

Evaluation of Locally Made Phantom Models for Gynecologic Ultrasound-guided Procedures Simulating Transabdominal and Transvaginal Approaches

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ABSTRACT

Background and Objectives. Phantom and simulation models are valuable training tools for teaching and skill enhancement, yet high costs and limitations of commercial options drive the search for alternatives. This study evaluated the locally sourced phantom models developed for transvaginal and transabdominal gynecologic interventional ultrasound procedures, aiming to cater to the educational needs of OB-GYN ultrasound subspecialists.

Methods. Four phantom models simulating biopsy and cyst aspiration/paracentesis through transvaginal and transabdominal approaches, were developed, and assessed by 37 ultrasound subspecialists in obstetrics and gynecology. The respondents, comprising 19 experienced and 18 with limited exposure to guided procedures, utilized an 11-item Likert-scored questionnaire to evaluate the models' acceptability and suitability for training. Responses were analyzed using descriptive statistics.

Results. Both experienced and less-experienced groups consistently assigned high scores, particularly highlighting the realistic ultrasound image and positioning of structures. The models proved effective in enhancing confidence and proficiency during simulation-based training for probe manipulation, aspiration, and biopsy procedures. While respondents identified concerns like durability and needle track marks, no significant differences emerged between the two groups in evaluating the model.

Conclusions. The overall evaluation of the developed phantom model was positive, showcasing its acceptability among end-users and suitability for training ultrasound-guided procedures in obstetrics and gynecology. The identified issues provide valuable insights for potential improvements in future iterations of the model.

Keywords: phantom models, ultrasound education, interventional ultrasound, ultrasound simulation

INTRODUCTION

The use of ultrasound in obstetrics and gynecology as a diagnostic imaging technique is well established. It has many advantages over other imaging modality that make it more acceptable for both the clinician and the patients. It is readily available, relatively cheaper, and requires minimal patient preparation. In the past few decades, the use of ultrasound has evolved, providing clinicians with a means of visualizing structures while performing either a diagnostic or a therapeutic interventional procedure. Notably, there has been a growing demand for less invasive ultrasound-guided gynecological interventions, such as aspiration, paracentesis, and biopsy.



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Exploratory laparotomy for certain benign cystic structures may be deferred for various reasons, making US-guided aspiration essential, whereas paracentesis serves both diagnostic and therapeutic purposes. Histopathologic diagnosis is crucial for solid abdominopelvic masses before definitive therapy, especially in cases of inoperable primary pelvic tumors, recurrent tumors, or advanced tumors benefiting from neoadjuvant chemotherapy followed by interval debulking surgery.¹ Biopsy is also essential for uncertain tumor origins or when surgery is not the primary management.² Guided by imaging modalities like CT, MRI, and ultrasound,³⁻⁶ these procedures are crucial for diagnosis and therapy. MRI, despite its high resolution, is underutilized due to specialized equipment requirements and doctor experience.⁷ CT-guided biopsy is safe but limited to deep pelvic masses. Ultrasound stands out as a cost-effective, real-time alternative, allowing various approaches, either transabdominal, transvaginal, or transrectal. Furthermore, it offers advantages over alternative modalities in terms of accessibility and minimal requirements for patient preparation. However, the proficiency required for such procedures demands specialized training and skill development, emphasizing the importance of mastering the anatomy, the performance of the scan, and the precision skills when executing the procedure in order to avoid complications, given the potential risks to structures and adjacent organs.⁶ Since skill development requires constant practice, the sonologists should be able to perform the procedure initially and multiple times in a model prior to the performance in an actual patient.

Phantom and simulation models have emerged as valuable training tools, facilitating skill enhancement for practitioners in various procedures.⁸ Simulation-based training, particularly in ultrasound-guided procedures, has shown notable improvements in efficiency, puncture techniques, and overall performance.⁹ Despite their utility, these models may have limitations in replicating the complexity of real cases. Current commercially available models, despite its prohibitive cost, lack the flexibility to replicate the dynamic nature of actual scans, where bimanual examination and manipulation optimize the image and position of structures. This realism is vital for preventing complications associated with needle courses through and potential damage to adjacent structures.

