



## Impact of robotics on the outcome of elderly patients with endometrial cancer



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### HIGHLIGHTS

- Robotic surgery in elderly patients with endometrial cancer decreases complication rates, blood transfusions, and hospital stay.
- No difference in 2-year disease-free survival was observed in elderly patients with endometrial cancer between open and robotic surgeries.

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### ABSTRACT

**Objective.** To evaluate the impact of introducing a robotics program on clinical outcome of elderly patients with endometrial cancer.

**Methods.** Evaluation and comparison of peri-operative morbidity and disease-free interval in 163 consecutive elderly patients ( $\geq 70$  years) with endometrial cancer undergoing staging procedure with traditional open surgery compared to robotic surgery.

**Results.** All consecutive patients  $\geq 70$  years of age with endometrial cancer who underwent robotic surgery ( $n = 113$ ) were compared with all consecutive patients  $\geq 70$  years of age ( $n = 50$ ) before the introduction of a robotic program in December 2007. Baseline patient characteristics were similar in both eras. Patients undergoing robotic surgery had longer mean operating times (244 compared with 217 minutes,  $p = 0.009$ ) but fewer minor adverse events (17% compared with 60%,  $p < 0.001$ ). The robotics cohort had less estimated mean blood loss (75 vs 334 mL,  $p < 0.0001$ ) and shorter mean hospital stay (3 vs 6 days,  $p < 0.0001$ ). There was no difference in disease-free survival ( $p = 0.61$ ) during the mean follow-up time of 2 years.

**Conclusion.** Transitioning from open surgery to a robotics program for the treatment of endometrial cancer in the elderly has significant benefits, including lower minor complication rate, less operative blood loss and shorter hospitalization without compromising 2-year disease-free survival.

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### Introduction

As life expectancy continues to rise, an increasing proportion of patients requiring treatment for malignancy are elderly, which has created new challenges for oncologists [1]. The cohort of people over the age of sixty-five accounts for almost two-thirds of new cancer cases and three-fourths of cancer related deaths [2,3]. Despite this trend, elderly patients have historically been under-represented in clinical trials [4]. This lack of participation has hampered the development of standardized treatment guidelines for the elderly based on best available evidence [5–7].

Endometrial cancer is the most common gynecologic malignancy in the western world, and parallel to the aging demographics, the incidence of endometrial cancer is increasing [8–10]. Surgical management of endometrial cancer traditionally includes comprehensive surgical staging, especially for high-risk histologies [11]. Elderly women often present with more advanced disease and higher-risk histology, and applying these complex procedures to elderly patients can be particularly challenging because these women have more medical comorbidities, and a greater potential for post-operative complications [12,13].

Although the application of minimally invasive surgical techniques has rapidly evolved, especially computer-assisted surgery using robotics, there is limited data regarding its value in the elderly population [14–16]. Since the 2005 approval of the da Vinci Surgical System for gynecologic procedures, reports comparing robotics to laparotomy have demonstrated reduced operative blood loss, lower incidence of

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postoperative complications, and faster recovery resulting in shorter hospital stay [17–24], with comparable recurrence rates and survival [19,25]. Nevertheless, technical considerations are voiced when using robotics in the elderly. Once the patient is docked to the robot, the Trendelenburg position cannot be reversed without undocking, and the respiratory and cardiovascular systems might be adversely affected by the Trendelenburg position and compromise the potential advantages of robotic surgery in the elderly.

Our study aims to evaluate how the use of robotics to complement laparoscopy is equivalent or better than the use of laparotomy for the treatment of endometrial cancer in elderly patients ( $\geq 70$  years). We compared the peri-operative morbidity and outcomes following staging procedures performed via traditional open surgery or robotic surgery.

## Materials and methods

### Patients

The institutional review board approved the study protocol and informed consent was obtained from all patients.

