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**Research Article** 

# **COMPARISON OF EVERTED END TO END ANASTOMOSIS** AND PENILE PEDICLE SKIN GRAFT IN MANAGEMENT OF LONG STRICTURES: CROSS SECTIONAL STUDY

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Abstract		

# Abstract:

Introduction: To treat patient with urethral stricture is a challenge for a surgeon. End to end anastomosis and graft of penile pedicle are two methods which are common for treatment of urethral stricture. This study was carried out to determine the outcome of everted end to end anastomosis compared with penile pedicle skin grafting so as to know which one is better of the two and should be offered to patients in future.

**Objective:** To compare the outcome of Everted End to End Anastomosis and Penile Pedicle Skin Graft in management of long strictures to evaluate its post operative complications, hospital stay, and cost. Study was conducted on 70 patients, admitted with stricture urethra from the outpatient department of Urology and referred from emergency of Lahore General Hospital Lahore, Pakistan, starting from 13 October, 2011 to 31st october 2013. Material and method: A thorough history and clinical examination was done. All the patients had retrograde and antigrade urethrogram to make diagnosis with detailed history and Physical examination and routine baseline investigations. The patients were divided in two equal groups. 35 patients in group a received end to end anastomosis, and 35 patients in group B underwent penile pedicle skin grafting. The patients were evaluated for the outcome parameters including infection, re-stricture, urinary stream grading. The data was collected on a specially designed Proforma.

**Results:** The mean age of the patients in group A was  $20.60\pm12.61$  years while in group B was  $23.61\pm11.29$  year [range 7 -50 years]. All the patients had urinary retention, while other symptoms were seen rarely. The majority of strictures were present at bulbo membranous level 57.1% in one group and 45.7% in other followed by bulbous level among i.e. 31.4% and 34.3% patients in both groups. In patients with end to end anastomosis, urinary stricture occurred in 22.9% patients while in penile pedicle skin graft was seen among 65.7% patients [p < 0.05]. None of the patient had infection. Uroflowmetery was 21.77 + 1.85 ml/sec in group A versus 17.00 + 7.04 mL/sec in group B at 1 year follow up [p < 0.05].

**Conclusion:** The outcome of everted end to end anastomosis is better than penile pedicle skin graft. So, this technique should be recommended in different settings.

**Keywords:** Everted end to end anastomosis, penile pedicle skin graft; urethral stricture, urinary retention, bulbo membranous.

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## **INTRODUCTION:**

Stricture of urethra is narrowing of the lumen of urethra which is due to scarring of epithelium of corpus spongiosum (1). Urethral strictures finally decrease the lumen and resist to the flow of urine during voiding (2). Strictures of urethra are constantly common. It is known somewhat that in which way the surgeons of Egypt in ancient time and other nations were treating urethral stricture about four thousand years back but treatment has been changed for about last fifty years (3). The occurrence of stricture in man is not known but has a great negative impact over patient's life (4). Former studies revealed that about ninety percent patients with urethral strictures are presented with complications (5).

Infective urethral strictures are commonly caused by Neisseria gonorrhea and less common by Chlamydia, Tuberculosis, Shistosomiasis. The incidence of traumatic urethral strictures is increasing due to accidents and war and this stricture develop early. The urethral stricture caused by catheter is also common and its pathophysiology is just like that of trauma. Malignancy of urethra and penis also causes stricture of urethra but is not common (2,6).

Urethral stricture is a recurrent disease making it an unresolved issue of about forty to fifty percent (7). Most patients having suffered from disease of urethral stricture develop symptoms of storage and voiding but stream is improved with straining and patient is able to empty his bladder and with repeated infections and frequent procedures for its treatment. Small number of patients develops serious complications as complete obstruction of urine, abnormal renal function, atonic bladder, Fournier's gangrene and malignancy (8,9)

The disease of stricture was a challenge for urologist in previous era and also remains a challenge (10,7). In the past urethral stricture was treated with bougie and oil was used for lubrication of bougie (11). Due to recurrence of stricture different modes of treatment have poor outcome (12).

stricture results Treatment of in various complications. Also the site and length of stricture have direct impact on recurrence of disease. However, results of open urethroplasty have a high success rate as compare to dilatation and internal optical urethrotomy (13,14,1). Our objective in treatment of urethral stricture is to maintain permanent passage for flow of urine. Different techniques for management of stricture are dilatation, urethrotomy, stenting and urethroplasty (15). With passage of time various methods of urethroplasty were performed but were unsuccessful because of lack of ideal graft (16,17,18,19).

