



Endoscopic plombage with polyglycolic acid sheets and fibrin glue for gastrointestinal fistulas

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Abstract

Background and study aims Gastrointestinal (GI) fistulas arise as adverse events of GI surgery and endoscopic treatment as well as secondary to underlying diseases, such as ulceration and pancreatitis. Until a decade ago, they were mainly treated surgically or conservatively. Bioabsorbable polyglycolic acid (PGA) sheets and fibrin glue, which are commonly used in surgical procedures, have also recently been used in endoscopic procedures for the closure of GI defects. However, there have only been few case reports about successful experiences with this approach. There have not been any case-series studies investigating the strengths and weaknesses of such PGA sheet-based treatment. In this study, we evaluated the clinical effectiveness of using PGA sheets to close GI fistulas.

Patients and methods Cases in which patients underwent endoscopic filling with PGA sheets and fibrin glue for GI fistulas at Kobe University Hospital between January 2013 and April 2018 were retrospectively reviewed.

Results A total of 10 cases were enrolled. They included fistulas due to leakage after GI surgery, aorto-esophageal/broncho-esophageal fistulas caused by chemoradiotherapy, or severe acute pancreatitis. The fistulas were successfully closed in 7 cases (70%). The unsuccessful cases involved a fistula due to leakage after surgical esophagectomy and broncho-esophageal fistulas due to chemoradiotherapy or severe acute pancreatitis. Unsuccessful treatment was related to fistula epithelization.

Conclusion Endoscopic plombage with PGA sheets and fibrin glue could be a promising therapeutic option for GI fistulas.

Keywords Fistula · Polyglycolic acid sheet · Fibrin glue

Gastrointestinal (GI) fistulas can be caused by anastomotic leakage after GI surgery or endoscopic treatment for GI tumors or can arise spontaneously due to underlying disease, such as ulceration, pancreatitis, or inflammatory bowel disease. Although some GI fistulas can potentially be managed conservatively, others can cause serious conditions and become life-threatening [1–3]. Until a decade ago, the main treatment for such conditions used to be surgery or

conservative management, including diet restriction, antibiotic therapy, or percutaneous catheter-based drainage [4–6]. However, surgery is associated with morbidity and mortality [7], and conservative management sometimes takes a long time to achieve recovery or requires frequent re-intervention.

Although GI defects are usually closed using conventional metal endoclips, some cannot be completely closed because of their size, edematous and/or fibrotic changes around edges of the defect, or poor endoscopic maneuverability.

On the other hand, several studies have suggested that endoscopic treatment, such as with the over-the-scope-clipping (OTSC; Ovesco Endoscopy AG, Tubingen, Germany) system [8–13] or covered stents [14–17], is effective at sealing GI defects. OTSC-based closure is a more reliable technique for completely closing relatively large mucosal defects than closure using conventional clips. However, the probability of achieving successful closure using OTSC is reported to decrease in cases involving fistulas with inflammatory, necrotic, or fibrotic margins, or excessively large

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perforations [8, 13]. On the other hand, stents are associated with high rates of adverse events, such as tissue in- or overgrowth, stent migration, stent cover rupturing, and severe pain [18].

As an alternative, bioabsorbable polyglycolic acid (PGA) sheets (Neoveil; Gunze Co., Kyoto, Japan), which are commonly used in surgical procedures [6, 19–24], have also recently been used to close intraoperative and delayed perforations, fistulas, and prevent postoperative bleeding, delayed perforation, and post-ESD stricture in endoscopic procedures [25–35]. However, with regard to endoscopic plombage with PGA sheets and fibrin glue for GI fistulas, the previous reports about this technique were case reports about successful procedures [34, 35], and there have been no case-series studies that included cases in which the procedure was unsuccessful. Therefore, we reviewed our consecutive experiences of this technique for fistulas and investigated its usefulness.

Patients and methods

Patients

We retrospectively reviewed the cases of all patients who underwent endoscopic filling with PGA sheets and fibrin glue for GI fistulas at Kobe University Hospital between January 2013 and April 2018. In such cases, endoscopic filling with PGA sheets and fibrin glue was used as a primary treatment for GI fistulas or if a previous treatment had failed to achieve sufficient closure.

