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Efficacy of Local Steroid Injection at the Site of Urethral Stricture During Direct Vision Internal Urethrotomy (DVIU); A Comparative Study

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Abstract—Background: *Urethral stricture is common and significantly affects morbidity and quality of life. The use of local steroid injections in the stricture area following internal urethrotomy shows promise in preventing recurrence, although the efficacy of this approach remains a topic of debate.* ***Aim of the study****: Is to assess the efficacy of incorporating steroid injections as an additional treatment during Direct Visual Internal Urethrotomy (DVIU) for urethral strictures with a specific emphasis on assessing the recurrence rate.* ***Patients and methods****: This is a non-randomized comparative study, conducted at Al-Emamain Al-Kadhmain Medical City and in the private sector, involved 30 patients divided into two groups. The treatment group underwent DVIU with steroid injections, specifically 40 mg of triamcinolone administered at the 3, 6, 9, and 12 o'clock around the urethral stricture. The control group received DVIU alone. Inclusion criteria comprised adult males aged 18 to 65 with obstructive symptoms, a peak flow rate below 15 ml/sec in uroflowmetry, and a short-segment stricture (maximum length of 2 cm) in the anterior urethral region. Maximum flow rate (Qmax) and post-void residual volume (PVRV) were assessed for potential recurrence at pre-operatively, 3-, and 6-months post-operatively.* ***Results****: The mean age of individuals with urethral strictures was 35.9 ± 7.4 years, with bulbar strictures being predominant at 70.0%. Infection was the leading cause (56.7%), followed by pelvic trauma (30.0%), post-instrumentation (10.0%), and unknown etiology (3.3%). No significant differences were observed between the two study groups in regard to age (p=0.2), stricture site (p=0.9), etiology (p=0.9), and short-term post-operative complications. The recurrence rate in the DVIU + Steroid group was notably lower, with no instances of recurrence reported, as opposed to a 26.7% recurrence rate in the DVIU alone group (P = 0.10). At 6-months follow-up mark, a significant improvement in Qmax, and PVRV were observed in those who received steroid injection during DVIU.* ***Conclusion****: Compared to DVIU alone, adjuvant steroids applied to the urethra may reduce risk of recurrence and improved Qmax and DVIU.*

Keywords— *Urethral stricture; Direct Vision Internal Urethrotomy; Steroid.*

I. Introduction

Urethral stricture disease can manifest along the entire male urethra due to a wide array of causes, leading to a diverse set of symptoms. A precise diagnostic evaluation is essential before embarking on any treatment approach. The historical context of managing urethral strictures reveals its long-standing presence in the field of urology. Urologists have been diligently seeking solutions for both simple and complex strictures for many decades. Recent research has primarily focused on refining established procedures to minimize postoperative complications. Nevertheless, despite substantial scientific advances, numerous studies indicate a concerning lack of knowledge about urethral stricture surgery among urologists, resulting in suboptimal treatment options for patients with this condition (1).

Often associated with challenging-to-treat strictures. Additionally, strictures can result from ischemia of the corpus spongiosum, which may occur during procedures like cardiac or neurosurgery, typically affecting the complete anterior urethra (2).

External trauma can lead to urethral strictures, particularly in cases of pelvic fractures that threaten the membranous part of the male urethra or straddle injuries that impact the bulbar urethra. Severe cavernosal injury can also cause a rupture of the penile urethra, potentially resulting in subsequent stricture formation. These traumas often involve hematoma formation and tissue damage, leading to urethral disruptions (3).

The aim of the study is to investigate the potential therapeutic benefits and outcomes of utilizing steroid injections as an adjunct treatment during Direct Visual Internal Urethrotomy (DVIU) for anterior urethral strictures (≤ 2 cm in length) in terms of recurrence rate.

II. Patients and Methods

This a non-randomized comparative study was conducted Al-Emamain Al-Kadhmain medical city and at the private sector during a 16 months period spanning from 1st of July 2022 till 1st of November 2023.

