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Original Article

A prospective comparative study to evaluate safety and efficacy of pneumatic versus laser lithotripsy in mini-percutaneous nephrolithotomy

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Abstract: Objective: The choice of lithotripter is an important part of planning in mini-percutaneous nephrolithotomy (mini perc) as the operating time is prolonged due to reduced sheath size and smaller working channel. Previous studies mostly reported the use of laser lithotripter for stone fragmentation while the literature on pneumatic lithotripter use in miniperc is scant. Methods: In this study, we compared the efficacy and safety of the laser lithotripter (LL) vs pneumatic lithotripter (PL) in miniperc for small to medium-sized renal/upper ureteric stones (size: 1-2 cm). All consecutive patients who underwent miniperc from September 2020 to August 2022 were included in the study. Laser lithotripter was used in 81 patients (group LL), while pneumatic was used in 75 patients (group PL). The preoperative, operative, and postoperative findings were compared. Results: Baseline patient characteristics (age, sex, body mass index, and co-morbid illness) and stone characteristics (size, stone number, laterality, presence of staghorn calculi, presence of hydronephrosis, Guy's stone scores) were comparable between the two groups (P>0.05). The mean operative time was comparable (P=0.38) while the mean fragmentation time was significantly higher in the PL group (35.42±6.34 vs 28.96±2.82 minutes; P<0.01). 29.3% required forceps/basket for stone removal in PL group as compared to 7.4% in LL group (P=0.02). Mean VAS (Visual Analog Scale) score on the first post-operative day, stone clearance, drop in hemoglobin, average hospital stay, stone clearance at 3 months postoperative, and complications were comparable (P>0.05). Conclusion: Lithotripsy with pneumatic lithotripter can be used as an equally effective and safe alternative to laser lithotripter in mini-perc for treatment of small-medium sized renal/upper ureteric calculi.

Keywords: Energy source, laser lithotripter, mini-PERC, mini-PCNL, pneumatic lithotripter

Introduction

Renal stone disease globally affects around 5-10% of the total world population [1]. There are various minimally invasive options available for renal stones including percutaneous nephrolithotomy (PCNL), retrograde intra-renal surgery (RIRS), and extra-corporeal shockwave lithotripsy (ESWL) depending upon stone burden, composition, and location [2]. PCNL is recommended as the standard therapy for the management of renal stones >2 cm in size while stones of size 1-2 cm can be managed by either ESWL, RIRS, or PCNL depending upon stone location and other factors [2]. Standard PCNL has higher stone clearance rates (SFRs) and cost-effectiveness than its contemporaries (RIRS, ESWL) however there are concerns about the more risk of bleeding, the requirement of blood transfusions, and increased analgesic requirements with the use of PCNL [3]. Minimally invasive PCNL (mini-PERC) was introduced as a modification of standard PCNL with miniaturization of working operative instruments including nephroscope and amplatz sheath to reduce operative morbidity. It was first described in children for the management of renal stones by Jackman et al. in 1998 and later on, this technique was used in adults as well [4, 5]. Mini-PERC has shown to have a lesser complication rate with comparable stone-free rates than standard PCNL but the main limiting factors are an indication for small or medium size stones, higher cost, and longer operative time [5-7].

The choice of lithotripter is an important element of planning in standard or mini-PCNL as operative time, rate and type of complications, SFRs, and cost-effectiveness may vary with the use of different lithotripter probes due to variation in size of probes, mechanism of stone fragmentation and cost of lithotripter. The stone fragments are retrieved by hydrodynamic effects of saline without any additional suction or pressure during mini-PERC. It also makes the selection of optimal lithotripter for stone fragmentation one of the key steps in mini-PCNL [8]. There is a paucity of comparative prospective studies in current literature for the evaluation of optimal energy sources or lithotripter probes during Mini-PCNL surgery. Various lithotripters like laser, pneumatic, electrohydraulic, ultrasonic, and combined pneumatic-ultrasonic are commonly used and studied for stone fragmentation in standard PCNL, however previous reports available in mini-PERC literature have mostly used holmium:YAG (Ho-YAG) laser for stone fragmentation [8]. Other modalities for stone fragmentation like pneumatic and ultrasonic lithotripter have been seldom used in mini-perc.

