

Randomized, noninferiority study between video versus hand ultrasound with wet foam dressing materials to simulate B-lines in lung ultrasound

A CONSORT-compliant article

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Abstract

Background: This study evaluated the efficacy of a teaching method using simulated B-lines of hand ultrasound with a wet foam dressing material.

Methods: This prospective, randomized, noninferiority study was conducted on emergency medical technician students without any relevant training in ultrasound. Following a lecture including simulated (SG) or real video clips (RG) of B-lines, a posttest was conducted and a retention test was performed after 2 months. The test consisted of questions about B-lines in 40 randomly mixed video clips (20 simulated and 20 real videos) with 4 answer scores (R-1 [the correct answer score for the real video clips] vs S-1 [the correct answer score for the simulated video clips] in the posttest, R-2 [the correct answer score for the real video clips] vs S-2 [the correct answer score for the simulated video clips] in the retention test).

Results: A total of 77 and 73 volunteers participated in the posttest (RG, 38; SG, 39) and retention test (RG, 36; SG, 37), respectively. There was no significant ($P > .05$) difference in scores of R-1, S-1, R-2, or S-2 between RG and SG. The mean score differences between RG and SG were -0.6 (95% confidence interval [CI]: -1.49 to 0.11) in R-1, -0.1 (95% CI: -1.04 to 0.86) in S-1, 0 (95% CI: -1.57 to 1.50) in R-2, and -0.2 (95% CI: -1.52 to 0.25) in S-2. The mean differences and 95% CIs for all parameters fell within the noninferiority margin of 2 points (10%).

Conclusion: Simulated B-lines of hand ultrasound with a wet foam dressing material were not inferior to real B-lines. They were effective for teaching and simulations.

Trial registration: The study was registered with the Clinical Trial Registry of Korea: <https://cris.nih.go.kr/cris/index.jsp> (KCT0002144).

Abbreviations: CI = confidence interval, EMT = emergency medical technician, R-1 = the correct answer score for the real video clips from posttest, R-2 = the correct answer score for the real video clips from retention test, RG = the real B-lines video lecture group, S-1 = the correct answer score for the simulated video clips from the post-test, S-2 = the correct answer score for the simulated video clips from the retention test, SG = the simulated B-lines video lecture group.

Keywords: B-lines, education, pulmonary interstitial syndrome, ultrasound

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1. Introduction

Lung ultrasound has emerged as a useful technique in the diagnosis and treatment of various cardiopulmonary diseases.^[1] B-lines are regarded as sonographic vertical reverberation artifacts. They are very useful for differentiating diseases with cardiac or pulmonary origins because the exacerbation of chronic obstructive pulmonary disease, pulmonary embolism, pneumonia, and pneumothorax have noninterstitial sonographic patterns.^[1,2] However, it is difficult for novices or less experienced physicians to perform lung ultrasound, interpret the results, or obtain confident decisions in critical situations without adequate training.^[3] The significance of proper training for medical practitioners in the use of ultrasound has recently been emphasized.^[3,4]

Simulation training is an effective method for increasing clinical skills and improving decision-making processes.^[5-7] Shokoohi and Boniface^[3] have introduced a lung ultrasound simulation model using hand ultrasound that can be easily used. However, this modality does not allow the identification of B-lines.

