

Laparoscopic adjustable gastric banding: a 10 year follow-up study



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BACKGROUND: *A comprehensive obesity management can only be accomplished by a multidisciplinary team. Despite the numerous efforts made, a winning solution has not been reached yet. When patients do not respond to conventional treatment, LAGB (Laparoscopic Adjustable Gastric Banding) is a generally effective approach with minimal involvement in anatomical modification.*

STUDY AIM: *The aim of this study is to highlight how LAGB can guarantee long-term weight loss and a reduced incidence of complications and reoperations, when it is integrated in a multidisciplinary context and in a long period of close follow-up.*

METHODS: *50 patients underwent LAGB between 2007 and 2008. From the sixth month after surgery, the LAGB was calibrated every 8-12 weeks, depending on the patient's response to the dietetic program and on his/her clinical and psychological situation. The follow up was planned every two weeks during the first six months after surgery, subsequently once a month during the first year; then every three months up to three years after surgery and every six months thereafter.*

RESULTS: *After 6 months we found a significant weight loss that was progressive up to the second year. From the second year after surgery, the patients maintained their weight up to the tenth year of follow-up, without weight regain. In addition, an improvement of all metabolic parameters was found.*

CONCLUSIONS: *LAGB guarantees good results in terms of weight loss and metabolic control; the careful choice of patients and a close and accurate follow-up are essential for the success of this surgical procedure.*

KEY WORDS: LAGB, VLCD, KD, IWQOL

Introduction

According to World Health Organization data, obesity is nowadays considered a pandemic disease. In 2016 more than 1.9 billion people were overweight and 650 million were obese. It is estimated that in 2030 about

20% of the adult population will be obese. This condition also has an economic and social impact, causing directly and indirectly high costs for communities. Despite the numerous efforts made, a winning solution has not been reached yet ¹. Obesity is responsible for the occurrence of serious comorbidities such as cardiovascular diseases and hypertension, diabetes and metabolic syndrome, gastroesophageal reflux, OSAS, osteoarthritis. Moreover, mood disorders or real depressive syndromes often occur ^{2,3}. Obesity increases the risk of developing different types of cancer (endometrial, breast, ovarian, prostate, gallbladder, colon, liver and kidney cancer) ². For all these reasons, it leads to an increase in the mortality rate ⁴. A comprehensive obesity management can only be accomplished by a multidisciplinary team, which is able to act on several fronts reduc-

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ing the obesity-related comorbidities. In fact it is fundamental to focus on both nutritional and educational aspect, on physical exercise, on psychological side and on pharmacological aspect^{5,6}. Traditionally, after the evaluation of anthropometric parameters and the collection of nutritional habits, the first step in obesity treatment is a customized nutritional program⁷. Despite integrated interventions based on standardized guidelines, in severe obese patients it is common to come across poor compliance or even drop out cases due to the difficulty in radically changing habits associated with the need for a long-term treatment⁸. When patients do not respond to conventional treatment, bariatric surgery represents a further therapeutic possibility⁹. Among the different kind of invasive intervention, LAGB (Laparoscopic Adjustable Gastric Banding) is a generally effective approach with minimal involvement in anatomical modifications. It is completely reversible, effective in inducing weight loss with reduced morbidity, short hospitalization and low percentage of re-hospitalization¹⁰. However, some studies underline how in the long term this procedure is burdened by loss of effectiveness and weight rebound. *Arapis et al.* concludes the study by saying that a more accurate and close follow-up could change the outcome of this surgical procedure^{11,12}. The aim of our study is to show how the LAGB can guarantee long-term weight loss and a reduced incidence of complications and reoperations, when it is integrated in a multidisciplinary context with proper dietetic, physical and psychological programs planned with a long period of close follow-up.

