



## Outcomes of (chinese) mini-percutaneous nephrolithotomy for renal stones: a prospective trial

### Resultados de la mini nefrolitotomía percutánea (china) para cálculos renales: un ensayo prospectivo

Hesham M. Refaat,<sup>1\*</sup> Mohammed Zaza,<sup>1</sup> Tarek Salem,<sup>1</sup> Mohammed Hassan.<sup>1</sup>

#### Abstract

**Objective:** Mini-percutaneous nephrolithotomy (mini-PCNL) has been recently advocated as a minimally invasive procedure for the management of renal stone. In this trial, we assessed the postoperative outcomes of chinese mini-PCNL (MPCNL) in adult patients with renal calculi less than 3 cm in diameter.

**Material and methods:** We performed a single-arm prospective trial that recruited adult patients with unilateral single kidney stones less than 3 cm. Patients were followed up for the assessment of postoperative complications and stone-free status.

**Results:** Sixty patients were included in the present study, with a mean age of  $36.9 \pm 8.5$  years and slightly male predominance (56.7%). The mean operative time was  $133.7 \pm 29.2$  minutes. None of the patients needed a nephrostomy tube or DJ tube stent. The mean hospital stay was  $1.4 \pm 0.62$  days. Eight patients (13.3%) showed mild perinephric collection on the postoperative US. All patients had mild postoperative pain, with no incidence of post-operative bleeding, residual stone, sepsis, or pelvi-calyceal injury. A total of four patients (6.7%) had a postoperative fever. The incidence of postoperative urine was 13.3%.

**Conclusion:** Chinese Mini-PCNL is an effective minimally invasive modality for the management of renal calculi less than 3 cm, with a low rate of postoperative complications and excellent stone-free status. Mini-PCNL can be used in well-resourced centres to reduce postoperative complications and hospital stay among patients with renal calculi.

#### Keywords:

Renal calculi, chinese mini-percutaneous nephrolithotomy, complications

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#### Corresponding author:

\*Hesham M. Refaat.  
Address: Helwan University, Cairo, Egypt.-P. O: 11795. Email: hesham.refaat@med.helwan.edu.eg

<sup>1</sup> Helwan University Hospital, Cairo, Egypt.

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## Abstracto

**Objetivo:** Recientemente se ha recomendado la mini nefrolitotomía percutánea (mini NLP) como un procedimiento mínimamente invasivo para el tratamiento de los cálculos renales. En este ensayo, evaluamos los resultados posoperatorios de la mini-NLP china en pacientes adultos con cálculos renales de menos de 3 cm de diámetro.

**Material y métodos:** Realizamos un ensayo prospectivo de un solo grupo que reclutó a pacientes adultos con cálculos renales únicos unilaterales de menos de 3 cm. Se realizó un seguimiento de los pacientes para evaluar las complicaciones posoperatorias y el estado libre de cálculos.

**Resultados:** Se incluyeron en el presente estudio 60 pacientes, con una edad media de  $36.9 \pm 8.5$  años y ligero predominio masculino (56.7%). El tiempo operatorio medio fue de  $133.7 \pm 29.2$  minutos. Ninguno de los pacientes necesitó un tubo de nefrostomía o un stent de tubo DJ. La estancia hospitalaria media fue de  $1.4 \pm 0.62$  días. Ocho pacientes (13.3%) mostraron una colección perirrenal leve en la ecografía posoperatoria. Todos los pacientes tuvieron dolor posoperatorio leve, sin incidencia de sangrado postoperatorio, cálculos residuales, sepsis o lesión pelvicalicial. Un total de cuatro pacientes (6.7%) presentaron fiebre posoperatoria. La incidencia de orina postoperatoria fue del 13.3%.

**Conclusión:** La mini NLP china es una modalidad mínimamente invasiva efectiva para el manejo de cálculos renales menores de 3 cm, con una baja tasa de complicaciones posoperatorias y un excelente estado libre de cálculos. La mini NLPC se puede utilizar en centros con buenos recursos para reducir las complicaciones posoperatorias y la estancia hospitalaria entre pacientes con cálculos renales.

