



Laparoscopic adjustable gastric banding, the past, the present and the future

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Abstract: The laparoscopic implantation of an adjustable gastric banding (LAGB) was first described in 1993. Thereafter, the LAGB underwent to a lot of modifications, revision and refinements to become as it is currently defined. This procedure quickly became one of the most common bariatric surgical operations in the world in the first decade of the 2000s but, over the last few years, it has turned into the fourth more common procedure. A series of more or less clear reasons, led to this decrease of LAGB. The knowledge of the history of the LAGB, of its evolution over the years and its limitations can be the key-point to recognize the reasons that are leading to its decline. The adjustability and the absolute reversibility characteristic of LAGB, make this surgical procedure a “bridge treatment” to allow the specific goal of eradicating obesity.

Keywords: Laparoscopic adjustable gastric banding; reversible weight loss surgery; minimally invasive surgery; evolution of laparoscopic adjustable gastric banding (evolution of LAGB)

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Introduction

The laparoscopic implantation of an adjustable gastric banding (LAGB) was first described by Belachew *et al.* in 1993 (1). Thereafter, the LAGB underwent to a lot of modifications, revision and refinements to become as it is currently defined. These changes affected both the technological and the surgical techniques, but above all the pre- and post- operative management.

Technological improvement

Lubomyr Kuzmak is considered a pioneer in bariatric surgery and the inventor of the adjustable gastric banding. His great merit is that he firstly recognized the potentials of adjustability in the gastric banding. In fact, in 1983 Kuzmak projected an adjustable band introducing the

advantage of an adjustable inflatable part of the silicon band, which was connected by a tube to a reservoir. On June 1986, he obtained the US patent for the inflatable device (2) and performed his first operation the same month. Subsequently, he described his results showing the superiority of the adjustable gastric band compared with the nonadjustable one he had been using since 1983.

The laparoscopic gastric banding was for the very first time described in the literature ten years later, in 1993, when Broadbent *et al.* in Australia, and Catona *et al.* in Italy, reported on their initial experience. On September 1st, 1993 at the Centre Hospitalier Hutois, Belgium, the first laparoscopic adjustable silicone gastric band was implanted in a patient by Belachew *et al.* (1). Due to the success of the procedure, the industry started the mass production and marketing of different sizes of adjustable silicon bands ranging from 9.5 to 13 cm length. Following

the initial experience, only two sizes (9.75 and 10 cm) were maintained, as they could cover all the requirements.

In July 1994, the Lap-Band® System became available on the market to be used by the “trained surgeons”. In fact, at first, the BioEnterics, which was the manufacturer of the Lap-Band® (BioEnterics, Carpinteria, CA, USA), did not sell the device to the surgeons before participating in a training program in approved centers. In June 1995, clinical trials in selected US centers were approved by the Food and Drug Administration (FDA). Finally, in 2001, the US FDA approved the clinical application of the Lap-Band® system for the treatment of morbid obesity (3).

This Lap-Band® system consisted of a silicon 13 cm ring with an inner circumference of 9.75 or 10 cm. The connection tube was 50 cm long with a fill volume of 4 mL. The subsequent version, the Lap-Band VG® (Vanguard), approved in 2003, was larger than the previous system, with an inner circumference of 11 cm, and had a fill volume of 10 mL. Furthermore, this modified version was improved by soft, precurved individual sections of the inflatable balloon in order to reduce the risk of the leakages (Omniform technology).

The current device is the result of a final refinement applied in 2006, when the Lap-Band AP® version (Advanced Platform) was introduced. The Lap-Band AP® version (Advanced Platform) was designed in two different size: the standard (APS) with a fill volume of 10 mL, and large (APL) with a fill volume of 14 mL. Such variety offered a great range of adjustability in order to respond all patients' anatomical differences. Moreover, the Lap-Band AP® version included other modifications, such as an easy unlocking mechanism and a 360-degree Omniform inflating balloon component, which improved the reopening procedure and the pressure distribution, respectively (4).

In parallel in the United States, the Realize band, manufactured by the Ethicon Endosurgery Inc. (Cincinnati, OH, USA) was approved by the FDA in 2007 (5). The updated version, called “Realize-C band”, was approved in 2009. The latter version stressed the importance of the low inflation pressure with a 11 mL fill volume. It is also equipped with the unlocking mechanism as well as a prelock position to ease gastric band placement.

Evolution of the surgical technique

The original technique was described by Belachew and by Favretti (1,6). The key points of the LAGB technique were: (I) pouch volume of 25 cc; (II) perigastric technique;

(III) posterior dissection through the lesser sac, leaving the posterior gastric wall free to move up and down; (IV) two gastro-gastric stiches on the fundus.

