

Safe Implementation of Robotic Surgery for Gynecologic Diseases at a Tertiary Center: Retrospective Analysis of 149 Cases and Review of the Literature

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Abstract

Objectives: The initial learning curve is a barrier to introducing robotic surgery. Evidence regarding appropriate simulation programs that allow for a smooth introduction of gynecological robotic surgery remains limited.

Materials and Methods: We retrospectively analyzed 149 patients who underwent robotic surgery for gynecologic diseases. Before their first procedure, the surgeons completed a robotic surgery training program. Assistant surgeons also completed simulation programs, including setup procedures and manipulation of the robotic arm.

Results: The mean (\pm standard deviation) operative, setup, and console times were 170 ± 54 min, 22 ± 8 min, and 126 ± 51 min, respectively. No patient required blood transfusion or conversion to laparoscopy or laparotomy. Patients undergoing surgery by the same surgeon were divided into three groups (first-third, middle-third, and last-third of patients undergoing surgery) to assess chronological changes. No statistically significant differences were found between the operative and console times among these groups. The setup times for the middle and last third of patients were 20 ± 7 min and 18 ± 7 min, respectively, which were statistically significantly shorter than those for the first third of patients. No significant differences in the operative and console times done by five physicians who completed programs were observed between the first 75 and the latter 74 procedures; however, the setup times of the latter 74 procedures were significantly shorter than those of the first 74 procedures (25 ± 9 min vs. 19 ± 6 min; $P < 0.001$).

Conclusion: The setup time was influenced by clinical experience. An appropriate simulation program allowed a safe implementation of robotic surgery.

Keywords: Hysterectomy, learning curve, robotic surgery

INTRODUCTION

Although robotic surgeries have been rapidly adopted for minimally invasive hysterectomy because of their shorter learning curve compared to that with laparoscopic surgery, their surgical platforms require special training to allow for safe performance and familiarization with all associated features before they can be initiated. In the field of gynecology, robotic surgery has been steadily increasingly performed since it was first covered by health insurance in Japan. A robotic

platform has been applied to hysterectomy for benign diseases (leiomyoma, adenomyosis, and endometriosis) and early-stage endometrial cancer with or without pelvic lymphadenectomy (PLA). We introduced a robotic platform in our Department of Gynecology in 2019.

The advantages of robotic platforms have been reported, including their three-dimensional, surgeon-controlled view, comfortable ergonomics, and wristed instruments that allow

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for precise and delicate movements.^[1] Without robotics, these factors may contribute to the quality of surgeries and the fatigue of surgeons.^[2] However, the initial learning curve has been considered a burden, even for experienced laparoscopic surgeons^[2] with longer total operative time, indicating that inexperienced surgeons may encounter technical difficulties when introducing robotic surgery.

Although several retrospective studies that analyzed the technical learning curve of gynecologic robotic surgery have been published, evidence regarding appropriate simulation programs remains limited.^[3-6] Here, we established a simulation program and evaluated its efficacy during the introduction phase to shorten the learning curve. We also analyzed surgical outcomes during the same period.

MATERIALS AND METHODS

We retrospectively reviewed the medical records of all gynecological patients who underwent robotic surgery at Keio University Hospital between July 2019 and August 2021. This study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Keio University School of Medicine (Institutional Review Board approval numbers: 20120243, 20150105, and 20150197; approval date: 03/29/2021, 12/27/2021 and 04/26/2021). Informed consent was obtained in the form of an opt-out.

Simulation program

Each surgeon and medical staff member underwent a thorough training and simulation program using the da Vinci® Xi Surgical System prior to the initial surgery. Physicians performing their first robotic surgery completed training with the da Vinci® simulator twice per week for at least 1 month prior to performing their first robotic surgery. Assistant physicians also attended demonstrations regarding the setup procedures and robot arm manipulation in the operating room. We reviewed each procedure with anesthesiologists and nurses approximately 1 week before the first surgery.

