# Initial Prospective Study of Ambulatory Mini-Percutaneous Nephrolithotomy on Upper Urinary Tract Calculi

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**Purpose:** To explore the feasibility and safety of ambulatory mPCNL (mini percutaneous nephrolithotomy) on upper urinary tract calculi.

**Methods:** Clinical data of 18 patients who received ambulatory mPCNL during Auguest 2017 to January 2018 and 23 patients who were treated with routine inpatient mPCNL of the corresponding period were collected. All the patients included received 16Fr channel PCNL under the guidance of Doppler ultrasound. A 6Fr double J stent was placed in the ureter for internal drainage, and either an indwelling 14Fr open nephrostomy tube was placed or the puncture channel was filled with absorbable hemostatic materials alone, depending on the bleeding condition of the puncture channel and the intraoperative conditions. Preoperative parameters and surgery time, complications, total hospitalization costs and hospital stay time between the two groups were compared.

**Results:** Preoperative parameters regarding age ($P = 0.057$), sex distribution ($P = 0.380$), ASA score ($P = 0.388$), Calculi CT value ($P = 0.697$), and the S.T.O.N.E. score (P=0.122) were comparable between the two groups. Maximum diameter of calculi (cm) of the conventional hospitalization group, however, was larger than the ambulatory surgery group ($P = 0.041$). There were no significant differences in the mean surgery time ($P = 0.146$), postoperative hemoglobin drop ($P = 0.865$), Calculi-free rate on the next day after surgery ($P = 0.083$) and postoperative fever rate (P=0.200) between the two groups. With regard to tubeless rate ($P < 0.001$), total hospitalization costs ($P = 0.003$) and hospital stay time ($P < 0.001$), there were significant advantage favoring ambulatory mPCNL.

**Conclusion:** For patients with simple upper urinary tract calculi and relatively good performance status, ambulatory mPCNL is feasible as it's equally safe and efficient as compared with routine inpatient mPCNL. Moreover, ambulatory mPCNL decreases hospitalization costs and hospital stay time. Nevertheless, perioperative management should be carefully conducted, and well-designed studies are warranted.

**Keywords:** ambulatory surgery; mPCNL; renal calculi; safety

## INTRODUCTION

Urinary calculi are commonly encountered in the field of urology. The incidence of calculi in inpatients with urological diseases is more than 50% in high prevalence areas[1]. Calculi in the kidney and proximal ureter are typically treated via percutaneous nephrolithotomy (PCNL). Compared with conventional open surgery, PCNL causes less trauma, has superior reproducibility, less influence on renal function, and an equivalent or even better calculi extraction rate. Furthermore, the occurrence of perioperative complications associated with PCNL has been greatly reduced by the recent development of mPCNL, and the technique has been rapidly promoted[2,3]. While patients undergoing PCNL traditionally require planned inpatient admission, there is a growing evidence to support its potential feasibility as an ambulatory approach[4]. However, these studies are extensively criticized for design flaws, such as the retrospective study design or a single arm report. To our knowledge, there were no reports of ambulatory mPCNL safety or efficiency with a control study. This is a prospective study of the clinical data from 18 patients who underwent mPCNL in our hospital, with the aim of evaluating the safety and feasibility of mPCNL as ambulatory surgery, as well as providing a reference for the further development of ambulatory mPCNL.

## MATERIALS AND METHODS

### *Clinical data*

From August 2017 to January 2018, 18 patients diagnosed with calculi in the kidney or proximal ureter underwent mPCNL as ambulatory surgery (same-day procedures, ambulatory surgery group), while 23 were conventionally hospitalized for mPCNL (conventional hospitalization group). This study was approved by the local medical ethics committees of Guizhou Provincial People's Hospital (No. 2017040). The clinical features of both groups are summarized in **Table 1**.

### *Preoperative assessments*

All included patients were diagnosed with urinary calculi, and underwent mPCNL. Patients in the ambulatory surgery group agreed to undergo mPCNL as ambulato-

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**Table 1.** Clinical features of the ambulatory surgery group and the conventional hospitalization group

| Parameters | Ambulatory surgery group (n=18) | Conventional hospitalization group (n=23) | *P* value |
|---|---|---|---|
| Age (y) | 42.9 ± 9.6 | 52.3±11.5 | 0.057 |
| Sex [male/female] | 14/4 | 15/8 | 0.380 |
| ASA score | 1.44 ± 0.12 | 1.61±0.14 | 0.388 |
| Maximum diameter of calculi (cm) | 1.92 ± 0.72 | 2.74±0.94 | 0.041 |
| Calculi CT value (HU) | 1093 ± 290 | 1147±326 | 0.697 |
| S.T.O.N.E. score | 6.44±0.17 | 6.95±0.26 | 0.122 |

