ORIGINAL RESEARCH ARTICLE

Short-term outcomes of robotic-assisted laparoscopic rectal surgery: A pilot study during the introductory period at a local municipal hospital

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Abstract:

Objectives: The aim of this pilot study was to confirm the safety and feasibility of the induction of robotic-assisted laparoscopic rectal surgery (RRS) at a local municipal hospital. A municipal hospital does not indicate a small hospital. The most significant difference between a municipal hospital and a center or university hospital is that most surgeons in a municipal hospital are general surgeons. Methods: The first 30 patients who underwent RRS at the municipal hospital were enrolled between April 2015 and June 2016. All surgeries were performed by a single trained surgeon using the da Vinci® Si surgical system. The primary endpoint was the incidence of postoperative major complications. Results: Of the study patients, 29 had adenocarcinoma and 1 had ulcerative colitis. The surgical procedures included anterior resection (n = 22), intersphincteric resection (n = 2), abdominoperineal resection (n = 4), Hartmann's procedure (n = 1), and total coloproctectomy (n = 1). There were no intraoperative complications and conversion cases. The median operative time and blood loss were 283.5 min and 9 ml, respectively. The incidence rate of postoperative major complications was 10%, which included anastomotic leakage in 2 patients and ileus in 1 patient. Postoperative urinary dysfunction did not occur in any patient. Complete resection was achieved for all patients. Conclusions: We demonstrated that the induction of RRS was safe and feasible, even at a local municipal hospital, given that the surgeons had the sufficient skills and experience in both laparoscopic and colorectal surgery. *The study protocol was registered at the University Hospital Medical Information Network (UMIN000017022).

Keywords:
robotic surgery, rectal surgery, pilot study, municipal hospital

J Anus Rectum Colon 2019; 3(1): 27-35

Introduction

Although short-term outcomes of laparoscopic rectal surgery (LRS) have been reported to be superior or similar to conventional open rectal surgeries (ORS) [1-3], its superiority in long-term oncological outcomes has not been demonstrated [4-6]. On the contrary, several large trials failed to demonstrate the non-inferiority of long-term or pathologic outcomes in LRS compared with ORS [7,8]. Moreover, a few reports indicated that urinary or sexual dysfunction occurred more frequently after LRS than after ORS [9-12]. Robotic rectal surgery (RRS) is a useful technology that may overcome such disadvantages of LRS.

In Japan, robotic surgery using the da Vinci® surgical system (Intuitive Surgical Inc., Sunnyvale, CA, USA) was introduced in 2009, and more than 215 robots were in use in the country as of September 2015 [13]. At the end of 2015, the accumulated number of robotic surgeries was 30,000 cases, which is the second largest number following the United States. In 2016, da Vinci® Xi became available, and further

increases in the number of robotic surgeries are expected. However, most of the robotic surgeries are actually performed in the urological field, primarily for prostate cancer[14]. Robotic surgeries performed in the gastrointestinal field, including colorectal and gastric surgery, are extremely limited despite being the second largest category[13]. Robotic colorectal surgery has been primarily applied for rectal cancer, and more than 1,400 cases of RRS have been performed since 2009. However, approximately 60% of the cases have been performed in the leading five university or center hospitals, and cases at local municipal hospitals are very rare. In fact, most of the available data on RRS were reported from high-volume centers on a global scale. Today, the number of local municipal hospitals with robots is increasing as a result of the popularization of robotic prostatectomy. In addition, RRS is expected to become popular even at municipal hospitals.

There are large differences between university or center hospitals and municipal hospitals. In municipal hospitals, most surgeons are general surgeons, and there are a few trained experts both in the colorectal and minimally invasive surgical fields. As mentioned previously, most of the available data on RRS has been reported from high-volume centers having many experts. In a municipal hospital setting, it is uncertain whether we could safely introduce RRS as with high-volume centers. Therefore, we prospectively observed the initial 30 patients after the introduction of RRS at a local municipal hospital and evaluated the short-term outcomes.

Methods

Study design

This trial was designed as a pilot study at Toyohashi Municipal Hospital in the countryside of central Japan between April 2015 and June 2016. RRS is not yet covered by Japanese national health insurance; therefore, all medical expenses were at the patients' own charge. In November 2014, we introduced RRS, and the procedures for the first three cases before the beginning of this study were performed by experienced instructors who were not from the institution. Subsequently, 30 patients were enrolled in this study, and no RRSs out of this study were performed during the period. All surgeries were performed by a single trained surgeon (T.A.) with more than 10 years of experience in the colorectal and laparoscopic surgical fields but without RRS operator experience before initiating this study.

