Retrograde intrarenal surgery versus mini-percutaneous nephrolithotripsy to treat renal stones 20 mm or larger in diameter using holmium:YAG laser

Ayman Ali[a], Hany Mostafa[b], Ahmed Ismail[a], Mohamed Gamal[b], Ahmed Salah[a], Mamdouh Roshdy[a]

[a]Urology Department, Theodor Bilharz Research Institute, Giza, [b]Urology Department, Faculty of Medicine, Ain Shams University, Cairo, Egypt

Correspondence to Ayman Ali, MSC Urology Department, Theodor Bilharz Research Institute, P.O.Box 30, Imbaba, Giza 12411, Egypt. Tel: 02-25408277; fax: 02-25402582; e-mail: dr.aymansaad@hotmail.com

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Objective
To evaluate the efficacy and safety of mini-percutaneous nephrolithotripsy (mini-PCNL) and retrograde intrarenal surgery (RIRS) in the treatment of renal stones 20 mm or larger in the longest diameter using holmium:YAG laser.

Patients and methods
This was a prospective randomized study that included 40 patients who were divided into two groups, with 20 patients each. Group A underwent mini-PCNL using holmium:YAG laser lithotripsy for renal pelvic and calyceal stones. Group B underwent RIRS in which flexible ureteroscopy was used for pelvic and calyceal stones, and semi-rigid ureteroscope was used for only renal pelvic and upper calyceal stones using holmium:YAG laser. In both groups, the procedure outcomes in terms of operative time, blood loss, hospital stay, complications using modified Clavien grading system, the need of auxiliary procedures, and stone-free rates (SFRs) after 3 weeks by using CTUT were evaluated statistically.

Results
Statistical analysis of the data showed that there was significant difference in the operative time, which was higher in RIRS group compared with mini-PCNL group, whereas the blood loss in terms of mean±SD change in pre-treatment and post-treatment hemoglobin levels and the hospital stay were significantly higher in mini-PCNL group compared with RIRS group. The complications using modified Clavien grading system were higher in mini-PCNL group compared with RIRS group. The SFR was higher in mini-PCNL group.

Conclusion
In patients with renal stones 20 mm or larger, results showed that mini-PNCL has significantly shorter operative time with higher blood loss and longer hospital stay compared with RIRS. In both groups, the SFR and the need of the auxiliary procedures were comparable.

Keywords:
mini-percutaneous nephrolithotripsy, renal stones, retrograde intrarenal surgery

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Introduction

The incidence of renal stones has been increasing. Nephrolithiasis is one of the common causes of morbidity and deterioration of quality of life, with a lifetime prevalence of 5–10% [1]. Moreover, urolithiasis is a recurrent disease, with lifetime recurrence risks reaching 50% [2]. Dramatic improvement in minimally invasive techniques for treatment of renal stones is owing to the technological advances. Minimally invasive techniques include percutaneous nephrolithotomy (PCNL), extracorporeal shock wave lithotripsy (ESWL), and retrograde intrarenal surgery (RIRS) [3]. Although ESWL and RIRS are currently widely used as less invasive treatment modalities for renal stones, PCNL still has a role depending on the size, position, shape, and composition of the stones [3]. PCNL is recommended as the treatment of choice for large pelvic stones (>20 mm) and for stones of the lower calyx sized 10–20 mm with unfavorable factors for ESWL according to the updated guidelines of European Association of Urology [4]. The size of the tract is one of the most important factors influencing surgical morbidities associated with PCNL [5]. The mini-PCNL technique (tract size≤20 Fr) has been implemented with advances in technology. It offers comparable stone-free rates (SFRs) compared with standard PCNL, with less complications [6]. Pain and urine leak are markedly less after mini-PCNL than standard PCNL [5,6]. RIRS performed using a flexible ureterorenoscope marked the beginning of a new era in

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urology, as RIRS renders smaller kidney stones more accessible and upper urinary tract tumors treatable, using minimally invasive methods [7,8]. RIRS was first used to treat small kidney stones [9]. The approach attracted a great deal of attention, and it was suggested that larger stones could also be treated but over longer operative times. Initially, medium and then larger stones were treated via RIRS [10]. Some urologists have suggested that RIRS, which is associated with fewer complications and less morbidity, should be used to treat large stones also [8,10].

