

Robotically-enhanced surgical anatomy enables surgeons to perform distal gastrectomy for gastric cancer using electric cautery devices alone

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Abstract

Background Despite recent advances in robotic urological surgery, the feasibility and clinical merit of robotic gastric surgery have not yet been fully documented. Therefore, we designed a prospective, non-randomized study to determine the feasibility and safety of robotassisted distal gastrectomy (RADG) for gastric cancer using electric cautery devices, which are more familiar to open surgery.

Methods Between April 2010 and December 2012, 181 patients treated by distal gastrectomy for gastric carcinoma were eligible for this study. According to their intent to undergo uninsured robotic surgery, 21 patients were treated with RADG (RADG group) while 160 patients were treated by conventional laparoscopic distal gastrectomy (LDG group). Under a basic working hypothesis that the superior visualization and unique movement of the robotic arms during dissection would be closely associated with reduced amount of blood loss, even though an equivalent extension of lymph node dissection was carried out, we prospectively collected data from patients in the RADG and LDG groups. Results All patients were successfully treated without conversion except for one patient in the RADG group who underwent conversion to laparoscopic total gastrectomy. In comparison with the patient groups, the estimated blood loss in patients in the RADG group treated with electric cautery devices only was smaller, but not significantly, than patients in the LDG group treated with ultrasonicactivated devices, although the same extent of lymph node dissection was achieved. In contrast, there were four

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patients (2.5 %) in the LDG group who developed a pancreas fistula or intra-abdominal abscess, while no patients treated with RADG developed such complications.

Conclusions RADG using electric cautery instruments without ultrasonic-activated devices is feasible and safe. The robot enables particular surgical views, called robotically-enhanced surgical anatomy, and may contribute to reducing blood loss despite the fact that only electric cautery was used.

Keywords Gastric carcinoma · Distal gastrectomy · Robotic surgery · Energy device · Lymphadenectomy

In the treatment of patients with gastric cancer, laparoscopic gastrectomy has become widespread as a minimally invasive surgical method that provides faster postoperative recovery compared with conventional open gastrectomy [1-3]. However, surgeons are required to acquire additional skills for laparoscopic gastrectomy because laparoscopic procedures are associated with several limitations and disadvantages, such as a limited range of instrument movement, reduction of tactile sensation, amplification of hand tremors and the use of two-dimensional imaging. Therefore, a long learning curve of over 30 cases is required to achieve standard techniques for performing laparoscopic gastrectomy [4–6].

On the other hand, the ability to accurately identify established surgical anatomy is also required to perform fine and curable dissection without complications. Recently, it has become possible to outline the surgical anatomy during gastric cancer surgery using a laparoscopic magnified operative view. Employing a magnified highqualified video scope, Kanaya et al. [7] demonstrated the presence of a layer to be dissected between the tissues involving the lymph nodes and neural tissue around the arteries derived from the celiac axis during laparoscopic gastric cancer surgery. During dissection of the infrapyloric nodes around the pancreatic head, Shinohara et al. showed the presence of an apparent dissectible layer based on the embryological and topographic aspects [8]. These theoretical and practical concepts have been widely accepted by many gastric surgeons. However, such anatomical views cannot always be easily obtained, even when laparoscopic surgery is applied using a high-vision scope because the lymphatic tissues are located on the deep dorsal side beyond the pancreas and are commonly too fragile to be manipulated to obtain a good operative view.

Over the past decade, robotic surgery has been developed for the surgical treatment of gastric cancer [9, 10]. The da Vinci surgical system (Intuitive Surgical Inc., Sunnyvale, CA, USA) involves articulated movement of the robotic instruments, tremor filtering, scale motion and three-dimensional imaging. The meticulous and precise movement of the robotic instruments is expected to provide many advantages during gastric cancer surgery. However, the advantages of robot-assisted gastrectomy for gastric cancer have not been well documented [11–13]. Since 2009 when we were first allowed to use the da Vinci surgical system, we have been focusing on the improved visualization of surgical anatomy provided by the meticulous and precise movement of the stable robotic arms, as well as the superior visual system of three-dimensional technology. We hypothesized that robotic surgery improves the surgical treatment of gastric cancer by refining the surgical anatomy, which we call robotically- (or robo-) enhanced surgical anatomy. In this study, we prospectively determined the feasibility and safety of performing robotic surgery for the treatment of patients with gastric cancer in relation to the enhanced surgical anatomy.

