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Training ultrasound-guided percutaneous nephrostomy technique with porcine model

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Purpose: There is increasing interest in the use of ultrasound for endoscopic and percutaneous procedures. Access can be achieved without radiation exposure under ultrasound guidance. Our aim was to develop a porcine-based training model for ultrasound-guided percutaneous renal access that could also be personalized to a specific patient.

Materials and Methods: The Institutional Animal Care and Use Committee of Severance Hospital approved the study protocol. An anesthetized pig was placed in the dorsal lithotomy position. For the nephrostomy puncture, a Chiba biopsy needle with an echo tip was used under ultrasound guidance. Eight residents and three consultants in urology participated. Puncture time was defined as the nephrostomy time to confirm the flow of irrigation via the needle. After training, satisfaction survey results for clinical usability and procedural difficulty were evaluated.

Results: The 5-point Likert scale satisfaction survey for clinical usability and procedural difficulty found mean results of 4.64 and 4.09 points, respectively. There were no differences between residents and consultants for either variable. For all participants combined, there was a significant difference for nephrostomy time between the first and second trials (278.8±70.6 s vs. 244.5±47.0 s; p=0.007). The between-trial difference was greater for residents (291.5±71.2 s vs. 259.1±41.9 s; p=0.039). The difference for the consultant was not significant (245.0±69.4 s vs. 205.7±42.5 s; p=0.250).

Conclusions: We developed a porcine-based ultrasound-guided nephrostomy puncture training model. Satisfaction survey results indicated high clinical usability and procedural difficulty. For nephrostomy time, the model was more effective for urology residents than for consultants.

Keywords: Nephrolithotomy, percutaneous; Radiation; Teaching; Ultrasonography

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INTRODUCTION

various diseases, including those associated with both urologic and non-urologic conditions. Treatment of a urinary tract infection and protection of renal function is typically why

Obstruction of the upper urinary tract can be caused by

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an upper urinary tract obstruction requires immediate management. Urologically, urolithiasis is the most common cause of upper urinary tract obstruction. Urolithiasis is one of the three most significant and common urological diseases; it has a high incidence and a high prevalence [1,2] More than 50% of patients with urolithiasis experience at least one recurrence. These episodes worsen the patient's quality of life and can induce a life-threatening situation that can develop into a septic episode if accompanied by infection and an infected obstruction [3]. Complete obstruction of the ureter can result in reduced kidney function and life-threatening conditions.

The European Association of Urology (EAU) Guidelines on Urolithiasis recommend active management in patients with urolithiasis after infection or sepsis has resolved [4]. Based on the patient's condition, percutaneous nephrostomy (PCN) or ureteral stenting can be performed for immediate decompression of a urinary tract obstruction. The urologist is trained and performs ureteral stenting and PCN as part of the specialty of urology [5]. Because EAU Guidelines on Urolithiasis 2022 also emphasize reduction of radiation exposure [6], the PCN technique using ultrasound is more likely to be used. Radiation exposure is as important as treatment of stones and relates to the working conditions of surgeons and hospital workers [7,8]. However, recently, PCN is more often performed by interventional radiologists rather than urologists, and urology residents in Korea do not have adequate education on PCN insertion using ultrasound. Therefore, we developed and evaluated a porcine model for the purpose of resident training; we report our outcomes here. Our aim was to develop a porcine-based training model for ultrasoundguided percutaneous renal access that could be personalized to a specific patient.

MATERIALS AND METHODS

1. Population and participants

A 6-month-old female pig (weight, 47.1 kg) that was acclimated for 7 days in the animal facility (Department of Laboratory Animal Medicine, Medical Research Center, Yonsei University Health System, Seoul, Korea) was used for this study. The Institutional Animal Care and Use Committee of Yonsei University Health System (Seoul, Korea) approved the study protocol (Approval No. 2021-0317). Eight residents and three consultants in urology participated in the training model evaluation. The eight residents consisted of four lower graders (first and second years) and four upper graders (third and fourth years). The three consultants consisted of a fellow and two assistant professors specializing in urolithiasis and endourology, who had performed percutaneous puncture and percutaneous nephrolithotomy themselves, but had less than 100 cases of experiences.

