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Training Thoracic Ultrasound Skills: A Randomized Controlled Trial of Simulation-Based Training versus Training on Healthy Volunteers

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Keywords
Ultrasound · Education · Training · Chest ultrasound · Simulation

Abstract
Introduction: As ultrasound becomes more accessible, the use of point-of-care ultrasound examinations performed by clinicians has increased. Sufficient theoretical and practical skills are prerequisites to integrate thoracic ultrasound into a clinical setting and to use it as supplement in the clinical decision-making. Recommendations on how to educate and train clinicians for these ultrasound examinations are debated, and simulation-based training may improve clinical performance. ***Objectives:*** The aim of this study was to explore the effect of simulation-based training in thoracic ultrasound compared to training on healthy volunteers. ***Method:*** A total of 66 physicians with no previous experience in thoracic ultrasound completed a training program and assessment of competences from November 2018 to May 2019. After a theoretical session in ultrasound physics, sonoanatomy, and thoracic ultrasound, the physicians were randomized into one of three groups for practical training: (1) simulation-based training, (2) training on a healthy volunteer, or (3) no training (control group). Primary outcome was difference in the clinical performance score after the training period. ***Results:*** Using a multiple comparison, ANOVA with Bonferroni correction for multiplicity, there was no statistical significant difference between the two trained groups' performance score: 45.1 points versus 41.9 points (minimum 17 points, maximum 68 points; $p = 0.38$). The simulation-based training group scored significantly higher than the control group without hands-on training, 36.7 points ($p = 0.009$). ***Conclusions:*** The use of simulation-based training in thoracic ultrasound does not improve the clinical performance score compared to conventional training on healthy volunteers. As focused, thoracic ultrasound is a relatively uncomplicated practical procedure when taught; focus should mainly be on the theoretical part and the supervised clinical training in a curriculum. However, simulation can be used instead or as an add-on to training on simulated patients.

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Background

Technical development has made ultrasound easily accessible, and bedside ultrasound examinations are made daily by clinicians within all specialties. Ultrasound can promote a fast onset of therapy, optimize diagnosis, and save time in the primary assessment or as monitoring of patients with respiratory symptoms or suspected for pulmonary disease [1–3].

Thoracic ultrasound examinations are considered safe, without exposure to radiation or delay of patients' course, but ultrasound in general is highly operator dependent [4]. Lack of sufficient theoretical knowledge or practical skills can lead to misinterpretation, incorrect diagnosis, and thus treatment.

The widespread implementation of an operator-dependent procedure results in an increased demand for structured educational programs and courses. Guidelines and recommendations on minimum training requirements have been presented by several societies and federations, but so far, the evidence behind these recommendations is sparse [5–7]. Practical hands-on training on healthy volunteers is a commonly used training method but suffers from the limitations that healthy volunteers do not present any pathological artefacts. The ultrasound images are the same in all scanned zones, and the physician will not be exposed to pathological images during hands-on training when scanning healthy volunteers or simulated patients. Simulation-based medical education has been shown to accelerate the learning curve in the early stage of ultrasound training in several different ultrasound examinations [8–10]. The possibility to simulate pathological ultrasound artefacts is one advantage. Simulation can combine the simulated pathological images with cases so that the physician can blend a patient history with the practical execution and come up with a potential diagnosis. Additionally, it is possible to train critical or acute diagnoses repeatedly without interruptions or exposing the patients to risk. However, the efficacy of simulation-based training for learning transthoracic ultrasound has not been tested in a randomized trial [11]. The objective of this randomized controlled trial is to explore the immediate effect of simulation-based training compared to conventional training on healthy volunteers and no hands-on training, measured by clinical performance score.

Methods

Trial Design

The study was a three-armed, multicenter, blinded randomized controlled trial registered at clinicaltrials.gov (Identifier: NCT03728491), and reported according to the Consolidated Standards of Reporting Trials (CONSORT) [12]. The Regional Committee on Health Research Ethics for Southern Denmark assessed the study and found it not notifiable.