In cases of postoperative anastomotic insufficiency, the surgeons at our hospital first wait for spontaneous closure to occur, but if this seems unlikely they refer the patient for endoscopic treatment.

Endoscopic filling with polyglycolic acid sheets and fibrin glue for gastrointestinal fistulas

Endoscopic plombage with PGA sheets and fibrin glue was carried out under midazolam-based sedation. An endoscopic overtube was usually used to keep the PGA sheets from being exposed to saliva in order to achieve better attachment [36] and facilitate smooth repeated insertions of the endoscope. The PGA sheets were used in the following manner: They were cut into approximately 10×10 mm or larger pieces, held with biopsy forceps, and transported to the fistula site over the scope or through the channel of the scope. Then, they were stuffed into the fistula using closed biopsy forceps. If the fistula was large, PGA sheets were pasted onto the wall of the fistula. After the target site had been sufficiently covered with several sheets, solution A (fibrinogen) (Beriplast® P Combi-Set; CSL Behring K.K., Japan) was

applied to the sheet using a spray tube, and this was followed by the spraying of solution B (thrombin) using another spray tube. In some cases, the fistula wall was subjected to argon plasma coagulation (APC) or coagulation with diathermic dilator because it was reported that significantly lower adhesive strength was observed when PGA sheets were attached to the mucosal epithelium.

The success of the procedure was assessed based on endoscopic confirmation and/or the absence of radiographic evidence of contrast medium leakage through a fistula.

Ethics

The study protocol was approved by the ethics committee at Kobe University Hospital (no.180047).

Results

A total of 10 patients underwent endoscopic filling with PGA sheets and fibrin glue for GI fistulas. The characteristics of the patients and their fistulas are shown in Table 1. All of the patients were male.

Their ages ranged from 57 to 74 years (median age: 66.5 years). The patients' median performance status and their median serum albumin level at the time of the endoscopic plombage were 1.5 (range from 0 to 4) and 3.1 g/dl (range from 1.7 to 3.9 g/dl), respectively.

The affected organs were the esophagus in 7 cases and the stomach in 3 cases. The esophageal cases consisted of 3 cases involving fistulas due to suture failure after surgical esophagectomy, one case involving an aorto-esophageal fistula that arose after chemoradiotherapy for esophageal cancer, two cases involving bronchoesophageal fistulas that developed after chemoradiotherapy for lung cancer and severe acute pancreatitis, respectively, and one case involving an esophagocutaneous fistula due to APC for esophageal cancer. The gastric cases included a case involving a fistula caused by anastomotic leakage after additional total gastrectomy, which was performed after a perforation occurred during ESD for gastric cancer in a Billroth II anastomosis, and two cases involving gastrocutaneous fistula due to failure of wound closure after removal of a long-term percutaneous endoscopic gastrostomy tube.

The median size of the fistulas was 4 mm (range 2–10 mm). All the cases did not show any signs of infection.

Plombage using PGA sheets and fibrin glue was conducted as a primary treatment in 9 cases and as rescue therapy in the case involving a bronchoesophageal fistula caused by severe acute pancreatitis, in which treatment was initially attempted with the Twin Grasper type of OTSC, but failed.

Table 1 Characteristics of the patients who underwent endoscopic filling with PGA sheets and fibrin glue for GI fistulas and their fistulas

