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Robot-assisted surgery for women with endometrial cancer: Surgical and oncologic outcomes within a Belgium gynaecological oncology group cohort

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ABSTRACT

Objective: To evaluate surgical and oncologic outcomes of patients treated by robot-assisted surgery for endometrial cancer within the Belgium Gynaecological Oncology Group (BGOG).
Study design: We performed a retrospective analysis of women with clinically Stage I endometrial cancer who underwent surgical treatment from 2007 to 2018 in five institutions of the BGOG group.
Results: A total of 598 consecutive women were identified. The rate of conversion to laparotomy was low (0.8%). The mean postoperative Complication Common Comprehensive Index (CCI) score was 3.4. The rate of perioperative complications did not differ between age groups, however the disease-free survival was significantly lower in patients over 75 years compared to patients under 65 years of age ($p=0.008$). Per-operative complications, conversion to laparotomy rate, post-operative hospital stay, CCI score and disease-free survival were not impacted by increasing BMI.
Conclusion: Robot-assisted surgery for the surgical treatment of patients suffering from early-stage endometrial cancer is associated with favourable surgical and oncologic outcomes, particularly for unfavourable groups such as elderly and obese women, thus permitting a low morbidity minimally-invasive surgical approach for the majority of patients in expert centres.
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Introduction

Endometrial carcinoma (EC) represents the most common gynaecologic pelvic cancer. The number of newly diagnosed cases globally is 382,069 in 2018, with an age-standardized incidence of 8,4 per 100,000 women. Cumulative life risk of diagnosis of endometrial cancer is 1,01% [1]. The diagnosis is made at an early stage in about 80% of the cases, resulting in a favourable prognosis. However, at least a part of affected patients is fragile mainly due to their age and associated comorbidities [2]. Obesity is a major risk factor for endometrial cancer, and nearly 65% of endometrial cancer patients are obese with BMI superior to 30 kg/m^2 [3]. Furthermore, despite increased rates of endometrial cancer mortality in elderly patients [4], this group of patients is treated more conservatively (reduced surgical radicality, reduced use of adjuvant therapy) as treatment-related morbidity seems higher [5].

Total hysterectomy with bilateral salpingo-oophorectomy remains the standard of the surgical management [6]. Since the introduction of laparoscopy in the field of gynaecological oncology in the 1990's, minimally invasive surgery (MIS) has been promoted as the optimal surgical route to treat patients suffering from early endometrial cancer. It took more than two decades to firmly establish, with Level I of evidence, that MIS results in equivalent

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oncologic outcomes for those patients [7–9]. Multiple randomized trials and meta-analyses showed that MIS approach has advantages over traditional open hysterectomy including fewer complications, shorter hospital stay, accelerated recovery, improved quality of live, similar survival and lower cost [7,10–15]. As a consequence, international guidelines and consensus conferences recommend minimally invasive surgery as the standard of care for the treatment for low-and intermediate risk clinical stage I endometrial cancer (level I of evidence) and as a valid option for the treatment of high-risk endometrial cancer [6,16]. However, this laparoscopic approach is globally underused, particularly in obese patients. The main reasons are technical challenges due to limited exposure and cardiopulmonary compromise while in Trendelenburg position [17,18]. MIS is performed in only 55% of early stage endometrial cancer population in Belgium [19].

Knowing the challenges associated with the use of conventional laparoscopy, robot-assisted surgery (RAS) has been used as an alternative to permit access to MIS. These characteristics have the potential to overcome the challenges associated with laparoscopy: either to help surgeons to cross the bridge to minimally-invasive surgery with techniques that mirror the open technique, either to assist the experienced laparoscopic surgeon to push beyond the procedural barriers of standard laparoscopy thanks to the precise, controlled and fatigueless acts of the RAS [20,21].

The aim of this study is to evaluate the surgical and oncologic outcomes of RAS in patients with endometrial cancer treated in five institutions members of the Belgium and Luxembourg Gynaecological Oncology Group (BGOG).

Patients and methods

Study population

Data of consecutive patients with histologically proven endometrial neoplasia who received surgical treatment (RAS) between January 2007 and December 2018, were retrospectively abstracted from the databases of five institutions in Belgium (University Hospital Leuven, CHR Citadelle Liège, Onze-Lieve-Vrouwziekenhuis Aalst, General Hospital Klina Brasschaat, General Hospital Sint-Jan Bruges). The study was approved by the Ethics Committee of the CHR Citadelle. All enrolled women underwent preoperative radiologic assessment (pelvic MRI or abdomino-pelvic CT scan) as well as a pre-operative endometrial biopsy.

