



Prospective Randomized Study of Cases of Pelvic Fracture Urethral Distraction Defects (PFUDD) Managed by Initial Suprapubic Urinary Diversion with Delayed Urethroplasty versus Early Realignment with Evaluation of Erectile Dysfunction

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Introduction

Traumatic injury is a leading national and international health problem. Indeed, trauma is the leading cause of death for people between ages 1 and 37 years. The incidence of urethral injury in men with pelvic fracture varies widely. The results of 2 extensive reviews have shown that the incidence of posterior urethral injury varied from 1.6% to 25% (mean 9.9%).^{1,2} In the latest studies, it has been estimated to be between 3% and 25%, and the concomitant injuries of abdominal organs have been also reported in 27% of them³. Posterior pelvic fracture urethral distraction defect (PFUDD) is a challenging urologic problem that may result in complications, such as urinary incontinence and inability to void due to recurrent stricture leading to a lifelong disabling condition. Urethral injuries are overwhelmingly associated with bilateral pubic rami fractures so called straddle fractures and combination of straddle fractures with diastasis of sacroiliac joint has the highest risk of urethral injury.

The best line of treatment of posterior urethral disruption secondary to blunt pelvic trauma remains controversial. Although some investiga-

tors recommended early realignment of urethral distraction injuries; these series are often relatively small and follow-up is relatively short^[3,4] Although classic reports recommend suprapubic cystostomy placement at the time of trauma with delayed urethral reconstruction 4 to 6 months after trauma through perineal approach, series that advocate primary realignment show a lower rate of urethroplasty as well as the formation of potentially less significant strictures than those treated with suprapubic cystostomy and late repair.

The purpose of this study was to investigate the outcomes of patients undergoing primary realignment for the initial management of acute urethral injuries in Indian scenario. This is an on-going study and observations made so far are presented here. There are essentially two options for the initial management of traumatic posterior urethral injury; suprapubic catheter (SPC) placement followed by definitive urethral stricture repair after three to six months or primary urethral realignment, immediate or early (1-15 days following injury).

There is a dearth of literature in the Indian scenario comparing the various techniques of management of distraction injuries of posterior urethra. Hence the purpose of this study is to investigate the outcomes of patients with distraction injuries of the posterior urethra undergoing early alignment (either by rail-roading or endoscopic) compared with initial suprapubic urinary diversion with delayed urethroplasty and evaluate the incidence of erectile dysfunction in both groups at a tertiary level trauma center in Lucknow city.

Material and Methods

The study included a total of 20 patients admitted to Department of general surgery, KGMU, Lucknow with PFUDD of grade III, IV and V between April 2015 to September 2016. This is a prospective randomized comparative double arm study done on patients of pelvic fracture urethral distraction defects comparing outcomes of primary alignment versus suprapubic cystostomy with delayed urethroplasty and prospective evaluation of erectile dysfunction.

Patient excluded from the study were those who did not give consent, had associated bladder neck injury, PFUDD grade I and II injuries and those who had low levels of serum testosterone.

Patients were randomly assigned to 2 groups. In group 1 patients were managed by initial suprapubic cystostomy followed by urethroplasty at a later setting while the patients in group 2 were managed by early primary realignment (open/endoscopic).

Patients were followed up after 6 weeks and 6 months and the primary outcome measured was rate of stricture formation in both groups which was detected by RGU and uroflowmetry studies done at our institute. Secondary outcome measure was rate of erectile dysfunction and urinary incontinence in both groups at 6 weeks and 6 months follow up which was detected by measuring plasma testosterone levels, penile colour doppler and IIEF-5 scoring. Demographic characteristics and baseline biochemical

parameters were also compared between the both groups during the follow up.

For uroflowmetry, Qmax of 20ml/s was taken as cut off. IIEF-5 scoring interpretation

22-25-No erectile dysfunction

17-21-Mild erectile dysfunction

12-16-Mild to moderate erectile dysfunction

8-11-Moderate erectile dysfunction

5-7-Severe erectile dysfunction

Continuous data were summarized as Mean \pm SE (standard error of the mean) while discrete (categorical) in no. and %. Continuous groups were compared by independent Student's t test. Continuous groups were also compared by repeated measures two factor analysis of variance (ANOVA) and the significance of mean difference between (inter) the groups was done by Tukey post hoc test after ascertaining normality by Shapiro-Wilk's test and homogeneity of variance by Levene's test. Categorical groups were compared by chi-square (χ^2) test. The analyses were done according to intent to treatment basis (i.e. only inter group). A two-tailed p value less than 0.05 ($p < 0.05$) was considered statistically significant. Analyses were performed on Statistical Package for Social Sciences (SPSS) software (Windows version 17.0).

