## **Original Article**

# Indigenously Developed Ultrasound Phantom Model versus a Commercially Available Training Model: Randomized Double-blinded Study to Assess Its Utility to Teach Ultrasound Guided Vascular Access in a Controlled Setting

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## Abstract

**Background:** The commercially available training phantoms being expensive, homemade models are popular surrogates for training. We intended to study how comparable our indigenously developed ultrasound phantom (IDUP) was with the commercially available model for ultrasound-guided vascular access (USGVA) training. We also assessed the change in confidence among trainees using a 21-h standardized program. **Methods:** A prospective randomized double-blinded, parallel design study, with sequential allocation, was done after a standardized point of care ultrasound training course. Over three consecutive courses, 48 trainees volunteered to take part in the study. The models (IDUP and commercial phantom) were allocated as model A and model B. In each course, participants were also allotted sequentially to either perform in-plane or out of plane approach first, at the testing stations. Wilcoxon signed-rank test was used to compare pretest with posttest scores. **Results:** There was a statistically significant difference between IDUP and commercial phantom with respect to the resemblance to human tissue on tactile feedback and ease to perform the procedure. However, both models did not show a statistically significant difference in terms of ease of use, visual resemblance to human tissue, needle visualization, and artifacts on ultrasonography display. A significant change in the confidence levels of participants was seen postcourse. **Conclusion:** IDUP was a comparable alternative to the commercial model for USGVA training in a resource-limited setting. A 21-h standardized training program improved the trainee's confidence in performing and teaching USGVA.

Keywords: Education, simulation, ultrasound, vascular access

## INTRODUCTION

The use of point-of-care ultrasound (PoCUS) as an adjunct to the practice of emergency medicine (EM) to aid the evaluation of patients is well accepted.<sup>[1]</sup> Besides helping in diagnosing and confirming life-threatening emergencies, visualization under ultrasonography (USG) also assists in efficiently performing procedures such as nerve blocks, abscess drainage, foreign body exploration, and vascular access.<sup>[2]</sup> Novice providers are recommended to complete a systematic training program

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that includes a combination of simulation-based practice, supervised insertion on patients, and evaluation by an expert operator before attempting ultrasound-guided procedures independently on patients.<sup>[3]</sup> In simulation-based practice,

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several training models-both physical and virtual-are available commercially but are expensive and inaccessible to most.

In resource-limited settings, along with the training, the choice of the training model plays a pivotal role in ensuring module accessibility to all. This has led people to experiment with various models for training, ranging from basic gelatin molds to ballistic gel.<sup>[4-6]</sup> The homemade (indigenously developed) models are cheaper for training, making it a relatively favorable choice in resource-limited settings. A compendium of resources are available online to aid the novice and trainers alike in its manufacture.<sup>[7,8]</sup> However, there are only a few studies that offer a systematic comparison of these models with the commercially available products for educational purposes.<sup>[9,10]</sup> The investigators have been using a gelatin based, indigenously developed ultrasound phantom (IDUP) training model to train EM residents.

Through this study, the investigators evaluated how comparable IDUP was with the commercially available model (Blue Phantom®) for vascular access training. The investigators also sought to assess the change in the confidence of trainees undergoing a 21-h standardized training program [Figure 1a: Lecture and b: Hands on session].

## METHODOLOGY

#### Design

This was a parallel design, with 1:1 allocation ratio.

### **Settings**

This study was conducted as part of the ultrasound-guided vascular access (USGVA) training workshop, conducted



**Figure 1:** Training course and test images. (a) Lectures: Live demonstration of image acquisition (L) techniques on normal healthy human volunteers during the lecture sessions. (b) Hands-on session: Participants divided into groups with an instructor to the participant to machine ratio 1:5-6:1. (c) Testing station: Two independent examiners (E1, E2) evaluated the volunteers at each testing station. One recorded the time (E2) and the other instructed the conduct at the station (E1). Examiners observed and recorded the participant (P) performing ultrasound-guided vascular access on both the ultrasound models. (d) Masked models A and B

periodically at Jubilee Mission Hospital and Research Institute, Kerala, India. Trainees in consecutive courses (n = 3) were approached to participate in this study. The trial was approved by the Institute's Ethics Committee (03/19/IEC/JMMC and RI) and is registered under Clinicaltrials.gov NCT04527120.