All women had a total hysterectomy with bilateral salpingo-oophorectomy. Indication for lymph node staging was based on risk categories determined by preoperative histology and depth of myometrial invasion at MRI. Nodal staging consisted of sentinel node biopsy (SLN) or complete pelvic with or without para-aortic lymph node dissection (LND). Seven patients were referred after the completion of a total abdominal hysterectomy (TAH) or laparoscopic-assisted vaginal hysterectomy (LAVH) and were subsequently staged using the da Vinci® system (Intuitive Surgical Inc; Sunnyvale, CA). All included patients had presumed early stage disease. Type I and II histologies were allowed. The surgical procedures were performed by formally trained gynaecological oncologists.

Clinical, surgical, pathological and adjuvant therapy data were collected: the patient's age, body mass index (BMI), surgical procedure, nodal staging, final pathological analysis (histological type and grade, depth of myometrial invasion, and LVSI status) and type of adjuvant therapy. LVSI status was defined as positive (present) or negative (absent). We defined a group of women over 65 years old following the WHO (*World Health Organization*) [22] and INSEE (*Institut national de la statistique et des études économiques*) [22] thresholds, as well a group over 75 years old proposed by InCA (*Institut National du Cancer*) [23]. All women were classified according to the FIGO 2009 classification after final pathological analysis. Post-operative complications were classified according to the Clavien-Dindo Classification and the Comprehensive Complication Index (CCI®) [24].

Based on the endometrial biopsy and the radiologic assessment, women were classified pre-operatively in three subgroups: the low risk group included stage I endometrioid, grade 1–2, <50% myometrial invasion tumours; the intermediate group included stage I endometrioid, grade 1–2, ≥50% myometrial invasion tumours as well as stage I endometrioid tumours, grade 3, <50% myometrial invasion tumours; the high-risk group included stage I endometrioid tumours, grade 3, ≥50% myometrial invasion, stage II tumours and type 2 tumours. The same risk subgroup classification was applied post-operatively, based on the definitive histologic results.

Adjuvant therapies were administered according to the multidisciplinary tumour board conclusions and institutional policies. Recurrent disease was assessed by clinical examination, histologic confirmation and imaging. Local recurrence was defined by a vaginal vault localization and central pelvic recurrence by a pelvic localization except vaginal vault or pelvic node disease. Peritoneal carcinomatosis recurrence included disease limited to peritoneum, distant recurrence included liver, lung, bone, brain metastasis as well as supradiaphragmatic node disease.

Disease-free survival (DFS) was defined as the length of time from the date of surgery to any recurrence or cancer-related death, overall survival (OS) was defined as the time length from surgery to death as a result of any cause.

Statistical analysis

Descriptive analyses are presented as median and range for continuous variables and as frequencies and percentages for categorical variables. Statistical models are used for data analysis, with age, initial risk group or surgical treatment type as predictor variables and surgical and oncological outcomes as response variables. BMI is analysed as continuous and categorical predictor. Linear regression models are used for analysing the effect of predictors on continuous outcomes. Results of linear regression models are presented as slopes (for continuous predictors) or difference estimates (for categorical predictors) with 95% confidence intervals. Binary outcome variables are analysed using logistic regression models, and ordinal variables using proportional odds models. Results are presented as odds ratio (OR) with 95% confidence intervals. Time – to – event outcomes are analysed by Cox proportional hazards models. Results are presented as hazard ratio (HR) with 95% confidence intervals. The Kruskal Wallis test was used for comparing BMI groups on continuous variables. P-value <0,05 is considered to be as statistically significant. Analyses have been performed using SAS software (version 9.4 of the SAS System for Windows).

Results

Population characteristics

The demographic and clinical characteristics are reported in Table 1.

Surgical outcomes

The surgico-pathological profile of the global cohort is shown in Table 2. Five hundred and ninety-eight women were treated by upfront robotic surgery. Five initially robotic approaches (0.84%) were converted in laparotomy because of large uterine size, diffuse

Table 1
Demographic and clinical characteristics.

Characteristics	Population % (n) n = 598
Age, median (range)	68 (38–92)
Age group, % (n)	
<65	39.63 (237)
65-75	37.79 (226)
>75	22.58 (135)
BMI kg/m^2, median (range)	28.3 (16.6–61.3)
BMI kg/m^2 group, % (n)	3.85 (23)
<20	24.08 (144)
20-25	27.42 (164)
25-30	20.9 (125)
30-35	20.9 (125)
>35	2.84 (17)
NA	
Performance status (ECOG), % (n)	72.07 (431)
0-1	7.36 (44)
2	1.67 (10)
>2	18.9 (113)
NA	

Table 2
Surgical outcomes.

