Title: Role of portable laparoscopic simulators in surgical skills: a feasibility study

1. Summary
Simulation based training in surgery is often “add-ons” to operating room supervised training and its use often is left to the choice of trainees. Given a choice, many trainees would prefer not to use simulation for reasons relating to time, location, **cost, limited availability** and lack of interest [1]. Portable simulators could enhance the uptake of simulation based training. This feasibility study assessed the role of portable laparoscopic simulators in enhancing surgical skills acquisition and has clearly shown improvement in technical skills of laparoscopic naive medical students with access to portable simulator. If these results are reproducible in our continuing future research, portable laparoscopic simulators may be recommended to be incorporated into future surgical training curriculum. This may have a significant impact on training and patients’ safety as the current role of simulation, in particular availability of portable simulator remains poorly defined. The study provides useful data for power calculation for a large multicentre randomised trial and external funding, besides being a research project for foundation doctor training.

2. Original aims

The research proposal was aimed at:

1. Designing validated measurement tools of laparoscopic skills training on simulator and quantify the change in skills level by the introduction of portable simulator.

2. Identifying areas of future research and use pilot data in informing design, power calculation and conduct of randomized controlled trial assessing role of portable simulators in surgical skills education.

3. Background

Minimally invasive surgery, in particular laparoscopy has become standard of care in many areas of surgical practice. Significant patients’ benefits attributed to laparoscopy have led to increasing indications for this approach even for complex surgical procedures. The learning curve for laparoscopic skills is steep due to the complex psychomotor skills, two dimensional views and mechanical constraints of the instruments which are vastly different from those experienced in traditional open surgery. Simulation-based training has long provided the framework for training many other complex, high-risk professions (i.e nuclear power, aviation, and the military) with the goal of minimizing risk and maximising safety during training. Moreover, multiple external factors including European Working Time Directive, increasing cost of operating room time, ethics of learning basic skills on patients and patient
safety, have stimulated interest in learning laparoscopy skills in a laboratory setting (skill centres) and subsequently transferring them into actual surgical procedures carried out on patients. This requires a significant investment in surgical simulators. There has been a considerable amount of research into virtual reality simulators (Lapmentor, MIST VR™, Promis, SIMENDO or LapSim™) that suggest improved performance in both the animate and human operating rooms. However, virtual simulation training has limitations which have slowed down its clinical implantation. There are resource-derived constraints, such as trainees’ busy schedules, over sophisticated systems, limited availability and the considerable cost implications.

Portable laparoscopic simulators could enhance the uptake of simulation based training as they are inexpensive, portable and flexible systems. Their role and introduction into surgical curricula has not yet been defined and there are few validated to date. This study aimed to identify core laparoscopic skills, model these into exercises and evaluate the role of a portable laparoscopic simulator (iSIM) in enhancing laparoscopic skills acquisition.

4. Methodology

4.1 Identification of tasks and modeling of exercises on simulator (Fig. 1)

Five experienced surgeons with at least 4 years of laparoscopic surgical practice and senior surgical skills tutor identified following basic laparoscopic tasks necessary for education, training and procedure learning purpose:

- Retraction of tissues
- Trajectory of instruments (Time and motion)
- Instruments handling
- Preciseness in tissue handling
- Cutting
- Dissection of tissue planes
- Flow of procedure and forward planning
- Clipping
- Use of non-dominant hand
- Unnecessary movements

Subsequently, exercises were modeled on the basic tasks (Figure 2 and 3) and performed on fixed simulator in Cuschieri Skills Centre (Figure 4) by twenty surgically naive medical students with no exposure to laparoscopy surgery. All the participants were given a 10...
minute introductory presentation (TJ and BT) which included a brief video of the identified tasks, prior starting exercises on simulators.

