International Journal of Urology Research

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Comparison of deflazacort and clean intermittent self-catheterization after optical internal urethrotomy for reducing recurrent urethral stricture

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Abstract
Urethral stricture is a common urological condition, with optical internal urethrotomy (OIU) being the most widely used minimally invasive treatment. However, postoperative recurrence remains a significant challenge. This quasi-experimental study, conducted in the Department of Urology, Sir Salimullah Medical College Mitford Hospital, Dhaka, from March 2022 to August 2023, aimed to compare the effectiveness of oral steroid therapy (Deflazacort) versus clean intermittent self-catheterization (CISC) in reducing stricture recurrence following OIU. Seventy male patients with short-segment (≤1.5 cm) bulbar urethral strictures were enrolled and divided into two groups. Group A received oral Deflazacort (6 mg twice daily for 2 weeks, then once daily for 2 weeks), while Group B performed CISC using a 16 Fr Nelaton catheter according to a structured schedule. Patients were followed up at 3, 6, and 12 months postoperatively. The mean age of patients in Group A and Group B was 38.6±12.3 and 39.0±12.9 years, respectively (p=0.89). Preoperative maximum urinary flow rates were comparable (7.2±1.2 vs 7.1±1.2 mL/sec). Postoperatively, Group A showed significantly higher flow rates at 3 months (26.9±1.7 vs 25.9±2.4 mL/sec, p=0.042), 6 months (23.9±1.6 vs 22.9±2.4 mL/sec, p=0.046), and 12 months (22.2±1.7 vs 21.1±2.1 mL/sec, p=0.016). Recurrence of stricture was significantly lower in Group A compared to Group B (5.7% vs 25.7%, p=0.045). The study concludes that oral steroid therapy with Deflazacort is more effective than CISC in preventing recurrence of urethral stricture following OIU.

Keywords: Deflazacort, Clean intermittent self-catheterisation, optical Internal urethrotomy, recurrent urethral stricture

Introduction

Urethral stricture is one of the most difficult urological problems, which commences as a fibrous lesion of the urethral mucosa with decreased lumen and eventual symptom complexes [1]. The incidence of urethral stricture is as high as 0.2-1.2%, and its frequency markedly increases in males above 55 years of age [2]. Urethral stricture can occur due to trauma, infection, ischemia, inflammation, or unknown causes. These etiologies lead to scar formation in the epithelium, which narrows the urethral lumen. Strictures can develop in any part of the anterior urethra, most commonly in the bulbomembranous segment [3]. Urethral strictures often result in various lower urinary tract symptoms, such as difficulty in micturition, urgency, frequency, nocturia, urge incontinence, and stress incontinence. Some patients may experience secondary complications such as recurrent urinary tract infections, hydroureteronephrosis, urinary tract stone disease, gross hematuria, acute urinary retention, and renal failure [4]. Urethral stricture disease has always posed a challenge for urologists. Treatment modalities include dilatation, urethrotomy, stent placement, and urethroplasty [5]. Optical internal urethrotomy (OIU), also referred to as Direct Visual Internal Urethrotomy (DVIU), involves the transurethral incision or ablation of scar tissue to enlarge the stricture segment. OIU remains the most commonly employed technique due to its simplicity, safety, and short procedure time [6]. Despite favorable immediate results, recurrence occurs in 10-50% of cases, with most recurrences developing within the first year [7].

