Safety and Efficacy of Laparoscopic Adjustable Gastric Banding in the Elderly

Luca Busetto[1], Luigi Angrisani[2], Nicola Basso[3], Franco Favretti[4], Francesco Furbetta[5] and Michele Lorenzo[6] for the Italian Group for Lap-Band*

Objective: Bariatric surgery is not usually recommended in the elderly. The aim of this study is to evaluate the safety and efficacy of laparoscopic adjustable gastric banding (LAGB) in older patients registered in the database of the Italian Group for Lap-Band Gruppo Italiano Lap-Band (GILB).

Methods and Procedures: GILB is a centralized database which collects operative and follow-up data from 26 Italian surgical centers who utilize the Lap-Band System as a restrictive procedure. Patients ≥60 years were selected from the database of the GILB and analyzed according to co-morbidities, conversion, peri-operative complications, and weight loss.

Results: Of 5,290 patients, 216 (4.1%; 184F/32M) were ≥60 years old at surgery (mean age 64.1 ± 4.0 years; range 60–83). Baseline BMI was similar in both sets of patients i.e., ≥60 and <60 years of age (44.2 ± 7.6 kg/m^2 vs. 44.9 ± 7.4 kg/m^2). Patients ≥60 years of age were more frequently affected by co-morbidities than patients <60 years of age. Two cases of operative mortality were observed in patients <60 years old (0.04%) and one in patients ≥60 years old (0.46%). The proportion of patients requiring revision surgery was comparable as well. Weight loss was significantly lower in elderly patients. Despite their lower weight loss, patients ≥60 years of age experienced a significant improvement of obesity-related co-morbidities (they showed improvement 1 year after surgery in 100% of cases of diabetes or sleep apnoea, 67.1% of cases of hypertension, and 34.9% of cases of osteoarthritis).

Discussion: LAGB may be performed safely in patients ≥60 years old. Weight loss in older patients seems unsatisfactory if compared to younger subjects. However, the majority of elderly patients show an improvement in obesity-related co-morbidities.

Obesity (2008) **16,** 334–338. doi:10.1038/oby.2007.85

INTRODUCTION

The prevalence of morbid obesity in the elderly is increasing. According to a national 1999–2002 examination, the prevalence of extreme obesity among American adults aged >60 years was 1.7% in men and 5.6% in women (1). Obesity causes serious medical complications and impairs quality of life in the elderly just as much as in adults. Moreover, in older persons, obesity can exacerbate the age-related decline in physical function and lead to frailty (2). In the case of morbid obesity, the impact of being fat on the well-being and the physical functioning of the elderly is even more important.

Bariatric surgery is now widely accepted as the most effective therapeutic strategy in the management of morbid obesity in adults (3). However, despite official guidelines not providing specific age limits (4), the use of bariatric surgery in the elderly is not routinely recommended. A nationwide analysis of the age-distribution of patients undergoing bariatric surgery in the United States from 1998 to 2002 showed that only ~1% of the patients were >64 years old (5). The lesser use of bariatric surgery in the elderly may be related to concerns regarding the potential harmful effects of the sustained weight loss obtained by surgery in the older population. Weight loss usually results in a decrease in both fat mass and lean body mass and therefore it is possible that surgery-induced weight loss in obese older persons could worsen the age-related loss of muscle mass, increase sarcopenia, and cause disability (2). Moreover, advanced age carries a higher risk for peri-operative morbidity and mortality. In a study among Medicare beneficiaries undergoing bariatric surgical procedures, mainly gastric bypass, an age-related increase in early mortality was observed,

*Members of the Italian Group for Lap-Band (Gruppo Italiano Lap-Band—GILB) are listed in Supplementary Data online.

