SCANDINAVIAN JOURNAL OF UROLOGY
2020, VOL. 54, NO. 5, 431–437
https://doi.org/10.1080/21681805.2020.1798504

Taylor & Francis
Taylor & Francis Group

ARTICLE

Comparative study between Amplatz renal dilator vs visual internal urethrotomy (cold knife) for the treatment of male urethral stricture

Sherif Salah Azab

Urology Department, Faculty of Medicine, October 6 University, Cairo, Egypt

ABSTRACT

Aim: The study aimed to assess and compare urethral stricture (US) management outcomes, efficiency, and complications, treated by either Amplatz renal dilator or visual internal urethrotomy (VIU).

Patients and methods: This prospective comparative study was carried out on 88 male patients with stricture urethra. All patients have performed a physical examination, ascending and micturition urethrography, urodynamic, and pelvic ultrasound. The patients were randomized divided into group 1 (Amplatz group) 44 patients treated with Amplatz dilator, and group 2 (VIU group) 44 patients treated with a cold knife. Patients were followed up at 15 days,3,6, and 12 months after the procedure.

Result: The mean age was 41.2 (22–73) years. The mean stricture length in group 1 and group 2 was 1.01 ± 0.40 and 1.04 ± 0.30, respectively ($p = 0.421$). The average IPSS score at baseline for group 1 and group 2 was 21.2 and 21.9 points, respectively. During the 12 months follow-up, IPSS improved, with average scores of 16.1 and 17.3 for group 1 and group 2, respectively ($p > 0.05$). The mean values of (Q max) between group 1 and group 2 at baseline, day 15, day 90 and 180 days showed no significant difference but at 12 months, (Q max) showed a higher significant difference in group 1 than group 2 ($p = 0.003$). The post-void residual (PVR) displayed a significant decline in both groups from baseline. After 1 year, PVR showed that group 2 was a little higher than group 1 (no significance) compared to baseline The procedures were found effective without recurrence in all patients (both groups) during the 12 months (Q max > 15m/s). However, group 2 reported (11.4%) intra-operative bleeding, and (6.8%) extravasations.

Conclusion: The guided urethral dilation and internal urethrotomy are safe, short time procedures, and offer satisfactory results with the advance to VIUD in Qmax at 12 months. No recurrence was documented in both groups after 12 months. VIU reported 18% intraoperative complication.

ARTICLE HISTORY
Received 31 March 2020
Revised 15 June 2020
Accepted 15 July 2020

KEYWORDS
Urethral stricture (US); Amplatz renal dilator; visual internal urethrotomy (VIU); uroflometer; retrograde urethrogram (RGU)

Introduction

Urethral stricture in males is one of the most reported urologic problems and considered to be the greatest challenging urological condition to cure perfectly [1]. Urethral stricture disease is defined as a constriction and narrowing affecting the urethral lumen. The pathological development of urethral stricture disease refers to the fibrosis and scarring that disturb the urethral mucosa or the enveloped spongiosal erectile tissue of the corpus spongiosum [2]. Numerous insults stimulate fibroblastic damage to the urethra. These involve inflammatory factors, infections, and traumatic causes like iatrogenic injury or fracture of the pelvis [3]. Management of urethral strictures is composite and strongly related to the location, length of fibrosis, scare depth, and nature of the stricture [4,5]. Less invasive techniques like optical urethrotomy, stenting, or dilation remain the first-line treatment option in most of the patients [6].

Visual internal urethrotomy (VIU) by either incision or ablation is the most often performed operations for urethral stricture, as it is quick, straightforward to perform, and is accompanied by a short time for recovery [7]. Direct vision internal urethrotomy (DVIU) by applying a cold – knife incision (splitting) of the stenotic segment of the urethra was first performed by Sachse [8] in 1974.

Urethral dilatation has been carried out with a rigid metal dilator like Van Buren and Beniquet dilators [9]. This procedure is performed for dilatation post-urethroplasty and post VIU with limited urethral strictures. It is a short time procedure, no deep anesthesia needed and performed in the outpatient clinic. Since this procedure is achieved in a blind technique, possible complications may occur during the technique include bleeding, urethral perforation with extravasation, and false passage [9].

The study aims to assess and compare the outcomes and success of urethral stricture management using Amplatz renal dilator directed by guidewire versus conventional cold-knife VIU technique to find out if Amplatz dilatation procedure could be the initial approach to the patients with short stricture and therefore, the current study might be the premier comparative study on this matter in male urethral stricture.

