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ORIGINAL PAPER

Does a retropulsion prevention device equalize the surgical success of Ho:YAG laser and pneumatic lithotripters for upper ureteral stones? A prospective randomized study

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Abstract To establish if a retropulsion prevention device for ureteral stones equalizes surgical success and push-back rates of Ho:YAG laser and pneumatic lithotripters for upper ureteral stones. Patients with upper ureteral stones ($n = 267$) were treated endoscopically at the Department of Urology between April 2014 and December 2015. Patients were randomly assigned to pneumatic and Ho:YAG laser lithotripters as group-1 and group-2, respectively. Lithotripsy was performed with Stone Cone™ in both groups. The surgical success rate on the first postoperative day was 81.5 % ($n = 106$) and 90.6 % ($n = 116$) for group-1 and group-2, respectively, and the difference between the groups was statistically significant ($p < 0.05$). The relation between stone size and surgical success was statistically significant for both groups ($p < 0.01$). Surgical success for the stones closer than 2 cm to the UPJ was 23.1 % for the pneumatic group versus 64 % for the laser group ($p < 0.01$). Lithotripsy time was significantly longer in group-2 (16.48 ± 4.74 min) than group-1 (12.24 ± 3.95 min) ($p < 0.01$). Ho:YAG laser lithotripsy is more successful than pneumatic lithotripsy for upper ureteral stones and a retropulsion prevention device does not equalize the surgical success of Ho:YAG laser and pneumatic lithotripters for upper ureteral stones on the first postoperative day and one month after surgery. Although the success rate of the first month after surgery is higher in group-2, the difference is not statistically significant.

Keywords Instrumentation · Laser · Ureteral stones · Ureteroscopy · Urolithiasis

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Introduction

Ureteroscopic lithotripsy for upper ureteral stones unlikely to pass spontaneously is recommended as the first-line treatment option besides shock wave lithotripsy (SWL) [1]. Patients with ureteral stones that are treated endoscopically have less pain and shorter hospitalization postoperatively than open surgeries. Resolving the obstruction and clearing all the fragmented stone pieces is the main purpose of ureterolithotripsy. The main problem during ureterolithotripsy is retropulsion of the stone or its fragments, especially those located in the upper ureter.

There are different kinds of energy sources for lithotripsy, the most popular being pneumatic and laser lithotripters. They both have some advantages and disadvantages over each other. Although each method is effective for lithotripsy, effective lithotripsy alone is not enough for a successful surgical outcome for upper ureteral stones. For exact surgical success, surgery must be finished with a stone-free situation or with clinically unimportant fragments.

Endoscopic treatment for upper ureteral stones is more difficult and complication rates are higher than for lower ureteral stones. Reaching the upper ureter and also weak tissue support make the surgery difficult. In addition, push-back rates are higher than with lower ureteral stones. While laser lithotripters are more advantageous on push-back rates than pneumatics, there are currently devices for preventing retropulsion of the stones. These can prevent push-back of the stones and increase surgical success. In this study, we compare Holmium:YAG (Ho:YAG) laser and pneumatic lithotripters and aim to establish if a retropulsion prevention device for ureteral stones equalizes surgical success and push-back rates of Ho:YAG laser and pneumatic lithotripters for upper ureteral stones.

Materials and methods

After ethics board approval, 267 patients with upper ureteral stones were treated endoscopically at the Department of Urology, Medical School of Ahi Evran University between April 2014 and December 2015.

Patients older than 18, with obstructive, radiopaque and primary unilateral upper ureteral stones were included in this study. Exclusion criteria were abnormal coagulation profile, previous SWL, bilateral ureteral stones, radiolucent stones, likelihood of spontaneous stone passage, and presence of a non-functioning kidney. Patients with narrow ureters that required stenting and with push-back of the stone before activation of the stone-cone were excluded. Stone location under the fluoroscopic image immediately prior to the surgery was compared with preoperative stone locations. Patients with changing stone locations were excluded from the study. "Changing location" for exclusion of a patient defines both, the patients with the push-back of the stone prior to lithotripsy and the patients with the downward stone position change.

