SPECIAL ARTICLE

# Spanish Intragastric Balloon Consensus Statement (SIBC): practical guidelines based on experience of over 20 000 cases

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## ABSTRACT

**Background:** intragastric balloons (IGBs) are a minimally invasive, increasingly popular option for obesity treatment. However, there is only one worldwide guideline standardizing the technical aspects of the procedure (BIBC, SOARD 2018).

**Objectives:** to construct a practical guideline for IGB usage by reproducing and expanding the BIBC survey among the Spanish Bariatric Endoscopy Group (GETTEMO).

**Methods:** a 140-question survey was submitted to all GETTEMO members. Twenty-one Spanish experienced endoscopists in IGBs answered back. Eight topics on patient selection, indications/contraindications, technique, multidisciplinary follow-up, results, safety, and financial/legal aspects were discussed. Consensus was defined when there was ≥70% agreement.

**Results:** overall data included 20 680 IGBs including 12 different models. Mean age was 42.0 years-old, 79.9 % were women, and the mean preoperative body mass index (BMI) was 34.05 kg/m². Indication in BMI > 25 kg/m², 10 absolute contraindications, and nutritional and medication measures at follow-up were settled. A mean %TBWL (total body weight loss) of 17.66 % ± 2.5 % was observed. Early removal rate due to intolerance was 3.62 %. Adverse event rate was 0.70 % and 6.37 % for major and minor complications with consensual management. A single case of mortality occurred. IGBs were placed in private health, prior contract, and with full and single payment at the beginning.

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Seven lawsuits (0.034 %) were received, all ran through civil proceeding, and with favorable final resolution.

**Conclusions:** this consensus based on more than 20 000 cases represents practical recommendations to perform IGB procedures. This experience shows that the device leads to satisfactory weight loss with a low rate of adverse events. Most results are reproducible compared to those obtained by the BIBC.

**Keywords:** Consensus statement. Intragastric balloon. Obesity. Endoscopy. Bariatric endoscopy.

## INTRODUCTION

Intragastric balloon (IGB) is a temporary and minimally invasive treatment for obesity. Initially developed after the observation that gastric bezoar led to weight loss (2), it was first authorized back in 1985 when the Garren-Edwards gastric-bubble device was put to the test (3). Other models emerged later, but they had to be dismissed mainly due to excess adverse effects. This prompted a multidisciplinary international conference of experts (Florida, 1987) to establish the ideal recommendations to improve balloon safety and effectiveness (4).

It acts as a space-occupying device reducing stomach capacity and inducing satiety. Many studies support its safety and efficacy profile in short-term weight loss with significant improvements in obesity-related comorbidities (5-9), being currently a well-established tool to treat obesity (10) compared to dietary therapy alone (11).

As an endoscopic approach, it is positioned between clinical and surgical management. The IGB has a broad spectrum of indications from overweight to obese patients who do not meet the criteria for bariatric surgery. Also, for super-obese patients (BMI ≥ 50 kg/m$^2$), as a bridge therapy to bariatric surgery (12-14). IGBs can also be used as preparation for non-bariatric surgeries in obese patients, for comorbidity control and to treat NAFLD.

To further improve this device, newer IGBs concepts, designs, and models have recently emerged (15-18) with no significant difference in weight loss among them (19,20). There is an increasing need to standardize both technique and follow-up. To fill this gap, a first Brazilian Intragastric Balloon Consensus statement (BIBC) was published (1) that discussed and evaluated clinical and technical aspects (indications, contraindications, technique, adverse events, and multidisciplinary follow-up). Experience was also compiled among these experts through a questionnaire amounting to > 40 000 procedures.

Currently, we have expanded the BIBC 76-question survey to 140 questions and submitted these to Spanish bariatric endoscopists to confirm the results, evaluate their reproducibility and external validity, and stablish a Spanish Intragastric Balloon Consensus statement (SIBC).

## METHODS

We contacted the Brazilian group that published the BIBC (Surg Obes Relat Dis, 2018) (1). They were asked for the same survey and their authorization to distribute it to the Spanish group. The threshold for inclusion was set at being an endoscopist certified by the Spanish Bariatric Endoscopy Working Group (GETTEMO) of the Spanish Society of Digestive Endoscopy (SEED). To avoid bias regarding any possible conflicts of interest, no consideration was given to use specific balloon brands when selecting participants. Endoscopes were used according to the own hospital models: 42.86 % Olympus, 28.57 % Pentax, 7.14 % Fujinon, and 21.43 % other models.

The survey was submitted to all 82 GETTEMO members. Twenty-one endoscopists responded for a total of 20 680 IGBs. Nineteen of them were men with a mean age of 47 years (34-59 years), 23 years of medical graduates (11-35 years), and 17 years of endoscopic experience (5-29 years).

Nineteen were gastroenterologists and 2 were digestive surgeons. All of them were members of scientific societies related to endoscopy and/or surgery with bariatric affinity: 20 specialists were members of the Spanish Society of Digestive Endoscopy (SEED), 17 were also members of the Spanish Society of Digestive Diseases (SEPD), 3 of the Spanish Association of Surgery (AEC), 3 of the Spanish Society of Obesity Surgery (SECO), 4 of the IFSO, and 7 were members of other scientific societies.

