Published in final edited form as:

Int J Gynaecol Obstet. 2017 January ; 136(1): 64–69. doi:10.1002/ijgo.12001.

Randomized controlled trial comparing operative times between standard and robot-assisted laparoscopic hysterectomy ☆

Timothy A. Deimling^{a,*}, Jennifer L. Eldridge^a, Kristin A. Riley^a, Allen R. Kunselman^b, and Gerald J. Harkins^a

^aDepartment of Obstetrics and Gynecology, Division of Minimally Invasive GYN Surgery, Milton S Hershey Medical Center, Penn State University, Hershey, PA, USA.

^bDepartment of Public Health Sciences, Division of Biostatistics and Bioinformatics, Milton S Hershey Medical Center, Penn State University, Hershey, PA, USA.

Abstract

Objective—To compare the operative time between robot-assisted laparoscopic hysterectomies and standard laparoscopic hysterectomies.

Methods—A prospective, randomized controlled trial enrolled women aged 18–80 years attending Penn State Hershey Medical Center between April 23 and October 20, 2014 to undergo hysterectomy. Participants were randomized using a random number generator to undergo either robot-assisted or standard laparoscopic hysterectomy. The primary outcome was the total operative time (surgeon incision to surgeon stop, including robot docking time, if applicable). Intention-to-treat analyses were performed and the operative time was compared between the two treatments for non-inferiority, defined as a difference in operative time of no longer than 15 minutes.

Results—There were 72 patients randomized to each treatment arm. The mean operative time was 73.9 minutes (median 67.0 minutes; interquartile range 59.0–83.0 minutes) in the robot-assisted hysterectomy group and 74.9 minutes (median 65.5 minutes; interquartile range 57.0–90.5 minutes) in the standard laparoscopic hysterectomy group. The upper bound of the 95% confidence interval of the difference in operative time was 6.6 minutes, below the 15-minute measure of non-inferiority.

☆The data contained within this manuscript were presented at the AAGL 2015 Global Congress; November 15–19, 2015; Las Vegas, NV, USA.

*Corresponding author: Timothy A. Deimling, Mail Code H103, 500 University Dr, Hershey, PA 17033, USA. Tel.: +1 717 531 6447; fax: +1 717 531 0920. tdeimling@hmc.psu.edu.

[ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02118974): NCT02118974

Author contributions

T.A.D. contributed to the study design, obtaining institutional review board approval, data collection and analysis, and manuscript writing and review. J.L.E. contributed to the data collection and analysis, and manuscript writing and review. K.A.R. contributed to the study design, data collection and manuscript writing and review. A.R.K. contributed to the study design, data analysis, and manuscript writing and review. G.J.H. contributed to the study design, and manuscript writing and review.

Conflict of interest

G.J.H. was a proctor for Ethicon and Intuitive Surgical during the study period. A.R.K. owns stock in Merck. The authors have no other conflicts of interest.

Conclusion—When performed by a surgeon experienced in both techniques, the operative time for robot-assisted laparoscopic hysterectomy was non-inferior to that achieved with standard laparoscopic hysterectomy.

Synopsis

The operative time of robot-assisted laparoscopic hysterectomy was non-inferior to that of standard laparoscopic hysterectomy.

Keywords

Hysterectomy; Laparoscopic; Minimally invasive; Operative time; Robotic-assisted

1. Introduction

The American College of Obstetricians and Gynecologists (ACOG) Committee on Gynecologic Practice has indicated that laparoscopic hysterectomy is an alternative to abdominal hysterectomy for patients for whom vaginal hysterectomy is not indicated or feasible [1]. The ACOG Committee on Gynecologic Practice has cited multiple advantages of laparoscopic hysterectomy over abdominal hysterectomy, including faster recovery, shorter hospital stays, lower blood loss, and fewer abdominal wall/wound infections. Despite the recommendations of ACOG, 66% of all hysterectomies are performed abdominally [1]. Among the key reasons for the lag in the utilization of laparoscopic techniques are the technical obstacles of performing minimally invasive hysterectomies [2, 3].

