

# Efficacy of Holmium Laser Lithotripsy and Shock Pulse Lithotripsy in Terms of Stone Clearance Rate in Patients with Upper Ureteric Calculus in a Tertiary Care Centre: A Prospective Observational Study

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## Abstract

**Introduction:** As the popularity of retrograde ureteroscopy continues to rise, it is becoming more common for patients to have it done for the treatment of ureteric calculi. Although the use of new technologies such as laser and shock pulse lithotripsy has increased the number of options for the treatment of proximal calculi, the exact guidelines regarding the optimal energy source for this condition in URSL is still not clear. **Materials and Methods:** This is a prospective observational pilot study done in the Department of Urology, AIIMS Rishikesh from September 2020 till June 2022 with sample size of 30 in each arm (Holmium Laser—HL and Shock Pulse—SP) involving those participants planned for either Holmium Laser or shock pulse Ureteroscopic lithotripsy fulfilling inclusion and exclusion criteria. **Results:** In our study we have found that stone clearance rate of shock pulse (HL and SP,  $8.028 \pm 3.69$  and  $12.70 \pm 8.19$  mm<sup>3</sup>/mins, p value: 0.05) to be significantly higher than Holmium laser lithotripsy. We have also found significant reduction in operating time ( $64.68 \pm 10.62$  mins and  $36.78 \pm 5.24$  mins, p value < 0.05). Stone fragmentation quality of shock pulse is superior to that of Holmium Laser (Time taken for stone fragmentation, HL and SP,  $59.09 \pm 10.47$  mins and  $32.75 \pm 7.53$  mins, p value < 0.05). **Conclusion:** Our study has aided in better understanding the efficacy of the two lithotripter modalities. In order to build a deeper knowledge of the benefits and drawbacks connected with the device, large sample size and long term follow up are required.

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## Keywords

Ureteric Calculi, Ureteroscopy, URSL, Shock Pulse Lithotripsy, Holmium Laser Lithotripsy, Stone Clearance Rate, Stone Fragmentation Quality

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## 1. Introduction

Due to changing socio-economic conditions the prevalence and incidence of the upper urinary tract stones are on the rising trend [1]. In Asia, the prevalence of urolithiasis is about 1% - 19.1% [2].

There has been a dynamic progress in the management of urolithiasis over years. With the advancement in the endourological interventions over the last 30 years, the complications following endourological intervention are minor and do not require intervention [3].

Pharmacological treatment (medical expulsion therapy—MET) can be started in cases of uncomplicated ureteric stones of size less than 10 mm [4]. Beyond this size, the success rate of pharmacological treatment decreases and there is a need for surgical intervention [4].

Ureteroscopy (URS), Extracorporeal shock wave Lithotripsy (ESWL) and Percutaneous Nephrolithotripsy (PCNL) are techniques frequently used in recent days replacing open surgery [5] [6]. Various techniques have been used for stone fragmentation and include pneumatic, ultrasonic, electrohydraulic, and laser lithotripsy out of which pneumatic and laser lithotripsy are commonly used [7] [8].

In Ureteroscopic removal of calculus, various lithotripters with different energy sources are being used in fragmentation of calculus and the mechanisms of each lithotripter is unique. Holmium: YAG laser lithotripsy works by producing laser energy which gets absorbed by the ureteric stone leading to thermal combustion and also creates a vaporization bubble which will destabilize and decompose the calculus. Shock pulse is a lithotripter approved by the FDA in 2014. Shock Pulse lithotripter uses low frequency mechanical/pneumatic and high-frequency ultrasonic energy in breaking down and evacuating the calculus. Ultrasonic energy is sufficient in breaking down softer components of calculus and pneumatic energy is used in breaking the hard components [7]-[10].

For proximal ureteric stones  $\geq 10$  mm URS offers high success rate as a primary procedure when compared with SWL [9]. Moreover, Ureteroscopic stone removal can be done as outpatient procedure was found to be more beneficial and economical [10]. Several authors have reported Ureteroscopic stone removal as an alternative for PCNL in the removal of large renal stones also and also the efficacy and safety of URS are improving day by day.

