



Title	Efficacy and Safety of Intra-gastric Balloon in Obese and Overweight Patients. Systematic Review and Case-Registry
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Aim

To evaluate the effectiveness and safety of the intra-gastric balloon in overweight and obese patients. Also, to design a systematic data-capture process and to perform a retrospective case-registry of intra-gastric balloon (Galician hospitals, 2004-2006).

Conclusions and results

Systematic review. Seven studies were included: 1 clinical trial, 1 cohort study, 1 case-control study, and 4 case-series studies. All showed a decrease in weight (7%-18%) and comorbidities. But the weight reduction did not remain after removing the balloon. Technical complications were few, but minor adverse events were common.

Case-registry. 69 balloons were implanted in 68 patients (48 F and 20 M) with an average age of 42.1 years (18-68). Mean baseline weight and body mass index (BMI) were 128.6 kg (90.5-196) and 47.4 kg/m² (34.6-68.5), respectively. A 13% weight reduction was achieved with the intra-gastric balloon; and BMI decreased 5.3 kg/m². Both results were statistically significant. Weight was regained after removing the device. Technical complications were few, but minor adverse events were common. There were more major adverse events than expected.

Intra-gastric balloon (IB) appears to allow weight loss in obese patients, but this loss is not maintained. It should not be the first therapeutic option in obese or overweight patients. (Low-calorie diet, physical activity, and modified eating habits are first.) IB must be combined with other interventions (low-calorie diet, etc). Candidates for surgery could benefit from rapid weight loss from IB since the surgical risk diminishes. No studies compare IB to other weight-loss strategies. Since IB is not absolutely safe, patients must be informed and monitored to avoid or minimize complications. The specific indications for IB are important to define.

Recommendations

Patients should be carefully selected based on degree of obesity and comorbidities (BMI \geq 40 kg/m² or BMI \geq 35

kg/m² with obesity-related pathology) and on contraindications (eg, hiatal hernia, severe esophagitis). Interventions complementing the procedure should be protocolized (eg, diet, bariatric surgery). Patients should be informed about benefits and risks of IB. To minimize complications, the balloon should not be kept in more than 6 months. Active follow-up is proposed to minimize complications and guarantee withdrawal of the balloon. Centers that offer this method must have well-coordinated multidisciplinary teams for treating obesity. The teams must include endoscopy specialists experienced in the procedure, surgeons experienced in obesity surgery, endocrinologists, dieticians, and staff for psychological support.

Methods

Clinical review. We searched relevant databases to update a previous systematic review (December 2005) with a new review of health literature up to November 2006.

Case-registry. 69 IBs at 2 Galician hospitals were retrospectively analyzed. We designed an on-line database and collected data, eg, on patients' previous conditions, balloon implants, and follow-up.