



Cohort Study

Evaluation of mini-PCNL and RIRS for renal stones 1–2 cm in an economically challenged setting: A prospective cohort study

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ABSTRACT

Introduction: Retrograde intrarenal surgery (RIRS) and mini-percutaneous nephrolithotomy (mPCNL) are viable options for the treatment of renal calculi 1–2 cm. Both have their pros and cons, but also vary in costs. We aimed to evaluate them in an economically challenged setting.

Methods: Two-hundred-seventy-one patients who underwent mPCNL (120) or RIRS (151) for renal calculi 1–2 cm were recruited in the study. Cases were comparatively statistically analyzed for differences in patient and stone parameters, duration of operation and hospital stay, and clinical outcomes such as stone free rate and complications. Local costs were calculated compared.

Results: Patient and stone parameters did not differ for both procedures. Stone free rate was slightly higher for mPCNL, and significantly higher in the lower pole. Hospitalization was shorter for RIRS, but operation times did not differ significantly. Neither did the complication rates. There was a significantly higher Hb drop for mPCNL, but that did not translate in a significantly higher transfusion rate.

Conclusion: Given the fact that all parameters were very similar or not statistically significant, choosing and the option comes down to other factors, such as availability of methodology and infrastructure, availability of surgical competence, surgeon's preference, and patient's preference. Both mPCNL and RIRS, are viable, safe, and efficient options for the treatment of renal stones 1–2 cm in size. mPCNL is the more cost-effective option and therefore should be considered if minimally invasive treatment is endeavored in economically challenged countries.

1. Introduction

There has been an attempt to decrease the perioperative morbidity of standard percutaneous nephrolithotomy (PCNL) through the introduction of miniaturized PCNL (MPCNL) [1,2]. The assumption is that the smaller the diameter of the PCNL tract, the less renal parenchymal injury will be inflicted [3–5].

On the other hand, flexible ureterorenoscopy (fURS) has developed enormously through the evolution of laser technology, the miniaturization of the scope diameter with simultaneously offering working channels large enough to accommodate all necessary accessories,

enhanced digitalized image quality, and enhanced mechanical properties such as deflection and durability. This has greatly expanded the indications of retrograde intrarenal surgery (RIRS) by means of fURS [6–8].

It is well established in international guidelines that most renal stones >2 cm in diameter should be treated with PCNL and those with a diameter <1–2 cm with RIRS; however, mini-PCNL constitutes a viable and effective minimally invasive treatment option for ever smaller stones, whereas the limits of RIRS are continuously pushed towards ever larger stones.

Both methods have their pros and cons, but also vary in costs.

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Miniaturized PCNL instruments are reusable many times, whereas flexible ureteroscopes and devices are either disposable or still very fragile. The latter results in high running and/or repair costs on top of the necessary capital investment to buy the equipment in the first place. This is particularly important in a developing country like Iraq. International comparative studies from the western world might therefore not apply fully to our situation on the ground where economic limitations are a deciding factor.

Therefore, we attempted in this study to compare the local clinical outcomes for mPCNL and RIRS in the management of renal stones < 2 cm in diameter.

2. Methods

2.1. Registration

The current study was registered in accordance with the Helsinki declaration – “Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject”. The study was registered in the Research Registry with a registration number of (8070). The link is https://www.researchregistry.com/register-now#home/?view_2_search=%09researchregistry8070&view_2_page=1.

2.2. Setting and study design

During a period of 20 months, 271 patients who underwent either mPCNL (120 patients) or RIRS (151 patients) for a renal calculus ≤ 2 cm in diameter were included in our prospective cohort study. They were informed about treatment options, possible complications, and the potential need for a staged or ancillary procedure to achieve stone clearance. All patients were operated by the same experienced endourologist. In accordance with STROCSS 2021 guidelines the current study was written [9].

2.3. Ethical considerations

The study was approved by the local ethical committee. Patients were consented to the study and informed about various treatment options, possible complications, and the potential need for a staged or ancillary procedure.

2.4. Inclusion and exclusion criteria

Inclusion criterium was one renal stone ≤ 2 cm anywhere in the renal collecting system. Patients with abnormal renal anatomy (i.e. horseshoe, pelvic, or malrotated kidney), pregnant women, and pediatric patients (<17 years) were excluded.

2.5. Pre-treatment assessment

All patients underwent a routine preoperative workup with urinalysis, urine culture, complete blood count, serum biochemistry, and coagulation profile. Pre-operative imaging included an ultrasound kidney-ureter-bladder (US KUB), intravenous urography (IVU), or a non-contrast CT scan in all cases to assess the anatomy of the collecting system and determine the exact size and location of the renal stone.

