Introducing a novice surgeon to an experienced robotic gynaecological oncology team: an observational cohort study on the impact of a structured curriculum on outcomes of cervical cancer surgery.

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April 11, 2023

Abstract

Objective Effect on patient outcomes when introducing a novice robotic surgeon, trained in accordance with a structured learning curriculum, to an experienced robotic surgery team. **Design** Observational cohort study. **Setting** Tertiary referral centre. **Population** Patients with early-stage cervical cancer who were treated with primary robot-assisted surgery between 2007 and 2019. In addition to the 165 patients included in a former analysis, we included a further 61 consecutively treated patients and divided all patients over three groups: early learning phase of 61 procedures (group 1), experienced phase of the 104 procedures thereafter (group 2), and the final 61 procedures during introduction of a novice with structured training (group 3). **Methods** Risk-adjusted cumulative sum (RA-CUSUM) analysis was performed and patient outcomes between groups were compared. **Main Outcome Measures** Surgical proficiency based on recurrence, surgical and oncological outcomes. **Results** Based on RA-CUSUM analysis, no learning curve effect was observed for group 3. Regarding surgical outcomes, mean operation time in group 3 was significantly shorter than group 1 ($p<0.001$) and similar to group 2 ($p=0.96$). Proportions of intraoperative and postoperative adverse events in group 3 were not significantly different from the experienced group (group 2). Regarding oncological outcomes, the 5-year disease-free survival, disease-specific survival, and overall survival in group 3 were not significantly different from the experienced group. **Conclusions** Introducing a novice robotic surgeon, who was trained in accordance with a structured learning curriculum, resulted in similar patient outcomes as by experienced surgeons suggesting novices can progress through a learning phase without compromising outcomes of cervical cancer patients.

Manuscript version 1.0 – BJOG

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Running title: Learning curve of robot-assisted gynaecological surgery

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Methods Risk-adjusted cumulative sum (RA-CUSUM) analysis was performed and patient outcomes between groups were compared.

Main Outcome Measures Surgical proficiency based on recurrence, surgical and oncological outcomes.**Results** Based on RA-CUSUM analysis, no learning curve effect was observed for group 3. Regarding surgical outcomes, mean operation time in group 3 was significantly shorter than group 1 (p <0.001) and similar to group 2 (p =0.96). Proportions of intraoperative and postoperative adverse events in group 3 were not significantly different from the experienced group (group 2). Regarding oncological outcomes, the 5-year disease-free survival, disease-specific survival, and overall survival in group 3 were not significantly different from the experienced group.

Conclusions Introducing a novice robotic surgeon, who was trained in accordance with a structured learning curriculum, resulted in similar patient outcomes as by experienced surgeons suggesting novices can progress through a learning phase without compromising outcomes of cervical cancer patients.

Keywords Cervical cancer; robot-assisted surgery; learning curve; cumulative sum analysis

Introduction

Learning curve effects seem unavoidable when adopting new and complex surgical technologies.[1, 2] This appeared to be no different when robot-assisted surgery was adopted for gynaecological oncology two decades ago.[3] Since then, several studies in the gynaecological oncology field reported on short-term surgical outcomes of robot-assisted surgery during the learning curve, e.g. operation time or blood loss. Until recently, learning curve effect on long-term outcomes, such as survival, were often omitted.[4-7] Multiple studies on robot-assisted surgery for cervical cancer showed worse survival outcomes in early stages of the learning curve versus after mastery.[8-12] This learning curve effect could be one of the explanations for the results of recent retrospective and prospective studies reporting inferior survival of cervical cancer patients treated with minimally invasive surgery compared to open surgery.[13, 14] These results underscored the need for structured and validated learning curricula intended to improve quality of care when introducing surgeons to a new technology, while minimizing learning curve effects and patient harm.[15]

