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ROBOTIC VERSUS LAPAROSCOPIC HYSTERECTOMY FOR BENIGN DISEASE: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED TRIALS

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Abstract

We conducted a systematic review and meta-analysis to assess the safety and effectiveness of robotic versus laparoscopic hysterectomy in women with benign uterine disease, as determined by randomized studies. We searched MEDLINE, EMBASE, the Cochrane Library, ClinicalTrials.gov, and Controlled-Trials.com from inception to October 9th, 2014, using the intersection of the themes “robotic” and “hysterectomy.” We included only randomized and quasi-randomized controlled trials of robotic versus laparoscopic hysterectomy in women for benign disease. Four trials met inclusion criteria and were included in the analyses. Data was extracted and studies were assessed for methodological quality in duplicate. For meta-analysis, we used random effects to calculate pooled risk ratios (RR) and weighted mean differences. For our primary outcome, we used a modified version of the Expanded Accordion Severity Grading System to classify perioperative complications. We identified 41 total complications among 326 patients. When comparing robotic to laparoscopic hysterectomy, we found no statistically significant differences in the rate of class 1 and 2 complications (RR=0.66, 95% Confidence Interval (CI) 0.23–1.89) or in the rate of class 3 and 4 complications (RR=0.99, 95%CI 0.22–4.40). Analyses of secondary outcomes were limited due to heterogeneity, but showed no

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significant benefit of robotic compared to laparoscopic technique in terms of length of hospital stay (weighted mean difference= -0.39 days, 95%CI -0.92-0.14), total operating time (weighted mean difference=9.0 minutes, 95%CI -31.27-47.26), conversions to laparotomy, or blood loss. Outcomes of cost, pain, and quality of life were inconsistently reported and not amenable to pooling. Current evidence demonstrates neither statistically significant, nor clinically meaningful differences in surgical outcomes between robotic and laparoscopic hysterectomy for benign disease. The role of robotic surgery in benign gynecology remains unclear.

Keywords

laparoscopic hysterectomy; robotic surgery; meta-analysis; systematic review

INTRODUCTION

Hysterectomy is one of the most commonly performed surgeries, with nearly 500,000 women undergoing the procedure in inpatient settings annually in the United States alone, 87% of which were performed for benign uterine pathology (1). Surgical approaches to benign hysterectomy include laparotomy, laparoscopy, and vaginal techniques. Robotic-assisted laparoscopic surgical technique (henceforth, referred to as “robotic”) was introduced in 2005 with Food and Drug Administration approval of the da Vinci System (*Intuitive Surgical Inc., Sunnyvale, CA, USA*) (2). By 2010, robotic technique was used for 10% of all hysterectomies, and nearly 25% of hysterectomies in hospitals offering robotic surgery (3,4). Each approach to hysterectomy is associated with varying rates of complications and post-operative recovery time (5). In a recently published 2015 committee opinion, the American Congress of Obstetricians and Gynecologists (ACOG) reaffirmed a 2009 statement, stating that for patients undergoing hysterectomy for benign disease, the vaginal approach is preferred, “given its well-documented advantages and lower complications rates” (6,7). When vaginal approach is not feasible, ACOG states that laparoscopic hysterectomy may be considered as an alternative (6,7), consistent with the AAGL’s position statement that most hysterectomies for benign disease should be performed laparoscopically or vaginally, to avoid the morbidity of laparotomy (8). However, the data for minimally-invasive robotic technique for benign hysterectomy is not as well defined, leading to ACOG’s committee opinion that “randomized controlled trials or comparably rigorous nonrandomized prospective trials are needed to determine which patients are likely to benefit from robot-assisted surgery and to establish the potential risks,” (6).