In addition to expanding the topics selected by the BIBC (indications/contraindications, technique, preoperative evaluation, postoperative multidisciplinary follow-up, and adverse events), we expanded financial and legal issues as well. Finally, a total of 140 questions were included. Group responses were analyzed as defined to constitute a consensus (≥ 70 % agreement) or not (< 70 %).

The most important consensus aspects are exposed and listed in "tables 1 to 7". Topics on which no consensus was achieved are shown on the Appendix and listed in "tables A to E".

## RESULTS

### Participants' data. Patient selection

The total number of IGB procedures according to data from the group of 21 experts were 20 680 implants and 18 383 explants. Mean patient age was 42 years (32-49 years), 79.9 % were women. The youngest patient reported was a 15-year-old kid, and the oldest a 76 years-old patient. Mean preoperative BMI was 34.05 kg/m$^2$ (30.00-38.18 kg/m$^2$). The mean preoperative minimum BMI was 27.67 kg/m$^2$, and the minimum BMI was 22.80 kg/m$^2$. The mean maximum BMI was 47.90 kg/m$^2$, and the overall maximum BMI was 75.00 kg/m$^2$.

Twelve different IGB models were included (Fig. 1). The most frequently used was Medsil® (CSC Medsil, Mytischi Moscow, Russia) totaling 8921 implants (43.18 %) followed by a 6-month Orbera® balloon (Apollo Endosurgery Inc., Austin, TX) totaling 7196 implants (34.80 %). The Orbera365® 12-month balloon was implanted in 1321 patients (6.39 %). The adjustable fluid-filled balloon Spatz2® and Spatz3® models (Spatz FGIA Inc., Great Neck, NY) were implanted in 145 and 2349 patients, which amounts to 0.70 % and 11.36 % of the total. The Elipse® swallowable balloon (Allurion Technologies, Wellesley, Mass) was implanted


**Fig. 1.** *IGB models included in the SIBC. A. 6-month fluid-filled IGBs. Medsil (1), Orbera (2), Medicone (3), Silimed (4). B. 12-month fluid-filled IGBs. Spatz2 (1), Spatz3 (2), Orbera365 (3) and Easy life (4). C. Other IGBs models. Obalon (1) and Elipse (2) swallowable balloons, Helioscopie (HB) air-filled balloon (3), and new clinical trial guide-introducer Stella balloon (4).*

in 199 cases (0.96 %), the Medicone Corporea® (Medicone, Cachoeirinha, RS, Brazil) in 193 patients (0.93 %), the Helioscopie® air-filled balloon (Helioscopie Medical Implants, Vienne, France) in 145 cases (0.70 %), the Obalon® swallowable sequential balloon (Obalon Therapeutics Inc, Carlsbad, CA) in 112 patients (0.54 %), the Silimed® balloon (Silimed, Rio de Janeiro, Brazil) in 53 patients (0.25 %), the Easy Life® balloon (Synmed Medical, Life Partner Europe) in 42 cases (0.20 %), and the new clinical trial Stella® balloon (Mikromick, Barcelona, Spain) in 4 cases (0.02 %).

### *Indications and contraindications (Tables 1 and A)*

#### *Indications*

No consensus was reached on the minimum or maximum age limit for balloon implantation. No specialist considers that a balloon should be implanted before the age of 16 except for special situations. Regarding minimum age, 52.4 % say 16 years after established puberty with multidisciplinary evaluation, and parental consent while 47.6 % consider a minimum age of 18 years. There is not a maximum age limit for implantation purposes, and each patient was assessed individually according to 47.6 % of participants. Patients over 65 years should be closely monitored.

**Table 1.** *Indications and contraindications for balloon implantation*

| Consensus statement | Consensus (%) |
|---|---|
| *Indications and balloon selection* | |
| For patients with age < 16 years, the placement of an IGB should not be indicated except in selected cases | 100 % |
| The minimum BMI to authorize balloon implantataion is > 25 kg/m$^2$ (overweight) with progressive weight gain and patient refractory to clinical treatment | 76.2 % |
| For patients with BMIs between 25 kg/m$^2$ and 30 kg/m$^2$, the choice of the type of balloon is left to the physician's criterion, but a 6-month fluid-filled balloon is preferred | 76.5 % |
| For patients with BMI > 40 kg/m$^2$, the choice of balloon type is left to the physician's criterion, but a 6-month fluid-filled balloon is preferred | 75.0 % |
| *Absolute contraindications* | |
| Active gastric ulcers in the body or fundus without signs of bleeding | 85.7 % |
| Active gastric ulcers in the antrum without signs of bleeding | 80.9 % |
| Ulcers in any other location without signs of bleeding | 76.2 % |
| Previous gastric surgery | 100 % |
| Esophageal varices | 90.5 % |
| Gastric varices | 100 % |
| Hiatal hernia > 5 cm | 85.7 % |
| Use of anticoagulant drugs | 80.9 % |
| Psychiatric disorders without control or treatment | 95.2 % |
| Grade C-D esophagitis according to the Los Ángeles classification | 76.2 % |
| *Relative contraindications* | |
| Angioectasias without signs of bleeding | 71.4 % |
| Familial gastric polyposis | 85.7 % |
| *Not considered as contraindications* | |
| HIV-positive (immunocompetent) | 80.9 % |
| Gastritis | 71.4 % |
| Hyperplastic or benign polyp | 71.4 % |
| *H. pylori* positive | 76.2 % |

BMI, body mass index; HIV, human immunodeficiency virus.

