Micropercutaneous nephrolithotomy (microperc) vs retrograde intrarenal surgery for the management of small renal calculi: a randomized controlled trial

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Objective

- To compare micropercutaneous nephrolithotomy (microperc) and retrograde intrarenal surgery (RIRS) for the management of renal calculi <1.5 cm with regard to stone clearance rates and surgical characteristics, complications and postoperative recovery.

Patients and Methods

- Seventy patients presenting with renal calculi <1.5 cm were equally randomized to a microperc or a RIRS group between February 2011 and August 2012 in this randomized controlled trial. Randomization was based on centralized computer-generated numbers. Patients and authors assessing the outcomes were not blinded to the procedure.
- Microperc was performed using a 4.85-F (16-gauge) needle with a 272-μm laser fibre. RIRS was performed using a uretero-renoscope.
- Variables studied were stone clearance rates, operating time, need for JJ stenting, intra-operative and postoperative complications (according to the Clavien–Dindo classification system), surgeon discomfort score, postoperative pain score, analgesic requirement and hospital stay.
- Stone clearance was assessed using ultrasonography and X-ray plain abdominal film of kidney, ureter and bladder at 3 months.

Results

- There were 35 patients in each group. All the patients were included in the final analysis.
- The stone clearance rates in the microperc and RIRS groups were similar (97.1 vs 94.1%, $P = 1.0$).
- The mean [SD] operating time was similar between the groups (51.6 [18.5] vs 47.1 [17.5], $P = 0.295$). JJ stenting was required in a lower proportion of patients in the microperc group (20 vs 62.8%, $P < 0.001$). Intra-operative complications were a minor pelvic perforation in one patient and transient haematuria in two patients, all in the microperc group. One patient in each group required conversion to miniperc.
- One patient in the microperc group needed RIRS for small residual calculi 1 day after surgery. The decrease in haemoglobin was greater in the microperc group (0.96 vs 0.56 g/dL, $P < 0.001$). The incidence of postoperative fever (Clavien I) was similar in the two groups (8.6 vs 11.4%, $P = 1.0$). None of the patients in the study required blood transfusion.
- The mean [SD] postoperative pain score at 24 h was slightly higher in the microperc group (1.9 [1.2] vs 1.6 [0.8], $P = 0.045$). The mean [SD] analgesic requirement was higher in the microperc group (90 [72] vs 40 [41] mg tramadol, $P < 0.001$). The mean [SD] hospital stay was similar in the two groups (57 [22] vs 48 [18] h, $P = 0.08$).

Conclusions

- Microperc is a safe and effective alternative to RIRS for the management of small renal calculi and has similar stone clearance and complication rates when compared to RIRS.
- Microperc is associated with higher haemoglobin loss, increased pain and higher analgesic requirements, while RIRS is associated with a higher requirement for JJ stenting.

Keywords

microperc, retrograde intrarenal surgery, small renal calculi, laser lithotripsy

Introduction

The incidence of renal calculi is rising [1,2] and more patients are presenting with small renal calculi. The treatment options for small renal calculi (<1.5 cm) are ESWL, percutaneous nephrolithotomy (PCNL) and retrograde intrarenal surgery (RIRS) [3]. The drawbacks of ESWL are relatively lower stone clearance rates and the need for repeated sessions, especially in lower polar and harder stones [4]. While RIRS is a standard treatment option for small renal calculi, the actual cost of each procedure is about six times greater than for ESWL [3,5]. Although RIRS has a better safety profile, its stone clearance rate is inferior to that of PCNL [6], but although PCNL has good stone clearance rates it is associated with a significant risk of morbidity [7]. Since most of the morbidities associated with PCNL are related to the size of tract, a reduction in tract size can lower the number of complications associated with it [8,9]. Micro-PCNL (microperc) is a recently described modified PCNL technique in which renal access and stone fragmentation are performed in a single step using a 4.85-F 'all-seeing' needle [10]. RIRS is therefore an established method of treating small renal calculi, while microperc is a recently described minimally invasive treatment method for the treatment of small renal calculi. The aim of the present study was to compare microperc with RIRS for renal calculi <1.5 cm. The primary objective was to compare stone clearance rates and secondary objectives were to compare operating time, requirement for intra-operative JJ stenting, complications according to the Clavien–Dindo classification system [11], conversion to other procedures, surgeon discomfort score, haemoglobin drop, postoperative pain, analgesic requirement and hospital stay.

