



# Food Intolerance After Banded Gastric Bypass Without Stenosis: Aggressive Endoscopic Dilation Avoids Reoperation

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## Abstract

**Background** Roux-en-Y gastric bypass (RYGBP) controls obesity and comorbidities. However, there is no consensus on ring placement due to its complications. Surgical ring removal has been the standard approach, despite its inherent morbidity risks. Endoscopic dilation with achalasia balloon is a novel and minimally invasive option. We aimed to evaluate safety and efficacy of aggressive dilation as an outpatient procedure to treat food intolerance after banded RYGBP without stenosis; we also analyzed long-term weight regain.

**Methods** This prospective study included 63 patients presenting with more than four vomiting episodes per week. Therapeutic endoscopy with a 30-mm balloon (Rigiflex®) was performed with radioscopic guidance in the first 16 patients (25.4 %). Four dilation sessions were performed in 12 patients (19 %), three in 14 (22.2 %), two in 24 (38 %), and one in 13 (20.6 %).

**Results** Complete symptom improvement was achieved in 59 patients (93.6 %), partial improvement in 2 (3.2 %), and failure in 2, leading to ring removal by laparotomy. Complications rate was 9.5 %, including three cases of bleeding,

two intragastric ring erosions, and one pneumoperitoneum; all treated clinically with no need for reintervention. Mean preoperative body mass index (BMI) was 42.4 kg/m<sup>2</sup> and postoperative (before endoscopic treatment) BMI was 25.3 kg/m<sup>2</sup>. At a mean follow-up of 46.1 months after endoscopic intervention, mean BMI was 27.8 kg/m<sup>2</sup>.

**Conclusions** Aggressive endoscopic dilation for food intolerance is a safe and minimally invasive method that promotes symptom improvement. It avoided reoperation in 96.8 % of patients and led to a low rate of weight regain.

**Keywords** Banded gastric bypass · Silastic ring · Vomiting · Food intolerance · Endoscopy balloon dilation · Weight regain · Bariatric endoscopy

## Introduction

Roux-en-Y gastric bypass (RYGBP) is considered the gold standard operation for severe obesity, with a low mortality rate [1, 2]. However, there is no consensus on whether the placement of a ring is beneficial or not. The ring seems to be related to long-term weight loss maintenance [3], but vomiting may occur as a consequence of ring slippage, which can lead to gastric pouch outlet stenosis (GPOS) [4]. Vomiting may also occur even when there is no gastric stenosis, due to the presence of the prosthesis [5, 6].

Non-banded gastric bypass seems to be a global trend [7], but there are many patients that already have a ring implanted and may present with vomiting, requiring prosthesis removal. Despite being an invasive method that promotes the risk of intra- and postoperative complications, postoperative discomfort, hospitalization, and late return to regular activities, surgical ring removal has been the standard approach (Table 1).

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**Table 1** Author's table

Author	Surgery technique	Patients	Ring type	Ring size	Complication	Food intolerance definition	Treatment	Weight regain follow-up
Taddeucci [11]	Banded RYGBP	4	(1) silastic (3) ethibond suture	(1) 6.5 (3) 6.0	Dysphagia and emesis	No	Laparoscopic band removal (BMI, 30.07 kg/m <sup>2</sup> )	30.25 months—BMI, 32.27 kg/m <sup>2</sup>
Salinas [13]	SRVGB	89	Silastic	5.5	Persistent vomiting	No	Surgical removal (2)	5 years—BMI, 26.09±4.5 kg/m <sup>2</sup>
	SRVGB	42	Silastic	6.0	0	No	0	5 years—BMI, 28.79±5.3 kg/m <sup>2</sup>
Arceo-Olaiz [12]	Laparoscopic Banded RYGBP	30	Polipropilene	6.5	Stenosis	No	Laparoscopic band removal, after 4 unsuccessful balloon dilations	24 months—BMI, 30 kg/m <sup>2</sup>
Stubbs [10]	SRGBP	50	Silastic	5.5		No	Surgical removal: 7 (14 %)—5.5 cm 11(5.1 %)—6.0 cm	5 years, 6.8 kg ranging from 4.13 to 32.2 kg
	SRGBP or Fobi pouch	215	Silastic	6.0	Regurgitation >3 times/week or		3 (2 %)—6.5 cm	
	SRGBP	150	Silastic	6.5	Major food intake restriction		Surgical removal (n=9)	
Crampton [6]	SRGBP	64	Silastic	5.5	Difficult food intake	No	Surgical removal (n=1)	10–24 months: 10 kg ranging from 4 to 28 kg
	SRGBP	24	Silastic	6.0				

