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Super-mini percutaneous nephrolithotomy (SMP): a new concept in technique and instrumentation

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Objective

To present a novel miniature endoscopic system designed to improve the safety and efficacy of percutaneous nephrolithotomy, named the 'super-mini percutaneous nephrolithotomy' (SMP).

Patients and Methods

The endoscopic system consists of a 7-F nephroscope with enhanced irrigation and a modified 10–14 F access sheath with a suction-evacuation function. This system was tested in patients with renal stones of <2.5 cm, in a multicentre prospective non-randomised clinical trial. In all, 146 patients were accrued in 14 centres. Nephrostomy tract dilatation was carried out to 10–14 F. The lithotripsy was performed using either a Holmium laser or pneumatic lithotripter. A nephrostomy tube or JJ stent was placed only if clinically indicated.

Results

SMP was completed successfully in 141 of 146 patients. Five patients required conversion to larger nephrostomy tracts. The mean (SD) stone size was 2.2 (0.6) cm and the mean operative duration was 45.6 min. The initial stone-free rate (SFR) was 90.1%. The SFR at the 3-month follow-up was 95.8%. Three patients required auxiliary procedures for residual stones. Complications occurred in 12.8% of the patients, all of which were Clavien grade ≤II and no transfusions were needed. In all, 72.3% of the patients did not require any kind of catheter, while 19.8% had JJ stents and 5.7% had nephrostomy tubes placed. The mean hospital stay was 2.1 days.

Conclusions

SMP is a safe and effective treatment for renal stones of <2.5 cm. SMP may be particularly suitable for patients with lower pole stones and stones that ae not amenable to retrograde intrarenal surgery.

Keywords

super-mini percutaneous nephrolithotomy, kidney stones, complications

Introduction

Percutaneous nephrolithotomy (PCNL) is a well-established treatment method for renal stones. It offers high stone-free rates (SFRs) and is less invasive than open surgery [1]. Nevertheless, PCNL is an invasive and technically demanding procedure with inherent risks and complications [1]. The most troublesome morbidities are bleeding, and injury to the kidney and its adjacent structures [1]. PCNL complications tend to be associated with the accuracy of the nephrostomy tract placement and its size [2]. To improve the safety of PCNL, there has been a trend towards using progressively smaller nephrostomy tracts. With this aim, in addition to our previously reported experience with the Chinese minimally invasive PCNL (MPCNL) [3]; Desai et al. [4] have reported their ultra-mini PCNL (UMP), and lastly micro-PCNL [5] has been introduced for clinical use. Reducing the size of nephrostomy tracts mandates the development of miniature endoscopes and access sheaths. Also, with smaller nephrostomy tracts the problem of a compromised visual field arises and increased difficulty in stone extraction. Increasing irrigation, using a pressure pump, might improve the visualisation and passive egress of stone fragments, but it would also concomitantly increase the intra-luminal pressure. The present super-mini PCNL (SMP) system was developed to address many of the deficiencies in the current mini-PCNL. The basic components of this new system are a 7-F miniature nephroscope with enhanced irrigation capability and a modified nephrostomy access sheath with continuous negative pressure aspiration. Its design was intended not only to prevent excessive intrarenal pressure but also to improve visualisation and stone fragment extraction. In the present study, we present our experience of SMP in a multicentre prospective non-randomised clinical trial.

Patients and Methods

This clinical trial was approved by the Ethic Committee of each of the participating centres. Patients were informed that this was a new technique. The risks and benefits were explained and written informed consent was obtained from each of the participants or their legal guardians. Furthermore, the modified sheaths and specimen collection bottles were provided free of charge. A concurrent review of patients' charts was performed to monitor the safety and efficacy of this new procedure.

In all, 146 patients were accrued into this trial in 14 medical centres between September 2012 and September 2014. The inclusion criteria for SMP included all patients with kidney stones of <2.5 cm who agreed to undergo SMP, and patients who preferred to have SMP regardless of stone size. All patients with positive preoperative urine cultures were treated with appropriate antibiotics, according to the culture-antibiogram test results, for 3–5 days until the culture results were negative. All patients with negative urine cultures were treated with a single prophylactic dose of broad spectrum antibiotics 30 min before SMP. The data collected from these patients included demographics, stone data (size, location, and composition), operative, and recovery parameters. In particular, the potential strengths and weaknesses of the SMP procedure were assessed.

