A 3D Printing Personalized Percutaneous Nephroscope Puncture Guide Plate in Percutaneous Nephrolithotomy: A Pilot Study

Gao Keyu

The Affiliated Hospital of Xuzhou Medical University

Li Shuaishuai

The Affiliated Hospital of Xuzhou Medical University

Ashok raj

The Affiliated Hospital of Xuzhou Medical University

Li Shuofeng

The Affiliated Hospital of Xuzhou Medical University

Liu Shuai

The Affiliated Hospital of Xuzhou Medical University

Zhang Yuan

The Affiliated Hospital of Xuzhou Medical University

Zhu Haitao

The Affiliated Hospital of Xuzhou Medical University

Wang Junqi (✉ li1997shuaishuai@163.com)

The Affiliated Hospital of Xuzhou Medical University

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Abstract

Objective Using CTU, combined with 3D printing technology, digital design, the development of individualized PCNL) puncture guides, preliminary discussion of its feasibility for PCNL puncture positioning.

Methods Twenty-two patients with renal calculi who underwent PCNL in the hospital of Xuzhou Medical University in 2017-2018, including 10 experimental groups, used 3D printing technology to make guides (puncture guides); simulated punctures in vitro, after clearing the needle angle, PCNL was performed in 10 patients and PCNL in 12 patients in the control group. The accuracy of puncture positioning, puncture time and intraoperative blood loss were compared between the two groups.

Results In the experimental group, 10 patients had good puncture guide plate and the patient's skin. The puncture needle was puncture under the guidance of the guide plate and verified by the color Doppler. The 1 needle puncture was successful 100.00% (10/10), the positioning of the needle point, the depth of the puncture. The angles were consistent with the preoperative design. The success rate of 12 cases of color Doppler ultrasound in the control group was 75.00% (9/12). There was no significant difference between the two groups ($P>0.05$). The amount of hemorrhage was (7.78 ± 0.94) min and (49.31 ± 6.43) mL, respectively. The control group was (9.04 ± 1.09) min and (60.08 ± 12.18) mL, respectively. The two groups were statistically significant ($P<0.05$).

Conclusion 3D printing personalized percutaneous nephrolithotomy guide can improve the accuracy of PCNL renal puncture channel positioning, shorten the puncture time and reduce intraoperative blood loss, and provide a new method for PCNL renal puncture positioning, which is worthy of further clinical exploration.

Introduction

Percutaneous nephrolithotomy (PCNL) is still the mainstream treatment for complex renal calculi. However, the complications such as bleeding, Infection, and residual stones during and after PCNL operation are the main burden needed more attention. Among them, bleeding is the most common complication, and the cause of bleeding is mainly the poor selection of renal puncture site and damage to renal vessels. The establishment of the best skin-to-target renal puncture channel is a critical factor for successful operation. At present, the main preferable clinical methods of stone localization are X-ray (fluoroscopy) and Ultrasound^[1-2]. Fluoroscopy is a two-dimensional imaging system that lacks the stereoscopic sense of kidney tissue and stone location, with a low success rate of puncture and radiation damage^[3]. Ultrasound can position calculi in multiple layers and effectively improve the accuracy of positioning. However, its low resolution and high requirements on ultrasonic technology of the surgeons limit its clinical application to a certain extent. 3D printing technology is a new technology developed in recent years. Using 3D printing technology to make personalized guide plates for different surgeries has been more and more applied in orthopedics and stomatology^[4-5]. However, this technology is still in the

preliminary exploration stage in urology. The 3D printing plate can be implemented to avoid the damage of renal vascular puncture in the process of renal puncture localization and improve the accuracy of puncture localization. Through the 3D reconstruction modle, doctors, patients and their families can more clearly understand the stone localization, so it can make the communication between doctors and patients more comfortable, and has guiding significance for the planning of clinical surgery plan. In the experimental group, 10 patients who planned to undergo PCNL in the Affiliated Hospital of Xuzhou Medical University from 2017 to 2018 were selected. Using Computed Tomography Urography (CTU), combined with 3D printing technology and digital design, the individualized percutaneous nephrolithotomy guide plate was developed. The feasibility of its application in PCNL puncture localization was preliminary discussed.

