

Evaluation of Hybrid-Training Box for Laparoscopic Cholecystectomy

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Background: The training box is a simple tool for practice, but it does not use real tissue. The Hybrid-Training box for laparoscopic cholecystectomy simulator (LCS) was used in the laparoscopic cholecystectomy (LC) training.

Objective: To evaluate its face validity and construct validity.

Materials and Methods: Between January 2017 and December 2017, 30 participants were divided into two groups, an experienced group (EG) and a novice group (NV). There were 15 participants in each group, and each was asked to perform LC using the LCS. Face validity was evaluated after task completion using a questionnaire with scores ranging from one (very bad or unrealistic) to five (excellent or very realistic) on a five-point Likert scale. Operative time and accidental tearing of the gallbladder were used to evaluate construct validity.

Results: The participants in the EG were staff working in general surgery, and subjects in the NV were third- and fourth-year surgical residents. Face validity showed no significant difference on the Likert scale in terms of resembling reality or haptic feedback from tissue (23.6±2.8, 21.7±3.8, p=0.13). The mean operative time of the EG was 15±2.4 minutes while that of the NV was 32±4.1 minutes (p<0.01), and more errors in the form of accidental perforation of gallbladder during LC were found in the NV (67%, 13%, p<0.001).

Conclusion: The LCS is an all-in-one simulator that provides effective skill training for LC. The frozen pig gallbladder added realism and was convenient to use.

Keywords: Simulator, Laparoscopic cholecystectomy, Training model

Received 2 July 2019 | Revised 20 December 2019 | Accepted 21 December 2019

J Med Assoc Thai 2020;103(9):864-8

Website: <http://www.jmatonline.com>

Surgical skills are acquired gradually while learning in the operative field. Beginning as an assistant and progressing to the role of surgeon takes a long time, depending on the type of operations involved. Nowadays, most operations can be performed using minimally invasive surgery (MIS) that benefits the patients by reducing pain and facilitating early recovery. One disadvantage of MIS

is that it is more difficult to perform due to its limited haptic feedback and long instruments^(1,2). These MIS characteristics prolong the learning period for the trainee compared with open surgery. Laparoscopic surgery demands more psychomotor abilities and requires skills that are different from those necessary in open surgery^(3,4). The difficulties involved in acquiring laparoscopic skills, such as issues related to cost-effectiveness and patient safety, have prompted the requirement of skill training outside the operating room^(5,6). The training box is a simple tool for practice, but it does not utilize real tissue while virtual reality training is expensive. Initial practice using laboratory animals or cadaveric human bodies provides the surgeon with a more realistic environment⁽⁷⁾. The laparoscopic cholecystectomy simulator (LCS) (Figure 1) is used in the MIS training program in Rajavithi Hospital. After completing practice with the training box, every resident in general surgery has to perform cholecystectomy with the LCS to meet the requirements of the academic curriculum

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How to cite this article:

Subwongcharoen S, Sukkasem P. Evaluation of Hybrid-Training Box for Laparoscopic Cholecystectomy. *J Med Assoc Thai* 2020;103:864-8. doi.org/10.35755/jmedassocthai.2020.09.10405



Figure 1. (A) Training box with webcam camera inside the box connecting to computer and LCD display. (B) Rubber model resembles a real liver, duodenum and stomach lying on hard a plastic plate similar to normal human anatomy. There was a space inside rubber model of liver enough to insert part of cadaveric pig's liver attached to rubber model of liver. Pig's gallbladder and common bile duct were placed outside the rubber model of liver. The distal part of pig's common bile duct was fixed to rubber model of stomach with elastic rubber in order to allow movement during traction of pig's gallbladder.

before progressing to performing laparoscopic cholecystectomy (LC) on real patients under the supervision of surgical staff. The present study aimed to evaluate the face validity and the construct validity of the LCS.

Materials and Methods

The present study was performed between January and December 2017 after obtaining informed consent from the 30 participants and receiving approval from the ethical review board committee of Rajavithi Hospital. The 30 participants were divided into two groups, experienced and novice. The experienced group (EG) consisted of surgeons who had each performed LC in more than 50 cases regarding to many experts opinion for the learning cases of LC, while participants in the novice group (NG) had each completed fewer than five cases of LC. There were 15 participants in each group, and all were required to perform LC with the LCS which consisted of 1) a training box with webcam inside the box connected to a computer and LCD display, and 2) a rubber model resembling a real liver (RL) duodenum and stomach (RS) lying on a hard plastic

plate similar to normal human anatomy (Figure 1). There was a space inside the RL large enough to insert part of a cadaveric pig liver (CL), gallbladder (CG), and common bile duct (CCBD). Some parts of the CL were kept inside the RL and allowed CG and CCBD enface outside the RL to attach the CCBD to the RS. The RL could be moved in a vertical direction when lifted with laparoscopic instruments in a range of 0 to 90 degrees using a hinge-type plate fixed to the plastic plate. The CL, CG, and CCBD were replaced with new ones after completion of each procedure. The authors bought the CL, CG, and CCBD from the market, put them in a small plastic box, and kept them frozen. Before being used, the frozen organs were taken out of the refrigerator for two hours until thawed. Each participant performed one cholecystectomy via this LCS. After task completion, face validity was evaluated using a questionnaire with scores ranging from one (very bad or unrealistic) to five (excellent or very realistic) on a five-point Likert scale^(8,9).