Patients and methods

This was a prospective randomized comparative study conducted on 40 male and female patients admitted to the Urology Department of Theodor Bilharz Research Institute during the period from December 2016 till September 2018. All patients had radio-opaque renal stones of at least 20 mm in the longest diameter and were subjected to either RIRS or mini-PCNL, including 27 male and 13 female patients, with age range from 21 to 74 years old, and the BMI ranged from 22 to 51 kg/m^2. Informed consent was signed by all patients included in the study after explaining to them the risks of each procedure (including bleeding, infection, and associated neighboring organ injury).

Treatment was assigned on a randomized basis using sealed opaque envelope technique. Group A included 20 (15 males and five females) patients who were treated by mini-percutaneous nephrolithotripsy (mini-PCNL) using holmium laser. Group B included 20 (12 males and eight females) patients who were treated by RIRS using flexible ureteroscope for any renal stone site using holmium laser (14 cases) or semi-rigid ureteroscope for only renal pelvic stones and upper calyceal stones using holmium laser (six cases). All patients underwent routine laboratory investigations before the operation.

Mini-PCNL technique was done in prone flexed position. Dilation of the track was done using the first metal Alken dilator over the curved wire and a 20-Fr Amplatz sheath was positioned, allowing the introduction of 19-Fr nephroscope (Elcon, Tuttlingen, Germany). The stones were disintegrated using the holmium:YAG laser (Asclepion 110 W machine, Jena, Germany) using 600-μm laser fiber (fragmentation approach). A 20-Fr nephrostomy catheter was applied at the end of the procedure under fluoroscopic guidance. The operative duration was estimated from cystoscopy time till securing the nephrostomy tube to the skin.

RIRS was done by using flexible ureteroscopy for any renal stone site or semi-rigid ureteroscope used only for renal pelvic and upper calyceal stones using holmium laser. In flexible ureretroscope (URS) technique, cystoscopy was performed to advance a hydrophilic guide wire (0.038-inch) to the renal pelvis with fluoroscopic assistance followed by retrograde pyelography using a 6 F ureteric catheter or dual-lumen 10-F ureteric catheter to assess the pelvicalyceal system anatomy and accurate stone site. The ureter is then dilated with Teflon ureteric dilators up to ureteropelvic junction and a ureteral access sheath (12/14 Fr) was passed over the guide wire through the ureteropelvic unction (UPJ). Flexible ureterorenoscope either Wolf Boa or Pusen single-use flexible ureteroscope. Kidney stones were dusted with the aid of a holmium laser (Asclepion 110 W machine) using laser fiber 200 μm. Semi-rigid ureteroscope was used in accessible pelvic and upper calyceal stones which were dusted using the holmium: YAG lasers 600 μm. The operative duration was calculated from the time of cystoscopy to Double J (JJ) insertion. In all cases of RIRS, there was a need to apply Double J (DJ) stent which was removed 3–8 weeks postoperatively.

On the first postoperative day, plain radiograph Kidney-urinary ladder (KUB) was routinely done to all patients in both groups to assess initial stone clearance and exclude obstruction. Spiral Computed Domography (CT) was obtained for patients in mini-PCNL group with residual in KUB to assess accurate residual size and site. The procedure was considered successful if the patient was stone free or had residual fragments up to 4 mm in diameter. In patients with residual stones (5–10 mm in diameter) in inaccessible calyx, the ureteral catheter was replaced by JJ stent, and ESWL was done 2 weeks later. In RIRS group, spiral CT was done after 3 weeks, and ESWL was done to residual stones larger than 4 mm in diameter.

The obtained results were tabulated as mean±SD. Comparison between both groups was made using Student's *t*-tests and χ^2-test. Differences were considered significant at *P* value less than 0.05. Statistical package of the social sciences (SPSS, IBM, New York, USA) computer software (version 14) was used to carry out the statistical analysis.

Results

Regarding the characteristics of the patients included in the study, the difference between both groups was

not significant regarding the mean age group, sex of patients, mean BMI, mean stone size, and mean stone density.

In group A, the operative time ranged from 75 to 125 min, whereas in group B, the operative time ranged from 65 to 140 min. Statistical analysis showed that the mean±SD operative time of group A was 100.25 ±12.9 min, which was significantly ($P<0.05$) lower compared with group B, which was 120.3±13.4 min.

The range of hospital stay in group A was from 3 to 5 days, whereas in group B was from 1 to 3 days. Group A had mean±SD hospital stay of 3.4500±0.604 days, which was significantly ($P<0.05$) higher compared with group B (1.2500±0.638 days).

Blood loss in terms of the change in hemoglobin (Hb) level on first postoperative day in group A was 1.098 ±0.398 g/dl, which was significantly higher ($P<0.05$) when compared with group B (0.456±0.356 g/dl), and there was no need for blood transfusion in both groups.