[1]Università degli Studi di Padova, Clinica Medica 1, Padova, Italy; [2]Università Federico II, Ospedale S. Giovanni Bosco, Unità di Chirurgia Endoscopica, Napoli, Italy; [3]Università La Sapienza, Dipartimento di Chirurgia "P. Stefanini", Policlinico Umberto I, Roma, Italy; [4]Ospedale San Bortolo, Chirurgia 2, Vicenza, Italy; [5]Casa di Cura Leonardo, Chirurgia Generale e Laparoscopica, Sovigliana, Italy; [6]Italian Group for Lap-Band—GILB, Fondazione IDIS, Città della Scienza, Napoli, Italy. Correspondence: Luca Busetto (luca.busetto@unipd.it)

Received 21 March 2007; accepted 12 July 2007. doi:10.1038/oby.2007.85

with a 90-day mortality rate of 4.6% in patients 65–74 years of age and of 1.8% in patients 25–34 years of age (6). On this basis, a recent technical review and position statement on obesity in older adults by the American Society for Nutrition and North American Association for the Study of Obesity, the Obesity Society, suggests that laparoscopic adjustable gastric banding (LAGB) may be a better choice than gastric bypass for selected older patients, because LAGB is associated with fewer serious operative complications and a lower mortality rate (2). However, the joint experts panel concludes that more data are needed about the mortality risk, complication rate, weight loss efficacy, clinical outcomes, and cost-effectiveness of the specific surgical procedures (2). In this study, we report on the safety and efficacy of LAGB in a large group of older patients included in the multi-sites database of the Italian Group for Lap-band (Gruppo Italiano Lap-Band—GILB).

METHODS AND PROCEDURES

GILB is a centralized electronic database, which collects operative and follow-up data from 26 Italian surgical centers utilizing the Lap-Band System (Allergan Medical, Irvine, CA) as an adjustable gastric banding procedure (see **Supplementary Data** online). The structure of the GILB has been recently reported (7). Briefly, a pre-operative multidisciplinary assessment of the patients was performed in all centers, and patients were selected for bariatric surgery according to standardized international guidelines (4). Provided these simple requirements were fulfilled, no further limitations were placed upon participation. Inclusion of the centers in the database was on a voluntary basis. The decision as to what specific surgical procedure to perform in each patient (LAGB, gastric bypass or malabsorptive operation) and about what operative technique to use for the placement of LAGB (perigastric or pars flaccida) was left to the clinical judgment of surgeons at each center.

Specific questions about preoperative and postoperative comorbidites were included in the GILB database. At baseline, being diabetic was defined as having a fasting plasma glucose level ≥7.0 mmol/l or being under the use of any antidiabetic drug (8), and an improvement in the diabetic condition during follow-up was based upon a normalization of glucose levels or a reduction of antidiabetic medications. Dyslipidemia was diagnosed when either total cholesterol >5.2 mmol/l, high-density lipoprotein-cholesterol <0.9 mmol/l, or triglycerides >2.2 mmol/l (9) or when the patient was using any of the hypolipemic drugs, and an improvement in dyslipidemia meant a normalization of lipid levels or a reduction of hypolipemic medications. Hypertension was defined when the blood pressure ≥140/90 mm Hg or when the patient was using any of the antihypertensive drugs (10) and improvement of hypertension meant a normalization of blood pressure levels or a reduction of antihypertensive medications. Sleep apnea was diagnosed on the basis of the presence of subjective diurnal and/or nocturnal symptoms (11). An instrumental registration of the breathing pattern during sleep was not mandatory. Improvement of sleep apnea was acknowledged if there was a significant improvement in the subjective symptoms. Osteoarthritis was clinically defined as the presence of chronic pain at the weight-bearing joints with or without the use of pain-suppressant medications, and improvement of osteoarthritis was acknowledged if there was a significant reduction in pain or in the use of pain-suppressant medications.

On 31 December 2005, a total of 5,290 morbid obese patients treated by LAGB were included in the database. We performed a retrospective analysis by selecting from the database all patients ≥60 years old at surgery. The data of these older patients were analyzed for peri-operative mortality, laparotomic conversion, intra- and post-operative complications, BMI and BMI loss up to 5 years after surgery, and pre-operative and post-operative comorbidities. None of the centers that have submitted their data have been excluded from this analysis.

In all statistical analyses, patients <60 years old were used as a control group. Results are expressed as means ± s.d. and a P value <0.05 was considered to be significant. Differences between patients ≥60 and <60 years of age were tested with unpaired Student's t-test for numerical variables and Chi-square test for categorical variables. Statistical analysis was performed by using the SSPS statistical package, version 11.0 (SSPS, Chicago, IL).