The task included gallbladder retraction, tissue dissection, critical view of safety demonstration, clipping, cutting, and gallbladder separation

Table 1. Demographic data of participants using Rajavithi Hybrid Model

Demographic factors	Novice group (n=15)	Experienced group (n=15)	p-value
Sex: male/female	10/5	12/3	0.68
Age (years); mean±SD	29±0.9	36±3.5	<0.001
Dominant right hand; n (%)	15 (100)	14 (93)	1.00

SD=standard deviation

Table 2. Face validity questionnaire for evaluation of Rajavithi Hybrid Model

Realism score (range 1 to 5)	Novice group (n=15) Mean±SD	Experienced group (n=15) Mean±SD	p-value
1. Gallbladder retraction	4.1±0.74	3.7±0.62	0.20
2. Critical view of safety demonstration	3.2±0.77	3.5±0.64	0.30
3. Tissue dissection	3.7±0.62	3.5±0.64	0.40
4. Clipping	4.4±0.74	3.8±0.74	0.06
5. Cutting	4.4±0.74	3.8±0.74	0.06
6. Gallbladder separation from gallbladder base	3.8±0.80	3.3±0.90	0.10
Total score (30)	23.6±2.80	21.7±3.80	0.13

SD=standard deviation

Table 3. Construct validity for evaluation of Rajavithi Hybrid Model

	Novice group (n=15)	Experienced group (n=15)	p-value
Operative time (minute); mean±SD	32±4.1	15±2.4	<0.01
Error tearing of gallbladder; n (%)	10 (67)	2 (13)	<0.001

SD=standard deviation

from the gallbladder base. Operative time and inadvertent tearing of the gallbladder were used to measure construct validity and establish whether this model could differentiate operators' different levels of experience and thus be used to assess performance⁽¹⁰⁾.

Statistical analysis

Sample size calculation was based on operation time from previous study⁽¹¹⁾ with $\alpha=0.05$ and power=0.80. A minimum of seven subjects were needed in each group. Data were reported as mean \pm standard deviation (SD) and percentage. The Likert scale was analyzed using the Mann-Whitney U test. Demographic data were compared and analyzed with unpaired two-tailed Student's t-test or Fisher's exact test, and p-value of less than 0.05 was considered statistically significant. The IBM SPSS Statistics, version 22.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis.

Results

The 15 participants in the EG were surgical staff, while the other 15 in the NV were third- and fourth-year surgical residents, and each of them performed LC after completing the box training. All participants had experience of performing LC on a cadaveric pig. Demographic data are shown in Table 1. Face validity showed no significant difference in terms of resembling reality or haptic feedback from tissue (Table 2). The LCS is a useful training device, which is capable of differentiating experienced surgeons from novices in the laparoscopic procedure as witnessed by the infrequency of tearing in the gall bladder wall and lower operative time in the LC operations performed by the EG (Table 3).

Discussion

The problems encountered in laparoscopic surgery include lack of tactile feedback and sense of depth, which are already difficult to learn in traditional

surgical teaching sessions⁽¹²⁻¹⁴⁾. Therefore, surgeons need to learn additional skills apart from those that are routinely used in open surgery. Nowadays, there is general agreement among experts that novice surgeons can learn basic laparoscopic skills through simulators, which can assist in speeding up the early part of the learning curve^(15,16). These simulations are important because they allow the trainees to gain some skill before encountering real patients⁽¹⁷⁾.

There are many varieties of simulation devices, ranging from simple, low-cost training models to complex, expensive, and highly-efficient ones. Some examples are bench models, virtual reality models, and animal and cadaveric models⁽¹⁸⁻²⁰⁾. Artificial models have some disadvantages compared to cadaveric or animal ones because they lack realistic properties; however, they are re-usable⁽²¹⁾. Animal and cadaveric models in instruction courses and virtual reality models are expensive, and many training centers cannot afford to provide adequate instructional courses for all trainees to enable them to become more confident and skillful in performing LC. The LCS was developed for MIS and general surgical trainees in the authors' hospital. The advantages of this LCS are its provision of haptic feedback from the cadaveric pig organ inside the RL, its close resemblance to performing LC in humans, its ease of storage and preparation of CL, CG, CCBD before an operation, and its lower cost. Furthermore, it can be used at a time and place most convenient for the trainee. With regard to face validity, most participants' responses to the questionnaire agreed that the realism and usefulness of LCS was similar to those of the simulator of Nickel et al⁽⁹⁾. However, LCS could not demonstrate bleeding in case of accidental tearing of the cystic or hepatic arteries. Fundamentally, the pig's gallbladder is thin and more fragile than the human gallbladder, therefore, bile leakage from the gallbladder or common bile duct can be clearly identified when surgeons perform erroneous dissection.

Construct validity in the present study showed that the LCS was able to measure the different levels of experience between experts and novices as witnessed by the significant difference in operation time and accidental tearing of the gallbladder. Previous studies have also shown that simulator-learned skills can be transferred to real-life operating environments⁽²²⁾.

The LCS is an all-in-one simulator, with a high-quality built-in video camera and light source. All details of the procedures can be recorded via a computer when surgical residents practice using this

simulator and their performance can be evaluated by senior surgical staff before they are allowed to perform LC on patients.

Conclusion

The LCS is an all-in-one simulator that provides effective skill training in LC. The frozen pig organs such as the gallbladder, liver, and common bile duct, made the operation more realistic and were convenient to use.

What is already known on this topic?

The training box is a simple tool for practice, but it does not utilize real tissue. Therefore, it is difficult to improve laparoscopic skill.

What this study adds?

This training model consisting of parts of real tissue provides the novice surgeon better skill than the simple training box.

Acknowledgement

The present study was supported by the research fund from Rajavithi Hospital. The authors wish to thank all the individuals who contributed data for the purposes of the present study. The authors greatly appreciate the assistance of the staffs in the Division of Medical Research, Department of Research and Technology Assessment, Rajavithi Hospital for manuscript preparation.

Funding disclosure

Financial support grant from Rajavithi Hospital.

Conflicts of interest

The authors declare no conflict of interest.

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