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CLINICAL RESEARCH

Long-Term Outcomes of Laparoscopic Adjustable Silicone Gastric Banding (LAGB) in Moderately Obese Patients With and Without Co-morbidities

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Abstract
Background Overweight and obesity independently increase cardiovascular risk, while even modest weight loss can result in clinically significant improvements in cardiovascular risk and reduce long-term mortality. Lowering the body mass index (BMI) threshold for bariatric surgery to those with moderate obesity might be one way to lower the burden of this disease. The aim of this study was to evaluate the efficacy and safety of laparoscopic adjustable silicone gastric banding (LAGB) in moderately obese subjects with or without obesity-related co-morbidities.
Methods Thirty-four patients with BMI between 30 and 35 kg/m^2 (5 males/29 females, mean age 36±10 years, mean preoperative weight 87.9±7.1 kg, mean BMI 32.6±1.6 kg/m^2 and mean percentage excess weight 48.7±9 %) who underwent LAGB via pars flaccida between June 1, 2002 and August 31, 2010 were included. Good response was defined as BMI <30 kg/m^2 or percentage estimated weight loss (%EWL) >50. Poor response was defined as BMI >30 kg/m^2 or %EWL less than 50 after a minimum of 1 year.
Results Mean weight, BMI and %EWL were recorded at 1, 3, 5 and 7 years and were 77.4±7.6, 69.9±10.8, 70.9±9.3 and 73.3±12.0 kg; 28.8±2.9, 26.4±3.2, 26.5±3.4 and 27.4±5.0 kg/m^2; and 36±23, 46.1±33.8, 58.6±31.5 and 45±57, respectively (p<0.01). Co-morbidities were diagnosed in 17/34 (50 %) patients at baseline and underwent remission or improvement in all cases after 1 year.
Conclusions LAGB in a safe and effective procedure in patients with a BMI <35 kg/m^2.

Keywords Body mass index (BMI) · Co-morbidities · Efficacy · Lap band · Laparoscopic adjustable silicone gastric banding (LAGB) · Long term · Obesity · Safety · Weight loss

Introduction

Obesity is a growing health-care issue worldwide. Obese individuals have an increased likelihood of depression, asthma, sleep apnoea, diabetes, cancer, gastro-oesophageal reflux disease (GERD), gallstones, hernias, osteoarthritis, hypertension, coronary artery disease and hyperlipidaemia, among others [1]. In a study of 5,881 Framingham Heart Study participants, Kenchaiah et al. [2] showed that during a 14-year follow-up, for every 1-kg/m^2 increment in body mass index (BMI), the risk of heart failure increased 5 % in men and 7 % in women. Additionally, in the West of Scotland Coronary Prevention Study, BMI in 6,082 men (mean age 55 years) with hypercholesterolaemia, but no history of diabetes or cardiovascular disease, was related to the risk of fatal and non-fatal coronary heart disease (CHD) events [3]. Of particular note, the risk of fatal CHD events increased in men with BMI as low as 30.0 kg/m^2. However, it is not just obesity that has an impact on the risk

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of cardiovascular disease. Both overweight and obesity independently increased the risk of CHD and cardiovascular disease in patients with type 2 diabetes [4]. In these patients, a 5-unit increase in BMI increased the risk of coronary heart disease by 15 %, stroke by 11 % and total mortality by 27 % [4].

Several studies show that even modest weight loss can result in clinically significant improvements in all cardiovascular risk factors [5], and ample data demonstrate that weight loss after bariatric surgery is associated with significantly reduced long-term mortality [6–8]. Notwithstanding, weight loss is a considerable challenge for many, and willpower, diet and exercise often prove insufficient to resolve the problem. This may be partly due to the fact that the body's response to weight loss, which includes both activation of anabolic and inhibition of catabolic pathways, works against the individual [9].

Laparoscopic adjustable gastric banding (LAGB) is a popular bariatric procedure, which can result in significant weight loss [10–12]. Although mortality and morbidity for bariatric procedures are primarily determined by the volume of patients and the surgical experience of the treatment centre [13], LAGB has proved to have one of the lowest complication rates of currently available bariatric procedures [8, 14]. This, combined with the short operation time, enables LAGB to be performed safely on an outpatient basis in some centres [15].

