Porcine Cadaver Organ or Virtual-Reality Simulation Training for Laparoscopic Cholecystectomy: A Randomized, Controlled Trial

Siska Van Bruwaene, PhD,[*,†] Marlies P. Schijven, PhD,[‡] Daniel Napolitano, PhD,[§] Gunter De Win, PhD,[*,†,∥] and Marc Miserez, PhD[*,¶]

[*]Center for Surgical Technologies, Leuven, Belgium; [†]Department of Urology, University Hospitals Leuven, Leuven, Belgium; [‡]Department of Surgery, Academic Medical Center Amsterdam, Amsterdam, The Netherlands; [§]Universidad Catolica de Cordoba, Córdoba, Argentina; [∥]Department of Urology, University Hospitals Antwerp, Edegem, Belgium; and [¶]Department of Abdominal Surgery, University Hospitals Leuven, Leuven, Belgium

OBJECTIVES: As conventional laparoscopic procedural training requires live animals or cadaver organs, virtual simulation seems an attractive alternative. Therefore, we compared the transfer of training for the laparoscopic cholecystectomy from porcine cadaver organs vs virtual simulation to surgery in a live animal model in a prospective randomized trial.

DESIGN: After completing an intensive training in basic laparoscopic skills, 3 groups of 10 participants proceeded with no additional training (control group), 5 hours of cholecystectomy training on cadaver organs (= organ training) or proficiency-based cholecystectomy training on the LapMentor (= virtual-reality training). Participants were evaluated on time and quality during a laparoscopic cholecystectomy on a live anaesthetized pig at baseline, 1 week (= post) and 4 months (= retention) after training.

SETTING: All research was performed in the Center for Surgical Technologies, Leuven, Belgium.

PARTICIPANTS: In total, 30 volunteering medical students without prior experience in laparoscopy or minimally invasive surgery from the University of Leuven (Belgium).

RESULTS: The organ training group performed the procedure significantly faster than the virtual trainer and borderline significantly faster than control group at posttesting. Only 1 of 3 expert raters suggested significantly better quality of performance of the organ training group compared with both the other groups at posttesting ($p < 0.01$). There were no significant differences between groups at retention testing. The virtual trainer group did not outperform the control group at any time.

CONCLUSIONS: For trainees who are proficient in basic laparoscopic skills, the long-term advantage of additional procedural training, especially on a virtual but also on the conventional organ training model, remains to be proven. (J Surg 72:483-490. © 2015 Association of Program Directors in Surgery. Published by Elsevier Inc. All rights reserved.)

KEY WORDS: cholecystectomy, LapMentor, porcine, cadaver organ, training, virtual reality

COMPETENCIES: Patient Care, Medical Knowledge, Practice-Based Learning and Improvement

INTRODUCTION

Since several years, the established teaching method "see one, do one, teach one" is being increasingly preceded by simulation-based training of surgical skills. Especially the advent of laparoscopy, that introduced a whole new set of demanding technical requirements, and the increasing medicolegal and time pressure have accelerated this process.[1]

The use of virtual-reality (VR) surgical simulators as a training tool has increased rapidly over the past few years.[2]

These grants are unrelated to the research described in this article. Prof Miserez and Dr De Win received the OOI 2005/39 grant for Educational Research, Development and Implementation project from the Katholieke Universiteit Leuven. Part of the study was funded by this grant. The Center for Surgical Technologies Leuven received educational grants for training purposes by Johnson&Johnson medical as well as Storz Medical. The LapMentor (Simbionix) virtual simulator was partially funded by Ethicon Inc (Johnson&Johnson medical). This funding had no involvement in the collection, analysis, and interpretation of data; in the writing of the report; nor in the decision to submit the article for the publication.

