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Original Article

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Clinical Impact of Polyglycolic Acid Mesh to Reduce Pancreas-Related Complications After Minimally Invasive Surgery for Gastric Cancer: A Propensity Score Matching Analysis

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ABSTRACT

Purpose: Prevention of pancreas-related complications after gastric cancer surgery is critical. Polyglycolic acid (PGA) mesh reduces postoperative pancreatic fistula formation following pancreatic resection. However, the clinical efficacy of PGA mesh in gastric cancer surgery has not been adequately investigated.
Materials and Methods: This retrospective study compared the short-term outcomes between two groups: patients who underwent minimally invasive R0 gastrectomy for gastric cancer with the use of a PGA mesh (PGA group) and those without the use of a PGA mesh (non-PGA group) at the Cancer Institute Hospital, Tokyo, between January 2019 and May 2023. Propensity score matching (PSM) was performed to adjust for the possible confounding factors.
Results: A total of 834 patients were initially included, of whom 614 (307 in each group) remained after PSM. The amylase levels in the drained abdominal fluid on postoperative days 1 and 3 were similar between the PGA and non-PGA groups. The PGA group had a significantly lower incidence of pancreas-related complications of Clavien-Dindo grade ≥2 than that in the non-PGA group (6.8% vs. 2.9%, P=0.025). In subgroup analyses, the odds ratio for pancreas-related complications appeared to be better in the PGA group than in the non-PGA group in patients with American Society of Anesthesiologists Physical Status Classification score of 2 or 3, those operated via a laparoscopic approach, and those undergoing procedures other than proximal gastrectomy.
Conclusions: The use of PGA mesh significantly reduced pancreas-related complications after minimally invasive surgery for gastric cancer and might thus benefit patients at risk of such complications.

Keywords: Gastric cancer; Minimally invasive surgery; Polyglycolic acid; Postoperative complications; Pancreatic fistula

INTRODUCTION

Gastrectomy with lymphadenectomy is the established standard treatment for resectable gastric cancer, except for patients with early lesions that can be endoscopically dissected.

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

Author Contributions
Conceptualization: R.M., O.M., M.R., H.M., S.T., N.S.; Data curation: R.M.; Formal analysis: R.M.; Investigation: R.M.; Methodology: R.M., O.M.; Writing - original draft: R.M.; Writing - review & editing: R.M., O.M., M.R., H.M., S.T., N.S.

Recently, significant advancements have been made in minimally invasive surgical techniques for treating gastric cancer. Laparoscopic gastrectomy has produced favorable short-term outcomes and non-inferior long-term results compared to those observed with open surgery, not only for early stage but also for advanced cancer [1-4]. Moreover, the introduction of robotic surgery has made significant contributions to the establishment of minimally invasive procedures as mainstream approaches for gastric cancer surgery [5].

However, concerns have been raised that the incidence of postoperative pancreatic fistula (POPF) after minimally invasive gastrectomy is relatively high compared with that associated with open surgery, primarily because of limitations in the range of motion and visibility of surgical instruments during laparoscopic procedures [2,6]. A major postoperative pancreas-related complication, POPF, is caused by pancreatic juice leakage from the pancreatic surface due to blunt or thermal injury during lymph node dissection at suprapancreatic or infrapyloric sites and often results in peripancreatic abscess formation [7]. Postoperative pancreas-related complications have been observed to prolong hospitalization [8,9] and can delay the initiation of adjuvant therapy, owing to possible adverse effects on the survival of patients with advanced malignancies [10]. Furthermore, intra-abdominal infectious complications are reportedly an independent risk factor negatively influencing survival [11,12]. Hence, given the widespread use of minimally invasive surgery for gastric cancer in current practice, preventing postoperative pancreas-related complications is imperative.