The skin of penile pedicle is a standard graft because of lack of hairs, fat and can be easily developed into different shapes and positions. This penile pedicle skin is the result of long term success rate (20,21). The proposed study includes comparison of Everted End to End Anastomosis versus Penile Pedicle Skin Graft in management of urethral stricture.

In everted end to end anastomosis urethra is mobilized at site of stricture and fibrosed part is entirely removed. The two ends of urethra are re anastomosed. Complications of this procedure are infection, chordee, decrease in penile length of penis and erectile dysfunction. Following proper techniques mobilizing urethra anastomosis can be performed in stricture up to 5cm with minimal complications (22,23,24).In penile pedicle graft pedicle skin is used as a graft material. Complications of this type of treatment are post void dribbling, traction on penile skin, and fistulas. It is believed that such complications can be decreased and better results can be achieved by using proper skills (25).

For a stricture of  $\geq 1.5$ cm or more and urethroplasty should be performed as it will provide a chance to remove all scarred tissue which is likely to decrease recurrence and the patient will void with a good stream. Penile pedicle skin further is a perfect graft to be adapted as a lumen of urethra. There are no hairs and it also lack fat. By excision of scarred tissue completely and a proper tube is fashioned eventhen than it will further increase the chance of best outcomes (26). Treating stricture disease in a single stage will decrease the cost and will decrease likely hood of hospital acquired infections (27).

The aim of the study is to compare the results of everted end to end anastomosis and penile pedicle skin graft in management of urethral stricture in our set up in urology department, Lahore general hospital.

Urethral stricture is a chronic and common urologic problem. Many studies have been conducted internationally and nationally for the comparison of different techniques of stricture management. In long and complicated strictures open surgical treatment is considered gold standard over which all other procedures are judged. So, this study of two different open procedures will be conducted to compare the results of both Everted End to End Anastomosis and Penile Pedicle Skin Graft in management of long strictures. So, this study will help to understand the advantage of one technique over the other and helping in management of long and complicated stricture in a single stage with fewer complications.

#### **MATERIALS AND METHOD:**

#### **Research Design:**

Quasi experimental study design was used. Prospective review of records from files and discharge sheets of the Urethral Stricture patients admitted in the Department of Urology Lahore General Hospital, Lahore.

#### **SELECTION CRITERIA:**

#### Inclusion criteria:

- 1. Patients who had no passage on urethrogram with stricture length of 1.5-3cm.
- 2. Patients had undergone three repeated internal optical urethrotomies each attempt with the gap of less than three months.

#### **Exclusion criteria:**

- 1. Patients who were not fit for surgery.
- 2. Patients who had passage on urethrogram and no previous history of surgery for urethral stricture.
- 3. Patients having stricture less than 1.5cm on urethrogram.

A total of 70 patients with urethral stricture distal were enrolled: 35 to the Group A and 35 to the Group B. The two groups comprising N were assumed to be equal in number, and it was assumed that two-tailed statistical analysis was used. It was a hospital based study of 70 patients with urethral stricture distal who were divided equally in two groups "A" and "B" by using random number table.

Group A: Patients who had End to End Anastomosis

Group B: Patients who had Penile Pedicle Skin Graft

#### Sampling Technique:

Probability simple random sampling was used for allocating the patients in to two groups. The patients were randomly allocated to either **Group 1 or Group 2** using random tables after the inclusion criterion is met.

