Robotic Percutaneous Access to the Kidney: Comparison with Standard Manual Access

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ABSTRACT

Purpose: To evaluate the efficiency, accuracy, and safety of robotic percutaneous access to the kidney (PAKY) for percutaneous nephrolithotomy in comparison with conventional manual techniques.

Materials and Methods: We compared the intraoperative access variables (number of access attempts, time to successful access, estimated blood loss, complications) of 23 patients who underwent robotic PAKY with the remote center of motion device (PAKY-RCM) with the same data from a contemporaneous series of 23 patients who underwent conventional manual percutaneous access to the kidney. The PAKY-RCM incorporates a robotic arm and a friction transmission with axial loading system to accurately position and insert a standard 18-gauge needle percutaneously into the kidney. The blood loss during percutaneous access was estimated on a four-point scale ($1 =$ minimal to $4 =$ large). The color of effluent urine was graded on a four-point scale ($1 =$ clear to $4 =$ red).

Results: The mean target calix width was 13.5 ± 9.2 mm in the robotic group and 12.2 ± 4.5 mm in the manual group ($P = 0.57$). When comparing PAKY-RCM with standard manual techniques, the mean number of attempts was 2.2 ± 1.6 *v* 3.2 ± 2.5 ($P = 0.14$), time to access was 10.4 ± 6.5 minutes *v* 15.1 ± 8.8 minutes ($P = 0.06$), estimated blood loss score was 1.3 ± 0.49 *v* 1.7 ± 0.66 ($P = 0.14$), and color of effluent urine following access was 2.0 ± 0.90 *v* 2.1 ± 0.7 ($P = 0.82$). The PAKY-RCM was successful in obtaining access in 87% (20 of 23) of cases. The other three patients (13%) required conversion to manual techniques. There were no major intraoperative complications in either group.

Conclusions: Robotic PAKY is a feasible, safe, and efficacious method of obtaining renal access for nephrolithotomy. The number of attempts and time to access were comparable to those of standard manual percutaneous access techniques. These findings provide the groundwork for the development of a completely automated robot-assisted percutaneous renal access device.

INTRODUCTION

ADVANCES IN COMPUTER TECHNOLOGY, telecommunications, and electronics have profoundly altered the way we communicate and function, both in the workplace and at home. Automated tools, machinery, and robotics have increased both the efficiency with which we accomplish tasks and do business and overall productivity. Applications of such technological advances have also been realized in the field of med-

icine. The concept of robotics, which has been extensively used in the realm of manufacturing products, space exploration, and underseas applications, has more recently moved into the operating environment, providing assistance in simple surgical procedures. The utilization of robots in surgery was first explored in the 1980s in neurosurgery and orthopedic surgery.[1] Successes with robotic devices that could assist in precise stereotactic localization in neurosurgical procedures[2] and efficiently ream the shaft of a femur for prosthetic hip surgery[3]

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stimulated interest in other surgical fields, including urology. The earliest application of robotics to urologic surgery began in 1989 with the group at the Imperial College in London.[4,5] This group demonstrated the ability of robots to perform a precise, repetitive, and controlled task in accomplishing transurethral resection of the prostate.

Another application of robotics to urologic procedures is that of obtaining percutaneous renal access. The task of obtaining access manually requires substantial skill and can be particularly difficult when the collecting system is not dilated. Inaccurate placement of the needle can risk injuring the kidney and adjacent organs, thus compromising the planned percutaneous procedure, as well as the clinical outcome of the patient. For these reasons, coupled with the limitations in C-arm fluoroscopy in providing only a continuous two-dimensional view of the collecting system, obtaining renal access in the operating room remains a challenging task for many urologists. Many institutions have relinquished this task to the skills of interventional radiologists to perform under fluoroscopic, ultrasonographic, or CT guidance. Pioneering work by two groups has led to the development of robots that could assist with and simplify intraoperative percutaneous renal access.[6–8] Clinical applications of these devices, however, have not been investigated.