Recognizing the need for realistic training models for ultrasound-guided gynecologic procedures, a study was conducted which aimed to develop locally sourced, cost-effective phantom models for both transvaginal and transabdominal approaches. The initiative, comprising phantom development and end-user evaluation, addresses the limitations of commercially available models, which may be cost-prohibitive and lack flexibility in replicating real-time scanning and specific approaches, specifically the transvaginal approach. This paper specifically focuses on the evaluation phase, assessing the developed phantom model's suitability and acceptability among obstetrics-gynecology ultrasound subspecialists. The locally sourced and cost-effective materials,

chosen for their capacity to mimic soft and hard tissues, are evaluated for their realism, usability, and stability. Initial assessment involved trained sonologists who have been routinely performing ultrasound-guided procedures, forming the basis for iterative improvements and subsequent evaluation by sonologists with prior, though infrequent or limited, experience in these procedures.

Motivated by the growing necessity for ultrasound-guided procedures, particularly for inoperable pelvic masses requiring histopathological diagnosis, this study responds to the demand for a training model. The target model intends to fill educational gaps, especially in institutions where such procedures are not routine. It also endeavors to surpass the limitations of commercially available models by incorporating locally sourced inexpensive materials with physical properties enabling realistic sono-acoustic images with the durability to withstand multiple punctures and ensuring stability. These characteristics of the developed model, coupled with the acceptability by end-users and its suitability as an effective teaching tool, will be paramount in determining its utility to meet the needs of the ultrasound practitioners.

MATERIALS AND METHODS

The development of the phantom was conducted at the Composite Materials and Materials Characterization laboratories of the Department of Mining, Metallurgical, and Materials Engineering (DMMME), College of Engineering in the University of the Philippines (UP), Diliman, Quezon City. Materials were synthesized in the laboratory using locally available indigenous materials and were characterized in terms of their mechanical and viscoelastic properties to establish material formulations that will have properties similar to biological tissues, i.e. muscle and adipose tissues. Ex vivo animal tissues, representing biological tissues in the abdominopelvic region, were characterized in terms of their viscoelastic properties, which then served as the basis for identifying suitable materials for the phantom model. The identified materials were assembled into phantom models to simulate the abdominopelvic region of the human body to facilitate training in probe manipulation, aspiration, and biopsy procedures. Materials characterization and performance tests with the use of a curvilinear transducer of an ultrasound equipment (center frequency of 3.2 MHz, Sonoscape E2 color Doppler portable ultrasound system) was initially performed, results of which were used to adjust the formulations of the materials used in the phantom to create the specific required photoacoustic properties of the solid masses, the encysted fluid, and the three-dimensional suspension material (Details on the phantom development including evaluation of viscoelastic properties and cost of the materials are described in another paper awaiting publication as of this writing).

There were four phantom models as shown in Figure 1: (A) phantom model containing a solid mass to be used simulating

transvaginal approach for biopsy of solid mass using a Bard magnum biopsy gun mounted on an endovaginal transducer with a needle guide; (B) phantom model containing a cyst to be used simulating transvaginal approach for aspiration of cyst using a spinal needle; (C) phantom model containing solid mass to be used simulating transabdominal approach for biopsy of solid mass using alternately a 2 inches G18 needle and a disposable automatic biopsy gun (using either a free hand approach or mounted on curvilinear transducer with a needle guide); and (D) phantom model containing cyst to be used simulating transabdominal approach for paracentesis/aspiration of cyst using a Seldinger and free hand approach. Depth and position of the specific materials simulating the solid mass and cyst were varied to differentiate one appropriate for transvaginal or transabdominal approaches. These models were placed in four different stations for the training and workshop where evaluation of their suitability for the different procedures and assessment of the overall impression of trainees on the applicability of these tools to enhance their learning.

