Tubeless mini-percutaneous nephrolithotomy for renal stones larger than 20 mm

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INTRODUCTION

Nephrolithiasis is a common worldwide disease with a rising incidence in the last few decades.1 Current practice based on international guidelines, suggest percutaneous nephrolithotomy (PCNL) as the primary treatment for renal stones >20 mm, which is performed via 24–30F percutaneous renal dilatation.2,3 Although this technique offers excellent stone-free rates, it has a relatively high incidence of complications with a systematic review by Seitz et al. in 2012 of 11,929 patients demonstrating an overall complication rate of 23.3%.4 Recent evidence, including a systematic review, has identified that tract size is the main factor affecting blood loss during PCNL.5,6

In an attempt to reduce the morbidity, miniaturization of renal access size in PCNL was first introduced by Helal et al. in 1997.7 Over the next two decades, several techniques of miniaturized PCNL (mini-Perc, mini-PCNL, or minimally invasive PCNL) have been described using 14–20F percutaneous renal dilatation with the primary goal to achieve high stone-free rates with the reduction in procedure-related complications. More recently, even smaller renal access systems have been described, including ultra-mini PCNL with 11–13F sheath, super-mini PCNL with 10–14F sheath, mini-micro PCNL with 8F sheath and micro-PCNL with <5F sheath.8 Evidence for the superiority of any individual technique is poor with heterogeneous outcomes.

ABSTRACT

Introduction: The aim of this study is to evaluate the outcomes of tubeless mini- percutaneous nephrolithotomy (PCNL) for the treatment of large (>20 mm) renal stones.

Patients and Methods: This study included consecutive patients who underwent single-session tubeless mini-PCNL (tract size 16–20 F) for large (>20 mm) renal stones. Stone-free status meant complete clearance or residual fragments <4 mm. Complications were recorded and classified according to modified Clavien-Dindo classifications. Risk variables for significant residuals were determined with univariate (Chi-square and t-test) and multivariate logistic regression analyses.

Results: Between July 2015 and November 2018, 225 patients were included. The mean age was 42.9 years; the mean stone size was 30.2 ± 9.6 mm and 75% of patients were males. A single renal stone was present in 54 patients (24%), multiple stones in 108 (48%), and staghorn stones in 63 (28%). The stone-free rate was 87.6%. The complication rate was 8.4% (Grade I–II in 7.5%, III in 0.9%). Three patients (1.3%) required blood transfusion. Independent risk factor for significant residual fragments was the presence of stones in multiple sites inside the pelvicycalceal system (relative risk: 13.44, 95% confidence interval: 1.78–101.43, P = 0.012).

Conclusions: Mini-PCNL is an effective and safe treatment option for patients with large renal stones (>20 mm). Stones located in multiple sites is the only predictor of significant residual stones.
The evidence in the literature for mini-PCNL in the treatment of large renal stones is heterogeneous. Some authors reported that mini-PCNL was more effective for the treatment of small (>20 mm) than large renal stones (>20 mm). Therefore, they recommended mini-PCNL as an alternative to shockwave lithotripsy or retrograde intrarenal surgery (RIRS) for the treatment of small renal stones. On the contrary, other authors showed comparable or even better outcomes for mini-PCNL for medium-sized (15–30 mm) and large renal stones (>20 mm). This study was conducted to evaluate the outcomes of mini-PCNL for the treatment of large (>20 mm) renal stones.

**PATIENTS AND METHODS**

The study included consecutive adult patients who underwent mini-PCNL for large (>20 mm) renal stones between July 2015 and October 2018. Preoperative, operative, postoperative, and follow-up data during outpatients' visits were prospectively recorded and maintained using a computer database. The data were retrospectively analyzed. Exclusion criteria were concomitant ipsilateral obstructing ureteric calculi. Stone size was defined as the largest dimension of a single stone or the sum of the largest dimensions of multiple stones. Variables included were age, sex, stone location, history of urolithiasis, Guy’s stone score, stone size, percutaneous tract location and numbers, peroperative hemoglobin change, hospital stay, stone-free status, and 30-day complications. Noncontrast computed tomography (NCCT) was the preoperative diagnostic modality for all patients. All procedures adhered to the ethical guidelines of Declaration of Helsinki and its amendments. All patients included in the study provided an informed consent for undergoing the procedure. The authors confirm the availability of, and access to, all original data reported in this study.

