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

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Abstract: The adult hypospadias presentation is common in the developing countries due to ignorance, illiteracy, and unaffordability. Adult hypospadias repair is associated with high complication rates and poor outcome than in paediatric repair. In this study, we evaluated the outcome of adult hypospadias repair after the use of fibrin sealant over the suture lines of neo-urethra. A total of 33 adult patients of distal hypospadias and mid shaft hypospadias were randomly assigned into two groups. In group 1, a thin layer of fibrin sealant applied over the suture line of neo-urethra but no sealant was used in group 2. All patients underwent a tabularized incised plate (TIP) repair with a dartos vascularized pedicle flap to cover the neo-urethra. Postoperative surgical complications: urethrocutaneous fistula, flap dehiscence, flap necrosis, urethral stricture and penile torsion were recorded. Urethrocutaneous fistula, flap dehiscence, flap necrosis and urethral stricture were significantly lower in group 1 patients. There was no significant difference in postoperative penile torsion between two groups. Use of fibrin sealant in adult hypospadias repair is safe and can reduce complications.

Keywords: Adult, hypospadias, fibrin sealant, TIP, urethra, urethrocutaneous fistula

INTRODUCTION

Hypospadias is one of the most common anomalies in the boys that is usually repaired in childhood [1]. The adult hypospadias presentation is common in the developing countries like India because of ignorance, illiteracy, and unaffordability [2].

The results of hypospadias repair in adults different from the results in children. Adult hypospadias repair is associated with poor outcome in terms of wound healing, infection, complication rates and overall success [3,4]. 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 adult hypospadias repair.

MATERIALS AND METHODS

It was a prospective comparative study conducted in a tertiary care centre. After institute ethical committee clearance, we included the adult patients age more than 18 years presented with hypospadias to our department in this study. A total 33 patients of distal hypospadias and mid shaft hypospadias were studied from August 2013 to July 2015. On admission detail, history and examination included lower urinary tract symptoms, the location of urethral meatus, presence or absence of meatal stenosis and ventral chordee, any previous intervention or surgery, the condition of urethral plate and preputial skin. We excluded the patients with proximal hypospadias, previous failed repair and insufficient urethral plate and preputial skin for tabularized incised plate (TIP) with dartos vascularized pedicled flap repair.

Patients were randomly assigned into two groups (Group 1, 15 patients and Group 2, 18 Patients) by using computer generated software. In group 1, a thin layer of fibrin glue was used as a sealant on the suture line of neo-urethra, whereas, in group 2, no sealant was used. All patients underwent a tabularized incised plate (TIP) repair [Figure 1]. Surgical correction of chordee was done by degloving of penis and Nesbit’s procedure. The neo-urethra was created developing 2 suture layers. The first layers of the 5.0 vicryl running suture followed by the second layer of the interrupted vicryl 5.0. In group 1, a thin layer of fibrin glue (Tisseel, Baxter India Pvt Ltd, India) applied over the second layer of suture line [Figure 2] but no sealant was used in group 2. In all patients of both the groups, a dartos vascularized pedicle flap was used to cover the neo-urethra. All the operations were performed by a single surgeon. A Silastic 10Fr catheter was left for a period of 10 days in all patients. For the follow-up, patients were advised to come back after 1, 3, 6 and 12 months following surgery. Postoperative surgical complications: urethrocutaneous fistula, flap dehiscence, flap necrosis, urethral stricture and penile torsion were recorded.
Continuous data were expressed as mean (±SD). Comparative analyses between groups were done by Chi-square test or Mann-Whitney U test. IBM SPSS Statistics v20.0 software was used for statistical analysis.

RESULTS

Demographic data, original meatus location, the presence of chordee and meatal stenosis were similar in both groups [Table 1]. Mean follow-up of the study for group 1 patients was 15.2 (± 5.7) months and for group 2 patients was 14.3 (±5.6) months. Urethrocutaneous fistula, flap dehiscence, flap necrosis and urethral stricture were significantly lower in group 1 patients. There was no significant difference in postoperative penile torsion between two groups [Table 2].