Patients and methods

This prospective study was enrolled on 88 male patients, aged 18–80 years with established urethral strictures in the urology clinic from March 2016 to December 2019.

CONTACT Sherif Salah Azab ssazab@yahoo.com Urology Department, Faculty of Medicine, October 6 University, 6th October city, Cairo, 12411, Egypt

The study was approved by the scientific committee of the hospital, and Informed consent was signed from all participants after clearing up the steps and the consequences of the procedures. Patients were randomized *via* computer-created random figure into two groups in group 1 (Amplatz group) 44 patients; the patients performed urethral dilator with Amplatz dilator. In group 2 (Cold knife group) 44 patients, Sachse cold knife was performed for visual internal urethrotomy.

Inclusion criteria were the manifestation of obstructive symptoms, weak uroflowmetry (Q Max $<$ 15 ml/s) augmented by the pattern of uroflowmetry in stricture urethra (Plateau flow) (Figures 1 and 2) (length of segment strictures $<$1.5 cm) on retrograde urethrography (RGU) and micturating cystourethrography (Figure 3). Exclusion criteria were recurrent strictures, multiple or malignant strictures, patients with active urinary tract infection, and young patients $<$18 years.

All cases were evaluated by full medical history and clinical examination, complete blood picture, urine analysis and culture test, serum renal function, uroflowmetry study, retrograde, and micturition cystourethrography. Any Urinary tract infection was vigorously treated before the operation with appropriate antibiotics. The operation was achieved under spinal anesthesia in the lithotomy position. Parental Antibiotic (3rd generation cephalosporin, 1 gm/12 h) was started before the operation and continued for the following 3 days and kept on oral (Ciprofloxacin, 500 mg) for an additional 5 days. Diagnostic cystourethroscopy was initially introduced using 19 F sheath and 0° telescope to assess the urethra and the stricture.

Amplatz dilator process. Once the stricture is sited, a 5 (F) ureteral catheter is passed through the stricture and progressive to the bladder (Figure 4). A 0.038-inch firm guidewire is inserted through the ureteral catheter and the catheter is pulled out. Amplatz dilators used for sequential urethral dilatation starting from 10 F to 26 F over 8 F stylet as in (PCNL) percutaneous renal surgical operation and it is advanced to the bladder by rotation. Subsequently to dilatation, an 18 F silicon Foley catheter is inserted over the guidewire and removed on day 5 postoperative.

