

# Super-mini percutaneous nephrolithotomy (SMP) vs retrograde intrarenal surgery for the treatment of 1–2 cm lower-pole renal calculi: an international multicentre randomised controlled trial

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## Objectives

To compare the safety and effectiveness of super-mini-percutaneous nephrolithotomy (SMP) and retrograde intrarenal surgery (RIRS) for the treatment of 1–2 cm lower-pole renal calculi (LPC).

## Patients and Methods

An international multicentre, prospective, randomised, unblinded controlled study was conducted at 10 academic medical centres in China, India, and Turkey, between August 2015 and June 2017. In all, 160 consecutive patients with 1–2 cm LPC were randomised to receive SMP or RIRS. The primary endpoint was stone-free rate (SFR). Stone-free status was defined as no residual fragments of  $\geq 0.3$  cm on plain abdominal radiograph of the kidneys, ureters and bladder, and ultrasonography at 1-day and on computed tomography at 3-months after operation. Secondary endpoints included blood loss, operating time, postoperative pain scores, auxiliary procedures, complications, and hospital stay. Postoperative follow-up was scheduled at 3 months. Analysis was by intention-to-treat. The trial was registered at <http://clinicaltrials.gov/> (NCT02519634).

## Results

The two groups had similar baseline characteristics. The mean (SD) stone diameters were comparable between the groups, at 1.50 (0.29) cm for the SMP group vs 1.43 (0.34) cm for the RIRS group ( $P = 0.214$ ). SMP achieved a significantly better 1-day and 3-month SFR than RIRS (1-day SFR 91.2% vs 71.2%,  $P = 0.001$ ; 3-months SFR 93.8% vs 82.5%,  $P = 0.028$ ). The auxiliary procedure rate was lower in the SMP group. RIRS was found to be superior with lower haemoglobin drop and less postoperative pain. Blood transfusion was not required in either group. There was no significant difference in operating time, hospital stay, and complication rates, between the groups.

## Conclusions

SMP was more effective than RIRS for treating 1–2 cm LPC in terms of a better SFR and lesser auxiliary procedure rate. The complications and hospital stay were comparable. RIRS has the advantage of less postoperative pain.

## Keywords

super-mini percutaneous nephrolithotomy, retrograde intrarenal surgery, lower-pole renal calculi

## Introduction

The prevalence of stone disease is increasing and the optimal treatment of symptomatic lower-pole renal calculi (LPC) remains quite challenging [1]. Hence, current treatment modalities for 1–2 cm LPC continue to be contested [2–4]. According to the 2017 European Association of Urology (EAU) guidelines, shockwave lithotripsy (SWL), percutaneous nephrolithotomy (PNL), and retrograde intrarenal surgery (RIRS) are recommended treatment options for 1–2 cm LPC [3]. Although the non-invasive nature and high patient acceptance rates are the main advantages of SWL, low stone-free and higher retreatment rates constitute the major drawbacks of this approach in the management of LPC [4–6]. RIRS is increasingly performed and has a good safety profile for the surgical management of LPC. Whereas, PNL has a higher stone-free rate (SFR), but it is more invasive and has higher complication rates compared to RIRS [3].

Taking the higher risk of complications associated with standard PNL into account, endourologists aimed to decrease the rate of severe complications (mainly bleeding) by using reduced tract sizes to limit the trauma induced in the renal parenchyma [7]. With this concept of reducing the risk of PNL-related complications, we developed the super-mini-PNL (SMP), which refers to an access sheath size of 10–14 F. It provides a safe and effective treatment method for renal calculi of  $\leq 2.5$  cm [8]. It also has been suggested as an alternative treatment technique in the management of patients with LPC not amenable to RIRS [8]. However, Level-1 evidence comparing the two modalities for treating 1–2 cm LPC is lacking. To investigate this, we carried out a multicentre, prospective, randomised controlled trial to compare the safety and effectiveness of SMP and RIRS for the treatment of patients with 1–2 cm LPC.

