

Original Article

Safety and Efficacy of Pneumatic Lithotripters Versus Holmium Laser on Multiple Ureteral Calculi

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Abstract

Background: Different energy sources can be used for ureteroscopic stone fragmentation, such as pneumatic, ultrasonic, laser or electrohydraulic. The aim of this study was to compare the efficacy and safety of pneumatic lithotripters versus Ho: YAG laser in the treatment of multiple stones in the distal ureter.

Methods: A retrospective evaluation was done using the data of patients to whom ureteroscopic lithotripsy (URL) was applied for ureter stones in our clinic. From these patients, those with multiple unilateral distal ureter stones were identified, then these patients were separated into 2 groups according to the type of lithotripter used in stone fragmentation as laser lithotripsy (Group 1) and pneumatic lithotripsy (Group 2).

Results: Statistically, the two groups were similar in respect of the number of stones, stone burden and the number of double J stents applied intra-operatively. The mean operating time was similar in the 2 groups as 53.47 (± 17.3) minutes in Group 1 and 50.59 (± 15.3) minutes in Group 2. On postoperative day 1 after the URL, the stone free rate (SFR) of Group 1 (78.7%) was found to be significantly high compared to the SFR of Group 2 (63.6%), while at postoperative month 1, the SFR of both groups was found to be similar. Binary logistic regression was applied to determine the effect of related independent variables on the 1st month SFR. In this model, age and stone burden were affecting variables.

Conclusion: Compared to the pneumatic lithotripter, the Ho: YAG laser seems to have advantages of a higher SFR in the early postoperative period, even though there are statistically similar success rates and complication rates.

Keywords: Laser lithotripsy, multiple calculi, pneumatic lithotripsy, ureteral calculi

Cite this article as: Ercil H, Alma E, Bas O, Unal U, Sener NC, Vuruskan E, Senturk AB, Gurbuz ZG. Safety and efficacy of pneumatic lithotripters versus holmium laser on multiple ureteral calculi. *Arch Iran Med.* 2016; **19**(11): 786 – 790.

Introduction

Symptomatic ureterolithiasis is one of the most important emergency situations encountered by urologists.¹ Both the European Association of Urology and the American Urological Association have focused on the changes in the management of ureter stones. According to these guidelines, the two main modalities in the treatment of symptomatic ureter stones are shockwave lithotripsy (SWL) and ureteroscopic lithotripsy (URL).² Traditionally, URL has been preferred for the treatment of stones in the lower and mid ureter and SWL has been preferred more for the treatment of stones in the upper ureter.³ The success of URL treatment may be affected by factors such as the stone size, localization, whether or not it is impacted, the stone composition and number.

Together with developing technology, different energy sources can be used for ureteroscopic fragmentation, such as pneumatic, ultrasonic, laser or electrohydraulic.⁴ If the number of stones

increases, then the operating time in URL is prolonged, with associated increases in morbidity and decreases in success rates.⁵ Generally, studies in literature which have compared the effectiveness of lithotripters used in URL have been formed of patient series with a single stone in the ureter.⁶⁻⁹ To the best of our knowledge, there are no studies in literature which have compared different lithotripters in URL of multiple ureter stones. The aim of this study was to compare the efficacy and reliability of pneumatic lithotripters versus Ho: YAG laser in the treatment of multiple stones in the distal ureter.

Material and Method

This retrospective analysis of patient data was conducted between January 2009 and January 2015. The URL was applied to the patients for ureteral stones in our clinic. From these patients, those with multiple distal ureteral stones were identified, then these patients were separated into 2 groups according to the type of lithotripter used in stone fragmentation as Ho: YAG laser lithotripsy (HLL-Group 1) and pneumatic lithotripsy (PL-Group 2).