Ideal management of recurrent strictures should involve a non-invasive intervention offering long-term resolution with minimal complications [8]. Clean intermittent self-catheterization (CISC), performed after OIU for postoperative calibration, is a self-managed method but is often difficult and less convenient for patients. Complications such as urinary tract infections and mild bleeding-mostly from friction injuries during initial use-are common. Infection risk arises from the inability to maintain aseptic conditions during the procedure, although proper hand, catheter, and genital hygiene can reduce this risk [7]. Several adjunct therapies have been investigated to minimize stricture recurrence after OIU. These include intralesional steroid injection, mitomycin C, captopril, platelet-rich plasma, hyaluronidase, drug-coated catheters or balloons (e.g., paclitaxel), brachytherapy, oral steroids, and tamoxifen. Recurrence rates and complications vary among these options [9]. Steroid application during urethrotomy has shown better outcomes than urethrotomy alone in preventing recurrence. While injectable steroids are more commonly used, the role of oral steroids remains underexplored [10]. Corticosteroids reduce scar formation by inhibiting collagen and glycosaminoglycan synthesis and the expression of inflammatory mediators [9]. Deflazacort, a corticosteroid introduced in 1969, is an oxazoline derivative of prednisolone with anti-inflammatory and immunosuppressive effects. It has a favorable safety profile, minimal side effects, and is primarily excreted in urine (70%). Caution is advised in patients with liver disease, during pregnancy, and lactation [3]. Although intralesional steroids have proven effective post-OIU, few studies have evaluated the efficacy of oral steroids in this context. This study aims to assess the role of oral steroids in reducing postoperative urethral stricture recurrence. This study was therefore designed to evaluate and compare the efficacy of oral steroid (Deflazacort) and clean intermittent self-catheterization in reducing stricture recurrence following optical internal urethrotomy. Urethral stricture disease is common, yet its management remains a therapeutic challenge for urologists, despite advances in endoscopic and reconstructive procedures. Optical internal urethrotomy (OIU) is an effective method for treating short-segment bulbar urethral strictures, but postoperative recurrence is a major issue. The low success rate and high recurrence have led urologists to explore different adjuvant therapies. CISC, though widely used, is often difficult for patients to perform and carries risks such as infection and bleeding, reducing patient compliance. Several agents including intralesional steroid triamcinolone, hyaluronidase, and mitomycin C have been employed to reduce recurrence. However, these are invasive and require hospital settings. Oral steroid therapy, on the other hand, allows for extended treatment duration with greater convenience. Deflazacort, with its anti-inflammatory and immunosuppressive properties and good safety profile, emerges as a promising candidate. This study thus aims to compare the efficacy of oral Deflazacort and CISC in preventing recurrence after OIU. As limited data exist on the use of oral steroids in this setting, this study can contribute valuable insight into its potential clinical utility.

Materials and Methods

This quasi-experimental study was conducted over a period of eighteen months (March 2022 to August 2023) in the Department of Urology at Sir Salimullah Medical College Mitford Hospital, Dhaka, to evaluate and compare the efficacy of oral steroid (Deflazacort) and clean intermittent self-catheterization (CISC) in reducing recurrence of urethral strictures following optical internal urethrotomy (OIU). A total of 70 adult male patients, aged ≥18 years, with single, short-segment (≤1.5 cm) bulbar urethral strictures were purposively selected and alternately assigned to two equal groups. Group A (n=35) underwent OIU followed by oral Deflazacort, while Group B (n=35) underwent OIU and practiced CISC. Patients with post-traumatic, post-TURP, or post-urethroplasty strictures, neurogenic bladder, BXO, recurrent strictures, or prior corticosteroid use were excluded. The sample size was calculated using recurrence rates from previous studies, assuming a significance level of 95% and power of 80%. Following surgery, all patients had a Foley catheter in place for 7 days. Group A received Deflazacort 6 mg twice daily for 2 weeks, then once daily for another 2 weeks. Group B followed a structured CISC schedule using a 16 Fr Nelaton catheter. Patients were followed up with uroflowmetry at 3, 6, and 12 months postoperatively. Stricture recurrence was defined as maximum urinary flow rate <10 mL/sec, confirmed by retrograde urethrogram and micturating cystourethrogram. Other outcomes included postoperative urinary tract infections, per-urethral bleeding, and time to recurrence. Data were collected using a semi-structured questionnaire and recorded in a case record form. Data analysis was performed using SPSS version 26.0. Qualitative variables were summarized as frequencies and percentages, while means and standard deviations were calculated for quantitative variables. Pearson's chi-square and unpaired t-tests were applied to assess statistical significance, with a p-value <0.05 considered significant. Ethical clearance was obtained from the Institutional Ethics Committee of Sir Salimullah Medical College, Dhaka, and informed written consent was taken from all participants, ensuring confidentiality and voluntary participation.

Results

Table 1: Distribution of the patients according to age group (N=70)

Age group (years)	Group A N=35, N (%)	Group B N=35, N (%)	p-value
18-29	7 (20)	7 (20)	
30-40	18 (51.4)	17 (48.6)	0.963*
>40	10 (28.6)	11 (31.4)	
Mean ± SD (range)	38.6±12.3 (18-71)	39±12.9 (18-73)	0.887**

p-value was determined by *Chi-square test and **Independent sample t test.

