



## Long-term Results of Endoscopic Balloon Dilatation for Gastric Outlet Obstruction Caused by Peptic Ulcer Disease

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### ABSTRACT

#### BACKGROUND

Gastric outlet obstructions (GOO) is a disabling complication of peptic ulcer disease (PUD). The introduction of endoscopic through the scope balloon dilatation (EBD) has eased the management but there are few reports on the long term results of this modality of treatment on patients' symptoms.

#### METHODS

Over a period of 4 years from January 2012 to December 2015 in two major referral hospitals affiliated to Shiraz university, medical endoscopy reports were reviewed retrospectively to identify those who received EBD for the treatment of GOO due to PUD. All of these patients were recalled and their current status were evaluated.

#### RESULTS

22 consecutive patients with symptomatic GOO secondary to benign stricture underwent endoscopic balloon dilatation by a single operator. Of them, 14 had balloon dilatation twice and 6 had ballooning three times. The interval between the first referral and the last follow-up was  $25.2 \pm 10.3$  (min: 4.8 max:43.4) months.

The averages of maximum balloon size were  $14.4 \pm 5$  mm in the first session,  $14.3 \pm 3.1$  mm in the second session, and  $16 \pm 2.4$  mm in the third session. 73% of the patients had a significant improvement in clinical symptom with two sessions of EBD and did not require repeat dilatation.

#### CONCLUSION

EBD is a safe and efficient method in the management of GOO with good long term results.

#### KEYWORDS:

Duodenal Ulcer, Stomach Ulcer, Gastric Outlet Obstruction, Endoscopy, *Helicobacter Pylori*

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### INTRODUCTION

Gastric outlet obstruction (GOO) is known as a clinical and pathophysiological complication of some diseases, which interrupts gastric emptying and is characterized by postprandial fullness, abdominal discomfort, and vomiting due to mechanical obstruction in the outlet of stomach. The entity includes obstructive lesions in the antropyloric area, and the bulbar or post bulbar duodenal segments.



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The term GOO is a misnomer since many cases are not due to isolated gastric pathology, but rather involve duodenal or extraluminal disease.

Though malignancy remains as an important cause of GOO in adults,<sup>1,2</sup> a significant number of patients with GOO have benign diseases. Among the latter are peptic ulcer disease, caustic ingestion, post-operative anastomotic strictures, and inflammatory causes including Crohn's disease and tuberculosis. Less common causes include chronic pancreatitis, annular pancreas, and non-steroidal anti-inflammatory drug-induced strictures.<sup>1,2</sup>

Despite numerous studies, the incidence of GOO is not exactly clear. It seems that the incidence and prevalence of GOO have declined in recent years due to widespread use of proton pump inhibitors (PPIs). A recent study reported that the incidence of GOO had been less than 5% in patients with PUD, the leading cause of benign GOO.<sup>3</sup>

The pattern of the disease has changed substantively with the introduction of more effective treatment of acid peptic disease including eradication of *Helicobacter pylori* (*H. pylori*) and the use of PPIs. Studies showed that until 1970s, benign diseases were the most common causes of GOO while 10-39% of GOO was due to malignancy.<sup>3-7</sup> In contrast, in recent years, 50-80% of GOO is due to malignant cause.<sup>3</sup>

The most common clinical symptoms among patients with GOO were epigastric pain (94%), vomiting (92%), weight loss (63%), early satiety (53%), and bloating (50%).<sup>8</sup>

Although the diagnosis of GOO may be suspected based on clinical symptoms and physical examination but it should be confirmed by radiological evaluation and/or endoscopy. Upper endoscopy is often needed to exclude malignancy.

In past years the only available treatment for GOO was surgical drainage procedures with variable success rates and many complications. There are concerns about the physiological effects of these procedures, which could result in reducing quality of life.<sup>9</sup> The introduction of endoscopic through the scope balloon dilation (EBD) has simplified the treatment without the need for surgery.<sup>9</sup> Although there is risk of perforation in complex strictures, it is considered more physiological treatment with overall less hazards for the patients.<sup>9</sup>

There are few studies on the long term follow up of this treatment for GOO due to PUD. In this study we report our experience with this treatment.

