Health Technology Assessment 2009; Vol. 13: No. 41

Appendices

Go to main text

The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation

J Picot, J Jones, JL Colquitt,
E Gospodarevskaya, E Loveman,
L Baxter and AJ Clegg

September 2009
DOI: 10.3310/hta13410

Health Technology Assessment
NIHR HTA programme
www.hta.ac.uk

How to obtain copies of this and other HTA programme reports
An electronic version of this publication, in Adobe Acrobat format, is available for downloading free of charge for personal use from the HTA website (www.hta.ac.uk). A fully searchable CD-ROM is also available (see below).

Printed copies of HTA monographs cost £20 each (post and packing free in the UK) to both public **and** private sector purchasers from our Despatch Agents.

Non-UK purchasers will have to pay a small fee for post and packing. For European countries the cost is £2 per monograph and for the rest of the world £3 per monograph.

You can order HTA monographs from our Despatch Agents:

– fax (with **credit card** or **official purchase order**)
– post (with **credit card** or **official purchase order** or **cheque**)
– phone during office hours (**credit card** only).

Additionally the HTA website allows you **either** to pay securely by credit card **or** to print out your order and then post or fax it.

Contact details are as follows:

HTA Despatch
c/o Direct Mail Works Ltd
4 Oakwood Business Centre
Downley, HAVANT PO9 2NP, UK

Email: orders@hta.ac.uk
Tel: 02392 492 000
Fax: 02392 478 555
Fax from outside the UK: +44 2392 478 555

NHS libraries can subscribe free of charge. Public libraries can subscribe at a very reduced cost of £100 for each volume (normally comprising 30–40 titles). The commercial subscription rate is £300 per volume. Please see our website for details. Subscriptions can be purchased only for the current or forthcoming volume.

Payment methods

Paying by cheque
If you pay by cheque, the cheque must be in **pounds sterling**, made payable to *Direct Mail Works Ltd* and drawn on a bank with a UK address.

Paying by credit card
The following cards are accepted by phone, fax, post or via the website ordering pages: Delta, Eurocard, Mastercard, Solo, Switch and Visa. We advise against sending credit card details in a plain email.

Paying by official purchase order
You can post or fax these, but they must be from public bodies (i.e. NHS or universities) within the UK. We cannot at present accept purchase orders from commercial companies or from outside the UK.

How do I get a copy of *HTA on CD*?

Please use the form on the HTA website (www.hta.ac.uk/htacd.htm). Or contact Direct Mail Works (see contact details above) by email, post, fax or phone. *HTA on CD* is currently free of charge worldwide.

The website also provides information about the HTA programme and lists the membership of the various committees.

Appendix 5

Data extraction tables: surgery versus non-surgical interventions

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Dixon *et al.* (2008)[117] Design: single centre, RCT Follow-up: 24 months	Country: Australia Number: Total 60, LAGB 30, Conventional (Con) therapy 30 Age (mean ± SD): LAGB 46.6 (7.4); Con therapy 47.1 (8.7) years Sex (male): LAGB 15 (50%), Con therapy 13 (43%) BMI (mean ± SD): LAGB 37.0 (2.7); Con therapy 37.2 (2.5) Weight, kg (mean ± SD): LAGB 105.6 (13.8); Con therapy 105.9 (14.2) Hypertension, no (%): LAGB 28 (93); Con therapy 27 (90) Metabolic syndrome, no (%): LAGB 29 (97%); Con therapy 29 (97%) Coronary artery disease, no (%): LAGB 0; Con therapy 1 (3) *Neck circumference, cm* (mean ± SD): LAGB 41.8 (4.0); Con therapy 42.4 (4.5) p = ns for all baseline characteristics *Other baseline characteristics linked to outcomes noted in results below* Characteristics of target population: aged 20–60 years, BMI of 30–40, diagnosed with clearly documented Type 2 diabetes within the previous 2 years, had no evidence of renal impairment or diabetic retinopathy, and were able to understand and comply with the study process Exclusion criteria: history of type 1 diabetes, diabetes secondary to a specific disease, previous bariatric surgery, history of medical problems such as mental impairment, drug or alcohol addiction, recent major vascular event, internal malignancy, or portal hypertension; or a contraindication for either study group. Also excluded if did not attend two initial information visits	1. LAGB in addition to the conventional-therapy programme 2. Conventional therapy. Best medical practice for treatment, education and follow-up of Type 2 diabetes. Visits at least every 6 weeks throughout the 2 years. Lifestyle modification programmes individually structured to reduce energy intake, fat (< 30%) and saturated fats, to encourage low glycaemic index and high-fibre foods. Physical activity advice to encourage 10,000 steps per day and 200 minutes per week of structured activity. Low-calorie diets and medications discussed with all participants and used in some cases	Primary outcome: Proportion of patients achieving remission of Type 2 diabetes (fasting plasma glucose < 126 mg/dl and HbA_{1c} < 6.2% without the use of oral hypoglycaemic agents or insulin) Secondary outcomes: % change in HbA_{1c} Weight loss Blood pressure Waist circumference Fasting lipids (including total cholesterol, triglycerides, and high-density lipoprotein cholesterol) Changes in medication use Changes in proportion with metabolic syndrome (as defined by the National Cholesterol Education Program Adult Treatment Panel III criteria) Changes in indirect measures of insulin resistance (using homeostatic model assessment method) Adverse events	Method of data analysis: states data analysed using an ITT analysis. Data expressed as mean (SD) and differences with 95% confidence intervals given Sample size/power calculation: selected to provide power of 80% to detect a 1% difference in HbA_{1c} at 2 years and for diabetes remission rates to be approximately 60% in the surgical group and 20% in the conventional-therapy group. This required a minimum of 27 patients in each study group. Paper states caution required as not powered for multiple outcome measures Conflict of interests: study funded by manufacturers of the technologies involved. Paper states they had no role in the design or conduct, data collection, analysis or interpretation of the study Other: 16/26 Con therapy participants who completed the 2 years elected to use a very-low-calorie diet (n = 11) or sibutramine (n = 7) at some stage

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Percentage weight loss (mean ± SD): LAGB 20.0% (9.4) at 2 years; Con therapy 1.4% (4.9), $p < 0.001$. Using BMI of 25 as ideal weight this represents a loss of 62.5% of excess weight in the LAGB group compared with 4.3% in the Con therapy group and a reduction in BMI from 36.9 to 29.5 compared with 37.1 to 36.6 in the two groups respectively *Weight loss, kg* (mean ± SD): LAGB 84.6 (15.8) [change –21.1 (10.5)]; Con therapy 104.8 (15.3) [change –1.5 (5.4)], difference (in change) between groups: –19.6 (95% CI –23.8 to –15.2), $p < 0.001$ Reported change in self-reported rates of physical activity and relationship with weight loss, but not data extracted *Waist circumference* (mean ± SD cm) at baseline: LAGB 114.1 (10.2); Con therapy 116.0 (10.0). At end point LAGB 95.8 (10.3) [change –17.9 (10.8)], Con therapy 112.7 (10.3) [change –4.0 (9.1)], difference (in change) between groups: –13.9 (95% CI –19.0 to –8.7), $p < 0.001$ *Waist to hip ratio* (mean ± SD cm) at baseline: LAGB 0.96 (0.09); Con therapy 0.96 (0.10). At end point LAGB 0.90 (0.06) [change –0.06 (0.06)], Con therapy 0.95 (0.08) [change –0.01 (0.06)]. Difference (in change) between groups: –0.05 (95% CI –0.07 to –0.007), $p = 0.02$	Remission of Type 2 diabetes at 2 years: LAGB 22/30 (73%); Con therapy 4/30 (13%), $p < 0.001$. Relative risk of remission for LAGB 5.5 (95% CI 2.2 to 14.0), $p < 0.001$. (ITT analysis). Text states this represented 76% and 15% remission rates among completers in the LAGB and conventional therapy groups respectively Data on the association between weight loss and lower HbA_{1c}/remission reported but not data extracted *Metabolic syndrome (NOT meeting criteria):* Baseline LAGB 1 (3%), Con therapy 1 (3%) 2 years LAGB 21 (70%), Con 4 (13%), $p < 0.001$ *HbA1c* (mean ± SD%) at baseline: LAGB 7.8 (1.2); Con therapy 7.6 (1.4). At end point LAGB 6.00 (0.82) [change –1.81 (1.24)]; Con therapy 7.21 (1.39) [change –0.38 (1.26)], difference (in change) between groups –1.43 [95% CI –2.1 to –0.80], $p < 0.001$ *Proportion with* $HbA_{1c} < 6.2\%$ at baseline: LAGB 2 (7%), Con therapy 4 (13%). At 2 years LAGB 24 (80%), Con therapy 6 (20%). Statistical analysis within group comparison only reported *Systolic blood pressure* (mean ± SD mmHg) at baseline: LAGB 136.4 (15.6); Con therapy 135.3 (14.4). At end point LAGB 130.4 [19.0) (change –6.0 (17.9)]; Con therapy 132.6 (17.7) [change –1.7 (14.2)], difference (in change) between groups: –4.3 (95% CI –13.6 to 5.1), $p = 0.37$ *Diastolic blood pressure* (mean ± SD mmHg) at baseline: LAGB 86.6 (9.4); Con therapy 84.5 (9.8). At end point LAGB 85.4 (7.0) [change –0.7 (11.1)], Con therapy 83.1 (8.5) [change –0.9 (11.1)], difference (in change) between groups: 0.2 (95% CI –5.4 to 6.0), $p = 0.92$ *Plasma glucose* (mean ± SD mg/dl) at baseline: LAGB 156.7 (38.5); Con therapy 158.0 (48.7). At end point LAGB 105.6 (30.3) [change –51.2 (37.6)]; Con therapy 139.6 (38.1) [change –18.4 (41.2)], difference (in change) between groups: –32.8 (95% CI –53.1 to –12.3), $p = 0.002$ *Plasma insulin* (median + IQR μIU/ml) at baseline: LAGB 19.7 (16.5–27.5); Con therapy 18.7 (13.7–30.7). At end point: LAGB 9.8 (4.7) [change –12.4 (8.4)]; Con therapy 24.1 (13.6) [change 1.0 (14.8)], difference (in change) between groups: –13.4 (95% CI –19.6 to –7.3), $p < 0.001$ *Total cholesterol* (mean ± SD mg/dl) at baseline: LAGB 201.8 (32.7); Con therapy 198.2 (56.7). At end point: LAGB 205.4 (46.6) [change 3.6 (51.6)]; Con therapy 197.8 (59.3) [change -0.4 (31.4)], difference (in change) between groups: 4.0 (95% CI –18.8 to 26.0), $p = 0.72$	*Adverse events* LAGB: one superficial wound infection, two gastric pouch enlargement at 10 months (both had revisional surgery to replace band), one band removal after 15 days because of eating difficulties and regurgitation, one patient febrile episodes, one minor hypoglycaemic episode, one gastrointestinal tract intolerance to metformin Con therapy: two minor gastrointestinal tract adverse events (not defined), one persistent diarrhoea with metformin, one vasculitic rash (possibly due to rosiglitazone), one multiple hypoglycaemic episodes, one angina and transient cerebral ischaemic episode, two intolerant to very low-calorie meal replacement Mean procedure time 54 minutes (SD 10.8, range 40–74 minutes) Hospital admissions for LAGB: 23 (80%) stayed in for 1 day; five (17%) for 2 days; one (3%) for 4 days (band was removed on day 15 due to intolerance)

continued

Table of results *(continued)*

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
	Triglycerides (mean ± SD mg/dl) at baseline: LAGB 190.6 (106.6); Con therapy 188.7 (111.8). At end point: LAGB 118.9 (79.7) [change −71.7 (92.9)]; Con therapy 186.7 (127.2) [change −2.1 (120.6)], difference (in change) between groups: −69.6 (95% CI −125.3 to −13.6), $p = 0.02$ *HDL-C* (mean ± SD mg/dl) at baseline: LAGB 47.1 (10.1); Con therapy 48.1 (11.1). At end point: LAGB 59.7 (13.6) [change 12.6 (9.8)]; Con therapy 50.7 (12.1) [change 2.6 (6.1)], difference (in change) between groups: 10.0 (95% CI 5.8 to 14.2), $p < 0.001$ *Total cholesterol to HDL-cholesterol ratio* (mean ± SD mg/dl) at baseline: LAGB 4.41 (0.87); Con therapy 4.23 (1.11). At end point: LAGB 3.58 (1.00) [change −0.82 (1.9)]; Con therapy 4.1 (1.4) [change −0.14 (1.04)], difference (in change) between groups: −0.68 (−1.24 to −0.14), $p = 0.02$ Use of diabetes medication (numbers): *No medication*. At baseline: LAGB 2, Con therapy 4. At 2 years LAGB 26, Con therapy 8 *Metformin use*. At baseline: LAGB 28, Con therapy 26. At 2 years LAGB 3, Con therapy 18. Statistical analysis within group comparison only reported *Other hypoglycaemic use*. At baseline: LAGB 9, Con therapy 8. At 2 years LAGB 1, Con therapy 7. Statistical analysis within group comparison only reported *Insulin use*. At baseline: LAGB 1, Con therapy 0. At 2 years LAGB 0, Con therapy 3 Use of non-diabetes medication (numbers): *Antihypertensive agents*. At baseline LAGB 20/29, Con therapy 15/26. At 2 years LAGB 6/29, Con therapy 15/26. Statistical analysis within group comparison only reported *Lipid-lowering agents*. At baseline LAGB 12/29, Con therapy 8/26. At 2 years LAGB 4/29, Con therapy 7/26. Statistical analysis within group comparison only reported HOMA IR (insulin resistance by homeostatic model assessment) also reported at end point but not reported here	

BMI, body mass index; CI, confidence interval; HbA_{1c}, glycosylated haemoglobin; HDL-C, high-density lipoprotein-cholesterol; IQR, inter quartile range; ITT, intention to treat; LAGB, laparoscopic adjustable gastric banding; ns, not statistically significant; SD, standard deviation.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Yes	Randomisation was computer derived, with blocking into three groups to allow for orderly recruitment into both study groups and to reduce the risk of uneven recruitment late in the series
Allocation concealment?	Unclear	Not reported
Blinding of outcome assessors?	No	States study not blinded
Blinding of participants on self-reported outcomes?	n/a	Not blinded, but no self-reported measures
Incomplete outcome data addressed? Weight loss	Yes	Of the 30 randomised to LAGB one withdrew preoperatively. Of the 30 randomised to conventional therapy, four withdrew after randomisation. Reasons not given
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	Yes	As above
Free of selective outcome reporting?	Unclear	All the outcomes mentioned in the methods section seem to be reported as results, although 'physical activity' is not mentioned in the methods but results are reported. Protocol not available
Free of other sources of bias?	No	Participants took part in at least 3 months of run-in where alterations to eating, exercise, glucose self-monitoring and medications were suggested. Compliance was measured during this time. The endocrinologist then independently determined when a participant was ready for randomisation Of 158 potentially eligible participants only 60 were randomised. Reasons for exclusions before randomisation were noted No statistically significant differences in baseline characteristics Block randomisation used in an unblinded trial, which may be possible to predict assignments

LAGB, laparoscopic adjustable gastric banding; n/a, not applicable; QoL, quality of life.

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Mingrone *et al.* 2002[119] Design: RCT, single centre Follow-up: 1 year	Country: Italy Number: Total 79, BPD 46, Diet 33 Age: 30–45 years Sex: 27 men (BPD 15, Diet 12), 52 women (BPD 31, Diet 21) BMI: Women, Diet 48.4 (8.9), BPD 48.3 (6.3). Men, Diet 47.8 (8.8), BPD 48.0 (5.4) Mean weight (SD), kg: women, diet 121.6 kg (24.1), BPD 125.3 kg (12.8). Men, diet 147.3 kg (26.8), BPD 151.8 kg (17.1) Characteristics of target population: Morbidly obese. Non smoking, normal electrocardiogram at rest and during exercise test Exclusion criteria: Pregnancy, history or diagnosis of diabetes, heart disease, hypertension or other chronic diseases, hormone replacement therapy, chronic steroid therapy, history of alcohol or drug abuse, glucose intolerance (2 hour glucose level > 140 mg/dl after 75 g oral glucose load and of stable weight, within ± 2 kg, 6 months before testing)	1. Biliopancreatic diversion (BPD) 2. Diet (20 kcal/kg fat-free mass, 55% carbohydrates, 30% fat, 15% proteins). Modified every 6 months according to analysis of fat-free mass	Mean weight BMI Fat-free mass Fat mass Metabolic variables reported but not extracted	*Allocation to treatment groups:* Randomised, method not reported *Blinding of outcome assessors:* Not reported *Comparability of treatment groups:* Baseline weight, BMI, fat-free mass, fat mass presented, no statistical comparisons made. Groups appear to be similar *Method of data analysis:* Means and SD presented. Student's *t* test used to compare the same groups before and after BPD or diet *Sample size/power calculation:* Not reported *Attrition/dropout:* None

BMI, body mass index; SD, standard deviation.

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Mean weight (SD): Women. Baseline: Diet 121.6 kg (24.1), BPD 125.3 kg (12.8); 1 year: Diet 114.5 kg (24.5), BPD 90.2 kg (15.0)[a] Men. Baseline: Diet 147.3 kg (26.8), BPD 151.8 kg (17.1); 1 year: Diet 138.2 kg (27.1), BPD 99.7 kg (7.0)[a] *Mean BMI (SD):* Women. Baseline: Diet 48.4 (8.9), BPD 48.3 (6.3); 1 year: Diet 43.8 (7.7), BPD 35.2 (7.6)[a] Men. Baseline: Diet 47.8 (8.8), BPD 48.0 (5.4); 1 year: Diet 44.8 (8.4), BPD 30.4 (3.5)[a] *Fat-free mass (SD)* Women. Baseline: Diet 58.3 kg (8.8), BPD 59.3 kg (5.6); 1 year: Diet 56.7 kg (8.8), BPD 50.5 kg (4.7)[a] Men. Baseline: Diet 87.3 kg (11.4), BPD 88.7 kg (8.1); 1 year: Diet 83.7 kg (11.8) BPD 74.2 kg (5.4)[a] *Fat mass (SD)* Women. Baseline: Diet 63.3 kg (16.2), BPD 65.9 kg (10.2); 1 year: Diet 57.8 kg (16.5), BPD 39.8 kg (12.7)[a] Men. Baseline: Diet 60.0 kg (15.6), BPD 63.1 kg (10.2); 1 year: Diet 54.6 kg (15.6), BPD 25.5 kg (2.7)[a]	Not reported	Not reported

BMI, body mass index; BPD, biliopancreatic diversion; QoL, quality of life; SD, standard deviation.
Maximal percentage reduction of body fat (60%) and fat-free mass (17%) observed in men.
a $p < 0.0001$ before vs after BPD.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Not reported
Allocation concealment?	Unclear	Not reported
Blinding of outcome assessors?	Unclear	Not reported
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Yes	No losses
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	Adverse effects not reported
Free of other sources of bias?	Unclear	

n/a, not applicable; QoL, quality of life.

DOI: 10.3310/hta13410

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
O'Brien (2006)[115,116] Design: single centre, RCT Follow-up: 24 months	Country: Australia Number: total 80, LAGB $n = 40$, non-surgical $n = 40$. One patient assigned to LAGB withdrew from the study before surgery and declined to be followed further LAGB $n = 40$, non-surgical $n = 40$ Age [mean (SD)]: LAGB 41.8 (6.4) years; non-surgical 40.7 (7.0) Sex (male%): LAGB 25; non-surgical 22.5 BMI [mean (SD)]: LAGB 33.7 (1.8), 95% CI 32.9 to 34.4; non-surgical 33.5 (1.4) 95% CI 32.7 to 34.3, $p = 0.71$ Weight [mean (SD) kg]: LAGB 96.1 (11.2); non-surgical 93.6 (11.9) Different baseline weight data are given in Table 2 of O'Brian[115] [mean (95% CI) kg]: LAGB 95.0 (94.1–95.9); non-surgical 94.8 (93.9–95.7) $p = 0.88$ Mean Short Form-36 QoL domain scores below estimated from figure by reviewer (note 95% CIs presented in figure but not possible to extract accurately) *Physical function*: LAGB 65; non-surgical 74 *Physical role*: LAGB 63; non-surgical 70 *Pain*: LAGB 68; non-surgical 76 *General health*: LAGB 52; non-surgical 59 *Energy*: LAGB 42; non-surgical 42 *Social functioning*: LAGB 65; non-surgical 72 *Emotional role*: LAGB 63; non-surgical 65 *Mental health*: LAGB 65; non-surgical 65	1. Laparoscopic adjustable gastric band (Lap-Band system) (LAGB) 2. Intensive non-surgical programme (Non-surgical) The non-surgical programme centred on the use of behavioural modification, very-low-calorie diet (VLCD), and pharmacotherapy with education and professional support on appropriate eating and exercise behaviour. The programme began with a 6-month VLCD (500–550 kcal/day) which used Optifast for 12 weeks, then over 4 weeks some VLC meals with 120 mg orlistat before the non-VLC meals, and then 120 mg orlistat before all meals. The 6-month intensive phase was followed by further courses of VLCD or orlistat as tolerated, as well as continuous behavioural, dietary and exercise advice. Physician saw each patient every 2 weeks during the VLCD programme, and every 4–6 weeks during the rest of the study	Primary end points related to weight change: change in absolute weight (kg), body mass index, percentage of initial weight lost and excess weight lost, and the percentage of patients who lost more than 50% of excess weight at 2 years Secondary end points were health, quality of life and side effects of treatment (adverse drug reactions, protocol violations, perioperative problems, need for revisional surgery) Health status was also documented at baseline and reassessed at later time points Related paper[116] reports on body composition measurements for those participants who completed all of the body composition studies (voluntary aspect of the study)	Method of data analysis: States an intention-to-treat analysis was used Continuous data expressed as means (SDs). $p < 0.05$ considered statistically significant Sample size/power calculation: set on the basis of weight loss, expressed as percentage of excess weight lost, at 2 years after entry into the study. From existing data, it was expected that the mean excess weight lost for the surgical programme would be 54%. A difference of at least 20% (either < 44% or > 64%) would be clinically significant. To achieve 80% power of detecting this 20% difference (at a two-sided significance level of 5%), 72 patients in total would be required. A total initial recruitment of 80 patients was planned Potential conflict of interests: stated (consultancies and grants received)

Study	Participants	Interventions	Outcomes	Notes
	States no significant differences between the groups at baseline, but *p* values not shown Recruitment took place between May 2000 and November 2001. Final patient follow-up at 2 years after entry complete by November 2003 Characteristics of target population: age between 20 and 50 years, BMI 30 to 35 with identifiable problems, including an obesity-related comorbid condition (such as hypertension, dyslipidaemia, diabetes, obstructive sleep apnoea, or gastro-oesophageal reflux disease), severe physical limitations, or clinically significant psychosocial problems associated with their obesity; had attempted to reduce weight over at least the previous 5 years; could understand the options offered and the randomisation process; and were willing to comply with the requirements of each programme Exclusion criteria: candidates with a history of bariatric surgery or medical problems that contraindicated treatment in either study group, such as impaired mental status, drug or alcohol addiction, or portal hypertension. Participants were also excluded if they had undergone an intensive, physician-supervised programme that used very-low-calorie diets or pharmacotherapy or if they did not attend the two initial patient information visits	Common programme: All patients were instructed and encouraged to follow appropriate lifestyle behaviour of good eating practices and increased exercise and activity. All participants were encouraged to exercise for at least 200 minutes a week		Supported by a grant from the Department of Surgery, Monash University. Equipment devices and products supplied by IN-AMED health (manufacturer of the Lap-Band system); Novartis (manufacturer of Optifast); and US Surgical Corp (manufacturer of disposable laparoscopic instruments)

BMI, body mass index; CI(s), confidence interval(s); LAGB, laparoscopic adjustable gastric banding; SDs, standard deviations.

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Weight at 12 months [mean (95% CI) kg]: LAGB 76.3 (74.1–78.5), non-surgical 85.3 (83.0–87.5). $p < 0.001$	SF-36 QoL domain scores	*Total of adverse events* [Value (%)]: LAGB 7/39 (18); non-surgical 18/31 (58)
Weight at 18 months [mean (95% CI) kg]: LAGB 75.2 (73.1–77.4), non-surgical 87.7 (79.9–83.0). $p < 0.001$	At 2 years the non-surgical group had statistically significant improvements in three domain scores: physical function, vitality and mental health. The LAGB group had statistically significant improvements in all eight domain scores. The change in domain scores between baseline and 2 years shows a statistically significantly greater improvement in five of the eight domains in the LAGB group than in the non-surgical group	*5-mm port site infection* [Value (%)]: LAGB 1/39 (2.6); non-surgical n/a
Weight at 24 months [mean (95% CI) kg]: LAGB 74.5 (72.4–76.7), non-surgical 89.5 (80.5–83.6). $p < 0.001$		*Acute cholecystitis* [Value (%)]: LAGB 1/39 (2.6); non-surgical 4/31 (13)
BMI at 12 months [mean (95% CI)]: LAGB 27.0 (26.2–27.8), non-surgical 29.9 (29.1–30.8). $p < 0.001$		*Prolapse, posterior (laparoscopic revision)* [Value (%)]: LAGB 4/39 (10); non-surgical n/a
BMI at 18 months [mean (95% CI)]: LAGB 26.7 (25.9–27.5), non-surgical 30.9 (30.0–31.8). $p < 0.001$	Mean SF-36 QoL domain scores below estimated from figure by reviewer (note 95% CIs presented in figure) at 2 years	*Loss to follow-up* [Value (%)]: LAGB 1/39 (2.6); non-surgical 5/31 (12.5)
BMI at 24 months [mean (95% CI)]: LAGB 26.4 (25.6–27.2), non-surgical 31.5 (30.6–32.4). $p < 0.001$	*Physical function:* LAGB 90; non-surgical 87*	*Operative interventions* [Value (%)]: LAGB 5/39 (13); non-surgical 4/31 (13)
Percentage of initial weight lost at 2 years (95% CI): LAGB 21.6% (19.3 % to 23.9%); non-surgical 5.5% (3.2% to 7.9%)	*Physical role:* LAGB 92; non-surgical 70*	*Intolerance to very-low-calorie diet* [Value (%)]: LAGB n/a; non-surgical 1/31 (3)
Percentage of excess weight lost at 12 months [mean (95% CI)]: LAGB 78.6 (69.2–88.1); non-surgical 41.1 (31.2–50.9). $p < 0.001$	*Pain:* LAGB 83; non-surgical 78	*Intolerance to orlistat* [Value (%)] LAGB n/a; non-surgical 8/31 (26)
Percentage of excess weight lost at 18 months [mean (95% CI)]: LAGB 83.6 (74.2–93.1); non-surgical 29.01 (19.0–38.9). $p < 0.001$	*General health:* LAGB 73; non-surgical 68*	
Percentage of excess weight lost at 2 years [mean (95% CI)]: LAGB 87.2 (77.7–96.6); non-surgical 21.8 (11.9–31.6) ($p < 0.001$)	*Vitality (note this is 'Energy' on the figure):* LAGB 66; non-surgical 57*	
Proportion achieving excess weight loss greater than 50% at 2 years: 33/39 (85%) LAGB, 8/31 (26%); non-surgical (chi-square; $p < 0.001$)	*Social functioning:* LAGB 85; non-surgical 81	
Proportion achieving satisfactory weight loss (greater than 25% of excess weight lost): 39/40 (98%) LAGB, 14/40 (35%); non-surgical ($p < 0.001$)	*Emotional role:* LAGB 92; non-surgical 72*	
39 (98%) of LAGB participants, and 33 (83%) of non-surgical participants completed the 2-year follow-up programme	*Mental health:* LAGB 76; non-surgical 72	
	*Statistically significantly greater improvement in LAGB vs non-surgical group ($p < 0.05$)	
	Comorbidity outcomes	
	Metabolic syndrome: LAGB before treatment $n = 15/40$ (37.5%), 2 years after treatment $n = 1/39$ (2.7%). non-surgical before treatment $n = 15/40$ (37.5%), 2 years after treatment $n = 8/33$ (24%). (Difference between groups at end point $p = 0.006$.) Reduction within group $p < 0.001$ for surgical group, $p = 0.22$ for non-surgical group	
	Paper also reports data on BP, cholesterol, data not extracted	

BP, blood pressure; CI, confidence interval; LAGB, laparoscopic adjustable gastric banding; n/a, not applicable; QoL, quality of life.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Yes	Computer-derived random allocation sequence prepared at the trial office. No blocking or stratification
Allocation concealment?	Yes	Trial co-ordinator contacted the trial office by telephone to obtain the allocation
Blinding of outcome assessors?	No	States that the study was not blinded (outcomes assessors not specified but assume not blinded)
Blinding of participants on self-reported outcomes?	No	Participants could not have been blinded to treatment.
Incomplete outcome data addressed? Weight loss	Unclear	Withdrawals noted in both groups: one LAGB participant withdrew preoperatively, five non-surgical participants withdrew (weeks 4, 6, 8, 10 and 52), and two non-surgical participants moved overseas. Uneven withdrawals between groups but as reasons not provided for all withdrawals it is unclear whether withdrawals were related to the outcome. States intention-to-treat analysis conducted but in the surgical group the one patient who withdrew preoperatively was not included in the analysis
Incomplete outcome data addressed? QoL	Unclear	As above, however for QoL data were analysed only for those who completed the study (case analysis, LAGB $n = 39/40$, non-surgical $n = 33/40$)
Incomplete outcome data addressed? Comorbidity	Unclear	As above with a case analysis
Free of selective outcome reporting?	Unclear	Study protocol not available. Outcomes listed in the methods reported on
Free of other sources of bias?	Unclear	Study appears free of other sources of bias

LAGB, laparoscopic adjustable gastric banding; QoL, quality of life.

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Buddeberg-Fischer *et al.* (2006)[105,133] DESIGN: Prospective cohort study with subjects recruited from specialised surgical units (one paper[32] states three units, the other paper[105] states two units) INTERVALS [mean (SD)]: Baseline to first follow-up 25 months (6.19) Surgery to first follow-up 10 months (5.67) (less than 12 months so not data extracted) Surgery to second follow-up 3.2 years (1.3), range 0.28–5.8 years Interval Recruitment took place from 1998 to 2000	Country: Switzerland Number: Total $n = 93$. Surgery $n = 63$, no surgery $n = 30$ [131 approached, a total of 119 at first follow-up (Surgery = 9, no surgery = 50, not extracted), 93 at second follow-up] Total = 93 BMI [mean (SD)]: Surgery ($n = 63$), 44.7 (6.1) [LGBP ($n = 23$), 47.3 (7.8); LAGB ($n = 40$), 43.4 (4.5)]; no surgery ($n = 30$) 42.9 (5.5) Sex (M : F) 23 : 70 Mean age 43.5 years (SD 9.8, range 21.65) States no difference in age and gender Weight: not reported Duration of morbid obesity $n = 119$ [mean, (range)]: 20 years (4–45 years) Medication for weight loss: 96/119 (81%) Medication for obesity-related comorbidity: 50/119 (42%) Antidepressants: 21/119 (18%) (Data above not reported for each group) HADS – Anxiety [Mean (SD)]: surgery 5.86 (4.14); no surgery 7.10 (3.99) HADS – Depression [Mean (SD)]: surgery 6.62 (4.56); no surgery 6.23 (3.62) BSQ (Mean (SD)): surgery 12.11 (9.10); no surgery 12.47 (9.61) PAssQ [Mean (SD)]: surgery 1.92 (1.86); no surgery 2.17 (2.17) Characteristics of target population: Patients applying for Surgery. Patient has already tried to lose weight by strict dieting for 2 years, and has a BMI > 40, or > 35 with substantial comorbidity Exclusion criteria: Being over 60 years of age[105]	1. Surgery group: laparoscopic gastric banding (Lap-band) (LAGB) $n = 57$ (not specified if band adjusted), laparoscopic Roux-en-y gastric bypass (LRYGBP) $n = 12$ (two after debanding) 2. No Surgery	BMI,% BMI change between time points,% EWL. Medication use for weight reduction, physical comorbidity or psychiatric comorbidity, Physical and psychological health, HADS anxiety and HADS depression scores, BSQ scores and PAssQ scores Also reported but not data extracted are outcomes on Doctor consultations,[105,133] employability,[105] Time off work in last 3 months,[105] Nutritional habits,[105] Attitude toward the decision to have surgery,[105] and Reasons against opting to have surgery[105] Psychosocial Stress and Symptom Questionnaire (PSSQ): this consisted of three validated instruments. The Hospital Anxiety and Depression Scale (HADS), the Binge Scale Questionnaire (BSQ), and the Psychosocial Assessment Questionnaire (PAssQ). HADS contains 14 items on a four-point response scale, summed up to separate scores on anxiety and depression; scale scores of less than 8 are in the normal range, 8–10 indicates possible psychiatric morbidity, and scores over 10 probable mood disorder. The BSQ consists of nine items. A sum score which is an indicator of the severity of binge eating is computed from the nine items. The PAssQ consists of 11 dichotomous items which are not specifically obesity-related. A sum score which is an indicator of psychosocial stress is computed from the 11 items	Method of data analysis: Descriptive statistics by means and standard deviations, and by sample sizes and percentages. ITT not used where there are missing data. *p*-value that would be considered statistically significant not noted. Sample size/power calculation: not reported Conflict of interests: not reported Patient flow is described in a figure[105] which indicates that patients at the second follow-up are different to those at the first follow-up as 16 patients changed group (two Surgery group to no Surgery (debanded), nine no Surgery to Surgery (RYGBP), and five Surgery LAGB to RYGBP) One study reports[133] that all patients included in the study met the criteria of having already tried to lose weight by strict dieting for 2 years, and having a BMI > 40, or > 35 with substantial comorbidity. The same reference later states that of the 13 male subjects and 37 female subjects who did not receive surgery, 23.1% males and 16.2% females gave the reason against surgical treatment that their BMI was under the limit for morbid obesity. However, the second study report[105] states that all but three included patients met the criteria: one had a BMI of 31.6, and two were over 60 years of age. In all three cases there were special indications for Surgery.

BMI, body mass index; EWL, excess weight loss; ITT, intention to treat; SD, standard deviation.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
BMI [mean (SD)] $n = 93$ Surgery ($n = 63$): 34.9 (5.5); no surgery ($n = 30$): 40.6 (7.4). Between-group comparison $p = 0.09$ Group × time interaction $p < 0.001$ *BMI change* [mean (SD)]: Surgery ($n = 63$): −21.0 (13.4); no surgery ($n = 30$): −5.5 (11.1). Between-group comparison $p < 0.001$ % *EWL* [mean (SD)]: Surgery ($n = 63$): 42.2 (23.4); no surgery ($n = 30$): 11.5 (25.8). Between-group comparison $p < 0.001$ *BMI* [mean (SD)] $n = 63$ LGBP ($n = 23$): 32.9 (3.7); LAGB ($n = 40$): 35.8 (6.1). Between-group comparison $p = 0.68$ Group × time interaction $p < 0.001$ *BMI change* [mean (SD)]: LGBP ($n = 23$): −27.7 (12.6); LAGB ($n = 40$): −17.2 (12.5). Between-group comparison $p = 0.002$ % *EWL* [mean (SD)]: LGBP ($n = 23$): 52.8 (17.0); LAGB ($n = 40$): 36.0 (24.5). Between-group comparison $p = 0.005$	*Medication for obesity (number of different drugs) in the last 3 months* [mean, median (range)]: Surgery ($n = 59/63$): 0.03, 0 (0–1); no surgery ($n = 30/30$): 0.32, 0 (0–2). Between-group comparison $p < 0.001$ *Medication for somatic comorbidity (number of different drugs) in the last 3 months* [mean, median (range)]: Surgery ($n = 59/63$): 2.29, 2 (0–15); no surgery ($n = 30/30$): 2.10, 1 (0–9). Between-group comparison $p = 0.98$ *Medication for psychiatric comorbidity (number of different drugs) in the last 3 months* [mean, median (range)]: Surgery ($n = 59/63$): 0.17, 0 (0–3); no surgery ($n = 30/30$): 0.6, 0 (0–2). Between-group comparison $p = 0.25$ *Assessment of overall physical health (good)* [n (%)]: Surgery ($n = 59/63$): 46 (79.3); no surgery ($n = 30/30$): 20 (64.5). Between-group comparison $p = 0.10$ *Assessment of overall mental health (good)* [*n* (%)]: Surgery ($n = 59/63$): 45 (77.6); no surgery ($n = 30/30$): 21 (67.7). Between-group comparison $p = 0.22$ *HADS – Anxiety Score* [mean (SD)] Surgery ($n = 63$): 5.76 (4.27); no surgery ($n = 30$): 6.53 (4.29). Between-group comparison $p = 0.21$ *HADS – Depression Score* [mean (SD)] Surgery ($n = 63$): 4.67 (4.58); no surgery ($n = 30$): 4.33 (3.01). Between-group comparison $p = 0.65$ *BSQ Score* [mean (SD)] Surgery ($n = 63$): 7.16 (9.68); no surgery ($n = 30$): 8.87 (9.52). Between-group comparison $p = 0.55$ *PAssQ Score* [mean (SD)] Surgery ($n = 63$): 2.11 (2.04); no surgery ($n = 30$):1.87 (2.08). Between-group comparison $p = 0.99$	$n = 119$. Reoperations 7/69 (LAGB to RYGBP = 5, LAGB to debanding = 2)

BMI, body mass index; BSQ, Bing Scale Questionnaire; EWL, excess weight loss; HADS, hospital anxiety and depression scale; LAGB, laparoscopic adjustable gastric banding; LGBP, laparoscopic gastric bypass; PAssQ, Psychosocial Assessment Questionnaire; SD, standard deviation.

