Health Technology Assessment 2002; Vol. 6: No. 12

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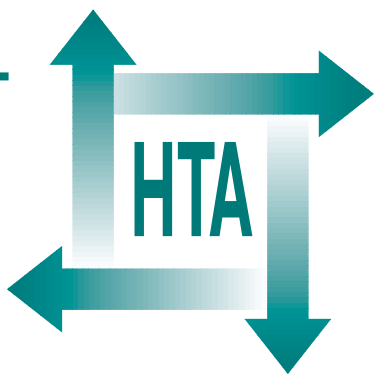
Health Technology Assessment
NHS R&D HTA Programme



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Declared competing interests of authors: none

Published July 2002

This report should be referenced as follows:

Clegg AJ, Colquitt J, Sidhu MK, Royle P, Loveman E, Walker A. The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation. *Health Technol Assess* 2002;**6**(12).

Health Technology Assessment is indexed in *Index Medicus*/MEDLINE and *Excerpta Medica*/EMBASE. Copies of the Executive Summaries are available from the NCCHTA website (see opposite).

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The research reported in this monograph was commissioned by the HTA Programme on behalf of the National Institute for Clinical Excellence (NICE). Rapid reviews are completed in a limited time to inform the appraisal and guideline development processes managed by NICE. The review brings together evidence on key aspects of the use of the technology concerned. However, appraisals and guidelines produced by NICE are informed by a wide range of sources.

The research reported in this monograph was funded as project number 01/22/01.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme, NICE or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for any recommendations made by the authors.

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ISSN 1366-5278

Published by Core Research, Alton, on behalf of the NCCHTA.
Printed on acid-free paper in the UK by The Basingstoke Press, Basingstoke.

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Contents

List of abbreviations

AGB	adjustable gastric banding
ANOVA	analysis of variance*
ASGB	adjustable silicone gastric banding
BMI	body mass index
BP	blood pressure*
CHD	coronary heart disease
CI	confidence interval
CVD	cardiovascular disease
DBP	diastolic blood pressure
DOP	Danish Obesity Project
EQ5D	EuroQol-5 dimensions
EWL	excess weight loss*†
GB	gastric bypass
GBan	gastric banding
GG	gastrogastrostomy*
GHRI/CH	general health rating index – current health scale
GP	gastroplasty (also known as gastric partitioning)
HAD scale	hospital anxiety and depression scale
HDL	high-density lipoprotein
HDU	high-dependency unit
HRQoL	health-related quality of life
IBW	ideal body weight*
IGB	isolated gastric bypass*
IHRQoL	index of health-related quality of life
IQR	interquartile range*
ITT	intention-to-treat*
ITU	intensive therapy unit
JB	jejunoileal bypass
LDL	low-density lipoprotein
MACL	mood adjective checklist
MBW	maximal body weight*
MW	Mann–Whitney *U* test*
NA	not applicable*
NHANES	National health and nutrition examination survey
NHP	Nottingham Health Profile
NHS CRD	NHS Centre for Reviews and Dissemination (University of York)
NICE	National Institute for Clinical Excellence
ns	not significant
OP scale	obesity-related psychosocial problems scale
OR	odds ratio*
PAR	population attributable risk*
PSS	Personal Social Services
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomised controlled trial
RYGB	Roux-en-Y gastric bypass (also known as Roux-en-Y gastrojejunostomy and Roux-en-Y gastric exclusion)
SBP	systolic blood pressure
SD	standard deviation
SEK	Swedish krona
SEM	standard error of the mean*
SF-36	short form-36 health survey questionnaire
SIP/SI	sickness impact profile – social interaction category
SOS	Swedish Obese Subjects
VAS	visual analogue scale
VBG	vertical banded gastroplasty
VLCD	very-low-calorie diet

* Used only in tables
† % excess weight loss = (weight loss) × 100/ (initial weight – ideal weight)

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 complications 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.

Chapter 1

Background and aim

Background

Description of the underlying health problem

Severe or morbid obesity is commonly defined as a body mass index (BMI) of over 40 (*Table 1*), where BMI is calculated as body weight in kilograms divided by height in metres squared. Obesity is associated with significant excess disease and mortality, and imposes a considerable economic burden on society. Direct costs of obesity in England for 1998 have been estimated at £480 million or about 1.5% of NHS expenditure, and indirect costs (lost earnings due to mortality and sickness) at £2.1 billion.[2]

TABLE 1 *Description of BMI*[1]

BMI (kg/m^2)	Description
20 or less	Underweight
Over 20–25	Desirable
Over 25–30	Overweight
Over 30	Obese
Over 40	Morbid obesity

Reproduced from ref. 1

Epidemiology

The prevalence of obesity (BMI > 30) amongst adults in England has been reported at 17.3% of men and 21.2% of women. Of these, 0.6% of men and 1.9% of women were classified as morbidly obese (BMI > 40).[1] For a typical health authority with a population of 500,000 there would be approximately 6250 cases of morbid obesity, and for a typical primary care trust with a population of 200,000 there would be approximately 2520 cases. The prevalence of obesity in England has been increasing, with an overall age-standardised increase in mean BMI from 1994 to 1998 of 0.44 kg/m^2 (95% confidence interval (95% CI), 0.31 to 0.57) for men and 0.57 kg/m^2 (95% CI, 0.41 to 0.72) for women. Prevalence increases with age until 55–64 years in men and 65–74 years in women, and then begins to decline (*Table 2*). The number of men and women with obesity in England and Wales can be seen in *Table 3*. Obesity is more common among manual than non-manual social classes in both men and women (*Table 4*), with prevalence of morbid obesity increasing from 0.4% and 0.7% respectively in social class I to 1.6% and 3.3% respectively in social class V.[1]

Significance in terms of ill-health

Obesity is a risk factor for a number of diseases, in particular cardiovascular disease (CVD) and type 2 diabetes, and is also associated with increased all-cause mortality at any given age, even after adjustment for potential confounding variables such as smoking. The risk of mortality for a person with a BMI of 30 is approximately 50% higher than that for someone with a healthy BMI, and the risk is more than doubled with a BMI of 35.[4] Some studies have demonstrated a linear relationship between BMI and mortality, although others show a 'U'- or 'J'-shaped relationship with increased mortality in those with a low BMI.[4,5]

CVD refers to coronary heart disease (CHD), stroke and peripheral vascular disease. Obesity predisposes to a number of CVD risk factors including hypertension, raised cholesterol and impaired glucose tolerance, but it is also an independent risk for CVD. After adjustment for age and smoking, the risk of both non-fatal myocardial infarction and fatal CHD was found to be more than three times higher in women with a BMI of 29 or more than in women with a BMI less than 20.[6] Similarly, the risk of developing CHD in men with a BMI greater than 33 is three times that of men with a BMI less than 23.[7]

The evidence for an association between obesity and stroke is less conclusive. Recently reported results from the United States national health and nutrition examination survey (NHANES I) demonstrated a complex relationship among stroke risk, ratio of subscapular to triceps skinfold thickness, BMI, smoking, sex and race, with no significant associations seen in white women or black men.[8]

The positive association between blood pressure and BMI is well documented. The US NHANES III study[9] found that mean systolic and diastolic

TABLE 2 *Prevalence of BMI by age and sex, 1994 and 1998*[1]

BMI (kg/m^2)	Age							Total
	16–24 %	25–34 %	35–44 %	45–54 %	55–64 %	65–74 %	75+ %	%
1994								
Men								
20 or under	16.0	4.8	1.9	1.8	1.4	2.9	2.6	4.5
Over 20–25	53.4	45.6	36.4	30.3	29.4	26.1	34.6	37.3
Over 25–30	24.9	39.8	46.2	50.7	51.4	53.1	48.2	44.3
Over 30–40	5.5	9.5	15.1	16.7	17.4	17.6	13.9	13.4
Over 40	0.2	0.4	0.4	0.5	0.4	0.2	0.8	0.4
All over 30 (obese)	5.7	9.8	15.5	17.2	17.8	17.9	14.7	13.8
Mean	23.5	25.3	26.4	26.8	27.0	27.0	26.5	26.0
SEM	0.12	0.10	0.11	0.11	0.12	0.13	0.21	0.05
Women								
20 or under	19.6	9.5	4.9	3.8	2.4	4.9	8.0	7.4
Over 20–25	52.2	52.9	50.3	42.0	33.4	29.1	39.6	43.9
Over 25–30	20.3	24.7	27.9	36.4	38.7	40.7	36.1	31.4
Over 30–40	7.1	11.6	15.0	16.5	23.2	23.0	15.4	15.7
Over 40	0.8	1.3	1.8	1.3	2.3	2.3	0.9	1.6
All over 30 (obese)	7.9	12.9	16.9	17.8	25.5	25.3	16.3	17.3
Mean	23.5	24.8	25.7	26.3	27.5	27.3	25.7	25.8
SEM	0.14	0.12	0.13	0.14	0.16	0.15	0.18	0.06
1998								
Men								
20 or under	13.5	3.1	2.4	1.9	0.9	1.7	3.9	3.6
Over 20–25	58.7	40.6	32.9	24.8	23.6	21.7	32.1	33.5
Over 25–30	22.7	40.4	47.9	52.0	52.2	55.3	48.0	45.5
Over 30–40	5.1	15.3	16.4	20.1	22.4	20.4	15.7	16.7
Over 40	0.1	0.6	0.5	1.1	0.9	0.8	0.2	0.6
All over 30 (obese)	5.2	15.9	16.8	21.2	23.3	21.2	15.9	17.3
Mean	23.5	26.1	26.7	27.4	27.8	27.5	26.4	26.5
SEM	0.13	0.12	0.11	0.12	0.13	0.14	0.19	0.05
Women								
20 or under	18.6	7.7	4.3	3.7	3.0	4.5	7.2	6.6
Over 20–25	54.0	48.8	45.1	36.3	29.2	25.3	34.6	40.0
Over 25–30	16.6	27.1	30.1	36.1	39.2	41.3	37.4	32.1
Over 30–40	9.5	14.7	17.5	21.9	26.3	27.2	20.0	19.3
Over 40	1.2	1.6	3.0	2.0	2.3	1.8	0.7	1.9
All over 30 (obese)	10.7	16.3	20.5	23.9	28.6	29.0	20.7	21.2
Mean	23.8	25.5	26.4	27.0	27.6	27.8	26.4	26.4
SEM	0.16	0.13	0.14	0.14	0.16	0.17	0.18	0.06

SEM, standard error of the mean

Reproduced from ref. 1

TABLE 3 *Numbers (000s) with obesity by age and sex in England and Wales*[1,3]

BMI (kg/m^2)	Age							
	16–24	25–34	35–44	16–44	45–64*	65–74	75+	Total
Men								
Over 30–40	164.9	641.1	623.7	1429.6	1279.0	416.2	217.0	3451.4
Over 40	3.2	25.1	19.0	47.4	60.2	16.3	2.8	124.0
Women								
Over 30–40	291.7	586.1	649.6	1527.3	1466.5	642.2	501.2	4192.2
Over 40	36.8	63.8	111.4	212.0	130.8	42.5	17.5	412.7

* *Owing to differences in age groupings for data on prevalence and population numbers, these data for age 45–64 represent rough estimates of numbers with obesity. Caution should be taken when interpreting the data*

Reproduced from refs 1 and 3

TABLE 4 *Age-standardised BMI by social class of head of household*[1]

BMI (kg/m^2)	Men						Women					
	Social class of head of household						Social class of head of household					
	I %	II %	IIINM %	IIIM %	IV %	V %	I %	II %	IIINM %	IIIM %	IV %	V %
Over 25–30	45.9	46.8	43.1	43.9	43.5	39.5	30.4	32.5	31.0	32.2	31.7	31.8
Over 30	11.6	15.7	16.4	19.6	15.8	17.7	14.4	18.4	18.2	24.0	25.1	28.1
Over 40	0.4	0.5	0.2	0.8	0.5	1.6	0.7	1.5	1.1	2.4	2.8	3.3
Mean	25.9	26.5	26.2	26.7	26.2	26.2	25.4	26.0	25.9	26.7	26.9	27.2
SEM	0.17	0.09	0.16	0.10	0.14	0.26	0.21	0.10	0.14	0.12	0.16	0.28

NM, non-manual; M, manual

Reproduced from ref. 1

blood pressure (SBP and DBP) increased with increasing BMI in men and women. Defining hypertension as SBP ≥ 140 mmHg and DBP ≥ 90 mmHg, the prevalence of hypertension increased from 15% of men and women with a BMI less than 25, to 42% of men and 38% of women with a BMI over 30.

Obesity is associated with abnormalities in serum lipid levels, whereby total cholesterol, triglycerides and LDL (low-density lipoprotein)-cholesterol are raised, and HDL (high-density lipoprotein)-cholesterol is reduced. These abnormalities may be associated with increased risk of CHD. NHANES III[9] found that the prevalence of raised cholesterol (≥ 240 mg/dl) in obese men and women was 22% and 27% respectively, compared with 13% of adults with a BMI less than 25. HDL-cholesterol decreased with increasing BMI. The prevalence of low HDL-cholesterol (< 35 mg/dl men, < 45 mg/dl women) in obese adults was 31% of men and 41% of women compared with 9% and 17% respectively in adults with desirable weight.

Type 2 diabetes is a serious life-shortening condition, which predisposes to high blood pressure and heart disease. The risk of developing diabetes rises with increasing BMI even below the threshold of clinical obesity. The risk of diabetes in women and men with a BMI between 25 and 26.9 was found to be 6.5[10] and 2.2[11] respectively, after controlling for other risk factors such as age, family history of diabetes and smoking. The risk rose to 15.9 for women with a BMI of 31 or more[10] and to 42.1 for men with a BMI of 35 or more.[11] A comprehensive review of international studies examining the association between diabetes and obesity estimated the relative risk of diabetes in adults with a BMI over 30 as 12.7 in women and 5.2 in men[2] (*Table 5*). However, precise relative risks for BMI over 30 are difficult to produce because of the different cut-off points used in published studies, and ethnic differences in the prevalence of diabetes despite no significant difference in BMI.[12]

A positive linear relationship between BMI and risk of death from cancer has been demonstrated, with

TABLE 5 *Estimated increased risk for obese individuals of developing associated diseases*[2]

Disease	Relative risk	
	Women	Men
Type 2 diabetes	12.7	5.2
Hypertension	4.2	2.6
Myocardial infarction	3.2	1.5
Cancer of the colon	2.7	3.0
Angina	1.8	1.8
Gallbladder diseases	1.8	1.8
Ovarian cancer	1.7	–
Osteoarthritis	1.4	1.9
Stroke	1.3	1.3

Reproduced from ref. 2

a 40–80% increase in risk among the heaviest men and women.[5] Obesity is associated with an increased risk of cancer at a number of sites. A recent meta-analysis of the association between obesity and cancer risk[13] estimated the excess risk of postmenopausal breast cancer at 12% for overweight and 25% for obese women. The increase in risk for overweight and obese people respectively was 15% and 33% for colon cancer, 36% and 84% for kidney cancer, and 34% and 78% for gallbladder cancer. A 6% increase in risk of prostate cancer for overweight men and a 12% increase for obese men was demonstrated, while risk of endometrial cancer was increased by 59% for overweight women and 152% for obese women. The proportion of cancers in Europe attributable to excess weight was estimated at 8.5% of breast cancer cases in women aged 50 years and over and 6.6% of cases for all ages, 11% of colon cancers, 4% of prostate cancers, 39% of endometrial cancers, 25% of male cases and 24% of female cases of kidney cancer, and 24% of gallbladder cancers.

Osteoarthritis, or degenerative disease of the knee and other weight-bearing joints, and lower back pain are common in obesity. Although these effects are thought to be due to excess weight, there may also be a metabolic effect as an association between obesity and incident symptomatic osteoarthritis in the hands has been demonstrated.[14]

Respiratory disorders such as obstructive sleep apnoea are associated with obesity. An increase in BMI of 1 standard deviation (SD) has been associated with an odds ratio of 4.2 for sleep-disordered breathing.[15]

Reproductive disorders are common in obesity, occurring in both women and men, and obese women have a higher risk of complications during pregnancy, such as hypertensive disease, pre-eclampsia, diabetes[16] and neural tube defects.[17,18] There is also an increased risk of Caesarean delivery among obese women with or without antenatal complications. Among those with antenatal complications, 15% of normal weight women have Caesarean delivery, compared with 24% of obese and 23% of morbidly obese women, while 10% of normal weight women without antenatal complications have Caesarean delivery compared with 12% of obese and 20% of morbidly obese women.[16]

Summary of increased risk of disease associated with obesity

Using data from international studies due to the lack of comparable data in the UK, the National Audit Office report[2] has summarised the relative risk of disease in men and women with obesity (*Table 5*). Different methodologies and definitions of obesity were used by the different studies, so caution should be taken when using these estimates.

Consequences of weight loss in obese individuals

Despite evidence from a number of studies of the health benefits of weight loss in the short-term, there have been few studies examining the benefits of long-term weight loss. Published estimates of the impact of weight loss on CVD and diabetes suggest that substantial benefits are produced by modest weight loss. The benefits of 10 kg of weight loss have been summarised by a review of the literature[19] and can be seen in *Table 6*.

Adverse effects of weight loss should also be noted, as there is evidence that obese women who lose 4–10 kg in weight have a 44% increase in risk of gallstones caused by the increase in circulating cholesterol, and bone density may be decreased.[20] In addition, an observational study in the USA showed that moderate intentional weight loss is associated with lower total mortality from CVD or diabetes, but that higher mortality from these causes is associated with weight loss over 30 kg.[21] However, limited information is provided on the reasons for intentional weight loss, methods used or long-term patterns of weight loss.

Limitations of the evidence on the health consequences of obesity

There are a number of limitations that should be considered when using the information on co-morbidities in the cost-effectiveness analysis:

TABLE 6 *Benefits of a 10-kg weight loss*[19]

Blood pressure	Angina	Lipids	Diabetes
• Fall of 10 mmHg systolic pressure • Fall of 20 mmHg diastolic pressure	• 91% reduction in symptoms • 33% increase in exercise tolerance	• 10% fall in total cholesterol • 15% fall in LDL-cholesterol • 30% fall in triglycerides • 8% increase in HDL-cholesterol	• > 50% reduction in risk of developing diabetes • 30–50% fall in fasting blood glucose • 15% fall in glycosylated haemoglobin

Adapted from a table published in ref. 19

- The relative risk data reported comes from a number of large-scale prospective studies based in North America and Western Europe. There are therefore uncertainties about applying this data to the UK population.
- Published studies often use different cut-off points for defining obesity.
- There is a continuous relationship between BMI and risk of diseases such as diabetes that is not taken into account when examining risk of disease according to BMI ranges.
- The majority of studies looking at the impact of weight loss in the obese are short-term. Longer-term studies face difficulties in maintaining weight loss and in the need to distinguish intentional from unintentional weight loss. Unintentional weight loss may indicate disease-driven weight loss and is often associated with increased mortality and morbidity.

Current service provision

In the NHS, obesity is managed mainly in general practice, with the most common approach being advice on weight control, diet, physical exercise and lifestyle provided by the general practitioner or practice nurse.[2] Depending on the degree of obesity and extent of clinical complications, drug therapy may be prescribed and/or onward referral given to a weight loss specialist such as a state-registered dietitian, private sector slimming group or physician specialising in weight problems. The National Institute for Clinical Excellence (NICE) have recently recommended that orlistat should be available as part of the overall treatment plan management of obesity for adults with a BMI of at least 30 kg/m^2 or 28 kg/m^2 with serious co-morbid disease, and sibutramine for adults with a BMI of at least 30 kg/m^2 or 27 kg/m^2 with serious co-morbid disease.[22,23] Patients should have lost at least 2.5 kg by diet and increased activity in the month prior to their first prescription of orlistat. Specialist obesity clinics use a combination of interventions, including drug therapy, very-low-calorie diets (VLCDs) and sometimes psychologist input. However, just 12 obesity clinics were identified in England by an unpublished survey by the NHS Clinical Group in 1998,[2] and these have long waiting lists despite limited evidence of their effectiveness. Around 200 operations for obesity are carried out each year in the UK and many of them are funded privately.[24] However, not all of these options are available to all NHS patients due to limited local access.

Description of interventions considered in this review

Surgery for morbid obesity is usually considered an intervention of last resort for patients who have attempted other forms of medical management (such as dieting, behaviour change, increased physical activity and drug therapy) without achieving permanent weight loss. Surgery is restricted to those with morbid obesity (BMI ≥ 40) or with a BMI ≥ 35 with serious co-morbidities such as arthritis, back or disc disease, diabetes, hypertension, hiatus hernia, gallbladder disease, shortness of breath, fatigue, elevated serum cholesterol or disability. Ideally, patients should have no major perioperative risk factors, a stable personality, and no eating disorders.[25]

Surgical procedures for those with morbid obesity aim to reduce weight and maintain any loss through restriction of intake and/or malabsorption of food. It is hoped that eating behaviour is modified as a consequence, with patients consuming smaller quantities of food more slowly. If not, patients will suffer complications such as vomiting, dumping syndrome and diarrhoea. In addition to modifying eating

habits, patients are encouraged to commit to daily exercise as part of a wider change in lifestyle. Advice on postoperative diet is required to help patients modify their eating habits irrespective of the particular procedure. In fact, patients undergoing any surgical procedure for morbid obesity will need to follow some form of liquid diet, progressing to a 'sloppy diet' and then a more normal diet. Patients will require advice to prevent complications such as vomiting and dumping syndrome and failure to lose weight through high-calorie foods.

The importance of diet and lifestyle modification as part of the management of morbid obesity emphasises the role of the dietitian and/or nutrition nurse as part of a multidisciplinary team. Expert advice suggests that it is generally believed that care should involve a physician, surgeon, anaesthetist and dietitian/nutrition nurse, all with a special interest in obesity. Some teams may also include a psychologist or psychiatrist.

Surgery for morbid obesity is a major surgical intervention with a risk of significant early and late morbidity and of perioperative mortality. Surgery may be contraindicated if patients suffer from certain conditions, including: perioperative risk of cardiac complications; poor myocardial reserve; significant chronic obstructive airways disease or respiratory dysfunction; non-compliance with medical treatment; psychological disorders of a significant degree that would be considered by a psychologist/psychiatrist to become exacerbated or to interfere with the long-term management of the patient after the operation; eating disorders of significance; or, severe hiatus hernia/gastro-oesophageal reflux. The severity of these conditions will need to be assessed prior to considering surgery.

Prior to surgery, patients should be made aware of the nature of the procedure and how it fits into the overall management programme for morbid obesity. Patients may require antibiotic prophylaxis at anaesthesia and must have prophylactic measures to guard against perioperative thromboembolic disease.

Several different surgical procedures have been used for people with morbid obesity, including jejunoileal bypass (JB), biliopancreatic diversion, gastric bypass (GB), gastroplasty (GP) and gastric banding (GBan). The following section briefly discusses these procedures and their complications. The section does not provide a comprehensive discussion of the many variants that have developed. Intragastric balloons are not discussed as these are considered a short-term or temporary measure and not a comparator for the other surgical procedures.

Malabsorptive procedures

Jejunoileal bypass

JB is generally considered to be of historical interest, rarely undertaken in Europe and the USA owing to the unacceptably high morbidity and mortality (liver failure and cirrhosis) due to the procedure.[25,26] The procedure involves bypassing large parts of the nutrient absorptive gastrointestinal tract and undertaking end-to-end or end-to-side anastomosis of the proximal jejunum to distal ileum. There are inevitable complications as people are affected by the malabsorption of carbohydrate, protein, lipids, minerals and vitamins. With the end-to-side JB, some reflux of bowel content may occur, thereby reducing weight loss. Other complications of JB include: diarrhoea due to irritation of the colon by bile acid and fat usually absorbed in the small intestine; increased risk of cholesterol stones in the gallbladder; hepatic cirrhosis; osteoporosis; osteomalacia; neuropathy; and night blindness associated with mineral and vitamin deficiency. As a consequence, these procedures are not recommended and people with such procedures still intact are carefully monitored and early reversal considered. Developments of the JB, known as the ileogastrostomy, have been reported.[27] Although a case series of 50 patients has suggested that the unacceptable complications from JB have been overcome whilst maintaining weight loss and high levels of patient satisfaction, the results should be interpreted cautiously due to selective reporting of patients and outcomes.

Biliopancreatic diversion (Scopinaro's procedure)

Biliopancreatic diversion was first reported in 1978 by Scopinaro and has become popular in Europe. It involves a limited gastrectomy to limit oral intake and induce weight loss, followed by the construction of a long limb Roux-en-Y anastomosis with a short, common, 'alimentary' channel of 50 cm in length causing malabsorption to maintain weight loss. As the procedure does not defunctionalise any part of the small intestine, fewer liver problems are caused. Biliopancreatic diversion is considered to be a technically demanding procedure with an operative mortality of 2% and a major perioperative morbidity of 10%.[25] Complications of the procedure include loose stools, stomal ulcers, offensive body odour

and foul smelling stools and flatus. Serious complications include anastomotic ulceration (3–10%), protein malnutrition (3–4%), hypoalbuminaemia, anaemia (< 5%), oedema, asthenia and alopecia.[25,28] In some instances patients require further hospitalisation and hyperalimentation. As a result of malabsorption, for the rest of their lives patients usually need calcium and vitamin supplements and follow-up. In an attempt to overcome these complications, particularly stomal ulceration and diarrhoea, several variants of the procedure have been developed. Sleeve resection of the stomach maintains continuity of the gastric lesser curve, while the duodenal switch maintains continuity of the gastroduodeno-jejunal axis. Despite the complications it is considered to be an attractive option as patients may remain on a totally free diet in all instances.

GB (Roux-en-Y and resectional)

The Roux-en-Y and resectional GB procedures combine restriction and malabsorption techniques, creating both a small gastric pouch and a bypass that prevents the patient from absorbing all they have eaten. The Roux-en-Y procedure entails partition of the upper part of the stomach using surgical staples to create a small pouch (50 ml or less) with a small outlet (gastroenterostomy stoma) to the intestine that is attached to the pouch. The Roux-en-Y technique is used to avoid loop gastroenterostomy and bile reflux that may ensue. Adaptations of the procedure, including lengthening of the Roux-en-Y limb to 100–150 cm and use of retrocolic and retrogastric routing of the gastrojejunostomy, have been used to increase both malabsorption and weight loss. Often, a prosthetic band, such as a Silastic ring or Gortex band, is positioned above the junction of the gastric pouch and small intestine to stabilise the gastroenterostomy, preventing late stretching of the opening and improving long-term weight control. Resectional GB differs in that it consists of a subtotal gastrectomy (removal of part of the stomach) with a Roux-en-Y reconstruction.[25]

Complications associated with the surgery include: failure of the staple partition; leaks at the junction of the stomach and small intestine; acute gastric dilatation either spontaneously or secondary to a blockage at the Y-shaped anastomosis; and problems experienced by obese people undergoing surgery (such as lung collapse, blood clots, wound infections and fluid collection). Failures of the staple line have been reduced by either staple transection of the stomach or superimposed staple rows causing firm scarring along the staple line. Other complications may occur following surgery, including: vomiting caused by narrowing of the stoma due to scar tissue development, correctable through stretching by use of an endoscopic balloon dilatation as a day case; wound hernias and intestinal obstruction; anaemia due to lack of absorption of iron and vitamin B_{12} and calcium deficiency (all are overcome by supplements); and dumping syndrome, which is caused by eating refined sugar and includes rapid heart beat, nausea, tremor, a faint feeling and diarrhoea. It is thought that the dumping syndrome aids weight loss by conditioning the patient against eating sweets.

Advice on diet suggests a liquid diet for several weeks after the operation and improved eating habits involving small meals and multivitamin supplementation. Typically, GB requires up to 10 days of inpatient stay, with most patients unable to go back to work until after 1 month following surgery.

Restrictive procedures

GP (horizontal banded and vertical banded)

Horizontal GP and vertical banded gastroplasty (VBG) involve the partitioning of the stomach into two parts. Using surgical staples, a small segment at the top of the stomach is partially separated from the remainder of the stomach, with only a small gap (stoma) remaining. The intention is to cause the individual to have the sensation of fullness from a limited intake of food, a consequence of the reduced capacity of the small upper segment of the stomach and the slow emptying through the small gap into the remainder of the digestive system. Horizontal GP has a staple line placed transversely across the entire stomach with a gastrogastrostomy (anastomotic channel between upper and lower parts of the stomach) to preserve intestinal continuity. This method allows the diameter of the anastomotic channel to be precisely regulated, helping to overcome the stretching of the muscular stomach wall and the enlarging of the gap that tended to result from partial stapling of the stomach. A band may be used to help prevent stretching. Horizontal banded GP is very rarely used, if at all, owing to the advent of other more successful procedures in terms of weight loss and complications.

VBG is more commonly performed due to fewer complications and higher durability compared with horizontal GP. Although it can be undertaken laparoscopically, it is a difficult procedure. It overcomes the limitations of the horizontal procedure by placing the GP vertically in the

part of the stomach with the least curvature and thickest wall in order to limit stretching. In addition, a polypropylene band is used around the lower end of the vertical pouch to prevent stretching. This procedure has the advantage of being a restrictive procedure with no malabsorption component or dumping. Postoperative mortality rates are relatively low (1%). Revision rates requiring further surgical intervention are often high at approximately 30%. Specific complications include bolus obstruction and there are few instances of anaemia or calcium or vitamin deficiencies. The only restrictions are that people should chew food thoroughly to avoid vomiting and high-calorie liquids should be avoided. Other complications associated with the operative procedure include leakage, stenosis, ulcer, incisional hernia, wound infection, staple line disruption, pouch dilation and band erosion. Open VBG usually requires similar inpatient stay and time to return to work as that of GB: up to 10 days hospitalisation and return to work after at least a month.

Gastric banding

GBan limits food intake by placing a constricting ring completely around the stomach below the junction of the stomach and oesophagus. While early bands were non-adjustable, those used currently incorporate an inflatable balloon within their lining to allow adjustment of the size of the stoma to regulate food intake. Increasingly, gastric bands are placed through laparoscopic surgery, decreasing wound complication rates and time spent in hospital to 1 day, with patients returning to work within 7 days. Adjustment is undertaken without the need for surgery by adding or removing an appropriate material (e.g. saline) through a subcutaneous access port. As a restrictive procedure, GBan avoids the problems associated with malabsorptive techniques such as anaemia, dumping and vitamin/mineral deficiencies. Other complications associated with GBan include those associated with operative procedures, such as splenic injury, oesophageal injury and wound infection, and those occurring later, such as band slippage, reservoir deflation/leak, persistent vomiting, failure to lose weight and acid reflux. Following surgery patients are usually seen regularly until they achieve their target weight and then on an infrequent basis thereafter. Often, patients will be advised on nutrition postoperatively.

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.

Chapter 2

Methods for systematic review and economic evaluation

The *a priori* methods for systematically reviewing evidence of clinical effectiveness and the economic evaluation are described in the research protocol (appendix 1). Expert comments were obtained from the review advisory group (see *Acknowledgements*, page 57). Although many helpful comments were received relating to the general content of the research protocol, there was none that identified specific problems with the methods of the review. Some changes, additions or points of clarification were made to the methods discussed in the original protocol and these are outlined below.

- Originally excluded from the review, JB was included in the review following a request from NICE with the aim of addressing the issue concerning the effects of complications and mortality following this procedure. Gastric balloons were excluded as expert advice suggested that these were not a definitive treatment.
- Appropriate follow-up for assessing the effectiveness of interventions for morbid obesity should extend to 5 years rather than 1 year. Although this was noted in the research protocol, a 1-year minimum follow-up was used for inclusion of studies and the period of follow-up was noted in the data extractions.
- The composition of the multidisciplinary team involved with gastric surgery was emphasised, including an endocrinologist, psychologist, dietitian or nutrition nurse, and surgeon.
- The economic evaluation will be from the perspective of the NHS and Personal Social Services (PSS) for both costs and benefits.

Sources of information, search terms and a flowchart outlining the identification of studies are described in appendix 2. Although manufacturers' submissions to NICE were reviewed no additional studies on the clinical effectiveness or cost-effectiveness of surgery for morbid obesity were included. Information on quality of life (QoL) was provided by Roche Pharmaceuticals from a previous submission to NICE and was used in the economic evaluation.

Studies identified by the search strategy were assessed for inclusion through three stages. The titles and abstracts of all identified studies were screened by one reviewer and checked by a second reviewer. The full text of relevant papers was obtained and inclusion criteria applied independently by two reviewers. Data were extracted by one reviewer using a standard data extraction form and checked by a second reviewer. At each stage, any differences in opinion were resolved through discussion. Recent studies reported only as abstracts are listed in appendix 3, and studies excluded from the review of clinical effectiveness are listed in appendix 4.

The quality of included systematic reviews was assessed using criteria recommended by the NHS Centre for Reviews and Dissemination (NHS CRD, University of York) (appendix 5),[29] while primary studies were judged using a modified version of Spitzer criteria (appendix 6).[30] Economic evaluations were assessed using a modified version of the Drummond criteria[31] (appendix 7). Quality criteria were applied by one reviewer and checked by a second reviewer. Any disagreements were resolved through discussion.

Some data considered for this review were submitted in confidence. These commercial in confidence data have been omitted from the results presented, as noted in the following text.

Chapter 3
Clinical effectiveness

Quantity of research available

One systematic review,[32,33] 17 published randomised controlled trials (RCTs)[34–61] and one published cohort study[62–70] met the inclusion criteria for this review and are shown in *Tables 7–14* and appendices 8–14. Although the systematic review[32,33] was of good methodological quality (NHS CRD quality score 4/5), it was excluded from the main review of clinical effectiveness as it addressed a broader question of the effectiveness of all interventions for morbid obesity and appeared to have been surpassed by the emergence of additional evidence. The data extracted from the systematic review are presented in appendix 15.

Surgery versus non-surgical interventions

Quantity and quality of research

Two RCTs[34,39,58–60] and one cohort study with a concurrent control group[62–70] assessed the clinical effectiveness of surgery compared with non-surgical interventions (*Table 8*, appendix 8). Andersen and colleagues[34,39] compared GP with a VLCD, while the other two studies compared conventional treatment or medical management, defined as the best non-surgical options available, with gastric surgery (Swedish Obese Subjects (SOS))[62–70] or jejunoileostomy (Danish Obesity Project (DOP)).[58–60] The methodological quality of the studies was compared using a modified version of the criteria identified by Spitzer and colleagues[30] (*Table 7*). The RCT by Andersen and colleagues was of good quality,[34,39] while the other two studies lacked consideration of key elements of methodological quality.[58–60,62–70] All three studies adequately discussed outcomes, eligibility criteria, patient attrition and the generalisability of findings. While none of the studies blinded the assessment of outcomes, this was expected given the difference in treatments compared. The good-quality RCT reported by Andersen and colleagues discussed sampling methods and comparability of groups appropriately, only failing to report on the methods of randomisation used for allocating consecutive patients included.[34,39] The DOP study failed to adequately report methods of randomisation, sampling methods and comparability of groups,[58–60] while the SOS study did not use proper sampling methods and had non-comparable groups. Patients were recruited from pre-existing surgical waiting lists and media advertisements, and the study included an interval between matching of controls and start of treatment that led to significant differences in weight and other possible risk factors. For the cohort study, randomisation of patients was not appropriate.[62–70]

Weight change

In the RCT by Andersen and colleagues, the comparison of the net weight change from a VLCD with that from horizontal GP showed no significant difference at 12 months follow-up (VLCD 18 kg versus GP 23 kg, p = not significant (ns)) or 18 months (VLCD 10.5 kg versus GP 18.5 kg, p = ns) follow-up.[34] At 24 months, net weight loss had increased for patients with horizontal GP, significantly more than that experienced by patients who received a VLCD (32 kg versus 9 kg, $p < 0.05$). Some 58% of GP patients were less than 40% overweight at 24 months compared with only 7% of VLCD patients ($p < 0.05$). When assessed at 5 years follow-up, 30% of patients with horizontal GP had a net weight loss of ≥ 10 kg compared with 17% of those receiving VLCD (p = ns).[39] At 5–6 years, the cumulated success rate for horizontal GP was 16% compared with 2% for VLCD ($p < 0.05$). It should be noted that 6% of VLCD patients had a horizontal GP after regaining all lost weight.

The SOS study[65] reported a significantly ($p < 0.001$) greater weight loss among gastric surgery patients (23%) after 2 years than for those receiving conventional treatment (0%). At 8 years, patients in the surgical group had a 16.3% weight loss compared with a 0.9% gain in weight for patients on conventional treatment, a significant difference in change of weight of 20.7 kg ($p < 0.001$).[69] Weight reduction was greater among each of the three different gastric surgery procedures of GB, GBan and GP than for conventional treatment ($p < 0.001$).[69] GB patients had a lower weight at 8 years than GP patients (p = ns) and GBan patients ($p < 0.05$).[69] The DOP study,[58–60] comparing end-to-side jejunoileostomy with medical management, found significantly ($p < 0.001$) higher weight loss at 24 months follow-up

TABLE 7 *Comparison of the methodological quality of studies using a modified version of the criteria identified by Spitzer and colleagues (1990)*[30]

Study	Random assignment	Proper sampling	Sample size	Objective outcomes	Blind assessment	Eligibility criteria	Attrition reported	Comparable groups	Generalisable results
Surgery versus non-surgical interventions									
Andersen *et al.*, 1984[34], 1988[39]	NR	✔	✔	✔	✗	✔	✔	✔	✔
DOP[58–60]	NR	NR	NR	✔	NR	✔	✔	Sub	✔
SOS[62–70]	✗	✗	NR	✔	NA	✔	✔	✗	✔
Comparison of different surgical procedures									
GB versus GP									
Hall *et al.*, 1990[45]	✔	✔	✔	✔	NR	✔	✔	✔	✔
Howard *et al.*, 1995[46]	NR	NR	NR	✔	NR	✔	✔	✔	✔
Laws & Piantadosi, 1981[47]	✔	✔	NR	✔	NR	Sub	✗	Sub	✔
Lechner & Callender, 1981[48]	NR	NR	NR	✔	NR	✔	✗	✔	✔
MacLean *et al.*, 1995[49], 1993[50]	NR	NR	NR	✔	NR	✗	✔	✔	✔
Naslund*	✔	✔	NR	✔	NR	✔	✔	✔	✔
Pories *et al.*, 1982[57]	✔	NR	NR	✔	✔	Sub	✔	✔	✔
Sugerman *et al.*, 1987[61]	✔	NR	NR	✔	NR	✔	✔	✔	✔
GB versus jejunoileostomy									
Buckwalter *et al.*, 1977[40] Buckwalter, 1980[41], 1978[42]	✔	NR	NR	✔	NR	✔	✗	✔	✔
Griffen *et al.*, 1977[44]	Sub	NR	NR	✔	NR	✔	✗	✔	✔
VBG versus horizontal GP									
Andersen *et al.*, 1987[38]	✔	✔	NR	✔	NR	Sub	✗	Sub	Uncertain
VBG versus AGB									
Nilsell *et al.*, 2001[35]	✔	NR	NR	✔	✗	✔	✔	✔	✔
Open versus laparoscopic GB									
Nguyen *et al.*, 2001[37]	✔	✔	✔	✔	✗	✔	✔	✔	✔
Westling & Gustavsson, 2001[36]	✔	Sub	NR	✔	Sub	✔	✔	✗	✔
Open versus laparoscopic ASGB									
De Wit *et al.*, 1999[43]	✔	NR	✔	✔	NR	✔	✔	✔	✔

* *Naslund, 1986*[51]*; Naslund* et al.*, 1986*[52]*; Naslund, 1987*[53]*; Naslund & Beckman, 1987*[54]*; Naslund* et al.*, 1988*[55,56]

NR, not reported; ✔, yes; ✗, no; Sub, substandard or incomplete; NA, not applicable; AGB, adjustable gastric banding; ASGB, adjustable silicone gastric banding

TABLE 8 *Summary of evidence of the effectiveness of surgery versus non-surgical interventions for morbid obesity*

Study details	Weight change	QoL/co-morbidities	Complications and additional procedures
Andersen *et al.*, 1984[34],1988[39] ***Design*** RCT (single centre) ***Intervention*** GP (horizontal) + diet (500 kcal, 34 g protein daily) (n = 27) VLCD: cycles of 8 weeks (341 kcal) and 2 weeks (900 kcal) (n = 30) ***Patients*** At least 60% overweight (n = 57)	***Net weight change*** 12 months VLCD 18 kg; GP 23 kg (p = ns) 18 months VLCD 10.5 kg; GP 18.5 kg (p = ns) 24 months VLCD 9 kg; GP 32 kg (p < 0.05) ***Less than 40% overweight*** 24 months GP 58% (95% CI, 28 to 85); VLCD 7% (95% CI, 0 to 34), p < 0.05 ***Success defined as a net weight loss of ≥ 10 kg*** 60 months GP 30% (95% CI, 14 to 50); VLCD 17% (95% CI, 6 to 35) ***Median (range) weight loss of patients with 'success'*** 60 months GP 18.2 kg (14.2–50.3 kg); VLCD 26.8 kg (13.0–38.2 kg), p = ns ***Cumulated success rate*** 5–6 years GP (n = 8) 16% (95% CI, 11 to 21) VLCD (n = 8) 2% (95% CI, 1 to 3), p < 0.05	Not assessed	***Re-operations*** None of GP patients were re-operated ***Perioperative complications (GP only, n = 27)*** Subphrenic abscess 7%; atelectasis/ pneumonia 4%; wound infection 4% ***Later complications (GP (n = 27) vs VLCD (n = 30))*** Thrombophlebitis (4% vs 0%); nausea (15% vs 7%); heartburn (11% vs 0%); ructus (1% vs 0%); pain projected to left shoulder (15% vs 0%); epigastric pain (22% vs 10%); outlet obstruction (4% vs 0%); vomiting (52% vs 0%, p < 0.05); cholesystectomy (7% vs 0%); obstipation (26% vs 13%); orthostatic hypotension (7% vs 27%); dizziness (7% vs 17%); transient loss of hair (15% vs 10%); headache (11% vs 17%); fatigue (30% vs 53%); irritability and low spirits (0% vs 33%, p < 0.05); gout (0% vs 3%); staple line rupture (4% vs 0%), ventral hernia (4% vs 0%); abortion (4% vs 0%) 2 (6%) VLCD patients had GP elsewhere having regained all weight lost on diet

continued

***TABLE 8* contd** *Summary of evidence of the effectiveness of surgery versus non-surgical interventions for morbid obesity*

Study details	Weight change	QoL/co-morbidities	Complications and additional procedures
DOP Stokholm *et al.*, 1982[58] Backer *et al.*, 1979[59] Quaade, 1977[60] ***Design*** RCT (14 centres) ***Intervention*** Medical management (n = 66) Jejunoileostomy (end-to-side) (n = 130) ***Patients*** At least 80% overweight (n = 196)	***Median weight loss (range) 24 months*** **Medical** 5.9 kg (–11.9 to 40.4) **Surgical** 42.9 kg (20.5–108.5), $p < 0.001$ ***Body weight at MBW change at median 24 months (range 12–48), median and 5%–95% percentiles*** **Surgical** Baseline 124.0 kg (104.2–164.9) MBW 81.2 kg (64.0–103.9), $p < 0.0001$ **Medical** Baseline 129.0 kg (104.6–166.3) MBW 119.0 kg (74.3–159.0), $p < 0.0005$	***QoL (> 15 months post randomisation) (medical vs surgical)*** **Somatic symptoms** Dyspnoea 42% vs 14%*; precordial pain 21% vs 7%†; heartburn 38% vs 14%*; abdominal pain 54% vs 87%*; flatulence 40% vs 93%*; anal complaints 17% vs 40%‡; low back pain 63% vs 41%‡; pain in hips/knees/ankles 67% vs 22%*; excessive sweating 54% vs 15%*; heat intolerance 69% vs 22*; cold intolerance 6% vs 39%*; dermal irritation/rashes 77% vs 16%* **Psychological symptoms** Excessive fatigue 69% vs 41%*; periodic depression 62% vs 36%‡; periodic irritability 71% vs 41%*; insecurity 65% vs 40%‡; inferiority/ insufficiency 65% vs 37%*; isolation 35% vs 11%*; loneliness 35% vs 14%‡; exposure to contempt 69% vs 21%* **Social factors** Exercise daily 35% vs 55%†; participates in organised sport 12% vs 26%†; normal sex life 52% vs 78%‡; wear ready-made clothes 46% vs 96%‡; socially satisfied 52% vs 76%‡; sexually satisfied 48% vs 82%‡ * $p < 0.001$; † $p < 0.05$; ‡ $p < 0.01$ ***BP at MBW change, median and 5%–95% percentiles*** **Surgical** Systolic: baseline 140 mmHg (116–180), MBW 120 mmHg (105–150), $p < 0.0001$ Diastolic: baseline 85 mmHg (70–109), MBW 80 mmHg (60–99), $p < 0.0001$ **Medical** Systolic: baseline 140 mmHg (118–197), MBW 140 mmHg (110–187), p = ns Diastolic: baseline 90 mmHg (67–112), MBW 90 mmHg (70–100), p = ns	No surgical deaths (95% CI, 0 to 2.7) 2 deaths in medical (1 complications of liver biopsy, 1 after bypass surgery 4 years after medical treatment) Surgical: 3% pulmonary complications, 6% wound infection or dehiscence, 1.5% severe but transient hepatic dysfunction Other complications encountered but not reported Intestinal continuity re-established in 0.7%

continued

among the surgical group (42.9 kg) than the medical group (5.9 kg).

QoL and co-morbidities

Two studies assessed QoL (SOS[66] and DOP[58–60]). The SOS study[66] used the HRQoL measure to compare the effects of gastric surgery and conventional treatment. At baseline patients in the gastric surgery group had significantly worse current health perception (GHRI/CH scale, 26.9 versus 29.4, $p < 0.0001$), higher dysfunction on psychosocial functioning (OP scale, males 1.60 versus 0.99, $p < 0.0001$ and females 1.94 versus 1.45, $p < 0.0001$; SIP/SI category, males 10.4 versus 8.2, p = ns and females 11.3 versus 7.4, $p < 0.0001$) and lower mental well-being and increased symptoms (MACL, pleasantness/unpleasantness 2.96 versus 3.04, p = ns; activation/deactivation 2.86 versus 3.01, $p < 0.001$; calmness/tension 2.90 versus 2.98, p = ns; and HAD scale,

***TABLE 8* contd** *Summary of evidence of the effectiveness of surgery versus non-surgical interventions for morbid obesity*

Study details	Weight change	QoL/co-morbidities	Complications and additional procedures
SOS 1. Sjostrom *et al.*, 2001[70] 2. Sjostrom *et al.*, 2000[69] 3. Karason *et al.*, 2000[65] 4. Sjostrom *et al.*, 1999[68] 5. Karason *et al.*, 1999[63] 6. Narbro *et al.*, 1999[67] 7. Karason *et al.*, 1999[64] 8. Karlsson *et al.*, 1998[66] 9. Karason *et al.*, 1997[62] 10. Torgerson & Sjostrom, 2001 (overview)[71] ***Design*** Multicentre (25 surgical and 480 non-surgical) Cohort study with matched controls ***Intervention*** Surgical a. VBG b. GBan c. GB ***Controls*** conventional treatment ***Patients*** BMI ≥ 38 kg/m^2 women, ≥ 34 kg/m^2 men	***Weight (kg)*** (surgical *n* = 1210 vs control *n* = 1099) Baseline: difference 7 kg (95% CI, 5.7 to 8.3) 24 months: difference –21 kg (95% CI, –23 to –19) ***Weight loss after 24 months*** Surgical 28 kg (23%); control unchanged, $p < 0.001$ ***Weight changes at 8 years*** (surgical *n* = 232, control *n* = 251) Baseline: surgical 120.4 kg (SD 16.0); control 114.7 kg (SD 17.8) 8 years: surgical 100.3 kg (SD 17.8); control 115.4 (SD 19.2) ***Difference in weight change between groups at 8 years*** 20.7 kg ($p < 0.001$) ***Relative weight change at 8 years*** Surgical –16.3% (SD 12.3%); control 0.9% (SD 10.8%) ***Weight at 8 years*** GB 92 kg vs VBG 100 kg (p = ns) vs GBan 103 kg ($p < 0.05$) All had a larger weight reduction than controls ($p < 0.01$)	***HRQoL*** **Current health perception** GHRI/CH scale (mean; 95% CI) Baseline Surgery 26.9 (26.1 to 27.7); control 29.4 (28.5 to 30.2) 2 years Surgery 34.3 (33.4 to 35.1); control 30.2 (29.4 to 31.1) **Psychosocial functioning** OP scale change by 2 years (mean; 95% CI) Surgery: males –1.01 (–1.14 to –0.87); females –1.10 (–1.19 to –1.00) Control: males –0.07 (–0.17 to 0.03) ($p < 0.001$); females –0.16 (–0.22 to –0.09) ($p < 0.001$) SIP/SI change by 2 years (mean; 95% CI) Surgery: males –3.3 (–5.0 to –1.5); females –5.2 (–6.5 to –4.0) Control: males 1.5 (0.2 to 3.2) ($p = 0.001$); females 1.2 (0.2 to 2.2) ($p = 0.0001$) **Mental well-being** MACL change by 2 years (mean; 95% CI) *Pleasantness/unpleasantness*: Surgery 0.21 (0.16 to 0.26) Control –0.04 (–0.09 to 0.01) ($p < 0.001$) *Activation/deactivation*: Surgery 0.32 (0.27 to 0.37) Control 0.00 (–0.04 to 0.05) ($p < 0.001$) *Calmness/tension*: Surgery 0.20 (0.15 to 0.26) Control –0.01 (–0.06 to 0.04) ($p < 0.001$) HAD change by 2 years (mean; 95% CI) *Anxiety*: surgery –1.7 (–2.0 to –1.4); control –0.6 (–0.9 to –0.2) ($p = 0.0001$) *Depression*: surgery –2.2 (–2.5 to –1.9); control –0.4 (–0.6 to –0.1) ($p = 0.0001$) **At 24 months** Improvement in surgical vs controls on all HRQoL measures ($p < 0.0001$) Changes in all HRQoL measures significantly related to magnitude of weight loss ***Diabetes*** **2-year unadjusted incidence** Controls 4.7%, surgical 0.0% ($p = 0.0012$) **8-year unadjusted incidence** Controls 18.5%, surgical 3.6% ($p = 0.0001$) **Adjusted OR of developing diabetes, 8 years**: Completers (*n* = 437) 0.17 (95% CI, 0.08 to 0.38) All (ITT) (*n* = 611) 0.16 (95% CI, 0.07 to 0.36)	***Postoperative mortality*** 4 (0.2%) deaths: 3 due to leakage detected too late and 1 due to a technical laparoscopic mistake ***Perioperative complications*** 13% experienced complications. Bleeding 0.9%, thromboembolic events 0.8%, wound complications 1.8%, abdominal infection 2.1%, pulmonary symptoms 6.2%, miscellaneous 4.8% ***Re-operation*** 2.2%

continued

***TABLE 8* contd** *Summary of evidence of the effectiveness of surgery versus non-surgical interventions for morbid obesity*

Study details	Weight change	QoL/co-morbidities	Complications and additional procedures
SOS *contd* 1. Sjostrom *et al.*, 2001[70] 2. Sjostrom *et al.*, 2000[69] 3. Karason *et al.*, 2000[65] 4. Sjostrom *et al.*, 1999[68] 5. Karason *et al.*, 1999[63] 6. Narbro *et al.*, 1999[67] 7. Karason *et al.*, 1999[64] 8. Karlsson *et al.*, 1998[66] 9. Karason *et al.*, 1997[62] 10. Torgerson & Sjostrom, 2001 (overview)[71]		***Hypertension*** **2-year unadjusted incidence** Controls 9.9%, surgical 3.2% (p = 0.032) **8-year unadjusted incidence** Controls 25.8%, surgical 26.4% (p = 0.91) **Adjusted OR of developing hypertension at 24 months** Completers (n = 257) 0.27 (95% CI, 0.07 to 0.99) All (ITT) (n = 377) 0.27 (95% CI, 0.09 to 0.76) **Adjusted OR of developing hypertension at 8 years** Completers (n = 257) 1.05 (95% CI, 0.58 to 1.89) All (ITT) (n = 377) 1.01 (95% CI, 0.61 to 1.67) ***Lipids*** **Adjusted OR at 24 months** Hypertriglyceridaemia 0.10 (95% CI, 0.04 to 0.25), p < 0.001 Hypo HDL-cholesterolaemia 0.28 (95% CI, 0.16 to 0.49), p < 0.001 Hypercholesterolaemia 1.24 (95% CI, 0.84 to 1.8), p = ns **Relative risks for recovery from disease** Hyperinsulinaemia (n = 221) 1.4 (95% CI, 1.2 to 1.7), p < 0.00001 Hypertriglyceridaemia (n = 314), 1.9 (95% CI, 1.5 to 2.4), p < 0.00001 Hypo HDL-cholesterolaemia (n = 216), 1.7 (95% CI, 1.4 to 2.1), p < 0.00001 Hypercholesterolaemia (n = 531), 1.2 (95% CI, 0.95 to 1.5), p = ns	

MBW, maximal body weight; BP, blood pressure; HRQoL; health-related quality of life; GHRI/CH scale, general health rating index – current health scale; OP scale, obesity-related psychosocial problems scale; SIP/SI category, sickness impact profile – social interaction category; MACL, mood adjective checklist; HAD scale, hospital anxiety and depression scale; OR, odds ratio; ITT, intention-to-treat

anxiety 6.3 versus 5.7, p = ns; depression 5.2 versus 4.5, $p < 0.01$) than those in the conventional treatment group. These differences may reflect the significant differences in BMI and prevalence of hypertension that developed between matching of controls and start of treatment, or may indicate bias in the selection of patients for surgery. At 2 years gastric surgery patients had significant improvements in all HRQoL measures compared with patients receiving conventional treatment. On current health perception the GHRI/CH improved to 34.3 for surgery compared with 30.2 for conventional treatment ($p < 0.0001$). Similarly, psychosocial functioning (OP scale, males –1.10 versus –0.07, $p < 0.001$ and females –1.01 versus –0.16, $p < 0.001$; SIP/SI category, males –3.3 versus 1.5, $p = 0.001$ and females –5.2 versus 1.2, $p = 0.0001$) and mental well-being and symptoms (MACL pleasantness/unpleasantness 0.21 versus –0.04, $p < 0.001$; activation/deactivation 0.32 versus 0.00, $p < 0.001$; calmness/tension 0.20 versus –0.01, $p < 0.001$; HAD anxiety –1.7 versus –0.6, $p = 0.0001$; depression –2.2

versus –0.4, $p = 0.0001$) had improved significantly at 2 years. These changes were significantly related to the magnitude of the weight lost and may have been expected given that the patients in the surgical group had significantly higher BMI at the time of treatment compared with the controls.

