Cost-effectiveness and budget impact of obesity surgery in patients with type-2 diabetes in three European countries
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study examined two bariatric operations, adjustable gastric banding (AGB) and gastric bypass (GBP), for the treatment of obesity in patients with Type 2 diabetes mellitus (T2DM). Obesity was defined as a body mass index (BMI) of at least 35 kg/m2.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised a hypothetical cohort of obese patients (BMI at least 35 kg/m2) with T2DM who had not responded to at least 1 year of well-conducted medical treatment.

Setting
The setting was a hospital. The economic study was carried out in France, Germany and the UK.

Dates to which data relate
The effectiveness data were derived from studies published 1998 and 2003. No dates for the resource use or costs were reported. The price year was 2005.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of published studies and expert opinion.

Modelling
The authors stated that a deterministic model was constructed to compare the clinical and economic impact of the alternative treatments in a hypothetical cohort of 1,000 patients over a 5-year time horizon. In reality, a mathematical approach based on a deterministic linear algorithm appears to have been used rather than a conventional decision analysis.

Outcomes assessed in the review
The outcomes assessed were treatment effectiveness (in terms of the impact on both BMI and T2DM prevalence), the frequency of surgery-related complications and utility estimates.
Study designs and other criteria for inclusion in the review
A review of the literature was undertaken to identify relevant studies. Clinical data were derived mainly from publications quoted in Health Technology Assessment (HTA) reports issued by NICE, ANAES, ASERNIP-S, SBU and the DGA. Limited information on the primary studies was reported. The treatment effect of AGB (in terms of the reduction in BMI and T2DM prevalence) and complication rates were taken from 13 publications. The treatment effect of GBP was taken from 11 publications, while complications rates came from 2 published literature reviews. The treatment effect of CT was obtained from 2 published literature reviews. Health-related quality of life was derived from a database of 13,547 individuals provided by the Health Outcomes Data Repository Cardiff Research Consortium, in which utility scores associated with specific conditions were elicited using the EQ-5D tool based on the time trade-off approach.

Sources searched to identify primary studies
MEDLINE was searched in June 2005 to identify clinical trials and non-comparative prospective series of consecutive patients that were published after the HTA reports.

Criteria used to ensure the validity of primary studies
The authors stated that the best available evidence was used whenever possible.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Twenty-eight primary studies provided the clinical data.

Methods of combining primary studies
Clinical estimates were pooled using weighted averages, where possible, otherwise a narrative approach was used.

Investigation of differences between primary studies
Not reported.

Results of the review
The BMI reduction associated with CT was 2 kg/m² in the first year and 0 kg/m² yearly in the subsequent years. The reduction in T2DM prevalence with CT was 20% in the first year and 0% in subsequent years.

The BMI reduction associated with AGB was 9.2 kg/m² in the first year, 11.2 kg/m² in the second year, 12.3 kg/m² in the third year, 14.9 kg/m² in the fourth year and 13.2 kg/m² in the fifth year. The reduction in T2DM prevalence with AGB was 64% in the first year, 45% in the second year and 56% in the third year.

The BMI reduction associated with GBP was 17.7 kg/m² in the first year, 16.9 kg/m² in the second year, 16.9 kg/m² in the third year, 16.2 kg/m² in the fourth year and 16.1 kg/m² in the fifth year. The reduction in T2DM prevalence with GBP was 82% in the first year, 50% in the second year, 75% in the third year, 50% in the fourth year and 50% in the fifth year.

For complications of AGB that required re-hospitalisation or re-intervention, the rates used were:

2.62% for band removal;

1.57% for band removal and conversion to other bariatric surgery or major intervention on digestive tract;
4.05% for band replacement;

1.22% for band revision, repair and disconnection;

3.67% for re-intervention on port, connector or tube;

0.34% for incisional hernia repair, other wall intervention;

0.04% for other re-intervention with general anaesthesia (e.g. adhesion removal) or re-hospitalisation for other complications.