Since the adoption of the surgical robot by gynaecologists, the learning environment has evolved. Training modalities like virtual reality simulation, cadaver training, proctoring and use of dual consoles emerged and showed to be effective in acquiring robotic skills.[16-20] In the past years, these training modalities have been brought together into several structured learning curricula for robot-assisted gynaecological surgery, such as the Society of European Robotic Gynaecological Surgery (SERGS) curriculum.[21] A prospectively validated curriculum is, however, still lacking.[22] While training modalities keep evolving and qualitative research shows that fellows experience increased confidence when having access to these modalities, little is known about how existing curricula are performing in terms of actual skill acquisition, and how the acquired robotic skills translate into patient outcomes.[22, 23]

The aim of our study was to assess the learning curve of robot-assisted surgery for early-stage cervical cancer when introducing a novice robotic surgeon to an experienced surgical team and assess the effect on patient outcomes. Previously, we demonstrated a single-institutional learning curve required at least 61 procedures before levelling out when initially starting with robot-assisted surgery.[8] By expanding our cohort with 61 consecutively treated cases during introduction of a novice, who was trained in accordance with a structured learning curriculum, we evaluated whether the learning curve of this novice surgeon impacted surgical and oncological outcomes of early-stage cervical cancer patients.

Methods

Population and procedure

This article is an expansion of our previous publication where we performed an observational cohort study to assess the initial learning curve of robot-assisted surgery for early-stage cervical cancer. There, we demonstrated a learning phase of at least 61 procedures (of a single surgical team) with significant negative impact on the oncological outcomes of cervical cancer patients.[8]

In April 2017, after 165 procedures performed by a single surgical team (surgeon A + B), a novice robotic surgeon (surgeon C) was introduced, replacing one of the experienced surgeons. The newly introduced surgeon, who had previous experience with conventional laparoscopy, was trained in accordance with the structured and stepwise robotic training of the SERGS learning curriculum[24], including simulation and cadaver training, before he started in real-life patient setting under supervision of a proctor (surgeon B) in April 2017. The first 61 consecutive cases performed by this new surgical team (surgeon B + C) were added to our cohort, resulting in an updated total cohort of 226 cervical cancer patients treated between December 2007 and August 2019: the learning phase of 61 procedures (group 1), the experienced phase of 104 procedures thereafter (group 2), and the 61 consecutive procedures during introduction of a novice (group 3).

The same inclusion criteria were applied: patients diagnosed with FIGO 2009 stage IA1 (with lymph-vascular space invasion (LVSI)) up to IB1 or IIA1 cervical cancer who were consecutively treated with primary robot-assisted laparoscopy.[25, 26] The FIGO 2009 edition was used as reference because a majority of cases were staged according to this FIGO edition. Excluded were patients with ongoing pregnancy or who were treated with neoadjuvant chemotherapy (EORTC 55994).

All robot-assisted procedures were performed at our tertiary referral centre using the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA, type S until 2010, Si until 2018, and X or Xi since 2018 onwards). During the inclusion period, robot-assisted surgery was the standard of care, with laparotomy only performed incidentally for those who had an absolute contraindication (e.g. advanced pregnancy). All details on surgical technique, data collection, and statistical analysis were described previously.[8]

Data collection and statistical analysis

Clinical, surgical, histopathological and follow-up data were collected from medical records. Baseline characteristics were compared between the different learning phases. The institutional review board approved this study and waived individual consent requirements for the use of these pseudonymised retrospective data. Participants were not involved in the development of this analysis and no core outcome sets were used in this study.

Primary outcome of interest was surgical proficiency when introducing a novice, based on cervical recurrence rate. To evaluate surgical proficiency (i.e. learning curve) in this new phase, a risk-adjusted cumulative sum analysis (RA-CUSUM) was performed (see previous publication for a detailed description of this analysis[8]). The probability of recurrence for each individual patient was modelled by a multivariate logistic regression analysis. To prevent overfitting, we limited this model to three degrees of freedom. As previously described, we used two RA-CUSUM functions: the RA-CUSUM+ chart, designed to detect a doubling of the odds of recurrence, and the RA-CUSUM- chart, designed to detect a halving of the odds of recurrence. Details of these RA-CUSUM functions are provided in the supplementary material (Appendix S1).