The DOP study[59] examined the QoL of patients who had a jejunoileostomy and those in receipt of medical management through the completion of a questionnaire at least 15 months following randomisation. On somatic symptoms, patients with a jejunoileostomy had significantly ($p < 0.05$) lower breathlessness (dyspnoea), precordial pain, heartburn, low back pain, pain in hips/knees/ankles, excessive sweating, heat intolerance, cold intolerance and dermal irritation compared with those on medical management. In contrast, jejunoileostomy patients suffered significantly ($p < 0.05$) higher abdominal pain, flatulence and anal complaints (e.g. anal fissures and haemorrhoids). Importantly, jejunoileostomy was associated with significantly ($p < 0.05$) improved psychological symptoms and social factors compared with medical management.

Change in blood pressure from baseline to MBW change was assessed in the DOP study for jejunoileostomy compared with medical management.[58] SBP and DBP decreased significantly for jejunoileostomy patients (SBP 140 mmHg to 120 mmHg, $p < 0.0001$; DBP 85 mmHg to 80 mmHg, $p < 0.0001$) compared with no change for medically managed patients (SBP 140 mmHg to 140 mmHg, p = ns; DBP 90 mmHg to 90 mmHg, p = ns).[58] Similarly, the SOS study[69] found that the 2-year unadjusted incidence of hypertension was significantly ($p < 0.05$) lower in surgical patients (3.2%) compared with those receiving conventional treatment (9.9%). After 8 years follow-up any significant difference had disappeared (surgical 26.4%, controls 25.8%, p = ns). The adjusted OR of developing hypertension at 8 years was 1.01 (95% CI, 0.61 to 1.67).[69] The unadjusted incidence of diabetes was significantly lower among gastric surgery patients compared with patients on conventional treatment at 2 years (0.0% versus 4.7%, $p < 0.005$) and 8 years (3.6% versus 18.5%, $p < 0.0005$). The adjusted OR of developing diabetes at 8 years was 0.16 (95% CI, 0.07 to 0.36).[69] At 2 years the adjusted OR for hypertriglyceridaemia (0.10; 95% CI, 0.04 to 0.25) and hypo HDL-cholesterolaemia (0.28; 95% CI, 0.16 to 0.49) were significant ($p < 0.001$), although hypercholesterolaemia (1.2; 95% CI, 0.84 to 1.8) was not (p = ns). The relative chance of recovery from hyperinsulinaemia was 1.4 (95% CI, 1.2 to 1.7; $p < 0.001$), hypertriglyceridaemia 1.9 (95% CI, 1.5 to 2.4; $p < 0.001$) and hypo HDL-cholesterolaemia was 1.7 (95% CI, 1.4 to 2.1; $p < 0.001$).[68] There was no significant difference in the chance of recovery from hypercholesterolaemia (1.2; 95% CI, 0.95 to 1.5; p = ns).[68]

Complications and additional operative procedures

No surgical deaths were reported by the two RCTs; however, in a recently published overview the SOS study noted four postoperative deaths (three from leakage and one due to technical laparoscopic mistake).[71] The DOP study found two deaths in the medical group: one from complications following liver biopsy and one after bypass surgery 4 years later.[59]

Perioperative and/or late complications were reported by all three studies. Perioperative complications included subphrenic abscess (7%), atelectasis/pneumonia (4%), wound infection (4–6%), pulmonary complications (3–6.2%) and hepatic dysfunction (1.5%).[39,59,71] Comparison of later complications between GP and VLCD showed significantly ($p < 0.05$) greater occurrence of vomiting among GP patients (52% versus 0%) but less irritability and low spirits (0% versus 33%).[58–60] Other complications did not differ significantly.

Andersen and colleagues[39] reported that none of the GP patients required re-operation. Some 2.2% of surgical patients underwent re-operation in the SOS study,[71] while reversal was performed in 0.7% of jejunoileostomy patients in the DOP study.[58]

Summary

There is good evidence that gastric surgery leads to the loss of large amounts of weight in patients who are very obese, and in whom all other remedies have failed. Before surgery, an average weight would be around 120 kg, or about double normal weight. In the trials, patients lost from 23 kg to 37 kg by 2 years, and in the study with 8 years of follow-up the surgical group had lost 21 kg whereas the control group had gained weight.

Overall, patients who had surgery had improvements in QoL, partly due to reduced symptoms such as joint pain and breathlessness, partly due to improved psychological and social functioning. But some did have side-effects of the procedure such as heartburn and vomiting, and

complications of surgery, such as wound infection and intra-abdominal abscesses. A few had to have re-operations. No operative deaths were reported in these studies.

The longer-term benefits included a reduction in the prevalence of diabetes and high blood pressure, and many patients could stop diabetes medications.

Comparison of different surgical procedures

Quantity and quality of research

A total of 15 RCTs compared different surgical procedures: eight RCTs comparing GB with GP,[45–57,61] two RCTs comparing GB with JB,[40–42,44] one RCT comparing VBG with horizontal GP,[38] one RCT comparing VBG with AGB,[35] two RCTs comparing open versus laparoscopic GB,[36,37] and one RCT that compared open versus laparoscopic ASGB.[43] Methodological quality varied between RCTs (*Table 7*). In all, 11 of the RCTs had proper random assignment,[35–38,40–43,45,47,51–57,61] in three studies the method of randomisation was not stated,[46,48–50] and in one study randomisation was substandard as hospital numbers were used.[44] Consecutive patients were included in five studies.[37,38,45,47,51–56] In three studies the sample size allowed adequately precise estimates of weight loss, as demonstrated by a sample size calculation.[37,43,45] All included studies were thought to have clear methods for measuring primary outcomes. Outcome assessment was blinded in only one study,[57] while the rest of the studies did not mention blinding or reported that outcome assessors were not blinded.[35,37] Most studies described objective criteria for eligibility of patients; however, in three studies this was inadequate,[38,47,57] and one study did not describe any eligibility criteria.[49,50] Losses to follow-up were not reported by five studies.[38,40–42,44,47,48] The comparability of groups assessed was demonstrated in most studies, although two studies simply made a statement regarding comparability without presenting any data[38,47] and in one study the groups were not comparable at baseline due to differences in BMI.[36] The generalisability of results from the study by Andersen and colleagues[38] was thought to be uncertain, as only patients who were successful in achieving and maintaining 40% excess weight loss were eligible for surgery. All other studies were thought to include a representative sample. Recruitment to one RCT was stopped early (after 9 months) following an *a priori* stopping rule which stated that when a significant difference ($p < 0.05$) in weight loss was noted for either treatment, patient recruitment would cease until patients had achieved the same follow-up after surgery.[61]

GB versus GP

Weight change

Two of the three RCTs that compared VBG with undefined GB[46] or Roux-en-Y gastric bypass (RYGB)[49,61] demonstrated significantly greater weight loss with GB (*Table 9*, appendix 9). Howard and colleagues[46] found that patients with GB ($n = 20$) had 78% excess weight loss compared with 52% excess weight loss for patients undergoing VBG ($n = 22$) ($p < 0.05$) at 12 months follow-up. At 5 years, excess weight loss was 70% and 37% for GB and VBG respectively ($p < 0.05$), although only six patients in each group were followed for this length of time. All GB patients had lost at least 50% of excess weight at 12 months and 60 months follow-up, whereas only 55% of VBG patients had achieved this at 12 months, and none by 60 months (p value not stated). Similarly, Sugerman and colleagues[61] found that excess weight loss for GB was significantly greater than for VBG at 12 months (68% versus 43%, $p < 0.001$), 24 months (66% versus 39%, $p < 0.001$) and 36 months (62% versus 37%, $p < 0.001$). As previously stated, recruitment to this study was stopped after 9 months when a significant difference ($p < 0.05$) in weight loss was noted in favour of GB. At this point 20 patients had been recruited to each arm of the study, and were followed up for 3 years. When comparing the decrease in excess weight for 'sweets eaters' with non-'sweets eaters' (sweets eaters consumed > 300 calories of sweet foods > 3 times/week and non-sweets eaters were all others), it was evident that GB surgery led to a significantly greater decrease in excess weight for sweets eaters than VBG ($p < 0.0001$). For non-sweets eaters GB caused greater decreases in excess weight compared with VBG, but differences were not significant (p = ns). Success rates, defined as a BMI < 35 or < 50% excess weight and re-operation not required, were compared for GB and VBG by MacLean and colleagues.[49] When compared at 3 years and 5–6 years follow-up, there was no significant difference in success rates between GB and VBG (~ 3 years: 58% versus 39% (p = ns); ~ 5–6 years: 34% versus 16% (p = ns)). Failures were converted to isolated GB, which had a success rate of 63% at 5–6 years. Although comparisons of the three procedures were reported to show a significantly greater success rate for isolated GB compared with GB ($p < 0.01$) and VBG ($p = 0.001$), these were not valid as the periods of follow-up differed.

TABLE 9 *Summary of evidence of the effectiveness of GB versus GP for morbid obesity*

Study details	Weight change	QoL/co-morbidities	Complications and additional procedures
GB versus VBG			
Howard *et al.*, 1995[46] ***Design*** RCT (single centre) ***Interventions*** GB (*n* = 20) VBG (*n* = 22) ***Patients*** BMI > 40 (*n* = 42)	% ***EWL compared to maximum excess weight*** 12 months GB 78%; VBG 52% ($p < 0.05$) 60 months GB (*n* = 6) 70%; VBG (*n* = 6) 37% ($p < 0.05$) % ***patients with at least 50% of EWL*** 12 months GB 100%; VBG 55% (*p* value not stated) 60 months GB (*n* = 6) 100%; VBG (*n* = 6) 0% (*p* value not stated) % ***patients with more than 75% of EWL*** 12 months GB 60%; VBG 18% (*p* value not stated) 60 months GB (*n* = 6) 50%; VBG (*n* = 6) 0% (*p* value not stated)	Not assessed	***Early complications*** Deaths GB 0, VBG 0 Wound infection 1 (2%) super-obese patient ***Late complications*** Symptomatic ulcer disease GB 25% (50% further surgery), VBG 0%; intraoperative cholecystectomy GB 20%, VBG 14%; postoperatively cholecystectomy VBG 29%, GB 29%
MacLean *et al.*, 1995,[49] 1993[50] ***Study design*** RCT (single centre) ***Interventions*** VBG (*n* = 54) RYGB (*n* = 52) ***Patients*** Not stated (*n* = 106)	***Success rate (BMI < 35 or < 50% excess weight and no re-operation)*** ~ 36 months VBG (*n* = 31) success rate 21 (39%) RYGB (*n* = 40) success rate 30 (58%) VBG vs RYGB; *p* = ns ***Success rate (BMI < 35 or < 50% excess weight and no re-operation)*** ~ 78 months VBG (*n* = 25) success rate 9 (16%) RYGB (*n* = 32) success rate 16 (34%) VBG vs RYGB; *p* = ns	Not assessed	***Deaths*** VBG 0, RYGB 0 ***Conversions*** ~ 36 months VBG 9% to normal, 33% to IGB RYGB 0% to normal, 23% to IGB Up to 6.5 years VBG 9% to normal, 44% to IGB RYGB 2% to normal, 37% to IGB ***Re-operation*** Total VBG 43%, RYGB 23%; stenosis VBG 20%, RYGB 0%; enlarged orifice VBG 13%, RYGB 0%; staple line fistula VBG 4%, RYGB 23%; clinical failure VBG 4%, RYGB 0%; abscess VBG 2%, RYGB 0%; stomal ulcer VBG 0%, RYGB 13% Of 160 operations and 35 re-operations: 6 intra-abdominal abscesses and/or leaks (3.8% of patients or 3.1% of operations), of which only 5 required re-operation, 1 drained by percutaneous catheter

continued

***TABLE 9* contd** *Summary of evidence of the effectiveness of GB versus GP for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
GB versus VBG *contd*			
Sugerman *et al.*, 1987[61] ***Design*** RCT (single centre) ***Intervention*** RYGB (n = 20) VBG (n = 20) ***Patients*** More than 100 lb above IBW (n = 40)	**% *IBW (± SD)*** 12 months RYGB 138% ± 32; VBG 176% ± 41 ($p < 0.01$) 24 months RYGB 139% ± 32; VBG 178% ± 41 ($p < 0.01$) 36 months RYGB 142% ± 37; VBG 180% ± 44 ($p < 0.01$) ***Weight loss in kg (± SD)*** 12 months RYGB 43.5 kg ± 11.3; VBG 32.2 kg ± 10.9 ($p < 0.001$) 24 months RYGB 43.5 kg ± 15.4; VBG 30.4 kg ± 12.2 ($p < 0.001$) 36 months RYGB 41.3 kg ± 12.7; VBG 27.2 kg ± 14.5 ($p < 0.01$) **% *weight lost (± SD)*** 12 months RYGB 33% ± 7; VBG 22% ± 8 ($p < 0.001$) 24 months RYGB 33% ± 9; VBG 22% ± 9 ($p < 0.001$) 36 months RYGB 32% ± 9; VBG 20% ± 10 ($p < 0.01$) **% *EWL (± SD)*** 12 months RYGB 68% ± 17; VBG 43% ± 18 ($p < 0.001$) 24 months RYGB 66% ± 29; VBG 39% ± 24 ($p < 0.001$) 36 months RYGB 62% ± 18; VBG 37% ± 19 ($p < 0.001$) **% *decrease in excess weight (± SD) (n) for sweets eaters vs non-sweets eaters*** **RYGB** 12 months Sweets eaters 69% ± 12 (n = 12), non-sweets eaters 67% ± 17 (n = 7); p = ns 24 months Sweets eaters 62% ± 11 (n = 11), non-sweets eaters 75% ± 19 (n = 7); p = ns 36 months Sweets eaters 59% ± 11 (n = 11), non-sweets eaters 71% ± 21 (n = 7); p = ns **VBG** 12 months Sweets eaters 36% ± 13 (n = 12), non-sweets eaters 57% ± 18 (n = 6); $p < 0.05$ 24 months Sweets eaters 35% ± 14 (n = 11), non-sweets eaters 53% ± 22 (n = 6); $p < 0.05$ 36 months Sweets eaters 32% ± 18 (n = 11), non-sweets eaters 50% ± 21 (n = 5); $p < 0.05$ Difference in decrease in excess weight (%) for RYGB compared with VBG for sweets eaters was significant ($p < 0.0001$), while for non-sweets eaters was non-significant (p = ns)	Not assessed	***Mortality*** RYGB 10%, 3 days and 12 months (both assumed arrhythmia) No significant deficiencies in most vitamins, electrolytes, renal or liver function tests. RYGB lower vitamin B_{12} levels (286 pg/ml ± 149) than VBG (461 pg/ml ± 226) at 24 months ($p < 0.05$) ***Other complications*** **RYGB** 25% intractable vomiting and stomal stenosis; 5% marginal ulcer of jejunal side of gastrojejunostomy **VBG** 5% superficial stomal erosions ***Conversions from VBG to RYGB*** 5% at 1 month, 5% at 18 months, 10% at 38 months

continued

***TABLE 9* contd** *Summary of evidence of the effectiveness of GB versus GP for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
GB versus horizontal GP			
Laws & Piantadosi, 1981[47] ***Design*** RCT (single centre) ***Intervention*** GB with Roux-en-Y gastrojejunostomy (RYGB) (*n* = 27) Pace gastric partitioning (GP) (*n* = 26) ***Patients*** Twice ideal weight for height (*n* = 53)	***Fraction of initial weight*** 12 months RYGB 0.65; GP 0.84 ($p < 0.001$)	Not assessed	***In-hospital mortality*** RYGB 0; GP 0 ***Early complications*** Wound infection RYGB 4%, GP 0%; perforation RYGB 4%, GP 0%; pulmonary embolis RYGB 0%, GP 4% ***Late complications*** Readmitted with vomiting RYGB 7%, GP 12%; stoma stenosis RYGB 4%, GP 4%; hypoglycaemia RYGB 7%, GP 0%; wound hernia RYGB 4%, GP 0%; ureteral stone RYGB 4%, GP 0%; stomal ulcer RYGB 4%, GP 0%
Lechner & Callender, 1981[48] ***Design*** RCT ***Intervention*** Gastric partitioning (GP) (*n* = 50) Gastric exclusion (RYGB) (*n* = 50) ***Patients*** At least 100 lb over Metropolitan Life Insurance desirable weight table (*n* = 100)	***Mean weight loss (lb) ± SD (SEM)*** 12 months RYGB (*n* = 15) 45.2 kg ± 11.3 (2.9) GP (*n* = 14) 33.5 kg ± 13.3 (3.6) MW $p < 0.01$; ANOVA $p < 0.01$ ***% of EWL ± SD (SEM)*** 12 months RYGB (*n* = 15) 64.0% ± 13.9 (3.6) GP (*n* = 14) 54.1% ± 18.6 (5.0) MW p = ns; ANOVA p = ns ***% of initial body weight lost ± SD (SEM)*** 12 months RYGB (*n* = 15) 36.6% ± 7.2 (2.7) GP (*n* = 14) 28.8% ± 10.2 (1.9) MW $p < 0.01$; ANOVA $p < 0.05$	Not assessed	***Mortality*** GP 1 (2%); RYGB 1 (2%) ***Early complications (≤ 30 days)*** Leak: GP 4%, RYGB 2%; splenectomy: GP 0%, RYGB 4%; repair spleen: GP 2%, RYGB 0%; minor dehiscence: GP 0%, RYGB 4%; minor infection: GP 0%, RYGB 4%; major infection: GP 2%, RYGB 2%; pulmonary embolism: GP 2%, RYGB 0%; pulmonary atelectasis: GP 2%, RYGB 6%; pulmonary pneumonia: GP 2%, RYGB 2%; pulmonary effusion: GP 6%, RYGB 0% ***Late complications*** Gastritis: GP 4%, RYGB 0%; dumping: GP 0%, RYGB 8%; cholelithiasis: GP 2%, RYGB 2%; hair thinning: GP 16%, RYGB 10%; phlebitis: GP 0%, RYGB 2%; anxiety: GP 10%, RYGB 10%; staple breakdown: GP 4%, RYGB 0%; neuralgias (retractor): GP 4%, RYGB 2%; incisional hernia: GP 0%, RYGB 6%; readmission for IVS*: GP 3%, RYGB 4%; total complications: GP 24, RYGB 22; patients with complications: GP 42%, RYGB 32% ***Re-operation for staple line breakdown or inadequate weight loss*** GP 12%, RYGB 2% * *Not defined*

continued

***TABLE 9* contd** *Summary of evidence of the effectiveness of GB versus GP for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
GB versus horizontal GP *contd*			
Naslund, 1986[51]; Naslund *et al.*, 1986[52]; Naslund, 1987[53]; Naslund & Beckman, 1987[54]; Naslund *et al.*, 1988[55,56] ***Design*** RCT (single centre) ***Interventions*** GB (n = 29) GP (n = 28) ***Patients*** Morbidly obese with Broca's index 1.50* (n = 57) * *Broca's index: ideal weight (kg) = height (cm) – 100*	***Mean weight loss (± SD)*** 12 months GB 42.3 kg ± 10.9; GP 29.9 kg ± 10.0 (p < 0.001) 18 months GB 43.4 kg ± 12.6; GP 27.9 kg ± 11.9 (p < 0.001) 24 months GB 42.9 kg ± 13.6; GP 27.6 kg ± 10.7 (p < 0.001) 36 months GB 38.4 kg ± 13.2; GP 24.7 kg ± 13.1 (p < 0.001) ***% of preoperative weight (± SD)*** 12 months GB 64% ± 7.5; GP 75% ± 7.6 (p < 0.001) 18 months GBP 63% ± 8.8; GP 77% ± 9.0 (p < 0.001) 24 months GB 64% ± 9.1; GP 77% ± 8.8 (p < 0.001) ***% over IBW (± SD)*** 12 months GB 32% ± 19.7; GP 54% ± 21.3 (p < 0.001) 18 months GB 29% ± 18.5; GP 57% ± 23.3 (p < 0.001) 24 months GB 32% ± 18.1; GP 57% ± 24.0 (p < 0.001) ***Characteristics of failure*** **Weight, % of preoperative weight > 75** GB 3%; GP 50% (p < 0.001) **Overweight > 20 kg** GB 34%; GP 82% (p < 0.001) **Overweight > 30 kg** GB 14%; GP 46% (p < 0.01) **Overweight, % of IBW > 30** GB 55%; GP 89% (p < 0.01) **Weight, % of IBW > 150** GB 17%; GP 54% (p < 0.01) **Weight loss < 25 kg** GB 3%; GP 36% (p < 0.01) ***Broca's index (± SD)*** Baseline GB 1.79 ± 0.25; GP 1.79 ± 0.22 (p = ns) 12 months GB 1.15 ± 0.19; GP 1.34 ± 0.20 (p < 0.001) 18 months GB 1.13 ± 0.17; GP 1.37 ± 0.21 (p < 0.001) 24 months GB 1.15 ± 0.17; GP 1.37 ± 0.22 (p < 0.001) 36 months GB 1.20 ± 0.18; GP 1.42 ± 0.26 (p < 0.001)	***Back pain*** 58% of all patients suffered preoperative back pain; 85% improved or pain-free after 12 months; 9% more post-operative pain; 1 GB with great weight loss had no back problems preoperatively but progressive, severe post-operative back pain ***Patients' own evaluation (12 months)*** 100% GB, 89% GP expressed satisfaction with the operation 96.5% of 57 patients stated they did not regret their decision to undergo surgery All patients with re-operation were more satisfied with GB than GP	***Deaths*** GB 0, GP 0 ***Serious complications (GB vs GP)*** Intraoperative splenic injury requiring splenectomy (7% vs 0%); anastomotic leakage requiring surgical intervention (3% vs 0%); iron deficiency anaemia 18 months after surgery (3% vs 0%); cholecystectomy during 1st year (7% vs 14%). Symptoms of gallstones developed postoperatively (3% vs 11%) ***Other complications*** Dumping syndrome GB 28%, GP 0% (p < 0.05); heartburn GB 59%, GP 32% (p < 0.05) ***Late operations/re-operations due to poor weight loss*** GP: 18% (7% during the first 24 months; 11% between 24 and 36 months) GB: 0% ***Preoperative and postoperative (< 30 days) complications*** Pleural effusion GB 7%, GP 3.5%; wound dehiscence GB 3%, GP 0%; wound abscess GB 10%, GP 7%; superficial wound infection GB 14%, GP 18%; splenectomy GB 7%, GP 0%; anastomotic leakage GB 3%, GP 0% ***Second surgical procedures in the first postoperative year*** Repair of anastomotic leakage GB 3%, GP 0%; endoscopic dilation of stomal stenosis GB 0%, GP 3.5%; repair of wound dehisence GB 3%, GP 0%; lysis of adhesions GB 0%, GP 3.5%; cholecystectomy GB 7%*, GP 14%*; ventral hernia repair GB 10%, GP 7%; abdominal plastic surgery GB 14%†, GP 0% * *in 1 case for gallstones discovered at obesity operation* † *in 3 cases in connection with other procedure*

continued

***TABLE 9* contd** *Summary of evidence of the effectiveness of GB versus GP for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
GB versus horizontal GP *contd*			
Pories *et al.*, 1982[57] ***Design*** RCT (single centre) ***Intervention*** RYGB (*n* = 42) GP (*n* = 45) ***Patients*** At least twice their normal weight (*n* = 87)	***% of original weight (SE)*** 12 months GP (*n* = 31) 76.9% (1.36); RYGB (*n* = 34) 61.8% (1.04) 18 months GP (*n* = 14) 81.0% (2.64); RYGB (*n* = 16) 60.0% (2.02) ***Failures (< 25% weight lost)*** RYGB 0%; GP 62%	***Diabetes*** 11/12 with diabetes reverted to normoglycaemia (one patient who remained a diabetic was a juvenile onset) ***Hypertension*** GP 1/19, RYGB 2/16 remained hypertensive during first 12 months	***Deaths*** GP 0; RYGB 0 ***Complications*** 12% of all patients, evenly distributed between groups (*p* value not stated) GP vs RYGB Wound infection 9% vs 12%; wound haematomas 4% vs 7%; subphrenic abscess 0% vs 2%; stenosis of anastomosis 11% vs 0%; depression 6% vs 10% ***Revisions*** GP 8 revised, 10 revisions scheduled
GB versus vertical GP versus GG			
Hall *et al.*, 1990[45] ***Design*** RCT (two-centre) ***Interventions*** GP (vertical) (*n* = 106) GG (*n* = 105) RYGB (*n* = 99) ***Patients*** > 160% IBW (*n* = 310)	***Median body weight (IQR, range)*** **GP** Baseline 112 kg (100–125, 88–157) 12 months 76 kg (65–87, 50–115) 24 months 75 kg (66–89, 49–121) 36 months 79 kg (70–94, 44–125) **GG** Baseline 110 kg (100–126, 78–162) 12 months 81 kg (74–95, 56–132) 24 months 86 kg (75–98, 58–132) 36 months 93 kg (79–106, 60–156) **RYGB** Baseline 115 kg (104–125, 83–170) 12 months 73 kg (63–84, 53–128) 24 months 71 kg (63–83, 49–140) 36 months 76 kg (65–86, 55–140) ***Successful outcome at 3 years (> 50% EWL or pregnant)*** GP 48.1%; GG 17.1%; RYGB 66.7% ($p < 0.001$)	***Co-morbidities*** At 36 months 50 (60%) patients who initially had a co-morbid condition were free of specific medication ***Proportion of patients off medication*** Diabetes mellitus 6/8 (75%); arthropathy 16/25 (64%); hypertension 22/39 (56%); asthma 6 of 12 (50%)	***Obesity-related surgical procedures*** Trimming procedures: GP 18%, GG 13%, RYGB 35%; cholesystectomy: GP 4%, GG 7%, RYGB 7%; incisional hernia: GP 0%, GG 1%, RYGB 2% ***Additional postoperative surgical procedures performed (< 3 years)*** Revisional surgery: GP 9%, GG 19%, RYGB 4%; reversal surgery: GP 5%, GG 1%, RYGB 2% ***Perioperative deaths*** GP 0%, GG 0%, RYGB 0% ***Postoperative deaths*** GP 0%, GG 0%, RYGB 2% ***Intraoperative complications*** **GP** 1% nasogastric tube stapled to stomach; 1% staple-gun malfunction; 1% incidental splenectomy **GG** 1% pouch haematoma; 1% laceration of splenic vein **RYGB** 1% incidental splenectomy ***Postoperative complications (GP vs GG vs RYGB)*** Wound infection (4% vs 6% vs 4%); atelectasis/pneumonitis (2% vs 5% vs 3%); delayed pouch emptying (1% vs 6% vs 2%); crisis reaction (2% vs 0% vs 0%); subphrenic abscess (1% vs 0% vs 0%); wound dehiscence (1% vs 0% vs 0%); respiratory failure (1% vs 0% vs 0%); haematemesis (0% vs 2% vs 1%); pulmonary embolis (0% vs 0% vs 3%); phlebitis (0% vs 0% vs 3%); small bowel necrosis (0% vs 0% vs 1%); deep vein thrombosis (0% vs 0% vs 1%); urinary tract infection (0% vs 0% vs 1%)

EWL, excess weight loss; IGB, isolated gastric bypass; IBW, ideal body weight; MW, Mann–Whitney U test; ANOVA, analysis of variance; GG, gastrogastrostomy; IQR, interquartile range

All four RCTs comparing horizontal GP with undefined GB or RYGB demonstrated greater weight loss for those undergoing GB (*Table 9*, appendix 9).[47,48,51–57] The RCT reported by Laws and Piantadosi found that patients who had a RYGB lost 35% of their initial weight at 12 months, significantly more than that lost by horizontal GP patients (16%, $p = 0.0001$).[47] Similarly, Pories and colleagues[57] reported significantly greater weight loss for patients with a RYGB compared with patients with a horizontal GP at 12 months (38% versus 23%, $p < 0.001$) and 18 months (40% versus 19%, $p < 0.001$). None of the GB patients failed to achieve 25% weight loss, whereas 62% of the horizontal GP patients were unsuccessful. Naslund and colleagues found that GB patients lost 36% of their preoperative weight at 12 months compared with 25% weight loss by horizontal GP patients ($p < 0.001$).[51–56] With little further weight change at 18 and 24 months, the differences remained significant ($p < 0.001$). These changes equated to a mean weight loss at 12 months of 42.3 kg for GB patients compared with 29.9 kg for horizontal GP ($p < 0.001$). By 36 months, patients in both groups had gained some weight again – GB had a mean weight loss of 38.4 kg and horizontal GP a loss of 24.7 kg – although differences remained significant ($p < 0.001$). At 24 months GB patients remained 32% over their ideal weight compared with 57% for horizontal GP patients. The significantly greater weight loss experienced by GB patients compared with horizontal GP patients was evident in all measures of weight loss used. Lechner and Callender[48] reported that patients with RYGB lost significantly more of their initial body weight in 12 months than those with gastric partitioning (horizontal GP) (37% (SD 7.2) versus 29% (SD 10.2) respectively, $p < 0.05$). The change in weight equated to a loss of 45.2 kg for patients with a RYGB and a loss of 33.5 kg for patients with gastric partitioning ($p < 0.01$). However, the per cent of excess weight loss did not differ significantly between RYGB and gastric partitioning (64% versus 54% respectively, p = ns).

A comparison of vertical GP, gastrogastrostomy (horizontal GP) and RYGB by Hall and colleagues[45] showed that a significantly ($p < 0.001$) greater proportion of patients undergoing a RYGB (66.7%) had a successful outcome at 3 years (defined as > 50% excess weight loss or pregnancy) compared with those receiving vertical GP (48.1%) or gastrogastrostomy (17.1%) (*Table 9*, appendix 9). Median weight loss from baseline to 36 months follow-up was 39 kg for patients with RYGB compared with 33 kg for vertical GP and 17 kg for gastrogastrostomy (p value not stated).

QoL and co-morbidities

Although none of the studies comparing GB with VBG assessed the effects on measures of QoL or co-morbidities, two RCTs comparing horizontal GP with GB assessed the effects of surgery on co-morbidities though not on QoL.[51–57] An improvement in diabetes and hypertension was demonstrated by Pories and colleagues.[57] Some 92% of patients with type 2 diabetes reverted to normoglycaemia (remaining patient had type 1 diabetes), while only 5% of hypertensive patients undergoing gastric partitioning and 12.5% undergoing GB remained hypertensive after 12 months. An RCT reported by Naslund and colleagues found that 85% of patients with back pain preoperatively had improved or were pain free at 12 months, although 9% had more pain postoperatively.[51–56] In the RCT comparing vertical GP, gastrogastrostomy and GB, Hall and colleagues[45] reported that 60% of patients who initially had a co-morbid condition were free of specific medication at 36 months follow-up, including 75% with diabetes mellitus, 64% with arthropathy, 56% with hypertension and 50% with asthma. No comparison between the three procedures was reported. Naslund and colleagues reported that all GB patients and 89% of patients with horizontal GP expressed satisfaction with the operation.[51–56]

Complications and additional operative procedures

Of the three RCTs comparing VBG with GB surgery, two reported no deaths.[46,49] The third RCT reported no deaths in the VBG group but two deaths (10%) in the GB group, occurring after 3 days and 12 months due to assumed arrhythmia.[61] Three of the four RCTs comparing GB with horizontal GP reported no operative mortality.[47,51–57] Lechner and Callender[48] reported one death 6 days after GP due to cerebrovascular accident and anastomosis leak, and one death within 30 days following GB due to pulmonary embolism. In the comparison of vertical GP, gastrogastrostomy and GB, Hall and colleagues[45] noted two postoperative deaths: one from complications of a subsequent cholecystectomy and one from carcinoma of the colon.

Complications differed between the various surgical procedures. In the comparisons of VBG and GB, GB patients suffered from symptomatic ulcer disease (25% of patients),[46] intractable vomiting and stomal stenosis (25%) and marginal ulcer of the jejunal side of gastrojejunostomy (5%),[61] and VBG patients suffered superficial stomal erosions (5%).[61] Intraoperative cholecystec-

tomy and postoperative cholecystectomy were reported for GB (20% and 29% respectively) and VBG (14% and 29% respectively).[46] Early and late complications were reported by all four RCTs comparing horizontal GP and GB and the comparison of vertical GP, gastrogastrostomy and GB. It appeared that a large proportion of patients suffered some postoperative complication, although these were varied and often relatively minor. Lechner and Callender[48] found 42% of GP patients and 32% of GB patients experienced some form of postoperative complication. Pories and colleagues[57] reported that 12% of all patients suffered postoperative complications, with limited differences between the procedures. However, some complications were associated with particular procedures. Naslund and colleagues noted that significantly more GB patients than GP patients experienced dumping syndrome (28% versus 0%, $p < 0.05$) or heartburn (59% versus 32%, $p < 0.05$). Other early and late complications appeared to show limited variation between the different surgical procedures (p value not stated).[45,51–56]

Failures of VBG due to stenosis and enlargement of the GP orifice, and of GB due to perforation of the vertical staple line, were converted to normal (9% versus 2%) or isolated GB (44% versus 37%).[49] In another RCT by Sugerman and colleagues, 20% of VBG patients were converted to RYGB at 1 month, 18 months and 38 months following surgery.[61] Re-operations were performed in 43% of VBG patients and 23% of GB patients due to stenosis, enlarged orifice, staple line fistula, clinical failure, abscess and stomal ulcer.[49]

Re-operation was more common following horizontal GP than GB, with 19%,[45] 12%,[48] 18%[51–56] and 40%[57] of GP patients requiring revision in these studies, compared with 4%,45 2%,[48] 0%[51–56] and 0%[57] of GB patients. Hall and colleagues[45] also reported that 9% of vertical GP patients underwent revisional surgery, and reversal surgery was experienced by 5% of vertical GP patients, 1% of gastrogastrostomy patients and 2% of GB patients. Additional obesity-related procedures were undertaken either as a consequence of postoperative complications (e.g. repair of wound leakage and hernia repair) or of weight change (e.g. trimming procedures). Hall and colleagues[45] reported that 35% of patients with GB, 18% with vertical GP and 13% with gastrogastrostomy underwent trimming procedures. Naslund and colleagues also found that 14% of GB patients required abdominal plastic surgery.[51–56] Some 7% of GB patients,[45,51–56] 4% to 14% of patients with vertical GP[45,51–56] and 7% of gastrogastrostomy patients[45] had cholecystectomies, while procedures for incisional hernia were undertaken on 2% of those with GB and 1% of those with gastrogastrostomy.[45]

Summary

There is reasonable quality evidence that GB surgery leads to a greater loss of weight in morbidly obese patients than from VBG or horizontal GP. Patients lost approximately 25% more excess weight by 1 year after GB than those patients who had a VBG. By 5 years the difference had increased to 33%. Compared with horizontal GP, GB led to a similar difference in the loss of excess weight. QoL was not assessed by any of the RCTs. The effects of co-morbidities were reduced following gastric surgery, with 60% of gastric patients free from medication at 3 years. Side-effects of the procedures, including dumping syndrome and heartburn, were more evident following GB than the different forms of GP. Postoperative deaths were reported following GB (five deaths) and horizontal GP (one death). Revisions, re-operations and/or conversions were more common following GP (VBG: 2–53% of patients; horizontal GP: 1–19% of patients) than following GB (0–39% of patients). Additional procedures following weight loss, such as trimming procedures, were more common following GB than GP (35% versus 13–18%).

GB versus JB

Weight change

Two RCTs compared GB with end-to-end JB (*Table 10*, appendix 10).[40–42,44] Griffen and colleagues[44] demonstrated that there was a slightly higher mean weight loss at 12 months following JB (57.9 kg, range 15.2–116.3) than with GB (51.0 kg, range 13.0–100.0), although the difference was not statistically significant. Similarly, Buckwalter and colleagues[41] found a greater excess weight loss with JB than with RYGB at 12 months (53% versus 44%), 24 months (66% versus 50%) and 36 months (64% versus 55%) (p value not stated). At 24 months, 10% of JB patients and 32% of those with a GB had lost less than one-third of their excess weight.[41] By 36 months, the proportion of GB patients losing a third of their excess weight had decreased slightly to 30%, compared with an increase to 22% for JB patients.

QoL and co-morbidities

Neither RCT assessed the effects of the operative procedures on QoL. One RCT that performed liver biopsies at 12 months showed an improvement in liver pattern for 83% of patients who had a GB and a worsening in 80% of patients

TABLE 10 *Summary of evidence of the effectiveness of GB versus JB for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
Buckwalter *et al.*, 1977[40] Buckwalter, 1980[41], 1978[42] ***Design*** RCT (single centre) ***Intervention*** JB (end-to-end) (*n* = 19) GB (Roux-en-Y limb of jejunum in 11 patients, loop of jejunum in 8 patients) (*n* = 19) ***Patients*** At least twice normal body weight or ≥ 45 kg overweight for 5 years (*n* = 38)	***% mean EWL*** 12 months JB 53%, GB 44% 24 months JB 66%, GB 50% 36 months JB 64%, GB 55% (*p* value not stated) ***Proportion of patients with categories of excess weight lost*** 24 months Poor JB 10%, GB 32%; good JB 58%, GB 37%; very good JB 32%, GB 32% 36 months Poor JB 22%, GB 30%; good JB 33%, GB 60%; very good JB 55%, GB 40% 48 months (*n* = 3) Poor JB 0%, GB 50%; good JB 100%, GB 50%; very good JB 0%, GB 0%	***Fatty metamorphosis*** At operation JB (*n* = 19) 18; GB (*n* = 19) 17 12 months JB (*n* = 19) 19; GB (*n* = 17) 4 24 months JB (*n* = 13) 13; GB (*n* = 3) 0 36 months JB (*n* = 2) 2; GB (*n* = 0) ***Progression of fatty metamorphosis after operation*** JB 6 (including 1 with initially normal liver); GB 0 Fibrosis persisted in 4 JB and appeared at 24 months in 1 JB ***Fibrosis*** At operation JB (*n* = 19) 4; GB (*n* = 19) 3 12 months JB (*n* = 19) 4; GB (*n* = 17) 0 24 months JB (*n* = 13) 5; GB (*n* = 3) 0 36 months JB (*n* = 2) 1; GB (*n* = 0)	***Hospital deaths*** GB 1(5%), JB 0 (0%) ***Postoperative complications (JB vs GB)*** Wound infection (11% vs 11%); incisional hernia (11% vs 21%); pulmonary embolism (0% vs 5%); enteritis (21% vs 0%); metabolic (16% vs 0%); urinary stones (16% vs 0%); intestinal obstruction (5% vs 0%); anastomotic leak (0% vs 5%); bile reflux (0% vs 5%); cholelithiasis (0% vs 11%) ***Subsequent operations (JB vs GB)*** Wound infection drainage (5% vs 5%); incisional hernia repair (11% vs 21%); panniculectomy (16% vs 26%); haemorrhoidectomy (11% vs 0%); cholecystectomy (11% vs 0%); drainage of subphrenic abscess (0% vs 5%); revisions (0% vs 16%); closure or reversal (32% vs 0%) ***Revisions and reversals*** GB 16%, JB 32% (closed or reversed due to severe diarrhoea with malaise and sickness (2), progressive liver damage (2), recurring enteritis (1), and excessive weight loss (1). Simultaneous GB or GP performed in all 6 patients
Griffen *et al.*, 1977[44] ***Design*** RCT (single centre) ***Intervention*** JB (end-to-end) (*n* = 27) GB (*n* = 32) ***Patients*** 50 kg over IBW (*n* = 59)	***Mean (range) weight loss (12 months)*** GB (*n* = 18) 51.0 kg (13.0–100) JB (*n* = 22) 57.9 kg (15.2–116.3) (*p* = ns)	***Liver biopsies (12 months)*** GB (*n* = 12) 17% no change, 83% improvement JB (*n* = 15) 20% no change, 80% worsening of liver pattern	***Postoperative deaths*** JB 1; GB 1 ***Re-hospitalisation*** GB 4 (12.5%); JB 10 (37%) ***Reanastomosis*** GB 1 (3%); JB 1 (4%) ***Early surgical complications (GB vs JB)*** Wound infection (25% vs 22%); dehiscence (3% vs 4%); other sepsis (6% vs 4%); urinary tract infection (12.5% vs 15%); anastomotic leak (6% vs 0%); 'other' (9% vs 4%); total (62.5% vs 48%); incidental splenectomies (9% vs 0%) ***Late complications (GB vs JB)*** Nausea and vomiting (34% vs 7%); diarrhoea (6% vs 56%); pulmonary embolus (6% vs 4%); kidney stones (0% vs 15%); re-operations excluding takedowns (9% vs 37%); on medication (antidiarrhoeal, oral potassium supplements) (9% vs 74%); severe liver disease (0% vs 7%)

with a JB.[44] The progression of fatty metamorphosis and of fibrosis after surgery persisted in 32% and 21% of JB patients respectively, but neither were evident in patients who had GB surgery.[41]

Complications and additional operative procedures

No perioperative deaths were reported by either study. Griffen and colleagues[44] stated that there was one death 3 months following GB and one death 10 months following JB, while Buckwalter and colleagues[40,42] noted one death 20 days after GB.

Early surgical complications were experienced by 63% of GB patients and 48% of JB patients.[44] Most common were wound infection, affecting 25% of GB patients and 22% of JB patients, and urinary tract infection, affecting 12.5% of GB patients and 15% of JB patients. The effect of late complications varied between the different procedures. Nausea and vomiting was experienced by 34% of GB patients compared with 7% of JB patients. Diarrhoea affected 6% of GB patients and 56% of JB patients, with the consequence that 74% of JB patients were on antidiarrhoea medication or oral supplements compared with 9% of patients with GB. Similar differences were evident for kidney stones (JB 15% versus GB 0%), re-operations excluding takedowns (JB 37% versus GB 9%) and severe liver disease (JB 7% versus GB 0%). In contrast, Buckwalter and colleagues[41] did not regard diarrhoea, flatulence, nausea and vomiting as complications. However, it should be noted that the authors report that reversal of JB was due to persistent severe diarrhoea in 11% of patients, and that 16% of patients had serious social and vocational disability due to continuing diarrhoea and flatulence. Postoperative complications suffered by both JB and GB patients included wound infection (11% versus 11% respectively) and incisional hernia (11% versus 21% respectively). Other complications affected JB patients but not GB patients, specifically enteritis (21%), metabolic complications (16%) and urinary stones (16%).

Re-operation, revision or reversal was required in 16% of GB patients and 32% of JB patients.[41] Reanastomosis occurred in 3% of GB patients and 4% of JB patients.[44]

Summary

Studies comparing the clinical effectiveness of GB and JB were of poor quality. The evidence showed that JB led to slightly greater loss of excess weight than GB, with morbidly obese patients losing at least 9% more excess weight at 1, 2 and 3 years. QoL was not assessed by any of the studies. Complications affected more of the JB patients than GB patients, with 80% of JB patients suffering a worsening of liver disease compared with improvements in liver disease among 83% of GB patients. Some 63% of GB and 48% of JB patients experienced complications of surgery, such as wound infection and urinary tract infection. Re-operation was necessary in 16% of GB and 32% of JB patients. There were two postoperative deaths following GB and one following JB.

VBG versus horizontal GP

Weight change

Andersen and colleagues[38] compared VBG with horizontal GP after pretreatment with a VLCD (*Table 11*, appendix 11). To be eligible for surgery, patients were required to reduce their initial overweight by at least 40% and maintain this whilst on the surgery waiting list. Of the 74 patients who underwent pretreatment, 61% then underwent surgery. A significant reduction in weight at 12 months compared with preoperative weight was demonstrated for VBG patients (median 9.7 kg, range –28.2 to 28.7; $p < 0.01$), but not for horizontal GP patients, who actually gained weight (median 1 kg, range –15.0 to 36.5). The difference in weight change between VBG and horizontal GP was statistically significant ($p < 0.001$). The total weight loss for the surgical procedures combined with pretreatment was 48.5 kg (range 6.4–104.0) for VBG and 32.6 kg (range 3.7–125.1) for horizontal GP ($p < 0.02$). This weight equated to the total reduction of overweight of 80% (range 10–96%) and 56% (range 8–92%) for VBG versus horizontal GP respectively ($p < 0.005$).

QoL and co-morbidities

QoL and co-morbidities were not assessed.

Complications and additional operative procedures

No deaths were reported. Postoperative complications were similar, although occasional vomiting occurred significantly more frequently in VBG than in horizontal GP (57% versus 18%, $p < 0.02$).

Summary

The study comparing VBG with horizontal GP was in patients who managed to lose a lot of weight before surgery. After surgery, the vertical banded group lost another 10 kg on average (some gained again, others lost much more), but the horizontal GP group regained weight. However, there was more vomiting in the VBG group, which probably reflects the greater success of that procedure in reducing stomach capacity.

TABLE 11 *Summary of evidence of the effectiveness of VBG versus horizontal GP for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
Andersen *et al.*, 1987[38] ***Design*** RCT (single centre) ***Intervention*** VBG (*n* = 23) Horizontal GP (GP) (*n* = 22) All pretreated with a VLCD ***Patients*** Morbid obesity, ≥ 40% of initial overweight lost and maintained (*n* = 45)	***Median preoperative weight loss*** GP 30.3 kg (10.3–88.6) VBG 34.0 kg (17.4–75.3) ***Median (range) postoperative weight loss (12 months)*** GP (*n* = 20) –1 kg (gained) (–15.0 to 36.5) VBG (*n* = 21) 9.7 kg (–28.2 to 28.7), $p < 0.001$ Weight reduced compared with preoperative weight for VBG ($p < 0.01$) but not GP ***Median (range) total weight loss (12 months)*** VLCD + GP 32.6 kg (3.7–125.1) VLCD + VBG 48.5 kg (6.4 – 104.0), $p < 0.02$ ***Total reduction of overweight (12 months)*** GP 56% (8–92) VBG 80% (10–96), $p < 0.005$	Not assessed	***Complications*** GP (*n* = 22) vs VGB (*n* = 23): Deaths (0% (95% CI, 0 to 8) vs 0%); splenectomy required (5% vs 0%); wound infection (9% vs 4%); ventral hernia (5% vs 4%); postanaesthetic jaundice (0% vs 4%); outlet obstruction (14% (95% CI, 3 to 35) vs 0%); haemorrhagic gastritis (9% vs 0%); pronounced dyspepsia (9% vs 9%); occasional vomiting (18% (95% CI, 5 to 40) vs 57% (95% CI, 34 to 77), $p < 0.02$); heartburn (9% vs 0%); obstipation (0% vs 4%); transient loss of hair (0% vs 4%); orostatic hypotension (0% vs 4%)

VBG versus AGB

Weight change

Nilsell and colleagues[35] compared VBG with AGB (*Table 12*, appendix 12). At the 1-year follow-up, weight loss was greater for the VBG group, but these patients then began to regain weight. The patients with AGB experienced lower initial weight loss, but this continued over 5 years resulting in a weight reduction of 43 kg at 5 years compared with 35 kg for VBG (statistical significance not given).

QoL and co-morbidities

At 5 years follow-up, patients were asked if they were satisfied with or regretted having undergone the operation. Only 56% of VBG patients were satisfied with the result of the operation, while 81% of the patients with AGB were satisfied (statistical significance not given).

Co-morbidities were not assessed.

Complications and additional operative procedures

No postoperative deaths occurred, and although one patient from each group died during follow-up, these are reported to be unrelated to the surgery. Gastro-oesophageal reflux disease was slightly more common in patients with VBG (14.8%) than AGB (11.5%). Staple line disruption occurred in 18.5% of VBG patients, although not all of these were re-operated for various reasons. A third of VBG patients were re-operated due to staple line disruption with rapid weight regain or to strictures of the stoma with vomiting or intolerance of solid food. Three (10%) AGB patients were re-operated: two due to dilation of the gastric pouch, and one patient requested that the band be removed for reasons that were unclear.

Summary

There was only one trial comparing VBG with AGB. There was greater weight loss over 5 years with

TABLE 12 *Summary of evidence of the effectiveness of VBG versus AGB for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
Nilsell *et al.*, 2001[35] ***Study design*** RCT (single centre) ***Intervention*** AGB (*n* = 29) VBG (*n* = 30) ***Patients*** BMI > 40 (*n* = 59)	***Weight (mean (SEM))*** Baseline AGB 124 kg (29); VBG 123 kg (30) 1 year AGB 98 kg (28); VBG 82 kg (25) 2 years AGB 88 kg (23); VBG 85 kg (29) 3 years AGB 85 kg (13); VBG 90 kg (15) 4 years AGB 86 kg (17); VBG 95 kg (15) 5 years AGB 81 kg (16); VBG 88 kg (16)	***Patient satisfaction*** AGB 81%; VBG 56%	***Complications*** Deaths: 1 patient per arm died due to causes unrelated to surgery. No postoperative deaths Gastro-oesophageal reflux disease: AGB 11.5%; VBG 14.8% Anastomotic leak: AGB 0, VBG 1 ***Late re-operations*** 3 AGB re-operated (2 due to dilation of gastric pouch (band replaced), 1 removed at patient's request) 10 VBG re-operated (due to strictures of stoma with vomiting or intolerance of solid food or to staple line disruption leading to regain of weight). Types of operation: removal of band (4), GG (3), longer band (1), GB (2) 3 VBG with staple line disruption were not re-operated. Total incidence of staple line disruption 18.5%

adjustable banding (43 kg) than with VBG (35 kg). There were also fewer side-effects and greater patient satisfaction with adjustable banding.

Open versus laparoscopic GB

Weight change

Two RCTs compared open GB with laparoscopic GB (*Table 13*, appendix 13).[36,37] Nguyen and colleagues[37] demonstrated a slightly higher percentage of excess body weight loss following laparoscopic GB (68%, SD 15) compared with open GB (62%, SD 14) at 1 year, but this difference was not statistically significant ($p = 0.07$). Similarly, Westling and Gustavsson[36] found a non-significant difference in reduction of BMI 1 year following laparoscopic (14 kg/m^2, SD 3) and open (13 kg/m^2, SD 3) GB.

QoL and co-morbidities

Nguyen and colleagues[37] found that the SF-36 scores in four of eight domains (physical functioning: 60.9 (SD 24.7) versus 46.3 (SD 24.7); bodily pain: 59.2 (SD 21.5) versus 45.1 (SD 24.4); general health: 71.3 (SD 18.0) versus 64.0 (SD 18.1); social functioning: 67.6 (SD 24.5) versus 51.9 (SD 29.1)) were significantly better among laparoscopy patients than the open group 1 month following surgery. However, at 3 months follow-up both groups were comparable with US norms and not significantly different between groups. Scores for sexual interest/activity (0.20 (SD 0.21) versus 0.09 (SD 0.24), $p < 0.05$) and work conditions (labour) (0.24 (SD 0.19) versus 0.13 (SD 0.29), $p < 0.05$) on the Moorehead–Ardelt QoL questionnaire were higher following laparoscopic than open GB at 3 months, but at 6 months there was no significant difference between the groups.

Westling and Gustavsson[36] reported that 92% of all patients described themselves as 'very satisfied' with the result of the operation after 1 year, while the remaining patients described themselves as 'satisfied'. The authors report no significant difference between the groups, but data were not provided.

