

Transurethral Holmium Laser Cystolithotripsy under Local Anaesthesia in Adult Patients: A Prospective Observational Study at a Tertiary Care Centre in North-east India

STEPHEN LALFAKZUALA SAILO¹, LALTANPUII SAILO², CORNERSTONE WANN³

ABSTRACT

Introduction: Urinary bladder stones comprise 5% of all urinary stones. Various modalities for the treatment of symptomatic bladder stones are available. They are open cystolithotomy, extra corporeal shock wave lithotripsy, cystolitholapaxy, suprapubic or transurethral cystolithotripsy using various energy sources. Presently transurethral holmium laser cystolithotripsy is considered as the treatment of choice for symptomatic bladder stones.

Aim: To report the experience of holmium laser cystolithotripsy for the treatment of symptomatic urinary bladder stones under local anaesthesia in adult patients.

Materials and Methods: This prospective observational study was conducted on 86 patients at Department of Urology, North-eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS), Shillong, Meghalaya, India, between June 2016 and August 2019. It included consecutive adult patients with symptomatic bladder stones of size upto 4 cm who underwent transurethral holmium laser cystolithotripsy under local

anaesthesia during the study period. Laser energy was delivered through a 9.5F semi rigid ureteroscope using 365 µm or 550 µm end-firing fibre. Pain during the procedure was assessed using Visual Analogue Scale (VAS). Descriptive statistics was used for analysis of the results.

Results: During the study period, 86 patients (84 men, 2 women) underwent transurethral holmium laser cystolithotripsy under local anaesthesia. Complete fragmentation of the stones was achieved in all patients. The mean stone size was 15.04 mm and the mean operating time was 23.81 minutes. The procedure was well tolerated by the patients and the mean pain score was 3.26. It was associated with minor complications only. There was no major complication or mortality during the study.

Conclusion: Transurethral holmium laser cystolithotripsy under local anaesthesia is a safe procedure. It is well tolerated by adult patients and it can be used for the treatment of bladder stones of size upto 4 cm.

Keywords: Complications, Pain, Ureteroscope, Visual analogue scale

INTRODUCTION

Urinary bladder stones comprise 5% of all urinary stones and they commonly form as a result of foreign bodies, obstruction, or infection [1]. They cause lower urinary tract symptoms, infections, pain and haematuria and they may be associated with bladder cancer [2,3]. They are more common in developing countries and in male patients [4,5]. Open suprapubic cystolithotomy, the traditional method of treatment of bladder stones, has high success rate but this procedure requires postoperative catheterisation and hospitalisation [6]. Extracorporeal shock wave lithotripsy, the least invasive procedure for treatment of bladder stones, has low success rate [7,8]. Percutaneous cystolithotripsy is associated with shorter duration of operation, catheterisation and less blood loss compared to open cystolithotomy [9]. But this procedure requires making a small suprapubic incision into the bladder. Now-a-days transurethral cystolithotripsy is considered to be the treatment of choice for symptomatic bladder stones [6]. In this procedure, various energy sources (electrohydraulic, ultrasonic, mechanical, laser), passed via an instrument through the urethra, are used to fragment the stones. Normally these procedures are performed under regional or general anaesthesia and require hospitalisation [3]. Transurethral cystolithotripsy using holmium laser was reported to be highly effective and safe [10-12]. It was also reported that the operation could be performed under local anaesthesia, as the procedure was associated with minimal pain [11,12]. The aim of this study is to report the experience of transurethral cystolithotripsy of bladder stones using holmium laser under local anaesthesia in adult patients.

MATERIALS AND METHODS

This was a prospective observational study conducted in the Department of Urology, North-eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS), Shillong, Meghalaya, India, from June 2016 to August 2019. The study was approved by the Institute's Ethics Committee (NEIGR/IEC/M13/F13/2020). The sample included all patients presenting with symptomatic bladder stones who underwent transurethral holmium laser cystolithotripsy under local anaesthesia during the study period.

Inclusion criteria: Inclusion criteria for laser cystolithotripsy were adult patients (age more than 18 years) and bladder stone of size upto 4 cm.

Exclusion criteria: Exclusion criteria were patients not willing for operation under local anaesthesia, paraplegia, stricture urethra, concomitant ureteric stone and benign prostatic hyperplasia.