The use and evaluation of the phantom models by the end users were conducted at the Division of Ultrasound, Department of Obstetrics and Gynecology, UP - Philippine General Hospital (PGH), Manila City on May 4, 2023, and August 10, 2023. The hands-on training per model or station was conducted by 1-2 consultants from the first

group of evaluators, further described below, who used the phantom to demonstrate the procedure to the trainees. A return demonstration of the procedure was performed by each participant thereafter. All participants were able to use the four phantom models and perform each of the procedures for 15 to 20 minutes. Each phantom model was used by 5-6 participants, after which both transabdominal and transvaginal models were deemed not optimal for use as evaluated by the participants, and hence were replaced with a new model. The techniques, approaches, and maneuvers for insertion and optimization of needle visualization were demonstrated and performed using the phantom models (Figure 2).

Immediately after the simulated hands-on activities, the participants were requested to anonymously answer a questionnaire (Tables 1 and 2) that has been adapted and modified from a previous phantom model evaluation.¹⁰ The questionnaire used a 5-point Likert scale (1-very poor, 2-poor, 3-neutral, 4-good, 5-very good), consisting of six questions related to the evaluation on the practical feeling of the phantom as an acceptable model and five questions on the evaluation on overall personal impression on the suitability of the phantom. Acceptability for teaching is based on the property of the model to simulate the anatomy and the procedure. The parameters evaluated were the image formed (sono-acoustic appearance and positioning of structures) and the materials used, in terms of its compressibility (firmness or softness or

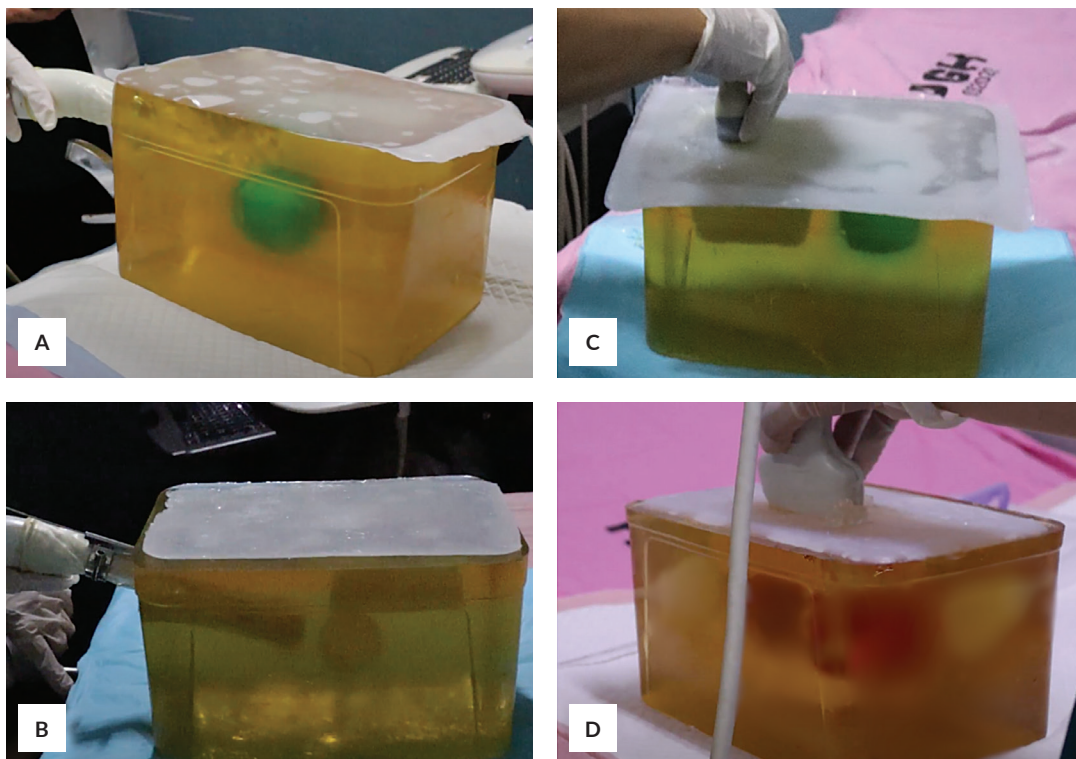


Figure 1. Four phantom models for (A) transvaginal approach for biopsy of solid mass; (B) transvaginal approach for aspiration of cyst; (C) transabdominal approach for biopsy of solid mass; and (D) transabdominal approach for paracentesis/aspiration of cyst.

