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ORIGINAL PAPER

Urology

Efficacy of various laser devices on lithotripsy in retrograde intrarenal surgery used to treat 1-2 cm kidney stones: A prospective randomized study

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Abstract

Aims: To compare the efficacy of different laser devices and power ranges on lithotripsy in retrograde intrarenal surgery (RIRS) for 1-2 cm kidney stones.

Methods: A total of 223 participants undergoing RIRS for 1-2 cm kidney stones at our clinic between January 2015 and January 2017 were recruited for this prospective study (NCT02451319). Two hundred and four participants included in our study were randomly allocated into either ≤20 W with 20 W laser device (group 1) or ≤20 W with 30 W laser device (group 2) or >20 W with 30 W laser device (group 3).

Results: There was no significant difference between the groups in terms of demographic and stone characteristics. Operation and fluoroscopy times were significantly longer ($P = .003$ and $P < .001$, respectively) and stone-free rate (SFR) was significantly lower in group 1 ($P = .002$). Complications were similar in all three groups ($P = .512$). However, post-operative pain scores were significantly higher in group 1 ($P < .001$). The multivariate analysis revealed that stone size (95% CI: 0.654-0.878, OR = 0.758, $P < .001$), ureteral access sheath use (95% CI: 1.003-20.725, OR = 4.560, $P = .049$), and lithotripsy with 30 W laser device (95% CI: 1.304-11.632, OR = 3.895, $P = .015$; 95% CI: 1.738-17.281, OR = 5.480, $P = .004$, groups 2 and 3, respectively) were independent factors predicting SFR for RIRS used in 1-2 cm kidney stones.

Conclusion: The 30 W laser device used in RIRS for 1-2 cm kidney stones had shorter operation times, higher SFRs, and lower post-operative pain scores compared with the 20 W device. The 30 W laser device is safe and more efficient in RIRS for treatment of 1-2 cm kidney stones.

What's known

- Ho:YAG laser devices with 20 and 30 W power are commonly used in the RIRS process.

What's new

- There are no studies in the literature examining the effect of 20 and 30 W laser devices that are commonly used in the treatment of 1-2 cm kidney stones with RIRS on clinical results.
- Therefore, we aimed to compare the efficacy of different laser devices and power ranges on clinical results following lithotripsy in RIRS for 1-2 cm kidney stones.

1 | INTRODUCTION

Retrograde intrarenal surgery (RIRS) is widely used in the treatment of kidney stones because of its high efficiency and low complication rates. RIRS is the main surgical procedure for kidney stones <2 cm.[1] Holmium:yttrium-aluminium-garnet light amplification by stimulated emission of radiation (Ho:YAG laser) has become the lead actor among lasers currently used for lithotripsy during the RIRS procedure.[1,2] It provides an effective and safe lithotripsy for all urinary stone types.[3] Ho:YAG laser is a versatile instrument used in many procedures such as prostate enucleation or ablation, endopyelotomy, urethral strictures, bladder neck incision, tumour ablation, beyond ureter and kidney stones.[4]

Ho:YAG laser devices with 20 and 30 W power are commonly used in the RIRS process. A study was reported from our clinic on 20 and 30 W laser devices used in the treatment of 2-3 cm kidney stones with RIRS.[5] However, there are no studies in the literature examining the effect of 20 and 30 W laser devices that are commonly used in the treatment of 1-2 cm kidney stones with RIRS on clinical results. Therefore, in this study, we aimed to compare the efficacy of different laser devices and power ranges on clinical results following lithotripsy in RIRS for 1-2 cm kidney stones.

2 | METHODS

2.1 | Ethical issues and study endpoints

This study was performed as a prospective, randomised study after receiving approval from the Institutional Research Ethics Committee of our tertiary healthcare provider university hospital [Institutional Review Board (IRB) decision number IRB-19/17, dated 26.01.2015] with registration at ClinicalTrials.gov [NCT02451319]. All procedures were performed in accordance with the ethical norms of the local ethics committee and the 1975 Helsinki declaration and its subsequent amendments. Informed consent was obtained from each participant enrolled in the study. The primary endpoint of the study was to compare the efficacy of different laser devices on lithotripsy. The secondary endpoint was to evaluate the effect of different laser devices and power ranges on perioperative outcomes such as complications, post-operative pain and hospitalisation.

