Characteristics of Gastric Stasis due to Deformation after Endoscopic Submucosal Dissection in the Lower Part of the Stomach

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Running head：

Gastric stasis due to deformation after endoscopic submucosal dissection

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ABSTRACT

Introduction: Gastric stasis due to deformation occurs after endoscopic submucosal dissection in the lower part of the stomach. Endoscopic balloon dilation can improve gastric stasis due to stenosis; however, endoscopic balloon dilation cannot improve gastric stasis due to deformation. Furthermore, the characteristics of gastric stasis due to deformation are unknown. This study aimed to evaluate the characteristics of gastric stasis due to deformation after endoscopic submucosal dissection in the lower part of the stomach, focusing on the differences between stenosis and deformation.

Methods: We retrospectively reviewed 41 patients with gastric stasis after endoscopic submucosal dissection in the lower part of the stomach. We evaluated the characteristics of cases with gastric stasis due to deformation, such as the risk factors of deformation and the rate of deformation in each group with risk factors.

Results: Deformation was observed in 12% (5/41) of the patients with gastric stasis. All cases of deformation had a circumferential extent of the mucosal defect greater than 3/4. The number of cases with pyloric dissection was significantly lower in the deformation group than in the non-deformation group (0% vs. 72%; $p=0.004$). The deformation group also had a significantly higher number of cases with angular dissection than the non-deformation group (100% vs. 17%; $p<0.001$). Moreover, the deformation cases had a significantly larger specimen diameter ($p<0.001$). Deformation was observed only in cases with angular and non-pyloric dissections. Deformation was not observed in cases with angular and pyloric dissections.

Conclusions: All cases of gastric stasis due to deformation had a circumferential extent of the mucosal defect greater than 3/4. Deformation was also likely to occur in cases with a larger dissection that exceeded the angular region without pyloric dissection.

Key words: deformation, gastric stasis, stenosis, endoscopic submucosal dissection

Introduction

The establishment of endoscopic submucosal dissection (ESD) has made it possible to treat early gastric cancer without lymph node metastasis [1-6]. Bleeding and perforation are known as early-stage complications after ESD [2, 7, 8], and gastric stasis due to stenosis is a late-stage complication after ESD [9-15]. Although it is generally known that gastric stasis is caused by stenosis, it has been also reported that gastric stasis is caused by gastric dysmotility or gastric deformation [17-19]. Particularly in the lower part of the stomach, the difference between gastric stasis due to stenosis and that due to deformation is not completely elucidated.

In cases of gastric stasis due to deformation, endoscopy showed a strong deformation of the antrum and a large amount of food residue in the stomach, although the endoscope could pass through the duodenum [17, 18]. Sufficient therapeutic effect of endoscopic balloon dilation (EBD) has been reported for gastric stasis due to stenosis after ESD [13-15]. However, even frequent EBD cannot improve gastric stasis due to deformation [17, 18]. Thus, the therapeutic effect of EBD on deformation in the lower part of the stomach is different from that of stenosis.

It has been reported that circumferential extent of a mucosal defect greater than 3/4 is a risk factor for stenosis after gastric ESD [10-15]. However, no reports have examined the characteristics of gastric stasis due to deformation after sufficiently distinguishing

between stenosis and deformation. Knowledge of the characteristics of gastric stasis due to deformation is important for additional treatment strategies. Therefore, this study aimed to evaluate the characteristics of gastric stasis due to deformation after ESD in the lower part of the stomach, focusing on the differences between stenosis and deformation.

Methods

Study design

This retrospective observational study was conducted at Kobe University Hospital and Kishiwada Tokushukai Hospital. Data were collected from the electronic medical records.

Ethical standards

The study protocol was approved by the Institutional Review Board (IRB) of Kobe University Hospital and Kishiwada Tokushukai Hospital. Opt-out informed consent protocol was used for this study. This consent procedure was reviewed and approved by the IRB of Kobe University Hospital and Kishiwada Tokushukai Hospital (approval number: B200347, 22-30).

