SCIENTFIC PAPER

Laparoscopic Common Bile Duct Exploration Four-Task Training Model: Construct Validity

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ABSTRACT

Background: Training models in laparoscopic surgery allow the surgical team to practice procedures in a safe environment. We have proposed the use of a 4-task, low-cost inert model to practice critical steps of laparoscopic common bile duct exploration.

Methods: The performance of 3 groups with different levels of expertise in laparoscopic surgery, novices (A), intermediates (B), and experts (C), was evaluated using a low-cost inert model in the following tasks: (1) intraoperative cholangiography catheter insertion, (2) transcystic exploration, (3) T-tube placement, and (4) choledochoscope management. Kruskal-Wallis and Mann-Whitney tests were used to identify differences among the groups.

Results: A total of 14 individuals were evaluated: 5 novices (A), 5 intermediates (B), and 4 experts (C). The results involving intraoperative cholangiography catheter insertion were similar among the 3 groups. As for the other tasks, the expert had better results than the other 2, in which no significant differences occurred. The proposed model is able to discriminate among individuals with different levels of expertise, indicating that the abilities that the model evaluates are relevant in the surgeon's performance in CBD exploration.

Conclusions: Construct validity for tasks 2 and 3 was demonstrated. However, task 1 was no capable of distinguishing between groups, and task 4 was not statistically validated.

Key Words: Laparoscopy, Training, CBD, Choledocholithiasis.

INTRODUCTION

Minimally invasive surgery has great advantages over its conventional counterpart in the treatment of various pathologies. It is the gold standard for such procedures as cholecystectomy, esophageal hiatus surgery, and appendectomy. The benefits of decreased postoperative pain, length of stay, and improved esthetic outcome have been solidly proven.[1–3]

Laparoscopic cholecystectomy was introduced in 1987 and promptly become the gold standard for surgical treatment of gallstone disease. It was only a matter of time before going to the next level with minimally invasive bile duct surgery: laparoscopic common bile duct exploration (LCBDE). The first reports of outcomes of this technique appeared in 1991. Since then, multiple series have shown that it is an effective procedure with low morbidity and mortality rates.[4–7]

The technological development and surgical team's experience have lead to great results in laparoscopic surgery of the common bile duct. The management of a patient with choledocholithiasis is about to enter a new era, and surgery might once again play the main therapeutic role.

Multiple studies have demonstrated the management of choledocholithiasis in a single stage; in other words, laparoscopic cholecystectomy and laparoscopic exploration of the bile ducts are comparable in terms of effectiveness and morbidity to the traditional 2-stage management (endoscopic sphincterotomy and laparoscopic cholecystectomy). As a matter of fact, the National Institutes of Health (NIH) expert consensus published in 2002 and the British Gastroenterology Association recognize that both approaches have a similar rate of effectiveness.[5,8,9]

Most of the current evidence comes from prospective randomized controlled trials that took place at specialized centers. Therefore, their results might not be applicable in any surgical department around the world. Availability of instruments, technology, and surgeon's experience are great limitations.

LCBDE involves the management of instruments and technology that are not usually handled by the surgeon.

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These include balloon dilators, helicoidal baskets, Dormia baskets, and choledochoscope, which require special coordination between surgical team members. Keeling et al[10] compared their first 60 cases with their following 60 to assess the learning curve and showed a significant difference in success rate and morbidity.

The current authors designed an inert, simple, very low-cost, and readily available training model.[11] It allows the surgeon to practice critical steps of the surgery. The objective of this investigation was to determine the evaluation capabilities of the model to differentiate the performance among individuals with different levels of expertise (construct validity), as a fundamental factor in the validation of training models.

MATERIALS AND METHODS

This was an experimental study in which 3 groups of individuals with different levels of expertise in laparoscopic surgery were evaluated: Group A=medical students with no training at all in laparoscopic surgery (novices); Group B=first-year general surgery residents familiar with basic laparoscopic surgery but not with advanced laparoscopic procedures; and Group C=surgeons who had performed over 20 cases of LCBDE.

Materials required for the construction of this model are a "black box," available in any surgical department, and easily obtainable medical surgical materials: latex vesical catheters, silastic vesical catheters, endotracheal tubes, "T" tubes, and a "Y" connector. The laparoscopic instruments to be used in the drill should replicate basic dissection and prehension instruments. Additionally and as a fundamental part of the surgical procedure, a helicoidal basket or Dormia basket utilized for the capturing and extraction of stones is required. In our service, we use an Olympus® CHF P20 4.9-mm choledochoscope with a working channel for evaluation.

