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Retrograde intrarenal surgery versus percutaneous nephrolithotomy in larger kidney stones. Could SuperPulsed Thulium-fiber laser change the game?

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Introduction The aim of this article was to compare retrograde intrarenal surgery (RIRS) and percutaneous nephrolithotomy (PCNL) efficacy and safety with SuperPulsed Thulium-fiber laser (SP TFL) for stones 20 mm and larger.

Material and methods Patients with large kidney stones (20 mm and larger) were recruited to undergo PCNL or RIRS with SP TFL lithotripsy. Both groups were comparable in terms of stone size and density, operation time, laser-on time (LOT), stone-free rate, residual fragments and complication rate. Stone retropulsion and visibility were assessed based on the surgeon's feedback using Likert scales.

Results A total of 14 and 56 patients were included in the RIRS and PCNL groups, respectively. The mean stone density was 833.8 ±298.3 HU in the RIRS group and 882.3 ±408.5 HU in the PCNL group ($p = 0.072$). The median LOT was 11.7 (10.0–15.5) min for RIRS and 10.0 (6.0–12.1) min for PCNL ($p = 0.207$). The median total energy for stone ablation was 13.8 (11.8–25.0) kJ for RIRS and 12.0 (7.0–20.1) kJ for PCNL ($p = 0.508$). The median ablation speed was 3.9 (3.9–5.7) mm^3/sec for RIRS and 5.0 (4.6–11.3) mm^3/sec for PCNL ($p = 0.085$). We found a significant correlation between retropulsion and the type of surgery performed: with higher retropulsion in the PCNL ($r = 0.298$ with $p = 0.012$). The stone-free rate at 3-months was 85.7% in RIRS and 89.3% in PCNL ($p = 0.505$).

Conclusions SP TFL is a safe and effective modality for lithotripsy for both, RIRS and PCNL, achieving minimal retropulsion and good visibility. No discrepancies in procedure duration, complications, or LOT were identified between the different modalities.

Key Words: Thulium-fiber laser ‹› urolithiasis ‹› urinary stones ‹› kidney ‹› retrograde intrarenal surgery ‹› percutaneous nephrolithotomy

INTRODUCTION

Currently, the treatment of choice for big stones (≥20 mm) is the percutaneous nephrolithotomy (PCNL), followed by the retrograde intrarenal surgery (RIRS) as a second option [1, 2]. The reason why PCNL remains the standard procedure for large renal stones is that it allows fast stone fragmentation and extraction. On the other hand, RIRS itself proved to be an effective modality for managing stones smaller than 2 cm in diameter with a decreased number of complications, blood loss, and shorter hospital stay [2]. Moreover, previous studies showed that RIRS is also acceptable for larger stones [3], but its efficacy could be limited by suboptimal visualization [4].

Recently, the novel SuperPulsed Thulium-fiber laser (SP TFL) was approved for clinical use in Europe and

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the USA. SP TFL proved itself to be an effective tool for highly efficient dusting [5]. In preclinical studies, it was demonstrated that SP TFL produces higher stone ablation rates, three to four-times more dust, smaller stone fragments, when compared to Ho:YAG laser with similar laser parameters [6]. Moreover, SP TFL can operate within a large range of energy, frequency, and pulse duration settings which leads to wide and more comprehensive parameter combinations [5].
All the above-mentioned advantages of SP TFL raise the question of its possible higher efficacy in terms of RIRS vis-à-vis PCNL. This study aims to compare the lithotripsy performance of the SP TFL in RIRS vs PCNL, for stones larger than 20 mm.

MATERIAL AND METHODS

Patients

After protocol approval by the Institutional Review Board, patients with renal calculi who were treated from 2017 to 2019 with RIRS or PCNL with the SP TFL U2 (NTO IRE-Polus, Russia) were prospectively enrolled, after a retrospective analysis of the data was performed. All patients underwent contrast-enhanced computed tomography (CT) of the urinary tract, performed by one experienced radiologist, to assess stone size and location, the number of calyces involved, and stone density (HU). The three different size dimensions of the stones were measured using CT. For this particular study inclusion criteria were large single renal calculi (20 mm and larger). Exclusion criteria were patients on anticoagulant therapy or patients undergoing secondary simultaneous surgical intervention (e.g. for benign prostatic hyperplasia (BPH), upper tract carcinoma, urethral and ureteral stricture). To evaluate the outcomes, patients were divided into the RIRS or PCNL group.