2.2 | Study design and participant selection

Sample size was calculated with the G-Power software by examining studies that used similar parameters, with a confidence interval of 0.80. Two hundred and twenty-three patients who had 1- to 2-cm-sized kidney stones and were scheduled to undergo RIRS were enrolled in the current study. Patients with urinary system anomalies, active urinary infections, bleeding diatheses, who were under 18 years of age, and whose kidney could not be accessed during RIRS because of ureteral stricture were excluded. The enrolled participants were randomly divided into three equal groups according to lithotripsy procedure with three different power ranges and two different laser devices that are routinely used in our clinic. A research assistant not otherwise participating in the study randomly allocated the patients into group and kept selections in sealed envelopes.

Demographic data (age, gender, body mass index [BMI], American Society of Anesthesiologists [ASA] score and stone intervention history) and stone characteristics (stone location, burden and Hounsfield unit [HU]) of the patients were recorded on case forms. Routine physical examination of the patients was performed. In the pre-operative non-contrast computed tomography (CT) scan, the longest axis of the stones in three different sections was recorded as mm. Stone size was determined as the longest diameter. Ellipsoid formula (length $\times$ width $\times$ height $\times \pi \times 1/6$) was used in calculating the stone volume.[6] In the case of multiple stones, each stone was measured individually and then the measurements were added together. Stone density was calculated in HU by a radiologist with 20 years of experience. All the participants who underwent RIRS had pre-operative sterile urine cultures and prophylactic antibiotic was administered to all patients. The operations were performed by a team of four experienced surgeons with at least 5 years of experience and at least 500 RIRS.

In group 1, the lithotripsy procedures were completed by fragmentation with a power below 20 W by using a 20 W laser device, while in group 2 a 30 W laser device was used to achieve power of below 20 W. In group 3, a 30 W laser device was used to achieve a power above 20 W. Complications were evaluated according to modified Clavien and Dindo classification.[7] All patients who underwent RIRS in our clinic were treated with 50 mg intravenous dexketoprofen trometamol twice a day for post-operative analgesic and anti-inflammatory treatment.[8,9] Although this affects the post-operative pain score, we think that analgesic and anti-inflammatory treatment did not create a bias in the comparison between the groups in our study, as it was applied to all patients. If required, additional dose of 50-mg dexketoprofen trometamol was given. The patients were asked to fill out a visual analogue scale (VAS) questionnaire at 24 hours post-operatively.

2.3 | RIRS implementation technique

After general anaesthesia was administered to the patient, a guidewire was inserted into the ureter in the dorsal lithotomy position. Then, the ureter was accessed with a semi-rigid 9.5F ureteroscope and diagnostic ureteroscopy was performed. A ureteral access sheath (UAS) of 9.5-11.5F thickness was placed into the ureter over the guidewire that was inserted in the ureter under fluoroscopic control. In cases where UAS could not be placed, flexible ureteroscope was inserted via guidewire to access the kidney. After reaching the stone by entering through the UAS with a flexible ureteroscope (Flex-X2S; Karl Storz, Tuttlingen, Germany) of 7.5F outer diameter, lithotripsy was performed with a 272 μm Ho:YAG laser probe (Ho:YAG Laser; Dornier MedTech; Munich, Germany) at a frequency of 8-15 Hz and 0.8-3.0 J pulse energy range. We started the lithotripsy procedure with low pulse energy in all stones. The operation was completed both safely and in the shortest

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time by increasing pulse energy in hard stones, especially for stones with a stone density above 1000 HU. The operation was terminated by inserting a double-J stent (DJS) if deemed necessary. DJS was removed within the first post-operative month. The operation was considered successful or stone free if there were no stones or if the residual fragments were ≤2 mm based on kidney-ureter-bladder radiograph, ultrasonography or CT scan in the post-operative third month.

