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INTRALESIONAL TRIAMCINOLONE ACETONIDE AS AN ADJUNCT TO DIRECT VISUAL INTERNAL URETHROTOMY FOR SHORT ANTERIOR URETHRAL STRICTURE: A PROSPECTIVE RANDOMIZED CONTROLLED STUDY

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ABSTRACT

Background. Direct visual internal urethrotomy (DVIU) is widely used for short anterior urethral stricture, but recurrence due to recurrent fibrosis remains a major limitation. Intralesional triamcinolone has anti-inflammatory and anti-fibrotic effects that may suppress restricture formation.

Methods. This prospective randomized controlled study included men aged 18–65 years with symptomatic anterior urethral stricture ≤2 cm confirmed by retrograde urethrography. Patients were allocated 1:1 to DVIU plus intralesional triamcinolone acetonide 80 mg or DVIU alone and followed for 12 months.

Results. Fifty-four patients were randomized; 24 intervention patients and 26 controls were available for the 12-month endpoint. Baseline characteristics were comparable. Recurrence at 12 months was 25.0% with triamcinolone versus 53.8% with DVIU alone (p=0.048). Recurrence-free survival favored the intervention group (log-rank p=0.014). Mean time to recurrence was 9.33±1.21 versus 7.07±2.13 months (p=0.03). Qmax was higher and PVR lower during follow-up in the intervention group. No steroid-related complications were reported.

Conclusion. Intralesional triamcinolone acetonide appears to be a simple and well-tolerated adjunct to DVIU that may reduce recurrence and prolong recurrence-free survival in selected patients with short anterior urethral stricture. Larger multicenter studies with longer follow-up are warranted.

KEYWORDS: urethral stricture; DVIU; triamcinolone acetonide; spongiofibrosis; recurrence; uroflowmetry; Qmax.

1. INTRODUCTION

Urethral stricture disease (USD) is a chronic fibrotic disorder characterized by narrowing of the urethral lumen due to fibrosis of the corpus spongiosum and periurethral tissues (figure1). It is an important cause of bladder outlet obstruction in men and is associated with recurrent treatment and impaired quality of life[1]. The reported prevalence is approximately 229–627 cases per 100,000 men, with incidence increasing with age[1]. The etiology of USD is multifactorial. Contemporary epidemiological studies have demonstrated that iatrogenic injury accounts for nearly 45% of cases, followed by idiopathic, traumatic, and inflammatory causes[4] . Treatment options include urethral dilatation, DVIU, and urethroplasty. Urethroplasty provides the most durable results, but DVIU remains attractive for selected short anterior stricture because of its minimally invasive nature and shorter recovery[6] . The principal limitation of DVIU is recurrence caused by reactivation of wound-healing pathways, fibroblast proliferation, and excessive collagen deposition at the urethrotomy site. Long-term recurrence after DVIU has been reported in the range of 40–70% in selected series[6,7]. Triamcinolone acetonide is a potent corticosteroid with anti-inflammatory and anti-fibrotic actions, including inhibition of fibroblast proliferation, collagen synthesis, extracellular-matrix deposition, and TGF-β-mediated fibrotic signaling[8,9] (figure2) . Clinical studies have reported lower recurrence and improved urethral patency when intralesional steroid therapy is used after urethrotomy, although published studies vary in sample size, technique, dosage, and follow-up duration 10–12. The present study evaluated the efficacy and safety of intralesional triamcinolone acetonide following DVIU in men with short anterior urethral stricture, with recurrence at 12 months as the primary endpoint.