One surgeon who performed the first robotic surgery (Surgeon A) conducted an initial series of surgeries comprising benign diseases (5 cases) and endometrial cancer (10 cases) at our institution. After surgeon A completed surgeries for the aforementioned series of cases, other physicians who had completed the training program performed robotic surgeries. When these physicians performed their first robotic surgeries, Surgeon A participated in each surgery and supported the setup and console procedure. The training program mentioned above was set up within our institution and was not provided by the company.

Assessment of surgical outcomes

We retrospectively reviewed the medical records, including

the operative time and intraoperative or postoperative complications, with regard to the chronological order of each surgery. Data including basic demographic information, body mass index (BMI; calculated as weight [kg]/height² [m²]), parity, medical history, operative time, intraoperative injury, uterine weight, conversion to laparoscopy or laparotomy, and postoperative complications within 6 weeks after surgery were collected. The operative time was defined as the time of the initial incision until its closure. The operative time included setup time, which was defined as the time from making the initial incision until the time the surgeon began operating the console, and console time, which was defined as from the time the surgeon began operating the console until the time the surgeon completed operating the console. The presence of adhesions attributable to endometriosis and the size of the uterus (normal size or not) were evaluated by two gynecologists reviewing intraoperative images.

For surgeries, including PLA for endometrial cancer, information about laparoscopic surgery performed by the same surgeon during the same period was also collected from medical records for comparison with those through robotic surgery. We defined severe lymphedema as lymphedema requiring specialized outpatient care. Ultrasonography and computed tomography (performed for endometrial cancer follow-up) were used to determine the presence of lymphatic cysts.

Literature review

We searched PubMed using the following search terms: “robotic surgery,” “gynecology,” “hysterectomy,” and “learning curve.” We selected 180 publications, reviewed all the articles, and excluded the following irrelevant articles: 17 review articles (16 reviews, 1 editorial); 10 articles about single-site surgery; 18 articles about radical hysterectomy for cervical cancer, para-aortic lymphadenectomy, myomectomy, or ovarian cystectomy; and 27 articles that did not show chronological changes in operative times. Finally, eight references were selected, and their results were compared with ours.

Statistical analysis

Statistical analysis was performed using JMP® 15 (SAS Institute Inc., Cary, NC, USA). We used the *t*-test for BMI and operative time, the Wilcoxon test for blood loss, and Fisher’s exact test for the remaining variables. Tukey’s honestly significant difference test was used to compare operative times among the three groups. Statistical significance was set at *P* < 0.05.

RESULTS

Patient characteristics and surgical outcomes

A total of 149 patients were identified. The mean age at

the time of surgery was 50.8 years (standard deviation [SD], ± 7.8 years), and the mean BMI was 24.4 kg/m² (SD, ± 5.2 kg/m²). Eighty-two patients (55%) with benign diseases, including leiomyoma, adenomyosis, cervical intraepithelial neoplasm, and endometrial hyperplasia/atypical endometrial hyperplasia, and 67 patients (45%) with Stage IA endometrial cancer underwent robotic surgery. Thirty-two patients (21%) had a history of laparotomy.

All patients underwent hysterectomy, and PLA was conducted for 22 (15%) patients. The mean total operative, setup, and console times were 170 min (SD, ± 54 min), 22 min (SD, ± 8 min), and 126 min (SD, ± 51 min), respectively. The mean total operative and console times for patients without lymphadenectomy were 155 min (SD, ± 35 min) and 111 min (SD, ± 32 min), respectively. A frozen section diagnosis was performed for all endometrial cancer patients to determine whether PLA was necessary. The median blood loss was 5 g (range, 5–300 g), and the median weight of the resected uterus was 280 g (range, 50–1210 g). The median length of hospital stay was 5 days (range, 3–9 days). None of the patients required blood transfusions or conversion to laparoscopy or laparotomy. No bladder or bowel injuries were observed during the study.

Learning curve of the operative time

We analyzed the learning curve of each surgeon in chronological order. All physicians performed robotic hysterectomy with a short learning curve and consistent operative times compared with those reported in previous studies. Figures 1 and 2 present the learning curves for all surgeons and surgeon A, who first completed our simulation

program. Furthermore, learning curves for robotic surgeries performed for benign and malignant diseases were analyzed separately; both had stable console times throughout the study period [Figure 3].

