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Results of the Italian Multicenter Study on 239 Super-obese Patients Treated by Adjustable Gastric Banding

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Background: Laparoscopic adjustable gastric banding (LAGB) is the most common bariatric operation. This study is a retrospective analysis of the multicenter Italian experience in patients with BMI >50 over the last 4 years.

Methods: An electronic data sheet made for LAGB-operated patients since January 1996, was mailed and e-mailed to all surgeons involved in this kind of procedure in Italy. Items regarding patients with BMI >50 were selected. Analysis used Fisher's exact test and logarithmic regression analysis (P<0.05 significant). Data were expressed as mean ± SD.

Results: 239 patients (13.3%), out of 1,797 Lap-Band® operated patients entered the study (179F / 60M), with mean age 37.6±11.3 years (19-69) and mean BMI 54.6±4.8 (50.1-83.6). Laparotomic conversion rate was 5.4% (44/239). Postoperative complications occurred in 24 / 239 patients (9.0%). Follow-up was obtained in 218 / 218, 198 / 198, 121 / 147, 75 / 93, 30 / 38 LAGB patients at 6, 12, 24, 36, and 48 months respectively. At these time periods, mean BMI was 46.7, 43.9, 42.2, 41.9, and 39.3 kg/m². At the same intervals, mean %EWL was 24.1, 34.1, 38.8, 38.9, and 52.9%. The number of patients with <25% EWL at 12, 24, 36, and 48 months follow-up were 34, 10, 4, and 0. Serious co-morbidities (189 in 124 of 239, 57%) had completely resolved 1 year postoperatively in 74 / 124 of the patients (59.6%).

Conclusion: Although super-obese patients following the LAGB remain obese with BMI >35, in the short-term most lose their co-morbidities, with a very low morbidity and mortality rate.

Key words: Morbid Obesity, bariatric surgery, laparoscopy, gastric band, co-morbidity

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Introduction

Laparoscopic adjustable gastric banding (LAGB) with the Lap-Band® (INAMED Health) is a minimally invasive procedure, which is the most common bariatric operation performed. Patient selection criteria still are being defined.[1] Dixon et al[2] have recently analyzed the predictive value of initial BMI on percent excess weight loss (%EWL) in 730 Australian morbidly obese patients undergoing the LAGB. They found a negative influence of preoperative BMI on weight loss in the first year (P<0.001), which was not confirmed at the second year and beyond. MacLean, proposing a new type of classification, reported that 43% of super-obese patients (ie. BMI >50) operated by laparotomic Roux-en-Y gastric bypass have body mass index (BMI) >35 kg/m² at 5 years follow-up;[3] these results should be considered, taking into account the invasiveness of that operation and its mortality

risk. LAGB is minimally invasive both on the abdominal wall and the gastrointestinal tract. An analysis of the multicenter Italian experience on LAGB-operated patients with BMI >50 over the last 4 years was conducted. The relationship between weight loss and resolution of co-morbidities was specifically analyzed.

Patients and Methods

A retrospective multicenter study on Lap-Band® patients was performed. Data were recruited from January 1996 to March 2001 from all surgeons involved LAGB, indicated by the local distributor (McGhan Medical S.r.l.). An electronic data sheet was specifically created with more than 150 items, and mailed and e-mailed to all surgeons in the study. The software used was Microsoft Access (7.0).

All patients inserted in the data-base were operated under general anesthesia in lithotomy and reverse Trendelenburg (30-45°). Closed CO_2 pneumoperitoneum was usually performed. All patients underwent anti-thrombotic and antibiotic prophylaxis. Patients were allocated into two BMI groups: ≥50 and <50 kg/m^2. Items considered were age, sex, BMI, intraoperative complications, laparotomic conversion, postoperative complications, mortality, preoperative and postoperative co-morbidities. Definitions and resolution of co-morbidities followed Table 1. Anxiety, depression and other related disorders were considered according to the DSM-IV.[4] Follow-up was obtained at 6, 12, 24, 36, and 48 months.

Data were expressed as mean ± standard deviation (SD), except as otherwise indicated. Statistical analysis was done by Fisher's exact test and logarithmic regression analysis (P<0.05 was considered significant).