1. Materials And Methods

1.1 General information:

From 2017-2018, in the Affiliated Hospital of Xuzhou Medical University, a total of 22 patients with kidney stones were admitted. And all patients have signed informed consent forms. Among them, two groups were created, i.e., Experimental and Control groups. The experimental group (n=10) were divided into five males and five females according to gender. According to the stone side, there were 4 cases on the left side and 6 cases on the right side. According to the type of calculi, there were 5 cases of staghorn calculus, 2 cases of single calculi, and 3 cases of multiple calculi. Among them, lumbar pain and discomfort were found in 6 cases, asymptomatic physical examination found in 2 cases, gross hematuria in 2 cases. Two patients had a history of hypertension, and 4 patients had undergone extracorporeal shock wave lithotripsy(ESWL). The mean age was 48.60 ± 9.69 (28 ~62) years old. The control group (n=12) was divided into 7 males and 5 males according to gender. According to the stone side, there were 5 cases on the left side and 7 cases on the right side. According to the type of calculi, there were 4 staghorn calculi, 5 single calculi and 3 multiple calculi. Among them, 7 cases complained of lumbar pain and discomfort, 3 cases were found asymptomatic on physical examination, and 2 cases were found gross hematuria. ESWL was performed in 5 patients. The mean age was 45.33 ± 8.52 (22-58) years old. There was no statistically significant difference in age, sex, stone side, stone type and stone associated sympotomes between the two groups ($P>0.05$) [Table 1]. Inclusion criteria: 1. All patients were diagnosed as renal calculi by CTU before surgery; 2.Surgical indications consistent with PCNL^[6];3. There was no significant disease of cardiopulmonary and other vital organ dysfunction; 4. Preoperative urine culture was negative, no urinary tract infection or infection had been controlled; 5. No obvious bleeding tendency, normal liver, and kidney function; 6. Invertebrate deformity and unable to prone patients; 7.Fully communicate with patients and their families about the PCNL combined with 3D technology, digital design and development of personalized percutaneous nephrolithotomy guide plate, and obtain the consent of patients and their families and sign the informed consent of surgery.

Table 1. General information of two groups of patients

Patients profile	Experience group (n=10)	Control group (n=12)	P
Age: (years)	48.60±9.69	45.33±8.52	0.410
Stone side: (L/R)	4/6	5/7	0.937
Gender: (M/L)	5/5	7/5	0.696
Stone types: (staghorn/solitary / Multiple occurrences (e.g.))	5/2/3	4/5/3	0.542
Complaint: (lumbar pain / discomfort/ naked hematuria)	6/2/2	7/3/2	0.953

1.2 A construction of 3D printing individualized percutaneous nephroscopy guides plate.

All the 10 patients in the experimental group were placed in prone position. CTU examination (256-slice spiral CT Philips) was performed with 5 mm thickness and 1.25 mm reconstruction. During a plain scan, the gray values of ribs and stones were higher than those of surrounding soft tissues, and the gray values of ureters, pelvis, and calyx were higher than those of renal artery, renal vein, aorta, and renal cortex; during arterial phase, the gray values of ureters, pelvis, and calyx were higher than those of renal artery, renal vein. During the excretion period, the gray value of the pelvis, calyx, and ureter can be increased because of the contrast agent, to distinguish it from other soft tissues; Dicom image file obtained by CT scan is used as initial data, and then Dicom file is imported into Mimics 17.0 software (Materialise Company of Belgium), according to the corresponding threshold segmentation and regional growth functions, kidney and pelvic calculi are established. 3-D reconstruction models of ribs and skin are saved in STL format. Then STL was imported into 3-Matic software, and the skin was smoothed with the guide plate. L1 and L2 were fixed points, and the lower edge of twelve or eleven ribs of the posterior axillary line were puncture points. Draw the surface surrounded by the positioning point, cut the surface appropriately, make the middle hollow, leave space for the color Doppler ultrasound probe, simulate the needle insertion cylinder to increase to 5 mm, use "Boolean subtraction" to determine the inner diameter of the needle insertion channel (1.5 mm), and generate the digital model of the guide. PLA material is used to print on the 3D printer (Raise 3D N2, Suzhou Wuchuang 3D Technology Co., Ltd.); after printing, the guiding device is used for reserve during operation after plasma sterilization[Figure 1]. Each guide plate costs about 500 USD.

