

Polyglycolic acid sheets and fibrin glue decrease the risk of bleeding after endoscopic submucosal dissection of gastric neoplasms (with video)

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Background: The prevention of bleeding after endoscopic submucosal dissection (ESD) for gastric neoplasms is still an important problem.

Objective: To investigate the efficacy and safety of a shielding method that uses polyglycolic acid (PGA) sheets and fibrin glue to prevent post-ESD bleeding in high-risk patients.

Design: A nonrandomized trial with historical control subjects.

Setting: A single academic hospital in Japan.

Patients: From July 2013 to February 2014, 45 ESD-induced ulcers in 41 patients with a high risk of bleeding were enrolled in a study group. Forty-one consecutive ESD-induced ulcers in 37 control subjects with a high risk of bleeding were treated in 2013 before the first enrollment.

Interventions: We placed PGA sheets on the mucosal defect and fixed with fibrin glue in the study group.

Main Outcome Measurements: The post-ESD bleeding rate.

Results: The post-ESD bleeding occurred at a rate of 6.7% in the study group (3/45 lesions) and 22.0% in the historical control group (9/41 lesions). There was a significant difference in the post-ESD bleeding rate between the 2 groups ($P = .041$).

Limitations: A nonrandomized trial with historical control subjects; a single-center analysis; small sample size.

Conclusions: The endoscopic tissue shielding method with PGA sheets and fibrin glue appears to be promising for the prevention of post-ESD bleeding. (Clinical trial registration number: UMIN000011058.) (Gastrointest Endosc 2015;81:906-12.)

(footnotes appear on last page of article)

Endoscopic submucosal dissection (ESD) has been accepted as an excellent treatment for gastric neoplasms because a large tumor or lesion with an ulcer scar can be successfully resected in an en bloc fashion.¹⁻⁴ ESD is minimally invasive and can be applied to elderly patients.⁵ Moreover, ESD is reported to be safe and effective,

even for early gastric cancer in the altered anatomy, such as a remnant stomach or gastric tube, and locally recurrent early gastric cancer after endoscopic resection.⁶⁻⁸ According to guidelines from the Japanese Gastric Cancer Association,⁹ absolute guideline criteria for tumors indicated for ESD are differentiated-type mucosal adenocarcinoma ≤ 2 cm without ulcerative findings. The indication criteria for endoscopic resection have been expanded based on the large case series treated by gastrectomy with lymph node dissection,¹⁰ and there have been some reports about the validity of the expanded criteria.^{1,11,12} The tumors categorized into expanded criteria were as follows: a differentiated-type mucosal adenocarcinoma > 2 cm without ulcerative



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findings, a differentiated-type mucosal adenocarcinoma \leq 3 cm with ulcerative findings, and undifferentiated-type mucosal adenocarcinoma \leq 2 cm without ulcerative findings.⁹

Although ESD has its advantages, it has a substantial risk of adverse events, such as post-ESD bleeding or perforation.^{2,3} In particular, post-ESD bleeding may lead to serious conditions, including massive bleeding and life-threatening hemorrhagic shock. Therefore, preventing post-ESD bleeding is desirable.^{13,14} To date, proton pump inhibitors or histamine-2 receptor antagonists have been used to prevent post-ESD bleeding.^{4,15-17} Moreover, Takizawa et al¹⁴ reported that preventive coagulation of visible vessels in the resection area after ESD might lead to a lower bleeding rate. However, previous studies revealed the rate of post-ESD bleeding is still approximately 5%, even with such preventive methods.^{12,13,18-20} Several reports revealed that antithrombotic drug usage and a large resection size (\geq 40 mm) may be independent risk factors for post-ESD bleeding, but there is still a question regarding how to overcome post-ESD bleeding in high-risk patients.^{13,18,20-23}

More recently, Takimoto et al²⁴ reported a novel endoscopic tissue shielding method that uses polyglycolic acid (PGA) sheets (Neoveil; Gunze Co, Kyoto, Japan) and fibrin glue (Beriplast P Combi-Set; CSL Behring Pharma, Tokyo, Japan). PGA is an absorbent suture reinforcement material, and PGA sheets have been applied to video-assisted major lung resection, partial glossectomy, pancreaticoduodenectomy, and gastrectomy.²⁵⁻²⁸ As for the field of endoscopy, this method may be effective for the prevention of adverse events after colorectal ESD, such as bleeding or perforation.²⁹ However, to our knowledge, there are no reports regarding the application of this technique for the prevention of bleeding after gastric ESD. Therefore, we prospectively enrolled patients with PGA sheets as a study group and evaluated the efficacy and safety of this novel method with the purpose of preventing post-ESD bleeding in high-risk patients, comparing the results with the historical control group of those without PGA sheets.

METHODS

This nonrandomized trial with historical control subjects was undertaken at the University of Tokyo Hospital, Tokyo, Japan. The study protocol was approved by the research ethics committee of the University of Tokyo on June 24, 2013 and was registered in the University Hospital Medical Network Clinical Trial Registry (UMIN-CTR) on July 1, 2013 (UMIN000011058). The first study patient was enrolled after the study registration, and all study patients gave written informed consent for the intervention and for gastric ESD.

Patients

Written informed consent for gastric ESD was obtained from all patients before performing ESD regardless of enrollment for clinical studies. The target lesions had to be within the expanded indication criteria of gastric ESD, and CT had to reveal no lymph node or other organ metastasis.

We defined high-risk patients for post-ESD bleeding as follows: those who took antithrombotic drugs regularly, or those who were expected to undergo large mucosal resection (\geq 40 mm). Aspirin, ticlopidine, clopidogrel, cilostazol, ethyl icosapentate, warfarin, and dabigatran were defined as antithrombotic drugs. The cessation and resumption of antithrombotic drugs were carried out according to the newest guideline by the Japan Gastroenterological Endoscopy Society.³⁰

Study group

We enrolled patients who were scheduled to undergo gastric ESD and had an above-mentioned high risk for post-ESD bleeding. Because the latter criterion could not be obtained preoperatively, we enrolled patients with a tumor \geq 20 mm in preoperative size or with an ulcer scar inside or close to a tumor, where the resection size would exceed 40 mm. The exclusion criteria were contraindications of PGA sheets or fibrin glue as follows: (1) those who have systemic adverse events (as to PGA sheets); (2) those who have a history of anaphylaxis to components of fibrin glue or drugs made of bovine lung, such as aprotinin; and (3) those who were treated with procoagulants (hemocoagulase made from snake venom), antifibrotic agents, and aprotinin (as to fibrin glue).

Historical control group

Between January and July 2013 before the first enrollment of a study patient, 126 gastric neoplasms in 101 consecutive patients were treated with ESD. Among them, 44 lesions in 37 patients were extracted as a high-risk group, fulfilling the definition of high-risk patients for post-ESD bleeding. In 2 patients, 2 or 3 adjacent neoplasms were resected as 1 piece to yield 1 ulcer, so 41 ESD-induced ulcers were finally enrolled as control subjects.

ESD procedure

ESD was performed with the patient under intravenous sedation with diazepam and pentazocine using a video endoscope (GIF-Q260J; Olympus Medical, Tokyo, Japan) and an electrosurgical unit (VIO 300D; Erbe, Tübingen, Germany). The ESD procedure was performed as follows. First, circumferential markings were made by a dual knife (KD-650L; Olympus Medical). After submucosal injection using a mixture of .4% sodium hyaluronic acid solution (Mucoup; Johnson and Johnson K.K., Tokyo, Japan) and normal saline solution, a mucosal incision and submucosal

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