The trial took place at three simulation centers in Denmark: at Odense University Hospital, Rigshospitalet, and Aarhus University Hospital from November 2018 to May 2019. All data were entered and handled in an online database; Research Electronic Data Capture hosted by Odense Patient data Explorative Network [13], in which the randomization generation was also done. The allocation ratio was 1:1:1 with block allocation of 6 and 9; no stratification for site (location) was made.

Participants

Physicians employed at public hospitals in Denmark without previous experience in thoracic ultrasound were eligible for inclusion in the trial. No exclusion criteria were established based on specialty, department of employment, or years of clinical experience, but physicians close related to instructors or members of the project group were not allowed to be included.

Promotion of and invitation for the educational program and trial was done through posters at departments, social media, and educational groups. Physicians signed up for participation and inclusion by e-mail and received a reply including written information about the trial. First author (P.I.P.) enrolled the participants, and the enrolled physicians filled out an online questionnaire regarding previous experience with ultrasound in general and TUS (to ensure that they were all novices), current position and employment and received a study identification number to pair the results from the questionnaire to the intervention and performances. Exclusion criteria were lack of informed consent, and physicians involved in the study design, planning, or conduct of the trial.

Prior to Randomization and Intervention

When enrolled, all included physicians completed an online theoretical session in sonographic physics, knobology, TUS protocol, sonographic anatomy, normal TUS, and pathological TUS. Participants had to pass a theoretical test developed and validated prior to this study in order to reach sufficient theoretical knowledge prior to hands-on training [14]. The theoretical educational program was presented as an online platform comprising text, podcasts, and ultrasound clips and was provided by publishing company, Munksgaard [15]. The content fulfilled the recommendations and publications in clinical thoracic ultrasound provided by the American Thoracic Society [16, 17], European Respiratory Society [18, 19], and European Federation and Society for Ultrasound in Medicine and Biology [5].

Intervention

After completion of the theoretical test and within 3 weeks, the participants were invited to one of the three medical educational simulation centers in Denmark. All participants received a brief introduction to the ultrasound machine (GE LOCIQ S8) used in the project. The introduction comprised how to turn on/off the

