Brazilian Experience on the Use of Intragastric Balloons

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Introduction

A consensus meeting was organized in Brazil, gathering expert endoscopists, with the aim of filling the gap of intragastric balloons (IGB) technique and follow-up standardization. The goal of the meeting was to reach a consensus on best practice based on scientific literature and practice of experts [1].

Prior to 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. In addition to providing a source of information for the meeting, they reflect the panel's extensive experience in this procedure.

Brazilian Experience Data

The total number of IGBs in the group's experience were 41,866 implants and 38,120 explants. Mean patient age was 37.7 years, with 75.9% being female, on average. The mean pre-procedure BMI was 34.4 kg/m^2. The minimum reported

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pre-procedure BMI was 25 kg/m^2 and the maximum was 102 kg/m^2 (patient with dwarfism) (Table 4.1).

The most used balloon was the non-adjustable, fluid-filled Orbera® (Apollo Endosurgery Inc., Austin, TX, USA), totaling 32,735 implants (78.2%) (Table 4.2). The mean percentage of total body weight (TBW) loss was 18.4 ± 2.9%. The minimum %TBW loss reported was 0.0% and the maximum was 52%. Patients lost a mean of 18.3 ± 4.4 kg, with a minimum reported TBW loss (kg) of 0 kg and maximum of 87.5 kg. The failure rate (defined as %TBW loss <10%) was 8.3 ± 6.7% (Table 4.3).

The most common adverse events were hyperinflation (0.9%) and spontaneous deflation (0.8%). Migrations needing surgical treatment happened in 24 cases, most common with air-filled balloons (1%). Gastric ulcers occurred in 141 cases, more common with the adjustable balloon (5.7%). There were no esophageal or gastric perforations during the implant procedure and a total of six perforations during the explant, mostly with the Silimed® balloon, a device with a more rigid structure and difficult removal (Table 4.4).

Table 4.1 Demographic data

Variable	Mean ± SD	Minimum	Maximum
Male (%)	24.1 ± 8.6	8.0	45.0
Female (%)	75.9 ± 8.6	55.0	92.0
Minimum age (yrs)	14.3 ± 2.3	10.0	18.0
Maximum age (yrs)	71.2 ± 5.0	62.0	83.0
Mean age (yrs)	37.7 ± 4.4	28.0	45.0
Minimum BMI (kg/m^2)	26.8 ± 1.2	25.0	30.0
Maximum BMI (kg/m^2)	63.8 ± 12.0	43.0	102.0
Mean BMI (kg/m^2)	34.4 ± 2.4	30.0	42.0

Table 4.2 Number of implanted and explanted balloons, by brand

Balloon type	Implants (*N*)	Explants (*N*)
Orbera®	32,735	30,394
Medicone®	5172	4429
Silimed®	1882	1788
Spatz®	1020	388
Helioscopie®	1054	1120
Bioflex®	3	0
Others	0	1
Total	41,866	38,120

Table 4.3 Weight loss results from IGB

Variable	Mean ± SD	Minimum	Maximum
TBW (%) mean	18.43 ± 2.92	13.0	25.0
TBW (kg) mean	18.3 ± 4.39	12.50	32.50
BMI reduction (mean)	7.23 ± 3.13	3.50	18.0
Failure (%)	8.33 ± 6.70	0.50	32.0

Table 4.4 Adverse events

	Orbera	Medicone	Silimed	Spatz	Helioscopie	Total
N	32,735	5172	1882	1020	1054	41,866
Hyperinflation[a]	164 (0.5%)	29 (0.56%)	1 (0.05%)	5 (0.49%)	6 (0.57%)	205 (0.49%)
Hyperinflation[b]	146 (0.45%)	4 (0.08%)	12 (0.64%)	4 (0.39%)	0 (0%)	166 (0.40%)
Spontaneous deflation	206 (0.63%)	75 (1.45%)	50 (2.66%)	11 (1.08%)	23 (2.18%)	365 (0.87%)
Migrations[c]	8 (0.02%)	3 (0.06%)	2 (0.11%)	0 (0%)	11 (1.04%)	24 (0.06%)
Migrations[b]	28 (0.09%)	10 (0.19%)	29 (1.54%)	2 (0.20%)	10 (0.95%)	79 (0.19%)
Ulcer[a]	13 (0.04%)	5 (0.1%)	0 (0%)	6 (0.59%)	4 (0.36%)	28 (0.07%)
Ulcer[b]	32 (0.10%)	20 (0.39%)	5 (0.27%)	52 (5.10%)	4 (0.38%)	113 (0.27%)
Bleeding[a]	12 (0.04%)	5 (0.1%)	2 (0.11%)	1 (0.10%)	0 (0%)	20 (0.05%)
Bleeding[b]	30 (0.09%)	2 (0.04%)	5 (0.27%)	2 (0.20%)	0 (0%)	39 (0.09%)
Perforations on implant	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Perforations (during treatment)	9 (0.03%)	2 (0.04%)	2 (0.11%)	1 (0.10%)	0 (0%)	14 (0.03%)
Perforations on explant	2 (0.01%)	0 (0%)	4 (0.22%)	0 (0%)	0 (0%)	6 (0.01%)
Total	650 (1.99%)	155 (3.0%)	112 (5.95%)	84 (8.24%)	58 (5.5%)	1059(2.53%)

[a]Treated by balloon removal
[b]Treated conservatively
[c]Treated surgically

Intolerance leading to early removal happened in 2.2% (n = 928). The air-filled device had the lowest early removal rate (0.8%), probably because of its lightweight leading to less symptoms. Fungal infection of the device occurred in 5.8% of the cases, more frequent in the air-filled balloon (14.9%), probably because of its double-layer characteristic.

