

VALIDATION OF AFFORDABLE AND APPLICABLE KIDNEY PHANTOM MODEL (AARM) FOR ULTRASOUND-GUIDED PERCUTANEOUS NEPHROSTOMY SIMULATION

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ABSTRACT

Objective: Percutaneous nephrostomy (PN) is a medical skill that requires the repetition of hand and eye coordination exercises. The limited opportunity to achieve learning curve at mastering it, increases the morbidity risk to the patient. We therefore developed an Affordable and Applicable Renal Model (AARM) phantom to simulate percutaneous nephrostomy with ultrasound (USG) guiding. Our goal is to present the development of an affordable cost kidney phantom model and evaluate validity (face, content, and construct) with its reliability. **Material & Methods:** The AARM phantom made from mixture of gelatin, glycerin and sorbitol, then molded with latex gloves comprising the parenchymal portion and the renal pelvicalyceal system connected to a 10Fr nasogastric tube and a 20 cc syringe. Phantom then assessed by urology residents at Hasan Sadikin Hospital Bandung. Senior resident (n=20) who are adept at performing independent PN then compared with junior resident (n=15), and then we analysis both group skills by measure PN initial puncture time and its failure to establish its validity and reliability. **Results:** This phantom cost production was 30USD (400.000 IDR) and after tested by urology residents, it had simulated the series of PN action steps which described the face and content validation test, with correlation results (Pearson, $p < 0.05$); Very strong (53.8%), strong (30.8%), and medium (15.4%). The reliability test with cronbach alpha value was 0.934 (reliable if cronbach alpha > 0.60). The average initial puncture time measure and PN failure result of junior and senior residents are respectively 37.03 ± 9.5 vs 10.90 ± 0.65 seconds and 4.93 ± 1.33 vs 0.75 ± 0.63 times. When both skills performance was analyzed, the senior resident showed significantly ($p < 0.01$) faster and fewer errors. **Conclusion:** This AARM phantom had successfully represent the whole sequence actions key step of PN skills and this study has been established its validity (face, content and construct). In addition, this phantom material not only made from affordable cost but also applicable and could be used repeatedly (recycled). We propose the use of this AARM phantom simulator as an initial steps practices to introduce percutaneous nephrostomy skills to residents before they went to the operating room.

Keywords: Percutaneous nephrostomy (PN) with ultrasound guide, affordable and applicable phantom (AARM), validation and reliability.

ABSTRAK

Tujuan: Nefrostomi perkutan adalah tindakan medis yang memerlukan latihan koordinasi mata dan tangan yang berulang. Terbatasnya kesempatan mencapai kurva belajar (learning curve) meningkatkan risiko morbiditas terhadap pasien. Untuk itu kami mengembangkan phantom ginjal AARM untuk simulasi tindakan nefrostomi perkutan dengan panduan ultrasonografi (USG). Tujuan kami adalah mempresentasikan pembuatan alat peraga ginjal yang aplikatif dengan biaya terjangkau serta menguji validitas (muka, isi dan konstruksi) dan realibilitasnya. **Bahan & Cara:** Alat Peraga AARM dibuat dari bahan campuran gelatin, gliserin dan sorbitol (rasio 3:2:2), yang kemudian dicetak dengan sarung tangan latex yang terdiri dari bagian parenkim dan sistem pelvokalises ginjal yang dihubungkan dengan selang nasogastrik 10Fr dan spuit 20cc. Alat peraga kemudian dilakukan pengujian oleh residen (PPDS) Urologi RS Hasan Sadikin Bandung. Residen senior (n=20) yang sudah mahir melakukan nefrostomi mandiri dibandingkan dengan residen junior (n=15), dan kami analisis tingkat keterampilan kedua kelompok tersebut dengan cara dengan mengukur rerata waktu tusukan nefrostomi (puncture time) dan kegagalannya (errors) untuk menegaskan validitas dan realibilitasnya. **Hasil:** Biaya produksi alat peraga ini adalah 30USD (Rp 400.000,-), dan setelah diujikan kepada para residen urologi, alat ini berhasil mensimulasikan rangkaian tindakan nefrostomi perkutan yang digambarkan oleh hasil uji validasi dengan korelasi pearson ($p < 0.05$); sangat kuat (53.8%), kuat (30.8%), dan sedang (15.4%) serta uji realibilitas dengan nilai cronbach alpha 0.934 (reliabel jika cronbach alpha > 0.60). Hasil rerata pengukuran waktu tusukan inisial dan kegagalan nefrostomi pada residen PPDS junior dan senior berturut-turut adalah 37.03 ± 9.5 vs 10.90 ± 0.65 detik dan 4.93 ± 1.33 vs 0.75 ± 0.63 kali. Ketika perbandingan tingkat keterampilan kedua kelompok tersebut dianalisis, residen senior menunjukkan

