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Short-term Outcomes of Robot-assisted Surgery for Rectal Cancer

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Objective: To clarify the safety and efficacy of robot-assisted surgery for rectal cancer.
Methods: We evaluated the short-term clinical outcome of 50 patients who underwent robot-assisted laparoscopic rectal resection for primary rectal cancer in our hospital from November 2016 through June 2018.
Results: The median operation time was 358 minutes (range, 271−747 min). The median console time was 201 minutes (range, 143−332 min). The median volume of intraoperative blood loss was 5 ml (range, 0−998 ml). No patients had adjacent organ injuries, and none were converted to conventional or laparoscopic surgeries. Postoperative complications were classified according to the Clavien-Dindo classification as grade II or higher in 9 patients (18.0%). No mortality was observed. As for histopathological findings, the median number of dissected lymph-nodes was 14 (range, 2−48 nodes), and the median length of postoperative hospital stay was 11 days (range, 6−62 days). No patients had a positive proximal or distal margin, however 1 patient had a positive radial margin.
Conclusion: Robot-assisted laparoscopic surgery was safely performed with good short-term outcomes.

Key words: robot-assisted surgery, rectal cancer, short-term outcomes

Introduction

Surgery for rectal cancer requires both curability by total mesorectal excision (TME), a precise dissection of the rectal layer, and preservation of organ functions (e.g., sexual, bladder, and defecatory). Laparoscopy enables a clear understanding of the anatomical structure by providing a magnified view of the narrow pelvic cavity, allows precise surgery, and leads to the broad dissemination of laparoscopic surgery. In a narrow pelvic cavity, the necessary manipulation of surgical instruments may be restricted, thereby making dissection by straight forceps harder. Precise tangential dissection of the right side of the rectum may be particularly difficult. Such disadvantages of laparoscopic surgery can be overcome by robot-assisted surgery, allowing more precise manipulation of surgical instruments.

In Japan, the robot-assisted surgery for rectal cancer was covered by the National Health Insurance in April 2018 and has rapidly been disseminated. To ensure the safety of robot-assisted surgery with insurance coverage, each institute must meet the following criteria: at least 30 cases per year of rectal resection and amputation, a full-time employed surgeon with the experience of performing at least 10 cases of robot-assisted surgery. The Japan Society for Endoscopic Surgery recommends these conditions for surgeons to promote the safe introduction and dissemination of robot-assisted surgery.

Robot-assisted surgery with high-resolution three-dimensional visual fields and multi-joint instruments allows surgeons to perform precise dissections. The learning curves are expected to be faster in robot-assisted surgery than in laparoscopic surgery.[1-3] However, to facilitate the safe introduction of robot-assisted surgery, its characteristics should be adequately understood. The robotic thick arms may easily interfere with each other, leading to restricted motion. To perform surgery smoothly, methods to avoid interactions of the arms should be understood. Tactile sensation is not transmitted to the operator during robot-assisted surgery. Because pushing force and pulling force are extremely strong in a narrow surgical field of vision, mistaken operative moves

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may cause organ injuries. To prevent procedure-specific complications, robot-assisted surgery should be performed with gentle forceps manipulation, based on an understanding of the visual information, on what the surgeon sees.

Robot-assisted rectal surgery was introduced in our department in November 2016. To date, we have performed robot-assisted rectal surgery in 63 cases. In this study, to clarify its safety and efficacy, we evaluated the short-term outcomes of patients who underwent robot-assisted surgery for primary rectal cancer.

Subjects and Methods

We have performed robot-assisted laparoscopic rectal resections and amputations in 57 patients with primary rectal cancer in the Department of Lower Gastrointestinal Surgery, Kitasato University from November 2016 through June 2019. Of these patients, we evaluated the short-term safety of robot-assisted laparoscopic surgery in 50 patients who underwent TME without lateral lymph node dissection or tumor-specific mesorectal excision (TSME). Surgery was performed using either the da Vinci Si or Xi Surgical Systems. All postoperative complications within 30 postoperative days were regarded as adverse events and were evaluated according to the Clavien-Dindo classification. We retrospectively reviewed clinical records of 50 patients. The primary endpoint was the incidence of postoperative complications, which was grade II or higher according to the Clavien-Dindo classification. Surgery was conducted by 2 specialists of colorectal cancer, each of whom had 15 or more years experience, were digestive surgeons certified in endoscopic surgery, and had passed a training program conducted by Intuitive Surgical Inc. (USA).

Written informed consent was obtained from all the patients. The study was approved by an ethics committee of Kitasato University School of Medicine (B19-191).

