

Original Article

Clinical Outcomes of Endoscopic Hemostasis in Marginal Ulcer Bleeding

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The usefulness of endoscopy in marginal ulcer bleeding has rarely been studied, and the optimal method for preventing rebleeding is unclear. Here we assessed the efficacy of endoscopy in marginal ulcer bleeding and examined the efficacy of proton pump inhibitors (PPIs) in the prevention of rebleeding. A total of 28 patients with marginal ulcer bleeding (21 men, 7 women; median age 58.5 years) were treated by endoscopy. We analyzed the clinical characteristics, results of endoscopic therapy, characteristics of rebleeding patients, and relation between the use of PPIs and the duration of rebleeding. Sixteen patients had active bleeding. Initial hemostasis was achieved in all patients. There were no procedure-related adverse events. Rebleeding occurred in one patient within the first month and in 7 patients thereafter. There was a significant difference in the rebleeding rate between the patients who received a PPI and those who did not. In a multivariate analysis, the non-use of PPIs was a risk factor for rebleeding (hazard ratio, 6.22). Therapeutic endoscopy is effective in achieving hemostasis from marginal ulcer bleeding. PPIs may prevent rebleeding from marginal ulcers.

Key words: marginal ulcer, upper gastrointestinal bleeding, endoscopic hemostasis, proton-pump inhibitor

A marginal ulcer is defined as an ulcer at or around a gastrointestinal anastomosis following partial gastric resection, pancreaticoduodenectomy (PD), pylorus-preserving pancreaticoduodenectomy (PPPD) or Roux-en-Y gastric bypass (RYGB). The incidence of marginal ulcer following these procedures has been reported as 1-16% [1-5]. A marginal ulcer typically presents on the jejunal side of the anastomosis, due to several factors such as gastric acid and local ischemia. Upper gastrointestinal bleeding is a major clinical complication of marginal ulcers, and this bleeding is considered to be more severe than that of

a peptic ulcer bleeding from a non-operative stomach [6,7].

Although there have been great advances in endoscopic therapy and medication, marginal ulcer bleeding is still a common medical condition that results in a high rate of morbidity [8,9]. The efficacy of therapeutic endoscopy in active marginal ulcer bleeding has rarely been studied [9,10]. In addition, although proton pump inhibitors (PPIs) are effective in treating gastroduodenal ulcers [11-13], the role of PPIs in the prevention of rebleeding from marginal ulcers is unclear. The aim of this study was to assess the safety and efficacy of therapeutic endoscopy in the treatment

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of patients with active or recent marginal ulcer bleeding. We also examined the efficacy of PPIs in the prevention of rebleeding from marginal ulcers.

Materials and Methods

Patients and methods. Between January 2000 and July 2012, a total of 87 patients with marginal ulcers underwent upper gastrointestinal endoscopy at Okayama University Hospital and Tsuyama Chuo Hospital. Among those, 54 patients were excluded from this study because they had non-bleeding marginal ulcers. Of the remaining 33 patients, 5 were excluded because they were treated by conservative therapy. A total of 28 patients with active or recent marginal ulcer bleeding treated by endoscopic therapy were thus enrolled in this study (Fig. 1).

Emergency upper gastrointestinal endoscopy was performed within 24 h after a patient first visited either of the above-named hospitals if hematemesis, melena or progressive anemia were seen. When emergency endoscopy was performed, a standard forward-viewing endoscope was used. Endoscopic therapy was performed when a marginal ulcer with bleeding stigmata was disclosed. The bleeding stigmata were classified into Forrest Ia (spurting bleed), Forrest Ib (oozing bleed), Forrest IIa (non-bleeding visible vessel), or Forrest IIb (adherent blood clot).