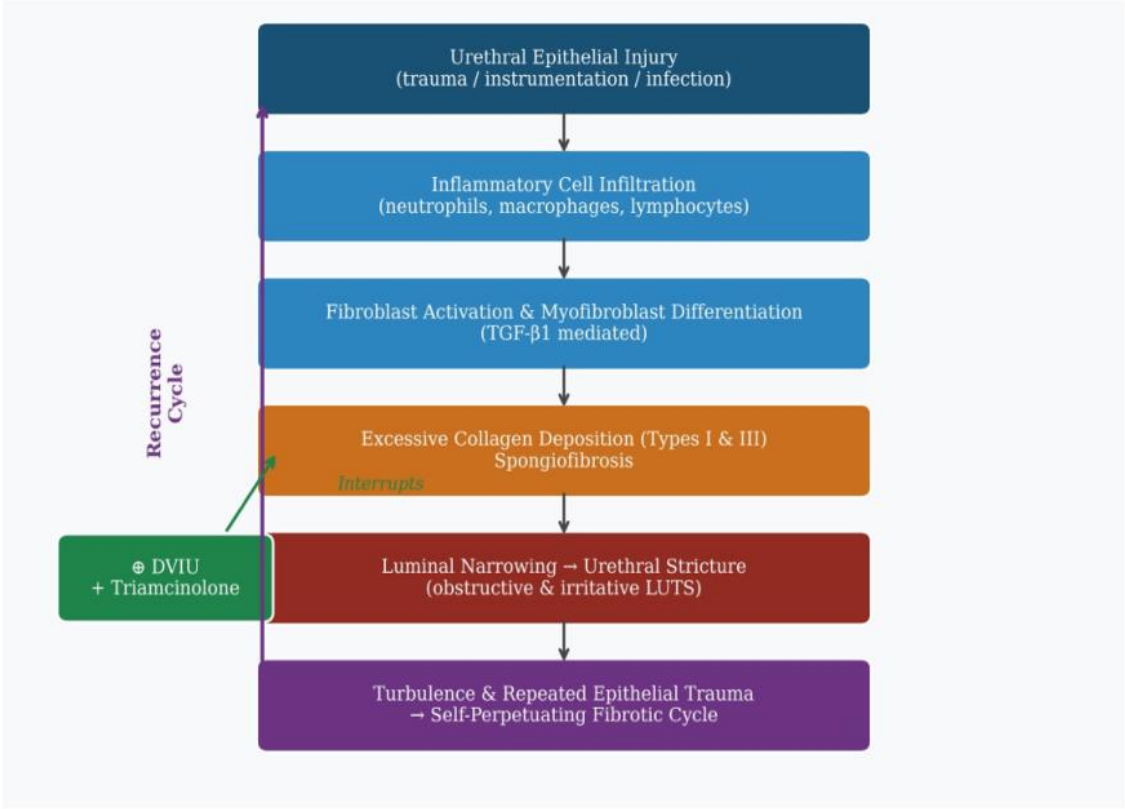

Figure 1. Pathophysiology of urethral spongiofibrosis and the fibrotic recurrence cycle.

(TGF-β1 = Transforming Growth Factor beta-1; ECM = Extracellular Matrix; DVIU = Direct Visual Int Urethrotomy)

Figure 1. Pathophysiology of urethral spongiofibrosis and the fibrotic recurrence cycle.