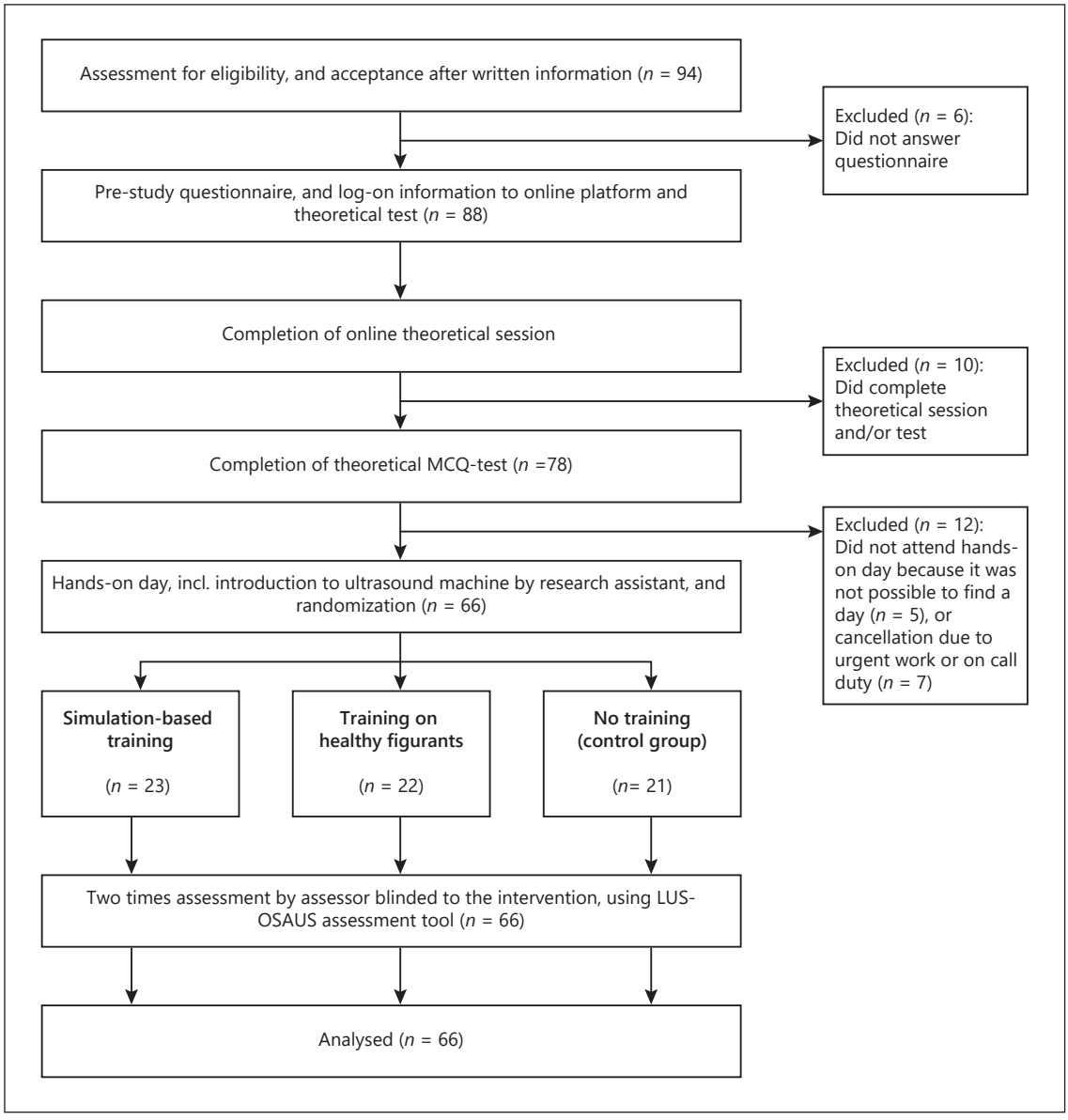


Fig. 1. Flowchart of study showing participant enrollment, randomization, and allocation of intervention. LUS-OSAUS, lung ultrasound objective structured assessment of ultrasound skills.

machine, select and change transducer, select preset, adjust depth, gain and focus, and store images/clips but did not comprise any theory on thoracic ultrasound. Randomization was computer generated and was performed using Research Electronic Data Capture. Participants were randomized into one of the three groups: (1) unsupervised training on a virtual-reality ultrasound simulator, (2) unsupervised training on a healthy volunteer, or (3) no training (control group), see Figure 1.

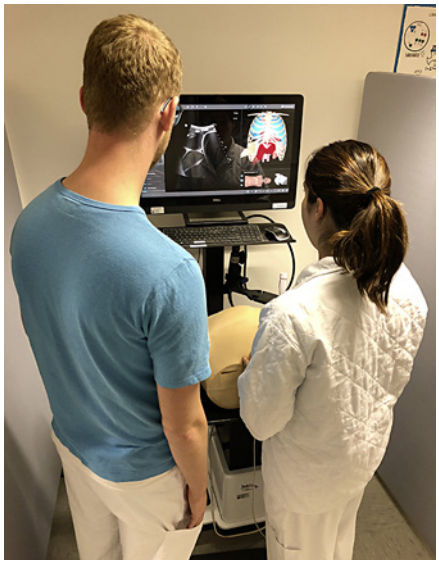
The thoracic ultrasound module for the US Mentor Simulator was made in collaboration with 3D Systems (3D Systems Healthcare, Littleton, CO, USA, formerly known as Simbionix) and previously described and validated (see Figure 2 [20]). A project coordinator assisted the participants in how to change the cases (patient history and pathologies) in the lung module but did not provide any comments or supervision on the training. Participants in the first and second group were allowed to train up to 2 h but could end the hands-on training when they felt confident in the procedure.

