Research Square

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Preparing Residents for Surgery Using a Low-cost Laparoscopic Salpingectomy Simulation

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Abstract

Introduction: Laparoscopic salpingectomy is a commonly performed procedure and is often one of the first laparoscopic procedures performed by novice residents in Obstetrics and Gynecology (OB/GYN). Opportunities to practice before the operating room can be limited.

Methods: We developed an animal tissue model and incorporated it into a laparoscopic salpingectomy simulation for OB/GYN residents in a single academic program. The simulation included a pre-simulation video describing the steps of laparoscopic salpingectomy, the laparoscopic salpingectomy simulation using an electrosurgical device, a post simulation survey, and debriefing with learner targeted feedback. Validity evidence for the simulation model was gathered using the Messick framework. Resident performance was assessed using the Objective Structured Assessment of Laparoscopic Salpingectomy (OSA-LS) and the Global Operative Assessment of Laparoscopic Skills (GOALS). Performance was correlated to the year of training with upper-level residents grouped for analysis.

Results: Twenty-five simulations of laparoscopic salpingectomy were performed by 14 learners (first through fourth year). The tool was highly rated by participants. We found a significant correlation between the mean OSA-LS score and surgical experience. The mean GOALS score also increased with experience and was significantly different between 1st and 2nd years and between 1st and upper-level residents. A passing score of 12 was established for each assessment rubric.

Discussion: This low-cost surgical model addresses a gap in simulation options for preoperative use of electrosurgical devices. This simulation can be used in OB GYN residency as a method to assess competency or provide feedback.

Introduction

Laparoscopic surgery is a challenging skill set that requires judgement in depth and spatial relationships, video-eye-hand coordination, the fulcrum effect, and a reduced surgical field view.[1] As a result, simulation has become a staple for the training and assessment of surgical residents without jeopardizing patient safety.[2] Simulation has taken on an increasingly important role in certification of surgeons, with the American Board of Obstetrics and Gynecology now requiring simulation based surgical skill assessment for board certification in the United States.

Although there are many laparoscopic trainers and models available for general surgery and urology trainees, there are limited models designed specifically for gynecology residents and their respective procedures.[3,4] Also, few laparoscopic simulators train learners in the hands-on use of electrosurgery or energy devices.[5] In gynecology, laparoscopic salpingectomy performed with an energy device, is a commonly performed procedure and is often one of the first laparoscopic procedures performed by novice surgical trainees.[6] The rate of salpingectomy has increased significantly since the release of the 2013 and 2015 practice statements by the Society of Gynecologic Oncology and the American College of Obstetricians and Gynecologists supporting salpingectomy for ovarian cancer prevention.[7]

Existing virtual reality simulation models (e.g. LapSim by Surgical Science) for laparoscopic surgery using electrosurgical devices can be cost prohibitive, and do not include hands-on use of the actual device.[8] The goal of this project was to develop a realistic simulation to assist in feedback and assessment for novice surgeons in laparoscopic salpingectomy using an energy device, and gather validity evidence utilizing Messick's validity framework.[9]

Methods

We developed this simulation to provide an opportunity for the preoperative preparation of residents early in OBGYN training (PGY 1 and PGY 2). The simulation and assessment tool were designed to measure the following constructs:

trainee knowledge of surgical steps of laparoscopic salpingectomy, safe use of an electrosurgical device, and appropriate tissue handling and traction. The following types of evidence were gathered to support validity of the simulation model: content, response process, internal structure, relationship to other variables, and consequence evidence.

Human ethics approval and declaration to consent were not required as the Institutional Review Board at Mayo Clinic determined this to be an exempt project per the Declaration of Helsinki and US Law. Written consent was not required. The simulation was first piloted and then implemented as part of the OBGYN resident simulation curriculum during protected weekly didactics. The simulation was designed to take approximately 20 minutes- including a pre-simulation video describing the steps of laparoscopic salpingectomy, the simulation itself, a post simulation survey, and debriefing with learner targeted feedback. During the initial pilot phase, the simulation was performed by two medical students, two PGY 4 residents and two minimally invasive gynecologic surgeons. Residents PGY 1- 4 completed the simulation for assessment and simulation feedback. The simulation was led by the Associate Program Director (APD) for the OB GYN residency program (1st author) and the 2nd author, an OB GYN resident at the time of the simulation delivery.

