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Efficacy and safety of polyglycolic acid sheets for prevention of intra-abdominal infectious complications following minimally invasive surgery for gastric cancer: A prospective, multicenter, single-arm clinical trial

Nobuaki Hoshino [a], Shigeo Hisamori [a,*], Seiichiro Kanaya [b], Hisahiro Hosogi [b], Dai Manaka [c], Yosuke Kinjo [d], Koichi Matsuo [e], Masazumi Sakaguchi [e], Masato Kondo [f], Yasutaka Nakanishi [g], Michihiro Yamamoto [h], Eiji Tanaka [i], Kosuke Toda [j], Hiroyasu Abe [k], Tatsuto Nishigori [a], Shigeru Tsunoda [a], Kazutaka Obama [a]

[a] Department of Surgery, Kyoto University Graduate School of Medicine, Japan
[b] Department of Surgery, Osaka Red Cross Hospital, Japan
[c] Department of Surgery, Kyoto Katsura Hospital, Japan
[d] Department of Surgery, National Hospital Organization Himeji Medical Center, Japan
[e] Department of Surgery, Kyoto City Hospital, Japan
[f] Department of Surgery, Kobe City Medical Center General Hospital, Japan
[g] Department of Surgery, National Hospital Organization Kyoto Medical Center, Japan
[h] Department of Surgery, Tenri Hospital, Japan
[i] Department of Surgery, Kitano Hospital, Japan
[j] Department of Surgery, Shiga General Hospital, Japan
[k] Department of Regulatory Science and Pharmaceutical Informatics, School of Pharmaceutical Sciences, Wakayama Medical University, Japan

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ABSTRACT

Background: Serious intra-abdominal infectious complications are common after gastric cancer surgery, including anastomotic leakage, pancreatic fistula, and intra-abdominal abscess. Although polyglycolic acid sheets are often used to reinforce soft tissue and prevent postoperative complications in various types of surgery, including gastric cancer surgery, their effectiveness has not yet been fully demonstrated.

Methods: Patients with gastric cancer and no distant metastasis undergoing minimally invasive distal or total gastrectomy at Kyoto University Hospital or its 9 affiliated facilities between March 2022 and December 2023 were enrolled. The primary outcome was incidence of Clavien–Dindo (CD) grade ≥ III intra-abdominal infectious complications, including anastomotic leakage, pancreatic fistula, and intra-abdominal abscess. Secondary outcomes were incidence of overall complications (CD grade ≥ III), pancreatic fistula (CD grade ≥ III), or anastomotic leakage (CD grade ≥ III).

Results: In total, 210 patients were included. Distal gastrectomy was performed in 186 cases (88.6 %) and total gastrectomy in 24 (11.4 %). No cases required conversion to laparotomy. The incidence of CD grade III intra-abdominal infectious complications was 1.4 % (90 % confidence interval 0.6–3.5), below the pre-defined limit of 7.0 %. The rate of CD grade ≥ III overall complications was 4.3 %, that of CD grade ≥ III pancreatic fistula was 1.0 %, and that of CD grade ≥ III anastomotic leakage was 0.5 %. The polyglycolic acid sheet was not associated with any serious complications or abnormal laboratory values.

Conclusion: Polyglycolic acid sheets were safe and effective in preventing serious intra-abdominal infectious complications after minimally invasive surgery for gastric cancer.

Trial registry number: jRCTs052210188

* Corresponding author. 54 Shogoin-Kawahara-cho, Sakyo-ku, Kyoto 606-8507, Japan.
E-mail address: hisamori@kuhp.kyoto-u.ac.jp (S. Hisamori).