Surgery techniques

Patients were placed in the lithotomy or Trendelenburg position. A camera port was placed at the umbilicus. Six ports were used for the da Vinci Si Surgical System, and 5 or 6 ports were used for the da Vinci Xi Surgical System (Figure 1). Similar to laparoscopic rectal resection and amputation, internal mobilization was begun. After the ureter was dropped dorsally, the inferior mesenteric artery was clipped and transected. After the inferior mesenteric vein and the left coronary artery were transected, internal mobilization was progressively done. The gonadal blood vessels and the prerenal fascia were dropped dorsally and were dissected until the level of the descending colon. In the caudal region, internal mobilization was extended to around the level of the promontorium. Subsequently, external mobilization was performed and switched to intrapelvic manipulation. In intrapelvic manipulation, after gauze wrapped around the rectum held by the assistant was pulled cranially and ventrally, mobilization of the posterior wall was begun. The posterior wall was dissected until the levator ani muscle was exposed. Subsequently, while regarding the Denonvilliers' fascia in the anterior wall as a landmark, dissection was performed until adequate mobilization of the dorsal part

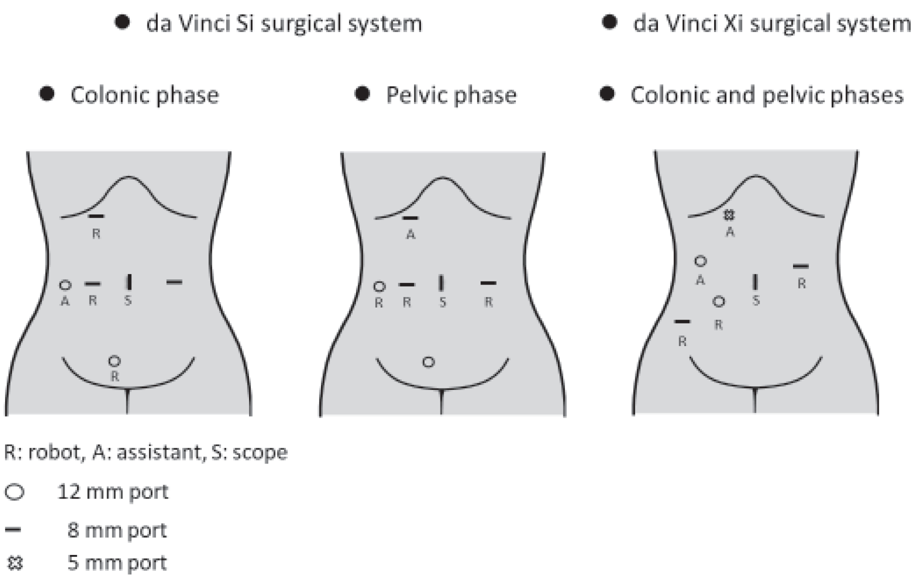

Figure 1. Port placement

of the prostate and the posterior wall of the vagina could be achieved. The lateral wall was also dissected to match the level of the anterior and posterior walls. TSME or TME were performed according to the tumor localization. The mesentery was dissected with the da Vinci Si stapler or the EndoWrist Stapler for the da Vinci Xi Surgical System. Subsequently, the da Vinci System was undocked. Laparoscopic anastomosis or perineal anastomosis were performed either under laparoscopic or direct visual inspection.

Results

Regarding patient characteristics, the ratio of male to female patients was 35 (70%) to 15 (30%), with a median age of 66 years (range, 21−85 years) and a median body mass index of 22.8 kg/m^2 (range, 15.4−38.6 kg/m^2). The tumor locations were: in the rectosigmoid region (n = 10, 20%), the upper rectum (n = 14, 28%), and the lower rectum (n = 26, 52%). The clinical tumor stage was I in 22 patients (44%), II in13 patients (26%), III in 13 patients (26%), and IV in 2 patients (4%).

Preoperative chemoradiotherapy was performed in 6 patients (Table 1).

Surgical procedures were: abdominoperineal resection (n = 7, 14%), anterior resection (n = 3, 6%), low anterior resection (n = 33, 66%), intersphincteric resection (n = 6, 12%), and Hartmann's procedure (n = 1, 2%). TME or TSME were performed in 38 (76%) and 12 patients (24%), respectively. Diverting ileostomy was performed in 33 (75%) of 44 patients who underwent anastomosis. The median operation time was 358 minutes (range, 271−

