

# Italian Group for Lap-Band System®: Results of Multicenter Study on Patients with BMI $\leq 35$ kg/m<sup>2</sup>

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**Background:** The Lap-Band System® is the most common bariatric operation world-wide. Current selection criteria do not include patients with BMI  $\leq 35$ . We report the Italian multicentre experience with BMI  $\leq 35$  kg/m<sup>2</sup> over the last 5 years.

**Patients and Methods:** Data were obtained from 27 centres involved in the Italian Collaborative Study Group for Lap-Band System®. Detailed information was collected on a specially created electronic data sheet (MS Access 2000) on patients operated in Italy since January 1996. Items regarding patients with BMI  $\leq 35$  were selected. Data were expressed as mean  $\pm$  SD except as otherwise indicated.

**Results:** 225 (6.8%) out of 3,319 Lap-Band® patients were recruited from the data-base. 15 patients, previously submitted to another bariatric procedure (BIB=14; VBG=1) were excluded. 210 patients were eligible for study (34M/176F, mean age 38.19 $\pm$ 11.8, range 17-66 years, mean BMI 33.9 $\pm$ 1.1, range 25.1-35 kg/m<sup>2</sup>, mean excess weight 29.5 $\pm$ 7.1, range 8-41). 199 co-morbidities were diagnosed preoperatively in 55/210 patients (26.2%). 1 patient (0.4%) (35 F) died 20 months postoperatively from sepsis following perforation of dilated gastric pouch. There were no conversions to laparotomy. Postoperative complications presented in 17/210 patients (8.1%). Follow-up was obtained at 6, 12, 24, 36, 48 and 60 months. At these time periods, mean BMI was 31.1 $\pm$ 2.15, 29.7 $\pm$ 2.19, 28.7 $\pm$ 3.8, 26.7 $\pm$ 4.3, 27.9 $\pm$ 3.2, and 28.2 $\pm$ 0.9 kg/m<sup>2</sup> respectively. Co-morbidities completely resolved 1 year postoperatively in 49/55 patients (89.1%). At 60 months follow-up, only 1 patient (0.4%) has a BMI  $>30$ .

**Conclusions:** Although surgical indications for BMI  $\leq 35$  remain questionable, the Lap-Band® in this study demonstrated that all but 1 patient achieved normal weight, and most lost their co-morbidities with a very low mortality rate.

*Key words:* Obesity, bariatric surgery, gastric banding, laparoscopy, complications, weight loss, co-morbidities

## Introduction

The LapBand System® (Inamed, Santa Barbara, CA, USA) is the most common bariatric operation performed world-wide. Indications for primary bariatric operations suggested by international organizations include patients with BMI  $\geq 40$  or  $>35$  with life-threatening co-morbidities such as diabetes, sleep apnea, hypertension, dyslipidemia, and coronary heart disease.<sup>1-4</sup> These criteria are presently also recommended by the Italian Society for Surgery of Obesity (Società Italiana di Chirurgia dell'Obesità – SICOB). Nevertheless in a number of Italian centres, patients with BMI  $\leq 35$  kg/m<sup>2</sup>, have occasionally undergone Lap-Band® placement. Because in Italy an ongoing multicenter computerized study is being conducted on this operation by the Collaborative Study Group for Lap-Band® (Gruppo Italiano Lap-Band® – GILB), this was considered a unique opportunity to evaluate the outcome of a larger number of patients in this weight

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population than in a single surgeon's experience. This study is a retrospective analysis of the multicenter experience of this group in patients with BMI  $\leq 35$  kg/m<sup>2</sup>.

## Patients and Methods

A retrospective multicenter study on Lap-Band<sup>®</sup> patients from January 1996 to December 2002, was performed focusing on BMI  $\leq 35$  kg/m<sup>2</sup>. Data were recruited from all surgeons involved with this surgery, as indicated by the local distributor (Inamed). A data sheet, with more than 150 items was programmed using Microsoft Access 2000, and was mailed and e-mailed to all surgeons participating in the Italian collaborative study Group for Lap-Band<sup>®</sup> System.