Since its introduction, the robotic technique has been widely adopted without extensive data (4). More recent literature includes several systematic reviews of robotic hysterectomy, for benign disease, malignant disease, or both (9–14). For benign disease, compared with laparotomy, one review found robotic technique resulted in shorter length of stay and less blood loss (9). In the comparison of robotic versus laparoscopic hysterectomy, meta-analyses of surgical outcomes, mostly from observational cohort studies, have shown quite mixed results. Some reviews have found evidence for select advantages of robotic technique, particularly shorter length of stay, in pooled analyses of benign hysterectomy, and combining hysterectomy for both benign and malignant disease (11–13,15). However,

many reviews have demonstrated no significant advantages of robotic over laparoscopic technique for clinical outcomes in hysterectomy for benign disease (9,10,14). In addition, evidence has consistently demonstrated one clear disadvantage of robotic compared to laparoscopic technique in hysterectomy for benign disease: higher cost (9,10,14). One recent estimate puts per-case cost for robotic hysterectomy at 1.5 to 3 times higher than for laparoscopy, with a greater cost difference in cases for benign disease (14). This higher cost is driven by a combination of an up-front investment of \$1 to \$2.5 million for the robotic equipment, high annual maintenance costs, and the per-case cost of replacing the limited use arms (16). To date, theorized improvements in surgical outcomes, patient experience, and cost have not been clearly demonstrated in the literature on hysterectomy for benign disease, though the evidence in these reviews comes almost entirely from observational studies highly vulnerable to selection bias.

The primary objective of this systematic review and meta-analysis is to assess the safety and efficacy of robotic compared with laparoscopic hysterectomy for benign disease, limiting our analyses to only randomized and quasi-randomized controlled trials. As the vast majority of the literature on the topic comes from observational studies and offers conflicting evidence, we hope to overcome some of the methodological shortcomings from prior systematic reviews by analyzing these newly published randomized trials, offering an in-depth pooled analysis, with particular interest in the frequency and severity of complications, for which the individual studies may be underpowered to detect differences.

METHODS

Search Strategy

A standard methodology was used to perform our search and analyses, following the PRISMA Statement guidelines (17,18). The original protocol is available upon request. The MEDLINE, OvidSP, EMBASE, and Cochrane databases were queried from inception through October 9th, 2014. Additionally, trial registries Clinicaltrials.gov and Controlled-Trials.com ISRCTN Register were searched and the reference lists of eligible studies were scanned. Medical Subject Heading terms and keywords were used to populate thematic sets related to 'Hysterectomy' and 'Robotic,' then the Boolean term "AND" was used to find the intersection. Limits or restrictions on time or language were not used.

Study Selection

Studies were required to meet the following eligibility criteria: (1.) the intervention was a robotic hysterectomy, defined as any hysterectomy performed with a robot as a surgical tool; (2.) the comparison was laparoscopic hysterectomy; (3.) participants included adult females undergoing hysterectomy for benign disease; (4.) trial design was a randomized- or quasi-randomized; (5.) the study reported at least one of our pre-specified outcomes; and (6.) the study was published as a peer-reviewed manuscript amenable to judging methodological quality.

After removing duplicate records, titles and abstracts were manually reviewed and clearly irrelevant studies excluded. Two reviewers (B.B.A. and J.C.) then reviewed the full text of

each remaining record to determine final eligibility. Data extraction, including methodological quality assessment, was completed in duplicate using a standardized form by a combination of three reviewers (J.C., A.N.T., and T.W.), with disagreements resolved by consensus. In assessing quality, we utilized the Cochrane Risk of Bias tool, which uses pre-defined criteria to label studies as no risk, unclear risk, or high risk of bias on each of seven included domains: randomization method, allocation concealment, blinding of participants and staff, blinding of outcome assessment, attrition/completeness of data, selective reporting, and other biases (17). Authors were contacted to provide missing or clarifying information when needed.

Outcomes

Our main outcome was perioperative complications, defined as any deviations from the normal course of surgery or postoperative period. We included all complications reported by the eligible studies with the exception of uncomplicated urinary tract infections, which were inconsistently reported across studies. We utilized the Expanded Accordion Severity Grading System for surgical complications, which we modified to accommodate intraoperative complications by defining visceral injury or unexpected deviation from the surgical plan requiring additional intervention or resources as Class 4, defined otherwise as a complication that “requires management by an operation under general anesthesia,” (19). Deviation of the surgical plan leading to conversion of technique was considered a complication, in that this adds both additional costs from opening extra equipment, and additional room and anesthesia time for the procedure. In order to uniformly categorize postoperative complications, three authors (J.D.B., V.B.D., and E.A.E.) independently classified all complications, with disagreements resolved by discussion and consensus. Analyses were performed at three levels of complication severity: mild/moderate (classes 1 and 2), severe requiring procedural intervention (classes 3 and 4), and severe with organ system failure or death (classes 5 and 6). To ensure that the conversions did not skew our results, a sensitivity analysis excluding conversions as a complication was performed.

