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One or two trainees per workplace for laparoscopic surgery training courses: results from a randomized controlled trial

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Abstract

Background There are no standards for optimal utilization of workplaces in laparoscopic training. This study aimed to define whether laparoscopy training should be done alone or in pairs (known as dyad training).

Methods This was a three-arm randomized controlled trial with laparoscopically naïve medical students ($n=100$). Intervention groups participated alone ($n=40$) or as dyad ($n=40$) in a multimodality training curriculum with e-learning, basic, and procedural skills training using box and VR trainers. The control group ($n=20$) had no training. Post-performance of a cadaveric porcine laparoscopic cholecystectomy (LC) was measured as the primary outcome by blinded raters using the objective structured assessment of technical skills (OSATS). Global operative assessment of laparoscopic skills (GOALS), time for LC, and VR performances were secondary outcomes.

Results There were no differences between groups for performance scores [OSATS: alone (40.2 ± 9.8) vs. dyad (39.8 ± 8.6), $p=0.995$; alone vs. control (37.1 ± 7.4), $p=0.548$; or dyad vs. control, $p=0.590$; and GOALS score: alone (10.6 ± 3.0) vs. dyad (10.0 ± 2.7), $p=0.599$; alone vs. control (10.1 ± 3.0), $p=0.748$; or dyad vs. control, $p=0.998$]. Dyad finished LC faster than control [median = 62.5 min (CI 58.0–73.0) vs. 76.5 min (CI 72.0–80+); $p=0.042$], while there were no inter-group differences between alone vs. control [median = 69.0 min (CI 62.0–76.0) vs. control; $p=0.099$] or alone vs. dyad ($p=0.840$). Dyad and alone showed superior performance on the VR trainer vs. control for time, number of movements, and path length, but not for complications and application of cautery.

Conclusions The curriculum provided trainees with the laparoscopic skills needed to perform LC safely, irrespective of the number of trainees per workplace. Dyad training reduced the operation time needed for LC. Therefore, dyad training seems to be a promising alternative, especially if training time is limited and resources must be used as efficiently as possible. *Trial registration* German Clinical Trials Register: DRKS00004675.

Keywords Minimally invasive surgery · Education · Training · Cholecystectomy · Laparoscopy · Dyad training

Minimally invasive surgery (MIS) has become the gold standard for many operations, including cholecystectomy and appendectomy. It differs from open surgery in that it requires advanced psychomotor and visuospatial skills in addition to the basic and procedural skills already required for surgery, thus resulting in steeper learning curves and prolonged operations [1, 2]. Due to these increased demands, training programs and modalities have been designed to standardize training benchmarks, thereby allowing a prospective surgeon to demonstrate competency in his or her skills before operating on patients [3–7]. Current modalities include e-learning, box trainers and pelvi trainers, computer simulators, cadavers and cadaveric organs, and live animal models. Basic skills e.g., suturing and knot tying are most easily acquired through repetition using real instruments on box and pelvi trainers [8]. Similarly, computer simulators, or virtual reality (VR) trainers, provide for the acquisition of basic skills through repetition, but additionally enable a trainee to practice procedural skills and full operations. VR

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trainers also offer the added benefits of instruction, feedback, and progression monitoring, but these benefits are diminished by the drawback of limited performance feedback metrics e.g., path length, velocity, and time, as well as lack of haptic realism [9–11]. In contrast to the aforementioned modalities, cadaveric organs and animal models provide the most realistic training with haptic feedback. However, their use is limited by availability and ethical constraints [11, 12].

Box and VR trainers have proven positive effects on the learning of practical laparoscopic skills, on the duration of operations, and to some extent also on clinical outcomes [3, 4, 7, 13, 14]. In combination with cadaveric organs, box trainers can be used to realistically simulate various interventions e.g., laparoscopic cholecystectomy (LC) [15–17]. In addition to the aforementioned modalities, trainees can reinforce their intellectual and procedural understanding of various operations through online learning platforms, which offer videos of full operations with explanations and teaching of surgical techniques, relevant anatomy, and perioperative management [18, 19]. Online learning programs have demonstrated training efficacy when used alone or in combination with other modalities [20, 21]. Optimal training outcomes are achieved by combining available modalities, in what is known as multimodality training [11, 22, 23]. Modern surgical education plays a pivotal role in ensuring patient safety and also needs to take into account the work-hour restrictions and availability of training opportunities [24, 25]. There are currently no standards regarding the use of training workplaces in laparoscopy training curricula. The sharing of a workplace by two trainees, a concept known as dyad practice, could maximize efficiency of training [26].