The data from a total of 206 patients were evaluated. Exclusion criteria were pediatric age group ($n = 34$), a history of renal or ureter surgery ($n = 13$), formation of steinstrasse following SWL ($n = 10$), creatinine level > 2 mg/dL ($n = 4$), ureterocele ($n = 2$), and ureterovesical junction obstruction ($n = 2$). Between 2009 and 2011, patients were treated with PL, and then following the

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Accepted for publication: 5 October 2016

purchase of HLL device, all patients were treated using HLL. However, PL had to be used in cases of technical failures of HLL.

Patients were evaluated with preoperative ultrasonography (USG) and intravenous urography (IVU) or non-contrast computed tomography (NCCT). Operations were performed by surgeons with at least five years of ureteroscopy experiences (HE, NCS, EV, ZGG, EA). Stone number and size were evaluated with kidney-ureter-bladder (KUB) X-rays and/or USG in opaque stones and with NCCT in non-opaque stones.

In the operations, which were performed under general or spinal anesthesia, the ureter orifices of all the patients were firstly evaluated with cystoscopy. Ureteral balloon dilatation was not performed routinely, but only when the ureteroscope could not be advanced to the ureteral orifice directly or using a guide-wire. The ureteroscopy procedure was applied with a semi-rigid ureteroscope (8/9.5 fr Sopro Comeg, Tutlingen, Germany). After placing a security guide wire in all patients, the stone fragmentation was started with a pneumatic lithotripter (Vibrolith, Elmed, Ankara, Turkey) or a 550- μ m Ho: YAG laser lithotripter (Sphinx, LISA, Katlenburg-Lindau, Germany). In our clinic, the routine settings for PL was 4 bar pressure and 10 Hz frequency using a 3 F probe. Routine settings for HLL were 1 – 1.5 J energy and 8 – 12 Hz frequency. The fragmentation procedure was continued until all the stone fragments were \leq 3 mm. Fragments were removed using a stone basket or forceps. Double J (JJ) stenting was not routinely performed. A JJ catheter was applied to patients with severe oedema, mucosal damage, hematuria, and migration of stone or fragments or in cases where the surgeon thought it appropriate. Operative time was defined as the duration between introducing the ureteroscope into the urethra and the placement of the JJ catheter and removing the ureteroscope from the urethra at the end of the procedure.

Patients were evaluated for residual stones on postoperative day 1 and after one month. KUB and USG were used for opaque stones and NCCT for non-opaque stones. NCCT was used when any kind of residual stone was suspected. Terminating the operation because of intraoperative stone migration, oedema or haematuria, the application of additional surgical intervention or the determination of clinically significant (\geq 3 mm) residual fragments in the postoperative follow-up were evaluated as a failure. Success was defined as a stone-free rate (SFR) in the postoperative first month. The JJ stents placed in patients were removed with flexible cystoscope under local anesthesia after 14 – 21 days. In patients with an increasing degree of hydronephrosis because of residual stones during follow-up, re-URL or SWL or retrograde intrarenal surgery (RIRS) treatment was applied 2 – 4 weeks after the first operation.

The two groups were compared statistically in terms of demographic characteristics, stone dimensions, stone burden, number of stones, operating time, application of JJ stent, complications, SFR on postoperative day 1, duration of hospitalization and postoperative 1st month SFR. To demonstrate the factors affecting success and complication rates, multivariate analysis was applied.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Sciences SPSS 22 software (IBM SPSS Statistics, IBM Corporation, Chicago, IL). Numerical variables were presented as mean and standard deviation, and quantitative variables as

frequency and percentage. The Shapiro Wilk test was used to assess the conformity to the normal distribution of the data. The independent samples *t*-test was used for comparisons of parametric variables between the two groups. The Pearson Chi-square, Yates Chi-square and Fisher's Exact Chi-square tests were used for comparisons of quantitative variables. Binary logistic regression was applied to determine the effect of related independent variables on 1st month SFR. For all statistical comparisons, a value of $P < 0.05$ was considered as significant.