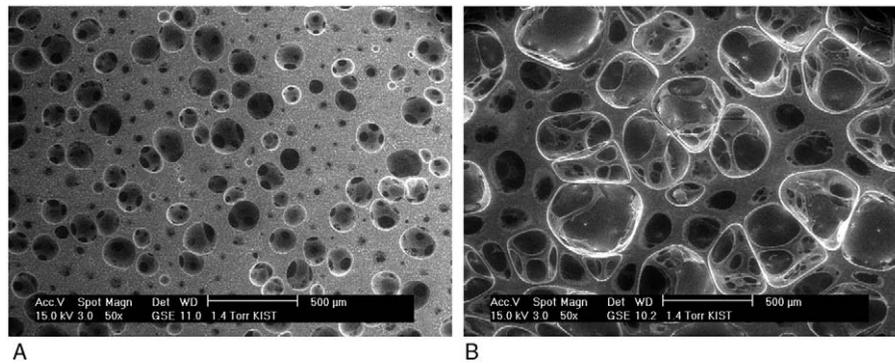


Figure 1. Microscopic structure of a wet foam dressing material (Medifoam by Ildong pharmaceuticals, Seoul, Korea). (A) The surface was 50 times magnified. (B) The surface of wet foam dressing material after soaking in water. It was also 50 times magnified. More than 2 layers of differently sized microbubbles and a curved cuneiform lamina of liquid and the origin of the B-lines are shown. The images were taken with an environmental scanning electron microscope (XL-30 Field Emission ESEM, FEI/Philips, the Netherlands).

The structure, acoustic impedance, porosity, and sound velocity of porous polyurethane in both normal and pathologic lung parenchyma (on the order of 10–100 μm) have been reported to be similar to each other.^[8] Soldati et al^[8] have reported that B-lines generated in a model of wet porous polyurethane have pore diameters ranging from 50 to 150 μm . We hypothesized that a wet foam dressing material made with porous polyurethane material soaked in water might be applicable for demonstrating B-lines similar to wet lung parenchyma. This dressing material consists of 3 layers with pore diameters ranging from 50 to 150 μm . Figure 1 shows the structure of the wet foam dressing material before and after soaking in water. Figure 2 depicts simulated B-lines. Our previous pilot study has revealed that simulated A-lines, lung sliding, and B-lines are sufficient enough to teach real lung ultrasound findings to medical students.^[9]

The aim of this study was to evaluate the effectiveness of a teaching method using simulated B-lines through hand ultrasound with wet foam dressing material for emergency medical technician (EMT) students without previous knowledge of ultrasound.

2. Materials and methods

2.1. Study design and setting

This prospective study was a randomized study to determine the educational effect according to the method used for teaching B-lines between July 11 and September 12, 2016. The conventional method for teaching B-lines in lectures consisted of video clips of real B-lines. The new method employed simulated B-lines. This study was approved by the Institutional Review Board (IRB) of Bundang Jesaeng hospital (IRB No.: EMC 16–02). It was registered with the Clinical Trial Registry of Korea (KCT0002144).

2.2. Participants

All participants enrolled in this study were EMT student volunteers who attended lectures about lung ultrasound without previous knowledge of ultrasound. These participants were first contacted during introductory lectures in their first classes of the semester and later by e-mail. Information about this study such as the aim, design, and lecture was not provided to students until the end of posttest because such knowledge might have biased study

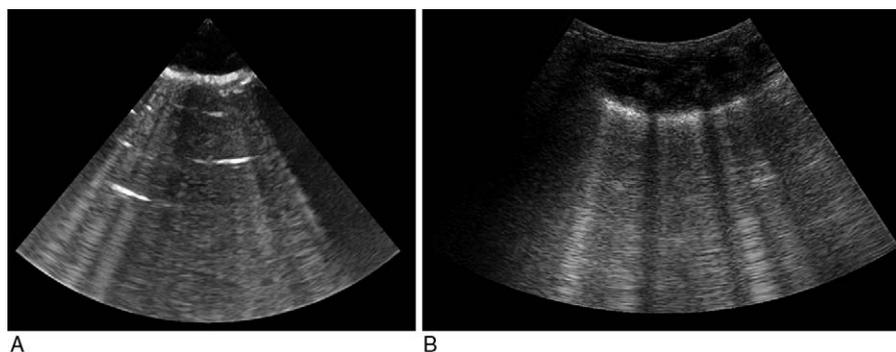


Figure 2. Simulated image showing a metacarpal bone with posterior shadowing. The hyperechoic narrow artifacts which simulate B-lines are visible. (A) Cardiac probe. (B) Convex probe. Although the evidence of the relation between radio-frequency signals and the generation of B-lines has not been well established, all probes with wet form dressing material in this study can generate B-lines. In our experience, it seems that the cardiac probe might be superior and easier to produce B-lines compared to other ones.