Secondary outcomes were disease-free survival (DFS), disease-specific survival (DSS) and overall survival (OS) in this new phase compared to the previous phases. Survival was defined as the time interval between date of diagnosis or first visit and date of disease recurrence diagnosis (DFS), diagnosed clinically, by imaging, or histopathological biopsy, or death due to the sequelae of cervical cancer (DSS) or death from any cause (OS). Survival curves were estimated using Kaplan-Meier method and the newly added group (group 3) was compared with the previous groups (group 1 and group 2) using log-rank test: group 1 versus group 3 and group 2 versus group 3.

In addition to the previous analysis, we also assessed differences in operation time and short-term surgical complications between the three learning phases. Operation time was defined as the time (in minutes) between first incision and end of closure by the surgeon. If the procedure was performed in two tempi the operation time of the uterine procedure was included in the analysis. All intraoperative complications, defined as complications diagnosed intraoperatively and postoperative complications within 42 days were registered in adherence to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 (published November 27, 2017).[27] In the current analysis main focus was on severe surgical complications, i.e. grade 3 to 5 adverse events.

Continuous data were compared between the groups using one-way analysis of variance (ANOVA) or its non-parametric counterpart, as appropriate. In the event of significance, post-hoc tests were conducted to determine differences between each pair of groups. Categorical data were reported as proportions and compared between groups using chi-square test or Fisher's exact test, as appropriate. Statistical tests were two-sided with significance set at $p<0.05$, with confidence intervals (CI) at the 95% level.

Analyses were performed using the Statistical Package for the Social Sciences version 27.0.0 (SPSS; International Business Machines, Armonk, NY, USA) and Microsoft Excel 2016 (Microsoft, Redmond, WA, USA).

Results

Baseline characteristics of cohort

Table 1 shows the baseline characteristics of the three groups: early learning phase of 61 procedures (group 1), experienced phase of 104 procedures thereafter (group 2), and 61 procedures during introduction of a novice surgeon (group 3). Patients characteristics were comparable for the newly added group 3. Median follow-up duration and number of lymph nodes harvested (based on pathology report) were significantly lower in group 3 compared to group 1 and group 2. In all groups the majority of patients completed 3-year follow-up at the time of data collection: 56 patients (91.8%) in group 1, 96 patients (92.3%) in group 2, and 54 patients (88.5%) in group 3 (p =0.76).

In total 52 (23.0%) patients received adjuvant therapy; proportions across the three groups were not significantly different (see Table 1). Indications for adjuvant therapy (i.e. chemoradiation or radiotherapy) included positive lymph nodes (n = 27), parametrial invasion (n = 6), positive or insufficient resection margins (n = 10), fulfilled Sedlis criteria (n = 3)[28], or a combination of any of these criteria (n = 5). One patient received chemoradiation because radical hysterectomy was unachievable due to extensive pelvic fibrosis.

Learning curve

Based on significant predictors in univariate logistic regression, multivariate risk models were fitted. The final multivariate risk model used for RA-CUSUM analysis included age (odds ratio = 1.03, 95% CI 1.00-1.06, p=0.03) and adjuvant or adjusted treatment (odds ratio = 3.15, 95%CI 1.41-7.04, p=0.01), which summarises multiple prognostic factors significant at univariate analysis (e.g. lymph node status, LVSI and tumour size). Adjusted treatment was defined as replacing radical hysterectomy with chemoradiation because of an intraoperative finding of positive lymph node at frozen section.

Figure 1 shows the expanded RA-CUSUM charts. From the introduction of the novice surgeon (group 3) no new peak in RA-CUSUM+ chart is observed and the chart moves around zero, indicating satisfactory results with regard to the observed recurrence rate. The RA-CUSUM- chart, indicating further improvement of surgical performance by moving more negatively, has stabilized in group 3 and does not show further improvement.

Surgical outcomes

Operation time significantly decreased with increasing case volume: cases in group 1 had a significantly longer operation time compared to group 2 and group 3 (both p <0.001). Operation time in the newly added group 3 was similar to group 2 (p =1.00) (**Figure 2**).