The stone size was defined as the largest diameter of the largest stone on plain abdominal radiograph of the kidneys, ureters and bladder (KUB). In the case of multiple stones, the summation of the diameters of the stones was used. KUB and non-contrast CT scans were taken on postoperative day 1 and at 3 months, to assess residual stone fragments. 'Stone-free' was defined either as the absence of any residual stone fragment or the presence of clinically 'insignificant' residual stones in the kidney. An 'insignificant' residual stone was defined as ≤2 mm, asymptomatic, non-obstructive, and non-infectious residual fragment. Complications of all patients were recorded according to the modified Clavien classification system. The operating duration was recorded from the time of the first percutaneous renal puncture to the completion of stone removal. The postoperative stay was rounded to the nearest whole day and calculated from the day of surgery to the day of discharge. Data are reported as numbers, percentages, and means (SDS).

Instruments

Miniature nephroscope

The nephroscope has a 7 F outside diameter (OD) and 6.5 F inside diameter (ID) dismountable sheath. Inside the sheath there are two 0.6 mm OD/0.4 mm ID fine tubes located at the left and right side of the lumen, just lateral to the space for the fibre-optic bundle (Fig. 1). These are the auxiliary irrigation channels. The mini-nephroscope was designed at our institute and fabricated locally. The telescope consists of a 1 mm (3 F) fibre-optic bundle. When the telescope is inserted into the sheath, the fibre-optic bundle sits in between the irrigation channel, which leaves a 3.3-F space at the bottom half of the sheath to serve as the working and main irrigation channel (Fig. 2). The nephroscope has two separate irrigation systems (the main and auxiliary system). The perfusion liquid via an irrigated side-port inflow passes the internal surface of the 7-F sheath (≈3.3-F space) as the main irrigation systems. The irrigation port can be connected to an irrigation pump. In addition to irrigation, the working channel can accommodate a 0.8-mm pneumatic lithotripter probe, a laser fibre up to 365 μm, or a 2.5 F stone basket, or forceps. The working length of the scope is 25.2 cm.

Fig. 1 The miniature nephroscope for SMP.

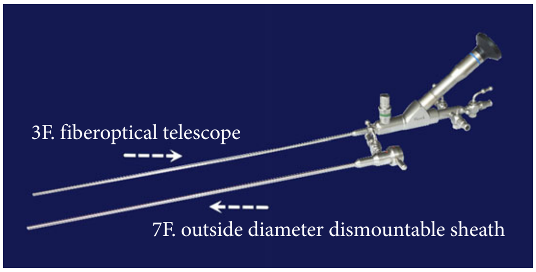
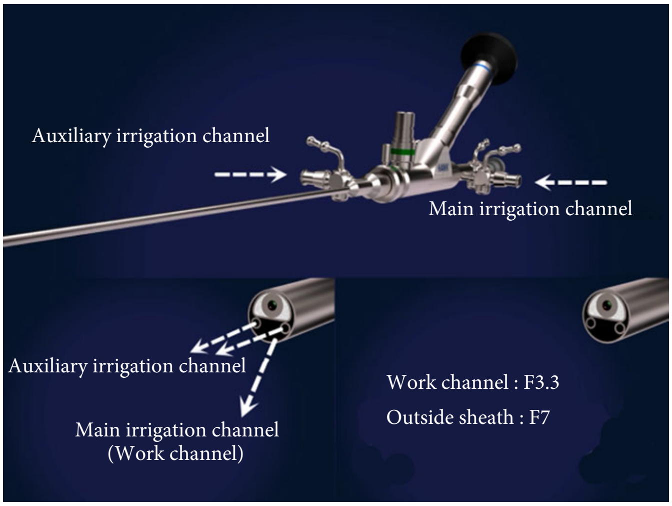


Fig. 2 Detailed structure of the mini-nephroscope.



Modified access sheath

The standard PCNL access sheath was modified by adding a 'handle' to the sheath. The handle consists of a straight and an oblique bifurcated tube at 45° (Fig. 3). The lumens of the straight and the oblique tubes have the same ID as the access sheath. The handle is constructed from clear plastic material. The straight tube is contiguous with the access sheath and has a receptacle for a silicone or rubber cap at the proximal end. There is a longitudinal slit along the axis of the oblique tube to be used as a pressure vent (Fig. 3). The end of the oblique tube is connected to a continuous negative pressure aspirator through clear flexible tubing with the same or larger lumen. The negative aspiration pressure can be adjusted by either partially or completely occluding the pressure vent with the surgeon's thumb while holding the handle with the rest of the hand. The sheath has an ID of 10 F, 12 F, or 14 F. Later, a specimen collection bottle was added between the handle and the aspirator to facilitate stone fragment collection. The full assembly diagram of the access sheath and the miniature nephroscope is shown in Fig. 4.