Complications and additional operative procedures

One postoperative death was reported by Westling and colleagues,[36] this was due to malignant hyperthermia. Gastrointestinal symptoms such as dumping, vomiting or diarrhoea were experienced by 5% of all patients.[36] Major complications occurred in 9.2% of open GB patients and 7.6% of laparoscopy patients ($p = 0.78$).[37] Minor complications were more common following the open procedure (7.6% versus 11.8%, $p = 0.42$), whereas late complications were more common following laparoscopy (18.9% versus 15.8%, $p = 0.52$).[37] Most complications affected a small proportion of patients, the most common being colicky pain and vomiting due to stricture of the tunnel through the mesocolon (laparoscopy 16.7%, open 0%),[36] jejunal ulcers (laparoscopy 10%, open 9.5%),[36] minor or superficial wound infection (laparoscopy 1.3%, open 7.9%[37] to 14.3%[36]), anastomotic stricture (laparoscopy

TABLE 13 *Summary of evidence of the effectiveness of open versus laparoscopic GB for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
Nguyen *et al.*, 2001[37] ***Design*** RCT (single centre) ***Intervention*** Laparoscopic GB (lap) (*n* = 79) Open GB (open) (*n* = 76) ***Patients*** BMI 40–60	***Percentage excess body weight loss (± SD)*** **12 months** lap (*n* = 29) 68% (± 15) open (*n* = 25) 62% (± 14) (*p* = 0.07)	***QoL SF-36 scores**** (mean (± SD)) preoperative lap *n* = 70; open *n* = 73 3 months lap *n* = 54; open *n* = 42 ***Physical functioning*** Preoperative lap 46.5 (21.3); open 40.0 (24.4); *p* = ns 1 month lap 60.9 (24.7); open 46.3 (24.7); *p* < 0.05 3 months lap 80.2 (19.1); open 67.8 (26.6); *p* = ns US norms 84.2 (23.3) ***Role – physical*** Preoperative lap 47.2 (40.2); open 37.5 (37.9); *p* = ns 1 month lap 29.7 (39.2); open 18.5 (32.3); *p* = ns 3 months lap 80.7 (32.5); open 76.8 (33.3); *p* = ns US norms 81.0 (34.0) ***Bodily pain*** Preoperative lap 51.0 (22.7); open 48.7 (24.1); *p* = ns 1 month lap 59.2 (21.5); open 45.1 (24.4); *p* < 0.05 3 months lap 75.1 (24.7); open 68.1 (25.6); *p* = ns US norms 75.2 (23.7) ***General health*** Preoperative lap 54.5 (21.6); open 52.9 (22.3); *p* = ns 1 month lap 71.3 (18.0); open 64.0 (18.1); *p* < 0.05 3 months lap 77.2 (15.7); open 72.4 (16.5); *p* = ns US norms 72.0 (20.3) ***Vitality*** Preoperative lap 38.5 (20.0); open 36.6 (19.9); *p* = ns 1 month lap 45.4 (20.5); open 39.1 (18.9); *p* = ns 3 months lap 65.8 (17.7); open 73.1 (95.2); *p* = ns US norms 60.9 (21.0) * *The short form-36 health survey questionnaire. Ware JE, Snow KK, Kosinski M, Gadek B. SF-36 Health Survey: manual and interpretation guide. Boston, MA: The Health Institute, New England Medical Center; 1993*	***Operative outcomes*** **Operative time in minutes (± SD)** lap 225 (± 40); open 195 (± 41); *p* < 0.001 **Estimated blood loss in ml (± SD)** lap 137 (± 79); open 395 (± 284); *p* < 0.001 **Proportion requiring intensive care unit stay** lap 7.6%; open 21.1%; *p* = 0.03 **Median length of hospital stay in days** lap 3 (IQR 1); open 4 (IQR 2); *p* < 0.001 **Proportion requiring re-operation** lap 7.6%; open 6.6%; *p* = ns **Return to activities of daily living in days (± SD)** lap 8.4 (± 8.6), open 17.7 (± 19.1); *p* < 0.001 **Return to work in days (± SD)** lap 32.2 (± 19.8); open 46.1 (± 20.6); *p* = 0.02 **Intraoperative transfusion** lap 0, open 3.9% Conversion from lap to open: 2.5% due to failure of circular stapler; inability to insufflate abdomen safely ***Complications*** **Major complications** Total: lap 7.6%, open 9.2% (*p* = 0.78); anastomotic leak: lap 1, open 1; gastric pouch outlet obstruction: lap 0, open 1; hypopharyngeal perforation: lap 1, open 0; jejunojejunostomy obstruction: lap 3, open 0; pulmonary embolism: lap 0, open 1; respiratory failure: lap 0, open 1; gastrointestinal bleeding: lap 1, open 0; wound infection: lap 0, open 2; retained laparotomy sponge: lap 0, open 1 **Minor complications** Total: lap 7.6%, open 11.8% (*p* = 0.42); gastrointestinal ileus: lap 1, open 0; C difficile colitis: lap 1, open 0; gastrogastric fistula: lap 0, open 1; asymptomatic leak: lap 0, open 1; gastrointestinal bleeding: lap 2, open 0; wound infection: lap 1, open 6; deep venous thrombosis: lap 1, open 1 **Late complications** Total: lap 18.9%, open 15.8% (*p* = 0.52); anastomotic stricture: lap 9, open 2; prolonged nausea/vomiting: lap 1, open 2; small bowel obstruction: lap 1, open 0; cholelithiasis: lap 3, open 0; ventral hernia: lap 0, open 6 (*p* = 0.01); anaemia: lap 0, open 2; protein-calorie malnutrition: lap 1, open 0

continued

***TABLE 13* contd** *Summary of evidence of the effectiveness of open versus laparoscopic GB for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
contd Nguyen *et al.*, 2001[37]		***Social functioning*** Preoperative lap 64.4 (26.3); open 61.6 (29.5); p = ns 1 month lap 67.6 (24.5); open 51.9 (29.1); $p < 0.05$ 3 months lap 87.3 (17.9); open 74.1 (30.0); p = ns US norms 83.3 (22.7) ***Role – emotional*** Preoperative lap 49.1 (24.4); open 45.5 (27.2); p = ns 1 month lap 78.5 (28.2); open 69.5 (33.5); p = ns 3 months lap 83.0 (29.6); open 74.6 (40.7); p = ns US norms 81.3 (33.0) ***Mental health*** Preoperative lap 73.0 (15.1); open 71.9 (17.3); p = ns 1 month lap 76.8 (17.4); open 70.8 (19.4); p = ns 3 months lap 82.9 (14.2); open 75.0 (19.2); p = ns US norms 74.7 (18.1) ***Moorehead–Ardelt QoL scores*** 3 months lap n = 47; open n = 36 6 months lap n = 34; open n = 28 ***Self-esteem*** 3 months lap 0.81 (0.3); open 0.73 (0.32); p = ns 6 months lap 0.84 (0.27); open 0.80 (0.28); p = ns ***Physical*** 3 months lap 0.48 (0.40); open 0.46 (0.44); p = ns 6 months lap 0.37 (0.17); open 0.34 (0.18); p = ns ***Social*** 3 months lap 0.31 (0.19); open 0.24 (0.21); p = ns 6 months lap 0.33 (0.19); open 0.29 (0.21); p = ns ***Labour*** 3 months lap 0.24 (0.19); open 0.13 (0.29); $p < 0.05$ 6 months lap 0.28 (0.21); open 0.21 (0.27); p = ns ***Sexual*** 3 months lap 0.20 (0.21); open 0.09 (0.24); $p < 0.05$ 6 months lap 0.26 (0.20); open 0.19 (0.26); p = ns	

continued

***TABLE 13* contd** *Summary of evidence of the effectiveness of open versus laparoscopic GB for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
Westling & Gustavsson, 2001[36] ***Design*** RCT (single centre) ***Intervention*** Laparoscopic GB (lap) (n = 30) Open RYGB (n = 21) ***Patients*** BMI > 40 or BMI > 35 with significant co-morbidity	***Mean BMI (± SD)*** 1 year lap 27 kg/m^2 (± 4); open 30.6 kg/m^2 (± 4) ***Mean change (± SD) in BMI*** 1 year lap 14 kg/m^2 (± 3); open 13 kg/m^2 (± 3) (p = ns)	***Patient satisfaction*** All patients: 92% very satisfied, 8% satisfied. No difference between groups (no data reported)	***Complications*** Deaths: 1 lap from malignant hyperthermia (family history) Gastrointestinal symptoms (dumping/vomiting/diarrhoea): 5% of all patients Incisional hernia: 1 lap; small embolus: 1 lap; colicky pain and vomiting due to narrow stricture of tunnel through mesocolon: 5 lap, and to herniated Roux limb: 1 lap; leakage due to failure of hand-sewn part: 1 open; jejunal ulcers: 3 lap, 2 open (p = ns); stricture in gastrojejunostomy: 1 lap (treated by endoscopic dilation); superficial wound infection: 3 open Readmission for unexplained fever (1), pneumonia (1), epigastric pain and/or vomiting with normal gastroscopy (2) ***Surgical outcomes*** **Conversions** 23% of lap patients converted to open Duration (minutes): lap (n = 30) 245 (135–390); open (n = 21) 100 (70–150) **Preoperative bleeding (ml)** lap (n = 30) 250 (50–1500); open (n = 21) 300 (200–500) 20% lap patients without conversion re-operated ***Early postoperative outcomes*** **Pain – morphine dose in mg (± SD)** lap (n = 29) 98 (± 71.5) (p = ns) lap: conversions excluded (n = 22) 69 (± 46.4) (p < 0.005); open (n = 21) 140 (± 90) **Hospital stay in days (± SD)** lap (n = 29) 4.5 (± 1.2) (p = ns) lap: conversions excluded (n = 22) 4 (± 0.8) (p = 0.025); open (n = 21) 6 (± 3.8) **Sick leave in weeks (± SD)** lap (n = 24) 3.9 (± 2.1) (p = ns) lap: conversions excluded (n = 18) 2.8 (± 1.8) (p = 0.025); open (n = 14) 5 (± 3.3)

8.9%, open 2.4%) and ventral hernia (laparoscopy 0%, open 7.9%, p = 0.01).[37]

Conversion from laparoscopy to open procedure occurred in 2.5% of patients in one RCT[37] and 23% of patients in the other.[36] Re-operation was required in 7.6%[37] to 20%[36] of laparoscopy patients and 6.6%[37] of patients with open GB (p = ns).[37]

Operative time was longer for laparoscopy (225 minutes[37] to 245 minutes[36]) than open GB (100 minutes[36] to 195 minutes[37]). Nguyen and colleagues found significantly less blood loss with laparoscopy (137 ml (SD 79) versus 395 ml (SD 284), p < 0.001),[37] whereas Westling and colleagues found only a slight reduction in blood loss (250 ml (range 50–1500) versus 300 ml (range 200–500), p = ns).[36]

When excluding patients who were converted to open procedures, Westling and colleagues found significant reductions in postoperative pain indicated by morphine dose, hospital stay and sick leave with laparoscopy, although the observations were not significant when using ITT analysis. Nguyen and colleagues, however,

found significant reductions in the proportion requiring intensive care unit stay (laparoscopic versus open) (7.6% versus 21.1%, $p = 0.03$), median length of hospital stay (3 days versus 4 days, $p < 0.001$), days to return to activities of daily living (8.4 days (SD 8.6) versus 17.7 (SD 19.1), $p < 0.001$), and days to return to work (32.2 days (SD 19.8) versus 46.1 (SD 20.6), $p = 0.02$) following laparoscopy.

Summary

The two trials of open versus laparoscopic GB gave similar results in terms of weight loss and patient satisfaction. Laparoscopic surgery took longer in theatre but patients went home and back to work earlier. Complications were not uncommon with both operations, but there was little overall difference. Laparoscopic surgery had to be converted to open in 2.5% to 23% in different studies.

Open versus laparoscopic ASGB

Weight change

De Wit and colleagues[43] compared open and laparoscopic ASGB (*Table 14*, appendix 14). No significant difference in weight loss was demonstrated between the procedures 12 months after surgery (p = ns). However, both laparoscopic and open ASGB were associated with a significant reduction in weight compared with baseline (35 kg and 34.4 kg respectively, $p < 0.05$).

QoL and co-morbidities

Data on QoL or co-morbidities was not assessed.

Complications and additional operative procedures

Surgical complications and access port complications did not differ significantly between the two procedures, although patients undergoing the open procedure had higher proportions of incisional hernia complications compared with laparoscopy (12% versus 0%). Similarly, early postoperative complications differed little between open and laparoscopic ASGB, although there were greater proportions of cholecystectomy and gallbladder punctures among those undergoing open procedures (20% versus 8% and 28% versus 0%, respectively). Re-admissions

TABLE 14 *Summary of evidence of the effectiveness of open versus laparoscopic ASGB for morbid obesity*

Study details	Weight change	QoL/ co-morbidities	Complications and additional procedures
De Wit *et al.*, 1999[43] ***Study design*** RCT (single centre) ***Intervention*** Laparoscopic ASGB (lap) (n = 25) Open ASGB (open) (n = 25) ***Patients*** BMI > 40 (n = 50)	***Mean weight loss at 12 months*** lap 35 kg, open 34.4 kg (p = ns) Reduction from baseline $p < 0.05$ for lap and open ***BMI reduction at 12 months*** lap 11.6, open 10.6 (p = ns) Reduction from baseline $p < 0.05$ for lap and open	Not assessed	***Early postoperative complications (lap vs open)*** Cholecystectomy (8% vs 20%); adhesiolysios (4% vs 0%); gallbladder puncture (to obtain samples for study purposes) (0% vs 28%); pulmonary complications (8% vs 8%); urinary infection (8% vs 0%); rhabdomyolysis (4% vs 0%); neurologic complication (neuropraxi) (4% vs 4%); perforation pouch (0% vs 4%); wound abscess (0% vs 4%); fever (0% vs 8%); gout (0% vs 4%) ***First year surgical complications (lap vs open)*** Incisional hernia (0% vs 28% (12% patients), p = ns); migration band (0% vs 4%, p = ns); umbilical hernia (4% vs 0%, p = ns) ***First year access port complications (lap vs open)*** Total (28% (20% patients) vs 24% (20% patients), p = ns); dislocation (8% vs 4%, p = ns); dislodgement (20% vs 16%, p = ns); infection (0% vs 4%, p = ns); replacement (20% vs 16%, p = ns) ***Readmissions (lap vs open)*** Patients 20% vs 28%, p = ns; total readmissions: 24% vs 60%, $p < 0.05$ ***Conversions*** lap to open procedure: 8%

(60% versus 24%, $p < 0.05$) and mean overall length of hospital stay (11.8 days versus 7.8 days, $p < 0.05$) were significantly higher in those undergoing open compared with laparoscopic procedures.

Two (8%) patients were converted from laparoscopic to open procedures due to inability to obtain pneumoperitoneum.

Summary

The one RCT of open versus laparoscopic placement of ASGB showed similar weight loss (> 34 kg) at 12 months. Laparoscopic surgery led to shorter patient stays in hospital and fewer readmissions. Complications were not uncommon with both operations, but there was little overall difference. Two patients were converted from laparoscopic to open procedures.

Chapter 4
Economic analysis

Literature review

A literature review was carried out to identify economic studies or costing papers on the use of surgery for the morbidly obese. Four economic evaluations were found. A list of excluded studies can be seen in appendices 16 and 17.

One study looked at RYGB versus VLCD, one considered VBG (VBG) versus no treatment, the third study compared laparoscopic VBG versus open GB and the fourth looked at GBan, VBG or GB versus conventional treatment.

The characteristics of the four papers are presented in appendices 18–21.

Summary of findings of cost-effectiveness

RYGB versus VLCD

Martin and colleagues[72] found that RYGB was more cost-effective at producing and maintaining weight loss than VLCDs. Surgical therapy was costed at US$24,000 for the procedure only, whilst medical therapy was costed at US$3000. If patients lost to follow-up were included, the cost per pound lost through surgical therapy was between US$250 and US$750, whilst through medical therapy the cost was US$100 to US$1600, for follow-up of 2–6 years. The cost per pound lost, if patients lost to follow-up were excluded was between US$230 and US$260 for surgical therapy, and between US$65 and US$300 for medical therapy, for follow-up of 2–6 years. This study found that after 7 years all patients on medical therapy were unable to maintain their weight loss, and regained all weight to their initial levels.

VBG versus no treatment

Van Gemert and colleagues[73] found that VBG was more cost-effective than no treatment, thus saving US$3928 to US$4004 per quality-adjusted life-year (QALY). VBG dominates no treatment, with VBG resulting in significant weight loss and improved QoL. VBG resulted in a gain of 12 QALYs in a life-long scenario, with the total percentage of individuals performing labour increased after VBG (19.6–48%), resulting in a productivity gain of US$2765 per annum.

Open GB versus laparoscopic VBG

Chua and Mendiola[74] found that laparoscopic VBG versus open GB was a feasible surgical procedure with lower costs resulting from shorter hospital stay, in spite of a longer operating time. Average hospital charge for laparoscopic VBG was US$12,800 (1993/94) compared to US$11,900 (1986) (US$16,700 adjusted to 1994 prices) for open GB. The study was carried out retrospectively, used hospital charges as the costing mechanism, and did not indicate effectiveness in terms of weight loss. However, longer-term results await follow-up.

Gastric surgery (GBan, VBG, GB) versus conventional management

Sjostrom and colleagues[75] compared various surgical procedures with conventional treatment. The surgical procedures used were GBan, VBG or GB, whilst conventional treatment was not adequately described. This study found that the benefits over 2 years of efficient obesity treatment are extremely positive, though longer-term (10-year) data are needed. The direct cost of surgical treatment was 16.5 million Swedish krona (SEK)/100 surgical patients over 10 years, with surgical patients losing between 30 kg and 40 kg of body weight over 2 years. HRQoL was said to improve over 2 years for the surgical intervention group, but not in the control group.

Conclusion

The economic evaluations reported above were not UK-based economic evaluations, but were based in either the USA, The Netherlands, or Sweden. Surgery was found to be more cost-effective or cost-saving than no treatment. Incremental cost-effectiveness was not carried out, and sensitivity analyses were performed in only one study. QoL and discounting was not carried out, many of the studies used hospital charges as their costs, follow-up costing was not used, and co-morbidity costing was only included in one study.

Internal validity

The internal validity of the studies seems reasonable. There are three types of comparator in the economic evaluations: another surgical intervention, VLCD or no treatment (conventional

management). RYGB is compared with VLCD, VBG versus no treatment, laparoscopic VBG versus open GB and surgery (GBan, VBG or GB) versus conventional management.

The majority of the studies do not include costing of adverse effects caused by surgery, discounting, sensitivity analysis, or incremental costing analysis, and all exclude non-healthcare costs.

External validity

The studies were conducted in either the USA or Europe. In terms of cost-effectiveness it is not reasonable to convert costs by a simple currency conversion, since components of the costings may differ from the UK. Also, practices for conventional treatment or surgical treatments may differ between countries.

Estimating cost-effectiveness of surgery in the UK

Potential economic benefits of surgery for morbid obesity

As the clinical effectiveness chapter (chapter 3) makes clear, surgery for morbid obesity does appear to produce a benefit to patients but the extent of this benefit differs between studies. This introduces some uncertainty into the economic evaluation, although this can be addressed by considering a number of plausible scenarios. Additional complicating factors are that:

- no validated economic measure of HRQoL has been carried out alongside trials
- there are long-term consequences of weight reduction that cannot be precisely quantified owing to uncertainty in the clinical evidence.

The potential benefits of surgery for morbid obesity can be broken down into five parts:

(i) efficacy data showing reduction in excess weight
(ii) gain in HRQoL as a result of weight loss
(iii) gain in HRQoL as a result of reduced morbidity from diseases resulting from obesity (co-morbidities and/or secondary disease)
(iv) gain in survival from avoiding premature mortality associated with obesity and subsequent diseases
(v) indirect benefits from (i)–(iv), such as gains in economic productivity.

In line with NICE guidance, this evaluation has not considered item (v).

The economic evaluation method – a note for non-specialists

Economic evaluation identifies, measures and values the resources used and the benefits from two or more courses of action from a clearly stated perspective and time horizon. While the handling of costs is conceptually straightforward, benefits are more of an issue in at least two respects.

- First, interventions often avoid the need for future treatments. A cost can be calculated for these treatments and be included in the evaluation as a 'saving' (a negative cost). However, this is an economic saving, that is the value attached to resources freed up for other uses. It is not a financial saving, that is an amount of money that can be taken from that service and re-invested elsewhere. For example, if weight loss reduces the incidence of diabetes, that will free up resources (outpatient clinic time, vascular surgery time, renal clinic time, and so on). We can attach a cost to this to include in the model, but the real benefit comes from the patients who now use the resources freed – the 'saving' is thus a proxy value for these 'knock-on' effects.
- Secondly, health gain commonly encompasses changes in HRQoL and length of life. Economists have attempted to combine these into a single index called the QALY. HRQoL is measured on a cardinal scale ranging from one (equivalent to full health) through zero (a state that is as bad as being dead) and even into negative states. These HRQoL figures are then used as weights to attach to life-years. The technique is imperfect and has its critics; however, it is a very powerful concept in that it can be applied to a very wide range of health services to give a generic measure of outcome.

The aim of the economic evaluation in this case was to estimate the net costs of surgery compared with 'no surgery' over a stated time horizon. Resource use is costed using stated assumptions, and reductions in resource use in the future are included as 'savings', as per the brief discussion above. Estimates of the QALY gained from surgery are made based upon the available evidence.

The aim is to produce a net cost per QALY gained. This can then be compared with the same ratio for other services to give an indication of relative cost-effectiveness. Again, this is controversial and not without its problems: a lot of information is being combined into a single ratio. However, these data do form one of the few ways of comparing 'apples-and-oranges', cutting across seemingly quite different health services.

The economic evaluation is hugely demanding of data, so a number of sources are required; sometimes, expert judgement is called for to fill gaps. To allow for the variable quality of the data inputs, an economic evaluation should include an extensive sensitivity analysis. This involves testing the robustness (or sensitivity) of the results to changes in the data inputs (or even the model structure). For example, suppose that some RCTs show a 20% weight loss following surgery while others show a 30% loss. A figure of 25% might be used in the initial analysis; this could then be replaced with the lower and upper figures to see whether this made a difference to the results. When this difference is sufficient to change the conclusion of the evaluation then this should be highlighted and the conclusion suitably qualified.

Which types of surgery should be evaluated?

The clinical literature review considered four types of surgery, one of which (GP) had three variants; in other words, there were six types of operation. To reduce this to a manageable number for the economic evaluation, the following exclusions have been made:

- horizontal GP was excluded because (i) it appeared to be less efficacious than vertical GP, and (ii) expert opinion suggested that it was very rarely carried out in the UK
- jejeunoileostomy was excluded because (i) experts advise that it is widely regarded as unsafe, and (ii) it would be very difficult to cost given that it was almost never carried out in the UK.

Of the remaining scenarios, vertical GP and VBG were only differentiated in the sensitivity analysis through cost of the banding.

The different treatment options considered are as follows:

- GB (Roux-en-Y)
- VBG
- adjustable GBan
- non-surgical management.

The next stage is to make efficacy assumptions for each of these.

Constructing efficacy 'scenarios'

The aim of this section is to take the data on clinical efficacy reported in chapter 3 and to convert it into scenarios in order to estimate the benefits of surgery for the economic evaluation. The aim is not to carry out a detailed meta-analysis of the different trials but to draw up a set of baseline assumptions about weight loss after each type of surgery that reflect the clinical evidence. The approach used is to summarise the clinical data for each of the four treatment options above, then to set out the rationale behind the assumption used.

*GB (Roux-en-Y) (***Table 15***)*

The data initially appear to be incredibly varied; however, once weight loss is focused upon the evidence can seem to become more coherent. Examining the trial of Hall and colleagues[45] as the starting point (on grounds of size and length of follow-up) then the results from a baseline of 115 kg show a loss of 42 kg after 1 year, 44 kg after 2 years and 39 kg after 3 years. *Table 16* compares that with the weight loss in the other trials (using an initial baseline weight of 115 kg).

MacLean and colleagues[49,50] studied patients with a BMI of 50 initially and reported that 58% of patients had lost at least half their excess weight at 3 years and 34% at 6.5 years. These results are quite hard to interpret given that so few data are provided on the actual mean weight loss. However, it is important to note that MacLean and colleagues[49,50] appear to show that longer-term results beyond 5 years deteriorate slightly. Set against this, the weight losses shown in the study by Howard and colleagues[46] appear to be holding up well at 5 years.

If these weight reductions are converted back to percentage reductions on baseline weight for each trial then the results shown in *Table 17* are seen. These figures indicate that a much greater degree of consistency between results exists than initially appeared likely.

For the economic evaluation, the baseline assumption is as follows:

- after 1 year, weight loss is 36% of initial weight
- this is maintained until year 5.

Vertical banded gastroplasty

Table 18 summarises clinical data for VBG. Weight loss over time, based upon *Table 18*, is represented in *Table 19*. A conversion of the data in *Table 19* to percentage reductions on initial weight was carried out and is shown in *Table 20*.

Combining these data into a single set of assumptions is more difficult than for GB: there are fewer studies and more variability between them. Thus, the baseline assumptions used are:

TABLE 15 *Summary of clinical data for RYGB*

Study and participants	Key results	Complications
Howard *et al.*, 1995[46] *n* = 20, BMI > 40 Average age 38 years Average weight 154 kg	% of EWL: at 1 year = 78% at 5 years = 70% Initial EW was 71 kg so this is equivalent to 55 kg at 1 year and 50 kg at 5 years	0% mortality 25% symptomatic ulcer disease (half need surgery) 29% cholecystectomy
MacLean *et al.*, 1995[49], 1993[50] *n* = 52 Average age 40 years Average BMI 50	Success = BMI < 35 or < 50% EWL and no re-operation: at 3 years = 58% at 6.5 years = 34%	0% mortality At 3 years 23% to IGB At 6.5 years 37% to IGB
Sugerman *et al.*, 1987[61] *n* = 20, more than 100 lb above IBW Average age 38 years Average weight 132 kg	At 1 year = 44 kg (33%) At 2 years = 44 kg At 3 years = 41 kg	10% mortality 25% intractable vomiting and stomal stenosis
Hall *et al.*, 1990[45] *n* = 99, > 160% IBW Median age 35 years Median weight 115 kg	Baseline = 115 kg At 1 year = 73 kg At 2 years = 71 kg At 3 years = 76 kg 66.7% had EWL > 50%	2% postoperative mortality 35% need trimming procedures 7% cholecystectomy 2% incisional hernia 4% revision 2% reversal
Laws & Piantadosi, 1981[47] *n* = 27, twice IBW for height Average weight 137 kg females, 175 kg males	65% of initial weight at 1 year	0% mortality 7% readmitted with vomiting 4% stoma stenosis 4% wound hernia
Lechner & Callender, 1981[48] *n* = 50, at least 100 lb over IBW Average age 36 years Average weight 121 kg	Average weight loss = 36.6% at 1 year	2% operative mortality 6% incisional hernia rate 4% readmit for IVS* 2% re-operation for inadequate weight loss
Naslund[51–56] † *n* = 29, morbidly obese with Broca's index 1.5 Average age 36 years Average weight 118 kg	Mean weight loss: at 1 year = 42 kg (64% of preoperative weight) at 1.5 years = 43 kg (63%) at 2 years = 43 kg (64%) at 3 years = 38 kg (?) 32% have postoperative weight > 75% of preoperative weight (failures)	0% operative mortality 7% cholecystectomy 3% anastomotic leakage requiring operation 10% hernia repair 14% plastic surgery but 3/4 have this with hernia repair
Pories *et al.*, 1982[57] *n* = 42, at least twice normal weight Average age 37 years Average weight 130 kg	62% of original weight at 1 year 60% of original weight at 18 months	0% operative mortality
Buckwalter *et al.*, 1977[40] **Buckwalter, 1980[41], 1978[42]** *n* = 19, at least twice normal weight or > 45 kg overweight for 5 years Average age 34 years Average weight 141 kg	% mean EWL: at 1 year = 44% at 2 years = 50% at 3 years = 55%	5% operative mortality 5% wound infection drainage 21% incisional hernia repair 26% panniculectomy 5% abscess drainage 16% revisions

continued

***TABLE 15* contd** *Summary of clinical data for RYGB*

Study and participants	Key results	Complications
Griffen *et al.*, 1977[44] *n* = 32, 50 kg over IBW Average age 33 years Average weight 148 kg	Mean weight loss = 51 kg at 1 year	3% postoperative mortality 12.5% readmitted (3 for hernia, 1 for reanastomosis)
Nguyen *et al.*, 2001[37] *n* = 155, average BMI 48	EWL at 1 year 68% in laparoscopy group 62% in open group	Complications recorded but unclear how many required surgery
Westling & Gustavsson, 2001[36] *n* = 51, BMI average 42	Mean BMI at 1 year: 27 in laparoscopy group 31 in open group	23% of laparoscopy procedures converted to open procedures

* *Not defined*

† *Naslund, 1986[51]; Naslund* et al.*, 1986[52]; Naslund, 1987[53]; Naslund & Beckman, 1987[54]; Naslund* et al.*, 1988[55,56]*

TABLE 16 *Actual weight loss with RYGB*

Study	Baseline	After 1 year	After 2 years	After 3 years	After 4 years	After 5 years
Hall *et al.*, 1990[45]	115	42	44	39	–	–
Naslund[51–56] *	118	42	43	48	–	–
Lechner & Callender, 1981[48]	121	44	–	–	–	–
Pories *et al.*, 1982[57]	130	49	–	–	–	–
Sugerman *et al.*, 1987[61]	132	44	44	41	–	–
Laws & Piantadosi, 1981[47]	Approx. 140	49	–	–	–	–
Griffen *et al.*, 1977[44]	148	51	–	–	–	–
Howard *et al.*, 1995[46]	154	55	–	–	–	50

* *Naslund, 1986[51]; Naslund* et al.*, 1986[52]; Naslund, 1987[53]; Naslund & Beckman, 1987[54]; Naslund* et al.*, 1988[55,56]*

All figures in kg

TABLE 17 *Percentage weight reduction with RYGB*

Study	After 1 year	After 2 years	After 3 years	After 4 years	After 5 years
Hall *et al.*, 1990[45]	37%	38%	34%	–	–
Naslund[51–56] *	36%	36%	41%	–	–
Lechner & Callender, 1981[48]	36%	–	–	–	–
Pories *et al.*, 1982[57]	38%	–	–	–	–
Sugerman *et al.*, 1987[61]	33%	33%	31%	–	–
Laws & Piantadosi, 1981[47]	35%	–	–	–	–
Griffen *et al.*, 1977[44]	34%	–	–	–	–
Howard *et al.*, 1995[46]	36%	–	–	–	32%

* *Naslund, 1986[51]; Naslund* et al.*, 1986[52]; Naslund, 1987[53]; Naslund & Beckman, 1987[54]; Naslund* et al.*, 1988[55,56]*

TABLE 18 *Summary of clinical data for VBG*

Study and participants	Key results	Complications
Howard *et al.*, 1995[46]		
n = 20, BMI > 40 Average age 37 years Average weight 142 kg	% of EWL: at 1 year = 52% at 5 years = 37% Initial EW was 67 kg so this is equivalent to 35 kg and 25 kg, respectively	0% mortality 29% postoperative cholecystectomy
MacLean *et al.*, 1995[49], 1993[50]		
n = 54 Average age 39 years Average BMI 48	Success = BMI < 35 or < 50% EWL and no re-operation: at 3 years = 39% at 6.5 years = 16%	0% mortality At 3 years = 33% to IGB At 6.5 years = 44% to IGB
Sugerman *et al.*, 1987[61]		
n = 20, more than 100 lb above IBW Average age 38 years Average weight 146 kg	At 1 year = 32 kg (22%) At 2 years = 30 kg At 3 years = 27 kg (20%)	0% mortality Convert to Roux-en-Y: at 1 month = 5% at 18 months = 5% at 38 months = 10%
Andersen *et al.*, 1987[38]		
n = 23, all given VLCD and must lose and maintain > 40% of initial EW	VLCD + VBG = 48.5 kg at 1 year VBG alone = 10 kg	
Nilsell *et al.*, 2001[35]		
n = 30, average BMI 44 Average weight 122 kg	Baseline = 122 kg At 1 year = 82 kg At 2 years = 85 kg At 3 years = 90 kg At 4 years = 95 kg At 5 years = 92 kg	10 VBG re-operated

TABLE 19 *Actual weight loss with VBG*

Study	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Nilsell *et al.,* 2001[35]	122	40	37	32	27	30
Howard *et al.*, 1995[46]	142	35	–	–	–	25
Sugerman *et al.*, 1987[61]	146	32	30	27	–	–

All figures in kg

TABLE 20 *Percentage weight reductions with VBG*

Study	Year 1	Year 2	Year 3	Year 4	Year 5
Nilsell *et al.*, 2001[35]	33%	30%	26%	22%	25%
Howard *et al.*, 1995[46]	25%	–	–	–	18%
Sugerman *et al.*, 1987[61]	22%	21%	19%	–	–

- 25% weight loss at year 1
- declining by 2 percentage points per annum thereafter (i.e. 23%, 21%, etc.).

*Adjustable silicone gastric banding (***Table 21***)*

The evidence base for ASGB is more limited with only the Nilsell and colleagues[35] study reporting beyond 1 year. Encouragingly, this study suggests that weight loss is not only maintained (in contrast to GB and VBG) but actually increases slightly over time.

The assumptions used for this intervention are:

- at 1 year, lose 20% of initial weight (weight loss is 25 kg)
- at 2 years, 28% (35 kg)
- at 3 years, 31% (38 kg)
- at 4 years, 30% (37 kg)
- at 5 years, 33% (41 kg).

Whilst the absolute loss in year 1 is less than that reported by de Wit and colleagues,[43] the percentage is very similar (20% in the Nilsell and colleagues study,[35] 23% for de Wit and colleagues[43]).

*Non-surgical management (***Table 22***)*

The data from the Swedish trial[62–70] suggests that long-term weight loss in the non-surgical management group is very unlikely. Small, temporary gains can be achieved but these are relatively modest. Andersen and colleagues[34] and the Danish study[58–60] report results that suggest a 6–9 kg weight loss can be achieved after 2 years, but this is quickly lost thereafter.

TABLE 21 *Summary of clinical data for ASGB*

Study and participants	Key results	Complications
Nilsell *et al.*, 2001[35] *n* = 29, BMI 43 Average age 38 years Average weight 123 kg	Baseline weight = 123 kg At 1 year = 98 kg At 2 years = 88 kg At 3 years = 85 kg At 4 years = 86 kg At 5 years = 82 kg	3 re-operations (10.3%)
De Wit *et al.*, 1999[43] *n* = 50, BMI > 40 Equal numbers to laparoscopic and open procedures Mean weight 149 kg Mean BMI 50	At 1 year: open – BMI down 10.6, weight loss = 34.4 kg laparoscopy – BMI down 11.6, weight loss = 35 kg	Cholecystectomy in 8% of laparoscopic and 20% of open procedures Hernia repair in 0% of laparoscopic and 28% of open procedures Readmitted: 20% laparoscopic and 8% open procedures

TABLE 22 *Summary of clinical data for non-surgical management*

Study and participants	Key results	Complications
Andersen *et al.*, 1984[34] *n* = 30, at least 60% overweight VLCD cycles of 900 kcal every 2 weeks and 341 kcal every 8 weeks	Weight loss: at 1 year = 18 kg at 1.5 years = 10.5 kg at 2 years = 9 kg at 5 years 17% had lost 10 kg or more	
DOP[58–60] *n* = 66, at least 80% overweight 'Medical management'	Median weight loss: at 2 years = 6 kg	
SOS[62–70] *n* = 1099, but full follow-up on *n* = 251 'Conventional treatment'	Baseline = 115 kg At 8 years = 115 kg	

Given that the control arm of these surgical trials use medical management that exceeds standard practice in the UK, the simplifying assumption is made that these patients will have no change in their weight over time. In the sensitivity analysis, this is varied to allow for a reduction of 3 on the BMI in the year of the VLCD; however, this reverts to previous BMI after 1 year.

Summary of the efficacy scenarios

The data in *Tables 15–22* are expressed as percentage reductions on baseline weight and are summarised in *Table 23*.

TABLE 23 *Summary of % weight reduction in each clinical efficacy scenario*

Year	GB	VBG	ASGB	Non-surgical
1	36%	25%	20%	0
2	36%	23%	28%	0
3	36%	21%	31%	0
4	36%	19%	30%	0
5	36%	17%	33%	0

These percentage weight reductions are applied to a baseline weight of 135 kg

If a weight of 135 kg is assumed to be equivalent to a BMI of 45, then a loss of 3 kg (i.e. 135/45) is equivalent to a drop of 1 on the BMI (*Table 24*).

TABLE 24 *Actual weight reduction in each clinical scenario, given a baseline weight of 135 kg*

Year	GB	VBG	ASGB	Non-surgical
Baseline weight	135	135	135	135
1	86	101	108	135
2	86	104	97	135
3	86	107	93	135
4	86	110	95	135
5	86	113	90	135

In the worst case scenario for surgery, patients will revert to their baseline BMI after 5 years. However, in the best case scenario, the BMI at year 5 is taken as the steady state for the remainder of the lifetime for patients with GB and ASGB, but with VGB BMI will continue to rise at the same rate until it reaches the baseline weight (*Table 25*).

Based upon these assumptions, the efficacy data are then taken forward and incorporated into the calculation of QALYs in the following section.

TABLE 25 *Reduction in BMI for each clinical scenario*

Year	GB	VBG	ASGB	Non-surgical
Baseline BMI	45	45	45	45
1	29	34	36	45
2	29	35	32	45
3	29	36	31	45
4	29	37	32	45
5	29	38	30	45

Gains in HRQoL

A literature search looking for articles that have estimated the QALY gain of treatments for obesity identified two studies: the van Gemert and colleagues'[76] economic evaluation of VBG; and the Wessex DEC[77] report on the use of orlistat in obesity. In addition, previous work by NICE on drug treatment for obesity[22,23] has been used.

Van Gemert and colleagues[76]

This study assessed HRQoL for 21 patients treated with VBG in Amsterdam. Patients were almost all female with an average age of 33 years. Average BMI was 47 before surgery, 30 at 1 year and 29 at 2 years. Assessments were made 1 month before surgery, and at 1 and 2 years after surgery, using the Nottingham Health Profile (NHP) and a visual analogue scale (VAS), ranging from best imaginable QoL (rated 10) to worst imaginable (rated 0). The VAS scores were as follows:

- preoperatively – mean 4.6 (SD 2.3)
- at 1-year follow-up – mean 8.2 (SD 2.2)
- at 2-year follow-up – mean 7.1 (SD 2.9).

Ideally, this study would have used a validated questionnaire such as the EuroQol-5 dimensions (EQ5D). This includes a stage where patients rank 'death' (or a state regarded as being equivalent to death) on the scale. Values are then rescaled with death being equivalent to zero. This is not possible here, but the data available are sufficient to make inferences about patients' self-assessed HRQoL.

Wessex DEC[77]

The authors of this evaluation of drug treatment could find no previous evidence of estimates of HRQoL in a format that was directly applicable to QALYs. After considering the available QoL literature, they used their own judgement to estimate which generic health states the typical patient would be in as measured by the index of health-related QoL (IHRQoL). This describes health states in terms of eight disability states,

four pain states, and five anxiety/depression states. The 175 possible combinations of states have been rated using the standard gamble on a scale from one (full health) to zero (equivalent to death); negative values are possible but rare.

The authors considered two scenarios for a person with obesity. In the worst case they would have:

- major physical limitations (state D5 on the disability scale)
- moderate pain (state P3 on the pain scale)
- moderate distress (state E3 on the anxiety/depression scale).

In the best case, they would have:

- slight physical disability (D3)
- no pain (P1)
- slight distress (E2).

These would rate at 68% of full health (i.e. 0.68) and 94% (0.94) respectively.

They then considered the health states if drug treatment resulted in the loss of 10% or more of initial body weight. They judged that the 'worst case' person would then have:

- some physical limitations (state D4)
- slight pain (P2)
- slight distress (E2).

In the 'best case' the gain would be to a state of:

- no physical limitations but slight social disability (D2)
- no pain (P1)
- no distress (E1).

These would give an HRQoL index of 0.861 and 0.99 respectively.

If a comparison is made of their high 'before and after' estimates, the difference is (0.99 – 0.94 =) 0.05, with their low 'before and after' estimates difference being (0.86 – 0.68 =) 0.18. As a cross-check, an obesity clinician and a researcher estimated the utility gain from a weight loss of 10 kg at 0.1 and 0.19 respectively. While it is not made explicit, these estimates appear to apply to patients with a BMI in the range 25–35 – the indication for drug treatment.

Using the same logic, the health states described for obesity can be translated into EQ5D states, rather than IHRQoL. States are expressed on a 1–3 scale for 'none', 'some' and 'a lot' for each of five dimensions (i.e. mobility, self-care, usual activities, pain/discomfort and anxiety/depression). The state of full health would thus be expressed 11111, denoting the absence of any problems on all dimensions. The pre-intervention states would be 31322 and 21112. From the time-trade-off values supplied by Dolan and colleagues,[78] these states would be valued as 0.05 and 0.78. Considering the post-treatment states described above, these might equate to 11222 and 11211, valued as 0.689 and 0.883. These values are much lower than those suggested by IHRQoL for all states.

Roche submission on orlistat

The Roche submission in support of orlistat provides a range of utility values categorised by the ages of the patients and their BMI, based upon time-trade-off values. Focusing on females aged 35–44 years as the typical candidate for obesity surgery, utility values by BMI were obtained. [Commercial in confidence data not shown.]

Modified Wessex approach

Some attempt was made to use a modified version of the Wessex[77] approach above. This involved taking health status measures from the RCTs[37] and other QoL papers[76,79–84] and using judgement to match them to EQ5D states. While this is reasonable to give broad estimates of pre- and postoperative utility, it is very difficult when it comes to small changes in weight reflecting (say) the difference between the second and third year of follow-up. There are two problems: first, health status measures were not usually recorded this regularly in the RCTs, and secondly the health state descriptions in EQ5D are not sensitive enough to detect such subtle changes. It is also unsatisfactory to be using the judgements of one or two researchers to interpret QoL in this way. While this exercise suggested that the utility estimates from the other methods were of the right order of magnitude, they were not used in the calculations.

Assumptions used

In the analysis, the Roche data were applied to the BMI figures calculated above. They are the most comprehensive source of values and an equation allows estimation of the utility values for any BMI. They have the additional advantage of having been used in a previous NICE appraisal, so their strengths and weaknesses are understood. The NICE guidance on orlistat notes that it is believed that the approach used by Roche over-estimated the utility gain. The only direct evidence from

asking patients how they valued their health is supplied by the van Gemert[76] trial cited above. How does this compare to the Roche-based estimate of gain in utility? [Commercial in confidence data not shown.]

The only alternatives to the Roche method would be either to make a series of assumptions matching utility scores from various sources to obesity states or to abandon the attempt to estimate QALYs for this group. Unfortunately, this would mean expressing the benefits as a change in weight, such as £X/kg of weight reduced or £X/percentage-point reduction in baseline weight. The problem is in interpreting these figures: how does one know whether £X represents good value per kilo of weight lost? The advantage of the QALY is that it has been applied to several hundred common health services so comparisons can be made. The view taken here, therefore, is that the QALY is worth persisting with, despite its problems.

Avoiding secondary disease and premature mortality

Obesity is associated with an increased risk in a number of conditions, as noted elsewhere in this report. Among those that are likely to have important cost consequences are diabetes, angina, myocardial infarction, stroke, osteoarthritis, gall-bladder disease, selected cancers (colon and ovarian), hypertension and hyperlipidaemia.

Initially, it was hoped to use data on the relative risk of these factors to estimate potential savings from the 'knock-on' costs of obesity. While this is possible for a cost-of-illness study, very little is known about how these risks are reversed by surgery. The approach was modified, therefore, with attention confined to co-morbidities recorded in the RCTs listed in the review of efficacy data. Even this raises problems as little is known about the differential impact of the various types of surgery.

Co-morbidity data from the RCTs of surgery

Unfortunately, only a few trials include co-morbidities in their main reports. The data that are available suggest surgery makes a dramatic impact but it is possible that this is due to the greater likelihood of reporting interesting results. Bearing this in mind, the efficacy papers show the following.

Diabetes

- 11 of 12 patients who were diabetic had reverted to normoglycaemia at 1 year[57]
- six of eight patients were off medication at 3 years[45]
- at 2 years after surgery, the incidence of diabetes in surgical patients was 0% versus 4.7% in controls;[69] at 8 years the figures were 3.6% and 18.5% respectively.

Hypertension

- 32 of 35 patients were normotensive at 1 year[57]
- 22 of 39 patients were off medication at 3 years[45]
- at 2 years after surgery, the incidence of hypertension in surgical patients was 3.2% versus 9.9% in controls;[69] at 8 years the figures were 25.8% and 26.4%, respectively.

Asthma

- six of 12 patients were off medication at 3 years.[45]

Arthropathy

- 16 of 25 patients were off medication at 3 years.[45]

In summary, the impact on diabetes appears to be substantial and lasting; by contrast, the impact on hypertension is transient. This suggests caution should be taken with extrapolating the findings into the long-term. To be conservative, only the gains from avoiding diabetes were included in the baseline. Reflecting this deliberate underestimate, the sensitivity analysis shows the effects of increasing these benefits by a given percentage to proxy the inclusion of some of the other diseases as well.

Estimate of costs averted

For diabetes, it is assumed that UK data from the CODE2 study of type 2 diabetics can be applied. This showed the annual health care cost per person to be £1550, including all NHS costs of disease management and treatment of complications.

The baseline prevalence of diabetes has been recorded in some RCTs but the figures are very variable. *Table 26* summarises these.

It was assumed for the baseline analysis that 10% of patients have diabetes. From Hall and colleagues,[45] 75% of patients are off their medication at 3 years. This is assumed to apply until at least year 8, in line with the SOS[68,69] follow-up. In the baseline analysis, these savings stop at this point and the previous incidence rate starts again. In addition, those individuals with diabetes at the start of the mode who came off medication after surgery all revert to medication at this point.

The SOS[68,69] data are used for diabetes incidence. The incidence is thus 2.3% per annum without surgery and 0.45% with surgery.

TABLE 26 *Summary of clinical evidence for baseline diabetes prevalence*

Study	Diabetes prevalence
SOS, study 2 (Sjostrom *et al.*, 2000[69]), control arm	6%
SOS, study 2 (Sjostrom *et al.,* 2000[69]), surgery arm	8%
SOS, study 4 (Sjostrom *et al.*, 1999[68]), control arm	18%
SOS, study 4 (Sjostrom *et al.*, 1999[68]), surgery arm	19%
Pories *et al.*, 1982[57]	14%
Hall *et al.,* 1990[45]	3%
Griffen *et al.*, 1977[44]	28%
De Wit *et al.*, 1999[43]	12%
Nguyen *et al.*, 2001[37]	10%
Westling & Gustavsson, 2001[36]	2–3%
Nilsell *et al.*, 2001[35]	7%

Life expectancy

No change in life expectancy is assumed in the baseline analysis; this reflects clinical caution in assuming an effect that can only be indirectly inferred. In the 'best case' sensitivity analysis, a gain of 0.29–0.6 life-years per patient is assumed. These figures are derived from the UKPDS trial[85] and represent the difference between intensive blood glucose control and standard care. (The range represents the discounted and undiscounted gain.) This is not a direct estimate of the gains of avoiding diabetes altogether. It is an underestimate because the gains of disease prevention are being proxied by the gains of better disease control.

Costs of surgery

There are four treatment options to cost, as noted earlier. An additional complication is the emerging evidence on open versus laparoscopic procedures. The approach taken was to assume that the procedure was laparoscopic where that was feasible, but conversion to an open procedure might be necessary. The conversion rate was taken from the trials.

Gastric bypass

Preoperative

Andersen and colleagues[38] report that 165 patients were admitted with morbid obesity: 92 were eligible for the trial, 74 underwent a VLCD to assess their suitability for treatment, and 45 were eventually randomised. It is therefore assumed that for every patient undergoing surgery, two undergo work-up and four are screened for suitability.

The assumed preoperative care per patient (including assessment for 'failures) is seven outpatient visits, four dietitian consultations, and one session with a psychologist.

Surgery

Where possible a laparoscopic procedure is carried out. This involves:

- time in theatre: 235 minutes (average of Westling and Gustavsson[36] and Nguyen and colleagues[37] figures)
- length of stay: 3.5 days (average of Westling[36] and Nguyen[37] figures). One surgical expert view is that it would be at least 7–10 days, while a second surgical view is 2–4 days; the baseline assumption is 6 days, with the range tested in the sensitivity analysis
- intensive therapy unit (ITU) admission for one night for 7.6% of patients,[37] assuming the remainder spend one night in the high-dependency unit (HDU).

However, in 0–23.3% (Westling and Gustavsson[36] and Nguyen and colleagues[37]), the operation is converted to an open procedure in theatre. The baseline assumption is 10%. When this occurs:

- time in theatre is 147.5 minutes (average of Westling[36] and Nguyen[37] figures); 150 minutes in Naslund and colleagues,[51–56] but surgical expert view is 180 minutes. The baseline assumption is 160 minutes
- length of stay is more difficult to judge: the most recent studies suggest a stay of 5 days (average of Westling[36] and Nguyen[37] figures). Results reported in the RCTs include 8 days,[45] 7.7 days but postoperation only,[47] 12 days but postoperation only.[51–56] One surgical expert view is that it would be at least 7–10 days, but another surgical view is 5–7 days. The baseline assumption is 7 days, with the range tested in the sensitivity analysis

- ITU admission for one night for 21.1% of patients,[37] assuming the remainder spend one night in the HDU.

Complications/revisions/additional procedures
Expert view suggests:

- mortality rate 1%
- incisional hernia in 5% after open operation (based on 10% hernia rate, with half the patients having their repair at the same time as apronectomy)
- apronectomy in 10% after 3 years.

In the efficacy section:

- 6/22 laparoscopic procedures subsequently needed emergency care[36]
- 7.6% of laparoscopic patients needed a repeat surgical procedure[37]
- 6.6% of open surgery patients needed one.[37]

The baseline analysis rests on the views of experts rather than RCTs.

Post-discharge
Post-discharge care in the first month after surgery is: six general practitioner visits, two practice nurse visits, four district nurse visits. For the first year: four outpatient clinics, 12 community dietitian contacts, and two psychology consultations. In year 2, there are four outpatients clinics, four community dietitian contacts, and two psychology consultations. In year 3 (and thereafter), this becomes two outpatient clinics, two community dietitian contacts, and one psychology consultation.

Vertical banded gastroplasty

Preoperative
For VBG the preoperative care per patient (including assessment for 'failures') was assumed to be the same as that for GB with seven outpatient visits, four dietitian consultations, and one session with a psychologist.

Surgery
- Surgical expert opinion time in theatre is taken as 120 minutes.
- Assumed that one band is used.
- Four days preoperative inpatient ward stay.
- Assumed one night stay in the HDU.

Complications/revisions/additional procedures
The efficacy papers report no deaths in 119 patients (minimum 1 year of follow-up).[38,46,49,50,61] It is assumed the mortality rate is 0.5%.

The RCTs are less helpful in terms of surgery in subsequent years: for example, MacLean and colleagues[49,50] converted 'failures' to isolated GB, Sugerman and colleagues[61] converted to RYGB, while Nilsell and colleagues[35] appear to have favoured repeating the operation.

In terms of revisions to the initial operation, the experts consulted suggested:

- reservoir infection 5%, requiring revision surgery
- band leakage 5%, requiring revision surgery
- band slippage 5%, requiring revision surgery.

In the baseline, it is assumed that 15% require surgery after 1 year.

In the longer-term, it has been estimated that the need for repeat surgery is 30% at 5 years[35] and 43% at 3 years.[49,50] Sugerman and colleagues report[61] that 20% of the VBG patients required conversion to GB within 3 years. Ideally, this would be modelled in a sensitivity analysis but in practice this is very difficult. It is relatively straightforward to estimate the costs but there are no data on the impact of this on BMI, or even of which patients undergo GB.

Post-discharge
Similarly to post-discharge for GB, VBG post-discharge care in the first month after surgery involves: six general practitioner visits, two practice nurse visits, four district nurse visits. Thereafter, in the first year: four outpatient clinics, 12 community dietitian contacts, and two psychology consultations. Year 2 involves four outpatient clinics, four community dietitian contacts, and two psychology consultations. In year 3 (and thereafter), there are two outpatient clinics, two community dietitian contacts, and one psychology consultation.

Adjustable silicone gastric band

(All figures from de Wit and colleagues[43] unless otherwise stated.)

Preoperative
Preoperative care for ASGB is as for GB and VBG.

Surgery
Laparoscopy is the preferred intervention. When it is possible it requires:

- 150 minutes in theatre
- 5 days on the ward
- one night in either ITU or HDU – same proportions as for GB.

However, 8% of patients need an open operation. When this occurs:

- 76 minutes in theatre
- 6 days on ward
- one night in either ITU or HDU – same proportions as for GB.

Complications/revisions/additional procedures
No deaths reported in 29 patients, so assumed mortality rate is as for VBG.

Since ASGB is also a banding procedure, one option would be to use the same re-operation rate at year 1 as is used for VBG. However, this may be an overestimate; Nilsell and colleagues[35] found that 3 of 29 patients needed repeat surgery at 5 years.

De Wit and colleagues[43] found that after 1 year, patients undergoing laparoscopic ASGB needed a further 2.9 days in hospital after discharge, compared with 4.6 for open ASGB. These figures were used in the baseline assumption.

This is assumed to include de Wit and colleagues'[43] figures that after an open procedure 28% need hernia repair and 20% cholecystectomy (compared with 0% and 8% respectively for laparoscopy).

Post-discharge
Post-discharge care for ASGB is as for GB and VBG.

Non-surgical management
Annual follow-up involving:

- four general practitioner visits
- two dietitian contacts
- two practice nurse contacts
- two district nurse contacts
- every 3 years: VLCD for 12 weeks (two cans of Slimfast per day).

Costs of different items of resource use

Cost data have been calculated using the Scottish Health Service costs for the year ending 1999/2000[86] and Netten and Curtis.[87]

The following costs have been calculated from the Scottish Health Service costs 1999/2000[86]:

- surgical ward costs (excluding theatre costs) £241 per day (page 72)
- theatre per hour £335
- ITU costs £1222 per day (page 105)
- outpatient clinic (general medical) £74 (page 178)
- consultation with community dietitian £23 (page 231)
- consultation with psychologist £52 (page 215)
- HDU costs £731.50 per day (average of ward and ITU cost).

The following costs have been calculated from Netten and Curtis[87]:

- general practitioner consultation £14.60
- contact with district nurse £20.50 (based on two patients per hour)
- contact with practice nurse £5.50 (based on four patients per hour).

Also:
- Slimfast per can £1.07
- variable band costs £940 including VAT
- apronectomy/incisional hernia repair requires 1 hour in theatre plus 3 days stay at a cost of £1058.

Other model parameters

Other model parameters included the following.

- The model was created in an Excel spreadsheet and was run for a hypothetical cohort of 100 patients.
- The cohort had an average age of 40 years, and 90% of patients were female. Average body weight was 135 kg, and average BMI was 45.
- The time horizon for the model was 20 years after surgery (i.e. to age 60). This was selected as a trade-off between allowing the benefits of treatment to accrue but recognising that data were being extrapolated from a maximum of 8 years of follow-up. The only deaths occurring during the 20 years are postoperative.
- Costs and savings (i.e. the value of resources freed) occurring in future years were discounted at 6%. QALYs were discounted at 6%, 0% and 1.5%.
- It is assumed that all patients are suitable for all types of surgery.
- In the face of such extensive uncertainty in the data inputs, an extensive sensitivity analysis was carried out using different scenarios that reflected different views held by experts in the field.

Results

Under the assumptions stated between pages 37 and 47, results were calculated in terms of total net

costs (costs minus 'savings', the value of resources freed for other uses) and QALYs. The results are shown in *Table 27*. All costs are discounted at 6% while QALYs are discounted at 1.5%. Weight loss with surgery ceases after 5 years; the impact on diabetes ceases after 8 years.

TABLE 27 *Total net costs and QALYs for each intervention*

Intervention	QALYs	Total net cost
Usual care	1123	£696,415
VBG	1149	£962,690
SAGB	1168	£1,079,516
GB	1167	£976,435

The costs of the different interventions varied from £336 for usual care to £3223 for VBG, to £3333 and £3392 for open and laparoscopic GB, and £4450 and £4753 for laparoscopic and open ASGB. The total net costs of treating morbid obesity (over 20 years) through surgical procedures varied from £9626.90 for VBG to £9764.35 for GB and £10,795.16 for ASGB. 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.

Comparing the non-surgical option with surgery
These data show that with the assumptions used all of the surgical options offer additional QALYs at an additional cost. The final column of *Table 28* provides one way of showing whether that additional cost is 'acceptable' for the size of the net benefit. Many common health service procedures have a net cost per QALY gained that exceeds this level. It should also be borne in mind that many assumptions have been included that are unfavourable to surgery.

Comparing different types of surgery
While the comparison of surgery with a non-surgical option is relatively clear, the comparison between surgical options is much less clear-cut. If taken at face value, the results suggest that GB is the preferred form. It has a very modest net cost per QALY gained compared with VBG. In comparison with ASGB, it offers almost identical health gain at a reduced cost. The ASGB estimates rest upon two RCTs, only one of which goes beyond 1 year of follow-up. There is some suggestion from this single study that weight gain may still be accruing after 5 years, in contrast with GB. In contrast, GB has demonstrated its impact beyond 5 years. VBG looks to be an inferior option from the economic point of view, but this may be because the assumptions are quite unsophisticated – a policy of VBG with GB for those who do not achieve or maintain weight loss may be an interesting hybrid. The comparison between options is thus best regarded as hypothesis forming rather than being conclusive.

Cost per QALY comparisons
The most obvious comparator of net cost per QALY gained is with drug treatment of obesity using either orlistat or sibutramine. According to NICE[23,28] guidance to the NHS:

- the independent review of the cost-effectiveness of orlistat suggested a figure of £46,000 per QALY, although the restrictions placed on the drug's use may well result in the figure in practice being in the range £20,000 to £30,000
- the true cost per QALY for sibutramine lies in the range £15,000 to £30,000.

Sensitivity analysis
From the above results, the key implications are that:

- under the baseline assumptions, surgery offers health gain at an additional cost that is comparable with other health services, and
- the uncertainties in the data make it very difficult to choose between the types of surgery.

