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Original article

Does mitomycin-C and triamcinolone injection therapy during optical urethrotomy able to reduce the recurrence of urethral stricture? A comparison study.

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Abstract:

- ***Background***: Male urethral stricture is one of the common diseases. Stricture disease may lead to severe complications which badly affect the quality of life like urinary tract infection, vesical stones, urethrocutaneous fistulas, sepsis, and finally renal impairment. Due to its high recurrence rates, it is one of the most complex and challenging issues in urological practice. The aim of the study is to evaluate the effect of intralesional mitomycin-C and triamcinolone after direct visualized internal urethrotomy on the recurrence of urethral stricture.
- ***Method and patient:*** An observational comparative study that was conducted between September 2019 and October 2021. It included 34 male participants with urethral stricture. Twelve participants were in group A in whom participants underwent direct visualized internal urethrotomy with no adjuvant treatment, 11 participants were in group B who underwent direct visualized internal urethrotomy with mitomycin-C injection and another 11 patients underwent direct visualized internal urethrotomy with triamcinolone injection were in group C. Patients were selected from outpatient clinic. Patients with idiopathic causes of stricture, traumatic non-instrumental or post-urethroplasty stricture, recurrent stricture and stricture more than 15 mm in length were excluded from the study. Follow up was done at 3, 6 and 12 months post-operatively.
- ***Result:*** In this study, only one patient among 11 who received mitomycin-C injection (9.1%) had recurrence while 2 out of 11 patients who received triamcinolone (18.2%) had recurrence. Six out of 12 patients (50%) who undergone direct visualized internal

urethrotomy only had recurrence. Adjuvant therapy decreased the recurrence rates, and the results were statistically significant. No correlation between stricture recurrence time and the type of adjuvant therapy used was found. Relationship between recurrence rate of stricture and various other variables such as age of the patient, length of stricture, stricture site and etiology were not observed in the study as the p-value was greater than 0.05.

- ***Conclusions:*** Intralesional injection of either Mitomycin-C or Triamcinolone reduces the recurrence rate of urethral strictures with statistically significant results.
- **Keywords:** Urethral stricture, mitomycin-C, triamcinolone, direct visualized internal urethrotomy.

INTRODUCTION

Urethral stricture is a known historical disease even before the century. It's peculiar to male because female urethra is wide and capacious and hardly affected by stricture disease [(1)].

Stricture disease may lead to severe complications which badly affect the quality of life like urinary tract infection, vesical stones, urethrocutaneous fistulas, sepsis, and finally renal impairment. In untreated patients, the natural history of the disease runs a severe progressive course with high rates of complications due to disease recurrence even after treatment [(2)].

Although the treatment of urethral stricture is developing, it is still one of the most complex and challenging subjects in urological work [(3)].

Urethroplasty is the gold standard and definitive treatment for urethral stricture. It is considered the most durable treatment with lifetime success rates approaching 98%. However, strictures may recur long after urethroplasty. Consequently, long-term surveillance for stricture recurrence following urethroplasty is an essential component of disease management [(4)].

The underlying etiologies of urethral stricture disease varies in different geographical areas. During the last decades, it is documented that infection-induced urethral stricture has decreased, especially in the developed countries [(5)]. The causes of urethral stricture are:

1. Iatrogenic-induced are the most common etiology for anterior urethral stricture [(3)]. Urethral catheterization is the most common iatrogenic cause, followed by hypospadias reconstruction and transurethral resection procedures.
2. Idiopathic strictures of unknown etiology occur more frequently in the bulbar urethra and are more common in younger peoples than olders (48% vs. 23%).
3. Falling astride injury causes scarring of the bulbar urethra including the surrounding spongiosum tissue.

4. Inflammatory stricture involves the infection-induced inflammatory reaction which leads to narrowing of the urethral lumen. This inflammatory stricture is considered to be the leading cause in underdeveloped countries, while in developed countries, lichen sclerosus et atrophicus is more frequently seen as an inflammatory stricture and usually involves the whole urethra [6].