This proposed model reproduces in 4 stations, the fundamental steps for CBD laparoscopic surgery, which are intraoperative cholangiography (IOC) catheter insertion, transcystic exploration, "T" tube placement, and choledochoscope management for the extraction of calculi under direct vision **(Figure 1)**.

Task 1. Intraoperative cholangiography catheter insertion: During this task, the model allows the surgeon to simulate the necessary movements and steps to perform cholangiography through the cystic duct.

Task 2. Transcystic exploration: The use of a transparent catheter allows the surgeon to practice the capture of

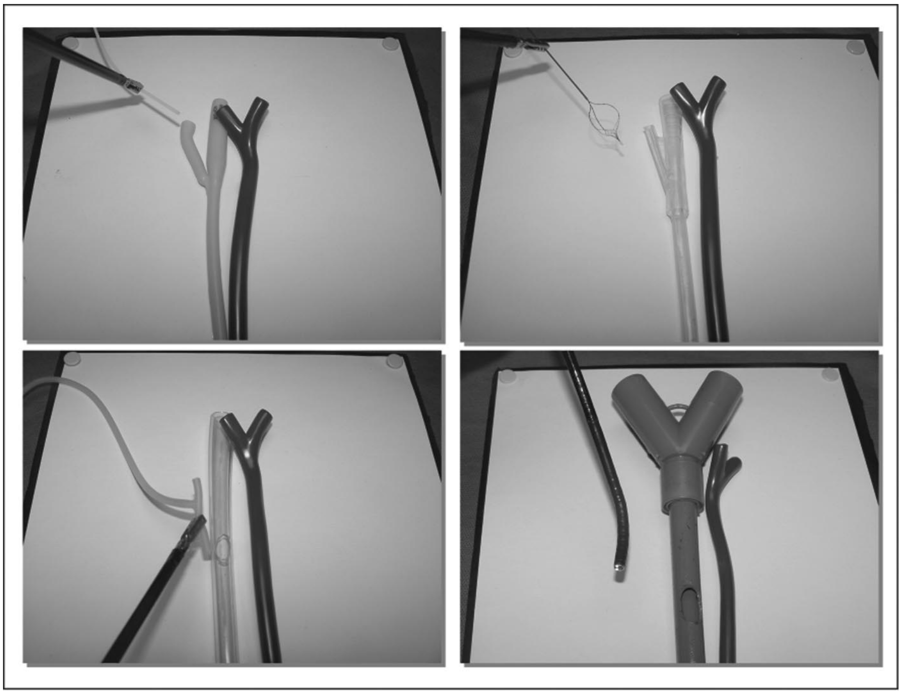

Figure 1. Laparoscopic common bile duct exploration 4-task training model. (1) Intraoperative cholangiography catheter insertion, (2) Transcystic exploration, (3) T-tube placement, (4) Choledochoscope management.

fictitious calculi in a 2-dimensional plain, as would be done in fluoroscopic-guided LCBDE.

Task 3. During this task, surgeons have the opportunity to practice one critical step of LCBDE, that is T-tube placement.

Task 4. Choledochoscope management: Three members of the surgical team practice stone capture under direct vision with the choledochoscope.

Practice sessions took place in the laparoscopic practice laboratory of Surgery Department III at the University Hospital of Caracas. The sessions were filmed in DVD format for academic use. Participants were provided with written instructions and were shown a video presentation of the tasks. Afterwards, all had the opportunity to familiarize themselves with the model and the various instruments.

The time it took for each individual on each team to complete the tasks was measured. In the case of the choledochoscope, a single operating time was determined for each group. This required the coordinated participation of 3 members of the team, each one fulfilling a specific role.

Statistical Analysis

The Kruskal-Wallis test was performed to detect significant differences among the groups. If the answer was positive, the Mann-Whitney test was used to establish the differentiating groups. Levels of significance were considered P=.05 and P=.10.

RESULTS

A total of 14 individuals were evaluated in each task, 5 belonging to the novice group (A), 5 to the intermediate group (B), and 4 to the expert group (C). The presence of extreme values in some of the activities produced intervals that lacked precision and made the comparison difficult between the median values of the 3 groups, in particular those from groups A and B. The homogeneity in the data belonging to group C (experts) is characteristic of experienced surgical teams. In other words, training reduces the variability among individuals **(Figure 2)**.

