Robotic Compared With Conventional Laparoscopic Hysterectomy

A Randomized Controlled Trial

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OBJECTIVE: To compare surgical outcome and quality of life of robot-assisted laparoscopic hysterectomy with conventional laparoscopic hysterectomy.

METHODS: For this controlled clinical trial, patients with benign indications for hysterectomy were randomized to receive either a robotic (robotic group) or conventional laparoscopic hysterectomy (conventional group). The primary end point was total operating time; secondary end points were perioperative outcome, blood loss, and the change in quality of life.

RESULTS: Ninety-five patients out of 100 randomized patients completed the study. Patient age, body mass index, and uterus weight showed no significant differences between both groups. All results are given as mean (±standard deviation; median). Total operating time for the robotic group was significantly higher with 106 (±29; 103) compared with 75 (±21; 74) (conventional group) minutes. Blood loss, complications, analgesics use, and return to activity for both groups were comparable. The change in preoperative to postoperative quality-of-life index (quality of life measured on a linear scale from 0 to 100) was significantly higher in the robotic group, with 13 (±10; 13) compared with 5 (±14; 5) (conventional group).

CONCLUSION: Robot-assisted laparoscopic hysterectomy and conventional laparoscopy compare well in most surgical aspects, but the robotic procedure is associated with longer operating times. Postoperative quality-of-life index was better; however, long-term, there was no difference. However, subjective postoperative parameters such as analgesic use and return to activity showed no significant difference between both groups.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, www.clinicaltrials.gov, NCT00683293.

(Obstet Gynecol 2012;120:604–11)

DOI: http://10.1097/AOG.0b013e318265b61a

LEVEL OF EVIDENCE: I

Major improvements in endoscopic surgery in gynecology over the last 35 years have changed the management of many gynecologic procedures. Today nearly all gynecologic procedures can be performed by laparoscopy without difficulties. Even for advanced procedures like prolapse surgery, cancer surgery, or surgery for deep infiltrating endometriosis, laparoscopy has become a standard technique in many specialized centers worldwide.

The first laparoscopic hysterectomy was performed by Reich[1] more than 20 years ago in 1988. With significant improvements in optical systems, electrosurgical devices and other instruments such as uterine manipulators, laparoscopic hysterectomy became a standardized and reproducible surgical procedure. Many studies in the past have demonstrated that laparoscopic hysterectomy has lower perioperative morbidity than abdominal hysterectomy[2–5] and should therefore be considered the gold standard for all cases in which vaginal hysterectomy is not feasible or for cases in which intra-abdominal access is needed because of additional intra-abdominal pathology.

Nevertheless, abdominal hysterectomy remains the most common approach for hysterectomy in nearly all countries world wide.[6,7] An unfavorable learning curve for laparoscopic hysterectomy, higher operating room costs, and the lack of teaching programs in laparoscopic surgery could be a reason.

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Financial Disclosure

The authors did not report any potential conflicts of interest.

ISSN: 0029-7844/12

In 1998, the first robotic procedures were performed in gynecology[8,9]; these have gained more interest over the past years. Since 2005, the daVinci surgical system is the only U.S. Food and Drug Administration-approved robotic device for gynecologic surgery, and several studies have been published about robotic hysterectomy (daVinci)[9–14] demonstrating the feasibility and safety of this new procedure. Today the role of robotic hysterectomy in benign cases[12–14] remains open to discussion.

Most studies about robotic hysterectomy are retrospective with low case numbers[15,16] or are comparing robotic with abdominal hysterectomy.[17] Because operating room costs for robotic surgery are high,[18] the most important question is whether there is a benefit for the patient regarding outcome and quality of life compared with conventional laparoscopic hysterectomy.

Our objective was to compare robotic with conventional laparoscopic surgery regarding perioperative outcome and morbidity and quality of life.