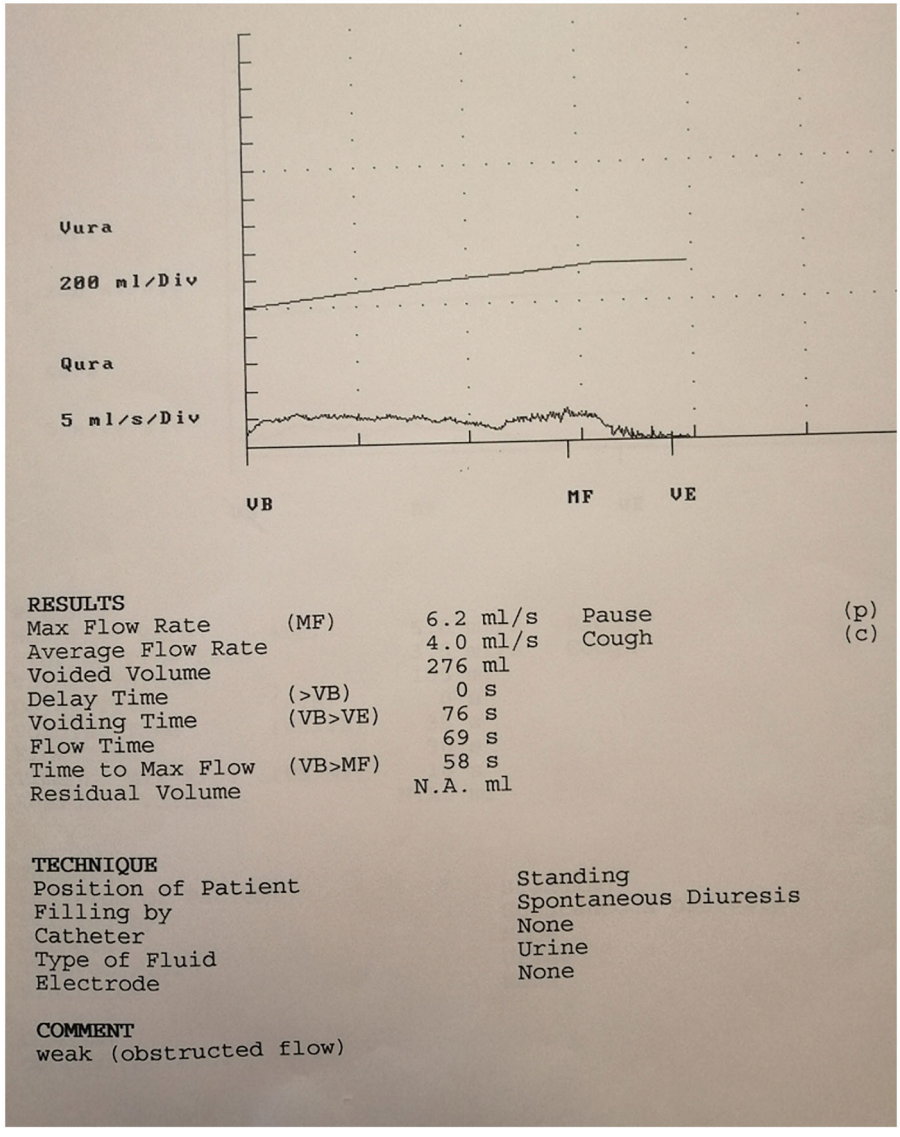

Figure 1. Obstructed uroflowmetry- (plateau flow) (stricture urethtra).

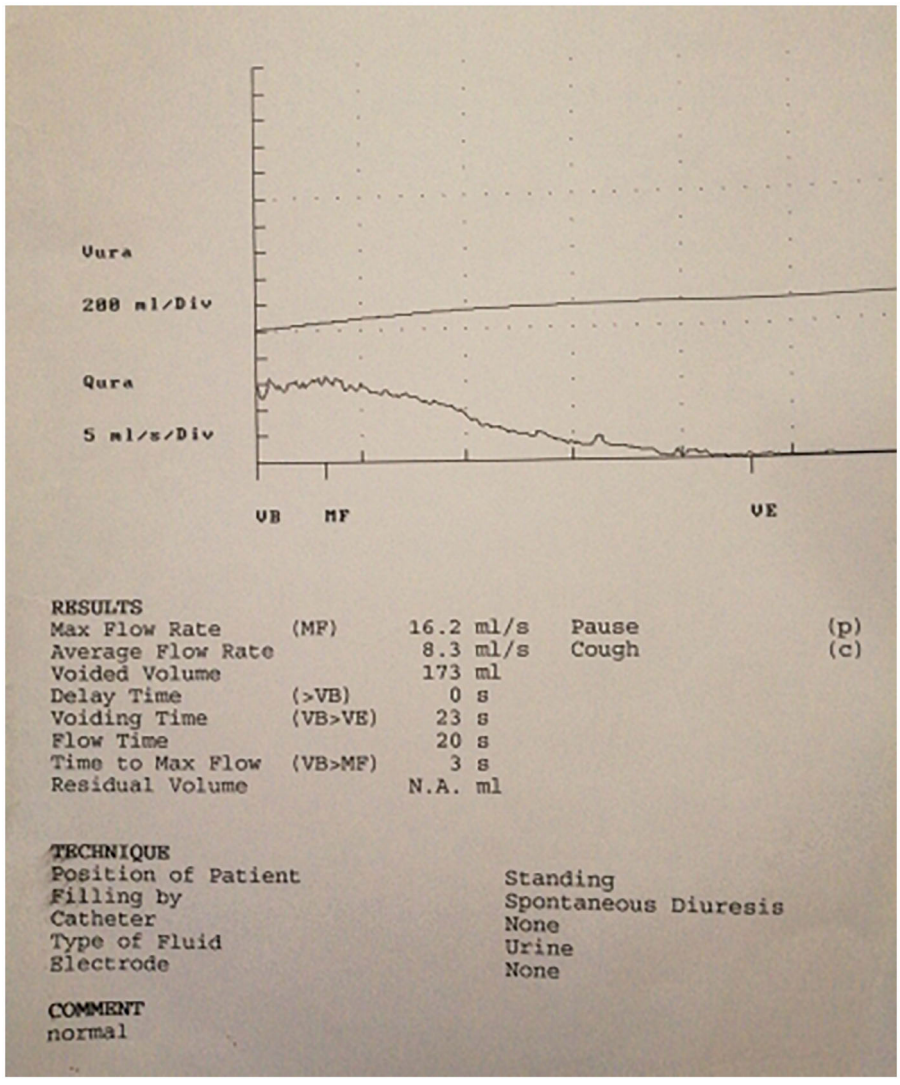

Figure 2. Normal uroflowmetry.

