

# Laparoscopic Adjustable Gastric Banding in 1,791 Consecutive Obese Patients: 12-Year Results

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**Background:** This study examines 1,791 consecutive laparoscopic adjustable gastric banding (LAGB) procedures with up to 12 years follow-up. Long-term results of LAGB with a high follow-up rate are not common.

**Methods:** Between September 1993 and December 2005, 1,791 consecutive patients (75.1% women, mean age 38.7 years, mean weight 127.7 ± 24 kg, mean BMI 46.2 ± 7.7) underwent LAGB by the same surgical team. Perigastric dissection was used in 77.8% of the patients, while subsequently pars flaccida was used in 21.5% and a mixed approach in 0.8%. Data were analyzed according to co-morbidities, conversion, short- and long-term complications and weight loss. Fluoroscopy-guided band adjustments were performed and patients received intensive follow-up. The effects of LAGB on life expectancy were measured in a case/control study involving 821 surgically-treated patients versus 821 treated by medical therapy.

**Results:** Most common baseline co-morbidities (%) were hypertension (35.6), osteoarthritis (57.8), diabetes (22), dyslipidemia (27.1), sleep apnea syndrome (31.4), depression (21.2), sweet eating (22.5) and binge eating (18.5). Conversion to open was 1.7%: due to technical difficulties (1.2) and due to intraoperative complications (0.5). Together with the re-positioning of the band, additional surgery was performed in 11.9% of the patients: hiatal hernia repair (2.4), cholecystectomy (7.8) and other procedures (1.7). There was no mortality. Reoperation was required in 106 patients (5.9%): band removal 55 (3.7%), band repositioning 50 (2.7%), and other 1 (0.05%). Port-related complications occurred in 200 patients (11.2%). 41 patients

(2.3%) underwent further surgery due to unsatisfactory results: removal of the band in 12 (0.7%), biliopancreatic diversion in 5 (0.27%) and a biliopancreatic diversion with gastric preservation ("bandinaro") in 24 (1.3%). Weight in kg was 103.7 ± 21.6, 102.5 ± 22.5, 105.0 ± 23.6, 106.8 ± 24.3, 103.3 ± 26.2 and 101.4 ± 27.1 at 1, 3, 5, 7, 9, 11 years after LAGB. BMI at the same intervals was 37.7 ± 7.1, 37.2 ± 7.2, 38.1 ± 7.6, 38.5 ± 7.9, 37.5 ± 8.5 and 37.7 ± 9.1. The case/control study found a statistically significant difference in survival in favor of the surgically-treated group.

**Conclusions:** LAGB can achieve effective, safe and stable long-term weight loss. In experienced hands, the complication rate is low. Follow-up is paramount.

**Key words:** Morbid obesity, laparoscopy, adjustable gastric banding, intragastric balloon, bariatric surgery, long-term outcome

## Introduction

Laparoscopic adjustable gastric banding (LAGB) with the Lap-Band<sup>®</sup> is the most commonly performed surgical procedure for morbid obesity in Europe, Australia and South America.<sup>1</sup> Since FDA approval in 2001, the Lap-Band<sup>®</sup> has ranked second among all bariatric procedures performed in the U.S.,<sup>1</sup> and, to date, approximately 300,000 of these procedures have been performed worldwide. Short- and medium-term series have found the band to be both safe and effective. However, a paucity of large long-term follow-up studies has created uncertainty

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in some about the Lap-Band®'s efficacy over time. This paper reports the long-term outcomes of a very large group of Lap-Band® patients.

## Materials and Methods

From September 1993 through December 2005, 1,791 consecutive patients underwent LAGB surgery for morbid obesity at our institutions (Obesity Centers of Vicenza Regional Hospital and Padova University) (Table 1). All operations were performed by the same team of surgeons utilizing the Lap-Band® (Inamed/Allergan), Santa Barbara, CA, USA) and all patients met the eligibility criteria for bariatric surgery according to the NIH Consensus Conference Statement of 1991.<sup>2</sup>

Outcomes measured over 12 years included mortality, complications, weight loss and resolution/improvement of co-morbidities. Life expectancy was evaluated in an adjunct study of LAGB vs medical therapy.

