## **CLINICAL REPORT**

# Ten Years Experience of Banded Gastric Bypass: Does It Make a Difference?

William Awad · Alvaro Garay · Cristián Martínez

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Abstract Many surgeons support some sort of restriction of the gastric pouch outlet by placing a ring around the gastric reservoir. Previous studies have shown positive results of banded gastric bypass (BGBP); however, there are not many comparative long-term studies to assess the real advantage of placing a ring during gastric bypass (GBP) surgery. This study aims to evaluate the long-term outcome of patients subjected to BGBP and nonbanded GBP procedures. We studied 260 retrospective, nonrandomized obese patients who underwent BGBP and 218 patients without the ring (i.e., GBP). They were followed up for 10 years, and the following parameters were evaluated: excess weight loss (EWL), quality of life (QOL), food tolerance, and correction

of comorbidities. The study was approved by the Committee on Ethics, and all the patients gave their informed consent. There is a significant difference in %EWL from the third year until the tenth year of observation, with the proportion being 82% in BGBP versus 63% in nonbanded GBP patients at the end of the study. Although there was some increased intolerance to food intake in the BGBP patients, this was not felt to reduce the QOL. The outcome in terms of comorbidities was not conclusive. There is a clear advantage in terms of %EWL in the BGBP patients. No differences in QOL were found in both groups. Further, selecting the right type of material and the right size of the ring is important to improve results and avoid complications.

W. Awad (⊠)

Department of Surgery, Hospital Clínico Universidad de Chile, Eliodoro Yáñez 2035, P.O. Box 16556-9, Providencia, Santiago, Chile

 $e\hbox{-mail: williamawad} @obesidadycirugia.cl\\$ 

W. Awad · A. Garay Department of Surgery, Clínica Las Lilas, Santiago, Chile

A. Garay

e-mail: agamoff@gmail.com

W. Awad Department of Bariatric Surgery, Clínica Las Lilas, Santiago, Chile

C. Martínez Department of Surgery, Hospital Sótero del Río, Santiago, Chile e-mail: c.marbelb@gmail.com

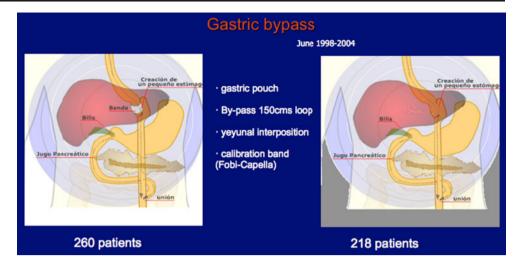
## Introduction

Gastric bypass (GBP) surgery is a very controversial subject. There have been many attempts to improve GBP outcome [1]. The idea of restricting the outlet of the gastric pouch with a ring, either transversal or vertical, came from the Mason technique of carrying out gastroplasties; the initial procedure, conducted without a restrictive band, was soon abandoned because the results were very poor. This same procedure was carried out in the early 1980s; nevertheless, as learned from Mason, there was a great improvement in the long-term follow-up when a ring was placed, avoiding the pouch- or stomach-opening dilatation and, thus, reducing weight regain [2–4].

Dr. Mal Fobi developed his particular pouch, vertical, banded, and interposing the jejunal loop over the anastomosis site, around the year 1976. At the same time, Dr. Rafael



**Fig. 1** Fobi-Capella technique for banded and nonbanded RY-GBP. Two groups of patients



Capella arrived to the same conclusion and popularized this technique in Latin America [4, 5]. Linner was the first to place a band at the gastrojejunal outlet of the bypass. Dr. Fobi began the practice of placing the ring in the anastomotic site; however, his patients faced many complications, especially migration of the band inside the stomach. Then, he started to use a silastic ring approximately a centimeter over the anastomosis, and in this way, he almost no longer detected migrations in his patients.

There is not much literature comparing the long-term results of GBP with and without a band.

This retrospective, nonrandomized study compares the long-term results at 10-year follow-up, in terms of excess weight loss (EWL) and quality of life (QOL), in a group of patients who either had or did not have a restricting outlet ring.