MATERIALS AND METHODS

This study was conducted in the gynecologic department of the cantonal hospital Aarau, Switzerland, from 2008 to 2011 after being approved by the local ethics committee. For this randomized controlled clinical trial, a total of 100 patients with benign indications for hysterectomy were randomized to receive either a conventional laparoscopic total hysterectomy or a robot-assisted laparoscopic total hysterectomy using the daVinci surgical system. The randomization scheme was generated by using the web site www.Randomization.com (first [and original] generator, last modified: August 1, 2008, 15:02:45; www.randomization.com). All patients were recruited from our clinic and participated after informed consent was obtained. Indications were benign lesions if vaginal hysterectomy was expected to be difficult because of myomas or nulliparity and if the uterus weight was estimated to be less than 500 g.

Unfortunately, randomization could not be blinded for the patients because the robot was situated in a different building of the hospital complex. For ethical and legal reasons, it was necessary to inform the patient if she was transported to a different building to receive the robotic procedure.

Demographic and clinical data such as patient age, body mass index (calculated as weight (kg)/[height (m)]^2), parity, gravidity, and previous surgeries were collected before surgery (Table 1). Time for robot docking, total operating time, blood loss, possible complications, and weight of the uterus were recorded in the operating room. Total operating time was defined as the time from skin incision to the last skin closure suture. Robot docking time was defined as the time when the robot is brought to the operating table until the surgeon starts the operation at the console including attachment of the robot to trocars. Because in the conventional laparoscopic group there is no procedure corresponding to docking of a robot, we also analyzed net operating time, which is total operating time less docking time and equals total operating time in the conventional study arm. Intraoperative uterine weight was recorded with a digital scale. According to the protocol, we recorded all intraoperative and postoperative complications (bowel and bladder lesions, urinary tract infections, blood loss, wound infection, fever), amount of postoperative analgesics, and the total postoperative hospital stay.

Table 1. Demographic and Clinical Data of Patients for Both Groups

Patient Characteristics	Conventional Laparoscopic Group	Robotic Group
Age (y)	45.8±6 (46)	46.3±4.2 (45)
BMI (kg/m^2)	26.0±5.3 (24)	25.7±5 (24)
Gravidity	2.4±1.5 (2)	2.1±1.6 (2)
Parity	2 (0–5)	2 (0–6)
Uterus weight (g)	247±190.0 (199.5)	254.5±147.3 (222.5)
Previous surgery	35	43

BMI, body mass index.
Data are mean±standard deviation (median), mean (range) or %.

Quality of life was assessed before surgery and twice after surgery (after 2–3 and 6–8 weeks) using the validated EQ-5D questionnaire (1990 EuroQol Group; EQ-5D is a trade mark of the EuroQol Group) with overall scores between 0 and 100.[19,20] In our study, the German, Italian, Serbo-Croatian Spanish, and Turkish versions were applied. A sample of the English version of the EQ-5D questionnaire is shown in the Appendix, available online at http://links.lww.com/AOG/A312. The EQ-5D questionnaire is a descriptive system of health-related quality-of-life states consisting of five dimensions (mobility, self-care, usual activities, pain and discomfort, anxiety and depression), each of which can take one of three responses. The responses record three levels of severity (no problems or some or moderate problems or extreme problems) within a particular EQ-5D dimension. The EQ visual analog scale records the respondent's self-rated health on a vertical, visual analog scale in which the end points are labeled "best imaginable health state" (score 100) and "worst imaginable health state" (score 0). This information can be used as a quantitative measure of health outcome

(Quality of Life Index) as judged by the individual respondents.

The robotic surgery was performed with a three-armed daVinci standard surgical robot that is being used in our public teaching hospital, Kantonsspital Aarau, Aarau, Switzerland, by the urology department since 2005. We started our first robot-assisted laparoscopic procedures in 2007. Both procedures (robotic and conventional laparoscopic hysterectomy) were performed by two senior gynecologic surgeons experienced in laparoscopic surgery routinely performing an average of 50 laparoscopic total hysterectomies per year for almost 10 years. The surgeons had performed at least 30 robotic hysterectomies before begin of this study. All operations took place under general anesthesia in a lithotomy position with a Foley catheter in the bladder. All patients received perioperative antibiotic prophylaxes of 2 g intravenous cephazolin. A Clermont-Ferrand manipulator was inserted into the uterus.