results and aims. At the end of posttest, the study purpose, simulated video clips, real video clips, and answers of the posttest were explained to and discussed with all students. Those who wanted to participate in the study were enrolled. Before obtaining consent, participants were informed that the study time would take up to 50 min for the posttest and that the retention test would take 20 min 2 months later.

2.3. Randomization

The participants were randomly assigned to 2 lecture groups by computer-generated randomization (www.graphpad.com/quickcalcs). The real B-lines video lecture group (RG) received a lecture on ultrasound using video clips of patients with real B-lines. The simulated B-lines video lecture group (SG) received a lecture using video clips of simulated B-lines.

2.4. Simulated B-lines

Simulated B-lines were produced by hand ultrasound with a wet foam dressing material using a 6 to 2 MHz convex probe and a 4 to 2 MHz cardiac probe by ACUSON X500 (Siemens, Mountain View, CA, USA). These B-lines were generated by an emergency-medicine board-certified attending physician who was also a member of World Interactive Network Focused on Critical Ultrasound (WINFOCUS) group and a faculty member with 10 years of experience in abdominal ultrasound, 8 years of experience in echocardiography, and 5 years of experience in lung ultrasound.

Simulated B-lines were defined as follows: hyperechoic narrow-based ring-down artifacts that spread like laser rays or rockets from the pleural line to the edge of the screen as previous definitions of B-lines; abolishment of A-lines; inclusion of 3 B-line types as B7- and B3-lines as well as confluent ones; and no white-lung inclusion. B-lines were defined as vertical artifacts from the pleura and those extended to the edge of the screen.^[1,2,8,10-12] Various patterns of B-lines have been reported depending on the degree of lung aeration loss. Pathologic B-lines have been shown to be ranging from a white lung (a completely white echographic

field with coalescent ultrasound lung comets but no horizontal reverberation) to B-lines at 7 mm apart.^[1,10-12] Multiple B-lines at a distance of 7mm are believed to indicate thickened interlobular septa characterizing interstitial edema (B7-lines).^[10-12] B-lines 3 mm or less apart are assumed to exhibit ground-glass areas characterizing alveolar edema (B3-lines or confluent lines).^[10,12] White lung might affect the alveolar wall by inflammatory cells and edema through the pleural surface between 2 septa.^[11,12]

The wet foam dressing material used in this study was Medifoam (Ildong pharmaceuticals, Seoul, Korea). It was squeezed gently after 4 min of soaking necessary for generating separated B-lines such as B3-lines, confluent lines, and B7 lines. In a previous study, the length of time for microporous polyurethane representing white lungs to become completely wet has been reported to be 4 min.^[8] The mean drying time to generate separate B-lines ranges from 34 to 50 min.^[8] Medifoam soaked in water was attached to a hand's dorsum. A transducer was placed on the palm. The transducer was perpendicularly positioned to the metacarpal bones mimicking the ribs and intercostal spaces. From this view, an anterior echogenic surface and posterior shadowing standing for rib echoes can be observed. Lung sliding and B-lines were simulated when the wet Medifoam attached on the dorsum of the hand was gently moved back and forth and video recorded (Fig. 2).

2.5. Intervention and measurements

Figure 3 outlines the study design. An emergency physician who had 3 years of experience in lung ultrasound conducted a 20-min lecture. This emergency physician was not a participant of this study. The lecture contained text organized by bullet points and pictorials as well as still ultrasound images and video clips of normal lungs in the absence of B-lines, lung sliding, B-lines, information about diseases, or situations that produced B-lines in patients. Information about the study was not conveyed to the instructor.