Eligibility criteria and definition

We investigated 3,833 patients with 4,553 gastric epithelial neoplasms who underwent ESD at Kobe University Hospital and Kishiwada Tokushukai Hospital between January 2003 and March 2020. This study enrolled 41 patients with 41 lesions who had gastric stasis after ESD in the lower part of the stomach.

Definitions

Gastric stasis was defined as a condition of poor intake of food associated with massive gastric residue observed by esophagogastroduodenoscopy (EGD).

Stenosis was defined as a condition in which an endoscope (GIF-Q230, GIF-Q240, GIF-Q260J, GIF-H260, or GIF-H290; Olympus Corporation, Tokyo, Japan) with a diameter of 10.5–11.9 mm could not pass from the antrum to the duodenum **(Fig. 1a)**.

Deformation was defined as a condition in which a large luminal curvature was shown on EGD, resulting in gastric stasis, but the endoscope could pass from the antrum to the duodenum (**Fig. 1b)**.

ESD procedure

We used endo-knives, such as the Flush knife, Flush knife-BT, Flush Knife-BTS, and IT knife (DK2618JN, DK2618JB, DK2620JBS; FUJIFILM Medical Co., Ltd., and KD-610L; Olympus Corporation, Tokyo, Japan) to make a mucosal incision around the lesion and perform submucosal dissection. We also used the ICC 200, VIO 300D, and VIO3 (Erbe Elektromedizin GmbH, Tübingen, Germany) as electrosurgical generators. We made a mucosal incision around the lesion and performed submucosal dissection using an Endo-knife after local injection of saline with an injection needle. Endo-knives and hemostatic forceps (Coagrasper G; Olympus Corporation, Tokyo, Japan) were used for hemostasis and vessel coagulation [19-23]. Locoregional triamcinolone injections (40 or 80 mg) were administered at the ulcer floor after ESD in some cases with wide circumferential mucosal defects. We first administered omeprazole (40 mg) intravenously to post-ESD patients for two days. Subsequently, we administered rabeprazole or esomeprazole or vonoprazan (20 mg) orally for two months.

Post-ESD follow-up

The pathologist evaluated the curability of the resected specimens based on the Japanese gastric cancer treatment guidelines [24-26]. We performed additional surgical treatment when the lesion was pathologically diagnosed as a non-curative resection. In contrast, we performed regular endoscopic follow-up when the resected lesion was subjected to curative resection. Follow-up EGD was performed 2–3 months after ESD to confirm ulcer healing, and subsequently every 6 or 12 months to check for recurrence. EGD was performed before the scheduled examination in patients with symptoms such as fullness, abdominal pain, nausea, and vomiting and in patients with wide circumferential mucosal defects. Follow-up EGD was performed at least one week after ESD and once every 1–2 weeks thereafter. If there was no tendency for stenosis, the interval was gradually extended to one month.

EBD procedure

EBD was performed in patients with gastric stasis during the follow-up period. EBD was performed using a controlled radial expansion balloon dilator (CRE Wireguided Balloon Dilators; Boston Scientific Japan Corp., Tokyo, Japan) with diameters of 12–15 mm, 15–18 mm, or 18–20 mm. We chose the balloon size according to the size of the gastric lumen. We started EBD at a pressure of 0.5 standard atmospheric pressure (atm) and increased the pressure by 0.5 atm to the point of resistance. We maintained the pressure for one minute and checked for bleeding and perforations. The same procedure was repeated until the scope passed through the lumen. If the gastric stasis remained even though the scope passed, the size of the balloon was changed to a larger one. EBD was

continued approximately once every 1–2 weeks. If gastric stasis remained even though the scope was able to pass using the largest balloon (18-20 mm), it was judged that EBD was ineffective.

Endoscopic antralplasty

We performed endoscopic antralplasty (EAP) in some cases of gastric stasis due to deformation, in which EBD was ineffective. This was a method of releasing the deformation by performing ESD on the opposite side of the scar [17]. The deformation was gradually released by the contralateral traction that occurred during the process of improving the new artificial ulcer after ESD **(Fig. 2a-d)**.