Median operative time, min (range)	150 (55–480)
Median blood loss, ml (range)	50 (0–1000)
Transfusion, % (n)	2.01 (12)
Per-operative complications, % (n)	5.02 (30)
Vascular	23.3 (7)
Bladder injury	10 (3)
Intestinal	13.3 (4)
Other	26.7 (8)
NA	26.7 (8)
Conversion, % (n)	0.84 (5)
Post-operative complications, % (n)	14.38 (86)
Clavien-Dindo classification, % (n)	
Grade I and II	73.26 (63)
Grade III	23.26 (20)
Grade IV	1.16 (1)
Grade V	2.33 (2)
CCI score, mean (range)	3.4 (0–100)
Postoperative hospital stay, median (range)	3 (1–60)

dense adhesions and anaesthesiologic contra-indications for prolonged steep Trendelenburg position. Two hundred and thirty-one women (38.6%) had no nodal staging, 176 women (29.4%) had exclusive sentinel node staging (SLN), 189 women (31.6%) had complete pelvic lymph node dissection (LND), 39 women (6.5%) had complete pelvic and para-aortic lymph node dissection. Thirty women (5.01%) presented per-operative complications (Table 3). The median skin-to-skin operative time was 150 min (range 55–480). Median blood loss was 50 mL (range 0–1000 mL). Median post-operative hospital stay was 3 days (range 1–60). 85 women presented post-operative complications within 30 days from the procedure (14.21%), mean CCI was 3.4 (range 0–100). Post-operative complications consisted mainly of ileus, lymphocele or vaginal vault dehiscence.

In a univariable model women staged with exclusive SLN had significantly lower CCI score compared to women staged with complete pelvic or pelvic and para-aortic LND (Estimate −3.332, 95% CI, −6.248 to −0.416, $p=0.0251$). No significant difference for CCI was found between women staged with SLN and women with no lymph node staging ($p=0.47$). Increasing age was not correlated with complication profile assessed either by the Clavien Dindo classification ($p=0.0698$) or the CCI score ($p=0.3697$).

Table 3
Oncologic characteristics.

	Population, % (n) n = 598
Histology, % (n)	
Endometrioid	85.0 (508)
Mucinous	0.5 (3)
Squamous	0.17 (1)
Serous	7.86 (47)
Clear cell	1.34 (8)
Carcinosarcoma	3.34 (20)
Other[a]	1.19 (7)
Postoperative histologic grade, % (n)	
G1	54.18 (324)
G2	23.41 (140)
G3	20.4 (122)
FIGO stage 2009	
I	84.62 (506)
IA	60.54 (362)
IB	24.08 (144)
II	3.85 (23)
III	10.54 (63)
IIIA	2.51 (15)
IIIB	0.33 (2)
IIIC1	6.19 (37)
IIIC2	1.51 (9)
IV	0.67 (4)
IVA	0.33 (2)
IVB	0.33 (2)
LVSI, % (n)	30.6 (183)
Node staging group, % (n)	
None	37.79 (226)
SLN	29.43 (176)
LAD (+SLN)	32.11 (192)
NA	0.67 (4)
Adjuvant treatment	
None	69.9 (418)
Refused	0.67 (4)
Yes	28.76 (172)
NA	0.67 (4)

Patients outcomes

The post-operative clinico-pathological profile is reported in Table 3. Five hundred and eight women (84.94%) were classified as FIGO stage I. Increasing age was associated with higher FIGO stage (OR 1.028, 95% CI, 1.01–1.046, $p=0.0019$), patients over 75 years of age had higher FIGO stages compared to women under 65 years (OR 1.888, 95% CI, 1.248–2.855, $p=0.0026$). Women over 75 years had higher odds for having positive pelvic or para-aortic lymph nodes compared to women under 65 years (OR 2.304, 95% CI, 1.07–4.962, $p=0.033$).

