Cohort Study

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Kidney stone management in the era of miniaturized percutaneous nephrolithotomy: does it improve safety? a prospective cohort study

Aymen Sakly, MD*, Walid Zakhama, MD, Nejm Jleli, MD, Anas Chafik, MD, Yassine Binous, MD

Objective: to compare the safety and the efficacy of standard percutaneous nephrolithotomy (sPCNL) vs. mini PCNL (mPCNL).
Methods: The authors conducted a prospective single-centre cohort study over a 2-year period of all consecutive patients who underwent sPCNL or mPCNL for 2–4 cm renal stones. Patients with active urinary tract infection, abnormal coagulopathy state, malformative uropathies and multitract-access procedures were excluded. In total, 90 patients underwent sPCNL using a 30 Fr access sheath with 24 Fr nephroscope while 52 patients underwent mPCNL using a mPCNL system: 12 Fr nephroscope and a 16.5/17.5F access sheath. Blood loss estimation was assessed postoperatively after 6 h by considering haemoglobin drop and blood transfusion if required. Stone free rate at 1 month was defined by the absence of stone or residual fragments less than or equal to 3 mm on computed tomography scan.
Results: Stone characteristics were comparable in both treatment arms. The mean stone size was comparable for sPCNL and mPCNL groups (32.6 ± 10.8 mm vs. 29.4 ± 11.8 mm). Operative time was longer in the mPCNL group (124 ± 40.4 min vs. 95.8 ± 32.3 min, $P < 0.001$). According to the Clavien–Dindo classification, no statistical difference was found between the groups in terms of complication rate ($P = 0.092$). However, the mean of haemoglobin drop and transfusion rate were significantly in favour of mPCNL (1.43 ± 1.5 vs. 0.88 ± 1.4 g/dcl, $P = 0.04$). Hospital stay was found to be significantly shorter for patients undergoing mPCNL (4.4 ± 3.9 vs. 2.7 ± 1.7 days, $P < 0.001$). The success rate in the sPCNL group was higher than mPCNL group in terms of stone clearance at one month (69.4% vs. 62.7%, $P = 0.06$).
Conclusion: Both sPCNL and mPCNL have shown good outcomes in this indication. Although the stone free rate was equal for both techniques, hospital stay, bleeding and transfusion rate are much lower with the use of mPCNL.

Keywords: Bleeding, minimally invasive surgery, outcome assessment, percutaneous nephrolithotomy, renal stone

Introduction

Recently, there has been a paradigm shift in the management of nephrolithiasis resulting from the technological advances and growing experience which have dramatically changed the concepts of kidney stone management in the last two decades.

Percutaneous nephrolithotomy remains the reference technique for the treatment of renal stones greater than or equal to 2 cm as recommended by international guidelines. This approach has shown high rates of stone clearance in comparison with ureteroscopy and extracorporeal shockwave.

HIGHLIGHTS

- Percutaneous nephrolithotomy (PCNL) is the recommended option to treat kidney stones greater than 2 cm.
- Both standard PCNL (sPCNL) and mini PCNL (mPCNL) have shown good outcomes in this indication.
- The success rate for sPCNL group was higher than standard mPCNL group in terms of stone clearance at the first month, but this difference was not statistically significant.
- Hospital stay, bleeding and transfusion rates are much lower with the use of mPCNL.

In fact, mPCNL was first introduced by Jackman et Helal in the paediatric population in 1997 to reduce parenchymal damage, then it was adopted to adults[1]. Further miniaturisation of the access tract has led to the introduction of ultra-mPCNL and micro PCNL[2]. The learning curve is faster in high volume centres. Owing to promising results, many centres have invested in acquiring mPCNL equipment.

Despite the continuous efforts to reduce the access sheath diameter, urologists are still apprehensive of haemorrhagic complications. In fact, bleeding and infections are the most serious concerns for urologists. A debate is ongoing regarding the safety and efficacy of these techniques.