## Participants: Eligibility criteria

All the participants of the PoCUS training module who underwent the vascular access course were recruited. Before the workshop, the participants were asked to fill a questionnaire. A consent was sought at this time to use the questionnaire for research purposes. After completion of the course, the participants were informed regarding the conduct of the study and a second consent was sought at this juncture to recruit participation in the interventional study [Figure 2]. The participants were given the choice to withdraw their consent at any point of time. The data of the participants who withdrew consent was removed from abstraction.

#### Intervention

All participants underwent an initial 16-h ultrasound training, followed by an additional 5 h of vascular access training (total 21 h). The USGVA module comprises 2 h of interactive lectures with 3 h of hands-on practice sessions before assessment and certification. They were trained on the Blue Phantom® vascular access training block during the course.

#### Preworkshop

Before the workshop, the participants were asked to fill a questionnaire. The questionnaire collected baseline characteristics of the participants with regard to their level of expertise and access to USG. It also assessed their confidence level, in performing and teaching USGVA. After completion of the course, a research assistant informed the participants about the conduct of the study in the skills lab and those who volunteered their time were recruited for the study.

#### Interim analysis

Although, no interim analysis or stop rule was planned initially, due to the Covid19 pandemic and travel restrictions, further participants could not be recruited within the speculated time frame, and the recruitment was terminated prematurely.

### **Conduct of the study**

An independent team of seven individuals were formed and appraised with regard to the methodology of the study and a team leader (TL) to coordinate the activity was chosen.

They helped conduct the study. The TL was not directly involved in testing the participants, data collection, or analysis [Figure 1c: Testing station]. They were given scripted instructions by the TL to be read out to the participant to unify the test pattern.

Feedback or debriefing was not allowed at the stations. The participants were asked to demonstrate needle tracking and aspirate fluid from the vessel in both in-plane (IP) and

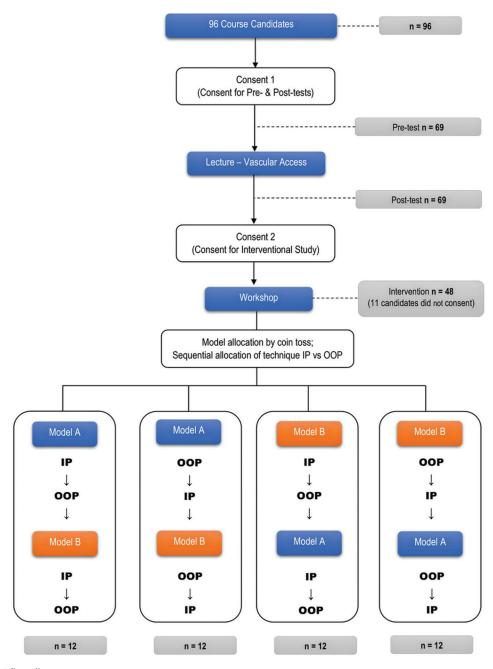


Figure 2: Participant flow diagram

out-of-plane (OOP) approaches. Whether a participant got IP or OOP approach first was determined sequentially. Participants were instructed to leave the testing station through a different exit once the test was completed.

#### Training

All participants initially underwent training using Blue Phantom® training model during the formal USG course.

## Testing

All those who volunteered and consented to participate in the study underwent testing using the standard commercially available Blue Phantom® and IDUP training model.

#### **Outcome measures**

The first examiner graded the participants on a Likert scale of 1–5 (1-worst, 5-best) in terms of their performance for each attempt. The second examiner timed the participants using a stopwatch. The time taken for needle tip visualization and time to puncture, and the number of attempts to draw fluid were recorded. Once the skill test was completed, the participants were asked to fill out a questionnaire that compared the two models with regard the ease of use, needle visualization, tactile feedback, visual resemblance to human tissue, artifacts, and ease of learning the procedure. It also assessed their postworkshop confidence level in performing and teaching needle tracking and vascular access, with both IP and OOP approaches.