This study aimed to investigate whether laparoscopy training alone or dyad practice should be used in laparoscopy training curricula to attain optimal training benefits.

Materials and methods

Trial design

This study was a registered prospective, single-center, rater-blinded, three-arm, parallel-group randomized controlled trial and is reported according to the Consolidated Standards of Reporting Trials (CONSORT) [27]. The study protocol was officially registered in the German Clinical Trials Register (DRKS00004675) and published [28]. This study was conducted in the MIS training center of the Department of General, Visceral, and Transplantation Surgery at Heidelberg University Hospital. Data were recorded anonymously, treated confidentially, and evaluated by authorized staff for scientific purposes only. Participation was voluntary and offered in addition to compulsory university courses. Students could end participation at any time. Benefits of participation included laparoscopic experience, increased stamina, focus and interest in surgery, and manual dexterity. There were no foreseeable negative consequences related to participation. Involved Heidelberg MIS center staff were trained in the handling of training modalities and tutoring MIS. Ethical approval was obtained by the local ethics committee at Heidelberg University prior to the beginning of the study (Code S 334/2011). Written informed consent was obtained from each trainee.

The study aimed to investigate the optimal number of trainees per workplace in MIS training, specifically whether trainees should train alone or as dyad. A third group without training acted as control. At the beginning and end of the study, trainees were tested on a VR trainer. A post-test porcine cadaveric LC in the pulsatile organ perfusion (POP) trainer was used and evaluated by blinded raters based on validated scores [29].

Participants

This study offered an elective laparoscopic training course to medical students at Heidelberg University between October 2012 and June 2014. Inclusion criteria mandated that students were enrolled at Heidelberg University Medical School during their clinical years (3rd to 6th year out of 6 years of medical school in Germany). Exclusion criteria dismissed students who had formerly participated in laparoscopy training courses or who had experience of more than 2 h assisting in laparoscopic surgeries.

Interventions

All trainees began the study with a 2-h online learning module to familiarize them with the basic principles and techniques of LC [30]. This was completed in the same environment and conditions for each participant to rule out confounding factors. Trained staff assisted trainees with the compulsory registration at http://www.webop.de, and provided a standardized introduction to the LC module. From here, participants were instructed to use the module to study the anatomy, illustrations, and videos of the procedural techniques. Upon completion of this general introduction to LC, trainees then began to study more procedure-specific aspects. To reinforce this material, trainees then went to http://www.websurg.com and watched the "Laparoscopic cholecystectomy: a gold standard case for dissection of Calot's triangle" module. After finishing the online learning module, students took a standardized multiple-choice knowledge test for LC. This test was discussed at the inception of the online learning module to ensure adequate motivation.

Following online learning, trained staff provided participants with a standardized introduction to the use of the box and VR trainers, thereby allowing students to familiarize

themselves with the training center and its devices prior to performing any tasks or tests. Once finished, all participants performed a baseline test on the VR trainer for an initial assessment of basic skills and LC performance. They were then randomly assigned to one of the three aforementioned study groups.

Basic skills were trained using the box and VR trainers (LAP Mentor II, Simbionix, Cleveland, OH). Procedural skills and complete LCs were practiced on the VR trainer. Training groups repeated the basic and procedural skills exercises of the curriculum over two 4-h training sessions until time was over. The LC modules were repeated on the VR trainer with the second 4-h training session. Furthermore, the VR trainer permanently recorded all data from the training exercises e.g., time, precision, economy of motion, instrumental distance, and the number of misaligned clips. During the training sessions, all participants that were randomized to training alone had to take at least a 10-min break every hour as evidence in training psychology suggests higher efficiency with reflective pauses and feedback between sets of repetitions, supporting the principle of "train less and learn more" [31].