There is consensus that the minimum BMI for balloon implantation is 25.00 kg/m² (some say 27.00 kg/m²) after failed clinical treatment. Regarding patients with BMI of 25-30 kg/m², a 6-month fluid-filled balloon is preferred, and in patients with BMI of 31-40 kg/m² and BMI > 40 kg/m² a 12-month fluid-filled balloon is the preferred one.

*Absolute contraindications*

Esophageal, gastric, and duodenal ulcers were considered absolute contraindications regardless of the presence of active bleeding. As stated in the medical literature available, previous gastric surgery was considered a contraindication. Other absolute contraindications were gastric and esophageal varices, hiatal hernia > 5 cm, grade C-D esophagitis, use of anticoagulants, and uncontrolled/untreated psychiatric disorders.

*Relative contraindications*

The two consensual relative contraindications were gastric angioectasias without signs of bleeding and familial gastric polyposis.

*Not a contraindication*

The presence of immunocompetent HIV-positive patients, gastritis, hyperplastic or benign polyps or H-*pylori* positivity were not considered a contraindication.

Among the items on which no consensus was reached but most frequently considered a relative contraindication were eosinophilic esophagitis, grade A/B esophagitis, portal-hypertensive gastropathy, and the use of antiplatelet agents.

***Technique (Tables 2 and B)***

*Balloon implantation*

– *Preparation.* 8-hour fasting is advised. No strict diet is advised beforehand.

– *Technique.* The procedure must be performed in, at least, an outpatient center with advanced life support such as endoscopy (57.1 %) or surgical room (42.9 %). The adult gastroscope was preferred by 95.2 %. The preferred position is the left lateral position through direct oro-esophageal introduction.

– *Anesthesia.* Deep/general sedation without orotracheal intubation was preferred by 76.2 % and performed by the anesthesiologist in 95.2 %.

– *Balloon volume.* There was consensus that the recommended balloon fill volume should be between 500 mL and 599 mL (for liquid-filled adjustable and non-adjustable balloons). On the readjustment session, there is consensus that it should be done according to the patient clinical progression, not on the additional filling volume: 68.4 % recommended 200 mL to 300 mL, and 31.6 % between 100 mL to 200 mL. The most frequently used filling method is the 60 mL syringe (61.9 %) followed by the hydraulic pump (33.3 %). For downward adjustments (intolerance), 61.1 % felt that the volume to be reduced should be 100 mL to 200 mL, and 38.9 % believed that it should be ≤ 100 mL

– *Prophylaxis.* There is consensus on the prophylactic use of methylene blue. The use of antifungal drugs to prevent hyperinflammation is ill-advised.

– *Balloon explantation.*

– *Preparation*. At least 3-days of liquid diet is recommended by consensus before balloon removal followed by 8-hour fasting. Intake of sugar-free cola-carbonated drinks is not used.

– *Technique.* It is recommended that the procedure should be performed, at least, in an outpatient center with advanced life support capabilities (type II or III) and with patient transfer service available; 71.4 % agreed that the most appropriate place is the operating room and 42.8 % also agreed that it could be performed at the endoscopy suite. Regarding removal, 90.5 % prefer an adult gastroscope being the preferred accessory a double hook forceps in all cases. In most cases, esophageal overtubes or small amounts of vegetable cooking oil to lubricate the esophagus have never been used. There is no preferred patient position: left lateral decubitus position (47.6 %), supine position (47.6 %), and indifferent (4.8 %).
During elective removal, when significant food stasis is found, 52.4 % recommend removal under tracheal intubation; 23.8 % reschedule the procedure for a new preparation; 19.0 % recommend removal without intubation and with lighter sedation; and 4.8 % recommend puncturing and deflating the balloon and scheduling a new removal. When removal is performed as an emergency procedure and food stasis is found, 80.9 % recommend removal with tracheal intubation and 19.1 % recommend removal without intubation.

– *Anesthesia.* 71.4 % prefer general anesthesia with intubation while only 28.6 % deep/general sedation without intubation. A total of 95.2 % was performed by and anesthesiologist.

***Preoperative assessment and multidisciplinary follow-up (Tables 3 and C)***

*Preoperative assessment*

Prior endoscopy was not considered essential because it is possible to evaluate the stomach during implantation. No imaging modalities were considered mandatory before the procedure unless there was clinical indication for these and/or at the request of the anesthesiologist.

Regarding lab tests, 76.2 % agree that these should always be requested, 14.3 % believe the choice for lab tests should be left to the physician's own criterion and 9.5 % believe it should only be requested in patients with clinical conditions that justify it. H-*pylori* screening is not essential, except in gastric injuries or in cases where the patient's past medical history justifies it.