Outcomes

We evaluated the characteristics of the cases with deformation, among the cases with gastric stasis; these included risk factors for deformation, rate of deformation in each group with risk factors, and treatment methods of deformation. The survey items of the risk factors for deformation were age, sex, pyloric dissection, angular dissection, location of mucosal defect, circumferential extent of mucosal defect, macroscopic type, invasion depth, ulcer findings, specimen diameter, and use of steroids. Pyloric dissection was defined as a condition in which the mucosal defect created by ESD was located on the pyloric ring. Angular dissection was defined as a condition in which the mucosal defect created by ESD extended beyond the angular region. The circumferential extent of mucosal defects was measured using a computer software (Windows Ink; Microsoft Corporation, Washington, USA). The depth of invasion, ulcer findings, and specimen diameter were assessed pathologically.

All cases were reclassified according to the presence of categorical variables or risk factors of deformation, and the deformation rate of each group was evaluated. We also summarized the size of specimen, circumferential extent of the mucosal defect, period from ESD to the onset of gastric stasis, number of EBDs, maximum diameter of EBDs, period from ESD to additional treatment, and methods of additional treatment in each deformation case. In addition, we evaluated the characteristics of cases with perforation due to EBD.

Statistical analysis

Risk factors of deformation were analyzed using Fisher's exact test and Mann-Whitney U-test. Statistical significance was set at $p < 0.05$. All statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphic user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).

Results

Deformation was observed in 12% (5/41) of the patients with gastric stasis. Stenosis was observed in the remaining 88% (36/41) of the patients with gastric stasis. Thus, the non-deformation cases were stenosis cases **(Fig. 3)**. In all cases of gastric stasis due to deformation, the effects of EBDs could not be determined and additional treatment was required. All steroid use cases underwent locoregional triamcinolone injections**,** and there were no cases of oral prednisolone intake **(Table 1)**. The deformation group had a significantly lower number of pyloric dissection cases than the non-deformation (stenosis) group (0% vs. 72%; p=0.004). The number of cases with angular dissection

was significantly higher in the deformation group than in the non-deformation (stenosis) group (100% vs. 17%; $p<0.001$). Moreover, the deformation group had a significantly larger diameter of the specimen than the non-deformation (stenosis) group ($p<0.001$) **(Table 2)**.

Deformation was observed only in cases of angular and non-pyloric dissections. Deformation was not observed in cases with angular and pyloric dissections **(Table 3)**.

The characteristics of all cases of deformation are listed in **Table 4**. All cases of gastric stasis due to deformation had a circumferential extent of the mucosal defect greater than 3/4. In all cases of deformation, the therapeutic effect on gastric stasis could not be achieved by performing EBD with a maximum diameter of 18–20 mm in the absence of stenosis. Gastric stasis improved with additional treatment in all cases with deformation. Gastric stasis improved in two patients with EAP and without surgery. In case 4, the patient did not wish to undergo surgical treatment; therefore, we performed up to 14 EBDs to improve gastric stasis. However, repeated EBDs did not improve gastric stasis, and EAP eventually improved gastric stasis. In case 5, long-term gastric stasis resulted in delayed healing of a post-ESD ulcer and prolonged anemia, which improved after EAP.

Three cases of perforation were associated with EBD **(Table 1)**. All three cases had stenosis but did not have deformation. In these cases, there was a circumferential extent of mucosal defect more than 3/4 and non-pyloric dissection. Of the three cases of perforation, two cases were treated with surgery (distal gastrectomy) and one case improved with conservative treatment.

Discussion

In this study, we evaluated the characteristics of cases in which gastric stasis

occurred because of deformation after ESD in the lower part of the stomach. As a result, all cases of deformation had a circumferential extent of the mucosal defect greater than 3/4. Deformation was also prone to occur in cases with a larger dissection that exceeded angular region without non-pyloric dissections.