Correspondence: Inquiries to Siska Van Bruwaene, MD, PhD, Parijsstraat 1, 1602 Vlezenbeek, Belgium; fax: (325) 680-132; e-mail: siska.vanbruwaene@gmail.com

 1931-7204/$30.00 http://dx.doi.org/10.1016/j.jsurg.2014.11.015

Several studies demonstrate that prior training of basic psychomotor skills such as hand-eye coordination, depth perception, and knot tying on VR simulators results in an improved resident performance in the operating room.[3-6] However, consistent proof of benefit over conventional and much cheaper box trainers is still lacking.[7-9]

Training in basic laparoscopic skills is normally followed by organ-specific or procedural skills. Until now, live animal or cadaver organ models have been used to teach these advanced laparoscopic skills such as dissection, cutting, and coagulation.[10-12] However, significant financial and time resources are required for such endeavors not to forget the ethical concerns that come along with this kind of training.[13] The provision of continuous expert feedback is another drawback of this conventional training system. Technologies are evolving rapidly and nowadays VR simulators not only offer basic psychomotor exercises but also can simulate entire procedures with real-life characteristics and realistic haptic feedback. Therefore, these VR simulators would provide an attractive alternative when proving equally valid in teaching procedural skills.

The LapMentor VR trainer (Simbionix USA Corp) provides a structured stepwise training program for the laparoscopic cholecystectomy. The procedure is separated into 4 different exercises (1- or 2-handed clipping and cutting, dissection of the Calot triangle, and dissection of the gall bladder from the liver bed) to ensure a stepwise acquisition of the technique. Furthermore, 6 full cholecystectomy procedures, each with specific patient characteristics (i.e., short cystic duct and variations in cystic artery position), are provided. For every exercise and for the full procedures, several assessment parameters on quantity and quality of performance are measured simultaneously.[14] In this study we investigated whether the skill acquisition on this virtual cholecystectomy simulator results in better operative performance. The effect of training was compared with the conventional training model on cadaver organs.

METHODS

Study Setup

In total, 30 medical students were included in the study. After completing an intensive training in basic laparoscopic skills and suturing and knot tying, participants entered the study and were evaluated at baseline on their procedural skills during a laparoscopic cholecystectomy on a live anaesthetized pig. The control group did not receive any additional training. The second group attended 5 hours of cholecystectomy training on porcine cadaver organs in a conventional box trainer module (= organ training). The third group attended a proficiency-based cholecystectomy training on the LapMentor VR trainer with a minimum duration of 5 hours (= VR training). Posttesting and retention testing during a laparoscopic cholecystectomy on a live anesthetized pig took place 1 week (= post) and 4 months (= retention) after finishing the training program (the basic training program for the control group and the procedural training program for both the experimental groups). After completion of the study, students completed a 5-point Likert scale on how useful they estimated the training (1 = not useful at all, 5 = very useful). They scored the entire training course and specific parts of it (clip-cut, the Calot triangle, and the gall bladder dissection). Personal comments were allowed. This protocol was approved by the local ethical committee and met the University of Leuven guidelines of laboratory animal care.

Study Population

In total, 30 medical students were recruited without prior experience in laparoscopy or minimally invasive surgery. This study population was chosen to avoid any interference with previous or simultaneous clinical or laboratory-based practice in surgical techniques. Informed consent was obtained from all the participants. Through randomization, 3 groups of 10 students were created. Before entering the study, all the subjects attended an intensive training course in basic psychomotor skills (30 repetitions of the bean drop, rope pass, checkerboard,[15] and the E3 bimanual coordination Laparoscopic Skills Testing and Training exercise[16]) as well as in suturing and knot tying (30 repetitions of the sliding knot on the Penrose drain model[17,18]). At the beginning of the study, basic laparoscopic skill level was measured as the average time score on 5 trials for each exercise. This skill level was compared with proficiency (= mean performance score on 10 trials by 2 expert laparoscopists) to ensure adequate skill acquisition.[17,18]