*kecepatan tusukan yang lebih baik dan tingkat kegagalan yang lebih rendah secara signifikan ($p < 0.01$). **Simpulan:** Alat peraga AARM ini telah mewakili keseluruhan langkah penting pada rangkaian tindakan nefrostomi perkutan dan penelitian ini telah menegaskan validitasnya (muka, isi dan konstruksi). Sebagai tambahan, material alat peraga ini selain dapat dibuat dengan biaya terjangkau namun juga mudah diaplikasikan dan dapat digunakan berulang kali (didaur ulang). Kami mengusulkan penggunaan alat peraga AARM ini sebagai media praktek pengenalan bagi pelatihan tindakan nefrostomi perkutan PPDS sebelum mereka bekerja di kamar operasi.*

Kata Kunci: Nefrostomi perkutan dengan panduan ultrasonografi, alat peraga dengan biaya terjangkau dan mudah diterapkan (AARM), validitas dan realibilitas.

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INTRODUCTION

Percutaneous nephrostomy (PN) is a urological procedure that aims to create a urinary diversion, usually in a urinary tract obstruction cases.¹ Although the procedure is safe, it has various risks of complications and deaths (5% and 0.04%).¹ Medical is not all about knowledge, but also required special psychomotor skills and hand-eye coordination that should be obtained from numbers of exercises and repetitions. However, changes in work patterns in educational centers led to a lack of practical experiences to learn various competencies of medical procedures.²⁻⁴

Medical phantoms offer a practice-based training model that is safe and does not pose a risk to patient safety in educational purposes, so the learning process becomes more conducive and safe because of reduced stress factors caused by lack of confidence when dealing with patients.³⁻⁷ In addition, the phantoms can produce the same standard in the students learning experience.⁸⁻¹⁰ This practice-based learning methods can improve the competence of surgeons, in knowledge, techniques, and tools that used so that it can reduce the risk of action to the patients.^{2,11-13} The used of minimally invasive procedures in various medical fields are growing. The availability of medical simulation tools for the procedure becomes an invaluable solution in the process of education and transfer of knowledge in learning a medical procedure.^{3,14-16}

Some literatures have elaborated various descriptions of medical phantoms.^{2-3,17-19} Yet some of them have some shortfalls in hygiene, malfunction, anatomical mismatches, difficult manufacturing, hard to obtained, or expensive costs. Also, a medical phantoms should be well tested before used in a teaching curriculum by undergoing a standardization

process, one of which is validation with reliability and validity.²³ Our goal is to present an affordable and economic production of a medical phantoms for simulating ultrasound-guided PN while also testing its validity and reliability.^{12,22-24}

OBJECTIVE

Percutaneous nephrostomy (PN) is a medical skill that requires the repetition of hand and eye coordination exercises. The limited opportunity to achieve learning curve at mastering it, increases the morbidity risk to the patient. We therefore developed an Affordable and Applicable Renal Model (AARM) phantom to simulate percutaneous nephrostomy with ultrasound (USG) guiding. Our goal is to present the development of an affordable cost kidney phantom model and evaluate validity (face, content, and construct) with its reliability.

