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ABSTRACT

INTRODUCTION

The ScanTrainer transvaginal ultrasound simulator has been developed to facilitate initial training of transvaginal ultrasound skills without patient contact. Due to the intimate nature of the examination and in some cases, limited training opportunities, the need for simulation-based education in ultrasound has gained momentum. Currently, research into the effectiveness of the ScanTrainer is limited.

METHODS

A mixed method study was conducted in a single institution between October 2011 and January 2012. Participants were recruited using convenience sampling and allocated to the control (clinical training) or experimental (simulation training) group following a pre-test. After 10 hours of their allocated transvaginal ultrasound training method a post-test assessment was conducted and the results statistically analysed. Participants then experienced the alternative method of training and completed questionnaires. The results were used to inform semi-structured interviews for each group. Interview transcripts were interpreted using theme analysis.

RESULTS

A small number of doctors completed the study, 9 (82%) out of the 11 recruited. The majority of participants (89%) felt that practice on the ScanTrainer can increase confidence prior to attempting a real transvaginal ultrasound scan. Average scores showed that the simulation training group outperformed the clinical training group on overall score and each of the five post-test components. No statistically significant

differences were demonstrated for overall score (u= 13, p= 0.556) or the five components (p= 0.190-1).

CONCLUSIONS

Transvaginal ultrasound training on the ScanTrainer has the potential to replace initial clinical training, however further larger trials are required to evaluate. Clinically significant outcomes exist if the ScanTrainer training is proven to be more effective than initial clinical training. The ScanTrainer prepares a trainee and builds confidence to progress to clinical scanning, which has the potential to improve the patient experience.

INTRODUCTION

Transvaginal ultrasound (TVUS) is now the most routinely requested imaging examination for gynaecology referrals.[1] However, it is a difficult examination for the operator to perfect due to its invasive nature and the fact that patients are less willing to tolerate extended examination times due to an inexperienced operator.[2] In addition, capacity for ultrasound training within imaging departments has been reduced by European working time directives mandatory time restrictions now placed on in-hospital work for doctors,[3] a national shortage of sonographers,[4] and the need for rapid patient throughput.

For over 100 years medicine has adopted an apprenticeship model of education whereby trainees gain experience whilst being supervised by senior colleagues.[5] Ideally, using this model, trainees would be involved in a vast number of cases over a long period of training, however in reality, training can utilise a "see one, do one, teach one" approach.[5-7] Consequently it is not only difficult for doctors to gain

competency in practical examinations such as TVUS using this model, it is also becoming less acceptable to the general public, who are increasingly commencing litigation as a result of poor outcomes.[6]

In 2009, the Chief Medical Officer Sir Liam Donaldson[8] highlighted the potential for simulation-based medical education to reform the way clinical training is provided, citing examples of success in other industries and current uses in medicine for basic clinical skills. With a view to extending the use of simulation throughout medical education each Royal College appointed a director for simulation training indicating their commitment to developing resources in this area (ibid).

"A simulator is a physical object that reproduces, to a greater or lesser degree of realism, a medical procedure that must be learned, and that incorporates a system of metrics that allows progress and learning to be recorded".[9] The development of ultrasound simulators with built in virtual examinations has made standardised ultrasound training possible and could represent a new era in ultrasound education.[10] However, whilst previous research has demonstrated improvements with ultrasound simulation training in areas such as detecting fetal anomalies (ibid), with the constant development of new simulators more up to date research is required.

In April 2010, MedaPhor unveiled a new haptic virtual reality TVUS simulator called ScanTrainer, using modules with "easy-to-follow tutorials and assignments" allowing the operator to learn through trial and error.[11] The ScanTrainer utilises haptic technology to provide a realistic experience of TVUS scanning, for example if the pressure exerted by the user is too great the equipment emits a scream. This product has the potential to positively change the way that ultrasound training is

provided by allowing doctors to reach a basic level of competence in a safe environment without causing discomfort to patients.

The overall aim of this study was to compare the use of the ScanTrainer with standard clinical training for teaching radiology and gynaecology doctors basic TVUS skills. Both the ScanTrainer's ability to teach trainees to adequately examine anatomy and its effect on their confidence levels when scanning real patients was investigated. However, due to the small sample size which evolved during the course of this project, this article will focus mainly on the quantitative and qualitative analysis of results relating to confidence levels of trainees.

