Jikeikai Med J 2022 ; 69 : 21-7

# Initial Experience with Robot-assisted Laparoscopic Surgery for Rectal Cancer

Yasunobu KOBAYASHI, Yasuhiro TAKEDA, Tomotaka KUMAMOTO, Naoki TAKADA, Seiichiro ETO, Saori YATABE, Masahisa OHKUMA, Makoto KOSUGE, and Ken ETO

*Division of Digestive Surgery, Department of Surgery, The Jikei University School of Medicine*

*ABSTRACT*

Objective : To evaluate short-term outcomes after the introduction of robot-assisted laparoscopic surgery for rectal cancer at our hospital.

Methods : The participants of this retrospective study were 19 patients with rectal cancer who had undergone operations from April through October 2021 : 10 with robot-assisted laparoscopic surgery (RALS) performed by a single surgeon and 9 with laparoscopic surgery (LS). Clinicopathological characteristics, operative findings, and postoperative complications were compared between the types of surgery.

Results : Patients who had undergone RALS had a median operative time of 334 minutes and a console time of 166.5 minutes. No operations were converted to laparotomy, and the median postoperative hospital stay was 12 days. Complications of Clavien-Dindo grade II were stoma outlet obstruction in 2 patients and anastomotic leakage in 1 patient. Pathological examination revealed no residual tumor, and resection was curative in all patients. No variables of operative findings or postoperative complications differed significantly between RALS and LS.

Conclusion : The RALS for rectal cancer at our hospital has been safely performed.

(Jikeikai Med J 2022 ; 69 : 21-7)

Key words : rectal cancer, robot-assisted surgery, initial experience

## INTRODUCTION

Colorectal cancer (CRC) was the second leading cause of cancer mortality worldwide in 2020. In addition, CRC was newly diagnosed in approximately 730,000 patients and has the third highest incidence rate among all malignant tumors[1]. This data indicates that CRC is a common disease throughout the world. Furthermore, as a treatment of CRC, laparoscopic surgery (LS) has been demonstrated as feasible with good postoperative courses and outcomes[2,3]. However, because the needed instruments are rigid, LS continues to have technical limitations. An alternative treatment of rectal cancer, robot-assisted laparoscopic surgery (RALS) has been covered by national insurance in Japan since 2018 and is becoming increasingly common owing to its advantage of being performed when the surgical field is smaller than for LS.

We have performed LS for rectal cancer at our hospital but started performing RALS with the da Vinci X Surgical System® (Intuitive Surgical, Sunnyvale, CA, USA) in April 2021. Before we can apply for insurance coverage of RALS in Japan, a clinical research study must include 10 RALS operations.

Because widespread use of RALS is needed, the clini-

Received : April 20, 2022 / Accepted : June 29, 2022
小林 康伸，武田 泰裕，隈本 智卓，髙田 直樹，江藤誠一郎，谷田部沙織，大熊 誠尚，小菅 誠，衛藤 謙
Mailing address : Yasunobu KOBAYASHI, Division of Digestive Surgery, Department of Surgery, The Jikei University School of Medicine, 3-19-18 Nishi-shimbashi, Minatoku, Tokyo, 105-8461, Japan
E-mail : h20mskobayashi@yahoo.co.jp

cal course of this procedure should be investigated. Therefore, in the present study we investigated and compared the short-term outcomes of 10 patients who had undergone RALS and 9 patients who had undergone LS.

## MATERIALS AND METHODS

*Patient selection*

The participants of this retrospective study were 19 patients with rectal cancer who had been treated with surgery at our hospital from April through October 2020 : 10 patients had undergone RALS operations performed by a single surgeon and 9 patients had undergone LS. The surgery was selected on the basis of the surgeon's decision and the availability of the da Vinci Surgical System. The presence and progression of rectal cancer were diagnosed on the basis of endoscopic computed tomographic examinations and magnetic resonance imaging. Strategies for treating rectal cancer were determined in consultation with radiation oncologists.

Preoperative chemoradiotherapy (capecitabine + 45 Gy in 25 fractions) was performed for all patients with locally advanced cancer located in the rectum below the peritoneal reflection (stage cT3/T4 or cT any cN1/2, cM0), and lateral lymph nodes were not dissected if the patients had been found preoperatively to be negative for metastases. Preoperative radiotherapy was performed at a dose of 45 Gy (25 fractions in 5 weeks) to all pelvic tissue, including lateral lymph nodes. The radiotherapy technique used was intensity-modulated radiotherapy. The chemotherapy regimen was given concurrently with radiotherapy : capecitabine at 825 mg/m$^2$ orally administered twice daily for 5 days per week. For patients positive for lateral lymph node metastases, we have a strategy to perform lateral lymph node dissection ; however, no patients were positive before surgery. After surgery, a multidisciplinary approach after staging work-up was completed consistently for all included patients.