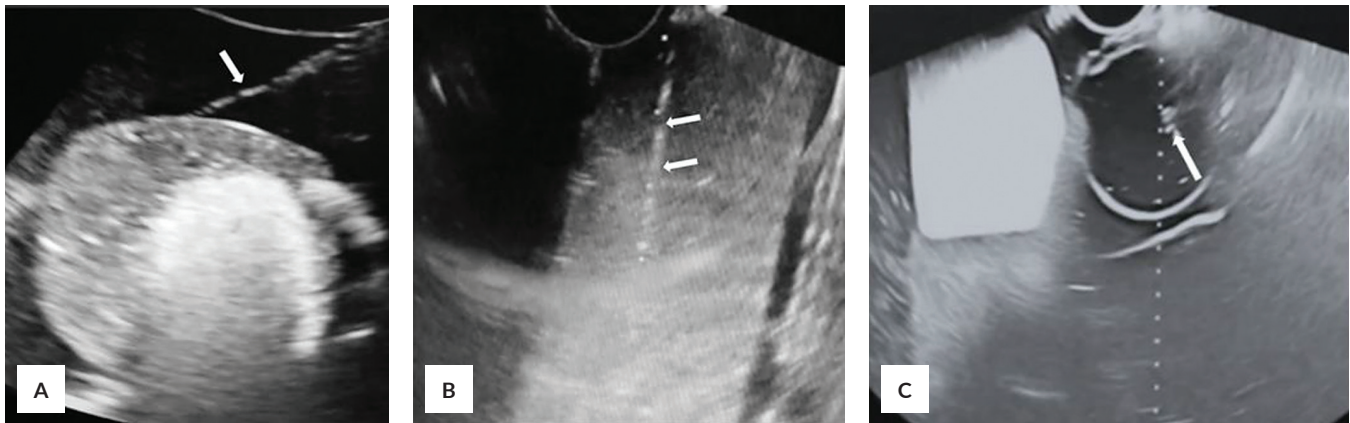


Figure 2. Ultrasound images of the model simulating: **(A)** tru-cut biopsy of a solid mass by transabdominal, and **(B)** transvaginal approach showing the echogenic biopsy needle (*arrows*); and **(C)** aspiration of an encysted fluid by transvaginal approach showing the needle tip (*arrow*).

give) and execution of the procedures (aspiration, and biopsy by transvaginal and transabdominal approaches). Suitability to the user is based on the overall personal impression of the operator for use in simulation-based training for interventional US and the overall impression that the model increased confidence and improved performance in terms of probe manipulation for US image focusing, orientation, and optimization, and the performance of aspiration procedures and biopsy procedures (questions 7-11). The respondents were also asked to provide other comments that they think may help in the improvement of the phantom.

The models were twice evaluated. The first evaluation involved a total of 19 participants consisting of 8 trainees and 11 ultrasound subspecialists of the Division of Ultrasound who have already been regularly performing the procedures in actual cases but with no formal theoretical and hands-on training using a phantom model. Based on the feedback from this first group, the models were re-designed, improved, and optimized and were subsequently used by the second group of evaluators. The second evaluation was performed by 21 ultrasound subspecialists who had limited exposure to the performance of the procedures, with 18 providing feedback and answering the questionnaire.

The participant's responses were encoded and analyzed. Statistical analysis was performed using the software, JASP version 0.17.1.0. Descriptive statistics such as the frequency, percentage, median, and interquartile range were used to present the study variables. A series of z-tests of proportion and Wilcoxon rank-sum tests were used to compare the scores across the exposure of the participants to interventional procedures. A multiple percent bar chart was also used to display the distribution of the said ratings. All statistical analyses were used using a p-value less than 0.05 as basis for statistical significance.

This study is a collaborative work between the Department of Obstetrics and Gynecology UP-PGH and the Department of Mining, Metallurgical, and Materials

Engineering, UP-Diliman through the UP Surgical Innovations and Biotechnologies Laboratory (SIBOL) of the College of Medicine, UP Manila. The study protocol was submitted to the UP-PGH Ethics Review Board and was given a certificate of exemption from ethical review (UPMREB 2023-0284-EX).