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1. Introduction

Gastric cancer is common in Japan, and surgery is the mainstay of treatment. Surgical procedures for gastric cancer are determined by the location of the cancer and the extent of its growth [1,2]. According to the National Clinical Database, standard procedures for gastric cancer in Japan include distal gastrectomy and total gastrectomy, which were performed in approximately 33,000 and 12,000 cases, respectively, in 2019 [3]. Various complications may occur after surgery, including bleeding and intestinal obstruction. The most serious intra-abdominal infectious complications are anastomotic leakage, pancreatic fistula, and intra-abdominal abscess, which occur in about 6 %–8 % of cases [4,5]. In recent years, minimally invasive surgery (MIS), namely, laparoscopic gastrectomy or robotic-assisted gastrectomy, has become the mainstay of treatment for gastric cancer because it is less invasive and more precise than conventional open surgery [6–8]. However, serious intra-abdominal infectious complications still occur.

The polyglycolic acid sheet (Neoveil™; Gunze Medical, Osaka, Japan) is an absorbable reinforcement material that is used to reinforce soft tissue and prevent air and fluid leak. The processed sheets are elastic and absorbed by the body within about 15 weeks [9]. Since their launch in Japan in 1992, these sheets have been used in various types of surgery, including pancreatic and lung surgery, and their efficacy and safety have been demonstrated [10,11]. They have also been used in gastric cancer surgery to reinforce anastomoses and prevent pancreatic fistula after lymph node dissection and some retrospective studies suggested their usefulness [12,13]; however, there are few clinical trials on their efficacy and safety in gastric cancer surgery [14,15]. We hypothesized that the polyglycolic acid sheet would reduce postoperative infectious complications by preventing anastomotic leakage, pancreatic fistulas, and subsequent intra-abdominal abscesses.

The aim of this study was to determine the efficacy and safety of polyglycolic acid sheets in preventing postoperative intra-abdominal infectious complications in patients undergoing MIS.

2. Patients and methods

2.1. Study design and setting

This was a prospective, multicenter, single-arm clinical trial of the efficacy and safety of polyglycolic acid sheets for prevention of intra-abdominal infectious complications after gastric cancer surgery. Patients who underwent minimally invasive distal or total gastrectomy for gastric cancer at Kyoto University Hospital or its 9 affiliated facilities between March 2022 and December 2023 were included in the study. Before embarking on the study, a joint meeting was held with the facilities participating in the study. Surgical videos of actual cases in which polyglycolic acid sheets were applied were shown to ensure uniformity of technique. Polyglycolic acid sheets 0.15 mm thick and 10 cm × 10 cm in size were cut into 2-cm squares and applied to vulnerable areas, namely, sites of peripancreatic lymph node dissection, duodenal transection, and anastomosis. Polyglycolic acid sheets were only applied to the tissue, and no additional fixation was applied. One polyglycolic acid sheet per surgery was set as the standard usage amount. The product standards and usage amounts can be changed as needed. No surgeon criteria were set, and the surgical teams continued to follow routine practice at each participating institution.

2.2. Eligibility criteria

The inclusion criteria were as follows: pathologically diagnosed gastric neoplasm; MIS planned; distal or total gastrectomy planned; clinical stage I–III disease; age 18–85 years at the time of obtaining written informed consent; and Eastern Cooperative Oncology Group performance status 0 or 1. Patients were eligible regardless of sex. The following exclusion criteria were applied: distant metastasis, invasion of other organs, or spread to the esophagus; neoadjuvant chemotherapy administered; past history of irradiation to the upper abdomen; past history of upper abdominal surgery; combined surgery for other diseases planned (excluding cholecystectomy); severe infectious disease or other comorbidity; severe drug allergy; use of immunosuppressive drugs or steroids; peritoneal dialysis or hemodialysis; concomitant use of antiplatelet or anticoagulant drugs or warfarin; pregnancy or suspected pregnancy; and deemed inappropriate for participation by the researcher. The discontinuation criteria were as follows: withdrawal of consent; study participant found to be ineligible; onset of adverse events that would make it difficult for the subject to continue the study; and subject unsuitable to continue in the opinion of the investigator.

2.3. Ethics statement

The Certified Review Board of Kyoto University approved the study (approval number Y0115), which is registered in jRCT (number jRCTs052210188) [16]. The study was performed in accordance with the Declaration of Helsinki and complied with the Clinical Research Act in Japan. Written informed consent was obtained from all study participants.