Preoperatively-recorded characteristics of 1,345 female (75.1%) and 446 male (24.9%) patients were: mean age  $38.7 \pm 10.9$  years, mean height  $1.66 \pm 0.09$  meters, mean weight  $127.7 \pm 24.3$  kg, and mean BMI  $46.2 \pm 7.7$ .

Baseline co-morbidities were present in 71% of our patients: 57.8% suffered from osteoarthritis, 35.6% hypertension, 31.4% obstructive sleep apnea syndrome (OSAS), 27.1% dyslipidemia, 22.0%

type II diabetes, 21.2% depression, 9.3% hyperuricemia, 8.7% gallstones, 4.9% amenorrhea, and 1.4% heart failure.

Out of 1,791 patients, 125 (7%) underwent preoperative application of a Bioenterics Intra-gastric Balloon (BIB) with the aim of reducing the surgical risk. Their mean age was  $44.8 \pm 11.8$  years, mean height  $1.68 \pm 0.10$  meters, mean weight  $161.4 \pm 30.1$  kg and mean BMI  $56.8 \pm 9.1$ .

The perigastric dissection, as has been previously described,<sup>3</sup> was performed in 1,393 patients (77.8%), the pars flaccida technique was subsequently used in 384 (21.5%) and the combined approach<sup>5</sup> in 14 (0.8%). Table 1 shows the number of operations performed per year.

Patients were followed at 1, 3, 6, and 12 months postoperatively and yearly thereafter. All data concerning mortality, complications, reoperations, weight loss and co-morbidities were recorded during the follow-up visits. Band adjustments were performed with barium swallow under fluoroscopy.

The co-morbidities were specifically investigated in 830 consecutive patients, consisting of 647 women (77.9%) and 183 men (22.1%), from September 1993 until November 2005.<sup>6</sup> For this group of patients, a complete cardiovascular risk factor profile was collected both before and 12 to 18 months after surgery (mean follow-up time:  $15.3 \pm 2.1$  months).

The effects of gastric banding surgery on life expectancy were measured in a case/control study of 821 patients from our Lap-Band® series com-

**Table 1. Number of operations per year and follow-up rate (mean follow-up: 91%)**

Year	No. of operations	Total	Follow-up Years	No. of Patients Follow-up	Follow-up Rate
1993	4	4	12	4	100%
1994	18	22	11	22	100%
1995	59	81	10	74	91.3%
1996	129	210	9	188	89.5%
1997	130	340	8	311	91.4%
1998	143	483	7	415	85.9%
1999	168	651	6	588	90.3%
2000	192	843	5	765	90.7%
2001	133	976	4	895	91.7%
2002	143	1119	3	1001	89.4%
2003	201	1320	2	1198	90.7%
2004	198	1515	1	1381	90.9.1%
2005	273	1791	—	—	—

pared with 821 patients treated by medical therapy in other Italian medical centers included in the Multi-site Cohort of the Italian Study Group on Morbid Obesity<sup>7</sup> (Figure 1).

## Results

The follow-up rate at 12 years was 91%. The conversion rate was 1.7%, of which 1.2% was due to technical problems such as difficult perigastric dissection and giant left liver lobe hypertrophy, and 0.5% was caused by intraoperative complications such as gastric perforation and bleeding. There was no surgical mortality in our entire series of 1,791 patients.

The 125/1791 patients who had a BIB applied preoperatively lost  $24.7 \pm 11.7$  kg, 8.7 points of BMI, and a %EWL of  $27.9 \pm 11.8$  at time of Lap-Band<sup>®</sup> placement. This group of patients showed the same conversion and intraoperative complication rate as the rest of the series.