Robotic technology has emerged as an additional tool available to gynecologic surgeons; however, a review of current literature reveals few randomized trials evaluating the efficacy of standard laparoscopic hysterectomy compared with robot-assisted laparoscopic hysterectomy [4, 5]. This is particularly true when comparing robot-assisted and standard laparoscopic approaches that are performed by surgeons with high case volumes for both techniques [6]. ACOG Committee Opinion No. 628 [6] indicated that the rapid adoption of robotic technology for gynecologic surgery has not been supported by high-quality studies performed in patients and identifies a need for quality prospective randomized trials comparing robot-assisted and standard laparoscopic techniques.

The aim of the present study was to compare the operative time of hysterectomy procedures performed using robot-assisted and standard laparoscopic techniques [7]. It was hypothesized that robot-assisted laparoscopic hysterectomy would prove non-inferior to standard laparoscopic hysterectomy with respect to operative time. Conducive to such a study design, the present study was performed at a high-volume practice, with more than 600 minimally invasive procedures performed annually that are distributed between both robot-assisted and standard laparoscopic techniques.

2. Materials and methods

The present study was a prospective, randomized non-inferiority trial that enrolled patients from the Penn State Hershey Medical Center Minimally Invasive Gynecologic Surgery

Division, Pennsylvania, USA, between April 23 and October 20, 2014. Eligible patients included all patients scheduled to undergo hysterectomy at the study institution aged 18–80 years who were able to give informed consent in English. Patients with medical conditions contraindicating pneumoperitoneum or proper ventilation during anesthesia, who were pregnant, who had a pelvic organ prolapse allowing for a vaginal approach, or who were anticipated to undergo combined surgical procedures (other than coincidental appendectomy) were excluded from the study. All participants provided written informed consent at enrollment and the Penn State Hershey Medical Center Institutional Review Board approved the study design.

On the morning of surgery, participants were randomized by the study statistician (A.R.K.), who had no prior access to patient data, to undergo either robot-assisted or standard laparoscopic hysterectomy; randomization was performed using a random number generator and treatment allocations were sealed in opaque envelopes. The envelopes were numbered consecutively and were given to participants in sequential order on the day of surgery. Envelopes were opened to reveal each patient's treatment allocation by the surgical team on the day of surgery after concluding the preceding surgical procedure. For the present study, dual surgical procedure carts were prepared with appropriate equipment for each potential treatment allocation. Participants and study investigators were unmasked to group assignments.

A single surgeon (G.J.H.) performed all hysterectomies according to standard protocols at the study institution (unpublished) with the assistance of residents and/or fellows who were assigned based on clinical duties without exception. Residents who assisted with procedures were primarily in their third year of training and all fellows were completing fellowships in minimally invasive gynecologic surgery. The primary surgeon had a high-volume surgical case load (greater than 300 total hysterectomies each year) that included both standard laparoscopic and robot-assisted laparoscopic techniques.

Hysterectomies were performed by the primary surgeon and primary assistant (described above), with each completing half of the procedure. At the study institution, the primary assistant would routinely be allowed to perform colpotomy and vaginal-cuff closure. An additional assistant, typically a junior-level resident, would apply temporary pressure to a vaginal sponge stick in the anterior cervico-vaginal junction during the creation of the colpotomy. During robot-assisted hysterectomies, the primary surgeon and the primary assistant would each perform half of the procedure at the robotic console and the bedside assistant was a junior-level resident.

