Impact of Simulation Exercises on Total Laparoscopic Hysterectomy Surgical Outcomes: A Systematic Review and Meta-Analysis

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ABSTRACT

BACKGROUND: As resources into gynecological surgical simulation training increase, research showing an association with improved clinical outcomes is needed.

OBJECTIVE: To evaluate the association between surgical simulation training for total laparoscopic hysterectomy (TLH) and rates of intraoperative vascular/visceral injury (primary outcome) and operative time.

SEARCH STRATEGY: We searched Medline OVID, Embase, Web of Science, Cochrane, and CINAHL databases from the inception of each database to April 5, 2022.

SELECTION CRITERA: Randomized controlled trials (RCTs) or cohort studies of any size published in English prior to April 4, 2022.

DATA COLLECTION AND ANALYSIS: The summary measures were reported as relative risks (RR) or as mean differences (MD) with 95% confidence intervals using the random effects model of DerSimonian and Laird. A Higgins I2 >0% was used to identify heterogeneity. We assessed risk of bias using the Cochrane Risk of Bias tool 2.0 (for RCTs) and the Newcastle Ottawa Scale (for cohort studies).

MAIN RESULTS: The primary outcome of this systematic review and meta-analysis was to evaluate the impact of simulation training on the rates of vessel/visceral injury in patients undergoing TLH. Of 989 studies screened 3 (2 cohort studies, 1 randomized controlled trial) met the eligibility criteria for analysis. There was no difference in vessel/visceral injury (OR 1.73, 95% CI 0.53–5.69, p=0.36) and operative time (MD 13.28, 95% CI –6.26 to 32.82, p=0.18) when comparing before and after simulation training.

CONCLUSION: There is limited evidence that simulation improves clinical outcomes for patients undergoing TLH.

INTRODUCTION

The utility of surgical simulation (a technique to replace or amplify real experiences with guided experiences, often immersive in nature, that evoke or replicate substantial aspects of the real world in a fully interactive manner) has been long recognized,[1] with the oldest documented utilization of surgical simulators dating to 600BC in India.[2] Multiple factors have led to an appreciable increase in the use of surgical simulation over the past several decades, including ACGME restrictions on resident work hours, the advancement of technology, and the introduction of the Fundamentals of Laparoscopic Surgery course.[3,4] While there is extensive literature demonstrating the impact of simulation on surgical training and procedures,[5-8] literature on gynecological surgery is limited.[9]

It is estimated that over 1,300 hysterectomies are performed in the United States every day.[10] Nearly two-thirds of all hysterectomies are performed via a minimally invasive (laparoscopic or robotic) approach.[10,11] There is a high variation in reported rates of complications including bowel and bladder injuries for patients undergoing hysterectomy.[12-14] Multiple publications have examined the use of simulation for total laparoscopic hysterectomy (TLH), and these studies have demonstrated increased provider comfort, knowledge, and confidence in the procedure, as well as improved technical skills.[15-17] However, there is a paucity of research examining whether TLH simulation improves clinical outcomes.

The primary outcome of this systematic review and meta-analysis was to evaluate the impact of simulation training on the rates of vessel/visceral injury in patients undergoing TLH. Secondary outcomes included operative time, transfusion rates, conversion rates and hospital readmission. We hypothesized that implementation of simulation training would lead to a decrease in vessel/visceral injury.

METHODS

Information sources and search strategy

This meta-analysis was performed according to a protocol recommended for systematic review.[18] The review protocol was designed by a priori defining methods for collecting, extracting, and analyzing data. Registration of this systematic review and meta-analysis on the PROSPERO database (CRD42022312403) was performed prior to initiation of the study. The study was reported per the PRISMA criteria, and a PRISMA-2 Reporting guideline is included in the supplement (email corresponding author for supplementary material).