METHODS

Study Design

A small-scale single centre pilot study was designed as no other research on the ScanTrainer existed. A single phase mixed method study design was utilised that incorporated both quantitative and qualitative data collection elements. According to Creswell & Plano Clark,[12] this type of mixed method study is best described as a triangulation design. To maximise the sample size, radiology and gynaecology doctors of any training grade were eligible for participation and were recruited using convenience sampling. Exclusion criteria were prior qualifications in gynaecological ultrasound, 10 or more hours of practical gynaecological ultrasound experience or involvement in a concurrently running research project. No power analysis was performed as this was a pilot study.

Quantitative Data Collection

A quasi-experimental non-equivalent control group pre-test-post-test study design was used to compare the ScanTrainer with standard clinical training for teaching novice scanners basic TVUS skills. Pre-test and post-test assessment forms were designed and their content validity assessed by four experts in ultrasound training. Following methods advocated by Polit & Beck,[13] a scale-level content validity index using the average approach was calculated and an index of 0.9 was obtained for the pre-test and 0.93 for the post-test, indicating excellent content validity for both assessments. The four experts also graded each component on the forms as either a basic, intermediate or advanced task to enable the marks awarded for a pass to be weighted accordingly. A pilot of the assessment forms was conducted on three qualified sonographers. Ethical approval for the study was granted by the School of Health Sciences, City University London (Ref:MSc/10-11/30). The study was deemed to be akin to service evaluation by the local research ethics committee.

All participants underwent a pre-test assessment, after a standardised induction to the ScanTrainer. This was marked by the simulator and determined initial scanning ability, to enable stratified randomisation of participants into one of two groups. Demographics and background speciality were anonymised and participants were allocated to either the control group (supervised clinical training lists with patients) or the experimental group (simulator training).

Participants then completed ten hours of training, either under the supervision of the same qualified sonographer (control group) or without supervision (experimental group). A post-test was then carried out on all participants using the ScanTrainer which included two cases, one normal and one with pathology and related questions. The ability to adequately examine relevant anatomy, determine orientation, record accurate measurements, differentiate between normal and abnormal findings and

produce high quality images were tested, either by the simulator (anatomy, measurements and normality), by the researcher during the examinations (orientation) or through image review by one of two qualified sonographers (image quality).

Unpaired results from the pre and post-test were analysed using the non-parametric Mann-Whitney U test as because of the small sample size it was not possible to test the data for normality.[14] An alpha value of 0.05 was used.

Qualitative Data Collection

To assess the ScanTrainer's effect on the confidence levels of novice scanners, each participant completed a short questionnaire after attending a session of training using the alternative method to their originally allocated method. Responses were used to develop questions for semi-structured interviews. Five semi-structured interviews were conducted, comprising of a mix of individual and group interviews, depending on participant's availability. The questionnaire results were interpreted using descriptive data and the interviews were transcribed and analysed using theme analysis following a method advocated by Newell & Burnard.[15]

RESULTS

Sample

Of the 17 doctors who volunteered to take part in this study, 11 were eligible to do so and gave informed consent. Training grades ranged from foundation year 1 to speciality trainee year 5, with ten doctors from gynaecology and one from radiology. Following the pre-test assessment, 5 (45%) were allocated to the control group (clinical training) and six (55%) to the experimental group (simulator group). There

was no significant difference in the average scores of the two groups in the pre-test (U = 12, p = 0.6623). In the time period available, 9 participants completed their ten hours of training (4/5, 80% of the control group and 5/6, 83% of the experimental group). Two participants were unable to do so due to timetabling constraints.

Quantitative Results

Comparison of average scores showed that the simulator group outperformed the clinical group in the post-test assessment both for overall score and each of its five components. No statistically significant differences were demonstrated (See Table 1).

Qualitative Results

Eight out of nine participants (89%) thought that using the ScanTrainer prior to attempting a real TVUS scan could help increase a trainee's confidence (see Figure 1).

All participants in the simulator group felt fairly confident when attempting a TVUS scan on a real patient for the first time. Reasons given for why prior simulation training increased their confidence were; they became familiar with the routine of the scan, learnt how to alter the controls and to examine basic anatomy. However, aspects of the scan they remained unconfident about were inserting the probe and actually being able to find the required anatomy. Comments given included:

"I felt confident that I could tell what each thing was when I saw it but less confident that I'd actually be able to find it."

In comparison only one participant in the clinical group felt fairly confident when attempting their first real TVUS scan and although this individual was from a

gynaecology background they had no prior transvaginal ultrasound experience. The remaining three participants (75%) thought their confidence would have been increased with prior simulation training. They explained that in clinical training they felt under pressure to perform well in front of the patient yet struggled to understand the ultrasound images and were unfamiliar with the routine of the scan and controls. For example:

"On a real patient when you first start you don't really know what you're looking at, it doesn't make any sense. You can't really work out why the probe is producing that image.