RESULTS

A total of 216 (4.1%) out of the 5,290 morbid obese patients registered in the GILB database were ≥60 years old at surgery. In particular, 173 patients were 60–69 years of age, 41 patients were 70–79 years of age, and only two patients were ≥80 years at surgery. The characteristics of these older patients before surgery, as compared to younger subjects, are reported in **Table 1**. Data are reported for the older group as a whole and for patients in the age groups of 60–69 years and 70–79 years separately. Mean age at surgery in the older group was 64.1 ± 4.0 years, with a range from 60 to 83 years. There were no significant differences between the two main groups or in any subgroup in the sex distribution or in the BMI levels at surgery. Despite a similar degree of obesity, patients ≥60 years old were more significantly affected by obesity-related co-morbidities. In particular, we observed a fourfold higher prevalence of type 2 diabetes and a eightfold higher prevalence of obstructive sleep apnea syndrome in the older group. The prevalence of type 2 diabetes was higher in patients in the age group of 60–69 years than in patients who

Table 1 Clinical characteristics before surgery in 5,074 patients <60 years old and in 216 patients ≥60 years old treated by the laparoscopic adjustable gastric banding (LAGB) and registered in the Gruppo Italiano Lap-Band (GILB) database. Data are reported for the older group as a total and for patients 60–69 years old and 70–79 years old separately

	<60 years old	≥60 years old	60–69 years old	70–79 years old
Number	5,074	216	173	41
Male sex (%)	22.4	14.8	15.0	12.2
Age (years)	36.5 ± 11.0	64.1 ± 4.0*	61.6 ± 3.5*	71.4 ± 3.1*
Body weight (kg)	115.2 ± 22.2	116.4 ± 21.1	119.0 ± 24.1	114.3 ± 18.7
BMI (kg/m^2)	44.9 ± 7.4	44.2 ± 7.6	44.3 ± 8.7	42.1 ± 6.0
Hypertension (%)	15.4	35.2*	34.1*	36.6*
Type 2 diabetes (%)	5.7	21.1*	23.7*	13.1
Dyslipidemia (%)	1.6	11.9*	11.6*	14.6*
Sleep apnea (%)	2.2	15.6*	14.4*	17.1*
Osteoarthritis (%)	22.4	38.8**	30.7**	70.7*

Values are means ± s.d. and percent values. Two patients ≥80 years old were excluded from the subgroups analysis. Unpaired student's t-test for numerical variables and Chi-square test for categorical variables were performed with patients <60 years old as the reference group: *P < 0.001; **P < 0.05.

were 70–79 years of age, whereas the prevalence of osteoarthritis was higher in patients who were 70–79 years of age than in patients of 60–69 years.

Among the 216 patients ≥60 years of age, 207 were operated in centers performing >100 procedures per year, representing 4.3% of the patients operated in these centers, and only nine in centers performing <100 procedures per year, representing the 1.7% of the patients operated in these centers ($P < 0.01$). The low number of patients treated in low volume centers precluded any analysis about the effects of center size on the outcome of LAGB in the elderly.

We did not observe any significant difference in the operative data between patients ≥60 and <60 years old. Further surgical procedure, mainly simultaneous cholecystectomy in patients with cholelithiasis and simultaneous hiatal hernia repair in patients with large hiatal hernia, was done in 17 patients in the older group (7.8%) and in 285 patients in the younger group (5.6%). The rate of intra-operative complications was <1% in both groups. Laparotomic conversion was necessary in one patient ≥60 years of age (0.5%) and in 71 patients <60 years of age (1.4%). One patient (0.46%) in the older group and two patients (0.04%) in the younger group died in the first 30 days after surgery. The case of peri-operative mortality in the older group was represented by a 60 years old woman affected by dilated cardiomyopathy who died 7 h after surgery due to a massive pulmonary embolism. No differences in operative data were observed between patients in the age groups of 60–69 years and 70–79 years. The proportion of patients requiring revision surgery was also similar in the two groups (Table 2). In particular, the proportion of patients requiring band removal, mainly for erosion, or band repositioning, mainly for slippage of the banding, was similar in the two groups. In patients <60 years of age, 56 patients (1.1%) were shifted to malabsorptive techniques because of insufficient weight loss. This option was not followed in any patient >60 years of age at surgery. All cases of revision surgery in patients ≥60 years were performed in patients <70 years of age.