**Table 2.** *Technique for balloon implantation/explantation*

| Consensus statement | Consensus (%) |
|---|---|
| *Balloon implant* | |
| Preparation: | |
| - Fasting of at least 8 hours should be observed | 90.5 % |
| Technique: | |
| - Outpatient clinic with advanced life support capabilities | 100 % |
| - Adult gastroscope | 95.2 % |
| - Left lateral position | 90.5 % |
| - Direct oro-esophageal introduction | 85.7 % |
| Anesthesia: | |
| - Deep/general sedation without orotracheal intubation | 76.2 % |
| - Performed by the anesthesiologist | 95.2 % |
| Balloon volume: | |
| - The minimum filling volume for nonadjustable liquid-filled balloons is 500 mL | 95.2 % |
| - The minimum filling volume for adjustable liquid-filled balloons is 500 mL | 84.2 % |
| - Readjustment session should be performed based on the patient's clinical progression | 94.1 % |
| Prophylactic: | |
| - The substance recommended to fill the balloon is saline solution with methylene blue | 100 % |
| - Anti-fungical drugs are ill-advised | 100 % |
| *Balloon explantation* | |
| Preparation: | |
| - Liquid diet for at least 3 days before balloon removal is necessary | 71.4 % |
| - Fasting of, at least, 8 hours is necessary | 80.9 % |
| - Intake of carbonated cola drinks (zero/diet) is not used as preparation for balloon removal | 95.2 % |
| Technique: | |
| - Outpatient clinic with advanced life support capabilities | 100 % |
| - Surgical room | 71.4 % |
| - Adult gastroscope | 90.5 % |
| - The preferred accessory for removal is a double hook clamp | 100 % |
| - An esophageal overtube is not necessary | 85.7 % |
| - Vegetable cooking oil is not used | 90.5 % |
| Anesthesia: | |
| - General anesthesia with intubation | 71.4 % |
| - Performed by an anesthesiologist | 95.2 % |
| - When significant food stasis is found during urgent removal it must be performed with tracheal intubation | 80.9 % |

**Table 3.** *Follow-up*

| Consensus statement | Consensus (%) |
|---|---|
| *Preoperative assessment* | |
| There is not mandatory endoscopy before placing the balloon. This can be performed during balloon implantation and suspended if necessary | 95.2 % |
| No imaging modalities are considered mandatory before placing the balloon (except for those imaging modalities required by the anesthesiologist) | 95.2 % |
| Lab tests should always be requested | 76.2 % |
| *Multidisciplinary team* | |
| Essentials: | |
| - The presence of a dietician is mandatory | 95.2 % |
| - The presence of a psychologist is mandatory | 80.9 % |
| Post-implantation diet: | |
| - Liquid diet | 100 % |

*(Continues on next page)*

**Table 3 (Cont.).** *Follow-up*

| Consensus statement | Consensus (%) |
|---|---|
| Other recommendations: | |
| - The intake of noncarbonated alcoholic beverages during balloon treatment is ill-advised | 85.7 % |
| - Carbonated drinks are ill-advised | 90.5 % |
| - When a second balloon implantation as new treatment for weight loss is needed, it should be performed within the same procedure used to remove the existing balloon. | 71.4 % |
| *Medications* | |
| During adaptation period: | |
| - The prescription of medication is advised to avoid reactive symptomatology after implantation for 3 to 5 days | 76.2 % |
| - PPIs | 100 % |
| - Ondansetron | 100 % |
| - Hyoscine/Scopolamine | 80.9 % |
| - Anti-inflammatory drugs are ill-advised | 100 % |
| After the adaptation period: | |
| - The use of PPIs in mandatory throughout the entire treatment | 100 % |
| - Anxiolytic/antidepressants are ill-advised | 90.5 % |
| - Antifungal drugs are ill-advised | 100 % |

*Multidisciplinary team*

It is embedded in the unit itself in 47.6 % of cases while 23.8 % is outsourced/external, 19.0 % is mixed, and 9.6 % use other methods or non-use. The 2 professionals considered essentials other than the endoscopist are the dietician and the psychologist.

After implantation, liquid diet is recommended (100 %), which will progress to solid diet after 1 week (38.1 %), 2 weeks (9.5 %) or at the nutritionist's discretion (52.4 %).

Concerning the psychological follow-up, 66.7 % believe the psychologist should follow the patient throughout treatment; 19 % believed that only patients with diagnosed psychological disorders need follow-up; 9.5 % believed only an early evaluation is needed while 4.8 % believed that it is responsibility of the endoscopist to decide which type of follow-up the patient actually needs.

After balloon removal, there is no consensus on the minimum clinical follow-up period: 42.9 % believe that the patient should have a minimum follow-up of 6 months, 38.1 % believe that the minimum period should be 12 months, 9.5 % recommend follow-ups of 24 months, and 9.5 % believe that it is a relative issue or not strictly necessary.

*Medications*

During the adaptation period to attenuate symptoms, PPIs, ondansetron, and hyoscine/scopolamine are recommended, usually for up to 3 to 5 days after implantation.

The use of PPIs should be maintained throughout treatment (100 %): 42.9 % in double doses, 19.0 % in single doses, and 38.1 % beginning in double doses and decreasing to single doses between 7 days and 3 months depending on the patients. Anti-H2 are not used.

Anxiolytic and antidepressant drugs should not be routinely used, but can be used selectively (61.9 %). Also, to decrease nausea and vomiting, 33.3 % recommend using metoclopramide and 19.0 % domperidone. Cinitapride and aprepitant are very sparsely used (4.8 %). Anti-inflammatory drugs are ill-advised in the adaptation period. There was consensus that antifungal drugs should not be used systematically.

There was no consensus on the combination of IGB and classic anti-obesity drugs to improve weight loss results*. Their use is left to the physician's criterion (33.3 % of participants), but 66.7 % believe that this combination is ill-advised (*Questions refer to classic anti-obesity drugs: new and recent anti-obesity drugs —e.g. GLP-1 agonists— were not included in the questions).

