#### **ORIGINAL PAPER**



# Ultramini-percutaneous nephrolithotomy versus retrograde intrarenal surgery in the treatment of 10–30 mm calculi: a randomized controlled trial

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#### Abstract

The surgical management of renal stones 10-30 mm is usually performed with percutaneous nephrolithotomy (PCNL) and retrograde intrarenal surgery (RIRS). Standard form of percutaneous nephrolithotomy has paved the way for miniaturized PCNL in many centres. We wanted to evaluate the efficacy, safety and the cost-effectiveness of ultramini-percutaneous nephrolithotomy (UMP) versus RIRS in the treatment of renal stones with stone burden 10-30 mm. Patients with renal stone burden 10-30 mm were prospectively randomized into either UMP or RIRS. The demographic data, stone characteristic, operative time and cost of the equipment were recorded. The stone free status, analgesic requirement, deterioration of the renal function and hemoglobin and the postoperative complications as per Clavein-Dindo grade were recorded. One hundred and fifty patients met inclusion criteria. Out of these 98 underwent UMP and 46 RIRS. Six withdrew the consent before the procedure. Mean stone size was comparable in either of the groups. Mean laser time and stone extraction time was significantly less for UMP compared to RIRS (41.17 min versus 73.58 min p < 0.0001). Mean consumable costs in the UMP group were considerably less at US\$45.73 compared to the RIRS group at \$423.11 (p < 0.0001). The stone free rates at 1 month of follow-up were 100% for UMP group and 73% for RIRS group. There were insignificant changes to mean hemoglobin and glomerular filtration rate (GFR) in all patients and the average length of the stay was similar in both the groups. The postoperative complications revealed Grade I and II rate of 10% in the UMP group and 35% in the RIRS group, respectively. We concluded that UMP to be safe, effective and more economical to the RIRS for renal stones up to 3 cm in size. Trial registered with ISRCTN registry ID ISRCTN20935105, Retrospective.

**Keywords** Minimal invasive management of renal calculi  $\cdot$  Retrograde intrarenal surgery (RIRS)  $\cdot$  Ultramini-percutaneous nephrolithotomy (UMP)  $\cdot$  Randomized controlled trial

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## Introduction

Renal calculi are one of the most common acute urological conditions capable of causing significant symptoms including pain, infection and bleeding. With an estimated prevalence of 1-20% varying in geographical regions it poses a significant health burden to the society [1, 2]. Treatment objectives include the removal of any calculi present while minimising treatment complications.

The last few decades have witnessed significant advances in the minimally invasive management of the renal calculi with the current treatment options of shock wave lithotripsy (SWL), percutaneous nephrolithotomy (PCNL) and retrograde intrarenal surgery (RIRS). PCNL is currently the treatment of choice for renal stones greater than 20 mm but has associated risk of complications [3]. A consistent attempt to PCNL and micro-PCNL [4–6]. Similarly, improvements in Retrograde Intra-Renal Surgery (RIRS) with improved optics and use of the laser for stone fragmentation has provided a reliable alternative to PCNL and the advent of the digital scopes has reduced the operating time as well [7, 8]. Increased adoption of this technique has increased the cost of RIRS in relation to capital (scopes and laser) and consumables (baskets, access sheaths, wires, stents) and cost of removal of stents adding to the total cost of the procedure [9, 10].

In this randomized control trial (RCT), we investigated the efficacy, cost-effectiveness and safety of UMP versus RIRS in renal calculi between 10 and 30 mm. We analysed the stone free rate at 1 month postoperatively, the need for intra-operative adjuncts, length of stay and post-operative complications as per the Clavien–Dindo classification [11].

## Methods

## Patients

This was a prospective RCT of UMP and RIRS over an 18-month period, July 2015 to December 2016, Ahmedabad, India. Ethical committee approval was obtained, and the principles of good clinical practice were followed. All patients provided informed consent for the study and the procedure.