Although gastric stasis due to post-ESD stenosis is well known [9-15], there are few reports of gastric stasis due to deformation [17, 18]. Furthermore, no reports have examined the characteristics of gastric stasis due to deformation after sufficiently distinguishing between stenosis and deformation. In this study, we evaluated the characteristics of gastric stasis due to deformation, focusing on the differences between stenosis and deformation.

It has been reported that the circumferential extent of the mucosal defect greater than 3/4 is a risk factor of stenosis after gastric ESD [10-15]. In this study, all cases of gastric stasis due to deformation had a circumferential extent of the mucosal defect greater than 3/4, which was a risk factor of stenosis. In addition, it was found that deformation was prone to occur in cases with a large dissection on the vertical axis that exceeded the angular region with non-pyloric dissection. When we reclassified all cases according to the presence of angular and pyloric dissections, deformation was observed only in cases with angular and non-pyloric dissections. This was because the lumen from the antrum to the oral side of the pylorus bends significantly because of the contraction caused by artificial ulcer healing, which prevents food passage. In contrast, deformation was not observed in cases with angular and pyloric dissections. The reason for this was that the lumen from the antrum to the pylorus did not bend during the process of ulcer healing and maintained a straight lumen along the lesser curve, including the pyloric ring, which provided a pathway for food.

In all cases with deformation, a therapeutic effect on gastric stasis could not be obtained by performing EBD with a maximum diameter of 18–20 mm. Even in cases where EBD was performed 14 times, it did not improve gastric stasis. Therefore, it was found that stenosis and deformation were completely different and that EBD had no effect on deformation. Additional treatments other than EBD should be considered if deformation features are noted in the lower part of the stomach. There have been reports of surgery and EAPs for the treatment of gastric deformation [17, 18]. In this study, we were able to avoid surgery and improve gastric stasis by EAP in two cases, indicating that less invasive EAP could be an additional treatment option. Post-ESD bleeding is likely to occur in cases of gastric stasis [16], and gastric stasis may affect ulcer healing. In case 5, delayed ulcer healing and prolonged anemia were observed; however, EAP improved these conditions. We also suggest that the improvement of gastric stasis by EAP may improve conditions such as delayed ulcer healing and prolonged anemia due to gastric stasis.

In addition, there were three cases of perforation due to EBD for stenosis, all of which were cases of non-pyloric dissention in the antrum. In all cases of EBD for stenosis after pyloric ESD with pyloric dissection, stenosis was released without perforation [14, 15]. However, there have been reports of EBD perforation for stenosis in the lower part of the stomach [10, 27]. In a report that clearly stated the presence or absence of pyloric dissection, only cases of antral ESD without pyloric dissection had an EBD perforation [28]. Anatomically, post-ESD scars containing a strong and thick pyloric sphincter are formed in cases of pyloric dissection. In contrast, in cases with non-pyloric dissection, post-ESD scars were formed only in weak areas without the pyloric sphincter. Because

EBD was performed only at this weak site, perforation was likely to occur in cases with non-pyloric dissection. Therefore, when performing ESD for the circumferential extent of the lesion greater than 3/4 in the lower part of the stomach, dissection of the pylorus should be considered instead of leaving the pylorus to prevent deformation and EBD perforation.

Our study had several limitations. First, this was a retrospective study based on medical records; therefore, it could be affected by selection and measurement biases. In cases of steroid use, the selection criteria and dosage of steroids used were unclear. Second, the study was conducted at two institutions; therefore, the number of cases was limited, and the results may not be generalizable. Nevertheless, this study has high clinical significance, as it is the first study to evaluate a deformation that is clearly distinguished from stenosis by objective indicators.

Conclusion

All cases of gastric stasis due to deformation after gastric ESD in the lower part of the stomach had a circumferential extent of the mucosal defect greater than 3/4. Deformation was also likely to occur in cases with a larger dissection that exceeded the angular region without pyloric dissection.

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Statement of Ethics: The study protocol was approved by the Institutional Review Board (IRB) of Kobe University Hospital and Kishiwada Tokushukai Hospital. Opt-out

informed consent protocol was used for this study. This consent procedure was reviewed and approved by the IRB of Kobe University Hospital and Kishiwada Tokushukai Hospital (approval number: B200347, 22-30).