Patients and Methods

A multi-specialist team (nutritionist, endocrinologist, internist, psychologist, surgeon, dietitian and nurse) carefully evaluated every potential candidate admitted to the Department of Dietetic and Clinical Nutrition of

Ospedali Riuniti of Ancona between January 2007 and December 2017 during a Day Hospital (DH) diagnostic regime. The clinical evaluation proposed to patients was the DH study protocol (Table I). Eligibility for surgery was defined according to the 1991 National Institutes of Health Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity¹³, and all subjects enrolled in the study subscribed a written informed consent. Patients with gastrointestinal problems like hiatal hernia, reflux esophagitis or gastric ulcers and patients with mental disorders and bulimia have been excluded. The patients included in the study had undertaken different conservative therapeutic strategies for a period of 5 years or more without success. The study was performed on 50 patients (mean age $41,42 \pm 7,5$ years; 14 males and 36 females; mean initial BMI $44,6 \pm 2,6$ Kg/m²). Between 2007 and 2008, recruited patients underwent LAGB with LAP BAND AP® adjustable gastric banding system (Apollo Endosurgery INC). The band was fixed to the wall of the stomach with two sutures using the pars flaccida technique. The wide banding model has been chosen in order to have a greater range of calibration (0-14 ml) and at the beginning no calibration was performed (0 ml). Starting from the sixth month, the LAGB was calibrated every 8-12 weeks introducing each time 2 ml of sterile saline. During the first 24 months after surgery, the maximum quantity of sterile saline introduced was 10 ml (70% of the maximum filling possible) and the number of calibration was between 0 and 6. The calibration of the banding depended on the patient's response to the dietetic program and on his/her clinical and psychological situation. The follow up was planned every two weeks during the first six months after surgery, subsequently once a month during the first year; then every three months up to three years after surgery and every six months thereafter. The visit consisted of nutritional status evaluation: weight, BMI (kg/m²), EWL% (percentage of excess weight loss). Furthermore, compliance to dietary and physical activity program and psychological counseling were evaluated. The physical activity program was personalized and consisted of at least 180 minutes of aerobic activity per week. For the first six months after surgery, the dieticians scheduled lessons on nutritional education about nutrients and about the needs of the organism. Education also concerned the planning for grocery shopping, the reading of labels and cooking methods.

TABLE I - DH study protocol

- Clinical History;
- Physical Examinations;
- Anthropometric Measures;
- Blood tests: Carbohydrate metabolism (ogtt); Lipid metabolism; (total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides); Protein metabolism (protein electrophoresis); Haemochrome; Liver, Kidney, Thyroid function; Hormones and Electrolytes;
- Basal Metabolism Evaluation (indirect calorimetry);
- Body Composition (bioimpedentiometry);
- Ergospirometry With Aerobic and Anaerobic Evaluation;
- Electrocardiogram;
- Upper Abdominal Ultrasound;
- Thyroid Ultrasound;
- Interview with a Personal Trainer;
- Psychological Tests and Interview.

TABLE II - Dietary Protocol

	VLCD (800 Kcal/die)	KD (800 Kcal/die)
Protein	25%	40%
Lipids	23%	40%
Carbohydrates	52%	20%

VLCD (Very Low Calorie Diet); KD (Ketogenic Diet)

All patients followed a customized nutritional scheme consisted in a low calorie diet (LCD, table II) according to the needs. An individual psychological cognitive-behavioral support was provided weekly during the same period. In case of weight stall or weight regain both nutritional and psychological program were reviewed as first approach.

If despite this, there was no further weight loss for at least 40-50 days, a calibration was done. After each calibration the patient remained under observation for 4 hours and had a meal. Any complication was investigated and treated. In case of vomiting, regurgitation, swallowing difficulty or a sense of excessive gastric fullness appeared, the band was deflated. If necessary, the patient had surgical, gastroenterological and psychiatric counseling. In addition, they were asked to fill in the Impact of Weight on Quality of Life – Lite (IWQOL – Lite) before the surgery and then every year until the end of the study. This evaluation tool is the shortened version of IWQOL, it is an obesity-QOL instrument consisting in 31 items and 5 domains about physical function, self-esteem, sexual life, public distress and work; lower scores indicate better QOL^{14,15}. An EGDS (esophagogastroduodenoscopy) was performed 2 years, 5 years and 10 years after surgery to check the clinical situation of the digestive tract. When the target weight had been reached the LAGB calibration was returned to the starting point and the patient continued with a balance diet and a correct lifestyle. Statistical analysis was performed with Student's t test and expressed as mean \pm SD. A p value < 0,05 was considered statistically significant. All data were retrospectively analyzed and patients who did not show up for the visits were called back for a medical examination and a psychological interview.