Banded RYGBP banded Roux and Y gastric bypass, SRVGB silastic ring vertical gastric bypass, SRGBP silastic ring gastric bypass

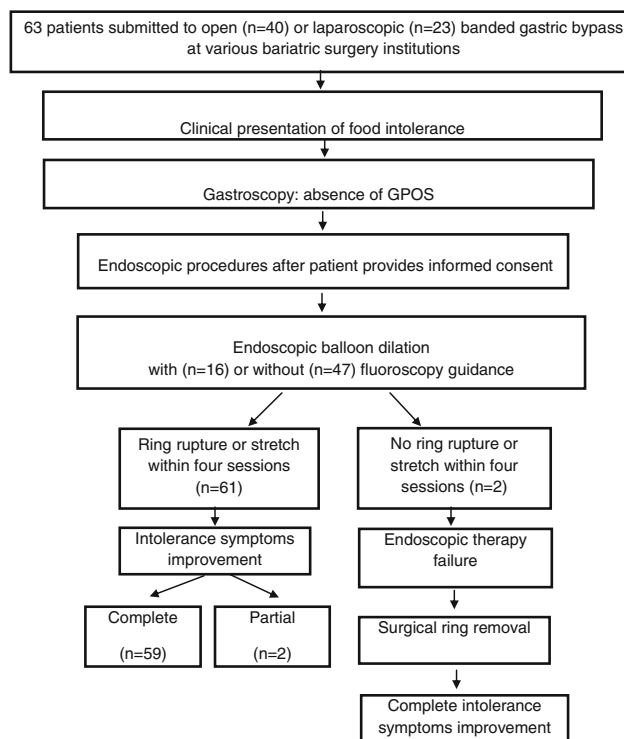
Endoscopic dilation with achalasia balloon has emerged as a less invasive option. This procedure promotes either rupture or stretching of the thread running inside the ring, resolving patient's symptoms [4].

We aimed to evaluate the safety and efficacy of aggressive dilation as an outpatient procedure for the treatment of solid food intolerance after banded RYGBP without GPOS. Long-term weight regain after this procedure was also analyzed.

**Methods**

Sixty-three patients [45 women (71.4 %); mean age 42.4 years] with an average preoperative body mass index (BMI) of 42.4 kg/m<sup>2</sup> who underwent either open (n=40) or laparoscopic (n=23) banded (silastic ring) RYGBP at various Brazilian bariatric surgery institutions took part in this study. Balloon dilation was performed at two institutions of gastrointestinal endoscopy and surgery in Brazil, with extensive experience in the management of bariatric surgery postoperative complications (Fig. 1, Table 2).

In this longitudinal prospective study, we evaluated the endoscopic management of food intolerance. From 2002 to 2011, the authors enrolled all patients who underwent banded RYGBP and were referred to us with food intolerance symptoms of greater than four vomiting episodes per week due to solid food. All patients had good dental health.



**Fig. 1** Flow chart of food intolerance treatment

**Table 2** Demographic data and descriptive analysis

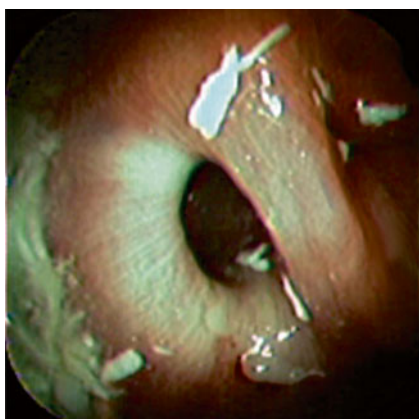
Variable	Average
Age (years)	42.4
Sex (71.4 % women)	
Preoperative BMI (kg/m <sup>2</sup> )	42.4
Time RYGBP—dilation (months)	35.5
Dilation BMI (kg/m <sup>2</sup> )	25.3
Follow-up after dilation (months)	46.1

Exclusion criteria were gastrojejunal anastomotic stenosis, gastric stenosis due to ring slippage, or presence of a ring other than a silastic ring. The local institutional review board approved this study and all patients provided informed consent. Patients who refused endoscopic procedure or presented with any contraindications were referred for surgical ring removal.

