



# Robotic technology could contribute to performing precise gastrectomy with D2 lymphadenectomy for gastric cancer while decreasing the risk of local complications

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We found the article of Kim *et al.*—entitled “Multicenter Prospective Comparative Study of Robotic Versus Laparoscopic Gastrectomy for Gastric Adenocarcinoma” published in the January 2016 issue of the journal *Annals of Surgery*—quite interesting (1).

First, we congratulate the authors for their efforts and the excellent clinical results obtained in the initial stage of the multicenter prospective comparative study of robotic versus laparoscopic gastrectomy for gastric adenocarcinoma.

This study is the first published prospective and comparative study, conducted over a relatively short period with a large number of participants recruited from multiple centers to compare the merits and demerits of robotic versus laparoscopic surgery of gastrointestinal tract in gastric adenocarcinoma.

Patients were categorized according to the operating surgeon, extent of gastric resection, and gender into two comparable groups. Surprisingly, a total of 434 patients were enrolled for the treatment (223 cases of robotic surgery *vs.* 211 cases of laparoscopic surgery) during a short period of 22 months. The results suggest that the use of the robot led to poor cost effectiveness. Both groups showed similar complication rates, and major complications were associated with no postoperative mortality in both groups. Robotic surgery was costlier and slightly lengthier than laparoscopic surgery. Other factors such as approximate

blood loss, rate of open conversion, diet build-up, and length of hospital stay were similar between the two groups.

The authors concluded that the potential benefits of robotic gastrectomy should be clarified to justify the longer operative time and higher costs associated with it. However, the authors admitted that robotic surgery requires a rather technically superior operative environment compared to minimally invasive surgery.

However, there are several controversial aspects in their conclusions.

- (I) One of the biggest problem is that robotic gastrectomy requires costlier copayment, especially with regard to the amount charged to the patients. Although the Korean National Health Insurance System covers the cost for preoperative care, including both the cost for the procedure and the operation fee for the laparoscopic group, none of the insurance systems covered the operation fees in the robotic group. Consequently, the actual cost paid by the patients was US \$7,326 more for the robotic surgery group. It means that the patients in the robotic surgery group paid 2.8 times higher than those enrolled in the laparoscopic group. Since randomization could not be carried out because of the limited study budget, the decision regarding the type of operation was based on the

patient's preference after receiving a comprehensive explanation of each procedure with regard to their individual social background.

- (II) More than 80% of the patients enrolled in the study were in p-stage I, and the total number of gastrectomies carried out in each group was less than 20%. Moreover, there was no reference to combined operations such as splenectomy or pancreaticosplenectomy.

To eliminate selection bias, patients were matched according to the operating surgeon, extent of gastric resection required, and gender to generate two comparable groups. The primary endpoints of the study were morbidity and mortality. In several previous studies, a couple of factors including extended lymphadenectomy, total gastrectomy, and combined resection (splenectomy or pancreaticosplenectomy) have been identified as predictors of morbidity and mortality after radical gastrectomy (2,3). Dissection of the suprapancreatic area, especially in No. 11d and 12a, and total gastrectomy with splenic hilar lymph node dissection is technically more demanding (4). However, in p-stage I cases, such extended dissection is not necessary because of the low risk of nodal metastasis.

- (III) This study fails to eliminate the learning effect. As Kim mentioned in the discussion, "most of the participating surgeons were experts in laparoscopic surgery but were less experienced in robotic surgery." Before initiating the study, the surgeons' experiences with robotic gastrectomy ranged from 4 to 450 cases. Nine out of the 17 surgeons had experience with less than 29 cases of robotic gastrectomy, with the annual median number of robotic gastrectomies being 5 (range: 1–108). Park *et al.* presented that surgeons with sufficient experience in laparoscopic gastrectomy needed to carry out 8.2 cases before the operative time gets stabilized (5). Son referred that 11–25 cases of laparoscopic surgical experience are required for robotic surgery (6). Though there are several reports that suggest a short learning curve for robotic gastrectomy, few surgeons have sufficient experience in robotic surgery (5,7,8).

The da Vinci surgical system (DVSS) has been accepted because of its benefits of a high degree of freedom through its articulating surgical

