

Case Report

Hybrid Abdominal Robotic Approach Using the hinotori[™] Surgical Robot System with Transanal Total Mesorectal Excision for Rectal Cancer: The First Ever Case Report for Rectal Cancer

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Abstract

In Japan, the hinotori[™] Surgical Robot System obtained pharmaceutical approval for use in colorectal cancer surgery in October 2022. This system has an operating arm with eight axes, adjustable arm base, and flexible three-dimensional viewer, which are expected to be advantageous in colorectal cancer surgery. A 55-year-old man presented to our hospital with melena and was diagnosed with cStage IIA (cT3N0M0) rectal cancer. The patient underwent intersphincteric resection using hinotori[™] Surgical Robot System. Appropriate port placement was available for rectal manipulation, lymph node dissection, and arm base angle adjustment. Herein, we report the world's first rectal cancer surgery using the hinotori[™] Surgical Robot System with TaTME by two teams.

Keywords

rectal cancer, hybrid surgery, TaTME

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Introduction

Total mesorectal excision (TME) is fundamental for the curable resection of rectal cancer[1]. Based on the TME, a circumferential resection margin (CRM) >1 mm prevents local recurrence and distant metastasis[2].

In a meta-analysis, laparoscopic surgery was reported as non-inferior to open surgery for TME achievement while ensuring a CRM of >1 mm[3]. Additionally, laparoscopic surgery has superior short-term postoperative outcomes compared with that of open surgery; thus, in recent years, minimally invasive surgery (MIS) is increasingly being performed for rectal cancer[4]. However, as laparoscopic surgery requires the use of linear forceps, its use in rectal cancer surgery is limited to pelvic manipulation; therefore, it is difficult to perform in patients with lower rectal cancer. The unique feature of the multi-joint capability of robotic surgery helps overcome these challenges. Thus, robotic surgeries are more widely performed in recent years[5]. In Japan, robotic surgery for rectal cancer has been covered by insurance since 2018, leading to an increase in the number of these surgeries[4]. However, it is challenging to perform robotic surgery in men with a narrow pelvis, obesity, and large tumors. Reportedly, transanal TME (TaTME) is effective in cases where manipulation is difficult using the abdominal approach[5]. TaTME has a few advantages over the transabdominal approach, such as superiority in a CRM of >1 mm, easier securing of the distal resection margin (DRM), and a shorter operative time using two teams[6]. Hybrid surgery combining robotic surgery and TaTME is expected to combine the advantages of both procedures; however, there are few reports on this to date.

Previously, most robotic surgeries were performed using the da Vinci system (Intuitive Surgical, Sunnyvale, CA,

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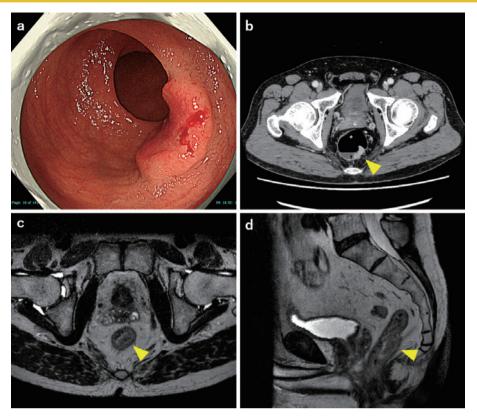


Figure 1. Imaging findings of the present tumor.

(a) Colonoscopy reveals type 2 advanced cancer located on the left wall of rectum.

(b) Computed tomography axial section indicates advanced cancer in the rectum (arrow head).

(c) Axial MRI revealed advanced cancer beyond the muscular layer (arrow head).

(d) Sagittal MRI revealed advanced cancer the muscular layer (arrow head).