The aim of this study was to confirm the safety and feasibility of RRS for benign and malignant disease in a local municipal hospital. The study protocol was approved by the institutional review board of Toyohashi Municipal Hospital and registered at the University Hospital Medical Information Network (UMIN000017022). Written informed consent was obtained from each patient before enrollment.

Patient selection and clinical management

The main indication of this study was patients requiring pelvic surgery accompanied with rectal mobilization regardless of benign or malignant disease. The additional inclusion criteria were as follows: (1) age 20-80 years, (2) no prior chemotherapy or pelvic irradiation for any malignancy, and (3) Eastern Cooperative Oncology Group performance status of 0-1. The exclusion criteria were as follows: (1) emergency cases, (2) malignant tumors with distant metastases, (3) recurrent tumors, (4) patients with contraindication for prolonged pneumoperitoneum, and (5) more than two laparotomy procedures.

Baseline assessment included clinical examination, total colonoscopy, and chest and abdominopelvic computed tomography. High-resolution pelvic magnetic resonance imaging was performed when necessary. If lateral pelvic lymph nodes metastases were suggested (larger than 7 mm in greatest dimension), we had intended to perform therapeutic lateral lymph nodes dissection robotically. All patients who had colorectal cancer were evaluated in accordance with the classification by the Japanese Society for Cancer of the Colon and Rectum[15] and were additionally staged using the seventh edition of the International Union Against Cancer Tumor-Node-Metastasis classification[16].

Data collection and evaluation parameters

Preoperative data included the following parameters: patients' general characteristics, American Society of Anesthesiology scores, body mass index, tumor location in cases with malignant disease, and history of laparotomy. Intraoperative data considered the following parameters: surgical procedures with or without diverting ileostomy, total operative and surgeon console time, estimated blood loss, and conversion to an open or unplanned laparoscopic procedure. The postoperative results included hospital stay, mortality and morbidity, incidence of urinary and sexual dysfunction, and pathologic outcomes. Postoperative mortality was defined as 30 days or same-stay hospital mortality, and postoperative complications were defined as adverse events that occurred within 30 days after surgery and were graded by the Clavien-Dindo classification[17,18]. Urinary dysfunction was defined when the patients required transurethral self-catheterization. All male patients were interviewed regarding their sexual activity preoperatively and again at 12 weeks after surgery for sexually active male patients.