2.6. Data collection

Patients' demographic data recorded included age, gender, body mass index (BMI), and history of ipsilateral renal surgery. Stone parameters recorded included stone size (in mm), location, side and Hounsfield units on the preoperative CT. Complications were classified according to the Clavien classification system [10] (Table 1).

For this study, the stone size was defined as the maximum diameter

Table 1
Modified Clavien grading system [10].

Clavien grade	Complication
I	Fever. Pain. Transient increase in creatinine. Postoperative nausea and vomiting. Transient hearing loss secondary to prophylactic amikacin.
II	Nephrostomy site leakage for 12 h Blood transfusion Episode of fast atrial fibrillation Infection requiring additional antibiotics
IIIa	Double-J stent placement for urine leakage >24 h Double-J stent placement for uretero-pelvic junction and pelvis injury Stent migration Urinoma Pneumothorax Retention and colic due to blood clots Perirenal hematoma
IIIb	Ureter-bladder stone. Calyx neck stricture. Secondary uretero-pelvic junction stenosis. Arterio-venous fistula. Intra-operative bleeding requiring quitting the operation. Intra-operative pus requiring quitting the operation.
IVa	Neighboring organ injury
IVb	Myocardial infarction
V	Urosepsis Death

of the single stone on non-contrast CT.

2.7. Procedure

RIRS was performed under either general or spinal anesthesia. Initially, a semi-rigid ureteroscopy with a diameter of 9.5F (Karl Storz, Tuttlingen, Germany) was used to dilate the ureter and assess eventual ureter pathologies and stones. We did not routinely use a ureteric access sheath except in selected cases where, due to a large stone burden, frequent re-insertions of the scope and basketing of fragments were anticipated.

Subsequently, RIRS was performed with either a flexible reusable URS (Flex-X2S, Karl Storz, Tuttlingen, Germany) or a digital disposable URS (Uscope 3022, Zhuhai Pusen Medical Technology, Guangdong, China).

The stone was fragmented using a full dusting technique (0.5–0.8 J/15–30 Hz) with a Ho: YAG laser (cyber Ho 60 holmium laser system, Quanta, Milan, Italy). At the end of the procedure, the entire pelvicalyceal system was visualized for any residual stone fragments. A 6F/26 cm double-J stent was placed in all cases. Patients were usually discharged on postoperative day 1.

Miniaturized PCNL was performed in the prone position. The tract was created under fluoroscopic guidance using serial coaxial telescopic dilators. Amplatz sheaths of 16–20F were used. A 12F nephroscope (RZ-Medizintechnik GmbH, Tuttlingen, Germany) was used in all cases. Laser lithotripsy was performed in a similar way as described above for RIRS. At the end of the procedure, the entire collecting system was examined by direct endoscopic examination and fluoroscopy to confirm complete stone clearance. A 6F/26 cm double-J stent was inserted in selected cases with infected stone, pelvi-calyceal injuries and extravasation. A bladder catheter and a 12-14Fr nephrostomy tube (12–14F) were left in all cases. The nephrostomy tube and the bladder catheter were usually removed on postoperative day 1 when urine was clear.

2.8. Patient follow-up

Follow-up imaging included US KUB and Xray KUB at 2 weeks and 3

months. At the 2-week visit, the double-J stent was removed if there were no significant residual fragments. Otherwise, the patient would be scheduled for an ancillary procedure. Complete stone clearance with no residual fragments at 3 months was defined as stone free.

Comparative parameters between mPCNL and RIRS were a) procedure time, b) hospital stay, c) complications, d) Hb-drop, e) transfusion rate and f) Stone-free rate at 3 months' follow-up.

2.9. Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS version 21). Chi-square and Fisher's exact tests of association were used to compare proportions. The student's t-test was used to compare the means of the two groups. A p-value of ≤ 0.05 was considered statistically significant.

3. Results

In this study, 271 patients with a renal calculus ≤ 2 cm participated. One hundred twenty underwent mPCNL, 151 patients were treated by RIRS. Patient and stone characteristics were not significantly different in both groups (Table 2).

The average stones size was 16.02 mm for mPCNL and 15.03 mm for RIRS, respectively. The overall stone free rate (SFR) after a single session was significantly greater for mPCNL with 93% compared to RIRS with 89%, respectively. When stratified for intrarenal stone location, the difference did not significantly differ for the renal pelvis, the upper and middle pole. However, it was even more significant in the lower pole with 98% for mPCNL versus 78% for RIRS, respectively.