2. Porcine ultrasound nephrostomy puncture model

Animal sedation was achieved using tiletamine 5 mg/kg and xylazine 2 mg/kg. Mechanical ventilation was applied to maintain respiration during the study, while the animal received anesthesia with 2% isoflurane and underwent muscle relaxation using 4 mg vecuronium bromide (0.10 mg/kg). The anesthetized animal was placed in the dorsal lithotomy position. Before training, cystoscopic insertion of a guidewire was performed under fluoroscopic guidance (OEC 9900 Elite, GE Healthcare). A hydrophilic guidewire (Roadrunner[®] PC Hydrophilic Wire Guide, Cook Medical) was inserted into the ureter and renal pelvis and the kinked ureter was straightened using a double-lumen ureteral catheter (Dual Lumen, Boston Scientific) and a super-stiff guidewire (Amplatz Super StiffTM, Boston Scientific), due to the characteristics of the pig ureter. Using a super-stiff guidewire, a ureteral access sheath (NavigatorTM HD, 11/13 Fr×36 cm, Boston Scientific) was inserted into the ureter. The super-stiff guidewire was then removed, but the obturator of the access sheath was not. Through the working lumen of the obturator of the access sheath, retrograde irrigation to the intrarenal space with 100 cmH₂O was performed to dilate the renal collecting system using an intravenous administration set that included 1 L normal saline (0.9% Sodium Chloride Inj, JW Pharmaceutical).

3. Nephrostomy procedures in the porcine model

After preparation of the porcine model, ultrasound examinations were performed using an abdominal curved array probe (iU22, Philips Healthcare). Ultrasound was used to confirm whether the required hydronephrosis was achieved via retrograde irrigation. A Chiba biopsy needle with an echo tip (18 gauge and 20 cm, Cook Medical), which is designed to be hyperechogenic under ultrasound vision, was used for the ultrasound-guided nephrostomy puncture. The collecting system was punctured parallel to the wide side of the transducer without attachable biopsy needle guides (Fig. 1). The ultrasound probe was fine-tuned to ensure that the needle tip was continuously observed in the ultrasound field of view throughout the whole procedure, and ultrasound confirmation was obtained that the needle tip was located in the intended renal calyx.

The punctures were performed in two rounds on the same day, first by three consultants and then by eight residents. After all of the participants performed the punctures,

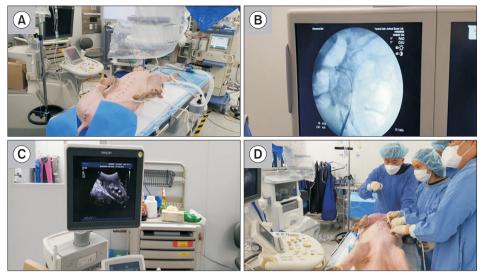


Fig. 1. Ultrasound-guided percutaneous nephrostomy. (A) Anesthetized pig placed in the dorsal lithotomy position. (B) Ureteral access sheath inserted to induce hydronephrosis. (C) Required hydronephrosis achieved. (D) Needle puncture performed under ultrasound guidance.

the second round was done in the same order as the first round.

4. Evaluation and statistical analyses

Eight residents and three consultants in urology participated the training model evaluation. To see the differences based on previous training experience, we performed a subgroup analysis between lower and higher grades within the resident group. Puncture time was defined as the nephrostomy time required to confirm the flow of irrigation using a Chiba needle. After training, satisfaction surveys for clinical usability and procedural difficulty were completed. The survey was administered shortly after the second round, and respondents were asked to indicate whether they were consultants, residents, and if so, what year they were in residency, but not their real names. Question 1 was, "This model can help you with the real clinical procedure." Question 2 was, "The difficulty to perform the nephrostomy puncture in this model is appropriate." The two questions were answered based on a 5-point Likert scale score: 1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, 5=strongly agree [9,10]. All analyses were performed using R version 4.2.1 (R Foundation for Statistical Computing; http:// www.r-project.org).

RESULTS

Eight urology residents and three urology consultants participated in the training model. All participants successfully performed the nephrostomy puncture under ultrasound guidance. In the anesthetized animal, there were no complications and or events including severe hematoma or changes in vital signs during the procedures.

1. Satisfaction survey

The mean satisfaction survey score for clinical usability was 4.64, based on the 5-point Likert scale. The 5-point Likert scale scores for the satisfaction survey for clinical usability indicated that three urology residents scored clinical usability as 4 points and five residents scored it as 5 points. One urology consultant gave clinical usability a score of 4 points; two gave it a score of 5 points. There was no difference between the residents and consultants (p=0.903). The satisfaction survey for procedural difficulty found that the mean overall score was 4.09. One resident assigned procedural difficulty a Likert score of 3 points, four residents gave procedural difficulty a score of 4 points, and three residents gave it a score of 5 points. One consultant gave procedural difficulty a Likert score of 3 points, and two assigned it a score of 4 points. The difference between residents and consultants was not significant (Table 1). In the subgroup analysis, the difference between lower and higher grades was not significant (Table 2).