There were 12 deaths (0.03%) reported during the presence of the balloon, with a variety of causes, with balloon-related deaths in only three cases. The balloon-related causes were gastric rupture due to overfeeding in a superobese patient (n = 1), pulmonary aspiration with uncoercive vomiting 4 days after implant (n = 1), and one case of pulmonary embolism (n = 1), which may not have been caused directly by the balloon.

Consensus Results

Indications and Contraindications

Placement

According to the experts, minimum age for balloon implant is 12 years, after established puberty, with multidisciplinary evaluation and parental consent. There is no maximum age limit for implant, each case should be considered individually.

The minimum BMI for balloon implant is 25 kg/m^2, after failure of clinical treatment, with no influence of BMI on choice of balloon type.

Absolute Contraindications

Esophageal, gastric, and duodenal ulcers were considered absolute contraindications for balloon implant, owing to the increased risk of perforation. Previous gastric surgery was considered a contraindication by 93.8% of the participants.

Relative Contraindications

Gastric angioectasias without signs of bleeding (75%), eosinophilic esophagitis (81.3%), immunocompetent HIV positive patient (96.9%), and uncontrolled/untreated psychiatric disorders (75.8%).

Pre-procedure Evaluation and Multidisciplinary Follow-Up

Prior Endoscopy and Exams

Regarding pre-procedure evaluation, prior endoscopy was not considered essential (84.4%), since it is possible to evaluate the stomach during the implant procedure. No imaging exams were considered mandatory before the procedure (84.4%), unless there is clinical indication for such, and/or the request of the anesthesiologist. Regarding laboratory exams, no consensus was reached, 41.9% agree that these should always be requested.

Technique

Balloon Implant

It is recommended that the minimum required structure is an outpatient clinic with advanced life support and patient transfer service available if needed (83.9%).

Anesthesia

No consensus was reached regarding sedation: 14.7% prefer conscious sedation; 41.2% prefer deep/general sedation, without orotracheal intubation or the presence of an anesthesiologist; 17.7% prefer a deep/general sedation without orotracheal intubation, performed by anesthesiologist and 26.5% prefer to have an anesthesiologist choose and perform the sedation.

Balloon Volume

No consensus was reached for recommended maximum balloon filling volume. For the adjustable liquid balloon, 54.8% agree that minimum initial filling volume is between 500 and 600 ml; 38.7% believe minimum volume should be between 400 and 500 ml. At the readjustment session, there was no consensus on the additional filling volume: 42.9% recommend a maximum additional volume of 200–300 ml, 25% recommend 100–200 ml, 14.3% recommend 300–400 ml.

For downward adjustments, owing to intolerance (nausea and vomiting), 59.3% believe the minimum filling volume to remain in the adjustable balloon is between 300 and 400 ml, leading to symptom improvement and subsequent upward adjustment.

Balloon Explant

At least 2 days of liquid diet is recommended prior to balloon removal (90.9%), followed by 12-hour fasting (80.7%). Ingestion of cola carbonated drinks (without sugar) is useful as preparation for balloon removal, since this helps to clean any food residues from the stomach (78.1%).

Anesthesia

Regarding explant sedation, once again no consensus was reached.

Technique

A hybrid jaw grasper (alligator + rat tooth) is the preferred accessory for balloon removal (75%). In selected cases, an esophageal overtube may be used to facilitate removal (74.1%); whilst 56.7% also agree that a small amount of vegetable cooking oil can be selectively used to lubricate the esophagus and 30% believe it should always be used [2].

Post-implant Follow-Up

Medications recommended to be administered during the adaptation period to attenuate symptoms are ondansetron, hyoscine, corticosteroid, proton pump inhibitor (PPI), analgesic and dimenhydrinate, usually for up to 3–5 days after implant. The use of PPIs should be maintained throughout treatment (87.5%). Metoclopramide is not recommended in the adaptation period (70.4%) because it increases gastrointestinal motility and may worsen symptoms. Anti-inflammatory drugs are not recommended (96.3%), due to the risk of gastric injury.

Adverse Events

IGB removal is recommended in cases of moderate or severe pancreatitis (90.6%), gastrointestinal bleeding successfully treated only by endoscopic methods (76.5%), gastric ulcer with nonadjustable balloon (90%), recurrent antral impaction (86.7%), symptomatic hyperinflation (96.9%), and recurrent hydro electrolytic disorder (76.7%). In the case of antral impaction, the balloon can be repositioned. In the event of pregnancy, the balloon should be removed (81.3%), preferably in the second trimester.

In the case of adjustable balloon, 53.9% believe the presence of an ulcer demands balloon removal, even if the patient does not agree. In cases where removal is not performed, repositioning the balloon-filling catheter together with clinical

treatment is recommended, except in cases of deep ulcers, with increased risks of perforation, in which case the removal is necessary.

In the presence of mild pancreatitis, removal is not mandatory (76.7%). In the cases of gastrointestinal bleeding that is spontaneously stopped, the balloon can also remain in place (84.4%). In the presence of severe erosive esophagitis, 87.1% recommend that the balloon not be removed before appropriate treatment, due to the increased risk of esophageal lesion during removal. The Mallory–Weiss Syndrome cases should also be treated with the balloon in place.

Conclusions

The full version of the Brazilian Intragastric Balloon Consensus has been published as a scientific paper [1]. This consensus and data collection represents the extensive experience of Brazilian experts, a country that pioneered IGB therapy.

References

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