

**A Comparative Study of Tubeless Percutaneous Nephrolithotomy With or Without Reverse Ureteral Catheter Insertion**

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1. Title: A comparative study of tubeless percutaneous nephrolithotomy with or without reverse ureteral catheter insertion.
2. Trial registration: Clinical Trial Registry (<https://www.clinicaltrials.gov>).
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4. Funding: Key Clinical Research Project of University of South China (No. USCKF201902K01).
5. Investigator and responsibilities: Li Mingyong, deputy chief physician (study leader) : trial design, surgical implementation, protocol management, and process guidance; Research group postgraduate: data collection and analysis, article writing and publication.
6. Research background and principle: PCNL is the first-line treatment for renal calculi and upper ureteral calculi. With the development of minimally invasive urological endoscopic technology and the improvement of patients' medical requirements, it has become a consensus that PCNL surgery will develop in the direction of less trauma, more concise operation and more reasonable innovation. The emergence of tubeless PCNL (without indwelling nephrostomy tube) has been proved to be safe and effective in reducing postoperative discomfort, shortening hospitalization time and reducing hospitalization costs, so it has been paid more and more attention by clinical medical workers. Traditional tubeless PCNL usually requires placing the patient in the lithotomy position and retrograde insertion of the ureteral catheter under transurethral ureteroscopy, which is theoretically considered to be used to establish "artificial hydronephrosis" guided puncture and to prevent stones from falling into the ureter to form ureteral stone street. However, a large number of practices have found that the reverse insertion of ureteral catheter can cause many ureteral-related surgical complications. And for those who have had spinal injury, spinal deformity or large joint stiffness of the body of the patient, often can not swing the lithotomy position. At this time, without reverse insertion of ureteral catheter can show its unique advantages: simplify the operation steps, shorten the operation time, reduce the repeated operation of the ureter and thus

reduce the risk of long-term ureteral stenosis. However, there are few reports on tubeless PCNL without reverse ureteral catheter insertion. With the continuous update of ultrasound equipment and the continuous progress of physician puncture technology, ultrasound-guided percutaneous renal puncture is less and less dependent on retrograde pyelography or artificial hydronephrosis. Therefore, we believe that for patients with certain hydronephrosis and little stone burden, it is theoretically feasible to perform tubeless PCNL without reverse insertion of the ureteral catheter.

7. Objective: The purpose of this study is to explore the safety and clinical efficacy of this new surgical method in the treatment of upper urinary calculi by combining the application of non-inverse insertion technique in the operation of tubeless PCNL, and to explore the applications of this new surgical method.

8. Experimental design: A two-arm parallel trial design was carried out. The participants who underwent tubeless PCNL without reverse insertion of a ureteral catheter were selected as the experimental group, and the participants who underwent traditional tubeless PCNL with reverse insertion of a ureteral catheter were selected as the control group.

9. Site: This was a single-center study conducted at the First Affiliated Hospital of the University of South China.

10. Inclusion and exclusion criteria: Inclusion Criteria: 1. Participants who met the the applications of PCNL surgery in the 2019 Chinese Guidelines for the Diagnosis and Treatment of Urological Diseases; 2. Participants who agree to undergo tubeless PCNL; 3. The participants' maximum diameter of the stone should be less than 3.5cm. Exclusion Criteria: 1. Confirmation by computerized tomography (CT) images and blood biochemical indicators of infectious stones or complex staghorn stones; 2. Obvious surgical contraindications, such as severe heart and lung insufficiency, abnormal coagulatory function; 3. Previous PCNL or nephrolithotomy, presence of an indwelling ureteral stent or nephrostomy tube before surgery; 4. Renal trauma or congenital malformation of the urinary system. If the following variations occurred during the operation: puncture difficulties in the

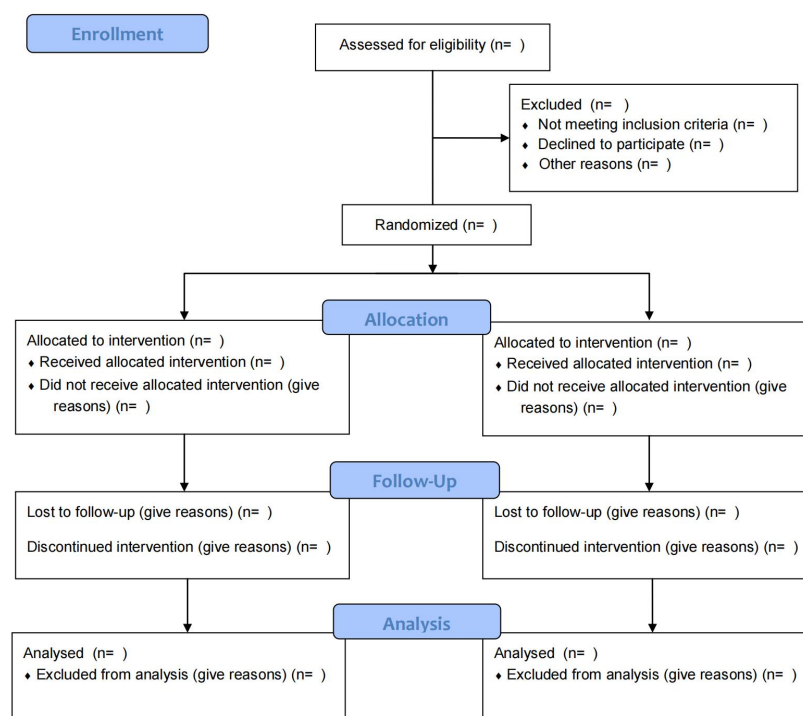
lithotomy position and inverse insertion of ureteral catheter-guided puncture, a finding that pyonephrosis demanded the treatment of nephrostomy, channel bleeding that was required to maintain a nephrostomy tube, larger residual calculi that needed a nephrostomy tube for a secondary surgery, or a ureteral stone street that necessitated ureteroscopic lithotomy by changing to the lithotomy position; Or incomplete postoperative clinical data will be recorded by the study recruitment flow chart, but not included in the final data analysis.