Various studies have been done in order to find out the appropriate management for ureteric calculus but to the best of our knowledge, no research has been conducted in the world to compare the efficacy of Holmium laser and shock pulse lithotripsy in terms of stone clearance rate in patients with upper ureteric calculus

via ureteroscopic removal. Thus, this study will help us in finding the lithotripter with effective stone clearance rate and also in choosing the appropriate lithotripsy technique in the management of upper ureteric calculus.

## 2. Methods

We have conducted a two-arm nonrandomized prospective observational pilot study in the Department of Urology, AIIMS Rishikesh, after obtaining Ethical clearance. A total of 64 patients visiting the department of Urology were included from September 2020 till June 2022 based on the pre specified selection criteria.

**Inclusion Criteria:** Participants  $\geq 18$  years of age with Solitary upper ureteric calculus  $\leq 1.5$  cm in maximum diameter as measured on preoperative CT scan who are willing and able to provide informed consent to undergo Ureteroscopic lithotripsy as treatment.

**Exclusion Criteria:** Pregnant females and Patients with urinary tract infections are excluded.

**Sampling Technique:** All consecutive patients meeting the inclusion and exclusion criteria were included in this study until the desired sample size was achieved (30 in each arm). Minimum sample size of 30 was taken in each arm in view of observational pilot study.

**Sampling Method:** All consecutive patients above 18 years of age who are diagnosed to have upper ureteric calculus willing to take part were included in this study. This will be a non-randomized prospective observational pilot study and individuals were enrolled into the study if the inclusion criteria were fulfilled. Written consent has been obtained from the participants after explaining the aims, objectives, plan and duration of the study in a language which they are able to understand better.

During the study, demographic and patient data was recorded. Baseline evaluation of each participant will be carried out. After this work up patients were randomized into any one of the following groups (Holmium laser—HL and Shock Pulse—SP). Ureteroscopic lithotripsy was performed using any one of the lithotripters in the Operating Room, Department of Urology by the Surgeon. After fragmentation of the calculus DJ stent will be placed in the ureteric tract.

**Following Parameters Has Been Evaluated:** Preoperatively Stone volume ( $\text{mm}^3$ ) & Stone density (Hounsfield units, HU) are assessed by CT-Urography or NCCT-KUB & Diuretic Renal scan (in case of mild CKD). Intraoperatively, Operating time (OT) (Time interval between ureteroscope insertion and removal following stone fragmentation through urethra), Time taken for stone fragmentation and extraction (Time interval between the start of lithotripter unit for fragmentation till the removal of all fragments the ureter, based on visual inspection prior to the last visual inspection through the ureteroscope) were noted. Post operatively stone clearance rate (Stone volume divided by time taken for stone fragmentation and extraction), stone volume at post operative day 10 & after 4 weeks were assessed. If no fragments, individual was considered as stone free.

Residual stone if any was assessed (if  $\leq 2$  mm: Clinically Insignificant Residual fragments (CIRF),  $\geq 2$  mm: Failed). Complications if any was assessed and classified according to Clavien Dindo classification. On post operative day 1, Xray KUB was used to assess the position of the DJ stent. On post operative day 10, NCCT KUB was used for assessment following stent removal. Routine follow up at 4 weeks.

### 3. Statistical Analysis

Data was entered in Microsoft Excel spreadsheet.

Categorical variables described as frequency and proportion. Continuous variables described as mean  $\pm$  standard deviation or median with inter-quartile range as applicable.

We compared proportions by using Chi-square test, Fishers exact test as and when required. Student's t-test and Mann Whitney U test used to compare means between two groups. Paired t-test used to compare readings of continuous variables at two points of time. All statistical tests will be performed with a significance level of  $\alpha = 0.05$  (95% C.I) and analysis will be conducted using IBM SPSS STATISTICS (version 23.0).