We divided the 63 patients of Surgeon A into three groups to analyze any chronological changes in surgical outcomes (the first one-third of patients comprised Group A [$n = 21$]; the middle one-third of patients comprised Group B [$n = 21$]; the last one-third of patients comprised Group C [$n = 21$]). The surgical outcomes of each group are shown in Table 1. Patient characteristics were similar across these groups. Group C had higher rates of adhesion attributable to endometriosis and a lower incidence of normal uterine size. These results indicated that the last one-third of patients had difficult surgical cases. The mean setup times of Groups B and C were 20 min (SD, ± 7 min) and 18 min (SD, ± 7 min), respectively, which were significantly shorter than that of Group A (28 ± 7 min). No statistically significant differences in console times among the three groups were observed.

In terms of program, surgeon A managed the first five benign cases and 10 malignant (endometrial cancer) cases, followed by surgeon B, surgeon C, surgeon D, and surgeon E, who started to perform the robotic surgery sequentially. We divided the surgeries into the first half (first 75 surgeries) and the latter half, more of the first 75 surgeries were performed by surgeon A (first surgeon) than by surgeon B through surgeon E. Surgeon A performed more of the first half of surgeries than the latter half of the surgeries (57% vs. 27%; $P < 0.001$). In terms of the resected uterine size, the incidence of cases with a normal uterine size among the first half of

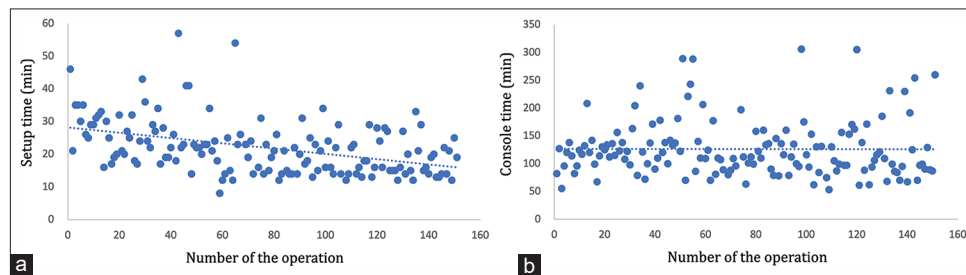


Figure 1: Learning curve for all surgeons. Although the setup time shortened over time (a), the console time was stable from the beginning (b)

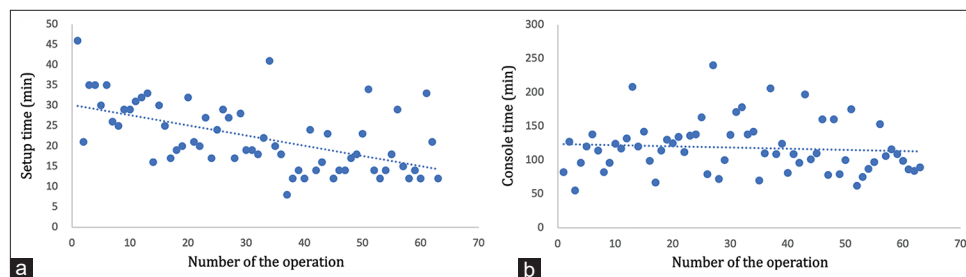


Figure 2: Learning curve for surgeon A (who performed the most surgeries). The setup time shortened over time (a), whereas the console time was stable from the beginning (b)

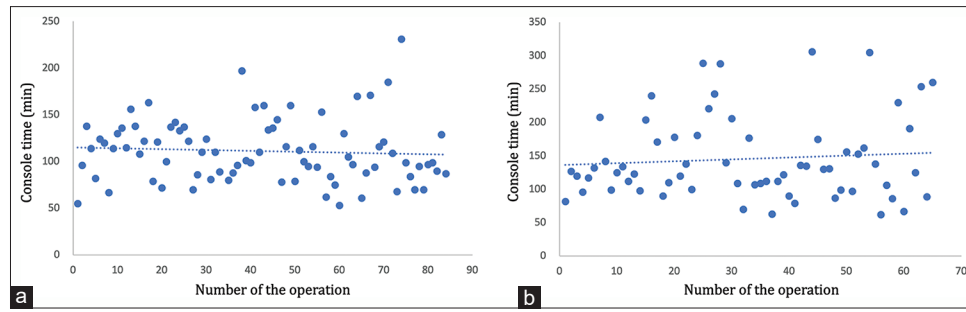


Figure 3: Learning curve for benign diseases (a) and endometrial cancer (b). The console time was stable from the beginning for both benign and malignant diseases

