ORIGINAL PAPER

UROLITHIASIS

High-power holmium laser versus pulsed thulium laser for ureteroscopic lithotripsy: Results of a randomized prospective study

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Introduction Current evidence indicates that the outcomes obtained with the holmium laser (Ho:YAG) and the thulium fiber laser (TFL) in the endoscopic treatment of upper urinary tract stones are at least equivalent. The recent introduction of the pulsed thulium laser (p-Tm:YAG) could result, due to its characteristics, in the ideal combination of its predecessors. The aim of this study was to compare the performance and outcomes between high-power Ho:YAG and p-Tm:YAG.

Material and methods This prospective randomized clinical study included patients with a single renal or ureteral stone, who underwent retrograde endoscopic surgery.

Results A total of 122 patients were recruited, of whom 66 (54%) received treatment with the p-Tm:YAG laser. The overall stone-free rate was 65.1% for p-Tm:YAG and 62.5% for Ho:YAG ($p = 0.76$). Specifically, for renal stones, the stone-free rates were 60.9% vs 48.4% ($p = 0.28$), respectively. The median energy used in the p-Tm:YAG group was 4.71 kJ compared to 5.31 kJ in the Ho:YAG group ($p = 0.28$). The post-operative requirement for a double-J catheter was higher in the Ho:YAG group (67.8% vs 50%; $p = 0.04$). The analysis showed no statistically significant difference in the energy required to treat 1 mm^3 of stone (20 J/mm^3 for p-Tm:YAG vs 22 J/mm^3 for Ho:YAG; $p = 0.48$).

Conclusions Intracorporeal lithotripsy with p-Tm:YAG shows non-inferior results in terms of stone-free rates compared to high-power Ho:YAG. There is a trend in favor of p-Tm:YAG regarding the total energy required and a lower need for a subsequent double-J catheter, which should be corroborated by further studies in this field of urology.

Key Words: laser ‹› ureteral stones ‹› ureteroscopy instrumentation ‹› urolithiasis

INTRODUCTION

The holmium:YAG (Ho:YAG) laser has long been the standard for lithotripsy due to its safety and effectiveness [1, 2]. However, the thulium fiber laser (TFL) has challenged this dominance, showing higher stone-free rates (SFRs) and shorter operative times in some trials [3–5], although others found no significant differences [6]. More recently, a new solid-state pulsed thulium:YAG laser (p-Tm:YAG) has shown superior *in vitro* ablation performance compared to Ho:YAG, especially at longer pulse durations [7]. Its efficacy appears consistent across stone types [8], and early clinical experience shows SFRs around 80%, positioning it as a promising hybrid between Ho:YAG and TFL [9]. While initial data suggest its efficiency may rival Ho:YAG and outperform TFL, no direct clinical comparison between p-Tm:YAG and Ho:YAG has been published. Therefore, we designed a prospective randomized trial to compare these two technologies in terms of SFR, energy use, operative time, laser time, stent placement, and complication rates.

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MATERIAL AND METHODS

Study design, setting, and population

This is a prospective, randomized, single-center study conducted at a tertiary health center. Patients over 18 years old with a single renal or ureteral stone larger than 5 mm in their major axis, meeting criteria for surgical resolution, and scheduled for ureteroscopy (URS) or retrograde intrarenal surgery (RIRS) were invited to participate. Informed consent was obtained verbally at least 48 hours before surgery and in writing 24 hours before. Exclusion criteria included active urinary tract infection, acute renal failure, pregnancy, and anatomical abnormalities of the urinary tract. The preoperative study included a non-contrast computed tomography scan (NCCT), urine culture, and renal function assessment. All patients followed the previously established protocol.

The study began its recruitment on August 4, 2023, and ended on August 1, 2024. During this period, 164 surgeries were performed on 153 patients who were potential candidates to participate in the study. Of these, 30 decided not to be included in the study and were therefore not considered for analysis. Of the remaining 134, eight did not undergo the follow-up imaging, nor did they attend the scheduled medical follow-up appointment.