Patient groups, randomization and sample size

Patients were treated with pneumatic and Ho:YAG laser lithotripters in group-1 and group-2, respectively. Randomization was arranged with "=Rand()" formula in Microsoft Office Excel® 2007 (Microsoft Corporation, Redmond, WA, USA) software. Patients were randomly allocated with the use of a computer-generated schedule to receive pneumatic or Ho:YAG laser lithotripsy. Single-blinding was used for this study. Among the 267 patients, three and four patients were excluded due to changing stone locations and narrow ureters in group-1 and group-2, respectively. Pneumatic lithotripsy was performed in 130 patients and laser lithotripsy was performed in 130 patients. Two patients in group-2 were excluded due to inappropriate follow-up.

For calculating a priori sample size, we could not find a similar study comparing two different energy sources with the use of a retropulsion prevention device for upper ureteral stones in the literature and decided to perform post hoc analysis. Power value was 96.4 % for an effect size value (0.2343563) that was calculated for a surgical success rate of 81.5 % in the pneumatic group and 90.6 % in the laser group. With this power value, it was found that the sample size was sufficient.

Patient and stone size evaluation

All patients were evaluated with urine analysis, blood biochemical parameters, a plain X-ray of the kidney-ureter and bladder (KUB) and non-contrast abdominal computerized tomography (CT) before surgery. The proximal ureter was considered as the ureteral portion between the ureteropelvic junction (UPJ) and the proximal edge of the sacroiliac joint. The distance from the UPJ to the superior edge of the stone, length, width and depth of the stone and dilatation of the ureter and kidney were all assessed on the abdominal CT. Size of stone was measured for its greatest length, width and depth on the abdominal CT, preoperatively. Stone volume was calculated by an ellipsoid algebra formula ($\pi \times$ length $\times$ width $\times$ depth $\times$ 0.167) [2]. Fluoroscopic stone locations immediately before the surgery were compared with the preoperative KUB films, and patients were excluded if there was a difference in the stone locations. Radiologic evaluation was performed by a radiolog.

Patients were evaluated on the first postoperative day before discharge, and one month after surgery with plain X-ray and ultrasonography for residual stone fragments and hydronephrosis. A decision was made one month after surgery for auxiliary procedures. Patients with residual fragments $\geq$4 mm were accepted as surgical failures. Patients with stone-free status or with residual fragments <4 mm were accepted as surgical success [3]. Late follow-up was made for the late complications.

Surgical technique

Ureteroscopy and lithotripsy were performed under spinal anesthesia for all patients. The surgeries were performed by the same surgical team—two experienced urologists. Semi-rigid 6/7.5 or 8/9.8 Fr ureterorenoscopes (Richard Wolf, Knittlingen, Germany) were used for ureteroscopy under lithotomy position. Initially, a hydrophilic guidewire for safety was inserted into the ureter under fluoroscopy or direct vision. After that, a Stone-cone™ Nitinol Retrieval Coin (Boston Scientific, Marlborough, MA, USA) was placed but not activated. Thereafter, the stone-cone was opened under direct vision or fluoroscopy directly proximal to the stone and lithotripsy was performed with pneumatic (Vibrolith Pneumatic Lithotripter, ELMED, Turkey) or Ho:YAG laser (Sphinx 30 Minimally Invasive Surgical Laser, LISA laser, Pleasanton, CA, USA) lithotripters for group-1 and group-2, respectively. For group-1, lithotripsy was started with 4–5 bars, and then, the frequency of the lithotripter was increased if necessary. The frequency settings were 50–500 pulse/min. For group-2, 365-μm laser fibers were used and lithotripsy was performed with 1.0–2.0 J, 5–10 Hz (5–20 W) settings. At the end of efficient fragmentation, extraction of the stone fragments was performed with stone forceps and the Stone-cone™ was closed and withdrawn. Flexible ureterorenoscopy was not performed in any of the patients simultaneously. A double-J stent was inserted for two weeks in patients with residual stone fragments, bleeding and ureteral edema.