Surgical procedure

Both RIRS and PCNL procedures were performed by four highly experienced surgeons in percutaneous nephrolithotomy and retrograde intrarenal laser lithotripsy who had performed in aggregate at least 50 cases with SP TFL before the beginning of the study.
According to local clinical practice, RIRS patients were 'pre-stented' 4–7 days before the surgery for further use of ureteral sheath (10–12 Fr, Cook, USA, and 11–13 Fr, Navigator HD, Boston Scientific, Marlborough, USA). RIRS was performed under general anesthesia with all the patients in lithotomy position. During the procedure, we used either of these two flexible ureteroscopes, the FLEX-X2 (Karl Storz Gmbh Germany) or the LithoVue™ (Boston Scientific, Marlborough, USA) with a 200 μm laser fiber. Intraoperative irrigation was passive in all patients (falling water from 60-70 cm from the level of the patients' body). After lithotripsy, a double J stent was placed for up to 14 days. The bladder was drained with a Foley catheter for 1 day.
PCNL was also delivered under general anaesthesia, with patients in the prone position. All PCNL procedures were performed using a 12 Fr nephroscope with a minimally invasive PCNL (MIP) set (16.5–17.5 Fr) (Richard Wolf Gmbh, Germany). Lithotripsy was performed with a 400 μm laser fiber using a fragmentation and dusting settings. But it should be mentioned that analysis of efficacy (ablation speed, ablation efficacy, energy consumption) were performed only in patients with dusting regimens. Irrigation was passive (falling water from 60–70 cm from the level of the patients' body) in all cases. A Foley catheter (16–20 Fr) was placed systematically after surgery. The nephrostomy tube (16 Fr) was removed 2–4 days after the operation.

Outcome assessment

All the data was recorded by one single researcher. The primary outcome, to assess lithotripsy efficacy, was the laser-on time (LOT). The stone ablation speed (stone volume/laser-on time), the energy for ablation of 1 mm^3 (Total J /stone volume) and energy consumption (Total J / laser-on time) were also assessed postoperatively. Stone volume was calculated with the ellipsoid volume formula (4/3 x ϖ x radius length x radius width x radius depth). Secondary outcomes were the total energy delivered, the retropulsion and visibility. Retropulsion was assessed throughout the operation and the surgeon gave his feedback using the three-point Likert scale (0 = no retropulsion, 1 = retropulsion which does not affect stone ablation, 2 = retropulsion that interferes with stone ablation) as well as intraoperative visibility (0 = clear visibility, 1 = decrease of visibility, which does not affect the procedure, 2 = poor visibility that interferes with the procedure). The surgeon reported any problems or bad outcomes. In the event of any discrepancies in the Likert scaling, the record of the surgery was reviewed by the researcher and the two surgeons taking part in the research. The efficacy estimation was done according to the visibility and retropulsion.
The postoperative stone-free rate (SRF), without residual fragments, and any short-term complications (strictures and hydronephrosis) were assessed in all patients with low dose CT imaging and ultrasonography completed within three months after surgery. Meanwhile, we evaluated intraoperative and post-

operative complications using the modified Clavien–Dindo classification for both procedures.

The primary objectives of the study were to assess lithotripsy efficiency, measured through the following parameters: LOT, ablation speed (mm^3/sec), ablation efficacy (J/mm^3), and the energy consumption (J/sec) in RIRS and PCNL groups. The secondary objectives were to compare the retropulsion, visibility with the complication rates.

Statistical analysis

SPSS Statistics 23.0 (IBM, USA) was used for statistical analysis. Patients' data were expressed by the mean ± standard deviation (SD) and by the median (interquartile range). For comparison of the means, the nonparametric Mann-Whitney U test and Kolmogorov-Smirnov test were used. Categorical variables were compared using Pearson's chi-square test. Ranked variables were compared using the Spearmen test. A two-sided p-value of 0.05 was considered the threshold for statistical significance.

RESULTS

A total of 318 patients were treated with RIRS or PCNL. Based on study criteria, after assessment a total of 70 patients were included in the final set. There were 14 patients in the RIRS group and 56 patients in the PCNL group. The mean stone density was 833.8 ±298.3 HU in the RIRS group and 882.3 ±408.5 HU in the PCNL group (p = 0.072). The median stone volume was 2743 (1451–4213) mm^3 in the RIRS group and 3285 (2210-3775) mm^3 in the PCNL group (p = 0.304). The maximum stone size for the PCNL group was 36 mm in the RIRS group and 55 mm in the PCNL group.

