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Original Article

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Novel Clean End-to-End Anastomosis Method, Without Opening the Stomach Lumen, in Totally Laparoscopic or Robotic Pylorus-Preserving Gastrectomy

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ABSTRACT

Purpose: Intra-abdominal infection is a common postoperative complication of laparoscopic pylorus-preserving gastrectomies (PPGs). Many studies have reported that intra-abdominal infectious complications after gastrectomy adversely affect patient survival outcomes. To prevent gastric fluid leakage into the abdominal cavity, we developed a novel anastomosis method in which the stomach lumen is not opened (termed the non-opened clean end-to-end anastomosis method [NoCEAM]) and evaluated its feasibility.
Materials and Methods: Subsequent to lymphadenectomy, the oral and anal resection lines were sutured using an intraoperative endoscope. After closing the stomach circumferentially with clips, the specimen was rolled outward like a "donut." We resected the specimen circumferentially using a linear stapler, and anastomosis was completed simultaneously. We examined the feasibility of this procedure ex vivo, using three porcine stomachs, and in vivo, using one pig. Subsequently, we applied the procedure to 13 consecutive patients with middle-third early gastric cancer utilizing laparotomic, laparoscopic, and robotic PPG.
Results: NoCEAM was completed in all porcine models and human cases. In the human cases, the mean operation time (±standard deviation) was 279±51 minutes, and mean blood loss volume was 22±45 mL. The mean number of linear staples used was 5.06±0.76. None of the patients had complications, and all were discharged on the eighth postoperative. The serum total protein, serum albumin, and hemoglobin levels did not change significantly after surgery.
Conclusions: NoCEAM is feasible and safe for performing totally laparoscopic or robotic PPG. It may reduce postoperative complications, such as intra-abdominal infections.

Keywords: Robot surgery; Gastrectomy; Intra-abdominal infection; Postoperative complication; Pylorus

INTRODUCTION

Pylorus-preserving gastrectomy (PPG) was initially introduced by Maki et al. [1] for the treatment of peptic ulcers. Subsequently, PPG has been performed to treat early gastric

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Informed consent was obtained from all patients.

Conflict of Interest
No potential conflict of interest relevant to this article was reported.

Author Contributions
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cancer and is widely accepted as a function-preserving surgery. Compared with distal gastrectomy, PPG is reported to have nutritional and functional benefits, such as small change in body weight, and a lower incidence of dumping syndrome, bile reflux, or gallstone formation [2-5]. According to the Japanese Gastric Cancer Treatment Guidelines 2018, PPG is indicated for treating cT1N0 gastric cancer located in the middle portion of the stomach with a distal tumor border at least 4 cm proximal to the pylorus [6].

In a recent study, intra-abdominal infectious complication (IAIC) was reported as a common complication of laparoscopic PPG, with an incidence of 6.5% in the Clavien–Dindo classification grade II or higher [7]. Furthermore, in 2013, Tokunaga et al. reported that after curative surgery for gastric cancer, IAIC adversely affected long-term survival outcomes, and these results were confirmed in several studies [8-10]. When using the propensity score matching analysis, the overall survival of patients was significantly poorer in those with IAIC (hazard ratio [HR], 1.43; 95% confidence interval [CI], 1.02–2.00; P=0.036), as was the relapse-free survival (HR, 1.42; 95% CI, 1.03–1.96; P=0.034). Although these studies indicate the importance of avoiding IAIC to improve long-term survival, no alternative operative method has been developed thus far.

IAIC is thought to occur through various mechanisms, one of which is the direct leakage of gastric fluid to develop an infection. The intestinal flora is the main causative agent of IAIC [11,12]; therefore, we hypothesized that reducing intestinal fluid leakage from the stomach during gastrectomy would lead to a reduction in IAIC. Thus, we developed a non-opened clean end-to-end anastomosis method (NoCEAM) with a completely new concept that avoids opening the stomach lumen to prevent the spillage of gastric juice into the abdominal cavity during surgery.

MATERIALS AND METHODS

Informed consent was obtained from all the patients. The study was conducted in accordance with the research ethics and was approved by the Institutional Animal Care and Use Committee and the Ethics Committee of Dokkyo University Hospital (clinical research registration number: 1968).

Ex vivo and in vivo studies

Three whole stomachs harvested from freshly slaughtered swine were used in the *ex vivo* study. We laparoscopically performed novel NoCEAM on these stomachs mounted on a laparoscopic training box. A virtual lesion was drawn on the middle body of the stomach using a permanent marker.