Endpoints and statistical analysis

The primary endpoint was the incidence of postoperative major complications, which was defined as grade 3 or higher by the Clavien-Dindo classification. The secondary
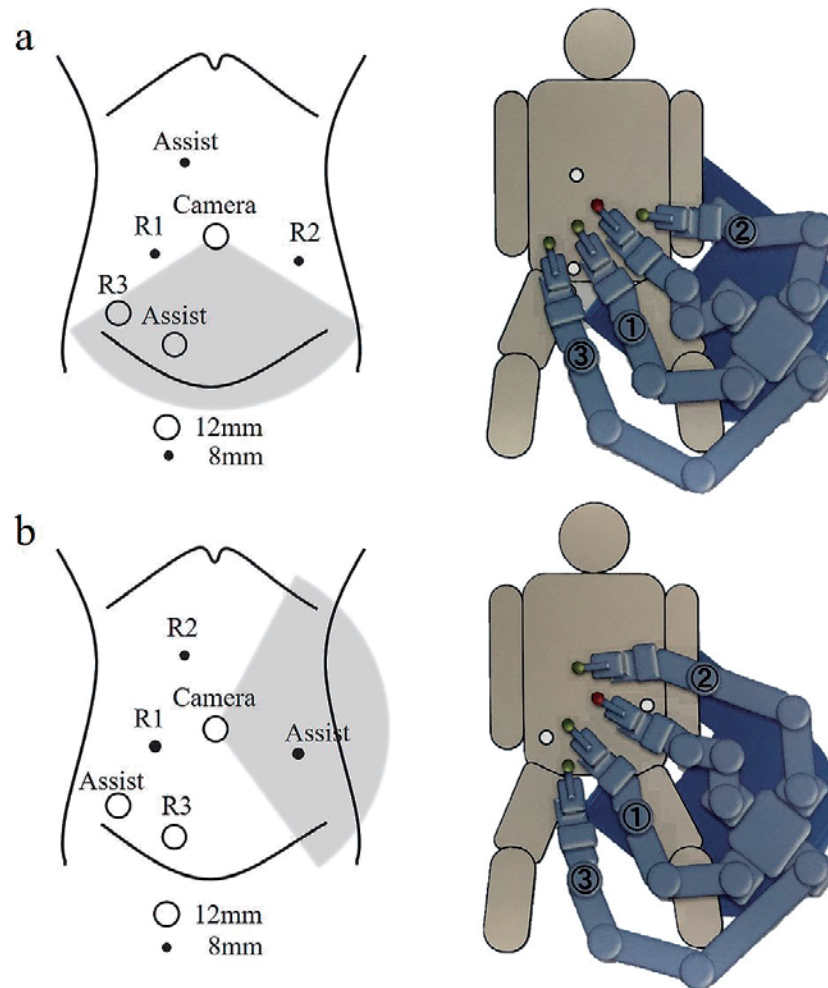
Figure 1. Schema of the docked robotic arms and the accompanied surgical field. (a) Pelvic configuration. After laparoscopic lateral-to-medial mobilization of the left-side colon, the robot is docked for rectal mobilization. (b) Abdominal configuration. After pelvic manipulation, the robotic arms are repositioned in this abdominal configuration. In this phase, the mobilization of the left-side colon is completed, and the inferior mesenteric artery and vein are divided.

endpoints were total operative and console times, intraoperative blood loss, mortality and any morbidity, complete resection rate for malignant cases, and the incidence of urinary and sexual dysfunction.

Sample size calculations were based on an expected incidence of postoperative major complications of 5% and a threshold complication rate of 20% using a 2-sided alpha error of 0.05 and a statistical power of 80%. The planned sample size was 30 patients, allowing for a 10% dropout rate. Parametric variables are expressed as a median (range) or a number (percentage).

Surgical technique

Our RRS process and principles were similar to those used in LRS. We used six trocars, and the port placement is presented in Figure 1. After creation of pneumoperitoneum,

patients were positioned in a 20°-25° Trendelenburg position and tilted 15°-20° to the right. During surgery, the patient's position was not altered. A hybrid technique with a single-stage robotic procedure using the da Vinci® Si surgical system was applied for all procedures. The robotic procedures were performed without changing the position of the robotic cart. Instead, only the robotic arms were repositioned between the pelvic and abdominal phases (Figure 1).

In preparation for the procedure, the uterus or base of the bladder was lifted to the anterior abdominal wall through a stitch using a straight laparoscopic needle (Figure 2a). First, laparoscopic lateral-to-medial mobilization of the left-side colon was performed (Figure 2b). Mobilization of the splenic flexure was also performed if necessary. Next, the robot was docked in the pelvic configuration (Figure 1a), and the rectum was completely mobilized (Figure 2c). In
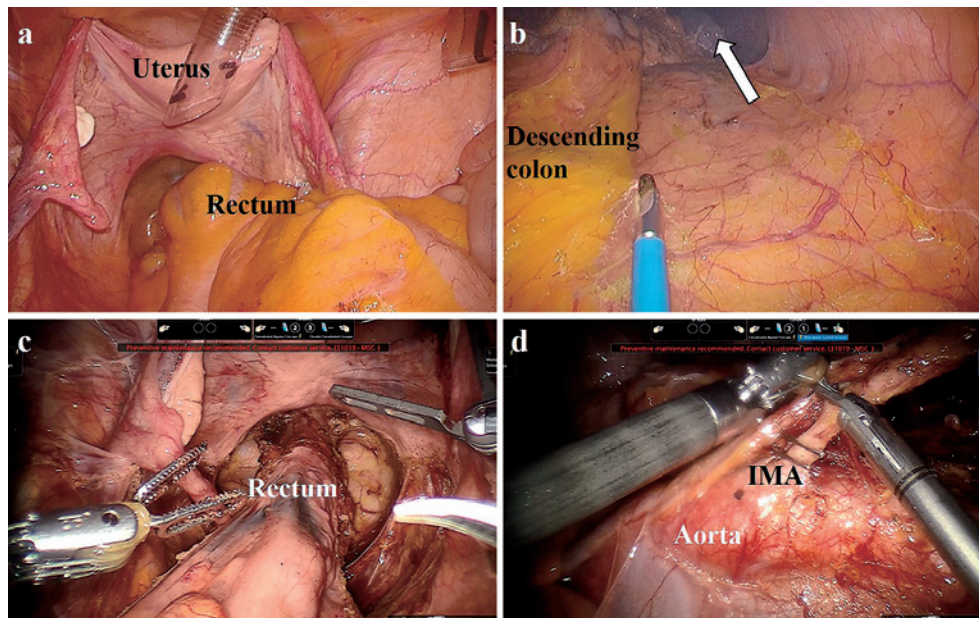
Figure 2. A hybrid technique with a single-stage robotic procedure using the da Vinci® Si surgical system. (a) The uterus is raised to the anterior abdominal wall laparoscopically. (b) The left-side colon is mobilized using a laparoscopic lateral-to-medial approach. The arrow indicates the spleen. (c) TME is performed robotically in the pelvic configuration. (d) After pelvic manipulation, the inferior mesenteric artery is divided robotically in the abdominal configuration. IMA, inferior mesenteric artery.