A convenience sampling technique was employed to enlist 30 patients diagnosed with an anterior urethral stricture based on predefined study criteria. These patients were evenly divided into two groups: the treatment cohort, which comprised individuals receiving DVIU along with steroid injections, and the control cohort, encompassing those who solely underwent DVIU.

Ethical issues: Scientific approval for the research was obtained from the Scientific Committee at the Department of Urology, Arab board for medical specialization.

Verbal approval was secured from all participants prior to initiating data collection, following an explanation of the study's objectives and a guarantee of confidentiality.

Inclusion criteria

1. Population: Adult males aged 18-65 years

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2. Symptoms: Exhibited obstructive symptoms
3. Peak Flow Rate: Recorded peak flow rate <15 ml/sec during uroflowmetry
4. Stricture: Short segment stricture (length not exceeding 2 cm)
5. Imaging Confirmation: Observed on retrograde urethrography (RUG) and/or micturating cystourethrography (especially, in patients who have suprapubic cystostomy).
6. Location: Specifically in the anterior (bulbar or penile) urethral region

Exclusion criteria

1. Previous Urethrotomy
2. Posterior Urethral Disease
3. Neurogenic Bladder
4. Vesicle Stones
5. Benign Prostatic Hyperplasia
6. Multiple Strictures
7. Active Urinary Tract Infections

Surgical protocol: All patients underwent a comprehensive assessment involving a detailed medical history, thorough physical examination, complete blood count, urine analysis, renal function tests, ultrasonography of the bladder to measure the post-void residual (PVR) volume, uroflowmetry, and retrograde urethrography, with micturating cystourethrography performed when necessary. Urethroscopy was conducted using a 20 F sheath and a 0° telescope to determine the site and length of the stricture, as well as the passage of the telescope through the stricture. Prior to the procedure, patients received a 500 mg dose of Ciprofloxacin as an antibiotic. We made the decision to allocate patients into two groups for one for utilizing steroid injections during the procedure and the other as a control group.

The necessary equipment's were prepared for the procedure, comprising a urethrotomy sheath with a straight, rounded, blunted aperture, accompanied by a side arm working channel, an obturator, a lens for urethroscopy (12-degree viewing angles), a working element, a flat cold knife blade, a fiberoptic light cable, an inflow for the irrigating solution, a guide wire, and a Williams's cystoscopic injection needle (figure 1). Normal saline was used for irrigation during the procedure.

Surgical procedure: The procedure involved lubricating the sheath with a 2% lidocaine in an ointment form, which was then inserted into the meatus and navicular fossa. Following this, the obturator was removed, and the working element, along with the lens, was introduced. With direct visual guidance, the instrument was advanced into the urethra until reaching the narrowed area. Subsequent to this, the guide wire was introduced into the narrowing of the urethra, serving as a navigational aid for the surgical procedure then the blade was positioned at the 12 o'clock position.

The incision was made by moving the instrument upwards and backwards, ensuring a shallow cut to prevent perforation using the cold knife. Subsequently, additional incisions were performed to elongate the initial one, extending the cut beyond the stricture margins by approximately 0.5 cm into the normal urethra, excluding the external sphincter area. This process aimed to create a smooth transition from the normal urethra to the incised stricture, resulting in a relatively uniform circular urethral passage of about 24 Fr to 28 Fr caliber. After inspecting the prostatic urethra, vesicle neck, and bladder, Triamcinolone (KENALOG, 40 mg) diluted in 10 ml of distilled water was injected at the 3, 6, 9, and 12 o'clock positions of the urethra stricture using a 22 G William's cystoscopy injection needle passed through the side arm working channel as shown in figure 1.

Follow up: After the procedure, patients were administered Ciprofloxacin (500 mg) 12 hours post-operation and continued this medication twice a day for the subsequent 7 days. An 18 F urinary catheter was used for post-operative catheterization, maintained for a duration of 7 days. Following the removal of the urinary catheter, patients were advised to attend scheduled follow-up appointments at 3 months, and 6 months following the procedure. In cases where patients missed these appointments, they were contacted via phone for evaluation.