One pig was used for the in vivo study according to the approved ethical guidelines of the facility. The procedure was performed laparoscopically under general anesthesia, and the pig was euthanized immediately after the operation. Thus, we examined the feasibility of this procedure using ex vivo and in vivo models.

Patients and feasibility evaluation

Between December 2018 and August 2020, we performed NoCEAM on 13 consecutive patients with cT1N0 middle-third early gastric cancer with a distal tumor border at least 4 cm proximal to the pylorus.

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To evaluate the feasibility of this method, we analyzed the total operation time and anastomosis time, starting from the insertion of the suture thread into the abdominal cavity until the excision of the specimen. Additionally, we evaluated whether an en bloc resection could be successfully completed while retaining the dissected fat attached to the specimen. The pathological specimens were examined for maximal lesion diameter, oral and anal margins, and the number of retrieved lymph nodes.

Operation procedures

Setting and port placement of laparoscopic or robotic PPG

On the day prior to the surgery, we placed marking clips on the oral and anal sides of the mucosal lesion. Lymph node dissection was performed based on a previously reported PPG method [5]. For both laparoscopic and robotic surgeries, a camera port was inserted at the umbilicus, and pneumoperitoneum was established. In laparoscopic PPG, a 5-mm trocar was placed in the right and left upper quadrants, and a 12-mm trocar was placed in the right and left lower quadrants (**Fig. 1A**). In robotic PPG using the da Vinci Xi Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA), an 8-mm trocar was inserted horizontally from the umbilical camera port of the second arm to the outermost right and left sides of the first and fourth arms, respectively (**Fig. 1B**). A 12-mm trocar for the third arm was inserted between the umbilical port and fourth arm port, and one 12-mm trocar was inserted at the right and slightly upper sides of the umbilical port for assistance.

In all the cases, the right gastric artery and vein, as well as the infra-pyloric artery and vein, were preserved to ensure adequate blood supply and drainage to the remaining antral cuff. The celiac branch of the vagus nerve was not preserved due to the findings from retrospective data from our institution (not published) and a published report [13] that indicated no clinical benefits associated with the preservation. Radical lymph node dissection was performed in accordance with the Gastric Cancer Treatment Guidelines [6].