#### **Data collection Procedure:**

Tool designed for this study was used for data collection. The demographic information was recorded. All patients meeting the inclusion criteria were examined and investigated routinely to confirm diagnosis. Seventy male patients with urethral stricture were selected on the basis of convenient sampling from outpatient department of the urology department Lahore General Hospital, Lahore.

Detailed history and physical examination was followed by routine laboratory investigations Hemoglobin, Total erythrocyte count, Sedimentation rate, Differential leukocyte count, urinalysis, urine culture. Ultrasonography was done to rule out hydronephrosis. X-ray chest, X-ray KUB, Retrograde and Antigrade Urethrogram, Uroflowmetery, Cystometry, Complete blood count, Pt, APTT, INR, Viral profile, ECG, RFT's, LFT's, and Blood sugar.

#### **Statistical Analysis:**

The relevant data of the respondents was entered into the MS-Office Excel 2003 and subjected to statistical analysis using the statistical package – SPSS [statistical package for social sciences], Version 18.0. All the study variables like Age, Gender, Mode of Injury, length of stricture, evaluation procedure, and duration of hospital stay and cost of the treatment.,...etc were entered to SPSS data sheet.

Numeric variables Age, length of stricture, duration of hospital stay and cost of the treatment. Mean standard deviation and Range was calculated for quantitative variables like Age, length of stricture, duration of hospital. Qualitative variables were Gender, Mode of Injury, and Mode of urethroplasty was presented as frequency distribution tables.

Sample Size:

#### **Ethical consideration:**

The data was collected after obtaining permission from ethical committee of Lahore General Hospital. Fully informed, understood [explain procedure] consent of the patient was obtained in written before the procedure and data collection. All benefits and risk of procedure were explained. It has been top priority that no question should hurt the cultural and moral values of the patients. The data collected from the hospital was confidential and used for statistical analysis.

#### **RESULTS:**

### Distribution of patients by age:

The mean age of the patients in group A was  $20.60\pm12.61$  years [range 7 – 50 years]. There was only 1 [2.9%] patient of age less than 10 years. There were 14 [40%] patients of age range of 11 - 20 years, 10 [28.5%] patients of age range of 21 - 30 years, 5 [14.3%] patients of age range of 31 - 40 years, 5 [14.3%] patients of age range of 41 - 50 years and none [0%] patients of age more than 50 years.

In group B, the mean age of the patients was  $23.63\pm11.29$  year [range 7 – 50 years]. Of the 35 patients included in the study, 4 [11.4%] patients were of less than 10 years, 8 [22.9%] patients of age range of 11 – 20 years, 14 [40%] patients of age range of 21 – 30 years, 4 [11.4%] patients of age range of 31 – 40 years, 5 [14.3%] patients of age range of 41 – 50 years and none [0%] patients of age range of more than 50 years.

#### **Distribution of patients by presenting complaints:**

The urinary retention was the most common complaint which was observed among all [100%] patients of the study. There were 4 [11.4%] patients in group A and 1 [2.9%] patients in group B, who presented with urinary fistula. None of the patients had any other complaint.

#### Distribution of patients by mode of trauma:

Direct trauma was seen among 4 [11.4%] patients of group A, and 7 [20%] patients of group B while 31 [88.6%] patients in group A and 28 [80%] patients in group B had indirect trauma.

#### **Distribution of patients by Etiology:**

In group A, 4 [11.4%] patients and in group B, 7 [20%] patients presented with fall over the pelvis. While history of road traffic accident was present among 31 [88.6%] patients in group A and 28 [80%] patients in group B. None of the patients in both groups had urinary tract infection.

# Distribution of patients by retrograde urethrogram findings:

The mean length of stricture in group A and B was 2.06 + 0.54 mm and 1.89 + 0.29 mm, respectively. The strictures were present at bulbo\_membaranous level among 20 [57.1%] patients in group A and 16 [45.7%] patients in group B, at bulbar level among 11 [31.4%] patients in group A and 12 [34.3%] patients in group B and at membranous level among 4 [11.4%] patients in group A and 7 [20%] patients in group B.