Following the lecture, the same tests were administered to both groups. A 20-min posttest was conducted after the lecture and a

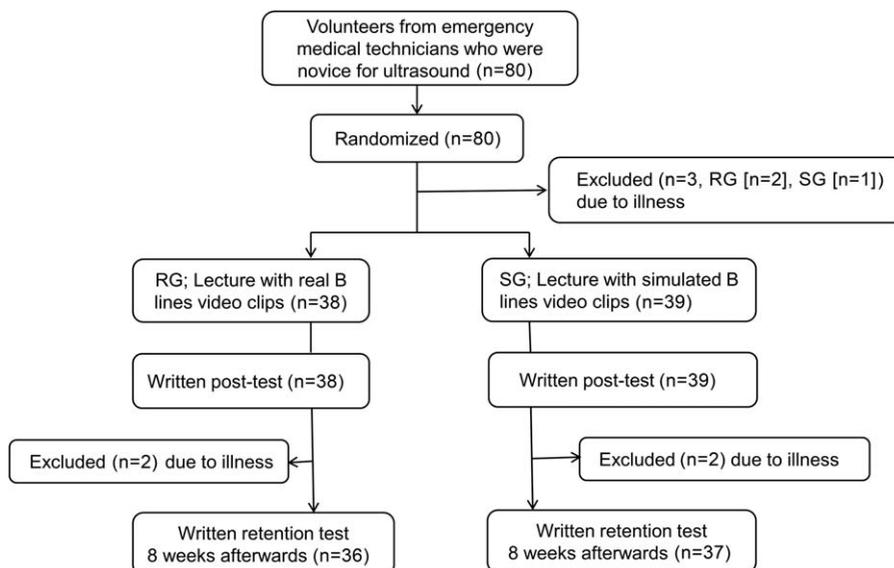


Figure 3. Flow chart of this study.

retention test was performed 2 months later. The test consisted of 40 video clips; each clip was inserted in 1 Microsoft PowerPoint slide, thus making a total of 40 slides. The 40 clips which consisted of 10 simulated B-lines, 10 simulated non-B-lines, 10 real B-lines, and 10 real non-B-lines were first numbered and randomized after using www.graphpad.com/quickcalcs: Randomization was conducted twice, once for the posttest and then for the retention test. The participants had 30 s to see 1 video clip and answer the binary question related to the presence or absence of B-lines. The same test was administered for the retention test except that the order of the video clips was re-randomized as mentioned previously. RG and SG were separated during and after the lecture for absolute blocking of information exchange. The lecturer moved to the second classroom to present the same lecture and conducted the posttest without a break in between for the same reason. R-1 was defined as the correct answer score for the real video clips and S-1 was defined as the correct answer score for the simulated video clips from the posttest. R-2 was defined as the correct answer score for the real video clips and S-2 was defined as the correct answer score for the simulated video clips from the retention test. Twenty points were the highest score for R-1, S-1, R-2, and S-2 each.

2.6. Data analysis

All data were analyzed using SPSS 23 statistics software (SPSS, Inc, Chicago, IL). Continuous data were expressed as means and standard deviations. Categorical data were treated as absolute values. Chi-square tests were performed to compare gender differences between the 2 groups. The difference in scores (R-1, S-1, R-2, S-2) between RG and SG was analyzed using Mann–Whitney *U* test or independent *t* tests. Comparisons between R-1 and S-1 (or R-2 and S-2) in 1 group (RG or SG) were conducted with Wilcoxon rank test or paired *t* test.

Power analysis for the primary hypothesis was based on a pilot study involving teaching and testing 20 inexperienced individuals (RG, 10; SG, 10), yielding a common standard deviation of 2.85 for the total score points. Based on this, difference in S-1 or R-1 between groups in excess of 2 out of a total of 20 points was declared to be noninferior.^[4] This prespecified 2-point (10%)

noninferiority margin was determined with a 5% 2-sided significance level, 90% power, and a 1:1 sample size ratio. A total of 35 participants were needed for each group. Anticipating dropout, the sample size was increased to 40 participants for each group.