Polyglycolic acid (PGA) mesh, which is an absorbable textile that degrades via hydrolysis 3 weeks after application, is widely used to achieve tissue reinforcement in various surgical settings [13-16]. Several studies have examined the efficacy of PGA meshes for preventing POPF after pancreatic resection [17,18]. Notably, one of these investigations with a randomized controlled study design demonstrated a significant reduction in POPF after distal pancreatectomy utilizing a PGA mesh [17]. Recently, PGA meshes have been increasingly used in gastric cancer surgery to prevent postoperative pancreas-related complications. A previous study obtained evidence suggesting that the use of PGA mesh may contribute to reducing the incidence of POPF compared to the non-use of PGA mesh after gastrectomy for gastric cancer. However, the aforementioned study had a small sample size, such that demonstrating the effectiveness of PGA mesh, especially after the application of propensity score estimation was not possible [19]. Therefore, evidence supporting the preventive effect of PGA meshes on pancreas-related complications following gastric cancer surgery is limited.

Here, we compared the incidence of postoperative pancreas-related complications after gastric cancer surgery with and without a PGA mesh to confirm the clinical impact of the PGA mesh in preventing such complications.

MATERIALS AND METHODS

Patients

The consecutive patients included in this study were diagnosed with histologically confirmed gastric adenocarcinoma and had all undergone minimally invasive R0 gastrectomy for gastric cancer at the Department of Gastroenterological Surgery, Cancer Institute Hospital, Tokyo, Japan, between January 2019 and May 2023. The types of gastrectomy included distal, total, pylorus-preserving, and proximal. This study was approved by the Institutional Review Board of the Cancer Institute Hospital (No. 2023-GB-092).

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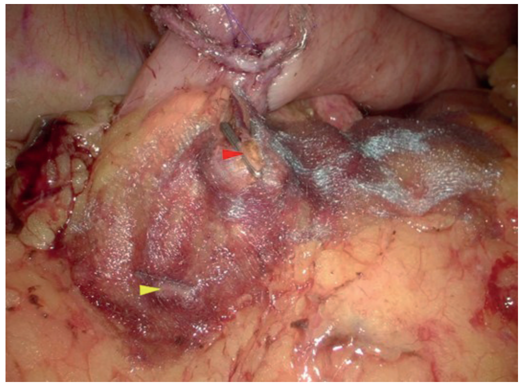

Fig. 1. Representative images depicting the application of PGA mesh to the pancreatic surface during gastrectomy for gastric cancer. Representative image demonstrating the application of a PGA mesh (Neoveil sheet; GUNZE LIMITED, Tokyo, Japan) to the pancreatic surface at the sites of infrapyloric and suprapancreatic lymph node dissection after laparoscopic distal gastrectomy with Billroth I reconstruction. The PGA mesh was divided into eight sections and affixed to cover all areas. Red and yellow arrows indicate transected ends of the right gastroepiploic artery and vein, respectively.
PGA = polyglycolic acid.

Surgical procedure and intraoperative application of PGA mesh

The type of gastrectomy selected was determined by the tumor location to secure appropriate resection margins according to the Japanese Gastric Cancer Treatment Guidelines [20]. All procedures were performed laparoscopically or robotically by highly experienced surgeons or under their supervision. These surgeons had extensive experience, having performed at least 500 laparoscopic gastrectomies and/or held certification in the field of gastric cancer from the Japan Society for Endoscopic Surgery. During the dissection of the superior border of the pancreas, we employed a technique in which the connective tissues along the inferior border of the pancreas and nerves along the common hepatic and splenic arteries were pulled and controlled to establish the surgical field rather than directly compressing the pancreas itself, as previously reported [21]. A PGA mesh (Neoveil sheet; GUNZE LIMITED, Tokyo, Japan) was affixed to the pancreatic surface at the sites of lymph node dissection, including the pancreatic head (station No. 6) and superior border of the pancreas (stations No. 8a and 11p), followed by the completion of all reconstructions (**Fig. 1**).

