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Resident surgical laparoscopic salpingectomy training: a randomized controlled trial

Submission date 18/06/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/07/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 07/08/2019	**Condition category** Surgery	[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study investigates whether a single session of practicing surgical techniques on a porcine (pig) cadaver improves Ob-Gyn resident (medical student) surgical skills.

Who can participate?
All PGY-1 through PGY-4 Ob/Gyn residents at Christiana Care Hospital.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention) attend a session involving pre-session reading, a lecture, viewing a procedural video and then practicing a surgical procedure (laparoscopic salpingectomy) on a porcine cadaver. Those in group 2 (control) receive traditional training. All participants undergo on-site assessment and training (OSAT) before and after the training session. They are also asked to fill in surveys before and after the session to assess their comfort levels.

What are the possible benefits and risks of participating?
A potential benefit of the study is that simulation may improve surgical technique.

Where is the study run from?
Christiana Care Hospital, Newark (USA)

When is the study starting and how long is it expected to run for?
December 2013 to January 2014

Who is funding the study?
Christiana Care Hospital, Newark (USA)

Who is the main contact?
Dr Nima Patel

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CCC #33254

Study information

Scientific Title
Traditional versus simulation resident surgical laparoscopic salpingectomy training: a randomized controlled trial

Study objectives
We conducted a randomized controlled trial to examine whether a single session of simulated practice of surgical techniques utilizing a porcine cadaver improved Ob-Gyn resident surgical skills. The study's primary hypothesis was formal training including video observation followed by a single session of procedural simulation in a porcine cadaver model would improve laparoscopic salpingectomy performance compared with traditional training methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Christiana Care Hospital Institutional Review Board, 11/29/2013, ref: CCC #33254

Study design
Single blinded (evaluator) single center randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Traditional versus simulation resident surgical laparoscopic salpingectomy training

Interventions
1. The intervention group participated in a training module of assigned pre-session reading on pelvic anatomy from a gynecology textbook and a designated article on ultrasonic energy and a formal 3 hour simulation session. The simulation session included a 40-minute didactic introduction reviewing indications for, and the benefits of, laparoscopic salpingectomy and review of relevant anatomy and analogous structures between human and porcine models. It also outlined the fundamental steps of laparoscopic salpingectomy; reviewed the advanced Bipolar or ultrasonic energy sources used; and a video review of a simulated porcine model laparoscopic salpingectomy performed at our institution. Following this didactic presentation, participants had 60 minutes to familiarize themselves with and practice using instrumentation. Participants were then paired to each engage in a 30-minute simulation of laparoscopic tubal salpingectomy on a porcine cadaver model. During this time, each trainee performed a unilateral salpingectomy on the model. An experienced laparoscopist was present to give direction and feedback to participants during the simulation session to facilitate their training in instrumentation and on procedure performance.
2. The control group was not assigned any of the reading, educational activities or simulation session of the intervention group. They continued standard residency training of surgical skills.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The primary outcomes are the OSAT scores, based on a multi-item assessment that measures 9 aspects of surgical technique. Each item is rated from 1-5 using a Likert scale where 1 signifies a low and 5 a high score. For this study, the minimum score on the OSAT was 5 and the maximum achievable score was 45. This instrument has acceptable internal reliability (there was a single evaluator) and its validity is supported through correlations with conceptually related measures from a previously validated surgical skills Global Rating Scale.

Key secondary outcome(s))
Resident comfort level with laparoscopic surgical salpingectomy

Completion date
13/01/2014

Eligibility

Key inclusion criteria
All PGY-1 through PGY-4 Ob/Gyn residents at Christiana Care Hospital

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
22

Key exclusion criteria
Unable to complete OSAT evaluation

Date of first enrolment
19/12/2013

Date of final enrolment
13/01/2014

Locations

Countries of recruitment
United States of America

Study participating centre
Christiana Care Hospital
4755 Ogletown-Stanton Rd.
Room 1903
Newark
United States of America
19718

Sponsor information

Organisation
Christiana Care Health System

ROR
https://ror.org/02h905004

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Christiana Care Hospital, Newark (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016	07/08/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes