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# Title: Comparison of Holmium Laser and Pneumatic Lithotripsy Using Semirigid Scope in Managing Ureteric Calculus

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**ABSTRACT**

**Background:**Urinary tract stones (urolithiasis) are known to the mankind since antiquity. Early reports of the disease can be found in the Aphorisms of Hipparchos and even in Hippocrates.In India, the earliest Sanskrit documents like the *Vedas*, the *Puraṇas* and the *Samhitās* also described urinary calculi and their remedies.**Objective:**To study and compare holmium LASER and pneumatic lithotripsy in managing ureteric calculus**. METHODS:**A prospective randomized comparative study on a total of 120 patients,diagnosed with single,unilateral ureteric calculus with appropriate imaging studies was conducted over period of 2 years. **RESULTS:**The immediate stone free rates were 75% in the holmium: YAG group and 63.3% in the pneumatic lithotripsy group (*p 0.166* ). The two weeks stone free rates were 96.7% and 88.3% respectively ($p = 0.08$). The mean ± SD operative time in the PL group (7.08±4.93 min) was shorter than those with LL group (12.45±5.17 min).Stone up migration up occurred in 3 patients of LL group while in 6 patients of PL group.Intraoperative complications such as ureteral perforation was encountered in only one patient who underwent pneumatic lithotripsy. Other complications, such as mucosal injury, postoperative fever and hematuria were comparable in both groups.

**CONCLUSION:**Both Ho:YAG laser and Pneumatic lithotripsy are equally efficient in managing ureteral stones with effective stone clearance, minimum morbidity, and reduced stone up-migration.

**KEYWORDS:** Laser lithotripsy, Pneumatic lithotripsiy,Ureterorenoscopy,DJ stenting

**INTRODUCTION:** Urolithiasis is the existence of stones in the urinary system characterized by the symptomatic manifestations of many metabolic turbulences that are due to the pathological parameters and their interactions. This disease is widespread and recurrent with highest incidence of stones in the ureters.1 Historically ESWL was the preferred treatment for patients with proximal ureteral calculi,Until now, extracorporeal shock wave lithotripsy (ESWL) and ureteroscopic lithotripsy (URS) are the commonly-used treatments for the ureteral stones, producing good results in most of the patients; however, these treatments have their own merits and demerits. 2 The use of ESWL began in 1980s and it is recognized to be an entirely noninvasive, cost-effective,

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and almost risk-free. Also, it requires no significant protracted care at the hospital. 3 On the contrary, URS is a relatively invasive procedure, being performed under the anaesthesia, however considerably effective in respect of time period for the procedure, time period needed for fluoroscopy, and time needed to accomplish destoning. 4The advantage of URS is that it is very effective in the fragmentation of the hard calculi and at the same time, the ureteroscope is used to dilate the ureters to help with the further passage of the calculi. According to Middela.S studyESWL was proved to be an efficient and least invasive treatment for dealing with the ureteral calculi.5 The therapeutic options for the ureteral stones vary from medical expulsion to extracorporeal shock wave lithotripsy (ESWL) to endoscopic procedures. 6.The treatment strategy of watchful waiting with ultrasound follow-up is an appealing and efficacious approach for ureteric stones with a diameter up to 7 mm. The overall spontaneous passage rate is 25% for the proximal ureteric stones, 45% for the mid ureteric stones and 70% for the distal ureteric stones, provided that the mean diameter does not exceed 7 mm. In this modern era where a variety of endoscopic urological interventions are available medical management of ureteral stones should not delay prompt definitive cure of ureteric calculi.