Statistical analysis

The normal distribution assumption was tested with Kolmogorov–Smirnov and Shapiro–Wilk tests. Kurtosis and skewness values were also examined. It was found that the data were normally distributed for both groups. Data are expressed as mean ± SD for continuous variables and number and/or percentage for categorical variables.

In this study, Pearson's Chi-squared test was used for the categorical variables, and independent *t* test was used for continuous variables. In all tests, $p < 0.05$ was considered to indicate statistical significance.

Statistical Package for Social Sciences version 21.0 software for Windows (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp., USA) was used for descriptive statistics, independent *t* test and Chi-squared tests. G-power 3.1 (Department of Psychology, University of Düsseldorf, Germany) was used for post hoc power analysis [4].

Results

The baseline data and clinical characteristics of the groups are given in Table 1. There were no significant differences between the groups for age ($p = 0.41$) (95 % CI −4.04 to 1.68) or gender ($p = 0.48$) (Table 1).

The success rates in groups-1 and 2 were 81.5 and 90.6 %, respectively. There was a significant difference between the groups for surgical success rates ($p < 0.05$) (Fig. 1). Stone-free rates were 69.2 and 78.1 % in group-1 and 2, respectively, on the first postoperative day. The stone-free rate was 86.15 % in group-1 and 93 % in group-2, one month after surgery. Although the stone-free rate in group-2 was higher, there was not a significant difference between groups for stone-free rates on the first postoperative day ($p = 0.06$) and one month after surgery ($p = 0.07$).

Proximal ureter diameters were grouped as 1–5, 6–10, 10–15 and >15 mm. In group-1, there were four (3.1 %) patients with a proximal ureter diameter of 1–5 mm, 99 (76.1 %) patients with a proximal ureter diameter of 5–10 mm, and 27 (20.8 %) patients with a proximal ureter diameter of *10-15* mm. In group 2, 8 (6.3 %), 90 (70.3 %), 30 (23.4 %), and 1 (0.8 %) patients had proximal ureter diameters of 1–5, 5–10, 10–15, and ≥15 mm, respectively. The groups did not have any differences for the diameters of their proximal ureters ($p = 0.3$). There was a significant association between a greater proximal ureter diameter and push-back of the broken stone fragments in both groups ($p < 0.01$).

In group-1, stone size in 106 successful cases was 1.15 ± 0.34 and 1.39 ± 0.38 cm^2 in 24 unsuccessful cases. Stone volume in successful cases was 0.72 ± 0.34 and 0.93 ± 0.41 cm^3 in unsuccessful cases. In group-2, stone size in 116 successful cases was 1.08 ± 0.40 and 1.53 ± .59 in 12 unsuccessful cases. Stone volume in successful cases was 0.68 ± 0.40 and 1.12 ± 0.57 cm^3 in unsuccessful cases. It was found that the stone size and stone volume had a significant effect on surgical success in group-1 [stone size ($p < 0.01$) (95 % CI 0.08, 0.40) and stone volume ($p < 0.01$) (95 % CI 0.05–0.37)] and group-2 [stone size ($p < 0.05$) (95 % CI 0.10–1.11) and stone volume ($p < 0.01$) (95 % CI 0.18–0.69)].

In patients who had successful fragmentation of the stone, the mean distance of the stone to the UPJ was 3.18 ± 0.93 cm in group-1. This distance was found to be 2.88 ± 1.04 cm in group-2. There was a statistically significant difference between the mean distance of the stone to the UPJ of successful cases in both groups ($p < 0.05$) (95 % CI 0.03–0.55).

The success rate was 6/26 (23.1 %) in the pneumatic lithotripsy group and 16/25 (64.0 %) in the laser group in patients with a stone–UPJ distance <2 cm. In this group of patients, comparison of the energy sources for surgical success rates yielded a statistically significant difference between the two groups ($p < 0.01$).

In our study groups, we did not encounter any complications higher than grade III according to the Clavien classification.