In 50 patients a grade 3-4 (severe) adverse event occurred at any time during follow-up of whom 31 patients (19.4%) had a grade 3-4 adverse event that occurred intraoperatively or within the initial 42 postoperative days. No grade 5 event (death related to surgery) occurred. The number of severe adverse events was highest in group 1 but did not significantly differ between the three groups: 13 patients (21.3%) in group 1, 10 (9.6%) patients in group 2, and 8 (13.1%) patients in group 3 (p =0.11)(see **Table 1**). When comparing the three groups separately, the proportion of severe adverse events in group 3 was not significantly different from group 1 and group 2, but severe adverse events were significantly lower in group 2 compared to group 1 (p =0.04).

One case was converted to conventional laparoscopy because technical issues hindered robot-assisted surgery (i.e. clashing robotic arms). No intraoperative surgical adverse events necessitated a direct conversion to laparotomy or laparoscopy. **Table 2** provides an detailed overview of all intraoperative and postoperative grade 3-5 adverse events within 42 days after surgery, of which multiple adverse events could occur in one patient. In total 36 severe adverse events occurred within 42 days in 31 patients: 28 grade 3 events in 23 patients and eight grade 4 events in eight patients. Six patients underwent laparotomy as a secondary procedure to manage their grade 4 adverse event: three with ureter injury, two with postoperative hypovolemic shock due to intraabdominal haemorrhage, and one with perforation of the sigmoid. One patient with a grade 4 event needed surgical intervention for a severe cervical bleeding but no laparotomy. The eighth patient with a grade 4 event had an obstructed airway caused by a pneumomediastinum. This was detected directly after detubation and managed by reintubation and ICU admission where laryngoscopy excluded an airway injury.

Regarding the distribution of severe adverse events across the three groups, a shift from intraoperative to postoperative adverse events was observed: in group 1 four intraoperative events occurred compared to zero in group 3. This shift is inherent to the shift from severe urological injuries to postoperative symptomatic lymphoceles (see**Supplementary Table S1**). Subgroups of adverse events were too small to perform reliable statistical analysis on.

Oncological outcomes

In total 31 patients (13.7%) developed a recurrence of whom 28 patients (reflecting 12.4% of total cohort) developed the recurrence within five years of follow-up: 12 patients (19.7%) in group 1, eight patients (7.7%) in group 2, and eight patients (13.1%) in group 3. All three late recurrences occurred in group 1; compared to the previous analysis, one additional late recurrence (i.e. time interval of 14 years between diagnosis and recurrence) was observed. Ten patients in group 1 (10/15, 66.7%), eight patients in group 2 (8/8, 100%), and six patients in group 3 (6/8, 75.0%) presented with a locoregional recurrence of top of vagina, cervical tissue, pelvic side wall, and/or pelvic lymph nodes (with or without additional distant recurrence). The other patients presented with distant recurrence only. The 5-year DFS in group 1 and group 2 was similar to what was previously reported (slightly different because of the updated follow-up times): 80.3% in group 1 and 91.8% in group 2. In the newly added group 3, the 5-year DFS was 86.4%.

In total 16 patients died due to the sequelae of cervical cancer: nine patients (14.8%) in group 1, three patients (2.9%) in group 2 and four patients (6.6%) in group 3. Compared to the previous analysis, two additional patients died of disease within five years of follow-up in group 2, leading to the following 5-year DSS rates: 84.8% in group 1, 96.5% in group 2 and 92.9% in group 3. Two patients in this cohort died of other cases, both in group 2, leading to the following 5-year OS rates: 84.8% in group 1, 94.3% in group 2, and 92.9% in group 3.**Figure 3** shows the Kaplan-Meier curves of 5-year DFS, 5-year DSS and 5-year OS of the three groups altogether.

When the newly added group 3 was compared to group 1, no significant differences existed in either the 5-year DFS (p =0.36), 5-year DSS or 5-year OS (p =0.22). Also, when group 3 was compared to the experienced phase, group 2, no significant differences existed in either the 5-year DFS (p =0.25), 5-year DSS (p =0.15) or 5-year OS (p =0.37).