Equipment/Environment

The salpingectomy simulation model was modified from a previously published model,[6] with the following modifications: a silicone lid was added as a base, a dishwasher basket was added to provide a structure representing the pelvic side wall, utero-ovarian ligament and ovaries were constructed using copper wire and felt pads, secured with 3.0 Vicryl. Porcine intestine was used to replicate the fallopian tubes and uterus. The porcine intestine utilized was a commercial item and consumer grade; and was purchased at a local grocery. The Fallopian tubes were built to a length of 8.2 cm. Each model cost about $25 and took about 15 minutes to construct. Replacement tissue models cost approximately $10 each. The necessary supplies, approximate cost, and step-by-step instructions with images of how tobuild themodel are outlined in the Appendix A. Laparoscopic instruments included a box trainer, camera, light source, bipolar electrosurgical forceps (LigaSure), and grasping forceps. Two contralateral ports were used for instrumentation. The ports were placed in the model by the instructors in the same position for each session. LigaSure devices were provided by MedTronic industry representatives through an educational program for surgical training programs. The complete simulation set-up is illustrated in Appendix A. A chux pad was placed at the base of the simulator prior to the introduction of the model. We have executed this simulation with reserved equipment from our simulation center, and on other occurrences with loaned equipment by industry representatives.

The simulation was conducted in a meeting room reserved weekly for resident didactics. It was unable to be performed in our institution's simulation center due to the use of an animal product, each simulation center may have different regulations. Residents rotated through a series of simulation and learning stations during the didactic session, with a salpingectomy station representing one learning objective for the day. A computer tablet was set up at the station to allow the resident to view a video describing steps of laparoscopic salpingectomy immediately prior to beginning the simulation. We prepared a video from de-identified surgical footage with narration of the steps of salpingectomy including role of retraction, avoidance of the pelvic sidewall, and principles of utilization of the electrosurgical device safely for generalized use (Appendix B). The Objective Structured Assessment of Laparoscopic Salpingectomy (OSA-LS) and the Global Operative Assessment of Laparoscopic Skills (GOALS) (Appendix C) were printed and available for the precepting faculty at the simulation station. The faculty were oriented to the assessment tools for data collection including a recorded video and practice scoring prior to data collection.

Personnel

Two preceptors, the APD who is a minimally invasive gynecologic surgeon, and the 2nd author, a 3rd year resident, were present for the simulation. However, in most cases, the preceptor would be able to set up the simulator and guide

learners through feedback. The preceptor should be a faculty surgeon or a chief resident or surgical fellow to allow appropriate targeted learner feedback in the debrief. During sessions assisted by loaned equipment from industry representatives, at least one representative can be present, but not involved in the execution of the simulation or feedback. The preceptor or a co-resident can serve as a surgical assistant and hold the camera. For the initial simulation and assessment, this role was completed by the faculty preceptor (APD) for consistency.

Roles:

Learner: PGY1-2 resident as the primary surgeon

Preceptor: faculty member (surgeon, fellow or chief resident) is responsible for setting up the simulation, holding the camera, and providing constructive feedback to the learner.

Model Builder: The 2nd author built the models for this simulation. OB GYN resident simulation sessions commonly involve model building or preparation, and each residency program may approach this task differently. Some implement simulation model building into a didactic day with shared responsibility by the residents, while in others the simulation preceptors build the models in advance.

Implementation

Three days before the simulation, materials were purchased and the models constructed by the 2nd author. These required refrigeration until use. They were transported to the simulation session by cooler. The week prior to the simulation, the resident learners receive a routine email outlining the agenda for the next week's didactic session. The simulation was introduced to the learners at that time. The didactic room is routinely reserved 30-60 min prior to the didactic start time to allow for preparation time for faculty. Thirty minutes prior to the simulation session, the APD and the 2nd author set up the simulation. The residents rotated to the simulation station individually. On arrival, they were told the simulation objectives. They viewed the video describing the steps of the salpingectomy. They were instructed to perform a unilateral salpingectomy per standard surgical technique. Removal of the fallopian tube from the box trainer was omitted as a surgical step, and the procedure was considered complete once the fallopian tube was completely excised. The learner was provided the Ligasure device and grasping forceps. They were instructed to operate using both hands. Bilateral lower ports were set up in the trainer prior to learner use. The laparoscopic camera was held by the faculty preceptor. If the learner had not previously utilized the LigaSure device, we oriented them to the tool prior to starting the procedure. The simulator procedure was video recorded for simulation assessment. Audio was not recorded to help blind the raters. The OSA-LS is an assessment tool of the essential steps of laparoscopic salpingectomy. [10] This was at the simulation station for completion immediately following the simulation by the faculty preceptor, along with the global assessment of laparoscopic skills using the GOALS form (Appendix C). Feedback was then provided to each resident based on their performance. The simulation models were disposed of after removal of both tubes. The silicone base and dishwasher basket were washed and kept for re-use.