Food intolerance was considered when patient presented with vomiting episodes and was confirmed by upper digestive endoscopy to be without GPOS, allowing standard 9.8 mm endoscope passage. The endoscopic procedure was then indicated based on the clinical symptoms (Fig. 2). Four patients were not suitable to undergo endoscopic dilation based on exclusion criteria: two cases of food intolerance due to ring slippage, one case of gastrojejunal anastomotic stenosis, and one had a ring other than a silastic ring which was removed by laparoscopy. The other three underwent a different endoscopic technique.

Patients who had some degree of malnutrition received nutritional counseling with specific replacement of deficient nutrients, which usually involved dense liquid nutrition. After stability of minimal nutritional status, endoscopic procedure was performed.

The procedures were carried out in outpatient endoscopic units under deep sedation, with the presence of a consultant



**Fig. 2** Gastric pouch endoscopic image evidencing presence of food due to delayed gastric emptying caused by the ring, despite endoscopic free passage

anesthesiologist. A standard flexible endoscope was used in all procedures. The ring area in the gastric pouch was dilated up to 30 mm, using a Rigiflex<sup>®</sup> balloon (Boston Scientific, Natick, MA), which was gradually inflated (maximum 20 psi), according to endoscopic technique as previously described [5].

The aim was to promote rupture or stretch of the thread running inside the ring, widening the luminal diameter (Fig. 3). The first 16 (25.4 %) procedures were performed under fluoroscopic guidance. After that, according to early experience, sessions were performed exclusively under endoscopic control. Each dilation session lasted 5 to 30 min, per protocol.

When thread rupture or appropriate pouch diameter for symptoms resolution were not achieved after the first session, the procedure was subsequently performed every other week up to four sessions, until symptoms resolved. Patients who still showed four or more vomiting episodes after four sessions were considered treatment failures and referred to surgery. Patients presenting with up to two vomiting episodes per week after four sessions were considered to have partial symptom improvement. No vomiting episodes corresponded to complete symptom improvement. Symptom recurrence, procedure complications, and long-term weight regain were also evaluated.

Data analysis was carried out using one-way ANOVA, chi-square, and Tukey test with SPSS software, version 13. An alpha risk of 5 % was assumed for statistical significance.

## Results

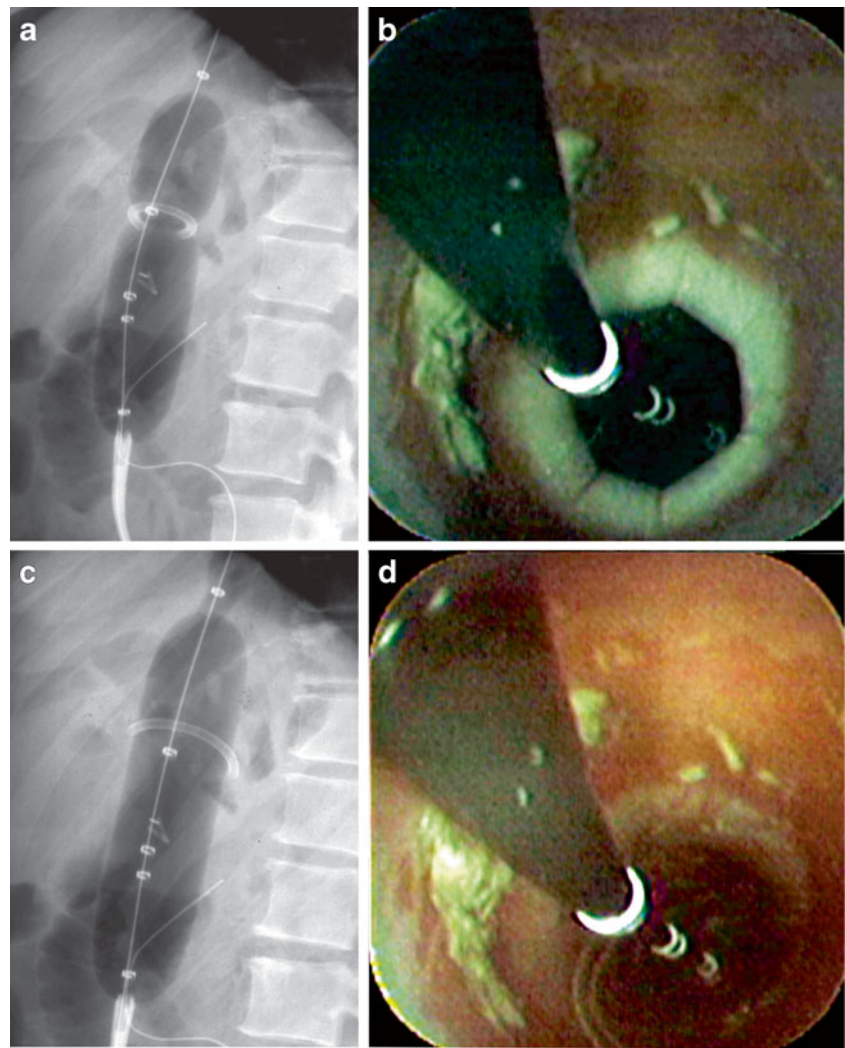
Endoscopic dilation for vomiting treatment was performed an average time of 35.5 months (range, 11 to 156 months) after banded RYGBP. At the time of the first session, mean BMI was 25.3 kg/m<sup>2</sup> (range, 17.9 to 40 kg/m<sup>2</sup>; Table 2).