Surgical Technique

All routine preoperative biochemical testing and preparation were performed as for any of percutaneous surgery. Under general anaesthesia, a 6-F open ended ureteric catheter was first inserted into the collecting system in a retrograde fashion in the lithotomy position. The patient was then turned prone and the desired calyx was punctured under fluoroscopic guidance. Nephrostomy tract dilatation was carried out using fascial dilators of 10–14 F, as indicated. The smallest nephrostomy tract was always used, which was judged by the operating surgeon to be sufficient for the given stone. The corresponding size of suction-evacuation sheath was then placed. The sheath was connected to the specimen collection bottle and the bottle then to the negative pressure aspirator. A rubber cap, with a centre aperture, was placed at the straight proximal end of the sheath. The negative pressure was adjusted to a setting of 150–200 mmHg. The miniature endoscope was inserted into the sheath through the cap. The main irrigation was delivered through the working channel of the endoscope sheath using a pump. Auxiliary pressurised irrigation was delivered, if needed, through the two fine tubes. The stone was visualised and lithotripsy was performed using either a holmium-yttrium aluminium garnet (YAG) laser or pneumatic lithotripter. Laser lithotripsy was our preferred method. The pneumatic lithotripter was used in the centres where laser lithotripters were not available. With active and continuous suction, the tiny stone fragments would pass within the space between the scope and the sheath then exit through the oblique sluice. When larger fragments came into the sheath that could not pass around the scope, the scope was slowly withdrawn to just proximal to the bifurcation of the handle to open up an unimpeded channel for the passage of such fragments through the oblique side-port. The negative pressure could be adjusted by either partially or completely

Fig. 3 The modified access sheath assembly.

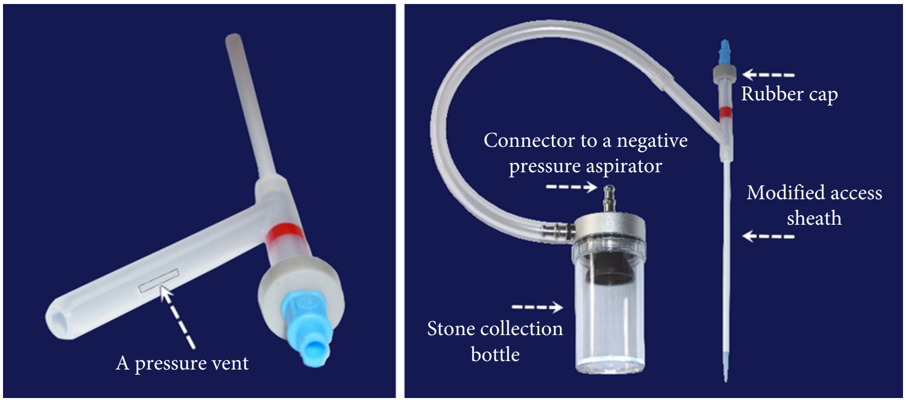
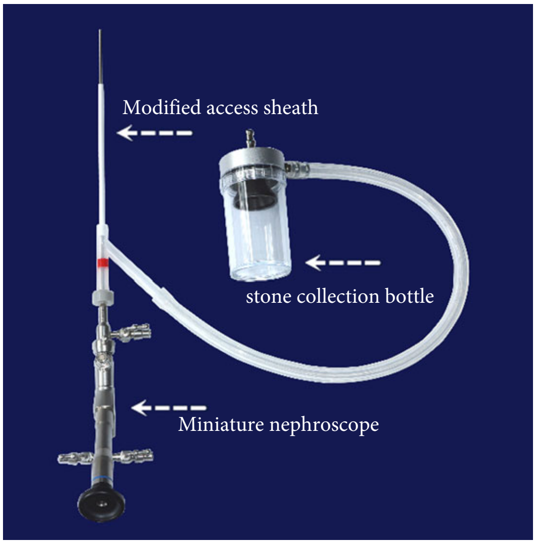


Fig. 4 The fully assembly access sheath and miniature nephroscope.



occluding the pressure vent. The high flow of the irrigation fluid coupled with continuous suction created a vortex that brought the stone fragments to the opening of the sheath and at same time negated the high intra-luminal pressure created by the pressurised irrigation. When the flow of the main irrigation systems was insufficient, sometimes due to the jamming of the 3-F working channel by the laser fibre, pneumatic lithotripter probe and forceps, the auxiliary irrigation system could be used. This was generally accomplished by injection of pressurised irrigation fluid through the side-port on the dismountable sheath (see accompanying Video S1).