Informed consent for operation was taken from all patients. Though the patients who gave consent for the operation to be conducted under local anaesthesia were recruited for the study, during any stage of the operation, if any patient found the operation under local anaesthesia to be too painful, they were given the choice of stopping the operation and converting the operation to be performed under general or regional anaesthesia in the next operating day. So, the patients underwent complete blood count, kidney function test, serum electrolytes {serum creatinine, Sodium (Na), and Potassium (K)}, random blood sugar and Glycated Haemoglobin (HbA1c), coagulation studies like Prothrombin Time (PT), Partial Thromboplastin Time (PTT), International Normalised Ratio (INR)

and platelets, urine analysis and culture. These investigations were performed to assess the fitness of the patients to undergo operation for the stone either under general or regional anaesthesia. So, during the study, fitness for operation under general or regional anaesthesia was taken for each patient before the operation.

Study Procedure

X-ray and ultrasound of Kidney, Ureter and Bladder (KUB) region was done to look for concomitant renal or ureteric stones. The patients with concomitant renal or ureteric stones also underwent Intravenous Urogram (IVU) to assess the functional status of the kidneys. Few patients with poorly opaque or radioluscent bladder stones underwent non contrast Computed Tomography (CT) scan of KUB region for better evaluation of the stones. Maximum diameter of the stones in millimeter was measured on KUB x-ray/ultrasound/CT scan. They were started on appropriate antibiotics if culture was positive or given single dose of Ceftriaxone (1 gm, i.v.) one hour before the operation, if culture was sterile. All patients underwent transurethral holmium laser (VersaPulse PowerSuite, Lumenis, Israel) cystolithotripsy under local anaesthesia. The operations were performed in the operating theatre with monitoring of Electrocardiography (ECG), blood pressure, heart rate, and peripheral oxygen saturation (SpO₂). Patients were set up for operation in lithotomy position and 10 ml of 2% lignocaine jelly was instilled into the urethra. Ten minutes after local anaesthetic instillation, 7F infant feeding tube was inserted to drain the urinary bladder during the procedure. Semi rigid ureteroscope (9.5F, Karl Storz, Germany) was then inserted into the bladder through which holmium laser energy (0.6-1.5 J/Pulse at 5-20 Hz) was applied using 365 µm or 550 µm end-firing fibre with video monitoring. The stones were fragmented to the smallest size possible so that the patients could pass the fragments through the urethra. Once the operation was over, the bladder was filled with saline. Then the patients were instructed to pass the stone fragments. Patients were not catheterised after completion of the procedure.

The pain score during operation was assessed by VAS. VAS is a validated pain rating scale for subjective measure of pain [13]. The patients were asked to rate the pain experienced during the operation and they were asked to mark a point on a 10 cm line (scale) in a paper. The score varies between 0, on the right end of the scale. The duration of the operation was assessed from the start of laser firing till complete fragmentation was achieved. Analgesic injection (Inj. Diclofenac 75 mg, im) was given on demand. Tablet Aceclofenac (100 mg) was given on request in the postoperative period. Postoperative KUB x-ray was done on the day of operation or the day after operation to check for residual stones. Complete clearance was defined as absence of any stone fragments in the x-ray. Patients were discharged, if they passed urine well and no residual stones were detected on postoperative KUB x-ray. Patients were asked to come for follow up after one, six and 12 months. At each follow-up, urine analysis and culture, uroflowmetry and x-ray of the kidney, ureter and bladder region were done.

STATISTICAL ANALYSIS

Continuous variables were presented as mean and range while categorical variables were expressed as frequencies and percentages.

