Laparoscopic adjustable gastric banding for clinically severe (morbid) obesity

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Authors' objectives
To highlight evidence from published scientific literature regarding the safety, efficacy and effectiveness of the laparoscopic adjustable gastric band (LAGB). Efficacy is defined as performance of a technology under 'ideal' conditions of best practice, whilst effectiveness is defined as its performance under 'routine' conditions. The author intended this report to inform a decision on whether LAGB surgery can safely be performed outside a hospital setting.

Searching
The following databases were typically searched from 1993 to August 1999: MEDLINE, PREMEDLINE, EMBASE, Dissertation Abstracts, Current Contents, Best Evidence, HTA, NHS EED, DARE, the Cochrane Database of Systematic Reviews, HealthSTAR, CMA Infobase: Clinical Practice Guidelines, and National Guideline Clearinghouse. The search terms used for each database were listed.

In addition, the Internet was searched (search terms not provided) and the indices of the Obesity Surgery journal (1998 to 1999) were examined for relevant articles. There were no language restrictions reported. Authorities in Canada and the United States were contacted with respect to regulatory approval for the LAGB.

Study selection
Study designs of evaluations included in the review
All study types, with the exception of single case reports and animal studies, were considered. Each study had involve over 20 patients and have a follow-up of more than one year.

Specific interventions included in the review
LAGB surgery for morbid obesity. Comparison groups were one or more of the following: vertical banded gastroplasty, Roux-en-Y gastric bypass, open gastric band surgery and Swedish adjustable banding.

Participants included in the review
No inclusion criteria relating to the participants were reported. The participants were adult men and women with morbid obesity, defined as a body mass index (BMI) greater than 35 kg/m2; a BMI exceeding 40 kg/m2; or 45 kg overweight, according to Metropolitan Life Weight tables. The participants were aged from 17 to 72 years, and had BMI values ranging from 34 to 75 kg/m2.

Outcomes assessed in the review
One or more of the following outcomes were assessed: excess weight loss; score on the Bariatric Analysis and Reporting Outcome System (BAROS; see Other Publications of Related Interest no.1); BMI; weight loss; intra- and post-operative complications; length of hospital stay; need to change from laparoscopic to open surgery; and mortality. None of these were identified as the primary outcome of interest in the review.

How were decisions on the relevance of primary studies made?
All studies that met the selection criteria were included.

Assessment of study quality
Validity was assessed using a combination of the 4-point scale devised by Jovell and Navarro-Rubio (see Other Publications of Related Interest no.2), and the criteria published by the American Society for Bariatric Surgery (see Other Publications of Related Interest no.3). These two classification systems were based on length of follow-up and study type, respectively. The methodological quality of the individual studies was not assessed in further detail. The author does not state how the papers were assessed for validity, or how many of the reviewers performed the validity assessment.
Data extraction
The author does not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. The following data from each study were tabulated: the number of participants, age, gender, BMI and/or weight, follow-up period, surgery duration, length of hospital stay, intra- or post-operative complications, and study outcome (e.g. BMI, weight loss, BAROS results).

Methods of synthesis
How were the studies combined?
Each study was tabulated and described individually. Studies were then considered according to the outcomes of weight loss and/or BMI, and the complications experienced, in the narrative.

How were differences between studies investigated?
The author does not report any investigation of differences between the studies.

Results of the review
Nine studies with 1,658 patients, were included: 1 randomised controlled trial (RCT; 50 patients), 7 uncontrolled studies and 1 observational study (1,608 patients). Follow-up data were available for 1,569 of these patients; the remaining 39 were lost to follow-up from 3 studies.

All nine studies reported weight loss, excess weight loss, or decreases in BMI after LAGB surgery. However, it is noted that the studies included were based on poor to fair levels of scientific evidence. The only RCT found no significant differences in weight loss or change in BMI between the two groups studied, i.e. laparoscopic versus open adjustable gastric banding. The complications reported included aspiration pneumonia, band slippage, and rotated or infected access ports. Band migration was more common if the band injections were performed by residents or nurses, rather than senior surgeons.

Authors' conclusions
ThLAGB surgery appears to be an effective restrictive surgical treatment for morbid obesity, based on fair to poor levels of scientific evidence. The author also concludes that, since all the studies included in the review took place in a hospital, this synthesis provides no information on whether LAGB surgery can be offered to morbidly obese patients outside a hospital setting. LAGB surgery gives similar results to other restrictive surgeries such as vertical banded gastroplasty.

CRD commentary
This was a poorly presented review of an area in which data are sparse. The aims of the review were clearly stated, although to state that the aim was to investigate whether LAGB surgery could be used outside of the hospital setting seemed inappropriate, considering the safety of the procedure had not been established in in-patients. The search strategy was comprehensive, although it was unclear why date restrictions were imposed; this may relate to the timing of the introduction of LAGB surgery.

The inclusion criteria were unclear, and the included studies were noted as providing only a fair to poor evidence base. Details of the primary data were provided in a clear manner. Validity assessment of the studies was absent, and the fact that only one randomised study was found was not emphasised sufficiently.

The conclusions made by the author were too strong in view of the poor evidence. Based on the data in this review, no conclusions regarding the comparative safety and efficacy of LAGB surgery can be made. The review omitted the evidence on which the Canadian regulatory authorities approved the use of LAGB surgery, which incidentally, has not been approved in the United States. The review also included numerous sections that were unrelated to the author's objective, such as 'general considerations for bariatric surgery'. These were presented after the review results rather than as an introduction or an appendix, which was confusing.
Implications of the review for practice and research

Practice: The author did not state any implications for practice.

Research: The author states that whether LAGB surgery will replace current standard of care, or become part of mainstream treatment for morbid obesity, can only be determined by well-designed studies reporting greater than 5-year outcomes of patients who have undergone the procedure. The single RCT included in this study was small, had a follow-up of only one year, and provided insufficient evidence on which to base clinical recommendations. The author states that a subgroup of obese patients, in whom LAGB surgery could be employed as an alternative to standard care, could possibly be identified pre-operatively.

Bibliographic details
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Other publications of related interest

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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.