## Patients and Methods

### Patient Population

A prospective, randomised, unblinded controlled study was conducted at eight centres in China, one centre in India, and one centre in Turkey, from August 2015 to July 2017. Ethics Committee approval was obtained at each site (ClinicalTrials.gov NCT02519634). Table 1 presents the details of the inclusion criteria. The primary endpoint was the SFR at 3-months after surgery. Stone-free status was defined as no residual fragments of  $\geq 0.3$  cm on plain abdominal radiograph of the kidneys, ureters and bladder (KUB) and ultrasonography at 1-day and CT at 3-months after operation [2,9]. Secondary endpoints included haemoglobin decrease, transfusion rate, operating time, postoperative pain, auxiliary procedures, hospital stay, and complications (using the Clavien–Dindo grading system [10]).

**Table 1** Patient selection criteria.

Inclusion criteria	
Willing to sign informed consent	
Aged 18–70 years	
Normal renal function (serum creatinine level $<177$ $\mu\text{mol/L}$ )	
ASA score 1–2	
Absence of congenital abnormalities	
A single LP renal calculus with a diameter of 1–2 cm*	
Exclusion criteria	
Multiple LPC	
Multiple renal calculi in the ipsilateral kidney in middle/upper pole calyces	
Active UTI at time of treatment	
Uncorrected coagulopathy	
Solitary kidney	
Renal malformation	
Patients who underwent renal transplant or urinary diversion	
Patients undergoing any other surgical procedure during the same admission (e.g. ureteroscopy)	
<p>ASA, American Society of Anesthesiology; LP, lower pole; LPC, lower-pole renal calculi. *The stone size was defined as the maximum diameter as determined by non-contrast CT.</p>	

The sample size was determined based on historical data of the SFR at 3-months after SMP and RIRS for LPC (98% and 85%, respectively). According to non-continuous sample size calculation formula, the minimum sample size for each group was estimated to be 72 (power  $>0.80$ ) with a type-I error rate  $<0.05$ . To account for patients lost to follow-up and study withdrawals, this number was increased to 80.

Parallel randomisation was conducted at a ratio of 1:1, stratified by site, and was carried out using computer-generated random numbers. The coordinating centre revealed randomisation to the operating surgeon at the time of surgical scheduling. The number of patients enrolled in the study at each participating institution was equally distributed. The surgeons and patients were not blinded to group assignment. Investigators who had not been involved and who were blinded to the surgical procedures performed the postoperative clinical assessment. In each centre, surgeries were performed only by one surgeon experienced in both procedures ( $\geq 50$  SMPs and RIRs per year).

### Endoscopic Procedure

Preoperative assessment was the same for the entire study group. IVU and non-contrast CT were done in all patients to assess stone characteristics and renal anatomy. All procedures were carried out under general anaesthesia. Prophylactic antibiotics were given to all patients according to local antimicrobial guidelines.

### Super-Mini-Percutaneous Nephrolithotomy

Super-mini-percutaneous nephrolithotomy surgical procedure was performed as previously described [8]. In summary, under general anaesthesia, in lithotomy position, a 5-F open-end ureteric catheter was placed under ureteroscopic guidance

into the renal pelvis. The patient was then turned to prone position. Percutaneous access was achieved using either ultrasonographic or fluoroscopic guidance. Tract dilatation was performed with fascial dilators up to 14 F. Next a 14-F irrigation-suction sheath was introduced into the pelvicalyceal system. Lithotripsy was performed using a 200- $\mu$ m holmium-laser fibre at an energy level of 8–20 W. At the end of procedure, fluoroscopic images were taken to assess stone clearance. A 6-F JJ stent or 5-F ureteric catheter was inserted only in the presence of pyelocalyceal blood clots and/or pelvic perforation. Indications for 12-F nephrostomy tube placement included significant residual stone fragments requiring a second-look procedure and significant pyelocalyceal blood clots or bleeding. The operating time for SMP was recorded from the time of the first percutaneous renal puncture to wound closure.