We have previously reported on our early clinical application of a simple robotic device for percutaneous access to the kidney.[9] Unlike the design of previous robots that relied on computer-based imaging and targeting system, PAKY was designed to mimic standard manual percutaneous renal access techniques and thus provide an easy-to-use, surgeon-friendly device. Caddedu and associates[9] reported a 100% success rate in both *in vitro* and clinical applications, with access being obtained in a mean of 8.2 minutes in nine patients. With the intent of ultimately developing a completely automated system for robot-assisted percutaneous renal access, this study updates our experience with PAKY using a second-generation robot designed with a remote center of motion (RCM) device. The PAKY-RCM allows a urologist to remotely align the percutaneous needle along a selected trajectory path under fluoroscopic guidance using the superimposed registration principle, while minimizing radiation exposure to the hands. The feasibility and accuracy of this robotic device was determined by comparison of intraoperative access parameters with those of a contemporaneous group of patients undergoing conventional manual renal access for percutaneous nephrolithotomy. Future applications of PAKY-RCM within the genitourinary system are also discussed.

MATERIALS AND METHODS

PAKY-RCM robot

The robot used in this study incorporates two unique devices developed at our institution. The first device is Percutaneous Access to the Kidney (PAKY), a radiolucent, sterilizable needle driver located at the terminal end of the robot arm (Fig. 1). The needle driver utilizes an axial-loaded rotational-to-translational friction transmission principle to grasp, stabilize, and advance an 18-gauge access needle into the kidney percuta-
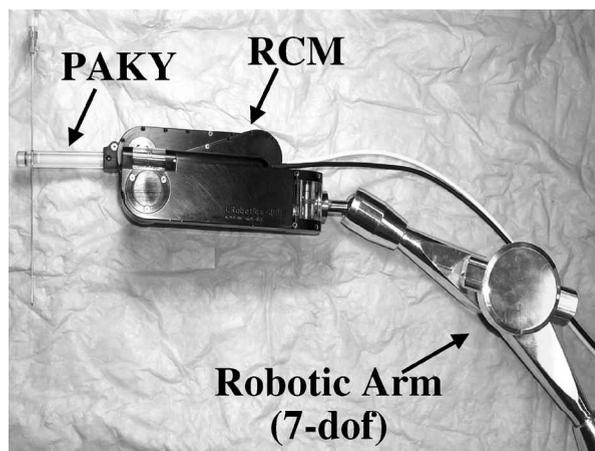
FIG. 1. Percutaneous access of the kidney device (PAKY). Remote center of motion active robotic device (RCM). Robotic arm has 7 degrees of freedom (dof).

neously. Needle insertion is driven by a variable-speed, battery-powered DC motor. The needle is secured by the needle driver along its barrel near the tip in order to minimize deflection or bowing of the unsupported length of the needle during passage through various tissue planes. The second component of the robot is the RCM device, an active robotic arm attached to PAKY that allows the tip of the needle to pivot about a fixed point on the skin (RCM fulcrum point). This allows the urologist to properly align the needle at the skin level along a selected trajectory path during fluoroscopic imaging all by remote control, thus minimizing radiation exposure to his or her hands. The PAKY-RCM tandem device is connected to a passive robotic arm designed with seven degrees of freedom (dof) and mounted on the operating table using a custom-designed siderail (Fig. 2). This allows the robot to be positioned in close proximity to the target and provides the necessary stabilization for accurate needle advancement into the collecting system. Controls for both the PAKY and RCM devices are located on a robot control box at the base of the robot.

Patients

Between April 21, 1997, and May 21, 2001, 23 patients who were scheduled for percutaneous nephrolithotomy were enrolled in the PAKY-RCM study. The indications for percutaneous nephrolithotomy included stone >2 cm, multiple caliceal stones, or failures of previous shockwave lithotripsy. The control group consisted of 23 patients who underwent manual percutaneous renal access for nephrolithotomy during the same period. The indications were identical to those of the PAKY-RCM group. Patients who had undergone prior ipsilateral attempts at percutaneous renal access or prior open or laparoscopic renal surgery were excluded from the study. Informed consent was obtained from all patients enrolled in the study.