Quality criteria (CRD Report 4)

Quality item	Yes/No/Uncertain	Methodological comments
Cohort studies		
1. Is there sufficient description of the groups and distribution of prognostic factors?	No	The characteristics of the whole sample are described, but the characteristics of each group are only reported separately for BMI and psychosocial stress and symptoms
2. Are the groups assembled at a similar point in their disease progression?	Uncertain	For the study sample as a whole subjects mean duration of morbid obesity was 20 years (range 4–45 years). However, this was not reported for each group separately
3. Is the intervention/treatment reliably ascertained?	Yes	Although there may be minor reporting errors, on the whole it is clear how many people received which intervention
4. Were the groups comparable on all important confounding factors?	Uncertain	Not reported
5. Was there adequate adjustment for the effects of these confounding variables?	No	
6. Was outcome assessment blind to exposure status?	No	All measures, including BMI, were self-reported
7. Was follow-up long enough for the outcomes to occur?	Yes	
8. What proportion of the cohort was followed-up?	Yes	Proportion of cohorts followed up reported. 119/131 at first follow-up, 93/131 at second follow-up. Dropouts noted but reasons not always reported
9. Were dropout rates and reasons for dropout similar across intervention and unexposed groups?	No	Baseline ($n = 131$), 12 dropouts before first follow-up ($n = 119$) not reported separately for each group. After first follow-up ($n = 119$) a further 26 dropouts: surgery 13/69 (19%) (RYGBP 3/12, LAGB 10/57), no surgery 13/50 (26%), occurred before the second follow-up ($n = 93$). In addition, of the $n = 93$ assessed at the second follow-up, some had switched status: surgery LAGB reoperation to RYGBP $n = 5$, surgery LAGB to debanding (joined no surgery group) $n = 2$, no surgery to surgery (RYGBP) $n = 9$. Reasons for dropouts from each group not reported. In addition to the dropouts, data on four patients were missing from the surgery group for some outcomes (doctor consultations, etc.)

BMI, body mass index; LAGB, laparoscopic gastric banding; RYGBP, Roux-en-Y gastric bypass.

DOI: 10.3310/hta13410

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
SOS 1997 to 2007[82,83,85–100] Design: Multicentre, cohort study with matched controls Follow-up: (Length of follow-up and sample size varies with publication of different outcomes) Weight loss 10 years Diabetes 8 years Blood pressure 8 years HRQoL 10 years Lipid disturbances 2 years Comorbidities 10 years Medication use 6 years Cancer incidence average 11 years	Country: Sweden Baseline characteristics, mean (SD) unless stated Karason 2000,[85] weight loss outcomes at 2 years: Number: total 2620. After mortality, dropouts and data pending: Surgical 1210; controls 1099 Age: surgical 47 years (SD 6), control: 49 years (SD 6) Sex: surgical 67% women, control 67% women Weight: surgical 121 kg (SD 17), control 114 kg (SD 16) BMI: surgical 42.2 (SD 4.4); control 39.7 (SD 4.4) Sjostrom 2000,[89] weight loss/diabetes/blood pressure outcomes: Number: total 483, surgical 251, control 232 Age (mean): surgical 46 yrs (6), control 47 years (6) Sex: surgical 65.9% female, control 65.9% female Weight: surgical 119.7 kg (15.6), control 117.4 kg (16.6) BMI: surgical 41.6 (3.9), control 41 (4.7) Karlsson 1998,[86] HRQoL at 2 years: Number: total 974, surgical 487, control 487 Age (mean): surgical 46.6 years (95% CI 46.1 to 47.1), control 47.7 years (95% CI 47.2 to 48.3) Sex: surgical 67% female, control 67% female. Sjostrom 1999,[88] lipid disturbances: Number: total 1479, surgical 767, control 712 Age: surgical 47 years (5.8), control 48.6 years (6.3) Sex: surgical 69% female, control 68% female Weight: surgical 120.5 kg (16), control 114.1 kg (17) BMI: surgical 42.1 (4.3), control 39.8 (4.6) Togerson 2003,[96] gallstones, gall bladder disease and pancreatitis: Number: total 2682, surgical 1422, control 1260 Age, years, Men: surgical 47.3 (5.7), controls 48.4 (6.1), $p = 0.005$. Women: surgical 47.1 (5.9), controls 48.3 (6.3), $p < 0.001$ Sex (M : F): surgical 468 : 954, controls 418 : 842.	1. Surgical: a. Vertical banded gastroplasty (VBG) b. Gastric banding (fixed or variable) (Gband) c. Gastric bypass (GBP) 2. Controls: conventional treatment, not standardised, best non-surgical options available at the time	Weight loss (kg) BMI Blood pressure, systolic and diastolic Health-related quality of life (HRQoL) Diabetes Lipid disturbances Gallstones, Gall bladder disease, pancreatitis Medication for CVD and diabetes Pharmaceutical costs (not extracted) Cancer incidence	*Allocation to treatment groups:* Patients could volunteer for conventional or surgical treatment. For each surgical case a computerised matching procedure selects the optimal control from a registry taking 18 different variables into account [inc. gender (absolute match) age, weight, height, waist and hip circumferences, systolic blood pressure, serum cholesterol and triglyceride concentrations, smoking, diabetes, pre/postmenopausal, four psychosocial variables with known associations with mortality, two personality traits related to treatment preferences] *Blinding:* Not applicable *Comparability of treatment groups:* Average interval between matching of controls and inclusion into study (surgery) was 0.8 years (SD 7). During this period, surgical group gained weight and control group lost weight, resulting in average difference of 6.4 kg ($p < 0.001$). At inclusion, 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). Also reports higher BMI ($p < 0.001$), blood pressure ($p < 0.001$) and energy intake ($p < 0.001$) in surgical patients

continued

Characteristics of study *(continued)*

Study	Participants	Interventions	Outcomes	Notes
	Height, m, men: surgery 1.79 (0.07), controls 1.80 (0.07), $p = 0.263$. Women: surgery 1.64 (0.06), controls 1.65 (0.06), $p = 0.207$. Weight, kg, men: surgery 132.4 (16.9), controls 125.3 (16.6), $p < 0.001$. Women: surgery 115.7 (13.4), controls 110.4 (14.3), $p < 0.001$. BMI, men: surgery 41.2 (4.7), control 38.8 (4.7), $p < 0.001$. Women: surgery 42.8 (4.1), controls 40.6 (4.4), $p < 0.001$. Agren 2002,[136] medication use Number: total 965, surgery 510, control 455. Mean age, yrs: surgery 47.1 (5.8), control 48.6 (6.1). Sex,% of men: surgery 31.0, control 31.0. Mean BMI: surgery 41.8 (4.1), control 39.9 (4.6). % on medication for CVD: surgery 29.4, control 27.5 Diabetes: surgery 6.3, control 4.6. Sjostrom 2007,[99] mean follow-up of 10.9 (3.5) years. Number: total 4047, surgery 2010, control 2037 Mean age, yrs: surgery 47.2 (5.9), control 48.7 (6.3), $p < 0.001$ Sex (M:F): surgery 590/1420, control 590/1447, $p = 0.79$ Weight: surgery 121.0 (16.6), control 114.7 (16.5), $p < 0.001$ Height: surgery 1.69 (0.09), control 1.69 (0.09), $p = 0.68$ Mean BMI: surgery 42.4 (4.5), control 40.1 (4.7), $p < 0.001$ Other baseline measures reported, but not extracted. Karlson 2007,[100] HRQoL at 10 years: Number: total 1703, of these 1276 (74.9%) were available for analysis. surgery 655 (of 851), control 621 (of 852) Mean age: surgery 47.0 (5.7), control 48.4 (6.7) years Weight: surgery 120.1 (16.5) kg, control 113.9 (16.8) kg BMI: surgery 41.9 (4.2), control 39.9 (4.6) HRQoL (all measures validated): Current health perceptions (scale 0–100, high score = well-being): surgery 51.8 (24.1), control 58.8 (24.8) Social interaction (scale 0–100, high score = dysfunction): surgery 11.7 (11.0), control 7.2 (9.7)			*Method of data analysis:* Analysis on completers except where ITT specified. When all included patients were analysed, missing data 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. *t* tests, paired *t* tests and ANOVA used according to the general linear model used. ANOVA used to test differences between surgical procedure. For comparisons of changes in proportions between two groups, a two-sample McNemar test was used. Unconditional logistic regression was used for comparing incidences in the two treatment groups, because these were matched on a group level and not on an individual level. HRQoL: 15 reversals and eight 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 approx. 4 years, which they report to suffice 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

DOI: 10.3310/hta13410

Study	Participants	Interventions	Outcomes	Notes
	Obesity-related problems (scale 0–100, high score = dysfunction): surgery 58.0 (27.0), control 40.9 (26.8) Overall mood (scale 1–4, high score = well-being): surgery 2.93 (0.59), control 3.06 (0.60) Depression (scale 0–21, high score = symptoms): surgery 5.1 (3.6), control 4.2 (3.3) Anxiety (scale 0–21, high score = symptoms): surgery 6.1 (4.6), control 5.4 (4.5) N.B.: Statistical analysis for differences in baseline undertaken on those completing and those not completing, or between these two groups and a third 'reference group', so not reported here Sjostrom 2004,[97] comorbidity data at 2 and 10 years Those completing 2 years: Number: total 3505, surgery 1845, control 1660 Mean age: surgery 47.4 (5.9), control 48.8 (6.2), $p < 0.001$ Sex (% male): surgery 29.3%, control 29.7%, p = ns Weight: surgery 120.6 (16.4) kg; control 114.6 (16.4) kg, $p < 0.001$ Height: surgery 1.69 (0.09), control 1.69 (0.09), p = ns BMI: surgery 42.3 (4.4), control 40.0 (4.6), $p < 0.001$ Those completing 10 years: Number: total 1268, surgery 641, control 627 Mean age: surgery 47.0 (5.6), control 48.4 (6.3), $p < 0.001$ Sex (% male): surgery 30.6%, control 31.4%, p = ns Weight: surgery 120.0 (16.4) kg; control 113.9 (16.7) kg, $p < 0.001$ Height: surgery 1.69 (0.09), control 1.69 (0.09), p = ns BMI: surgery 41.9 (4.2), control 39.9 (4.6), $p < 0.001$ Gummesson 2008,[101] cancer incidence (abstract only) Number: total 4047, surgery 2010, control 2037. No further details although note that participant numbers are the same as those reported by Sjostrom 2007[99] Characteristics of target population: between 37 and 60 years, BMI of ≥34 for men and ≥38 for women			*Attrition/dropout:* As a result of mortality, dropouts and data pending (numbers not specified), data reported on 73% of surgical and 67% of control patients in study with 8-year follow-up. In controls, future dropouts higher prevalence of diabetes (22%, 8%, $p = 0.002$) and smoking (40%, 24%, $p = 0.002$) than completers at inclusion. In surgical, future dropouts 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 Of 965 patients who completed 6 years follow-up on medication use, five had missing data on weight, and four had missing data on medication use at 2 years follow-up, group not specified Sjostrom 2007:[99] At follow-up examinations at 2, 10 and 15 years (from substudy with mean of 10.9 years follow-up) participation rates in the surgery group were 94%, 84% and 66% respectively. For the control groups these rates were 83%, 75%, and 87% Karlsson 2007:[100] Of the 1703 patients in the 10-year HRQoL substudy, 77% of the surgery group and 72.9% of the control group were followed up Sjostrom 2004:[97] Losses to follow-up Patients followed for 10 years:

continued

Study	Participants	Interventions	Outcomes	Notes
	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 co-operation, regular use of cortisone or non-steroidal anti-inflammatory drugs			Surgery 210/851 (24.7%), controls 225/852 (26.4%) Patients followed for 2 years: Surgery 165/2010 (8.2%), controls 377/2037 (18.5%)

BMI, body mass index; CI, confidence interval; ITT, intention to treat; ns, not statistically significant; SD, standard deviation; SOS, Swedish Obese Subjects.

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Karason 2000[85] *Weight loss at 2 years* *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, $p < 0.001$ Sjostrom 2000[89] *Weight changes at 8 years:*(surgical $n = 232$, control $n = 251$) Baseline: surgical 120.4 kg (16.0), control 114.7 kg (17.8) 8 years: surgical 100.3 kg (17.8), control 115.4 kg (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% (12.3%); control 0.9% (10.8%) *Weight at 8 years:* GBP 92 kg vs VBG 100 kg (p = ns) vs GBand 103 kg ($p < 0.05$). All had a larger weight reduction than controls ($p < 0.01$) Togerson 2003[96] *Weight loss at 2 years:* Men: surgery 29.4 kg (15.3), 21.9% (10.0), controls 0.3 kg (9.5), 0.1% (7.4), $p < 0.001$ Women: surgery 28.0 kg (13.8), 23.9% (10.7), controls 0.6 kg (8.6), 0.3% (7.9), $p < 0.001$	Karlsson 1998[86] *Health Related QoL* *Current health perception GHRI/CH* (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 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 scales* 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) ($p = 0.001$) *HADs 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 HQRL measures ($p < 0.0001$) Changes in all HRQoL measures significantly related to magnitude of weight loss Sjostrom 2000[89] *Diabetes and Hypertension* *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 odds ratios 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)	Sjostrom 1999[88] (lipid disturbances data) 15 surgical operations reversed during first 2 years. Five GBand were converted to GBP, one GBand converted to VBG, seven VBG converted to GBP Togerson 2001[137] (overview paper) *Postoperative mortality*: Four (0.2%) deaths, three due to leakage detected too late and one due to a technical laparoscopic mistake *Perioperative complications ($n = 1164$)*: 151 patients (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% *Complications requiring reoperation*: 26 patients (2.2%) Sjostrom 2007,[99] mean 10.9 years follow-up Cumulative overall mortality during a period of up to 16 years: Surgery group hazard ratio compared with control group: 0.76 (95% CI 0.59 to 0.99), $p = 0.04$ *Deaths, n*(%) Surgery: 101/2010 (5.0%), control: 129/2037 (6.3%) *Cause of death:* *Cardiovascular condition:* Any event: surgery 43, control 53 of which: Cardiac: surgery 35 (myocardial infarction 13, heart failure 2, sudden death 20); control 44 (myocardial infarction 25, heart failure 5, sudden death 14)

continued

DOI: 10.3310/hta13410

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Agren 2002[136] *Relative weight change, mean (SD)*: 2 years: surgery –22.6% (10.6), control –0.3% (7.9) 6 years: surgery –16.2% (11.5), control 0.8% (9.6) Sjostrom 2007[99] *Mean % weight loss*, mean 10.9 years follow-up (reported 10 and 15 years only here, note different values of *n*) Control group, weight remained within ± 2% at 10 years (886/2037 followed up) and 15 years (190/2037 followed up) Surgery, mean % weight losses were 25 ± 11% for GBP, 16 ± 11% for VBG, 14 ± 14% for banding at 10 years. The numbers followed up for each of the three procedures were 58/265, 746/1369 and 237/376 for the three groups, respectively After 15 years, weight losses were 27 ± 12% for GBP, 18 ± 11% for VBG and 13 ± 14% for banding (corresponding numbers followed up were: 10/265, 108/1369, 52/376) Karlsson 2007[100] At 10 years follow-up *Weight at 10 years*: surgery 100.5 kg (17.7), change –19.7 kg (15.8); control 115.2 kg (19.9), change 1.3 kg (13.8). Surgery vs control $p < 0.0001$ *Weight loss between surgical subgroups at 10 years:* 13.2% (SD 13) banding ($n = 161$); 16.5% (SD 11) VBG ($n = 457$); 25.1% (SD 11) GBP ($n = 37$) *Weight change at 10 years:* Surgery (loss of weight): 16% (12.1), men 15.8% (12.3), women 16.1% (12.1) Controls (gain of weight): 1.5% (9.9), men 1.9% (12.8), women 1.4% (12.1)	*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 odds ratios of developing hypertension, 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 odds ratios of developing hypertension, 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) Sjostrom 1999[88] *Lipid disturbances:* *Lipids:* Adjusted odds ratios at 24 months (95% CI): 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 Togerson 2003[96] *Biliary disease:* Biliary disease and pancreatitis; frequencies over 2 years (%), Fisher's exact test and OR (95% CI) adjusted for age and BMI at baseline Cholelithiasis, men: surgery 4.0, controls 1.2, $p = 0.011$, OR 4.2 (1.5 to 12.0). Women: surgery 5.5, controls 4.5, $p = 0.328$, OR 1.1 (0.7 to 1.8) Cholecystitis, men: surgery 2.5, controls 0.7, $p = 0.058$, OR 4.5 (1.2 to 17.1). Women: surgery 3.3, controls 2.5, $p = 0.379$, OR 1.4 (0.7 to 2.5) Cholecystectomy, men: surgery 3.4, controls 0.7, $p = 0.008$, OR 5.4 (1.5 to 19.6). Women: surgery 3.5, controls 2.3, $p = 0.191$, OR 1.6 (0.9 to 3.0) Total biliary disease, men: surgery 4.1, controls 1.5, $p = 0.024$, OR 3.5 (1.3 to 9.2). Women: surgery 6.8, controls 5.3, $p = 0.223$, OR 1.2 (0.8 to 1.9) Pancreatitis, men: surgery 1.1, controls 0.2, $p = 0.219$, OR 3.6 (0.4 to 31.2). Women: surgery 0.7, controls 0.4, $p = 0.514$, OR 1.8 (0.4 to 7.6)	Stroke: surgery six (intracerebral haemorrhage two, infarction one, subarachnoid bleeding three); control six (intracerebral haemorrhage four, infarction two) Other: surgery two (aortic aneurysm one, diabetic gangrene one); control three (aortic aneurysm two, aortic thrombosis one) *Non-cardiovascular condition:* Any event: surgery 58, control 76, of which: Tumour: surgery 29 (Cancer 29); control 48 (cancer 47, meningioma one) Infection: surgery 12, control three Thromboembolic disease: surgery five (pulmonary embolism four, vena caval thrombosis one); control seven (pulmonary embolism 7) Other: surgery 12, control 18 *Deaths within 90 days of surgery*: Five in surgery group (0.25%)(four from peritonitis with organ failure, one sudden death) and two in control group (0.10%) (one from pancreatic cancer, one from alcohol-related causes) *surgical reoperations or conversions* (excluding operations caused by postoperative complications) in those followed up for at least 10 years ($n = 1338$): banding 31%, VBG 21%, GBP 17%

Table of results *(continued)*

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
BMI at 10 years: Surgery 35.3 (5.4), change -6.7 (5.4); control 40.6 (5.9), change 0.7 (4.9). Surgery vs control $p < 0.0001$ Sjostrom 2004[97] At 2 and 10 years follow-up (N.B. different cohort numbers for each). At 2 years: *Weight*,% change: Surgery – 23.4, control 0.1, difference 22.2 (95% CI 21.6 to 22.8), $p < 0.001$ *BMI*,% change: Surgery –23.3, control 0.1, difference 22.1 (95% CI 21.5 to 22.7), $p < 0.001$ At 10 years: *Weight*,% change: Surgery – 16.1, control 1.6 (12), difference 16.3 (95% CI 14.9 to 17.6), $p < 0.001$ *BMI*,% change: Surgery – 15.7, control 2.3, difference 16.5 (95% CI 15.1 to 17.8), $p < 0.001$	Agren 2002,[136] *medication use:* Proportion on CVD medication, risk ratio (95% CI adjusted to mean values of sex, age, and BMI at baseline): Subjects on medication at baseline, surgery $n = 150$, control $n = 125$ Proportion on medication at: 2 years,%: surgery 61.7, control 91.2, RR 0.69 (0.60 to 0.80), $p < 0.05$ 6 years,%: surgery 64.7, control 86.4, RR 0.77 (0.67 to 0.88), $p < 0.05$ Subjects not on medication at baseline, surgery $n = 360$, control $n = 330$ Proportion on medication at: 2 years,%: surgery 3.1, control 10.1, RR 0.28 (0.14 to 0.56), $p < 0.05$ 6 years,%: surgery 13.3, control 16.7, RR 0.80 (0.56 to 1.16) Proportion on diabetes medication, risk ratio (95% CI adjusted to mean values of sex, age and BMI at baseline): Subjects on medication at baseline, surgery $n = 32$, control $n = 21$ Proportion on medication at: 2 years,%: surgery 56.2, control 100.0, RR 0.56 (0.41 to 0.76), $p < 0.05$ 6 years,%: surgery 68.8, control 100.0, RR 0.71 (0.56 to 0.89), $p < 0.05$ Subjects not on medication at baseline, surgery $n = 478$, control $n = 434$ Proportion on medication at: 2 years,%: surgery 0.2, control 3.7, RR 0.08 (0.01 to 0.58), $p < 0.05$ 6 years,%: surgery 2.1, control 11.3, RR 0.20 (0.10 to 0.38), $p < 0.05$ Karlsson 2007[100] HRQoL at 10 years *Current health perceptions*: 1-year follow-up: surgery 48% improvement, control 7% improvement 10-year follow up: surgery 57.5 (26.8), change 5.8 (27.6) (11% improvement); control 55.4 (25.1), change – 3.4 (25.2), p = ns difference between groups, $p < 0.0001$ difference in change. Effect size (ES) of change calculated (where 0 to < 0.20 trivial, 0.20 to < 0.50 small, 0.50 to < 0.80 moderate, ≥0.80 large) reported to be 0.21 for surgery and -0.13 for control groups *Social interaction*: 1-year follow-up: surgery ~ 60% improvement, control 7% 10-year follow-up: surgery 8.4 (12.4), change – 3.2 (13.0); control 7.7 (11.1), change 0.5 (10.0), p = ns difference between groups, $p < 0.01$ difference in change. Effect size (ES) of change surgery 0.25, control – 0.05 *Obesity-related problems*: 1-year follow-up: surgery ~ 63% improvement, control 7% 10-year follow-up: surgery 29.7(27.3), change 28.3 (28.3); control 31.3 (25.5), change 9.6 (22.6), p = ns difference between groups, $p < 0.0001$ difference in change. Effect size (ES) of change surgery 1.00, control 0.42	

continued

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
	Overall mood 10-year follow-up: surgery 3.06 (0.59), change 0.14 (0.56); control 3.11 (0.56), change 0.05 (0.51), p = ns (between groups and change between groups). Effect size (ES) of change surgery 0.25, control 0.10 *Depression* 10-year follow-up: surgery 3.7 (3.7), change –1.4 (3.9); control 3.7 (3.5), change –0.5 (3.4), p = ns difference between groups, $p < 0.05$ difference in change. Effect size (ES) of change surgery 0.35, control 0.14 *Anxiety* 10-year follow-up: surgery 4.6 (4.4), change –1.4 (4.3); control 4.0 (4.2), change –1.4 (3.9), $p < 0.01$ difference between groups, p = ns difference in change. Effect size (ES) of change surgery 0.33, control 0.35 HRQoL at 10 years in surgically treated patients by weight change, and 10-year trends in weight loss and HRQoL in surgically treated patients with weight loss ≥ 10% vs < 10% after 10 years reported but not extracted Sjostrom 2004[97] *comorbidity at 2 and 10 years* (N.B. different cohort numbers for each) *2-year outcomes:* Systolic blood pressure at baseline: surgery 143.5 (18.8), control 137.5 (17.9), $p < 0.001$. Change at end point: surgery –4.4, control 0.5, difference 2.8 (95% CI 2.1 to 3.6), $p < 0.001$ Diastolic blood pressure at baseline: surgery 88.7 (11.2), control 84.7 (10.5), $p < 0.001$. Change at end point: surgery –5.2, control 0.3, difference 3.2 (95% CI 2.4 to 3.9), $p < 0.001$ Glucose (mmol/l) at baseline: surgery 5.4 (2.1), control 5.2 (1.9), $p < 0.001$. Change at end point: surgery -13.6, control 5.1, difference 16.6 (95% CI 15.0 to 18.3) $p < 0.001$ Insulin (mU/l) at baseline: surgery 21.2 (12.6), control 18.0 (11.5), $p < 0.001$. Change at end point: surgery –46.2, control 10.3, difference 51.4 (95% CI 48.0 to 54.8), $p < 0.001$ Uric acid (μmol/L) at baseline: surgery 359.4 (80.1), control 353.3 (79.3), $p < 0.05$. Change at end point: surgery – 14.9, control –0.4, difference 13.5 (95% CI 12.5 to 14.6), $p < 0.001$ Triglycerides (mmol/l) at baseline: surgery 2.23 (1.52), control 2.01 (1.35), $p < 0.001$. Change at end point: surgery –27.2, control 6.3, difference 29.9 (95% CI 27.4 to 32.5), $p < 0.001$ HDL cholesterol (mmol/L) at baseline: surgery 1.20 (0.28), control 1.19 (0.29), $p < 0.001$. Change at end point: surgery 22.0, control 3.5, difference – 18.7 (95% CI –20.1 to – 17.3) Total cholesterol (mmol/l) at baseline: surgery 5.85 (1.12), control 5.60 (1.06), $p < 0.001$. Change at end point: surgery –2.9, control 0.1, difference 1.0 (95% CI 0.1 to 1.9), $p < 0.05$	

Table of results *(continued)*

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
	10-year outcomes: Systolic blood pressure at baseline: surgery 143.8 (19.3), control 138.4 (17.6), $p < 0.001$. Change at end point: surgery 0.5, control 4.4, difference 1.1 (95% CI −0.3 to 2.6) Diastolic blood pressure at baseline: surgery 89.6 (11.3), control 85.8 (10.6), $p < 0.001$. Change at end point: surgery −2.6, control −2.0, difference −2.3 (95% CI −3.5 to −1.0), $p < 0.001$ Glucose (mmol/l) at baseline: surgery 5.5 (2.1), control 5.1 (1.7), $p < 0.001$. Change at end point: surgery −2.5, control 18.7, difference 18.4 (95% CI 14.7 to 22.1) $p < 0.001$ Insulin (mU/l) at baseline: surgery 21.2 (11.4), control 18.3 (11.2), $p < 0.001$. Change at end point: surgery −28.2, control 12.3, difference 30.3 (95% CI 23.9 to 36.6), $p < 0.001$ Uric acid (μmol/l) at baseline: surgery 366.2 (84.2), control 357.7 (78.9), p = ns. Change at end point: surgery −6.2, control 3.9, difference 8.8 (95% CI 6.4 to 11.1), $p < 0.001$ Triglycerides (mmol/l) at baseline: surgery 2.30 (1.56), control 2.12 (1.49), $p < 0.05$. Change at end point: surgery −16.3, control 2.2, difference 14.8 (95% CI 10.4 to 19.1) $p < 0.001$ HDL-cholesterol (mmol/l) at baseline: surgery 1.19 (0.28), control 1.18 (0.29), p = ns. Change at end point: surgery 24.0, control 10.8, difference −13.6 (95% CI −16.5 to −10.6), $p < 0.001$ Total cholesterol (mmol/l) at baseline: surgery 6.02 (1.13), control 5.76 (1.10), $p < 0.001$. Change at end point: surgery −5.4, control −6.0, difference −2.0 (95% CI −0.2 to −3.8), $p < 0.05$ *Incidence of comorbidities* after 2 and 10 years in those without disease at baseline *(n values for numerators calculated by reviewer and rounded)*: Hypertriglyceridaemia at 2 years: surgery 58/731 (8%), control 176/801 (22%), odds ratio 0.29 (95% CI 0.21 to 0.41), $p < 0.001$ Hypertriglyceridaemia at 10 years: surgery 38/225 (17%), control 75/281 (27%), odds ratio 0.61 (95% CI 0.39 to 0.95), $p = 0.03$ Low HDL-cholesterol at 2 years: surgery 25/1293 (2%), control 117/1174 (10%), odds ratio 0.21 (95% CI 0.14 to 0.32), $p < 0.001$ Low HDL-cholesterol at 10 years: surgery 13/431 (3%), control 26/440 (6%), odds ratio 0.57 (95% CI 0.29 to 1.15), $p = 0.12$ Hypercholesterolaemia at 2 years: surgery 136/504 (27%), control 143/596 (24%), odds ratio 1.27 (95% CI 0.95 to 1.69), $p = 0.11$ Hypercholesterolaemia at 10 years: surgery 40/135 (30%), control 51/188 (27%), odds ratio 1.16 (95% CI 0.69 to 1.95), $p = 0.57$ Diabetes at 2 years: surgery 15/1489 (1%), control 112/1402 (8%), odds ratio 0.14 (95% CI 0.08 to 0.24), $p < 0.001$ Diabetes at 10 years: surgery 36/517 (7%), control 129/539 (24%), odds ratio 0.25 (95% CI 0.17 to 0.38), $p < 0.001$ Hypertension at 2 years: surgery 149/623 (24%), control 223/770 (29%), odds ratio 0.78 (95% CI 0.60 to 1.01), $p = 0.06$	

continued

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
	Hypertension at 10 years: surgery 88/215 (41%), control 137/279 (49%), odds ratio 0.75 (95% CI 0.52 to 1.08), $p = 0.13$ Hyperuricaemia at 2 years: surgery 42/1044 (4%), control 163/1017 (16%), odds ratio 0.22 (95% CI 0.15 to 0.31), $p < 0.001$ Hyperuricaemia at 10 years: surgery 58/342 (17%), control 107/382 (28%), odds ratio 0.49 (95% CI 0.34 to 0.71), $p < 0.001$ *Recovery From comorbidities* after 2 and 10 years in those with disease at baseline *(n values for numerators calculated by reviewer and rounded)*: Hypertriglyceridaemia at 2 years: surgery 683/1102 (62%), control 187/850 (22%), odds ratio 5.28 (95% CI 4.29 to 6.49), $p < 0.001$ Hypertriglyceridaemia at 10 years: surgery 185/402 (46%), control 79/331 (24%), odds ratio 2.57 (95% CI 1.85 to 3.57), $p < 0.001$ Low HDL-cholesterol at 2 years: surgery 338/445 (76%), control 154/396 (39%), odds ratio 5.28 (95% CI 3.85 to 7.23), $p < 0.001$ Low HDL-cholesterol at 10 years: surgery 123/169 (73%), control 88/166 (53%), odds ratio 2.35 (95% CI 1.44 to 3.84), $p < 0.001$ Hypercholesterolaemia at 2 years: surgery 292/1327 (22%), control 178/1048 (17%), odds ratio 1.22 (95% CI 0.98 to 1.51), $p = 0.07$ Hypercholesterolaemia at 10 years: surgery 105/498 (21%), control 74/435 (17%), odds ratio 1.30 (95% CI 0.92 to 1.83), $p = 0.14$ Diabetes at 2 years: surgery 246/342 (72%), control 52/248 (21%), odds ratio 8.42 (95% CI 5.68 to 12.5), $p < 0.001$ Diabetes at 10 years: surgery 42/118 (36%), control 11/84 (13%), odds ratio 3.45 (95% CI 1.64 to 7.28), $p < 0.001$ Hypertension at 2 years: surgery 409/1204 (34%), control 185/880 (21%), odds ratio 1.72 (95% CI 1.40 to 2.12), $p < 0.001$ Hypertension at 10 years: surgery 81/424 (19%), control 38/342 (11%), odds ratio 1.68 (95% CI 1.09 to 2.58), $p = 0.02$ Hyperuricaemia at 2-years: surgery 562/792 (71%), control 197/637 (31%), odds ratio 5.36 (95% CI 4.23 to 6.78), $p < 0.001$ Hyperuricaemia at 10-years: surgery 140/292 (48%), control 66/243 (27%), odds ratio 2.37 (95% CI 1.61 to 3.47), $p < 0.001$	

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
	Gummesson 2008,[101] cancer incidence, average 11 years follow-up Cancer status not known for 3/4047 (follow-up rate 99.9%), group not specified Cases of first-time cancers: surgery 126/2010, control 173/2037 Unadjusted hazard ratio for overall cancer incidence: 0.71 ($p = 0.003$) for surgery group compared with control group. Hazard ratio adjusted for risk factors: 0.74 ($p = 0.011$). 95% CIs not reported. Unadjusted hazard ratio for: Men ($n = 1178$): 0.98 (95% CI 0.63 to 1.51, $p = 0.91$) Women ($n = 2867$): 0.63 (95% CI 0.48 to 0.82), $p = 0.001$) Hazard ratios using specific cancer types as outcomes did not reach statistical significance	

BMI, body mass index; BSQ, Bing Scale Questionnaire; CI, confidence interval; GBand, gastric banding; GBP, gastric bypass; GHRI/CH, general health rating index/current health; HADS, hospital anxiety and depression scale;HDL, high-density lipoprotein; HRQoL, health-related quality of life; ITT, intention to treat; MACL, mood adjective checklist; ns, not statistically significant; OR, odds ratio; QoL, quality of life; RR, relative risk; SD, standard deviation; VBG, vertical banded gastroplasty.

Quality criteria (CRD Report 4)

Quality item	Yes/No/Uncertain	Methodological comments
Cohort studies		
1. Is there sufficient description of the groups and the distribution of prognostic factors?	Yes	Differences between groups
2. Are the groups assembled at a similar point in their disease progression?	Unclear	
3. Is the intervention/treatment reliably ascertained?	Yes	
4. Were the groups comparable on all important confounding factors?	No	Significant differences between groups
5. Was there adequate adjustment for the effects of these confounding variables?	Yes	States adjustments made where appropriate
6. Was outcome assessment blind to exposure status?	No	
7. Was follow-up long enough for the outcomes to occur?	Yes	
8. What proportion of the cohort was followed-up?	At 2 years: 84% surgical, 93% control At 8 years: 73% of surgical, 67% control At 10 years: varies between the different substudies	
9. Were dropout rates and reasons for dropout similar across intervention and unexposed groups?	Unclear	Numbers and reasons not given

DOI: 10.3310/hta13410

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Stoeckli, 2004[102] Von Mach 2004[103] Christ-Crain 2006[104] Design: prospective cohort study, single centre Follow-up: 24 months	Country: Switzerland *Stoeckli 2004 and Christ-Crain 2006:* Number: total 20, LAGB 8, RYGBP 5, controls 7 Mean age, years (SE): LAGB 41.1 (2.6), RYGBP 43.8 (4.4), controls 49.9 (2.6) Sex (F:M): LAGB (6:2), RYGBP (5:0), controls (5:2). Mean BMI (SE): LAGB 41.7 (1.0), RYGBP 43.6 (2.0), controls 41.1 (1.0) *Von Mach 2004* Number: total 19, LAGB 9, RYGBP 4, controls 6 Mean age (SEM), years: LAGB 41.1 (2.2), RYGBP 44.5 (4.8), controls 49 (2.9) Sex (F:M): LAGB 6:3, RYGBP 4:0, controls 4:2 BMI (SEM): LAGB 41.0 (1.1), RYGBP 42.7 (2.2), controls 41.2 (1.2) Characteristics of target population: Patients with morbid obesity (BMI > 37) undergoing bariatric surgery. Controls were obese subjects who did not receive operations Exclusion criteria: not reported	1. Laparoscopic adjustable silicone gastric banding (LAGB) 2.Open Roux-en-Y gastric bypass (RYGBP) 3. Control	Plasma ghrelin concentration (data not extracted) BMI Fat mass Bone mineral content (data not extracted)	*Allocation to treatment groups:* Observational study. Patients opting for surgical treatment chose LAGB or RYGBP after detailed discussion of the individual situation. Patients who attended a diet consultation served as controls. Reasons for control group not undergoing surgery are not given in Stoeckli 2004 *Blinding of outcome assessors:* Not reported *Comparability of treatment groups:* No significant differences between groups for age, BMI and laboratory parameters *Method of data analysis:* Data expressed as means (SE). Spearman correlation tests, unpaired Student's *t* tests (two-sided) and Mann–Whitney *U* tests used for comparison of single time points among groups, depending on whether data showed a normal distribution. Repeated measures ANOVA performed for serial measurements. Bonferroni correction applied when multiple comparisons made among groups *Sample size/power calculation:* Not reported *Attrition/dropout:* Not reported. Additional information from the author: 'the papers are from the same study, and depending on the available samples, the *n* of patients may have been slightly different'

BMI, body mass index; SE, standard error; SEM, standard error of the mean.