Evaluation of Procedural Skills

At baseline, posttesting, and retention testing, all students were evaluated on their surgical skills during a laparoscopic cholecystectomy on a live anesthetized pig. Before the procedure, they received appropriate cognitive information using a video instruction and detailed text. Their procedural knowledge was evaluated through a written examination before they were allowed to start. The operative performance was evaluated on time needed to perform the procedure. Furthermore, all the procedures were videotaped and reviewed in a blinded manner by the research fellow who supervised the training sessions (rater 1) and an experienced general surgeon who had performed >100 laparoscopic cholecystectomies but was not extensively trained in the rating scale (rater 2). The procedures at posttesting, where difference between the groups was expected to be the largest, were assessed by an additional general surgeon (>100 laparoscopic cholecystectomies performed), with experience in rating scales and simulation (rater 3). It was permitted to use the fast-forward module; however, all important parts of the tape were reviewed.[19] A validated 5-point rating scale was used combining 5 global[20] and 3 specific[21] rating items with a maximum score of 40 (addendum 1). The sum of all items was averaged for the 2 or 3 raters. Raters were not blinded for the time point of the procedure (baseline, post, and retention).

VR Procedural Training Program

Those subjects randomized to train on the LapMentor (Simbionix USA Corp) attended a didactic hands-on session of the 4 procedural exercises, including a presentation of the parameters measured for assessment (familiarization run). The 4 tasks focused on clipping and cutting, dissection of the Calot triangle, and dissection of the gall bladder from the liver bed. Afterwards, they performed the tasks independently with available guidance concerning software or technical problems but without expert feedback concerning the procedure. Standardized feedback by the virtual simulator through the assessment parameters was available for each trial. Training consisted of distributed, daily training modules of 30 minutes.[22] Training was organized in a proficiency-based and chronologic manner. Procedural task 1 (1-handed clipping and cutting) was practiced until expert performance was reached for all parameters (= quantitative and qualitative) on 2 consecutive times, and then 5 additional trials were performed for reinforcement. Only then trainees proceeded with procedural task 2. To determine expert performance, 5 faculty abdominal surgeons attended a familiarization run and then performed 2 repetitions of each task. Their time and quality performance scores for each parameter were averaged. Training continued until the trainees were proficient in all the 4 procedural exercises and had performed each of 6 full gall bladder procedures once. The trainees had to attend a minimum of 10 training sessions or 5 hours of training. When they completed the training schedule earlier than expected, they performed additional trials of the full procedures.

Conventional Organ Training Program

The subjects randomized to organ training were required to train approximately an hour daily for 10 days.[22] Training was organized in pairs, so half of the time the trainee had to act as camera navigator and the other half as the surgeon. Every training session, one gall bladder was dissected, the first student focused on the dissection of the Calot triangle, followed by the clipping and cutting part, and the second student performed the dissection of the gall bladder. Next training session, it was the other way around. At the end of the training, every subject attended 5 hours of actual hands-on training and had performed 5 entire cholecystectomies. The organs, i.e., en bloc porcine liver and gall bladder,[23] were obtained from the slaughtery. All training sessions were supervised with continuous expert feedback.

Statistics

Data are shown as median (interquartile range [IQR]). The Kruskall-Wallis and the Mann-Whitney *U* tests are used to compare groups. Interrater reliability was calculated using the Spearman correlation. A $p = 0.05$ was considered significant. Previous work assessing technical differences between trained and untrained novices calculated a minimum required number of 9 participants per group using a power of 0.8, $\alpha = 0.05$, and known effect size of 1.3.[24]

RESULTS

All the 30 students completed the whole study protocol and attended baseline, posttesting, and retention testing. Basic laparoscopic skill level at the beginning of the study did not differ between the groups and reached proficiency for every exercise (Table 1).

