

RIRS versus mPCNL for single renal stone of 2–3 cm: clinical outcome and cost-effective analysis in Chinese medical setting

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Abstract The aim of the study was to compare the clinical outcome and the cost-effectiveness between retrograde intra renal surgery (RIRS) and mini-percutaneous nephrolithotripsy (mPCNL) for the management of single renal stone of 2–3 cm in Chinese medical setting. From May 2005 to February 2011, 115 patients with solitary renal calculi were treated either by RIRS or mPCNL. 56 patients were in RIRS group while 59 were in mPCNL group. Patients' demographics between the two groups, in terms of gender, age, BMI, history of ESWL as well as stone side, stone location and stone size were comparable. Peri-operative course, clinical outcome, complication rates and medical cost were compared. The effective quotient (EQ) of two groups was calculated. Data were analyzed using Fisher's exact test, Chi-square test and Student's *t* test. EQ for RIRS and mPCNL were 0.52 and 0.90. The

initial stone-free rate (SFR) of RIRS group and mPCNL group was 71.4 and 96.6 %, respectively ($P = 0.000$). The mean procedure number was 1.18 in RIRS group and 1.03 in mPCNL group, respectively ($P = 0.035$). The operative time for RIRS was longer ($P = 0.000$) while the mean hospital stay was shorter ($P = 0.000$). There was no statistical difference in peri-operative complications between the groups. The initial hospitalization cost, laboratory and radiology test cost of RIRS group were lower ($P = 0.000$). However, counting the retreatment cost in the two groups, the total medical expenditure including the overall hospitalization cost, overall laboratory and radiology test cost and post-operative out-patient department (OPD) visit cost was similar between two groups. In conclusion, with similar total medical cost, mPCNL achieved faster stone clearance and lower retreatment rate without major complications, which implied higher cost-effectiveness for the treatment of single renal stone of 2–3 cm in Chinese medical setting. RIRS is also a safe and reliable choice for patients having contraindications or preference against mPCNL.

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Introduction

PCNL is recommended as first method of choice for kidney stones >2 cm by guidelines on urolithiasis [1, 2]. More importantly, mPCNL is postulated to be less invasive compared with standard PCNL because of the miniaturized instruments [3]. Meanwhile, improvements in endoscopy technology make the flexible scopes become an appealing

treatment option for the majority of renal stones. Especially for patients having contraindications or preference against PCNL, the RIRS could be a viable treatment solution [4, 5]. However, the limited SFR, the necessity of retreatment and the relatively poor durability of the flexible ureteroscope [6] remain the major issues for such a technique dealing with large kidney stones. In the context of limited expenditure on public health and overloaded national medical insurance, the urologists should find out the most cost-effective option to offer the patients best clinical outcome. In this study, clinical outcome, EQ and medical cost of RIRS and mPCNL in patients with 2–3 cm single renal stones were compared. The purpose of this study was to determine the better cost-effective treatment modality for such kidney stones in Chinese medical setting.

Patients and methods

From May 2005 to February 2011, 115 patients with solitary renal calculi of 2–3 cm were treated either by RIRS (56 patients) or mPCNL (59 patients) by two experienced urologists at our institution. Exclusion criteria include multiple stones, abnormal renal collecting system and coagulative disorders. An IVU or CTU was performed for all cases before the treatment. Demographic data, including age, sex, body mass index (BMI), history of extracorporeal shock wave lithotripsy (ESWL), as well as stone side, stone size and location were recorded (Table 1). Urinary infection was treated preoperatively by antibiotics. A sterile urine culture was obtained in all the cases before the surgery. Operating time, hospital stay, peri-operative complications, treatment outcome and medical costs were addressed and compared between the two groups. All patients signed a consent form before the surgery.