Higher age was also significantly associated with LVSI (OR 1.025, 95% CIU, 1.006–1.044, $p=0.0107$). Women over 75 years old had higher odds of for having LVSI compared with women younger than 65 years and women between 65 and 75 years old had higher odds of having LVSI compared to the younger than 65 years group(OR 1.662, 95%CI, 1.052–2.625 and OR 1.449, 95%CI 0.967–2.171 respectively). Furthermore, women aged over 75 years had higher odds of having higher post-operative histologic grade than women younger than 65 years old (OR 1.632, 95% CI, 1.083–2.46. $p=0.0192$).

Four hundred and twenty-one women (70.4%) did not receive any adjuvant treatment, 44 (7.36%) had a vaginal vault brachytherapy, 52 patients (8.69%) received an external beam pelvic radiation therapy, 32 patients (5.35%) had an extended-field radiation therapy and 78 patients (13.04%) were administered an adjuvant chemotherapy.

Median follow-up was 2.21 years (range 0.03–11.06). 2-year DFS was 88.38% (95% CI, 85.08–91.24), 5-year DFS was 82.81% (95% CI, 78.29–86.86), 2-year OS was 92.32% (95% CI, 89.25–94.54) and 5-

year OS was 82.95% (95% CI, 77.71–87.06) (Figs. 1 and 2). Disease-free survival was significantly lower for women aged over 75 years old compared to women younger than 65 years old (HR 2.401, 95% CI, 1.257–4.585, $p=0.008$).

Among the 61 women (10.2%) presenting a recurrence, 7 (11.5%) had a vaginal vault relapse, 2 had a pelvic node relapse (3.3%), 2 had a para-aortic node relapse (3.3%), 14 women presented an abdominal metastasis (24.6%), 10 women had thoracic metastasis (16.4%) and 18 patients had multiple site recurrences (29.5%).

Obese and severely obese women' subgroup

Our cohort included 125 patients (20.9%) with BMI higher than 35 kg/m^2. Surgical time was higher for increasing BMI, with median skin-to-skin time of 160 min for this subgroup compared to 135 min for the BMI <20 group ($p=0.0074$). In a multivariable model (including BMI, age, per-operative complications, staging groups (none vs SLN vs LND) and blood loss), BMI, staging group(LND > SLN > none), blood loss and per-operative complications were significantly correlated independently to operative time ($p<0.001$, $p<0.001$, $p<0.001$, $p=0.0191$ respectively).

Blood loss was significantly higher for increasing BMI ($p=0.0019$), however this was not clinically relevant as the mean bleeding volume was 126.7 mL for BMI > 35 group and 57.6 mL for BMI < 20 group. In multivariable model analysis (including BMI, age, staging group (none vs SLN vs LND)), BMI and LND were independently correlated to higher blood loss ($p=0.0001$ and $p=0.0066$ respectively). Per-operative complications, conversion to laparotomy rate, post-operative hospital stay and CCI score were not altered by increasing BMI.

DFS was not impacted by BMI, however increasing BMI was independently correlated to a lower OS (HR 1.042, 95% CI, 1.008–1.078, $p=0.0161$).

Discussion

The analysis of this series indicates that RAS can be offered to patients with clinically early stage EC with favourable peri-operative and oncologic outcomes.

In the five BGOG centres in which consecutive early-stage EC women were operated by RAS, the MIS rate is above 99%. This appears to be a valuable observation, as MIS rate in Belgium for early-stage EC treatment reported by the EFFECT database was 56% [19]. The MIS rate in Belgium is consistent with what has been described in the United States [25], while French and Dutch studies report less than 20% of MIS rate for early-stage EC women [26,27]. The reasons behind these discrepancies are possibly the lack of broad surgical expertise in MIS, the surgeons' limited surgical workload, the long learning curves and the technical limitations of conventional laparoscopy for subgroups such as severely obese patients.

Our study shows low surgical morbidity for women treated for endometrial cancer by RAS. We found a very low rate of conversion to laparotomy (0.84%). Other studies observed conversion to laparotomy rates of RAS varying from 0 to 12% [28–32]. RAS seems to have lower rates of conversion compared to conventional laparoscopy. In 2017, a meta-analysis by Ind et al. [33] found a risk ratio of 0.41 (95% CI 0.29–0.59) for conversion of EC population treated by RAS compared to laparoscopy. This finding could be possibly due to improved RAS ergonomics [34]. The value of our very low rate of conversion is strengthened by the fact that the selection bias in this series are limited due to the inclusion of consecutive early-stage EC women.