RESULTS

A total of 37 respondents provided feedback and answered the questionnaire, 19 from the first group who have been routinely performing the guided procedures, and 18 from the second group who have limited exposure to these procedures. The respondents were 35 – 58 years old, who have been performing regular obstetric and gynecologic scans for 5 months to 26 years. Except for the 8 trainees, all other 29 participants have completed their fellowship training in ultrasound in obstetrics and gynecology. Those in the first group perform 1 to 4 interventional gynecologic procedures (biopsy, aspiration, paracentesis) monthly, whereas those in the second group have assisted or performed these procedures at most twice during their fellowship training.

Regarding the evaluation on the practical feeling of the phantom by appraising the image (sono-acoustic appearance and positioning of structures) and the materials used (compressibility and execution of the procedures, aspiration, and biopsy), both groups provided high scores of 4 and 5 (agree and strongly agree). Noticeable overall highest scores (5=strongly agree) were those of the US image created by the phantom which resembles structures or tissues, and the feeling of aspiration of fluid after needle insertion inside the phantom (Table 1).

Regarding the overall personal impression of the phantom, the respondents agreed that the model was suitable for use in simulation-based training for interventional US. Noticeable overall highest scores (5) were those pertaining to increasing confidence in terms of probe manipulation during

Table 1. Distribution of Responses to the Training across Exposure to Interventional Procedures

Characteristics	Overall	Routinely Performing	Limited Performance	p-value
Frequency	37 (100%)	19 (51.35%)	18 (48.65%)	-
Evaluation on the practical feeling of the phantom				
Q1. Do you agree that the ultrasound (US) image created by THE PHANTOM resembles structures or tissues that may be seen in the abdominopelvic cavity of the human body?	5 (4, 5)	5 (4, 5)	4 (4, 5)	0.88
Q2. Do you agree that the positioning of the structures in THE PHANTOM resembles the distribution or structures in the abdominopelvic cavity to help learn on probe manipulation for US image focusing, orientation, and optimization?	4 (4, 5)	5 (4, 5)	4 (4, 5)	0.30
Q3. Do you agree that the compressibility of the structures (firmness or softness or give) in THE PHANTOM resembles that in abdominopelvic cavity?	4 (4, 5)	4 (4, 5)	4 (4, 5)	0.67
Q4. Do you agree that the feeling of advancing a needle inside THE PHANTOM resembles advancing a needle in human soft tissue of a patient?	4 (4, 5)	5 (4, 5)	4 (4, 5)	0.54
Q5. Do you agree that the feeling of aspiration of fluid after needle insertion inside THE PHANTOM resembles that in the human tissue?	5 (4, 5)	5 (4, 5)	4 (4, 5)	0.24
Q6. Do you agree that the feeling of performing biopsy or obtaining tissue samples after needle insertion inside THE PHANTOM resembles that in a human tissue?	4 (4, 5)	4 (4, 5)	5 (4, 5)	0.42
Evaluation on overall personal impression				
Q7. Do you agree that THE PHANTOM is suitable for use in simulation-based training for interventional US in OB GYN?	4 (4, 5)	4 (4, 5)	4 (4, 5)	0.43
Q8. Do you agree that your confidence in performing US (in terms of probe manipulation for US image focusing, orientation, and optimization) improved after practicing simulation-based training in THE PHANTOM?	5 (4, 5)	5 (4, 5)	5 (4, 5)	0.59
Q9. Do you agree that your confidence in performing aspiration procedures improved after practicing simulation-based training in THE PHANTOM?	5 (4, 5)	5 (4, 5)	5 (4, 5)	0.56
Q10. Do you agree that your confidence in performing biopsy procedures improved after practicing simulation-based training in THE PHANTOM?	5 (4, 5)	5 (4, 5)	5 (4, 5)	0.65
Q11. After summing up all the factors, do you agree that performing the US-guided procedure in THE PHANTOM resembles that in a human body?	5 (4, 5)	5 (4, 5)	5 (4, 5)	0.91

median and interquartile range

Table 2. Perceived Distribution of Responses across Exposure to Interventional Procedures

