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DOI: 10.17235/reed.2019.4922/2017
Link: PubMed (Epub ahead of print)

Please cite this article as:

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ART ESP 4922 inglés
Spanish consensus document on bariatric endoscopy. Part 2: specific endoscopic treatments

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Received: 3/3/2017
Accepted: 3/10/2017

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Key words: Endoscopy. Obesity. Bariatric. Spanish consensus.

Conflicts of interest: Dr. Espinet-Coll and Dr. López-Nava act as consultants for Apollo Endosurgery and ReShape Medical, notwithstanding, any conflicts of economic interest may be excluded with regard to the present document.
INTRODUCTION

Obesity is a chronic, recurrent and progressive multifactorial disease, associated with important physical and psychological complications and also has a considerable morbidity and mortality. Therefore, the evaluation, treatment and follow-up of obese patients should be individualized within a multidisciplinary unit with adequate human and structural resources. Medical treatment via hygienic-dietetic measures, although essential, may be insufficient. Surgical approaches are reserved for severe or morbid obesity, they are not exempt from complications and may not always be to the patients’ liking.

In this context, there are three situations in which endoscopic treatment, as a complementary strategy with few complications, can contribute to the benefit of an obese patient. Firstly, a subgroup of patients with overweight grade II or non-morbid obesity, in whom isolated medical treatment has failed or needs to be complemented. Secondly, patients with morbid obesity who refuse surgery, with a contraindication or with an excessive risk. Finally, patients affected by super-obesity who need to lose weight prior to bariatric surgery in order to reduce the associated morbidity and mortality (Table 1).

During the last years, we have witnessed a significant increase in the number and type of bariatric endoscopic techniques (Table 2). Currently in Spain, there are different types of balloons, injection of substances, suture systems and malabsorptive techniques, among other primary procedures, as well as endoscopic revisional methods of bariatric surgery (Table 3). In addition, they can be applied sequentially in some cases. This makes it necessary to protocolize, position and regulate all these techniques via a consensus that allows their clinical application with the maximum medical rigor and scientific evidence available.

In this regard, the Spanish Group of Bariatric Endoscopy (Spanish Working Group for the Endoscopic Treatment of Metabolism and Obesity, GETTEMO of the SEED and SEPD), has prepared this Consensus Document after several working meetings. This document has been presented, discussed and approved during the XXXVII National Days of the Spanish Society of Digestive Endoscopy (Zaragoza, November 2015) with
the participation of the medical specialists that are included in the acknowledgments section.

The first part of the document deals with General Considerations, which includes the following:

1. General indications and contraindications.
2. Study, evaluation, previous explorations and informed consent.
3. Quality criteria and evaluation of the results.
4. Multidisciplinary follow-up.
5. Scientific development and research.
6. Structural resources of a Bariatric Endoscopy Unit.

The second part will describe the main technical peculiarities, methodology, results and the specific indications, if any, of each of these techniques which are performed in Spain. We hope that this will help to establish the minimum requirements necessary for the proper functioning of a Bariatric Endoscopy Unit.

**INTRAGASTRIC BALLOONS**

An intragastric balloon (IB) was first used in 1985, when the Garren-Edwards Gastric Bubble device was put to the test (1) and resulted in excessive side effects and complications. Other models emerged later with similar results and were also unsuccessful. This prompted a multidisciplinary international conference of experts (Tarpon Springs, Florida, 1987) to establish the ideal recommendations that would improve balloon safety and effectiveness (2). As a result, the Bioenterics® intragastric balloon (henceforth BIB, sequentially marketed by Allergan®, Orbera®, and Apollo®) was developed during the late 1990s and has remained the gold-standard balloon to this day. Numerous studies support its safety and effectiveness and the device is now a well-established tool for the treatment of obesity (3), as the efficacy is higher than that of dietary therapy alone (4). In an attempt to further improve this device, newer IB concepts, designs and models have emerged over the past ten years (5-8) (Tables 2 and 3), which will be described below.

Usually, the primary indications are for patients with: a) grade I-II (BMI 30-40 kg/m²) obesity; 2) superobesity (extreme obesity, grade IV with BMI > 50 kg/m²)
preoperatively in order to facilitate bariatric surgery; and 3) morbid obesity when surgery is excluded (Table 1). Antibiotic prophylaxis is not recommended for balloon implantation/explantation (Table 4). However, prophylaxis with antacids (ideally PPIs) is recommended for the duration of intragastric balloon therapy in order to minimize mucosal injury. In most cases, IB placement and removal occur on an outpatient basis including a short observation period.

**Bioenterics® intragastric balloon (BIB)/Orbera® intragastric balloon**

This has been available since 1999 and remains the most popular and widely used balloon to date. It is currently marketed by Apollo® (Apollo Endosurgery, Austin, Texas, USA) and consists of a spherical silicone balloon that is highly resistant to gastric acid and has a smooth surface to reduce the risk of mucosal erosion. The device stays in place for six months. The balloon is filled with isotonic saline (500-700 ml) mixed with methylene blue dye (10 ml) and has a radiopaque self-sealing valve that can be identified with simple radiographic techniques (8).

Similar to a tube, it is inserted via the mouth and advanced blindly under deep sedation or general anesthesia with endotracheal intubation, according to patient characteristics and endoscopist, anesthetist and site experience. For patients with a BMI > 40 kg/m² and obstructive sleep apnea syndrome (OSAS) or chronic obstructive pulmonary disease (COPD), endotracheal intubation is recommended whenever possible during placement and explantation. Filling and emptying are performed under direct endoscopic vision and control.

**Efficacy for weight loss**

Many randomized, prospective studies have shown the effectiveness of BIB for the management of weight loss (9-21). Three systematic reviews (19-21) including 409, 4,877 and 3,608 patients reported an average weight loss of 16.0, 17.8 and 14.7 kg and BMI reduction by 4.0, 9.0 and 5.7 kg/m² at six months, respectively, mostly in patients with a baseline BMI of 30-40 kg/m². Reviews suggest that approximately 80% of weight loss occurs within the first three months. Furthermore, major improvements (in up to 100%) or resolution (52%) were reported for associated comorbidities (21), including
metabolic syndrome, high blood pressure, dyslipemias, diabetes and non-alcoholic steatohepatitis (17,21-23).

**Maintaining weight loss after BIB removal**

Four studies/systematic reviews (19,22,24,25) have documented a persistent mean weight loss of 43-68% of total weight loss at 12 months after explantation. Moreover, the review by Kotzampassi (24) found that 53%, 27% and 23% of patients maintained excess weight loss above 20% at one, two and five years of follow-up, respectively. Approximately 10% of weight loss is seemingly maintained at 6-12 months after balloon removal, with better weight maintenance results as compared with a control (11) or drug therapy group (16). Similar results were obtained compared with sequential therapy with one or two balloons (12).

