Robotic-assisted laparoscopic hysterectomy seems safe in women with early-stage endometrial cancer

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ABSTRACT

INTRODUCTION: Robotic surgery is increasingly used in the management of endometrial cancer; and although it is known that minimally invasive surgery reduces post-operative morbidity, the outcomes of this novel treatment should be monitored carefully. The aim of this study was to examine the incidence of complications according to the Clavien-Dindo scale after robotic-assisted laparoscopic hysterectomy (RALH) for early-stage endometrial cancer and atypical complex hyperplasia. The Clavien-Dindo scale grades the severity of complications.

METHODS: This was a retrospective, descriptive cohort study of 235 women with endometrial cancer or atypical complex hyperplasia who had RALH. Surgeries were stratified into two groups: with or without pelvic lymphadenectomy.

RESULTS: A total of 6% developed a grade 3 or higher complication with no significant difference (p = 0.24) between the groups. The overall incidence of complications was 15%, also with no significant difference between groups (p = 0.32). The most frequent complications were urinary tract infections (6%) and port site/wound infections (3%). A total of 21% of the women who had lymphadenectomy developed lymphoedema within 12 months.

CONCLUSION: The types and frequency of complications observed in this study resemble those reported in similar studies of RALH for malignant gynaecologic conditions. Health-care professionals treating and caring for women with early-stage endometrial cancer should know of the types and frequency of post-operative complications following RALH.

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Robotic surgery is increasingly being used in the management of endometrial cancer (EC) [1]. Although it is known that minimally invasive surgery reduces post-operative morbidity and patient discomfort [2], the outcomes of this novel treatment should be carefully monitored. The robotic technique has been used in Denmark in gynaecology since 2008 and at Herlev Hospital since 2009. Compared with traditional laparoscopy, robotic-assisted laparoscopic hysterectomy (RALH) has the advantage of 3D-vision, higher magnification, greater precision, a shorter learning curve and better ergonomy for surgeons. The disadvantages are lack of tactile feedback and high costs [2].

The most common gynaecological cancer in the developed world is EC with an incidence of 11-20 per 100,000 women in Europe [3]. In Denmark, the incidence has been constant over the past 20 years with approximately 750 new cases diagnosed annually [4]. The standard treatment is hysterectomy and bilateral salpingo-oophorectomy (BSO). Lymph node involvement is an important prognostic factor [5], and in Denmark cases with more than 50% myometrial invasion (MI) or high-risk histology are offered pelvic lymphadenectomy (PLA). The risk versus benefit of lymphadenectomy in women with clinical stage I EC is a constant subject of debate [6, 7]. The aim of this study was to examine the types and incidence of complications according to the Clavien-Dindo scale after RALH for early stage EC and atypical complex hyperplasia (ACH).

METHODS

This explorative retrospective descriptive study included women with EC or ACH who underwent RALH at Herlev Hospital between March 2009 and December 2012. In all cases, a four-arm da Vinci S or da Vinci Si robot (da Vinci Surgical System, Intuitive Surgical Inc, CA, USA) was used. All the women had a simple hysterectomy and BSO. PLA was performed when more than 50% MI was present or when indicated by high-risk histology. Infracolic omentectomy was performed in case of serous or clear cell carcinoma. The women received a single dose of prophylactic antibiotics at the beginning of surgery and low-molecular heparin and anti-thrombotic stockings during the hospital stay.

All post-operative complications were classified according to the Clavien-Dindo scale (Appendix) [8]. The primary outcome was the incidence of complications grade ≥ 3 according to the Clavien-Dindo scale as these complications are considered clinically significant and include severe complications [9]. The secondary outcome was the incidence of overall post-operative complications requiring treatment.