Table 1: Chronological changes in outcomes of surgeries performed by surgeon A

	Group A, patients 1–21, <i>n</i> (%)	Group B, patients 22–42, <i>n</i> (%)	Group C, patients 43–63, <i>n</i> (%)
Patient characteristics			
BMI (kg/m ²), mean±SD	22.6±4.7	24.0±4.1	25.1±5.0
History of laparotomy	3 (14)	5 (24)	4 (19)
Surgery details			
Lymphadenectomy	1 (5)	4 (19)	2 (10)
Adhesions attributable to endometriosis	3 (14)	4 (18)	9 (43)
Normal uterine size	10 (48)	14 (67)	6 (29)
Operative time (min), mean±SD			
Total operative time (min)	164±30	171±50	151±40
Setup time (min)	28±7	20±7	18±7
Console time (min)	115±32	129±44	111±37
Blood loss, g (range)	5 (5–100)	5 (5–150)	5 (5–320)

SD: Standard deviation, BMI: Body mass index

surgeries was significantly higher than that among the latter half of surgeries (59% vs. 42%; $P = 0.040$), and the rate of adhesion attributable to endometriosis among the latter half of surgeries tended to be higher than that of the first half of surgeries (15% vs. 23%; $P = 0.193$), indicating that more complicated cases were included during the expansion of robotic surgery. No significant differences in patient characteristics or the amount of blood loss were observed between these two groups. Although no significant differences in the total operative and console times were observed, the setup time of the latter half of surgeries was significantly shorter than that of the first half of surgeries (25 ± 9 min vs. 19 ± 6 min; $P < 0.001$).

Surgical outcomes of endometrial cancer cases with pelvic lymphadenectomy

Among the 149 surgeries, 22 included PLA for endometrial cancer. We compared 20 laparoscopic surgeries, including PLA for endometrial cancer, which were conducted by the same surgeon performed during one period. The outcomes of the robotic and laparoscopic surgeries were compared as shown in Table 2. The median number of retrieved nodes during robotic surgeries was 39 (range, 18–69), which was similar to the number resected during laparoscopic surgeries. The BMI was higher among patients who underwent robotic

surgery (25.8 ± 6.1 kg/m² vs. 22.9 ± 4.9 kg/m²; $P = 0.0090$), and the incidence of normal uterine weight was significantly higher among patients who underwent laparoscopic surgery (41% vs. 75%; $P = 0.033$). Although the difficulty of the surgery may have been greater in terms of BMI and uterine size, the operative time tended to be shorter for robotic surgery (258.2 ± 57.9 min vs. 285.7 ± 42.7 min; $P = 0.090$). No intraoperative or intraoperative/delayed organ injuries were observed in either group. The rate of postoperative lymphatic cysts was lower in the robotic group (5% vs. 20%; $P = 0.175$), but it was not statistically significant.

Literature review

The extracted references are listed in Table 3. The number of cases analyzed by the selected eight studies ranged from 20 to 154; four articles included benign cases, one article included malignant cases, and two articles included both benign and malignant cases. Although Akazawa *et al.* investigated robotic surgeries including PLA,^[8] no cases of para-aortic lymphadenectomy were included in the aforementioned articles. In terms of the learning curve analysis, Tang and Tsai analyzed the operative times of each part of the procedure;^[4] however, the total operative time was analyzed by six studies.^[5–10] The majority of articles indicated that it is necessary to perform approximately 20–40 procedures before

Table 2: Comparison of outcomes of robotic and laparoscopic surgery including pelvic lymphadenectomy