The surgical team consisted of a console surgeon, a bedside assistant, and a surgical nurse standing on the left side of the patient and a second assistant sitting between the legs of the patient and—once the robot was in place—underneath the arms of the robot for manipulation of the uterus. After assistants and nurse were in position and the uterus manipulator was inserted vaginally, the robot was moved to the operating table. Then the surgeon performed the skin incisions for the trocars, which are the connections to the robot.

The optic port was 12 mm in diameter and was placed 3–5cm above the umbilicus and two robotic working ports consisting of 8-mm trocars were placed lateral to the rectus abdominis muscle and approximately 3 cm inferior to the level of the umbilicus and an additional 10-mm trocar on the left side of the umbilicus for assistance and transport of suturing material. The following robotic instruments were used: a fenestrated EndoWrist bipolar forceps on the left robotic arm and monopolar EndoWrist curved scissors on the right side.

For conventional laparoscopic hysterectomy, a 10-mm optical port and three 5-mm working trocars were used. Most of the instruments used in the conventional laparoscopic group were reusable and we used standard bipolar and monopolar devices.

Both robotic and conventional laparoscopic surgeries were performed according to the same standard operating procedure for conventional laparoscopic hysterectomy in our institution. Starting with transection of the round ligament, the broad ligament was dissected anteriorly and posteriorly. The bladder was dissected from the proximal vagina. The ascending branches of the uterine vessels were coagulated with bipolar current and transected by scissors. After transection of the ligamentum transversalis colli (Mackenrodt's ligament), colpotomy was performed using the monopolar cutting current and the uterus was extracted vaginally. Large-sized uteri were cut into extractable pieces with a knife and removed vaginally. In these cases, the robot had to be undocked and the vagina was closed vaginally. The vaginal cuff was closed by robotic suturing using five interrupted sutures with intracorporal knotting technique for all other cases. For conventional laparoscopic hysterectomy, endoscopic morcellation of large-sized uteri was performed and laparoscopic suturing was applied to close the vagina.

The primary end point of this study, the total operating time, was compared between study arms using a Wilcoxon rank-sum test (Mann-Whitney test). Assuming a difference of 15 minutes between study arms, a power of at least 80% was estimated or this comparison in advance of the trial for the anticipated trial size of 100 patients. Missing values (no operation performed on two laparoscopic hysterectomy and three robotic hysterectomy patients) were replaced by the median of available measurements in the respective study arm. As a conservative sensitivity analysis, we replaced missing values in the conventional and robotic study arm by the maximum and the minimum value measured in the respective study arm (opposite to our expectation). In addition, we used a parametric analysis of covariance to adjust the effect of surgery type for potential confounders (listed in Table 1). The analysis of covariance included 93 patients (two patients had missing covariate information).

Secondary endpoints were net operating time (robotic hysterectomy arm: total operating time less docking time, laparoscopic hysterectomy arm: total operating time), blood loss, and change in quality of life (EQ-5D, difference 6 weeks after to before the operation). The change in quality of life could be evaluated for 75 patients (as a result of noncompletion of questionnaires). Missing values were treated as for total operating time. Furthermore, baseline variables, complication rates, and postoperative analgesics were compared between study arms.

The box plots used in Figures 1 through 3 show the median and the first and third quartiles (boxes) as well as the range of data within 1.5 times the interquartile range (whiskers). All analyses were done according to the intention-to-treat principle and using the statistical software package R 2.13.1.[21]

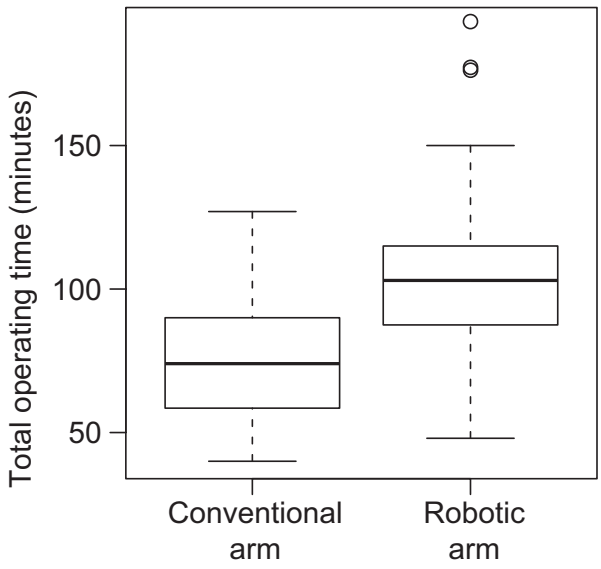

Fig. 1. Box plot comparing the operating times for conventional laparoscopic and robotic hysterectomy (related statistics are shown in Table 2).