We assessed the incidence of overall complications as follows: intraoperative complications (lesions of organs), estimated blood loss > 500 ml, any infections requiring antibiotic treatment within 30 days (port site/

ORIGINAL ARTICLE

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TABLE 1

Preoperative characteristics

	HYS + BSO (N = 167)		HYS + BSO + PLA (N = 68[a])			Total (N = 235)	
	mean (SD)	n (%)	mean (SD)	n (%)	p-value	mean (SD)	n (%)
Age, yrs	67.3 (10.09)		69.7 (8.1)		0.1[d]	68 (10.2)	
Menopausal							
Premenopausal		15 (9)		2 (3)			17 (7)
Postmenopausal		152 (91)		66 (97)			218 (93)
Body mass index, kg/m²	29.5 (7.5)		26.9 (4.9)		0.01[d]	28.7 (7.0)	
Obesity class III > 40 kg/m²		19 (11)		1 (1)			20 (9)
Smoking							
Never smoked		91 (54)		33 (49)			124 (53)
Stopped smoking		44 (26)		19 (28)			63 (27)
Smoker		15 (9)		11 (16)			26 (11)
Alcohol consumption							
≤ 7 units/week		110 (66)		39 (57)			149 (63)
> 7 units/week		38 (23)		22 (32)			60 (26)
ASA score							
I		26 (16)		14 (21)			40 (17)
II		106 (63)		50 (88)			156 (66)
III		24 (14)		2 (3)			26 (11)
Cardiovascular disease[b]		95 (57)		37 (54)			132 (56)
Respiratory disease[c]		20 (12)		3 (4)			23 (10)
Diabetes type 2		26 (16)		10 (15)			36 (15)

ASA = American Society of Anesthesiologists; BSO = bilateral salpingo-oophorectomy; HYS = hysterectomy; PLA = pelvic lymphadenectomy; SD = standard deviation.
a) 16 women in this group also had infracolic omentectomy.
b) Definition: hypertension, atrial fibrillation, arteriosclerotic heart disease, heart failure. New York Heart Association Classification of Heart Failure: 1) cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc., 2) mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
c) Definition: chronic obstructive pulmonary disease, asthma, emphysema.
d) Independent sample T test.

wound-, lung-, urinary tract- or vaginal cuff infection), any circulatory events (deep vein thrombosis, pulmonary embolism), respiratory events, abdominal events (ileus), urogenital events (acute tubular necrosis) or neurological events (stroke) requiring treatment within 30 days. Hernia, vaginal cuff dehiscence and vaginal prolapse were monitored within 12 months as these complications are surgically related, but may occur later. Lymphoedema occurring within 12 months was considered separately as a disability according to the Clavien-Dindo scale (Appendix).

We reported length of stay (LOS) by calculating the day of surgery as day one and summing the number of days the women were hospitalised. Two data assessors (SH, MH) independently assessed data from hospital records to minimise bias, and an arbitrator (TT) settled any disagreements. All data were stratified according to whether lymphadenectomy was performed or not. We analysed data using descriptive statistics. Fisher's exact test was used for categorical variables and independent sample T-tests for continuous variables. The Mann-Whitney U test was used when data were not normally distributed. Binary logistic regression was used to examine the influence of the following factors on the risk of post-operative complications: cardiovascular disease and body mass index (BMI). All tests were two-sided, and $p < 0.05$ was considered statistically significant. Data were analysed using SPSS version 19.9 (Inc., Chicago, Illinois, USA).

ABBREVIATIONS

ACH = atypical complex hyperplasia
ASA = American Society of Anesthesiologists
ATN = acute tubular necrosis
BMI = body mass index
BSO = bilateral salpingo-oophorectomy
CI = confidence interval
EC = endometrial cancer
HYS = hysterectomy
LOS = length of stay
MI = myometrial invasion
OR = odds ratio
PLA = pelvic lymphadenectomy
RALH = robotic-assisted laparoscopic hysterectomy
UTI = urinary tract infection

TABLE 2

Perioperative findings and hospital course.

	HYS + BSO (N = 167)			HYS + BSO + PLA (N = 68[a])				Total (N = 235)		
	mean (SD)	median (IQR)	n (%)	mean (SD)	median (IQR)	n (%)	p-value	mean (SD)	median (IQR)	n (%)
Operative										
Intraoperative bleeding, ml	49 (58.9)			75 (59.8)			0.04[d]	57 (60.4)		
Conversion to open surgery			4 (2)			5 (7)				9 (4)
Skin to skin time, min.	106 (34.3)			165 (43.9)			< 0.001[d]	124 (45.7)		
Console time, min.	55 (16.3)			118 (38.8)			< 0.001[d]	72 (37.1)		
Lymph node count	–			25 (7.3)						
Technical breakdown with robot			1 (1)			3 (4)				4 (2)
Caused prolonged time in OR			1 (1)			2 (3)				3 (1)
Caused conversion			0			1 (1)				1(1)
Post-operative										
Diagnosis of endometrial cancer			144 (86)			67 (99)				211 (90)
Diagnosis of ACH			23 (14)			1 (1)[b]				24 (10)
Length of stay, days[c]		2.0 (1-3)			2.0 (2-3)		0.12[f]		2.0 (1-3)	
Readmission within 30 days			4 (2)			5 (7)	0.13[e]			9 (4)
Reoperation within 30 days			2 (1)			3 (4)	0.15[e]			5 (2)
Mortality within 90 days			0			0				0
Additional treatment										
Chemotherapy			4 (2)				4 (6)			8 (3)
Radiotherapy			3 (2)				0			3 (1)
Radiotherapy & chemotherapy			1 (1)				0			1 (< 1)