We included all consecutive women aged 70 years and over who underwent surgical staging for endometrial cancer since the initiation of the division of gynecologic oncology in March 2003 (Fig. 1) at a tertiary care center that serves as a teaching site for Obstetrics and Gynecology residents and Gynecologic Oncology fellows. The patients were divided into two cohorts: (1) women  $\geq 70$  years old who underwent staging procedure via laparotomy (from March 2003 to December 2007) and (2) women  $\geq 70$  years old who underwent staging procedure via robotic surgery (January 2008 to January 2013). Of note, with the initiation of the robotic program, all women found suitable to undergo surgery for the treatment of their endometrial cancer were offered robotic surgery regardless of body habitus, previous medical/surgical history, uterus size, or parity.

The primary end points were peri-operative outcomes, including complications and the length of stay. The secondary end point was disease-free survival.

### Data collection

All study variables and their categories were defined at the initiation of the robotic program, prior to any data collection. Since the introduction

of robotics in December 2007, information was collected prospectively, and a database was created for the purpose of documenting and evaluating the experience with this new minimally invasive technique. Data collection for the laparotomy era was based on data retrieval using patients' electronic medical records. The clinical research staff was extensively trained to ensure that data collection was performed systematically and uniformly, regardless of study era. Demographic and clinical data collected included age, body mass index (BMI), comorbidities, American Society of Anesthesiologists (ASA) score, and previous abdominal or pelvic surgeries. Operative data included type of procedure, conversion to open surgery, and any intraoperative complications. Operating time was recorded as total operating time defined as skin incision to skin closure. Estimated blood loss (EBL) was calculated by the difference in the total amount of suctioned fluids and irrigation fluids. Uterus size and weight were collected. For the classification of surgical complications, we used the modified Clavien-Dindo system [26]. The lengths of hospital stay and readmissions were documented. Tumor histological subtype, grade, and International Federation of Gynecology and Obstetrics (FIGO) stages (2008 classification [27]) were retrieved from the final pathological reports. Recurrence was confirmed with tissue diagnosis or imaging techniques. Recurrence-free interval was defined as the time from surgical staging to first recurrence. Patients were censored at point of last contact.

### Surgical technique

Open surgery procedures and robotic surgical procedures were performed and supervised by 3 primary surgeons (S.L., J.P., and W.H.G.) as previously described [25]. All patients received prophylactic antibiotics and thromboprophylaxis using subcutaneous heparin 5000 units and full-length lower extremities pneumatic compression stockings. Until July 2012, all patients underwent a total hysterectomy, bilateral salpingo-oophorectomy, and complete bilateral pelvic lymphadenectomy (iliac and obturator). Patients with poorly differentiated cancers, clear cell cancers, and papillary serous cancer on the preoperative endometrial biopsy also underwent a para-aortic lymphadenectomy up to the level of the gonadal vessels on the right and inferior mesenteric artery on the left and an infracolic omentectomy. Since December 2010, patients also underwent a sentinel node dissection prior to lymphadenectomy, as previously described [28].

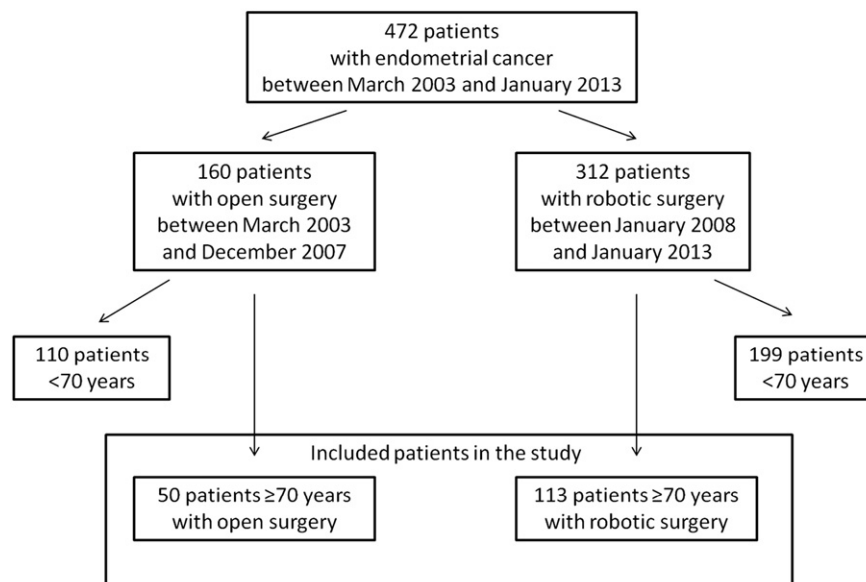


Fig. 1. Flow chart inclusion of the study.

