The influence of proficiency-based progression training on peri-operative and survival outcomes in robot-assisted laparoscopic surgery for endometrial cancer: an observational cohort study.

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Abstract

Objective To assess the influence of proficiency-based progression (PBP) training in robot-assisted laparoscopic (RAL) surgery for endometrial cancer on peri-operative and survival outcomes. **Design** Observational cohort study. **Setting** Tertiary referral and subspecialty training centre. **Population** All women with primary endometrial cancer treated with RAL surgery between 2015 and 2022. **Methods** Proficiency-based progression training cases were identified pre-operatively by consultant surgeons based on clinical factors, such as BMI and comorbidities, and case complexity matching the experience of the trainee. **Main Outcome Measures** Intra- and post-operative complications, blood transfusions, readmissions $<$ 30 days, return to theatre rates and 5-year disease-free and disease-specific survival for training versus non-training cases. **Results** Training cases had a lower BMI than non-training cases (30 versus 32 kg/m ^{2}), but were comparable in age, performance status and comorbidities. Training had no influence on intra- and post-operative complications, blood transfusions, readmissions $<$ 30 days, return to theatre rates and median 5-year disease-free and disease-specific survival. Operating time was longer in training cases (161 versus 137 min). Estimated blood loss, conversion rates, CCU-admissions and lymphoedema rates were comparable. **Conclusions** Proficiency based progression training can be safely used to teach RAL surgery for women with endometrial cancer. Prospective trails are needed to further investigate the influence of distinct parts of RAL surgery performed by a trainee on endometrial cancer outcomes.

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Running title: the effect of training in RAL surgery on endometrial cancer outcomes.

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Methods Proficiency-based progression training cases were identified pre-operatively by consultant surgeons based on clinical factors, such as BMI and comorbidities, and case complexity matching the experience of the trainee.

Main Outcome Measures Intra- and post-operative complications, blood transfusions, readmissions $<$ 30 days, return to theatre rates and 5-year disease-free and disease-specific survival for training versus non-training cases.

Results Training cases had a lower BMI than non-training cases (30 versus 32 kg/m^2), but were comparable in age, performance status and comorbidities. Training had no influence on intra- and post-operative complications, blood transfusions, readmissions $<$ 30 days, return to theatre rates and median 5-year disease-free and disease-specific survival. Operating time was longer in training cases (161 versus 137 min). Estimated blood loss, conversion rates, CCU-admissions and lymphoedema rates were comparable.

Conclusions Proficiency based progression training can be safely used to teach RAL surgery for women with endometrial cancer. Prospective trails are needed to further investigate the influence of distinct parts of RAL surgery performed by a trainee on endometrial cancer outcomes.

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Keywords Endometrial cancer, robot-assisted laparoscopic surgery, progression-based proficiency training, peri-operative outcomes, post-operative outcomes survival.

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Introduction

In the last two decades, the use of minimally-invasive surgery for endometrial cancer has become widespread since the Laparoscopic Approach to Cancer of the Endometrium (LACE) trial and Gynecologic Oncology Group (GOG) LAP2 study established non-inferiority of laparoscopic versus laparotomic surgery for disease-free and overall survival in endometrial cancer.[1-3] Robot-assisted laparoscopic (RAL) surgery was introduced in gynaecological surgery in 2005[4] and may provide more precision, better views, reduced patient morbidity and improved surgeon ergonomics compared to conventional laparoscopy.[5-8] These advantages are especially beneficial in obese patients undergoing open or laparoscopic hysterectomy as they are more prone to post-operative morbidity compared to non-obese patients.[9] Obesity is the main risk factor for endometrial cancer and since its incidence is rising[10], the preferred approach in minimally-invasive surgery has shifted from straight-stick to robotic.

Over the last years an increased number of gynaecological oncology surgical fellowship programs have adopted RAL surgery as part of their training. The introduction of a new surgical technique is accompanied with a learning curve, which has been assessed in conventional laparoscopic and robotic surgery[11-14] and underpins the need for training curricula and guidelines.

Urologists were the first to assess the effect of training in robotic surgery on peri-operative outcomes and developed proficiency-based progression (PBP) training curricula for robotic surgery.[15] The Society of European Robotic Gynaecological Surgery (SERGS) and British & Irish Association of Robotic Gynaecological

Surgeons (BIARGS) followed by providing curricula and guidelines for training in robot-assisted gynaecological surgery.[16,17] However, the effect of training on peri-operative and survival outcomes in endometrial cancer patients undergoing RAL surgery has not been assessed.