No.	Age	Sex	PS	Alb (g/dl)	Underlying disease	Type of fistula	Width of the hole (mm)	Infection of the hole
Successful cases								
1	60	M	1	3.4	Anastomotic leakage after esophageal cancer surgery	Esophagomediastinal	3	No
2	69	M	1	3.3	Chemoradiotherapy for esophageal cancer	Aortoesophageal	2	No
3	65	M	1	3.9	Incomplete closure after removal of a long-term gastrostomy tube	Gastrocutaneous	3	No
4	68	M	2	3.1	APC for superficial esophageal cancer at an anastomotic site	Esophagocutaneous	9	No
5	68	M	3	2.6	Anastomotic leakage after esophageal cancer surgery	Esophagomediastinal	7	No
6	74	M	2	3.1	Anastomotic leakage after additional total gastrectomy due to perforation occurring during ESD for gastric cancer in a Billroth II anastomosis	Anastomotic-intraabdominal	5	No
7	64	M	0	3.9	Incomplete closure after removal of a long-term gastrostomy tube	Gastrocutaneous	3	No
Unsuccessful cases								
8	57	M	4	1.7	Chemoradiotherapy for lung cancer	Bronchoesophageal	10	Unknown
9	74	M	3	2.0	Anastomotic leakage after subtotal esophagectomy	Esophagomediastinal	10	Unknown
10	63	M	0	3.0	Acute pancreatitis	Bronchoesophageal	3	No

PS performance status, Alb serum albumin level, ESD endoscopic submucosal dissection, APC argon plasma coagulation

The median duration of the period from the detection of the hole to the first treatment was 38 days (range 0–98 days) (Table 2).

The PGA sheets were cut into 7–30 mm pieces, and 1–3 pieces were used in each plombage procedure, together with 3–5 ml of fibrin glue. APC or coagulation with a diathermic dilator on the fistula mucosa before applying PGA sheet were performed in 3 cases involving bronchoesophageal fistula (due to severe acute pancreatitis) and gastrocutaneous fistulas after removal of a long-term gastrostomy tube.

Other concurrent treatments were employed in 6 cases, i.e., percutaneous catheter-based drainage was conducted in 4 cases involving fistulas caused by suture failure after esophagectomy or gastrectomy, thoracic endovascular aortic repair was carried out in a case involving an aortoesophageal fistula that arose after chemoradiotherapy, and clipping was applied in a case involving incomplete closure of a gastrostomy.

During the procedure, it was confirmed that the fistula had been appropriately filled with PGA sheets in each case, except the case (case 8) in which a bronchoesophageal fistula arose after chemoradiotherapy for lung cancer, in which the PGA sheets fell deep into the fistula, and the defect could not be filled.

If closure was not promoted after the first PGA sheet-based procedure, then the procedure was repeated.

As a result, successful fistula closure was achieved in 7 of 10 (70%) cases. Representative endoscopic and radiographic images of the successful and unsuccessful cases are shown in Figs. 1 and 2, respectively. The PGA plombage procedure for a fistula is also shown being performed in Video 1. The median number of occlusive procedures performed until closure was achieved was 2, ranging from 1 to 4, and the median duration of the period from the first endoscopic plombage procedure to the point at which it was confirmed that the defect had closed was 36 days (range 7–127 days). During the observation period (median duration: 31 months; range 0–60 months), no re-opening of the fistula was seen in any case.

The cases in which the fistula did not close included one involving a fistula caused by anastomotic insufficiency after surgical esophagectomy (case 9) and two in which bronchoesophageal fistulas arose after chemoradiotherapy for lung cancer and severe acute pancreatitis, respectively (cases 8 and 10).

In case 9, a 10-cm-long portion of the fistula had been epithelized, and the PGA sheets had fallen deep into the fistula at the second look after the first plombage. A covered stent was inserted as a rescue therapy and was removed 1 month later (when it was confirmed that the fistula remained although it had become smaller).

Table 2 Details of endoscopic filling with PGA sheets and fibrin glue for GI fistulas and their outcomes