Lowering the BMI threshold for bariatric surgery to those with moderate obesity might be one way to lower the burden of this disease. To widen the indication of LAGB to patients with a BMI of 30 to 35 kg/m^2 and for it to become acceptable as the standard of care, data regarding the long-term efficacy and safety outcomes of this procedure in this population are necessary. The aim of this study was to evaluate the efficacy and safety of LAGB in moderately obese subjects with or without obesity-related co-morbidities.

Materials and Methods

Patients

We reviewed the database of our institution for all patients with BMI of 30 to 35 kg/m^2 undergoing LAGB via pars flaccida between June 1, 2002 and August 31, 2010. All patients were evaluated by a nutritionist/dietician, psychologist, internist, anaesthetist and bariatric surgeon. Each patient signed an informed consent form before surgery. All patients were informed that they did not meet the current NIH guidelines for bariatric surgery, and thus, the risks and benefits of the surgery had not been proved yet. However, the Institutional Ethics Committee approved the indication of LAGB in first-stage obese patients. When necessary, other specialists (psychiatrist, cardiologist, pneumologist) were consulted as required.

The presence of hiatal hernia was investigated preoperatively with an X-ray double-contrast barium swallow and gastroscopy. Presence of hiatal hernia was not considered a contraindication to band implantation.

Data included all demographic information, including perioperative variables such as anthropometric data, co-morbidities, surgical complications and follow-up information. Parameters considered were mortality, intra- and post-operative complications, laparotomic conversion, reoperations, need for band removal, co-morbidities outcome (improvement or remission of type 2 diabetes [T2 DM], arterial hypertension, dyslipidaemia and GERD were based on drug reduction or discontinuation or on symptoms relief), weight loss-related parameters (body weight, BMI) and percentage of excess weight loss (%EWL).

Partial remission of T2DM was defined as sub-diabetic hyperglycaemia (A1C not diagnostic of diabetes [<6.5 %], fasting glucose [100–125 mg/dl]) after at least 1 year in the absence of active pharmacologic therapy. Complete remission was defined as a return to "normal" measures of glucose metabolism (A1C in the normal range (<6 %), fasting glucose [100 mg/dl]) after at least 1 year in the absence of active pharmacologic therapy [16].

The remission of arterial hypertension is defined as a systolic blood pressure <140 mmHg and a diastolic blood pressure <90 mmHg in the absence of anti-hypertensive drugs. The improvement of arterial hypertension is defined as reduction of anti-hypertensive drugs.

The remission of dyslipidaemia is defined as normal blood lipid levels in the absence of hypolipidaemic drugs (LDL <100 mg/dl, HDL >40 mg/dl, triglycerides <150 mg/dl). The improvement of dyslipidaemia is defined as reduction of hypolipidaemic drugs.

The remission of sleep apnoea is defined as the absence of symptoms attested by a normal polysomnography testing.

Participants underwent a preoperative assessment of GERD symptoms using a standardised questionnaire evaluating the prevalence of typical GERD symptoms (heartburn and/or regurgitation). The frequency of heartburn and regurgitation was scored from 0 to 3 (0= absent, 1=2 days/week, 2=3–5 days/week and 3=6 or 7 days/week). The intensity of heartburn and regurgitation was scored from 0 to 3 (0=absent, 1=not very bothersome, not interfering with daily activities; 2= bothersome, but not interfering with daily activities; and 3=interfering with daily activities). A score out of a maximum of 6 was obtained for each symptom, which was defined as a mild (1–2), moderate (3–4) and severe (5–6) symptom frequency–intensity score (23, 24) [17].

All patients underwent a reassessment of anthropometric characteristics, prevalence of co-morbidities and GERD symptoms after surgery.

Good response was defined as BMI <30 kg/m^2 or %EWL >50. Poor response was defined as BMI >30 kg/m^2 or %EWL less than 50 after a minimum of 1 year.