Endoscopic therapy such as hemoclips, heater probe coagulation, soft coagulation, and/or hypertonic saline with epinephrine (HSE) was selected depending on the situation. Hemoclips (HX-610-135, HX-610-135XS, HX-610-090L, Olympus, Tokyo,

Japan) were deployed to the bleeding point, and then the vessel was clamped. The heater probe (HPU-20, Olympus) was used at pulses of 20–30 J. The distal tip of the heater probe was applied directly to the bleeding site. Soft coagulation was performed using monopolar, hemostatic forceps (FD-410LR, Olympus, or HDB2418W, Pentax, Tokyo, Japan) and an electrosurgical unit (ICC-200, ERBE, Tübingen, Germany) at soft-mode coagulation with a 70W current. The hemostatic forceps was applied directly over the bleeding vessels or visible vessels [14–16].

HSE injection therapy was performed mainly as combination therapy when it was difficult to maintain a good view because of blood spurting or oozing during the procedure. HSE was injected into the ulcer bed or around the ulcer. When the bleeding was stopped and the vessel had disappeared after the HSE injection, hemostasis was considered to be attained by HSE monotherapy. When the bleeding could not be stopped by endoscopic therapy, intervention radiology (IVR) or surgical therapy was performed. The endoscopic therapy was performed by endoscopists who had at least 2 years of upper gastrointestinal endoscopy experience. Before emergency endoscopy, written informed consent was obtained from all patients or their relatives.

H. pylori infection was checked by using a serum IgG antibody to *H. pylori* or by the rapid urease test. The operation etiology and method of reconstruction were checked using operative notes or medication records.

Initial hemostasis was defined as the endoscopically verified cessation of bleeding and the disappearance of visible vessels when the first endoscopic therapy was finished. A second-look endoscopy was routinely performed to confirm hemostasis within 24 h of prior endoscopic therapy. Patients with marginal ulcer bleeding were managed with intravenous lansoprazole 30 mg, omeprazole 20 mg or famotidine 20 mg every 12 h for 2 days after initial hemostasis. A oral PPI (i.e., lansoprazole 30 mg/day, omeprazole 20 mg/day, or rabeprazole 10 mg) was then administered for 2 months. The PPI was continued in the patients with gastroesophageal reflux disease thereafter. Some patients who received anti-platelet drugs including low-dose aspirin and non-steroidal anti-inflammatory drugs were also managed with oral PPI.

Rebleeding was suspected when the patient presented with tarry stools and/or fresh hematemesis and

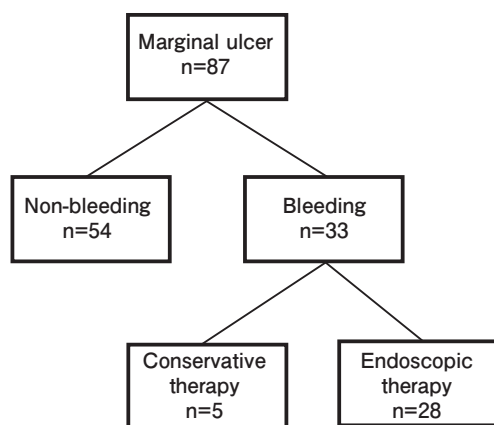


Fig. 1 Patient flow chart.

was confirmed when emergency endoscopy revealed active or recent rebleeding from the marginal ulcers. When rebleeding occurred, it was treated again with endoscopic therapy. Surgery or IVR was performed if the endoscopic therapy still did not stop the rebleeding. Ultimate hemostasis was defined as the successful control of bleeding including rebleeding after the endoscopic therapy until the end of the follow-up.

We stratified the patients in whom ultimate hemostasis was attained by endoscopic treatment into 2 groups according to whether they had received a PPI or not, based on their medical records or telephone interviews. The clinical characteristics of each group and the efficacy of the PPIs were retrospectively analyzed. This study was approved by the Ethics Committee of our hospitals (No. 782).

