Application of one-handed lithotripsy in percutaneous nephrolithotomy

Clinical study protocol

1. Title：Application of one-handed lithotripsy in percutaneous nephrolithotomy.
2. Trail registration： Clinical Trials Registry（https://www.clinicaltrials.gov）。
3. Version number and date：Version number：V1.0 Version Date：November 19, 2022。
4. Funding：New technology of the First Affiliated Hospital of the University of South China
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： Percutneous nephrolithotomy(PCNL)is the treatment of choice for staghorn stone,complex renal caculi,large volume calcilo（especially ≥ 2 cm in diameter）.This procedure is the highest level of urology surgery and is characterized by high difficulty and high risk.Traditional PCNL usually adopt the left hand holding nephroscope to adjust depth and direction of the lens and the right hand to control the fiber for lithotripsy.It requires the operator to undergo long-term practical training to achieve tacit cooperation between the hands.There are analysis of the learning curve for percutaneous nephrolithotomy suggests that operators take at least 20 cases of PCNL to learn basic surgical skills, and at least 60 cases to initially master surgical competence.So, we propose a new surgical method - one-handed lithotripsy technique.The core of this technology is to use the same hand to hold the nephroscope and control the laser fiber,thereby avoiding the running-in problem of the two hands controlling the nephroscope and the laser fiber respectively，and the operator can continuously adjust the fiber and nephroscope to continuously crush the litholysis during the surgery, which significantly shortens the learning curve, operation time and difficulty of PCNL.Therefore, we believe that the promotion and

popularization of percutaneous nephroscopic with one-handed lithotripsy is of great clinical practical significance.

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 one-handed lithotripsy in the PCNL.

8.Experimental design：: A two-arm parallel trial design was carried out.The participants who underwent PCNL with one-handed lithotripsy were selected as the experimental group, and the participants who underwent traditional PCNL were selected as the control group.Prospective exploration studies were conducted on a 1:1 basis.

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: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 PCNL with one-handed lithotripsy.Exclusion Criteria： 1).Obvious surgical contraindications, such as severe heart and lung insufficiency, abnormal coagulatory function.2 ） If the following variations occurred during the operation: a finding that pyonephrosis demanded the treatment of nephrostomy,channel bleeding that was required to maintain a nephrostomy tube,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 PCNL with one-handed lithotripsy or traditional PCNL;

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 PCNL with one-handed lithotripsy：

a).After general anesthesia, the patient was placed in lithotomy position, routinely

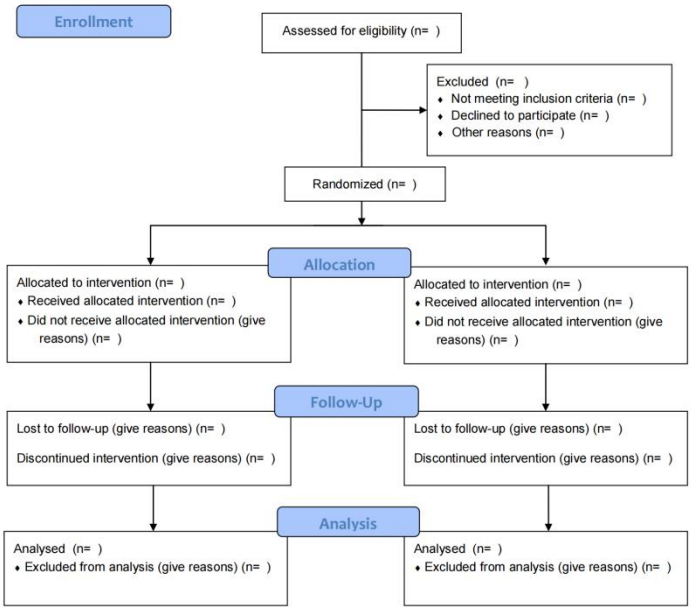
disinfected and covered with towels. Transurethral cystoscopy/ureteroscopy was performed to observe the ureteral opening on the affected side, and the ureteral catheter was retrograde inserted at a depth of 15 to 25cm.Exit the ureteroscope and fix the ureteral catheter on the urinary catheter. Then,the patient was moved to prone position, disinfected again and covered with towel,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.Holmium laser was used for lithotripsy

b).According to different lithotripsy methods, the operation was randomly divided into group 1 (one-handed lithotripsy group):using one hand to control the nephroscope and laser fiber at the same time, the other hand to adjust the depth and angle of the sheath at same time.Group 2 (traditional lithotripsy group) : lithotripsy was carried out by holding the nephroscope with one hand and controlling the laser fiber with the other one. It was often necessary to stop the lithotripsy to adjust the depth and angle of the sheath.

c).After the broken stones were removed,the ureteropelvic opening was located,the guide wire was placed anteriorly, and the ureteral stent was placed under the guidance of the guide wire.After no residual calculi were detected under the nephroscope, the endoscope was removed and the nephrostomy tube was indwelled and fixed.The incision skin is then sutured.

12.Outcome measures： The primary clinical end point are operative time、 stone clearance rate、number of tracts、rate of second operation、rate of auxiliary procedure、intraoperative renal pelvis mucosal injury rate 、 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。

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 100 patients with renal and/or upper ureteral calculi who underwent traditional PCNL surgery in our hospital from November 2022 to November 2023,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:Using the coin toss method, patients with the flip side of the coin were divided into PCNL surgery group using one-handed lithotripsy technique (group 1), and patients with the reverse side of the coin were assigned to the traditional PCNL procedure group (group 2).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:operative time、stone clearance rate、number of tracts、rate of second operation、rate of auxiliary procedure、intraoperative renal pelvis mucosal injury rate、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）； Secondary end points included:postoperative renal function changes, operative blood loss, postoperative bleeding rate, postoperative patient pain score, postoperative inflammation changes。

19. Statistical analysis plan: SPSS26.0 statistical software was used for analysis. Measurement data were expressed as mean ± standard deviation (X ± S) and t-test was used. Enumeration data were expressed as frequency and percentage by X2 or Fisher exact test. Rank sum test was used for rank data.P＜0.05 was considered tatistically 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：2022ll1120001）

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.