During the follow-up period, if patients manifested symptoms suggestive of a potential recurrence, such as a weakened urine stream, burning micturition, or heightened urinary frequency with urgency, the confirmation of recurrence relied on the following: uroflowmetry results indicating a flow rate of less than 15 mL/second, and post-void residual volume exceeding 100 ml. In addition, the presence of complication like UTI during the follow-up period was also documented.

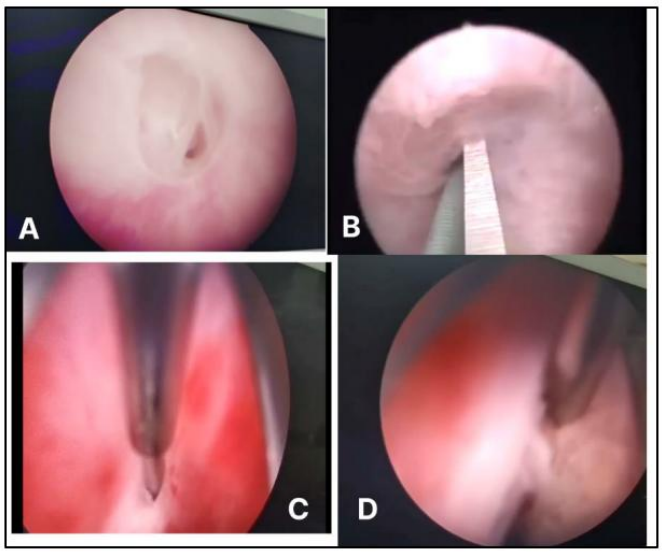

Figure 1: Camera view during direct vision internal urethrotomy (DVIU); A: showing urethral stricture; B: showing cold knife cutting through the fibrosed layer; C,D: injection of steroid using williams's cystoscopic injection needle.

At the 6 months mark post-DVIU, the procedure was deemed successful if the patient did not report any difficulty in urination and exhibited a uroflowmetry flow rate above 15 mL/second with a residual volume of at least 150 ml.

Data collection

The current study gathered data on various aspects which included age, location of the urethral stricture, the cause of the stricture, recurrence frequency and the duration until recurrence, as well as post-operative complications such as

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infection, bleeding, and extravasation. Additionally, flow rate and post-void residual volume was documented at regular intervals including: preoperative measurement, at 3, and 6 months postoperatively.

Statistical analysis

Continuous variables were represented as means and standard deviations. Categorical variables were represented as frequencies and percentages. The Welch's t-test (for normally distributed variables) was used to test the difference in means. The difference between categorical variables was investigated using either the $\chi 2$ test with yates' correction or Fisher's exact test, depending on the context. A P-value less than 0.05 was considered statistically significant. R software packages (dplyr, gt_summery and ggplot) were used for data processing, visualization, and statistical analysis ("R version 4.3.0, R Foundation for Statistical Computing).

III. Results

In this comparative analysis between DVIU with steroid injection (N = 15) and DVIU alone (N = 15), the study examined several key demographic and clinical characteristics. The mean age of patients in the DVIU + Steroid group was 34.3 ± 6.2 years, while the DVIU group had a slightly higher mean age of 37.6 ± 8.4 years (P = 0.2) as shown in table 1.

Regarding stricture site distribution, no significant differences were observed between the two groups, with both demonstrating comparable proportions in bulbar and penile stricture locations (P > 0.9). Etiological factors contributing to urethral stricture, including infection, pelvic trauma, post-instrumentation, and unknown causes, exhibited similar distributions across the two groups (P > 0.9) as shown in table 2 and figure 2.

TABLE 1: Description of age in both study groups.

Characteristic	DVIU + Steroid, N = 15[1]	DVIU, N = 15[1]	P-value[2]
Age (years)	34.3 ± 6.2	37.6 ± 8.4	0.2
[1]Mean ± SD [2]Welch Two Sample t-test;			

TABLE 2: Description of stricture site, and etiology of urethral stricture in both study groups.

