

# The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation

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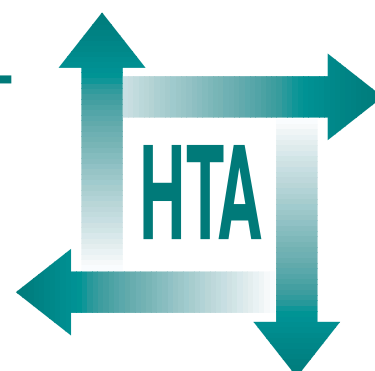
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## *Executive summary*

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## Executive summary

### Background

In 1998, amongst adults in England, 17.3% of men and 21.2% of women were obese (body mass index (BMI) > 30), and 0.6% of men and 1.9% of women were morbidly obese (BMI > 40). The prevalence of obesity in England has been increasing. Obesity is associated with increased morbidity and mortality, and is a recognised risk factor for cardiovascular disease, type 2 diabetes, cancer, degenerative diseases of the musculo-skeletal system, reproductive disorders and respiratory disorders. Weight loss has beneficial effects on co-morbidities and long-term survival. Currently, obesity tends to be managed by the NHS within primary care. Other interventions may be considered. Provision of specialist obesity clinics is limited in England and Wales. Gastric surgery is considered when all other measures have failed. It is not a common procedure; around 200 gastric operations are carried out annually in England and Wales, with a large proportion funded privately.

### Aim of the review

To systematically review the clinical effectiveness and cost-effectiveness of surgery for the management of morbid obesity and to develop a cost-effectiveness model using the best available evidence to determine cost-effectiveness in a UK setting.

### Methods

A systematic review of the literature and an economic evaluation were undertaken.

### Data sources

A total of 16 electronic databases were searched from inception to October 2001. Bibliographies of related papers were assessed for relevant studies and experts were contacted for advice and peer review and to identify additional published and unpublished references. Manufacturer submissions to the National Institute for Clinical Excellence were reviewed.

### Study selection

Studies were included if they fulfilled the following criteria.

- **Interventions:** surgical procedures, performed either as open procedures or laparoscopically, including restrictive procedures such as gastroplasty (vertically banded or silicone ring) or gastric banding, and malabsorptive procedures such as biliopancreatic diversion, Roux-en-Y gastric bypass or jejunoileal bypass. The review concentrated on the clinical effectiveness of the different surgical interventions when compared with each other or with non-surgical interventions.
- **Participants:** individuals diagnosed as morbidly obese, defined as a BMI > 40, or with BMI > 35 with serious co-morbid disease, in whom previous non-surgical interventions had failed.
- **Outcomes:** measures of weight change, measures of fat content, measures of fat distribution, quality of life (QoL), peri- and postoperative mortality and morbidity, revision rates, and obesity-related co-morbidities as primary outcomes at baseline and follow-up (minimum 12 months).
- **Design:** clinical effectiveness – systematic reviews of randomised clinical trials (RCTs) and RCTs comparing the different surgical interventions with each other and with non-surgical interventions, and systematic reviews of prospective controlled clinical trials (cohort studies with concurrent controls) and prospective controlled clinical trials comparing surgical procedures with non-surgical treatment; cost-effectiveness – economic evaluations of surgery for people with morbid obesity that included a comparator (i.e. ‘usual care’) and both the costs and the consequences (outcomes) of treatment.

Studies in non-English language, and abstracts and conference poster presentations were excluded.

Two reviewers identified studies: one reviewer screened titles and abstracts and a second reviewer checked decisions. Then two reviewers independently examined the full text of selected studies to decide on inclusion. Any differences in opinion were resolved through discussion.

### Data extraction and quality assessment

Both were undertaken by one reviewer and checked by a second reviewer, with any disagreement resolved through discussion. The quality



of RCTs and prospective controlled clinical trials was assessed using a modified version of the Spitzer criteria, and the quality of systematic reviews was assessed using criteria developed by the NHS Centre for Reviews and Dissemination. The quality of economic evaluations was assessed by their internal validity using a standard checklist, and by external validity using a series of relevant questions.

### Data synthesis

The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity were synthesised through a narrative review with full tabulation of the results of all included studies. In the economic evaluation, a cost-effectiveness model was constructed using the best available evidence to determine cost-effectiveness in a UK setting.

## Results

### Number and quality of studies

In all, 17 RCTs and one non-randomised clinical trial were included in the systematic review. Two RCTs and the non-randomised clinical trial compared surgical interventions with conventional treatment. The remaining 15 RCTs compared different types of surgery. The methodological quality of the included studies varied. Surgery was more effective than conventional treatment in achieving long-term weight loss and improving QoL and co-morbidities. Gastric bypass surgery was more beneficial than gastroplasty or jejunoileal bypass, with laparoscopic placement producing fewer complications than open procedures.

Searching revealed four economic evaluations: two were from the USA, one from The Netherlands and one from Sweden. When assessed on recognised criteria of internal and external validity, all four economic evaluations were considered of poor quality. Surgery was shown to be cost-effective or cost-saving compared with non-surgical treatment or no treatment.