Major complications requiring reoperation occurred in 106 patients (5.9%). These included stomach slippage and pouch dilatation in 70 patients

(3.9%) (band removed in 20 patients – 1.1%, repositioned in 50 patients – 2.8%), erosion in 16 patients (0.9%) (band removed), psychological intolerance in 14 patients (0.7%) (band removed), miscellaneous (HIV, infection, microperforation) in 5 patients (0.27%) (band removed) and gastric necrosis in 1 (0.05%) patient (gastrectomy performed) (Table 2). If we exclude the 31 major complications of the learning curve period (first 100 patients), the complication rate is reduced to 4.4%.

Of the 41 patients (2.3 %) with unsatisfactory results, the band was removed in 12 (0.7%). A classical biliopancreatic diversion (BPD) was performed in 5 (0.27%), and a BPD with gastric preservation (“bandinaro”) was done in 24 (1.3%) (Table 2).

Minor complications requiring reoperation occurred at the port-site in 200 patients (11.2%). The port was substituted in 182 (10.2%), repositioned in 9 (0.5%) and removed in 9 (0.5%). These port issues, almost entirely related to the port-tubing transition, were more common early in our experience. With refinements to the placement technique and design improvements, these complications have been largely eliminated.

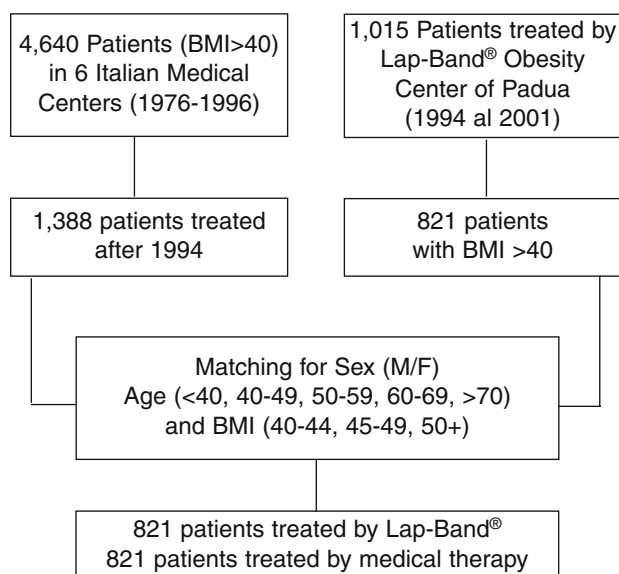
Weight loss (kg, BMI, %EWL) for the entire series is shown in Table 3 and in Figures 2, 3 and 4. At 10 years, the average weight was  $101.4 \pm 27.1$  kg (loss of 26.3 kg), the BMI  $37.7 \pm 9.1$  (loss of 8.5 points) and the %EWL was  $38.5 \pm 27.9$ .

Results of morbidly obese (BMI  $\leq 49$ ) and super-obese (BMI  $\geq 50$ ) were separated into two groups for evaluation/comparison and weight loss in terms of kg and BMI is reported in Table 4 and shown in Figures 5 and 6. At 10 years the weight of the morbidly obese group was  $94.6 \pm 18.0$  kg of the super-obese group and was  $123.2 \pm 38.5$  kg, indicating weight losses of 23.8 kg and 29.6 kg, respectively.

At 10 years, the BMI in the morbidly obese group was  $35.2 \pm 5.4$  and in the super-obese group was  $44.9 \pm 13.9$ , down 7.4 and 11.3 points, respectively. The %EWL in the morbidly and super-obese groups is reported in Table 5 and shown in Figure 7. At 10 years, %EWL was  $40.3 \pm 27.6$  and  $36.0 \pm 30.2$ , respectively.

The effect of LAGB was specifically analyzed in our first 830 consecutive patients. At baseline, the prevalence of diabetes was 11.2% (17.7% of men and 9.2% of women,  $P < 0.05$ ); 36.2% of the diabetic patients had been treated with oral hypoglycemic drugs and the remainder with diet; none were on

### Matching and Selection of Patients in the Case Group and Control Group



**Figure 1.** Case/Control Study involving 821 patients of our Lap-Band<sup>®</sup> series and 821 patients treated by medical therapy in other Italian Medical Centres.