D'Souza et al. used laser lithotripsy for stone fragmentation in 8 pediatric cases of mini-PERC and found around 90% stone clearance rates [8]. Akbulut et al. did a comparative study of laser vs ultrasonic lithotripsy and found laser lithotripsy to be more cost-effective in mini-perc [9]. Previous studies mostly report the use of laser lithotripter for stone fragmentation while comparative studies between laser and pneumatic lithotripter use in mini-perc are scant. In the present study, we compared the efficacy and safety of laser lithotripsy with 65 Watt (W) Ho-YAG laser (LL group) versus pneumatic lithotripsy (PL group) in patients with small to medium-sized renal/upper ureteric stones (size 1-2 cm) who underwent mini-perc.

Materials and methods

Study design

The present prospective study was conducted in one of the national pioneer tertiary care institutes from September 2020 to August 2022. The present study was conducted in line with the Good Clinical Practice guidelines and the ethical principles laid down in the latest version of the Declaration of Helsinki. The inclusion criteria included all consecutive patients with small to medium-sized renal/upper ureteric stones (size 1-2 cm) who underwent mini-PCNL with either a 65 W Ho-YAG laser or a pneumatic lithotripter. The exclusion criteria included patients having active urinary tract infection, deranged coagulation profile, pregnancy, severe skeletal deformities, anomalous kidney, or patients refusing consent to study. All the procedures were performed by urologists having good experience in endourology. All the surgeries in pneumatic lithotripsy (PL) and laser lithotripsy (LL) Mini-PERC groups were done according to a random number table allotment and was performed by two expert urologists at our institute.

Study procedure

For all patients, pre-operative urine cultures were obtained, and in case of any significant microbial growth, appropriate antibiotic therapy was given. The procedures were done under either spinal anesthesia (adolescents and adults) or general anesthesia (children). The procedure was started by placing the patient in a lithotomy position after induction of anaesthesia and then a 5 Fr (French) ureteric catheter was placed under cystoscopic guidance. The patient's position was then changed to prone. Entry into the pelvicalyceal system was done under fluoroscopic guidance and subsequently, a guide wire (Terumo, Tokyo, Japan) was inserted. Then dilatation of tract to 16 Fr was done over guide wire and a 16.5 Fr mini perc sheath (Karl Storz, Tuttlingen, Germany) was placed. A 14 Fr miniature Storz nephroscope was then used which had a 6 Fr working channel.

Stone fragmentation was done using either of the followings: 1. 14 Fr, pneumatic lithotripter (Swiss lithoclast, EMS Medical Systems, Nyon, Switzerland). Fragmentation with a pneumatic lithotripter was done initially using a single pulse mode and a probe of 3 Fr size. 2. 65 W holmium:yttrium-aluminum-garnet (Ho:YAG) laser with 550 μm fiber. The initial fragmentation of stones by laser was started at the energy of 0.5-1.0 joules and a frequency of 6-20 Hz at 65 W power.

Immediate stone clearance was assessed using nephroscopy and fluoroscopy. Need of DJ stenting or nephrostomy catheter placement was done at the sole discretion of the operating surgeon.

The ureteral catheter and per urethral catheter were removed mostly on the first post-operative day. The nephrostomy tube and DJ stent (if placed) were removed on the second and tenth post-operative day respectively. Most patients were discharged on the first or second post-operative day in case there were no complications. During follow up X-RAY KUB/Non-Contrast CT KUB and/or ultrasonography were performed at postoperative day one and three months post-operative to see stone clearance rates.