### Retrograde Intrarenal Surgery

The patient was placed in lithotomy position, and a 0.089 cm guidewire was first placed into the renal pelvis. A 12/14-F ureteric access sheath was then advanced into the proximal ureter over the guidewire. An Olympus-P5 or Storz-X2 flexible ureteroscope was passed through the ureteric access sheath. Lithotripsy was performed using a 200- $\mu$ m holmium-laser fibre at an energy level of 8–20 W. We attempted to mobilise the LPC to the upper or middle calyx before fragmentation. If this was not successful, the calculus was fragmented in the lower calyx. Large stone fragments were removed with a nitinol stone basket and sent for stone analysis. Stone fragments of <2 mm were left *in situ* for spontaneous passage. A 6-F JJ stent was routinely placed at the end of the procedure. The operating time was recorded from insertion of the endoscope into the urethra to the completion of stent placement.

### Postoperative Evaluation and Follow-Up

KUB and ultrasonography were performed on postoperative day 1 to assess the one-session stone-free status. Low-dose CT, with a 2-mm section thickness, was obtained for all patients at the 3-month follow-up to evaluate the stone-free status. This interval was chosen to allow time for patients in the RIRS group to pass remaining stone fragments spontaneously.

Postoperative pain severity was assessed at 6, 24 and 48 h postoperatively using a visual analogue scale (VAS; range: 1–10) [6]. Hospital stay was rounded to the nearest whole day and calculated from the day of surgery to the day of discharge. Second-look SMP, SWL and external physical vibration lithotripsy (EPVL) were auxiliary procedures used to treat patients with significant residual stones postoperatively. The JJ stents were removed 2 weeks after the procedures.

### Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS®), version 20.0 (SPSS Inc., IBM Corp., Armonk, NY, USA). Continuous variables were analysed using Student's *t*-test to compare the two means. Categorical variables between groups were analysed using the chi-squared or Fisher's exact tests. The analysis was done according to the intention-to-treat principle. We also did a per-protocol analysis of the primary endpoints, in which we compared patients who underwent the assigned RIRS (i.e., those who did not have a conversion to SMP and those who did not have purulent urine in the kidney) with those who had been randomly assigned to and underwent SMP. A  $P < 0.05$  was considered statistically significant.