The Royal Marsden Hospital is a tertiary cancer centre in the United Kingdom (UK) treating high-risk endometrial cancer patients as a part of the Southwest Thames Gynaecological Cancer Centre. It was the first centre in the UK to adopt RAL surgery for gynaecological cancer in 2007 and has been training subspecialty trainees in gynaecological oncology in RAL surgery since 2015 in a PBP training manner.

The objective of this study was to compare peri-operative and survival outcomes for PBP-training versus non-training cases in endometrial cancer patients undergoing RAL surgery.

MethodsThis project has received ethical approval from the ethics committee in our centre (see Details of Ethics Approval Section). There was no public involvement.

Design

An observational cohort study was performed between 2015 and 2022. All patients intended to undergo RAL surgery for any stage of endometrial cancer as part of routine care at the Royal Marsden Hospital or any other hospital of the Southwest Thames Gynaecological Cancer Centre we operated in due to capacity constraints were included. All surgeries were performed by three robot-trained gynaecological oncology surgeons. Three generations of Da Vinci robots were used (S, Si, Xi).

Inclusion criteria were women diagnosed with endometrial cancer and the intention of performing RAL hysterectomy, bilateral salpingo-oophorectomy and/or any lymph node dissection. Patients with non-endometrial primary histology or any additional cancer were excluded from analysis.

Data collection

Data collection was done prospectively by consultant surgeons MAEN and TEJI from 2015 to 2022 and was stored in a secured database. Missing data was completed retrospectively by independent researcher AAS in 2022 using information on the hospital's electronic patient record (EPR).

Identification of training cases

Proficiency-based progression training cases were identified pre-operatively by consultant surgeons based on clinical factors, such as BMI and comorbidities, and case complexity matching the experience of the trainee. Trainees in gynaecological oncology followed the PBP training curricula provided by BIARGS and SERGS.[18,19]All operations were performed at the Southwest Thames Gynaecological Cancer Centre under direct supervision of one of two consultant surgeons.

Outcomes

Primary outcomes are intra- and post-operative complications before and after 30 days, blood transfusions, readmissions $<$ 30 days, return to theatre rates and 5-year disease-free and disease-specific survival. Intra-operative complications are defined as any type of surgical complication occurring during the operation. Post-operative complications within 30 days are graded according to the Clavien-Dindo classification.[20]

Secondary outcomes are estimated blood loss, operating time, rate of conversions, CCU-admissions, length of stay longer than 1 day and lymphoedema. A conversion was defined as the need to convert to laparotomy after docking of the robot due to an intra-operative complication or impossibility to continue robotically due to adhesions.

Prognostic risk groups according to European Society of Gynaecological Oncology (ESGO) were assessed.[21] These recently developed guidelines for risk group determination incorporate clinicopathologic and molecular parameters and effectively predict survival in endometrial cancer.[22]

Statistical analysis

Analyses were performed with the Statistical Package for the Social Sciences (SPSS) 28.01.1. Missing data analysis revealed missing data > 5% for ASA and WHO performance status. Therefore, imputation of missing data was done in SPSS using the median of nearby points for the variables ASA status and WHO performance status.[23]

Mann-Witney U testing was used to assess significant differences in median values. Pearson's chi-squared testing was performed to assess the correlation between categorical dependent variables with [?] 2 groups and the dichotomous independent variable (training case yes/no). Multivariable logistic regression analysis was performed to assess the correlation between continuous clinical variables and the dichotomous independent variable. Multivariable logistic regression analysis was performed to assess the correlation between clinical, operative, histopathological and treatment variables and post-operative outcomes. Cox-regression analysis was performed for 5-year disease-free and disease-specific survival. Statistical tests were two-sided with significance set at $p < 0.05$, with confidence intervals (CI) at the 95% level. Post-hoc testing was performed if Pearson's chi-squared testing rendered group differences. Bonferroni-adjusted p-values reached significance when p < (0.05/number of analysed groups).[24]

Results

Patient characteristics

In total 595 endometrial cancer cases were analysed, of which 294 (49.4%) were a training case and 301 (50.6%) were not. 502 cases (84.8%) were performed at the Royal Marsden Hospital and 92 cases (15.5%) were performed at other hospitals within the Southwest Thames Gynaecological Cancer Centre. Eighteen gynaecological oncology trainees were trained in RAL surgery for endometrial cancer in a PBP manner.