Operative technique

After induction of general anesthesia, patients were placed in the prone position with all pressure points padded, including the head, arms, legs, and chest. The patient's legs were placed
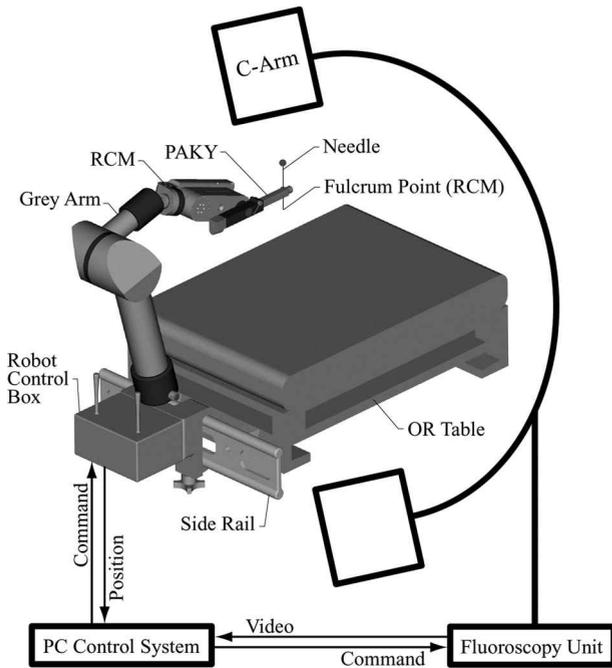
FIG. 2. PAKY-RCM set-up.

on spreader bars to allow access to the urethra. After administration of broad-spectrum antibiotics, flexible cystoscopy was performed, and a 5F open-end ureteral stent was passed into the ipsilateral ureter for retrograde injection of contrast medium into the collecting system. In both the PAKY-RCM-assisted and conventional (manual) percutaneous access techniques, a C-arm fluoroscopy unit was employed to define the proper trajectory for percutaneous access and to monitor the progress of the needle continuously during advancement. The anesthesiologist was asked to hold the patient's ventilation at a fixed point (e.g., end inspiration) to provide a stationary target during fluoroscopic imaging and advancement of the needle. The targeted calix differed among individual patients depending on the location of the stone(s) and was chosen by the urologist on the basis of the most appropriate access to accomplish percutaneous nephrolithotomy. No patients required percutaneous access above the 12th rib.

For PAKY-RCM cases, a sterile plastic drape was used to cover the robotic arm and to allow the urologist access to its controls throughout the operation. After proper securing of an 18-gauge needle in the needle driver, the robotic arm was positioned directly above the skin overlying the approximate location of the desired calix by manipulation of the passive robotic arm. A small incision was created with a scalpel in the skin just below the needle tip to facilitate advancement during attempts at percutaneous renal access. Under fluoroscopic control, the RCM device was maneuvered by the urologist using a joystick on the robot control box to align the needle along the appropriate trajectory path. The path was determined on the basis of complete alignment of the targeted calix with the needle and the fluoroscope (i.e., superimposed registration principle). A joystick control located on the control box was used to advance the needle through the posterior flank musculature and

into the kidney. The progress and trajectory of the needle were continuously monitored under fluoroscopy.

For the manual access group, percutaneous access was achieved using standard techniques. An 18-gauge needle was aligned and advanced manually into the collecting system under fluoroscopic guidance after proper alignment as described above. In all cases, once the collecting system was accessed, a 0.038-inch J-tip guidewire was passed through the access needle and into the kidney to facilitate dilation and establishment of a nephrostomy tract. Percutaneous nephrolithotomy proceeded following successful percutaneous renal access.

