Chapter 9

Simulator training in fetoscopic laser surgery for TTTS: a randomized controlled trial.

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ABSTRACT

Objective: To evaluate the effect of a newly developed training curriculum on performance of fetoscopic laser surgery for twin-twin transfusion syndrome (TTTS) using an advanced high-fidelity simulator model.

Methods: Ten novices were randomized to receive verbal instructions and skills training using the simulator (study group, n=5) or no training (control group, n=5). Both groups were evaluated with a pre-training test and post-training test. Assessment was performed by two independent observers and compromised a 52-item checklist for surgical performance (SP score), measurement of procedure time and number of anastomoses missed. Face validity, educational value and user friendliness of the simulator were assessed using a questionnaire. Eleven experts from three fetal therapy centers set the benchmark level of performance.

Results: Both groups showed an improvement in SP score compared to the pre-training test. The simulator-trained group significantly outperformed the control group with a median SP score of 28 (52%) in the pre-test and 46 (88%) in the post-test versus 25 (48%) and 36 (69%) (p=0.008). Procedure time decreased 11 min in the study group versus 1 min in the control group; to 32 min versus 38 min, respectively (p=0.69). The number of missed anastomoses was not different between the groups (1 versus none). Feedback provided by the participants indicated that training on the simulator was perceived as a useful educational activity.

Conclusion: Proficiency-based simulator training improves performance on surgical performance score for fetoscopic laser therapy. Practice on a simulator is recommended before trainees carry out laser therapy for TTTS in pregnant women.

INTRODUCTION

Twin–twin transfusion syndrome (TTTS) is a serious complication affecting approximately 10% of monochorionic (MC) twin pregnancies.[1] Treatment is offered in specialized fetal therapy centers around the world.[2] Fetoscopic laser surgery enables both twins to survive in 60–70% of cases, and at least one twin survives in 80–90%.[3] Only a few studies have been performed to gain more insight in the learning curves and pitfalls of this complex procedure.[4-8]

In the coming years, we anticipate an increasing number of fetal surgeons to start training for fetoscopic laser surgery. With the economic growth in developing countries, and increasing knowledge of this treatment option through internet information, the interest of both patients and doctors in fetoscopic laser surgery will continue to grow. In addition, the next generation of fetal surgeons will gradually start to take over practice from the pioneers in the established centers. Therefore, attention is gradually shifting from pregnancy outcomes per center towards appropriate training and exposure of surgeons to a sufficient number of procedures. This will secure proper skills and satisfactory results. To support this process, an evidence-based training curriculum and continuous process of reporting and monitoring of outcomes is highly valuable.

Since fetoscopic procedures are performed on an infrequent basis, a surgeon-in-training is forced to a lengthy and expensive stay in a (often distant) fetal therapy center to accumulate at least some hands-on experience. Even large centers have limited numbers of cases, therefore teaching and training this procedure is challenging. A growing need for alternative methods to train surgical skills through simulation has been recognized.[4,5,9] Several attempts have been made to develop simulators for invasive fetal procedures with various levels of physical resemblance and functional task alignment.[9-13] Most reported simulators were used for teaching in absence of well-planned and comprehensive training curricula.

A procedure-specific simulator for fetoscopic laser surgery has not yet been developed before and standardized surgical training programs are nonexistent. Therefore, the aim of this study was to demonstrate face and construct validity of a highly realistic simulator and training for fetoscopic laser surgery for TTTS.

METHODS

Study design

For this study we recruited volunteers with special interest in fetal therapy and no practical experience with the fetoscopic laser procedure (novices), and all currently active fetal therapy experts in three Fetal Medicine centers: Leiden University Medical Center (the Netherlands), University Hospitals KU Leuven (Belgium) and Karolinska University Hospital, Stockholm (Sweden) from September 2014 until December 2014. All participants completed a questionnaire to establish baseline demographic characteristics, previous experience in surgical/obstetrical skills in order to exclude potential confounding factors that may affect performance. Participants were eligible to take part in this study if they were: fetal medicine specialists without practical fetal therapy experience OR obstetrician/gynecologists attending a fellowship perinatology OR senior OBGYN residents with special interest in perinatology and/or minimal invasive therapy; AND had a high level of skills in diagnostic ultrasound, appropriate knowledge of TTTS and its treatment options, but little or no previous experience with other ultrasound-guided invasive procedures (amniocentesis, chorionic villus sampling, cordocentesis and/or intrauterine transfusion).