Department of urology, University Hospital Tahar SfarMahdia, Tunisia

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**Corresponding author. Address: Universite de Monastir Faculte de Medecine de Monastir, Monastir, Tunisia. Tel: +21697444965. E-mail address: dr.aymen.sakly@gmail.com (A. Sakly).*

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Methods

Patients and methods

We carried out a prospective single-centre cohort study over a 2-year period of all consecutive patients who underwent sPCNL or mPCNL procedures for renal stones. This study has been reported in line with the STROCSS 2021 criteria[3]. The patients were assigned to groups based on stone complexity and burden volume. Patients with complete or partial staghorn calculi or a burden volume less than 3 cm or multiple calculi less than 3 were assigned mostly to the sPCNL group.

The primary objective of this study was to assess haemorrhagic complications basing on haemoglobin drop and transfusion rate. Secondary objectives were to investigate stone free rate (SFR), operative time, hospital stay and overall complications. Patients with 2–4 cm renal stones were included. Patients with active urinary tract infection, abnormal coagulopathy state, malformative uropathies and multitract-access procedures were excluded. All eligible patients who met the selection criteria were included. Data concerning stone characteristics, patient details, and intraoperative and postoperative parameters were recorded. The preoperative assessment included patients' past medical history, physical examination, blood tests and urine culture. Computerised tomography (CT)-scan) was indicated for all patients before surgery to assess stone characteristics, and the pelvicalyceal system anatomy and to rule out a retro-renal bowel. The stone size was measured by analysing the stone longest diameter or in cases of multiple calculi by measuring the sum of each stone's diameter.

SFR at 1 month was defined by the absence of stone or residual fragments less than or equal to 3 mm on CT-scan. Blood loss estimation was assessed postoperatively after 6 h by considering haemoglobin drop and blood transfusion was mentioned if required. All complications were evaluated according to the Clavien–Dindo classification.

Surgical procedure

A second -generation cephalosporin was administered for antibiotic prophylaxis during the induction phase. All procedures were performed by an unblinded single surgeon under general anaesthesia in the supine-modified position (Galdakao-modified Valdivia position). Percutaneous access to the collecting system was established under fluoroscopic guidance. The first step was to insert a 6Fr ureteric catheter into the renal pelvis and instill the contrast solution, then, the puncture was performed according to the 'Bull's Eye' technique with an 18-gauge Chiba needle. After parking a safety guidewire, regarding sPCNL, the tract was gradually dilated up 30 Fr using Alken's telescopic dilators. Stone localisation was ensured with a 22Fr nephroscope (Karl Storz). The stone was fragmented using a pneumatic lithotripsy (Swiss Lithoclast Master). During mPCNL, the access to the renal collecting system was gained by a single-step dilation and insertion of an 16.5/17.5F, metal Amplatz sheath. A 12 Fr nephroscope (Karl Storz MIP M System) was used to explore the renal collecting system. Fragmentation was achieved using Holmium:YAG laser energy via a 550-um fibre. Stone fragments were retrieved by using primarily the 'vacuum cleaner effect' and retrograde saline push through the ureteric catheter during withdrawal of the nephroscope. At the end of the procedure, a 16Fr nephrostomy or double j for patients undergoing sPCNL, a 12 Fr nephrostomy or double j for those undergoing mPCNL, were placed for drainage. The nephrostomy tube was removed before discharge, while the double j stent was left for 3–4 weeks.

Statistical analysis

Statistical analysis was performed using SPSS software version 21. Comparison of continuous and categorical variables was done by Student's *t*-test and χ^2 test, respectively. A *P* value less than 0.05 was considered statistically significant.

Results

In total, 142 of patients who underwent a percutaneous nephrolithotomy procedure matched the selection criteria (sPCNL $n=90$, mPCNL $n=52$). The mean age was 49.6 ± 15.1 years in the sPCNL group vs. 48.2 ± 17.1 years in the mPCNL group. The American Society of Anesthesiologists score was comparable between sPCNL and mPCNL arms (1.4 ± 0.7 vs. 1.5 ± 0.6, $P=0.28$). However, BMI was slightly higher in the mPCNL group (25.2 ± 3.3 vs. 29.6 ± 4.1 kg/m², $P<0.001$). The stone characteristics were comparable in both treatment arms in term of stone burden, number and radiolucency. The mean stone size was comparable for sPCNL and mPCNL groups (32.6 ± 10.8 vs. 29.4 ± 11.8 mm) (Table 1).

The operative time was longer in the mPCNL group (124 ± 40.4 vs. 95.8 ± 32.3 min, $P<0.001$).