Outcomes

Immediately after the intervention, all participants were assessed twice while scanning patients in a clinical setting (emergency department, department of respiratory medicine, or department of cardiothoracic surgery). The assessor (P.I.P.) was blinded to the intervention, and thereby training modality, and provided all assessments in the study to decrease potential interrater vari-

Table 1. Participant demographic and characteristics

	Simulation-based training (n = 23)	Training on healthy volunteer (n = 22)	No training (control group) (n = 21)
Age, mean (SD)	31.2 (4.5)	30.3 (6.2)	31.3 (6.9)
Gender, n (%)			
Female	13 (56.5)	12 (54.5)	13 (61.9)
Male	10 (43.5)	10 (45.5)	8 (38.1)
Education/career, n (%)			
Consultant	1 (4.4)	2 (9.1)	2 (9.5)
Senior registrar	2 (8.7)	3 (13.6)	1 (4.8)
Registrar	7 (30.4)	3 (13.6)	8 (38.1)
Senior house officer	13 (56.5)	14 (63.6)	10 (47.6)
Specialty, n (%)			
Respiratory medicine	6 (26.1)	5 (22.7)	2 (9.52)
Emergency medicine	9 (39.1)	10 (45.5)	11 (52.4)
Other	8 (34.8)	7 (31.8)	8 (38.1)
	General practitioner (n = 1)	General practitioner (n = 4)	General practitioner (n = 2)
	Internal Medicine (n = 2)	Internal Medicine (n = 2)	Internal Medicine (n = 3)
	Rheumatology (n = 1)	Rheumatology (n = 1)	–
	Geriatrics Medicine (n = 1)	–	Geriatrics Medicine (n = 1)
	Nephrology (n = 1)		Cardiology (n = 1)
	Neurology (n = 1)		Hematology (n = 1)
	Urology (n = 1)		



Color version available online

Fig. 2. Physicians training on the simulator.

ance. Primary outcome was difference in lung ultrasound objective structured assessment of ultrasound skills (LUS-OSAUS) score between the three groups; the adjusted assessment tool is presented in Figure 3 [21]. The LUS-OSAUS score is calculated as the sum of all 17 items in the tool and were then recalculated so that minimum was 0 and maximum was 68 (originally: min. 17, max. 85 point). The conversion was made to increase the intuition, so that zero points corresponded to a very bad and incomplete performance, and the conversion did not change the validity of the clinical performance score. The LUS-OSAUS tool is, to our knowledge, the first assessment tool with established evidence of validity even though several assessment tools have been developed [7, 22]. Secondary outcomes were differences in time used for hands-on training and time used for performing the ultrasound examinations.

Statistical Analyses

Sample size calculation was performed prior to the trial, based on the LUS-OSAUS score by Skaarup et el [21]. Expected clinically relevant difference in the LUS-OSAUS score was 8.5 points (a mean of 0.5 point in each item). The assumption was made by the author group, which used to work with the LUS-OSAUS score for educational purposes. Twenty-two participants in each group were needed to get a level of significance at 5% (alpha = 0.05) and a power of 90% (beta = 0.1).

Participant demographics and descriptive analysis of participant characteristics were performed by means of frequency distribution and mean, standard deviations, median, and range. Assessment scores were calculated as means and confidence intervals. A two-way ANOVA with Bonferroni correction for multiplicity was performed with training modality (intervention) as independent variable and assessment scores as dependent variable in order to compare the results.

Primary investigator (P.I.P.) and co-author (L.K.) analyzed the data using SPSS (IBM SPSS Statistics version 22), and L.K. was blinded to the randomization groups during the analysis. A two-sided significance level $p < 0.05$ was used for all analyses.