A training curriculum using a simulator for fetoscopic laser surgery was generated based on a previously developed evaluation instrument.[5] We conducted a non-blinded randomized controlled trial using a parallel study design. For randomization, we used a block randomization list (non-stratified, with the same block lengths), generated by www.random.org sequentially. Novices were randomly assigned to either the training group (study group) or the no-training group (control group). Because of the nature of the intervention, blinding for randomization allocation was not possible. Lack of data regarding training for fetoscopic laser surgery prevented a formal sample size calculation. Giving the rarity of the procedure and the estimation that in the coming years two eligible trainees per fetal center will be trained, a sample size of 12 was chosen for this study. A pre-test/post-test research design was used to evaluate the effect of simulator-based training on surgical performance. Performance was assessed with an assignment involving the complete fetoscopic laser procedure, comparing the two groups before and after training. A flowchart of participant enrolment is shown in figure 1.

All currently practicing experts (n=11) from the three MFM centers were asked to complete the same assignment to define a benchmark level. An “expert” was defined as an individual who is currently practicing fetoscopic laser surgery for TTTS and has

independently performed >25 fetoscopic laser procedures.[4] Baseline characteristics of all study participants are listed in table 1.

Demographics	Experts n/11 (%)	Novices (no training) n/5 (%)	Novices (training) n/5 (%)	p value
Gender				
Male	8/11 (73)	2/5 (40)	0	0.44
Female	3/11 (27)	3/5 (60)	5/5 (100)	
Age				
(median in years, range)	52 (35-59)	30 (30-34)	34 (30-37)	0.15
Experience with invasive obstetric procedures				
Has experience with invasive obstetric procedures	11/11 (100)	0/5 (0)	2/5 (40)	0.44
Years of experience (median, range)	15 (7-23)	0	2 (1-2)	
Type of invasive obstetric procedures				
Amniocentesis	11/11 (100)	0	2/5 (40)	
Chorionic villus sampling	11/11 (100)	0	2/5 (40)	
Intrauterine transfusion	8/11 (73)	0	0	
Fetal shunt placement	8/11 (73)	0	0	
Bipolar cord occlusion	11/11 (100)	0	0	
Open fetal surgery	4/11 (36)	0	0	
Other	4/11 (36)	0	1/5 (20)	
No. of FLS attended (incl. assisting or watching procedure)				
None	0	2/5 (40)	0	0.28
< 10 procedures	0	2/5 (40)	4/5 (80)	
10-25 procedures	0	1/5 (20)	0	
25-50 procedures	1/11 (9)	0	0	
50-100 procedures	1/11 (9)	0	1/5 (20)	
>100 procedures	9/11 (82)	0	0	
Experience with simulator training				
Never	2/11 (18)	1/5 (20)	0	1.00
A few times	4/11 (36)	2/5 (40)	3/5 (60)	
Regularly	5/11 (46)	2/5 (40)	2/5 (40)	

FLS: fetoscopic laser surgery

Table 1. Demographics of study participants

Simulator characteristics

An advanced simulator (Francis LeBouthillier, Surgical Touch, Toronto, Canada) that was previously used for the training of amniocentesis [11] was modified. A monochorionic twin placenta model and realistic models of twin fetuses were inserted. (R. Bakker, Manimalworks, Rotterdam, The Netherlands). Placenta and fetuses had a size comparable to 17 weeks of gestation. The silicone interface at the top of the model

mimicked the abdominal wall. The simulator contained water and had appropriate sonographic properties. The model allowed an operator to perform ultrasound examination of the monochorionic pregnancy and to select the site for introduction of the instruments. The model provided a realistic intrauterine environment, optimal to practice manual dexterity skills and to train navigation along the placental surface. The "stuck" donor twin was positioned on the placenta. The addition of a "free-floating" recipient simulated the floating fetal extremities and umbilical cord in the recipients' sac. Besides the simulator model, all standard equipment (i.e. fetoscope, introduction set, ultrasound machine, endoscopy tower etc.) clinically used in the participating fetal therapy centers was used to perform the assignment.