Discussion

Main Findings

Our results show that a novice robotic surgeon, who was trained in accordance with the SERGS structured learning curriculum and started under proctor supervision, can pass through a learning phase without compromising the surgical and oncological outcomes of cervical cancer patients treated with robot-assisted surgery. The expanded RA-CUSUM analysis (**Figure 1**), used to assess the learning curve, revealed no new peak in the last 61 cases (group 3), which indicates the observed recurrence rate remained as expected after introduction of the novice surgeon. Also, the mean operation time remained equal compared to the preceding experienced phase (group 2). Furthermore, short-term surgical outcomes, defined as severe (grade 3-5) adverse events occurring intraoperatively or within the first 42 days postoperatively, were not significantly increased. Using Kaplan-Meier curves (**Figure 2**), the 5-year DFS, DSS and OS during introduction of the novice (group 3) showed to be lower than in the experienced phase (group 2) and higher than in the early learning phase (group 1), but no significant difference in survival outcomes existed. Although based on a single surgical team, our results suggest that structured training (including proctoring) performs better than unstructured training (consisting of case observation, box training, and limited proctoring), which was available for novices during the initial phase (group 1).[8]

Strengths and Limitations

To our best knowledge, this is the first study presenting a learning curve analysis during introduction of a novice robotic surgeon in the gynaecological oncology field. We used RA-CUSUM analysis, which is considered the reference standard for studying surgical learning curves[29] and has an additional value in its individual risk adjustment compared to standard CUSUM analysis wherein parameters are set based on literature. Another strength is that we use oncological outcomes, i.e. survival, which is considered the foremost relevant measure of performance when treating cancer. We were able to correlate these oncological outcomes to the introduction of a novice to an experienced surgical team.

Several limitations to this study exist. Since we report a single-institution analysis of a small surgical team, our results might not be transferrable to other centres. Although the reported learning curves should be considered institutional learning curves, given the team effort of robotic procedures, individual aspects within the small surgical team could contribute to different outcomes in other centres. Not all surgeons new to robot-assisted surgery will learn at the same pace. With the current analysis we are not able to present an individual learning curve for the novice surgeon, as the learning curve fades into the institutional learning curve. To quantify the performance of a structured learning curriculum, validation in larger, preferably multicentre, datasets is warranted.

We expanded our cohort with 61 procedures as we previously reported this to be the learning phase. Inherently, the follow-up times of the latter group are shorter and additional recurrences could present in the upcoming years as not all patients in group 3 have completed the recommended five years of follow-up yet. However, the majority of patients in group 3 completed three years of follow-up, the period in which most recurrences occur. More importantly, Kaplan-Meier curves were used to correct for differences in follow-up time through censoring.

Interpretation

Recently, several studies showed that surgical proficiency and surgical volume seem to play a substantial role in the oncologic outcomes of patients with early-stage cervical cancer treated with a surgical robot, with reported learning curves varying from 19 to 77 cases.[9-12] Analysing our own cohort retrospectively, we demonstrated a learning curve of at least 61 procedures during which the survival of patients was inferior to the experienced phase thereafter.[8] These nationwide and institutional studies all started their inclusions from the first robot-assisted procedures, soon after the robot was adopted for gynaecological purposes. In the early days of robot-assisted surgery, a structured learning curriculum, as we know it today, did not exist.[30] Now that several structured learning curricula for robot-assisted surgery within gynaecological oncology exist[31, 32], it is critical to assess its performance in terms of patient outcomes.

Studies in prostate, pancreas and oesophageal cancer already showed that a structured learning curriculum allows for safe introduction of less experienced robotic surgeons without compromising patient outcomes. Their results were mostly based on surgical outcomes such as operation time, blood loss and specimen radicality.[33-35]Regarding oncological outcomes, several studies performed after the LACC trial suggest it would be safe to continue with minimally invasive surgery when performed by experienced (high-volume) surgeons.[36, 37] However, these studies do not specify how the surgeons were trained, other than one study mentioning the surgeons were fellowship-trained.