Regarding the site of occurrence, the bulbar urethral strictures are the most common site (about 50%), penile urethral strictures come next (about 30%), followed by the navicular fossa (about 20%). The posterior urethral strictures are less common and frequently caused by traumatic urethral rupture secondary to pelvic bone fractures and to much less extent result from pelvic radiotherapy for treatment of prostate cancer [7].

Urethral stricture is a relatively common disease in men with an associated lifetime prevalence of 200-600 per 100,000 males. Pathologically speaking, the connective tissue of normal urethra is replaced by dense fibers interspersed with fibroblasts and a reduction in the type III to type I collagen ratio happens. These changes are accompanied by reduced ratio of smooth muscle to collagen, as well as significant loss in the synthesis of nitric oxide in stenosed urethral tissue. Spongiofibrosis of corpus spongiosum is the main pathology of anterior urethral strictures which typically happen following trauma or infection [2].

A thorough history and detailed physical examination are the key to initial diagnosis of urethral stricture. In history, we should ask about details of previous urethral catheterization or endoscopy, genital trauma, features of urethral inflammation and sexually transmitted infections such as urethral discharge, bleeding, and dysuria [8].

Obstructive and irritative voiding symptoms are the main symptoms of urethral stricture and its diagnosis should be suspected particularly in patients who have previously undergone transurethral surgery or had a history of long-term indwelling catheter during management for other disorders. Prolonged voiding time and a feeling of incomplete bladder emptying, combined with daytime and night-time frequency and urgency to void. Some patients may also be presented with typical sequelae of high voiding pressure such as prostatitis or epididymitis. Minority of patients do not present until acute urinary retention happens, since early in the course of the disease, detrusor hypertrophy can compensate for the raised bladder outlet resistance. This leads to a rise in intravesical pressure during urination and may be noticed on ultrasonography as a thickening of the bladder wall. Later, decompensation of the bladder voiding function and incomplete voiding will occur with raised post-void residual urine volume, which may progress into complete urinary retention. At the end, these changes can lead to secondary urinary tract obstruction or high-pressure vesicoureteral reflux, either of which may lead to impairment of renal function [7].

During physical examination, the clinician should examine the urethra to identify fibrotic tissue and look for skin changes (e.g., Balanitis xerotica obliterance), the presence of mental stenosis, cellulitis, fistulas, or abscesses, the presence and quality of foreskin to potentially use in later urethral reconstruction and the presence of scars from previous trauma or surgical repair. These surgical scars may reveal important information about the type of prior reconstruction which is sometimes unknown to the patient. Ideally, the examination of the patient also includes a digital rectal examination (benign prostatic hyperplasia; prostatitis) and an evaluation of the scrotum and testicles which might reveal an epididymitis or an orchitis [(9)].

Typical options for evaluation of urethral stricture include uroflowmetry, urethroscopy, retrograde urethrography (RUG), voiding cystourethrography (VCUG), and color doppler ultrasound. The AUA guidelines insisted that retrograde urethrography and/or urethroscopy are necessary to make the diagnosis of a urethral stricture [(10)].

The approach to urethral stricture disease is mainly driven by the anatomical site of the stricture, whether it is in the penile, bulbar, or posterior urethra, and its relationship to the external urethral sphincter muscles [(11)]. Dilation and direct visualized internal urethrotomy (DVIU) continue to lead the treatment for urethral strictures. The principle of DVIU is to incise the stricture by cold or hot knife or laser fiber following which, a catheter is left in situ for several days to splint the urethra open, allowing re epithelialization [(12)]. The most performed procedures for treatment of stricture diseases among board-certified urosurgeons are dilation (95%) and DVIU (85%). However, these minimally invasive procedures are characterized by a well-documented high failure rate [(13)]. The most common early complications of DVIU are urethral bleeding and perineal hematoma with up to 20% incidence of each of these complications. The most frequent late complications include erectile dysfunction, in 7% of cases, and recurrence of stricture in 50% [(14)].