At the end of procedure, fluoroscopic images were taken to assess stone clearance. A JJ ureteric stent was placed only when there was the presence of a ureteric inflammatory polyp from the obstruction stone, evidence of PUJ obstruction, concurrent treatment of ipsilateral ureteric stone with rigid ureteroscope, presence of significant pyelocalyceal blood clots after the lithotripsy; and in patients with significant residual stones. Indications for nephrostomy tube placement included significant residual stone fragments, which would require a second-look procedure and significant pyelocalyceal blood clots or bleeding after the lithotripsy.

Results

In all, 146 patients underwent SMP. The procedures were successfully completed in 141 patients. Five (3.4%) patients required conversion to the conventional mini-PCNL. Among them, two cases were due to the larger than expected stone burden; one case of compromised vision from bleeding; and two cases of inaccessibility to the upper ureteric stone at the level of the fourth lumbar vertebra (because of the shorter length of our nephroscope). The mean (SD; range) age of the 141 patients was 41.5 (17.3; 0.92–77) years. There were 27 children (aged ≤14 years) of which 17 were aged <3 years. The mean (SD; range) body mass index (BMI) was 21.6 (4.5; 11.2–29.3) kg/m^2; 15 patients (10.6%) had a BMI of >25 kg/m^2. The mean (SD; range) preoperative stone size was 2.2 (0.6; 0.7–5.1) cm. Detailed characteristics of the patients are given in Table 1.

In all, 144 nephrostomy tracts were established, and 138 patients were treated with a single tract and three patients required two tracts. In all, 135 of the 144 tracts were 12 F in size; seven tracts were 10 F, and two were 14 F. Access for 57 of the nephrostomy tracts was obtained via a supracostal puncture (39.6%) and in 87 (60.4%) via an infracostal puncture. The mean (SD; range) operating duration was 45.6 (21.5; 25–112) min and the mean (SD; range) haemoglobin decrease was 11.3 (8.7; 0–38) g/L. No patient required a blood transfusion.

In all, 102 of the 141 patients (72.3%) did not require any kind of upper tract drainage catheter (total tubeless). Among the patients who did require catheters, 28 (19.9%) were JJ ureteric stents for 2–4 weeks; eight (5.7%) had nephrostomy tubes placed; and seven (4.9%) had ureteric catheters for 1 day. There were four patients who required both JJ stents and a nephrostomy tube.

After the SMP procedures, 14 patients had residual calculi of >2 mm on postoperative KUB/CT. The initial SFR was 90.1% (127/141). One patient required a second-look SMP through the same nephrostomy tract 2 days after the first procedure and the other two cases required extracorporeal shockwave

Table 1 Demographics and stone characteristics of the patients that underwent SMP.

Variable	Value
No. patients	146
Conversion to PCNL, *n* (%)	5 (3.4)
SMP completed, *n* (%)	141
Male/female, *n* (%)	91 (64.5)/50 (35.5)
Mean (SD, range) BMI, kg/m^2	21.6 (4.5; 11.2–29.3)
Mean (SD, range) stone size, cm	2.2 (0.6; 0.7–5.1)
No. stone site, *n* (%)	
Upper ureter	16 (11.3)
Pelvis	40 (28.4)
Lower calyx	35 (24.8)
Middle calyx	26 (18.5)
Upper calyx	8 (5.7)
Multiple	16 (11.3)
Complex cases, *n* (%)	
Solitary kidney	8 (5.7)
Paediatric cases (aged <14 years)	27 (19.1)
Overweight (BMI 25–30 kg/m^2)	15 (10.6)
Failed RIRS	11 (7.8)
Failed UAS placement of RIRS	8 (5.7)
Residual stones after PCNL	21 (14.9)
Mean (SD, range) Hounsfield units	1009.6 (287; 511–1 545)
Positive preoperative urine culture, *n* (%)	8 (5.7)

lithotripsy (ESWL) to disintegrate the residual fragments. At the 3-month follow-up, the SFR increased to 95.8% (135/141). Among these 135 patients, 121 were completely stone free (a true SFR of 85.8%) and 14 patients had insignificant residual stone fragments of <2 mm. Among the patients who still had residual stones, five had residual fragments of 3–6 mm. The other patient had an 8-mm calculus in a lower pole calyx. All these cases were asymptomatic and chose to be followed expectantly.

