

The Role of Topical Steroid Application During Intermittent Self Urethral Dilatation in Reducing the Recurrence Rate of Anterior Urethral Stricture Following Direct Visualized Internal Urethrotomy - A Cohort Study

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Abstract

Background: Direct visual internal urethrotomy (DVIU) is recommended initial treatment of single or multiple anterior urethral strictures shorter than 2 cm that are of different underlying etiologies. But due to the risk of stricture recurrence after such intervention a large series of researches were conducted during the last few decades trying to reduce such drawbacks and enhance its effectiveness to improve success rate of DVIU. **Objective:** The aim of this study was to evaluate the role of use of local steroid (triamcinolone ointment) during intermittent self urethral catheter dilatation in the reducing or prevention of urethral stricture recurrence after DVIU, prolongation of time to recurrence, with low complications and drawbacks of this adjuvant simple to learn and cheap maneuver. **Methods:** A prospective comparative study included 30 male patients in total who were recently diagnosed with anterior urethral stricture involving the penile and/or the bulbar urethra and undergoing DVIU. Post-operatively, the patients were subgrouped into two main groups (group A and group B) each of them containing 15 cases. The first group instructed to do a clean intermittent self catheter dilatation (ISCD) using triamcinolone ointment as a lubricant whereas the second group used lidocaine gel for lubrication of the catheter over the next six months after DVIU. Those patients were followed-up for at least twelve months in minimum with urethroscopy and/or retrograde urethrogram. Re-evaluation was done at six and twelve months of follow-up period. **Results:** During follow-up studies, the urethral stricture rate of recurrence was studied between the two patients groups. Regarding the age of patients, there were significant statistical differences in the demographic age data of the patients with the P-value = 0.0025. The stricture site, length and underlying etiology, there were no statistically significant differences between the two studied groups. In contrast, the stricture recurrence rate was statistically significantly lower in the first group (group A) in whom triamcinolone ointment was used as a lubricant (2 out of the 15 patients (13%)) than group B in whom only the water-soluble lubricant gel was used (6 out of 15 patients in the control group (40%)) with P-value = 0.048. There was also a statistically significant correlation between the stricture recurrence and the stricture length in millimeters (P=0.02). **Conclusions:** The usage of triamcinolone in the form of ointment on the surface of catheter and installation into urethral lumen during self intermittent urethral dilatation by patients for six months after DVIU has reduced the stricture recurrence rate in significant proportion of cases. Such simple and cheap practice during dilatation may reduce long-term complications, avoiding a lot of future surgical procedures and improve patient quality of life and reduce the overall cost or re-intervention.

Keywords: Intermittent Self Catheter Dilatation, ISCD, Direct Visual Internal Urethrotomy, DVIU, Triamcinolone Ointment, Urethral Stricture.

INTRODUCTION

The urethral stricture is one of the common problems in urology and one of the oldest recognized urologic disorders and still carries a higher morbidity.^[1]

In males, a urethral stricture term refers to a narrowed stenosed segment or segments of the anterior portion of the urethra resulting from a process of inflammatory fibrosis and cicatrization that involving the urethral mucosa and may extend to the surrounding spongiosus tissue of corpus

spongiosum (spongiofibrosis).^[2] In contrast, in the posterior portion of male urethra, there is absence of spongiosus tissue surrounding the posterior urethra and the term stenosis at this location is much more logical and preferred to be used.^[3]

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The pathophysiology of urethral stricture disease usually begins with an incident lesion that affects the urethral mucosa with superadded infection and ischemia followed by the formation of a fibrotic scar lesion.^[4] Nowadays the majority of anterior urethral strictures happen as a result of iatrogenic (after repair of hypospadias or after instrumentation) or external trauma, and inflammatory strictures secondary to sexually transmitted gonococcal or non-gonococcal urethritis which were much less likely to be seen nowadays than in the past decades. However, in increasingly much more cases of stricture disease that involves anterior urethra, the underlying etiology remains idiopathic of unrecognized etiologies.^[5,6] Spongiofibrosis occurs as a result of mechanical, inflammatory or chemical injury that affects the anterior urethra and leads to scarring of the spongy tissue of the underlying corpus spongiosum that surrounds the anterior urethra. This injury occurs outside the corpus spongiosum secondary to penetrating or blunt injury, or occurs as a result of internal disruption of the fragile epithelial tissue of the urethra via instrumentation (catheters or endoscope) or inflammatory disease (infection, autoimmune or chemicals).^[6] The disrupted continuity and partial loss or tear of the epithelial lining of the urethral mucosa is the initiating factor in the stricture disease of the anterior urethra and its the triggering inducing factor for a sequels of local inflammatory and pathological events leading to bad changes in the quality of local tissues during healing process. These changes typically result in a fibrotic narrowing of the anterior urethral caliber because the healing process is initiated by the remaining healthy epithelial tissue which is re-approximated by natural urethral closure pressure during the healing inflammatory phase. The injured de-epithelialized regions of urethral mucosa expose the underlying highly vascular spongy tissue of corpus spongiosum, which heals by cross-adhesion with release and laying down of a lot of fibrous tissue and subsequent spongiofibrosis. Contraction of this abnormal amount of fibrous tissue in spongiosum leads to narrowing of urethral caliber. In addition, during voiding, passage of urine through these defects and leak of its constituents through mucosal defect to underlying inflamed spongy tissue results in further inflammation and much more subsequent spongiofibrosis specially if infected urine.^[7]