Due to minimal use of laser energy in fragmentation cases, only those who underwent dusting were included in efficacy analysis. The median LOT was 11.7 (10.0–15.5) minutes for RIRS and 10.0 (6.0–12.1) minutes for PCNL (p = 0.207). The median total energy for stone ablation was 13.8 (11.8-25.0) kJ for RIRS and 12.0 (7.0–20.1) kJ for PCNL (p = 0.508). The median ablation speed was 3.9 (3.9–5.7) mm^3/sec for RIRS and 5.0 (4.6–11.3) mm^3/sec for PCNL (p = 0.085). The median ablation efficacy was 4.6 (2.9–5.5) J/mm^3 for RIRS and 3.8 (2.1–5.8) J/mm^3 for PCNL (p = 0.09). The median energy consumption was 18.0 (15.1–22.5) J/sec for RIRS and 30.0 (23.8–34.2) J/sec for PCNL (p = 0.989) (Table 1). In RIRS group, basketing was used in 5 cases, in PCNL group – in 3 cases. The mean postoperative stay was 2-3 days vs 3–4 days in the RIRS and PCNL group, respectively. The mean follow-up was 3 months in both groups. The most frequently used settings were 0.15J, 30W, 200 Hz /0.5J, 15 W, 30 Hz for RIRS and 0.8 J / 25–30 W / 31–38 Hz for PCNL.

In both groups LOT was positively correlated with total energy (RIRS: r = 0.865 with p <0.001; PCNL: r = 0.834 with p <0.001). Stone density was not correlated with LOT or ablation speed in both groups. No correlation was found between stone volume for RIRS and PCNL (Table 2).

A higher frequency regimen (200 Hz) showed a correlation with visibility in the RIRS group only (r = 0.704 with p = 0.007). In both groups, higher energy regimens (0.8 J) were associated with increased retropulsion. It should be mentioned that we only found a significant correlation between LOT and retropulsion (r = 0.457 with p = 0.005) in the PCNL group (Table 2).

In the RIRS group, insignificant retropulsion (retropulsion score = 1) was seen in 1 case (7.1%). During PCNL, surgeons reported stone retropulsion that interfered with surgery (retropulsion score = 2) in 1 (1.7%) case with the stone density of 1000 HU and stone diameter of 28.5 mm; insignificant retropulsion (retropulsion score = 1) was noted in 13 (24.5%) cases. In the RIRS group, minor difficulties with vis-

Table 1. *Patient characteristics and intraoperative data*

	RIRS (N = 14)	PCNL (N = 56)	p-value
Kidney (right/left)	5/9	27/29	–
Fragmentation/dusting	4/11	33/24	–
Fiber diameter	200 mcm	400 mcm	
Mean stone size, mm ± standard deviation (SD) (range)	23.5 ±6.3 (20–36)	26.2 ±6.7 (20–55)	0.072
Median stone volume, mm^3 (IQR)	2743 (1451–4213)	3285 (2210–3775)	0.304
Mean stone density, HU ±SD	833.8 ±298.3 (400–1394)	882.3 ±408.5 (300–2100)	0.874
Median laser-on time, min (IQR)+	11.7 (10.0–15.5)	10.0 (6.0–12.1)	0.207
Median total energy for stone ablation, kJ (IQR) +	13.8 (11.8–25.0)	12.0 (7.0–20.1)	0.508
Median ablation speed mm^3/sec (IQR) +	3.9 (3.9–5.7)	5.0 (4.6–11.3)	0.085
Median ablation efficacy J/mm^3 (IQR) +	4.6 (2.9–5.5)	3.8 (2.1–5.8)	0.09
Median energy consumption J/sec (IQR) +	18.0 (15.1–22.5)	30.0 (23.8–34.2)	0.989
Retropulsion, n (%)	1 (7.1%)	14 (26.4%)	0.010*
Decreased visibility, n (%)	3 (21.4%)	11 (19.6%)	0.570

Data presented as mean ± standard deviation (SD) (range) or median (IQR) where appropriate
* – statistically significant difference with p <0.05
+ – in patients who underwent dusting
PCNL – percutaneous nephrolithotomy; RIRS – retrograde intrarenal surgery;
N – Number of patients; n – percentage of patients; IQR – interquartile range;
SD – standard deviation