Conflict of Interest Statement: Takashi Toyonaga has received a portion of the sales of Flush knife-BT and Flush Knife-BTS, which were developed in collaboration with FUJIFILM Medical Co, as royalties. He has also received a portion of the sales of Coagrasper G, which were developed in collaboration with Olympus Corporation, as royalties. The other authors have no conflicts of interest or financial ties to disclose.

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Author Contributions:

Hiroshi Takayama was involved in data collection, analysis and writing the manuscript. Takashi Toyonaga was involved in inventing the study concept and revising the manuscript. Tetsuya Yoshizaki, Hirofumi Abe, Tatsuya Nakai, Chise Ueda, Satoshi Urakami, Hidetoshi Kaku, Yusaku Shimamoto, Kei Matsumoto, Kazunori Tsuda, Hiroya Sakaguchi, Shinichi Baba, Hiroshi Takihara, Nobuaki Ikezawa, Shinwa Tanaka, Madoka Takao, Toshitatsu Takao, Yoshinori Morita and Yuzo Kodama were involved in the analysis and revising of the manuscript. All authors read and approved the final manuscript.

Data availability statement: All data generated or analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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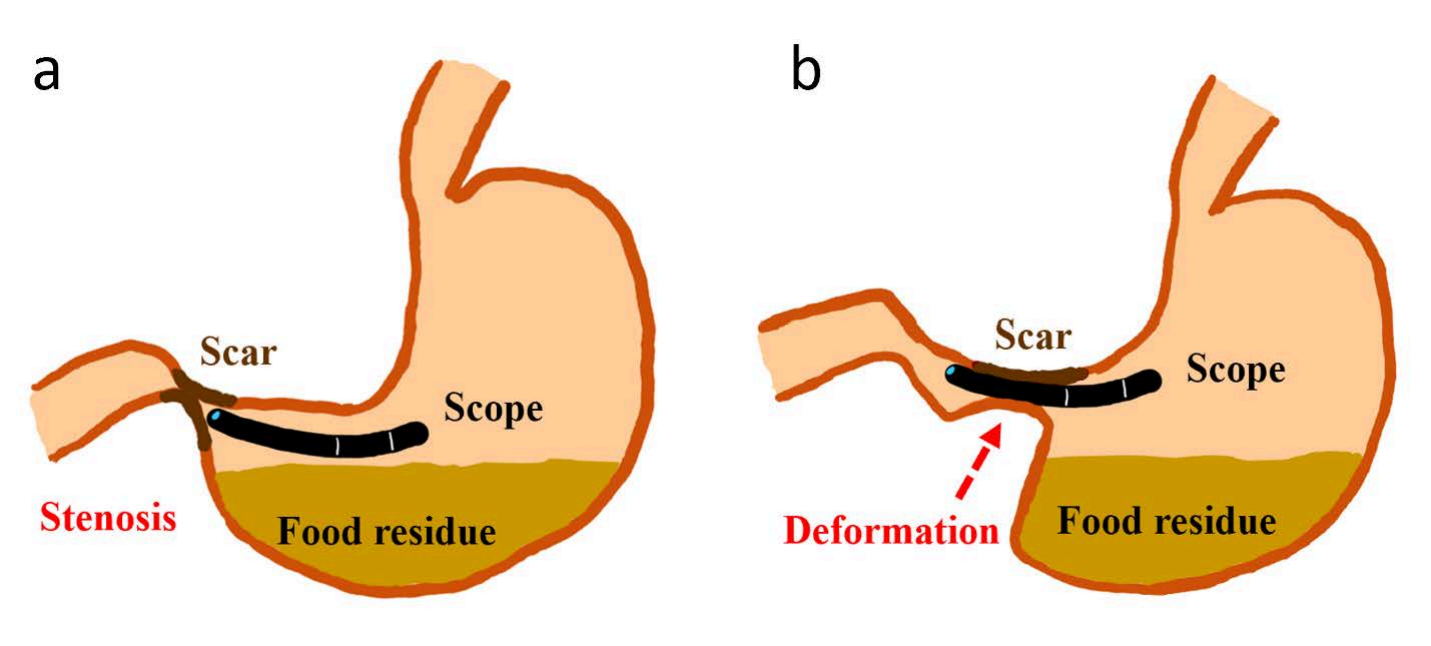
Figure legends