No.	PGA sheets used	APC or coagulation with a diathermic dilator of the fistula mucosa before applying PGA sheets	Amount of fibrin glue used (ml)	Concurrent occlusive treatment	Drainage	Number of PGA sheets application required for successful hole closure	Time from hole detection to the 1st occlusive procedure (days)	Time from the 1st endoscopic plom-bage procedure to hole closure (days)
Successful cases								
1	1 × 1-cm squares	No	5	None	Yes	3	61	42
2	1.5 × 1.5-cm squares × 3	No	3	Thoracic endo-vascular aortic repair	None	1	24	7
3	Unknown	Yes	3	Clipping	None	2	41	127
4	Unknown	No	3	None	None	1	0	7
5	3 × 3 cm, 3 × 1.5 cm, 1.5 × 1.5 cm	No	3	None	Yes	1	35	8
6	1 × 1-cm squares × 2	No	5	None	Yes	4	56	36
7	1.5 × 0.7-cm squares × 2	Yes	3	None	None	2	98	42
Unsuccessful cases								
8	Unknown	No	3	None	None	1	0	—
9	4 × 3 cm, 2 × 2 cm	No	3	None	Yes	1	3	—
10	1 × 1-cm squares × 1	Yes	3	None	None	8	56	—

PGA polyglycolic acid, APC argon plasma coagulation

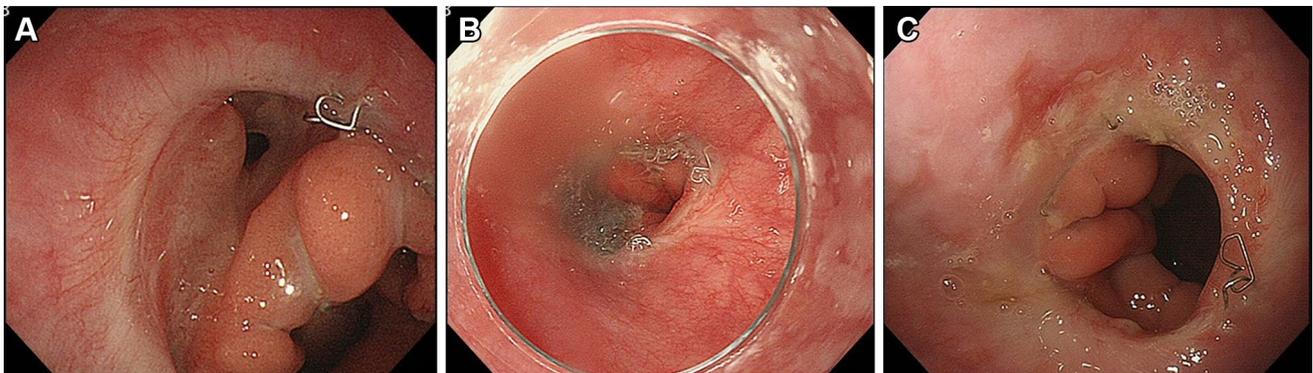


Fig. 1 **A** A fistula was detected at an anastomotic site at 3 weeks after surgical esophagectomy. **B** The fistula was filled with PGA sheets 2 months later because it was decided that spontaneous closure was unlikely. The procedure was repeated three times. **C** The endoscopic

view at 77 days after the first PGA sheet-based plom-bage procedure is shown. The fistula had closed completely and some scar formation was seen

In case 8, the PGA sheet fell deep into the fistula during the procedure, and so filling could not be achieved.

In case 10, the primary OTSC-based treatment failed, and PGA sheet-based plom-bage was performed as a rescue

therapy. The duration of the period from the identifica-tion of the hole to the PGA sheet-based filling procedure was 56 days. After it was determined that the procedure had failed, treatment with anchor-type OTSC, which was