3. Results

A total of 77 out of 80 EMT students participated in the posttest (RG, *n* = 38, SG, *n* = 39, Fig. 3) and 73 participants of the posttest completed the retention test (RG, *n* = 36, SG, *n* = 37, Fig. 3). There was no statistically significant difference in age or gender for the posttest or retention test between the 2 groups (*P* = .443, *P* = .731, *P* = .337, *P* = .555, Table 1).

Results of independent *t* test, paired *t* test, and difference with 95% confidence intervals (CIs) in posttest and retention test are summarized in Table 1. Independent *t* test revealed that there was no significant difference in scores of R-1, S-1, R-2, or S-2 between RG and SG (R-1, *P* = .157; S-1, *P* = .848; R-2, *P* = .542; S-2, *P* = .534). Paired *t* tests revealed that the score difference between R-1 and S-1 in RG or between R-2 and S-2 in RG was insignificant (differences between R-1 and S-1 in RG, *P* = .065; difference between R-2 and S-2 in RG, *P* = .066). However, the difference between R-1 and S-1 in SG and between R-2 and S-2 in SG was significant (*P* < .01, *P* = .044). However, R-1 and R-2 (correct answer score of real video clips) in SG is greater than S-1 and S-2 (correct answer score of simulated video clips) in SG (Table 1).

Results of score difference in R-1, S-1, R-2, and S-2 between RG and SG considering the noninferiority margin of 2 points (10%) in posttest and retention test are shown in Figure 4A. The difference in each score between RG and SG was assessed, yielding mean difference of −0.6 points (95% CI: −1.49 to 0.11) in R-1, −0.1 (95% CI: −1.04 to 0.86) in S-1, 0 (95% CI: −1.57 to 1.50) in R-2, and −0.2 (95% CI: −1.52 to 0.25) in S-2 (Fig. 4A). Results of difference between R-1 and S-1 or between R-2 and S-2 in SG or RG considering the noninferiority margin of 2 points (10%) in posttest and retention test are shown in Figure 4B. The mean score difference between R-1 and S-1 was −0.7 points (95% CI: −0.09 to 1.35) in RG and −1.2 points (95% CI: 0.83 to

Table 1
B-lines' scores, and 95% CI between groups in the posttest and the retention test.

	RG	SG	Difference in 95% CI between RG and SG	<i>P</i>
Posttest				
Gender (M:F)	18:20	20:19		.731
Age	22.8 ± 1.2	22.5 ± 1.0	−0.19 to 0.80	.443
B-lines out of 20 in the posttest				
Real video clips (R-1)	17.1 ± 2.0	17.7 ± 1.4	−1.49 to 0.11	.157*
Simulated video clips (S-1)	16.4 ± 2.4	16.5 ± 1.8	−1.04 to 0.86	.848*
Difference in 95% CI between R-1 and S-1	−0.09 to 1.35	0.83 to 1.63		
<i>P</i> value	.065†	<.001†		
Retention test				
Gender (M:F)	16:20	19:18		.555
Age	22.9 ± 1.2	22.5 ± 1.0	−0.17 to 0.87	.337
B-line out of 20 in the retention test				
Real video clips (R-2)	14.7 ± 3.0	14.7 ± 3.5	−1.57 to 1.50	.542*
Simulated video clips (S-2)	14.1 ± 3.2	14.3 ± 2.8	−1.52 to 1.25	.534*
Difference in 95% CI between R-2 and S-2	−0.04 to 1.15	−0.10 to 1.02		
<i>P</i> value	.066†	.044†		

CI = confidence interval, RG = the real B-lines video lecture group, SG = the simulated B-lines video lecture group.

* *P* values were calculated by independent *t* test to compare S-1 or Mann–Whitney *U* test to compare R-1, R-2, and S-2 between RG and SG.