The mean (SD; range) postoperative hospital stay was 2.1 (1.1; 1–6) days. There were complications in 18 patients (12.8%), which were classified using the Clavien system. The most common complication was fever that occurred in 16 patients (11.3%). However, only eight of these patients (5.7%) required additional i.v. antibiotic management (a Grade II complication). Two patients had prolonged hospitalisation (4 and 5 days) due to haematuria (Grade I). The haematuria resolved spontaneously in both cases without further intervention. No other major complications, including pneumothorax and prolonged extravasation, were noted.

Chemical analysis of the stone composition was available in 132 patients; there were infection stones in 14.5% (19 patients), uric acid stones in 4.2% (6), and calcium-based stones in 81.1% (107) (Table 2).

Table 2 Intraoperative and postoperative variables.

Variable	Value
Mean (SD, range) operative time, min	45.6 (21.5; 25–115)
Mean (SD, range) haemoglobin drop, g/L	11.3 (8.7; 0–38)
Single tract, *n* (%)	138 (97.9)
No. of puncture locations (*n* = 144)	
Upper/middle/lower pole calyx, %	6.2/65.3/28.5
Supracostal/infracostal, *n* (%)	57 (39.6)/87 (60.4)
Initial SFR, *n*/*N* (%)	127/141 (90.1)
Requiring auxiliary procedure, *n* (%)	3 (2.1)
Second-look SMP	1 (0.7)
ESWL	2 (1.4)
Final SFR at 3 months, *n*/*N* (%)	135/141 (95.8)
Completely stone free	121 (85.8)
Insignificant residual stone fragments	14 (9.9)
Significant complication, *n* (%)	18 (12.8)
Fever (>38.5 °C)	16 (11.3)
Grade I	8 (5.7)
Grade II	8 (5.7)
Haematuria	2 (1.4)
Blood transfusion rate	0
Mean (SD, range) postoperative hospital stay, days	2.1 (1.1; 1–6)
N (%)	
Tubeless rate	133 (94.3)
Nephrostomy tube	8 (5.7)
JJ stent	28 (19.8)
Ureteric catheter	7 (4.9)
Total tubeless rate	102 (72.3)
Stone composition	132
Struvite stones	14 (10.7)
Urate stones	11 (8.2)
Calcium-based stones	107 (81.1)

Discussion

There is a trend toward minimally invasive procedures for the treatment of urinary stones. The optimal therapy is a procedure that offers high stone clearance, a short treatment time, and minimal injury to the patients. One of the options is to miniaturise PCNL and there are already several developments along this line. These included the Chinese MPCNL, the UMP, and the micro-PCNL [3–5]. The SMP presented in the present study was based on a proprietarily designed miniature nephroscope and suction-evacuation access sheath. The new SMP system was tested in a multicentre trial. The results showed that in the treatment of moderate sized stones, SMP was safe and effective. SMP had a short operating duration, high stone clearance rate, and low incidence of complications. More noteworthy, was fact that it was possible to reduce the nephrostomy tract size in most patients to 12 F. Compared with the average 18-F nephrostomy tract used in the MPCNL, this represented a 55.6% reduction in the surface area of the nephrostomy tract [6,7].

The major difference between SMP and the UMP and the micro-PCNL is the way the stone fragments are managed. In UMP, the stone fragments are removed using either pressurised irrigation or left *in situ* for spontaneous passage by the patient [4]. In micro-PCNL, the stone fragments are simply left *in situ* for later spontaneous passage [5]. In the SMP procedure, stone fragments are removed by negative pressure aspiration, with the ultimate goal of rendering the patient stone free at the end of the procedure. In the present study, SMP was able to achieve a true SFR of 85.8% and a 95.8% SFR when clinically insignificant stone fragments were counted as stone free.

