

## The Feasibility, Safety, and Efficacy of the Preemptive Indwelling of Double-J Stents in Percutaneous Nephrolithotomy Surgery: A Randomized Controlled Trial

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**Purpose:** The goal of this study is to compare the feasibility, safety, and efficacy of the preemptive indwelling of double-J stents (PI-DJS) versus the conventional preemptive indwelling of ureteral catheters (PI-UC) in percutaneous nephrolithotomy (PCNL) via a randomized, controlled clinical study.

**Materials and methods:** A total of 75 patients with complex renal calculi underwent PCNL surgery and were randomized, using random number table, to receive either a PI-DJS (37 cases) or a PI-UC (38 cases). All operations were performed by the same experienced surgeon. Several outcomes were measured, including duration of operation, time to establish passage, level of hemoglobin decline, rate of stone clearance and incidence of complications.

**Results:** Guided by B-ultrasound, percutaneous passages were successfully established in all patients who then underwent one-stage PCNL. The time required to establish a passage using a PI-DJS was 7.5min, whereas that of the group who received a PI-UC was 11.5min ( $P < 0.01$ ). There was no significant difference between the two groups in terms of operation duration, postoperative Hb decline rate, stone clearance rate, and perioperative complication incidences (all  $P > 0.05$ ).

**Conclusion:** PI-DJS during PCNL allowed for a reliable and stable reflux from the bladder into the renal pelvis to produce an artificial hydronephrosis without the formation of microbubbles, unlike conventional ureteral catheters.

**Keywords:** percutaneous nephrolithotomies; randomized controlled study; indwelling of double-J stents; indwelling of ureteral catheters

### INTRODUCTION

Ever since it was described by Fernstorm et al in 1976<sup>(1)</sup>, percutaneous nephrolithotomy (PCNL) has become an important therapeutic strategy for the treatment of complex renal calculi<sup>(2)</sup>, even in complicated situations like pregnancy<sup>(3,4)</sup>. PCNL was demonstrated as an effective therapy to achieve stone-free rates in about 80% of patients with staghorn stones<sup>(5)</sup>, one of the most challenging forms of urolithiasis. However, there are always challenges in the management of complex renal calculi during the PCNL process<sup>(6)</sup> and many improvements have been described that significantly enhance the safety and surgical outcome of PCNL<sup>(3,7-9)</sup>. In order to have a successful PCNL, it is very essential to have an accurate puncture through the papilla into the target calyx, thereby creating the percutaneous access for stone disintegration and removal. In recent years, B-ultrasound localization for percutaneous renal puncture has seen higher adoption due to its enhanced accuracy, reliability, and safety, which was routinely used for PCNL surgery<sup>(2)</sup>. Importantly, percutaneous puncture often requires artificial hydronephrosis, which was traditionally achieved through perfusion of saline via a ureteral catheter. This method, however, might generate bubbles in the renal pelvis, leading to interference of B-ultrasound-guided percutaneous punctures<sup>(10)</sup>. Addi-

tionally, sometimes indwelling of the double J stents at the end of the surgery presents difficulties and the positioning of the stent might be inaccurate. In this study, a randomized, controlled clinical trial was conducted to investigate the feasibility, safety, and efficacy of the preemptive indwelling of double-J stents (PI-DJS) before PCNL, hoping to simplify the procedure in order to optimize surgical outcomes.