The patients were randomised using block randomisation software into either the UMP or RIRS group with a ratio of 2:1. Block randomisation design was used to reduce bias and achieve balance. Block sizes of 6 were used. A computerbased allocation was used and the trial was a single-blind study.

The inclusion criteria were patients age > 16 with 10–30 mm renal calculi of any position with no history of bleeding diathesis. Exclusion criteria included patients who had abnormal renal or musculoskeletal anatomy, receiving anticoagulants or of high anaesthetic risk.

Pre-operatively, every patient had a full blood count, serum biochemistry, urine microscopy and culture.

The patients' renal stones were identified prior to intervention using non-contrast enhanced computed tomography (NCCT). These stones were then subsequently classified based on their laterality (right, left and bilateral) and position (lower calyx, middle calyx, upper calyx, renal pelvis, and pelviureteric junction). The sizes of the calculi were measured along their longest axis and grouped into 10–15 mm, 15.1–20 mm, 20.1–25 mm, and 25.1–30 mm.

#### UMP and RIRS procedures

The consumable equipment used during the procedure was noted to calculate the total cost of the intervention. The requirement and duration of a nephrostomy and the insertion of double J stent was noted. The stone-free rate was decided with NCCT performed at 1-month postprocedure. The operative room (OR)time although noted for each procedure was not taken into account in the final cost analysis as the OR time in India is calculated in hours rather than minutes as compared to the practice in the developed world and there is not much cost difference in the OR costs for either procedure in our centre.

RIRS was standardised and involved the placement of safety wire (routine practice), access sheath and stent post procedure. Balloon dilatation was used if there was difficulty passing the access sheath.

The UMP procedure has been described previously [12]. Initially, a ureteric catheter was inserted in the renal pelvis and contrast was instilled supine. The puncture was performed prone under image intensifier guidance with the placement of 13F ultramini PCNL sheath with a 365 µm fibre attached to a holmium laser to fragment the calculus. The vortex effect was used to wash out fragments by irrigating from the sheath itself and the ureteric catheter. There was no routine requirement for stent or nephrostomy unless there was an intraoperative indication of bleeding or extravasation.

#### Post-procedure and follow-up

Deterioration in renal function and bleeding was assessed by comparing pre-operative haemoglobin (Hb) and GFR levels with those on the first postoperative day. The need and duration of post-operative opioid IM/IV analgesia was recorded and validated visual analogue scale (VAS) score was used to grade the severity of pain with scores of 45–74 mm as moderate and severe at 75 mm or above. Prolonged pain was defined as greater than 2 days in duration requiring analgesia. Post-operative complications were recognised and classified as per the Clavien–Dindo grading system. The length of stay for each patient and the number of patients that were required to return (e.g., stent removal) were recorded. Following discharge, patients were invited back in 1 month for a follow-up low dose NCCT scan to identify the presence of residual fragments which were classified as less than 2 mm.

#### **Statistical analysis**

All our analyses were performed using the statistical software GraphPad Prism 6. All categorical data were presented by number and percentage and the unpaired

# Results

## Patients

One hundred and fifty patients met our inclusion criteria from 2015 to 2016 which underwent 2:1 randomisation favouring UMP. Six patients withdraw consent prior to surgery. 98 PATIents underwent UMP and 46 RIRS. 17 patients were lost to follow-up (did not attend 1-month CT scan and clinic). A CONSORT flow diagram to summarise trial data is included in Fig. 1.

The main results are shown in Table 1.

## **Stone demographics**

The mean stone size for those patients who had UMP was 16.31 mm, and 16.01 mm for RIRS. The distribution of stones in both groups is shown in Table 2.

## **Surgical intervention**

Mean laser and extraction time were significantly less for UMP compared to RIRS (41.17 min versus 73.58 min, p < 0.0001). All patients undergoing RIRS required stent removal under flexible cystoscopy at 1 week with only one patient required a stent in the UMP group due to concern about the injury to the renal pelvis. A nephrostomy was required in 22 (22.4%) of the UMP patients. The mean dwell time of nephrostomy was 17 h. No patient in the RIRS group required a nephrostomy. Mean consumable costs in UMP were considerably less at US\$45.73 compared to the RIRS group at \$423.11 (p < 0.0001). The cost of the consumables is shown in Table 3.



