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ORIGINAL PAPER

Comparison of the efficiency, safety and pain scores of holmium laser devices working with 20 watt and 30 watt using in retrograde intrarenal surgery: One center prospective study

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Summary

Objectives: Holmium:Yttrium Aluminum Garnet laser lithotripsy is used in Retrograde Intrarenal Surgery. Fragmentation is made with a certain value of pulse energy (Joule) and frequency (Hertz) in Holmium laser lithotripsy and the multiplication of these values gives us total power (Watt). Devices with maximum power of 20 Watt and 30 Watt are used in clinical practice. We want to compare the efficiency, safety and pain scores of the lithotripsy made below 20 Watt and over 30 Watt with 30 Watt laser device.
Materials and methods: 60 patients who had 2-3 cm sized kidney stones and operation planned were prospectively divided into three groups. Groups were random identified. In the first group, fragmentation was performed below 20 Watt power with 20 Watt laser device. In the second group, fragmentation was performed below 20 Watt power with 30 Watt laser device. In the third group, fragmentation was performed over 20 Watt power with 30 Watt laser device. Demographic, stone, intraoperative and postoperative data were recorded. We compared these groups regarding efficiency, safety and pain score.
Results: For demographic and stone data, there was a statistically significant difference only for stone number. For intraoperative and postoperative data, there was a statistically significant difference only for ureteral access sheath usage between the groups. Success was lower than the other groups in Group 1.
Conclusions: Success was higher in groups using 30 Watt laser device. There was not statistically significantly difference between complications and pain. 30 Watt laser device is safe and efficient in Retrograde Intrarenal Surgery.

KEY WORDS: *Comparison; Efficiency; Kidney stone; Pain; Safety; Watt.*

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INTRODUCTION

The increasing incidence of kidney stone disease caused the increasing number of lithotripsy in urology clinics (1). Retrograde intrarenal surgery (RIRS) is a new method. Its usage recently widened with advances of technology (2). *Holmium:Yttrium Aluminum Garnet* (Ho:YAG) laser lithotripsy is a lithotripsy method used in RIRS. Ho:YAG laser lithotripsy fragments stone with the photothermal mechanism (3). In Ho:YAG laser lithotripsy fragmentation is made with a certain value of pulse energy (Joule/J) and frequency (Hertz/Hz.).
The multiplication of these values gives us total power (Watt/W). In clinical practice, the device with the maximum power of 20 W was at first available. Recently the device with maximum power of 30 W has been used. In our study, we used these two devices. We want to compare efficiency, safety and pain scores of the lithotripsy made below 20 W and over 30 W with 30 W laser device.

MATERIALS AND METHODS

After receiving local ethical board approval, a randomized prospective study was planned. Study was recorded into *National Clinical Trials* (NCT) and NCT code was taken (NCT 02443909). Sixty patients who had 2-3 cm sized kidney stones and for whom RIRS was planned were divided into three groups. Groups were random identified. Informed consent was obtained from all individual participants included in the study. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Blood count, biochemical tests, coagulation tests, urine analysis, urine culture, *kidney ureter bladder X-graphy* (KUBG), urinary system *ultrasonography* (US), *computerized tomography* (CT) were preoperatively performed. Patients age, gender, body mass index (BMI), history of *shock wave lithotripsy* (SWL), *American Society of Anesthesiologists* (ASA) score, previous stone surgery history, preoperative *double J* stent (JJ) history, anticoagulant usage, kidney anomaly, stone laterality, stone number, stone size and stone localization were recorded.

No conflict of interest declared.

Preoperative urine culture was sterile

Patients were taken Dexketoprofen Trometamol twice a day as the analgesic and anti-inflammatory treatment after the operation. *Visual analogue scale* (VAS) was filled at postoperative eighth hours by patients. Patients marked the value equal to his/her pain in the VAS. The marked value was recorded. Intraoperative operation time, scopy time, postoperative JJ stent rate, *ureteral access sheath* (UAS) usage, hospitalization time and complications were recorded. Complications were evaluated according to modified Clavien and Dindo classification.