According to the Clavien–Dindo classification, no statistical difference was observed between the groups in terms of complication rate (17.6% vs. 19.1%, $P=0.092$). However, the mean haemoglobin drop and transfusion rates were significantly in favour of mPCNL(1.43 ± 1.5 vs. 0.88 ± 1.4 g/dl, $P=0.04$) . Severe haemorrhagic complications required blood transfusion in seven cases and an arterial embolization in two cases for the sPCNL group. Only one patient required transfusion in the second group. Indeed, high-grade complications (grade II–III) were more likely to occur in the sPCNL group (10% vs. 7.6%, $P=0.031$).

Hospital stay was found to be significantly shorter for patients undergoing mPCNL (4.4 ± 3.9 vs. 2.7 ± 1.7 days, $P<0.001$). The

Table 1

Patients and stone characteristics

	sPCNL	mPCNL	
	N=90	*N*=52	*P*
Mean age (year)	49.6 ± 15.1	48.2 ± 17.1	0.592
Sex ratio (M/F)	73/17	31/21	0.79
BMI (Kg/m²)	25.2 ± 3.3	29.6 ± 4.1	< 0.001*
ASA Score	1.4 ± 0.7	1.5 ± 0.6	0.288
(Radio-opaque/ Rxlucient)	81/9	41/11	0.94
Mean stone size (mm)	32.6 ± 10.8	29.4 ± 11.8	0.071
Stone location, *n* (%)			< 0,001*
Renal pelvis	19 (21.1)	8 (15.3)	
Lower calyx	2 (2.2)	14 (27)	
Renal pelvis + one calyx	47 (52.2)	12 (23.1)	
Renal pelvis + two calyx	7 (7.7)	2 (3.8)	
Partial staghorn	4 (4.4)	10 (19.3)	
Complete staghorn	11 (12.2)	6 (11.5)	

ASA, American Society of Anesthesiologists; BMI, body mass index; F, female; M, male; mPCNL, mini standard percutaneous nephrolithotomy; sPCNL, standard percutaneous nephrolithotomy.*Values are statistically signifiant.

Table 2

Comparison of postoperative outcomes

	sPCNL	mPCNL	*P*
Access sheath diameter (Fr)	30 Fr	16.5/17.5Fr	
Operative time (min)	95.8 ± 32.3	124 ± 40.4	< 0.001*
Haemoglobin drop (g/dcl)	1.33 ± 1.5	0.88 ± 1.4	0.04*
Transfusion rate, *n* (%)	7 (7.7)	1 (1.9)	0.039*
Clavien–Dindo, *n* (%)			0.092
Grade I	6 (6.6)	6 (11.5)	
Grade II	6 (6.6)	3 (5.7)	
Grade III	4 (4.4)	1 (1.9)	
SFR overall (30 days) (%)	69.4	62.7	0.06
Operative stay (days)	4.4 ± 3.9	2.7 ± 1.7	< 0.001*

mPCNL, mini standard percutaneous nephrolithotomy; sPCNL, standard percutaneous nephrolithotomy.*Values are statistically significant.

success rate in the sPCNL group was higher than standard mPCNL group in terms of stone clearance at one month, but this difference was not statistically significant (69.4% vs. 62.7%, P = 0.06) (Table 2).

Discussion

In the present study performed in a Caucasian population the success rate was slightly higher for sPCNL group at one month. The overall complication rate was equal for both techniques. However, the mean haemoglobin drops and transfusion rates were significantly in favour of mPCNL.

Recently, technological advances in the urological field has led to the miniaturisation of endoscopic procedures including sophisticated optics, dilators, and fragmentation devices. At the beginning, most mPCNL were achieved with instruments which were not designed specifically for this procedure. Thereafter, the MIP system was initiated by Lahme using a 15Fr Amplatz sheath and a 12 Fr rigid nephroscope allowing a continuous low-pressure irrigation. This system had the advantage of minimising hydrostatic pressure leading to a reduction of infectious complications.

mPCNL is conventionally performed through a small tract of less than or equal to 20 Fr. Therefore, the terminology has not been well defined. A standardized nomenclature is required for more reproducible results when comparing PCNL techniques.

The first attempts were dedicated to paediatric population as an alternative treatment method. The success of the initial trials led the development of minimally invasive PCNL, introduced by Nagele with several technical modifications[4].