Our median skin-to-skin operative time was 150 min, with lymph node staging (sentinel node/complete pelvic dissection/complete pelvic and para-aortic dissection) performed for 368 women (61.54% of RAS). Other studies of RAS-treated EC women find similar operative times [35], Corrado et al. [36] reports lower median operative time of 115 min (range 60–325) but with lower lymph node staging rate of 37.5%. Operative times for RAS do not seem to significantly differ from conventional laparoscopy in a 2016 meta-analysis [37]. However, a systematic review by Nevis et al. reports consistently higher operative times for RAS compared to laparotomy [38], with just one study showing lower operative times [39].

In the present series, 14.21% of operated women presented post-operative complications with an overall very low mean CCI score of 3.4. Other studies reported rates of post-operative complications ranging from 9% to 19.1% [40,41]. We found that women surgically

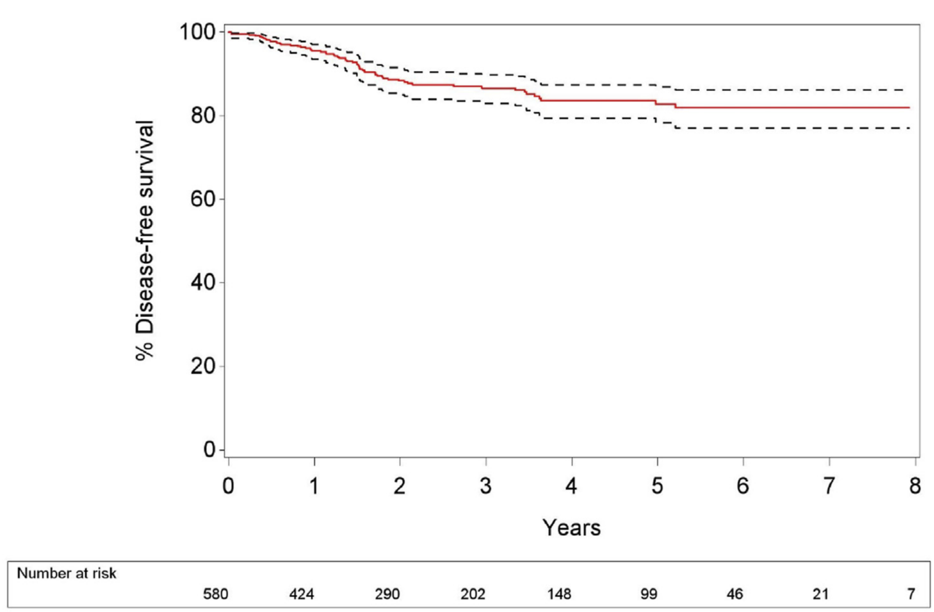

Fig. 1. Disease-free survival curve.

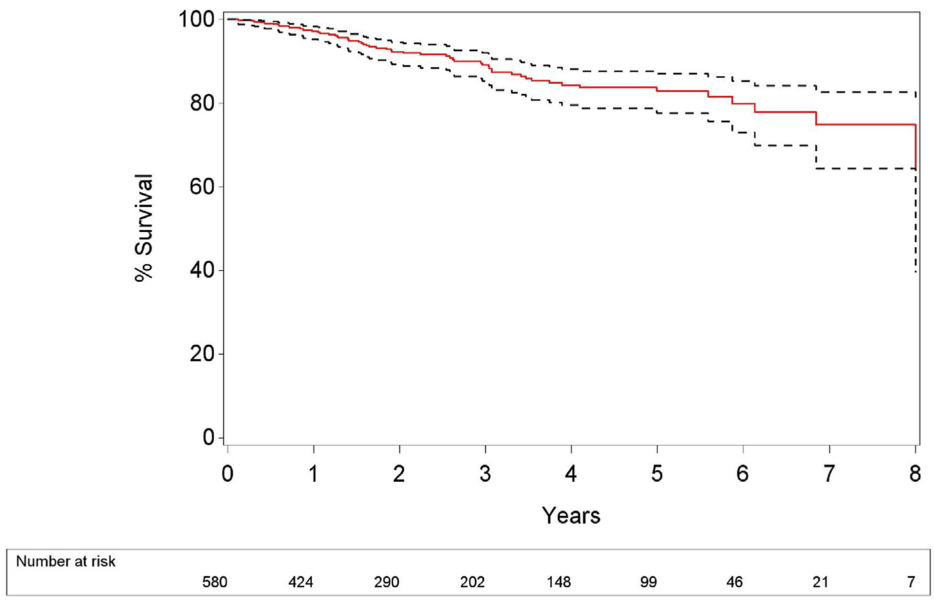

Fig. 2. Overall survival curve.

staged by exclusive sentinel node biopsy had lower CCI score than the complete pelvic node or complete pelvic and para-aortic node dissection groups. Sentinel node staging has been investigated for apparent early stage endometrial cancer showing less morbidity than complete node staging [42–44]. We did not find any association between increasing age and CCI score (*p=0.3697*). A 2018 Cochrane review [45] found no significant difference between MIS and laparotomy for major post-operative complications. However, overall complication rate seems lower for MIS compared to laparotomy [31,35,40,46–53]. Studies investigating outcomes for elderly versus younger women treated by MIS similarly found no significant differences for overall or post-operative complications [54–57].