RESULTS

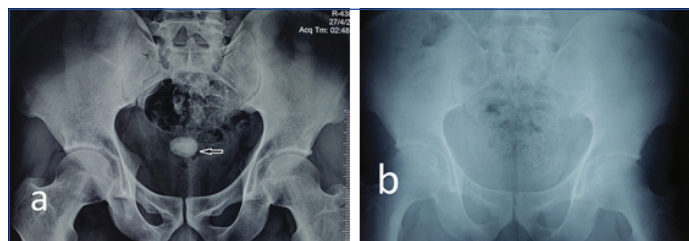
A total of 102 patients were treated during the study period [Table/Fig-1]. Out of these 102 patients, 16 patients were excluded from the study based on exclusion criteria (concomitant ureteric stone-5, children-3, BPH-2, not willing for operation -2, stone bigger than 4 cm-1, stricture urethra-1, paraplegia-1, laser not working-1). Eighty-six adult patients (84 men, 2 women) underwent transurethral holmium laser cystolithotripsy during the study period. Their mean age was 36.44 years (range 18-72 years). The common presenting symptoms were acute urinary retention in 56 (65.12%); dysuria in

43 (50%) and suprapubic pain in 40 (46.51%) patients, respectively. The mean serum creatinine concentration was 1.1 mg% (range, 0.6-3.3 mg%). Ultrasound was done in 50 patients, IVU in 18 patients and CT scan in four patients. All bladder stones were visible on KUB x-ray except stones in four patients for which CT scan was done. Urine culture was positive in 17 patients (*Escherichia coli*-10, *Pseudomonas aeruginosa*-3, *Staphylococcus aureus*-2, *Enterococcus faecalis*-1, *Klebsiella pneumoniae*-1). The mean stone size was 15.04 mm (range, 5-40 mm).

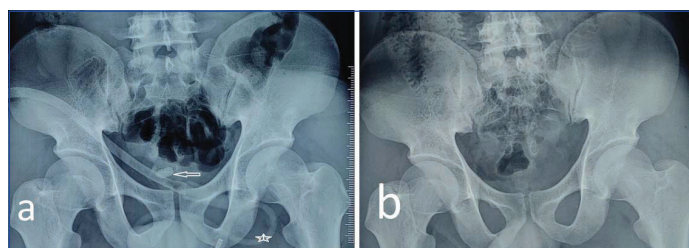
Variables	Values
Total patients in the study	102
Total patients excluded	16
Total patients recruited	86 (84 men, 2 women)
Mean age (SD)	36.44 years (11.98 years)
Patients presenting with acute urinary retention	56 patients
Mean stone size (SD)	15.04 mm (6.56 mm)
Mean VAS pain score (SD)	3.26 (1.94)
Mean operating time (SD)	23.81 min (16.35)
Postoperative complications	Haematuria-12, fever-3, urinary retention-1

[Table/Fig-1]: Patients and treatment characteristics.

Complete fragmentation of the stones was achieved in all patients ([Table/Fig-2a,b] and [Table/Fig-3a,b]). The procedure was well tolerated with mean VAS score of 3.26. Only four patients (with pain score of 3, 3, 7 and 8) wanted analgesic injection during the operation and they were given Injection Diclofenac (75 mg, intramuscular). The procedure could be completed successfully in all patients under local anaesthesia. No patient opted to convert the operation under spinal or general anaesthesia because of pain. In the postoperative period, 12 patients received Tablet Aceclofenac (100 mg) and three patients received Diclofenac injection. The mean operating time was 23.81 minutes (range, 10-120 minutes).



[Table/Fig-2]: a) A 2 cm urinary bladder stone (arrow) in a 26-year-old man; b) The stone was completely fragmented after holmium laser cystolithotripsy.



[Table/Fig-3]: a) A 1.5 cm urinary bladder stone (arrow) in a 28-year-old man causing acute urinary retention. Foley catheter (star) was inserted; b) The stone was treated with holmium laser cystolithotripsy.

All patients except one could pass urine well after the operation. This patient was catheterised for one day and he passed urine well after removal of the catheter. Small residual stone fragments were detected in one patient in the postoperative KUB x-ray. This patient passed urine well and no residual stone was seen on KUB x-ray done after one month. All patients, except one patient who had retention of urine after the operation, were discharged the day after the operation.

Twelve patients had mild haematuria in the immediate postoperative period. The haematuria resolved with increased fluid intake. Three

patients developed mild fever which subsided with antipyretics and antibiotics within a day. There was no major complication (e.g., bladder perforation or gross haematuria) or mortality. Eleven patients came for follow-up. All of them had normal urinary flow rate, normal urine analysis and normal KUB x-ray.