### MATERIALS AND METHODS

#### Targeted patients and methods

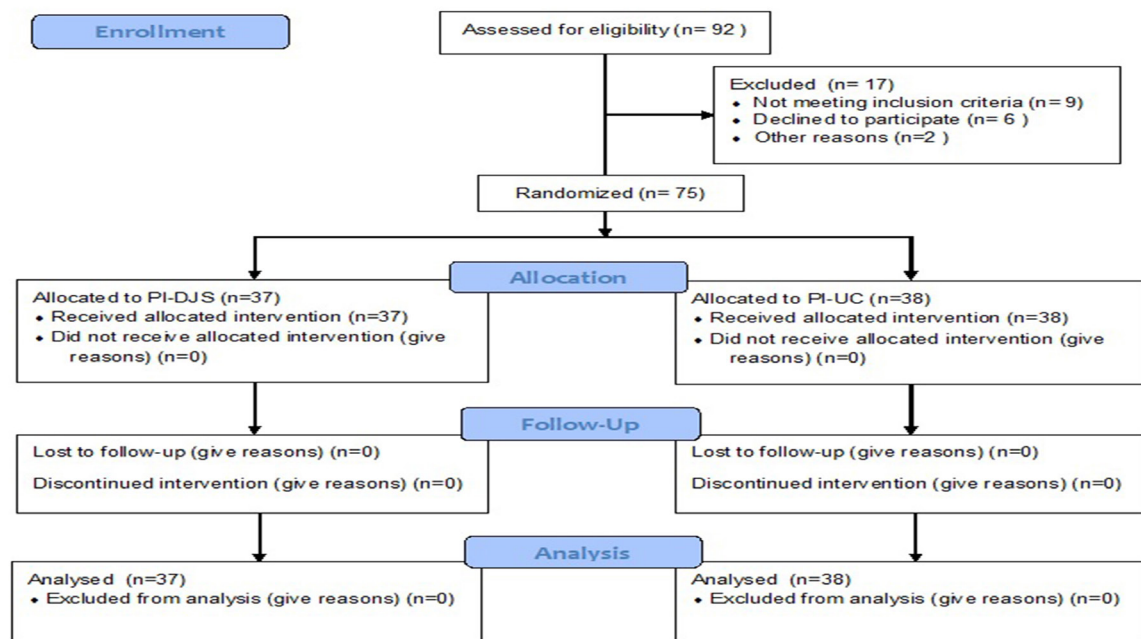
The present clinical trial is registered in the Chinese Clinical Trial Register (ChiCTR, 1900021443). From August 2014 to December 2016, 75 cases of patients with complex renal calculi were randomly assigned to two different groups to undergo PCNL operations. 37 out of 75 cases underwent the procedure entailing the PI-DJS, while the remaining 38 cases underwent the procedure involving the conventional preemptive indwelling of the ureteral catheter (PI-UC). All operations were performed by the same experienced surgeon. All patients underwent one-stage PCNL in which percutaneous renal punctures were successfully established via B-ultrasound guidance. The general information of the two groups of patients is shown in **Table 1**.

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**Figure 1.** The CONSORT flow diagram. PI-DJS: Preemptive indwelling of double-J stent group; PI-UC: Conventional Pre-emptive indwelling of ureteral catheter group.

### Inclusion and exclusion criteria

Renal stones were diagnosed by either CT or kidney, ureter, and bladder (KUB) examinations. Patients (18-80 years old) with stone sizes larger than 2cm that required PCNL treatment were included in this study. The exclusion criteria include coagulation disorders, anatomic anomalies, urinary tuberculosis, previous PCNL history, and severe cardiac and pulmonary dysfunctions.

Total 92 patients were assessed for eligibility (Figure 1). Among them, 17 patients were excluded from the study due to not meeting inclusion criteria (n=9), declined to participate (n=6) and other reason (n=2).

**Preemptive indwelling of double-J stent group (PI-DJS)**  
Under general anesthesia, patients were placed in the lithotomy position. The retrograde insertion of an Fr6 double-J stent via the ureter to the kidney was performed under transurethral ureteroscopy. Subsequently, a three-way Foley catheter was placed, and the urine drainage port was closed. Physiological saline (bag of 3000ml, height about 60 ~ 80cm) was connected to the irrigating cavity.

With the patient in prone position, the cavity was infused with normal saline to produce artificial hydronephrosis depending on reflux from the bladder to the renal pelvis. The posterior renal calyx was punctured under the guidance of B-ultrasound. Guided by zebra guidewire, the percutaneous passage was expanded from F8 to F20 and a renal sheath was used for the entrance of kidney calices. Subsequently, ureteroscopic lithotripsy was performed with a holmium laser under 8/9.8F ureteroscope.

An F18 nephrostomy tube was retained subsequent to surgery. Plain film of kidneys, ureters and bladder (KUB) or B-ultrasound examination was performed 3-5 days after the operation to evaluate the presence of any

residual stones. Stones larger than 5mm would be considered incomplete removals.

### Conventional Pre-emptive indwelling of ureteral catheter (PI-UC) group

Under general anesthesia, the patient was placed in the lithotomy position. Retrograde ureteral catheterization was performed under transurethral ureteroscopy and an F6 ureteral catheter was inserted into the kidney. After the patient was placed in the prone position, physiological saline was infused through the ureteral catheter to generate artificial hydronephrosis. The posterior renal calyx was punctured under the guidance of B-ultrasound technology.

After the stone fragments were removed, the ureteral catheter was removed and an Fr6 double-J stent was placed under the nephroscope. The rest of the procedure was identical to the description above for the PI-DJS group.

### Study outcomes

The primary outcome measure is time to establish passage for PCNL, whereas a secondary outcome measure is incidence of complications, including pneumothorax, postoperative fever, significant hemorrhage and need for blood transfusion.