## **Materials and Methods**

Two hundred and sixty morbidly obese patients, with body mass index (BMI) between 35 and 39.9 kg/m<sup>2</sup>, with comorbidities, or with BMI  $\geq$ 40 kg/m<sup>2</sup>, were submitted to a

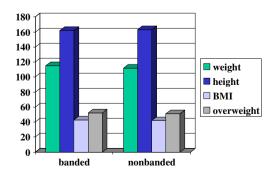
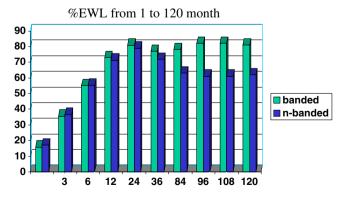


Fig. 2 Demography. Both groups of patients are equivalent



banded gastric bypass (BGBP) between June 1998 and June 2004. At the beginning, we operated in two different clinics. In one of them, we used a polytetrafluoroethylene (PTFE) vascular patch because that was available in that clinic. At the second clinic, we used a vascular patch of polyurethane, Gore-Tex® Acuseal Brand, which is a very thin, soft, and well-tolerated material.

We placed a strip of 6.5 cm, sutured with a polypropylene stitch (group A). After 2 years, we found two migrations of the band at the first clinic, and we thought it might have had some relation to the material we used at that clinic. At the same time, we wanted to know whether the ring would have any effect on EWL during the long-term follow-up; hence, we decided to perform banding only at the second clinic and not at the first one where we detected the migrations. Consequently, patients were not really randomized. We operated on 118 patients without placing a ring (group B) (Fig. 1). All the patients had indicated their informed consent. All the patients have been followed up for at least 6 years, and many of them for 10 years. Both groups have an identical demography (Fig. 2)



**Fig. 3** Comparative %EWL up to 10 years. There is a significant difference from month 36 up to 10 years

## Surgical Technique

All the patients underwent a GBP by the same surgical team, based on the Fobi-Capella [4, 5] technique. Of these, 80% of the surgeries were of the open type and 20% were conducted laparoscopically. A Roux-en-Y (RY) jejunal loop of 150 cm length was constructed with an entercenteroanastomosis at a point 50 cm distal to the ligament of Treitz. Then, a gastric pouch of approximately 20 ml volume was created. In group A, a 6.5-cm-long and 7mm-wide polyurethane (Gore-Tex®) strip was placed around the pouch at a distance of 1 cm above the anastomotic margin of the stomach through an opening of the lesser omentum. A polypropylene-0 stitch was used to secure both ends to close the ring. This constitutes a restrictive device of 1.9 cm diameter around the stomach wall. The jejunal loop was passed through the retrocolic-retrogastric route and interposed, with a running Vicryl® suture, between the two parts of the stomach. A 4-cm-wide handsewn gastrojejunal anastomosis was made with the same material. The band was allowed to stay on site with the interposed loop (Fig. 2)

In group B, the procedure was exactly the same, but without placement of the ring. In this group of patients, the gastrojejunal anastomosis was calibrated to 1.5 cm diameter.

## Clinical Follow-up

The follow-up was conducted every month in the first year, every 3 months in the second year, and every 6 months from the third year onward.

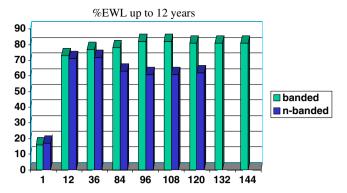
Postoperative evaluation included the parameters % EWL, using as ideal weight a BMI value of 23, and QOL, using (1) the BAROS test and (2) the modified Moorehead–Ardelt questionnaire. Special attention was directed toward food tolerance (FT). Complications related to the ring were also evaluated.

## Statistics

The data were collected and analyzed on the LapBase data system. The Student's t test was used for analyzing weight loss differences. A p value of 0.05 was considered to be of statistical significance.