The cold knife process. The Sachse Urethrotome used with a 21 F sheath and 0° telescopic lens. It was progressed into the urethra lumen with lubrication till the stricture location and the knife should be withdrawn. A 5 F guide wire pushed through the sideway channel to direct the urethrotome. Splitting the stricture with the cold Knife at 12'o clock in a backward direction and repeat the process until the fibrosis was sufficiently incised. The process was accomplished by diagnostic cystoscopy and an 18 F Foley catheter is left for 5 days.

Statistics

Statistical analysis was performed with IBM® SPSS® (SPSS Inc., IBM Corporation, NY, USA) Statistics Version 25 for Windows. The normal distribution of data (Shapiro–Wilk's test) was assessed. The parametric data were expressed as mean- ± standard deviation while non-parametric data expressed as frequency and percent. Also, an independent *t*-test was used to compare the parametric data when fitting, while the fisher exact and ($\chi 2$) tests were performed for the comparison of the non-parametric data. All *p*-value <0.05 was considered as significant.

Result

A total of 88 male patients with urethral stricture were evaluated. The mean age was 41.2 (22–73) years, (median 39 y). The median stricture length was 0.9 cm (0.5–1.5). Patient characteristics and intraoperative data are summarized in (Table 1). At baseline (before treatment), IPSS was evaluated and the average score for group 1 and group 2 was 21.2 and 21.9 points, respectively. Immediately after treatment, although, group 1 obtained 19.9 points while group 2 obtained 18.9, no statistically significant difference was reported between the groups ($p > 0.05$). During the 12 months follow-up, IPSS was also evaluated and reported improvement, with average scores of 16.1 and 17.3 points for group 1 and group 2, respectively with no statistically significant difference between the groups ($p > 0.05$).

The etiology and sites of the strictures of both groups were shown in (Table 1). It was determined that the 2 groups were similar concerning age distribution, cause of stricture, and location of the stricture.

The Q max was compared between group 1 and group 2 pre-operative (baseline) and at 15 days, 3 months, 6 months, and 12 months post-operative (Figure 5). At baseline, at day

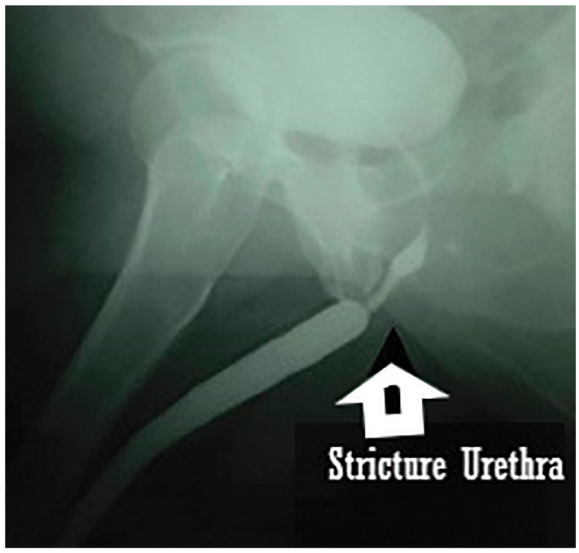

Figure 3. Retrograde urethrogram (stricture urethra).

Figure 4. Amplatz renal dilators.

15, 3 months, and 6 months there was no significant difference between the mean values of (Q max) and results were comparable. At 12 months, the man (Q max) in group 1 showed a statistically higher significant difference between compared to group 1 ($p = 0.003$) (Table 2).

Changes in Q max were reported high value in group 1: after 15 days a strong increase ($p = 0.001$) concerning baseline (before the procedure) and after 3 months an insignificant decline ($p > 0.05$) were observed concerning (15 days' measure), but still, significantly higher than (baseline) ($p = 0.002$). After 6 months, a further insignificant decline occurred ($p > 0.05$) from (3 months) but still higher than baseline, without statistical significance ($p > 0.05$). At 12 months, a more insignificant decline occurred ($p > 0.05$) from (6 months) but still higher than baseline, without statistical significance ($p > 0.05$). Q max for group 2 exposed comparable changes as in group 1, both as in pattern and significance (Figure 5).