Results

The study included 141 patients. Ho: YAG laser was used for 75 patients (Group 1) and 66 patients were treated using pneumatic lithotripsy (Group 2).

Group 1 comprised 75 patients; 48 males and 27 females with a mean age of 41.23 (\pm 11.87) years. Group 2 comprised 66 patients; 42 males and 24 females with a mean age of 40.17 (\pm 12.4) years. Stones were determined in the right ureter in 39 patients in Group 1 and in 36 in Group 2. Stones in the left ureter were determined in 36 patients in Group 1 and in 30 in Group 2. Impacted stones were determined in 14 patients in Group 1 and in 12 patients in Group 2.

Statistically, the two groups were similar in respect of the number of stones and stone burden ($P = 0.632$, $P = 0.97$, respectively). The patient demographic data, preoperative findings and statistical evaluations are shown in Table 1.

Mean operating time was calculated as 53.47 (\pm 17.3) minutes in Group 1 and 50.59 (\pm 15.3) minutes in Group 2. The mean operating time was found to be similar in both groups ($P = 0.301$). On postoperative day 1 after the URL, the SFR rate of Group 1 (78.7%) was found to be statistically significantly high compared to the SFR of Group 2 (63.6%) ($P = 0.048$), while at postoperative month 1, the SFR of both groups (Group 1 86.6%, Group 2 80.3%) was found to be similar ($P = 0.428$). The intraoperative and postoperative findings and the statistical evaluations are shown in Table 2.

When impacted stones were evaluated separately, in Group 1, immediate postoperative success was 50% and after one month, that success rate improved to 64.3%. In Group 2, those rates were 33.3% and 66.6%, respectively. Success rates were similar in both groups for both postoperative first day and first month. Multivariate analysis revealed a negative impact of impacted stones on immediate success, but no difference was shown after the first month.

In Group 1, superficial ureter mucosal injury developed in 6 patients (8%), but did not cause loss of visualization. Following stone fragmentation in these patients a JJ stent was applied. In 5 patients, a fever developed postoperatively and this was brought under control with non-steroid anti-inflammatory drugs (NSAID). In this group, stone migration to the kidney developed in 3 patients (4%) during the operation. In one patient where the stone migrated to the kidney, successful treatment was applied with a flexible URL in the same surgical session and to the other 2 patients with SWL postoperatively. In the postoperative follow-up, residual stones were determined in the ureter in 7 patients and 6 of these patients were treated with re-URL because of increasing hydronephrosis and pain while SWL treatment was applied to the other patient. The mean follow-up period in Group 1 was 24.96 (\pm 12.7) months and during this follow-up ureteral stricture was

Table 1. Demographics and preoperative findings among groups

	Group 1, (n = 75)	Group 2, (n = 66)	P
Mean age (year)	41.23 ± 11.87	40.17 ± 12.4	0.608 [#]
Male/Female ratio	48/27	42/24	0.964 [*]
Stone location (right/left)	39/36	36/30	0.762 [*]
Mean number of stones	2.85 ± 1.15	2.77 ± 0.84	0.632 [#]
Mean stone burden (mm)	16.6 ± 6.02	16.64 ± 5.3	0.970 [#]
Impacted stone ratio	14 (%18,7)	12 (%18,2)	1.000 ⁺

P is considered statistically significant when < 0.05; [#]Independent samples t test; ^{*}Pearson Chi-Square test; ⁺ Yates Chi-Square test