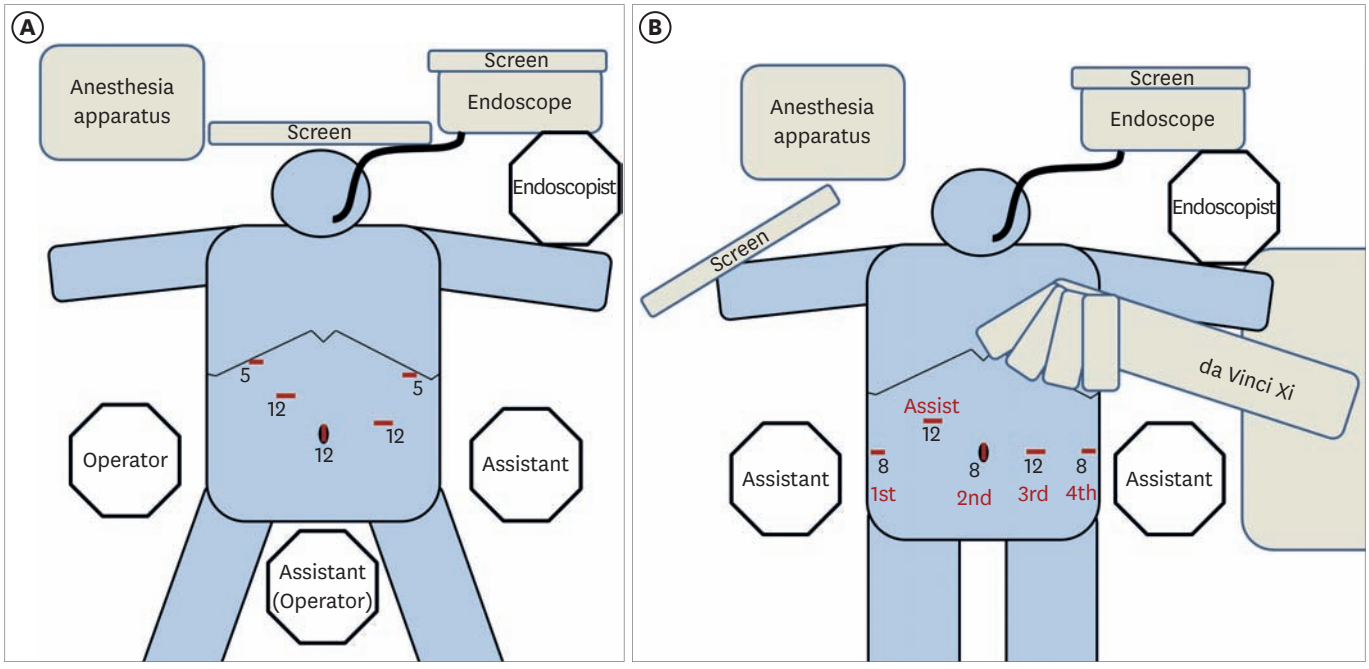

Fig. 1. Schema of the setting. (A) Setting and port placement of totally laparoscopic pylorus-preserving gastrectomy. A 12-mm trocar is needed in the left lower quadrant when using the linear stapler. (B) Setting and port placement of totally robotic pylorus-preserving gastrectomy using the da Vinci Xi Surgical System. A 12-mm trocar is needed in the left third arm port for anastomosis.

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NoCEAM

We developed the following unique four-step procedure to facilitate precise removal of the specimen at the planned excision line with the appropriate cancer margin:

1) Marking (**Fig. 2A**): After radical lymphadenectomy, we clamped the jejunum using a laparoscopic intestinal clip to inflate the stomach sufficiently for endoscopic observation. We confirmed the tumor location and marked it on the serosa under the guidance of an intraoperative oral endoscope. We marked the oral and anal resection lines on the posterior and anterior gastric walls using indigo carmine dye (Alfresa Pharma Corporation, Osaka, Japan), with an adequate safety margin from the serosal tumor markings (**Fig. 2B**). Additionally, three points were marked on the resection lines of each posterior and anterior wall at the greater and lesser curvatures and their midpoints (**Fig. 2C**).
2) Suturing (**Fig. 2D**): During laparoscopic PPG, the operator repositioned between the patient's legs. The stomach was sutured from the oral mark to the opposite anal mark using a large needle (coated VICRYL Plus, CTX 1, 48 mm 1/2 circle Taper; Ethicon, Johnson & Johnson, Raritan, NJ, USA) with absorbable suture clips (LAPRA-TY® Suture Clips; Ethicon, Johnson & Johnson) attached to the thread's end (**Fig. 2E and F**). Using one thread, we placed three stitches in both the posterior and anterior walls: the lesser curvature, mid-point, and greater curvature. The peroral endoscopist regulated the stomach tension by inflating and deflating it and informed the operator whether the needle correctly sutured the area containing the cancer without complications (**Fig. 2G and H**).
3) Closing (**Fig. 3A**): The operator pulled the thread with the oral side clip to the anal side. The thread was then fixed with a clip at the anal side so that the gastric wall was sandwiched between the oral and anal clip.(**Fig. 3B**). The specimen bulged outward resembling a "donut" after the circumferential gastric wall was closed (**Fig. 3C**).
4) Excision (**Fig. 3D**): Following the closure of the stomach, we cut the specimen vertically using a 60-mm linear stapler (Powered Echelon FLEX 60, PLEE60A, Blue cartridge GST60B; Ethicon, Inc. Johnson & Johnson or SureForm 60 device, SureForm 60 reloads Blue; Intuitive Surgical Inc.) from the greater curvature of the stomach by carefully avoiding cancer dissection (**Fig. 3E and F**). If the tumor was located on the greater curvature, we initiated the cut from the anterior wall, which showed no signs of cancer. Subsequently, the anterior and posterior walls were cut circumferentially along the clips using two 60-mm stapler cartridges for each wall (**Fig. 3G and H**). We adjusted the stapler position to remove all the clips. By cutting the stomach circumferentially with linear staples, the specimen was removed, completing the NoCEAM procedure (**Fig. 3I**).

Specimen extraction

To facilitate the removal of the long, thin specimen, we expanded the umbilical port wound to 25 mm in all the cases. The specimen was carefully retrieved from the small umbilicus wound by grasping its end using forceps (**Fig. 3J**). Using an intraoperative endoscope, we confirmed that there was no bleeding at the anastomosis and no major deformation of the stomach (**Fig. 3K**). Finally, we performed an air leak test to ensure there was no air leak by pouring normal saline into the anastomosis, with the stomach distended using sufficient air supply (**Fig. 3L**). A 19-Fr round drain (UK drain; Nipro Corporation, Osaka, Japan) was placed on the upper side of the pancreas.