2.4 | Statistical analysis

The data analysis was performed with the Statistical Package for the Social Sciences version 22.0 for Windows (SPSS Inc, IBM, NY, USA). One-sample Kolmogorov-Smirnov test was applied to evaluate the normality of the distribution for quantitative data. The one-way analysis of variance (ANOVA) analysis was used for the variables of quantitative data that had a normal distribution and the Kruskal-Wallis test was utilised for the others. The Pearson chi-square or Fisher's exact tests were used for the dual or triple comparison of independent categorical variables. Independent risk factors predicting RIRS success were determined by using binary logistic regression analysis. Multivariate analysis was used with parameters that were found to be significant in univariate analysis. Two-sided $P < .05$ values were defined as the statistical significance level.

3 | RESULTS

Two hundred twenty three patients were assessed for eligibility in the current study, 19 of those were excluded from the study because of falling under the exclusion criteria, and 204 participants were included in the study and randomised (Figure 1). There was no

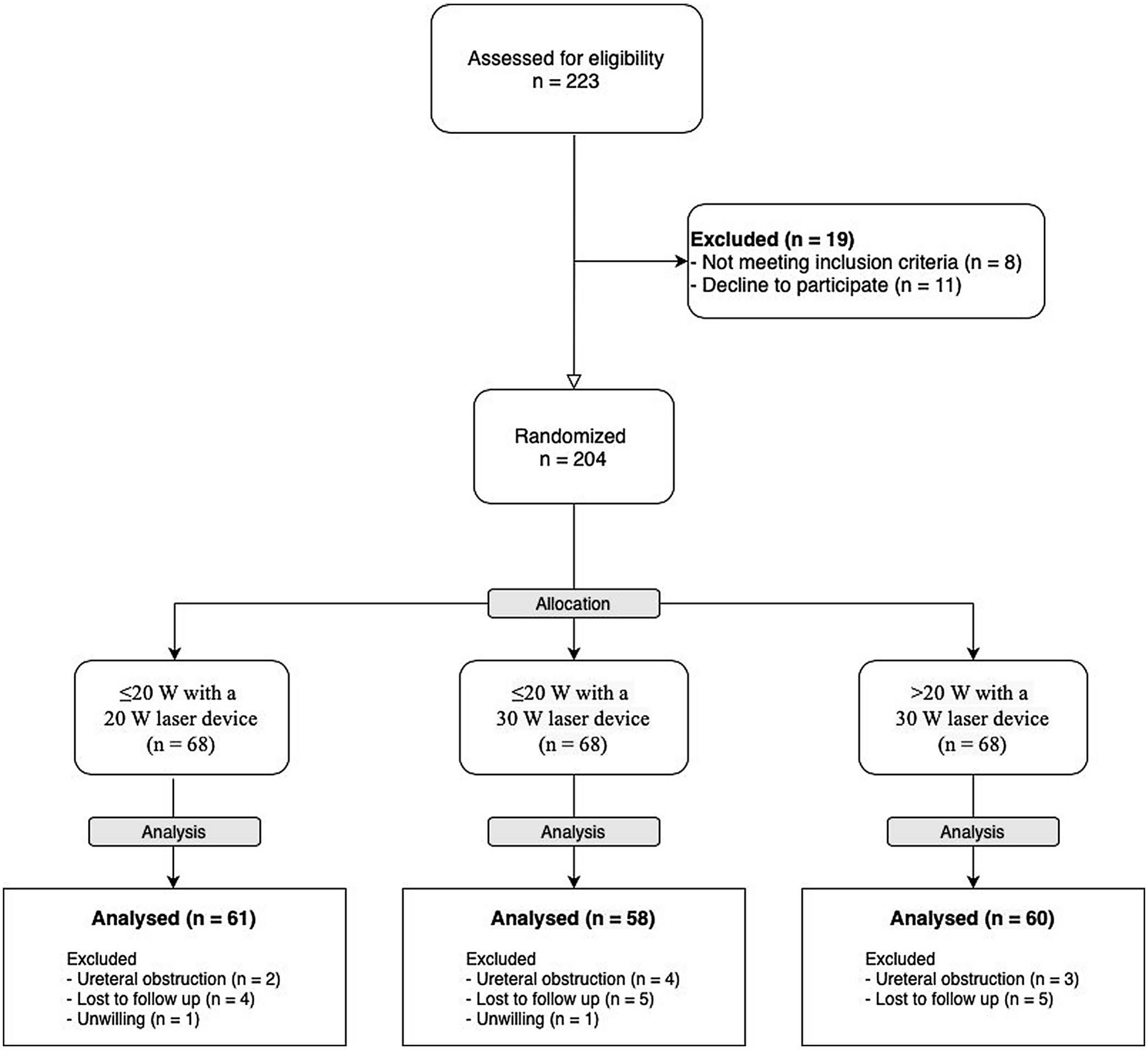

FIGURE 1 Consort flow diagram

statistically significant difference between the groups in terms of demographic characteristics such as age, gender, BMI, ASA score, history of SWL or surgery and stone characteristics (Table 1).

Median operation times were 45 minutes in group 1 and 35 minutes in groups 2 and 3. Mean fluoroscopy times were 44.7 ± 32.5 seconds in group 1, 25.9 ± 27.8 seconds in group 2 and 18.9 ± 14.2 seconds in group 3. Operation and fluoroscopy times were significantly longer in group 1 ($P = .003$ and $P < .001$, respectively). Moreover, the SFR was significantly lower in group 1 compared with the other two groups ($P = .002$). Complications graded according to the modified Clavien-Dindo classification were similar in all three groups ($P = .512$). However, the scores of visual analogue scale, which assessed post-operative pain, were significantly higher in group 1 ($P < .001$). The number of patients who needed additional doses after the administration of dexketoprofen trometamol, which is a routine analgesic and anti-inflammatory treatment, was 2, 2 and 1 for groups 1, 2 and 3 respectively. The VAS scores at the post-operative 24th hour were 3.9 ± 2.5 in group 1, 2.5 ± 1.7 in group 2 and 2.3 ± 1.4 in group 3 (Table 2).

