

# LAGB: regular follow-up with an interdisciplinary team is the key to success in terms of weight loss and complications



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**LAGB: regular follow-up with an interdisciplinary team is the key to success in terms of weight loss and complications**

**BACKGROUND:** *In severe obesity, most patients do not respond to conventional treatment. Bariatric surgery must only be proposed in specific cases. LAGB gives excellent long-term results if patient scrupulously complies the follow-up.*

**STUDY AIM:** *To evaluate patients who comply with the follow-up procedure over time in terms of weight loss, maintenance of the result, complications and quality of life.*

**METHODS:** *209 patients underwent LAGB between October 1999 and December 2007 and followed for 5 years. all patients were offered interdisciplinary counseling to update the therapeutic strategy.*

**RESULTS:** *Out of 92 patients who after two years had reached the desired weight 58 patients (63%) had a regular follow-up and, when necessary, specific counseling. 34 patients (37%) who did not plan follow-up did not maintain the weight loss, and progressively put on weight between the second and fifth year and had a higher incidence of complications. (SF-36) established in patients regularly followed improvement of the quality of life (QoL), up to the fifth year. Short Form Health Survey patients who did not regularly have follow-up the SF-36 showed a worsening of all the test domains between the second and the fifth year.*

**CONCLUSIONS:** *After 5 years, patients with severe obesity (BMI > 40) who underwent LAGB, that took part in a interdisciplinary follow-up procedure, obtained a full rehabilitation with a change of lifestyle, and maintained the weight loss obtained after 24 months. The perceived quality of life (QoL) shows a progressive improvement throughout the period of intensive intervention. Long-term efficacy of LAGB depends on a scrupulous followup and interdisciplinary support.*

**KEY WORDS:** LAGB, Obesity, Psychotherapy, SF-36

## Introduction

In the Western world the obesity rate has been steadily increasing<sup>1</sup>. Overweight and obesity are known to be associated with increased mortality and pathologies such

as diabetes, metabolic syndrome, sleep apnea, gastroesophageal reflux, osteoarthritis, hypertension, immune system alteration and cardiovascular diseases<sup>2-6</sup>. Moreover, obesity has a negative effect on most of the physical and psychological functions, decreasing quality of life<sup>7,8</sup>. Weight loss help to decrease risk factors for cardiovascular, metabolic and oncological diseases, reducing mortality.<sup>9-11</sup> In cases of severe obesity the conservative (dietary, behavioral and pharmacological) approach often fails in the long run, making it necessary to resort to bariatric surgery.<sup>12-14</sup> However, with this kind of surgery, which is not life saving nor devoid of complications, the patient must be selected correctly, and a long term follow-up must be ensured to reduce the number of complications or to correctly treat them, and to obtain

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and maintain a weight loss,<sup>15</sup> improving the clinical-metabolic conditions and quality of life<sup>16,19</sup>.

In many countries LAGB was the first choice surgical procedure in the past decade<sup>20</sup>. The LAGB procedure is completely reversible, effective in order to obtain a significant weight loss, with reduced morbidity and very low mortality, short hospitalization and low percentages of re-hospitalization, if the procedure is performed by a surgical center with proven experience<sup>21,22</sup>. Till 2012 in the US LAGB steadily increased and were carried out only slightly less than RYGB<sup>23-25</sup>. Due to a lack of appropriate follow-up the incidence and severity of complications increased,<sup>26-28</sup> and results in terms of loss of weight very worst in the long run<sup>29-30</sup>. In Europe, the technique was widely performed in the 90s, but during the last decade, the number of procedures was progressively reduced for the specific reason, and preference was given to sleeve gastrectomy<sup>31-33</sup>. In our center LAGB procedure has been used for 15 years in patients with severe obesity. Over the years with our experience we have been able to set up an effective and efficient follow-up with reduction of complications and improvement of quality of life.

The purpose of this study is to verify whether LAGB, when integrated with a interdisciplinary contest with adequate dietetic and psychological program, can guarantee adequate long-term weight loss and a reduced incidence of major complications and reoperation.

## Patients and Methods

Patients were carefully selected by a multi-disciplinary team of specialists composed by a nutritionist, a surgeon, an endocrinologist and a psychologist.