Characteristic	DVIU + Steroid, N = 15[1]	DVIU, N = 15[1]	P-value[2]
Stricture site			>0.9
Bulbar	10 (66.7%)	11 (73.3%)	
Penile	5 (33.3%)	4 (26.7%)	
Aetiology			>0.9
Infection	9 (60.0%)	8 (53.3%)	
Pelvic Trauma	5 (33.3%)	4 (26.7%)	
Post Instrumentation	1 (6.7%)	2 (13.3%)	
Unknown	0 (0.0%)	1 (6.7%)	
[1]n (%) [2]Fisher's exact test			

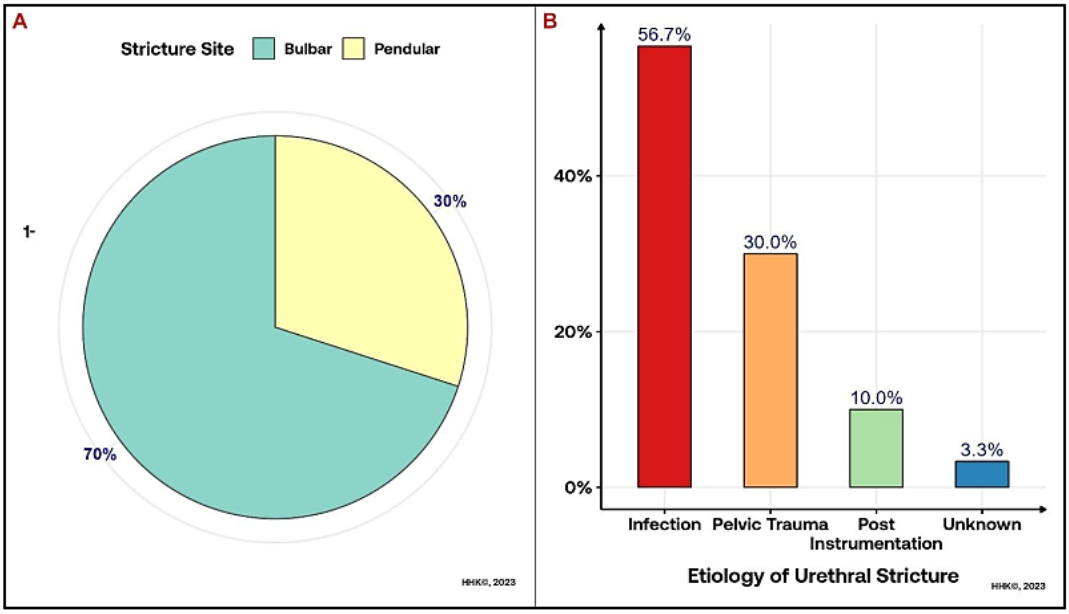

Figure 2: A: proportion of stricture sites of origin; B: proportion of the etiology of urethral strictures.

The study compared the occurrences of postoperative complications between patients undergoing DVIU with steroid injection, and those undergoing DVIU alone. Regarding bleeding, 13.0% of individuals in the DVIU + Steroid group experienced this complication, while 20.0% in the DVIU group encountered bleeding (P > 0.9). The incidence of infection was consistent between the two groups, with 6.7% in both the DVIU + Steroid and DVIU alone cohorts (P > 0.9). Notably, no instances of extravasation were reported in either group as shown in table 3 and figure 3.

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TABLE 3: short-term complications experienced post-operatively

Characteristic	DVIU + Steroid, N = 15[1]	DVIU, N = 15[1]	P-value[2]
Bleeding	2 (13.0%)	3 (20.0%)	>0.9
Infection	1 (6.7%)	1 (6.7%)	>0.9
Extravasation	0 (0.0%)	0 (0.0%)	

[1]n (%);
[2]Fisher's exact test

Table 4 delineates the changes in flow rate and post-void residual volume over time in the DVIU + Steroid and DVIU groups. Pre-operatively, the maximum flow rate in the DVIU + Steroid group was 7.5 ± 1.8 mL/s, slightly lower than the DVIU group's 8.8 ± 2.2 mL/s, though the difference did not reach statistical significance (P-value = 0.10). Notably, at 6 months post-operation, the DVIU + Steroid group exhibited a significant improvement in maximum flow rate (18.7 ± 1.5 mL/s) compared to the DVIU group (15.3 ± 5.7 mL/s, P-value = 0.036) as shown in figure 4.

