Educational Program on Robotic Gastrectomy

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Background

The surgical support robot, the “da Vinci Surgical System”, has been used for total prostatectomies, hysterectomies and surgeries for gastrointestinal carcinoma since 1999, when it was approved as a medical device by the American FDA, and it has been popular mainly in Europe and the United States. In Japan, it was approved by the Pharmaceutical Affairs Act in November 2009, after which Prof. Uyama of Fujita Health University started carrying out robotic surgeries using the da Vinci Surgical System for gastric cancer. Total prostatectomies were first covered by insurance in 2014 and subsequently, in April 2018, insurance adaptation to 12 surgeries, including surgeries for gastric cancer was approved. It is speculated that robotic gastrectomy will be rapidly spread in Japan.

Laparoscopic surgery itself has various advantages compared to open surgery. It is possible to understand microstructures by magnifying view, enabling meticulous procedures, limited bleeding, small wounds, and early recovery following surgery. On the other hand, it has some drawback such as difficulty of space recognition due to 2D image or restricted forceps movement, in addition to requiring long learning curve. Robotic surgery is a technique that overcomes the drawbacks of laparoscopic surgery. Accurate and detailed image information acquisition via a 3D enlarged image, 360-degree rotation and multi-joint forceps with seven degrees of freedom, motion scale and filtering etc.,
have made it possible to perform more meticulous surgery. Multi institutional prospective cohort study testing has been conducted under the advanced medical care system since October 2014 in order to evaluate the safety of robotic surgery for stomach cancer. Case registration was completed in March 2017 and the safety was indicated (presented at the 30th Japan Society of Endoscopic Surgery in Dec 2017).

However, until now, including within the trial of advanced medicine, limited surgeons, mainly those who had excellent experience in technology, belonging to high volume center, have been performing robotic surgeries. It is expected that the number of robotic surgeries will increase explosively in the future, due to the insurance coverage; therefore, education for surgeons is urgently needed because a wide range of surgeons with skilled techniques and years of experience are considered to be involved in such surgeries. However, as a drawback of robotic surgery such as loss of tactile sensation, arm collision, and learning curve. Furthermore, compared with conventional open surgery and laparoscopic surgery, there is little room for assistants to support, making it difficult for experienced senior medical doctors to work as assistants in order to educate surgeons. Therefore, we planned an educational program specializing in robotic surgery.
Purpose

Educating surgeons who can safely perform robotic gastrectomy

Method

Implement the education according to the educational program for surgeons. Furthermore, positively collect information on the number of people completing the program along with the surgical results of the program in order to evaluate the effectiveness of the program.

Educational program

- The program consists of the following 3 steps. Once each target item is achieved, proceed to the next step.

- However, in the event of an absence of longer than 6 months during participation, a retraining program stipulated by the Japan Society for Endoscopic Surgery will be required.

- Step 0 must be achieved as the criterion for participating to the program.
Step 0：Acquisition of surgeon standards

<table>
<thead>
<tr>
<th>Target items</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>· As a surgeon, perform more than 10 laparoscopic gastrectomies (including one or more total laparoscopic gastrectomies).</td>
<td>Be proficient in laparoscopic gastrectomies and secure certain techniques.</td>
</tr>
<tr>
<td>· Laparoscopic distal gastrectomy can be completed within 4 hours without intraoperative trouble.</td>
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<tr>
<td>· Has taken the training courses led by Intuitive Surgical G.K. and acquired assistant certification.</td>
<td>Learn about the flow of robotic gastrectomies.</td>
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<tr>
<td>· Has experienced more than 10 cases as the first assistant in robotic gastrectomies.</td>
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Step 1：Acquisition of surgeon qualification

<table>
<thead>
<tr>
<th>Target items</th>
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</thead>
<tbody>
<tr>
<td>· Has taken the training courses led by Intuitive Surgical G.K. and acquired surgeon certification</td>
<td>Learn the basic operation of the da Vinci Surgical System and perform</td>
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<tr>
<td>certification.</td>
<td>repetitive training of surgical techniques and surgical procedures.</td>
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<tr>
<td>· Perform at least 10 hours of offsite training using the da Vinci Surgical System.</td>
<td>Learn the smooth operation of the da Vinci Surgical System.</td>
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### Step 2: Training as a surgeon

<table>
<thead>
<tr>
<th>Target items</th>
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<tbody>
<tr>
<td>· Under the guidance of the proctor, perform over 10 robotic gastrectomies (including total gastrectomies, cardia side gastrectomies) ※1-4.</td>
<td>Gain experience on robotic gastrectomy surgery.</td>
</tr>
</tbody>
</table>

※1: The proctor performs surgery mainly for the first case and the operator learn beside him or perform surgery partly.  
※2: At least the second case should be a case of distal gastrectomy, D1 + dissection, with BMI <25, PS = 0, ASA - PS 2 or less.
<table>
<thead>
<tr>
<th>Step 3: Independence as a surgeon of robotic gastrectomies</th>
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<tbody>
<tr>
<td>※3: Teaching by dual console is desirable until the third case.</td>
</tr>
<tr>
<td>※4: In the case of an absence of longer than 6 months during participation, 2 cases of experience will be added after receiving retraining program provided by Intuitive G.K., regardless of the number of experienced cases.</td>
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<tr>
<td>· Do not cause other organ damage requiring repair, arterial injuries requiring reconstruction or other intraoperative trouble requiring an open conversion.</td>
</tr>
<tr>
<td>· Perform one or more robotic total gastrectomies.</td>
</tr>
<tr>
<td>Gain experience as a surgeon for robotic total gastrectomies to acquire esophagus jejunal anastomosis.</td>
</tr>
<tr>
<td>Target items</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Achieve a rating of B or higher in all items of the surgeon evaluation on</td>
</tr>
<tr>
<td>robotic distal gastrectomy from the proctor.</td>
</tr>
<tr>
<td>※</td>
</tr>
<tr>
<td>Acquire a certification as a credential surgeon (stomach) from the Japan</td>
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<tr>
<td>Society for Endoscopic Surgery.</td>
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※Evaluation by Proctor

A proctor evaluates the following items in three stages. In order to become independent, it is necessary to achieve B or higher in all items.