Urethroplasty is the definitive surgical treatment for urethral stricture and enjoys a high success rate between 85 and 90% for simple procedures and about 80% for extremely complex repairs. Data show that when compared with urethral dilation or DVIU, open urethroplasty provides the best chance at definitive success with low recurrence rate [(13)]. In fact, multiple studies evaluated cost-effectiveness of treatment of urethral strictures and found that either early or immediate urethroplasty or a single attempt at DVIU, followed by urethroplasty if its failed. This strategy is more cost-effective than long-term dilation, or multiple DVIU procedures with urethroplasty used only as salvage procedures after failure of several attempts do dilation or DVIU [(14)].

Although numerous percentages of patients undergoing initial minimally invasive treatment of urethral stricture can achieve successful early outcome with satisfactory results, a significant percentage of patients may develop recurrent, refractory or recalcitrant stricture disease. Hence,

this group of patients with recurrent disease may pose clinical dilemmas and their definitive management can be challenging to reconstructive urosurgeons with high failure rate of salvage urethral reconstructive procedures [29]. Table 1 lists the factors which should be considered as risk factors for recurrence of urethral strictures [15].

Table 1. Factors important for urethral stricture recurrence [15].

Age	Length	Location	Etiology	Recurrent
Good prognosis	<2cm	Bulbar urethra	Idiopathic	No
Poor prognosis	>2cm	Penile urethra	Inflammatory, Iatrogenic, Lichen sclerosis	Yes

Mitomycin-C is an antibiotic with cytotoxic properties first isolated from Streptococcus caespitosus and later shown to have potent antineoplastic actions in vitro and in vivo. MMC as a potential antifibrotic agent and intravesical chemotherapeutic agent to treat urological conditions and tumors shows promise to decrease and delay the recurrence rates of many neoplasms with minimal toxic systemic side effects [16]. In a very recent data from interesting studies, their work up studied the efficacy of using intralesional MMC (injections of 0.4-mg/mL MMC in 0.2- to 0.4- mL aliquots at various points along the length of each incision for a total volume of 10 mL) with clean intermittent catheterization (CIC) and visual internal urethrotomy (VIU) for management of recurrent urethral strictures and bladder neck contractures and they finally offered all of these interventions and maneuvers can provide minimally invasive and widely available tools for managing urethral strictures which is less than 3 cm and bladder neck contractures specially for patients who are poor candidates for or refuse open surgery [17]. Side effects of systemic mitomycin include nausea, vomiting, rash, fever, bone marrow suppression, diarrhea, stomatitis and malaise. Uncommon but potentially severe adverse events include hemolysis, neurological abnormalities, hemolytic uremic syndrome, renal impairment and interstitial pneumonitis [18].

Triamcinolone falls under the class of corticosteroids—specifically a glucocorticoid. It exhibits anti-inflammatory and immunosuppressant activity via inhibiting the phospholipase A2 enzyme on the cell membrane phospholipid layer, and thereby hinders the breakdown of leukocyte lysosomal membranes and prevents the formation of arachidonic acid. It ultimately reduces the expression of cyclooxygenase (COX) and lipoxygenase (LOX) and thus prevents the biosynthesis of prostaglandins and leukotrienes, respectively [19]. Corticosteroids manifest anti-inflammatory effects via inhibiting macrophage and leukocyte migration to the affected site by reversing vascular dilation and permeability. These actions work to minimize edema, erythema, and pruritus. An important anti-inflammatory mechanism gets mediated by the inhibition of

nuclear factor kappa-B (NF-kappa-B) which leads to decrease protein expression of interleukin-6 (IL-6), interleukin-8 (IL-8), monocyte chemo-attractant protein-1 (MCP-1), COX-2(20). The aim this study to evaluate the effect of intralesional mitomycin-C and triamcinolone after direct visualized internal urethrotomy on the recurrence rates of urethral stricture and timing of recurrence.

PATIENT and METHOD

This study was a comparative study which involved 34 male patients diagnosed with urethral stricture divided into three groups:

1. Group (A) with 12 participants underwent direct visualization internal urethrotomy.
2. Group (B) with 11 participants underwent direct visualization internal urethrotomy with submucosal MMC injection.
3. Group (C) with 11 participants underwent direct visualization internal urethrotomy with submucosal triamcinolone injection.