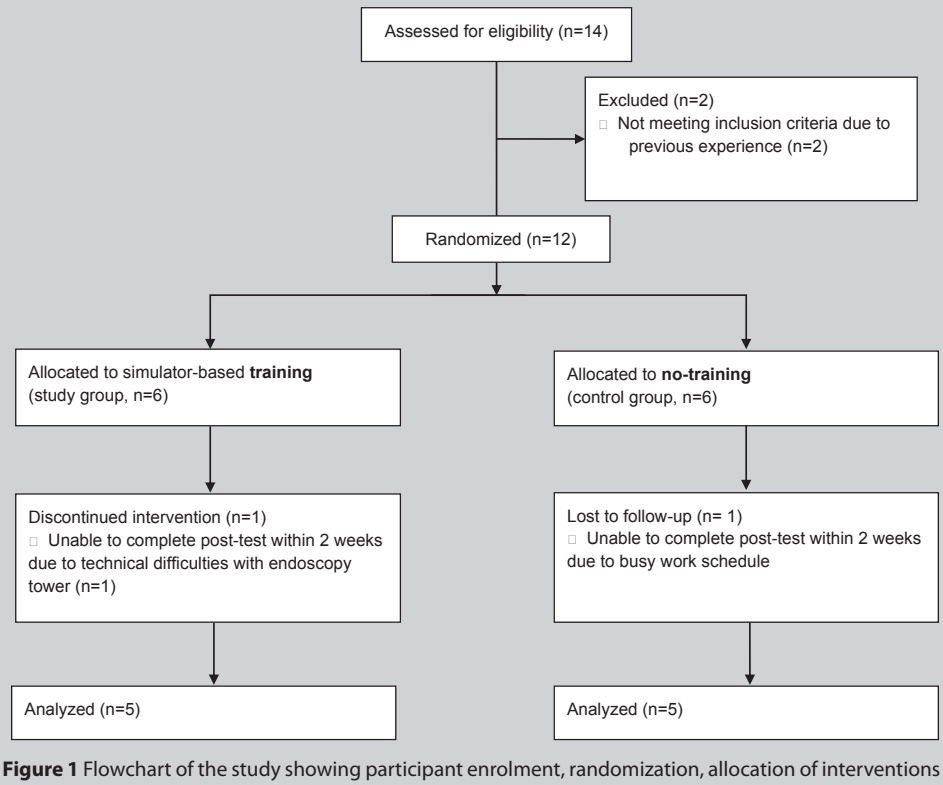


Figure 1 Flowchart of the study showing participant enrolment, randomization, allocation of interventions and follow-up.

Evaluation and training

Participants and experts were evaluated by 2 independent observers (S.P. and J.A.), using the evaluation instrument created by the Delphi consensus.[5] The list of essential steps was modified into a surgical performance score (SP score) adjusted to the simulated scenario. This 52–item list consisted of 'achieved' and 'failed' items in 11 domains pertaining specifically to the fetoscopic laser procedure for TTTS. (Appendix 1) Each item was awarded 1 point if it was done properly (range 0-52). Procedure time, defined as 'the moment the surgeon enters the operating room until the moment that direct post-operative management is ordered' and fetoscopy time, defined as 'the moment the trocar was introduced until final removal' was recorded. A map of the placental architecture was used by the observers to mark the coagulated anastomoses (total n=8). Since there was no international consensus on the Solomon technique[3] at the time of development of the checklist, participants were instructed to coagulate all vascular anastomoses (that connected the circulation of the donor and the recipient twin) one by one; referred to as the 'selective laser technique'.

The structured fetoscopic laser surgery skills training and evaluation consisted of five phases:

Phase 1: Introduction

Each participant was familiarized with the simulator by a member of the study team (SP or JA).

All participants were shown a standardized multimedia presentation outlining the background and aim of the study to explain the task; including the assessed performance metrics. Finally, the context of the scenario was presented. No assistance was provided during completion of the assignment unless the participant was unable to proceed with the procedure. In that case (for example: 'switch on the laser') the item was appointed but scored as 'failed'.

Phase 2: Pre-training test

All subjects in the study participated in a pre-training test to assess baseline competency and technical skills in fetoscopic surgery. The participants performed an assignment in the simulator, including the complete fetoscopic laser procedure for a patient of 17 weeks' gestation with stage 3 TTTS; starting from the moment the operation room is entered, until the surgery was finished and direct post-operative management was ordered.

