

Study protocol for a randomized controlled trial on a multimodal training curriculum for laparoscopic cholecystectomy – LapTrain



Mirco Friedrich^a, Karl-Friedrich Kowalewski^a, Tanja Proctor^b, Carly Garrow^a, Anas Amin Preukschas^a, Hannes Götz Kenngott^a, Lars Fischer^a, Beat-Peter Müller-Stich^{a,*}, Felix Nickel^a

^a Department of General, Visceral and Transplantation Surgery, University of Heidelberg, Im Neuenheimer Feld 110, 69120 Heidelberg, Germany

^b Institute for Medical Biometry and Informatics, University of Heidelberg, Im Neuenheimer Feld 305, 69120 Heidelberg, Germany

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ABSTRACT

Background: Although minimally invasive surgery (MIS) has replaced many open procedures in visceral surgery, technical and psychomotor obstacles remain a constant challenge for surgeons and trainees. However, there are various training curricula enabling surgeons to acquire the visuospatial and psychomotor abilities additionally required when performing MIS. Currently accepted training modalities include box-trainers, organ and animal models as well as completely simulated training environments, realized in virtual reality (VR) trainers. All of these methods facilitate an adequate training prior to patient contact, so patient safety can benefit as well. This study aims to evaluate the benefit of a structured multi-modality laparoscopy training curriculum.

Methods: Junior and senior surgical residents are included ($n = 60$). Groups are stratified with concern to previous experience and training of participants. The training curriculum consists of a standardized sequence of available modalities and exercises on box- and VR-trainers. Specific consideration applies to the training effect during the repeated performance of a laparoscopic cholecystectomy (LC) between intervention (training in between LCs) and control group (no training in between LCs). Analysis of training effects is performed using a cadaveric model for LC and objectified using the validated scoring system Global Operative Assessment of Laparoscopic Skills (GOALS).

Discussion: This study assesses the value of a multimodal training platform in medical education and postgraduate training and aims at illustrating possible guidelines when establishing such a curriculum. Possible factors of influence, such as varying backgrounds, learning motivation and –success among participants are explored in the data analysis and add beneficially to further evaluating the efficacy of such training to more heterogeneous participant groups like medical students and other professionals.

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1. Background

Although minimally invasive surgery (MIS) has replaced many open procedures in visceral surgery, technical and psychomotor obstacles remain a constant challenge for surgeons and trainees. There are various training curricula enabling surgeons to acquire the visuospatial and psychomotor abilities additionally required when performing MIS. Currently accepted training modalities include organ and animal models, e-Learning modalities, as well as completely simulated training environments, realized in virtual

reality (VR) trainers [1,2]. All of these methods facilitate an adequate training prior to patient contact, so patient safety can benefit as well. The Global Operative Assessment of Laparoscopic Skills (GOALS) is a tool to assess both procedural and technical skill in laparoscopic surgery [3–5]. It reflects subsets of skill like bimanual dexterity, tissue handling and efficiency and has been validated in numerous studies.

Thus far, there have not been competitive studies assessing so-called multimodal training curricula when learning laparoscopic techniques. Here, we propose a study to examine such a training algorithm benefiting from multiple of the currently available training modalities. We include a total of $N = 60$ surgical residents and attending surgeons, half of which undergo an intensive 12 h training consisting of both widespread laparoscopic training modules and virtual reality training. The study's main

Abbreviations: MIS, minimally invasive surgery; LC, laparoscopic cholecystectomy; VR, virtual reality; POP, Pulsating Organ Perfusion; GOALS, Global Operative Assessment of Laparoscopic Skills.

* Corresponding author. Fax: +49-6221-568645.

E-mail address: beat.mueller@med.uni-heidelberg (B.-P. Müller-Stich).

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objective is to assess and elucidate the possible impact of such a training on basic skill development as well as handling of full operative procedures under realistic conditions using the GOALS score as primary outcome measure.

2. Methods

2.1. Objectives

Primary objective is to show an overall positive effect of multi-modal training curricula on laparoscopic skills and procedure-specific performance, specifically for a laparoscopic cholecystectomy (LC), objectified by the validated GOALS score. Secondary objectives include the reduction in operating time, assessment of correlations between psychometric and personal parameters on learning curves and inter-individual benefit of these nouveau training methods.

2.2. Study design

This is a registered prospective, single-center, rater-blinded, two-arm, randomized controlled trial.

2.3. Setting and participants

This study offers voluntary laparoscopic training courses to junior and senior surgical residents. All participants receive information about the study and provide informed consent.

