Validation study of AR Gynae endotrainer - a new mobile laparoscopic simulator

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ABSTRACT

Introduction: In gynaecology, laparoscopy is the choice of treatment for a lot of procedures as it is considered safe and effective. However, laparoscopic surgery requires skills that are different from those required for open surgery. In order to acquire the skills, a surgeon needs specific training. The aim of this study was to validate the AR Gynae endotrainer, a new mobile laparoscopic simulator, as a comparable box trainer for gynaecology laparoscopic training, comparing it with the well-established Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer.

Materials and Methods: A randomised prospective crossover study was designed to compare the AR Gynae endotrainer versus Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer as a tool for training gynaecology laparoscopic skills. Participants were assigned to perform two specially designed tasks used for laparoscopic training using both endotrainers. All subjects evaluated both simulators concerning their performance by the use of a questionnaire comparing: design, ports placement, visibility, ergonomics, triangulation of movement, fulcrum effect, depth perception, ambidexterity, resources for training, and resources for teaching. The overall score was defined as the median value obtained. The ability and time taken for participants to complete the tasks using both endotrainers were also compared. A total of 26 participants were enrolled in this study, including 13 Masters's students from the Department of Obstetrics & Gynaecology and 13 Masters's students from the Department of Surgery, Hospital Universiti Sains Malaysia (HUSM), Kelantan, Malaysia.

Results: A better performance was observed with AR Gynae as compared to Karl Storz endotrainer in five out of ten items evaluated in the questionnaire. Additionally, the overall score of AR Gynae endotrainer (median of 3.98) was comparable to that of Karl Storz endotrainer (median of 3.91) with p=0.519. For the items design and resources for teaching, the evaluation for AR Gynae endotrainer was significantly higher with p-values of 0.003 and 0.032, respectively. All participants were able to complete both tasks using both endotrainers. The time taken to complete both tasks was comparable on both endotrainers. Also, the AR Gynae endotrainer was cheaper.

Conclusions: The AR Gynae endotrainer was found to be a convenient and cost-effective laparoscopic simulator for gynaecology laparoscopic training and was comparable to the established Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer.

KEYWORDS:
Laparoscopy, AR Gynae endotrainer, simulator, endotrainer, minimally invasive surgery

INTRODUCTION

Minimally invasive surgery, and laparoscopy, in particular, have been the 'gold standard' for several surgical procedures in the last decade. In gynaecology, laparoscopy is the choice of treatment for several procedures, for example, dye test to assess the tubal patency, tubal ligation as one of the sterilisation methods, salpingostomy or salphingectomy in ectopic pregnancy, cystectomy, myomectomy as well as hysterectomy in benign cases.

Laparoscopic procedures are considered safe and effective. The implementation of operative laparoscopy has reduced the duration of hospital stay and the convalescence period, which has helped to improve patient outcomes and enhance recovery after surgery.[1,2]

Laparoscopic skills, however, are very different from those used in open surgery and require specific training. The surgeon has to become proficient in handling the new instruments with a limited range of movement, the considerable loss of depth perception and haptic feedback, dealing with the counter-intuitive manipulation of the instruments (fulcrum effect), and the two-dimensional (2-D) representation of the three-dimensional (3-D) operating field.[3,4]

It is difficult to teach these skills to the surgeons in training by apprenticeship method because it requires a longer time to practice and more learning opportunities in clinical practice. Thus, simulation training was developed. Training can be done on either traditional box trainers or virtual reality simulators (VRS), which have been shown to be effective methods for providing laparoscopic skills training.[5]

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Unfortunately, barriers to simulation training, including the unaffordability of conventional endotrainers due to the high prices and low accessibility have been a constraint. This can be improved by using mobile box trainer, as it is more affordable, accessible, and mobile and therefore allow trainees to train according to their own schedule.[6,7]

In Malaysia, to date, there is no proper training centre for minimal invasive surgery, specifically in gynaecology. As an initiative, five lecturers from the Department of Obstetrics and Gynaecology (O&G), School of Medical Sciences, Universiti Sains Malaysia (USM), Kelantan, Malaysia, have collaborated to produce the AR Gynae endotrainer.

AR Gynae endotrainer is a mobile box trainer that was invented specifically for the practice of laparoscopy surgery in gynaecology. It is the first of its kind invented locally in Malaysia with the intention of making it available to gynaecologists at an affordable price. A patent application has been deposited at the Intellectual Property Corporation of Malaysia under the number CRLY00017323.

The purpose of this study was to validate the AR Gynae endotrainer, a new mobile laparoscopic simulator, as a comparable BT for gynaecology laparoscopic training, comparing it with the well-established Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer.