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Focused lung ultrasound – assessment

	0	1	2	3	4
Indication					
Evaluates the inducations for lung ultrasound	Not suffiecient		Some		Sufficient
Suggests focused questions that can be examined by lung ultrasound	Not suffiecient		Some		Sufficient
Systematic lung ultrasound examination					
Performs lung ultrasound systematically	No systematic approach		Some systematic approach		Sufficient systematic approach
Performs lung ultrasound on the basis of focused questions	No correlation between focused questions and scanning		Some correlation between focused questions and scanning		correlation between focused questions and scanning
Technical skills					
Correst placement of patient (e.g., supine when scanning for pneumothorax)					Optimal placement
Correst choice of transducer					Optimal choice
Correct depth					Optimal depth setting
Correct gain					Optimal setting
Correct handling of transducer					Optimal transducer handling
Findings					
Correct assessment of pleura	Not properly assessed		Properly assessed sometimes		Properly assessed every time
Correct assessment of B-lines	-		-		-
Correct assessment of consolidation	-		-		-
Correct assessment of pleura effusion	-		-		-
Correct assessment of whether ultrasond guided thoracocentesis is safe	-		-		-
Documentation					
Documents findings in patient's chart	Findings not described		Main findings described		Described sufficiently
Conclusion					
Able to make a diagnosis on the basis of the lung ultrasound findings	No diagnoses made		Some diagnoses		Correct diagnoses
Able to integrate lung ultrasound findings with patient's history	No integration		Some integration		Optimal integration

Adjusted from Skaarup SH, Laursen CB, Bjerrum AS et al. Objective and Structured Assessment of Lung Ultrasound Competence. A Multispecialty Delphi Consensus and Construct Validity Study. Annals of the American Thoracic Society 2017; 14: 555-560

Fig. 3. Clinical assessment tool used for evaluation of participants scanning patients with respiratory symptoms or pathology in a clinical setting. Modified after Skaarup et al. [21].