Importantly, learning curve effects do not merely apply to robot-assisted surgery. In cervical cancer specifically, research showed that surgeons in the early phase of laparoscopic and open radical hysterectomy are also subjected to a learning curve.[12]Results from studies across the full spectrum of medical specialities and procedures suggest that the learning curve concept applies to adopting many complex surgical procedures, if not all.[2, 38-40] Such a learning curve should not be perceived as negative but surgeons need to understand how to limit its effect on patient outcomes while effectively acquiring skills.

In group 3 a lower number of lymph nodes were harvested at pelvic lymph node dissection compared to the other two groups, which could not be explained. No clear consensus exists regarding the relationship between surgical experience and number of lymph nodes harvested.[41, 42] The number of lymph nodes removed was not associated with the recurrence rate (non-significant in univariate logistic regression).

Robot-assisted surgery is evolving fast and training programs have a hard time keeping up.[43] In previous years, several curricula for robot-assisted gynaecological surgery have been developed, including the SERGS curriculum, which is based on the (so far only) validated curriculum of the European Association of Urology (EAU) Robotic Urologic Section (ERUS).[31, 44] The SERGS curriculum follows a validated format[30] including didactic training, dry lab, virtual reality simulation, cadaver training, and a stepwise approach of patient training with a minimum of 10 proctored cases.[24] Although volume based criteria are not completely abandoned yet, focus is shifted towards competency based criteria. Still, as our results also show, room for further improvement exists since curricula are a crucial step in the standardisation of training and certification of robotic surgeons. Besides curricula development, strategies to assess maintenance of robotic proficiency and to teach the trainers are also needed.[45]

Quantitative robot-generated performance metrics, so far a rather unused potential in robot learning curricula, could play a crucial role in improving robotic training.[46] Incorporating these metrics into a curriculum could be an inexpensive and effective way to quantify skill acquisition. Research on learning curves of conventional laparoscopy trainees already demonstrated that use of force, motion and time metrics could indicate progression of skills over time.[47-49] Future areas of research should include validating existing curricula, determining how to translate the acquired skills into patient outcomes (prospectively), and find strategies to assess maintenance of surgical proficiency.

Conclusion

Based on these single-institution results, introducing a novice robotic surgeon who was trained in accordance with a structured curriculum did not significantly compromise surgical or oncological outcomes of early-stage cervical cancer patients treated with robot-assisted surgery. Further research should explore ways to objectively quantify skill acquisition during training and, thereby, minimize the impact of learning curves on patient outcomes.

Acknowledgements

The authors are grateful to R.H.M. Verheijen (emeritus professor Gynaecological Oncology, UMC Utrecht) for his contribution to this study and to the manuscript.

Disclosure of Interests

RPZ is a proctor for robot-assisted surgery in gynaecological oncology on behalf of Intuitive Surgical. All other authors declare they have no conflicts of interests related to the presented research.

Contribution to Authorship

IGTB : Conceptualization, Methodology, Formal analysis, Investigation, Writing – Original Draft, Visualisation. **JPH** : Conceptualization, Methodology, Validation, Writing – Review & Editing. **HWRS** : Validation, Writing – Review & Editing.**IMJ** : Validation, Writing – Review & Editing. **CGG** : Conceptualization, Methodology, Validation, Writing – Review & Editing. **RPZ** : Conceptualization, Methodology, Validation, Writing – Review & Editing, Supervision.

Details of Ethics Approval

This study was based on the departmental complication and treatment outcome register for robot-assisted surgery, which is maintained as a part of standard clinical care and primarily aims to improve that care. The institutional review board approved this study and waived individual consent requirements for the use of these pseudonymised retrospective data in accordance to Dutch law. The Medical Research Involving Human Subjects Act (WMO) did not apply to our study and therefore official approval by the Medical Research Ethics Committee was not required under the WMO (MREC number 21-250, date April 7th 2021).

Funding

None.