MATERIALS AND METHODS

AR Gynae Endotrainer

AR Gynae endotrainer is made from fiberglass. Its shape is very special, it mimics a real patient's abdomen in laparoscopy surgery which is inflated and distended. It is a one-piece product, relatively small and very light, thus portable and can easily be carried anywhere. The size is about 49×35×24cm, and it weighs only two kilograms. The ports are placed as in actual laparoscopy gynaecology surgery. There are two ipsilateral ports on each side (right and left) and one suprapubic port placed 12cm from the pubic bone area. Each port's hole is covered with a round rubber clip. The distance between the ports is 8 to 1 cm. It has a fixed camera and LED light inside positioned at the umbilical site. It needs to be connected to a laptop with a front camera and ready to be used. No electrical power supply is needed (Figure 1). AR Gynae endotrainer comes with a specially designed board with different exercises used for practice. The board is inserted inside the 'abdomen' through a door placed at the lower part of the endotrainer. Two exercises used in AR Gynae endotrainer – 'Beans Transfer' and 'Bands Transfer' are inspired by one of the tasks used in the Fundamental of Laparoscopic Surgery (FLS) simulator, which is Peg Transfer. Peg Transfer is used to develop eye-hand coordination, depth perception as well as visual-spatial perception in a monocular viewing system. It also develops coordinated use of dominant and non-dominant hands (ambidexterity), a skill proven to translate into better intracorporeal suturing skills.8 AR Gynae endotrainer is very cheap and affordable. It costs about MYR2,000.

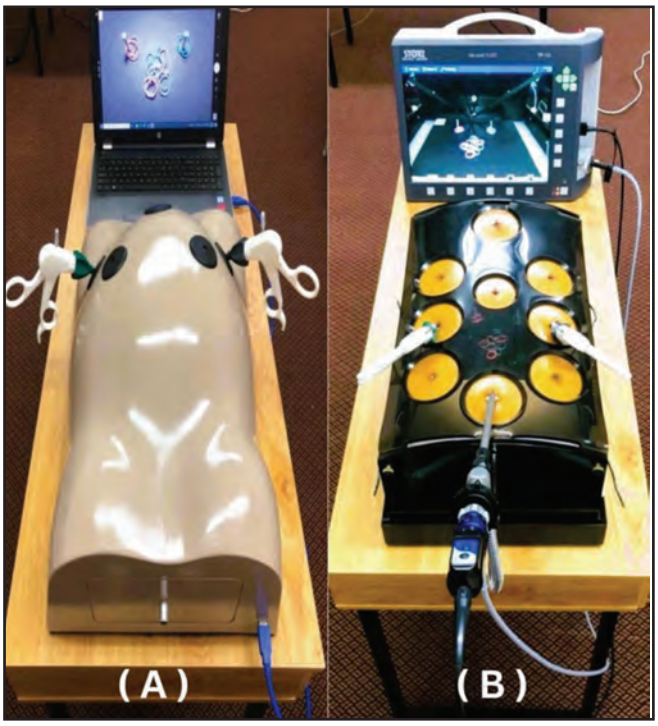

Fig. 1: AR Gynae endotrainer (A) and SZABO-BERCI-SACKIER laparoscopic trainer (B).

KARL STORZ SZABO-BERCI-SACKIER LAPAROSCOPIC TRAINER

Karl Storz is the leading endoscope manufacturer based in Germany. It is an established brand and very well known for its advanced technology and quality. Karl Storz had produced endotrainers for different types of surgery, and one of them is SZABO-BERCI-SACKIER laparoscopic trainer, which is used for training laparoscopy in surgery, gynaecology and urology. It was designed to simulate various laparoscopic procedures, especially the different suturing techniques. It contains diaphragms at the typical puncture sites and a flexible endoscope holder that provides the surgeon with the ability to manipulate instruments with both hands. The endoscope is connected to a compact and portable all-in-one system called TELE PACK X LED that has a high-resolution display and powerful LED light source just like the real one used in the operating room (Figure 1). The exercise board can just be placed inside the endotrainer. The SZABO-BERCI-SACKIER laparoscopic trainer costs about MYR12,000. Together with the endoscope and the system, it costs more than MYR100,000, according to the local supplier.

STUDY DESIGN

This study was a randomised prospective crossover study that was designed to validate AR Gynae endotrainer as a comparable box trainer for gynaecology laparoscopic training, comparing it with Karl Storz SZABO-BERCI-SACKIER laparoscopic trainer. It was conducted at the Department of Obstetrics & Gynaecology, Hospital Universiti Sains Malaysia (HUSM), Kelantan, Malaysia. It has been approved by the Ethics Committee of the School of Medical Sciences, USM (USM/JEPeM/20120642).