Regarding the etiology of penile and bulbar urethral stricture disease, it may be broadly subcategorized into four main leading etiologies, iatrogenic (catheter or endoscopy), traumatic (blunt or penetrating), inflammatory (infection, chemicals) and idiopathic causes. Idiopathic and iatrogenic urethral stricture were found to be the most common etiologies, responsible for 33% and 33% of all cases of anterior urethral stricture worldwide, respectively. While the post-traumatic and inflammatory etiologies were found in only 19% and 15% of all cases, respectively.^[8]

There is an acute sharp increase in epidemiological incidence of the urethral stricture disease observed beyond the age of 55 years, with a 45 years as a mean age.^[9] The most commonly affected segment of male urethra is the anterior urethra (92% of cases), with the bulbar urethra the dominantly involved part of all the four urethral segments (47%).^[10]

With regards to the pathophysiologic effects of urethral stricture disease on general and psychological health of patients, including its squeale and disastrous complications like recurrent infections, functional urinary bladder compensation, ureteral reflux, hydroureteronephrosis, and renal impairment. So it adversely impacts the physical health of patients and impair their quality of life (QoL),^[11] notwithstanding the financial costs associated with the diagnosis (laboratory, radiological and endoscopic instruments) and treatment tools (usually interventional endoscopic or surgical) of primary stricture and recurrent stricture diseases, and costs of rehabilitation of patients from its complications.^[12]

The urethral stricture disease is suspected in males with complaints of poor stream obstructive lower urinary tract voiding symptoms and in case of recurrent lower or upper urinary tract infections like cystitis, prostatitis, and pyelonephritis. These patients requires a comprehensive sequential diagnostic evaluation tests encompasses detailed clinical history and focused physical examination of genitalia and abdomen including digital rectal examination, laboratory tests such as urinalysis (urine culture) and renal function tests, uroflowmetry (maximum flow rate) and post-void residual (PVR) measurement by abdominal ultrasonography, radiological assessment including retrograde urethrography, endoscopic evaluation (urethrocystoscopy), urethral ultrasonography and may be MRI as an ancillary test if needed.^[13]

Management of urethral stricture disorder is a step-leader starting with simple less invasive treatment options and progressing according to the results to more invasive reconstructive surgical treatment. Direct visualized internal urethrotomy using urethroscope has been recommended as a first line treatment option for most uncomplicated urethral strictures shorter than 2 cm, but it is well recognized to be accompanied by high short or long-term rate of recurrence.^[14] Large number of studies have been performed since the 1970s trying to enhance the success rate and reduce the stricture recurrence. A number of auxiliary complementary procedures have been suggested to overcome this high recurrence rate problem such as foley catheter indwelling, intermittent self catheter dilatation (ISCD) and even urethral stents to reduce the chance of early and late recurrence. First time in history the use of triamcinolone ointment through transurethral route was admitted by Hebert in 1972.^[15] Different types of corticosteroid are used to decrease collagen and fibrous tissue production and deposition in

urethra, and a lot of studies have proven some efficacy of this auxiliary treatment in reducing incidence and recurrence of stricture.^[16] However, there are limited studies in the scientific literature that encourage the application of these agents during DVIU procedures for patients with urethral stricture diseases whether intralesional injection or topical application.^[17]

Our aim of this study is to evaluate the efficacy of using the topical corticosteroid (1% triamcinolone) ointment during lubrication of the catheter in comparison with lidocaine (water-based lubricant) gel in reducing or preventing the recurrence of anterior urethral stricture disease in those patients on ISCD following direct visualized internal urethrotomy procedure. Also, its role in prolongation of time to recurrence with no additional financial or health burden on the patients and health resources.