Despite the liberal use of SWL,ureteroscopic lithotripsy is still the preferred treatment modality for managing ureteric stones at many hospitals. 7 Different kinds of lithotripters are used through the ureteroscope that revolutionized the treatment of ureteric calculi.8 Two most common lithotripters used in urologic fields are pneumatic and Ho:YAG laser. Pneumatic lithotripsy is more popular among the urologists because of its low cost, easy setup, and high success rate. 9 Nevertheless, proximal migration of calculi may be a limiting factor of this methodHo:YAG laser is a reliable method for the treatment of ureteric stones especially in proximal and impacted ureteric stones, but it is expensive and not available in most of the urologic centers.10 Hence this study was conducted to study and compare holmium LASER and pneumatic lithotripsy in managing ureteric calculus**.**

**MATERIALS AND METHODS:** This prospective randomized comparative study was carried out at Kasturba Medical College Hospital, Dr. B. R Ambedkar Circle, Mangalore, Karnataka. The study population included the patients admitted with diagnosis of single, unilateral ureteric calculus in the department of urology at the study site mentioned above. The study was carried out over a period of two years from July 2015 to June 2017. Ethical clearance was obtained from the institutional ethical committee for the present study. A total sample size of 120 patients was taken {60 in each arm, PL arm (pneumatic lithotripsy ) and LL arm ( laser lithotripsy )}.

**Inclusion criteria:**

- All patients with single ureteric calculus of size 7 mm to 20 mm were included in the study

**Exclusion criteria:**

- Patient’s with infected Hydroureteronephrosis

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- Patient's with associated UTI and Sepsis
- Patient's with ureteric stricture
- Patient's with associated renal stones

## METHODOLOGY

The patients diagnosed with single,unilateral ureteric calculus disease with appropriate imaging studies (X-ray KUB/USG KUB and NCCT /CECT Urogram) were included into the study after informed consent. A detailed history was obtained.
All patients underwent URSL (ureterorenocopic lithotripsy) with DJ stenting by one designated surgeon, well versed with both the techniques, either by Pneumatic lithotripsy or Laser lithotripsy ( PL group and LL group ) .

A retrograde pyelogram was performed, and a safety guide wire was placed into the renal pelvis.The lower ureter was dilated with a 6/12F Nottingham dilator under fluoroscopic control**.**Under appropriate anaesthesia in lithotomy position,Ureterorenoscopic lithotripsy was performed in a standard fashion with a 8/9.5F semirigid ureteroscope (Karl Storz). The ureteroscope was advancedup the ureter, and the ureteral lumen was inspected for location of stone,appearance of stone,stone impaction,inflammatory polyps and for any other abnormal findings.Swiss Pneumatic lithoclast with 1mm probe was used to fragment the stone with either single or continuous pulses and pressure was set at 2 bars in PL group.In LL group stone was fragmented using LISA Sphinx (LISA laser, Germany) holmium laser (100 watts). The laser fiber used was 272/420 *u*m,Laser energy was generally applied at an initial setting of 0.6 to 0.8 joules (J) energy at a frequency of 8 to 10 hertz (Hz) and increased incrementally by 0.2 J as necessary. We started with the low-power setting and then increased according to stone hardness. To prevent stone up migration during fragmentationa zero-tip nitinol stone basket (Boston Scientific) was used in both groups as deemed necessary.An attempt was made to retrieve all stone fragments usinga grasper or basket**.**In order to maintain a clear ureteroscopic view, irrigation was pumped manually and intermittently during the procedure. After stone fragmentation, final ureteroscopy was performed to detect any residual stone (approximate assement of size was done with tip of lithoclast probe or laser fibre accordingly) or injury to the ureter (mucosal injuries,perforation ). Operating time was calculated from first hit to last hit. 11 A 5 Fr. Double J stent was indwelled in all patients at the end of the procedure.On table fluoroscopy was performed for reassessing any residual fragments or up migration in immediate post operative period.Endoscopic and fluoroscopic scrutiny was done to asses immediate clearance rate..

Ultrasound abdomen and pelvis and X ray KUB was done prior to scheduled time of DJ stent removal after 2 weeks, to check for the clearance of calculus or any residual fragments.

**Statistical analysis:**A statistical package for social science (SPSS) vers.20.0 was used to analyze the data.Additionally, descriptive statistics was carried out to describe the negative or positive result of the patients and ANOVA was determined from each gender.The continuous data were

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expressed as mean ± SD, while the categorical data were expressed as percentage. P value of <0.05 was considered as significant.