### Palabras clave:

Cálculos renales, mini nefrolitotomía percutánea china, complicaciones

## Introduction

For large or complicated renal stones, percutaneous nephrolithotomy (PCNL) is the primary treatment.<sup>(1)</sup> Compared with other minimally invasive techniques, PCNL is the most effective procedure for large or complicated renal stones despite the frequent morbidities and complications such as bleeding.<sup>(2)</sup> Therefore, enhanced skills and procedural improvements can reduce the risk of adverse events. Most of the processes in the procedure have improved in the last few years. This includes establishing access tracts

through dilating the urinary system for stone removal.<sup>(3,4)</sup>

Mini-PCNL is performed with a miniature endoscope via a small percutaneous tract (11–20 F). The mini-PCNL procedure has been utilized to remove not only small lower caliceal stones but also largely impacted proximal ureteral stones and staghorn calculi.<sup>(5)</sup> Mini-PCNL is indicated in case of cystine calculi or failure of extracorporeal shock wave lithotripsy.<sup>(6)</sup> If the patient is taking anticoagulant drug, he has

to stop it few days prior the operation.<sup>(7)</sup> Mini-PCNL is not indicated in some circumstances such as malignant renal tumor, abnormal visceral position (e.g. retroperitoneal colon), pregnancy, untreated urinary tract infections (UTIs).<sup>(2)</sup> The effectiveness of mini-PCNL is still debatable.<sup>(8)</sup> With a stone burden of 1.2 cm<sup>2</sup> and 1.5 cm<sup>2</sup>, Jackman *et al.* found an SFR of 85% in children and 89% in adults.<sup>(9)</sup> Compared to standard PCNL, the mini-PCNL had a higher stone clearance rate for several calyceal stones 85.2% vs. 70%, respectively.<sup>(10)</sup> Regarding postoperative complications, mini-PCNL is related to less blood loss and shorter hospitalization than standard-PCNL. With Chinese Mini-PCNL technique, a ureteroscope is used through a percutaneous approach.<sup>(11)</sup>

This study aimed to assess the postoperative outcomes of chinese mini-PCNL in adult patients with renal calculi less than 3 cm in diameter.

## Materials and methods

The study gained the ethical clearance from the local ethics committee of our university hospitals the Declaration of Helsinki principles.<sup>(12)</sup> We followed the STROBE guidelines during the drafting of this manuscript.<sup>(13)</sup>

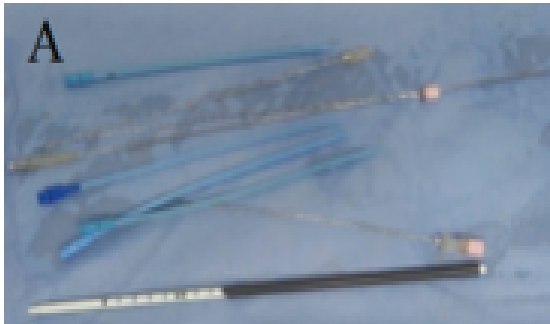
We conducted a prospective, single-arm, single-centre trial that recruited adult patients with renal calculi less than 3 cm in diameter who presented to the department of our university hospitals through the period from June 2019 to September 2020. Patients were

included only if they had unilateral single stone (<3cm) and normal kidney function. We excluded patients with impaired coagulation profile, complicated urinary tract infection, congenital anomalies of the renal system or solitary kidney, staghorn stone, history of kidney transplant or urinary diversion. pregnant women are excluded as well.

## Study's Procedures and Follow-up

All instruments needed for the operation are shown in Figure 1a. Patients were prepared preoperatively according to the standard protocol of the institution. All procedures took place under general anaesthesia, while the patients were in lithotomy position to introduce a 5-6Fr ureteric catheter in a retrograde fashion as shown in Figure 1b. The patients were then situated in a prone position under a C-arm image intensifier. Then, the operator introduced a fluoroscopically-guide needle (18-gauge) towards the lower calyx through a small incision in the flank; the needle was then used to pass a 0.35 guidewire. This single track was dilated by active dilatation and 11-13 Fr Amplatz sheath was used as in Figure 1c. A semi-rigid ureteroscope (sized 9.8- 13Fr and 38 cm long) was passed through the sheath. To fragment the calculus, pneumatic lithotripters were used, followed by a forceps extraction of these fragments and confirmation of clearance using an ureteroscope and the C-arm. Patients received diclofenac postoperatively and were discharged on the next postoperative day.