Phase 3: Training

After the pre-training test, novices who were randomized to the training curriculum were trained in a 1 day session by a fetal therapy expert who was not involved in the evaluation process. The curriculum comprised two components: a theoretical part and practical session. The procedure-specific instrument served as a framework for curricular development. An instructor script and multimedia presentation including step-by-step actions and decisions required to perform the fetoscopic laser surgery, were developed by DO, RD and SP.

The theoretical part of the training consisted of a multimedia presentation outlining the indication for surgery, relevant anatomy, control of the instruments including the fetoscope, and a video demonstration of the simulated steps. The purpose of this session was to allow participants to understand the flow of the procedure and to conceptualize how to plan and execute the fetoscopic laser surgery.

The training continued with a practical session using the simulator with three subsequent practice rounds. In round 1, an attending fetal expert showed how to perform the procedure step-by-step, in round 2 the trainee performed the procedure under supervision of the expert provided with direct verbal feedback. In the last round, the complete procedure was performed by the trainee and evaluated directly afterwards with the expert.

The participants that were allocated to the control group did not receive feedback with regard to their performances. They were also not involved in the training sessions.

Phase 4: Post-training test

Within 2 weeks after the training, all novices (study group and control group) performed a post-training test, evaluated by the same independent observers (J.A. and S.P.). The post-training test included a different assignment (regarding the location of the placenta and the fetuses), but was performed on the same simulator.

Phase 5: User experience evaluation

Participants completed a survey to collect qualitative data regarding participant perceptions of the value of the simulation and training. Face and content validities were assessed concerning participants' opinions about realism (9 items), usefulness (5 items), and overall opinion about the simulator (3 items). All items were scored on an ordinal 10-point Likert scale (1 = not at all realistic/useful and 10 = very realistic/useful).

Statistical analysis

Demographics, SP score, procedure time, fetoscopy time and presence of residual anastomoses, of both pre-training and post-training tests, were compared for the groups. For the SP score, a higher score is better; therefore an improvement is reflected by a positive pre- and post-test difference. For procedure time and fetoscopy time, improvement was calculated as pre-training test minus post-training test value.

Due to the small sample size and non-normal distribution of the data, the Mann Whitney U test was used to test for differences between groups for the continuous variables. To test for differences between groups on non-ordinal categorical outcomes, Fisher exact test was used. For ordinal outcome such as a Likert agreement scale the χ^2 test was used. Spearman correlation coefficient was used to measure the inter-observer reliability. A correlation of 0.9 or higher was considered to be indicative of an excellent agreement. A p value ≤ 0.05 was considered statistical significant. Statistical analysis was performed with IBM SPSS version 21.0 (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.).

RESULTS

Participant enrolment, randomization and follow-up are illustrated in figure 1. Within the three participating centers 12 volunteers were included in the trial and randomized. One participant was lost to follow up, another was not able to complete the test due to technical difficulties, therefore we were able to analyze the results of 10 participants (study group n=5 and control group n=5).

The randomized study group (with training) and control group (without training) were well balanced for baseline characteristics (Table 1). Analysis revealed no differences between the groups regarding prior knowledge of the procedure or experience with other obstetric invasive procedures or simulators. In the expert group, 9/11 (82%) of participants had attended > 100 laser procedures and 5/11 (45%) had performed >100 procedures themselves. A median of 10 procedures per expert (range 8-20) was performed annually.

Experts

The expert benchmark level was set with a median SP score of 44/52 (85%) (range: 44-51), a procedure time of 32 minutes (range: 26-46 minutes) and fetoscopy time of 11 minutes (range: 10-18 minutes). One expert missed a small AV anastomosis at the

margin of the placenta (1/11, 9%). In table 2 results of performance of all participants are shown.

	Expert (benchmark)		Novices (study group)		Novices (control group)		p value
	n=11	*range*	n=5	*range*	n=5	*range*	
SP score (max 52)							
pre-training test	48 (92%)	(44-51)	28 (52%)	(27-41)	25 (48%)	20-44	0.55
post-training test			46 (88%)	(43-51)	36 (69%)	30-41	<0.01
difference			plus 18		plus 11		
Procedure time (minutes)							
pre-training test	33	(26-46)	44	40-50	39	33-45	0.06
post-training test			33	29-44	38	27-49	0.69
difference			minus 11		minus 1		
Fetoscopy time (minutes)							
pre-training test	12	(10-18)	22	18-25	18	16-20	0.06
post-training test			14	(10-20)	14	(11-24)	0.69
difference			minus 8		minus 4		
Missed anastomoses							
pre-training test	1/11 (9%)		4/5 (80%)		2/5 (40%)		0.52
post-training test			1/5 (20%)		0 (0%)		1.00