Follow-up rate declined from 93.3% at 1 year after surgery to 69.3% at 5 years after surgery, without any significant difference between the age groups. Weight loss in the first 5 years after surgery was lower in the group of patients ≥60 years of age than in the group of patients <60 years of age (Figure 1). BMI 1-year after surgery was 35.1 ± 7.6 kg/m^2 in younger and 38.6 ± 7.2 kg/m^2 in older patients ($P < 0.05$). This difference was maintained up to 5 years after surgery (32.8 ± 7.9 kg/m^2 vs. 37.9 ± 6.9 kg/m^2 at 2 years, $P < 0.05$; 33.1 ± 6.9 kg/m^2 vs. 37.8 ± 7.3 kg/m^2 at 3 years, $P < 0.01$; 30.9 ± 8.1 kg/m^2 vs. 38.1 ± 8.8 kg/m^2 at 4 years, $P < 0.001$; 29.9 ± 8.8 kg/m^2 vs. 35.9 ± 7.6 kg/m^2 at 5 years, $P < 0.01$). No differences in weight loss were observed between patients in the age groups of 60–69 years and 70–79 years.

Obesity-related co-morbidities were re-assessed 1 year after surgery in all patients. The proportion of patients showing an improvement in their co-morbidities in the two age groups is shown in Figure 2. Despite lower weight loss, patients ≥60 years of age experienced a significant improvement in most of their co-morbidities. All patients suffering from type 2 diabetes (46/46 patients, 100%) or sleep apnoea (34/34 patients, 100%) had an improvement 1 year after surgery, as found in the younger group (279/289 patients, 96.5% and 110/112 patients, 98.2%, respectively). Hypertension improved in two-thirds of patients ≥60 years of age (51/76 patients, 67.1%), a proportion significantly lower than in patients <60 years

Table 2 Patients requiring revision surgery during follow-up in 216 patients ≥60 years old and in 5,074 patients <60 years old treated by the laparoscopic adjustable gastric banding (LAGB) and registered in the Gruppo Italiano Lap-Band (GILB) database. Data are reported for the older group as a total and for patients 60–69 years old and 70–79 years old separately

	<60 years old	≥60 years old	60–69 years old	70–79 years old
Band removal	74 (1.4%)	2 (0.9%)	2 (1.1%)	0 (0.0%)
Band repositioning	114 (2.2%)	6 (2.7%)	6 (3.4%)	0 (0.0%)
Malabsorption	56 (1.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	244 (4.8%)	8 (3.7%)	8 (4.6%)	0 (0.0%)

Values are absolute numbers and percent values. Chi-square test was performed and no significant differences were detected.

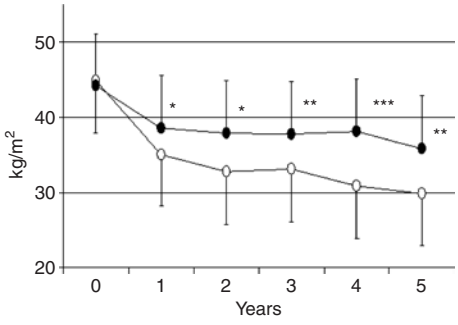

Figure 1 BMI curves in the first 5 years after surgery in 216 patients ≥60 years old (closed symbols) and in 5,074 patients <60 years old (open symbols) treated by the Lap-Band System and registered in the Gruppo Italiano Lap-Band (GILB) database. Unpaired student's *t*-test: *$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

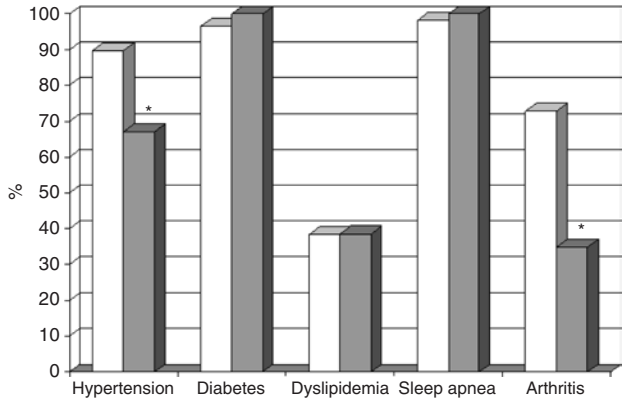

Figure 2 Proportion of patients showing an improvement of obesity-related co-morbidities 1 year after surgery in 5,074 patients <60 years old (white bars) and in 216 patients ≥60 years old (gray bars). Chi-square test: *$P < 0.001$.