Patients and Methods

This study was conducted as a parallel-arm randomized controlled study at a single tertiary care urological hospital in Western India. Our institutional ethics committee approved the study. Informed consent was obtained from all study participants. Between February 2011 and August 2012, 70 patients presenting with renal calculi <1.5 cm were prospectively randomized into either a microperc or a RIRS group in a ratio of 1:1 (Fig. 1). Simple randomization was performed centrally using computer-generated random numbers. Randomization was revealed to the operating surgeon just before starting each procedure. The enrollment of patients was carried out by all the authors, while the generation of the random allocation sequence and assignment of participants to interventions were carried out by the second and third authors. The inclusion criteria were a single renal stone or multiple stones in the same line (which can be accessed in a single puncture) <1.5 cm in size. The stone size was defined as the maximum diameter as determined by non-contrast CT. Exclusion criteria were patients undergoing any other surgical procedure during the same admission (e.g. ureteroscopy), multiple stones at different locations, pregnancy, age <18 years, uncorrected coagulopathy and active UTI. Neither patients nor the study authors were blinded to the procedure. Assuming a stone clearance rate

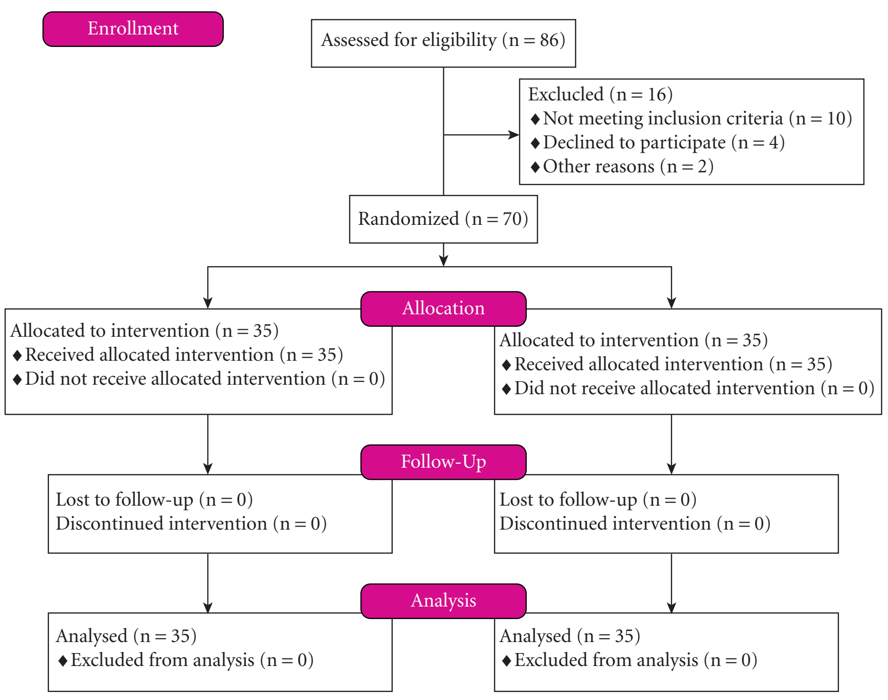


Fig. 1 Flow diagram and patient disposition.

with RIRS of 80% and an expected rate of nearly 100% with microperc, the sample size for each group was calculated as 35 (power >0.80) with a type I error rate <0.05. All procedures were performed under general anaesthesia. A hospital antibiotic coverage policy that was similar for both groups was used.