Patients and methods

A non-randomized prospective study was designed at a single institution to determine the advantages of robotassisted distal gastrectomy (RADG) using the da Vinci surgical system compared with conventional laparoscopic distal gastrectomy (LDG), focusing on improved visualization of the surgical anatomy. Our basic working hypothesis was that the superior visualization during dissection would be closely associated with a reduced amount of blood loss, even when an equivalent extension of lymph node dissection was carried out. However, there was a limitation in our ability to demonstrate the superiority of RADG because the rationale and method of dissection are somewhat different between RADG and LDG. In laparoscopic gastric surgery, an ultrasonic-activated device with a greater capability of achieving hemostasis than electric cautery instruments is commonly used for dissection. However, ultrasonic-activated devices appear to taint the benefits of robotic surgery because the devices equipped with the da Vinci surgical system are not capable of articulation. In addition, the regulations posed regarding the use of ultrasonic activating devices are not given by Japanese medical law, but are under the control of the medical insurance program. Therefore, we determined the feasibility and safety of RADG using only electric cautery instruments during dissection with LDG employing an ultrasonic-activated device. Our expectations of this study were based on the non-inferiority of the amount of operative blood loss while achieving an equivalent extent of lymph node dissection. Another endpoint was the non-inferiority of RADG with respect to postoperative complications in relation to damage to the surrounding tissues or organs.

Patients

At our institutions, patients with gastric cancer who are judged to need surgery are generally treated with laparoscopic or robot-assisted procedures without minilaparotomic procedures. Distal gastrectomy is applied for patients with gastric cancer located in the middle and lower portion of the stomach. The criteria for enrollment in this study included consecutive operative patients with histologically proven and resectable gastric carcinoma treated with distal gastrectomy between April 2010 and December 2012. Patients with a history of gastric surgery or other synchronously planned major surgery were excluded from this study. First, all patients were offered robotic surgery. Patients who agreed to the procedure using the da Vinci surgical system, which was not covered by the public health insurance program, underwent RADG with lymphadenectomy (RADG group), while the remaining patients, who refused the uninsured use of the surgical robot, underwent the same operation via conventional laparoscopic procedures covered by the national health insurance program (LDG group). All robotic operations were performed by the same surgical team, which consisted of three surgeons certified as console surgeons. With respect to laparoscopic surgery, two surgeons were given a Certificate for Outstanding Endoscopic Surgical Skill from the Japanese Society for Endoscopic Surgery (JSES), and all laparoscopic procedures were performed or supervised by these two surgeons. All patients were fully involved in the decision-making process, and written informed consent was obtained from each patient. This clinical study was approved by the Institutional Review Board of Saga University Hospital and registered in the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR).

Surgical procedures

The setting of the robotic procedures was similar to that previously reported by Uyama et al. [14]. Briefly, the patient was placed in a supine position under general anesthesia, and five trocars, including one assistant's service port, were inserted. Three 8 mm robotic ports were inserted: one in the right abdomen and the remaining two in the left abdomen. An assistant's service port was placed in the right side of the camera port. This port was used to introduce other laparoscopic forceps in order to obtain a better operative view or better counter traction and to introduce small gauze or suction units into the abdominal cavity. No energy devices were inserted through this assistant's port.

Following appropriate retraction of the lateral segment of the liver, distal gastrectomy with lymph node dissection was performed in the same manner as that previously reported in laparoscopic surgery [3, 6-8]. The surgeon performed dissection using the first arm of the da Vinci device holding monopolar scissors equipped with the VIO system (Erbe, Tubingen, Germany) in the dry cut mode or forced coagulation mode. For the second arm of the da Vinci system, we used Maryland bipolar forceps or fenestrated bipolar forceps, and coagulated the vessels using the soft coagulation mode or high-powered forced coagulation mode of the VIO system when necessary. The third arm held the Cadiere forceps on the left side of the patient in order to define the operative field. Large vessels were divided sharply after clipping. We did not use any ultrasonic-activated devices during the da Vinci surgery. The extent of gastrectomy and lymphadenectomy (D1+ or D2) was decided according to the recommendations of the Japanese Gastric Cancer Association (JGCA) [15].