2.4. Outcome measures

The primary outcome was the incidence of intra-abdominal infectious complications (Clavien–Dindo [CD] grade ≥ III) [17]. Intra-abdominal infectious complications were defined as anastomotic leakage, pancreatic fistula, and intra-abdominal abscess. Secondary outcomes were the incidence of overall complications (CD grade ≥ III), the incidence of pancreatic fistula (CD grade ≥ III), and incidence of anastomotic leakage (CD grade ≥ III). All patients were checked for the presence or absence of postoperative complications at 30 days after surgery.

2.5. Statistical analysis

The sample size required for this study was estimated based on the one-sample test of proportions with respect to the primary outcome, namely, the rate of infectious complications after surgery for gastric cancer. Based on previous reports, the proportion was set at 7 % for the null hypothesis [4,5]. The estimated proportion when using polyglycolic acid sheets was 3.5 %, which corresponds to a decline by at least half in the incidence of intra-abdominal infectious complications with the polyglycolic acid sheet and is consistent with a clinically meaningful difference according to the literature on gastric cancer and statistical principles. Allowing for a 5 % dropout rate, it was estimated that a total sample size of 210 would be needed for the study to have 70 % power for detection of a treatment difference by a test with a one-sided alpha level of 0.05 using the Wilson's score 90 % CI.

3. Results

3.1. Patient characteristics

Informed consent was obtained preoperatively from 226 eligible patients. After 16 exclusions, 210 patients were included in the study (Fig. 1). The patient characteristics are shown in Table 1. Median age was 72 years (interquartile range [IQR] 65, 77). Eighty patients (38.1 %) were female. The tumor was located in the upper third of the stomach in 12 patients (5.7 %), in the middle third in 101 (48.1 %), and in the lower third in 97 (46.2 %). Pathology examination showed that 114 patients (54.3 %) had differentiated and 94 (44.8 %) had undifferentiated disease. Forty-three patients (20.5 %) were cT3–T4 and 45 (21.4 %) were cN+.

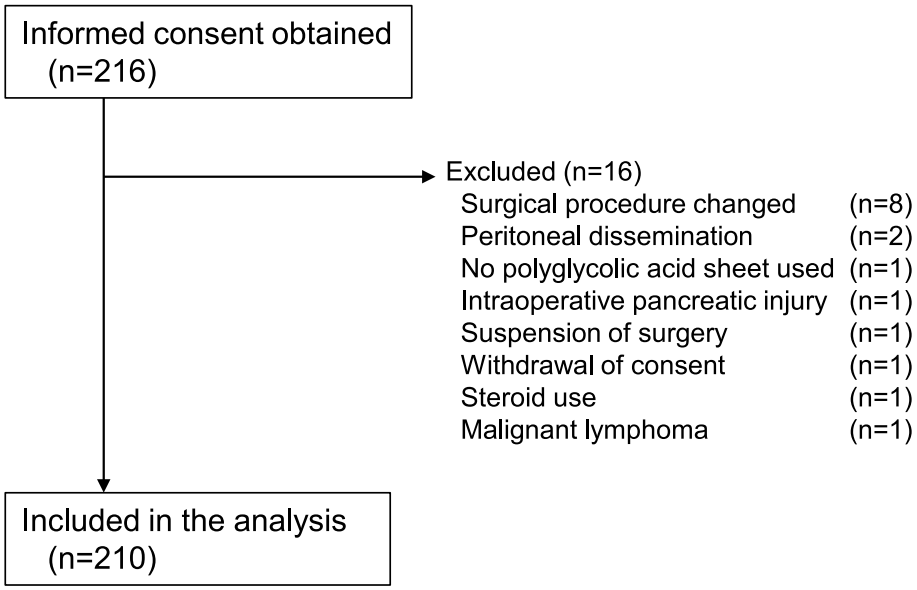

Fig. 1. Flow diagram showing the patient selection procedure.

Table 1
Patient characteristics.

