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Short-term Results of Robot-assisted Rectal Cancer Surgery

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SUMMARY

Aim：To clarify the short-term results of robot-assisted rectal cancer surgery performed at our department.

Materials and Methods：Twenty-five patients with rectal cancer who underwent robot-assisted surgery at our department between May 2020 and March 2021 were enrolled in this study. The safety and short-term outcomes of this procedure were evaluated.

Results：The mean age of the patients was 69.2±9.3 years (18 men and 7 women). The locations of cancer included the sigmoid region of the rectum (8 cases), the upper rectum (5 cases), the lower rectum (10 cases), and the anal canal (2 cases). The surgical techniques were as follows：anterior rectal resection (14 cases) (temporary ileostomy in 4 cases：29%), Hartmann's operation (4 cases), and perineal rectal amputation (7 cases). The median operation time was 306 (195-622) minutes, with 40 (1-460) ml of blood loss and 169 (85-377) minutes of console operation time. There were no cases of conversion to open surgery. Preoperative treatment was performed in 7 patients. The pathological stages were as follows：stage I：3 cases；stage II：9 cases；stage III：9 cases；stage IV：3 cases. The median number of dissected lymph nodes was 11 (2-24), and the tumor diameter was 44.8 ±18.6 mm. Postoperative complications were observed in 3 patients (12%)：paralytic bowel obstruction (1 case), outlet syndrome (1 case), and enteritis (1 case). No suture failure, sexual dysfunction, or urinary dysfunction was observed. The median postoperative hospital stay was 14 (8-69) days.

Conclusion：Robot-assisted rectal cancer surgery is safe and effective in terms of short-term outcomes. In the future, it will be necessary to improve safety further by standardizing each technique and to develop an education system from a perspective different from that of laparoscopy. It is considered necessary to further investigate the recurrence rate and survival rate by continuing this method for a long period of time.

Key Words：Robotic Surgery, Rectal cancer, Short-term outcome

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Table 1 Patient background

Age (years old)		70 (47−87)
Sex	Male : Female	18 : 7
ASA* score	1 : 2 : 3	2 : 20 : 3
BMI** (Kg/m²)		21 (16−32.5)
Location of cancer	Rs : Ra : Rb : P	8 : 5 : 10 : 2
cT	is : 1 : 2 : 3 : 4a	0 : 2 : 3 : 18 : 2
cN	0 : 1a : 1b : 2a	15 : 5 : 4 : 1
cStage	0 : Ⅰ : Ⅱa : Ⅲa : Ⅲb : Ⅳ	0 : 4 : 10 : 2 : 6 : 3
Preoperative treatment	Yes : No	18 : 7
Procedure	AR*** : Hartmann's operation : APR****	14 : 4 : 7
Diverting ileostomy	Yes : No	4 : 10

ASA* ; American Society of Anesthesiologists, BMI** ; Boddy Mass Index
AR*** ; Anterior resection, APR**** ; Abdominoperineal resection

INTRODUCTION

In Japan, since robot-assisted rectal resection and amputation started to be covered by insurance in April 2018, the number of surgeries has been increasing significantly. Rectal cancer surgery is one of the most difficult colorectal cancer surgeries because the rectum needs to be removed and mobilized along the anatomical dissection layer in the narrow pelvis and because the autonomic nervous system needs to be preserved to maintain body normal functions. In the case of laparoscopic rectal cancer surgery, the degree of freedom in the manipulation of forceps is limited due to its linear movement in the narrow pelvis[1,2] and thus the assistant's field of view often becomes hard to control. Therefore, in our department, we actively perform robot-assisted surgery for rectal cancer because the robot's articulated surgical instruments and anti-shake mechanism as well as the delicate movements of the motion scale[3] can make up for the disadvantages, such as difficulty in operation, of conventional laparoscopic surgery.

The purpose of this study was to clarify the safety and short-term outcomes of robot-assisted rectal cancer surgery performed by the same surgeon and assistant surgeons at the same institution under controlled perioperative management.