The second problem cannot readily be resolved without further data. The economic results are very finely balanced. Taken at face value, the results give a slight edge to GB, but the newer

TABLE 28 *Net cost per QALY gained for each intervention*

Comparator	Intervention	Additional QALYs	Additional cost	Net cost per QALY gained
VBG	Non-surgical	26	£266,275	£10,237
SAGB	Non-surgical	45	£383,102	£8,527
SAGB	VBG	19	£116,826	£6,176
GB	Non-surgical	45	£280,020	£6,289
GB	VBG	19	£13,745	£742
ASGB	GB	0.4	£103,082	£256,856

techniques such as ASGB are still developing. In addition, the resource use estimates in the economic model are based on those reported from RCTs: as experience with the newer technologies develops their costs may well fall.

The main aim of the sensitivity analysis is to test the strength of the first implication above. To explore this, the analysis focuses on comparisons between GB surgery and the non-surgical option. This is NOT intended to imply that GB is the economic 'gold standard'; the real issue is to determine under what circumstances surgery ceases to be cost-effective relative to medical management.

Since the results seem to suggest that surgery (of whichever type) is cost-effective, some of the sensitivity analyses mentioned earlier become unnecessary. For example, including any gains in life-expectancy as a result of reducing the prevalence of diabetes would make the figures look still better for surgery. Instead, this analysis focuses on scenarios that might reduce the economic advantages of surgery.

Scenario 1 – A surgical expert comment was that the hospital stay for GB could be up to 14 days
In the baseline, it was assumed that length of stay for GB was 6 days for laparoscopic surgery and 7 days for open surgery. If these figures are increased to 14 days (i.e. 13 on the surgical ward and one in either ITU or HDU), the impact on the net cost per QALY gained for GB compared with non-surgical care can be noted. With the baseline assumptions it was £6289. With the new assumptions it rises to £10,323.

Scenario 2 – A general view among experts was that the costs before admission and after discharge might have been underestimated
The pre-admission assumptions were substantially increased to reflect expert comment, based on data from Andersen and colleagues,[38] in order to arrive at the baseline assumptions listed above. The post-discharge care has also been increased substantially, including surgical outpatient follow-up and dietitian input.

To take this one stage further, some of the RCTs specify a VLCD either before or after surgery (see, for example, Sugerman and colleagues,[61] Lechner and Callender,[48] Naslund and colleagues[51–56]). Including a cost for either of these would require an additional cost of around £180 (two cans of Slimfast per day for 12 weeks). Even combined with a further dietitian consultation per week, this comes to £456. This takes the cost per QALY to £7255.

Scenario 3 – Effectiveness does not reflect efficacy (e.g. the review of the clinical evidence notes that some results were not expressed on an ITT basis)
In the baseline analysis, RCT data were used as the basis for an assumption that GB surgery would reduce the BMI from 45 to 29 for 5 years. If the BMI only fell to 33, the net cost per QALY gained rises to £9155. If efficacy is halved (to a BMI of 37), the result rises further to £16,819.

Scenario 4 – The assumptions on non-surgical management are too pessimistic
In the baseline, it was assumed that VLCD incurred costs but had no effect on weight. If the effect were to reduce BMI by 3 to 42 in every year the patients tried VLCD, with the effect lasting for 1 year, the result rises to £8931.

Scenario 5 – In the UK, there are very few experienced surgeons so wider use of the operation would initially involve many who were at the earliest stage of the learning curve
This is slightly more complicated as it involves changing several of the assumptions. To construct the new scenario, assume:

- operative mortality is 2% rather than 1%
- length of time in theatre increases by 50%
- the rate of revision surgery doubles
- weight loss achieved is to a BMI of 33 rather than 29 because patient selection is not as good as in the RCTs.

This increases the net cost per QALY gained to £18,278. Assuming, in addition, that for the cohort one surgeon requires a 6-month sabbatical in America (with locum cover) plus expenses (proxied by adding £50,000 to the GB costs) increases this still further to £20,768. Note, however, that this would ascribe all of the costs of training the surgeon to the first 100 operations – hopefully, his or her skills would last a little longer than that!

Scenario 6 – The diabetes cost per year is from a study sponsored by a pharmaceutical company with a new product in that field; as such it may be an overestimate
The cost from CODE2 is £1550 per annum. Halving this to £775 increases the net cost per QALY gained to £8715.

Scenario 7 – The Roche utility gains from weight reduction are overestimates
In the NICE guidance on orlistat,[23] the company proposed a figure of £10,000 per QALY. The guidance talks about a range of £20,000 to £30,000 that suggests the perceived overestimate is by a

factor of between two and three. The impact of these changes is actually quite easy to calculate. Given that no impact on mortality is assumed, then halving the utility gain also halves the denominator of the cost per QALY ratio, so the result doubles; similarly, reducing the utility gain to one-third of its original value triples the ratio. This would make the ratio £12,578 if utility gains are halved and £18,867 if the gains are divided by three. While this is quite a major impact it is only just within the £20,000 to £30,000 range discussed in the NICE guidance on orlistat.

Discussion

The results are shown to be robust in the face of each of the scenarios above, in the sense that the conclusion that surgery is a cost-effective alternative to non-surgical management continues to hold. Of course, the same could not be said if all of the scenarios occurred at the same time. However: (i) if this were not the case then there might well be something wrong with the spreadsheet model specification, and (ii) this would also be true of most health services that have been evaluated in this way (including orlistat and sibutramine).

An additional consideration is that each of the scenarios considers ways in which the evaluation could be further slanted against surgery – attention should be given to the number of ways in which the assumptions used are already unfavourable. For example:

- No beneficial effects are assumed beyond 5 years, so patients regain all their weight overnight and diabetics who came off medication after surgery now need treatment again.
- Even in the 5 years when benefits are assumed to occur, the van Gemert and colleagues[73] study suggests the utility gain from weight loss after surgery is underestimated by the Roche data.
- Any life-expectancy gain from reduced weight or reduced secondary disease is ignored, while loss of life expectancy from operative mortality is included.
- The costs of co-morbidities and secondary disease other than diabetes are ignored.
- Effects beyond 20 years are ignored and QALYs are discounted at 1.5% when some believe they should not be discounted at all.
- The baseline age is assumed to be 40, which is slightly older than in the trials – younger patients have more time to benefit from weight loss (especially in terms of secondary disease).
- The average results for a cohort of 100 patients reported here conceal big variations between patients – with experience, surgeons may be able to judge who is most likely to benefit, which would improve the cost-effectiveness of surgery.
- Many of the NHS costs used are from Scottish data sources. Given that healthcare funding per capita is higher in Scotland than in England, it is possible that these are slight overestimates of the cost in the UK as a whole.
- The perspective of the economic evaluation under NICE guidance is NHS plus PSS. If obesity causes greater use of PSS, then some savings might be anticipated as a result of weight loss but these have been excluded.

The final judgement must be made in a broader context than economics alone, but the sensitivity analysis suggests that the economic case for surgery is a strong one.

Chapter 5
Discussion

Statement of principal findings

The main findings of this review of surgery for morbid obesity are summarised below.

Clinical effectiveness of surgery compared with non-surgical interventions

Evidence from one good-quality RCT and two poorer quality studies (one RCT and one cohort study with concurrent control) comparing surgery with non-surgical interventions suggests that surgery results in very good weight loss, with morbidly obese people losing between 23 kg and 37 kg more weight after 2 years than patients on non-surgical interventions who do not lose any weight. Importantly, the difference in weight loss is maintained in the long-term beyond 8 years. Although surgery appeared to cause some worsening in somatic symptoms, specifically gastrointestinal and bowel functioning, other symptoms such as heartburn and joint pain were significantly improved compared with non-surgical interventions. Other psychological and social QoL characteristics were significantly improved following surgery, due directly to the benefits associated with loss of weight. Co-morbidities associated with morbid obesity, particularly hypertension and diabetes, improved significantly following surgery. There were no deaths during surgery or in the early postoperative period. Late postoperative deaths were noted, as were deaths among the conventionally treated patients. Surgery was associated with a significantly greater occurrence of vomiting but less irritability and low spirits. Only 2% of surgical patients required re-operation.

Comparison of clinical effectiveness of different surgical procedures

The clinical effectiveness of the different surgical procedures was assessed through 15 RCTs of varying methodological quality. Of the three RCTs assessing VBG and GB, one RCT was of reasonable methodological quality and two were of poor quality. Five RCTs compared horizontal GP with vertical GP and/or GB, two were good-quality RCTs and three were of poorer quality. The two RCTs contrasting the clinical effectiveness of GB with JB were of poor methodological quality. Similarly, the RCT assessing VBG and horizontal GP following a VLCD was of poor methodological quality. The RCT comparing VBG with AGB and the RCT comparing open versus laparoscopic ASGB were of reasonable methodological quality. Two RCTs assessed the clinical effectiveness of open compared with laparoscopic GB: one was of good and the other of poor methodological quality.

Comparison of GB surgery with different types of GP and JB showed that GB appeared more beneficial for patients suffering from morbid obesity. GB led to a loss of 25% more excess weight than VBG at 12 months, a difference that was maintained at 3 and 5 years follow-up. The loss of weight equated to an increased weight loss of between 11 kg and 14 kg at 3 years for GB. Similar differences in excess weight loss were evident when GB was compared with horizontal GP, with a 10–19% increased loss at 12 months that remained at 24 months follow-up. Differences in weight loss of between 6 kg and 14 kg in favour of GB were maintained from 12 to 36 months. In contrast, comparison of GB and JB surgery found a greater weight loss from JB, although the difference was not significant. JB led to an increased loss in excess weight of 9% at 12 months compared with GB, which continued at 3 years follow-up. At 12 months the difference in weight loss was approximately 7 kg.

Unfortunately, none of the studies compared the effects of the different procedures on patients' QoL. All patients with GB and 89% of patients with horizontal GP expressed satisfaction with the operation. Co-morbidities were compared for GB with GP and with JB. GB appeared to lead to greater improvements in co-morbidities compared with GP. Differences between GB and JB were greater. In 80% of patients receiving JB, liver co-morbidities worsened compared with improvements in 83% of GB patients. Similarly, fatty metamorphosis and fibrosis worsened following JB but were not evident in GB patients. Deaths were evident in all comparisons, but were usually late and differed little between groups. Complications, particularly nausea and vomiting, dumping syndrome and heartburn, were more frequent in GB patients compared with GP and

JB patients. However, JB patients suffered more diarrhoea, kidney stones and re-operations (other than takedowns). In fact, compared with GB, re-operations and revisions were more common following VBG (23–39% versus 43–54% respectively), GP (0–4% versus 9–40% respectively) and JB (25% versus 69% respectively). It should be noted that JB operations are not routinely undertaken in Europe and the USA due to the morbidity and mortality associated with the procedure (see page 6).

Other comparisons between procedures noted that following VLCD, VBG led to a significantly greater reduction of weight compared with horizontal GP, losing 24% more weight at 12 months. This equated to an additional 15.9 kg of weight lost. There was no comparison of QoL, co-morbidities or re-operations. No deaths were reported from either procedure and complications differed little. Assessment of the clinical effectiveness of VBG versus AGB found a greater loss of weight following AGB, approximating to an 8 kg difference in weight loss. More patients undergoing AGB were satisfied with the procedure (81%) than VBG patients (56%). No postoperative deaths occurred from either procedure. Complications were more common following VBG than AGB, as were re-operations (33% versus 10%). A comparison of open versus laparoscopic ASGB found a significant loss of weight following both procedures of over 34 kg at 12 months. QoL, co-morbidities and deaths were not reported. Postoperative complications varied little between the procedures, with the open procedure incurring significantly higher occurrences of cholecystectomy, readmissions and length of hospital stay than the laparoscopic procedure. Similarly, the comparison of open versus laparoscopic GB found a large loss of excess weight following both procedures (> 60% loss of excess weight), but no significant difference between the procedures. Early differences in QoL associated with the laparoscopic procedure had disappeared by 3–6 months follow-up and there were no differences in patient satisfaction with the procedures. Early complications were more common following the open procedure but late complications were more evident following the laparoscopic procedure, although differences were not statistically significant. Conversions from laparoscopic to open procedure occurred in 2.5% to 23% of patients. Re-operations were less common after open surgery (6.6%) than laparoscopic surgery (7.6% to 20%). Other surgical indicators showed that laparoscopic surgery had a longer operative time compared with open surgery, but resulted in reduced blood loss, proportion requiring intensive care unit stay, length of hospital stay, days to return to activities of daily living and days to return to work.

Overall summary of clinical effectiveness of surgery for morbid obesity

The benefits of surgery for morbid obesity may be classed into three groups:

1. Early weight loss leading to reductions in diabetes and blood pressure, with effects starting within weeks of surgery.
2. Later weight loss leading to improved QoL and reductions in the use of medications. There will be social benefits such as the opportunity to go shopping, better personal hygiene and other so-called normal activities of daily life.
3. Long-term health gain from reduced illness such as heart disease and diabetes. Such benefits may occur some 20 years later, although patients with a BMI > 35 and co-morbidities may experience more rapid gains.

Cost-effectiveness of surgery for morbid obesity

Searching revealed four economic evaluations: comparing GB with VLCD, VBG with no treatment, VBG with GB, and GBan, VBG and GB with conventional treatment. The evaluations were conducted in the USA, The Netherlands and Sweden, and showed that gastric surgery was more cost-effective than non-surgical interventions. An economic evaluation was undertaken to consider the three types of surgical procedure that appeared most clinically effective, specifically GB (Roux-en-Y), VBG and AGB, and non-surgical management. Comparison of surgery with non-surgical management showed that surgery offered additional QALYs at an additional cost. When compared with non-surgical management, GB had a net cost per QALY of £6289, while VBG and ASGB had a net cost per QALY of £10,237 and £8527 respectively. Comparison of the different procedures suggests that the difference between the procedures is less clear. GB appears to have a very modest net cost per QALY gained compared with VBG (£742/QALY). ASGB has a large net cost per QALY gained compared with GB (£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. Several different scenarios were examined in the one-way sensitivity analyses for GB surgery compared with non-

surgical management. Increases in the length of hospital stay (£10,323/QALY), increases in costs of pre- and postoperative care (£7255/QALY), increases in weight loss from non-surgical management (£8931/QALY), decreases in weight loss from surgery (£16,819/QALY), increases in the costs associated with developing the service (£20,768/QALY), increases in the cost of treating co-morbidities (£8715/QALY) and decreases in the utility gain from surgery (£18,867/QALY) resulted in cost per QALYs of between £20,000 and £30,000. The baseline economic evaluation and the sensitivity analysis suggest that surgery for morbid obesity appears to be cost-effective.

Strengths and limitations of the review

The systematic review has certain strengths, including the following.

- The systematic review is independent of any vested interests.
- The systematic review brings together the evidence for the effectiveness of surgery for morbid obesity and an economic evaluation applying consistent methods of critical appraisal and presentation. In addition, the results appear to concur with the findings of previous systematic reviews and HTA reports.[32,33,77,88–90]
- The review was guided by the principles for undertaking systematic reviews. Before undertaking the review the methods of the review were set out in a research protocol (appendix 1), which was commented on by an advisory group. The protocol defined the research question, inclusion criteria, quality criteria, data extraction process and methods used to undertake the different stages of the review.
- An advisory group has informed the review from its initiation, through the development of the research protocol and completion of the report.

In contrast, there were certain limitations placed upon the review.

- Owing to time constraints placed upon the review there was a lack of follow-up with authors of studies to clarify methodological details and results from the primary studies.
- The review was limited to including published and unpublished systematic reviews of RCTs and non-RCTs, as well as reports of RCTs and non-RCTs. Abstracts and conference proceedings were excluded from the study as these usually fail to provide adequate details of the methods of the study and their results. A list of recent abstracts is provided in appendix 3.
- The quality of RCTs and non-RCTs was assessed using a modified version of the Spitzer criteria. The use of quality scales for judging the validity of studies has been criticised.[91] As such, we concentrated on reporting the key elements for judging bias in these study designs.
- The economic evaluation was limited by the availability of information on the clinical effectiveness of the different procedures, the costs, and the organisation of service provision. Importantly, the model was based on several unsophisticated assumptions, although several scenarios were examined in one-way sensitivity analyses.
- One problem with RCTs is that they may be done in selected patients in select situations, and may give results not generalisable to routine care; they may show efficacy and not real-life effectiveness. However, we are aware of data from one of the largest case series in the UK, obtained for the Scottish Health Purchasing Information Centre report, which shows that results in routine care in a district general hospital in Elgin, admittedly by a surgeon with a special interest, show similar results in terms of weight loss, with an average loss of 50% of excess weight.[89]

Other issues

- An important question concerning interventions used in managing weight loss is whether the procedure offers a long-lasting effect. Frequently, initial weight loss has been modified by subsequent weight regain. This review included studies that considered lengths of follow-up of 12 months or more. However, expert opinion suggests that follow-up should consider outcomes beyond 5 years. Comparison of the periods of follow-up reported in the 18 studies shows that seven presented outcomes to 12 months, while only four reported outcomes to 5 years or beyond.
- Within the review, types of surgery were broadly classified as malabsorptive or restrictive types and the procedures within those groups. Limited attention is given to the numerous modifications developed by different clinicians within these categories.
- The primary outcome assessed in most studies was weight change. Most studies provide no

details concerning the measurement of weight at baseline or at the different periods of follow-up, whether assessed by the patient or health professional.

- Limited attention was given to QoL in the studies included in the systematic review. People with morbid obesity tend to suffer from several psychological symptoms, such as low self-esteem and agoraphobia. Only three of the 18 studies included some assessment of QoL issues, affecting assessment of clinical effectiveness and cost-effectiveness.
- The systematic review focuses on the evidence from RCTs and non-RCTs. In so doing, it may have excluded evidence that may be considered relevant to the assessment of clinical effectiveness and cost-effectiveness. This is likely to affect the assessment of surgical procedures that have only been in use for a short period, for which there may be relatively few studies. Expert opinion has suggested that the JB, through the development of the ileogastrostomy, has overcome the unacceptable morbidity and mortality that limited it to a procedure of historic interest only. However, no RCTs or non-RCTs were found, with evidence limited to case series. Similarly, biliopancreatic diversion was heralded by expert opinion as the 'state-of-the-art' procedure, particularly for people who were superobese. Again, no RCTs or non-RCTs were found, only case series. In fact, others have commented that biliopancreatic diversion may cause metabolic and nutritional disturbance.[92] In addition, experts have noted that mortality reported in the clinical trials was lower than expected following surgery. In fact, peri-operative deaths of 2% have been experienced following GB.[25]
- The majority of patients included in clinical trials were women in their late 30s to early 50s who were morbidly obese. However, the potential benefits of weight loss from surgery may be greater among morbidly obese men of a similar age who tend to be at greater risk from CVD. Similarly, greater benefit may occur following surgery among younger adults who have a longer period to accrue benefit, if weight loss and effects on co-morbidity are maintained.
- The methodological quality of the primary studies was judged using a modified version of the criteria identified by Spitzer and colleagues.[30] It was evident that the majority of studies inadequately reported their research methods. Such studies were judged, like those that did not comply or were substandard in their application of methods, to be of poor quality.
- A limited number of studies reported their results on an ITT basis. Where results were not ITT, there is the potential for bias when there are high numbers of drop-outs.

Chapter 6
Conclusions

Implications for the NHS and other parties

An important factor in planning NHS services for morbidly obese patients is whether the benefits of particular treatment options are sufficient to justify the costs of developing, and operating, the service. Conservative forms of treatment, including diet, exercise and lifestyle advice have shown limited long-term benefit for patients with morbid obesity. Gastric surgery, particularly GB, appears to provide a clinically and cost-effective treatment for reducing weight. At present, there are a limited number of surgical procedures for people with morbid obesity in England and Wales (around 200 per year), with a large proportion privately funded. Within England and Wales there are about 536,700 people with a BMI > 40. Given the contraindications for surgery for those with morbid obesity (see pages 5 and 6), the pre-operative regime that patients should adhere to and the morbidity and mortality associated with the operative procedures, it is unlikely that a large proportion of morbidly obese patients would undergo surgery. Advice from experts suggests that between 2% and 10% of morbidly obese patients may have surgery. In England and Wales, this would equate to between 10,000 and 50,000 patients, that is 250–1250 people per standard health authority with a population of 500,000. Inevitably there may be some impact on other parties both within and outside the NHS, unless additional funding is available to fund any service development.

If 10% of those individuals with a BMI > 40 were to be treated, and if we assume based on the economic evaluation and based on clinical advice that 50% of patients would undergo GB and 50% VBG (as well as assuming that the weight loss rates are as quoted in our model), then the additional cost would be around £136.5 million for the total lifetime of these patients, assumed to be 20 years (using the marginal cost over non-surgical management). It is important to highlight that this additional cost is based upon 50,000 patients over 20 years. Thus, equating to £2731 per patient as a total additional cost over 20 years. Caution should be taken when interpreting this figure as it is based on an economic evaluation that employs several assumptions in its development. In judging the impact on the service it is important to recognise that the 50,000 patient figure represents a 'backlog' of patients that may present for surgical treatment for morbid obesity. Information on the incidence of morbid obesity is not available, but expert opinion suggests that there may be as many as 5000–8000 patients per year. If 10% of morbidly obese patients underwent surgery, then the additional cost for the 800 patients would be £2.2 million for the total lifetime of the patients (assumed to be 20 years). Any development of the service to meet these needs would take several years to establish, spreading the burden of cost over several years.

To meet any increased need for surgery for people with morbid obesity the NHS would need to ensure that there are adequate multi-disciplinary teams available to undertake the operation and support the patient through a programme of long-term maintenance. Expert advice has suggested that teams should include a dietitian or specialist nurse to provide counselling before and after surgery, a physician to assess fitness for surgery and to judge whether patients meet the necessary criteria for surgery, a psychologist to help patients adjust to changes following surgery, an anaesthetist experienced in anaesthetising obese patients, and, where appropriate, a radiologist.[24] The availability of the different health professionals with training and experience in treating obesity, thought important to successful outcomes following surgery, may be a limiting factor in developing services. Inevitably, a considerable lead time would be required to ensure that an adequately trained and funded service is put in place. Whether services should be located within every health authority or within specialist regional facilities has been queried.[93] With the relatively small numbers of people with morbid obesity resident within each health authority and the importance of having experienced teams with appropriate facilities (e.g. HDUs, intensive care etc.) providing surgery, expert opinion suggests that any service should be provided in a limited number of specialist centres within England and Wales.

As part of a successful weight loss strategy, support services may be required for patients and their

carers. Postoperative care should include advice on diet to manage weight loss and the complications associated with gastric surgery, as well as support or counselling to cope with the process and consequences of long-term weight management. There is also likely to be reduced attendance at diabetes and hypertension clinics.

Recommendations for future research

In undertaking the systematic review, certain implications for research have become evident. These include the following.

- It is evident that there is little good-quality evidence on the epidemiology of morbid obesity or on assessing the clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity. In particular, there are few trials comparing surgery with non-surgical interventions and the different restrictive with malabsorptive procedures. This may reflect the fact that different centres specialise in particular operative procedures and are restricted by financial and other resource constraints in the types of comparisons that are possible. Additional epidemiological studies of morbid obesity as well as RCTs and quasi-experimental studies of good methodological quality comparing different operative techniques are needed.
- Typically, the outcomes of surgery were assessed over relatively short periods, usually up to 12 months. With only one study considering the long-term effects of surgery compared with conventional management beyond 5 years, there is a need for further good-quality, long-term RCTs and non-RCTs.
- Only three studies assessed the effects of surgery for morbid obesity on the QoL of patients. Additional studies are required.
- Searching revealed only four economic evaluations assessing the cost-effectiveness of surgery for morbid obesity. Further good-quality economic evaluations are required, necessitating the collection of good-quality costing data and information on the epidemiology of co-morbidities.

Acknowledgements

This report was commissioned by the NHS R&D HTA Programme, project number 01/22/01.

The authors are grateful to the advisory panel who provided expert advice and comments on the research protocol and/or a draft of this report:

Professor JN Baxter, University of Wales, Department of Surgery, Morriston Hospital, Swansea.

Professor Bruce Campbell, Consultant General Surgeon, Royal Devon & Exeter Hospital, Exeter.

Dr Ian Campbell, NOF Chairman, Park House Medical Centre, Nottingham.

Sir Alfred Cuschieri, Professor of Surgery, Department of Surgery and Molecular Oncology, University of Dundee, Ninewells Hospital and Medical School, Dundee.

Professor Philip James, Chairman, International Obesity Task Force, London.

Professor Roland Jung, Consultant Physician, Chief Scientist to Scottish Executive, Tayside University Hospitals NHS Trust, Dundee Teaching Hospital, Ninewells Hospital, Dundee.

Mr JDB Miller, Consultant Surgeon, Department of Surgery, Dr Gray's Hospital, Elgin.

Dr AM Mir, University of Wales College of Medicine, Heath Park, Cardiff.

Ms Mary O'Kane, Chief Dietitian, The General Infirmary, Great George Street, Leeds.

Mr Peter Sedman, Consultant Surgeon, Hull Royal Infirmary, Aulaby Road, Hull.

Dr JPH Wilding, Reader in Medicine, General (Internal) Medicine, University Hospital Aintree, Liverpool.

Also, we would like to thank the following people for information:

Ms Liz Hodson, Information Service, Wessex Institute for Health Research and Development, Southampton.

Dr Alison Avenell, Health Services Research Unit, University of Aberdeen Medical School, Foresterhill, Aberdeen.

David Carson, Head of Financial Performance Management, Tayside Health Board, Dundee.

Dr Janis Baird, Specialist Registrar in Public Health Medicine, Health Care Research Unit, University of Southampton.

The report remains the responsibility of the Southampton Health Technology Assessments Centre, Wessex Institute for Health Research and Development, University of Southampton.

The **protocol** was prepared by Andrew Clegg (Senior Research Fellow) and Emma Loveman (Research Fellow). **Searching** was conducted by Pam Royle (Senior Researcher). Reviewing papers against the **inclusion criteria** was carried out by Andrew Clegg, Jill Colquitt (Research Fellow), Manpreet Sidhu (Researcher) and Andrew Walker (Senior Lecturer). **Data extraction** was performed by Andrew Clegg, Jill Colquitt, Manpreet Sidhu, Pam Royle, Emma Loveman and Andrew Walker. The **economic evaluation** was carried out by Manpreet Sidhu and Andrew Walker. The **report draft** was prepared by Andrew Clegg, Jill Colquitt, Manpreet Sidhu and Andrew Walker.

The views expressed are those of the authors, who are also responsible for any errors.

References

1. Erens B, Primatesta P, editors. Health survey for England: cardiovascular disease '98. Vol. 1. Findings. London: Stationery Office; 1999. Series HS No.: 8.
2. National Audit Office. Tackling obesity in England: report by the Controller and Auditor General. London: Stationery Office; 2001. No.: HC 220 Session 2000–2001.
3. Office for National Statistics. Health statistics quarterly. London: The Stationery Office; 2000. No.: 8.
4. Manson JE, Willett WC, Stampfer MJ, Colditz GA, Hunter DJ, Hankinson SE, *et al.* Body weight and mortality among women. *N Engl J Med* 1995; **33**:677–85.
5. Calle EE, Thun MJ, Petrelli JM, Rodriguez C, Heath CW, Jr. Body-mass index and mortality in a prospective cohort of US adults. *N Engl J Med* 1999;**341**:1097–105.
6. Manson JE, Colditz GA, Stampfer MJ, Willet WC, Rosner B, Monson RR, *et al.* A prospective study of obesity and risk of coronary heart disease and women. *N Engl J Med* 1990;**322**:882–9.
7. Rimm EB, Stampfer MJ, Giovannucci E, Ascherio A, Spiegelman D, Colditz GA, *et al.* Body size and fat distribution as predictors of coronary heart disease among middle-aged and older US men. *Am J Epidemiol* 1995;**141**:1117–27.
8. Gillum RF, Mussolino ME, Madans JH. Body fat distribution, obesity, overweight and stroke incidence in women and men: the NHANES I Epidemiologic Follow-up Study. *Int J Obes* 2001;**25**:628–38.
9. Brown CD, Higgins M, Donato KA, Rohde FC, Garrison R, Obarzanek E, *et al.* Body mass index and the prevalence of hypertension and dyslipidemia. *Obes Res* 2000;**8**:605–19.
10. Carey VJ, Walters EE, Colditz GA, Solomon CG, Willet WC, Rosner BA, *et al.* Body fat distribution and risk of insulin dependent diabetes mellitus in women. The Nurses' Health Study. *Am J Epidemiol* 1997;**145**:614–19.
11. Chan JM, Rimm EB, Colditz GA, Stampfer MJ, Willet WC. Obesity, fat distribution, and weight gain as risk factors for clinical diabetes in men. *Diabetes Care* 1994;**17**:961–9.
12. Mather HM, Keen H. The Southall diabetes survey: prevalence of known diabetes in Asians and Europeans. *BMJ* 1985;**291**:1081–4.
13. Bergstrom A, Pisani P, Tenet V, Wolk A, Adami HO. Overweight as an avoidable cause of cancer in Europe. *Int J Cancer* 2001;**91**:421–30.
14. Oliveria SA, Felson DT, Cirillo PA, Reed JI, Walker AM. Body weight, body mass index, and incident symptomatic osteoarthritis of the hand, hip and knee. *Epidemiology* 1999;**10**:161–6.
15. Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle-aged adults. *N Engl J Med* 1993;**328**:1230–5.
16. Garbaciak JA, Richter M, Miller S, Barton JJ. Maternal weight and pregnancy complications. *Am J Obstet Gynecol* 1985;**152**:238–43.
17. Shaw GM, Velie EM, Schaffer D. Risk of neural tube defect affected pregnancies among obese women. *JAMA* 1996;**275**:1093–6.
18. Werler MM, Louik C, Sharpiro S, Mitchell AA. Prepregnant weight in relation to risk of neural tube defects. *JAMA* 1996;**275**:1089–92.
19. Jung RT. Obesity as a disease. *Br Med Bull* 1997; **53**:307–21.
20. World Health Organization. Obesity: preventing and managing the global epidemic. Geneva: WHO; 2000. WHO Technical Report Series, No. 894. p. 1–253.
21. Williamson DF, Thompson TJ, Thun M, Flanders D, Pamuk E, Byers T. Intentional weight loss and mortality among overweight individuals with diabetes. *Diabetes Care* 2000;**23**:1499–504.
22. National Institute for Clinical Excellence. Guidance on the use of sibutramine for the treatment of obesity in adults. London: NICE; 2001. Technology Appraisal Guidance No.: 31.
23. National Institute for Clinical Excellence. Guidance on the use of orlistat for the treatment of obesity in adults. London: NICE; 2001. Technology Appraisal Guidance No.: 22.
24. Baxter J. Obesity surgery – another unmet need. *BMJ* 2000;**321**:523–4.
25. Jung RT, Cuschieri A. Obese patients. In: Cuschieri A, Steele RJC, Moosa AR, editors. Essential surgical practice. 4th ed., Vol. 1. Oxford: Butterworth Heinemann; 2000. p. 227–40.
26. Gastrointestinal surgery for severe obesity. NIH Consensus Development Conference. *Consens Statement* 1991 (Mar 25–27);**9**(1):1–20.

27. Cleator IGM, Gourlay RH. Ileogastrostomy for morbid obesity. *Can J Surg* 1988;**31**:114–16.

28. Scopinaro N, Adami GF, Marinari GM, Traverso E, Camerini G, Baschieri G, *et al.* Long term results of biliopancreatic diversion in the treatment of morbid obesity. *Acta Chir Austriaca* 1998;**30**:166–71.

29. NHS Centre for Reviews and Dissemination. Database of abstracts of reviews of effectiveness. York: University of York; 2000. URL: http://agatha.york.ac.uk/darehp.htm

30. Spitzer WO, Lawrence V, Dales R, Hill G, Archer MC, Clark P, *et al.* Links between passive smoking and disease: a best-evidence synthesis. *Clin Invest Med* 1990;**13**:17–42.

31. Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the BMJ. *BMJ* 1996;**313**:275–83.

32. NHS Centre for Reviews and Dissemination. Systematic review of interventions in the treatment and prevention of obesity. York: University of York; 1997. CRD Report 10.

33. Glenny AM, O'Meara S, Melville A, Sheldon TA, Wilson C. The treatment and prevention of obesity: a systematic review of the literature. *Int J Obes* 1997;**21**:715–37.

34. Andersen T, Backer OG, Stokholm KH, Quaade F. Randomized trial of diet and gastroplasty compared with diet alone in morbid obesity. *N Engl J Med* 1984;**310**:352–6.

35. Nilsell K, Thorne A, Sjostedt S, Apelman J, Pettersson N. Prospective randomised comparison of adjustable gastric banding and vertical banded gastroplasty for morbid obesity. *Eur J Surg* 2001;**167**:504–9.

36. Westling A, Gustavsson S. Laparoscopic vs open Roux-en-Y gastric bypass: a prospective, randomized trial. *Obes Surg* 2001;**11**:284–92.

37. Nguyen NT, Goldman C, Rosenquist CJ, Arango A, Cole CJ, Lee SJ, *et al.* Laparoscopic versus open gastric bypass: a randomized study of outcomes, quality of life, and costs. *Ann Surg* 2001;**234**:279–89.

38. Andersen T, Backer OG, Astrup A, Quaade F. Horizontal or vertical banded gastroplasty after pretreatment with very-low-calorie formula diet: a randomized trial. *Int J Obes* 1987;**11**:295–304.

39. Andersen T, Stokholm KH, Backer OG, Quaade F. Long-term (5-year) results after either horizontal gastroplasty or very-low-calorie diet for morbid obesity. *Int J Obes* 1988;**12**:277–84.

40. Buckwalter JA, Mason EE, Payne JH. A prospective comparison of the jejunoileal and gastric bypass operations for morbid obesity. *World J Surg* 1977;**1**:757–68.

41. Buckwalter JA. Clinical trial of jejunoileal and gastric bypass for the treatment of morbid obesity: four-year progress report. *Am Surg* 1980;**46**:377–81.

42. Buckwalter JA. Clinical trial of surgery for morbid obesity. *South Med J* 1978;**71**:1370–1.

43. De Wit LT, Mathus-Vliegen L, Hey C, Rademaker B, Gouma DJ, Obertop H. Open versus laparoscopic adjustable silicone gastric banding – a prospective randomized trial for treatment of morbid obesity. *Ann Surg* 1999;**230**:800–5.

44. Griffen-WO J, Young VL, Stevenson CC. A prospective comparison of gastric and jejunoileal bypass procedures for morbid obesity. *Ann Surg* 1977;**186**:500–9.

45. Hall JC, Watts JM, O'Brien PE, Dunstan RE, Walsh JF, Slavotinek AH, *et al.* Gastric surgery for morbid obesity. The Adelaide Study. *Ann Surg* 1990;**211**:419–27.

46. Howard L, Malone M, Michalek A, Carter J, Alger S, van Woert J. Gastric bypass and vertical banded gastroplasty – a prospective randomized comparison and 5-year follow-up. *Obes Surg* 1995;**5**:55–60.

47. Laws HL, Piantadosi S. Superior gastric reduction procedure for morbid obesity: a prospective, randomized trial. *Ann Surg* 1981;**193**:334–40.

48. Lechner GW, Callender AK. Subtotal gastric exclusion and gastric partitioning: a randomized prospective comparison of one hundred patients. *Surgery* 1981;**90**:637–44.

49. MacLean LD, Rhode BM, Forse RA, Nohr C. Surgery for obesity – an update of a randomized trial. *Obes Surg* 1995;**5**:145–53.

50. MacLean LD, Rhode BM, Sampalis J, Forse RA. Results of the surgical treatment of obesity. *Am J Surg* 1993;**165**:155–60.

51. Naslund I. The size of the gastric outlet and the outcome of surgery for obesity. *Acta Chir Scand* 1986;**152**:205–10.

52. Naslund I, Wickbom G, Christoffersson E, Agren G. A prospective randomized comparison of gastric bypass and gastroplasty. Complications and early results. *Acta Chir Scand* 1986;**152**:681–9.

53. Naslund I. Gastric bypass versus gastroplasty. A prospective study of differences in two surgical procedures for morbid obesity. *Acta Chir Scand Suppl* 1987;**536**:1–60.

54. Naslund I, Beckman KW. Gastric emptying rate after gastric bypass and gastroplasty. *Scand J Gastroenterol* 1987;**22**:193–201.

55. Naslund I, Jarnmark I, Andersson H. Dietary intake before and after gastric bypass and gastroplasty for morbid obesity in women. *Int J Obes* 1988;**12**:503–13.

56. Naslund I, Hallgren P, Sjostrom L. Fat cell weight and number before and after gastric surgery for morbid obesity in women. *Int J Obes* 1988;**12**:191–7.

57. Pories WJ, Flickinger EG, Meelheim D, van Rij AM, Thomas FT. The effectiveness of gastric bypass over gastric partition in morbid obesity: consequence of distal gastric and duodenal exclusion. *Ann Surg* 1982;**196**:389–99.

58. Stokholm KH, Nielsen PE, Quaade F. Correlation between initial blood pressure and blood pressure decrease after weight loss: a study in patients with jejunoileal bypass versus medical treatment for morbid obesity. *Int J Obes* 1982;**6**:307–12.

59. Danish Obesity Project. Randomised trial of jejunoileal bypass versus medical treatment in morbid obesity. *Lancet* 1979;**ii**:1255–8.

60. Quaade F. Studies of operated and nonoperated obese patients. An interim report on the Scandinavian Obesity Project. *Am J Clin Nutr* 1977;**30**:16–20.

61. Sugerman HJ, Starkey JV, Birkenhauer R. A randomized prospective trial of gastric bypass versus vertical banded gastroplasty for morbid obesity and their effects on sweets versus non-sweets eaters. *Ann Surg* 1987;**205**:613–24.

62. Karason K, Wallentin I, Larsson B, Sjostrom L. Effects of obesity and weight loss on left ventricular mass and relative wall thickness: survey and intervention study. *Br Med J* 1997;**315**:912–16.

63. Karason K, Wikstrand J, Sjostrom L, Wendelhag I. Weight loss and progression of early atherosclerosis in the carotid artery: a four-year controlled study of obese subjects. *Int J Obes Relat Metab Disord* 1999;**23**:948–56.

64. Karason K, Molgaard H, Wikstrand J, Sjostrom L. Heart rate variability in obesity and the effect of weight loss. *Am J Cardiol* 1999;**83**:1242–7.

65. Karason K, Lindroos AK, Stenlof K, Sjostrom L. Relief of cardiorespiratory symptoms and increased physical activity after surgically induced weight loss: results from the Swedish Obese Subjects study. *Arch Intern Med* 2000;**160**:1797–802.

66. Karlsson J, Sjostrom L, Sullivan M. Swedish obese subjects (SOS) – an intervention study of obesity. Two-year follow-up of health-related quality of life (HRQL) and eating behavior after gastric surgery for severe obesity. *Int J Obes Relat Metab Disord* 1998;**22**:113–26.

67. Narbro K, Agren G, Jonsson E, Larsson B, Naslund I, Wedel H, *et al.* Sick leave and disability pension before and after treatment for obesity: a report from the Swedish Obese Subjects (SOS) study. *Int J Obes Relat Metab Disord* 1999;**23**:619–24.

68. Sjostrom CD, Lissner L, Wedel H, Sjostrom L. Reduction in incidence of diabetes, hypertension and lipid disturbances after intentional weight loss induced by bariatric surgery: the SOS Intervention Study. *Obes Res* 1999;**7**:477–84.

69. Sjostrom CD, Peltonen M, Wedel H, Sjostrom L. Differentiated long-term effects of intentional weight loss on diabetes and hypertension. *Hypertension* 2000;**36**:20–5.

70. Sjostrom CD, Peltonen M, Sjostrom L. Blood pressure and pulse pressure during long-term weight loss in the obese: the Swedish Obese Subjects (SOS) intervention study. *Obes Res* 2001;**9**:188–95.

71. Torgerson JS, Sjostrom L. The Swedish Obese Subjects (SOS) study – rationale and results. *Int J Obes* 2001;**25** Suppl 1:S2–S4.

72. Martin LF, Tan TL, Horn JR, Bixler EO, Kauffman GL, Becker DA, *et al.* Comparison of the costs associated with medical and surgical treatment of obesity. *Surgery* 1995;**118**:599–606.

73. Van Gemert WG, Adang EM, Kop M, Vos G, Greve JW, Soeters PB. A prospective cost-effectiveness analysis of vertical banded gastroplasty for the treatment of morbid obesity. *Obes Surg* 1999;**9**:484–91.

74. Chua TY, Mendiola RM. Laparoscopic vertical banded gastroplasty: the Milwaukee experience. *Obes Surg* 1995;**5**:77–80.

75. Sjostrom L, Narbro K, Sjostrom D. Costs and benefits when treating obesity. *Int J Obes Relat Metab Disord* 1995;**19** Suppl 6:S9–S12.

76. Van Gemert WG, Adang EM, Greve JW, Soeters PB. Quality of life assessment of morbidly obese patients: effect of weight-reducing surgery. *Am J Clin Nutr* 1998;**67**:197–201.

77. Foxcroft D, Ludders J. Orlistat for the treatment of obesity. Southampton: Wessex Institute for Health Research and Development; September 1999. Development and Evaluation Committee Report No.: 101.

78. Dolan P, Gudex C, Kind P, Williams A. A social tariff for EuroQol: results from a UK general population survey. York: Centre for Health Economics, University of York; 1995. DP138.

79. Doll HA, Petersen SE, Stewart-Brown SL. Obesity and physical and emotional well-being: associations between body mass index, chronic illness, and the physical and mental components of the SF-36 questionnaire. *Obes Res* 2000;**8**:160–70.

80. Dymek MP, le Grange D, Neven K, Alverdy J. Quality of life and psychosocial adjustment in patients after Roux-en-Y gastric bypass: a brief report. *Obes Surg* 2001;**11**:32–9.

81. Horchner R, Tuinebreijer MW, Kelder PH. Quality-of-life assessment of morbidly obese patients who have undergone a Lap-Band operation: 2-year follow-up study. Is the MOS SF-36 a useful instrument to measure quality of life in morbidly obese patients? *Obes Surg* 2001;**11**:212–18.

82. Schok M, Geenen R, van Antwerpen T, de Wit P, Brand N, van Ramshorst B. Quality of life after laparoscopic adjustable gastric banding for severe obesity: Postoperative and retrospective preoperative evaluations. *Obes Surg* 2000;**10**:502–8.

83. Wyss C, Laurent JA, Burckhardt P, Jayet A, Gazzola L. Long-term results on quality of life of surgical treatment of obesity with vertical banded gastroplasty. *Obes Surg* 1995;**5**:387–94.

84. Samsa GP, Kolotkin RL, Williams GR, Nguyen MH, Mendel CM. Effect of moderate weight loss on health-related quality of life: an analysis of combined data from 4 randomized trials of sibutramine vs placebo. *Am J Manag Care* 2001;**7**:875–83.

85. Gray A, Raikou M, McGuire A, Fenn P, Stevens R, Cull C, *et al.* Cost-effectiveness of an intensive blood glucose control policy in patients with type 2 diabetes: economic analysis alongside randomised controlled trial (UKPDS41). *BMJ* 2000;**320**:1373–8.

86. National Health Service in Scotland. Scottish Health Service costs (year ended 31st March, 2000). Edinburgh: ISD Publications; November 2000. URL: http://www.show.scot.nhs.uk/isd/Scottish_Health_Statistics/subject/Costs/2000/costs2000.pdf

87. Netten A, Curtis L. Unit costs of health and social care. Canterbury: PSSRU, University of Kent; 2000.

88. Australian Safety & Efficacy Register of New Interventional Procedures – Surgical. Laparoscopic adjustable gastric banding for the treatment of obesity. North Adelaide: ASERNIP–S; April 2000. No.: 9.

89. Robertson A, Douglas S, Waugh N. Gastric surgery for obesity. Aberdeen: Scottish Health Purchasing Information Centre (SHPIC); 1998.

90. Schneider WL. Laparoscopic adjustable gastric banding for clinically severe (morbid) obesity. Alberta: Alberta Heritage Foundation for Medical Research; 2000. No.: 7 (b).

91. Juni P, Altman DG, Egger M. Assessing the quality of randomised controlled trials. In: Egger M, Davey Smith G, Altman DG, editors. Systematic reviews in health care. Meta-analysis in context. London: BMJ Books; 2001. p. 87–108.

92. Shikora SA. Surgical treatment for severe obesity: the state-of-the-art for the new millennium. *Nutr Clin Pract* 2000;**15**:13–22.

93. Kark AE, Owen E. Obesity surgery [Rapid response]. bmj.com 13 September 2000. URL: http://www.bmj.com/cgi/eletters/321/7260/523#EL5

94. NHS Centre for Reviews and Dissemination. Undertaking systematic reviews of research on effectiveness. CRD's guidance for those carrying out or commissioning reviews. York: University of York; 2001. CRD Report 4, 2nd ed.

Appendix 1

Rapid and systematic review methods from the research protocol

Research question

To undertake a systematic review of the clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity.

Clarification of the research question and scope

The aim of the review is to provide a rapid and systematic review to assess the effects of surgery in reducing the weight of people with morbid obesity.

The review will be from the perspective of the NHS and PSS regarding costs and the valuation of benefits.

Report methods

The rapid systematic review will be undertaken following the general principles outlined in NHS CRD Report 4 (2nd ed).[94]

This research protocol may be updated as the research programme progresses. Any changes in the protocol will be notified and agreed with the NCCHTA and NICE.

Search strategy

Electronic databases that will be searched include:

- BIOSIS
- Cochrane Controlled Trials Register
- Cochrane Systematic Reviews Database
- Current Controlled Trials
- DARE
- Early Warning System
- EconLIT
- EMBASE
- MEDLINE (SilverPlatter)
- MRC Trials Database
- National Research Register
- NHS EED and HTA database
- PubMed
- Science Citation Index.

These will be searched for the periods covered by the databases up until November 2001 and will be limited to English language. Bibliographies of related papers will be assessed for relevant studies. Experts will be contacted for advice and peer review, and to identify additional published and unpublished references and any currently ongoing studies. Sponsor submissions to NICE will be checked to ascertain the completeness of our searches.

Inclusion and exclusion criteria

Interventions include surgical procedures, performed either as open procedures or laparoscopically, including restrictive procedures such as GP (vertically banded or silicone ring) or GBan, and malabsorptive procedures such as biliopancreatic diversion, RYGB or JB. The review will concentrate on the clinical effectiveness of the different surgical interventions when compared with each other or with non-surgical interventions. In addition, the method by which these are performed, whether by open procedure or laparoscopically, will be taken into account.

Participants include those individuals who are diagnosed as morbidly obese, defined as a BMI > 40, or with a BMI > 35 with serious co-morbid disease, in whom previous non-surgical interventions have failed (e.g. diet, exercise, behavioural modification, social support, psychotherapy and pharmacotherapy).

Systematic reviews of RCTs and RCTs comparing the different surgical interventions with each other will be included. As there are unlikely to be RCTs comparing surgical with non-surgical interventions, the review will include systematic reviews of prospective controlled clinical trials (cohort studies with concurrent controls) and prospective controlled clinical trials comparing the different surgical procedures with standard treatment or no treatment. If searches show that

there are no clinical trials with control groups, cohort studies without controls may be considered for inclusion. As surgery tends to be an intervention of 'last resort' it is likely that non-surgical interventions will have failed, so the comparators used are likely to be limited to usual care. Usual care may vary, but is likely to consist of no treatment or combinations of dietary therapy, physical activity, behaviour modification, social support and pharmacotherapy. Economic evaluations of surgery for people with morbid obesity must include a comparator (i.e. 'usual care') and both costs and consequences (outcomes), including later plastic surgery.

Studies will be included if they report one or more of the following as primary outcomes at baseline and follow-up:

- measures of weight change (e.g. absolute weight loss, percentage of weight loss, relative to baseline)
- measures of fat content (e.g. BMI, ponderal index, skin-fold thickness, fat-free mass, fat loss)
- measures of fat distribution (e.g. waist–hip ratio, waist size)
- QoL
- peri- and postoperative mortality and morbidity
- revision rates
- obesity related co-morbidities.

Short-term weight loss is common, so to be considered effective interventions should be assessed over the long term – preferably over 5 years. However, studies will be included if they follow-up after a minimum of 1 year.

Inclusion criteria will be applied by one reviewer and checked by a second reviewer, with any disagreements resolved through discussion.

Data extraction strategy

Data extraction will be undertaken by one reviewer and checked by a second reviewer, with any disagreements resolved through discussion.

Quality assessment strategy

The quality of included systematic reviews will be assessed using criteria recommended by the NHS CRD (University of York), while primary studies will be judged using modified versions of Spitzer criteria (appendix 6). Quality of economic evaluations will be assessed for their internal validity (i.e. the methods used) using a standard checklist, and external validity (i.e. the generalisability of the economic study to the population of interest) using a series of relevant questions. QoL studies will be assessed using a locally developed checklist.

Quality criteria will be applied by one reviewer and checked by a second reviewer, with any disagreements resolved through discussion.

Methods of analysis/synthesis

The clinical effectiveness of surgery for people with morbid obesity will be synthesised through a narrative review with full tabulation of results of all included studies. Subgroup analyses by surgical procedure and patient group will be undertaken where possible to allow guidance on targeting treatment to people most likely to benefit. If appropriate a meta-analysis will be considered.

Methods for estimating QoL, costs and cost-effectiveness and/or cost per QALY

Cost-effectiveness will be assessed by a two-stage procedure. First, a narrative review of published economic evaluation studies will be synthesised. The second stage will be to adapt an existing cost-effectiveness model or construct a new one using the best available evidence to determine cost-effectiveness in a UK setting.

In order to determine applicability and resource implications to the NHS, resources and costs will be sought from published UK sources (e.g. British National Formulary or published studies) and where appropriate and available from local NHS.

Effectiveness data, in terms of the outcomes described in the above section, will be extracted from published trials and used in association with the cost data to obtain measures of cost-effectiveness. If available, QoL information will be obtained from the literature or other sources to calculate cost–utility estimates in terms of cost per QALY.

Sensitivity analysis and/or probabilistic sensitivity analysis will be used to examine the robustness of the results to changes in the underlying assumptions of the model.

Appendix 2

Sources of information, including databases searched and search terms

The databases in *Table 29* were searched for published studies, and recently completed and ongoing research.

Clinical effectiveness searches (*Figure 1*)

The following strategy was used to search MEDLINE and the Cochrane Library.

((Gastroplasty OR (gastric surgery) OR (gastric band*) OR (gastric bypass) OR (lap-band) OR roux-en-y OR (biliopancreatic diversion) OR (biliopancreatic bypass) OR gastro?gastrostomy OR (restrictive surgery) OR (malabsorptive surgery) OR (bariatric surgery) OR (jejunoileal bypass) OR (jejuno-ileal bypass)) AND ((obesity OR obese OR (weight loss) OR (weight reduction)) OR 'Obesity-morbid'/surgery)).

The publication types of letters or editorials were excluded.

The above strategy was adapted as appropriate for the remaining databases shown in *Table 29*.

The details of all search strategies used are available on request.

Cost-effectiveness and QoL searches (*Figures 2* and *3*)

The following keywords were used to search the databases shown below:

((costs OR cost OR costed OR costing OR economic* OR price* OR (quality AND life) OR wellbeing OR well-being)) AND (obesity OR obese OR BMI OR body mass index).

Additional searching

Bibliographies

All references of articles for which full papers were retrieved were checked to ensure that no eligible studies had been missed.

Industry submissions

Industry submissions to NICE were examined for any further studies that met the inclusion criteria.