The effectiveness of mPCNL is still questionable and the proof of benefit is still controversial since the publication of Guisti 'mini perc! No thank you'. First studies reported high SFR for renal stones less than 2 cm: primarily SFR (80.6–97.8%); Final SFR (87.5–97,6%)[5]. These findings suggested a wide variation resulting in heterogeneous definitions of SFR with regard to the time of the stone-free state. However, no significant difference was found regarding SFR between mPCNL and sPCNL. In our study, we reported more patients with partial or complete staghorn stone for mPCNL group (30.8% vs. 16.6%) which may reduce stone clearance for mPCNL approach.By the implementation of minimally invasive techniques, many researchers have investigated their efficacy for different stone burdens. Initially, most procedures were dedicated to stones between 1 and 2 cm with an excellent result since the limited working sheath may increase the operating time. mPCNL have also shown equivalent efficacy to RIRS as a complementary treatment for residual stones after sPCNL. Improvements in technology and growing experience have dramatically boosted the concept of miniaturisation. Consequently, mPCNL has further expanded the indications to high stone burden and staghorn calculi especially in children with an acceptable SFR. In a prospective study, the primary SFR was 78%, which increased to 89% after an auxiliary procedure. The success rate was directly dependent on stone complexity[6]. In another comparative study, mPCNL demonstrated a greater SFR for small stones less than 2 cm than for large calculi. However, a higher SFR was achievable when considering a single auxiliary procedure[7]. Moreover, recent literature in this field has investigated the effectiveness of mPCNL in the treatment of partial and complete staghorn calculi either as one-stage or two-stage procedure. In a multicenter retrospective study, both sPCNL and mPCNL had comparable SFR, respectively (83% vs. 88.6%, $P = 0.339$). The need for auxiliary procedure was significantly lower in the mPCNL group. However, in this current study, patients who underwent sPCNL were older and more obese. Moreover, patients in this group required more multiple tracts[8]. It seems also that multitract attempts have been significantly more efficacious in these challenging cases. The high renal pelvic pressure resulting from a longer operative time and small access sheath is a potentially major threat. Working at high intraluminal pressure leads to urothelial damage which triggers bacterial translocation and toxin release into the blood circulation. Currently, by the implementation of new generation nephroscope, pressure-controlled systems represent a revolutionary approach in percutaneous stone removal which offers continuous low irrigation flow[9,10].

Designed by Nagele *et al.*[11], the Modular Miniature Nephroscope System with Automatic Pressure Control, known as 'Vacuum cleaner effect' offers a quick, complete and safe retrieval of fragments. Hydrodynamic simulation of the flow conditions demonstrated that a round shaped nephroscope with 12 F with a 16.5/17.5Fr access sheath allows optimal benefits[12]. Consequently, this effect contributes to less auxiliary procedures and high stone clearance rate. Despite a high stone burden, we achieved an acceptable SFR in the mPCNL arm. This novel trend has improved the outcomes of miniaturised approaches and led to cost reduction with no further need of graspers and extraction devices.

There is a strong conviction that mPCNL is linked to a reduced risk of bleeding. This evidence is not clearly demonstrated through enough randomized controlled trial (RCT)s. We think that such hypothesis is directly dependent on the dilation tract area in the parenchyma. Nevertheless, several factors affect blood loss during PCNL such as the dilation method, number of tracts, operative time, and stone characteristics. In a retrospective study comparing sPCNL($n = 95$) and mPCNL($n = 79$), Bhandari *et al.*[13] reported a significantly higher haemoglobin drop in the sPCNL group (3.3 ± 0.5 vs. 1.3 ± 0.8 g/dl). In another similar study, Thakur *et al.*[14] found that mPCNL had significantly less haemoglobin drop (1.61 ± 0.9 vs. 1.21 ± 0.7 g/dl) but transfusion rate was similar in both groups. In a multicenter RCT, no statistically significant difference was demonstrated in the haematocrit drop rate between sPCNL and mPCNL for renal stones of 2–4 cm[15]. It seems that haematocrit drop is an excellent marker of early postoperative bleeding given that it depends on intravenous fluid intake. Subsequently, this parameter should be