For complications of GBP that required re-hospitalisation or re-intervention, the rates used were:

0.7% for reoperation due to revision, fistula, perforation or erosion;

0.35% for reoperation due to splenectomy;

1.74% for reoperation due to cholecystectomy;

4.9% for endoscopic dilation of gastro-jejunal stenosis;

0% for intestinal segment resection;

0.38% for abdominal wall (incisional hernia, infection/haematoma);

3.37% for adhesiolysis, internal hernia, colon stenosis or occlusion;

1.63% for other complications (pulmonary embolism, ulcer).

The utility values were not presented.

Methods used to derive estimates of effectiveness
The authors used expert opinion to derive estimates of effectiveness that were not available from the review of the literature or did not reflect practice in 2005.

Estimates of effectiveness and key assumptions
Some of the assumptions made were reported. For example, a BMI reduction or increase of 1 kg/m2 was considered to have the same utility whatever the starting BMI. CT led, at best, to a temporary moderate reduction in BMI, with a return to baseline or possibly an overshoot after year 1. The relative prevalence of T2DM increases (decreases) when BMI increases (decreases).

Measure of benefits used in the economic analysis
The summary benefit measure used was the expected number of quality-adjusted life-years (QALYs). These were derived using an algorithm design that was extensively described in the paper. The QALYs were discounted at an annual rate of 3.5%. Two more measures, kg/m2 x years (which combines the magnitude and duration of BMI variation) and T2DM-free years, were also generated. Details on the estimation of these were reported. Specifically, kg/m2 x years represented the cumulative reduction of BMI scores over the 5-year time horizon of the analysis.

Direct costs
The analysis of the costs was restricted to direct medical costs relevant to the third-party payer. It included the costs of personnel (surgeons, physicians, nurses and nutritionists), imaging and laboratory tests, operating room overheads, postsurgical recovery room, hospital stay, consultations, reoperations in the case of complications, implants and other minor...
resources. The costs of managing T2DM were also included. These consisted of glycaemia control and the treatment of T2DM complications. The unit costs were presented separately from the quantities of resources used for some items. The quantities of resources used were derived from the literature, augmented with expert opinion, in order to reflect recent treatment patterns in each country. The costs came from national tariffs, registries, publications, and interviews when no other source was available. The costs of diabetes came from a published survey. Discounting was relevant, as 5-year costs were considered, and an annual discount rate of 3.5% was used. The price year was 2005.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not included in the economic analysis.

Currency
UK pounds sterling () in the UK and euros (EUR) in Germany and France.

Sensitivity analysis
A conventional sensitivity analysis was not carried out. However, a worst-case scenario was considered in which both ABG and GBP were assumed to be about 20% less effective in terms of BMI reduction and T2DM remission than in the base-case, and CT was low-cost watchful waiting only with no BMI reduction and no T2DM remission at all.

Estimated benefits used in the economic analysis
The expected QALYs over a 5-year time horizon were 2.00 with CT, 3.34 with GBP and 3.03 with AGB.

The cumulative kg/m² x years were 3.0 with CT, 83.8 with GBP and 60.8 with AGB.

The cumulative T2DM-free years were 0.2 with CT, 2.8 with GBP and 2.7 with AGB.

Cost results
In Germany, the cumulative 5-year costs per patient were EUR 17,197 with CT, EUR 12,166 with GBP and EUR 13,610 with AGB.

In France, the cumulative 5-year costs per patient were EUR 19,276 with CT, EUR 13,399 with GBP and EUR 14,796 with AGB.

In the UK, the cumulative 5-year costs per patient were 7,088 with CT, 9,121 with GBP and 9,072 with AGB.

Thus, both in Germany and in France, the extra cost of surgery for GBP and AGB was more than offset by a reduction in costs associated with T2DM.

Synthesis of costs and benefits
Incremental cost-utility ratios were calculated in order to combine the costs and benefits of the alternative treatments.

In France and Germany, ratios were not calculated since the incremental analysis revealed that both GBP and AGB dominated CT, which was both less effective and more expensive.