Number of dilations was indicated according to each patient's symptom improvement, ranging from one to four. Four sessions were needed in 12 (19 %), three in 14 (22.2 %), two in 24 (38 %), and one in 13 (20.6 %) patients.

Symptom improvement was reached in 61 cases: 59 (93.6 %) demonstrated complete improvement and two (3.2 %) had partial improvement (Table 3). These two patients with partial improvement reported that symptom relief was adequate and opted to quit further dilations. As the prior surgery was a laparotomic RYGBP, the two patients who failed to achieve improvement were referred for surgical ring removal by laparotomy, considering the existent adhesences.

There was no symptom recurrence in the group of patients showing improvement (complete or partial) at a mean of 46.1 months follow-up. At this time, mean BMI increased from 25.3 to 27.8 kg/m<sup>2</sup> (Table 4).

**Fig. 3** X-ray and endoscopic image of gastric pouch evidencing Rigiflex® balloon inflated revealing ring compression. X-ray and endoscopic image evidencing ring opened ring after few minute dilation



In terms of complications related to the procedure, three (4.7 %) cases of bleeding were found and treated with adrenaline solution injection, hospitalization (ranging from two to four days) for observation, liquid diet, sucralfate, double dose proton pump inhibitor administration, endoscopic control, and hematologic tests. There was no need for blood transfusion in any case. Two (3.2 %) intragastric ring erosions were identified and treated by endoscopic removal using scissors and foreign body forceps [8], and one (1.6 %) case of pneumoperitoneum managed with hospitalization for clinical treatment, which included antibiotic therapy and nothing per oral for 2 days. After clinical

improvement, liquid diet was initiated, being the patient discharged after two more days (Table 5).

## Discussion

Although silastic ring placement is associated with long-term weight control and maintenance [3, 7, 9], its placement is still a matter of controversy since it may cause complications such as intraluminal erosion, slippage, gastric stenosis, and food intolerance without GPOS.

**Table 3** Endoscopic treatment outcomes

Symptoms follow-up	No.	Percent
Complete symptoms improvement	59	93.6
Partial symptoms improvement	2	3.2
Surgical ring removal	2	3.2

**Table 4** BMI analysis before and after endoscopic dilation

Variable	Average	<i>p</i> value
Preoperative BMI	42.4	<0.001
Dilation BMI	25.3	
Current BMI	27.8	

*p* value ANOVA; Tukey 1–2 and 1–3 (*p* value<0.001); Tukey 2–3 (*p* value=0.019)

**Table 5** Mild complications due to aggressive balloon dilation

Procedure complication	No.	Percent
Bleeding	3	4.7
Intragastric ring erosion	2	3.2
Pneumoperitoneum	1	1.6

Currently, non-banded gastric bypass seems to be a global trend [7], but there are a large number of patients with an implanted ring that may present with gastric stenosis or the newly defined food intolerance without GPOS. Both conditions may lead to vomiting, excessive weight loss, and malnutrition, which are unfavorable factors for surgical ring removal. Despite this, surgery has been the standard approach at many institutions worldwide.

In 2006, Stubbs et al. presented a prospective study in which 5 % of 415 banded gastric bypass patients underwent surgical ring removal due to major restriction to eating [10]. Surgical intervention in these cases is more challenging once ring adherence to the gastric pouch is considered, with a greater risk of perforation and bleeding [11].

These ring complications have been treated by endoscopy at our medical service with high success rates, low morbidity, and no mortality [4]. We also described the use of endoscopic dilation with a 30-mm Rigiflex® balloon as treatment of GPOS due to ring slippage [5].