#### Sample size

The sample size was calculated after doing a pilot study of 10 participants using the formula,  $n = (Z\alpha + Z\beta)^2 \times S^2 \times 2/d^2$ . The mean time difference to Needle Visualization OOP in IDUP and commercial Phantom was taken for sample size calculation. The mean time in the IDUP model was 13.8 + 7.23 whereas in the commercial phantom model it was 17.8 + 10.086. At  $\alpha = 0.10$  and  $\beta = 0.20$ , the sample size was calculated as 58. A nonresponse rate of 5% was considered and the sample size was rounded off to 61.

#### Data analysis and interpretation

The statistical software, namely, Statistical Package for the Social Sciences, SPSS; (International Business Machines Statistical Package for the Social Sciences, IBM Corp. Released 2013, Version 22.0. Armonk, NY, USA: IBM Corp) was used for the analysis of the data. Microsoft Word and Microsoft Excel (2013 version) were used to enter data and generate graphs, tables, and charts. Numerical variables are expressed as median (interquartile range, means  $\pm$  standard deviation). Categorical variables are expressed as frequency and percentages. Wilcoxon signed-rank test was used to compare the models and pretest with posttest scores.

#### **Randomization**

The allocation of the training model as A or B was randomized using coin toss method by the TL before each course. Whether the participant performed on model A or B first was sequentially determined by the examiner. The examiners were instructed by the TL to arbitrarily begin with one model and continue with the other model for every alternate participant. That is, if the examiner asked the first participant to perform on model A followed by model B, he had to allot model B followed by model A for the subsequent participant. The participants were also allotted to either IP or OOP approach first, sequentially by the examiner at the station. This led to four parallel allocation sequences [Figure 2: CONSORT participants flow diagram].

#### Allocation concealment

The commercial and indigenous phantom models were allocated as models A and B during the beginning of each course. The allocation made was concealed in opaque envelopes that were opened only after the data collection was deemed complete and the data entry to the excel sheet commenced.

#### Blinding

The examiners, examinees, and statistician were blinded to the nature of the model. The TL and data entry officer were not blinded. The model made was matched in color, shape, and size with the commercially available model [Figure 1d]. The models were stored in an air conditioned room with ambient temperature recorded at 26°C for at least 4 h before the test. The model's identity was known to the TL and was marked

unto a sealed envelope which was opened only after data entry and analysis. Any untoward event needing unmasking of the models-like damage to the model, warranting replacement-was also carried out by the TL. Data set from three courses were abstracted. During the three courses, the indigenous phantom model got assigned model A once and model B twice. The unmasking occurred before data entry to the excel sheet.

#### Test of blinding

All examiners who participated were tested prior to the conduct of the course. They were asked to confidently identify (on a scale 0%–100%) the ultrasound training phantom by looking, touching, feeling, and performing vascular access on the model after concealment. Three of the ten examiners identified the model correctly, two of whom self-reported 20% confidence and one reported <5% confidence in identifying the model correctly.

#### **Quality assurance check**

Throughout the process, the TL was given a checklist that ensured that the quality of the study was maintained uniformly. The TL oversaw the conduct of the study.

#### **Definitions**

IP approach was defined as when the ultrasound probe was held in the same plane as the needle, so that the needle in its entire length was visible on the ultrasound machine's monitor.

OOP approach was defined as when the ultrasound probe was held perpendicular to the plane of the needle so that the cross-section of the needle was visible on the ultrasound machine's monitor.

Needle tracking meant following the needle so that it was visualized in real-time on screen, as it was advanced or retracted, using USG probe.

In the IP approach needle tracking was defined as successful if visualizing the needle in its longitudinal axis during the entire sequence of the procedure from phantom puncture to vascular access, aspiration, and withdrawal of the needle;

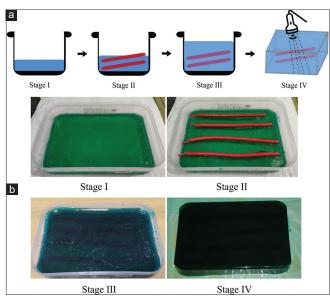
Whereas in the OOP approach needle tracking was defined as visualization of the tip of the needle, throughout the sequence of the procedure from phantom puncture to vascular access, aspiration, and withdrawal of the needle.