Postoperative outcomes

According to the clinical pathway at our hospital, the patients were allowed to start drinking liquids on the first postoperative day and begin eating on the second postoperative day. The

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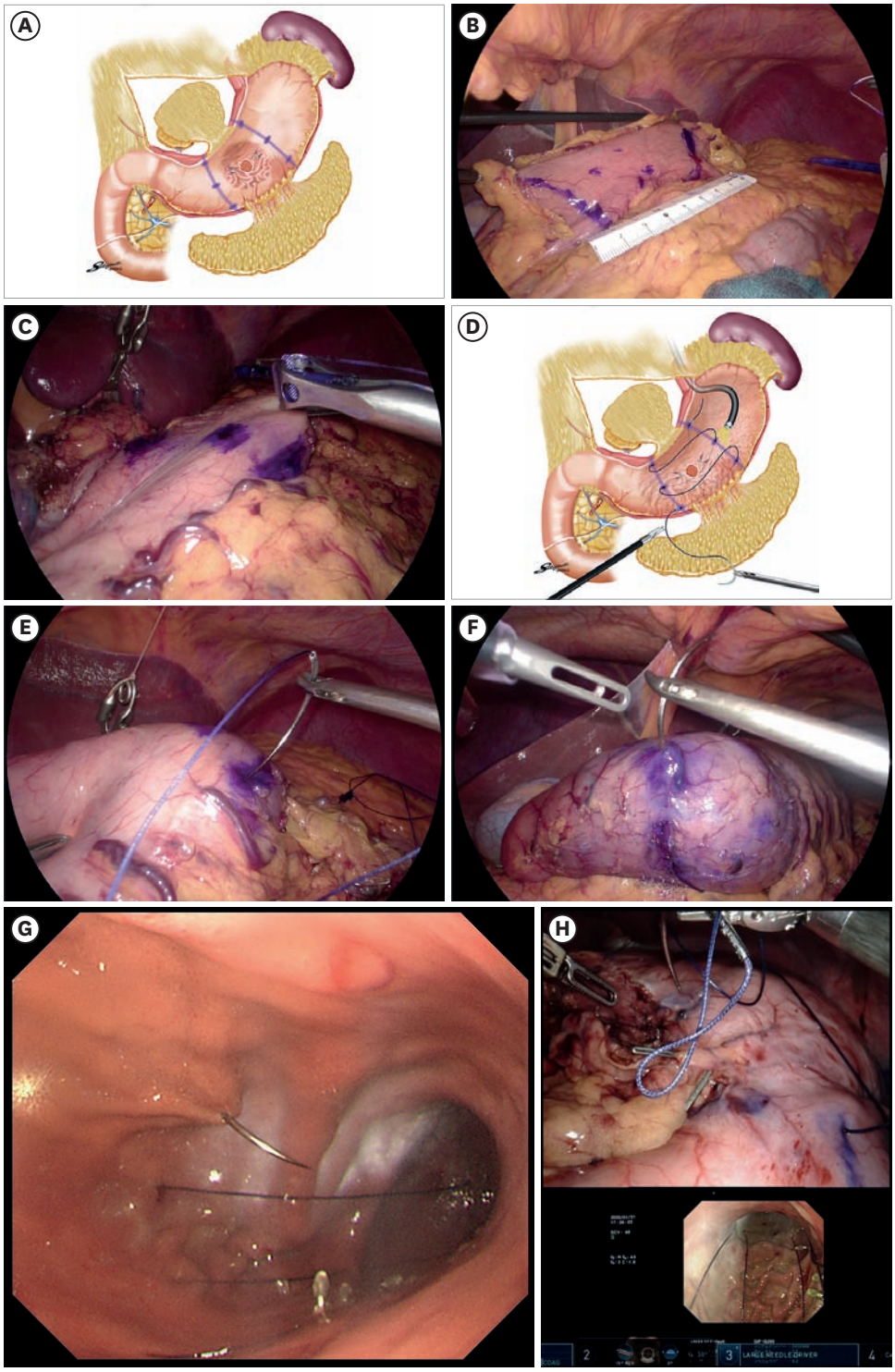

Fig. 2. First half of the non-opened clean end-to-end anastomosis method. (A) Marking: after determining the lines for gastric resection using an intraoperative peroral endoscope, three points are marked on these lines for needle insertion and ejection. (B) The oral and anal resection lines are marked on the anterior and posterior gastric wall. (C) The three points: the greater and lesser curvature, and the mid-point, are marked on all four lines. (D) Suturing: the stomach is sutured circumferentially from the oral insertion mark to the anal ejection mark, using a large needle with absorbable suture clips at the end of the thread. (E) A large needle is inserted into the stomach from the oral mark. (F) The needle is ejected from the opposite anal mark. Three stitches are placed on both the anterior and posterior walls. (G) The peroral endoscopist controlled the stomach tension by insufflation, degassing, and informed the operator whether the needle is being inserted without complications. (H) In robotic surgery, the operator can simultaneously confirm in one operator screen the accuracy of the procedure in the gastric lumen.