### 4. Results

Most our participants were in the range of 31 - 60 years of age, comprising of 19 (59.4%) and 17 (53.1%) out of 32 in each group. From our data we can conclude that majority of our participants belong to young and middle age group. Mean age was found to be  $39.3 \pm 12.2$  and  $37.4 \pm 14.4$  in HL and SP group respectively (**Table 1**). No significant statistical difference was found in age group on analysis. In our study Males were predominant, 23 (71.9%) while Females where about 9 (28.1%) in each group (**Table 1**). Mean height and mean weight was found to be similar in both groups. More than 50% of our participants were in the normal BMI range in both the groups.

**Table 1.** Table showing distribution of patients as per age, gender and its p-value.

Age category (in years)	Procedure Performed		p Value
	HL	SP	
<30	11 (34.4%)	13 (40.6%)	0.870
31 - 60	19 (59.4%)	17 (53.1%)	
>61	2 (6.3%)	2 (6.3%)	
<b>Total</b>	32 (100%)	32 (100%)	
<b>Mean <math>\pm</math> SD (in years)</b>	39.3 $\pm$ 12.2	37.4 $\pm$ 14.4	0.570
Gender	Procedure performed		p Value
	HL	SP	
Female	9 (28.1%)	9 (28.1%)	1.000
Male	23 (71.9%)	23 (71.9%)	
Total	32 (100%)	32 (100%)	

Duration of complaints in both the groups ranged from  $8.5 \pm 11.10$  and  $7.7 \pm 11.0$  in Holmium YAG laser and shock pulse group respectively (**Table 2**). Majority of our patients (56 out of 64), presented with flank pain followed by dysuria, fever and haematuria as chief complaint.

**Table 2.** Table showing pre-operative parameters assessed in the participants of both groups (HL—Holmium Laser Lithotripsy, SP—Shock pulse lithotripsy) with their mean and p-value.

Group	HL	SP	p Value*
	Mean $\pm$ Sd N = 32	Mean $\pm$ Sd N = 32	
Age year	39.3 $\pm$ 12.2	37.4 $\pm$ 14.4	0.570
Height m	1.7 $\pm$ 0.1	1.7 $\pm$ 0.06	0.975
Weight kg	67.7 $\pm$ 13.7	62.8 $\pm$ 8.4	0.092
BMI kgm <sup>2</sup>	23.4 $\pm$ 3.4	21.81 $\pm$ 2.2	0.035
Duration of complaints	8.5 $\pm$ 11.1	7.7 $\pm$ 11.0	0.786
Preop urea	30.5 $\pm$ 19.6	30.9 $\pm$ 15.9	0.919
Preop creatinine	1.2 $\pm$ 0.7	1.18 $\pm$ 0.7	0.985
Post op urea	27.1 $\pm$ 10.4	31.8 $\pm$ 16.7	0.185
Post op creatinine	1.1 $\pm$ 0.4	1.1 $\pm$ 0.5	0.969
Preop creatinine clearance	92.1 $\pm$ 38.8	87.5 $\pm$ 40.9	0.648
Post-op creatinine clearance	86.1 $\pm$ 26.6	84.3 $\pm$ 31.0	0.806
Stone length (mm)	10.5 $\pm$ 2.8	9.3 $\pm$ 2.6	0.064
Breadth (mm)	9.1 $\pm$ 2.1	8.6 $\pm$ 2.7	0.361
Height of craniocaudal dimension (mm)	8.9 $\pm$ 1.9	8.9 $\pm$ 2.2	0.943
Pre Stone volume (mm <sup>3</sup> )	492.6 $\pm$ 266.4	431.0 $\pm$ 316.1	0.402
Pre stone density (HU)	927.8 $\pm$ 276.6	957.1 $\pm$ 188.8	0.623

No significant difference in both groups in preoperative and postoperative urea and creatinine values. No significant difference elicited between preoperative and postoperative creatinine clearance.