Results

The present prospective randomized study deals with cases of pelvic fracture urethral distraction defects (PFUDDs) managed by early realignment versus initial suprapubic urinary diversion with delayed urethroplasty with evaluation of dysfunction. Total 20 male patients were recruited and randomized equally in to two groups and treated with initial SPC f/b delayed urethroplasty (Group 1) or early realignment (Group 2). The primary outcome measures of the study were Retrograde urethrogram and uroflowmetry. The secondary outcome measures were IIEF-5 scoring, Penile colour Doppler and urinary incontinence. The biochemical parameters were assessed at 2 wk, 6 wk and 6 month post treatment while

Retrogradeurethrogram, uroflowmetry, IIEF-5 score, RBS, serum testosterone level, penile colour doppler and urinary incontinence were assessed at 6 wk and 6 month post treatment. The objective of the study was to compares the outcome measures over the time between the two groups.

The comparison of demographic (age, mode of injury and general biochemical parameters) and outcome measures between two groups are summarized below:

Demographic characteristics

The demographic characteristics viz. age and mode of injury of two groups at presentation is summarized in Table 1 and also depicted in Fig. 1 and 2 respectively. The age of Group 1 and Group 2 ranged from 18-40 yrs and 24-40 yrs respectively with mean (\pm SE) 28.30 ± 2.56 yrs and 31.90 ± 1.78 yrs respectively and median 26

yrs and 32 yrs respectively. The mean age of Group 2 is slightly higher than Group 1. Comparing the mean age of two groups, t test showed similar age between the two groups (28.30 ± 2.56 vs. 31.90 ± 1.78 , $t=1.16$, $p=0.263$) i.e. did not differ significantly.

Further, in Group 1, the mode of injury of 7 (70.0%) patients were RTA, 2 (20.0%) fall from height and 1 (10.0%) miscellaneous while in Group 2, it were 8 (80.0%), 2 (20.0%) and 0 (0.0%) respectively. Comparing the mode of injury frequency (%) of two groups, χ^2 test showed similar mode of injury between the two groups ($\chi^2=1.07$, $p=0.587$) i.e. also not differ significantly. The comparisons concluded that the subjects of two groups were demographically matched and thus comparable and may also not influence the study outcome measures.

Demographic characteristics	Group 1 (n=10) (%)	Group 2 (n=10) (%)	t/ χ^2 value	p value
Age (yrs):				
Mean \pm SE	28.30 ± 2.56	31.90 ± 1.78	1.16	0.263
Mode of injury:				
RTA	7 (70.0)	8 (80.0)	1.07	0.587
Fall from height	2 (20.0)	2 (20.0)		
Miscellaneous	1 (10.0)	0 (0.0)		