Secondary outcomes were pre-specified as follows: length of hospital stay (days), total operating time (minutes, defined explicitly as skin-to-skin time from incision to closure, including docking time for the robot), conversion to laparotomy, blood loss (mL estimated, or % decrease in hemoglobin), cost (US dollars, defined as the total cost of the operation and associated hospitalization, including physician fees and equipment costs), and patient experience measures of post-operative pain and quality of life.

Statistical Analysis

Pooled risk ratios (RR) were used to summarize dichotomous outcomes, weighted mean differences to summarize continuous outcomes reported similarly across studies, and standard mean differences to summarize blood loss, which was reported variably as either estimated blood loss (mL) or percent decrease in hemoglobin between pre- and post-operative blood draws. For outcomes that were reported with adequate detail for statistical pooling, RevMan 5.3 (*The Cochrane Collaboration, Copenhagen, DK*) was used to calculate summary estimates (20). Due to the more conservative assumptions about the similarity of included studies, random effects modeling was chosen to minimize risk of type I error (17).

For outcomes with insufficient data for quantitative pooling, findings were summarized qualitatively by considering the magnitude, direction, statistical significance, and risk of bias of the reported findings.

RevMan was used to calculate χ^2 and I^2 tests of heterogeneity among the studies contributing to each pooled estimate (20). Thresholds of p-value less than 0.10 and I^2 greater than 50% were used to define excessive heterogeneity. When heterogeneity was encountered, a visual examination of the findings contributing to each outcome was conducted to identify outliers. Clinical and methodological characteristics of outlying studies were reviewed, aiming to identify explanatory variables. Secondary analyses were executed on the largest group of homogenous studies for each outcome. To assess for reporting bias, funnel plots were created (20).

Sensitivity analyses were completed to evaluate the impact of including studies considered to be at high risk for bias in one or more domains of the methodological quality assessment. For each domain, the results of outcomes were re-analyzed after excluding the high-risk studies. Direction, magnitude, and significance of the restricted findings were compared to the overall findings.

RESULTS

Characteristics of Included Studies

In total, 2,024 records were identified via searches of electronic databases through October 9th, 2014. One additional record was identified via searches of trial databases (NCT02118974), but this study is ongoing and no peer-reviewed published results were available at the conclusion of the defined search period. After removing duplicate records, 1,499 citations were excluded by review of titles and abstracts, and a further 20 studies were excluded by full text review. One disagreement on eligibility was resolved by consensus, as a meeting abstract describing an otherwise eligible study was found to have no corresponding peer-reviewed manuscript, and therefore excluded (21). No additional studies were identified through reference review. Study selection flow is detailed in Figure 1.

Characteristics of the four eligible trials identified are presented in Table 1 (22–25). All four were published in or after 2012. They were conducted within four different countries, all in tertiary academic medical centers, and included a total of 326 women, all undergoing total hysterectomy. We contacted authors of three studies to clarify reported results or collect additional data (22,24,25). Baseline patient characteristics are summarized and were comparable in terms of patient age, body mass index (BMI), parity, and rate of prior abdominal surgery (Table 2). Fibroids were the most common indication, present in 42% to 59% of patients across studies. The largest difference in rates of fibroids between robotic and laparoscopic surgery patients within a study was non-significant ($p=.16$) (22). There were observed differences in mean uterine weight (averages ranged 157 to 301 g) within studies, including a statistically significant difference in one study, for those undergoing robotic compared with laparoscopic surgery ($p=.02$) (22).