METHODS

In this comparison study, a total of 30 male adult cases with the recently diagnosed anterior urethral stricture who attend the urologic outpatient clinic in Azadi teaching hospital in Kirkuk city between December 2021 and October 2023 were collected and included in this prospective randomized clinical trial. Six of total cases had penile urethral stricture and 24 cases had bulbular stricture. Before endoscopic procedure, all the cases were undergone a clinical evaluation including a detailed clinical history and focused physical examination of abdomen and external genitalia with digital rectal examination to exclude other differential diagnosis of bladder outlet obstruction and lower urinary tract symptoms. General urine examination, urine culture, retrograde urethrography and flexible office urethroscope were performed in all cases prior to inclusion. We excluded patients with posterior urethral stenosis, and those patients who have anterior urethral strictures longer than 2 cm. We took informed consent from all the included patients and they were scheduled for DVIU and ISCD after proper preparation. The 30 cases were randomly distributed equally into 2 groups. Each group include 15 cases (3 penile stricture and 12 bulbar stricture).

During operation, the patients anesthetized regionally (spinal or epidural) or generally (laryngeal mask or endotracheal tube), DVIU was performed using cold-knife incision of the urethral stricture using a 21 Fr Storz optical urethrotome using the same principle and technique in all cases. Sound bougie dilatation at the summit of DVIU is done up to 28 F in all cases followed by insertion of

16-18 F Foley catheter for 3-5 days in all cases. In both groups postoperative ISCD is to be performed by patients themselves after detailed teaching of technique using 16-18 F single use Nelaton catheter immediately after removal of indwelling foley's catheter that inserted at the end of DVIU procedure. Group A were informed to use lubrication by triamcinolone ointment (triamcinolone group) and group B using lidocaine water-based gel as a lubricant (control group) after DVIU. The amount of ointment or gel that is supposed to be used inside the urethral and on the surface of the catheter each time is 5 ml with a single passage of catheter. The age of patients range from 18 -55 years in both groups with an average of 35+2. No patient lost from follow-up.

The schedule of ISCD was once daily during the first two weeks, then every other day during the next two weeks. During the second month, twice weekly while during the last 4 months dilatation done once weekly. Suppressive dose of oral 250 mg ciprofloxacin tablet is added to the strict clean technique. All cases were followed for 12 months after the procedure. The frequency of check out follow-up visits of all patients was on a monthly basis to the outpatient clinic during the first 6 months and every 2 months during the last 6 months. after the procedure. During the whole period of follow-up we did retrograde urethrography or urethrocystoscopic evaluation at 3, 6, 9 and 12 months. Random urethroscope was performed at any time if there is difficulty in voiding complaint or if there is failure of passage of the dilation catheter by the patient. Statistical analyses of our data were performed by using Chi square test and Student's t-test with the P-value of <0.05 was regarded as significant.

RESULTS

Statistical analyses were performed on the data that were collected from all the 30 patients in both groups of cases (the triamcinolone and lidocaine groups) who had followed for a period of at least twelve months after the last performed internal optical urethrotomy. There were significant statistical differences in the demographic age data of the patients with the P-value = 0.002 as shown in table 1. Although there was minimal difference in stricture length between the two groups with the mean being 1.4 cm in triamcinolone group and 1.5 in the control lidocaine group but this was not significant statistically (P-value = 0.45), whereas the differences of the underlying etiologies of the stricture between the two groups of cases were not statistically significant as seen in table 2 and 3.

Table 1: Age of Patients in Triamcinolone and Control Groups.

Data	Triamcinolone (n=15)	Control (n=15)	P-value
Mean age (years)	35.5 ± 1.6 (18–53)	37.5 ± 1.7 (20–55)	0.0025

Table 2: Length of urethral stricture of triamcinolone and control groups.

Data	Triamcinolone (n=15)	Control (n=15)	P-value
Stricture length (cm)	1.4 ± 0.35 (0.9–2)	1.5 ± 0.37 (1–2)	0.45

Table 3: Underlying Etiologies of Urethral Stricture of Triamcinolone and Control Groups.

Etiology of Stricture	Triamcinolone (n=15)	Control (n=15)	P-value
1. Traumatic	7 (47%)	8 (53%)	0.65
2. Inflammatory	3 (20%)	3 (20%)	1.0
3. Idiopathic	5 (33%)	4 (27%)	0.67

In the triamcinolone group the recurrence of stricture happened in 2 out of the 15 patients (13%) while the stricture recurrence had occurred in 6 patients out of 15 in the control group (40%). These results show statistically significant differences between both groups with the P-value = 0.048. So the stricture stabilization and cure rate was 86% in cases who used triamcinolone during self dilatation versus only 60% in the plain group who didn't use steroid during dilatation. Patients with recurrent urethral stricture underwent a second attempt of DVIU and re-scheduled on ISCD during the period of follow-up for another 12 months after second attempt of DVIU. The success was achieved urethra was stabilized in all patients in the triamcinolone group (100%) and in 4 out of 6 patients in the control group (66%) without any re-stricture during the follow-up period after second attempt of DVIU. These results were also statistically significant (P=0.014).

