Laparoscopic adjustable gastric banding for the treatment of obesity

Chapman A, Kiroff G

Authors' objectives
To assess the literature regarding the procedure of laparoscopic adjustable gastric banding and to make recommendations on its safety and efficacy.

Searching
MEDLINE, EMBASE, the Cochrane Library and Current Contents were searched from inception to February 1999. The search terms were reported in the article. Foreign language papers were identified from their abstracts, but were not included unless they appeared to be 'superior'.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), controlled clinical trials and prospective case series were eligible for inclusion.

Specific interventions included in the review
Laparoscopic adjustable gastric banding (LAB), including both Lap-band and the Swedish Gastric Band (SAGB), was the eligible intervention. It was compared with other surgical interventions such as biliopancreatic division, Roux-en-Y gastric bypass and vertical banded gastroplasty.

Participants included in the review
The participants had to be receiving the intervention for obesity.

Outcomes assessed in the review
The studies must have reported information on one or more of the following: weight loss, complications, psychosocial effects, revision rates, mortality rates or cost-effectiveness.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The included papers were assessed against a hierarchy of evidence that used study design to rank the evidence. In addition, they were assessed for retrospective design, the use of an unsuitable measure of variance, imprecise weight-loss data, whether the procedures were aggregated, violation of intention-to-treat analysis, and reporting errors. The authors do not state how the papers were assessed for validity, or how many of the reviewers performed the validity assessment.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. The data extracted included location, intervention details, follow-up, participant characteristics (gender, age, weight) and inclusion criteria. Relative risks (RR) and the RR reduction were calculated where possible for safety outcomes.

Methods of synthesis
How were the studies combined?
A narrative synthesis was undertaken with the studies grouped under different types of outcome.
How were differences between studies investigated?
Differences between the studies were discussed in relation to study design and the methods used to measure the outcomes.

Results of the review
Thirty-seven studies were included: 1 RCT (n=60), 2 prospective controlled cohort or case-control studies (n=241), 7 comparative studies with historical controls (n=1,177) and 27 case-series (range of n: 1 to 500).

All studies reported weight loss with both the Lap-band and the SAGB. At 12 months, the mean or median body mass index (BMI) had reduced to 35 kg/m² or less. Only one study reported a reduction in the mean BMI to below 30 kg/m². The mean excess weight loss was 41 to 71%, while the mean gross weight loss was 22 to 54 kg. Variances were seldom reported.

Of the 8 comparative studies, 4 used a statistical analysis. One with concurrent controls found no significant statistical difference between the laparoscopic non-adjustable and SAGB groups at 36 months. The remaining 3 studies used historical controls; only one study reported a significant statistical difference, with vertical banded gastroplasty more effective than LAB up to 18 months, but comparable at 24 months.

Long-term weight-loss data of at least two years were reported in 7 studies, with weight loss continuing in the second year. The weight loss appeared to plateau in the third year in 2 out of 3 studies with 3-year follow-up, but with very wide ranges: the BMI ranged from 20 to 35 kg/m2 for SAGB or Lap-band, while excess weight loss ranged from 6 to 122% for Lap-band. The single small study (n=12) with a 4-year follow-up showed continuing loss with LAB.

The morbidity rates reported for LAB varied from 60 to 0%, with an aggregated rate of 10.5%. The most common complications were pouch displacement (3.6%) and pouch dilatation (3.2%). The rates of other complications were all under 1%. Five studies reported data on vomiting and food intolerance. One study reported significantly lower vomiting in the Lap-band group in comparison with first-generation INAMED adjustable bands fitted via laparotomy; it also reported a lower rate of vomiting associated with SAGB than with Lap-band. The only study with concurrent controls found a RR reduction of 0.86 (95% confidence interval: 0.10, 0.98) for the Swedish band when compared with the non-adjustable band at 1, 2 and 3 years' follow-up.

Cost information
None. There were no direct cost data, but data on the duration of hospital stay and post-operative recovery were reported, including re-operation rates.

Authors' conclusions
The safety and efficacy of LAB cannot be determined due to an incomplete and poor quality evidence-base. More research is required.

The available evidence appears to demonstrate the feasibility of LAB, but the dearth of good-quality data makes it difficult to assess the procedure properly. However, there appears to be little alarming about the procedure in terms of its safety, with peri-operative and long-term mortality less than 1 in 1,000. The patients appeared to be discharged from hospital more quickly with laparoscopic procedures than with open procedures.

There was limited evidence that LAB is as efficacious as vertical banded gastroplasty at 24 months, but longer term data are lacking. The data on variations in weight loss were poor. While the procedure was extremely successful with some individuals, the range of success was wide. The mean BMI did not typically decrease below 30 kg/m² after 2 to 3 years, so it is unlikely that LAB will prove a cure for the typically obese.

CRD commentary
The review question and inclusion criteria were clear, except in relation to foreign language papers. The search for published studies was adequate, but excluded 'grey' literature; some data may therefore have been missed. Details of
the individual studies were reported in full. The review procedures for selecting and abstracting the studies were not described, so it is impossible to assess whether they were sufficient to guard against error or bias. The validity assessment was adequate. The synthesis method was appropriate and the conclusions were justified from the data presented.

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

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

**Research:** The authors state that well-conducted better-designed studies that use well-defined measures of success and safety, and have at least 5-years' follow-up, are required.

**Bibliographic details**


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