The basic skills and LC modules of the VR trainer were followed over time and also integrated in the post-test. Additionally, a porcine cadaveric LC on the POP trainer was performed once as the post-test assessment. The post-test cadaveric porcine LC on the POP trainer was used to evaluate and compare the operative performance of all participants. The objective structured assessment of technical skills (OSATS) was used as the primary endpoint of the study [32]. The OSATS consists of two evaluative spectra and allows for the evaluation of general laparoscopic surgical skills (GRS, general rating scale) as well as specific procedural and technical skills (STS, specific technical skills scale) for the operation. The unweighted sum of the two scales was evaluated as the primary endpoint. The global operative assessment of laparoscopic surgical skills (GOALS) score, time required to perform the operation, and VR parameters were used as secondary endpoints [33]. Assessment was done by blinded expert raters. To ensure the logistical feasibility of this study, 80 min was provided as the maximum duration to complete the LC. Former research has shown 80 min as sufficient to assess each participant's competence for all major parts of the operation.

Sample size/study size

Sample size determination was calculated by a statistician who was not involved in practical measures of the study such as rating or instruction. As described in the study protocol, a total of 100 students were included (alone: $n=40$, dyad: $n=40$, control: $n=20$) [28]. Using $\alpha=0.05$ and a power of 80%, the sample size is sufficient to detect a standardized effect of $d=0.64$ between the two active arms regarding OSATS. Assuming a standard deviation of 7.86 for both groups, this effect corresponds to a difference of 5 points. Detailed information on sample size calculation can be found in the study protocol [28].

Randomization

Literature suggests that men and women exhibit differences in the acquisition of laparoscopic skills [34, 35]. Study participants were stratified according to sex and randomly assigned to the training groups or control group in a 2:2:1 ratio (alone–dyad–control) by block randomization with a variable block length. An employee of the Department of Surgery at Heidelberg University used sealed envelopes from a computer-generated list to perform the randomized distribution of a subject upon completion of the VR trainer baseline test. The employee responsible for the randomization and group assignment was otherwise not involved with the training, tests, or data from the present study.

Blinding (masking)

The expert raters involved were blinded to the training status of the participants. Those involved with data and statistical analysis were blinded to the identity of trainees. Participants' names were kept separate from all study data and were not used for the study. Each participant was assigned a designated code that was used for the entire study documentation and data collection.

Statistical methods

OSATS scores were analyzed by a linear mixed model with the main effects group (alone, dyad, control), gender (stratification factor), rater (stratification factor), and training pair as a random factor nested in the dyad group. The intention-to-treat population was the basis for statistical analysis. Data in the primary and secondary endpoints were complete; therefore, no imputation was needed. The secondary endpoints were analyzed in similar mixed models, with main effects group, gender, and rater (no interactions): multiple regression for continuous variables, logistic regression for binary outcomes, and mixed Cox models for operation times.

Results

A total of 100 medical student were included and randomized to one of the three groups (alone = 40; dyad = 40; control = 20). The groups were homogeneous for most baseline characteristics (Table 1). Only in the dyad group were 2 (5%) trainees who assessed themselves as having advanced

Table 1 Baseline characteristics of the three groups

	Control ($n=20$)	Alone ($n=40$)	Dyad ($n=40$)
Sex (male)	9 (45%)	20 (50%)	19 (47.5%)
Age (mean ± SD)	24.1 ± 2.3	24.3 ± 3.6	24.8 ± 2.9
Semester (mean ± SD)	8.0 ± 1.8	8.0 ± 1.9	8.8 ± 2.0
Experience with open surgery in %			
None	35	20	22
Limited	30	52	48
Moderate	35	28	22
Advanced	0	0	5
NA	0	0	2

open surgery experience, and in the control group were less trainees with limited experience but slightly more with none or moderate experience compared to the alone and dyad group. There were no dropouts (Fig. 1).

Objective structured assessment of technical skills (OSATS)

There were no significant differences between the three groups for the average OSATS score and its subscores GTS and STS (Table 2).