During the study period, patients with resectable gastric cancer were under the care of seven surgeons, each of whom was responsible for a subset of patients randomly assigned to them. The decision to use a PGA mesh was made by each surgeon. Eventually, five of the seven surgeons consistently employed a PGA mesh, whereas two did not. One of the five surgeons who employed a PGA mesh placed it only on the anastomotic sites. However, even surgeons who typically refrain from the PGA mesh utilized it in cases where maintaining a good surgical exposure around the pancreas was challenging or where saponification was observed on the surface of the pancreas after lymph node dissection. Patients in whom a PGA mesh was used but not applied to the aforementioned pancreatic areas were excluded from this study.

Perioperative management of intra-abdominal drain

At the end of the surgery, at least one drain was placed in the suprapancreatic area. Postoperative amylase concentration in the drained abdominal fluid (D-AMY) was measured from the suprapancreatic drain. The drain position was checked using abdominal radiography immediately after surgery and on postoperative days (POD) 1 and 3. When a drain misplacement was identified, the drain was typically removed immediately; otherwise, it was left in place until POD 3.

Data collection

Data including patient characteristics, surgical findings, and postoperative outcomes were retrospectively obtained from our database and the hospital's electronic medical records. The patient characteristics included sex, age, body mass index (BMI), American Society of Anesthesiologists Physical Status Classification (ASA-PS) score, clinical tumor-node-metastasis factors, and neoadjuvant chemotherapy. The following surgical findings were collected: surgical approach, type of gastrectomy, extent of lymph node dissection, duration of surgery, and intraoperative blood loss. Postoperative outcomes included hematological findings such as white blood cell count, C-reactive protein level, D-AMY, and the incidence of postoperative pancreas-related complications.

Classification and definition

For clinical T-factor assessment, a comprehensive evaluation was conducted by reviewing the endoscopic findings obtained by an endoscopist and computed tomography (CT) features documented by a radiologist. The final determination of the depth of tumor wall invasion was made by reaching a consensus at a gastric cancer team conference that included surgeons, endoscopists, and chemotherapists. Regional lymph nodes with a long-axis diameter of 10 mm or greater on pre-treatment CT were defined as clinically metastatic lymph nodes. The clinical stage was determined according to the 15th edition of the Japanese Classification of Gastric Carcinoma [22]. Postoperative pancreas-related complications were defined as the presence of fluid collection around the pancreas or along the abdominal drain, pus-like fluid from the drain, or a positive culture test from the tip of the abdominal drain, irrespective of the D-AMY levels. Furthermore, patients suspected of having an abscess due to anastomotic leakage were excluded from the pancreas-related complications group. The severity of postoperative complications was determined according to the Clavien-Dindo classification (C-D) [23].

Propensity score matching (PSM) and statistical analysis

PSM was performed to adjust for confounding factors. The propensity score was estimated by applying a logistic model with the aforementioned nine items (sex, age, BMI, ASA-PS, clinical T-factor, clinical N-factor, neoadjuvant chemotherapy, surgical approach, and type of gastrectomy) as covariates. Optimal matching (ratio=1:1 without replacement) was performed, with a 0.15 standard deviation of the estimated logit. The primary evaluation outcomes were the incidence of postoperative pancreas-related complications of C-D 2 or greater and D-AMY values on POD 1 and 3. All continuous variables are expressed as median values. Statistical analyses were conducted using the Mann–Whitney U test, chi-squared test, or Fisher's exact test. In subgroup analyses for risks of pancreas-related complications of C-D 2 or greater, the odds ratio (OR) and 95% confidence intervals were estimated. All statistical tests were two-sided and a P-value <0.05 was considered statistically significant. All statistical analyses were performed using JMP Pro 17 software (SAS Institute Japan Ltd., Japan) for Windows.

RESULTS

Patient characteristics

In total, 834 patients were included in this study (**Supplementary Table 1**). After a 1:1 PSM, 307 patients were selected from the non-PGA and PGA groups. **Table 1** summarizes the patient's background findings. The clinical characteristics of all patients were well-balanced.