MATERIALS AND METHODS

Twenty-five patients who underwent robot-assisted rectal cancer surgery at our department between May 2020 and March 2021 were included in the study (Table 1). All surgeries were performed by one colorectal surgeon with more than 15 years of experience with the da VinciXi (Intuitive Surgical Inc, State of California, USA) who was certified for techniques by the Japan Society for Endoscopic Surgery. Additionally, surgeons who had completed the training program recommended by Intuitive (Intuitive Surgical Inc, USA), as well as assistants and operating room nurses, attended the operation. The indication for robot-assisted surgery was rectal cancer with clinical stage 0-IV. The endpoints were defined as patient factors, intraoperative factors, and postoperative factors. Short-term outcomes were calculated from the postoperative complication rates to examine wound infection, bowel obstruction, the presence of suture failure, postoperative hospital stay, the presence of laparotomy, reoperation, and operative death.

All data collected before, during, and after surgery were registered to a database, which were used to examine and analyze the short-term results. All adverse events occurred within 30 days after surgery were defined as postoperative complications and were evaluated according to the Clavien-Dindo Classifica-

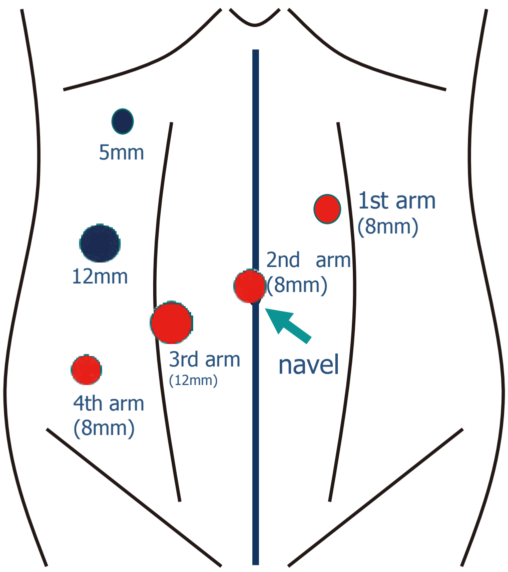

Figure 1 Port location of the robot-assisted rectal surgery

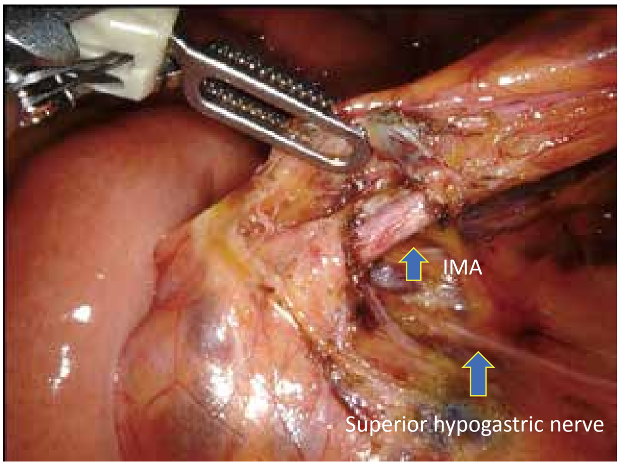

Figure 2 Dissection of Inferior mesenteric artery (IMA)

tion[4]. Informed consent to participate in a clinical observational study was obtained from all patients.

Our protocol was approved by the institutional ethics committee of Dokkyo Medical University (Tochigi, Japan) on May 24, 2021 (R-46-6J).

This study was performed in accordance with the Declaration of Helsinki, as amended in Edinburgh, Scotland, in October 2000.

Surgical technique (*surgical technique of low anterior resection*)

(1) Port placement and body position

Place the patient in the lithotripsy position, with the maximum 20 degrees of head-down position and 17 degrees of right lateral lying position. Three 8-mm ports and one 12-mm port, including camera ports, are used for da VinciXi. One 12-mm port is prepared for the assistant. When necessary, 5-mm ports are additionally used. Locations of the ports and the connection of forceps and the camera are shown in Fig. 1.