This study was approved by the Ethics Committee of The Jikei University School of Medicine for Biomedical Research (IRB code : 31-412).

*Data collection*

The following variables at the time of the operation were reviewed : sex, age, body mass index (BMI), American Society of Anesthesiologists Physical Status, history of laparotomy, location of the primary tumor (rectosigmoid [Rs], rectum above the peritoneal reflection [Ra], or rectum below the peritoneal reflection [Rb]), distance from the tumor to the anal verge, history of neoadjuvant chemoradiotherapy, surgical procedure (high anterior resection [HAR] or low anterior resection [LAR]), and construction of diverting ileostomy. Also assessed was information related to surgery : operative time, console time, blood loss, conversion to laparotomy, pathological findings according to the Union for International Cancer Control TNM classification, postoperative hospital stay, and postoperative complications (surgical site infection, ileus, anastomotic leakage, urological disorder, neurological disorder, and stoma outlet obstruction).

*Surgical procedure*

The operations for all 10 patients who underwent RALS were performed by a single surgeon under the guidance of an invited proctor. For patients who received preoperative chemoradiotherapy, surgery was scheduled 6 to 8 weeks after its completion. Trocars were inserted into 12-mm and 5-mm ports placed under the right costal arch for assistants (Fig. 1). All surgical procedures were performed with the standardized laparoscopic total mesorectal excision technique defined by Heald and Ryall[4] and with a pelvic autonomic nerve preservation technique. Complete dissection of all regional lymph nodes was defined as D3 dissection. In the treatment of rectal cancer, D3 represents lymph node dissection along the superior rectal and inferior mesenteric arteries. In cases of cancer located in the rectum below the peritoneal reflection, lateral lymph nodes are included in regional lymph nodes ; however, lateral lymph node dissection can be eliminated if the patient has undergone preoperative chemoradiotherapy. The SureForm® green 60-mm stapler (Intuitive Surgical, Sunnyvale, CA, USA) was used to resect the rectum, and the SureForm® green 45-mm stapler was used twice when the pelvic area was more narrow. The anastomotic technique was performed laparoscopically with a 28-mm purple EEA® circular stapler with Tri-Staple® technology (Medtronic, Minneapolis, MN, USA) being used for the double-stapling technique. To prevent severe complications from being caused by postoperative anastomotic leakage in patients treated with LAR, a protective stoma with the distal ileum was constructed as a diversion method.

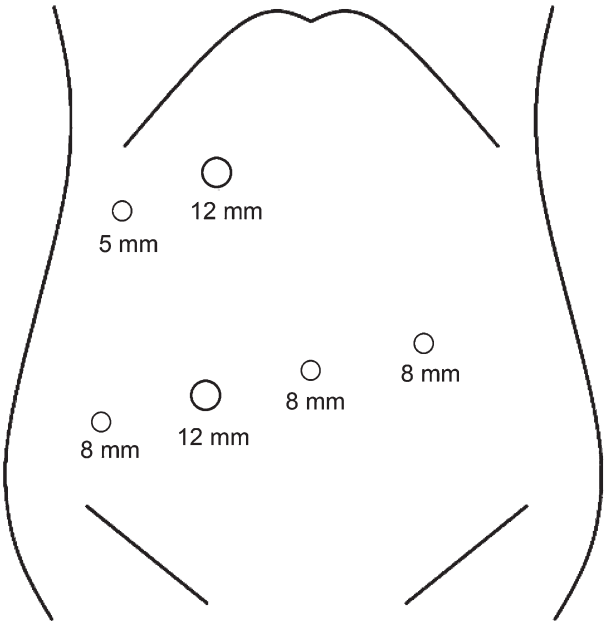


Fig. 1. Placement of trocars
An 8-mm port for the da Vinci surgical system was placed in the umbilicus. The ports were 8 cm apart, and 1 port was 12 mm. Ports of 12 mm and 5 mm were placed under the right costal arch for assistants.