Results

There were 2 cases (4.0%) of early complications during the first 30 days after surgery (1 case of scar dehiscence and 1 case of abdominal hemorrhage); 6 cases (12.0%) of late complications from 30 to 365 days occurred (2 cases of gastritis of the upper pocket). These

TABLE III - Complications (First EGDS two years after surgery performed on 39 patients)

Complications	No.	%
Grade I esophagitis	15	38,5
Grade II esophagitis	5	12,8
Chronic Gastritis of the pouch	6	15,4
Neither esophageal nor gastric alteration	13	33,3

TABLE IV - Complications (Second EGDS five years after surgery performed on 35 patients)

Complications	No.	%
Grade I esophagitis	4	11,4
Grade II esophagitis	2	5,7
Chronic Gastritis of the pouch	1	2,9
Neither esophageal nor gastric alteration	28	80,0

events did not influence the patient's compliance to the program. Removal of the gastric bandage was required between 12 and 18 months in 6 patients (12%) because of complications: 2 cases of gastric occlusion, 2 cases of incoercible vomiting, 2 cases of III grade esophagitis. Patients who had been removed the LAGB dropped-out, while the ones who had early and late complications continued the follow-up regularly. At 6th month of follow-up, the average weight loss was $19,0 \pm 6,0$ Kg, BMI $36,4 \pm 1,8$ Kg/m² (p<0.05) and EWL% $42,0 \pm 7,1$ %. Patients who kept losing weight continued with LCD, while those who did not lose weight anymore for at least 40-50 days underwent a calibration. As soon as the patient began to lose weight again, the band was deflated and so on, until the target weight was reached. After 12 months BMI was $35,7 \pm 1,7$ Kg/m² and EWL% was $45,4 \pm 6,0$ % (weight loss $25,8 \pm 11,0$ Kg). After two years, 78% of patients who underwent LAGB (39 patients) kept following the assistance procedure and they had lost an additional 5% of their weight on average. In those patients, weight loss at two years was

TABLE V – Improvement of Metabolic Complications After LAGB

Metabolic Complications	Time of follow-up			
	t0	2 years	5 years	10 years
Glucose (mg/dl)	109,8 \pm 1,3	93,3 \pm 1,2 (p<0,001)	94,0 \pm 1,3 (p<0,001)	94,1 \pm 1,5 (p<0,001)
HbA1c (mmol/mol)	40,0 \pm 0,8	32,0 \pm 0,9 (p<0,001)	32,0 \pm 0,7 (p<0,001)	33,0 \pm 0,9 (p<0,001)
Tryglicerides (mg/dl)	149,3 \pm 2,1	120,9 \pm 2,0 (p<0,001)	121,2 \pm 1,9 (p<0,001)	121,1 \pm 1,9 (p<0,001)
Total cholesterol (mg/dl)	193,0 \pm 2,1	171,9 \pm 2,0 (p<0,001)	172,0 \pm 2,2 (p<0,001)	172,1 \pm 2,3 (p<0,001)
LDL cholesterol (mg/dl)	118,1 \pm 2,0	94,5 \pm 1,9 (p<0,001)	94,7 \pm 1,9 (p<0,001)	94,6 \pm 2,5 (p<0,001)
HDL cholesterol (mg/dl)	45,0 \pm 1,3	53,2 \pm 1,4 (p<0,001)	53,1 \pm 1,2 (p<0,001)	53,0 \pm 1,6 (p<0,001)
Systolic Blood Pressure (mmHg)	135,8 \pm 5,7	128,6 \pm 6,0 (p<0,001)	127,1 \pm 6,1 (p<0,001)	127,2 \pm 6,3 (p<0,001)
Diastolic Blood Pressure (mmHg)	85,0 \pm 7,1	80,2 \pm 6,8 (p<0,05)	80,5 \pm 6,9 (p<0,05)	80,7 \pm 7,2 (p<0,05)