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Stoeckli 2004 and Christ-Crain 2006: *MEAN BMI* (SE, SD) Baseline: LAGB 41.7 (1.0, SD 2.8), RYGBP 43.6 (2.0, SD 4.4), controls 41.1 (1.0, SD 2.6) 24 months: LAGB 33.2 (1.7, SD 4.7), RYGBP 32.9 (3.0, SD 6.7), controls 41.0 (1.4, SD 3.4) ($p < 0.001$ controls vs LAGB, and controls vs RYGBP) *Stoeckli 2004* *Change in BMI* (majority estimated from figure) 3 months: LAGB –5, RYGBP –6.5*#, controls –1.5 6 months: LAGB –6**, RYGBP –9*##, controls –1.7 12 months: LAGB –8**, RYGBP –11.2*, controls –0.3 24 months: LAGB –8**, RYGBP –10.8*, controls –0.3 (0.4) *$p < 0.01$ vs controls, **$p < 0.001$ vs controls (Note: these p-values seem incorrect) #$p < 0.05$ RYGBP vs LAGB, ##$p < 0.01$ RYGBP vs LAGB *Von Mach 2004* *BMI* Baseline: LAGB 41.0, RYGBP 42.7, control 41.2 3 months: LAGB 36, RYGBP 36, control 40. (Estimated from figure). 6 months: LAGB 35, RYGBP 33, control 39, $p < 0.05$ LAGB and RYGBP vs controls. (Estimated from figure.) 12 months: LAGB 34, RYGBP 30, control 41, LAGB and RYGBP $p < 0.05$ vs controls. (Estimated from figure.) 24 months: LAGB 34.0, RYGBP 30.5, control 41.4, LAGB and RYGBP $p < 0.05$ vs controls *Mean body weight*, kg (SEM). Baseline: LAGB 117.2 (2.5), RYGBP 113.3 (4.9), control 113.5 (4.9). % change: LAGB –16.0 (3.2)*, RYGBP –28.6 (3.6)*, control + 0.5 (1.2). *$p < 0.01$ *Total fat mass*, kg (SEM). Baseline: LAGB 63.7 (2.2), RYGBP 63.6 (2.2), control 64.8 (4.7). % change: LAGB –33.9 (5.3)*, RYGBP –51.0 (5.2)*, control + 2.5 (3.3). *$p < 0.001$	Not reported	Not reported

BMI, body mass index; LAGB, laparoscopic gastric banding; RYGBP, Roux-en-Y gastric bypass; SD, standard deviation; SE, standard error of the mean; SEM, standard error of the mean.

Quality criteria (CRD Report 4)

Quality item	Yes/No/Uncertain	Methodological comments
Cohort studies		
1. Is there sufficient description of the groups and the distribution of prognostic factors?	Yes	
2. Are the groups assembled at a similar point in their disease progression?	Unclear	
3. Is the intervention/treatment reliably ascertained?	Yes	
4. Were the groups comparable on all important confounding factors?	Yes	
5. Was there adequate adjustment for the effects of these confounding variables?	Not applicable	
6. Was outcome assessment blind to exposure status?	Uncertain	
7. Was follow-up long enough for the outcomes to occur?	Yes	
8. What proportion of the cohort was followed-up?	Uncertain	
9. Were dropout rates and reasons for dropout similar across intervention and unexposed groups?	Uncertain	

Appendix 6

Data extraction tables: gastric bypass versus vertical banded gastroplasty (versus gastric banding)

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Agren 1989[73] (abstract only) Sweden Single-centre, RCT	Total: 77 1. 27 2. 25 3. 25 *Characteristics of target population:* Morbidly obese *Exclusion criteria:* Not reported *Participants:* Mean preoperative weight 123.6, BMI 42.8	*Treatment arms:* 1. Vertical banded gastroplasty (VBG) 2. Loop gastric bypass (Loop GBP) 3. Gastric banding (not adjustable and therefore not included in the current review)	*Primary and secondary outcome measures used:* mortality, morbidity, excess weight loss *Method of assessing outcomes:* not stated *Length of follow-up:* 12 and 18 months	*Allocation to treatment groups:* randomised, but method not stated *Blinding of outcome assessors:* not reported *Comparability of treatment groups:* states groups comparable in age, sex, preoperative weight and ideal body weight. Data not presented *Method of data analysis:* standard deviation or CI not reported *Sample size/power calculation:* not reported *Attrition/dropout:* not reported *Generalisability:* eligibility criteria not reported *Outcome measures:* per cent excess weight loss *Intercentre variability:* single centre study *Conflict of interests:* funding support not mentioned

BMI, body mass index; CI, confidence interval; RCT, randomised controlled trial.

Table of results

Weight change	QoL and comorbidities	Events/procedures (complications, reoperations)
Mean excess weight loss: 12 months: loop GBP 76.6%; VBG 58.3%, GBand 62.2% 18 months: loop GBP 76.6%; VBG 59.8%, GBand 62.5%. *p* not reported	Not assessed	*Mortality:* one patient (group not specified) *Morbidity:* states low and not significantly different, but data not presented One VBG: reoperation for staple-line disruption 11 (44%) GBand: reoperation, mainly for inadequate weight loss or nutritional disorder and increased vomiting which commonly occurred without stomal stenosis

GBand, gastric banding; GBP, gastric bypass; VBG, vertical banded gastroplasty.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Randomised, but method not stated
Allocation concealment?	Unclear	
Blinding of outcome assessors?	Unclear	
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Unclear	Not reported
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	Limited information as reported in abstract only. Reports % excess weight loss; SD or CI not reported
Free of other sources of bias?	Unclear	Limited information as reported in abstract only.

CI, confidence interval; n/a, not applicable; QoL, quality of life; SD, standard deviation.

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Howard 1995[120] Design: single centre, RCT Follow-up: 12 to 78 months.	Country: USA Number: Total 42, GBP 20, VBG 22 Age (mean): GBP 38.1 years (SE 1.9), VBG 36.5 years (SE 2.3) Sex: GBP 75% female, VBG 22% female Mean Max. weight: GBP 154 kg (SE 26), VBG 142 kg (SE 17) $p = 0.09$ Mean excess preoperative weight: GBP 71 kg (SE 19), VBG 67 kg (SE 15) $p = 0.41$ *Characteristics of target population:* Class IV obesity (BMI > 40); < 50 years; attempts at non-operative weight loss; realistic view of operation and likely impact on life *Exclusion criteria:* BMI < 40, 50 years or older, psychiatrically unstable	1. Gastric bypass (GBP) 2. Vertical banded gastroplasty (VBG)	Weight change (preoperative and postoperative) % excess weight loss compared to maximum excess weight % lost > 50% and > 75% of excess weight Early postoperative complications (wound dehiscence, infection and thromboembolism)	*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 (BMI > 50) *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/dropout:* two of 44 (5%) patients withdrew from study within 4 weeks of surgery, and only 12 patients followed up for 60 months [GBP 6/20 (30%), VBG 6/22 (28%)] *Generalisability:* excluded patients with BMI < 40, and age ≥ 50 years, and those psychiatrically unstable *Outcome measures:* mean weight loss as a percentage of weight loss relative to patients' maximum excess weight, and percentage of excess weight lost *Intercentre variability:* setting not known *Conflict of interests:* not mentioned

BMI, body mass index; ITT, intention to treat; SE, standard error.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidities	Events/procedures (complications, reoperations)
% excess weight loss compared to maximum excess weight (data from figure): 12 months GBP 78%, VBG 52%, $p < 0.05$ 60 months GBP ($n = 6$) 70%, VBG ($n = 6$) 37%, $p < 0.05$ *% patients with at least 50% of excess weight loss (data from figure):* 12 months GBP 100% (20/20), VBG 55% (12/22) (p not stated) 60 months GBP 100% (6/6), VBG 0% (0/6) (p not stated) *% patients with more than 75% of excess weight loss:* 12 months GBP 60% (12/20), VBG 18% (4/22) (p not stated) 60 months GBP 50% (3/6), VBG 0% (0/6) (p not stated) Data from figure	Not assessed	*Early complications:* Deaths GBP 0, VBG 0; wound infection one (2%) super-obese patient. *Late complications:* Symptomatic ulcer disease GBP 25% (50% further surgery), VBG 0%; intraoperative cholecystectomy GBP 20%, VBG 14%; postoperative cholecystectomy VBG 29%; GBP 29%

GBP, gastric bypass; VBG, vertical banded gastroplasty.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Randomised, method not stated
Allocation concealment?	Unclear	
Blinding of outcome assessors?	Unclear	Not stated
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Yes	Two of 44 (5%) patients withdrew from study within 4 weeks of surgery, and only 12 patients followed up for 60 months. Numbers at each follow-up are given. Reasons not given
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	
Free of other sources of bias?	Unclear	

n/a, not applicable; QoL, quality of life.

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Lee, 2004[115] Design: RCT, single centre Follow-up: Mean 20 months (range 18 to 30)	Country: Taiwan Number: total 80, LVBG 40, LBG 40 Mean age (SD): LVBG 32.5 years (7.8), LRYGBP 31.6 years (8.6) Sex (F : M): LVBG 29 : 11, LRYGBP 27 : 13 Mean weight: LVBG 119.0 kg (21.4), LRYGBP 120.7 kg (26.3) BMI: LVBG 43.14 (6.1), LRYGBP 43.18 (7.5) Previous abdominal surgery: LVBG 3, LRYGBP 5 Waist circumference: LVBG 123.7 cm (16.7), LRYGBP 123.3 cm (18.5) Systolic bp: LVBG 136 mmHg (16), LGB 136 mmHg (17) Diastolic bp: LVBG 87 mmHg (14), LRYGBP 86 mmHg (13) Blood glucose: LVBG 117 mg/dl (56), LRYGBP 106 mg/dl (35) Cholesterol: LVBG 207 mg/dl (34), LRYGBP 191 mg/dl (43) Triglyceride: LVBG 179 mg/dl (121), LRYGBP 171 mg/dl (128) GOT: LVBG 32 IU/l (22), LRYGBP 29 IU/l (19) GPT: LVBG 41 IU/l (33), LRYGBP 43 IU/l (29) Uric acid: LVBG 7.5 mg/dl (1.8), LRYGBP 7.1 mg/dl (1.8) Albumin: LVBG 4.5 mg/dl (0.3), LRYGBP 4.5 mg/dl (0.5) WBC: LVBG 8.3 (2.1), LRYGBP 8.9 (3.2) Haemoglobin: LVBG 13.8 g/dl (1.5), LRYGBP 13.6 g/dl (1.2) MCV: LVBG 87.6 fl (6.2), LRYGBP 87.7 fl (6.8) Characteristics of target population: Significant obesity > 5 years, BMI > 40 or BMI > 35 with comorbidities, documented past weight loss attempts, good motivation for surgery, age 18–59 years Exclusion criteria: Previous bariatric surgery, previous gastric surgery, large abdominal ventral hernia, pregnancy, psychiatric disease or BMI > 60	1. Laparoscopic vertical banded gastroplasty (LVBG) 2. Laparoscopic Roux-en-Y gastric bypass (LRYGBP)	Perioperative clinical parameters: operative time, estimated blood loss, dosages required during hospital stay, length to postoperative flatus passage, hospital stay, early complications (occurring within 30 postoperative days), major complications (required interventional management and hospitalisation > 14 days), late complications (related to operation occurring after 30 days and requiring readmission) BMI % excess weight loss 36-item gastrointestinal quality of life index (GIQLI). Scored 0–4 (worst-best), max score 144. 4 domains	*Allocation to treatment groups:* randomised using sealed envelopes *Blinding of outcome assessors:* not reported *comparability of treatment groups:* comparable in sex, age, mean weight, BMI and laboratory tests, differences all statistically non-significant *Method of data analysis:* ITT analysis. Expressed as mean (SD) or median (range). Analyses of differences between groups for demographic and operative data were performed using two-sample *t* tests or Fisher exact test for categorical data. Mann–Whitney *U* tests were performed for non-parametric data. Paired Student's *t* test used to compare each item before and after surgery. Two-tailed *t* test used for comparison of total scores and scores in each subgroup, before operation and at follow-up *Sample size/power calculation:* not reported *Attrition/dropout:* not reported

BMI, body mass index; GOT, glutamic oxaloacetate transaminase; GPT, glutamic–pyruvate transaminase; ITT, intention to treat; MCV, mean corpuscular volume; RCT, randomised controlled trial; SD, standard deviation; WBC, white blood cells.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Mean BMI Baseline: LVBG 43.14, LRYGBP 43.18 3 months: LVBG 36.7, LRYGBP 35.6 6 months: LVBG 33.3, LRYGBP 31.8 9 months: LVBG 32.2, LRYGBP 30.7 12 months: LVBG 31.1, LRYGBP 29.6 24 months: LVBG 31.9, LRYGBP 28.5 Numbers of participants providing data for BMI outcome at different time points not reported *Percentage excess weight loss* 12 months: LRYGBP 62.9% ($n = 40$), LVBG 55.4% ($n = 40$) 24 months: LRYGBP 71.4% ($n = 26$), LVBG 53.1% ($n = 27$)	Note: baseline data presented for both groups combined only *GIQLI at 12 months* Overall: preoperative 106.9, LVBG 106.4, LRYGBP 121 Symptoms domain: preoperative 63.7, LVBG 54.3, LRYGBP 60.9 Physical domain: preoperative 16.1, LVBG 20.9, LRYGBP 24 Emotional domain: preoperative 12.8, LVBG 14.7, LRYGBP 17.7 Social domain: preoperative 14.3, LVBG 16.5, LRYGBP 18.4 Significantly higher subtotals at follow-up were found for physical function, social function and emotional function domains in both groups. LVBG patients had a significant decrease in domain of symptoms, resulting in no improvement in total score LRYGBP scored better ($p = 0.04$ to $p < 0.001$) than LVBG in 7/19 symptom items, 4/5 emotional items, 1/7 physical items, 2/5 social items. LVBG scored better than LRYGBP in symptom of abdominal flatulence ($p = 0.02$) *GIQLI score for each item* (preoperative, follow-up LVBG, follow-up LRYGBP, *p* value LVBG vs LRYGBP) Abdominal pain: 3.3, 3.1, 3.4, $p =$ ns Abdominal fullness: 2.7, 2.7, 2.7, $p =$ ns Abdominal bloating: 3.2, 2.2**, 3.5, $p = 0.02$ Flatulence: 3.1, 2.4**, 1.8**, $p = 0.02$ Belching: 3.5, 2.7**, 3.2, $p = 0.04$ Abdominal noises: 3.6, 2.8**, 2.7**, $p =$ ns Bowel frequency: 3.4, 3.1, 3.5, $p =$ ns Enjoyed eating: 2.2, 2.1, 2.8, $p = 0.01$ Restricted eating: 2.8, 1.5***, 2.5, $p = 0.001$ Regurgitation: 3.6, 3.0*, 2.8**, $p =$ ns Dysphagia: 3.9, 2.9**, 3.9, $p = 0.001$	*Perioperative parameters* Mean operative time, minutes: LVBG 126 (38), LRYGBP 209 (50), $p < 0.001$ Mortality: LVBG 0, LRYGBP 0, $p =$ ns Conversion rate: LVBG 0, LRYGBP 1 (2.5%), $p =$ ns Intraoperative blood loss, ml: LVBG 31 (77), LRYGBP 35 (26), $p =$ ns Early postoperative complication: LVBG 1 (2.5%), LRYGBP 7 (17.5%), $p < 0.05$ Early complication – major: LVBG 0, LRYGBP 3 (7.5%) Early complication – minor: LVBG 1 (2.5%), LRYGBP 4 (10%) Postoperative flatus passage, days: LVBG 1.9 (0.6), LRYGBP 2.5 (1.2), $p < 0.01$ Analgesic use, units: LVBG 1.4 (1.5), LRYGBP 2.4 (3.0), $p < 0.05$ Postoperative stay, days: LVBG 3.5 (0.9), LRYGBP 5.7 (2.2), $p < 0.001$ Late complication (readmission): LVBG 2 (5%), LRYGBP 4 (10%), $p =$ ns *Complications details* LRYGBP Major complications (three): two anastomotic leakage (5%), requiring reoperation by laparoscopy and open laparotomy, one abdominal abscess requiring percutaneous drainage and total parenteral nutrition Minor complications (four): upper gastrointestinal bleeding, sutured nasogastric tube, minor leakage from drainage tube

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
	Eating speed: 3.7, 2.3***, 3.7, $p < 0.001$ Nausea: 3.5, 3.1, 3.3, $p =$ ns Diarrhoea: 3.2, 3.4, 3.1, $p =$ ns Bowel urgency: 3.7, 3.7, 3.7, $p =$ ns Constipation: 3.1, 2.3**, 3.7*, $p < 0.001$ Blood in stool: 3.7, 3.8, 3.8, $p =$ ns Heartburn: 3.6, 3.4, 3.8, $p =$ ns Incontinence: 3.9, 3.8, 4.0, $p =$ ns Emotional items Coping with stress: 2.5, 2.7, 2.6, $p =$ ns Sadness: 2.4, 2.9*, 3.7***, $p = 0.01$ Nervousness: 2.9, 2.9, 3.6**, $p = 0.02$ Frustration: 2.6, 3.1*, 3.9**, $p = 0.01$ Happiness: 2.4, 3.1**, 3.9***, $p = 0.01$ Physical items Fatigue: 2.6, 2.8, 3.4**, $p = 0.05$ Feeling unwell: 2.6, 2.8, 3.1*, $p =$ ns Wake-up at night: 3.2, 3.4, 3.4, $p =$ ns Appearance: 2.0, 3.6**, 4.0***, $p =$ ns Physical strength: 1.9**, 2.9***, 3.1, $p =$ ns Endurance: 1.7, 2.7**, 2.9**, $p =$ ns Feeling unfit: 2.1, 2.7*, 3.1**, $p =$ ns Social items Daily activities: 2.9, 3.1, 3.6*, $p = 0.05$ Leisure activities: 2.7, 3.5*, 3.9**, $p =$ ns Bothered by treatment: 2.8, 3.2, 3.8**, $p = 0.03$ Personal relationship: 3.1, 3.4, 3.6, $p =$ ns Sexual life: 2.8, 3.2, 3.5*, $p =$ ns Compared with preoperative data, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$	Late complications (four, 10%): one anastomotic stricture requiring endoscopic dilatation, two marginal ulcer requiring blood transfusion and prolonged medication, one pyothorax 2 months postoperatively requiring percutaneous drainage LVBG Minor complication (one): wound infection related to a minimal staple-line leakage, healed within 14 days Late complications (two, 5%): reflux oesophagitis requiring medication with one case receiving laparoscopic revision surgery
BMI, body mass index; GIQLI, gastrointestinal quality of life index; LRYGBP, laparoscopic Roux-en-Y gastric bypass; LVBG, laparoscopic vertical banded gastroplasty; n/s, not statistically significant.		

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Randomised using sealed envelopes
Allocation concealment?	Unclear	Not reported
Blinding of outcome assessors?	Unclear	Not reported
Blinding of participants on self-reported outcomes?	Unclear	Not reported
Incomplete outcome data addressed? Weight loss	Unclear	Not reported
Incomplete outcome data addressed? QoL	Unclear	Not reported
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	
Free of other sources of bias?	Unclear	

n/a, not applicable; QoL, quality of life.

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
MacLean 1995[121,122] Design: single centre, RCT Follow-up: 3–6.5 years	Country: Canada Number: total 106, VBG 54, RYGBP 52 Age (mean): VBG 38.8 years (SD 9.5), RYGBP 40.1 years (SD 7.7) Sex: not reported Weight (mean): VBG 278 lb (SD 41) (126 kg; SD 19), RYGBP 295 lb (SD 53) (134 kg; SD 24) BMI (mean): VBG 48.2 (SD 6.5), RYGBP 49.9 (SD 7.4) *Characteristics of target population:* Not stated *Exclusion criteria:* Not stated	1. Vertical banded gastroplasty (VBG) (with a division between staple lines) 2. Roux-en-Y gastric bypass (RYGBP) (staple lines not divided)	Success: BMI < 35 or < 50% excess weight and reoperation not required Reoperation defined as failure, regardless of ultimate outcome Mean length of follow-up Reoperation rates	*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 (two groups) or ANOVA (more than two groups). Chi-squared 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/dropout:* one patient possibly lost to follow-up after conversion to IGBP, but information contradictory *Generalisability:* inclusion/exclusion criteria not defined *Outcome measures:* mean BMI or weight loss after surgery not reported *Intercentre variability:* not mentioned *Conflict of interests:* funding information not given

BMI, body mass index; IGBP, isolated gastric bypass; RCT, randomised controlled trial; SD, standard deviation.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidities	Events/procedures (complications, reoperations)
~ 36 months Mean follow-up: VBG 38.6 months (SD 8.5); RYGBP 33.1 months (SD 12.4) *Success rate (BMI < 35 or < 50% excess weight and no reoperation)* VBG (31 remained with op) success rate 21 (39%) RYGBP (40 remained with op) success rate 30 (58%) VBG vs RYGBP $p = 0.08$ *up to 78 months:* Mean follow-up: VBG 70.9 months (SD 5.8); RYGB 66.5 months (SD 9.1) *Success rate (BMI < 35 or < 50% excess weight and no reoperation)* VBG (25 remained with operation) Success rate 9 (16%) RYGBP (32 remained with operation) Success rate 16 (34%) VBG vs RYGBP $p = 0.112$	Not assessed.	*Deaths:* VBG 0, RYGBP 0 *Conversions, Approx. 36 months:* VBG 5 (9%) to normal, 18 (33%) to isolated gastric bypass (IGBP) RYGBP 0 to normal, 12 (23%) to IGBP *Up To 6.5 years:* VBG 5 (9%) to normal, 24 (44%) to IGBP RYGBP 1 (2%) to normal, 19 (37%) to IGBP *Reoperation:* total VBG 43% (23 patients), RYGBP 23% (12 patients); stenosis VBG 20% (11 patients), RYGBP 0%; enlarged orifice VBG 13% (7 patients), RYGBP 0%; staple-line fistula VBG 4% (2 patients), RYGBP 23% (12 patients); clinical failure VBG 4% (2 patients), RYGBP 0%; abscess VBG 2% (1 patient), RYGBP 0%; stomal ulcer VBG 0%, RYGBP 13% (7 patients, these were 7 of the 12 patients with staple-line fistula)

BMI, body mass index; RYGBP, Roux-en-Y gastric bypass; SD, standard deviation; VBG, vertical banded gastroplasty.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Randomisation took place at time of surgery. No other details
Allocation concealment?	Unclear	
Blinding of outcome assessors?	Unclear	Not stated
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Unclear	One patient possibly lost to follow-up after conversion to IGBP, but information contradictory
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	Reported success (BMI < 35 or < 50% excess weight and reoperation not required), did not report BMI or weight loss
Free of other sources of bias?	Unclear	

BMI, body mass index; IGBP, isolated gastric bypass; n/a, not applicable; QoL, quality of life.

DOI: 10.3310/hta13410

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Olbers *et al.* (2005)[108,109] Design: single centre, RCT Follow-up: 24 months	Country: Sweden Number: total originally 100, but after randomisation 13 participants expressed a preference (nine for LRYGBP, four for LVBG) and were excluded. A further four participants were found to have a BMI > 50 and were also excluded. Therefore 83 remained, 37 randomised to LRYGBP, 46 to LVBG Note: in related paper[109] baseline weight, BMI and age data are very slightly different to those reported below. For weight and BMI the re ason for the discrepancy is unclear, but maybe the result of a reporting error, or rounding error. For age the related paper reports mean (SD) whereas median and range is reported below Age (median, range): LRYGBP 37 years, 34–61 years; LVBG 34 years, 26–60 years Sex (M:F): LRYGBP 12:25; LVBG 10:36 BMI [mean (SD)]: LRYGBP 42.7 (4.0); LVBG 42.1 (4.2) Weight [mean (SD) kg]: LRYGBP 123.9 (16.4) LVBG 123.3 (15.0) States no statistically significant differences between groups at baseline Recruitment: March 2000 to April 2001 Characteristics of target population: BMI > 40 or > 35 with obesity-associated morbidity, and BMI < 50 Exclusion criteria: BMI > 50	1. Laparoscopic Roux-en-Y gastric bypass (LRYGBP) 2. Laparoscopic vertical banded gastroplasty (LVBG)	Perioperative complications Change in BMI (states primary outcome) Excess body weight loss Remedial surgical intervention (states primary outcome) Oxygen saturation, forced vital capacity, peak expiratory flow, grip force and time to mobilisation after surgery (these results not data extracted) Related paper[109] reports on body composition, energy expenditure and dietary intake (not extracted)	Method of data analysis: the results for the 17 excluded participants were analysed separately Data given as median with range, or mean with 95% confidence intervals. $p < 0.05$ considered statistically significant Sample size/power calculation: reported that sample size was determined by calculations based on previous data on weight change and postoperative pulmonary complications, which indicated the need for about 80 patients (40 per group) to give sufficient power to demonstrate a difference at the 95% significance level (group sizes were 37 and 46) Conflict of interests: not stated Supported in part by a grant from the Research Council of the Västra Götaland Region, Sweden

BMI, body mass index; RCT, randomised controlled trial; SD, standard deviation.

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Mean BMI at 1 and 2 years: Results [mean (SD)] presented in a figure only, mean values below estimated by researcher. Text states weight loss significantly better after LRYGP but *p*-values not reported for the BMI outcome *Mean BMI at 1 year*: LRYGBP 29 ($n = 36/37$); LVBG 32 ($n = 39/46$). *p*-value not reported *Mean BMI at 2 years*: LRYGBP 28 ($n = 36/37$); LVBG 32 ($n = 35/46$). *p*-value not reported % *excess weight loss* at 1-year (mean (SD)): LRYGBP 78.3 (20.0)%; LVBG 62.9 (28.4)%, $p = 0.009$ % *excess weight loss* at 2 years [mean (SD)]: LRYGBP 84.4 (22.1)%; LVBG 59.8 (29.6)%, $p < 0.001$ *Proportion achieving excess weight loss of at least 50% without remedial surgery after 2 years*: 34/36 LRYGBP, 21/35 LVBG		*Conversions to open surgery perioperatively*: None *Operating time [mean (SD)]*: 138 (41) minutes LRYGBP; 105 (35) minutes LVBG, $p < 0.001$ *Early reoperations*: five LRYGBP (three haemorrhage, one for stenosis, one suspected leak); 1 LVBG (suspected leak), not significantly different between groups $p = 0.080$ *Perioperative complications (in addition to conversion to open surgery and reoperations above)*: LRYGBP two minor bleeding, one deep infection; LVBG four minor bleeding, one deep infection *Thrombotic complications* – none *Pulmonary complications* – no difference between groups, $p = 0.888$ *Median hospital stay*: LRYGBP 3 days (range 2–15 days), LVBG 3 days (range 1–16 days) *Remedial surgical intervention*: 0 LRYGBP; eight LVBG (four in the first year, four in the second. Conversion to RYGBP. Due to one migration of outlet restricting band, five vomiting and insufficient weight loss, two vomiting and excessive weight loss) One LRYGBP had an intra-abdominal abscess after discharge Results (perioperative complications, postoperative respiratory function, time to mobilisation, weight change over 2 years,% excess weight loss) also presented for the 17 excluded patients

BMI, body mass index; LRYGBP, laparoscopic Roux-en-Y gastric bypass; LVBG, laparoscopic vertical banded gastroplasty; RYGBP, Roux-en-Y gastric bypass; SD, standard deviation.

DOI: 10.3310/hta13410

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Yes	Randomisation by a computer program that stratified for weight, BMI, age and associated morbidity
Allocation concealment?	Unclear	Not described
Blinding of outcome assessors?	Unclear	Not described
Blinding of participants on self-reported outcomes?	n/a	No participant self-reported outcomes
Incomplete outcome data addressed? Weight loss	Yes	Reasons for missing outcome data given and unlikely to be related to true outcome. Missing data for similar reasons across groups (other than the four LVBG participants reoperated on)
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	Follow-up rate was 97.6%. One paper[108] states that one patient in each group was lost to follow-up 1 year after surgery and two patients who had undergone LVBG could not be contacted at the 2-year follow-up. Two women were pregnant at the 1-year follow-up and another two were pregnant at the 2-year follow-up. Their weights were excluded from the analysis. Figure 1 in reference 108 indicates 36/37 LRYGBP and 39/46 LVBG at 1-year follow-up, and 36/37 LRYGBP and 35/46 LVBG at 2-year follow-up. This statement is in agreement with that in the second paper:[109] At the 1-year follow-up four patients randomised and operated on with LVBG had been reoperated on (conversion to GBP), and two women were pregnant. These patients were excluded from the analysis. In addition, one patient from each group was lost to follow-up therefore 1-year follow-up was for 36 LRYGBP and 39 LVBG At the 1-year follow-up there was a tolerance of ± 6 weeks
Free of selective outcome reporting?	Unclear	Primary outcomes not prespecified. Some outcomes listed in the methods but unclear whether these match some of the outcomes reported because different terminology is used, e.g. methods lists Major haemorrhage and Minor haemorrhage with definitions for both, whereas results reports on Bleeding and Minor bleeding with no definitions provided
Free of other sources of bias?	Unclear	Uncertainty around the effect of the 17 patients who were excluded after randomisation either because they expressed a preference about the surgery they received, or were found to have a BMI > 50

BMI, body mass index; LRYGBP, laparoscopic Roux-en-Y gastric bypass; LVBG, laparoscopic vertical banded gastroplasty; n/a, not applicable; QoL, quality of life.

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Sugerman 1987[123] Design: single centre, RCT Follow-up: 3 years	Country: USA Number: total 40, RYGBP 20, VBG 20 Age: RYGBP 38 years (± 11), VBG 38 years (± 9) Sex: RYGBP 90% female, VBG 90% female % ideal weight: RYGBP 213% (± 49), VBG 225% (± 41) *Characteristics of target population:* More than 100 lb (45 kg) 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-dependent adult-onset diabetes, pseudo-tumour cerebri, etc.) *Exclusion criteria:* none reported	1. Roux-en-Y gastric bypass (RYGBP) 2. Vertical banded gastroplasty (VBG)	Weight loss Percentage weight lost Percentage excess weight lost Percentage ideal body weight achieved Mortality Complications	*Allocation to treatment groups:* feasibility of performing either procedure determined at laparotomy. Cards designating each operation were combined in groups of five, shuffled, and a card selected 'blindly'. *Blinding:* not stated *Comparability of treatment groups:* No differences in baseline characteristics of groups (age, sex, ideal body weight, percentage of ideal body weight) *Method of data analysis:* not ITT. Analysis of covariance or Student's *t* test for unpaired data *Sample size/power calculation:* not stated *Attrition/dropout:* VBG: one patient lost to follow-up immediately after surgery, one patient fatally stabbed at 25 months. Two patients converted to RYGBP, within 1 year and at 18 months and excluded from further analysis. Number of patients analysed were: 1 year, 19 RYGBP, 18 VBG; 2 year, 18 RYGBP, 17 VBG; 3 year, 18 RYGBP, 16 VBG *Generalisability:* Inclusion criteria described *Outcome measures:* appropriate outcome measures used *Intercentre variability:* not applicable *Conflict of interests:* No funding information provided *Other:* Study stopped after 9 months when a difference ($p < 0.05$) noted in favour of RYGBP

ITT, intention to treat; RCT, randomised controlled trial.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidities	Events/procedures (complications, reoperations)
Percentage ideal body weight (SD): 12 months RYGBP 138% ± 32; VBG 176% ± 41 ($p < 0.01$) 24 months RYGBP 139% ± 32; VBG 178% ± 41 ($p < 0.01$) 36 months RYGBP 142% ± 37; VBG 180% ± 44 ($p < 0.01$) *Weight loss (SD) (kg):* 12 months RYGBP 43.5 kg ± 11.3; VBG 32.2 kg ± 10.9 ($p < 0.001$) 24 months RYGBP 43.5 kg ± 15.4; VBG 30.4 kg ± 12.2 ($p < 0.001$) 36 months RYGBP 41.3 kg ± 12.7; VBG 27.2 kg ± 14.5 ($p < 0.01$) *Percent weight lost:* 12 months RYGBP 33% ± 7; VBG 22% ± 8 ($p < 0.001$) 24 months RYGBP 33% ± 9; VBG 22% ± 9 ($p < 0.001$) 36 months RYGBP 32% ± 9; VBG 20% ± 10 ($p < 0.01$) *Percent excess weight lost:* 12 months RYGBP 68% ± 17; VBG 43% ± 18 ($p < 0.001$) 24 months RYGBP 66% ± 29; VBG 39% ± 24 ($p < 0.001$). (From figure) 36 months RYGBP 62% ± 18; VBG 37% ± 19 ($p < 0.001$). (From figure) *Percent decrease in excess weight (SD) (n) for sweets eaters vs non-sweets eaters:* RYGBP 12 months: sweet eaters 69% ± 12 ($n = 12$), non-sweet eaters 67% ± 17 ($n = 7$), p = ns 24 months: sweet eaters 62% ± 11 ($n = 11$), non-sweet eaters 75% ± 19 ($n = 7$), p = ns 36 months: sweet eaters 59% ± 11 ($n = 11$), non-sweet eaters 71% ± 21 ($n = 7$), p = ns VBG 12 months: sweet eaters 36% ± 13 ($n = 12$), non-sweet eaters 57% ± 18 ($n = 6$), $p < 0.05$ 24 months: sweet eaters 35% ± 14 ($n = 11$), non-sweet eaters 53% ± 22 ($n = 6$), $p < 0.05$ 36 months: sweet eaters 32% ± 18 ($n = 11$), non-sweet eaters 50% ± 21 ($n = 5$), $p < 0.05$	Not assessed	*Mortality:* RYGBP two (10%), 3 days and 12 months (both assumed arrhythmia) No significant deficiencies in most vitamins, electrolytes, renal or liver function tests. RYGBP lower vitamin B_{12} levels (286 ± 149 pg/ml) than VBG (461 ± 226) at 24 months ($p < 0.05$) RYGBP: 25% intractable vomiting and stomal stenosis, 5% marginal ulcer of jejunal side of gastrojejunostomy VBG: 5% superficial stomal erosions Conversions from VBG to RYGBP: 5% at 1 month (one patient disrupted vertical staple line), 5% at 18 months (one patient failed to lose weight because of eating sweets and high starch foods), 10% at 38 months (two patients failed to lose weight)

ns, not statistically significant; RYGBP, Roux-en-Y gastric bypass; SD, standard deviation; VBG, vertical banded gastroplasty.
Difference in decrease in excess weight (%) for RYGBP compared to VBG for sweet eaters was significant ($p < 0.0001$), while for non-sweet eaters it was non-significant (p = ns).

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Yes	Feasibility of performing either procedure determined at laparotomy. Cards designating each operation were combined in groups of five, shuffled, and a card selected 'blindly'
Allocation concealment?	Unclear	
Blinding of outcome assessors?	Unclear	Not stated
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Yes	One patient lost to follow-up immediately after surgery, one patient fatally stabbed at 25 months. Two patients converted to RYGBP, within 1 year and at 18 months and excluded from further analysis. Number of patients analysed were: 1 year 19 RYGBP, 18 VBG; 2 years 18 RYGBP, 17 VBG; 3 years 18 RYGBP, 16 VBG
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	
Free of other sources of bias?	No	Groups of five cards used, unclear exactly what this means but may refer to blocked randomisation

n/a,not applicable; QoL, quality of life; RYGBP, Roux-en-Y gastric bypass; VBG, vertical banded gastroplasty.
Study stopped early at 9 months as the result of a stopping rule, when a statistically significant difference at $p < 0.05$ was noted in favour of gastric bypass.

DOI: 10.3310/hta13410

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
VanWoert 1992[106] (abstract only) USA Single-centre, RCT *Length of follow-up:* 36 months	*Total: 32* 1. 15 2. 17 Characteristics of target population: BMI > 40 Exclusion criteria: Not reported Participants (mean ± SD): GBP: Max weight % IBW 228 ± 55, BMI 52 ± 10, age 38 ± 8, M : F 4 : 11 VBG: Max weight % IBW 222 ± 27, BMI 51 ± 6, age 38 ± 10, M : F 3 : 14	Treatment arms: 1. Gastric bypass (GBP) 2. Vertical banded gastroplasty (VBG)	*Primary and secondary outcome measures used*: % of IBW, mortality, major operative complications Method of assessing outcomes: *not stated*	Allocation to treatment groups: randomised, but method not stated Blinding of outcome assessors: not reported Comparability of treatment groups: similar reported characteristics Method of data analysis: mean % IBW reported, no standard deviation or CI reported Sample size/power calculation: not reported Attrition/dropout: not reported General comments Generalisability: eligibility criteria not reported Outcome measures: % IBW reported Intercentre variability: single centre study Conflict of interests: funding support not mentioned

BMI, body mass index; CI, confidence interval; IBW, ideal body weight; RCT, randomised controlled trial; SD, standard deviation.