## Statistical analysis

Descriptive parameters were expressed as mean  $\pm$  standard deviation (SD) (and median [range] when indicated). Frequencies were presented as percentages. We compared demographics and medical characteristics of patients in the open surgery cohort and robotic surgery cohort using chi-square or Fisher exact tests, as appropriate, for categorical or ordinal variables and *t*-test analysis for continuous variables. The Kaplan–Meier method was used for the survival calculations, with an event being either death (regardless of cause) or cancer recurrence. Tick marks are censored data and represent the date of tumor recurrence or the date of last news of patient. The comparison test chosen for survival between the two cohorts was the log-rank test. A *p*-value of  $<0.05$  was considered to be statistically significant.

## Results

Between March 2003 and December 2007, 160 consecutive women underwent staging for endometrial cancer via laparotomy, 50 of whom were 70 years of age or older (31%) and were included in the study. Between January 2008 and January 2013, 312 consecutive women underwent robotic staging procedure, of whom 113 patients  $\geq 70$  years old were included (36%) (Fig. 1). Demographic and clinical data are shown in Table 1. There were no significant differences between the two groups with regard to patient age, BMI, ASA score, number of comorbidities, number of medications and previous surgical history. Histological and pathologic characteristics of endometrial cancer are shown in Table 1 and did not differ significantly between the two cohorts.

Surgical data are presented in Table 2. The rate of para-aortic lymphadenectomy did not differ between the two cohorts and the mean

**Table 1**  
Patient characteristics and clinical parameters of the tumors.

Variables	Robotic cohort (n = 113)	Open surgery cohort (n = 50)	<i>p</i>
Age (mean $\pm$ SD) (in years)	77.9 $\pm$ 5.4	76.8 $\pm$ 4.6	0.21
Age (in years)			
70–74	36 (31%)	18 (36%)	0.82
75–79	38 (34%)	17 (34%)	
$\geq 80$	39 (35%)	15 (30%)	
Body mass index (kg/m <sup>2</sup> ) (mean $\pm$ SD)	29.5 $\pm$ 6.7	29.3 $\pm$ 6.6	0.87
Body mass index (kg/m <sup>2</sup> )			
Normal ( $\leq 25$ )	34 (30%)	19 (38%)	0.38
Overweight (25–29.9)	36 (32%)	10 (20%)	
Obese (30–39.9)	36 (32%)	16 (32%)	
Morbidly obese ( $\geq 40$ )	7 (6%)	5 (10%)	
ASA score			
1–2	66 (58%)	28 (56%)	0.86
$\geq 3$	47 (42%)	22 (44%)	
Smoker	12 (11%)	9 (18%)	0.21
Parity			
None	19 (17%)	5 (10%)	0.28
1–2	50 (44%)	28 (56%)	
3–4	41 (36%)	14 (28%)	
$\geq 5$	3 (3%)	3 (6%)	
No of medication (mean $\pm$ SD)	4.4 $\pm$ 2.6	4.9 $\pm$ 2.7	0.23
No of comorbidities (mean $\pm$ SD)	3.2 $\pm$ 1.6	3.6 $\pm$ 1.8	0.19
Comorbidity			
Hypertension	75 (66%)	39 (78%)	0.14
Diabetes	25 (22%)	13 (26%)	0.68
Cardiovascular	31 (27%)	15 (30%)	0.85
Cerebrovascular	7 (6%)	4 (8%)	0.73
Pulmonary disease	25 (22%)	13 (26%)	0.69
Gastrointestinal disease	21 (19%)	15 (30%)	0.15
Second malignancy	22 (19%)	7 (14%)	0.50
No. of abdominal or pelvic previous surgeries			
None	59 (52%)	20 (40%)	0.42
1	35 (31%)	17 (34%)	
2	13 (12%)	8 (16%)	
$\geq 3$	6 (5%)	5 (10%)	
Tumor stage <sup>a</sup>			
I	79 (70%)	30 (61%)	0.30
II	8 (7%)	8 (15%)	
III	23 (20%)	10 (20%)	
IV	3 (3%)	2 (4%)	
Grade			
1	30 (27%)	13 (26%)	0.97
2	30 (27%)	13 (26%)	
3	53 (46%)	24 (48%)	
Histology			
Endometrioid	79 (70%)	31 (62%)	0.43
Clear cell	4 (3%)	2 (4%)	
Serous	21 (19%)	8 (16%)	
Adenosquamous	2 (2%)	2 (4%)	
Carcinosarcoma	7 (6%)	7 (14%)	