Methodological quality is summarized in Figure 2. Blinding of surgeon to surgical technique is not possible, and only Paraiso, *et al.* blinded patients (24). Consequently, allocation concealment was generally not well described and also rated as unclear or high risk of bias in all four studies. Of note, Lönnerfors, *et al.* described randomization of patients to robotic or “minimally invasive” hysterectomy (22). At the time of surgery, all patients were assessed for feasibility of a vaginal approach by the surgeon. Patients assigned to “minimally invasive” surgery and deemed eligible for vaginal hysterectomy underwent this approach, and the remainder underwent laparoscopic hysterectomy. Those assigned to robotic surgery were similarly assessed, but underwent robotic hysterectomy irrespective of the feasibility of vaginal approach. In this meta-analysis, we limited the comparison to robotic and laparoscopic techniques; therefore, only the subsets of patients who underwent laparoscopic hysterectomy because they were deemed ineligible for vaginal approach were included. Conversely, patients randomized to robotic hysterectomy who were deemed eligible for vaginal approach were also excluded. Also of note, Martínez-Maestre, *et al.* used a quasi-randomization technique that depended on robot and operating room availability, but did not allow surgeon selection or patient preference to influence the chosen surgical approach (23).

Primary Outcome: Perioperative Complications

Our primary outcome, perioperative complications, occurred in 12.6% of patients ($n/N=41/326$), with nearly identical overall pooled occurrence rates in patients undergoing robotic (12.3%) compared with laparoscopic approach (12.8%). The most common perioperative complications were vaginal cuff hematoma or bleeding ($n=12$), robotic difficulties necessitating conversion to laparoscopy or vaginal cuff closure ($n=8$), and blood transfusion ($n=4$). In classifying complications by severity, discussion for consensus assignment was required for intra-operative surgical conversions (class 4) and vaginal vault hematomas and post-operative bleeding (class 2–4 depending on treatment), (Table 3 for complete definitions and counts) (19). In pooled analysis of robotic compared to laparoscopic hysterectomy (Figure 3), we found no significant differences in the rate of mild/moderate (classes 1 or 2) complications ($RR=0.66$, 95% CI 0.23–1.89, $I^2=0\%$), or in the rate of severe (classes 3 or 4) complications ($RR=0.99$, 95% CI 0.22–4.40, $I^2=53\%$). There were no severe complications constituting organ system failure (class 5) or death (class 6). Results from sensitivity analyses excluding the quasi-randomized Martínez-Maestre, *et al.* study (23), and excluding surgical conversions as complications did not substantially differ from the primary analysis (Figure S.1).

Secondary Outcomes

For most secondary outcomes, adequate data for inclusion in meta-analysis was acquired from all four eligible trials (22–25).

Length of stay—A small, non-significant reduction in length of stay (Figure 4A) was identified for patients undergoing robotic versus laparoscopic hysterectomy (weighted mean difference = -0.39 days, 95% CI $-0.92 - 0.14$). There was significant heterogeneity among contributing findings ($I^2=83\%$), which was found to be largely attributable to Martínez-Maestre, *et al.*, the methodology of which was considered high risk of bias in several

domains (23). Pooling the three homogeneous and higher quality trials resulted in a non-significant result (weighted mean difference= -0.17 days, 95% CI $-0.36 - 0.02$, $I^2=0\%$; $p=0.08$).

Skin-to-skin operating time—All four studies reported skin-to-skin operating times, including robot docking time. Patients who underwent robotic hysterectomy had a small non-significant increase in mean skin-to-skin operating times (Figure 4B), though there was significant heterogeneity between studies (weighted mean difference=9.0 minutes, 95% CI $-30.0 - 48.0$, $I^2=95\%$). Reviewing the contributing study findings, two studies (22,23) reported significant results favoring robotic surgery, while the other two studies (24,25) reported statistically significant results favoring laparoscopic surgery.

Conversion to alternative surgical approach—Event rates were low across all four studies for the pre-specified outcome of conversions from robotic or laparoscopic approaches to laparotomy, with only three instances occurring among the 326 patients (0.9%; $n/N=3/326$). All three conversions to laparotomy were among patients randomized to laparoscopic approach. Additionally, there were eight cases in which there was a deviation from the planned approach that did not include laparotomy. All eight of these cases were in patients undergoing the planned robotic approach: three were converted from robotic to laparoscopic approach, and five from robotic to vaginal approach for cuff closure, due to an inability to complete the operation using the planned robotic technique.

