



The Italian Group for LAP-BAND

Predictive value of initial body mass index for weight loss after 5 years of follow-up

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Received: 25 June 2003/Accepted: 11 March 2004/Online publication: 26 August 2004

Abstract

Background: Laparoscopic of the LAP-BAND System placement stage of obesity is a safe operation, but its indication in terms of stage of obesity is controversial. The aim of this study was to evaluate the 5 years stage of obesity results for weight loss in patients with varying preoperative ranges of body mass index (BMI).

Methods: Data were obtained from the Italian Collaborative Study Group for LAP-BAND System (GILB) registry. Detailed information was collected on a specifically created database (MS Access 2000) for patients operated on in Italy from January 1996 to 2003. Patients operated on between January 1996 and December 1997 were allocated to four groups according to preoperative BMI range: 30–39.9 kg/m² (group A), 40–49.9 kg/m² (group B), 50–59.9 kg/m² (group C), and =60 kg/m² (group D) percent estimated weight loss respectively. Postoperative complications, mortality, BMI, BMI loss, and (%EWL) were considered in each group. Data are expressed as mean ± SD, except as otherwise indicated. Statistical analysis was done by means of Fisher's exact test, and $p < 0.05$ was considered significant.

Results: After 5 years from LAP-BAND System surgery, 573 of 3,562 patients were eligible for the study. One hundred fifty-five of 573 (27.0%) were lost to follow-up, 24 of 418 (5.7%) underwent band removal due to complications (gastric pouch dilation, band erosion), eight of 418 (1.9%) were converted to other bariatric procedures, five of 418 (1.2%) died of causes not related to the operation or the band, and 381 of 573 (66.5%) were available for follow-up. Based on 96, 214, 64, and seven patients their preoperative BMI, Were allocated to groups A, B, C, and D, respectively. At time of follow-up mean BMI was 27.5 ± 5.2 in group A, 31.6 ± 4.7 in

group B, 37.6 ± 17.3 in group C, and 41.4 ± 6.9 kg/m² in group D. Mean BMI loss was 9.8 ± 5.4, 12.9 ± 5.2, 15.8 ± 8.1, and 23.2 ± 4.9 kg/m², respectively, in groups A, B, C, and D. Mean %EWL at the same time was 54.6 ± 32.3 in group A, 54.1 ± 17.2 in group B, 51.6 ± 35 in group C, and 59.1 ± 17.1 in group D.

Conclusion: Initial BMI in this series did not correlate with %EWL 5 years after the operation. In fact %EWL was almost the same in each group, independent of preoperative weight. Initial BMI was an accurate indicator of the results obtained 5 years after LAP-BAND in group C (50–59.9 kg/m²) and D (=60 kg/m²) patients, who remained morbidly obese despite their %EWL.

Key words: Obesity Surgery — LAP-BAND System — Complications — Weight loss

The LAP-BAND System (Inamed Health, Santa Barbara, CA, USA) for the surgical treatment of morbid obesity has been shown to be safe, and it is now the most common bariatric procedure performed worldwide. Although several studies have reported long-term follow-up with good results in terms of weight loss, the patients selection criteria remain controversial [1–4]. Factors that would objectively exclude or indicate candidates for LAP-BAND remain unknown in spite of long-term studies and the large number of operated patients. The aim of this study was to evaluate different preoperative ranges of body mass index (BMI) to determine their predictive value for weight loss after 5 years of follow-up in patients with LAP-BAND System placement.

Patients and methods

We conducted a retrospective multicenter study on LAP-BAND System patients in Italy. Data were collected from January 1996 to

December 1997 from all surgeons participating in the Italian Collaborative Study Group for LAPBAND (GILB), (Euroconsult, Naples, Italy). Patient data were collected by means of an electronic datasheet specifically created using Microsoft Access 2000.

All patients had been operated on under general anesthesia in lithotomy and reverse (30–45°) Trendelenburg Position. A closed carbon dioxide pneumoperitoneum was usually used. All patients underwent antithrombotic and antibiotic prophylaxis. The LAP-BAND System was implanted by perigastric dissection.

For the purpose of this study, patients were allocated into four groups according to their preoperative BMI: 30–39.9 kg/m² (group A); 40–49.9 kg/m² (group B); 50–59.9 kg/m² (group C), and ≥ 60 kg/m² (group D). The following parameters were considered in all groups: age, sex, BMI, intraoperative complications, laparotomic conversion, postoperative complications, mortality, and preoperative and postoperative comorbidities. In each group, BMI, BMI loss, and percent estimated weight loss (%EWL) were calculated after 5 years of follow-up.

Data are expressed as mean \pm SD, except as otherwise indicated. Statistical analysis was done by means of Fisher's exact test, and $p < 0.05$ was considered significant.