Debriefing

Once the simulation ended, learners had the opportunity to debrief with the preceptor. The learners were asked "what did you find challenging?" The rating scales provided a helpful rubric for feedback, as each of the domains of the rating provides specific skills that can be improved. In the initial simulation session, the video was recorded to assess the simulation as a tool, but the video was not used in the debriefing.

Validity Evidence

Content:

We selected two formal assessment tools to accompany the simulation. We utilized the Objective Structured Assessment of Laparoscopic Salpingectomy (OSA-LS) (Appendix C) and the Global Operative Assessment of Laparoscopic Skills (GOALS) (Appendix C). The OSA-LS assesses procedural steps in 5 categories, each on a 5-point Likert scale with a maximum score of 20 points: presentation of anatomic structures, use of diathermy, dissection of fallopian tube, care for round ligament and pelvic wall.[10] We omitted the step "extraction of the fallopian tube" as this was not the focus of the exercise and would increase cost with the use of specimen retrieval bags, therefore a total of 4 domains were assessed (Appendix C). The GOALS scale assesses technical competence in laparoscopy in 5 categories, each on a 5-point Likert scale with a maximum score of 25 points: depth perception, bimanual dexterity, efficiency, tissue handling, and autonomy.[11]

To assess if consensus exists between the constructs designed to be studied in the simulation and those actually assessed from the user perspective, a post-simulation survey was used for participating residents. Residents rated the model on a 5-point Likert scale in similarity to the live procedure. The residents were asked to write down their level of training, but otherwise the post simulation survey was anonymous, and names were not recorded. In addition, learner perceptions of an educational tool can be helpful as a way to improve engagement and uptake;[12] therefore learner satisfaction with the simulation was also assessed in the survey, and they were offered the opportunity to provide feedback for improvements.

Response Process:

To minimize unwanted variability, the orientation video was provided to each resident prior to beginning the procedure, regardless of year or training or surgical experience. The scoring rubric was shared with the resident prior to starting the simulation. In addition, raters were instructed on the details of the model and how to complete the OSA-LS and GOALS. Raters scored a sample video and then reviewed criteria for scoring to assure consistency prior to the study. The decision to forego an assistant was intentional, to reduce variability of faculty involvement. Therefore, residents were required to operate with both hands and assist themselves in the procedure.

Internal Structure:

Each recorded simulation was graded by 2 blinded minimally invasive gynecologic surgeons after the simulation session, using the assessment tools (OSA-LS and GOALS). The intraclass correlation coefficient (ICC), derived from a two-way random effects analysis of variance model, was used to assess the agreement between the two graders for OSA-LS and GOALS, respectively. With good agreement observed, the scores from the two graders for each participant were averaged for the subsequent analyses.

Relationship to Other Variables:

Simulation performance was compared to the level training of the resident, as a surrogate marker for resident surgical experience. Total scores were compared between the three PGY groups (PGY-1, PGY-2, and PGY-3 or -4) based on the F-test from a one-way analysis of variance model, whereas scores for the individual domains were compared using the non-parametric Kruskal-Wallis test. All calculated p-values were two-sided and p-values less than 0.05 were considered statistically significant.

Consequence:

To assess the validity evidence of the residents scores, we utilized the contrasting groups methods to establish a cut-off competency for the OSA-LS and GOALS respectively.[13] The cut-off was determined by identifying the intersection of the two normally distributed curves for the novice group (PGY-1) and the experienced group (PGY-2 or -3 or -4). As part of

this method, both the observed false negative (FN) and false positive (FP) rates along with theoretical FN and FP rates were calculated.