Mean Hb drop was 0.78 gm for mPCNL versus 0.2 gm for RIRS, respectively. This difference was statistically significant. Two patients required blood transfusions, both underwent mPCNL. However, this finding was not statistically different.

Hospitalization was significantly shorter for RIRS with 1.01 days versus 1.18 days for mPCNL ($p = 0.029$).

Table 2
Demographic and preoperative characteristics.

Parameters	MPCNL	RIRS	p. value
Number of patients	120	151	
Mean age \pm SD (year)	42.75 \pm 16.15	41.12 \pm 13.7	0.037
Mean BMI \pm SD (Kg/m ²)	27.36 \pm 6.1	28.1 \pm 5.4	0.42
Gender 0.15			
Female (%)	34(28.3)	60(39.7)	0.15
Male (%)	86(71.7)	91(60.3)	
Mean stone size \pm SD (mm)	16.02 \pm 2.9	15.03 \pm 3.46	0.069
Previous intervention (%)			
(-)	101(84.2)	106(70.2)	0.015*
(+)	19(15.8)	45(29.8)	
Laterality (%)			
Right	53(44.2)	60(39.7)	0.609
Left	67(55.)	91(60.3)	
Stone number (%)			
Single	97 (80.8)	110(72.8)	0.06
Multiple	23 (19.2)	41(27.2)	
Mean stone density \pm SD H.U)	963.51 \pm 323.23	951.08 \pm 335.07	0.75
Hydronephrosis (%)			
Mild or no Hydronephrosis	63(52.5)	89 (58.9)	0.87
Moderate	45(37.5)	53(35.1)	
Severe	12(10)	9(6.0)	
Stone localization			
upper calyx	15	17	0.74
middle calyx	19	26	0.75
lower calyx	31	32	0.36
single pelvis	29	60	0.006*
multiple calyx	26	16	0.012*

MPCNL: mini-percutaneous nephrolithotomy; RIRS retrograde intrarenal surgery, SFR: stone free rate; BMI: body mass index, (*): statistically significant using student t-test, Hb: hemoglobin.

Complications were few and differences were not statistically significant between the two procedures.

No serious complications (Clavien > III) were encountered for mPCNL. For RIRS, two (1.3%) patients required a second session ureteroscopy (Clavien IIIb) due to fragments in the ureter causing renal colic, and one patient (0.7%) developing urosepsis (Clavien IVb) necessitating an extended hospitalization (Table 3).

4. Discussion

Currently, the most common minimally invasive management options for the treatment of mid-sized renal calculi (10–20 mm) are extracorporeal shock wave lithotripsy (ESWL), standard PCNL, mPCNL, and RIRS [11,12]. Miniaturized PCNL has become an accepted way to reduce perioperative morbidity of PCNL [3,13,14]. However, the technological advancement in flexible URS has expanded indications for RIRS that, in turn, has shown a favorable risk profile as compared to PCNL [15–17]. Therefore, mPCNL and RIRS are now competing for the same mid-sized stones.

The overall stone free rate in our hands was significantly higher after mPCNL (93.3 vs 89.4%; $p = 0.001$). Most other studies confirmed the superiority of mPCNL [14,17–20]. However, in some studies, SFR were found similar [16,22]. or even better for RIRS [23].

In the lower pole, there is a clear advantage of mPCNL with significantly higher SFR. This corresponds with the literature [18,24–26]. Difficult retrograde access and reduced maneuverability of the ureteroscope in the lower pole can jeopardize a successful RIRS [12].

Regarding procedures' safety profiles both methods are considered safe [14,18,21–23], and rates of complications were generally low in our study as well. Although mPCNL had a slightly higher overall complication rate with 15.8% versus 9.3% for RIRS, this difference did not reach statistical significance.

When stratified according to the Clavien-Dindo classification [10], most complications for both methods were Clavien I-II, and the rate did not differ significantly between them. Two patients required blood transfusions after mPCNL. Two patients had more serious Clavien-graded complications (IIIb) after RIRS, namely a Steinstrasse requiring further intervention (URS), and urosepsis.

There was a significant Hb drop after mPCNL which has been documented in the literature as well [22,27].

Given the fact that all the other parameters (Table 2) were very similar or not statistically significant, we may conclude that both options are viable, safe, and effective for stones < 2 cm in size.