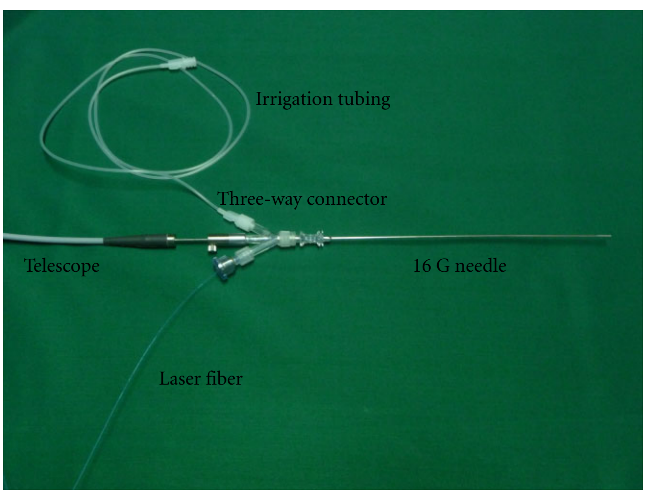
Microperc

The microperc procedure was performed as follows. Under general anaesthesia, in the lithotomy position, a 7-F ureteric catheter was placed under cystoscopic guidance into the renal pelvis. In the prone position, either the stone-containing calyx or the appropriate calyx leading straight to the pelvic stone was selected for puncture. Calyceal puncture was done using a 16-gauge three-part needle under ultrasonography and/or fluoroscopy guidance. In none of the cases, renal access was achieved under vision using all-seeing option. The beveled inner needle with stylet was removed, the telescope was inserted through one connector side port and the other side port was used for irrigation (Fig. 2). The 272-μm laser fibre was inserted through the central port and the calculus was completely fragmented using a holmium:YAG laser (LISA Laser, Pleasanton, CA, USA). The operating surgeon controlled the amount of irrigation from the irrigation pump using a foot pedal. A JJ stent was inserted if the fragmented stone burden was felt to be significant. If a JJ stent was required, the previously placed ureteric catheter was replaced with a JJ stent over a guidewire in supine position at the end of the procedure.

Retrograde Intrarenal Surgery

In RIRS, cystoscopy was performed and the ureteric orifice was cannulated with a 150 cm guidewire (Terumo, Tokyo, Japan). The ureter was dilated with fascial dilators and a 12-F ureteric access sheath (Cook Medical Inc., Bloomington, IN, USA) was placed. A 7.5-F Flex X2 (Karl Storz, Tuttlingen, Germany) flexible ureteroscope was used along with a 272-μm laser fibre for laser lithotripsy. If the calculus was in the lower calyx, it was attempted to basket and place it in the upper calyx before fragmentation. If this was not successful, the calculus was fragmented in the lower calyx. Holmium laser power was set in the range 5–15 W. If the fragments were large, they were removed with a 1.7-F zero-tipped nitinol stone basket (Cook Medical Inc.). After laser lithotripsy, either a JJ stent or 5-F ureteric catheter was placed. A JJ stent was inserted when (i) any ureteric injury was visualized at the end of the procedure, (ii) the fragmented stone burden was felt to be significant, or (iii) access sheath was in place for >45 min.

Fig. 2 Microperc instrument assembly used during stone fragmentation.



Both the procedures were performed by two senior surgeons of the department. At the end of either procedure, the surgeon was asked about the discomfort in performing it in terms of shoulder pain, wrist strain and overall discomfort. This score was noted on a visual analogue score ranging from 1 to 10. After both procedures, fragmentation and clearance were assessed by fluoroscopy intra-operatively. X-ray and plain abdominal film of kidney, ureter and bladder (KUB) were performed to assess the stone clearance on the first postoperative day. The Foley catheter, along with ureteric catheter (if placed), was removed on the first postoperative day and then the patient was discharged if there was no complication. X-ray and KUB were repeated at 3 months follow-up. Clearance was defined as no residual stone on KUB at 3 months. Data were recorded prospectively in a database and reported as the number and percent or mean (SD) values, as appropriate.