Ureteroscopy and laser settings

All procedures were performed under general anesthesia. All surgical procedures were performed by three board-certified urologists, each with experience in over 200 prior endourological procedures, including flexible ureteroscopy and laser lithotripsy. Throughout all arms of the study, these experienced surgeons carried out the procedures with the assistance of fourth-year urology residents. Residents did not perform any critical steps independently, and all interventions were directly supervised to ensure standardization and safety across cases. As part of our routine practice, a standard nitinol safety guidewire (0.038 inches) was used in all patients. A semi-rigid ureteroscope (8/9.8 Fr; Richard Wolf Medical Instruments, Vernon Hills, IL, USA) was then inserted using a second guidewire to achieve optimal optical dilation of the distal ureter, followed by endoscopic treatment of stones located in the distal and mid-ureter. For proximal or renal stones, the initial steps were similar to those described for semi-rigid ureteroscopy. When possible, an 11/13 Fr ureteral access sheath (Navigator HD; Boston Scientific) was used. In all cases, a single-use flexible ureteroscope model Lithovue® (Boston Scientific) was advanced under endoscopic and fluoroscopic guidance until the stone was visualized. The renal collecting system was inspected before performing lithotripsy. Depending on the stone's location, an open-front grasper (Dakota™; Boston Scientific) was used to reposition the stones to a more favorable location for laser lithotripsy. Before anesthetic induction, patients were randomized to undergo treatment with either the Ho:YAG laser (Lumenis Pulse™ 120H; Lumenis, San Jose, CA, USA) or the p-Tm:YAG laser (Tm:YAG, Dornier MedTech Laser GmbH, Wessling, Germany). At the end of the procedure, all data were recorded from the laser equipment screens. At the conclusion of the procedure, stone fragments were collected for spectroscopic analysis when a sufficient sample size was available. A double-J stent was placed at the surgeon's discretion based on residual fragments, mucosal edema, or suspected ureteral damage. Regarding the parameters used for each laser, previous experience with these lasers, expert recommendations, and manufacturer guidelines were considered. For the Ho:YAG laser, a 270 μm fiber was used, with parameters for dusting set at 0.3 J/30 Hz (9 W) in the ureter; 0.4 J/50 Hz (20 W) in the kidney, both with long pulse wave, and for fragmentation, 1.2 J/10 Hz (12 W) in the ureter; 1.4 J/15 Hz (21 W) in the kidney, both with short pulse wave. For the p-Tm:YAG laser, a 270 μm fiber was used, with parameters for dusting mode set at 0.3 J/25 Hz (7.5 W) in the ureter; 0.3 J/75 Hz (22.5 W) in the kidney, and for captive fragmenting mode, 0.4 J/25 Hz (10 W) in the ureter and 2.5 J/10 Hz (25 W) in the kidney. These parameters were only modified if the surgeon deemed the treatment to be ineffective, never exceeding 12 W in the ureter and 25 W in the kidney. Based on a previous study on the risk of thermal injuries caused by high-power lasers, continuous laser activation periods never exceeded 20 seconds, and irrigation was maintained between 10 and 20 ml/min (for 10 ml/min the 3 l saline solution bag was hung at 70 cm over the tip of the ureteroscope, and for 20 ml/min at 130 cm over the tip of the ureteroscope; we temporarily used a syringe for manual irrigation when necessary to improve visibility during laser treatment of the stone) [10].

Outcomes

The primary outcome of this study was the SFR achieved with each laser. To determine this parameter, a NCCT scan was performed 6 weeks postoperatively, with residual fragments less than or equal to 2 mm as reported by a radiologist. Secondary outcomes included total surgical time (minutes), laser activation time (seconds), fluoroscopy time (seconds), total energy per case (kJ), energy used per mm^3 in cases of successful lithotripsy, the need for a postoperative double-J stent, and intraoperative and postoperative complications (up to 30 days postoperatively). When considering the stones as an ellipsoidal body, the formula used to calculate their volume is height × width × depth × 0.52, according to the measurement along each of its axes [11].

Other measured variables included age (years), sex, stone hardness (HU), largest stone diameter (mm), location of the lithiasis, and previous use of a double-J catheter.

Statistical analysis

Based on a non-inferiority study, the required sample size to show a statistically significant difference in the stone-free rate is approximately 110 patients (55 per group), plus an additional 10% in case of losses during follow-up. This is based on the success rates reported for p-Tm:YAG in some series (81-84%) and for Ho:YAG (65-69%) [12–14].

For the randomization of the patients, a computer-generated allocation sequence was used. Patients were assigned treatment on a masked basis, which was maintained until the data analysis. The software used was RStudio, version 2023.03.0. Assignment to each group was performed using consecutive numbers in sealed envelopes. Microsoft Excel was used for data collection, which was utilized solely for the purposes of this research, and confidentiality was ensured through internal protocols.