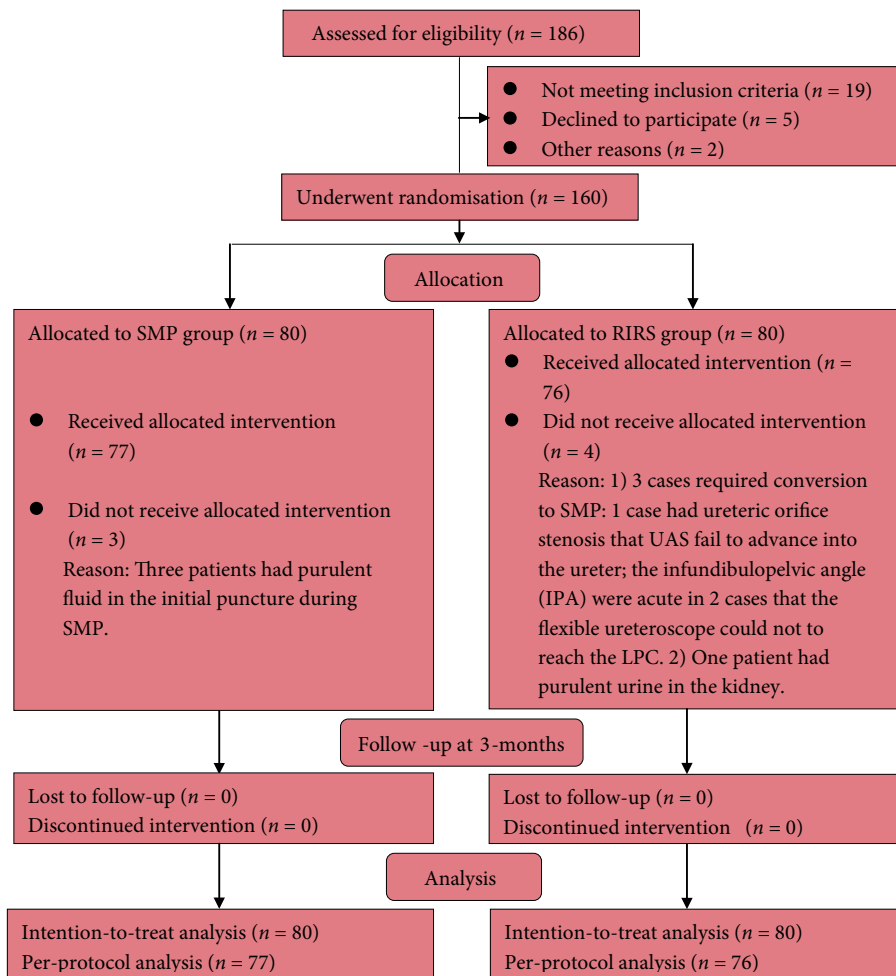
### Results

The flow chart for trial inclusion is shown in Fig. 1. Of the 186 eligible patients, 160 patients were randomised into the two groups. Three patients in the SMP group were found to have purulent fluid in the collecting system during SMP puncture. Thus, a nephrostomy tube was placed and SMP postponed avoiding septic complications for these patients. In the RIRS group, three patients required conversion to SMP. One had an unfavourable ureteric orifice for RIRS access; two had steep infundibulopelvic angles (IPAs) preventing access of the LPC by flexible ureterorenoscopy. Additionally, one patient was found to have purulent urine in the kidney. A JJ stent was inserted for this patient and the procedure was postponed to avoid septic complications. The baseline characteristics of the two groups were comparable (Table 2).

The SFR after a single treatment was significantly higher in the SMP group than in the RIRS group (91.2% vs 71.2%,  $P = 0.001$ ). Clinically significant residual fragments (CSRF) were detected in four patients in the SMP group after a single treatment session. Of these cases, whilst one patient required a second-look SMP, one patient needed subsequent SWL to achieve stone clearance, and two patients required EPVL to remove residual fragments. For the RIRS group, CSRF were detected in 19 patients after a single treatment session. Nine of the 19 patients achieved complete stone clearance with subsequent SWL, whilst 10 patients required EPVL. At the 3-month postoperative follow-up, patients in the SMP group continued to have a significantly higher SFR than those in the RIRS group (93.8% vs 82.5%,  $P = 0.028$ ; Table 3).

The mean operating times were similar between the groups (58.6 vs 52.3 min,  $P = 0.081$ ). Intraoperatively, one patient had a minor renal pelvic perforation in the SMP group and required prolonged JJ stenting for 2 weeks (Clavien–Dindo Grade II). One patient in the RIRS group was found to have an iatrogenic false passage at the distal ureter requiring prolonged JJ stenting for 4 weeks (Clavien–Dindo Grade II)

**Fig. 1** Flow diagram showing study recruitment. UAS, ureteric access sheath.



after abandoning the procedure. The mean pain VAS score at 6, 24, and 48 h was significantly lower in the RIRS group, at 4.1 vs 3.2 ( $P = 0.001$ ), 2.7 vs 2.0 ( $P = 0.004$ ), and 1.7 vs 1.3 ( $P = 0.043$ ), respectively.

The haemoglobin drop was significantly lower in the RIRS group (4.3 vs 10.2 g/L,  $P < 0.001$ ). Blood transfusion was not required in either group. Three patients in the SMP group and one patient in the RIRS group had mild haematuria, all lasting for <6 h and which settled spontaneously.

Postoperative fever occurred in four patients in the SMP group and six patients in the RIRS group ( $P = 0.499$ ). Two patients in each group required additional i.v. antibiotic treatment (Clavien–Dindo Grade II). None of the patients developed urosepsis postoperatively. All the patients had stone analysis and there was no significant difference in stone composition between the groups ( $P = 0.695$ ). There was no significant difference in hospital stay and postoperative creatinine levels between the groups.

The per-protocol analysis incorporated the 77 patients who underwent a completed SMP and the 76 patients who were

assigned to and received RIRS. SMP in the per-protocol analysis achieved significantly better 1-day and 3-month SFRs than RIRS (1-day SFR 94.8% and 75.0%,  $P = 0.001$ ; 3-month SFR 97.4% and 86.8%,  $P = 0.015$ ).