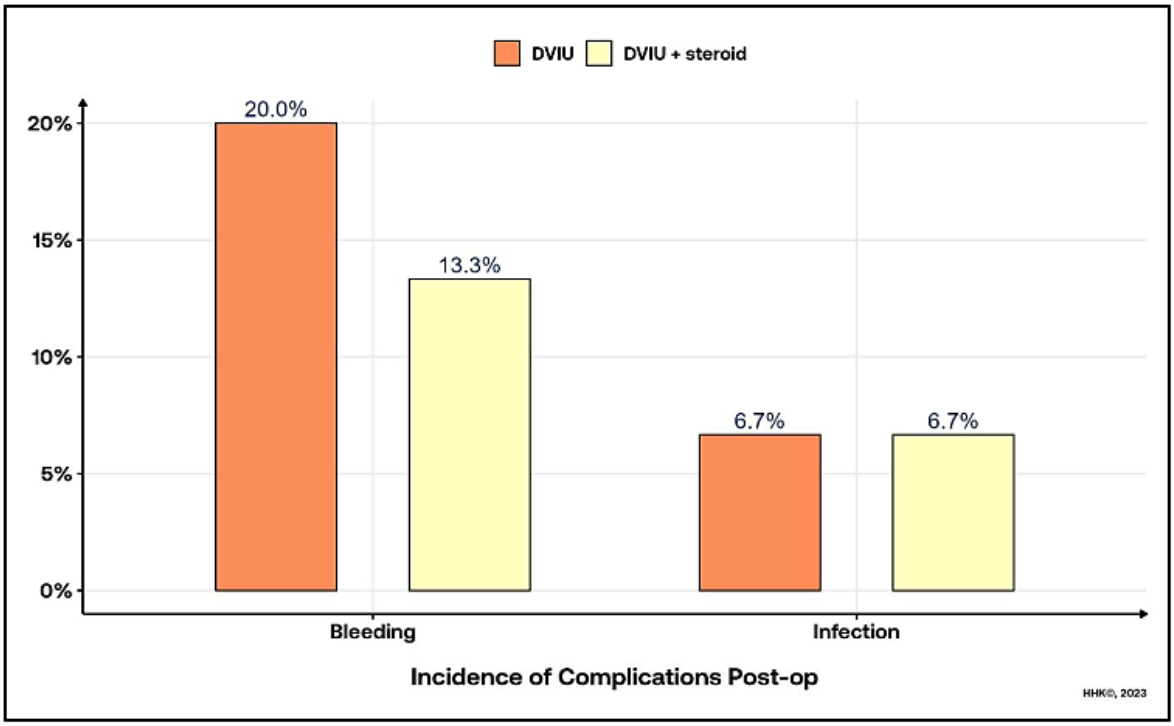

Figure 3: incidence of complications stratified by the treatment and control arms.

TABLE 4: maximum flow rate and post-void- residual volume differences between the two study groups overtime.

Parameter	DVIU + Steroid, N = 15[1]	DVIU, N = 15[1]	P-value[2]
Max flow rate (mL/s)			
Pre-operatively	7.5 ± 1.8	8.8 ± 2.2	0.10
At 3 months post-op	19.1 ± 1.5	18.4 ± 1.5	0.2
At 6 months post-op	18.7 ± 1.5	15.3 ± 5.7	**0.036**
Post-void residual volume (ml)			
Pre-operatively	58.8 ± 11.8	63.0 ± 13.4	0.7
At 3 months post-op	11.1 ± 4.8	14.4 ± 4.7	0.069
At 6 months post-op	13.0 ± 3.0	32.0 ± 8.0	**0.002**

[1]Mean ± SD
[2]Welch Two Sample T-test

Regarding post-void residual volume, no significant differences were observed pre-operatively between the two groups (P-value = 0.7). However, at 6 months post-operation, the DVIU + Steroid group demonstrated a noteworthy reduction (13.0 ± 3.0 mL) compared to the DVIU group (32.0 ± 8.0 mL, P-value = 0.002). These findings, assessed using Welch Two Sample T-tests, suggest that the incorporation of local steroid injections in DVIU may positively affect maximum flow rates and reduce post-void residual volumes over the 6-month postoperative period.