Statistical analysis was performed using a *t*-test for continuous variables with normal distribution and a Mann–Whitney *U*-test for variables without normal distribution. For categorical variables, the chi-squared test or Fisher's exact test was applied. A *P* value <0.05 was considered to indicate statistical significance.

Results

The patient demographics and stone characteristics were similar in the two groups (Tables 1,2). In the microperc group one patient required conversion to miniperc to retrieve fragments which migrated to another calyx and could not be reached. All patients in the RIRS group completed the procedure in one session. One patient in the RIRS group required conversion to miniperc as the infundibulum was narrow and angulated and hence inapproachable. The mean [SD; range] operating times were similar in the microperc (51.6 [18.5; 20–90] min) and RIRS

Table 1 Patient demographics and clinical characteristics in the two study groups.

Variable	Microperc group	RIRS group	*P*
Patients, *n*	35	35	
Mean (SD) age, years	38.6 (14.6)	43.7 (12.1)	0.103
Gender, male : female	22:13	24:11	0.802
Mean (SD) body mass index, kg/m^2	23.9 (4.9)	24.9 (4.3)	0.377
Comorbidities, *n*			
Diabetes mellitus	2	4	0.673
Hypertension	3	7	0.306
Ischaemic heart disease	0	1	1.0
Chronic kidney disease	1	2	1.0

Table 2 Stone characteristics in the two study groups.

Variable	Microperc group	RIRS group	*P*
Patients, *n*	35	35	
Mean (SD) stone size, cm	1.10 (0.23)	1.04 (0.25)	0.303
Laterality, right : left	19:16	17:18	0.811
Mean (SD) Hounsfield units	1313 (203)	1247 (191)	0.158
Site of stone, *n*			
Pelvis	14	13	1.0
Upper calyx	3	2	1.0
Middle calyx	3	3	1.0
Lower calyx	15	17	0.811

groups (47.1 [17.5; 30–100] min; $P = 0.295$). The mean [SD] surgeon discomfort score was significantly higher in RIRS group than in the microperc group (3.1 [0.7] vs 4.1 [1.2]; $P < 0.001$). One patient in the microperc group required RIRS 2 days after surgery to remove residual fragments. These fragments were not detected during intra-operative fluoroscopy but were detected on X-ray KUB 1 day after surgery. Another patient in the microperc group required JJ stenting 1 day after surgery to relieve ureteric colic owing to fragmented calculi.

Although the haemoglobin drop was marginal in both the groups, it was significantly lower in the RIRS group (0.96 vs 0.56 g/dL, $P < 0.001$). Blood transfusion was not required in any patient. Intra-operatively, there was a minor pelvic perforation in one patient in the microperc group, which was managed by insertion of a JJ stent (Clavien II). Two patients in the microperc group had mild haematuria lasting for 8 h and three patients had mild haematuria lasting for 2 h; however, none of these patients required any intervention and haematuria subsided on its own. Postoperative fever (all Clavien grade I) occurred in three patients in the microperc and four patients in the RIRS group ($P = 1.0$). All these patients were managed with antipyretics without any change or addition of antibiotics. None of the patients in either group developed urosepsis. In the microperc group, significantly fewer patients required a JJ stent than in the RIRS group (20 vs 62.8%, $P < 0.001$). The mean [SD] pain visual analogue score (1 to 10) at 24 h was slightly lower in the RIRS group (1.9 [1.2] vs 1.6 [0.8], $P = 0.045$). The mean [SD] analgesic requirement was significantly lower in the RIRS group (90 [72] vs 40 [41] mg tramadol, $P < 0.001$). One patient in the microperc group and two patients in the RIRS group had residual calculi at 3 months follow-up. The stone clearance rates at 3 months follow-up were 97.1% for the microperc group and 94.3% for the RIRS group ($P = 1.0$). The results are shown in Table 3.

Discussion

Percutaneous nephrolithotomy is the current standard of care for large bulk renal calculi [12]. For small renal calculi the currently available management options include ESWL, standard PCNL/miniperc and RIRS. In a Cochrane review, the efficiency quotient of PCNL was found to be higher than that of ESWL for renal calculi [4]. For treatment of lower pole stones of 10–20 mm, RIRS provides a significantly higher stone-free rate and lower retreatment rate compared with ESWL [13]; thus, PCNL and RIRS are superior to ESWL in terms of stone clearance rates, but at the cost of slightly higher complication rates [4,13].