In Group 1 (Amplatz), the mean operative time (from diagnostic cystoscopy till the end and urethral catheter) was 18.8 min (range 15–35 min), The mean postoperative hospital stay was 18.5 h (range 12–24). All procedures were performed perfectly and quickly. No false passage or extravasation was recorded during the operation, but only mild hematuria observed in 7 patients (15.9%). After the operation, no major complications were recorded. In group 2, VIU was performed effectively in all cases selected under it, the mean operative time was 11.44 min (range 9–20 min), the mean postoperative hospital stay was 22 h (range 18–36 h). Five patients (11.4%) developed intra-operative bleeding which was treated by effective perineal compression. 3 patients (6.8%) had fluid extravasations in the perineum and treated conservatively. The procedures were found effective without recurrence in all patients (both groups) during the 12 months (Q max $>$ 15 m/s).

Group 1 displays the significance of changes in PVR. The high baseline PVR showed a sharp decline at 15 days after surgery ($p < 0.001$) and more decline through the next 3 months (insignificant, $p > 0.05$), approaching a level significantly less than baseline ($p < 0.001$).

Nevertheless, at 6 months, a statistically insignificant increase displayed ($p > 0.05$) but lesser than baseline ($p < 0.001$). Finally, at (12 months), a slight insignificant increase occurred ($p > 0.05$) from (6 months) but still lesser than baseline ($p < 0.00$). The changes in the measures of PVR in (group 2) were similar to those observed in (group 1) (Table 2). After 15 days, there was a significant decrease in PVR from the baseline ($p < 0.001$). At 180 days, PVR of (group 2) was insignificantly lower than (group 1) ($p > 0.05$). After 1 year of observation, PVR showed that group 2 was a little higher than group 1 (no significance) compared to baseline.

Discussion

Urethral stricture (US) is considered one of the greatest confronting diseases in urology [10]. Various modalities of treatment have been reported regarding the site, stricture length, the thickness of fibrotic tissue involved, selection of cases, and experience of the urologist [11].

Direct Optical internal urethrotomy (DVIU) is unitary of the preferable modalities of management in numerous cases with stricture because of being an easy routine, less expensive and could be repeated safely [12]. Surveys have reported that DVIU provides success rates (33%–89%) and recurrence rates (39%–76%) [13]. It has been documented that success rates with urethral dilatation procedure and using the laser in urethrotomy are almost 60% and 70%, respectively [14].

There have been several trials to document which surgical procedure is the most healing and effective in the treatment of (US) in men, but clinical records are inadequate [15]. There are limited, prospective, randomized studies comparing the success of dilatation versus (DVIU) as first-line management for (US). Wong et al. [16] evaluated the outcomes of urethral dilatation

Table 1. Patients characteristics and demographic.

	Type of operation						
	Amplatz Dilator ($n = 44$)		Cold Knife incision ($n = 44$)		Test value	p Value	Significance
Site of stricture							
Penile urethra	12 (n)	27.3%	14 (n)	31.8%	0.461[a]	0.92	NS
Bulbar urethra	20 (n)	45.4%	18 (n)	40.9%			
Membranous urethra	9 (n)	20.4%	8 (n)	18.2%			
Posterior urethra	3 (n)	6.8%	4 (n)	9.1%			
Causes of urethral stricture							
Inflammatory	18 (n)	40.9%	17 (n)	38.6%	0.479[b]	0.91	NS
Post catheter	10 (n)	25.0%	9 (n)	20.4%			
Traumatic	7 (n)	15.9%	6 (n)	13.6%			
Idiopathic etiology	5 (n)	11.3%	7 (n)	15.9%			
Age	59.2 (mean) ± 19.1 (SD)		60.2 (Mean) ± 20.87 (SD)		1.03[c]	0.31	NS
Stricture length	1.01 (Mean) ± 0.40 (SD)		1.04 (Mean) ± 0.30 (SD)		1.01[c]	0.41	NS

[a]Fisher's exact test.
[b]Chi-square test.
[c]Independent Samples *T*-test.
NS: not significant; SD: standard deviation; n: number.

