Randomized trial to examine procedure-to-procedure transfer in laparoscopic simulator training

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Background: Laparoscopic simulation has become a standard component of surgical training, but there is limited knowledge regarding skills transfer between procedural tasks. The objective was to investigate the specificity of procedural simulator training.

Methods: This was randomized single-centre educational superiority trial. Surgical novices practised basic skills on a laparoscopic virtual reality simulator. On reaching proficiency, participants were randomized to proficiency-based training. The intervention group practised two procedures on the simulator (appendicectomy followed by salpingectomy), whereas the control group trained on only one procedure (salpingectomy). The main outcomes were number of repetitions and time to proficiency for the second procedure.

Results: Ninety-six participants were randomized, of whom 74 per cent were women, with a median age of 26 years. The intervention group needed significantly fewer attempts than the control group to reach proficiency in the second procedure: median (i.q.r.) 22 (17–34) *versus* 32 (26–41) attempts, which corresponded to 24·1 per cent fewer attempts as assessed by multivariable analysis ($P = 0.004$). The intervention group required significantly less time than the control group to reach proficiency: median (i.q.r.) 88 (63–127) *versus* 131 (101–153) min respectively, corresponding to a difference of 31·1 min as assessed by multivariable analysis ($P = 0.001$).

Conclusion: Practising two procedures, compared with only one, reduced the number of attempts and time to reach proficiency in the second procedure. Skills transfer is seen between two tasks in laparoscopic simulator training; however, task specificity is still present when practising procedures. Registration number: NCT02069951 (http://www.clinicaltrials.gov).

Background

Surgical education has changed with the introduction of simulators as training tools. Simulators have undergone substantial improvements and enabled training of procedures instead of just basic skills tasks. Although structured surgical curricula using simulation-based training have become more common, procedural training is still not used widely in laparoscopic training and assessment[1,2]. Limited availability of virtual reality modules and other practical challenges have meant that few procedural virtual reality modules exist that have solid validity evidence and

for which relevant proficiency levels have been defined[3]. Although skills transfer has been demonstrated from basic skills training on simulators to real procedures in the operating room, practising isolated tasks alone has not proved to be an optimal strategy in acquiring the more complex skills necessary to become a proficient surgeon[4–8].

The 'specificity of practice' hypothesis suggest that there is a high degree of task specificity when learning new laparoscopic procedures[9]. In contrast, the concept of positive skills transfer applies to different procedural tasks because they share many identical elements, such as isolated skills integration, procedure planning and surgical

error awareness[9]. The limited number of randomized trials examining laparoscopic skills transfer are contradictory; some have found that laparoscopic skills are generalizable, but others have reported high task specificity[7,10–12].

The hypothesis tested in this randomized trial was that some training skills (planning, isolated skills integration, decision-making) would be transferable between two laparoscopic procedures that differed in anatomy, instruments and possible complications. The objective was to evaluate the specificity of proficiency-based procedural simulator training by examining transfer between two procedural tasks on a laparoscopic simulator.

Methods

The randomized single-centre educational superiority trial design has been described in detail previously[13]. The trial complied with the Helsinki Declaration on biomedical research and was submitted to the Regional Scientific Ethics Committee, which found that ethical approval was not required (H-4-2013-FSP). Participation was voluntary and there was no financial compensation. The trial was registered at Clinicaltrials.gov (NCT02069951).

Participants

Senior medical students were recruited through the student newspaper and student associations for general surgery and gynaecology. Participants attended an introductory meeting and were included if they met the following eligibility criteria: were enrolled at the Faculty of Health Sciences at the University of Copenhagen, had a bachelor's degree in medicine, and provided verbal and signed informed consent for participation in the trial. Exclusion criteria were: participation in previous projects involving laparoscopic training, any experience with laparoscopic surgery, and inability to speak Danish at a conversational level.