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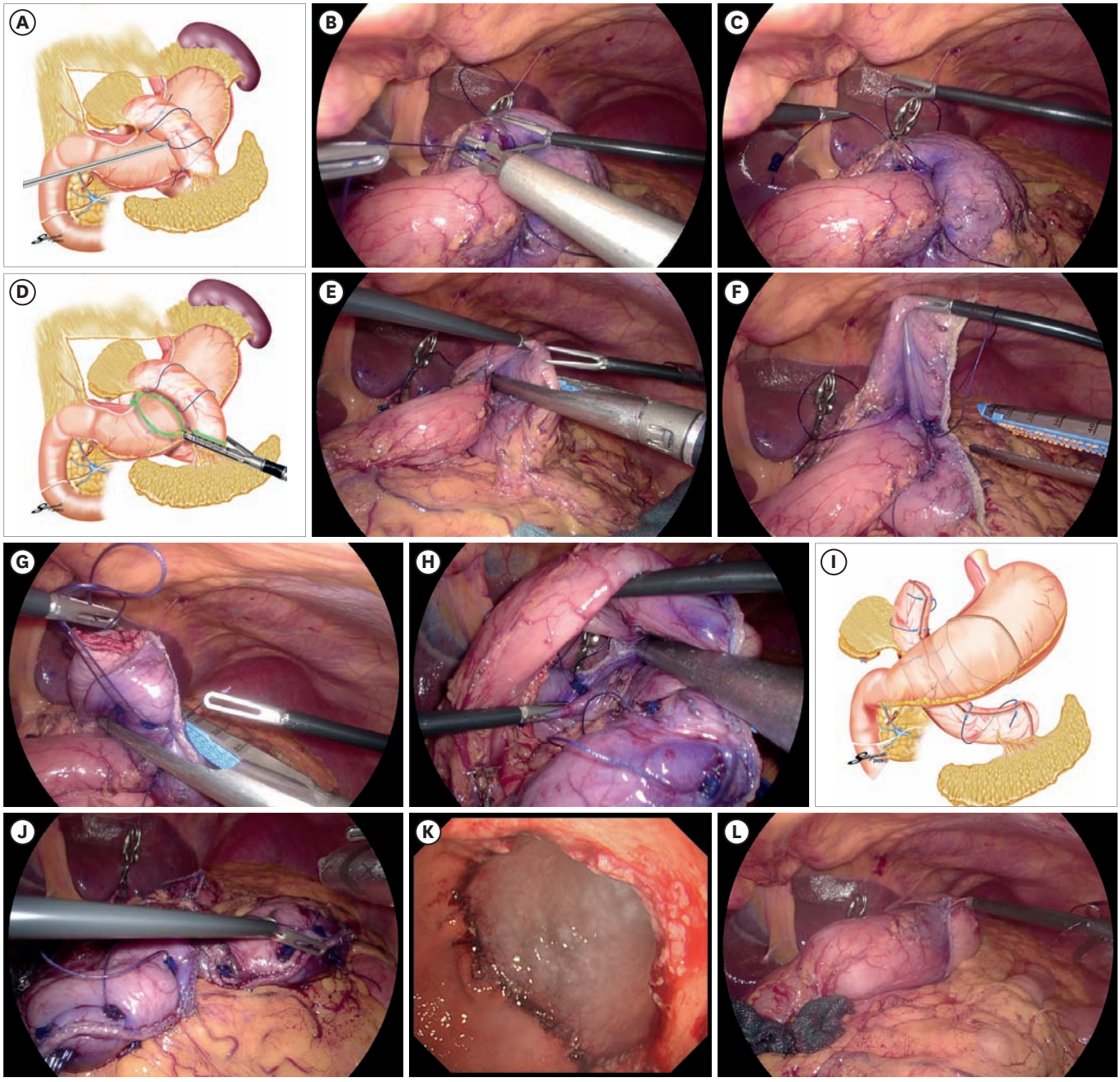