The study was conducted between September 2019 to October 2021. Participant had been selected from outpatient clinic. A questionnaire had been prepared and a detailed full urological and medical history had been obtained. All patients reported features of urinary obstruction. Full clinical examination had been conducted and laboratory investigations had been ordered for the participants and involved complete blood count and general urine examination. Diagnosis has been confirmed by both flexible cystoscopy and retrograde urethrography (RUG).

Participant should have the following criteria in order to be involved in the study:

1. Aged between 20 – 60 years.
2. First time stricture
3. Stricture due to either infection or instrumentation
4. Stricture less than 15mm in length

Any participant with any of the following settings has been excluded from the study:

1. Age less than 20 years and more than 60 years
2. Idiopathic causes of stricture
3. Traumatic non instrumental or post urethroplasty stricture
4. History of recurrent stricture
5. Stricture more than 15 mm in length

Prophylactic antibiotics in the form of third generation cephalosporin or fluoroquinolone were given to all patients 1 hour prior to surgery. For group A, direct visualization internal

urethrotomy (DVIU) was done under anesthesia using a rigid cystoscope with cold knife. Incision of the stricture was done at 12 o' clock along the stricture length. Foley catheter has been placed for all patients and had been removed after 5-7 days plus prophylactic antibiotic were prescribed. Mitomycin-C and triamcinolone were prepared at the day of operation. MMC vial 10 mg were diluted with 100 cc normal saline.

In group B, following direct visualization internal urethrotomy, 1 ml of 0.1 mg/ml of mitomycin-C was injected at the edge of the scar at multiple sites for every 1 cm of stricture using metallic needle used for Botox injection or INJETAC needle. Foley catheter has been placed for all patients and had been removed after 5-7 days plus prophylactic antibiotic were prescribed. In group C, following direct visualization internal urethrotomy, 1 ml of 40 mg/ml of triamcinolone suspension was injected at the edge of the scar at multiple sites for every 1 cm of stricture using metallic needle used for Botox injection or INJETAC needle. Foley catheter has been placed for all patients and had been removed after 5-7 days plus prophylactic antibiotic were prescribed. All participants were being followed up initially after the surgery to look for complications. Late follow up was done at 3, 6- and 12-months post operatively. Inquiries about urinary tract obstruction features with clinical examination were obtained. Urethroscopy and retrograde urethrography was performed at each visit.

The statistical analysis of the data was done, and quantitative continuous variables were presented as mean and standard deviation. Categorical nominal and ordinal variables were presented in the form of frequencies and percentages. One-way ANOVA test was used to compare the continuous variables among study groups accordingly. To test for normal distribution, a Z test were used. Chi square test had been conducted to compare the categorial variables. Kruskal–Wallis test were conducted to compare quantitative with nominal data out of normal distribution. A level of P-value less than 0.05 was considered significant. All patients were informed about methodology and purpose of study and written consent was obtained.

RESULTS

The age of participants was ranging from 21 to 60 years with a mean of 40.0 years ± 12.136 standard deviation with different age range among different causes of urethral stricture. In terms of stricture site, most of the participants had stricture at bulbar urethra with a percent of 66.7%, 72.7% and 63.6% for group A, B and C respectively. The percent of patients with stricture at the penile urethra were 33.3%, 27.3% and 36.4% for group A, B and C respectively. The stricture was due to either an infection or trauma due to instrumentation but most of the patients had a secondary stricture due to infection with a percent of 66.7%, 63.6% and 54.5 % for group A, B and C respectively. The rest of patients were due to instrumentation.

Only one patient from 11 in group B (MMC) had recurrence with a rate of 9.1% while in group C (triamcinolone), 18.2% (2 patients) of the participant had a recurrence. In the control group A, 50% of participant had recurrent urethral stricture. it is clear that the result is statistically significant for those who had MMC and triamcinolone injection as the p-value is 0.027.

Table 2. Recurrence rates among different study groups.

	Group A		Group B (MMC)		Group C (Triamcinolone)	
	Number	Percent %	Number	Percent %	Number	Percent %
Recurrence	6	50.0	1	9.1	2	18.2
No recurrence	6	50.0	10	90.9	9	81.8

Although the stricture recurrence time mean in patients received MMC were longer than the other groups, correlation between recurrence time and type of adjuvant therapy is not significant as the Kruskal-Wallis H value was about 0.858 and the p-value was 0.651. This correlation is illustrated in table3.