All procedures were completed using the assigned approach including vaginal-cuff closure. Vaginal-cuff closure was completed using a single barbed suture and a running, non-locked two-layer closure. The same suture and technique was used for robot-assisted and standard laparoscopic procedures. Standard laparoscopic hysterectomies were performed using three 11-mm trocars, placed through the umbilicus, and the right and left lower quadrants of the abdomen. Robot-assisted laparoscopic hysterectomies were performed with three 8-mm robotic trocars placed at the same locations as in standard laparoscopic hysterectomy plus one additional accessory trocar in the left upper quadrant. A harmonic scalpel (Harmonic

Synergy; Ethicon, Somerville, NJ, USA) was used as the primary energy source for both robot-assisted and standard laparoscopic hysterectomies and a vaginal sponge stick was used during creation of the colpotomy. No uterine manipulators were used during the procedures; uterine manipulation was performed abdominally with the use of a laparoscopic single-tooth tenaculum. Bilateral salpingectomy and cystoscopy were routinely performed. Appendectomy was completed if indicated, and the operating time was not adjusted for appendectomy.

Baseline demographic data, including age, past medical and surgical history, gravidity, parity, menopausal status, body mass index, smoking status, and previous cesarean delivery were collected for all participants. Study participants were evaluated in the office at both 3 weeks and 8 weeks post-operatively. Participants underwent evaluation of their vaginal cuff via speculum examination 8 weeks after surgery. Additional phone calls and office visits were monitored up to 12 weeks after surgery. The incidence of adverse events was tracked for 12 weeks and the total number and number within sub-categories were recorded. The categories included infection, bleeding, vaginal-cuff dehiscence, and readmission.

The primary outcome of the study was operating time, and robot-assisted laparoscopic hysterectomy and standard laparoscopic hysterectomy were compared for non-inferiority. A margin of 15 minutes was considered to indicate non-inferiority in operating time; that is, if the operating time for the robot-assisted hysterectomy was faster, or no longer than 15 minutes slower than for standard laparoscopic hysterectomy, then robot-assisted laparoscopic hysterectomy would be considered non-inferior. The operating time was defined as the duration between first incision and surgeon stop time (skin closure); for robot-assisted hysterectomy, robot docking and un-docking time was included. The secondary outcomes included intra- and post-operative variables; the intra-operative outcomes recorded included estimated blood loss, additional procedures performed, and adverse events. Post-operative outcomes included post-operative pain at 2 hours (measured using a 10-point numeric analog scale), length of stay (hours), uterine weight, and adverse events.

Based on a data gathered previously at the study institution (unpublished data), mean operating times of 98.3 ± 40.2 minutes and 90.1 ± 25.9 minutes were assumed for standard laparoscopic and robot-assisted laparoscopic hysterectomy surgery, respectively. A sample size of 128 patients (64 per arm) would provide 81% power to detect non-inferiority using a one-sided test with a significance level of 0.025. For this power calculation, the margin of equivalence was 15 minutes, the difference between the mean operating times was assumed to be 0, and the standard deviation was expected to be 30 minutes. A drop-out rate of 10% was anticipated; therefore, the target sample size was 144 patients.

Intention-to-treat analyses were performed. Categorical variables were reported as absolute numbers and percentages; continuous variables were reported as mean $\pm$ SD if the data were normally distributed or as the median and interquartile range [IQR] if the data were not normally distributed. Non-inferiority of operating times was determined using a nonparametric, one-sided, bootstrapped bias-corrected, and accelerated 95% confidence interval (CI) [8] of the difference in mean operative time from 10 000 bootstrapped samples. As sensitivity analyses, one-sided, bootstrapped 95% CIs of the difference in median

operative times were also performed. For secondary continuous variables that had skewed distributions, quantile regressions [9] were used to compare the medians of the two surgical groups. Log-binomial regression [10] was used to compare secondary binary variables between the two surgical groups to obtain risk ratios, 95% CIs, and *P* values. Owing to the present study being prospective, the log-binomial model facilitated estimating the risk ratio rather than the odds ratio, which is estimated using ordinary logistic regression. In the event of zero cell counts, where log-binomial regression fails to provide an accurate estimate, logistic regression using the profile penalized likelihood [11] was used to obtain an odds ratio, 95% CI, and *P* value. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC, USA) and graphics were constructed using R version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria). $P < 0.025$ was considered statistically significant.