The patients who had kidney anomalies, were < 18 years old, had urinary system infections in the preoperative evaluations were excluded from the study. The patients were divided into three groups. In the first group, fragmentation was performed below 20 W power with 20 W laser device. In the second group, fragmentation was performed below 20 W power with 30 W laser device. In the third group, fragmentation was performed over 20 W power with 30 W laser device. We used dusting and fragmentation methods in our study.

Preoperative antibiotic was administered to all patients. RIRS was performed under general anesthesia with 7.5 *French* (Fr) flexible renoscope (Flex-X2; *Karl Storz, Tutlingen, Germany*). After general anesthesia in modified supine position, the patient was taken to modified dorsal lithotomy position. Semi-rigid ureterorenoscope was applied into the ureter under fluoroscopic control and 0.035/0.038 inch hydrophilic safety wire was placed into the ureter under fluoroscopic control. Semi-rigid ureterorenoscopy was performed. In case of semirigid ureterorenoscopy failure due to ureteral stricture, JJ stent was placed and the operation ended. After semirigid ureterorenoscopy, 9.5-11.5 Fr or 11-13 Fr access sheath (Elit Flex, Ankara, Turkey) was placed into the ureter up to the ureteropelvic junction under fluoroscopic control. Then flexible renoscope was placed through the UAS to provide access to the kidney. When access sheath was not placed, flexible renoscope was moved via safety wire to access the kidney. Fragmentation was performed via 200 mm: Yttrium Aluminum Garnet laser probe (*Dornier Medilas H20 and HSolvo; Medtech, Munich, Germany*) after the stone had been reached. In Group 1 and 2, 8-10 Hz. frequency and 1.2-1.8 J pulse energy were used. In Group 3, 10-12 Hz. frequency and 2-3 J pulse energy were used. We used dusting and fragmentation methods. All calices were explored with flexible renoscope at the end of operation under fluoroscopic control. JJ stent was placed into the ureter due to intraoperative conditions. JJ stent was taken three weeks later with an outpatient procedure.

KUBG and US were performed on postoperative first day. CT was performed at postoperative third month. Patients who were stone free or had clinically insignificant residual fragment (< 2 mm) after intraoperative and postoperative controls, were evaluated as successful. We compared groups regarding efficiency, safety and pain score.

Statistical analysis

Analysis was made with SPSS for Windows 16.0 package program. Normality of numerical measurement values distributions was at first researched. One-Sample Kolmogorov-Smirnov test was used to determine the distributions of parameters except for age, BMI and operation time. The distributions were not normal ($p < 0.05$). Kruskal Wallis test was used to determine whether there was difference between two groups for gender, ASA score, stone laterality, stone localization, stone number, stone size, UAS usage, postoperative JJ stent usage, residual stone, scopy time, previous stone surgery history, SWL history, intraoperative and postoperative complications, anticoagulant usage and VAS score. In the patients with statistically significant differences in Kruskal Wallis test, to determine from which group the difference originated in the analyze, Mann-Whitney U test was used to perform dual comparisons. One-Way Anova test was performed to determine whether there was a statistical difference between the groups for age, BMI and operation time. $P < 0.05$ value was accepted as statistically significant for results.

Results

When we look at demographic and stone data, there was no statistically significant difference for the parameters age, gender, BMI, ASA, SWL history, previous stone surgery history, anticoagulant usage, preoperative JJ stent, stone laterality, stone size and stone localization between the groups. There was a statistically significant difference for stone number ($p = 0.036$) (Table 1).

When we evaluate intraoperative and postoperative data, there was no statistically significant difference for operation time, scopy time, postoperative JJ stent usage and hospitalization time. There was a statistically significant

Table 1.
Demographic and stone characteristics.