The time needed to perform the laparoscopic cholecystectomy procedures is shown in Table 2. At baseline, there was no difference between the groups. The organ training group performed significantly faster than the VR training group at posttesting ($p = 0.015$) and borderline significantly faster than the control group ($p = 0.089$, Fig. 1). There was no difference between the control and the virtual

TABLE 1. Basic Laparoscopic Skill Level at Beginning of the Study for Control (No Training), Organ Training (Porcine Cadaver Organs), and LapMentor Virtual-Reality (VR) Training Groups*

	Bean Drop (s)	Rope Pass (s)	Checkerboard (s)	LASTT (s)	Suturing (s)
Control	39 (6)	34 (5)	163 (48)	60 (19)	134 (30)
Organ	34 (14)	34 (6)	146 (44)	50 (13)	132 (34)
VR	38 (10)	35 (10)	183 (42)	39 (32)	143 (19)
p-Value†	0.681	0.849	0.754	0.508	0.467
Proficiency‡	49	38	191	65	143

LASTT, Laparoscopic Skills Testing and Training.

*Data are shown in seconds as median (interquartile range).

†Kruskall-Wallis tests were used to compare the 3 groups.

‡Proficiency = mean performance on 10 trials by 2 expert laparoscopists.

TABLE 2. Time Needed to Perform a Cholecystectomy at Start (PreTraining), Posttesting, (1 Wk After Training) and Retention Testing (4 Mo After Training)*

Time	Control	Organ	VR	p-Value†
Baseline	47 (21)	46 (11)	47 (10)	0.642
Post	39 (12)	30 (2)	37 (22)	0.046‡
Retention	39 (18)	26 (9)	35 (16)	0.059

*Data are shown in minutes as median (interquartile range).
†Kruskall-Wallis tests were used to compare the 3 groups.
‡Post hoc Mann-Whitney *U* tests show significantly better performance for the organ vs virtual training group (p = 0.015) and borderline significantly better than the control group (p = 0.089).

TABLE 3. Quality of Performance (Averaged Scores for 2 or 3 Raters)*

Quality	Control	Organ	VR	p-Value†
Start	27 (10)	25 (5)	25 (13)	0.796
Post‡	21 (6)	29 (5)	20 (7)	0.007§
Rater 1	16 (7)	29 (9)	20 (6)	0.0004
Rater 2	25 (7)	29 (7)	24 (5)	0.293
Rater 3	23 (7)	26 (8)	16 (12)	0.128
Retention	20 (12)	29 (12)	21 (7)	0.180

*Data are shown as median score (interquartile range).
†Kruskall-Wallis tests were used to compare the 3 groups.
‡At posttesting, the scores of the individual raters are shown.
§Post hoc Mann-Whitney *U* tests show significantly better performance for the organ vs both control (p = 0.006) and virtual training group (p = 0.009).

training groups (p = 0.68). The same trend, i.e., organ training group performing the procedure faster than both the other groups, was identified at retention testing but this did not reach statistical significance (Kruskall-Wallis test, p = 0.059).

The quality of performance (averaged scores for 2 or 3 raters) is shown in Table 3. The Spearman correlation for interrater reliability between the 2 main raters was 0.65 (p < 0.0001). Between those 2 raters and the third rater (at posttesting), interrater reliabilities were 0.49 (p = 0.006) and 0.47 (p = 0.008), respectively. At baseline, there was no difference between the groups. The organ training group performed significantly better at posttesting compared with both control (p = 0.006) and VR training groups (p = 0.009, Fig. 2). Only rater 1 distinguishes between the groups very clearly. No significant differences were seen at retention testing.

The results of the questionnaire are shown in Fig. 3. For the entire training, course students in the organ training group assessed its usefulness with a median score of 5 (IQR = 0) and the students in the VR training group 4 (IQR = 1.5, p = 0.002). For the clip-cut exercise, this was 5 (IQR = 0.25) and 4 (IQR = 1.25) correspondingly (p = 0.036). For the dissection of the Calot triangle, this was 4 (IQR = 1.25) and 3 (IQR = 2.25) correspondingly (p = 0.529). For the dissection of the gall bladder from the liver bed, this was 5 (IQR = 0) and 4 (IQR = 2.5) correspondingly (p = 0.005). Table 4 shows the personal comments of the subjects.