Time

The dyad group finished the LC significantly faster than the control group [dyad: median = 62.5 min (CI 58.0–73.0) vs. control: median = 76.5 min (CI 72.0–80+); HR 2.1; $p = 0.042$] and there was a trend for the alone group [median = 69.0 min (CI 62.0–76.0)] being faster than control (HR 1.82; $p = 0.099$). There was no significant difference between alone and dyad (HR 1.15; $p = 0.840$) (Fig. 2). The percentage of trainees in the alone (82%) and the dyad (82%) groups who finished the operation in time were not significantly higher compared to the control

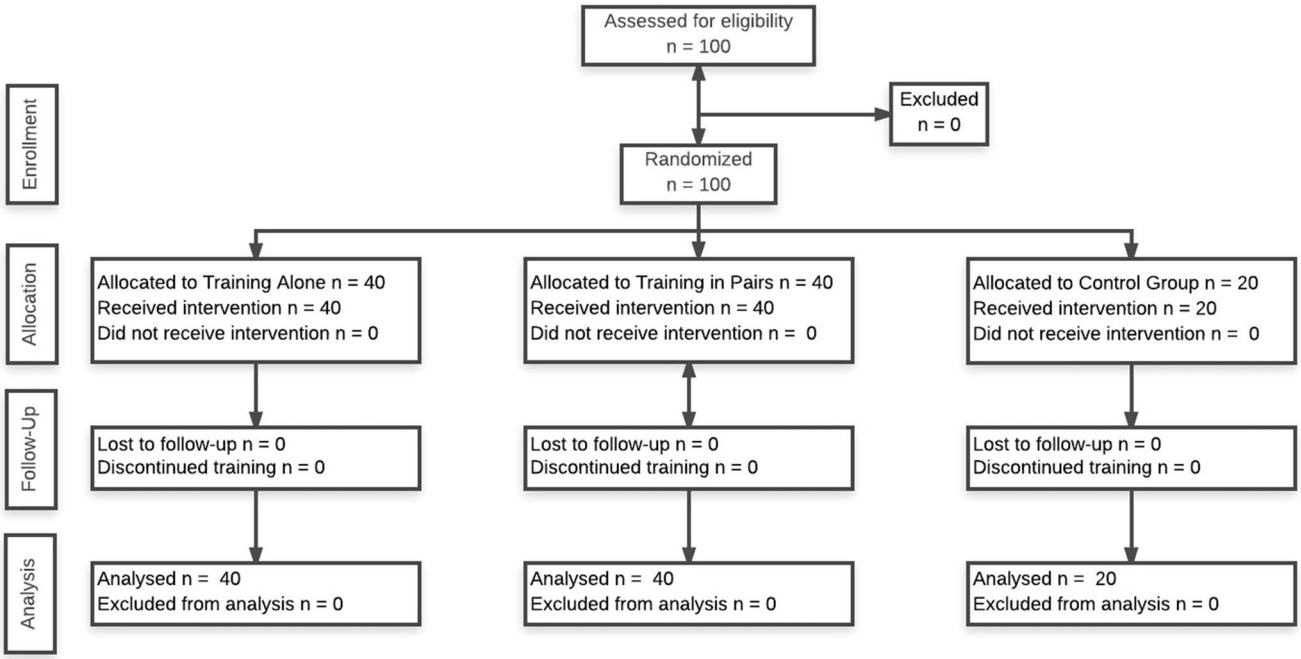

Fig. 1 The CONSORT flow diagram

Table 2 Comparison of objective structured assessment of technical skills (OSATS) and sub scores (mean ± SD)

	Alone	Dyad	Control	*p* value* (alone vs. control)	*p* value* (dyad vs. control)	*p* value* (alone vs. dyad)
OSATS	40.2 ± 9.8	39.8 ± 8.6	37.1 ± 7.4	0.548	0.590	0.995
GTS	10.6 ± 3.2	10.2 ± 3.0	9.6 ± 1.6	0.508	0.789	0.836
STS	29.6 ± 7.0	29.6 ± 6.3	27.5 ± 6.4	0.622	0.553	0.991