of age (702/781 patients, 89.8%, $P < 0.001$). Dyslipidemia improved only in a minority of the affected patients both in the older and in the younger group (10/26 patients, 38.5% and 31/81 patients, 38.3%, respectively). Finally, while in patients <60 years old the large majority of patients suffering from osteoarthritis at baseline had an improvement 1 year after surgery (821/1,137 patients, 72.9%), an improvement of joint pain was observed only in one-third of patients ≥60 years of age (29/83 patients, 34.9%, $P < 0.001$). No significant differences in the proportion of patients showing an improvement in their co-morbidities were observed between patients in the age groups of 60–69 years and 70–79 years.

DISCUSSION

In this study, we analyzed the outcome for a large group of morbidly obese elderly patients treated with LAGB and registered in a multi-site national registry. Our data confirmed that LAGB can be performed safely in the elderly as well as in adults. The weight loss obtained in older patients is lower than expected, but it is still associated with a significant improvement in most of the obesity-related co-morbidities.

A recent position statement on obesity in older adults concluded that more clinical studies are needed to evaluate the use of bariatric surgery in the treatment of extreme obesity in older persons (2). Our study is an observational retrospective analysis that may not be considered at the same level of scientific soundness as a prospective randomized clinical trial. However, only a few single-site small series of studies have to date specifically evaluated the effect of bariatric surgery in patients >60 years of age (12–15) and our study now presents the largest series of older persons ever published. These patients have been selected from a multi-site database that collects peri-operative and follow-up data from 26 surgical centers well distributed over the entire Italian territory. The database comprises high volume institutions with >100 procedures per year, middle volume centers with 20–50 procedures per year and also some centers who utilized the LAGB only for a limited period of time and then shifted to other types of operations (see **Supplementary Data** online). The database may therefore be considered truly representative of the general practice of gastric banding in Italy and our data on elderly patients are probably more clinically significant than those available from single-site small series. On the other hand, the clinical setting in which the multi-site data were collected probably explains the lower follow-up rate observed in our study. Approximately 30% of the patients were not followed 5 years after surgery and this may affect the reliability of our results. However, no differences in follow-up rate were observed between older and younger patients.

Roux-en-Y gastric bypass is the most frequently performed bariatric procedure in the United States. Estimated peri-operative mortality after gastric bypass is ~0.5% in adults (16). Composite data from single-site studies evaluating the use of gastric bypass in the elderly suggests greater peri-operative morbidity, but the small sample size precludes any reliable estimate of specific peri-operative mortality (12–15). On the other hand, a large cohort analysis among Medicare beneficiaries undergoing bariatric surgical procedures, mainly gastric bypass, showed an alarming 90-days' mortality rate of 4.6% in patients 65–74 years of age (6). LAGB had a lower peri-operative morbidity than gastric bypass, with an estimated early mortality of 0.1% in adults (16). Our multi-site study on >200 elderly patients demonstrated that LAGB may performed safely also in older persons, with a very low rate of operative complications and a peri-operative mortality still <0.5%.

Previous reports about the outcome of patients treated with LAGB suggested that advancing age and some other age-related factors, like insulin resistance, poor physical activity and poor general health, are related to a lower degree of weight loss after LAGB (17,18), as was found in our study. Indeed, patients >60 years registered in the GILB database have a weight loss that is nearly half of the weight loss observed in younger patients. Despite this lower level of weight loss, patients >60 years had an improvement of their co-morbidity after surgery similar to that observed in more successful younger patients. One year after banding, all patients with diabetes or sleep apnoea syndrome and ~70% of the patients suffering from hypertension had an improvement in their co-morbidities. However, the clinical relevance of this observation may be decreased by the fact that the assessment of comorbidities and their evolution, sleep apnoea in particular, was not performed with a gold standard methodology in our multi-sites study. On the other hand, not all the co-morbidities suffered by elderly patients at baseline showed the same degree of improvement after surgery. In particular, only one-third of the large number of patients affected by osteoarthritis at baseline reported an improvement in this comorbidity 1 year after surgery. Arthritis is the leading cause of physical disability in older adults and a high BMI is associated with an increased risk of osteoarthritis in older persons (2).