In March 2022, a trained medical librarian (LO), started a systematic search to compile literature on Laparoscopic Hysterectomies and Simulation Training. Using Medline OVID (Medline on OVIDSP) as the primary database. The topic was explored and determined to have two main concepts: Hysterectomies (Laparoscopic) (1) and Simulation (2). The search was deliberately developed to be as broad as possible, utilizing two concepts, due to the overall lack of literature found on the topic and was developed as broad as possible.

The concepts were developed using both controlled and natural languages. MeSH terms were identified, and keywords were gathered along with various synonyms. The keywords were searched using the title, abstract, and keyword fields within the Medline OVID database. The English language filter was used, but no other limiters were implemented. Searching was completed from March 25, 2022 through April 4, 2022. Once the searches were thoroughly developed, they were given to the investigators for final approval.

The Medline OVID search strategy was approved on April 1, 2022. Five databases were used: Medline OVID, Embase, Web of Science, Cochrane Library, and CINAHL w/Full Text (EBSCO). For continuity, after translation, the searches were all run again on April 5, 2022 individually, in each database. The results from these final searches were then uploaded to the EndNote citation manager for de-duplication. De-duplication was completed on April 5, 2022 within the citation manager system, and then performed manually. Before de-duplication citations totaled 1,751; after de-deduplication, the total number of citations was 989.

Eligibility criteria and study selection

Selection criteria included randomized controlled trials (RCTs) and prospective and retrospective cohort studies published in English that reported on the association between simulation training and at least one of our primary or secondary outcomes of interest. Abstracts were independently screened by two investigators (TG, AH), and if the abstract was identified as being possibly relevant the full text was double-screened. Studies that did not report on simulation training for TLH or did not report the primary or secondary outcomes were excluded.

Data extraction

A custom data extraction form in Microsoft Excel® was independently completed by two investigators (TG, AH), with discrepancies resolved by a third investigator (SW). Variables that were extracted included: study design, publication type, year of study publication, study country, rates of intraoperative vascular/vesicular injury (primary outcome) and operative time, transfusion rates, conversion rates, hospital length-of-stay, and readmission.

Risk-of-bias assessment

Risk-of-bias assessment was independently completed by two authors (SW, MM). The Cochrane Risk-of-Bias 2.0 tool for randomized trials (RoB 2) was used for RCTs,[19] and the Newcastle-Ottawa Scale (NOS) was used for cohort studies.[20] A third investigator (AH) was available to resolve any discrepancies in the risk-of-bias assessment.

Data synthesis

Data analysis was completed using Review Manager 5.4.1 (Copenhagen: The Nordic Cochrane Center, Cochrane Collaboration, 2020). The summary measures were reported as summary relative risks (RRs) or as summary mean differences (MDs) with 95% of confidence intervals (CIs) using the random effects model of Der-Simonian and Laird.[12] (Higgins I2) >0% was used to identify heterogeneity. Potential publication biases were assessed graphically by using the funnel plot. The meta-analysis was reported according to the Preferred Reporting Item for Systematic Reviews and Meta-analyses (PRISMA) statement.[21] Due to the limited number of studies, no subgroup analyses were undertaken.

RESULTS

Summary of identified evidence

Following de-deduplication, the total number of unique records to screen was 989 (**Figure 1**); 62 full-text articles were screened and 59 of them were excluded. The most common reasons for exclusion were either incorrect outcomes, most commonly physician comfort/confidence with performing the surgery, (34 studies) or study designs without comparator groups (12 studies). Three articles (describing three studies)