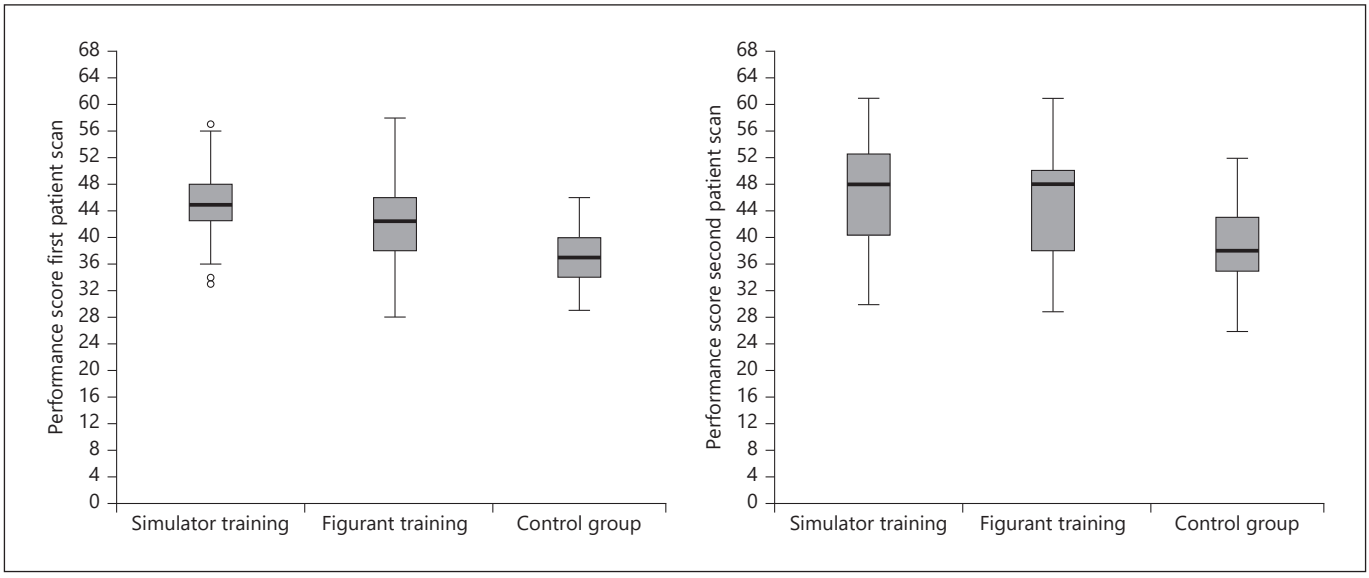

Fig. 4. Boxplot of first and second performance scores. Mean scores of the simulation-based training group were 45.1 points (95% CI 42.2–47.9) at the first assessment and 46.4 points (95% CI 42.9–49.8) at the second clinical assessment. The group training on a healthy volunteer scored a mean of 41.8 points (95% CI 38.4–45.3) and 45.2 (95% CI 41.4–49.1). The control group had no hands-on training prior to assessment, but they succeeded to score 36.7 points (95% CI 34.6–38.9) in first assessment and 38.5 points (95% CI 35.6–41.5) in the second assessment.

Results

Of 94 participants enrolled at the three simulation centers from November 2018 to June 2019, 66 completed the trial. Trial design including participant enrollment, randomization, and clinical assessment is presented in Figure 1. Participant demographic and characteristics are shown in Table 1.

Mean scores of the simulation-based training group were 45.1 points (95% CI 42.2–47.9) at the first assessment and 46.4 points (95% CI 42.9–49.8) at the second clinical assessment. The group training on a healthy volunteer scored a mean of 41.8 points (95% CI 38.4–45.3) and second, 45.2 (95% CI 41.4–49.1). The difference in the LUS-OSAUS performance score between the intervention groups was 3.3 points in the first assessment and 1.2 points in the second assessment and proved no statistically significant difference (p = 0.384). The median LUS-OSAUS scores for each group including interquartile and minimum and maximum scores are presented in 2 boxplots in Figure 4.

Using the ANOVA with Bonferroni corrections for multiplicity, the simulation-based group performed significantly better than the control group (p = 0.09) but the group training on healthy volunteers did not (p = 0.370). There was no statistically significant difference in time used for the ultrasound examinations dependent of hands-on training modality either in the first assessment (15.6, 18.2, and 20.0 min, respectively) or in the second assessment (13.8, 15.4, and 15.6 min), but the overall decrease of 9 min from the first to the second examination was statistical significant ($p > 0.05$).

We compared the second assessment score of the control group to the first assessment scores of the trained groups in order to explore the effect of one test scan on a real patient. The descriptive results of this analysis and the comparisons are presented in Table 2. There was a significant difference in LUS-OSAUS between the simulation-based training group (first assessment) and the control group (second assessment) but not between the results from the group training on healthy volunteers (first assessment) and control group (second assessment).

Discussion

This study showed no statistically significant difference between the 2 hands-on training modalities assessed. The third group who went directly from the theoretical part of the study to the clinical assessment performed better than expected. The results could indicate that thoracic ultrasound has a very steep learning curve because of

Table 2. Descriptive and comparison statistics for the comparison of the second control group performance to the first training group performances

	Mean score (points)	95% confidence interval	min, max
Simulation-based training (1st assessment)	45.1	42.2–48.0	33, 57
Training on healthy figurant (1st assessment)	41.9	38.4–45.3	28, 58
No training (control group) 2nd assessment	38.5	35.6–41.5	26, 52
ANOVA multiple comparison with Bonferroni correction for multiplicity	Mean difference (points)	95% confidence interval	Sig.
Control group vs. simulation-based training group	−6.6	−11.8 to −1.3	0.009
Control group vs. training on healthy figurant	−3.3	−8.6 to 1.9	0.370

the small difference in the performance score between the trained and not-trained groups. Therefore, main focus should be on the theoretical knowledge and clinical supervision when integrating the ultrasound examination in the clinical decision-making.

We found that simulation-based training effectively can be incorporated in an educational program and can contribute to the visualization of pathological ultrasound patterns which not are to be seen when scanning healthy volunteers.