Characteristics	Overall	Routinely Performing	Limited Performance	p-value
Frequency	37 (100%)	19 (51.35%)	18 (48.65%)	-
Do you have other comments that you think may help in the improvement of the phantom?	17 (100+)	11 (64.71+)	6 (35.29+)	-
Educational	5 (29.41+)	2 (18.18+)	3 (50+)	0.28
Confidence-booster	3 (17.65+)	1 (9.09+)	2 (33.33+)	0.21
Problem: durability	10 (58.82+)	6 (54.55+)	4 (66.67+)	0.63
Problem: track marks retention	1 (5.88+)	1 (9.09+)	-	0.45
Problem: lack simulation of some layer/s	2 (11.76+)	1 (9.09+)	1 (16.67+)	0.64
Other materials suggested	1 (5.88+)	1 (9.09+)	-	0.45
Availability for future use	1 (5.88+)	-	1 (16.67+)	0.16
Make more economical	1 (5.88+)	-	1 (16.67+)	0.16

procedure, and in the performance of both aspiration and biopsy procedures.

There were no notable differences between the groups in terms of evaluating the practical feeling and overall impression of using the models (Table 1). Figures 3 and 4, respectively, display the distribution of the ratings per question under the evaluation on the practical feeling of the phantom (questions 1-6) and the evaluation on overall personal impression (questions 7- 10).

The respondents in both groups also gave high scores, agreeing that their confidence in performing procedures improved after practicing simulation-based training in the models (Table 2). When asked for additional comments, some respondents found the models educational and considered them as “confidence-booster”. However, some recurring problems identified were durability, retention of needle track marks, and the lack of simulation of some layers. Only one respondent each commented on its future use and making

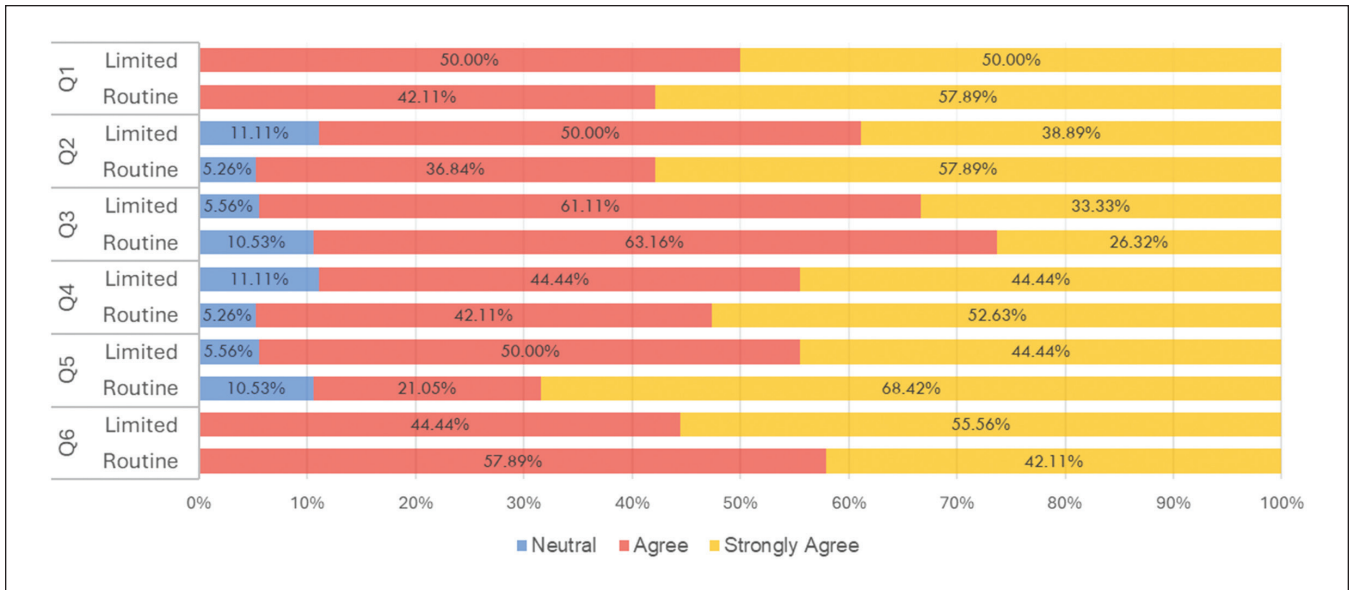


Figure 3. Distribution of responses to using the phantom across exposure to procedures.