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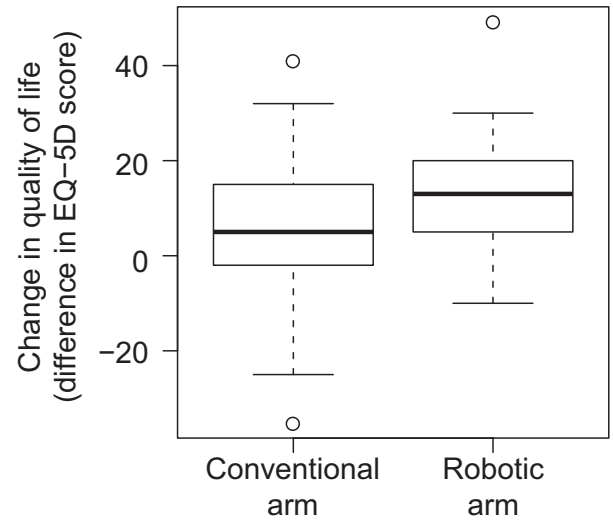

Fig. 3. Difference in the quality-of-life index before and after surgery according to the EQ-5D questionnaire (related statistics are shown in Table 2).

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RESULTS

Ninety-five out of 100 randomized patients completed the study. The demographic and clinical data for both groups are shown in Table 1. Total operating time in the robotic group with 106 (±29; 103) (laparoscopic hysterectomy) minutes was significantly ($P<.001$) higher compared with 75 (±21; 74) minutes in the conventional laparoscopic group (Table 2). Even when corrected for docking time, robotic surgery still took significantly longer (Figures 1 and 2).

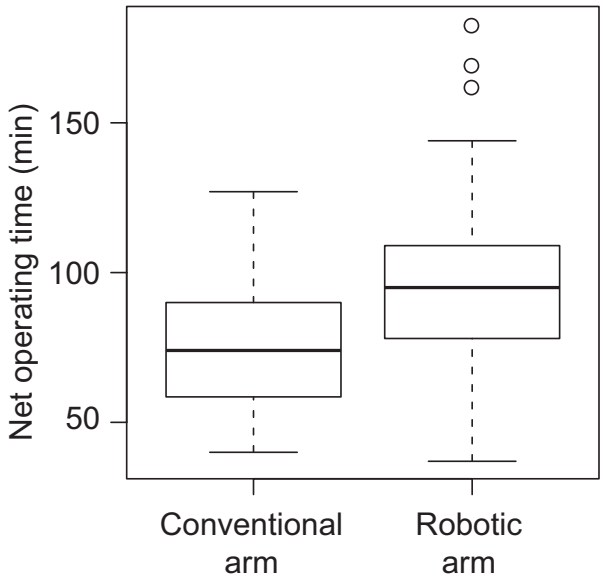

Fig. 2. Net operating time. Box plot comparing the operating times for conventional laparoscopic and robotic hysterectomy without robot docking times (related statistics are shown in Table 2).

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The median of the difference in total operating time estimated by Wilcoxon rank-sum test was 29 minutes. The sensitivity analysis and the analysis of covariance provide consistent results as does the analysis of net operating time (Table 2).

No severe intraoperative complications occurred in either group. Intraoperative and postoperative complications as well as blood loss with 87 mL (±67; 50) (robotic hysterectomy) mL, respectively, 79 (±57; 50) (laparoscopic hysterectomy) mL did not show any statistical differences for both groups and are listed in Tables 2 and 3.

There was no conversion to laparotomy in either group but one conversion to conventional laparoscopy in the robotic group. As a result of anatomical proportions, a very small woman with a short upper body and large uterus (greater than 500 g), the bulky three-armed robot could not be positioned without interfering with anesthesia instrumentation.