In the current study, food intolerance was not related to GPOS but was also treated with endoscopic dilation. This was a safe outpatient approach that avoided surgical procedures and their associated complications in 96.8 % of patients.

Despite the safety of the endoscopic procedure, the occurrence of balloon distal slippage in three of the initial cases was responsible for the one case of pneumoperitoneum and three digestive bleeding during balloon dilation. However, such events can be avoided through gradual balloon inflation using a manometer and by firmly holding the balloon catheter [4].

Although discussed in the literature (Table 1) [6, 10–13], patients presenting with food intolerance are a poorly defined group as there is no consensus to characterize the clinical presentation and give a proper diagnosis. We defined food intolerance as absence of GPOS, allowing 9.8 mm endoscope passage with no difficulty through the ring area. Nevertheless, this group may present with solid food intolerance, major dysphagia, and more than four vomiting episodes per week [5, 8].

Balloon dilation consists of attempting to rupture or stretch the internal ring thread, leading to symptom improvement. However, if the ring is closed, as in an adjustable gastric band with a locker and no internal tying, dilation should not be performed. Gastrointestinal ischemia at the ring area is another contraindication due to the risk of perforation [14].

Concerning the authors' experience, balloon dilation may cause weight regain and, in some cases, should not be performed [4]. In cases like VBG, where the gastric pouch is involved by a Marlex mesh, endoscopic dilation has resulted in mild food intolerance improvement but with early recurrence. If the ring has a lock with no internal thread, as in adjustable gastric bands, balloon dilation is not indicated [15]. Thus, the authors restricted this procedure indication only for cases involving a silastic ring with internal thread.

If the thread is not ruptured, the balloon will at least cause stretching, leading to a wider gastric pouch diameter at the ring site. It is not possible to determine precisely whether the thread is going to rupture or stretch. Silk thread is more likely to rupture than polyester thread. As it is more elastic, polypropylene thread tends to stretch during balloon dilation [4].

Procedures were performed under deep sedation because 30 mm balloon inflation usually causes abdominal pain, which may persist for several minutes after balloon deflation. When patients presents with shoulder and back pain, pneumoperitoneum can be in the differential diagnosis. After performing 16 procedures under fluoroscopy, endoscopic guidance was then elected. This technique proved to be safe, with no cases of pneumoperitoneum in those performed without fluoroscopic guidance. Additionally, this procedure avoids radiation exposure and allows the dilation session to be an outpatient procedure [16].

Endoscopic guidance reveals effective dilation during the procedure, once the extrinsic compression is no longer observed. Immediately after balloon deflation, an increase in the diameter of the gastric pouch is seen. As a collateral effect, the gastrojejunal anastomosis is also dilated because the balloon has a 10 cm length and the gastric pouch a 5 to 7 cm length. This could lead to dumping syndrome in some cases, which can be improved with clinical management.

Weight regain of patients presenting with intraluminal ring erosion is described in the literature [8]. Similar weight regain was expected after balloon dilation and surgical ring removal [8, 11], due to interruption of the restrictive function of the ring. However, in this study, patient's BMI only increased from 25.3 to 27.8 kg/m<sup>2</sup>. This indicates that non-banded RYGBP also achieves good results and that silastic ring restriction is not the exclusive determinant factor in terms of weight loss maintenance.

As an outpatient procedure, the technique described here has advantages when compared to inpatient surgery, including reduced cost, less stressful environment, and more rapid patient discharge. In addition, this minimally invasive procedure has a high success rate with more than 96 % of patients reporting complete or partial symptom resolution, low morbidity, and no mortality. Despite the two patients in

this study who failed to achieve improvement and had the ring removed by laparotomy, currently at our service, the laparoscopic procedure has been our first choice when surgical ring removal is needed.

Complications related to the procedure are infrequent and can be managed without the need for reoperation.

In conclusion, food intolerance is a condition that may occur even when GPOS is absent. Breaking the paradigm of surgical resolution, aggressive endoscopic dilation for the treatment of food intolerance is as a viable, safe, and minimally invasive alternative, with a low rate of weight regain.

**Conflict of Interest** Drs. Álvaro Ferraz, Josemberg Campos, Victor Dib, Lyz B. Silva, Patricia S. de Paula, Amador Gordejuela, Francisco Felipe Rolim, Luciana Siqueira, and Manoel Galvão Neto declare that they have no conflict of interest or financial ties to disclose.

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