instruments, filtering the tremor of the surgeon and scales motion with a three-dimensional motion, and a ten-fold magnified view of the operating field. As a result, this robotic system facilitates precise dissection in a confined surgical field with impressive dexterity (9–11). The Japanese Gastric Cancer Association has recommended that non-early, potentially curable gastric cancers should be treated with D2 lymphadenectomy, including dissection of distal suprapancreatic area and total gastrectomy. Particularly, dissection of the suprapancreatic area is technically more demanding because of the severe risk of intraoperative bleeding or postoperative pancreatic fistula following micro-injury of pancreas (12). To improve the safety, efficacy, and reproducibility of suprapancreatic lymphadenectomy, we developed a method, called medial approach for laparoscopic gastrectomy, and proposed the concept of the outermost layer of the autonomic nerve (13,14). However, operative difficulties in the laparoscopic procedure remained. To overcome these issues, we hypothesized that the robotic system contributes to reduction in local complications, including pancreatic fistula, rather than systemic complication. In 2009, our institution introduced robotic gastrectomy using the da Vinci S surgical system (Intuitive Surgical, Sunnyvale, CA, USA) and carried out more than 250 cases with both early gastric cancer (EGC) and advanced gastric cancer (AGC) (14,15). In our experience, using a combination of our original surgical approach and the robot, visualization of the outermost layer was stable and precise due to the motion-scaling function in combination with tremor filtering, even in the deep dorsal area of the suprapancreatic major arteries. Furthermore, we experienced less tissue laceration and hemorrhage than those experienced when the laparoscopic approach was employed. In our single institutional retrospective, comparative cohort study, 526 patients who underwent radical gastrectomy were enrolled (16). Finally, 88 patients were included as they consented to the uninsured use of the robot, while the remaining 438 patients refused. The robotic group included 43% cases of pstage II or more, whereas the laparoscopic group included 35%. A total of 34% patients underwent gastrectomy in the robotic group and 47% in

the laparoscopic group. In the robotic group, morbidity was significantly improved, even though operative time and estimated blood loss were slightly greater. In particular, local rather than systemic complication rates were attenuated using the surgical robot. Multivariate analyses revealed that the non-use of the surgical robot, total gastrectomy, and D2 lymphadenectomy were the most important determining factors related to the complications following minimally invasive radical gastrectomy. Though our data were obtained from a single institutional retrospective cohort study, the results suggest that the greater the extent of gastric resection and lymphadenectomy, the more effective is the use of the surgical robot in reducing postoperative complications and improving short-term outcomes. Additionally, we proposed that the best indication for the use of the robot is radical gastrectomy for AGC accompanied by D2 dissection (7).

Based on the outcomes of our previous study, we have been conducting a multi-institutional single-arm prospective trial, which has been approved for Advanced Medical Technology (“senshiniryō”) by the Japanese Ministry of Health, Labor and Welfare (MHLW) since early October 2014 (15,17). Senshiniryō is a special interim system for the newly developed uninsured medical technologies approved by MHLW. Using this system, patients are requested to pay the specific cost, and MHLW determines whether the designed technology is worth being covered by the universal medical insurance from a cost-effective viewpoint. This clinical trial is designed to determine the impact of robot use for minimally invasive radical gastrectomy to treat resectable gastric cancer, on short-term outcomes, mainly focusing on postoperative complications as well as long-term outcomes and cost (18). The specific hypothesis of this study is that the use of the robot in patients with c-stage I or II diseases reduces the morbidity from 6.4% to 3.2%. To prove this hypothesis, a single-arm study was conducted using the historical control (morbidity of 6.4% in laparoscopic gastrectomy previously performed in three leading hospitals in our country). In the prospective arm, robotic gastrectomy will

be conducted for consecutive patients who were diagnosed gastric cancer with c-stage I or II. The sufficient sample size was calculated to be 330. All patients will be registered within 2 years after starting this trial and followed up for 3 years; thus, the expected study period is 5 years in total. To maintain safety and ensure optimum quality of robotic operations, the institutions and operating surgeons must meet the following requirements: institutions, at least one year after launching robotic gastrectomy, should have performed more than 20 robotic gastrectomies including not less than total 5 gastrectomies and more than 50 laparoscopic gastrectomies during the past 4 years; morbidity (Clavien-Dindo classification grade  $\geq$  III) in laparoscopic gastrectomies during the past 4 years should be  $\leq$ 12%; operating surgeons must be either an endoscopic surgical skill qualification system qualified surgeon (Japan Society for Endoscopic Surgery), Board Certified Surgeon in Gastroenterology (the Japanese Society of Gastroenterological Surgery), certified Console Surgeon in da Vinci Surgical System Off-Site Training (he or she should have performed more than 10 robotic gastrectomies including not less than 1 robotic total gastrectomy). The operating surgeon’s level of robotic skill is also to be assessed by reviewing a non-edited video recording of robotic total gastrectomy before allowing his or her participation in the trial.

Although more studies are required to assess the indications and oncological effectiveness of robotic surgery for gastric cancer, we believe robotic technology contributes to performing precise D2 lymphadenectomy and efficient enlarged resections, and decreases the risk of intra/postoperative local complications.

In conclusion, we think that the excellent results of the initial multicenter prospective series of RG reported by Kim should be interpreted as a result from a complicated background such as the national Korean insurance system, as enrolled patients were mainly diagnosed with EGC or there was no need to perform enlarged resection. We need further examination to reveal other important roles and suitable indications for robotic surgery for AGC as well as EGC, although longer duration of operation and higher costs cannot be resolved.

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## Footnote

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