After mobilizing the stomach and performing complete dissection of the lymph nodes, the stomach was transected using a couple of passes of an endoscopic linear stapler at the cancer-free margin. Then, the robotic arms were undocked and the excised specimen was removed through the extended umbilical port site. According to the extent of the remnant stomach or duodenum, Billroth I gastroduodenostomy, Billroth II gastrojejunostomy or Roux-en-Y anastomosis using endoscopic linear staplers was performed intracorporeally to reconstruct the alimentary tract following distal gastrectomy. The anastomotic procedure using endoscopic linear staplers was performed under the assistance of the da Vinci surgical system. No drains were placed in either group.

Postoperative management

Patients who underwent robotic gastrectomy were managed in the same way as those treated with laparoscopic gastrectomy using a standardized postoperative clinical pathway. Prophylactic antibiotics were administered every 6 h for 24 h from the beginning of surgery. Intake of water was initiated the day after surgery, and liquid meals were resumed on postoperative day 2. If a fever lasted longer than 2 days after surgery, computed tomographic examinations and gastrograffin-swallowing studies were performed to determine the presence of anastomotic leakage or intra-abdominal abscesses. Intra-abdominal abscesses without anastomotic leakage were punctured, if possible, as no drains were placed in most patients. If the contents were amylase-rich, the condition was diagnosed as a pancreatic fistula. All postoperative complications were monitored according to the Clavien–Dindo classification (C–D) [16]. Any event over grade II was counted as a postoperative complication.

Statistical analysis

All clinical data were recorded on a prospectively maintained comprehensive database. Statistical analysis was performed using the JMP software program (SAS Institute, Cary, NC, USA). Values are expressed as the mean \pm standard deviation. Significant differences were determined based on Student's *t*-test or the χ^2 test. For all tests, p < 0.05 was interpreted as being statistically significant.

Results

A consort diagram of the study is presented in Fig. 1. During the study period, a total of 279 patients with gastric cancer were admitted to our department for surgical treatment, 189 patients of whom were treated with distal gastrectomy with curative intent. Of these 189 patients, seven were excluded from the present study due to a history of gastric surgery (n = 1) or synchronous other major abdominal surgery (n = 6). The remaining 182 patients were enrolled in this study. Twenty-two patients agreed to undergo uninsured robotic surgery. The remaining 160 patents were treated with distal gastrectomy by conventional laparoscopy procedure. In one of the 22 patients who were candidates for RADG, conversion to laparoscopic total gastrectomy was required because cancer cells were detected at the proximal margin on intraoperative pathological examination. Consequently, 21 patients treated with RADG (RADG group) and 160 patients treated with LDG (LDG group) were compared in this study. The clinical profiles of the enrolled patients are shown in Table 1. There were no significant differences in age, sex, body mass index or pathological TNM-tumor stage between the two groups.

Fig. 1 A consort diagram of the patients enrolled in this study. *LDG* laparoscopic distal gastrectomy, *RADG* robot-assisted distal gastrectomy

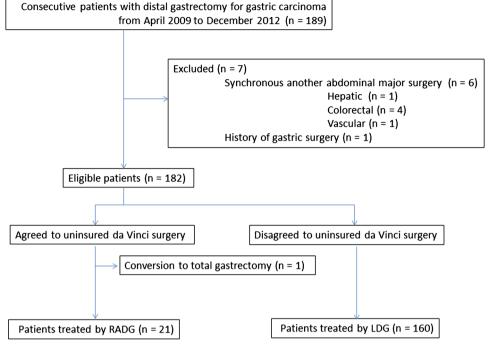


Table 1 Clinical characteristics of patients

	RADG group $(n = 21)$	LDG group $(n = 160)$	p value
Age (years)	66 ± 10	69 ± 12	0.2220
Sex (male/female)	14/7	102/58	0.9829
Body mass index (kg/m ²)	22.8 ± 3.1	21.8 ± 2.8	0.5555
Concomitant illness (presence/absence)	15/6	80/80	0.1057
Cardiovascular	3	53	
Respiratory	1	11	
Diabetic	4	27	
Others	1	9	
pTNM stage (pStage I/pStage II–IV)	18/3	113/47	0.2317

Data are expressed as mean \pm SD. The numbers alone indicate the number of patients

LDG laparoscopic distal gastrectomy, RADG robot-assisted distal gastrectomy

The presence of a loose layer to be dissected by the robot was more strikingly demonstrated during dissection of the infrapyloric nodes (Fig. 2), suprapancreatic nodes (Fig. 3), nodes along the proper and common hepatic arteries (Fig. 4), nodes around the celiac axis (Fig. 5), and nodes along the splenic artery (Fig. 6). Although we were able to find a loose layer that could be dissected during conventional laparoscopic surgery, we were able to better identify an enhanced loose layer in the longer-lasting stable intraoperative view provided during robotic surgery due to the availability of the third manipulator for traction which

can be controlled by the operator, as well as the tremor filtering function of the da Vinci surgical system.