Between October 1999 and December 2007, 209 patients (average age  $\pm$  SD  $39 \pm 3$ , women/men 161/48, average body weight  $126 \pm 27$  kg, average initial BMI  $44.6 \pm 6.3$  kg/m<sup>2</sup>) were underwent to laparoscopic adjustable gastric band (LAP BAND, INAMED, adjustable gastric banding system, BioEnterics corporation, carpentry Santa Barbara, CA USA now became Apollo Endosurgery INC). Initially, the band was not calibrated (0 ml)<sup>10-33</sup>. During the entire period of observation we have used the same model of adjustable gastric banding system, with regulation between 0 ml and 4 ml. Serious mental disorders and bulimia were considered contraindications to the procedure as indicated by the NIH. The follow-up consisted of clinical nutritional controls every two weeks during the first three months after surgery, subsequently a monthly check-up until the end of the first year, every two months until the second year, and on a quarterly basis until the fifth year. During outpatient visits the nutritional status, weight control, compliance with dietary protocol and proposed physical activity plan, and vital signs were evaluated. Symptoms related to complica-

tions of the procedure were checked upon and treated. A customized program of aerobic physical education for at least 180 minutes per week was provided and re-evaluated. The dietitian scheduled lessons on nutritional education (regarding the needs of the organism, nutrients, programming of shopping, reading labels and cooking methods) for the first six months after surgery. During the same period individual psychological cognitive-behavioral support was provided on a weekly basis.

In case of weight regain the nutritional and psychotherapeutic program was revalued. If necessary, the patient had surgical, gastroenterological or psychiatric consultations.

The LAGB was calibrated every 8-12 weeks, each time introducing 0.5 to 1 ml of sterile saline.

The maximum quantity introduced was 3.5 ml. The band was calibrated on the basis of the patient's response to the dietetic program (weight loss) and her or his clinical/psychological situation.

Each time the calibration was modified, the patient remained in observation for 1-2 hours.

In case of a steady weight loss of at least 3-4 kg a month or no weight loss for a period of up to 40 days, no calibration was carried out. If the patient complained of difficulty in swallowing or frequent regurgitation the band was deflated.

If the patient put on more than 3 kg in a month the bandage was filled with 1 ml for at least 2 months in combination with psychological therapy every two weeks for 2 months and motivational weight control twice a month. Once the desired weight loss was obtained, and the patient followed dietary regimen and with the psychotherapist's consent, the calibration was agreed upon with the patient in order to find the optimal setting.

At the end of the second year, the patients were underwent to a gastroscopy. EGDS was performed to check esophagus and the upper pouch, especially grade I esophagitis which is often asymptomatic, to improve both pharmacological and behavioral therapy. The evidence of esophagus pathology led the team to reduce the interval between follow-up visits. A second EGDS was performed in these patients as follow-up at the fifth year to verify the therapy efficacy.

The results were evaluated by BMI and EW%.

In addition to the psychological evaluation patients filled out the SF-36 Health Survey (SF-36) as a method of self-judgment of quality of life. Patients filled in the test, first before surgery and then every year afterwards until the fifth year. The SF-36 evaluates both physical and mental stress and positive health, explores eight dimensions of health (physical functioning, physical limitations, physical pain, general health, vitality, social activities, role and emotional state, mental health) on a scale from 0 to 100, where higher scores correspond to a state of better health<sup>34,35</sup>.

## STATISTICAL ANALYSIS

Results are expressed as mean  $\pm$ SD, statistical analysis was made with Student's t test for paired variables. A p value of  $<0.05$  was considered significant. All statistical analyses were performed using Primer-e 5 version for windows. All data were retrospectively analyzed, and patients who didn't come to the visits were again requested for a medical examination.

## Results

## NO MORTALITY

There were 9 cases of early (first month) complications (4.3%) (2 cases of abdominal hemorrhage, 3 of hepatic hemorrhage, 2 of splenic rupture, 1 of esophageal rupture, 3 of scar dehiscence).

There were 26 cases of late complications (30 to 365 days) (12.4%) (2 cases of distal esophageal dilation, 3 of dilatation of the upper pouch, 5 of symptomatic gastritis of the upper pocket, 16 cases of grade I esophagitis).

After 5 years we found bandage related complications in 13 cases (6.2%): 2 cases of intra-gastric penetration, 2 of dislocations of the band with gastric occlusion, 3 of disconnection of the port, 1 of infection of the port, 3 of port decubitus, 2 tube leakage, 4 of which (1.91%) required removal of the band. Patients who had been removed the LAGB dropped out after surgery, while the ones who had early and late complications continued to follow up the programmed visits regularly.