Variables		Category	n	%	Median	IQR
Age (years)					72	65, 77
Sex		Female	80	38.1		
Comorbidity	Hypertension	+	96	45.7		
	Hyperlipidemia	+	55	26.2		
	Diabetes	+	35	16.7		
Past history	Angina pectoris	+	3	1.4		
	Myocardial infarction	+	2	1.0		
	Asthma	+	5	2.4		
	COPD	+	7	3.3		
	Cerebral infarction	+	8	3.8		
	Cerebral bleeding	+	0	0.0		
Body mass index					22.6	20.5, 24.4
ECOG PS		0	173	82.4		
		1	37	17.6		
Tumor located in stomach		Upper third	12	5.7		
		Middle third	101	48.1		
		Lower third	97	46.2		
Pathology findings		wel	59	28.1		
		mod	53	25.2		
		pap	2	1.0		
		por	72	34.3		
		sig	21	10.0		
		muc	1	0.5		
		others	2	1.0		
cT		1	124	59.0		
		2	33	15.7		
		3	36	17.1		
		4a	17	8.1		
cN		0	165	78.6		
		1	35	16.7		
		2	9	4.3		
		3a	1	0.5		

ECOG, Eastern Cooperative Oncology Group; IQR, interquartile range; mod, moderately differentiated adenocarcinoma; muc, mucinous adenocarcinoma; por, poorly differentiated adenocarcinoma; PS, performance status; sig, signet-ring cell carcinoma; wel, well differentiated adenocarcinoma.

3.2. Surgical outcomes

All patients underwent surgery under general anesthesia; epidural anesthesia was additionally used for 30 patients. Median anesthesia time was 371 min (IQR 322, 443), median surgical time was 307 min (IQR 257, 371), and median estimated blood loss was 5 mL (IQR 0, 26). All procedures were performed laparoscopically, and 87 (41.4 %) were robotic-assisted. There were no cases of conversion to laparotomy. Distal gastrectomy was performed in 186 cases (88.6 %) and total gastrectomy in 24 (11.4 %). D1+ lymph node dissection was performed in 107 cases (51.0 %) and D2 lymph node dissection in 103 (49.0 %). Intraoperative organ damage was observed in 2 cases (1.0 %), with 1 in the jejunum and 1 in the transverse colon, but was judged not to affect evaluation of the polyglycolic acid sheet. Reconstruction was performed using the Billroth I method in 94 cases (44.8 %), the Billroth II method in 36 (17.1 %), and the Roux-en-Y method in 80 (38.1 %). Drains were implanted in the abdominal cavity in 143 cases (68.1 %) (Table 2).

Table 2
Surgical outcomes.

Variable	Category	n	%	Median	IQR
Epidural anesthesia	+	30	14.3		
Anesthesia time (min)				371	322, 443
Approach	Laparoscopic	123	58.6		
	Robotic-assisted laparoscopic	87	41.4		
Surgical method	Distal gastrectomy	186	88.6		
	Total gastrectomy	24	11.4		
Lymph node dissection	D1+	107	51.0		
	D2	103	49.0		
Organ injury	+	2	1.0		
Combined surgery	+	13	6.2		
Reconstruction	Billroth I	94	44.8		
	Billroth II	36	17.1		
	Roux-en-Y	80	38.1		
Abdominal drain	+	143	68.1		
Operation time (min)				307	257, 371
Estimated blood loss (mL)				5	0, 26

IQR, interquartile range.

3.3. Postoperative outcomes

Median amylase level in the abdominal drain was 477 U/L (IQR 259, 885) on postoperative day 1. Median time to resumption of food intake was 4 days (IQR 3, 4). Median time to abdominal drain removal was 4 days (IQR 2, 6), and median postoperative hospital stay was 11 days (IQR 9, 13) (Table 3).