Table I: Socio-demographic characteristics of participants

Variables	Mean (SD)	n(%)
Age (Years)	33.92(1.41)	
Years of service as a medical officer	7.27(1.51)	
Year of masters training	3.50(0.65)	
Gender		
Male		16(61.5)
Female		10(38.5)
Ethnic		
Malay		15(57.7)
Chinese		4(15.4)
Indian		5(19.2)
Others		2(7.7)
Dominant hand		
Right		24(92.4)
Left		2(7.7)
HKCOG level (O&G)		
2		7(53.8)
3		6(46.2)

Table II: Comparison of quality between AR Gynae and Karl Storz endotrainers

Variables	Tools		Mean difference (95%CI)	t-statistics (df)	p-value*
	AR Gynae Endotrainer Mean (SD)	Karl Storz Endotrainer Mean (SD)			
Q1 (Design)	4.19(0.63)	3.54(0.76)	0.65(0.24,1.07)	3.28(25)	0.003
Q2(Ports placement)	4.00(0.57)	3.92(0.63)	0.08(-0.18,0.33)	0.63(25)	0.538
Q3 (Visibility)	3.69(0.93)	3.88(0.71)	-0.19(-0.62,0.24)	-0.93(25)	0.363
Q4 (Ergonomics)	3.81(0.75)	3.81(0.75)	0.00(-0.58,0.27)	0.00(25)	>0.950
Q5 (Triangulation of movement)	3.77(0.77)	3.92(0.69)	-0.15(-0.58,0.27)	-0.75(25)	0.461
Q6 (Fulcrum effect)	3.85(0.61)	4.04(0.66)	-0.19(-0.54,0.15)	-1.15(25)	0.259
Q7 (Depth perception)	3.88(0.82)	3.85(0.68)	0.04(-0.33,0.41)	0.21(25)	0.832
Q8 (Ambidexterity)	4.00(0.75)	4.08(0.56)	-0.08(-0.36,0.20)	-0.57(25)	0.574
Q9 (Resources for training)	4.31(0.68)	4.00(0.63)	0.31(-0.03,0.65)	1.87(25)	0.073
Q10 (Resources for teaching)	4.35(0.69)	4.08(0.56)	0.27(0.03,0.51)	2.27(25)	0.032
Total score	3.98(0.54)	3.91(0.46)	0.07(–0.16,0.30)	0.65(25)	0.519

*Paired t-test was applied.

Table III: Comparison of ability to complete both tasks using both endotrainers

Variables	Tools		p-value*
	AR Gynae endotrainer n(%)	Karl Storz endotrainer n(%)	
Task 1 (Beans transfer)			
Complete	26(100.0)	26(100.0)	-
Not complete	0(0.0)	0(0.0)	
Task 2 (Bands transfer)			
Complete	26(100.0)	26(100.0)	-
Not complete	0(0.0)	0(0.0)	

*Pearson Chi-square test was applied.

Table IV: Comparison of time taken to complete both tasks using both endotrainers

Variables	Method		Mean difference (95%CI)	t-statistics (df)	p-value*
	AR Gynae Endotrainer Mean (SD)	Karl Storz Endotrainer Mean (SD)			
Task 1 (Beans transfer)	2.48(0.54)	2.41(0.49)	0.07(–0.10,0.24)	0.84(25)	0.410
Task 2 (Bands transfer)	3.04(0.55)	2.72(0.77)	0.32(0.02,0.62)	2.19(25)	0.038

[a]Paired t-test was applied.

A total of 26 participants were recruited among Masters's students of O&G HUSM who are of level two and above according to Hong Kong College of Obstetricians and Gynaecologists (HKCOG) criteria of levels of gynaecological laparoscopic surgery and also Masters's students of Surgery HUSM who may perform basic laparoscopic procedures, i.e., appendicectomy and cholecystectomy.

Written informed consent was taken after an explanation of the study design was given. Before performing the tasks on the simulators, participants received a general introduction to the AR Gynae and Karl Storz endotrainers. They were given a standardised and thorough explanation of the tasks, including a video demonstration.

There are two tasks that were performed by all participants, which are 'beans transfer' and 'bands transfer'. In the first task, which is 'beans transfer', two types of beans, ten of each type, were mixed together and placed in a container in the middle of the training board. Participants transferred the beans into two containers on the board according to the type of beans using atraumatic graspers. Both hands were used alternately in this task.