(2) Ensuring the operative field and robot docking

Place the patient in a 20-degree head-down position and a 17-degree right lateral lying position during laparoscopy. Extract the transverse colon including the greater omentum and the small intestine to the right cranial side and confirm the Treitz ligament. Roll in the patient cart in from the left side of the patient. Attach a camera to the 2nd arm. After targeting to the Sigmoid colon/ Descending colon (SD) junction, connect the remaining arms and ports and attach forceps. Specifically, insert Fenestrated Bipolar Forceps (hereinafter : Bipolar) into the 1st arm, a camera into the 2nd arm, Monopolar Curved Scissors (hereinafter : Mono) into the 3rd arm, and Tip-up Fenestrated Grasper (hereinafter : Tip-up) into the 4th arm.

(3) Medial approach

After confirming the course of the common iliac artery at the height of the promontorium, start the medial approach by grasping the mesorectum caudally with Tip-up and then the sigmoid mesocolon including the inferior mesenteric artery (IMA) cranially with Bipolar of the 1st arm. Dissect and remove the mesorectum, drop it dorsally when the left ureter and the gonadal artery are identified. Pull the IMA cranioventrally with Tip-up from the medial dissection surface. Treat the area around the IMA root, paying attention to the course of the superior hypogastric nerve plexus and the main trunk of the lumbar splanchnic nerves (Fig. 2). Expose the blood vessel at the root of the IMA and clip it using a clip applier to dissect it. After dissecting the colic branch of the lumbar splanchnic nerve, drop the gonadal artery fully dorsally, and dissect the inferior mesenteric vein after clipping it at the same level as the IMA dissection (Fig. 3). Remove and mobilize the sigmoid mesocolon cranially to the lower pole of the left

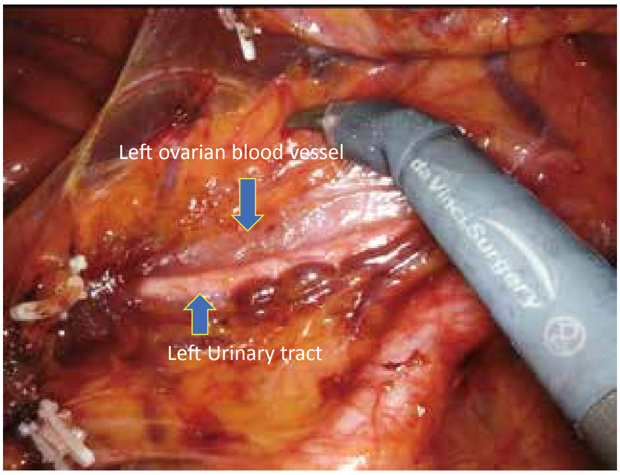

Figure 3 The left ovarian blood vessels and the left urinary tract (after dissection of the inferior mesenteric vein)

