Original Article

A randomized clinical trial comparing intracorpus spongiosum block versus intraurethral lignocaine in visual internal urethrotomy for short segment anterior urethral strictures

Deepak Kumar Biswal, Bastab Ghosh, Malay Kumar Bera[1], Dilip Kumar Pal

Department of Urology, Postgraduate Institute of Medical Education and Research, [1]Department of Urology, Medical College and Hospital, Kolkata, West Bengal, India

Abstract

Objectives: The primary objective was to compare the effectiveness in pain relief of intracorpus spongiosum block (ICSB) versus intraurethral topical anesthesia (TA) using 2% lignocaine jelly for performing visual internal urethrotomy (VIU) for short segment anterior urethral strictures.

Materials and Methods: It was a randomized, parallel group controlled trial. Participants are adult patients with a single anterior urethral stricture up to 2 cm in length. Patients were allocated to two intervention groups with thirty patients in each group. For anesthesia of the urethra, Group 1 patients received ICSB whereas Group 2 patients received intraurethral TA using 2% lignocaine jelly before VIU. Patient discomfort was assessed with visual analog scale (VAS) during the procedure and 1 h postprocedure. The increase in pulse rate and the change in systolic blood pressure (BP) during the procedure were recorded. The procedure was considered successful if there was absence of symptoms or signs of recurrent stricture and ability to pass freely 18Fr catheter during urethral calibration at last follow-up.

Results: From March 2014 to June 2015, sixty patients were randomized into two groups of thirty patients each. The mean (±standard deviation) intraoperative VAS score was 2.8 ± 1.1 in Group 1, which was significantly less ($P < 0.05$) than the 5.6 ± 1.7 score in Group 2. The mean 1 h postoperative VAS score was also significantly lower in Group 1 patients (1.0 ± 1.0) than in Group 2 patients (3.2 ± 1.5). The change in pulse rate was significantly greater in Group 2 (21.3 ± 10.1 beats/min) than in Group 1 (10.6 ± 4.6 beats/min, $P < 0.05$). The change in systolic BP was also significantly higher in Group 2 (16.3 ± 8.6 mmHg) than in Group 1 (9.1 ± 4.4 mmHg, $P < 0.05$). The stricture-free rate at 6-month after VIU in Group 1 and Group 2 patients were 88.5% and 89.6%, respectively.

Conclusions: ICSB has better pain control with similar complication and recurrence rate than intraurethral lignocaine jelly alone in VIU.

Key Words: Internal urethrotomy, intracorpus, local anesthesia, randomized, trial, visual internal urethrotomy

Address for correspondence:
Prof. Dilip Kumar Pal, Department of Urology, Postgraduate Institute of Medical Education and Research, 244, AJC Bose Road, Kolkata - 700 020, West Bengal, India. E-mail: drdkpal@yahoo.co.in

Received: 10.02.2016, **Accepted:** 01.04.2016

Access this article online	
Quick Response Code:	Website: www.urologyannals.com
	DOI: 10.4103/0974-7796.184901

How to cite this article: Biswal DK, Ghosh B, Bera MK, Kumar DP. A randomized clinical trial comparing intracorpus spongiosum block versus intraurethral lignocaine in visual internal urethrotomy for short segment anterior urethral strictures. Urol Ann 2016;8:317-24.

INTRODUCTION

Urethral strictures are an extremely common entity and account for a significant part of every urologist's workload. Its incidence is varied globally. In a US Medicare beneficiaries survey urethral stricture incidence reported to be 0.9%.[1]

The treatment options for urethral strictures range from minimally invasive methods such as visual internal urethrotomy (VIU) and urethral dilatation to open reconstructive urethroplasty. The optimal indications for dilatation or internal urethrotomy are simple bulbar strictures shorter than 2 cm without spongiofibrosis or history of previous treatment.[2-4]

The appeal of VIU/dilation is its relative ease of performance, minimal resource requirements, and simplicity in not requiring expertise in urethral reconstruction. The procedure can also be performed on an outpatient basis in the office (under local anesthesia), requires minimal recovery time and has a low-cost burden to the patient in terms of disability precluding work. For highly selected patients with optimal stricture characteristics (primary bulbar stricture, <1 cm, soft), a stricture-free rate (SFR) of up to 50–70% can be achieved. Thus, urethrotomy remains the first-line therapy for these select patients. The SFR is still well below that of anastomotic urethroplasty (90–95%), but urethrotomy can be justified by its simplicity and relatively low morbidity to the patient.[3]