#### **Distribution of patients by Pelvic fracture:**

Pelvic fracture was present among 27 [77.1%] patients in group A and 24 [68.8%] patients in group B.

#### **Distribution of patients by Infection:**

The patients in the study did not get wound and infection during the study.

## Distribution of patients by fistula formation:

Fistula was formed in only 1 [2.9%] patients in group A which was detected at 4th month follow up while in group B, 4 [11.4%] patients developed fistula after surgery. The two [5.7%] developed at 2nd week of follow up and 2 [5.7%] at 4th month of follow up. On comparison, there was no statistically significant difference between the two groups [p > 0.05].

#### Distribution of patients by total disruption:

None of the patients had total disruption at any time of follow up.

#### **Distribution of patients by recurrence:**

In group A, recurrence of stricture was seen among 8 [22.9%] patients. Out of these 8 patients, 1 [2.9%] patients developed recurrence at  $1^{st}$  week follow up after removal of foley and 7 [20%] patients developed recurrence at  $2^{nd}$  week of the follow up.

In group B, total 23 [65.7%] patients developed recurrence of stricture. Out of these 22 patients, 9 [25.7%] patients developed recurrence at  $2^{nd}$  week follow up after removal of foley, 11 [31.4%] patients at  $4^{th}$  month follow up and 3 [8.6%] patients developed recurrence at 1 year follow up. Statistically, there was significant difference between the two groups [ p < 0.05].

# Distribution of patients by urinary stream [grading]:

#### First Week follow up:

In group A, at 1<sup>st</sup> week follow up after removal of foley, urinary stream of grad I was detected among 22 [62.8%] patients, grade II in 12 [34.3%] patients

and grade III in 1 [2.9%] patients. In group B, 18 [51.4%] patients had grade I urinary stream, 17 [48.6%] patients had grade II and none of the patients had grade III urinary stream. Statistically, there was no significant difference between the two groups [ p > 0.05] [Table 1].

#### Second week follow up:

In group A, 28 [80%] patients had urinary stream of grade I, 4 [11.4%] patients had urinary stream of grade II and 3 [8.6%] patients had urinary stream of grade III. In group B, 26 [74.3%] patients had urinary stream of grade I, 6[17.1%] patients had grade II and 3 [8.6%] had urinary stream of grade II. Statistically, there was no significant difference between the two groups.

#### Fourth month follow up:

In group A, 28 [80%] patients had grade I urinary stream, and 7 [20%] patients had grade II urinary stream and none of the patients had grade III urinary stream. In group B, 16 [45.7%] patients had urinary stream of grade I, 11 [31.4%] patients had urinary stream of grade II and 8 [22.9%] patients had urinary stream of grade II. Statistically, there was no

significant difference between the two groups [p > 0.05].

#### One year follow up:

In group A, there were 33 [94.2%] patients who had urinary stream of grade I, 2 [5.8%] patients had urinary stream of grade II and none of the patients had urinary stream of grade III. In group B, 17 [48.6%] patients had urinary stream of grade I, 16 [45.8%] patients had urinary stream of grade II and 3 [8.6%] patients had urinary stream of grade III. Statistically, there was significant difference between the two groups [p < 0.05].

#### **Distribution of patients by Uroflowmetery:**

In group A, the mean urinary stream at uroflowmetery was 21.58 + 3.94 mL/sec, 21.31 + 4.52 mL:/sec, 20.21 + 6.25 mL/sec and 21.77 + 1.85 mL/sec, at 1<sup>st</sup> week, 2<sup>nd</sup> week, 4<sup>th</sup> month and 1 year follow up.

In group B, 21.03 + 4.37. mL/sec, 20.29 + 3.40 mL/sec, 16.69 + 7.49 mL/sec and 17.00 + 7.04 mL/sec, respectively. On comparison, only significance difference was found among patients with follow up at 1 year [p < 0.05].