The normality of the data was assessed using the Shapiro-Wilk test. The median was used as a measure of distribution for all continuous variables. The Mann-Whitney test or chi-square test was conducted as appropriate. For the comparison of the graphs, a logistic regression model was used. A statistically significant difference was considered with a p-value <0.05. All graphs and tests were performed using RStudio software, version 2023.03.0+386.

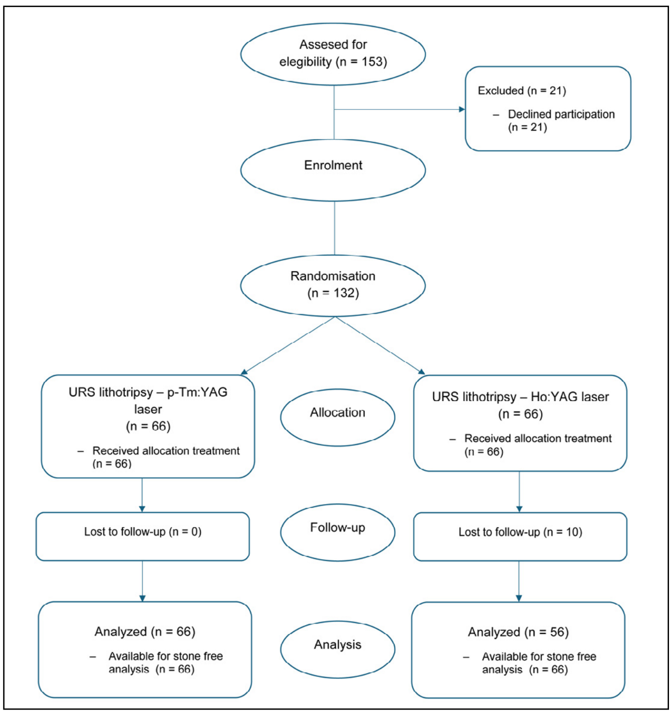

Figure 1. *Flowchart of patient selection and exclusion criteria.*
Ho:YAG – holmium:YAG; p-Tm:YAG – pulsed thulium:YAG; URS – ureteroscopy

Bioethical standards

This study was approved by the Ethics Committee of the Finis Terrae University (approval no. 271011-23), and written informed consent was obtained from each participant.

RESULTS

The final analysis included 122 patients – 66 patients in the p-Tm:YAG laser group and 56 in the Ho:YAG laser group (Fig. 1). Table 1 summarizes the demographic characteristics and the stone parameters in each group, showing that the groups were comparable when analyzing these parameters.

Regarding intraoperative variables, there were no statistically significant differences in total operating time between the p-Tm:YAG laser and Ho:YAG laser groups (45 min vs 40 min, respectively), p = 0.7 (Table 2). In terms of total laser activation time, the p-Tm:YAG laser group had 360 seconds, while the Ho:YAG group had 390 seconds, a difference that was not statistically significant, p = 0.37. The only significant difference in this part of the analysis was the frequency of post-ureteroscopy ureteral stent placement between p-Tm:YAG and Ho:YAG (50% vs 67.8%, respectively), p = 0.04. Table 3 shows the analysis of SFR, where no differences were observed in the overall rate between p-Tm:YAG and Ho:YAG (65.1% vs 62.5%, respectively), p = 0.76, renal stones (60.9% vs 48.4%), p = 0.28, or ureteral stones (72% vs 82%), p = 0.25. Finally, the analysis of total energy required to complete the case was lower for p-Tm:YAG compared to Ho:YAG, but without reaching a statistically significant difference (4.71 kJ vs 5.31 kJ), p = 0.28. Regarding energy consumption, the p-Tm:YAG laser used 20 J/mm³ vs the Ho:YAG laser, which used 22 J/mm³ of stone in the group considered free of residual fragments (p = 0.48). In a sub analysis considering chemical composition of the stone, a total of 54 patients had sufficient samples for stone analysis – 32 in the p-Tm:YAG laser group and 22 in the Ho:YAG laser group. Of these, the proportion of stones composed 100% of calcium oxalate monohydrate (COM), potentially harder lithiasis, was similar, and no differences were observed in total energy used, total laser activation time, total surgery time, or SFR (Table 4). Concerning complications, there were no intraoperative events that required the procedure to be suspended, and no significant bleeding was recorded. The hospital stay did not differ between the groups (19.3 hr in p-Tm:YAG group vs 21 hr in Ho:YAG; p = 0.63). Postoperative complications recorded were one case of acute pyelonephritis and two cases of renal colic 48 hours after discharge, all in the p-Tm:YAG laser group, and one punctiform perforation of the distal ureter in the Ho:YAG group, which was managed with a double-J catheter, without the development of stenosis by the end of the study.