A: CTU examination shows arterial phase and left kidney stone; B: Three-dimensional reconstruction of the kidney, renal vessels, and kidney stones was achieved by software through CTU images; C: Reconstructing the puncture location point according to the model, the angle, and depth of puncture, avoiding the main vessels; D: Designing the puncture guide plate that fits the skin; E: 3D printed percutaneous nephroscope puncture guide plate was fixed on the patient skin. F: The percutaneous puncture localized in patients with percutaneous nephroscope puncture guides by 3-D printing. (Figure legend: This figure is our own, drawn by Gao Keyu^{1*} and Li Shuaishuai^{2*}.)

1.3 Position and surgical methods

Under general anesthesia, all 22 patients were placed in a prone position. Then, the surgical area was disinfected and draped. In the experimental group, we wear virtual reality glasses and can observe the 3D model established before the operation, which can better assist the surgical puncture. After that, the sterilized puncture guide plate was fixed on the patient body. The assistant holds the puncture guide plate to prevent displacement. Then, the puncture needle was inserted through a puncture hole, and the angular position and accuracy of the puncture needle were assessed under the aid of USG. In the control group, a Puncture needle was inserted under the direct guidance of USG, and stone is detected in the renal pelvis. Then, PCNL was performed in both groups.

1.4 The accuracy of puncture (success rate of single needle puncture), intraoperative blood loss (intraoperative blood loss = Hb concentration in the sample of flushing fluid * volume of flushing fluid / preoperative Hb concentration^[7] . combined with intraoperative estimation), puncture time (puncture start to find the calyces where the stones are successfully located) were recorded.

1.5 Statistical data were analyzed by SPSS 20.0 software. The mean of measurement data (±standard deviation, t-test, counting data (%) and Fisher exact test were used for statistical analysis. There was a significant difference in P<0.05.

2. Results

All ten patients were successfully designed and printed with a 3D percutaneous nephrolithotomy guide plate in the experimental group before the operation. The direction, depth and angle of puncture were consistent with the design in the computer solid model. In all 10 patients, the intraoperative puncture guide plate was well fitted to the patients’ skin, and the puncture needle under the guidance of the guide plate and verified by ultrasound, the success of one puncture was 100.00% (10/10). In the control group, the success rate of one puncture was 75.00% (9/12), and there was no statistical significance between the two groups (P>0.05). In both experimental and control group, the puncture time and intraoperative blood losses were (7.78±0.94/9.04±1.09) min and (49.31±6.43/60.08 ±12.18) mL, respectively; there was a significant difference between the two groups (P<0.05, Table 2).

Table 2. Comparison of puncture time, intraoperative bleeding and puncture success of the first attempt between two groups

Parameter	Puncture time [min]	Blood loss [mL]	Successful puncture rate in the first attempt [%]
experimental group	7.78±0.94	49.31±6.43	100.00±10
control group	9.04±1.09	60.08±12.18	75.00±9
<i>t</i>	2.913	2.652	
<i>P</i>	0.010	0.017	0.221*