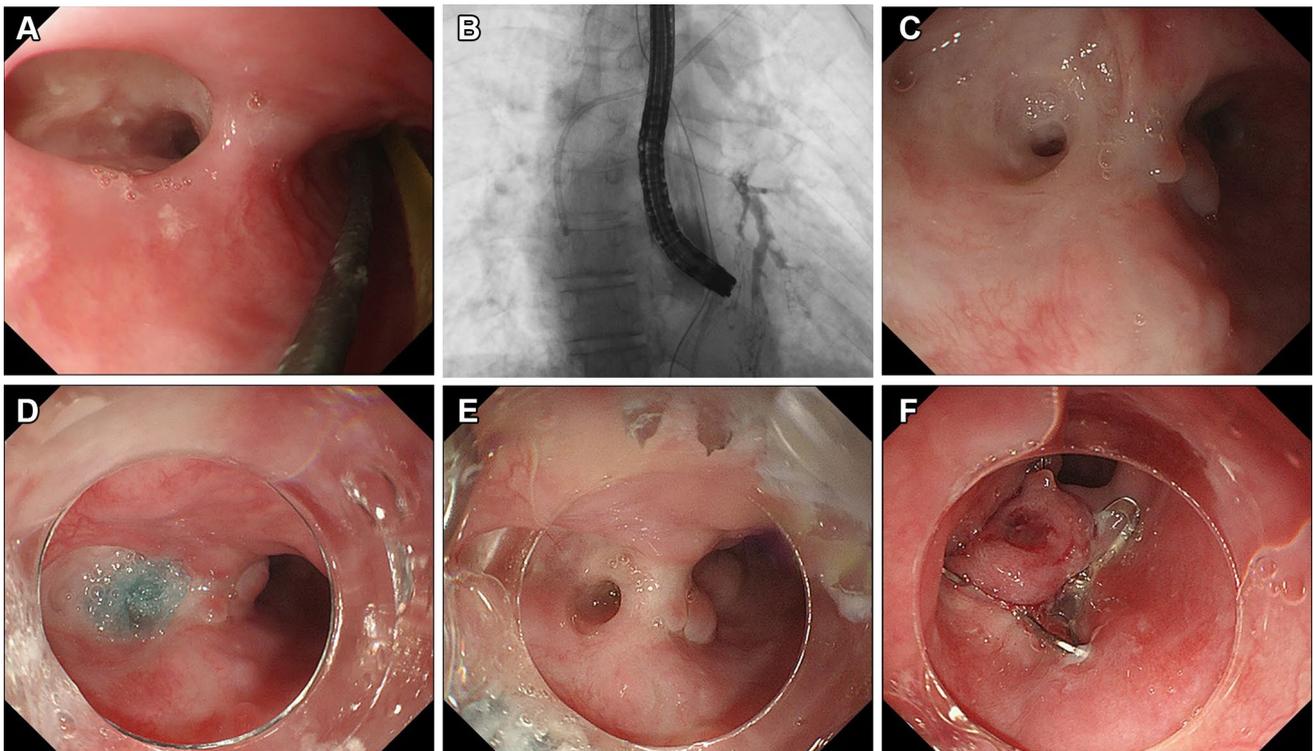


Fig. 2 **A** A bronchoesophageal fistula caused by severe acute pancreatitis is shown. **B** Esophageal radiography showed contrast medium leakage into the left bronchi. **C** OTSC attachment was performed as a primary therapy. However, the fistula remained, although it reduced in size. **D** The fistula was filled with PGA sheets as a secondary

treatment. **E** Although the PGA sheet-based plombage procedure was repeated 6 times and APC was conducted concurrently, the fistula remained patent. **F** OTSC was used again, and the fistula finally closed

a different type from that used in the primary procedure, was tried, and complete closure of the fistula was achieved.

The median performance status and serum albumin level of the unsuccessful cases were 3 (range 0–4) and 2.0 g/dl (range 1.7–3.0 g/dl), respectively, while it was 1 (range 0–3) and 3.3 g/dl (range 2.6–3.9 g/dl), respectively, in the successful cases. A declining tendency for both parameters was seen in the failed group.

Discussion

In the present study, the efficacy of using PGA sheets to close GI fistulas was evaluated by reviewing our experience of such cases, and this approach was confirmed to have succeeded at achieving closure in 7 out of 10 (70%) cases.

The unsuccessful cases included a case involving fistula epithelization and another case involving a patient that had undergone chemoradiotherapy.

First of all, GI defects can be managed conservatively. Actually, cases involving anastomotic insufficiency after surgery are often initially treated with antibiotics and the insertion of percutaneous drainage catheters without surgical

or endoscopic interventions, and improvements are seen in the majority of cases. Therefore, only those in which it seems difficult to achieve spontaneous closure are referred for endoscopic treatment in our department.