***Results (Table 4)***

The mean percentage of total body weight loss (%TBWL) was 17.66 ± 2.5 % (r = 11.87-25.00 %). The minimum %TBWL reported was 0 % while the maximum %TBWL was 52 %.

The mean total weight loss (TBWL) was 17.13 ± 1.5 kg (r = 11.60-22.60 kg). The minimum TBWL reported was 0 kg while the maximum TBWL reported was 72.0 kg.

The mean percentage of excess weight loss (%EWL) was 58.68 ± 6.1 % (r = 41.0-94.0 %). The minimum %EWL reported was 0 % and the maximum %EWL reported was 110 %.

The mean BMI loss was 5.73 ± 1.7 kg/m$^2$ (r = 4.0-8.1 kg/m$^2$). The minimum BMI loss reported was 0 kg/m$^2$ while the maximum BMI was 22.90 kg/m$^2$.

The failure rate (defined as % of patients with %TBWL < 10 %) was 11.20 ± 2.0 % (r = 0-38 %).

**Table 4.** *Weight loss results from IGB*

| Variable | Mean ± SD | Minimum (mean) | Maximum (mean) |
|---|---|---|---|
| TBWL (%), mean | 17.66 ± 2.5 | 2.14 | 33.48 |
| TBWL (kg), mean | 17.13 ± 1.5 | 1.60 | 46.49 |
| EWL (%), mean | 58.68 ± 6.1 | 3.35 | 90.94 |
| BMI reduction, (mean) | 5.73 ± 1.7 | 0.36 | 11.91 |
| Failure, % | 11.20 ± 2.0 | 1.0 | 38.0 |

***Adverse events (AE) (Tables 5, 6 and D)***

Early removal rate due to intolerance was 3.62 % (n = 748). We presented an intolerance rate < 5 % in all balloons models except for the Elipse (7.03 %), Spatz2 (6.20 %), and Silimed (5.66 %) balloons.

Regarding AE, there is an overall rate of complication of 7.07 % (n = 1461) of which 0.70 % (n = 144) and 6.37 % (n = 1317) amounted to major and minor complications, respectively.

*Major AE*

The most common major AE was gastric ulcer requiring balloon removal (0.41 %), most commonly the in the

**Table 5.** *Adverse events (AE) from IGB*

| Orbera *n = 7196* | Medsil *n = 8921* | Orbera 365 *n = 1321* | Spatz2 *n = 145* | Spatz3 *n = 2349* | Elipse *n = 199* | Medicone *n = 193* | Silimed *n = 53* | HB *n = 145* | Easylife Stella Obalon *n = 42,4,112* | Total *n = 20680* |
|---|---|---|---|---|---|---|---|---|---|---|
| **Rate of intolerance** | | | | | | | | | | |
| 1.12 % | 2.15 % | 2.65 % | 6.20 % | 4.77 % | 7.03 % | 1.03 % | 5.66 % | 1.38 % | 0 % | 3.62 % *(n = 748)* |
| **Major AE** | | | | | | | | | | |
| 0.36 % | 0.38 % | 0.83 % | 28.27 % | 1.23 % | 0.50 % | 0 % | 0 % | 1.38 % | 0 % | 0.70 % *(n = 144)* |
| **Minor AE** | | | | | | | | | | |
| 2.78 % | 3.61 % | 5.22 % | 29.00 % | 14.00 % | 11.56 % | 0.52 % | 24.53 % | 2.07 % | 25.00 %<br>0 %<br>0 % | 6.37 % *(n = 1317)* |

**Table 6.** *Recommendations regarding complications and balloon removal*

| Removal of the device is advised if: Consensus statement | Consensus (%) |
|---|---|
| Upon patient request for whatever reason | 80.0 % |
| Premature balloon removal is defined when performed up to 1 month after implantation | 80.9 % |
| Presence of a gastric ulcer in the case of nonadjustable balloon | 71.4 % |
| Presence of a gastric ulcer in the case of adjustable balloon | 80.9 % |
| Recurrent antral balloon impaction | 90.5 % |
| Symptomatic balloon hyperinflation | 80.9 % |
| In spontaneous asymptomatic hyperinflation, the balloon must remain inside the stomach | 100 % |
| Recurrent hydro-electrolytic disorder | 80.9 % |
| In the event of balloon rupture (green urine) … | 100 % |
| …and must be performed within 72 hours after diagnosis | 95.2 % |
| In the event of pregnancy during treatment | 90.5 % |
| With a diagnosis of moderate pancreatitis | 76.2 % |
| With a diagnosis of severe pancreatitis | 100 % |

Spatz2 balloon (26.89 %). Each and every other major AE had a prevalence rate < 0.10 %: perforation (0.10 %), 50 % during explantation, 40 % during the period of treatment, and 10 % in the implantation maneuver; bronchial aspiration (0.08 %), gastric bleeding (0.04 %), symptomatic hyperinflation (0.03 %), and migration with intestinal occlusion (0.02 %). All other major complications like acute pancreatitis or renal failure with ICU stay are described almost anecdotally (0.02 %).

Focusing on the balloon model, in all cases a rate of major AE < 1 % was observed, except for the Spatz2 (28.27 %, mainly due to ulcer), HB (1.38 %, mainly due to ulcer and symptomatic hyperinflation), and Spatz3 balloons (1.23 %, mainly due to ulcer).

