Brazilian Intragastric Balloon Consensus Statement (BIBC): practical guidelines based on experience of over 40,000 cases

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Abstract

Background: Intragastric balloons (IGBs) are a minimally invasive option for obesity treatment, acting as a space-occupying device and leading to weight loss through increased satiety. This device has been growing in popularity owing to its safety profile and good weight loss results. However, there are no published guidelines that standardize the technical aspects of the procedure.

Objectives: XXX

Setting: XXX

Methods: A consensus meeting was held in São Paulo, Brazil, in June 2016, bringing together 39 Brazilian endoscopists with extensive experience in IGBs from all regions of the country. Topics on patient selection, indications, contraindications, multidisciplinary follow-up, technique, and adverse events were discussed in the form of questions. After electronic voting, a consensus was defined when there was ≥70% agreement. Experts were also requested to provide data on their experience with IGBs.

Results: The selected experts discussed and reached a consensus on 76 questions, mainly concerning specific indications and contraindications for the procedure; technical details, such as patient preparation, minimum balloon-filling volume, techniques for implant and explant; patient follow-up and recommended medication for the adaptation period; and adverse event management. The overall Brazilian expert data encompassed 41,186 IGBs, with a mean percentage total weight loss of 18.4% ± 2.9%. The adverse event rate after the adaptation period was 2.5%, the most common being hyperinflation (0.9%) and spontaneous deflation (0.8%) of the device. The early removal rate due to intolerance was 2.2%.

Conclusions: The present consensus represents practical recommendations for performing IGB procedures and reflects Brazil’s significant experience with this device. The experience of over 40,000 cases shows that the device leads to satisfactory weight loss with a low rate of adverse events. (Surg Obes Relat Dis 2017;:00–00.) © 2017 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords: Consensus statement; Intragastric balloon; Obesity; Endoscopy; Bariatric endoscopy
leads to weight loss through increased satiety [1]. As an endoscopic approach, it is positioned between clinical and surgical management, currently being the most used endoluminal obesity therapy. It acts as a space-occupying device, reducing stomach capacity and inducing satiety. There are different models of IGBs, whether filled with liquid or air, adjustable or not, with no significant difference in weight loss among them [2].

Many studies have shown the efficacy of IGBs in short-term weight loss, with significant improvements in obesity-related co-morbidities [3–7]. The IGB has a broad spectrum of indications, from overweight patients (body mass index \(\text{BMI} \geq 27 \text{ kg/m}^2\)), to obese who do not meet criteria for bariatric surgery, and for super-obese (\(\text{BMI} \geq 50 \text{ kg/m}^2\)), as a bridge to bariatric surgery [8]. Due to its good safety profile, IGBs can also be used in morbid obese patients who qualify for bariatric surgery but have high risk of adverse events or prefer not to undergo the procedure. Other indications have also been described, such as preparation for nonbariatric surgeries, in which weight loss is required to achieve better results, and for co-morbidity control.

With growing acceptance of the device worldwide, there is an increasing need to standardize technique and follow-up. To fill this gap, a consensus meeting was organized, gathering expert Brazilian gastroenterologists and surgeons with certification in digestive endoscopy, and a large number of IGB cases. The goals of the meeting were to discuss and evaluate clinical and technical aspects of IGBs (indications, contraindications, technique, adverse events, multidisciplinary follow-up), with the aim of reaching a consensus on best practice based on scientific literature and practice of experts. The Brazilian experience was compiled among these experts through a questionnaire, representing \(>40,000\) procedures and reflecting part of the country’s experience with this device.

These consensus guidelines are, to our knowledge, the first of their kind regarding IGBs, integrating the consensus of the participants’ clinical expertise with current scientific evidence.

### Methods

A Brazilian expert meeting was held June 15 to 17, 2016, in São Paulo, Brazil. There were 39 endoscopists, with broad IGB experience going back 17 years [9], when the device first became clinically available in the country, selected to participate in this meeting. The expert panel of endoscopists was selected by the organizing committee, according to individual levels of experience with IGBs. The threshold for inclusion was set at a minimum of 300 procedures, in addition to being an endoscopist certified by the Brazilian Society of Digestive Endoscopy (gastroenterologists or digestive surgeons by background), representing all regions of the country. To avoid bias regarding conflict of interest, no consideration was given to use of specific balloon brands when selecting the participants, and selected experts paid for their own travel and accommodation expenses.

Before the meeting, a questionnaire was sent to all participants to compile data of IGB procedures performed by the group. These data comprised a total of 41,866 IGB cases, reported by 37 endoscopists (Appendix A). In addition to providing a source of information for the meeting, they reflect the panel’s extensive experience in this procedure.

The themes selected by the chairpersons to be discussed, with predetermined categories of selected questions formulated to be posed for consensus, consisted of indications and contraindications of the procedure; preprocedure evaluation and multidisciplinary follow-up; technique; and postprocedure follow-up and adverse events. The agenda for the 2-day meeting was as follows:

Day 1: program presentation; working strategy; literature review of most important evidence regarding IGBs; review of the collective data submitted by all invited experts; short overview of categories of predetermined questions, discussion of changes, and new questions to be added; and

Day 2: discussion, literature data review before each set of questions, viewing of predetermined questions, and voting.

The consensus voting process was as follows: for each category, a literature data review, casuistic data review, and discussion were conducted. Next, questions were presented, and participants were invited to vote using an anonymous electronic voting system. The group’s responses were calculated as defined by the group to constitute either a consensus (\(\geq 70\%\) agreement) or not (\(<70\%\)). The entire panel immediately reviewed the distribution of the group’s responses after each individual question. If consensus was not achieved, there was a brief round of discussion facilitated by a mediator, followed by a new opportunity to vote, with greater chances of achieving consensus.

### Participant’s data

The total numbers of IGB procedures in the group’s data from 37 experts were 41,866 implants and 38,120 explants. The mean patient age was 37.7 years, with 75.9% being female. The youngest reported patient was 10-years old (in an experimental protocol for pediatric obesity), and the oldest was 83-years old. The mean preprocedure BMI was 34.4 kg/m². The minimum reported preprocedure BMI was 25 kg/m² and the maximum was 102 kg/m² (patient with dwarfism).

The most frequently used balloon was the nonadjustable, fluid-filled Orbera (Apollo Endosurgery Inc., Austin, TX), totaling 32,735 implants (78.2%). This was followed by similar balloons, such as the Medicone Corporea (Medicone, Cachoeirinha, RS, Brazil; 12.4%) and Silimed (Silimed Brazil, Rio de Janeiro, RJ, Brazil; 4.5%). The adjustable fluid-filled balloon Spatz (Spatz FGIA Inc., Great Neck, NY) was implanted in 1020 patients, comprising 2.4% of the total. The Helioscopic air-filled balloon...
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