SP score: surgical performance score

Table 2. Performance of experts and study participants

Pre-training test

The median SP score for the study group was 28/52, 54% (range: 27-41) versus 25/52, 48% (range: 27-41) in the control group (p=0.55). Median procedure time in the study group was 44 minutes (range: 40-50 minutes) versus 39 minutes (range: 33-45 minutes) in the control group (p=0.06). Fetoscopy time was 22 minutes (range: 18-25 minutes) in the study group versus 18 minutes (range: 16-20 minutes) in the control group (p=0.06). In the study group 4/5 (80%) participants did not coagulate all anastomoses versus 2/5 (40%) in the control group (p=0.52). In the study group 3 participants missed 2 out of 8 anastomoses and 1 participant 1 out of 8 anastomoses, all located on the placenta margin. In the control group one participant missed 3 anastomoses in the center of the placenta and one participant 2 anastomoses on the placenta margin.

Post-training test

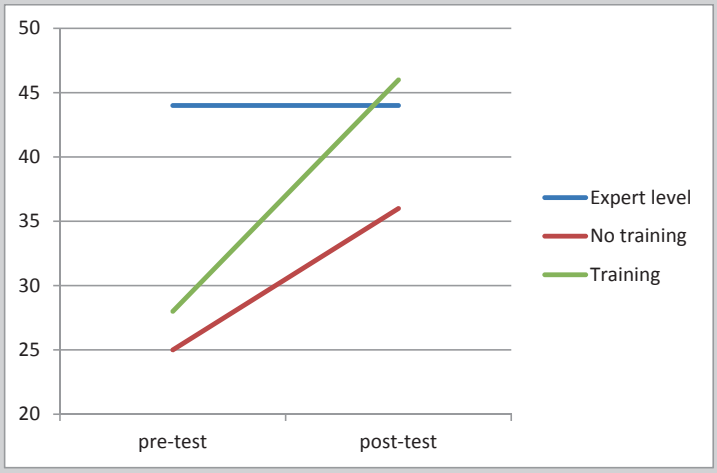
Novices in both groups showed an improvement in SP scores and performed the procedure in less time compared to the pre-training tests. The study group outperformed the control group after the training session significantly with median SP scores 46/52 88% (range 43-51) versus 36/52 69% (range 30-41) (p=0.008).

Median procedure time decreased 11 minutes in the study group versus 1 minute in the control group, to 32 minutes (range: 29-44 minutes) and 38 minutes (range: 27-49) respectively. Median fetoscopy time improved to 14 minutes in both groups; study group range: 10-20 minutes, control group range: 11-24 minutes (p=0.69). In the post-training test one participant (1/5 (20%)) in the study group missed 1 (out of 8 anastomoses) located on the placenta margin versus none in the control group (p=1.00).
Figure 2 shows the performance of both groups in the pre-training test and post-training test on SP scores, procedure time and fetoscopy time plotted against the expert benchmark level.

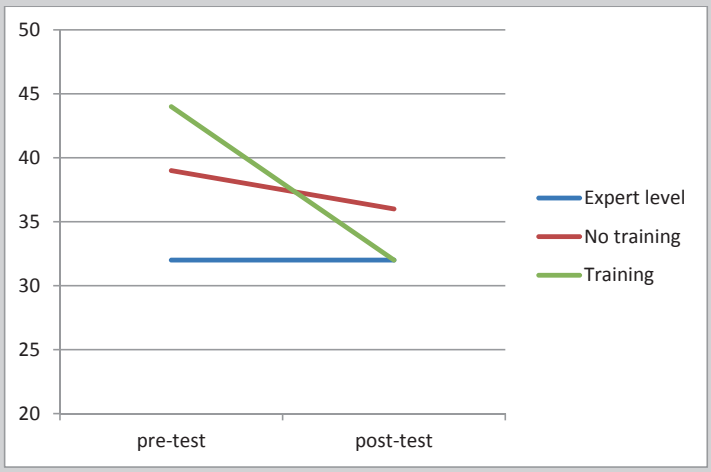
Figure 3 shows that experts felt that the simulator was very useful in training to identify the vascular equator and to practice the complete laser procedure. (score of 9 on Likert scale 1-10) All experts stated that training with the simulator provided good preparation before starting to operate on real patients. Except for the sonographic properties, the simulator was judged highly realistic.