The overall postoperative complication rates including colic episodes were 14.6 % in group-1 and 11.7 % in group-2. Groups did not differ in terms of postoperative complications and colic episodes ($p = 0.49$).

The mean follow-up period was 11.28 ± 4.43 months in group-1, and 11.52 ± 4.24 months in group-2.

Table 1 Baseline data and clinical characteristics

	Group-1	Group-2	*p*	95 % CI
Gender (*n*)				
Male	83	87	0.48	
Female	47	41		
Total	130	128		
Age (years)				
Male				
Min	19	24	0.41	
Max	70	64		
Mean ± SD	44.2 ± 11.2	44 ± 9.9		−4.04 to 0.68
Female				
Min	22	20		
Max	73	82		
Mean ± SD	44.6 ± 12.4	48.8 ± 14.3		
Stone size				
Stone area (mm^2) min–max (mean ± SD)	0.64–2.10 (1.17 ± 0.03)	0.40–2.60 (1.12 ± 0.03)	0.15	−0.02 to 0.17
Stone volume (mm^3) min–max (mean ± SD)	0.34–1.76 (0.76 ± 0.36)	0.21–2.08 (0.72 ± 0.44)	0.54	−0.06 to 0.12
Distance between stone and UPJ (cm)				
Min–max (mean ± SD)	0.5–5.8 (2.86 ± 1.10)	0.5–6 (2.73 ± 1.12)	0.36	0.14 to 0.40
Surgical success rates in groups [*n* (%)]				
Successful	106 (81.5 %)	116 (90.6 %)	<0.05	
Unsuccessful	24 (18.5 %)	12 (9.4 %)		
Total	130	128		
Surgical success rates in stones that closer than two cm to UPJ [*n* (%)]				
Successful	20 (23.1 %)	16 (64 %)	<0.01	
Unsuccessful	6 (76.9 %)	9 (36 %)		
Total	26	25		
Push-back of stone fragments [*n* (%)]				
Clinically significant	24 (18.5 %)	12 (9.4 %)		
Clinically insignificant	16 (12.3 %)	16 (12.5 %)		
Total	40	28		
Auxiliary procedures for clinically significant fragments [*n* (%)]				
ESWL	14 (10.8)	5 (3.9)		
Retrograde intrarenal surgery	4 (3.1)	4 (3.1)		
Spontaneous passage	6 (4.6)	3 (2.3)		
Lithotripsy time				
Mean ± SD	12.24 ± 3.95	16.48 ± 4.74	<0.01	−5.3 to −3.1
Operation time				
Mean ± SD	43.09 ± 7.61	48.59 ± 9.31	<0.01	−7.5 to −3.1
Postoperative DJ stent	93 (71.5 %)	79 (61.7 %)	0.09	
Postoperative 1st month stone-free rates	86.15 %	93 %	0.07	

Discussion

Retrograde ureteroscopy and SWL in situ are the first-line treatment options for proximal ureteral stones [1]. Laparoscopy, antegrade ureteroscopy and, rarely, open surgery are the other treatment options for upper ureteral stones [5]. Technological advancements for endosurgical procedures have increased surgical success rates in recent years. Of late, small caliber semi-rigid and flexible ureteroscopes are being used for the endoscopic treatment of upper ureteral stones with high success rates. However, many clinics may not have unlimited access to flexible ureteroscopy.