^{ns} $p>0.05$ - as compared to Group 1

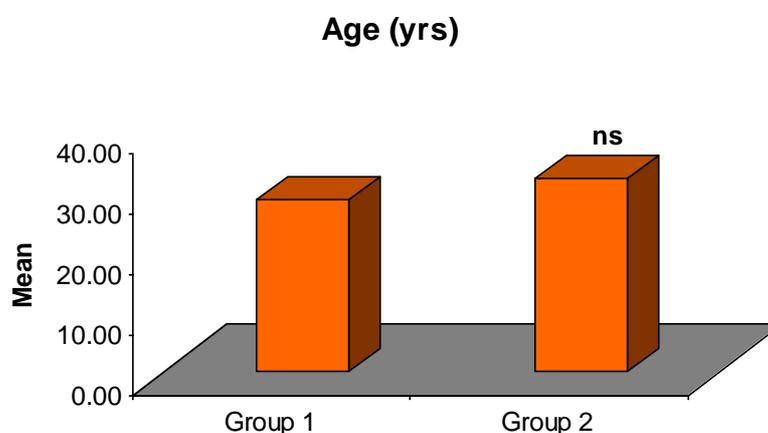


Fig. 1. Mean age of two groups

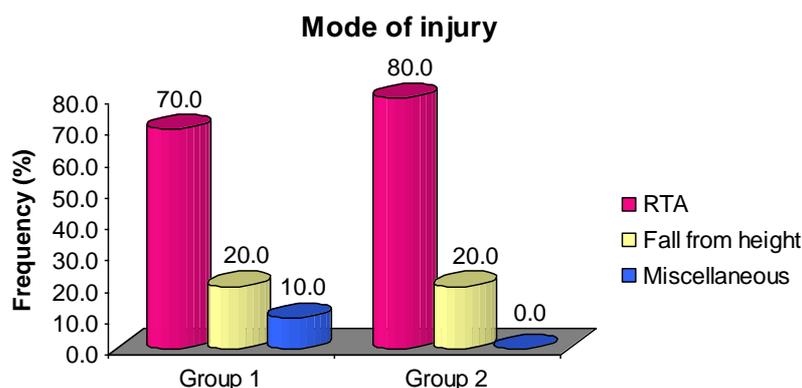


Fig. 2. Distribution of mode of injury of two groups.

Outcome measures

Primary outcome measure

I. Retrograde urethrogram

The post treatment (6 week and 6 month) retrograde urethrogram distribution (stricture present/absent) of two groups is summarized in Table 3. At week 6, it remains present 100.0% in Group 1 while 50.0% in Group 2. At 6 month, it remains present 20.0% in Group 1 and 10.0% in Group 2.

For each period, comparing the retrograde urethrogram distribution (stricture present/absent) of two groups, χ^2 test showed significant less stricture presence (improvement in retrograde urethrogram) at 6 wk in Group 2 as compared to Group 1 (100.0% vs. 50.0%, $\chi^2=6.67$, $p=0.010$).

However, at 6 month, the improvement in retrograde urethrogram was similar ($p>0.05$) between the two groups though the stricture presence was 10.0% less in Group 2 than Group 1. In group -1 all the 10 patients were operated (bulboprostatic urethral anastomosis) and at 6 months follow up 80% patients were stricture free while 20% patients had recurrent stricture formation.

In group 2, 50% patients who had stricture at 6 weeks were treated with DVIU/Co-axial dilatation. At 6 months follow up 80% patients were stricture free and voided normally while 20% had recurrent stricture formation requiring urethroplasty.

Table 3: Post treatment distribution of retrograde urethrogram of two groups over the periods

Period	Retrograde urethrogram stricture	Group 1 (n=10) (%)	Group 2 (n=10) (%)	χ^2 value	p value
6 week	Absent	0 (0.0)	5 (50.0)	6.67	0.010
	Present	10 (100.0)	5 (50.0)		
6 month	Absent	8 (80.0)	8 (80.0)	0.49	0.431
	Present	2 (20.0)	2(20.0)		

NA: not applicable

II. Uroflowmetry

The post treatment (6 week and 6 month) distribution of uroflowmetry (abnormal $Q_{max}<20ml/s$ / normal flow $Q_{max}>20ml/s$) of two groups is summarized in Table 4. Q_{max} of

20ml/s was taken as cutoff value. At week 6, the frequency (%) of normal flow was significantly higher in Group 2 as compared to Group 1 (0.0% vs. 50.0%, $\chi^2=6.67$, $p=0.010$). However, at 6 month, the improvement in uroflowmetry was

similar ($p>0.05$) between the two groups though the normal flow was 10.0% higher in Group 2

than Group 1. No flow was present in group-1 at 6 weeks and voiding trial was failed.

Table 4: Post treatment distribution of uroflowmetry of two groups over the periods

Period	Uroflowmetry	Group 1 (n=10) (%)	Group 2 (n=10) (%)	χ^2 value	p value
6 week	Abnormal flow	10 (100.0)	5 (50.0)	6.67	0.010
	Normal flow	0 (0.0)	5 (50.0)		
6 month	Abnormal flow	2 (20.0)	2 (20.0)	0.49	0.431
	Normal flow	8 (80.0)	8 (80.0)		

Secondary outcome measure

i. IIEF-5 score

The IIEF-5 score of two groups at two different post periods (6 week and 6 month) is summarized in Table 5 and also depicted in Fig. 7. The mean

IIEF-5 score at both 6 week (21.20 ± 1.37 vs. 22.50 ± 1.37 , $p=0.511$) and 6 month (22.00 ± 1.36 vs. 23.20 ± 1.31 , $p=0.533$) was higher in Group 2 than Group 1 but the difference was statistically insignificant i.e. did not differ significantly.