Time to needle tip visualization was defined as the time taken from starting the procedure to clearly demonstrating the needle tip on the ultrasound monitor.

Time to puncture was defined as the time taken from starting the procedure to aspirating fluid in the syringe. The participants were allowed a maximum of 5 attempts after which the attempt was determined as unsuccessful.

#### **Equipment used**

Needle and syringe from a Braun Certofix® central venous cannulation set  $(1.3 \text{ mm} \times 73 \text{ mm}; 18G, 27/8")$  was used for cannulation. The real-time ultrasound-guided technique was performed with a USG machine (SonoSite Edge® Portable



**Figure 3:** (a) Graphical representation of indigenously developed ultrasound phantom preparation stages. Stage I: Gelatin and glycerine mixed with cold water and coloring agent. Heated and cooled down to room temperature. Stage II: Balloons filled with tap water are placed at evenly spaced intervals and kept at 2°C for 2 h. Stage III: A second cooled layer of the mixture is carefully poured into the container from the sides, sandwiching the balloons and kept at 2°C overnight Stage IV: The final solidified product can now be scanned using a ultrasonography probe. (b) Images of indigenously developed ultrasound phantom preparation stages

Ultrasound Machine) and 13–6 MHz linear probes were used for the study.

#### The ultrasound training (phantom) models

A review of various simulation models and materials used to prepare PoCUS training phantoms, was done by searching PubMed and Google scholar from 1970 to 2017. The team repeated experiments with various commonly available materials (gelatin,<sup>[11-13]</sup> glycerin,<sup>[14,15]</sup> agar,<sup>[16]</sup> gel<sup>[17]</sup>) as surrounding materials at various ratios with target materials to mimic vessels like latex balloon,<sup>[18,19]</sup> Foley catheters,<sup>[20]</sup> latex gloves,<sup>[21]</sup> iv drip sets and plastic tubes.<sup>[22]</sup> Powdered ispaghula husk (psyllium)[11] at various ratios was also tried for added echogenicity but was not used in the final preparation. IDUP preparation was divided into the following stages. Stage I: Gelatin was mixed with cold water initially to let it "bloom," into which boiling water was poured in. Glycerin and coloring agent were then added and cooked on a conventional stove without allowing the mixture to boil over. Once it reached a one-string consistency, it was cooled down to room temperature. Stage II: Once cooled and when beginning to set, balloons filled with tap water (colored red using food color, ensuring no air pockets) were placed at evenly spaced intervals (this would float to the top), and later the block was set completely in a refrigerator at 2°C for approximately 2 h. Stage III: A second cooled layer of the mixture was then poured through the sides of the plastic container, taking care to cause as little disruption as possible, on top of the first layer, sandwiching the balloons. The entire model was then

refrigerated at 2°C overnight. Stage IV: The final product gets a solid consistency and is ready to be scanned using a USG probe [Figure 3a and b: IDUP preparation stages]. 'Blue Phantom select series branched 2 vessel vascular access ultrasound phantom' was used as the standard commercial model for training the participants and to compare against.<sup>[23]</sup>

## RESULTS

A total of 96 trainees participated in the ultrasound training workshops conducted, of which 69 individuals filled the pre questionnaire, but only 48 individuals participated in the intervention [Figure 2 Participant flow diagram]. Eleven individuals refused to provide consent to participate in the study, five stated they did not have time to participate whereas six did not provide a reason. The required sample size of 61 was not met since the study had to be stopped prematurely.

#### **Baseline data**

The precourse questionnaire data were used to abstract the baseline data (n = 69). The participants in the study were mostly residents in EM (46, 66.7%). Twenty (29%) of the participants had attended a USG in the form of a workshop before, and 39 (56.5%) had experience with USGVA. However, none had formal ultrasound training in the form of a fellowship or as part of their specialization. Forty-three (62.3%) were novice users, having performed <5e USGVA procedures in the past. Fifty-nine (85.5%) had a dedicated ultrasound machine in their department. Out of those with a dedicated USG in the department, 8 (13%) had never used it before. Forty-two (60.9%) participants were taught USGVA procedure on a patient first, whereas 5 (7.2%) used a simulation model to train.