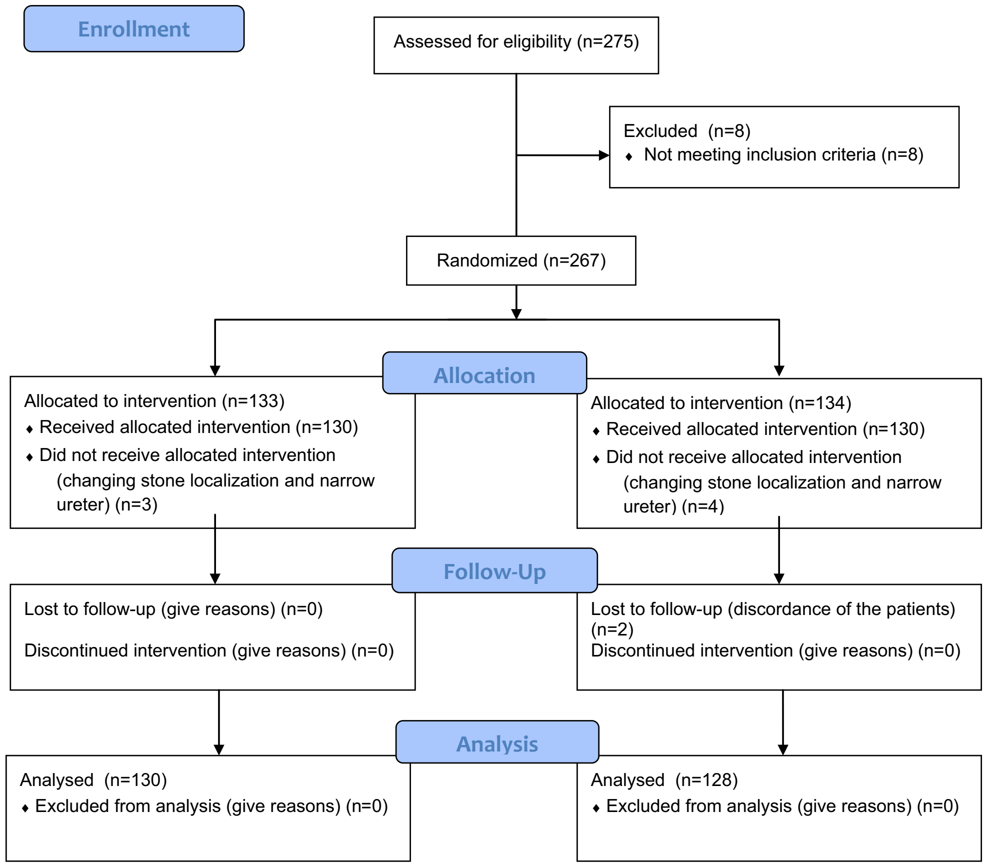

Fig. 1 Flow diagram

There are different kinds of energy sources for lithotripsy, the most popular being pneumatic and laser lithotripters [6]. Ho:YAG laser lithotripsy is the preferred method for intracorporeal ureteroscopic lithotripsy [7]. Low push-back rates, fragmenting the stones regardless of stone composition and fragmenting them to smaller pieces than the other lithotripsy energy sources are the advantages of the Ho:YAG laser. Pneumatic lithotripters have low costs and low urothelium injury rates but give higher push-back rates and fragment the stones into bigger pieces [6]. In this study, we compared the Ho:YAG laser and pneumatic lithotripters prospectively and aimed to establish if a retropulsion prevention device equalized surgical success, the stone-free situation and push-back rates of the Ho:YAG laser versus pneumatic lithotripters for upper ureteral stones. The CONSORT statement has been followed for this study [9].

It is indicated that pneumatic lithotripters have a 90 % success rate for the endoscopic treatment of ureteral stones [10]. However, some other studies indicate that the proximal migration of upper ureteral stones can be as high as 48 % for pneumatic lithotripters [11]. Also, in the literature, stone-free rates for proximal ureteral stones with Ho:YAG laser lithotripsy are between 79.4 and 84.5 % [12, 13]. Push-back of the stone is the main problem for upper ureteral stones, and retropulsion prevention devices decrease the push-back rates. In a study comparing pneumatic lithotripsy with and without an anti-retropulsion device, a retropulsion prevention device for proximal ureteral stones, the success rates were higher and push-back rates were lower in the anti-retropulsion group [14]. In another study comparing two different push-back prevention devices (stone-cone and entrapment net) for proximal ureteric stones, ($n = 195$) patients were randomized into three groups [15]. Stone-free rates were 95.24, 83.05, and 72.41 % in the stone-cone, entrapment and control groups, respectively. In the literature, studies assessing the effectiveness of Ho:YAG laser lithotripsy for upper ureteral stones using stone-cones indicate that success rates are higher and push-back rates lower with stone-cones [16–18]. In our study, postoperative first-day surgical success rates for group-1 and group-2 were 81.5 and 90.6 %, respectively. The laser treatment group had statistically significantly higher success rates even using stone-cones in both groups. Postoperative first-month stone-free rates for group-1 and group-2 were 86.15 and 93.0 %, respectively. Although the first month stone-free rates were different between the groups, they were statistically insignificant. This may be due to the higher incidence of DJ stent usage, which may increase the clearance of stone fragments in group-1.