Table 5: Post treatment IIEF-5 score (Mean \pm SE, n=10) of two groups at two different periods

Period	Group 1	Group 2	p value
6 week	21.20 ± 1.37	22.50 ± 1.37	0.511
6 month	22.00 ± 1.36	23.20 ± 1.31	0.533

^{ns} $p>0.05$ - as compared to Group 1

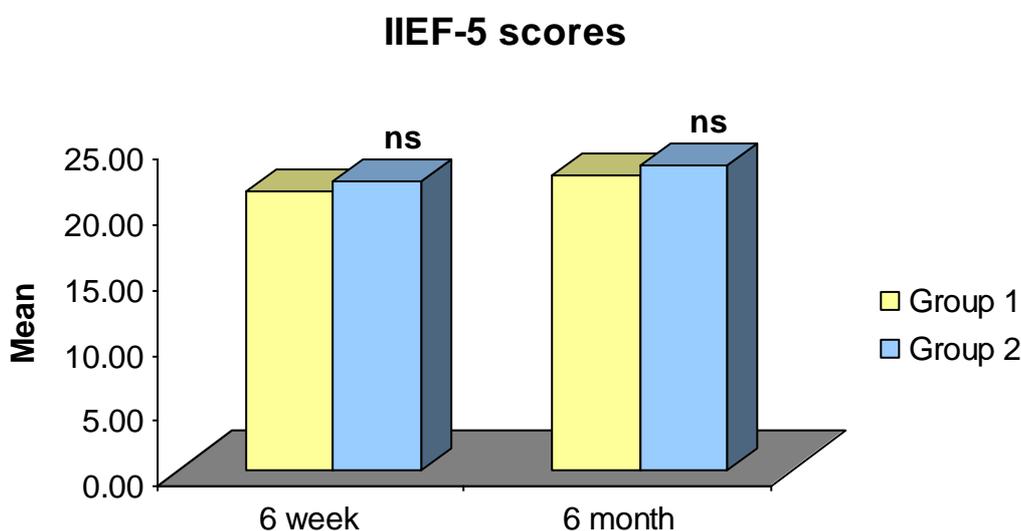


Fig. 7. Mean IIEF-5 score of two groups at two different periods.

II Penile color Doppler

The penile color Doppler distribution (abnormal/normal) of two groups at two different post periods (6 week and 6 month) is summarized in Table 8 and shown in Fig. 10. In both groups, the

penile color Doppler distributions remain similar at both 6 wk and 6 month. Further, at both periods, the penile color Doppler frequency (%) “normal” did not differ between the two groups (70.0% vs. 80.0%, $\chi^2=0.27$, $p=0.606$) though it

was 10.0% higher in Group 2 as compared to Group 1 at both the periods.

Table 8: Post treatment penile color Doppler distribution of two groups at two different periods

Period	Penile color Doppler	Group 1 (n=10) (%)	Group 2 (n=10) (%)	χ^2 value	p value
6 week	Abnormal	3 (30.0)	2 (20.0)	0.27	0.606
	Normal	7 (70.0)	8 (80.0)		
6 month	Abnormal	3 (30.0)	2 (20.0)	0.27	0.606
	Normal	7 (70.0)	8 (80.0)		