3. Results

There were 72 patients randomized to each arm; all patients received the assigned treatment except for one patient who was randomized to the standard laparoscopy group. This patient had severe adhesive disease and did not receive a hysterectomy, but instead underwent laparoscopic lysis of adhesions and the hysterectomy was aborted (Figure 1).

The two surgical groups were very similar with respect to baseline patient characteristics (Table 1); the biggest discrepancy appeared to be with respect to a history of cesarean delivery (17 [24%] patients in the robot-assisted group and 32 [44%] in the standard group). However, as a randomized trial any baseline differences were due to chance and, consequently, the primary analysis did not include any baseline characteristics as covariates [12].

The mean operative time among patients in the robot-assisted group was 73.9 minutes (median 67.0 minutes [IQR 59.0–83.0 minutes]) compared with 74.9 minutes (median 65.5 minutes [IQR 57.0–90.5 minutes]) in the standard laparoscopic group (Figure 2). The nonparametric, one-sided, bootstrapped bias-corrected, and accelerated 95% CI of the difference in mean operative time was 6.6 minutes ($P < 0.001$). The upper bound of this 95% CI was smaller than the specified non-inferiority margin of 15 minutes, indicating non-inferiority. As a sensitivity analysis, a one-sided, bootstrapped 95% CI of the difference in median operative time yielded a similar 95% CI of 6.0 minutes.

Post-operative follow-up data were included for all 144 enrolled patients (Table 2). A statistically significant increase in the resection of endometriosis lesions performed at the time of hysterectomy was recorded in the robot-assisted laparoscopy group ($P = 0.006$). All other intra-operative outcomes were similar between both groups, including non-significant numerically increased incidences of estimated intra-operative blood loss at least 50 mL ($P = 0.049$) and lysis of adhesions ($P = 0.056$). There was one intra-operative adverse event (a ureteric transection) recorded in the robot-assisted laparoscopy group; this was identified intra-operatively and was repaired robotically, with the repair time included in the operative time for this patient. There were no major intra-operative adverse effects recorded in the standard laparoscopy group. Post-operative adverse events were recorded in 3 (4%) patients

in the robot-assisted laparoscopic group and 6 (8%) patients in the standard laparoscopic group; this difference was not statistically significant ($P=0.313$). A numerically lower incidence of post-operative vaginal bleeding was observed in the robot-assisted laparoscopic group but this was not statistically significant (Table 2).

The study outcomes were re-analyzed to include an adjustment for a history of cesarean delivery; this did not affect the primary outcome and the bootstrapped 95% CI of the mean difference in operative time was 7.4 minutes. The secondary outcomes were also re-analyzed to adjust for history of cesarean delivery, the incidence of intra-operative resection of endometriosis was higher in the robot-assisted laparoscopic group ($P=0.005$), with no other significant differences recorded between the two groups ($P<0.05$).

4. Discussion

Robotic-assisted laparoscopic surgery is still in the early stages of adoption and high-level evidence regarding its utility is needed [13]. In the present study, it was observed that in the hands of high volume surgeons with expertise in both robot-assisted and standard laparoscopic surgery, robot-assisted surgery was non-inferior to standard laparoscopic techniques with respect to hysterectomy operative time. This has not been reported in previous studies [14, 15]. It is suggested here that the similarity in operative times between the two groups was most likely secondary to decreased time sewing the vaginal cuff. In a high-volume practice, the time necessary to dock and undock the robot would be expected to decrease as experience increases, and the time needed for docking is negated by the ease of sewing with wristed instruments. Additionally, similar to previous reports [13, 16], the present study found that adverse-event rates and short-term outcomes were similar between the two surgical approaches.