Results

From January 1996 to March 2001, 1797 operated patients were entered in the Registry of the Italian Group for Lap-Band System® (1,450F / 347M with mean BMI 43.7±6.1, (range 30.4-83.6) and mean age 37.9±10.8 (range 17-74). BMI >50 kg/m^2 was recorded in 239 patients (179F / 60M, with mean BMI 54.6±4.8 (range 50.04-83.6) and mean age 37.9±10.8 (range 19-69), and they are the object of this study. These patients were compared with 1,558 morbidly obese patients with BMI <50

Table 1. Co-morbidity definition and their resolution criteria*

Co-morbidity	Definition	Resolution Criteria†
Respiratory problems	Sleep apnea and/or tachypnea after little physical activity	Absence of symptoms
Osteoarthropathy	Subjective reduction of physical activity for joint pain	Pain absence
Diabetes	Fasting glycemia >120-130 mg/dl HbA1c > 9%	Fasting glycemia <110 mg/dl HbA1c <6 %
Hypertension	>140/90 mmHg	120-130/80 mmHg
Anxiety and depression	DSM-IV	Absence of symptoms
Dyslipidemia	LDL cholesterol > 250 mg/dl Tryglycerides > 250 mg/dl	LDL cholesterol < 200 mg/dl Tryglycerides < 250 mg/dl

*= already diagnosed in anammesis or incidentally found during patient screening for surgery.
†= without pharmacologic support.

(1,271F / 287M, with mean BMI 42±4.1 (range 30.4-50), and mean age 38±10.8 (range 17-74). Laparotomic conversions in the super-obese were done in 13 / 239 (5.4%), significantly higher ($P<0.05$) than in morbidly obese patients (31 / 1,558, 2.2%). Causes of conversion are reported in Table 2.

The most common postoperative complications (pouch dilations, tube-port system leak and/or rupture, band erosion) and their incidence in the 2 groups of patients, are listed in Table 3. Pouch dilatation was significantly less frequent ($P<0.05$) in super-obese versus morbidly obese. No statistically significant difference was found for tube-port complications and band erosions between the groups. Postoperative mortality rate was higher in the BMI >50 group (3 / 239, 1.3% vs 7 / 1,558, 0.45%; $P=0.05$).

Follow-up was obtained in 218/218, 198/198, 121/147, 75/93, 30/38, operated patients at 6, 12, 24, 36, and 48 months respectively. At these times, mean BMI was 46.7±5.1, 43.9±4.9, 42.2±6.7, 41.9±7.1, and 38.9±7. At the same intervals, mean %EWL was 24.1±19.7, 34.1±18.1, 38.8±19. 38.9±20.3, and 52.9±19.9%. Weight loss in terms of BMI and %EWL are shown in Figures 1 and 2. No significant difference was found for mean BMI or %EWL between the two groups. Figure 3 shows the patients in whom the %EWL was <25% at the times of follow-up.

Co-morbidities (n=189) were diagnosed preoperatively in 124 / 239 patients (51.8%). Of these 124 patients with associated morbidity, 74 (59.6%) had lost all their co-morbidities 1 year following LAGB placement. The success rate for single co-morbidities is reported in Table 4.

Table 2. Laparotomic conversion

	BMI <50	BMI >50	Total
Technical difficulties	14	7	21
Gastric perforation	4	1	5
Bleeding	5	1	6
Hepatomegaly	3	2	5
Splenomegaly	1	-	1
Adhesions	1	-	1
Not reported	3	2	5
	31/1558 (2.2%)	13/239 (5.4%)	44/1797 (2.4%)

Table 3. Postoperative complications

	BMI <50	BMI >50	Total
Pouch Dilatation	107 (6.8%)	7 (2.9%)	114 (6.3%)
Tube-port leak	105 (6.7%)	11 (4.6%)	116 (6.4%)
Erosion	25 (1.6%)	6 (2.5%)	31 (1.7%)
	237/1558 (15.2%)	24/239 (10%)	261/1797 (14.5%)

Discussion

The results in this study are based on the experience of 28 Italian surgical teams with different levels of experience in laparoscopic and/or bariatric surgery. Overall postoperative mortality is 10 / 1,797, mainly due to the co-morbidities and the obesity. The mortality rate in the present study is comparable to other published studies.[5-7] Although the mortality rate was higher with BMI >50 versus BMI <50, this difference was not statistically significant (P= ns). By the present analysis, when performing LAGB, the presence of a severe grade of obesity does not imply a risk of operative mortality higher than that of patients with a less advanced stage of the disease (morbid obesity).

The overall laparotomic conversion rate (44 /1,797 patients) is similar to other reported experiences, but patients with BMI >50 in this series were converted to open surgery more frequently ($P<0.05$). Abdominal wall thickness, visceral and omental fat, and hepatomegaly increase the complexity of the laparoscopic procedure, limiting access and the view of the retrogastric passage.[5-7] Surgeons in the initial phase of their experience

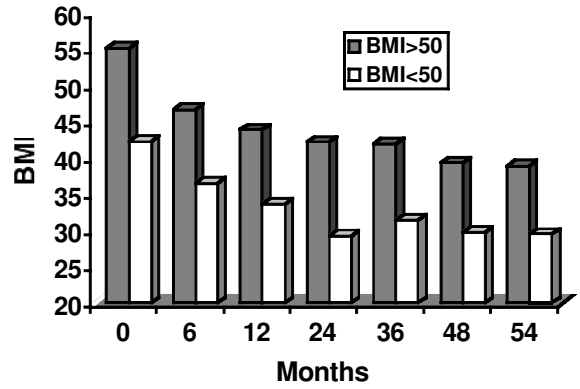

Figure 1. Postoperative BMI (kg/m^2).