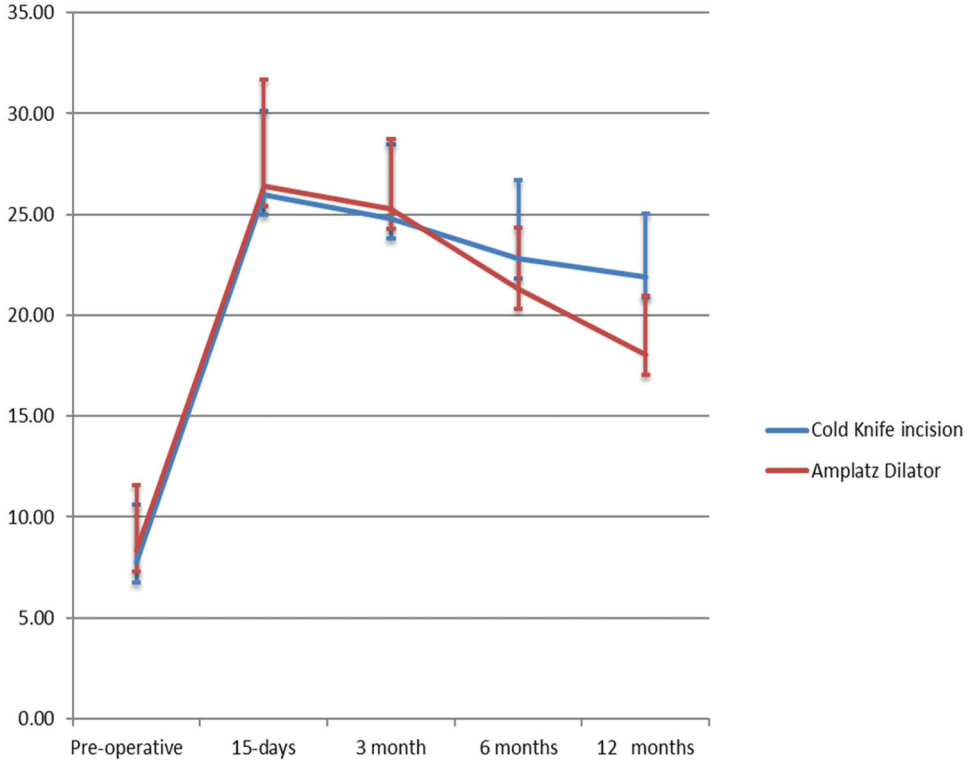

Figure 5. Cluster line chart showing the effect of type of operation used on Q max in different follow-up periods.

Table 2. Changes in Q max during follow-up intervals.

	Amplatz Dilator (group 1)		Cold Knife incision (group 2)		
	Mean ± SD	Range Ml/s	Mean ± SD	Range Ml/s	p Value
Pre-operative	8.31 ± 3.25	4.7–10.9	7.73 ± 2.87	4.1–10.1	0.112
15 days*	26.39 ± 5.30*	20.1–35.8	25.96 ± 4.15**	21.2–33.4	0.091
3 month*	25.28 ± 3.45*	19.9–27.9	24.8 ± 3.69**	18.9–29.8	0.130
6 months*	21.33 ± 3.02*	16.9–26.1	22.8 ± 3.91**	17.9–27.8	0.099
12 months*	18.06 ± 2.90*	16.3–22.1	21.9 ± 3.13**	16.6–26.3	0.003

*Qmax in (group 1); Preoperative versus 15 day, 3, 6, 12 months postoperative: statistically significant ($p < 0.001$).
**Qmax in (group 2) Preoperative versus 15 day, 3, 6, 12 months postoperative: statistically significant ($p < 0.001$).

versus visual urethrotomy in 210 patients with urethral stricture. They reported no significant difference in the percentage of men considered free from stricture at 36 months or in the median period to stricture recurrence.

Steenkamp et al. [14] reported a prospective randomized study between dilatation versus internal urethrotomy involved 100 patients in each group. After 48 months, the tendency for urethrotomy was higher, but without significant difference. Most of the recurrence strictures occurred during the first 12 months following the procedure. The studies showed that both procedures give comparable outcomes, but their efficacy is decreased with long stricture length. Consequently, the surgeons recommend these procedures only for strictures < 2 cm and from (2–4 cm); strictures >4 cm must be managed with initially urethroplasty [14].

The result of endoscopic treatment of Longer strictures are less promising, the success rates of strictures > 4 cm in the bulbar urethra are almost 20% [17].