Table 2: Distribution of the patients according to cause of urethral stricture (N=70)

Causes	Group A N=35, N (%)	Group B N=35, N (%)	p-value*
Idiopathic	11 (31.4)	13 (37.1)	0.615
Infective	24 (68.6)	22 (62.9)	

*p-value was determined by Chi-square test.

Table 3: Comparison of pre-operative maximum urine flow rate in both group (N=70)

Maximum flow rate of urine (mL/min)	Group A N=35, Mean ±SD (Range) (ml/Sec)	Group B, N=35, Mean ±SD (Range) (ml/Sec)	p-value*
Pre-operative	7.2±1.2 (6-8.4)	7.1±1.2 (5.9-8.3)	0.673

*p-value was determined by independent sample t test.

Table 4: Comparison of frequency of urinary tract infection at 3rd and 6th month period in both group (N=35)

UTI	Group A N=35, N (%)	Group B N=35, N (%)	p-value*
After 3 months	4 (11.4)	7 (20)	0.673
After 6 months	2 (5.7)	5 (14.3)	0.752

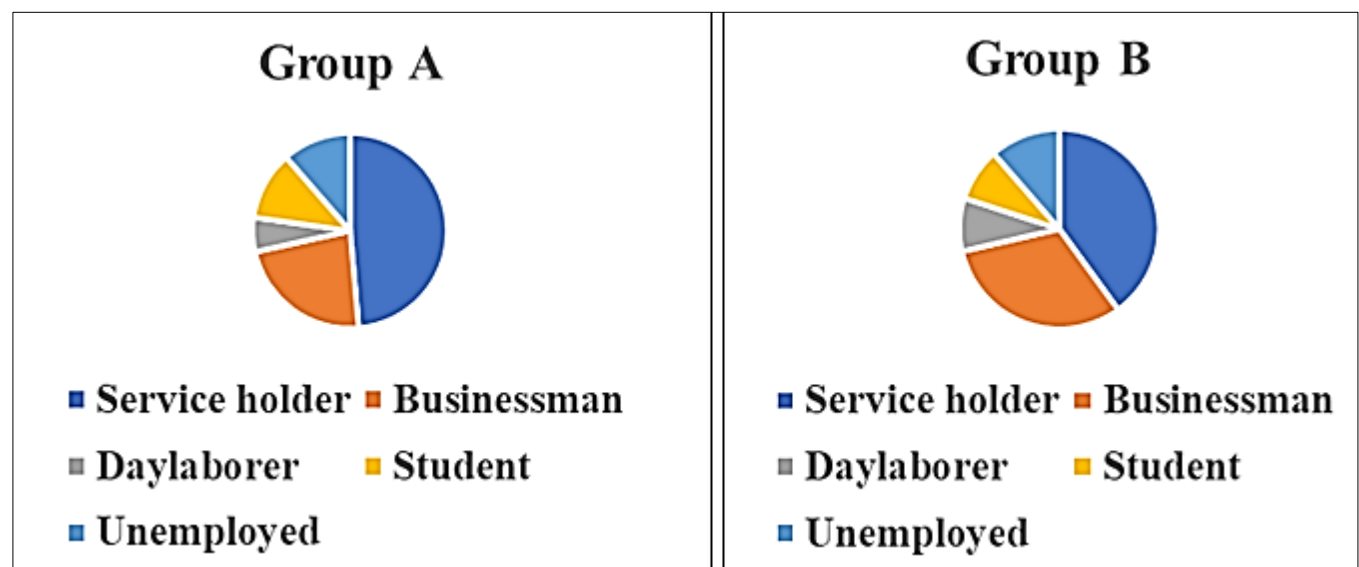*p-value was determined by Fisher Exact test.

Table 5: Distribution of patients according to maximum flow rate of urine at 3rd, 6th and 12th months of post-operative period (N=70)

Maximum flow rate of urine (mL/min)	Group A (N=35) Mean ±SD (Range) (ml/Sec)	Group B (N =35) Mean ±SD (Range) (ml/Sec)	p-value*
Post-operative flow at 3 months	26.9±1.7 (25.2-28.6)	25.9±2.4 (23.5-28.3)	0.042
Post-operative flow at 6 months	23.9±1.6 (22.3-25.5)	22.9±2.4 (20.5-25.3)	0.046
Post-operative flow at 12 months	22.2±1.7 (20.5-23.9)	21.1±2.1 (19-23.2)	0.016