While in the second task, which is 'bands transfer', two different colour bands, ten of each colour, were mixed together and placed in the middle of the training board. Participants transferred the bands into two polls on the board according to the colour of the bands using atraumatic graspers. Both hands were used alternately in this task. The time taken to transfer all those beans and bands was recorded. Time started when graspers entered the endotrainer and stopped once all beans or bands were in place. The ability of participants in completing the tasks was also recorded.

Participants performed both tasks using both AR Gynae endotrainer and Karl Storz endotrainer consecutively. The starting order of simulators was randomised for each participant based on a random draw (13 participants started with AR Gynae endotrainer first, and another 13 participants started with Karl Storz endotrainer first). The estimated time taken to complete both tasks on both endotrainers was about 30 minutes.

Before performing the tasks, a 10-minute warm-up period was given to each participant. After completing the tasks, participants responded to a questionnaire containing ten items based on a five-point Likert scale, with scores from 1 to 5: 1. Insufficient; 2. Regular; 3. Good; 4. Very good; 5. Excellent. The following items will be analysed: 1. Design; 2. Ports placement; 3. Visibility; 4. Ergonomics; 5. Triangulation of movement; 6. Fulcrum Effect; 7. Depth perception; 8. Ambidexterity; 9. Resources for training; 10. Resources for teaching. The overall score was defined as the median of the ten items.

Data entry and analysis were done using Statistical Package for the Social Sciences (SPSS) version 24.0. Descriptive statistics included the calculation of the mean and standard deviation (SD) for numerical and frequency (n) and percent (%) for categorical variables. Comparison between the two endotrainers regarding the scores of each item of the questionnaire and also the time taken to complete the tasks was carried out using Paired t-test while comparison regarding the ability to complete the tasks was carried out using Pearson's Chi-square test. In all analyses, the significance level was set at 0.05 ($p<0.05$).

RESULTS

A total of 26 participants were recruited for this study. The mean years of masters training was 3.50 years (0.65). The socio-demographic data of all participants were presented in Table I.

Table II described the comparison of quality between AR Gynae and Karl Storz endotrainers. There was no significant mean between both endotrainers except for Q1 and Q10, where participants rated higher scores for AR Gynae endotrainer. However, the differences were quite small. For the total score, the mean between both groups shows no significant differences.

A comparison of the ability to complete both tasks using both endotrainers was presented in Table III.

Table IV presented the comparison time of completion of tasks in both endotrainers. There were no significant mean differences in the time taken to complete task 1 (beans transfer) using both endotrainers. However, there were significant mean differences for task 2 (bands transfer; $p=0.038$). The time taken to complete the bands transfer task by AR Gynae endotrainer was longer by 0.32 minutes.

DISCUSSION

The advent of laparoscopy marked a fundamental change in the evolution of surgery. It advanced rapidly and influenced gynaecology as well. Nowadays, it has become a routine approach due to its safety and effectiveness. Troncoso-Bacelis et al.,[9] advocate that laparoscopic skills gained from training using simulators promote the transfer of learning to the operating room, which was proven by the reduction of the operating time of surgery.

There are various models of simulators for training in the acquisition of basic and advanced laparoscopic skills available in the current market. Generally, they can be subdivided into two categories: box trainer and virtual reality simulators, according to Loukas et al.[10] Box trainer is a traditional method used for laparoscopic training. It is a system of physical reality, where trainees can use the actual surgical instruments and interact with physical models such as inanimate models (rubber bands, beans, silicone, sponges) and animal organs, thus allowing the real feel of force feedback. Virtual reality simulators (VRS) are a new concept for laparoscopic training. In VRS, only virtual instruments are used, and the control mechanisms are integrated through appropriate sensors. They came with simulation software that reproduces scenarios and platforms with various procedures of different difficulty levels (e.g., salphingectomy and cystectomy). Training on both types of simulators results in a significant overall improvement in laparoscopic surgical skills with no significant differences between both methods, as proven in many studies.[11-13] However, VRS has

disadvantages for its high cost and inability to reproduce important tasks like suturing, although they are better models to simulate advanced laparoscopic procedures.