ACH = atypical complex hyperplasia; BSO = bilateral salpingo-oophorectomy; HYS = hysterectomy; IQR = interquartile range; OR = operating room; PLA = pelvic lymphadenectomy; SD = standard deviation.

a) 16 women in this group also had infracolic omentectomy.

b) This patient had ACH and a borderline ovary tumour I A. Lymph nodes were suspicious and therefore resected.

c) 1 woman was hospitalised for 119 days due to a coagulation defect. Excluding this outlier resulted in a range of 1-15 days.

d) Independent samples T test.

e) Fisher´s exact test.

f) Mann-Whitney U test.

The Danish Data Protection Agency (2007-58-0015/HeH.750.16-28) approved the study. According to Danish law, formal approval from The Danish National Committee on Biomedical Research Ethics System was unnecessary for this study. Likewise, the Danish Health and Medicines Authority did not find the study notifiable (3-3013-64/1/HKR).

Trial registration: not relevant.

RESULTS

We included 235 women with EC or ACH. Of these, 167 (71%) had a hysterectomy and a BSO; 68 (29%) had a hysterectomy, a BSO and PLA (**Table 1**). In all, 211 (90%) of the women were diagnosed with EC; 24 (10%) had ACH at final histology (**Table 2**). The women who did not have PLA had a significantly higher mean BMI than those who had PLA (Table 1). We found an overall conversion rate to open surgery of 4%. The reasons for conversion were enlarged uterus (n = 2), poor visibility (n = 1), adhesions (n = 4), technical difficulties (n = 1) and suspicion of ovarian malignancy (n = 1). The median LOS was two days. Overall 4% were readmitted (no differences between groups, p = 0.13). The reasons for readmission were ileus (n = 3), vaginal cuff infection (n = 1), vaginal bleeding (n = 1), wound infection (n = 1), urinary retention (n = 1), hernia (n = 1) and urinary infection (n = 1). Mean LOS for readmission was seven days (range: 1-16 days). The mean lymph node resection was 25 nodes, and two women had positive lymph nodes. No deaths occurred perioperatively or within 90 days post-operatively (Table 2).

The difference between women with and without PLA of having a Clavien-Dindo score of 3 or higher was (5% versus 9%) non-significant (p = 0.24) (**Table 3**). The risk of developing a grade 3 or higher grade complication was not significantly increased in the PLA group; odds ratio (OR) adjusted for cardiovascular disease and BMI was 2.14 kg/m^2 (95% confidence interval (CI): 0.68-6.71 kg/m^2; p = 0.19). A total of 21% (14/68) of the women developed lymphoedema that persisted for months after the surgery.

The overall incidence of one or more complications was 15% with no significant difference between those

TABLE 3

Complications according to the Clavien-Dindo scale. The values are n (%).

Grade[a]	HYS + BSO (N = 167)	HYS + BSO + PLA (N = 68[b])	Total (N = 235)
I	12 (7)	7 (10)	19 (8)
II	20 (12)	9 (13)	29 (12)
IIIa	1 (< 1)	2 (3)	3 (1)
IIIb	6 (4)	4 (6)	10 (4)
IVa	1 (<1)	0	1 (< 1)
IVb	0	0	0
V	0	0	0

BSO = bilateral salpingo-oophorectomy; HYS = hysterectomy; PLA = pelvic lymphadenectomy.
a) Definitions of grades: see Appendix.
b) 16 women also had infracolic omentectomy.

TABLE 4

Complications according to extent of surgery. The values are n (%).