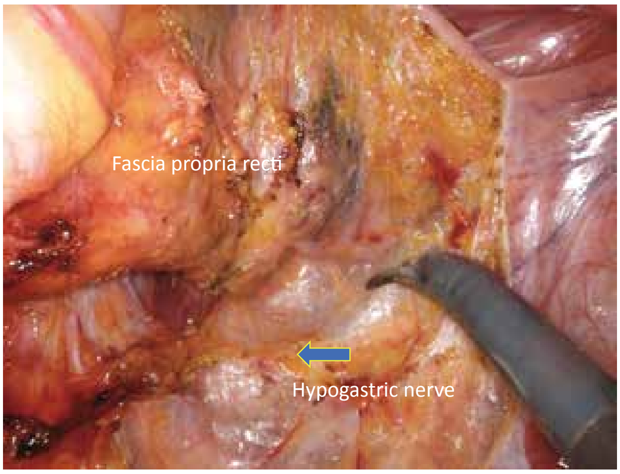

Figure 5 Removal of the posterior rectal wall

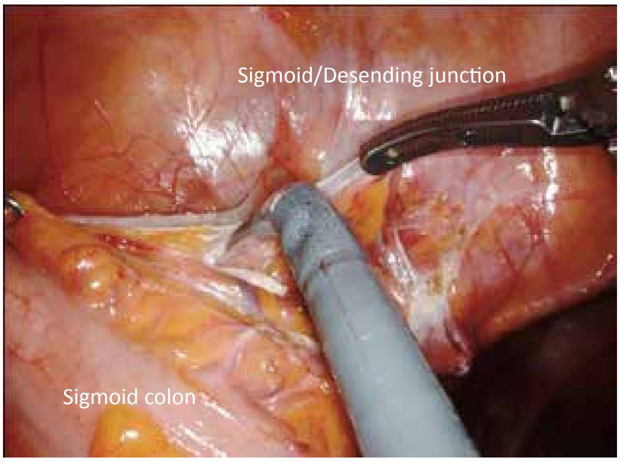

Figure 4 Lateral dissection

kidney (i.e., about 2 cm laterally to the gonadal artery) and caudally to the intersection of the left common iliac artery and the left ureter. Place gauze over the ureter to complete the medial dissection.

(4) External mobilization

Dissect the outer peritoneum of the colon cranially from the SD junction (Fig. 4). Remove and mobilize by grasping the outer peritoneum with Tip-up and pealing back the medial mesentery cranially with Bipolar. Communicate with the inside when the gauze can be seen through from the inside. Perform lateral dissection cranially along the left side of the descending colon to the point at which the spleen is visible and then caudally to the SD junction.

(5) Removal of the posterior rectal wall

Place the patient in a 10 degree right lateral decubitus position. After pulling the mesorectum cranially with gauze (by the assistant), pass the Bipolar under the gauze and elevate the posterior rectal wall using Tip-up to check the left and right hypogastric nerves. After confirming the fascia propria recti, peel off the released layer of the pre-hypogastric nerve fascia of the posterior rectal wall further to proceed with removal and mobilization to the levator ani muscle (Fig. 5).

(6) Removal of the anterior rectal wall from the left side of the rectum

Pull the left side of the rectum to the right side using Tip-up and dissect the mesorectum. After confirming the left pelvic fascia and the middle rectal artery, dissect them at the inverted part of the peritoneum. Expand the field of view by pulling the bladder (of men) or uterus (of women) ventrally using Tip-up and by pushing it caudally using Mono. Confirm the left neurovascular bundle and preserve it. Dissect the Denonvilliers fascia after confirming the seminal vesicle and prostate (or the posterior wall of vagina).

(7) Removal of the left side of the rectum from the anterior rectal wall

Using Tip-up, pull the right pelvic fascia cranially, spread the released layer of the anterior rectal wall

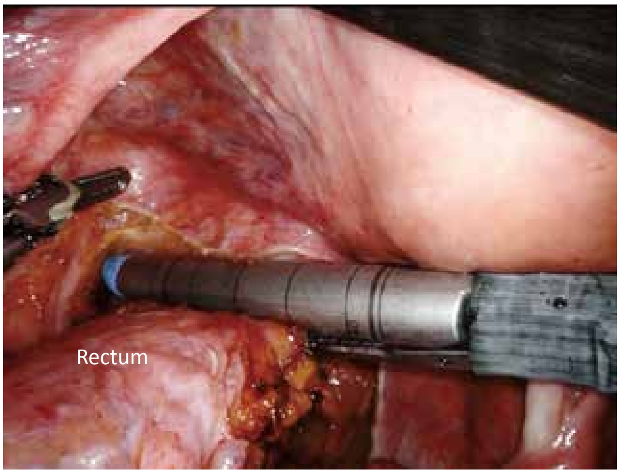

Figure 6 Dissection of the rectum

toward the right side of the rectum, dissect the right seminal vesicle and prostate (or the posterior wall of the vagina) fully toward the ventral side, and confirm the right neurovascular bundle to preserve it. There is no need for the assistant to pull the rectum cranially when removing and mobilizing the anterior rectal wall. Confirm and preserve the right hypogastric nerves, dissect them toward the posterior rectal wall, and then mobilize the rectum.

(8) Removal of the posterior rectal wall

After pulling the rectum cranially, pull the posterior rectal wall ventrally using Tip-up. Confirm the right and left levator ani muscles, and then expose the hiatal ligament to remove it. At this point, make sure that the levator ani muscle is fully removed and mobilized to both the right and left sides.