The 3D anatomy feature of the ScanTrainer (see Figure 2) was highlighted by all participants in the clinical group as a learning aid they would have benefited from and increased their confidence. Other features identified that can help build confidence were that there is no time limit, trainees can make mistakes, don't learn everything at once and can learn normal anatomical appearances first. For instance:

"The really useful part was the 3D anatomy picture because you can correlate the images on the ultrasound with the patient in front of you."

"You don't have the patient there so you can train for as long as you like or make as many mistakes as you like. You have modules you can follow, so you acquire each skill at one level and don't have to learn everything at once."

A difference of opinion existed as to whether the ScanTrainer could provide trainees with a false confidence in their abilities. The general consensus was that whilst it can prepare trainees for clinical training and increase confidence, it does not result in overconfidence. However, two participants were concerned that the anatomy on the

ScanTrainer is fairly easy and could potentially give trainees a degree of false confidence in their ability to locate the relevant organs. A comment given was:

"I think if you became really used to finding the anatomy right there straight away on the simulator then you would probably feel quite frustrated if you get to a woman and you can't even locate the uterus."

All participants felt that simulation training should be utilised at the beginning of TVUS training. The majority (n=7, 78%) would opt to begin their training using a combination of both simulation and clinical training. The two training methods were considered complementary and consequently simulation training should be an adjunct not a replacement for clinical training.

When asked how long they would have used the ScanTrainer before feeling confident enough to commence clinical training answers ranged from two and a half to more than ten hours (see Figure 3). In this time they would hope to learn to orientate and manipulate the probe, become familiar with the scan routine and be able to recognise normal anatomy. However, it was suggested that a better motivator for trainees using the ScanTrainer would be progression onto clinical training, with a sonographer, after reaching a certain level as opposed to an enforced number of hours training. For example:

"I think it would be a really good thing for us to say once you've done the simulation training and passed, then you can organise clinical teaching."

All participants thought that prior practise on the ScanTrainer could improve the patient's experience of having a TVUS performed by a trainee and that there is a role for simulation training in US education. It was thought that the increased confidence

felt by trainees following simulation training would enable them to perform better when attempting to scan a real patient and reduce the scan duration. Patient comfort was also thought to be increased as a result of prior practise at handling the probe on the ScanTrainer which emits a scream if too much pressure is exerted on the patient. A comment from the simulator group was:

"We were all conscious about what the patient was experiencing and in a way I think the simulator has taught us that because it kept screaming at us every time we used a pressure that maybe wouldn't be acceptable in a real life situation."

DISCUSSION

To aid interpretation of the results, the discussion has been divided into two sections – the quantitative results alone and combined analysis of the quantitative and qualitative results.

Quantitative Results

The limited sample size is a weakness of this study. Results suggest no significant differences between abilities of the two groups, when using non-parametric tests, indicating that simulation could replace initial clinical training. Similar conclusions were reached in studies by Knudson and Sisley[16] on the UltraSim and by Stather et al[17] on endobronchial US simulation training, which found no significant differences in abilities[16] or number of successful biopsies ($p = 0.13$)[17] when compared with traditional methods of training.

Comparison of the average scores of the two groups however indicates that simulation training may actually be more effective than clinical training when learning basic TVUS skills, a finding which could have further implications for clinical practice.

This replicates findings of similar studies into virtual reality simulators ability to teach laparoscopic skills which demonstrated improved performance of simulator-trained participants compared with control groups.[18-20] The results are also in line with findings in a systematic review by Harder[21] which concluded "the use of simulation as opposed to other education and training methods, increased the students' clinical skills in the majority of studies". Repeat trials incorporating multiple centres to gain a larger sample size are now necessary to determine the value of the ScanTrainer.

Combined Analysis of Quantitative and Qualitative Results

Unfortunately much medical education research is hindered by small sample size,[22] with the issues surrounding the statistical analysis of the results illustrating how the collection of only quantitative data would have resulted in a limited understanding of TVUS training using the ScanTrainer. At present there is a lack of existing research on simulation-based medical education which considers the learner's perspective.[23] Consequently, with no concrete guidelines available on how to implement simulation training within the hospital US curriculum it was considered important to rectify this and obtain an understanding of the trainee's experience of the ScanTrainer and its effect on confidence levels using qualitative methods.

