—**Review**—

Current Status of Robotic Gastrointestinal Surgery

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Development of surgical support robots began in the 1980s as a navigation and auxiliary device for endoscopic surgery. For remote surgery on the battlefield, a master-slave-type surgical support robot was developed, in which a console surgeon operates the robot at will. The da Vinci surgical system, which currently dominates the global robotic surgery market, received United States Food and Drug Administration and regulatory approval in Japan in 2000 and 2009 respectively. The latest, fourth generation, da Vinci Xi has a good field of view via a three-dimensional monitor, highly operable forceps, a motion scale function, and a tremor-filtered articulated function. Gastroenterological tract robotic surgery is safe and minimally invasive when accessing and operating on the esophagus, stomach, colon, and rectum. The learning curve is said to be short, and robotic surgery will likely be standardized soon. Therefore, robotic surgery training should be systematized for young surgeons so that it can be further standardized and later adapted to a wider range of surgeries. This article reviews current trends and potential developments in robotic surgery. (J Nippon Med Sch 2023; 90: 308–315)

Key words: robotic surgery, minimally invasive surgery, gastrointestinal system

Introduction

Progress in minimally invasive surgery (MIS) over the last 30 years reflects the development of modern surgery. MIS has revolutionized surgery and benefited patients, health economics, and society[1]. Patients develop fewer postoperative complications, recover faster, and have fewer cosmetic scars after MIS than after open surgery[2].

Although the laparoscopic approach has advantages, it is not always a comfortable operation because of the absence of a three-dimensional (3D) field of view, limitations in the degree of freedom of surgical instruments, and physiological tremor. In recent years, robotic surgery has managed to overcome these limitations of laparoscopic surgery and has spread rapidly worldwide[3]. Moreover, gastroenterological robotic surgery for malignant diseases is becoming widespread and will be discussed in this review.

Robotic Surgery for Gastrointestinal Surgery

Robotic surgery with the master-slave system was performed mainly on the ZEUS and da Vinci platforms[4]. In 1997, the first cholecystectomy was performed using da Vinci in Belgium[5], and a remote-controlled cholecystectomy called the Lindbergh operation was performed across the Atlantic Ocean, between New York and France, using the ZEUS system[6]. After 2003, the two companies, da Vinci's Intuitive Surgical and ZEUS's Computer Motion, merged and the da Vinci system subsequently dominated robotic surgery for almost a decade. Consequently, further innovations and improvements focused on the da Vinci system, which was granted FDA approval in 2000. It is beneficial for surgical procedures that require suture ligation in a narrow space in which the forceps angle may require unnatural movement. It is also used in fundoplication[7], colorectal cancer surgery[8], and gastrojejunal bypass[9].

The da Vinci surgical system was approved by the

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Japanese Ministry of Health, Labor, and Welfare in November 2009 and promoted as an advanced medical technology. In 2012, robot-assisted total prostatectomy commenced. In 2016, robot-assisted resection of malignant renal tumors was approved for cover by national insurance and became widespread-mainly in urology-but not in gastrointestinal surgery. A later randomized controlled trial (RCT) comparing robotic gastrectomy and laparoscopic gastrectomy[10] recognized robotic gastrectomy as an advanced medical treatment that resulted in fewer complications, including pancreatic fistula, than laparoscopic surgery. Subsequently, 12 surgical procedures in respiratory and cardiac surgery were approved for cover by insurance; esophagomediastinal surgery, pancreaticoduodenectomy, and distal pancreatectomy were approved in 2020. In 2022, colectomy for malignant colon tumors and hepatectomy were approved (**Table 1**).

Table 1 Milestones in robotic surgery

1995	Intuitive surgical founded and produces first platform
1997	First robotic human cholecystectomy performed
2000	Davinci approved by FDA for human general surgery
2001	World's first transatlantic telesurgery of cholecystectomy performed
2003	Zeus merged with Intuitive Surgical
2009	Davinci approved by MLHW in Japan
2012	Total prostatectomy covered by insurance in Japan
2014	Davinci Xi and SP approved by FDA
2017	Senhance approved by FDA
2018	Twelve surgical procedures covered by insurance in Japan†
2020	Japanese robot Hinotori approved by MLHW in Japan