ESWL is the least invasive treatment for urinary stones. However, the size, location, and hardness of the stone; and the anatomy of the pyelocalyceal system can all affect the final outcome of ESWL [8]. With advances in technology, retrograde intrarenal surgery (RIRS) with flexible ureteroscopes has become a popular option for the treatment of urinary tract stones. Nevertheless, RIRS has its own limitations for dealing with the large stones and stones in difficult to access calyces [9]. There is also the issue of removing all the stone fragments [9]. Last but not the least, flexible ureteroscopes are not readily available everywhere.

From the present data, we think SMP may have at the very least a role in filling the gap between RIRS and conventional PCNL or as a substitute for RIRS. If RIRS is unsuccessful or anticipated to be difficult or failed; antegrade super-mini-access may be a good option to remove the stones. It is clear that if the super-mini-access is insufficient for the procedure, conversion to the standard 16–20 F tract of mini-PCNL by extending the dilatation would be simple, as the access tract has already been established. It should be noted that 35 cases of SMP were performed for lower calyceal stones, 11 of which had failed previous RIRS. Eight additional patients had SMP for mild or moderate ureteric stricture that rendered them unsuitable for RIRS. Five patients were electively converted to mini-PCNL successfully.

The basic requirements for a good miniature PCNL system are a small endoscope and access sheath, which can still offer good ingress and egress of the irrigation fluid, efficient extraction of stone fragments, a clear visual field, and low intra-luminal pressure. The SMP was designed considering these tenets. In our development, it was found that for the SMP system to be efficient, the endoscope should be at the least 3 F smaller than the access sheath. The size of stone fragments that could be evacuated was limited only by the diameter of the access sheath. We found several advantages to the new SMP system. In addition to the improved irrigation and stone extraction, it was found that the stone fragments tended to aggregate at the opening of the sheath resulting in a more efficient lithotripsy and removal of stone fragments. With continuous irrigation, it was also noted that the visual field was clearer, as the 'dust storm' resulting from stone pulverisation and the often encountered minor bleeding no longer affected the field of vision. There is still not enough data to confirm, except by inference, that the intra-luminal pressure was reduced with the SMP system. This issue is important and remains to be confirmed in future studies. Finally, the system has no additional learning curve.

The benefits of miniaturisation of PCNL were reaffirmed with the present SMP system. No transfusions were needed, 94.3% of the present patients were nephrostomy tubeless, and 72.3% did not require any kind of tube for upper urinary tract drainage after SMP.

To explore the suitability of SMP for paediatric patients, we tentatively performed successful SMP in 27 children. The small size and compact collecting system of the paediatric kidney necessitates the use of the smallest and least traumatic instruments to reduce the likelihood of major complications, such as bleeding and renal injury [10,11]. Bilen et al. [11] reported higher transfusion rates in children treated with nephrostomy tracts of 20–26 F, whereas no transfusions were needed in the cohort treated using a 14-F access tract. We think that the SMP can meet the challenge of the paediatric kidney.

The hospitalisation for SMP was longer than necessary. Most SMPs could be accomplished in an outpatient setting. However, due to the health reimbursement policy, the low cost of hospitalisation, and the prevailing custom in China, it was difficult to convince our patients to have this procedure done in an outpatient setting.

There were some limitations to our present SMP study. The system was only tested in stones of <2.5 cm; therefore, SMP could only be a supplement to but not a substitute for conventional PCNL. We plan to prospectively investigate SMP and compare it with other minimally invasive PCNL techniques for larger stones.

In conclusion, we have developed a new minimally invasive PCNL system, the SMP. The SMP system is based on an innovatively designed miniature nephroscope and a suction-evacuation access sheath. In all, 141 SMP procedures were performed in 14 medical centres and the initial results were promising. The SMP appears to be a safe and effective procedure for renal stones of <2.5 cm. It might be particularly useful in patients with lower pole stones and stones not amenable to RIRS.

Conflicts of Interest

None declared.

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Abbreviations: ESWL, extracorporeal shockwave lithotripsy; ID, inside diameter; KUB, plain abdominal radiograph of the kidneys, ureters and bladder; OD, outside diameter; (M)PCNL, (minimally invasive) percutaneous nephrolithotomy; RIRS, retrograde intrarenal surgery; SFR, stone-free rate.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Video S1. The step-by-step simulation process of super-mini-Percutaneous nephrolithotomy (SMP).