The knowledge on the weakness points and on the complications of the LAGB, led to the progressive surgical technique evolution. As a consequence, the above key-points were modified as follows:

- ❖ The volume of the pouch, initially set at 25 cc, has been gradually reduced and today we talk about a “virtual pouch” (<15 cc). Moreover, the band-E/G junction distance, which was initially set as 3 cm, has been shortened to 1 cm;
- ❖ The “pars-flaccida positioning technique” has become the most widespread technique for (I) the better handling of the instruments and the band; (II) the low complexity in dissection maneuvers; and (III) the low complication rate;
- ❖ The posterior dissection above the bursa omentalis is minimized to reduce the risk of posterior slippage.

Finally, some authors suggest to avoid any stitches for an even better result. Furthermore, other improvements were proposed. The gastrostenometer, which was employed in the past to calibrate the pressure at the band level, is no longer used. To prevent a post-operative edema and obstructive acute complications, the connecting tube, is cut outside the abdomen, so that the natural spilling of the liquid guarantees a self-adjusted mechanism, unanimous identify as “point zero”. Some authors support the port positioning using mesh fixation on the port. It could have several advantages: avoiding deep incision during the placement; postoperative pain reduction; facilitating port removal (7).

Finally, the shortening of the connection tube is introduced to reduce the risks of complications related to the tube path among ileal loops, or diaphragmatic irritation and shoulder tip pain.

The close relation between bariatric surgery, hiatal hernia and reflux disease, frequently present at the same time in the obese patients, dictated specific rules and indications to be followed.

All the bariatric surgical procedures can worsen or cause reflux and reflux diseases. As a result, the identification of the patients affected by such comorbidities is important to correctly select the right bariatric surgical procedure and possibly solve the contemporary hiatal associated dysfunction.

As to the LAGB, in order to treat the hiatal hernia,

when present, the diaphragmatic esophageal hiatus is routinely dissected, the hiatal hernia reduced and the crura approximated.

In our center, a routine gastroscopy is made prior the LAGB in order to investigate the presence of direct or indirect signs of hiatal hernia and to exclude other diseases.

To confirm the diagnosis of a significant hiatal hernia two laparoscopic parameters are also evaluated: a deeper than 2 cm hernia sac, measured by a clinch, and/or the easy passage of the 20 cc inflated balloon of the calibrating tube (gently attracted by the anesthesiologist) throughout the diaphragmatic hiatus.

Pre and post-operative management

The LAGB was born as a surgical procedure supported by a surgical team. The importance of dedicated surgical skills as well as the presence of an interdisciplinary team (IDT) to assist the patient before and after the surgical procedure, has been rapidly recognized. In 2002, Favretti *et al.* (8) reported on the importance of the “healthy food choices”, the activity and exercise, and the behavioral changes. This study emphasized the relevance in monitoring the comorbidities and the metabolic/nutritional changes during the scheduled post-operative checks, and the power of the communication and collaboration with the patient’s primary care provider to support the patient weight control.

Any bariatric surgery is rationally performed within a multidisciplinary team which is the key element for the success of the treatment itself. The IDT professionals are predominantly psychologists, dieticians and motor rehabilitation professionals; the bariatric surgical team is formed and skilled on laparoscopic and endoscopic surgeries, and integrated with dedicated anesthesiologists and aesthetic/reconstructive surgeons.

In the pre-operative period, the IDT prepares the patient in order to cut down risks and failures: organic and behavioral pathologies are highlighted and treated, and, at the same time, the patient is motivated to lose weight. Furthermore, the IDT clearly describes to the patients the complexity of the pathway required to reach the desired weight loss, which include the surgical treatment but also changes in diet and life-style behaviors. Finally, the IDT explains the meaning of the informed consent regarding the procedures (9-11).

Postoperative follow-up gained more and more importance over the years and the timing of scheduled exams, although variable from one center to another, has

been established. Follow-up adjustments of the band, initially based only on band filling, are nowadays performed according to numerous variables, such as the radiopaque bolus swallow appearance, the clinical interdisciplinary evaluation of weight loss, the appetite or symptoms, and the patient motivation (12,13).

Results of LAGB

Obesity is a chronic behavior disease which should be treated by ensuring a long-term benefit. As a result the efficacy of all the bariatric procedures should be assessed in a long term follow-up period. Following this consideration in the analysis were included only studies showing a 3-year minimum follow-up. Every surgical procedures, and therefore also LAGB, as well as the peri-operative management, require a variable learning curve. To eliminate the learning phase and to obtain more homogeneous results in our analysis, only series with more than 250 cases were taken into account.

Tables 1 and *2* summarized the results of the included studies about weight loss (estimated at 3- and 5-year follow-up) and erosion and dilatation/herniation of the gastric pouch, which are considered the main long-term complications.