Category I   Progression of Surgery
1. Progression of Surgery/speed

   A: The progression of surgery is systematic and smooth, and the operation time is standard.

   B: Although there are points to be improved in terms of the planning and smoothness of surgery, operations are being safely carried out.

   C: It cannot be said that the progression of surgery is systematic and smooth.

2. Collaboration with assistants

   A: Good collaboration with assistants, good development of the field of view, and counter attraction are achieved.

   B: While collaboration is sometimes inadequate, it is safely carried out.

   C: Cooperation with assistants is poor and extension of the operation time and bleeding are observed.

Category II Robot Operation

1. Insert port

   A: The indwelling position of the access port and the indwelling method are both appropriate.

   B: It is expected that the difficulty level of the surgical technique will be lowered by
improving the indwelling position of the access port and the indwelling method.

C: Bleeding or extension of operation time, due to the indwelling position of the access port or the indwelling method, has been observed or organ damage has occurred.

2. Arm Interference

A: Surgery has been carried out, with absolutely no interference of the arm.

B: Although the arm interferes from time to time, it is corrected to safely conduct surgery.

C: The operation time is extended due to interference of the arm or organ damage has been caused thereby.

3. Surgical Field Development

A: The use of forceps for surgical field deployment is good.

B: Although there are points to be improved in using forceps for surgical field deployment, the surgery is safely carried out.

C: The use of forceps for surgical field deployment is inappropriate and dangerous or tissue damage has occurred.

4. Is the surgical field displayed in the center of the monitor?

A: The surgical field is well-captured at the center of the visual field.
B: Despite occasionally being carried out within the surgical field, outside the center of the field of vision, the surgery is performed safely.

C: Blind operation has been observed.

Category III Surgical Techniques

1. Forceps to be used

A: Forceps selection is appropriate and the usage thereof is also appropriate.

B: The operation time could possibly be shortened via improvement of forceps selection or the usage thereof.

C: Bleeding or dangerous procedures, due to inappropriate forceps selection, are observed or organ damage has been caused.

2. Tissue handling

A: Tissue grasping method and towing method are both appropriate.

B: While the operation time could possibly be shortened via improvement of the tissue grasping and towing methods, the operation is safely carried out.

C: Inappropriate tissue grasping or towing method has caused bleeding or tissue damage.

3. Selection of energy device
A: The selection of energy device and the usage thereof are both appropriate.

B: Although the operation time could possibly be shortened via selection of the energy source or improving the usage, surgery is safely carried out.

C: Tissue damage requiring repair, due to inappropriate selection of the energy source or misusage, is observed.

Category IV Lymph node Dissection and Anastomosis

1. Is lymph node dissection properly carried out?

A: Clean dissection without bleeding is carried out without damaging tissue.

B: Although some tissue damage is found or bleeding is present, it is controlled and sufficient lymphadenectomy is performed

C: Tissue injury requiring repair or bleeding with poor control occurs and dissection is insufficient.

2. Were gastrointestinal anastomoses performed without fail?

A: There is no excessive tension and anastomosis is performed smoothly using the device.

B: Although there are parts in which the use of device is not smooth, anastomosis is safely carried out.
C: The use of the device is dangerous and anastomosis is uncertain or tissue damage associated with anastomosis is observed.

Evaluation Items

1) Main evaluation item

Percentage of program participants achieving Step 3 in 24 months

The period of the program (from the commencement of Step 1 to the end of Step 3) will be 24 months in total, wherein the above will be evaluated.

2) Secondary evaluation items

The achievement status of each step, the surgical-related death rate, the rate of occurrence of postoperative intraperitoneal infectious complications, the operation time, and the bleeding volume

Goals and Handling

<Main evaluation item>

Evaluate the program itself 24 months after commencing the program.

If the proportion of the program participants achieving Step 3 in 24 months is higher than
80%, this educational program will be considered effective.

<Secondary evaluation items>

1. Achievement status of each step

   The goal period for each step is defined as follows and the achievement rate after 24 months of program commencement will be evaluated.

   • Step 1: 4 months
   
   • Step 2: 20 months

2. Surgical-related mortality rate

   Mortality deemed to be caused by surgery during postoperative hospitalization or within 30 days following surgery

3. Occurrence rate of postoperative intraperitoneal infectious complications

   Evaluate the occurrence rate of intraperitoneal infectious complications (suture insufficiency, pancreatic juice leakage, abdominal abscess) of Clavien-Dindo classification Grade III, within 30 days following surgery

<Handling>

• If the main evaluation item is not achieved two years after commencing the program, revise the program.
• Revise the program, even if the occurrence rate of intraperitoneal infectious complications is 10% or higher, two years after commencing the program.

• If surgical-related death occurs in even one case, the program will be canceled and revised

**Program commencing time**

This program will commence from April 1, 2018.