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Needle-perc: a new instrument and its initial clinical application

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Percutaneous nephrolithotomy (PCNL) has achieved remarkable acceptance during the past decade. The minimization of the instruments used and flexible scope improvements helped lead to its popularity. A previous literature proved that the tract size was positively correlated with the rate of bleeding and renal injuries.[1] On the basis of this conception, we devised a new PCNL technique, called "needle-perc" as the needle was even thinner than the micro-perc technique. In this study, we present our initial experience of using the needle-perc method to deal with small renal stones and to assess its feasibility and safety as new instrumentation in the field of minimally invasive endourology.

This clinical trial was approved by the ethics committee of Beijing Tsinghua Changgung Hospital. The inclusion criterion was the presence of a single small stone (<1.5 cm) in the kidney. Patients who met this inclusion criterion were informed that the PCNL would be performed using a new instrument. All patients gave their informed consent. The disposable instruments, including the needle-perc sheath, were provided free of charge. Hence, from March 2019 to July 2019, 24 patients with renal stones underwent PCNL with the use of needle-perc needles at our hospital. All operations were performed by one experienced surgeon (Li JX).

The novel instruments included reusable optical microfibers of 0.6 mm in diameter, with a resolution of 10,000 pixels (Youcare, Wuhan, China). The microfiber, with a light lead, was inserted into the working sheath through the central port of a three-way connector at the proximal end of the sheath. The depth of the fiber could be adjusted manually during the operation to ensure clear visualization [Figure 1]. One lateral port of the connector was for the irrigation system, in which a pump system or gravity irrigation with saline bags could be used. The other lateral port was designed for the laser fiber, a 200-μm fiber (Swiss Laserclast®, EMS; Nyon, Switzerland) used for dusting or fragmenting the stones during surgery. The optic fiber was connected to a standard endoscopic camera system and light source via a zoom ocular and light adapter.

Procedures were performed under general anesthesia. A 5F catheter was inserted with the patient in lithotomy position, after which the patient was placed in prone position for the puncture. The needle-perc was introduced to the target calyx under ultrasonography guidance. The stone was fragmented or dusted with the power set at 8 to 12 W (0.8–1.0 joules/10–15 Hz) with long or short pulses. After the procedure was completed, any residual stones were assessed by ultrasonography [Supplementary Video, http://links.lww.com/CM9/A179]. The ureteral catheter was removed on post-operative day 1. The stone-free rate was evaluated 1 month after surgery. Hemoglobin loss and the pain index were evaluated 24 h post-operatively.

Altogether, 24 renal units underwent PCNL with needle-perc in 16 (67%) male and eight (33%) female patients. The mean age of patients was 42.5 years (range 1–67 years). In all, there were 13 left-sided and 11 right-sided renal units. The mean calculus size was 12 mm (range 5–15 mm). Among the 24 patients, 20 were treated with a single puncture, and the other four required re-puncture to confirm correct positioning. Two patients underwent conversion to use of a mini-perc (16F) to remove the stones (which had been transferred to the proximal ureter during the surgery). The mean operative time was 49.2 min (range 22–75 min). The mean hemoglobin loss was 5.2 g/L (range 0–13.8 g/L). The mean visual analog scale to assess pain was 3.2 (range 1–6, based on the 20 adult patients whose procedures were done with the needle-perc).

Of the 24 patients, 20 (83%) had no residual stones according to the kidneys-ureters-bladder examination on post-operative day 1, and 4 patients had 2- to 3-mm residual calculi (three in the lower pole calyx, one in the upper ureter). At the 1-month follow-up, two of the

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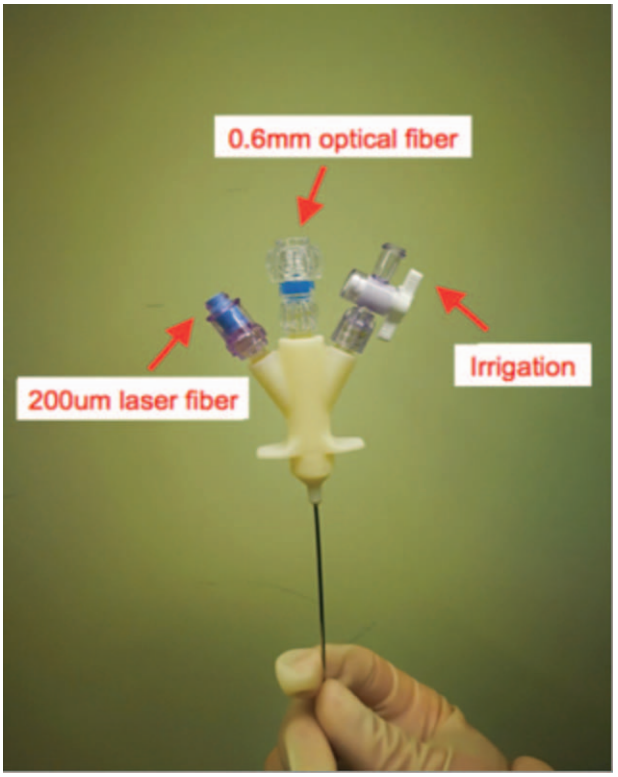