TABLE 29 *Databases searched*

Databases searched	Dates or issues of databases searched	
	Clinical effectiveness searches	**Cost-effectiveness and QoL searches**
Cochrane Library (all sections)	Issue 4, 2001	
MEDLINE (SilverPlatter)	1966–08/2001	1966–08/2001
EMBASE (SilverPlatter)	1980–09/2001	1980–09/2001
PubMed (Internet version)	Records added from 01/01/01 to 19/10/01	Records added from 01/01/01 to 19/01/01
PsycINFO	1967–10/2001	1977–10/2001
Science and Social Sciences Citation Index	1998–10/2001	1980–10/2001
British Nursing Index	1993–07/2001	
CINAHL (SilverPlatter)	1982–07/2001	
Web of Science Proceedings	1990–06/2001	
AMED	1985–07/2001	
BIOSIS	1990–10/2001	
National Research Register	Issue 2, 2001	Issue 2, 2001
HealthSTAR (SilverPlatter)		1981–12/2000
EconLIT (SilverPlatter)		1969–09/2001
NHS EED (Internet version)		Web version searched October 2001
Health Management Information Consortium (HMIC) databases (SilverPlatter)		Entire database searched October 2001

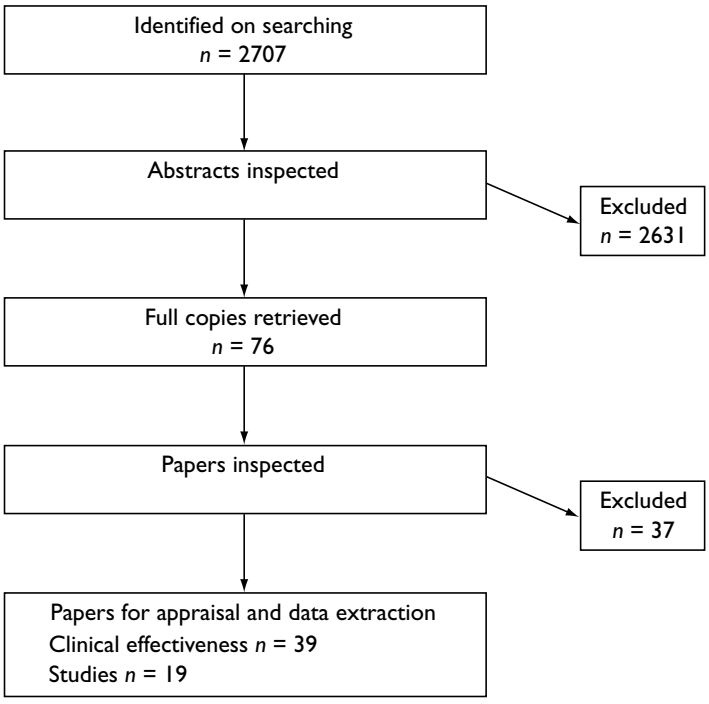

FIGURE 1 *Identification of studies (RCTs and systematic reviews) for the clinical effectiveness systematic review*

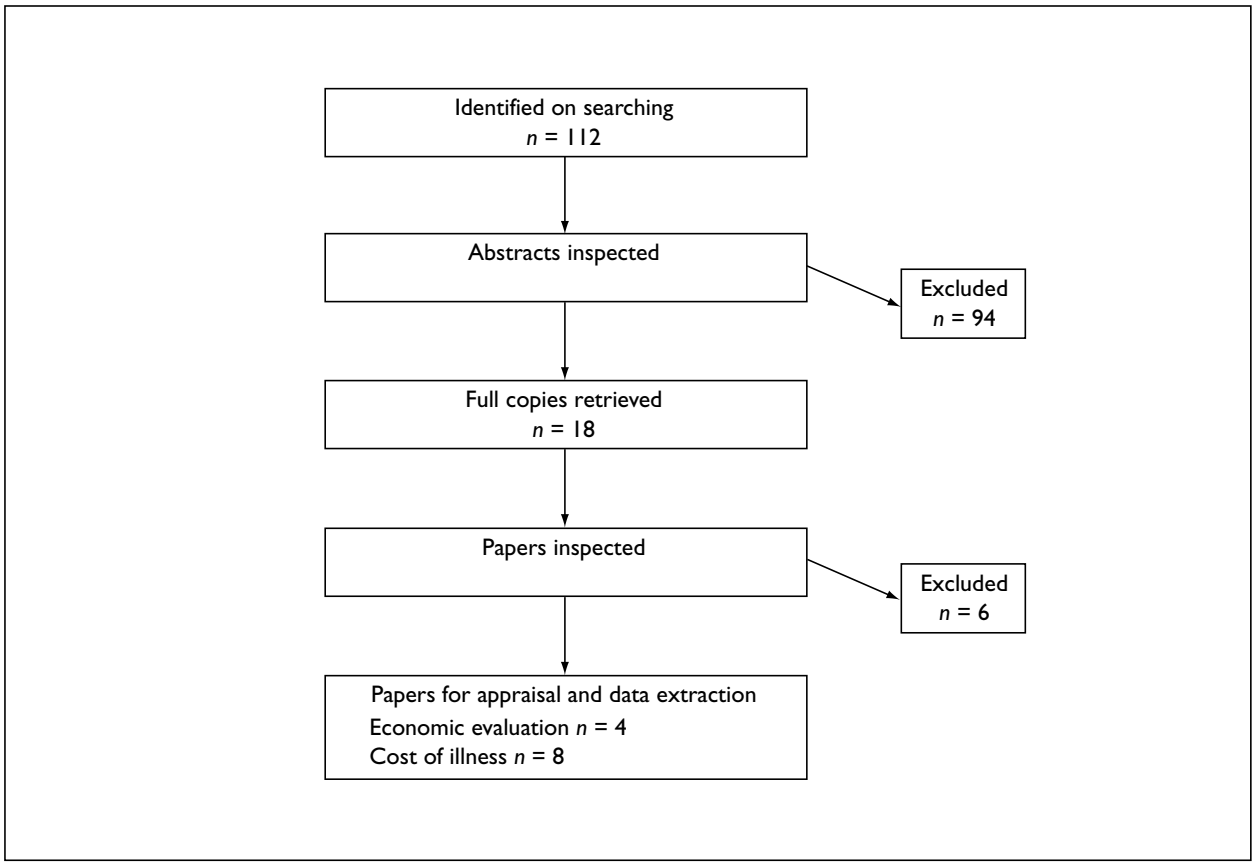

FIGURE 2 *Identification and inclusion of economic evaluation and cost of illness papers*

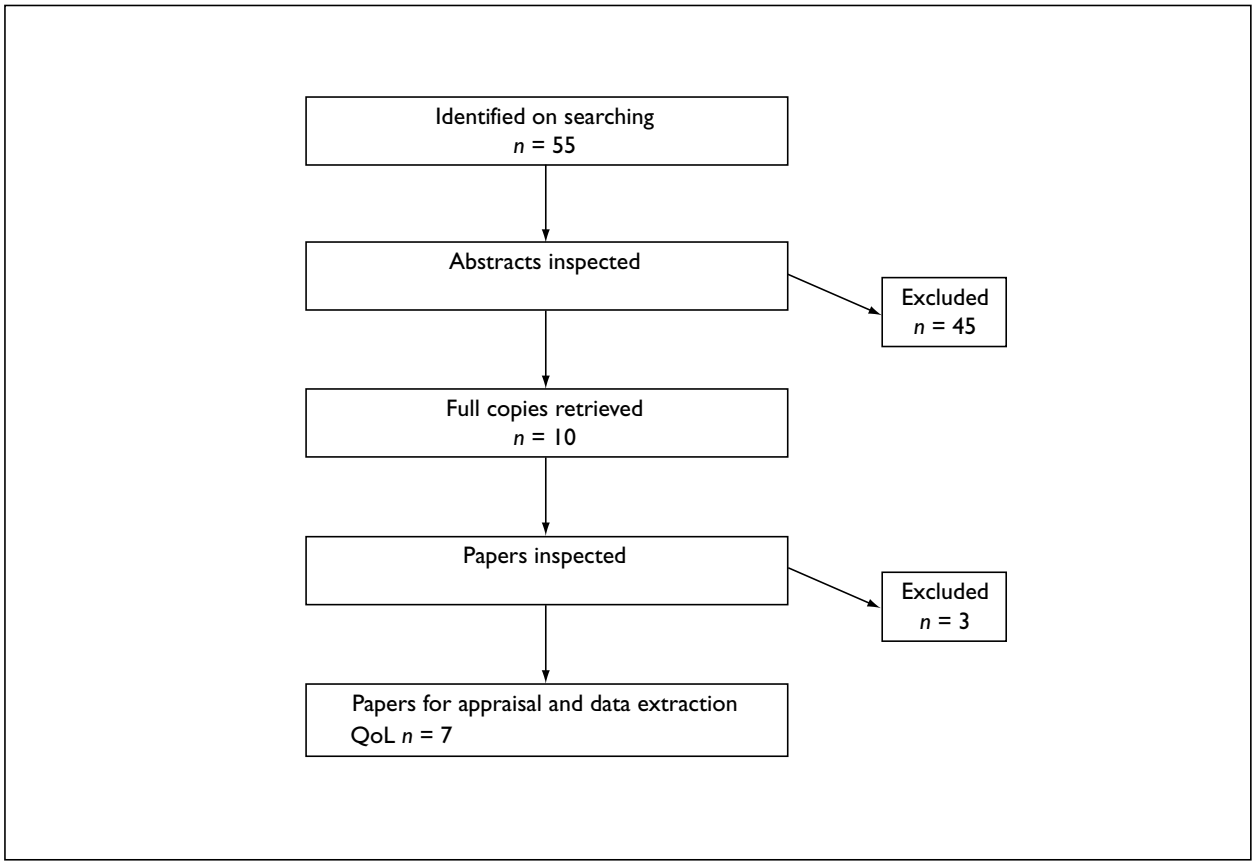

FIGURE 3 *Identification and inclusion of QoL studies*

Appendix 3

List of recent studies published only as abstracts

Gustavsson SO. Laparoscopic, open and handport-assisted laparoscopic Roux-en-y Gastric bypass: a comparative study. *Gastroenterology* 2000;**118**(4):2332.

Hardt J, Egle UT, Heintz A, Klages S, Muller KM. Treatment of extreme obesity: quality of life after gastric banding. *J Psychosom Res* 2000;**48**:276.

Kiviluoto T, Siren J, Sane T, Kivilaakso E. Laparoscopic adjustable silicone gastric banding vs. open vertical banded gastroplasty for morbid obesity. A 2-year follow-up. *Gastroenterology* 1999;**116**(4):S0134.

O'Boyle CJ, Walters D, Watson DI, Game PA. Twelve-year experience with gastric bypass and vertical banded gastroplasty for morbid obesity. *Br J Surg* 2001; **88** Suppl 1:24.

Scott DJ, Provost DA, Huber PJ, Capehart SL, Jones DB. Short-term weight loss similar following Roux-Y gastric bypass and vertical banded gastroplasty for morbid obesity. *Gastroenterology* 1999;**116**(4):G2528.

Appendix 4

List of excluded clinical effectiveness studies

Ackerman NB. Changes in serum cholesterol and triglyceride levels after jejunoileal and gastric bypasses in morbidly obese patients. *Surg Gynecol Obstet* 1982;**154**:1–7.
[Non-RCT]

Alden JF. Gastric and jejunoileal bypass. A comparison in the treatment of morbid obesity. *Arch Surg* 1977; **112**:799–806.
[Non-RCT]

Andersen T. Gastroplasty and very-low-calorie diet in the treatment of morbid obesity. *Dan Med Bull* 1990;**37**:359–70.
[Non-systematic review]

Andersen T, Backer O-G, Stokholm K-H, Quaade F. [Gastroplasty versus very low calorie diet in morbid obesity. Short-term results of a randomized clinical trial.] *Ugeskr Laeger* 1982;**144**:390–4.
[Not English]

Andersen T, Pedersen BH, Dissing I, Astrup A, Henriksen JH. A randomized comparison of horizontal and vertical banded gastroplasty: what determines weight loss? *Scand J Gastroenterol* 1989;**24**:186–92.
[Outcomes]

Andersen T, Stokholm KH, Nielsen PE. Blood pressure and arm circumference during large weight reduction in normotensive and borderline hypertensive obese patients. *J Clin Hypertens* 1987;**3**:547–53.
[Insufficient follow-up]

Ashy ARA, Merdad AA. A prospective study comparing vertical banded gastroplasty versus laparoscopic adjustable gastric banding in the treatment of morbid and super-obesity. *Int Surg* 1998;**83**:108–10.
[Non-RCT]

Azagra JS, Goergen M, Ansay J, De Simone P, Vanhaverbeek M, Devuyst L, *et al.* Laparoscopic gastric reduction surgery. Preliminary results of a randomized, prospective trial of laparoscopic vs open vertical banded gastroplasty. *Surg Endosc* 1999;**13**:555–8.
[Insufficient follow-up]

Backman L, Granstrom L. Initial (1-year) weight loss after gastric banding, gastroplasty or gastric bypass. *Acta Chir Scand* 1984;**150**:63–7.
[Non-RCT]

Barzilai A, Toledano C, Argov S, Barzilai G, Antal SC. [Comparison of gastric bypass and gastroplasty for morbid obesity.] *Harefuah* 1985;**108**(3):113–19.
[Not English]

Belachew M, Jacquet P, Lardinois F, Karler C. Vertical banded gastroplasty vs adjustable silicone gastric banding in the treatment of morbid obesity: a preliminary report. *Obes Surg* 1993;**3**:275–8.
[Non-RCT]

Boman L, Ericson M. Lipoprotein A levels after intestinal bypass operation for morbid obesity. *Obes Surg* 1997;**7**:125–7.
[Non-RCT]

Brolin RE, Bradley LJ, Wilson AC, Cody RP. Lipid risk profile and weight stability after gastric restrictive operations for morbid obesity. *J Gastrointest Surg* 2000;**4**:464–9.
[Non-RCT]

Brolin RE, Kenler HA, Gorman JH, Cody RP. Long-limb gastric bypass in the superobese. A prospective randomized study. *Ann Surg* 1992;**215**:387–95.
[Comparison of surgical techniques]

Brolin RE, Kenler HA, Gorman RC, Cody RP. The dilemma of outcome assessment after operations for morbid obesity. *Surgery* 1989;**105**:337–46.
[Non-RCT]

Buchwald H, Menchaca HJ, Menchaca YM, Michalek VN. Surgically induced weight loss: gastric bypass versus gastroplasty. *Probl Gen Surg* 2000;**17**(2):23–8.
[Non-RCT]

Buckwalter JA. Morbid obesity: good and poor results of jejunoileal and gastric bypass. *Am J Clin Nutr* 1980; **33** Suppl 2:476–80.
[Case studies]

Bull RH, Engels WD, Engelsmann F, Bloom L. Behavioural changes following gastric surgery for morbid obesity: a prospective, controlled study. *J Psychosom Res* 1983;**27**:457–67.
[Non-RCT]

Bull RH, Legorreta G. Outcome of gastric surgery for morbid obesity: weight changes and personality traits. Psychother *Psychosom* 1991;**56**:146–56.
[Cross-sectional study]

Capella JF, Capella RF. The weight reduction operation of choice: vertical banded gastroplasty or gastric bypass? *Am J Surg* 1996;**171**:74–9.
[Non-RCT]

Capella RF, Capella JF. Ethnicity, type of obesity surgery and weight loss. *Obes Surg* 1993;**3**:375–80.
[Non-RCT]

Choi Y, Frizzi J, Foley A, Harkabus M. Patient satisfaction and results of vertical banded gastroplasty and gastric bypass. *Obes Surg* 1999;**9**:33–5.
[Non-RCT]

Cowan GSM. Long versus short limb Roux-en-Y procedures. Early results in a prospective randomized study of metabolic, nutritional and anthropometric outcomes. *Obes Surg* 1996;**6**(4):25.
[Abstract]

Davila-Cervantes A, Ganci-Cerrud G, Gamino R, Gallegos-Martinez J, Gonzalez-Barranco J, Herrera MF. Open vs laparoscopic vertical banded gastroplasty: a case control study with 1-year follow-up. *Obes Surg* 2000;**10**:409–12.
[Non-RCT]

Deitel M, Zakhary GS. Intestinal bypass and gastric partitioning for morbid obesity: a comparison. *Can J Surg* 1982;**25**:283–9.
[Non-RCT]

Delin CR, Anderson PG. A preliminary comparison of the psychological impact of laparoscopic gastric banding and gastric bypass surgery for morbid obesity. *Obes Surg* 1999;**9**:155–60.
[Non-RCT]

De Luca M, de Werra C, Formato A, Formisano C, Loffredo A, Naddeo M, *et al.* Laparotomic vs laparoscopic lap-band: 4-year results with early and intermediate complications. *Obes Surg* 2000;**10**:266–8.
[Non-RCT]

Doherty C, Maher JW, Heitshusen DS. An interval report on prospective investigation of adjustable silicone gastric banding devices for the treatment of severe obesity. *Eur J Gastroenterol Hepatol* 1999;**11**:115–19.
[Non-RCT]

Eckhout GV, Prinzing JF. Surgery for morbid obesity: comparison of gastric bypass with vertically stapled gastroplasty. *Colo Med* 1981;**78**(4):117–22.
[Non-RCT]

Fakhry SM, Herbst-CA J, Buckwalter JA. Complications requiring operative intervention after gastric bariatric surgery. *South Med J* 1985;**78**:536–8.
[Non-RCT]

Fobi MA, Fleming AW. Vertical banded gastroplasty vs gastric bypass in the treatment of obesity. *J Natl Med Assoc* 1986;**78**:1091–8.
[Non-RCT]

Fobi MA, Lee H, Igwe D, Stanczyk M, Tambi JN. Prospective comparative evaluation of stapled versus transected silastic ring gastric bypass: 6-year follow-up. *Obes Surg* 2001;**11**:18–24.
[Non-RCT]

Fobi MAL. Vertical banded gastroplasty vs gastric bypass: 10 years follow-up. *Obes Surg* 1993;**3**:161–4.
[Non-RCT]

Fox SR, Oh KH, Fox K. Vertical banded gastroplasty and distal gastric bypass as primary procedures: a comparison. *Obes Surg* 1996;**6**:421–5.
[Non-RCT]

Fox SR, Oh KH, Fox KM. Adjustable silicone gastric banding vs vertical banded gastroplasty: a comparison of early results. *Obes Surg* 1993;**3**:181–4.
[Non-RCT]

Freeman JB, Burchett HJ. A comparison of gastric bypass and gastroplasty for morbid obesity. *Surgery* 1980;**88**:433–44.
[Non-RCT]

Fried M, Peskova M, Kasalicky M. The role of laparoscopy in the treatment of morbid obesity. *Obes Surg* 1998;**8**:520–3.
[Non-RCT]

Goran A, Naslund I. A prospective randomized comparison of vertical banded gastroplasty (VBG), loop gastric bypass (GBY) and gastric banding (GB). *Int J Obes* 1989;**13**:595.
[Abstract]

Greenstein RJ, Rabner JG, Taler Y. Bariatric surgery vs conventional dieting in the morbidly obese. *Obes Surg* 1994;**4**:16–23.
[Insufficient follow-up]

Halmi KA, Stunkard AJ, Mason EE. Emotional responses to weight reduction by three methods: gastric bypass, jejunoileal bypass, diet. *Am J Clin Nutr* 1980;**33** Suppl 2:446–51.
[Not prospective]

Hanson F, Perera A. Surgery for morbid obesity in a provincial centre. *N Z Med J* 1982;**95**:426–7.
[Non-RCT]

Headley WM. Gastric bypass versus vertical banded gastroplasty. *Probl Gen Surg* 1992;**9**:332–44.
[Non-systematic review]

Heindorff H, Hougaard K, Larsen PN. Laparoscopic adjustable gastric band increases weight loss compared to dietary treatment: a randomized study. *Obes Surg* 1997;**7**:300–1.
[Abstract]

Hell E, Miller KA, Moorehead MK, Samuels N. Evaluation of health status and quality of life after bariatric surgery: comparison of standard Roux-en-Y gastric bypass, vertical banded gastroplasty and laparoscopic adjustable silicone gastric banding. *Obes Surg* 2000;**10**:214–19.
[Non-RCT]

Herbst-CA J, Buckwalter JA. Weight loss and complications after four gastric operations for morbid obesity. *South Med J* 1982;**75**:1324–8.
[Non-RCT]

Hoekstra SM, Lucas CE, Ledgerwood AM, Lucas WF. A comparison of the gastric bypass and the gastric wrap for morbid obesity. *Surg Gynecol Obstet* 1993;**176**:262–6.
[Non-RCT]

Hughes TA, Gwynne JT, Switzer BR, Herbst C, White G. Effects of caloric restriction and weight loss on glycemic control, insulin release and resistance, and atherosclerotic risk in obese patients with type II diabetes mellitus. *Am J Med* 1984;**77**:7–17.
[Non-comparative study]

Husemann B, Kluy JP. VBG and adjustable silicone gastric band – a prospective randomized clinical trial. *Obes Surg* 1997;**7**:290.
[Abstract]

Kalfarentzos F, Dimakopoulos A, Kehagias I, Loukidi A, Mead N. Vertical banded gastroplasty versus standard or distal Roux-en-Y gastric bypass based on specific selection criteria in the morbidly obese: preliminary results. *Obes Surg* 1999;**9**:433–42.
[Non-RCT]

Kenler HA, Brolin RE, Cody RP. Changes in eating behaviour after horizontal gastroplasty and Roux-en-Y gastric bypass. *Am J Clin Nutr* 1990;**52**:87–92.
[Non-RCT]

Kiviluoto T, Siren J, Sane T, Kivilaakso E. Laparoscopic adjustable silicone gastric banding vs. open vertical banded gastroplasty for morbid obesity. A 2-year follow-up. *Gastroenterology* 1999;**116**:S0134.
[Abstract]

Lechner GW, Elliott DW. Comparison of weight loss after gastric exclusion and partitioning. *Arch Surg* 1983;**118**:685–92.
[Non-RCT]

Lee WJ, Lai IR, Huang MT, Wu CC, Wei PL. Laparoscopic versus open vertical banded gastroplasty for the treatment of morbid obesity. *Surg Laparosc Endosc* 2001;**11**:9–13.
[Non-RCT]

Linner JH. Comparative effectiveness of gastric bypass and gastroplasty: a clinical study. *Arch Surg* 1982;**117**:695–700.
[Non-RCT]

Long SD, O'Brien K, MacDonald-KG J, Leggett FN, Swanson MS, Pories WJ, *et al.* Weight loss in severely obese subjects prevents the progression of impaired glucose tolerance to type II diabetes. A longitudinal interventional study. *Diabetes Care* 1994;**17**:372–5.
[Outcomes]

Lonroth H, Dalenback J, Haglind E, Josefsson K, Olbe L, Fagevik OM, *et al.* Vertical banded gastroplasty by laparoscopic technique in the treatment of morbid obesity. *Surg Laparosc Endosc* 1996;**6**:102–7.
[Non-RCT]

Lundell L, Ruth M, Olbe L. Vertical banded gastroplasty or gastric banding for morbid obesity: effects on gastro-oesophageal reflux. *Eur J Surg* 1997;**163**:525–31.
[Outcomes]

Lygidakis NJ. Late complications after total gastrectomy and their surgical prevention (part II of two parts). *Med Chir Dig* 1982;**11**:131–7.
[Non-RCT]

Mallory GN, Macgregor AMC, Rand CSW. The influence of dumping on weight loss after gastric restrictive surgery for morbid obesity. *Obes Surg* 1996;**6**:474–8.
[Non-RCT]

Marceau P, Hould FS, Simard S, Lebel S, Bourque RA, Potvin M, *et al.* Biliopancreatic diversion with duodenal switch. *World J Surg* 1998;**22**:947–54.
[Non-RCT]

Mason EE. Gastric bypass and gastroplasty for morbid obesity. *Mil Med* 1981;**146**:91–4.
[Non-RCT]

Miller K, Hell E. The adjustable silicone gastric band (Lap-Band®) versus the Swedish Adjustable Gastric Band (SAGB®): preliminary results of a prospective randomized study. *Obes Surg* 1997;**7**:301.
[Abstract]

Miller K, Mayer E, Pichler M, Hell E. Quality-of-life outcomes of patients with the Lap-Band registered versus non-operative treatment of obesity. Preliminary results of an ongoing long-term follow-up study. *Obes Surg* 1997;**7**:280.
[Abstract]

Monteforte MJ, Turkelson CM. Bariatric surgery for morbid obesity. *Obes Surg* 2000;**10**:391–401.
[Non-systematic review]

Murr MM, Balsiger BM, Kennedy FP, Mai JL, Sarr MG. Malabsorptive procedures for severe obesity: comparison of pancreaticobiliary bypass and very very long limb Roux-en-Y gastric bypass. *J Gastrointest Surg* 1999;**3**:607–12.
[Non-RCT]

Niville E, Vankeirsbilck J, Dams A, Anne T. Laparoscopic adjustable esophagogastric banding: a preliminary experience. *Obes Surg* 1998;**8**:39–43.
[Non-RCT]

Nyhlin H, Brydon G, Danielsson A, Eriksson F. Bile acid malabsorption after intestinal bypass surgery for obesity. A comparison between jejunoileal shunt and biliointestinal bypass. *Int J Obes* 1990;**14**:47–55.
[Non-RCT]

Ovrebo KK, Hatlebakk JG, Viste A, Bassoe HH, Svanes K. Gastroesophageal reflux in morbidly obese patients treated with gastric banding or vertical banded gastroplasty. *Ann Surg* 1998;**228**:51–8.
[Non-RCT]

Quaade F. Jejunoileostomy in the treatment of obesity – on the way out. A randomised clinical investigation compared with accounts from the literature. *Ugeskr Laeg* 1981;**143**:599–603.
[Not English]

Quaade F, Backer O, Stokholm KH, Andersen T. The Copenhagen PLAFA project: a randomized trial of gastroplasty versus very-low-calorie diet in the treatment of severe obesity (preliminary results). *Int J Obes* 1981;**5**:257–61.
[Insufficient follow-up]

Rabkin RA. Distal gastric bypass/duodenal switch procedure, Roux-en-Y gastric bypass and biliopancreatic diversion in a community practice. *Obes Surg* 1998;**8**:53–9.
[Non-RCT]

Rhode BM, Arseneau P, Cooper BA, Katz M, Gilfix BM, MacLean LD. Vitamin B-12 deficiency after gastric surgery for obesity. *Am J Clin Nutr* 1996;**63**:103–9.
[Non-RCT]

Robinson BE, Gjerdingen DK, Houge DR. Obesity: a move from traditional to more patient-oriented management [see comments]. *J Am Board Fam Pract* 1995;**8**:99–108.
[Non-systematic review]

Rubenstein RB, Fischer MG. Surgery for morbid obesity. Comparison of jejunoileal and gastric bypass. *N Y State J Med* 1979;**79**:1227–9.
[Case study]

Rucker RD Jr, Chan EK, Horstmann J, Chute EP, Varco RL, Buchwald H. Searching for the best weight reduction operation. *Surgery* 1984;**96**:624–31.
[Non-RCT]

Rucker RD, Goldenberg F, Varco RL, Buchwald H. Lipid effects of obesity operations. *J Surg Res* 1981;**30**:229–35.
[Outcomes]

Rucker RD Jr, Horstmann J, Schneider PD, Varco RL, Buchwald H. Comparisons between jejunoileal and gastric bypass operations for morbid obesity. *Surgery* 1982;**92**:241–9.
[Non-RCT]

Salmon PA. Comparison of weight losses following horizontal, vertical and vertical banded gastroplasty of equal pouch and stoma size: comparison with results of intestinal bypass surgery. *Clin Nutr* 1986;**5** Suppl:91–5.
[Non-RCT]

Salmon PA. Gastroplasty/distal gastric bypass: an operation producing excellent and prolonged weight loss in the super-obese. *Obes Surg* 1993;**3**:391–6.
[Non-RCT]

Salmon PA, McArdle MO. Horizontal and vertical gastroplasties: extended follow-up and late results. *Obes Surg* 1992;**2**:51–9.
[Non-RCT]

Sayenko VF, Lavryk AS, Stetsenko OP. Report on bariatric surgery in the Ukraine. *Obes Surg* 2000;**10**:54–7.
[Non-RCT]

Scott HW Jr. Jejunoileal bypass versus gastric bypass or gastroplasty in the operative treatment of obesity. *Langenbecks Arch Chir* 1982;**356**:25–35.
[Non-RCT]

Scruggs DM, Cowan J, Klesges L, Defibaugh N, Walker R, Kuyper B, *et al.* Weight loss and caloric intake after regular and extended gastric bypass. *Obes Surg* 1993; **3**:233–8.
[Comparison of surgical techniques]

Shearman CP, Baddeley RM. Which gastroplasty for the correction of massive obesity? *Ann R Coll Surg Engl* 1986;**68**:139–42.
[Non-RCT]

Sjostrom L. Surgical intervention as a strategy for treatment of obesity. *Endocrine* 2000;**13**:213–30.
[Non-systematic review]

Sjostrom L, Larsson BB. Swedish obese subjects (SOS). Recruitment for an intervention study and a selected description of the obese state. *Int J Obes Relat Metab Disord* 1992;**16**:465–79.
[Outcomes]

Stahl RD, Sherer RA, Seevers CE, Johnston D. Comparison of 21 vs. 25 mm gastrojejunostomy in the gastric bypass procedure–early results. *Obes Surg* 2000;**10**:540–2.
[Non-RCT]

Sugerman HJ, Londrey GL, Kellum JM, Wolf L, Liszka T, Engle KM, *et al.* Weight loss with vertical banded gastroplasty and Roux-Y gastric bypass for morbid obesity with selective versus random assignment. *Am J Surg* 1989;**157**:93–102.
[Non-RCT]

Sugerman HJ, Wolper JL. Failed gastroplasty for morbid obesity. Revised gastroplasty versus Roux-Y gastric bypass. *Am J Surg* 1984;**148**:331–6.
[Outcomes]

Suter M, Giusti V, Heraief E, Jayet C, Jayet A. Early results of laparoscopic gastric banding compared with open vertical banded gastroplasty. *Obes Surg* 1999;**9**:374–80.
[Non-RCT]

Suter M, Jayet C, Jayet A. Vertical banded gastroplasty: long-term results comparing three different techniques. *Obes Surg* 2000;**10**:41–6.
[Non-RCT]

Svacina S, Haas T, Nedelnikova K, Sonka J, Sucharda P, Fried M, *et al.* Long-term results of aggressive weight reduction treatment. *Sb Lek* 1998;**99**:273–7.
[Retrospective study]

Sylvan A, Rutegard JN, Janunger KG, Sjolund B, Nilsson TK. Normal plasminogen activator inhibitor levels at long-term follow-up after jejuno-ileal bypass surgery in morbidly obese individuals. *Metabolism* 1992;**41**:1370–2.
[Retrospective study]

Taskin M, Apaydin BB, Zengin K, Taskin U. Stoma adjustable silicone gastric banding versus vertical banded gastroplasty for the treatment of morbid obesity. *Obes Surg* 1997;**7**:424–8.
[Non-RCT]

Torgerson JS, Sjostrom L. The Swedish Obese Subjects (SOS) study – rationale and results. *Int J Obes* 2001;**25** Supp 1:s2–s4.
[Not primary study]

Trostler N, Mann A, Zilberbush N, Avinoach E, Charuzi I. Weight loss and food intake 18 months following vertical banded gastroplasty or gastric bypass for severe obesity. *Obes Surg* 1995;**5**:39–51.
[Non-RCT]

Trostler N, Mann A, Zilberbush N, Charuzi I, Avinoach E. Nutrient intake following vertical banded gastroplasty or gastric bypass. *Obes Surg* 1995;**5**:403–10.
[Non-RCT]

Van Gaal L, Delvigne C, Vandewoude M, Cogge E, Vaneerdeweg W, Schoofs E, *et al.* Evaluation of magnesium before and after jejuno-ileal versus gastric bypass surgery for morbid obesity. *J Am Coll Nutr* 1987;**6**:397–400.
[Non-RCT]

Van Gemert WG, Adang EM, Greve JW, Soeters PB. Quality of life assessment of morbidly obese patients: effect of weight-reducing surgery. *Am J Clin Nutr* 1998;**67**:197–201.
[Non-RCT]

Van Gemert WG, Greve JWM, Soeters PB. Long-term results of vertical banded gastroplasty: Marlex versus Dacron banding. *Obes Surg* 1997;**7**:128–35.
[Non-RCT]

Viddal KO. Intestinal bypass. A randomized, prospective clinical study of end-to-side and end-to-end jejunoileal bypass. *Scand J Gastroenterol* 1983;**18**:627–34.
[Comparison of surgical technique]

Vita PM, Lattuada E, Zappa MA, Doldi SB, Semeraro GC. [Gastroplasty and jejunoileal bypass in the surgical treatment of severe obesity.] *Minerva Med* 1986; **77**:511–15.
[Not English]

Weiner R, Bockhorn H, Rosenthal R, Wagner D. A prospective randomized trial of different laparoscopic gastric banding techniques for morbid obesity. *Surg Endosc-Ultrasound Interv* 2001;**15**:63–8.
[Comparison of surgical techniques]

Wolfel R, Gunther K, Rumenapf G, Koerfgen P, Husemann B. Weight reduction after gastric bypass and horizontal gastroplasty for morbid obesity. Results after 10 years. *Eur J Surg* 1994;**160**:219–25.
[Non-RCT]

Yale CE. Gastric surgery for morbid obesity. Complications and long-term weight control. *Arch Surg* 1989;**124**:941–6.
[Non-RCT]

Yamazaki K, Kawamura I, Miyazawa Y, Isono K. [A comparison of gastric bypass and vertical banded gastroplasty for morbid obesity.] *Nippon Geka Gakkai Zasshi* 1990;**91**:1685–90.
[Not English]

Zimmerman V, Campos CT, Buchwald H. Weight loss comparison of gastric bypass and Silastic registered ring vertical gastroplasty. *Obes Surg* 1992;**2**:47–9.
[Retrospective]

Appendix 5

Quality assessment scales for systematic reviews (NHS CRD)

Criteria for assessing good-quality systematic reviews

Systematic reviews will be examined to determine how many of the following criteria for methodological quality they met.

1. Are any inclusion/exclusion criteria reported relating to the primary studies that address the review question?

A good review should focus on a well-defined question, which ideally will refer to the inclusion/exclusion criteria by which decisions are made on whether to include or exclude primary studies. The criteria should relate to the four components of study design, participants, healthcare intervention or organisation, and outcomes of interest.

In addition, details should be reported relating to the process of decision-making, i.e. how many reviewers were involved, whether the studies were examined independently, and how disagreements between reviewers were resolved.

2. Is there evidence of a substantial effort to search for all relevant research?

This is usually the case if details of electronic database searches and other identification strategies are given. Ideally, details of the search terms used, and date and language restrictions should be presented. In addition, descriptions of hand-searching, attempts to identify unpublished material, and any contact with authors, industry and research institutes should be provided.

The appropriateness of the database(s) searched by the authors should also be considered; for example if MEDLINE is searched for a review looking at health education, then it is unlikely that all relevant studies will have been located.

3. Is the validity of included studies adequately assessed?

Authors should have taken account of study design and quality, either by restricting inclusion criteria, or systematic assessment of study quality. For example, if inclusion criteria have been restricted to 'double-blind randomised controlled trials, with at least 200 participants' then the need for quality assessment is not so crucial as when authors have less stringent inclusion criteria and/or include less rigorous study designs.

A systematic assessment of the quality of primary studies should include an explanation of the criteria used (e.g. method of randomisation, whether outcome assessment was blinded, whether analysis was on an intention-to-treat basis). Authors may use either a published checklist or scale, or one that they have designed specifically for their review. Again, the process relating to the assessment should be explained (i.e. how many reviewers involved, whether the assessment was independent, and how discrepancies between reviewers were resolved).

4. Is sufficient detail of the individual studies presented?

The review should demonstrate that the studies included are suitable to answer the question posed and that a judgement on the appropriateness of the authors' conclusions can be made. If a paper includes a table giving information on the design and results of the individual studies, or includes a narrative description of the studies within the text, this criterion is usually fulfilled. If relevant, the tables or text should include information on study design, sample size in each study group, patient characteristics, description of interventions, settings, outcome measures, follow-up, drop-out rate (withdrawals), efficacious results and side-effects (adverse events).

5. Are the primary studies summarised appropriately?

The authors should attempt to synthesise the results from individual studies. In all cases, there should be a narrative summary of results, which may or may not be accompanied by a quantitative summary (meta-analysis).

For reviews that incorporate a meta-analysis, heterogeneity between studies should be assessed

using statistical techniques. If heterogeneity is present, the possible reasons (including chance) should be investigated. In addition, the individual evaluations should be weighted in some way (e.g. according to sample size or inverse of the variance) so that studies that are considered to provide the most reliable data have greater impact on the summary statistic.

For some reviews, it may be inappropriate to include a meta-analysis, and therefore a narrative synthesis of studies should be presented. It is not usual to include a formal assessment of heterogeneity or to introduce weighting in such syntheses, so a discussion relating to the main differences between studies, and the better sources of evidence, should be highlighted.

Appendix 6

Quality assessment scale for non-RCTs

Assessment of the quality of non-RCTs using quality criteria adapted from Spitzer and colleagues (1990).[30]

1. Did the study use proper random assignment?
A study with proper random assignment would include multiple conditions with random assignment and would use an appropriate method for the assignment with allocation concealment.
('Yes' = random numbers table, computer-generated, etc.)

2. Did the study use proper sampling?
A study with proper sampling would allow for all patients to be equally likely to enter the study.
('Yes' = patients selected consecutively or randomly sampled.)

3. Was the sample size adequate?
Proper sample size enables adequately precise estimates of priority variables found to be significant.
('Yes' = for example, can compute CIs within relatively small range or relatively small SEM.)

4. Were criteria for definition or measurement of outcomes objective or verifiable?
('Yes' = clear methods (operational definition) for measuring outcomes that are public, verifiable and repeatable.)

5. Was assessment of outcomes double-blind?
('Yes' = if it is stated that neither the person doing the assessments nor the study participant could identify the intervention being assessed.)

6. Were objective criteria used for the eligibility of subjects?
('Yes' = clear, public, verifiable characteristics that are applied for inclusion and exclusion.)

7. Were attrition rates (%) provided?
('Yes' = reporting the number of patients who could not be contacted for outcome measures or, later, drop-outs or withdrawals for example due to treatment.)

8. Were groups under comparison comparable?
('Yes' = comparable groups show similar results across a reasonable range of baseline characteristics that could be expected to affect results.)

9. Are the results generalisable?
('Yes' = sample was a representative group of population from which it was chosen.)

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment						
Proper sampling						
Sample size enables precise estimate of significance						
Criteria for outcomes objective						
Blind assessment						
Objective criteria for eligibility (inclusion/exclusion)						
Attrition rates (%) – losses to follow-up						
Comparability of groups demonstrated						
Generalisability of results to parent population						

Appendix 7

Quality assessment of economic evaluations

Economic evaluations were assessed using a modified version of the Drummond criteria.[31]

Internal validity of studies

Item	Study
1. Well-defined question	
2. Clear description of alternatives	
3. Reasonable study type	
4. Effectiveness established	
5. Estimates related to population risks	
6. Relevant costs and consequences identified: • Healthcare resources (adverse events) • Patient/family resources • Social care sector resources • Patient benefits • Carer benefits	
7. Costs and consequences measured accurately	
8. Costs and consequences valued credibly	
9. Differential timing considered	
10. Incremental analysis performed	
11. Sensitivity analysis performed	
12. Modelling conducted reasonably	

?, unclear or unknown; ✔, item included or judged to have acceptable internal validity; ✗, factor not included or judged to have unacceptable internal validity

External validity of studies

Item	Study
1. Patient group Are the patients in the study similar to those of interest in England and Wales?	
2. Healthcare system/setting Comparability of available alternatives? Similar levels of resources? No untoward supply constraints? Institutional arrangements comparable?	
3. Treatment Comparability with clinical management?	
4. Resource costs Comparability between study and setting/population of interest?	
5. Marginal versus average costs What difference does this make? Are there real cost savings?	

?, unclear or unknown; ✔, judged item suitable to generalise to England and Wales with or without some re-adjustment; ✗, factor judged not suitable to generalise to England and Wales – either not possible to see how an adjustment could be made easily in short/medium term, or relevant data unavailable

Appendix 8

Summary of evidence of effectiveness of surgery versus non-surgical interventions for morbid obesity

Reference and design	Intervention	Participants	Outcome measures
Andersen *et al.*, 1984[34] (study 1); 1988[39] (study 2) Denmark ***Study type/design*** Single centre, RCT ***Duration*** September 1979–May 1981	***Treatment arms*** 1. GP (horizontal) + diet (500 kcal, 34 g protein daily) 2. VLCD: cycles of 8 weeks (341 kcal) and 2 weeks (900 kcal), stopped when patients failed to lose weight for 2 months ***Other interventions used*** Vitamin and other supplements VLCD: group meetings with clinical dieticians	***Number of patients*** 128 consecutive patients evaluated, 60 randomised Total: 57 (GP: 27; VLCD: 30) ***Characteristics of target population*** Consecutive patients referred for surgery assessed for eligibility and asked for consent ***Exclusion criteria*** Less than 60% overweight (3), not aged between 18 and 54 years (14), not attempted previous treatments (3), chronic bronchitis (1), alcohol or drugs abuse (6), on-going obesity treatment (2), unwillingness to cooperate or occupational or geographic factors impeding participation (21). Of 78 eligible, 11 refused surgical and 3 refused non-surgical treatment, 4 dropped out before random assignment, 2 refused after random assignment to GP, GP could not be performed in 1 patient due to hepatomegaly caused by fatty infiltration ***Participants*** GP: (24 women, 3 men), median age 35 years (21–53), median body weight 120 kg (94–166), median excess weight 82% (61–160) VLCD: (26 women, 4 men), median age 33 years (18–53), median body weight 115 kg (98–206), median excess weight 87% (68–174)	***Primary outcomes*** Weight loss Weight regain Net weight change ***Secondary outcomes*** Time to maximum weight loss Median maximum weight loss Relative reduction in percentage excess weight Patient < 40% overweight Successful net weight loss of 10 kg or more (number of patients and median weight loss) Complications ***Assessment of outcomes*** Study 1: 1-week intervals initially and 2-week intervals after 3 months in outpatients. Outcomes were assessed at 3, 6, 12, 18 and 24 months Study 2: twice-yearly check-up ***Length of follow-up*** Study 1: up to 24 months Study 2: 5–6 years

continued

Results

Absolute weight loss in kg (excluding data on regained weight) [range in central 50%] (data from graph):
3 months: VLCD 14.5 [11.6–20.1]; GP 19.7 [17.9–22.6]; ($p < 0.05$)
6 months: VLCD 21.6 [15.9–30.1]; GP 25.2 [21.8–29.5]; (p = ns)
12 months: VLCD 21.6 [16.7–33.2]; GP 25.8 [22.0–36.0]; (p = ns)
18 months: VLCD 21.8 [15.6–33.3]; GP 26.1 [22.4–35.7]; (p = ns)
24 months: VLCD 21.8 [15.9–33.5]; GP 26.1 [22.4–36.2]; (p = ns)

Median time to maximum weight loss: GP 9 months (range 3–24); VLCD 9 months (range 3–21) [VLCD = 6 months (range 3–21) in study 1]

Median maximum weight loss: GP 26.1 kg; VLCD 22.0 kg (p = ns)

Patients with excess weight < 40%: GP 18 (immediate success rate 67%; 95% CI, 46 to 83; VLCD 11 (immediate success rate 37%; 95% CI, 20 to 56); $p < 0.05$

Median relative reduction in percentage excess weight: GP 0.57 (range 0.15–1.04); VLCD 0.46 (range 0.07–0.81); $p < 0.05$

Weight regained (data from graph):
Median regain in GP = 10 kg during first year, followed by stabilisation. Higher regain in VLCD but not significantly different between groups at 3, 6 or 12 months. Regain at 18 months significantly higher in VLCD group ($p < 0.05$). After 18 months, median amount of regained weight in VLCD close to median maximum weight loss (about 21 kg)

Net weight change in kg (data from graph) (not ITT):
3 months: VLCD 15 (n = 30); GP 20 (n = 27) ($p < 0.05$)
6 months: VLCD 21 (n = 29); GP 25 (n = 27) (p = ns)
12 months: VLCD 18 (n = 28); GP 23 (n = 27) (p = ns)
18 months: VLCD 10.5 (n = 23); GP 18.5 (n = 19) (p = ns)
24 months: VLCD 9 (n = 14); GP 32 (n = 12) ($p < 0.05$)

Less than 40% overweight at 2 years:
GP 7/12 patients (58%; 95% CI, 28 to 85); VLCD 1/14 patients (7%; 95% CI, 0 to 34); $p < 0.05$

Successful net weight loss of 10 kg or more at 5 years:
GP 8/27 patients (30%; 95% CI, 14 to 50); VLCD 5/30 patients (17%; 95% CI, 6 to 35)

Median weight loss of patients with 'success' at 5 years:
GP 18.2 kg (range 14.2–50.3); VLCD 26.8 kg (range 13.0–38.2); (p = ns)

Cumulated success rate at 5–6 years:
GP (n = 8) 16% (95% CI, 11 to 21); VLCD (n = 8) 2% (95% CI, 1 to 3); ($p < 0.05$)

Re-operations:
No GP patients were re-operated on

Complications:
Perioperative complications (GP only, n = *27)*: subphrenic abscess 7%; atelectasis/pneumonia 4%; wound infection 4%
*Later complications (GP (*n = *27) vs VLCD (*n = *30))*: thrombophlebitis (4% vs 0%); nausea (15% vs 7%); heartburn (11% vs 0%); ructus (1% vs 0%); pain projected to left shoulder (15% vs 0%); epigastric pain (22% vs 10%); outlet obstruction (4% vs 0%); vomiting (52% vs 0%, $p < 0.05$); cholesystectomy (7% vs 0%); obstipation (26% vs 13%); orthostatic hypotension (7% vs 27%); dizziness (7% vs 17%); transient loss of hair (15% vs 10%); headache (11% vs 17%); fatigue (30% vs 53%); irritability and low spirits (0% vs 33%, $p < 0.05$); gout (0% vs 3%); staple line rupture (4% vs 0%); ventral hernia (4% vs 0%); abortion (4% vs 0%)
2 (6%) VLCD patients had GP elsewhere having regained all weight lost on diet

Comments

Methodological comments

Allocation to treatment groups: described as random allocation made by a third party, no other details; reports that assigned patients in equal numbers

Blinding: patients unable to be blinded; data collection not blinded

Comparability of treatment groups: baseline characteristics reported similar; data presented but no statistics presented

Method of data analysis: not ITT analysis. Where data were missing, estimates were made based on a continuation of patterns evident. Difference in weight loss tested for significance with 2-tailed MW rank-sum test for unpaired data. Success rates and prevalence of side-effects tested for significance using 2-tailed chi-squared test with Yates' correction. A 5% level of significance was chosen. Greenwood's method estimated 95% CI for cumulative success; differences between groups tested according to Gehan

Sample size/power calculation: size of each group sufficient to determine a 10-kg difference in weight loss with less than a 5% risk of a type 1 or type 2 error

Attrition/drop-out: 4% drop-out (1 GP, 1 VLCD) reported in 2-year study; 1 patient reported to be lost to follow-up in 5-year study. Some 11/187 and 18/206 determinations of weight were lacking from GP and VLCD, respectively. Conflicting data appear in the different papers

continued

***Comments* contd**

General comments

Generalisability: predominantly women aged 18–53 years with morbid obesity

Outcome measures: relative reduction in percentage excess weight defined as initial excess minus minimum excess during treatment, divided by initial excess weight

Inter-centre variability: single-centre study

Conflict of interests: funding support not stated

Other: caution should be taken as many measures are based on small numbers and/or interpreted from graphs. Some discrepancies are evident between the different papers

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	**Uncertain/ incomplete/ substandard**	**No**	**Don't know/ not reported**	**NA**	**Comments**
Proper random assignment				Not reported		
Proper sampling	Yes					
Sample size enables precise estimate of significance	Yes					
Criteria for outcomes objective	Yes					
Blind assessment			No			
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Reference and design	Intervention	Participants	Outcome measures
DOP Stokholm *et al*., 1982[58] Backer *et al*., 1979[59] Quaade, 1977[60] Denmark ***Study type/design*** Multicentre (14 centres), RCT ***Duration*** September 1973– September 1976	***Treatment arms*** 1. Medical management 2. Jejuno-ileostomy (end-to-side) which was further randomised into (a) 1/3 ileum/jejunum (b) 3/1 ileum/jejunum Shunt length 50 cm, except in those > 120% overweight, shunt length 47.5 cm ***Other interventions used*** None stated	***Number of patients*** 202 randomised but 196 entered treatment Total: 196 (medical: 66; surgical: 130) Stokholm *et al*. examined a subset of: medical: 33; surgical: 101 ***Characteristics of target population*** Referred to clinics for intestinal bypass surgery, following history of obesity resistant to conventional treatments. Participants at least 80% overweight, resistant to medical and dietary treatment, aged 18–50 years, agreeable to all treatments and follow-up, no previous resectional surgery, no abnormalities in liver besides fatty metamorphosis, no history of psychosis or alcohol abuse, no cardiac, pulmonary or renal disease, no substantial weight loss in a 2-month pre-trial period. No consent undertaken for randomisation ***Exclusion criteria*** None stated ***Participants*** **Backer *et al*.**: (36 males, 160 females), median age 32.2 years (18–50), median weight 125.3 kg (90–213), median height 166.4 cm (145–190), median W/H^2 (BMI) 45.1 (39.5–70.7) **Stokholm *et al*.** Surgical: (86 female, 15 male), median age 32 years (19–46), height 165 cm (147–189), weight 124 kg (96–179), overweight 100% (80–164) Medical: (27 female, 6 male), median age 31 years (19–47), height 166 cm (152–186), weight 129 kg (100–178), overweight 97% (80–186)	***Primary and secondary outcomes*** **Backer *et al*.**: Weight loss QoL **Stokholm *et al*.**: BP ***Assessment of outcomes*** Up to 24 months and beyond 24 months for weight loss. QoL was measured by postal questionnaire (177 items, no discussion validity). BP by mercury manometer with diagnostic BP at cessation of Korotkoff V ***Length of follow-up*** **Backer *et al*.**: Medical patients, median 42 months (26–70); surgical patients, median 45 months (2–69) **Stokholm *et al*.**: Median 24 months (12–48) at MBW change

continued

Results

Median weight loss at 24 months (range):

Medical: 5.9 kg (–11.9 to 40.4); surgical: 42.9 kg (20.5 to 108.5) ($p < 0.001$)
Shunt 47.5 cm: 60.3 kg; shunt 50 cm: 40.1 kg ($p < 0.01$)
No difference between 1/3 jejunum/ileum and 3/1 jejunum/ileum (weight loss and p value not stated)

QoL (> 15 months post-randomisation) (medical versus surgical):

Somatic symptoms:
Dyspnoea 42% vs 14% ($p < 0.001$); precordial pain 21% vs 7% ($p < 0.05$); heartburn 38% vs 14% ($p < 0.001$); abdominal pain 54% vs 87% ($p < 0.001$); flatulence 40% vs 93% ($p < 0.001$); anal complaints 17% vs 40% ($p < 0.01$); low back pain 63% vs 41% ($p < 0.01$); pain in hips/knees/ankles 67% vs 22% ($p < 0.001$); excessive sweating 54% vs 15% ($p < 0.001$); heat intolerance 69% vs 22% ($p < 0.001$); cold intolerance 6% vs 39% ($p < 0.001$); dermal irritation/rashes 77% vs 16% ($p < 0.001$)
Psychological symptoms:
Excessive fatigue 69% vs 41% ($p < 0.001$); periodic depression 62% vs 36% ($p < 0.01$); periodic irritability 71% vs 41% ($p < 0.001$); insecurity 65% vs 40% ($p < 0.01$); inferiority/insufficiency 65% vs 37% ($p < 0.001$); isolation 35% vs 11% ($p < 0.001$); loneliness 35% vs 14% ($p < 0.01$); exposure to contempt 69% vs 21% ($p < 0.001$)
Social factors:
Exercise daily 35% vs 55% ($p < 0.05$); participates in organised sport 12% vs 26% ($p < 0.05$); normal sex life 52% vs 78% ($p < 0.01$); wear ready-made clothes 46% vs 96% ($p < 0.01$); socially satisfied 52% vs 76% ($p < 0.01$); sexually satisfied 48% vs 82% ($p < 0.01$)

Median body weight at MBW change (median 24 months, range 12–48) [5%–95% percentiles]:

Surgical: baseline 124.0 kg [104.2–164.9]; MBW change 81.2 kg [64.0–103.9]; $p < 0.0001$
Medical: baseline 129.0 kg [104.6–166.3]; MBW change 119.0 kg [74.3–159.0]; $p < 0.0005$

Median SBP and DBP at MBW change (median 24 months, range 12–48) [5%–95% percentiles]:

Surgical SBP: baseline 140 mmHg [116–180]; MBW change 120 mmHg [105–150]; $p < 0.0001$
Surgical DBP: baseline 85 mmHg [70–109]; MBW change 80 mmHg [60–99]; $p < 0.0001$
Medical SBP: baseline 140 mmHg [118–197]; MBW change 140 mmHg [110–187]; p = ns
Medical DBP: baseline 90 mmHg [67–112]; MBW change 90 mmHg [70–100]; p = ns

Positive correlation between maximum changes in body weight and mean BP ($r = 0.43$, $p < 0.001$), mean SBP ($r = 0.46$, $p < 0.001$) and DBP ($r = 0.36$, $p < 0.001$) in all 134 patients
Positive correlation between mean baseline BP and changes in mean BP at MBW change in all 134 patients ($r = 0.55$, $p < 0.001$), and corresponding SBP and DBP and BP changes
Positive correlation ($p < 0.001$) between MBW change and SBP and DBP ($r = 0.39$ and $r = 0.39$, respectively) in 113 females before treatment. Corresponding correlation not shown in 21 males
SBP and SBP changes were significantly positively correlated ($r = 0.62$, $p < 0.001$) as were DBP and DBP changes ($r = 0.56$, $p < 0.001$). No correlation between weight change and mean BP before weight change ($r = 0.12$, $p < 0.10$)

Complications:

No surgical deaths (95% CI, 0 to 2.7); 2 deaths in medical group (1 complications of liver biopsy, 1 had bypass surgery 4 years after medical treatment, acquired cirrhosis of the liver and bleeding duodenal ulcer and died after restoration of intestinal continuity)
Surgical complications: pulmonary complications 3%, wound infection or dehiscence 6%, severe but transient hepatic dysfunction 1.5%. Other complications encountered but not reported. Intestinal continuity re-established in 1 (0.7%) patient due to duodenal ulcer

Comments

Methodological comments

Allocation to treatment groups: states random, method not described

Blinding: not stated

Comparability of treatment groups: reported to be comparable on age, sex, height, weight, presence of concomitant diseases, liver biopsy findings and biochemical investigations, no data or statistical analysis given in Backer paper (weight loss). Baseline data presented in Stokholm paper (BP)

Method of data analysis: ITT analysis not discussed. Stokholm data not normally distributed, therefore Spearman rank correlation coefficient (2-tailed) used. Wilcoxon rank sum test for paired data (2-tailed). Mean BP = DBP + (SBP – DBP)/3. Lowest BP before allocation and corresponding body weight compared with BP and body weight after MBW change

Sample size/power calculation: not stated

Attrition/drop-out:
Medical: 14 lost to follow-up – median 9 months (1–26); surgical: 2 lost to follow-up during second year. In addition, 6 of 202 dropped out prior to commencement (3 medical patients disappeared, 1 surgical patient refused, 2 surgical patients had surgery elsewhere) For Stokholm data, 16 patients (11 surgery, 5 medical) were excluded as receiving anti-hypertensive therapy and 46 (18 surgery, 28 medical) as insufficient recording of BP given

continued

***Comments* contd**

General comments

Generalisability: predominantly morbidly obese women aged 18–50 years

Outcome measures: no reporting of validity or reliability of QoL outcome, how items rated, maximum score etc. Retrospective analysis of QoL at 15 months in 166 patients (111 surgery and 55 medical). Response 98%. Late weight gains observed in surgical group but have been minor and infrequent, perhaps due to limited period of observation

Inter-centre variability: 14 centres, but any variability not discussed

Conflict of interests: none stated

Other: no details of medical group's treatment, simply described as consisting of diet, exercise and possibly anorectic drugs. Informed consent not obtained

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment				Not reported		
Proper sampling				Not reported		Possibly self-selected
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment				Not reported		
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated		Incomplete				Baseline data not reported in Backer (weight loss)
Generalisability of results to parent population	Yes					