Consequently, when choosing an option, it comes down to other

Table 3
Operative and postoperative outcomes.

Parameters	MPCNL	RIRS	P value
Mean operative time \pm SD (min)	39.58 \pm 24.713	38.79 \pm 10.66	0.42
Overall Stone free (%) \pm SD	93.3 \pm 0.25	89.4 \pm 0.309	0.001*
SFR according to the location:			
Upper calyx (free rate%)	14/15(93.3)	15/17(88.2)	0.64
Middle calyx (free rate%)	17/19(89.1)	22/26(84.6)	0.072
Lower calyx (free rate%)	30/31(97.0)	25/32(78.1)	0.024**
Single pelvis (free rate%)	28/29(97)	49/60(81.7)	0.12
Multiple calyx (free rate%)	23/26(88.5)	12/16(75.0)	0.28
Hb. drop. g/dl \pm SD	0.78 \pm 0.49	0.3 \pm 0.2	0.001*
Mean hospitalization times (day)	1.18 \pm 0.944	1.01 \pm 0.115	0.029*
Complications %			
Fever (Clavien I)	10(8.3)	8(5.3)	0.262
UTI (Clavien II)	1(0.8)	3(1.9)	0.631
urine leak \geq 12 h (Clavien II)	6(5)	0	1.0
blood transfusion (Clavien II)	2(1.6)	0	0.49
Stienstrasse (Clavien III _b)	0	2(1.3)	0.49
sepsis (Clavien IV _b)	0	1(0.7)	1.0

MPCNL: mini-percutaneous nephrolithotomy; RIRS retrograde intrarenal surgery, SFR: stone free rate; (*): statistically significant using student t-test; (**): statistically significant using chi square test, Hb: hemoglobin.

factors such as a) availability of methodology and infrastructure, b) availability of surgical competence, c) surgeon's preference and d) patient's preference.

In endourology, there is always the capital investment in a technology (instruments, light source, camera, disposables) and the running costs. Here, mPCNL has a huge advantage since the capital investment is less than for RIRS, and the metallic scopes and instruments are less fragile and can be sterilized and used many times without damage. An initial investment of <10,000USD when switching from PCNL to mPCNL will set you on track for quite some time.

On the other hand, flexible ureterorenoscopes remain fragile and need repair (7,500USD) and replacement (15,000USD) after an average of <20 uses in general [3,20,21].

As for running costs, mPCNL requires fewer disposables. Running costs remain limited. For RIRS, disposables are indispensable and expensive. If disposable scopes are used, this adds to the running costs at 600-900USD per case [20,21]. Other running costs such as operation theatre time and time in the hospital have been found comparable.

Surgeon's choice may depend again on various factors. Expertise in one or another technique is certainly paramount. In addition, patients should always be consented for all available options. In many countries, patients will have to pay or part-pay for treatment. Then, of course, factors like costs of disposables weigh in heavily.

5. Conclusions

Both, mPCNL and RIRS, are viable, safe and efficient options for the treatment of renal stones 1–2 cm in size. Miniaturized PCNL may have an advantage in stones in the lower pole. More importantly, mPCNL is the more cost-effective option and therefore should be considered if minimally invasive treatment is endeavored in economically challenged countries.

Ethical approval

Ethical approval was obtained from the ethical committee of the university of Sulaymaniyah -college of medicine (approval no.55).

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No source to be stated.

Author contribution

Sarwar Mahmood: The endourologist who operated on the patients, follow up, and final approval of the manuscript. Rawa Bapir: literature review, writing the first draft of the manuscript, and final approval of the manuscript. Hewa Tawfeeq: Data collection, and Final approval of the manuscript. Saman Salih Fakhralddin: Writing the first draft of the manuscript, Final approval of the manuscript. Renato N. Pedro: Wrote an amended the second draft, and final approval of the manuscript. Berwn A. Abdulla: Literature review, and final approval of the manuscript. Choman J. Ahmed: Data collection, and writing the first draft of the manuscript. Noor Buchholz: Supervised the manuscript, and final approval of the manuscript.

Conflicts of interest

There is no conflict to be declared.

Registration of research studies

The study was registered in the Research Registry with a registration number of (8070). The link is

https://www.researchregistry.com/register-now#home/?view_2_se arch=%09researchregistry8070&view_2_page=1.

Guarantor

Rawa Bapir is Guarantor of this submission.

Consent

Consent has been taken from the patients and the family of the patients.

Provenance and peer review

Not commissioned, externally peer reviewed.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.amsu.2022.104235>.

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