Results

Fourteen trainees (five first-year residents, four second-year residents, one third-year and four fourth-year residents) participated in the simulation session using the porcine salpingectomy model. This cohort presents 78% (14/18) of the residents in the OB GYN program. 25 salpingectomies were performed as part of the simulation; most residents performed bilateral salpingectomies, while three only performed unilateral procedures due to the models' availability. The model was rated highly on a 5-point Likert scale in domains of anatomy, quality, tactility, similarity to live procedure, and overall satisfaction with means of 4.6, 4.5, 4.5, 4.4, and 4.9, respectively.

Correlation between the two graders of these 25 salpingectomies was good; the ICCs were 0.63 (95% CI, 0.33-0.82) and 0.79 (95% CI, 0.59-0.90), respectively, for OSA-LS and GOALS. As presented in Table 1 and depicted in Figure 1, the mean OSA-LS score increased with PGY year and was significantly different between PGY-1 and PGY-3/4. The mean GOALS score also increased with PGY year and was significantly different between PGY-1 and PGY-2 and between PGY-1 and PGY-3/4 as noted in Table 1 and Figure 1. The individual domains of the assessment rubrics demonstrated the same correlation as the total scores, with the average or median scores increasing with increasing post-graduate year. There was a moderate correlation between PGY year and completion time with a Spearman correlation coefficient of -0.63; the higher the PGY level the less time was needed to complete the task.

Using the contrasting groups method, we identified 12 as a passing score separately for the OSA-LS and GOALS (Figure 2). For the OSA-LS, 2 of the 7 procedures by a novice had a score higher of 12 or higher with an observed false positive (FP) rate of 28.6%. The observed false negative (FN) rate was 22%, with 4 of the 18 procedures by an experienced resident scoring below 12. Using the cumulative distribution function for a normal distribution, we determined that theoretically 20.4% of the novices should have had a passing OSA-LS score and 28.3% of the experienced residents should have had a non-passing OSA-LS score. For the GOALS, the observed FP rate was 14.3% (1/7) and the observed FN rate was 5.6% (1/18), with corresponding theoretical rates of 12.7% and 5.6%, respectively.

Discussion

One role of surgical simulators is to improve a trainee's laparoscopic skills prior to the operating room, reserving precious time in the operating room for nuanced practice, application, and refinement of technical skill, rather than as a first-time exposure to both a new procedure and a surgical tool.[3,14] This model offers the opportunity for simulation with an electrosurgical device for laparoscopic salpingectomy on animal tissue before learning on a live patient. It requires the learner to utilize two hands, retract and expose tissue, and minimize trauma to neighboring structures. Based on these qualities, it may assess a more advanced skill set than exercises such as the transferring of pegs in the Fundamentals of Laparoscopic Surgery (FLS) examination, while not requiring a cadaver or live animal lab.

Evidence of validity of this model is supported by the utilization of well designed and previously studied surgical rubrics for both laparoscopic skills (GOALS) and specifically laparoscopic salpingectomy (OSA-LS). GOALS was already in use in our simulation curriculum, and both residents and faculty were familiar with this assessment tool and routinely provide feedback with this instrument. Both participants and raters were oriented to the model and scoring rubrics prior to the simulation, and good correlation was seen between the graders of simulation performance. The model was well liked: residents rated their overall satisfaction at 4.90 on 5-point Likert scale, and all participants supported continued use of the simulation in the resident curriculum. More importantly, as evidence of content validity, the model was rated as very similar to the live procedure by participating residents (4.4 on 5-point Likert scale).

Relying on the assumption that resident surgical experience in laparoscopic salpingectomy increases by year of training (PGY), performance on the model positively correlated with surgical experience. However, the validity argument could have been strengthened by correlation of simulation performance with real-world performance in the operating room. In our program 1st year residents do not perform laparoscopic salpingectomy, thus using this year should separate experienced from novice users, but we did not actually record the residents' prior procedural experience, which may have affected the determination of a cut-off competency score. Using the OSA-LS rubric specifically, false positive and false negative rates were high at 28.6% and 22% respectively. Additional research correlating performance to actual experience is needed prior to implementation of this model as a qualifying tool for progression to live surgery. The validity assessment could be strengthened by identifying the actual experience of participants (number of salpingectomies performed) and also correlating performance to real-world performance in the surgical setting.