Statistics. The significance of differences between each group of patients was determined by the chi-square test or Fisher's exact test for discontinuous variables and the Mann-Whitney *U*-test for continuous variables. We used the Kaplan-Meier method to analyze the rebleeding curve, and the differences between each group were estimated using the log-rank test. For estimating the risk factors associated with time to rebleeding, we used the Cox proportional hazards regression model. JMP software ver. 8 (SAS, Cary, NC, USA) was used for all statistical analyses. *P*-values < 0.05 were considered significant.

Results

Table 1 summarizes the clinical characteristics of the patients. The subjects were 21 men and 7 women with a median age of 58.5 years. Of the 28 patients, 14 had undergone a partial gastric resection due to peptic ulcers. The interval between the patients' operations and the episode of bleeding ranged from 0 to 57 years (median 10.0 years). The location of each ulcer was classified as follows: anastomotic site, 20 (71%); saddle portion, 6 (21%); efferent loop, 2 (7%); afferent loop, 0 (0%). Sixteen patients had active bleeding (4 spurting and 12 oozing bleeds).

Table 2 shows the results of the endoscopic therapies. Initial hemostasis was achieved in 28 patients (100%). Rebleeding occurred in one patient with an anastomotic site marginal ulcer 5 days after the initial hemostasis. The patient received heater probe coagu-

lation following HSE at the first treatment, and was administered lansoprazol for 5 days. Emergency endoscopy revealed that the size of the exposed vessel was 5 mm in dia. Because contrast-enhanced computed tomography showed that the vessel was a pseudo-aneurysm arising from the gastroduodenal artery, this patient was treated with IVR, resulting in permanent hemostasis.

More than 1 month after the treatment, rebleeding occurred in 7 patients (25%). They were treated with endoscopic therapy again, resulting in permanent

Table 1 Characteristics of the 28 patients with marginal ulcer bleeding

	n	%
Age (yrs)	*58.5	(26–88)
Male	21	75%
Female	7	25%
<i>H. pylori</i> infection		
Positive	4	14%
Negative	10	36%
Unknown	14	50%
Drug use		
Anti-platelet drugs	3	11%
Anticoagulants	0	0%
NSAIDs	7	25%
Operation etiology		
Gastric ulcer	5	18%
Duodenal ulcer	9	32%
Gastric cancer	7	25%
Pancreatic cancer	5	18%
Traumatic pancreatic injury	1	4%
Unknown	1	4%
Method of reconstruction		
B-I	14	50%
B-II/R-Y/etc.	14	50%
Interval between operation and the episode of bleeding (yrs)		*10.0 (0–57)
Location of ulcer		
Anastomotic site	20	71%
Saddle portion	6	21%
Efferent loop	2	7%
Bleeding stigmata		
Spurting bleed	4	14%
Oozing bleed	12	43%
Non-bleeding visible vessel	9	32%
Adherent blood clot	3	11%

*Values are median (range). NSAIDs, nonsteroidal anti-inflammatory drugs.

hemostasis. Among them, 6 patients did not receive a PPI because rebleeding occurred > 4 months after the initial hemostasis. There were no procedure-related

adverse events.

Table 3 shows the characteristics of the patients stratified into 2 groups according to whether they received a PPI or not after marginal ulcer healing. There were no significant differences between the 2 groups regarding age, sex, drug use, operation etiology, method of reconstruction, or the location of the ulcer. Rebleeding was more likely to develop in the non-PPI group, but the difference was not significant ($p = 0.077$). When the observation period was considered, a significant difference was observed in the rebleeding rates between the 2 groups ($p = 0.047$) (Fig. 2).

In the multivariate analysis adjusted for age and sex, non-PPI was a risk factor for rebleeding (incidence of rebleeding, hazard ratio [HR] = 6.22, confidence interval [CI] 1.01–119.3). Rebleeding occurred in only one patient in the PPI group. This patient had undergone a gastric bypass for traumatic pancreatic injury. The patient's initial bleeding occurred 2 years

Table 2 Results of the endoscopic therapies

	n	%
Initial hemostasis	28	100%
Hemoclips	9	32%
Hemoclips following HSE	2	7%
Heater probe coagulation	6	21%
Heater probe coagulation following HSE	3	11%
Soft coagulation	3	11%
Soft coagulation followed by hemoclips	2	7%
HSE	3	11%
Rebleeding within the 1st month	1	4%
Rebleeding after the 1st month	7	25%
Ultimate hemostasis	27	96%
Perforation	0	0%
Emergency IVR or surgery	1	4%

HSE, hypertonic saline with epinephrine; IVR, interventional radiology.