Complication	HYS + BSO (N = 167)	HYS + BSO + PLA (N = 68[a])	p-value	Total (N = 235)
Intraoperative complications	0	0		0
Bleeding > 500 ml	0	0		0
30-day timeframe				
UTI	9 (5)	6 (9)		15 (6)
Pneumonia	0	1 (1)		1 (< 1)
Port site/wound infection	5 (3)	1 (1)		6 (3)
Vaginal cuff infection/ haematoma	3 (2)	2 (3)		5 (2)
DVT or PE	0	0		0
Stroke	0	0		0
Ileus	0	2 (3)		2 (1)
ATN	1 (< 1)	0		1 (< 1)
12-month timeframe				
Vaginal cuff dehiscence	3 (2)	1 (1)		4 (2)
Hernia	2 (1)	1 (1)		3 (1)
Vaginal prolapse	0	1 (1)		1 (< 1)
Total	23 (14)	15 (22)		38 (16)
≥ 1 complication	23 (14)	13 (19)[b]	0.32[c]	36 (15)

ATN = acute tubular necrosis; BSO = bilateral salpingo-oophorectomy; DVT = deep vein thrombosis; HYS = hysterectomy; PE = pulmonary embolism; PLA = radical pelvic lymphadenectomy; UTI = urinary tract infection.
a) 16 women also had infracolic omentectomy.
b) 2 women developed > 1 complication.
c) Fisher's exact test.

undergoing PLA and those who did not (14% versus 19%; p = 0.32) (**Table 4**). The OR for developing one or more complications for women having PLA adjusted for cardiovascular disease and BMI was 1.52 kg/m^2 (95% CI: 0.70-3.27 kg/m^2; p = 0.29). Two women having PLA developed more than one complication. The most frequent complication was urinary tract infection within 30 days of surgery, which occurred in 6% of the women; 3% developed a port-site infection or wound infection within 30 days (Table 4). Among the women who underwent PLA, 21% developed symptomatic lower extremity lymphoedema requiring compression stockings and physiotherapy during the first 12 months after surgery. The lymphoedema was stage 1 (n = 8), stage 2 (n = 3) and unknown stage (n = 3) according to the stages defined by the International Society of Lymphology.

DISCUSSION

The women included in this study were burdened with many of the known risk factors for EC: high age, obesity, hypertension and type 2 diabetes; and we found that 6% of the women developed a grade 3 or higher grade complication according to the Clavien-Dindo scale. In comparison, a recent larger study (n = 1,155) that pooled all gynaecological, oncological robotic surgery cases (n = 220) found a 7.8% incidence of grade 3 or higher grade complications [9]. Our incidence may be lower because of a different case mix as we only included women who had simple hysterectomy.

Our results are comparable to those of other studies of RALH for EC [10], but the complication rate is a higher than reported for benign cases treated by robotic surgery [9, 11]. The incidence identified in the present study is, however, similar to that observed for benign cases treated by laparoscopy [12]. The overall incidence of post-operative complications was 15% in our study in which no comparison with an alternative surgical method was made.

El Sahwi et al reported a 10% incidence of post-operative complications in a sample of RALH in comparison with 27% in an open surgery group [13]. Direct comparison is difficult because of the use of different definitions of complications, different case mixes, different lengths of follow-up and different methods for detecting complications. Hence, we recommend future registration of complications using the Clavien-Dindo system so that comparison can be made across populations and centres.

The Clavien-Dindo scale has the advantage of including any deviation from the normal post-operative course. The Clavien-Dindo scale is particularly relevant in retrospective analyses which involves a risk of post-operative problems being poorly reported in patient records. Using the Clavien-Dindo classification also prevents the use of poorly defined terms such as "major and minor" complications. It is a valid system for grading the severity of complications and has been proven to be both simple, comprehensive and reliable [8, 11]. The severity of complications is important both from a patient, a clinical and a socioeconomic perspective.

Our study showed no significant difference in the incidence of grade 3 or higher complications between women undergoing PLA and those who did not. Nor did the former develop more overall complications or have a longer LOS than the latter. This contrasts with previous

studies reporting that lymphadenectomy increases the risk of post-operative morbidity and increases costs [14]. The lack of a significant difference between the groups in our study may be related to the fact that complications are rare or that our sample may be too small (type 2 error).

