A prospective cost-effectiveness analysis of vertical banded gastroplasty for the treatment of morbid obesity

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
Vertical banded gastroplasty for the treatment of morbid obesity.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised morbidly obese patients (BMI greater than 40kg/m^2).

Setting
The setting was a hospital; the economic analysis was carried out in The Netherlands.

Dates to which data relate
Effectiveness and resource use data were collected from studies published between 1979 and 1996 and from a sample of 21 patients. Cost data were collected from a source published in 1994. The price year was not reported.

Source of effectiveness data
Effectiveness data were taken from a single study for the intervention, and from a review of previously completed studies and authors' assumptions for the comparator.

Link between effectiveness and cost data
The costing was carried out prospectively on the same patient sample as that used in the effectiveness analysis for the intervention.

Study sample
Twenty-one consecutive morbidly obese patients were enrolled in the study. The mean age before surgery was 33.1 years and the male:female ratio was 1:20. No power calculations were reported.

Study design
A prospective, before-and-after study was carried out at a single centre. Patients were followed-up for two years after surgery. No patient was lost to follow-up.
Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcomes used in the analysis were body weight, weight loss, complications, and quality of life. Effectiveness data were collected by means of a questionnaire 1 month before surgery and 1 and 2 years after surgery. Quality of life questionnaires included the Nottingham Health Profile part I (NHP-I), the Nottingham Health Profile part II (NHP-II), and a Visual Analogue Scale for quality of life assessment (VAS).

Effectiveness results
Body weight decreased from 125.6 kg before VBG to 79.7 kg one year after VBG (p<0.001) and 77.1 kg two years after surgery.

Body mass index decreased from 47.22 kg/m2 before VBG to 30.10 kg/m2 one year after VBG (p<0.001) and 29.17 kg/m2 two years after surgery.

Two years after VBG, 15 patients had a good result, three patients had a satisfactory result, and three patients had an unsatisfactory result.

Surgical complications were encountered in 14 patients, and revisional surgery was required in five patients.

NHP-I scores for mobility were 34.3 before VBG, 4.0 one year after VBG, (p<0.001), and 8.6 two years after VBG, (p<0.001).

NHP-I scores for energy were 68.0 before VBG, 11.2 one year after VBG, (p<0.001), and 19.8 two years after VBG, (p<0.001).

NHP-I scores for pain were 21.1 before VBG, and 4.9 one year after VBG, (p<0.05).

NHP-I scores for emotional reaction were 35.0 before VBG, and 11.8 one year after VBG, (p<0.05).

NHP-II scores were 16.7 before VBG, 8.0 one year after VBG (p<0.001), and 9.6 two years after VBG, (p<0.001).

VAS scores were 4.6 before VBG, 8.2 one year after VBG (p<0.001), and 7.1 two years after VBG, (p<0.001).

There was a significant improvement of the mobility domain of NHP-I in favour of the subgroup with satisfactory or good weight loss.

Clinical conclusions
The results showed a statistically significant improvement in outcome measures including quality of life, by VBG 1 year after the procedure.

Outcomes assessed in the review
The review assessed the prevalence of morbid obesity in the population, and diabetes mellitus, coronary heart disease, hypertension, cholecystolithiasis, and osteoarthritis in the total population and in the morbidly obese population.

Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
Not stated.
Criteria used to ensure the validity of primary studies
Not stated.

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

Number of primary studies included
At least 15 primary studies were included.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The prevalence of morbid obesity was estimated at 0.25% (optimistic) and 1% (pessimistic). The prevalence of diabetes mellitus was 2% in the total population and 24% in the morbidly obese population. The prevalence of coronary heart disease was 2.4% in the total population and 13% in the morbidly obese population. The prevalence of hypertension was 7.3% in the total population and 45% in the morbidly obese population. The prevalence of cholecystolithiasis was 0.5% in the total population and 20% in the morbidly obese population. The prevalence of osteoarthritis was 6.9% in the total population and 33% in the morbidly obese population.

Methods used to derive estimates of effectiveness
The authors made a number of assumptions regarding the calculation of the cost of morbid obesity ("no treatment"). The PAR was calculated as PAR = P(RR-1)/P(RR-1)+1), where P is the prevalence of morbid obesity, assumed to be either 0.25% (optimistic) or 1.00% (pessimistic), and RR is the Relative Risk of morbid obesity-related disease (as given in the review).

Estimates of effectiveness and key assumptions
PAR (at 0.25% and 1.00% prevalence) was:

- for diabetes mellitus, 2.7% and 9.9%;
- for coronary heart disease, 1.1% and 4.2%;
- for hypertension, 1.3% and 4.9%;
- for cholecystolithiasis, 8.9% and 28.1%; and
- for osteoarthritis, 0.9% and 3.7%.

Measure of benefits used in the economic analysis
Quality-adjusted life years (QALYs) were used as the outcome measure. Quality of life instruments included the Nottingham Health Profile part I (NHP-I), the Nottingham Health Profile part II (NHP-II), and a Visual Analogue Scale for quality-of-life assessment (VAS). Values were elicited from the 21 consecutive morbidly obese patients. QALYs were calculated with the DEALE method based on the mortality rate taken from a previously published study. Benefits
were discounted at an annual rate of 5%.