Fig. 1 CONSORT 2010 flow diagram

#### Table 1 Results

	UMP	RIRS	%UMP	%RIRS	Statistically significant
Total patients	98	46			
Male	59	29	60	63	
Female	39	17	40	37	
Mean age	39.08	40.54			
BMI	23.59	24.27			
Mean stone size-maximum diameter (mm)	16.31	16.02			
Mean laser and evacuation of stones time (mins)	41.12	73.71			$(p < 0.0001)^{****}$
Number of patient's that required D-J Stenting	1	46	1.02	100	$(p < 0.0001)^{****}$
Number of patient's that required nephrostomy	22	0	22.44	0.00	
Number of patients who required IV/IM opioid analgesia	23	11	23	24	
Number of patients that required stent removal	1	46		100	$(p < 0.0001)^{****}$
Number of patients that did have residual fragments (1 month)	0	11	0.00	27	$(p < 0.001)^{****}$
Average consumable cost (US\$ 2016 prices)	45.61	423.02			$(p < 0.0001)^{****}$
Average duration of opioid analgesia use (h)	18.26	15.18			$(p = 0.0354)^*$
Average pre-op Creatinine (mg/dl)	1.09	1.11			
Average post-op Creatinine (mg/dl)	1.19	1.23			
Average pre-op Hb (g/dl)	13.13	13.09			
Average post-op Hb (g/dl)	12.67	12.78			
Average number of hours with nephrostomy	16.95	NA			$(p < 0.0001)^{****}$
Average length of stay (h)	39.21	39.08			
Loss to 1-month CT follow-up (n)	11	6	11.22	13.04	
Clavien complications	10	16	10	35	$(p = 0.0006)^{***}$
Post op fever (treated conservatively) Clavien 1	3	10	0.03	0.22	
Prolonged Pain (requiring antispasmodics and analgesics) Clavien 1	3	6	0.03	0.13	
Peri-nephric collection (treated conservatively) Clavien 2	4	0	4.08	0.00	

\* *p*-value < 0.05 is statistically significant

## Table 2 (Stone demographics)

Stone characteristics	UMP (%)	RIRS (%)
Left side	45	69
Right side	55	31
Size		
0–5 mm	0	0
5.1–10 mm	0	0
10.1–15 mm	45	47
15.1–20 mm	45	47
20.1–25 mm	6	6
25.1-30 mm	3	1
Site		
Renal pelvis	37	36
Upper calyx	12	9
Interpolar calyx	8	13
Lower calyx	26	23
PUJ/upper ureter	17	19

#### Table 3 Consummables

	Items	(\$US)
1	Access sheath	120.00
2	Ureteroscopic Basket	180.00
3	Stent	5.00
4	Guide wire	15.00
5	Flexible ureteroscope (two used during the study)	12,000.00
6	Teflon dilators	70.00
7	Ureteric catheter	10.00
8	Nephrostomy tube (infant feeding tube)	1.00
9	Laser fibre	300.00

# Post-operative outcome and follow-up

At 1-month follow-up, 11 UMP and 6 RIRS patients did not attend. In the remaining patients, none of the UMP group showed any residual fragments, in comparison to around 27% of the RIRS group (p < 0.001) showing stone free rate of about 73% in RIRS and 100% for UMP. Further analysis of the group with residual stones in the RIRS group showed stones in the lower pole calyx in 5 out of 11 patients.

There were insignificant changes to mean haemoglobin and GFR for all patients studied. The mean length of stay for patients in both groups was similar (39.21 h for UMP and 39.08 h for RIRS).