Figure 1. PRISMA flow diagram

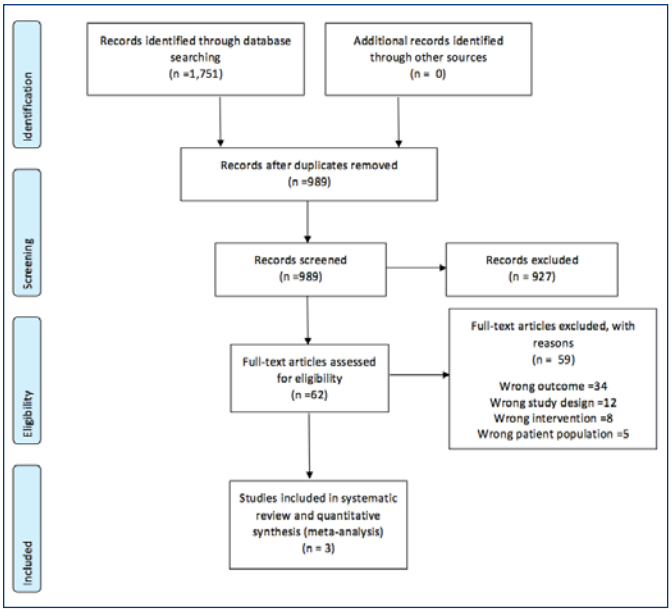


Table 1. Study Characteristics

Author	Publication year	Study location	Study type	Total Hysterectomies		Total Laparoscopic Hysterectomy	
				Pre-Intervention	Post-Intervention	Pre-Intervention	Post-Intervention
Asoglu et al	2016	USA	Cohort	188	1209	40	232
Jokinen et al	2019	Finland	RCT	10	10	10	10
Oman et al	2013	USA	Cohort	855	751	396	500

met the eligibility criteria. These three studies encompassed two cohort studies and one RCT (**Table 1**).[22-24]

The two cohort studies encompassed 1,168 TLHs of which 732 (62.6%) were performed following the implementation of simulation training.[22,24] Both studies were conducted in the United States and were rated as having a high risk of bias (**Table 2a**). Concerns regarding the lack of control for potential differences in patient populations drove the high risk of bias in both cohort studies.

The one RCT, done in the United States, examined 20 TLHs, 10 (50%) were with residents who underwent simulation training. This study was rated as having a low risk of bias (**Table 2b**).[23]

Risk of Vessel/Visceral Injury

In the primary meta-analysis (three studies), simulation training was not associated with a decreased risk of vessel/visceral injury (OR 1.73, 95% CI 0.53–5.69, p=0.36) (**Figure 2**).[22-24]

Risk of Secondary Outcomes

Two studies (one cohort, one RCT) reported on operative time.[22,23] There was no difference in operative time (MD 13.28, 95% CI –6.26 to 32.82, p=0.18) when comparing before and after simulation training (**Figure 3**). None of the studies reported on the association between TLH simulation training and transfusion rates, conversion rates, hospital length-of-stay, and readmission.

DISCUSSION

This systematic review and meta-analysis did not demonstrate a decreased risk of vessel/visceral injury in patients undergoing TLH following the implementation of simulation training. Likewise, there was no difference in operative time, and a lack of data on further secondary outcomes.

These findings are not consistent with the impact of simulation on surgical outcomes in

Table 2a. Newcastle-Ottawa Scale (NOS) for assessing the quality of non-randomized studies

Studies	Selection (Maximum 4)	Comparability (Maximum 2)	Outcome (Maximum 3)
Asoglu et al (2016)	3	0	3
Oman et al (2013)	2	0	2

Thresholds for converting the Newcastle-Ottawa scales to AHRQ standards (good, fair, and poor):

Good quality: 3 or 4 stars in selection domain AND 1 or 2 stars in comparability domain AND 2 or 3 stars in outcome/exposure domain

Fair quality: 2 stars in selection domain AND 1 or 2 stars in comparability domain AND 2 or 3 stars in outcome/exposure domain

Poor quality: 0 or 1 star in selection domain OR 0 stars in comparability domain OR 0 or 1 stars in outcome/exposure domain

Table 2b. Revised Cochrane risk-of-bias tool for randomized trials (RoB-2)

	Bias arising from the randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall risk of bias
Jokinen et al.	Low	Low	Low	Low	Low	Low