2. Nephrostomy time

The nephrostomy times for each participant were measured and recorded separately (Table 3). The difference in nephrostomy time between the first and second trials was significant for all participants (278.8 \pm 70.6 s vs. 244.5 \pm 47.0 s, respectively; p=0.007). The difference between the two trials was significant for the resident group (291.5 \pm 71.2 s vs. 259.1 \pm 41.9 s, respectively; p=0.039), but not for the consultant group (245.0 \pm 69.4 s vs. 205.7 \pm 42.5 s, respectively; p=0.250; Table 4). In the subgroup analysis, the average nephrostomy times between two trials were relatively lower in higher grade residents, but not statistically significant (1st trial 318.8 \pm 84.9 s vs. 264.2 \pm 51.5 s, 2nd trial 279.2 \pm 39.6 s vs. 239.0 \pm 38.1 s; Table 5).

Table 1. Training satisfaction survey results for clinical usability and procedural difficulty

	3 points	4 points	5 points	p-value ^a		
Question: This model can help you with the real clinical procedure ^b						
Residents	0	3 (75.0)	5 (71.4)	0.903		
Consultants	0	1 (25.0)	2 (28.6)			
Question: The difficulty to perform the nephrostomy puncture in this model is appropriate ^b						
Residents	1 (50.0)	4 (66.7)	3 (100.0)	0.215		
Consultants	1 (50.0)	2 (33.3)	0 (0.0)			

Values are presented as number (%).

^a:Kruskal–Wallis rank sum test.

^b:1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, 5=strongly agree.

Table 2. Training satisfaction survey results for clinical usability and procedural difficulty

	3 points	4 points	5 points	p-value ^a		
Question: This model can help you with the real clinical procedure ^b						
Lower grade residents	0	1 (33.3)	3 (60.0)	>0.999		
Higher grade residents	0	2 (66.7)	2 (40.0)			
Question: The difficulty to perform	m the nephrostomy punctu	re in this model is appropria	te ^b			
Lower grade residents	0 (0.0)	1 (25.0)	3 (100.0)	0.082		
Higher grade residents	1 (100.0)	3 (75.0)	0 (0.0)			

Values are presented as number (%).

^a:Kruskal–Wallis rank sum test.

^b:1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, 5=strongly agree.

Table 3. Nephrostomy times for each participants, between two trials

	R1_1	R1_2	R2_1	R2_2	R3_1	R3_2	R4_1	R4_2	C1	C2	C3
1st trial	325	425	307	218	267	336	230	224	201	325	209
2nd trial	305	312	275	225	217	289	247	203	189	254	174
Difference	20	113	32	-7	50	47	-17	21	12	71	35

The unit of each variable is second.

Rn, nth year of residency; C, consultant.

Table 4. Nephrostomy times for residents and consultants, between two trials

	Total	Residents	Consultants	p-value ^a
1st trial	278.8±70.6	291.5±71.2	245.0±69.4	0.184
2nd trial	244.5±47.0	259.1±41.9	205.7±42.5	0.103
p-value ^b	0.007	0.039	0.250	

The unit of each variable is second.

^a:Kruskal–Wallis rank sum test.

^b:Wilcoxon signed rank exact test.

DISCUSSION

In this study, we evaluated a porcine model-based training protocol aimed at enhancing the proficiency of residents in urology in the PCN procedure under ultrasound guidance. By employing a porcine model, we successfully established a controlled and realistic setting that used identical equipment and closely replicated procedural conditions encountered
 Table 5. Nephrostomy times for lower grade and higher-grade residents, between two trials

	Total	Lower grade	Higher grade	p-value ^a
1st trial	291.5±71.2	318.8±84.9	264.2±51.5	0.564
2nd trial	259.1±41.9	279.2±39.6	239.0±38.1	0.149
p-value ^b	0.039	0.250	0.250	

The unit of each variable is second.

^a:Kruskal–Wallis rank sum test.

^b:Wilcoxon signed rank exact test.

during actual interventions on patients. Furthermore, posttraining surveys revealed statistically significant results.

Establishment and widespread adoption of endourologic techniques for treatment of urolithiasis has increased concern about radiation exposure, and has led to an increasing number of studies on this topic. Although the increased risk of malignancy from radiation exposure is an area of great interest, no study has specifically assessed the potential risks

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of radiation-induced malignancies in urologists [11,12]. It is well-known that 50 mSv is the maximum annual occupational exposure suggested by The International Commission on Radiological Protection [13]. Nevertheless, because there is no definite threshold dose for stochastic effects, even low levels of radiation exposure are potentially hazardous and capable of promoting cancer development [14]. Therefore, EAU guidelines on urolithiasis underscore the significance of minimizing radiation exposure by emphasizing the importance of implementing protective measures and adhering to the "as low as reasonably achievable" principle. However, several studies found that a significant number of urology residents do not receive adequate radiation safety training [15,16]. They also found that despite the recommendation to use radiation protection instruments, including lead aprons and thyroid shields, in-practice compliance was not high due to the lack of standardized education programs [15] and musculoskeletal problems (e.g., pain) resulting from the weight of the aprons [17].

