Use of the Schelin Catheter for transurethral intraprostatic anesthesia prior to Rezūm treatment

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Minimally invasive surgery techniques (MIST) have become newly adopted in urological care. Given this, new analgesic techniques are important in optimizing patient outcomes and resource management. Rezūm treatment (RT) for BPH has emerged as a new MIST with excellent patient outcomes, including improving quality of life (QoL) and International Prostate Symptom Scores (IPSSs), while also preserving sexual function. Currently, the standard analgesic approach for RT involves a peri-prostatic nerve block (PNB) using a transrectal ultrasound (TRUS) or systemic sedation anesthesia. The TRUS approach is invasive, uncomfortable, and holds a risk of infection. Additionally, alternative methods such as, inhaled methoxyflurane (Penthrox), nitric oxide, general anesthesia, as well as intravenous (IV) sedation pose safety risks or mandate the presence of an anesthesiology team. Transurethral intraprostatic anesthesia (TUIA) using the Schelin Catheter (ProstaLund, Lund, Sweden) (SC) provides a new, non-invasive, and efficient technique for out-patient, office based Rezūm procedures. Through local administration of an analgesic around the prostate base, the SC has been shown to reduce pain, procedure times, and bleeding during MISTs. Herein, we evaluated the analgesic efficacy of TUIA via the SC in a cohort of 10 patients undergoing in-patient RT for BPH.

Key Words: Schelin Catheter, TUIA, Rezūm, TRUS, PNB, BPH

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A video clip is available online at www.canjurol.com

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Introduction

Overview of procedure/technology

Benign prostatic hyperplasia (BPH) is a common urological condition presenting with lower urinary tract symptoms (LUTS), significantly affecting the

quality of life (QoL) of aging men.[1] While lifestyle modifications and pharmacological interventions are used in BPH management, surgery is often required for more effective symptom resolution. However, reduced sexual function is an important complication of BPH surgery that affects patient decision-making.[2]

The introduction of Rezūm Treatment (RT) as a minimally invasive surgical therapy (MIST) with its FDA approval in 2015, has shown a promising alternative to transurethral resection of the prostate (TURP) conventionally used to treat BPH.[3] RT has shown benefit in patients with LUTS related to BPH by improving International Prostate Symptom Scores (IPSSs) and QoL, while also preserving erectile and ejaculatory function including in those with large volume prostates and median lobe presence.[4] Given the versatility of Rezūm in treating even large prostates, a broader patient demographic can now benefit from preserved sexual function while treating BPH, an important component that is often compromised by other surgical approaches.

As surgical care continues to advance in urology, perioperative pain management has also evolved. Unlike TURP and its tissue respective counterparts (Greenlight, holmium laser enucleation of the prostate (HoLEP), Aquablation), MISTs do not require general anesthesia and can be conducted in out-patient and clinical settings with a simple peri-prostatic nerve block (PNB) using transrectal ultrasound (TRUS) guidance.[3] Nonetheless, ultrasound (US) equipment poses challenges due to its substantial financial burden, space requirement, and limited availability in certain urology offices. In addition, patient discomfort, infectious complications, and contraindications such as, perianal inflammation, active hemorrhoids, and prostatitis, limit its clinical use.[5]

Penthrox, a portable handheld inhaler that delivers low dose methoxyflurane 99.9%, was shown to have reduce pain scores in patients undergoing prostate biopsy compared to TRUS-guided PNB.[6] While Penthrox provides a minimally invasive pain management option, its cost and risks, such as hypotension, bradycardia, potential for malignant hyperthermia, and nephrotoxicity prevent its routine application in out-patient settings. Further, Penthrox use requires close monitoring of vital signs approximately every 5 minutes following its use and every 30 minutes until discharge.[7] At the present time, TRUS-guided PNB remains the standard preoperative analgesic procedure.[5] However, given the limitations of TRUS, establishing less invasive and safer analgesic methods is of importance, especially as surgical care for BPH continues to excel in minimally invasive techniques, such as RT.

A recent development in the field of urology introduces Transurethral Intraprostatic Anesthesia (TUIA) using the Schelin Catheter (ProstaLund AB, Lund, Sweden) (SC), Figure 1. The SC is a simple, disposable, single use, light catheter device that contains a retractable injection needle for local anesthetic injection, drainage outlet, and balloon port. This method exhibits potential in alleviating pain and enhancing the efficacy of MISTs, which conventionally require TRUS, spinal anesthesia, or general anesthesia. The SC offers better local peri-urethral anesthesia by achieving injection sites in and around all angles of the prostate[8].