#### **Course evaluation data**

Before the course, grading their confidence in performing USGVA was done on a Likert scale of 1–5 to grade their confidence in performing USGVA (1, being not at all confident and 5 extremely confident).

All the pre- and post-course difference in scores, in performing and teaching USG in IP, OOP, and needle tracking were statistically significant (P < 0.05). A Wilcoxon signed-rank test was done to compare the pre- and post-course confidence level among participants. The test elicited a statistically significant change in the confidence levels of participants when compared to their pre-confidence level. The median post-confidence score increased two to four times after the course when compared to pre-confidence scores [Table 1].

The course design was also evaluated after the workshop using the post-course questionnaire. Thirty-three participants (n = 48, 68.8%) felt that the course content was introduced well and 97.9% (n = 47) found the course workshop hands-on was sufficient. Fifty-eight percent (n = 28) scored the vascular access module, "extremely beneficial" whereas the rest scored it "very beneficial", on a 5-point Likert scale.

#### Model comparison

A Wilcoxon signed-rank test done to compare the two models among the participants, elicited a statistically significant difference between IDUP and commercial phantom with respect to resemblance to human tissue on tactile feedback and ease to perform the procedure.

However, both models did not show a statistically significant difference in terms of ease of use, visual resemblance to human tissue on the USG, needle visualization, and artifacts on USG display. The models were comparable and a median score obtained was 4; for both IDUP and commercial phantom in all the above criteria except for needle visualization and artifacts on USG display [Table 2]. The median needle tip visualization time or time to puncture was not significantly different in either approaches-IP or OOP-on either models [Table 3].

# DISCUSSION

Being portable, easily accessible, and giving real-time guidance with minimal radiation, PoCUS has turned out to be a quintessential tool in the armamentarium of the Emergency Physician (EP). PoCUS is not a replacement to consultative radiology performed ultrasound practice but a focused ultrasound examination usually performed at the bedside of the patient, often in suboptimal conditions with time limitations. This has led to its utility to transcend specialty boundaries with increasing relevance to other clinician groups.<sup>[24]</sup>

It helps in diagnosing life-threatening conditions and guiding interventions optimally by reducing risks associated with conventional landmark techniques.<sup>[25]</sup> USGVA represents the majority of procedural PoCUS in the ED.<sup>[26]</sup>

### About ultrasound training

Bedside ultrasound is recognized as a basic necessity for the EP but a standardized PoCUS curriculum is yet to be defined in India.<sup>[2,24,27]</sup> Even though it was EP that attended the ultrasound training workshop, none had any formal training in the same. There are no accredited fellowship programs in the country or training pathway that the EP can pursue to train in PoCUS. At the time of writing of this article, the ultrasound training is dependent on ultrasound workshops and brief training modules. In this study a 21-h, 2-day course was conducted which seemed to significantly improve the confidence of the trainees to start using ultrasound. Whether this would translate to clinical proficiency for the resident with limited clinical experience is questionable. Such training programs could be primers to introduce PoCUS.

In a resource limited setting for practicing EM, series of short courses or preceptorship maybe utilised for training consultants who completed residency without specific PoCUS training.<sup>[2]</sup> Most of the residents in this study had an ultrasound machine in their department, but they lacked any training or mentoring on how to use them. Training the trainers with these short modules could pave the pathway for establishing better curriculum-based learning for the EM residents.

### Simulation model training

In most of the ultrasound workshops, the resource material to train would be human volunteers. More than 60% of the participants in this study were first trained to use ultrasound-guided procedures on patients directly under supervision. There exists a question of patient safety in conventional PoCUS training.<sup>[28]</sup> Only 7% in this study had access to any simulation-based training in their institute. The human volunteer models are an excellent resource to understand the normal (and rarely the abnormal) human anatomy, but it would be unethical to subject these models to interventional procedures.<sup>[29]</sup>