Table 2. *Correlations between parameters in RIRS and PCNL*

Parameter	Stone density	Stone volume	Energy	Frequency	Ablation speed (mm³/sec)	Ablation efficacy (J/ mm³)	Energy consumption (J/sec)
RIRS							
Stone density	–	0.493 (0.104)	0.452 (0.140)	-0.043 (0.895)	0.549 (0.065)	-0.042 (0.897)	0.342 (0.277)
Stone volume	0.493 (0.104)	–	0.566 (0.035)*	-0.371 (0.192)	0.222 (0.445)	-0.390 (0.169)	-0.132 (0.653)
Laser-on time	-0.217 (0.499)	0.478 (0.084)	0.208 (0.475)	-0.349 (0.221)	-0.506 (0.065)	0.307 (0.286)	-0.370 (0.193)
Total energy	0.041 (0.900)	0.354 (0.214)	0.121 (0.681)	-0.005 (0.986)	-0.489 (0.076)	0.665 (0.009)*	0.305 (0.907)
Retropulsion	0.482 (0.112)	0.378 (0.182)	0.500 (0.069)	-0.477 (0.085)	0.241 (0.407)	-0.172 (0.557)	0.035 (0.907)
Visibility	-0.129 (0.705)	-0.049 (0.874)	-0.658 (0.014)*	0.704 (0.007)*	0.342 (0.253)	-0.195 (0.523)	0.589 (0.034)*
PCNL							
Stone density	–	-0.070 (0.613)	0.415 (0.002)*	-0.011 (0.937)	0.089 (0.607)	0.132 (0.340)	0.087 (0.614)
Stone volume	-0.070 (0.613)	–	0.109 (0.424)	-0.132 (0.334)	0.138 (0.424)	-0.371 (0.005)*	0.0 (1.0)
Laser-on time	0.239 (0.160)	0.274 (0.106)	0.559 (<0.001)*	-0.455 (0.005)*	-0.570 (<0.001)*	0.440 (0.007)*	0.063 (0.714)
Total energy	0.205 (0.136)	0.303 (0.023)*	0.339 (0.010)*	-0.189 (0.164)	-0.462 (0.005)*	0.388 (0.003)*	0.539 (0.001)*
Retropulsion	0.184 (0.183)	0.186 (0.170)	0.798 (<0.001)*	-0.676 (<0.001)*	-0.179 (0.296)	0.020 (0.886)	0.278 (0.101)
Visibility	0.182 (0.189)	0.089 (0.514)	0.170 (0.210)	-0.137 (0.315)	0.044 (0.799)	-0.010 (0.943)	-0.057 (0.739)

Presented as Pearson or Spearman (used where appropriate) coefficient (p-value)
* – significant correlation; RIRS – retrograde intrarenal surgery; PCNL – percutaneous nephrolithotomy; n – number of patients

ibility were reported in 3 (21.4%) cases (visibility score = 1). In PCNL minor difficulties with visibility were reported in 11 (19.6%) cases (visibility score = 1). No significant decreases in visibility that interfered with surgery were reported in any of the groups.

The stone-free rate (SFR) was 85.7% (12/14 cases) vs 89.3% (50/56 cases) in the RIRS and PCNL group, respectively (p = 0.505). The absence of residuals fragments (>3 mm) was 92.9% (13 cases) in the RIRS group and 94.6% (53 cases) in the PCNL group (p = 0.599). No predictors for stone-free rate were identified.

There were no differences in postoperative complications rates between the groups according to Clavien-Dindo. At a 3-month follow-up, contrast-enhanced CT imaging revealed no strictures or stenosis of the upper urinary tract in any patient (Table 3).

Table 3. *Complications*

Complications	RIRS (n = 14)	PCNL (n = 56)	p
Clavien Grade I			
Fever	1 (7.1)	4 (3.3)	0.648
Transient creatinine elevation	1 (7.1)	1 (1.9)	0.429
Clot retention	–	1 (1.9)	–
Clavien Grade II			
Transient urine leakage	–	1 (1.9)	–
Urinary tract infections	–	1 (1.9)	–

Data presented as n (%)
RIRS – retrograde intrarenal surgery; PCNL – percutaneous nephrolithotomy

DISCUSSION

SP TFL has already proven itself to be an effective tool for stone dusting. In first preclinical trials with Ho:YAG laser, it demonstrated a two-fold increased efficacy in fragmentation and more than 3-fold increased efficacy in dusting regimens [7]. It is worth mentioning that in clinical practice SP TFL also allowed for high efficiency and ablation speed in RIRS [8]. This increased efficacy can be explained by the higher frequency of SP TFL (up to 2000 Hz) compared to other laser devices [9]. Moreover, the increased energy density of SP TFL may allow for smaller dust formation during lithotripsy [10]. The smaller dust diameter has pivotal importance in RIRS as it increases the possibility of washing out all the stone fragments [11].

However, SP TFL is also effective for stone fragmentation which was confirmed both during in-vitro [7,12] and clinical trials [13]. SP TFL was observed to fragment stones more rapidly than the conventional holmium laser due to high pulse rates, high average power, and reduced stone retropulsion [12]. Preclinical trials showed an absence of significant retropulsion and temperature elevation during lithotripsy compared with standard Ho:YAG lithotripsy [7, 14] In clinical trials, the minimal rate of retropulsion was previously reported – 13%, we believe that an increased rate of retropulsion in PCNL in our study (24%) is associated with increased stone size which necessitated the use of high power regimens [13].