**Table 2. Major complications requiring reoperation (106/1791 patients; Sept. 1993-Dec. 2005)**

Complications	Number	Rate of Complications	Reoperation	Number	Rate of Complications
Stomach Slippage + Pouch Dilatation	70	3.9%	Removal	20	1.1%
Erosion	16	0.9%	Repositioning	50	2.8%
Psychological Intolerance	14	0.7%	Removal	16	0.9%
Miscellaneous (HIV, Infections, Microperforations)	5	0.27%	Removal	14	0.7%
Gastric Necrosis	1	0.05%	Removal	5	0.27%
<b>Total</b>	<b>106</b>	<b>5.9%</b>	<b>Total</b>	<b>106</b>	<b>5.9%</b>
Unsatisfactory Results (Lack of Compliance)	41	2.3%	BPD Removal	5	0.27%
			"BandInaro"	12	0.7%
				24	1.3%

insulin. Also preoperatively, hypercholesterolemia was diagnosed in 53.9% of patients (48.4% in men and 55.4% in women), low HDL-cholesterol in 13.1% (18.8% in men and 11.5% in women) and hypertriglyceridemia in 19.4% (30.6% in men and 16.0% in women,  $P<0.01$ ). The prevalence of hypertension was 32.2% (45.9% in men and 27.9% in women,  $P<0.001$ ), with 60.6% of hypertensive patients being treated pharmacologically.<sup>6</sup> Postoperatively, these co-morbidities resolved or have been markedly improved.

**Table 3. Weight loss (kg, BMI, %EWL) of the entire series**

Time	Weight	BMI	%EWL*
0	127.7±24.3	46.2±7.7	---
1 y	103.7±21.6	37.7±7.1	40.3±19.7
2 y	101.5±23.3	36.8±7.6	43.7±21.7
3 y	102.5±22.5	37.2±7.2	41.2±23.2
4 y	104.1±23.5	37.8±7.5	38.6±24.4
5 y	105.0±23.6	38.1±7.6	37.3±25.3
6 y	105.3±24.6	38.1±8.1	37.4±28.2
7 y	106.8±24.3	38.5±7.9	35.9±26.7
8 y	105.0±24.0	37.8±7.9	37.7±26.7
9 y	103.3±26.2	37.5±8.5	38.5±27.9
10 y	101.4±27.1	37.7±9.1	35.4±29.6
11 y	101.2±31.9	38.1±11.5	38.4±32.8
12 y	84.0±27.5	31.6±8.5	49.2±49.5

Values are mean ± SD. \*Based on Metropolitan tables.

The results of the case/control study on the life expectancy after LAGB are shown in Figure 8. Kaplan-Meier survival curves were calculated at 6 months and at 1, 2, 3 and 5 years, and differences in survival between groups was evaluated by log-rank test. The survival rate was significantly higher in the LAGB group ( $P<0.0007$ ). Relative risk of death after adjustment for sex, age and BMI in the surgical group was 0.38 (95% CI: 0.17 – 0.85).<sup>7</sup>

The results of the case/control study showed increased life expectancy after of the Lap-Band®, as compared with medical treatment alone (Figure 8).

## Discussion

True judgment of any bariatric procedure requires sound data, not only with regard to the surgical technique and its related mortality, morbidity and weight loss, but also regarding the procedure's impact on baseline co-morbidities and life expectancy. Such data can be provided only by studies that have a very high follow-up rate extended over the long term. Thus, it was our aim to provide a thorough analysis of the Lap-Band® procedure by comprehensive long-term data. A homogeneous series of 1,791 consecutive patients was treated by the same team and followed for up to 12 years. In addition, the impact of the band on life expectancy was analyzed by a con-