Intervention

The trial was conducted at the surgical skills centre at Rigshospitalet, University of Copenhagen[14]. Participants were able to book 3-h training sessions using a web-based system; only one session per day was permitted. At the first session, participants were instructed on how to use the simulator, adjust ergonomic settings and handle the laparoscopic instruments. All participants took part in basic skills training that consisted of six modules (coordination, instrument navigation, grasping, lifting and grasping, fine dissection and cutting). On reaching proficiency, participants were allocated randomly to either the intervention or control group.

The intervention group started by practising laparoscopic appendicectomy, using a hook electrode and endoloop technique (procedure A). After reaching the proficiency level, they practised removing an ectopic pregnancy by laparoscopic salpingectomy using bipolar forceps (procedure B). The control group only practised procedure B to proficiency. There was no delay when moving from practising basic skills to a procedural module or between the two procedural modules. The predefined proficiency level was based on performance curves of experienced surgeons from previous studies[13].

Proficiency was reached for all modules when all parameters were fulfilled simultaneously using the correct technique for at least two of five consecutive attempts. After each attempt, the simulator generated automated feedback, with standard instructor feedback given after the first and tenth attempts. Standard feedback focused on operating technique, and the correct use of instruments and diathermy[15]. The principal investigator was present at all sessions, supervised training and provided all feedback.

Four identical LapSim® virtual reality laparoscopy simulators (software version 2013; Surgical Science, Gothenburg, Sweden) were connected to a central server storing all data obtained. Wall dividers separated simulators, and participants wore noise-cancelling headphones to minimize distractions and prevent them from hearing each other.

Randomization

The Copenhagen Trial Unit was responsible for central computerized 1 : 1 randomization. A computer-generated allocation sequence with a varying block size of 8, 6 and 4 was used, and kept concealed from the investigator. The investigator employed a web-based randomization programme to allocate participants. Two stratification variables were used: sex and time to proficiency for basic skills (more than 2 h, 2 h or less).

Outcomes

The primary outcome was the number of repetitions to reach proficiency in procedure B (salpingectomy). The secondary outcome was the total effective training time for procedure B in minutes; this was the time spent practising the procedure not including pauses during training, time for feedback, and time spent reviewing automated feedback and previous attempts. Exploratory outcomes were: motor skills parameters for the first attempt at procedure B (task completion time, cumulative instrument tip length in metres, and cumulative angular path length in degrees).

Additionally, the cognitive load for the first procedure B attempt was assessed using the Subjective Mental Effort Questionnaire (SMEQ), which allowed individuals to rate the amount of effort invested on a scale from 0 to 150, including nine markers with verbal statements ranging from 'not at all hard to do' to 'tremendously hard to do'[16,17].

Data handling

A person not involved in the trial performed external data monitoring and extracted the simulator data. All other data were collected on paper case record forms and entered into an OpenClinical database hosted by the Copenhagen Trial Unit using double data entry by external personnel.

Blinding

Owing to the nature of the interventions, it was not possible to blind the participants or the principal investigator.

However, all other trial aspects were blinded if possible. Statistical analyses were performed blinded with the two intervention groups coded as X and Y. Subsequently, two conclusions were drawn by the steering committee, one assuming that X was the intervention group and Y was the control group, and one assuming the opposite. Following this, an independent data manager at the Copenhagen Trial Unit broke the code.