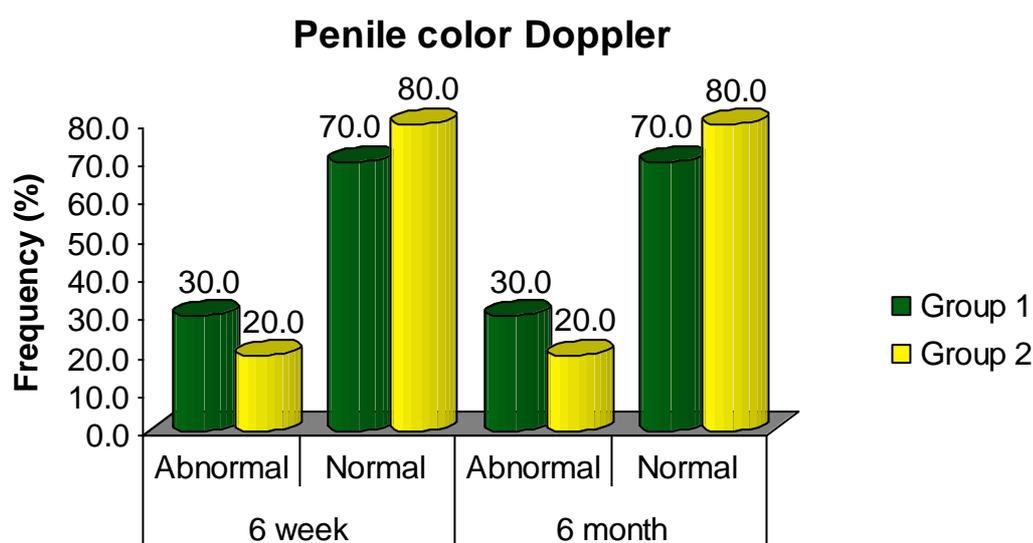


Fig. 10. Post treatment penile color Doppler distribution of two groups at two different periods

Discussion

Patients included in the study were all male patients between the age of 21-40 years. This age group (21-40 years) is the most productive age group, where in people enjoy taking risks, perform strenuous jobs and drive fast (Eustace and Wei, 2010; Gulliver and Begg, 2007)^{i,ii} just because of thrill or because of occupational compulsions (Jenkins *et al.*, 1993; Leigh *et al.*, 1993)^{11,12}

In present study, major mode of injury was RTA. It was 70% in group-1 and 80% in pts of group-2. Next to this mode of injury was fall from height and it was 20% in both groups. There was no significant difference in mode of injury between two groups. Stein *et al.* reported vehicular accidents as a cause for nearly 36% of urethral strictures in India, vs. 15% in a cohort from the USA and Italy

In our study PUC inserted by railroading method in 25% cases and 25% by endoscopic primary

realignment. The selection of technique was done by simple randomization method.

We encountered good results using different techniques of management. Though complications such as stricture formation were encountered in group-1 and group-2, 100%, and 50% cases respectively at first follow up of 6th weeks, requiring the additional procedure in patients of group-2. like urethral calibration, co-axial dilatation in 20%,10% cases respectively and DVIU in 20% cases. At 6 months follow up 30% patients had no stricture with Qmax>20ml/s whereas 20% patients had recurrent stricture and required bulbo prostatic urethroplasty eventually.

In group 1 patients were managed initially by suprapubic catheterization for urinary diversion followed by delayed urethroplasty. In this group 100% stricture formation was present in follow up after 6 wks which was evident by RGU and uroflowmetry studies. After 6months all the

patients had undergone urethroplasty and only 10% patients still had stricture urethra which warranted further surgical interventions like DVIU or Co-Axial di Manikandan, *et al.*: (Current concepts in the management of PFUDD distraction defects, 2011) The success rates of urethroplasty varied widely from 77% to 95% in various series, which was due to various definitions of surgical success. Restricture after anastomotic urethroplasty occurs in about 15% of cases. But most of these can be successfully corrected by 1 or 2 sessions of endoscopic internal urethrotomy. In Group 2 patients were managed by primary realignment (open/endoscopic). In this group 50% patients didn't have stricture urethra at 6 weeks follow up and were managed by self catheterization and CIC. 30% patients had partial urethral stricture at 6 weeks follow up and were managed by DVIU/Co-axial dilatation. After 6 months follow up, only 20% patients had significant stricture urethra and required urethroplasty whereas 80% patients did not have any stricture on the RGU and normal Qmax and flow.

Koraitim, 2005 reviewed different techniques used in a personal series of 100 patients combined with a review of 771 patients from published reports. Immediate and early realignment was associated with rates of 53% for stricture, 5% for incontinence, and 36% for impotence. 42% needed subsequent instrumentation to attempt stabilization of stricture. Urethroplasty was ultimately necessary in 33%.^{16,17,18}

In Group 1 the incidence of erectile dysfunction was 30% whereas in Group 2 the incidence of erectile dysfunction was 20%.

Anger et al, 2009 37 men with current contact information available were contacted; 26 completed the IIEF questionnaire, including men who completed the questionnaires either at home or in the office, and men who were completed the IIEF over the telephone. The mean (range) patient age at the time of the interview was 40.2 (20–68) years and the mean time from the PFUDD repair to the interview was 4.4 (1–14) years.