The advantage of PCNL is its higher stone clearance rate in a single hospital admission but the downside is the higher incidence of complications. In the Clinical Research Office of the Endourological Society global study on PCNL, involving 5803 patients, major procedure-related complications included significant bleeding (7.8%), renal pelvis perforation (3.4%), hydrothorax (1.8%) and blood

Table 3 Comparison of intra-operative and postoperative variables in the microperc and RIRS groups.

Variable	Microperc group	RIRS group	*P*
Mean (SD) operating time, min	51.6 (18.5)	47.1 (17.5)	0.295
Mean (SD) surgeon discomfort score: scale 1–10	3.1 (0.7)	4.1 (1.2)	<0.001
Intra-operative JJ stenting, *n* (%)	7 (20)	22 (62.8)	<0.001
Mean (SD) pain visual analogue score: scale 1–10			
At 6 h	4.8 (1.6)	3.8 (1.1)	0.003
At 12 h	3.4 (2.0)	2.4 (0.9)	0.009
At 24 h	1.9 (1.2)	1.6 (0.8)	0.045
Mean (SD) analgesic requirement, mg tramadol	90 (72)	40 (41)	<0.001
Conversion to miniperc, *n* (%)	1 (2.8)	1 (2.8)	1.0
Intra-operative complication), *n* (%)			
Minor (Clavien II) pelvic perforation	1 (2.8)	0	1.0
Postoperative complications, *n* (%)			
Mild haematuria (Clavien I)	5	0	0.054
Fever (Clavien I)	3 (8.6)	4 (11.4)	1.0
Mean (SD) haemoglobin drop, g/dL	0.96 (0.41)	0.56 (0.31)	<0.001
Mean (SD) hospital stay, h	57 ± 22	49 ± 18	0.08
Auxiliary procedures, *n* (%)	2 (5.7)	0	0.151
RIRS	1	-	
Postoperative JJ stenting	1	0	
Complete stone clearance, *n* (%)	34 (97.1)	33 (94.3)	1.0

transfusion (5.7%) [14]. Many of the complications associated with PCNL can be attributed to the tract size. It has been shown that blood loss in PCNL increases with increasing tract size [8,15,16]; a new method, miniperc, was therefore developed by which smaller tract size and smaller instruments were used. Miniperc has a lower haemoglobin drop and shorter hospital stay but similar stone clearance rate when compared with standard PCNL [9,17]. Miniperc has been shown to have a good stone clearance rate and similar complication rates when compared with RIRS [18]. Both standard PCNL and miniperc are multistep procedures that require initial ultrasound or fluoroscopic access, guidewire placement in the system, removal of the initial puncture needle over the guidewire, serial or single-step dilation of the tract with resultant tract bleeding during the manoeuvres and finally the placing of a sheath over the tract dilators [19]. These individual manoeuvres are time-consuming and often have disadvantages, such as increased fluoroscopic time and radiation, tract bleeding and inadvertent complications, including calyceal or infundibular tearing and pelvic perforation [7,19]. A single-step procedure with as small a tract size as possible could greatly reduce these complications. Bader et al. [20] developed the 'all-seeing needle' to puncture the kidney properly and confirm access for PCNL. The same technique was modified to perform renal access and PCNL in one step using the all-seeing needle (microperc) by Desai et al. [10].

Retrograde intrarenal surgery has good efficacy and a low complication rate with small renal stones [21,22]. Severe bleeding or infection after intrarenal surgery is rare. When compared with PCNL, RIRS has a lower disintegration rate because of limited manoeuvres with ureteroscopes and the inability to suck up all debris [23]. The other disadvantages of RIRS are the need to postpone the procedure in case of a tight ureter, the high cost of instruments, the need for staged procedures, severe ureteric injuries and the need for longer duration of ureteric stenting [24,25].