In conclusion, our results support the use of LAGB in the elderly, at least on the side of safety. On the side of efficacy, a lower weight loss should be expected in older patients. The impact of the weight loss induced by LAGB on comorbidities, the physical performance, and the health-related quality of life of elderly morbid obese patients needs to be evaluated in more specific studies.

ACKNOWLEDGMENTS

The activities of the Italian Group for Lap-Band (Gruppo Italiano Lap-Band (GILB)) are sponsored by Allergan Medical (Irvine, CA), the manufacturer of the Lap-Band System. However, the sponsor does not have any role in the analysis of the data collected in the database, in their interpretation, or in the preparation of the manuscript. Preliminary data from this study have been presented at the International Symposium on Obesity in the Elderly, Rome, Italy, 26–28 January 2006 (abstract in *The Journal of Nutrition, Health and Aging* 2006;10:56–57).

DISCLOSURE

The authors declared no conflict of interest.

REFERENCES

1. Hedley AA, Ogden CL, Johnson CL *et al.* Prevalence of overweight and obesity among US children, adolescents, and adults, 1999-2002. *JAMA* 2004;291:2847–2850.

2. Villareal DT, Apovian CM, Kushner RF, Klein S; American Society for Nutrition; NAASO, The Obesity Society. Obesity in older adults: technical review and position statement of the American Society for Nutrition and NAASO, The Obesity Society. *Obes Res* 2005;13:1849–1863.
3. NHLBI Obesity Education Initiative Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults—the evidence report. *Obes Res* 1998;6:S51–S209.
4. National Institutes of Health Consensus Development Draft Statement. Gastrointestinal surgery for severe obesity. *Obes Surg* 1991;1:257–266.
5. Santry HP, Gillen DL, Lauderdale DS. Trends in bariatric surgery procedures. *JAMA* 2005;294:1909–1917.
6. Flum DR, Salem L, Broeckel Elrod JA *et al.* Early mortality among medicare beneficiaries undergoing bariatric surgical procedures. *JAMA* 2005;294:1903–1908.
7. Angrisani L, Favretti F, Furbetta F *et al.* for the Italian Collaborative Study Group for Lap-Band System. Obese teenagers treated by Lap-Band System: the Italian experience. *Surgery* 2005;138:877–881.
8. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 1997;20:1183–1197.
9. National Cholesterol Education Program. Second Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment panel II). *Circulation* 1994;89:1333–1445.
10. The Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure: The 1984 Report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure. *Arch Intern Med* 1984;144:1045–1057.
11. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. *Sleep* 1999;22:667–689.
12. Sugerman HJ, DeMaria EJ, Kellum JM *et al.* Effects of bariatric surgery in older patients. *Ann Surg* 2004;240:243–247.
13. Sosa JL, Pombo H, Pallavicini H, Riuz-Rodriguez M. Laparoscopic gastric bypass beyond age 60. *Obes Surg* 2004;14:1398–1401.
14. St Peter SD, Craft RO, Tiede JL, Swain JM. Impact of advanced age on weight loss and health benefits after laparoscopic gastric bypass. *Arch Surg* 2005;140:165–168.
15. Quebbemann B, Engstrom D, Siegfried T, Garner K, Dallal R. Bariatric surgery in patients older than 65 years is safe and effective. *SOARD* 2005;1:389–393.
16. Buchwald H, Avidor Y, Braunwald E *et al.* Bariatric surgery: a systematic review and meta-analysis. *JAMA* 2004;292:1724–1737.
17. Busetto L, Segato G, De Marchi F *et al.* Outcome predictors in morbidly obese recipients of an adjustable gastric band. *Obes Surg* 2002;12:83–92.
18. Dixon JB, O'Brien PE. Selecting the optimal patient for LAP-BAND placement. *Am J Surg* 2002;184:S17–S20.