(9) Dissection and anastomosis of the rectum

After confirming the location of the cancer, dissect the mesorectum all around using an ultrasonic coagulation incision device (Fig. 6). Dissect the rectum using the Endo Wrist Stapler Blue 45mm without applying tension to the rectum. After confirming that neither bleeding nor gauze remains, undock the patient cart. Perform laparoscopy-assisted Double Stapling Technique (DST) anastomosis.

Preoperative and postoperative management

All patients received preoperative mechanical bowel preparation (one packet of magnesium citrate and one bottle of sodium picosulfate on the day before operation). Chemical bowel preparation consisted of oral administration of kanamycin and flagyl on the day before operation. As prophylactic antibacterial agents, 1 g per dose of cefmetazole sodium was administered basically at the beginning of operation, followed by an intravenous infusion of 1 g per dose of cefmetazole sodium and additional dose every 3 hours thereafter but only intraoperatively.

Postoperative course

The postoperative observation period was less than 30 days after surgery. After discharged from hospital, patients were required to return for follow-up visit every 2 to 4 weeks. For those who were in stage III or higher of wound confirmation or pathological stage, adjuvant chemotherapy was started within 4 to 8 weeks after surgery. The preoperative and postoperative courses were examined retrospectively using medical records.

RESULTS

The median age of the patients was 70 years (47-87 ; 18 male and 7 Female). The median BMI was 21 (16-32.5) kg/m^2. Two patients were classified in Class I, 20 patients in Class II, and 3 patients in Class III. The locations of cancer included the sigmoid region of the rectum (8 cases), the upper rectum (5 cases), the lower rectum (10 cases), and the anal canal (2 cases). The surgical techniques were as follows : anterior resection (14 cases) (Diverting ileostomy in 4 cases : 29%), Hartmann's operation (4 cases), and Abdominoperineal resection (7 cases). There were no cases of lateral lymph node dissection. The median operation time was 306 (195-622) minutes, with 40 (1-460) ml of blood loss and 169 (85-377) minutes of console operation time. There were no cases of conversion to open surgery. As preoperative treatment, 7 patients received anticancer drugs (TS-1, Oxaliplatin therapy) and 1 patient received chemoradiotherapy. Treatment was completed in all cases. Postoperative complications were observed in 3 patients (12%) : paralytic bowel obstruction (1 case, Clavien-Dindo grade II), outlet syndrome (1 case, Clavien-Dindo grade IIIa), and enteritis (1 case, Clavien-Dindo grade II). No suture failure, sexual dysfunction,

Table 2 Surgery outcomes

Operation time (min.)		306 (195−622)
Console time (min.)		169 (85−377)
Bleeding (ml)		40 (1−460)
Postoperative complications		3 (12%)
	Wound infection	0
	Paralytic bowel obstruction	1 (Clavian-Dondo Ⅱ)
	Outlet syndrome	1 (Clavian-Dind Ⅲa)
	Suture failure	0
	Enteritis	1 (Clavian-Dindo Ⅱ)
Postoperative hospital stay (days)		14 (8-69)

Table 3 Histopathological findings

pStage	0：Ⅰ：Ⅱa：Ⅲa：Ⅲb：Ⅲc：Ⅳ	0：3：10：2：5：2：3
The number of dissected lymph nodes		11 (2−24)
Tumor diameter (mm)		45 (11−90)
Histological type	Well differentiation：Moderate differentiation：Mucinous carcinoma	6：18：1
Proximal resection margin	Negative：Positive	25：0
Distal resection margin	Negative：Positive	25：0
Surgical resection margin	Negative：Positive	25：0

or urinary dysfunction was observed. The median postoperative hospital stay was 14 (8-69) days (Table 2). The pathological stages were as follows：stage I：3 cases；stage IIa：10 cases；stage IIIa：2 cases；stage IIIb：5 cases；stage IIIc：2 cases；stage IV：3 cases. There were no cases of Pathological complete response after preoperative treatment (ypCR) in patients who received preoperative treatment. There were also no cases of positive circumferential resection margin. The median number of dissected lymph nodes was 11 (2-24), and the median tumor diameter was 44.8±18.6 mm (Table 3).

