Peri-prostatic nerve block using Clarius EC7 HD_3 handheld ultrasound guidance

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Transrectal ultrasound (TRUS) is a common modality used during urological procedures that require real-time visualization of the prostate, such as prostate biopsy and peri-prostatic nerve blocks (PNB) for surgical procedures. Current practice for TRUS-guided PNB requires use of costly, fixed, and non-portable ultrasound machinery that can often limit workflow. The Clarius endocavity EC7 probe, a digital, handheld and pocket-sized endocavity ultrasound (US) device, is an alternative, portable technology which was recently shown to accurately visualize and measure prostate dimensions and volume. Moreover, in recent years, there has been a renaissance of office-based treatments for minimally invasive surgical therapies (MIST) for the treatment of benign prostate hyperplasia (BPH). More specifically, the Rezūm procedure has been demonstrated to offer men a short, outpatient therapy with excellent 5-year outcomes in durability and preservation of antegrade ejaculation. While other anesthetic techniques have been described for Rezūm, including inhaled methoxyflurane (Penthrox), nitrous oxide, IV sedation and general anesthesia (which often mandate the presence of an anesthesiology team), US-guided local blocks offer the urologist an independent method for pain management. While most urologists may not have direct access to expensive, cart-based ultrasound systems, point of care ultrasound (POCUS) technology, such as Clarius (Vancouver, BC, Canada) and Butterfly (Butterfly Network, Inc, Guilford, CT, USA), can provide high-resolution imaging in combination with smart phone technology. Herein, we sought to describe the technique for using Clarius EC7 for TRUS-guided PNB and its use in urological application with the Rezūm BPH procedure.

Key Words: Clarius EC7, POCUS, Rezūm, TRUS, PNB, BPH

Introduction

Overview of procedure/technology

Over the past two decades, the urological community continues to search for less invasive methods for benign prostatic hyperplasia (BPH) surgical care. While cost and out-patient offerings have emerged, the principle of sexual function preservation (erectile and ejaculation) have become a forefront discussion point during patient counseling.

The introduction of Rezūm as a minimally invasive surgical therapy (MIST) with its FDA approval in 2015, now offers a mean alternative to transurethral resection of the prostate (TURP).[1] While TURP and its tissue respective counterparts (Greenlight, holmium laser

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enucleation of the prostate [HoLEP], Aquablation) require general analgesia, MIST procedures can be safely conducted in out-patient and clinical settings with a simple peri-prostatic nerve block (PNB) using transrectal ultrasound (TRUS) guidance.[1] Traditional ultrasound (US) machinery is expensive, requires a large footprint, and may not be readily available in most Canadian urological office sites. Among urology practices, TRUS is required for prostate visualization and dimensional measurements for planning and preparing procedures including BPH volume assessments and prostate biopsy.[2] Recently, the use of Penthrox, a portable handheld inhaler that delivers low dose methoxyflurane 99.9%, was shown to be an adjuvant or even an alternative to TRUS-guided PNB, with lower reported pain scores in patients undergoing prostate biopsy.[3]

While Penthrox provides a minimally invasive pain management option, its cost and risks (hypotension, bradycardia, and potential for malignant hyperthermia and nephrotoxicity) prevent its routine application for most out-patient urology procedures in Canada. Further, Penthrox use requires close monitoring of vital signs approximately every 5 minutes following its use and every 30 minutes until discharge.[4] At the present time, TRUS-guided PNB remains a standard preoperative analgesic procedure which most urologists are familiar with and comfortable performing.[5] With advanced wireless technology, handheld point of care US (POCUS) probes have allowed increased US access to the urology community.

Clarius Mobile Health (Vancouver, BC, Canada) technologies provide wireless, handheld, and pocket-sized US devices introduced in 2016 that connect to any mobile device for visualization of the scanned field. Medical imaging with handheld US devices has gained popularity in the fields of obstetrics and gynecology, urology, emergency medicine, cardiology, and among others.[6] Clarius has been approved in Canada, the United States, Europe, and pending approval in other countries. Given its lightweight, handheld, and wireless functioning, the device is easily portable, increasing the accessibility of POCUS in various clinical settings.[6] Moreover, Clarius devices are more affordable (MSRP 5395 USD for Clarius EC7 HD_3), provide monthly online training and application updates, and require little maintenance or training compared to traditional cart-based US machinery.