Univariate regression analyses showed that the history of stone surgery and stone burden, Hounsfield unit, usage of UAS, operation time and lithotripsy with 30 W laser device significantly affected the SFR of RIRS ($P < .05$). The multivariate logistic regression analysis including these statistically significant factors showed that stone size (95% confidence interval (CI): 0.654-0.878, odds ratio (OR)=0.758, $P < .001$), UAS use (95% CI: 1.003-20.725, OR = 4.560, $P = .049$) and lithotripsy with 30 W laser device (95% CI: 1.304-11.632, OR = 3.895, $P = .015$; 95% CI: 1.738-17.281, OR = 5.480, $P = .004$, groups 2 and 3, respectively) were independent factors predicting success for RIRS used to treat 1-2 cm kidney stones (Table 3).

TABLE 1 Demographic characteristics of patients and pre-operative distribution of kidney stones

	Group 1 (n = 61)	Group 2 (n = 58)	Group 3 (n = 60)	*P* value
Age, y, mean ± SD	48.6 ± 11.3	50.3 ± 13.6	51.8 ± 17.2	.466
Gender (male/female)	42/19	40/18	39/21	.870
Body mass index (kg/m^2), median (range)	26.5 (19.0-37.5)	26.5 (19.5-53.3)	27.5 (19.5-40.6)	.428*
American Society of Anesthesiologists classification				.570*
ASA I	23	20	27	
ASA II	34	36	30	
ASA III	4	2	3	
SWL history, n (%)	15 (24.6)	13 (22.4)	10 (16.7)	.547
Stone surgery history, n (%)				.403
Retrograde intrarenal surgery	10 (16.4)	10 (17.2)	8 (13.3)	
Percutaneous nephrolithotomy	3 (4.9)	6 (10.3)	4 (6.7)	
Open nephrolithotomy	4 (6.6)	4 (6.9)	2 (3.3)	
Stone laterality (right/left)	30/31	24/34	27/33	.693
Stone location group, n (%)				.104
Calyx	38 (62.3)	40 (69)	27 (45)	
Renal pelvis	17 (27.9)	14 (24.1)	26 (43.3)	
Multiple	6 (9.8)	4 (6.9)	7 (11.7)	
Stone number, median (range)	1 (1-5)	1 (1-3)	1 (1-3)	.951*
Stone size, mm	15.0 ± 3.4	14.9 ± 3.9	15.7 ± 3.4	.466
Stone volume, mm^3	625 ± 437	722 ± 574	870 ± 713	.070
Hounsfield unit	1116.9 ± 216.9	1150.4 ± 223.3	1065.3 ± 223.1	.111
Pre-operative DJS placement, n (%)	9 (14.8)	8 (13.8)	9 (15)	.981

Abbreviations: ASA, American Society of Anesthesiologists; DJS, double-J stent; SWL, shock wave lithotripsy.