## Results

We find significantly better %EWL in group A, starting from the 24th month until 10 years (Fig. 3). In Fig. 4, we see that the BGBP patients have the same %EWL at their



**Fig. 4** We followed up banded patients for 12 years and they kept the same %EWL. We do not have enough nonbanded patients to compare with

11- and 12-year follow-ups. We could not follow-up nonbanded GBP patients after a period of more than 10 years. QOL, as seen in Fig. 10, shows no difference in both groups. Regarding the complications related to the band, with the PTFE ring, we see three migrations inside the stomach at the beginning of the study. With the polyurethane vascular patch strip, we observe no migrations or slippage for more than 10 years. On the contrary, the anastomotic stricture is significantly more frequent in the nonbanded GBP patients with 4% versus in the BGBP category with 0.4%. No articles have hitherto been published with reference to the resolution of comorbidities. Our experience is summarized in Table 1. In the first year, the resolution of comorbidities is very similar in both groups; however, at the 10-year follow-up, more patients in group B again developed diabetes or dyslipidemia. The numbers at 10 years are, however, very few to come to a specific conclusion (Table 2).

#### Discussion

There are very few published articles comparing GBP with and without a ring on a long-term basis [12]. It is important to assess not only the %EWL in both these groups, but also the QOL and whether they have vomiting

Table 1 The correction of comorbidities at 10 years

At 10 years	Diabetes	Dyslipidemia	Apnea
Banded	3/4, 75%	10/15, 66%	3/4, 75%
Nonbanded	2/4, 50%	4/8, 50%	3/5, 60%

These are patients that had comorbidities corrected at 1 year, but some have recurred at 10 years. Numbers are small to get any conclusion



**Table 2** Percent follow-up at different periods of time

	Banded	Follow-up	% follow-up	Nonbanded	Follow-up	% follow-up
1 year	260	244	93.85	218	194	88.89
3 years	244	169	69.26	194	163	84.02
7 years	151	111	73.51	80	56	70.00
8 years	94	78	82.98	52	41	78.85
9 years	68	51	75.00	37	29	78.38
10 years	49	34	69.39	24	17	70.83

or intolerance and difficulty in food intake. In addition, we need to know whether the ring creates a problem such as slippage or migration, which might reduce the benefits of using a band.

It is clear to us from the results that we have a much better %EWL value in the BGBP group, if we follow them up for 10 years or more. Most of the surgeons who use restrictive bands have published the results of 2 or 3 years of following up only [6–9]. Only one study, thus far, shows no differences in both groups; however, they have been followed up for only 2 years [10]. Dr. Buchwald finds an EWL of 61.5% in more than 4,204 bypasses [1] after 2 years of follow-up, and Salinas, in a group of 3,500 BGBP patients, shows a %EWL of 83.5% after a 5-year follow-up [11, 12]. In our groups of patients, we have a rate of follow-up of around 70% at 10 years. We achieved this by calling or sending mails to the patients who had not come for a

checkup for a long time. We usually encourage them to come for a personal consultation; nevertheless, in some cases, we had to trust the telephone-based or mailed information. In Fig. 7, we show the actual numbers of the patients and the percentage of follow-up results. In Figs. 5, 6, 7, 8, and 9, the results of the Student's *t* test for the significance of the differences between the means of the values for groups A and B at follow-up at 3 years and after the seventh year until the tenth year are shown; the results are very significant.

The second aspect to survey is the QOL. There is a consensus that the ring does not impair QOL [6–11], and the same is our experience. We find no difference in QOL between both groups. We also pay special attention to the food intake and FT. Group A has more difficulty in eating; however, this happens only when they try to eat fast without chewing enough. It seems to us that this is a desirable fact

Fig. 5 %EWL at 3 years: t test

### t Test at 3 years

A statistical test of the null hypothesis that two population means are equal is based on the t value, which measures how many standard errors the difference in the sample means is from 0. This standard error can be estimated without assuming that the population standard deviations are equal, or by assuming that they are equal and using a pocled variance.