TABLE 5: success and recurrence rate in both treatment and control cohorts.

Characteristic	DVIU + Steroid, N = 15[1]	DVIU, N = 15[1]	P-value[2]
Recurrence rate	0 (0.0%)	4 (26.7%)	0.10
Success rate	15 (100.0%)	11 (73.3%)	0.10
Recurrence duration (months)	--	4.8 ± 1.5	

[1]n (%); Mean ± SD
[2]Fisher's exact test

Remarkably, the recurrence rate in the DVIU + Steroid group was notably lower, with no instances of recurrence reported, as opposed to a 26.7% recurrence rate in the DVIU alone group (P = 0.10). The success rate for the DVIU + Steroid cohort was 100.0%, whereas the DVIU alone group demonstrated a success rate of 73.3% (P = 0.10). The DVIU

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alone group exhibited a mean recurrence duration of 4.8 ± 1.5 months. As shown in table 5 and figure 5.

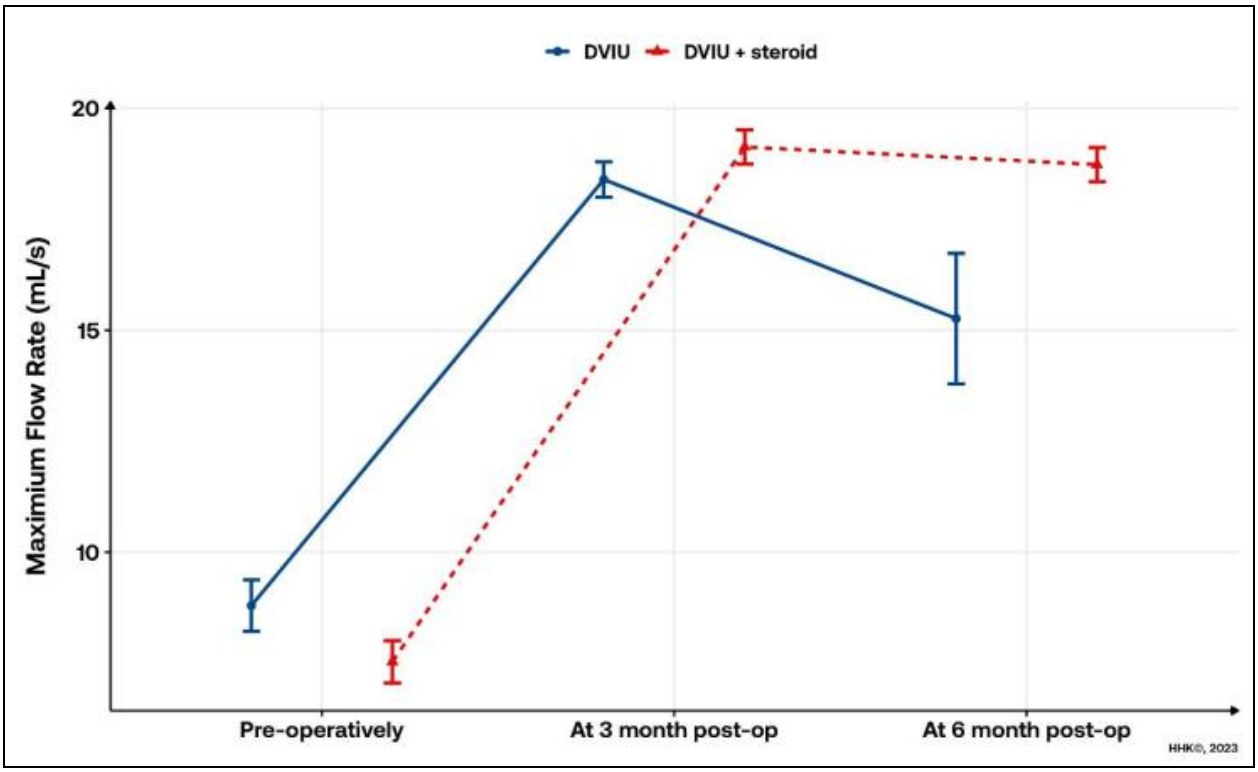

Figure 4: Changes of maximum flow rate over time stratified by the study groups.