*Fisher Precise test

Discussion

PCNL is an effective treatment for complicated kidney stones^[8]. Foreign studies have reported that PCNL stone clearance rate and surgical risk are closely related to the choice of renal puncture site, and the establishment of the correct renal puncture channel is the premise to complete lithotripsy and reduce the incidence of complications such as intraoperative and postoperative massive hemorrhage, liver and pleural injury, and intestinal injury^[9]. Therefore, the successful establishment of the renal puncture pathway is the main factor and difficulty of PCNL. We have researched and produced 3D printed guide plate to solve puncture positioning problem and increase the accuracy and safety of puncture positioning. The traditional methods of assisted renal puncture positioning mainly include X-ray or Ultrasound. Ultrasound and X-ray have their own advantages and disadvantages. The X-ray can detect the whole process of a puncture in real-time and determine the residual stones after lithotripsy. But there is radiation damage to patients and surgeons, so the vertical depth of the stones can not be located, and multiple puncture positioning may be required for patients with mild hydronephrosis^[10–11]. Ultrasound can distinguish the location of renal calculi and the thickness of surrounding renal parenchyma without radiation damage, thus improving the success rate of puncture and reducing the occurrence of bleeding and corresponding complications. However, ultrasound requires high ultrasonic knowledge of the surgeon, and the learning period is long, and it is not as clear as X-ray for stone imaging^[12]. In this study, it was found that the 3D percutaneous nephrolithotomy guide plate was made and applied to locate the kidney before puncture and guide the direction and angle of the puncture needle during puncture, so as to reach the optimal calices where the calculi were located, which could increase the accuracy of kidney puncture and simplify the puncture process, and improve the accuracy of surgery. Moreover, the 3D reconstruction model can enable patients and their families to more clearly understand the location of stones, specific surgical methods and possible surgical risks compared with imaging images, which has a guiding significance for the planning of clinical surgical plans, improve patients' trust in doctors, and makes the doctor-patient relationship more harmonious.

In this study, the design of individualized percutaneous nephrolithotomy guide plate with 3D printing was carried out. L1 and L2 were selected as bone markers points, and the puncture guide plate was reconstructed according to the scanning data of CTU in plain scan period, arterial phase and excretion period combined with PLA material. The thickness of the guide plate base was designed to be about 1mm. The angle and depth of the puncture hole of guide plate were selected according to the three-dimensional reconstructed renal vascular structure, and the relatively large safety gap was selected, and the internal diameter of the puncture hole was designed to be 1.5mm according to the type of the puncture needle. Excess internal diameter of the puncture hole would increase the puncture needle's instability and may cause the puncture angle deviation. The shape of the whole guide plate is designed as a long strip according to the bony marks and puncture points. The hollow design is adopted in the part without support, which can not only save the costs, but also leave space for the color ultrasound probe to monitor the puncture progress in real time and assist positioning during puncture. We use PLA material, because it has the characteristics of heat resistance, impact resistance, low cost, and low pollution, which can reduce the possibility of deformation of the guide plate in the progress of sterilization and disinfection. Under ultrasound-assisted verification during the operation, all the 10 patients succeeded in one needle puncture (100.00%) under the guidance of percutaneous nephroscope puncture guide plate. The positioning of the entry point, the depth and angle of the puncture were consistent with the preoperative design. Compared with the control group (75.00%), the accuracy of puncture location was significantly increased in the experimental group, and the puncture time was shortened, and the amount of intraoperative bleeding was reduced.

In the localization of renal puncture in PCNL surgery, we need to pay attention to the changes of uncontrollable factors such as body position change, bony marker localization deviation, and respiratory activity, which can reduce the accuracy of puncture and even lead to puncture failure. In order to minimize these uncontrollable factors, we in the experimental group adopted the following measures : (1) Preoperative CT examination position consistent with intraoperative position remain prone position, and should be given abdominal augmentation according to PCNL position requirements, select the same hardness and flat operation beds because of the change of subtle body position will cause stones and surrounding tissue structure difference; (2) During CTU examination, electrodes were attached to the L1 and L2 positions of patients, so as to ensure the accuracy of preoperative examination and intraoperative bony marker localization; (3) During the operation, the patients' spontaneous breathing was suspended intermittently, and the breathing was carried out with the assistance of the anesthesiologist's manual breathing apparatus, which could reduce the impact of respiratory activity on puncture positioning; (4) Color ultrasonography can increase the accuracy of puncture localization during operation.