## MATERIALS AND METHODS

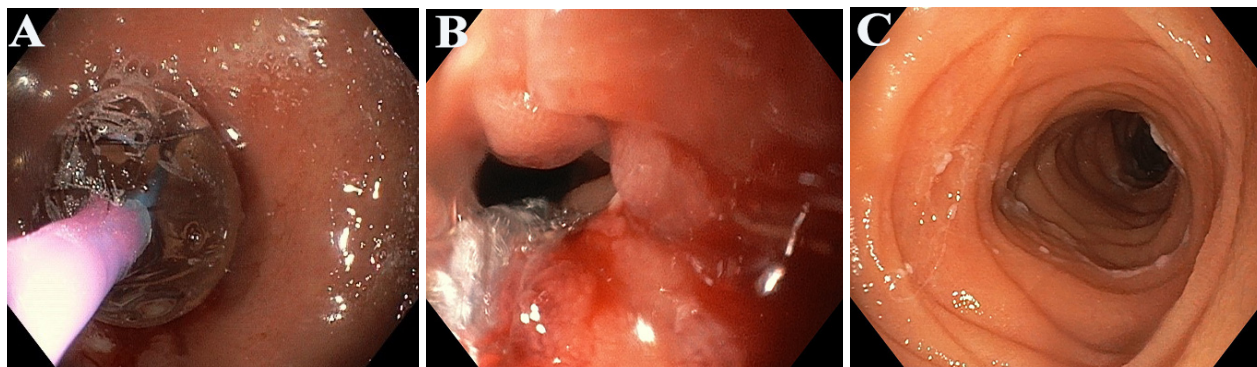
Over a period of 4 years from January 2012 to December 2015 in two major referral university-affiliated hospitals in Shiraz (Nemazee and Faghihi hospitals), medical endoscopy reports were reviewed retrospectively to identify those who received EBD for the treatment of GOO due to PUD. The patients were excluded if they had malignancy.

A total of 22 cases were found who received EBD for GOO secondary to PUD. All of them were recalled in 2016-2017 and were evaluated clinically. Their clinical symptoms evolution after EBD were specifically asked using a 5- digit score (the worse was 5) done at least on two sessions of clinical visits by two different interviewer to increase the validity. The questioned symptoms were: nausea, vomiting, reflux, weight loss, and abdominal pain. Their hospital and outpatient files were also reviewed.

### Procedure:

Patients should not receive anything by mouth for at least 12 hours. Endoscopic dilatation was performed under conscious sedation by titrated intravenous opiate and benzodiazepine (midazolam and meperidine). We used through the scope (TTS) balloon (Boston Scientific CRE wire guided, esophageal/pyloric wire guided balloon dilatation catheter, Business & Technology Park, Cork, IRELAND) sizes between 12-18 mm based on the estimation of the operator. We usually started with 12 mm and increased the diameter up to 3 mm in each session. The TTS balloon was positioned across the stricture with endoscopic control over the guide wire inside the balloon. The balloon was distended with air up to 3-4.5 atmosphere according to the manufacturer's instruction and maintained in position for maximum 45 second. The balloon was then deflated and two more dilatations were performed in the same manner in each session. We did not use radiological control. After the procedure we passed the scope to second part of the duodenum to see the post-stricture mucosa (figure 1).

Patients were discharged after 4 hours of observation following the procedure with access to emergency visit if they felt pain or any other discomfort. A control endoscopy was done on one month after EBD. Repeat EBD was done whenever symptoms recurred and/or if strictures were still present in the 1-month follow-up



**A.** Balloon dilatation with endoscopic control of pyloric channel  
**B.** The immediate view of pyloric channel after dilatation  
**C.** The passage of endoscope to second part of duodenum after dilatation for monitoring of possible complication and for evaluation of distal parts

**Fig.1:** The endoscopic view of the procedure

endoscopy. All patients were treated with PPIs in full therapeutic doses (omeprazole 20 mg twice a day or its equivalent from other PPIs) for 3 months after dilatation. *H. pylori* infection was investigated in the first endoscopy by taking at least two biopsy samples from the antrum and those with infection received eradication treatment with quadruple therapy (PPI, amoxicillin, Bismuth subcitrate, and metronidazole for the first time treatments and levofloxacin, amoxicillin, and PPI for those who had history of previous eradication treatment). Confirmation of eradication was done with *Helicobacter stool* Ag assay 1 month after discontinuation of PPI.