Discussion

The LAGB, which was the first operation proposed for a laparoscopic approach to the obese patient, due to the technical attraction and encouraging results, spread worldwide. Since its first placement in 1993, LAGB underwent a series of technical, technological and management evolutions (27) (*Table 3*).

Nowadays, LAGB is a standardized operation and a reproducible technique to evaluate, compare and improve results in the long-term follow-up. Technological improvements, especially the Omnicore technology and the different gastric outlet size, led to a reduction in some complications and causes of re-operations. Although some authors documented the complication decrease, it remains difficult to prove because of the coexisting of a series of bias like the different experience and technique in the various studies. As for the technique, the reduction of the initial volume of the gastric pouch (17) was one of the first technical refinements, which greatly reduced the incidence of gastric pouch enlargement/dilation. The impact on the result offered by the pars flaccida technique

Table 1 Published results after LAGB with at least 250 patients and a minimum follow-up of 3 years in regard to weight loss at 3 and 5 years follow-up

Study	Band	N of patients	3-year patients' follow-up, % [n]	3-year EWL%	5-year patients' follow-up, % [n]	5-year EWL%
O'Brien, 1999 (14)	First generation	277	NR	61.6%	NR	NR
Angrisani, 2001 (15)	First generation	1,265	<60%	62.3%	NR	NR
Belachew, 2002 (16)	First generation	763	90%	40%	90%	35%
Vertruyen, 2002 (17)	First generation	543	95.9% [521]	62%	NR	53%
Angrisani, 2003 (18)	First generation	1,893	70%	51.3%	70%	47.6%
Holloway, 2004 (19)	First generation	502	93% [40]	65%	NR	NR
Miller, 2007 (20)	First generation	554	92% [510]	65%	92% [510]	68%
Favretti, 2007 (21)	First generation	1,791	91%	41.2%	91%	37.3%
O'Brien, 2013 (12)	Both	3,227	81%	50.5%	81%	49.6%
Arapis, 2017 (22)	Both	897	NR	NR	90.4%	45.9%
Carandina, 2017 (23)	Both	301	NR	44.5%	86.7%	41.4%
Vinzens, 2017 (24)	Both	405	85%	51%	85%	48%
O'Brien, 2018 (25)	Both	8,378	85% [6,877]	51.4%	68.6% [5,235]	47.7%
Furbetta, 2019 (13)	Both	3,566	NR	NR	79.9% [1,840]	50.7%

LAGB, laparoscopic adjustable gastric banding; NR, not reported.

is still debated in the literature: some authors reported data on the reduction in the incidence of erosion [from 8.5% to 2.2% (12)], slippage and dilatation of the gastric pouch (24), whereas others did not obtained any improvements (22). However, both techniques, the “pars-flaccida” and the “perigastric” ones, maintain an important complementary role in specific anatomic circumstances. Another strength point of the surgical technique evolution is the perioperative diagnosis of GERD and hiatal hernia and its surgical treatment contemporary to LAGB. Worsening or *de novo* GERD, is a well-known problem every bariatric procedure have to deal with. The LAGB's adjustability allows to relieve reflux. In fact, the gradual modification of the pouch outlet is performed in parallel to the patient's behavioral improvements in the eating attitude. The no-compliant patients can benefit from different solutions offered subsequently, thanks to the complete and easy reversibility of the LAGB.

The features of this less invasive technique, adjustable and completely reversible, impose a well-structured interdisciplinary team. The pre-operative program is fundamental to select, educate, inform and motivate patients before undergoing the bariatric surgical operation

(9,11). Postoperative management in bariatric surgery is always of primary importance, and in the LAGB, which is characterized by the adjustability and reversibility, the follow-up is an integral part of the treatment to obtain the better long-term result.

The LAGB is chosen by surgeons to start the learning curve on bariatric procedures. The related, puzzling results contributed to jeopardize its standing and evolution. This procedure, when properly performed by skilled surgeons and supported by an IDT, shows effective results with percentages of excess weight loss ranging from 40% and 65%, 35% and 68% at 3-year and 5-year follow-up. Furthermore, papers with longer follow-up (more than 15 years) confirm these results with percentages of excess weight loss ranging from 47.9% and 52.6% (13,25).

The long-term results obtained in high-volume centers (13,25), both in terms of efficacy and complications, should lead to think, as said by O'Brien, that “the band must not be abandoned” (28).