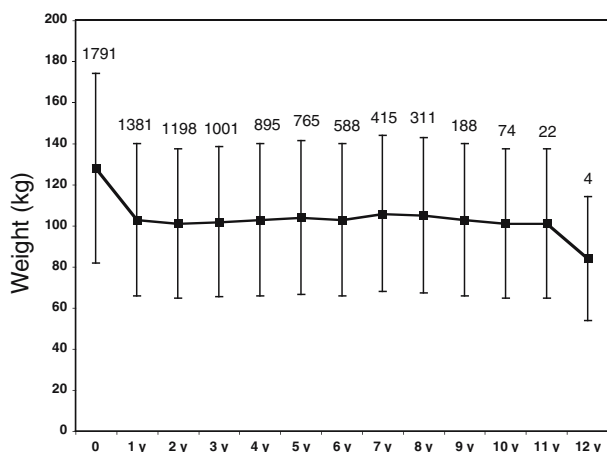


Figure 2. Weight loss (kg) of the entire series.

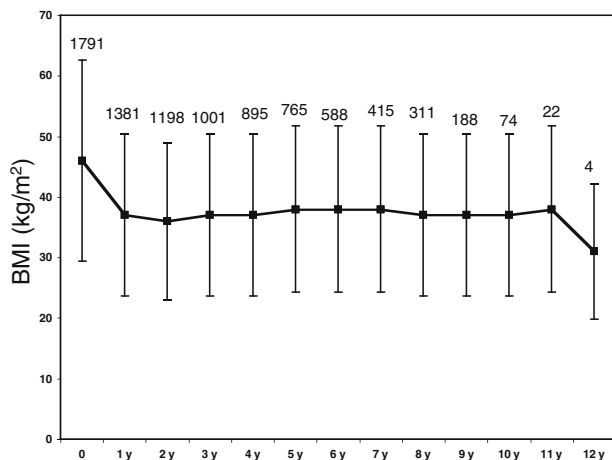


Figure 3. Weight loss (BMI) of the entire series.

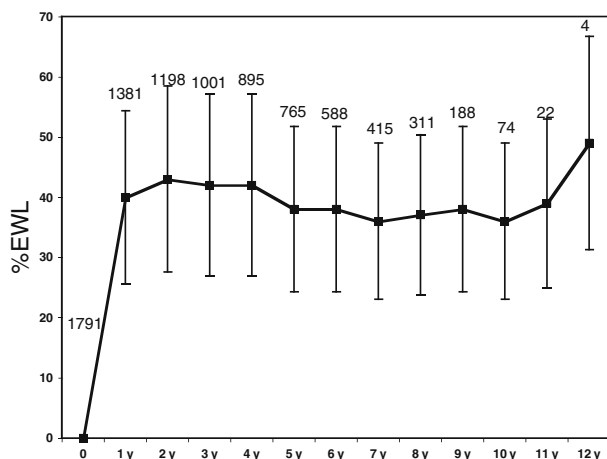


Figure 4. Weight loss (%EWL) of the entire series.

sistent case/control epidemiological study.

The 91% follow-up rate has allowed us to provide reliable data regarding what actually happens to this group of patients. It is well known in bariatric circles that not all the patients accept the stipulated follow-up plan. We were able to track most of our patients using an aggressive approach that sometimes involved the Registry Offices, the Health Authorities and even the Police.

A mortality rate of 0 in 1,791 consecutive LAGB patients attests to the benign nature of the surgery. In addition, this standardized laparoscopic procedure offered patients a low rate of major complications requiring reoperation (only 5.9 %, including the learning curve period).

Although most of the Lap-Bands® in the series were placed using the perigastric dissection technique (77.8 %),<sup>3</sup> we used the pars flaccida technique (21.5 %)<sup>4</sup> in the last 3 years and have utilized the combined approach<sup>5</sup> in only 0.8% of our cases. The pars flaccida technique is the easiest to use and has been found to have drastically reduced the occurrence of certain complications.<sup>9-12</sup> Lap-Band® surgeons should be experienced in all three approaches to apply whichever is necessary according to the local anatomy and fat distribution.