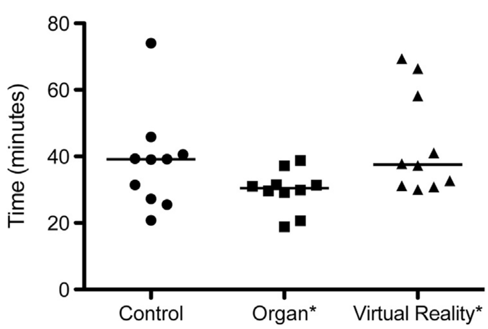

FIGURE 1. Scatter dot plot for time needed to perform the cholecystectomy at posttesting. *Mann-Whitney *U* test: p = 0.015.

DISCUSSION

The use of VR simulation in surgical training has been extensively validated in the past decade. Abundant evidence shows that training of basic laparoscopic and suturing skills on virtual simulators results in improved technical performance in the operating room.[2-6] Proof of superiority in teaching these basic skills over the conventional and much cheaper box trainers is, however, lacking.[7-9] The next step in surgical training comprises procedural exercises. As virtual simulation obviates the need for live animals or cadaver organs, this might be an area where its advantage truly lies. This study focused on the LapMentor virtual simulator, which provides a stepwise training program for the laparoscopic cholecystectomy.

The aim of this study was to evaluate the transfer of procedural skills acquired during VR or organ training to a real procedure.

For the organ training group, significant higher quality of performance was seen at posttesting compared with both the other groups. At that time, they also performed the procedure significantly faster than the VR training group and borderline significantly faster than the control group. Although the porcine training model, live anesthetized or cadaveric, for the laparoscopic cholecystectomy was already proposed in the beginning of the 1990s,[23,25] validation

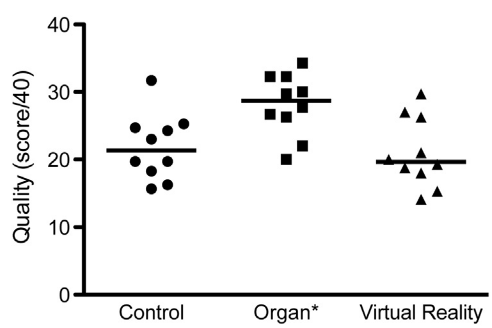

FIGURE 2. Scatter dot plot for quality of performance at posttesting (= average score by 2/3 raters [maximum score 40]). *Mann-Whitney *U* test < 0.01 when compared with both the other groups.

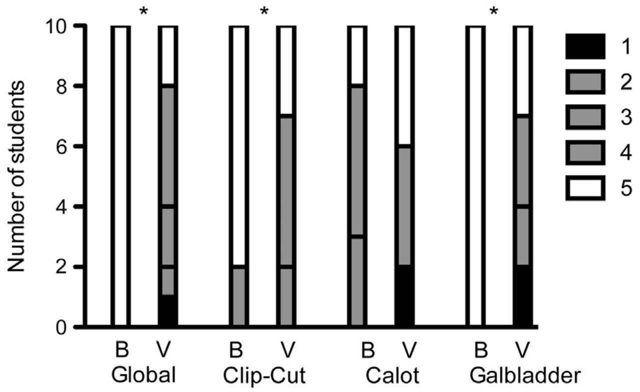

FIGURE 3. Questionnaire concerning perceived usefulness of the training by the (O) organ training and (V) virtual-reality training group. Results of the 5-point Likert scale (1 = not useful at all [black], 2-4 moderately useful [gray] to 5 = very useful [white]). *Significant difference (Mann-Whitney *U* test).

studies are lacking. This is, to our knowledge, the first study that explicitly shows a transfer of skill to a real-life procedure after training on a porcine cadaver cholecystectomy model. However, to our surprise the effect of organ training seen in this study was rather small. Firstly, only the rater most enganged in the study could significantly discriminate between the groups whereas the others could not. Secondly, concerning the quantitative aspect time, the better performance of the organ training group compared with the control group did not reach statistical significance. Furthermore, the performance during the live procedure in this study is even only a substitute of performance in a human cholecystectomy. The transfer of skill to this latter model remains to be proven.