**Adverse effects**

Overall, BIB has a variable rate of minor adverse events (epigastralgia, gastroesophageal reflux [GER], constipation, etc.), ranging from 2.8% to 40% according to different series. Most of these events are resolved with conservative medical treatment. Major adverse events are rare and the procedure may be deemed easy and safe (5-9,11,23,26) (Table 5). Most commonly reported adverse events include the following.

**Gastric symptoms**

Nausea, vomiting and abdominal pain are the most common (70%-90% of patients) within the first 3-7 days. Afterwards, tolerability is good in over 80% of cases, although the above mentioned adverse effects may occasionally persist for up to three weeks (11-18%). In the latter setting, hospital readmission may be necessary to provide rehydration and prevent hypokalemia (6-8%) or renal failure (1-4%). Recurrent abdominal pain, esophagitis, edema or constipation/diarrhea are less common. Upper GI bleeding, regurgitation/aspiration, tachyarrhythmia and gastroparesis have been rarely reported. Some of these events, if severe and persistent, may lead to early BIB removal (1-4.2%) (20,21).
Procedure-related technical incidents

1. In relation to implantation/explantation: these are safe procedures. Iatrogenic esophageal mucosal laceration or gastric bleeding may develop. Bronchoaspiration cases have been reported, mainly when removal is performed without OTI. Isolated cases of iatrogenic esophageal or gastric perforation have also been reported (0.2%) (20,26) (Table 5).

2. In relation to BIB permanence in the stomach: BIB rupture-deflation (19-27% in early series and 0-4% in later series) may result in intestinal migration with either spontaneous evacuation or small-bowel obstruction (0-4%) (20,21,26). A ruptured balloon may be identified early by tinted urine. Other severe, almost anecdotal adverse effects include gastric and esophageal necrosis and gastric or intestinal perforation (0.1-0.19%) (21,23). Deaths have been very rarely reported following severe complications, primarily in patients with a history of gastric surgery.

Sequential BIB use

After explantation of an initial BIB and ideally after a balloon-free period to allow for the recovery of gastric motility (one month recommended by some authors), a second BIB may be sequentially implanted for further weight loss or to prevent rebound weight gain (12,13). In this way, Genco et al. (12) reported an increased percentage of excess weight loss (%EWL) that reached up to 51.9% (compared to 25.1% in the group without second BIB), whereas the review by Dumonceau et al. (20) found an additional average weight loss of 9.0 kg above the 14.6 kg lost with the first BIB.

IB as bridge therapy to surgery

Multiple studies confirm the efficacy of IB as a bridge therapy to subsequent bariatric surgery, mainly including Roux-en-Y gastric bypass (RYGB), in patients with superobesity (BMI > 50 kg/m²) (25,27). In fact, Zerrweck et al. (27) demonstrated the efficacy of pre-RYGB IB on weight loss parameters, reduced surgery duration and complications, ICU stay, reconversion to open laparotomy and mortality in patients
with a baseline BMI of 66.5 kg/m². Similar efficacy results were found in terms of weight loss at one year after RYGB in the groups with or without pre-RYGB IB.

**Dual Intragastric Balloon System or ReShape Duo Balloon (DIGB)**

ReShape Duo or Integrated Dual Intragastric Balloon System (ReShape Medical®, San Clemente, CA) is comprised of two interconnected balloons with an independent volume, filled with 900 ml of an evenly distributed sterile saline/methylene blue solution (450 ml in each balloon), for a period of six months. Theoretical advantages of this design include the maximization of the space occupation in the stomach and a better fit for to the stomach anatomy. If one balloon deflates, the other balloon will remain intact, thus preventing migration.

Three randomized pilot studies (28-30) that included 416 patients and 24 weeks of follow-up showed an excess weight loss (%EWL) of 31.8, 27.9 and 47.1% respectively, with significantly higher results when compared with the control groups (%EWL between 11-18%). At 48 weeks, which is 24 weeks after device removal, the DIGB group maintained 64% of their weight loss (28). An overall good tolerability to the DIGB balloon was observed. However, occasional deflation (but not migration) (6%) or early device removal due to intolerance (9%) have been documented, including an isolated case of gastric perforation (no mortality). Likewise, after a modification of the device design, a substantial reduction of the incidence of gastric ulceration and complications was obtained, decreasing from 39 to 10%.

**One year balloons**

New models of intragastric balloons include a one-year duration of the implanted device. They offer some advantages, such as an increased time of dietary re-education and the possibility of adjusting the volume of the balloon, filling the balloon in the case of a loss of satiety sensation or partially emptying the balloon when there is a poorer tolerance. Compared to the standard balloon, a few indications may be added, such as severely overweight patients, patients requiring a longer period of dietary re-education or when a patient experiences weight regain after the removal of a standard balloon.
Spatz® adjustable intragastric balloon (SAIB)

Spatz3 (Spatz GFAR, Inc., NY) consists of a 12-month silicone balloon, with an emerging semi-elastic catheter to allow volume adjustments. It is inserted and fixed externally to the distal tip of the endoscope using bands, which are released as the balloon is inflated. This is filled with methylene blue stained sterile saline solution, around 400-500 cc, which can be increased to about 700 cc in subsequent refills. In three studies published by Machytka (31), Brooks (32) and Espinet-Coll (6) between 2011 and 2014 that used an old version of the balloon (named Spatz2®), a weight loss of 21 to 24 kg (45-48% EWL) was observed per year. However, an excessive incidence rate and major complications were reported (15-39%), such as early withdrawals due to intolerance, deflation, failed adjustments, device ruptures, Mallory-Weiss dilacerations, ulcers, pancreatitis and surgical interventions to remove the impacted catheter or to resolve gastric perforations (6,26,31,32) (Table 5). Improvements offered by the new generation of SAIB (Spatz3) mainly consist of the absence of the anti-migratory metal axis, including an expected better tolerance and safety of the device. However, these data should be confirmed in future controlled trials, which are not available to date.