Fig. 3. Second half of the non-opened clean end-to-end anastomosis method. (A) Closing: the anterior and posterior threads are pulled and fixed using the suture clips. The specimen circumferentially bulges outward like a "donut." (B) The gastric wall is sandwiched between the absorbable suture clips allowing the oral mark to stick to the anal mark. (C) The specimen is rolled outward after circumferentially closing the gastric wall. (D) Excision: the specimen is cut vertically from the greater curvature of the stomach using a linear stapler. The anterior and posterior wall is cut circumferentially along the clips to remove all the clips. (E) The specimen is clamped while carefully avoiding severing the cancer. (F) The specimen is cut vertically. (G) The anterior wall is cut underneath the clips by two 60-mm staplers. (H) The posterior wall is cut using two 60-mm staplers to remove all the clips. (I) The non-opened clean end-to-end anastomosis method is completed. The long thin specimen with lymph nodes is removed and the en bloc resection is completed. (J) The long thin specimen can be removed from a small 25-mm umbilical port. (K) The big anastomosis can be observed in the endoscopic view and no major deformation is confirmed. (L) An air leak test is performed with the stomach distended using sufficient air supply.

drain was removed on the fourth postoperative day. The patient was discharged on the eighth postoperative day. Postoperative complications were classified according to the Clavien–Dindo classification of surgical complications, and the grades of these were recorded for each patient.

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To evaluate changes in the patient's nutritional status, we analyzed the serum total protein, serum albumin, and hemoglobin levels before surgery and at 6 and 12 months after surgery. Relative body weight (postoperative/preoperative) was calculated for each patient at 6 and 12 months after surgery.

Statistical analyses

All data were expressed as mean±standard deviation (SD). The paired samples t-test was used to compare nutritional parameters between preoperative and postoperative levels. A P-value of <0.05 was considered statistically significant. Statistical analyses were performed using JMP Pro 13 (SAS Institute, Cary, NC, USA).

RESULTS

Ex vivo and in vivo studies

The feasibility of NoCEAM was successfully demonstrated in the *ex vivo* study, involving three harvested stomachs (**Table 1**). The end-to-end anastomosis was performed without any complications, and no major deformation of the stomach was observed. In the in vivo study involving one pig, the laparoscopic NoCEAM was performed without any intraoperative complications and with minimal intraoperative bleeding. The stomach did not show any major deformation, and the end-to-end anastomosis was performed without any difficulties. Due to the thick stomachs of the pigs, the mean number of endoscopic linear staplers used was 7.25. A complete en bloc resection of the specimen and fat tissue, including the lymph nodes, was performed in all ex vivo and in vivo cases, and no leaks were detected during the leak test.

Human cases

The operative outcomes are summarized in **Table 2**. The NoCEAM was performed in 13 consecutive patients between December 2018 and August 2020. In the first patient, NoCEAM was performed using laparotomy because of a history of frequent open surgeries. The next four patients were operated on laparoscopically, while the remaining eight patients underwent robotic NoCEAM. The mean age (±SD) of the patients was 72±7.3 years. The mean operative time was 279±51 minutes, and the mean anastomosis time was 72±14 minutes. The mean volume of blood loss was 22±45 mL. All operations were performed safely without any intraoperative complication. The mean number of endoscopic linear staplers used was 5.06±0.76. A complete en bloc resection of the specimen and fat tissue, including the lymph node, was performed in all the cases. Intraoperative endoscopic observation revealed a large anastomosis, as expected, and no leak was detected in the leak test (**Fig. 3K**). Additionally, no deformation of the stomach shape was observed.

All patients followed the clinical pathway of our hospital. An upper gastrointestinal series conducted on the second postoperative day using Gastrografin demonstrated good passage without gastric stasis, stomach deformity, or constriction at the anastomotic site (**Fig. 4A**). No postoperative complications classified as grade I or higher in the Clavien–Dindo

Table 1. Operative data of the non-opened clean end-to-end anastomosis method for the ex vivo and in vivo porcine model studies

Case No.	Model	Virtual lesion location	Total number of linear staples used	Complete en bloc resection	Air leak test
1	Harvested stomach	Middle body/Anterior wall	7	Yes	No leakage
2	Harvested stomach	Middle body/Anterior wall	7	Yes	No leakage
3	Harvested stomach	Middle body/Anterior wall	6	Yes	No leakage
4	Live pig	Middle body/Posterior wall	9	Yes	No leakage

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Table 2. Patient characteristics and operative and pathological data