Surgical Technique

Patients were positioned in the reverse Trendelenburg lithotomy position. A closed carbon dioxide pneumoperitoneum was created, and five trocars (two of 10 mm and three of 5 mm) were inserted. The dissection was started near the angle of His, above the greater curvature of the stomach. The lesser omentum was opened through the pars flaccida, and the fat on the posterior wall of the lesser sac was retracted to expose the right crus of the diaphragm. A point along the anterior border of this muscle at its lowest aspect was selected, and the peritoneum was opened. The Endo-Grasper Roticulator (US Surgical, Covidien formerly Tyco Healthcare, Norwalk, CT) was then passed along this retrogastric tunnel to appear on the greater curvature of the stomach at the site of the previous dissection at the angle of His. The LAP-BAND System (Inamed-Allergan, Santa Barbara-Carpinteria, CA) was passed along this pathway and closed and fixed to the stomach using three to five gastro-gastric stitches. The port was sutured to the left anterior rectal sheet. In case of intra-operative diagnosis of hiatal hernia, the oesophagus was prepared and encircled; then, a concomitant posterior cruroplasty with non-absorbable stitches was performed.

Postoperative Follow-up

Patients followed a liquid diet for the first 7 days after the procedure and then a semi-liquid diet for another 7 days. The LAP-BAND System was adjusted and calibrated depending on the patient's clinical condition and weight loss. The clinical follow-up examination included anthropometric measurements, dietary counselling and evolution of recorded obesity-associated co-morbidities.

Additional radiological or endoscopic studies were performed whenever patients reported symptoms suggesting complications. Vitamin supplementation was prescribed for the first 6 months and then depending on the patient's clinical condition. Post-operative mortality was assessed at day 30.

Statistical Analysis

This is a retrospective review of a prospectively collected database. Data are expressed as mean±standard deviation except as otherwise indicated. Fisher's exact test and the Student's *t* test were used for statistical analysis. Signifi cance was defined as $p<0.05$.

Table 1 Preoperative demographic data on 34 patients undergoing LAGB

Characteristic	Mean	Range
Age	36±10	16–49
Gender		
Male	5 (14.7 %)	
Female	29 (85.3 %)	
Weight (kg)	87.9±7.1	76.4–107
BMI (kg/m^2)	32.6±1.6	30.4–34.7
EW (%)	48.7±9	32–68

Results

Baseline Characteristics

A total of 34 patients with a BMI of 30 to 35 kg/m^2 underwent LAGB positioning (5 males/29 females, mean age 36±10 years, mean preoperative weight 87.9±7.1 kg, mean BMI 32.6±1.6 kg/m^2, and mean %EWL 48.7±9). Preoperative demographic data are summarised in Table 1.

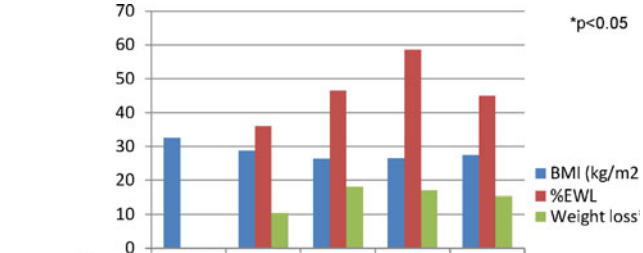
Patients had multiple co-morbidities as presented in Table 2, and a total number of 27 co-morbidities were diagnosed in 17 out of 34 (50 %) patients at baseline. The co-morbidities reported included arterial hypertension, type II diabetes and metabolic disease, dyslipidaemia, obstructive sleep apnoea, hiatus hernia, GERD and degenerative lumbar disc disease.

Seven patients suffered from hiatal hernia and GERD symptoms. They had endoscopic preoperative diagnosis in two cases and intra-operative diagnosis in the remaining five cases. One patient suffered from GERD symptoms without hiatal hernia.

All patients were submitted to LAGB positioning via pars flaccida, 10/34 patients (29.4 %) received a small LAP-BAND System and 7/34 patients (20.6 %) received a concomitant posterior cruroplasty for the presence of hiatal hernia. Operative time was 60±15 min and overall hospital stay was 3±1 days. All patients underwent an X-ray barium swallow on post-operative day 2 to ensure correct positioning of the LAP-BAND System and to rule out possible complications.