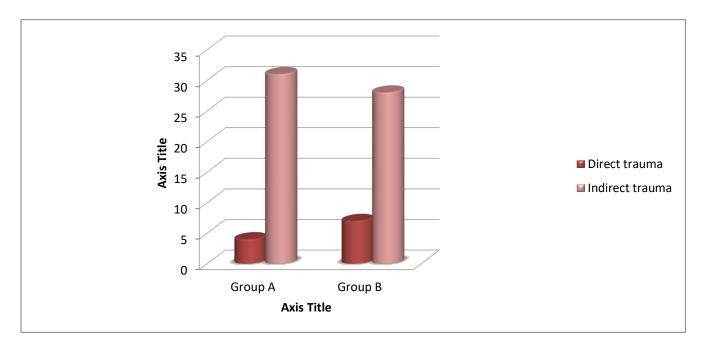


Figure 1 Direct & Indirect Trauma Distribution by age

### **Distribution of patients by Age**

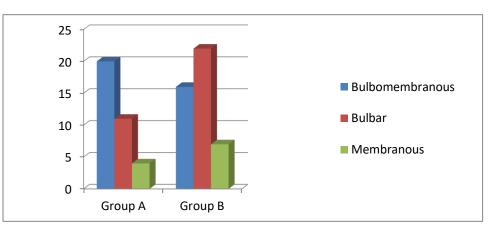
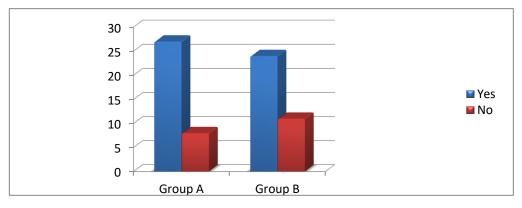
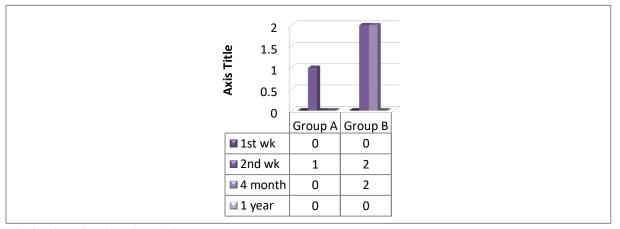


Figure 2: Distribution of patients by Mode of trauma [n = 70]

# **Distribution of patients by Etiology** [n = 70]



Distribution of patients by Reterograde urethrogram findings [n = 70]



Distribution of patients by Pelvic Fracture

Distribution of patients by Fistula formation

# Distribution of patients by Recurrence Figure 6 Distribution of patients by Recurrence

		Urinary Stre				
Follow up	Group A		Group B		p-value	
	No.	%	No.	%		
	Grade I	22	62.8	18	51.4	
1 <sup>st</sup> week	Grade II	12	34.3	17	48.6	0.091
G	Grade III	1	2.9	0	0	
	Grade I	28	80	26	74.3	
	Grade II	4	11.4	6	17.1	0.345
	Grade III	3	8.6	3	8.6	
	Grade I	28	80	16	45.7	
4 <sup>th</sup> month	Grade II	7	20	11	31.4	0.531
	Grade III	0	0	8	22.9	0.551
	Grade I	33	94.2	17	48.6	
1 year	Grade II	2	5.8	16	45.8	0.014
	Grade III	0	0	2	5.7	

\* Chi – square test

Table 1: Distribution of patients by Urinary stream [Grading]

#### **DISCUSSION:**

The treatment of urethral stricture had always been a challenge for the treating urologists. Various treatment options had been suggested in the past and at the present. Surgical treatment is considered ideal. However, still there is no single surgical technique had been taken as gold standard, because the surgical techniques are evolving? End to end anastomosis and penile pedicle skin grafting are two different techniques each of which has its own advantages and disadvantages.