2.4. Inclusion and exclusion criteria

Surgical residents in their clinical training are included in the study. There are no exclusion criteria as possible factors of influence such as gender and experience in laparoscopic procedures are being considered as stratification factors during randomization (see below).

2.5. Introduction to the training modalities in the training center

The participants receive a standardized introduction and instructions on using the box-trainer, VR-trainer and Pulsating Organ Perfusion (POP)-trainer by trained staff [6]. Thus, participants can familiarize themselves with the training facilities and training devices prior to the start of the tests and exercises.

2.6. Baseline test

All participants complete a rater-blinded baseline test, which includes the completion of a LC on a porcine liver using a POP trainer. Participants are then randomized to multi-modality training (training group) or no training (control group). Raters use the validated GOALS scoring system for LC, which has been validated and introduced earlier by Gumbs et al. [7].

2.7. Randomization

Participants are randomized to either a training or control group in a 1:1 ratio by block randomization with a variable block length stratified for experience levels. Participants who are at least in their 3rd year of residency and/or have performed more than 10 laparoscopic surgeries as primary surgeon, or have participated in a 2-day MIS training course are considered for the more experienced surgeons. After the participants have finished the baseline test on the POP-trainer, an employee performs the randomized distribution of subjects using opaque, sealed envelopes. The employee responsible for the randomization and group assignment is other-

wise not involved with the training, tests, and data from the present study.

2.8. Training curriculum

The multi-modality training group completes 12 h of training, while the group with no training acts as a control (See Fig. 1). Laparoscopic and surgical basic skills are to be revised by the training group for a total of 6 h on box-trainers [8]. The training group subsequently receives another 6 h of laparoscopy training using the VR-trainer (Lap Mentor™, Simbionix©, Cleveland, USA), [9]. The simulator software enables training within 8 laparoscopic basic skills scenarios as well as procedural skills training in the form of partial or complete laparoscopic operations. LC was chosen as training procedure. Training curriculum is conducted as described before [10]. All participants then complete a LC on the VR-trainer before performing another LC using a POP-trainer as a post-test [11].

2.9. Post-test and blinded test evaluation

Both control group and training group participants complete a second LC. The control group receives no further training in between tests, training group participants perform the post-test task after completing a 12-h multimodal training curriculum (See Fig. 1). Participants perform a LC on cadaveric porcine models and are evaluated by blinded raters using the previously validated

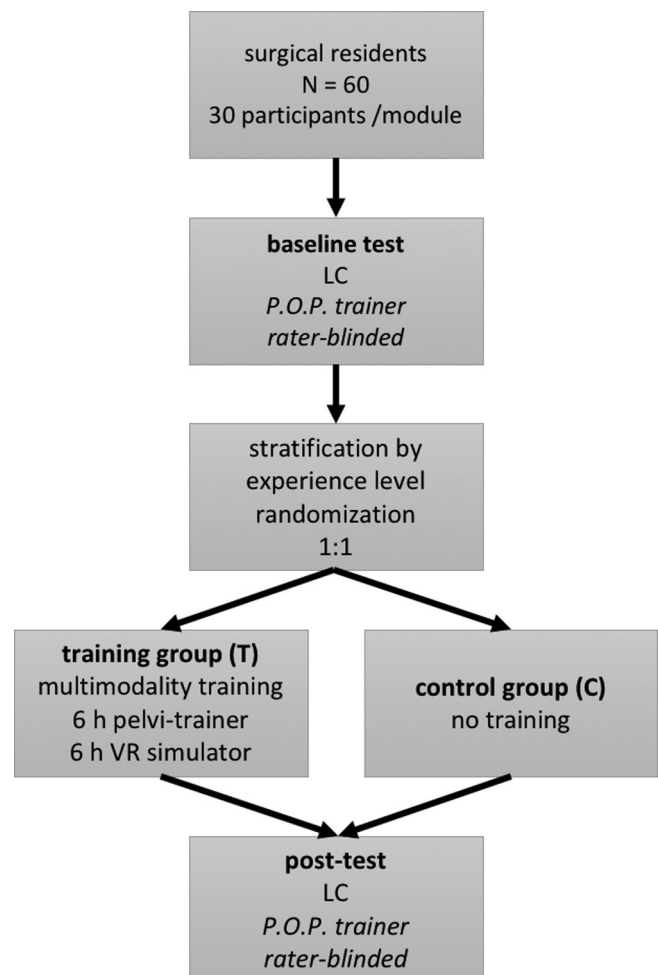


Fig. 1. Study flowchart.

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