Age over 75 years (versus less than 65 years) was significantly correlated with peritumoral LVSI presence (OR 1.662, 95% CI, 1.052–2.625, *p=0.0295*), higher histologic grade (OR 1.632, 95% CI, 1.083–2.46, *p=0.0192*) and higher FIGO stage (OR 1.888, 95% CI, 1.248–2.855, *p=0.0026*). A 2015 Canadian study evaluating endometrial cancer surgery by RAS for elderly women found also a higher FIGO stage for women over 80 years old (*p=0.023*) [58]. Another study by Vankin et al. found similarly advanced FIGO stage for women aged over 70 years compared to an under 70 years old group (*p<0.04*) [59]. In our study, women aged over 75 years had a hazard ratio of 2.401 of a recurrence or disease-related death compared to women younger than 65 years (*p=0.008*). This poorer prognosis could be related to the aggressiveness of the disease or due to delays in surgical management, as it seems that 20% of elderly symptomatic people wait at least one year before consulting [60].

Our subgroup of obese and severely obese women (n = 125) showed longer surgical times and more bleeding (*p=0.0074* and *p=0.004* respectively). However, conversion to laparotomy rate, per-operative complications, hospital stay, CCI score and DFS were not correlated to increasing BMI. The GOG LAP-2 trial reported a high 57.1% conversion rate to laparotomy for women presenting a BMI higher than 40 kg/m^2 [7] operated by conventional laparoscopy, however almost all of these patients underwent complete pelvic and para-aortic node staging contrary to 6.5% of our patients. In a 2019 review of laparoscopic and robotic hysterectomy for obese women treated for EC, Cusimano et al. suggest different reasons for laparoconversion between RAS and conventional laparoscopy: for laparoscopic hysterectomy, conversion is more often attributed to obesity-related anaesthetic indications whereas for RAS it is more often due to uterine size [61]. In 2018, a study by Corrado et al. [62] retrospectively including 655 obese and severely obese women with endometrial cancer found no impact of higher BMI on surgical or oncologic outcomes.

Our study's limitations include its retrospective character and the fact that we cannot exclude bias related to surgeon variability inherent to the multicentric design, even if all surgeons were formally trained gynaecological oncologists. The median follow-up of operated women is also rather short despite the long duration of the study. The study's strengths are the size of the cohort and the fact that all patients were treated either in tertiary university centres or by surgeons trained in specialized oncologic departments, making surgical treatment modalities more homogenous.

Conclusions

Our results indicate that the majority of endometrial cancer patients treated in expert centres may benefit from an MIS approach under the form of robot-assisted surgery. In this context, their surgical outcome in terms of per- and post-operative morbidity is favourable and the rate of conversion to laparotomy is low. This benefit appears particularly interesting for the subgroups of fragile patients such as elderly and overweight women. Robot-assisted surgery allows to overcome surgical challenges and to propose an optimal surgical management.

SNL = sentinel node lymphadenectomy; LAD = lymphadenectomy (pelvic ± para aortic) a Undifferentiated histologies, giant cell tumour, neuro-endocrine tumour, adenosquamous tumour, mixed tumour.

CRediT authorship contribution statement

A. Kakkos: Conceptualization, Methodology, Writing - original draft, Writing - review & editing. **C. Ver Eecke:** Resources, Writing - review & editing. **S. Ongaro:** Conceptualization, Resources, Writing - original draft. **K. Traen:** Resources. **F. Peeters:** Resources. **Ph Van**

Trappen: Resources. **A. Laenen:** Methodology, Validation, Formal analysis, Writing - review & editing. **E. Despierre:** Resources. **E. Van Nieuwenhuysen:** Resources. **I. Vergote:** Conceptualization, Methodology, Resources, Writing - review & editing, Supervision. **F. Goffin:** Conceptualization, Methodology, Resources, Writing - review & editing, Supervision.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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