MATERIAL & METHODS

The model of AARM kidney phantoms consists of 2 main parts, part A; pelvicalyceal system which contains fluid, and part B; parenchymal layer. Pelvicalyceal system of kidney phantom is made of latex gloves, the tip of fingers are tied to simulate the calyx and pyelum of the kidney pelvicalyceal system (Figure 1). The glove is connected to a 10 Fr silicone nasogastric tube, which will simulate the hydronephrosis fluid (we use 100 cc of aquadest solution for hydronephrosis simulation puncture test).

In order to have an acoustic appearance under ultrasonographic imaging, the renal parenchymal material is made from gelatin solution mixed with fiber powder that will provide relatively hyperechoic appearance. The mixture that fills the

parenchymal layer is made from a gelatin powder dissolved in water and then mixed with sorbitol and glycerin with a ratio of 3:2:2 (the ratio is 4:2:2 for the layer that covering the kidney and 4:2:4 for the outer layer). The solution then heated until the mixture is perfectly mixed and flattened.

We duplicate the shape and size of an adult kidney (10-12 cm long, 5-7.5 cm wide and 2.5-3 cm thick).²⁵ The 12th costal bone rib is added on the

outside (figure 2), which can be made from a piece of plastic fiber and the outer surface is then covered with a thin layer of latex gloves to give a different consistency and tactile feedback when the needle penetrates the surface of the phantom. The purpose of this layer is to simulate the real skin layers (subcutaneous and fascia layers) as possible on ultrasound imaging. The box inserted into a modified torso mannequin (Figure 3).

Validity testing in this study was divided into; face, contents, and construction validity. The face and content validation of the teaching phantom based on assessment and experience of those who are considered experts in this field. In this study, even though the enforcement of the face and content validity is subjective, the questionnaires had been standardized and tested for reliability with cronbach alpha instruments. The question for face validity is to assess whether the teaching objectives have designed this teaching phantom. While the list of questions to enforce content validity is based on detailed observations from experts in assessing each component of a specific teaching phantom. Answers from each question were provided in the form of a Likert scale (consist of 5 points; 1 to 5).²

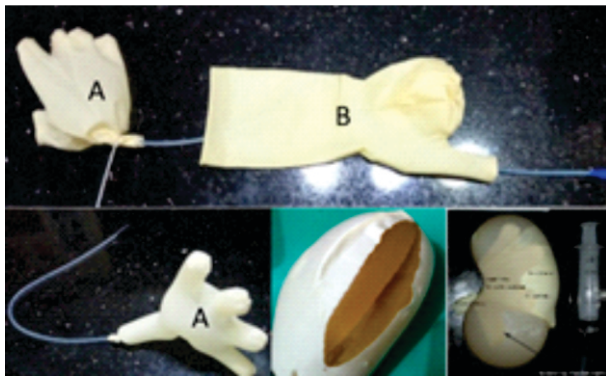


Figure 1. Pelvicalyceal system: A. Made from latex gloves. Renal parenchymal. B. Covering the pelvicalyceal system.

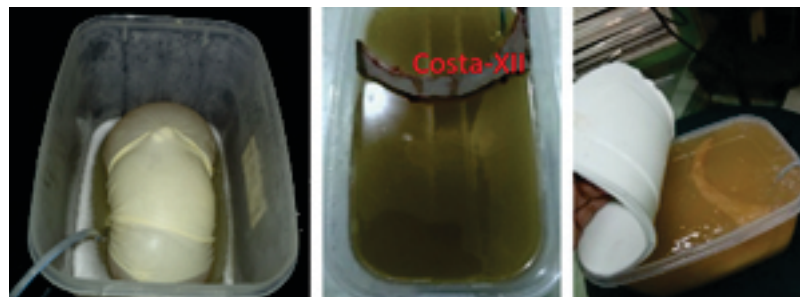


Figure 2. Gelatin filling on boxes contains kidney models covered in 12th costae which serves as a nephrostomy landmark.