*Kruskal-Wallis test.

TABLE 2 Intra-operative data and post-operative evaluations of patients

	Group 1 (n = 61)	Group 2 (n = 58)	Group 3 (n = 60)	*P* value
Ureteral access sheath usage, n (%)	53 (86.9)	55 (94.8)	57 (95)	.165
Operation time, min, median (range)	45 (25-120)	35 (30-70)	35 (30-80)	**.003***†
Fluoroscopy time, s	44.7 ± 32.5	25.9 ± 27.8	18.9 ± 14.2	**<.001**‡
Post-operative DJS placement, n (%)	60 (98.4)	56 (96.6)	58 (96.7)	.780
Hospitalisation, day, median (range)	1 (1-14)	1 (1-5)	1 (1-2)	.219*
Success, n (%)				**.002**§
Stone free	43 (70.5)	52 (89.7)	55 (91.7)	
Residual fragment >2 mm	18 (29.5)	6 (10.3)	5 (8.3)	
Complications, n (%)				.164
Mucosal injury	1 (1.6)	—	—	
Bleeding	1 (1.6)	2 (3.4)	2 (3.3)	
Perforation	1 (1.6)	—	—	
Fever	2 (3.3)	1 (1.7)	3 (5.0)	
Urinary tract infection	2 (3.3)	1 (1.7)	1 (1.7)	
Steinstrasse	2 (3.3)	2 (3.4)	—	
Sepsis	—	—	1 (1.7)	
Clavien-Dindo classification, median (range)	2 (1-3)	2 (1-3)	1 (1-4)	.512*
Grade I, n (%)	3 (4.9)	2 (3.4)	4 (6.7)	
Grade II, n (%)	3 (4.9)	3 (5.2)	1 (1.7)	
Grade III, n (%)	3 (4.9)	1 (1.7)	—	
Grade IV, n (%)	—	—	1 (1.7)	
Visual analogue scale score	3.9 ± 2.5	2.5 ± 1.7	2.3 ± 1.4	**<.001**
Additional procedure requirement n (%)	7 (11.5)	4 (6.9)	3 (5)	.185

The bold number means statistical significance.
Abbreviation: DJS, double-J stent.
*Kruskal-Wallis test.
†Group 1 vs Group 2 $P = .001$; Group 1 vs Group 3 $P = .037$; Group 2 vs Group 3 $P = .163$.
‡Group 1 vs Group 2 $P < .001$; Group 1 vs Group 3 $P < .001$; Group 2 vs Group 3 $P = .309$.
§Group 1 vs Group 2 $P < .05$; Group 1 vs Group 3 $P < .05$; Group 2 vs Group 3 $P > .05$.

4 | DISCUSSION

During lithotripsy in RIRS, the laser beam is transmitted to the stone through a thin fibre passed through the endoscopic instrument. The Ho:YAG laser is the most efficient laser lithotripter because of its high energy absorption in water and its significant peak power (10 kW). It rapidly sends heat balls to the stone and quickly performs the lithotripsy process. Another advantage of this laser is that the stone is divided into much smaller fragments compared with other methods. The fragments almost turn into dust so they are easier to be extracted spontaneously at the end of the procedure. The fragmentation and dusting techniques commonly used during Ho:YAG laser lithotripsy are defined as laser ablation modes.[3,10] Generally, dusting method is preferred as a result of its more favourable clinical outcomes and is commonly used in our clinic. Ho:YAG laser lithotripsy involves two steps. First, it creates an enormous explosion of energy that instantly heats the stone and leads to its chemical decomposition, then it shatters the stone fragments with the effect of photomechanical power.[11] The Ho:YAG laser operates at an infrared wavelength of 2120 nm, providing energy through silica optical fibres with a 200-1000 µm core. Depending on the pumped configuration of the flash lamp, the laser operates in pulsed mode with pulse energy of 0.2-6.0 J, pulse duration of 250-1500 ms and pulse rates of 5-80 Hz. Multiplying the energy (J) and frequency (Hz) values for the Ho:YAG laser derives the power (W).[12]