In recent years, laparoscopic training outside the operating room has been strongly encouraged due to patient safety concerns, resident work-hour restrictions, and an increasingly litigious medico-legal environment. It is significant to have a proper laparoscopic training program to validate the teaching through systematic simulation of technical skills as the next step to integrate the simulation training within the curricular breadth. However, as of now, there is no standardised laparoscopic training program available for gynaecology residents. Training can be time-based, repetition-based, or proficiency-based.[14] General surgery literature has shown that structured proficiency-based training in simulation-enhanced curricula is superior to conventional residency training with regard to knowledge and technical skills acquisition.[15,16] Eliane et al.[17] have described a laparoscopic training program for residents in gynaecology at a tertiary academic centre in Canada through a comprehensive laparoscopy curriculum consisting of cognitive didactic and interactive sessions, low-fidelity box trainer and high-fidelity virtual reality simulator technical skills, and high-fidelity team simulation. The outcome of the study indicated that participation in a comprehensive simulation-based training curriculum for gynaecology laparoscopy leads to a superior improvement in knowledge and technical performance in the operating room compared with conventional residency training. A standardised structured laparoscopic training program for gynaecology residents should be developed to acquire proficiency in laparoscopic techniques.

Palter et al.[18] have developed a structured training system and a comprehensive assessment curriculum in surgical instrumental laparoscopy, demonstrating effectiveness with significant improvement in performance on surgical skills with laparoscopic box training. In the present study, the AR Gynae endotrainer is a box trainer that was specially invented for the practice of laparoscopy surgery in gynaecology. It has a unique design that mimics real patients' abdomen with the placement of the ports like in actual laparoscopy gynaecology surgery. It comes with specially designed training boards with two different exercises inspired by one of the tasks used in the FLS simulator, Peg Transfer. Another four tasks used in the FLS simulator are Pattern Cutting, Endoloop Placement, Extracorporeal Suturing, and Intracorporeal Suturing in which all of them have been extensively tested to ensure that they reflect those technical skills that are fundamental to the performance of laparoscopic surgery.[19-21] Henao et al.[22] in their study, observed a progressive effect in the surgical skills after the implementation of laparoscopic simulator training according to the FLS. In the future, AR Gynae endotrainer probably should have produced more training boards with various kinds of exercises implementing other tasks in FLS as they reflect different technical skills needed for laparoscopic surgery.

In addition, the AR Gynae endotrainer is very light and portable. It does not require an electrical power supply and just needs to be connected to a laptop with a front camera, thus making it readily used for training everywhere, even at home. Most importantly, it is also cheap and much more affordable. In this study, the novel AR Gynae endotrainer was compared to a commercially available model, SZABO-BERCI-SACKIER laparoscopic trainer by Karl Storz, regarding technical, training, and teaching aspects with the purpose of demonstrating its utility as a tool for gynaecology laparoscopic training. Generally, the study demonstrated that all parameters that evaluated the devices showed good performance for both studied simulators. It was found that AR Gynae endotrainer performance was better than the reference simulator in several technical aspects, such as the simulator's design, port placement, and depth perception. Moreover, the AR Gynae endotrainer was also rated better concerning its ability as a resource for training and teaching laparoscopic surgical skills, as well as the global performance, evaluated by the overall score. However, there were no significant mean differences between both endotrainers except for design and resources for teaching aspects ($p<0.05$), in which AR Gynae endotrainer was rated higher. However, the time taken by the participants to complete both tasks by using AR Gynae endotrainer was a bit longer. This is possibly because Karl Storz endotrainer is a transparent box, and the training board inside it can be seen through directly by the participants while handling the tasks. Vice versa, AR Gynae endotrainer is opaque, and in fact, it is more real. Another possible contributing factor was that the Karl Storz endotrainer is connected to the TELE PACK X LED system that has a high-resolution display and powerful LED light source, thus having a better clarity effect. However, the duration differences were quite small, and furthermore, all participants were able to complete both tasks using both simulators. These findings demonstrated that AR Gynae endotrainer is a comparable box trainer for gynaecology laparoscopic training.

In a nutshell, more laparoscopic simulators developments must be pursued. This initial study appears to be promising, but more randomised controlled studies are required to confirm the present results. This study had limitations as it did not evaluate objective parameters. Also, the number of participants involved was small to draw definitive conclusions.

CONCLUSION

Hundreds of studies done over the years throughout the world have proved that laparoscopic surgical skills can be acquired by simulation training. Although simulation training cannot substitute the operating room practice in total, it does increase patient safety and reduce the operating time of surgery. The low accessibility of conventional simulators can be improved by using a mobile, low-cost box trainer. The present study intended to validate AR Gynae endotrainer as a comparable box trainer for gynaecology laparoscopic training, which may help gynaecologists to practise laparoscopic skills at an affordable price. The AR Gynae endotrainer appears to be a useful, convenient, and cost-effective simulator for gynaecology laparoscopic training.

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