cases of abdominoperineal resection (APR), the levator muscle was transabdominally dissected during this step. The robotic arms were repositioned in the abdominal configuration (Figure 1b), and mobilization of the left-side colon was completed. This manipulation could be completed in a short time given the preceding laparoscopic mobilization. The inferior mesenteric artery and vein were then divided (Figure 2d). After the robot was undocked, laparoscopic rectal transection using a linear stapler and subsequent anastomosis were performed by anterior resection (AR). The resected specimen was extracted through the umbilical small incision. In case of APR or intersphincteric resection (ISR), the surgeon moved to a position between the legs. The resected specimen was extracted through the perineal incision or anus. If necessary, a diverting ileostomy was created in cases of ISR and AR.

Results

Patient characteristics

Between April 2015 and June 2016, 30 patients were enrolled in this study at Toyohashi Municipal Hospital. The patients' baseline characteristics are presented in Table 1. The median age of the patients was 68years (range 34-77), and 13 patients were female. All patients had distal sigmoid or rectal adenocarcinoma, excluding a patient with ulcerative

colitis with ascending colon cancer who underwent total coloproctectomy. Nine patients (30%) had a previous history of laparotomy.

Operative and perioperative outcomes of safety and feasibility

The operative findings are presented in Table 2. The surgical procedures included AR in 22 patients (73.4%), ISR in 2 patients (6.7%), APR in 4 patients (13.3%), Hartmann's procedure in 1 patient (3.3%), and coloproctectomy with ileoanal hand-sewn anastomosis in 1 patient (3.3%). AR included low anterior resection (LAR) in 6 patients and ultra-low anterior resection (u-LAR) requiring rectal division at the level of levator ani with double-stapled coloanal anastomosis in 5 patients. In cases with rectal cancer, if lateral pelvic lymph nodes metastases were suggested, we had intended to perform therapeutic lateral lymph nodes dissection robotically; however, none of the present cases satisfied the requirements. The median total operative and surgeon console times were 283.5 (147-490) and 100.5 (41-214) min, respectively, and the median blood loss was 9 (0-400) ml. No cases required conversion to open or unexpected laparoscopic surgery (0%) and had intraoperative organ injury (0%). Diverting ileostomy was created in 2 of 25 anastomosed patients (8%).

The median postoperative hospital stay was 9.5 (7-77) days. The incidence of postoperative major complication

Table 1. Baseline Characteristics of 30 Patients.