The simulation training group felt that their confidence was increased as a result of being able to learn normal anatomical appearances first, make mistakes, take as long as they like and practice small sections of the scan individually. This may offer insight into why the simulation training group were better able to differentiate between normal and abnormal appearances. The areas the simulation training group felt more confident in when they progressed to clinical training were altering the controls and assessing the anatomy, both areas in which they outperformed the

clinical training group in the post-test. This adds further weight to existing evidence that indicates that simulation training can enhance a trainee's confidence level.[21,24-26] Conversely, only one study was identified which disputed these findings with confidence levels unaffected by training method.[27]

Whilst this current study was not large enough to evaluate performance, it illustrates how practice on the ScanTrainer can enable a trainee to become more familiar with the routine of the scan and increase their confidence to progress onto clinical training. This was further reinforced by the opinions of the majority of the clinical training group who felt that their confidence would have been increased by prior simulation training. Nevertheless, it was felt that trainees would be more adequately prepared for clinical training if the ScanTrainer incorporated less textbook anatomy and more pathology. Inclusion of these elements would decrease the risk of overconfidence in trainees. This suggests that the content validity (i.e. does the ScanTrainer contain the required material for the training that it is designed for?) may be lacking at present and needs to be measured and compared with other TVUS simulators to determine this aspect of its effectiveness, as advised by Matsumoto.[28]

A further implication of increased confidence levels resulting from simulation training suggested by participants was that the patient's experience of having a trainee undertake their scan could be improved due to a reduction in the anxiety felt by the trainee, enabling them to perform better. This was evidenced in research by Erickson cited by Goff,[29] which showed the ability to learn motor skills is improved by reduced anxiety, and was further confirmed by Kneebone,[30] who agreed, stating that an individual's ability to learn is hindered when dealing with "uncertainty, anxiety, overload, and stress". It's also possible that if the improved abilities of the simulation

training group do transfer effectively to clinical training then the overall length of the examination may be reduced. This idea was reinforced by participants, who suggested that the duration the probe is inserted for is just one aspect of the experience that could be improved with prior simulation training. This illustrates how the ScanTrainer can allow technical skills to be developed in a safe environment, before scanning real patients,[5,31] however designing studies which actually confirm these perceived benefits of the ScanTrainer in improving patient outcomes is challenging.

Eight out of the nine participants suggested a preference for TVUS training with the ScanTrainer initially, to develop confidence prior to scanning patients. The general view was that the ScanTrainer should be used until set goals are achieved by the trainee, to help motivation, rather than a set number of hours. Gurusamy et al[18] argue that "different trainees have different learning curves for learning different tasks and the time period sufficient to attain proficiency in a task in one individual may not be sufficient for another individual". However, regardless of end training point used, two studies[23,32] suggest that for simulation training to be successful it must be integrated within the curriculum and made mandatory.

CONCLUSION

In conclusion, the statistical results of this project suggest that US training on the ScanTrainer when compared with clinical training is equal in its ability to teach basic TVUS skills and could therefore replace initial clinical training. However, this study lacked power due to the small sample size involved. Comparison of the average scores of the two groups indicated that the ScanTrainer may actually be more effective than clinical training at teaching basic TVUS skills and if proven this could

have important implications for clinical practice and patient care. Larger multi-centre trials are now required to evaluate this further.

The collection of qualitative data on the effect of the ScanTrainer on trainee confidence increased the validity of this research allowing an understanding to be gained of the trainee's perspective. Training on the ScanTrainer was found to affect a trainee's confidence to progress to clinical scanning. The majority of participants indicated that practice on the ScanTrainer can increase a trainee's confidence level prior to attempting a TVUS scan on a real patient, a finding which has clinical significance regarding the patient's experience. Findings suggest that the ScanTrainer can build confidence in a number of areas such as enabling familiarity with the equipment controls and normal anatomy, in a non-threatening environment, where individual components of the scan can be undertaken until the basic skills are learned.

Although it was beyond the realms of this project to ascertain whether the increased performance of the simulation group in the post-test equated with increased performance in clinical training, participants felt that as the ScanTrainer decreased their anxiety and increased their confidence they were likely to perform better when faced with a real patient. In essence, it helps to prepare them for the progression to clinical training with the potentially clinically significant outcome of improving the patient's experience of having their scan performed by a trainee. In fact, use of the ScanTrainer was unanimously thought to be able to improve the patient's experience through increasing patient comfort, better probe handling and a reduction in the duration the probe is inserted for. However, the limited number of cases available on the ScanTrainer was thought to have the potential to result in overconfidence in a trainee, due to a lack of non-standardised anatomy and pathology, an outcome

which could be to the detriment of the patient. Consequently, the development of studies which are able to assess the content validity of the ScanTrainer and the effect on patient outcomes of prior training on it would now be useful.