Of the major complications requiring reoperation (5.9%), stomach slippage with pouch dilatation accounts for 3.9%. In many cases, these complications share overlapping aspects and the same treatment: removal of the band in 20 (1.1%) and repositioning in 50 (2.8%) in our series. These data compare favorably with those reported in other series,<sup>12-15</sup> likely due to the fact that we were able to identify and standardize the key points of the perigastric technique at a very early stage in our experience. Our low erosion rate of 0.9% is similar to that reported in other series.<sup>15,17-20</sup> One of the most appealing aspects of the LAGB is its total reversibility, which is important in cases of psychological intolerance of the prosthesis. In fact, 14 patients (0.8%) of our series required removal of the prosthesis.

In case of unsatisfactory results, due mainly to the patient's lack of compliance, we offer the patient a biliopancreatic diversion with gastric preservation ("band-inaro").<sup>8</sup> This procedure was performed by laparoscopy in 24 patients (1.3%), while the classic biliopancreatic diversion was done in 5 (0.27%). Removal of the band was requested by 12 patients (0.7%).

**Table 4. Weight loss (kg, BMI) in morbidly obese and super-obese patients**

Time	Number of Patients		Weight (kg)		BMI (kg/m <sup>2</sup> )	
	MORBID	SUPER	MORBID	SUPER	MORBID	SUPER
0 y	1307	484	118.4±16.9	152.8±23.7***	42.6±4.3	56.2±5.8***
1 y	998	383	96.6±16.3	122.1±22.9***	34.8±4.7	45.0±7.0***
2 y	862	336	95.3±20.2	117.4±23.4***	34.3±6.2	43.3±7.3***
3 y	710	291	96.4±18.1	118.0±24.8***	34.7±5.2	43.5±7.7***
4 y	642	253	97.7±18.7	120.3±26.6***	35.2±5.4	44.3±8.1***
5 y	546	219	98.6±18.9	121.3±26.6***	35.6±5.5	44.6±8.4***
6 y	417	171	98.6±19.4	122.3±28.0***	35.4±5.8	44.9±9.1***
7 y	290	125	100.5±19.8	121.8±27.4***	35.8±5.7	44.8±8.7***
8 y	227	84	99.0±19.1	122.0±28.1***	35.4±5.6	44.5±9.4***
9 y	140	48	96.7±18.2	123.6±35.2***	35.0±5.4	44.9±13.9***
10 y	56	18	94.6±18.0	123.2±38.5**	35.2±5.4	45.7±13.5***
11 y	17	5	92.1±20.3	137.7±48.9*	34.4±6.6	53.0±16.2**
12 y	4	0	84.0±27.5	—	31.6±8.5	—

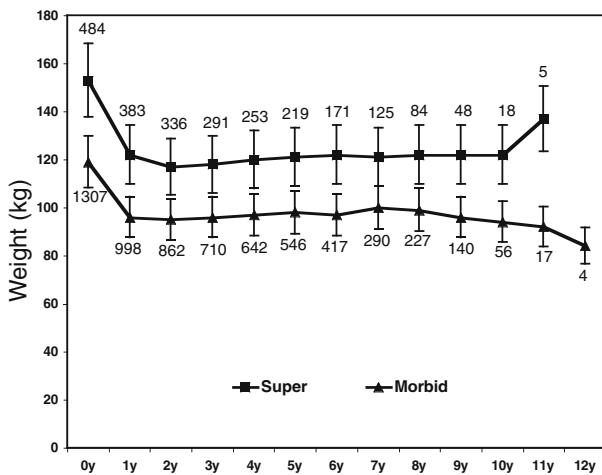
Student's *t*-test: \**P*<0.05; \*\**P*<0.01; \*\*\**P*<0.001. Values are mean ± SD.