Descriptive statistics for categorical and continuous variables were reported as frequency (percent) and median (IQR: Inter quartile range), respectively. To assess the effect of dilatation, score of each symptom was compared before and after the 1st and 2nd and other dilatation using Wilcoxon test. Mann Whitney U test was also used to compare the differences of periods between the 1st, 2nd, and time of interview. All the statistical analyses were performed using SPSS software version 18.0 and level of significant was considered as 0.05.

## RESULTS

During the 4-year period, 22 patients with GOO due to benign conditions received EBD in these two centers. The mean age of the patients was  $56.4 \pm 19.3$  years while most of them were male (68.2%) and non-smoker (72.2%) (table 1).

None of the patients were alcohol or substance users.

Of the 22 participants, 14 had two sessions of balloon dilatation and 6 cases had ballooning three times. The interval between the first referral and last follow-up was  $25.2 \pm 10.3$  (min:4.8, max:43.4) months. The average maximum sizes of the balloons used in the first session were  $14.4 \pm 5$ mm,  $14.3 \pm 3.1$  mm in the second, and  $16 \pm 2.4$  mm in the third session. 73% of the patients had a significant improvement in clinical symptom with two sessions of EBD and did not need to receive repeat dilatation. Others had to receive further sessions with maximum of 7 in one patient (table 1).

Table 2 shows the evolution of each symptom after dilatation. Figures 2 and 3 and table 3 (in supplement) demonstrate the effect of dilatations on each of the symptoms after dilatation and reveal improving of all of the five symptoms naming nausea, vomiting, reflux, weight loss, and abdominal pain after each session of dilatation. Median of the total score of patients' symptoms before the first dilatation was  $21.1 \pm 4.4$  that was significantly decreased to  $10.9 \pm 5.2$  ( $p < 0.001$ ) after the first session. Also the median of total score of symptoms before and after the second dilatation were 18.4 and 10.0, respectively. All patients reported improvement after dilatation in all sessions. The body mass index of the patients increased from median  $19.4 \pm 3.8$  to  $22.3 \pm 3.4$  after the first session of balloon dilatation ( $p < 0.001$ ). At the end of treatment and follow-up all patients were comfortable and asymptomatic.

Only three patients had positive histological findings for *H. pylori* and were treated as described above. There was no significant difference between those with active

Table 1: Patients and procedure characteristics

Characteristics	Amount/n (%)
<b>Age (year)</b>	
Mean ± SD	56.4 ± 19.3
Median (min-max)	60 (27-91)
<b>Sex</b>	
Male	15(68.2)
Female	7(31.8)
<b>Smoking</b>	
Yes	9 (40.9)
No	13 (59.1)
<b>Number of gastric ballooning</b>	
Mean ± SD	2.2 ± 1.7
Median (min-max)	2 (1-7)
<b>Maximum diameter of balloon (mm)</b>	
Mean ± SD	14.2 ± 4.6
Median (min-max)	14.5 (6.5-30)