Overall, the mean IIEF score was 49.1 (10–73) of 75 possible points. Some degree of ED, as shown by scores on the EF domain, was present in 14 of 26 men (54%). Fifteen men (58%) had spontaneous EF, as shown by a mean EF domain score of >20, and 11 men had a score of ≤20 (42%). Eight men (30%) met the criteria for severe ED. Five men of the eight who tried phosphodiesterase inhibitors responded well to them, and one had tried and responded to intracorporal injection therapy. One patient had a penile implant. Among the men with normal erections, one had previously had a successful penile revascularization procedure for a vascular injury at the time of his pelvic fracture.

Patwardhan et al, 2016 All patients with pelvic fracture urethral distraction defect (PFUDD) who required end-to-end urethroplasty (E-E urethroplasty) from August 2010 to July 2014 were included. Thirty-four per cent had defect length of 0.5–2 cm, 50% had defect length of 2.1–4 cm. Of 32, 34% required re-intervention. Inferior pubectomy was required in 36% in the 0.5–2 cm group and in 94% in the 2.1–4 cm group. On follow-up, 22% of patients had neurogenic ED, and 63% had vascular ED, of whom 44% had arterial, 3% had venous, and 16% had mixed aetiology. Patients with neurogenic aetiology had shorter urethral defect and 43% needed inferior pubectomy. Patients with vascular aetiology had longer urethral defect, 90% required inferior pubectomy.

In our study during the follow up of 2 weeks, 6 weeks and 6 months in both Group 1 and Group 2, no incidence of Incontinence was found. It is probably associated with bladder neck injury but as these patients were not included in the present study therefore incidence of incontinence is zero.

In the stable patient with posterior urethral injury, primary urethral realignment, either surgical (with minimal paravesical dissection) or endoscopic, should be the treatment of choice since it results in a less than 50% incidence of stricture (most of which can be managed by minimally invasive techniques) and an acceptable rate of impotence

and incontinence. This decrease in the need for surgery has a large positive impact because the perineal approach anastomotic urethroplasty can be lengthy and arduous for the surgeon and the patient. If patients are being explored for concomitant intra-abdominal, bladder neck or rectal injury, an attempt at immediate primary realignment using railroading techniques (without disturbance of the retropubic hematoma) should be made. If there are no indications for surgical exploration, endoscopic realignment should be attempted at any time from 1-15 days after the patient has stabilized. These techniques should not be performed by inexperienced surgeons or in centers where facilities for endoscopy/fluoroscopy are not available. In experienced hands, such an approach has been demonstrated to have better outcomes as compared to suprapubic cystostomy alone

Conclusion

- 1) Major mode of injury was road traffic accidents (70% in group 1 and 80% in group 2) followed by fall from height (20% in group-1 and group-2) ($\chi^2=1.07$, $p=0.587$)
- 2) Patients in group-1 were followed by RGU at 6 weeks which showed 100% stricture formation with no flow on voiding trial and uroflowmetry at 6 weeks. At 6 months follow up patients had undergone urethroplasty and on RGU 80% patients had no stricture with $Q_{max}>20$ ml/sec while 20% patients still had stricture on RGU and abnormal flow on uroflowmetry which required further interventions like DVIU/Co-axial dilatation.
- 3) Patients in group-2 were treated by early realignment (open/endoscopic). At 6 weeks follow up 50% patients had no stricture on RGU and $Q_{max}>20$ ml/s. 50% patients still had stricture formation. At 6 months follow up only 20% patients had stricture on RGU and $Q_{max}<20$ ml/s and required bulbo prostatic urethroplasty while 30%

patients were treated by DVIU and Co-Axial dilatation and had $Q_{max}>20$ ml/s and no stricture on RGU.

- 4) Erectile dysfunction was 20% in group 2 as compared to 30% in patients in group 1 with mean IIEF-5 score in group 1 at 6 weeks 21.20 and at 6 months 22.0 while in group 2 at 6 weeks 22.5 and at 6 months 23.20.
- 5) Early realignment (open/endoscopic) seems to be the better option as it is associated with reduced stricture formation and the strictures formed are manageable by simpler techniques like DVIU/Co-axial dilatation and was also associated with reduced incidence of erectile dysfunction after follow up of 6 months. The study is ongoing and long term follow up is required to check the incidence of complications and treatment outcomes. But the procedure requires surgical expertise and equipment.

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