Blood loss—Four studies reported measures aimed at quantifying blood loss related to surgery (Figure 4C); three reported estimated blood loss (mL) at the end of the procedure (22,24,25), and one reported percent decrease in hemoglobin from pre-operative to post-operative blood draws (23). Our primary analysis found results were similar between patients undergoing robotic versus laparoscopic hysterectomy (standard mean difference= -0.28 , 95% CI $-0.69 - 0.13$), but this finding demonstrated significant heterogeneity ($I^2=71\%$). Results were similar when limiting analysis to the three studies reporting in terms of mL estimated blood loss (excluding Martínez-Maestre, *et al.*) and calculating weighted mean difference. Finally, we considered bleeding-related complications (hematomas, postoperative bleeds, and blood transfusions), and found similar rates for patients undergoing robotic (8/162) or laparoscopic (9/164) approaches.

Cost—Only Lönnerfors, *et al.* provided data on the comparative cost of robotic and laparoscopic techniques (22). This trial was conducted in Sweden with costs reported in US\$ using the exchange rate at the time of the study. We executed an original analysis using their raw data, limited to the restricted comparison of patients deemed ineligible for vaginal approach. We found that the robotic technique was associated with a statistically significant higher mean cost per-case when compared to laparoscopic technique (\$8,771 vs. \$7,059, mean difference=\$1,711, 95% CI \$1,202 – \$2,221; $p<.001$) when considering all hospitalization, procedural, and staff (surgeon, anesthesia, and nursing) costs through 4 months post-operatively, including the robot fixed (purchase price and annual maintenance depreciated over 7 years with 300 annual procedures) and variable costs (robotic instruments, ports, optics, and draping).

Patient experience measures: post-operative pain and quality of life—Two of the four eligible studies reported outcomes related to pain, quality of life, or return to activity (24,25). However, significant heterogeneity in metrics precluded formal pooling. Using the validated EQ-5D questionnaire, Sarlos, *et al.* found a significant improvement in quality of life with robotic relative to laparoscopic technique, but all other patient experience outcomes reported by individual studies showed no statistically significant differences (Table S.1).

Finally, we executed further secondary analyses to eliminate heterogeneity, and sensitivity analyses excluding Martínez-Maestre, *et al.*, the only study labeled as high-risk in random sequence generation because of the quasi-randomized technique used (23). None of these analyses differed meaningfully from the results above (Figures S.1–2).

DISCUSSION

Overall, in meta-analysis of four randomized or quasi-randomized trials including 326 total participants, we found no statistically significant or clinically meaningful difference between the robotic and laparoscopic approaches to hysterectomy for benign disease. In meta-analysis, we observed similar pooled rates of perioperative complications between the two approaches, whether considered collectively, or stratified and analyzed separately at different levels of severity. While we sought to analyze seven different secondary outcomes, three (cost, pain, and quality of life) were inconsistently reported, precluding formal pooling for meta-analysis. Significant heterogeneity of pooled results from the other four outcomes hampered our ability to make generalizable inferences, but we found no meaningful and significant differences between laparoscopic and robotic approaches for these secondary outcomes. As evidence grows for comparability on hard clinical outcomes, the literature would benefit from future randomized trials focusing on standardized patient experience measures amenable to pooling.

The strengths of our study include our strict inclusion criteria and our detailed analysis of complications by level of severity. We limited our review to randomized and quasi-randomized trials, excluding observational studies from meta-analysis. We feel that the rigor of randomized controlled trials is acutely relevant for evaluating a new surgical approach for an indicated, but ultimately elective surgical procedure. Indeed, selection bias is a concern in observational literature, particularly as providers still gaining experience and comfort with the technology may be inclined to trial their skills on simpler cases or healthier patients (26). In addition, the promotion of robotics in direct-to-consumer marketing and advertisement likely exacerbates the risk of a range of biases related to patient preference and expectations (27). We limited our analysis to patients with benign, as opposed to malignant, indications for hysterectomy. We feel that differences in patient populations and surgical complexity make these distinct entities with *a priori* differences in the likelihood of benefit from robotic technique (11,13). Vaginal approach was excluded as a comparator due to consistent prior evidence of superiority on outcomes and cost (5,7,28). Another strength was our use of a modified Expanded Accordion Severity Grading System that allowed us to consider and analyze intraoperative and postoperative complications collectively and consistently across the four studies (Table 3) (19). Finally, the inclusion of two recently published randomized