Easy Life Balloon® (ELB)

The Easy Life Balloon® (Synmed Medical, Life Partner Europe) consists of a 12-month volume-adjustable intragastric balloon. It is inserted folded with the help of a disposable snare in an external position and parallel to the distal tip of the endoscope (like a foreign body). The balloon is filled with 400-600 ml of air or sterile stained saline through a single 3.0 mm diameter atraumatic catheter emerged from the balloon. Subsequently, the filling can be expanded up to 800 cc and this maneuver is recommended six months after implantation. The balloon may be punctured and aspirated or deflated directly through the catheter for removal around a year later. Initial unpublished case series appear to show excellent tolerance with promising efficacy results. However, these data should be confirmed in future controlled trials, which are not available to date, as well as the one-year Spatz3 balloon.
Air-filled balloons
These balloons are filled with air and are composed of polyurethane instead of silicone. The aim is to palliate the alterations of the gastric motility as they weigh less than the standard balloon. Theoretically, this would mean that the indications can be extended to those patients with a poorer tolerance to the standard balloon. The three most commonly used models are Endalis®, Easy Life Balloon® and Heliosphere®. However, only the latter has available published scientific reports. The Heliosphere® Balloon (Helioscope Medical Implants, France) is filled with 750 cc of air, only a total weight of 30 g. Five studies have been published using this device (33-37) and it seems to show a similar efficacy profile for total weight loss as compared to BIB. Nevertheless, it has more pitfalls for extraction and a higher incidence of balloon deflation with undetectable migrations (8,26,33) (Table 5).

Swallowed balloons
The Elipse® swallowed and self-expelled balloon (Allurion Technologies, Wellesley, Mass) consists of a single capsule sized balloon that is swallowed and externally filled with 550 cc of sterile saline through a thin catheter, which is then released. The balloon is degraded after around four months and is naturally eliminated. This model does not require endoscopy or sedation to deploy or extract. An observational study showed a total body weight loss of 10% at four months with improvement of the metabolic parameters, thus offering a safe alternative (38). However, a technique should be evaluated to rule out organic contraindications prior to implantation.

The Obalon® swallowable sequential balloon (Obalon Therapeutics Inc., Carlsbad, CA) is ingested as a capsule that will be inflated with nitrogen gas up to 250 cc once in the stomach. It allows the successive introduction of up to three balloons at one-month intervals, according to patient tolerance and the degree of satiety. Thus, it avoids an endoscopic procedure for implantation but requires the simultaneous removal of all ingested balloons by endoscopy after three months (currently allowed for six months). Initial studies indicate lower BMIs (from 27 to 35 kg/m²) for the Obalon device and a significant weight loss of up to 36.2% of EWL at three months was obtained (39). It is a safe technique, without major complications (26,39,40) (Table 5) and could be
administered in pediatric morbidly obese cases (40).

Other balloons similar to the BIB
The BI Silimed® (Silimed Company, Brazil) is similar to the BIB and offers greater safety and speed of insertion and removal. Initial published studies (41) found some adverse effects (21% early extraction and 3.8% deflation), with weight loss results of 11.3 kg at six months (3.9 BMI or 65.3% EWL). There are no randomized studies available to support these results. BI Medsil® (CSC Medsil, Mytischi Moscow, Russia) is similar to BIB and offers greater safety and speed of insertion and removal. Initial published studies (41) found some adverse effects (21% early extraction and 3.8% deflation), with weight loss results of 11.3 kg at six months (3.9 BMI or 65.3% EWL). There are no randomized studies available to support these results. BI Medsil® (CSC Medsil, Mytischi Moscow, Russia) is similar to BIB in design, duration, results and incidence (26,42) (Table 5), although more safety and efficacy studies are needed.

INJECTION THERAPIES
Gastric injections of botulinum toxin
Botulinum toxin type A (BTX-A) is a neurotoxin that inhibits acetylcholine release in the neuromuscular junction. It is used clinically for conditions characterized by prolonged muscular contraction. The inhibitory effects on the gastric smooth muscles, in theory, make it a potential agent for obesity treatment via a delayed gastric emptying and increased satiety. Under endoscopic or ultrasonographic endoscopic guidance (43), 100 to 500 of BTX-A units are injected in the stomach at 8-24 different puncture sites using a circular distribution inside the muscular layer in the antrum or in the antrum and fundus (44,45). Six studies were published between 2005 and 2007 (45-50) that showed poor results and only one study showed a significant decrease in body weight (45). Recent studies and a meta-analysis of eight studies and 115 patients (51) demonstrated the efficacy, with a BMI decrease of 4-5 kg/m². Satiety was also increased and gastric emptying was also delayed. The best results of the technique are obtained when multiple injections are used (better with more than ten) and when injections are applied in the gastric fundus and antrum, not only in antrum. The total amount of BTX-A injected, the administration location in the antrum and the depth of injection are not thought to influence the effectiveness (45,51). Nevertheless, it is a safe, well-tolerated and reproducible technique, with no significant adverse events, neither neuromuscular nor in the
stomach (52). The efficacy of this therapy is limited and it only lasts between three and six months. It could be useful in some special cases such as: a) overweight grade II or mild obesity grade I; b) cases where other techniques are contraindicated or as a complement of other more aggressive techniques; and c) when the intragastric balloon is explanted to reduce the potential rebound effect, which in some cases may appear.

**SUTURES SYSTEMS**

**The Primary Obesity Surgery Endolumenal (POSE®) method**

The POSE® method (Usgi medical, Inc, San Clemente, CA) is an endoscopic technique that places individual plications, which create folds in the gastric cavity. The plications are placed in the fundus, creating a reduced distention of the stomach and in the anterior wall of the distal body. This creates a dismotility that decreases the gastric emptying and provokes an earlier sensation of satiety. The POSE® efficacy is described by three mechanisms of action: a) a restrictive mechanic effect; b) a physiologic action due to a decrease in the intake between 30-40%, as presented in the MOTIVATE study (53); and c) hormonal changes that produce a decrease in ghrelin secretion and increase the PPY peptide (54), which results in a decrease in the desire to eat (poor appetite) and an increase of early satiety.

