Title: An assessment of the efficacy and risks of endoscopic balloon dilatation in corrosive-induced upper gastrointestinal strictures

Authors:
Yi-Chun Chiu 1/ E-mail address: chiuku@ms14.hinet.net
Keng-Liang Wu 1/ E-mail address: kengliang_wu@yahoo.com.tw
William Tam 2/ E-mail address: William.Tam@health.sa.gov.au
Ming-Luen Hu 1/ E-mail address: luen@adm.cgmh.org.tw
Wei-Chen Tai 1/ E-mail address: wctai@adm.cgmh.org.tw
Seng-Kee Chuah 1/ E-mail address: chuahsk@seed.net.tw
King-Wah Chiu 1/ E-mail address: c471026@ms6.hinet.net

Institution:

1 Division of Hepato-Gastroenterology, Department of Internal Medicine, Kaohsiung Chang Gung Memorial Hospital and Chang Gung University College of Medicine, Kaohsiung, Taiwan.

2 Lyell McEwin and Royal Adelaide Hospitals, Adelaide, Australia.

*These authors contributed equally to this work

Correspondence to: Keng-Liang Wu, Division of Hepato-Gastroenterology, Department of Internal Medicine, Kaohsiung Chang Gung Memorial Hospital and Chang Gung University College of Medicine,

123 Ta Pei Road, Niao Sung District, 833 Kaohsiung, Taiwan.

Telephone: +886-7-7317123, ext. 8301 /Fax: +886-7-7322402

Email: kengliang_wu@yahoo.com.tw
ABSTRACT

Background

Esophageal stricture (ES) and gastric outlet obstruction (GOO) are considered different entities, but in patients injured by the ingestion of corrosive agents, they may occur concurrently. There was no study to investigate the use of endoscopic balloon dilation (EBD) in these strictures simultaneously. The aim of this study is to assess the effectiveness and safety of EBD in patients with corrosive-induced upper gastrointestinal strictures.

Methods

From July 2002 to December 2009, 36 patients with corrosive-induced upper gastrointestinal strictures in a tertiary hospital were recruited into this study. The patients were divided into three groups ES, GOO and ES+GOO. All strictures were dilated under direct visualization by using through-the-scope balloon catheters to the end point of 15 mm. The treatment outcome was considered successful when patients were able to maintain a solid or semisolid diet without additional dilation for more than 12 months.

Results

These 36 patients included 15 males and 21 females with average age of 47 years ranging from 25 to 79 years. The patients were divided into three groups: ES group
with 18 patients, GOO group with 7, and ES + GOO group with 11. The successful rates of ES, GOO, and ES+GOO response to EBD were 83.3%, 57.1% and 36.4% respectively. The reasons of treatment failure were perforation (6 cases, 6/36=16.7%), ineffectiveness of dilation (5 cases, 13.9%) and active bleeding (2 cases, 5.6%). Patients with ES alone significantly had a higher success rate (15/18, 83.3% vs. 8/18, 44.4%, \( P = 0.035 \)) and a lower major complication rate (1/18, 5.6% vs. 7/18, 38.9%, \( P = 0.041 \)) than those with either GOO or ES+GOO. For the effective cases, significantly more EBD sessions were required to achieve a successful outcome in patients with ES+GOO than in those with either ES or GOO (13.7±4.9 vs. 6.0±4.4, \( P = 0.011 \)).

**Conclusions**

EBD can be used effectively and safely to manage corrosive-induced ES. However, when GOO with or without ES develops in patients with corrosive injury, the success rate of EBD is lower with a higher complication rate compared to those with ES alone.

Keyword: esophageal stricture; gastric outlet obstruction; corrosives; balloon dilation
BACKGROUND