Reference and design	Intervention	Participants	Outcome measures
SOS 1. Sjostrom *et al.*, 2001[70] 2. Sjostrom *et al.*, 2000[69] 3. Karason *et al.*, 2000[65] 4. Sjostrom *et al.*, 1999[68] 5. Karason *et al.*, 1999[63] 6. Narbro *et al.*, 1999[67] 7. Karason *et al.*, 1999[64] 8. Karlsson *et al.*, 1998[66] 9. Karason *et al.*, 1997[62] 10. Torgerson & Sjostrom, 2001 (overview)[71] Data extracted from study with most participants (study 3), longest follow-up (study 2), *post hoc* analysis (study 1). HRQoL (study 8) and lipid disturbances (study 4) from most recent publications Sweden ***Study type/design*** Cohort study with matched concurrent controls Multicentre (25 surgical and 480 primary healthcare centres) ***Duration*** 1991–2000	***Treatment arms*** 1. Surgical a. VBG b. GBan c. GB 2. Controls: conventional treatment, not standardised, best non-surgical options available at the time ***Other interventions used*** None stated	***Number of patients*** **Study 2: *n* = 692** Mortality, drop-outs and data pending: surgical = 95 (27%); control = 114 (33%) Surgical = 251 (VBG = 164, GBan = 63, GB = 24) Controls = 232 **Study 3: *n* = 2620** Mortality, drop-outs and data pending: surgical = 100 (7.6%); control = 211 (16.1%) Surgical = 1210 Controls = 1099 **Study 4: *n* = 1690** Mortality, drop-outs, pregnancies and data pending: surgical = 78 (9.2%); control = 133 (16%) Surgical = 767 (VBG = 534, GBan = 191, GB = 42) Controls = 712 **Study 8: *n* = 974** Surgical = 487 Control = 487 Data missing for 80 controls (16%) and 10 surgical patients at 24 months ***Characteristics of target population*** Age 37–60 years BMI ≥ 38 kg/m^2 for women and ≥ 34 kg/m^2 for men ***Exclusion criteria*** Previous bariatric surgery, gastric surgery for other causes in last 6 years, serious health problems including active malignancy and recent myocardial infarction, bulimic eating pattern, drug or alcohol abuse, psychological problems likely to lead to poor cooperation, regular use of cortisone or NSAIDs ***Participants*** **Study 2** (*n* = 692) at matching Control: mean age 47 years (SD 6), 65.9% women, 27.8% smokers, 6.1% diabetes, 37.1% hypertension, 19.4% BP medication, weight 117.4 kg (SD 16.6), BMI 41 (SD 4.7), SBP 142 mmHg (SD 20), DBP 89 mmHg (SD 11) Surgical: mean age 46 years (SD 6), 65.9% women, 31.5% smokers, 7.8% diabetes, 42.5% hypertension, 23.1% BP medication, weight 119.7 kg (SD 15.6), BMI 41.6 (SD 3.9), SBP 141 mmHg (SD 19), DBP 89 mmHg (SD 11) **Study 3** (*n* = 2309) at inclusion Control: mean age 49 years (SD 6), 67% women, 20% smokers, 18% diabetes, 38% hypertension, weight 114 kg (SD 16), BMI 39.7 (SD 4.4) Surgical: mean age 47 years (SD 6), 67% women, 25% smokers, 19% diabetes, 53% hypertension, weight 121 kg (SD 17), BMI 42.2 (SD 4.4) **Study 4** (*n* = 1479) at inclusion Control: mean age 48.6 years (SD 6.3), 68% women, weight 114.1 kg (SD 17), BMI 39.8 (SD 4.6) Surgical: mean age 47 years (SD 5.8), 69% women, weight 120.5 kg (SD 16), BMI 42.1 (SD 4.3) **Study 8** (*n* = 974) at inclusion Control: 67% women, mean age 47.7 years (95% CI, 47.2 to 48.3) Surgical: 67% women, mean age 46.6 years (95% CI, 46.1 to 47.1)	***Primary and secondary outcomes*** Weight loss (kg) BMI BP, SBP and DBP HRQoL Diabetes Lipid disturbances ***Assessment of outcomes*** Follow-up examinations at 3 and 6 months, and 1, 2, 3, 4, 6 and 8 years after surgery Weight measured in indoor clothing without shoes to 0.1 kg using calibrated balances or electronic scales. Height to nearest 0.01 m SBP and phase-5 DBP measured once after 15 minutes with patient in supine position. Patient spent last 5 minutes in complete rest. Cuff width and upper arm circumference recorded in each individual case. BP adjusted for any incongruities in measurements before analysis Energy and alcohol intake measured by questionnaire validated in obese and non-obese individuals. Level of physical activity at work and leisure time recorded by 4 graded scales Diagnosis of diabetes based on self-reported data in questionnaires Diagnosis of hypertension required an SBP of at least 160 mmHg or a DBP of at least 95 mmHg or medication prescribed specifically against hypertension HRQoL assessed by questionnaire at each follow-up interval using battery of self-assessment measures: 1. Current health perception assessed with GHRI/CH 2. Psychosocial functioning assessed by SI and OP scale 3. Mental well-being/mood disorders assessed with MACL and HAD scale ***Length of follow-up*** Study 3: 2 years Study 2: 8 years Study 8: 2 years Study 4: 2 years

continued

Results

Weight change from baseline to 2 years:

Study 3 (surgical, n = *1210; control,* n = *1099)*

Baseline: surgical = 121 kg (SD 17); control = 114 kg (SD 16); difference: = 7; 95% CI, 5.7 to 8.3

2 years: surgical = 93 kg (SD 16); control = 114 kg (SD 17); difference = –21; 95% CI, –23 to –19

Weight loss after 2 years: surgical = 28 kg (23%); control = unchanged; $p < 0.001$

Weight change from baseline to 8 years:

Study 2 (surgical = 232, control = 251)

Baseline: surgical = 120.4 kg (SD 16.0); control = 114.7 kg (SD 17.8)

1 year: GB ~ 75 kg; VGB ~ 89 kg; GBan ~ 95 kg; control ~ 114 kg (~ data from graphs)

8 years: GB ~ 92 kg; VGB ~ 100 kg; GBan ~ 103 kg; control = 115.4 kg (~ data from graphs)

8 years: surgical = 100.3 kg (SD 17.8); control = 115.4 (SD 19.2)

Difference in weight change between the 2 groups (20.7 kg) was statistically significant ($p < 0.001$)

Relative weight change: surgical = –16.3% (SD 12.3%); control = 0.9% (SD 10.8%)

GB (weight at 8 years ~ 92 kg) was more efficient than VBG (weight at 8 years ~ 100 kg) ($p = 0.057$) and GBan (weight at 8 years ~ 103 kg) ($p = 0.034$). Data from figures. Each of these had a significantly ($p < 0.01$) larger weight reduction than controls

Diabetes (Study 2):

Unadjusted prevalence over 8 years: control group increased from 7.8% to 24.9%; surgical group almost stable from 10.8% to 10.5% ($p < 0.0001$ for change in proportions over time between the 2 groups)

2-year unadjusted diabetes incidence: control = 4.7%; surgical = 0.0% ($p = 0.0012$)

8-year unadjusted diabetes incidence: controls = 18.5%; surgical = 3.6% ($p = 0.0001$)

OR of developing diabetes, 8 years (95% CI):

Completers ($n = 437$) unadjusted = 0.17 (0.08 to 0.37), adjusted = 0.17 (0.08 to 0.38)

All (ITT) ($n = 611$) unadjusted = 0.16 (0.07 to 0.34), adjusted = 0.16 (0.07 to 0.36)

BP (Study 2):

During first 6 months of rapid weight loss in surgical completers, SBP reduced by 11.4 mmHg (SD 19.0) and DBP reduced by 7.0 mmHg (SD 11.0) (unadjusted changes)

During next 6 months, with continuous but slower weight loss in the surgical group, the reduction in DBP ceased and SBP increased

From 1 year, SBP and DBP in the surgical group increased gradually over remaining 7 years

From inclusion to 8 years, surgical SBP increased by 2.9 mmHg (SD 22) and DBP decreased by 1.9 mmHg (SD 14)

In control completers, SBP increased gradually by 5.5 mmHg (SD 19.0) over 8 years ($p < 0.001$), DBP reduced by 2.2 mmHg ($p < 0.002$)

No difference in SBP between groups at 8 years (before and after adjustments)

Adjusted DBP was 2.5 mmHg (95% CI, 0.5 to 4.5; $p = 0.012$) higher in the surgical than control group at 8 years, despite significantly lower body weight

2-year unadjusted incidence of hypertension: controls = 9.9%; surgical = 3.2% ($p = 0.032$)

8-year unadjusted incidence of hypertension: controls = 25.8%; surgical = 26.4% ($p = 0.91$)

OR of developing hypertension, 2 years (95% CI):

Completers ($n = 257$) unadjusted = 0.30 (0.10 to 0.95), adjusted = 0.27 (0.07 to 0.99)

All (ITT) ($n = 377$) unadjusted = 0.27 (0.09 to 0.70), adjusted = 0.27 (0.09 to 0.76)

OR of developing hypertension, 8 years (95% CI):

Completers ($n = 257$) unadjusted = 1.03 (0.59 to 1.80), adjusted = 1.05 (0.58 to 1.89)

All (ITT) ($n = 377$) unadjusted = 0.96 (0.59 to 1.55), adjusted = 1.01 (0.61 to 1.67)

Post hoc analysis to separate the effect of time (ageing) from the effect of weight change per unit time (study 1: surgery = 1157, controls = 1031; follow-up = 5.5 years, SD 2.1, range 3–10 years). Final BP values were more closely related to follow-up time (ageing) and ongoing weight increase than to initial body weight or initial weight loss. Analysis adjusted for gender, age, inclusion weight, inclusion BP, present values at each measuring point for BP medication, smoking, alcohol intake, energy intake and physical activity

Final SBP (mmHg) and DBP (mmHg) (95% CI) of surgically treated and control patients regressed by years of follow-up, inclusion weight, weight change to 1st year examination (I), weight change from 1 to 2 years (II), weight change from 2 to 3 years (III)

Follow-up (years): surgical mean 5.4 (± 2), SBP 1.24 (0.73 to 1.77), DBP 0.54 (0.24 to 0.84); control mean 5.6 (± 2), SBP 1.25 (0.80 to 1.70), DBP 0.09 (–0.18 to 0.36)

Inclusion weight (kg): surgical mean 121 (± 16), SBP 0.16 (0.06 to 0.27), DBP 0.11 (0.05 to 0.17); control mean 114 (± 16), SBP –0.02 (–0.10 to 0.06), DBP 0.00 (–0.04 to 0.05)

Period I (kg/years): surgical mean –30.3 (± 13), SBP 0.14 (0.04 to 0.25), DBP 0.14 (0.08 to 0.20); control mean –1.3 (± 8), SBP 0.23 (0.09 to 0.37), DBP 0.14 (0.07 to 0.22)

Period II (kg/years): surgical mean 2.4 (± 5), SBP 0.34 (0.11 to 0.57), DBP 0.27 (0.14 to 0.41); control mean 0.9 (± 4), SBP 0.29 (0.00 to 0.56), DBP 0.14 (–0.03 to 0.30)

Period III (kg/years): surgical mean 1.9 (± 5), SBP 0.30 (0.10 to 0.51), DBP 0.20 (0.08 to 0.32); control mean 0.6 (± 5), SBP 0.23 (0.03 to 0.42), DBP 0.17 (0.06 to 0.29)

continued

***Results* contd**

HRQoL (Study 8):

Current health perception

GHRI/CH (mean; 95% CI):

Baseline: surgical 26.9 (26.1 to 27.7), control 29.4 (28.5 to 30.2); 2 years: surgical 34.3 (33.4 to 35.1), control 30.2 (29.4 to 31.1)

Psychosocial functioning

OP scale change by 2 years (mean, 95% CI):

surgical males –1.01 (–1.14 to –0.87), females –1.10 (–1.19 to –1.00); control males –0.07 (–0.17 to 0.03) ($p = 0.001$), females –0.16 (–0.22 to –0.09) ($p = 0.001$)

SIP/SI change by 2 years (mean, 95% CI):

surgical males –3.3 (–5.0 to –1.5), females –5.2 (–6.5 to –4.0); control males 1.5 (0.2 to 3.2) ($p = 0.001$), females 1.2 (0.2 to 2.2) ($p = 0.0001$)

Mental well-being scales

MACL change by 2 years (mean, 95% CI):

Pleasantness/unpleasantness: surgical 0.21 (0.16 to 0.26), control –0.04 (–0.09 to 0.01) ($p = 0.001$)

Activation/deactivation: surgical 0.32 (0.27 to 0.37), control 0.00 (–0.04 to 0.05) ($p = 0.001$)

Calmness/tension: surgical 0.20 (0.15 to 0.26), control –0.01 (–0.06 to 0.04) ($p = 0.001$)

HAD change by 2 years (mean, 95% CI):

Anxiety: surgical –1.7 (–2.0 to –1.4); control –0.6 (–0.9 to –0.2) ($p = 0.0001$)

Depression: surgical –2.2 (–2.5 to –1.9); control –0.4 (–0.6 to –0.1) ($p = 0.0001$)

At 24 months: improvement in surgical versus control patients on all HRQoL measures ($p < 0.0001$)

Changes in all HRQoL measures significantly related to magnitude of weight loss

Dyspnoea, chest pain, physical inactivity (Study 3):

Change in percentage of patients at 2 years

Dyspnoea: climbing 2 flights of stairs – surgical 68%, control 12% ($p < 0.001$); walking with people of own age – surgical 56%, control 8% ($p < 0.001$); walking on level surface at own speed – surgical 12%, control 2% ($p < 0.001$); washing or dressing – surgical 21%, control 2% ($p < 0.01$)

Chest pain: walking uphill or climbing stairs – surgical 24%, control 8% ($p < 0.01$), associated with anger or anxiety – surgical 8%, control 5% ($p < 0.05$)

Physical inactivity: surgical 29%, control 4% ($p < 0.001$)

Lipids (Study 4):

Impossible to determine HDL-cholesterol in 45 patients due to hypertriglyceridaemia

Baseline: all risk factors except uric acid and HDL-cholesterol where slightly but significantly higher in surgical patients

At 2 years: all risk factors except SBP and total cholesterol were more favourable in surgical patients

SBP (mmHg) – baseline: surgical 144 (± 19), control 139 (± 18), $p < 0.001$; 2 years: surgical –7 (± 18), control 0 (± 15), $p < 0.001$

DBP (mmHg) – baseline: surgical 90 (± 11), control 86 (± 11), $p < 0.001$; 2 years: surgical –6 (± 11), control –1 (± 9), $p < 0.001$

Triglyceridaemia (mmol/l) – baseline: surgical 2.3 (± 1.4), control 2.2 (± 1.7), $p < 0.05$; 2 years: surgical –0.7 (± 13), control –0.1 (± 1.2), $p < 0.001$

Glucose (mmol/l) – baseline: surgical 5.5 (± 2.1), control 5.2 (± 1.8), $p < 0.001$; 2 years: surgical –1.1 (± 1.8), control 0.1 (± 1.4), $p < 0.001$

Insulin (mmol/l) – baseline: surgical 21.8 (± 13), control 18.5 (± 11), $p < 0.001$; 2 years: surgical –11.4 (± 12), control –0.7 (± 10), $p < 0.001$

Uric acid (mmol/l) – baseline: surgical 365 (± 84), control 358 (± 80), p = ns; 2 years: surgical –62 (± 72), control –12 (± 60), $p < 0.001$

Cholesterol (mmol/l) – baseline: surgical 6.0 (± 1.1), control 5.8 (± 1.1), $p < 0.001$; 2 years: surgical –0.25 (± 1), control –0.06 (± 0.8), $p < 0.001$

HDL (mmol/l) – baseline: surgery 1.19 (± 0.28), control 1.17 (± 0.28), p = ns; 2 years: surgery 0.18 (± 0.3), control 0.01 (± 0.2), $p < 0.001$

2-year unadjusted incidence:

Hypertriglyceridaemia: control 7.7%; surgical 0.8%

Hypo HDL-cholesterol: control 8.6%, surgical 3.0%

Hypercholesterolaemia: control 12.1%, surgical 14.9%

OR at 2 years (95% CI) adjusted for baseline characteristics for surgery versus controls:

Hypertriglyceridaemia: 0.10 (0.04 to 0.25), $p < 0.001$

Hypo HDL-cholesterol: 0.28 (0.16 to 0.49), $p < 0.001$

Hypercholesterolaemia: 1.24 (0.84 to 1.8), p = ns

In patients with disease or risk factors at baseline, recovery from disease and improvements in risk profile were significantly more likely in the surgical than the control group. Relative risks (95% CI) for recovery from disease for surgery versus controls were as follows:

Hyperinsulinaemia: 1.4 (1.2 to 1.7), $n = 221$, $p < 0.00001$

Hypertriglyceridaemia: 1.9 (1.5 to 2.4), $n = 314$, $p < 0.00001$

Hypo HDL-cholesterol: 1.7 (1.4 to 2.1), $n = 216$, $p < 0.00001$

Hypercholesterolaemia: 1.2 (0.95 to 1.5), $n = 531$, p = ns

Adverse effects:

Mortality and perioperative complications reported in abstract (taken from overview (Torgerson & Sjostrom 2001[71])). There were 4 (0.2%) postoperative deaths: 3 due to leakage detected too late; 1 due to a technical laparoscopic mistake

Perioperative complications reported in subset of 1164 patients: 151 (13%) experienced 193 complications. Bleeding (0.9%), thromboembolic events (0.8%), wound complications (1.8%), abdominal infection (2.1%), pulmonary symptoms (6.2%), miscellaneous (4.8%). Postoperative complications severe enough to necessitate re-operation in 26 (2.2%)

Study 4: 15 surgical patients had operations reversed during first 2 years and 5 GBan converted to GB, 1 GBan converted to VBG, 7 VBG converted to GB

continued

Comments

Methodological comments

Allocation to treatment groups: patients could volunteer for conventional or surgical treatment. For each surgical case a computer-ised matching procedure selects the optimal control from a registry taking 18 different variables into account (including gender (absolute match) age, weight, height, waist and hip circumferences, SBP, serum cholesterol and triglyceride concentrations, smoking, diabetes, pre/post-menopausal, 4 psychosocial variables with known associations with mortality, 2 personality traits related to treatment preferences)

Blinding: NA

Comparability of treatment groups: study 3 – average interval between matching of controls and inclusion into study (surgery) was 9 months (0.8 years, SD 7; study 2). During this period, the surgical group gained weight and control group lost weight, resulting in an average difference of 7.1 kg (significance not given) (6.4 kg, $p < 0.001$; study 2). At inclusion, the surgical group were younger than controls ($p < 0.001$), had a higher prevalence of hypertension ($p < 0.05$) and were more often smokers (not significant). Study 2 also reports higher BMI ($p < 0.001$), BP ($p < 0.001$) and energy intake ($p < 0.001$) in surgical patients

Method of data analysis: analysis on completers except where ITT specified (only study 4). When all included patients were analysed, missing data were handled by last-value imputation according to ITT principles. Completer and ITT analysis resulted in almost identical results. Dissimilarities between groups at inclusion were adjusted for in calculations. According to the general linear model used, *t* tests, paired *t* tests and ANOVA were used. ANOVA was used to test differences between the surgical procedures. For comparisons in changes of proportions between 2 groups, a 2-sample McNemar test was used. Unconditional logistic regression was used for comparing incidences in the 2 treatment groups because these were matched on a group level and not on an individual level. Study 8: 15 reversals and 8 controls who demanded and received surgery were considered as belonging to their original treatment groups according to ITT principles. Differences between groups were analysed by Fisher's permutation test and Kruskal–Wallis ANOVA of mean ranks and Tukeys range test

Sample size/power calculation: study aimed to recruit 2000 surgical cases and 2000 matched controls over approximately 4 years, which they report to be sufficient for the detection of a 10-year excess mortality risk that is 50% higher in the non-surgically treated group. No calculation given for other outcomes

Attrition/drop-out: owing to mortality, drop-outs and data pending (numbers not specified), data reported on 73% of surgical and 67% of control patients in study 2 (8-year follow-up), and 84% of surgical and 93% of patients in study 3 (2-year follow-up). Study 2: in controls, future drop-outs had a higher prevalence of diabetes (22%, 8%, $p = 0.002$) and smoking (40%, 24%, $p = 0.002$) than completers at inclusion. In surgical patients , future drop-outs had higher body weight (125 kg vs 120 kg, $p = 0.02$) and alcohol consumption (7.0 g/day vs 4.8 g/day, $p = 0.01$) than completers at inclusion

General comments

Generalisability: participants were predominantly females, aged 37–60 years, and were either obese or morbidly obese

Inter-centre variability: not stated

Conflict of interests: major sponsors – Swedish Medical Research Council, Hoffmann-La Roche Ltd Switzerland. Support also from Volvo Research Foundation, CEFOS, The Swedish Social Welfare Board, Ministry of Education, Skandia Insurance

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment			No			Matched group design
Proper sampling			No			
Sample size enables precise estimate of significance				Not reported		Calculation for mortality
Criteria for outcomes objective	Yes					
Blind assessment					N/A	
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated			No			Significant differences at start of intervention
Generalisability of results to parent population	Yes					

Appendix 9

Summary of evidence of effectiveness of GB versus GP for morbid obesity

Reference and design	Intervention	Participants	Outcome measures
Howard *et al.*, 1995[46] USA ***Study type/design*** Single centre, RCT ***Duration*** Not reported	***Treatment arms*** 1. GB 2. VBG ***Other interventions used*** Patients managed conservatively for 3 months preoperatively to educate them about the surgery, determine psychological stability and comply temporarily with dietary restraint Postoperatively: routine post-operative care and dietary counselling	***Number of patients*** 44 recruited, 2 withdrew from study within 4 weeks of surgery Total: 42 1. GB: 20 2. VBG: 22 ***Characteristics of target population*** Class IV obesity (BMI > 40); < 50 years old; a history of at least one and usually several attempts at non-operative weight loss; must be considered psychiatrically stable; hold a realistic view of the operation and the likely impact on his or her life ***Exclusion criteria*** None stated ***Participants*** Mean age: GB 38.1 (SEM 1.9); VBG 36.5 (SEM 2.3) Gender: M/F GB 5/15; VBG 4/18 Mean maximum weight (kg): GB 154 (SEM 26); VBG 142 (SEM 17); $p = 0.09$ Mean excess preoperative weight (kg): GB 71 (SEM 19); VBG 67 (SEM 15); $p = 0.41$ Number of super-obese: (> 225% IBW/BMI, BMI > 50): GB 8 (47%); VBG 10 (50%) Intraoperative cholecystectomy (M/F): GB 2/2; VBG 0/3 Postoperative gallstones (M/F): GB 0/4; VBG 2/3 Both groups had an equal proportion of super-obese (> 225% of IBW or BMI > 50)	***Primary and secondary outcomes*** Weight change (pre- and postoperative) % of EWL compared to maximum excess weight % lost > 50% and > 75% of excess weight Early postoperative complications (wound dehiscence, infection and thromboembolism) ***Assessment of outcomes*** Outcomes were assessed weekly for first 4 weeks, monthly for 6 months and then every 3 months. Prior to surgery, patients had complete medical and dietary history, physical examination and routine laboratory tests. Subsequent monitoring via outpatient visits ***Length of follow-up*** Range from 12 to 78 months 12 patients followed for 60 months (GB 6 (30%); VBG 6 (28%))

Results

Preoperative weight loss decrease from the maximum mean percentage of IBW:
GB from 222% (SE 31) to 202% (SE 24); VBG from 219% (SE 30) to 204% (SE 27)

Postoperative weight loss:
Patients who underwent GB demonstrated a significantly greater postoperative weight loss ($p < 0.05$) which was apparent for 6 months afterwards. Patients in both groups lost most of their weight during the initial 12 months. The weight of the GB patients stabilised after 12–24 months, whereas the weight of VBG patients did not

% of EWL compared with maximum excess weight (not ITT) (data from graph):
12 months: GB ~ 78%, VBG ~ 52%; $p < 0.05$
60 months: GB ~ 70%, VBG ~ 37%; $p < 0.05$

% of patients who have lost at least 50% of excess weight (not ITT) (data from graph):
12 months: GB 100% (20/20), VBG 55% (12/22); p value not stated
60 months: GB 100% (6/6), VBG 0% (0/6); p value not stated

% of patients who have lost more than 75% of excess weight (not ITT) (data from graph):
12 months: GB 60% (12/20), VBG 18% (4/22); p value not stated
60 months: GB 50% (3/6), VBG 0% (0/6); p value not stated

Early complications:
Deaths – GB 0, VBG 0; wound infection – 1 (2%) super-obese patient

Late complications:
Symptomatic ulcer disease – GB 25% (50% further surgery), VBG 0%
Intraoperative cholecystectomy – GB 20%, VBG 14%
Postoperative cholecystectomy – VBG 29%, GB 29%

continued

Comments

Methodological comments

Allocation to treatment groups: randomised, method not stated

Blinding: not stated

Comparability of treatment groups: no significant difference ($p > 0.05$) between the groups with respect to age, gender, maximum or preoperative weight. Both groups equal with respect to proportion of super-obese patients (BMI > 50), although the proportions presented appear inaccurate

Method of data analysis: not ITT. Statistical comparison between the groups made using Student's *t* test and a *p* value of less than 0.05 was considered significant

Sample size/power calculation: not stated

Attrition/drop-out: 2 of 44 (5%) patients withdrew from study within 4 weeks of surgery, and only 12 patients were followed-up for 60 months

General comments

Generalisability: predominantly women in late 30s who are morbidly to super-obese

Inter-centre variability: single-centre study

Conflict of interests: not stated

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment				Not reported		
Proper sampling				Not reported		
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment				Not reported		
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Reference and design	Intervention	Participants	Outcome measures
MacLean *et al*., 1995,[49] 1993[50] Canada ***Study type/design*** Single centre, RCT ***Duration*** October 1987–February 1990	***Treatment arms*** 1. VBG (with a division between staple lines) 2. RYGB (staple lines not divided) ***Other interventions used*** IGB for failures	***Number of patients*** Total: 106 (VBG: 54; RYGB: 52) ***Characteristics of target population*** Not stated ***Exclusion criteria*** Not stated ***Participants*** VBG: mean age 38.8 years (SD 9.5), mean BMI 48.2 (SD 6.5), mean weight 278 lb (SD 41), super-obese 31% (BMI > 50) RYGB: mean age 40.1 years (SD 7.7), mean BMI 49.9 (SD 7.4), mean weight 295 lb (SD 53), super-obese 44% (BMI > 50)	***Primary and secondary outcomes*** Success – BMI < 35 or < 50% excess weight and re-operation not required Re-operation defined as failure, regardless of ultimate outcome Mean length of follow-up Re-operation rates ***Assessment of outcomes*** Patients seen once a month for first 3 months, every 3 months for first year, semi-annually thereafter. Weighed and examined at each visit and BMI calculated. Gastroscopy performed at 6 weeks, 6 months, then annually ***Length of follow-up*** Between 3 and 6.5 years

Results

Outcome at approximately 3 years:

Mean follow-up (months): VBG 38.6 (SD 8.5), RYGB 33.1 (SD 12.4), IGB 21.8 (SD 9.3)
Remained with operation: VBG 31, RYGB 40
Converted to normal: VBG 5 (9%), RYGB 0 (0%)
Converted to IGB: VBG 18 (33%), RYGB 12 (23%)
Success rate: VBG 21 (39%), RYGB 30 (58%), IGB 24 (83%) (VBG-RYGB, p = ns; RYGB-IGB, $p < 0.0005$; VBG-IGB, $p < 0.05$)

Outcomes up to 6.5 years:

Mean follow-up (months): VBG 70.9 (SD 5.8), RYGB 66.5 (SD 9.1), IGB 35.8 (SD 19.4)
Remained with operation: VBG 25, RYGB 32
Converted to normal: VBG 5 (9%), RYGB 1 (2%)
Converted to IGB: VBG 24 (44%), RYGB 19 (37%)
Success rate: VBG 9 (16%), RYGB 16 (34%), IGB 25 (63%)* (VBG-RYGB, p = ns; RYGB-IGB, $p < 0.001$; VBG-IGB, $p < 0.001$)
(Patient reported in table as revised to normal, but this is contradictory to earlier data and information in text. Note: the proportions presented appear inaccurate.)*

Complications:

Deaths: VBG 0, RYGB 0
Re-operation: total VBG 43%, RYGB 23%; stenosis: VBG 20%, RYGB 0%; enlarged orifice: VBG 13%, RYGB 0%; staple line fistula: VBG 4%, RYGB 23%; clinical failure: VBG 4%, RYGB 0%; abscess: VBG 2%, RYGB 0%; stomal ulcer: VBG 0%, RYGB 13%
Of 160 operations and 35 re-operations: 6 intra-abdominal abscesses and/or leaks (3.8% of patients or 3.1% of operations), of which only 5 required re-operation, 1 drained by percutaneous catheter

Comments

Methodological comments

Allocation to treatment groups: randomisation took place at time of surgery. No other details

Blinding: not stated

Comparability of treatment groups: no significant differences in baseline characteristics (age, BMI and mean weight)

Method of data analysis: differences in continuous variables evaluated using Student's t test (2 groups) or ANOVA (more than 2 groups). Chi-squared test used for categorical variables. Multiple linear regression and ANOVA used to test differences with respect to change in BMI from baseline

Sample size/power calculation: not stated

Attrition/drop-out: 1 patient possibly lost to follow-up after conversion to IGB, but information contradictory

General comments

Generalisability: limited to morbidly obese people aged 30–40 years

Inter-centre variability: not stated

Conflict of interests: not stated

continued

Quality assessment for clinical trials (Spitzer* et al., *1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment				Not reported		
Proper sampling				Not reported		
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment				Not reported		
Objective criteria for eligibility (inclusion/exclusion)			No			
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Reference and design	Intervention	Participants	Outcome measures
Sugerman *et al.*, 1987[61] USA ***Study type/design*** Single centre, RCT ***Duration*** From June 1982 for 9 months when stopped early due to a significant difference in weight loss ($p < 0.05$) in favour of RYGB over VBG	***Treatment arms*** 1. RYGB 2. VBG ***Other interventions used*** Dietary instruction by dietitian. Blenderised diet for 6 weeks, minimum 44 g protein per day. Multivitamin and mineral capsule, calcium if required	***Number of patients*** Total: 40 (RYGB: 20; VBG: 20) ***Characteristics of target population***: More than 100 lb above ideal weight: 1959 Metropolitan Life Insurance tables. Failed to lose weight by supervised dietary programme(s) or had a significant medical problem related to obesity (respiratory insufficiency, insulin-dependant adult-onset diabetes, pseudo tumor cerebri etc.). Patients were classified into 'sweets eaters' (consume > 300 calories of sweet foods > 3 times/week) and non-'sweets eaters' (all others) ***Exclusion criteria*** None reported ***Participant characteristics*** RYGB: age 38 ± 11 years, M/F 2/18, black/white 5/15, % IBW 213 ± 49 VBG: age 38 ± 9 years, M/F 2/18, black/white 10/10, % IBW 225 ± 41	***Primary and secondary outcomes*** Weight loss (lb) % weight lost % EWL % IBW achieved Mortality Complications ***Assessment of outcomes*** Follow-up visits attended at 2 weeks, 1.5, 3, 6, 9 months, 1 year and yearly ***Length of follow-up*** 3 years

Results

% IBW ± SD:
Baseline: RYGB 213% ± 49 ($n = 20$), VBG 225% ± 41 ($n = 20$)
1 year: RYGB 138% ± 32 ($n = 19$), VBG 176% ± 41 ($n = 18$); $p < 0.01$
2 years: RYGB 139% ± 32 ($n = 18$), VBG 178% ± 41 ($n = 17$); $p < 0.01$
3 years: RYGB 142% ± 37 ($n = 18$), VBG 180% ± 44 ($n = 16$); $p < 0.01$

Weight loss ± SD:
1 year: RYGB 43.5 kg ± 11.3 ($n = 19$), VBG 32.2 kg ± 10.9 ($n = 18$); $p < 0.001$
2 years: RYGB 43.5 kg ± 15.4 ($n = 18$), VBG 30.4 kg ± 12.2 ($n = 17$); $p < 0.001$
3 years: RYGB 41.3 kg ± 12.7 ($n = 18$), VBG 27.2 kg ± 14.5 ($n = 16$); $p < 0.01$

% weight lost ± SD:
1 year: RYGB 33% ± 7 ($n = 19$), VBG 22% ± 8 ($n = 18$); $p < 0.001$
2 years: RYGB 33% ± 9 ($n = 18$), VBG 22% ± 9 ($n = 17$); $p < 0.001$
3 years: RYGB 32% ± 9 ($n = 18$), VBG 20% ± 10 ($n = 16$); $p < 0.01$

% EWL ± SD:
1 year: RYGB 68% ± 17, VBG 43% ± 18; $p < 0.001$
2 years: RYGB 66% ± 29, VBG 39% ± 24; $p < 0.001$ (data from figure)
3 years: RYGB 62% ± 18, VBG 37% ± 19; $p < 0.001$ (data from figure)

% decrease in excess weight (± SD) for 'sweets eaters' versus non-'sweets eaters':
RYGB
1 year: sweets eaters 69% ± 12 ($n = 12$), non-sweets eaters 67% ± 17 ($n = 7$); p = ns
2 years: sweets eaters 62% ± 11 ($n = 11$), non-sweets eaters 75% ± 19 ($n = 7$); p = ns
3 years: sweets eaters 59% ± 11 ($n = 11$), non-sweets eaters 71% ± 21 ($n = 7$); p = ns
VBG
1 year: sweets eaters 36% ± 13 ($n = 12$), non-sweets eaters 57% ± 18 ($n = 6$); $p < 0.05$
2 years: sweets eaters 35% ± 14 ($n = 11$), non-sweets eaters 53% ± 22 ($n = 6$); $p < 0.05$
3 years: sweets eaters 32% ± 18 ($n = 11$), non-sweets eaters 50% ± 21 ($n = 5$); $p < 0.05$
Difference in decrease in excess weight (%) for RYGB compared to VBG for sweets eaters was significant ($p < 0.0001$), while for non-sweets eaters it was non-significant (p = ns)

Adverse effects:
2 (10%) deaths in RYGB group, after 3 days, and at 1 year (both assumed arrhythmia)
No significant deficiencies for haemoglobin, transferrin, albumin, vitamins B_1, B_6 or C, folic acid, serum iron, total calcium, magnesium or zinc levels at 1 or 2 years after surgery. No abnormalities in renal function tests, liver function tests, or standard electrolytes were noted at 1, 2 or 3 years. RYGB group had lower ($p < 0.05$) vitamin B_{12} levels (286 ± 149 pg/ml) than VBG group (461 ± 226) at 2 years
RYGB: 5 (25%) intractable vomiting and stomal stenosis; 1 (5%) developed a marginal ulcer of the jejunal side of the gastrojejunostomy
VBG: 1 (5%) superficial stomal erosions; 1 (5%) disrupted the vertical staple line 1 month after surgery and converted to RYGB, and another patient who failed due to eating sweets and high-starch foods was converted to RYGB at 18 months (5%). 2 (10%) were converted to RYGB at 38 months

continued

Comments

Methodological comments

Allocation to treatment groups: feasibility of performing either procedure determined at laparotomy. Cards designating each operation were combined in groups of 5, shuffled, and a card selected 'blindly'

Blinding: not stated

Comparability of treatment groups: no differences in baseline characteristics of groups (age, sex, IBW, % of IBW)

Method of data analysis: not ITT. Analysis of covariance or Student's *t* test for unpaired data

Sample size/power calculation: not stated

Attrition/drop-out:
VBG: 1 patient lost to follow-up immediately after surgery, 1 patient fatally stabbed at 25 months. 2 patients converted to RYGB, within 1 year and at 18 months, and excluded from further analysis. Number of patients analysed were: 1 year = 19 RYGB, 18 VBG; 2 year = 18 RYGB, 17 VBG; 3 year = 18 RYGB, 16 VBG

General comments

Stopping rule: if one procedure was superior at $p < 0.05$ then the study would be stopped until all patients achieved same follow-up point post-surgery. If $p < 0.01$ not present when at equivalent time interval study would be re-opened until significance achieved

Generalisability: predominantly morbidly obese women aged between late 30s and early 50s with subgroup analysis for 'sweets eaters' and non-'sweets eaters'

Inter-centre variability: single-centre study

Conflict of interests: not stated

Note: weight converted from lb to kg for this review

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment	Yes					Block method in groups of 5 cards
Proper sampling				Not reported		
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment				Not reported		
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Reference and design	Intervention	Participants	Outcome measures
Hall *et al.*, 1990[45] Australia ***Study type/design*** 2-centre, RCT ***Duration*** 3 years until closure in 1984	***Treatment arms*** 1. GP (vertical) 2. GG 3. RYGB (control) ***Other interventions used*** Information and counselling about different treatment arms. Iron supplementation and multivitamins for 1 year. Drug therapy for those with co-morbidities (diabetes, hypertension, asthma or arthropathy). Concomitant cholesystectomy (GP 16; GG 21; RYGB 18)	***Number of patients*** 350 patients referred to surgeons; 40 excluded Total: 310 (GP: 106; GG: 105; RYGB: 99) ***Characteristics of target population*** > 18 years, > 160% ideal weight, no prior abdominal surgery for obesity, had undergone vigorous attempts at weight reduction by conservative means, reviewed by physician and psychiatrist to exclude presence of underlying endocrinopathy or psychotic disorder ***Exclusion criteria*** 40 eligible patients excluded due to failure to randomise (16); surgeon's decision due to concern about access (8) and duodenal ulcer (1); physician's decision due to pulmonary disease (3), history of thromboembolism (1) or pregnancy (1); patient refused (7); and non-compliance by surgeon (3) ***Participants*** GP: median age 34 (18–59; IQR 29–39), M/F 8/98, median % ideal weight 198 (164–318; IQR 186–219), socio-economic status (professional 13, clerical 19, skilled labour 17, unskilled 57), psychiatric medication (current 5, previous 25) GG: median age 34 (18–62; IQR 28–40), M/F 9/96, median % ideal weight 194 (162–284; IQR 180–215), socio-economic status (professional 11, clerical 15, skilled labour 24, unskilled 57), psychiatric medication (current 0, previous 17) RYGB: median age 35 (19–57; IQR 29–44), M/F 5/94, median % ideal weight 198 (160–269; IQR 181–224), socio-economic status (professional 10, clerical 14, skilled labour 23, unskilled 50), psychiatric medication (current 2, previous 13)	***Primary outcomes*** Successful loss of excess weight (defined as > 50% loss of excess weight or pregnancy) ***Secondary outcomes*** Median body weight Co-morbidities Complications Length of hospital stay Revisional surgery, reversal surgery Other surgical procedures ***Assessment of outcomes*** Weight at baseline, 10 weeks post-procedure and then annually by research nurses, except when patient moved (then weighed by local doctor). Only 3-year outcomes were reported ***Length of follow-up*** 3 years

Results

Successful loss of excess weight at 3 years (> 50% EWL or pregnant):
GP: 51/106 (48.1%) (> 50% EWL = 47 patients, pregnant = 4 patients)
GG: 18/105 (17.1%) (> 50% EWL = 17 patients, pregnant = 1 patient)
RYGB: 66/99 (66.7%) (> 50% EWL = 65 patient, pregnant = 1 patient)
Successful loss of excess weight varied significantly between GP versus GG versus RYGP ($p < 0.001$)

Median body weight (IQR, range) – (excludes pregnant patients and patients classified as failed):
Baseline: GP (*n* = 106) 112 kg (100–125, 88–157); GG (*n* = 105) 110 kg (100–126, 78–162); RYGB (*n* = 99) 115 kg (104–125, 83–170)
12 months: GP (*n* = 99) 76 kg (65–87, 50–115); GG (*n* = 95) 81 kg (74–95, 56–132); RYGB (*n* = 95) 73 kg (63–84, 53–128)
24 months: GP (*n* = 89) 75 kg (66–89, 49–121); GG (*n* = 80) 86 kg (75–98, 58–132); RYGB (*n* = 92) 71 kg (63–83, 49–140)
36 months: GP (*n* = 80) 79 kg (70–94, 44–125); GG (*n* = 67) 93 kg (79–106, 60–156); RYGB (*n* = 85) 76 kg (65–86, 55–140)

Obesity-related surgical procedures (excluding reversal or revisional operations):
Trimming procedures: GP 19 (18%); GG 14 (13%); RYGB 35 (35%)
Cholesystectomy: GP 4 (4%); GG 7 (7%); RYGB 7 (7%)
Incisional hernia: GP 0 (0%); GG 1 (1%); RYGB 2 (2%)

Additional postoperative surgical procedures performed within 3 years:
Revisional surgery: GP 10 (9%); GG 20 (19%); RYGB 4 (4%)
Reversal surgery: GP 5 (5%); GG 1 (1%); RYGB 2 (2%)

Complications:
Perioperative deaths: GP 0; GG 0; RYGB 0
Postoperative deaths: GP 0; GG 0; RYGB 2 (2%) (1 colon cancer, 1 haemorrhage after subsequent cholesystectomy)

Intraoperative complications:
GP: 1 (1%) nasogastric tube stapled to stomach; 1 (1%) staple-gun malfunction; 1 (1%) incidental splenectomy
GG: 1 (1%) pouch haematoma; 1 (1%) laceration of splenic vein
RYGB: 1 (1%) incidental splenectomy

continued

***Results* contd**

Postoperative complications (GP (*n* = 106) versus GG (*n* = 105) versus RYGB (*n* = 99)):
Wound infection (4% vs 6% vs 4%); atelectasis/pneumonitis (2% vs 5% vs 3%); delayed pouch emptying (1% vs 6% vs 2%); crisis reaction (2% vs 0% vs 0%); subphrenic abscess (1% vs 0% vs 0%); wound dehiscence (1% vs 0% vs 0%); respiratory failure (1% vs 0% vs 0%); haematemesis (0% vs 2% vs 1%); pulmonary embolis (0% vs 0% vs 3%); phlebitis (0% vs 0% vs 3%); small bowel necrosis (0% vs 0% vs 1%); deep vein thrombosis (0% vs 0% vs 1%); urinary tract infection (0% vs 0% vs 1%)

Median postoperative hospital stay, days (IQR, range):
GP 8 (7–9, 5–68); GG 8 (7–10, 5–20); RYGB 8 (7–10, 6–29)

Co-morbidity:
At 3 years: 50 of 84 patients (60%) who initially had a co-morbid condition were free of specific medication
Proportion of patients off medication: diabetes mellitus 6/8 (75%); arthropathy 16/25 (64%); hypertension 22/39 (56%); asthma 6/12 (50%)

Comments

Methodological comments

Allocation to treatment groups: stratified randomisation with a block size of 6, with allocation of operations within each block determined by computer-generated random numbers. 32 strata: sex, 4 age categories, 4 categories of % ideal weight. Baseline adaptive randomisation procedure used to ensure an equitable dispersion of the 3 operations between the participating surgeons

Blinding: no report of patient or outcome assessors blinding

Comparability of treatment groups: reports that dispersion of demographic variables and perceived risk factors is equitable, but no statistical testing reported. Only psychiatric history seen to be greater in GP. Operative procedures were standardised between surgeons. Some of the numbers in the baseline characteristics appear inaccurate

Method of data analysis: ITT analysis reported on selected variables. Non-parametric statistics including median and IQR. Difference between groups assessed using chi-squared test for overall trend using $p = 0.05$ and 2-tailed test. No CIs stated

Sample size/power calculation: 300 patients required to reliably detect or reject a 20% difference in success rates after surgery using a 2-tailed test and assuming a probability of a Type 1 error of 5%, a power of 90%, and a failure rate of 10% after 1 year for the control group (GB)

Attrition/drop-out: compliance with follow-up at 3 years was 91%. Lost to follow-up: GP 7 (6%), GG 16 (15%), RYGB 5 (5%). Prior to randomisation 40 patients were excluded due to poor communication

General comments

Generalisability: predominantly to women aged 18–62 years weighing > 190% ideal weight

Outcome measures: classification of success and failure of treatment may differ from other studies. Paper presents full range of values for % EWL but only analyses 50% or more. Classified pregnant patients as successes although they could not be weighed

Inter-centre variability: stated as standardised from outset and reviewed on a 3-month basis, although not clearly discussed

Conflict of interests: supported by the Royal Australasian College of Surgeons Research Foundation, the Flinders Medical Centre Research Foundation, the Royal Adelaide Hospital Research Foundation, and the National Health and Medical Research Council of Australia

Others: no statistical measure given for any other point in time, although authors point out that the median weight of all the groups was higher at the end of year 3 than year 2

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment	Yes					
Proper sampling	Yes					
Sample size enables precise estimate of significance	Yes					
Criteria for outcomes objective	Yes					
Blind assessment				Not reported		
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Reference and design	Intervention	Participants	Outcome measures
Laws & Piantadosi, 1981[47] USA ***Study type/design*** Single centre, RCT ***Duration*** Not stated	***Treatment arms*** 1. GB with Roux-en-Y gastro-jejunostomy (GB) 2. Pace gastric partitioning (GP) ***Other interventions used*** None	***Number of patients*** Total: 53 (GB: 27; GP: 26) ***Characteristics of target population*** 'Usually' under 50 years. Minimum weight twice ideal weight for height (Metropolitan Life Insurance). Associated disorders encouraged operative intervention. Patients required to agree to follow-up exams and to comprehend implications and after-effects ***Exclusion criteria*** Attempted to exclude if: aortic stenosis, ischaemic heart disease, reflux oesophagitis, unrealistic expectations (number not given) ***Participants*** Mean weight: females 136.62 kg, males 174.54 kg; 34% hypertension; 58% diabetic glucose tolerance tests; 30% hypertriglyceridaemia No other details given	***Primary and secondary outcomes*** Fraction of initial weight (mean weight/ initial weight) In-hospital mortality Early and late complications ***Assessment of outcomes*** Patients followed at clinic at variable lengths of time, which were grouped to the nearest 3 months for analysis. Outcomes presented at 3, 6, 9 and 12 months ***Length of follow-up*** 1 year

Results

Fraction of initial weight (not ITT):

3 months: GB 0.82 (n = 38), GP 0.87 (n = 36), ($p < 0.01$)
6 months: GB 0.77 (n = 17), GP 0.83 (n = 24), ($p < 0.05$)
9 months: GB 0.73 (n = 12), GP 0.79 (n = 11), ($p = 0.05$)
12 months: GB 0.65 (n = 11), GP 0.84 (n = 6), ($p = 0.0001$)

Complications:

Postoperative hospital stay (days): GB 7.7, GP 7.7 (excludes 1 GB with suture line leaks, 58 days)
In-hospital mortality: GB 0, GP 0
Early complications: wound infection – GB 1, GP 0; perforation – GB 1, GP 0; pulmonary embolis – GB 0, GP 1
Late complications: readmit. vomiting – GB 2, GP 3; stoma stenosis – GB 1, GP 1; hypoglycaemia – GB 2, GP 0; wound hernia – GB 1, GP 0; ureteral stone – GB 1, GP 0; stomal ulcer – GB 1, GP 0

Comments

Methodological comments

Allocation to treatment groups: randomised using pre-shuffled cards drawn at time of operation
Blinding: not stated
Comparability of treatment groups: comparable in age, sex distribution, weight, frequency of hypertension, hypertriglyceridaemia and diabetes (data or statistical analysis not provided)
Method of data analysis: ITT for complications but not weight loss. Means compared by t test or chi-squared test. CIs not stated. Significance level stated as $p < 0.05$
Sample size/power calculation: not stated
Attrition/drop-out: not given. Report describes number of patient visits, which decrease from 38 to 10 in GB, and 36 to 6 in GP; no explanation is offered as to what these figures relate to

General comments

Generalisability: morbidly obese adults aged ≤ 50
Outcome measures: final weights not reported. No indication of distribution of weights at start or end. Fraction of mean end weight/initial weight given only
Inter-centre variability: single-centre study
Conflict of interests: no

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment	Yes					
Proper sampling	Yes					
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment				Not reported		
Objective criteria for eligibility (inclusion/exclusion)		Substandard				'Attempted' to exclude
Attrition rates % – losses to follow-up			No			
Comparability of groups demonstrated		Incomplete				Data not presented
Generalisability of results to parent population	Yes					

Reference and design	Intervention	Participants	Outcome measures
Lechner & Callender, 1981[48] USA ***Study type/design*** RCT ***Duration*** Not reported	***Treatment arms*** 1. GP 2. RYGB ***Other interventions used*** Behavioural modifications and dietary instructions (e.g. protein foods, calorie-free liquids, multiple vitamin and mineral tablet, oral zinc supplements)	***Number of patients*** Total: 100 (GP: 50; RYGB: 50) ***Characteristics of target population*** Weight at least 100 lb over Metropolitan Life Insurance desirable weight table; obese for at least 5 years; age 18–65 years; absence of evidence of endocrine cause for obesity; willingness to cooperate in follow-up; inability to achieve and maintain weight loss by other means; informed consent ***Exclusion criteria*** Not stated ***Participants*** GP: mean preoperative weight 120.6 kg (86–228), mean ideal weight 53.4 kg (44.5–72), mean excess weight 148.3% (98–345, mean age 35.7 years (18–48), F/M 45/5 RYGB: mean preoperative weight 120.9 kg (90–194), mean ideal weight 53.1 kg (44.5–77.6), mean excess weight 154.1% (98–321), mean age 35.6 years (18–60), F/M 46/4	***Primary and secondary outcomes*** Mean weight loss % EWL % initial weight lost Early (≤ 30 days) and late postoperative complications Additional operative procedures Laboratory and other preoperative tests ***Method of assessing outcomes*** Follow-up was monthly for first 12 months, then at 15, 18 and 24 months, then annually ***Length of follow-up*** 1 year

Results

Mean weight loss ± SD (SEM):

3 months: RYGB (n = 46) 22.8 kg ± 4.8 (0.7), GP (n = 45) 19.3 kg ± 6.5 (0.9) (MW $p < 0.001$) (ANOVA $p < 0.01$)
6 months: RYGB (n = 34) 34.3 kg ± 7.8 (1.3), GP (n = 33) 25.7 kg ± 11.0 (1.9) (MW $p < 0.001$) (ANOVA $p < 0.01$)
9 months: RYGB (n = 21) 41.3 kg ± 12.1 (2.6), GP (n = 22) 31.6 kg ± 10.0 (2.1) (MW $p < 0.02$) (ANOVA $p < 0.01$)
1 year: RYGB (n = 15) 45.2 kg ± 11.3 (2.9), GP (n = 14) 33.5 kg ± 13.3 (3.6) (MW $p < 0.01$) (ANOVA $p < 0.01$)

% of EWL ± SD (SEM):

3 months: RYGB (n = 46) 33.7% ± 7.7 (1.1), GP (n = 45) 30.2% ± 9.4 (1.4) (MW $p < 0.03$) (ANOVA $p < 0.05$)
6 months: RYGB (n = 34) 49.3% ± 11.4 (2.0), GP (n = 33) 40.0% ± 14.9 (2.6) (MW $p < 0.003$) (ANOVA $p < 0.01$)
9 months: RYGB (n = 21) 57.6% ± 14.6 (3.2), GP (n = 22) 51.8% ± 18.2 (3.9) (MW $p < 0.03$) (ANOVA p = ns)
1 year: RYGB (n = 15) 64.0% ± 13.9 (3.6), GP (n = 14) 54.1% ± 18.6 (5.0) (MW p = ns) (ANOVA p = ns)

% of initial body weight lost ± SD (SEM):

3 months: RYGB (n = 46) 15.9% ± 4.6 (0.7), GP (n = 45) 18.7% ± 3.1 (0.5) (MW $p < 0.001$) (ANOVA $p < 0.01$)
6 months: RYGB (n = 34) 27.9% ± 4.7 (1.3), GP (n = 33) 21.6% ± 7.4 (0.8) (MW $p < 0.001$) (ANOVA $p < 0.01$)
9 months: RYGB (n = 21) 30.0% ± 6.0 (1.9), GP (n = 22) 27.4% ± 8.9 (1.5) (MW $p < 0.03$) (ANOVA $p < 0.05$)
1 year: RYGB (n = 15) 36.6% ± 7.2 (2.7), GP (n = 14) 28.8% ± 10.2 (1.9) (MW $p < 0.01$) (ANOVA $p < 0.05$)

Mean postoperative hospital stay (days):

RYGB 8.9, GP 10.9

Additional procedures:

Total – GP 26 (21 patients), RYGB 46 (27 patients); umbilical herniorrhaphy – GP 9, RYGB 10; hiatus herniorrhaphy – GP 7, RYGB 19; cholecystectomy – GP 4, RYGB 8; tubal ligation – GP 3, RYGB 2

Complications (GP n = 50; RYGB n = 50):

Mortality:
GP: 1 (cerebrovascular accident/anastomosis leak); RYGB 1 (< 30 days pulmonary embolism)
Early complications (≤ 30 days):
Leak – GP 2, RYGB 1; splenectomy – GP 0, RYGB 2; repair spleen – GP 1, RYGB 0; minor dehiscence – GP 0, RYGB 2; minor infection – GP 0, RYGB 2; major infection – GP 1, RYGB 1; pulmonary embolism – GP 1, RYGB 0; pulmonary atelectasis – GP 1, RYGB 3; pulmonary pneumonia – GP 1, RYGB 1; pulmonary effusion – GP 3, RYGB 0
Late complications:
Gastritis – GP 2, RYGB 0; dumping – GP 0, RYGB 4; cholelithiasis – GP 1, RYGB 1; hair thinning – GP 8, RYGB 5; phlebitis – GP 0, RYGB 1; anxiety – GP 5, RYGB 5; staple breakdown – GP 2, RYGB 0; neuralgias (retractor) – GP 2, RYGB 1; incisional hernia – GP 0, RYGB 3; readmission for IVS* – GP 3, RYGB 2; total complications – GP 24, RYGB 22; patients with complications – GP 21, RYGB 16

Re-operation for staple line breakdown or inadequate weight loss:

GP 12%, RYGB 2%

* *Not defined*

continued

Comments

Methodological comments

Allocation to treatment groups: method of randomisation not stated

Blinding: not stated

Comparability of treatment groups: limited information provided, but appear similar

Method of data analysis: not ITT; MW, 1-way ANOVA

Sample size/power calculation: not stated

Attrition/drop-out: not reported. At 1-year follow-up, only 15 patients in RYGB group and 14 in GP group

General comments

Generalisability: predominantly morbidly obese women aged 18–60 years

Inter-centre variability: single-centre study

Conflict of interests: none stated

Note: weight converted from lb to kg for this review

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment				Not reported		
Proper sampling				Not reported		
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment				Not reported		
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up			No			
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Reference and design	Intervention	Participants	Outcome measures
Naslund, 1986[51] (study 1) Naslund *et al.*, 1986[52] (study 2) Naslund, 1987[53] (study 3) Naslund & Beckman, 1987[54] (study 4) Naslund *et al.*, 1988[56] (study 5) Naslund *et al.*, 1988[55] (study 6) Sweden ***Study type/design*** Single RCT ***Duration*** June 1982–September 1983	***Treatment arms*** 1. GB 2. GP ***Other interventions used*** Prophylaxis against thrombosis and antibotics. Analgesics and sedatives were noted. Liquid diet postoperatively for 6 weeks. Iron and multivitamin supplements were given in first 4 months	***Number of patients*** Total: 57 (GB: 29; GP: 28) ***Characteristics of target population*** Patients consecutively accepted for obesity surgery. Criterion for acceptance: Broca's index 1.50 ***Exclusion criteria*** Patients older than 55 or with overt alcoholism or severe psychiatric disorder ***Participants* (Studies 1–4)** **GB:** M/F 3/26; age 36.5 years (SD 7.3); height 166.3 cm (SD 7.3); IBW 57.4 kg (SD 5.8); preoperative weight 117.7 kg (SD 13.9); Broca's index 1.79 (SD 0.26); overweight 60.1 kg (SD 12.6); overweight, % of ideal weight 206% (SD 26.8) **GP:** M/F 3/25; age 35.6 years (SD 8.0); height 166.0 cm (SD 6.8); IBW 57.4 kg (SD 5.4); preoperative weight 117.8 kg (SD 13.6); Broca's index 1.79 (SD 0.22); overweight 60.3 kg (SD 12.3); overweight, % of ideal weight 205% (SD 23.7) **Studies 5 & 6** Only the 51 female patients were analysed – GB *n* = 26, GP *n* = 25	***Primary outcomes*** Stoma size Gastric emptying rates Dietary intake ***Secondary outcomes*** Weight loss (kg) Loss of excess weight Change of preoperative weight (%) Change in Broca's index Fat cell weight and number ***Assessment of outcomes*** Measured fat cell weight and number – pre-operative and post-operative needle biopsies of subcutaneous fat taken from 4 locations: epigastric, hypogastric, femoral and gluteal. During the operation, intra-abdominal fat biposies were obtained from the greater omentum and colonic mesenterium. Assessed at 1, 2, 3, 6, 12, 18, 24 and 36 months depending on the measure ***Length of follow-up***: Up to 36 months