Characteristics	Value
Number of cases	13
Sex (male/female)	5/8
Age (yr)	72±7.3
Body mass index (kg/m^2)	24±4.0
American Society of Anesthesiologists score (1/2/3/4–)	0/12/1/0
Circumference (Less/Gre/Ant/Post)*	6/1/1/5
Approach (laparotomy/laparoscopically/robotically)	1/4/8
Operation time (min)	279±51
Blood loss (mL)	22±45
Conversion to open surgery	0 (0)
Anastomosis time (min)	72±14
Total number of linear staples used	5.06±0.76
Complete en bloc resection (%)	100
Postoperative complication (≧CD-I) (%)	0
Postoperative hospital stays (days)	8±0
Pathological T factor (pT1a/T1b/T2/T3/T4)	4/6/2/1/0
Pathological N factor (pN0/N1/N2/N3)	12/1/0/0
Maximal tumor diameter (mm)	36±13
Harvested lymph nodes	41±8.3
Surgical margins (mm)	
Proximal	28±15
Distal	36±21
Residual tumor (R0/R1/R2)	13/0/0

Values are presented as mean±standard deviation or number (%).
Less = lesser curvature; Gre = greater curvature; Ant = anterior wall; Post = posterior wall; CD = Clavien–Dindo classification.
*Four equal parts of the gastric circumference.

classification occurred. The postoperative length of hospital stay was 8 days in all the cases, and no postoperative readmission was observed.

Upon removing all the staples and suture clips from the resected specimen and opening it, we observed that the shape resembled that of the ordinary PPG specimen in all cases (**Fig. 4B and C**). Negative margins were confirmed by intraoperative frozen section analysis in three cases. Final pathological data are presented in **Table 2**. The mean±SD maximal tumor diameter was 36±13 mm. In five patients who underwent endoscopic submucosal dissection for cancer, no residual tumor in the surgically resected specimen was observed. The mean proximal and distal margins of the tumors were 28±15 mm and 36±21 mm, respectively. No

Fig. 4. Postoperative examination and specimen. (A) Upper gastrointestinal imaging reveals that the stomach has a natural shape, and in this case, anastomosis is not immediately recognizable. (B) The specimen is long, thin and has a unique shape. All suture clips are removed from the specimen. (C) After the staples and clips are removed and the specimen is opened, the specimen of the non-opened clean end-to-end anastomosis method has the same shape as that of an ordinary pylorus-preserving gastrectomy.

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Table 3. Preoperative and postoperative evaluation of nutritional status

Variables	Preoperation (n=13)	6 months after operation (n=8)		12 months after operation (n=4)	
		Value	P-value (vs. preoperation)	Value	P-value (vs. preoperation)
Total protein (g/dL)	7.27±0.28	7.33±0.41	0.71	7.38±0.68	0.65
Albumin (g/dL)	4.24±0.25	4.32±0.28	0.49	4.34±0.50	0.61
Hemoglobin (g/dL)	13.7±1.90	13.4±1.14	0.67	14.0±1.42	0.8
Relative body weight (%) (postoperative/preoperative)	100	92±5.4		92±6.4	

Values are presented as mean±standard deviation.

residual cancer cells were detected at the proximal and distal stumps in any of the cases. The mean number of retrieved lymph nodes ±SD was 41±8.3.

The results of the comparison of the postoperative and preoperative levels serum total protein, serum albumin, and hemoglobin for evaluating the postoperative nutritional status are presented in **Table 3**. No significant differences were observed in the levels of serum total protein, serum albumin, and hemoglobin at 6 and 12 months when compared to that of the corresponding preoperative data. The mean relative body weights (postoperative/preoperative) at 6 and 12 months after the operation were 92%±5.4% (n=8) and 92%±6.4% (n=4), respectively. Gastroscopy performed 12 months after surgery revealed that none of the patients required endoscopic intervention for anastomosis.

DISCUSSION

We developed a new anastomosis method to eliminate gastric fluid exposure, which is the main route of intra-abdominal infection transmission. The NoCEAM is expected to improve long-term outcomes by eliminating gastric fluid exposure.

Based on a public database search, Ju et al. [14] reported that for class II/clean-contaminated surgery in Surgical Wound Classification Grades, the complication rate of total surgical site infections (SSI), organ space SSI, and sepsis or septic shock was 4.8%, 1.6%, and 2.7%, respectively. In contrast, for class I/clean surgery, the total SSI, organ space SSI, and sepsis or septic shock was 1.8%, 0.3%, and 1.0%, respectively. Converting a class II surgery into class I surgery would dramatically reduce the infectious complications. Although the NoCEAM is not strictly considered as class I due to the passage of the needle through the stomach, our non-open technique drastically reduced the number of bacterial exposed to the abdominal cavity. The NoCEAM allowed the infectious complication rate of gastrectomy to move closer to that of class I. The NoCEAM is expected to improve not only short-term outcomes, such as incisional SSI, organ space SSI, and sepsis or septic shock, but also long-term outcomes.