Figure 3. Ultrasound-guided nephrostomy puncture, pelvicalyceal fluid seen after needles are removed until guidewire insertion.

Comparative observational was used to test the construct validity of the phantom. Construction validity was evaluated by its capability to differ experts and novices skills.²³ In this study, the subject's skill was judged by their PN procedure approach using AARM phantom by the duration from the initial puncture, and number of errors made along with the procedure.

The subject consisted of urology residences of Hasan Sadikin Hospital (Bandung-Indonesia), that were divided to senior/experts (n=20) and junior/novices (n=15) based on their skills to do PN (p<0.001). Data collection was divided into 2 parts. First, senior residences (experts) filled out the questionnaires, and then skill assessment was measured based on the duration of the puncture time (seconds), and we count the failures (errors) in performing the nephrostomy procedure. All of the subjects were given the introduction and training session. Each subject was asked to perform a nephrostomy procedure (we use Chiba needle with 22G and 20 cm long, Bioteq nephrostomy set for the puncture trial).

The mean time of the successful puncture into the pelvicalyceal system duration was recorded (3 trials). The nephrostomy is considered successful when the needle entered the pelvicalyceal system (visualized with an ultrasound), and the fluid was obtained. The number of action failures was also calculated, it's when the needle was not visualized on ultrasound, pelvicalyceal fluid did not obtain, or there was an error or missed the action in the series of PN procedures. Test results from the senior and junior groups were compared to see the differences between the two.

RESULTS

Our phantom model dimension were 10x6x3 cm and weighted about 150 grams. The pelvicalyceal system inside the kidney model stuffed with gelatin solution was consisted of pyelum and 4 calyces that can hold up to 100 cc water.



Figure 4. Kidney phantoms on torso mannequin.

The parenchymal and pelvicalyceal system of AARM phantom on ultrasound image were shown the differences of the particle density and consistency (Figure 5). The mixing technique of the solution is important to prevent bubbles on the surface of the gelatin.



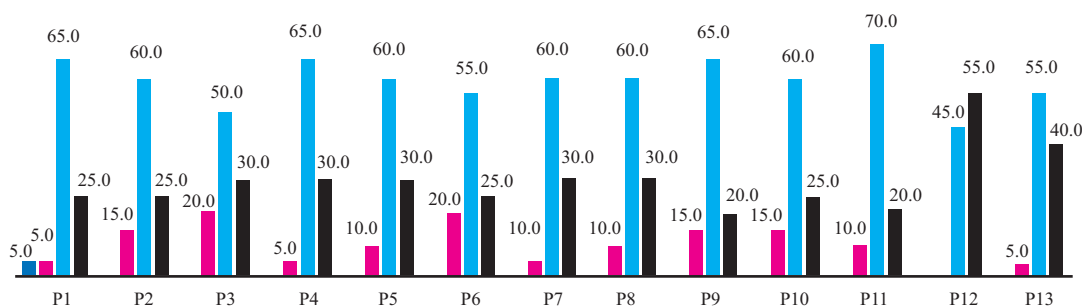
Figure 5. Normal pelvicalyceal system (right), widened pelvicalyceal system on the sagittal cut (middle), and transverse cut (left).

Based on our experience, the time needed to create this phantom was approximately 5 hours with total cost of 11 USD (150.000 IDR) per unit or 30 USD (400.000 IDR) with the torso mannequin. The phantom could be used repeatedly up to 30 times, and the gelatin dough can be reproduced. Gelatin solution can be contaminated by bacterial colonization, but with the used of preservative mixtures such as formalin, this model can last for more than 4 weeks at room temperature (25°C) and last more than 6 months when stored at 0-10°C.