All patients considered were operated under general anesthesia in lithotomy and reverse Trendelenburg (30-45°). Closed CO<sub>2</sub> pneumoperitoneum was usually performed. All patients underwent antithrombotic and antibiotic prophylaxis. Items considered were age, sex, BMI, intra-operative complications, laparotomic conversion, postoperative complications, mortality, and preoperative and postoperative co-morbidities. Data were expressed as mean  $\pm$  standard deviation (SD), except as otherwise indicated.

## Results

Of 3,319 Lap-Band System<sup>®</sup> patients, 225 (6.8%) had a BMI  $\leq 35$  kg/m<sup>2</sup> at time of surgery. Fifteen patients, previously submitted to another bariatric procedure (BioEnterics Intra-gastric Balloon – BIB<sup>®</sup>, n=14; and laparoscopic vertical banded gastroplasty – VBG, n= 1) were excluded. Thus, 210 patients were eligible for this study (34 M/176 F; mean age 38.19 $\pm$ 11.8, range 17-66 years; mean BMI 33.9 $\pm$ 1.1, range 25.1-35 kg/m<sup>2</sup>; mean excess weight - EW 29.5 $\pm$ 7.1, range 8-41). In 5 patients affected by gastroesophageal reflux disease (GERD), a hiatoplasty was performed with non-absorbable stitches (n=3) or with mesh placement (n=2). There were no intra-operative complications.

One 35 year-old-female (0.4%) died 20 months postoperatively from sepsis following gastric perforation of a dilated gastric pouch. Postoperative complications occurred in 17/210 patients (8.1%) (Table 1).

Gastric pouch dilation (GPD) presented in 11/210 patients (5.2%); 5/11 (45%) were treated successfully by band deflation, 2/11 (18.2%) underwent band repositioning, and 4/11 (36.4%) band removal. Intra-gastric band migration (erosion) was diagnosed in 2/210 (0.9%), treated by band removal. Connecting tube-port complications were observed in 4/210 patients (1.9%); 2/4 (50%) had port replacements (system infection), and 2/4 required only tube-port re-connection. One patient (0.4%) underwent band removal for psychological intolerance, and 7 patients requested and underwent band removal after satisfactory weight loss.

Weight loss follow-up was obtained in 210/210 (100%), 182/197 (92.3%), 119/148 (80.4%), 75/99 (75.7%), 49/73 (67.1%), and 21/29 (72.4%) at 6, 12, 24, 36, 48, and 60 months, respectively. At these times, mean BMI was 31.1 $\pm$ 2.15, 29.7 $\pm$ 2.19, 28.7 $\pm$ 3.8, 26.7 $\pm$ 4.3, 27.9 $\pm$ 3.2, and 28.2 $\pm$ 0.9 kg/m<sup>2</sup> respectively (Figure 1).

At the same intervals, mean % excess weight loss (%EWL) was 28.1 $\pm$ 20.7, 52.5 $\pm$ 13.2, 61.3 $\pm$ 14.7, 64.7 $\pm$ 12.2, 68.8 $\pm$ 15.3, and 71.9 $\pm$ 10.7, respectively (Figure 2). At 60 months follow-up, only one patient (0.4%) had a BMI >30. Co-morbidities (n=109) were diagnosed preoperatively in 55/225 patients (24.4%); after 1 year, these had completely resolved in 49/55 (89.1%) (Table 2).

**Table 1.** Intra- and postoperative complications and their treatment

	Number (%)	Treatment
Gastric pouch dilation	11/210 (5.2%)	Band deflation = 5 Band repositioning= 2* Band removal= 4
Tube-port leak	4/210 (1.9%)	Tube-port reconnection = 2 Port replacement = 2
Intra-gastric migration	2/210 (0.9%)	Band removal = 2

\* = 'slipping band'

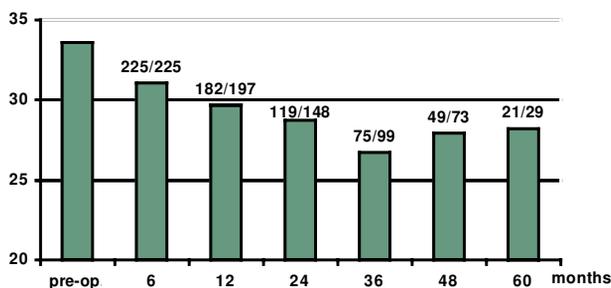


Figure 1. BMI loss in patients with initial BMI  $\leq 35$  kg/m<sup>2</sup>.