*Statistical analysis*

Descriptive data are presented as the median and interquartile range (quartile 1 to quartile 3) for continuous outcomes, and groups were compared via the Mann-Whitney U test. Categorical data are presented as proportions, and comparisons between groups were performed with Pearson's chi-squared test. A p-value $<0.05$ was considered statistically significant. All statistical analyses were performed with the JMP14 software program (SAS Institute Japan Ltd., Tokyo, Japan).

## Results

*Patient characteristics*

Of the 10 patients who had undergone RALS, 7 were men and 3 were women (Table 1). The median age was 65 years, and the median BMI was 19.4 kg/m$^2$. Five patients had a history of laparotomy. Primary tumor locations were the Rs in 3 patients, the Ra in 2 patients, and the Rb in 5 patients. The surgical produce was HAR for Rs cancer and

Table 1. Clinicopathological characteristics of patients

| Characteristic | Category | Number of patients (%) | | *p* value |
|---|---|---|---|---|
| | | Robot-assisted laparoscopic surgery (n=10) | Laparoscopic surgery (n=9) | |
| Sex | male | 7 (70%) | 5 (56%) | 0.51 |
| | female | 3 (30%) | 4 (44%) | |
| Age, median, years (IQR) | | 65 (61.2-71.2) | 68 (52-72.5) | 0.50 |
| Body mass index, median, kg/m2 (IQR) | | 19.4 (18.3-22.1) | 22.7 (20.2-25.6) | 0.12 |
| American Society of Anesthesiologists Physical Status | 1 | 4 (40%) | 5 (50%) | 0.35 |
| | 2 | 6 (60%) | 4 (40%) | |
| | 3 | 0 (0%) | 1 (10%) | |
| History of laparotomy | yes | 5 (50%) | 4 (44%) | 0.80 |
| | no | 5 (50%) | 5 (56%) | |
| Tumor location | rectosigmoid | 3 (30%) | 4 (45%) | 0.45 |
| | rectum above peritoneal reflection | 2 (20%) | 3 (33%) | |
| | rectum below peritoneal reflection | 5 (50%) | 2 (22%) | |
| Distance from tumor to anal verge, median, cm (IQR) | | 10 (5-15) | 15 (6.5-15) | 0.39 |
| Neoadjuvant chemoradiotherapy | yes | 5 (50%) | 2 (22%) | 0.21 |
| | no | 5 (50%) | 7 (78%) | |
| Surgical procedure | high anterior resection | 3 (30%) | 4 (44%) | 0.76 |
| | low anterior resection | 7 (70%) | 5 (56%) | |
| Diverting ileostomy | yes | 7 (70%) | 5 (56%) | 0.51 |
| | no | 3 (30%) | 4 (44%) | |

IQR, interquartile range

LAR for Ra and Rb cancer. In both treatment groups, all patients with Rb cancer had locally advanced cancer and had been treated with preoperative chemoradiotherapy. With regard to the patients' characteristics, the RALS and LS treatment groups were comparable.

*Results related to operation*

Among patients who had undergone RALS, the median operative time was 334 minutes and the median console time was 166 minutes (Table 2). The median blood loss was 0 mL, and no operations were converted to laparotomy. The pathological diagnosis was stage I in 6 patients, stage IIA in 2 patients, and stage IIIB in 2 patients. The median lymph node yield was 17, and both distal resection margin and circumferential resection margin were negative in all patients. The median postoperative hospital stay was 12 days. The 2 treatment groups did not differ significantly in operative time, blood loss, conversion to laparotomy, lymph node yield, distal resection margin, circumferential resection margin, or postoperative hospital stay.

The operative time and the console time in cases of LAR, as the number of operations increased, tended to shorten (Fig. 2). The reason for the time taken in the third case of HAR to be longer was that we took time to detect the locations of tumor markers. The second patient with LAR was a woman with a low BMI for whom a short console time was required. Postoperative complications of patients who had undergone RALS were anastomotic leakage and stoma outlet obstruction in 1 patient and stoma outlet obstruction in another patient (Table 3). However, not found in any patient was surgical site infection, ileus, urological disorder, or neurological disorder. All complications were grade II of the Clavien–Dindo classification. On the other hand, of the patients who had undergone LS, 2 had anastomotic leakage. However, the rates of postoperative complications did not differ significantly between the types of surgery.