For comparison, the patients were divided into two groups (Groups PL and LL). Both the groups were compared for demographic features (age, sex, BMI), stone characteristics (size, location, laterality, pre-operative Guy's stone score), total operative times, total fragmentation time, use of auxiliary procedures, postoperative complications according to Clavien-Dindo classification, hemoglobin drop, stone clearance rate, postoperative pain score using a visual analog scale (VAS) and hospital stay [10, 11]. Success after mini-PCNL was defined as either stone-free status (no evidence of residual stones in post-operative X-Ray KUB/Non Contrast CT KUB and/or ultrasonography) or the presence of clinically insignificant residual fragments <3 mm at 3 months of follow-up.

Guy's stone score (GSS) is based on parameters such as number of stones, any abnormal anatomy, location of the stone, presence of any partial or complete staghorn stone and spinal injury/bifida. On the basis of these parameters on CT scan, there are four grades of GSS [10].

The Clavien-Dindo classification is the most common, post-surgery classification system. It includes 5 grades. Grade I (Any deviation from normal postoperative period without any need of pharmacological treatment, surgical, endoscopic and radiological interventions), Grade II (Requires pharmacological treatments other than required in grade I), Grade III (Requires surgical, endoscopic and radiological interventions, a: not under general anesthesia, b: under general anesthesia), Grade IV (Life threatening complications requires ICU facilities, a: single organ dysfunction, b: multiorgan dysfunction), Grade V (death). The grading system is based on the principle of the extent of treatment, required to resolve a complication [11].

Visual Analogue Scale (VAS) - The simplest type of VAS assessment is by measuring the length (mm) on a 10-cm horizontal straight line between the "no pain" (origin) and the patient's point, providing a range from 0-100. A higher score suggests greater pain intensity. There are predefined cut-points: no pain (0-4 mm), mild pain (5-44 mm), moderate pain (45-74 mm), and severe pain (75-100 mm).

Ethical statement

Ethical approval was obtained from the institutional ethical clearance board (MGMC&H/IEC/JPR/2022/940). Written informed consent was taken from all the patients for the procedure.

Statistical analysis

All data were prospectively entered in excel sheets and statistical analysis was performed using IBM SPSS Statistics ver. 28.0 software (IBM Co., Armonk, NY, USA). Discrete categorical data were expressed as numbers and percentages. Continuous data were expressed as mean ± standard deviation. Categorical variables were analyzed using the Pearson Chi-square test or Fisher's exact test. Continuous variables were compared between the two groups using independent samples Student's t-test or Mann-Whitney U test. A *P*-value <0.05 was considered statistically significant.

Results

Demographic characteristics

The comparison of patient demographic and stone characteristics is depicted in **Table 1**. There was no difference observed in baseline patient characteristics (age, sex, body mass index, and co-morbid illness) and stone characteristics (size, stone number, laterality, presence of staghorn calculi, the presence of hydronephrosis, Guy's stone scores) between the two groups (P>0.05). The procedure was start-

Table 1. Baseline patient demographics and stone characteristics

Parameter	Laser group (n=81)	Pneumatic group (n=75)	*P* value
Age (Mean ± SD)	27.02±10.38	28.33±11.13	0.61
Sex			
Male	49	50	0.62
Female	32	25	
BMI (Mean ± SD)	22.27±1.72	22.55±0.70	0.47
Co-morbidities			
Diabetes	16	12	0.76
Hypertension	12	8	0.72
Stone location			0.80
Upper calyx	6	5	
Inferior calyx	24	30	
Pelvis	30	25	
Upper ureter	22	16	
Stone size (cm)	1.33±0.38	1.65±0.46	0.95
Stone Laterality			0.79
Right	57	55	
Left	24	20	
Stone number	1.43±0.15	1.22±0.13	0.49
Staghorn calculus	16	15	0.17
Presence of Hydronephrosis	24	20	0.41
Guy's stone score	2±0.49	1.5±0.42	0.05*

*represents significant *p*-value (≤0.05).

ed with Ho:YAG laser lithotripter in two patients; however due to inadvertent intra-operative malfunctioning of the laser machine just after starting the mini-perc, it was shifted to pneumatic lithotripter and complete stone clearance was achieved. These two patients were included in the PL group during the final statistical analysis.