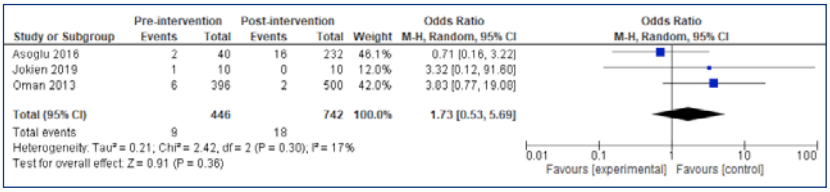
Overall risk-of-bias judgement criteria

Low risk of bias: The study is judged to be at low risk of bias for all domains for this result.

Some concerns: The study is judged to raise some concerns in at least one domain for this result, but not to be at high risk of bias for any domain.

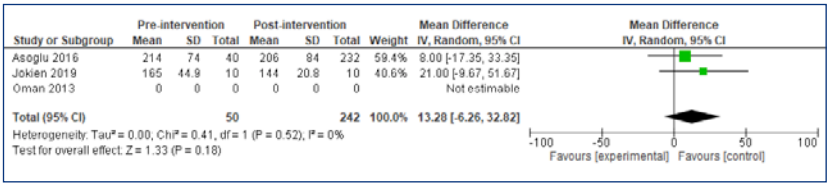
High risk of bias: The study is judged to be at high risk of bias in at least one domain for this result. The study is judged to have some concerns for multiple domains in a way that substantially lowers confidence in the result.

Figure 2. Meta-Analysis of the Association Between Total Laparoscopic Hysterectomy Simulation and intraoperative vascular/vesicular injury



I2: measure of heterogeneity

Figure 3. Changes in Total Laparoscopic Hysterectomy Operative Time



other specialties , where decreased adverse outcomes (e.g., decreased damage to gallbladder and surrounding structures during cholecystectomy, decreased capsule tears during cataract surgery)[7,25] and operative time have been demonstrated.[26] Limited research on simulation training in vaginal hysterectomy and robotic hysterectomy has failed to show a reduction in operative time, consistent with the results found in this study.[27,28] The conclusions drawn in this systematic review and meta-analysis highlight the paucity of data examining the impact of TLH simulation training on patient level outcomes.

As part of an initiative to incorporate simulation and standardize surgical training, the American Board of Obstetrics and Gynecology (ABOG) added the Fundamentals of Laparoscopic Surgery course certification as a pre-requisite for board certification in obstetrics and gynecology for residents graduating after May 31, 2020. More recently, on January 9, 2023, the Essentials in Minimally Invasive Gynecologic Surgery certification was approved as an alternative option to meet the Surgical Skills Program standard for ABOG certification. The limited studies identified in this systematic review and the lack of improved patient outcomes call into question whether there is sufficient evidence to support these training requirements and certification procedures.

There are several limitations to this systematic review and meta-analysis that should be acknowledged. Only three studies meet the inclusion criteria for this analysis and the only randomized controlled trial had a sample size of 20 patients. All three studies were performed in the United States or Finland, so the applicability of simulation in low-resource settings is unclear. Furthermore, this study did not examine the cost effectiveness of simulation training.

A strength of this analysis is that, to our knowledge, it is the first systematic review and meta-analysis to explore the impact of TLH simulation training on patient-level outcomes. A recent well-designed systematic review and meta-analysis examined the impact of simulation on gynecological surgeries, but TLH was excluded from that analysis.[9] The primary limitation to this analysis is the lack of studies and small sample size, which included only 1,168 TLHs in total. Furthermore, both cohort studies were rated to be poor quality per the NOS.

CONCLUSIONS

The current data is limited and fails to demonstrate that clinical outcomes for patients undergoing TLH are improved with the implementation of simulation training. This systematic review and meta-analysis highlight the need for further research to support the national mandates for simulation training for gynecological surgeons.

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