In the simulation session, as many as 20 senior subjects from a total of 30 sample populations of the study participants entered the inclusion criteria and successfully completed the simulation. The subjects then filled out a structured questionnaire (consist of 13 points, which had been validated previously using the SPSS 22® software) regarding their experience of performing PN in this kidney phantom based on their previous experience with real patients. Survey results on questionnaires are shown in graphic 1.

Based on the questionnaire data, senior residents states that the AARM phantom can represent the appearance of the human body's anatomy (p=0.046). The 12th ribs palpation in the phantom was a useful landmark in determining the location of nephrostomy needle insertion and provide added value to the more realistic simulation experience of PN.

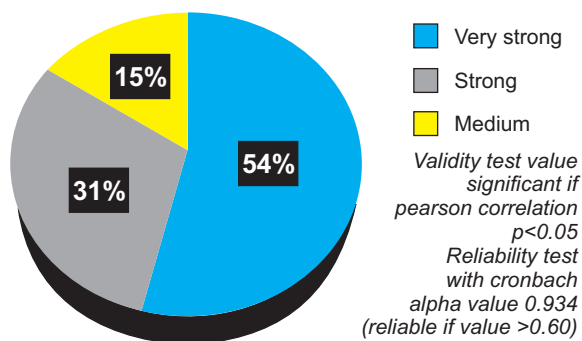
Based on the analysis of the questionnaire on ultrasound imaging of the phantom, all participants were able to recognize parenchymal



Graphic 1. Distribution of subject responses.

Statistical correlation (R) value: 0.0 - <0.2 (Very weak), 0.2 - <0.4 (Weak), 0.4 - <0.6 (Medium), 0.6 - <0.8 (Strong), 0.8 - 1.0 (Very Strong). Color information; Blue : disagree, red: neutral, green: agree, purple: strongly agree.

tissue and renal pelvicalyceal system. Ultrasound images of AARM phantom can represent true kidney ultrasound (p=0.000). In addition, a series of PN actions can be performed fairly well by all the participants, represented by the response of the subject; very strong (53.8%), strong (30.8%), and moderate (15.4%) with positive Pearson correlation.



Graphic 2. Subject respond analysis of the AARM phantom.

Table 1. Validity test results.

No	P	R	Validity
1	0.046	0.45	Valid Medium
2	0.000	0.85	Valid Very Strong
3	0.000	0.81	Valid Very Strong
4	0.003	0.63	Valid Strong
5	0.000	0.78	Valid Strong
6	0.000	0.86	Valid Very Strong
7	0.000	0.84	Valid Very Strong
8	0.000	0.81	Valid Very Strong
9	0.000	0.77	Valid Strong
10	0.000	0.89	Valid Very Strong
11	0.000	0.83	Valid Very Strong
12	0.010	0.56	Valid Medium
13	0.005	0.60	Valid Strong

N=20, p value=Pearson Correlation, Valid when p<0.05.

Table 2. Reliability test results.

Variable	Cronbach	Information
AARM phantom	0.934	Reliable

*An instrument was considered reliable when Cronbach alpha>0.60.

The PN skills in this study were judged by two measurable parameters of puncture time and number of errors during the procedure.

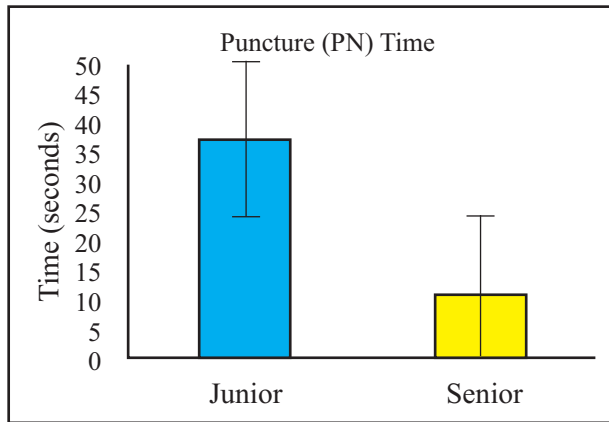
Table 3. Average number of individual PN experiences senior vs junior residents (unpaired t-test results p<0.001).