Table 2. Intra operative and postoperative findings among groups

	Group 1, (n = 75)	Group 2, (n = 66)	%95 CL of Difference	P
Operative time (minutes)	53.47 ± 17.3	50.59 ± 15.3	-2.60 – 8.35	0.301 [#]
Hospital stay (days)	1.32 ± 0.52	1.39 ± 0.68	-0.27 – 0.13	0.467 [#]
Mean follow-up (months)	24.9 ± 12.7	27.9 ± 10.6	-6.85 – 0.99	0.142 [#]
Odds Ratio (%95 CI)				
DJ catheter placement (%)	28 (37.3%)	33 (50%)	0.60 (0.29–1.23)	0.130 [^]
Stone-free rate after primary URL (first day) (%)	59 (78.7%)	42 (63.6%)	2.11 (0.94–4.76)	0.048[^]
Stone-free rate after primary URL (first month) (%)	65 (86.6%)	53 (80.3%)	1.59 (0.60–4.30)	0.428 [#]
Re-URL (%)	6 (8%)	5 (7.6%)	1.06 (0.27–4.26)	0.825 ⁺
SWL (%)	3 (4%)	6 (9.1%)	0.42 (0.08–1.99)	0.305 [*]
Flexible URL (%)	1 (1.3%)	3 (3%)	0.28 (0.01–3.18)	0.340 [*]

P is considered statistically significant when < 0.05; DJ: Double J; URL: Ureteroscopic lithotripsy; SWL: Shockwave lithotripsy; [#]Independent samples t-test; ^{*}Fisher Exact Chi-Square test; ⁺Yates Chi-Square test; [^]Pearson Chi-Square test.

Table 3. Complications among groups according to the Modified Clavien's grading scores

Complications	Group 1, (n = 75)	Group 2, (n = 66)	Modified Clavien's Score	Odds Ratio (%95 CI)	P
Fever (%)	5 (6.6%)	5 (7.6%)	1	0.87 (0.21–3.68)	1.000 [*]
LUTS (%)	25 (33.3%)	25 (37.8%)	1	0.82 (0.39–1.73)	0.573 [#]
Mild hematuria (%)	34 (45.3%)	36 (54.5%)	1	0.69 (0.34–1.42)	0.275 [#]
Post treatment pain (%)	22 (29.3%)	24 (36.4%)	1	0.73 (0.34–1.56)	0.374 [#]
Mucosal injury (%)	6 (8%)	7 (10.6%)	3a	0.73 (0.20–2.60)	0.809 [#]
Stone migration (%)	3 (4%)	8 (12.1%)	3a	0.30 (0.06–1.33)	0.139 ⁺
Ureteral stricture (%)	1 (1.3%)	0	3b	---	1.000 [*]
Avulsion	0	0	---	---	---
Perforation	0	0	---	---	---

LUTS : Lower urinary tract symptoms; [#]Fisher Exact Chi-Square test; ^{*}Pearson Chi-Square test; ⁺Yates Chi-Square test.

Table 4. Binary logistic regression analysis

	Regression coefficient	Standart error	Wals	Degree of freedom	P	Odds ratio
Intercept	3.47	1.12	9.67	1	0.002	32.15
Age	0.04	0.02	2.67	1	0.102	1.04
Stone burden	-0.18	0.04	17.49	1	0.000	0.83

determined in 1 patient, which was treated with ureteral balloon dilatation.

In Group 2, superficial ureter mucosal injury developed in 7 patients (10.6%), but did not cause loss of visualization. Following stone fragmentation in these patients, a JJ stent was applied. In 5 patients, fever developed postoperatively and this was brought under control with NSAID in 4 patients and in the other, 7 days of antibiotic treatment was applied as a result of urine culture. In this group, stone migration to the kidney developed in 8 patients (12%) during the operation. Two of these patients with fragments migrated to the kidney were successfully treated with flexible URL and the other 6 with SWL postoperatively. In the postoperative follow-up, residual stones were determined in the ureter in 5 patients and these were treated with re-URL because of increasing hydronephrosis and pain. The mean follow-up period in Group 2 was 27.9 (±10.6) months and during this follow-up, no

ureteral stricture was determined in any patient.