*Corrected for covariates

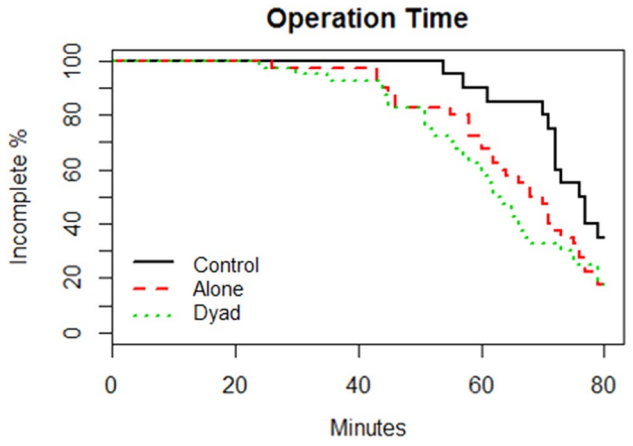

Fig. 2 Operation time for the laparoscopic cholecystectomy by group on the pulsatile organ perfusion trainer

group (65%; alone vs. control $p = 0.286$; dyad vs. control $p = 0.295$). There were no differences between the alone and the dyad group ($p = 0.999$).

Global operative assessment of laparoscopic skills (GOALS)

The GOALS score did not show differences between the three groups [control = 10.1 ± 3.0 vs. alone = 10.6 ± 3.0 ($p = 0.748$); control vs. dyad = 10.0 ± 2.7 ($p = 0.998$); and alone vs. dyad ($p = 0.599$)].

Virtual reality trainer

Analyses of VR trainer performances for LC showed significant differences for time, number of movements, and path length, while there were no differences found for complications and clipping (Table 3A). The training times (Fig. 3), number of movements, and path lengths for each VR assignment are summarized in Table 3B.

Learning progress

VR Peg Transfer and VR LC showed no differences between the two intervention groups for operation time and respective attempt number (Fig. 4). Furthermore, the alone group did

Table 3 Virtual reality parameters for the (A: laparoscopic cholecystectomy, B: different training scenarios)

A: LC	Control	Alone	Dyad	*p* value (alone vs. control)	*p* value (dyad vs. control)	*p* value (alone vs. dyad)
Time (min)[a]	13.5 (11.8–17.5)	10.2 (7.9–11.3)	10.2 (9.2–11.1)	< 0.001	< 0.001	0.987
Total number of movements	871 ± 234	683 ± 215	684 ± 187	0.002	0.002	0.995
Total path length (cm)	1640 ± 466	1316 ± 368	1344 ± 346	0.004	0.008	0.975
Complications	2.1 ± 3.5	1.5 ± 1.6	2.3 ± 2.5	0.619	0.944	0.294
Number of perforations	0.9 ± 2.7	0.7 ± 1.6	1.2 ± 1.8	0.881	0.884	0.496
Number of bleedings	0.3 ± 0.8	0.1 ± 0.5	0.2 ± 0.7	0.633	0.925	0.802
Efficiency of cautery (in %)	70.8 ± 10.2	71.9 ± 9.5	71.0 ± 10.1	0.979	0.944	0.987
Safe cautery (in %)	60 ± 14.1	62.6 ± 13.2	64.3 ± 14.3	0.604	0.477	0.968
B: training time	Control	Alone	Dyad	*p* value (alone vs. control)	*p* value (dyad vs. control)	*p* value (alone vs. dyad)
Peg transfer[a]	168 (144–300+)	126 (117–137)	121 (115–133)	< 0.001	< 0.001	0.787
Basic skills[a]	114 (107–125)	79 (74–82)	79 (75–87)	< 0.001	< 0.001	1.000
Procedural tasks[a]	204 (192–258)	121 (115–133)	121 (111–146)	< 0.001	< 0.001	0.706
Number of movements						
Peg transfer	528 ± 104	432 ± 113	450 ± 112	< 0.001	0.003	0.367
Basic skills	1061 ± 244	698 ± 152	721 ± 188	< 0.001	< 0.001	0.983
Procedural tasks	1348 ± 266	870 ± 270	821 ± 301	< 0.001	< 0.001	0.629
Path length						
Peg transfer	928 ± 230	863 ± 260	895 ± 233	0.130	0.476	0.586
Basic skills	3081 ± 840	2253 ± 437	2300 ± 609	< 0.001	< 0.001	0.997
Procedural tasks	3518 ± 713	2519 ± 830	2378 ± 906	< 0.001	< 0.001	0.475

Data reported in mean ± SD if not indicated otherwise

[a]Median (CI)