Results

Since January 1996, 3,562 patients, operated on at 26 centers (Table 1), have been recorded in the database of the Italian Group for LAP-BAND (GILB). After 5 years from surgery, 573 of 3,562 patients were eligible for the study (122 men and 451 women, mean age; 38.3 ± 11.7 years; range, 16–74 years; mean BMI, 44.2 ± 6.5 kg/m²; range, 30–83.6 kg/m²; EW, 58.2 ± 18.1 kg range, 11–138 kg; %EWL, 93.3 ± 30.8 ; range, 16.7–297%) (Table 2). During 5 years of follow-up, twenty four of 573 patients (4.2%) underwent band removal, eight of 573 (1.4%) were converted to other bariatric procedures, and five of 573 (0.9%) died. One fifty five of 573 patients (27.0%) were lost at 5 years of follow-up, and 381 of 573 (66.5%) were present.

Complications according to group are reported in Table 3. The mortality rate was significantly higher ($p < 0.01$) in patients with a BMI of 50–59.9 (group C), whereas gastric pouch dilation was more frequent in patients with a BMI of 30–39.9 (group A) ($p < 0.05$) and > 60 (group D); ($P < 0.01$). Intra gastric migration (erosion) had the same incidence rate in all groups. Mean BMI, mean BMI loss, mean %EWL and %EWL < 25 by group after 5 years of follow-up are reported in Table 4. There was no difference among the four group in mean %EWL.) However, in group B only, 1.9% of patients had a %EWL < 25 at 5 years ($p < 0.05$).

Discussion

Placement of the LAP-BAND System is a very elegant operation, easy to learn, quick to perform, and well-accepted by patients, with a low rate of mortality and mild complications that very rarely become lethal. For these reasons, it is widely applied for the treatment of morbid obesity. Surgical complications and death are not consistent problems of this operation. At 5 years, the overall mortality rate was five of 573 patients (0.9%) in the present study. It was more frequent (p

Table 1. Participating centers in the Italian Group for LAP-BAND (GILB)

Surgeon	Center	No. of patients	Inception
F. Favretti	Vicenza	828	1993
F. Furbetta	Pisa	593	1995
S. B. Doldi	Milano	365	1993
E. Lattuada	Milano	215	1995
M. Paganelli	Milano	206	1996
M. Lucchese	Firenze	188	1996
A. Iuppa	Catania	182	1997
N. Basso	Roma	174	1996
L. Angrisani	Napoli	140	1996
F. D. Capizzi	Bologna	117	1999
G. Lesti	Lanciano	116	1997
A. Paganini	Ancona	60	1995
N. Di Lorenzo	Avezzano	58	2000
L. Di Cosmo	Siena	57	1997
C. Giardiello	Napoli	44	1999
M. Alkilani	R. Calabria	43	1997
S. Lacitignola	M. Franca	35	2000
A. Veneziani	Roma	30	1997
P. Forestieri	Napoli	29	1995
M. Toppino	Torino	29	1996
A. Gardinazzi	Brescia	17	2000
F. Puglisi	Bari	13	1999
P. Bernante	Padova	10	1999
F. Campanile	Roma	10	2000
B. Marzano	Pordenone	10	2000

Table 2. Preoperative patient data

No. of patients	3,562	573
M/F	596/2,966	122/451
Age (yr)	37.9 ± 11.8 (range; 15–74)	38.3 ± 11.7 (range; 16–74)
Mean BMI	43.4 ± 6.5 (range; 26.9 ^a –83.6)	44.2 ± 6.5 (range; 30–83.6)
Mean EW	55.1 ± 19.9 (range; 13–154)	58.2 ± 18.1 (range; 11–138)
Mean %EW	87.9 ± 32.1 (range; 16.4–305.8)	94.3 ± 30.8 (range; 16.4–297)

BMI, body mass index; EW, estimated weight

^a Patients underwent preoperative treatment with a Bioenterics Intra gastric Balloon (BIB; Inamed Health, Santa Barbara, CA)

< 0.01) in superobese patients (BMI 50–59.9, group C). All but one of these patients were affected pre-operatively by severe hypertension. The 30-day mortality rate was 0.3% (three of 381 patients) and was not related to surgery or its complications. In these cases, death was due to myocardial infarction ($n = 2$) and pulmonary embolism ($n = 1$). One other patient, after hospital discharge, also died of pulmonary embolism 60 days later. The only patient who died of surgically related complications suffered from gastric pouch dilatation, perforation, and sepsis. Gastric pouch dilation occurred in 24 patients (4.1 %). It was more frequent in group A ($p < 0.05$) and group C ($p < 0.01$) patients. Intra gastric migration was reported in 12 patients (2%). These technical complications occurred in to the early phase of the learning curve at most of the Italian centers collaborating in this study [2]. Unsatisfactory weight loss represents the main