Data are n(%) unless otherwise specified; NS: not significant; ASA: American society of Anesthesia.

<sup>a</sup> We used the 2009 surgical International Federation of Gynecology and Obstetrics classification.

**Table 2**  
Surgical procedures and intraoperative data.

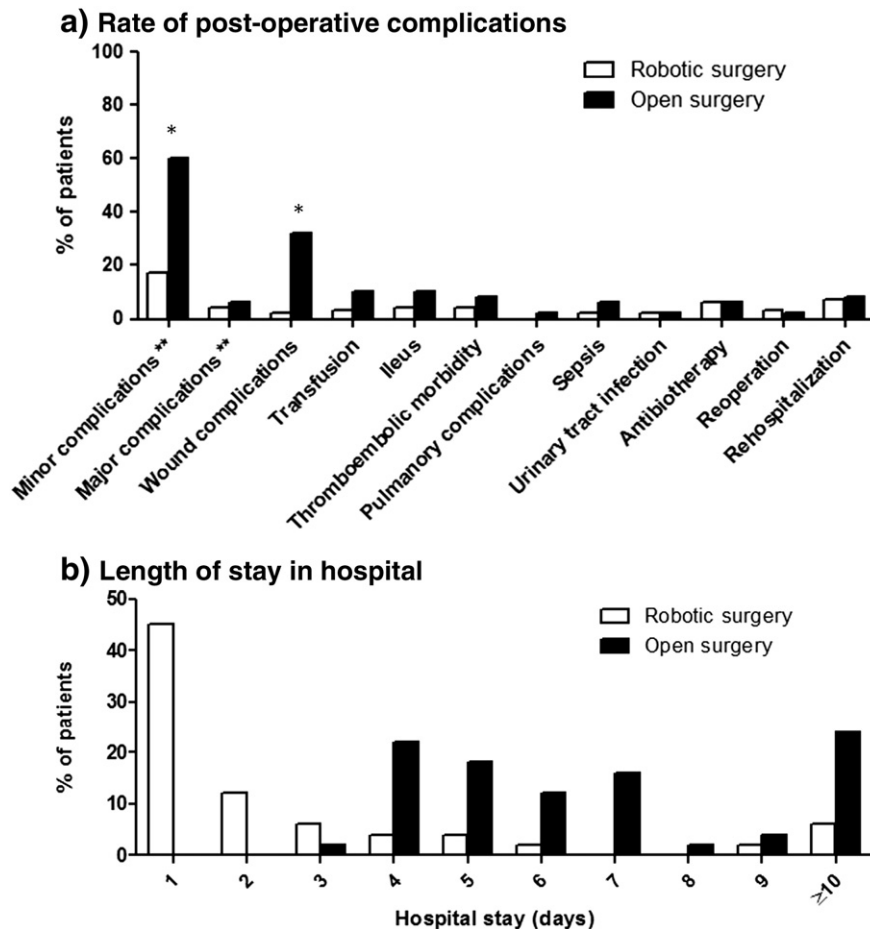
	Robotic cohort (n = 113)	Open surgery cohort (n = 50)	P
Estimated blood loss (mL)			
Mean ± SD	74.8 ± 115.7	334 ± 407.0	<b>&lt;0.0001</b>
Median [min–max]	40 [10–800]	200 [10–2500]	
Operation time (skin to skin, min)			
Mean ± SD	244.2 ± 54.6	217.7 ± 66.9	<b>0.009</b>
Median [min–max]	237 [137–440]	216 [120–431]	
No. of total lymph nodes <sup>a</sup>			
Mean ± SD	10.3 ± 5.6	9.7 ± 5.8	0.59
Median [min–max]	9 [2–33]	9 [2–27]	
No. of pelvic lymph nodes			
Mean ± SD	8.8 ± 4.1	8.4 ± 5.4	0.81
Median [min–max]	8.5 [2.0–20]	8 [2–27]	
Intra-operative complications			
Bowel injury	3 (3%)	1 (2%)	1.00
Vessel injury	0 (0%)	1 (2%)	0.30
Urinary injury	3 (3%)	3 (6%)	0.37
Uterus weight (g)			
Mean ± SD	149 ± 133	107 ± 60	<b>0.036</b>
Median [min–max]	114 [40–970]	90 [29–329]	