**Surgical technique**

All procedures were carried out under spinal anesthesia by a single surgeon (SK) at a tertiary care hospital. In the lithotomy position, a 6F ureteric catheter was secured at the level of the ipsilateral pelvi-ureteric junction. The patient was then turned to the prone position and secured on the operating table with padding of the chest and pelvis and pressure points. Prepping and draping were done, so the tip of the ureteric catheter was accessible in the sterile field. A fluoroscopic guided renal puncture was performed using 2 planes (0°C and 30°C-arm rotation) after retrograde pyelography to enable access to the desired calyx. The preferred percutaneous entry point of the operating surgeon was a supra 12th rib approach with an interpolar approach with an interpolar. A 0.035-inch Zebra Guidewire (Boston Scientific, USA) was passed to the PCS and either secured down the ureter or coiled in a renal calyx. The needle was removed, and either a single-step or serial dilatation was performed using fascial dilators with the eventual placement of a 16, 18, or 20F peel-away renal access sheath.

The 12F mini-nephroscope (MIP, Karl Storz Endoskope, Tuttlingen, Germany) was connected to an intermittent flow irrigation system, which enabled high flow irrigation for <3 s followed by a subsequent 2 s pause. A pneumatic ballistic lithotripter with a 1.2F probe was used to disintegrate the stones. Fragment evacuation was achieved by a combination of the vacuum cleaner effect and saline flushing through the retrograde ureteral catheter. Tri-radiate grasper was rarely used to remove persistent stone fragments. At the end of the procedure, the ureteric catheter was removed, and an antegrade double-J stent was placed. No nephrostomy tubes were placed even in patients who required multiple tracts. Operative time was calculated from the insertion of the ureteric catheter till ureteric stent insertion.

Complications were recorded and classified according to the modified Clavien-Dindo classification. Stone-free status was evaluated with X-ray kidney-ureter-bladder for radiopaque stones and NCCT for radiolucent stones within 2 weeks after PCNL. Patients were declared stone-free if they had complete clearance or an insignificant residual renal fragment <4 mm. Stent removal was performed under topical anesthesia 2–4 weeks after the procedure if no significant residual fragments were seen.

**Statistical analysis**

The data were stored and analyzed using SPSS (v20) software (IBM SPSS Statistics, Armonk, NY, USA). Univariate analysis (Chi-square or t-test) was used to compare the variables between stone-free patients and those with significant residual fragments. Multivariate logistic regression analysis was used to define independent risk factors. P < 0.05 was considered to indicate statistical significance.

**RESULTS**

**Patient and stone characteristics**

The study included 225 patients with mean age 42.9 ± 13.8 years (range 18–79) and mean stone size 30.2 ± 9.6 mm (range 20–70). Male patients constituted 75% of the total. A single renal stone was present in 54 patients (24%), multiple stones in 108 patients (48%), and staghorn stones were detected in 63 patients (28%).

**Outcomes**

Mean operative time was 61.8 ± 30.1 min (range 25–180). Operative data and outcomes are summarized in Table 1. The average number of tracts per renal unit was 1.26. The stone-free rate following the single-session of mini-PCNL.
was 87.6% \((n = 197)\). Complete clearance was achieved in 80% \((n = 180)\) and insignificant residual fragments in 7.6% \((n = 17)\). Mean hospital stay was 2.9 ± 0.9 days.

The overall intraoperative and 30-day postoperative complication rate was 8.4% \((n = 19)\), with the majority being Clavien classification Grades I and II \((n = 17)\). Minor Grade (I–II) complications included postoperative fever requiring antibiotics in 11 cases, postoperative haematuria requiring blood transfusion in two cases, severe postoperative pain requiring prolonged opioid analgesia in two cases, and perinephric haematoma that was managed conservatively in two cases. Grade III complications were observed in only 0.9% \((n = 2)\) as one patient required renal angiembolization for severe haematuria 7 days following the procedure. The other patient had pleural effusion following upper calyx puncture requiring an intercostal chest drain. Both patients recovered well following the intervention and were discharged with no further procedures required. Blood transfusion was needed in 3 patients (1.3%). The average hemoglobin decrease was 1.3 g/dL (range 0–3.9). No patients had life-threatening complications (Grade IV) or death (Grade V).