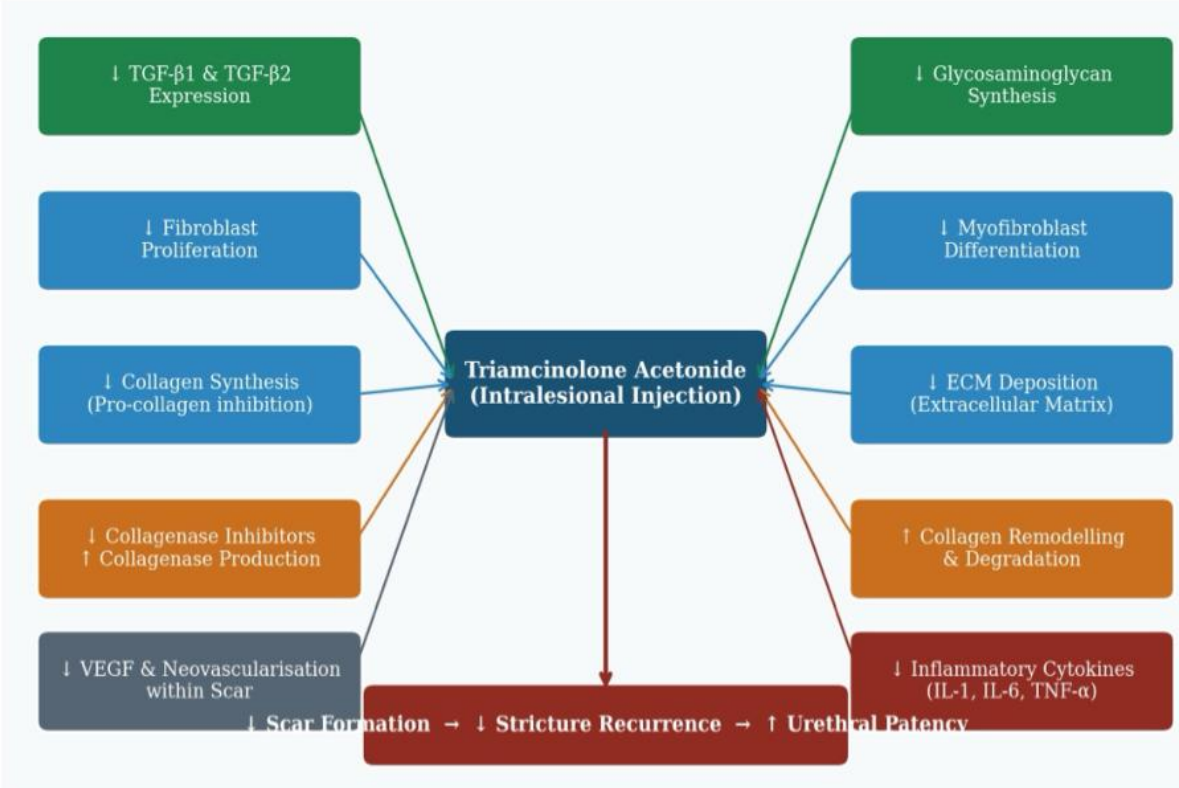

Figure 2. Schematic representation of the multi-target anti-fibrotic mechanisms of intralesional triamcinolone acetonide at the urethrotomy site.

Aim and Objectives

Aim: To evaluate the efficacy and safety of intralesional triamcinolone acetonide injection following DVIU in the management of anterior USD.

Primary objective: To compare stricture recurrence at 12 months between DVIU plus triamcinolone and DVIU alone.

Secondary objectives: To compare Qmax at 3, 6, and 12 months; evaluate recurrence-free survival and time to recurrence; assess secondary interventions; evaluate complications; and explore clinical and stricture-related factors associated with recurrence.

MATERIALS AND METHODS

Study design and setting

This was a prospective, randomized, controlled, parallel-group interventional study conducted in the Department of Urology, ESIC Medical College and PGIMSR, Rajajinagar, Bengaluru, Karnataka, India. The study period was June 2024 to December 2025 and followed Institutional Ethics Committee approval.

Participants and eligibility

Men aged 18–65 years with symptomatic bulbar or penile urethral stricture ≤2 cm on RGU were eligible. Exclusion criteria included pan-urethral/obliterated or posterior stricture, neurogenic bladder dysfunction, systemic immunological or connective-tissue disease, current systemic corticosteroid or immunosuppressive therapy, steroid hypersensitivity, inadequately treated UTI, previous urethroplasty at the stricture site, and inability or refusal to complete follow-up.

Randomization and intervention

Eligible patients were randomized 1:1 using computer-generated random numbers and sequentially numbered sealed opaque envelopes. Group A underwent DVIU followed by intralesional triamcinolone acetonide 80 mg; Group B underwent DVIU alone.

Standardized preoperative assessment included clinical evaluation, urine analysis/culture, uroflowmetry, RGU, ultrasonography KUB with PVR, laboratory investigations, and anesthetic assessment. Cefotaxime 1 g was administered intravenously 30 minutes before surgery, adjusted according to culture where appropriate. DVIU was performed with a Sachse urethrotome using a cold knife at 12 o'clock. In Group A, 80 mg triamcinolone acetonide (2 mL of 40 mg/mL diluted with 6 mL sterile distilled water) was injected at 12, 3, 6, and 9 o'clock using a 5-Fr, 23-gauge Williams cystoscopic injection needle. An 18-Fr Foley catheter was maintained for 5 days.

Follow-up and outcomes

Patients were assessed on day 5 and at 3, 6, and 12 months. Success was defined as absence of voiding symptoms with Qmax >15 mL/s for a voided volume ≥150 mL. Recurrence was defined as Qmax <15 mL/s and/or symptomatic recurrence confirmed by uroflowmetry or imaging. Treatment failure was defined as need for secondary intervention because of documented recurrence.