Data are n (%) unless otherwise specified; bold: significant value; NA: not allowed.

number of lymph node number retrieved was similar in both groups. Mean operative time was longer for the robotic cohort compared with open surgery cohort (244 vs 217 minutes). Mean blood loss was significantly higher in the open surgery cohort compared with the robotic

cohort (334 vs 75 mL). Mean uterine weight (typically greater in laparotomy cohorts) was higher in the robotic cohort (149 vs 107 g). The rate of intra-operative complications was similar between the two cohorts. We did not exclude patients with enlarged uteri and/or nulliparity in the robotic cohort, leading to a mini-laparotomy in 3 (3%) patients at the end of the robotic procedure in order to remove a large uterus, that could not be placed in a 15-cm endobag and delivered vaginally after dissection within the endobag without spillage [29].

The perioperative data showed significantly less grade I or II complications (Clavien–Dindo classification) for robotic cohort compared with open surgery cohort (17% vs 60%) mainly due to the rate of wound complications (2% vs 32%,  $p < 0.0001$ ) (Fig. 2a). The rate of grade III or IV complications was not significantly different between the two cohorts (4% for robotic cohort vs 6% for open surgery cohort). In the robotic cohort, there were 3 patients that needed reoperation. The first patient was 83 years old, had FIGO stage IIb, grade 2, endometrioid adenocarcinoma, had 5 previous laparotomies related to peritonitis, and a BMI of 38 kg/m<sup>2</sup>. She returned to the operating room on postoperative day 3 for small bowel perforation and underwent resection with primary re-anastomosis. She was discharged on post-operative day 44 in good condition. The second patient was 81 years old, had FIGO stage Ia, grade 3 endometrioid carcinoma, who presented with strangulated small bowel in a previous umbilical hernia (not in a trocar incision), and had a mini-laparotomy in the umbilical region with small resection with end-to-end anastomosis and umbilical hernia repair. The third patient was 89 years old, had FIGO stage Ib, grade 2 endometrioid adenocarcinoma, was undergoing chemotherapy for lymphoma, and developed a large retroperitoneal hematoma in the meso-sigmoid recognized in the recovery room. She required transfusion and had a laparotomy



**Fig. 2.** Post-operative outcome. (a) Rate of post-operative complications. (b) Length of stay in hospital. \* $P < 0.0001$ . Major complications are grade III or IV and minor complications are grade I or II complications of Clavien Dindo classification.

with partial sigmoidectomy and colostomy. Another patient in the robotic cohort was re-hospitalized 10 days after surgery for a pelvic abscess. She required antibiotics and monitoring in the intensive care unit for 2 days. In the open surgery cohort, no patient needed reoperation. There were no peri-operative deaths in robotic cohort, while one patient died in the open surgery cohort 27 days following surgery in the context of congestive heart failure. The odds ratio for overall complication was 0.38 with 95% confidence interval (CI) between 0.19 and 0.75 in robotic cohort, compared with the open surgery cohort ( $p = 0.007$ ).

The mean hospital stay was  $3.1 \pm 6.3$  days vs  $8.0 \pm 5.8$  days ( $p < 0.0001$ ), and the median hospital stay was 2 [1–44] vs 6 [3–32] days for the robotic cohort and open surgery cohort, respectively (Fig. 2b). The odds ratio risk of length of stay  $> 2$  days was 333 (95% CI = 20–5594) in the open surgery cohort, compared with the robotic cohort ( $p < 0.0001$ ).