Table 2 summarizes univariate analysis for factors affecting stone-free status. On multivariate analysis, independent risk factor for significant residual stones was the presence of the stones in multiple sites inside the PCS (relative risk: 13.4, 95% confidence interval: 1.78–101.43, \(P = 0.012\)).

### DISCUSSION

The evolution of mini-PCNL originated in the pediatric population by Helal et al. in 1997, by using a 15F peel-away Hickmann sheath and 10F pediatric cystoscope for the percutaneous treatment of nephrolithiasis in a 2-year child weighing 10 kg.\(^7\) This technique was further developed by Jackman et al. in 1998 who reported 11 pediatric cases of “mini-PERC” using an 11F sheath with a combination of a 7F cystoscope and 9.5F flexible ureteroscope to perform nephrolithotomy demonstrating a stone-free rate of 85%.

Monga and Oglevie subsequently adapted this technique for adults and used a 20F tract, coining the term “mini-PCNL” and reported 90% stone clearance rate.\(^16\) Lahme et al. were the first to design a 12F mini-nephroscope for the “mini-PERC” in 2001 for use through a 19F tract in 19 adult patients reporting a 100% stone clearance rate.\(^17\)

The surgical technique of mini-PCNL in this study has been adapted from the Chinese method described by Li et al. of Guangzhou Medical College in China.\(^18\) They reported a stone-free rate of 89% in their retrospective series, which contained 4760 mini-PCNLs. This is slightly more than the 87.6% stone-free rate in the present study, but they reported their experience with all stone sizes while we reported only for large stones.

Zeng et al. published the largest series of mini-PCNL outcomes of 13,984 cases.\(^19\) This retrospective series analyzed 7234 complex stones. They reported an average of 1.25 tract per renal unit, with 79.3% single tract procedures. In the present study, similar results were observed (1.26 average number of tracts with 80% performed through a single tract). Another advantage of mini-PCNL in the treatment of large renal stones is the ability to access most of the PCS through one tract, as shown in this study and Zeng et al. study.\(^19\) The reason for the use of a single tract in 76% of cases in this study is attributed to the preference of accessing the PCS through the middle calyx. This interpolar renal access enabled accessibility to almost all the PCS and therefore allowing complete stone clearance without the need for multiple tracts in the majority of cases.\(^20\) Recently, Lahme published outcomes of mini-PCNL for larger stones >5 cm\(^2\) in 321 patients and reported a stone-free rate of 94.7%.\(^21\) However, this was achieved after a retreatment rate of 38.7%.

The main advantage of mini-PCNL is lesser bleeding-related complications compared with standard PCNL. In a systematic review, complications of standard PCNL included blood transfusion in 7% of cases and an average hemoglobin drop of 2.3 g/dL.\(^4\) In the present study, these bleeding complications were decreased as blood transfusion was needed in 1.3%, and the average hemoglobin drop was 1.3 g/dL. Moreover, lower overall and Clavien-Dindo grade III-V complication rates were observed in this study compared with that of the standard PCNL from Seitz’s review (Grade III: 8.4% vs. 23.3% and Grade IV: 0.9% vs. 4.74% respectively).\(^4\) A randomized controlled trial by Cheng et al. in 2010 found that blood loss and the need for blood transfusion was significantly lower in mini-PCNL using a 16F sheath compared to standard 24F PCNL (\(P < 0.05\)).\(^22\) These findings were supported by a recent systematic review by Ruhayel et al. in 2017 that analyzed 18 mini-PCNL studies (tract size <22Fr) and found that smaller tracts tended to be associated with significantly lower blood loss or need.
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for blood transfusion. Another advantage of mini-PCNL is omitting the need for nephrostomy tube placement after the procedure in most cases. A meta-analysis comparing tubeless versus standard PCNL procedures reported that tubeless procedures led to shorter hospital stay, less postoperative pain, and possibly quicker recovery. The mean hospital stay in this study was 2.9 days because all patients were admitted 1 day prior to surgery and stayed for one or 2 days after the procedure as per hospital policy.