The limitations of this study include that it was performed at a single institution with a limited number of trainees, although the number of trainees is in the range of studies designed to assess validity of a simulation model tool.[14,15] Generalizability for model implementation may be limited based on access to box trainers and electrosurgery devices designated for simulation. However, the model could be used in any box trainer and with a variety of electrosurgical devices including ultrasound, monopolar or bipolar devices, or cold shears. Learners may have objections to the animal tissue utilized, and alternative simulation methods would need to be provided in those circumstances. The other supplies were deliberately chosen from local hardware stores to support generalizability and limit cost. Total cost for the simulator may be higher if donated vessel sealers are not available. However, other reusable bipolar devices could be substituted for the Ligasure, for example to lower the cost of the simulation. The model does take approximately 15 minutes to construct, and portions are not reusable. It could be combined however with other simulations such as laparoscopic suturing or enterotomy repair to maximize utility. One long-term limitation of this model is maintaining the role of the model builder over each academic year. This role could fall to the faculty leading the simulation curriculum, or an education chief resident, or as previously described could be shared by all the residents. However it is planned, this role is essential to continue the successful use of this highly rated model.

Future research could include participant and faculty video review of the recorded simulation with formative feedback. This opens the possibility for video-based coaching as part of the simulation. In our study, the video grading took place after the simulation and was not shared with participants. Debriefing was performed, but this did not include a video-play back. If Incorporated into the debrief for formative feedback, the video can show examples of areas of competency and areas for improvement with specific recommendations for adjustments.

A recent randomized controlled trial by Muir et al. demonstrated that video-based coaching significantly improved resident performance of laparoscopic salpingectomy between attempts.[16] Additional assessment of this simulation model could focus on learner confidence for the procedure, and improvements in technical skill between salpingectomy procedures.

Incorporation of this simulation into a resident curriculum can offer the opportunity for pre-operative surgical teaching and preparation of novice learners in a procedure using an electrosurgical device. In turn, this could support focusing operating room time on fine tuning skills.

Declarations

Ethics Approval: The study was confirmed as exempt by the institutional review board at the Mayo Clinic, Minnesota. While an animal product was utilized, the porcine uterus was a commercial item, and consumer grade. It was purchased at a local grocery store. The research was not conducted on or using live animals, and the authors endorse the careful consideration for use of animals in research as outlined in the Basel Declaration.

Data Availability: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Competing Interests: Daniel Breitkopf MD has the following disclosure – Bayer AG. Site investigator for an Essure device follow-up study, research grant, with all funds directly to Mayo Clinic. Isabel C. Green, MD, MEHP; Sharon J. Kim, MD; Amy L. Weaver, MS; Adela G. Cope, MD; and Matthew R. Hopkins, MD have no conflict of interest to disclose.

Authorship:

ICG made substantial contributions to the conception, design, acquisition, analysis and interpretation of the data, and approved the submitted version, and has agreed to be personally accountable for contributions.

SJK made substantial contributions to the conception, design, acquisition, analysis and interpretation of the data, and approved the submitted version, and has agreed to be personally accountable for contributions.

KAS made substantial contributions to the design, analysis and interpretation of the data, and approved the submitted version, and has agreed to be personally accountable for contributions.

AGC made substantial contributions to the acquisition and interpretation of the data, and approved the submitted version, and has agreed to be personally accountable for contributions.

MRH made substantial contributions to the conception and acquisition of the data, and approved the submitted version, and has agreed to be personally accountable for contributions.

DMB made substantial contributions to the conception and acquisition of the data, and approved the submitted version, and has agreed to be personally accountable for contributions.

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Table

Table 1. Comparison between PGY levels of OSA-LS and GOALS total scores and individual domain scores