Statistical analysis

Based on previous studies, the control group was expected to require a mean of 30 repetitions to reach proficiency[13,15,18]. A minimum difference of ten repetitions was deemed relevant, meaning that the intervention group was expected to use a mean of 20 repetitions to reach proficiency. A s.d. of 15 in both groups was assumed. With a significance level set at 0·05 and a power of 0·90, 48 participants were required in each group.
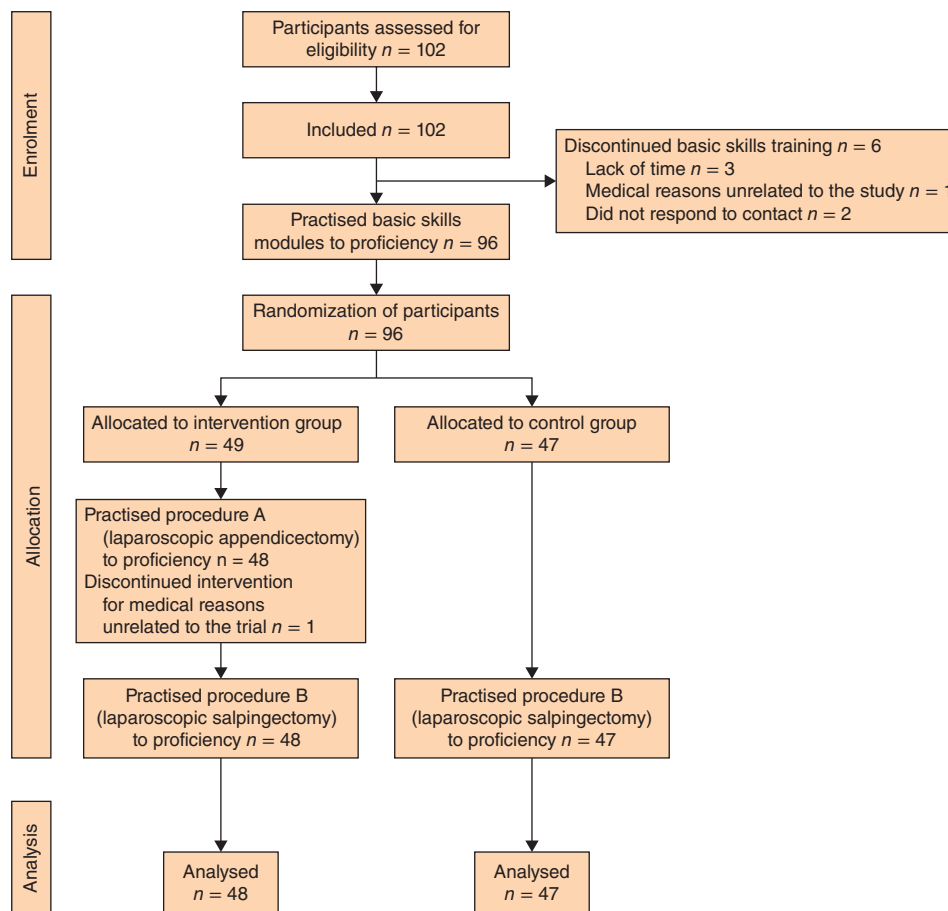

Fig. 1 CONSORT diagram for the trial

Continuous data are presented as median (i.q.r.). The Wilcoxon rank sum test was used for group comparisons. For each outcome, a stratification-adjusted multivariable normal linear model was used to determine the intervention effect. Right-skewed outcomes were log-transformed and the corresponding differences reported as percentages. Statistical analysis was performed using the software package R version 3.0.3 (R Project for Statistical Computing, Vienna, Austria) with a two-sided significance level of 0·05. The *P* values for secondary and exploratory outcomes were adjusted for multiple testing using the Benjamini–Hochberg procedure[19]. In accordance with the published statistical plan, complete-case analysis was applied as the drop-out rate after randomization was less than 5 per cent[13].

Results

Participant enrolment and intervention completion is shown in *Fig. 1*, in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement[20].

A total of 102 participants provided informed consent to participate in the trial, of whom 96 completed basic skills training and were randomized. Of those randomized, 95 (99 per cent) complied fully with the intervention. A single participant from the intervention group dropped out for unrelated medical reasons. The two groups had similar baseline characteristics, and took an equivalent time to reach proficiency in the basic skills modules (*Table 1*). The intervention group took 17 (10–28) attempts, spending 105 (65–161) min of effective training time before reaching proficiency in procedure A.