Relevant historical studies

Application of handheld US devices

The adoption of handheld or pocket-sized US devices in medical practice is becoming increasingly popular as advancements in medical technology continues to grow and provide more efficient patient care. Considering their simple user interface and minimal training requirement, handheld US devices yield a promising learning tool for medical students and trainees. Slader et al compared the learning experience of medical students trained with the Hitachi Arietta V70 (Hitachi Corp, Chiyoda City, Japan) conventional US machine versus the Butterfly iQ (Butterfly Network, Inc, Guilford, CT, USA) handheld US device at three different schools.[7] Medical students trained with the handheld US showed a similar ability to obtain correct images with no difference in perceived task difficulty compared to students trained with the standard US machine. Given that cost is an important factor limiting access to US education, handheld devices offer an affordable and simple solution for medical programs wishing to introduce POCUS imaging into their curriculum.

In obstetrics, Pymar and colleagues compared dating of gestational age in early pregnancy using Clarius C_3 versus a larger portable US device, Zonare Z3 (Mindray North America, *Mahwah*, *NJ*, USA), in a prospective study.[8] The Clarius device was found to be a useful tool in dating gestational age (GA) prior to first trimester induced abortion. The authors also found that both devices showed concordance for the majority of patients and accurately predicted GA.

Clarius in urology

Although image quality and utility differ between brands of handheld devices, such technologies continue to improve and gain approval in various countries. In fact, Clarius HD_3 wireless US, the third and most recent generation, has been approved in Canada as of 2022 and remains the only approved handheld and wireless device for endocavity use. This newest generation is 30% smaller and lighter and contains longer lasting charge with integrated battery compared to previous generations.

POCUS has become an increasingly important tool in urologic care especially in the investigation of bladder obstruction, placement of suprapubic catheters, and trauma assessment.[9] The new handheld and wireless Clarius devices provide features, such as B-wave, Doppler, and power, which are useful in assessing urological emergencies including acute penile injuries.[10]

Given that many urological surgeries require visualization and assessment of pelvic structures, Clarius has potential applications in TRUS. Moussaoui and colleagues evaluated the accuracy of preoperative transabdominal US (TRAUS) using Clarius C3 and TRUS using Clarius EC7 in measuring prostate volume

TABLE 1. **Performing PNB using Clarius EC7**

Supplies needed		
TRUS	-	Clarius (Vancouver, BC, Canada) EC7 (endocavity 3–10 MHz, maximal depth 15 cm) HD_3
	-	2 latex probe covers (sizes: 2 x 20 cm and 3.5 x 20 cm) (CIVCO, Kalona, IA, USA)
Modified PNB (J.R. Beahrs, MD)	-	2 x 22 G 18 cm needle (1 per side)
	-	20 cm endocavity needle guide (CIVCO, Kalona, IA, USA)
	-	30 cc (15 cc per side) intrarectal lidocaine gel 2% (Istillagel, Montreal, QC, Canada)
Steps		
Preparation of the endocavity probe, Figure 1	-	The probe was disinfected as per manufacturer's protocol.
	-	2 latex probe covers were applied to cover the endocavity probe.
Field visualization on the Clarius application, Figure 1	-	With the patient in the left lateral decubitus position, the endocavity probe was inserted transrectally.
	-	Brightness and contrast were easily adjusted on the mobile
	-	application with one hand while the other hand navigated probe positioning.
	-	Doppler was selected as needed.
Measurement of prostate volume, Video 1	-	The length, width and height of the bladder was measured and saved to the device cloud.
Local anesthetic injection, Figure 2 and Video 1	-	22 G needle was inserted with a 20 cm needle guide in place for injection of the anesthetic.
	-	In our case, a modified PNB (J.R. Beahrs, MD) was done using lidocaine 2%, with 5 cc at each of the 3 injection sites (15 cc per side for a total of 30 cc).
Completion	-	The probe was gently removed from the endocavity and latex covers were discarded. The patient is monitored as needed.

TRUS = transrectal ultrasound; PNB = peri-prostatic nerve block

and morphology in 98 patients undergoing radical prostatectomy (RP).[10] The study demonstrated that TRAUS and TRUS with Clarius technology accurately identified the median lobe in all patients. In addition, Clarius-measured prostate size was strongly correlated

Figure 1. Clarius EC7 HD_3 with latex covers prior to use **(left)** and during TRUS-guided PNB with image visualization on a mobile device **(right)**.