The ingestion of corrosive agents can cause extensive damage to the gastrointestinal tract. This can lead to significant morbidity requiring prolonged and repeated hospitalization. In the acute state, the damage may be so severe that perforation of the esophagus and the stomach as well as death can ensue.\(^1\) Long-term complications of the gastrointestinal strictures, including esophageal stricture (ES) and gastric outlet obstruction (GOO), may develop from weeks to years after ingestion of corrosive agents.\(^2\) ES and GOO are considered different entities, but in patients injured by the ingestion of corrosive agents, they may occur independently or they may occur concurrently in up to 20%.\(^3\) Endoscopy can be used to assess the degree and extent of damage of gastrointestinal tract within the first 48 hours, and later it can also be used to treat strictures developing in the esophagus and stomach.\(^4\)\(^-\)\(^6\) Previous studies have reported the successful use of the endoscopic balloon dilation (EBD) to treat corrosives-induced ES or GOO in isolation.\(^6\)\(^-\)\(^9\) In contrast, the use of EBD to treat patients who have both ES and GOO has not been formally evaluated. When they occur concurrently, endoscopic treatment may be more complicated. In this study, we investigated the treatment response and complication related to the use of EBD in corrosive-induced upper gastrointestinal strictures entirely.
METHODS

From July 2002 to December 2009, patients with upper gastrointestinal stricture induced by corrosive injury in a university-affiliated tertiary care center were recruited into this study. These patients had received early upper gastrointestinal endoscopy (GIF-Q240; Olympus Optical Co., Ltd., Tokyo, Japan) within 48 hours of ingestion. Mucosal burns of the esophagus, stomach, and duodenum were graded following a method previously reported by Zargar et al.: grade 0, normal examination; grade I, edema and hypermia of the mucosa; grade II, subdivided into grade IIa (friability, hemorrhages, erosions, blisters, whitish membranes, exudates and superficial ulcerations), grade IIb (grade IIa plus deep discrete or circumferential ulceration), and grade III, multiple ulcerations and areas of necrosis. If the patients demonstrated symptoms of upper gastrointestinal stricture, including dysphagia or easy satiety with postprandial vomiting, endoscopy was performed in the forth week after corrosive injury to examine the upper gastrointestinal tract. For patients with ES and/or GOO, EBD was performed from the fourth week. Patients who satisfied the selection criteria were subjected to EBD by using through-the-scope balloon dilators. Exclusion criteria were (1) patients had no early endoscopy within 48 hours of ingestion, (2) patients demonstrated symptoms of stricture but no upper gastrointestinal stricture on endoscopic examination, and (3) patients decided to
receive surgical intervention but not EBD. The patients were divided into three groups: esophageal stricture alone (ES), gastric outlet obstruction alone (GOO) and combination of ES and GOO (ES+GOO).

**Endoscopic balloon dilation**

With consent of each patient, ES and GOO were dilated under direct visualization by using controlled radial expansion (CRE) balloon catheter (Microvasive, Boston Scientific Corporation, Natick, MA, USA) without fluoroscopic guidance. Intramuscular hyoscine butylbromide 20mg as an antispasmodic agent and intramuscular meperidine hydrochloride 50mg as an analgesic agent was given approximately 10 minutes before staring the procedure, if not contraindicated. In each dilation session, we first selected balloon size based on diameter of aperture and then passed the balloon through the biopsy channel of the endoscope into the stricture without fluoroscopic monitoring. The balloon was inflated with water to the recommended pressure for 60 seconds. In each session, the patient received three consecutive dilations with increment of dilation diameter not more than 3 mm (rule of three).\(^{11}\) The patients were kept fasting for four hours post procedure and prescribed proton pump inhibitors to suppress gastric acid. Inpatients received two sessions a week and outpatients one session a week. The goal was to increase dilating diameters incrementally until the end point of 15 mm. Serial dilations were performed until solid
or semisolid food could be tolerated. If GOO were encountered after dilating ES, EBD of GOO were performed at the same time, and the dilations of ES and GOO were counted together in one session. If symptoms of stricture recurred, additional dilations were performed until symptoms were relieved again. The treatment outcome was considered successful when patients were able to maintain a solid or semisolid diet without additional dilation for more than 12 months.

Clinical follow-up

Following dilation, patients were treated with antacids or proton pump inhibitors for gastric acid suppression. Each patient was recorded the presence and severity of dysphagia as well as postprandial distension when ingesting solids in follow-up period. If the problems of intake relapsed and upper gastrointestinal stricture recurred on clinical follow-up after termination of a series of dilations, additional dilation was performed until solids or semisolids tolerated.

Study definitions

The treatment was defined as successful when patients were able to maintain a solid or semisolid diet for more than 12 months without additional dilation. Any untoward event after endoscopic treatment was considered a complication. Mild pain or minimal blood oozing after endoscopic balloon dilation was acceptable. On the other hand, gastrointestinal tract perforation or bleeding with clinical signs of hematemesis, coffee-ground vomitus, hematochezia, or melena, or significant pain requiring
hospitalization, was defined as a major complication

The study received approval No. 98-2106B from the ethics committee of our institution and conformed to its guidelines.