Amplatz renal dilators have been performed for tract dilatation in (percutaneous renal operation) for a long duration, however, these dilators were not used habitually for the dilatation of (US). Guidewire supported urethral dilatation prevents the risks accompanying blind dilatation methods, such as injury or false path [15].

Akkoc et al. [17] in a cohort of 26 patients with urethral strictures $<$ 1.5 cm, (median length 0.82 cm), estimate that no relapses at 12 months follow-up after using Amplatz dilators alone, regardless the stricture location. Multiple studies have presented no proof that VIU is superior to dilate, but many surgeons instinctively believe so [18]. However, we reported significantly better responses in the Amplatz dilator group compared to VIU group in flowmetry at 12 months ($p = 0.003$).

Earlier studies reported that the Complications related to old-style blind dilatation techniques are popular, such as recurrent scarring tissue, the formation of a false path, incontinence, and injury of the rectum and surrounding organs [19]. Therefore, we avoid these complications by using Guidewire aided urethral dilatation and rotation maneuver in our study.

The percent of complications of VIU versus urethral dilatation was reviewed in the literature [16], intraoperative complications were obvious in the dilatation cases, (dilatation 14% vs urethrotomy 11%) with no statistically important deviation. The severity of stricture seemed to be more challenging among the dilatation cases (dilatation 8.5% vs urethrotomy 6.7%).

For hemorrhage/hematoma, the percent was lesser in the dilatation cases (dilatation 2.8% VS urethrotomy 3.8%). For false path creation, both groups had nearly a similar percent (dilatation 0.94% versus 0.96%). Fluid extravasation and ache seemed to be entirely related to the urethrotomy group while breaking and twisting of the filiform guide was related to the dilatation group only [16]. However, our operations were performed safely and fast. In group 1, no false passage or extravasation during the operation was recorded, but mild hematuria observed in 7 patients (15. 9%).In (group 2), five patients (11.36%) developed intra-operative bleeding which was treated by effective perineal compression and three patients (6.8%) had fluid extravasations.

Albers et al. [20] documented that keeping the urethral catheter in place for 3 days or lower is correlated with fewer recurrence rates (34%), however keeping it for 4–7 days or $>$7 days (recurrence percent of 43% and 65%, respectively).

Multiple surveys have documented the optimum catheterization duration range (1–4) days [21]. Likewise, the size of the catheter does not participate expressively to the development of (US) [22,23]. However, in the present study, we used an 18 F silicon folly urethral catheter that was removed on day 5 postoperative and the following up during 12 months was promising.

At the Mayo Clinic, a retrospective study was conducted on 199 men with stricture urethra, 101 (67%) treated by dilatation, and 39 (26%) performed (DVIU). follow-up of a median 3.5 years, the chance of recurrence-free during 3 years was 65% for dilatation vs 68% for urethrotomy, representing that both techniques were similarly effective as primary management of bulbar strictures [24]. Also, Steenkamp et al. [14] performed a prospective randomized clinical study between dilatation and internal urethrotomy on 100 patients in each group. Afterward 4 years, the movement for urethrotomy was better, but no significant difference was recorded. Although, we reported improvement in both groups, the mean (Qmax) in group 2 showed a higher statistically significant difference than group 1 at 12 months ($p = 0.003$). Generally, the recurrent of strictures occur within the first 12 months [25]. Santucci et al. [26] observed that the usual period for the recurrence after urethrotomy is 9 months. The observing period during 12 months of our study stated that all of our cases had an adequate result regarding the urinary flow (Q max $>$ 15 m/s).

We conclude that both the guided urethral dilation and internal urethrotomy are safe, short time procedures and offer satisfactory results with the advance to VIUD in Q max at 12 months. Also, urethral dilation is a cost-effective method. Whereas Amplatz renal dilatators are single-use, 6–8 processes can be achieved by one Amplatz set; and consequently decreases the costs of the operations.

Disclosure statement

There is no conflict of interest.