trials that have not been included in any prior systematic reviews and meta-analysis offers new insight into the comparison of robotic and laparoscopic approaches for benign hysterectomy (22,23).

Our study is limited by the relatively small number of published randomized trials (four with a total of 326 women randomized). This increases risk of type II error, that we did not find a significant difference between robotic and laparoscopic hysterectomy when a true difference might exist due to small sample size (6). By pooling the results of 4 separate studies, we add insight to individual trial results, however we echo ACOG's opinion of need for more rigorous experimental studies of robotic surgery (6). As with any surgical trial, variability in surgeon skill somewhat limits the generalizability of the evidence. Additionally, none of the 4 examined trials were powered to examine the impact of indication for hysterectomy, uterine weight, body mass index, or blood loss on the outcomes observed with the robotic and laparoscopic techniques, and data were not reported in a way that permitted subgrouping by these factors in meta-analysis. In a prior meta-analysis comparing robotic versus laparoscopic technique for malignant disease, O'Neill, *et al.* parsed out results according to procedure complexity (total hysterectomy versus total hysterectomy with lymph node dissection) and demonstrated that robotic technique was advantageous in cases requiring node staging, perhaps indicating added value of in cases with greater surgical complexity (11). A larger, multi-centered surgical trial could better account for variability in outcomes between surgeons and different patient subgroups.

Heterogeneity of findings may also be influenced by differences in practice patterns and patient expectations across the four different countries represented. In particular, cost data, available only from a Swedish study, is not generalizable, and length of stay standards vary by country, with hospital specific protocols, medical training, insurance coverage, and cultural and societal values all playing a role in discharge timing (29). This measure is additionally limited in our analyses by a lack of granularity in measurement, as all included trials collected length of stay in whole number days, rather than hours, which would allow for more robust and meaningful comparisons. Finally, we are limited by methodological concerns related to blinding common across the included studies. Because blinding of operating room personnel was not possible, some outcomes under study may have been influenced by the surgeon's behavior (30).

The results of prior systematic reviews of robotic hysterectomy for benign disease, which include mostly observational studies, have found that the robotic technique demonstrates some improvements relative to open surgery, but mixed or comparable results relative to laparoscopic technique (9–14). Our pooled analysis of experimental studies is in general agreement with the observational literature, demonstrating no clear significant improvements in outcomes for robotic compared with laparoscopic hysterectomy.

In the decade since its introduction, robotic surgery has generated enormous public excitement and achieved impressive market penetration. With increasing pressure to contain costs moving into the future, the cost/benefit ratio for this tool will come under increased scrutiny. With the available evidence, it remains unclear if the theorized benefits of the robotic approach can be demonstrated in clinical practice. Our understanding of the role of

robotics in benign gynecology is still evolving and will require additional and more targeted research to clearly delineate advantages of this technique in the well-selected patient population.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
PRISMA Study Selection Flow Diagram.

*Cochrane Library includes the following databases:

- CENTRAL=Cochrane Central Register of Controlled Trials
- CDSR=Cochrane Database of Systematic Reviews
- DARE=Database of Abstracts of Review of Effects
- Health Technology Assessment Database
- NHS Economic Evaluation Database

Figure 2. Methodological quality assessment of included studies: **(A)** study summary, and **(B)** risk of bias graph

Figure 3.

Forest plots and pooled risk ratio for perioperative complications following robotic versus laparoscopic hysterectomy, stratified according to the modified Expanded Accordion Severity Classification System: **(A)** mild/moderate (Classes 1 and 2) complications, **(B)** severe (Classes 3 and 4) complications.

Figure 4.