Most cost-effective strategy for the management of short bulbar urethral strictures is to reserve urethroplasty for patients in whom a single endoscopic attempt fails. For longer strictures, in which the success rate of VIU is expected to be < 35%, urethroplasty as primary therapy is cost-effective.[5] Similar studies confirmed that initial urethrotomy or dilation followed by urethroplasty in patients with recurrent strictures is the most cost-effective.[6,7] Moreover, failure of primary VIU does not have any effect on the outcome of future urethroplasty surgery.[8]

In recent surveys, most urologists perform VIU as initial management of urethral strictures.[1,9-12] Most commonly, VIU is performed under spinal anesthesia. In developing countries where resources are limited and caseload is more, VIU is performed commonly under local anesthesia on an outpatient basis.

Although intracorpus spongiosum block (ICSB) has been described since 2002, there were very few reports in medical literature available for VIU using this technique.[13] This randomized controlled trial may prove valuable while making a decision in the management of short segment anterior urethral stricture in a swift and cost-effective way.

In the current study, we tested the hypothesis that ICSB would be a more effective local anesthesia technique than topical anesthesia (TA) for performing VIU for short segment anterior urethral strictures.

Our primary objective was to compare the effectiveness in pain relief of ICSB with versus intraurethral TA using 2% lignocaine jelly for performing VIU for short segment anterior urethral strictures. Other objectives were to compare the safety and success rate of VIU using ICSB versus TA for short segment anterior urethral strictures.

MATERIALS AND METHODS

This was a randomized, parallel group controlled trial conducted at a tertiary care institution in India. All adult patients with a single anterior urethral stricture up to 2 cm in length, who were planned for VIU as the treatment for their urethral stricture, were accessed for eligibility for the study. Patients with multiple strictures, stricture of fossa navicularis or penile urethra were excluded from the study. Moreover, patients with associated urethral or vesical calculus, benign prostatic hyperplasia, neurovesical dysfunction, or significant cardiovascular diseases were excluded. Enrollment started on March 2014 till June 2015 when the sample size was reached. Patients were allocated to two intervention groups with thirty patients in each group. For anesthesia of the urethra, Group 1 patients received ICSB whereas Group 2 patients received intraurethral TA using 2% lignocaine jelly before VIU.

Following informed written consent to participate in the study, the patients were randomized to receive either ICSB or TA for the procedure of VIU based on computer-generated random numbers using block randomization method. Allocation concealment was done by using sealed envelopes that were opened in the operating room by the surgeon performing the procedure after the patient consented to participate in the study. Both performing surgeon and patient were not blinded about the method of intervention received.

The patients were placed in lithotomy position. After cleansing and the anesthesia was given, described as below.

In ICSB group (Group 1), a dosage of 3 ml of 1% lignocaine slowly injected into the dorsal glans in at least 1 min with a 26 Gauge hypodermic needle [Figure 1]. To avoid bleeding, the glans was squeezed with a swab for 1–3 min. After that, the VIU procedure was immediately performed. In this group, water soluble nonanesthetic lubricant jelly (K-Y® Jelly, Johnson & Johnson, Sezanne, France) was used for introduction of the VIU sheath.

In TA group (Group 2), 10 ml of 2% lignocaine jelly (Lox® 2% Jelly, Neon Laboratories Limited, Mumbai, Maharashtra,

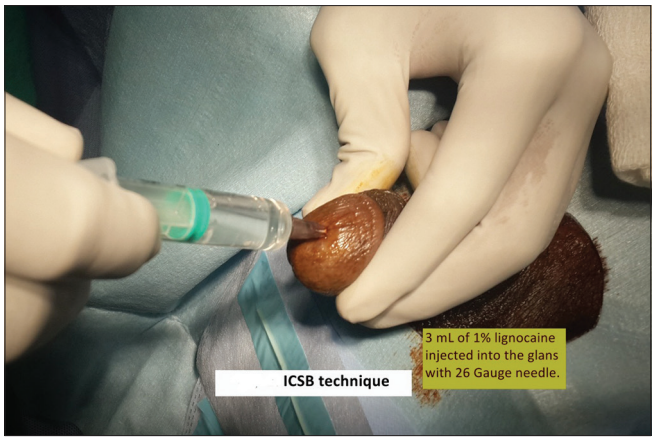


Figure 1: Intracorpus spongiosum block technique

India) was instilled through the urethral meatus, and the meatus was clamped for 10 min to allow the anesthetic agent to act.