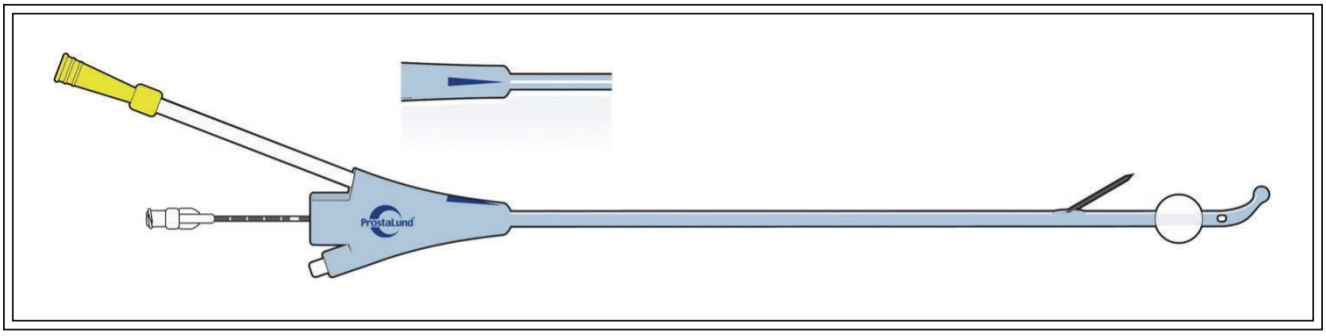

Figure 1. Device overview for intraprostate needle injections. The catheter is a CE-marked device for injections of legally marketed drugs into the prostate. While the Schelin Catheter may appear as a normal urinary catheter, it has an extra channel through which a thermoplastic cannula is inserted. The cannula is connected to a syringe for drug delivery (injection) directly into the prostate in a sterile transurethral way. When local anesthesia is administered with the Schelin Catheter: pain and discomfort is decreased, the risk of pathogens from the rectum entering the body is eliminated, and the need for general anesthesia is eliminated.

Relevant historical studies

Application of TUIA

The application of TUIA via the SC has been recorded in the setting of MISTs, notably RT. In fact, the SC provided full operative and postoperative pain control during RT while reducing operative time in a cohort of 20 patients with a median prostate size of 75 cc.[8] Prostate injection with mepivacaine and adrenaline using SC in patients undergoing microwave thermal therapy (TUMT) and TURP reduced bleeding, operative time, and postoperative pain.[8,9] Furthermore, in a cohort of 81 patients, injection of mepivacaine via SC lead to larger resection weights compared to those not treated with mepivacaine.[10] As such, TUIA via SC shows potential in providing effective pain management, enhancing surgical outcomes.

In this paper, we aim to outline the use of TUIA via SC and determine its effectiveness in controlling operative and postoperative pain related to RT within a subset of 10 male patients in an out-patient clinic. Additionally, we aim to compare pain scores with those from patients who underwent TRUS-guided PNB in our previous pilot study.[11]

Method and technique

Patient assessment

After obtaining IRB approval of a prospective Rezūm database, 10 patients were recruited and evaluated based on medical history, physical examination, and standard urological measures for the assessment of LUTS and BPH. These included the International Prostate Symptom Score (IPSS), quality of life (QoL), prostate volume, serum prostate-specific antigen (PSA), urodynamic evaluation (maximum urinary flow rate (Qmax), and post-void residual volume (PVR)).

Male patients with known BPH and LUTS who were candidates for Rezūm MIST underwent the procedure along with TUIA lidocaine 2% injection via SC prior to Rezūm. Our experience included 10 consecutive patients from a single surgeon at an out-patient clinic. Men were excluded if they presented with foley retention or contraindications to transurethral manipulation.