3.4. Primary endpoint

There were 10 intra-abdominal infectious complications (grade I, n = 1; grade II, n = 6; grade IIIa, n = 3). The primary endpoint, namely, the incidence of grade ≥ III intra-abdominal infectious complications was 1.4 % (90 % CI 0.6–3.5). The upper limit of the 90 % CI was 3.5 %, which was below the pre-specified 7 %, indicating a significant reduction in grade ≥ III intra-abdominal infectious complications (Table 4).

3.5. Secondary endpoints

Overall complications were grade I in 4 cases, grade II in 12 cases, grade IIIa in 6 cases, and grade IIIb in 3 cases. There were 5 cases of pancreatic fistula (grade I, n = 2; grade II, n = 1; grade IIIa, n = 2) and 2 of anastomotic leakage (grade II, n = 1; grade IIIa, n = 1). There were 9 cases of grade ≥ III overall complications (4.3 %, 90 % CI 2.5–7.2), 2 of pancreatic fistula (1.0 %, 90 % CI 0.3–2.8), and 1 of anastomotic leakage (0.5 %, 90 % CI 0.1–2.1) (Table 4).

3.6. Safety

No patient died within 30 days of surgery, and no postoperative complications caused by polyglycolic acid sheets were observed. There were no serious adverse events or abnormal laboratory values associated with use of these sheets.

4. Discussion

In this study, the incidence of grade ≥ III intra-abdominal infectious complications was 1.4 %, indicating that polyglycolic acid sheets significantly reduce the risk of intra-abdominal infectious complications. Furthermore, there were no serious adverse events or laboratory abnormalities that could be attributed to the polyglycolic acid sheet.

Polyglycolic acid sheets are used in a variety of surgical procedures. They have been reported to be effective in preventing pneumothorax after lung surgery, promoting healing of oral mucosal defects, preventing bleeding and perforation after endoscopic mucosectomy for gastric cancer, reducing post-pancreatectomy hemorrhage, and preventing anastomotic leakage after esophageal, gastric, colon, and rectal cancer surgery [18–31]. In randomized controlled trials, polyglycolic acid mesh significantly reduced the risk of pancreatic fistula in patients undergoing distal pancreatomy (11.4 % vs 28.3 %, P = 0.04) and the amount of drainage in patients undergoing thyroid cancer surgery (60.9 mL vs. 72.3 mL, P = 0.005) [10,32].

Polyglycolic acid sheets are also used in gastric cancer surgery to reinforce anastomoses and prevent pancreatic fistula. Although we have determined its efficacy and safety empirically, there are few other relevant reports. An observational study by Hiura et al. found that polyglycolic acid sheets significantly reduced the risk of pancreatic fistula after gastrectomy (0 % vs. 4.7 %, P = 0.049) [14]. The only clinical trial reporting the efficacy or safety of polyglycolic acid sheets for gastric cancer surgery is that of Misawa et al. who reported that the sheets reduced suture failure in duodenal transection [15].

Serious postoperative complications after gastric cancer surgery include anastomotic leakage, pancreatic fistula, and intra-abdominal abscess, which are often difficult to distinguish and may coexist; therefore, for the purposes of this study, we defined them as intra-abdominal infectious complications. The incidence of these complications was low at 1.4 %, and no serious adverse events or abnormal laboratory values related to the polyglycolic acid sheet were observed, confirming the efficacy and safety of the polyglycolic acid sheet in gastric cancer surgery.

The strength of this study lies in the fact that it was conducted at multiple institutions where the quality of surgical procedures was assured. Surgical videos of actual cases in which polyglycolic acid sheets were applied were shown in regular consensus meetings to ensure uniformity of technique. No surgeon-related criteria were set, and the surgical teams adhered to the routine practices in place at each participating institution. These allowed us to accurately assess the efficacy and safety of the polyglycolic acid sheet and to enhance the external validity of the study. Furthermore, the study was in line with current practice in gastric cancer surgery, which targets MIS.

Table 3
Postoperative outcomes.

Variable	Median	IQR
Amylase level in abdominal drain (U/L)	477	259, 885
Resumption of food intake (POD)	4	3, 4
Abdominal drain removal (POD)	4	2, 6
Length of hospital stay (days)	11	9, 13

IQR, interquartile range; POD, postoperative day.