**RESULTS:** Of the 120 patients in our study population 94 (78.3%) were males and 26(21.7%) were females. Of the total 120 cases, majority 23.3% (38) of the cases belonged to 31-40 years of age group followed by, 22.5%(27) of cases were in 51-60 years age group. Least frequent group was ≤ 20 years age group with 2.5 % (3) incidence. Mean age distribution was 46.38 ± 14.037 years,with eldest and youngest patients being 79 and 19 years old respectively.

Most common presenting complaints in our study population was loin pain in 98.33 % (118) cases, followed by Scalding voiding and Fever in 6.7%(8) & 5.8%(7) patients respectively

In our study ,Combination of X ray KUB & USG was used as the most common imaging modality in 80.8%(97) patients. CT KUB was added imaging in 18.3% (22) patients while IVU was used in one of our patient.

In our study 43.33 % (52) patients had upper ureteric calculus while least common location of stone was mid ureteric in 18.33% (22) patients.

Table 1: Comparison of location of stone and energy source used for fragmentation

| **Location of stone** | **Energy Source Used** | | **Total** | **p value** |
|---|---|---|---|---|
| | **Laser Lithotripsy group (n=60)** | **Pneumatic Lithotripsy group (n=60)** | | |
| Rt. Upper Ureteric | 17 (28.3%) | 12 (20.0%) | 29 (24.2%) | 0.143 (N.S) |
| Rt. Middle Ureteric | 6 (10.0%) | 8 (13.3%) | 14 (11.7%) | |
| Rt. Distal Ureteric | 11 (18.3%) | 13 (21.7%) | 24 (20.0%) | |
| Lt. Upper Ureteric | 16 (26.7%) | 7 (11.7%) | 23 (19.2%) | |
| Lt. Middle Ureteric | 3 (5.0%) | 5 (8.3%) | 8 (6.7%) | |
| Lt. Distal Ureteric | 7 (11.7%) | 15 (25.0%) | 22 (18.3%) | |
| **Total** | **60 (100.0)** | **60 (100.0)** | **120 (100.0)** | |

50 (41.7%) patients had stone of size range 7 - 10 mm, while 62 (51.7%) had stone of size range 11 to 15 mm. Stone of size range 16-20 mm was found in 8 (6.7%) patients. Patients with stone size > 20 mm were excluded from study.There was no significant difference in the mean stone size between energy source used.

Out of 120 patients in our study, 99 (82.5%) had radioopaque stones while 11(17.5%) had radiolucent stones.49 of 60 (81.7%) patients randomized to laser lithotripsy group had radioopaque stones while 50 of 60 (83.33%) patients in pneumatic lithotripsy group had radioopaque stones. Table 2

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Table 2: Comparison of opacity of stone on radiograph (X ray KUB) and energy source used for fragmentation

| **Radioopaque / Radiolucent** | **Energy Source Used** | | **Total** |
|---|---|---|---|
| | **Laser Lithotripsy group (n=60)** | **Pneumatic Lithotripsy group (n=60)** | |
| Radioopaque | 49 (81.7%) | 50 (83.3%) | 99 (82.5%) |
| Radiolucent | 11 (18.3%) | 10 (16.7%) | 21 (17.5%) |
| **Total** | **60 (100.0%)** | **60 (100.0%)** | **120 (100.0%)** |

In our study 48 of 60 patients (80%) in the pneumatic lithotripsy group had operating time range of ≤10 min, while it was noted only in 13 of 60 patients (21.7%) in laser lithotripsy group. In the Laser lithotripsy group majority of patients (45/60,70 %) had an operating time range of 10-20 min,which was noted only in 11 of 60 (18.3%) patients of pneumatic lithotripsy group.> 20 min operating time was required in 2 & 1 patient in laser and pneumatic lithotripsy groups respectively.

In our study Laser Lithotripsy group had a higher mean operative time (12.45±5.17 min) while Pneumatic Lithotripsy group had a lower mean operative time (7.08±4.93 min).On statistical analysis p value was found to be <0.01, which was statistically significant in our study.

It was observed that 86.4% and 91.7% of the patients in Laser Lithotripsy and Pneumatic Lithotripsy group respectively did not have any significant difficulty in visibility due to bleeding or stone dust (snow storm effect) during fragmentation. Numerically laser arm had more visibility issues (9 cases) as compared to pneumatic lithotripsy arm (5 cases), however on calculating p value, the difference was not statistically significant between 2 arms.