There were five cases in which as a result of a large uterus, the robot had to be undocked and the uterus was cut into extractable pieces with a knife and removed vaginally. In these cases, the colpotomy site was sutured through vaginal access.

Table 2. Comparison of Perioperative Outcome Variables Between the Robot-Assisted and Conventional Study Arms

End Point	Method	Conventional Laparoscopic Hysterectomy Mean	Robotic Hysterectomy Mean	Difference (95% CI)	*P*
Primary end point					
Total operating time (min)	Main analysis	75±21 (74)	106±29 (103)	29 (20–38)	<.001
	Sensitivity analysis	78±23 (75)	102±32 (100)	25 (14–35)	<.001
	ANCOVA			30 (20–40)	<.001
Secondary end points					
Net operating time* (min)	Main analysis	75±21 (74)	96±28 (95)	20 (11–29)	<.001
	Sensitivity analysis	78±23 (75)	93±32 (92.5)	16 (5–26)	.005
Blood loss (mL)	Main analysis	79±57 (50)	87±67 (50)	0 (−10 to 20)	.388
	Sensitivity analysis	87±65 (55)	86±68 (50)	0 (−20 to 20)	.933
Change in quality of life	Main analysis	5±14 (5)	13±10 (13)	8 (5–11)	<.001
	Sensitivity analysis	7±11 (20)	5±15 (5)	−7 (−14 to 0)	.094

CI, confidence interval; ANCOVA, analysis of covariance.
Data are mean±standard deviation (median) unless otherwise specified.
Mean±standard deviation (median), *P* values, and estimate of the difference are derived from Wilcoxon rank-sum tests, except for the ANCOVA on the primary end point.
* Docking time in the robot-assisted arm was 9±3.6 (8) minutes.

Another robot-associated problem resulted in a minor vascular lesion: the uterine artery was severed by an assistant pushing the uterine manipulator against the robotic scissors because the robot was blocking the view of the camera screen. The surgeon could not feel this resistance as a result of the lack of haptic feedback of the robotic system. The bleeding could be stopped immediately and surgery was continued according to standard procedure because fortunately there was no excessive bleeding (total blood loss 50 mL).

Another laparoscopic revision was performed because of an arterial slow oozing bleeder from the vaginal vessels at the colpotomy site. This was repaired by coagulation and placement of a laparoscopic suture. Also in the robotic group, one patient had to be revised as a result of an infected vaginal cuff hematoma, which was treated vaginally by draining of the colpotomy site and antibiotic therapy.

There was one more diagnostic laparoscopy performed, when a patient was readmitted for acute signs of peritonitis. However, during laparoscopy, no obvious source of infection or a bowel lesion could be established. One patient presented with an acute subileus on the first postoperative day, which was managed conservatively. Also, one periumbilical hematoma was evacuated on the first postoperative day under local anesthesia.

In one patient with severe peritoneal endometriosis, the ureter had to be dissected before coagulating the uterine artery. This dissection was extremely difficult as a result of a fibrosis around the ureter. Because microlacerations of the ureter could not be excluded, a double J stent was placed during surgery. The stent was removed after 6 weeks and no further problems occurred. For statistical analysis, it was considered as a lesion because it was handled like a ureter lesion with extensive diagnostic assessment.

There was one major vascular lesion: the external iliac vein was accidentally injured with the monopolar scissors while dissecting the anterior peritoneum of the bladder resulting in a 5-mm cut. The bleeding could be stopped immediately with a laparoscopic intracorporeal single-knot suture and surgery was continued according to the standard procedure. The postoperative Doppler examination showed no stenosis or thrombosis of the repaired vessel.

In the conventional laparoscopic group, there was one vaginal cuff dehiscence and one bleeder from the colpotomy site; both were treated by laparoscopy. Additionally, there was one wound infection of the port incision, which was treated with oral antibiotics.