This technique is mainly performed in patients with a BMI between 30-40 kg/m², without previous bariatric surgery, or patients with higher BMI who refuse surgery or where surgery is contraindicated (Table 1). An endoscopic platform (IOP) with four working channels is used for this intervention. The three central channels are for the tools and the fourth lateral channel is for endoscopic vision and control via a pediatric endoscope. The g-Prox® is a 33 mm grasper that has an inner channel where the stitches are charged (g-Cath®), which is placed on the central channel. The g-Lix® is passed through one of the lateral central channels, which helps to pull the tissue into the grasper. The last channel is used for CO₂ insufflation. Eight to ten sutures are placed in the fundus and three to four are placed in the anterior wall of the distal body. These plications are transmural and allow the fusion of the serosa layers of the stomach; this is fundamental for durability. In expert hands, the intervention can be performed in less than 40 minutes with general anesthesia and antibiotic prophylaxis.
The patient can be discharged if there are no relevant incidents after a few hours. Pharyngeal, thoracic-abdominal pain and sickness usually appear in the first 24-72 hours, which is controlled by the diet and pharmacologic treatment. There is a very high safety index with adverse events lower than 1% (26,53-56) (Table 5); bleeding is the most common event that usually stops with the pressure of the sutures. The first three studies reported between 2013-2015 showed results of 15.5%, 19.1% and 15.1% of total weight loss (TWL) and 49.4%, 63.7% and 44.9% of EWL at six, 12 and 15 months, respectively (53-55). Miller et al. (56) observed significant differences at 12 months between a patient group treated only with diet and exercise (%TWL 5.3%, %EWL 18%) and another with diet, exercise and POSE® (%TWL 13%, %EWL 54%). BMI pre-POSE®, gastric emptying post-POSE® and the increase of tPYY after eating have been described as predictors of response at six months (54). In the cases of insufficient weight loss or regain, the technique allows the performance of bariatric surgery or re-POSE® placement of additional sutures (57), in expertise hands and without too many difficulties.

**Endoscopic sleeve gastroplasty (ESG, Endosleeve, Apollo® System)**

Abu Dayyeh et al. initially documented this technique in 2013 (58). It consists of the application of several continuous sutures along the gastric wall by the endoscopic and transmural via, with the aim to simulate and resemble the surgical gastric sleeve. A specific esophageal overtube, a double-channel therapeutic upper endoscope (currently, only the Olympus Medical Systems Corp., Tokyo, Japan, GIF-2T160, GIF-2T180 and GIF-2T240 models are adaptable) and the OverStitch® suturing system (Apollo Endosurgery, Inc., Austin, TX), which is inserted in the endoscope and the tissue retractor (Helix), are all required. They ensure that the cinch crosses the total thickness of the gastric wall, which is crucial to obtain each plication as transmural and durable. The procedure is performed under general anesthesia with endotracheal intubation and antibiotic prophylaxis, as the sutures are made through the full-thickness of the gastric wall (Table 4) and CO₂ insufflation is used. Initially, and mainly in the case of less experienced endoscopists, two parallel anterior and posterior suture placement sites
can be mapped using argon plasma coagulation. This maintains a correct orientation as the gastric anatomy is modified with the plications. The sutures are made in a distal to proximal direction, starting at the incisure and extending proximally to the GE junction. A triangular (transverse) or longitudinal (Z) suture pattern can be performed. The first begins at the anterior wall, followed by the greater curvature and finally the posterior wall, after which the pattern repeats itself to the inverse. Each triangular suture pattern consists of approximately 3-6 transmural stitches (from mucosa to serosa). This cinching system replaces the surgical knot and brings the cinches together to form a plication. A total of 5-8 plications are made. The longitudinal pattern includes 3-4 sutures of 8-14 continuous stitches/sutures, ascending proximally in a “Z” pattern from the distal body to the body-fundus union. The goal of each pattern is to create a tubular gastric sleeve-shaped restriction, reducing not only the gastric volume but also turnbuckle with an “accordion effect”.

After completing the procedure, a second endoscopy must be performed to ensure the final tubular configuration, examine any defects in the technique that need to be addressed for a complementary closure and discard bleeding or any other adverse effect. The immediate postoperative includes patients admitted overnight for observation (clinical control, analgesic and antiemetic drugs) and being able to initiate tolerance to liquids at 4-8 hours. During hospital admission, analytical controls and/or an upper GI series with oral contrast may be performed (other protocols include it after a month past) to check the configuration of the gastroplasty and discard adverse effects and the absence of a suture line leak.

The physiological action mechanism (59) includes delay in gastric emptying, induction of early satiety and a significant reduction in weight. This is achieved by a decrease of 59% of caloric consumption to achieve maximum satiety, a decrease in emptying gastric solids and a tendency to increase insulin sensitivity. Its indication, quite similar to that of the POSE® method, is as follows: patients with a BMI between 30 and 40 kg/m², no previous history of bariatric surgery, or a higher BMI and rejection or a contraindication for surgery (Table 1). However, it could also be indicated in excessively overweight individuals, as it is a more restrictive technique.
This procedure has been shown to be safe and reproducible. Most published series with a follow up of 24 months have not shown any other major adverse effects (61-65), as well as in the 55 cases initially presented by the Spanish Group of Bariatric Endoscopy (26) (Table 5). Except for three major adverse effects documented with the old OverStitch® model (pulmonary thromboembolism, perigastric collection and pneumothorax) (59) and an isolated case of perigastric leakage (60), which were resolved favorably with conservative treatment.

Published results reflect an average EWL of 55.3%, 30% and 53.9% at six months (61-63) and a TBWL of 19% and 18.7% at 12 months (64,65), with sleeve image conservation in endoscopy and X-Ray (59,61,64). The two studies with longer-term results obtained an EWL of 53%, 54% and 45%, respectively, at six, 12 and 20 months (59) and a TBWL of 14.4%, 17.6% and 2.9% at six, 12 and 24 months (60), respectively. In addition, a metabolic improvement in HbA1c parameters, systolic blood pressure and serum TG and ALT at 12 months was also verified. There seems to be an adequate correlation three months after the procedure between weight loss and the intensity of gastric morphological changes assessed by radiological transit with contrast (66). New studies are being designed comparing safety and efficacy between endoscopic and surgical gastroplasty, as well as longer-term follow-up.

MALABSORPTIVE SYSTEMS

**Endobarrier®**

Endobarrier® (GI Dynamics, Inc., Watertown, Mass) is the first strictly endoscopic malabsorptive device designed to create a duodenal-jejunal endoluminal by-pass. It consists of a teflon intraluminal lining in the form of a thin, flexible and coated tube, which is anchored in the duodenal bulb (with endoscopic and fluoroscopic control) and extended through the duodenum to the proximal jejunum (60 cm) and remains in place for 12 months. The main indication is obese patients with type 2 diabetes (especially patients with obesity grade I and type 2 diabetes with a very poor glycemic control) (67). Other indications include more severe obesity with any contraindication for surgery or before surgery is performed in order to reduce the risk of the intervention (68-71). All these indications are particularly for patients with type 2
diabetes and obesity.