Regarding complications after DVIU and ISCD, there were no reported significant systemic or local complications like febrile urinary tract infection, retention, sepsis or bleeding. Meanwhile, no specific sequels are seen related to the application of triamcinolone ointment in all patients involved in this study. In addition, regarding the relation of re-stricture rate and age of patients, no significant statistical correlation was found.

With regard to the urethral stricture length and its relation to the recurrence rate, there was a statistically significant correlation between them with the mean length of stricture was 1.67 ± 0.3 cm in patients with re-stricture during follow-up period and 1.36 ± 0.36 cm in patients without recurrence (P-value = 0.037). Also the recurrence of stricture was earlier in those who not using triamcinolone during ISCD and the mean time duration to stricture recurrence in the control group was much shorter than the triamcinolone group (5.8 ± 2 months vs. 9.5 ± 0.5 months respectively), and this difference was significant statistically (P = 0.048).

DISCUSSION

In our prospective study, we conclude that the use of steroid during ISCD after optical urethrotomy the recurrence rate of stricture significantly from 40% to 14% and raise the successful stabilization of urethral stricture after DVIU to approach 86% which significantly higher than that achieved with self catheter dilatation without steroid usage which was only 60%. This was confirmed also by a study of Wesley Verla and his colleagues in a meta-analysis big study from 978 records involving 250 patients where they found that steroid use during self dilatation had achieved 77% success rate versus 64% in non-steroid users.^[18]

Prajsner *et al.*^[19] had proved that although it has been associated with high recurrence rates, Prajsner *et al.*^[19] internal visualization urethrotomy alone has been recommended as a good choice for anterior urethral strictures that are shorter than 1.5 cm. In a study concluded by Heyns *et al.*^[20], they found that after the first DVIU the urethral stricture recurrence rate was reported in almost half of cases, which may be reduced to almost zero after second and third time of DVIU. This also proved in our study where after a second attempt of DVIU that was done in patients who suffered from recurrence during follow-up the successful rate was achieved in all cases in the steroid use arm and in two third of cases that not used steroid during self dilatation.

In our study we found no relationship between urethral stricture rate and several parameters like the age of patients, length of stricture, site of stricture in the anterior urethra, and underlying causes of stricture, which is the same conclusion that obtained by Ishigooka and associates who also concluded that urethral stricture length had been proved to influence significantly the outcome of DVIU regardless of the usage of steroid during self catheter dilatation with a recurrence rate of only 4.4% in those short urethral strictures, while it was much higher at 42.9% in those longer urethral strictures which is the same as our conclusion where higher recurrence rate was seen in those with longer stricture.^[21]

The results of the study of Regmi *et al.*^[17] also confirmed that applying triamcinolone ointment to ISCD dilation regimen had significantly reduced the recurrence rate of urethral stricture after internal optical urethrotomy because its application is so easy to be use by patients and with low cost, and minimal or no risk of complications, which was the same as the result of our study.

A recent systematic review and meta-analysis conducted in 2022 by Christopher Soliman and his colleagues, they analyze seven studies in which 365 participants were randomized to DVIU plus local urethral steroids versus DVIU only, and they concluded that the application of local steroids appeared to reduce recurrence rates (risk ratio, 0.67; 95% confidence interval [CI], 0.49–0.90) and time-to-recurrence (hazard ratio, 0.58; 95% CI, 0.39–0.85). Maximum urinary flow rate (Qmax) also improved following steroid application (mean difference, 0.82; 95% CI, -1.02–2.66). Although the Qmax parameter was not studied in our research, all other results support our conclusion.^[22]

During 2023, a systematic review and meta-analysis was undertaken by the European association of urology which also corroborates our results regarding effectiveness and complications of adjuvant use of steroid dilatation. It

included five randomized controlled trials composed of 250 cases, and the conclusion was successful stabilization of the stricture was achieved in 77% and 64% of patients in the group with and without corticosteroids, respectively ($p=0.04$). No extra complications related to the addition of corticosteroids to the ISCD regimen were reported.^[18] Another emerging mode to reduce recurrence of urethral stricture after optical internal urethrotomy is intralesional injection during DVIU, we conclude from our previous study that supplemental intralesional injection therapy of urethral stricture with triamcinolone or mitomycin-C had supported a much better recurrence rate than optical stricture incision alone during urethrotomy incision procedure.^[23]

CONCLUSIONS

The recommendation of topical steroid ointment use during ISCD has a greater chance of decreasing the re-stricture rate after performing DVIU and improving the outcome of this procedure, so with minimal drawbacks of topical steroids and its limited added cost, this easy to learn technique by our patients is highly recommended to be used by most of patients with minimal adding cost on the patients or on the health resources.

Recommendations

Longer follow-up of patients and larger samples of cases are required to better delineate its effectiveness and safety in long-term use. However, such a simple and cheap technique with minimal drawbacks and good outcome can be recommended to all patients with urethral stricture who underwent endoscopic incision.

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