Overall total scores and individual domain sores	Mean (SD) Median PGY-1 (N=7 simulations)	PGY-2 (N=8 simulations)	PGY-3/4 (N=10 simulations)	Correlation between score and PGY level†	P-value to identify any differences between the groups‡	P-value for pairwise group comparisons‡ PGY-1 vs PGY-2	PGY-2 vs PGY-3/4	PGY-1 vs PGY-3/4
OSA-LS total score	10.0 (3.0) 11.0	13.2 (3.5) 14.3	15.5 (3.4) 15.3	0.60	0.010	0.08	0.17	0.004
Presentation of anatomic structures	2.1 (0.8) 2.0	3.1 (0.9) 3.3	3.6 (1.1) 3.8	0.55	0.022	0.054	0.27	0.010
Use of diathermy	2.7 (1.0) 2.5	3.4 (0.9) 3.5	4.1 (0.9) 4.0	0.53	0.034	0.19	0.17	0.014
Dissection of fallopian tube	2.6 (0.7) 2.5	3.7 (1.0) 3.8	4.0 (0.9) 4.3	0.52	0.027	0.054	0.51	0.010
Care for pelvic wall and round ligament	2.6 (0.9) 3.0	3.0 (0.9) 3.0	3.9 (0.9) 4.0	0.54	0.027	0.46	0.07	0.014
GOALS total score	8.9 (2.8) 9.5	14.3 (3.5) 15.5	16.3 (2.3) 16.3	0.71	<0.001	0.006	0.17	<0.001
Depth perception	2.6 (0.7) 3.0	3.9 (1.0) 4.3	4.4 (0.6) 4.5	0.66	0.003	0.020	0.46	<0.001
Bimanual dexterity	2.2 (0.7) 2.5	3.3 (0.7) 3.5	3.8 (0.7) 3.5	0.64	0.004	0.028	0.36	<0.001
Efficiency	2.1 (1.0) 2.5	3.7 (1.0) 3.8	4.3 (0.7) 4.3	0.69	0.002	0.014	0.24	<0.001
Tissue handling	1.9 (0.9) 2.0	3.3 (1.1) 3.8	3.9 (0.7) 4.0	0.68	0.003	0.020	0.20	<0.001

† Spearman rank correlation coefficient

‡Total scores were compared between the three PGY groups based on the F-test from a one-way analysis of variance model, whereas scores for the individual domains were compared using the non-parametric Kruskal-Wallis test.