A total of 9 cases of surgical repair were reported (0.043 %): 4 gastric perforations (2 Orbera and 2 Medsil balloons) and 5 cases of migration with intestinal occlusion (4 Spatz3 and 1 Spatz2 balloons).

One death was reported (0.0048 %) as associated with the presence of the balloon: uncoercible vomiting with massive pulmonary aspiration during the orotracheal-intubation maneuver performed by the anesthesiologist prior to emergency balloon removal due to intolerance.

*Minor AE*

The most common minor AE were esophagitis (3.56 %) followed by spontaneous balloon deflation (1.19 %), migration with spontaneous evacuation (0.56 %), fungal infection (0.50 %), ulcer and bleeding with no need for balloon removal (0.42 % and 0.10 %), and asymptomatic hyperinflation (0.04 %).

A rate of minor AE < 5 % was found in all IGB models except for the Spatz2 (29.00 %, mainly migration and asymptomatic hyperinflation), Easylife (25.00 %, all hyperinflation), Silimed (24.53 % mainly deflation, migration, esophagitis, and fungal infection), Spatz3 (14.00 %, mainly esophagitis), and Elipse models (11.56 %, mainly spontaneous deflation).

*AE consensus*

The removal of the IGB is advised by consensus in cases of gastric ulcer (both with adjustable and nonadjustable balloons), recurrent antral impaction, symptomatic hyperinflation, and recurrent electrolytic disorder.

If rupture of the balloon is detected (greenish urine), the extraction is mandatory and must be performed within 72 hours.

Premature balloon removal is defined as explantation up to 1 month after implantation due to AE or at the patient's request.

In cases of GI bleeding, there was no consensus on the need to remove the balloon; most (57.9 %) consider that the balloon should be removed even with spontaneous stop of bleeding while 5.3 % only when drugs are needed while 36.8 % would only remove the IGB if the bleeding requires endoscopic therapy.

In the presence of severe erosive esophagitis, IGB should be removed; 61.9 % recommend it after appropriate treatment due to the increased risk of esophageal tearing. There was no consensus in cases of Mallory-Weiss syndrome: while 28.6 % considered that it should be treated with the balloon while in place, 23.8 % would perform immediate removal of the balloon, and 47.6 % late removal due to the increased risk of bleeding during removal maneuvers.

There is no consensus on balloon handling after a first antral impaction: 52.4 % would leave the decision to the attending physician, 28.6 % would recommend its removal, and 19 % would keep the balloon inside the stomach. In case of recurrent antral balloon impaction, 90.5 % of respondents recommend its removal.

In case of pregnancy, the balloon should be removed (90.5 %) usually in the second trimester (66.7 %), but always under obstetrical supervision.

When spontaneous asymptomatic hyperinflation without gastric lesions occurs, all endoscopists considered that patients could keep the gastric balloon: 40.0 % believed management can be conservative; 40.0 % agreed that the balloon would need to be removed but with simultaneous balloon substitution while 20 % believed removal should be carried out with delayed substitution.

Endoscopists agreed that acute pancreatitis should condition IGB removal. There was no consensus for the balloon removal when pancreatitis was mild (33.3 %), but this consensus existed when pancreatitis was of moderate (76.2 %) or severe (100 %) intensity.

In the presence of balloon fungal colonization, 61.9 % agreed that no treatment is needed. In the occurrence of a thromboembolic event, balloon should be removed according to 57.1 %. In case of hypovitaminosis or mild eating disorder, balloon removal should be left to the physician´s discretion in most cases.

***Financial/legal aspects (Table 7A/B and E)***

*Financial*

A 61.9 % always used contracts, while 33.3 % never used and 4.8 % used it selectively. The budget included implantation, explantation, and follow-up with payment at the beginning of treatment (85.7 %). Only private health patients were treated (85 %).

One-time and payment on demand is preferred by 50 % of respondents; 20 % accepted installment payments; and 30 % accepted other terms of payment. The average cost of treatment (including the balloon) in adjustable IGB is between € 5000 and € 6.000 (47.4 %), and in the non-adjustable IGB it is between € 3000 and € 4000 (57.1 %).

*Legal.* There was consensus (100 %) that a specific informed consent document should be signed. If the patient does not show up for balloon removal at the recommended time and

**Table 7.** *Financial and legal aspects of IGBs*

**7A.** *Financial/legal consensus statement*

| Consensus statement | Consensus (%) |
|---|---|
| *Financial* | |
| Payment at the beginning of treatment with budget including implantation, explantation, and follow-up | 85.7 % |
| Only private health patients are treated | 85.0 % |
| *Legal* | |
| An informed consent document is systematically used | 100 % |
| If the patient does not show up for balloon removal after a reasonable amount of time, the most recommended measure is to send a registered letter (burofax or similar) | 80.9 % |
| Based on our own experience with lawsuits: | |
| - Judiciary proceedings are civil acts | 100 % |
| - Rulings are favorable to the endoscopist | 100 % |

**7B.** *Legal cases description*

| Cause | Balloon | Judiciary proceeding | Ruling | Resolution |
|---|---|---|---|---|
| Broncoaspiration | Spatz3 | Civil | Pending | Medical |
| Insufficient weight loss | Orbera | Civil | Favorable | - |
| Insufficient weight loss | Orbera | Civil | - | Economic agreement |
| Insufficient weight loss | Orbera365 | Civil | Pending | - |
| Intolerance | Spatz3 | Civil | Favorable | Early removal of the IGB |
| Esophagus perforation during explantation | Spatz2 | Civil | Favorable | Surgery |
| Esophagus perforation during implantation | Medsil | Civil | Pending | Surgery |

their situation is unknown, all panelists agreed that some kind of contact measure should be taken: a registered letter should be sent (80.9 %) or a phone call should be made or e-mail sent (14.3 %).