Regarding postoperative complications using modified Clavien grading system, six patients developed complications in group A, including three patients with transient fever more than 38°C (grade I), which required only the use of antipyretics, two patients with urine leakage less than 24 h after nephrostomy tube removal (grade II), which required delaying ureteric catheter removal for 48 h, and one patient with DJ stent who developed pyelonephritis on postoperative day 10 which required inpatient admission, fixation of urethral catheter, and IV antibiotics according to urine and blood cultures but the episode did not resolve. Decision was taken to remove the DJ (grade III). The episode clinically resolved, and the patient was discharged after complete remission of fever with normal white blood cells count and C-reactive protein (CRP) (Table 1).

However, in group B, only three patients developed complications, including two patients with transient fever more than 38°C (grade I), which required only the use of antipyretics, and one patient with ureteric DJ stent who developed pyelonephritis 1 week after the procedure, which required inpatient admission, fixation of urethral catheter, and IV antibiotics according to urine and blood cultures. The episode resolved on medical treatment with no further intervention required (grade II).

Regarding auxiliary procedure in group A, four patients underwent auxiliary procedures, where three underwent

Table 1 Patient demographics and study outcomes

Demographic data	Group A (mini-PCNL)	Group B (RIRS)	*P* value
Number of patients	20	20	
BMI (kg/m^2)	27.850±3.183	29.700±7.927	0.339
Sex			
Female	5/20 (25)	8/20 (40)	
Male	15/20 (75)	12/20 (60)	
Stone size	2.665±0.470	2.430±0.255	0.057
Stone density	1068.81±383	1031.35±358	0.686
Site of renal stones			
Renal pelvis	8 out of 20	12 out of 20	
Calyceal	2 out of 20	3 out of 20	
	Upper 0 out of 2	Upper 2 out of 3	
	Middle 0 out of 2	Middle 1 out of 3	
	Lower 2 out of 2	Lower 0 out of 3	
Pelvic and calyceal	10 out of 20	5 out of 20	
Outcomes			
Operative time (min)	100.250±12.924	120.333±13.425	0.0001*
Hospital stay (days)	3.4500±0.604	1.2500±0.638	0.0001*
Blood loss (change in hemoglobin level) (g/dl)	1.098±0.398	0.456±0.356	0.0001*
Complications			
Grade 1	3/6	2/3	
Grade 2	2/6	1/3	
Grade 3	1 (6)	0	
Grade 4	0	0	
Stone-free rate	16/20	13/20	0.288
Patients underwent auxiliary procedure	4/20	6/20	

Mini-PCNL, mini-percutaneous nephrolithotripsy; RIRS, retrograde intrarenal surgery. *$P<0.05$, significantly different.

one session of ESWL because of inaccessible residual calyceal renal stones more than 4 mm and less than 1 cm, and one patient with DJ stent developed pyelonephritis, requiring removal after failure of medical treatment with antimicrobial according to culture.

Regarding failed procedures in group A, one patient underwent RIRS because of failure to reach the stone, which was an intrarenal pelvis of a double moiety kidney with narrow calyceal necks.

Regarding auxiliary procedures in group B, six patients underwent ESWL (four patients underwent one session and two patient underwent two sessions) because of residual calyceal stones more than 4 mm and less than 1 cm. All patients in group B underwent removal of DJ stent after 3–8 weeks.

Regarding failed procedures in group B, one patient underwent mini-PCNL because of failure of ureteric dilation and placement of ureteral access sheath.

Discussion

With the improvements in the technology of RIRS, several recent studies have found RIRS with the use of holmium laser lithotripsy can be an effective and safe option for larger renal stones [10]. Moreover, as it is less invasive than conventional PCNL, URS/laser lithotripsy has become an increasingly considered option for patients, especially for the stones in an intermediate size range 2–3 cm especially with innovation of auxiliary equipment such as guide wires, ureteral access sheaths, and stone baskets [11]. However, the high retreatment rate and high cost of flexible ureteroscopic replacement and repair remain the major issues for such a technique. On the contrary, PCNL is still recommended as a first-line treatment for kidney stones more than 2 cm by the European urological guidelines 2018 on urolithiasis [12]. Mini-PCNL is postulated to be less invasive than standard PCNL with decreased Hb drop, less requirement of analgesics, shorter hospital stay, and comparable SFRs [13]. Therefore, mini-PCNL is a safe and efficient solution for large renal stones [14].

Regarding the characteristics of the patients included in this study, the difference between both groups was not significant regarding the mean age group, sex of patients, mean BMI, mean stone size, and mean stone density.