	Group 1 (n = 20)	Group 2 (n = 20)	Group 3 (n = 20)	p
Age (years) (± SD)	51.15 ± 12.58	47.75 ± 14.26	54.45 ± 14.45	0.315
Gender (M/F) (n)	8/12	14/6	12/8	0.154
BMI (kg/m^2) (± SD)	28.57 ± 4.43	28.12 ± 4.60	26.42 ± 3.97	0.265
ASA mean (n)	1.551	1.3525	1.671	0.409
SWL history (n, %)	5 (25)	2 (10)	3 (15)	0.438
Previous surgery history (n, %)	9 (45)	5 (25)	5 (25)	0.298
Anticoagulant usage (n, %)	1 (5)	0	0	0.368
Preoperative JJ stent (n, %)	8 (40)	2 (10)	5 (25)	0.094
Stone laterality (R/L) (n)	9/11	7/13	7/13	0.758
Stone number (n) (± SD)	1.85 ± 0.48	2.20 ± 0.89	1.75 ± 1.41	0.036
Stone size (mm) (± SD)	22.30 ± 3.21	22.60 ± 3.33	23.90 ± 4.09	0.56
Stone localization (n, %)				0.55
Upper calyx (n, %)	1 (5)	1 (5)	1 (5)	
Lower calyx (n, %)	6 (30)	6 (30)	5 (25)	
Mid calyx (n, %)	0	0	2 (10)	
Pelvis (n, %)	2 (10)	3 (15)	8 (40)	
Multicaliceal (n, %)	11 (55)	10 (50)	4 (20)	

M/F: Male/female; BMI: Body Mass Index; ASA: American Society of Anesthesiologists; JJ: Double J; SWL: Shock Wave Lithotripsy.

Table 1.
İntraoperative and Postoperative Data.

	Group 1 (n = 20)	Group 2 (n = 20)	Group 3 (n = 20)	p
Average Operation Time (min.) (± SD)	52.40 ± 21.29	61.45 ± 21.60	52 ± 18.23	0.263
Average Scopy Time (Sc.) (± SD)	57.05 ± 74.40	35.85 ± 24.13	32.50 ± 21.13	0.57
Postoperative JJ stent, n (%)	19 (95)	20 (100)	19 (95)	0.368
Uretheral Access Sheath Usage, n (%)	14 (70)	20 (100)	19 (95)	0.007
Average Hospitalisation Time (± SD) (day)	1	1	1	1
Success, (n) (%)	7 (35)	16 (80)	15 (75)	0.006
Stone-free	7 (35)	16 (80)	15 (75)	
Residual fragment (< 3 mm)	0	0	0	
Residual fragment (≥ 3 mm)	13 (65)	4 (20)	5 (25)	
VAS Score (point) (± SD)	3.30 ± 2.15	2.20 ± 1.61	2.60 ± 1.23	0.409
Complication rate, n (%)	5 (25)	8 (40)	4 (20)	0.35
Intraoperative complication	3 (15)	5 (25)	1 (5)	0.214
Mucosal Injury, n (%)	1 (5)	1(5)	0	
Bleeding, n (%)	1 (5)	3 (15)	0	
Malfunctioning or breakage of instruments, n(%)	1 (5)	1(5)	0	
Perforation, n (%)	0	0	1 (5)	
Postoperative complication	2 (10)	6 (30)	3 (15)	
Fever (Clavien I), n (%)	1 (5)	2 (10)	2 (10)	
Bleeding (Clavien I), n (%)	0	3 (15)	0	
Urinary Tract Infection (Clavien II), n (%)	1 (5)	1(5)	0	
Steinstrasse (Clavien IIIb), n (%)	0	0	1 (5)	

Min: Minutes; Sec: Seconds; JJ: Double J ; VAS: Visuel Analog Scale.

difference for UAS usage between the groups. There was no statistically insignificant difference between the groups for VAS score (Table 2).

When we look at success, in Group 1 seven patients, in Group 2 sixteen patients, and in Group 3 fifteen patients were stone free. The difference was statistically significant (p = 0.006). In Group 1 the operation was unsuccessful in one patient due to malfunctioning of the device, in four patients due to ureteral stricture and in eight patients due to inability to reach the stone. In Group 2, the operation was unsuccessful in one patient due to the malfunctioning of the device, in three patients due to inability to reach the stone. In Group 3, the operation was unsuccessful due to ureteral stricture in one patient, in two patients due to inability to reach the stone and in two patients due to stone burden. There was not clinically insignificant residual fragment in any group (Table 2).

Complications were seen in five patients for Group 1, eight patients for Group 2 and four patients for Group 3 (p = 0.35). Intraoperative complications were seen in three patients for Group 1, five patients for Group 2 and one patient for Group 3 (p = 0.214). Postoperative complications were seen in two patients for Group 1, six patients for Group 2 and three patients for Group 3. Bleeding was the intraoperative and postoperative associated complication in Group 2 (Table 2).