Groups	N	Mean ± SD	P
Junior Resident	15	7.47 ± 2.00	<0.001
Senior Resident	20	76.85 ± 6.03	

In the senior resident group we got an average puncture time (out of 3 trials) 10.90 ± 0.65 seconds (6.4-16.2 seconds), while the mean puncture time of junior residents was 37.03 ± 9.5 seconds, so when we compared using independent t-test, the junior and senior residents nephrostomy punctures were significantly different; 37.03 ± 9.5 seconds vs 10.90 ± 0.65 seconds (p<0.01).

Table 4. Comparison of puncture time (sec) between groups.

Groups	Puncture Time (P1A)			P
	N	Mean (sec) ± SD	Std. Error Mean	
Junior Resident	15	37.03 ± 9.5	2.45	<0.01
Senior Resident	20	10.90 ± 2.90	0.65	

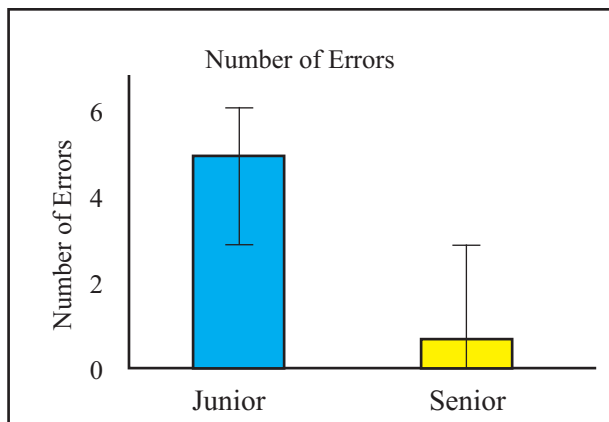


Graphic 3. Time (sec) comparison between senior and junior resident (significant, $p < 0.05$, independent t-test).

The mean errors of PN in senior residents had a value of 0.75 ± 0.63 times, with the majority of failures being the initial puncture. While the average comparison of errors, when compared to junior residents, was 0.75 ± 0.63 times vs. 4.93 ± 1.33 times, so it was concluded that the average procedure failure or errors of the senior group were less than junior with a significant result ($p < 0.01$).

Table 5. Comparison number of errors.

Groups	Junior vs. Senior Residents			
	N	Mean \pm SD	Std. Error Mean	P
Junior Resident	15	4.93 ± 1.33	0.34	< 0.01
Senior Resident	20	0.75 ± 0.63	0.143	



Graphic 4. Comparison number of errors between groups.

Based on the two skill parameters comparison, it shows a significant skill difference, in which it establishes the construct validity.²³

DISCUSSION

The validity of a medical phantom is based on face, content, and construct validity. In this study, face and content validity of the AARM phantom were based on the respond of the structured questionnaire (we using Likert scoring with a score of 1-5, where 1=not representative and 5=very representative) of the senior resident. It was concluded that PN action on AARM phantom resembles and can represent PN actions in patients, expressed by positive Pearson correlation and significant Cronbach alpha from questionnaire scores.²³

According to Wanzel et al. in 2002, a medical phantom should be able to differ expert and novice skills. Each individual skill and experience will be measured based on a hypothesis.^{20,22-25} In this study, the senior resident group had higher PN experience compared to the junior resident, thus senior resident should have better skills than the junior resident in the operating room, as well as on the phantom.

We have compared the skills between the two groups, represented by mean puncture time and number of PN failures. It showed that senior resident has significantly better skills, both at puncture time and the number of failures. It can be concluded that the AARM phantoms can distinguish the capabilities between the two groups objectively, which means the validity of the construction of these props can be established.^{23,25}

Based on this study, the beginner's mistakes in PN procedure often can be identified as follows; Failed to identify the acoustic shadow of the nephrostomy needle under the ultrasound guidance, failed to determine the location of the initial puncture site that caused the position of the ultrasonographic probe blocked by the shadow of the 12th costae mannequin, or the position of the needle is too steep under ultrasonography probe, PN needle puncture false routes (too deep, too shallow or outside the pelvicalyceal system).