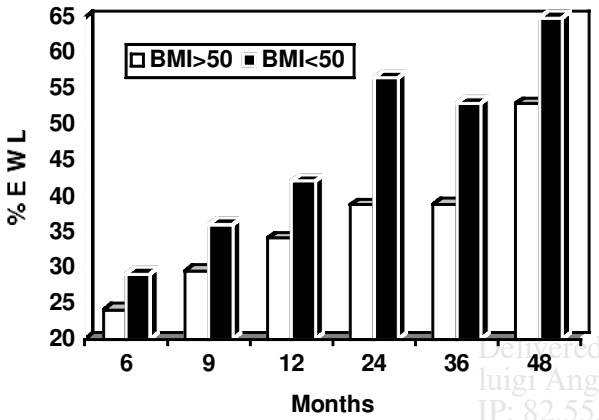

Figure 2. Postoperative percent excess weight loss (%EWL)

with the LAGB should likely avoid treating super-obese patients because of technical complexity in this advanced stage of obesity.

Pouch dilatation was less frequent in the super-obese patients ($P< 0.05$). A possible explanation is that surgeons tend to operate on this kind of patient beyond their learning curve. This is important not only for the technical details of LAGB, but also for the experience gained in band adjustment and patient management in diet counselling. Pouch complications can initially be managed conservatively by band deflation, with a minority of patients requiring reoperation, rarely requiring laparotomic access.[8,9]

Weight loss has traditionally been the main outcome measure in bariatric surgery. However, quality of life has recently been acknowledged as a criterion of success in patients submitted to obesity surgery.[10]

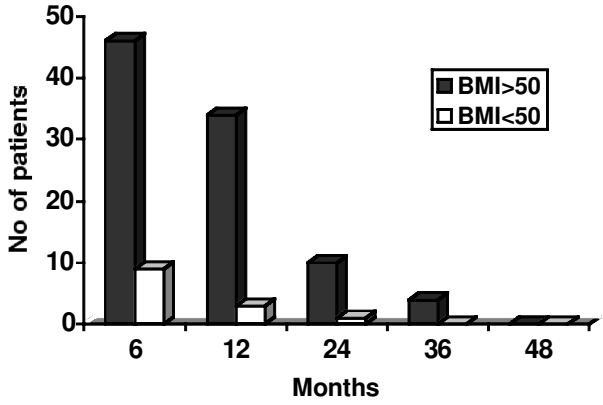

Figure 3. Patients with %EWL <25%.

Reinhold[11] in 1982 classified as *poor* results, patients who underwent gastric bypass with <25 %EWL. Mason[12] in 1992 considered as *successful,* patients operated by vertical banded gastroplasty with >25 %EWL. MacLean[3] considered as *unsuccessful* patients with BMI >35 at 5 years after Roux-en-Y gastric bypass. Although we do not yet have 5 years follow-up of super-obese patients following LAGB, the mean BMI after 4 years is 38.2. The majority of these patients have been *unsuccessful* according to MacLean criteria,[3] and would be in the *fair* category of Reinhold[11] and *successful* by Mason criteria.[12]

Weight loss eventually followed by clinical improvement and/or resolution of co-morbidities is the main reason for the surgical treatment of clinically severe obesity. Most morbidly obese patients have several co-morbidities secondary to the obesity, and particularly in patients with BMI >50, they can be life-threatening. In this series, after 12 months of follow-up, most co-morbidities had resolved. These co-morbidities were also resolved in patients that maintain a BMI >35 several years after surgery. The importance of these data have recently been confirmed by a study that demonstrated the benefits of 10 kg weight loss in terms co-morbidities (diabetes, blood pressure, lipids, etc.) and related mortality.[13,14]

In conclusion, super-obese patients who undergo LAGB obtain significant improvement in co-morbidities. An interesting policy adopted in some centers in Italy is to position a Bioenterics Intragastric Balloon (BIB, INAMED) to test patient compliance with dietary regulations and counselling.[15] With a successful response following 6 months of treatment with the BIB, patients are considered candidates for LAGB.[16]

Table 4. Co-morbidities in patients with initial BMI >50, at 1 year follow-up.

	Preop	Postop (%)	Success (%)
Respiratory problems	39	0	100
Osteoarthropathy	53	3 (5.6%)	94.4
Diabetes	12	1 (8.3%)	91.7
Hypertension	17	2 (11%)	89
Anxiety and Depression	50	28 (56%)	44
Dyslipidemia	18	14 (77%)	23

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