Table 1. *Demographic and stone characteristics*

Parameter	p-Tm:YAG (n = 66)	Ho:YAG (n = 56)	p-value
Gender, n (%) Male Female	 35 (53%) 31 (47%)	 40 (71%) 16 (29%)	0.47
Age at surgery (years)	54 (45–63)*	47 (39.7–58.2)*	0.22
Side Right Left	 44 (66.6%) 22 (33.4%)	 36 (64.2%) 20 (35.8%)	0.75
Stone density (HU)	972.5 (747.5–1,115)*	1000 (777.7–1,175)*	0.63
Kidney stone	41 (62.1%)	33 (58.9%)	0.5
Lower pole stone (%)	15 (36.5%)	14 (42.4%)	
Kidney stone larger axis (mm)	12 (7.25–19.5)*	13.5 (8.2–17.7)*	0.53
Kidney stone volume (mm³)	374.4 (134.7–985.4)*	400 (199–1934)*	0.36
Ureteral stone	25 (37.8%)	23 (41%)	0.88
Ureteral stone larger axis (mm)	8 mm (7.7–8)*	7.5 mm (7–8.7)*	0.9
Ureteral stone volume (mm³)	143 (114.7–174.7)*	113.1 (84.2–166.1)*	0.86
Prestenting, n (%)	40 (60.6%)	24 (42.8%)	0.07

*interquartile range

Table 2. *Intraoperative outcomes*

Parameter	p-Tm:YAG (n = 66)	Ho:YAG (n = 56)	p-value
Lasing time (seconds)	360 (135–765)*	390 (180–1,200)*	0.37
Fluoroscopy time (seconds)	11.5 (3.8–29.2)*	24 (7–49.2)*	0.07
Operative time (minutes)	45 (30–60)*	40 (34.5–55.5)*	0.70
Post-operative stenting, n (%)	33 (50%)	38 (67.8%)	0.04

* interquartile range

DISCUSSION

The debate over which laser is more effective has taken over the endourological world. So far, the Ho:YAG laser continues to be considered the gold standard for intracorporeal lithotripsy [15], mainly due to the results obtained regardless of the chemical composition of the stones. Despite the increasing use of high-power lasers, it remains unclear whether they achieve better results than low-power lasers [16]. On the other hand, the TFL has been

Table 3. *Descriptive derived quality*

Parameter	p-Tm:YAG (n = 66)	Ho:YAG (n = 56)	p-value
Stone-free rate			
Global, n (%)	43 (65.1)	35 (62.5)	0.76
Renal, n (%)	25 (60.9)	16 (48.4)	0.28
Ureteral, n (%)	18 (72)	19 (82)	0.25
Total energy (kJ)	4.71 (1.7–12.7)*	5.31 (2–15.7)*	0,28
Laser energy consumption (J/mm³)	22 (8.48–31.3)*	20 (8.7–34.3)*	0.48

* interquartile range

Table 4. *Descriptive statistics of quality-derived parameters based on stone composition*

Parameter	p-Tm: YAG (n = 32)		Ho:YAG (n = 22)		p-value
	COM	Other	COM	Other	
Stone free (%)	11/14 (78.5)	10/18 (55.5)	6/8 (75)	8/14 (57.1)	0.84
Total energy (kJ)	5.4 (1.2–14.8)*	7.7 (4.9–17.3)*	3.3 (1.6–9.3)*	13.7 (2.2–24)*	0.85
Lasing time (s)	360 (120–660)*	330 (150–750)*	540 (330–900)*	660 (300–1,260)*	0.82