Forest plots and weighted or standard mean differences of robotic versus laparoscopic hysterectomy for primary analyses of **(A)** length of hospital stay (in days), **(B)** total operating time (skin-to-skin, in minutes), and **(C)** blood loss (Estimated Blood Loss, in mL; Decrease in Hemoglobin, in %).

Table 1

Operative and procedural characteristics of included studies evaluating robotic versus laparoscopic hysterectomy for benign disease.

Study, Year Country	Number of Included Surgeons	Minimum Case Experience		Number of Ports		Length of Follow Up	Post-Discharge Complications?
		R	L	R	L		
Sarlos, 2012 Switzerland	2	30	~500	4	4	6–8 weeks	Assessment unclear, none reported
Paraíso, 2013 USA	5	20	75	5	4	6 months	Assessment unclear, none reported
Martínez-Maestre, 2014 Spain	1 team	NR	NR	NR	NR	1 month	Assessed, none reported
Lönnfors, 2015 Sweden	6	49	NR	4	4	4 months	Yes

R= robotic; L= laparoscopic; NR= not reported

Table 2

Baseline characteristics of patients from included studies evaluating robotic versus laparoscopic hysterectomy for benign disease.

Study, Year Country	Study arm	N	Age* (Years)	BMI* (Kg/m ²)	Parity [†] (Count)	Prior abdominal surgery [‡] (%)	Uterine weight* (Grams)
Sarlos, 2012 Switzerland	Robotic	47	46.3 ± 4.2	25.7 ± 5.0	2	89.6%	254.5 ± 147.3
	Laparoscopic	48	45.8 ± 6.0	26.0 ± 5.3	2	74.5%	247 ± 190.0
Paraiso, 2013 USA	Robotic	26	43.8 ± 7.0	29.9 ± 7.4	2	52.0%	293.9 ± 299.9
	Laparoscopic	26	45.6 ± 5.1	31.4 ± 7.5	2	40.0%	282.9 ± 214.7
Martínez-Maestre, 2014 Spain	Robotic	51	46.6 ± 9.5	28.8 ± 4.2	2	NR	157.1 ± 74.5
	Laparoscopic	54	50.0 ± 9.9	28.4 ± 5.1	2	NR	183.9 ± 112.9
Lönnfors, 2015 Sweden	Robotic	38	47.0 ± 8.7	26.6 ± 4.9	2	63.2%	301.0 ± 208.0 [§]
	Laparoscopic	36	46.4 ± 6.9	26.0 ± 5.7	2	55.6%	198.0 ± 144.0

N = number of patients in study arm; BMI = body mass index; NR = not reported

* Mean ± standard deviation

[†] Median count

[‡] Percent of patients in that study arm

[§] Statistically significant difference between study arms

Table 3

Modified Expanded Accordion Severity Classification system class definitions and counts of perioperative complications reported by included studies, by study arm.

Class	Class Definition	Complication Type	Robotic (n)	Laparoscopic (n)
Class 1	Mild: Minor procedures at bedside (i.e. intravenous lines, urinary catheters) or drugs including antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy	Partial intestinal obstruction	1	-
Class 2	Moderate: Drugs other than those listed for class 1, including antibiotics, also blood transfusions and total parental nutrition	Wound infection requiring antibiotics	-	1
		Intraoperative or postoperative blood transfusion	2	2
		Vaginal cuff hematoma treated conservatively with antibiotics	3	6
Class 3	Severe: Invasive procedure without general anesthesia	Periumbilical hematoma drained under local anesthesia	1	-
Class 4	Severe: Operation under general anesthesia or unplanned alteration to surgical technique requiring additional time,	Robotic problem requiring conversion to laparoscopy or vaginal suturing	8	-
		Conversion to laparotomy	-	3
		Intraoperative visceral or vascular injury	2	4
		Vaginal cuff hematoma or bleeding requiring reoperation	2	1
		Vaginal cuff dehiscence with reoperation	-	2
		Suspected peritonitis treated with diagnostic laparoscopy	1	-
Class 5	Severe: Organ system failure	-	-	-
Class 6	Death	-	-	-
ARM TOTALS			20	21

n=total count of respective complication across four included studies, by arm