Table 2 Preoperative co-morbidities

Preoperative co-morbidities	*n* (%)
Hiatal hernia and/or GERD	8 (23.5)
Arterial hypertension	7 (20.6)
Dyslipidaemia	4 (11.7)
Obstructive sleep apnoea	4 (11.7)
T2DM	2 (5.8)
Degenerative lumbar disc disease	2 (5.8)



Year	Baseline	1	3	5	7
BMI (kg/m2)	32.6	28.8	26.4	26.5	27.4
%EWL	0	36	46.4	58.6	45
Weight loss** (kg)	0	10.5	18	17	15.3

Fig. 1 Efficacy outcomes post-LAGB. *$p<0.05$, for each time point versus preoperative values. *Double asterisks* indicate weight loss from a baseline value of 87.9 kg

Impact on Weight

The impact on BMI and %EWL at each time point is summarised in Fig. 1.

All 34 patients presented at 1-year follow-up with a mean weight of 77.4±7.6 kg, BMI of 28.8±2.9 kg/m^2 and %EWL of 36±23 ($p < 0.01$). A total of seven patients (20 %) presented with a BMI >30 kg/m^2 or %EWL <50.

At 3 years, 24/27 eligible patients (88 %) presented with a mean weight of 69.9±10.8 kg, BMI of 26.4±3.2 kg/m^2 and %EWL of 46.1±33.8 ($p<0.01$). A total of six patients (22 %) presented with a BMI >30 kg/m^2 or %EWL <50. One patient was admitted for a port replacement to address a port-related problem.

At 5 years, 14/19 eligible patients (73.6 %) presented with a mean weight of 70.9±9.3 kg, BMI of 26.5±3.4 kg/m^2 and %EWL of 58.6±31.5 ($p<0.01$). A total of two patients (11 %) presented with a BMI >30 kg/m^2 or %EWL <50.

At 7 years, 10/12 eligible patients (83.3 %) presented with a mean weight of 73.3±12.0 kg, BMI of 27.4±5.0 kg/m^2 and %EWL of 45±57 ($p<0.01$). Two patients (16.7 %) presented with a BMI >30 kg/m^2 or %EWL <50.

None of the patients had a BMI <18.5 kg/m^2 at any time point.

Impact on Co-morbidities

Diabetic patients were under hypoglycaemic oral drug therapy preoperatively. They experienced complete remission of T2DM at 1- and 3-year follow-up.

Patients affected by arterial hypertension experienced improvement of their condition with reduction of antihypertensive drugs. No patient experienced remission and discontinuation of medical therapy. Two patients suffering from dyslipidaemia experienced improvement of their condition, and two patients remitted with discontinuation of medical therapy.

In the GERD group, pre-postoperative comparison showed that there was a significant decrease of the heartburn and regurgitation frequency–intensity scores (at 1-year follow-up: heartburn 2.80±0.77 versus 0.20±0.41, $p=0.001$; regurgitation 3.07±0.96 versus 0.13±0.35, $p=0.001$). All patients who suffered from obstructive sleep apnoea preoperatively experienced remission in the absence of symptoms attested by a normal polysomnography testing.

Patients affected by degenerative lumbar disc disease experienced reduction of pain intensity and frequency, but they did not have a post-operative diagnostic evaluation or specialist counselling.

LAGB has a significant effect on the remission or improvement of these co-morbidities. Overall, co-morbidities remission was obtained in 10/17 (58.2 %) and improvement in 7/17 (41.8 %) after 1 year. After this time point, no further resolution/improvement in co-morbidities was observed and no new co-morbidities appeared.

Safety Outcomes

Intraoperative complications and laparotomic conversion were absent. Post-operative complications occurred in two patients (Table 3). There were no deaths reported.

Lost to Follow-up and Discontinuations

There was only 1 out of 34 eligible patients lost to follow-up after 1 year. After 3 years, 3 out of 27 eligible patients were lost at follow-up. After 5 years, 3 out of 19 eligible patients were lost to follow-up. After 7 years, 1 out of 12 eligible patients was lost to follow-up.