Table 1 shows the baseline characteristics for training and non-training cases. Training and non-training cases were similar in age (66 versus 67 years, p = 0.0946), ASA score (2 versus 2, p = 0.680) and Carlson Comorbidity Index 10-year median survival estimates (21.6% versus 21.4%, p = 0.259). However, training cases had a lower BMI (30 versus 32 kg/m^2, p = 0.016) than non-training cases and there was a difference in distribution of WHO performance status (p = 0.026), but post-hoc testing according to Bonferroni[24]rendered no significant differences.

No differences were found in median FIGO stage between training and non-training cases (1 versus 1, p = 0.168), but training cases had patients with a higher median histopathological grade (3 versus 2, p = 0.010) and a lower rate of endometrioid tumours (56.8% versus 69.1%, p = 0.002*). Post-hoc testing showed a lower rate of grade 1 (33.9% versus 45.6%, p = 0.004*) and a higher rate of grade 3 tumours (50.3% versus 39.3%, p = 0.007*) in training cases. This resulted in a higher percentage of adjuvant treatment in training cases (69.9% versus 59.6%, p = 0.034). The distribution of ESGO risk scores did not differ between training and non-training cases (p = 0.078). More sentinel lymph node dissections (77.2% versus 67.8%, p = 0.010) were performed in training cases, which is possibly associated with the gradual increase in training cases over time (37.2% in 2015 versus 55.3% in 2022) accompanied with the simultaneous increase in sentinel lymph node procedures (39.5% in 2015 versus 72.4% in 2022). The median number of harvested lymph nodes (3 versus 3, p = 0.325), and rates of pelvic (25.3% versus 29.2%, p = 0.276) and para-aortic lymphadenectomies (0.3% versus 1.3%, p = 0.188) were comparable. Median follow-up in months was comparable (25 versus 28 months, p = 0.140) between training and non-training cases.

Peri-operative outcomes

Table 2 shows the peri-operative and survival outcomes in training and non-training cases. A significant difference was found in mean estimated blood loss (EBL) (134 ml versus 160 ml p = 0.005) favouring training cases, but this did not result in a difference in blood transfusions (2.1% versus 4.7%, p = 0.076). The rate of conversions (4.0% versus 3.1%, p = 0.476) and CCU-admissions (2.6% versus 3.9%, p = 0.925) were comparable. Mean operating time was found to be longer (161 min versus 137 min, p = <0.001) in training cases. Median length of stay (LOS) was found to be shorter in training cases (1 day versus 2 days, p = 0.008), which might be associated to a gradual increase in the amount of training cases over time (37.2% in

2015 versus 55.3% in 2022) and a simultaneous slight decrease in LOS over time (2 days in 2015 versus 1 day in 2022). The rate of intra- and post-operative complications were comparable across groups (4.8% versus 7.7%, p = 0.146; 30.4% versus 30.3%, p = 0.969 respectively). There was no difference in the distribution of Clavien-Dindo complication grades between training and non-training cases (p = 0.665). The rates of readmissions < 30 days (3.8% versus 6.0%, p = 0.208), return to theatre (1.0% versus 1.7%, p = 0.495) and lymphoedema (8.2% versus 11.3%, p = 0.193) did not differ between groups.

Multivariable logistic regression analysis

The effects of training on post-operative and survival outcomes are expressed as odds and hazard ratio's in Table 3. Effect sizes were corrected for age, stage (<2/[?]2) and grade (low grade/high grade) using multivariable logistic regression and cox proportional hazard analysis. Variables were included in multivariable logistic and cox proportional hazard analyses if they rendered clinical relevance and showed a significant effect on disease-free and disease-specific survival in univariate regression analysis.

After correction training did not increase the odds ratio's (OR) for intra-operative complications (0.6, p = 0154), post-operative complications (1, p = 0.994), Clavien-Dindo complications, (0.9, p = 0.583), readmissions < 30 days (0.6, p = 0.202), return to theatre (0.6, p = 0.553) or lymphoedema (0.6, p = 0.110). Training cases had a lower odds for LOS > 1day (0.6, p = 0.004).