Fig 1: Flow of participants through the study

Fig 2. Model used for scissor dissection task
4.2 Metrics and validation on simulators
The tasks were recorded on a computer disks (CD-ROM) as baseline assessment. Participants were then randomized into two groups using third party computer generated random numbers. Group A had access to portable simulator for 3 weeks and group B had none. Participants with access to portable stimulator (Figure 5) were provided with an instruction sheet and CD-ROM to practise for 1 hour every day (for at least 14 hours in 2-3 weeks). A log-book was maintained by an independent person to ensure compliance with practice. At the end of the training period, all the participants were asked to repeat the same exercises on the fixed simulator and their performances were recorded on CD-ROM. The recorded exercises were scored by independent members of the team (BT and GN) not associated with the recording process and unaware of the group allocation.
5. **Skills assessment and data analysis**

The performances of CD-ROM exercises were scored using a validated Objective Structured Assessment of Technical Skill [2]. The instrument has been validated and published previously (Table 1). One of the team members (BT) had experience of using this assessment tool. The team did not feel it necessary to develop another assessment tool in the presence of a well validated existent one.

<table>
<thead>
<tr>
<th>General Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect For Tissue</td>
<td>Frequently used unnecessary force or</td>
<td>Careful handling but occasionally</td>
<td>Consistently handled tissues</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>caused damage by inappropriate use of</td>
<td>caused inadvertent damage</td>
<td>appropriately with minimal damage</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>instruments</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time &amp; Motion</td>
<td>Many unnecessary moves</td>
<td>Efficient time/motion but some</td>
<td>Economy of movement and maximum</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>unnecessary moves</td>
<td>efficiency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instrument Handling</td>
<td>Repeatedly makes tentative or awkward</td>
<td>Competent use of instruments though</td>
<td>Fluid moves with instruments and no</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>moves with instruments</td>
<td>occasionally appeared stiff or awkward</td>
<td>awkwardness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of Left Hand</td>
<td>Consistent poor or failed use of left</td>
<td>Good use of left hand</td>
<td>Strategically used left hand to the</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>hand</td>
<td>most of the time</td>
<td>best advantage at all times</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flow of Operation &amp;</td>
<td>Frequently stopped operating or needed</td>
<td>Demonstrated ability for</td>
<td>Obviously planned course of operation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forward Planning</td>
<td>to discuss next move</td>
<td>forward planning with steady</td>
<td>with effortless flow from one move to</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>progression of operative procedure</td>
<td>the next</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Differences between the surgical groups were assessed at 1 and 3 weeks to compare the difference in skill levels, using 2-sample t-test and Mann-Whitney U-test. Intra-group
comparisons were assessed at pre and post intervention stages to determine the within-group levels of improvement, using the paired t-test and Wilcoxon matched pairs test. GraphPad InsTat software programme (http://www.graphpad.com/quickcalcs/ttest2.cfm) was used for statistical analysis.

7. Results

Analysis included pre and post intervention (availability of simulator) skills in all the 20 participants. There were no differences in baseline skills assessment between the two groups (Table 2).

Table 2: Baseline skills score for dissection and cutting in the two groups.

<table>
<thead>
<tr>
<th>Skills</th>
<th>Group A Mean (SD)</th>
<th>Group B Mean (SD)</th>
<th>Statistical significance</th>
<th>P value (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scissors handling and dissection (score)</td>
<td>7.0 (2.261)</td>
<td>5.5 (0.7071)</td>
<td></td>
<td>0.0731 (3.16917 to 0.16917)</td>
</tr>
<tr>
<td>Time taken for dissection task</td>
<td>276.8 (50.57)</td>
<td>292.2 (24.66)</td>
<td></td>
<td>0.402 (-23.0366 to 53.8366)</td>
</tr>
<tr>
<td>Clipping tasks</td>
<td>7.1 (2.983)</td>
<td>6.4 (1.265)</td>
<td></td>
<td>0.507 (-2.93246 to 1.53246)</td>
</tr>
<tr>
<td>Time taken for clipping task</td>
<td>121.48 (61.48)</td>
<td>110.9 (38.29)</td>
<td></td>
<td>0.659 (-59.1187 to 38.5187)</td>
</tr>
</tbody>
</table>

Group A had better quality of scissor dissection (p value 0.0038; 95% CI 3.43-14.56); improved cutting skills (p value 0.0051; 95% CI -14.90- -3.29) and took less time to accomplish the task (p value 0.0099; 95% CI 11.15-64.89) in comparison to group B (Table 3). Similarly economy of movements and errors rate were significantly less in the group A with availability of training on portable simulator.