11. Intervention measures: a. According to the randomization, the same associate chief urologist performed tubeless PCNL without reverse ureteral catheter or traditional reverse ureteral catheter; B. During the perioperative period, participants were given comprehensive blood biochemical examination and imaging evaluation, and antibiotics (second-generation cephalosporins or penicillins) were prophylactic. Participants with hypertension, diabetes and other comorbidities were given relevant drugs to control the tolerable level of surgery. C. Implementation process of tubeless PCNL without reverse insertion: After detaining urethral catheter for patients with tracheal intubation general anesthesia, to take a prone position, suffer renal biopsy under ultrasound guided look straight into the target under the calyces, syringe after water injection and suction is smooth, the guide wire guided by micro fascia dilator (Fr16 or Fr18) continuous build percutaneous renal channel expansion, step by step with holmium laser remove all break "can see the stone", A 6Fr double J tube was placed antegrade under the guidance of the guide wire, and no stone residue was detected. No active bleeding was observed in the channel during the withdrawal of the lens. The implementation process of traditional reverse insertion of tubeless PCNL was as follows: the participants were intubated for general anesthesia. First, the ureteral catheter was inserted under transurethral ureteroscopy in the lithotomy position and fixed on the catheter. The process of establishing percutaneous renal channel under ultrasound guidance and stone removal was the same as that of tubeless PCNL without the use of a retro-inserted ureteral catheter. Double J tubes were placed antegrade under the guidance of guide wire, and the

skin incision was sutured and closed after no residual "visible stones" and no active bleeding under endoscopic observation.

12. Outcome measures: The primary clinical end point was the incidence of postoperative complications (including postoperative fever, bleeding, pain, and changes in renal function; Ureterostone street was formed after operation. Air - fluid chest after operation); The secondary clinical end points were operation time, hospital stay, hospital cost and stone clearance rate.

13. Recruitment flow chart:



14. Sample size: Combined with the number of outpatient calculi patients and the number of PCNL surgeries in our department of Urology each year, we planned to initially include 200 patients with renal and/or upper ureteral calculi who underwent tubular PCNL surgery in our hospital from October 2022 to December 2024, and randomly assigned at 1:1.

15. Participants: Patients with upper urinary stones attending the Urology Clinic of the First Affiliated Hospital of the University of South China were recruited.

16. Allocation sequence generation, allocation hiding, implementation methods: Computer random number generator was used. Participants with odd numbers were assigned to experimental group, where they underwent tubeless PCNL without

reverse insertion of a ureteral cathete. Participants with even numbers were assigned to control group and underwent tubeless PCNL with reverse insertion of a ureteral cathete. This process takes place in the operating room.

17. Blinding: In a single-blind approach, patients are told to participate in a clinical trial but are not informed about the specific intervention, while the person administering the intervention is clearly informed.

18. Data collection: The measured data of all the required: 1. The demographic data, stone characteristics and preoperative baseline data, including the proportion of gender, age, body mass index (BMI) and basic diseases distribution, location, stones, stone maximum cross-sectional area, the longest diameter antler shape proportion and pelvic effusion width, partial side and puncture operation, etc. 2. Data of the main end points included: Postoperative fever and inflammation (temperature, preoperative blood leukocyte count difference after operation, neutrophils ratio difference, post-operative sepsis), postoperative bleeding (preoperative differential postoperative hemoglobin and hematocrit value and blood in the urine, subcapsular renal week or hematoma after operation, postoperative DSA guided by selective renal artery embolization bleeding), postoperative pain, postoperative analgesia drug demand, Mainly non-steroidal anti-inflammatory analgesic drugs), renal function changes (preoperative and postoperative serum creatinine difference), ureteral stone street formation rate and the incidence of gas and fluid chest (postoperative CT showed the presence of gas and fluid accumulation in the chest); Secondary end points included operation duration, length of hospital stay, hospitalization cost, and stone clearance rate. 3. Follow-up was conducted for 1 month after discharge, including: high fever, obvious pain and hematuria after discharge; Whether there is readmission; Whether to remove the double J tube as scheduled.

19. Statistical analysis plan: SPSS26.0 statistical software was used for analysis. Measurement data were expressed as mean  $\pm$  standard deviation ( $X \pm S$ ) and t-test was used. Enumeration data were expressed as frequency and percentage by  $X^2$  or Fisher exact test. Rank sum test was used for rank data.  $P < 0.05$  was considered

statistically significant.

20. Ethical approval: This trial was a human life science and medical study and was approved by the Medical Ethics Committee of the First Affiliated Hospital of the University of South China (No. : 2022110924001).

21. Informed consent: All participants enrolled in the study signed a surgical consent and a clinical trial informed consent to collect and use the medical behavior information and biological samples for the study.

22. Confidentiality measures: The identifiable information of the subjects is replaced by irrelevant character sequences to ensure that the relevant personal information of the subjects will not be disclosed in any form.

23. Declaration of Interest: There is no conflict of interest between the investigator and the organization.

24. Data Acquisition: When proper editing or review requirements are met, the study data may be obtained from the study manager after the study is completed.