Table 4
Postoperative complications.

	Grade	n	%
Overall complications[a]	I	4	1.9
	II	12	5.7
	IIIa	6	2.9
	IIIb	3	1.4
Intra-abdominal infectious complicationsmlt	I	1	0.5
	II	6	2.9
	IIIa	3	1.4
Pancreatic fistula	I	2	1.0
	II	1	0.5
	IIIa	2	1.0
Anastomotic leakage	II	1[b]	0.5
	IIIa	1	0.5
Abdominal abscess	II	4	1.9
	IIIa	1	0.5
Other complications[a]	I	4	1.9
	II	7	3.3
	IIIa	4	1.9
	IIIb	3	1.4
Delayed gastric excretion	I	2	1.0
	II	4	1.9
	IIIa	1	0.5
Intra-abdominal bleeding	IIIb	2	1.0
Wound infection	I	1	0.5
	IIIa	1	0.5
Gastrointestinal bleeding	IIIa	1	0.5
Anastomotic bleeding	IIIa	1	0.5
Afferent loop syndrome	IIIb	1	0.5
Common bile duct stones/cholangitis	IIIb	1[b]	0.5
Cholecystitis	II	1	0.5
Constipation	I	1[b]	0.5
Abdominal drain infection	II	1	0.5
Catheter-related blood stream infection	II	1	0.5
Wound dehiscence	IIIa	1	0.5
Cellulitis	II	1	0.5
Aspiration pneumonia	II	1	0.5
Pneumothorax	IIIa	1	0.5
COVID-19 infection	II	1	0.5
Pulmonary embolism	II	1	0.5
Fever	I	1	0.5

Complications were reported as the number of cases in which they occurred.
[a] Includes cases with multiple complications.
[b] Complications after discharge.

However, this study also had some limitations. First, 11.0 % of the patients underwent total gastrectomy, which is less than 14.4–32.5 % of those in previous studies used to calculate the number of cases in this study [4,5]. However, the previous studies included D1 lymph node dissection [4] and restricted clinical stage I/II [5]. Second. Although we actively perform proximal gastrectomy for early-stage cancer of the upper gastric region, we did not include patients undergoing proximal gastrectomy in this study because applying a polyglycolic acid sheet to the back of the reconstructed intestine after this type of surgery is difficult and the risk of pancreatic fistula is lower than in other types of surgeries because the No. 6 lymph node is not dissected. Third, the study had a single-arm design. Therefore, randomized controlled trials are needed to validate the efficacy of polyglycolic acid sheets.

5. Conclusion

Polyglycolic acid sheets are safe to use and effective in preventing serious intra-abdominal infectious complications in patients undergoing MIS for gastric cancer.

CRediT authorship contribution statement

Nobuaki Hoshino: Writing – original draft, Formal analysis, Data curation, Conceptualization. **Shigeo Hisamori:** Writing – review & editing, Data curation, Conceptualization. **Seiichiro Kanaya:** Writing – review & editing, Supervision. **Hisahiro Hosogi:** Writing – review & editing, Data curation. **Dai Manaka:** Writing – review & editing, Data curation. **Yosuke Kinjo:** Writing – review & editing, Data curation. **Koichi Matsuo:** Writing – review & editing, Data curation. **Masazumi Sakaguchi:** Writing – review & editing, Data curation. **Masato Kondo:** Writing – review & editing, Data curation. **Yasutaka Nakanishi:** Writing – review & editing, Data curation. **Michihiro Yamamoto:** Writing – review & editing, Data curation. **Eiji Tanaka:** Writing – review & editing, Data curation. **Kosuke Toda:** Writing – review & editing, Data curation. **Hiroyasu Abe:** Writing – review & editing, Formal analysis. **Tatsuto Nishigori:** Writing – review & editing, Supervision. **Shigeru Tsunoda:** Writing – review & editing, Data curation. **Kazutaka Obama:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization.

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