TUIA procedure using the SC

To ensure efficacy of TUIA using SC, several steps outlined in Table 1 and Video 1 were carried out. The procedure was completed after following the device

TABLE 1. **Performing TUIA using Schelin Catheter**

Supplies needed	
TUIA	- Schelin Catheter (ProstaLund, Lund, Sweden) - 20 cc syringe - 10 cc NS - 20 cc lidocaine 2% (Istillagel, Montreal, QC, Canada)
Steps	
Preparation	- The catheter was disinfected as per manufacturer's protocol. - The balloon was inflated with 20 cc of NS such that it rested against the bladder neck. - The bladder was emptied through the drainage outlet of the catheter.
Local anesthetic injection (see video)	- The catheter was equipped with a pre-installed needle and guide for injection of the anesthetic. - With the 20 cc syringe, aspiration was performed followed by 20 cc transurethral injection of the anesthetic. To inject, the catheter was rotated clockwise according to Cleggs/Walsh's prostate anatomy: o 3 cc was injected at the 10-11 0'clock and again at the 1-2 0'clock positions of the prostate. o 7 cc was injected at the 8 o'clock and again at the 4 o'clock positions of the prostate.
Completion	- The balloon was deflated by fluid aspiration using the syringe and the catheter was gently removed. The patient was monitored as needed.

TUIA = transurethral intraprostatic anesthesia; NS = normal saline; PNB = prostatic nerve block

set-up instructions (e.g., sterility, aspiration testing). The Cleggs/Walsh's neurovascular anatomy located at the base of the prostate was used as a landscape for guiding injection sites, Video 1. The catheter was inserted through the urethra and the protruding needle was adjusted by rotating the catheter around the prostate. Injections were performed at 4 quadrants surrounding the prostate base to ensure optimal analgesic effect. Specifically, in a clockwise sequence, 3 cc of lidocaine 2% was injected at 1-2 o'clock and 10-11 o'clock positions, as well as 7 cc at the 4 o'clock and 8 o'clock positions, Video 1.

Monitoring pain

The efficacy of TUIA via SC was estimated by the patients' reported pain using a validated Visual Analogue Scale (VAS) where pain was reported on a scale from 0 (no pain) to 10 (worst possible pain). Pain was reported at five time points: (1) baseline, (2) after TUIA via SC, (3) immediately after Rezūm scope insertion, (4) during Rezūm treatment, and (5) immediately after case completion (primary efficacy outcome). Pain scores reported at the 4th time point (during Rezūm treatment) were based on subject recall.

Statistical analysis

The baseline cohort characteristics were described as median and range. Reported pain using a 0-10 VAS was described as mean ± standard deviation (SD). All statistical analyses were performed using Excel.

Results

Baseline cohort characteristics included a subject demographic (n = 10) described in Table 2. The median age of participants was 67 years old (range 55-92), with a median prostate volume of 97 cc (range 45-156). 40% of subjects presented with urinary retention at baseline. Median lobe was present in 70% of subjects. Median Qmax was 4.9 mL/s (range 1.7-8.2) and median PVR was 298.5 mL (range 181-720). Participants had a median IPSS of 29 (range 23-35) and QoL of 5 (range 4-6). The median procedure time for Rezūm was 4 minutes 27 seconds (range 3 minutes 45 seconds – 6 minutes 57 seconds) with a median of 8 injections (range 6-20).

The treatment outcome (patient reported pain using the VAS) of the TUIA is outlined in Table 3. Mean ± SD at the 5 time points was 0.0 ± 0.0, 1.3 ± 0.48, 1.3 ± 0.48, 3.0 ± 0.67, 1.1 ± 0.57 (primary efficacy outcome), respectively.

Table 4 outlines our results in comparison with those from the Rezūm II study, the Penthrox pilot study, and our preliminary data using TRUS-guided PNB.[3,6,11] The Rezūm II study included 136 subjects who received either oral sedation, PNB, or conscious IV sedation as analgesia prior to Rezūm treatment, whereas the Penthrox study included 10 subjects who received inhaled methoxyflurane 99.9%. The TRUS-guided PNB study included 10 subjects who received lidocaine 2% prostatic injections. The average number of Rezūm injections for Rezūm II, Penthrox, TRUS-guided PNB, and our current study in terms

TABLE 2. **Baseline cohort characteristics (n = 10)**

Characteristic	Median (range)
Age (years)	67 (55-92)
Prostate volume (cc)	97 (45-156)
Urinary retention	4 (40%)
Presence of median lobe	7 (70%)
Q_{max} (mL/s)	4.9 (1.7-8.2)
PVR (mL)	298.5 (181-720)
IPSS	29 (23-35)
IPSS QoL	5 (4-6)
PSA	3.4 (1.3-13.2)
Procedure time	4 minutes 27 seconds (3 minutes 45 seconds – 6 minutes 57 seconds)
Number of injections	8 (6-20)

