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Original Article

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# Outcome of Oral Steroids After Optical Internal Urethrotomy (OIU) In Comparison eith OIU Only

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**Conflicts of interest:** None

## Abstract

***Objectives:*** *To evaluate the effects of Oral Steroid as Tablet Deflazacort(6mg) in the prevention of recurrence of short segment anterior urethral stricture after optical internal urethrotomy compare with OIU only.*

***Material and methods:*** *This present Randomized clinical comparative study was designed to observe the efficacy of Oral Steroid as Tablet Deflazacort (6mg) after optical internal urethrotomy. All male patients of age between 18-45 years, who were diagnosed as short segment anterior urethral stricture(<1.5cm) and planned for optical internal urethrotomy, were divided into two groups after fulfilling selection criteria. After informed consent and random allocation by lottery, patients under group A were given oral steroid as Tab. Deflazacort (6mg) twice daily for 2weeks then once daily for another 2weeks after catheter removal on 7th post-operative day following optical internal urethrotomy, while patients under group B were managed by optical internal urethrotomy only. 26 patients were enrolled in group A and 25 patients in group B. In group A, 4 patients and group B, 3 patients were lost during follow up. Hence total of 44 patients completed the study with 22 patients in each group, during the period of January 2018 to December 2018.*

***Result:*** *In present study, there were no significant differences found in age, preoperative American urological association (AUA) score, preoperative maximum urinary flow rate, and preoperative PVR between two groups. Postoperative comparison of AUA score at 6th month follow up between two groups showed the decrease in AUA score in group A in compare to group B and the difference was statistically significant (5.8±5.1 versus 10.9±7.1, p=0.009). Maximum flow rates at 3rd month (23.7±5.8 ml/sec versus 20.0±2.9 ml/sec( p= 0.010) and 6th month (20.0±5.2 ml/sec versus 15.9±5.8 ml/sec, p=0.018) follow up were significantly higher in group A than group B. Post void residual urine were significantly decrease in group A than group B (21.5±26.5 ml versus 42.0±30.9 ml, P=0.023). Study also showed a significant reduction in recurrence of anterior urethral stricture of 3(13.6 %) in the group A versus 9 (40.9% ) in the group B (p=0.042).*

***Conclusion:*** *Use of the Oral steroid after optical internal urethrotomy in preventing recurrence of short segment anterior urethral strictures were effective.*

**Keywords:** CISC- Clean intermittent self-catheterization, MCU- Micturating cystourethrogram, MCU- Micturating cystourethrogram, LUTS- Lower Urinary Tract Symptoms, LUTS- Lower Urinary Tract Symptoms, OIU-Optical internal urethrotomy, VCUG- Voiding cystourethrogram

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**Introduction**

Urethral stricture is one of the oldest known urologic disease and remains a common problem with high morbidity and associated prevalence of 229-627 per 100,000 males or 0.6% of the at risk population.[1] Urethral strictures can occur due to trauma (external & iatrogenic), infection, inflammation, congenital or unknown causes. As a result, scar tissue forms in the epithelium, and fibrosis usually extends into the surrounding corpus spongiosum,causing spongiofibrosis, which leads to decrease in caliber of the urethral lumen.[2] Men with symptomatic stricture disease typically present with obstructive voiding symptoms such as straining, incomplete emptying and a weak stream, they might also have a history of recurrent UTI,prostatitis, epididymitis, haematuria, or bladder stones. On physical examination, induration in the area of the stricture may be palpable. Other findings may include, tender enlarged masses (periurethral abscesses), urethrocutaneous fistula & palpable bladder (chronic retention).[3] Urinary flow rate is measured as part of initial investigation followed by retrograde urethrography (RUG) and voiding cystourethrography (VCUG) to determine the location, length, and severity of the stricture.[3] Sonourethrography can be used as an adjunct to determine the length and degree of spongiofibrosis, and can influence the operative approach. Ultrasonography of KUB region also helps to diagnose associated bladder pathology and upper tract changes.[3,4]

There are several procedures for the management of urethral stricture, ranging from urethral dilatation, minimally invasive optical internal urethrotomy (OIU) to invasive modalities such as buccal mucosal graft urethroplasty and even tissue engineering in the 21st century. However, the greatest concern in urethral strictures is the high recurrence rate.[5]