	Robotic surgery (n=22), n (%)	Laparoscopic surgery (n=20), n (%)	P
Patient characteristics			
BMI (kg/m ²), mean±SD	25.8±6.1	22.9±4.9	0.090
History of laparotomy	2 (9)	2 (10)	1.000
Surgery details			
Adhesions attributable to endometriosis	1 (5)	2 (10)	0.598
Normal uterine size	9 (41)	15 (75)	0.033
Operative time (min), mean±SD	258.2±57.9	285.7±42.7	0.090
Blood loss (g), median (range)	5 (5–350)	37.5 (5–450)	0.240
Intraoperative/delayed organ injury	0	0	1.000
Results and complications of lymphadenectomy			
Dissected lymph nodes, median (range)	32 (18–69)	33.5 (14–66)	0.715
Severe lymph edema	0	1 (5)	0.476
Pelvic lymphocyst	1 (5)	4 (20)	0.175
Cellulitis/lymphocyst infection	0	1 (5)	0.476

BMI: Body mass index, SD: Standard deviation

the operative time stabilizes during the introduction phase of robotic surgery.^[7–10] The rate of intraoperative complications was relatively high (range, 5%–9%) in three studies.^[7,9,10] In contrast to previous studies, we observed a shorter learning curve and no intraoperative complications.

DISCUSSION

Our study provides valuable data regarding the safe implementation by simulation platform at one of Japan's largest academic medical centers. Learning curves should be quantified using patient-oriented (postoperative complications, optimal resection of diseased tissue) or procedure-oriented (operative time including docking time) factors. We retrospectively demonstrated the safe introduction of a robotic platform and expanded robotic surgery for gynecologic diseases. We observed stable total operative and console times from the introduction phase, although the setup time did not become stable until after the completion of 21 procedures.

The learning curve for robotic hysterectomy for the benign gynecologic disease was analyzed, and the total operative time ranged from 131 to 181 min.^[5–7] The operative outcome of our results was similar to the aforementioned studies. In other studies, including surgery for malignant disease, it was revealed that the mean or median operative time ranges from 75 to 147 min.^[8–10] Although the operative times reported by these studies were shorter than that of our study, our median uterine weight was heavier than that reported by the aforementioned studies, and the rate of cases requiring PLA was different. Moreover, the operative time in our study included the time required for the intraoperative frozen section diagnosis which usually takes approximately 30 min. Therefore, our operative time is not inferior to those observed in previous studies. This suggests that we could perform robotic surgery from the early introduction phase with rapid

operative times and without intraoperative complications. We did not observe any intraoperative complications of PLA cases, and the mean operative time was equal or superior to that of laparoscopic surgeries performed by the same surgeon. These results also support the successful introduction of robotic surgery for endometrial cancer cases.

Regarding the learning curve, our total operative and console times were already stabilized at the beginning of 21 surgeries when analyzing 63 procedures by the same surgeon. Previous studies demonstrated that 9–40 procedures were required before stabilization of the operative time for robotic hysterectomy.^[5,7–10] Our operative time was already stabilized in the first 21 surgeries, indicating that our simulation program was useful. However, regarding the robotic surgery setup time, which is unique to robotic platforms, 21 procedures were required before stabilization occurred. Similar to our study, previous studies showed that 14 procedures were required before docking time stabilization occurred.^[4] The simulation program including assistants and operating room staff before surgery may have effectively reduced the setup time; however, expertise specific to robotic surgery and experience are essential.

An adequate simulation program is desirable when introducing robotic surgery because of its characteristic technique; however, a standardized and universal robotic surgery curriculum does not exist.^[11] Rusch *et al.* reported that the curriculum of the Society of European Gynaecological Surgery for robotic gynecological surgery is feasible and acceptable.^[12] However, the relationship with surgical outcomes in clinical practice has not been assessed. Our surgeons completed a training program using a visual simulator at least once per week for 1 month before performing their first robotic surgery. Previous reports showed that approximately 60% of gynecologists received <5 h of basic skills training;