Table 3. Average stricture recurrence time among study groups.

	Group A	Group B (MMC)	Group C (Triamcinolone)	P value
	Mean ± STD	Mean ± STD	Mean ± STD	
Recurrence time (months)	7.17 ± 3.971	11.0 ± 0	9.5 ± 3.536	0.651

The mean of stricture length in participants who had recurrent urethral stricture is 9.67+2.875, 14.0+0, 11.0+828 for group A, B, and C respectively. When conducting statistical analysis to correlate between these variables, it appeared that there is no statistical correlation as the p-value is 0.521. The mean of age in participants who had recurrent urethral stricture is 47.0 ± 8.319, 32.0 ±0, 44.0 ± 12.728 for groups A, B, and C respectively, which seems to be statistically insignificant as the p-value is 0.643.

Regarding etiology of stricture and stricture recurrence, 6 patients with post infectious stricture had recurrence: 3 of them in group A, 1 in group B (MMC) and 1 in group C (triamcinolone). Three patients with post-instrumentation stricture had recurrence: 2 patients in group A while only 1 in group C (triamcinolone). When comparing those data among the three study groups, we found out the stricture recurrence and etiology had no significant association as the p-value was 0.724, as seen in figure 1.

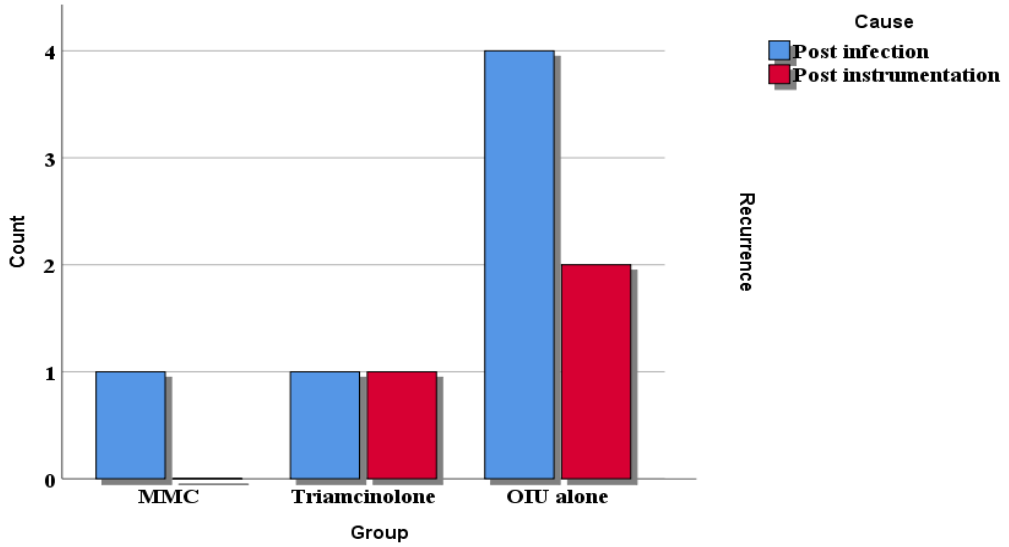

Figure 1. Stricture recurrence and etiology.

It is shown that the stricture recurrence in regard to stricture site, 7 cases of bulbar stricture had recurrence; 5 cases in group A while 2 cases in group C. Two cases of penile stricture had recurred; one case in group A and the other case in group B. Again, no statistical correlation was found between the site and stricture recurrence as the p-value was 0.449, as shown in figure 2.