Table 3 Characteristics of the patients who did/did not receive a PPI after marginal ulcer healing

	PPI	Non-PPI	<i>p</i> -value
n	13	14	
Age	59 (36–88)	55.5 (26–78)	0.23
Male	10	11	0.92
Female	3	3	
Drug use			
Anti-platelet drugs	2	1	0.50
NSAIDs	4	3	0.58
Operation etiology			
Gastric ulcer	3	2	0.23
Duodenal ulcer	2	7	
Gastric cancer	3	3	
Pancreatic cancer	4	1	
Traumatic pancreatic injury	1	0	
Unknown	0	1	
Method of reconstruction			
B-I	7	6	0.56
B-II/R-Y/etc.	6	8	
Location of ulcer			
Anastomotic site	11	8	0.21
Saddle portion	1	5	
Efferent loop	1	1	
Outcome			
Rebleeding	1	6	0.077

NSAID: non-steroidal anti-inflammatory drug.

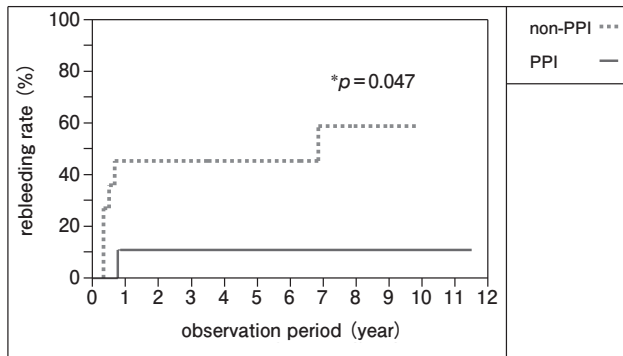


Fig. 2 Kaplan-Meier curves for rebleeding rates in the patients who did/did not receive a PPI after marginal ulcer healing. There was a significant differences between the 2 groups ($p = 0.047$).

after the operation, and rebleeding occurred 9 months after the initial hemostasis.

Discussion

Marginal ulcer bleeding is one of the most severe complications after gastric resection, PD, or RYGB [9,10,17,18]. Few reports have been published on endoscopic hemostasis for marginal ulcer bleeding or long-term outcomes after the treatment, because the incidence of marginal ulcer bleeding is relatively low [9,10]. In the present study, endoscopic hemostasis was achieved in all 28 patients, and rebleeding occurred in one patient (4%) within the first month.

After the first month, rebleeding occurred in 7 patients (25%), and the patient management that did not include a PPI was a significant risk factor associated with rebleeding.

Although marginal ulcer bleeding after gastrectomy was reported to be more severe than peptic ulcer bleeding in a non-operated stomach [6,7], several reports suggested that endoscopic therapy was safe and effective in controlling marginal ulcer bleeding [6,7,9,10]. In those reports, initial hemostasis for marginal ulcer bleeding was achieved in 88–100% of the procedures, but the rebleeding rate within the first month was high (5–33%) (Table 4). In the present study, initial hemostasis was achieved in all 28 patients and the incidence of rebleeding within the first month was only 4% (1/28).