In the 77 patients who were randomly assigned to and received SMP, 52 patients (67.5%) did not require any upper tract drainage catheter (total tubeless). Amongst the patients who did require catheters, 16 (20.8%) had a JJ stent for 2 weeks and five (6.5%) had ureteric catheters for 1 day after the procedure. Four patients (5.2%) required a nephrostomy tube (Table 4).

## Discussion

The management of LPC is more demanding than treatment of kidney stones in other locations due to the inherent anatomical challenges. Techniques such as RIRS and PNL have their advantages and disadvantages, and the optimal primary treatment for patients with 1–2 cm LPC is yet to be determined [2–4]. PNL provides overall significantly higher

**Table 2** Patient's demographics and preoperative clinical characteristics in the two study groups.

Variable	SMP	RIRS	P	95% CI	
Patients, <i>n</i>	80	80	–	NA	NA
Age, years, mean (SD)	49.4 (12.8)	47.1 (13.9)	0.275	–1.860	6.485
Gender, male: female	50:30	46:34	0.519	NA	NA
Body mass index, kg/m <sup>2</sup> , mean (SD)	24.6 (4.1)	24.1 (3.0)	0.379	–0.627	1.639
Comorbidities, <i>n</i> (%)	20 (25.0)	13 (16.3)	–	NA	NA
Hypertension	16 (20.0)	10 (12.5)	0.384		
Diabetes mellitus	4 (5.0)	3 (3.8)			
Previous surgery, <i>n</i> (%)	22 (27.4)	33 (41.3)	–	NA	NA
PNL	9 (11.2)	12 (15.0)	0.323		
URS	9 (11.2)	15 (18.8)			
Open surgery	4 (5.0)	6 (7.5)			
Laterality, left:right	38:42	42:38	0.527	NA	NA
Radiolucent stones, <i>n</i> (%)	7 (8.8)	9 (11.2)	0.598	NA	NA
Stone size, cm, mean (SD)	1.50 (0.29)	1.43 (0.34)	0.214	–0.037	0.162
Hounsfield units, mean (SD)	927.5 (272.7)	846.5 (271.5)	0.061	–3.943	166.020
Lower-pole spatial anatomy, mean (SD)					
IPA, °	55.8 (12.9)	50.8 (13.7)	0.307	–4.737	14.572
Infundibular length, cm	2.6 (0.7)	2.9 (0.6)	0.261	–0.721	0.203
Infundibular width, cm	0.6 (0.2)	0.5 (0.2)	0.107	–0.030	0.287
Grade of hydronephrosis, <i>n</i> (%)	80	80	–	NA	NA
None or mild	67 (83.8)	64 (80.0)	0.538		
Moderate or severe	13 (16.2)	16 (20.0)			
Preoperative serum creatinine level, μmol/L, mean (SD)	89.0 (21.2)	84.6 (24.2)	0.223	–2.708	11.498
Positive preoperative urine culture, <i>n</i> (%)	9 (11.2)	10 (12.5)	0.807	NA	NA

NA, not applicable; RIRS, retrograde intrarenal surgery; SMP, super-mini-percutaneous nephrolithotomy; URS, ureteroscopy.