The post-operative complications that were present in our patient cohort included: prolonged pain, fever, and peri-nephric collections. These were graded as per the Clavien–Dindo Classification of Surgical Complications as I for both prolonged pain and fever and II for peri-nephric collections. Peri-nephric collections were present in 4% of UMP patients and were treated conservatively. No patient from the RIRS group developed this complication. Analysis of these figures revealed a grade I–II post-operative complication rate of 10% for patients undergoing UMP and 35% for RIRS (p = 0.0006) although the majority of the complications were Clavien 1. No patient in either group received blood transfusion.

### Discussion

Current guidelines recommend PCNL for renal stones greater than 2 cm. With the recent widespread use of the flexible ureterorenoscopy, it is possible to achieve good stone clearance with reduced morbidity even in patients with renal stones 2–3 cm. However, it may sometimes result in RIRS to be performed as a staged procedure. It may be the preferred treatment options in a select cohort of patients who may be unsuitable for PCNL [13, 14].

The morbidity of PCNL is widely known and the established scientific evidence has demonstrated that miniaturisation of the tracts results in reduced bleeding, hence, the use of ultramini PCNL is quite appealing [15]. Liao-Yuan et al., however, demonstrated no statistically significant difference in the invasiveness with either minimally invasive PCNL and standard PCNL by measuring the serum acute phase markers. On the contrary, operative time was prolonged and the procedure seemed technically more challenging to perform. They did acknowledge the risk of bleeding and need for blood transfusion was statistically significant in patients undergoing standard PCNL [16]. The advantage of miniaturisation is hence very obvious and proven in various studies.

The data from our study has indeed demonstrated the efficacy and safety of the technique of ultramini PCNL for renal stones up to 30 mm. It can be suitable for calculi in any part of the kidney and achieves excellent stone-free rates when checked with CT 1-month postprocedure. This has been demonstrated by Aggarwal et al. [17] who have shown this procedure to be safe and effective in management of

stones up to 20 mm with complete stone clearance seen in 95% of their patients.

The mean laser and evacuation time of stone fragments were significantly less compared to RIRS in our study. Quicker fragmentation coupled with the faster retrieval of the fragments with the aid of the whirlpool effect also leads to reduction in the operating time. This may amount to reduced morbidity as has been demonstrated in studies with increased operating times result in increased morbidity [18].

One of the key advantages of UMP is the direct access to the lower calyx stone, which can be difficult to access with RIRS. Almost a quarter of the cohort of patients in the UMP group had stones in the lower pole calyx and none of the patients had residual stones at 1-month follow-up. Of the patients in the RIRS group with residual stones about 46% had stone/stones in the lower pole calyx prior to intervention.

Zeng et al. [19] in their international, multicentre, prospective, randomised and unblinded study have shown that super or ultramini-PCNL is more effective than RIRS for treatment of 1–2 cm lower calyx stone with more stone free rates and less supplemental procedure.

Rippel et al. [20] concluded the residual fragments were present in more than 50% of patients with pre-treatment stones larger than 1 cm in patients undergoing RIRS. Our study showed stone free rates of around 73% in RIRS group and evidence has shown similar results in the studies which have utilized non-contrast CT for follow-up of patients who underwent RIRS. Ghani and Wolf Jr [21] reviewed stone free rates following RIRS and concluded that using CT as a strict follow-up imaging method, the mean stone free rates were around 77%. RIRS often leads to the placement of the stent resulting in troublesome stent symptoms that occur in majority of the patients and an added procedure to remove the stent afterwards [22].

The smaller instruments of UMP results in less need for insertion of nephrostomies and some studies have shown that high proportion of the patients undergoing UMP were tubeless [5].

It is a well-known fact that tubeless procedure is associated with lower postoperative pain scores and less analgesia requirement [23]. However, in our study about 22% patients required a nephrostomy which can be considered a high percentage but the reasons for nephrostomy were either deemed risk of bleeding or extravasation.

In this study, the UMP procedure has the same length of stay compared to RIRS as well as similar analgesic requirements. However, the duration of opiate requirements is a little higher by a mean of 3 h. This could be related to the need of a nephrostomy tube in select cases.