To the best of our knowledge, this is the first study to evaluate the effect of the laser device on the efficacy of RIRS for 1-2 cm kidney stones. In this study, we aimed to compare the efficiency and safety of the 20 and 30 W Ho:YAG laser device in patients who underwent RIRS for 1-2 cm kidney stones.

TABLE 3 Multivariate logistic regression analysis of predicting factors for stone-free rate following retrograde intrarenal surgery

Binary logistic regression (n = 179)	Univariate model			Multivariate model		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Age	0.975	0.947 – 1.003	.081			
Gender (Ref: female)	0.618	0.247 – 1.542	.302			
BMI	0.966	0.898 – 1.039	.355			
ASA Score	0.539	0.266 – 1.092	.086			
SWL history	0.656	0.265 – 1.626	.363			
History of stone surgery	0.418	0.184 – 0.947	**.037**			
Renal pelvis stone (Ref: caliceal)	0.904	0.502 – 1.628	.738			
Stone number	0.734	0.432 – 1.247	.253			
Stone size	0.809	0.712 – 0.919	**.001**	0.758	0.654 – 0.878	**<.001**
Stone volume	0.535	0.291 – 0.984	**.044**			
Stone density (Hounsfield unit)	0.998	0.996 – 1.000	**.035**			
Pre-operative DJS placement	0.456	0.172 – 1.211	.115			
Usage of UAS	3.264	1.007 – 10.577	**.049**	4.560	1.003 – 20.725	**.049**
Intra-operative complication	0.862	0.176 – 4.211	.854			
Operation time	0.967	0.945 – 0.990	**.004**			
Fluoroscopy time	0.992	0.979 – 1.005	.206			
Laser power						
Group 2	3.628	1.323 – 9.945	**.012**	3.895	1.304 – 11.632	**.015**
Group 3 (Ref: Group 1)	4.605	1.582 – 13.399	**.005**	5.480	1.738 17.281	**.004**

The bold number means statistical significance.

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; DJS: double-J stent; SWL, shock wave lithotripsy; UAS, ureteral access sheath.

No statistical difference was observed in all three groups in terms of patients' demographic characteristics such as age, gender, BMI and ASA score distributions. SWL or operation history was also not different between the groups. Calyx stones were in the majority in all three groups in our study. The average of the longest diameter of the stones and their volume were not different between the groups. Moreover, the stone characteristics and pre-operative DJS insertion rate of the groups were similar. We did not pre-operative insert the DJS to the majority of patients. Contrary to some studies published in the literature, in our study, we did not approach every patient as if they have ureteral stricture. If a ureteral stricture was detected in the patient after the operation had started, we placed the DJS and left it until the second session.[13] Post-operative DJS was inserted in almost all patients in line with the recommendation of the EAU guideline because it reduced post-operative pain and increased residual fragment passage.[14,15] We think that post-operative DJSs do not affect comparison of stone-free status because of DJS insertion rates were similar between the groups. In addition, none of the patients had DJS since we evaluated stone-free status at the post-operative 3rd month. We have also used UAS in almost every case. Among the advantages of using UASs are shortening the operation time, increasing stone-free rates (SFR) and providing a better visibility by decreasing the pelvicalyceal pressure.[16,17] In our study, UAS was found to be one of the predictive factors that increase SFR.