A rate of legal claims of 0.034 % (n = 7) was seen. In 42.9 % due to insufficient weight loss and in 57.1 % for some technical complication. To this date, all claims are civil acts with final rulings favorable to the endoscopist.

### *Special topics*

When a second implant is decided as new treatment for weight loss, 71.4 % recommended that it should be performed during the same procedure used to remove the existing balloon. The second balloon should be of same model as the first one according to 61.9 % of participants.

The limit of sequential implantations —whenever the patient still had an indication— was 2, 1, and 3 in 52.4 %, 14.3 %, and 9.5 %, respectively; there is no limit to sequential balloon implantations in 23.8 % of participants.

The desired professional requirements for a physician to perform IGB implantations and explantations are endoscopic field experience of, at least, 5 years plus a specialization degree to perform endoscopic exams or have a residency or specialization in endoscopy.

## CONCLUSIONS

The popularity of IGBs is growing worldwide. For this reason, standardization of the technique to improve safety and weight loss outcomes is required.

The extensive experience of the SIBC participants is reflected in > 20 000 procedures performed. Good results on efficacy and safety profile are shown and reflective of a 17-year practice with this device in Spain.

Limitations include the retrospective nature of data resulting in heterogeneity. Longer prospective studies are needed with valuable information on multiple technical procedural aspects. This consensus report is the second of its kind on IGB (after BIBC) and serves as a guide for endoscopists.

# APPENDIX

**Table A.** *No-consensus statement for indications and contraindications regarding balloon implantation*

| Indications and balloon selection | Absolute indication | | |
|---|---|---|---|
| *Minimum age:* | | | |
| > 16 years | 52.4 % | | |
| > 18 years | 47.6 % | | |
| *Maximum age:* | | | |
| 65 years | 23.8 % | | |
| 70 years | 23.8 % | | |
| 75 years | 4.8 % | | |
| No limit if adequate clinical conditions | 47.6 % | | |
| For patients with BMI between 31 kg/m$^2$ and 40 kg/m$^2$, the choice of the type of balloon is at the discretion of the physician, but is preferably, a 12-month fluid-filled balloon | 65.0 % | | |
| **Contraindications and balloon selection** | **Absolute contraindications** | **Relative contraindications** | **Not considered contraindications** |
| Eosinophilic esophagitis | 42.9 % | 57.1 % | 0 % |
| Grade A/B esophagitis | 9.5 % | 47.6 % | 42.9 % |
| Congestive gastropathy | 9.5 % | 61.9 % | 28.6 % |
| Antiplatelet agents | 38.1 % | 61.9 % | 0 % |

**Table B.** *No-consensus statement for technique of balloon implantation/explantation*

| Consensus statement | No-consensus (%) |
|---|---|
| *Balloon implantation* | |
| Technique: | |
| - Endoscopy room | 57.1 % |
| - Surgical room | 42.9 % |
| Anesthesia: | |
| - Oro-tracheal intubation | 19.0 % |
| Balloon volume: | |
| - Readjustment with 60 mL syringe | 61.9 % |
| - Readjustment with hydraulic pump | 33.3 % |
| - Other readjustment methods | 4.8 % |
| - Additional filling volume at readjustment should be 100 mL to 200 mL | 31.6 % |
| - Additional filling volume at readjustment should be 200 mL to 300 mL | 68.4 % |
| - Downward volume at readjustment should be ≤ 100 mL | 38.9 % |
| - Downward volume at readjustment should be 100 mL to 200 mL | 61.1 % |
| *Balloon explantation* | |
| Patient position: | |
| - Left lateral | 47.6 % |
| - Supine | 47.6 % |
| - Indifferent | 4.8 % |
| When significant food stasis is found during elective removal: | |
| - It should be done with tracheal intubation | 52.4 % |
| - Procedure should be rescheduled after a new preparation | 23.8 % |
| - It should be performed without intubation and lighter sedation | 19.0 % |
| - Balloon should be punctured and deflated, and a new removal scheduled | 4.8 % |