When the complications of the two groups were evaluated, there was a statistical similarity in fever ($P = 1$), stone migration ($P = 0.139$), postoperative pain ($P = 0.374$), mucosal injury ($P = 0.809$), lower urinary tract symptoms (LUTS) ($P = 0.573$) and ureteral stricture ($P = 1$). The complications for both groups according to the modified Clavien's classification are shown in Table 3.

The stone burden, number of stones, age, gender and type of lithotripter were the variables of the logistic regression model of postoperative success and failure rates when that was accepted as a dependent variable. In this model, age and stone burden were affecting variables. However, the only stone burden was a significant variable ($P < 0.01$) although the explanatory variable calculation was low (25.3%). The binary logistic regression analysis of the factors affecting the postoperative success rates is summarized in Table 4.

Discussion

Despite the determination of multiple stones in 20% – 25% of patients with urinary system stones, the guidelines are not specific about the treatment method for these stones.^{10,11} In analyses made of SWL treatment, the number of stones has been reported as one of the most important parameters affecting treatment success.¹⁰⁻¹² Similarly, in studies of ureter stones treated endoscopically, it has been reported that the number of stones and stone burden are significant factors affecting treatment success.¹³⁻¹⁵ To the best of our knowledge, there is no study in literature, which has compared the efficacy and reliability of different lithotripters in the ureteroscopic treatment of multiple ureter stones. Therefore, this study can be considered to be the first to compare Ho: YAG laser and pneumatic lithotripters in the ureteroscopic treatment of multiple ureter stones.

Pneumatic lithotripter is very often preferred in daily practice in urolithiasis treatment and has successful treatment results. These instruments operate on the principle of separating the stone into small fragments due to the air pressure created by the pneumatic lithotripter of the metal probe which makes direct contact with the stone by passing through the straight endoscopic canal within the ureteroscope.¹⁶ The major disadvantages of the pneumatic lithotripter are that it can cause stone migration and sufficient fragmentation cannot be achieved in hard stones. In a study by Gürbüz, et al. the pneumatic lithotripter was used on 15 patients with ureter stones, and success rates were reported as 80% after the first URL and 93.3% after the second URL. In one patient, open surgery was required because of perforation.¹⁴ In a study by Isen, 36 patients (87 stones) were evaluated after the use of pneumatic lithotripter for fragmentation of multiple ureter stones. The success rate was reported as 88.5%, the mean operating time as 56.4 minutes and the re-operation rate as 11.5%. When the patients were evaluated in terms of the stone burden, the stone-free rate of the group with stone burden < 1cm was 91.5% and in the group with the stone burden > 1 cm, the stone-free rate was 75% ($P < 0.05$).¹⁵ In the current study, the success rate in Group 2 was 63.6% on postoperative day 1 and 80.3% at postoperative month 1 and the mean operating time was found to be 50.59 ± 15.3 minutes. In this context the re-treatment rate in this group was 19.7%. The reason for a relatively lower success rate in the current study can be attributed to a greater mean stone burden and a greater number of stones. In addition, impacted stones were included in the present study, which may have also lowered the success rate.

Ho: YAG laser is a laser type, which is rapidly absorbed in water at 2100 nm wavelength. The most important advantages are that up to 100% stone fragmentation can be achieved and, as no time is lost with additional procedures such as stone removal, operating time is short. The major disadvantage of the Ho: YAG laser is its high purchase price.¹⁷ Takazawa, et al. used Ho: YAG laser in the treatment of multiple urinary system stones and the stone clearance rate was determined as 76.9% in 13 patients with multiple stones (28 stones). In the same study, while stone burden and impaction were reported as the most important factors affecting success, stone localization was reported not to affect success rates.¹³ In the current study, the success rate in Group 1 after the first URL was determined as 78.7% on postoperative day 1 and as 86.6% in the postoperative month 1. The mean operating time was calculated as 53.47 ± 17.3 minutes.