The width of the proximal ureter and stone size are other parameters that influence surgical success and stone migration. The width of the proximal ureter may influence the transfer of pneumatic shock to the stone negatively and may increase migration of the broken fragments of stones independently from the lithotripsy energy source. However, in a study that evaluated the impact of hydronephrosis and some other parameters on the efficacy of Ho:YAG laser ureterolithotripsy, hydronephrosis was not associated with success rates [12]. Also, the width of the push-back prevention device has an important role in preventing stone migration. The effectiveness of the device decreases with the increasing width of the proximal ureter, not for fragmentation but for the backflow of the fragments. In our study, there was a statistically important association between the width of the proximal ureter and backflow of the fragments in both groups. Stone size is another important parameter for upper ureteral stone surgery. Although some studies indicate that the stone size did not affect stone clearance rates for Ho:YAG or pneumatic ureterolithotripsy, we found an important association between stone size and surgical success for both groups [12, 19, 20].

Anatomically, the ureter is divided into three parts: upper, middle and lower. The upper ureter starts from the renal pelvis and ends on the upper border of the sacrum [21]. Although it varies depending on the individual person, it lies between the L3 vertebra and the upper border of the sacrum and is 10–15 cm long in an adult. An upper ureteral stone is a stone localized in any part of the upper ureter. It is well known that if the distance between the UPJ and the stone decreases, the surgery may become difficult. An activated Stone-cone has a depth of 4 mm and there must be a minimum 5 mm of ureter portion proximal to the stone to use the device effectively. The push-back rates are higher if you do not use a device to prevent migration. In our study, there was a statistically important association between surgical success and the distance between the UPJ and the stone for both groups. For stones that are closer than 2 cm to the UPJ, our success rates were low for both groups. We also compared the surgical success of the groups on stones that were closer than 2 cm to the UPJ. Success rates of the laser treatment group were significantly higher than the pneumatic group in this part of the ureter. The manipulations during surgery can move the assistive devices back and forth, so the effectiveness of such devices worsens when the distance to the UPJ decreases. Ho:YAG lasers can fragment the stones in place at low-power settings providing higher success rates than pneumatic ones with the use of a push-back prevention device in the very high levels of the upper ureter.

Pneumatic energy sources fragment stones faster than laser energy sources, and it has been indicated that the operation and lithotripsy times are shorter in pneumatic lithotripsy for ureteral stones [22]. In our study too, both operation and lithotripsy times were significantly longer in group-2. Stone size is another factor that has a bearing on lithotripsy and operation times. It is indicated in the CROES-URS study that there is a significant relationship between operation time and stone burden [13]. In our study, there was a significant association between stone size and lithotripsy-operation times in both groups.

Conclusions

In recent years, laser technologies have become more popular in urologic surgery. Ho:YAG lasers can fragment the stones locally in the low-power settings and this provides high success rates with the use of a push-back prevention device, especially for very high level upper ureteral stones. Ho:YAG laser lithotripsy is more successful than pneumatic lithotripsy for upper ureteral stones, and a retropulsion prevention device does not equalize the surgical success of Ho:YAG laser and pneumatic lithotripters for upper ureteral stones on the first postoperative day and one month after surgery. Although the success rate of the first month after surgery is higher in group-2, the difference is not statistically significant.

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Compliance with ethical standards

This study has been performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The authors have no financial disclosure for this study. Informed consents were obtained from all participants included in the study.

Conflict of interest The authors declare that they have no conflict of interest.

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