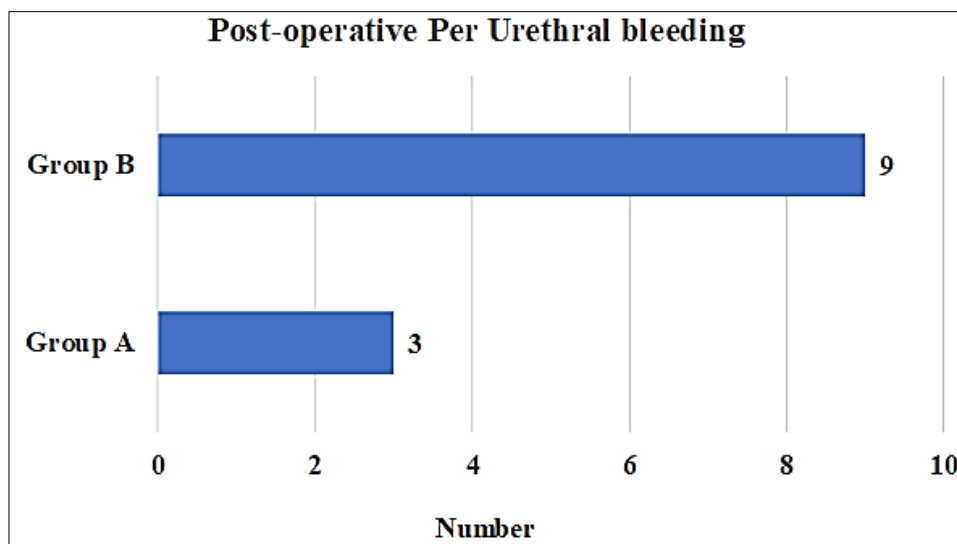*p-value was determined by Independent sample t test.

Table-6: Development of Urethral stricture at 6th & 12th month follow-up in both group (N=11)

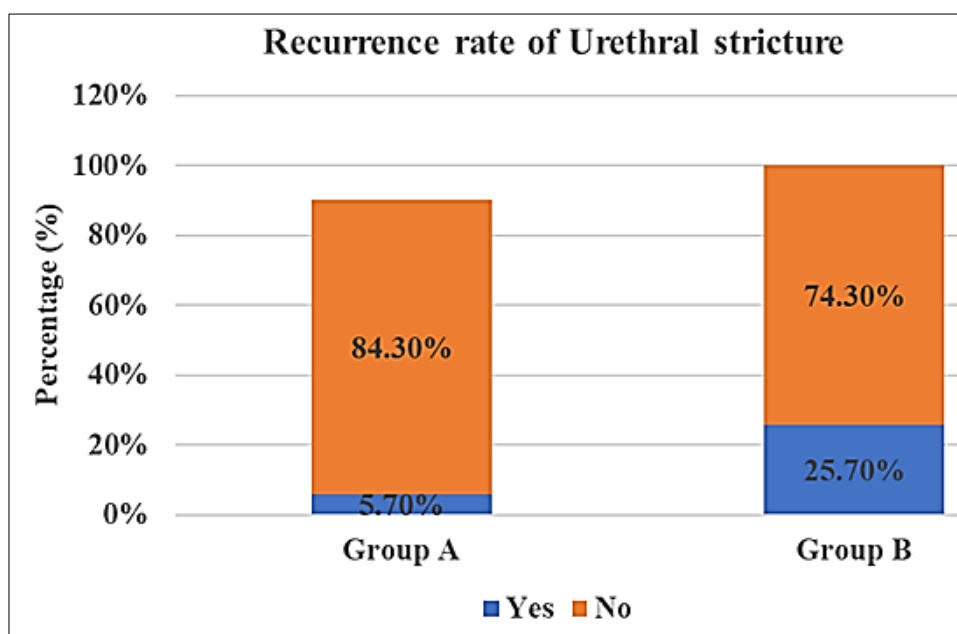| Recurrence time	Group A N=2, N (%)	Group B N=9, N (%)	p-value
At 6 months	0 (0)	2 (22.2%)	0.045
At 12 months	2 (100%)	7 (77.8%)	

*p-value was determined by Fisher Exact test (p-value=0.904).

Fig 1: Distribution of the patients according to Occupation (N=70)

*p-value was determined by Fisher Exact test (p-value=0.110).