Sample size and statistics

The planned sample size was 25 per group based on an expected recurrence of 52% in controls and 20% with triamcinolone, with α=0.05 and 80% power; allowing 10% loss to follow-up, the target was 56 patients. Continuous variables were analyzed using the independent-samples t-test or Mann–Whitney U test, and categorical variables using χ^2 or Fisher exact tests. Repeated-measures ANOVA with Bonferroni correction was planned for longitudinal uroflowmetric outcomes. Kaplan–Meier analysis with log-rank testing assessed recurrence-free survival. Multivariable logistic regression was planned for predictors of treatment failure. Statistical significance was set at $p<0.05$.

Ethics

The study was conducted according to the Declaration of Helsinki and ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). IEC approval and written informed consent were obtained; data were anonymized.

RESULTS

Patient disposition and baseline characteristics

A total of 54 patients were randomized, with 27 allocated to each group. Three patients in Group A and one in Group B were lost to follow-up before the 12-month endpoint. The final analyzed cohort comprised 24 intervention patients and 26 controls. Baseline demographic, stricture-related, and preoperative uroflowmetric characteristics were comparable (Table 1).

Table 1. Baseline demographic, clinical, and preoperative uroflowmetric characteristics.

Variable	DVIU + triamcinolone	DVIU alone	p-value
Age, years	41.42 ± 11.84	46.73 ± 11.62	0.12
Bulbar urethra	20 (83.3%)	19 (73.1%)	0.53
Traumatic etiology	10 (41.7%)	13 (50.0%)	0.25
Mean stricture length, cm	1.03 ± 0.23	1.15 ± 0.30	0.10
Pre-op Qmax, mL/s	4.87 ± 1.03	5.60 ± 1.57	0.12
Pre-op PVR, mL	107.00 ± 24.10	115.35 ± 25.77	0.24
Positive pre-op culture	8 (33.3%)	9 (34.6%)	1.000

Uroflowmetric outcomes

Both groups demonstrated marked immediate improvement in Qmax after DVIU, with no significant difference on day 5. At 3 months Qmax remained similar. At 6 months, Qmax was significantly higher in Group A (20.15±2.55 vs 16.20±5.27 mL/s; p=0.01), and at 12 months among non-recurrent completers it remained higher (22.89±2.19 vs 12.92±1.44 mL/s; p<0.001) (figure 3). PVR fell substantially after DVIU and remained lower in Group A at 3, 6, and 12 months (figure 4).

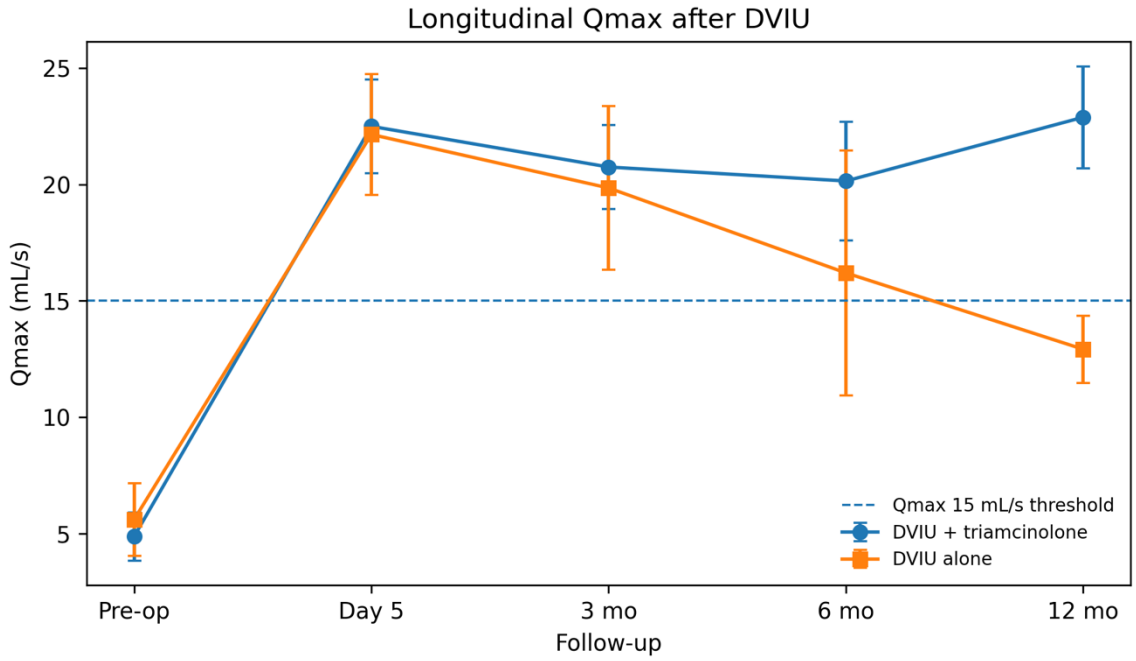

Figure 3. Longitudinal Qmax after DVIU. Values are mean±SD; 12-month values are reported for non-recurrent completers.