The overall inter-observer reliability of the two raters' total scores (J.A. and S.P.) for the fetoscopic laser procedure was excellent (Spearman correlation coefficient: 0.984 $p<0.001$).

Checklist score (52-items) medians per group



Procedure time in minutes



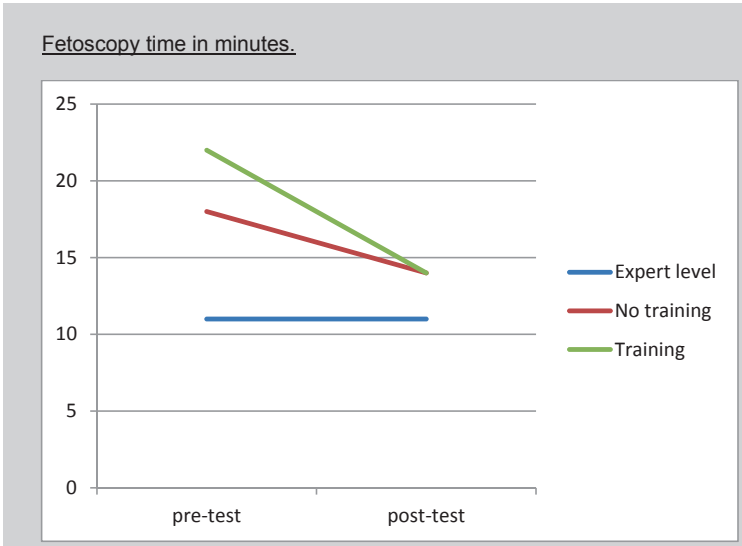
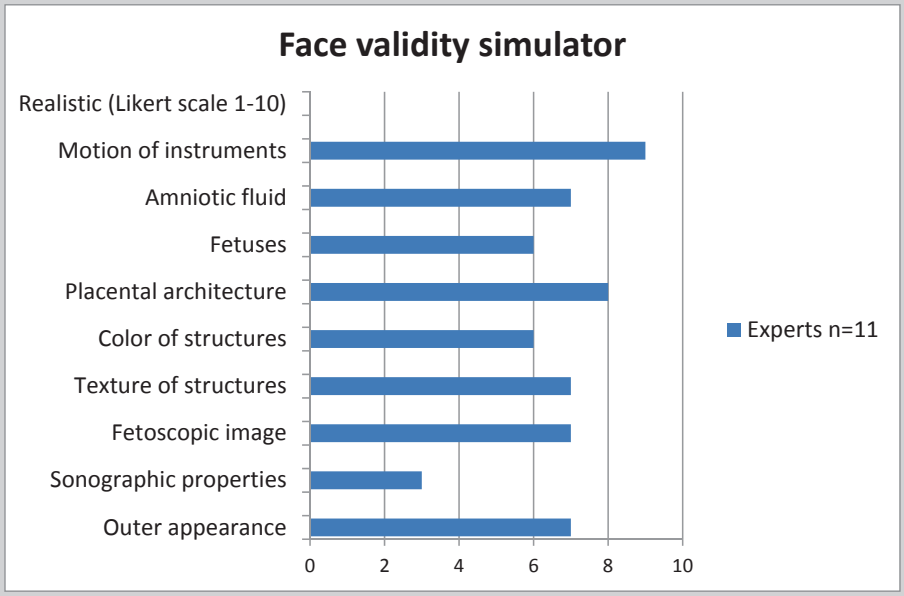


Figure 2 Performance of both groups in the pre-test and post-test on checklist scores, procedure time and fetoscopy time plotted against the expert benchmark level.