Table 3: Comparison of difficulty in visibility during fragmentation of stone with energy source used for fragmentation

| **Visibility issues** | **Energy Source Used** | | **Total** | **p value** |
|---|---|---|---|---|
| | **Laser Lithotripsy group (n=60)** | **Pneumatic Lithotripsy group (n=60)** | | |
| No | 51 (86.4%) | 55 (91.7%) | 106 (89.1%) | 0.361 (N.S) |
| Yes | 9 (13.6%) | 5 (8.3% ) | 13 (10.9%) | |
| **Total** | **60 (100.0%)** | **60 (100.0%)** | **120 (100.0%)** | |

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In our study we observed that overall 69.2% of the patients were stone free during immediate scrutiny (by fluoroscopy and endoscopy) including 75.0% in Laser Lithotripsy group and 63.3% Pneumatic Lithotripsy group. Since p value was 0.166, hence we could not establish any statistical significance in immediate stone clearance rates between these 2 energy sources.

Table 4:Comparison of Immediate Clearance Rates with Energy Source used for fragmentation

| **Immediate clearance** | **Energy Source Used** | | **Total** | **p value** |
|---|---|---|---|---|
| | **Laser Lithotripsy group (n=60)** | **Pneumatic Lithotripsy group (n=60)** | | |
| No | 15 (25.0%) | 22 (36.7%) | 37 (30.8%) | 0.166 (N.S) |
| Yes | 45 (75.0%) | 38 (63.3%) | 83 (69.2%) | |
| **Total** | **60 (100.0%)** | **60 (100.0%)** | **120 (100.0%)** | |

In our study we observed that overall 92.5% of the patients were Stone free after 2 weeks. Further 96.7% and 88.3% of the patients in Laser Lithotripsy and Pneumatic Lithotripsy group respectively were Stone free after 2 weeks. In our study there was no statistically significant difference between 2 energy sources in terms of destoning however 7 (11.7%) cases in Pneumatic Lithotripsy group and 2 (3.3%) cases in Laser Lithotripsy group had clinically significant residual fragments.

Table 5: Comparison of Stone free rates after 2 weeks with Energy Source used for fragmentation

| **Stone free after 2 weeks** | **Energy Source Used** | | **Total** | **p value** |
|---|---|---|---|---|
| | **Laser Lithotripsy group (n=60)** | **Pneumatic Lithotripsy group (n=60)** | | |
| No | 2 (3.3%) | 7 (11.7%) | 9 (7.5%) | 0.083 (N.S) |
| Yes | 58 (96.7%) | 53 (88.3%) | 111 (92.5%) | |
| **Total** | **60 (100.0%)** | **60 (100.0%)** | **120 (100.0%)** | |

In our study we observed that in Laser Lithotripsy Group,out of 2 patients with clinically significant residual fragment one underwent surgical intervention while other was managed with medical expulsive therapy and in Pneumatic Lithotripsy group out of 7 patients 3 patients needed surgical intervention,2 were managed with medical expulsive therapy while remaining 2 patients preferred observation.

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Table 6 : Comparison of need for Additional Intervention for residual fragments during followup with Energy Source used

| **Need for additional intervention** | **Energy Source Used** | | **Total** | **p value** |
|---|---|---|---|---|
| | **Laser Lithotripsy group (n=60)** | **Pneumatic Lithotripsy group (n=60)** | | |
| Medical | 1 (1.7%) | 2 (3.3%) | 3 (2.5%) | **0.313** |
| Surgical | 1 (1.7%) | 3 (5.0%) | 4 (3.3%) | |
| Observation | 0 (0.0%) | 2 (3.3%) | 2 (1.7%) | |

**DISCUSSION:**The mean age of presentation in our study was 44.32 in PL group and 48.45 in LL group with 31-40 years of age group having higher number of patients (23.3%). In our study age incidence of patients were similar with the study of Garg et aland Seong Soo Jeon et al. 12, 13 Mohammad Reza Razzaghi et al reported mean age incidence as 36.4 & 35.9 years in PL and LL groups respectively in their study, which was slightly lower than our study. 11

In our series male : female ration were similar with the study done by Shivadeo S Bapat et al. 14 Men as compared to women are seen working outdoors in the hot and humid climate as is in south western coastal India, which could be one of the contributing factors for male preponderance of the urolithiasis.