References

[1] Lumen N, Hoebeke P, Willemsen P, et al. Etiology of urethral stricture disease in the 21st century. J Urol. 2009;182:983–987.
[2] Bhargava S, Chapple CR, Bullock AJ, et al. Tissue-engineered buccal mucosa for substitution urethroplasty. BJU Int. 2004;93:807–811.
[3] Santucci RA, Joyce GF, Wise M. Male urethral stricture disease. J Urol. 2007;177:1667–1674.
[4] Hampson LA, McAninch JW, Breyer BN. Male urethral strictures and their management. Nat Rev Urol. 2014;11:43–50.
[5] Mangera A, Chapple C. Management of anterior urethral stricture: an evidence-based approach. Curr Opin Urol. 2010;20:453–458.
[6] Naudé AM, Heyns CF. What is the place of internal urethrotomy in the treatment of urethral stricture disease? Nat Clin Pract Urol. 2005;2:538–545.
[7] Farrell MR, Sherer BA, Levine LA. Visual internal urethrotomy with intralesional mitomycin C and short-term clean intermittent catheterization for the management of recurrent urethral strictures and bladder neck contractures. Urology. 2015;85:1494–1499.
[8] Sachse H. [Treatment of urethral stricture: trans urethral slit in view using sharp section]. Fortschr Med. 1974;92:12–15. German.
[9] Gelman J, Liss MA, Cinman NM. Direct vision balloon dilation for the management of urethral strictures. J Endourol. 2011;25:1249–1251. discussion 1251. Erratum in: J Endourol. 2012;26:77.
[10] Kekre NS. Urethral stricture disease – have we found the magic wand? Indian J Urol. 2011;27:303–304.
[11] Cooperberg MR, McAninch JW, Alsikafi NF, et al. Urethral reconstruction for traumatic posterior urethral disruption: outcomes of a 25-year experience. J Urol. 2007;178:2006–2010. discussion 2010.

[12] Latini JM, McAninch JW, Brandes SB, et al. SIU/ICUD consultation on urethral strictures: epidemiology, etiology, anatomy, and nomenclature of urethral stenoses, strictures, and pelvic fracture urethral disruption injuries. Urology. 2014;83:S1–S7.

[13] Saavedra-Briones DV, Merayo-Chalico CE, Sanchez-Turati G, et al. Urethral stricture recurrence following internal urethrotomy. Rev Mex Urol. 2009;69:153–158.

[14] Steenkamp JW, Heyns CF, de Kock ML. Internal urethrotomy versus dilation as a treatment for male urethral strictures: a prospective, randomized comparison. J Urol. 1997;157:98–101.

[15] Bres-Niewada E. The initial treatment of urethral strictures: simple dilatation or urethrotomy?: "Bougie urethral dilators: revival or survival?" – pros. Cent European J Urol. 2014;66:494–495.

[16] Wong SS, Aboumarzouk OM, Narahari R, et al. Simple urethral dilatation, endoscopic urethrotomy, and urethroplasty for urethral stricture disease in adult men. Cochrane Database Syst Rev. 2012; 12:CD006934.

[17] Akkoc A, Aydin C, Kartalmıs M, et al. Use and outcomes of Amplatz renal dilator for treatment of urethral strictures. Int Braz j Urol. 2016;42:356–364.

[18] Zehri AA, Ather MH, Afshan Q. Predictors of recurrence of urethral stricture disease following optical urethrotomy. Int J Surg. 2009;7:361–364.

[19] Scherz HC, Kaplan GW. Etiology, diagnosis, and management of urethral strictures in children. Urol Clin North Am. 1990;17: 389–394.

[20] Albers P, Fichtner J, Brühl P, et al. Long-term results of internal urethrotomy. J Urol. 1996;156:1611–1614.

[21] Heyns CF, Steenkamp JW, De Kock ML, et al. Treatment of male urethral strictures: is repeated dilation or internal urethrotomy useful? J Urol. 1998;160:356–358.

[22] Hart AJ, Fowler JW. Incidence of urethral stricture after transurethral resection of prostate. Effects of urinary infection, urethral flora, and catheter material and size. Urology. 1981;18:588–591.

[23] Stormont TJ, Suman VJ, Oesterling JE. Newly diagnosed bulbar urethral strictures: etiology and outcome of various treatments. J Urol. 1993;150:1725–1728.

[24] Smith PJ, Dunn M, Roberts JB. Surgical management of urethral stricture in the male. Urology. 1981;18:582–587.

[25] Buckley JC, Heyns C, Gilling P, et al. SIU/ICUD consultation on urethral strictures: dilation, internal urethrotomy, and stenting of male anterior urethral strictures. Urology. 2014;83: S18–S22.

[26] Santucci R, Eisenberg L. Urethrotomy has a much lower success rate than previously reported. J Urol. 2010;183:1859–1862.