Table of results

Weight change	QoL/comorbidities	Events/procedures (complications, reoperations)
% *IBW* at 36 *months:*	Not assessed	Mortality: no deaths
GBP 121%, VBG 123%, p = ns		Major late operative complications: Cholelithiasis: GBP 13%, VBG 24% Peptic gastro-oesophagitis: GBP 33%, VBG 18%

IBW, ideal body weight; GBP, gastric bypass; ns, not statistically significant; VBG, vertical banded gastroplasty.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Not reported
Allocation concealment?	Unclear	
Blinding of outcome assessors?	Unclear	
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Unclear	Not reported
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	Limited data as reported in abstract only. Reports % ideal body weight, no SD or CI
Free of other sources of bias?	Unclear	Limited information as reported in abstract only

CI, confidence interval; n/a, not applicable; QoL, quality of life; SD, standard deviation.

Appendix 7

Data extraction tables: gastric bypass (non-banded) versus banded gastric bypass

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Bessler *et al.* 2007[118] Design: single centre, RCT Follow-up: up to 36 months	Country: USA Number: total 90 (out of 278 patients who underwent surgery during the recruitment period) Banded GBP $n = 46$ Non-banded GBP $n = 44$ Age (years): banded GBP 40.6 ± 7.4; non-banded GBP 42.6 ± 7.2. p = ns Sex (% women): banded GBP 56.5; non-banded GBP 73.8. $p = 0.09$ BMI: Banded GBP 59.4 ± 7.3; non-banded GBP 59.7 ± 7.1. p = ns Weight: not reported Hypertension (%): banded GBP 50; non-banded GBP 46. p = ns Diabetes mellitus (%): banded GBP 26; non-banded GBP 26. p = ns Hyperlipidaemia (%): banded GBP 31; non-banded GBP 30. p = ns Arthritis (%): banded GBP 91; non-banded GBP 72. $p < 0.05$ Gastro-oesophageal reflux disease (GERD) (%): banded GBP 39; non-banded GBP 43. p = ns Stress urinary incontinence (%): banded GBP 27; non-banded GBP 36. p = ns Characteristics of target population: BMI > 50 Exclusion criteria: Patients who had undergone previous gastric surgery. Minors	1. Banded long-limb gastric bypass (Banded GBP) 2. Non-banded long-limb gastric bypass (Non-banded GBP) Surgery took place from June 2001 and July 2005 by one surgeon	% excess weight lost, improvement or resolution of comorbidities; incidence of complications Assessments at 6, 12, 24 and 36 months postoperatively Postoperative gastrointestinal symptoms were scored according to a subjective scale where 0 = none, 1 = mild, 2 = moderate, 3 = severe	Method of data analysis: where point estimates are provided the paper does not state which measure is being presented. However, it is presumed that the data presented are means. A measure of variability around the point estimate (presumed to be ± SD although not stated) is provided for baseline data. No measure of variability is provided for outcome measures. $p < 0.05$ was considered significant Sample size/power calculation: not reported Conflict of interests: reported, the primary author is a consultant to, and has received research support from Ethicon Endo-Surgery. This author is also a consultant to, and receives marketing support from Inamed (LabBand) and is a consultant to USGI, Intrapace, Metacure, and Bard/Davol

BMI, body mass index; RCT, randomised controlled trial; SD, standard deviation.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
% *EWL at 12 months*: banded GBP 64; non-banded GBP 57.4. p = ns % *EWL at 24 months*: banded GBP 64.2; non-banded GBP 57.2. p = ns % *EWL at 36 months*: banded GBP 73.4; non-banded GBP 57.7. $p < 0.05$ *Achieving a BMI of < 35 at 12 months (%)*: banded GBP 47.8; non-banded GBP 41.0. p not reported *Achieving a BMI of < 35 at 24 months (%)*: banded GBP 52.9; non-banded GBP 37.5. p not reported	*Resolution of comorbidities*: study does not state which follow-up period is being reported, or numerators and denominators Hypertension (%): banded GBP 79; non-banded GBP 90. p = ns Resolution of diabetes mellitus (%): banded GBP 92; non-banded GBP 98. p = ns Hyperlipidaemia (%): banded GBP 50; non-banded GBP 62. p = ns Arthritis (%): banded GBP 76; non-banded GBP 91. p = ns Gastro-oesophageal reflux disease (GERD) (%): banded GBP 94; non-banded GBP 83. p = ns Stress urinary incontinence (%): banded GBP 83; non-banded GBP 93. p = ns	*Mortality*: 0 *Total complications* [*n* (%)]: banded GBP 12 (26); non-banded GBP 13 (29.5). p = ns *Wound infection* [*n* (%)]: banded GBP 7 (15.2); non-banded GBP 5 (11). p = ns *Anastomotic leak* [*n* (%)]: banded GBP 0; non-banded GBP 2 (4.8). p = ns *Pneumonia (n (%))*: banded GBP 1 (2.1); non-banded GBP 1 (2.2). p = ns *Pulmonary embolism* [*n* (%)]: banded GBP 0; non-banded GBP 0. *Small bowel obstruction* [*n* (%)]: banded GBP 1 (2.1); non-banded GBP 1 (2.2). p = ns *Band erosion/slippage/removal* [*n* (%)]: banded GBP 0; non-banded GBP N/A. *Other* [*n* (%)]: banded GBP 3 (6.5); non-banded GBP 4 (9.0). p = ns Gastrointestinal symptoms (average scores) Dumping: banded GBP 0.12; non-banded GBP 0.05. p = ns ($p = 0.06$) Emesis: banded GBP 0.35; non-banded GBP 0.13. $p = 0.0002$ Diarrhoea: banded GBP 0.11; non-banded GBP 0.13. p = ns Constipation: banded GBP 0.07; non-banded GBP 0.08. p = ns Flatulence: banded GBP 0.22; non-banded GBP 0.13. p = ns Abdominal pain: banded GBP 0.04; non-banded GBP 0.06. p = ns Food intolerance (%): banded GBP 79; non-banded GBP 33. $p < 0.05$ (Study does not state which follow-up period is being reported or *n*-values)
BMI, body mass index; EWL, excess weight loss; GBP, gastric bypass; n/a, not applicable; ns, not statistically significant.		

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Sequence generation not reported. Paper states 'Randomisation was performed by opening 1 of 100 sequentially numbered sealed envelopes' but it is not clear whether any process was used to generate the sequence of items contained within these envelopes
Allocation concealment?	Yes	Group allocation was concealed within 100 sequentially numbered sealed envelopes containing the words 'banded' or 'non-banded; (50 each in random order) on a folded piece of paper. However, it is not clear whether the envelopes were opaque
Blinding of outcome assessors?	Unclear	Not reported. Assume no blinding (although it would have been possible to blind patients and outcome assessors in this study)
Blinding of participants on self-reported outcomes?	Unclear	Uncertain how gastrointestinal symptom scores were ascertained. Methods imply that these were scored by the study authors 'We scored…' but presumably participants would have reported on these outcomes to the study investigators. Presume participants were not blinded
Incomplete outcome data addressed? Weight loss	Unclear	Ninety randomised out of 278. Reasons not given. Numbers not reported. % EWL at 36 months – the paper reports a significant difference between groups but states 'However, this was calculated from the small number of patients reaching the 36-month follow-up period.' The number of participants at the 36-month follow-up is not stated. There were no significant differences between the groups for this outcome at earlier time points. Sample sizes not reported for any outcome measures. In the discussion the authors state 'our total rate of follow-up was close to 90%', but goes on to say 'the follow-up at 36 months included a limited number of patients'
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	Unclear	As above
Free of selective outcome reporting?	No	% EWL reported at 6, 12, 24 and 36 months (significant difference at 36 months). BMI reported at 12 and 24 months only, *p* values not reported. SDs not reported
Free of other sources of bias?	Unclear	

BMI, body mass index; EWL, excess weight loss; n/a, not applicable; QoL, quality of life; SDs, standard deviations.

Appendix 8

Data extraction tables: laparoscopic gastric bypass versus laparoscopic adjustable gastric banding

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Angrisani et al (2007)[107] Design: single centre, RCT Follow-up: 60 months	Country: Italy Number: total 51, LRYGBP 24, LAGB 27 Age [mean ± SD (range)]: LRYGBP 34.1 ± 8.9 (21–50) years; LAGB 33.8 ± 9.1 (21–50) years Sex (M : F): LRYGBP 4 : 20; LAGB 5 : 22 BMI [mean ± SD (range)]: LRYGBP 43.8 ± 4.1 (38.9–48.9); LAGB 43.4 ± 4.2 (38.1–49.2) Weight [mean ± SD (range) kg]: LRYGBP 118.2 ± 13.2 (92–152); LAGB 117.1 ± 12.8 (95–147) Comorbidities reported below Characteristics of target population: BMI > 35 to < 50, age > 16 years, but < 50 years Exclusion criteria: history of hiatal hernia, previous major abdominal surgery	1. LRYGBP 2. LAGB	Mortality Conversion to open procedure Postoperative complications leading to reoperation Hospital stay Weight loss and percentage of excess weight loss BMI and decrease in BMI Comorbidities Operative time	Method of data analysis: states not an ITT analysis Sample size/power calculation: not reported Conflict of interests: states none

BMI, body mass index; ITT, intention to treat; LAGB, laparoscopic adjustable gastric banding; LRYGBP, laparoscopic Roux-en-Y gastric bypass; SD, standard deviation.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Mean weight at 5 years (range 60–66 months): LRYGBP 84 kg, LAGB 97.9 kg, $p < 0.001$ *Mean weight at 12 months*: LRYGBP 92.8 kg; LAGB 102.4 kg *Mean weight at 36 months*: LRYGBP 83.5 kg; LAGB 98.7 kg *Mean BMI at 5 years (range 60–66 months):* LRYGBP 29.8; LAGB 34.9, $p < 0.001$ *Mean BMI at 12 months*: LRYGBP 35.4; LAGB 38.7 *Mean BMI at 36 months*: LRYGBP 29.1; LAGB 35.6 % *Excess weight loss at 12 months*: LAGB 34.7, LRYGBP 51.3 % *Excess weight loss at 36 months*: *LAGB* 47.3, LRYGBP 67.3 % *Excess weight loss at 5-years (range 60–66 months)*: LRYGBP 66.6%; LAGB 47.5%, $p < 0.001$ *Weight loss failure (BMI > 35 at 5 years)*: LRYGBP 1/24 (4.2%); LAGB 9/26 (34.6%), $p < 0.001$ *BMI < 30 at 5 years*: LRYGBP 15/24 (62.5%); LAGB 3/26 (11.5%), $p < 0.001$	*Comorbidities.* Baseline: LRYGBP two hyperlipaemia, one hypertension, one Type 2 diabetes; LAGB three hypertension, one sleep apnoea At 5-year reports diabetes, sleep apnoea and hyperlipaemia resolved	*Mortality*: none *Reoperation*: LRYGBP 3/24 (12.5%) (each for a potentially lethal complication); LAGB 4/26 (15.2%) (two pouch dilatation, two band removal because of inadequate weight loss: one of these was converted to biliopancreatic diversion, three waiting list for LRYGBP) *Early complications* (occurring < 30 days postoperatively): LRYGBP 1/24 (4.2%) posterior pouch leak intraoperatively causing conversion to open surgery, one (4.2%) sepsis caused by jejunal perforation (sutured and intestine resected). LAGB: none *Late complications*: LRYGBP one internal hernia/small bowel obstruction at 15 months; LAGB 2/26 (7.6%) gastric pouch dilatation (treated by band removal) *Mean operative time*: LRYGBP 220 ± 100 minutes; LAGB 60 ± 20 minutes, $p < 0.001$ *Mean hospital stay*: LRYGBP 4 ± 2 days, LAGB 2 ± 1 days, $p < 0.05$. One LRYGBP required intensive care stay of 40 days

BMI, body mass index; LAGB, laparoscopic adjustable gastric banding; LRYGBP, laparoscopic Roux-en-Y gastric bypass.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Described as randomised but no detail of the method used to generate the randomisation sequence
Allocation concealment?	Unclear	Randomisation by sealed envelopes but no further details
Blinding of outcome assessors?	Unclear	Blinding of outcome assessors not reported
Blinding of participants on self-reported outcomes?	n/a	Patients were informed of the operation to which they had been randomised preoperatively, but no self-reported outcomes
Incomplete outcome data addressed? Weight loss	Yes	Eight patients were excluded after randomisation because they refused to undergo the procedure to which they had been assigned (five LRYGBP, three LAGB); one LAGB reported to be lost to follow-up
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	Yes	
Free of selective outcome reporting?	Unclear	Outcomes listed in methods section all reported in results but no way to check if all results reported in protocol are reported in paper
Free of other sources of bias?	Unclear	Authors state that for LRYGBP they were in the early phase of the learning curve, whereas for LAGB approximately 150 people had been operated by the senior author

LAGB, laparoscopic adjustable gastric banding; LRYGBP, laparoscopic Roux-en-Y gastric bypass; n/a, not applicable; QoL, quality of life.

Appendix 9

Data extraction tables: laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy

Characteristics of included study

Study	Participants	Interventions	Outcomes	Notes
Karamanakos 2008[125] Design: single centre, RCT Follow-up: 12 months	Country: Greece Number: total 32, LRYGBP 16, LSG 16 Age, years [mean (SD, range)]: LRYGBP 37 (8.25, 21–55), LSG 30.6 (7.8, 19–50), $p = 0.023$ Sex (M:F): LRYGBP 4:12, LSG 1:15 BMI [mean (SD, range)]: LRYGBP 46.6 (3.7, 40.2–51.9), LSG 45.1 (3.6, 36.8–51.1) Weight, kg [mean (SD, range)]: LRYGBP 125.2 (14.7, 100–150), LSG 122.1 (18.1, 96–160) LRYGBP: two diabetes mellitus, one anaemia, five hypercholesterolaemia, five hypertriglyceridaemia LSG: one glucose intolerance, three anaemia, three hypercholesterolaemia, three hypertriglyceridaemia Characteristics of target population: not reported Exclusion criteria: chronic medical or psychiatric illness, substance abuse, previous gastrointestinal surgery	1. LRYGBP Gastric pouch 15–20 ml, 150 cm Roux limb used 2. Laparoscopic sleeve gastrectomy (LSG) Gastric sleeve tube 40–60 ml remained, 85% of stomach excised	BMI % EWL The following not data extracted: Ghrelin levels Peptide-YY levels Appetite	Method of data analysis: data expressed as mean (SD). Differences between means evaluated using analysis of variance or Student's *t* test. Significance at $p < 0.05$ Sample size/power calculation: not reported Conflict of interests: not reported

BMI, body mass index; EWL, estimated weight loss; SD, standard deviation.

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
BMI at 12 months [mean (SD)]: LRYGBP: 31.5 (3.4) LSG: 28.9 (3.6), $p = 0.41$ *% EWL at 12 months* [mean (SD)]: LRYGBP: 60.5 (10.7) LSG: 69.7 (14.6), $p = 0.05$ *Weight loss at 12 months* [mean (SD)], kg: LRYGBP: 40.0 (8.3) LSG: 43.6 (11.7), $p = 0.322$	Diabetes resolved in both LRYGBP patients	Conversions to open surgery = 0. Intraoperative and postoperative complications = 0

BMI, body mass index; EWL, estimated weight loss; LRYGBP, laparoscopic Roux-en-Y gastric bypass; LSG, laparoscopic sleeve gastrectomy; SD, standard deviation.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Yes	Computer-generated numbers were used to assign the type of surgery
Allocation concealment?	Unclear	Type of surgery was written on a card sealed in a completely opaque envelope. Not stated if sequentially numbered
Blinding of outcome assessors?*	Yes	States that 'blinding as to the type of the procedure involved the patient and the medical staff, and the independent data collector'
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed?* Weight loss	Yes	States that all patients had a complete evaluation at all time points of the follow-up
Incomplete outcome data addressed?* QoL	n/a	
Incomplete outcome data addressed?* Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	
Free of other sources of bias?	Unclear	

n/a, not applicable; QoL, quality of life.

Appendix 10

Data extraction tables: vertical banded gastroplasty versus adjustable gastric banding

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Morino, 2003[110] Design: RCT, single centre. Follow-up: minimum 2 years, mean 33.1 months (range 24–46 months) LAGB: 1 year 98% 2 years 94% 3 years 90% LVBG 1 year 90% 2 years 88% 3 years 95%	Country: Italy Number: total 100, LAGB 49, LVBG 51 Age, years: LAGB 37.2 (20–55), LVBG 38.2 (21–58) Sex (F : M): LAGB 38 : 11, LVBG 43 : 8 BMI: LAGB 44.7 (40.1–50.0), LVBG 44.2 (40.0–50.0) Weight, kg: LAGB 121.5 (90–175), LVBG 118.7 (90–160) Percentage excess weight: LAGB 106.5 (79.3–142.6), LVBG 104.8 (79.4–136.0) Characteristics of target population: history of obesity at least 5 years, documented weight loss attempts in the past, BMI 40–50, aged 18–60 years Exclusion criteria: contraindications to creation of pneumoperitoneum (e.g. glaucoma), large oesophageal hiatal hernias (> 3 cm), symptomatic gastro-oesophageal reflux disease, pregnancy, drug or alcohol abuse, psychological disorders (e.g. bulimia, depression), hormonal or genetic obesity-related disease, previous gastric surgery. Evaluated by a dietitian to exclude concentrated sweet eaters and binge eaters 175 submitted to surgery, 75 excluded from study: BMI > 50 (35), BMI < 40 with comorbidities (5), specific contraindication to pneumoperitoneum (4), previous gastric surgery (6), severe reflux disease (14), refused (11)	1. Laparoscopic adjustable silicone gastric banding (LAGB) 2. Laparoscopic vertical banded gastroplasty (LVBG)	Primary end point: reoperation rate Secondary end points: early and late complication rates,% excess weight loss at 1, 2, 3 years Surgical time (skin incision to wound closure) Anaesthesiology time (global time in operative room) Conversion rate Intraoperative and postoperative morbidity 60-day mortality Length of hospital stay Residual BMI Percentage of excess weight loss Reinhold classification: Excellent 0–25% excess weight, Good 26–50%, Fair 51–75%, Poor 76–100%, Failure > 100% excess weight at time of evaluation	*Allocation to treatment groups:* randomisation performed 1 day before surgery by means of sealed opaque envelopes containing computer-generated numbers *Blinding of outcome assessors:* not reported *Comparability of treatment groups:* comparable in sex, age, mean weight, BMI, % excess weight, laboratory test results *Method of data analysis:* categorical variables compared by chi-squared test, with Yates correction and the Fisher exact test (two-tailed) when necessary. Continuous variables compared by Student's *t* test or the Mann–Whitney *U* test, depending on distribution. All *p* values were two-sided. $p < 0.05$ indicated statistical significance *Sample size/power calculation:* calculated based on assumption of a difference of 5% in the reoperation rate between LAGB and LVBG, a difference of 5% in early and late complications, and a difference of 10% in % excess weight loss. These differences were considered clinically significant, and a sample size of 100 (50 in each group) was needed *Attrition/dropout:* per cent present at 1-, 2- and 3-year follow-up reported for each group

BMI, body mass index; RCT, randomised controlled trial.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
BMI 1 year: LAGB 35.5, LVBG 30.1, $p < 0.05$ 2 years: LAGB 34.8, LVBG 29.7, p = ns 3 years: LAGB 35.7, LVBG 30.7, p = ns *Percentage of excess weight loss* 1 year: LAGB 39.2, LVBG 62.3, $p < 0.05$ 2 years: LAGB 41.4, LVBG 63.5, p = ns 3 years: LAGB 39.0, LVBG 58.9, p = ns *Reinhold classification* Patients with an excellent or good result (residual excess weight < 50%) 2 years: LAGB 35%, LVBG 74%, $p < 0.001$ 3 years: LAGB 25%, LVBG 63%, $p = 0.056$ *Patients with procedural failure resulting from insufficient weight loss (residual excess weight > 100%)* 2 years: LAGB 5%, LVBG 0 3 years: LAGB 6%, LVBG 0	Not assessed.	*Mortality*, %: LAGB 0, LVBG 0 *Operative time*, min: LAGB 65.4 (35–120), LVBG 94.2 (40–270), $p < 0.05$ *Hospital stay*, days: LAGB 3.7 (2–6), LVBG 6.6 (3–58), $p < 0.05$ *Conversion to open surgery*, %: LAGB 0, LVBG 0 *Early morbidity*, %: LAGB 6.1, LVBG 9.8, $p = 0.754$ *Late complications*, %: LAGB 32.7, LVBG 14, $p < 0.05$ *Late reoperations*, %: LAGB 24.5, LVBG 0, $p < 0.001$ *Associated procedures* (10% of both groups) LAGB: four cholecystectomies, one lymph node biopsy LVBG: five cholecystectomies LAGB: One early postoperative band slippage on day 7, treated with laparoscopic repositioning, one port infection, one haematoma at port site LVBG: One fistula at staple line day 2, treated with open gastric bypass; two prolonged postoperative pyrexia, non-operative treatment; two respiratory failures without evidence of pulmonary embolism, conservative therapy *Late complications*: LAGB 32.7% (16/49), LVBG 14% (7/50), $p < 0.05$ LAGB: Nine gastric band slippage, three symptomatic reflux disease, one complete food intolerance, one poor compliance, one infected port, one port twisted LVBG: One pouch dilatation, one asymptomatic pouch-to-fundus fistula, four symptomatic reflux diseases, one gastric bezoar *Late reoperations*: LAGB: 24.5% (12/49), LVBG 0/50, $p < 0.001$ LAGB: Eight bands removed (six for slipping, one for severe reflux oesophagitis, one for poor compliance), one slipped band replaced laparoscopically, one gastric bypass due to food intolerance without complications related to the band, one port repositioned, one port removed

BMI, body mass index; LAGB, laparoscopic adjustable silicone gastric banding; LVGB, laparoscopic vertical banded gastroplasty.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Yes	Randomisation performed 1 day before surgery by means of sealed opaque envelopes containing computer-generated numbers
Allocation concealment?	Yes	Sealed opaque envelopes
Blinding of outcome assessors?	Unclear	Not reported
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Yes	Per cent present at 1-, 2- and 3-year follow-up reported for each group. Reasons for losses not given
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	
Free of other sources of bias?	Unclear	

n/a, not applicable; QoL, quality of life.

DOI: 10.3310/hta13410

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Nilsell 2001[126] Design: single centre, RCT Follow-up: 4–5 years	Country: Sweden Number: total 59, AGB 29, VBG 30 Age: AGB 38 years (20–58), VBG 39 years (19–59) Sex: AGB 72% female, VBG 80% female Weight: AGB 124 kg (24.0), VBG 123 kg (11.4) BMI: AGB 42.8 (5.4), VBG 43.9 (3.8) *Characteristics of target population:* people with BMI > 40 or BMI > 37 with obesity-associated comorbidity *Exclusion criteria*: age > 60 years, severe psychiatric disorders or alcoholism	1. Adjustable gastric banding (AGB) 2. Vertical banded gastroplasty (VBG)	Complications Late reoperations Weight change Patient satisfaction Reflux symptoms	*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/dropout*: two died from causes unrelated to bariatric operation. three AGB and two VBG were lost to follow-up *Generalisability*: predominantly limited to females, aged in mid- to late 30s who are morbidly obese *Intercentre variability*: single centre *Conflict of interests*: none stated

BMI, body mass index; RCT, randomised controlled trial; SEM, standard error of the mean.

Table of results

Weight change	QoL/comorbidities	Events/procedures (complications, reoperations)
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) (Data for years 1 to 4 are estimated from graph)	*Patient satisfaction:* Patients satisfied: AGB 21/26 (81%); VBG 15/27 (56%)	*Complications:* Deaths: one patient per arm died of 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 (reoperation third postoperative day) *Late reoperations:* 3/26 AGB reoperated (two due to dilatation of gastric pouch (band replaced), one removed at patient's request) 10/27 VBG reoperated (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 (four), gastrogastrostomy (three), longer band (one), gastric banding (two) Three VBG with staple-line disruption were not reoperated. Total incidence of staple-line disruption 18.5% (5/27)

AGB, adjustable gastric banding; VBG, vertical banded gastroplasty.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Randomised using sealed envelopes the day before surgery
Allocation concealment?	Unclear	As above
Blinding of outcome assessors?	No	States that staff and patients not blinded (outcome assessors not specified, but assume not blinded)
Blinding of participants on self-reported outcomes?	No	Staff and patients were not blinded to treatment
Incomplete outcome data addressed? Weight loss	Yes	Two died from causes unrelated to bariatric operation. Three AGB and two VBG were lost to follow-up
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	
Free of other sources of bias?	Unclear	

AGB, adjustable gastric banding; n/a, not applicable; QoL, quality of life; VBG, vertical banded gastroplasty.

DOI: 10.3310/hta13410

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
van Dielen (2005)[127,128] Design: single centre, RCT Follow-up: 24 months 84 months follow-up reported in abstract only[128]	Country: Netherlands Number: total 100, open VBG 50, LAGB 50 (but one converted to GBP during surgery) Age (mean ± SD) Open VBG 39 ± 8.5 years; LAGB 37.2 ± 9.7 years, p = ns Sex (M : F): open VBG 10 : 40; LAGB 10 : 40, p = ns BMI (mean ± SD): open VBG 46.6 ± 6.4; LAGB 46.7 ± 6.1, p = ns Number of comorbidities per patient (mean ± SD): open VBG 1.3 ± 1.1; LAGB 1.3 ± 1.0, p = ns Recruitment: May 1999 to December 2001 Characteristics of target population: BMI > 40 or > 35 with comorbidities; age between 18 and 60 years; had failed previous non-surgical attempts at weight loss Exclusion criteria: previous obesity surgery or gastric surgery; patients with severe psychological disorders	1. Open vertical banded gastroplasty (VBG) 2. Laparoscopic adjustable gastric banding (LAGB, with Lap-Band)	Mortality Conversion to open procedure Immediate postoperative complications, late complications Hospital length of stay Per cent excess weight loss BMI Reduction in comorbidities	Method of data analysis: whether ITT not stated, but does state follow-up of 100% achieved for both groups. Data given as mean ± SD. $p < 0.5$ denoted as statistically significant Sample size/power calculation: not reported Conflict of interests: not stated Supported by AGIKO-stipendium of the Netherlands Organisation of Scientific Research

AGIKO, [assistent-geneeskundige in opleiding tot klinisch onderzoeker] MD clinical research trainee; BMI, body mass index; ITT, intention to treat; ns, not statistically significant; SD, standard deviation.

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Mean BMI at 1 year: Open VBG 31.1 ± 6.2; LAGB 35.0 ± 6.3 *Mean BMI at 2 years*: Open VBG 31.0 ± 6.0; LAGB 34.6 ± 6.5, $p \leq 0.002$ (in favour of VBG)	*Comorbidities*. Preoperative: open VBG 41 (82%) patients with comorbidity – 29 (58%) joint problems, 8 (16%) pulmonary problems, 10 (20%) hypertension, 7 (14%) diabetes mellitus, 3 (6%) cardiovascular problems, 2 (4%) hypercholesterolaemia, 2 (4%) reflux disease, 1 (2%) sleep apnoea, 0 (0%) neurological problems LAGB 39 (78%) patients with comorbidity – 28 (56%) joint problems, 9 (18%) pulmonary problems, 7 (14%) hypertension, 5 (10%) diabetes mellitus, 2 (4%) cardiovascular problems, 2 (4%) hypercholesterolaemia, 3 (6%) reflux disease, 1 (2%) sleep apnoea, 1 (2%) neurological problems	*Mortality*: open VBG 2 (4%) one due to sepsis, one due to pneumonia. LAGB none *Immediate postoperative complications*: open VBG: complications occurred in nine patients: three (6%) leakage, requiring reoperation, two (4%) splenectomy (intraoperative due to iatrogenic injury), two (4%) obstruction (gastroscopy necessary), with seven infections in five (10%) patients [sepsis three (6%) one of these patients died, urinary tract infection one (2%), pneumonia three (6%) one of these patients died), wound infection one (2%). LABG two (4%) conversion to open LABG due to technical problems, one (2%) conversion to gastric bypass as a result of perforation during retro-gastric tunnelling. There were no infections

BMI, body mass index; LAGB, laparoscopic adjustable gastric banding; QoL, quality of life; VBG, vertical banded gastroplasty.

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
% *Excess weight loss at 1-year*: Open VBG 71.1 ± 24.0%; LAGB 53.3 ± 21.2%, $p \leq 0.001$ (in favour of VBG) % *Excess weight loss at 2 years*: Open VBG 70.1 ± 25.5%; LAGB 54.9 ± 23.3%, $p \leq 0.001$ (in favour of VBG) At mean 84 months follow-up:[128] % *excess BMI loss*: VBG 68.8%, LAGB 56.9%. States significant, but statistics not reported	At 1 year: Open VBG 14 (30.4%)[a] patients with comorbidity – 7 (15.2%)[a] joint problems, 3 (6.5%)[b] pulmonary problems, 8 (17.4%) hypertension, 1 (2.2%)[b] diabetes mellitus, 2 (4.3%) cardiovascular problems, 1 (2.2%) hypercholesterolaemia, 0 (0%) reflux disease, 0 (0%) sleep apnoea, 0 (0%) neurological problems LAGB 18 (37.5%)[a] patients with comorbidity – 10 (20.8%)[a] joint problems, 3 (6.3%)[b] pulmonary problems, 5 (10.4%) hypertension, 1 (2.1%)[b] diabetes mellitus, 2 (4.2%) cardiovascular problems, 2 (4.2%) hypercholesterolaemia, 0 (0%) reflux disease, 0 (0%) sleep apnoea, 1 (2.1%) neurological problems At 2 years: Open VBG 23 (47.9%)[a] patients with comorbidity – 13 (27.1%)[a] joint problems, 3 (6.3%)[b] pulmonary problems, 7 (14.6%) hypertension, 1 (2.1%)[b] diabetes mellitus, 1 (2.1%) cardiovascular problems, 1 (2.1%) hypercholesterolaemia, 0 (0%) reflux disease, 0 (0%) sleep apnoea, 1 (2.1%) neurological problems LAGB 20 (40%)[a] patients with comorbidity – 12 (24%)[a] joint problems, 1 (2%)[b] pulmonary problems, 5 (10%) hypertension, 1 (2%)[b] diabetes mellitus, 3 (6%) cardiovascular problems, 1 (2%) hypercholesterolaemia, 0 (0%) reflux disease, 0 (0%) sleep apnoea, 1 (2%) neurological problems Although the number of comorbidities in both groups decreased following surgery no differences in comorbidities were observed between groups	*Mean length of hospital stay*: Open VBG 6.8 ± 10.4 days (range 2–56 days), LAGB 3.5 ± 1.5 days (range 2–9 days), $p < 0.001$ *Late complications*: Open VBG: revisional surgery (conversion to gastric bypass) 18 (36%) (due to vertical staple-line disruption 15 (30%), Narrow outlet two (4%), Insufficient weight loss one (2%). A further eight (16%) patients developed an incisional hernia for which surgical repair was needed. Outlet stenosis or obstruction in six (12%) patients required gastroscopy. Two patients developed peroneal nerve paralysis associated with rapid weight loss [table records neurological problems for only one patient (2%)]. LAGB: 20 reoperations (40%) took place, 16 were major reoperations (pouch dilatation/pouch slippage 12 (24%), band leakage 2 (4%), band erosion 2 (4%)). Four were minor operations [painful access-port 2 (4%), infection around access-port 1 (2%), port leakage 1 (2%)]. Of the 12 (24%) patients reoperated on for pouch dilatation/pouch slippage, the band was repositioned in eight cases, reduction and refixation of the pouch was performed in three cases and one new LAGB was placed At mean 84 months follow-up:[128] States that long-term complications 'were mainly' (assume all not reported): VBG: staple-line disruption 51%, incisional hernia 27% LAGB: pouch dilatation 24%, anterior slippage 15% Major reoperation: VBG: conversion to gastric bypass 59% LAGB: total 46%, refixation or band replacement 35%, conversion to another procedure in 11% Major complications after reoperation that necessitated reintervention: VBG 4% LAGB 2%

BMI, body mass index; LAGB, laparoscopic gastric banding; VBG, vertical banded gastroplasty.
a $p \leq 0.001$ compared to preoperative.
b $p \leq 0.05$ compared to preoperative.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Yes	Computer-generated randomisation list, made before the start of the study, used for randomisation
Allocation concealment?	Unclear	Not described
Blinding of outcome assessors?	Unclear	Not described, assume no blinding
Blinding of participants on self-reported outcomes?	n/a	No self-reported outcomes. Patients were informed about their surgical treatment group during administration to hospital
Incomplete outcome data addressed? Weight loss	Yes	The authors state that 100% follow-up in both groups was achieved at 2 years. One LAGB converted to open GBP during procedure. At mean 84 months, follow-up was 91%. No further details given
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	Yes	
Free of selective outcome reporting?	Unclear	Outcomes not-prespecified
Free of other sources of bias?	Unclear	No other obvious sources of bias

GBP, gastric bypass; LAGB, laparoscopic adjustable gastric bypass; n/a, not applicable; QoL, quality of life.

Appendix 11

Data extraction tables: laparoscopic adjustable gastric banding versus laparoscopic isolated sleeve gastrectomy

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Himpens *et al.* 2006[129] Design: single centre, RCT Follow-up: 36 months	Country: Belgium Number: total 80, LAGB 40, LISG 40 Age (median, range) years: LAGB 36 (20–61); LISG 40 (22–65), p = ns Sex: LAGB ratio M : F: 7 : 33; LISG 9 : 31, p = ns BMI (median, range): LAGB 37 (30–47); LISG 39 (30–53), p = ns Weight: baseline not reported Gastro-oesophageal reflux disease (GERD) requiring drug therapy with proton pump inhibitors (PPI): LAGB 6/40 (15%); LISG 8/40 (20%) Characteristics of target population: only inclusion criteria are candidates for laparoscopic restrictive operation Exclusion criteria: none reported	1. LAGB 2. Laparoscopic isolated Sleeve Gastrectomy (LISG)	Primary: relative weight loss Other outcomes: BMI, GERD (number on PPI medication), complications and reoperations. Also feeling of hunger, craving for eating sweets as assessed by questionnaire (latter two not extracted here)	Method of data analysis: not reported if ITT analysis, median values used for analyses of outcomes, p values < 0.05 were statistically significant Sample size/power calculation: text refers to the statistical test used depending on the requirements by sample size but no details of the sample size calculation reported Conflict of interests: none reported

BMI, body mass index; ITT, intention to treat; RCT, randomised controlled trial.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Weight loss (median and range): After 1 year: LAGB 14 kg (–5 to 38); LISG 26 kg (0 to 46), $p < 0.0001$ After 3 years: LAGB 17 kg (0 to 40); LISG 29.5 kg (1 to 48), $p < 0.0001$ *Excess weight loss* (median%, range): At 1 year: LAGB 41.4% (–11.8 to 130.5); LISG 57.7% (0 to 125.5), $p = 0.0004$ At 3 years: LAGB 48% (0 to 124.8); LISG 66% (–3.1 to 152.4), $p = 0.0025$ *BMI* (decrease, median and range): After 1 year: LAGB 15.5 (5 to 39); LISG 25 (0 to 45), $p < 0.0001$ After 3 years: LAGB 18 (0 to 39); LISG 27.5 (0 to 48), $p = 0.0004$	*GERD* Appeared by 1 year in 3/34 (8.8%) LAGB and 7/32 (21.8%) LISG, p = ns Appeared by 3 years in 7/34 (20.5%) LAGB and 1/32 (3.1%) LISG, p = ns Numbers for denominator are those without GERD at baseline, although figure 3 (Himpens *et al.*, 2006)[129] notes these as those who had GERD at baseline. Disappeared by 1 year in 5/6 (83.3%) LAGB and 6/8 (75%) LISG. This remained the same at 3 years.	*Complications (not requiring surgery)*: At 1 year: LAGB shoulder pain three (7.5%); frequent vomiting six (15%), poor choice of alimentation two (5%); LISG gastric pain two (5%), frequent vomiting one (2.5%), mineral deficiency two (5%). At 3 years: LAGB shoulder pain three (8.5%); frequent vomiting ten (28.5%), poor choice of alimentation 17 (48.5%), gastric ulcer one (2.8%); LISG frequent vomiting five (16.6%), poor choice of alimentation eight (26.6%), mineral deficiency three (10%) *Complications (requiring surgery)*: LAGB: no early postoperative complications, seven late complications of which: three pouch dilatation (treated with band removal in two, and conversion to RYGBP in one); one gastric erosion (treated by conversion to RYGBP); three disconnections of the port (treated by reconnection). In addition, two patients presented insufficient weight loss and treated by conversion to RYGBP. LISG: two early postoperative complications of which: one was an intraperitoneal bleed requiring laparoscopy and one gastric ischaemia requiring laparoscopic total gastrectomy. No late complications were recorded. Two patients presented insufficient weight loss and were converted to laparoscopic duodenal switch

BMI, body mass index; GERD, gastro-oesophageal reflux disease; LAGB, laparoscopic gastric banding; LISG, laparoscopic isolated sleeve gastrectomy; ns, not statistically significant; RYGBP, Roux-en-Y gastric bypass.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	States patients '…operated consecutively and randomly assigned…'. No details of randomisation sequence reported
Allocation concealment?	Unclear	No details reported
Blinding of outcome assessors?	Unclear	No details reported
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Unclear	States that 80 randomised, 40 in each group. No discussion of any attrition or exclusions, appears to be no losses at 3 years but unable to check as numbers not presented in any details of weight loss results
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	Unclear	GERD outcomes: all numbers were reported, but data were statistically analysed by subgroup for this outcome – those without GERD at baseline to see if it appeared, those with it at baseline to see if it disappeared
Free of selective outcome reporting?	Unclear	Reports data on outcomes listed in methods, but study protocol not available, only reports mean change and range, not standard deviations
Free of other sources of bias?	Unclear	The characteristics of the patients were reported to be similar for the two groups, although states medians and ranges were performed unclear what the reason is for this. Insufficient information to assess whether an important risk of bias exists

GERD, gastro-oesophageal reflux disease; n/a, not applicable; QoL, quality of life.