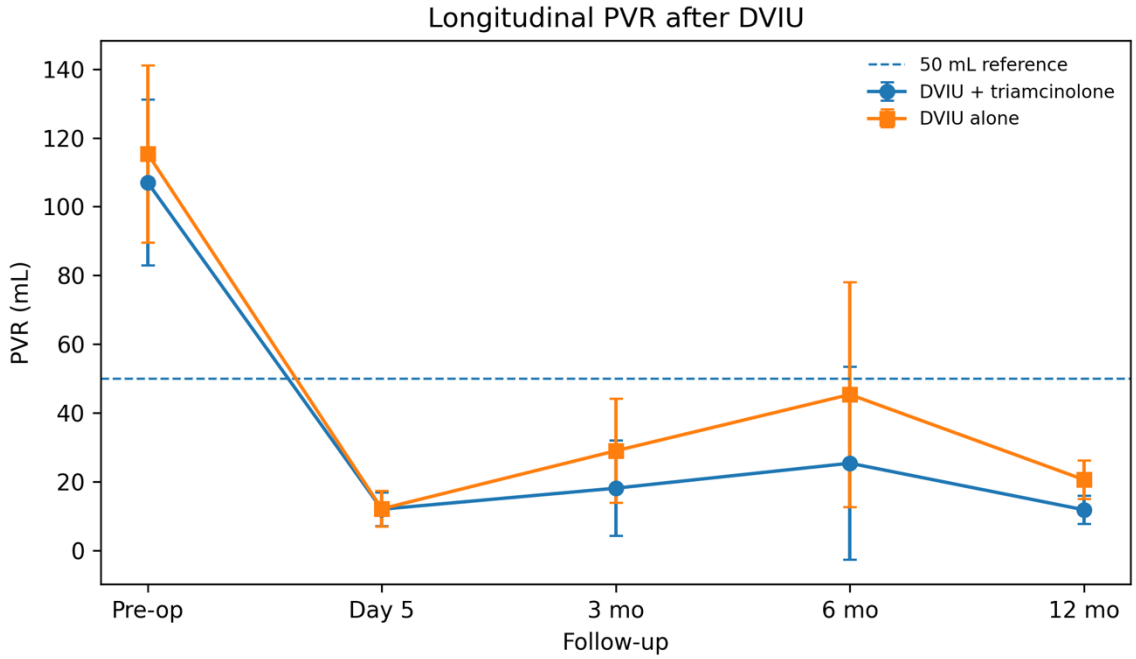

Figure 4. Longitudinal PVR after DVIU. Values are mean±SD; 12-month values are reported for non-recurrent completers.

Recurrence and recurrence-free survival

At 12 months, recurrence occurred in 6/24 patients (25.0%) in Group A compared with 14/26 (53.8%) in Group B (p=0.048). In figure 5(A) it shows the stacked bar chart of stricture recurrence at 12 months where Group B has a 53.8% recurrence rate and Group A has 25.0% recurrence rate, (*p = 0.048; OR = 3.50 [95% CI: 1.05–11.66]; ARR = 28.8%; NNT = 3.5). And figure 5(B) demonstrates the distribution of time to recurrence, where Group B recurrences cluster occur in the 4–6-month window whereas Group A recurrences occur in the 7–12-month period (mean TTR: Group B 7.07 months vs Group A 9.33 months; *p = 0.027).