Table 2. Operative findings and results

| Variable | Category | Number of patients (%) | | *p* value |
|---|---|---|---|---|
| | | Robot-assisted laparoscopic surgery (n=10) | Laparoscopic surgery (n=9) | |
| Operative time, median, minutes (IQR) | | 334 (298.5–368) | 277 (248.5–414) | 0.65 |
| Console time, median, minutes (IQR) | | 166.5 (134.5–200) | – | |
| Blood loss, median, mL (IQR) | | 0 (0–10) | 0 (0–21) | 0.59 |
| Conversion to laparotomy | no | 0 (0%) | 0 (0%) | 1.00 |
| pT stage | 1a | 0 (0%) | 1 (11%) | |
| | 1b | 3 (30%) | 0 (0%) | |
| | 2 | 3 (30%) | 3 (33%) | |
| | 3 | 3 (30%) | 5 (56%) | |
| | 4a | 1 (10%) | 0 (0%) | |
| pN stage | 0 | 8 (80%) | 8 (89%) | |
| | 1a | 1 (10%) | 0 (0%) | |
| | 1b | 1 (10%) | 0 (0%) | |
| | 2a | 0 (0%) | 1 (11%) | |
| p stage | I | 6 (60%) | 4 (44%) | |
| | IIa | 2 (20%) | 4 (44%) | |
| | IIIb | 2 (20%) | 1 (11%) | |
| Lymph node yield, median, n (IQR) | | 17 (10–22) | 18 (11–32) | 0.59 |
| Distal resection margin, median, mm (IQR) | | 30 (21.5–38.7) | 28 (24–41.5) | 0.83 |
| Distal resection margin involved | no | 0 (0%) | 0 (0%) | 1.00 |
| Circumferential resection margin involved | no | 0 (0%) | 0 (0%) | 1.00 |
| Postoperative hospital stay, median, days (IQR) | | 12 (10–18) | 11 (8–26) | 0.90 |

IQR, interquartile range

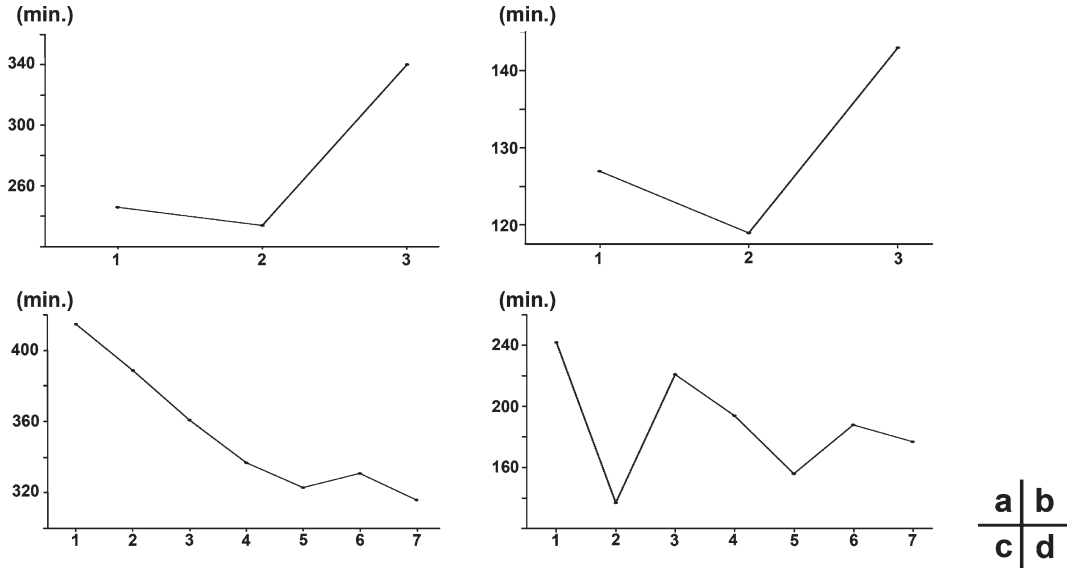


Fig. 2. Trends of the operative time and console time for HAR and LAR

Fig. 2a : operative time for HAR ; Fig. 2b : console time for HAR ; Fig. 2c : operative time for LAR ; Fig. 2d : console time for LAR

The reason for the longer time taken in the third case of HAR was that we took time to detect the location of tumor marking. In cases of LAR, as the number of operations increased, both operative time and console time tended to shorten.