Primary and secondary outcomes

The primary and secondary outcomes are shown in *Table 2*. The intervention group took significantly fewer attempts than the control group to reach proficiency for procedure B: 22 (17–34) *versus* 32 (26–41). This corresponded to 24·1 (95 per cent c.i. 8·5 to 36·9) per cent fewer attempts as assessed by multivariable analysis (*P* = 0·004). The intervention group needed significantly less time than the control group to reach proficiency: 88 (63–127) *versus* 131 (101–153) min. Multivariable analysis showed that this corresponded to a difference of 31·1 (14·0 to 48·3) min (*P* = 0·001).

Exploratory outcomes

Multivariable analyses showed that the intervention had no significant effect on the SMEQ score after the first attempt at procedure B; there was an observed difference of 3·85 (95

Table 1 Participant baseline characteristics

	Intervention group (*n* = 49)	Control group (*n* = 47)	Total (*n* = 96)
Age (years)*	26 (25–27)	26 (25–27)	26 (25–27)
Sex ratio (F : M)	36 : 13	35 : 12	71 : 25
Handedness			
Right-handed	46	45	91
Left-handed	3	1	4
Ambidextrous	0	1	1
Total effective training time to reach proficiency for all basic skills modules (min)*	198 (147–254)	184 (150–233)	

*Values are median (i.q.r.).

Table 2 Primary, secondary and exploratory outcomes

	Intervention group (*n* = 48)	Control group (*n* = 47)	*P*†
Primary outcome			
No. of attempts to proficiency for procedure B*	22 (17–34)	32 (26–41)	0·005
Secondary outcome			
Time to proficiency for procedure B (min)	88 (63–127)	131 (101–153)	0·001
Exploratory outcomes			
SMEQ after first attempt at procedure B (score 0–150)	55 (38–77)	65 (38–70)	0·326
Total procedure time for first attempt at procedure B (min)*	6·1 (5·3–7·6)	9·7 (7·3–11·6)	< 0·001
Total instrument-tip path length (right + left) for first attempt at procedure B (m)*	11·2 (8·9–13·6)	14·6 (11·7–18·5)	< 0·001
Total angular path length (right + left instrument) for first attempt at procedure B (°)*	1553 (1250–2087)	2312 (1856–3162)	< 0·001

Values are median (i.q.r.). *Data were right-skewed and therefore log-transformed for the subsequent multivariable analyses. SMEQ, Subjective Mental Effort Questionnaire. †Wilcoxon rank sum test.

per cent c.i. −5·0 to 12·7) points in favour of the intervention group ($P = 0.391$). A significant effect in favour of the intervention was observed for the three motor skills parameters (all $P < 0.001$) (*Table 2*). The control group spent 44·9 (95 per cent c.i. 27·0 to 65·3) per cent more time on the first attempt, had a 39·0 (20·1 to 60·9) per cent longer total instrument-tip path length and 53·7 (30·2 to 81·4) per cent more total instrument angular movement.

Discussion

The intervention group that practised two procedures needed fewer attempts and took less time to reach proficiency in the second procedure than the control group, which practised only one procedure. This implies that some skills obtained by the intervention group while practising the first procedure were transferred to the second procedure.

The intervention group required a relatively long time to reach proficiency in the second procedure; although the observed effect was statistically significant, the reduction in number of attempts (24·1 per cent) was slightly less than the minimum expected effect of 33 per cent, as the sample size was based on an expected reduction from 30 to 20 attempts. However, this reduction cannot be ruled out as the 95 per cent c.i. runs from 8·5 to 36·9 per cent, leaving both a large reduction and a very modest reduction in attempts possible. It is also possible that the effect observed in the intervention group was merely the result of the participants in this group spending more time training on the simulator, regardless of the tasks being practised, and that little transfer of skills between the two procedures occurred. The motor skills improvement demonstrated by the intervention group can explain, in part, the observed transfer effect. This is supported by the previous finding that practising a procedure on a virtual reality simulator transfers to an unfamiliar laparoscopic procedure[11]. Nonetheless, practising one procedure could not completely replace practising a different procedure on the simulator.