DISCUSSION

In this study, all the surgeries and perioperative treatment were provided under constant conditions by the same surgeon and assistant surgeons at a single institution to evaluate short-term results. Not a single conversion to laparotomy or surgery-related death occurred. Postoperative complications were observed in 3 patients (12%), but no suture failure was observed, and also no reoperation or surgery-related death occurred. All four patients who had temporary ileal colostomy after surgery have completed colostomy closure. Thus, excellent short-term results were obtained from the robot-assisted rectal cancer surgery performed at our department.

In Europe and the United States, Weber et al. were the first to report robot-assisted colorectal resection for benign diseases in 2001, while Pigazzi et al. reported robot-assisted total mesorectal excision (TME) for rectal cancer in 2006. Robot-assisted surgery can make up for the disadvantages of conventional laparoscopic surgery, such as difficulty in operation, by using the robot's articulated surgical instruments and anti-shake mechanism as well as the delicate movements of the motion scale. In Japan, the da Vinci Surgical System was approved by the Pharmaceutical Affairs Law in 2009, and robot-assisted rectal resection and amputation was covered by insurance in April 2018. Since then, the number of robot-assisted rectal surgeries has been steadily increasing. Although there is currently no robust evidence of superiority over laparotomy or laparoscopy, it has been shown to be useful in cases with high technical difficulty[7,8]. Conventional laparoscopic surgery for rectal cancer is difficult to perform because of the limited movement of forceps in the narrow pelvis. A multicenter randomized controlled trial showed that laparoscopic surgery for rectal cancer had a higher rate of positive circumferential resection margin as compared to open surgery[1,2]. Again, since robot-assisted surgery for rectal cancer can make up for the disadvantages of conventional laparoscopic surgery, such as difficulty in operation, it is suitable for performing precise surgical operations in a narrow pelvic cavity. So, its usefulness is expected to increase. The evidence for the short-term results on robotic-assisted surgery for rectal cancer is as follows. In randomized controlled trials and meta-analyses reported since 2012, it was found that robot-assisted surgery had a longer operation time but a lower conversion-to-laparotomy rate than laparoscopy, and that the positive rate of circumferential resection margin was lower in robot-assisted surgery than in laparoscopy, with no significant difference[9~11]. In the ROLARR trial, no superiority of robot-assisted surgery over laparoscopic surgery was found in either intraoperative or postoperative short-term results. On the other hand, in subgroup analysis, robot-assisted surgery had a lower conversion-to-laparotomy rate in the relatively more difficult subgroups such as men, obesity, and low anterior resection[3].

Laparoscopic rectal cancer surgery for obese patients is considered difficult because of its long operation time, high rate of postoperative complications, and high conversion-to-laparotomy rates[7,8]. However, robot-assisted rectal surgery had no significant difference in conversion-to-laparotomy rates, positive circumferential resection margin rates, peri- and postoperative complications, and postoperative hospital stay between obese and non-obese patients[11~14]. Shiomi et al. reported that there was no difference in intraoperative blood loss, operation time, conversion-to-laparotomy rates, and postoperative hospital stay in robot-assisted surgery, whereas laparoscopic surgery resulted in more intraoperative blood loss, longer operation time, and longer postoperative hospital stay in obese patients[15]. In rectal cancer surgery, it is important not only to resect tumor completely but also to preserve the urogenital organs and their functions to prevent postoperative urogenital dysfunction. Postoperative urogenital dysfunction is mainly caused by intraoperative injury to the pelvic visceral nerves or pelvic plexus. Robot-assisted surgery enables precise recognition and preservation of the nerve course by using highly flexible surgical instruments with a stable, high-resolution field of view[16]. In terms of urogenital dysfunction after rectal cancer surgery, robot-assisted surgery compares favorably compared with laparoscopic surgery for International Prostate Symptom Score (IPSS) and International Index of Erectile Function (IIEF) score. Since men are more likely to experience postoperative dysuria and sexual dysfunction, robot-assisted surgery may be particularly useful for preserving urogenital function in men[17,18]. In this study, it was possible to operate safely in men, obesity, and low anterior resection cases without many postoperative complications.