Var1, row 1 to row 163, number of actual observations:	169
Number of missing observations:	0
The mean of the first sample:	77.0118
The standard deviation of the first sample:	18.1862
Var2, row 1 to row 163, number of actual observations:	163
Number of missing observations:	0
The mean of the second sample:	72.3497
The stancard deviation of the second sample:	17.3203
The t value with 329.9483 degrees of freedom:	2.3924
The two-sided p value:	0.0173
Assuming equal population standard deviations, the pooled variance:	315.6456
The t value with 330 degrees of freedom:	2.3903
The two-sided p value:	0.0174



Fig. 6 %EWL at 7 years: t test

#### t Test at 7 years

,,	
Var4, row 1 to row 56, number of actual observations:	111
Number of missing observations:	0
The mean of the first sample:	78.2162
The standard deviation of the first sample:	13.9678
Var5, row 1 to row 56, number of actual observations:	56
Number of missing observations:	0
The mean of the second sample:	63.8571
The standard deviation of the second sample:	15.3059
The t value with 101.9286 degrees of freedom:	5.8911
The two-sided p value:	0.0000005
Assuming equal population standard deviations, the pooled variance:	208.1556
The t value with 165 degrees of freedom:	6.0720
The two-sided p value:	0.000000008

because we are always trying to change this habit and teach the patients to eat slowly with small portions of food. This limitation is not felt by the patients as an impairment of the QOL (Fig. 10).

In this context, the type of material used for the band and the size of the ring are important [13]. Many different materials, such as silastic rings, polypropylene mesh, and others, have been used so far. The ideal ring should be very well tolerated and have a little elasticity, which, even if causing a restriction, allows an easier food intake than that allowed by a rigid band. Different lengths of the bands were used between 4.5 and 7.5 cm long [9, 12–14]. When we used to do vertical banded gastroplasty, we

started to place a 5.5-cm band, and many patients developed dysphagy. When we started to do bypasses, we soon figured out that a 6.5-cm-long band was the optimal length, and when we close it with a stitch, it constitutes a 19-mm diameter outside the wall of the stomach, so that the actual diameter of the outlet may vary a little, depending on the stomach thickness. Mali and Valezzi have endoscopically measured the size of the outlet, which may vary depending on the thickness of the stomach wall, and have found a good correlation between the actual diameter of the outlet and the %EWL [14]. The idea in our method is not to narrow the gastric output, but to control the stomach pouch output, and in this way, to avoid

Fig. 7 %EWL at 8 years: t test

#### t Test at 8 years

Var7, row 1 to row 41, number of actual observations:	78
Number of missing observations:	0
The mean of the first sample:	82.2179
The standard deviation of the first sample:	12.6846
Var8, row 1 to row 41, number of actual observations:	41
Number of missing observations:	0
The mean of the second sample:	61.1220
The standard deviation of the second sample:	16.1388
The t value with 66.5497 degrees of freedom:	7.2721
The two-sided p value:	0.000000005
Assuming equal population standard deviations, the pooled variance:	194.9375
The t value with 117 degrees of freedom:	7.8328
The two-sided p value:	2.40380x10^-12



Fig. 8 %EWL at 9 years: t test

# t Test at 9 years

Var10, row 1 to row 29, number of actual observations:	51
Number of missing observations:	0
The mean of the first sample:	82.3333
The standard ceviation of the first sample:	13.1006
Var11, row 1 to row 29, number of actual observations:	29
Number of missing observations:	0
The mean of the second sample:	61.2759
The standard ceviation of the second sample:	14.7670
The t value with 52.7532 degrees of freedom:	6.3826
The two-sided p value:	0.0000005
Assuming equal population standard deviations, the pooled variance:	188.2965
The t value with 78 degrees of freedom:	6.5982
The two-sided p value:	0.000000005

dilation of the small bowel close to the gastrojejunal anastomosis; otherwise, this will form a truly new stomach and allow much more food intake. Besides, this reduces the dumping syndrome, which is more frequently seen in nonbanded bypass. Usually, at the end of the operation, the ring appears to be loose around the stomach wall. Karcz has made an interesting and novel study to

assess the value of multislice computed tomography to have volumetric measurements of the gastric pouch, gastrointestinal (GI) anastomosis, and proximal jejunum. All GI anastomoses bigger than 3 cm increase the risk of gaining weight [15] (Fig. 11).