**Table 3** Comparison of intraoperative and postoperative variables in the SMP and RIRS groups.

Variable	SMP	RIRS	P	95% CI	
Operating time, min, mean (SD)	58.6 (21.6)	52.3 (22.4)	0.081	–0.771	13.282
Intraoperative complications, <i>n</i> (%)	1	1	–	NA	NA
Minor pelvic perforation (Clavien–Dindo Grade II)	1 (1.3)	0	0.319		
False passage (Clavien–Dindo Grade II)	0	1 (1.3)	0.313		
Pain VAS score (range 1–10), mean (SD)					
At 6 h	4.1 (1.6)	3.2 (1.6)	0.001	0.344	1.365
At 24 h	2.7 (1.7)	2.0 (1.5)	0.004	0.246	1.288
At 48 h	1.7 (1.4)	1.3 (1.2)	0.043	0.015	0.861
One-session SFR, <i>n</i> (%)					
Intention-to-treat analysis	73 (91.2)	57 (71.2)	0.001	NA	NA
Per-protocol analysis	73 (94.8)	57 (75.0)	0.001	NA	NA
Haemoglobin drop, g/L, mean (SD)	10.2 (8.9)	4.3 (8.8)	<0.001	3.148	8.820
Blood transfusion rate	0	0	–	–	–
Hospital stay, day, mean (SD)	2.5 (1.1)	2.2 (1.1)	0.156	–0.099	0.612
Postoperative complications, <i>n</i> (%)	7	7	–	NA	NA
Mild haematuria (Clavien–Dindo Grade I)	3 (3.9)	1 (1.3)	0.317		
Fever (>38.5 °C)	4 (5.2)	6 (7.9)	0.499		
Clavien–Dindo Grade I	2 (2.6)	4 (5.3)	0.396		
Clavien–Dindo Grade II	2 (2.6)	2 (2.6)	0.989		
Postoperative serum creatinine level, μmol/L, mean (SD)	90.1 (23.6)	85.3 (21.7)	0.193	–2.453	12.056
Auxiliary procedures, <i>n</i> (%)	4 (5.2)	19 (25.0)	0.001	NA	NA
Second-look SMP	1 (1.3)	–	–		
SWL	1 (1.3)	9 (11.8)	0.008		
EPVL	2 (2.6)	10 (13.2)	0.015		
Final SFR at 3-month postoperatively, <i>n</i> (%)					
Intention-to-treat analysis	75 (93.8)	66 (82.5)	0.028	NA	NA
Per-protocol analysis	75 (97.4)	66 (86.8)	0.015		
Stone composition, <i>n</i> (%)	80	80	–	NA	NA
Calcium oxalate	58 (72.5)	52 (65.1)	0.695		
Uric acid	8 (10.0)	9 (11.2)			
Struvite	6 (7.5)	10 (12.5)			
Carbonate apatite	8 (10.0)	9 (11.2)			

NA, not applicable; RIRS, retrograde intrarenal surgery; SMP, super-mini-percutaneous nephrolithotomy.



**Table 4** Tubeless rate of 77 patients who were randomly assigned to and received SMP.

Type	N (%)
Tubeless rate	73 (94.8)
JJ stent only	16 (20.8)
Ureteric catheter only	5 (6.5)
Totally tubeless	52 (67.5)
Nephrostomy tube	4 (5.2)

*SMP, super-mini-percutaneous nephrolithotomy.*

SFRs than RIRS, at the expense of higher complication rates, blood loss, and longer hospital stay [3].

To decrease PNL-related morbidity rates, possibly caused by its large tract size, we developed and have previously described the use of SMP [8]. It is a modified mini-PNL technique using a miniaturised scope through a smaller, 10–14 F nephrostomy tract. With the newly designed irrigation-suction sheath, the critical limitations of new miniaturised PNLs, i.e., poor irrigation and challenging stone extraction, were completely addressed [11]. Several studies have suggested that SMP is highly effective and safe for moderate-sized stones [8,11].

In our present study, SMP had a significantly higher SFR for treating 1–2 cm LPC when compared to RIRS. This was probably due to the favourable location and angulation of the lower calyx of the kidney for SMP puncture, meaning that percutaneous access could be achieved directly in line with the target stones in the lower pole. This ‘direct-attack’ approach enhanced the economy of movement of stone extraction, resulting into the effective removal of all stone fragments in a single treatment session. Another advantage of SMP procedure was the use of the negative pressure aspiration component of the device, which actively removed the relatively smaller stone fragments by safely controlled suction [8].

Maximal ureterorenoscope deflection is commonly required with RIRS to access renal stones located in the lower pole. Prolonged laser lithotripsy at an acute IPA, in particular for those of <30°, could make complete stone clearance challenging [12]. Another anatomical restriction for access to the lower pole in RIRS is the presence of a long lower pole calyx infundibulum [13]. As such, in the present study there was a significantly higher auxiliary procedure rate in the RIRS group when compared with the SMP group (25.0% vs 5.2%). It is noteworthy that three patients in the RIRS group had their procedure abandoned, and required conversion to SMP. One was due to ureteric orifice stenosis, and two were due to acute the IPA hindering access to the LPC by the flexible ureterorenoscope.