Initial studies performed on morbidly obese individuals confirmed a decrease in the percentage of EWL of 19-24% with respect to the control group at three months (68-71). The EWL was higher than 10% in 62-100% of patients with an important improvement in the glycemic parameters, confirming that 80% of patients could stop or reduce antidiabetic pharmacological treatment (70). Other comorbidities such as hypertension or hyperlipemia can also be corrected (71,72). Subsequent studies have shown different results in weight loss such as 19.9% TBWL (47% EWL) (73) and an EWL of 12.6% in a meta-analysis with a systematic review of 436 patients (74). Our experience of the first 30 patients with a two-year surveillance after therapy for mild obesity and advanced diabetes, the adequate weight loss (EWL) registered was 45.5%, TBWL was 14.9% per year and the EWL was 26% after two years. Although improvements in DM were not as significant as those published previously, 27% of patients were able to suspend insulin with an overall decrease of 0.62% of HbA1c per year, mainly in those patients with initial HbA1c < 7%. Furthermore, there were significant increases in ghrelin, glucagon and PYY (72,75,76).

Adverse events do not seem to be caused from implantation or removal of the device, as most events are caused by the barbs of the anchor whilst the device is implanted. The second generation of the device has some improvements that reduced the global complications to less than 5%. The system is now considered to be a safe and reliable technique (26,68,70) (Table 5). The most frequent adverse events are nausea, vomiting and abdominal pain during the first 72 hours. Even so, occasional cases of upper gastrointestinal bleeding (UGIB) (69), cholangitis/hepatic abscesses (2%) (77) and cholecystitis have been documented (78), mostly associated with the anchor barbs. Nevertheless, new and less traumatic fixation designs are being developed.

Valen-Tx®

Valen-Tx (ValenTx®, Inc., Carpenteria, CA) is a device that allows a gastro-duodenal shunt. It consists of a 120 cm long intraluminal sleeve, which is secured at the gastroesophageal junction using an endoscopic-laparoscopic mixed technique and therefore excludes the stomach, duodenum and proximal jejunum. The device is
extracted endoscopically and mimics the mechanisms of gastric bypass surgery. ValenTx® was implanted in two studies of morbidly obese patients for 12 weeks and one year (79,80) and achieved an average EWL of 39.7% at 12 weeks and 54% at one year. There was a 70% improvement of comorbidities and the authors concluded that it was a safe technique, although it was occasionally removed prematurely due to an esophageal-gastric tear or intolerance.

OTHER PRIMARY PROCEDURES

Aspire® method

This aspiration method (Aspire Bariatrics, King of Prussia, Penn) is a novel treatment approach for obesity, which allows obese patients to dispose of a portion of their ingested meal via a percutaneous modified gastrostomy tube, known as the A-tube (of 30 Fr). The external device is composed of a connector that is joined to a port (skin port) in order to be able to perform the aspirations, with a limit of 115 uses. There is also a pump with the key pass, the tubes kit and a water bag. The patient can perform the aspiration 20 minutes after intake, usually three times per day. The external device is connected to the skin port and opens the key pass allowing the gastric content to come out through the tubes. Water can also be introduced through the tubes. The aspiration process takes around ten minutes and allows up to 30% of the caloric intake to be removed. There are no reported nutritional deficits in patients with the Aspire® device.

The principal indication is for patients with morbid obesity that refuse bariatric surgery as a therapeutic option. Their main advantages are as follows: a) durability, as the device can be used long term and some of the pieces of the device only need to be replaced; b) the modification of the eating habits, which is essential for a correct mastication in order to optimize the gastric emptying; and c) safety, as the levels are similar to those of a standard gastrostomy. The PIVOTAL study and early publications with morbidly obese patients report an %EWL of 40%, 49% and 54% at six, 12 and 24 month (81,82), respectively. There is also a good safety and tolerance profile, with periostomal tissue granulation in 40% of cases and isolated cases of abdominal pain and/or small abdominal collections (82).
**REVISIONAL ENDOSCOPY OF BARIATRIC SURGERY**

The surgical gastric bypass (RYGB) remains the most effective long-term therapeutic option for patients with morbid obesity and for their comorbidities, with an average EWL of 65-80% at two years. However, the partial or total weight lost regain in these patients is a reality in our society. Some studies report an average weight regain of 18 kg at two years (83), mean recoveries of more than 30% of the weight lost at ten years and over 25% of patients regained almost all the weight that they had lost (84,85). Surgical revision in these patients carries a high rate of complexity and complications and many patients reject it (86). Recently, a positive linear association has been reported between the size of the gastro-jejunal anastomosis and weight regain; a diameter > 15 mm was proposed as a cut-off for dilated anastomosis (87). The endoscopic methods of gastric bypass repair, both non-invasive and less aggressive that aim to close the stoma, can have a huge potential in patients who have regained weight after surgery.

**Revision Obesity Surgery Endoscopic (ROSE) method**

This system (ROSE) uses the same materials as the POSE® method (Usgi medical, Inc., San Clemente, CA) but with a transport modification that allows a greater mobility in the fourth quadrants. There is also a smaller g-Prox and 16 mm blades instead of the conventional 33 mm, in order to be able to work in small spaces. This transmural suture method usually allows 3-4 folds to be placed in the anastomotic mouth in order to reduce the diameter (reduction of 50%). Additional folds can be applied in the gastric pouch when it is dilated that require a minimum length of 7 cm (reduction about 61%) (88,89), which aids an early satiety sensation of the patient. Although initial studies (88) have proved the safety and reproducibility of the technique with satisfactory short-medium term results (loss of 9.3, 8 and 6.7 kg in six, 12 and 24 month) (89), the long term follow up showed an increase of the stoma after 12 months and weight regain after 36 months (89).

**Transoral outlet reduction method TORe (Overstitch® of Apollo)**
This TORRe system uses the same materials as those described in the Apollo® vertical gastroplasty (Apollo Endosurgery, Inc., Austin, TX). This allows the application of around 2-3 stitches in the dilated anastomotic stoma (> 15 mm) (87), after ablating its circumference with argon plasma coagulation to increase fibrosis (1.5-2 l, 50-60 w). It decreases its diameter to less than 12 mm, and is able to improve the Dumping syndrome. In addition, if the gastric pouch is dilated, other sutures may be applied to favor a decrease in its volume. This treatment requires a deep sedation and/or general anesthesia. The safety and short duration (30 minutes) allow the patient to be discharged on the same day and a liquid diet is recommended for 7-10 days, which will progressively normalize.