Takahashi et al. [7] reported that intra-abdominal infection is significantly related to the development of early postoperative gastric stasis. The most common complication of laparoscopic PPG was early postoperative gastric stasis (7.6%, 68/897). Univariate analyses revealed that IAIC was significantly related to the incidence of stasis (HR, 3.91; 95% CI, 2.00–7.36; P<0.001). Multivariate analysis further identified IAIC as the highest risk factor for stasis (HR, 3.56; 95% CI, 1.92–6.60; P<0.001). These data indicated that the prevention of IAIC leads to a low gastric stasis rate. In all our cases, neither infectious complications nor gastric stasis were observed. The NoCEAM is expected to reduce the two most common complications of PPG.

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The NoCEAM was considered appropriate for postoperative technical evaluation. Although the mean operation time for totally laparoscopic PPG was 255–275 minutes [15-18] and that for the NoCEAM was 279±51 minutes. Owing to the learning curve, the duration of the last three surgeries was shortened to 219±6.7 minutes. The number of lymph nodes dissected in this study was equivalent to that reported previously. In postoperative pathological specimens, the oral and anal margins were secured as planned in all the cases, and cancer positivity at the surgical margin was not observed. If the intraoperative frozen tissue analysis revealed a positive surgical margin, additional resections were performed by grasping the staple line and pulling it or suturing and closing it using suture clips. Nutritional evaluation of serum levels did not show any significant decrease. The procedure data of this reconstruction method were comparable to those of the existing procedures.

The NoCEAM has the conflicting advantages of a large anastomosis diameter and the use of a small number of staples. More staples result in a larger anastomotic diameter; however, this makes the procedure more expensive. The delta-shaped anastomosis, one of the major anastomosis methods used in totally laparoscopic PPG, is triangularly shaped anastomosis, which uses a minimum of five staples with a 60-mm stapler [15]. The piercing method is another triangular anastomosis, which uses a minimum of six staples with a 60-mm stapler, which [16]. The NoCEAM has quadrilateral anastomosis using 60-mm staples, which have the largest diameter among the existing reconstruction methods of totally laparoscopic PPG. The total number of staples used in the NoCEAM was five, which was the lowest number reported for PPG. The NoCEAM has the largest anastomosis diameter and lowest cost in totally laparoscopic PPG.

Although many reports are available on laparoscopy-assisted PPG with 5-cm laparotomy for anastomosis, there is only one report of robot-assisted PPG [19] and none of totally robotic PPG without laparotomy for anastomosis. The NoCEAM can be performed robotically and laparoscopically using the same exact steps. Our study is the first report of a totally robotic PPG.

The possibility of contact or contamination of the tumor by the piercing needle cannot be denied. The potential risk of tumor cell dissemination is debated in the field of endoscopic full-thickness resection [20]. However, we believe that the risk of seeding through needle holes is extremely low, and that the benefits of preventing seeding by the non-opening method are higher. With these potential risks in mind, suturing should be performed slowly and meticulously.

An immediate benefit of this procedure to all patients is that the specimen can be obtained from the umbilical port without an additional incision. The NoCEAM specimen was long and thin compared to that of conventional gastrectomy. The umbilical port was expanded to 35–50 mm for specimen removal in the conventional method (totally laparoscopic PPG, 38±4 mm; laparoscopy-assisted PPG, 47±6 mm) [18]; however, in our method, all specimens could be removed with a 25-mm umbilical port. Postoperative pain is expected to be less compared to that of the conventional method because of the resultant small incisions.

Regarding indications, this procedure could be performed regardless of the location of the lesion. Even in the case of a maximum tumor diameter of 49 mm, the NoCEAM can be performed without any difficulties; therefore, if the lesion is within the PPG indication, there is no limitation on the indication for this reconstruction method.

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A limitation of this study was the relatively small sample size, making it difficult to conclude a definite improvement in short-term complications. It was not possible to judge the evaluation of nutritional status or long-term prognosis, because the observation period was short. In addition, our study is a report based on the procedure being performed by a single operator in a single facility.

In conclusion, the NoCEAM is feasible and can be safely integrated into clinical practice. This intracorporeal reconstruction method, based on the novel concept of not opening the gastrointestinal tract, is a useful procedure in totally laparoscopic or robotic PPG. This reconstruction method is expected to reduce the IAIC. Future clinical trials examining short- and long-term results, such as nutritional indicators, quality of life surveys, and overall survival, are warranted to confirm the effectiveness of this method.

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