FDA: Food and Drug Administration, MLHW: Ministry of Health, Labor and Welfare, SP: Single Port.
†: Five gastrointestinal tract surgeries were covered by insurance:
(1) Thoracoscopic surgery for esophageal malignant tumor
(2) Laparoscopic gastrectomy
(3) proximal gastrectomy
(4) total gastrectomy
(5) Laparoscopic rectal resection/amputation

Operator and Facility Standards in Robotic Surgery

To safely perform robotic surgery, the surgeon's skill must be evaluated. However, in the United States, robotic surgery is considered a subtype of laparoscopic surgery and has an insurance claims process similar to that of laparoscopic surgery. There is no unified national standard, as each facility has an operator standard, and there are no regulations for operative procedures. Currently, robotic surgery is not included in the general surgery residency curriculum and is not considered essential training for surgeons[11,12].

In Japan, academic societies have proposed criteria for surgeons, facilities, and proctor systems. A standard for surgeons was proposed by the Society of Endoscopic Surgery in June 2018. Initially, obtaining endoscopic surgical skill qualification system (ESSQS) certification by the society was essential and recommended, to ensure strict regulation. This requirement was revised in March 2020 because of widespread safety. The requirement of ESSQS certification was changed to board certification in gastroenterology surgery with more than 20 cases of assisting in a procedure supervised by a proctor. In the latest revision in December 2022, the need to be a board-certified surgeon in gastroenterology was removed as a criterion, and it became possible to perform robotic surgery under the guidance of a proctor with 10 cases of assistant experience. In addition, the above assistant experience was not required for a board-certified surgeon[13].

The facility standard requires a clinical visit with a medical team, including the operator, assistant, and surgical nurse, where the surgery is performed under proctor supervision. Participation in the registry system of the Japanese Society of Endoscopic Surgery and related societies is also required. Proctor certification is performed for each surgical procedure; the procedure can be performed by an operator if a number of conditions are satisfied, including being a board-certified surgeon in gastroenterology, an ESSQS-qualified surgeon, experience with 20 esophagectomy cases, gastric surgery experience in 40 resection cases, 40 cases of colorectal resection, 10 cases of liver resection, and 10 cases of pancreatic resection.

Robotic Surgery for Colorectal Cancer

In 2002, Weber et al.[14] first reported successfully completing via robotic-assisted surgery a right hemicolectomy and sigmoid colectomy for benign disease. In 2004, D'Annibale et al.[8] performed tumor-related colectomies for 22 patients, reporting that the intraoperative and postoperative results were similar to those for standard laparoscopic colectomy. Pigazzi et al.[15] was the first to report total mesorectal excision (TME) during a robotic rectal resection in 2006, concluding that the procedure was safe and easy. In Japan, Katsuno et al.[16] started robotic sigmoid colectomy for early sigmoid colon cancer in 2009, and in 2012 reported using robotic-assisted surgery for intersphincteric resection[17].

Robotic colon (RC) surgery differs from rectal surgery with limited space manipulation, principally because the surgical field is wide. Moreover, overcoming obstacles such as splenic curvature, hepatic curvature, and lymph node dissection is necessary, as is repositioning and relocating the robot arm. Studies have noted that RCTs of right hemicolectomy are expensive and prolong surgery time[18]. Hence, the uptake of RC outside of Japan is 22%, lower than the 46% for rectal surgery[19]. The advantages of RC are precise lymph node dissection around blood vessels and intracorporeal anastomosis, which is easier than in laparoscopic colon surgery[20].

Larger controlled trials have reported reduced conversion rates to laparotomy (6.0% vs. 11.5%), length of stay (4.6 days vs. 5.2 days), postoperative complications, and incisional hernia[21]. Regarding long-term prognosis, complete mesocolic excision is said to reflect prognosis, and accurate dissection is required. Although robotic surgery has many advantages, no difference from laparoscopic surgery was observed[22].

Clinical studies are underway in Japan to assess the safety and feasibility of RC. The primary endpoint is laparotomy conversion rate, which aims to verify noninferiority of RC. Since it has been covered by insurance from April 2022, its use is expected to increase.