The mean stone size in our study was 11.18±2.75 mm in PL group and 11.42±2.59 mm in LL group which were similar with the study of Garg et aland Cimino et al.12,15

In the present study, the immediate stone-free rates of holmium:YAG laser lithotripsy and pneumatic lithotripsy group were 75 % and 63.3 % respectively, with p value of 0.166 ,hence no statistically significant superiority of one over other could be established ( though percent wise Laser group had better immediate stone free rates ), which was inconsistent with results reported in studies by Mohammad Reza Razzaghi et al, Garg et al etc. 11,12While this result was in agreement with a study conducted by Bhandri et al inwhich figures of (92% vs 94% ,p 0.696 ) for laser and pneumatic lithotripsy respectively was reported. 16 Interestingly Naqvi et al reported significantly higher immediate stone free rates with pneumatic lithotripsy group however there was significant difference in sample size between two groups in their study, which could have been the cause for their results. 17The Overall Stone free rates after 2 weeks in our study was 92.5 % (111/120) and were 88.3% (53/60) and 96.7% (58/60), respectively in PL and LL groups ($p$=0.083).

Our success rates were similar to those reported by Bhandari BB et al16, Seong Soo Jeon et al13,while were inconsistent with results reported by Mohammad Reza Razzaghi et al11and Cimino et al who found higher clearance rates with laser lithotripsy.Both energies were found to be effective in fragmenting stones in our study. 11,15

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In our study laser lithotripsy had higher mean in operating time than pneumatic lithotripsy group with statistically significant difference (7.08±4.93 in PL group Vs 12.45±5.17 in LL group p <0.01 ),which was similar with studies done byGarg et al[162] , Mohammad Reza Razzaghi et al. 12, 11Meticulous techniques and more gentle ureteroscopic manipulations may significantly reduce chances of mucosal injuries.

In our study, Post operative hematuria was found in 4/60 (6.7%) and 3/60 (5%) patients in Pneumatic and Laser lithotripsy group respectively (Clavien-Dindo Grade 1) which is in line with the most of studies except study done by T Manohar et al. 18

In our study post operative fever (Clavien-Dindo Grade 1) was seen in 5/60 (8.35) and 3/60(5 %) cases of pneumatic and laser lithotripsy respectively with no statistically significant difference between two groups and was in concurrence with most of the studies. 19

In the study by *de la Rosette* et al,Postoperative fever was most frequent complication of Ureteroscopy.*20 Koji Mistuzuka* et al concluded that preoperative pyuria was significant risk factor for post operative fever after ureteroscopy. 21The European Association of Urology Guidelines recommend the use of cephalosporin or fluoroquinolone as prophylactic antibiotics prior to diagnostic ureteroscope and ureteroscopic lithotripsy. 22 The bacteria in the stones as well as the endotoxin may increase the risk of postoperative infection. Patients with infectious stones were reported to have a high risk of postoperative infectious complications. 23

When perfusion fluid accumulates to a certain extent, the high pressure may cause pyelovenous backflow; consequently, bacteria and bacterial endotoxins can enter the bloodstream along with perfusion fluid absorption, and cause postoperative fever, bacteremia, or even sepsis. 24 However renal pelvic pressure was not assesed in the present study, and were hence unable to assess these risk factors, However maintenance of low pressure in the renal pelvis may help reduce the intra operative absorption of fluid and the incidence of postoperative fever and bacteremia.

**Conclusion:**The Ho:YAG laser and the Pneumatic lithotripsy are equally efficient in the management of ureteric stones. They have comparable immediate and overall stone clearance rates.Pneumatic lithotripsy is not only simple, reliable, highly effective, rapid and safe method of lithotripsy but also cost effective in terms of initial installation, maintenance and durability.

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