Lateral lymph node dissection is recommended as the standard procedure for patients with lower advanced rectal cancer (LARC). LARC is rectal cancer in which the lower tumor margin is located on the anal side of the peritoneal reflection and the depth of invasion is cT3 or deeper)[19]. The procedure requires to dissect the lymph nodes in a manner to preserve the autonomic nerves that are responsible for urogenital function as much as possible. The number of facilities performing laparoscopic lateral dissection is increasing, but since it requires a high level of proficiency, the current standard technique is still laparotomy. Yamaguchi et al. reported that robotic-assisted surgery is more useful as an approach for lateral lymph node dissection than laparotomy or laparoscopy[20,21]. They also reported on the long-term prognosis and showed that the 5-year local recurrence-free survival rate after robot-assisted lateral dissection was 98.6%, which was better than that of open surgery (90.9%)[22].

Lateral lymph node dissection is a procedure used to resect adipose tissue along with lymph nodes from the closed cavity between the internal and external iliac arteries, the lateral portion of the rectal cavity surrounded by the internal iliac artery, and the urinary bladder cavity. First, both ureters are taped near the anterior aspect of the common iliac artery and pulled laterally. The hypogastric nerve is taped and pulled medially, preserving the autonomic nerves. The lymph nodes, located at the anterior aspect of the common iliac artery in the region extending from the bifurcation of the aorta to the bifurcation of the internal and external iliac arteries are resected together with the adipose tissue. The dissection is extended to expose the lateral wall of the pelvis and the posterior sciatic nerve ; the obturator nerve and obturator artery and vein can then be clearly seen. Obturator lymph node dissection is then completed. The surrounding tissue is dissected along the internal iliac artery, and the superior vesical artery is confirmed. Because the pelvic nerve plexus is located medially and inferiorly, the blood vessels should be taped and pulled laterally, and a space should be created between the pelvic nerve plexus and blood vessels to avoid neural injury. Peripherally, the obturator artery arising from the internal artery, the inferior vesical vein, and the pelvic nerve (S3,4) extending from the mediodorsal side of the piriformis muscle toward the pelvic plexus are preserved, and the surrounding adipose tissue is resected. This step completes the lateral lymph node dissection[23].

As for long-term prognosis, the history of robotic-assisted surgery is still short and there are few papers reporting long-term results. Kim et al. reported that robotic-assisted surgery turned out to be a favorable prognostic factor for overall survival and cancer-specific survival[21].

In terms of the learning curve and surgical education of this technique, it is considered that 15-44 cases of experience is needed to acquire skillful hands for performing robot-assisted surgery[24,25], as reported in many studies that they have used the cumulative sum method for evaluation. On the other hand, some studies reported that about 40-90 cases of experience was required for laparoscopic surgery[26~28], suggesting that robot-assisted surgery has a shorter learning curve. From an educational point of view, the use of a dual console system can provide a safe and highly effective learning experience. The dual-console supervisory physician and trainee doctor can view the same high-resolution 3D operative field from each console and can easily take turns at operating some or all of the forceps. The dual console system is useful for reducing operation time and intra- and postoperative complications.

In order to advocate the safety of this technique in the future, not only it is important to standardize the surgical techniques and provide surgical education in our own institutions, but also it is desirable to have a multicenter prospective randomized controlled trial conducted by physicians skilled in robot-assisted surgery in Japan. In addition, since the learning curve is shorter than that of laparoscopic surgery, the use of the dual console system is expected to help not only to standardize the surgery but also to enhance the effectiveness of surgical education in a safe manner. From now on, lower prices caused by competition among companies, combination of intraoperative navigation system and AI (Artificial Intelligence) that are not available in conventional surgical support robots, as well as development of next-generation system that enables remote surgery, will lead to further improvements in the safety, quality, and outcomes of this procedure. It is considered necessary to further investigate the recurrence rate and survival rate by continuing this method for a long period of time.

Conflict of interest

The authors declare no conflict of interest.

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