The main concerns of mini-PCNL for large renal stones are the lower stone-free rate and longer operative time in comparison with standard PCNL. The high success rates for mini-PCNL in this study (87.6%) and the studies by Zeng et al. of 87% and Zhong et al. of 89.7% are promising as all reported stone-free for mini-PCNL in treatment of large or complex stone burden. Kukreja proved that mini-PCNL had a comparable success with standard PCNL for the treatment of medium-sized stones of 15–30 mm. The mean operative time of 61 min in the present study was shorter in comparison with 90 min reported by Zeng et al. and 116 min reported by Zhong et al. The reasons for short operative time in this study are the use of spinal anesthesia and experience of the surgeon. With increasing experience, it is expected that operative time will decrease.

Another criticism of mini-PCNL has been the high intrarenal pressures and the potential increased risk in postoperative fever and sepsis rates. Zhong et al. suggest that high intrarenal pressure over 30 mmHg contributes to the onset of fever. Loftus et al. compared the intrarenal pressures and infectious complications in porcine models between mini and standard PCNL. They found that intrarenal pressures were higher in the mini-PCNL group, and longer time was spent with intrarenal pressures above 30 mmHg, with higher rates of positive blood cultures. Contrary to this, our study has demonstrated a low postoperative fever and sepsis rates of 3.1% and 1.8%, respectively. We believe this is in part due to the intermittent irrigation pump, which helps prevents high sustained intra-renal pressures and due to the free drainage of the irrigation fluid between a 12F nephroscope and 16–20F renal access sheath.

When looking for risk factors for residual stones in this study, the presence of stones in multiple sites inside the PCS was the only independent predictor in multivariate analysis. Of note, neither Guy’s classification for stone burden nor the presence of staghorn stones was a significant risk factor in predicting residual stones in multivariate analysis. The stone size was not significant in univariate analysis. This indicated the versatility of mini-PCNL for the treatment of various stone burdens.

There are some limitations in the present study. The data analysis was performed in a retrospective manner and it is a single-arm study therefore, no direct statistical comparison can be made with other treatment modalities such as RIRS or standard PCNL. All cases were performed by a single, experienced surgeon who exclusively performs mini-PCNL. Therefore, multicenter studies are recommended to reduce surgical experience bias.

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Table 2: Univariate analysis of factors affecting stone-free status for mini-percutaneous nephrolithotomy of large renal stones

| Categorical variables | Total (n=225) | Stone free (n=197; 87.6), n (%) | P* |
|-----------------------|--------------|---------------------------------|----|
| Sex                   |              |                                 |    |
| Male                  | 57           | 47 (82.5)                       | 0.264 |
| Female                | 168          | 150 (89.3)                      |    |
| Previous stone treatment |            |                                 |    |
| No                    | 156          | 140 (89.7)                      | 0.202 |
| Yes                   | 69           | 57 (82.6)                       |    |
| Laterality            |              |                                 |    |
| Left                  | 111          | 99 (89.2)                       | 0.596 |
| Right                 | 114          | 98 (86.0)                       |    |
| Stone size (mm)       |              |                                 |    |
| 20-40                 | 189          | 169 (89.4)                      | 0.052 |
| 40+                   | 36           | 28 (77.8)                       |    |
| Stone location        |              |                                 |    |
| Renal pelvis          | 63           | 62 (98.4)                       | 0.003 |
| Single calyx          | 18           | 17 (94.4)                       |    |
| Multiple sites        | 144          | 118 (81.9)                      |    |
| Staghorn stones       |              |                                 |    |
| No                    | 162          | 148 (91.4)                      | 0.006 |
| Yes                   | 63           | 49 (77.8)                       |    |
| Guy’s stone score     |              |                                 |    |
| 1                     | 50           | 49 (98)                         | 0.022 |
| 2                     | 106          | 93 (87.7)                       |    |
| 3                     | 34           | 28 (82.4)                       |    |
| 4                     | 34           | 26 (76.5)                       |    |

| Continuous variables | Mean (SD) | P* |
|----------------------|-----------|----|
| Age (years)          | 42.6 (13.7) | 0.314 |
| Stone free           | 45.3 (14.4) |    |

*Chi-square test, *Independent sample t-test. SD=Standard deviation
CONCLUSIONS

Mini-PCNL is a safe and effective treatment for the management of adult patients with large renal stones. Stones located in multiple sites inside the PCS is the only predictor of unsuccessful outcome.

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