Comparative analysis

A comparison of intra-operative and postoperative data between the two groups is depicted in **Table 2**. The mean operative time was comparable while the mean fragmentation time was significantly higher in PL group as compared to LL group (35.42±6.34 vs 28.96±2.82 minutes; P<0.01). Two patients required re-look procedures in the pneumatic lithotripter group. Two patients in each group required placement of the ureteral stent intra-operatively. Around 29.3% of patients required the use of stone forceps or baskets for stone removal in PL group compared to only 7.4% in LL group which was significantly higher (P=0.02).

The mean VAS score on first post-operative day, stone clearance (on the first post-operative day/after 3 months), drop in hemoglobin and average hospital stay were comparable between the two groups. Minor complications (Clavien grade 1 and 2) were seen in ten patients in LL group and eight patients in PL group which were not significant (P>0.05).

Discussion

Mini-PERC as a modality to manage renal stones was introduced based on the concept that it will lead to comparable stone clearance rates with decreased morbidity as it uses smaller size tracts compared to conventional PCNL. Mini-PCNL advantages include decreased blood loss, increased maneuverability, reduced post-operative pain, analgesic requirements, and short hospital stay. However, there are some limitations of mini-PCNL; it is necessary to break the stone into small pieces to fit into a reduced size sheath (11-20 Fr) resulting in comparatively longer operative times [12]. Mini-PCNL commonly uses an 8/9.8 Fr rigid/semi-rigid ureteroscope or a 12-16 Fr mini nephroscope which has a 6 Fr working channel with automatic pressure control [13, 14]. In the present study most cases were done using a

Table 2. Comparison of intra-operative and peri-operative parameters

Parameter	Laser group (n=81)	Pneumatic group (n=75)	*P* value
Total operating time (min)	52±7.56	56±7.84	0.38
Total fragmentation time (min)	28.96±2.82	35.42±6.34	<0.01*
Need for stone removal	6 (7.4%)	22 (29.3%)	0.02*
Auxillary procedures	2	4	0.30
DJ stenting	2	2	
Need of Re-look surgery	0	2	
Mean VAS			
After 6-hours	3.52±0.67	2.97±0.61	<0.01*
On 1st post-op day	1.64±0.37	1.70±0.61	0.31
Stone clearance			
On first post-op day	75/81 (92.5%)	65/75 (86.67%)	0.45
After 3 months	79/81 (97.5%)	70/75 (93.33%)	0.57
Hemoglobin drop	0.88±0.16	0.89±0.23	0.45
Serum Creatinine rise	0.22±0.13	0.24±0.14	0.52
Hospital stay duration	1.67±0.45	1.73±0.45	0.29
Clavein-Dindo Complications	10	8	1.00
Grade 1			
Fever	5	4	
Pain	1	0	
Nausea/vomiting	2	3	
Grade 2			
Minor pelvis/ureter perforation	1	0	
Urinary tract infection	1	1	

*represents significant *p*-value (<0.05).