Table 1 Patients' data of RIRS Group and mPCNL group

| | RIRS | mPCNL | <i>P</i> |
|-----------------------------------|------------------|------------------|----------|
| Gender | | | |
| Male | 36 (64.3) | 37 (62.7) | 0.861 |
| Female | 20 (35.7) | 22 (39.3) | |
| Age \pm SD | 49.32 \pm 13.7 | 49.37 \pm 14.2 | 0.984 |
| BMI (Kg/m ²) \pm SD | 23.69 \pm 3.6 | 23.52 \pm 3.7 | 0.811 |
| History of ESWL | 11 (19.6) | 14 (23.7) | 0.655 |
| Stone side (left/right) | 30/26 | 23/36 | 0.137 |
| Stone location | | | |
| Upper calyx | 7 (12.5) | 5 (8.5) | 0.762 |
| Middle calyx | 7 (12.5) | 11 (18.6) | |
| Lower calyx | 29 (51.8) | 31 (53.0) | |
| Renal pelvis | 13 (23.2) | 12 (19.9) | |
| Stone size (mm) \pm SD | 22.28 \pm 2.6 | 22.37 \pm 2.7 | 0.827 |

RIRS technique

A hydrophilic guidewire was placed into the renal pelvis under general anesthesia. An 8/9.8 F Wolf rigid ureteroscope was inserted along with the guidewire to observe and dilate the ureter and then a 12F ureteral access sheath was placed if possible. The Olympus P3 (before October 2009) and P5 (after November 2009) flexible ureteroscope and a 200 μ m laser fiber were used for treatment. For the large stones located in lower calyx, firstly we tried to crush them into several fragments and then relocated them to middle or upper calyx by a Bard Dimension articulation stone basket so that the lithotripsy can be performed easily. The Lumenis holium laser was applied as an energy source set at 0.8–1.2 J and at a rate of 6–10 Hz. At the end of the procedure, a 4.7F Double-J ureteral stent was placed in all the cases, which usually remained in place for 2 weeks post-operatively. Intravenous antibiotics were routinely administered during the first two post-operative days. An abdominal CT scan was scheduled 4 weeks after the surgery and residual fragments \geq 2 mm were considered significant. A second stage RIRS lithotripsy was programmed if single or multiple significant fragments existed.

mPCNL technique

A 6F ureteral catheter was placed initially under general anesthesia. The percutaneous access was obtained under the guidance of ultrasonography in prone position. After calyceal puncture of the collecting system, a guidewire was inserted. The tract was dilated with Amplatz Renal Dilator Set. When the dilation finished, an 18Fr Amplatz sheath was placed. Nephroscopic lithotripsy was performed with a rigid Wolf 14F nephroscope. The Lumenis holium laser was applied as an energy source set at 0.8–1.8 J and a rate of 8–12 Hz. Fragments were removed by irrigation or with graspers. A 16Fr nephrostomy tube was placed at the end of the procedure. Intravenous antibiotics were routinely administered during the first three post-operative days. The nephrostomy tube was removed 2 weeks after the surgery if no significant fragments (\geq 2 mm) were left. However, for those who had single or multiple residual fragments at 4 weeks after surgery, a second procedure was performed through the previous nephrostomy tract.

Medical cost calculation and statistical analysis

In this study, we calculated the initial hospitalization cost, the initial laboratory and radiology test cost as well as the overall hospitalization cost, the overall laboratory and radiology test cost for those who got staged procedures. The hospitalization cost included the anesthesia, operation,

pharmacy, supplies, disposable materials, stent and catheter. In addition, the post-operative OPD visit cost was also recorded. The data of the medical expenditure were extracted from the National Healthcare Insurance system.

EQ was addressed for both modalities. It was calculated by the following formula [7]:

$$\frac{\text{Percentage of stone – free}}{100 + \text{percentage of retreatment} + \text{percentage of auxiliary procedure}}$$

Proportions of the variables were analyzed using *Fisher's exact test* or *Chi-square test*, while continuous variables were compared with *Student's t test*. Statistical significance was set at $P < 0.05$ and all the P values were two-sided. The SPSS 18.0 was applied to perform the data analysis.

Results

A total of 115 patients with solitary renal calculi of 2–3 cm were included in the study. No statistically significant difference was found in the patients' demographics between the two groups, in terms of gender, age, BMI, history of ESWL as well as stone side, stone location and stone size (Table 1).