Ambulatory surgery group: patients who underwent percutaneous nephrolithotomy for urinary calculi as ambulatory surgery; conventional hospitalization group: patients who underwent percutaneous nephrolithotomy for urinary calculi as hospital inpatients.

ry surgery, and underwent the following preoperative examinations in the outpatient clinic: routine blood and urine examinations, coagulation function tests, liver and kidney function tests, electrolyte levels, fasting blood glucose levels, electrocardiography, chest and abdominal radiography, and urinary CT scan. After preoperative examination, an anesthesia risk assessment was completed for each patient in the anesthesia clinic. The conventional hospitalization group underwent similar routine preoperative checks.

### *Exclusion and inclusion criteria*

Exclusion criteria were: insufficiencies of the heart, lung, liver or other vital organs; hypertension; uncontrolled diabetes mellitus (those with satisfactory blood pressure and blood glucose control were included); systemic bleeding disorders or other surgical contraindications; pregnancy; severe anatomical deformity; severe obesity; intolerance of the prone position; severe mental illness; uncontrolled urinary tract infection; or other conditions that rendered the patient unsuitable for PCNL.

The advantages and disadvantages of ambulatory surgery were thoroughly explained to the patients (and their guardians) who were candidates for mPCNL preoperatively. For patients suitable for (ASA score ≤ 2 and S.T.O.N.E. score ≤ 7) and willing to accept ambulatory mPCNL were include in the ambulatory surgery group. Postoperatively, the ambulatory surgery group were monitored by specifically designated nurses who understood the major complications that could potentially occur; it was also ensured that the patients were able to reach the hospital within 30 minutes from their residences. Patients with poorer physical condition, complex calculi or unwilling to accept ambulatory mPCNL were include in the conventional hospitalization group.

### *Surgical methods*

After induction of general anesthesia, each patient was placed in the lithotomy position. A cystoscope or ureteroscope was used to place a 5Fr ureteral catheter into the ipsilateral ureter, and to place an indwelling 16Fr Foley catheter. After moving the patient to the prone position, the target renal pelvis was punctured under the guidance of Doppler ultrasound. A zebra guidewire was used to guide a fascial dilator, which was expanded gradually from 8Fr to 16Fr, and then pushed into the sheath. A 12Fr nephroscope was then introduced for examination. After identifying the target calculi, a holmium laser was used to crush the calculi and the fragments were flushed out of the body. After satisfactory calculi removal, a 6Fr double J stent was placed in the ureter for internal drainage. The nephroscope and outer sheath were removed under the guidance of the safety guidewire. In accordance with the bleeding condition of the puncture channel and the intraoperative conditions, either an indwelling 14Fr open nephrostomy tube was placed or the puncture channel was filled with absorbable hemostatic materials alone.

### *Discharge standards*

Patients were discharged when the following criteria were satisfied: stable vital signs; no obvious postoperative infection and/or bleeding; no discomfort after eating semi-liquid food; no or mild abnormalities in routine blood examination, hepatic and renal function tests, and electrolyte levels; good positioning of the double J stent on plain abdominal radiography; and the presence of family members to accompany the patient.

### *Follow-up*

All patients had at least one telephone follow-up per day for 2 weeks after discharge. The follow-up included questions regarding general patient condition, surgical area symptoms and wound condition, presence of fever, amount and color of urine, and other special situations.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Patients (and their guardians) met the ambulatory mPCNL criteria would discuss the advantages and disadvantages of ambulatory surgery preoperatively, and informed consents were obtained. No formal consents were required with the patients in the conventional hospitalization group.

### *Statistical analysis*

The SPSS 21.0 statistical software package was used for statistical analysis. Measurement data accord with normal distribution were expressed as the mean ± standard deviation. The t-test for two independent samples was used for intergroup numerical data comparisons, while the intergroup count data were analyzed using the □2 test. The significance level of the hypothesis test was set at $\alpha = 0.05$.