A multicenter preliminary study in Spain (90) of ten morbidly obese patients that underwent a surgical gastric bypass with subsequent weight regain observed a weight loss of 13.98 kg (30.95% EWL, 13.4% of BMI loss) six months after TORRe. Changela reported a TBWL of 10.1 kg at three months in 55 patients (91), whereas the study by Gitelis reported an EWL of 12.4% and 17.1% at six and 12 months, respectively, in 25 patients (92). Jirapinyo obtained a TBWL of 11.7 and 10.8 kg at six and 12 months, respectively, in 25 patients, (93) and Kumar obtained a TBWL of 10.5, 9.0 and 9.5 kg at one, two and three years, respectively (EWL of 24.9, 20.0 and 19.2%, respectively) in 150 patients (94). This was all conditioned by a considerable reduction in stoma diameter, from 40 to 10 mm in our series (90) and from 24.85 to 8 mm (91), 26.4 to 6 mm (93) and > 20 to 6.9 mm (94) in other series. The technique seemed safe and without complications in all these studies.

**Endoscopic retrograde cholangiopancreatography (ERCP) after RYGB**

The surgical gastric bypass (RYGB) remains the most effective long-term treatment for morbid obesity. This technique involves the creation of a small gastric pouch, with a gastro-jejunal anastomosis and a reconstructed intestinal transit in Roux-en-Y with a variable length. The most common formula consists of a loop of proximal jejunum to the jejunal-jejunal anastomosis of around 100-150 cm, a jejunal loop connected to the duodenum of 50-70 cm and the duodenum itself of around 20 cm. There is around 300 cm of endoscopic scope from the mouth in order to access the papillary region (95,96).
We should bear in mind that patients with RYGB have an altered biliary-enteric circulation, with a higher tendency than the general population (in almost half of patients) for the formation of cholelithiasis. Thus, due to the marked post-surgical anatomical modifications discussed, the technical characteristics of the RYGB should be reflected in the surgical report, in order to help the endoscopist easily access the papillary region. Among the endoscopic difficulties, the following factors should be taken into account: the jejunal-jejunal anastomosis (depending on the surgical technique, its closed angle of 180° and certain stenosis), cannulation in the correct direction of the biliary loop, the existence of a long biliopancreatic loop or the frequent formation of internal hernias (95). After accessing the jejunal-jejunal anastomosis, which is usually achieved in almost all cases with the DBE (97), the biliary loop and the jejunal alimentary loop are endoscopically indistinguishable. Radiological control for the endoscopic advance in the direction of the biliary handle may be helpful, as well as tattooing a loop so that it can be subsequently identified and the correct one is chosen. The complete biliary loop is explorable in 92% of patients (97). Once the ampullary region has been accessed, the fact that the papillary anatomical arrangement with respect to the endoscope is different from standard duodenoscopy must be taken into account. The papilla is usually located between the 11 and 1 o’clock position and will have to be placed at the 6 o’clock position to align with the accessories that emerge from the endoscope.

Balloon-assisted enteroscopy (single or double) has also demonstrated its effectiveness, although it does not have a lifting tab and has frontal vision (98). Rectal access of enteroscopy has also been successfully used in cases of short alimentary loops and very low jejunojejunal anastomosis (99). Other alternatives, such as percutaneous access, may require endoscopic visualization due to the difficulty of papillary cannulation. When they fail, the surgical option represents another alternative.

**SEQUENTIAL TREATMENTS**

We describe three different types of sequential endoscopic treatment:
1. Endoscopic-endoscopic treatment: it increases the efficacy of long-term endoscopic treatment. It can be carried out between two identical or different balloons (ideally a minimum of one month after removal of the first balloon to recover gastric motility) (12,13,20) or by successive balloons (Obalon®) (39,40). Different techniques can be used in a sequential manner, as long as each one is reversible and does not leave gastric sequelae. Suture techniques alter gastric compliance, thus it does not seem appropriate to insert balloons into previously sutured stomachs. However, recent cases indicate that previously sutured stomachs may be successfully re-sutured.

2. Endoscopic-surgical treatment: endoscopic treatments should allow the subsequent surgical conversion without a significant increase in the rate of surgical complications, if weight loss is insufficient or there is weight re-gain (25,27,57). There are cases where a balloon was implanted before surgery in superobese patients to reduce weight with the aim of reducing the rate of adverse events caused by the BMI.

3. Surgical-endoscopic treatment: there are several endoscopic techniques after bariatric surgery such as gastric bypass revision techniques, removal of migrated surgical bands, endoscopic treatment of the complications of bariatric surgery (prosthesis, sutures, adhesives, sclerosis, etc.) or ERCP after bariatric surgery.

In the near future, it would be interesting to study the possibility of performing simultaneous combined endoscopic treatments within different endoscopic strategies for selected patients.

**CONCLUSIONS**

The increased obese population in our society conditions the appearance and development of new therapeutic strategies for its treatment. Medical treatment via hygienic-dietary measures, although essential, may be insufficient. The surgical option is reserved for severe or morbid obesity and is not free of complications or to the liking of many patients.
The transition to new minimally invasive techniques can mean that endoscopy has an important role in the management of these patients. The use of endoscopic techniques should be complementary and provide a greater efficacy than isolated dietary treatment. In addition, it should offer maximum cost-effectiveness, accessibility and reversibility in some cases, compared to surgical methods, with the aim to reduce postoperative convalescence, pain, abdominal scars, incisional hernias and infection risk and increase its overall safety.

Bariatric endoscopy can cover different roles: the primary treatment of obesity, a bridge treatment to surgery and the endoscopic revision of bariatric surgery. Currently, in Spain there are different space-occupying devices (basically different balloon models), restrictive procedures (POSE® or Apollo® type suture systems) and by-pass type devices (Endobarrier®, Aspire®). The recent EEC and FDA approval of some of these devices suggest that bariatric endoscopy enters a commercial era. Training programs, specialized centers and the development and improvement of the devices will be required. As the safety, efficacy and cost-effectiveness data with regard to bariatric endoscopic treatments accumulate over the next few years, we believe that endoscopists will play a leading role in the management of obesity and metabolic diseases.