Appendix 12

Data extraction tables: open versus laparoscopic gastric bypass

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Luján, 2004[130] DESIGN: RCT, single centre FOLLOW-UP: mean 23 months	Country: Spain Number: total 104, LGBP 53, open GBP 51 Age, years: LGBP 37 (18–64), open GBP 38 (20–63), p = ns Sex (M : F): LGBP 10 : 43, open GBP 13 : 38, p = ns. BMI: LGBP 48.53 (36–78), open GBP 52.20 (37–80), p = ns WEIGHT: LGBP 130.70 (92–208), open GBP 137.57 (96–214), p = ns Characteristics of target population: BMI > 40 without coexisting pathological disorders or BMI > 35 with coexisting pathological disorders Exclusion criteria: patients evaluated by the Psychiatry, Endocrinology, Anaesthesia and Surgery units to rule out significant contraindications for surgery	1. Laparoscopic gastric bypass (LGBP) 2. Open (open GBP) gastric bypass	Operating time Intraoperative complications Early (< 30 days) postoperative complications Late (> 30 days) postoperative complications Hospital stay Short-term evolution of BMI	*Allocation to treatment groups:* randomisation performed before assessment by computer generated numbers, concealed in sequentially numbered sealed opaque envelopes *Blinding of outcome assessors:* not reported *Comparability of treatment groups:* similar age, gender, preoperative weight and BMI, no statistically significant differences *Method of data analysis:* mean, SD, medians and range calculated, Comparisons between groups performed with Student's t test for quantitative variables and chi-squared Pearson test for qualitative variables *Sample size/power calculation:* not reported *Attrition/dropout:* 100% follow-up. States mean follow-up is 23 months, but range not given. Not clear how many patients are included at each follow-up point

BMI, body mass index; ns, not statistically significant; RCT, randomised controlled trial; SD, standard deviation.

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
BMI (estimated from figure), p = ns 3 months: LGBP 41, open GBP 47 6 months: LGBP 36, open GBP 41 12 months: LGBP 33, open GBP 37 18 months: LGBP 31, open GBP 36 24 months: LGBP 32, open GBP 35 36 months: LGBP 31, open GBP 35.5		*Postoperative mortality*: LGBP two (one unrelated to surgery), open GBP one *Mean operating time*, minutes: LGBP 186.4 (125–290), open GBP 201.7 (129–310), $p < 0.05$ LGBP Conversions to laparotomy: four (8%), due to extreme hepatomegaly, portal hypertension secondary to hepatic cirrhosis discovered in the course of the operation, anaesthetic problems (hypercapnia), and splenic lesion during dissection of the angle of His. All occurred in the first 20 patients Open GBP Intraoperative complications four (8%): three splenectomies, one splenic vein tear requiring suture *Early complications (< 30 days)*: LGBP 12 (22.6%), open GBP 15 (29.4%), p = ns LGBP: three intestinal subocclusions, two asymptomatic leaks, two intra-abdominal bleeding, two upper gastrointestinal haemorrhage (one requiring blood transfusion), one lower gastrointestinal haemorrhage, one thromophlebitis, one stenosis of gastro-entero-anastomosis Open GBP: four subphrenic abscesses, three upper gastrointestinal haemorrhage, four wound infections, three respiratory infections, one evisceration (death) *Late complications (> 30 days)*: LGBP 6 (11%), open GBP 12 (24%), $p < 0.05$ LGBP: three intestinal obstructions (conservative, death, reoperation), two pancreatitis/ cholecystectomy, one sudden death (possible pulmonary thromboembolism) Open GBP: 10 eventrations, one subphrenic abscess, one intestinal constriction (reoperation) *Mean hospital stay*: LGBP 5.2 days (1–13), open GBP 7.9 days (2–28), $p < 0.05$

BMI, body mass index; LGBP, laparoscopic gastric bypass; ns, not statistically significant; open GBP, open GBP gastric bypass; QoL, quality of life.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Yes	Randomisation performed before assessment by computer-generated numbers
Allocation concealment?	Yes	Concealed in sequentially numbered sealed opaque envelopes
Blinding of outcome assessors?	Unclear	Not reported
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Unclear	100% follow-up. States mean follow-up is 23 months, but range not given. Not clear how many patients are included at each follow-up point
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	BMI reported in figure only, with no exact data reported and no measure of variance
Free of other sources of bias?	Unclear	

BMI, body mass index; n/a, not applicable; QoL, quality of life.

DOI: 10.3310/hta13410

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Nguyen *et al* 2001[113] Puzziferri *et al* 2006[114] Design: single centre, RCT Follow-up: 36 months. Mean 39 ± 8 months (range 24–58)	Country: USA Original publication: Number: total 155, LGBP 79, open 76 Age: LGBP 40 years (± 8), open 42 years (± 9) Sex: LRYGBP 91% female, RYGBP 88% female Weight: LGBP 289 lb (± 38) (131 ± 17 kg), open 296 lb (± 44) (135 ± 20 kg) BMI: LGBP 47.6 (± 4.7), open 48.4 (± 5.4) Updated publication: Number: total 116, RYGBP 57, LRYGBP 59 Age [mean (SD)]: LRYGBP 47 (± 7) years: RYGBP 50 (± 8) years Sex: LRYGBP female 56; male 3: RYGBP female 51, male 6 BMI (mean SD): LRYGBP 48 (± 5): RYGBP 49(± 6) Weight: not reported History cholecystectomy: LRYGBP 16 (27%): RYGBP 17 (30%) Comorbidities (see results section) Characteristics of target population: BMI 40–60; 21–60 years of age, failed previous medical interventions for weight loss Exclusion criteria: those with previous bariatric surgery, previous gastric surgery, large abdominal ventral hernia, history of deep vein thrombosis or pulmonary embolism, and severe cardiovascular, respiratory, hepatic or renal disease	1. Laparoscopic gastric bypass (LRYGBP) 2. Open gastric bypass (RYGBP) Cholecystectomy undertaken concomitantly with the procedures in some cases	Length of time for return to activities of daily living 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 reoperation (< 30 days), weight loss (mean % of excess body weight loss), time to return to work, quality of life (SF-36 and BAROS) and costs Weight loss, Changes in comorbidities, QoL [Moorehead-Ardelt Quality of Life Questionnaire (MAQoL)] The Bariatric Analysis and Reporting Outcome System (BAROS) Late complications (occurring > 3 months after surgery) The Moorehead-Ardelt QoL questionnaire assesses five categories; self-esteem, physical activity, social life, work conditions, sexual interest/activity. Points are added for positive changes and deducted for negative changes The BAROS takes into account three outcomes: % excess body weight loss, changes in comorbidities, the MAQoL. A maximum of three points are given for each category. Points are deducted for complications and reoperations. The scale is rated as excellent (> 7–9); very good (> 5–7); good (> 3–5); fair (> 1–3); failure (≤ 1)	Method of data analysis: states ITT analysis and LRYGBP converted to RYGBP were analysed as laparoscopic. However, two patients initially allocated to RYGBP were excluded after randomisation (one withdrew consent; one had an intraoperative splenic injury) and unclear if included in analysis. Differences between groups were assessed using two-sample *t* tests or Fisher exact tests. Mann–Whitney *U*-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 GBP – with difference of 7 days between procedures clinically significant – 73 patients per group necessary to detect difference using two tailed test type 1 error of 0.05 and Type 2 error 0.2 Conflict of interests: not stated

BMI, body mass index; GBP, gastric bypass; ITT, intention to treat; RCT, randomised controlled trial.

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Nguyen *et al*. 2001: *Percentage excess body weight loss (SD)*: 12 months: LGBP ($n = 29$) 68% (± 15); open ($n = 25$) 62% (± 14) ($p = 0.07$) Puzziferri *et al*. 2006: (for 116 participants) % *Excess body weight lost at 3 years (mean SD)*: LRYGBP ($n = 30$) 77% ± 22%; RYGBP ($n = 33$) 67% ± 21%, p = ns % *Excess body weight lost at 4 years (mean SD)* LRYGBP ($n = 22$) 76% ± 19%; RYGBP ($n = 18$) 71% ± 25%, p = ns	Nguyen *et al.* 2001: *Quality of Life SF-36 Scores* [mean (± SD)] (preoperative LRYGBP $n = 70$, RYGBP $n = 73$; 3 months LRYGBP $n = 54$, RYGBP $n = 42$) *Physical functioning:* preoperative LRYGBP 46.5 (21.3), RYGBP 40.0 (24.4), p = ns; 1 month LRYGBP 60.9 (24.7), RYGBP 46.3 (24.7), $p < 0.05$; 3 months LRYGBP 80.2 (19.1), RYGBP 67.8 (26.6), p = ns; US norms 84.2 (23.3) *Role-physical:* preoperative LRYGBP 47.2 (40.2), RYGBP 37.5 (37.9), p = ns; 1 month LRYGBP 29.7 (39.2), RYGBP 18.5 (32.3), p = ns; 3 months LRYGBP 80.7 (32.5), RYGBP 76.8 (33.3), p = ns; US norms 81.0 (34.0) *Bodily pain:* preoperative LRYGBP 51.0 (22.7), RYGBP 48.7 (24.1), p = ns; 1 month LRYGBP 59.2 (21.5), RYGBP 45.1 (24.4), $p < 0.05$; 3 months LRYGBP 75.1 (24.7), RYGBP 68.1 (25.6), p = ns; US norms 75.2 (23.7) *General health:* preoperative LRYGBP 54.5 (21.6), RYGBP 52.9 (22.3), p = ns; 1 month LRYGBP 71.3 (18.0), RYGBP 64.0 (18.1), $p < 0.05$; 3 months LRYGBP 77.2 (15.7), RYGBP 72.4 (16.5), p = ns; US norms 72.0 (20.3) *Vitality:* preoperative LRYGBP 38.5 (20.0), RYGBP 36.6 (19.9), p = ns; 1 month LRYGBP 45.4 (20.5), RYGBP 39.1 (18.9), p = ns; 3 months LRYGBP 65.8 (17.7), RYGBP 73.1 (95.2), p = ns; US norms 60.9 (21.0) *Social functioning:* preoperative LRYGBP 64.4 (26.3), RYGBP 61.6 (29.5), p = ns; 1 month LRYGBP 67.6 (24.5), RYGBP 51.9 (29.1), $p < 0.05$; 3 months LRYGBP 87.3 (17.9), RYGBP 74.1 (30.0), p = ns; US norms 83.3 (22.7) *Role-emotional:* preoperative LRYGBP 49.1 (24.4), RYGBP 45.5 (27.2), p = ns; 1 month LRYGBP 78.5 (28.2), RYGBP 69.5 (33.5), p = ns; 3 months LRYGBP 83.0 (29.6), RYGBP 74.6 (40.7), p = ns; US norms 81.3 (33.0) *Mental health:* preoperative LRYGBP 73.0 (15.1), RYGBP 71.9 (17.3), p = ns; 1 month LRYGBP 76.8 (17.4), RYGBP 70.8 (19.4), p = ns; 3 months LRYGBP 82.9 (14.2), RYGBP 75.0 (19.2), p = ns; US norms 74.7 (18.1) *Moorehead-Ardelt QoL scores* (3 months LRYGBP $n = 47$, RYGBP $n = 36$; 6 months LRYGBP $n = 34$, RYGBP $n = 28$) *Self-esteem*: 3 months LRYGBP 0.81 (0.3), RYGBP 0.73 (0.32) (p = ns); 6 months LRYGBP 0.84 (0.27), RYGBP 0.80 (0.28) (p = ns)	Nguyen *et al*. 2001 *Operative outcomes* Operative time (minutes): LRYGBP 225 (± 40), RYGBP 195 (± 41) $p < 0.001$ Estimated blood loss (ml); LRYGBP 137 (± 79), RYGBP 395 (± 284) $p < 0.001$ Proportion requiring intensive-care unit stay: LRYGBP 7.6%, RYGBP 21.1% $p = 0.03$ Median length of hospital stay (days): LRYGBP 3 (IQR 1), RYGBP 4 (IQR 2) $p < 0.001$ Proportion requiring reoperation: LRYGBP 7.6%, RYGBP 6.6% p = ns Return to activities of daily living (days): LRYGBP 8.4 (± 8.6), RYGBP 17.7 (± 19.1) $p < 0.001$ Return to work (days): LRYGBP 32.2 (± 19.8), RYGBP 46.1 (± 20.6) $p = 0.02$ Intraoperative transfusion: LRYGBP 0, RYGBP 3.9% Conversion from LRYGBP to RYGBP: 2.5% due to failure of circular stapler; inability to insufflate abdomen safely *Complications* *Major complications:* total LRYGBP 7.6%, RYGBP 9.2% ($p = 0.78$); anastomotic leak LRYGBP 1, RYGBP 1; gastric pouch outlet obstruction LRYGBP 0, RYGBP 1; hypopharyngeal perforation LRYGBP 1, RYGBP 0; jejunojejunostomy obstruction LRYGBP 3, RYGBP 0; pulmonary embolism LRYGBP 0, RYGBP 1; respiratory failure LRYGBP 0, RYGBP 1; gastrointestinal bleeding LRYGBP 1, RYGBP 0; wound infection LRYGBP 0, RYGBP 2; retained laparotomy sponge LRYGBP 0, RYGBP 1

DOI: 10.3310/hta13410

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
	Physical: 3 months LRYGBP 0.48 (0.40), RYGBP 0.46 (0.44) (p = ns); 6 months LRYGBP 0.37 (0.17), RYGBP 0.34 (0.18) (p = ns) *Social*: 3 months LRYGBP 0.31 (0.19), RYGBP 0.24 (0.21) (p = ns); 6 months LRYGBP 0.33 (0.19), RYGBP 0.29 (0.21) (p = ns) *Labour*: 3 months LRYGBP 0.24 (0.19), RYGBP 0.13 (0.29) ($p < 0.05$); 6 months LRYGBP 0.28 (0.21), RYGBP 0.21 (0.27) (p = ns) *Sexual*: 3 months LRYGBP 0.20 (0.21), RYGBP 0.09 (0.24) ($p < 0.05$); 6 months LRYGBP 0.26 (0.20), RYGBP 0.19 (0.26) (p = ns) Puzziferri *et al*. 2006: MAQoL scores [LRYGBP (n = 22) RYGBP (n = 22)] *Self-esteem*: 3 years LRYGBP 0.89, RYGBP 0.88, p = ns *Physical activity*: 3 years LRYGBP 0.40, RYGBP 0.36, p = ns *Social life*: LRYGBP 0.34, RYGBP 0.33, p = ns *Labour or work conditions*: LRYGBP 0.33, RYGBP 0.25, p = ns *Sexual interest/activity*: LRYGBP 0.20, RYGBP 0.24, p = ns Puzziferri *et al.* 2006: BAROS scores [LRYGBP (n = 22) RYGBP (n = 22)] *Rates as %:* *Fair*: 3 years LRYGBP 4.5%, RYGBP 9.1% *Good, very good or excellent*: LRYGBP 95.5%; RYGBP 86.4%, p = ns *Failure*: text states for LRYGBP and RYGBP overall failure rate, 2.3%; figure suggests failures in RYGBP group only *Scores on BAROS* (estimated from graph, unsure if mean) *Excellent*: LRYGBP 3, RYGBP 5 *Very good*: LRYGBP 14, RYGBP 11 *Good*: LRYGBP 4, RYGBP 3 *Fair*: LRYGBP 1, RYGBP 2 *Failure*: LRYGBP 0, RYGBP 1	*Minor complications:* total LRYGBP 7.6%, RYGBP 11.8% (p = 0.42); gastrointestinal Ileus LRYGBP 1, RYGBP 0; *Clostridium difficile* colitis LRYGBP 1, RYGBP 0; gastrogastric fistula LRYGBP 0, RYGBP 1; asymptomatic leak LRYGBP 0, RYGBP 1; gastrointestinal bleeding LRYGBP 2, RYGBP 0; wound infection LRYGBP 1, RYGBP 6; deep venous thrombosis LRYGBP 1, RYGBP 1 *Late complications:* total LRYGBP 18.9%, RYGBP 15.8% (p = 0.52); anastomotic stricture LRYGBP 9/79 (11.4%), RYGBP 2/76 (2.6%) p = 0.06; prolonged nausea/vomiting LRYGBP 1, RYGBP 2; small bowel obstruction LRYGBP 1, RYGBP 0; cholelithiasis LRYGBP 3, RYGBP 0; ventral hernia LRYGBP 0, RYGBP 6 (p = 0.01); anaemia LRYGBP 0, RYGBP 2; protein-calorie malnutrition LRYGBP 1, RYGBP 0 Puzziferri *et al*. 2006, late complications at 3 years (LRYGBP n = 59, RYGBP n = 57) Incisional hernia: LRYGBP 3 (5%), RYGBP 22 (39%), $p < 0.01$ Anaemia: LRYGBP 8 (14%), RYGBP 3 (5%), p = ns Vitamin B_{12} deficiency: LRYGBP 3 (5%), RYGBP 6 (11%), p = ns Chronic nausea/vomiting: LRYGBP 3 (5%), RYGBP 2 (4%), p = ns Chronic abdominal pain: LRYGBP 2 (3%), RYGBP 1 (2%), p = ns Marginal ulcer: LRYGBP 0, RYGBP 1 (2%), p = ns Small bowel obstruction: LRYGBP 2 (3%), RYGBP 1 (2%), p = ns Cholecystectomy (excludes those with previous cholecystectomy): LRYGBP 12/43 (28%), RYGBP 2/40 (5%), p = 0.03 No perioperative deaths No late deaths

continued

Table of results *(continued)*

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
	Puzziferri *et al*. 2006: (for 116 participants) *Osteoarthritis*: baseline LRYGBP 30 (51%), RYGBP 31 (54%) (p = ns); improvement/resolution at 3 years LRYGBP 24 (80%), RYGBP 19 (61%) ($p < 0.05$) *Hypertension*: baseline LRYGBP 18 (31%), RYGBP 28 (49%) (p = ns); improvement/resolution at 3 years LRYGBP 15 (83%), RYGBP 28 (100%) (p = ns) *Depression:* baseline LRYGBP 17 (29%), RYGBP 17 (30%) (p = ns); improvement/resolution at 3 years LRYGBP 13 (76%), RYGBP 12 (71%) (p = ns) *Gastro-oesophageal reflux*: baseline LRYGBP 14 (24%), RYGBP 21 (37%) (p = ns); improvement/resolution at 3 years LRYGBP 14 (100%), RYGBP 21 (100%) (p = ns) *Dyslipidaemia*: baseline LRYGBP 8 (14%), RYGBP 14 (25%) (p = ns); improvement/resolution at 3 years LRYGBP 7 (88%), RYGBP 17[a] (100%) ($p < 0.01$). *Sleep apnoea*: baseline LRYGBP 5 (8%), RYGBP 15 (26%) ($p < 0.05$); improvement/resolution at 3 years LRYGBP 5 (100%), 12 (86%) (p = ns) *Diabetes mellitus*: baseline LRYGBP 5 (8%), RYGBP 8 (14%) (p = ns); improvement/resolution at 3 years LRYGBP 5 (100%), RYGBP 7 (88%) (p = ns) *Infertility*: baseline LRYGBP 7 (12%), RYGBP 5 (9%) (p = ns); improvement/resolution at 3 years LRYGBP 2 (29%), RYGBP 2 (40%) (p = ns) *Urinary incontinence*: baseline LRYGBP 8 (14%), RYGBP 4 (7%) (p = ns); improvement/resolution at 3 years LRYGBP 7 (88%), RYGBP 4 (100%) (p = ns) *Lower extremity oedema*: baseline LRYGBP 2 (3%), RYGBP 3 (5%) (p = ns); improvement/resolution at 3 years LRYGBP 1 (50%); RYGBP 3 (100%) (p = ns)	

BAROS, bariatric analysis and reporting outcome systems; LGBP, laparoscopic adjustable gastric banding; LRYGBP, laparoscopic Roux-en-Y gastric bypass; ns, not statistically significant; QoL, quality of life; RYGBP, Roux-en-Y gastric bypass; SD, standard deviation.

a Assume error as 14 had dyslipidaemia at baseline, and Table 4 (Puzziferri *et al*., 2006[114]) suggests 14.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Randomisation was performed by the use of sealed envelopes, stratified by BMI (< 50; ≥ 50) and in blocks of six patients however method of sequence generation not reported
Allocation concealment?	Unclear	Sealed envelopes but no further details
Blinding of outcome assessors?	Unclear	Not described
Blinding of participants on self-reported outcomes?	No	Patients were informed of their treatment during preoperative clinic visit
Incomplete outcome data addressed? Weight loss	Unclear	Patients who withdrew consent or did not undergo GBP were excluded from the analysis; 19 eligible patients did not undergo randomisation; 13 requested laparoscopic GBP and 6 requested open GBP; 2 randomised to GBP were excluded after randomisation (1 withdrew consent, 1 needed splenectomy) Second publication reports data for 117 of the original 155 participants for weight loss and comorbidities. No reasons for missing data are given
Incomplete outcome data addressed? QoL	Unclear	Only 44 participants were reported for QoL
Incomplete outcome data addressed? Comorbidity	Unclear	Second publication reports data for 117 of the original 155 participants for weight loss and comorbidities. No reasons for missing data are given
Free of selective outcome reporting?	Unclear	% EBW reported but data are integers and appear to have been rounded. Weight loss or BMI not reported. Some listed outcomes have not been reported on
Free of other sources of bias?	No	Baseline characteristics in second publication (Puzziferri *et al.*) were reanalysed for those who had the 3-year follow-up only. Block randomisation used in an unblinded trial therefore may be possible to predict assignment to groups

BMI, body mass index; EWL, excess weight loss; GBP, gastric bypass; QoL, quality of life.

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Sundbom, 2004[112] Design: RCT, single centre. Follow-up: 12 months	Country: Sweden Number: total 50, hand 25, open 25 Median age (range), years: hand 37 (19–54), Open 38 (24–54) Sex (M:f): hand 2:23, open 3:22 BMI: hand 44 (36–54), open 45 (34–54) Previous abdominal surgery: hand 11, open 11 Comorbidity requiring medication: hand 14, open 21 Characteristics of target population: Patients who had not undergone previous bariatric surgery. All had undergone thorough medical investigation in the hospital metabolic unit and had failed conservative treatment, including dietary advice and pharmacological treatment. Fully informed and motivated to undergo gastric bypass Exclusion criteria: BMI > 55, simultaneous cholecystectomy One eligible patient refused to participate, one could not be randomised because of availability of techniques, five were excluded because of BMI > 55, one excluded as the result of planned simultaneous cholecystectomy	1. Hand-assisted laparoscopic Roux-en-Y gastric bypass (hand) 2. Open Roux-en-Y gastric bypass (open)	Length of postoperative hospital stay Morphine requirement Sick leave Weight reduction BMI Blood transfusion Duration of surgery Peroperative bleeding Abdominal wall thickness	*Allocation to treatment groups:* randomised by sealed envelope after induction of anaesthesia. Stratified by sex *Blinding of outcome assessors:* identical dressings were used so that nursing staff and patients were blinded to the treatment received. Patients informed of procedure at discharge *Comparability of treatment groups:* states well matched for age, sex, BMI, previous abdominal surgery and comorbid conditions. Data presented, no statistics reported. Appears to be higher comorbidity in the Open group *Method of data analysis:* ITT analysis. Presented as median (range). $p < 0.050$ considered statistically significant. ANOVA and Mann–Whitney *U* test used *Sample size/power calculation:* sample size was calculated at 21 patients in each group when using a power of 90%, a standard deviation of 1 (as in the pilot study) and an expected difference in postoperative hospital stay of 1 day or more *Attrition/dropout*: no patient dropped out after randomisation and follow-up data were available for all patients Protocol violated in two patients in hand group – cholecystectomy performed through slightly enlarged incision for the hand-assisted device, and fenestration of incidentally discovered large liver cyst. Both remained in study analysis, but exclusion did not alter results substantially

BMI, body mass index; ITT, intention to treat; RCT, randomised controlled trial.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Median weight reduction (range):		Hand
4–6 weeks: hand 13 kg, open 13 kg		Laparoscopic conversions to laparotomy: 0
1 year: hand 39 kg (23–57), open 41 kg (26–57)		Oozing intra-abdominal bleeding: three (two developed arterial bleeding after removing the left 12-mm epigastric trocar, stopped by compression in one, and in one the retracted traumatised epigastric artery was ligated after a fascial incision has been made)
Median BMI:		Open
1 year: hand 29, open 30		Two intense intraluminal bleeding from the gastrojejunostomy, managed by digital compression through the jejunotomy
Reduction in BMI was 15 units in both groups		*Peroperative and postoperative data*, median (range)
		Abdominal wall thickness, cm: hand 6 (3–9), open 6 (5–7)
		Peroperative bleeding, ml: hand 250 (0–1300), open 250 (0–900)
		Duration of surgery, minutes: hand 150 (110–265), open 85 (60–150), $p < 0.001$
		Reoperation: hand 1[a], open 0
		Patients requiring blood transfusion: hand 1 (2 units)[b], open 1 (2 units)[b]
		Morphine requirement, mg:
		Day 1: hand ($n = 25$) 48 (12–148), open ($n = 25$) 32 (6–150)
		Day 2: hand ($n = 20$) 36 (14–123), open ($n = 22$) 30 (12–118)
		Day 3: hand ($n = 16$) 28 (12–99), open ($n = 11$) 25 (10–62)
		Total days 1–3: Hand 98 (12–370), open 66 (6–318)
		Length of hospital stay, days: hand 6 (4–14), open 6 (3–7)
		Deaths within 30 days postoperation: hand 0, open 0
		Respiratory systems requiring prolonged antibiotic treatment and physiotherapy treatment: hand 8, open 5
		Clinical deep vein thrombosis, pulmonary embolism, or wound dehiscence: hand 0, open 0

continued

Table of results *(continued)*

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
		One month follow-up: Various grades of dysphagia: 18 (group not stated) Narrow anastomosis revealed by gastroscopy, with successful balloon dilatation (no stomal ulcers seen): Hand 2, Open 4 Wound infection with pus: hand 1, open 1 Abnormal secretions: 4 (group not stated) Total sick leave, days ($n = 40$), median (range): hand 30 (15–59), open 37 (19–95) 10 patients retired or on long-term sick leave One year follow-up Anaemic requiring intensive treatment: two women Symptomatic incisional hernia: hand 0, open 1 Short-term treatment with a proton pump inhibitor: hand 3, open 3 Small stomal ulcer revealed by gastroscopy: hand 0, open 1 One patient died 11 months after operation from metastatic breast cancer. Treatment not affected by gastric bypass

BMI, body mass index; hand, hand-assisted laparoscopic Roux-en-Y gastric bypass; open, open Roux-en-Y gastric bypass; QoL, quality of life.
a Due to leakage of gastrojejunostomy
b Due to postoperative anaemia.

DOI: 10.3310/hta13410

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Randomised by sealed envelope after induction of anaesthesia. Stratified by sex
Allocation concealment?	Unclear	
Blinding of outcome assessors?	Unclear	Identical dressings were used so that nursing staff and patients were blinded to the treatment received. Patients informed of procedure at discharge
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Yes	No patient dropped out after randomisation and follow-up data were available for all patients. Protocol violated in two patients in Hand group – cholecystectomy performed through slightly enlarged incision for the hand-assisted device, and fenestration of incidentally discovered large liver cyst. Both remained in study analysis, but exclusion did not alter results substantially
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	Median BMI reported at 12 months. No measures of variance reported
Free of other sources of bias?	No	Appears to be higher co morbidity in the Open group

BMI, body mass index; n/a, not applicable; QoL, quality of life.

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Westling and Gustavsson 2001[131] Design: single centre, RCT Follow-up: 1 year	Country: Sweden Number: total 51, LRYGBP 30, open 21 Age: 36 years (± 9) Sex: 94% female BMI: LRYGBP 41 (± 4), open 44 (± 4) *Characteristics of target population:* people with BMI > 40 or BMI > 35 with significant comorbidity; 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 before randomisation because they were unsuitable for laparoscopy ($n = 21$), had gallstones ($n = 7$), or were scheduled for RYGBP as a revisional procedure ($n = 42$)	1. Laparoscopic Roux-en-Y gastric bypass (LRYGBP) 2. Open Roux-en-Y gastric bypass (open)	Complications from standard questionnaire on stomach pain, vomiting, dysphagia, nausea, diarrhoea, excessive dumping, general well-being, need for sick leave Body weight Incisional hernias	*Allocation to treatment groups*: blocked randomisation 60% laparoscopic and 40% open 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 ($p < 0.05$). Well balanced for concomitant medications. No other comparative information provided *Method of data analysis*: mean and standard deviation, median and range, Student's *t* test, chi-squared, rank sum test and linear regression. Significance at $p < 0.05$ *Sample size/power calculation*: none stated *Attrition/dropout*: no patients were lost to follow-up *Generalisability*: predominantly limited to females, aged in mid- to late 30s who are morbidly obese *Intercentre variability*: single centre *Conflict of interests*: none stated

BMI, body mass index; RCT, randomised controlled trial; RYGBP, Roux-en-Y gastric bypass.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Mean BMI 1 year: LRYGBP 27 (± 4); open 30.6 (± 4) *Mean change in BMI* 1 year: LRYGBP 14 (± 3); open 13 (± 3) (p = ns)	*Patient satisfaction* All patients: 92% very satisfied, 8% satisfied. No difference between groups (no data reported)	*Complications* Deaths: one LRYGBP from malignant hyperthermia (family history) Gastrointestinal symptoms (dumping/vomiting/diarrhoea): 5% of all patients Incisional hernia one LRYGBP; small embolus one LRYGBP; colicky pain and vomiting because of narrow stricture of tunnel through mesocolon five LRYGBP, and to herniated Roux limb one LRYGBP; leakage because of failure of hand sewn part, one open (reoperated); jejunal ulcers three LRYGBP, two open (p = ns); stricture in gastrojejunostomy: one LRYGBP treated by endoscopic dilatation; superficial wound infection: three open Readmission: LRYGBP one (for unexplained fever); open: three [pneumonia (one), epigastric pain and/or vomiting with normal gastroscopy (two)] *Surgical outcomes* Conversions: seven (23%) LRYGBP patients converted to open (due to either bleeding (four) or other operative concerns). Duration (minutes): LRYGBP(n = 30) 245 (135–390); open (n = 21) 100 (70–150) Preoperative bleeding (ml): LRYGBP(n = 30) 250 (50–1500); open (n = 21) 300 (200–500) Six (20%) LRYGBP patients without conversion reoperated (these were the 6 LRYGBP above with colicky pain and vomiting) *Early postoperative outcomes* Pain – morphine dose (mg): LRYGBP (n = 29) 98 (± 71.5) (p = ns); LRYGBP: conversions excluded (n = 22) 69 (± 46.4) (p < 0.005); open (n = 21) 140 (± 90) Hospital stay (days): LRYGBP (n = 29) 4.5 (± 1.2) (p = ns); LRYGBP: conversions excluded (n = 22) 4 (± 0.8) (p = 0.025); open (n = 21) 6 (± 3.8) Sick leave (weeks): LRYGBP (n = 24) 3.9 (± 2.1) (p = ns); LRYGBP: conversions excluded (n = 18) 2.8 (± 1.8) (p = 0.025); open (n = 14) 5 (± 3.3)

BMI, body mass index; LRYGBP, laparoscopic Roux-en-Y gastric bypass; ns, not statistically significant; open, open Roux-en-Y gastric bypass

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Blocked randomisation 60% laparoscopic and 40% open due to presupposed need for conversion. Stratified for gender, not BMI
Allocation concealment?	Unclear	Used sealed envelopes in theatre
Blinding of outcome assessors?	Unclear	Patients and ward staff were blinded to procedure with the use of sham bandages. Patients were informed on discharge. No description of blinding of outcome assessors
Blinding of participants on self-reported outcomes?	No	Patient satisfaction at 1 year reported (patients were informed on discharge)
Incomplete outcome data addressed? Weight loss	Yes	No patients were lost to follow-up
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	
Free of other sources of bias?	No	Mean preoperative BMI was lower in the laparoscopy group ($p < 0.05$). Well balanced for concomitant medications. No other comparative information provided. Blocked randomisation in an unblinded study

BMI, body mass index; n/a, not applicable; QoL, quality of life.

Appendix 13

Data extraction tables: open versus laparoscopic vertical banded gastroplasty

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
Davila-Cervantes 2002[111] Design: RCT, single centre Follow-up: 1 year	Country: Mexico Number: total 30, open 14, LVBP 16 Age median: open 36.5 years (22–56), LVBP 34.5 years (24–46) Sex, F:M: open 13:1, LVBP 14:2 BMI median: open 43 (37–50), LVBP 45 (38–50) Excess body weight: open 91%, LVBP 100% Comorbid, *n*: open 8, LVBP 9 Characteristics of target population: all morbidly obese patients seen at the Obesity Clinic between 1999 and 2000 who were considered candidates for bariatric surgery Inclusion criteria: BMI 40–50, no previous surgery in upper abdomen, no formal contraindication for laparoscopic surgery Exclusion criteria: active peptic ulcer disease, history of high carbohydrate intake	1. Open vertical banded gastroplasty (open) 2. Laparoscopic vertical banded gastroplasty (LVBG)	Surgical time Blood transfusions Conversions Length of stay BMI % excess body weight Analgesic requirements Spirometric parameters postoperatively (not extracted) Mobilisation postoperatively (not extracted) Daily activities (not extracted)	*Allocation to treatment groups:* randomised on morning of operation using sealed envelopes *Blinding of outcome assessors:* identical dressings were used in all patients to avoid bias of the patient or evaluator. All dressings removed after 72 postoperative hours or before if complication occurred (therefore unblinding) *Comparability of treatment groups:* states that groups were highly comparable in terms of general characteristics, no statistically significant differences. Baseline data for age, sex, BMI, % excess body weight and number of comorbid diseases presented *Method of data analysis:* frequencies or medians and minimum and maximum values presented. Groups compared using Pearson's chi-square, Fisher's exact test or Mann-Whitney *U* test *Sample size/power calculation:* not reported *Attrition/dropout:* states that the surgical procedure was completed in all patients and none were lost during follow-up

BMI, body mass index; RCT, randomised controlled trial.