Although the above measures were taken to minimize the influence of uncontrollable factors, we believed that due to the fact that preoperative intestinal preparation, intraoperative abdominal elevation, respiration and other factors of the patient could not be absolutely consistent with preoperative conditions, there might be some deviation between the intraoperative renal position of the patient and the preoperative CTU, which could affect the puncture accuracy. In the past, 3D printing technology has been widely used in orthopedics and maxillofacial surgery because of its bony structure, relative position is

fixed, but percutaneous renal puncture for breathing very demanding, mild kidney movement can affect puncture. Even if intraoperative breathing pause is used, the relative kidney position at this time cannot be guaranteed to be the same as that at preoperative CT examination. We preserve a large space for the ultrasonic probe under the puncture guide plate. During the puncture process, we can fine-tune the puncture angle in real time and correct the puncture accuracy according to the images provided by the Ultrasound, which basically solves the above problems. However, due to the finalization of the puncture template, the puncture angle and position cannot be adjusted too much during the surgery. In the following improvement, we will connect the puncture channel and the base of puncture template in the way of ball joint, which is believed to solve this problem more perfectly. As for the precise positioning of L1 and L2, we think that we can use a C-arm X-ray machine to locate L1 and L2 and mark L1 and L2 locations on the patients' body surface with a marker pen. During the design of puncture guide plate, two markers can be designed on the guide plate. In clinical application, the markers on the guide plate can be aligned with the marked positions of L1 and L2 on the patients' body surface, and the puncture guide plate can be fixed through two sides. Through the above methods, the error between clinical positioning of template and computer simulation can be reduced as much as possible. In this paper, the 3D puncture guide plate is established by relying on CTU, and CTU is related to patients' renal function. If patients' renal function is inferior, it may affect the CTU imaging, which is a limitation. In the following improvements, we can consider combining various imaging examinations to establish a 3D model, such as magnetic resonance urography. Although the 3D printing guide plate increases the economic cost of patients, we believe that with the development of 3D technology, the cost will not become a restriction on the clinical application of 3D printing technology in urology department. In addition, another limitation of this paper is that the sample size is too small, which may affect our statistical result. Therefore, in the following work, we still need more samples to verify our conclusion.

Conclusion

In summary, the 3D printing puncture guide provides a new method for PCNL puncture location of the kidney, and has obvious accuracy and safety compared with traditional color ultrasound location. This paper is a preliminary exploration of the application of 3D printing technology in clinical puncture in urology. It is believed that with the continuous maturity and development of 3D printing technology, it will be more prevalent in urology in the future.

Declarations

Availability of data and materials:

The datasets used during the current study are available from the corresponding author on reasonable request.

Ethical Approval: The study was approved by Clinical Trial Ethics Committee, Affiliated Hospital of Xuzhou Medical University.

Approval Number: XYFY2015-JS015-01

Ethics declarations:

Ethics approval and consent to participate

The study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and compliance with the International Council for Harmonization Good Clinical Practice Guidelines. All patients provided written informed consent. The final protocol, any amendments, and informed consent documentations were reviewed and approved by the Institutional Review Boards at each of the investigational centers participating in the study.

Consent for publication:

Informed consent to publish was obtained.

Contribution of Each Author:

Gao Keyu: Data Collection, Manuscript Writing, Data Analysis

Li Shuaishuai: Data Collection, Manuscript Writing, Data Analysis

Ashok raj: Data Collection, Manuscript Writing, Data Analysis

Li Shuofeng: Data Collection

Liu Shuai: Data Collection

Zhang Yuan: Data Collection

Zhu Haitao: Manuscript Writing

Wang Junqi: Manuscript Writing

*Contributed equally to the work

Competing interests:

The authors declare that they have no competing interests.

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Figures

Figure 1

A Construction and application of a 3-D printing personalized percutaneous nephroscope puncture guide for a patient with left kidney stones shown above. A: CTU examination shows arterial phase and left kidney stone; B: Three-dimensional reconstruction of the kidney, renal vessels, and kidney stones was achieved by software through CTU images; C: Reconstructing the puncture location point according to the model, the angle, and depth of puncture, avoiding the main vessels; D: Designing the puncture guide plate that fits the skin; E: 3D printed percutaneous nephroscope puncture guide plate was fixed on the patient skin. F: The percutaneous puncture localized in patients with percutaneous nephroscope puncture guides by 3-D printing. (Figure legend: This figure is our own, drawn by Gao Keyu1* and Li Shuaishuai2*.)