Discussion

RIRS is a method of increasing use in kidney stone treatment (4). Ho:YAG laser is used in RIRS. A certain value of frequency (Hz.) and pulse energy (J) are used in Ho:YAG laser lithotripsy. The multiplication of these values give us power (W). There are studies to determine optimum power settings in Ho:YAG laser lithotripsy in the literature (5-7). These are in vitro studies. Human stones or stone-like material were used in these studies. In the same power settings, low frequency/high pulse energy and high frequency/low pulse energy were compared in these studies. In the same power settings, the low-frequency high pulse energy is more effective. There are studies that report pulse energy is the major variable affecting fragmentation efficiency (6). Total fragmentation increases as pulse energy increase (6). The increase of pulse energy provides fast fragmentation but produces larger fragments (6). Retropulsion increases due to the increase of pulse energy (7-10). As retropulsion increases, the distance between fiber tip and stone decreases (7) and the energy applied to the stone decreases (11), so retropulsion decreases fragmentation efficiency (9). Also, the high pulse energy is associated with fiber tip malfunctioning and this causes low efficiency (6, 12).

When we look at literature, fragmentation speed increases as total power increases. There are studies about low power settings (13). In a study, shorter lithotripsy time was reported by high power settings (2.8 J and 15 Hz.), but there was not a comparison (14). In our study, we aimed to compare the efficiency, safety and pain score of the lithotripsy under 20 W and over 20 W power with two different laser devices in the same sized stones.

When we look at demographic and stone characteristics, there was no statistically significant difference between the groups except the stone number. When we look at the operation data, there was statistically significant difference between the groups for UAS usage rate and success. In group 1, UAS usage rate was lower than the other groups, that may explaun the higher number of ureteral stricture observed in Group 1.

When success was evaluated, it was lower than the other groups in Group 1. The inability to reach the stone was seen in 8 patients for group 1, three patients for group 2 and two patients for group 3. The lower caliceal stone rates were similar between the groups. Multicaliceal stones rate was higher in group 1 and 2 than group 3. Failure due to ureter stricture was higher in group 1 than the other groups. This result can explain the lower success rate in group 1. Success was higher in the group in which 30 W laser device was used. The success rate was similar with literature except for group 1. In group 1, due to ureter stricture and multicaliceal stones, success was lower.

In our study, first operation success was evaluated. Success reached 90-95% after repeating operations in all groups.

There was no statistically significant difference between the groups for complications. The increasing pulse energy produces larger fragments (6), so larger residual fragments were seen in group 3. Also, steinstrasse was seen in one patient of group 3. Operation time was lower in group 3 than group 2 due to increasing pulse energy. Operation

time was similar between group 1 and 3. Due to the high number of unsuccessful patients in group 1, operation time was lower in group 1. The complication rate is higher in our study when we compared it with literature data. The fewer patient number may explain this result, therefore studies with larger patient number are needed.
There was not a statistically significant difference between the groups for VAS score. There are few studies evaluating pain in the literature. *Shoshtari et al.* reported the main cause of admission to the hospital was pain (15). *Singh et al.* reported that patients undergoing RIRS had more pain than patients undergoing SWL at postoperative first and second day (16). *Oguz et al.* reported that female gender, stone size and UAS duration time in ureter were statistically significant factors affecting pain (17). In a review researching the effect of female gender on pain scores, *Tighe et al.* observed that postoperative pain scores at first day were higher in females (18). Although there are studies that report postoperative JJ stent decreases postoperative pain significantly, other studies report that JJ stent increases postoperative pain (19). In our study, postoperative JJ stent rate was similar between the groups.
A limitation of our study was the absence of stone analysis. In a study, comparing Ho:YAG laser settings, different types stones or stone-like materials were used in vitro (5-7). Another limiting factor was the type of laser fiber used. A study reported that fragmentation changed due to use of different laser fiber types (6). The same laser fiber was used in three groups. Patient number is another limiting factor because larger patient number studies are needed.

Conclusions

For Ho:YAG laser lithotripsy in RIRS, success was higher in groups using 30 W laser device. There was not statistically significantly difference between complication and pain rates. 30 W laser device is safe and efficient in RIRS.

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