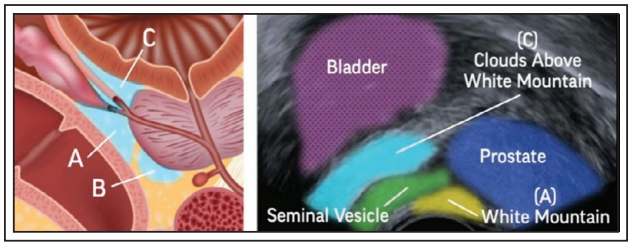

Figure 2. Modified PNB (courtesy J.R. Beahrs, MD) performed by injection in 3 areas bilaterally.[11] **(A)** Between the prostate and the seminal vesicles ("White Mountain"). **(B)** From the vascular peduncle to the apex, between the prostate and the rectum. **(C)** Between the prostate and bladder neck ("Clouds Above the White Mountain"). **A-C** are repeated bilaterally. Additional images courtesy Boston Scientific Company Inc.

with true prostate weight in patients with prostate sizes greater than 60 g.

While the use of Clarius and other handheld wireless devices in various bedside settings has been applied and studied, urological procedures such as TRUS-guided PNB merits trial. In this paper, we aim to outline the use of Clarius EC7 HD_3 in performing a TRUS-guided PNB in a subset of 10 male patients within an out-patient clinic.

Method and technique

Patient assessment in perioperative Rezūm therapy

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 lower urinary tract symptoms (LUTS) and BPH. These included the International Prostate Symptom Score (IPSS), quality of life (QoL), prostate TRUS volume, serum prostate-specific antigen (PSA) and urodynamic evaluation (maximum urinary flow rate (Qmax), post-void residual volume (PVR)).

Male patients with known BPH and LUTS who were candidates for Rezūm MIST underwent the procedure along with a TRUS-guided PNB using Clarius EC7 (endocavity 3–10 MHz, maximal depth 15 cm) HD_3 handheld US scanner, Figure 1, 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 any of the following: Foley retention, anal fissures, active hemorrhoids, and prostatitis.

TRUS-guided PNB procedure using Clarius EC7

For effective use the Clarius EC7 scanner in performing a TRUS-guided PNB, we recommend a few main steps detailed in Table 1. The procedure was completed after following the device set-up instructions (e.g., device charging, disinfection, Bluetooth connection).

Using the Clarius TRUS guidance, we performed a modified PNB (J.R. Beahrs, MD), Figure 2, based on our prior clinical observations to optimize analgesic delivery.[11] In short, a total of 30 mL of lidocaine 2% was delivered bilaterally to 3 ipsilateral zones of apex, supra-seminal vesical space, and the standard prostate-seminal vesical junction (5 mL in each zone) with a 22G 18 cm spinal needle. The interval time proved between the PNB and Rezūm water vapor thermal therapy was 15 minutes to allow for maximal analgesic effect.

Following PNB, the Rezūm treatment procedure was conducted as previously reported by Cantrill et al.[11] The number of vapor injections was adjusted based on the length of prostatic urethra (in general, 1 injection per cm) and the presence or absence of a median lobe.

Monitoring pain

Accuracy of the Clarius EC7 TRUS-guided PNB 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 TRUS-guided PNB using Clarius EC7, (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) was 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

The baseline subject demographic (n = 10) is listed in Table 2. Median age of participants was 65 years old (range 53-76), and the median prostate volume was 62 cc (range 52-93). None of the subjects presented with urinary retention at baseline. Median lobe was present in 50% of subjects. Median Qmax was 5.05 mL/s

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

Characteristic	**Median (range)**
Age (years)	65 (53-76)
Prostate volume (cc)	63 (52-93)
Urinary retention	No in all 10
Presence of median lobe	5 (50%)
Q_{max} (mL/s)	5.05 (3.2-9)
PVR (mL)	151 (45-291)
IPSS	22 (14-27)
IPSS QoL	5 (2-6)
Procedure time	4 minutes 45 seconds (4 minutes 5 seconds-5 minutes 41 seconds)
Number of injections	10 (5-12)