We suspect that the reasons why it was possible to control marginal ulcer bleeding in our patients were as follows. First, we tried to ensure a good endoscopic view because marginal ulcer bleeding was often located at narrow and tight spaces. HSE was applied to control bleeding, and disposable soft straight transparent attachments were used to obtain the optimal distance. Second, we selected an appropriate endoscopic method according to the situation. When a correct frontal positioning against the bleeding point was easily obtained, hemoclips or thermal coagulation was useful to achieve hemostasis. When the ulcer was small and it was possible to close the border of the ulcer, hemo-

Table 4 Outcomes of endoscopic treatments for marginal ulcer bleeding

First Author	No. of patients	Age, mean	M/F ratio	Interval between operation and the bleeding (range)	Endoscopic Treatment	Initial hemostasis rate (%)	Rebleeding rate within the 1st mo. (%)	Rebleeding rate after the 1st mo. (%)
Chung [6]	14	62	—	—	—	—	16	—
Nikolopoulos [7]	35	68	—	—	Hemoclips, Epinephrine inj.	—	12	—
Lee [9]	50	65	39/11	19 yrs (2–40 yrs)	Hemoclips, Epinephrine inj. and Heater probe	100	[¶] 5–33	—
Shin [10]	18	65	18/0	13 yrs (1–30 yrs)	Epinephrine inj., Alcohol inj., Heater probe	88	—	—
Our report	28	[¶] 58	21/7	10 yrs (0–57 yrs)	Hemoclips, Heater probe, Soft coagulation	100	4	25

[¶]Age is the median. [¶]The rebleeding rate after hemoclips was 5%. The rebleeding rate after epinephrine injection and heater probe was 33%. M/F: male to female ratio.

clips were particularly useful. In the patients in whom frontal positioning was difficult, thermal coagulation such as soft coagulation with hemostatic forceps could achieve hemostasis even from a tangential direction. Compared with heater probe thermal coagulation, soft coagulation with hemostatic forceps yielded a higher hemostasis success rate and lower rebleeding rate for peptic ulcer bleeding [16].

Long-term outcomes of marginal ulcer bleeding have rarely been studied. Our present analysis showed that the rebleeding rate after the first month was very high (25%) in the marginal ulcers (Table 4). In most cases, the marginal ulcer recurred in the same location after the patient stopped taking a PPI. Only one patient was administered a PPI when rebleeding occurred; this patient had undergone bypass surgery due to a traumatic pancreatic injury. The reason why rebleeding occurred in this patient despite the PPI treatment is unclear.

Among factors such as gastric acid, *H. pylori* infection, local ischemia, anastomotic tension, tobacco use, and NSAID use, increased gastric acid is considered a main cause of marginal ulcers [6,19–21]. Because PPIs suppress gastric acid, they might be useful to prevent marginal ulcer [22,23]. However, it has not been determined whether PPIs are effective in preventing the recurrence and bleeding of marginal ulcers. In light of the results of the present study, it is noteworthy that PPIs might have the potential to prevent the recurrence of marginal ulcer bleeding regardless of the use of NSAIDs or anti-platelet drugs.

H. pylori plays an important role in the pathogenesis of marginal ulcers after gastric bypass, and the eradication of *H. pylori* reduced the incidence of postoperative marginal ulcers [24–27]. However, the association between marginal ulcers after gastric resection or PD and *H. pylori* infection remains unclear [6,28]. In the present study, rebleeding occurred 8 months after the eradication of *H. pylori* in one patient who had undergone a partial gastric resection. This patient was not administered a PPI at that time. The patient had no co-morbidity and did not use NSAIDs. After the rebleeding was treated, a PPI was administered and re-bleeding did not occur for another 2 years. This result demonstrated that the eradication of *H. pylori* might not be enough to prevent marginal ulcer bleeding, although further studies to clarify the role of *H. pylori* are needed.

The limitations of our study are the small sample size and the retrospective design. A randomized prospective study may be necessary to clarify whether PPIs are useful for preventing rebleeding from marginal ulcers.

In conclusion, therapeutic endoscopy is effective and safe for achieving initial hemostasis and managing rebleeding in patients with active or recent marginal ulcer bleeding. The administration of a PPI might prevent rebleeding from a marginal ulcer.

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