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STEER

Surgical interventions for morbid obesity

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The Wessex Institute for Health Research & Development incorporating Public Health Medicine

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Surgical interventions for morbid obesity

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Conflict of Interest
None

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Surgical interventions for morbid obesity

Question

1. **What are the effects of surgical interventions compared with behavioural, motivational, and psychological interventions on weight reduction in people with a body mass index of greater than 40?**

Summary

We found evidence from one systematic review of randomised trials and subsequent studies that surgery is more effective than non-surgical treatments for weight reduction in the short term in people with morbid obesity, although adverse effects are more common and sometimes severe. Poorer quality evidence suggests that surgery might also improve health related quality of life and obesity related disease in the short term compared to conventional treatment. However, this conclusion must be regarded as tentative pending higher quality research.

We found no evidence for longer term effects, persistence of weight loss or cost effectiveness.

Background

The prevalence of obesity has increased rapidly in recent decades. People with obesity are at increased risk of conditions such as coronary heart disease, non-insulin dependent diabetes mellitus, sleep apnoea and joint disease. Obesity also has a negative impact on a person's general emotional, social and psychological well-being. The cost of treating obesity related diseases is high and effective ways of reducing obesity are a public health priority.

Obesity is most frequently measured by body mass index (BMI). The desirable BMI value is between 20 and 25. People with BMI 25 – 30 are classified as over-weight; with 30 – 40 as obese and over 40 as morbidly or severely obese.

Interventions to reduce weight and maintain weight loss include behavioural, dietary, pharmacological, exercise and surgical interventions. Surgery is an invasive procedure and may be associated with severe complications and increased mortality. It is, therefore, usually reserved for severely obese people, in whom other interventions for weight reduction have failed.

Surgical options fall into two general categories: restrictive operations and gastric bypass. Restrictive procedures, such as gastric banding and vertical banded gastroplasty (VBG), slow down food intake by restricting the width of the opening of the oesophagus into the stomach with a rigid implanted band. In gastric bypass, a small stomach pouch is created and part of the small intestine is bypassed. This reduces the stomach's capacity to hold food by approximately 90% and means that the patient has to make life-long dietary modifications. It can be performed as an 'open' procedure or laparoscopically.

Search Methods

Primary sources: Medline 1966 to date; Embase 1980 to date; Cochrane 2001 issue 3; Database of Abstracts of Reviews of Effectiveness; NHS Health Technology Assessment Database; NHS Economic Evaluation database. Search date: October 2001.

Evidence found

We found one systematic review (published in 1997 by the NHS Centre for Reviews and Dissemination), which evaluated methods to prevent and treat obesity in overweight or obese adults and children.[1,2] It included controlled trials with at least one year of follow-up. All studies were randomised except for two trials of preventative methods. The review examined dietary, behavioural, exercise, pharmacological and surgical interventions to reduce weight and maintain weight loss in severely obese people. 15 RCTs were of surgical interventions.

We found two other reviews.[3,4] The first (published in 1999) was excluded because its methods were not as rigorous as those of the NHS review.[3] Relevant studies may have been missed

as only one electronic database was searched and the quality of the included studies was not formally assessed. The second (published in 1997) was excluded because it only examined effects of vertical band gastroplasty and methods were not explicitly stated within the review.[4]

We found one randomised trial,[5] one non-randomised trial that compared surgical treatment versus non-surgical intervention in a control group selected for characteristics matching those of the surgically treated participants,[6] and two case-series[7,8] published since the search date of the NHS systematic review.

The randomised trial compared laparoscopic gastroplasty with dietary treatment for effective weight reduction in 16 obese adults whose BMI ranged from 40 to 56.[5] Patients were evaluated every four weeks for 40 weeks. Surgical complications were reported. This study was only available in abstract form.

The non-randomised trial examined health-related quality of life and eating behaviour after weight reduction in 487 patients treated surgically and 487 similar controls treated with dietary, behavioural, or pharmacological interventions.[6] Participants were aged between 37 - 60 years and had a BMI of at least 34 for females and 38 for males. They were followed up for 2 years. This analysis is part of an on-going study that will examine mortality and morbidity at 10 years follow-up.

The first of the case-series evaluated effects of vertical band gastroplasty among 35 morbidly obese adults with an average BMI of 44.1 (range 37.5-49.8).[7] Patients were followed up for an average of 4.1 years (range 29-75 months). Weight loss, improvement in pre-existing co-morbidities, and patients' quality of life were evaluated at frequent intervals. Adverse effects were also reported.

In the second case-series, 172 obese adults underwent gastroplasty (109 of them laparoscopically.[8] Mean BMI was 46.3 (range 35.1-69.5). Weight loss and technical complications were reported at three years follow-up.

We found a Cochrane protocol for a review to be published shortly that will focus specifically on the effects on morbidity and mortality of weight reduction for people with obesity.[9] It will include only randomised controlled trials with at least one year follow-up.

Quality of Evidence Found

The systematic review was of good quality.[1,2] The question was clear and the search for studies was comprehensive. A search strategy was supplied and clear inclusion and exclusion criteria were stated. To be included, studies had to satisfy criteria of relevance, outcome and design. Detailed tables of the primary studies were also included.

Identified studies were assessed for relevance according to the inclusion criteria by one author and a sample checked by a second. All data extraction was assessed by a second reviewer. Assessment of publication bias was not reported. Identified studies were generally of poor quality and likely to be biased due to small sample size, high drop out rates and a lack of intention to treat analysis. 64% of studies had less than 30 participants, drop outs were excluded in the final data analysis in the majority of studies and only 6 studies analysed by intention to treat.