Short-term surgical outcomes are summarized in Table 2. All 21 patients successfully underwent distal gastrectomy with proposed lymph node dissection using the da Vinci system with an electric cautery device alone. No patients in the LDG group underwent conversion to celiotomy. All patients in both groups were treated with R0 surgery. The extent of lymph node dissection (D1 + or D2)and the methods of alimentary tract reconstruction following distal gastrectomy did not differ between the two groups. The total operative time was significantly longer in the RADG group than in the LDG group (439 \pm 86 and 315 ± 90 min; p < 0.0001). However, estimated blood loss in the RADG group was smaller than that observed in the LDG group (96 \pm 114 and 115 \pm 174 g, respectively), although statistical significance was not reached (p = 0.5087). No patients treated with RADG received blood transfusions, while six patients treated with LDG received a blood transfusion. However, five of these six patients had been anemic preoperatively. The number of retrieved lymph nodes in the RADG group was larger than that in the LDG group (44 \pm 19 and 40 \pm 15, respectively); however, the difference was not significant (p = 0.2901). There were no mortalities in either group. There were no differences in postoperative morbidities, defined as an event more than the grade II according to the C–D, between the RADG and LDG groups (Table 2). Two patients experienced postoperative complications in the RADG group; one patient developed anastomotic hemorrhage that required endoscopic hemostasis on postoperative

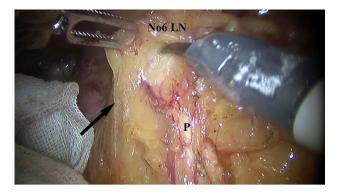


Fig. 2 Dissection of the infrapyloric nodes (No. 6 LN). The *arrow* indicates the loose layer to be dissected on the prepancreatic fascia. LN lymph node, P pancreas

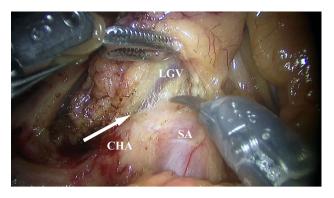


Fig. 5 Dissection of the nodes around the celiac axis. The *arrow* indicates the outermost layer to be dissected. *CHA* common hepatic artery, *LGV* left gastric vein, *SA* splenic artery

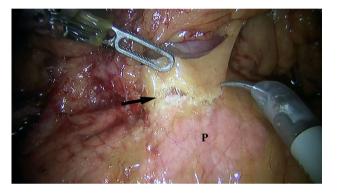


Fig. 3 Initial phase of dissection of the suprapancreatic nodes. The *arrow* indicates the apparently enhanced loose layer indicated by the robot. P pancreas

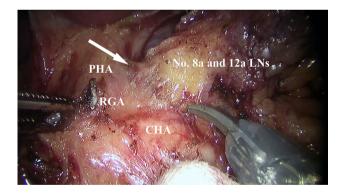


Fig. 4 Dissection of lymph nodes along the common and proper hepatic arteries (No. 8a and No. 12a LNs). The *arrow* indicates the outermost layer exposed by the robot arm. *CHA* common hepatic artery, *LNs* lymph nodes, *PHA* proper hepatic artery, *RGA* right gastric artery

day 3 (C–D grade III), and the other developed a pulmonary embolism (C–D grade II). In the LDG group, five patients experienced C–D grade II complications, 10 patients experienced C–D grade III complications, and one patient experienced C–D grade IV complications. No patients in the RADG group developed surgical site

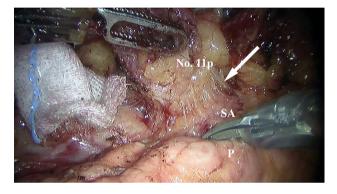


Fig. 6 Dissection of the lymph nodes along the splenic artery (No. 11p LN). The *arrow* indicates the loose layer to be dissected. *LN* lymph node, *SA* splenic artery

infectious complications in contrast to the four cases of pancreatic fistulas and intra-abdominal abscesses observed in the LDG group, although no significant differences in the incidence of pancreatic fistulas or intra-abdominal abscesses were observed. The mean length of postoperative hospital stay in the RADG group was 8 ± 5 days, which was significantly shorter than that observed in the LDG group.

