



DOUBLE BLIND STUDY TO ASSESS EFFICACY OF INJECTION MITOMYCIN POST VIU

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ABSTRACT

Aim:- To evaluate the efficacy of intralesional Mitomycin C injection in reducing recurrence rates and improving urinary flow following direct visual internal urethrotomy (VIU) in patients with short-segment bulbar urethral strictures.

KEYWORDS :

INTRODUCTION

In males, a urethral stricture refers to a narrowed segment of the anterior urethra due to a process of fibrosis and cicatrization of the urethral mucosa and surrounding spongiosus tissue ("spongiofibrosis") [1,2]. In the male posterior urethra, there is no spongiosus tissue and at this location the terms stenosis is preferred [1,2].

Urethral stricture is a relatively common disease in men with an associated prevalence of 229-627 per 100,000 males, or 0.6% of the at risk population, who are typically older men [3].

The burden of urethral stricture disease in India has not been reported, but the etiology patterns have been reported in limited studies. A study of over 400 patients in eastern India has reported iatrogenic injury as the most frequent cause. Urethral catheterization was a more frequent cause than transurethral surgery in this population. [4] most urologists perform DVIU as the initial management of urethral strictures especially bulbar urethral strictures upto 2 cm as it is minimally invasive procedure with less morbidity [5]. Success rate after initial urethrotomy was 35.5% [6]. Success of VIU depends on complete progress of epithelisation before wound contraction. Nevertheless, if wound contraction occurs before completion of the epithelialisation, stricture recurs. Therefore, scientists used anti-fibrotic drugs, such as mitomycin C (MMC), botulinum toxin A, somatostatin analogue and corticosteroids, as an adjunctive therapy to delay wound contraction, hence improving USD recurrence [7].

MATERIALS AND METHODS

This is randomized control trial with double blind study done in a tertiary care center over the period of 1 year between march 2024 to march 2025 Sample size calculated using

Parameters

Control group success -35% [6] ($p_1 = 0.35$)

Mitomycin group success - 70% ($p_2 = 0.70$)

Power -80%

Significance level -0.05

Allocation ratio -1:1

$$n_1 = (Z_{1-\alpha/2} + Z_{1-\beta})^2 \frac{p_1(1-p_1) + p_2(1-p_2)}{(p_1 - p_2)^2}$$

$Z_{1-\alpha/2} = 1.96$ for 95% confidence interval

$Z_{1-\beta} = 0.84$ for 80% power

Sample size = 60 (30 per group)

Inclusion Criteria:-

1. Male
2. Bulbar urethral stricture
3. Single stricture < 2 cm

Exclusion Criteria:-

1. Multiple strictures
2. History of urethroplasty or previous VIU
3. > 2cm stricture
4. Obliterative stricture

Methodology:-

Patients were randomized into two groups: group A study group in which viU with inj mitomycin given group B (control) in which viU alone done.

In preop evaluation, UFR with PVR, USG KUB full bladder with PVR, RGU done.

Procedure was done under spinal anesthesia. Patient kept in lithotomy position. Guidewire 0.035" kept. VIU done @ 12 o'clock position with sache's cold knife.

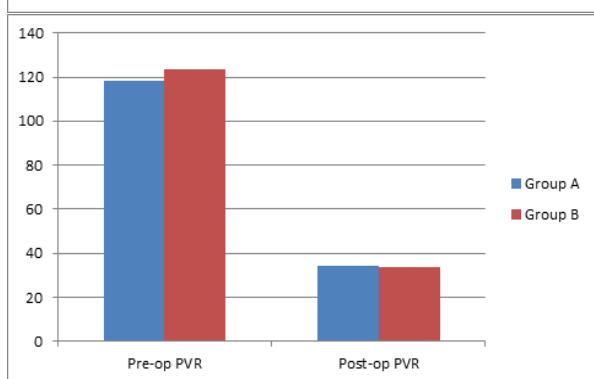
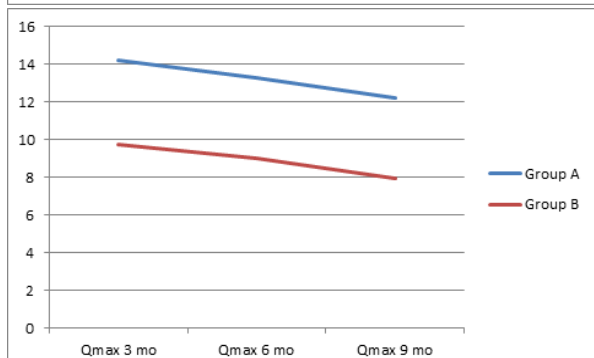
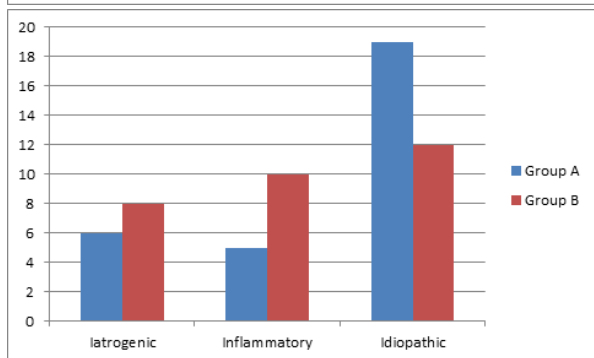
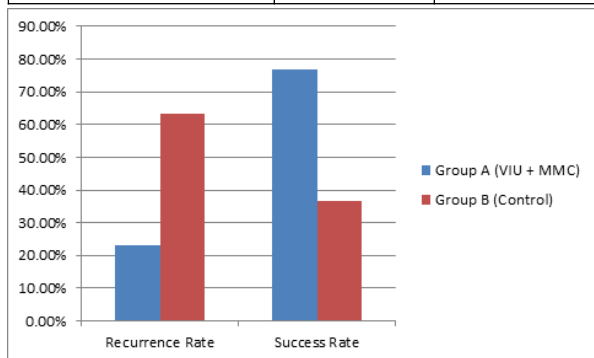
Post VIU, cystoscopic injection needle used to inject mitomycin 4mg over incision site in group A patients [7]. Injection mitomycin (0.4 mg/kg) was prepared by diluting in 40 mL NS then taking 4ml of it for injecting into the lesion.