DOI: 10.3310/hta13410

Table of results

Weight change	QoL/comorbidity	Events/procedures (complications, reoperations)
Excess body weight loss at 12 months: Open 55% (30–88), LVBP 47% (22–97) *BMI at 12 months* (estimated from figure): open 33, LVBP 33		*Surgical details* (median, min–max) Surgical time: open 1.45 hours (1.1–2.5), LVBP 2.1 hours (1.5–4.0), $p < 0.002$ Blood transfusions: open 0, LVBP 0 Conversion: LVBP 0 Hospitalisation: open 4 days (3–42[a]), LVBP 4 days (3–97[a]), p = ns *Complications* Open: six wound problems (seroma, dehiscence or infection) LVBP: one pulmonary atelectasis requiring physical therapy, one wound infection No significant difference in pain intensity Number of extra doses of analgesics: 1st postoperative day: open 2 (0–3), LVBP 1 (0–2), $p = 0.04$ 2nd postoperative day: open 1 (0–1), LVBP 2 (0–2), $p = 0.78$ 3rd postoperative day: open 1 (0–1), LVBP 0 (0), $p = 0.46$ 12 months follow-up (median, range): Patient satisfaction: open 1 (0–2), LVBP 2 (0–2), $p = 0.006$. (0 = dislike, 1 = neutral, 2 = satisfied) Number with pathological scar: open 12, LVBP 5, $p = 0.002$ Open: two patients developed abdominal wall hernias

BMI, body mass index, LVBP, laparoscopic vertical banded gastroplasty; ns, not statistically significant; open, open vertical banded gastroplasty; QoL, quality of life.
a One patient in each group developed a fistula at the gastric partition which required reoperation and prolonged hospital stay.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Unclear	Randomised on morning of operation using sealed envelopes
Allocation concealment?	Unclear	No details
Blinding of outcome assessors?	Unclear	Identical dressings used in all patients to avoid bias of the patient or evaluator. All dressings removed after 72 hours or before if complication occurred (therefore unblinding)
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Yes	States that the surgical procedure was completed in all patients and none were lost during follow-up
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	
Free of other sources of bias?	Unclear	

n/a, not applicable; QoL, quality of life.

Appendix 14

Data extraction tables: open versus laparoscopic adjustable silicone gastric banding

Characteristics of study

Study	Participants	Interventions	Outcomes	Notes
de Wit 1999[132] Design: single centre, RCT Follow-up: 1 year	Country: Netherlands Number: total 50, LAGB 25, open AGB 25 Age: not reported Sex: LAGB 68% female, open AGB 68% female Weight (mean): LAGB 152.2kg (SD 31.4), open AGB 146.4kg (SD 19.9) BMI: LAGB 51.3 (SD 10.4), open AGB 49.7 (SD 5.6) *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, hormonal or genetic obesity related diseases Considered ineligible by gastroenterologist after evaluation. High risk for anaesthesia	1. Laparoscopic adjustable silicone gastric banding (LAGB) 2. Open adjustable silicone gastric banding (open AGB)	Surgical complications Length of hospital stay Difficulty of procedure Surgical time In-hospital deaths Long-term complications Additional procedures Readmissions Mean weight loss Reduction of BMI	*Allocation to treatment groups*: randomised after stratification into gender and BMI 40–45, 45–50, and greater, by computer generated randomisation by separate group *Blinding*: outcome assessments not stated *Comparability of treatment groups*: two 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, two LAGB patients were converted to open AGB. Mann–Whitney *U* test used to compare data. Means, SD and *p* values given *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 AGB to 4 days after LAGB (significance 95%, power 90%) *Attrition/dropout*: one patient in group 2 lost to follow-up after 1 year *Generalisability*: inclusion/exclusion criteria defined, unclear what cut-offs were to be used for various investigations, or if any were excluded *Outcome measures*: weight loss yes, unclear how objective other measures are. Only 1 year follow-up *Intercentre variability*: all one surgeon and one of two anaesthetists *Conflict of interests*: not mentioned *Other*: significant weight lost but BMI remained around 40

BMI, body mass index; ITT, intention to treat; SD, standard deviation.

Table of results

Weight change	QoL/comorbidities	Events/procedures (complications, reoperations)
Mean weight loss (12 months): LAGB 35kg, open AGB 34.4 kg (p = ns) Reduction from baseline $p < 0.05$ for LAGB and open AGB *BMI reduction (12 months):* LAGB 11.6, open AGB 10.6 (p = ns) Reduction from baseline $p < 0.05$ for LAGB and open AGB	Not assessed	*Early postoperative complications (LAGB vs open AGB):* cholecystectomy (8% vs 20%); adhesiolysios (4% vs 0%); gall bladder puncture (to obtain samples for study purposes): (0% vs 28%); pulmonary complications (8% vs 8%); urinary infection (8% vs 0%); rhabdomyolysis (4% vs 0%); neurological complication (neuropraxis) (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 (LAGB vs open AGB):* incisional hernia [0% vs 28% (seven hernias in three (12%) patients; p = ns]; migration band (0% vs 4%, p = ns); umbilical hernia (4% vs 0%, p = ns) *First year access port complications:* 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) *Mean days in hospital:* LAGB 5.9 (range 4–10); open AGB 7.2 (range 5–13) $p < 0.05$ *Readmissions (LAGB vs open AGB):* patients 20% vs 28%, p = ns; total readmissions: 24% vs 60%, $p < 0.05$ *Mean overall length of hospital stay (LAGB vs open AGB)*: 7.8 days (SD 6) vs 11.8 days (SD 10.5), $p < 0.05$ *Conversions:* LAGB to open AGB procedure: 8% *Surgical time*: LAGB 150 minutes (SD 48), open AGB 76 minutes (SD 20) $p < 0.05$ *Mean rating of difficulty of procedure on 1–10 scale (1 = easy, 10 = could not be performed or had to be converted:* LAGB 4.7 (SD 2.1, range 3–10), open AGB 3.8 (SD 1.1, range 3–7) $p < 0.05$

BMI, body mass index; LAGB, laparoscopic adjustable silicone gastric banding; ns, not statistically significant; open AGB, open adjustable silicone gastric banding; QoL, quality of life; SD, standard deviation.

Risk of bias

Item	Judgement	Description
Adequate sequence generation?	Yes	Randomised after stratification into gender and BMI 40–45, 45–50, and greater, by computer-generated randomisation by separate group
Allocation concealment?	Yes	Central allocation – patients randomly allocated by computer on day of surgery
Blinding of outcome assessors?	Unclear	Not stated
Blinding of participants on self-reported outcomes?	n/a	
Incomplete outcome data addressed? Weight loss	Yes	One patient in group 2 lost to follow-up after 1 year. No reasons documented
Incomplete outcome data addressed? QoL	n/a	
Incomplete outcome data addressed? Comorbidity	n/a	
Free of selective outcome reporting?	Unclear	
Free of other sources of bias?	Unclear	

BMI, body mass index; n/a, not applicable; QoL, quality of life.

Appendix 15

Data extraction tables: systematic review of cost-effectiveness studies

Reference

Ackroyd, R. Mouiel, J. Chevallier J.-M. Daoud F.[138]

Cost-effectiveness and budget impact of obesity surgery in patients with Type 2 diabetes in three European countries

Study characteristics

Research question

What are the stated objectives of the evaluation?

To establish a payer-perspective cost-effectiveness and budget impact model of adjustable gastric banding (AGB) and gastric bypass (GBP) versus conventional treatment (CT) in patients with BMI ≥ 35 kg/m^2 and Type 2 diabetes (T2DM) in Germany, UK and France.

Study population

What definition was used for obesity?

BMI ≥ 35 kg/m^2, i.e. eligibility for bariatric surgery

What are the characteristics of the baseline cohort for the evaluation?

Age	Not reported
Sex	Not reported
Race (if appropriate)	Not reported
Comorbidities	Type 2 diabetes
Other characteristics	The population in the cost-effectiveness analysis consists of obese T2DM patients who failed at least one previous year of well-conducted medical treatment (not elaborated)

Interventions and comparators

What number of interventions/strategies were included?

Two

Was a no treatment/supportive care strategy included?

Yes – the conventional treatment (CT) although no single standard was identified across the countries. Therefore CT was identified as either 'annual follow-up watchful waiting' or 'continuation of the second year of a medically guided dieting'. In the latter case it was assumed to take place for the first year followed by conventional treatment of T2DM and no weight-reducing interventions over the remaining 4 years assumed in an economic evaluation.

Describe interventions/strategies

Intervention/strategy 1:

adjustable gastric banding (AGB)

Intervention/strategy 2:

[laparoscopic] gastric bypass (GBP)

Pair-wise comparisons were performed, i.e. AGB versus CT and GBP versus CT; AGB was not compared to GBP in cost-effectiveness analysis.

Analytical perspective

What is the perspective adopted for the evaluation [health service, health and personal social services, third party payer, societal (i.e. including costs borne by individuals and lost productivity)]?

The payers' perspective
(in case of the UK this is the National Health Service)

Study type

Cost-effectiveness/cost–utility/cost–benefit analysis?

CEA (incremental cost per BMI × year; incremental cost per T2DM-free year)
CUA (Incremental cost per QALY)

Institutional setting

Where is/are the intervention(s) being evaluated usually provided?

Not indicated, but presumably hospitals for AGB and GBP and predominately ambulatory care for CT

Country/currency

Has a country setting been provided for the evaluation? In what currency are the costs expressed and does the publication give the base year to which those costs relate?

Currency is a 2005 euro (€) in the case of Germany and France and a 2005 British Pound (£) in surgical interventions. The cost of comparator treatment is expressed in 1998 prices (according to the source – CODE-2 data)

Data sources

Effectiveness

Were the effectiveness data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single study		
A review/synthesis or combination of previous studies	✓	It does not seem that a systematic review was undertaken, clinical data were obtained from the HTA reports (Clegg, 2002, NICE guidelines) and their analogues in EU countries. These data were complemented by the search in June 2005 of PubMed for the RCT and non-comparative prospective series of consecutive surgery patients that were published after the HTA reports. For AGB the data on BMI reduction and T2DM prevalence (and the rates of complications though these are not effectiveness outcomes) were taken from 13 publications (ref 46–58 in Ackroyd *et al.*[138]). For GBP the data on BMI reduction and T2DM prevalence were extracted from (ref 59–69 in Ackroyd *et al.*[138]) the rate of complications from one systematic literature review (24) and a single cohort study of 400 patients (70). Effectiveness of the comparator CT in terms of BMI and T2DM over 3 years was taken from the Swedish HTA systematic review (2002) and the US Clinical guidelines (1998) (ref 23, 25 in Ackroyd *et al.*[138]) and extrapolated for years 4 and 5.
Expert opinion	✓	In particular in estimating the frequency of complications, where experts opinion took priority over the published data (p. 1489)

Give the definitions of treatment effect used in the evaluation

In each year over the period of 5 years (the time interval used in cost-effectiveness analysis) the outcome is defined as a change in BMI from the baseline multiplied by 1 year. This is called annual marginal effectiveness and expressed in kg/m^2 × year. The aggregate outcome is a *cumulative* reduction in BMI over the specified period (e.g. 5 years).

In each year over the period of 5 years the effectiveness with respect to the T2DM status is assessed in an incremental change in proportion of patients free of T2DM from the baseline. This is called an 'annual marginal T2DM-free year gained at a particular year'. The average cumulative T2DM-free years are calculated by aggregating T2DM-free years over the specified period (e.g. 5 years).

Give the size of treatment effect used in the evaluation

The authors did not elaborate on the clinical meaning of the reduction in BMI which varied across the interventions

include values used for subgroups (if applicable). Indicate the source for individual treatment effects (if appropriate)

Intervention costs

Were the cost data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single (observational) study		
A review/synthesis or combination of previous studies	✓	Some cost inputs were taken from the literature, e.g. annual cost of diabetes treatment (Jonsson, 2002)[159]. The complete list of references was not provided.
Expert opinion	✓	Resource use for (alternative interventions?) in natural units was obtained from the literature (no references were provided). Clinicians were asked to provide their opinion on the plausibility of the amount of resources (lowest in the range, average, highest number)

List the direct intervention costs used in the evaluation – include resource estimates (and sources for these estimates, if appropriate) as well as sources for unit costs used

Resource category	**Type of resources**	**Unit cost estimate (UK data)**		**Source**
Intervention costs (laparoscopic GBP and AGB)	It seems that for each type of surgical intervention the range of resource items was identified, checked with experts and multiplied by the corresponding unit costs	Not reported in detail		Not elaborated 'Ranges and unit costs were collected using applicable national tariffs, registries, publications and interviews when no other source was available' (p. 1489). Usual resource use for initial admission was confirmed by two NHS hospitals (p. 1492) See tables 6–8 in Ackroyd *et al.*[138] In Germany and France the DRG-type tariffs were used to estimate the cost of initial admission
	In UK the costs of initial admission was based on 'micro-costing' (p. 1491) and seems to include:	**AGB**	**GBP**	
	aggregated cost of preoperative assessment	£610	£610	
	hospital staff costs (surgeons, physicians, nurses, nutritionists)	Not indicated		
	implants	£1175	£2591	
	imaging and laboratory tests	Not indicated		
	operating room overheads (in proportion to hours);	£492 hours = 1.9	£186.71 hours = 3.84	
	postsurgical recovery room [per diem × length of stay (LOS)]	£241, LOS = 5	£235, LOS = 4.88	
	[other?] consultations	Not indicated		
	average annual cost of follow-up	£439	£312	
		£492 £186.71 hours=1.9 hours=3.84 £241 £235 LOS=5 LOS=4.88 Not indicated £439 £312		

Comparator conventional treatment (1999 prices)

Cost of treating T2DM applies to all patients in the comparator and patients from intervention groups who did not achieve a remission	**First year**		CODE-2 survey published in Jonsson[159] Original estimates are reported in euros Conversion rate is not reported but it seems to be £1 = 1.54€
	GP consultations *n* = 4	£14	
	District nurse consultations *n* = 2	£20.50	
	Practice nurse consultations *n* = 2	£5.50	
	Dietician consultations *n* = 2	£23	
	Laboratory assessments	£150	
	Food substitutes *n* = 56	£1	
	Ambulatory care	£543	
	Anti-diabetic drugs	£44	
	Other drugs	£337	
	Hospital care	£500	
	The cost of years 2–5 does not include district nurse and practice nurse consultations, food substitutes or dietitian consultations		

Other direct costs

(Cost of postsurgical complications)

Were the cost data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single (observational) study		
A review/synthesis or combination of previous studies	✓	The ranges and averages reported in the literature (no references were provided) served as a reference base.
Expert opinion	✓	Authors' expert opinion was used instead when published data appeared obsolete.

List the costs used in the evaluation – if quantities of resource use are reported separately from cost values, show sources for the resource estimates as well as sources for unit costs used.

Cost of complications (not clear whether the resource items were collected by the type of complication, specific to each intervention, and then aggregated as a weighted sum where weights are the frequency of each complication Tables 3–4. Alternatively average cost across all complication was attributed to each intervention in some way)		
Tables 6, 7	AGB	GBP
Preoperative assessment	£610	£610
Initial hospital admission for surgery	£3314.80	£4455.64
Annual follow-up	£439	£312
indicate the source for individual cost values (if appropriate)		

Indirect costs

(costs due to lost productivity, unpaid inputs to patient care)

Were indirect costs included:

Not applicable

Describe how indirect costs were estimated (e.g. how days of lost productivity were estimated and how those days were valued)

Not applicable

indicate the source for individual cost values (if appropriate)

Health state valuations/utilities (if study uses quality of life adjustments to outcomes)

Were the utility data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
The EQ-5D utility estimates were derived from a database of 13,547 individuals according to their BMI and T2DM status.	✓	The methods for deriving utility estimates were not clearly described. The source of the estimates is empirical data from the Health Outcomes Data Repository. HODaR Cardiff Research Consortium. www.crc-limited.co.uk
A review/synthesis or combination of previous studies		
Expert opinion		

List the utility values used in the evaluation

Although the methods for deriving utility estimates were not clearly explained, it seems that initially the utility weights for T2DM and non-T2DM subgroups were estimated from two separate regression equations derived from the empirical data (HODaR). for T2DM: $u = -0.0108\,\text{BMI} + 0.8654$ for non-T2DM: $u = -0.0128\,\text{BMI} + 1.0254$ The authors reasonably assumed that there might not be a statistically significant difference in the estimates of regression coefficients (slope) between T2DM and non-T2DM subgroups. Therefore alternative (not specified) regression equations were used to estimate utility values in both subgroups. It seems that the modified regression equations for T2DM and non-T2DM subgroups have different constant terms (from the original regression equations) but the same slope, equal to the weighted average of the slopes in regression equations for two separate subgroups.

indicate the source for individual utility values (if appropriate)

Modelling

If a model was used, describe the type of model used (e.g. Markov state transition model, discrete event simulation)

The authors used a 'deterministic linear algorithm' which can be interpreted as a simple decision analytic model. The cumulative outcomes with respect to BMI and T2DM over the 5-year period were obtained by multiplying the probability of reduction in BMI from the baseline and reduction in% of patients with T2DM from the baseline (100% of patients with T2DM) in each year and aggregating across the time interval. It was assumed that the probability of obtaining a particular value of the outcome in each year was independent of the value of this or another outcome in the previous year (i.e. the implicit assumption is that the BMI reduction occurs independently of the T2DM status). No discounting was used with respect to these outcomes. The outcome expressed in QALYs was obtained by combining separate utility estimates in proportion to T2DM and non-T2DM prevalence and according to the BMI reduction observed in any particular year and aggregating the calculated values over the 5 year period. The cost was calculated by combining the resources (multiplied by the corresponding unit prices) used in any particular year over the 5-year period. The 3.5% discounting rate was used.

Was this a newly developed model or was it adapted from a previously reported model? If an adaptation, give the source of the original.

The authors are aware of the more advanced modelling techniques but stated that 'deterministic models prove reasonably accurate and more intuitive for stakeholders' (p. 1496)

What was the purpose of the model (i.e. why was a model required in this evaluation)?

How do the surgery and continued conventional treatment compare in terms of outcomes, costs and value for money in patients in whom conventional treatment has already been proven to fail (p. 1496)

What are the main components of the model (e.g. health states within a Markov model)? Are sources for assumptions over model structure (e.g. allowable transitions) reported – list them if reported.

The health state to which utility weights are applied is solely determined by the combination of BMI and the T2DM status. No other obesity related comorbidity was included. The postsurgery complications are not considered to be a differential clinical outcome in comparing different types of interventions therefore no corresponding health state was identified in the calculation. This is inconsistent with the differential accounting of the cost of complications associated with GBP and AGB. Also, an implicit assumption in cost-effectiveness calculations is that no patient dies over the 5-year period (i.e. a health state associated with 'death' was not included).

Extract **effectiveness data** for [natural history/disease progression] model and show sources (refer to table 1 and table 5, p. 1492, p. 1494, sources are not clearly indicated)

Comparator		
Change from the baseline status: 100%T2DM and BMI≥ 35 kg/m^2 prevalence	Change in BMI	Change in T2DM
Year 1	–2.0	20%
Year 2	0	0%
Year 3	0	0%
Year 4	0	0%
Year 5	0	0%
AGB		
Change from baseline status: T2DM and BMI≥35 kg/m^2	Change in BMI (SD or range?)	Change in T2DM prevalence
Year 1	–9.2 (6.6–13.9)	64%
Year 2	–11.2 (9.0–17.9)	45%
Year 3	–12.3 (8.5–19.0)	56%
Year 4	–14.9 (14.9–19.1)	50%
Year 5	–13.2 (12.3–15.0)	50%
GBP		
Change from baseline status: T2DM and BMI≥35 kg/m^2	Change in BMI (SD or range?)	Change in T2DM prevalence
Year 1	–17.7 (13.0–20.0)	82%
Year 2	–16.9 (13.0–18.0)	50%
Year 3	–16.9 (13.0–18.0)	75%
Year 4	–16.2 (10.0–18.0)	50%
Year 5	–16.1 (8.0–18.0)	50%

What is the model time horizon? Duration of the cycle?

The time interval in cost-effectiveness analysis is 5 years. The authors stated that this time interval was recommended by Clegg et al. (2002).[15]

What, if any, discount rates have been applied in the model? Same rate for costs and outcomes?

All costs and QALYs were discounted at a 3.5% annual rate. The BMI × year and T2DM-free years were not discounted. It is not clear whether discounted or undiscounted incremental cost was used in calculating cost-effectiveness ratios with respect to these outcomes.

Results/analysis

What measure(s) of benefit were reported in the evaluation?

BMI × year; T2DM-free year; QALY

Provide a summary of the clinical outcome/benefits estimated for each intervention/strategy assessed in the evaluation (**UK data only**. See table 10, p. 1496)

Over 5-year time interval

LAGB as compared to CT is associated with

incremental undiscounted 57.8 kg/m^2 × year;

incremental undiscounted 2.5 years free of T2DM

incremental discounted 1.0 QALY

LGBP as compared to CT is associated with

incremental undiscounted 80.8 kg/m^2 × year;

incremental undiscounted 2.6 years free of T2DM

incremental discounted 1.3 QALY

Provide a summary of the costs estimated for each intervention/strategy assessed in the evaluation (table 13, p. 1498)

Over the 5-year time interval

ABG as compared to CT is associated with

incremental £1984 per patient

GBP as compared to CT is associated with

incremental £2033 per patient

It is not clear whether the costs reported in table 13 were discounted or not as there is no correspondence with the discounted cumulative costs reported in tables 6–9.

Synthesis of costs and benefits – are the costs and outcomes reported together (e.g. as cost-effectiveness ratios)? If so, provide a summary of the results.

The comparative performance of alternative treatment strategies was measured by the incremental cost-effectiveness ratio (ICER), defined as the incremental cost of a surgery, divided by the incremental outcome. (p. 1494)

AGB as compared to CT

ICER = £34.3 per kg/m^2 year

ICER = £810 per T2DM-free year

ICER is equal to £1929 per QALY gained, costs and outcomes are discounted at 3.5%

GBP as compared to CT

ICER = £25.2 per kg/m^2 year

ICER = £776 per T2DM-free year

ICER is equal to £1517 per QALY gained, costs and outcomes are discounted at 3.5%

Give results of any statistical analysis of the results of the evaluation.

None provided

Was any sensitivity analysis performed – if yes, what type(s) (i.e. deterministic (one-way, two-way etc) or probabilistic).

The authors conducted analysis called 'worst case scenario'. In this analysis the clinical effectiveness of AGB and GBP is said to be reduced by 20% with respect to both BMI reduction and T2DM prevalence in interventions and no temporary benefits from CT assumed in the first year. No change in cost estimate was assumed. The figures reported in table 14 (p. 1500) that were allegedly used in the sensitivity analysis do not seem to correspond to the 20% reduction in BMI and T2DM prevalence.

Because removal of the small benefits of CT assumed in the first year in the base-case scenario are unlikely to have a significant contribution to the change in the ICER estimated in the 'worst-case scenario', it may be considered as a two-way sensitivity analysis with respect to the outcome expressed in QALYs and one-way sensitivity analysis with respect to the ICER expressed in terms of BMI reduction and T2DM prevalence.

UK data only

The ICER for AGB compared to CT changed from £1929 to £3251 per QALY and almost doubled with respect to T2DM-free years.

The ICER for GBP compared to CT changed from £1517 to £2599 per QALY and almost doubled with respect to T2DM-free years

What scenarios were tested in the sensitivity analysis? How do these relate to structural uncertainty (testing assumptions over model structure such as relationships between health states), methodological uncertainty (such as choices of discount rate or inclusion of indirect costs) or parameter uncertainty (assumptions over values of parameters in the model, such as costs, quality of life or disease progression rates)?

Assuming that patients in CT do not continue receiving any active medical treatment that they have failed in Year 1 can be considered an equivalent to scenario analysis. However, this was not conducted independently of the sensitivity analysis which varied the estimates of clinical effectiveness.

Give a summary of the results of the sensitivity analysis – did they differ substantially from the base-case analysis. If so, what were the suggested causes?

The ICER (regardless of the choice of the outcome) is very sensitive to the assumptions about clinical effectiveness. The sensitivity of results to the variations in utility estimates was not tested.

The authors concluded that 'The level of reaction displayed by the model… suggests that the model is a relatively reliable instrument to address the questions for which it has been designed with real life inputs. Moreover, the ability to BMI × years and T2DM-free years as an alternative to QALY removes the inevitable uncertainty related to interpretation of outcomes as patient-interpreted utility."

Conclusions/implications

Give a brief summary of the author's conclusions from their analysis

Authors suggested that in patients with BMI ≥ 35 kg/m^2 and T2DM in AGB and GBP (in comparison to CT) are effective at 5 year follow-up in cost-savings in Germany and France, and are cost-effective in UK (p.1488 –abstract).

What are the implications of the evaluation for practice?

The authors stated (p. 1495–6) that the budget impact over 5 years of treating a cohort of 1000 in Germany with bariatric surgery instead of conventional treatment is a net saving of 5.03 million euros in the case of GBP and 3.6 million euros in the case of AGB. In France a net savings of 5.88 million euros in the case of GBP and 4.48 million euros in the case of AGB. In the UK it is a net cost increase of 2.03 million pounds in the case of GBP and 1.98 million pounds in the case of AGB.

The authors do not comment on the reversal in the results with respect to the UK but it seems that this can be explained by the difference in the cost of CT, which is estimated as more expensive in Germany and in France than in UK (approximately by €6000 and €4000, respectively). This difference in estimates of the cost of CT may relate to the difference in methodological approach to cost data collection or the differences in the resource use associated with comparator treatment or a combination of both. In either case, the results are not strictly comparable across the countries.

Reference

van Mastrigt, G.A.; van Dielen, F.M.; Severens, J.L.; Voss, G.B.; Greve,J.W.[139]

One-year cost-effectiveness of surgical treatment of morbid obesity: vertical banded gastroplasty versus Lap-Band®

Study characteristics

Research question

What are the stated objectives of the evaluation?

To evaluate the 1-year cost-effectiveness of surgical treatment of morbid obesity comparing two strategies: [open] Vertical Banded Gastroplasty (VBG) versus Lap-Band® (Laparoscopic Adjustable Gastric Banding System – AGB) by conducting an economic evaluation alongside a randomised clinical trial ($n = 100$, split equally between the arms $n_{VBG} = 50$; $n_{AGB} = 50$)

Study population

What definition was used for obesity?

BMI > 40 kg/m^2 or between 35 and 40 if significant comorbidity is present.

What are the characteristics of the baseline cohort for the evaluation?

Age	In VBG arm mean age was 38.9 (SD = 8.53)
	In AGB arm mean age was 37.2 (SD = 9.64)
Sex	In VBG arm female patients = 80%
	In AGB arm female patients = 78%
Race (if appropriate)	Not reported
Comorbidities	14% in VBG arm and 10% in AGB arm had Type 2 diabetes
	20% in VBG arm and 14% in AGB arm had hypertension
	For the full list of comorbidities see table 1 p. 78
Other characteristics	In VBG arm the mean BMI was 46.5 (SD = 6.42)
	In AGB arm the mean BMI was 46.5 (SD = 6.42)
	Occupational status was recorded (to conduct CEA from the societal perspective)

Interventions and comparators

What number of interventions/strategies were included?

Two

Was a no treatment/supportive care strategy included?

No

Describe interventions/strategies

Intervention/strategy 1:
Vertical banded gastroplasty (VBG)
Intervention/strategy 2:
Laparoscopic adjustable gastric banding (AGB)

Analytical perspective

What is the perspective adopted for the evaluation [health service, health and personal social services, third-party payer, societal (i.e. including costs borne by individuals and lost productivity)]?

A societal perspective (including non-health-care system costs, e.g. the costs of informal care and lost productivity)

Study type

Cost-effectiveness/cost–utility/cost–benefit analysis?

CEA (incremental cost per 1% of extra weight loss – EWL)
CUA (Incremental cost per QALY)

Institutional setting

Where is/are the intervention(s) being evaluated usually provided?

Apparently a single Netherlands hospital. The randomised patients undertook either VBG or AGB from April 1999 to December 2002

Country/currency

Has a country setting been provided for the evaluation? In what currency are costs expressed and does the publication give the base year to which those costs relate?

The resource use was originally assessed in Netherlands 1999 guilders and then converted to euros the conversion rate and a year to which it applied was not reported (2002?)

Data sources

Effectiveness

Were the effectiveness data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single study	✓	The clinical effectiveness data are reported in van Dielen *et al.*[123]
A review/synthesis or combination of previous studies		
Expert opinion		

Give the definitions of treatment effect used in the evaluation

Percentage of excess weight loss. Clinical effect is not expressed in terms of BMI and is not easy to convert because the average height of the patients in each arm was not reported (maybe in the clinical paper?).

Give the size of treatment effect used in the evaluation

The percentage of excess weight loss (% EWL) at 12 months. The authors did not elaborate on the effect size that would be meaningful in clinical and economic senses (i.e. sufficient to detect a change in utility weights)

include values used for subgroups (if applicable). Indicate the source for individual treatment effects (if appropriate)

Intervention costs

Were the cost data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single (observational) study	✓	Quantity of resource use in natural units with respect to surgery costs were obtained from the observational study for 10 surgical procedures of both types of surgery (p. 79). Other hospital costs were obtained from the hospital billing system. Other medical resource items (e.g. medications) were obtained from patients' cost-diaries.
A review/synthesis or combination of previous studies		
Expert opinion		

List the direct intervention costs used in the evaluation – include resource estimates (and sources for these estimates, if appropriate) as well as sources for unit costs used

Resource category	**Type of resources**	**Unit cost estimate**	**Source**
Intervention costs (open VBG and laparoscopic AGB)	**Medical cost components:** Inpatient days Clinical procedures Surgery Outpatient clinics Dietitian consults GP consultations prescribed medications	The only unit costs that were reported were those that were subjected to the deterministic sensitivity analysis (see below). The unit cost of 'time of the personnel' involved in surgical procedures used in the base-case analysis was €2.96 per minute (p. 79) The inpatient cost per day (per diem) used in the base-case analysis was €332 (p. 81)	Quantity of resource use in natural units with respect to surgery costs was obtained from the (observational) study. Other hospital costs were obtained from the hospital billing system

Other direct costs

(cost of postsurgical complications)

Were the cost data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single (observational) study	✓	Out-of-pocket medical and non-medical expenses were obtained from patients' cost-diaries.
A review/synthesis or combination of previous studies		
Expert opinion		

List the costs used in the evaluation – if quantities of resource use are reported separately from cost values, show sources for the resource estimates as well as sources for unit costs used.

Out-of-pocket medical and non-medical expenses (not reported as a comprehensive list of items, no unit costs were not provided). Examples: cost of paid help over-the-counter medications
indicate the source for individual cost values (if appropriate)

Indirect costs

(costs due to lost productivity, unpaid inputs to patient care)

Were indirect costs included:

Unpaid help was included Productivity loss was included
Describe how indirect costs were estimated (e.g. how days of lost productivity were estimated and how those days were valued)
Quantity of unpaid help was apparently obtained from patients' cost-diaries kept for the first 3 months after the surgery. How the change in occupational status and change in the sick leave days were collected is not clear Productivity loss was estimated by the friction cost method (not elaborated)

indicate the source for individual cost values (if appropriate)

Health state valuations/utilities

(if study uses quality of life adjustments to outcomes)

Were the utility data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
The EQ-5D utility estimates were derived from a database of 13,547 individuals according to their BMI and T2DM status.	✓	Yes. The EQ-5D data were collected from the trial participants at the baseline and at 3, 6 and 12 months of follow-up. (p. 77)
A review/synthesis or combination of previous studies		
Expert opinion		

List the utility values used in the evaluation

The utility values were collected observed at baseline, 3, 6 and 12 months using the EQ-5D. To obtain a QALY the EQ-5D scores were multiplied by the duration of time to which these scores related (p. 77). The mean utility values observed at each observation point were reported in the graphical format in figure 3 p. 79. There is a possibly statistically significant difference in utility values at the baseline (absolute baseline difference was not reported). At 3 and 6 months the utility scores in the comparator arm (VBG), which is associated with the higher values of%EWL are nevertheless lower than the utility scores in the AGB arm that correspond to the lesser%EWL.

indicate the source for individual utility values (if appropriate)

Modelling

If a model was used, describe the type of model used (e.g. Markov state transition model, discrete event simulation)

Model was not required for the economic evaluation alongside a clinical trial

Was this a newly developed model or was it adapted from a previously reported model? If an adaptation, give the source of the original.

Not applicable

What was the purpose of the model (i.e. why was a model required in this evaluation)?

Not applicable

What are the main components of the model (e.g. health states within a Markov model)? Are sources for assumptions over model structure (e.g. allowable transitions) reported – list them if reported.

The economic evaluation is not model-based. A 'health state' was not defined in terms of the disease progression.

Extract effectiveness data for (natural history/disease progression) model and show sources

The economic evaluation is not model-based. The intermediate outcome of %EWL was not converted in the final outcomes. See the observed clinical effectiveness results below

What is the model time horizon? Duration of the cycle?

One year

What, if any, discount rates have been applied in the model? Same rate for costs and outcomes?

Given the one-year time horizon discounting rates were appropriately not applied

Results/analysis

What measure(s) of benefit were reported in the evaluation?

%EWL; EQ-5D utility scores

Provide a summary of the clinical outcome/benefits estimated for each intervention/strategy assessed in the evaluation

Statistical methods and assumptions in relation to comparing clinical effectiveness between the two arms were reported elsewhere (see van Dielen *et al.*[123])

At 12 months in the **VBG** arm the mean loss of excess weight was 71.69% (SD = 20.79)

In the **AGB** arm the mean loss of excess weight was 53.87% (SD = 20.64)

The mean difference in %EWL of 17.82% was statistically significant ($p < 0.001$)

At 12 months in the **VBG** arm the mean EQ-5D scores (weighted according to the time interval to which the observed values relate) was 0.76 (SD = 0.2)

At 12 months in the **AGB** arm the mean EQ-5D scores (weighted according to the time interval to which the observed values relate) was 0.81 (SD = 0.13)

The mean difference of 0.05 utility scores is not statistically significant ($p = 0.138$)

Two patients from the VBG arm died within 30 days after surgery. EQ-5D data were missing in 8% of observations. Missing observations were substituted with mean values (calculated across the entire sample?).

Provide a summary of the costs estimated for each intervention/strategy assessed in the evaluation (table 13, p. 1498)

Cost components	**VBG**	**AGB**
Cost of surgery (p.79)		
'Capacity' cost	€67	€158
Material cost (including medication)	€691	€2,143
Overheads	€87	€87
Personnel (minutes x €2.96 -cost per minute)	2.50 × 2.96 = €444	3.26 × 2.96 = €579
Reported subtotal (not equal to the sum of the above)	€1676	€3861
Other costs of initial hospitalisation		
Cost of inpatient days, including intensive care (length of stay by per diem specific to the type of care?)	not reported	not reported
Total cost of initial hospitalisation	€5954	€5258

Total cost of rehospitalisation (surgical department)	€599	€724
Reported total hospitalisation (≠ to the sum of the above)	€6679	€5857
Outpatient care	€869	€1214
Prescribed medications	€218	€193
Primary care	€339	€71
Cost of follow-up	€1426	€1479
Non-medical costs (change in productivity, paid help?)	€5080	€3963
Total direct and indirect costs (*≠ to the sum of the above)*	€**13,185** *(€ 14,611)*	€**11,299** *(€12,777)*

In addition, the difference in length of stay was reported: AGB was associated with the mean stay of 5.56 (median 4) days and VBG was associated with the mean stay of 6.78 (median 4) days. Five patients from the VBG arm were admitted to the intensive-care unit and none from the AGB arm.

In the AGB arm nine (18%) were readmitted to the hospital department and in the VBG arm five (10%) were readmitted (p. 80)

Cost data from the patients' diaries were missing in three cases (6%) in the VBG arm and in two cases (4%) in the AGB arm. Missing observations were substituted with mean values (calculated across the entire sample?).

Synthesis of costs and benefits – are the costs and outcomes reported together (e.g. as cost-effectiveness ratios)? If so, provide a summary of the results.

On the basis of the observational data collected alongside an RCT involving 100 patients it appears that at 12 months the LAGB is both less expensive and less effective than VBG in terms of %EWL. The authors erroneously claimed that moving from VBG (comparator) to LAGB would involve an additional amount of €105.80 per each additional %EWL (–€1885.91/–€17.82) (p. 80). In fact, this amount is what society would be spending for choosing not to switch from VBG to LAGB. Moving from VBG to AGB would involve a saving of €105.80 per each % extra weight retained.

With respect to the outcome expressed in QALYs a different (and somewhat contradictory) result was reported: LAGB appears to be both less expensive and more effective than VBG (i.e. a dominant strategy).

In QALY calculations the utility values were adjusted for the duration of the time interval to which they relate (therefore the values reported on p. 79 do not correspond to the values in figure 3). The procedure is likely to have reduced the bias in the estimate of the utility gain that comes from the difference in utility scores observed at the baseline.

Give results of any statistical analysis of the results of the evaluation.