With a mean weight of 255 g (±147; 223) (robotic hysterectomy) and 247 g (±190; 190) (laparoscopic hysterectomy), there were no statistical differences in uterine weights (Table 1). The overall postoperative use of analgesics is listed in Table 4 and did not show any difference between the groups. Regarding postoperative hospitalization, both groups were comparable, with 3.3 days (±0.9; 3) (robotic hysterectomy) compared with 3.1 (±1.0; 31) days for the conventional laparoscopic group.

Both groups showed similar results for return to work as well as for return to activity (Table 4).

Table 3. Comparison of Complications Between the Two Study Arms

End Point or Method	Conventional	Robot-Assisted	*P*
Specific complications			
Intraoperative			
Conversion	—	1	
Vascular lesion	1	1	
Ureter lesion	1 (possible)	—	
Requiring laparoscopic revision			
Postoperative bleeding	1	1	
Infection	—	2	
Vaginal cuff dehiscence	1	—	
Evacuation of hematoma	—	1	
Postoperative infection (conservative therapy)	1	—	
Partial intestinal obstruction	—	1	
Robot-associated problems and complications			
Preoperative			
Technical problems		3	
Intraoperative			
Conversion (see above)		1	
Vascular lesion (see above)		1	
Total		5	
Patients with more than one complication			
Intraoperative complications	7	12	.208
Postoperative complications	5	6	.759
All complications	11	15	.364

Fisher's exact test was used to compare complication rates (numbers of patients with at least one complication) between study arms.

Quality-of-life index as evaluated by the EQ-5D questionnaire showed a significantly higher change of preoperative to postoperative quality of life in the robotic group (Table 2; Fig. 3).

DISCUSSION

This is a randomized controlled trial comparing intraoperative and postoperative outcome and quality of life of robotic compared with conventional laparoscopic hysterectomy for benign indications. The total operating time in our study was significantly longer in the robotic group compared with the conventional laparoscopic group. In our institution we needed 31 minutes more (mean total operating time) to perform a robotic compared with a conventional laparoscopic hysterectomy. This finding is in line with most other papers comparing operating times between robotic and laparoscopic hysterectomy.[12,15,18,22,23]

There are mainly three variables that influence operating time for endoscopic hysterectomy: surgeons' experience, uterine weight, and other patient characteristics like adhesions or the presence of endometriosis. In our study, mean uterine weight (255 g in the robotic and 247 g in the conventional laparoscopic group) as well as body mass index and other patient-related pathologies were similar in both groups.

According to surgeons' experience, it has to be mentioned that all operations in our study were performed by two senior surgeons who were much more experienced in conventional laparoscopic surgery (approximately 500 conventional laparoscopic hysterectomies performed before starting the study) than in robotic surgery (approximately 30 robotic procedures performed before starting the study). Nevertheless, mean operating times for robotic hysterectomy of 106 minutes were quite low in our study compared with other studies[10,23,24] reporting operating times between 89 and 242 minutes.

In our study, the intraoperative outcome of most parameters like blood loss, complication rates, and conversion rates shows no differences between the two groups. It has to be mentioned that the caseload of this study might be too small to detect any differences in complications because the mean incidence is very low.

Most comparative studies,[15,24] could not demonstrate any differences in conversion rates between robotic and laparoscopic hysterectomy. Our study as well showed a very low conversion rate with no conversion in the conventional laparoscopic group and only one conversion in the robotic arm (2%). Payne and Dauterive[23] reported on higher (4% compared with 9%) conversion rates for laparoscopic hysterectomy compared with robotic hysterectomy. It has to be mentioned that a conversion rate of 9% for conventional laparoscopic hysterectomy is much higher than that reported in other large series,[22,25,26] and our own experience.[22]

Also the mean uterine weights of 255 g (robotic hysterectomy), respectively, 247 g (laparoscopic hysterectomy) in our study was quite high compared with the cited studies[10,15,23,24] that reported on uterine weights between 122 and 347 g. Only the study performed by Boggess et al[10] stated significantly higher uterine weights than all the other studies.