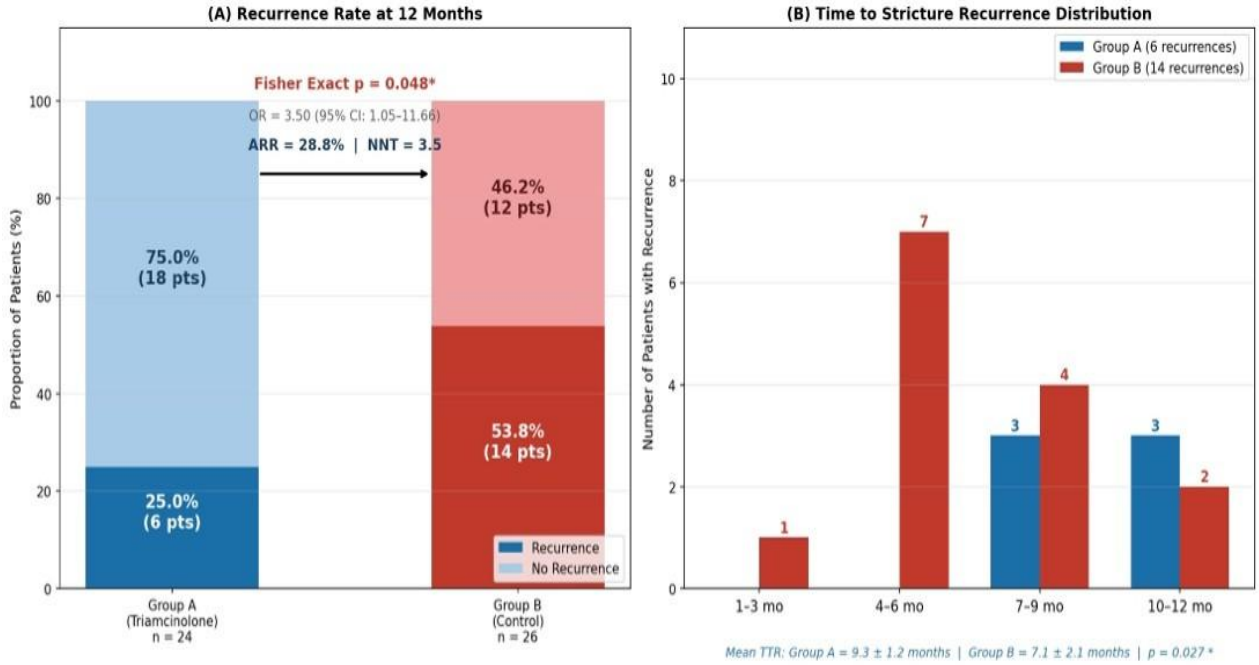

Figure 5: Distribution of stricture recurrence over the follow-up period for Group A and B.

Subgroup Analysis

Subgroup analysis of recurrence rates stratified by stricture site, aetiology, and length is presented in Table 2.

In bulbar urethral stricture, recurrence was significantly lower in Group A: 5/20 (25.0%) vs 13/19 (68.4%) in Group B (p = 0.01). In the smaller penile stricture subgroup, rates were comparable (Group B 14.3%; Group A 25.0%; p = 1.000).The largest numerical benefit was observed in traumatic strictures: Group A 10.0% (1/10) vs Group B 30.8% (4/13) recurrence, though this did not reach statistical significance (p = 0.34), possibly due to limited numbers. In idiopathic strictures, Group A showed lower recurrence (50.0% vs 87.5%), with a trend towards significance (p = 0.28). The inflammatory and iatrogenic subgroups were too small for meaningful statistical comparison.

For the 1.0–1.5 cm stricture length category (the most prevalent), triamcinolone significantly reduced recurrence: 4/17 (23.5%) in Group A vs 10/16 (62.5%) in Group B (p = 0.03). Shorter strictures (<1.0 cm) showed a numerical but non-significant trend (p = 0.54).

Table 2. Subgroup Analysis: Stricture Recurrence Rates Stratified by Site, Aetiology, and Stricture Length

Subgroup	Group A n/N (%)	Group B n/N (%)	p-value
STRICTURE LOCATION			
Bulbar urethra	5 / 20 (25%)	13 / 19 (68.4%)	0.01 *
Penile urethra	1 / 4 (25%)	1 / 7 (14.3%)	1.000
AETIOLOGY			
Traumatic	1 / 10 (10%)	4 / 13 (30.8%)	0.34
Idiopathic	4 / 8 (50%)	7 / 8 (87.5%)	0.28
Inflammatory	0 / 4 (0%)	1 / 3 (33.3%)	0.43
Iatrogenic	1 / 2 (50%)	2 / 2 (100%)	1.000
STRICTURE LENGTH			
< 1.0 cm	1 / 5 (20%)	3 / 6 (50%)	0.54
1.0 – 1.5 cm	4 / 17 (23.5%)	10 / 16 (62.5%)	0.03 *
1.6 – 2.0 cm	1 / 2 (50%)	1 / 4 (25%)	1.000

* $p < 0.05$ (statistically significant).