Table 3: Review of literature

	Patients	Surgeon number and experience	Indications for surgery	Mean or median uterine weight (g)	PLA	Mean or median total operative time (min)	Learning curve	Mean or median blood loss (g)	Blood transfusion	Intraoperative complication
Tang and Tsai ^[4]	43	1, experienced	Benign	435.48±250.62	No	NA (only for each part)	8 cases for console time, 14 cases for docking time, 26 cases for suturing time	NA	NA	NA
Sendag <i>et al.</i> ^[5]	35	1, experienced	Benign	256.4±190.1	No	169±54.5	9 cases for total operative time	56.6±84.5	NA	0/35
Gutierrez <i>et al.</i> ^[6]	20	1, NA	Benign	205.9	No	180.7	Inverse correlation between the docking time and number of surgeries	NA	NA	NA
Elessawy <i>et al.</i> ^[7]	56	1, experienced	Benign	185.64	No	131.31	30 cases for total operative time	NA	0/56	5/56
Akazawa <i>et al.</i> ^[8]	81	1, experienced	Malignant	155 (85–835)	Yes	147 (80–345)	30–40 cases for total operative time	50 (50–300)	NA	0/81
Favre <i>et al.</i> ^[9]	154	2, experienced and less experienced	Benign and malignant	158.9±147.1	No	129.7±44.6	20 cases for total operative time (for the experienced physician)	62.7±97.1	1/154	7/154
Rajadurai <i>et al.</i> ^[10]	45	2, NA	Benign and malignant	111.5	No	75.42±30.4	20 cases for total operative time and console time	NA	0/45	3/45
This study	149	5, experienced	Benign and malignant	280 (50–1210)	Yes	170±54	21 cases for setup times (for a single physician)	5 (5–550)	0/149	0/149

SD: Standard deviation, PLA: Pelvic lymphadenectomy, NA: not available

furthermore, approximately 80% received <10 h of animal or cadaver training.^[13] In contrast, a longer training period was provided at our institution before the first robotic surgery was performed, indicating that adequate training may have contributed to its smooth introduction.

Our study had several limitations. The surgeons were board-certified gynecologic oncologists familiar with minimally invasive surgery, resulting in limited generalization to physicians with little or no experience with minimally invasive surgery. Lim *et al.* mentioned that the surgical experience of surgeons before adopting robotic surgery might contribute to earlier proficiency.^[14] On the other hand, it has been reported that training using a simulation box trainer improves the technique of laparoscopic surgery even among trainee surgeons,^[15] indicating that a similar effect may be achieved in robotic surgery. In addition, a cost analysis is lacking. Previous studies have demonstrated that robotic surgery costs at the single-case level are higher;^[16] however, the long-term cost reductions associated with decreased laparotomy rates and postoperative complications are beneficial for populations with obesity or other comorbidities, and particularly those with endometrial cancer. Despite the cost associated with the robotic platform, its advantages are significant. This study did not perform a quality assessment of the training program; however, it is difficult to accurately evaluate training quality. Further studies should analyze the relationship between training before surgery and surgical outcomes. Nevertheless, it is desirable to provide a well-prepared introduction to robotic surgery.

Appropriate training and simulation programs are important for the safe implementation of robotic surgery for gynecologic procedures. While the importance of training has been recognized and programs established in the field of laparoscopic surgery,^[17] it is insufficient in robotic surgery. Since the importance of training during the introduction phase was demonstrated in this study, a well-designed program should be established for robotic surgery as well. Future research should apply our protocol to a larger number of surgeons across other surgical specialties or techniques.

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Author contributions

Takuma Yoshimura and Hiroshi Nishio performed the conception and design of the study, data collection, data analysis, and manuscript preparation. Hiroshi Nishio, Kensuke Sakai, Yuya Nogami, Shigenori Hayashi, and Wataru Yamagami performed patient recruitment. All authors commented on the previous manuscript and approved the final manuscript.

Data availability statement

All data generated or analyzed during this study are included in this published article.

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Nil.

Conflicts of interest

Dr. Hiroshi Nishio received honoraria from Intuitive Surgical Inc. The other authors have no relevant financial or nonfinancial interests to disclose.

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