Figures

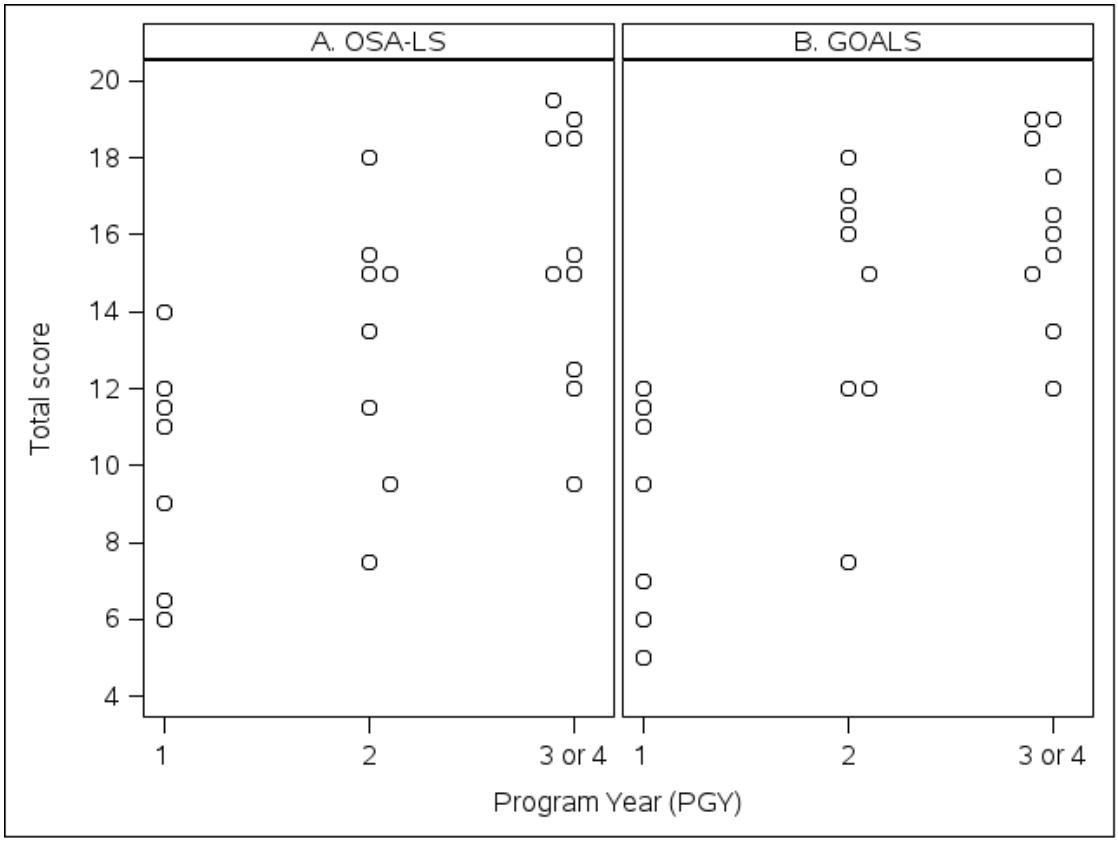


Figure 1

Results of measurement of Objective Structured Assessment of Laparoscopic Salpingectomy (OSA-LS) versus Global Operative Assessment of Laparoscopic Skills (GOALS)

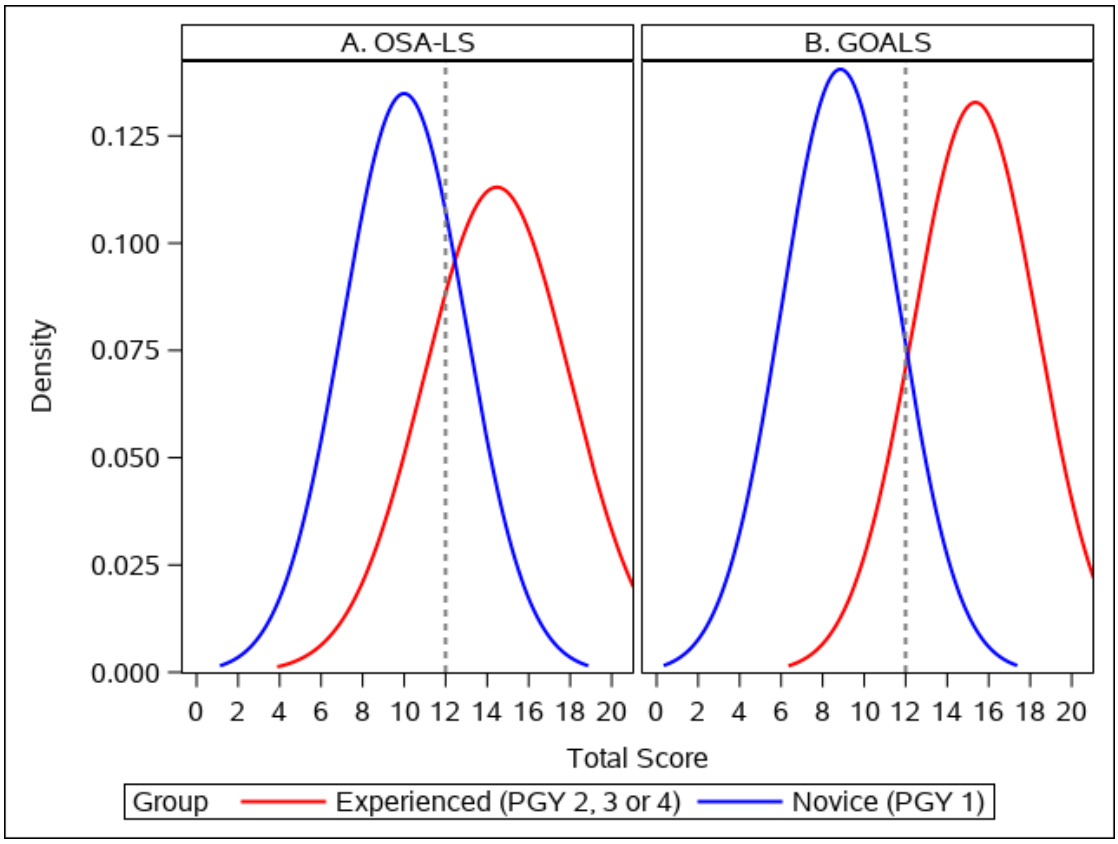


Figure 2

Depiction of data for contrasting groups for GOALS and OSA-LS. PGY=postgraduate year.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AppendixAInstructionsforAssembly.docx
- AppendixBSalpingectomyVideo.mp4
- AppendixCrubrics.docx