Table 3. Mortality and complications by group

Group	BMI (range)	No. of patients	M/F	Age (yr) (mean \pm SD) (range)	Mortality (n) (%)	Gastric pouch dilation (n) (%)	Intragastric migration/shill erosion (n) (%)
A	30–39.9	166	138/258	36.9 \pm 12.1 (18–61)	1 (0.6)	12 (7.2) ^a	3 (1.8)
B	40–49.9	302	61/241	37.8 \pm 10.9 (21–63)	1 (0.3)	10 (3.3)	6 (1.9)
C	50–59.9	96	19/77	39 \pm 12.5 (18–74)	3 (3.1) ^b	1 (1)	3 (3.1)
D	=60	9	1/8	37.1 \pm 14.7 (23–65)	0	1 (11.1) ^c	0
Total		573	122/451	38.3 \pm 11.7 (16–74)	4 (0.87)	24 (4.1)	12 (2.1)

BMI, body mass index

^a $p < 0.05$

^b $p < 0.01$

^c $p < 0.01$

Table 4. Results after 5 years of follow-up

Groups	No. of patients (%)	BMI	BMI loss	%EWL	< 25 %EWL	< 50 %EWL
A	96/166 (57.8)	27.5 \pm 5.2	9.8 \pm 5.4	54.6 \pm 32.3	9 (9.7)	17 (18.4)
B	214/302 (70.8)	31.6 \pm 4.7	12.9 \pm 5.2	54.1 \pm 17.2	4 (1.9) ^a	51 (24.8)
C	64/96 (66.6)	37.6 \pm 17.3	15.8 \pm 8.1	51.6 \pm 35	9 (9.3)	23 (23.9)
D	7/9 (77.7)	41.4 \pm 6.9	23.2 \pm 4.9	59.1 \pm 17.1	0	0
Total	381/573 (66.5)	30.2 \pm 8.3	12 \pm 6	54.8 \pm 22.3	22/365 (6)	91/365 (24.9)

BMI, body mass index; %EWL, percent estimated weight loss

BMI, BMI loss, %EWL are expressed as mean \pm SD

^a $p < 0.05$

problem of the LAP-BAND System operation for morbid obesity. After 5 years of follow-up, 6% and 24.9% of patients in this series remained at <25 and <50 %EWL, respectively. Therefore it is clear that the identification of preoperative selection criteria is a priority. There have been a few papers in the international literature that have recently addressed this topic [1, 4, 6]. Dixon et al. [6] found that older age, hyperinsulinemia, and impaired physical ability were predictive of a significantly lower %EWL at 1 year of follow-up after LAP-BAND placement. They concluded that although these preoperative conditions were responsible for a lower weight loss, they should not be considered a contraindication to LAP-BAND surgery. BMI was not predictive of %EWL. At 2 years and beyond, In a study of 260 morbidly obese patients followed up for 3 years, Busetto et al. [4] found that the only statistical predictors of success (%EWL > 50) for LAP-BAND surgery were young age and preoperative low BMI. They found that the success rate was significantly higher ($p < 0.001$) in patients =40 years old than in older patients. Similar results were observed in patients with a BMI <50 kg/m², who had a higher success rate ($p < 0.05$) than superobese patients. Moreover the failure rate (%EWL <20) was higher in women ($p < 0.01$) and in sweet eaters ($p < 0.05$).

In our study, family history of obesity, current status as a smoker, type 2 diabetes, depression, and other eating disorders were not predictive of success or failure of LAP-BAND placement. For our 381 patients with 5 years of follow-up, weight loss predictivity analysis was based only on preoperative BMI. In terms

of the mean BMI loss in different groups of patients, those with a higher initial BMI (groups C and D) achieved a greater mean BMI loss. Super-and super-superobese patients lost more units of BMI than their counterparts, but the difference was not statistically significant. These data also confirm our previous report that the mean BMI at 5 years in superobese patients undergoing LAPBAND surgery remains in the range of morbid obesity.

An other interesting finding of the present study is that, independent of their preoperative BMI, the patients in the four groups analyzed here obtained a similar mean %EWL (51.6–59.1). The differences were not statistically significant. Translated into clinical practice, this finding could be interpreted to mean that when the LAP-BAND System is implanted in patients with a BMI of 30–60 kg/m², it produces a 50% EWL. Thus, the results of LAP-BAND surgery in terms of %EWL are independent of the preoperative BMI. Data regarding the percentage of patients who failed to obtain a %EWL <25% show that group B obtained the worst results. Considering those patients with an EWL <50% no statistically significant difference could be found among the four groups. In this respect, these data do not appear to be conclusive.

In conclusion, three options are presently offered to super-and super-superobese patients considered for LAP-BAND System surgery. One is to receive the operation and enjoy the limited benefit of their 50% EWL, while remaining morbidly obese. The second is to consider preoperatively a conservative approach that would enable them to reduce their initial weight to a BMI <50. The third is to receive the band operation

and, in case of unsatisfactory weight loss, to subsequently consider more invasive types of procedures [5, 7].

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