Clinical variables

Intraoperative variables assessed included the width of the target calix, the number of access attempts, time to successful access, estimated blood loss, and complications. The width of the target calix was calculated on the basis of the measured distance in millimeters between the fornices of the calix as noted under fluoroscopy. An access attempt was defined as each separate passage of the needle into the kidney. Time to successful access into the collecting system was calculated in minutes starting from the placement of the needle on the skin surface to the identification of urine efflux from the end of the needle or syringe aspiration of urine. Blood loss was estimated on a four-point scale (1 = minimal, 4 = large), as was the color of the effluent urine (1 = clear, 4 = red). All complications during percutaneous access attempts were recorded.

Statistical analysis

All intraoperative variables were compared for the PAKY-RCM and manual control groups using Student's t-test. A P value <0.05 was considered significant.

RESULTS

The mean target calix width was similar in the PAKY-RCM and manual control groups (13.5 ± 9.2 v 12.2 ± 4.5 mm; $P = 0.57$). The mean number of access attempts with PAKY-RCM was 2.2 ± 1.6 v 3.2 ± 2.5 manually ($P = 0.14$), the time to access was 10.4 ± 6.5 v 15.1 ± 8.8 minutes ($P = 0.06$), estimated blood loss score was 1.3 ± 0.49 v 1.7 ± 0.66 ($P = 0.14$), and color of effluent urine following access was scored as 2.0 ± 0.90 v 2.1 ± 0.7 ($P = 0.82$), respectively.

The PAKY-RCM was successful in obtaining access to the desired calix in 20 of 23 cases (87%). Three patients (13%) required conversion to manual percutaneous access techniques. The first patient was early in our series. After six failed attempts with PAKY-RCM, manual attempts were utilized, with access obtained after two attempts. In a second patient, mechanical malfunction resulted in needle slippage within the PAKY needle holder and inability to advance the needle. Subsequent manual access was successful after two attempts. The third patient had a large cystine staghorn calculus occupying the entire targeted calix. After four attempts with the PAKY-RCM device, manual techniques were used to obtain access but required multiple attempts lasting more than 30 minutes. In the control group, manual percutaneous renal access was successful in all 23 patients (100%).

Percutaneous nephrolithotomy was successful in all cases. No patients required a second percutaneous tract to accomplish nephrolithotomy. There were no intraoperative or perioperative complications in either the PAKY-RCM or the control group.

DISCUSSION

Unlike the stationary targets in neurosurgical and orthopedics procedures, robot-assisted percutaneous renal access faces the added task of targeting the more mobile kidney within the retroperitoneum, compounded by the inherent movement of the kidney during respiratory variation and various tissue interfaces that the needle must traverse before reaching the collecting system. With endeavors to design and develop a completely automated, remote-control robot for percutaneous renal access, several obstacles were quickly realized, including: (1) the design of a surgeon-friendly operator–device interface; (2) the design of an efficient, accurate, and safe device–patient interface; (3) the integration of image-guided systems and computer software to track the position of the target calix and adjust for changes in its position during respiratory movement and tissue deformation during needle advancement; (4) the development of a sophisticated feedback mechanism to confirm successful percutaneous access into the collecting system; and (5) the critical assessment of cost effectiveness as newer-generation and more complex robots are developed. To date, only the first task has been fully addressed, although studies addressing many of the others are currently under way.

The initial PAKY robot was designed to provide a simple device to aid in percutaneous renal access that was surgeon friendly. By adhering to the same principles and mimicking conventional manual access techniques, this robot was constructed to provide a transparent operator–device interface. Instead of relying on a complex computer-based imaging and targeting system, PAKY utilized the radiologic needle alignment principle of superimposed registration to target a selected calix. The ease in use of this simple operator–device interface was reflected in the 100% success rate in both *in vitro* and early clinical studies reported by Caddedu and colleagues in 1998.[9]