The latest da Vinci Xi system reduces repetitive docking and is equipped with an interlocking bed for repositioning. It further shortens surgical time and is convenient for RC resection[23]. It was expected to be superior to laparoscopic surgery for rectal cancer, as robotic surgery increases precision in narrow spaces, as was reported in the ROLARR study[24], a large-scale randomized institutional study, in 2017. There was no significant difference in the open abdominal conversion rate of 8.1% for robotic surgery and 12.2% for laparoscopic surgery, indicating no superiority in intraoperative or postoperative short-term results. However, subgroup analysis showed a low rate of abdominal conversion in difficult cases, such as those involving male patients, obese patients, and low anterior resection. Shiomi et al.[25] reported that operation time, rate of conversion to laparotomy, bleeding, and length of stay were similar for obese and non-obese patients who underwent robotic surgery. Of note, in procedures involving obese patients, outcomes were significantly worse for laparoscopic surgery than for robotic surgery.

Because of the good visual field made possible by 3D viewing and the high degree of freedom of operation in the narrow pelvis, the autonomic nerve can be carefully preserved for postoperative urinary and reproductive function. Some RCTs reported good postoperative urinary and reproductive function[26], although others showed no benefit[27].

In Europe and the United States, chemoradiotherapy is the standard treatment for lower rectal cancer. In Japan, the JCOG0212 trial did not confirm that TME alone was noninferior to the TME + lateral lymph node dissection (LLND) with respect to recurrence-free survival (RFS), the primary endpoint. Nevertheless, LLND is still considered a useful treatment because the TME group was inferior to the TME + LLND group in the secondary outcome of overall survival and local RFS[28]. Morohashi et al.[29] reported that patients who underwent robotic LLND had a shorter postoperative hospital stay and lower rate of postoperative leakage than did those who underwent laparoscopic surgery. Additionally, Yamaguchi et al.[30] reported that the 5-year local RFS rate was significantly higher, at 98.6%, than that for open surgery, thus confirming Morohashi's report of the benefits of robot-assisted LLND.

Robotic surgery is still in development, and few reports have compared it with laparoscopic surgery. Regarding long-term outcomes, Cho et al.[31] compared 5-year local and systemic recurrence in 278 robotic and laparoscopic rectal surgeries and reported rates of 5.9% and 16.3% for robotic rectal surgery and 3.9% and 18% for laparoscopic rectal surgery, respectively. Additionally, in an analysis of independent prognostic factors, there was no difference in relation to surgical procedure, as all cases were Stage III, or the degree of histological differentiation. However, Cho et al.[31] concluded that robotic surgery was not superior in their study.

Conversely, in Japan, Yamaguchi et al.[32], Katsuno et al.[33], and others reported good long-term survival rate after robotic rectal surgery, although the reports were retrospective studies at a single center. Insurance coverage has been available in Japan since April 2018, and the number of cases is expected to increase. The National Clinical Database shows that the number of robotic rectal surgeries in 2021 is 20 times that before insurance coverage[34]. The cost of robotic rectal surgery is reported to be 1.34 to 1.54 times that of laparoscopic surgery in South Korea[35,36] and 1.1 times that reported in the ROLLAR trial[24] in Europe and the United States.

Robotic Surgery for Gastric Cancer

Robot-assisted gastrectomy (RG) for gastric cancer was first reported worldwide by Hashizume of Kyushu University in 2002[37]. However, it has not achieved global recognition because it is expensive and complicates lymph node dissection[38,39]. Subsequently, in Japan, Uyama et al.[10] started RG with standard lymph node dissection in 2009 after a multicenter phase II clinical trial was conducted in gastric cancer patients up to cStage II for insurance coverage from 2014. The primary endpoint was identifying a benefit of RG for laparoscopic gastrectomy (LG), which was confirmed by the fact that the incidence of Clavien-Dindo (CD) Grade III or worse complications was 6.4% for LG and 3.2% or lower for robotic surgery. Consequently, 330 cases were collected in this study; the overall complication rate for RG was 2.45%, indicating that RG results in fewer severe complications than LG. With the safety of robotic surgery proven, 12 surgical procedures, including gastrectomy, have been covered by insurance since April 2018.