**Radiological Analysis of Stone:** There was no significant difference between the two groups with regards to dimensions of the stone. Stone volume of more than 50% of the study group assessed was found to be in the range of  $<500 \text{ mm}^3$  with mean value of  $492.62 \pm 266.41 \text{ mm}^3$  and  $431.0 \pm 316.1 \text{ mm}^3$  respectively. Stone density which was measured in terms of HU was predominantly between 500 - 1000 HU with mean value of  $927.8 \pm 276.6$  and  $957.1 \pm 188.8$  in HL and SP group respectively (**Table 3**).

Operating time was found to be shorter in SP group ( $36.8 \pm 5.2$  mins) as compared to HL group ( $64.7 \pm 10.6$  mins) with p value of  $<0.05$  (**Table 3**). The Time

taken for stone fragmentation was found to be less in SP ( $32.7 \pm 7.5$  mins) when compared to HL ( $59.1 \pm 10.4$  mins) which in turn has a significant on total operating time (Table 3). Stone clearance of SP group was found to be  $12.7 \pm 8.2$  mm<sup>3</sup>/min which is statistically significant when compared with HL group (p value-0.05). Intraoperatively we had 4 patients who had altered from our normal course of treatment. 3 of which were planned for other alternative operative intervention later due to stone migration.

**Table 3.** Table showing intra and post-operative parameters assessed in the participants of both groups (HL—Holmium Laser Lithotripsy, SP—Shock pulse lithotripsy) with their mean and p-value.

Outcome	Procedure performed		p Value*
	HL	SP	
Stone free	29 (90.6%)	29 (90.6%)	
Failed	1 (3.1%)	1 (3.1%)	
PA	2 (6.25%)	1 (3.1%)	0.280
CIRF	0 (0%)	1 (3.1%)	
Total	32 (100%)	32 (100%)	
Operating time in mins	$64.7 \pm 10.6$	$36.8 \pm 5.2$	<0.001
Time taken for stone fragmentation in mins	$59.1 \pm 10.4$	$32.7 \pm 7.5$	<0.001
Stone clearance rate mm <sup>3</sup> /min	$8.03 \pm 3.7$	$12.7 \pm 8.2$	0.05

No complications recorded on POD-0. On POD-1, 4 participants developed grade 2 complication and 1 developed grade 1 complication (Table 4). Out of 32 participants in each arm, 29 (90.6%) in Holmium laser group and 31 (96.9%) in shock pulse group did not experience any complication on POD-10.

**Table 4.** Complications observed in the participants of both groups (HL—Holmium Laser Lithotripsy, SP—Shock pulse lithotripsy) graded as per Clavien Dindo classification.

Complications (Clavien dindo)	Intraoperative period	POD-0	POD-1	POD-10	After 4 weeks
Grade 1	0	0	1	0	0
Grade 2	0	0	4	0	0
Grade 3	3	0	0	2	0
Grade 4	0	0	0	0	0
Grade 5	0	0	0	0	0

## 5. Discussion

### 5.1. Stone Size and Stone Density

Mean pre procedural stone volume was found to be  $492.6 \pm 266.4$  and  $431.0 \pm$

316.1 in Holmium YAG laser and shock pulse group respectively. Mean pre procedural Stone density was found to be  $927.8 \pm 276.6$  and  $957.1 \pm 188.8$  in Holmium YAG laser and shock pulse group respectively. Stone density can help in identifying the composition of the stone. Studies done by Kawahara *et al.* and Halinski *et al.*, it has been found that majority of the stones found in Ureter contained Calcium and their Hounsfield units (HU) were more than 1000 [11] [12].