For each group, the task that took longer was transcystic exploration. Groups A and B additionally had great variability in the results among individuals in the same group.

The activities involving transcystic exploration and T-tube placement constitute differentiating activities among the group of doctors; meanwhile, the IOC catheter insertion is, on average, very similar between the groups **(Table 1)**. Based on the Kruskal-Wallis test, it became evident that there existed no statistically significant difference among the groups when IOC catheter insertion was evaluated.

In the transcystic exploration and T-tube placement tasks, the Kruskal-Wallis test demonstrated significant differences among the groups, and the Mann-Whitney test was

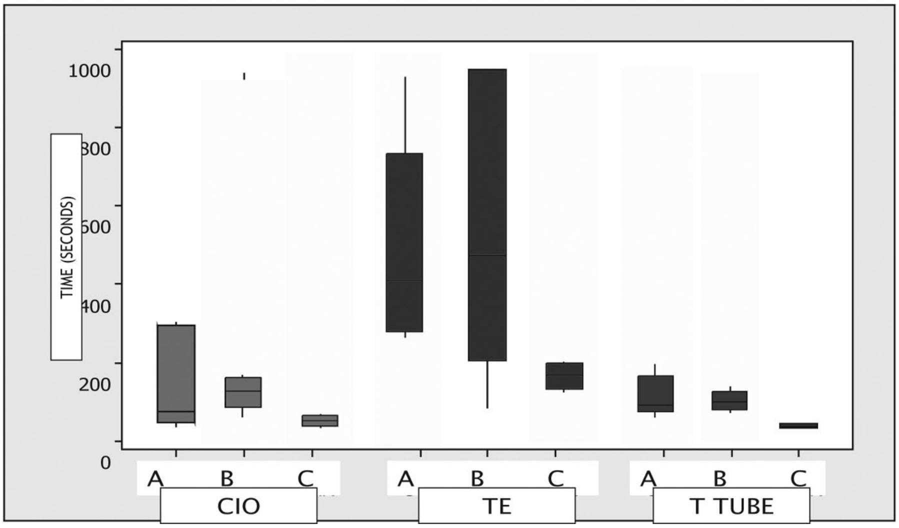

Figure 2. Performance comparison of the 3 groups in the stations. IOC: intraoperative cholangiography catheter insertion, TE: transcystic exploration, T TUBE: T-tube placement. (A: Novices, B: Intermediates, C: experts).

Table 1.
Performance of the 3 Groups in the 4 Tasks: IOC Catheter Insertion, Transcystic Exploration, T-tube Placement, and Choledochoscope (seconds)

	IOC Catheter Insertion	Transcystic Exploration	T-tube Placement	Choledochoscope
A	151.6”	496”	118”	588”
	(37–300)	(272–938)	(63–202)	
B	125.8”	557”	100.2”	364”
	(63–170)	(84–950)	(70–140)	
C	49.75”	158”	36.75”	272”
	(32–65)	(120–195)	(32–42)	

applied to compare the various groups in each task. This resulted in a significant difference between the expert and the novice-intermediate groups, which in turn had no differences among them **(Table 2)**.

The choledochoscope was only used once by each team. It is very hard to draw any real conclusions from that very limited experience. However, the evaluation showed that groups A and B completed the task in times 116% and 33% longer than the time of the expert group (C).

DISCUSSION

Minimally invasive surgery techniques in abdominal surgery are a great advancement in general surgery; however, safety and success of procedures requires surgical team training.

Performing advanced laparoscopic surgery requires acquisition of particular skills, because this kind of approach requires overcoming difficulties inherent to this technique, such as (1) 2-dimensional vision with loss of depth perception, (2) diminished range of instrument motion compared with that in instruments performed freely by wrists and elbows during open surgery, (3) diminished tactile perception, and (4) disparity between visual and proprioceptive feedback brought on by hand movements, leading to a contrary effect on the opposing end of the instrument, know as the *fulcrum effect*.

We have described our personal experience with LCBDE since 2005.[12] After 5 years, the effectiveness is 84% with a morbidity of 6%. It is important to take into consideration the fact that we are dealing with a complex surgical technique, successful performance of which depends highly on the surgical team's expertise and the availability of the required instruments. That is why in our department we have used the model described by Sánchez et al[11] to develop the abilities required to complete successful CBD exploration.