TABLE VI - IWQOL-Lite Score

Pre- surgery	56.7 ± 28.9	
Ten years after surgery	38.9 ± 19.0	p< 0.05

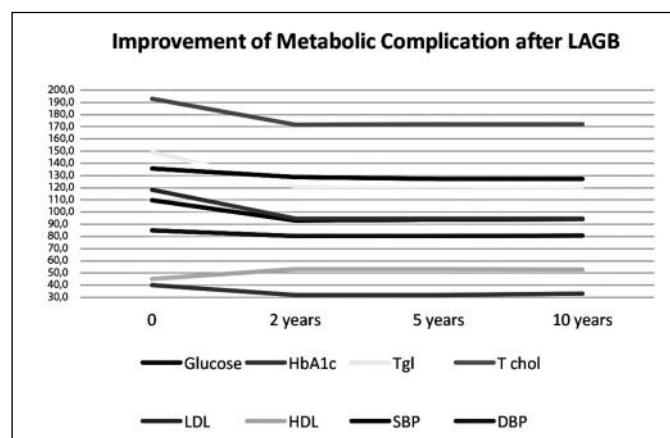


Fig. 1: Glucose: mg/dl; HbA1c (Glycated Hemoglobin): mmol/mol; Tgl (Triglycerides): mg/dl; T chol (Total Cholesterol): mg/dl; LDL Cholesterol: mg/dl; HDL Cholesterol: mg/dl; SBP (Systolic Blood Pressure): mmHg; DBP (Diastolic Blood Pressure): mmHg.

30,9 ± 2,9 Kg with an average BMI of 33,9 ± 1,2 Kg/m² and EWL% 54,6 ± 6,3 %. The average calibration of the band between 6 and 24 months was 8 ml (min 6 ml and max 10 ml). Each calibration was maintained for a period of 3-4 months, then a reduction in the filling was made. Five years after surgery, 35 patients (70%) continued the programmed follow-up, maintaining the weight loss at 24 months: with an average calibration of 4 ml. After 10 years, those same patients had continued to follow the controls with maintenance of weight loss (BMI 33,5 ± 1,6 Kg/m² and EWL% 56,6 ± 7,2%). In this group, 18 patients had returned to the initial calibration (0 ml), while 17 patients were calibrated with

an average of 4-6 ml and undertook a ketogenic diet (KD – Table II) in order to avoid further calibrations. The incidence of complications has been investigated with EGDS at the end of the second, fifth and tenth year. The complication rate was 66,7% (26 patients) of different severity at the end of the second year (Table III). After 5 years, a second EGDS was performed and we observed a reduction in severity and number of complications in patients who regularly participate to follow-up (Table IV). The complication rate had dropped to 20% (7 patients). The severity of complications was greater and durable in patients who were not assiduous to controls. The same complications remain after 10 years but the patients tolerate them better, probably because they have internalized a new lifestyle and they have medical support for any discomfort. The metabolic parameters were improved after two years from surgery with a 15% reduction in fasting blood glucose, 20% of LDL cholesterol and 19% triglycerides. These results have been maintained over time and are in line with other results found in scientific literature (Table V; Fig. 1) ¹⁶. Patients filled in IWQOL – Lite before surgery and then once a year after surgery till the end of the study. The quality of life after 10 years had improved significantly compared to baseline (Table VI) ¹⁷.

Discussion

LAGB is a surgical technique that guarantees good results in terms of weight loss and metabolic control; both caloric intake and gastric banding can be adapted and gradually modulated to individual patient's need ¹⁸. It has a very low rate of complications (both early and late) ¹⁹ and these complications are less severe rather than other bariatric surgical procedures; moreover is reversible and modifiable. This fact prevents any post-surgical adjustment. LAGB is a safe and effective technique and many studies have shown that the weight loss reached can be maintained over years. *Micheletto et Al.* obtained a mean EWL% of 54% 5 years after gastric banding ²⁰. Also

TABLE VII - Summary Results

No. Patients	t0	Time of follow up months (t)					years	
	50	t6 50	t12 50	t24 39	5 35	10 35		
BMI (Kg/m ²)	44,6 ± 2,6	36,4 ± 1,8 (p<0,05)	35,7 ± 1,7 (p<0,001)	33,9 ± 1,2 (p<0,001)	33,9 ± 1,4 (p<0,001)	33,5 ± 1,6 (p<0,001)		
Weight loss (Kg)		19,0 ± 6,0	25,8 ± 11,0 (p<0,001)	30,9 ± 2,9 (p<0,001)	30,9 ± 2,9 (p<0,001)	32,1 ± 2,8 (p<0,001)		
EWL %		42,0 ± 7,1	45,4 ± 6,0 (p<0,05)	54,6 ± 6,3 (p<0,001)	54,6 ± 7,1 (p<0,001)	56,6 ± 7,2 (p<0,001)		

