Safety and effectiveness of the intragastric balloon for obesity: a meta-analysis

Imaz I, Martinez-Cervell C, Garcia-Alvarez EE, Sendra-Gutierrez JM, Gonzalez-Enriquez J

CRD summary
The review concluded that use of BioEnterics intragastric balloon as part of a multidisciplinary weight management program for the treatment of obesity provided short-term effectiveness for weight loss, but that effects and maintenance in the longer term were unknown. The reliability of the authors' cautious conclusions are uncertain due to a lack of study details and the poor-quality evidence.

Authors' objectives
To determine the safety, efficacy and effectiveness of treatment for obesity with BioEnterics intragastric balloon.

Searching
MEDLINE and EMBASE were searched from inception to 2006. The Cochrane Library, INAHTA, DARE and Center for Devices and Radiological Health databases were searched. Search terms were reported. Bibliographies of retrieved articles and relevant journals were scanned for relevant articles. Articles in English, Spanish, Italian, French and Portuguese were eligible for inclusion. Articles in other languages were included provided the abstract was in English.

Study selection
Studies evaluating BioEnterics intragastric balloon for the treatment of obesity in addition to conventional treatment for a minimum of 10 patients for at least 12 weeks were eligible for inclusion. Conventional treatment was defined as a multidisciplinary weight management program, including diet, behavioural modifications, psychotherapy, dietary counselling or physical training. Included studies had to reported outcomes of kg lost, percentage of kg lost, body mass index lowered, excess weight lost, complications during treatment and causes of early removal of the intragastric balloon.

Two randomised controlled trials (RCTs) were included, but most included studies were uncontrolled case series.

Two reviewers independently selected studies for inclusion. Disagreements were resolved through discussion.

Assessment of study quality
Validity was assessed using published criteria and included assessment of inclusion criteria, randomisation, double blinding, consecutive cases and dropout rate. Two reviewers independently assessed validity. Disagreements were resolved through discussion.

Data extraction
Weight loss data were extracted on an intention-to-treat basis; it appeared that the value zero was input for patients who dropped out, but this was unclear. The difference in weight change between treatment groups was calculated for the RCTs. For each study, average weight loss was calculated for each treatment group. Standard deviations were extracted, estimated from reported statistics or imputed using reported methods.

Two reviewers independently extracted data on the outcomes of interest. Disagreements were resolved through discussion.

Methods of synthesis
Pooled weighted mean differences (WMD) were calculated using inverse variance methods. Heterogeneity was assessed using the DerSimonian and Laird method, with p<0.05 taken to indicate significant heterogeneity.

Results of the review
Sixteen studies (n=3,608) were included in the review: two RCTs and 14 studies uncontrolled case series. Fifteen studies were included in the analysis. Both RCTs met all validity assessment criteria. Nine uncontrolled case series...
met all relevant validity assessment criteria.

Pooled analysis (two RCTs, n=75) reported that the intragastric balloon with conventional treatment demonstrated greater weight loss compared to placebo with conventional treatment at end of treatment. Mean differences were: weight loss of 6.7kg; 1.5% of initial weight loss; 3.2kg/m² lowering of body mass index; and 17.6% of excess weight lost. There was evidence of statistical heterogeneity for this analysis (data not reported).

The estimates for weight lost at balloon removal for intragastric balloon with conventional treatment were (15 studies, n=3,608): 14.7kg lost; 12.2% of initial weight lost; 5.7 kg/m² lowering of body mass index; and 32.1% of excess weight lost. There was evidence of statistical heterogeneity for these measures (data not reported).

The early balloon removal rate was 4.2% (13 studies, n=3,442). Almost 43% of early removals were voluntary. Most complications were mild; however, 26 patients experienced digestive tract obstructions and four patients experienced gastric perforation, which resulted in two deaths.

**Authors' conclusions**

BioEnterics intragastric balloon as part of a multidisciplinary weight management program was effective in providing short-term weight loss, but effects and maintenance in the longer term were unknown.

**CRD commentary**

Inclusion criteria were specifically defined for intervention and outcomes and broadly defined for participants and study design. Some relevant databases were searched and the authors made some attempts to reduce the potential for language bias. However, the authors also reported that they excluded two studies based on language, which suggested that relevant studies may have been missed. No efforts were made to reduce publication bias. Appropriate methods were used to select studies, assess validity and extract data, which reduced the potential for reviewer bias and errors. Validity was assessed using specified criteria and results of the assessment were reported. No details were presented on the demographics of participants, interventions and co-interventions or usual care in the included studies. The authors suggested caution when interpreting the results as heterogeneity may be due to differences in study participants, endoscopic intervention or co-interventions. It was, therefore, not possible to assess the generalisability of these results. The methods used to combine studies were not clearly described. Although there was evidence of statistical heterogeneity, details were not reported. It was unclear why only 15 out of 16 studies were included in the overall analysis. Most included studies were uncontrolled case-series and so subject to various potential biases. Therefore, results from these studies and any synthesis may not be reliable. The reliability of the authors' cautious conclusions are uncertain due to lack of study details and most of the included studies being uncontrolled case series which, therefore, provided poor-quality evidence.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Research:** The authors did not state any implications for research.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.