DISCUSSION

Holmium laser has transformed the treatment of urinary bladder stones as it can fragment stones satisfactorily with minimal trauma to the bladder mucosa [10-12]. Fragmentation of the stone using holmium laser is associated with mild pain and so the procedure can be performed under local anaesthesia [10,11]. In the present study, complete fragmentation of bladder stones was achieved in all patients. The procedure was well tolerated with a mean VAS score of 3.26.

The rate of successful fragmentation of bladder stones in the present study is comparable to those reported by other studies [10,14-17]. Thirty-seven men with bladder stones (mean size, 2.1 cm) underwent transurethral laser cystolithotripsy under local anaesthesia [15]. All the stones were completely fragmented and the mean VAS score was 2.8. Kara C et al., performed holmium laser cystolithotripsy in 13 patients with bladder stones ≥ 3 cm using flexible cystoscope [10]. They reported 100% success rate with mean VAS score of 2.15. Sixteen patients with mean bladder stone size of 2.15 cm underwent holmium laser cystolithotripsy under local anaesthesia and sedoanalgesia [16]. Clearance rate was 89% and mean pain VAS score was 1.75. Similarly, holmium laser cystolithotripsy was performed in 85 patients with bladder stones (mean size, 3 cm) as a day care procedure [14]. Complete stone clearance was achieved in all patients with mild VAS score in 50 patients. Forty-eight patients with bladder stones (mean size, 3.7 cm) underwent holmium laser cystolithotripsy as outpatient [17]. The procedure was successful in 98.5% of patients with mean VAS score of 4.2. The average size of the stones (1.5 cm) in the present study was smaller than those reported by other studies because other studies excluded smaller stones in their study while we included all stones upto 4 cm in the present study [Table/Fig-4] [10,14-17].

The mean VAS score in our study was lower than that of the study by Karami H et al., who used cystoscope (19 F) to provide laser energy [17]. The lower pain score in the present study may be due to the use of smaller calibre (9.5 F) ureteroscope in comparison to the cystoscope. The mean VAS score (3.26) in the study was higher than those of the studies by Kara C et al., and D'Souza N and Verma A in which mean VAS scores were 2.15 and 2.8 respectively [10,15]. In these two studies, flexible cystoscope was used to provide laser energy. Although we used the same instrument (ureteroscope, 9.5 F) as Uzun H et al., the mean VAS score in their study was lower than that of the present study [16]. This may be because of sedoanalgesia (medazolam and alfentanil) used by them, in addition to local anaesthesia.

The mean duration of operation in the present study was 23.81 minutes, which is less than those of other studies [10,15,16,18]. Smaller stones were excluded in these studies. Therefore, the duration of operation was longer. Although Uzun H et al., excluded stones smaller than 1 cm, the mean duration of operation was only 19.2 minutes [16]. This may be due to the sedoanalgesia (medazolam and alfentanil) used by them, so, that there is no interruption of fragmentation. In the present study, occasionally the procedure had to be interrupted because of pain.

Holmium laser also produces tiny fragments, which are smaller than the fragments produced by other lithotripters [12]. During holmium laser cystolithotripsy, the bladder stones are fragmented to the smallest size possible so that they may be spontaneously passed or washed out using aspirator, ellik evacuator, or with irrigation [10,14,15].

The use of local anaesthesia avoids many complications associated with spinal or general anaesthesia. It also reduced the cost of treatment of the stone [10]. Moreover, patients who are unfit and who are not willing for operation under spinal or general anaesthesia can be treated by this procedure under local anaesthesia [15]. Holmium laser cystolithotripsy can be performed as a day care procedure [14,17]. However, most of the patients were from distant villages, so they were admitted one day before the operation and discharged the day after the operation.