In the present study, stone clearance rates were similar in the microperc and RIRS groups and were similar to those of previous single-arm studies [26,27]. Tepeler et al. [26] reported a stone clearance rate of 85.7% (18 of 21 cases) using microperc in 21 patients with lower pole calculi. Thus, microperc has a high stone clearance rate that can offset its invasive nature. The surgeon discomfort score was higher in the RIRS group and RIRS has an initial learning curve. Even after the technique of RIRS is mastered, the manoeuvrability of the flexible and long instrument is definitely limited as compared to the rigid and short instruments used in microperc. Moreover, microperc provides direct access to the lower calyx of the kidney, while a flexible ureteroscope needs to be bent and manipulated to reach the lower calyx. As all the surgeons in the present study were trained in both the standard PCNL and miniperc, they could perform microperc comfortably. Although microperc is a relatively new procedure it can be easily mastered by any urologist trained in PCNL [28]. The mean duration of surgery was similar in the two groups. Stone fragmentation in microperc was easier because of the short and rigid instrument, but all the fragments needed to be dusted since they could not be retrieved. In the RIRS group, fragments could be retrieved using a basket, but the fragmentation was more difficult owing to the long and flexible instrument. Moreover, in the microperc group the surgeon had to be careful regarding migration of the stone. In fact, this was the reason for conversion to miniperc in one of the patients in the microperc group. One patient in the RIRS group needed conversion to miniperc because of the acute angle of the lower calyx which meant the ureteroscope could not reach to basket or fragment the stone. Microperc may be advantageous in such situations as it provides direct access to the lower calyceal stone.

Complication rates were similar in the two groups studied. Haemoglobin drop was higher in the microperc group and five patients in the microperc group had mild haematuria lasting for a few hours, but none of the patients in either group had haemodynamic instability or required blood transfusion. The major concern with PCNL, significant bleeding, is very rare with microperc because of its single-step access with a small-calibre needle. Patients in the RIRS group had a lower analgesic requirement and lower pain scores when compared with the microperc group; however, the mean pain score in the microperc group had lowered after 24 h to a score similar to that of the RIRS group (1.9 vs 1.6, $P = 0.045$). The higher pain scores in the microperc group were probably attributable to the percutaneous access involved. The pain in microperc could possibly be reduced by infiltration of a local anaesthetic agent [29], but this aspect was not included in the present study.

Insertion of a JJ stent was required in a higher proportion of patients in the RIRS group. Infrequent JJ stent requirement is an important advantage of microperc as it avoids stent-related symptoms and obviates the need for another procedure to remove the stent. Microperc may have an advantage when the infundibulum is narrow or highly angulated where the flexible ureteroscope cannot reach. It may also have an advantage in cases where the ureter cannot be adequately dilated to pass the ureteroscope.

A flexible ureteroscope is subject to wear and tear and may require a major repair after as few as 4–14 cases [30]. It also requires disposable components such as baskets, adding to the overall cost of the procedure. The microperc telescope, being small, may have much less wear and tear; however, cost-effectiveness was not evaluated in the present study.

The use of non-contrast CT rather than X-ray KUB for follow-up would have allowed a more accurate assessment of stone clearance, but we do not do use follow-up CT routinely in view of its radiation hazards and economic implications.

In conclusion, the stone clearance rates in both microperc and RIRS are high and complications are low. RIRS has a higher surgeon discomfort, requires insertion of JJ stent in more patients and has a lower haemoglobin drop. Microperc is associated with more pain and higher analgesic requirement. Microperc can be a safe and effective alternative to RIRS in the management of small renal calculi. Both microperc and RIRS have some minor limitations that are unique to their instrumentation and each procedure can have specific advantage over the other in specific situations.

Acknowledgements

None.

Conflict of Interest

None declared.

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Abbreviations: Microperc, micropercutaneous nephrolithotomy; RIRS, retrograde intrarenal surgery; PCNL, percutaneous nephrolithotomy; KUB, plain abdominal film of kidney, ureter and bladder.