The simulation models like Blue Phantom® have been universally used for training purposes in this regard. The design of the IDUP used in our program was based on the commercially available ultrasound phantom model which is conventionally used for training. The training phantom used in this study was gelatin-based, with fluid-filled latex tubular balloon, which could easily be replicated for training purposes in their respective training programs. IDUP was comparable to the commercial model except in resemblance to human tissue on tactile feedback and in the ease to do the procedure. If we presume that the goal in procedural PoCUS education is target acquisition, coordination between targets and needles, and needle finding; the tactile difference in resemblance to human tissue need not affect the utility of the models in achieving those goals. The increased difficulty of the individual to learn the procedure on the model could be a challenge with the time constraints of a short training course. For visual comparison, USG images of the two models in IP and OOP approaches with similar scanning settings can be found in Figure 4.

### Vascular access training

Since there was insufficient evidence to definitively choose either IP or OOP approach in patients undergoing USGVA, we employed sequential allotment of the procedure to the individuals so that equal division occurred amongst the group. There was no significant difference noted in the two approaches in training, but the median time to puncture was higher in the OOP approach.

## Advantages and disadvantages of indigenously developed ultrasound phantom model

The major disadvantages of homemade models are often the lack of reusability, need for specific storage conditions, shelf life, and resemblance to human tissue.

The model required replacement in two out of three of the courses. We estimate a total number of 80–100 punctures after which the model has to be reset, and balloon replaced, whereas the commercially available model is 'self-healing' and can sustain more than 1000 pricks at the same site using an 18–21G needle before being damaged. It requires refrigeration for extended shelf life. The addition of a preservative or antibiotic or anti-fungal have been tried by many, but since the courses are of relatively short duration, increasing the shelf life was not

	$Mean \pm SD$		Median		IQR		Z score*
	Precourse	Postcourse	Precourse	Postcourse	Precourse	Postcourse	
Confidence in performing							
USGVA	2.41±1.30	4.12±0.79	2	4	2	1.75	-5.47#
USGVA using IP technique	$1.77 \pm 1.32$	3.87±1.20	1	4	2	2	-5.16#
USGVA using OOP technique	$1.71 \pm 1.47$	4.10±0.99	1	4	1.75	1	-5.55#
Confidence in teaching							
USGVA using IP technique	1.77±1.24	3.93±1.02	1	4	1.75	2	-5.51#
USGVA using OOP technique	$1.75 \pm 1.31$	$4.02 \pm 1.00$	1	4	2	2	-5.62#
Needle tracking	1.44±1.11	3.35±1.41	1	3.5	0.75	1.75	-5.20#

\*Wilcoxon signed ranks test, "Significant at P<0.10. USGVA: Ultrasonography guided vascular access IP: In plane, OOP: Out of plane SD: Standard deviation, IQR: Interquartile range

Table 2: Model evaluation $(n=48)$						
Parameter evaluated	Ultrasound model	Mean±SD	Median	IQR	Z score*	
Ease of use	IDUP	3.85±1.05	4	2	-1.618	
	Commercial phantom	4.15±0.87	4	1		
Resemblance to human tissue on tactile feedback	IDUP	$3.65 \pm 0.89$	4	1	-2.335#	
	Commercial phantom	3.96±0.87	4	2		
Sonographic resemblance to human tissue on USG display	IDUP	$3.92 \pm 0.92$	4	2	-0.987	
	Commercial phantom	$4.06 \pm 0.78$	4	1		
Needle visualization on screen	IDUP	$4.00{\pm}1.01$	4	1	-1.463	
	Commercial phantom	$4.27 \pm 0.84$	4.5	1		
Artefacts on the USG display	IDUP	3.33±1.19	3.5	1	-1.469	
	Commercial phantom	3.60±1.18	4	2		
Ease to perform USGVA	IDUP	3.71±0.92	4	1	-2.288#	
	Commercial phantom	4.15±1.07	4	1		

\*Wilcoxon signed rank test, "Significant at P<0.10. IDUP: Indigenously developed ultrasound phantom, USG: Ultrasonography, USGVA: Ultrasonography guided vascular access, SD: Standard deviation, IQR: Interquartile range

Table 3: Needle visualization and time taken to puncture: Indigenously develo	oped ultrasound phantom versus commercial
phantom in s $(n=48)$	