interpreted carefully. In another RCT including 148 patients who had a history of PCNL and/or open renal surgery, Kandemir *et al.*[16] Emphasised the advantage of mPCNL in terms of blood loss reduction (0.7 vs. 1.4 g/dl, $P = 0.011$). In a recent systematic review, authors have concluded that a reduced tract access contributes to minimising bleeding complications. However, optimising patient safety is directly dependent on the surgeon's expertise[17]. In accordance with previous studies, Sakr and collegues have demonstrated a lower procedure-related morbidity for mPCNL by decreasing mean drop in haemoglobin level and bleeding requiring blood transfusion. For Mahmood *et al.*[18], mPCNL can provide a strong safety profile among the paediatric population owing to a decreased haemoglobin drop (0.35 ± 0.29 vs. 0.56 ± 0.33 g/dl, $P = 0.001$) and less blood transfusion. In our study, the clinical relevance of a decrease in haemoglobin by a mean of 1.33 or 0.88 g/dl is not much significant in the general population. However, reducing blood loss and the need for blood transfusion have clinical benefits especially for patients with coronary disease, anaemia or those at high haemorrhagic risk. We believe that mPCNL can be a safe approach in these situations without reducing stone clearance.

Puncture is the key step to guarantee better outcomes. In fact, an ideal calyceal puncture through the papilla of the calix contributes to reducing haemorrhagic complications. Also, concerns have been raised about using colour Doppler ultrasound guidance in minimally invasive percutaneous nephrolithotomy to avoid blood vessels injury during the puncture[19]. One shot dilation is a novel technique which has been demonstrated to reduce X-ray exposure and dilation time. When compared with serial dilation, the results of a meta-analysis published by Yutao revealed no significant difference regarding blood loss and transfusion rate between the two techniques, whereas Peng and colleagues concluded that one shot dilation yields better outcomes in terms of bleeding reduction[20,21].

Regarding infectious complications, in the porcine renal pelvis, a small access sheath was associated with a higher risk of bacterial dissemination[22]. But, it seems that overall complication rate does not differ between sPCNL and mPCNL. Infection is the most common complication and usually occurs in the following circumstances: positive preoperative urine culture, a long operative time, high operative irrigation pressure especially in infected stones and insufficient or poor drainage at the end of the procedure. Another factor was the need for multiple tracts in 70% of sPCNLs vs. 35% in mPCNLs. This fact was attributed to the feasibility of navigation of most renal calyces by a small 12 F nephroscope through a single access without damage to the calyceal necks. These manoeuvres would lead to severe bleeding from calyceal neck injury if tried with large 24-F nephroscope.

In the present study, the advantage of a mean of 29 min for sPCNL over mPCNL may be clinically relevant and may reduce infectious complications. As reported in previous studies, the mean operative time was longer for mPCNL. This result could be explained by the high stone burden for this group and fragments retrieval using mainly the Vacuum cleaner effect. It seems that a long operative time does not affect safety and such parameter is dependent on the surgeon's expertise. mPCNL is associated with a short hospital stay. This is most likely due to the use of double j stent or small calibre nephrostomy tube which reduce pain and therefore the need for pain medications[23–25]. But it is still uncertain whether this advantage was due to the smaller tract or to the omission of the nephrostomy tube.

The major advantage of this prospective study was the use of one single tract in all procedures which were performed by the same surgeon. However, there are some limits: First, the groups were not randomized to either treatment arm. Second, the two groups were not comparable in terms of body mass index and stone location. Third, we did not evaluate the intravenous fluid transfusion status of operated patients, which might affect the postoperative haemoglobin levels.

Conclusion

Both standard and minimally invasive PCNL have shown good outcomes in the treatment of symptomatic renal stones greater than or equal to 20 mm. Although the success rates are similar for both techniques, hospitalisation time, bleeding and transfusion rates are much lower with the use of mPCNL. With the availability of high energy Holmium lasers, even a high stone burden is amenable to mPCNL.

Ethical approval

Ethical approval was obtained from the Local Health Research Ethics Commission University Hospital TS (number: 2949)

Consent to participate

Written informed consent to surgery was routinely obtained from all patients prior to PCNL.

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The authors did not receive support from any organisation for the submitted work.

Authors contribution

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by A.S., A.C. and N.J. The manuscript was written by A.S. and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Conflicts of interest disclosure

The authors have no competing interests to declare that are relevant to the content of this article.

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