Study	Inclusion criteria	Type of anaesthesia	No. of patients and gender	Mean age (year)	Mean stone size (cm)	Instrument used	Laser fibre size and laser setting	Mean pain score (VAS)	Mean operative time (min)	Clearance (%)	Post procedure
Kara C et al., [10]	Inclusion: BPH patients with calculi ≥ 3 cm.	Pethidine (50 mg, i.m.) plus 2% Lidocaine gel (10 mL)	13 men	58.2	3.6	13.8/16.5F Flexible cystoscope (Olympus)	365 or 550 μ m, 0.5-1 J @ 5-20 Hz.	2.15	51	100	20F Foley catheter inserted
Uzun H et al., [16]	Inclusion: Stone >1 cm, 4 BPH patients included.	Lidocaine gel (2%, 10 ml) plus i.v. medazolam and alfentanil	16 men	52.3	2.15	9.5F Ureteroscope	365 μ m, 1 J @ 10 Hz.	1.75	19.2	89	Foley catheter inserted
D'Souza N and Verma A et al., [15]	Inclusion: Few BPH patients included, exclusion: stones >4 cm.	Lignocaine gel (2%)	37 men	46.6	2.1	Flexible cystoscope	365 μ m, 0.5-0.8 J @ 30-40 Hz.	2.8	35	100	3-way 18-F Foley catheter placed for bladder irrigation.
Karami H et al., [17]	Inclusion: Stones >2 cm, exclusion: BPH patients.	Pethidine (50 mg, i.v.) plus Lidocaine gel (2%, 20 mL)	48 (45 men, 3 women)	46	3.7	19F Cystoscope	365 Or 550 μ m, 0.5-1 J @ 5-15 Hz.	4.2	43.5	98.5	14-16 F Foley catheter inserted.
Namreirakpam S et al., [14]	Inclusion: Stone ≥ 1.5 cm, exclusion: BPH patients.	Tramadol (100 mg, i.v.) plus lidocaine gel (2%, 20 mL)	85 (80 men, 5 women)	52	3	19F Cystoscope	365 μ m, 1.2 J @ 8 Hz.	Mild VAS in 50 patients	40	100	Stone fragments removed by Ellik evacuator; Foley catheter not inserted.
Present study	Exclusion: Stones >4 cm and BPH patients.	Lignocaine gel (2%, 10 mL) plus Diclofenac (75 mg, i.m., on demand only)	86 (84 men, 2 women)	36.4	1.5	9.5F Ureteroscope	550 μ m, 0.6-1.5 J at 5-20 Hz.	3.26	23.8	100	Foley catheter not inserted.

[Table/Fig-4]: Synopsis of studies on transurethral holmium laser cystolithotripsy under local anaesthesia [10,14-17].

The thermal injury associated with holmium laser is superficial and it is only 0.5 to 1 mm deep [19]. The stone can be focussed accurately because holmium laser has aiming beam and stone vibration is minimal [2]. So, holmium laser cystolithotripsy is quite safe and is usually associated with minimal complications like mild haematuria due to mucosal abrasion. In the present study, in the immediate postoperative period, 12 patients had mild haematuria, three patients developed mild fever and one patient developed acute urinary retention. The haematuria and fever subsided within 24 hours with increased fluid intake and antibiotics. Other studies also reported minor complications like mild haematuria and transient fever [10,15,17]. None of these studies reported any major complications. In the present study, all patients (except one patient who developed urinary retention) were discharged on the first postoperative day.

The follow-up in the present study was not satisfactory. Only 11 patients came for follow-up at one, six and 12 months. This could be due to our patients residing in distant villages and many of them being illiterate. The patients who came for follow-up had no recurrent stones and no urethral stricture. Since, in the present study, a small calibre (9.5F ureteroscope) was used, the patients were unlikely to develop urethral strictures.

Limitation(s)

The present study was limited by the absence of a comparative group treated under spinal or general anaesthesia and poor follow-up.

CONCLUSION(S)

Transurethral cystolithotripsy of bladder stones using holmium laser under local anaesthesia was a safe technique. It was well-tolerated by adult patients and it can be used for the treatment of bladder stones of size upto 4 cm.

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PARTICULARS OF CONTRIBUTORS:

1. Professor, Department of Urology, North-eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong, Meghalaya, India.
2. Assistant Professor, Department of Anaesthesiology, Zoram Medical College, Aizawl, Mizoram, India.
3. Associate Professor, Department of Urology, North-eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong, Meghalaya, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Stephen Lalfakzuala Sailo,
A-19, Faculty Quarters, Neigrihms, Mawdiangdiang, Shillong, Meghalaya, India.
E-mail: stephensailo@gmail.com

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