The European Respiratory Society has launched a new educational program in thoracic ultrasound that include the parts; (I) a theoretical session, (II) a practical session, and (III) an examination at the ERS congress [23]. However, due to the limited number of seats for the course and costs, there is still a need of structured training programs at national or institutional level.

Several studies have presented and assessed different educational strategies for training thoracic ultrasound [11]. A minor part of the studies evaluated simulation-based training, but most used a pretest-posttest study design comparing a pre-educational assessment with a post-educational assessment. In educational research this study design is considered obsolete [24, 25]. It proves that the trainees have obtained a learning outcome but not whether they have learned in the most effective way, and the design is susceptible to several validity threats. Others study and compare simulation-based training with no training which does not add any evidence on the science of education.

To our knowledge this is the first randomized trial comparing different hands-on training modalities for thoracic ultrasound. Validity evidence has been established for the lung ultrasound module on the simulator used in the study, but this does not equal significant effect of practical training or transfer to a clinical setting [20].

Simulation-based medical education and simulation-based assessment of competence have gained substantial attention within the last decades [10, 26–29]. Simulation-based medical education has been shown to accelerate the level of competence in the beginning of the learning curve, and it is a complex educational intervention that enables both immersive and experimental learning. Thereby, it is possible to acquire and maintain skills in a calm environment [9, 27, 30]. The trainee is able to practice a particular case or high risk repeatedly if doubt arises, without consequences if wrong interpretations are made or if the trainee does not provide a satisfying result. Simulators can be expensive, and without solid educational research on the utility and effect, it is hard to define how the simulators should be used and incorporated in a curriculum [31–33]. Simulation-based training is proven advantageous among others due to the possibility of providing several ultrasound pathologies and the capability to change and train cases over and over again. It suffers as well from disadvantages such as requiring updates, maintenance, need of an instructor in the beginning for introduction, and for emphasizing trainee reflection and peer review elements [30]. Last, but not least, simulation training cannot replace traditional apprenticeship or stand alone but must be seen as an add-on approach prior to supervised training in a clinical setting [30, 34]. As thoracic ultrasound is a relatively simple, safe, and uncomplicated procedure with high accuracy [1–4], this study advocates that thoracic ultrasound can easily be learned with or without simulation.

The second performance of the control group reached a performance score that was not statistically significant

different from the group training on healthy volunteers and closer to the simulation-based group's score. This aspect demonstrates that only very few procedures are required in order to perform an examination that is sufficient when adequate theoretical knowledge has been demonstrated. These findings indicate a short and very steep learning curve (i.e., the procedure is quickly learned) and are aligned with results in published literature [4, 35, 36].

An arbitrary and fixed number of procedures are often needed to prove adequate skills and knowledge according to the recommendations from the societies [5, 6]. The guidelines and future educational programs in thoracic ultrasound should – based on the results from this randomized controlled trial – focus more on obtaining and ensuring theoretical knowledge including a theoretical assessment. Subsequently, clinical training which could start unsupervised equivalent to the beginning of the learning curve when getting familiar with the ultrasound machine and examination, advantageously as dyad training. Then, supervised when starting to interpret and integrate the images. This reverse setup saves resources as the supervision from the expert is being integrated after the basic skills (e.g., eye-hand coordination, knowledge on the adjustments and optimization of the images, etc.) are learned.

Simulation-based training or training on simulated patients can be incorporated as preclinical training session in order to make acquaintance with ultrasound prior to performing examinations on patients. Furthermore, sonopathological patterns with low prevalence and that are not often seen in the clinic can be taught using simulators.