## 5.2. Intraoperative Parameters

Intraoperatively the operating time was found to be shorter in patients undergoing Shock pulse lithotripsy ( $36.8 \pm 5.2$  mins) in comparison to Holmium YAG laser group ( $64.7 \pm 10.6$  mins) and was found to be statistically significant on analysis (p value < 0.05). In a prospective randomized trial by Linjin Li *et al.*, the mean operating time was found to be operative time  $28 \pm 9.2$  vs  $41 \pm 12.4$ , P = 0.001 in Holmium YAG laser and pneumatic lithotripsy group but this study has can be carried out for middle and distal ureteric calculi which can explain the much shorter operating time in Holmium YAG Laser group as the access distance is shorter [13]. The time taken for stone fragmentation or stone disintegration time was also shorter in shock pulse ( $32.7 \pm 7.5$  mins) group as compared to Holmium laser group ( $59.1 \pm 10.4$  mins) with p value < 0.05 [13]. Stone clearance was significantly higher in Shock pulse group  $12.7 \pm 8.2$  mm<sup>3</sup>/mins when compared to Holmium YAG Laser group  $8.03 \pm 3.7$  mm<sup>3</sup>/mins with p value = 0.05. This is in agreement with previous study by Rajeev TP *et al.* where stone clearance rate of shock pulse lithotripsy was comparatively better than Holmium YAG Laser via PCNL [14]. No other studies has compared the efficacy of shock pulse and Holmium Laser. Shock pulse lithotripsy is efficacious when compared to Holmium Laser in terms of stone clearance rate. Reason for shock pulse being efficacious than holmium laser can be attributed to the superior fragmentation effect of pneumatic component combined with ultrasonic component which can help in evacuation of stone fragments.

Stone free rate was found to be 87.5% in Holmium YAG laser group and 90.6% in Shock pulse with p value of 0.280 (no statistically significant difference). CIRF rate was 3.1 % in Shock pulse group. Failure rates were 3.33% in Holmium laser group and 3.22% in shock pulse group.

In a metanalysis by Matlaga *et al.*, Stone free rate in proximal ureteral stone following Ureteroscopic lithotripsy was found to be 96% initially which increased upto 100% on a 13-week follow up [15].

As per AUA guidelines report the stone free rate for ureteroscopy was found to be 81%. Among different modalities of lithotripsy Holmium YAG laser was found to have higher stone free rate till the advent of shock pulse. In a study by Rajeev TP *et al.* where he has analyzed the stone free rate among various energy modalities in PCNL, has found stone free rate to be high in shock pulse (82.35 %) as compared to Holmium YAG laser (81.25%) [14]. Failure rate was found to be 5.89% in shock pulse group and 6.25% in Holmium YAG laser group in treatment

of renal stones with PCNL [14]. This difference in failure rates can be because of the difference in procedure and sample size used.

### 5.3. Complications

We observed complications during the intraoperative period, Post operative day-0, 1, 10 and after 4weeks. These complications were graded using Clavien Dindo classification. Intraoperatively, 3 of our participants developed grade 3 complications following which the proposed procedure was changed to another procedure. On POD-0 no complications were noted. On POD-1 one participant developed grade 1 and 4 developed grade 2 complication. On POD-10, 2 patients were identified to have residual stone > 2 mm in NCCT KUB following which they were termed as “Failure”. No statistically significant complications noted between the two groups. Further studies are required to explore the complications following shock pulse lithotripsy. However, the quality of life (QoL) was not affected as participants were able to resume activities on POD-1 and are discharged on the same day. Participants who developed complications were able to carry out their daily activities but had increased stay in the hospital.

### 5.4. Limitations

Follow up beyond 4 weeks must be carried out further to identify further complications and recurrent formation of stones which is lacking in our follow up period. Further analysis of these two lithotripters should be carried out with a larger sample size. The results of the procedure can be affected by a number of circumstances, and this study did not assess the experience of the surgeon. Furthermore, the study’s objective was to analyse the effectiveness of two lithotripters; additional research may be required to examine other variables that may affect the result.

## 6. Conclusion

With innovations in energy modalities used in lithotripters, the technical factors are improving at a greater pace. From our study, we can conclude that shock pulse is efficacious than Holmium YAG Laser lithotripsy in terms of stone clearance rate which in turn has resulted in decreased operating time which can be beneficial in planning more number of operative procedures. Surgeons must stay updated on new technology and techniques in order to deliver tailored therapies for each patient with the best possibility of success.

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Alexander the Great**

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## Conflicts of Interest

The authors declare that there were no conflicts of interest.

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