Optical internal urethrotomy refers to any procedure that opens the stricture by incising or ablating it transurethrally to allow the scar to expand. The goal is for the resultant larger caliber to be maintained after healing.[5] OIU is the treatment modality in the management of urethral stricture. Being a minimally invasive procedure with less morbidity, it is commonly performed.[5] The success rates of OIU vary widely, ranging from 8–80%.In general, recurrence is more likely with longer strictures, the risk of recurrence at 12 months is 40% for strictures shorter than 2 cm, 50% for strictures between 2–4 cm, and 80% for strictures longer than 4 cm. Recurrence rates also vary according to stricture location; 58% of bulbar strictures will recur after urethrotomy, compared with 84% for penile strictures and 89% for membranous strictures.[3,2]

Numerous techniques have been adopted to reduce the recurrence of stricture after OIU, such as prolonged catheterization, clean intermittent self catheterization (CISC) and intralesional injection of triamcinolone and mytomycin C with varying success.[3,5,6]

Urologists commonly prefer CISC after OIU to prevent the recurrence of stricture. CISC following urethrotomy might decrease recurrence rates. However, other studies have shown that self dilation does not decrease recurrence rates and that self-dilation is associated with significant long-term complications and high dropout rates.[3] There is no level I evidence to support the use of clean intermittent catheterization following DVIU.[7]

Corticosteroids decrease the scar formation by reducing collagen and glycosaminoglycan synthesis and expression of inflammatory mediators.[8]

The aim of this study to assess the effectiveness of oral steroids as Tablet Deflazacort in reducing postoperative recurrence of stricture urethra after optical internal urethrotomy.

**Methods**

This present Randomized clinical comparative study was carried out in the department of urology, Bangabandhu Sheikh Mujib Medical University from January 2018 to December 2018.So Total 44 patients need in this study and each group 22patients who were planned for optical internal urethrotomy for short segment anterior urethral stricture. In this study inclusion criteria male patient age between 18-45 years with short segment (<1.5) anterior urethral stricture and exclusion criteria multiple urethral strictures, urethro-cutaneous fistula,history of repeated optical internal urethrotomy and urethroplasty,urethral strictures of a length more than 1.5 cm, neuropathic bladder, concomitant bladder neck obstruction.

By simple random sampling, total 44 patients were selected as sample from all male patients of age between 18-45 years, who were diagnosed as short segment anterior urethral stricture and planned for OIU as day case surgery at BSMMU after fulfilling selection criteria.

At operation theatre, simple randomization was done by lottery and the patient was either grouped into group A or group B. Both the groups underwent OIU but patients in group A received Oral Steroid as Deflazacort in addition to OIU and group B only OIU. Outcome Variables are American urological association symptoms score (AUA score), Maximum urinary flow rate (Qmax), Post void residual Urine (PVR),Recurrence of stricture.

Statistical analyses of the results were done by using computer based statistical software (SPSS version 20) and excel free software. Results obtained from the between study group and control group were analyzed. Quantitative variables (AUA score, Maximum flow rate and PVR) were analyzed by Independent t-test and qualitative variables (pericatheter bleeding and recurrence) were analyzed by Chi-square test.

**Results and Observations**

Comparison of preoperative variables between groups:

Table I Comparison of preoperative variables like age, preoperative AUA score, preoperative maximum urinary flow rate and preoperative PVR between two groups and no statistically significant differences were found between them. The majority patients in both groups belonged to age 26-35 years, 13 (59.1%) in group A and 11(50.0%) in group B.The mean age was found 33.0±7.4 years in group A and 30.2±7.3 years in group B (p=0.213).Preoperatively both the groups have similar AUA score and the mean AUA score was found 29.6±1.8 in group A and 29.1±1.8 in group B (p=0.362). The preoperative mean maximum flow rate was found 7.8±2.4 mL/sec in group A and 8.0±2.0 mL/sec in group B ( p=0.767). The preoperative mean PVR was found 67.2±45.5 ml in group A and 66.2±31.5 ml in group B ( p=0.933)

**Table I :** *Comparison of preoperative variables in both groups (n=44)*

| Out come | Group A ($n_1$-22) | Group B ($n_2$-22) | P-value |
|---|---|---|---|
| Age (year) | 33.0±7.4 | 30.2±7.3 | 0.213 |
| (Range) | (18–45) | (18–45) | |
| Preoperative AUA score | 29.6±1.8 | 29.1±1.8 | 0.362 |
| (Range) | (27 – 33) | (26 – 33) | |
| Preoperative Qmax (mL/sec)(Range) | 7.8±2.4(3.6 – 11.2) | 8.0±2.0(4.8 – 12.3) | 0.767 |
| Preoperative PVR(ml) | 67.2±45.5 | 66.2±31.5 | 0.933 |
| (Range) | (16 – 45) | (13 – 55) | |

(Independent t-test was performed and p-value <0.05 was considered significant)

**Comparison of location of stricture urethra between groups**

Table II shows distribution of location of stricture urethra of study patient It was observed that, bulbar urethra was the most common site of urethral stricture in both group, 17(77.3%) in group A and 19(86.4%) in group B. The difference was statistically not significant (p=0.439) between two groups.