Table 1. Clinical characteristics

	N = 50
Gender, n (%)	
Male	35 (70)
Female	15 (30)
Age (years median (range)	66 (21−85)
Body mass index (kg/m^2) median (range)	22.8 (15.4−38.6)
ASA class, n (%)	
I	5 (10)
II	39 (78)
III	6 (12)
Tumor size (mm) median (range)	35.5 (5−82)
cT, n (%)	
cT1b	13 (26)
cT2	12 (24)
cT3	14 (28)
cT4a	8 (16)
cT4b	3 (6)
cN, n (%)	
cN0	35 (70)
cN1a	6 (12)
cN1b	2 (4)
cN2a	6 (12)
cN3	1 (2)
Location of tumor, n (%)	
Rectosigmoid	10 (20)
Upper rectum	14 (28)
Lower rectum	26 (52)
Neoadjuvant therapy, n (%)	
No	44 (88)
Yes	6 (12)

ASA, American Society of Anesthesiologists

747 min). The median console time was 201 minutes (range, 143−332 min). The median volume of intraoperative blood loss was 5 mL (range, 0−998 ml). There were no intraoperative adverse events an no adjacent organ injuries. No patients were converted to conventional or laparoscopic surgery. The number of dissected lymph nodes was 14 (range, 2−48).

The length of the postoperative hospital stay was 11 days (range, 6−62 d). No patients had positive proximal or distal margins, while 1 patient (2%) had a positive radial margin (Table 2). Postoperative complications were classified according to the Clavien-Dindo classification as grade II or higher in 9 patients (18.0%). The details were grade II ileus in 2 patients (4%), grade II anastomotic leakage in 1 patient (2%), grade IIIa anastomotic leakage in 3 patients (6%), grade IIIb anastomotic leakage in 1 patient (2%), and grade II wound infection in 3 patients (6%). No patients had urinary or sexual dysfunction (Table 3).

Discussion

The safety of robot-assisted surgery has been sporadically reported. The operation time required for robot-assisted surgery was significantly longer than that compared with laparoscopic surgery. However, the volume of intraoperative blood loss, the number of dissected lymph nodes, and the incidence of postoperative complications did not differ between robot-assisted and laparoscopic surgeries.[4,5] In a systematic review reported by Mak et al. in 2014,[6,7] the median incidence of postoperative complications in patients who underwent robot-assisted surgery was 20% (range, 10.7%−41.3%). The median incidence of suture failure was 6.4% (range, 0%−20%),

Table 2. Surgical procedure and perioperative clinical outcome

	N = 50
Procedure, n (%)	
Abdominoperineal resection	7 (14)
Anterior resection	3 (6)
Low anterior resection	33 (66)
Intersphincteric resection	6 (12)
Hartman	1 (2)
Operative time (min) median (range)	358 (271−747)
Surgeon console time (min) median (range)	201 (143−332)
Estimated blood loss (ml) median (range)	5 (0−998)
Docking type, n (%)	
Dual	15 (30)
Single	35 (70)
DaVinci type, n (%)	
Si	27 (54)
Xi	23 (46)
Intervention, n (%)	
Total mesorectal excision	38 (76)
Tumor-specific mesorectal excision	12 (24)
Conversion rate, n (%)	0 (0)
Combined resection, n (%)	
Right hemicolectomy	1 (2)
Vagina	2 (4)
Hospital stay, days median (range)	11 (6−62)
Radial margin Cn (%)	
Negative	49 (98)
Positive	1 (2)
Lymph nodes harvest median (range)	14 (2−48)

Table 3. Postoperative complications

	N = 50
Total, n (%)	9 (18.0)
Ileus (G2)[a]	2 (4.0)
Anastomotic leak (G2)	1 (2.4)
Anastomotic leak (G3a)[a]	3 (7.1)
Anastomotic leak (G3b)[a]	1 (2.4)
Wound infection (G2)[a]	3 (6.0)
Urinary retention	0 (0)

[a]Clavien-Dindo classification

which was similar to that in patients who underwent laparoscopic surgery. The incidences of sexual dysfunction and urinary dysfunction were lower in patients who underwent robot-assisted surgery and in those who underwent laparoscopic surgery, suggesting that robot-assisted surgery is useful for functional preservation.

Compared to previous results, treatment outcomes in Kitasato University Hospital were as follows. The operation time tended to be slightly longer. However, compared with the results of studies in other countries, the console time, the volume of intraoperative blood loss, and the rate of conversion to laparotomy were similar or improved, suggesting the safety of robot-assisted surgery. The incidence of postoperative complications in the present study was also similar to that in previous studies. However, suture failure occurred in 5 of 44 patients (11.4%), which was slightly higher than that in previous studies.