**Statistical analysis**

Continuous variables are given by mean and standard deviation. The continuous variables were analyzed by using the Mann-Whitney U test. Categorical variables were given in total and as percentages. They were analyzed by using the Fisher’s exact test. Two-sided \( P \) value of \(<0.05\) were considered significant. All statistical operations were performed using SPSS WIN version 15.0 (SPSS Inc., Chicago, IL, USA).

**RESULTS**

A total of 43 patients developed intake problems after ingestion of corrosives. Of them, 36 patients were recruited into this study, and seven were excluded (four patients received surgical management and three had no stricture on endoscopic examination). These 36 patients included 15 males and 21 females with average age of 47 years ranging from 25 to 79 years. The patients were divided into three groups: ES group with 18 patients, GOO group with 7, and ES + GOO group with 11. As seen in table 1, there was no significant difference in age, gender and ingested substance (acid/alkali) among these three groups. Grade III injury over stomach was more
common in patients with GOO including GOO and ES+GOO group than those with ES alone. (18/18, 100% v.s 8/18, 44.4%, P=0.001)

**ES Group**

Of the 18 patients with ES alone, 6 had orifices of strictures located in the upper third of the esophagus, 6 in the middle third, and 6 in the lower third. Fifteen patients (15/18, 83.3%) had persistent symptom relief (average follow-up 25.5±10.6 months). These patients received a total of 92 dilation sessions with an average number being 6.1±4.7 per patient over a median period of 10±15.9 weeks. EBD was not successful in three patients (16.7%), including one had esophageal perforation related to EBD and two opted out of dilation because their symptom was persistent and refractory to serial dilations (8 and 11 sessions). These three patients underwent surgical treatment with satisfactory effect on follow-up.

**GOO Group**

Of the seven patients with GOO alone, the orifices of strictures were all located in the gastric antrum. Four patients (4/7, 57.1%) had persistent symptom relief (average follow-up 30±15.8 months). These patients received a total of 22 dilation sessions with an average number of sessions being 5.5±2.1 per patient over a median period of 6.0±1.0 weeks. In other three (3/7, 42.9%), there was EBD-induced perforation over channel of GOO. These patients were treated with subtotal gastrectomy successfully.
No surgery-related complication or mortality occurred.

**ES+GOO Group**

Of the eleven patients with ES+GOO, three had orifices of ES located at upper third section of the esophagus, four the middle third, and four the lower third. The orifices of GOO were all located over the antrum. Four patients (4/11, 36.4%) achieved persistent symptom relief (average follow-up 35±27.2 months) (figure 1). These patients received a total of 55 dilation sessions with an average number of sessions being 13.8±4.9 per patient over a median period of 21.0±15.1 weeks. The outcomes of the other seven patients (7/11, 63.6%) were unsuccessful. Major complication related to EBD occurred in four patients (4/11, 36.4%), including perforation over channel of GOO in two and active bleeding in two. EBD was discontinued, and these patients received subtotal gastrectomy. The other three (3/11, 27.3%) had no symptom relief after serial dilations (10, 12 and 13 sessions) and, then, received gastrojejunostomy and esophagectomy with colon interposition. There was no operative complication in these patients.

The successful rates of ES, GOO, and ES+GOO response to EBD were 83.3%, 57.1% and 36.4% respectively. The reasons of treatment failure were perforation (6 cases, 6/36=16.7%), ineffectiveness of dilation (5 cases, 13.9%) and active bleeding (2vcases, 5.6%). The overall incidence of major complications was 3.3% per dilation
session (8/239), including 2.5% (6/239) with perforation and 0.8% (2/239) with bleeding. As can be seen in table 2, which summarizes our comparisons of ES, GOO, and ES+GOO response to EBD, patients with ES alone had a significantly better treatment response to EBD than those with either GOO or ES+GOO (ES 15/18, 83.3% vs. GOO and ES+GOO 8/18, 44.4%, \( P = .035 \)). Patients with ES alone had a significantly lower major complication rate than those with either GOO or ES+GOO. (ES 1/18, 5.6% vs. GOO and ES+GOO 7/18, 38.9%, \( P = .041 \)). For the effective cases, patients with ES+GOO required significantly more EBD sessions to achieve persistent symptom relief than those with either ES or GOO alone (13.7±4.9 vs. 6.0±4.4, \( P = .011 \)).