Arrow head indicating tumor. MRI: Magnetic resonance imaging

USA). The Hinotori Surgical Robot System (hinotoriTM), was developed in Japan by the Medicaroid Corporation (Kobe, Hyogo, Japan) and jointly funded by Kawasaki Heavy Industries, Ltd. (Kobe, Hyogo, Japan) and the Sysmex Corporation (Kobe, Hyogo, Japan). After Japanese regulatory approval in August 2020 in urology, the first surgery using this system was conducted in December 2020. Insurance coverage for colorectal cancer surgery using the hinotoriTM Surgical Robot System was approved in October 2022, and the first colon cancer surgery using this system was performed at our institution[7,8]. Herein, we report the first hybrid surgery for rectal cancer using a new robot (hinotoriTM) developed in Japan.

Case Report

All procedures in this study were performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Informed consent was obtained from the patient for the publication of this case report. Colorectal cancer surgery using the hinotori[™] Surgical Robot System was approved by the Evaluating Committee for Highly Difficult New Medical Technologies (approval number 22-007) in Japan and the Institutional Review Board of Sapporo Medical University (approval number 342-184).

A 55-year-old man with a BMI of 27.6 kg/m² presented to our hospital with melena. Colonoscopy revealed a type 2 advanced cancer located 5 cm from the anal verge (AV) on the left wall of the rectum. Histological examination indicated a well-differentiated adenocarcinoma. Magnetic resonance imaging (MRI) revealed that the cancer penetrated beyond the muscular layers. Computed tomography (CT) and positron emission tomography (PET-CT) revealed no lymph node findings or distant metastases (Figure 1). The patient was diagnosed with cStage IIa (cT3N0M0) rectal cancer according to the Japanese Classification of Colorectal, Appendiceal, and Anal Carcinoma, 3rd English Edition[9]. Consequently, two teams performed intersphincteric resection (ISR) of the tumor using the hinotoriTM Surgical Robot System combined with TaTME. Ichiro Takemasa was selected by Medicaroid Corporation as the first surgeon to perform

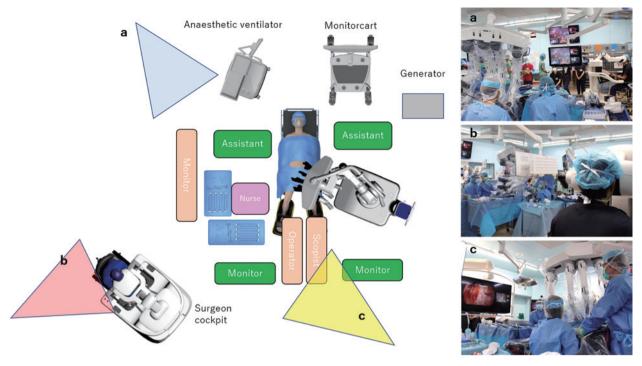


Figure 2. Operator positions in the present case.

(a) View from the upper right of the patient.

(b) View from the back of the surgeon's cockpit.

(c) View from behind the perineal operator.

colorectal cancer surgery using the robot system and received relevant training, including cadaver training, under the approval of the Japan Society for Endoscopic Surgery.

The abdominal and transanal approaches were performed simultaneously (Figure 2). Standard robotics procedures for rectal cancer resection using the abdominal approach have been established at our institution. A 3-cm vertical skin incision was taken in the umbilicus. A GelPOINT Mini (Applied Medical, Rancho Santa Margarita, CA, USA) and an assistant port were inserted in the incision. Four robotic ports and two additional assistant ports were placed. The port placement for this surgery was performed similarly to the method we have previously reported[8]. The patient's head was positioned 12° and 10° downward. After removing the small intestine to the cranial right side, the operation unit was rolled from the left side, and the arm base arrangement, which was in a 6-degree backward position, was targeted slightly caudal to the common iliac artery. Bipolar fenestrated forceps were used for the first robotic arm, monopolar curved scissors or bipolar Maryland forceps for the third arm, and cross-grasping forceps for the fourth arm. A medial approach was used and the inferior mesenteric artery was dissected. Following adequate mobilization of the mesentery, the left colic artery and inferior mesenteric vein were dissected, and the rectum was mobilized (Figure 3). The anterior wall was rendezvoused at the peritoneal reflection and