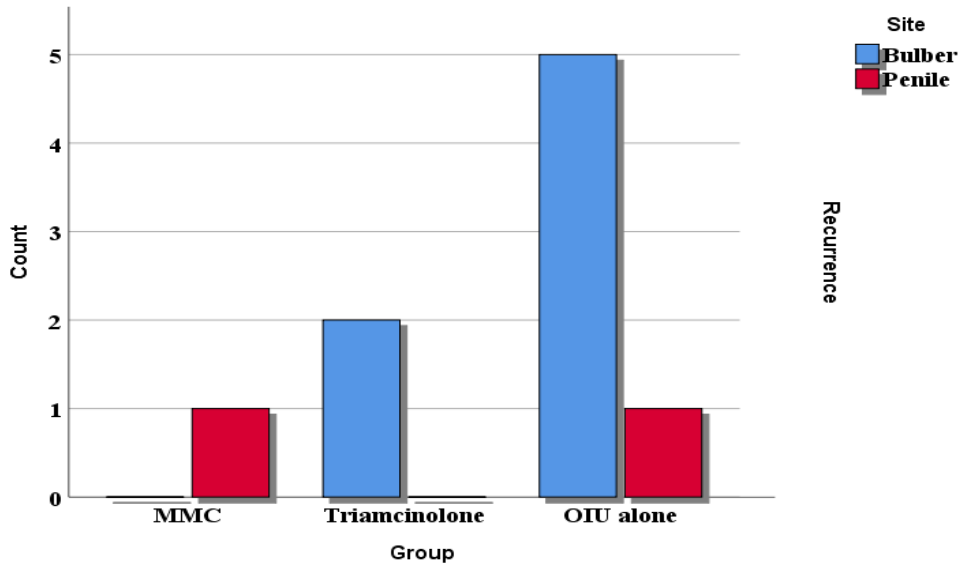

Figure 2. Stricture recurrence and site of stricture.

DISCUSSION

When comparing our data with patients did direct visualization internal urethrotomy without adjuvant treatment (50% had recurrence); the data was statistically significant as the p-value was 0.007 (group B); this agrees with Ali et al [21] and Farrell et al [22]. Ali et al found that 14.1% of participants with DVIU and MMC injection had recurrence as compared to 36.9% rate of recurrence for those undergone DVIU alone. Farrel et al found that 75.7% of participants had no recurrence with DVIU and MMC injection. For those who underwent DVIU and triamcinolone injection, our study conducted that the recurrence rate was 18.2% with a statistically significant p-value of 0.035 which agrees with Mazdak et al [23] and Yıldırım et al [24]. Mazdak et al found that 21.7% of participants had recurrence for those undergone DVIU with triamcinolone injection while 50% for those who undergone DVIU alone had recurrence [23]. Yildirim et al found that a lower rate of recurrence with triamcinolone injection (5% of participants) [24].

After following up the patients for 12 months, our study showed that it took those patients after MMC injection longer time to recur but statistically; no correlation between stricture recurrence time and the type of adjuvant therapy used was found as the p-value was 0.651. This result disagrees with Ali et al as it states that most of participants with MMC injection had recurrence at mean of 6 months following injection which was more delayed than those undergone DVIU alone and it was statistically significant [21]. This difference could be possibly explained previously by the larger sample size, longer follow up time and inclusion of anterior strictures

only in their study. Regarding stricture length, mean stricture length was 9.12mm but no significant correlation was found between recurrence rates and stricture length as the p-value was 0.521. This disagrees with Mazdak et al as it stated that the success rates were higher in those with shorter stricture length [23].

In terms of age, our study did not find a correlation between age of the participants and stricture length as the p-value was 0.643. Regarding etiology of stricture, despite the slightly higher success rates in post instrumentation cases, those results were not significant statistically with a p-value of 0.724. Mazdak et al concluded similar results with a difference of including idiopathic cases of stricture in addition to infectious and traumatic causes in their study [23].

Regarding location, patients who had recurrence in group A involved both bulbar and penile stricture. Recurrent stricture in group B occurred in one patient with bulbar stricture while those who had recurrence in group C had penile location of stricture. Overall, no significant correlation was recorded between stricture site and recurrence with a p-value of 0.449.

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Conflicts of interest:

There are no conflicts of interest**.**

CONCLUSION

Supplemental injection therapy of urethral stricture during urethrotomy incision procedure confirmed better recurrence rate than stricture incision alone, but larger sample studies with longer follow up periods are required to better outline the benefit of theses adjuvant drugs, and their dosage and drawbacks.

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