**Figure 1. Instruments**

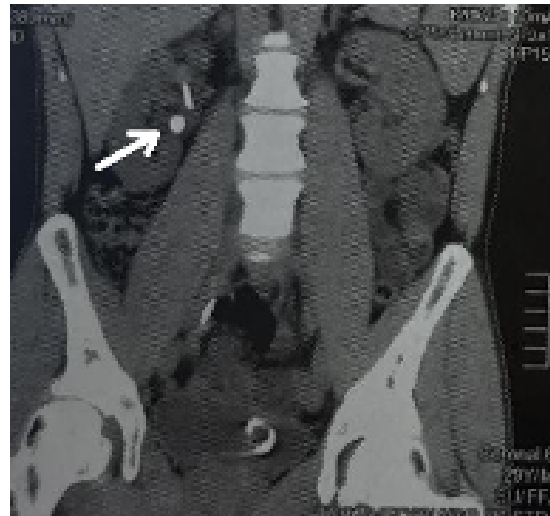


A-C: M-PCNL Instruments (puncture needles, dilators and Amplatz sheath) (a). Intra-operative retrograde pyelography by ureteric catheter (b). Insertion of Amplatz sheath during M-PCNL operation (c).

### *Data Collected*

The following data were collected preoperatively: age, sex, comorbidities, surgical history, routine laboratory findings, kidney, ureter, and bladder (KUB) X-ray findings, ultrasound findings, computed tomography, or intravenous pyelogram (CT or IVP) findings, as demonstrated in Figure 2 that shows CT for one of the patients underwent Mini-PCNL who has a history of double J insertion and failed ESWL three times. When CT is done for him, right pelvic stone is shown with size of 1cmx1.2cm with HU=1000.

**Figure 2. CT before M-PCNL**

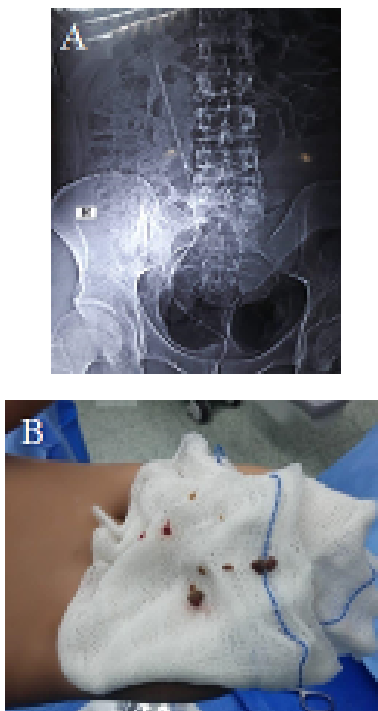


CT before M-PCNL shows right pelvic stone with size of 1cm × 1.2cm with HU= 1000.

Besides, the intraoperative characteristics, including operative time, puncture time, use of nephrostomy tube or DJ stent, clearance, and intraoperative complications, were recorded. Patients were followed-up postoperatively to assess hospital stay, stone-free status assessed by KUB the next day after the operation

(Figure 3), and complications. The classification of postoperative complications was evaluated using the modified Clavien grading system.<sup>(14)</sup>

**Figure 3. Post-operative X-Ray**



Post-operative X-Ray showing no residual stones (a) and extracted stone after its fragmentation to smaller size to fit the smaller sheath (b).

### *Statistical analysis*

For sample size calculation STATCALC of Epi-Info is used. The one-sided confidence level was set to 95%; power was set to 80% and  $\alpha$  is 0.05. Data were analysed using the SPSS V0.25 software for Windows. We used frequencies to summarise categorical data, while continuous data were presented as mean $\pm$ standard deviation (SD).

### **Results**

Sixty patients were included with a mean age of 36.9 $\pm$ 8.5 years and with male predominance (56.7%). About 20% (n=12) of patients had previous ESWL Failure with DJ insertion. In all patients, radiopaque shadow was observed in the KUB. The KUB showed a radiopaque shadow in all patients, while the mean renal stone size was 1.7 $\pm$ 0.9cm. The CT-IVP showed mild, moderate moderate, and severe back pressure, mild (renal pelvis and calyceal dilatation), moderate (as mild plus medullae is short and thin cortex normal) and severe (cortex is thin and corticomedullary dilatation) in 40%, 46.7% and 13.3% of the patients, respectively (Table 1).