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Table 1. Patient demographic and clinical characteristics (after propensity score matching)

Variables	Non-PGA (n=307)	PGA (n=307)	P-value
Sex			0.211
Male	200 (65.0)	185 (60.0)	
Female	107 (35.0)	122 (40.0)	
Age (yr) [IQR]	68 [57.0–75.0]	69 [56.0–75.0]	0.795
BMI (kg/m²) [IQR]	23.0 [20.5–25.4]	22.6 [20.7–25.0]	0.660
ASA-PS			0.984
1	145 (47.2)	145 (47.2)	
2	145 (47.2)	144 (46.9)	
3	17 (5.5)	18 (5.9)	
Clinical T factor			0.375
cT1	212 (69.1)	222 (72.3)	
cT2 or more	95 (30.9)	85 (27.7)	
Clinical N factor			0.802
cN0	270 (88.0)	272 (88.6)	
cN1-3	37 (12.0)	35 (11.4)	
Clinical stage			0.922
cStage I	240 (78.2)	239 (77.9)	
cStage II or more	67 (21.8)	68 (22.1)	
Neoadjuvant chemotherapy			0.254
Absence	302 (98.4)	305 (99.4)	
Presence	5 (1.6)	2 (0.6)	

Values are presented as number (%) unless otherwise indicated.
Non-PGA = non-polyglycolic acid; PGA = polyglycolic acid; IQR = interquartile range; BMI = body mass index; ASA-PS = American Society of Anesthesiologists Physical Status Classification.

Table 2. Surgical findings

Variables	Non-PGA (n=307)	PGA (n=307)	P-value
Approach			0.491
Laparoscopic	238 (77.5)	245 (79.8)	
Robotic	69 (22.5)	62 (20.2)	
Type of gastrectomy			0.714
Distal	195 (63.5)	206 (67.1)	
Total	30 (9.8)	26 (8.5)	
Pylorus-preserving	36 (11.7)	37 (12.0)	
Proximal	46 (15.0)	38 (12.4)	
Extent of lymph node dissection			0.176
Less than D2	191 (62.2)	207 (67.4)	
D2 or more	116 (37.8)	100 (32.6)	
Operative duration (min) [IQR]	305 [259.0–379.0]	330 [278.0–397.0]	<0.001
Intraoperative blood loss (mL) [IQR]	15 [10.0–45.0]	15 [10.0–50.0]	0.747

Values are presented as number (%) unless otherwise indicated.
Non-PGA = non-polyglycolic acid; PGA = polyglycolic acid; IQR = interquartile range.

Surgical findings

The details of the surgical findings are presented in **Table 2**. The surgical approach, type of gastrectomy, and extent of lymph node dissection were similar between the two groups. The operative duration was longer in the PGA group than in the non-PGA group (330 minutes vs. 305 minutes, P<0.001).

Postoperative outcomes

Table 3 lists postoperative blood biochemical findings. The D-AMY levels on POD 1 and 3 were similar in the non-PGA and PGA groups. The rate of decrease in the D-AMY level from POD 1 to POD 3 was greater in the PGA than in the non-PGA group but the difference did not reach statistical significance.

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Table 3. Postoperative blood and biochemical results

Variables	Non-PGA (n=307)	PGA (n=307)	P-value
WBC on POD 1, ×10^3 u/L [IQR]	8.8 [7.5–10.5]	9.2 [7.7–11.0]	0.067
WBC on POD 3, ×10^3 u/L [IQR]	7.5 [5.8–9.0]	7.1 [5.6–8.6]	0.138
CRP on POD 1, mg/L [IQR]	5.3 [3.5–6.9]	5.2 [3.4–7.1]	0.965
CRP on POD 3, mg/L [IQR]	9.7 [6.2–13.8]	9.3 [6.1–13.2]	0.826
D-AMY on POD 1, U/L [IQR]	534 [310.0–887.0]	536 [329.0–1,249.0]	0.224
D-AMY on POD 3, U/L [IQR]	194 [126.0–327.0]	195 [112.0–378.0]	0.772
Decrease in D-AMY level from POD 1 to POD 3, %	59.6 [38.0–75.8]	64.5 [32.6–78.3]	0.184

Non-PGA = non-polyglycolic acid; PGA = polyglycolic acid; WBC = white blood cell; POD = postoperative day; IQR = interquartile range; CRP = C-reactive protein; D-AMY = amylase in drained abdominal fluid.