† *P* values were calculated by Wilcoxon rank test to analyze the differences between R-1 versus S-2 and R-2 versus S-2 in each group (RG or SG).

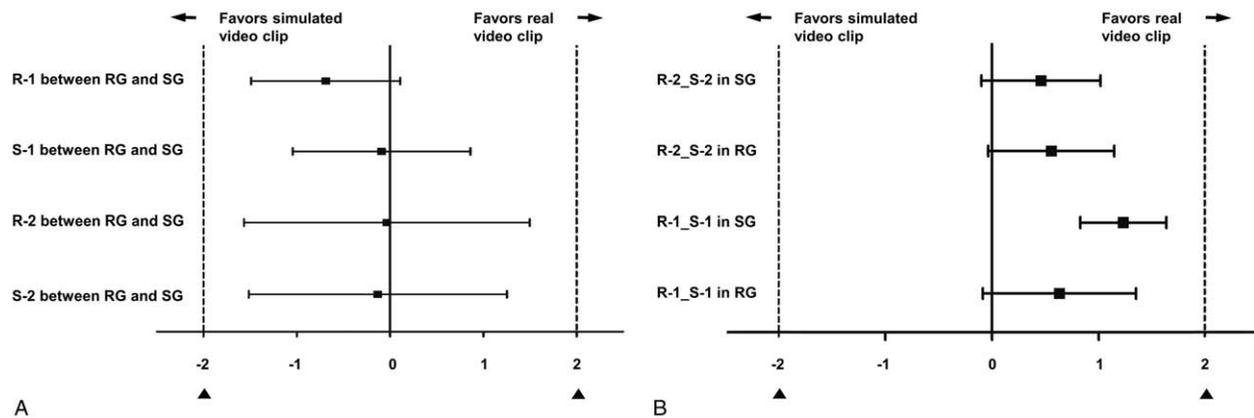


Figure 4. Primary outcome. (A) X axis showing difference in R-1, S-1, R-2, or S-2 between RG and SG. (B) X axis displaying difference between R-1 and S-1 or between R-2 and S-2 for each group (RG or SG). Data are presented as the arithmetic mean with 95% CIs. The dashed line at $X = \pm 2.0$ points indicates noninferior margins. CI = confidence intervals, R-1 = the correct answer score for the real video clips from posttest, R-2 = the correct answer score for the real video clips from retention test, RG = the real B-lines video lecture group, S-1 = the correct answer score for the simulated video clips from the posttest, S-2 = the correct answer score for the simulated video clips from the retention test, SG = the simulated B-lines video lecture group.

1.63) in SG (Fig. 4B). The mean score difference between R-2 and S-2 was -0.6 points (95% CI: -0.04 to 1.15) in RG and -0.4 points (95% CI: -0.10 to 1.02) in SG (Fig. 4B). The mean difference with 95% CI for all parameters fell within inferior margins. Therefore, B-lines generated by simulation were noninferior to real B-lines.

Both groups demonstrated similar decline in retention test for video clips included in the test. The score difference between R-1 and R-2 was -2.5 ± 3.2 in RG and -3.0 ± 3.8 in SG ($P = .528$). The score difference between S-1 and S-2 was -2.3 ± 3.7 in RG and -2.2 ± 3.2 in SG ($P = .912$).

4. Discussion

In this study, the teaching method using B-lines simulation of hand ultrasound with wet foam dressing material made of microporous polyurethane was found to be not inferior to traditional real B-lines. Testing the teaching method for EMT students who had no prior knowledge of lung ultrasounds or B-lines revealed that the scores in posttest and retention test between SG and RG did not differ significantly. The retention test score was declined regardless of group. There was no intergroup statistical significance. Therefore, we conclude that B-lines simulated with hand ultrasound using wet foam dressing material can be used as a simple, real-time, reproducible, and readily available teaching method.