Incremental costs and effects were analysed using bootstrap sampling method to estimate the joint distribution of incremental costs and outcomes.

In the bootstrap analysis with respect to %EWL outcome was conducted and involved 1000 replications. In this analysis LAGB in comparison to VBG was both less effective and less costly in 86% of trials; in 14% of trials it was less effective and more expensive (i.e. dominated by VBG).

With respect to the outcomes expressed in QALYs a different (and somewhat contradictory) result was reported: LAGB appears to be both less expensive and more effective than VBG (i.e. a dominant strategy). A bootstrap analysis with respect to a QALY showed that in 79% of trials LAGB was both more effective and less expensive in comparison to VBG (i.e. dominant); and in 14% of trials it was more effective but also more expensive. There was a negligible probability of VBG being dominant (3%) or being both less effective and less expensive (4%).

Was any sensitivity analysis performed – if yes, what type(s) (i.e. deterministic (one-way, two-way etc) or probabilistic).

The results of eight one-way sensitivity analyses (in terms of the outcomes of a bootstrapping analysis of joint distribution of incremental costs and outcomes) were reported in table 3 (p. 82).

The cost of personnel time (€2.96 per minute) was substituted in turn for the maximum and minimum values of €3.56 and €2.66 per minute, respectively and the joint distribution of costs and outcomes (%EWL and QALY in turn) was investigated.

The per diem cost (€332 per day in hospital) was substituted in turn for the maximum and minimum values of €432 and €232 per day, respectively. Also the joint distribution of costs and outcomes (%EWL and QALY in turn) was investigated.

What scenarios were tested in the sensitivity analysis? How do these relate to structural uncertainty (testing assumptions over model structure such as relationships between health states), methodological uncertainty (such as choices of discount rate or inclusion of indirect costs) or parameter uncertainty (assumptions over values of parameters in the model, such as costs, quality of life or disease progression rates)?

An alternative perspective for an economic evaluation that excluded non-medical costs (paid and unpaid help + productivity change, presumably) was tested in the scenario analysis. Exclusion of non-medical costs that constitute 39% and 35% in VBG and AGB, respectively, has not altered the overall results; however, the certainty about the AGB being less costly than VBG has been reduced. For example, a bootstrapping analysis with respect to a QALY showed that VBG in comparison to AGB was both more effective and less costly in 68% (instead of 79% in the base-case analysis) of trials (i.e. dominant); and in 27% (instead of 14% in the base-case analysis) of trials it was more effective but also more costly.

Give a summary of the results of the sensitivity analysis – did they differ substantially from the base-case analysis. If so, what were the suggested causes?

The joint distribution of incremental costs and outcomes (regardless of the choice of the outcome) varied very little with respect to the variables tested in the one-way sensitivity analyses.

Conclusions/implications

Give a brief summary of the author's conclusions from their analysis

The study estimated the cost-effectiveness of VBG versus AGB (using Lap-Band® as opposed to other types of gastric banding, e.g. Swedish Adjustable Gastric band). The authors (somewhat inconsistently with the results of the CEA) concluded that at 12 months after surgery the costs and outcomes (in terms of QALYs) of the two alternative technologies were found to be equal (p. 75; abstract). Therefore the selection of the procedure can be based on the clinical aspects, efficacy and safety at one year.

What are the implications of the evaluation for practice?

Assuming that the conclusions are valid (see below) replacing VBG with LAGB is associated with the considerable savings to the society (with respect to QALY gained). Although the authors do not seem to realise that in such cases comparisons with haemodialysis and artery bypass are not appropriate as these technologies are associated with additional resource use rather than savings

Reference

Craig, B.M.; Tseng, D.S.[140]

Cost-effectiveness of gastric bypass for severe obesity

Study characteristics

Research question

What are the stated objectives of the evaluation?

To estimate the cost-effectiveness of (open) gastric bypass (versus no treatment) in the treatment of severe obesity

Study population

What definition was used for obesity?

Stated BMI > 40 kg/m^2 and BMI < 50 kg/m^2

However, Pories *et al*.[148] (see below) reported data on 608 obese patients who were eligible for GBP if BMI ≥ 40 kg/m^2 or BMI ≥ 35 kg/m^2 with comorbidities such as diabetes, arthritis or cardiopulmonary failure

What are the characteristics of the baseline cohort for the evaluation?

From Pories et al.[148] cohort study used for clinical effectiveness inputs

Age	Stated as 35 to 55 years old; however, Pories *et al*. reported data on 608 obese patients with age range 14 to 64 years (average age at the time of surgery was 37.3)
Sex	Separate analysis is conducted by male/female subgroups
Race (if appropriate)	Not reported [in Pories *et al*. cohort of 608 patients 506 were women (66.4% were white and 16.8% were African-American) and 102 were men (14.3% were white and 2.5% were African-American)]
Comorbidities	In Pories *et al*. cohort of 608 patients 27% of the patients had non-insulin-dependent diabetes and 27% had impaired glucose tolerance; 58.1% had hypertension at the baseline.
Other characteristics	All patients were assumed non-smoking without a cardiovascular disease (CVD), drug addiction or major psychological disorder who failed conservative therapies consisting of dieting, exercise, behaviour therapy and pharmacotherapy. However, this is not consistent with characteristics of the population from whom utility values and life expectancy data were derived

Interventions and comparators

What number of interventions/strategies were included?

One

Was a no treatment/supportive care strategy included?

Yes

Describe interventions/strategies

Intervention/strategy 1: [open?] gastric bypass

Comparator: not specified, 'no-treatment', it is not clear whether dieting, exercise, behaviour therapy and pharmacotherapy are assumed to continue

Analytical perspective

What is the perspective adopted for the evaluation [health service, health and personal social services, third-party payer, societal (i.e. including costs borne by individuals and lost productivity)]?

The authors stated that the perspective is a payer's one. However, this can be interpreted as either the health-care system perspective as in the base-case scenario or as a perspective of an insured individual whose out of pocket expenses are only a part of the total medical cost (as in the scenario analysis).

Study type

Cost-effectiveness/cost–utility/cost–benefit analysis?

CEA cost per additional LY

CUA (Incremental cost per incremental QALY)

Institutional setting

Where is/are the intervention(s) being evaluated usually provided?

Hospitals

Country/currency

Has a country setting been provided for the evaluation? In what currency are costs expressed and does the publication give the base year to which those costs relate?

Medical costs are reported in 2001 US$

Data sources

Effectiveness

Were the effectiveness data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A number of single studies for the short-term (1–5 years) clinical effectiveness inputs (weight loss; postsurgery complications; rates of revision; rates of reversal) were used	✓	1. Weight loss (and some complication rates – included only on the cost side) were taken from the case series study (Pories *et al.*[148]) $n = 608$ follow-up was 14 years with 96.3% of follow-up rate (47% were interviewed by phone). 2. Complication rates were taken from Pories *et al.*,[148] and the International Bariatric surgery registry (Mason *et al.*[193]; Wu *et al.*[194]) 3. Rates of revision surgery were also taken from Pories *et al.*[148] and Hall *et al.*[149] (abdominoplasty) 4. Rates of reversal surgeries were taken from RCT of GBP versus VBG Hall *et al.*[149] Different lengths of hospital stay and post-hospital recovery attract different utility weights. Length of hospital stay associated with initial surgery (by gender) was apparently obtained from the Healthcare Cost and Utilisation project database (1997)[195]
A review/synthesis or combination of previous studies		
Expert opinion	✓	The length of post-hospital recovery associated with initial surgery, revision and reversal surgeries and various complications was obtained from experts' opinion

Give the definitions of treatment effect used in the evaluation

Pories *et al.* reported weight loss in BMI over the period of 14 years. The weight loss is stabilised and even slightly reversed after 5 years (figure 3B, p. 344)

Give the size of treatment effect used in the evaluation

Although the size of treatment effect is not explicitly identified, utility weights are assumed to be different for the patients with different BMI (in increments of 5 kg/m^2) which is probably assumed to be the least clinically meaningful weight loss

include values used for subgroups (if applicable). Indicate the source for individual treatment effects (if appropriate)

Intervention costs

Were the cost data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
Cost components of the intervention and its short-term (1–5 years) consequences (postsurgery complications; cost of revision surgery; cost of reversal surgery)	✓	Aggregated cost categories (ICD-9-CM code charges) for the GBP and, complications, revision and reversal surgeries were obtained from the Healthcare Cost and Utilisation project database (1997)[158] and adjusted for inflation using medical care component of the consumer price index.
Use of medications		Unit costs were obtained from the 2000 Drug topics Red Book, Montvale, NJ: Medical Economics Company. 2000
A review/synthesis or combination of previous studies		
Expert opinion		

List the direct intervention costs used in the evaluation – include resource estimates (and sources for these estimates, if appropriate) as well as sources for unit costs used. **Quantity of resource use in natural units are not reported.**

Resource category	**Type of resources (not elaborated by cost components)**	**Cost estimate (US$2001 prices)**		**Source**
		Men	Women	Aggregated cost categories (ICD-9-CM code charges) for the GBP and, complications, revision and reversal surgeries were obtained from the Healthcare Cost and Utilisation project database (1997)[158] and adjusted for inflation using the medical care component of the consumer price index
Cost of surgery	Gastric bypass	26,100	20,500	
Cost of complications	Minor wound infection	192	192	
	Major wound infection	20,600	19,200	
	Deep vein thrombosis	8700	8100	
	Pulmonary embolism	14,700	13,900	
	Cholelithiasis	27,100	22,700	
	Incisional hernia	13,200	12,500	
	Abdominoplasty	13,600	12,200	
	Rrvision surgey	38,500	25,600	
	Reversal surgery	38,500	25,600	
	Perioperative death	27,600	29,000	

Other direct costs

(Cost of postsurgical complications)

Were the cost data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single data source was used for the estimates of the expected lifetime medical cost [of selected obesity-related diseases] reported by age/gender/BMI *in* Thompson *et al*.[144]	✓	Not clear how the estimates reported in Thompson *et al*.[144] were used to obtain the expected lifetime medical cost for the BMI values other than reported.
A review/synthesis or combination of previous studies		
Expert opinion	✓	Cost of follow-up visits and was obtained from written personal communication It is not clear from where *the quantities* and types of supplements (vitamins, minerals, etc.) used by postsurgical patients for the duration of their life time were obtained. Unit costs were obtained from the 2000 Drug topics Red Book, Montvale, NJ: Medical Economics company.[195]

List the costs used in the evaluation – if quantities of resource use are reported separately from cost values, show sources for the resource estimates as well as sources for unit costs used.

Follow-up costs (annual?)	Follow-up visits	$150 (both genders)
	Pharmaceuticals	$68 (both genders)
Expected lifetime cost medical cost estimates of selected obesity-related diseases	See Results section below for the cost values associated with selected age/gender/BMI baseline characteristics	Taken from Thompson *et al*.[144] and extrapolated to include expected lifetime medical cost for the BMI values other than reported

indicate the source for individual cost values (if appropriate)

Indirect costs

(costs due to lost productivity, unpaid inputs to patient care)

Were indirect costs included:

Not included

Describe how indirect costs were estimated (e.g. how days of lost productivity were estimated and how those days were valued)

Not applicable

indicate the source for individual cost values (if appropriate)

Health-state valuations/utilities

(if study uses quality of life adjustments to outcomes)

Were the utility data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
Not clear. Utilities might have been elicited from two questions (activity limitations and perceived health status) that were included in the 1997 USA National Health Interview Survey and interpreted as attributes of the (non-existent) QoL generic instrument	✓	A reference to methodology for eliciting utilities using the data from the 1997 USA National Health Interview Survey was provided (Erickson *et al*.[155]). It is not clear whether the complex modelled calculations reported in Erickson *et al*.[155] were fully replicated with respect to the data from the US population which participated in the 1997 National Health Survey stratified by gender. It does not seem that the 1997 National Health Survey data were also adjusted for BMI values.

List the utility values used in the evaluation

These are reported in table 2 (p. 493), by age, gender and BMI categories. The utility values vary from 0.93 in a 35-year-old male with BMI of 25 kg/m^2 to 0.58 in a 75-year-old female with BMI of 50 kg/m^2

In addition arbitrary utility values are applied to the period of time spent in hospital and in postsurgery recovery. In the first instance the age/gender/BMI-specific utility value is reduced by 200% (assuming that being in hospital is equivalent to the health state which is 'worse than death'). The utility value associated with the recovery time was 50% of the applicable age/gender/BMI-specific utility value. No justification for the choice of these values was provided. Reduced (by 50% apparently) utility weights also apply to the patients during their postreversal surgery years of life.

indicate the source for individual utility values (if appropriate)

Modelling

If a model was used, describe the type of model used (e.g. Markov state transition model, discrete event simulation)

A deterministic decision model (a decision tree)

Was this a newly developed model or was it adapted from a previously reported model? If an adaptation, give the source of the original.

Newly developed model

What was the purpose of the model (i.e. why was a model required in this evaluation)?

To compare the lifetime expected costs and outcomes between [open] gastric bypass and no treatment of severe obesity from a payer's perspective (p. 491)

What are the main components of the model (e.g. health states within a Markov model)? Are sources for assumptions over model structure (e.g. allowable transitions) reported – list them if reported.

The no-treatment arm of the decision tree model assumes that the patients do not lose or gain weight and their QALY depends on the initial BMI, gender and the baseline age.

The open gastric bypass arm of the decision tree model assumes four surgery outcomes that occur in the first instance: successful surgery, revision surgery, reversal surgery and death. Revision surgery and reversal surgery are in turn associated with probability of a postsurgical death, while the former may be followed (in 4% of the cases) by the subsequent reversal surgery, which is also associated with the probability of death (figure 1 p. 492).

The life expectancy depends on the eventual BMI, gender and the age at which the surgery was undertaken. Life expectancy was adjusted for the estimated perioperative mortality (assumed at 1.5% for the original and 3% for the revisional and reversal surgeries). Utility values (differentiated by gender, age and BMI) are applied to the estimated life-years spent with the eventual BMI to obtain QALYs. The arbitrary assigned utility values are applied to the period of time spent in the hospital and in recovering (presumably after the hospital stay). It was also assumed that the patients who underwent the reversal surgery have 'never recovered completely' (p. 493). A 50% reduction in utility weights was applied to these patients for the rest of their lives.

Extract **effectiveness data** for [natural history/disease progression] model and show sources

Short-term (1–5 years apparently) effectiveness data for the open gastric bypass comprised the following

1. Weight loss in BMI was apparently taken from the cohort study (Pories *et al.*[148]) (not reported)

2. Complication rates were taken from Pories *et al.*[148] and the International Bariatric surgery registry (Mason *et al.*,[193], Wu *et al.*[194]), reported in table 1, p. 493

3. Rates of revision surgery were also taken from Pories *et al.*[148], Hall et al.[149] (abdominoplasty) reported in table 1, p.493

4. Rates of reversal surgeries were taken from RCT of GBP versus VBG reported by Hall *et al.*[149] reported in table 1, p. 493

Long-term outcomes (QALYs) were obtained from combining

1. Life-years (as a function of gender, age and BMI) reported in Thompson *et al.*[144] that were extrapolated by 'simple linear approximation' (p. 493) to include BMI categories other than reported

2. With utility weights elicited from the USA population participated in the National Health Survey, 1997 using the methods reported in Erickson *et al.*[155]

QALYs were also adjusted for the arbitrary utility estimates that applied to the time spent in hospital and in post-hospital recovery

What is the model time horizon? Duration of the cycle?

Lifetime

What, if any, discount rates have been applied in the model? Same rate for costs and outcomes?

3% discounting rates applied to both costs and outcomes (QALYs)

Results/analysis

What measure(s) of benefit were reported in the evaluation?

Life expectancy and QALYs

Provide a summary of the clinical outcome/benefits estimated for each intervention/strategy assessed in the evaluation

Results are reported for the four 'risk subgroups' identified by gender and the age at which the surgery is undertaken (35 years or 55 years). Results in a numerical format for men and women in the lower (40 kg/m^2) and the upper (50 kg/m^2) BMI limits are reported in tables 3 and 4. Results in graphical format for the range of other baseline BMI values for men and women of either 35 or 55 years at the baseline is presented in figure 2, p. 496.

For the risk subgroup of the adults of **35 years of age** who had BMI of **40 kg/m^2** at the baseline the outcomes are as follows:

Life expectancy				**QALY**			
Gastric bypass		No treatment		Gastric bypass		No treatment	
Men	Women	Men	Women	Men	Women	Men	Women
23.00	24.63	22.97	24.72	19.56	19.82	18.51	18.21

For the risk subgroup of the adults of **35 years of age** who had BMI of **50 kg/m^2** at the baseline the outcomes are as follows:

Life expectancy				**QALY**			
Gastric bypass		No treatment		Gastric bypass		No treatment	
Men	Women	Men	Women	Men	Women	Men	Women
22.83	24.46	22.52	24.46	18.87	18.88	16.83	16.03

For the risk subgroup of the adults of **55 years of age** who had BMI of **40 kg/m^2** at the baseline the outcomes are as follows:

Life expectancy				**QALY**			
Gastric bypass		No treatment		Gastric bypass		No treatment	
Men	Women	Men	Women	Men	Women	Men	Women
16.44	18.58	16.15	18.49	13.32	13.94	12.48	12.62

For the risk subgroup of the adults of **55 years of age** who had BMI of **50 kg/m^2** at the baseline the outcomes are as follows:

Life expectancy				**QALY**			
Gastric bypass		No treatment		Gastric bypass		No treatment	
Men	Women	Men	Women	Men	Women	Men	Women
16.22	18.41	15.51	18.08	12.81	13.23	11.17	10.88

Provide a summary of the costs estimated for each intervention/strategy assessed in the evaluation (table 13, p. 1498)

For the risk subgroup of the adults of **35 years of age** the costs (US$) are as follows:

Baseline BMI of 40 kg/m^2				**Baseline BMI of 50 kg/m^2**			
Gastric bypass		No treatment		Gastric bypass		No treatment	
Men	Women	Men	Women	Men	Women	Men	Women
68,600	59,000	38,500	35,300	75,000	54,800	53,200	48,500

For the risk subgroup of the adults of **55 years of age** the costs (US$) are as follows:

Baseline BMI of 40 kg/m^2				**Baseline BMI of 50 kg/m^2**			
Gastric bypass		No treatment		Gastric bypass		No treatment	
Men	Women	Men	Women	Men	Women	Men	Women
77,600	69,600	47,900	48,200	85,300	77,000	63,500	64,100

Synthesis of costs and benefits – are the costs and outcomes reported together (e.g. as cost-effectiveness ratios)? If so, provide a summary of the results.

For the risk subgroup of the adults of **35 years of age** the baseline costs (US$) per life-year saved and cost per QALY are reported below

Incremental cost per extra life-year saved				**Incremental cost per additional QALY**			
BMI of 40 kg/m^2		BMI of 50 kg/m^2		BMI of 40 kg/m^2		BMI of 50 kg/m^2	
Men	Women	Men	Women	Men	Women	Men	Women
844,700	No treatment strategy is dominant	70,300	9,130,000	28,600	14,700	10,700	5700

For the risk subgroup of the adults of **55 years of age** the costs are reported below

Incremental cost per extra life-year saved				**Incremental cost per additional QALY**			
BMI of 40 kg/m^2		BMI of 50 kg/m^2		BMI of 40 kg/m^2		BMI of 50 kg/m^2	
Men	Women	Men	Women	Men	Women	Men	Women
100,200	248,500	30,700	38,900	35,600	16,100	13,300	5400

Give results of any statistical analysis of the results of the evaluation.

None provided

Was any sensitivity analysis performed – if yes, what type(s) [i.e. deterministic (one-way, two-way etc) or probabilistic].

A series of one-way sensitivity analyses were performed that varied the estimated loss of excess weight, mortality rates and complication rates (clinical effectiveness parameters).

A sensitivity analysis was conducted to assess the impact of the variation in utility estimates. However, instead of varying the utility values used in calculation of QALYs, the regression coefficients in the (unreported) multiple regression equation used to obtain utility values were decreased by 25%. It is not clear how this affected the actual utility values used to estimate QALYs.

A sensitivity analysis was conducted to test the various assumptions about incremental (from 0% to 100%) loss of life-years as a result of the elevated BMI.

The two-way sensitivity analysis varying both the lifetime medical cost and the discount rate was undertaken. Another two-way sensitivity analysis varied the estimated of loss of weight and the medical cost adjusted for the different reimbursement rate (see below), which was used a threshold analysis for the subgroup of 55-year-old men with BMI of 40 kg/m^2.

What scenarios were tested in the sensitivity analysis? How do these relate to structural uncertainty (testing assumptions over model structure such as relationships between health states), methodological uncertainty (such as choices of discount rate or inclusion of indirect costs) or parameter uncertainty (assumptions over values of parameters in the model, such as costs, quality of life or disease progression rates)?

Cost incurred by the payer was also reduced by the median reimbursement rate, which is effectively an equivalent to the change of the perspective of economic evaluation from the one of the health-care system (regardless of who is paying) to the perspective of the individual insured patient.

Give a summary of the results of the sensitivity analysis – did they differ substantially from the base-case analysis. If so, what were the suggested causes?

The cost-effectiveness ratios appear to be sensitive to the change in clinical effectiveness parameters (in particular, to the excess weight loss), assumptions about additional loss of life as the result of the elevated BMI, lifetime medical-care cost, values of regression coefficients used to estimate utility values. However, according to figure 3, which presents the results of the one-way sensitivity analysis with respect to the above parameters for the 45-year-old men and women with BMI 40 kg/m^2, the threshold of $50,000 per QALY was breached when the base-case value of excess weight loss of 58% was reduced to 38%. When the rate of gastric bypass mortality was changed from 0.015% to 0.03%, the complication rates were increased by 25% and the procedure remained cost-effective except in some older less obese men (not specified).

The threshold analysis for the subgroup of 55-year-old men with BMI of 40 kg/m^2 where both loss of weight and the different reimbursement rate were varied indicated that under the base-case assumptions about the 67% reimbursement rate, the loss of excess weight greater than 46% is sufficient for the incremental cost per incremental QALY to be below $50,000.

Conclusions/implications

Give a brief summary of the authors' conclusions from their analysis

Although an open gastric bypass is not a cost-saving strategy from the payer's perspective, it is cost-effective among all categories of patients under the base-case assumptions. The results appear to be robust to parameter variations with respect to women and younger more obese men. An open gastric bypass may not be cost-effective for some subgroups of older and less obese men, i.e. exceeding $50,000 per QALY when the base-case assumptions about some clinical effectiveness parameters are varied.

What are the implications of the evaluation for practice?

Although an open gastric bypass is a cost-effective strategy, the decision to undergo a procedure must be individualised because of the associated risks, and patients should understand the long-term commitment that the treatment entails

Reference

Jensen C, Flum D R[141]

The costs of nonsurgical and surgical weight loss interventions: is an ounce of prevention really worth a pound of cure?

Study characteristics

Research question

What are the stated objectives of the evaluation?

The study was intended to answer the hypothetical question of which of the two interventions for the treatment of obesity, was more cost-effective from a societal perspective: open gastric bypass surgery (GBP) implemented at the age of 40 or diet and exercise implemented at the age of 18.

Study population

What definition was used for morbid obesity/eligibility for bariatric surgery?

BMI > 40 kg/m^2

What are the characteristics of the clinical trial population used in economic evaluation?

Age	Intervention group: white 18-year-old females who undergo a bariatric surgery at the age of 40 years and BMI > 40 kg/m^2 The patients from the study (Sjostrom *et al.*[89]) used to obtain parameters of the model were on average more than 40 years old Not clear. Comparator group: white 18-year-old female with BMI > 33 kg/m^2 (as stated on p. 353) or white 18-year-old female with BMI ≥ 35 kg/m^2 (as stated in the diagram of the model, p. 354) The average weight of the participants of the weight loss programme used to obtained parameters of the model was 33.8 kg/m^2 (Heshka *et al.*[196]). The participants were older (age was not indicated) than the 18-year-old population in the comparator arm.
Sex	Female
Race (if appropriate)	White
Comorbidities	Not indicated
Other characteristics	The weight in the comparator group was derived from the cut-off BMI value for the upper 4.4% in the distribution of the 18-year-old white female obese population in the USA. (http://www.soph.uab.edu/statgenetics/Research/Tables/YLL.htm)

Interventions and comparators

What number of interventions/strategies were included?

One

Was a no treatment/supportive care strategy included?

Yes; a commercial programme of diet and exercise

Describe interventions/strategies

Intervention/strategy 1: open gastric bypass

Comparator: dieting and exercise

Analytical perspective

What is the perspective adopted for the evaluation [(health service, health and personal social services, third-party payer, societal (i.e. including costs borne by individuals and lost productivity)]?

A societal perspective

Study type

Cost-effectiveness/cost–utility/cost–benefit analysis?

CUA (Incremental cost per incremental QALY)

Institutional setting

Where is/are the intervention(s) being evaluated usually provided?

Hospitals

Country/currency

Has a country setting been provided for the evaluation? In what currency are costs expressed and does the publication give the base year to which those costs relate?

All costs are reported in 2004 US$.

Data sources

Effectiveness

Were the effectiveness data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
Intervention (GBP). Clinical effectiveness data assessed in the weight loss (in BMIs) were taken from a single study for the mid-term (8 years) Control. Diet and exercise. Clinical effectiveness data assessed in the weight loss (in BMIs) were taken from a single study for the short-term (2 years)	✓	Weight loss and complication rates are taken from the Swedish case–control longitudinal study by Sjostrom *et al*.[89] 346 GBP patients were matched with 346 non-surgical controls and followed up for 8 years. Weight loss is taken from the USA case–control longitudinal study by Heshka *et al*.[196] 211 patients undergoing a commercial programme were matched with 212 controls undergoing a self-help programme and followed up for 2 years.
A review/synthesis or combination of previous studies		
Expert opinion		

Give the definitions of treatment effect used in the evaluation

Weight loss in BMI was converted into the differential years of life that applied to the patients from the different arms.

Give the size of treatment effect used in the evaluation

Although the size of treatment effect is not explicitly identified, both longevity and utility weights are assumed to be different for the patients with different BMI (in increments of 1 kg/m^2)

include values used for subgroups (if applicable). Indicate the source for individual treatment effects (if appropriate)

Intervention costs

Were the cost data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
Intervention (GBP). Cost data were taken from a single study comparing open with laparoscopic GBP. Control. Diet and exercise. Cost data were taken from a single study	✓	Nguyen *et al*.[113] ($n = 68$ in each arm) The costs were inflated to 2004 US prices using the Bureau of Labor statistics Inflation calculator (rather than the health-care-specific inflator) Costs (including the unit costs) were taken from the USA case–control longitudinal study by Heshka *et al*.[196]
A review/synthesis or combination of previous studies		
An educated guess in relation to the cost of GBP-related complications	✓	No

List the direct intervention costs used in the evaluation – include resource estimates (and sources for these estimates, if appropriate) as well as sources for unit costs used.

Resource category	Type of resources	Unit cost estimate (US$2001 prices) (± SD)	Source
Cost of surgery	Operative costs		Nguyen *et al.*[113]
Gastric bypass	Operative time and supplies	4,098 ± 1,538	
	Postanaesthesia	504 ± 487	
	Hopsital service cost		
	diagnostic	467 ± 170	
	nursing	1,201 ± 821	
	pharmaceutical	418 ± 232	
	therapeutic	97 ± 249	
	other	268 ± 213	
	Indirect costs	6,645 ± 2,437	
	Total	14,087 ± 5,237	
Cost of complications	Not specified	$5,000	An educated guess
Cost of diet and exercise	1 hour weekly weight loss program	Annual cost $9 cost per session × 52 × 2 years	Heshka *et al.*[196]

Other direct costs

(Cost of postsurgical complications)

Were the cost data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single data source was used for the estimates of the expected lifetime medical cost (of selected obesity-related diseases) reported by age/gender/BMI in Thompson *et al.*[144]	✓	As only the limited (up to 37.5 BMIs by increments of 5 BMIs) cost data were reported in Thompson *et al.*[144] the authors undertook a linear regression analysis to obtain estimates of costs for each value of BMI within the studied range (figure 3, p. 356) The cost was based on the patient at age 49 and divided by the remaining years of life to achieve a yearly cost
A review/synthesis or combination of previous studies		
Expert opinion		

List the costs used in the evaluation – if quantities of resource use are reported separately from cost values, show sources for the resource estimates as well as sources for unit costs used.

The aggregated costs associated with obesity-related diseases (hypertension hypercholesterolemia, Type 2 diabetes, coronary heart disease and stroke)	Using a linear regression equation the authors estimated that with each additional kg/m^2 the aggregated cost increases by US$1100. The regression equation is Lifetime cost US$ = 1100 (BMI in kg/m^2) – 6500)

indicate the source for individual cost values (if appropriate)

Indirect costs

(costs due to lost productivity, unpaid inputs to patient care)

Were indirect costs included:

Cost of patient time in the GBP arm is assumed to be zero to the society (a transfer) as most of the patients are on disability benefits (Narbro *et al.*[87]) Caregiver time in the GBP arm (Nguyen *et al.*[113]) Cost of patient time in the diet and exercise arm was inconsistently assumed not to be zero

Describe how indirect costs were estimated (e.g. how days of lost productivity were estimated and how those days were valued)

Caregiver time in the GBP arm was calculated as follows: US average hourly wage × 4 hours/day × 18 days (the average period for which the GBP patients were unable to complete the daily activities; Nguyen *et al.*[113])
Cost of patient time in the diet and exercise arm was calculated as follows: (1 hour to attend the programme + ½ hours to travel) × US average hourly wage × 52 weeks × 2 years
Note: The US average hourly wage was obtained from the bureau of Labour statistics

indicate the source for individual cost values (if appropriate)

Health state valuations/utilities

(if study uses quality of life adjustments to outcomes)

Were the utility data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single study	✓	Hakim *et al.*[197] used time trade-off techniques to estimate utility for persons for the range of BMI values. They also investigated the relationship between utility weights and kg/m^2
A review/synthesis or combination of previous studies		
Expert opinion		

List the utility values used in the evaluation

Using the estimate reported in Hakim *et al.*[197] a utility gain of 0.017 is associated with each BMI reduction of 1 kg/m^2

indicate the source for individual utility values (if appropriate)

Modelling

If a model was used, describe the type of model used (e.g. Markov state transition model, discrete event simulation)

A deterministic decision model (a decision tree)

Was this a newly developed model or was it adapted from a previously reported model? If an adaptation, give the source of the original.

A newly developed model

What was the purpose of the model (i.e. why was a model required in this evaluation)?

To compare the lifetime expected costs and outcomes between open gastric bypass and diet and exercise programme from the societal perspective.

What are the main components of the model (e.g. health states within a Markov model)? Are sources for assumptions over model structure (e.g. allowable transitions) reported – list them if reported.

The decision tree model has the following options (1) 'Intervention (a reduced BMI) without immediate complications', (2) 'Intervention (a reduced BMI) with immediate complications'; (3) Death; (4) 'Alive with reduced BMI' and 'Alive with baseline BMI'.
The diet and exercise arm of the decision tree model reasonably assumes that no patient experiences complications associated with GBP. The surviving patients from the control arm follow the pathway corresponding to the no-complication branch in the GBP arm of the decision tree.
The open gastric bypass arm of the decision tree model assumes two outcomes: surgery resulting in immediate complications and surgery without immediate complications. In both cases patients face the probability of death. The surviving patients may have a reduced BMI or remain with their initial BMI.
Life expectancy depends on the BMI. The starting age of patients is 18 years **in both** arms (*although this can be confusing and could only be deduced from the commentaries on scenario analyses, p. 356*) the GBP takes place when the GBP cohort exceeds 40 kg/m^2 which happens when they are 40 years old. In the base-case scenario BMI values increase from one year to another at the rate observed in general USA population in the 95.6th percentile for weight (a cut-off point for the BMI of > 40 kg/m^2 which corresponds to 4.4% of the population at age 40). In the base case this rate is applied to all surviving patients in each branch of the decision tree. However, the BMI reduction obtained as a result of the GBP or a diet and exercise programme is retained for life. As a result the BMI in such patients, although increasing at the above rate, is always reduced by the incremental BMI value observed after the intervention. Utility values corresponding to the BMI observed in each year (Hakim *et al.*[197]) were applied to obtain QALYs.

Extract **effectiveness data** for (natural history/disease progression) model and show sources

Control group (diet and exercise) has apparently attained some weight loss achieving 31.8 kg/m^2 at the age of 19 starting from either > 33 kg/m^2 or > 35 kg/m^2 (Heshka *et al*.[196])

The open gastric bypass group has achieved a larger weight loss of 29.93 kg/m^2 at the age of 48 starting from > 40 kg/m^2 (Sjostrom *et al*.[89])

Long-term outcomes (QALYs) were obtained from combining

life-years (as a function of age, and BMI) reported in Thompson *et al*.[144] that were extrapolated by linear approximation to obtain life expectancy for each BMI category

with utility weights reported in Hakim *et al*.[197]

What is the model time horizon? Duration of the cycle?

Lifetime

What, if any, discount rates have been applied in the model? Same rate for costs and outcomes?

Discounting seems to have been conducted however the discounting rates were not reported.

Results/analysis

What measure(s) of benefit were reported in the evaluation?

QALYs

Provide a summary of the clinical outcome/benefits estimated for each intervention/strategy assessed in the evaluation

Not reported. GBP is associated with additional 0.61 of life expectancy (not adjusted for quality of life)

Provide a summary of the costs estimated for each intervention/strategy assessed in the evaluation

Not reported. GBP is associated with additional cost of $4600

Synthesis of costs and benefits – are the costs and outcomes reported together (e.g. as cost-effectiveness ratios)? If so, provide a summary of the results.

It appears that the cost-effectiveness was determined using an ICER, but this was not entirely clear (NHS EED)

ICER = $7126/QALY gained

Give results of any statistical analysis of the results of the evaluation.

None provided

Was any sensitivity analysis performed – if yes, what type(s) [i.e. deterministic (one-way, two-way etc) or probabilistic].

The authors investigated uncertainty in the model parameters, but the parameters included and the ranges, and methods used to derive them, were not clear. However, the authors did not report the results satisfactorily. A series of one-way sensitivity analyses were performed that proved to be sensitive to the estimated cost of complications (although the range was not reported) and the discount rate (neither the value nor the range were reported).

What scenarios were tested in the sensitivity analysis? How do these relate to structural uncertainty (testing assumptions over model structure such as relationships between health states), methodological uncertainty (such as choices of discount rate or inclusion of indirect costs) or parameter uncertainty (assumptions over values of parameters in the model, such as costs, quality of life or disease progression rates)?

Worst-case and best-case scenarios for the assumption of the weight trajectory after the intervention were also investigated. In the worst-case scenario all weight lost through the interventions was regained within 3 years and the patients followed the trajectory of the 95.6th percentile.

In the best-case scenario the BMIs were unchanged at the postintervention levels in both groups for the remaining duration of their life.

Give a summary of the results of the sensitivity analysis – did they differ substantially from the base-case analysis. If so, what were the suggested causes?

In both worst-case and best-case scenarios the results were higher than in the base case but still cost-effective at < $35,000 per QALY

Conclusions/implications

Give a brief summary of the author's conclusions from their analysis

Gastric bypass (GBP) surgery is a worthwhile investment that provides the greatest amount of QALYs for the invested dollar

What are the implications of the evaluation for practice?

When it come to the obesity 'an ounce of prevention does not appear to be worth a pound of cure'

Reference

Salem, L.; Devlin, A.; Sullivan, S.D.; Flum, D.R.[142]

Cost-effectiveness analysis of laparoscopic gastric bypass, adjustable gastric banding, and non-operative weight loss interventions

Study characteristics

Research question

What are the stated objectives of the evaluation?

Given the differential risk and effectiveness of the laparoscopic gastric bypass (LGBP) and laparoscopic adjustable gastric banding (LAGB), the aim of the study was to evaluate the incremental cost-effectiveness of these two surgical procedures compared with non-operative weight loss interventions and with each other

Study population

What definition was used for obesity?

By implication, BMI > 40 kg/m^2

What are the characteristics of the baseline cohort for the evaluation?

Age	1. Aged 35 with BMI = 40 kg/m^2 2. Aged 45 with BMI = 50 kg/m^2 3. Aged 55 with BMI = 60 kg/m^2
Sex	Separate analysis is conducted by male/female subgroups
Race (if appropriate)	Not specified
Comorbidities	Patients are assumed to have no obesity-related comorbidities at the baseline
Other characteristics	None specified

Interventions and comparators

What number of interventions/strategies were included?

Two

Was a no treatment/supportive care strategy included?