These findings seem to confirm that a considerable learning curve is needed to perform robotic

Table 4. Comparison of Postoperative Outcome Variables Between Study Arms

	Conventional Laparoscopic Hysterectomy	Robotic Hysterectomy	*P*
Hospitalization (d)	3.6±3.9 (3)	3.3±0.9 (3)	.153
Return to activity (d)	31.2±15.4 (29.5)	28.8±15.9 (28)	.413
Return to work (d)	38.1±15.7 (33)	35.2±14.7 (32.5)	.424
Analgesics (mg)			
Paracetamol	11,374.5±4,574.7 (11,000)	12,923.5±3,899.0 (13,000)	.182
Diclofenac	300.0±176.3 (325)	308.3±187.5 (300)	.929
Novaminsulfate	4,843.8±4,603.3 (3,500)	5,269.2±3,967.9 (5,000)	.638
Opiates	12.4±6.5 (10)	10.7±7.2 (7.5)	.195

Data are mean±standard deviation (median) unless otherwise specified.
Mean±standard deviation (median) and *P* values are from the Wilcoxon rank-sum test.

hysterectomy even for experienced laparoscopic surgeons. In our study, we could see no significant trend toward shorter operating times. However, compared with other publications,[10,23,24] operating times for both surgeons are already quite low as a result of many years of experience in laparoscopy. Therefore, there is only limited potential for improvement and operating times are more likely to correlate to other factors like uterus size and technical problems. However, even so, the approach to robotic surgery is probably much easier for laparoscopic surgeons because they just have to go through the learning curve of handling the robot. Unfortunately, surgeons experience is not cited in most studies. This may cause considerable bias, making it difficult to compare the different studies.

Postoperative hospital stay and analgesic use were similar in our study for both groups. This finding is not surprising, because both procedures are endoscopic minimally invasive procedures, therefore resulting in comparable postoperative outcomes.

Consequently, the biggest comparative analysis by Pasic et al[18] showed no difference in postoperative hospital stay between the robotic hysterectomy group and the conventional laparoscopic hysterectomy group. In a comparative study by Payne et al,[23] a shorter hospital stay in the robotic hysterectomy group of 1 compared with 1.6 days in the conventional laparoscopic group was stated. These findings have to be carefully interpreted relating to their clinical relevance. Regarding the large difference in postoperative hospital stay in this study of more than 3 days compared with most other studies[15,18,23] stating a mean hospital stay between 1 and 1.6 days, one has to consider the different hospitalization practices between the United States and Europe.

Apart from operating times, the change from preoperative to postoperative quality of life appeared to be the only other significant difference between the conventional and the robotic laparoscopic technique. These findings are remarkable because parameters such as postoperative use of analgesics, hospital stay, return to activity, and return to work were very similar in both groups. Because this is the first study comparing postoperative quality of life, it is quite difficult to give a good explanation. Because quality-of-life assessment is a very subjective parameter, this finding has to be interpreted carefully because we were not able to blind the study for the patient. These results are even more surprising because against our expectations, recruitment for the study was very slow because most patients preferred conventional laparoscopic surgery.

With this study we could demonstrate that for a standard procedure like benign hysterectomy, the use of the robot has to be questioned, because intraoperative and postoperative outcome of the patients seem to be mostly equivalent to conventional laparoscopy and operating room costs for the robotic procedure are significantly higher, approximately $2,600 U.S. (robotic hysterectomy) more according to two studies.[18,22]

Unfortunately, laparotomy is still the most frequent access for hysterectomy in most countries.[6,7] In this aspect, the use of the robot could reduce laparotomy rates in the future. Over the past few years, there seems to be more widespread acceptance of robotics compared with conventional laparoscopy,[27] although there are no conclusive data on the learning curve of robotic gynecologic surgery.[28] An increasing implementation of robotic programs could give more patients the access to minimally invasive surgery.

In our opinion, in experienced laparoscopic centers, patients with a benign pathology should preferentially be treated by conventional laparoscopic hysterectomy. As a consequence in our institution, patients with benign pathology all receive a conventional laparoscopic hysterectomy unless a patient

specifically prefers robotic hysterectomy. Robotic surgery possibly is more of an advantage in technically complicated procedures like cancer surgery or prolapse surgery in which sound surgical skills are required to perform it by conventional laparoscopy. In these cases, it might be easier to switch to robot-assisted laparoscopy.

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