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

TABLE 3. **Treatment outcome**

Outcome	Mean ± SD
VAS	
Baseline before any PNB	0.0 ± 0.0
After TRUS-guided PNB using Clarius EC7	1.6 ± 1.5
Immediately after Rezūm scope insertion	3.5 ± 1.6
During Rezūm treatment (recall)	5.2 ± 1.5
Immediately following Rezūm treatment (primary efficacy outcome)	2.1 ± 0.99

SD = standard deviation; VAS = visual analogue scale; PNB = peri-prostatic nerve block; TRUS = transrectal ultrasound

(range 3.2-9) and median PVR was 151 mL (range 45-291). Participants had a median IPSS of 22 (range 14-27) and QoL of 5 (range 2-6). The median procedure time for Rezūm was 4 minutes 45 seconds (range 4 minutes 5 seconds – 5 minutes 41 seconds) with a median of 10 injections (range 5-12).

The treatment outcome (patient reported pain using the VAS) of the PNB is outlined in Table 3. Mean ± SD at the 5 timepoints was 0.0 ± 0.0, 1.6 ± 1.5, 3.5 ± 1.6, 5.2 ± 1.5, 2.1 ± 0.99 (primary efficacy outcome), respectively.

Table 4 outlines our results in comparison with those from the Rezūm II study and the Penthrox pilot study.[1,3] The Rezūm II study included 136 subjects who received either oral sedation, PNB, or conscious intravenous (IV) sedation as analgesia prior to Rezūm treatment, whereas the Penthrox study included 10 subjects who received inhaled methoxyflurane 99.9%. The average number of Rezūm injections for Rezūm II, Penthrox, and our current study in terms of mean ± SD or mean (range) based on the authors' reported results was 4.5 ± 1.8, 11 (range 5-21), and 9.5 ± 2.7 (range 5-12), respectively. VAS after

TABLE 4. **Study comparisons**

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

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

insertion of the Rezūm scope prior to Rezūm therapy was 5.0 ± 2.7, 1.4 ± 2.7 (range 0-7), and 3.5 ± 1.6 (rage 3-7), respectively. Finally, VAS immediately following Rezūm treatment (primary efficacy outcome) was 6.4 ± 2.6, 1.3 ± 2.1 (range 0-6), and 2.1 ± 0.99 (range 1-4), respectively.

Our experience

Based on our experience, the Clarius EC7 HD_3 was easy to prepare and disinfect. The user interface was simple enough such that the probe was manipulated with one hand and the application was navigated with the other hand (e.g., measuring the prostate, selecting Doppler). Delivery of the anesthetic was easily visualized on the mobile device, and the imaging quality and integrity of the device following several weeks of use remained intact. For the out-patient setting, access to this handheld device was convenient and the device was easy to set up and maintain, omitting the need for more costly and bulkier TRUS devices.

Discussion and conclusions

Clarius EC7 HD_3 wireless and hand-held ultrasound is a convenient and cost-effective technology available to all urologists for performing simple out-patient procedures requiring TRUS, notably PNB. Although POCUS is becoming an increasingly important modality for patient care and treatment, its minimal fixed cost and minute size has tremendous potential in efficient and timely patient work up and management. Handheld and wireless ultrasounds, such as Clarius devices, used to perform local anesthetic procedures will promote MISTs while providing a safer anesthetic alternative to general or spinal anesthesia in indicated patients.

In our current study, patients reported pain intensity on a 0-10 VAS of mean ± SD of 2.1 ± 0.99 immediately following Rezūm treatment. This was an improvement compared to the Rezūm II study which reported patient pain of 6.4 ± 2.6 under oral sedation, conscious IV sedation or PNB (with tradition TRUS devices).[1] While the Penthrox study showed a lower pain score of 1.3 ± 2.1 at the same time point, its use in out-patient urology settings is difficult to adopt given its cost and requirement for increased patient monitoring.[3] Future studies using a larger cohort size is an important next step in evaluating the efficacy of TRUS-guided PNB with the Clarius EC7 HD_3.

This paper serves as a brief framework for implementing cost-effective US technology that enhances the efficiency of managing out-patient cases requiring POCUS. This is particularly important as the capacity for office-based urological procedures continues to evolve to include MISTs. □

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