Table 3. Postoperative complication rates

| Complication | Number of patients for type of surgery (%) | | *p* value |
|---|---|---|---|
| | Robot-assisted laparoscopic (n = 10) | Laparoscopic (n = 9) | |
| Surgical site infection | 0 (0%) | 0 (0%) | 1.00 |
| Ileus | 0 (0%) | 0 (0%) | 1.00 |
| Anastomotic leakage | 1 (10%) | 2 (22%) | 0.58 |
| Urological disorder | 0 (0%) | 0 (0%) | 1.00 |
| Neurological disorder | 0 (0%) | 0 (0%) | 1.00 |
| Stoma outlet obstruction | 2 (20%) | 0 (0%) | 0.47 |

## Discussion

Significant advances have recently been made in the treatment of rectal cancer. Neoadjuvant chemoradiotherapy has been introduced, local recurrence has been further reduced, and sphincter-preserving surgery is now performed worldwide[5]. The most common type of operation has also changed from open surgery to minimally invasive surgery. In particular, LS has been shown to be oncologically equivalent to open surgery and has the advantages of lower complication rates and shorter hospital stays[6]. Furthermore, RALS with the Da Vinci surgical system has been shown to have similar characteristics to LS and is expected to have the additional advantage of lower rate of conversion to laparotomy[7].

The initial experiences with RALS have been reported in various studies. Many of these studies demonstrate no significant differences between RALS and LS in the rates of intraoperative or postoperative complications[7-10]. A study with a national clinical database in Japan finds that the total complication rate of LAR with RALS was 28.8% and that the anastomotic leakage rate was 7.8%[11]. In that study, complications of Clavien-Dindo grade III or higher were present in 9.4% of patients. In the present study, 2 patients had stoma outlet obstruction, 1 of whom also had anastomotic leakage. The anastomotic leakage rate in patients treated with LAR was 14.3%, but no patients had complications of Clavien-Dindo classification grade III or higher. These results

are consistent with our finding that all postoperative complications were Clavien–Dindo grade II, which suggests that RALS in our hospital has been safely performed. In addition, previous studies have demonstrated that the rate of conversion to laparotomy was lower with RALS than with LS[12–14]. Similarly, no operations in the present study were converted to laparotomy. On the other hand, operative time in the present study tended to be longer with RALS (median time, 334 minutes) than with LS (277 minutes), although the difference was not statistically significant. The operative time with RALS has also been suggested to be longer in previous studies and needs to be improved[15–17]. One patient in the present study had anastomotic leakage, which was asymptomatic and incidentally detected on computed tomography during a routine examination. However, we always constructed diverting ileostomy in patients undergoing LAR, which might have caused the complication to be asymptomatic.

In Japan, only technically certified laparoscopic surgeons are allowed to perform RALS for rectal cancer. Thus, all 10 RALS operations in the present study were performed by a single surgeon with a single console under the guidance of a proctor. Although few operations were performed (Fig. 2), both operative time and console time tended to shorten as the number of operations increased. On the other hand, several previous studies have reported that the dual console system is safe and effective for surgeons who are not proficient in RALS[18–20]. In the future, the learning curve could be further improved with the use of dual console system.

The present study had several limitations. First, this study initially included 10 patients, but the sample size might be too small to examine the short-term outcomes. A second limitation was that this study included 10 consecutive patients treated by a single surgeon who was experienced with LS, which might have decreased the operative time and the complication rate. In clinical practice, our results might differ from the actual learning curve because RALS will be performed by several surgeons. A third limitation of the present study is that in our hospital, diverting ileostomy was always performed in cases of LAR, which might have caused complications, such as asymptomatic anastomotic leakage, to be overlooked.

## CONCLUSION

The initial 10 RALS operations for rectal cancer at our hospital have been safely performed.

Authors have no conflict of interest.