At retention testing, the difference that was measured initially seemed to have diminished as no statistical differences were seen between the groups. This indicates deterioration of performance, which stresses the importance of maintenance training. Only 1 other study specifically addressed retention of procedural skills.[26] They found no deterioration of laparoscopic salpingectomy skill in novices after 6 months. In that study, surgical trainees were included who still had ongoing experience in the operating theater.

The virtual training group did not outperform the control group at any point. Previous studies concerning procedural training using virtual simulation have consistently had positive outcomes. Aggarwal et al.[27] showed a significantly better performance on a cadaver organ cholecystectomy within 4 weeks after training of basic and procedural tasks on the LapSim virtual simulator compared with a control group without training. Unfortunately, no retention testing was performed in that study. Beyer et al.[28] showed improvement of performance compared with baseline during a human cholecystectomy <3 months after training on basic and procedural tasks of the LapMentor virtual simulator. Palter et al.[24] showed a better performance of a trained vs control group during a human cholecystectomy within 6 months after training. The training course included theoretical learning, procedural exercises on the LapSim next to basic skills training on virtual and box trainer, as well as operating room participation. In our study however, the VR training group did not outperform the control group at any point. This might be owing to the fact that this study concentrated explicitly on the additive effect of procedural training. In those previous studies, training consisted of a combination of basic laparoscopic skills and procedural exercises. Therefore, the improvement of performance detected in those studies might very well be caused by the training in basic laparoscopic skills more than the addition of procedural exercises. Only 1 study adressed the question of the additive role of procedural exercises on a virtual simulator.[29] No benefit of procedural training was seen during a cholecystectomy in a swine model but the study might have been underpowered.

Another reason for a lack of training effect in the VR training group could be the absence of expert feedback, which might be indispensible especially in this novice trainees. Boyle et al.[30] suggested to add expert feedback to VR training in endovascular surgery as a prerequisite to improve quality of performance. Kruglikova et al.[31] found less perforations during colonoscopy when expert feedback was added to a VR training program. Wierinck et al.[32] described lower error score and better retention when adding expert feedback to a dental VR training program. Strandbygaard et al. found increased efficiency of training a virtual laparoscopic salpingectomy task when adding instructor feedback.[33] In our study, expert feedback was avoided on purpose as unproctored training forms one of the main advantages of virtual simulation, allowing

TABLE 4. Comments on Training

Virtual-reality training	
Positive	Helps to discover the safe margins of clipping and cutting
	Breaks up the procedure in several steps
	Good at initial training: hand coordination, and cognitive aspects
	Full procedure: best exercise for automatization of actions
	Good to get to know the instruments
Negative	Dissection gall bladder is too easy
	Plane between gall bladder and liver not realistic
	No possibility of practicing dissection with forceps in hilus
	Parameters were too strict and create time pressure and would be better to focus more on quality
	Totally different haptic feedback and exercises were too easy
Organ training	Good to build confidence, practice different situations like leakage, tear, etc
Positive	Gives a better clue of what you are doing, finding the correct plane, and positioning of instruments

deliberate practice on any time of day without the extra costs and efforts required to provide expert surgical assistance. This is one of the areas where virtual simulation can improve significantly, providing quality parameters that are usefull for adequate feedback and assessment of surgical skill. On this moment, in the evaluation of construct validity of surgical simulators the quantitative parameters have been validated extensively but the same evidence is lacking for many quality parameters.[34-36]

Eventually, it is possible that the lack of training benefit for the virtual training group in this study indicates that virtual simulation is not yet suitable and does not yet have the required features to teach the refined skills needed in procedural exercises. The students in our study indeed appreciated the cognitive imput of the virtual trainer to get to know the different steps of the procedure and the handling of the instruments but thought the realism of the haptic feedback and anatomical details were insufficient. Vapenstad et al.[37] similarly showed that surgeons assess haptic feedback as an important but currently insufficient feature in virtual simulation. Sharma et al. compared the opinion of residents concerning training on the LapMentor with fresh-frozen cadavers. The latter scored better for all items including anatomical detail, tactile feedback, demonstration of tissue plane, and feedback on performance by experts.[38] Overall, in the current study students in the organ training group were significantly more enthusiastic about the training than the students in the VR training group. Only on the dissection of the Calot' triangle, there was no difference in their opinion of usefulness of the training. Previous studies[39-40] already showed that residents prefer animal/organ training the most. In basic skills acquisition, box trainers are chosen over virtual simulators.[41]