ACKNOWLEDGMENTS
This second part of the Consensus Document has been presented, discussed and approved during the XXXVII National Days of the Spanish Society of Digestive Endoscopy (SEED, Zaragoza, November 2015) with the participation of the following medical specialists (in alphabetical order): Drs. Abad Belando, Calahorra Medrano, Castellot Martín, Cervera Centelles, Ducons García, Espinet Coll, León Montañés, Mata Bilono, Nebreda Durán, Rodríguez Téllez, Sánchez Gómez, Sánchez Muñoz, Silva González, Turró Arau, Vascónez Peña, Vázquez Sequeiros and Vicente Benede. Reviewed by Dr. Andrés J. Acosta Cárdenas, M.D., Ph.D. Clinical Enteric Neuroscience Translational and Epidemiological Research (C.E.N.T.E.R.), Division of Gastroenterology and Hepatology, Department of Medicine, Mayo Clinic, Rochester, Minnesota.
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11. Mathus-Vliegen EM, Tytgat G. Intragastric balloon for treatment resistant obesity: safety, tolerance, and efficacy of 1-year balloon treatment followed by a 1-year


Obes Surg 2014;24(6):909-15. DOI: 10.1007/s11695-014-1191-4


| **Patient-dependent** | Supplement dietary therapy with a favorable assessment by nutrition-dietetics and/or endocrinology departments  
Ability to understand the mechanisms of weight loss after endoscopic treatment  
Acceptance and understanding of treatment goals (often reaching a healthy rather than ideal or optimal weight)  
Commitment and adherence to follow-up  
Recommended age (BI): a minimum of 12 years with established puberty and no upper age limit |
| **Obesity grade-dependent** | Overweight grade II (selected cases)  
Moderate obesity grade I (BMI 30-34.9 kg/m²)  
Severe obesity grade II (BMI 35-39.99 kg/m²) with no associated metabolic disorders or < 3 major comorbidities  
Severe obesity grade II (BMI 35-39.99 kg/m²) with > 3 major comorbidities and morbid obesity (BMI > 40 kg/m²) when:  
| Patient rejects surgery  
| Surgery is contraindicated  
| Preoperatively indicated to reduce surgical morbidity (especially, BMI > 50 kg/m²) |
| **Medical team-dependent** | Need for multidisciplinary obesity treatment unit  
Site-related clinical experience and technical expertise  
Permanent availability of a bariatric endoscopy/surgery emergency room |
Table 2. Current endoscopic possibilities for the treatment of obesity (modified from Espinet-Coll et al.) (6)

<table>
<thead>
<tr>
<th>Effect</th>
<th>Endoscopic variants</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Gastric balloons and prostheses</td>
<td>1.1 Standard intragastric balloons: Bioenterics®-Allergan®-Orbera®-Apollo® Medsil® Silimed® Successive intragastric balloon 1.2 Intragastric balloons with anti-migration system: ReShape® Duo or Dual balloon 1.3 Adjustable intragastric balloons: Spatz3 (Spatz®) Bioflex® Easy Life Balloon (possibility of filling with air) 1.4 Air-filled intragastric balloons: Heliosphere® Bag Endalis de Endball 1.5 Swallowed intragastric balloons: Elipse® Obalon® (air-filled) 1.6 Other balloons: Ullorex® Antral semistationary balloon Endogast®-ATIIP (adjustable totally implantable intragastric prostheses) Sentinel Group – Full sense device Endosphere of SatiSphere® Transpyloric Shuttle of BaroNova</td>
</tr>
<tr>
<td>2. Injection therapies</td>
<td>2.1 Botulinum toxin type A 2.2 Hyaluronic acid</td>
</tr>
<tr>
<td>3. Sutures systems</td>
<td>3.1 Transoral gastroplasty (TOGa)</td>
</tr>
<tr>
<td>3.2</td>
<td>Endolumenal vertical gastroplasty (EVG) and variants (Endocinch® or RESTORE®)</td>
</tr>
<tr>
<td>3.3</td>
<td>Primary Obesity Surgery Endolumenal (POSE®)</td>
</tr>
<tr>
<td>3.4</td>
<td>Endoscopic sleeve gastroplasty (ESG, Endosleeve of Apollo®)</td>
</tr>
<tr>
<td>3.5</td>
<td>TERIS (Transoral endoscopic restrictive implant system)</td>
</tr>
<tr>
<td>3.6</td>
<td>Articulating circular endoscopic stapler</td>
</tr>
</tbody>
</table>

| 4. Malabsorptive systems | 4.1 | Endobarrier® |
|  | 4.2 | ValenTx |
|  | 4.3 | Duodenal mucosa resurfacing |

| 5. Other | 5.1 | Aspire® method |
|  | 5.2 | Neuroelectrostimulators – gastric pacemaker |
|  | 5.3 | Butterfly system |
|  | 5.4 | Tubular membranes |
|  | 5.5 | NOTES |
|  | 5.6 | Magnetics – anastomosis |
|  | 5.7 | Lumen-apposing metal stents (LAMS) |

| 6. Endoscopic revisional | 6.1 | ROSE method (Usgi) |
|  | 6.2 | TORe method (OverStitch®-Apollo) |
|  | 6.3 | Other: sclerotherapy, APC (argon-plasma coagulation), tissue expanders (polimetilmetacrilate), Stomaphix™, OTSC-clip, Endocinch™, etc. |
Table 3. The most common devices currently available in Spain

<table>
<thead>
<tr>
<th>Variants in Spain</th>
<th>Main features</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balloons</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orbera® (Apollo)</td>
<td>Spherical, silicone, 500 ml saline, 6 months</td>
<td></td>
</tr>
<tr>
<td>Medsil® (Medsil)</td>
<td>Spherical, silicone, 500 ml saline, 6 months</td>
<td></td>
</tr>
<tr>
<td>Duo Balloon (Reshape®)</td>
<td>Dual, interconnected, silicone, 900 ml saline (450 ml x2), 6 months</td>
<td></td>
</tr>
<tr>
<td>Spatz3 (Spatz®)</td>
<td>Spherical, silicone, adjustable, 400 to 700 ml saline, 12 months</td>
<td></td>
</tr>
<tr>
<td>Easy Life Balloon (Synmed®)</td>
<td>Spherical, polymer/silicone, 750 ml air, 6 months</td>
<td></td>
</tr>
<tr>
<td>Heliosphere® Bag (Helioscope)</td>
<td>Swallow, polymer, 550 ml saline, spontaneous evacuat., 4 months</td>
<td></td>
</tr>
<tr>
<td>Elipse® (Allurion)</td>
<td>Elliptical, swallow, 250 ml saline/air, 12 weeks (6 months), sequential (up to 3)</td>
<td></td>
</tr>
<tr>
<td>Obalon® (Obalon)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Injection therapies** | Botulinum toxin A | Acetylcholine inhibitor  
100-500 U, muscular layer antrum or antrum-fundus |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Suture systems</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POSE® (Usgi)</td>
<td></td>
<td>Individual sutures (10-12), polyester-nitinol, fundus-distal body, restrictive and hormonal</td>
</tr>
<tr>
<td>Sleeve gastroplasty (ESG) (Apollo®)</td>
<td></td>
<td>Continuous sutures (5-8), polypropylene, gastric body, restrictive “sleeve” and hormonal</td>
</tr>
<tr>
<td><strong>Malabsorptive systems</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EndobARRIER® (GI Dynamics)</td>
<td></td>
<td>Duodenal-jejunal bypass sleeve, teflon, 60 cm, 12 months, DM-2</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspire® method (Aspire)</td>
<td></td>
<td>External gastric bypass, A-tube, morbid obesity, &gt; 2 years</td>
</tr>
<tr>
<td><strong>Revisional systems</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ROSE method (Usgi)</td>
<td></td>
<td>Individual sutures (4-8), polyester-nitinol, perianastomotic +/- pouch (&gt; 7 cm)</td>
</tr>
<tr>
<td>TORe method (Apollo)</td>
<td></td>
<td>Continuous sutures (2-3), polypropylene, perianastomotic, +/- pouch</td>
</tr>
</tbody>
</table>