## REFERENCES

1. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global cancer statistics 2020 : GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin, 2021 ; 71 : 209–49.
2. Guillou PJ, Quirke P, Thorpe H, Walker J, Jayne DG, Smith AMH, et al. Short-term endpoints of conventional versus laparoscopic-assisted surgery in patients with colorectal cancer (MRC CLASICC trial) : multicentre, randomised controlled trial. Lancet. 2005 ; 365 : 1718–26.
3. Jayne DG, Guillou PJ, Thorpe H, Quirke P, Copeland J, Smith AMH, et al. Randomized trial of laparoscopic-assisted resection of colorectal carcinoma : 3-year results of the UK MRC CLASICC Trial Group. J Clin Oncol. 2007 ; 25 : 3061–8.
4. Heald RJ, Ryall RD. Recurrence and survival after total mesorectal excision for rectal cancer. Lancet. 1986 ; 1(8496) : 1479–82.
5. Local recurrence rate in a randomised multicentre trial of preoperative radiotherapy compared with operation alone in resectable rectal carcinoma. Swedish Rectal Cancer Trial. Eur J Surg. 1996 ; 162 : 397–402.
6. Bonjer HJ, Deijen CL, Abis GA, Cuesta MA, van der Pas MHGM, de Lange-de Klerk ESM, et al. A randomized trial of laparoscopic versus open surgery for rectal cancer. N Engl J Med. 2015 ; 372 : 1324–32.
7. Speicher PJ, Englum BR, Ganapathi AM, Nussbaum DP, Mantyh CR, Migaly J. Robotic low anterior resection for rectal cancer : A national perspective on short-term oncologic outcomes. Ann Surg. 2015 ; 262 : 1040–5.
8. Achilli P, Grass F, Larson DW. Robotic surgery for rectal cancer as a platform to build on : review of current evidence. Surg Today. 2021 ; 51 : 44–51.
9. Harsløf S, Stouge A, Thomassen N, Ravn S, Laurberg S, Iversen LH. Outcome one year after robot-assisted rectal cancer surgery : a consecutive cohort study. Int J Colorectal Dis. 2017 ; 32 : 1749–58.
10. Sugishita T, Tsukamoto S, Imaizumi J, Takamizawa Y, Inoue M, Moritani K, et al. Evaluation of the learning curve for robot-assisted rectal surgery using the cumulative sum method. Surg Endosc. 2022 Jan 3. Online ahead of print.
11. Matsuyama T, Endo H, Yamamoto H, Takemasa I, Uehara K, Hanai T, et al. Outcomes of robot-assisted versus conventional laparoscopic low anterior resection in patients with rectal cancer : propensity-matched analysis of the National Clinical Database in Japan. BJS Open. 2021 Sep 6 ; 5(5) : zrab083.

12. Hellan M, Ouellette J, Lagares-Garcia JA, Rauh SM, Kennedy HL, Nicholson JD, et al. Robotic rectal cancer resection : A retrospective multicenter analysis. Ann Surg Oncol. 2015 ; 22 : 2151-8.
13. Pai A, Marecik SJ, Park JJ, Melich G, Sulo S, Prasad LM. Oncologic and clinicopathologic outcomes of robot-assisted total mesorectal excision for rectal cancer. Dis Colon Rectum. 2015 ; 58 : 659-67.
14. Jayne DG, Thorpe HC, Copeland J, Quirke P, Brown JM, Guillou PJ. Five-year follow-up of the Medical Research Council CLASICC trial of laparoscopically assisted versus open surgery for colorectal cancer. Br J Surg. 2010 ; 97 : 1638-45.
15. Park SY, Choi GS, Park JS, Kim HJ, Ryuk JP, Yun SH. Urinary and erectile function in men after total mesorectal excision by laparoscopic or robot-assisted methods for the treatment of rectal cancer : a case-matched comparison. World J Surg. 2014 ; 38 : 1834-42.
16. Schmiegelow AF, Broholm M, Gögenur I, Fode M. Evaluation of sexual and urinary function after implementation of robot-assisted surgery for rectal cancer : A single-center study. Surg Laparosc Endosc Percutan Tech. 2016 ; 26 : 141-5.
17. deSouza AL, Prasad LM, Ricci J, Park JJ, Marecik SJ, et al. A comparison of open and robotic total mesorectal excision for rectal adenocarcinoma. Dis Colon Rectum. 2011 ; 54 : 275-82.
18. Bolger JC, Broe MP, Zarog MA, Looney A, McKevitt K, Walsh D, et al. Initial experience with a dual-console robotic-assisted platform for training in colorectal surgery. Tech Coloproctol, 2017 ; 21 : 721-7.
19. Smith AL, Scott EM, Krivak TC, Olawaiye AB, Chu T, Richard SD. Dual-console robotic surgery : a new teaching paradigm. J Robot Surg. 2013 ; 7 : 113-8.
20. Yamamoto M, Ashida K, Hara K, Sugezawa K, Uejima C, Tanio A, et al. Initial experience in rectal cancer surgery for the next generation of robotic surgeons trained in a dual console system. Yonago Acta Med. 2021 ; 64 : 240-8.