21 patients dropped out (10.04%).

In four patients with unsatisfactory results a restrictive-mal-absorptive intervention was recommended (e.g. RYGB).

Two years after the surgical procedure 138 patients who underwent LAGB (66%) kept following the assistance procedure, all of whom continued until 5 years after the surgery.

In the follow-up at two years 92 patients, 44.02% (74 women/18men), had reached the desired weight, which

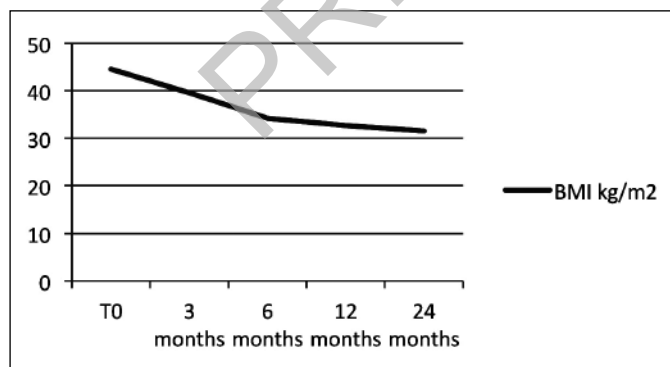


Fig. 1: Changes in BMI in the first two years.

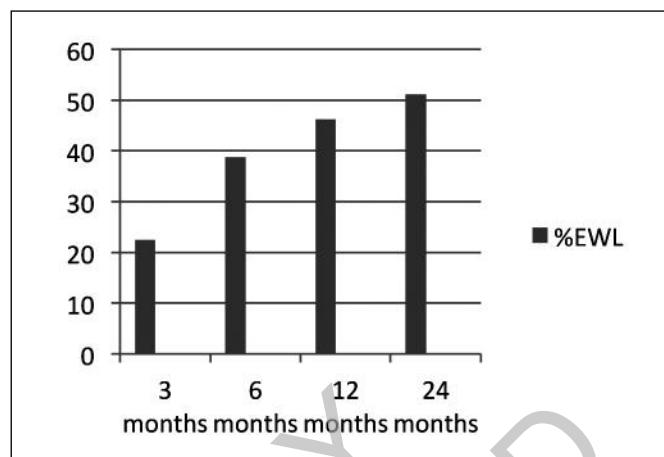


Fig. 2: %EWL changes in the first two years.

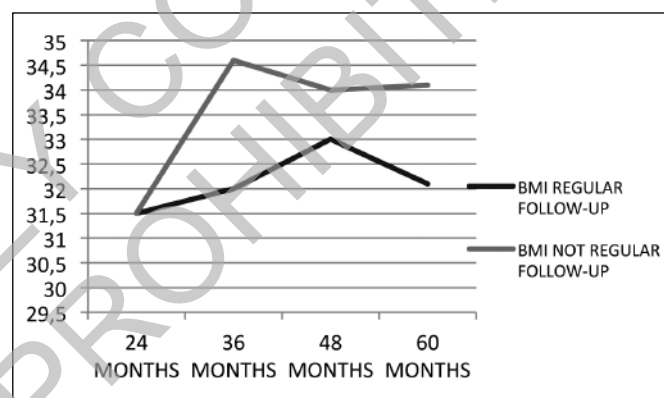


Fig. 3: Change in BMI between 2nd and 5th year in the comparison of two groups.

is the weight that provides the best physical and mental wellbeing.

Among, weight loss at two years was  $39 \pm 9$  kg (with an average weight loss of  $11 \pm 3$  kg in the third month,  $19 \pm 6$  kg after six months,  $26 \pm 11$  kg after one year).

The excess weight loss% (EWL%) was respectively  $22.4 \pm 8\%$ ,  $38.7 \pm 46.2 \pm 12\%$  and  $51.2 \pm 14\%$ . (three months, six months, one year, two years).

The BMI reduction became statistically significant ( $p < 0.01$ ) after just 90 days after LAGB positioning. (Fig. 1) These data were confirmed for as long as two years, when BMI was  $31.5 \pm 6$  and EWL %  $51.2 \pm 18$ . (Fig. 2) The average calibration of the band at the end of the first year was 2.5 ml (min 0 max 4 ml).