Discussion

Surgeons have been awaiting the development of articulated arms and the improvement of visualization for the many steps of laparoscopic surgery. Robotic surgery has enabled or improved these arms and the visualization and apparent benefits of robotic urological surgery have been demonstrated [17, 18]. However, the feasibility and clinical merit of robotic gastric surgery remain unclear because of the difficulty evaluating the advantages of robotic surgery based on existing clinical parameters [11–13, 19–22]. Therefore, we designed a prospective non-randomized

Table 2 Surgical outcomes

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	RADG group $(n = 21)$	LDG group $(n = 160)$	p value
Extent of lymph node dissection (D1+/D2)	13/8	79/81	0.3959
Reconstruction (Billroth I/Billroth II or Roux-en-Y)	11/10	80/80	>0.9999
Operative time (min)	439 ± 86	315 ± 90	< 0.0001
Estimated blood loss (g)	96 ± 114	115 ± 174	0.5087
Number of retrieved lymph nodes	44 ± 19	40 ± 15	0.2901
Postoperative complications ^a	2	16	>0.9999
Pancreatic fistula	0	2	>0.9999
Intra-abdominal abscess	0	2	>0.9999
Anastomotic complications	1	6	>0.9999
Respiratory	0	3	>0.9999
Circulatory	1	1	>0.9999
Others	0	2	>0.9999
Postoperative hospital stay (days)	8 ± 5	13 ± 30	0.0295

Data are expressed as mean \pm SD. The numbers alone indicate the number of patients

LDG laparoscopic distal gastrectomy, RADG robot-assisted distal gastrectomy

^a The number of complications over grade II according to the Clavien–Dindo classification were counted

study to determine the feasibility and safety of RADG for gastric cancer using electrocautery devices, while focusing on the benefits provided by the articulated arms and the improved visualization. In comparison with the non-randomized patient groups, the estimated amount of blood loss in the RADG group treated with only electrocautery devices was smaller, but not significantly, than that observed in the LDG group treated with ultrasonic-activated devices, while the same or greater extent of lymph node dissection was achieved. Moreover, we emphasize that no patient with RADG developed pancreatic fistulas or intra-abdominal abscesses in relation to damage to the surrounding tissues or organs.

We speculate that the present findings resulted from the articulated arms of the robot and the improved visualization. The surgical robot is designed to facilitate minimally invasive surgery using functions such as the Endowrist, tremor filtering, motion scaling and three-dimensional imaging [10]. Excellent and stable visualization of the operative field can be achieved with these useful functions. The robotic arms can be used to grasp fragile tissue more gently without causing laceration than human hands because the robotic arms are free from physiological tremors and are allowed seven degrees of freedom due to articulation. When the robotic arm lifts up a tissue or organ, loose layers among the stratified tissue are exposed. One of these loose layers is appropriate for dissection. The concept of lymph node dissection is the complete removal of soft tissue involving the lymphatic flow intervened by lymph nodes. Under a magnified laparoscopic view, there is a space between the soft tissue, including the lymphatic chain to be removed and the landmark organ to be preserved [7, 8]. Using the robotic arm, the surgeon can more clearly observe the space. We call this well-accentuated space the robotically-enhanced surgical anatomy. Moreover, energy devices can be placed in the most suitable angle in this space by using articulation of the robotic arm. Therefore, the use of articulated energy devices is more advantageous than ultrasonic-activated devices without articulation. However, electric cautery instruments unfortunately have a slightly lower capability of sealing vessels than ultrasonic-activated devices [23]. Therefore, there was a limitation to demonstrate the superiority of robot-assisted gastric surgery using articulated electric cautery instruments. Nevertheless, we employed electric cautery instruments during robotic gastric surgery, not only because ultrasonic-activated devices are not allowed for use in da Vinci surgery in our country but also because articulation of the robotic arms was attractive and promising. We believe that articulated robotic arms can overcome the demerits of laparoscopic surgery without articulation. Some reports have described performing robotic gastric surgery using electrocautery devices. Western surgeons have been reported to use robotic fine hook electrocautery devices during robotic gastric surgery; however, they partially employ ultrasonic shears near the major vessels [20]. Uyama et al. [14] introduced a novel dissecting technique using Maryland forceps with bipolar forced coagulation. Using this quite unique technique, a reduced amount of blood loss and a shortened operative time were demonstrated in robotic D2 distal gastrectomy. However, this technique is not currently familiar for other surgeons. Some surgeons who are experts in open gastric surgery but are not familiar with laparoscopic surgery may prefer to use robotic surgery with monopolar scissors because the dissecting technique is more popular than the use of ultrasonic shears and they find robotic procedures to be more intuitive than laparoscopic surgery [11, 24]. If articulated energy devices with the capability of sealing vessels similar or superior to ultrasonic-activated devices could be introduced in robotic surgery, the ability to reduce the amount of blood loss would increase without causing any increased injury to the surrounding tissue. Although the effects of reducing operative blood loss during robotic gastric surgery are controversial, reports of decreased blood loss during robotic gastric surgery suggest that the improvements are attributed to improved visualization [25–27]. We consider this speculation to be partially true; however, the meticulous and precise dissection achieved with articulated devices plays an important role in reducing operative blood loss.