Sex		
Male	17	56.7%
Female	13	43.3%
Age (year)	68	(34-77)
BMI (kg/m^2)	22.6	(17.0-29.2)
ASA score		
I	9	30.0%
II	20	66.7%
III	1	3.3%
IV	0	0%
History of laparotomy		
None	21	70.0%
1 time	9	30.0%
In cases with distal sigmoid or rectal cancer (n = 29)*		
Tumor location		
Distal sigmoid colon	4	13.8%
Upper rectum	7	24.1%
Middle rectum	8	27.6%
Lower rectum	10	34.5%
cT stage		
T1	9	31.0%
T2	9	31.0%
T3	11	37.9%
T4	0	0%
cN stage		
N0	25	86.2%
N1	4	13.8%
N2	0	0%
cTNM stage		
0	0	0%
I	16	55.2%
IIA	9	31.0%
IIIA	3	10.3%
IIIB	1	3.5%

BMI, body mass index, ASA, American Society of Anesthesiology
*excluding 1 patient with ulcerative colitis

was 10% (3 cases), comprising anastomotic leakage in 2 of 25 anastomosed patients and ileus requiring the insertion of a long tube in 1 patient. However, all complications could be managed conservatively. Postoperative urinary dysfunction did not occur in any patient (0%). In 14 of 17 male patients who had sexual activity preoperatively, both erection and ejaculation were possible in 6 patients (42.9%), and only erection was possible in 3 patients (21.4%). However, recovery of sexual activity could not be confirmed in the remaining 5 patients at 12 weeks after surgery.

Pathological outcomes

Pathological results for 29 patients with distal sigmoid or rectal cancer are presented in Table 3. The pathological stages based on the Union for International Cancer Control classification were stage 0 in 1 case (3.5%), stage I in 11 cases (37.9%), stage II in 6 cases (20.7%), and stage III in 11 cases (37.9%). The median number of harvested lymph nodes was 16 (4-30). Proximal, distal, and radial resection margins were negative, and pathological complete resection was achieved in all 29 patients.

Discussion

A municipal hospital simply means a municipally run enterprise in the countryside, and the term does not necessarily indicate a small hospital. Our facility contains 800 beds in a hospital ward, and we perform over 1,500 gastrointestinal surgical procedures under general anesthesia annually. We bought and have used a robot for urologic surgery since 2013. Our department of surgery comprised 7 staff surgeons and approximately 10 residents during this study period.

Table 2. Operative Results (n = 30).

Surgical procedures		
Anterior resection	22	73.4%
Intersphincteric resection	2	6.7%
Abdominoperineal resection	4	13.3%
Hartmann's procedure	1	3.3%
Total coloproctectomy	1	3.3%
Lateral pelvic lymph nodes dissection (n = 29)*		
Yes	0	0%
No	29	100%
Total operative time (min)	283.5	(147-490)
Surgeon console time (min)	100.5	(41-214)
Blood loss (ml)	9	(0-400)
Conversion to open or laparoscopy	0	0%
Intraoperative organ injury	0	0%
Diverting ileostomy	2/25	8%
Postoperative hospital stay (day)	9.5	(7-77)
Postoperative complications		
Anastomotic leakage	2	8%
Ileus	1	3.3%
Wound infection	1	3.3%
Urinary dysfunction	0	0%
Sexual function in male (n = 14)		
Both erection and ejaculation	6	42.9%
Only erection	3	21.4%
Both missing	5	35.7%

*excluding 1 patient with ulcerative colitis

However, in Japan, complete specialization has not been introduced at such a local municipal hospital. In fact, most surgeons are general surgeons and perform various surgeries, including general, emergent, digestive, hepatobiliary-pancreatic, and breast surgery. This situation is largely different from center and university hospitals, which retain numerous specialized surgeons. Zawadzki et al. reported their experiences of the introduction of robotic colorectal surgeries under community hospital settings[19]; they also interpreted community hospitals as a different environment from high-volume centers. It is uncertain whether RRS could be safely introduced to municipal or community hospitals as with high-volume centers. In this study, a surgeon with expertise in laparoscopic and colorectal fields but without experience of robotic surgery visited our hospital and introduced RRS to other non-expert members as a pilot study to evaluate its safety and feasibility.

In the introduction era of laparoscopic colorectal surgery, the primary difficulty was the high rate of conversion to open surgery and intraoperative complications[1,3,20-22]. At the time of RRS introduction, the surgeon and surgical team, including assistant surgeons, nurses, and medical engineers, had to be careful to avoid intraoperative complications, which consequently led to conversions. Unlike in conventional laparoscopic surgeries, in robotic surgeries, there is a possibility of collision between the robotic arms or between the robotic arm and the patient's body. Prior to our introduction of RRS, the team had visited other hospitals to observe RRSs, had planned operative procedures in detail, and had run simulations with a real surgical robot in the operating room. During actual surgery, the team attempted to communicate with each other about the condition of the robotic arms because the surgeon was in console that was apart from the patient. In this pilot study, there were no intraoperative complications such as organ injuries, bleeding, and conversion to open or unexpected laparoscopic surgery.