## Discussion

Surgical treatment of obese patients is currently indicated in patients with BMI  $\geq 40$  or  $>35$  with serious co-morbidities.<sup>1-4</sup> Recently, Fobi et al<sup>5</sup> have analyzed the results of gastric bypass in patients with BMI  $<40$  but  $>32$  without co-morbidities, considering not only the weight loss as the surgical target, but also the changes in psychological, social, and economic consequences of the weight loss. In the preliminary results of that study on 50 patients, the results favor treating this subgroup for several reasons: these patients have more underlying co-morbidities than apparent, they pose less risks and have fewer surgical complications, they are not severely traumatized by their obesity medically, and they can adjust to society more easily than with the higher BMI before surgery.

Results reported in the present study with Lap-Band<sup>®</sup> in patients  $\leq 35$  kg/m<sup>2</sup> are based on the experience of 27 Italian surgical teams with different levels of experience in laparoscopy and /or bariatric

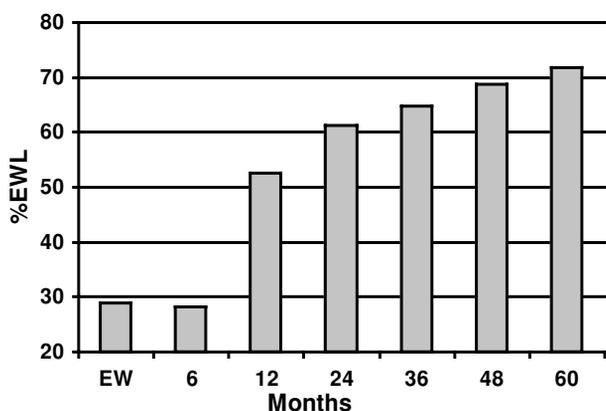


Figure 2. %EWL in patients with initial BMI  $\leq 35$  kg/m<sup>2</sup>.

Table 2. Co-morbidities in patients with initial BMI  $\leq 35$  kg/m<sup>2</sup>. Follow-up after 1 year.

	Preoperatively n	Postoperatively n (%)	Success n (%)
Anxiety and depression	47	2 (4.2)	45 (95.8)
Osteoarthropathy§	43	4 (9.2)	39 (90.8)
Hypertension	9	1 (11.1)	8 (88.9)
GERD†	5	0	5 (100)
Diabetes*	4	0	4 (100)
Respiratory disorders	1	1 (100)	0

§=including 2 patients with rheumatoid arthritis and 1 patient with poliomyelitis

†=Gastro-Esophageal Reflux Disease

\*=non-insulin dependent

surgery. The mortality rate in this study (0.4%) is comparable to the overall mortality reported (0-0.5%) in other single center studies<sup>6,7</sup> or a recent analysis of the GILB.<sup>8</sup> Laparotomic conversions were absent in this subgroup of patients. This observation can be related to the lesser grade of abdominal wall thickness, visceral and omental fat, and hepatomegaly present in patients with BMI  $\leq 35$ , with a low level of complexity of the laparoscopic procedure and a better view in retro-gastric band passage.<sup>9,10</sup> The complication rate for gastric pouch dilation (2.8%) is lower than reported in other series (4-4.6%).

Criteria of success in obesity surgery remain controversial, but in this particular subgroup, only one patient (1/21) remained with a BMI 31, and 89.1% were free of their co-morbidities after 1 year follow-up. These results appear very satisfactory. The price to pay was the 0.4% surgically-induced death (1/225 patients) due to the unfavourable and rare outcome of the patient who had perforated her dilated pouch. In light of this study, indications for this procedure should be carefully evaluated by surgeon and internist in each individual case. In selected cases, fully informed of the potentially lethal surgical complications, the procedure should be performed. The 5-year results of the Lap-Band<sup>®</sup> in patients with BMI  $<35$  should be compared prospectively with those obtained at 5 years by diet and medication.

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