Summary of Statistical Tests Applied

Table 3 provides a comprehensive summary of all statistical tests applied, the test used for each comparison, and the resulting p values. The normality of all continuous variables was assessed by the Shapiro-Wilk test prior to selecting parametric vs non-parametric tests.

Table 3. Statistical Analysis Summary: Variables Tested, Tests Applied, and Results

Variable / Comparison	Group A	Group B	P Value
Age (years)	41.42 ± 11.84	46.73 ± 11.62	0.12
Stricture Length (cm)	1.03 ± 0.23	1.15 ± 0.30	0.11
Pre-op Urine Culture +ve	33.3%	34.6%	1.000
Pre-op Qmax (mL/sec)	4.87 ± 1.03	5.60 ± 1.57	0.12
Pre-op PVR (mL)	107.00 ± 24.10	115.35 ± 25.77	0.24
Post-op Qmax (mL/sec)	22.50 ± 2.02	22.15 ± 2.60	0.49
Post-op PVR (mL)	12.00 ± 4.85	12.12 ± 5.16	0.92
Post-op Urine Culture +ve	16.7%	19.2%	1.000
Qmax at 3 Months (mL/sec)	20.75 ± 1.80	19.85 ± 3.52	0.51
PVR at 3 Months (mL)	18.12 ± 13.86	29.00 ± 15.09	0.01*
Qmax at 6 Months (mL/sec)	20.15 ± 2.55	16.20 ± 5.27	0.01*
PVR at 6 Months (mL)	25.38 ± 28.01	45.36 ± 32.70	0.02*
Qmax at 12 Months† (mL/sec)	22.89 ± 2.19	12.92 ± 1.44	<0.001*
PVR at 12 Months† (mL)	11.83 ± 4.09	20.58 ± 5.55	<0.001*
Recurrence at 12 Months	25.0% (6/24)	53.8% (14/26)	0.048 *
Time to Recurrence (months)	9.33 ± 1.21	7.07 ± 2.13	0.03 *

* $p < 0.05$ (statistically significant); KM = Kaplan-Meier; OR = Odds Ratio with 95% Confidence Interval.
Postoperative urine culture positivity was 16.7% in Group A and 19.2% in Group B (p=1.000). No steroid-related complications were reported.

DISCUSSION

This prospective randomized study suggests that intralesional triamcinolone acetonide may improve the durability of DVIU for selected short anterior urethral stricture. The observed reduction in recurrence from 53.8% to 25.0% is directionally consistent with earlier clinical reports of adjunctive corticosteroid therapy[10-12] . The biological rationale is based on the role of spongiofibrosis and dysregulated wound healing in restricture formation. TGF-β-mediated fibroblast activation, myofibroblast differentiation, collagen deposition, and extracellular-matrix remodeling are important components of scar formation, while corticosteroids can modulate several of these pathways[8,9,15] . The temporal pattern is clinically relevant: control-group recurrences were concentrated in months 4–6, whereas intervention-group recurrences occurred later. A treatment that delays rather than completely prevents recurrence may still extend symptom-free intervals and reduce early re-intervention.The functional findings support the recurrence results. DVIU produced a large immediate increase in Qmax in both groups, whereas later divergence at 6 and 12 months was compatible with progressive restricture in controls and sustained luminal patency in the intervention group. The parallel reduction in PVR provides an additional measure of more effective bladder emptying.The findings are consistent with previous reports. Mazdak et al. described lower recurrence with intralesional triamcinolone after internal urethrotomy, while other clinical series reported improved patency and recurrence outcomes with local steroid therapy[10,11,18] . The subgroup findings suggest a greater apparent benefit in bulbar stricture and in the 1.0–1.5 cm category. DVIU remains useful for appropriately selected short stricture, whereas urethroplasty remains the more durable reconstructive option for many patients, particularly those with longer, recurrent, or complex disease [5,7,16,22] .

Strengths include prospective randomized design, standardized operative and follow-up protocols, objective functional outcomes, recurrence-free survival analysis, and prospective data from an Indian tertiary-care population.

Limitations include the single-center design, modest sample size, one-year follow-up, limited power for subgroup analyses, and lack of routine imaging at every follow-up visit.