Post procedure catheter was kept in all patients for 7-10 days.

Patient was followed up after 7-10 days for per urethral catheter removal and UFR with PVR. Patients were followed up after 3 months, 6 months and 9 months. Parameters checked were complaint of LUTS, UFR with PVR. RGU was done in patients with box pattern in UFR.

Success was defined as no complaint of LUTS, max velocity of atleast 15mL/sec, by UFR or no visible stricture by RGU if done. Failure of VIU was considered if patient required additional procedures like urethral dilatation or another operation.

Parameters	Group A (VIU + MITOMYCIN)	Group B (Control group)
age	49.8	52.4
Etiology of stricture-		
a) Iatrogenic	6	8
b) Inflammatory	5	10
c) Idiopathic	19	12
Qmax 3months	14.23	9.77
Qmax 6 months	13.27	9.00
Qmax 9 months	12.23	7.97
Preop PVR	118.23	123.57
Postop PVR	33.97	33.43
No. of Recurrence	7	19
Recurrence rate	23.3 %	63.3 %
Success rate	76.7 %	36.7 %



DISCUSSION

Urethral stricture disease presents a recurrent challenge in urologic practice, often requiring multiple interventions due to its high likelihood of relapse. Although direct visual internal urethrotomy (VIU) is commonly employed as the initial treatment for short bulbar urethral strictures because of its low morbidity and procedural simplicity, its long-term efficacy is limited. Previous studies have reported success rates of VIU as low as 35.5%, with a significant proportion of recurrences linked to early fibrotic activity that precedes complete epithelial healing [6].

In this randomized double-blind trial, we investigated whether intralesional administration of Mitomycin C (MMC) post-VIU could improve treatment outcomes by reducing recurrence rates. Our study demonstrated a notable reduction in recurrence in patients receiving MMC (23.3%) compared to those undergoing VIU alone (63.3%). The corresponding success rates-76.7% in the MMC group versus 36.7% in the control group-highlight the potential benefit of this adjunctive approach.

The mechanism underlying MMC's effectiveness is attributed to its anti-proliferative and anti-fibrotic actions. By delaying fibroblast activity and collagen deposition, MMC provides an extended window for epithelial regeneration, reducing the risk of restenosis. Our findings are consistent with previous research indicating improved outcomes when anti-fibrotic agents are used to augment urethrotomy.

Additionally, sustained improvements in urinary flow rate (Qmax) were observed across 3-, 6-, and 9-month follow-up periods in the MMC group, indicating prolonged urethral patency. Notably:

- Qmax at 3 months was 14.23 ml/sec in the MMC group vs. 9.77 ml/sec in controls.
- At 6 months, values were 13.27 ml/sec and 9.00 ml/sec respectively.
- At 9 months, Qmax further declined to 12.23 ml/sec in the MMC group but remained higher than the control group (7.97 ml/sec).

Although both groups demonstrated reduced post-void residual urine (PVR) values post-procedure, the similarity in this metric suggests that PVR may not be as sensitive a marker of long-term success as Qmax or recurrence rates.

The safety of intralesional MMC was also reaffirmed in our trial. No significant complications were observed in the study group, consistent with reports from previous literature that describe the local use of MMC as generally well-tolerated, with minimal adverse events [7].

While the study offers promising results, limitations include a limited sample size and relatively short duration of follow-up. Additionally, strict inclusion criteria limit applicability to more complex stricture cases. Future studies with longer-term observation and larger cohorts would be beneficial for confirming these findings.

CONCLUSION

The intralesional injection of Mitomycin C following VIU significantly enhances treatment success by reducing stricture recurrence and sustaining urinary flow in patients with short-segment bulbar urethral strictures. Its ease of use, combined with a favorable safety profile, makes MMC a compelling adjunctive therapy. Incorporating MMC into standard practice may improve long-term outcomes in appropriately selected patients.

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