**Table II:** *Comparison of the study patients according to location of stricture urethra (n=44)*

| Location of stricture | Group A $n_1$-22 | | Group B $n_2$-22 | | p-value |
|---|---|---|---|---|---|
| | $n_1$ | % | $n_2$ | % | |
| Bulber | 17 | 77.3 | 19 | 86.4 | 0.439 |
| Penile | 5 | 22.7 | 3 | 13.4 | 13.4 |

**Comparison of American Urological Association symptoms score (AUA score) between groups :**

Table III shows, postoperative comparison of AUA score between group A and group B. At 3rd month mean AUA score was found 7.4±3.1 in group A and 8.9±3.5 in group B. At 6th month, mean AUA score was found 5.8±5.1 in group A and 10.9±7.1 in group B. The AUA score at 6th month is significantly decreased in group A as compare to group B (p=0.009).

**Comparison of Maximum flow rate (Qmax) between groups**

Table IV shows, postoperative comparison of Qmax between group A and group B. At 3rd month, mean maximum flow rate was found 23.7±5.8 mL/sec in group A and 20.0±2.9 mL/sec in group B. At 6th month, mean maximum flow rate was found 20.0±5.2 mL/sec in group A and 15.9±5.8 mL/sec in group B. Maximum flow rate at 3rd month (p= 0.010) and 6th month (0.018) were significantly increased in group A as compare to group B.

**Comparison of post void residual urine (PVR) between groups**

Table V shows, postoperative comparison of PVR between group A and group B.At 6th month, mean PVR was found 21.5±26.5 ml in group A and 42.0±30.9 ml in group B. Post void residual urine at 6th month was statistically significant (P=0.023) between two groups which implies significantly decrease in PVR in group A.

**Table III:** *Comparison of postoperative American Urological Association symptoms score (AUA score) in both groups (n=44)*

| AUA score | Group A ($n_1$-22) Mean±SD' | Group B ($n_2$-22) Mean±SD | p-value |
|---|---|---|---|
| Follow up at' 3rd month | 7.4±3.1 | 8.9±3.5 | 0.139 |
| Range(min-max) | 2-13 | 4-16 | |
| Follow up at 6$^{th}$ month | 5.8±5.1 | 10.9±7.1 | 0.009 |
| Range(min-max) | 1-21 | 4-21 | |

(Independent t-test was performed and p-value <0.05 was considered significant)

**Table IV:***Comparison of postoperative Maximum flow rate in both group (n=44)*

| Maximum flow rate **(mL/sec)** | Group A ($n_1$-22) Mean±SD' | Group B ($n_2$-22) Mean±SD | p-value |
|---|---|---|---|
| Follow up at' 3rd month | 23.7±5.8 | 20.0±2.9 | 0.010 |
| Range(min-max) | 17.4-23.9 | 15.8-04.2 | |
| Follow up at 6$^{th}$ month | 20±5.2 | 15.9±5.8 | 0.018 |
| Range(min-max) | 8.6-29.3 | 8.6-21.8 | |

(Independent t-test was performed and p-value <0.05 was considered significan

**Table V:** *Comparison of postoperative post void residual urine in both group*

| PVR (ml) | Group A ($n_1$-22) Mean±SD' | Group B ($n_2$-22) Mean±SD | p-value |
|---|---|---|---|
| Follow up at 6$^{th}$ month | 21.5±26.5 | 42.0±30.9 | 0.023 |
| Range(min-max) | 0-25ml | 0-35ml | |

(Independent t-test was performed and p-value <0.05 was considered significant)

**Table VI:** *Comparison of the study patients according to recurrence of stricture urethra in both group (n=44)*

| Recurrence | Group A ($n_1$-22) | | Group B ($n_2$-22) | | p-value |
|---|---|---|---|---|---|
| | $n_1$ | % | $n_2$ | % | |
| Yes | 3 | 13.6 | 9 | 40.9 | 0.042 |
| No | 19 | 86.4 | 13 | 59.1 | |

(Chi square test was performed and p-value <0.05 was considered significant)

**Comparison of recurrence of stricture urethra between groups**

Table V shows recurrence of the study patients, it was observed that 3(13.6%) patients had recurrence in group A and 9(40.9%) in group B. The difference was statistically significant between two groups (p=0.042) and symbolize the significantly higher rate of recurrence in group B as compare to group B.