We still observed some of the Clavien grade 1, 2 complications (5%) in UMP but this was significantly less than RIRS group. Many of the complications of PCNL are attributable to the tract size. Blood loss in PCNL surgery has been shown to increase with increasing tract size especially as one 26–30 Fr. [15]

RIRS has good efficacy and low complication rates with small renal stones [24]. Severe bleeding or infection after intrarenal surgery is rare. However, RIRS has a slower disintegration rate because of limited manoeuvrability with ureteroscopes and the inability to remove all debris especially while performing on the lower calyceal stone. This can lead to longer procedure times and reduced fragment removal leading to potentially higher chance of fever, sepsis, and pain. Other disadvantages of RIRS include the need to repeat a procedure due to cases of a tight ureter requiring pre-stenting, the high cost of instruments, the need for staged procedures for residual calculi, access sheath use, rarely severe ureteric injuries and the need for longer duration of ureteric stenting [25, 26]. Although rare, injury or stricture to the ureter can lead to the whole renal unit being placed at risk.

There is no statistical difference found between the post-operative haemoglobin drop and creatinine level. Mild haematuria was noted in six and ten patients in UMP and RIRS group, respectively, these all resolved within 36 h and no patients had haemodynamic instability or required a blood transfusion. The major concern of significant bleeding with PCNL is very rare with UMP because of the single-step dilatation and small calibre working sheath. Patients in the RIRS group had a lower analgesic requirement and lower pain scores. However, the mean pain score in the UMP group had lowered after 24 h to a score similar to RIRS. The higher pain scores in the immediate postoperative period in the UMP group are mostly due to the percutaneous access involved.

A flexible ureteroscope is subject to wear and tear and may require a major repair after as few as 4–14 cases [27]. It also requires disposable components such as baskets, which add to the overall cost of the procedure. In our study we had to change the flexible ureteroscope to a new one after use in about 20 cases. The cost of a new ureteroscope was a significant factor adding to the total cost of the RIRS as compared to UMP.UMP scope undergoes less wear and tear due to the small and rigid scope used. The cost of stent removal with flexible cystoscopy in our centre is around US\$120 and this cost is in addition to the consumables utilized during the procedure which would increase the overall cost of the procedure. Cost-effectiveness was evaluated in the present study which appears to be more in the RIRS group (UMP group US\$45.73 and RIRS \$423.11. (p < 0.0001).

Patients were followed up after 1 month with non-contrast CT-KUB for residual stone. Residual stones were not found in the UMP group. Twenty seven percent of patients from the RIRS group were found to have residual stones. It is not unusual to find residual stone fragments following RIRS even after thorough practice of basketing and the real significance lies if the residual fragments would result in a stone related event in the future including repeat surgical intervention [28].

Chew et al. [29] reviewed 232 patients who had residual fragments after ureteroscopy. During a mean follow-up of 16.8 months, 44% of patients experienced a stone related event, defined as stone growth, stone passage, need for reintervention of complication (e.g., Symptoms, emergency department (ED) visit, hospital admission or worsening renal function) [29]. Evidently, relatively higher percent of residual stones following RIRS as compared to UMP is not a favourable outcome for the patients.

# Conclusion

Our study has shown excellent outcome in favour of UMP for surgical management of renal stones 10–30 mm with minimal morbidity and has demonstrated better stone free rates as compared to RIRS. UMP has a clear advantage in the management of lower calyceal stones as compared to RIRS. UMP was also found to be safe and more economical as compared to RIRS.

There are certain limitations to the present study. In our study, all patients underwent surgery in a single centre and to recommend UMP as first-line treatment, more studies from multiple centres are needed. UMP as a surgical procedure when compared with RIRS has not yet been widely practiced and many urologists would feel reluctant to offer it to their patients with a similar renal stone burden unless trained to perform UMP.

#### Declarations

**Conflict of interest** The authors declare that they have no conflicts of interest.

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