We considered minor complications requiring reoperation to be those occurring at the port-site (11.2%). In most cases (10.2%), a leak was detected and the port was replaced. In a minority of patients, the port had to be repositioned for pain (0.5%) or removed because of infection (0.5%). Over the length of our series, we used all four generations of access port provided by the manufacturer (Inamed/Allergan), and experience indicates that with the present “low profile” port, the leakage rate has been greatly reduced.

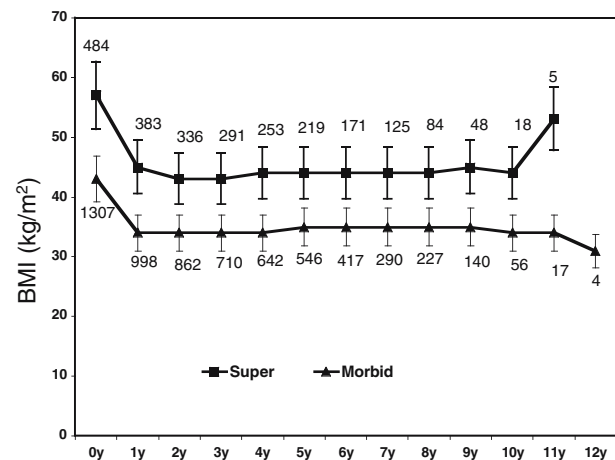
The preoperative weight loss (24.7 ± 11.7 kg) produced by the BioEnterics IntraGastric Balloon (BIB) in 125/1971 super-obese patients (BMI 56.8 ± 9.1)

was associated with the same conversion rate as the remaining series and the same rate of intra-operative complications as well. Preoperative weight loss to reduce the surgical risk in super-obese candidates for bariatric surgery is an established indication for use of the BIB.<sup>21</sup> This sequential therapy should be considered in patients with extreme obesity.

With regard to the weight loss curves (kg, BMI, %EWL) (Table 3, Figures 2, 3 and 4) for the entire series of 1791 patients, in the long term (i.e., at 10 years) the average weight had decreased 26.3 kg, BMI was down 8.5 points and %EWL was 38.5. The curves were stable over time, with no statisti-



**Figure 5.** Weight loss (kg) in super and morbid obese patients.



**Figure 6.** Weight loss (BMI) in super and morbid obese patients.

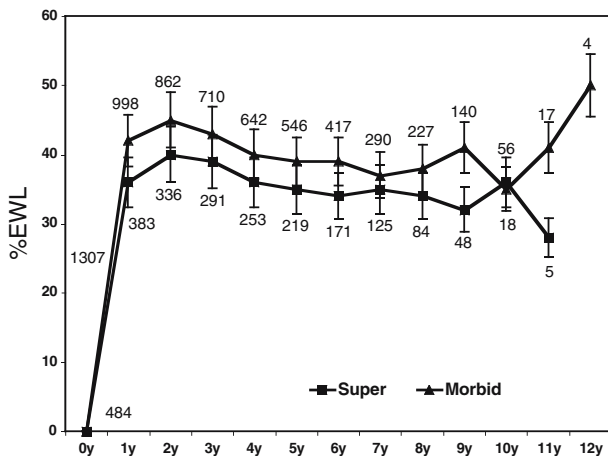
**Table 5. Weight loss (%EWL) in morbidly obese and super-obese patients**

Time	Number of Patients		Weight Loss		%EWL*	
	MORBID	SUPER	MORBID	SUPER	MORBID	SUPER
0 y	1307	484	---	---	---	---
1 y	998	383	21.7±11.2	30.9±15.6***	42.3±20.4	35.1±16.6***
2 y	862	336	23.2±15.5	34.4±16.9***	45.2±25.5	39.8±18.5**
3 y	710	291	21.8±13.4	33.7±18.0***	42.1±20.4	39.1±19.5*
4 y	642	253	20.5±13.5	31.0±19.2***	39.6±25.5	36.2±21.0*
5 y	546	219	19.8±13.8	30.1±19.6***	38.1±26.5	35.1±21.7
6 y	417	171	20.1±15.1	29.1±21.5***	38.7±29.7	33.9±23.9*
7 y	290	125	18.7±13.5	29.0±20.4***	36.6±27.8	34.0±23.9
8 y	227	84	19.9±13.9	28.7±20.5**	38.8±27.2	34.5±24.9
9 y	140	48	20.2±13.9	26.1±22.4	40.3±27.6	32.9±28.7
10 y	56	18	17.6±14.2	29.2±22.7	35.2±29.7	36.0±30.2
11 y	17	5	20.5±18.6	25.7±5.1	40.9±36.1	28.3±13.3
12 y	4	0	16.5±14.6	—	49.2±49.5	—