Previous studies have primarily been case series [17] or retrospective chart reviews [18] that have reported similar outcomes but differences in operative times. A literature search retrieved two prospective randomized trials. Paraiso et al. [19] reported a 72-minute increase in operative time in patients who underwent robot-assisted surgery, and Sarlos et al. [20] conducted a prospective randomized trial including 100 participants, reporting a 31-minute increase in operative time for robot-assisted hysterectomies. In these studies [19, 20], surgeons were required to have completed 20 or 30 robot-assisted hysterectomies, respectively. Based on the findings of the present study, it is suggested that to adequately compare robot-assisted and standard laparoscopy, surgeons should have substantial expertise with both techniques.

The strengths of the present study include the randomized prospective design and the participation of a surgeon with significant expertise in both robot-assisted and standard laparoscopic techniques. The significant expertise of the entire surgical team in both techniques allowed patients to be randomized on the morning of surgery, decreasing bias without impacting patient care. The standard approach to hysterectomy at the study institution using the harmonic scalpel and manipulating the uterus abdominally, independent of the type of hysterectomy performed, maximized the efficiency of the surgical team, likely contributing to the low operative times recorded in both arms of the study. Within the study

institution, residents and fellows are included when performing surgical procedures and they routinely complete 50% of a procedure or more; this could be the case in other academic centers and high-volume practices. However, a weakness of this study was that the findings could be inapplicable to all practices. As a high-volume referral center, the study institution could have a surgical procedure volume that is unrealistic across all practices. Additionally, the apparent discrepancy in patients having a history of cesarean delivery between the two groups is acknowledged, despite participants being randomly assigned. However, the post-hoc analyses demonstrated that, when adjusted for the difference in cesarean-delivery history, similar findings were recorded.

Another consideration when deciding between robot-assisted and standard laparoscopic techniques is cost. The present study was not powered to assess cost differences between the techniques. Further, the question of cost depends on perspective and whether costs are defined as reimbursement, equipment (disposable versus reusable), or total healthcare expenditure. At the study institution, robot-assisted hysterectomy has a \$700 higher supply cost when compared with standard laparoscopic hysterectomy. Current efforts are focused on modifying techniques to reduce this difference; however, further studies designed specifically to address this question are needed.

The ACOG committee opinion on robotic surgery in gynecology [6] recognized a need for quality prospective randomized comparative trials comparing robot-assisted and standard laparoscopic techniques; the present study represents a good start. As robot-assisted technology continues to advance and its utilization continues to increase, further studies are needed in this area.

Acknowledgments

The study was supported in part through The Penn State Clinical and Translational Research Institute, Pennsylvania State University CTSA, NIH/NCATS Grant Number UL1 TR000127. The authors would like to acknowledge Lawrie Romberger, Pam Keller, and Lynne Stipe for their contributions to the project.

References

1. ACOG Committee Opinion No. 444: choosing the route of hysterectomy for benign disease. *Obstet Gynecol.* 2009; 114(5):1156–1158. [PubMed: 20168127]
2. Orady M, Aslanova R, Fidela Paraiso M. Minimally invasive hysterectomy for benign indications. *Minerva Ginecol.* 2014; 66(1):13–21. [PubMed: 24569401]
3. Liu H, Lawrie TA, Lu D, Song H, Wang L, Shi G. Robot-assisted surgery in gynaecology. *Cochrane Database Syst Rev.* 2014; (12):CD011422. [PubMed: 25493418]
4. Advincula AP. Surgical techniques: robot-assisted laparoscopic hysterectomy with the da Vinci surgical system. *Int J Med Robot.* 2006; 2(4):305–311. [PubMed: 17520648]
5. Dubeshter B, Angel C, Toy E, Thomas S, Glantz JC. Current Role of Robotic Hysterectomy. *J Gynecol Surg.* 2013; 29(4):174–178. [PubMed: 24761131]
6. Committee opinion no. 628: robotic surgery in gynecology. *Obstet Gynecol.* 2015; 125(3):760–767. [PubMed: 25730256]
7. Catanzarite T, Saha S, Pilecki MA, Kim JY, Milad M. The effect of operative time on perioperative morbidity after laparoscopic hysterectomy. *Obstet Gynecol.* 2014; 123:123S.
8. Efron B. Better bootstrap confidence intervals. *Journal of the American statistical Association.* 1987; 82(397):171–185.