The primary outcome of this study was to compare the LOT between the RIRS and the PCNL group, which did not differ between the groups (11.7 minutes for the RIRS group and 10.0 minutes for the PCNL group). Previously, the achieved mean LOT was presented as 5.0 ±5.7 min for PCNL [13] and the median LOT was 4 min for RIRS [8]. However, in the current assessment, we were trying to compare only those patients who underwent dusting in both groups. That was the specific reason for increased LOT in comparison to previous trials. Neither retropulsion nor visibility correlated with LOT in the RIRS group; however, retropulsion had a significant correlation with LOT in the PCNL group probably due to higher energy output during PCNL.

Hardy et al. evaluated that the ablation rate is directly proportional to the SP TFL pulse rate. The authors concluded that higher SP TFL pulse rates lead to increased stone ablation rates which may have an obvious clinical benefit [15]. Currently, it is the higher frequency of SP TFL which distinguishes it from the other laser lithotripters, Keller et al. mentioned that high frequencies up to 200 Hz could lead to 3 times increased efficiency during dusting mode comparing with conventional Ho:YAG laser [16]. In the present study, the use of high frequencies was applied during RIRS and was associated with increased dust formation, higher lithotripsy speed, and an absence of retropulsion. One drawback of high frequency is lower visibility which also was demonstrated previously [8]. It should be mentioned that decreased visibility in higher frequencies was present only in the RIRS group whereas in the PCNL group we did not identify such a correlation [13]. However, despite suboptimal visibility in some cases no significant decreases in visibility (2 = poor visibility that needed to change the regimen) were registered.

In our study, we did not find any correlation between LOT or total energy and stone density. Additionally, stone density did not correlate either with ablation speed or ablation efficacy in both study groups, which is in line with the previous findings [8, 13]. In previous meta-analyses by Barone et al. and Tsai et al. it was shown that PCNL may have a higher rate of Hb drop or bleeding complications [17, 18]. The ability to identify such a difference may be associated with a smaller patient cohort in our study. Yet it should be mentioned that one of the major concerns regarding RIRS in larger stones is the possible temperature increase and laser-induced damage to the renal pelvis. In the current trial, we were unable to find any temperature-associated complications, bleeding due to mucosa damage, or late strictures of the upper urinary tract, which correlates with previous results [8, 13]. Reports focusing on the safety of the SP TFL also supports this data showing no extensive temperature increase or significant laser-induced damage to the mucosa, when comparing to the Ho:YAG laser [14, 19].

According to previous works in the field, RIRS tended to decrease the SFR at 3 months, when faced with PCNL [20]. SP TFL seems to be the perfect tool for a fine dusting of stones as it creates fragments less than 4 mm [2] and a 'fine dust' mostly with lower pulse energies (up to 0.15 J) and higher pulse rates (up to 2000 Hz) [10].

Limitations. The first: the relatively small cohort size. However, the current trial was a 'proof of concept' for ongoing large-scale trials on the topic. A second: the use of non-validated questionnaires (e.g. Likert scale from 0 to 2), which could be a potential source of bias. However, we believe that feedback from multiple surgeons allowed us to assess different opinions on laser performance and present reliable mean retropulsion and visibility scores. A third limitation is that the use of dusting regimens was limited in PCNL (0.8 J / 25–30 W / 31–38 Hz) which possibly led to lower overall energy used, making it comparable with the energy consumption in the RIRS group. Moreover, only patients with dusting regimens were included in the efficacy analysis. But, where the clinical data is concerned, all the patients were analyzed. The usage of fibers with different diameters (200 and 400 μm) could be a source of bias. However, 400 μm fibers are the most commonly used during PCNL procedure and reflect the live – surgery experience. The fact that a researcher participated in all surgeries and discussed the final score of each scale with surgeons allowed us to exclude inter-rater variability and to present data with a minimized bias.

CONCLUSIONS

Thulium-fiber laser (TFL) is a safe and effective modality for lithotripsy for both, retrograde intrarenal surgery (RIRS) and percutaneous nephrolithotomy (PCNL), achieving minimal retropulsion and good visibility. No discrepancies in procedure duration, complications, or laser-on time (LOT) were identified between the different modalities.

CONFLICTS OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

The study was approved by the Sechenov University (Moscow, Russia) institutional review board.

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INFORMED CONSENT

Informed consent was obtained from all individual participants included in the study.

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