**DISCUSSION**

EBD can be performed effectively and safely from four to six weeks after corrosive injury and is the treatment of choice for most of these injuries.\(^5\,11\,12\,13\) In patients with ES, esophagectomy followed by reconstruction operation can be performed, but this very invasive procedure is grueling for both the patients and their surgeons. They should only be considered when complications are so severe that EBD fails or when patients are unable to tolerate EBD procedures. Unlike ES, surgical intervention for GOO which usually involves subtotal gastrectomy or bypass gastrojejunostomy, is not so arduous and can be performed with relatively few complications 0% to 10.7%.\(^{14,15}\)
Therefore, surgery had been used as a standard treatment of caustic-induced GOO.\textsuperscript{14,15,16} Recently, Kochhar et al. suggested that EBD was also a safe and effective treatment option in patients with corrosive-induced GOO and reported that persistent symptom relief could be successfully achieved in 95.1% of their patients with a extremely low perforation rate (2.4%).\textsuperscript{6} However, the overall success rate including both GOO group and ES+GOO group in our study was only 44.4% (8/18). One reason for this discrepancy might be that four patients (22.2%) could not tolerate this procedure and opted out of dilation. All of these four patients belonged to ES+GOO group. Since more dilation sessions were needed to treat patients with ES+GOO, these patients may have felt less inclined to continue the course of treatment. Another reason might be that patients with GOO in our study had more dilation-related major complication (7/18, 38.9%), which reduced their chance for successful outcomes.

In our series, perforation was the major cause of treatment failure (6/13, 46.1%), including five in GOO and one in ES. This complication may occur when (1) inflating a balloon catheter within a straight stricture induces perforation caused by severe laceration on the narrowest area of the stricture during radial expansion (figure 2) or (2) inflating a balloon catheter within an angulated stricture erects it forward and perforates the distal end the angulation instead of curving at the corner (figure 3). Lacerations of the narrowest areas of the stricture mainly occur when balloon
diameters were overestimated. Experienced endoscopists chose the first balloon
diameter based on the diameter of the stricture. Subsequent dilations are usually based
on the ‘‘rule of 3,’’ referring to no greater than 3 consecutive dilators in increments of
1 mm per session.\textsuperscript{17} If the balloon diameter is chosen this way, lacerations of this kind
can be avoided. The perforation in ES group belonged to this situation (figure 2).
However, when an angulated stricture is encountered, a soft deflated balloon catheter
can negotiate the angle. But once the balloon is being inflated, the bent end may rise
up and tear the distal end of the stricture, especially if the stricture is at a sharp-angle
(figure 3). When the angle is sharp, even a careful approach still can damage the wall.
The caustic GOO is often located in a curved area such as the pylorus or duodenal
bulb. The corrosive agents may also deform the antrum and make the stricture further
angulated. This increased angulation might make perforation more likely in our
patients with GOO than in those with ES.

In conclusion, EBD can be used effectively and safely to manage corrosive-induced
ES. However, its success rate decreases and perforation rate increases with the
development of GOO regardless of whether ES coexists or not. And, patients with
concomitant ES and GOO require more EBD sessions than patients with ES or GOO
alone to achieve long-lasting relief of their symptoms.
List of abbreviations

ES — Esophageal stricture

GOO — gastric outlet obstruction

EBD — endoscopic balloon dilation

ES+GOO — combination of ES and GOO

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Yi-Chun Chiu for analysis and interpretation of the data; drafting of the article

Ming-Luen Hu, Wei-Chen Tai, Seng-Kee Chuah, King-Wah Chiu for critical revision of the article for important intellectual content

William Tam for critical and English revision

Keng-Liang Wu (corresponding author) for conception and design and final approval of the article.

Acknowledgements and Funding

The authors wish to thank Ms Rong-Ting Lin, supported by NSC grant #96-2314-B-182A-063, for her help with clinical follow-up and data collection.
REFERENCES


term results of endoscopic dilatation for corrosive oesophageal strictures. Gut
1993;34:1498-501.