Ultrasound is recommended as a useful alternative to reduce radiation exposure [18]. A recent meta-analysis demonstrated that fluoroscopy-free endourologic procedures exhibit stone-free complication rates comparable to those performed using fluoroscopic guidance [19]. Ultrasound-guided percutaneous nephrolithotomy also offers several advantages beyond radiation reduction. A meta-analysis performed by Liu et al. [20] revealed shorter puncture times, higher rates of first-puncture success, decreased blood loss, and fewer postoperative complications than fluoroscopy-guided procedures. Ultrasound also helps identify adjacent structures, such as the small and large intestines, thereby reducing the risk of inadvertent injury to neighboring organs during percutaneous puncture. Especially in pediatric patients, liver and spleen volumes have relatively large ratios, compared with kidney volumes [21,22]. Therefore, for pediatric patients, ultrasound-guided percutaneous nephrolithotomy has advantages for prevention of radiation exposure and for providing real-time clear visibility of vessels and tissues adjacent to kidneys during the procedure [23]. However, previous studies comparing ultrasound-guided and fluoroscopic procedures assume that an experienced surgeon performs the procedure. Therefore, the efficacy of this method depends on the surgeon's level of expertise and requires adequate training [24]. Song et al.'s [25] study found that with increasing experience, both ultrasound screening time and operation duration decreased. The authors concluded that a minimum case number of 60 procedures is necessary to attain the competence to achieve a high stone-free rate and avoid major complications. These findings highlight the significance of

accumulating training and experience to successfully implement ultrasound-guided endourological procedures.

In Korea, PCN procedures are often performed by interventional radiologists, although it varies depending on the medical facility. Consequently, residents in urology may not be familiar with ultrasound-guided kidney access and encounter difficulty when performing endourologic procedures. The recent expansion of stone surgeries, such as endoscopic combined intrarenal surgery has also increased the need to become familiar with PCN procedures [26]. To address these issues and develop an effective training model, we propose the use of a porcine model. Previously, we conducted a study using a robot-assisted retrograde intrarenal surgery system in pigs; we successfully performed PCN and introduced a renal calyx stone [27,28]. Based on this experience, we devised a training method employing swine. The anatomy of pigs is similar to that of humans, especially the urinary system. We were thus able to use this relationship to recreate conditions similar to that in humans. However, compared with the straight ureter of humans, the kinking present in some pig ureters makes it a little difficult to insert the access sheath to induce hydronephrosis.

This study had some limitations. First, the survey sample size was relatively small (i.e., eight residents and three consultants). As a result, while we found statistically significant results, caution should be used when generalizing the findings to a broader population. The fact that the study was performed over a single day within a single institution limits the generalizability of the results, to some extent. Therefore, future studies with larger sample sizes, performed across multiple institutions with longer durations, would provide a more comprehensive assessment of training protocol effectiveness. Second, this model is associated with considerable costs and prerequisites. Animal experimentation requires use of specifically-bred pigs. Obtaining approval from the Institutional Animal Care and Use Committee is essential to ensure compliance with ethical standards. Furthermore, given that porcine subjects do not naturally possess stones or hydronephrosis, additional efforts are required to simulate a realistic surgical scenario. Insertion of a stent into the pig's ureter via cystoscopy, followed by continuous infusion of fluid into the renal pelvis to effectively replicate surgical conditions is required.

CONCLUSIONS

We developed a porcine model used to train an ultrasound-guided nephrostomy puncture procedure. Satisfaction survey results indicated very high satisfaction with clinical

usability and procedural difficulty. For nephrostomy time, the training model was more effective for urology residents than for urology consultants.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Jae Yong Jeong and Joo Yong Lee. Data acquisition: Dae Young Jun, Young Joon Moon, Hae Do Jung, and Joo Yong Lee. Statistical analysis: Dae Young Jun and Dong Hyuk Kang. Data analysis and interpretation: Hae Do Jung and Joo Yong Lee. Drafting of the manuscript: Jae Yong Jeong and Joo Yong Lee. Critical revision of the manuscript: Seung Hyun Jeon and Joo Yong Lee. Obtaining funding: Joo Yong Lee. Administrative, technical, or material support: all authors. Supervision: Seung Hyun Jeon and Joo Yong Lee. Approval of the final manuscript: all authors.

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