A standard Sachse urethrotomy knife was used under the guidance of a 0.035-inch guidewire. A single 12 o'clock incision was made until the full thickness of the fibrous scar was divided and normal tissue below the stricture was reached. Complete incision of the stricture deemed achieved once the 21Fr sheath is passed freely into the bladder. After the procedure was concluded, an 18Fr Foley catheter was placed. Patients were discharged with an indwelling catheter after completion of the VIU. Oral fluoroquinolone was given until the catheter was removed. The catheter was usually removed after 5 days on an outpatient basis.

Patient discomfort was assessed with visual analog scale (VAS) during the procedure and 1 h postprocedure. The VAS consisted of scores 0 through 10, where 0 represents no pain and 10 reflect maximum pain. VAS score was recorded by a nurse at recovery room who was blinded about the anesthesia technique used.

Immediate preprocedure and perioperative pulse rate and systolic blood pressure (BP) were monitored. The increase in pulse rate (preoperative vs. maximum perioperative pulse rate) and the change in systolic BP (preoperative vs. maximum perioperative systolic BP) during the procedure were recorded for each patient as an objective indicator of the sympathetic response to pain.

Perioperative period complications (till 30 days post-VIU) were recorded and classified according to Clavien-Dindo Classification system.

All patients were called for followed up at 1 month and thereafter every 3 months. The postprocedure evaluation was performed by uroflowmetry and urethral calibration by an 18Fr Foley catheter. Retrograde urethrogram was performed in those who had any symptoms pertaining to recurrence, decreased flow rate in uroflowmetry, or failed to calibrate the urethra. The procedure was considered successful if there was the absence of symptoms or signs of recurrent stricture and ability to pass freely 18Fr catheter during urethral calibration at last follow-up.

Continuous data were expressed as a mean (±standard deviation [SD]). Comparative analysis between two groups was performed using the Chi-square test for categorical data and independent *t*-test or Mann–Whitney U-test for continuous data as applicable. All statistical tests were two-tailed, and $P < 0.05$ was considered as significant. We used SPSS software for analysis (version 20, IBM Corporation, NY, USA).

RESULTS

From March 2014 to June 2015, 109 patients were assessed. Thirty-seven patients were excluded after considering inclusion and exclusion criteria. Twelve patients refused to participate in the study. The remaining sixty patients were randomized into two groups of thirty patients each [Figure 2]. One patient in ICSB group failed to tolerate the pain during the procedure. VIU was abandoned and subsequently performed under spinal anesthesia. Data of rest 59 patients were analyzed for primary outcomes.

Mean (±SD) age of the patients was 42.6 (±15.4) years (range: 19–83 years). The mean duration of the symptoms of stricture disease was 13.8 months (median: 10 months, range: 1–72 months).