Fig. 1. a) Stenosis was defined as a condition in which an endoscope could not pass from the antrum to the duodenum. **b)** Deformation was defined as a condition in which a large luminal curvature was shown by esophagogastroduodenoscopy, resulting in gastric stasis, but the endoscope could pass from the antrum to the duodenum.

Fig. 2. a) We performed endoscopic submucosal dissection (ESD) in the lower part of the stomach so that the circumferential mucosal defect was greater than 3/4. The mucosal defect was beyond the angular region but not on the pyloric ring. **b)** During the healing process of the artificial ulcer, the antrum was deformed and the pyloric ring could not be seen. A large amount of food residue remained in the stomach. **c)** We performed additional ESD on the greater curvature in the antrum, which was contralateral to the post-ESD site. **d)** The deformation was gradually released by the contralateral traction that occurred during improvement of the new artificial ulcer. We could observe the gastric lumen in the antrum.

Fig. 3. The flow chart of patients and lesions included in this study.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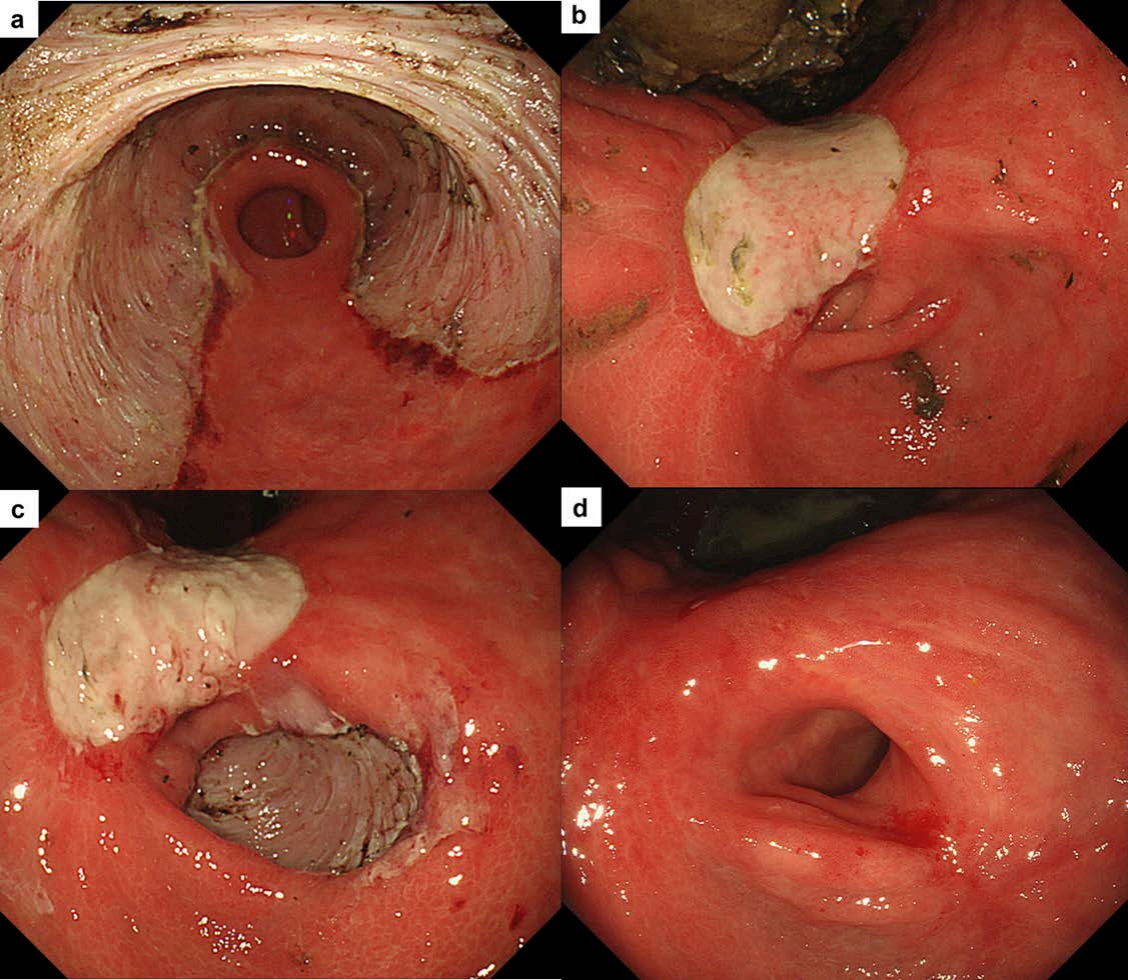
Scar
Scope
Stenosis
Food residue
b
Scar
Scope
Deformation
Food residue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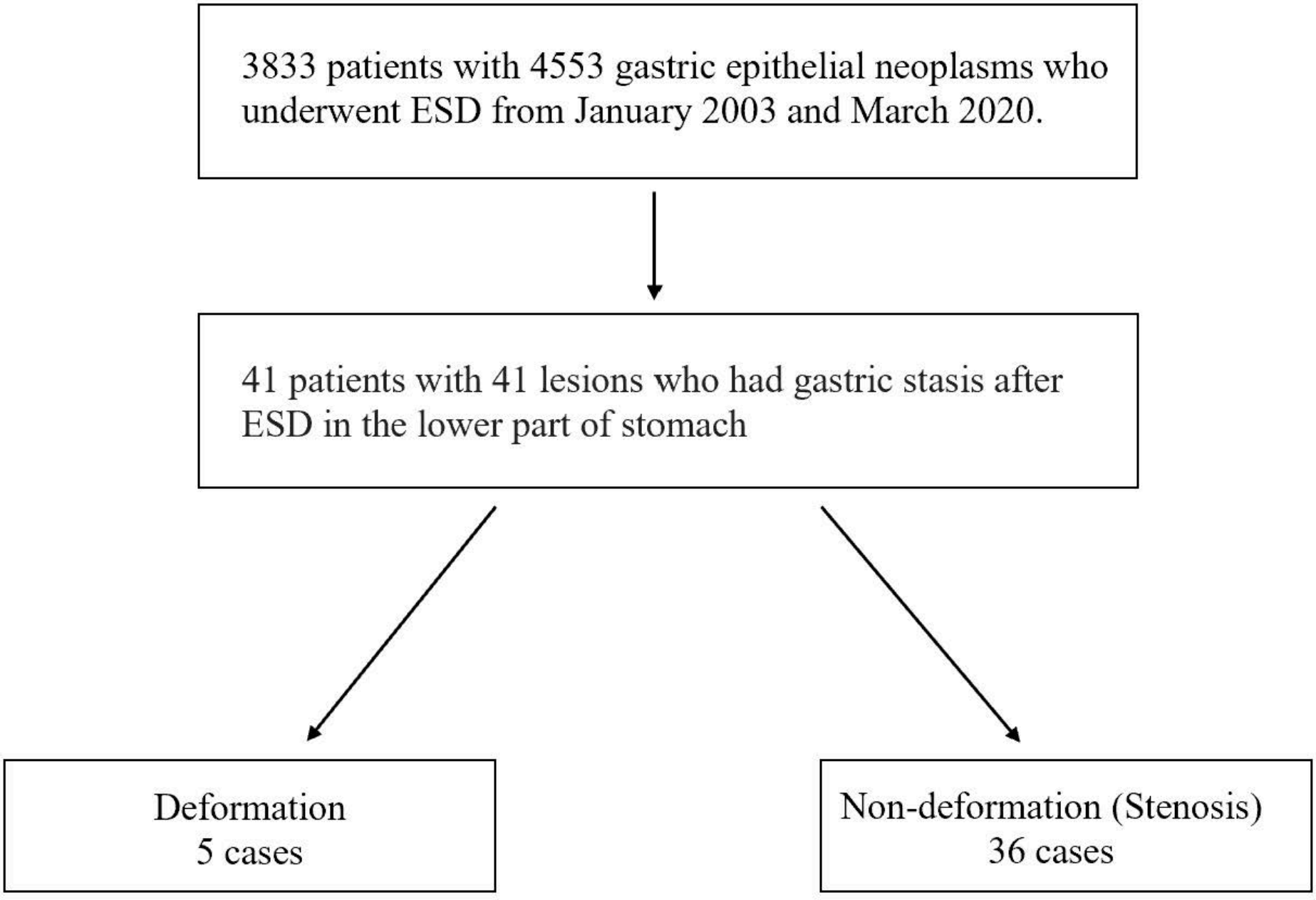
3833 patients with 4553 gastric epithelial neoplasms who underwent ESD from January 2003 and March 2020.
41 patients with 41 lesions who had gastric stasis after ESD in the lower part of stomach
Deformation
5 cases
Non-deformation (Stenosis)
36 cases