Student's *t*-test: \**P*<0.05; \*\**P*<0.01; \*\*\**P*<0.001. Values are mean ± SD. \*Based on the Metropolitan Tables.<sup>22</sup>

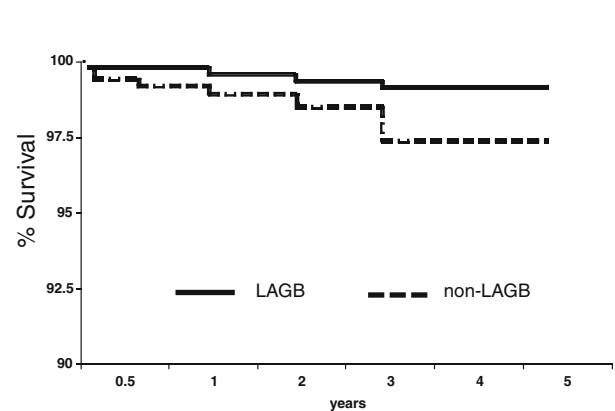
cally detectable rebound. Stable curves in the long term were visible in the weight loss curves (kg, BMI) of the morbidly obese and super-obese groups (Table 4, Figures 5 and 6) where we observed a weight loss of 23.8 and 29.6 kg, respectively at 10 years. The BMI was down 7.4 and 11.3 points in the same time-span, respectively.

%EWL in the morbidly obese and in the super-obese (Table 5 and Figure 7) was 40.3 and 36.0, respectively at 10 years. After the 4th year, there was no statistical difference between the value of the two curves and they tended to merge together.



**Figure 7.** Weight loss (%EWL) in super and morbid obese patients.

The weight loss observed in morbidly obese patients in the first 12 to 18 months after LAGB was associated with clinically-significant improvements in multiple cardiovascular risk factors. However, only a low level of correlation was observed between the degree of body weight reduction and the magnitude of cardiovascular risk improvement. In particular, a 10% to 11% weight loss appeared to be associated with the maximal benefit in diabetic control, with no further gain being derived from more pronounced levels of body weight reduction.<sup>6,23</sup>



**Figure 8.** Life Expectancy in a Case/Control Study involving 821 patients of our Lap-Band® Series and 821 patients treated by medical therapy in other Italian Medical Centers.

## Life Expectancy Study

Working together with Epidemiologists and Internists of the Multisites Cohort of the Italian Study Group on Morbid Obesity, our group was able to conduct a case/control study on the effect of LAGB on life expectancy.

Of our patients, 821/1791 were matched with 821 similar patients who received only medical treatment (Figure 1). The 5-year survival in the LAGB-treated group and in the medically-treated group is shown in Figure 8, where a statistically significant difference in survival is seen in favor of the surgically-treated group, with a 60% reduction in total mortality.<sup>7</sup>

It has been uncommon to find reports of long-term results with gastric banding. The fact that the band was only introduced in 1993 would explain the lack of long-term data. It is even less common to find studies that provide the impact of a single bariatric operation on the life expectancy of the patients. Thus, the data presented here will enable comparison of the different operations as bariatric surgery advances.

## Conclusions

This study affirms that the LAGB is safe and effective for the treatment of both morbidly obese and super-obese patients in the short, medium and long term. In experienced hands, the complication rate is low and stable weight loss to at least 12 years has occurred.

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