Table 4. Postoperative complications

Variables	Non-PGA (n=307)	PGA (n=307)	P-value
Pancreas-related complications*			
C-D≥2	21 (6.8)	9 (2.9)	0.025
C-D≥3	7 (2.3)	3 (1.0)	0.202
Anastomotic leakage			
C-D≥2	6 (2.0)	4 (1.3)	0.524
C-D≥3	2 (0.7)	4 (1.3)	0.412

Values are presented as number (%).
Non-PGA = non-polyglycolic acid; PGA = polyglycolic acid; C-D = Clavien-Dindo classification.
*Postoperative pancreas-related complications included fluid collection around the pancreas or along the abdominal drain, pus-like fluid from the drain, and a positive culture test from the tip of the abdominal drain.

The postoperative outcomes are displayed in **Table 4**. Regarding the postoperative complications, the PGA group exhibited a significantly lower incidence of postoperative pancreas-related complications of C-D 2 or more than the incidence in the non-PGA group (6.8% vs. 2.9%, P=0.025).

Subgroup analyses for the risk of postoperative pancreas-related complications

Forest plots of the ORs for postoperative pancreas-related complications are illustrated in **Fig. 2**. The results demonstrated that the benefits of using the PGA mesh to reduce pancreas-related complications were evident in patients with ASA-PS 2 or 3, those who underwent surgery via a laparoscopic approach, and those who underwent procedures other than proximal gastrectomy.

DISCUSSION

We investigated the effect of applying a PGA mesh on postoperative complications after minimally invasive gastric cancer surgery. This study used PSM to ensure a well-balanced clinical background between the PGA and non-PGA groups. Our findings confirmed that the PGA mesh significantly reduced the incidence of postoperative pancreas-related complications without significantly altering D-AMY levels on POD 1 or 3. Furthermore, subgroup analyses revealed a marked improvement in ORs for pancreas-related complications in the PGA as compared to that in the non-PGA group, particularly among patients with ASA-PS ≥2, those receiving laparoscopic surgery, and for all procedures except proximal gastrectomy.

Basic experiments using rats have reported the preventive effect of the PGA mesh on POPF [24]. In a rat model involving pancreatic surface cauterization, the PGA group demonstrated significantly improved survival rates and reduced incidence of peritonitis. Microscopic examination revealed the proliferation of fibroblasts and the formation of a barrier wall