Shokoohi and Boniface^[3] proposed a method to simulate lung ultrasound with hand ultrasound, which is very easy, simple, effective, and reproducible for A-lines and pleural sliding. However, it cannot simulate B-lines.^[3] The wet foam dressing material used in this study consisted of microporous polyurethane with acoustic impedance and density similar to that of lungs.^[8,13] Previous experimental studies have demonstrated that B-lines were generated using wetted microporous polyurethane.^[8,11] As shown in Figure 1B, the wet foam dressing material soaked with water makes a path for an ultrasonic pulse composed of more than 2 layers of different-sized microbubbles, believed to be the origin of the B-lines.^[8,11] The hands-on training of lung ultrasound and B-lines in the context of ultrasound courses is rarely possible in the context of clinical situations as patients tend to be critically ill. B-lines generated with a hand

ultrasound of wet dressing materials might be useful to teach lung ultrasounds by generating lung sliding, A-lines, and B-lines. A previous study reported 12 features for improving the effect of training, including deliberate practice and skill acquisition.^[3] Previous studies reported that motivation and interactive education are an important factor for deliberate practice in adult learning and the use of the sensorimotor skills (hand-eye coordination, guidance of the ultrasound probe) improved skill acquisition.^[14,15] From such pedagogical points of view, the hand ultrasound with wet foam dressing materials might be helpful in a hands-on ultrasound course in a small group compared to that using only video clips or electronic tools to educate B-lines by achieving the goal of deliberate practice and skill acquisition among pedagogical perspectives. If a teacher and learner cooperate to generate B-lines using this simulation model during hands-on courses in a small group, the learner tries to hold and locate the probe on his/her palm to be perpendicular to the surface of the hand and communicates with the teacher to acquire the correct B-lines. In this situation, a learner tries to locate the probe correctly and obtain its best scan plane, watching B-lines directly generated by the learner her/himself. In this situation, this simulation education method can provide feedback regarding the skill to hold and locate a probe to be perpendicular to the surface of the hand (one of the essential techniques that learners need to gain), the direct outcome measurement (generation of B-lines), and monitoring learners' skill themselves with a teacher. In such a situation, these educational processes can provide high motivation, well-defined objectives, informative feedback from a teacher, and focused, repetitive practice among the goals of deliberate practice. Skill acquisition can be achieved by a learner trying to hold and locate a probe correctly, which is one of the essential techniques that novice learners need to acquire. This simulation model of B-lines might have a greater advantage in situations including offline or bedside teaching, which is available neither on the Internet nor on the video clips. However, the simulation using an ultrasound with a wet foam dressing might have low-simulation fidelity because this model cannot provide reality similar to a real chest, such as well-made physical or hybrid models or real persons. This point can be a limitation to use this simulation model in a hands-on course in small groups. Also, the aforementioned educational effects of this simulation

have not been amply proven in this study because this study evaluated whether B-line images generated using this simulation can satisfy the needs to express the characteristics of the B-lines for use in educational purposes adequately. However, the authors believe that the previous studies and pedagogical theories can surely support such possibilities of the educational effects of this simulation method.^[3,14–16]

One limitation of this study is that various types of B-lines observed in septal, interstitial, and interstitial-alveolar syndromes were not generated because it was hard to control the density and distribution of microbubbles in the wet foam dressing material soaked in water. Further research is needed to delicately and quantitatively control the soaking and drying time of the wet foam dressing material. The use of video clips for training and testing was another limitation because they could not impart all the skills necessary to obtain an image. However, this might have had a negligible effect on this study because lung ultrasound is easy to obtain with high interobserver agreement.^[17,18]

In conclusion, a wet foam dressing material made with microporous polyurethane and soaked in water can be used to generate simulated B-lines. The simulation-based method of teaching using hand ultrasound with wet foam dressing material soaked in water is useful for hands-on training and bedside teaching. This might improve students' performance in acquiring and interpreting images of real patients with respect to B-line pathologies.

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