Table 1. Characteristics of 41 cases

Age	74（68-80)
Gender	
Male	28
Female	13
Pyloric dissection	26
Angular dissection	11
Location	
Lesser curve	26
Greater curve	5
Anterior wall	3
Posterior wall	7
Circumferential extent of mucosal defect, %	86 (83-95)
macroscopic type	
elevated	28
depressed	13
invasion depth	
mucosal	36
submucosal	5
Ulcer findings	10
Specimen diameter (mm)	60
Use of steroids	11
Deformation	5
Stenosis	36
Perforation by EBD	3

Data represents the number of patients or median (interquartile range)

EBD: Endoscopic balloon dilation

Table 2. Comparison of deformation and non-deformation (stenosis) cases

	Deformation (+) n=5	Deformation (-) n=34	p-value
Age, years	69 (68-75)	74 (68-83)	0.34
Gender			0.64
female	2	11	
male	3	25	
Pyloric dissection			0.004
present	0	26	
absent	5	10	
Angular dissection			<0.001
present	5	6	
absent	0	30	
Location			0.63
Lesser curve	5	21	
Greater curve	0	5	
Anterior wall	0	3	
Posterior wall	0	7	
Circumferential extent of mucosal defect (%)	84 (83-90)	86 (82-95)	0.79
Macroscopic type			0.30
elevated	2	26	
depressed	3	10	
Invasion depth			1
mucosal	5	31	
submucosal	0	4	
Ulcer findings			0.58
present	2	8	
absent	3	28	

Specimen diameter (mm)	110 (102-113)	57 (45-68)	0.003
Use of steroid			1
present	1	10	
absent	4	26	

Data represents the number of patients or median (interquartile range)

Table 3. Deformation cases depending on dissection range

Dissection range	Deformation rate
Angular dissection (+), Pyloric dissection (-)	63% (5/8)
Angular dissection (+), Pyloric dissection (+)	0% (0/3)
Angular dissection (-), Pyloric dissection (-)	0% (0/7)
Angular dissection (-), Pyloric dissection (+)	0% (0/23)

Data represents rate (Number of deformation cases/ Number of all cases)

Table 4. Characteristics of five cases with deformation

No	Specimen diameter (mm)	Circumferential extent of the mucosal defect (%)	Number of EBDs (number)	Maximum Diameter of EBDs (mm)	Period from ESD to gastric stasis (day)	Period from ESD to additional treatment (day)	Additional treatment
1	128	83	2	18	25	91	Distal gastrectomy
2	63	84	2	20	27	71	Distal gastrectomy
3	113	95	5	20	48	78	Gastrojejunostomy
4	102	90	14	20	41	125	EAP
5	102	83	2	20	46	157	EAP

EBD: Endoscopic balloon dilation, ESD: endoscopic submucosal dissection, EAP: Endoscopic antralplasty