Results

Stoma size (mm):
2 months: GB 11.9 ± 4.1, GP 11.3 ± 4.8
12 months: GB 14.2 ± 4.9, GP 16.1 ± 5.5

Mean weight loss (kg) ± 1 SD:
Baseline: GB 100, GP 100
3 months: GB 21.3 ± 4.7, GP 20.8 ± 4.88; p = ns
6 months: GB 32.7 ± 7.0, GP 27.5 ± 7.3; $p < 0.001$
12 months: GB 42.3 ± 10.9, GP 29.9 ± 10.0; $p < 0.001$
18 months: GB 43.4 ± 12.6, GP 27.9 ± 11.3; $p < 0.001$
24 months GB 42.9 ± 13.6, GP 27.6 ± 10.7; $p < 0.001$
36 months GB 38.4 ± 13.2, GP 24.7 ± 13.1; $p < 0.001$

% of preoperative weight:
Baseline: GB 106 ± 25.6, GP 106 ± 23.7; p = ns
3 months: GB 82 ± 2.7, GP 82 ± 3.5; p = ns
6 months: GB 72 ± 4.3, GP 77 ± 5.8; $p < 0.01$
12 months: GB 64 ± 7.5, GP 75 ± 7.6; $p < 0.001$
18 months: GB 63 ± 8.8, GP 77 ± 9.0; $p < 0.001$
24 months: GB 64 ± 9.1, GP 77 ± 8.8; $p < 0.001$

% > ideal weight:
3 months: GB 69 ± 21.4, GP 70 ± 22.6; p = ns
6 months: GB 48 ± 19.8, GP 56 ± 23.2; $p < 0.05$
12 months: GB 32 ± 19.7, GP 54 ± 21.3; $p < 0.001$
18 months: GB 29 ± 18.5, GP 57 ± 23.3; $p < 0.001$
24 months: GB 32 ± 18.1, GP 57 ± 24.0; $p < 0.001$

continued

***Results* contd**

Broca's index:
Baseline: GB 1.79 ± 0.25, GP 1.79 ± 0.22; p = ns
3 months: GB 1.47 ± 0.22, GP 1.48 ± 0.21; p = ns
6 months: GB 1.29 ± 0.19, GP 1.38 ± 0.21; p = ns
12 months: GB 1.15 ± 0.19, GP 1.34 ± 0.20; $p < 0.001$
18 months: GB 1.13 ± 0.17, GP 1.37 ± 0.21; $p < 0.001$
24 months: GB 1.15 ± 0.17, GP 1.37 ± 0.22; $p < 0.001$
36 months: GB 1.20 ± 0.18, GP 1.42 ± 0.26; $p < 0.001$

Characteristics of failure:
a Broca's index > 1.25: GB 17%, GP 64%; $p < 0.001$
b Broca's index > 1.50: GB 7%, GP 8%; p = ns
c Weight > 75% of preoperative weight: GB 3%, GP 50%; $p < 0.001$
d Overweight, > 20 kg: GB 34%, GP 82%; $p < 0.001$
e Overweight, > 30 kg: GB 14%, GP 46%; $p < 0.01$
f Overweight, > 30% IBW: GB 55%, GP 89%; $p < 0.01$
g Weight, % of IBW > 150: GB 17%, GP 54%; $p < 0.01$
h Weight loss < 25 kg: GB 3%, GP 36%; $p < 0.01$

Combinations of 3 criteria:
a + c + d: GB 35%, GP 89%; $p < 0.001$
a + c + e: GB 35%, GP 82%; $p < 0.001$

Mean subcutaneous fat cell weight (µg):
Preoperatively: GB 0.79 ± 0.12, GP 0.76 ± 0.13; p = ns
12 months: GB 0.42 ± 0.13, GP 0.55 ± 0.16; $p < 0.001$
Postoperative change significant for both groups: $p < 0.001$

Monolocular fat cell number (x 10^{10}):
Preoperatively: GB 7.0 ± 1.3, GP 7.4 ± 1.3; p = ns
12 months: GB 6.1 ± 1.4, GP 6.0 ± 1.0; p = ns
Postoperative change significant for both groups: $p < 0.001$

Body fat (kg):
Preoperatively: GB 54.7 ± 8.3, GP 55.1 ± 9.2; p = ns
12 months: GB 24.9 ± 7.0, GP 33.7 ± 8.4; $p < 0.001$
Difference: GB 29.8 ± 7.8, GP 21.3 ± 7.1; $p < 0.001$
Postoperative change significant for both groups: $p < 0.001$

Operative characteristics:
Average duration of operation: GB 150 minutes (SD 28), GP 118 minutes (SD 28); $p < 0.001$, including c. 25 minutes for intraoperative measurements
Postoperative hospital stay: GB 12.0 days (SD 4.6), GP 9.5 days (SD 2.6); $p < 0.05$
Normal bowel motility: returned later in GB 113 hours (SD 20), GP 104 hours (SD 24); p = ns
Mobilisation (until free walking): GB 49 hours (SD 32), GP 30 hours (SD 15); $p < 0.05$
Postoperative requirement for analgesics: GB 20 doses of ketobemidone chloride (SD 8); GP 14 doses (SD 8); $p < 0.05$

Complications:
Deaths: GB 0, GP 0
Serious complications (GB vs GP): intraoperative splenic injury requiring splenectomy (7% vs 0%); anastomotic leakage requiring surgical intervention (3% vs 0%); iron deficiency anaemia 18 months after surgery (3% vs 0%); cholecystectomy during 1st year (7% vs 14%). Symptoms of gallstones developed postoperatively (3% vs 11%)

Late operations/re-operations due to poor weight loss:
GP 18% (7% during the first 24 months; 11% between 24 and 36 months)
GB 0%

Morbidity:
All patients with preoperative morbidity had improved or were symptom-free 12 months postoperatively, except for one in each group with unchanged hypertension – both patients had unsatisfactory weight reduction

Back pain:
Preoperative: 58% of all patients, but 85% had improved or were pain-free after 12 months. 5 patients (9%) had more pain postoperatively – 1 from each group with satisfactory weight reduction and 3 with relatively poor weight loss after GP.
1 GB patient with great weight loss had no back problems preoperatively but progressive, severe back pain postoperatively

Dumping:
GB 28%, GP 0%; $p < 0.05$

Oesophagitis:
Endoscopic signs of oesophagitis were present only in the GB group (2 months: 3 patients, 6 months: 4 patients, 12 months: 5 patients, 24 months: 3 patients), except for 1 GP patient with mild signs. Mild symptoms of heartburn and regurgitation, requiring medication only during few and short episodes were reported. After 12 months, 17 GB (59%) patients reported heartburn and 11 (38%) regurgitation; 10 (34%) had both symptoms. The corresponding figures for GP were 9 (32%), 5 (18%) and 5 (18%) ($p < 0.05$, ns and ns, respectively)

continued

***Results* contd**

Patients' own evaluation:

All 29 GB (100%) patients and 25 of the 28 GP (89%) patients expressed satisfaction with the operation at the 12-month enquiry. All but 2 of 57 (3.5%) patients stated they did not regret their decision to undergo surgery. All patients with re-operation were more satisfied with GB than GP

Preoperative and postoperative (< 30 days) complications:

Pulmonary embolism: GB 0, GP 0
Thrombosis: GB 0, GP 0
Pleural effusion: GB 2 (7%), GP 1 (3.5%)
Wound dehiscence: GB 1 (3%)*, GP 0
Intra-abdominal abscess: GB 0, GP 0
Wound abscess: GB 3 (10%), GP 2 (7%)
Superficial wound infection: GB 4 (14%), GP 5 (18%)
Splenectomy: GB 2 (7%), GP 0
Anastomotic leakage: GB 1 (3%), GP 0

Second surgical procedures in the first postoperative year:

Repair of anastomotic leakage: GB 1 (3%), GP 0
Endoscopic dilation of stomal stenosis: GB 0, GP 1 (3.5%)
Repair of wound dehisence: GB 1 (3%), GP 0
Lysis of adhesions: GB 0, GP 1 (3.5%)
Cholecystectomy: GB 2 (7%)*, GP 4 (14%)*
Ventral hernia repair: GB 3 (10%), GP 2 (7%)
Abdominal plastic surgery: GB 4 (14%)†, GP 0

* *In 1 case for gallstones discovered at obesity operation*
† *In 3 cases in connection with other procedure*

Comments

Methodological comments

Allocation to treatment groups: sealed envelopes with randomly inserted directions for operation were drawn consecutively. Men and women were randomised separately

Blinding: not reported

Comparability of treatment groups: groups were comparable at baseline with regard to age, sex, height, weight, overweight and morbidity. The distribution of preoperative, complicating disorders was also similar. No statistics presented

Method of data analysis: for statistical analysis of differences between treatment groups, Student's *t* test and chi-squared test were performed. *p* values (2-sided tests) expressed as ns ($p > 0.05$), < 0.05, < 0.01 or < 0.001. Data were reported as ± 1 SD. Regression and significance tests

Sample size/power calculation: not given

Attrition/drop-out: no drop-outs

General comments

Generalisability: excluded patients > 55 years old with overt alcoholism or severe psychiatric disorder. Predominantly women in late 30s with morbid obesity

Inter-centre variability: single-centre study

Conflict of interests: not stated

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment	Yes					
Proper sampling	Yes					Patients selected consecutively
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment				Don't know		
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					No losses to follow-up
Comparability of groups demonstrated	Yes					Groups comparable
Generalisability of results to parent population	Yes					Morbidly obese

Reference and design	Intervention	Participants	Outcome measures
Pories *et al.*, 1982[57] USA ***Study type/design*** Single centre, RCT ***Duration*** February 1979–February 1981	***Treatment arms*** 1. RYGB 2. GP ***Other interventions used*** *Post hoc* addition to protocol that if pulse > 120 or temperature > 102°F, given chloramphenicol for 3 days. Also, if rapid weight loss led to hypesthesia, paresthesia, dizziness or weakness, vitamin supplementation given	***Number of patients*** Total: 87 (RYGB: 42; GP: 45) ***Characteristics of target population*** Morbidly obese adults weighing at least twice their normal weight and appropriately assessed for operative risk ***Exclusion criteria*** Not stated ***Participants*** **RYGB** Mean weight 130.4 kg (range 101.6–196.9), mean age 37 years (20–56), 5 diabetes mellitus, 34 female, 14 gynaecological pathology, 16 hypertension **GP** Mean weight 139.9 kg (range 99.3–222.7), mean age 34 years (22–54), 7 diabetes mellitus, 35 female, 11 gynaecological pathology, 19 hypertension	***Primary outcomes*** Mean weight (lb) % of original weight Failures (failed to lose > 25% of weight) ***Secondary outcomes*** Co-morbidities (hypertension and diabetes) Complications ***Assessment of outcomes*** Assessed at 2 weeks, monthly for 3 months, 3-monthly for 1 year and then at 6-monthly intervals by an assessor blind to type of surgery ***Length of follow-up*** Ranged from 3 months to 18 months

Results

Mean weight (range):

3 months: GP (n = 44) 116.8 kg (84.4–180.1), RYGB (n = 42) 105.2 kg (66.7–150.6); $p < 0.01$
6 months: GP (n = 41) 111.1 kg (82.5–173.3), RYGB (n = 42) 92.4 kg (63.0–135.6); $p < 0.001$
9 months: GP (n = 36) 110.7 kg (76.7–166.5), RYGB (n = 42) 86.5 kg (61.7–123.8); $p < 0.001$
12 months: GP (n = 31) 108.9 kg (70.3–161.9), RYGB (n = 34) 81.2 kg (58.5–122.5); $p < 0.001$
18 months: GP (n = 14) 109.9 kg (80.7–158.3), RYGB (n = 16) 79.1 kg (56.2–113.4); $p < 0.001$

% of original weight (SE):

3 months: GP (n = 44) 83.2% (0.69), RYGB (n = 42) 80.7% (0.61)
6 months: GP (n = 41) 78.4% (0.90), RYGB (n = 42) 70.8% (0.94)
9 months: GP (n = 36) 78.0% (1.11), RYGB (n = 42) 66.2% (0.87)
12 months: GP (n = 31) 76.9% (1.36), RYGB (n = 34) 61.8% (1.04)
18 months: GP (n = 14) 81.0% (2.64), RYGB (n = 16) 60.0% (2.02)

Failures (failed to lose > 25% of their weight):

RYGB 0 (0%), GP 28 (62%) (8 revised, 10 to be revised, 8 lost < 25%, 2 lost to follow-up)

Co-morbidities:

Diabetes

GP and RYGB improved diabetes, 11/12 diabetics reverted to normoglycaemia (the patient who failed to improve was a juvenile onset diabetic)

Hypertension

GP – preoperative 19, postoperative 1; RYGB – preoperative 16, postoperative 2

Adverse effects:

Deaths – GP 0, RYGB 0

12% of all patients had complications, evenly distributed between groups (no statistical analysis given)

GP versus RYGB – wound infection (4 (9%) vs 5 (12%)), wound haematomas (2 (4%) vs 3 (7%)), subphrenic abscess (0 (0%) vs 1 (2%)), stenosis of anastomosis (5 (11%) vs 0 (0%)), depression (3 (6%) vs 4 (10%))

Comments

Methodological comments

Allocation to treatment groups: method of randomisation reported to use Taves minimisation procedure. Stratified for sex, age, hypertension and diabetes

Blinding: patient unaware of procedure, outcome assessors reported to be unaware

Comparability of treatment groups: no statistically significant differences at baseline

Method of data analysis: not ITT. Methods not stated *a priori* but presents mean and standard error and Student's *t* test

Sample size/power calculation: not stated

Attrition/drop-out: 2 GP and 0 RYGB lost to follow-up. Comparison of weight loss included a declining number of patients

continued

***Comments* contd**

General comments

Generalisability: predominantly morbidly obese women aged 20–56 years

Outcome measures: unclear how co-morbidities measured

Inter-centre variability: single-centre study

Conflict of interests: not stated

Other: reported to have broken the randomisation code after 15 months once significant differences established at 3, 6, 9 and 12-month follow-up

Note: weight converted from lb to kg for this review

Quality assessment for clinical trials (Spitzer* et al., *1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment	Yes					Stratified on 5 criteria
Proper sampling				Not reported		
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment	Yes					
Objective criteria for eligibility (inclusion/exclusion)		Incomplete				No details of exclusion
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Appendix 10

Summary of evidence of effectiveness of GB versus JB for morbid obesity

Reference and design	Intervention	Participants	Outcome measures
Buckwalter *et al.*, 1977[40] Buckwalter 1980,[41] 1978[42] USA ***Study type/design*** Single centre, RCT ***Duration*** May 1975–May 1977 Trial stopped due to 'evidence that GB is superior to JB'	***Treatment arms*** 1. JB (end-to-end) 2. GB (Roux-en-Y limb of jejunum in 11 patients, loop of jejunum in 8 patients) ***Other interventions used*** Cholecystectomy in 9 JB and 6 GB patients; incisional and umbilical hernia repairs when necessary, no numbers given. Liver biopsy	***Number of patients*** Total: 38 (JB: 19; GB: 19) ***Eligibility criteria*** At least twice normal body weight for 5 years (1980 paper states at least 45 kg overweight for 5 years); history of unsuccessful weight loss; 'want' the operation after being informed of morbidity, mortality and expected weight loss; historical, physical, operative and laboratory findings consistent with at least an 80% survival rate; agreeable to randomisation ***Participants*** 37 females, 1 male JB: mean age 35.5 years (19–52), mean ideal weight 54.6 kg, mean actual weight 142.7 kg, mean excess weight 88.1 kg, % overweight 161.4% GB: mean age 34.3 years (18–50), mean ideal weight 56.0 kg, mean actual weight 140.9 kg, mean excess weight 84.9 kg, % overweight 151.6%	***Primary and secondary outcomes*** % mean EWL Poor, good and very good EWL based on < 1/3, 1/3–2/3 and > 2/3 weight lost, respectively Degree of fatty metamorphosis of the liver Morbidity and mortality ***Assessment of outcomes*** 1977 paper reports data for weight loss at 3, 6 and 12 months. Liver metamorphosis reported at 12 months 1978 paper reports weight loss at 1 year 1980 paper reports weight loss and liver metamorphosis at 1, 2 and 3 years ***Length of follow-up*** Up to 4 years

Results

% mean EWL (*p* value not stated) (not ITT):
12 months: JB (*n* = 19) 53%, GB (*n* = 19) 44%
24 months: JB (*n* = 19) 66%, GB (*n* = 19) 50%
36 months: JB (*n* = 9) 64%, GB (*n* = 10) 55%

Proportion of patients with categories of excess weight lost (see above for definitions):
24 months (*n*: JB = 19, GB = 19): poor – JB 10%, GB 32%; good – JB 58%, GB 37%; very good – JB 32%, GB 32%
36 months (*n*: JB = 10, GB = 13): poor – JB 20%, GB 23%; good – JB 30%, GB 46%; very good – JB 50%, GB 31%
48 months (*n*: JB = 1, GB = 2): poor – JB 0%, GB 50%; good – JB 100%, GB 50%; very good – JB 0%, GB 0%

Fatty metamorphosis:
Baseline: JB (*n* = 19) 18; GB (*n* = 19) 17
1 year: JB (*n* = 19) 19; GB (*n* = 17) 4
2 years: JB (*n* = 13) 13; GB (*n* = 3) 0
3 years: JB (*n* = 2) 2; GB (*n* = 0)
Progression of fatty metamorphosis after operation: JB 6 (including 1 with initially normal liver); GB 0
Fibrosis persisted in 4 JB patients and appeared at 2 years in 1 JB patient

Fibrosis:
Baseline: JB (*n* = 19) 4; GB (*n* = 19) 3
1 year: JB (*n* = 19) 4; GB (*n* = 17) 0
2 years: JB (*n* = 13) 5; GB (*n* = 3) 0
3 years: JB (*n* = 2) 1; GB (*n* = 0) 0

continued

***Results* contd**

Subsequent operations (JB vs GB):

Wound infection drainage (5% vs 5%); incisional hernia repair (11% vs 21%); panniculectomy (16% vs 26%); haemorrhiodectomy (11% vs 0%); cholecystectomy (0% vs 11%); drainage of subphrenic abscess (0% vs 5%); revisions (0% vs 16%); closure or reversal (32% vs 0%)

JB closed or reversed due to severe diarrhoea with malaise and sickness (2), progressive liver damage (2), recurring enteritis (1) and excessive weight loss (1). Simultaneous GB or GP performed in all 6 patients

Complications:

Hospital deaths:

GB 1 (5%) (day 20, pulmonary embolism); JB 0 (0%)

Postoperatively (JB vs GB):

Wound infection (11% vs 11%); incisional hernia (11% vs 21%); pulmonary embolism (0% vs 5%); enteritis (21% vs 0%); metabolic (16% vs 0%); urinary stones (16% vs 0%); intestinal obstruction (5% vs 0%); anastomotic leak (0% vs 5%); bile reflux (0% vs 5%); cholelithiasis (0% vs 11%). Although diarrhoea, flatulence, nausea and vomiting were not regarded as complications, 16% of JB patients had serious social and vocational disability due to continuing diarrhoea and flatulence

Comments

Methodological comments

Allocation to treatment groups: randomisation by computer, no other details stated

Blinding: not stated

Comparability of treatment groups: baseline weights reported to be comparable, no other demographic data discussed

Method of data analysis: not ITT analysis

Sample size/power calculation: not stated

Attrition/drop-out: all patients followed to 2 years; 9 JB and 11 GB were followed to 3 years; 1 JB and 2 GB were followed to 4 years

General comments

Generalisability: predominantly morbidly obese women up to age 52 years

Outcome measures: ideal weight based on metropolitan life insurance tables

Inter-centre variability: single-centre study

Conflict of interests: funding support by Public Health Research Grant

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment	Yes					
Proper sampling				Not reported		
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment				Not reported		
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up			No			
Comparability of groups demonstrated	Yes					Weight and age only
Generalisability of results to parent population	Yes					

Reference and design	Intervention	Participants	Outcome measures
Griffen *et al.*, 1977[44] USA ***Study type/design*** Single centre, RCT ***Duration*** January 1974	***Treatment arms*** 1. JB (end-to-end) 2. GB ***Other interventions used*** Oral codeine and calcium for diarrhoea. Multivitamin oral supplement	***Number of patients*** Total: 59 (GB: 32; JB: 27) ***Characteristics of target population*** 50 kg over ideal weight, no evidence of other causes of obesity (e.g. endocrine abnormality), concomitant diseases preferred (e.g. hypertension, diabetes, pulmonary insufficiency), psychiatric clearance, willingness to participate in protocol, lost weight in a diet programme, satisfactory operative risk ***Exclusion criteria*** None stated ***Participants*** **GB** Age 32.8 years (19–52), 23 females, preoperative weight 148.2 kg (110–209), height 162.9 cm (150–180). Concomitant conditions in 78%: 28% hypertension; 9% respiratory; 9% cardiac; 28% diabetes; 6% hyperlipidaemia; 34% cholelithiasis **JB** Age 33 years (23–49), 12 females, preoperative weight 157.5 kg (122–238), height 168.4 cm (155–190). Concomitant conditions in 67%: 19% hypertension; 15% respiratory; 7% cardiac; 30% diabetes; 11% hyperlipidaemia; 26% cholelithiasis	***Primary and secondary outcomes*** Postoperative weight loss (kg) Early and late complications Liver biopsies ***Assessment of outcomes*** Patients seen regularly (every month) as outpatients during first 6 months, then usually every 2 or 3 months. At monthly OP visits, blood tests and changes in medications and diet carried out, X-rays performed as dictated by patients' complaints. Patients re-hospitalised for major problems not able to be dealt with in OP. All patients admitted overnight at 12 months for needle biopsy of liver Patients classified as diabetics if showed glycosuria or abnormal glucose tolerance curve in absence of glycosuria. Outcomes presented for 3, 6 and 12 months ***Length of follow-up*** Up to 12 months

Results

Mean postoperative weight loss:

3 months: GB (n = 32) 20.1 kg (10.0–31.9), JB (n = 27) 21.0 kg (10.9–34.1); p = ns
6 months: GB (n = 32) 33.4 kg (13.0–64.1), JB (n = 27) 37.2 kg (16.1–72.1); p = ns
12 months: GB (n = 18) 51.0 kg (13.0–100), JB (n = 22) 57.9 kg (15.2–116.3); p = ns

Complications:

Postoperative deaths
JB: 1 (10 months, refused reanastomosis despite severe liver disease, died in hepatorenal syndrome); GB: 1 (3 months, cause not revealed by autopsy)
Re-hospitalisation
GB: 4 (12.5%) (1 fistula repair for anastomotic leak, 3 incisional hernia repair); JB: 10 (37%) ('mostly' for severe electrolyte imbalance, also 4 cholecystectomy, 1 incisional hernia repair)
Reanastomosis
GB: 1 (3%) (gastrojenunostomy stenotic); JB: 1 (4%) (patient lost 116 kg in 1 year, developed jaundice, ascites, peripheral oedema)
Early surgical complications (GB vs JB)
Wound infection (25% vs 22%); dehiscence (3% vs 4%); other sepsis (6% vs 4%); urinary tract infection (12.5% vs 15%); anastomotic leak (6% vs 0%); 'other' (9% vs 4%); total (62.5% vs 48%); incidental splenectomies (9% vs 0%)
Late complications (GB vs JB)
Nausea and vomiting (34% vs 7%); diarrhoea (6% vs 56%); pulmonary embolus (6% vs 4%); kidney stones (0% vs 15%); re-operations excluding takedowns (9% vs 37%); on medication (antidiarrhoeal, oral potassium supplements) (9% vs 74%); severe liver disease (0% vs 7%)

Liver biopsies at 1 year (GB n = 12, JB n = 15):

GB: 2 (17%) no change, 10 (83%) improvement; JB: 3 (20%) no change, 12 (80%) worsening of liver pattern

continued

Comments

Methodological comments

Allocation to treatment groups: pseudo-randomised using hospital numbers (odd: GB, even JB)

Blinding: not stated

Comparability of treatment groups: comparable in age. There were more females in GB, thought to lead to lower preoperative weight and height in GB (p = ns)

Method of data analysis: significance of weight loss at 12 months tested by Student's t test. No other statistics presented

Sample size/power calculation: not stated

Attrition/drop-out: not reported

General comments

Generalisability: morbidly obese, aged 19–52 years

Inter-centre variability: single-centre study

Conflict of interests: none stated

Quality assessment for clinical trials (Spitzer* et al., *1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment		Substandard				
Proper sampling				Not reported		
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment				Not reported		
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up			No			
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Appendix 11

Summary of evidence of effectiveness of VBG versus horizontal GP for morbid obesity

Reference and design	Intervention	Participants	Outcome measures
Andersen *et al.*, 1987[38] Denmark ***Study type/design*** Single centre, RCT ***Duration*** June 1981–June 1985	***Treatment arms*** 1. VBG 2. GP (horizontal) ***Other interventions used*** All patients were pretreated with VLCD: cycles of 8 weeks VLCD (388 kcals) and 2 weeks pause diet (900 kcals) until at least 40% of initial overweight lost. Median duration of VLCD 26 weeks (range 5–84), median length between success of VLCD and surgery 10 weeks (2–41). While on surgery waiting list, a diet similar to the pause diet but 1000 kcals. Postoperative diet 500 kcals 1 patient had concomitant cholecystectomy due to gall stones. No anorexic agents allowed	***Number of patients*** 165 admitted for morbid obesity, 163 evaluated. Of the 92 eligible, 4 refused VLCD, 14 refused surgical treatment. 74 underwent VLCD (30 of these commenced programme 1 year after others). Of 74 undergoing VLCD, 23 did not meet criteria for surgery during VLCD, 1 was unable to keep excess weight under limit for operation, and 5 refused operation ***Surgery*** Total: 45 randomised after VLCD (VBG: 23; GP: 22) ***Characteristics of target population*** Consecutively admitted for morbid obesity ***Exclusion criteria*** 71 excluded. Age <18 and > 54 years (22), undergoing other treatment (5), pregnant or lactating (1), unwilling to cooperate or occupational or geographical factors impeding participation (43) ***Participants*** *n* = 74, 60 female, mean age 34 years (range 19–54), median body weight 125.1 kg (range 91.4–224.0), median overweight 93% (range 61–222)	***Primary and secondary outcomes*** Weight loss and % overweight following pretreatment with VLCD and post-surgery Relative reduction of overweight Postoperative weight change at 3, 6 and 12 months Complications ***Assessment of outcomes*** For first 3 months met at weekly group patients' education sessions, held by dieticians, then once per month until 1 year and then twice yearly. Outcomes were assessed post-VLCD and at 3, 6 and 12 months post-surgery. Complications were assessed every 10 weeks during first 2 years and 3-monthly thereafter ***Length of follow-up*** Up to 1 year

Results

Outcome of pretreatment with VLCD (range) (*n* = 74):
Median weight 96.8 kg (68–180); median overweight 49% (19–122); median weight loss 25.7 kg (5.8–92.6); relative reduction of overweight 46% (9–83)

Baseline preoperative weight characteristics for GP (*n* = 22) and VBG (*n* = 23):
Median preoperative weight loss (range): GP 30.3 kg (10.3–88.6), VBG 34.0 kg (17.4–75.3)
Median actual body weight (range): GP 90.6 kg (65.0–135.4), VBG 90.1 kg (73.4–125.7)
Actual overweight (range): GP 41% (16–94), VBG 46% (17–73)

Postoperative median weight loss (50% central observations) [range] (data from graph):
1 month: GP 7 kg (5 to 8), VBG 8 kg (5 to 9.5); p = ns
3 months: GP 7 kg (4.5 to 8), VBG 12 kg (9 to 15); $p < 0.001$
6 months: GP 5.5 kg (3 to 7), VBG 13 kg (10 to 17); $p < 0.001$
12 months: GP –1 kg (–5 to 5) [–15.0 to 36.5], VBG 9.7 kg (7 to 15) [–28.2 to 28.7]; $p < 0.001$
At 1 and 3 months there was significant loss of weight from previous assessment for VBG and after 1 month for GP ($p < 0.05$). At 6 and 12 months for GP and 12 months for VBG weight increased significantly ($p < 0.05$). Weight at 12 months was significantly reduced compared with preoperative weight for VBG ($p < 0.01$) but not GP (p = ns)

continued

***Results* contd**

Weight loss after VLCD and gastric surgery (12 months):

Median (range) weight loss: GP 32.6 kg (3.7–125.1), VBG 48.5 kg (6.4–104.0); $p < 0.02$

Reduction of overweight (range): GP 56% (8–92), VBG 80% (10–96); $p < 0.005$

Complications:

GP ($n = 22$) vs VGB ($n = 23$): deaths (0% (95% CI, 0 to 8) vs 0%); splenectomy required (5% vs 0%); wound infection (9% vs 4%); ventral hernia (5% vs 4%); postanaesthetic jaundice (0% vs 4%); outlet obstruction (14% (95% CI, 3 to 35) vs 0%); haemorrhagic gastritis (9% vs 0%); pronounced dyspepsia (9% vs 9%); occasional vomiting (18% (95% CI, 5 to 40) vs 57% (95% CI, 34 to 77); $p < 0.02$); heartburn (9% vs 0%); obstipation (0% vs 4%); transient loss of hair (0% vs 4%); orostatic hypotension (0% vs 4%)

Comments

Methodological comments

Allocation to treatment groups: block randomisation procedure following VLCD

Blinding: patients and dietitians blinded to randomisation code; not clear if dietitians conducted all outcome assessments. All operations performed by 1 surgeon

Comparability of treatment groups: GP and VBG not significantly different in terms of preoperative weight loss, actual body weight and actual overweight, but no other baseline characteristics described

Method of data analysis: not ITT; key data presented in graph. 2-tailed MW rank sum test for unpaired data, 2-way ANOVA using Friedman's test, Pratt's test (2-tailed) for testing single data pairs, chi-squared test for prevalence of side-effects; p values < 0.05 were considered significant

Sample size/power calculation: not stated

Attrition/drop-out: numbers and explanation not given, evident from results that 2 lost from each group or follow-up not yet reached 12 months

General comments

Generalisability: predominantly women aged 19–54 years who are 93% overweight

Outcome measures: relative reduction of overweight was calculated as difference in initial and actual weight divided by initial overweight

Inter-centre variability: single-centre study

Conflict of interests: funded by The Foundation of 1870, The Foundation of P. Carl Petersen, The Ib Berg Foundation, The Danish Hospital Foundation for Medical Research of Cophenhagen, The Faroe Islands and Greenland

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment	Yes					
Proper sampling	Yes					
Sample size enables precise estimate of significance				Not reported		
Criteria for outcomes objective	Yes					
Blind assessment				Don't know		
Objective criteria for eligibility (inclusion/exclusion)		Incomplete				No details of inclusion
Attrition rates % – losses to follow-up			No			
Comparability of groups demonstrated		Incomplete				Weight only
Generalisability of results to parent population		Uncertain				Only VLCD successes

Appendix 12

Summary of evidence of effectiveness of VBG versus AGB for morbid obesity

Reference and design	Intervention	Participants	Outcome measures
Nilsell *et al.*, 2001[35] Sweden ***Study type/design*** Single centre, RCT	***Treatment arms*** 1. AGB 2. VBG ***Other interventions used*** Detailed written and oral information were given pre-operatively by a surgeon and dietician	***Number of patients*** Total: 59 (AGB 29; VBG 30) ***Characteristics of target population*** People with BMI > 40 kg/m^2 or BMI > 37 kg/m^2 with obesity-associated co-morbidity ***Exclusion criteria*** Age > 60 years, severe psychiatric disorders or alcoholism ***Participants*** **VBG** 80% female; mean age 39 years (range 19–59); mean height 168 cm (SD 9.3); mean preoperative weight 123 kg (SD 11.4); mean BMI 43.9 kg/m^2 (SD 3.8); hypertension 13%; diabetes mellitus 7%; asthma 13%; joint pain 33% **AGB** 72% female; mean age 38 years (range 20–58); mean height 170 cm (SD 10.8); mean preoperative weight 124 kg (SD 24.0); mean BMI 42.8 kg/m^2 (SD 5.4); hypertension 7%; diabetes mellitus 7%; asthma 3%; joint pain 31%	***Primary and secondary outcomes*** Complications Late re-operations Weight change Patient satisfaction Reflux symptoms ***Assessment of outcomes*** 1, 3, 6 and 12 months and then yearly thereafter to 4 or 5 years. In years 4 and 5 there were 64 observations on 52 patients ***Length of follow-up*** 4–5 years

Results

Surgical outcomes:

Late re-operations

3 AGB re-operated: 2 due to dilation of gastric pouch causing functional outlet stenosis (band replaced) and 1 had functioning AGB removed at patient's request

10 VBG re-operated due to strictures of stoma with vomiting or intolerance of solid food or due to staple line disruption leading to regain of weight. Types of operation: removal of band (4), GG (3), longer band (1), GBan (2)

3 VBG with staple line disruption were not re-operated. Total incidence of staple line disruption 18.5% (5/27)

Complications:

Deaths: 1 patient per arm died due to causes unrelated to surgery. No postoperative deaths

Gastro-oesophageal reflux disease: AGB 3/26 (11.5%), VBG 4/27 (14.8%)

Anastomotic leak: AGB 0, VBG 1

Mean weight (SEM) (figures for 1–4 years follow-up are estimated from graph and may be imprecise. Data of complete series not limited to those with original operation intact):

Baseline: AGB 124 kg (29); VBG 123 kg (30)
1 year: AGB 98 kg (28); VBG 82 kg (25)
2 years: AGB 88 kg (23); VBG 85 kg (29)
3 years: AGB 85 kg (13); VBG 90 kg (15)
4 years: AGB 86 kg (17); VBG 95 kg (15)
5 years: AGB 81 kg (16); VBG 88 kg (16)

Patient satisfaction:

AGB 21/26 (81%); VBG 15/27 (56%)

Comments

Methodological comments

Allocation to treatment groups: randomised using sealed envelopes the day before surgery

Blinding: staff and patients were not blinded to treatment

Comparability of treatment groups: groups similar in age, height, weight, diabetes, asthma, joint pain, hypertension

Method of data analysis: mean (SEM) with Fisher's exact test at $p = 0.05$ level

Sample size/power calculation: none stated

Attrition/drop-out: 2 died from causes unrelated to bariatric operation; 3 AGB and 2 VBG were lost to follow-up

continued

***Comments* contd**
General comments
Generalisability: predominantly limited to females, aged mid to late 30s, who are morbidly obese

Inter-centre variability: single-centre study

Conflict of interests: none stated

Quality assessment for clinical trials (Spitzer* et al., *1990[30])

	Yes	**Uncertain/ incomplete/ substandard**	**No**	**Don't know/ not reported**	**NA**	**Comments**
Proper random assignment	Yes					
Proper sampling				Don't know/ not reported		
Sample size enables precise estimate of significance				Don't know/ not reported		
Criteria for outcomes objective	Yes					
Blind assessment			No			
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Appendix 13

Summary of evidence of effectiveness of open versus laparoscopic GB

Reference and design	Intervention	Participants	Outcome measures
Nguyen *et al.*, 2001[37] USA ***Study type/design*** Single centre, RCT	***Treatment arms*** 1. Laparoscopic GB 2. Open GB Roux limb was 75 cm for those with BMI of 40–49 kg/m^2 and 150 cm for BMI of 50–60 kg/m^2 ***Other interventions used*** Preoperative and postoperative antibiotics, antiembolic stockings and sequential pneumatic compression devices. Postoperative pulmonary care incentive spirometry and deep-breathing exercises. Patient controlled analgesia using intravenous morphine	***Number of patients*** Total: 155 randomised (laparoscopic GB 79; open GB 76) ***Characteristics of target population*** All patients evaluated for surgical treatment of morbid obesity with BMI 40–60 kg/m^2, aged 21–60 years, failed previous non-surgical treatment ***Exclusion criteria*** Previous obesity surgery; previous gastric surgery; large abdominal ventral hernia; history of venous thrombosis/pulmonary embolism; severe cardiovascular, respiratory, hepatic or renal disease ***Participants*** **Laparoscopic** 91% female; aged 40 years (± 8); preoperative weight 289 lb (± 38); BMI 47.6 (± 4.7); hypertension 33%; sleep apnoea 26%; diabetes mellitus 10%; osteoarthritis 48%; depression 42%; dyslipidaemia 16% **Open** 88% female; aged 42 years (± 9); preoperative weight 296 lb (± 44); BMI 48.4 (± 5.4); hypertension 41%; sleep apnoea 30%; diabetes mellitus 18%; osteoarthritis 42%; depression 43%; dyslipidaemia 18%	***Primary outcomes*** Length of time for return to activities of daily living ***Secondary outcomes*** Operative time, length of skin incision, estimated blood loss, number of patients requiring intensive care unit stay, length of hospital stay, early and late (> 30 days) complications, early re-operation (< 30 days), weight loss (mean % of excess body weight loss), time to return to work, QoL (SF-36 and BAROS) and costs ***Assessment of outcomes*** Patient assessed in outpatient clinic post-operatively at 7 days and at 1, 3, 6 and 12 months post-surgery and yearly thereafter. Postoperative weight and outpatient complications were recorded at each visit. Weight measured on same scales. QoL using SF-36 was administered to all patients pre-operatively at 1, 3 and 6 months after surgery ***Length of follow-up*** Up to 1 year

BAROS, bariatric analysis and reporting outcome system

Results

Operative outcomes:

Operative time (minutes): laparoscopic 225 (± 40), open 195 (± 41); $p < 0.001$
Estimated blood loss (ml): laparoscopic 137 (± 79), open 395 (± 284); $p < 0.001$
Proportion requiring intensive care unit stay: laparoscopic 7.6%, open 21.1%; $p = 0.03$
Median length of hospital stay (days): laparoscopic 3 (IQR 1), open 4 (IQR 2); $p < 0.001$
Proportion requiring re-operation: laparoscopic 7.6%, open 6.6%; p = ns
Return to activities of daily living (days): laparoscopic 8.4 (± 8.6), open 17.7 (± 19.1); $p < 0.001$
Return to work (days): laparoscopic 32.2 (± 19.8), open 46.1 (± 20.6); $p = 0.02$
Intraoperative transfusion: laparoscopic 0, open 3.9%
Conversion from laparoscopic to open: 2 (2.5%) due to failure of circular stapler; inability to insufflate abdomen safely

continued

***Results* contd**

Complications:

Major complications

Total – laparoscopic 6 (7.6%), open 7 (9.2%) (p = 0.78); anastomotic leak – laparoscopic 1, open 1; gastric pouch outlet obstruction – laparoscopic 0, open 1; hypopharyngeal perforation – laparoscopic 1, open 0; jejunojejunostomy obstruction – laparoscopic 3, open 0; pulmonary embolism – laparoscopic 0, open 1; respiratory failure – laparoscopic 0, open 1; gastrointestinal bleeding – laparoscopic 1, open 0; wound infection – laparoscopic 0, open 2; retained laparotomy sponge – laparoscopic 0, open 1

Minor complications

Total – laparoscopic 6 (7.6%), open 9 (11.8%) (p = 0.42); gastrointestinal ileus – laparoscopic 1, open 0; C difficile colitis – laparoscopic 1, open 0; gastrogastric fistula – laparoscopic 0, open 1; asymptomatic leak – laparoscopic 0, open 1; gastrointestinal bleeding – laparoscopic 2, open 0; wound infection – laparoscopic 1, open 6; deep venous thrombosis – laparoscopic 1, open 1

Late complications

Total – laparoscopic 15 (18.9%), open 12 (15.8%) (p = 0.52); anastomotic stricture – laparoscopic 9, open 2; prolonged nausea/vomiting – laparoscopic 1, open 2; small bowel obstruction – laparoscopic 1, open 0; cholelithiasis – laparoscopic 3, open 0; ventral hernia – laparoscopic 0, open 6 (p = 0.01); anaemia – laparoscopic 0, open 2; protein-calorie malnutrition – laparoscopic 1, open 0

Weight loss:

% excess body weight loss (not ITT)

3 months: laparoscopic GB (n = 60) 37% (± 10); open GB (n = 56) 32% (± 10) (p = 0.01)
6 months: laparoscopic GB (n = 45) 54% (± 14); open GB (n = 44) 45% (± 12) (p = 0.01)
12 months: laparoscopic GB (n = 29) 68% (± 15); open GB (n = 25) 62% (± 14) (p = 0.07)

QoL (not ITT):

Mean SF-36 scores (± SD) – preoperative: laparoscopic n = 70, open n = 73; 3 months: laparoscopic n = 54, open n = 42

Physical functioning

Preoperative: laparoscopic 46.5 (21.3), open 40.0 (24.4), p = ns; 1 month: laparoscopic 60.9 (24.7), open 46.3 (24.7), $p < 0.05$; 3 months: laparoscopic 80.2 (19.1), open 67.8 (26.6), p = ns; US norms 84.2 (23.3)

Role – physical

Preoperative: laparoscopic 47.2 (40.2), open 37.5 (37.9), p = ns; 1 month: laparoscopic 29.7 (39.2), open 18.5 (32.3), p = ns; 3 months: laparoscopic 80.7 (32.5), open 76.8 (33.3), p = ns; US norms 81.0 (34.0)

Bodily pain

Preoperative: laparoscopic 51.0 (22.7), open 48.7 (24.1), p = ns; 1 month: laparoscopic 59.2 (21.5), open 45.1 (24.4), $p < 0.05$; 3 months: laparoscopic 75.1 (24.7), open 68.1 (25.6), p = ns; US norms 75.2 (23.7)

General health

Preoperative: laparoscopic 54.5 (21.6), open 52.9 (22.3), p = ns; 1 month: laparoscopic 71.3 (18.0), open 64.0 (18.1), $p < 0.05$; 3 months: laparoscopic 77.2 (15.7), open 72.4 (16.5), p = ns; US norms 72.0 (20.3)

Vitality

Preoperative: laparoscopic 38.5 (20.0), open 36.6 (19.9), p = ns; 1 month: laparoscopic 45.4 (20.5), open 39.1 (18.9), p = ns; 3 months: laparoscopic 65.8 (17.7), open 73.1 (95.2), p = ns; US norms 60.9 (21.0)

Social functioning

Preoperative: laparoscopic 64.4 (26.3), open 61.6 (29.5), p = ns; 1 month: laparoscopic 67.6 (24.5), open 51.9 (29.1), $p < 0.05$; 3 months: laparoscopic 87.3 (17.9), open 74.1 (30.0), p = ns; US norms 83.3 (22.7)

Role – emotional

Preoperative: laparoscopic 49.1 (24.4), open 45.5 (27.2), p = ns; 1 month: laparoscopic 78.5 (28.2), open 69.5 (33.5), p = ns; 3 months: laparoscopic 83.0 (29.6), open 74.6 (40.7), p = ns; US norms 81.3 (33.0)

Mental health

Preoperative: laparoscopic 73.0 (15.1), open 71.9 (17.3), p = ns; 1 month: laparoscopic 76.8 (17.4), open 70.8 (19.4), p = ns; 3 months: laparoscopic 82.9 (14.2), open 75.0 (19.2), p = ns; US norms 74.7 (18.1)

Moorehead–Ardelt QoL scores:

Score of 0 = same as before; + score = positive changes; – score = negative change
(3 months: laparoscopic n = 47, open n = 36; 6 months: laparoscopic n = 34, open n = 28)

Self-esteem (score range –1 to +1)

3 months (mean (SD)): laparoscopic 0.81 (0.3), open 0.73 (0.32), p = ns; 6 months: laparoscopic 0.84 (0.27), open 0.80 (0.28), p = ns

Physical (score range –0.5 to +0.5)

3 months (mean (SD)): laparoscopic 0.48 (0.40), open 0.46 (0.44), p = ns; 6 months: laparoscopic 0.37 (0.17), open 0.34 (0.18), p = ns

Social (score range –0.5 to +0.5)

3 months (mean (SD)): laparoscopic 0.31 (0.19), open 0.24 (0.21), p = ns; 6 months: laparoscopic 0.33 (0.19), open 0.29 (0.21), p = ns

Labour (score range –0.5 to +0.5)

3 months (mean (SD)): laparoscopic 0.24 (0.19), open 0.13 (0.29), $p < 0.05$; 6 months: laparoscopic 0.28 (0.21), open 0.21 (0.27), p = ns

Sexual (score range –0.5 to +0.5)

3 months (mean (SD)): laparoscopic 0.20 (0.21), open 0.09 (0.24), $p < 0.05$; 6 months: laparoscopic 0.26 (0.20), open 0.19 (0.26), p = ns

continued

***Results* contd**

Costs (mean US$ ± SD):

Direct costs: laparoscopic 7478 (2802), open 7440 (4661); p = ns
Operative costs: laparoscopic 4922 (1927), open 3591 (1000); $p < 0.01$
Operative time and supplies: laparoscopic 4098 (1538), open 2788 (674); $p < 0.01$
Post-anaesthesia: laparoscopic 504 (487), open 525 (382); p = ns
Hospital service costs: laparoscopic 2519 (1712), open 3742 (3978); $p = 0.02$
Diagnostic: laparoscopic 467 (170), open 609 (402); $p < 0.01$
Nursing: laparoscopic 1201 (821), open 1975 (2773); $p = 0.03$
Pharmaceutical: laparoscopic 418 (232), open 579 (413); $p < 0.01$
Therapeutic: laparoscopic 97 (249); open 146 (430); p = ns
Other: laparoscopic 268 (213), open 423 (443); $p < 0.01$
Indirect costs: laparoscopic 6645 (2437), open 6765 (4077); p = ns
Total costs: laparoscopic 14,087 (5237); open 14,098 (8527); p = ns

Comments

Methodological comments

Allocation to treatment groups: randomisation using sealed envelopes, stratified according to BMI of 40–49 kg/m^2 or 50–60 kg/m^2

Blinding: patients were informed of their treatment during preoperative clinic visit

Comparability of treatment groups: 2 groups were similar in age, sex, mean BMI and preoperative morbidity

Method of data analysis: ITT analysis – laparoscopic GB converted to open GB were analysed as laparoscopic, patients who withdrew consent or did not undergo GB were excluded from the analysis. Differences between groups were assessed using 2-sample *t* tests or Fisher's exact tests. MW test was used for non-parametric data. Repeated measures of variance and unpaired *t* test were used. $p < 0.05$ was considered significant

Sample size/power calculation: mean time to return to activities of daily living was 20 ± 17 days in open GB – with difference of 7 days between procedures clinically significant; 73 patients per group necessary to detect difference using 2-tailed test type 1 error of 0.05 and type 2 error 0.2

Attrition/drop-out: patients who withdrew consent or did not undergo GB were excluded from the analysis. 19 eligible patients did not undergo randomisation; 13 requested laparoscopic GB and 6 requested open GB; 2 randomised to GB were excluded after randomisation (1 withdrew consent, 1 needed splenectomy)

General comments

Generalisability: predominantly women aged 30–50 years who were morbidly obese

Inter-centre variability: single-centre study only

Conflict of interests: none stated

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment	Yes					
Proper sampling	Yes					
Sample size enables precise estimate of significance	Yes					
Criteria for outcomes objective	Yes					
Blind assessment			No			
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Reference and design	Intervention	Participants	Outcome measures
Westling & Gustavsson, 2001[36] Sweden ***Study type/design*** Single centre, RCT	***Treatment arms*** 1. Laparoscopic RYGB 2. Open RYGB ***Other interventions used*** Antibiotic prophylaxis with intravenous cefuroxime and metronidazole, thrombo-prophylaxis with enoxaparine or preoperative dextron. Advice from specially trained nurse for advice and regular checks from dieticians and internists	***Number of patients*** Total: 51 (laparoscopic RYGB 30; open RYGB 21) ***Characteristics of target population*** People with BMI > 40 kg/m^2 or BMI > 35 kg/m^2 with significant co-morbidity; failed in various supervised non-surgical long-term weight loss programmes within hospital; fully informed of operation and consequences ***Exclusion criteria*** 70 patients were excluded prior to randomisation as they were unsuitable for laparoscopy (n = 21), had gallstones (n = 7), or were scheduled for RYGB as a revisional procedure (n = 42) ***Participants*** 94% female; age 36 years (± 9); BMI 42 kg/m^2 (± 4) (laparoscopic 41 kg/m^2 (± 4), open 44 kg/m^2 (± 4), $p < 0.05$) Concomitant medical conditions: previous cholecystectomy – laparoscopic 10%, open 29%; joint and back pain – laparoscopic 33%, open 38%; hypertension – laparoscopic 23%, open 0%; asthma – laparoscopic 17%, open 24%; rheumatoid arthritis – laparoscopic 0%, open 5%; diabetes mellitus – laparoscopic 0%, open 5%	***Primary and secondary outcomes*** Complications from standard questionnaire on stomach pain, vomiting, dysphagia, nausea, diarrhoea, excessive dumping, general well-being, need for sick leave Body weight Incisional hernias ***Assessment of outcomes*** 4–6 weeks and 1 year following surgery ***Length of follow-up*** 1 year

Results

Surgical outcomes:

Conversions: 7 (23%) laparoscopic patients were converted to open RYGP due to either bleeding (n = 4) or other operative concerns (n = 3)

Duration (median minutes (range)): laparoscopy (n = 30) 245 (135–390); open (n = 21) 100 (70–150)

Preoperative bleeding (median ml (range)): laparoscopy (n = 30) 250 (50–1500); open (n = 21) 300 (200–500)

Early postoperative outcomes:

Pain (morphine dose in mean mg)

Laparoscopy (n = 29[*]) 98 (± 71.5 SD) (p = ns); laparoscopy: conversions excluded (n = 22) 69 (± 46.4 SD) ($p < 0.005$); open (n = 21) 140 (± 90 SD)

Hospital stay (mean days)

Laparoscopy (n = 29[*]) 4.5 (± 1.2 SD) (p = ns); laparoscopy: conversions excluded (n = 22) 4 (± 0.8 SD) (p = 0.025); open (n = 21) 6 (± 3.8 SD)

Sick leave (mean weeks)

Laparoscopy (n = 24[*†]) 3.9 (± 2.1 SD) (p = ns); laparoscopy: conversions excluded (n = 18[†]) 2.8 (± 1.8 SD) (p = 0.025); open (n = 14[†]) 5 (± 3.3 SD)

No correlation between preoperative BMI and amount of morphine used postoperatively, length of stay or sick leave (no data reported)

Complications:

Deaths: 1 laparoscopy patient from malignant hyperthermia (family history)

Gastrointestinal symptoms (dumping/vomiting/diarrhoea): 5% of all patients

Incisional hernia: 1 laparoscopy patient

6 (20%) laparoscopy patients without conversion re-operated: returned to hospital emergency department a median of 4 weeks (1–5 weeks) postoperation due to colicky pain and vomiting due to narrow stricture of tunnel through mesocolon (n = 5), and to herniated Roux limb (n = 1). Restriction was removed (n = 5) or Roux limb closely adherent to pancreas and excluded stomach (n = 1)

1 open RYGP patient suffered leakage due to failure of hand-sewn part

1 laparoscopy patient had a small embolus

Jejunal ulcers: 3 laparoscopy, 2 open RYGB (p = ns)

Stricture in gastrojejunostomy: 1 laparoscopy patient treated by endoscopic dilation

Superficial wound infection: 3 open RYGB

Readmission for unexplained fever (1), pneumonia (1), epigastric pain and/or vomiting with normal gastroscopy (2)

Weight loss:

Mean BMI (1 year): laparoscopy 27 kg/m^2 (± 4); open 30.6 kg/m^2 (± 4)

Mean change in BMI (1 year): laparoscopy 14 kg/m^2 (± 3); open 13 kg/m^2 (± 3) (p = ns)

Patient satisfaction (1 year):

All patients – 92% very satisfied, 8% satisfied. No difference between groups (no data reported)

[*] *Patient with malignant hyperthermia excluded;* [†] *excludes people receiving pensions or who are unemployed*

continued

Comments

Methodological comments

Allocation to treatment groups: blocked randomisation – 60% laparoscopy patients and 40% open RYGB patients due to presupposed need for conversion. Stratified for gender, not BMI. Used sealed envelopes in theatre

Blinding: patients and ward staff were blinded to procedure with the use of sham bandages. Patients were informed on discharge

Comparability of treatment groups: mean preoperative BMI was lower in the laparoscopy group. Well balanced for concomitant medications. No other comparative information provided

Method of data analysis: mean and SD, median and range, Student's *t* test, chi-squared test, rank sum test and linear regression. Significance at $p < 0.05$

Sample size/power calculation: none stated

Attrition/drop-out: no patients were lost to follow-up

General comments

Generalisability: predominantly limited to females, aged in mid to late 30s who are morbidly obese

Inter-centre variability: single-centre study

Conflict of interests: none stated

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment	Yes					
Proper sampling		Substandard				
Sample size enables precise estimate of significance				Don't know/ not reported		
Criteria for outcomes objective	Yes					
Blind assessment		Uncertain/ incomplete/ substandard				
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated			No			
Generalisability of results to parent population	Yes					

Appendix 14

Summary of evidence of effectiveness of open versus laparoscopic ASGB for morbid obesity