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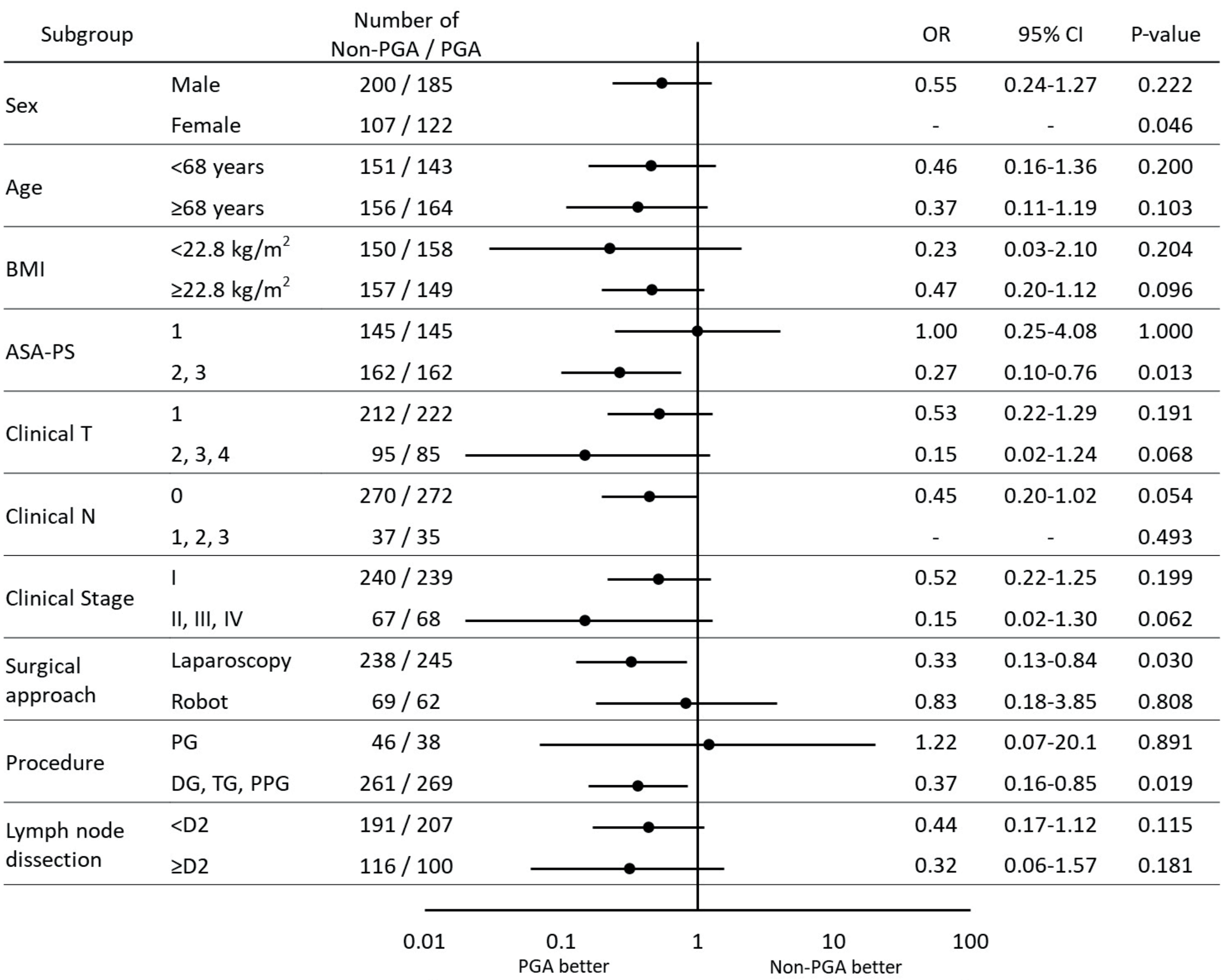

Fig. 2. Forest plot of OR for the risk of postoperative pancreas-related complications in subgroup analyses. In the subgroup analyses, the ORs for postoperative pancreas-related complications between the groups and 95% CIs were estimated. OR for patients with ASA-PS 2–3 (OR, 0.27; 95% CI, 0.10–0.76; P=0.013), those who received laparoscopic surgery (OR, 0.33, 95% CI, 0.13–0.84; P=0.030) or patients undergoing distal gastrectomy, total gastrectomy or pylorus-preserving gastrectomy (OR, 0.37; 95% CI, 0.16–0.85; P=0.019) were lower in the PGA group than in the non-PGA group.
Non-PGA = non-polyglycolic acid; PGA = polyglycolic acid; OR = odds ratio; CI = confidence interval; BMI = body mass index; ASA-PS = American Society of Anesthesiologists Physical Status Classification; PG = proximal gastrectomy; DG = distal gastrectomy; TG = total gastrectomy; PPG = pylorus-preserving gastrectomy.

throughout the cauterized surfaces of the pancreas in the PGA group, suggesting that PGA functioned as a scaffold to facilitate tissue repair. In clinical practice, the preventive effects of PGA meshes on POPF have been suggested in procedures such as distal pancreatectomy [17] and laparoscopic splenectomy in patients with hypersplenism [25]. Therefore, PGA meshes have been increasingly used for the prevention of POPF after gastric cancer surgery. However, substantial evidence regarding the effects of PGA mesh on pancreas-related complications after gastrectomy is lacking [19,26].