8. Lan LC, Wong KK, Lin SC, Sprigg A, Clarke S, Johnson PR, Tam PK.
Endoscopic balloon dilatation of esophageal strictures in infants and children: 17


10. Zargar SA, Kochhar R, Metha S, Mehta SK. The role of fiberoptic endoscopy in
the management of corrosive ingestion and modified endoscopic classification of

11. Standards of Practice Committee, Egan JV, Baron TH, Adler DG, Davila R,
Faigel DO, Gan SL, Hirota WK, Leighton JA, Lichtenstein D, Qureshi WA, Rajan
Gastrointest Endosc 2006; 63: 755-60.

12. Weintraub JL, Eubig J. Balloon catheter dilatation of benign esophageal strictures

Endoscopic dilation of benign esophageal strictures: report on 1043 procedures.


Table 1 Clinical parameters and early endoscopic findings of patients with varied corrosive gastrointestinal strictures

<table>
<thead>
<tr>
<th></th>
<th>ES (n=18)</th>
<th>GOO (n=7)</th>
<th>ES+GOO (n=11)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean±SD (years)</td>
<td>44.5±16.3</td>
<td>52±16.9</td>
<td>47.3±12.2</td>
<td>NS*</td>
</tr>
<tr>
<td>Male/Female</td>
<td>7/11</td>
<td>3/4</td>
<td>5/6</td>
<td>NS*</td>
</tr>
<tr>
<td>Acid/Alkali</td>
<td>15/3</td>
<td>7/0</td>
<td>11/0</td>
<td>NS*</td>
</tr>
<tr>
<td>Percentage of grade III injury</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Esophagus (%)</td>
<td>7 (38.9)</td>
<td>3 (42.8)</td>
<td>6 (75)</td>
<td>NS*</td>
</tr>
<tr>
<td>Stomach (%)</td>
<td>8 (44.4)</td>
<td>7 (100)</td>
<td>11 (100)</td>
<td>0.001</td>
</tr>
<tr>
<td>Duodenum (%)†</td>
<td>3 (16.7)</td>
<td>2 (33.3)</td>
<td>1 (20)</td>
<td>NS*</td>
</tr>
</tbody>
</table>

* no significance among varied groups

† operators refrained from forcing the scope through the pylorus in 7 cases because of severe gastric damage.

NS, no significance; ES, esophageal stricture; GOO, gastric outlet obstruction; ES+GOO, concurrent esophageal stricture and gastric outlet obstruction; SD, standard deviation.
Table 2 Comparisons of the outcomes of endoscopic balloon dilation in patients with varied corrosive gastrointestinal strictures

<table>
<thead>
<tr>
<th></th>
<th>ES (n=18)</th>
<th>GOO (n=7)</th>
<th>ES+GOO (n=11)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieving persistent symptom relief, No.</td>
<td>15 (83.3%)</td>
<td>4 (57.1%)</td>
<td>4 (36.4%)</td>
<td>0.035</td>
</tr>
<tr>
<td>Major complication induced by EBD, No.</td>
<td>1 (5.6%)</td>
<td>3 (42.9%)</td>
<td>4 (36.4%)</td>
<td>0.041</td>
</tr>
<tr>
<td>Sessions of dilation to achieve persistent symptom relief, mean±SD*</td>
<td>6.1±4.7</td>
<td>5.5±2.1</td>
<td>13.7±4.9</td>
<td>0.011</td>
</tr>
</tbody>
</table>

* for patients with effective outcome

ES, esophageal stricture; GOO, gastric outlet obstruction; ES+GOO, concurrent esophageal stricture and gastric outlet obstruction; SD, standard deviation.
LEGENDS

Figure 1 A 51 years-old woman with ingestion of corrosive agent. Stricture developed at lower esophagus (A) and distal antrum (B) concurrently 6 weeks after injury. After 17 sessions of dilation in total, both of esophageal stricture (C) and gastric outlet obstruction (D) were widened, and the scope could pass through them.

Figure 2 Illustrating the development of perforation in case of straight stricture (A) before and (B) after inflating balloon catheter. The perforation (arrow head) may occur at the narrowest site.

Figure 3 Illustrating the development of perforation in case of angulated stricture (A) before and (B) after inflating balloon catheter. The perforation (arrow head) may occur at the curved portion.