Readmissions are a measure of the quality of care and are also important in a socioeconomic perspective. We found a readmission rate of 4% within 30 days with no significant difference between women with or without PLA. The mean LOS for readmission was seven days. It has previously been reported that the rate of readmissions after robotic surgery for EC was 7.6% within three months and that the mean readmission LOS was 2.5 days [15]. The incidence of vaginal cuff dehiscence was 2% and dehiscence occurred either during coitus or spontaneously. Vaginal cuff dehiscence has been reported to occur from three days up to 30 years after surgery [16], and any dehiscence requires prompt surgical intervention. Vaginal cuff dehiscence is a known, but rare and unpleasant complication to hysterectomy and has been reported long before robotic surgery was introduced. It has, however, been suggested that robotic surgery may be associated with a higher incidence of dehiscence [16].

The incidence reported in the present study is comparable to those reported in similar studies on robotic surgery (varying 0.4-1.5%) [17, 18]. Possible causes of vaginal cuff dehiscence are thermal injury or insufficient suturing technique, which may be due to the magnification or the surgeon lacking tactile feedback. Increased age, previous vaginal surgeries, vaginal atrophy and factors associated with poor wound healing (malignancy, radiation), post-operative vaginal cuff infection and haematoma may also be risk factors [16]. The women in the present study were advised to postpone their first intercourse until eight weeks after RALH to reduce the risk of vaginal cuff dehiscence.

Nevertheless, vaginal cuff dehiscence occurred more than nine months post-operatively in one case. Fourteen (21%) of the women who underwent PLA developed symptomatic lower extremity lymphoedema within 12 months post-operatively – a condition that may persist throughout life. We defined lymphoedema as being present when the gynaecologist referred a woman to physiotherapeutic examination and treatment. Here the stage of lymphoedema was assessed and treatment given. Lymphoedema occurs after various surgical approaches. In a large evaluation of 1,298 women who were treated for EC, the overall incidence was 3.4% after more than ten lymph nodes were removed [19]. Our incidence of lymphoedema was higher than that reported in other robotic studies which may be due to our definition of lymphoedema. A large study of 471 women treated with RALH reported a 13.4% incidence of lymphoedema with a median of 25 months follow-up [18]. Different observation periods and defining criteria for lymphoedema may explain the different findings across studies. There is evidence that lymphoedema typically develops within the first post-operative year [20]. We therefore recommend that patients be followed for a minimum of 12 months post-operatively for lymphoedema. Additionally, further implementation of the sentinel node technique in the surgical treatment of EC will, hopefully, reduce the risk of this disability and associated morbidity.

Robotic-assisted laparoscopic hysterectomy at Herlev Hospital.

A strength of this study is the use of the Clavien-Dindo scale, a validated tool for exploring retrospective data [8] and for comparing post-operative complications across studies. Another strength is the use of two assessors and an arbitrator to obtain valid data. The study has inherent limitations due to its retrospective design, reliance on data from hospital charts and the lack of a control group undergoing transabdominal hysterectomy or laparoscopic hysterectomy.

CONCLUSION

This retrospective descriptive study showed that approximately 6% of women with early stage EC or ACH developed post-operative grade 3 or higher grade complications after RALH according to the Clavien-Dindo scale. This indicates that RALH is safe and well-tolerated in women with early-stage EC.

As more women are being treated with RALH worldwide and the indication for robotic surgery is widening to include more obese women and women with more co-morbidity, it is relevant to closely monitor the quality and safety of this technique in regard to post-operative complications. We recommend using the Clavien-Dindo scale to allow comparison across populations.

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APPENDIX

Classification of surgical complications – The Clavien-Dindo scale [8].

Grade	Definition
I	Any deviation from the normal post-operative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regiments are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy This grade also includes wound infections opened at the bedside
II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included
III	Requiring surgical, endoscopic or radiological intervention
IIIa	Intervention not under general anaesthesia
IIIb	Intervention under general anaesthesia
IV	Life-threatening complications (including CNS complications)[a] requiring IC/ICU management
IVa	Single-organ dysfunction (including dialysis)
IVb	Multiorgan dysfunction
V	Death of a patient
Suffix "d"	If the patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication This label indicates the need for a follow-up to fully evaluate the complication

CNS = central nervous system; IC = intermediate care; ICU = intensive care unit.
a) Brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks.

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