### Statistical analysis

All data were analyzed using SPSS 20.0 statistical software. Analyses and comparisons of the following characteristics were conducted between the two methods: duration to establish the passage, duration of the operation, level of hemoglobin decline, rate of stone clearance, and perioperative complications. All data were expressed as the mean  $\pm$  standard deviation ( $x \pm s$ ). T-tests were used for comparisons between the two groups. Chi-square ( $\chi^2$ ) tests were used to compare the rates or proportions among different subgroups. A

**Table 1.** Comparison of preoperative data between the two groups of patients

	PI-DJS (n=37)	PI-UC (n=38)	P value
Age (Year); mean±SD	48.3±12.2	47.7±13.4	<i>P</i> = 0.762
Gender; N			<i>P</i> = 0.944
Male	27	28	
Female	10	10	
Affected Side; N			$\chi^2 = 0.011, P = 0.916$
Left Kidney	20	21	
Right Kidney	17	17	
Stone diameter (mm); ; mean±SD	29.7 ± 4.4	28.5 ± 4.7	<i>t</i> = 1.141; <i>P</i> = 0.258
Percentage of staghorn stones	21.6%	23.7%	$\chi^2 = 0.045, P = 0.831$
Stone location; N			$\chi^2 = 1.144, P = 0.565$
Upper calyx	18	13	
Middle calyx	19	15	
Lower calyx	26	29	

All measurement data are expressed as the mean ± standard deviation or numbers unless otherwise specified. *T*-tests were used for comparisons between the two groups. Chi-square ( $\chi^2$ ) tests were used to compare the rates or proportions among different subgroups

*p*-value < 0.05 was considered to be statistically significant.

## RESULTS

### Characteristics of the Patient Population

The characteristics of patients included in the trial are summarized in Table 1. No significant difference was found between patients allocated to PI-DJS and PI-UC groups, in terms of age (PI-DJS vs PI-UC: 48 ± 12.2 vs 47.7 ± 13.4), sex (27 male/10 female vs 28 male/10 female), affected side of kidney (20 left, 17 right vs 21 left, 17 right), size of stone (29.7 ± 4.4 vs 28.5 ± 4.7), percentage of staghorn stones (21.6% vs 23.7%) and stone locations (upper calyx 18 vs 13; middle calyx 19 vs 15; lower calyx 26 vs 29).

### Study Outcomes

All patients underwent successful PCNL. The PI-DJS group (7.5 ± 2.0 min) showed significantly shorter duration to establish the PCNL passage when compared with PI-UC group (11.5 ± 2.5 min). However, there were no significant differences in other parameters, namely, the duration of operation, level of hemoglobin decline, incidence of complications and rate of stone clearance. A summary of the clinical outcomes for the two groups is shown in **Table 2**.

In the PI-DJS group, pneumothorax occurred in one patient after the removal of the nephrostomy tube and the patient was successfully treated via chest drainage. Fe-

ver was observed in two patients, without occurrence of septic shock, who were then successfully treated with antibiotics. In the PI-UC group, surgery was aborted in one patient due to surgical vision field impairment as a result of bleeding. In another case, bleeding was found 4 days after the surgery, which was administrated with treatments including absolute bed rest, transfusion and hemostatic therapies. Postoperative infection was observed in two cases, but the conditions improved upon administration of sensitive antibiotic therapies.

In the PI-UC group, there were 2 cases where the placement of a double-J stent into the bladder was unsuccessful. The stents were finally removed under ureteroscopy with intravenous anesthesia. When appropriate, patients who had residual stones after one-stage nephrolithotomy were administrated with second-stage treatments. Such procedures include extracorporeal shock wave lithotripsy, flexible ureteroscopic lithotripsy and two-stage PCNL.

## DISCUSSION

PCNL was first reported by Fernstrom and Johansson in 1976(1). The establishment of the percutaneous passage enabled larger stones to be disintegrated prior to their removal. This revolutionized the conventional concept that larger kidney stones could only be removed by open surgery<sup>(11)</sup>. After more than 40 years of development, the procedures of PCNL have gradually been

**Table 2.** Comparison of postoperative data between the two groups of patients

	PI-DJS (n=37)	PI-UC (n=38)	P Value
Duration to establish passage (min)	7.5 ± 2.0	11.5 ± 2.5	<i>P</i> < 0.001
Duration of operation (min)	75 ± 45	79 ± 46	<i>P</i> = 0.704
Rate of Hemoglobin decline (g/L)	15.6 ± 3.4	16.2 ± 5.3	<i>P</i> = 0.562
Incidence of Complications (%)	13.5	13.2	<i>P</i> = 0.781
• Pneumothorax	1	0	Clavien II
• Postoperative fever (>38.5° C)	2	2	Clavien II
• Significant hemorrhage	2	3	Clavien II
• Blood transfusion	0	1	Clavien II
Rate of Stone Clearance(%)	81.1	78.9	<i>P</i> = 0.817