Survival

The rates of recurrences (23.7% versus 23.6%, p = 0.949) and deaths of disease (13.9% versus 9.1%, p = 0.076) did not differ between groups. Likewise, median disease-free (26 versus 28 months, p = 0.427) and disease-specific survival (25 versus 28 months, p = 0.183) was comparable for training and non-training cases (table 3).

Figure 1 and 2 show the Kaplan-Meier curves for 5-year disease-free and disease-specific survival for training and non-training cases. The estimated 5-year disease-free survival is 59.1% (95%-CI: 48.5 – 68.3%) for non-training cases and 65.8% (95%-CI 58.0 – 72.5%) for training cases (p = 0.607). The estimated 5-year disease-specific survival is 81.7% (95%-CI 74.0 – 87.2%) for non-training and 75.5% (95%-CI 68.2 – 81.4%) for training cases (p = 0.276).

Discussion

Main Findings

Proficiency-based progression training can be safely used to teach RAL surgery for women with endometrial cancer. Training cases were less obese than non-training cases, but were comparable in age, performance status and comorbidities. No influence of PBP training on intra- and post-operative complications, blood transfusions, readmissions < 30 days, return to theatre rates and median 5-year disease-free and disease-specific survival in RAL surgery for endometrial cancer was found.

Strengths and Limitations

Our study has several strengths. First, all procedures were performed by one surgical team in a high-volume tertiary cancer centre service, which resulted in a large cohort with highly comparable surgical circumstances. Moreover, all consultants providing training completed the same LAPCO 'Train the Trainers' course.[25] Thereby, the manner of PBP training was similar in all training cases. Secondly, we trained 18 gynaecological oncology trainees in RAL surgery for endometrial cancer in a PBP manner. Consequently, our results represent a more general effect of PBP training in RAL surgery for endometrial cancer on peri-operative and survival outcomes than previous studies, that only assessed one trainee.[26,27]

Thirdly, our data was mainly collected prospectively which reduced the chance of information bias and resulted in a limited amount of missing data. One independent researcher completed the database retrospectively thereby further reducing the likelihood of information bias.

Our study also has some limitations. The main limitation of our study is that we did not record which part of the surgery was performed by the trainee. In PBP training trainees gradually build their contribution to the surgery, starting with vault suturing and ending with independent performance of hysterectomy, bilateral salpingo-oophorectomy and lymph node dissection. With our data we were unable to define the effect of performance of a specific part of the surgery by a trainee on peri-operative and survival outcomes. Thereby, we possibly underestimate the effect of training in individual steps of RAL surgery on our outcomes. On the other hand, our results highlight a real-world training environment and show some expected differences between training and non-training cases (lower BMI and longer operating time) suggesting that our study had the distinguishing capacities needed to pick up major differences between training and non-training cases. Our future aim is to further investigate the influence of distinct parts of RAL surgery performed by a trainee on peri-operative and survival outcomes.

Furthermore, compared to other robotic cohorts[28-30] we have a high percentage of high grade tumours (44.9%) and high stage disease (31.1%) which is related to the tertiary referral status of our department. This might limit the generalisability of our results. Direct comparison with other robotic cohorts is needed to further evaluate the effect of PBP training on peri-operative and survival outcomes for RAL surgery in all stages of endometrial cancer.

Interpretation

To date no other studies have evaluated the general effect of PBP training in RAL surgery for endometrial cancer on peri-operative and survival outcomes. However, a learning curve for RAL surgery in endometrial cancer has previously been assessed.[26.27]By comparing peri-operative outcomes between cases performed in the early stages of the learning curve and cases performed in later stages of the learning curve, we can roughly compare these results with our training and non-training cases. However, it must be noted that these studies were performed by single surgeons and only assessed a limited number of peri-operative outcomes. One study[26]observed a significant decreasing EBL between cases performed early in the learning curve and later cases, which was not observed in our cohort. However, our results on operating time are in line with two other studies[26,27], who found significant improvements in operating time between cases performed in early stages of the learning curve and later cases.