9. Koenker R, Bassett G Jr. Regression quantiles. *Econometrica: journal of the Econometric Society*. 1978;33–50.
10. Wacholder S. Binomial regression in GLIM: estimating risk ratios and risk differences. *Am J Epidemiol*. 1986; 123(1):174–184. [PubMed: 3509965]
11. Heinze G, Schemper M. A solution to the problem of separation in logistic regression. *Stat Med*. 2002; 21(16):2409–2419. [PubMed: 12210625]
12. de Boer MR, Waterlander WE, Kuijper LD, Steenhuis IH, Twisk JW. Testing for baseline differences in randomized controlled trials: an unhealthy research behavior that is hard to eradicate. *Int J Behav Nutr Phys Act*. 2015; 12:4. [PubMed: 25616598]
13. McGovern PG, Leitao MM Jr, Martino MA. Comparison of robotic and laparoscopic hysterectomy for benign gynecologic disease. *Obstet Gynecol*. 2014; 123(4):885.
14. Nezhat C, Lavie O, Lemyre M, Gemer O, Bhagan L, Nezhat C. Laparoscopic hysterectomy with and without a robot: Stanford experience. *JSLs*. 2009; 13(2):125–128. [PubMed: 19660202]
15. Pasic RP, Rizzo JA, Fang H, Ross S, Moore M, Gunnarsson C. Comparing robot-assisted with conventional laparoscopic hysterectomy: impact on cost and clinical outcomes. *J Minim Invasive Gynecol*. 2010; 17(6):730–738. [PubMed: 20850391]
16. Orady M, Hrynewych A, Nawfal AK, Wegienka G. Comparison of robotic-assisted hysterectomy to other minimally invasive approaches. *JSLs*. 2012; 16(4):542–548. [PubMed: 23484561]
17. Saceanu S, Cela V, Surlin V, Angelescu CM, Patrascu S, Georgescu I, et al. Hysterectomy for benign uterine pathology: comparison between robotic assisted laparoscopy, classic laparoscopy and laparotomy. *Chirurgia (Bucur)*. 2013; 108(3):346–350. [PubMed: 23790783]
18. Payne TN, Dauterive FR. A comparison of total laparoscopic hysterectomy to robotically assisted hysterectomy: surgical outcomes in a community practice. *J Minim Invasive Gynecol*. 2008; 15(3): 286–291. [PubMed: 18439499]
19. Paraiso MF, Ridgeway B, Park AJ, Jelovsek JE, Barber MD, Falcone T, et al. A randomized trial comparing conventional and robotically assisted total laparoscopic hysterectomy. *Am J Obstet Gynecol*. 2013; 208(5):368.e1–368.e7. [PubMed: 23395927]
20. Sarlos D, Kots L, Stevanovic N, von Felten S, Schär G. Robotic compared with conventional laparoscopic hysterectomy: a randomized controlled trial. *Obstet Gynecol*. 2012; 120(3):604–611. [PubMed: 22914470]

Figure 1.
Flow of study participants.

Figure 2. Operative time of patients undergoing hysterectomy. White diamond shape represents the mean operative time, the line represents the median operative time, the box represents the interquartile range, and the whiskers represent the range; outliers are included as individual data points.

Table 1Patient characteristics. ^a

Variable	Patients randomized to robot-assisted laparoscopic hysterectomy (n=72)	Patients randomized to standard laparoscopic hysterectomy (n=72)
Demographic data		
White ethnicity	63 (88)	59 (82)
Smoker	22 (31)	26 (36)
History of cesarean delivery	17 (24)	32 (44)
Prior laparotomy	3 (4)	4 (6)
Prior laparoscopy	15 (21)	20 (28)
Menopausal	8 (11)	7 (10)
Age, y	42.3±8.0	43.2±8.5
BMI	30.6±7.8	32.1±9.3
Gravidity	2.4±2.0	2.4±1.7
Parity	2.0±1.6	2.4±1.4
Diagnostic data		
Pelvic pain	17 (24)	17 (24)
Endometriosis	24 (33)	25 (35)
Abnormal uterine bleeding	29 (40)	20 (28)
Fibroids	24 (33)	29 (40)
Previous failure of ablation treatment	8 (11)	8 (11)

Abbreviation: BMI (calculated as weight in kilograms divided by the square of height in meters).