Table 2: Evolution of symptoms after balloon dilation

Body mass index- Before 1 <sup>st</sup> ballooning (kg/m <sup>2</sup> )		Body mass index-After 1 <sup>st</sup> ballooning (kg/m <sup>2</sup> )	
Mean ± SD	19.4 ± 3.8	Mean ± SD	22.3 ± 3.4
Median (min-max)	19.7 (11.7-28.1)	Median (min-max)	22.6 (12.5-26.3)
<b>Nausea: Before-after 1<sup>st</sup> Ballooning (n = 22)</b>		<b>Nausea: Before-after 2<sup>nd</sup> ballooning (n = 14)</b>	
Very severe and intolerable	7 (31.8)-1(4.5)	Very severe and intolerable	3 (13.6)-0(0)
Severe but tolerable	10 (13.6)-1(4.5)	Severe but tolerable	3 (13.6)-1 (4.5)
Moderate and very often	3 (13.6)-1(4.5)	Moderate and very often	3 (13.6)- 1(4.5)
Moderate and sometimes	0(0)-5 (22.7)	Moderate and sometimes	3 (13.6)-1 (4.5)
Weak	2(9.1)-9(40.9)	Weak	2 (9.1)- 6 (27.3)
No	0(0)-5(22.7)	No	0 (0)- 5 (22.7)
<b>Vomiting: Before-after 1<sup>st</sup> ballooning (n = 22)</b>		<b>Vomiting : Before-after 2<sup>nd</sup> ballooning (n = 14)</b>	
Very severe and intolerable	8 (36.4)- 0(0)	Very severe and intolerable	3 (13.6)- 0 (0)
Severe but tolerable	4 (18.2)- 1(4.5)	Severe but tolerable	4 (18.2)- 1 (4.5)
Moderate and very often	4 (18.2)- 2 (9.1)	Moderate and very often	2 (9.1)- 0 (0)
Moderate and sometimes	4 (18.2)- 6 (27.3)	Moderate and sometimes	1 (4.5)- 1 (4.5)
Weak	0 (0)- 7 (31.8)	Weak	2 (9.1)- 6 (27.3)
No	2(9.1)- 6 (27.3)	No	2 (9.1)- 6 (27.3)
<b>Reflux: Before-after 1<sup>st</sup> allooning (n = 22)</b>		<b>Reflux: Before-after 2<sup>nd</sup> ballooning (n = 14)</b>	
Very severe and intolerable	2 (9.1)- 1(4.5)	Very severe and intolerable	1 (8.3)- 1 (4.5)
Severe but tolerable	5 (22.7)- 1(9.1)	Severe but tolerable	1 (8.3)- 1 (4.5)
Moderate and very often	4 (18.2)- 0 (0)	Moderate and very often	2 (16.7)- 0(0)
Moderate and sometimes	3 (13.6)- 4 (18.2)	Moderate and sometimes	2 (16.7)- 2 (9.1)
Weak	0 (0)- 3 (13.6)	Weak	5 (41.7)- 4 (18.2)
No	8 (36.4)-12(54.5)	No	1 (8.3)- 6 (27.3)

Weight loss: Before-after 1st ballooning (n = 22)		Weight loss: Before-after 2nd ballooning (n = 14)	
Very severe and intolerable	5 (22.7)- 1(4.5)	Very severe and intolerable	1 (8.3)- 1 (4.5)
Severe but tolerable	8 (36.4)- 1 (4.5)	Severe but tolerable	1 (8.3)- 1 (4.5)
Moderate and very often	4 (18.2)- 0(0)	Moderate and very often	2 (16.7)- 0(0)
Moderate and sometimes	1 (4.5)- 4 (18.2)	Moderate and sometimes	4 (18.2)- 0(0)
Weak	3 (13.6)- 8(36.4)	Weak	5 (41.7)- 5 (22.7)
No	1 (4.5)- 8 (36.4)	No	1 (8.3)- 7 (31.8)
Abdominal pain: Before-after 1st ballooning (n = 22)		Abdominal pain: Before-after 2nd ballooning (n = 14)	
Very severe and intolerable	3 (13.6)- 0(0)	Very severe and intolerable	1 (4.5)- 0 (0)
Severe but tolerable	12 (54.5)- 1 (4.5)	Severe but tolerable	5 (22.7)- 1 (4.5)
Moderate and very often	2 (9.1)- 0 (0)	Moderate and very often	2 (9.1)- 0 (0)
Moderate and sometimes	3 (13.6)- 5 (22.7)	Moderate and sometimes	3 (13.6)- 2 (9.1)
Weak	1 (4.5)- 9 (40.9)	Weak	2 (9.1)- 6 (27.3)
No	1 (4.5)- 7 (31.8)	No	1 (4.5)- 5 (22.7)