the posterior wall at the level of the S4 nerve. In the transanal approach, a Lone Star retractor (Cooper Surgical, Trumbull, CT, USA) was employed to retract the anal canal. A 2-cm distal margin was then secured from the tumor under direct vision, and the internal anal sphincter was dissected up to the upper anal canal border. The intestinal transection was sutured using 3-0 vicryl, and the anal canal was washed with a large amount of saline. Subsequently, a Gel-POINT ® Path Transanal Access Platform (Applied Medical, Rancho Santa Margarita, CA, USA) was inserted into the anal canal. Three trocars were inserted in the platform in a triangular position. Following posterior endopelvic fascia identification, the TME plane was identified and dissected posteriorly. On the anterior wall, the prostatic apex was identified at the 1 and 11 o'clock positions, and the rectus urethralis muscle was dissected. The dorsal prostate was dissected, followed by dissection of the neurovascular bundle at the 2 and 10 o'clock positions. TaTME was performed until the cephalad dissection achieved a "rendezvous" with the abdominal dissected area (Figure 4). After specimen removal, handsewn anastomosis was performed from the anal side, creating a diverting ileostomy. The operative time was 232 min, with a cockpit time of 88 min. Specimens were assessed using a semi-open circular specimen processing method for pathological CRM assessment as in Japanese practice, according to multicenter validity studies (Figure

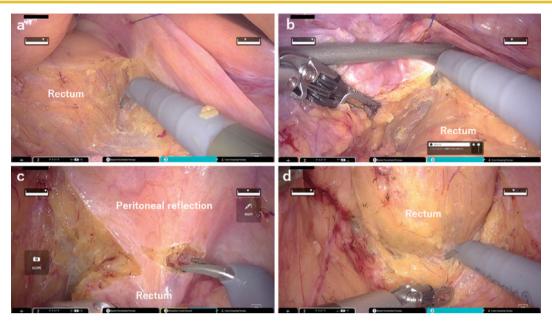


Figure 3. Surgical field rectal mobilization (abdominal approach).

- (a) Right side of the rectum.
- (b) Left side of the rectum.
- (c) Anterior view of the rectum.
- (d) Posterior view of the rectum

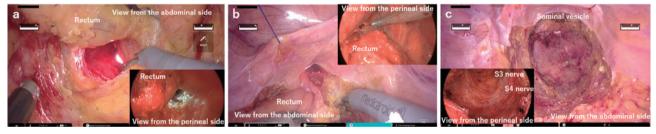


Figure 4. Surgical field in the pelvis.

- (a) View of rendezvous at the posterior wall of the rectum from the abdominal side (lower right view from the perineal side).
- (b) View of rendezvous at the anterior wall of the rectum from the abdominal side (upper right view from the perineal side).
- (c) View from the abdominal side of the pelvis after specimen removal (lower left: perineal side).

5)[10,11]. The patient was discharged eleven days postoperatively without complications.

Discussion

Herein, we reported the first hybrid robotic surgery to treat rectal cancer. The hinotoriTM Surgical Robot System differs from the da Vinci Surgical System in several aspects. Each robotic arm has eight axes and an adjustable arm base angle, which allows flexible arm motion and reduced interference between the arms. Although it is difficult to compare with the da Vinci Surgical System, there is a potential for more interference reduction and a wider surgical field. A docking-free design, in which the "pivot" position of the instrument is set by the software, eliminates the need for

docking of the arm and the trocar. The docking-free design is expected to provide more space around the trocar and easier maneuvering for the assistant. Furthermore, the surgeon cockpit has a flexible three-dimensional viewer, which may reduce surgical effort owing to its ergonomic design.

The REAL trial revealed that robotic surgery was superior to laparoscopic surgery for rectal cancer. The trial also found that a CRM of >1 mm helped achieved TME, and was associated with few postoperative complications. In the same study, a sub-analysis of CRM positivity revealed risk factors such as male sex, T3-4 advanced cancer, and an AV of 5 cm or less, suggesting that robotic surgery is challenging in complex cases[12].