In terms of adjuvant treatment, brachytherapy, pelvic teletherapy, and chemotherapy were performed in 45%, 21%, and 41% of robotic cohort patients, respectively, and in 48%, 40%, and 30% of open surgery cohort patients, respectively.

Mean follow-up time for survival patients was  $22.7 \pm 16.4$  months for the robotic cohort and  $52.0 \pm 28.4$  months for the open surgery cohort. The 2-year disease-free survival rate was 86% for the robotic cohort and 81% for the open surgery cohort ( $p = 0.61$ ) (Fig. 3).

## Discussion

Considering our aging population and the prevalence of endometrial cancer in elderly patients, it is essential to critically evaluate the most appropriate surgical approach for this growing group of patients. However, data focused specifically on experience with an elderly population in this context have remained scarce (Table 3) [14,15,30–32]. This study highlights the benefits of robotically assisted surgical staging when compared to traditional open surgery in women  $\geq 70$  years with endometrial cancer. The main benefits identified were a significant decrease in complication rates, surgical blood loss, and hospital stay. These advantages seem to outweigh the prolongation in operative time. Of note, although prolonged Trendelenburg increases the potential risk of blindness in patients suffering from moderate or high-pressure glaucoma (frequent in elderly) and could lead to complications with the development of robotic surgery [33], no ophthalmological complications occurred in the present series.

A large randomized trial comparing laparotomy to laparoscopy for the surgical management of endometrial cancer in the general population showed a 33% decrease in serious complications and a 50% reduction in hospital stay in favor of laparoscopy. Although elderly patients may particularly benefit from minimal invasive surgery, the conversion

rate from laparoscopy to laparotomy increases by 30% for each advancing decade of age [34], and the adoption of minimally invasive techniques has been slow, especially for the elderly [31,35,36]. Similar to many centers, in our academic hospital prior to the introduction of the robotics program in 2007, only 17% of patients with endometrial cancer benefitted from minimal invasive surgery using laparoscopy. In contrast, since the introduction of robotics, the number of patients receiving minimal invasive surgery has increased to over 95% [25]. This increase results from the decision in December 2007 to fully evaluate the role and value of robotic surgery, by offering this surgical approach to each operable patient unless the cancer could not be removed without spillage. The ability of the computer interface to integrate intuitive movements similar to conventional surgery and apply them to minimally invasive surgery, facilitated a quick learning curve with robotic surgery [20,37]. This is in contrast with the more complex approach required by strait stick laparoscopy that is safely performed by most surgeons in less complex surgeries or by highly skilled and talented laparoscopic surgeons in high-risk patients. As indicated in this study, and in our previous work [16,25,28], once the patient is deemed operable and has cancer that can be removed without spillage [29], irrelevant of age or BMI [38], she can safely and in a cost-efficient manner undergo the procedure robotically in the Canadian health care environment [25]. The reduction in use of laparotomy may be particularly beneficial in the more frail elderly population who are at higher risk for postoperative complications. After 2 years of follow-up, our data suggest robotic surgery in elderly patients is safe from an oncology point of view in terms of comparable rates of progression-free survival. This statement is further supported by the recent data showing similar 5-year survival of endometrial cancer patients treated by robotic surgery at the University of North Carolina [19]. The data presented in this manuscript indicate that minimal invasive surgery using the robotic platform offers elderly fragile patients a safe surgical approach with significantly fewer complications compared to open surgery.