* interquartile range

considered, up to now, the only potential alternative to the Ho:YAG laser. A prospective randomized study comparing TFL with the Ho:YAG laser demonstrated superior SFR rates of over 90% in the treatment of renal stones via retrograde approach for the former group [5]. However, the only meta-analysis available to date did not show that TFL was superior [17], although it seems to achieve better results in terms of SFR, laser activation time, total surgery time, ablation efficiency, and retropulsion, as long as it is compared to Ho:YAG without pulse modulation. In this complex scenario, this new p-Tm:YAG laser emerges. Our study did not show a significant difference in terms of SFR, although there was a trend towards better results when considering only the treatment of renal stones with the use of p-Tm:YAG. The overall SFR of 65.1% for p-Tm:YAG is close to that reported by Traxer's group in 2023 [12], where they described their first experience in 25 cases, achieving a 55% SFR when considering zero residual fragments. It is worth noting that this first experience only included 2 cases of ureteral stones and 1 bladder stone, using only the captive fragmenting mode for lithotripsy. A second experience in patients was described this year, which included 60 patients, reporting an SFR rate of nearly 92%, also using the captive fragmenting mode [18]. However, this study does not describe the imaging method used to determine the SFR status. In our study, we decided to sub-analyze the results based on the chemical composition of the stones, especially focusing on calcium oxalate monohydrate stones, which are recognized as having some of the hardest composition. In both lasers, the zero residual SFR achieved in this type of stone was over 75%. This should not come as a surprise, as previous studies have confirmed that the p-Tm:YAG laser performs excellently in any chemical composition of stones generated in humans [8]. Kwok et al. demonstrated in an *in vitro* study that the stone mass ablation rate is not different between COM stones and uric acid stones, regardless of the p-Tm:YAG laser settings used. The same author, in a previous study with the same laser, demonstrated that in the 7 most commonly found types of stones in humans, real dust with particles ≤250 μ could be achieved [19]. Particularly in this study, 3 different combinations of laser parameters were used, with an average total power of 10 W, and in all cases, tiny particles were obtained, even as small as 63 μm in COM stones. These data are relevant because particles of this size can be aspirated through a 3.6 Fr working channel of a conventional ureteroscope. This result has already been previously demonstrated with the Ho:YAG laser [20], and this could be one of the hypothetical reasons why similar zero SFR rates were obtained in our study when considering the chemical composition of the stones. The concept of energy consumption, i.e., "how much energy is required to treat 1 mm^3 of stone", has been clinically evaluated several times with the Ho:YAG laser. In a study using Moses technology in flexible ureteroscopy, where most of the stones were located in the lower calyx stones, with an average volume of 290 mm^3 and a laser activation time of 360 seconds, an average energy consumption rate of 38.2 J/mm^3 was obtained [21]. Following the same line, but this time with low-power Ho:YAG, Ventimiglia et al. [22] treated larger stones (average 1,599 mm^3) with a much longer activation time (average 68 minutes) and obtained an energy consumption of 19 J/mm^3, which is lower than the previous study. In our study, we used a high-power Ho:YAG device with conventional fibers for lithiasis with a median volume of 400 mm^3, generating an energy consumption of 22 J/mm^3, which we consider to be within the expected ranges for the performance of this type of laser technology. On the other hand, the evaluation of energy consumption in p-Tm:YAG in patients has been assessed in only one previous study [12], where larger stones were treated, ranging from 916 to 9,153 mm^3, with a median energy consumption of 14 J/mm^3, very close to the 20 J/mm^3 obtained in our study. Finally, regarding the postoperative period, the higher number of patients who required a double-J stent in the Ho:YAG laser group is noteworthy. We do not have a robust explanation for this result. A potential explanation could be related to the smaller number of patients in this group who arrived at surgery without a double-J stent, a factor that might influence the decision to place one after the procedure in patients treated with Ho:YAG over p-Tm:YAG. Additionally, the surgeon's subjective impression of larger fragment sizes achieved with Ho:YAG may have led to this decision. Our study has some limitations, including that it incorporates patients from a single hospital center. Furthermore, although it is a prospective, randomized study, the sample size for each group might be relatively small. From a technical standpoint, a weakness of this study is that high-power Ho:YAG was used without pulse modulation, whereas in the p-Tm:YAG group, pulse modulations were used, although these were predesigned by the manufacturer. Despite these limitations, this is the first study attempting to compare the outcomes of this innovative technology against the traditionally used energy for intracorporeal lithotripsy.

CONCLUSIONS

In this prospective randomized study, no significant differences were found between the Ho:YAG laser and the new p-Tm:YAG laser when considering SFR, regardless of the chemical composition of the stones. Additionally, the energy consumption behavior was similar in both technologies. The differences in the placement of double-J stents after the procedure will need to be clarified in future studies that include a larger number of patients.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

FUNDING

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ETHICS APPROVAL STATEMENT

This study was approved by the Ethics Committee of the Finis Terrae University (number of approval: 271011-23), and written informed consent was obtained from each participant.

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