## RESULTS

The mean surgery time in the ambulatory surgery group tended to be slightly shorter than that in the conventional hospitalization group, but this difference was not significant ($P = 0.146$, **Table 2**). There was no significant difference between the two groups in the postoperative hemoglobin decrease ($P = 0.865$), calculi-free rate (*P*

**Table 2.** Operative details of patients included in the study.

| Parameters | Ambulatory surgery group | Conventional hospitalization group | *P* value |
|---|---|---|---|
| Surgery time (min) | 74.4 ± 35.7 | 96.2 ± 31.4 | 0.146 |
| Hemoglobin drop (g/L) | 15.3 ± 6.9 | 14.8 ± 8.0 | 0.865 |
| Tubeless rate | 17/18 | 4/23 | < 0.001 |
| Immediate calculi-free rate after surgery (%) | 94.4 (17/18) | 73.9 (17/23) | 0.083 |
| Hospital stay (h) | | | |
| Mean | 18.3 ± 3.6(14-23) | 132.7 ± 31.9(98-253) | < 0.001 |
| Median | 17.5 | 154.0 | |
| 25 percentile | | 15.5 | 127.8 |
| 75 percentile | 21.5 | 214.3 | |
| Total hospitalization cost (US dollar) | 2114 ± 275 | 3097±854 | 0.003 |
| Major complications | | | |
| Blood transfusion | 0 | 0 | - |
| Fever | 0 | 2 (Clavien grade II) | 0.200 |

Ambulatory surgery group: patients who underwent percutaneous nephrolithotomy for urinary calculi as ambulatory surgery; conventional hospitalization group: patients who underwent percutaneous nephrolithotomy for urinary calculi as hospital inpatients.

= 0.083), or incidence of fever on postoperative day 1 ($P$ = 0.200, Table 2). Compared with the conventional hospitalization group, the ambulatory surgery group had a significantly greater incidence of tubeless rate ($P$ < 0.001), shorter hospital stay ($P$ < 0.001), and significantly lesser total hospitalization cost ($P$ = 0.003, Table 2).

No complications of Clavien grade III and above were encountered in both groups. One patient in the ambulatory surgery group required an indwelling nephrostomy tube due to the detection of mild bleeding during intraoperative examination of the puncture channel; the drainage fluid was red-tinged at 4 hours postoperatively, and the patient was discharged with the tube in place. At the third day postoperatively, the patient returned to the hospital for removal of the nephrostomy tube, and there was no bleeding or extravasation of urine. Two patients in the conventional hospitalization group had postoperative fever, which may have been related to their older age, larger of calculi, and slightly longer surgery time; these patients were discharged after effective anti-infection and symptomatic treatment.

## DISCUSSION

Ambulatory surgery originated in the western world and has since been widely promoted worldwide. As a new medical service model, ambulatory surgery has standardized the management of certain conditions that have relatively little variation in patients without severe comorbid diseases, which maximizes efficiency, shortens hospital stay, and improves medical expenses and hospital service levels.

PCNL is an important treatment method for upper urinary tract calculi, but is considered a high-risk surgery due to potential perioperative complications such as bleeding, infection, and damage to adjacent organs[5]. However, the emergence of mPCNL has greatly reduced the perioperative hemorrhage risks[6,7], and created conditions conducive to percutaneous nephroscopic ambulatory surgery. The performance of mPCNL as ambulatory surgery requires stricter control and management methods compared with other established ambulatory surgery procedures. The patients in the ambulatory surgery group in the present study were included in accordance with detailed inclusion/exclusion criteria, discharge standards, and strict follow-up monitoring to ensure maximal perioperative safety. The results of the present preliminary study showed that there were no significant difference regarding the safety and efficiency parameters between the two groups, and the ambulatory surgery group had a significantly reduced hospital stay and total hospital costs compared with the conventional hospitalization group.

The key issue that restricts the performance of PCNL as ambulatory surgery is the monitoring and treatment of postoperative complications. Generally, patients in our hospital received PCNL were required to stay for about 3 days postoperatively for observation of complications. The most common and potentially fatal complications of PCNL include postoperative infection and bleeding[2]. Postoperative infection manifest as fever, chills, and increased white blood cell count, severe cases may present with septic shock-related manifestations such as decreased blood pressure, decreased urine output, disturbance of consciousness, and circulatory failure. If timely treatment is not administered, the patient's life may be endangered. Risk factors for severe infection include preoperative urinary tract infection, females (especially postmenopausal females), diabetes mellitus and anemia, large numbers of calculi, long surgery time, high irrigation pressure, poor renal function, and an immunosuppressed status[8]. Hence, preoperative screening is critical for patients requiring PCNL. Clinicians should be very cautious when selecting ambulatory surgery for patients with severe infection. We consider that patients with more than two of the abovementioned risk factors for infection should not undergo PCNL as ambulatory surgery. Education and follow-up for patients and their families are also very important, so that they understand the potential risks of severe postoperative infections. If severe complications occur, patients must promptly return to hospital for treatment. According to our experience and that reported in the literature, the vast majority of serious post-PCNL infections occur intraoperatively and within 8 hours postoperatively[9,10]. Therefore, we believe that nearly 24 hours of observation after the surgery is sufficient for most patients, if not all. In our series, two patients in the conventional hospitalization group had postoperative fever, which were discharged after effective anti-infection and symptomatic treatment. No serious infections were encountered.