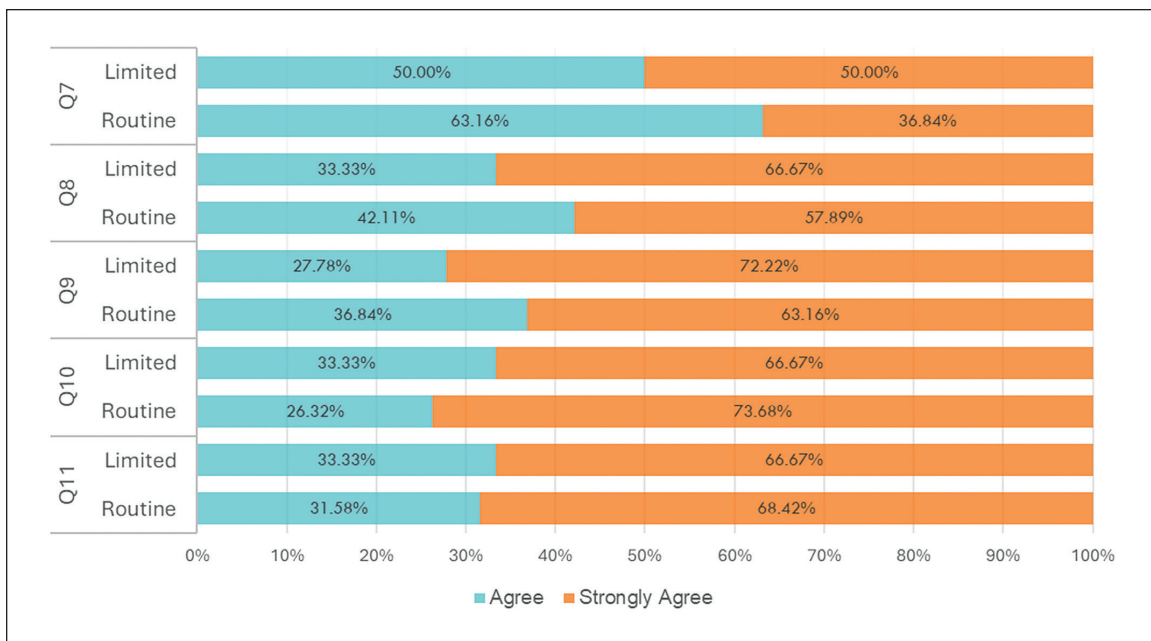


Figure 4. Distribution of perceived benefits to using the phantom across exposure to procedures.

the model more affordable. There were no notable differences between the groups in terms of perceived improvement or impact of using the phantom.

DISCUSSION

The evaluation of the developed phantom model showed positive reviews from the end users, both for those who have already been performing the procedures routinely and those with limited experience, in terms of the image

(sono-acoustic appearance and positioning of structures) and the materials used (compressibility and execution of the aspiration, and biopsy procedures). The results also showed an overwhelmingly good response on the improvement of their confidence when doing the scan while performing either aspiration or biopsy procedures. Although few, some respondents highlighted the problems identified with the developed phantom model used in this activity, specifically on durability, creation of artifacts from needle track marks, and the lack of simulation of some abdominopelvic layers.