This study was conducted on 70 patients with in a tertiary care hospital setting in order to compare the outcome of penile pedicle skin grafting with end to end anastomosis. The results of our study were in favor of end to end anastomosis with a lower rate of stricture recurrence at one year follow up i.e. 22.9% in group A versus 65.7% in group B and better urinary flow rate at one year follow up i.e.  $21.77 \pm 1.85$  in end to end anastomosis group and  $17.00 \pm 7.04$  in penile pedicle group. The results were statistically significant [p < 0.05].

In literature, there is no comprehensive trial which have compared the two techniques. All are the individual studies carried at certain centers. The mean age of the patients in our study was  $20.60\pm12.61$  years [range 7 – 50 years] in one group and was  $23.63\pm11.29$  year [range 7 – 50 years] in another group. This represents the population of relatively younger age group. In study by (28) the mean age of the patients was 39 years [range 17 – 80 years]. In another study by (29) the patients' mean age was 43.83 years [range, 19 to 73 years]. However, [30] have mentioned a young population of mean age 32 years. The results of our study have shown that young patients are more prone to get urethral injury.

The history of road traffic accident was present among 31 patients [88.6%] in group A and 28 patients [80%] in group B. The fall over the pelvis was the second most common injury followed by it. None of the patients in both groups had urinary tract infection. [31] Observed that blunt urethral trauma was seen in 45% patients and Pelvic fracture in 13.5% cases. Stricture was because of iatrogenic trauma in 20% patients. Infection was cause of stricture in 12.5% cases. In a study by [32] 54.6% had a trauma-related stricture; majority of them followed a pelvic ring fracture with posterior urethra distraction defect, 16% patients had inflammatory strictures, 17.3% were iatrogenic, 6 % had congenital strictures, and 6% of unknown etiology. In our study, the majority of the patient had stricture after trauma,

the road traffic accident being the most common cause. This could be due to poor traffic conditions and lack of awareness of our community to take precautionary measures. In our study, the majority of strictures were present at bulbomembranous level 20 patients [57.1%] in group A and 16 patients [45.7%] in group B followed by bulbous level amongthem 11 patients [31.4%] in group A and 12 patients [34.3%] in group B. The least strictures were formed at membranous levei.e.4 patients [11.4%] in group A and 7 patients [20%] in group B. The results were in conformity with study by [30] in which bulbar urethra was involved in 70 % patients followed by membranous in 30 % patients. The study by [32] showed that 54% strictures were located in the bulbous urethra, 6% in the penoscrotal junction and 1.3% in the penile urethra. They also described that 60.6% of the strictures or obliterative defects measured between 1 and 3 cm, 28% less than 1 cm and only 10.6% more than 3 cm. [29] described that in their study, the mean stricture length was 4.9 cm [range, 2.5 to 14 cm]. However, they only performed skin pedicle skin grafting as end to end anastomosis was not possible in such length. [32] End to end anastomosis is performed in 150 patient's stricture urethra. The follow-up has ranged from 6 to 168 months [mean 44.4]. The results were classified as good, fair [some re-stricturing, not needing treatment] and poor [recurrence].

14 patients in their study who were considered as failures were operated again, all successfully; in 4 of them, a repeat excision and end-to-end anastomosis was performed, elevating the final success rate of the series to 93.3%. (30) also performed ends to end anastomosis and showed very good outcome. They included 20 male patients with stricture urethra. In all patients, stricture was excised and overlapping end to end anastomosis of urethra with good spatulation was performed. In their study, wound infection was developed in 10% patients who were managed successfully. Minimum follow-up period was one year. Mean follow-up was 2.5 years. Twenty percent patients developed stricture at the site of anastomosis. Overall success rate was 90%. They showed encouraging results with end to end anastomosis. [33] end to end anastomosis is performed in 153 patients for bulbar urethral strictures of varied etiology of 153 cases 90.8% were successful and 9.2% were treatment failures. Performing an anastomotic urethroplasty for strictures of 2-3 cm in length would create a urethral defect of at least 4-5 cm as a 1 cm length of healthy urethra has to be mobilized along the proximal and distal urethra adjacent to the stricture. Some authors have expressed concern that bridging such long defects could lead to chordee and