Table-1: Demographic data and Anatomical Details

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1 [Fibrin sealant]</th>
<th>Group 2 [Without sealant]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>15</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Mean Age (±SD) [Years]</td>
<td>23.3 (±5.2)</td>
<td>23.6 (±4.0)</td>
<td>0.532</td>
</tr>
<tr>
<td>Distal Penile Hypospadias, n (%)</td>
<td>10 (66.6%)</td>
<td>11 (61%)</td>
<td>0.514</td>
</tr>
<tr>
<td>Mid Penile Hypospadias, n (%)</td>
<td>5 (33.3%)</td>
<td>7 (39%)</td>
<td>0.514</td>
</tr>
<tr>
<td>Ventral Chordee, n (%)</td>
<td>7 (46.7%)</td>
<td>9 (50%)</td>
<td>0.563</td>
</tr>
<tr>
<td>Meatal Stenosis, n (%)</td>
<td>4 (26.7%)</td>
<td>6 (33.3%)</td>
<td>0.488</td>
</tr>
<tr>
<td>Mean follow up (±SD) [Months]</td>
<td>15.2 (±5.7)</td>
<td>14.3 (±5.6)</td>
<td>0.630</td>
</tr>
</tbody>
</table>

Table-2: Postoperative Surgical Complications

<table>
<thead>
<tr>
<th>Postoperative surgical complications</th>
<th>Group 1 [Fibrin sealant]</th>
<th>Group 2 [Without sealant]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%)</td>
<td>1 (6.6%)</td>
<td>8 (44.4%)</td>
<td>0.018</td>
</tr>
<tr>
<td>Urethrocutaneous fistula</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flap dehiscence</td>
<td>3 (20%)</td>
<td>10 (55.6%)</td>
<td>0.041</td>
</tr>
<tr>
<td>Flap necrosis</td>
<td>2 (13.3%)</td>
<td>9 (50%)</td>
<td>0.030</td>
</tr>
<tr>
<td>Urethral stricture</td>
<td>0 (0%)</td>
<td>5 (27.7%)</td>
<td>0.036</td>
</tr>
<tr>
<td>Penile torsion</td>
<td>1 (6.6%)</td>
<td>2 (11%)</td>
<td>0.570</td>
</tr>
</tbody>
</table>

Fig-1: TIP repair in distal penile hypospadias
DISCUSSION

The ideal time for primary hypospadias repair is at 6-12 months old, although when this is not practicable there is another opportunity at 3-4 years age of the child. Complications of hypospadias surgery are very high in the later age (up to 50%) than in children because adult hypospadias repair associated with longer healing time, higher risk of infections due to hair growth in the penile area and more pain due to night time erections. Urethrocutaneous fistula is the commonest complication in hypospadias repair, other are wound infection, wound dehiscence, flap necrosis, penile torsion, urethrocultaneous fistula, urethral stents problems and urethral strictures.

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. The incidence of these complications can be minimized by surgical expertise, preoperative planning, choosing an appropriate surgical technique and judicious postoperative management.

Ambriz-González G 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.

Kinahan TJ 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.

Stanislav Kocherov et al. demonstrated no benefit using BioGlue surgical adhesive in hypospadias repair in pediatric patients.

Most of the studies included only paediatric patients where fibrin sealant was used but in our study, we included only adult patients with primary hypospadias repair.

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. Similarly, in our study none of the patients reported any sign or symptoms of allergic reaction and viral transmission.

CONCLUSION

Use of fibrin glue in adult hypospadias repair is safe and can reduce complications. Limitation of the study is that it has a relatively small sample size and short follow-up. Multicentric randomized trial with
adult hypospadias patients needs to be conducted with long-term follow-up.

**REFERENCES**