In the UK, the incremental cost per QALY gained with bariatric surgery over CT was 1,517 with GBP and 1,929 with AGB. Thus, both bariatric interventions were considered cost-effective, given the commonly quoted threshold of 20,000 per QALY.
The worst-case scenario confirmed the results achieved in the base-case analysis, with surgical interventions remaining dominant or cost-effective in all countries.

The budget impact analysis showed that treating a cohort of 1,000 patients led to cost-savings of EUR 5.03 million with GBP and EUR 3.59 million with AGB in Germany, and cost-savings of EUR 5.877 million with GBP and EUR 4.480 million with AGB in France. In the UK, there was a cost increase of 2.03 million with GBP and 1.98 million with AGB.

Authors' conclusions
Adjustable gastric banding (AGB) and gastric bypass (GBP) were cost-effective in the three European countries. Specifically, both bariatric surgical approaches were more effective and less expensive than conventional treatment (CT) in France and Germany, while they were highly cost-effective in the UK.

CRD COMMENTARY - Selection of comparators
The authors discussed the choice of the optimal comparator. It appears that the selection of CT was appropriate since it reflected the most conservative approach for the treatment of obese patients with T2DM. The two surgical procedures were appropriately selected. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from two sources, a review of the literature and expert opinion. The latter was used when published estimates were not available or relevant to the context in which the interventions were considered. The authors reported some details of the search but limited information on the primary studies was provided, although they stated that the best available evidence had been used. The authors did not report whether potential heterogeneity across the primary estimates was considered, and a weighted average appears to have been used to pool the clinical estimates. The issue of uncertainty surrounding the clinical estimates was not extensively investigated, as only a worst-case scenario was analysed.

Validity of estimate of measure of benefit
The use of QALYs as the summary benefit measure is appropriate since QALYs capture the impact of the intervention on two relevant dimensions of health for obese patients (i.e. survival and quality of life). QALYs have the further advantage of being comparable with the benefits of other health care interventions. Discounting was performed, as recommended by international guidelines. The approach used to evaluate QALYs was reported. The authors stated that the utility weights were elicited from a sample of 100 patients through a cross-sectional design, but longitudinal data derived from a larger group of patients would have been a more valid source of data. Two disease-specific measures were also reported.

Validity of estimate of costs
The analysis of the costs was consistent with the stated perspective. Some information on the unit costs and quantities of resources used was provided, although some costs were presented as macro-categories. This might limit the possibility of replicating the analysis in other settings. The sources of the costs were not extensively reported for all individual items. The costs were treated deterministically and the impact of using alternative cost estimates was not investigated. The authors noted that some costs might have been overestimated given the sources from which they were derived. The price year was reported, thus making reflation exercises in other time periods possible.

Other issues
The authors did not make extensive comparisons of their findings with those from other studies. Further, a conventional sensitivity analysis was not performed due to the uncertainty surrounding plausible ranges of values to be tested. Therefore, the use of a scenario analysis was preferred. Given the results of the worst-case scenario, the conclusions of the analysis would appear sound. The authors justified their choice of the time horizon for the analysis, which was appropriate for the study question. The issue of the transferability of the results was not addressed, but the study was
carried out in three European countries that showed similar findings. The study referred to obese patients with T2DM and this was reflected in the authors' conclusions.

**Implications of the study**
The study results support the use of bariatric surgery in obese patients with T2DM when at least 1 year of well-conducted medical treatment has failed.

**Source of funding**
Financial support from Ethicon Endo-Surgery.

**Bibliographic details**

**PubMedID**
17132416

**DOI**
10.1381/096089206778870067

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**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Body Mass Index; Budgets; Cost-Benefit Analysis; Diabetes Mellitus, Type 2 /complications /economics /surgery; Europe; Gastric Bypass /adverse effects /economics; Gastroplasty /adverse effects /economics; Health Care Costs; Humans; Models, Economic; Obesity /complications /economics /surgery; Treatment Outcome

**AccessionNumber**
22006002364

**Date bibliographic record published**
31/05/2007

**Date abstract record published**
31/05/2007