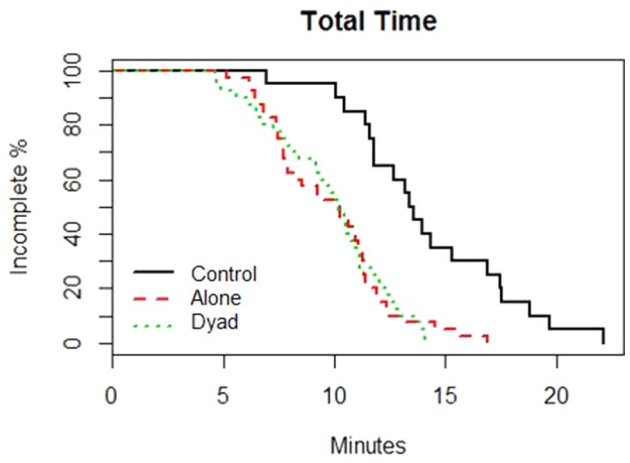

Fig. 3 Operation time for the laparoscopic cholecystectomy by group on the virtual reality trainer

not show further improvement with the VR Peg Transfer after the fifth attempt, while the dyad group plateaued after the fourth. For the VR LC, both groups (alone and dyad) plateaued after the fourth attempt.

Discussion

This randomized controlled trial found that dyad training for laparoscopy skills was as effective as training alone. Performance scores (OSATS and GOALS) were not different, but participants in the dyad group completed LC on real tissue faster than the control group. Furthermore, both intervention groups showed a superior performance on the VR trainer compared to the control group.

It seems intuitive to surgeons that training alone would be ideal, since a trainee would not need to share a modality i.e., the trainee would need less overall time in a training center for an equal amount of training repetitions. Furthermore, dyad training reduced the number of repetitions of each exercise by half for each trainee. However, dyad training offers a handful of potential advantages which could be witnessed and is also found in the literature, including but not limited to knowledge exchange, technical discussions between partners, analysis of errors, model learning when a partner trains, and more reflective pauses [36–38]. It has been demonstrated that the learning of practical skills in medical education e.g., physical examination skills, can be accelerated by observing peers [39]. In the present study, the dyad group completed the LC significantly faster than the control group, while there were no differences between control vs. alone or dyad vs. alone. There is little evidence on the optimal number of trainees per workplace in surgical training. The concept of dyad training was investigated in the field of psychology earlier by Shea et al. who showed that dyad training was superior compared to individual training in a balancing task since the acquired skills are retained longer [26]. Granados et al. reported that those findings were more based on observing the other learner, rather than on dialogue between partners [40]. However, the present study allowed trainees to talk to their partner, thus making it difficult to determine what led to the time reduction. One explanation could be that trainees who received feedback through the partner felt more confident. Dyad training contributing to confidence was described by Tolsgaard et al., who interviewed medical students after working in pairs [41]. Another contributor might be the competition between the two trainees, which leads to increased motivation as students aim to outperform each other [42]. However, it is not yet clear if the acquisition of complex medical skills benefits from dyad training as Räder et al. did not find any difference between the performance scores of a dyad and individual