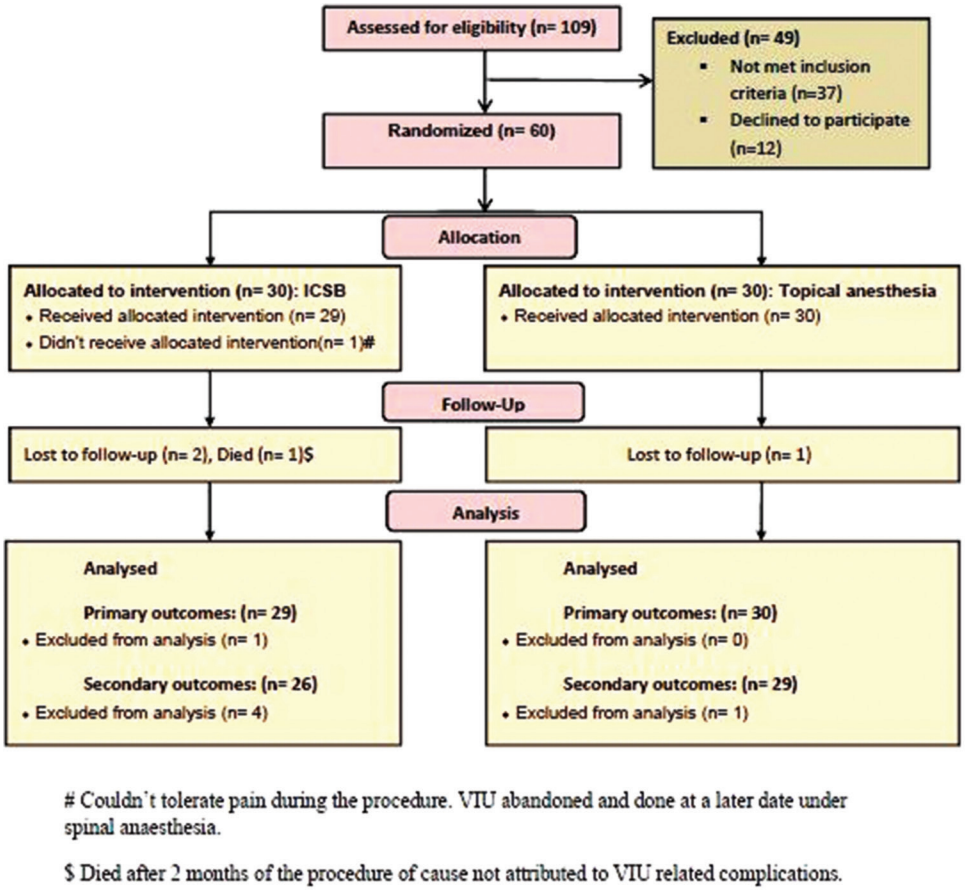
Two intervention groups were similar in terms of mean age, duration of symptoms, stricture length, stricture type (primary/recurrent), and stricture location.

Most of the patients (23 patients) in the two groups had an idiopathic stricture (38.9%). Inflammatory strictures were seen in ten patients (16.9%).

After evaluation preoperative maximum flow rate (Q_{max}) on uroflowmetry, the amount of postvoid residual urine, baseline pulse rate, and systolic BP were similar in both intervention groups [Table 1].

Mean baseline pulse rate was 77.4 (±7.0) per min in Group 1 and 76.4 (±9.2) per min in Group 2 patients. Mean baseline systolic BP was 127.6 (±10.5) mmHg in Group 1 and 129.1 (±9.7) mmHg in Group 2 patients.

The mean (±SD) intraoperative VAS score was 2.8 ± 1.1 in Group 1, which was significantly less ($P < 0.05$) than the



Couldn't tolerate pain during the procedure. VIU abandoned and done at a later date under spinal anaesthesia.

$ Died after 2 months of the procedure of cause not attributed to VIU related complications.

Figure 2: Consort diagram of the study

Table 1: Preoperative characteristics of two groups

Variable	Group 1 (ICSB)	Group 2 (TA)	*P*
Age (years) (range)	41.4±13.9 (19-69)	43.7±16.8 (20-83)	0.58
Duration (months) (range)	15.9±14.4 (3-60)	11.8±13.0 (1-72)	0.13
Stricture length (cm)	1.3±0.6	1.2±0.5	0.46
Type (*n*)			
Primary	27	27	0.51
Recurrent	2	3	
Etiology (*n*)			
Traumatic	6	7	0.52
Inflammatory	6	4	
Iatrogenic	8	5	
Idiopathic	9	14	
Stricture location (*n*)			
Penobulbar	6	10	0.55
Mid-bulbar	16	15	
Proximal bulbar	7	5	
Preoperative Q_{max} (ml/s)	7.5±3.0	6.2±2.7	0.08
Pre-PVRU (ml)	134.7±74.8	125.3±56.1	0.57
Preoperative pulse (rate/min)	77.4±7.0	76.4±9.2	0.65
Preoperative SBP (mmHg)	127.6±10.5	129.1±9.7	0.57

PVRU: Postvoid residual urine, ICSB: Intracorpus spongiosum block, SBP: Systolic blood pressure, TA: Topical anesthesia

5.6 ± 1.7 score in Group 2. The mean 1 h postoperative VAS score was also significantly lower in Group 1 patients (1.0 ± 1.0) than in Group 2 patients (3.2 ± 1.5). The change in pulse rate (preoperative vs. maximum intraoperative) was significantly greater in Group 2 (21.3 ± 10.1 beats/min) than in Group 1 (10.6 ± 4.6 beats/min, $P < 0.05$). The change in systolic BP was also significantly higher in Group 2 (16.3 ± 8.6 mmHg) than in Group 1 (9.1 ± 4.4 mmHg, $P < 0.05$) [Table 2].