Figure 1: Structure and composition of the needle-perc apparatus.

patients had expelled the residual stones, and the stone-free rate was 91%. Significant complications were assessed according to the modified Clavien classification system. Fever (>38.5°C, grade II) was found in two (8%) patients, who were then given intravenous antibiotics. One patient who suffered transient renal colic (grade II) on post-operative day 1 was managed conservatively with anti-spasmodic drugs. The ureteral catheter was maintained in place 2 days longer in the patients with residual ureteral stones. None of the patients needed blood transfusion, and no complications occurred that were deemed Clavien III or above.

Although traditional PCNL with 24 to 30F channels is believed to achieve better stone clearance, especially for staghorn stones, evidence in the literature has shown that small channels may be associated with a lower morbidity rate.[2] If the access route is kept at the smallest diameter possible — such as that with the initial puncture needle — morbidities such as bleeding can be avoided. The question of how to achieve the highest stone clearance with minimal kidney damage was the basis for designing the needle-perc. Compared with the micro-perc, the needle-perc has a smaller outer sheath, which means less damage to the kidney. Similar to the micro-perc experience, the stones cannot be removed with the needle-perc using the sheath because of its limited size. As most stones must escape by spontaneous passage, the "dusting effect" should be performed as much as possible.

To accomplish this effect, we tend to set the laser parameters at the "lower energy, higher frequency, and long pulse duration" modes to avoid large fragments.[3] For conventional access, the intra-pelvic pressure can be easily controlled. For small tracts; however, the pressure during the procedure should be adjusted with caution. We; therefore, measured the intra-pelvic pressure using a pre-placed ureteral stent, according to that described by Sameh *et al*.[4] The pressure throughout the procedure ranged between 16 and 35 cmH_2O (1 $cmH_2O = 98$ Pa), which effectively avoided bacterial reflux. Because of the small size of the intra-sheath space, gravity irrigation was preferred for the needle-perc procedure. The volume of water was small, which could explain the lower intra-renal pressure with even no outflow during the procedures.

The miniaturization of PCNL has some advantages in special anatomical situations, such as upper urinary tract stones in pediatric patents. We recently performed PCNL with the needle-perc in three cases of renal stones in infants. These cases were not included in this study because of the lack of sufficient follow-up and the limited number of cases. Compared with retrograde intra-renal surgery, the tubeless needle-perc technique may be associated with other possible benefits, such as a shorter hospital stay, less discomfort, and fewer patients who require general anesthesia, which is critical for infants.[5] Another use of needle-perc is as an auxiliary channel to the standard channels. Patients with parallel calyx renal stones may require the establishment of multiple channels for conventional surgery. Needle-perc can also be used as a "satellite access" point, and parallel calculus can be fragmented or pushed into the renal pelvis. The main access is used for the removal of stones, thereby avoiding the establishment of multiple channels and effectively protecting kidney function.

There are some limitations in this study. First, only patients with small stones were enrolled, so it is not clear whether patients with larger stones could achieve the same therapeutic effect. Second, needle-perc is still in the early stage of clinical application, so there is much room for improvement in its handling, materials, and performance. In this study, we used the first-generation needle-perc, but we have now developed a second-generation needle-perc. On the basis of the first-generation instrument, a vacuum suction device was added to allow more effluent discharge, thereby maintaining lower pressure in the collection system intra-operatively. We plan to explore application of the second-generation needle-percs to removing larger kidney stones (>2 cm). Finally, compared with the previous instruments, such as ultra-mini PCNL, super-mini nephrolithotomy, and micro-perc devices, randomized studies are needed to define the needle-perc's place in the treatment of renal calculi.

In conclusion, needle-perc is a smart instrument for PCNL to manage some special cases. For small, low, calyceal stones, it can be used as an appealing alternate to extracorporeal shock wave lithotripsy and flexible ureteroscopy. Pediatric patients would benefit more from this new technique than from flexible ureteroscopy. Complex and large stones usually require conventional and multiple tracts if we are to achieve a high stone-free status. Use of the needle-perc could increase the stone-free rate without adding complications.

Declaration of patient consent

The authors certify that they have obtained all appropriate, signed, patient consent forms. In those forms, the patients have given consent for their images and other clinical information to be reported in a journal. The patients understand that their names and initials will not be published, and due efforts will be made to conceal their identity, although anonymity cannot be guaranteed.

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Conflicts of interest

None.

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