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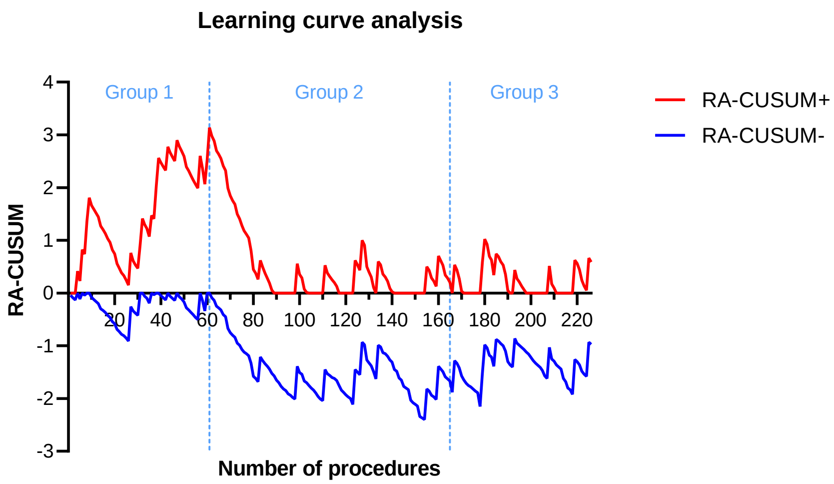
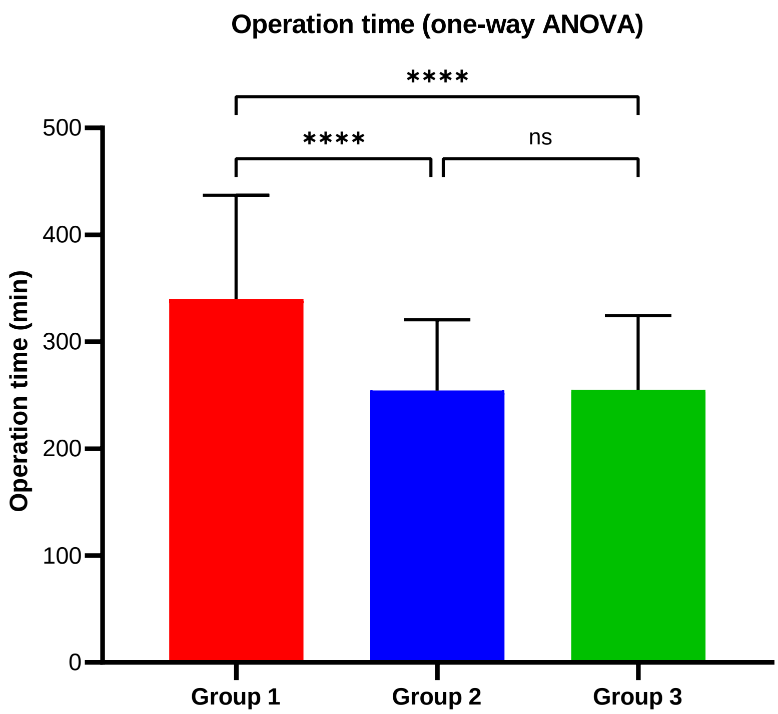
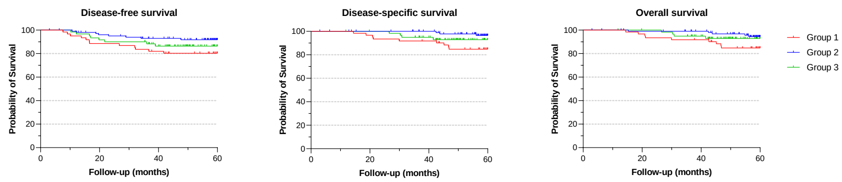
Figure legends

Figure 1.	Learning curve of robot-assisted surgery for treating early-stage cervical cancer. The x-axis indicates the numb
Figure 2.	One-way ANOVA of operation time (start of incision until end of closure) per group
Figure 3.	Survival curves: 5-year DFS (A), 5-year DSS (B), 5-year OS (C).







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