Comparison with Published Literature

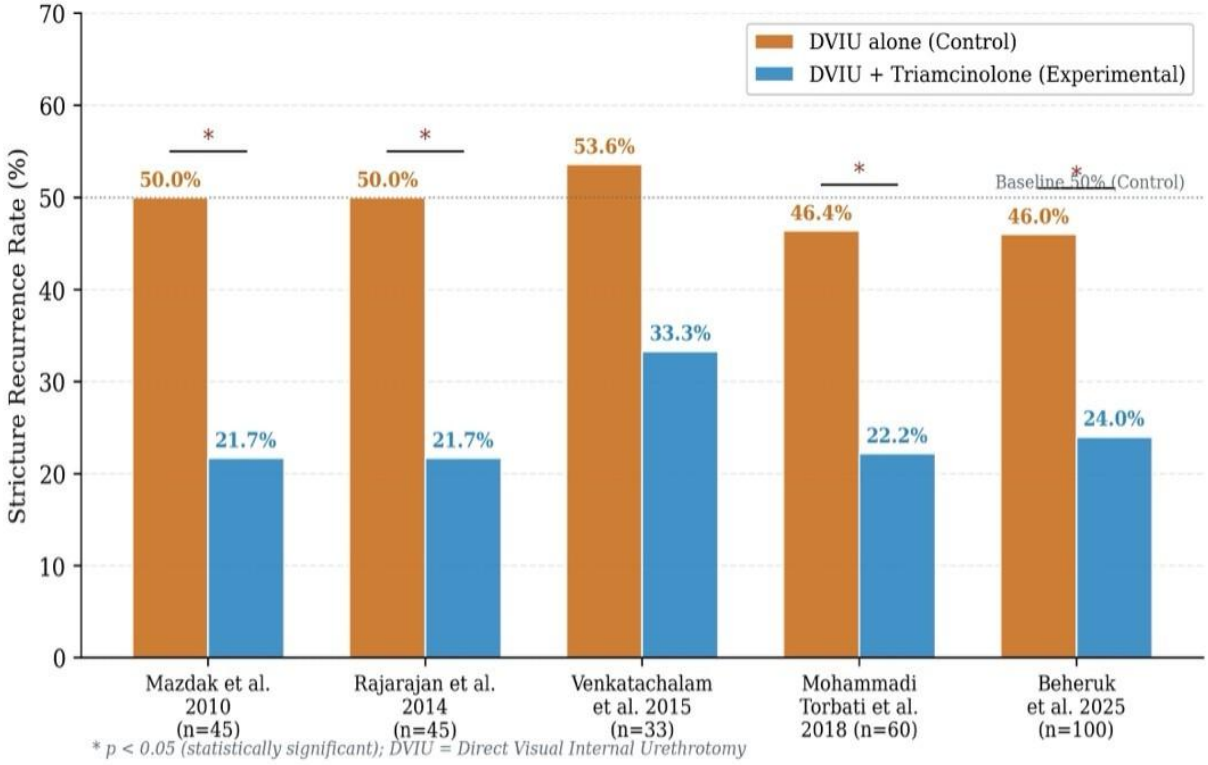

Figure 6 . Comparison of stricture recurrence rates (%) in the experimental versus control groups across published studies.

(* $p < 0.05$ is statistically significant. Horizontal dotted line = 50% baseline recurrence rate in control groups.)

The published studies summarized in the source document reported recurrence of approximately 21.7–33.3% in triamcinolone-treated groups and 46.0–53.6% in corresponding randomized control groups. The present study's 25.0% versus 53.8% pattern falls within this reported range.

CONCLUSION

In this prospective randomized study of men with short anterior urethral stricture, intralesional triamcinolone acetonide administered immediately after DVIU was associated with lower 12-month recurrence, longer recurrence-free survival, delayed recurrence, higher Qmax, and lower PVR compared with DVIU alone. No steroid-related complications were observed. Intralesional triamcinolone is a promising adjunct to DVIU in carefully selected patients; larger multicenter studies with longer follow-up and patient-reported outcomes are needed before definitive recommendations regarding routine use can be made.

DECLARATIONS

Ethics approval and consent

IEC approval and written informed consent were obtained as reported in the source study.

Funding

Not reported in the source document.

Conflict of interest

Not reported in the source document.

Data availability

The source document states that anonymized study data were maintained using study numbers; a public repository was not specified.

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