Dissection of the perigastric nodes along the left gastroepiploic artery and dissection of the right paracardiac nodes along the lesser curvature are complicated during robotic surgery. As the loose layer to be dissected is obscure and many vessels penetrate the gastric wall in these locations, performing dissection using monopolar scissors alone cannot be carried out. The most suitable regions for dissection using robotic surgery are the infrapyloric nodes and suprapancreatic nodes. A dissectible layer consistent with the fascia created following fusion of the peritoneum during the embryological period [8] can be demonstrated as a well-enhanced loose space during robotic surgery. Under robotic inspection, the outermost layers advocated by Kanaya et al. [7] between the tissues involving the lymphatic chains and the neural tissue around the proper hepatic artery, common hepatic artery, splenic artery and celiac artery can be more clearly identified, as shown in the figures.

The present finding that the operative time of RADG is longer than that of LDG is consistent with the results of other reports [11–14]. Performing gastric surgery for gastric cancer is meticulous and complicated. Robotic arms move somewhat slowly, although they work precisely. In addition, we wished to dissect more meticulously as the robotically-enhanced surgical anatomy demonstrated more minute structures during surgery. Changing devices or cleaning the scope during robotic surgery requires more time than that needed during conventional laparoscopic surgery. Robotic arms often conflict with each other during surgery, which cannot be released by the surgeon. Nevertheless, many surgeons feel that the improved ergonomics is advantageous compared with laparoscopic surgery. The operative time for RADG in this study was much longer than that required for RADG using a Harmonic scalpel [19, 21, 22]. Therefore, we cannot advocate the inferiority of ultrasonic-activated devices without articulation. We expect that the development of devices equipped for the robotic surgical system may therefore shorten the operative times.

We considered that the significantly shortened postoperative hospital stay of the patients treated with RADG observed in this study made little sense because the study design had a bias, and duration of hospital stays is not an essential factor required to demonstrate the superiority of a surgical procedure. Nonetheless, the surgical outcomes of da Vinci distal gastrectomy appear to be acceptable based on the results of the intraoperative estimated blood loss, number of retrieved lymph nodes and postoperative hospital stay compared with those observed in LDG, in spite of the longer operative time. In addition, there were no mortalities and minimal morbidities in this series, showing that our robotic distal gastrectomy procedure is safe and feasible for gastric cancer treatment, as previously reported [19, 21, 22]. However, the results are not conclusive because previous reports as well as the present study were not randomized controlled trials. Since the high cost of robotic surgery is not covered by the public health insurance program, randomization of patients cannot be performed in our country, as well as many other countries. Therefore, some extent of selection bias is inevitable. The decision to undergo the surgical procedure in the present non-randomized study was based on the patient's, not the physician's, decision. The matching of comparable groups was consequently reasonable. An apparent selection bias was limited, in that the RADG surgery was limited to patients who could afford to pay the high medical costs.

Conclusion

We successfully performed RADG using electric cautery devices alone. We believe that our procedure was made possible owing to the improved surgical views that were provided by the robot, and we call this the roboticallyenhanced surgical anatomy.

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Disclosure Hirokazu Noshiro, Osamu Ikeda, Masako Urata have no conflict of interest to declare.

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