Table 3: Final skills score for dissection and cutting in the two groups.

<table>
<thead>
<tr>
<th>Skills</th>
<th>Group A Mean (SD)</th>
<th>Group B Mean (SD)</th>
<th>Statistical significance</th>
<th>P value (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scissors handling and dissection (score)</td>
<td>20.7 (4.08)</td>
<td>11.70 (7.12)</td>
<td></td>
<td>0.0038 (3.43-14.56)</td>
</tr>
<tr>
<td>Time taken for dissection task</td>
<td>116.90 (52.02)</td>
<td>221.50 (74.49)</td>
<td></td>
<td>0.0019 (-164.9621 to -44.2379)</td>
</tr>
<tr>
<td>Cutting tasks</td>
<td>20.80 (3.49)</td>
<td>11.70 (7.67)</td>
<td></td>
<td>0.0051; 95% CI -14.90- -3.29</td>
</tr>
<tr>
<td>Time taken for clipping task</td>
<td>54.9 (14.271)</td>
<td>92.90 (35.91)</td>
<td></td>
<td>0.0061 -63.6784 to -12.3216</td>
</tr>
</tbody>
</table>
Figure 4: Improvement in dissection skills achieved by control group (A), who had no access to portable simulators and by interventional group (B), with access to the portable simulator.

8. Discussion

8.1 Key findings
The present study provides objective evidence that access to portable laparoscopic simulator for training on key laparoscopic surgical tasks does improve skills acquisition. The tasks were identified by expert laparoscopic surgeons taking into consideration instrumentation handling, depth perception and fine motor control. Availability of portable simulators can contribute to laparoscopic skills development and their use for surgical education can play a significant role, in particular reinforcement of learning. Access to portable simulator allows repeated practice of standardised laparoscopic surgical steps and reduces the time taken to perform steps with improvement in quality. Participants who had portable simulation-based training before final assessment using validated tools performed better than their counterparts who had no contact with the portable simulator. Whether availability of portable simulators will enhance safety and quality of actual surgical procedure remains to be seen.

5.2 Implications for future research
This feasibility study assessed the performance of portable simulators in enhancing laparoscopic surgical skills acquisition, further research is required in the following areas:

- Assess benefits of portable simulator availability to surgical trainees with different levels of training using a large cohort or in other words define the place of simulation in surgical training curriculum.
• Assess non-technical or human factors that contribute to all-round performance of safe surgical procedure.
• Define level of competencies (performance criteria) mandatory for surgical trainees to be achieved prior to performing surgical procedures on "real patients". With adequate "pretraining", trainees will be able to gain maximum advantages for training in the operating room.
• Assess the cost involved in providing simulation-based training.
• Focus on factors necessary for transfer of simulation-based training into surgical practice.

9. **Conclusions**

Access to portable laparoscopic simulators enhances the skills acquisition. This study provided useful data for the design of a large multicentre trial aimed to define the place of portable laparoscopic surgical simulators in surgical training curriculum.

10. **Research workers and acknowledgement**

• Dr Thomas Johnston performed this work as a part of his academic foundation year 2 training under the supervision of Mr Ghulam Nabi and Mr Benjie Tang.
• Mr Ian Tait and Mr Afshin Alijani provided intellectual input and suggestions at different stages of the project
• Cusheiri skills centre (name the members) provided necessary infrastructure for the completion of this work.

11. **Dissemination**

2. Abstract submitted for presentation to 29th World Congress of Endourology & SWL (WCE2011), Kyoto, Japan.
3. Manuscript being prepared for submission to Annals of Surgery

12. **References**