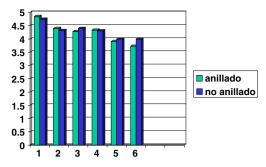
Another interesting aspect is that, as the band calibrates the gastric outlet of food, this allows the creation of a very

Fig. 9 %EWL at 10 years: t test

## t Test at 10 years

Var13, row 1 to row 17, number of actual observations:	34
Number of missing observations:	0
The mean of the first sample:	81,7353
The standard deviation of the first sample:	15,4180
Var14, row 1 to row 17, number of actual observations:	17
Number of missing observations:	0
The mean of the second sample:	62,3529
The standard deviation of the second sample:	14,6242
The t value with 33,6820 degrees of freedom:	4,3811
The two-sided p value:	0,0001
Assuming equal population standard deviations, the pooled variance:	229,9286
The t value with 49 degrees of freedom:	4,3032
The two-sided p value:	0,00008





**Fig. 10** QOL. *I* self-esteem, *2* physical activities, *3* social activities, *4* work, *5* sex, *6* FT

wide gastrojejunal anastomosis without jeopardizing the EWL. There is no need to calibrate the anastomosis as in the nonbanded GBP category. The more calibrated or narrow the anastomosis, the more the possibility of a stricture [8, 12, 14]. In our experience, we have had only 1 anastomotic stricture in 900 cases of RY-BGBP (0.11%) and 8 strictures in the nonbanded GBP group (4%), which means that strictures are almost 40 times more frequent in the latter group. Mali does not find any stricture with a 4-cm anastomosis [14].

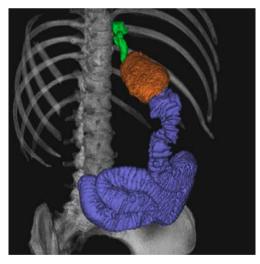


Fig. 11 Volume rendering image in right anterior cranial oblique projection of a 40-year-old female patient after laparoscopic conventional Roux-en-Y gastric bypass. Different color masks are employed to allow separate depiction of the pouch (orange), Roux limb (blue), and esophagus (green). A semitranslucent mask of the ribcage and spine is provided for better anatomical orientation. The pouch volume was dilated to 135 ml, the diameter of the gastrojejunostomy was 2.4 mm, and the volume of the first 20 cm of the Roux limb was 80 ml (with permission)

With the PTFE material, we find three migrations inside the stomach, which is a bothersome complication, even though it is easy to solve endoscopically [16–24]. We have hence stopped using this type of band and have started to use the Gore-Tex vascular patch; we have had neither migration nor slipping of the band in more than 10 years of its use. It is extremely important to find the right type of material for the band, which should be well tolerated and should not migrate. Anyhow, migration is not a frequent complication. Salinas showed, in the Hamburg IFSO Congress September 2001, a migration rate of 1.7% in 3,800 banded bypasses, and as he states, this is the price to pay for having 98.3% of patients with a more effective bariatric procedure in the long-term follow-up.

We should expect some more recurrences of comorbidities in the nonbanded GBP patients because they regained weight. There are no comparative studies on this subject. In our study, correction of comorbidities is the same in both groups at the 1-year follow-up. However, there seems to be a better long-term resolution of comorbidities in the BGBP patients and lesser recurrence rates of diabetes and dyslipidemia. Nevertheless, this result is not conclusive because the numbers are small. We consider a patient diabetic when the person has two blood glucose readings more than 1.26 g/l or a glycosylated Hb level more than 6.5%. Dyslipidemia in our group is defined as low-density lipoprotein levels more than 120, total/high-density lipoprotein levels more than 4.5, and triglyceride level more than 150.

It is clear to us that there are big advantages in using a restrictive device for the gastric outlet in GBP, and we place a ring in all our bypass patients. However, most surgeons are not willing to use it, probably because it involves a longer duration of surgery or an increased cost or because they are afraid to use a foreign material that could migrate or slip; another reason could be that because surgeons are not looking for results over a very long follow-up period. Probably, the most important reason is that the results without the band, even though much poorer, are not extremely bad and thus they consider the band not very essential [20]. The bariatric surgeons did not introduce all that they learned from open surgery about the bypass into the laparoscopic variation. Now with the development of new implants specially designed for this particular purpose, it will be easier to popularize the laparoscopic banded technique.

**Conflict of Interest Statement** The authors declare that they have no conflict of interest.



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