All patients were discharged after the VIU. The antibiotic was continued postoperatively until the catheter was removed. The Foley catheter was removed after 5 days in all patients except two patients in Group 1 and three patients in Group 2 who developed urinary extravasation (Clavien-Dindo Grade-I) and treated conservatively. The urethral catheters were removed after 7 days. All patients voided well after catheter removal. No anesthesia-related complications were noted [Table 3].

Median follow-up was 12 months (range: 6–22 months). During follow-up in Group 1, recurrence of stricture was noted in five patients at follow-up. In Group 2, recurrence of urethral stricture developed in seven patients. Median time to stricture recurrence was 6.5 months (range: 2–17 months). SFR at 6-month after VIU in Group 1 and Group 2 patients were 88.5% and 89.6%, respectively. By Kaplan–Meier survival analysis, there was no difference in recurrence of stricture in two groups ($P = 0.416$) [Figure 3].

Table 2: Comparison of primary outcomes

Variable	Group 1 (ICSB)	Group 2 (TA)	*P*
ΔIntraoperative pulse (rate/min)	10.6±4.6	21.3±10.1	0.000003
ΔIntraoperative SBP (mmHg)	9.1±4.4	16.3±8.6	0.000195
Intraoperative VAS	2.8±1.1	5.6±1.7	0.0000001
1 h postoperative VAS	1.0±1.0	3.2±1.5	0.0000001

ICSB: Intracorpus spongiosum block, SBP: Systolic blood pressure, VAS: Visual analog scale, TA: Topical anesthesia

Table 3: Perioperative complications

Variable	Group 1 (ICSB)	Group 2 (TA)
Complications (*n*) (*P*=0.86)		
Intraoperative bleeding	0	1
Penoscrotal edema	2	3
Recurrent bleeding	1	1
UTI	4	7

ICSB: Intracorpus spongiosum block, UTI: Urinary tract infections, TA: Topical anesthesia

Recurrent strictures were managed by repeat VIU ($n = 7$), end to end anastomotic urethroplasty ($n = 3$), and buccal mucosal graft augmentation urethroplasty ($n = 2$).

DISCUSSION

VIU first introduced by Sachse in 1974.[14] It is usually performed under spinal anesthesia. Although urethroplasty has a low recurrence rate, it is costly, technically demanding, and time-consuming procedure with greater morbidity than VIU. VIU has advantages of less invasiveness, short procedure time, less morbidity, less technically demanding, and with reasonable success rate. Hence, among the urologists, VIU widely practiced as first-line management of short segment anterior urethral strictures.[1,9,10] For performing these on an outpatient basis, to decrease the cost, lessen the burden on the operating room and recovery room, reduce procedure time, cost-effectiveness, and the morbidity of spinal/general anesthesia, alternative anesthetic techniques has been described. Feasibility of VIU under local anesthesia using topical 2% lignocaine jelly has been shown in various studies from a long period of time.[15-23]

In a recent study, 33 patients with urethral stricture underwent VIU by a single operator under local anesthesia (intraurethral 20 ml of 1% lignocaine solution) supplemented by 50–75 mg intravenous pethidine. Of these patients, 70% had dense stricture involving the corpora spongiosum. It was very well tolerated (average visual analog pain score: 2/10) with low complication rate. Only six patients gave a VAS of more than 3 of 10. Nine patients reported no discomfort during the procedure. In 91% the procedure was successful.[22] Comparatively lesser success was shown in 1993 for VIU with topical lignocaine anesthesia that gave a success of 83%.[19] Whereas in 2007, VIU with topical

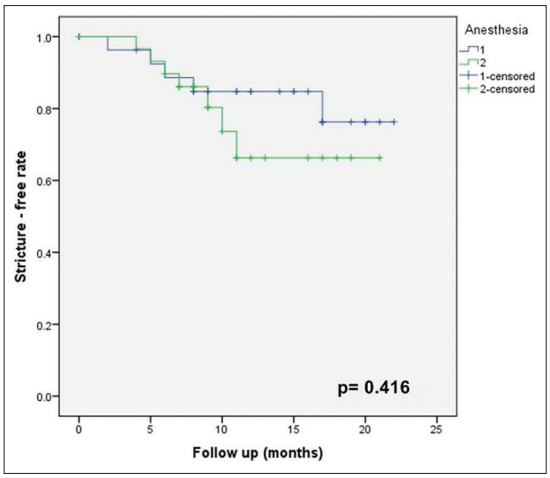


Figure 3: Comparison of stricture-free rate between two groups

lignocaine anesthesia was reported to be successful in 92.9% cases with short stricture length. Authors suggested this minimally invasive procedure was to be safe and comfortable and yet inexpensive.[21]