Peri- and post-operative parameters were compared in Table 2. In our series of 56 cases in RIRS group, a primary insertion of ureteroscope was failed in two cases. In one case, a tight stricture of upper ureter was identified, while in the other patient, a discontinuation of ureteroscopy was due to a ureteral kinking. In these two cases, a 4.7Fr Double-J stent was set in place successfully. A second time ureteroscopy was performed without difficulties 2 weeks later after the removal of Double-J stent. The mean operative time was significantly prolonged in RIRS group than in mPCNL group (73.07 ± 13.5 vs. 62.39 ± 10.6 min, $P = 0.000$), while the hospital stay was significantly shorter in RIRS group than in mPCNL group (1.95 ± 1.3 vs. 4.47 ± 1.4 , $P = 0.000$). As for the hemoglobin level, there was a significant decrease in mPCNL group compared to RIRS group ($P = 0.000$). Kidney function determined by serum creatinine measurement was changed in both groups. This change between the groups was less pronounced but still significant (0.29 ± 16.1 in RIRS group vs. 9.17 ± 14.8 $\mu\text{mol/l}$ in mPCNL group, $P = 0.003$).

A statistically significant difference was found in SFR at 4 weeks after the surgery (71.4 vs. 96.6 %, $P = 0.000$). There were 16 cases found to have significant residual

fragments in RIRS group, for whom 11 retreatment procedures were carried out. A higher SFR was achieved in middle calyx (85.7 %) and renal pelvis (84.6 %) compared to upper calyx (72.4 %) and lower calyx (62.1 %). However, a second mPCNL was required only for two cases in mPCNL group with a relatively low SFR in upper calyx

(75 %). The average number of procedure was 1.18 ± 0.4 for RIRS group while 1.03 ± 0.2 for mPCNL group, respectively. ($P = 0.035$) As given in Table 2, no major complications occurred in both groups. The incidence of minor complications such as fever, urosepsis, bleeding, collecting system perforation and the overall complications was comparable in both groups.

The details of cost-effectiveness analysis for each treatment modality were shown in Table 3. The EQ for mPCNL were greater than that for RIRS (0.904 vs. 0.523). The initial hospitalization cost and the initial laboratory and Radiology charge before the surgery were significantly lower in RIRS group than in mPCNL group (1362.08 ± 305.1 vs. 1653.26 ± 289.4 ; 126.84 ± 11.6 vs. 153.67 ± 15.8 , $P = 0.000$). However, since RIRS group had a significantly higher retreatment rate than mPCNL group, when the auxiliary procedures cost was considered, we found the overall hospitalization cost as well as the overall laboratory and radiology test cost were similar in both groups. As for the post-operative OPD visit charge including the oral antibiotics, analgesia, Double-J stent and/or nephrostomy tube removal, RIRS seemed to be more costly than mPCNL (134.99 ± 22.2 vs. 124.79 ± 2.3 , $P = 0.001$). Finally, the total medical cost constituted by overall hospitalization cost, overall laboratory and radiology charge and post-operative OPD visit cost did not differ significantly between the two groups ($1,857.71 \pm 704.1$ vs. $1,999.21 \pm 450.2$, $P = 0.205$).

Discussion

With the improvements in the technology of the flexible ureteroscope, several recent studies have found RIRS with holmium laser lithotripsy can be an effective and safe option for larger renal stones [8, 9]. Moreover, since it is less invasive than conventional PCNL, URS/Laser lithotripsy has become an increasingly considered option for patients, especially for the stones in an intermediate size

Table 2 Clinical outcome of RIRS Group and mPCNL Group

| | RIRS | mPCNL | <i>P</i> |
|---------------------------|---------------|--------------|----------|
| Operating time (min) ± SD | 73.07 ± 13.5 | 62.39 ± 10.6 | 0.000 |
| Hospital stay (day) ± SD | 1.95 ± 1.3 | 4.47 ± 1.4 | 0.000 |
| HB (g/l) ± SD | | | |
| Pre-operative | 129.91 ± 13.6 | 134 ± 23.2 | 0.000 |
| Post-operative (day 1) | 125 ± 14.6 | 121.3 ± 19.8 | |
| HB decrease | 4.91 ± 4.7 | 12.8 ± 8.1 | |
| Creatinine (umol/l) ± SD | | | |
| Pre-operative | 82.8 ± 34.6 | 86.71 ± 30.9 | 0.003 |
| Post-operative (day 1) | 83.09 ± 24.4 | 95.88 ± 33.6 | |
| Creatinine change | 0.29 ± 16.1 | 9.17 ± 14.8 | |
| Number of procedure ± SD | 1.18 ± 0.4 | 1.03 ± 0.2 | 0.035 |
| Stone-free at 4 weeks | 40 (71.4) | 57 (96.6) | 0.000 |
| Upper calyx | 5 (71.4) | 4 (75) | |
| Middle calyx | 6 (85.7) | 11 (100) | |
| Lower calyx | 18 (62.1) | 30 (96.8) | |
| Renal pelvis | 11 (84.6) | 12 (100) | |
| Complications | | | |
| Fever | 4 (7.1) | 2 (3.4) | 0.315 |
| Urosepsis | 3 (5.4) | 1 (1.7) | 0.356 |
| Bleeding | 1 (1.8) | 3 (5.1) | 0.329 |
| Perforation | 1 (1.8) | 1 (1.7) | 1.000 |
| Overall complication | 9 (16.1) | 7 (11.9) | 0.536 |