The average calibration of the bandage at the end of the second year was 1 ml

Over the subsequent three years, up to 5 years, 58 patients (63%) have continued the follow-up program every three months and maintained a significant weight loss, with 49.7 EWL % and BMI  $32.1 \pm 6.2$ .

The calibration of the band remained 1 ml.

TABLE I - *Asintomatic complication (EGDS two years later in 59 patients)*

Complication	No.	%
Grade I esophagitis	23	38.9
Grade II esophagitis	6	10.2
Chronic gastritis of the pouch	9	15.3
Neostomal ulcer	1	1.7
Neither esophageal nor gastric alteration	20	33.9

TABLE II - *Asintomatic complication (second EGDS in 39 patients following the program)*

Complication	No.	%
Grade I esophagitis	6	15.3
Grade II esophagitis	1	2.6
Chronic gastritis of the pouch	1	2.6
Neostomal ulcer	0	0
Neither esophageal nor gastric alteration	31	79.5

TABLE III - *Complications (second EGDS in 20 patients not following the program)*

Complication	No.	%
Grade I esophagitis	8	40
Grade II esophagitis	5	25
Chronic gastritis of the pouch	5	25
Neostomal ulcer	1	5
Neither esophageal nor gastric alteration	1	5

In 34 patients (37% of the 92 who had reached the desired weight) that did not follow the nutritional program and came to our observation without planning, the weight increased significantly ( $p < 0.01$ ) with %EWL  $42.3 \pm 12$  and BMI  $34.12 \pm 6.7$ . This group of patients underwent a follow-up visit at least once a year (Fig. 3). Average calibration of the bandage was 2.5 ml.

The incidence of complications from the third to the fifth year also turned out to be different in the two groups. In fact, in patients with good follow-up compliance, reported symptoms led to an early diagnosis and treatment of complications, which resulted in reduced complications and better weight loss with time.

In fact, at the end of the second year, 59 patients performed EGDS showing a complication rate of 66.1% (Table I) of various severity. At the consequent control, only 8 patients still presented minor signs of complications (20.5%) (Table II), while in 20 patients who underwent a second EGDS but did not comply with the follow-up, the persistence of complications was 95% (Table III).

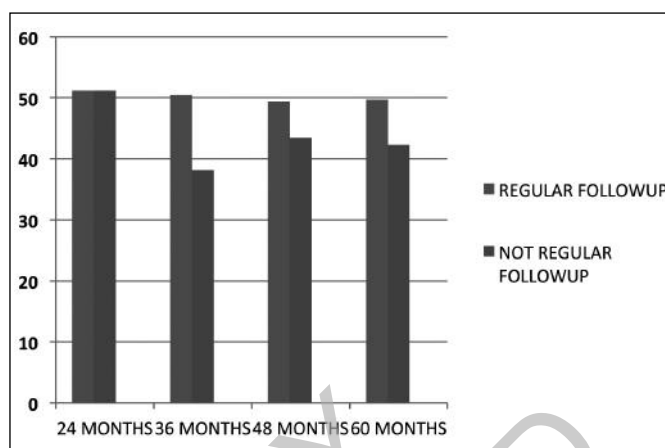


Fig. 4: %EWL changes between 2nd and 5th year in the comparison of two groups.

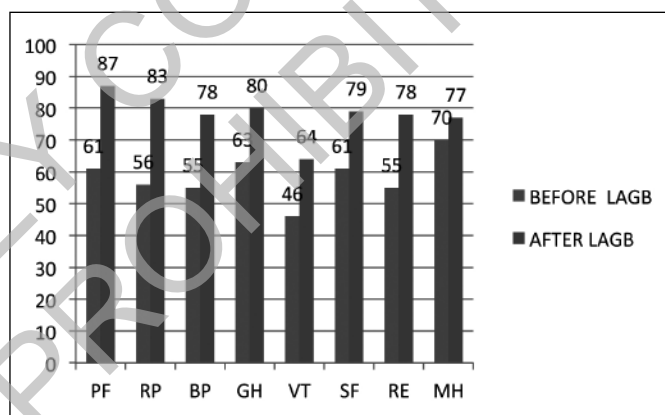


Fig. 5: Mean values of the items (Sx36) before and after LAGB after two years.