Q_{max} = maximal flow rate; PVR = post-void residual volume; IPSS = International Prostate Symptom Score; QoL = quality of life; PSA = prostate-specific antigen

TABLE 3. **Treatment outcome**

Outcome	Mean ± SD
VAS	
Baseline	0.0 ± 0.0
After TUIA using Schelin Catheter	1.3 ± 0.48
Immediately after Rezūm scope insertion	1.3 ± 0.48
During Rezūm treatment (recall)	3.0 ± 0.67
Immediately following Rezūm treatment (primary efficacy outcome)	1.1 ± 0.57

SD = standard deviation; VAS = visual analogue scale; TUIA = transurethral intraprostatic anesthesia

TABLE 4. **Study comparisons**

	Rezūm II study[3]	**Penthrox pilot study[6]**	**TRUS-guided PNB pilot study[11]**	**Schelin Catheter pilot study**
Number of patients receiving Rezūm treatment	136	10	10	10
Analgesia	Oral sedation, PNB, or conscious IV sedation	Penthrox (99.9% methoxyflurane)	PNB with lidocaine 2%	TUIA with lidocaine 2%
Average number of Rezūm injections				
Mean ± SD	4.5 ± 1.8	11	9.5 ± 2.7	8.0 ± 4.7
Range		5-21	5-12	6-20
VAS after insertion of Rezūm scope prior to Rezūm therapy				
Mean ± SD	5.0 ± 2.7	1.4 ± 2.7	3.5 ± 1.6	1.0 ± 0.48
Range		0-7	3-7	1-2
VAS immediately following Rezūm treatment				
Mean ± SD	6.4 ± 2.6	1.3 ± 2.1	2.1 ± 0.99	1.0 ± 0.57
Range		0-6	1-4	0-2

PNB = prostatic nerve block; IV = intravenous; VAS = visual analogue scale; SD = standard deviation

of mean ± SD or mean (range) based on the authors' reported results was 4.5 ± 1.8, 11 (range 5-21), 9.5 ± 2.7 (range 5-12), and 8.0 ± 4.7 (range 6-20), respectively. VAS scores after insertion of the Rezūm scope prior to Rezūm therapy was 5.0 ± 2.7, 1.4 ± 2.7 (range 0-7), 3.5 ± 1.6 (range 3-7), and 1.0 ± 0.48 (range 1-2), respectively. VAS scores immediately following Rezūm treatment (primary efficacy outcome) was 6.4 ± 2.6, 1.3 ± 2.1 (range 0-6), 2.1 ± 0.99 (range 1-4), and 1.0 ± 0.58 (range 0-2) respectively.

Finally, mean VAS scores were compared between TUIA via SC and TRUS-guided PNB at the 5 different time points, Figure 2. At baseline (prior to any analgesia or RT) and after analgesia (measured before Rezūm scope insertion), there was no significant difference between the two methods. However, at all other time points, TUIA via SC demonstrated significantly lower pain scores compared to TRUS-guided PNB. Specifically, immediately after Rezūm scope insertion ($p < 0.001$), during RT ($p < 0.001$), and immediately after case completion (primary efficacy outcome) ($p < 0.05$).

Our experience

In our experience, the SC was cost-effective as well as simple to prepare and manipulate. Delivery of the analgesic using the retractable needle resulted in effective pain control for patients undergoing RT. When factoring in set-up time, the SC method is more efficient compared to TRUS-guided PNB or other anesthetic methods such as general anesthesia and IV sedation. Finally, no complications were encountered in our cohort of patients.

Discussion and conclusions

MISTs have become a hallmark in the evolution of surgical care in urology. However, as surgical techniques continue to be refined for the purpose of minimizing invasiveness, the future of preoperative care, such as pain management, requires equal consideration. TUIA is a non-invasive technique for administering local prostatic analgesia. The SC provides a simple medium for performing TUIA, further minimizing invasiveness in procedures such as RT.