Bleeding after PCNL is another serious potential complication. Severe bleeding can manifest as fresh hematuria outflow in the catheter or nephrostomy tube; in

severe cases, a large number of blood clots can be seen in the drainage bag. Routine blood examination often reveals a progressive decrease in hemoglobin concentration, which can lead to hemodynamic instability and hemorrhagic shock. The two peak times at which postoperative bleeding usually occurs are within 24 hours postoperatively and within a few weeks postoperatively[5,11]. For patients at relatively high risk of bleeding, the selection of ambulatory surgery should be made cautiously, and detailed education should be given to day surgery patients and their families. In addition, it is essential to maintain smooth and effective communication between the patient and the hospital staffs so that patients can quickly return to the hospital for treatment if serious bleeding occurs.

The main purposes of the indwelling nephrostomy tube include urinary drainage, compression of the puncture channel to reduce bleeding, and secondary treatment of renal lesions. Nevertheless, insertion of the nephrostomy tube tends to be thought of a practice of the surgeon rather than a real need. Tubeless PCNL can reduce hospital stay, postoperative pain, use of analgesics, urinary leakage and hospitalization costs. Many studies have confirmed the safety of tubeless PCNL for relatively simple calculi[12-14]. Compared with the standard channel PCNL, the use of mPCNL in the present study greatly reduced the incidence of postoperative hemorrhage. Most patients of our study in the ambulatory surgery group had relatively simple calculi, and the intraoperative treatment was satisfactory. Postoperatively, puncture channel bleeding was checked using conventional direct vision under the guidance of the safety guidewire. Hemostasis was achieved by tamping the Surgicel Fibrillar™ absorbable hemostat (Ethicon Inc., Johnson and Johnson, Sommerville, NJ, USA) with a working sheath, except in cases with obvious substantial bleeding. Compared with the control group, the use of tubeless PCNL in the ambulatory surgery group did not increase complications such as postoperative bleeding, which further confirmed the safety and feasibility of tubeless mPCNL.

Most of the ambulatory PCNL studies in the literature were retrospectively design and with a standard percutaneous renal access[4,15]. We believe several aspects of our study could be helpful for further ambulatory PCNL study. To our knowledge, this is the first prospective report of PCNL as ambulatory surgery, which minimized the systematic errors. Secondly, we introduced microchannel PCNL for ambulatory surgery for the first time, which we believe caused less trauma and bleeding risks. Furthermore, we used absorbable hemostat for puncture channel tamping to reduce bleed and postoperative urinary leakage, which could be used for reference in the clinical practice. Compared with the conventional hospitalization group, the patients included in the ambulatory surgery group were younger, had fewer comorbidities and lower ASA score, simpler and smaller calculi, shorter operative time, better postoperative recovery, and no serious complications such as severe bleeding or infection that required readmission of further intervention. The present results confirm that performing mPCNL as ambulatory surgery can effectively reduce hospital stay and hospitalization costs without increasing perioperative risks in appropriate patients, and indicates that up to 24 hours of postoperative observation can rule out most complications, making mPCNL ambulatory surgery safe and feasible for selected patients. However, this present study is observational with inherent limitations and confounders. And the maximum diameter of calculi was lower in Ambulatory surgery group, as the sample size is relatively small and it is difficult to control the confounding. Effect the results should be carefully interpreted as the lack of randomization and the small sample size. Further efforts including miniaturization of the sheath size(16), anaesthesia(17) and improvements on postoperative analgesia(18) could be made to ease ambulatory PCNL recovery.

## CONCLUSIONS

Ambulatory mPCNL is generally safe and feasible. Considering the potentially fatal complications, this approach should only reserve for highly selected patients in centers with sufficient case volume. Well-designed studies are needed to confirm the safety and economic and social benefits of mPCNL as ambulatory surgery.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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