Table 3 EQ and medical cost of RIRS and mPCNL Group

| | RIRS | mPCNL | <i>P</i> |
|---|------------------|------------------|----------|
| EQ | 0.523 | 0.904 | – |
| Initial hospitalization cost (USD) ± SD | 1,362.08 ± 305.1 | 1,653.26 ± 289.4 | 0.000 |
| Initial laboratory and radiology test cost (USD) ± SD | 126.84 ± 11.6 | 153.67 ± 15.8 | 0.000 |
| Overall hospitalization cost (USD) ± SD | 1,574.7 ± 630.5 | 1,715.42 ± 428.9 | 0.163 |
| Overall laboratory and radiology test cost (USD) SD | 148.02 ± 60.3 | 159 ± 31.6 | 0.220 |
| Post-operative OPD visit cost (USD) ± SD | 134.99 ± 22.2 | 124.79 ± 2.3 | 0.001 |
| Total medical cost (USD) ± SD | 1,857.71 ± 704.1 | 1,999.21 ± 450.2 | 0.205 |

range 2–3 cm [4]. However, the high retreatment rate and high cost of flexible ureteroscopic replacement and repair remain the major issues for such a technique.

On the other hand, PCNL is still recommended as a first-line treatment for kidney stones >2 cm by the guidelines on urolithiasis. mPCNL is postulated to be less invasive compared to standard PCNL with lower hemoglobin drop, less analgesic requirement, shorter hospital stay and comparable complete stone clearance [3, 10]. Therefore, mPCNL is a safe and efficient solution for large renal stones.

According to CROES PCNL globe study, most stones removed were 2–3 cm (83 %) and fewer stones were seen as the stone size increased. When stones attain a size of 2–3 cm, patients become symptomatic or routine examination facilitates the detection of stone recurrence

predominantly at this size [11]. As mentioned above, a single renal stone of 2–3 cm could be treated either by RIRS or mPCNL, which leaves urologists with the dilemma of whether to use a percutaneous procedure or a less invasive procedure that potentially leaves more residual fragments in situ. Meanwhile, since the resources for public health are relatively limited in Chinese medical setting, the urologists should find out the most cost-effective option to offer the patients best clinical outcome with lower expenditure. The aim of the study was to compare the clinical outcome and the cost-effectiveness between RIRS and mPCNL for single renal stone of 2–3 cm in diameter.

This comparative study demonstrated that mPCNL led to higher initial SFR and lower retreatment rate compared to RIRS. Hussain et al. reported that for renal stones of

2–3 cm in diameter, the successful rate after single treatment of RIRS was 70.8 %. Of patients with stone size > 2 cm, 58.3 % were stone-free after 1 treatment, 86.1 % after 2, 88.9 % after 3, and 94.4 % after 4 [12]. In a match-paired analysis, Tolga et al. [5] also found that for renal stone > 2 cm, after second sessions of RIRS, SFR were comparable with those achieved using PCNL. Thus, the most important disadvantage of RIRS is requirement for a second session.