Although patients were not randomized, the cohorts in our study represent consecutive cases. However, because of limited access to robotic surgery during the first year of its implementation (2008), 66% of all patients, irrespective of age, underwent robotics and 34% underwent laparotomy. This could have introduced a bias during this first year following the introduction of robotics. Since 2009, over 95% of all patients who underwent surgery for endometrial cancer had robotics, including all patients over the age of 70. The spans of both eras (pre- and post-robotic) captured in the study included unchanged patient accrual and information management in our McGill teaching hospital. There were no variations in catchment area or in complexity of the cases during the study period. The fact that we collected data in the post-robotic era prospectively only indicates the direction of the study inquiry in terms of time and does not suggest that the level of relevant information obtained varied between phases. An obvious potential source of bias on the recording of surgical complications was the fact that the historic patients prior to December 2007 who had open surgery appear to have their complications collated retrospectively from chart review, while those newer patients enrolled after January 2008 appear to have had their complications documented prospectively. This would have resulted in a conservative bias, as more complications would have been recorded in real time during the robotic era. During the robotic era, the introduction of sentinel node biopsy could be a potential source of bias decreasing homogeneity between open surgery era and robotic surgery era. Indeed, a negative sentinel node biopsy might have resulted in the surgeons taking a much less aggressive surgical approach. Nevertheless, lymph node counts are similar in the two eras.

We have not addressed the issue of cost of robotics in this manuscript, as this was previously published by our group [25].

Most studies define the cutoff for elderly women at the age of 70 [16, 30,39–41]. In a previous study, we determined this cutoff of 70 years of age based on the increase in incidence of cardiovascular comorbidities

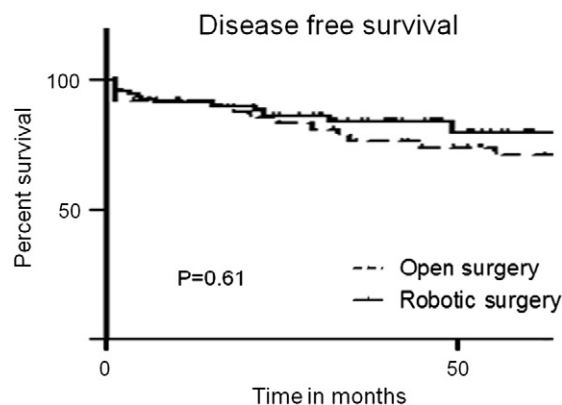


Fig. 3. Disease-free survival.



**Table 3**

Studies about surgical staging in elderly with endometrial cancer.

Study	Number of patients	Age (mean, years)	Surgical approach	Operative time (mn)	Blood loss (mL)	Nodal yield (n)	Hospital stay (days)	Transfusion rate	Overall complications rate
<b>Scribner et al. (2001)</b>	45	76	Open	148	336	29	5.8	19%	69%
	67	75	Laparoscopic	236	298	29	3.0	2%	28%
<b>Susini et al. (2005)</b>	43	74	Open	115	400	NR	8	NR	7% <sup>a</sup>
<b>Lachance et al. (2006)</b>	151	>65 <sup>b</sup>	Open	176	384	NR	8	NR	40%
<b>Moore et al. (2007)</b>	42 (staged patients)	84	Open or laparoscopic	NR	NR	NR	6.7	14%	21% <sup>c</sup>
<b>Lowe et al. (2010)</b>	27	84	Robotic	192	50	16	1	0%	0% <sup>a</sup>
<b>Present study</b>	113	78	Robotic	244	75	10	3	3%	21%
	50	77	Open	217	334	9	8	10%	66%

NR: not reported.

Table adapted from Lowe MP et al. [32].

<sup>a</sup> Only major complications.<sup>b</sup> Mean age was not reported.<sup>c</sup> Only reported transfusion and readmission rate.

found in the preoperative evaluation of our patients with endometrial cancer [16]. Defining elderly patients based on functional status using geriatric evaluation tools might be more discriminatory than age to define risks associated with surgery [42]. Meanwhile, these patients are at higher risk of suffering severe consequences from even minor complications or longer hospitalization, including disorientation, thromboembolic morbidity, and iatrogenic complications [12,13,43]. By decreasing complications and shortening length of hospital stay without affecting oncologic safety, surgery performed using the robot rather than traditional laparotomy improves the chances of a better outcome in our growing elderly populations.

## Disclosures

SL and WG have obtained travel support for proctoring robotic surgery

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## Conflict of interest

Drs. Lau and Gotlieb received partial travel support from Intuitive Surgical Inc. for proctoring robotics and presenting at meetings.

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