Reference and design	Intervention	Participants	Outcome measures
De Wit *et al.*, 1999[43] The Netherlands ***Study type/design*** Single centre, RCT ***Duration*** November 1995–February 1997 (recruitment)	***Treatment arms*** 1. Laparoscopic ASGB (Lap) 2. Open ASGB (Open) ***Other interventions used*** None	***Number of patients*** Total: 50 (Lap: 25; Open: 25) ***Characteristics of target population*** History of obesity > 5 years, BMI > 40, documented attempts at weight loss in past, good motivation for surgery, aged 18–55 years ***Exclusion criteria*** Previous gastric surgery, large hiatal hernias, alcohol abuse, pregnancy, psychiatric disease or treatment, and hormonal or genetic obesity-related diseases excluded Considered eligible by gastroenterologist after evaluation of haematology, blood chemistry, hormonal status, ECG, gastroscopy, barium meal and gallbladder ultrasound. Anaesthesiologist could exclude if high risk for anaesthesia. Surgeon agreement that patient suitable for both procedures ***Participants*** Lap: 8 male, 17 female; mean weight 152.2 kg (SD 31.4); BMI 51.3 (SD 10.4); hypertension 16%; diabetes mellitus 12%; gastro-oesophageal reflux 4% Open: 8 male, 17 female; mean weight 146.4 kg (SD 19.9); BMI 49.7 (SD 5.6); hypertension 8%; diabetes mellitus 0%; gastro-oesophageal reflux 8%	***Primary outcomes*** Surgical complications Length of hospital stay ***Secondary outcomes*** Difficulty of procedure Surgical time In-hospital deaths Long-term complications Additional procedures Readmissions Mean weight loss Reduction of BMI ***Assessment of outcomes*** Numbers and types of surgical complications and difficulty of procedure measured by surgeon. Long-term complications, additional procedures, readmissions, weight loss and reduction of BMI recorded by gastro-enterologist at follow-up Follow-up at 1, 4, 8, 11, 16, 20, 24, 36 and 52 weeks. Only outcomes at 52 weeks reported ***Length of follow-up*** 1 year

Results

Mean weight loss (12 months):
Lap 35 kg, Open 34.4 kg (change from baseline for Lap and Open, $p < 0.05$; difference Lap and Open p = ns)

BMI reduction (12 months):
Lap 11.6, Open 10.6 (change from baseline for Lap and Open, $p < 0.05$; difference Lap and Open p = ns)

Surgical time:
Lap 150 minutes (SD 48), Open 76 minutes (SD 20), $p < 0.05$

Mean difficulty of procedure (1–10 scale):
Lap 4.7 (SD 2.1, range 3–10), Open 3.8 (SD 1.1, range 3–7), $p < 0.05$

Means days in hospital:
Lap 5.9 (range 4–10), Open 7.2 (range 5–13), $p < 0.05$

Conversions:
Lap to Open procedure: 8% (inability to obtain pneumoperitoneum)

Early postoperative complications (Lap (n = 25) versus Open (n = 25)):
Cholecystectomy (8% vs 20%); adhesiolysios (4% vs 0%); gallbladder puncture (to obtain samples for study purposes): (0% vs 28%); pulmonary complications (8% vs 8%); urinary infection (8% vs 0%); rhabdomyolysis (4% vs 0%); neurologic complication (neuropraxi) (4% vs 4%); perforation pouch (0% vs 4%); wound abscess (0% vs 4%); fever (0% vs 8%); gout (0% vs 4%)

continued

***Results* contd**

First year surgical complications (Lap vs Open):
Incisional hernia (0% vs 28% (12% patients) p = ns); migration band (0% vs 4%, p = ns); umbilical hernia (4% vs 0%, p = ns)

First year access port complications (Lap vs Open):
Total 28% (20% patients) vs 24% (20% patients), p = ns
Dislocation (8% vs 4%, p = ns); dislodgement (20% vs 16%, p = ns); infection (0% vs 4%, p = ns); replacement (20% vs 16%, p = ns)

Hospital stay (Lap vs Open):
Patients readmitted: 20% vs 28%, p = ns; total readmissions: 24% vs 60%, $p < 0.05$; mean overall length of hospital stay: 7.8 days (SD 6) vs 11.8 days (SD10.5), $p < 0.05$

Comments

Methodological comments

Allocation to treatment groups: randomised after stratification into gender and BMI 40–45, 45–50 and > 50, by computer-generated randomisation by separate group

Blinding: outcome assessments not stated

Comparability of treatment groups: 2 groups were comparable in sex, age, mean weight, BMI and laboratory test results. No significant differences between groups

Method of data analysis: although results appeared to be ITT, 2 laparoscopic patients were converted to open. MW test used to compare data. Means, SD and p values

Sample size/power calculation: for weight loss assumed that no differences in weight loss will be found between groups, considered 10% difference of weight acceptable and clinically unimportant (significance 95%, power 80%). For hospital stay assumed a reduction in hospital stay could be expected from 8 days after open ASGB to 4 days after laparoscopic ASGB (significance 95%, power 90%)

Attrition/drop-out: 1 patient in group 2 lost to follow-up after 1 year

General comments

Generalisability: morbidly obese aged 18–55 years

Outcome measures: outcomes limited to effectiveness of open versus laparoscopic ASGB, assumed that effect on weight will not differ. Difficulty of procedure assessed by surgeon on VAS 1–10 (1 = easy procedure; 10 = procedure could not be performed or had to be converted)

Inter-centre variability: 1 surgeon operated and 2 anaesthetists provided postoperative care

Conflict of interests: not stated

Quality assessment for clinical trials (Spitzer* et al.*, 1990[30])

	Yes	Uncertain/ incomplete/ substandard	No	Don't know/ not reported	NA	Comments
Proper random assignment	Yes					Following stratification
Proper sampling				Not reported		
Sample size enables precise estimate of significance	Yes					
Criteria for outcomes objective	Yes					
Blind assessment				Not reported		
Objective criteria for eligibility (inclusion/exclusion)	Yes					
Attrition rates % – losses to follow-up	Yes					
Comparability of groups demonstrated	Yes					
Generalisability of results to parent population	Yes					

Appendix 15

Summary of evidence from systematic review

Reference	Research question and search strategy	Inclusion and quality criteria
NHS CRD, 1997[32] Glenny *et al.*, 1997[33] Extraction based on full report at http://www.york.ac.uk/inst/crd/obesity.htm ***Country*** UK ***Study topic*** Interventions to prevent and treat obesity NHS CRD quality score 4/5	***Aim*** To determine the effectiveness of interventions designed to prevent and treat obesity, and maintain weight loss ***Search strategy*** Databases searched: • AMED (Allied and Alternative Medicine) • ASSIA (abstracts and indexes) • CAB (Commonwealth Agricultural Board) • Conference Proceedings Index • Current Research in UK • DARE (CRD – database of systematic reviews) • DHSS Data • Directory of Published Proceedings (Interdok) • Dissertation Abstracts • DRUG Database • DrugINFO • EMBASE • Health Promotion Database • HPA • MEDLINE • NEED (CRD – database of health economic reviews) • NTIS (National Technical Information database) • PsycLIT • Purchasing Innovations Database • Science Citation Index • SIGLE (grey literature database) • Social Sciences Citation Index • Sport • SSRU ***Search terms*** see: http://www.york.ac.uk/inst/crd/docs/obrevtab.doc	Inclusion criteria detailed for surgical interventions only ***Study design*** Only RCTs ***Interventions*** Surgical interventions (behavioural, dietary, exercise, pharmacological and alternative therapies were also considered in this review, but only data on the surgical interventions will be extracted) ***Population*** Adults with morbid obesity (BMI > 40 kg/m^2) ***Setting*** Secondary care ***Outcome measures*** Measures of weight change, e.g. absolute weight loss, % weight loss, relative baseline values Measures of fat content, e.g. BMI, ponderal index, skin-fold thickness, fat-free mass, fat loss Measures of fat distribution, e.g. waist–hip ratio, waist size All studies had to observe participants for a minimum of 1 year from the start of the intervention ***Quality criteria*** Checked for randomisation; sample size, attrition and ITT described ***Application of methods*** Titles and abstracts assessed for relevance, and a sample checked by second reviewer. Data extraction checked by second reviewer
Results **Quantity of included studies (15 trials included):** 2 studies compared RYGB technique with VBG 3 studies compared RYGB technique with undefined GP 2 studies compared undefined GB with GP 1 study compared standard RYGB procedure with modified RYGB 1 study compared HBG with VBG 1 study compared horizontal GP with a VLCD 1 study compared end-to-end with end-to-side jejunoileostomy 1 study compared end-to-side jejunoileostomy with unspecified medical treatment 2 studies compared end-to-end jejunoileostomy with GP 1 study compared the effect of the Garren–Edwards gastric bubble with a sham replacement		

continued

***Results* contd**

Quality assessment of included studies:
Not reported

What was the combined treatment effect?:
Not combined

Adverse effects:
Mortality
6 studies reported no early death with no data available for later mortality. No deaths reported in 2 other studies
1 study reported 3 deaths post RYGB: 2 from cardiac arrhythmia, 1 unrelated to surgery
1 study reported 1 death post RYGB due to an anastomotic leakage
1 study reported 1 death: a fatal myocardial infarction following mock removal of a sham gastric bubble
1 study reported 2 deaths in the group receiving medical treatment: 1 due to complications of a liver biopsy; 1 related to cirrhosis of the liver
1 study reported 1 death after end-to-end jejunoileostomy arising from peritonitis due to anastomotic leakage
1 study reported 1 death after GB surgery due to an embolus to a brachial artery
1 study reported 2 deaths: 1 following jejunoileostomy, the other following GB

Other complications associated with surgical treatments for obesity:
Re-operation or surgical conversion
6 papers reported the need for re-operation or surgical conversion to the other procedure, normally due to a failure to lose weight postoperatively. The re-operation rates of patients undergoing GP ranged from 12% to 33%. Surgical conversion after GB occurred in 2% of patients in 1 study. 40% of those undergoing end-to-end jejunoileostomy required further surgery

Dumping syndrome
1 study reported that 10 (50%) patients who had undergone RYGB experienced dumping syndrome postoperatively
1 study presented results on 4 (8%) patients who experienced dumping syndrome following RYGB
1 study noted that 4 (14%) GB patients experienced dumping syndrome

Vitamin B_{12} deficiency
1 study reported vitamin B_{12} levels of < 300 pg/dl in 7 (35%) GB patients and 3 (15%) GP patients 2 years postoperatively
1 study that compared 2 versions of RYGB found that approximately 23% of patients undergoing both procedures suffered vitamin B_{12} deficiency

QoL assessments:
1 study reported that 80% of GB and 75% of GP patients felt their marital situation had remained the same or improved since the surgery. 50% of those whose marriages got worse believed that this was related to the operation
1 study reported statistically greater postoperative satisfaction in the group receiving intestinal bypass than in medically managed patients
1 study showed that 6/10 patients who had undergone JB experienced a postoperative improvement in social well-being, compared with 9/10 for the end-to-end procedure

Summary:
GB appears to be the most effective surgical intervention (compared with JB and VBG), and appears to have a low early mortality rate
Postoperative complications of GB include dumping syndrome
GB may result in both vitamin and mineral deficiency, but these can be overcome by supplementation

Assessment of heterogeneity:
Not assessed because studies not combined statistically

Comments

Methodological comments
Search strategy: very comprehensive database searching. Language restrictions on searching not mentioned. See page 125 for list of databases searched. In addition, references of relevant reviews were checked for additional references. Did not mention handsearching or contact with experts

Participants: appropriate

Inclusion/exclusion criteria: to be included, studies had to satisfy criteria of relevance, outcome and design. Only RCTs included. All studies had to observe participants for a minimum of 1 year from the start of the intervention. A sample of papers identified for inclusion was checked by a second reviewer. Data extraction was checked by a second reviewer

Quality assessment of studies: not formally assessed

Method of synthesis: narrative

General comments
Generalisability: morbidly obese patients

Appropriate outcome measures used?: yes

Any differences in baseline characteristics of patients and controls?: not mentioned

Appropriate analysis?: NA

Funding?: Department of Health, UK

continued

Quality assessment for systematic reviews (NHS CRD)

Question	**Score**
1. Are any inclusion/exclusion criteria reported relating to the primary studies which address the review question?	Yes
2. Is there evidence of a substantial effort to search for all relevant research?	Yes
3. Is the validity of included studies adequately assessed?	No
4. Is sufficient detail of the individual studies presented?	Yes
5. Are the primary studies summarised appropriately?	Yes

Appendix 16

List of excluded QoL studies

Is health-related quality-of-life assessment the key to helping patients with obesity? *Drugs Ther Perspect* 1998;**12**(8):13–16.
[QoL tool not economics based]

Alfonso VC. Measures of quality of life, subjective well-being, and satisfaction with life. In: Allison DB, editor. Handbook of assessment methods for eating behaviors and weight-related problems: measures, theory, and research. Thousand Oaks, CA: Sage Publications; 1995. p. 23–80.
[QoL tool not economics based]

Ardelt GE, Radlberger G, Seiser G, Schwaiger B. Psychological aspects of surgical treatment of severe obesity. *Acta Chir Austriaca* 1998;**30**:135–40.
[QoL tool not economics based]

Barajas-Gutierrez MA, Robledo ME, Tomils GN, Sanz CT, Garcia MP, Cerrada SI. Quality of life related to health and obesity at a primary care center. *Rev Esp Salud Publica* 1998;**72**:221–31.
[QoL tool not economics based]

Barofsky I, Fontaine KR, Cheskin LJ. Pain in the obese: impact on health-related quality-of-life. *Ann Behav Med* 1997;**19**:408–10.
[QoL tool not economics based]

Dano P, Hahn-Pedersen J. Improvement in quality of life following jejunoileal bypass surgery for obesity. *Scand J Gastroenterol* 1977;**12**:769–74.
[QoL tool not economics based]

De Leiva A. What are the benefits of moderate weight loss? *Exp Clin Endocrinol Diabetes* 1998;**106** Suppl 2:10–13.
[QoL tool not economics based]

Di Gregorio JM, Palkoner R. Quality of life after obesity surgery, an evidence-based medicine literature review: how to improve systematic searches for enhanced decision-making and clinical outcomes. *Obes Surg* 2001;**11**:318–26.
[QoL tool not economics based]

Finkelstein MM. Body mass index and quality of life in a survey of primary care patients. *J Fam Pract* 2000;**49**:734–7.
[QoL tool not economics based]

Fontaine KR, Barofsky I, Andersen RE, Bartlett SJ, Wiersema L, Cheskin LJ, *et al.* Impact of weight loss on health-related quality of life. *Qual Life Res* 1999;**8**:275–7.
[QoL tool not economics based]

Fontaine KR, Barofsky I, Cheskin LJ. Predictors of quality of life for obese persons. *J Nerv Ment Dis* 1997;**185**:120–2.
[QoL tool not economics based]

Fontaine KR, Bartlett SJ. Estimating health related quality of life in obese individuals. *Dis Manage Health Outcomes* 1998;**3**(2):61–70.
[QoL tool not economics based]

Fontaine KR, Bartlett SJ, Barofsky I. Health-related quality of life among obese persons seeking and not currently seeking treatment. *Int J Eat Disord* 2000;**27**:101–5.
[QoL tool not economics based]

Ford ES, Moriarty DG, Zack MM, Mokdad AH, Chapman DP. Self-reported body mass index and health-related quality of life: findings from the behavioral risk factor surveillance system. *Obes Res* 2001;**9**:21–31.
[QoL tool not economics based]

Hafner RJ, Watts JM, Rogers J. Quality of life after gastric bypass for morbid obesity. *Int J Obes* 1991;**15**:555–60.
[QoL tool not economics based]

Han TS, Tijhuis MA, Lean ME, Seidell JC. Quality of life in relation to overweight and body fat distribution. *Am J Public Health* 1998;**88**:1814–20.
[QoL tool not economics based]

Hardt J, Egle UT, Heintz A, Klages S, Muller KM. Treatment of extreme obesity: quality of life after gastric banding. *J Psychosom Res* 2000;**48**:276.
[Abstract only]

Hell E, Miller KA, Moorehead MK, Norman S. Evaluation of health status and quality of life after bariatric surgery: comparison of standard Roux-en-Y gastric bypass, vertical banded gastroplasty and laparoscopic adjustable silicone gastric banding. *Obes Surg* 2000;**10**:214–19.
[QoL tool not economics based]

Isacsson A, Frederiksen SG, Nilsson P, Hedenbro JL. Quality of life after gastroplasty is normal: a controlled study. *Eur J Surg* 1997;**163**:181–6.
[QoL tool not economics based]

Karlsson J, Sjostrom L, Sullivan M. Swedish Obese Subjects (SOS) – an intervention study of obesity. Measuring psychosocial factors and health by means of short-form questionnaires. Results from a method study. *J Clin Epidemiol* 1995;**48**:817–23.
[QoL tool not economics based]

Katz DA, McHorney CA, Atkinson RL. Impact of obesity on health-related quality of life in patients with chronic illness. *J Gen Intern Med* 2000;**15**:789–96.
[QoL tool not economics based]

Kawachi I. Physical and psychological consequences of weight gain. *J Clin Psychiatry* 1999;**60** Suppl 21:5–9.
[QoL tool not economics based]

Kolotkin RL, Crosby RD, Kosloski KD, Williams GR. Development of a brief measure to assess quality of life in obesity. *Obes Res* 2001;**9**:102–11.
[QoL tool not economics based]

Kolotkin RL, Head S, Brookhart A. Construct validity of the impact of weight on quality of life questionnaire. *Obes Res* 1997;**5**:434–41.
[QoL tool not economics based]

Kolotkin RL, Head S, Hamilton M, Tse CK. Assessing impact of weight on quality of life. *Obes Res* 1995;**3**:49–56.
[QoL tool not economics based]

Kral JG. Morbid obesity and related health risks. *Ann Intern Med* 1985;**103**(6 Pt 2):1043–7.
[Review of obesity]

Kral JG, Sjostrom LV, Sullivan MB. Assessment of quality of life before and after surgery for severe obesity. *Am J Clin Nutr* 1992;**55** Suppl 2:611S-4S.
[Narrative review]

Kushner RF, Foster GD. Obesity and quality of life. *Nutrition* 2000;**16**:947–52.
[QoL tool not economics based]

Lang T, Hauser R, Schlumpf R, Klaghofer R, Buddeberg C. Psychic comorbidity and quality of life in patients with morbid obesity applying for gastric banding. *Schweiz Med Wochenschr* 2000;**130**(20):739–48.
[QoL tool not economics based]

Larsen F. Psychosocial function before and after gastric banding surgery for morbid obesity: a prospective psychiatric study. *Acta Psychiatr Scand Suppl* 1990;**359**:1–57.
[QoL tool not economics based]

Lean ME, Han TS, Seidell JC. Impairment of health and quality of life using new US federal guidelines for the identification of obesity. *Arch Intern Med* 1999;**159**:837–43.
[QoL tool not economics based]

Le Pen C, Levy E, Loos F, Banzet MN, Basdevant A. 'Specific' scale compared with 'generic' scale: a double measurement of the quality of life in a French community sample of obese subjects. *J Epidemiol Community Health* 1998;**52**:445–50.
[QoL tool not economics based]

Lopez de-la-Torre-Casares M. Obesity and quality of life. *Nutr Hosp* 1999;**14**(5):177–83.
[QoL tool not economics based]

Mannucci E, Ricca V, Barciulli E, Di Bernardo M, Travaglini R, Cabras PL, *et al.* Quality of life and overweight: the obesity related well-being (Orwell 97) questionnaire. *Addict Behav* 1999;**24**:345–57.
[QoL tool not economics based]

Marchesini G, Solaroli E, Baraldi L, Natale S, Migliorini S, Visani F, *et al.* Health-related quality of life in obesity: the role of eating behaviour. *Diabetes Nutr Metab Clin Exp* 2000;**13**:156–64.
[QoL tool not economics based]

Mathias SD, Williamson CL, Colwell HH, Cisternas MG, Pasta DJ, Stolshek BS, *et al.* Assessing health-related quality-of-life and health state preference in persons with obesity: a validation study. *Qual Life Res* 1997;**6**:311–22.
[QoL tool not economics based]

Milheiro I, Gomes L, Lemos D, Ferreira PL, Costa EM, Bento A, *et al.* Quality of life in obesity. *Nascer e Crescer* 2000;**9**:S278–82.
[QoL tool not economics based]

Miller K, Mayer E, Pichler M, Hell E. Quality-of-life outcomes of patients with the Lap-Band registered versus non-operative treatment of obesity. Preliminary results of an ongoing long-term follow-up study. *Obes Surg* 1997;**7**:280.
[Abstract only]

Oria HE, Moorehead MK. Bariatric analysis and reporting outcome system (BAROS). *Obes Surg* 1998;**8**:487–97, 499.
[QoL tool not economics based]

Rippe JM, Price JM, Hess SA, Kline G, DeMers KA, Damitz S, *et al.* Improved psychological well-being, quality of life, and health practices in moderately overweight women participating in a 12-week structured weight loss program. *Obes Res* 1998;**6**:208–18.
[QoL tool not economics based]

Rosmond R, Bjorntorp P. Quality of life, overweight, and body fat distribution in middle-aged men. *Behav Med* 2000;**26**:90–4.
[QoL tool not economics based]

Sarlio-Laehteenkorva S. Weight loss and quality of life among obese people. *Soc Indic Res* 2001;**54**:329–54.
[QoL tool not economics based]

Sarlio-Lahteenkorva S, Stunkard A, Rissanen A. Psychosocial factors and quality of life in obesity. *Int J Obes Relat Metab Disord* 1995;**19** Suppl 6: S1–S5.
[QoL tool not economics based]

Sullivan M, Karlsson J, Sjostrom L, Backman L, Bengtsson C, Bouchard C, *et al.* Swedish obese subjects (SOS) – an intervention study of obesity. Baseline evaluation of health and psychosocial functioning in the first 1743 subjects examined. *Int J Obes Relat Metab Disord* 1993;**17**:503–12.
[QoL tool not economics based]

Sullivan MB, Sullivan LG, Kral JG. Quality of life assessment in obesity: physical, psychological, and social function. *Gastroenterol Clin North Am* 1987;**16**:433–42.
[QoL tool not economics based]

Weiner R, Datz M, Wagner D, Bockhorn H. Quality-of-life outcome after laparoscopic adjustable gastric banding for morbid obesity. *Obes Surg* 1999;**9**:539–45.
[QoL tool not economics based]

Appendix 17

List of excluded economics studies

Allison DB, Zannolli R, Narayan KM. The direct health care costs of obesity in the United States. *Am J Public Health* 1999;**89**:1194–9.
[Not relevant to UK]

Alvarez CR. Treatment of clinically severe obesity, a public health problem: introduction. *World J Surg* 1998;**22**:905–6.
[Not cost-of-illness or economic evaluation]

Baird IM. Obesity and insurance risk: the insurance industry's viewpoint. *Pharmacoeconomics* 1994; **5** Suppl **1**:62–5.
[Not cost-of-illness or economic evaluation]

Berke EM, Morden NE. Medical management of obesity. *Am Fam Physician* 2000;**62**:419–26.
[Not cost-of-illness or economic evaluation]

Birmingham CL, Muller JL, Palepu A, Spinelli JJ, Anis AH. The cost of obesity in Canada [see comments]. *Can Med Assoc J* 1999;**160**:483–8.
[Not relevant to UK]

Bjorntorp P, Vanitallie TB. The indirect socioeconomic costs of obesity – introduction. *Pharmacoeconomics* 1994; **5** Suppl 1:53.
[Not cost-of-illness or economic evaluation]

Black DR, Threlfall WE. Partner weight status and subject weight loss: implications for cost-effective programs and public health. *Addict Behav* 1989;**14**:279–89.
[Not cost-of-illness or economic evaluation]

Bradham DD, South BR, Saunders HJ, Heuser MD, Pane KW, Dennis KE. Obesity-related hospitalization costs to the U.S. Navy, 1993 to 1998. *Mil Med* 2001;**166**:1–10.
[Not relevant to UK]

Burton WN, Chen CY, Schultz AB, Edington DW. The economic costs associated with body mass index in a workplace. *J Occup Environ Med* 1998;**40**:786–92.
[Not cost-of-illness or economic evaluation]

Cerulli J, Malone M. Outcomes of pharmacological and surgical treatment for obesity. *Pharmacoeconomics* 1998;**14**:269–83.
[Not cost-of-illness or economic evaluation]

Choban P, Lu B, Flancbaum L. Insurance decisions about obesity surgery: a new type of randomization? *Obes Surg* 2000;**10**:553–6.
[Not cost-of-illness or economic evaluation]

Colditz GA. Economic costs of obesity and inactivity. *Med Sci Sports Exerc* 1999;**31**(11 Suppl):S663–S7.
[Not cost-of-illness or economic evaluation]

Collins RW, Anderson JW. Medication cost savings associated with weight loss for obese non-insulin-dependent diabetic men and women. *Prev Med* 1995;**24**:369–74.
[Not cost-of-illness or economic evaluation]

Cooney RN, Bryant P, Haluck R, Rodgers M, Lowery M. The impact of a clinical pathway for gastric bypass surgery on resource utilization. *J Surg Res* 2001;**98**:97–101.
[Not cost-of-illness or economic evaluation]

Cowan GS Jr, Hiler ML, Buffington C. Criteria for selection of patients for bariatric surgery. *Eur J Gastroenterol Hepatol* 1999;**11**(2):69–75.
[Not cost-of-illness or economic evaluation]

Detournay B, Fagnani F, Phillippo M, Pribil C, Charles MA, Sermet C, *et al.* Obesity morbidity and health care costs in France: an analysis of the 1991–1992 Medical Care Household Survey. *Int J Obes* 2000;**24**:151–5.
[Not relevant to UK]

Durkin AJ, Bloomston M, Murr MM, Rosemurgy AS. Financial status does not predict weight loss after bariatric surgery. *Obes Surg* 1999;**9**:524–6.
[Not cost-of-illness or economic evaluation]

Eisenstein EL, Shaw LK, Nelson CL, Anstrom KJ, Hakim Z, Mark DB. Assessing the relationship between obesity and long-term clinical and economic outcomes in coronary artery disease patients. *J Am Coll Cardiol* 2001;**37**:508A–9A.
[Not cost-of-illness or economic evaluation]

Elks ML. Optimising outcomes in the treatment of obesity: current evidence for the effectiveness of interventions and future prospects. *Dis Manage Health Outcomes* 1998;**3**(2):51–9.
[Not cost-of-illness or economic evaluation]

Erfurt JC, Foote A, Heirich MA. The cost-effectiveness of work-site wellness programs for hypertension control, weight loss, and smoking cessation. *J Occup Med* 1991;**33**:962–70.
[Not cost-of-illness or economic evaluation]

Evers S. Economic and social-factors associated with obesity in adult Canadians. *Nutr Res* 1987;**7**:3–13.
[Not cost-of-illness or economic evaluation]

Fontaine KR, Barofsky I, Cheskin LJ. Predictors of quality of life for obese persons. *J Nerv Ment Dis* 1997;**185**:120–2.
[Not cost-of-illness or economic evaluation]

Fried M, Peskova M, Kasalicky M. The role of laparoscopy in the treatment of morbid obesity. *Obes Surg* 1998;**8**:520–3.
[Not cost-of-illness or economic evaluation]

Gawdat K. Gastric restrictive procedures through a mini-incision: a cost-effective alternative to laparoscopic bariatric surgery in Egypt. *Obes Surg* 1999;**9**:456–8.
[Not cost-of-illness or economic evaluation]

Ghassemian AJ, MacDonald KG, Cunningham PG, Swanson M, Brown BM, Morris PG, *et al.* The workup for bariatric surgery does not require a routine upper gastrointestinal series [see comments]. *Obes Surg* 1997;**7**:16–18.
[Not cost-of-illness or economic evaluation]

Ginsberg GM, Viskoper RJ, Oren S, Bregman L, Mishal Y, Sherf S. Resource savings from non-pharmacological control of hypertension. *J Hum Hypertens* 1990;**4**:375–8.
[Not cost-of-illness or economic evaluation]

Gorsky RD, Pamuk E, Williamson DF, Shaffer PA, Koplan JP. The 25-year health care costs of women who remain overweight after 40 years of age. *Am J Prev Med* 1996;**12**:388–94.
[Not cost-of-illness or economic evaluation]

Greenway FL, Ryan DH, Bray GA, Rood JC, Tucker EW, Smith SR. Pharmaceutical cost savings of treating obesity with weight loss medications. *Obes Res* 1999;**7**:523–31.
[Not cost-of-illness or economic evaluation]

Grundy SM, Blackburn G, Higgins M, Lauer R, Perri MG, Ryan D. Physical activity in the prevention and treatment of obesity and its comorbidities: evidence report of independent panel to assess the role of physical activity in the treatment of obesity and its comorbidities. *Med Sci Sports Exerc* 1999;**31**:1493–500.
[Not cost-of-illness or economic evaluation]

Hainer V, Kunesova M, Parizkova J, Stunkard A. [Health risks and economic costs associated with obesity requiring a comprehensive weight reduction program.] *Cas Lek Cesk* 1997;**136**(12):367–72.
[Not cost-of-illness or economic evaluation]

Harvey EL, Glenny AM, Kirk SFL, Summerbell CD. A systematic review of interventions to improve health professionals' management of obesity. *Int J Obes* 1999;**23**:1213–22.
[Not cost-of-illness or economic evaluation]

Hauner H, Koster I, von Ferber L. Frequency of 'obesity' in medical records and utilization of out-patient health care by 'obese' subjects in Germany. An analysis of health insurance data. *Int J Obes Relat Metab Disord* 1996;**20**:820–4.
[Not cost-of-illness or economic evaluation]

Hauri P, Horber FF, Sendi P. Is bariatric surgery worth its costs? *Obes Surg* 1999;**9**:480–3.
[Not cost-of-illness or economic evaluation]

Heimbucher J, Tigges H, Fuchs KH, Benecke TA, Thiede A. [Patient selection for laparoscopic gastric banding operation.] *Langenbecks Arch Chir Suppl Kongressbd* 1998;**115**:1007–9.
[Not cost-of-illness or economic evaluation]

Heithoff KA, Cuffel BJ, Kennedy S, Peters J. The association between body mass and health care expenditures. *Clin Ther* 1997;**19**:811–20.
[Not cost-of-illness or economic evaluation]

Hodgson J. Obesity: where less is more. *Biotechnology* 1995;**13**:1060–3.
[Not cost-of-illness or economic evaluation]

Hutton J. The economics of treating obesity. *Pharmacoeconomics* 1994;**5**:66–72.
[Not cost-of-illness or economic evaluation]

James WP. A public health approach to the problem of obesity. *Int J Obes Relat Metab Disord* 1995; **19** Suppl 3:S37–S45.
[Not cost-of-illness or economic evaluation]

Johannesson M, Fagerberg B. A health–economic comparison of diet and drug treatment in obese men with mild hypertension. *J Hypertens* 1992;**10**:1063–70.
[Not cost-of-illness or economic evaluation]

Johnson RE, Vogt TM, Penn RL. An episode approach to the care and costs of obesity. *J Ambul Care Manage* 1984;**7**:47–60.
[Not cost-of-illness or economic evaluation]

Johnson WG, Stalonas PM, Christ MA, Pock SR. The development and evaluation of a behavioral weight-reduction program. *Int J Obes* 1979;**3**:229–38.
[Not cost-of-illness or economic evaluation]

Kennedy BP, Kawachi I, Glass R, Prothrow SD. Income distribution, socioeconomic status, and self rated health in the United States: multilevel analysis. *Br Med J* 1998;**317**:917–21.
[Not relevant to the UK]

Khaodhiar L, McCowen KC, Blackburn GL. Obesity and its comorbid conditions. *Clin Cornerstone* 1999;**2**(3):17–31.
[Not cost-of-illness or economic evaluation]

Kiefer I, Kunze U, Mitsche N, Kunze M. [Obesity in Austria: epidemiologic and social medicine aspects.] *Acta Med Austriaca* 1998;**25**(4–5):126–8.
[Not relevant to the UK]

Klein S. Alternative therapies for obesity: benefit or rip-off. *Crit Rev Food Sci Nutr* 2001;**41**:33–4.
[Not cost-of-illness or economic evaluation]

Kortt MA, Langley PC, Cox ER. A review of cost-of-illness studies on obesity. *Clin Ther* 1998;**20**:772–9.
[Not cost-of-illness or economic evaluation]

Kuhlmann HW, Falcone RA, Wolf AM. Cost-effective bariatric surgery in Germany today. *Obes Surg* 2000;**10**:549–52.
[Not relevant in the UK]

Kumanyika SK. Minisymposium on obesity: overview and some strategic considerations. *Annu Rev Public Health* 2001;**22**:293–308.
[Not cost-of-illness or economic evaluation]

Kurscheid T, Lauterbach K. The cost implications of obesity for health care and society. *Int J Obes Relat Metab Disord* 1998;**22** Suppl 1:S3–S5.
[Not cost-of-illness or economic evaluation]

Laird BC, Muller JL, Palepu A, Spinelli JJ, Anis AH. The cost of obesity in Canada. *Can Med Assoc J* 1999;**160**:483–8.
[Not relevant in the UK]

Lean MEJ. Obesity: burdens of illness and strategies for prevention or management. *Drugs Today* 2000;**36**:773–84.
[Not cost-of-illness or economic evaluation]

Leigh JP, Fries JF. Health habits, health care use and costs in a sample of retirees. *Inquiry* 1992;**29**:44–54.
[Not cost-of-illness or economic evaluation]

Levine AA. Obesity and income: the effect of overweight on wages in women. *J Pediatr Gastroenterol Nutr* 1995;**20**:354–5.
[Not cost-of-illness or economic evaluation]

Levy E, Levy P, Le Pen C, Basdevant A. The economic cost of obesity: the French situation. *Int J Obes Relat Metab Disord* 1995;**19**:788–92.
[Not relevant in the UK]

Macgregor AMC, Macgregor CC. Economic theory and physician behavior in bariatric surgery. *Obes Surg* 2000;**10**:4–6.
[Not cost-of-illness or economic evaluation]

Martin LF, Hunter SM. Are there effective treatments for the severely obese? *J La State Med Soc* 1994;**146**:348–54.
[Not cost-of-illness or economic evaluation]

Martin LF, Hunter SM, Lauve RM, O'Leary JP. Severe obesity: expensive to society, frustrating to treat, but important to confront. *South Med J* 1995;**88**:895–902.
[Not cost-of-illness or economic evaluation]

Martin LF, Robinson A, Moore BJ. Socioeconomic issues affecting the treatment of obesity in the new millennium. *Pharmacoeconomics* 2000;**18**:335–53.
[Not cost-of-illness or economic evaluation]

Martin LF, White S, Lindstrom W. Cost–benefit analysis for the treatment of severe obesity. *World J Surg* 1998;**22**:1008–17.
[Not cost-of-illness or economic evaluation]

Mcgarn S. Socio-economic aspects of obesity. *N Y State J Med* 1982;**82**:1118–19.
[Not cost-of-illness or economic evaluation]

McLean RA, Moon M. Health, obesity, and earnings. *Am J Public Health* 1980;**70**:1006–9.
[Not cost-of-illness or economic evaluation]

Must A, Spadano J, Coakley EH, Field AE, Colditz G, Dietz WH. The disease burden associated with overweight and obesity. *JAMA* 1999;**282**:1523–9.
[Not cost-of-illness or economic evaluation]

Narbro K, Jonsson E, Larsson B, Waaler H, Wedel H, Sjostrom L. Economic consequences of sick-leave and early retirement in obese Swedish women. *Int J Obes Relat Metab Disord* 1996;**20**:895–903.
[Not cost-of-illness or economic evaluation]

Narbro K, Sjostrom L. Willingness to pay for obesity treatment. *Int J Technol Assess Health Care* 2000;**16**:50–9.
[Not cost-of-illness or economic evaluation]

Novak K. NIH increase efforts to tackle obesity [news]. *Nat Med* 1998;**4**:752–3.
[Not cost-of-illness or economic evaluation]

Oppert JM, Rolland-Cachera MF. Prevalence, time trends, and economic cost of obesity. *Medicine Sciences* 1998;**14**(8–9):939–43.
[Not cost-of-illness or economic evaluation]

Oster G, Edelsberg J, O'Sullivan AK, Thompson D. The clinical and economic burden of obesity in a managed care setting. *Am J Manag Care* 2000;**6**:681–9.
[Not cost-of-illness or economic evaluation]

Oster G, Thompson D, Edelsberg J, Bird AP, Colditz GA. Lifetime health and economic benefits of weight loss among obese persons. *Am J Public Health* 1999;**89**:1536–42.
[Not cost-of-illness or economic evaluation]

Pacy PJ, Webster JD, Pearson M, Garrow JS. A cross-sectional cost/benefit audit in a hospital obesity clinic. *Hum Nutr Appl Nutr* 1987;**41**:38–46.
[Not cost-of-illness or economic evaluation]

Pezzot-Pearce TD, LeBow MD, Pearce JW. Increasing cost-effectiveness in obesity treatment through use of self-help behavioral manuals and decreased therapist contact. *J Consult Clin Psychol* 1982;**50**:448–9.
[Not cost-of-illness or economic evaluation]

Philipson T. The world-wide growth in obesity: an economic research agenda. *Health Econ* 2001;**10**:1–7.
[Not cost-of-illness or economic evaluation]

Popkin BM, Udry JR. Adolescent obesity increases significantly in second and third generation U.S. immigrants: the National Longitudinal Study of Adolescent Health. *J Nutr* 1998;**128**:701–6.
[Not cost-of-illness or economic evaluation]

Poston WS, Foreyt JP, Borrell L, Haddock CK. Challenges in obesity management. *South Med J* 1998;**91**:710–20.
[Not cost-of-illness or economic evaluation]

Pronk NP, Tan AW, O'Connor P. Obesity, fitness, willingness to communicate and health care costs. *Med Sci Sports Exerc* 1999;**31**:1535–43.
[Not cost-of-illness or economic evaluation]

Quesenberry CP Jr, Caan B, Jacobson A. Obesity, health services use, and health care costs among members of a health maintenance organization. *Arch Intern Med* 1998;**158**:466–72.
[Not cost-of-illness or economic evaluation]

Rand CS, Kuldau JM. Morbid obesity: a comparison between a general population and obesity surgery patients. *Int J Obes Relat Metab Disord* 1993;**17**:657–61.
[Not cost-of-illness or economic evaluation]

Ren A, Okubo T, Takahashi K. Health-related worries, perceived health status, and health care utilization. *Sangyo Ika Daigaku Zasshi* 1994;**16**:287–99.
[Not cost-of-illness or economic evaluation]

Rissanen AM. The economic and psychosocial consequences of obesity. *Ciba Found Symp* 1996;**201**:194–201.
[Not cost-of-illness or economic evaluation]

Roberts L, Haycox A. About the size of it. *Health Serv J* 1999;**109**:28–9.
[Not cost-of-illness or economic evaluation]

Rouse AD, Tripp BL, Shipley S, Pories W, Cunningham P, MacDonald K. Meeting the challenge of managed care through clinical pathways for bariatric surgery. *Obes Surg* 1998;**8**:530–4.
[Not cost-of-illness or economic evaluation]

Sarlio LS, Stunkard A, Rissanen A. Psychosocial factors and quality of life in obesity. *Int J Obes Relat Metab Disord* 1995;**19** Suppl 6:S1–S5.
[Not cost-of-illness or economic evaluation]

Schaefer DC, Cheskin LJ. Update on obesity treatment. *Gastroenterologist* 1998;**6**:136–45.
[Not cost-of-illness or economic evaluation]

Segal L, Carter R, Zimmet P. The cost of obesity – the Australian perspective. *Pharmacoeconomics* 1994;**5**:45–52.
[Not relevant to the UK]

Seidell JC. Obesity in Europe – causes, costs, and consequences. *Int J Risk Saf Med* 1995;**7**:103–10.
[Not cost-of-illness or economic evaluation]

Seidell JC. Societal and personal costs of obesity. *Exp Clin Endocrinol Diabetes* 1998;**106** Suppl 2:7–9.
[Not cost-of-illness or economic evaluation]

Sjostrom L, Larsson B, Backman L, Bengtsson C, Bouchard C, Dahlgren S, *et al.* Swedish obese subjects (SOS). Recruitment for an intervention study and a selected description of the obese state. *Int J Obes Relat Metab Disord* 1992;**16**:465–79.
[Not cost-of-illness or economic evaluation]

Sorensen TI. Socio-economic aspects of obesity: causes or effects? *Int J Obes Relat Metab Disord* 1995; **19** Suppl 6:S6–S8.
[Not cost-of-illness or economic evaluation]

Stunkard AJ. Socioeconomic status and obesity. *Ciba Found Symp* 1996;**201**:174–82.
[Not cost-of-illness or economic evaluation]

Swinburn B, Ashton T, Gillespie J, Cox B, Menon A, Simmons D, *et al.* Health care costs of obesity in New Zealand. *Int J Obes Relat Metab Disord* 1997;**21**:891–6.
[Not cost-of-illness or economic evaluation]

Thompson D, Edelsberg J, Colditz GA, Bird AP, Oster G. Lifetime health and economic consequences of obesity. *Arch Intern Med* 1999;**159**:2177–83.
[Not cost-of-illness or economic evaluation]

Thompson D, Edelsberg J, Kinsey KL, Oster G. Estimated economic costs of obesity to U.S. business. *Am J Health Promot* 1998;**13**:120–7.
[Not cost-of-illness or economic evaluation]

Tsukamoto H, Sano F. Body weight and longevity: insurance experience in Japan. *Diabetes Res Clin Pract* 1990;**10** Suppl 1: S119–S125.
[Not cost-of-illness or economic evaluation]

Vanitallie TB, Lissner L, Bjorntorp P, Beales PL, Kopelman PG, Colditz GA, *et al.* The cost of obesity – a seminar-in-print – questions and answers. *Pharmacoeconomics* 1994;**5**:73–9.
[Not cost-of-illness or economic evaluation]

West R. Obesity. London: Office of Health Economics; 1994.
[Not cost-of-illness or economic evaluation]

Wolf AM. Impact of obesity on healthcare delivery costs. *Am J Manag Care* 1998;**4**(3 Suppl):S141–S5.
[Not cost-of-illness or economic evaluation]

Wolf AM. What is the economic case for treating obesity? *Obes Res* 1998;**6** Suppl 1:2S–7S.
[Not cost-of-illness or economic evaluation]

Wolf AM, Colditz GA. The cost of obesity – the United States perspective. *Pharmacoeconomics* 1994;**5**:34–7.
[Not cost-of-illness or economic evaluation]

Wolf AM, Colditz GA. Social and economic effects of body weight in the United States. *Am J Clin Nutr* 1996;**63**(3 Suppl):466S–9S.
[Not cost-of-illness or economic evaluation]

Wolf AM, Colditz GA. Current estimates of the economic cost of obesity in the United States [see comments]. *Obes Res* 1998;**6**:97–106.
[Not cost-of-illness or economic evaluation]

Appendix 18

Characteristics of gastric surgery for morbid obesity economic evaluation studies

	Study number			
Item	**1**	**2**	**3**	**4**
Author/ref.	Martin *et al.*[72]	Van Gemert *et al.*[73]	Chua & Mendiola[74]	Sjostrom *et al.*[75]
Publication year	1995	1999	1995	1995
Base year prices	?	?	?	?
Intervention	Surgical: RYGB Medical: VLCD consumption for at least 12 weeks plus weekly behavioural modification meetings for at least 4 months	Treatment: VBG No treatment: no treatment given	Laparoscopy: laparoscopic VBG Open: open VBG and open RYGB	Surgery: banding or VBG, or GB Conventional: not clearly described
Study type	Cost-effectiveness	Cost-effectiveness and cost of illness	Cost-effectiveness	Cost-effectiveness
Study group – BMI	Obese	Morbidly obese (BMI > 40)	Morbidly obese	Obese
Perspective	?	?	?	Society
Industry role	?	?	?	?
Country of origin	USA	The Netherlands	USA	Sweden

?, unclear information reported

Appendix 19

Cost-effectiveness results

Results	Interpretation – study's conclusions
Study 1 ***Martin* et al.*, 1995***[72] **Base case** Cost of surgical therapy: US$24,000; cost of medical therapy: US$3000 Not excluding patients lost to follow-up, assuming they return to their original weight: • surgical cost per pound lost = ~ US$250 to ~ US$750 (for follow-up years 2–6) • medical cost per pound lost = ~ US$100 to ~ US$1600 (for follow-up years 2–6) Excluding patients lost to follow-up: • surgical cost per pound lost = ~ US$230 to ~ US$260 (for follow-up years 2–6) • medical cost per pound lost = ~ US$65 to ~ US$300 (for follow-up years 2–6) **Sensitivity analysis** None carried out	**Conclusion** Surgical treatment appears to be more cost-effective at producing and maintaining weight loss **Caveats** • No sensitivity analysis carried out • Base price not indicated • Patient/family/social costs not included • Charges for treatment, not cost, used • No costing for surgical or medical complications • No accurate accounting for possible cost savings from a possible decline in medications used for co-morbid conditions • No QoL data • Cost of pretreatment medical and psychosocial evaluation included • Cost of follow-up not included • Biopsychosocial characteristics of the patients who entered the medical programme are significantly different from those of patients entering surgical programme • Cost per pound lost depicted only graphically • ~ 50% of both medical and surgical patients were lost to follow-up at 5 years • Cost of additional treatments for 'failures' not included
	continued

Results	Interpretation – study's conclusions
Study 2 ***Van Gemert* et al., *1999*[73]** **Base case** • Surgical treatment of morbid obesity by VBG saves US$4004 to US$3928 per QALY • Surgical treatment by VBG dominate no treatment • VBG resulted in significant weight loss and improved QoL • VBG resulted in 12 QALYs gained in lifelong scenario • Lifelong costs of illness of morbidly obese persons ranged from US$8304 to US$9367 • Total direct costs of VBG equalled US$5865 • Total % of individuals performing paid labour from before VBG (19%) increased after VBG (48%), resulting in productivity gain of US$2765 per year **Sensitivity analysis** • Cost-of-illness analysis was carried out for two scenarios: an estimated prevalence of morbid obesity of 0.25% (optimistic) and 1.00% (pessimistic). Costs of illness attributable to morbid obesity amounted to US$37 million and US$131.3 million per year, respectively. Costs per morbidly obese person were US$987 and US$875 per year, respectively • The incremental savings on the costs of illness over a period of 47.8 years were US$8029 when a prevalence of 0.25% of morbid obesity was assumed and US$7118 when prevalence was 1.00% • Complication rates and definitions of success of surgery were varied; however, results were not shown – only indicated in the discussion. These variations did not affect the cost-effectiveness result significantly	**Conclusion** The treatment of morbid obesity via VBG is cost-effective. The cost-effectiveness is determined by the fact that weight loss results in decreased morbid obesity-related co-morbidities and in QALYs and productivity gained **Caveats** • QoL data – using NHP (parts I and II) and VAS • Group treatment (VBG) versus no treatment • No treatment group – using a prevalence-based cost-of-illness analysis based on the morbidly obese population and a preoperative QoL assessment of the 'treatment' group. No 'actual' group used to compare against treatment • Cost-of-illness prevalence-based analysis • Cost-effectiveness analysis of VBG • Decision tree analysis • Proportion of diseases attributable to morbid obesity – calculated from the prevalence and relative risk of diseases, using the PAR equation • Costs based on real prices, not charges • Direct and indirect costs of surgical treatment included • Cost (savings) of productivity losses included • No accurate accounting for possible cost savings from a possible decline in medications used for co-morbid conditions • Cost of complications/revisions included • Cost of follow-up not included • No patients lost to follow-up • Discounting at 5% • Patient/family costs not included • Social costs not included • Cost data in US$ • Cost of co-morbidities attributable to morbid obesity not included
Study 3 ***Chua & Mendiola, 1995*[74]** **Base case** Laparoscopic VBG is feasible and cost-saving: • average length of stay = 3.9 days • mean operation time = 202 minutes • average hospital charge = $12,800 Open VBG: • average length of stay = 9.3 days • mean operation time = 105 minutes • average hospital charge = $11,900 ($16,700 adjusted to current 1994 value) 11 consecutive patients with open GB performed in 1986 reviewed for comparison with laparoscopic VBG: • average length of stay = 7.2 days • average total hospital charge = US$6200 with an adjusted value of US$14,100 (current 1994) **Sensitivity analysis** None performed	**Conclusion** A limited study has been made comparing the length of hospital stay, operating time and hospital charges with the open GB. The laparoscopic VBG group had a shorter hospital stay and cost less, in spite of longer operating times. Longer-term results and weight loss await follow-up **Caveats** • No sensitivity analysis • Comparator group were compared retrospectively • No clear indication of base year • Patients recruited consecutively, no randomisation • No QoL data • No discounting • Cost of follow-up not included • Charges and not cost looked at • Social costs not included • Patient/family costs not included • Laparoscopic versus open • Complication costing not included • Charges in US$ • No reporting of weight loss

continued

Results	Interpretation – study's conclusions
Study 4 ***Sjostrom* et al.*, 1995***[75] **Base case** Direct costs: surgical = 16.5 million SEK/100 surgical patients over 10 years; 15.5 million SEK/100 control patients over 10 years Surgery patients lost between 30 kg and 40 kg of body weight over 2 years HRQoL said to improve over 2 years in the surgery group but not in the control group Cardiovascular risk factors reduced in the surgery group over 2 years: insulin reduced by 60%, glucose and triglycerides by 25%, BP by 10% and total cholesterol by 5%; HDL cholesterol increased by 4%. No improvements in control group, some deterioration occurred 2-year incidence rates for new diabetes cases: surgical = 0.5%; control = 7% Prevalence of diabetes at baseline: 16% vs 13% (surgical and control groups, respectively). Of those who had diabetes, 68% vs 16% (surgical and control groups, respectively) were cured Of those with hypertension at baseline, 43% vs 22% (surgical and control groups, respectively) were cured In the preoperative year, both groups had the same number of hospital visits. In the first postoperative year, surgical cases spent six times longer in hospital than controls. No significant difference, between groups, for visits to the doctors, either pre- or postoperatively *Sick-leave* Pre-inclusion there was no difference between the groups; during the first postoperative year, sick leave more than doubled for the surgical group; in the second year it had returned to the control level. The number of sick days lost due to disability grew faster in the control than surgery group. During the second year a significant difference between groups was achieved *Cost–benefit evaluation* In a 10-year perspective, costs attributable to diabetes and hypertension will be 1.8 million SEK/100 surgical patients and 4.5 million SEK/100 control patients. Direct costs will be 16.5 million SEK/100 surgical patients/10 years and 15.5 million SEK/100 control patients/10 years. However, important factors (such as premature death, myocardial infarction, stroke or musculoskeletal problems over 10 years) are missing **Sensitivity analysis** None performed	**Conclusion** The benefits over 2 years of efficient obesity treatment are extremely positive, but 10-year data are needed for more valid evaluations. Also, 10-year data on direct and non-direct costs are needed in weight-reduced and non-weight-reduced groups to evaluate the cost-effectiveness of obesity treatment Taking risk factors into account over 2 years, it seems likely that direct and indirect costs will increase more over the next 10 years in the non-weight-reduced than in the weight-reduced individuals **Caveats** • Swedish costs converted to US$ • QoL data (SIP, HAD scale, MACL, GHRI) collected but not reported here • Part of the SOS study • No discounting • No sensitivity analysis • Considers indirect (social) costs • Some co-morbidity data • Some costing of co-morbidity data • No patient benefits • Surgery versus control (conventional) • No description of what conventional involves • Diabetes and hypertension costs (cost–benefit analysis) may overlap with costs of hospital and outpatient care • No accounting for premature death, stroke, myocardial infarction or musculoskeletal problems over 10 years in cost–benefit analysis • Cost–benefit analysis does not include long-term data on sick leave and disability pension

PAR, population attributable risk

Appendix 20

Internal validity of economic evaluations

Item	Study 1 Martin *et al.*, 1995[72]	Study 2 Van Gemert *et al.*, 1999[73]	Study 3 Chua & Mendiola, 1995[74]	Study 4 Sjostrom *et al.*, 1995[75]
1. Well-defined question	✔	✔	✔	✔
2. Clear description of alternatives	✔ Roux-en-Y, VLCD	✔ VBG, no treatment	✔ Laparoscopic VBG, open RYGB	✔ Surgery, conventional
3. Reasonable study type	✔	✔	✔	✔
4. Effectiveness established	✔ Efficacy based on a non-randomised trial	✔ Efficacy based on consecutively included patients, and population of morbidly obese individuals	✔ Efficacy based on the 11 consecutive laparoscopic VBG patients and 11 open RYGB patients that were retrospectively compared	✔ Effectiveness based on the SOS trial, of which this is part
5. Estimates related to population risks	?	?	?	?
6. Relevant costs and consequences identified	✔ Healthcare resources ✗ Adverse effects ✗ Drug costs ✗ Follow-up visits ✗ Patient/family resources ✗ Social care sector resources ✗ Patient benefits ✗ Carer benefits	✔ Healthcare resources ✔ Adverse effects ✗ Drug costs ✗ Follow-up visits ✗ Patient/family resources ✗ Social care sector resources ✗ Patient benefits ✗ Carer benefits	✔ Healthcare resources (identified time in operation, hospital stay and hospital charges) ✗ Adverse effects ✗ Drug costs ✗ Follow-up visits ✗ Patient/family resources ✗ Social care sector resources ✗ Patient benefits ✗ Carer benefits	✔ Healthcare resources (some) ✗ Adverse effects ✗ Drug costs ✗ Follow-up visits ✗ Patient/family resources ✗ Social care sector resources ✗ Patient benefits ✗ Carer benefits
7. Costs and consequences measured accurately	✔ Direct medical costs only; complications not included	✔ Direct medical costs and indirect costs (productivity gains)	✔ Hospital charges used for direct costs	✔ Direct and indirect medical costs; complications not included
8. Costs and consequences valued credibly	✔ Direct costs only	✔	✔	✔
9. Differential timing considered	✗	✔ (Discounting at 5%)	✗	✗
10. Incremental analysis performed	✗	✔	✗	✗
11. Sensitivity analysis performed	✗	✔ (Only the results of PAR sensitivity analysis shown)	✗	✗
12. Modelling conducted reasonably	?	?	?	?

?, unclear or unknown; ✔, item included or judged to have acceptable internal validity; ✗, factor not included or judged to have unacceptable internal validity

Appendix 21

External validity of economic studies

Item	Study 1 Martin *et al.*, 1995[72]	Study 2 Van Gemert *et al.*, 1999[73]	Study 3 Chua & Mendiola, 1995[74]	Study 4 Sjostrom *et al.*, 1995[75]
1. Patient group Are the patients in the study similar to those of interest in England and Wales?	? Patient setting is from USA	? Patient setting is from The Netherlands	? Patient setting is from USA	? Patient setting is from Sweden
2. Healthcare system/setting Comparability of available alternatives?; similar levels of resources?; no untoward supply constraints?; institutional arrangements comparable?	✗ US private insurance	✗ Dutch perspective	✗ US perspective	✗ Swedish perspective
3. Treatment Comparability with clinical management?	? Treatment in USA	? Treatment in The Netherlands	? Treatment in USA	? Treatment in Sweden
4. Resource costs Comparability between study and setting/population of interest?	✗ US cost data	✗ Dutch costing in US$	✗ US cost data	✗ Swedish cost data
5. Marginal versus average costs What difference does this make? Are there real cost savings from averting co-morbidities (e.g. diabetes)?	✗	✗	✗	✗

?, unclear or unknown; ✔, judged item suitable to generalise to England and Wales with or without some re-adjustment; ✗, factor judged not suitable as either not possible to see how an adjustment could be made easily in short/medium term, or relevant data unavailable

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ISSN 1366-5278