

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



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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.

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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 new 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

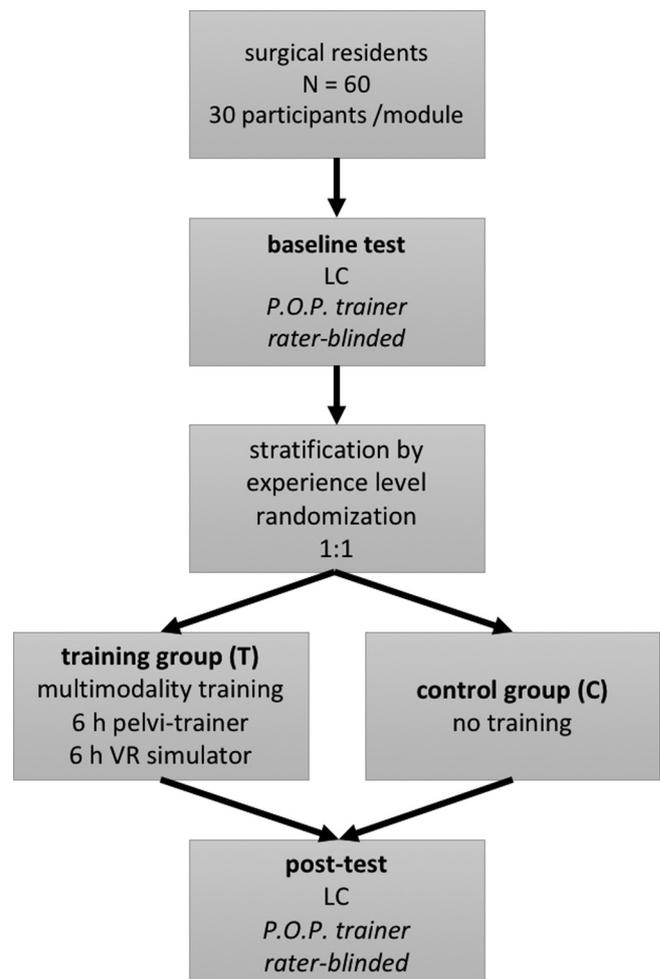


Fig. 1. Study flowchart.

GOALS score [4,5]. Furthermore, operation success and operative time of the procedure is recorded. Unblinding of raters or employees involved in data analysis and interpretation is not intended. In order to prevent selection bias, baseline characteristics including age, year of studies, previous experience, gender and hobbies will be compared.

#### 2.10. Primary outcome measure

The primary outcome measure is the operative performance and improvement from baseline to post-test of the study participants during the porcine cadaveric LC on the POP-trainer based on the standardized and validated GOALS score [5].

#### 2.11. Secondary endpoints

The operative times will be evaluated separately as secondary endpoint, as well as subgroup improvement. Additionally, the VR data of the LC will be analysed in the training group to analyse the impact of the curriculum on metric performance data, such as path length and number of movements as well. Psychometric and personal parameters will be collected for each participant using anonymous questionnaires. The questions will relate to prior laparoscopic experience and leisure behaviour with regards to gender, computer games and playing instruments. Explorative analyses will be performed using the collected data and possible relations to the training results.

#### 2.12. Statistical analysis

The normal distribution provides a fairly exact approximation of the distribution of the scale-specific scores, which allows standard parametric tests to be used to compare the mean GOALS scores of the two groups. All endpoints and subgroup analysis are descriptively analysed according to their respective empirical distributions. According to scale levels of the variables, means, standard deviations, medians, first and third quartiles and minimum/maximum or absolute and relative frequencies are provided. Descriptive p-values of the corresponding statistical tests are reported in combination with the associated 95% confidence intervals. Possible differences of the primary outcome, GOALS score, are tested using analysis of covariance with intervention group as factor, baseline GOALS score as covariate and GOALS score after intervention as dependent variable. Multiple imputation are applied to compensate for any missing data. If found to be appropriate, graphical statistical methods are deployed to illustrate findings.

#### 2.13. Sample size determination

We examine  $n = 60$  (50 + 20%) participants in the two study arms. This sample size determination was based on the paper by Gumbs et al. [7]. We assumed that the multimodal curriculum could reduce the difference between novices and expert by about 50%. Furthermore, we added 20% to compensate for potential drop-outs.

### 3. Discussion

This study assesses the value of a multi-modality training curriculum in surgical education and postgraduate training. 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 both heterogeneous participant groups and specific professionals. Provided conclusive results, we hereby aim at

illustrating possible guidelines when establishing such a curriculum.

### 4. Trial status

Recruitment started 09/24/2011 and ended 02/03/2016. Data acquisition and data analysis are currently running. Final results of this study will be published. Access to the dataset and statistical code will be granted individually upon request.

### 5. Declarations

#### 5.1. Ethical Approval and consent to participate

Ethical Approval was granted from the Ethics committee Heidelberg (S-334/2011). All data for the study are recorded anonymously, treated confidentially, and evaluated by authorized staff for scientific purposes only. Participants' names are kept separate from all study data and are not used for the study. Each participant is assigned a designated code that is used for the entire study documentation and data collection. Participation in the study is voluntary and may be ended at any time. There are no foreseeable negative consequences for participants related to participation. In the event that a participant's physical or mental health becomes jeopardized due to participation in the present study, the participant is dismissed immediately and excluded from the study. Written informed consent is obtained from each trainee. The CONSORT guidelines for randomized controlled trials and SPIRIT guidelines for implementation of study protocols were followed and the SPIRIT Checklist is attached to the manuscript [12].

#### 5.2. Trial registration

This trial was registered with the German Clinical Trials Register: DRKS00011040 and all protocol modifications will be registered, published in the final paper and communicated to the participants.

#### 5.3. Availability of data and materials

All datasets used and/or analysed during the current study will be made available by the corresponding author on reasonable request.

#### 5.4. Competing interests

The authors hereby declare that they have no financial or non-financial competing interests.

#### 5.5. Authors' contributions

All authors read and approved the final version of this manuscript.

Authorship eligibility guidelines according to the ICMJE were followed. The use of professional writers is not intended.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.isjp.2017.07.002>.

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