**Discussion**

Optical internal urethrotomy is a feasible option for short segment bulbar urethral strictures, but it is not free from the risk of recurrence. There have been studies that have evaluated the efficacy of intralesional steroid injections (like triamcinolone), and also mitomycin C after urethrotomy to assess their role in reducing stricture recurrence rates.

Tabassi et al. [8] in 2011 reported study on 70 patients treated by internal urethrotomy 34 with intraurethral submucosal triamcinolone injection and 36 without it. Recurrence rate was lower and time to recurrence was longer in the steroid group.

Kumar et al. [9] in 2012 studied 50 patients with urethral strictures<3 cm treated with Holmium laser with intralesional triamcinolone(80 mg) under spinal anesthesia. The overall recurrence rate was 24%. The success rate in patients with strictures less than 1cm in length was 95.8%, whereas that in patients with strictures of 1 to 3 cm in length it was 57.7%.

A study was conducted by Kumar et al. to assess the efficacy of OIU combined with intralesional injection of Triinject(triamcinolone, mitomycin-C and hyaluronidase), and it was found that success rate increased from 80.6% to 94.2% for short-segment anterior urethral strictures.

Another study in 2015 [10] by Modh et al. assessed the outcome of intralesional steroid injection after internal urethrotomy, and found that it helped to reduce recurrence rate of strictures when steroid was injected at high doses.Other studies have found mixed results with intralesional injections.

In present study, we used deflazacort. Deflazacort is a corticosteroid,which is actually a prodrug. It was introduced in 1969. It is an oxazoline derivative of prednisolone with anti-inflammatory and immunosuppressive activity. It has good safety profile amongst steroids and can be given without any serious side-effects. Usual dosage is 6 mg once or twice daily. It is mainly excreted in urine(70%). It should be used with caution in patients with liver disease, in pregnancy and during lactation.Liver function was normal who were used oral steroid.

Results of treatment of both groups were compiled and compared the outcome variables such as AUA score, maximum urinary flow rate, post void residual urine and recurrence of stricture postoperatively at 3 months and 6 months.

In this study, age of the patients ranged from 18 years to 45 years. The majority of patients were belonged to age 26-35 years in both groups (59.1% in group A and 50.0% in group B). The mean age of group A was 33.0±7.4 years and 30.2±7.3 years of group B, which is statistically insignificant (P=0.213). The mean age of this study was comparable with the study done [6,11] by Mazdak et al., 2007 and Ravi et al., 2014.

In present study, the most common site of stricture urethra was bulbar urethra i.e 77.3% in group A and 86.4% in group B. Our observation was similar with studies done[12,1,6]by Heyns et al., 2012; Alwaal et al., 2014 & Ali et al.,2015.

In present study, all the participants of both groups were evaluated for AUA score by self-questionnaire. The mean preoperative AUA score in group were similar, 29.6±1.8 in group A and 29.1±1.8 in group B . Postoperatively, at 3 months follow up, the mean AUA score in group A was decreased (7.4±3.1) in compare to group B(8.9±3.5) but result was statistically

insignificant. Whereas at 6th months follow up, AUA score was significantly (p=0.009) decrease in group A (5.8±5.1) in compare to group B (10.9±7.1).

The mean preoperative maximum flow rate was 7.8±2.4 ml/sec in s group A and 8.0±2.0 ml/sec in group B which was statistically insignificant. At 3rd month and 6th month follow up, there was statistically significant increase in maximum flow rate of group A in compare to group B. Our observation was similar with studies done by [13]Gupta,Sayak Roy,Dilip Kumar Pal, 2018.In present study, at 6th month follow up, PVR was significantly (p=0.023) decreased in group A as compare to group B. In present study showed a significant reduction in recurrence of anterior urethral stricture to 13.6 % in the group-A, OIU with Oral Steroid(Tablet Deflazacort) versus 40.9% in the group B, OIU only (p=0.042). This study was similar with studies done by[13] Sandeep Gupta et al, 2018.So, Deflazacort was shown to be effective in reducing the recurrence of stricture of urethra.

**Conclusion**

Comparing the findings of the present study, it can be concluded that Tab. Deflazacort can be effective in reducing recurrence rates of short segment(<1.5cm) stricture urethra after internal urethrotomy, and it can also maintain some what better flow rates postoperatively and thus alleviate bothersome symptoms of the patient in a better way.

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