Operative time is not clearly defined for the procedure of PCNL; the procedure includes many steps of variable duration (urethrocystoscopy and ureteral stent insertion, patient repositioning, puncture, dilatation, and nephroscopy). In this study, the operative time in mini-PCNL group was calculated from the time of cystoscopy till securing the nephrostomy tube to the skin similar to the study of De Sio *et al.* [15], on prone position versus modified supine in PCNL for treatment of renal stones.

In RIRS group, the operative time was calculated from time of cystoscopy to JJ insertion, similar to the study of Prabhakar [16], who studied RIRS for large (1.6–3.5 cm) renal stones, calculating the operative time from the start of the endoscopic procedure till catheterization.

The mean operative time of mini-PCNL group was 100.25±12.9 min, which was significantly lower compared with RIRS group, which was 120.3 ±13.4 min. These results are similar to the study of Knoll *et al.*, 2011 [17], who studied flexible ureterorenoscopy versus mini-PCNL on renal calculi of 10–30 mm in size and revealed that the mean operative time was 106±51 and 59±15 min, respectively; the study of Pan *et al.* [18], who studied RIRS versus mini-PCNL for single renal stone of 2–3 cm where the mean operative time was significantly prolonged in RIRS group than in mini-PCNL group (73.07±13.5 vs. 62.39±10.6 min, respectively); and the study by Zeng *et al.* [19], who compared between mini-PCNL and RIRS for treatment of renal stones larger than 2 cm in patients with a solitary kidney, where the mini-PCNL group had a shorter operation time (43.79 min) than RIRS group (55.38 min). In the study of Salvadó *et al.* [20], which presented a series of patients who underwent endoscopic surgery as a treatment for renal stones using the digital disposable ureteroscope, Uscope 3022 (Pusen, Zhuhai, Guangdong province, China), which was the same flexible ureteroscope used in the present study in 10 cases of group B, and recorded 123.3±29.4 min for operative time. These results were comparable to the operative time in this study, which was 120.3±13.4 min in the RIRS arm. However, in the systematic review and meta-analysis of Davis *et al.* [21], comparing the efficacy and safety of mini-PCNL versus RIRS in renal stones treatment, 15 studies reported on the operative time, and there was no significant difference between both groups (72.6. ±23.5 min for mini-PCNL vs. 72.1±24.4 min for RIRS).

Regarding hospital stay in this study, statistical analysis showed that the mean hospital stay of mini-PCNL group (3.4500±0.604 days) was significantly higher

compared with RIRS group (1.2500±0.638 days) calculated from the day of surgery to the day of discharge. These results were comparable to those of Zeng *et al*. [19], who stated that the mean hospital stay was significantly shorter in RIRS group when compared with mini-PCNL group for stones larger than 2 cm. Comparable results were observed also in the study of Pan *et al*. [18], on single renal stones of 2–3 cm using RIRS and mini-PCNL techniques, which reported that the hospital stay was 1.95±1.3 and 4.47±1.4 days, respectively.

Similarly, in the systematic review and meta-analysis of Davis *et al*. [21], which compared the clinical efficacy and safety profile of mini-PCNL versus RIRS, the mean hospital stay was significantly longer in the mini-PCNL group compared with the RIRS group (4±1.6 and 2.5±2.2 days, respectively).

In terms of the mean change in Hb level in mini-PCNL group blood loss was 1.098±0.398 g/dl, which was significantly higher when compared with RIRS group (0.456±0.356 g/dl), but there was no need for blood transfusion in both groups. Pan *et al*. [18], recorded comparable results to the current study while studying RIRS versus mini-PCNL for single renal stone of 2–3 cm in diameter; there was significant difference in blood loss (0.491±4.7 and 1.28±8.1 g/dl, respectively). On the contrary, the study by Knoll *et al*.[17], used the mini-PCNL versus flexible ureterorenoscopy on renal caliculi of 10–30 mm in size and stated that blood loss was not significant between both groups by comparing the preoperative and postoperative Hb levels. The study by Zeng *et al*. [19], comparing the results of mini-PCNL and RIRS for stones larger than 2 cm showed no significant difference in the mean decrease of Hb level between the two groups by comparing the preoperative and postoperative Hb levels, which were 1.085±0.94 and 0.93±0.73 g/dl, respectively. One patient in RIRS and two patients in mini-PCNL group needed blood transfusion.