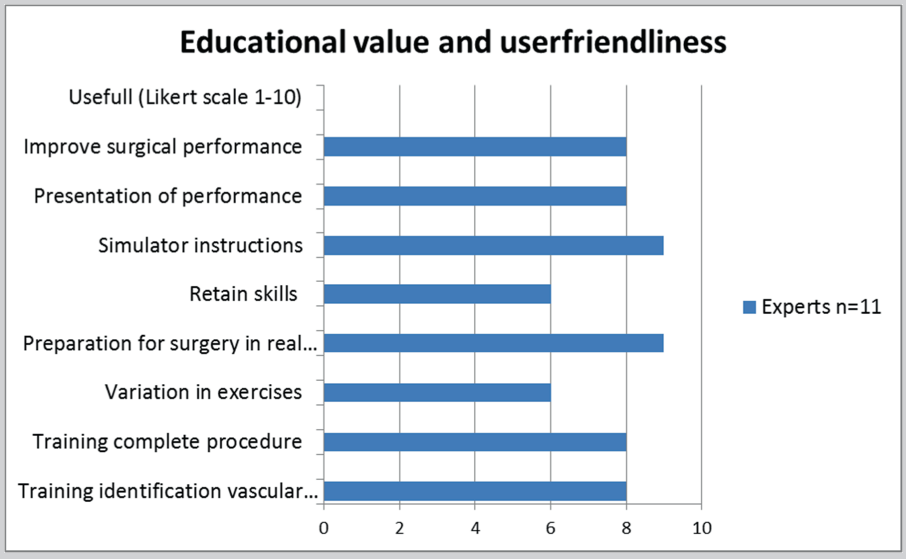


Figure 3 Expert responsens to questionnaire regarding: face validity, educational value and user friendliness of the simulator.

DISCUSSION

This study shows that training in a lifelike environment significantly increases performance for fetoscopic laser surgery in a standardized simulator model. The effect of the training was evaluated using a surgical performance score designed specifically for the evaluation of performance of therapists performing this procedure. In this study we found no difference in time taken or the presence of missed anastomoses between the groups. We defined expert benchmark levels for the curriculum to make it proficiency based. Feedback provided by the participants indicated that simulator training was perceived as a useful educational activity.

Fetoscopic laser surgery is a rarely performed, invasive procedure that is associated with a relatively high rate of fetal loss. The outcomes are shown to be operator and experience dependent.[4,8] Since the number of procedures per center is limited, organizing appropriate training and providing sufficient exposure is difficult.[2] To date, a standardized training curriculum is lacking. The main advantage of our simulator is that it enables to train fetal surgeons and trainees to gain experience in laser surgery without jeopardizing patient safety. In addition, it is readily available and allows training the entire procedure; including instrumentation set-up, which could be beneficial for a smooth workflow.

In other surgical fields, simulation based ex-vivo training has already been successfully integrated into different levels of education.[14-16] Several attempts have been made in the last years to develop simulators for invasive obstetrical procedures.[11,12,17,18] Most of these simulators are designed primarily to assess performance during critical parts of a procedure, rather than a complete operation. In this study we used a highly realistic simulator with the aim that the operators would treat the model like a real patient. There is evidence that physical resemblance can be reduced with minimal loss of educational effectiveness, provided there is appropriate correspondence between the functional aspects of the simulator and the applied context.[19] However, the choice of physical resemblance for the maximal training effectiveness depends on a number of factors, including the context within the simulator is used, kind of task that is trained, level of learning involved, abilities and capabilities of the trainee, difficulty of the task and effect of various instructional features.[20]

Most reported simulations are used for teaching in absence of well-planned and comprehensive curricula. A structured curriculum is designed with a logical sequence of learning objectives and associated activities.[21] The combination of our surgical

performance score and simulator appeared useful for training novice fetal surgeons. In addition, the set-up can be used to assess performance of practicing surgeons. Furthermore, it is an ideal environment to test new equipment or new techniques for experienced surgeons in a safe environment.[22]

Another objective of this study was to set a performance standard for the laser surgery assignment by using the parameters of the experts' performance. We expected no differences in these parameters since they had already achieved proficiency as demonstrated by other simulation studies[23], therefore experts performed the task only once. This performance standard can be used for training purposes and also for assessment or even certification in order to enhance patient safety. Performance was quite consistent as expressed by the small ranges in scores and procedure time.

The process of skills acquisition may demonstrate individual differences between trainees depending on cognitive capacity, perceptual speed, and psychomotor abilities.[24] Setting a certain number of procedures performed on simulator or actual patients to form an option for fetoscopic proficiency may cause bias. Furthermore, initial improvement in performance cannot be retained without regular repetition.[25] Therefore simulators provide a useful tool for the attainment and maintenance of trainees' surgical skills and for immediate or late assessment of their proficiency in those skills. However, a validation study of the simulator is always important to determine its capacities for training and objective assessment of the surgeons' performance with different levels of experience.
The current enthusiasm for validation of training and assessment tools and strategies is relatively new in the fetal therapy community. Before implementing a simulator in training curricula, it should be evaluated whether it trains what it is supposed to train, also known as its construct validity. In the design of a curriculum to train surgical skills, specification of the training objectives, including identification of the procedural steps and analysis of pitfalls, is essential.