Several studies have reported that the introduction of RRS was safe and feasible at center hospitals worldwide. Park et al. reported that the overall morbidity was 29.3%, including an anastomotic leakage rate of 9.7%. In addition, the incidence of major complications was 9.8% in their first 41 cases[23]. Feroci et al. reported that the incidence of any complications in their first 53 cases was 32.1%, including an anastomotic leakage rate of 5.7%[24]. Our short-term results for the initial 30 cases were equivalent to those obtained in previous reports, and we could demonstrate that RRS could be safely introduced even at a local municipal hospital setting. Although it was worrisome that none of the members had experience as an RRS operator but only as assistants or visitors, we believed that sufficient experience with LRS and

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Table 3. Pathological Results in 29 Patients with Distal Sigmoid or Rectal Cancer.

pT stage		
Tis	1	3.5%
T1	10	34.5%
T2	6	20.7%
T3	12	41.4%
T4	0	0%
pN stage		
N0	18	62.1%
N1	9	31.0%
N2	2	6.9%
pTNM stage		
0	1	3.5%
I	11	37.9%
IIA	6	20.7%
IIB	0	0%
IIC	0	0%
IIIA	4	13.8%
IIIB	7	24.1%
IIIC	0	0%
Number of harvested lymph nodes	16	(4-30)
Proximal margin		
Positive	0	0%
Negative	29	100%
Distal margin		
Positive	0	0%
Negative	29	100%
Distance of distal margin (mm)	40	(7-170)
Radial margin		
Positive	0	0%
Negative	29	100%
Complete resection		
Yes	29	100%
No	0	0

the invitation of outside proctors in the initial 3 cases before the induction could address the inexperience.

To increase the technical standard and promote leaders in conventional laparoscopic surgery, the Japanese Society for Endoscopic Surgery (JSES) established the Endoscopic Surgical Skill Qualification System (ESSQS) in 2004[25]. To secure the ESSQS accreditation, the applicants must submit their own unedited video of sigmoidectomy or AR in the colorectal field, and the video is assessed by the judging committee. The pass rate is approximately 30%, and there are presently approximately 500 certified colorectal surgeons. The JSES has strongly recommended that only certificated laparoscopic surgeons should perform robotic digestive surgeries as an operator. However, this recommendation has become a distinct barrier along with financial concerns in promoting the widespread use of RRS in Japan, despite its status as the second largest robotic holder in the world. This recommendation is likely in place to guarantee the

safety of RRS, particularly in loca areas.

Park et al. assessed the learning curve of robotic LAR for rectal cancer[26]. They analyzed the outcomes of 130 LARs using the hybrid technique by a single expert surgeon and concluded that the learning curve of robotic LAR comprised three phases: phase 1 [the initial learning period (1st-44th cases)], phase 2 [the competent period (45th-78th cases)], and phase 3 [the challenging period (79th-130th cases)]. In our study, the number of cases was only 30, which were within "phase 1," and various procedures were included. The surgeon console time for all 6 LARs in this study is shown in Figure 3. Although the number of cases is very limited, the reduction in surgeon console time appears steep. At the time this study was started, the console surgeon for this study had already performed more than 100 laparoscopic colorectal procedures and had been certificated by ESSQS in the colorectal field. Japanese ESSQS might contribute to shorten the learning curve of RRS, and the certification based on ESSQS seems to be an appropriate requirement for performing RRS.

Several possible advantages of RRS to LRS are supposed. Postoperative urinary and sexual dysfunction is one of major concerns following rectal resection. This condition impairs the patients' quality of life, but RRS might be superior to LRS in this regard. Several previous studies mentioned desirable postoperative urinary and sexual functions for RRS compared with LRS[27-29]. A possible reason is avoiding too much pressing of the autonomic nerve. Another possible explanation involves a decrease in heat conduction. These are because the instruments are designed with seven degrees of motion, which is greater than those of the human wrist. In this study, although the left-side colon was mobilized laparoscopically, rectal mobilization around the autonomic nerves, including the superior hypogastric plexus, was performed robotically and likely offered favorable outcomes. However, to assess the actual impact of RRS on postoperative urinary and sexual functions, further investigations using specific scores, such as the International Prostate Symptom Score, the International Index of Erectile Function, and the Female Sexual Function Index, are essential.