### Summary of benefits

When compared with conventional treatment, surgery resulted in a significantly greater loss of weight (23–37 kg more weight), which was maintained at 8 years. As a consequence, there were improvements in QoL and co-morbidities associated with the loss of weight from surgery. Comparison of the different types of surgery showed that gastric bypass appeared more beneficial, with a greater weight loss (6–14 kg more weight) and/or improvements in co-morbidities and com-

plications than either gastroplasty or jejunoileal bypass. Assessment of open versus laparoscopic gastric bypass and adjustable silicone gastric banding showed fewer serious complications with laparoscopic placement. Laparoscopic surgery had a longer operative time compared with open surgery, but resulted in reduced blood loss, proportion of patients requiring intensive care unit stay, length of hospital stay, days to return to activities of daily living and days to return to work.

### Costs

The costs of the different interventions varied from £336 for usual care to £3223 for vertical banded gastroplasty, to £3333 and £3392 for open and laparoscopic gastric bypass, and £4450 and £4753 for laparoscopic and open silicone adjustable gastric banding. The total net costs of treating morbid obesity (over 20 years) through surgical procedures varied from £9626.90 for vertical banded gastroplasty to £10,795.16 for silicone adjustable gastric banding. All surgical procedures were more costly than treatment through usual care, with total net costs of £6964.15 over 20 years. These costs are based on several assumptions concerning models of treatment.

### Cost/quality-adjusted life-year (QALY)

The economic evaluation considered three types of surgical procedure specifically: gastric bypass (Roux-en-Y), vertical banded gastroplasty and adjustable gastric banding, and non-surgical management. Comparison of surgery with non-surgical management over a 20-year period showed that surgery offered additional QALYs at an additional cost. When compared with non-surgical management, gastric bypass had a net cost per QALY of £6289 while vertical banded gastroplasty and silicone adjustable gastric banding had a net cost per QALY of £10,237 and £8527, respectively. Comparison of the different procedures suggests that the difference in cost per QALY is less clear. Gastric bypass appears to have a very modest net cost per QALY gained compared to vertical banded gastroplasty (£742/QALY). In contrast, silicone adjustable gastric banding has a large net cost per QALY gained compared to gastric bypass (£256,856/QALY).

Caution should be taken when comparing different surgical procedures as the economic evaluation is based on several unsophisticated assumptions, and evidence of clinical effectiveness varies between procedures. ►

## Sensitivity analyses

Several different scenarios were examined in the one-way sensitivity analyses for gastric bypass surgery compared to non-surgical management. Increases in the length of hospital stay (from 7 days for open and 6 days for laparoscopic to 14 days for both increases the cost/QALY to £10,323), increases in costs of pre- and post-operative care (addition of very-low-calorie diet and dietitian consultation increases the cost/QALY to £7255), increases in weight loss from non-surgical management (decrease in BMI from 45 to 42 increases the cost/QALY to £8931), decreases in weight loss from surgery (from BMI of 29 to 33 increases the cost/QALY to £9155 and to BMI of 37 to £16,819), increases in the costs associated with developing the service (additional training cost and lower efficiency increases the cost/QALY to £20,768), increases in the cost of treating co-morbidities (diabetic drug costs of £775 per annum increases the cost/QALY to £8715) and decreases in the utility gained from surgery (reducing utility gains to one-third increases the cost/QALY to £18,867) resulted in cost per QALYs of around £20,000.

## Limitations of the calculations

The economic evaluation is based on several assumptions due to the limitations of the data available. Evidence of the benefits of treatment varied among the different procedures and was restricted to the assessment of benefits in the short term (< 5 years). The effects of treatment were ignored beyond 20 years. Apart from diabetes, epidemiological data on the co-morbidities associated with morbid obesity and their effects on life-expectancy were limited and excluded from the evaluation. The baseline evaluation is based on a stereotypical patient aged 40 years with a BMI of 45, which conceals the variation between patients characterised in the trials. Many of the NHS costs were from Scottish data sources, which may overestimate the costs in England and Wales.

## Conclusions

### Implications of surgery for morbid obesity

Currently, limited numbers of morbidly obese people receive surgery in England and Wales.

A constraint upon the development of any service would need to ensure there are adequately trained multi-disciplinary teams to operate and provide long-term support to patients. Given the proportions of patients who may benefit from surgery and the need for experienced teams with appropriate facilities, it would seem appropriate that any service should be provided within specialist facilities.

If implemented, the additional total cost to the NHS in England and Wales may be £136.5 million over the 20-year life-expectancies of the 50,000 patients who are thought to be morbidly obese and who may meet the criteria for surgery. The impact on the annual budget of the NHS is difficult to assess given the limited information on the incidence of morbid obesity. Expert opinion suggests that some 800 morbidly obese people may meet the criteria for surgery each year at an additional total cost of £2.2 million over their 20-year life-expectancies. Any savings would depend on the non-financial constraints of any increase in surgery over the next few years, such as staffing, as well as the number of patients choosing to have surgery and the future costs of surgery that may change as the service develops.

## Recommendations for future research

Although surgery appears effective in terms of weight change, there is limited evidence addressing the long-term consequences and its influence on the QoL of patients. In addition, there have been few economic evaluations comparing the different surgical interventions, and the availability of costing and resource use data appears limited. It would be beneficial if these could be addressed through good quality research.

## Publication

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