Renal haemorrhage is one of the most worrisome and common complications of a percutaneous procedure. In

contrast, RIRS has the advantage of not violating the renal parenchyma, which might be an important consideration for patients with 1–2 cm LPC. In the present study, the mean drop in haemoglobin level in SMP group was significantly greater than for the RIRS group. However, none of the patients required a blood transfusion. Significant bleeding in patients who underwent SMP was infrequent and most probably due to the reduced access-tract size. Therefore, we found no evidence to support the claim that SMP would require more transfusions in patients with 1–2 cm LPC.

In the present study, other complications, including mild haematuria and fever, were comparable between the groups. Patients in the RIRS group had lower pain scores than those in the SMP group at initial points postoperatively. However, the difference becomes less prominent at 48 h. In our present study, a high proportion of patients underwent tubeless SMP, which seems to have favourable characteristics in terms of pain intensity.

A study conducted by Ozayar et al. [14] suggested that PNL requires a longer operating time as compared to RIRS for LPC, as the stones were usually fragmented and basket extraction was not required routinely during RIRS. However, in our present study, we did not identify any significant differences in operating time between the groups. The reason might be that SMP utilised active suction to remove the stone fragments. In SMP, the shattered stones tend to aggregate at the opening of the sheath instead of scattering, resulting in a more comfortable and quicker lithotripsy.

With regards to the hospital stay, a recently published meta-analysis showed a significantly shorter hospital stay for patients who underwent RIRS when compared with patients who had PNL for the treatment of renal stones [15]. But, in patients who were treated ‘tubeless’ following PNL, the hospital stay was reduced significantly [16,17]. In our present study, 94.8% of the patients did not require a nephrostomy tube after SMP, and 67.5% did not require a nephrostomy tube or JJ stent following SMP. This may explain why the mean hospital stay was similar in the groups.

We acknowledge that there are limitations to the present study. Firstly, the mean hospital stay was longer than that reported in the Western literature. The reason is that most patients in China do not leave hospital until they can return to normal activities. Secondly, we did not evaluate the cost-effectiveness of the two procedures. Thirdly, surgeries were only performed by expert/sub-specialised endo-urologists, who perform >50 cases/year of both SMP and RIRS, and therefore the results may not be generalisable to lower-volume surgeons. Finally, most participants in the present study were Asian, therefore the results might not be applicable to a non-Asian population.

## Conclusions

Our present study shows that both SMP and RIRS are safe and feasible surgical options in the treatment of 1–2 cm LPC. SMP was more effective than RIRS in terms of a better SFR and lesser auxiliary procedure rate. The operating time, complications, and hospital stay were comparable. RIRS has the advantage of less postoperative pain.

## Acknowledgements

Kemal Sarica, Guohua Zeng and Tao Zhang designed the research; Guohua Zeng, Madhu Agrawal, Xiang He, Wei Zhang, Kefeng Xiao, Hulin Li, Xuedong Li, Changbao Xu, Sixing Yang and Kemal Sarica conducted the research; Guohua Zeng, Tao Zhang, Junhong Fan, Wei Zhu and de la Rosette JJ wrote the paper; Guohua Zeng and Kemal Sarica had primary responsibility for the final content. All authors read and approved the final manuscript.

## Source of Funding

This study was supported in part by National Natural Science Foundation of China (No. 81670643, No. 81601273 and No. 81370804). Additional funding was provided by Science and Technology Planning Project of Guangdong Province (No. 2017B030314108) and Guangzhou Science Technology and Innovation Commission (No. 201604020001 and No. 201704020193).

## Conflicts of Interest

The authors have no conflicts of interest.

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**Abbreviations:** CSRF, clinically significant residual fragments; EPVL, external physical vibration lithotripsy; IPA, infundibulopelvic angle; KUB, plain abdominal radiograph of the kidneys, ureters and bladder; LPC, lower-pole renal calculi; PNL, percutaneous nephrolithotomy; RIRS, retrograde intrarenal surgery; SFR, stone-free rate; SMP, super-mini-percutaneous nephrolithotomy; SWL, shockwave lithotripsy; VAS, visual analogue scale.