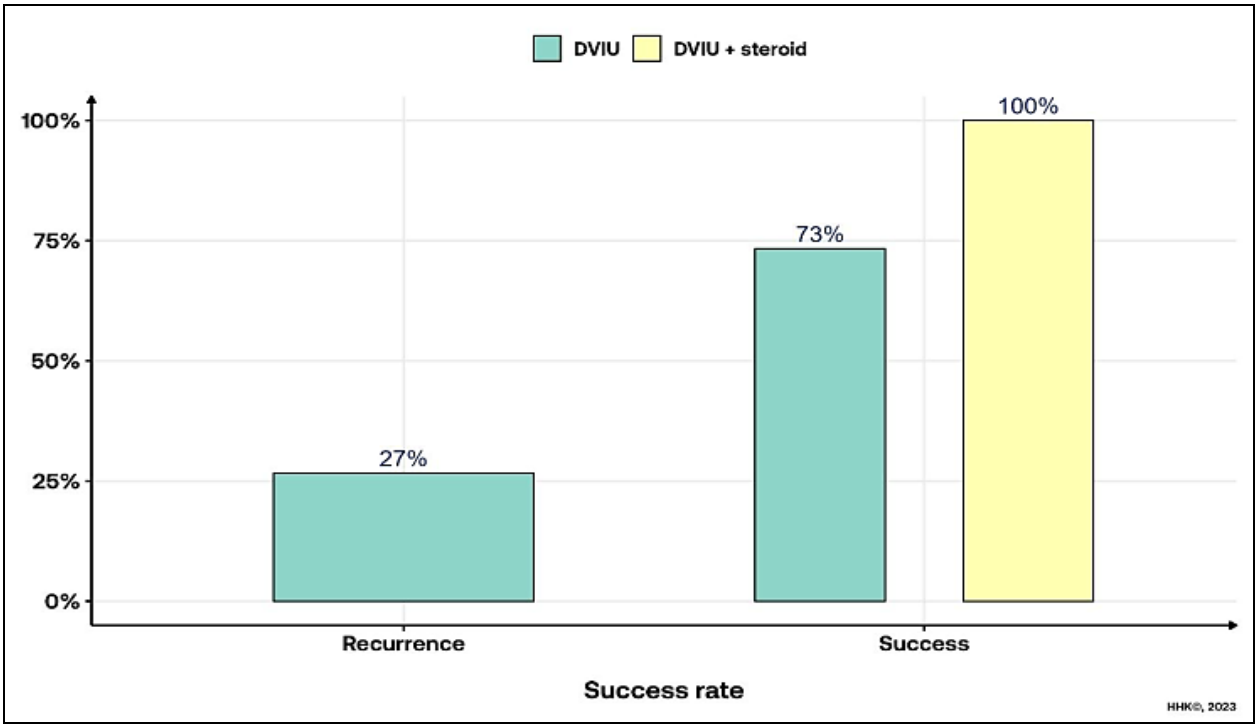

Figure 5: success rate in both DVIU and DVIU + steroid groups.

IV. Discussion

DVIU, introduced in the 1980s, is a primary treatment for urethral strictures, particularly those shorter than 1.5 cm. Despite its common use, both DVIU and urethral dilatation face challenges, including high recurrence rates in longer strictures. Studies, such as one by Steenkamp et al. (4) in 2005, demonstrated similar effectiveness between filiform

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dilatation and DVIU, but both became less effective with increasing stricture length. Recurrence rates after DVIU have been reported as high as 90%(5). This dramatic increase in recurrence rate may be related to an increased number of re-treatments (6).