The human body has the natural ability to heal GI defects such as fistulas and perforations; however, cases in which such healing is unsuccessful often involve factors that inhibit the spontaneous closure of fistulas/perforations. These factors include the continuous flow of digestive fluid, such as saliva, gastric acid, pancreatic juice, or bile, and coexisting infections.

Therefore, eliminating these inhibitory factors is considered to be essential when attempting to close GI defects. There are two main methods for inhibiting the flow of digestive fluid; one is minimizing the flow of the liquid using a stent or drainage catheter, which does not necessarily require closure of the defect, and the other is closing the defect itself.

Drainage catheters are frequently used to treat gall bladder or pancreatic fistulas, which helps to avoid invasive reoperations. However, draining the esophagus is often ineffective because the GI tract has a larger diameter than the biliary and pancreatic ducts. On top of that, stenting carries a

risk of stent migration when no stricture is present. Patients can also suffer from chest pain after the placement of metallic stents in the esophagus. On the other hand, clip-based closure, OTSC-based closure, or endoscopic plombage with PGA sheets and fibrin glue can be used to close GI defects.

In comparison with other types of endoscopic closure, such as clipping, and OTSC-based procedures, PGA sheet-based defect filling with fibrin glue has strengths in that it can be applied to any section of the GI tract, providing an endoscopic procedure is feasible and there is space for PGA sheets to be inserted in a manner that will prevent them from becoming dislodged. Furthermore, it can be applied even when the tissue surrounding the fistula is edematous or fibrotic, which makes OTSC placement difficult.

In two of our unsuccessful cases (cases 9 and 10), the continuous flow of digestive fluid was considered to have disturbed the regeneration of the affected tissue due to the insecure attachment of the PGA sheets within the fistulas. In case 10, in which the period from the hole formation to the PGA sheet-based plombage procedure was relatively long, the fistula had probably completely epithelialized, and epithelialization can lead to the insecure attachment of PGA sheets to fistulas and result in the insufficient fistula closure [36].

Furthermore, in the remaining unsuccessful case (case 8), which involved a bronchoesophageal fistula that arose after chemoradiotherapy for lung cancer, the fistula could not be completely filled with PGA sheets, unlike in the other unsuccessful cases, in which it seemed that the defects had been completely filled at the first attempt, but follow-up endoscopy showed that some of the PGA sheets were no longer fixed in place. The problem in this case might have been due to technical failure, complete fistula epithelialization, and/or the patient's post-chemoradiotherapy condition. In the second scenario, APC or coagulation with a diathermic dilator might have helped to remove the fistula epithelium and allowed the PGA sheets to be attached more securely.

When GI fistulas cannot be closed using clipping, OTSC, or a combination of PGA sheets and fibrin glue, another therapeutic option is needed. Endoscopic full-thickness suturing is currently under development, and it is expected to be a useful endoscopic alternative.

The limitations of the present study include its retrospective design and its small population, which was derived from a single institution. In addition, there was heterogeneity among the examined fistulas, patients, and the endoscopists' overall experience. Furthermore, endoscopists with adequate knowledge, skills, and experience of PGA sheet-based plombage are needed, and at present the cost of using PGA sheets and fibrin glue to treat GI fistulas is not covered by the Japanese national medical insurance system. Selection bias might also exist because cases involving post-operative leakage or fistula formation were referred to our department by the treating surgeons if spontaneous closure

was not expected after the patient had been observed for a while. However, this would support the effectiveness of PGA sheet-based plombage because it would mean that this study mainly included intractable cases. Further studies involving more cases should be performed to determine the optimal PGA sheet size; the best methods for filling fistulas, applying fibrin glue, and removing epithelialized tissue; and other appropriate countermeasures in the near future.

Conclusion

In conclusion, endoscopic plombage with PGA sheets and fibrin glue could be a promising alternative method for GI fistulas.

Compliance with ethical standards

Disclosures Dr. Nakano, Dr. Takao, Dr. Morita, Dr. Sakaguchi, Dr. Tanaka, Dr. Ishida, Dr. Toyonaga, Dr. Umegaki, and Dr. Kodama have no conflicts of interest to disclose.

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