The randomised controlled trial was only published as an abstract.[5] Limited information, therefore, prevented full appraisal for quality. The number of participants was very small and although allocation was said to be random, the randomisation method was not reported. There were more women than men in the surgical arm of the trial, although age range and BMI were similar in both groups.

The Swedish study was a non-randomised trial.[6] Most patients came from the same obesity register although surgical subjects were also recruited from existing surgical waiting lists, raising the possibility of selection bias. While matching of surgical and control participants for baseline characteristics was attempted, the design is prone to confounding and selection bias. Health related quality of life results were based on patient reports of health perception, mental well-being/mood disorders, and psychosocial functioning. Physical functioning, post-operative complications and morbidity rates, which the authors state are important in the overall evaluation of quality of life post surgery, were not taken into account in the evaluation of quality of life changes. Surgical subjects were more obese and had poorer health quality of life ratings than control subjects at baseline but baseline characteristics were controlled for in the statistical analysis. The fact that baseline differences were present suggests selection bias. Adjustment for known confounders still leaves open the possibility of confounding from unknown baseline differences between groups. Compliance rates were reported

The case series may not be considered reliable evidence.[7,8] They examined outcomes of surgery but had no control group with which to compare its effectiveness. Both studies had relatively long follow-up. The first series was small and reported explicit inclusion and exclusion criteria based on BMI, dietary and eating habits.[7] Treatment selection was dependant upon specific pre-operative criteria in order to identify patients who were best suited to this type of surgery.[7] External validity of results was therefore limited. The other series was much larger.[8] Explicit inclusion and exclusion criteria were also reported,

based on BMI, duration of obesity, resistance to conservative treatment, high compliance to follow-up, and co-morbidity. Drop out rate was low. Adverse effects were reported (see table). Case series are intrinsically weak studies when assessing comparative effectiveness of different treatments, because they lack control groups. They are particularly unreliable for examining weight change in morbid obesity, where the natural history of the condition is highly variable over the time period considered in the study.

Most of the studies included participants with a lower BMI than was specified in the original question of this review. No studies reported specifically on mortality.

Study Results

Many of the studies included in the systematic review were of poor methodological quality.[1,2] The review found that weight loss associated with surgical intervention was significantly greater than with other interventions or placebo and that weight loss may be sustained for longer. Six of seven randomised trials found a significantly greater weight loss after gastric bypass than after gastroplasty (45-65kg versus 30-35kg, respectively). However, the review found no evidence regarding long term effects and surgery was associated with important adverse effects. These included revision of initial surgery, vitamin and mineral deficiency, dumping syndrome, nausea and surgery-associated mortality. Six studies reported re-operation rates ranging from 12% to 33% after gastroplasty, one study reported a 2% surgical conversion rate after gastric bypass and one study reported that 40% of patients undergoing end-to-end jejunoileal bypass required further surgery. Because of long term complications, the review states that the latter procedure is no longer recommended. Eleven deaths were reported, eight of them related to surgery. Five deaths were reported following gastric bypass (3 days to one year post operation). Two of these deaths were due to cardiac arrhythmia; one due to anastomotic leak, and one due to an embolus in a brachial artery. Two deaths were reported following jejunoileal bypass (3 weeks and 10 months post operation). One death was due to anastomotic leak and cause was not stated in the othercase. One death was reported from myocardial infarction following a sham gastric bubble operation. Two deaths from liver related disease were reported in the medical group of one study and one death two years after gastric bypass was reported as unrelated to surgery.

The randomised trial found that weight loss was significantly greater in obese adults undergoing surgery compared to dietary interventions at 40 weeks follow-up ($P<0.001$).[5] No major

complications or deaths were reported but long-term efficacy remained uncertain.

Similarly, the non-randomised trial found that surgery resulted in greater weight loss than non-surgical interventions at two years follow-up (mean weight loss 28.45kg versus 0.85kg with surgery).[6] It reported that substantial weight loss led to a significant improvement in patients' quality of life. The magnitude of this effect was positively correlated with the amount of weight lost.

The smaller of the two case series found that the substantial initial weight loss seen after vertical band gastroplasty for adults with severe obesity was not sustained five years after surgery.[7] Average weight loss at one year was 30kg (range 14.5kg to 45kgs) compared with 19kg (range 12kg to 28kg) at five years. A quarter of patients had unsatisfactory outcomes in terms of weight loss and quality of life. Those with substantial weight loss suffered frequent vomiting. At three years, 14/29 (48%) patients suffered vomiting at least once a week; at four years 13/19 (68%) suffered vomiting at least once a week. Pre-existing obesity related diseases were found to recur if weight was regained.

The larger case series found a mean weight loss of 40.77kg (from an initial average weight of 135 kg, representing 30.2%) at three years post surgery for obese adults undergoing adjustable gastric banding.[8] Complications included gastric pouch dilatation, (10.4%) gastric perforation (2.3%), and band migration (0.6%). No deaths were observed.

Conclusions

We found evidence from one systematic review of 15 randomised trials that surgical interventions may be more effective than non-surgical interventions or placebo for reducing weight in the short term in people with morbid obesity. Subsequent studies do not alter this conclusion.

Patients' health related quality of life may also be improved with surgery versus non-surgical interventions or placebo, although this conclusion is based on poor quality studies and must therefore be regarded as tentative. Surgery may be associated with important and sometimes severe adverse effects, and we found no evidence that beneficial effects persist in the long-term.

None of the studies reported specifically on effects on mortality of surgical versus non-surgical treatments in people with morbid obesity.

A forthcoming Cochrane review[9] is awaited with interest but, in the absence of further higher quality primary studies, it is unlikely to significantly alter the main

conclusions of this review.

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[Study details are tabulated in an Appendix to this report, available at www.signpoststeer.org]

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