Fig 2: Comparison of early post-operative per urethral bleeding between two group (N=70)

*p-value was determined by Chi-square test (p-value=0.045).

Fig 3: Distribution of the patients according to the recurrence rate of urethral stricture (N=35)

This quasi-experimental study was conducted in the Department of Urology, Sir Salimullah Medical College Mitford Hospital, Dhaka, involving 70 male patients with short-segment bulbar urethral strictures (≤1.5 cm) who underwent optical internal urethrotomy (OIU) and were divided equally into two groups: Group A received oral Deflazacort, and Group B practiced clean intermittent self-catheterization (CISC). The baseline characteristics, including age distribution and occupational status, were comparable between the groups with no statistically significant differences. Infection was the predominant cause of stricture in both groups (68.6% in Group A vs 62.9% in Group B). Preoperative maximum urinary flow rates were similar in both groups (7.2±1.2 mL/min vs 7.1±1.2 mL/min). However, postoperative maximum flow rates were significantly higher in Group A at 3, 6, and 12 months (p=0.042, 0.046, and 0.016, respectively). Incidence of postoperative complications such as urethral bleeding and urinary tract infection (UTI) was higher in Group B,

although differences were not statistically significant. Recurrence of urethral stricture was significantly lower in Group A (5.7%) compared to Group B (25.7%) (p=0.045), with all recurrences in Group A occurring at 12 months, while in Group B, 22.2% occurred at 6 months and 77.8% at 12 months. Overall, oral Deflazacort following OIU demonstrated superior outcomes in terms of urinary flow and recurrence prevention compared to CISC.

Discussion
Optical internal urethrotomy (OIU) is a widely accepted and feasible treatment option for short-segment bulbar urethral strictures, though recurrence remains a common concern. Evidence suggests that adjuvant therapy with oral steroids, such as Deflazacort, may help reduce recurrence rates and improve postoperative urinary flow [11]. Additionally, clean intermittent self-catheterization (CISC) has been demonstrated as a safe, simple, cost-effective, and well-tolerated intervention to prevent urethral stricture recurrence

[12]. This study aimed to compare the efficacy of oral steroid therapy versus CISC following OIU in reducing recurrence. A total of 70 patients were enrolled and divided into two groups: Group A (n=35) received oral Deflazacort, and Group B (n=35) practiced CISC. Most patients were aged 30-40 years, with mean ages of 38.6±12.3 years in Group A and 39±12.9 years in Group B, consistent with prior studies [11, 13, 14]. Infective causes were the most common etiology in this study, contrasting with previous reports where trauma or idiopathic causes predominated [13, 15]. Preoperative urinary flow rates were similar across both groups, but at 6 and 12 months postoperatively, Group A exhibited significantly higher maximum flow rates ($p<0.05$), aligning with findings from Gupta et al. [11]. Postoperative urinary tract infections were more frequent in Group B at both 3 and 6 months, though differences were not statistically significant ($p>0.05$), a trend supported by Kumar et al. who reported a 15% UTI rate in the CISC group [12]. Early per-urethral bleeding was also more common in Group B, yet not statistically significant. The recurrence rate was significantly lower in Group A (5.7%) compared to Group B (25.7%) (p=0.045). Similar outcomes were reported by Farooq et al. and Ilyas et al., who found recurrence rates of 20% and 18.75% in steroid groups compared to 46.67% and 39.06% in control groups, respectively [16, 17]. Kumar et al. also reported a 20% recurrence rate in the CISC group versus 75% in patients without CISC (12), while Sajid et al. noted a 9.4% recurrence among CISC patients [13]. This study confirms that oral steroid therapy after OIU leads to significantly lower recurrence rates and improved flow metrics compared to CISC alone, corroborating findings from previous literature.

Conclusion
This study compared the effectiveness of oral steroid (Deflazacort) and clean Intermittent self-catheterization (CISC) following optical internal urethrotomy (OIU) for reducing the recurrence of urethral stricture. Study results found that, following optical internal urethrotomy oral steroid (Deflazacort) is effective over clean intermittent self-catheterization in maintaining better urinary flow rates postoperatively and thus alleviate bothersome symptoms of the patients in a better way. The complications like post-operative per-urethral bleeding and incidence of urinary tract infection is less in Deflazacort group comparing to CISC group. There is no problem regarding patient compliance in Deflazacort group.

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