Future goals of LAGB are strictly related to its mechanism of action: to reinforce the essential interdisciplinary bariatric treatment and to empower surgical operation through adjustability. Adjustability can

Table 2 Published results after LAGB with at least 250 patients and a minimum follow-up of 3 years in regard to the two main long-term complications, erosion and dilatation/herniation of the gastric pouch

Study	Band	N of patients	Dilation-herniation (%)	Erosion (%)
O'Brien, 1999 (14)	First generation	277	9	–
Angrisani, 2001 (15)	First generation	1,265	5.2	1.9
Belachew, 2002 (16)	First generation	763	8	0.9
Vertruyen, 2002 (17)	First generation	543	4.6	0.92
Angrisani, 2003 (18)	First generation	1,893	48.9	1.1
Holloway, 2004 (19)	First generation	502	5.58	0.4
Favretti, 2007 (21)	First generation	1,791	3.9	0.9
O'Brien, 2013 (12)	First generation	1,857	40.5	5.3
	Second generation	1,370	6.4	0.8
Arapis, 2017 (22)	Both	897	11.9	2.6
Carandina, 2017 (23)	Both	301	12	11
Vinzens, 2017 (24)	Both	405	32.7	0.6
Beitner, 2016 (26)	First generation	2,241	12.27	0.45
	Second generation	470	5.95	0.2
O'Brien, 2018 (25)	First generation	8,378	51.7	6.1
	Second generation		11.3	0.69
Furbetta, 2019 (13)	First generation	3,566	6.9	3.1
	Second generation		5.5	2.3

LAGB, laparoscopic adjustable gastric banding.

counterbalance the failures mainly due to the long-term anatomic and behavior modifications of any operation. An adjustable band allows a partition of the gastric cavity in order to modify the functional pouch outlet to improve restriction or to prepare to revision surgery, in particular to the adjustable by-pass (29). Moreover, the actual limits related to the erosions could be lowered by new devices and new connections to the port.

The present and potential future advantages of LAGB are counterbalanced by the organizing difficulty in scheduling and performing the follow-up for all the patients enrolled. As a consequence, to overcome the “post-surgical management limits”, as well as to response to a growing treatment demand, lots of centers propose not-adjustable surgical approaches, which do not require a close follow-up to reach the targeted results.

Our institution provides a section dedicated to obesity, which facilitates patient's recruitment, professionals' cooperation and economic acceptance. In our opinion

these premises allow to invest LAGB in the future; in fact, if correctly managed in the peri-operative period, it is an effective technique to achieve the targeted weight loss and food re-education.

In conclusion, the knowledge of the history of the LAGB, of its evolution over the years, of its results and its limits, strictly related to a well-structured IDT, can be the key-points to recognize the reasons that are leading to its decline in favor to “easy”, technological surgeries for a growing treatment demand. The adjustability and the absolute reversibility characteristic of LAGB, make this surgical procedure a “bridge treatment” to allow the specific goal of removing obesity. In fact, LAGB, as well as the others bariatric surgeries, does not treat the cause of the obesity, which has a complex pathogenesis, and the surgical medium-long term results highlight the distance between a feasible and a truly effective procedure. Thus, the proper treatment of obesity can be reached only by restoring a healthy life-style and by alimentary re-education.

Table 3 The evolution of laparoscopic adjustable gastric banding

Technical		Pre and post-operative management	
Past	Present	Past	Present
Site of the band 3 cm below the E-G junction	Site of the band 1 cm below the E-G junction	Subjective follow-up timing	Follow-up timing at scheduled intervals or in case of need
Long connection tube	Shortening tube length	No preoperative management	Preoperative management improved by IDT
Anchoring the port to the fascia	Using mesh fixation for the placement of the port	–	Use of BIB in the preoperative period
Rare dissection of the diaphragmatic esophageal hiatus	Common dissection of the diaphragmatic esophageal hiatus	No patient education	Extensive patient education
Subjective intraoperative diagnosis of hiatal hernia	Measurement of the hiatus with 20 cc inflated probe	Band adjustment principally based on band filling	Based on band filling and IDT evaluation
Subjective intraoperative decision on the treatment of hiatal hernia	Treatment of the concurrent hiatus hernia if the test is positive	Band examination by surgeon and radiologist	Band examination by surgeon in collaboration with IDT
pouch of 25–30 cc	Pouch of 15–20 cc	No material given to the patients	A brochure related to LAGB characteristics
True pouch at X-ray	Virtual pouch at X-ray	–	–
Initial outlet pressure measured by gastrostomometer	Point 0-autoregulation	–	–
Only peri-gastric positioning technique	Pars-flaccida or peri-gastric with a complementary role	–	–
Two gastro-gastric stitches	Gastro-gastric stitches to embedding the silicon band completely	–	–

LAGB, laparoscopic adjustable gastric banding; IDT, interdisciplinary team.

Efforts will be directed to further technological developments, mainly aimed at reducing the impact of complications. A slimmer band, alternative adjustment methods, the possibility of simple daily adjustments, new materials, including biological ones, are just a few ideas to work with.

In addition, the long-term results (15–20 years) of the other bariatric procedures, which at the moment are not present as they have a more recent history, will be important to draw definitive conclusions and a more objective comparison.

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