16 Fr nephroscope with a 6 Fr working channel.

At first, mini-perc was conceived as a low pressure irrigation system where the fragments could be drained through the Amplatz sheath; however, the system has evolved and new technologies have arrived. Now some different systems allow drainage with pressure and suction. In mini-perc, stone removal occurs via hydrodynamic effects that flush out stone fragments along the backflow of specially designed metallic Amplatz sheath without the use of additional pressure or suction [13]. The intrarenal pressure is commonly kept to a lower level to prevent pyelovenous backflow. The larger stone fragments can be retrieved through either stone forceps or baskets [15]. Zeng et al. proposed the use of an endoscopic pulsed perfusion pump for the retrieval of stone fragments [14]. The available modalities for stone fragmentation during conventional and mini-PCNL include pneumatic, laser, and ultrasonic lithotripter [2]. The choice of lithotripter is an important part of planning in mini-perc as the operating time is prolonged due to reduced sheath size and smaller working channel which admits smaller size instruments [16]. Both, LL and PL have been used successfully in the stone fragmentation in the urinary tract with modalities such as RIRS, and ureteroscopic lithotripsy but the data comparing the efficacy and safety of LL and PL in mini-perc is scant [17-19].

Most of the available previous studies in mini-perc have used a holmium laser as a lithotripter due to its ease of flexibility and fragmentation [20, 21]. The fiber is thin (273 μm to 550 μm), it can be passed in small caliber endoscopes that are used in mini-perc and it fragments all types of stones regardless of composition. Other advantages of LL include ease of modifying the fragmentation rate. The energy and frequency settings can be modified to produce a dusting effect or fragmentation based on the size of the calculi. In the present study, the total operating time between the two modalities was similar but the total fragmentation time was significantly higher in PL group compared to

LL group (35.42±6.34 vs 28.96±2.82 mins; P<0.01), which may be explained by the fact that larger fragments are produced with PL which requires more time to fragment and additional maneuvers for removal compared to LL. PL has been successfully used for fragmentation of renal/upper ureteric stones with comparable fragmentation efficacy and added advantages of low cost and easy installation [17]. The initial fragmentation is rapid with a pneumatic lithotripter, however, further fragmentation is challenging. PL produces large size fragments which are not easily retrievable through hydrodynamic effects. This was evident in the present study as well. A significantly higher number of patients (29.3%) in the PL group required additional measures like the use of forceps for stone removal compared to LL group (7.4%) (P=0.02). PL produces larger stone fragments and increases the chances of stone migration into other calyces compared to LL [22]. It has been shown that LL is associated with lower chances of stone migration during ureteroscopy as its predominant mode of stone fragmentation is based on the photothermal effect [23, 24].

The results of this study confirm the efficacy and safety of mini-perc in the treatment of small-medium sized renal/upper ureteric calculi. The pain scores at 6 hours and 24 hours post-operative were low in both groups and the type of energy used had minimal impact on pain scores after 24 hours of surgery. The total operative time and stone clearance rates were almost similar between the two groups at 3-months. The average drop in hemoglobin levels was less than 1 g/dl, mean hospital stay was less than 2 days. In both groups, most of the complications that occurred were clavein grade 1 and 2. The probable explanation for this is that mini-perc is a relatively safe procedure and we included patients who had a small bulk of calculi. The use of a pneumatic lithotripter probe during mini-PCNL is cheap & durable alternative with comparable stone free rates & procedure related complications and can be used in more cases as compared to laser lithotripter fiber, which has to be changed more frequently. This signifies its implication in routine Mini-PCNL procedures may be more useful and practical due to the non-availability of costly Holmium laser machines in developing and underdeveloped nations, which has financial constraints. The pneumatic lithotripter may also be useful in case of inadvertent intra-operative non-functioning of laser lithotripter during Mini-PERC. Although the present study is limited in the number of patients and includes data from a single center, it provides evidence that pneumatic lithotripter can be used as an equally effective and safe alternative to laser lithotripter in mini-perc.

Conclusions

The selection of lithotripter probes in Mini-PERC surgery is an important element. The readily available pneumatic lithotripter can be used as an equally effective, cheap, and safe alternative to laser lithotripter in mini-perc for treatment of small-medium sized renal/upper ureteric calculi.

Limitations

The study accounts for small and medium size stones, hence, need for research on large size stones or staghorn calculus is still required which is not covered under the spectrum of study. A large multi-center study is needed to further establish our outcomes.

Disclosure of conflict of interest

None.

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