**Table 4. Antibiotic prophylaxis in bariatric endoscopy**

<table>
<thead>
<tr>
<th>Endoscopic procedure</th>
<th>Indication of prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intragastric balloons</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Injection therapies</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Suture systems</td>
<td>Recommendable</td>
</tr>
<tr>
<td>Malabsorptive methods</td>
<td>Recommendable*</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>1. Aspire® method</td>
<td>Recommendable</td>
</tr>
<tr>
<td>2. Neuroelectroestimulator and gastric pacemaker</td>
<td>Recommendable</td>
</tr>
<tr>
<td>3. NOTES</td>
<td>Recommendable</td>
</tr>
<tr>
<td>4. Magnetics – anastomosis</td>
<td>Recommendable</td>
</tr>
<tr>
<td>Endoscopic revisional</td>
<td>Optional</td>
</tr>
</tbody>
</table>

*Mainly when the anchorage systems go through the serosa. Parenterally (intramuscular [i.m.] or intravenous [i.v]) 30 minutes before endoscopy: ampicillin i.m. or i.v. 2 g. In case of allergy to penicillin, assess: cefazolin i.m. or i.v. 1 g or cefotaxime 2 g i.v.; vancomycin i.v. 1 g.*
Table 5. Major adverse effects of endoscopic treatment for obesity (26)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. complications/No. cases (%)</th>
<th>Medical-endoscopic treatment</th>
<th>Surgical treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergan®/Orbera Medsil® Balloons</td>
<td>5/5,589 (0.09%)</td>
<td>1 aspiration, 3 migrations</td>
<td>1 perforation</td>
</tr>
<tr>
<td>Spatz2® balloon (previous generation)</td>
<td>44/225 (19.55%)</td>
<td>34 ulcers, 7 migrations, 1 pancreatitis</td>
<td>1 perforation, 1 intestinal occlusion</td>
</tr>
<tr>
<td>Heliosphere® balloon</td>
<td>1/70 (1.43%)</td>
<td>1 balloon rupture</td>
<td></td>
</tr>
<tr>
<td>Obalon® balloon</td>
<td>0/107 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>POSE® sutures</td>
<td>5/679 (0.74%)</td>
<td>2 UGIB, 1 subphrenic abscess, 1 pulmonary empyema</td>
<td>1 splenectomy</td>
</tr>
<tr>
<td>ESG sutures (Apollo®)</td>
<td>0/55</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malabsorptive prosthesis (Endobarrier®)</td>
<td>1/46 (2.17%)</td>
<td></td>
<td>1 cholecystitis</td>
</tr>
<tr>
<td>Total</td>
<td>56/6,771 (0.83%)</td>
<td>51 (0.75%)</td>
<td>5 (0.07%)</td>
</tr>
</tbody>
</table>

UGIB: upper gastrointestinal bleeding.
Table 6. Main bariatric endoscopic procedures in Spain. Efficacy, safety, level of evidence and degree of recommendation

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Efficacy*</th>
<th>Safety†</th>
<th>Evidence/Recommendation‡</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Balloons</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orbera®</td>
<td>Good</td>
<td>Excellent</td>
<td>1a/A</td>
</tr>
<tr>
<td>Duo or Dual</td>
<td>Acceptable</td>
<td>Acceptable</td>
<td>1b/A</td>
</tr>
<tr>
<td>Spatz3</td>
<td>Acceptable</td>
<td>ID (poor in Spatz2®)</td>
<td>5/D</td>
</tr>
<tr>
<td>Easy life balloon</td>
<td>ID</td>
<td>Acceptable</td>
<td>5/D</td>
</tr>
<tr>
<td>Heliosphere® Bag</td>
<td>Acceptable</td>
<td>Excellent</td>
<td>2b/B</td>
</tr>
<tr>
<td>Obalon®</td>
<td>Acceptable</td>
<td>Excellent</td>
<td>3b/B</td>
</tr>
<tr>
<td>Medsil®</td>
<td>Good</td>
<td>Excellent</td>
<td>4/C</td>
</tr>
<tr>
<td><strong>Injection therapies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Botulinum toxin A</td>
<td>Poor/Acceptable</td>
<td>Excellent</td>
<td>2a/B</td>
</tr>
<tr>
<td><strong>Suture systems</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POSE®</td>
<td>Good</td>
<td>Excellent</td>
<td>1b/A</td>
</tr>
<tr>
<td>ESG Apollo®</td>
<td>Good</td>
<td>Excellent</td>
<td>3b/B</td>
</tr>
<tr>
<td><strong>Malabsorption systems</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endobarrier®</td>
<td>Acceptable</td>
<td>Poor/Acceptable</td>
<td>2b/B</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspire®</td>
<td>Good</td>
<td>Acceptable</td>
<td>3b/B</td>
</tr>
<tr>
<td><strong>Endoscopic revisional</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ROSE of Usgi</td>
<td>Poor/Acceptable</td>
<td>Excellent</td>
<td>4/C</td>
</tr>
<tr>
<td>TORe of Apollo</td>
<td>Acceptable</td>
<td>Excellent</td>
<td>3b/B</td>
</tr>
</tbody>
</table>

ID: insufficient data. *Efficacy: results at one year. Excellent: EWL > 75%; Good: EWL 50-75%; Acceptable: EWL 25-49%; Poor: EWL < 25%. †Safety: adverse effects or major complications. Excellent: < 1%; Acceptable: 1-5%; Poor: > 5%. ‡Level of evidence and degree of recommendation according to the score of the Center for Evidence-Based Medicine of Oxford (www.cebm.net). Grade A: extremely recommendable; Grade B: favorable recommendation; Grade C: favorable recommendation but not conclusive;
Grade D: does not recommend or disapprove.