Two patients underwent laparoscopic band removal for gastric pouch at 5 years. One patient was debanded and converted to sleeve gastrectomy laparoscopically for insufficient weight loss at 7 years.

Discussion

In this study, a BMI <30 kg/m^2 was achieved and maintained in the majority of patients (80–90 %) for up to 7 years in moderately obese (BMI 30–35 kg/m^2) patients undergoing LAGB. In addition, the observed %EWL (range

Table 3 Postoperative surgical complications and treatment

Complication	Treatment	Number of patients
Access port complications (disconnection)	Port replacement and subsequent lap band removal and sleeve gastrectomy	1
Acute band slippage	Lap band removal	1

26.4–58.6) was comparable to that seen in previous studies [8, 18] and was maintained over 7 years. In association with the weight loss observed, substantial improvements in obesity-related co-morbidities were seen in the first year after surgery. These observations are supported by previous studies investigating the use of LAGB in patients with a BMI ≥35 kg/m^2 [8, 19].

The lack of operative mortality in this study was also comparable to the data reported in earlier studies, thus confirming that LAGB is one of the safest available bariatric procedures [20]. The long-term durability of LAGB in this study was also underlined by the small number (<10 %) of patients who discontinued use.

A review of national trends in bariatric surgery shows that patients selected for gastric banding have lower post-operative mortality and readmission rates and a shorter length of stay than did those selected for gastric bypass [21]. In an analysis of studies of severely obese patients, morbidity rates associated with procedures ranged from 4.6 % for LAGB to 10.8, 14.9 and 25.6 %, respectively, for sleeve gastrectomy, Roux-en-Y gastric bypass and biliopancreatic diversion with or without duodenal switch at 1 year [22]. LAGB also has a low impact on nutritional requirements, unlike other bariatric procedures [23].

This study had a number of limitations. Patient sample was relatively small (n=34), and as this was a rolling analysis of patients admitted for LAGB between 2002 and 2010, the number of patients available for follow-up at 3, 5 and 7 years progressively decreased. There were also more female patients than males (89 versus 11 %) available for analysis. In this study, the surgical procedure took an average of 1 h with a hospital stay of around 3 days, similar to that found in earlier studies [24–26]. However, it is possible for the procedure to take no more than 40 min [27], and in some centres, it can be performed on an ambulatory basis, with patients discharged within 2 h after the procedure [28].

Follow-up is an important determinant for weight loss after LAGB. Patients lost to follow-up are more likely to have poor weight loss, emphasising the importance of follow-up after LAGB [29]. With good local follow-up, weight loss after LAGB can rival to that achieved with more invasive procedures [30].

As this and another study in patients with BMI of 30 to 35 kg/m^2 have shown [31], the overall advantage of LAGB is the significant weight loss that is achieved and maintained in the majority of patients over the longer term.

The recent FDA approval for the use of LAP-BAND System in first-stage obese patients [32] has extended the use of this device to a huge number of American citizens. This procedure could induce a good control of obesity-related co-morbidities, thus reducing the long-term costs of US health-care system.

Moreover, in 2010, the Italian Society of Bariatric Surgery (SICOB) has approved the use of LAGB in first-stage obese patients who presented with one co-morbidity [33]: type 2 diabetes mellitus, hiatal hernia and GERD symptoms, arterial hypertension and severe osteoarthropathy.

The treatment of obese patients between 30 and 35 kg/m^2 still remain under debate. Nevertheless, a larger use of LAGB in patients with BMI of 30 to 35 kg/m^2 is expected in the next years. More single-centre outcomes, long-term data, RCTs and meta-analyses are necessary in order to produce standards and to validate this procedure as the most effective in the treatment of first-stage obesity and its related co-morbidities.

Conclusion

LAGB is a safe and effective procedure in patients with BMI of 30 to 35 kg/m^2. It results in excellent long-term outcomes with low complication rates and no increased risk of mortality in moderately obese patients with or without co-morbidities.

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Conflict of Interest There are no conflicts of interest.

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