The present results are consistent with the observation that performance curves for learning in the operating room appear to be procedure-specific[21]. The same task specificity has also been observed in other fields, such as sports[22,23]. The observed task specificity could be the result of examining two different procedural tasks where cognitive elements such as planning and operating strategy dominate, and where the training relies on rule- and knowledge-based behaviour. In contrast, basic skills rely more on skill-based behaviour and the motor skills component dominates[24]. Generalizing the findings to a clinical setting might imply

that even experienced surgeons must expect a significant learning period for new surgical procedures. This phenomenon is acknowledged in aviation where experienced pilots must undergo simulator training and certification whenever they switch to another aircraft type.

The findings of this trial are also consistent with other randomized trials[7,12] examining laparoscopic simulator training task specificity, where limited skills transfer was found. One study[8] found that transfer was present between isolated tasks, but did not affect overall skills acquisition. Another[25] reported that increased task similarity increased the transfer effect.

Previous studies using the SMEQ to assess cognitive load during simulator training noted a reduction with continued training of the same skill[17]. The lack of any cognitive load difference during the initial attempt in the present study could stem from new procedures requiring familiarization. A cognitive load reduction would become more apparent only during additional attempts, although this was not measured in the present study. The SMEQ's inability to detect small differences in cognitive load, as well as lack of power, may have been contributing factors to the lack of difference.

This trial examined transfer between two different procedures in simulator training. Participants practised basic skills to ensure the same proficiency level and similar starting point in terms of simulator familiarization before randomization. An intervention similar to a modern curriculum design with proficiency-based training was used, making extrapolation of the results to actual training programmes easier. The trial was conducted with adequate generation of allocation sequence, allocation concealment, blinding wherever possible, and reporting of all relevant outcomes with only a single drop-out. Participants' sex has previously been found to be a possible predictor of initial simulator training performance[15,26]; stratifying the randomization for sex, however, ensured an equal distribution of men and women in each intervention group.

Senior medical students were used as participants instead of residents and this may be a limitation. Participants were, however, recruited through surgical interest groups, ensuring that they were properly motivated. Additionally, simulation is typically used for novices who often have no previous surgical experience, such as medical students, and their simulator performance has been found to be comparable to that of residents[15]. The basic skills training before randomization also reduced the limitation of using medical students as participants, as well as the influence of innate abilities. Only transfer between two procedures in laparoscopy was examined, so the findings need be confirmed for other procedures and types of minimally invasive

surgery. Using procedures of greater similarity might have resulted in a larger transfer effect. Transfer to the clinical setting was not included, leaving its consequences to be examined.

Procedural training using a laparoscopic simulator is limited by the availability of training modules with sufficient validity evidence[3]. To counter this, other strategies, such as task deconstruction and part-task training, have been suggested[27]. However, practising procedures as a whole may be superior to practising each part or element separately, as the different components influence one another when combined[23,28].

Although some skills transfer was seen in the present study, practising one procedure as a substitute for a different procedure does not appear to be an effective training strategy. One of the characteristics of optimal simulator training is that training is focused on a well defined goal for a specific task that is aligned functionally with the clinical procedure[23]. This contrasts with the current status where many training programmes focus only on basic skills and isolated task training[2,29,30].

With the development of simulators and procedural task practice opportunities, surgical curricula need to evolve and incorporate simulated settings. Research to provide a better understanding of how and which skills are transferred will enable further development of simulator training.

A high degree of task specificity for procedural training may also have implications for the ongoing debate on assessment and simulator-based surgeon certification. Use of a specific model or set of exercises may not necessarily demonstrate whether surgeons are proficient in other procedures.

Acknowledgements

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