Regarding postoperative complications of this study by using modified Clavien grading system, six patients developed complications in mini-PCNL group with percentage rate of 30% (three patients had grade I complications in the form of transient fever<38°C, two patients had grade II complications in the form of urine leakage<24 h after nephrostomy tube removal, and 1 patient had grade III complications in the form of pyelonephritis), whereas only three patients developed complications in RIRS group, with percentage rate of 15% (two patients had grade I complications in the form of transient fever<38°C, and one patient had grade II complications in the form of pyelonephritis). These results are comparable to the study of Pan *et al*. [18], in RIRS group, who found that the complication rate in this group was 16% among patients who underwent RIRS in the form of fever (four patients), urosepsis (three patients), bleeding (one patient), and perforation (one patient), whereas these results are not comparable in mini-PNCL group in which seven (12.5%) of 56 patients developed complications in the form of fever (two patients), urosepsis (one patients), bleeding (three patient), and perforation (one patient), but these complications were not categorized according to modified Clavien system.

Moreover, the study by Knoll *et al*. [17], which compared the mini-PCNL versus RIRS on renal caliculi of 10–30 mm in size, found that the postoperative complications in the mini-PCNL arm was four of 19 patients, representing 21%, in the form of perforation (one patient), bleeding (one patient), and fever (two patients), whereas in the RIRS arm, five of 21 patients, representing 23% of the patients, developed complications in the form of perforation (one patients), bleeding (two patients), and fever (two patient), but these complications were not categorized according to the modified Clavien system.

The study by Zeng *et al*. [19], which compared the results of mini-PCNL and RIRS for stones larger than 2 cm, showed that the overall complications were close between RIRS and mini-PCNL groups (24.53 and 18.87%, respectively). These results are comparable to the results of the present study despite the higher complications in mini-PCNL group than the RIRS group. Zeng *et al*. [19], stated that in mini-PCNL group nine of 53 patients had Clavien grade 1, four patients had Clavien grade 2, and only one patient had Clavien grade 3, whereas in RIRS group 10 of 53 patients had Clavien grade 1, five patients had Clavien grade 2, one patient had Clavien grade 3, and one patient had Clavien grade 4. However, the study by Salvadó *et al*. [20], which presented a series of patients who underwent endoscopic surgery as treatment for renal stones using the digital disposable ureteroscope Uscope 3022 (Pusen), found that patients with renal stones larger than 20 mm in their longest diameter had no complications at all (zero of six patients). Davis *et al*. [21] conducted a systematic review and meta-analysis of comparing the efficacy and safety of mini-PCNL versus RIRS and reported that the complication rates were not significantly different between mini-PCNL and RIRS (19.5±19.1 vs. 15.5±18.9%, respectively).

The SFR in this study was estimated after 3 weeks by using noncontrast spiral CT imaging. We found that 16 (80%) of 20 patients treated in the mini-PCNL group, were stone free, whereas in RIRS group, 13 (65%) of 20 patients were stone free. In the study by Pan *et al.* [18], estimated SFR after 4 weeks of treatment of renal stone of 2–3 cm when using RIRS was 71.4%, whereas in mini-PCNL, it was 96.6%, which was statistically significant. However, the study by Alhamrani *et al.* [22], on RIRS and mini-PCNL for the treatment of renal stones larger than 2 cm, found that the SFR in RIRS group was 67.4 versus 90.3% in the mini-PCNL group. Moreover, the study by Salvadó *et al.* [20] presented a series of patients who underwent endoscopic surgery as treatment for renal stones using the digital disposable ureteroscope Uscope 3022 Pusen and found that the SFR in patients with renal stones larger than 20 mm was 78.3%. Moreover, in the systematic review and meta-analysis by Davis *et al.* [21] comparing the clinical efficacy and safety profile of mini-PCNL versus RIRS, two studies compared SFRs for calculi more than 2 cm and revealed higher significance in the mini-PCNL group compared with the RIRS group (84.8±17.6 and 57.8±19.8%, respectively).

Conclusion

In patients with renal stones 20 mm or larger, this study showed that mini-PNCL has higher but comparable SFR and shorter operative time than RIRS at the expense of higher complication rate, blood loss, and longer hospital stay. Both techniques are safe and effective with no superiority of one over the other. They can be alternative and complementary to each other in failed cases. In many clinical scenarios for treatment, there may be more than one reasonable approach, and the choice of surgical approach is dictated by patient factors, available equipment, and surgeon practice patterns. Therefore, it is advisable to weigh the benefits and risks of each technique according to the previously mentioned characteristics and choose the optimal option for patients.

Recommendation

Larger-volume prospective randomized controlled trials are needed to confirm these findings.

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Conflicts of interest

There are no conflicts of interest.

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