Our results suggest that for procedural skills, cadaver organ training is more efficient, at least on the short term, and more valued by trainees compared with virtual-reality training. However, when designing a curriculum for procedural laparoscopic training, it is equally important to consider the costs that come along with it. Cost estimation for surgical training centers is a complex exercise. According to Berg et al., the acquisition of a video trainer with electrocautery and endoscopic clip applier costs around $30,000. Costs for laparoscopic tools, organ purchase, preparation, and expert supervision need to be added. The purchase of a virtual simulator ranged from approximately $50,000 to 87,000.[42] This indicates that for either kind of model, procedural training is expensive and costs should definitely be weighed against the money one wants to spend.

This study has some limitations. Firstly, the study was performed in medical students without clinical or surgical experience. This group was chosen to prevent interference of previous or concurrent surgical practice. Compared with the residents, they might have had insufficient knowledge to fully profit from the training and training effect might have been underestimated. A theoretical introduction with written examination and an extended training in basic laparoscopic skills were included to minimize this problem. Also a large range in performance is expected in this population creating higher risk on a type II error. As the sample size calculation was based on a study including general surgery residents, our current study could have been underpowered. We do think this might have concealed existing benefits for the organ training group, given the several borderline significant data. However, the virtual training group has never even shown a trend of improved performance compared with the control group. We, therefore, do not believe increasing the number of participants would have changed this outcome. Furthermore, it is hard to verify equal amount of training in the organ and VR training group as the first one was restricted by time and the second by proficiency parameters. We tried to control for this by including a minimum amount of training (5 hours) in the VR training group as well. Interrater reliability was between 0.47 and 0.65, which is rather low. Although raters were trained on the rating scales, this can be explained by their different surgical or research backgrounds. Apparently, even more elaborate training in these rating scales is needed.

Recently, the benefit of incorporating a structured preclinical laparoscopy course for medical students just before entering surgical residency was shown.[43] The results of this study suggest that for this specific group of trainees (medical students), the additive effect of procedural training after a proficiency-based basic skills training is limited, especially on the long term. Therefore, the additional cost may not be worth it. Further research is definitely needed to elucidate the role of virtual simulation in procedural training. Our study highlights some pitfalls for this future research. Most importantly, it should focus on surgical residents and on the additive value of procedural training using study subjects that are adequately trained in basic laparoscopic skills. Ideally, it should include a comparative group that receives conventional training in the operating room. Probably the presence of expert feedback in this kind of training is indispensible, even in a virtual environment where proctoring is purported to be included in the system.[44] And finally, the ultimate outcome measure should be surgical performance on a human (cholecystectomy) model.

CONCLUSIONS

For trainees who are proficient in basic laparoscopic skills, the long-term advantage of additional procedural training, especially on a virtual but also on the conventional organ training model, remains to be proven.

DISCLOSURES

Drs Van Bruwaene and Napolitano report no proprietary or commercial interest in any product mentioned or concept discussed in this article. Dr. Schijven received the Dutch subsidiary "Pieken in de Delta" for enhancing patient safety through serious gaming and the Innovation subsidiary in augmented reality from the Surfnet/Kennisnet innovation program.

ACKNOWLEDGMENTS

Thanks to the Staff Members of the Department of Abdominal Surgery of the University Hospital Leuven and the Staff of the center for Surgical Technologies for their participation in the study. Furthermore, thanks to Jan-Maarten Luursema for his cooperation at the ASGBI meeting. Special thanks to the students that participated in the study, I hope you had a good time.

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