In our present study, of thirty patients in Group 2 who underwent VIU under local anesthesia using intraurethral 2% lignocaine jelly, 19 patients experienced moderate pain (VAS: 4–6) and eight patients experienced severe pain (VAS > 6) in the intraoperative period. Though all patients tolerated the procedure and in all patients, VIU was successfully completed.

Another study compares VIU in anterior urethral strictures under local urethral anesthesia, with or without sedoanalgesia. Mean pain VAS scores for patients under 2% lignocaine urethral gel anesthesia with or without sedoanalgesia were 2.86 and 4.5, respectively.[23] These studies prove that VIU can be done safely with minimum discomfort under intraurethral TA using lignocaine jelly.

Ye and Rong-gui in 2002 described a new anesthetic technique called "intracorpus spongiosum block" in VIU. The spongiosum block technique is based on male urethral anatomy. The anterior urethra is composed of urethral epithelium surrounded by corpus spongiosum with venous sinusoids. At the distal end, the corpus spongiosum expands to form the glans penis. When lignocaine is slowly injected subcutaneously into the syncytium of the spongiosum of the glans, an anesthetic agent spreads through the venous sinuses and rapidly anesthetizing the dermal nerve endings in the whole anterior urethra. The anesthetic effect of intracorpus spongiosum anesthesia is immediate. Twenty-two (95.7%) patients experienced no pain or discomfort. In one patient, there was minimal but tolerable discomfort during the period when the tissue above the stricture was cut. The anesthesia, which lasted approximately 1.5 h, proved very

satisfactory; there were no complications.[13] Later, he described this anesthesia can be used in other minor anterior urethral procedures in outpatients settings in a cost-effective manner.[24]

Later in a prospective study, 43 patients underwent VIU under intracorpus spongiosum anesthesia (3 ml of 2% lignocaine) plus topical application of eutectic mixture of local anesthetic applied to the glans penis 15 min before ICSB to reduce the pain during injection. The procedure was successful in 91% of cases. Pain scores reported by patients ranged between 0 and 4, with an average of 1.6.[25]

In a nonrandomized trial on safety and efficacy of VIU using spongiosum block with sedation compared to major regional or general anesthesia for anterior urethral stricture demonstrated that this method was equally effective and safe with shorter operating time and cost-effectiveness.[26]

Kumar *et al.* first reported a randomized controlled trial comparing combined spongiosum block and intraurethral lignocaine with intraurethral lignocaine alone in VIU for anterior urethral strictures. Fifty patients were prospectively randomized to undergo VIU under spongiosum block along with intraurethral lignocaine (Group 1 = 25 patients) and intraurethral lignocaine only (Group 2 = 25 patients). The mean VAS for pain in Group 1 (1.5 ± 1.4) was significantly lower than the score in Group 2 (2.7 ± 1.8) ($P = 0.006$). At 6 months follow-up, recurrent strictures were developed in three patients in Group 1 and five patients in Group 2.[27]

Ghosh *et al.* reported a randomized controlled trial comparing pain control by ICSB versus TA during VIU. Forty patients with single, short, passable anterior urethral stricture were randomized into two groups. Group 1 patients received topical 2% lignocaine jelly and Group 2 patients received 1% lignocaine ICSB. VAS scores intraoperatively (2.85 ± 1.34) and at 1 h postoperatively (1.17 ± 0.96) were significantly lower ($P < 0.01$) in Group 2 patients than the corresponding scores in Group 1 (4.9 ± 1.9 and 2.35 ± 1.34, respectively). They described the intraoperative rise in pulse rate and in BP as a marker of sympathetic overactivity due to pain, which significantly greater ($P < 0.05$) in Group 1 patients (13 ± 5.1/min and 11.3 ± 6.44 mmHg) than in Group 2 (8.05 ± 5.54/min and 6.35 ± 5.86 mmHg). They concluded that ICSB is safe and more effective than TA for providing pain relief during VIU.[28]