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TABLES

Table 1: Mean differences between groups for the post-test assessment.

Part of Post-Test Assessment	Mean Score of Control Group (Clinical Training)	Mean Score of Experimental Group (Simulation Training)	Difference between the mean scores of the two groups	Percentage difference between the mean scores of the two groups	Mann Whitney U Value	P Value
Assessment of Anatomy (out of 14.5)	9.00	11.70	2.70	18.60	13.5	**0.413**
Orientation (out of 8)	6.75	7.60	0.85	10.60	12	**1**
Accuracy of Measurements (out of 25)	10.88	16.20	5.32	21.28	16	**0.190**
Image Quality (out of 80)	56.38	58.40	2.02	2.53	11	**1**
Normal/ Abnormal Anatomy? (out of 12)	10.00	10.80	0.80	6.67	12	**0.730**
Overall Score (out of 139.5)	**93.00**	**104.7**	**11.70**	**8.34**	**13**	**0.0556**

FIGURES

Figure 1: Participants' answers to the question asking if use of the ScanTrainer could help increase a trainee's confidence level prior to attempting a real TVUS scan.
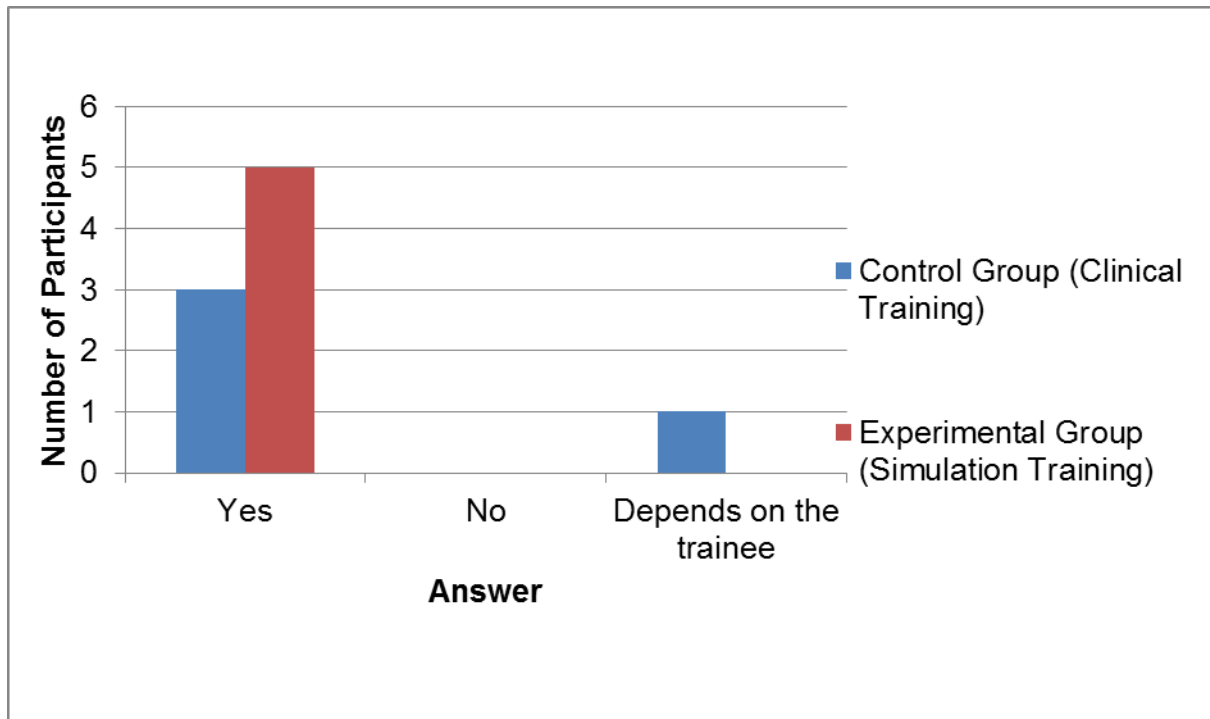

Figure 2: ScanTrainer display screen showing an anteverted uterus with the 3D anatomy feature on the left hand side of the screen (screenshot provided by and published with the permission of MedaPhor).

Figure 3: Response to the question: how long would you use the ScanTrainer for before feeling confident enough to progress to clinical training?