In the current study, we attempted to address the second obstacle in the development of a completely automated percutaneous renal access system; i.e., the design of an efficient, efficacious, and safe device–patient interface. Earlier studies had demonstrated that the first-generation PAKY robot facilitated access to the targeted calix on the first attempt with no added procedural complications.[9] We sought to compare intraoperative parameters of a second-generation robot with an added remote center of motion feature (PAKY-RCM) with those of a contemporaneous group of patients undergoing conventional manual percutaneous renal access. The RCM device was added to further automate robot-assisted percutaneous access by remote joystick control with the additional benefit of reducing radiation exposure to the urologist's hands. The mean size of the targeted calix was similar in the PAKY-RCM and control group. As such, no bias was incurred toward selecting patients with more dilated collecting systems in either group. The results from this study indicated that PAKY-RCM is an efficient, accurate, and safe device for percutaneous renal access. The number of attempts required to obtain access with PAKY-RCM was comparable and

the time to successful access approached statistical significance ($P = 0.06$) compared with conventional manual techniques. There were, however, three cases in which PAKY-RCM failed to obtain access to the collecting system, and conversion to manual techniques was required. One case was early in our experience and likely represented a learning curve associated with implementation of this new robotic device. In the second case, mechanical failure led to inability to advance the needle with the PAKY-RCM needle driver. Refinements in the needle holder now allow the urologist to adjust the friction control of the needle driver and thus adjust the maximum deliverable force during advancement of the needle. In the third case, successful access proved equally difficult using manual techniques because of a large, occlusive cystine stone.

In all cases, percutaneous nephrolithotomy was accomplished by the access achieved by PAKY-RCM without the need for a secondary access and with no added procedure-related morbidity. Estimated blood loss with PAKY-RCM was negligible and comparable to that in the control group. Various features of the PAKY-RCM, including a secure mounted siderail, remote controlled variable-speed drive motor for needle insertion, and the adjustable friction-controlled design of the needle driver to deliver a limited force during needle insertion are added safety features of this robot. The time that is required for assembly of the PAKY-RCM is negligible as this device is mounted and covered with a sterile plastic drape at the same time the patient is being positioned.

Further studies are under way at our institution investigating the integration of image-guided systems to track needle progress and the development of a sophisticated feedback mechanism to confirm successful access to the collecting system. Eight additional PAKY-RCM procedures have been performed with the assistance of cross-sectional CT guidance, including percutaneous biopsy of the kidney (six cases), percutaneous renal access for nephrostomy tube placement (one case), and percutaneous access to a neobladder (one case) for subsequent stone extraction. The CT fluoroscopy provides the additional advantage of real-time tracking of needle advancement, allowing the physician to make fine adjustments in needle trajectory while continuously monitoring the location of the needle with respect to adjacent organs. Undoubtedly, the use of CT guidance with PAKY-RCM will improve accuracy and further reduce the need for conversion to manual techniques (13% in the current series). By linking computer control to the PAKY-RCM device, percutaneous procedures can be accomplished remotely, reducing radiation exposure to the urologist. Taken together, image guidance using CT fluoroscopy has expanded the possibilities of PAKY-RCM within the genitourinary system. Studies investigating the efficacy of CT-guided PAKY-RCM for radiofrequency ablation of small renal masses is currently under way at our institution.

In keeping with a completely automated system, Smart Needle™ technology holds promise as a way of confirming access into the collecting system.[10] This device detects changes in bioimpedance as a needle is advanced through various tissue interfaces. This device may allow detection of entry into the collecting system during CT-guided PAKY-RCM without the need to confirm access by attempting to aspirate urine using a syringe.

Lastly, although the cost effectiveness of such "high-tech"

devices remains to be critically addressed, the promise of increased efficiency and accuracy with newer-generation robotic devices remains encouraging, thus potentially benefiting patient and surgeon alike. The application of modern-day technological advances in surgical procedures is limitless. The PAKY-RCM robotic device, although not 100% successful in obtaining percutaneous renal access in this study, demonstrates promise in its clinical application in humans. The problem that remains to be addressed is the development of a computer-based tracking system to automatically adjust and account for changes in the position of the target calix caused by tissue deformation during needle advancement as well as by respiratory movement. As the development of completely automated percutaneous access techniques within the genitourinary system continues to evolve, it behooves urologists to embrace this technology and remain active participants in its application to the care of the urologic patient.

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