Operation time was significantly longer in group 1. However, lithotripsy with a 30 W laser device above or below 20 W did not affect the operation time. Fluoroscopy time was also significantly longer in group 1, in correlation with operation time. In an in vitro study comparing 20 and 30 W laser devices Bell et al[18] reported that the 30 W laser had a significantly shorter lithotripsy time (14.3 ± 2.5 minutes vs 33.1 ± 8.9 minutes, P = .008). Similarly, Gould et al[19] reported that lithotripsy with a high-power settings had shorter lithotripsy time (2.8 J and 15 Hz). Kronenberg and Traxer[20] reported in an in vitro study that low-frequency, high pulse energy at the same power level was more effective in lithotripsy. Pulse energy was the basic parameter that increased fragmentation efficiency. In the same study, they also reported that the fibre diameter did not affect fragmentation performance.[20] In another study, it has been reported that high pulse energy increases optical fibre damage and may decrease lithotripsy efficiency in the medium to long term.[21] On the contrary, in our study, we found that the efficiency of the 20 W laser device in the power range below 20 W was statistically lower than the other two groups in which lithotripsy was applied with a 30 W device. Although SFR was slightly higher in the power range of 30 W laser device over 20 W, no statistical difference was observed in lithotripsy efficiency at power ranges below and above 20 W. However, in our multivariate analysis, lithotripsy over 20 W was found to be one of the independent factors in increasing SFR. Basulto-Martínez et al[4] stated that higher pulse energy might increase ablation, but generate larger fragments and higher retropulsion. Therefore, they suggested performing the lithotripsy with the lowest possible pulse energy rate that could achieve a dusting effect on the stone.[4] In the same study, they also reported that retropulsion distance was shorter in the group with a long pulse width. However, there are other studies that have reported that the stone ablation efficiency was not affected by pulse width.[22]

In our study, assessment of the perioperative complications showed that all three groups had similar rates of both major and minor complications. We found that different laser device or lithotripsy at different power ranges did not affect complication rates. Basulto-Martínez et al[4] reported that high-power lithotripsy may cause fewer complications as a result of shorter operative time. Numerous studies have used VAS score to evaluate post-operative patient comfort after RIRS.[8,23,24] One study reported that female gender, stone size and UAS duration in the ureter were significant factors affecting post-operative pain.[23] Interestingly, in our study, the VAS score was higher in group 1. This might be because of a longer operation time and higher intra-pelvicalyceal pressure in the longer period. In addition, the residual stone rate was higher in group 1. Since the number of patients who learned that there was residual stone in the kidney during visits immediately after the surgery was higher in group 1, this news may have affected this subjective pain scale. There are studies showing that DJS reduces post-operative pain.[15,25] Post-operative oedema and inflammation may result in decreased ureteral passage. Therefore, DJS insertion may increase the comfort of patients regarding pain.[15] However, post-operative DJS insertion had no effect on the comparison of VAS score, since there was no difference between the groups in our study.

Several risk factors that affect the success of RIRS have been defined as stone size, stone number, lower pole calculi, involvement of multiple calyces and infundibulopelvic variables.[26,27] However, to our knowledge, no study has assessed the effect of laser device on the efficacy of RIRS for 1-2 cm kidney stone. Our multivariate logistic regression analysis revealed that the independent factors affecting the success of RIRS in 1-2 cm kidney stones are stone size, use of UAS and use of 30 W laser device. Lithotripsy performed with a 30 W laser device below and above 20 W was 3.9 times and 5.5 times more effective, respectively, than lithotripsy with a 20 W device with a power below 20 W.

The limitations of our study include single-centre design and the lack of stone type analysis. Although there are operation time data in our study, the lack of lithotripsy time is another limitation. The lithotripsy time data would have been helpful in examining the effects of lithotripsy times of different laser devices to break a 1 mm^3 kidney stone. The strengths of the study include prospective, randomised design and that it is the first study to examine efficacy of different laser devices and settings by analysing clinical outcomes.

5 | CONCLUSIONS

Shorter operation times, higher SFRs and lower post-operative pain scores can be achieved by using the 30 W laser device in RIRS for 1-2 cm kidney stones compared with the 20 W device. Lithotripsy with above 20 W had similar operation times, SFRs, and post-operative pain scores to lithotripsy with below 20 W with 30 W laser device. Independent factors predicting post-operative SFR were stone size, UAS usage, use of a 30 W laser device and lithotripsy over 20 W with a 30 W laser device. We conclude that 30 W laser device is safe and more efficient in RIRS for 1-2 cm kidney stones.

DISCLOSURE

The authors declare that they have no conflict of interest.

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