In a short-term multicenter trial[40] in South Korea, the incidence of postoperative complications was 13.5% in an RG group and 14.2% in an LG group ($p = 0.817$), and the incidence of CD classification grade III or worse complications was compared between 223 RG cases and 211 LG cases. The incidence rates were similar: 1.3% in the RG group and 1.4% in the LG group ($p = 0.999$). In an RCT[41] in China, the RG group had a significantly lower rate of all postoperative complications than the LG group (9.2% vs. 17.6%, $p = 0.039$); onset of mobility, passage of gas, and oral intake were all significantly earlier. Therefore, the introduction of adjuvant chemotherapy took place earlier in the RG group than in the LG group. However, no prospective RCTs of long-term results have been conducted. An analysis of 684 cases extracted by propensity score matching (PSM) was reported by Hikage et al.[42]: the 5-year overall survival rate was 96.4% and 94.8% in RG and LG groups, respectively. However, no significant difference was observed. A South Korean study of 622[43] and 2,084 patients using PSM[44] also showed no difference between groups.

An RCT (JCOG1907) of the superiority of RG over LG in cT1-2N0-2 gastric cancer will be conducted by the Japan Clinical Oncology Group. The results of this large-scale multicenter joint study with 1,040 planned registrations will likely be noteworthy[45].

In Japan, RG has been covered by insurance since 2018; according to the 2018 NCD report, 1495 cases of robotic surgery were performed, accounting for 6% of laparoscopic surgeries[46]. Additionally, RG was first described in the 6th edition[47] of the Gastric Cancer Treatment Guidelines, revised in July 2021, which recommended that it should be performed by a technically certified doctor proficient in robotic surgery. Additionally, it must be performed at a facility that meets the facility standards. Under such conditions, it was stated that "robotic surgery is weakly recommended for cStage I gastric cancer." RG for gastric cancer is expected to increase in Japan, as suggested by guideline recommendations, with the additional surgical fee calculated from April 2022[48]. However, even with the additional surgical fee, the cost of the da Vinci surgical system is high, and depreciation, maintenance and inspection fees, and consumables costs are a heavy burden on hospitals.

Robotic Surgery for Esophageal Cancer

The use of surgical support robots in gastrointestinal surgery began in 2000. Melvin et al. [7] first performed robot-assisted minimally invasive esophagectomy (RAMIE) and intrathoracic anastomosis for lower esophageal cancer in the US in 2002. The author reported that there were no complications during the perioperative period. In 2003, Horgan et al.[49] reported a trans-hiatal approach; in 2004, Kernstine et al. [50] reported esophagectomy with a prone position approach. In Japan, Satoh et al. [51] started the prone position approach in 2009, and Mori et al. [52] started the trans-hiatal approach in 2013.

In a systematic review of the short-term results for 16 volumes and 300 cases reported by Ruurda et al. [53] in 2015, the observed complications were pneumonia (6-45%), anastomotic stenosis (10-68%), leakage (4-35%), cardiac complications (mainly atrial fibrillation: 5-36%), recu rrent laryngeal nerve palsy (RLNP) (4-35%), and death (0-6%), with room for improvement.

In Japan, Suda et al. [54] compared 16 cases of RAMIE using the prone position approach with 20 cases of minimally invasive thoracoscopic surgery (MIE). The in-hospital mortality rate of each group was 0%, postoperative pneumonia of RAMIE occurred in 6% of cases, and RLNP occurred in 38%. However, RLNP of RAMIE was significantly reduced compared to MIE (75%). In the trans-hiatal approach, Mori et al. [55] reported the results of short-term surgery in 22 cases. Although operation time was longer than that for 139 cases of thoracotomy, complications other than postoperative pneumonia and number of dissected lymph nodes were the same. Good results were reported, with 0% postoperative pneumonia and shorter hospital stays.

Regarding long-term results, globally, RAMIE is in its infancy. The number of prospective studies is limited, as compared with large-scale retrospective observational studies and RCTs. A randomized study by a Dutch group[56] showed that RAMIE had a lower pulmonary complication rate, and comparable survival rates, as compared with open surgery. In a comparison with MIE, in a cohort study of 297 cases[57], operation time was short, and the number of dissected lymph nodes around the recurrent laryngeal nerve was high (4.8 vs. 4.1, p = 0.012); however, RLNP was more common (29.2% vs. 15.1%, p < 0.001). Furthermore, long-term outcomes were similar between the groups. Park et al. [58] summarized the long-term results of RAMIE for 115 cases of thoracic esophageal cancer: the overall 3-year survival rate was 85.0% and the 3-year survival rates for Stage I, Stage II, and Stage IIIA were 94.4%, 86%, and 77.8%, respectively, which were good results. However, few reports have a high level of evidence, and further studies on RAMIE are required. The approach from the neck can be used with the da Vinci system. In the Xi system, Nakauchi et al. [59] performed 6 cases of esophagectomy and lymph node dissection with an approach from the neck and abdomen. There were no postoperative complications classified as CD III or worse, and the procedure was feasible.

