant p value of 0.0605 and 0.429 (Table 1).

Urethrocutaneous fistula, flap dehiscence, flap necrosis and urethral stricture were significantly lower in group (B) patients. There was increase in inter-operative bleeding post-operative edema in groups (B) (Table 2).

Table 1: Demographic data (n=15).

		Group (A) without fibrin sealant usage	Group (B) with fibrin sealant usage	Test value	P value	Sig.
Age in months	Median(IQR)	17 (9-26)	17 (10-32)	-0.415†	0.678	NS
	Range	6-41	6.5-42			
Meatal opening site before chordee release	Coronal	1 (6.7%)	2 (13.3%)	5.527*	0.137	NS
	Sub coronal	4 (26.7%)	3 (20.0%)			
	Mid penile	7 (46.7%)	2 (13.3%)			
	Distal penile	3 (20.0%)	8 (53.3%)			
Weight in kg	Mean \pm SD	11.27 \pm 3.20	12.20 \pm 3.17	-0.803•	0.429	NS
	Range	7-16	7-18			
HB%	Mean \pm SD	11.79 \pm 1.18	11.55 \pm 1.26	0.523•	0.605	NS
	Range	10-13.6	9.3-13.3			

Table 2: Intra-operative and post-operative surgical complications.

		Group (A) without fibrin sealant usage		Group (B) with fibrin sealant usage		Test value*	P value	Sig.
		N	%	N	%			
Bleeding+ tourniquet use	No	8	53.3	8	53.3	0.000	1.000	NS
	Yes	7	46.7	7	46.7			
Postoperative Edema	No	8	53.3	6	40.0	0.536	0.464	NS
	Yes	7	46.7	9	60.0			
Wound dehaisece	No	13	86.7	15	100.0	2.143	0.143	NS
	Yes	2	13.3	0	0.0			
Fistula	No	12	80.0	13	86.7	0.240	0.624	NS
	Yes	3	20.0	2	13.3			
Flap necrosis	No	13	86.7	14	93.3	0.370	0.543	NS
	Yes	2	13.3	1	6.7			
Urethral stricture or meatal stenosis and stent problem	No	13	86.7	13	86.7	0.000	1.000	NS
	Yes	2	13.3	2	13.3			

DISCUSSION

Urethrocutaneous fistula is the commonest complication in hypospadias repair, other are wound infection, wound dehiscence, flap necrosis, penile torsion, Urethrocutaneous fistula, urethral stents problems and urethral strictures.⁴ The outcome of primary hypospadias repair is vital because failed repair often require multiple surgeries throughout their life and have a significant impact on both psychologically and physically.⁵

Regarding frequency of postoperative complications Singh et al had reported a reduction in the frequency of postoperative complications with the use of fibrin sealant in hypospadias surgical repair in adults comparative to patients in whom fibrin sealant was not used.⁶ Ambriz-González et al reported a reduction in the frequency of postoperative complications with the use of fibrin sealant in hypospadias surgical repair comparative to patients in whom fibrin sealant was not used.⁹ In our study a reduction in the frequency of postoperative complications with the use of fibrin sealant in hypospadias surgical repair in children comparative to patients in whom fibrin sealant was not used

Kinahan et al used Tisseel (a fibrin sealant) in hypospadias repair and concluded that the incidence of fistula, edema and the duration of hospitalization were all reduced in 30 patients who underwent modified Mustardé repairs in which Tisseel was used when compared with a matched group of 30 repairs without Tisseel. In addition, the rate of complications in fistula repairs and complex revisions was reduced when Tisseel was used on urethral suture lines and under all skin flaps in our study we used Fibrogloo manufactured by Cairo Medical Central Blood Bank in hypospadias repair in pediatric both fistula and flap necrosis was found to be reduced.

Kocherov et al demonstrated no benefit using bioglu surgical adhesive in hypospadias repair in pediatric

patients.⁸ But in our study wound dehaisece didn't happen in 15 patient after fibrogloo application.

Regarding the safety of fibrin sealants, it was found that current manufacturing processes provide a very high degree of safety for fibrin sealants. In 20 years of worldwide use, there have been no known cases of hepatitis or HIV transmission associated with the use of commercial fibrin sealants.⁹ In our study none of the patients reported any sign or symptoms of allergic reaction. Wound dehaisece didn't happen with any case after application of fibrin sealant.

Fistula and flap necrosis both were found to be refused after fibrogloo application, So fibrogloo application to suture line in hypospadias repair was found to be safe and reduce post-operative complications specially wound dehaisece.

CONCLUSION

Use of Fibrogloo manufactured by Cairo Medical Central Blood Bank in hypospadias repair in pediatric is safe and can reduce complications. Limitation of the study is that it has a relatively small sample size and short follow-up and relatively high financial load.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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