sexual dysfunction and have advocated the use of buccal mucosa substitution urethroplasty for bulbar urethral strictures >2 cm in length. However, in a study, [34] managed 57 patients with strictures between 2-3 cm with anastomotic urethroplasty with a long-term success rate of 87%. There was no incidence of chordee in their series. Similarly [35] reported 98% success rate for bulbar strictures ranging from 0.5-4.0 cm [average 1.9 cm] over a mean follow-up of 50.4 months and [36] reported 95% success rates for excision and anastomosis of bulbar strictures ranging from 0.1-4.5 cm [mean 1.7 cm] over a mean follow-up of 70 months. These studies are important because they report long-term results to the tune of >90%.

[37] histopathological study performed among 12 patients. They performed histopathology of the resected portion of the urethra in order to determine the microvascular and serological changes do find out the factors that can possibly lead to recurrence. They found that after excision of the stenotic segment to a luminal caliber of 28Fr, the exposed and macroscopically proximal edge may present altered amounts of elastic fibers and smooth muscle cells, but are free from fibrotic tissue. When excising the peri-stenotic tissue, the surgeon should be more careful in the proximal end, which is the most altered.

[29] performed penile pedicle skin grafting among 55 patients with stricture urethra. The commonest complication being infection: wound infection in 9.1%, urosepsis in 3.6%, and epididymo-orchitis in 1.8% of the subjects. This was due to the reason that leading etiology of the stricture was urethral inflammation [76.4%]. When compared to our results, we did not have any skin infection in both groups as none of our patients had urinary infection as etiology. Moreover, prophylactic use of preoperative antibiotics may be another reason which has prevented this complication. In their study, only one recurrent stricture was reported [recurrence rate of 1.8%]. There was no permanent urethrocutanous fistula; the 3 reported fistulae closed spontaneously on conservative therapy within 3 weeks of follow-up. Their complication rate was much lower than ours. We did not have any infection in any of the case, but restructure was present in higher frequency i.e. 65.7% patients. This can be explained due to the reason that [29] followed up the patients for a shorter period than ours. i.e. 3 weeks, while we had a larger follow up i.e. up to 1 year. The recurrence of stricture was seen among 25.7% patients in our study at 2<sup>nd</sup> week follow up. [38] performed pedicle skin grafting among 18 patients. The urethral patency was achieved in 77% of patients. The complications were fistula in 5.5% patients restricture which occurred in 16.6% patients that required visual internal urethrotomy and two patients [11%] showed curvature on erection that does not interfere with sexual intercourse. Diverticulum [penile urethra] was seen in 5.5% patients containing stones and was excised surgically. There was penile skin loss in 16.6% patients.

Most of the complications with skin pedicle urethroplasty are recurrent stricture, troublesome post void dribbling, and diverticulum formation. In previous study by 16 of 17 patients with penile skin urethroplasty, urethral pseudodiverticulum developed in 11.7% patients. One patient developed a large urethral diverticulum 1 year after procedure and the other 10 years after the procedure.

Any kind of substitution urethroplasty deteriorates over time. Long-term results with skin flap urethroplasty show a decreasing success rate with time. In our study, the outcome of penile pedicle skin grafting was disappointing with a very high rate of restricture formation.

This study had certain limitations. This was not a double blind study as both the techniques are performed in a different way. So, the technique could not be hidden from the researcher. This was a single center study conducted in a limited population.

#### **CONCLUSION:**

Urethral stricture is seen frequently among young patients. Most of the time, this was the result of road traffic accident. Almost all the patients present with urinary stricture. Strictures were present at bulbomembranous level in majority of patients followed by bulbous and membranous level. End to end anastomosis showed better outcome as compared to penile pedicle skin grafting in terms of restricture and urinary flow rate and grading. So, it is recommended that end to end anastomosis should be encouraged among patients with stricture urethra. Prophylactic use of antibiotics may avoid skin infection.

#### **Conflicts of Interest**

The authors declare no conflict of interest

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