In the comparison of the two groups in the current study, while the SFR of Group 1 was significantly higher than that of Group 2 after the first URL on postoperative day 1, similar SFR rates were determined in both groups at the first month postoperatively. This was evaluated as being due to the stones being broken into smaller fragments by the Ho: YAG laser than by the pneumatic lithotripter, which resulted in a higher SFR in the early period.

The management of patients with impacted ureteral stones is difficult and currently there is no standard treatment.¹⁸ URL has become the preferred surgical method for most patients and surgeons due to relatively lower morbidity and shorter hospital stay.¹¹ However, intensive inflammation caused by impacted ureteral stones may increase ureteral damage in endoscopic procedures.¹⁹ The presence of impacted stones in patients with multiple ureteral stones, decreases the already-low success rates and increases patient morbidity. The success rates of Groups 1 and 2 in the current study were 64.3% and 66.6%, respectively. All patients with impacted stones were administered JJ stents. In the long-term, one patient suffered from ureteral stricture in Group 1.

Major complications seen during endoscopic ureter stone treatment are ureteral avulsion and perforation. In the current series, no major complications occurred in any patient. In the long-term follow-up, mild ureteral stricture developed in only 1 patient in Group 1. This patient was successfully treated with balloon dilatation. No statistically significant difference was determined between the groups in respect of intraoperative and postoperative complications. Although stone migration was determined in 3 patients in Group 1 and in 8 patients in Group 2, statistically the rates were similar. However, the statistical similarity could be due to the low number of patients in the current study.

In the present study, although both lithotripters had similar first month success rate, operation time and complication rates for ureteral stones, laser lithotripters are costlier than pneumatic lithotripters. Cost analysis has not been performed in the present study, however, Demir, et al. reported that the total cost analyses of laser and pneumatic lithotripsy as 311.7 ± 51.97 and 261.5 ± 66.13 US\$ ($P = 0.001$), respectively.²⁰ In addition, due to its high purchase price and maintenance costs, laser lithotripters increases the overall treatment cost. Hence, this will increase the overall financial burden on the community health. It would be wiser to consider costs for the selection of lithotripter for ureteral stones.

The main limitations of this study include its retrospective design. Furthermore, the low number of patients, that it was not randomized, the lack of long-term follow-up and that NCCT was not used routinely to determine stone-free status, are also important limitations of this study. Despite these limitations, to the best of our knowledge, this is the first study to compare the efficacy and reliability of two lithotripters, which are in common use in the treatment of multiple ureter stones, and as such is of importance in its contribution to literature.

In conclusion, both the lithotripters are effective and safe in the ureteroscopic treatment of multiple distal ureter stones. Compared to the pneumatic lithotripter, the Ho: YAG laser seems to have the advantages of a higher SFR in the early postoperative period, even though there are statistically similar success and complication rates. Nonetheless, there is a need for further prospective randomized studies with a greater number of patients.

Author's Contribution

Hakan Ercil: Research concept and design, writing the article; Ergun Alma: Collection and/or assembly of data; Okan Bas: Data analysis and interpretation; Umut Unal: Data analysis and interpretation; Nevzat Can Sener: Data analysis and interpretation; Ediz Vuruskan: Data analysis and interpretation; Aykut Buğra Sentürk: Final approval of article; Zafer Gokhan Gurbuz: Final approval of article.

Ethics

The study has a retrospective design, so ethics committee approval was not obtained.

Conflicts of interest

The authors of the study declare no conflicts of interest.

Abbreviations

SWL: Shockwave lithotripsy; URL: Ureteroscopic lithotripsy; USG: Ultrasonography; IVU: Intravenous urography; NCCT: Non-contrast computed tomography; KUB: Kidney-ureter-bladder x-rays; Ho:YAG: Holmium yttrium aluminum garnet laser; JJ: Double J; RIRS: Retrograde intrarenal surgery; SFR: Stone-free rate; NSAID: Non-steroid anti-inflammatory drugs; LUTS: Lower urinary tract symptoms.

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