We believe that the following factors might have influenced our results. Many patients had lower rectal cancer or were obese from the initial time of introduction. The learning curve of robot-assisted surgery has been reported to become stabilized in 15 to 30 patients[1,2,8] and is shorter than that of laparoscopic rectal resection. Therefore, to facilitate the safe introduction of robot-assisted surgery, we believe that robot-assisted low anterior resection should be performed by surgeons with adequate experience, about 20 nonobese patients with rectosigmoid cancer, at the time of introduction. In addition, after the learning curve stabilized, robotic-assisted surgery should be applied to more technically challenging cases, such as those with lower rectal cancer or obese patients. In Kitasato University Hospital, 162 patients underwent laparoscopic rectal resection or amputation in the same period. Median operative time was longer in the robotic cases compared to that in the laparoscopic cases (358 vs. 269 min, respectively). Blood loss and hospital stay were similar for both types of cases.

In general, surgery for rectal cancer is more technically challenging than that for colon cancer, with a higher rate of local recurrence. To appropriately perform surgery for rectal cancer, while maintaining both curability and functional preservation, adequate mobilization should be performed in the rectal layer, based on a precise understanding of perirectal anatomy. Subsequently, TSME or TME should definitely be performed.

The rate of a positive circumferential resection margin (CRM) may contribute to oncological outcomes. The rate of disease-free survival is lower in patients with a CRM of less than 1 mm than in those with a CRM of 1 mm or greater.[9,10] In a systematic review by Xiong et al.,[11] robot-assisted surgery was associated with a lower rate of positive CRM than was that of laparoscopic surgery. Robot-assisted surgery with high-resolution three-dimensional visual fields, multi-joint forceps, and an image stabilizer enables surgeons to perform more precise operations, evidencing the efficacy of robot-assisted surgery. In the Robotic vs Laparoscopic Resection for Rectal Cancer (ROLARR) trial,[12] a large study held in multiple countries, the rate of positive CRM (<1 mm) was 5.1% in patients who underwent robot-assisted surgery and 6.3% in those who underwent laparoscopic surgery, with no significant differences between the groups. The rate of conversion to laparotomy, the primary endpoint of this study, did not differ between patients who underwent laparoscopic surgery and those who underwent robot-assisted surgery. In a subgroup analysis, however, the rate of conversion to laparotomy was lower in men, obese patients, and patents who underwent low anterior resection, suggesting the usefulness of robot-assisted surgery in patients who require more technically challenging surgical procedures.

In the present series, 1 patient (2%) had a positive radial margin. In our hospital, 162 patients underwent conventional laparoscopic rectal resection or amputation in the same period. Eleven of these patients (6.9%) had a positive radial margin. This result cannot be directly compared with that obtained from countries other than Japan because the methods of evaluating rectal samples is different. In other countries, the rate of positive CRM may tend to be lower in patients who undergo robot-assisted surgery. Our results were similar to those in other countries. However, further studies of larger numbers of patients are required after introducing methods to evaluate CRM that are similar to those in other countries.

The disadvantages of robot-assisted surgery were as follows. The movement of the robot arms often conflicted with each other because they are thick and large. Therefore, the port location for an assistant is limited, highly restricting the movement of the assistant's instruments. Therefore, aspiration of fluid or blood cannot be appropriately performed, leading to a poor surgical field of vision and difficulty performing hemostasis. In such situations, dissection also becomes difficult in the proper layer. For the initial introduction, we inserted one 12-mm port into the epigastric region, and the assistant surgeon performed everything through that one port; handling the rectum, aspiration of fluid, and inserting the gauze, might have led to delayed aspiration and hemostasis. We, therefore, changed the port setting, inset a 5-mm port at the epigastric region and an additional 12-mm port at the right upper abdomen, allowing assistance in deployment and inserting and removing an aspirator and gauze. Thus, a better surgical field of vision was thereby obtained. Consequently, variations of deployments by the assistant were increased, allowing aspiration and hemostasis to be performed smoothly. However, patients who received chemoradiotherapy had edematous layers and a large amount of exudate fluid from the dissected layer owing to the influence of radiation. Because the exudate fluid that pooled onto the pelvic floor was frequently aspirated, an aspirator was inserted from the right upper abdomen. Aspiration may be difficult because of interference with the promontorium. To solve such problems, refinement of port placement and the development of a new aspirator may be necessary to improve the surgery.

Long-term outcomes of robot-assisted surgery have recently been reported but sporadically. Several studies assessed the usefulness of robot-assisted surgery on the basis of long-term outcomes such as overall survival, cancer-specific survival, and local recurrence rates after lateral lymph-node dissection.[13,14] Our study suggested that robot-assisted surgery is safe and can be used as a new key approach for treating colorectal cancer. Further studies with larger numbers of patients are needed to examine the long-term outcomes and efficacy of robot-assisted surgery. Robot-assisted laparoscopic surgery was associated with relatively good short-term outcomes and could be performed safely.

Conflicts of Interest: None

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