No studies assessing the learning curve of RAL surgery for endometrial cancer evaluated survival outcomes. However, Baeten et al[11] assessed 5-year disease-free and disease-specific survival for cervical cancer patients undergoing RAL surgery and found significantly worse outcomes for cases in the early stages of the learning curve compared to cases in later stages. Comparable results were found by two more studies.[13,14] We did not find such a trend in our cohort, which might be due to several differences compared to our study. First, whereas the previously mentioned studies[11,13,14] analysed cases between 2007 and 2018 when there was no set training curriculum, we analysed cases between 2015 and 2022 in which timeframe PBP training was developed and implemented. Secondly, we did not look into individual learning curves as Baeten et al did but investigated the overall effect of PBP training in a tertiary cancer service on survival outcomes, which renders the possibility of underestimation of our survival outcomes (see limitations). Lastly, the effects of training in RAL surgery might differ between cervical and endometrial cancer.

Due to limited studies of RAL surgery in gynaecological oncology, we have to look at other fields of robotic surgery to compare our results. The implementation of a training curriculum for robotic-assisted radical cystectomy by the European Association of Urologists (EAU) Robotic Urology Section (ERUS) was recently evaluated.[31] As in our cohort, operating time was significantly longer in training cases, but otherwise the trainee showed non-inferiority compared to the experienced surgeon in terms of EBL, positive soft tissue margins, number of resected lymph nodes, overall and high-grade complications, and 90-day readmissions. This suggests safety and efficiency of a PBP training curriculum in robotic prostatectomy.

Conclusion

Our results show that PBP training can safely be used in RAL surgery for endometrial cancer in a high-volume tertiary cancer service with no difference in peri-operative and survival outcomes. In the future we aim to design prospective trials to further investigate the influence of distinct parts of RAL surgery performed by a trainee on peri-operative and survival outcomes.

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Disclosure of Interests

MAEN is a proctor for robot-assisted surgery in gynaecological oncology for Intuitive Surgical. The hospital receives funding from Intuitive for case observations. Completed disclosure of interest forms for all authors are provided as supporting information.

Contribution to Authorship

AAS, EJTN, MAEN and TEJI designed the study and data was collected by AAS, MAEN and TEJI. MAEN, TEJI, and OMH performed or supervised all robotic surgeries. Statistical analyses were performed by AAS and results were interpreted by AAS, MAEN, TEJI and EJTN. AAS drafted the manuscript, which was critically reviewed and approved by all other authors.

Details of Ethical Approval

This project has received ethical approval from the Royal Marsden Committee on Clinical Research on 17-11-2022. Project number SE1234.

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Table/Figure Caption list

Table 1 – Baseline characteristics of training and non-training cases.

Table 2 – Peri-operative and survival outcomes in training and non-training cases.

Table 3 – Multivariable logistic regression on the effect of training on post-operative outcomes and cox proportional hazard ratios for disease-free and disease-specific survival.

Figure 1 – 5-year disease-free survival for training and non-training cases.

Figure 2 – 5-year disease-specific survival for training and non-training cases.

Table/Figure legends

Table 1 - ASA, American Society of Anesthesiologists; BMI, body mass index; FIGO, International Federation of Gynecology and Obstetrics; LN, lymph node. Data are presented as n (% of training cases/non-training cases, rounded to one decimal).

*Post-hoc analyses were performed for WHO performance status, histology and grade and p-values were adjusted following the Bonferroni method .

Table 2 – EBL, estimated blood loss; CCU, critical care unit. Data are presented as n (% of training cases/non-training cases, rounded to one decimal). The distribution of Clavien-Dindo complications is

presented as a percentage of all complications per group. *Post-hoc analyses were performed for CCU-admission and p-values were adjusted following the Bonferroni method .

Table 3 – LOS, length of stay; CI, confidence interval. Odds and hazard ratios are corrected for stage, grade and age. Stage was divided in stage 1 or [?]2. Grade was divided in low (grade 1 and 2) and high grade (grade 3). Age was categorised per five years.

Figure 1 - 5-year disease-free survival for training and non-training cases. Kaplan-Meier curves for 60 months of follow-up are presented. Training cases are depicted in green and non-training cases are depicted in blue.

Figure 2 – 5-year disease-specific survival for training and non-training cases. Kaplan-Meier curves for 60 months of follow-up are presented. Training cases are depicted in green and non-training cases are depicted in blue.

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