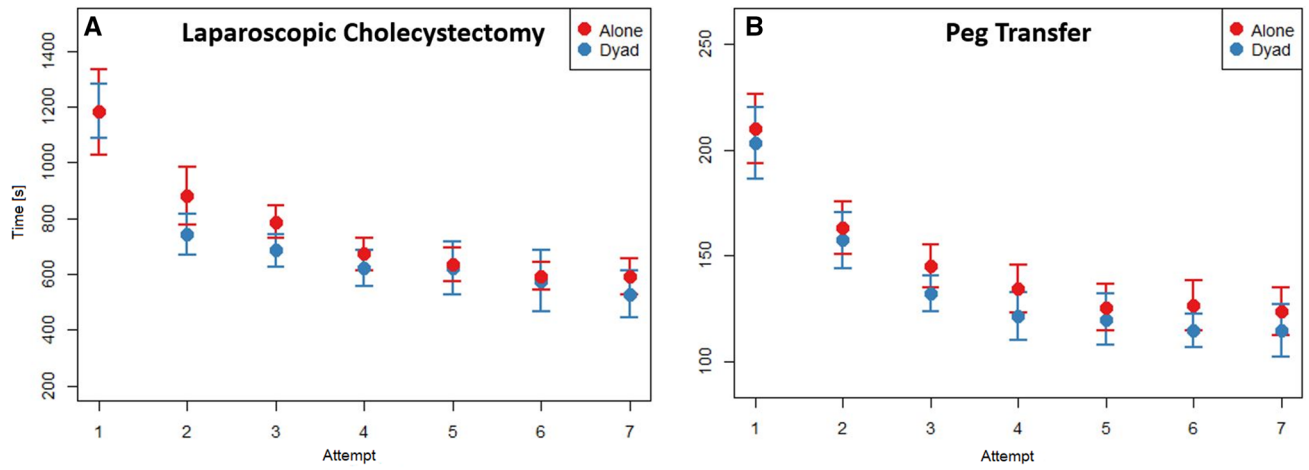

Fig. 4 Comparison of the operation time between the intervention groups on the VR trainer. **A** LC, **B** peg transfer (mean with 95% CI)

training group for learning angiography [43]. Similar results are reported by Shanks et al. for the training of simulation-based lumbar puncture [44]. Evaluation from a student's perspective whether training as dyad is wanted or beneficial could also help to tailor training programs. Even though the present study found no differences between groups for the performance scores, the reduction in time and the fact that two trainees could be trained at the same time made dyad training more efficient for learning laparoscopy.

In the present study, the intervention groups did not score higher than control on both the OSATS and GOALS score. This might be due to the fact that the curriculum focused mainly on a structured training of psychomotor skills and the acquisition of knowledge for a LC rather than tissue preparation. Another study of our group could already prove the benefits of a structured multimodality curriculum for surgical residents [45]. The literature does not show consistent findings for the impact of VR on the performance in the OR. In a study by Grantcharov et al., VR training of psychomotor skills was found useful because trainees needed less time for completion of a real LC [46]. Although the trainees were able to reduce the error rate compared to a non-training control group, the total difference of errors after training between the two groups was not reported in the study by Grantcharov. Another study by Ahlberg et al. did not find performance differences between a VR training group and a non-training group on a real porcine model post-test [47]. Additionally, since training was not completed on real tissue but post-test was, errors might have arisen from misinterpretation of the anatomy. In a study by McKinley et al., it was shown that the primary cause of damage to the biliary tract during LC is not due to lack of dexterity with the instrument but due to misinterpretation of the anatomy [48]. In contrast, Hyltander et al. found that an intervention group which trained on a VR trainer for 10 h performed significantly better on a porcine model than an untrained control group [49]. However, the tasks in the above-mentioned study focused on psychomotor skills instead of advanced tasks such as tissue preparation. To summarize, structured training of psychomotor skills on VR and box trainers improves performance on real operations for basic tasks, while gaining experience for advanced tasks (tissue preparation, interpretation of anatomy) requires more dedicated training.

Limitations

In the present study, the trainees had a given amount of time for training. Therefore, it is possible that trainees already reached a plateau level during the given training time for the VR exercises, which could explain the lack of difference between the two intervention group scores. On the other hand, the intervention groups outperformed the control group on the VR trainer and reached a sufficient proficiency level to gain more practice and experience in the real OR. According to the CONSORT guidelines, inter-rater reliability should be reported. A repeated rating was not possible in the course offered for the students in this study as expert time is a scarce resource. However, all performance scores and parameters used in the present study have been validated in numerous previous studies and were found to have good validity and reliability.

Furthermore, the OSATS score was originally developed for surgical residents by Martin et al. and not for naïve trainees. This should be kept in mind when interpreting the results [50]. However, to account for this, all participants received a structured introduction to laparoscopy both theoretically and practically. Additionally, only students who were in their clinical part of studies and successfully finished the first state examination were included. Thus, participants of the study were a homogenous group with pre-existing surgical skills. Moreover, the use of validated checklists such as OSATS and GOALS for performance assessment is common practice in surgical education research and has proven feasible [51].

Conclusions

The curriculum provided trainees with the laparoscopic skills needed to safely perform LC irrespective of the number of trainees per workplace. Trainees reached a sufficient skill set which will allow them to gain more experience assisting in live animal operations and the real OR. Dyad training reduced the operation time needed for both a VR and real LC. Therefore, dyad training seems to be a promising alternative, especially if training time is limited and resources must be used as efficient as possible.

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Compliance with ethical standards

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