**Table 3: Change of the scores of symptoms before and after ballooning**

Symptom	Time regarding ballooning	D1 <sup>1</sup> (n = 22)			D2 <sup>2</sup> (n = 14)		
		Median <sup>3</sup>	IQR <sup>4</sup>	p-value	Median	IQR	p value
Nausea	pre	5.0	1.2	< 0.001	4.0	2.2	0.002
	post	2.0	1.2		2.0	1.5	
Vomiting	pre	5.0	3.0	< 0.001	5.0	3.0	0.003
	post	2.0	2.0		2.0	1.0	
Reflux	pre	3.0	4.0	0.01	4.0	3.0	0.02
	post	1.0	2.0		2.0	2.0	
Weight Loss	pre	5.0	1.5	< 0.001	3.0	2.0	0.006
	post	2.0	2.0		2.0	1.0	
Abdominal pain	pre	4.0	2.5	< 0.001	0.0	3.0	0.002
	post	2.0	2.0		2.0	1.0	
Total score	pre	23.0	7.5	< 0.001	18.0	10.5	< 0.001
	post	10.0	9.5		9.0	8.0	

D1<sup>1</sup>: First dilatation; D2<sup>2</sup>: Second dilatation; IQR<sup>3</sup>: Interquartile range; Median<sup>3</sup>: For each of five symptoms was out of 6 and for total score was out of 30

infection with *H. pylori* and non-infected patients regarding the response to dilation. All other 19 patients had history of receiving eradication treatment for *H. pylori* infection in the past based on serology, urea breath test, or histology.

Among the 22 patients, 47% had stenosis at pyloric channel, 5% in the bulb of duodenum, and 42% in d<sup>1</sup> + d<sup>2</sup> + junction ( $p < 0.001$ ).

There was no complication in this series.

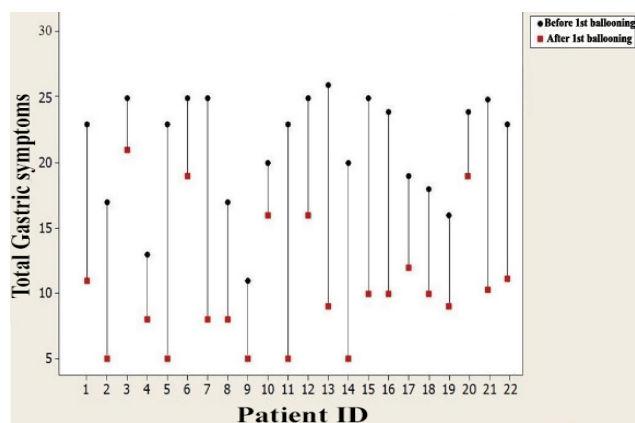
## DISCUSSION

A major cause of benign gastroduodenal obstruction is peptic ulcer disease including gastric and duodenal

ulcer.<sup>10</sup> Although surgery was considered as the main therapeutic intervention in such patients, the long term effects of surgery specially the effects of vagotomy, which is usually a part of the procedure, on the quality of life has been a major concern. Introduction of EBD was a momentum in more physiological management of this complication.<sup>10</sup>

In this study long term follow-up of 22 patients with benign GOO who were treated with balloon dilation is reported. 73% of the patient with two sessions of EBD dilatation had resolution of their symptoms while the others needed three or more sessions of EBD.





The symptom score was calculated by summation of the self-reported score of five symptoms (Nausea, vomiting, reflux, abdominal pain and weight loss) with a five digit score in which 5 was worse.

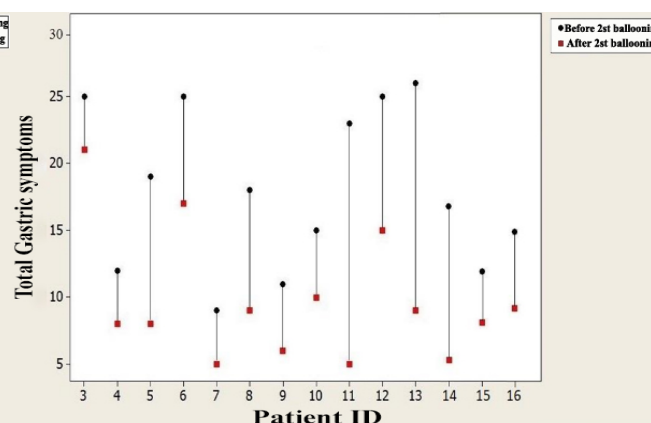
**Fig.2:** Evolution of symptom score after the first session of balloon dilation

All the five clinical symptoms improved after intervention. The BMI of the patients was also increased.