Models and simulators permit constant and systematic training, which allows, as well, the evaluation and certification of competence of a surgeon; however, these models require validation. The validation of a simulator requires evaluation of the quality of such a system as a tool of training and certification. This process comprises multiple aspects, such as reliability, resemblance to the in vivo procedure (face validity), the possibility of obtaining facts that can be interpreted, and the capacity of the model to differentiate among surgeons with different levels of expertise (construct validity). Construct validity results in the applicability of the tool as a means to evaluate the development of skills while practicing with it.[13]

One of the principal virtues of simulators is the capacity to measure the user's performance. If a training model is used to determine the surgeons competence, it may be able to identify individuals with different levels of training. If the model does not detect variations between novices and experts, then it would not be able to evaluate the progress of individuals either who are using it as an exercise tool. On the other hand, if the parameters that the model contemplates result in being useful to differentiate novices from experts, this will become useful to objectively classify the level of competence of a surgeon and furthermore evaluate the surgeon's progress through time.

The ideal simulator is one that offers objective, dependable feedback, along with the capability of predicting that the surgical performance acquired would be proportionally reflected during a real-time intervention.[14] Evaluating our experimental model, we were able to observe that it is sufficiently capable of identifying individuals with expertise in the procedure, which indicates that the abilities the model evaluates are relevant to the performance of LCBDE. The training and systematic evaluation through the model will enable individuals to identify the evolution

Table 2.
Performance Comparison of the 3 Groups in the Evaluated Activities. Capability of the Model to Discriminate the Different Levels of Expertise (seconds)

	A	B	C	Discrimination
IOC Catheter Insertion	151.6	125.8	40.75	A=B=C
Transcystic exploration	496	557	158	A=B>C
T-tube placement	118	100.2	36.75	A=B>C

in their performance, until they are able to develop the necessary skills to perform a safe and effective procedure, especially tasks 2 and 3.

Task 1 (IOC catheter insertion) could be performed by the individuals with different levels of training with no significant differences, demonstrating that it is an exercise that does not require any advanced laparoscopic skills, and it can be safely performed by surgeons with basic laparoscopic training. The model does not differentiate the level of training among the individuals. Although the resemblance to reality derives from subjective validation, it is rather evident that it would be necessary to conduct research with a greater sample and evaluate its impact on the acquisition of laparoscopic skills. This is currently being undertaken as a trial in our department.

In the activities involving the transcystic exploration and insertion of the T-tube, the performance of the experts was significantly better. This enables us to affirm that the evaluated model permits the identification of those individuals with expertise in the field of advanced CBD laparoscopic surgery, demonstrating the model's value as a tool for development and evaluation of skills during training.

Additionally training models offer surgeons the opportunity to learn in a controlled, safe environment, free from any adverse consequences for the patient. For this reason, we emphasize the importance of the use of training models as evaluated through the present study. Its applicability and low cost constitute a fundamental tool that will enable surgeons to develop abilities that they would not be able to acquire through other simple laparoscopic procedures.

The model evaluated is categorized as a simulator oriented to a specific procedure, which in comparison makes it superior to other models that only evaluate common activities for different types of surgeries. This enables the surgeon to concentrate on the development of skills that other models do not.

The use of the choledochoscope in CBD laparoscopic exploration leads to greater effectiveness, minimally decreasing conversions and the incidence of residual lithiasis[6]; however, it requires great coordination between surgical team members. Each one has to play a specific role. That is why a single time was used for the surgical team in task 4. No statistical comparison between the groups was made, making it very hard to draw any real conclusion.

New technologies and more complex procedures are leading to a change in where and how surgical skills are being developed. Supervised practices in real environments and tutorial surgeries have been left behind. Residents must acquire laparoscopic surgical skills in laboratories. This will also enable teachers to focus on key aspects in the performance of surgical tasks.

Simulation and practice are highly relevant in the teaching of laparoscopic surgery. To separate practice from the actual performance in real live scenarios has been demonstrated to have invaluable benefits in other fields, such as sports, music, and aviation. General surgery development programs must include step-by-step learning of laparoscopic surgery. Practice outside the OR must not be optional: it must be obligatory in the formation of a surgeon.

Construct validity for tasks 2 and 3 was demonstrated. However, in task 1, it was not possible to distinguish between groups, and task 4 was not statistically evaluated.

CONCLUSION

Tasks 2 and 3 were capable of differentiating between individuals with and those without levels of expertise in CBD laparoscopic surgery, validating the model as a useful tool in the training and evaluation of a surgeon's formation.

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