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Surgery in Motion

Ureteroscopy-assisted Percutaneous Kidney Access Made Easy: First Clinical Experience with a Novel Navigation System Using Electromagnetic Guidance (IDEAL Stage 1)

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Please visit www.europeanurology.com and www.urosource.com to view the accompanying video.

Abstract

Background: Puncture of the renal collecting system represents a challenging step in percutaneous nephrolithotomy (PCNL). Limitations related to the use of standard fluoroscopic-based and ultrasound-based maneuvers have been recognized.
Objectives: To describe the technique and early clinical outcomes of a novel navigation system for percutaneous kidney access.
Design, setting, and participants: This was a proof-of-concept study (IDEAL phase 1) conducted at a single academic center. Ten PCNL procedures were performed for patients with kidney stones.
Surgical procedure: Flexible ureterorenoscopy was performed to determine the optimal renal calyx for access. An electromagnetic sensor was inserted through the working channel. Then the selected calyx was punctured with a needle with a sensor on the tip guided by real-time three-dimensional images observed on the monitor.
Outcome measurements and statistical analysis: The primary endpoints were the accuracy and clinical applicability of the system in clinical use. Secondary endpoints were the time to successful puncture, the number of attempts for successful puncture, and complications.
Results and limitations: Ten patients were enrolled in the study. The median age was 47.1 yr (30–63), median body mass index was 22.85 kg/m^2 (19–28.3), and median stone size was 2.13 cm (1.5–2.5 cm). All stones were in the renal pelvis. The Guy's stone score was 1 in nine cases and 2 in one case. All 10 punctures of the collecting system were successfully completed at the first attempt without X-ray exposure. The median time to successful puncture starting from insertion of the needle was 20 s (range 15–35). No complications occurred.
Conclusions: We describe the first clinical application of a novel navigation system using real-time electromagnetic sensors for percutaneous kidney access. This new technology overcomes the intrinsic limitations of traditional methods of kidney access, allowing safe, precise, fast, and effective puncture of the renal collecting system.
Patient summary: We describe a new technology allowing safe and easy puncture of the kidney without radiation exposure. This could significantly facilitate one of the most challenging steps in percutaneous removal of kidney stones.

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1. Introduction

First described in 1976, percutaneous nephrolithotomy (PCNL) has gained an established role in the contemporary surgical management of urolithiasis [1,2]. Both European Urology Association and American Urological Association guidelines recommend PCNL as the treatment option for larger renal calculi [3,4].

The PCNL procedure includes several steps: percutaneous puncture of a renal calyx, tract dilatation, nephroscopy, and stone fragmentation and removal [5]. Among these steps, obtaining safe and appropriate access to the kidney represents one of the most difficult, and can ultimately impact the outcomes of the procedure [6]. Fluoroscopy and ultrasound, alone or combined, are the methods most often used to guide puncture of the renal collecting system [7]. However, access techniques based on these methods remain suboptimal [8]. Moreover, concerns related to radiation exposure when fluoroscopy is used have been raised [9].

We recently described experimental use of a novel visual-assisted navigation system in a porcine model using real-time electromagnetic sensors to allow kidney puncture for PCNL [10]. Here we report the first use of this device in humans and describe in detail the surgical technique and analyze early clinical outcomes.

Fig. 1 – Surgical set-up for puncture of the renal collecting system using electromagnetic sensors. A research group from the University of Minho (Braga, Portugal) has patented this new navigation system. The technology consists of the following components: (1) software for surgical guidance developed specifically for this work, which acts as a control station by gathering and processing information from different equipment needed for puncture for percutaneous nephrolithotomy; (2) an electromagnetic field generator placed on the opposite side of the puncture, close to the patient; (3) one 18G needle and one ureteral catheter, both with an electromagnetic sensor on the tip; (4) a monitor with a four-view 3D representation of the trajectory orientation and position of the needle and catheter; and (5) a monitor displaying the ureterorenoscopy video image.

2. Patients and methods

2.1. Study design

This was a prospective proof-of-concept phase 1 study according to the IDEAL criteria [11]. All procedures were performed by a single staff surgeon (E.L.) at the CUF Department of Urology of Braga Hospital (Braga, Portugal), which is a tertiary academic medical center. All patients gave their written informed consent to test our navigation system for renal colleting system puncture after the risks, benefits, and alternatives were discussed. Institutional review board approval was obtained before the start of the study. Patients were specifically informed that this was first clinical application of this novel system. The primary endpoint was the clinical applicability of the system for PCNL. Secondary endpoints were assessment of accuracy (in terms of time to successful puncture and number of attempts for successful puncture) and safety (in terms of puncture-related complications).

2.2. Patient selection criteria

Inclusion criteria for patient selection were: age older than 18 yr; stone in the renal pelvis; stone size $\leq$2.5 cm; and Guy's stone score of 1–2 [12].

Exclusion criteria were: obese patient (body mass index [BMI] $>$30 kg/m^2); lower calyx fully engaged with stones; bilateral stones, solitary kidney, renal insufficiency, anatomic renal anomalies, stone size $>$2.5 cm, and Guy's stone score of 3–4 [12].

2.3. Perioperative management

Patients underwent standard preoperative anesthesia testing. A computed tomography (CT) urogram with three-dimensional (3D) reconstruction was also obtained. Patients with negative urine cultures were treated with a single prophylactic dose of a broad-spectrum antibiotic.

2.4. Instrumentation

The commercially available Aurora EMT system (Northern Digital, Waterloo, Canada) was used to track the catheter and needle tip inside the ureteral and kidney calyx. This navigation system comprises the following components (Fig. 1):

(1) A planar, low-intensity, and varying electromagnetic field generator that establishes a tracking volume.
(2) Two sensor interface units (SIUs) that act as analog-to-digital converters and amplifiers of the electrical signals from the sensors to a system control unit (SCU). The SIUs decrease the possibility of electromagnetic interference in the operating room. The SCU transmits spatial data to a computer for subsequent processing and navigation using the software described below.
(3) One Chiba needle (18G/180 mm) and one ureteral catheter of 1.1 mm in diameter and 2 m in length. Both include an Aurora EMT sensor with five degrees of freedom at its tip.
(4) 3DPuncture software (EMT kidney and ureter percutaneous access software) for surgical guidance that was developed specifically for this work using C++ and VTK (The Visualization ToolKit). The software gathers and processes information from different equipment needed for PCNL puncture: images from the videoureterorenoscope, and the orientation and position of the needle and catheter EMT sensors. It allows the surgeon to choose the correct needle orientation in real time.

2.5. Technique

The accompanying video illustrates the technology and provides a step-by-step description of the procedure. Under general anesthesia, the patient is placed in the supine position to allow a combined approach with flexible ureterorenoscopy and percutaneous nephroscopy. The