In our series, the common site of obstruction was the pylorus, d<sup>1</sup>-d<sup>2</sup> junction, and bulb of duodenum. No complication including perforation was observed in this study, which might be related to selection bias.

The incidence of GOO is not known precisely. It is likely to have declined in recent years due to decline in PUD, which has been the most cause of GOO in the past. In 1990, as many as 2000 operations for GOO were performed annually only in the United States.<sup>3</sup> Jaka and colleagues reported that the annual incidence of this complication in developed countries is 1–3 per 100,000 while in developing countries the estimated annual incidence was higher and up to 4–13 per 100,000.<sup>11</sup>

The first successful EBD of the pylorus was reported on 1982 by Benjamin and co-workers,<sup>12</sup> and the technique has been used widely since then with variable modifications. The median number of dilatations per patient ranged from 1.5 to 3 times.<sup>13–15</sup> A single balloon dilatation session was sufficient in 30–67% of patients in some series.<sup>16–17</sup> The median balloon diameter was 15 mm in reported series.<sup>18,19</sup> In our series, the mean number of sessions of EBD was 2.4. 16 individuals (73%) had resolution of symptoms after two times ballooning with a median balloon diameter of 14.2 mm. No patient in our series was satisfied with one session of intervention and all needed more than one EBD. This might be related to our more conservative approach or our longer follow-up. The balance between speed and safety should be a major concern when performing EBD. This mandates starting with smaller size of balloons and more conservative



The symptom score was calculated by summation of the self-reported score of five symptoms (Nausea, vomiting, reflux, abdominal pain and weight loss) with a five digit score in which 5 was worse.

**Fig.3:** Evolution of symptom score after the second session of balloon dilation

approach.<sup>20</sup> In a recent study on EBD for PUD, the mean number of dilations required was three, which is in concordance to our study.<sup>21</sup>

There are other reports indicating EBD produced short- and medium-term remission and symptom improvement in 65–88% of patients with an immediate success in 76–100% of patients.<sup>21–24</sup> But even in these studies the relapse rate was as high as 39% with need for surgery in up to 29%.<sup>24</sup>

We used histology to pursue active *H. pylori* infection in our patients. *H. pylori* eradication after EBD has been associated with higher remission rate and less relapse.<sup>20,23</sup> Our patients with active infection were too few to see any difference. There are also reports of lower success rate of EBD in the presence of smoking and alcohol consumption.<sup>20</sup> None of our patients were alcohol users and most were non-smokers.

All of the symptoms of the patients in our series except for reflux improved after the first dilation. The earliest improvements were for nausea and abdominal pain after the first dilation followed by weight gain. In the second session nausea, vomiting, and abdominal pain decreased, but there was no clear improvement in the number of reflux and no further weight gain. Our hypothesis about the cause of failure in reflux is the presence of some form of gastric dysmotility in these patients.

This study showed that ballooning dilatation for GOO due to PUD is a safe and efficient method and may eliminate the need for surgery and its related complications in selected patients. Whether these results could be achieved in other etiologies of GOO is a matter of debate. It has been recently shown that strictures due to

caustic ingestion are more complex with higher rates of non-responsiveness to EBD, higher rates of perforation, and higher number of EBD sessions.<sup>20,21</sup>

This study was in a relatively highly selected patients with no coagulopathy, no severe comorbid disease contraindicating outpatient management, and was done by a single operator with more than two decades of experience in therapeutic endoscopy. These results could not be generalized to all patients and in all centers.

To further establish the benefit of balloon dilatation in patients with benign GOO, controlled and prospective cohort studies with larger numbers of patients might be needed.

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