In our study, in ICSB group we successfully performed VIU in 29 patients out of thirty patients (96.7%). Mean VAS scores were intraoperative (2.8 ± 1.1) and at 1 h postoperative (1.0 ± 1.0). These are comparable to pain reported in previous randomized controlled trials. The VAS scores intraoperatively (2.8 ± 1.1) and at 1 h postoperatively (1.0 ± 1.0) were significantly lower ($P < 0.05$) in Group 1 patients than the corresponding scores in Group 2 (5.6 ± 1.7 and 3.2 ± 1.5, respectively). Moreover, intraoperative rise in pulse rate and in BP was significantly greater ($P < 0.05$) in Group 2 patients (21.3 ± 10.1/min and 16.3 ± 8.6 mmHg) than in Group 1 (10.6 ± 4.6/min and 9.1 ± 4.4 mmHg).

Although discomfort experienced by patients in ICSB group is very minimal, the mild pain experienced during injection over glans can be minimized by topical application of EMLA cream over glans as described by Mensah *et al.*[25] We experienced discomfort in some patients of ICSB group while passing the VIU sheath through the posterior urethra into the bladder although strictures in our study are of the short segment (≤2 cm). It can be explained as ICSB cannot anesthetize posterior urethra. There was also a report of pain while manipulation in urethra proximal to dense stricture as anesthetic agent cannot pass beyond the stricture segment in corpus spongiosum.[29] These can be overcome by combining topical lignocaine jelly into the urethra with ICSB as explained by Kumar *et al.*[27]

In patients who underwent VIU under ICSB anesthesia, Kumar *et al.* reported a recurrence of stricture in three (12%) patients at 6 months follow-up,[27] whereas Ghosh *et al.* reported a recurrence of stricture in one (5%) patients at 1.5 years follow-up.[28] In our study, SFR at 6-month after VIU in Group 1 and Group 2 patients were 88.5% and 89.6%, respectively, with no significant difference between two groups ($P = 0.416$). Other minor perioperative complications such as penoscrotal edema, bleeding, and urinary tract infections were managed conservatively.

In a recent prospective study, thirty male patients of high anesthesia risk group (American Society of Anesthesiologist physical status grading 3 and 4) with stricture urethra were treated by VIU under ICSB. The effect of this anesthetic technique was evaluated by numerical rating scale for pain. Of the thirty patients, five patients have no pain, 23 patients have mild pain and 2 patients have moderate pain.[30] This shows the utility of this anesthetic technique for VIU in high anesthesia risk patients. In our study, we excluded the patients with high severe cardiorespiratory comorbidities as in our protocol VIU was to be performed on outpatient basis. It would be risky to immediately discharge those patients.

Another anesthetic technique, the transperineal urethrosphincteric block, has been described for performing VIU using 1% lignocaine showed favorable results in

treating anterior urethral strictures, with 92% patients very satisfied with the procedure.[31] Compared with this technique, ICSB provides equivalent analgesia with a simple technique and using a small volume of lignocaine (3 ml of 1% solution).

In our study, we did not have any ICSB anesthesia-related complications. Although Ather *et al.* and Kumar *et al.* reported the use of a rubber tourniquet at the base of the penis to prevent the rapid washout of lignocaine to the venous circulation, in our study we did not use it. The slow injection of lignocaine in the glans gave sufficient time for the drug to fix to the tissue. In a series of 69 patients who underwent spongiosum anesthesia, there were no serious complications related to an anesthetic technique, except for 3 (4.3%) patients who had instantaneous trance during the injection. None of the patients had spongiofibrosis resulting from intracorpus spongiosum anesthesia during a 6-month follow-up.[24] There was no lignocaine toxicity reported. This may be explained by the fact that the total dose of lignocaine (3 ml of 1% solution) was well below safe limit described for use in local anesthesia.

Limitations of this study were that it was nonblinded, small sample size in intervention groups, and interventions were not placebo controlled. Although the change in heart rate and systolic BP are objective parameters, pain perception recorded by VAS was a subjective parameter during outcome analyses. As the study was nonblinded, it may be a source of bias.

CONCLUSIONS

ICSB has better pain control with similar complication and recurrence rate than intraurethral lignocaine jelly alone in VIU. Hence, it should be the preferred local anesthetic technique than intraurethral lignocaine jelly for VIU in short segment anterior urethral stricture. It can be a useful and feasible anesthesia technique for VIU in high-risk patients for general/regional anesthesia.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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