The utilization of phantom and simulation models serves as a valuable tool for sonologists to enhance their skills and proficiency in performing procedures. While these models may not fully replicate all variables encountered in actual cases, as highlighted by one respondent's feedback (lack of simulation of some layers), they contribute significantly to refining teaching and training programs. The capacity to demonstrate, deconstruct, and then execute the procedure allows trainees to repeat and experiment with varying difficulty levels, a practice that should be done prior to handling and applying procedures to real patient scenarios.⁸ The present study primarily concentrated on assessing the acceptability and suitability of the locally developed model. While the results demonstrated a positive outcome and enhanced the respondents' confidence according to self-assessment, the evaluation did not extend to examining how the model could enhance the user's skill proficiency. Simulation-based training in ultrasound-guided procedures have demonstrated improvements in procedure time, skin punctures, needle adjustments, and subjective performance.⁹ However, a comprehensive systematic review involving 42 studies on simulated ultrasound-guided percutaneous abdominal and thoracic procedures highlights a lack of clear evidence in this aspect, primarily attributed to methodological challenges and a high risk of bias in the studies analyzed.¹¹

Various do-it-yourself phantom models are documented in the literature, each employing specific materials with unique advantages and drawbacks. The appropriate choice of materials in phantom model development has significantly enhanced the realism of training for operators in medicine, offering realistic imaging and tactile feedback essential for maneuvering during actual operations. In the realm of obstetrics and gynecology, however, further refinement is needed to improve the tactile feel, manipulation, and control for positioning internal organs or tissues during ultrasound-guided interventions. While the specific targets in this locally made phantom models replicate the photoacoustic response of specific tissues in the pelvic region, representation of each specific organs/structures, namely the cervix, corpus, ovaries, bladder, and adjacent bowels, properly positioned in the model is still not reflected. Nevertheless, the respondents found its design acceptable, specifically agreeing that the phantom resembles the distribution or structures in the abdominopelvic cavity to help learn on probe manipulation for US image focusing, orientation, and optimization (question 2). However, with either transabdominal or transvaginal approach, probe manipulation actions exert stress on phantom models, especially those based on gel materials, challenging their stability, durability, and reliability. In fact, one feedback given by the respondent is the problem of durability and creation of artifacts from needle track marks. Surprisingly, there is a lack of reports addressing these crucial aspects. Properties vital to these applications, including shear strength, rigidity, and potential degradation mechanisms, present opportunities for innovative strategies

that can enhance the materials' applicability in this specific medical training domain (a comprehensive discussion on this topic including evaluation of the physical properties of the materials, is described in another paper awaiting publication as of this writing). An exploration of these factors can pave the way for improved and more reliable phantom models in obstetrics and gynecology training. Nevertheless, despite these drawbacks, the phantom in its current form has been shown to be acceptable to the sonologists and suitable for training purposes regardless of their experience level.

In summary, the study involved 37 respondents, with 19 having routine experience in guided procedures and 18 with limited exposure. Both groups provided high scores for the practical feeling of the phantom, particularly regarding the ultrasound image resemblance and the sensation of fluid aspiration. Overall, respondents found the model suitable for simulation-based training, with notable increases in confidence for probe manipulation, aspiration, and biopsy procedures.

CONCLUSIONS

In conclusion, the study underscores the positive reception of the phantom model among users, irrespective of their experience level, with specific commendations for its ultrasound image representation and impact on users' confidence. However, some issues identified included concerns about durability, retention of needle track marks, and a lack of simulation for certain layers. Despite these challenges, the overall evaluation of the developed phantom model was positive, showcasing its acceptability for the end-users and suitability for training ultrasound-guided procedures.

Limitations and Recommendations:

This study acknowledges several limitations that warrant consideration. Although the assessment focused on the developed model's acceptability and appropriateness for simulating gynecologic ultrasound procedures for educational purposes, it did not measure users' proficiency in performing these procedures before and after engaging with the models, nor did it track skill progression over time. To provide a more comprehensive evaluation, future studies should incorporate proficiency assessments to gauge the impact of the training model on users' procedural skills and competence over different time intervals. Additionally, it is recommended to revisit and enhance the model based on feedback received from specialists, ensuring that any updates reflect the evolving needs and insights of the target user group. This iterative approach, similar to what the authors have done in this study, will contribute to refining the model's effectiveness and relevance in educational settings.

Statement of Authorship

All authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

All authors declared no conflicts of interest.

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