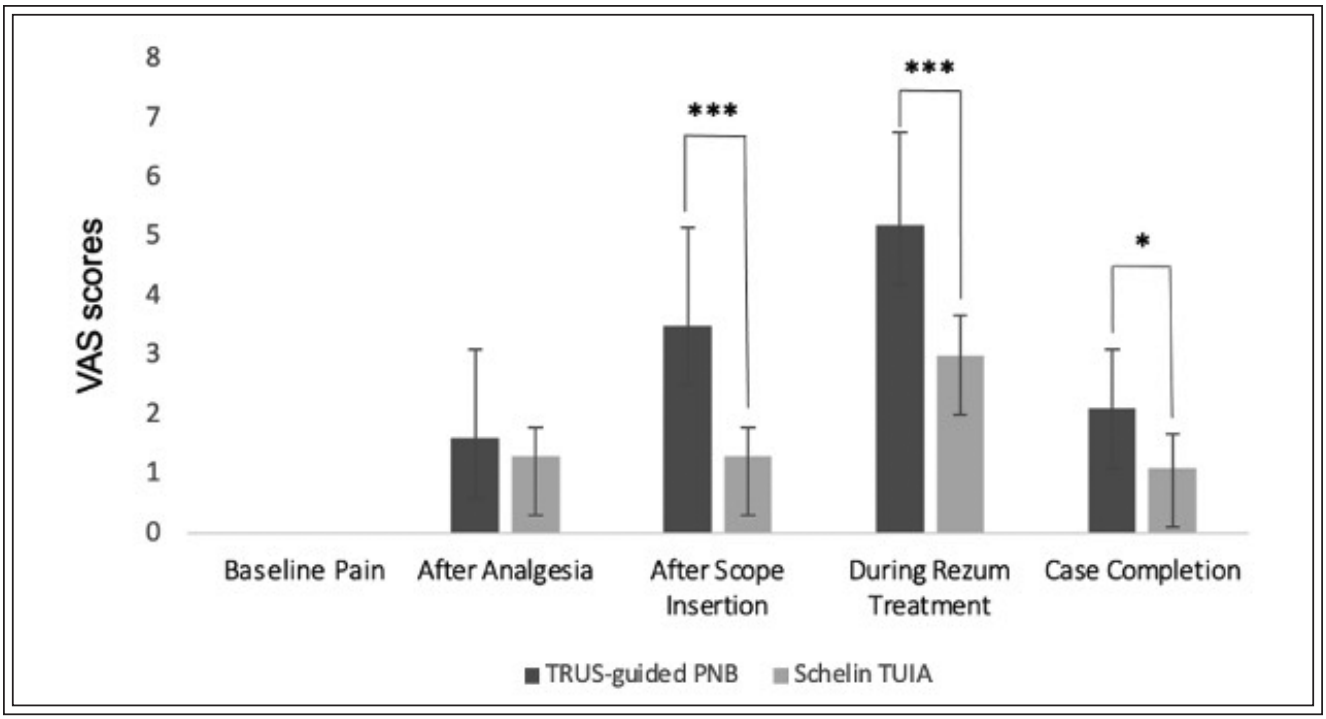

Figure 2. Visual Analogue Scale (VAS) scores measuring pain at five time points for TRUS-guided PNB versus Schelin Catheter TUIA: Baseline, after prostatic block, after scope insertion, during Rezūm treatment, and at case completion immediately following Rezūm treatment. Bars represent mean ± SD (n = 10). Student t-test. *$p < 0.05$, ***$p < 0.001$.

In this study we sought to evaluate the effectiveness of TUIA via SC in managing pain during and following RT. Our results demonstrate that TUIA effectively managed patient pain as measured by the VAS in a cohort of 10 patients. As well, we compared this method to the pain scores reported by patients who received TRUS-guided PNB in our previous pilot study. TUIA was superior to TRUS-guided PNB in reducing pain immediately after Rezūm scope insertion, during RT, and immediately after case completion (primary efficacy outcome). While the analgesic effect of TUIA was not significantly different from TRUS-guided PNB immediately following analgesia (before Rezūm scope insertion), this likely reflects the onset of action of the lidocaine 2% used in both studies. Given the reduced need for equipment, set-up, and training compared to other analgesic methods, time is greatly optimized by using the SC. Measuring overall set-up and procedure time compared to other standard analgesic methods would be valuable for future studies of SC efficiency.

While most urological procedures of the prostate require general anesthesia or TRUS-guided PNB, these preoperative measures require expensive equipment and pose the risk of complications that affect patient outcome. Given our current results, TUIA can be an effective non-invasive and simple analgesic method that reduces cost and training, bridging the gap between preoperative care and emerging MISTs. □

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