TaTME is advantageous in terms of ensuring a CRM of >1 mm, easier securing of the DRM, and a shorter operative

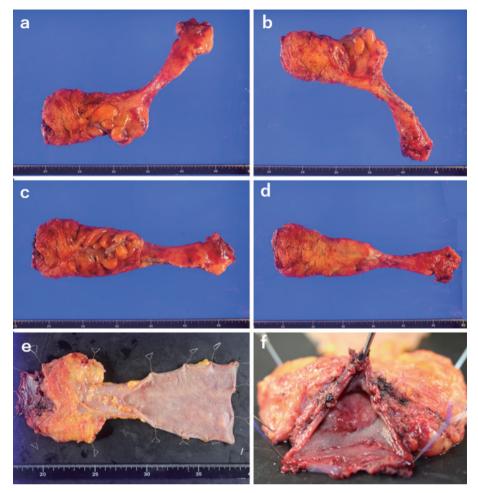


Figure 5. Resected specimen.
(a) Right view of the resected specimen.
(b) Left view of the resected specimen.
(c) Anterior view of the resected specimen.
(d) Posterior view of the resected specimen.
(e) Specimen is fully stretched and pinned to the board.
(f) Visualization of the tumor from the anal side.

time as it requires two teams[6]. While evidence on TaTME is limited compared with that on transabdominal laparoscopic surgery, it may demonstrate the effectiveness of TaTME in robotic surgery.

Here, positive CRM risk factors in the REAL trial were male sex, T3, and AV 5 cm, making the case challenging. In the present case, despite all of these risk factors met, the hybrid surgery using the hinotoriTM system helped to ensure a CRM of >1 mm. When employing a transabdominal approach, intraoperative endoscopy is generally required to confirm the transection line and ensure a DRM of \geq 2 cm. Intraoperative endoscopic findings may necessitate additional dissection. Furthermore, rectal dissection is difficult to perform in the deep pelvic region. In hybrid surgery, dissection can be initiated by tumor confirmation under direct vision using a perineal maneuver. This method is reliable and facilitates securing of a DRM of ≥ 2 cm. In a meta-analysis, the average operating time for robotic ISR was reported to be 330 min[13]. The 232-min operative time in the present case reflects an advantage of the two-team approach. The learning curve for rectal cancer surgery using the da Vinci system is 12-35 cases[14]. Thus, the operative time with the hinotori system may be reduced further as surgeons gain more experience with it.

The important organs and nerves in the pelvis are located around the rectum. An appropriate dissection line must be established to secure a CRM in this area; however, excessive external dissection may result in organ and nerve damage. Therefore, extremely delicate manipulation is required during rectal cancer surgery. The Japanese PRODUCT trial, a multicenter prospective observational study on CRM, focused on patients with advanced rectal cancer[15]. This trial showed the quality of MIS based on the CRM in Japan. The VITRUVIANO trial (UMIN000039685) is being conducted to evaluate CRM and postoperative urinary drainage in robotic surgery. The PRODUCT trial is a mix of laparoscopic and robotic, whereas the VITRUVIANO is robotic only. Case accumulation has been completed, and the results of this study are anticipated. The hinotori[™] system includes more joints than the da Vinci system, which may avoid interference and improve maneuverability in a narrow pelvis. However, limitations of this study include the requirement of sophisticated surgical intuition and development of sealing devices.

The hinotori[™] Surgical Robot System is cheaper than da Vinci Surgical System and may contribute to widespread employment of robotic surgical approaches. The efficacy of hybrid surgery using the hinotori[™] system warrants further investigation. While novel surgical robots may continue to emerge across various enterprises, it remains imperative to acknowledge the distinct individuality of each surgical robot. However, this study demonstrated that the hybrid robotic surgery using the hinotori[™] surgical system is safe and feasible.

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Conflicts of Interest There are no conflicts of interest.

Authors Contributions

All authors made substantial contributions to the study and agree with the content of the manuscript.

Approval by Institutional Review Board (IRB)

This study was approved by Institutional Review Board of Sapporo Medical University (approval number 342-184).

Disclaimer

Ichiro Takemasa is one of the Associate Editors of Journal of the Anus, Rectum and Colon and on the journal's Editorial Board. He was not involved in the editorial evaluation or decision to accept this article for publication at all.

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