**Direct costs**
Direct costs were discounted at an annual rate of 5%. Quantities and costs were not reported separately. Direct costs related to the costs of surgical treatment, including operations, diagnostic and therapeutic procedures, outpatient visits, and the days occupying a hospital bed. The quantity/cost boundary adopted was that of the hospital. The costs of treatment of diseases in the general population (used to calculate the cost of "no treatment") were taken from published sources and were also based on the authors' assumptions as outlined above. Costs were based on real prices, not on charges. The price year was 1995.

**Statistical analysis of costs**
Cost differences before and after surgery were analysed using appropriate statistical tests.

**Indirect Costs**
Indirect costs were discounted at an annual rate of 5%. Quantities and costs were reported separately. Indirect costs included the costs of paid and unpaid labour, housekeeping, school, sick leave, and retirement. The quantity/cost boundary adopted was that of society. The value of indirect costs was determined by interviewing patients about their productivity status before and two years after surgery. Costs were based on real prices, not on charges. The price year was not reported. The proportion of patients performing paid labour increased from 19% before VBG to 48% after VBG. The proportion of patients having sick leave decreased from 38% before VBG to 10% after VBG. Overweight as the reason for unemployment was more common before VBG than after VBG (47% versus 18%; p<0.05).

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were conducted on the prevalence of obesity, the complication rate, and the definition of surgical failure.

**Estimated benefits used in the economic analysis**
3.6 life years were gained with VBG. The improvement on the VAS scale was 0.25, resulting in 12 QALYs gained when a lifelong scenario was considered.

**Cost results**
The costs of illness attributable to morbid obesity ("no treatment") amounted to $37 million per year (prevalence of 0.25%), or $131.3 million per year (prevalence of 1%).

The costs per morbidly obese person were $987 per year (0.25% prevalence) and $875 per year (1% prevalence).

Over a lifetime this gives $9,367 (0.25% prevalence) and $8,304 (1.00% prevalence). Following VBG this was $1,338 (0.25% prevalence) and $1,186 (1.00% prevalence).

The direct costs of VBG were $5,865.

The mean yearly income after taxes of patients performing paid labour increased from $2,215 to $5,429, (p<0.05) due to VBG.

The increased employment rate and decreased sick leave after VBG resulted in a productivity gain of $2,765 per year
due to VBG or $48,879 over a lifetime.

This results in an incremental saving from VBG of $48,043 at a prevalence of 0.25% or $47,132 at a prevalence of 1.00%.

**Synthesis of costs and benefits**
It was stated that the sensitivity analysis showed that changing parameter values did not have a significant effect on the cost-effectiveness outcomes. No results were shown.

**Authors’ conclusions**
The authors argued that the treatment of morbid obesity with VBG produced more QALYs and lower costs than no treatment and should therefore be introduced or continued from a societal point of view.

**CRD COMMENTARY - Selection of comparators**
The explicit comparator was no treatment. You, as a user of the database, should decide if this approach is relevant to your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a prospective before and after study, supplemented with observational data from a literature review and the authors’ assumptions. The cost-effectiveness analysis was carried out on a small sample and the authors did not show whether this sample was representative of the study population, although they did report some demographic characteristics. Also, this study design is weak in terms of controlling for bias. Additional effectiveness estimates were taken from a number of studies. The authors undertook a literature review to derive prevalence estimates, which seemed appropriate, although they did not state that a systematic review of the literature had been undertaken. More information about the design of the review could have been provided. The authors stated that the prevalence of morbid obesity was not precisely known and that obesity-related comorbidities were not entered into the analysis if the prevalence was too low, or if not all the required information was available. Comorbidities such as heart failure, liver steatosis, and pulmonary disease were not included. There was also an implicit assumption that direct costs would be in proportion to the PAR.

**Validity of estimate of measure of benefit**
The estimation of benefits was modelled. The instruments used to derive measures of health benefit, the NHP-I and II and the VAS, were appropriate. Values were taken from patients.

**Validity of estimate of costs**
Good features of the cost analysis were that most relevant direct and indirect cost categories were included. However, quantities and costs were not reported separately, which makes it difficult to replicate the cost results in other settings. The authors did not conduct sensitivity analyses on costs which limits the generalisability of the results. Also, the results of the sensitivity analysis were not given. Costs were based on real prices, not on charges. Indirect costs were based on patient reports. Given that some comorbidities were excluded, the present study underestimated the costs attributable to morbid obesity.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies, and addressed the issue of generalisability to other settings. The study considered morbidly obese patients and this was reflected in the authors’ conclusions. As the authors acknowledged, the study extrapolated two-year results to a lifelong scenario with no allowance being made for change in the effect of treatment.
Implications of the study
"Because treatment of morbid obesity with VBG results in QALYs gained and less costs, there is no doubt that this procedure should be introduced or continued from a societal point of view." As the authors acknowledged, the quality of their data sources was generally low in terms of control for biases. They also had to make assumptions in instances where data were missing. The study would have been much improved by evidence of a thorough sensitivity analysis.

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