**Table 1. Preoperative data of the study group (n=60)**

Variables		Study group (n=60)	
		N/Mean	%/SD
<b>Age (years)</b>	Mean±SD	36.9	8.5
<b>Sex</b>	Males	34	56.7
<b>Comorbidities</b>	DM	4	6.7
	HTN	4	6.7
<b>Surgical History</b>	DJ & stricture ureter	0	0
	DJ& failed ESWL	12	20
	ESWL	4	6.7
<b>Laboratory findings</b>	Hg (g/dl)	13.09	1.05
	WBCs (thousand/ml)	8.17	1.76
	Platelet (thousand/ml)	255.60	43.31
	Creatinine (mg/dl)	0.93	0.19
	ALT (IU/L)	23.53	8.45
	AST (IU/L)	29.47	7.72
	PC	93.67	4.32
	PT (sec)	11.77	0.63
<b>KUB</b>	INR	0.99	0.10
	No radio opaque shadow	0	0
	Radio opaque shadow	60	100
<b>Renal stone size in cm</b>		1.7	0.9
<b>CT-IVP</b>	Mild back pressure	24	40
	Moderate back pressure	28	46.7
	Severe back pressure	8	13.3

The mean operative time was 133.7±29.2 minutes. On the other hand, the mean puncture time was 4.7±1.87 minutes, respectively. All the procedures were tubeless and without DJ tube In mini-PCNL, narrower tracts (≤18 Fr) are created to allow smaller scopes access to the kidney. Thus, no parenchymal trauma nor bleeding was happened. Consequently, difference between preoperative and postoperative haemoglobin was insignificant. Mean of preoperative and postoperative haemoglobin is 13.09 and 12.75, respectively. (Table 2)

**Table 2. Intraoperative data of the study group (n=60)**

Variables	Study group (n=60)	
	N/Mean	%/SD
Operation time (min)	133.73	29.18
Puncture time (min)	4.73	1.87
Puncture (ATTEMPT)	1.73	0.58
Nephrostomy tube	0	0
Clearance at operation	60	0
Bleeding	0	0
DJ tube	0	0

The mean hospital stay was  $1.4 \pm 0.62$  days. All patients exhibited stone clearance in the post operative KUB. All patients had mild postoperative pain and, sepsis). A total of four patients (6.7%) had a postoperative fever. The incidence of postoperative leakage was 13.3% (Table 3). Leakage lasted for only less than 72 hrs, so catheterization wasn't prolonged.

**Table 3. Postoperative data of the study group (n=60)**

Variables		Study group (n=60)	
		N/Mean	%/SD
Laboratory findings	Hg (g/dl)	12.75	1.06
	WBC (thousand/ml)	11.62	0.96
Hospital stay (days)		1.40	0.62
Postoperative KUB	Free	60	100
Post-operative US	Normal	52	86.7
	Mild collection	8	13.3
Postoperative pain	Mild	60	100
Bleeding		0	0
Post-operative leakage		8	13.3
Postoperative residual		0	0
Postoperative fever		4	6.7
Post-operative sepsis		0	0
pelvic injury		0	0

## Discussion

The main goal of surgical management of renal stone is to ensure maximum stone clearance with acceptable peri and post-operative morbidity. According to the current international guidelines, the PCNL has become the mainstay for the treatment of renal stones in adult patients, particularly stones larger than 2 cm.<sup>(15)</sup> Nonetheless, complications, such as leakage and bleeding still represent major concerns for urologists. Besides, the management of renal stones with a size of 1-2 cm is still debatable within the published literature.<sup>(4)</sup>

Over the past few decades, several modifications and “miniaturisation” approaches have been investigated to provide effective and safer alternatives for the traditional PCNL. Recently, mini-PCNL has gained popularity as a safer approach than the standard PCNL, as it is based on reducing the size of the access sheath while maintaining the same efficacy as the standard PCNL.<sup>(16)</sup> Although a plethora of comparative studies has established the efficacy and safety of mini-PCNL compared to the standard PCNL,<sup>(17)</sup> little is known about the outcomes of mini-PCNL in a real-world setting. In this trial, we assessed the postoperative outcomes of mini-PCNL (MPCNL) in adult patients with renal calculi less than 3 cm in diameter.

Presumably, mini-PNL can pose an advantage in terms of postoperative pain and, subsequently, the hospital stay because it employs a less invasive and tubeless approach.<sup>(18)</sup> In the present study, we found that the mean hospital stay of the included patients was  $1.4 \pm 0.62$  days. All patients had mild postoperative pain. In the Knoll *et al.* study, most of the patients who underwent mini-PCNL experienced mild postoperative pain, with a mean hospital

stay of  $3.8 \pm 2.1$ . The mild postoperative pain was reflected on the dosage of postoperative analgesic requirement, in which all patients received 1-2 vials of NSAIDs only. Likewise, in a large retrospective study from China on nearly 12 500 patients, the rate of postoperative pain following mini-PCNL was 5.7% only.<sup>(19)</sup> From-centre experiences from Egypt, the majority of the patients who underwent mini-PCNL had mild postoperative pain.<sup>(20)</sup> Concerning the hospital stay, a retrospective study by ElSheemy *et al.*, on 378 cases, who underwent mini-PCNL over three years, found that the mean hospital stay was  $2.43 \pm 1.46$ .<sup>(21)</sup> A similar finding was reported by other clinical trials and meta-analysis studies.<sup>(16)</sup>