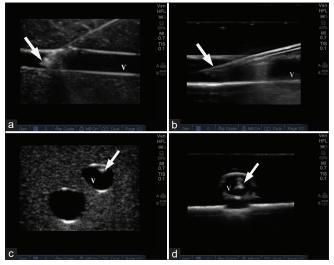
Parameter evaluated	Ultrasound model	Mean±SD (s)	Median (s)	IQR (s)	Z score*
Needle visualization IP	IDUP	18.71±14.50	15	16.75	-0.913
	Commercial phantom	20.04±21.84	13	14	
Needle visualization OOP	IDUP	16.04±12.52	12	14.5	-1.657
	Commercial phantom	19.60±14.23	14	20.25	
Time to puncture the vessel/aspirate fluid IP	IDUP	42.17±40.46	26.5	40.25	-1.251
	Commercial phantom	35.95±27.30	31.5	31.75	
Time to puncture the vessel/aspirate fluid OOP	IDUP	48.59±34.53	41.5	45.75	-0.22
	Commercial phantom	$53.00 \pm 48.95$	43.5	43.75	

\*Wilcoxon signed rank test, IDUP: Indigenously developed ultrasound phantom, IP: In plane, OOP: Out of plane, SD: Standard deviation, IQR: Interquartile range

an objective. The model is made from food-grade materials and periodic reheating in a microwave to reset and sterilize seems to extend its shelf-life. The material also requires storage at room temperature; since above 30°C, the model starts losing shape. The materials used for IDUP are easily available and the model is easily replicable. The average estimated manufacturing cost of IDUP in this study being INR 200 (USD 2.7) against the commercial model costing INR 80,000 (USD 1071), makes the former affordable in these settings. In short training courses, IDUP is ideal whereas in simulation labs where regular, long-term usage is anticipated, investment for a commercial product may be justified.

#### Limitations

The participants who volunteered additional hours would be more motivated to learn and possibly to teach. Anonymity and confidentiality of all participants were emphasized to aid increased participation of individuals to minimize the bias, but volunteer bias was inevitable as a well-motivated group



**Figure 4:** Ultrasonography images showing needle (arrow) inside the vessel (V) of both the ultrasound models. (a) IP approach on Blue Phantom model. (b) IP approach on IDUP model. (c) OOP approach on Blue Phantom model. (d) OOP approach on IDUP model

of individuals who sought training participated in the course. There was also a familiarity bias arising due to all participants being trained initially using the commercial phantom.

Although the study shows an increase in confidence of the participants by a 21-h course, long-term follow-up of the trainees with spaced reinforcement and reassessment may be necessary to assess their clinical proficiency, and to change their PoCUS utilization habits.

The IDUP in this study was compared against only a single commercial model since that was the most commonly available one. No comparison between various other home-made models or any other commercially available augmented reality or virtual reality models was done systematically. Standardization of the manufacturing process in homemade models being difficult in a non-commercial setup was also not done by the investigators. The study had to be stopped prematurely before the required sample size was met, due to the outbreak of the Covid19 pandemic.

Three IDUP had to be replaced in the third ultrasound course and one in the first course.

The material manufacturing process was hampered due to certain unforeseen manufacturing process errors. Subtle changes like the setting temperature at which the second layer is poured in, or the presence of micro air bubbles while mixing may affect the consistency of the model. The susceptibility to these human errors in the manufacturing process was not anticipated initially since a fixed recipe was used for manufacture.

# CONCLUSION

The IDUP model was a comparable alternative to the commercially available model for USGVA training in a resource-limited setting. A16-h standardized training program

with an additional 5-h vascular access training improved the participant's confidence in performing and teaching USGVA.

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#### **Conflicts of interest**

All India Institute of Medical Sciences Ultrasound Trauma Life Support (AUTLS) course along with which the study was conducted is organized in collaboration with ICCES. SVA, VKS, TPS, SB are faculty for ICCES. ICCES members (SVA, VKS) were involved in the design of the study and write up of the manuscript. None of the ICCES members were directly involved in the data collection or analysis of results.

#### Clinical trials registration number: NCT04527120.

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