DVIU, as a standalone procedure, targets the separation of scarred epithelium to facilitate secondary wound healing. However, it lacks the capability to achieve epithelial approximation. Therefore, the long-term success of DVIU hinges on the timely progression of epithelialization ahead of wound contraction; otherwise, stricture recurrence becomes an unavoidable outcome (6). The need for improved adjuvant techniques is evident, with the use of local steroid injections proposed to reduce scar formation and improve outcomes. Studies dating back to the 1960s and 1970s have highlighted the potential benefits of local steroid injections, particularly in cases involving distal urethra or meatus strictures and those post-radical prostatectomies (7, 8).

In the present study, the mean age of urethral stricture cases was 35.9 ± 7.4 years. The distribution of stricture sites revealed a predominance of bulbar strictures, constituting 70.0%, while pendular strictures accounted for 30.0%. In terms of etiology, infection emerged as the leading cause, identified in 56.7% of cases. Pelvic trauma contributed to 30.0%, post-instrumentation to 10.0%, and etiology remained unknown in 3.3% of instances. In the study by Gücüket al. (9), the average age of patients with urethral strictures was 33.4 years, ranging from 19 to 45 years. They identified trauma as the cause in 28.9% of 45 patients, infection in 11.1%, instrumentation in 24.4%, and 35.6% had unknown causes.

Conversely, Yildirim et al. (10) in Turkey reported a mean age of 56.4 years, ranging from 18 to 83 years.

The primary mechanism underlying stricture development involves the formation of fibrosis, attributed to an excess of collagen synthesis and alterations in the extracellular matrix of the urethral lumen resulting from endoscopic instrumentations, trauma, and infections. Spongiofibrosis occurs to different extents, leading to a narrowing of the urethral luminal caliber (11). The primary challenge urologists face concerning urethral strictures lies not in the condition itself but in its propensity for recurrence. In research involving 224 patients, recurrence rates stood at 68% following the initial internal urethrotomy (IU), escalating to 96% after the second IU, and reaching 100% after the third procedure. Additionally, recurrent IUs contributed to a decline in the success rates of urethroplasty (12).

In the current study, at 6-months follow-up mark, a significant improvement in Qmax, and PVRV was observed in those who received steroid injection during DVIU. These findings suggest that the incorporation of local steroid injections in DVIU enhanced maximum flow rates and reduced post-void residual volume over the 6-month postoperative period.

Furthermore, the group that received triamcinolone injections exhibited a no recurrence during the 6-month follow-up, in contrast to the 26.7% recurrence rate observed in the cohort that underwent DVIU alone. While this disparity did not achieve statistical significance (P-value = 0.10), it holds clinical importance. Comparatively, Yıldırım et al. (10) observed a lower recurrence rate of 5% in the steroid group compared to 28% in the group treated with DVIU alone. Tabassi et al. (13) conducted internal urethrotomy and triamcinolone injection in 34 out of 70 patients with strictures, noting a recurrence rate of 35.2% in the steroid-injected group and 41.6% in the DVIU-only group. Although the difference was not statistically significant (p: 0.584), the time to recurrence significantly decreased in the triamcinolone-treated group ($p < 0.05$). Zhang et al. (7)

concluded that the use of local steroids with IU appears to prolong the time to stricture recurrence but does not seem to impact the high stricture recurrence rate following IU. In a systematic review and meta-analysis by Soliman et al. (8), including seven studies with 365 patients, the application of local steroids seemed 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). Qmax also showed improvement following steroid application (mean difference, 0.82; 95% CI, -1.02–2.66); however, this was not statistically significant. Application of topical or injectable steroids reduces the formation of scars by diminishing the synthesis of collagen and glycosaminoglycans, as well as suppressing the expression of inflammatory mediators (14).

Limitations

Certain limitations should be acknowledged. Firstly, the relatively modest sample size of 30 participants might limit the generalizability of the findings to broader populations. Additionally, the study's duration, focusing on short-term outcomes up to 6 months post-operation, restricts the ability to assess long-term efficacy.

V. CONCLUSION

In conclusion, the study provides encouraging evidence regarding the potential benefits of incorporating local steroid injections (triamcinolone) during DVIU for urethral stricture management. The observed lower recurrence rates, improved Qmax, and PVRV, and higher success rates with the use of steroids suggest a positive impact of this adjunct therapy.

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