the Australian team of *O'Brien and colleagues* obtained a long term result: they performed a prospective longitudinal cohort study in LAGB patients and they demonstrate a durable weight loss with 47,1% mean EWL% maintained to 15 years ²¹. The careful choice of patients and a close follow-up are essential for the success of LAGB ²². This is the reason why we established a multidisciplinary approach to follow the patients throughout the process. Step by step, we could be able to change lifestyle of patients increasing physical activity and improving the quality of nutrition, in order to obtain and then maintain a significant weight loss ^{23,24}. Six months after surgery, we recorded a significant weight loss, which continued until the second year without arrests. Except for those who had removed the bandage (6 patients), the others participated constantly in the follow up and obtained the weight loss estimated for that phase. At the end of the second year, we observed some defections. Over time patients become bored of diet and side effects of calibration. This is probably the reason why 11 of them were not assiduous at the controls after two years. On the other hand, the weight loss itself can lead to reduced compliance, because the satisfaction in reaching the goal weight could induce the patients to get back to unhealthy habits. In this delicate phase of the path, it is very important to keep motivation high; so a multidisciplinary team is of fundamental importance, as it acts on all fronts. In addition, participation in the program allows, through the advice of dedicated specialists, early treatment and in many cases the resolution of complications. After the second year, the situation tended to stabilize. We compared the results of the EGDS made during the second year of follow up and the one done in the fifth year. The number of complications is significantly reduced, demonstrating that patients have considered a different eating behavior. The ability to adjust the bandage is an important weapon that can be used in those moments of body weight stall or poor patients motivation. After 10 years all the patients who regularly showed up at the controls had internalized a healthy lifestyle, to the point that the adjustment of the bandage was back to the beginning (0 ml) and the weight loss was maintained in 51.4% of them. The remaining 48.6 % still had an active calibration, which was really reduced compared to the beginning. Moreover, the use of a ketogenic diet allowed the maintenance of weight loss obtained without further calibrations, which would result in a higher incidence of complications. It is possible that not satisfactory long-term results depended on surgical procedure not supported by an adequate and interdisciplinary follow-up. Follow-up is necessary for therapeutic success in the end. In the lack of a long term therapeutic plan agreed with the patient, there is a high risk of losing the result obtained with surgery ^{11,25}. Some current surgical procedures are not reversible or modifiable. This fact prevents any post-surgical adjustment. After the surgical

approach to maintain weight loss the patient can rely on his will power, but not on further anatomic changes of stomach capacity. LAGB is an intervention that adapts to the patient step by step, it is a continuously evolving procedure according to the patient's need. If the patient is educated about possible complications and is supported when these complications occur through close follow-up; despite the difficulties the patient is able to maintain the results obtained. Once the critical phase is over, the complications are better tolerated, guaranteeing a normal lifestyle with an improvement in the quality of life. LAGB has shown a positive impact on quality of life, IWQOL – Lite score was significantly higher before surgery than 10 years later as evidence that the patient's quality of life was significantly improved. This result is similar to that obtained by *Billy et Al.*, which showed a significant improvement in the quality of life six months after the implantation of the bandage, an improvement that was still effective after 3 years ²⁵. We also observed that the score of the group of patients who regularly underwent follow-up was much smaller than the group that did not comply with the controls; demonstrating that the constant recall of patients in a multidisciplinary setting modifies the outcome of the intervention. Some studies underline how in the long term this procedure is burdened by loss of effectiveness and weight rebound. *Arapis et Al.* concludes the study by saying that a more accurate and close follow-up could change the outcome of this surgery ^{9-11,26}. Indeed, comparing our study with that of *Arapis et al.*, we see how the follow-up approach was very different. In their study, the first consultation was performed 1 month postoperatively and then every 3 months for the first 2 years. Thereafter, follow-up was performed twice a year or whenever needed ¹¹. Also *Aarts et Al.* in their study had planned a less close follow up. The patients were visited 6 times during the first 2 years and then once a year ²⁶. Instead, we visited the patients every two weeks for the first six months after the operation, subsequently once a month during the first year; then every three months up to three years after surgery and every six months thereafter. The assiduous patients have maintained the weight loss obtained even after 10 years from surgery. The reason why we obtained this result could be linked to our closer follow-up, especially in the initial and more critical phase of the path.

Conclusion

LAGB is a surgical technique that guarantees good results in terms of weight loss and metabolic control; both caloric intake and gastric banding can be adapted and gradually modulated to individual patient's need. The careful choice of patients and a close and accurate follow-up are essential for the success of LAGB.

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