The single-port da Vinci device is scheduled to be introduced in Japan after 2023, and a mediastinal approach that requires precision in a narrow surgical field is expected[60]. Furthermore, the prone position has been covered by insurance since 2018, and the trans-hiatal approach since 2020. Therefore, the number of cases is expected to increase.

New Technology

Navigation is performed in open surgery and laparoscopic surgery. The da Vinci system is equipped with a TilePro function for displaying images in the surgical field along with 3D vision[61]. Hence, endoscopic, ultrasound, and CT images can be easily viewed on the endoscope screen alongside the operative field screen in real-time by connecting a cable. This function provides accurate information on the dissection line and anterior-posterior organ relationship during surgery, enabling safe and reliable navigation and operation. It also has a firefly-a real-time intraoperative fluorescence guidance function that uses near-infrared imaging after ICG injection and is used as a navigation tool for tumor localization and evaluation of lymph nodes, urine flow, and blood perfusion. It is possible to identify the ureter, and prevent unexpected intraoperative damage. In addition, it is possible to evaluate blood perfusion and set the optimal dissection line and, in rectal and esophageal surgery, blood flow to the reconstructed organ before anastomosis can be evaluated[62]. Lymph node dissection is important for successful tumor surgery, and ICG evaluation has increased the number of lymph node dissections and clarified lymphatic channels[63]. The latest model of the da Vinci single-port device was released in the United States in 2018. This single-cylinder surgery support robot is equipped with a camera and 3 forceps in a cylinder with a diameter of 2.5 cm. It is expected to be applied to oral, trans-anal, and vaginal approaches[64].

The use of artificial intelligence (AI) for surgical support robots is also attracting attention. Automatic learning and image recognition using AI are extremely effective in recognizing image conditions in real-time and decision making[65]. Therefore, it can be effective for automobile driving support systems that must instantly assess visual information. Attempts have been made to increase the sophistication of robot-type endoscope operation support systems by incorporating surgical navigation systems created with AI automatic learning and image recognition methods developed for driving support functions and automatic driving functions[66]. In clinical practice, applications include real-time surgical navigation, alert systems for dangerous operations, automatic forceps exchange functions, and automation of suturing operations. Since the da Vinci system is limited by its lack of tactile sensation, TransEnterix has developed the Senhance TM Surgical Robotic System to convey adequate tactile sensation[67].

Learning Curve

The learning curve for MIS is shorter in robotic surgery than in laparoscopic surgery. For esophagectomy, experience with 20 to 30 cases can reduce RLNP[68]. Reportedly, the number of lymph node dissections performed increases after 30 cases[69]. For gastric cancer, the RG learning curve is achieved within 20 to 25 cases[70] This is significantly lower than the 60 to 90 cases required for LG[71]. Also noteworthy is the result of the ROLLAR study, which reported that the conversion rate in a robot-assisted surgery group correlated only with the number of robotic surgeries performed and did not depend on the number of laparoscopic surgeries[24]. Experience in laparoscopic surgery is not a requisite for robotic surgery and experience in robotic surgery is considered a good guide for discussing future rules for the introduction of and dissemination of robot-assisted surgery.

Conclusion

Although robotic MIS has a long operating time and high cost, its widespread use and development is imminent. In the future, with solid evidence and significant improvements in robot arm attachments, robotic surgery will be able to achieve precision in excision, lymph node dissection, and reconstruction that is equivalent to or better than open surgery.

To achieve widespread use of robotic surgery in Japan, it is important to enhance the original proctor system and gradually introduce robotic surgeries, starting from the less difficult to more difficult procedures to ensure safety and reliability. Moreover, development of cheaper, high-performance domestic surgery support robots other than the da Vinci system would promote widespread use. Because of the addition of insurance listings for surgical procedures, relaxation of facility standards, and additional medical fees, we propose that robotic surgery will be widely used for general medical treatment. Robots will compensate for the shortage of surgeons by allowing surgery to be performed remotely.

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