Intra and postoperative bleeding are major concerns to urologists performing traditional PCNL, which can increase the risk of blood transfusion and renal damage. The high risk of bleeding with traditional PCNL largely stem from the utilisation of large nephoscopes and their access tracts. Thus, minimizing the size of the access tracts with mini-PCNL can potentially reduce the risk of bleeding and its associated complications.<sup>(10)</sup> In the present study, there was no incidence of intra and postoperative bleeding, while there was a clinically insignificant drop in haemoglobin level.

Such results run in parallel with several published studies, revealing that mini-PCNL own an obvious advantage regarding bleeding and transfusion required.<sup>(22)</sup> In a 2015 meta-analysis, the incidence of blood transfusion following mini-PCL was 0.84%.<sup>(16)</sup> On the other hand, the current body of evidence demonstrated a significant reduction in the risk of leakage with mini-PCNL. This was in line with our results, in which the incidence of leakage was only 13.3%. Thus, our study also demon-



strated that Minin-PCNL was associated with lower leakage, in agreement with ElSheemy *et al.*, Zhong *et al.*, and Deng *et al.* studies.<sup>(21,23,24)</sup>

As previously mentioned, it is supposed that performing a tract of smaller size in mini-PCNL could minimise postoperative complications. Controversially, another hypothesis supposed that a small sized tract in mini-PCNL might increase the collecting system pressure, causing pyelosinus or pyelovenous backflowing, and consequently fever after mini-PCNL. However, in the present trial, we found that the rate of postoperative fever was only 6.7% after mini-PCNL. Such findings run in line with previous reports showing a postoperative fever rate of 3%.<sup>(25)</sup> Likewise, Sakr *et al.* and Zhong *et al.* reported higher rate of postoperative fever than the present report, 6.2% and 3.4%, respectively.<sup>(20,23)</sup>

Operative time plays an independent predictive role in the development of postoperative complications.<sup>(26)</sup> Traditional PCNL carries the merit of shorter operative time than that of the Mini- PCNL due to the highly limited field of vision owing to the miniaturised endoscopes and time required to fragmentise the stones into smaller ones to be easily removed throughout the small tract.<sup>(20)</sup> In the present study, the mean operative time was 133.7±29.2 minutes. Several studies showed that the durations of the operation in all stone types (pelvic, multicaliceal and staghorn stones) was significantly shorter in PCNL than mini-PCNL.<sup>(27)</sup> In terms of stone-free rate, we found that all of the patients in our cohort had stone-free status. Such findings are notably higher than stone-free rate in other reports. For example, Knoll *et al.* reported that the stone-free rate after mini-PCNL was 96% While, in Zhong *et al.*, it was 89.7%.<sup>(24)</sup>

To our knowledge, there are a limited number of published studies which explored the outcomes of mini-PCNL in the Middle East; nonetheless, certain limitations are present in our trial. The study was conducted in a single-centre only and the sample size was lower than the previously published literature, affecting the generalizability of our findings. Besides, patients were not followed to assess the long-term outcomes of the mini-PCNL. Another limitation is the inclusion of patients with renal stone <3 cm only. Thus, further trials should assess the outcomes of mini-PCNL in the setting of renal stones larger than 3 cm.

## Conclusion

Chinese mini-PCNL is an effective minimally invasive modality for the management of renal calculi, with a low rate of postoperative complications and excellent stone-free status. Mini-PCNL can be used in well-resourced centres to reduce postoperative complications and hospital stay among patients with renal calculi. The Chinese mini-PCNL has an advantage of using ureteroscope when mini-nephroscope isn't available.

## CRedit taxonomy

H.R. was involved in literature review, collecting cases, analysing data, processing and writing the manuscript.

M.Z. and M.H. were involved in concept, design, processing and supervision.

T.S. was involved in supervision, reviewing the manuscript, and worked on critical revision of the manuscript for important intellectual

content. All authors read and approved the final manuscript.

### Ethics approval and consent to participate

License to do this study was given by the research ethics committee (REC) for Human Subject Research at the Faculty of Medicine in our University with approval No. 10/2019 (R). All patients who participated in this investigation signed the consent letter after they had read it.

### Disclosure statement

The authors declare that they have no competing interests in this section.

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Not applicable.

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