Some limitations were notable in this study. While groups were not significantly different in gender demographics and previous technical skills training, the small number of participants makes it difficult to classify the groups as fully equivalent. In our study, participants were not matched according to demographics and technical capabilities. We emphasize that not only 'number of procedures attended', 'experience with other invasive obstetric procedures' and 'simulation training', but also sonographic experience, minimally invasive skills, and intrinsic qualities (such as spatial awareness) are of major

importance when selecting a cohort for training fetoscopic laser surgery. It is important to note that future fetoscopic surgeons in training are not compatible to a general population of residents.

Before training, we noticed a shorter procedure and fetoscopy time in the control group. We emphasize this illustrates that differences in baseline characteristics are probably related to many other factors than represented in our questionnaire. Therefore our results should be interpreted with care. Even though a greater number of participants in the study may have provided further evidence of significant differences in outcomes and increased study power, this would not reflect reality.
This simulator training can be an effective tool for improvement of technical skills under a safe learning environment before performing fetoscopic laser surgery in the operating room.
Certainly, future studies would be required to establish reliability and implementation of such a training in a more expanded setting. Research should be focused on validation of the curriculum to make sure that trainees that go through this curricular training process, actually perform better in the operating room with more technical proficiency. Above all, monitoring of quality of care is of utmost importance.

ACKNOWLEDGEMENTS

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APPENDIX

No.	Domain and substeps	Score
A	Preparation in operating room	7
1	Ultrasound correct settings	
2	Endoscopy tower settings	
3	Positioning of screens	
4	Adjusting lights	
5	Correct laser modus	
6	Correct power settings	
7	Positioning of patient	
B	Ultrasound examination (together with sonographer)	7
8	Identification of donor	
9	Identification of recipient	
10	Identification localization placenta	
11	Identification cord insertions	
12	Assess deepest pockets	
13	Determine expected position equator	
14	Determine insertion site fetoscope	
C	Pre-operative preparations	7
15	Surgical briefing (time out) about (complete) procedure to fetal therapy team	
16	Aseptic procedure for surgeon, scrub nurse and sonographer	
17	Mention maternal condition	
18	All instrumentation remains sterile	
19	All is sufficiently covered	
20	Pre-insertion connection scope - shaft	
21	Pre-insertion connection light cable	
D	Positioning and connection of instruments (pre-insertion)	6
22	Choose fetoscope	
23	Fetoscope: orientation	
24	Fetoscope: focus	
25	Fetoscope: white balance	
26	Connection of laser fiber	
27	Correct loading of laser fiber in fetoscope	
E	Insertion	5
28	Preparation of introduction method	
29	Performance of all manipulations under ultrasound visualization	
30	Correct administration of local anesthetic	
31	Make adequate-size skin incision with surgical knife	
32	Awareness of location of maternal uterine vessels and intestines, and placental edge during insertion	
F	Orientation	8
33	Assess visibility (optional: score visibility)	
34	Determine need for amniotic exchange	
35	Fetoscopic view of placenta	
36	Fetoscopic view of donor	

37	Fetoscopic view of cord insertion recipient	
38	Identification of placental edges	
39	Difference between artery and vene	
40	Find (part of) vascular equator	
G	Laser coagulation	4
41	Coagulation of all vascular anastomoses that cross the vascular equator	
42	Laser fiber correct position in fetoscope	
43	Laser fiber correct distance from vessel during coagulation	
44	Prevent the unnecessary sacrifice of placental tissue	
H	Assessment during procedure	3
45	Prevent unnecessary delay during procedure	
46	Check for complications(e.g. bleeding, rupture intertwin membranes)	
47	Identify and record number and type of anastomoses coagulated	
I	Amniodrainage	2
48	Controlled drainage of polyhydramnios	
49	Assess adequate drainage (ultrasound guided) until pre-defined level	
J	Closure	1
50	Closing skin incision (suture or suture free adhesive product)	
K	Direct post-operative management	2
51	Inform patient, partner/family and referring specialist	
52	Instructions for monitoring of maternal and fetal condition	

Appendix 1. Surgical performance score