During the first two years after surgery the results of SF36 showed significant improvement in all the evaluation scales, in particular the physical scales (Fig. 5).

Between the second and the fifth year, patients who strictly complied with the follow-up maintained or even further increased the positive perception of their state of health (Fig. 6).

However, the test scores of patients who did not continue the follow-up decreased, regarding both the physical and mental scales (in particular emotional state) (Fig. 7). Data in Figs. 5, 6, 7 are reported as mean and bar refers to SE. (PF: physical functioning; RP: role physical; BP: bone pain; GH: general health; VT: vitality; SF: social functioning; RE: role emotional; MH: mental health).

## Discussion

LAGB is one of the most used surgical techniques that guarantees good results in terms of weight loss and metabolic control <sup>31</sup>.

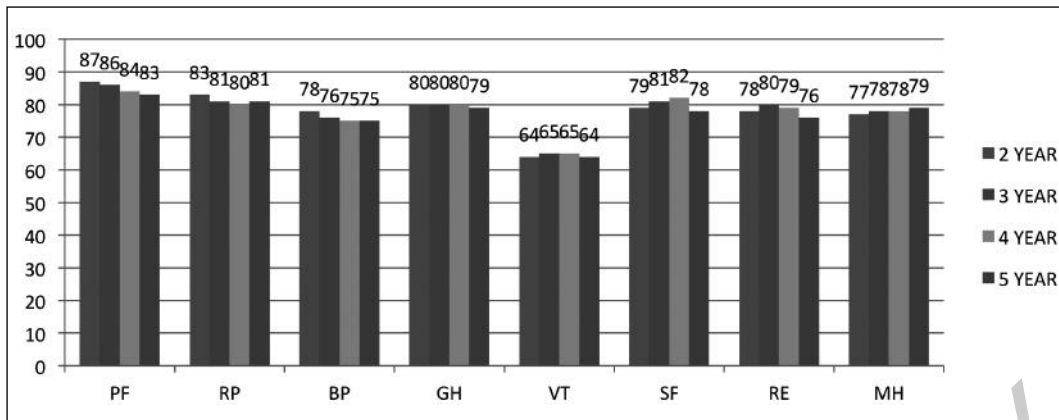


Fig. 6: Mean values of the items (SF36) between 2nd and 5th year in the patients having regular controls.

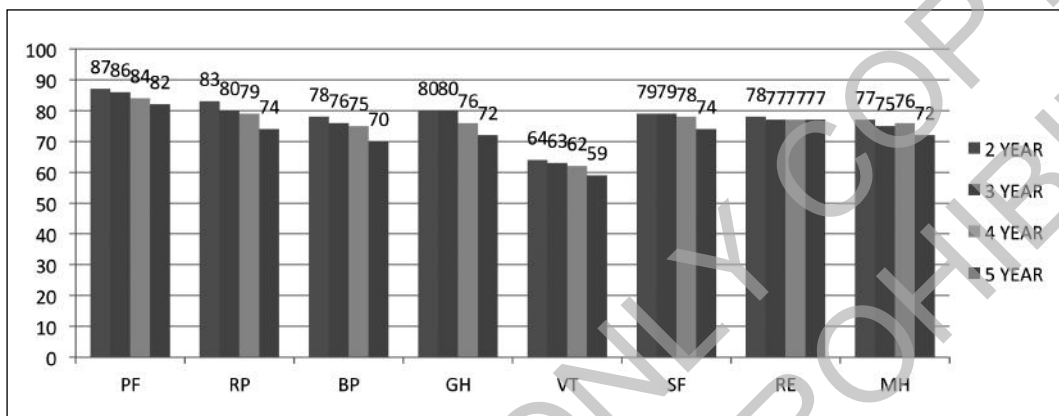


Fig. 7: Average values of the items (SF36) between 2nd and 5th year in patients having not regular controls.

The careful choice of patients is essential for the success of LAGB <sup>22</sup>.

An expertized chirurgial group and a strict follow up are able to obtain best clinical results reducing early and long term complications <sup>33</sup>.

Our study showed that the results obtained with the band are amplified by a strict post-operative follow-up which, if the patient cooperates, helps to achieve better results with fewer complications.

The multidisciplinary approach is of paramount importance to achieve the planned goals.

We observed at the end of the second year the trend to leave nutritional program, even in patients who reached the desired weight. It was maybe due to the natural weight loss reduction and consequent loss of compliance <sup>36,37</sup>.