^aValues are given as number (percentage) or mean±SD.

Table 2

Secondary outcomes.^a

Outcome	Robot-assisted laparoscopic hysterectomy group (n=72)	Standard laparoscopic hysterectomy group (n=72)	Risk ratio (95% CI) ^b	Adjusted odds ratio (95% CI) ^{b, c}	Difference in medians (95% CI)	P value
Intra-operative						
Any adverse event	1 (1)	0	NA	3.04 (0.12–77.65)	NA	0.501
Cystoscopy	58 (81)	63 (88)	0.92 (0.80–1.06)	NA	NA	0.258
Estimated blood loss 50 mL	2 (3)	9 (13)	0.22 (0.05–0.99)	NA	NA	0.049
Concurrent surgery	48 (67)	49 (68)	0.98 (0.78–1.23)	NA	NA	0.859
Oophorectomy	10 (14)	7 (10)	1.43 (0.58–3.55)	NA	NA	0.442
Unilateral oophorectomy	17 (24)	22 (30)	0.77 (0.45–1.33)	NA	NA	0.351
Appendectomy	18 (25)	15 (21)	1.20 (0.66–2.19)	NA	NA	0.553
Lysis of adhesions	5 (7)	13 (18)	0.38 (0.14–1.02)	NA	NA	0.056
Resection of endometriosis	16 (22)	3 (4)	5.33 (1.62–17.51)	NA	NA	0.006
Other	6 (8)	8 (11)	0.75 (0.27–2.05)	NA	NA	0.576
Post-operative						
Any adverse event	3 (4)	6 (8)	0.50 (0.13–1.92)	NA	NA	0.313
Infection	1 (1)	1 (1)	1.00 (0.06–15.68)	NA	NA	>0.99
Bleeding	0	5 (7)	NA	0.09 (0.01–1.59)	NA	0.099
Cuff dehiscence	2 (3)	1 (1)	2.00 (0.19–21.57)	NA	NA	0.568
Re-admission	0	0	not estimable	NA	NA	NA
Other	2 (3)	0	NA	5.14 (0.24–111.34)	NA	0.297

Outcome	Robot-assisted laparoscopic hysterectomy group (n=72)	Standard laparoscopic hysterectomy group (n=72)	Risk ratio (95% CI) ^b	Adjusted odds ratio (95% CI) ^{b, c}	Difference in medians (95% CI)	P value
2-hour post-operative pain score ^d	3.0 (2.0–5.5)	4.0 (2.0–5.5)	NA	NA	–1.00 (–2.28 to 0.28)	0.123
Duration of post-surgical admission, h	22.0 (9.5–24.0)	22.0 (19.0–25.0)	NA	NA	0.00 (–2.26 to 2.26)	>0.99
Pathology						
Endometriosis	18 (25)	10 (14)	1.78 (0.88–3.57)	NA	NA	0.108
Malignant	0	0	NA	NA	NA	NA
Uterine weight, g	124.5 (87.5–175.5)	140.0 (100.0–243.0)	NA	NA	–15.00 (–56.18 to 26.18)	0.473

Abbreviations: CI, confidence interval; NA, not applicable.

^aValues are given as number (percentage) or median (interquartile range), unless indicated otherwise.

^bValues from patients randomized to standard laparoscopic hysterectomy were used as referent values.

^cOwing to zero cell counts, logistic regression using the profile penalized likelihood was used to obtain odds ratio and, 95% CI.

^d10-point numeric analog scale.