Limitations and potential bias to the study exist. The reliability of the outcome assessments could be increased by recording the ultrasound examinations and use more than one expert to assess the participants and rate the procedures according to the LUS-OSAUS score. However, we used the same blinded rater at all three inclusion sites which is a robust design. The number of participants is an often discussed issue in educational research. Based on the sample size calculations, we aimed at and managed to include 66 participants. This number of participants is relatively high compared to other studies assessing the effect of simulation-based training [9, 37, 38]. The sample size calculation was made based on an expected clinically relevant difference of 8.5 points (a mean of 0.5 point in each item of the LUS-OSAUS score). This estimated number was determined by the author group: experienced ultrasound operators who frequently use the assessment tool for international courses hosted by the European Respiratory Society. However, if 8.5 points were clinically relevant was not tested or explored.

The study did not explore the overall educational strategy in thoracic ultrasound. The content of the theoretical part was identical in all three groups and predetermined based on a Delphi-like method including experts in thoracic ultrasound from different specialties in another study [14]. Physicians from different specialties, departments, or institutions might have different approaches and different educational needs which should be considered in future training programs. Additionally, the quality of clinical training might differ between departments and institutions due to difference in level of competence of supervisors and clinicians. The clinical assessment tool assessed the capability to assess pleura, interstitial syndrome (B-lines), consolidations, and pleura effusions, however, in another setting, a need of sonographic assessment of mediastinum, diaphragm, or lymph nodes could be required. The lung module used in this study does not provide cases with pathology in mediastinum or lymph nodes – pathologies and structures which are also hard to visualize and assess on healthy volunteers. Thereby, increased focus on the supervised clinical training is required if the trainees are to perform examinations which should include these topics.

The study did not explore the sustainability of competence which is a very important aspect of learning. We wanted to test the immediate effect of simulation-based training in the beginning of the learning curve as simulation-based training has the greatest effect on completely ultrasound naïve. Most mistakes and misinterpretations occur in the beginning where the experience is sparse. Thus, we wanted to test if simulation-based training could increase the level of competence at first ultrasound examination on patients. Exploring the long-term effect is affected by significant factors, for example, access to supervision, participants' workload, and institutional attitude toward thoracic ultrasound. Due to the minimal yet significant difference from the control group, hands-on training can probably be performed in a clinical setting without expected major errors that will harm the patient.

A proposal for future educational training programs could be the following: theoretical session (classroom-based lectures or online web-based education) ending with a theoretical test for ensuring sufficient theoretical knowledge [14]. Practical hands-on training either in a clinical setting, scanning patients without the scanning influencing the patient flow or in a simulated setting

scanning healthy volunteers or colleagues. Optionally, simulation-based training for trainees who wish to train on simulators (e.g., to ensure ultrasonic pathology) or for trainees having difficulties understanding and translating 2D ultrasound images into anatomical or sonopathological patterns. Apprenticeship training in a clinical setting when integrating the ultrasound examination into the clinical decision-making. An experienced supervisor would ensure quality and interpretation of the ultrasound images and be able to provide feedback on the performance. The LUS-OSAUS score or another clinical assessment score can be used for further competence development and clarification of specific items or components that require more training (formative assessment) [21, 22].

In conclusion, there was no difference in clinical performance score of those who trained on simulators and those who trained on healthy volunteers. Simulation training should not be mandatory but could be integrated as an add-on modality as part of a whole curriculum in clinical thoracic ultrasound.

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Statement of Ethics

The study complies with the World Medical Association Declaration of Helsinki.

Conflict of Interest Statement

The authors have no conflicts of interests (personal, political, or professional) that may relate to the planning, conduct, or reporting of this study.

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Author Contributions

Substantial contribution to conception and design: Pietersen, Jørgensen, Graumann, Konge, Skaarup, Schultz, and Laursen. Substantial contribution to acquisition of data: Pietersen, Jørgensen, Skaarup, and Schultz. Substantial contribution to data analysis and interpretation: Pietersen, Graumann, Konge, and Laursen. Substantial contribution to drafting of manuscript, critical revision, and approval of final version: Pietersen, Jørgensen, Graumann, Konge, Skaarup, Schultz, and Laursen.

Statement

Pia Iben Pietersen is the guarantor of the content of the manuscript, including the data and analysis.

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