In the present study, although the clinical significance of the hemoglobin drop was limited for mPCNL group, there was still a statistically significant difference compared to RIRS group. In a recent study, Mishira et al. [10] demonstrated significant advantages of the mPCNL procedure in terms of reduced bleeding leading to a tubeless procedure and reduced hospital stay. However, the transfusion rate was rather high in mPCNL group in our series. There were three cases presenting an important hemorrhage requiring transfusion after the procedure, two of which were performed in the very early time when we began the ultrasound-guided mPCNL. Moreover, one of these two cases had a malrotated kidney. The post-operative creatinine change was slightly higher in mPCNL group than in RIRS group. Nevertheless, this statistically significant data did not have a enough clinical significance, because after the surgical intervention, the kidney function was improved in several patients due to the relief of obstruction, while in other patients, minor kidney function impairment occurred as a result of access dilation or intrarenal reflux [13].

In our study, the complication rate, including fever, urosepsis, bleeding as well as collecting system perforation was comparable between the two groups. Even though no statistical significance was found, there still seemed to be a relatively high risk of urosepsis in RIRS group while bleeding in mPCNL group. Takazawa et al. [14] reported in 15 % of the cases treated by flexible ureteroscopic lithotripsy for renal stones of 2 cm or greater presented a high-grade fever with urosepsis. The intrarenal reflux-containing bacteria from infectious stones during fragmentation and too long operative time due to large stone burden are responsible for such a severe complication. In our series, 2-day post-operative intravenous antibiotics were given and a sterile urine culture was obtained before the surgery in all cases. Compared to the western countries, the incidence of urinary tract infection is rather high in China. Even for upper urinary tract calculus, lots of patients suffered from infectious calculus which leads to a relatively high risk of urosepsis after surgery. In this case, a 48-h post-operative administration of antibiotics is allowed after ureteroscopic procedure or PCNL according to the Chinese Ministry of health. Massive hematuria occurred after

excessive activities in one patient in URS group. In this case, no subcapsular hematoma or important extravasation was found in abdominal CT scan. This massive hematuria resolved after the removal of Double-J stent. Several studies have already proven the relationship between Double-stent and hematuria [15–18]. Chambade et al. [19] even reported the macroscopic hematuria could be found in 56 % of the cases with Double-J stent. Gentle endoscopic performance, avoiding excessive activities, drinking water and short-time ureteric stenting are the key points to prevent Double-J-related hematuria.

EQ determines the SFR in relation to repeat lithotripsy as well the number of auxiliary procedures performed to render the patient stone-free [7]. In this study, EQ was calculated to specifically address the efficiency for both RIRS and mPCNL. With higher initial SFR and lower re-treatment rate, EQ of mPCNL was obviously higher than that of RIRS, which implied mPCNL was an efficient technique rather than RIRS for the treatment of single renal stone of 2–3 cm.

The medical expenditure including hospitalization, laboratory and radiology test as well as the OPD visit was covered by the national health insurance in China. Although RIRS was less expensive than mPCNL for its initial treatment, when considering the relatively high re-treatment rate in RIRS group, there was no statistical difference in total medical cost for these two techniques. From the perspective of the health insurance disbursement, with similar overall medical cost, mPCNL is a more cost-effective technique because of its high EQ value.

Furthermore, it is noteworthy that the medical cost recorded in our study did not include the high charges of purchasing and maintaining the flexible ureteroscope, the nephroscope and the holium laser. The flexible ureteroscope is an expensive medical instrument with relatively poor durability. Knudsen et al. compared the durability of DUR-8E, Viper, URF-P5 and FlexVision U-500. For a new flexible ureteroscope, time with a laser fiber in the working channel was 31.3–100 min and the operating time in the lower pole was only 22.6–100.3 min when it needed to get the first major repair. [20] In China, the public spending for health care is very limited and the national health insurance is overloaded. In this case, choosing a cost-effective treatment is particularly important for the urologists.

Limitation of our study was its retrospective nature. Thus, a potential selection bias cannot be strictly ruled out in this study. A prospective randomized study with large case volumes should be carried out in the near future. In addition, the analysis of stone composition was not realized in all the cases. Since the stone composition might influence operating time for both techniques, it could cause the bias in statistics.

Conclusion

With similar overall medical cost, mPCNL achieves faster stone clearance and lower retreatment rate without major complications, which implied higher cost-effectiveness for the treatment of single renal stone of 2–3 cm in Chinese medical setting. RIRS is also a safe and reliable choice for patients having contraindications or preference against mPCNL.

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Conflict of interest There is no conflict of interest to be declared.

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