**Table C.** *No-consensus statement at follow-up*

| Consensus statement | No-consensus (%) |
|---|---|
| *Multidisciplinary team* | |
| Placement | |
| - Installed within the unit itself | 47.6 % |
| - Installed outsource/external | 23.8 % |
| - Installed mixed | 19.0 % |
| - Use other methods or non-use | 9.6 % |
| Essentials: | |
| - The presence of an endocrinologist is mandatory | 38.1 % |
| - The presence of a psychiatrist is mandatory | 4.8 % |
| - The presence of a physical trainer is mandatory | 19.0 % |
| Post-implantation diet: | |
| - Liquid diet will progress into solid diet after 1 week | 38.1 % |
| - Liquid diet will progress into solid diet after 2 weeks | 9.5 % |
| - Liquid diet will progress into solid diet at the nutritionist discretion | 52.4 % |
| Psychological follow-up: | |
| - Follow-up the patient throughout the entire treatment | 66.7 % |
| - Follow-up only patients with diagnosed psychological disorders | 19.0 % |
| - Only an early evaluation is need | 9.5 % |
| - It is the sole responsibility of the endoscopist to decide which type of psychologic follow-up the patient needs | 4.8 % |
| Clinical follow-up of the patient after balloon removal is advised: | |
| - For a minimum of 6 months | 42.9 % |
| - For a minimum of 12 months | 38.1 % |
| - For a minimum of 24 months | 9.5 % |
| - Not strictly necessary | 9.5 % |
| *Other recommendations* | |
| Air travel after IGB implantation: | |
| - It should be allowed after the adaptation period | 52.4 % |
| - There should be no restriction | 47.6 % |
| Physical activity: | |
| - Should be allowed after the adaptation period | 66.7 % |
| - There should be no restriction | 19.0 % |
| - It should be permitted 30 days after implantation | 14.3 % |
| - In patients who wish to receive a second balloon, model should be the same that the first one. | 61.9 % |
| For sequential balloon implantation, the limit number is: | |
| - 1 | 14.3 % |
| - 2 | 52.4 % |
| - 3 | 9.5 % |
| - There is no limit | 23.8 % |
| *Medications* | |
| Maintenance of PPIs: | |
| - Double doses | 42.9 % |
| - Single doses | 19.0 % |
| - From double and decreasing to single doses | 38.1 % |
| Other medication: | |
| - Anxiolytic/antidepressant drugs used selectively | 61.9 % |
| - Metoclopramide | 33.3 % |
| - Domperidone | 19.0 % |
| - Anti-obesity drugs are ill-advised | 66.7 % |

**Table D.** *No-consensus statement for recommendations regarding complications and balloon removal*

| Removal of the device is recommended if: Consensus statement | No-consensus (%) |
|---|---|
| *GI bleeding:* | |
| - The balloon should be removed even with spontaneous stop of bleeding | 57.9 % |
| - The balloon should be removed only when drugs are needed | 5.3 % |
| - The balloon should be removed only when endoscopy therapy is needed | 36.8 % |
| *Severe erosive esophagitis:* | |
| - The balloon should not be removed before proper treatment | 61.9 % |
| - The balloon should be immediately removed | 23.8 % |
| - The balloon should not be removed | 14.3 % |
| *Mallory-Weiss syndrome:* | |
| - Should be treated with the balloon in place | 28.6 % |
| - The balloon should be immediately removed | 23.8 % |
| - The balloon should be removed later | 47.6 % |
| *After an index antral impaction:* | |
| - Decision to the discretion of the physician | 52.4 % |
| - The balloon should be removed | 28.6 % |
| - The balloon should not be removed | 19.0 % |
| *In the event of pregnancy occurring during treatment:* | |
| - The balloon should be removed within the first trimester | 23.8 % |
| - The balloon should be removed within the second trimester | 66.7 % |
| - The balloon should be removed within the third trimester | 9.5 % |
| *When spontaneous hyperinflation occurs in asymptomatic patients without gastric lesions:* | |
| - Management can be conservative | 40.0 % |
| - The balloon should be removed but with simultaneous balloon substitution | 40.0 % |
| - The balloon should be removed but scheduled for balloon substitution later | 20.0 % |
| *With diagnosis of acute pancreatitis:* | |
| - The balloon should be removed in mild pancreatitis | 33.3 % |
| *In the presence of diagnosis of fungal colonization:* | |
| - Nothing should be done | 61.9 % |
| - Antifungal drugs alone | 23.8 % |
| - PPI interruption plus antifungal drug administration | 9.5 % |
| - Interruption of PPI therapy | 4.8 % |
| *Thromboembolic event:* | |
| - The balloon should be removed | 57.1 % |
| - Decision to the discretion of the physician | 38.1 % |
| - The balloon should not be removed | 4.8 % |
| *Hypovitaminosis or mild nutritional disorder:* | |
| - Decision to the discretion of the physician | 61.9 % |
| - The balloon should not be removed | 38.1 % |

**Table E.** *No-consensus statement for recommendations regarding financial and legal aspects of IGB*

| Consensus statement | No-consensus (%) |
|---|---|
| *Financial* | |
| Use of contract: | |
| - Always | 61.9 % |
| - Never | 33.3 % |
| - Selectively | 4.8 % |
| Terms of payment: | |
| - One-time and payment on demand | 50.0 % |
| - Installment payments | 20.0 % |
| - Other | 30.0 % |

*(Continues on next page)*

**Table E (Cont.).** *No-consensus statement for recommendations regarding financial and legal aspects of IGB*

| Consensus statement | No-consensus (%) |
|---|---|
| Average cost of treatment (including the balloon) in non-adjustable IGB: | |
| € 3000-€ 4000 | 57.1 % |
| € 4000-€ 5000 | 28.6 % |
| € 5000-€ 6000 | 14.3 % |
| Average cost of treatment (including the balloon) in adjustable IGB: | |
| € 3000-€ 4000 | 26.3 % |
| € 4000-€ 5000 | 26.3 % |
| € 5000-€ 6000 | 47.4 % |
| *Legal* | |
| Endoscopists having received legal claims: | |
| - Yes | 33.3 % |
| - No | 66.7 % |
| Reason for legal claim: | |
| - Complications (including intolerance, bronchial aspiration, and perforation) | 57.1 % |
| - Insufficient weight loss | 42.9 % |

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