The EGDS carried out at 2 and 5 years after surgery showed a significant reduction of reflux esophagitis and gastritis of the upper stomach pouch, demonstrating that patients have considered a different eating behavior, and that the band is a great help for them to achieve the desired weight.

Patients who have complied with the follow-up procedure, achieved an improvement in quality of life over the years after surgery.

In patients who complied with the proposed therapeutic procedure the results in terms of weight loss were

achieved with a minimal calibration (1-2 ml on average) in few months (2-3), with a reduced incidence of complications such as esophagitis, gastritis of the pouch, band dislocation and recurrent vomiting.

The LAGB calibrations, although minimal, made it possible to interact with the patient in the most delicate moments of the treatment.

The intervention of several specialists can avoid serious complications and solve them at the beginning.

Shortly, LAGB is a technique used for a large number of obese patients. Long term results were not significant because the surgical procedure was not supported by an adequate and interdisciplinary follow-up. Follow up is necessary for therapeutic success in the long run.

In the lack of a long term therapeutic plan agreed with the patient, there is a high risk of losing the result obtained with the surgery.

Nowadays there are some procedures that are not reversible and present more complications in the long run. The reason of band failure is not related to technique, but with the fact that in most cases the technique is not combined with a full psychological-nutritional recovery of the patient.

In severe obesity there is very often an eating disorder of mesencephalic origin that cannot be solved with bariatric surgery alone.

Obesity surgery reaches good results only if associated with educational and psycho-therapeutic support. These therapeutic approaches can provide long-term results only if carried out by an experienced and interdisciplinary team and only if there is a good cooperation between the specialists. Nowadays LAGB is a conservative and reversible technique and, if performed on a reliable and cooperative patient, offers good results in the long-term period (5 years) with rates of re-intervention of 6,2%. This technique can therefore be considered the first choice in patients with the previously mentioned characteristics who accepts an integrated post-operative follow-up by different specialists.

The surgery alone, without a complete psycho-nutritional education carries a high risk of failure.

No compliance to the nutritional program (use of hypercaloric soft foods e.g. sweets) lead to an inadequate weight loss and unsatisfactory quality of life; the presence of comorbidities in selected patients, (diabetes type 2 and severe OSAS) could suggest the restrictive-malabsorptive approach (e.g.: RYGB).

LAGB gives to the surgeon the chance to deal with the patient's psychological and clinical condition by progressively adjusting the gastric ring.

Other surgical techniques do not need this collaboration of the patient to the therapeutic plan. In our experience the cooperation between the patient and the interdisciplinary team gives good long-term clinical results with a great reduction (78%) of complications at 5 years follow-up.

This means that the patients has developed an ability to adapt to the new lifestyle induced by the LAGB with significant reduction of all symptoms related to the restriction of the bolus transit.

### Riassunto

L'obesità è una condizione foriera di molteplici complicanze cardiovascolari, metaboliche, immunologiche; il trattamento medico, dietetico e farmacologico è risultato essere inadeguato nei casi più gravi.

L'intervento di bendaggio gastrico regolabile per via laparoscopica è stato una delle tecniche più utilizzate in passato, ma la difficile scelta del paziente adeguato, affidabile nell'aderire allo stretto follow-up, negli anni successivi l'intervento ha fatto sì che altre tecniche prendessero progressivamente campo negli ultimi anni con risultati migliori e minor numero di complicanze.

Nella nostra esperienza, un team multidisciplinare composto da un chirurgo esperto, nutrizionista, endocrinologo, psicologo e dietista, può valorizzare al meglio i risultati a lungo termine di una procedura come il LAGB, che risulta essere l'unica tecnica completamente reversibile, riducendo al minimo le complicanze e inducendo nel paziente quelle modificazioni dello stile di vita necessarie per il mantenimento del calo ponderale nel tempo, tramite la stretta interazione con il team.

I risultati mostrano che, a 5 anni dall'intervento di LAGB, i pazienti con grave obesità (BMI > 40) che hanno partecipato ad un follow-up interdisciplinare pianificato, hanno ottenuto una riabilitazione completa attraverso il cambiamento di stile di vita, e hanno mantenuto la perdita di peso ottenuta dopo 24 mesi. La qualità percepita della vita (QoL) mostra un progressivo miglioramento per tutto il periodo di osservazione intensiva.

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