Several innovations in training and props for the medical practices have been published previously, where their use can be considered based on the simulation objectives and available costs.²⁰ Various commercial phantoms generally have more

expensive prices, so it is important to be able to develop affordable and appropriate medical phantoms for use in developing countries.^{20,26,27} Several new materials for imitating biological tissue that is compatible with ultrasonography at various medical simulation have been proposed previously.^{11,20} These materials are generally water-based material composed of natural or synthetic polymeric materials, which easily obtained and produced, also has high similarity to human body tissue.^{20,22} Gelatin have been previously used for making various models of biopsy teaching phantoms with ultrasound-guided.^{11,20-22} In this study a hydronephrotic kidney model has been created to show the anatomical features of the kidney and pelvicalyceal system in the ultrasound, which also provides adequate haptics and feedback when a puncture was performed, to accommodate the steps of the procedure. The assessment has been validated, both subjectively and objectively, through the validity of the face, contents, and the validity of the construction.^{20,24}

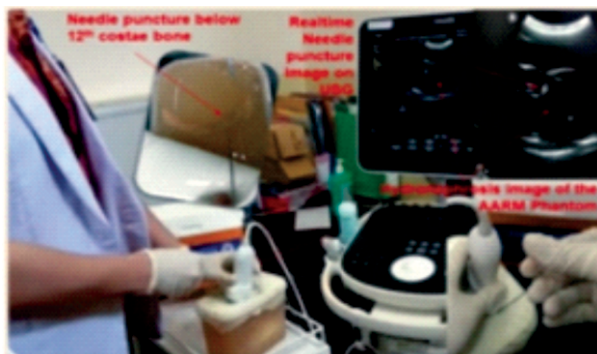


Figure 6. The phantom provides tactile sensation and realtime movement in ultrasound-guided percutaneous nephrostomy.

In this study, we have some limitations because PN skills assessment can only represented by drainage of the kidney pelvicalyceal system by nephrostomy needles and assessment of the additional steps such as access dilatation are not carried out due to various considerations that the dilatation procedure has more variables to measured. Various substitution materials for body layers such as skin, fascia, muscle and gerota fat must have a different standard of ultrasound acoustic shape and consistency, so more in-depth research is needed on another various affordable material that can be used before we can objectively asses another PN steps.

However, access to the pelvicalyceal system can be considered as the basis and key to PN's success (the subjects perform all the PN steps on the phantom with the subjective assessment).

Another limitation that is not owned by our phantom model is the mobilization of the kidneys when the patient breathes as in a real operating room, it will certainly produce a different experience and require further adjustment.

Although the validation methods discussed above had been standardized through the objective and subjective assessment process with validation tools, this process has disadvantages, such as the need for more assessment from the relevant and standard process of assessing medical actions performed on phantoms.

Further research is needed to compare similar phantoms that have been standardized before (concurrent validity), The benefits and influence of this tool in the learning process also had to be assessed, so it can be used as a props for training and practice-based teaching to prepare operators prior to the real procedure, especially for those with limited funds medical training facilities.

Despite those limitations, based on our experience, our self-made phantom will benefit more in the developing country with limited resources, because of the cheaper cost, self-repairable, and simple materials.^{27,28}

CONCLUSION

This AARM phantom had successfully represented the whole sequence actions key step of PN skills and this study has been established its validity (face, content and construct). In addition, this phantom material not only made from affordable cost, but also applicable and could be used repeatedly (recycled). We propose the use of this AARM phantom simulator as an initial steps practices to introduce percutaneous nephrostomy skills to residents before they went to the operating room.

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