Although PGA mesh significantly reduces the incidence of postoperative pancreas-related complications, the mechanism underlying this effect has not yet been determined. Although the mechanisms proposed by the aforementioned animal experiments may have contributed to the observed decrease in the development of postoperative pancreas-related complications, histopathological findings were evaluated on POD 5 [24]. Consequently, the measurement of the D-AMY levels on POD 1 and 3 in the present study as potential indicators of postoperative pancreas-related complications may have been premature. Additionally, the relatively delayed onset of pancreas-related complications in this study, with a median POD of 7 days (data not displayed), further supports this assumption. Moreover, the volume of pancreatic leakage after gastrectomy was likely much smaller than that after pancreatectomy, possibly explaining the near-complete absence of differences in D-AMY levels on POD 1 and 3 between the two groups.

Subgroup analyses revealed a favorable association with PGA mesh in patients with ASA ≥2, those receiving surgery by the laparoscopic approach, and procedures other than proximal gastrectomy. These observations support the primary outcomes of this study. This is due to the likelihood that these factors indicate populations at a high risk of pancreas-related complications after gastric cancer surgery [9,27-30]. A nationwide study in our country revealed that patients with comorbidities such as diabetes, hypertension, chronic obstructive pulmonary disease, and coronary artery disease had significantly elevated rates of postoperative intra-abdominal infectious complications following gastrectomy [29]. Additionally, when comparing robotic and laparoscopic surgeries, Gong et al. [30] and Li et al. [31], in their respective meta-analysis and multi-center retrospective studies, reported a significantly high incidence of POPF in patients who had undergone laparoscopic gastric cancer surgery. Furthermore, in proximal gastrectomy, lymph nodes in the infrapyloric area are not dissected, which is considered to reduce the risk of pancreas-related complications compared to other types of operations [28].

Among the outcomes assessed in this study, a statistically significant difference was also observed in surgical duration, with a 25-minute extension noted in the PGA group compared to that in the non-PGA group. This time was longer than that required to apply the PGA mesh to the pancreatic surface. The difference in operative time between the two groups could be attributed to several factors. More patients underwent robot-assisted proximal gastrectomy, which had the longest operative time among all procedures, in the PGA group than in the non-PGA group (data not displayed). In addition, the PGA group may have included more patients with potential anatomical difficulty in lymph node dissection around the pancreas than the non-PGA group. Furthermore, some variations may exist among surgeons regarding how they perform lymph node dissection or reconstruction.

This study has several limitations. First, although this study had a large sample size as compared to those in previous reports [19] and employed PSM analysis, the number of events remained low, which may have prevented achieving statistical differences between the two groups in pancreas-related complications of C-D 3 or more. Moreover, this was a single-institution and retrospective study, such that confounding factors could not be eliminated. However, considering the relatively short study duration and the similarity of the postoperative outcomes, even in the non-PGA group, to those reported previously [6,32], it appears rather unlikely that the time-related bias exerted a major influence on the results obtained in this study. Second, no adjustments were made to the variations among the operators employed for PSM, which raises the possibility that these biases cannot be completely ruled out. The proficiency of the responsible surgeons was based on their experience and qualifications, and the surgical technique for lymph node dissection around the pancreas was standardized. Additionally, the fact that postoperative D-AMY values were

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essentially the same in the two groups may suggest that surgical procedures of similar quality were performed in both the PGA and non-PGA groups. Finally, we were unable to elucidate the mechanism(s) underlying the preventive effects of the PGA mesh on the development of postoperative pancreas-related complications. Further studies are required to provide a comprehensive understanding of these mechanisms. Given these limitations, the results of an ongoing randomized phase II trial in Japan designed to evaluate the effect of PGA mesh in preventing postoperative pancreas-related complications are awaited [33].

In conclusion, the application of PGA mesh appears to have a significant impact in preventing pancreas-related complications following minimally invasive surgery for gastric cancer, suggesting that patients at risk of such complications may benefit from the proactive use of PGA mesh.

SUPPLEMENTARY MATERIAL

Supplementary Table 1

Patient demographic and clinical characteristics before propensity score matching

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