Another possible advantage of RRS over LRS is the better quality of total mesorectal excision (or tumor-specific mesorectal excision). Recently, in a meta-analysis, Sun et al. reported that robotic LAR was associated with a lower rate of circumferential margin (CRM) involvement compared with laparoscopic LAR[30]. Because resected specimens are typically separated into rectum or colon and lymph node immediately in Japan, CRM data were not available in this study. However, complete resection with negative proximal, distal, and radial resection margins was achieved in all patients.

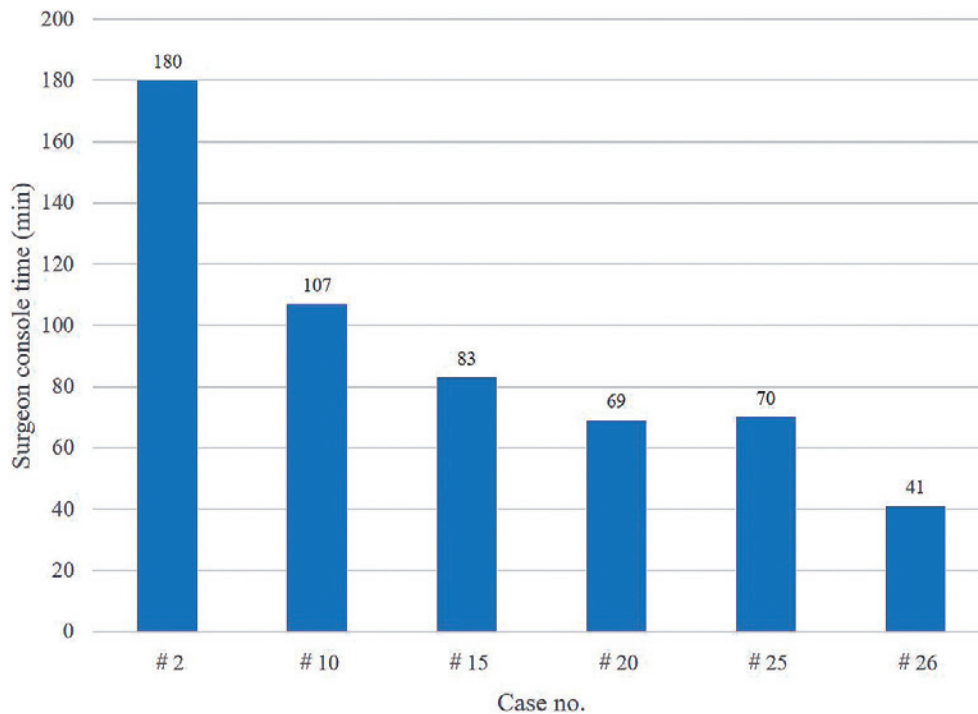This pilot study had several limitations. First, this was not a comparative study of conventional ORS or LRS. Second,

Figure 3. Surgeon console time of all 6 LAR cases.

this study could not investigate the long-term oncological outcomes given the short observation period. Further evaluation of the long-term outcomes, including the rate of local recurrences, disease-free survival, and overall survival, is essential in cases with malignant disease. The third limitation of this study is the lack of a cost analysis. The cost is the primary concern regarding robotic surgery. In the introductory period of RRS, the operative cost varied constantly because the devices to use were not fixed and multiple preparations for conversion were required. Therefore, a cost analysis was not planned for this study. However, the operative cost stabilized gradually throughout this study. A cost analysis of RRS is considered to be essential and is our next target of study.

Presently, there is insufficient evidence to confirm the advantages of RRS appropriate for its high cost. Additional experiences after overcoming the learning curve are required to reveal the merits of RRS. In a new era with an increasing number of robots, even in local areas, we believe that our data will facilitate the safe introduction and widespread use of RRS. In conclusion, this pilot study demonstrated that the induction of RRS was safe and feasible even at a local municipal hospital, given that surgeons had sufficient skill and experience in both LRS and colorectal surgery and were provided advice from experienced outside proctors in the beginning phase.

Conflicts of Interest
There are no conflicts of interest.

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