All measurement data are expressed as the mean ± standard deviation ( $x \pm s$ ). *T*-tests were used for comparisons between the two groups. Chi-square ( $\chi^2$ ) tests were used to compare the rates or proportions among different subgroups

standardized<sup>(11)</sup>. Initially, the patient was placed in the lithotomy position. Retrograde insertion of the ureteral catheter through the affected kidney via the urinary tract should be completed before the patient was placed in the prone position<sup>(12)</sup>. Conventional PCNLs were usually guided by X-ray technology to determine localization. In recent years, B-ultrasound localization has seen higher adoption due to its enhanced accuracy, reliability, and safety<sup>(13)</sup>.

A ureteral catheter was infused with physiological saline to create an artificial hydronephrosis. The puncture of the renal calyx was performed under the guidance of ultrasound, whereas expansion of the punctured passage by renal sheath or balloon dilatation was carried out under the guidance of zebra urological guidewire. A lithotripsy was conducted after the establishment of the percutaneous renal puncture passage. In conventional PCNL, several uncertainties were frequently encountered. In the process of establishing the operation passage for PCNL, saline was infused via a pre-set ureteral catheter to create an artificial hydronephrosis, but microbubbles were consequently generated. These bubbles then interfered with the ultrasound imaging which, in turn, may have affected the success of the calyceal puncture. Sometimes, problems such as inaccurate or difficult positioning of the double-J stent may occur toward the end of the surgery during the antegrade insertion of the stent as a result of a poor visual field or an inadequate angle between the ureter and the percutaneous puncture.

The current study unveiled that the major advantage of the preemptive indwelling of double-J tubes over the conventional preemptive indwelling of ureteral catheters was that the establishment of the percutaneous passage was significantly shortened. When saline perfusion reached a height of 60 ~ 80cm, the reflux properties of the double-J tube caused the renal collecting system to produce a stable artificial hydronephrosis with no appearance of microbubbles. This condition enhanced a stable B-ultrasound imaging, making it conducive for calyceal puncture with close to a 100% success rate. Hence, there was reduced interference under B-ultrasound and a shortened time spent for the percutaneous renal puncture and the establishment of a working passage. Due to persistent perfusion, the indwelling double-J procedure was less likely to form blood clots, which provided a clearer surgical vision field and a reduction in the number of accidental injuries to the renal system during laser lithotripsy. Additionally, PI-DJS prevented blindness during antegrade indwelling and ensured more reliable and accurate positioning. The present study concluded that PI-DJS was a safe and feasible method during PCNL.

In some scenarios of pyelolithiasis where the ureteropelvic junction was obstructed, the upper end of the double-J stent failed to coil in the renal pelvis; in such cases, the safety guide wire was first inserted under ureteroscopy to guide the subsequent indwelling of the double-J stent. When using the double-J stent, continuous perfusion, calyceal puncture, expansion of the punctured passage, and even the lithotripsy were much easier to achieve. In contrast to conventional PCNL, the newer method was less prone to clot formation and had a clearer visual field. This enhanced surgical safety and reduced the occurrence of accidental mucosal injuries to the renal collecting system. In addition, PI-DJS also

significantly shortened the operative time, a risk factor for surgical site infection.

PI-DJS prevented antegrade indwelling when used in the conventional way. In one conventional case, the patient's fragmented stones blocked the ureter and prevented placement of the guide wire into the bladder. The double-J stent could only be placed after the patient was in the lithotomy position. In a different case, the placement of the guide wire into the ureter failed as a result of an inadequate angle between the ureter and the inferior renal calyceal puncture. Similarly, the double-J stent was successfully placed after the patient assumed the lithotomy position. It is noteworthy that sheaths should be used during PCNL to prevent laser damage to the wall of the double-J stent, so as not to affect the effect of drainage and formation of mural stones after operation<sup>(14)</sup>.

## CONCLUSIONS

To summarize, our study shows that the PI-DJS is more advantageous than the conventional PCNL due to shortened time to establish passage (7.5 mins in PI-DJS vs 11.5 mins in PI-UC) for PCNL and no increase in the incidence of complications. Given that the current study has a limited sample size, a multi-center, large-scale, prospective, randomized, and controlled trial is warranted to further confirm observations from the present study.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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