Yes

Describe interventions/strategies

Intervention/strategy 1: Laparoscopic gastric bypass

Intervention/strategy 2: Laparoscopic adjustable gastric banding

Comparator: non-operative treatment of obesity

Analytical perspective

What is the perspective adopted for the evaluation [(health service, health and personal social services, third-party payer, societal (i.e. including costs borne by individuals and lost productivity)]?

The perspective of an economic analysis is that of a USA payer's.

Study type

Cost-effectiveness/cost–utility/cost–benefit analysis?

CUA (Incremental cost per incremental QALY)

Institutional setting

Where is/are the intervention(s) being evaluated usually provided?

Hospitals

Country/currency

Has a country setting been provided for the evaluation? In what currency are costs expressed and does the publication give the base year to which those costs relate?

All costs are reported in US$2004.

Data sources

Effectiveness

Were the effectiveness data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single study		
A review/synthesis or combination of previous studies	✓	Operative mortality was taken from the systematic literature review of LAGB by Chapman *et al*.[151] Primary clinical effectiveness outcomes (excess body weight loss) were taken from the range of studies including cohort and case series studies. It does not seem that the systematic review of the data obtained from the various sources was conducted. Base-case estimates were derived by averaging the reported values.
Expert opinion was sought on the following clinical outcomes: % of patients needing band removal Perioperative mortality after revision surgery % of patients with leak non-operative for LGBP		Not explained

Give the definitions of treatment effect used in the evaluation

The authors indicated that the major clinical end points were (surgery-related) survival and weight loss (in excess body weight loss converted to BMI). Other clinical effectiveness end points are the rates of revisional and reversal surgeries. Surgery-related complications for each intervention were included only on the cost side of the equation.

These intermediate outcomes were converted into the differential years of life that applied to the patients from different arms of the model.

Give the size of treatment effect used in the evaluation

The primary clinical end point was measured in excess body weight loss converted to BMI. The conversion rule was not reported.

include values used for subgroups (if applicable). Indicate the source for individual treatment effects (if appropriate)

Intervention costs

Were the cost data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
For both interventions (LAGB and LGBP). Cost data were taken from the published data source	✓	Aggregated cost categories for both interventions and some surgery-related complications, were obtained from the Healthcare Cost and Utilisation project database (1997) and adjusted for inflation using the medical-care component of the consumer price index. There are no corresponding costs for non-surgery treatment.
A review/synthesis or combination of previous studies		
Expert opinion was sought on the following cost components: Band adjustment (LAGB) Band removal (LAGB) Cost of revision surgery both (LAGB and LGBP) Number of follow-up visits for both interventions	✓	Not explained

List the direct intervention costs used in the evaluation – include resource estimates (and sources for these estimates, if appropriate) as well as sources for unit costs used (table 1, p. 28).

Resource category	**Type of resources – not elaborated by cost components**	**LAGB – cost estimates (US$2004 prices)**	**LGBP – cost estimates (US$2004 prices)**
Cost of surgery		16,200	27,560
	Band adjustment	150 (10 visits) [per visit?]	not applicable
	Revision surgery	5000	10,000
	Reversal surgery (band removal)	6000	not applicable
	Reversal srugery LGBP		not specified
Cost of complications	Minor wound infection	204	204
	Major wound infection	11,236	11,236
	Deep venous thrombosis	9222	9222
	Pulmonary embolism	15,582	15,582
	Leak non-operative	not applicable	50,000
	Laparoscopic cholecystectomy	16,000	16,000
	Incisional hernia	14,416	14,416
	Abdominoplasty	13,992	13,992

Other direct costs

(Cost of postsurgical complications)

Were the cost data derived from:

Lifetime medical costs associated with obesity	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single data source was used for the estimates of the expected lifetime medical cost reported by age/gender/BMI in Thompson *et al*.[144]	✓	Not clear how the estimates reported in Thompson *et al*.[144] were used to obtain the expected lifetime medical cost for the BMI values other than reported.
A review/synthesis or combination of previous studies		
Expert opinion	✓	Cost of follow-up visits It is not clear from where *the quantities* and type of supplements (vitamins, minerals, etc.) used by postsurgical patients for the duration of their life time were obtained. Unit costs were obtained from the 2000 Drug topics Red Book, Montvale, NJ: Medical Economics company. 2000.[195]

List the costs used in the evaluation – if quantities of resource use are reported separately from cost values, show sources for the resource estimates as well as sources for unit costs used.

Follow-up costs	Number of follow-up visits other than adjustments (LGBP = 6; LAGB = 0)	US$159
	Lifetime Pharmaceuticals (for 100% of LGBP patients and 0% for LAGB)	US$72

indicate the source for individual cost values (if appropriate)

Indirect costs

(costs due to lost productivity, unpaid inputs to patient care)

Were indirect costs included:

Not applicable

Describe how indirect costs were estimated (e.g. how days of lost productivity were estimated and how those days were valued)

Not applicable

indicate the source for individual cost values (if appropriate)

Health state valuations/utilities

(if study uses quality of life adjustments to outcomes)

Were the utility data derived from:

	Tick	Were the methods for deriving these data adequately described (give sources if using data from other published studies)?
A single study by Craig and Tseng[140] that reported utility values that were elicited from the general population	✓	Not explained. See comments to Craig and Tseng[140] for methodology used in eliciting utilities
A review/synthesis or combination of previous studies		
Expert opinion		

List the utility values used in the evaluation

See comments to Craig and Tseng[140]

indicate the source for individual utility values (if appropriate)

Modelling

If a model was used, describe the type of model used (e.g. Markov state transition model, discrete event simulation)

A deterministic decision model (a decision tree)

Was this a newly developed model or was it adapted from a previously reported model? If an adaptation, give the source of the original.

An adjusted model published in Craig and Tseng[140]

What was the purpose of the model (i.e. why was a model required in this evaluation)?

We designed a model to evaluate the incremental cost-effectiveness of LGBP and LAGB compared with non-operative weight loss interventions and with each other

What are the main components of the model (e.g. health states within a Markov model)? Are sources for assumptions over model structure (e.g. allowable transitions) reported – list them if reported.

The no-treatment arm of the decision tree model assumes that the patients do not lose or gain weight and that their QALYs depend on the initial BMI, gender and the baseline age.

Both arms of the decision tree model assume two surgery outcomes that occur in the first instance: successful surgery and death. In the LGBP arm the surviving patients may need to undergo a revisional surgery, which can be successful or result in the death of a patient. In the LAGB arm the surviving patients may need to undergo a reversal surgery (band removal), which is not associated with the risk of death. All surviving patients in both arms (except those who underwent a reversal surgery) achieve weight loss specific to the type of surgery (figure 1, p. 27).

It is not clear how the probability of revisional surgery for LAGB (5%) was incorporated into the model.

The remaining life-years and lifetime costs for the population in the surgical and non-surgical treatment alternatives depend on the gender; baseline age and the eventual BMI (Thompson *et al*.[144]). The BMI is determined by the decision analytic model with the horizon of 3 years. The utility values published in Craig and Tseng[140] (2002) and differentiated by gender, age and BMI are applied to remaining life-years to obtain QALYs.

Extract **effectiveness data** for [natural history/disease progression] model and show sources

Short term (1–3 years) effectiveness data for the open gastric bypass comprised the following

1. Weight loss (in percentage of excess body weight) for LGBP and LAGB was apparently taken from the range of studies (see table 1 for the references), averaged across them and converted into BMI (the formula is not provided so the actual values used in the model are not known).

2. Perioperative mortality (1% for LGBP and 0.05% for LAGB) and deep venous thrombosis rates were taken from the 2004 systematic literature review (Chapman *et al*.[151]).

3. Rates of revisional surgery (5% for LGBP and 5% for LAGB) were taken from the range of studies (see table 1 for the references)

4. Perioperative mortality rates for revisional surgery (1% for LGBP and 0.05% for LAGB) were taken from the experts' opinion

5. Other complication rates were taken from the US Health Cost and Utilization Project and the experts' opinion.

6. The rate of a reversal surgery (band removal – 5%) was taken from the experts' opinion

The clinical outcomes in terms of differential complication rates included only in the cost side of the incremental C : E ratio and are not reported here

Utility weights for men and women (for a specific values of BMI and age variables) were obtained from Craig and Tseng[140] (see relevant comments in the review of their paper).

What is the model time horizon? Duration of the cycle?

Although the decision analytic model covers costs and outcomes over the initial 3 years involving a surgical intervention in two out of three arms of the model, the economic evaluation extends to the lifetime due to the nature of the data on the life expectancy and lifetime costs available from Thompson *et al.*[144]

What, if any, discount rates have been applied in the model? Same rate for costs and outcomes?

Cost and QALYs were discounted at 3%

Results/analysis

What measure(s) of benefit were reported in the evaluation?

QALYs

Provide a summary of the clinical outcome/benefits estimated for each intervention/strategy assessed in the evaluation

Not reported

Provide a summary of the costs estimated for each intervention/strategy assessed in the evaluation (table 13, p. 1498)

Not reported.

Synthesis of costs and benefits – are the costs and outcomes reported together (e.g. as cost-effectiveness ratios)? If so, provide a summary of the results.

Although the objective of the study was to evaluate the incremental cost-effectiveness of LGBP and LAGB compared with non-operative weight loss interventions **and with each other** it does not seem that the ICER of LGBP versus LAGB was calculated.

The results are presented in terms of an incremental cost per additional QALY comparing LGBP with non-surgical treatment and LAGB with non-surgical treatment. A set of ICERs was produced for different combinations of gender, the baseline age and BMI.

The results are only available for men and women at 35 years of age and 40 kg/m^2 at the baseline.

LGBP versus non-surgical treatment

Incremental cost per additional QALY	
Baseline age **35 years; BMI 40 kg/m^2**	
Men	Women
18,543	14,680

LAGB versus non-surgical treatment

Incremental cost per additional QALY	
Baseline age **35 years; BMI 40 kg/m^2**	
Men	Women
11,604	8878

Although no other results are reported, the authors commented that for other baseline ages (35-, 45- and 55-year-old) and BMI categories (40, 50, 60 kg/m^2) the ICER comparing LGBP with no-treatment strategy is consistently higher than the ICER comparing LAGB with no-treatment strategy.

Give results of any statistical analysis of the results of the evaluation.

None provided

Was any sensitivity analysis performed – if yes, what type(s) [i.e. deterministic (one-way, two-way etc) or probabilistic].

The authors investigated uncertainty associated with parameter estimates in the model, but the source of the ranges in parameter estimates, and methods used to derive them, were not clear. A series of one-way sensitivity analyses were performed and results proved to be sensitive to the value of the primary clinical outcome (weight loss measured in the% of excess weight loss), cost of the surgical procedure, number of times the band adjustment was required for the LAGB procedure and the estimated rate of perioperative mortality for LGBP procedure (figure 2, p. 29).

A two-way sensitivity analysis was conducted where clinical effect (weight reduction measured in the% of excess weight loss) was varied simultaneously over the range of 0–100% in both arms. The results for a 45-year-old female with the baseline BMI of 40 kg/m^2 were presented in figure 3, p. 30. the authors concluded that for this subgroup of patients the 'difference in cost-effectiveness' mostly favours LAGB and that included the base-case point observations of 55% of excess weight loss in LAGB patients versus 71% of excess weight loss in LGBP patients. However, the 'difference in cost-effectiveness' apparently refers to the difference in cost-effectiveness ratios calculated in two arms of the model rather than the ICER. Therefore, the authors' conclusion of the likely superiority of the LAGB procedure over the LGBP procedure is not supported by the means of this particular two-way sensitivity analysis.

What scenarios were tested in the sensitivity analysis? How do these relate to structural uncertainty (testing assumptions over model structure such as relationships between health states), methodological uncertainty (such as choices of discount rate or inclusion of indirect costs) or parameter uncertainty (assumptions over values of parameters in the model, such as costs, quality of life or disease progression rates)?

None

Give a summary of the results of the sensitivity analysis – did they differ substantially from the base-case analysis. If so, what were the suggested causes?

In this study the authors found that both bariatric procedures were cost-effective at < $25,000 per QALY for all base-case scenarios (i.e. the combinations of baseline ages of 35, 45 or 55 years and BMI of either 40, 50, 60 kg/m^2).

Conclusions/implications

Give a brief summary of the author's conclusions from their analysis

The authors also concluded that LAGB is more cost-effective than LGBP for all base-case scenarios. However, because the ICER directly comparing these two surgical interventions was not calculated this conclusion may not be true across the range of combinations of the baseline age and BMI values.

What are the implications of the evaluation for practice?

Appendix 16

List of studies excluded from review of clinical effectiveness

Studies included in previous publications of the systematic review but excluded from 2008 update

The following 11 trials (21 publications) that were included in previous publications[15,70,71] of the systematic review have been excluded from the 2008 update.

Andersen 1984/88
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.

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.

Andersen 1987
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.

Buckwalter
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.

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.

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

Danish Obesity Project
Backer O, Gudmand HE, Andersen B, Baden H, Martiny P, Juhl E, *et al*. Randomised trial of jejunoileal bypass versus medical treatment in morbid obesity. The Danish Obesity Project. *Lancet* 1979;**2**:1255–8.

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.

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.

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

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

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

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

Naslund 1988
Naslund I. The size of the gastric outlet and the outcome of surgery for obesity. *Acta Chirurg Scand* 1986;**152**:205–10.

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

Naslund I. Gastric bypass versus gastroplasty. A prospective study of differences in two surgical

procedures for morbid obesity. *Acta Chirurg Scand Suppl* 1987;536:1–60.

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

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.

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.

Pories 1982
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.

Van Rij 1984
Van Rij AM. Gastric bypass and gastric partitioning in morbid obesity: results of a controlled trial [abstract]. *Aust N Z J Med* 1984;**14**(Suppl. 1):340.

Studies excluded from updated searches

Adams TD, Avelar E, Cloward T, Crosby RD, Farney RJ, Gress R *et al*. Design and rationale of the Utah obesity study. A study to assess morbidity following gastric bypass surgery. *Contemp Clin Trials* 2005;**26**:534–51. [Twelve-month results not reported, reports design and baseline only.]

Andersson I, Adolfsson B, Apelman J, Bengtsson B, Rossner S, Thorne A. Prospective randomised controlled study with a 3 year follow-up-behaviour modification + adjustable gastric banding (AGB) vs AGB. *Int J Obes* 2001;**25**(Suppl. 2):S27. [Intervention – behaviour modification, length of follow-up.]

Arcila D, Velazquez D, Gamino R, Sierra M, Salin-Pascual R, Gonzalez-Barranco J *et al*. Quality of life in bariatric surgery. *Obes Surg* 2002;**12**:661–5. [Study design – cross-sectional study.]

Batsis JA, Romero-Corral A, Collazo-Clavell M, Sarr MG, Somers V, Lopez-Jimenez F. The effect of bariatric surgery on metabolic syndrome: a population based, long-term controlled study. *Diabetes* 2008;**57**:A484–A485. [Study design.]

Blanco-Engert R, Weiner S, Pomhoff I, Matkowitz R, Weiner RA. Outcome after laparoscopic adjustable gastric banding, using the Lap-Band and the Heliogast band: a prospective randomized study. *Obesity Surgery* 2003;**13**:776–9. [Interventions – comparison of techniques rather than different procedures.]

Bouillot JL, Servajean S, Coupaye M, Berger N, Veyrie N, Poitou C *et al*. Laparoscopic surgery for morbid obesity: Results of a comparative study: Gastric banding vs gastric bypass. *Obes Surg* 2006;**16**:416. [Study design not an RCT for comparison of surgical procedures.]

Busetto L, Mirabelli D, Petroni ML, Mazza M, Favretti F, Segato G *et al*. Comparative long-term mortality after laparoscopic adjustable gastric banding versus nonsurgical controls. *Surg Obes Related Dis* 2007;**3**:496–502. [Study design, not concurrent controls.]

Christou NV, Sampalis JS, Liberman M, Look D, Auger S, McLean AP *et al*. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. *Ann Surg* 2004;**240**:416–23. [Study design – retrospective cohort study.]

Cummings DE, Weigle DS, Frayo RS, Breen PA, Ma MK, Dellinger EP *et al*. Plasma ghrelin levels after diet-induced weight loss or gastric bypass surgery. *N Engl J Med* 2002;**346**:1623–30. [Patients, study design, length of follow-up.]

DeMaria EJ. Bariatric surgery for morbid obesity. *N Engl J Med* 2007;**356**:2176–83. [Study design.]

Deveney CW, MacCabee D, Marlink K, Welker K, Davis J, McConnell DB. Roux-en-Y divided gastric bypass results in the same weight loss as duodenal switch for morbid obesity. *Am J Surg* 2004;**187**:655–9. [Study design.]

Dittmar M, Heintz A, Hardt J, Egle UT, Kahaly GJ. Metabolic and psychosocial effects of minimal invasive gastric banding for morbid obesity. *Metab Clin Exp* 2003;**52**:1551–7. [Unclear length of follow-up, no reply from authors.]

Dixon AFR, Dixon JB, O'Brien PE. Laparoscopic adjustable gastric banding induces satiety: a randomized crossover study. *Int J Obes* 2004;**28**:S39. [Patients, study design.]

Gravante G, Araco A, Araco F, Delogu D, De LA, Cervelli V. Laparoscopic adjustable gastric bandings: a prospective randomized study of 400 operations performed with 2 different devices. *Archiv Surg* 2007;**142**:958–961. [Intervention–comparison of devices rather than different procedures.]

Griffen WO, Jr., Young VL, Stevenson CC. A prospective comparison of gastric and jejunoileal bypass procedures for morbid obesity. 1977. *Surg Obes Related Dis* 2005;**1**:163–72. [Reprint of 1977 paper–excluded for intervention–jejunoileal bypass.]

Herron DM. Biliopancreatic diversion with duodenal switch vs. gastric bypass for severe obesity. *J Gastrointest Surg* 2004;**8**:406–7. [Overview.]

Holeczy P, Bolek M, Sevcikova J. Comparison of first 25 laparoscopic gastric banding and gastric sleeve resections with 1 year follow-up. *Obes Surg* 2008;**18**:482. [Study design.]

Keating C, Moodie M, O'Brien P, Peeters A, Dixon J. Cost-effectiveness of surgically induced weight loss for the management of type-2 diabetes: randomised trial. *Int J Obes* 2008;**32**(Suppl. 1). [Outcomes.]

Lawson ML, Kirk S, Mitchell T, Chen MK, Loux TJ, Daniels SR *et al*. One-year outcomes of Roux-en-Y gastric bypass for morbidly obese adolescents: a multicenter study from the Pediatric Bariatric Study Group. *J Pediatr Surg* 2006;**41**:137–43. [Study design–retrospective.]

Lee W-J. Laparoscopic Roux-en-Y versus mini-gastric bypass for the treatment of morbid obesity: a prospective randomized controlled clinical trial. *Ann Surg* 2005;**242**:20–8. [Comparison of surgical technique (gastric bypass vs mini gastric bypass).]

Lee WJ, Wang W, Huang MT. Laparoscopic adjustable silicone gastric banding versus vertical banded gastroplasty in morbidly obese patients. *Ann Surg* 2004;**240**:391–2. [Letter – overview.]

Liorci MP, Ilias EJ, Kassab P, Castro OA. [Roux en Y gastric bypass surgery or gastric band to the treatment of the morbid obesity?.]. [In Portuguese.]. *Rev Assoc Med Brasil* 1900;**52**:195-Aug. [Overview.]

Mummadi RR, Kasturi KS, Sood G. Effect of bariatric surgery on nonalcoholic fatty liver disease (NAFLD): a meta-analysis. *Hepatology* 2007;**46**(4, Suppl. S). [Before and after studies.]

Naslund I. Lessons from the Swedish Obese Subjects Study: the effects of surgically induced weight loss on obesity comorbidity. *Surg Obes Related Dis* 2005;**1**:140–4. [Overview.]

Rabl C, Palazzo F, Rogers S, Posselt A, Cello J, Campos G. Laparoscopic gastric bypass is as safe as laparoscopic gastric banding and provides superior weight loss outcomes. *Obes Surg* 2008;**18**:459–60. [Study design.]

Ryan D, Stenlof K, Martin P. Design and methods for a randomized clinical evaluation comparing gastric bypass surgery, an intensive medical intervention and usual care for class III obesity. *Obes Res* 2004;**12**:A42. [Abstract–no data. Authors contacted–no surgical arm in trial.]

Sampalis JS, Liberman M, Auger S, Christou NV. The impact of weight reduction surgery on health-care costs in morbidly obese patients. *Obes Surg* 2004;**14**:939–47. [Length of follow-up of control group.]

Shikora SA. 'What are the yanks doing?' The U.S. experience with Implantable Gastric Stimulation (IGS) for the treatment of obesity–update on the ongoing clinical trials. *Obes Surg* 2004;**14**(Suppl. 1):S40–S48.[Intervention – implantable gastric stimulation, length of follow-up.]

Skroubis G, Anesidis S, Kehagias I, Mead N, Vagenas K, Kalfarentzos F. Roux-en-Y gastric bypass versus a variant of biliopancreatic diversion in a non-superobese population: prospective comparison of the efficacy and the incidence of metabolic deficiencies. *Obes Surg* 2006;**16**:488–95. [Design–not randomised (confirmed with authors).]

Suter M, Giusti V, Worreth M, Heraief E, Calmes JM. Laparoscopic gastric banding: a prospective, randomized study comparing the Lapband and the SAGB: early results. *Ann Surg* 2005;**241**:55–62. [Intervention–comparison of techniques rather than different procedures.]

Thorne A, Lonnqvist F, Apelman J, Hellers G, Arner P. A pilot study of long-term effects of a novel obesity treatment: omentectomy in connection with adjustable gastric banding. *Int J Obes Related Metabol Disord: J Int Assoc Study Obes* 2002;**26**:193–9. [Intervention – omenectomy.]

Weiss HG, Nehoda H, Labeck B, Peer-Kuehberger R, Oberwalder M, Aigner F *et al*. Adjustable gastric and esophagogastric banding: a randomized clinical trial. *Obes Surg* 2002;**12**:573–8. [Intervention–comparison of techniques rather than procedures.]

Appendix 17

List of studies excluded from the review of cost-effectiveness

Caro JJ, Ozer Stillman I, Danel A, Getsios D, McEwan P. Cost-effectiveness of rimonabant use in patients at increased cardiometabolic risk: estimates from a Markov model. *J Med Economics* 2007;**10**:239–54. [Only non-surgical interventions are evaluated.]

Caro JJ, O'Brien J.A, Hollenbeak CS, Spackman E, Ben-Joseph R, Okamoto LJ, *et al.* Economic burden and risk of cardiovascular disease and diabetes in patients with different cardiometabolic risk profiles. *Value in Health* 2007;**10**(Suppl. 1):S12–S20. [Not an economic evaluation of the alternative therapies.]

Christou NV, Sampalis JS, Liberman M, Look D, Auger S, McLean AP, *et al*. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. *Ann Surg* 2004;**240**:416–23. [Intermediate outcome (percent excess weight loss) is not converted into the final outcome.]

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**:1–153. [The previous report.]

Clegg AJ, Colquitt J, Sidhu MK, Royle P, Loveman E, Walker A. Clinical and cost effectiveness of surgery for morbid obesity: a systematic review and economic evaluation. *Int J Obes Related Metabol Disord: J Int Assoc Study Obes* 2003;**27**:1167–77. [Journal publication of the previous report.]

Craig BM, Tseng DS, Fang J. Is bariatric surgery worth its weight in gold (costs)? *Evidence-Based Gastroenterol* 2003;**4**:88–9. [Not a complete economic evaluation; cost and outcomes are not reported.]

Encinosa WE, Bernard DM, Chen CC, Steiner CA. Healthcare utilization and outcomes after bariatric surgery. *Med Care* 2006; **44**:706–12. [Intermediate outcomes (complication rates, length of stay) are not converted into the final outcomes.]

Fang J. The cost-effectiveness of bariatric surgery. *Am J Gastroenterol* 2003;**98**:2097–8. [Not an economic evaluation. A comment to the included paper by Craig and Tseng, 2002.]

Flum DR. Cost and survival outcomes assessment of gastric bypass surgery. *Surg Obes Related Dis* 2005;**1**:41–44. [Not a complete economic evaluation, review.]

Flum DR, Salem L, Elrod JA, Dellinger EP, Cheadle A, Chan L. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. *JAMA* 2005;**294**:1903–8. [Not a complete economic evaluation. Intermediate outcomes (mortality) are not converted into the final outcomes.]

Gallagher SF, Banasiak M, Gonzalvo JP, Paoli DP, Allwood J, Morris D, *et al.* The impact of bariatric surgery on the Veterans Administration healthcare system: a cost analysis. *Obes Surg* 2003;**13**:245–8. [Not a complete economic evaluation; Costing study; outcomes are not reported.]

Haby MM, Vos T, Carter R, Moodie M, Markwick A, Magnus A, *et al.* A new approach to assessing the health benefit from obesity interventions in children and adolescents: the assessing cost-effectiveness in obesity project. *Int J Obes* 2006;**30**:1463–75. [Not a complete economic evaluation, method only.]

Jones Jr, AJD, Benotti PN, Capella RF, Cooper CG, Flanagan L, *et al*. Open versus laparoscopic Roux-en-Y gastric bypass: A comparative study of over 25,000 open cases and the major laparoscopic bariatric reported series. *Obes Surg* 2006;**16**:721–7. [Not a complete economic evaluation intermediate outcomes (complication rates) are not converted into the final outcomes.]

Katopodi T, Katostaras T. The weight reduction operation of choice: Mason vs gastric bypass. A comparative study. *Rev Clin Pharmacol Pharmacokin Int Edn* 2005;**19**:155–8. [Costs and outcomes are not converted into the final outcomes.]

Korenkov M, Sauerland S, Junginger T. Surgery for obesity. *Curr Opin Gastroenterol* 2005;**21**:679–83. [Not an economic evaluation. Not a systematic review.]

Kral JG, Christou NV, Flum DR, Wolfe BM, Schauer PR, Gagner M *et al*. Medicare and bariatric surgery. *Surg Obes Related Dis* 2005;**1**:35–63. [Not an economic evaluation. Not a systematic review.]

Lamotte M, Annemans L, Lefever A, Nechelput M, Masure J. A health economic model to assess the long-term effects and cost-effectiveness of orlistat in obese type 2 diabetic patients. *Diabetes Care* 2002;**25**:303–8. [Only non-surgical interventions are evaluated.]

Levy P, Fried M, Santini F, Finer N. The comparative effects of bariatric surgery on weight and Type 2 diabetes. *Obes Surg* 2007;**17**:1248–56. [Not an economic evaluation. Not a systematic review.]

Livingston EH, Fink AS. Quality of life: cost and future of bariatric surgery. *Archiv Surg* 2003;**138**:383–8. [Not an economic evaluation; review of non-utility based HRQoL.]

Monk JS, Nagib ND, Stehr W. Pharmaceutical savings after gastric bypass surgery. *Obes Surg* 2004;**14**:13–15. [Not an economic evaluation. Costing study.]

Narbro K, Agren G, Jonsson E, Naslund I, Sjostrom L, Peltonen M. Pharmaceutical costs in obese individuals: comparison with a randomly selected population sample and long-term changes after conventional and surgical treatment: the SOS intervention study. *Arch Intern Med* 2002;**162**:2061–9. [Costs and outcomes are not converted into the final outcomes.]

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. [Costs and outcomes are not converted into the final outcomes.]

Nguyen NT, Varela JE, Sabio A, Naim J, Stamos M, Wilson SE. Reduction in prescription medication costs after laparoscopic gastric bypass. *Am Surgeon* 2006;**72**:853–6. [Not an economic evaluation. Costing study.]

Paxton JH, Matthews JB. The cost effectiveness of laparoscopic versus open gastric bypass surgery. *Obes Surg* 2005;**15**:24–34. [Costs and outcomes are not converted into the final outcomes.]

Sampalis JS, Liberman M, Auger S, Christou NV. The impact of weight reduction surgery on health-care costs in morbidly obese patients. *Obes Surg* 2004;**14**:939–47. [Costs and outcomes are not converted into the final outcomes.]

Sanchez-Santos R, Del Barrio MJ, Gonzalez C, Madico C. Long-term health-related quality of life following gastric bypass: influence of depression. *Obes Surg* 2006;**16**:580–5. [Costs are not reported; outcomes are not converted into the final outcomes.]

Siddiqui A, Livingston E, Huerta S. A comparison of open and laparoscopic Roux-en-Y gastric bypass surgery for morbid and super obesity: a decision-analysis model. *Am J Surg* 2006;**192**(5):e1–e7. [Costs and outcomes are not converted into the final outcomes.]

Snow LL, Weinstein LS., Hannon JK, Lane DR, Ringold FG, Hansen PA, *et al*. The effect of Roux-en-Y gastric bypass on prescription drug costs. *Obes Surg* 2004;**14**:1031–5. [Not an economic evaluation. Costing study.]

Zlabek JA, Grimm MS, Larson CJ, Mathiason MA, Lambert PJ. Kothari SN. The effect of laparoscopic gastric bypass surgery on dyslipidemia in severely obese patients. *Surg Obes Related Dis* 2005;**1**:537–42. [Not a complete economic evaluation. Intermediate outcomes are not converted into the final outcomes.]

Appendix 21

List of ongoing studies

Comparison of laparoscopic sleeve gastrectomy and Roux-en-Y-gastric bypass in the treatment of morbid obesity

Laparoscopic sleeve-gastrectomy will be compared to laparoscopic proximal Roux-Y-gastric bypass in a prospective randomised study. Primary outcome measure is effectiveness in terms of weight loss, reduction in comorbidity and quality of life over five years. Secondary outcome measures are: early morbidity, duration and cost of the operation, late morbidity, reoperations (for complications, for insufficient weight loss) and postoperative changes of gastrointestinal hormones.

- Estimated enrolment: 90 (adults with BMI > 40).
- Study start date: July 2006.
- Estimated study completion date: August 2016.
- Estimated primary completion date: September 2010 (final data collection date for primary outcome measure).
- Sponsors and collaborators: University Hospital, Basel, Switzerland. Swiss National Science Foundation, Ethicon Endo-Surgery.
- http://clinicaltrials.gov/ct2/show/NCT00356213.

Laparoscopic adjustable gastric banding versus sleeve gastrectomy

Official title: Laparoscopic adjustable gastric banding versus laparoscopic sleeve gastrectomy: a prospective randomised trial

The investigators aim to determine the clinical and metabolic outcomes of two available bariatric restrictive procedures: laparoscopic adjustable gastric banding and laparoscopic sleeve gastrectomy for the treatment of morbid obesity in veterans. Primary outcome measures are only described as 'Short and long term clinical outcomes' over five years. Secondary outcome measures are: metabolic outcomes, oesophagogastric physiology, hormonal physiology and procedure costs.

- Estimated enrolment: 40 (veterans with BMI > 35 with comorbidities or BMI > 40).
- Study start date: January 2008.
- Estimated study completion date: December 2012.
- Estimated primary completion date: December 2010 (final data collection date for primary outcome measure).
- Sponsors and collaborators: North Texas Veterans' Healthcare System.
- http://clinicaltrials.gov/ct2/show/NCT00434655.

Laparoscopic bariatric surgery to treat Type 2 diabetes in obese patients

This pilot research study is being performed to determine whether bariatric surgery can safely provide better control of diabetes symptoms in obese diabetics than continuing medical management (antidiabetic drugs in combination with diet and lifestyle changes). This study will be comparing gastric bypass and adjustable gastric banding to treatment with a combination of drugs, diet and lifestyle changes for control of Type 2 diabetes. Primary outcome measure: diabetic control as assessed by HbA_{1c}. Secondary outcome measures: resolution of diabetes; improvement in diabetic control and cardiometabolic profile; weight loss and decrease in BMI; reduction in the usage of insulin or other diabetic drugs; improvement in diabetic complications and end-organ damage; improvement in health-related quality of life and depression scores; and, utilisation of resources and productivity losses. Duration of study not stated.

- Estimated enrolment: 72 (BMI 30 to < 40 kg/m^2) plus have had Type 2 diabetes mellitus for more than five years and have complications).
- Study start date: May 2007.
- Study end date: not stated.
- Sponsors and collaborators: Hamilton Health Sciences.
- http://clinicaltrials.gov/ct2/show/NCT00428571.

Mechanisms of diabetes control after weight loss surgery

The aim of this study is to determine whether the magnitude of the incretin effect on insulin secretion is greater after gastric bypass than after an equivalent diet-induced weight loss. We will compare, in obese patients with diabetes, randomised to VLCD or to gastric bypass, the effect of an equivalent weight loss on the incretin effect (difference in insulin secretion after comparable oral and intravenous glucose loads).

- Study type: observational.
- Study design: case–control, prospective.
- Estimated enrolment: 20.
- Study start date: September 2005.
- Estimated study completion date: July 2008.
- http://clinicaltrials.gov/ct2/show/NCT00571220.

Longitudinal assessment of bariatric surgery (LABS-1)– completed

The primary objectives of this study are to assess the safety of bariatric surgery by estimating the prevalence of short-term adverse outcomes in a multicentre cohort of patients undergoing bariatric surgical procedures and to determine the associations between short-term adverse outcomes after bariatric surgery and both clinical/demographic patient characteristics and features of operative/perioperative care.

- Study type: observational.
- Study design: cohort, prospective.
- Enrolment: 5102.
- Study start date: March 2005.
- Study completion date: December 2007.
- Primary completion date: December 2007. (Final data collection date for primary outcome measure.)
- Sponsors and collaborators: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
- http://clinicaltrials.gov/ct2/show/NCT00433810.

Long-term effects of bariatric surgery (LABS-2)

The primary objective of LABS-2 is to use standardised techniques and measures to assess the longer-term safety and efficacy of bariatric surgery by: (1) comparing postsurgical outcomes with preoperative status; and (2) examining risks and benefits of surgery. LABS-2 will determine the associations between clinical/demographic patient characteristics, components of the surgical procedure, and perioperative and postoperative care with postoperative risks and changes in patient status.

- Study type: observational.
- Study design: cohort, prospective.
- Estimated enrolment: 2400.
- Study start date: March 2006.
- Estimated study completion date: August 2009.
- Sponsors and collaborators: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
- http://clinicaltrials.gov/ct2/show/NCT00465829.

Advanced medical therapy versus advanced medical therapy plus bariatric surgery for the resolution of Type 2 diabetes

The aim of the study is to compare the relative clinical outcomes between advanced medical therapy alone or advanced medical therapy combined with bariatric surgery [either Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy] in patients with Type 2 diabetes and a BMI between 30 and 40 kg/m^2. The study will examine the short- and long-term effects of each intervention on biochemical resolution of diabetes, diabetic complications and end-organ damage.

- Study type: interventional.
- Study design: treatment, randomised, open label, parallel assignment, safety/efficacy study.
- Official title: STAMPEDE: Surgical Therapy And Medications Potentially Eradicate Diabetes Efficiently.
- Estimated enrolment: 150.
- Study start date: February 2007.
- Estimated study completion date: December 2013.
- Estimated primary completion date: January 2011. (Final data collection date for primary outcome measure.)
- Sponsors and collaborators: The Cleveland Clinic, Ethicon Endo-Surgery, LifeScan.
- http://clinicaltrials.gov/ct2/show/NCT00432809.

A prospective randomised controlled intervention study of conventional management versus the placement of the Lap-Band system in severely obese adolescents in effecting weight loss

A group of 50 severely obese adolescents will be randomised to either a conventional management plan incorporating the Active8 Adolescent Programme with dietary and behavioural modification or surgical management with the Lap-Band system.

- Open parallel study.
- Start date: 1 February 2005.
- Closed, but follow-up is continuing.
- Funding: NHMRC, Inamed Health, Centre for Obesity Research and Education (CORE).
- http://www.anzctr.org.au/trial_view.aspx?ID=181.

Double-blind randomised controlled study to compare the outcomes of laparoscopic gastric banding and laparoscopic Roux-en-Y gastric bypass in morbidly obese patients attending the Multidisciplinary Morbid Obesity Clinic at King's College Hospital

- Anticipated start date: 1 September 2003.
- Anticipated end date: 1 September 2009.
- Status of trial: ongoing.
- Trial design: double-blind randomised controlled study.

Interventions: To compare the outcomes of laparoscopic gastric banding and laparoscopic Roux-en-Y gastric bypass.

  - 1. To compare the early outcome (first six months postoperatively) of the two operations with that of a matched group of morbidly obese patients who are on a low-calorie diet only (controls).
  - 2. To determine if there is any clinical and statistical difference in the outcomes of the two surgical procedures in the early, medium and long term (up to five years postoperatively).
- Contact name Mr A. G. Patel, King's College Hospital, London, UK.
- ISRCTN Register ISRCTN33929407.

Feedback

The HTA programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (www.hta.ac.uk) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

NETSCC, Health Technology Assessment
Alpha House
University of Southampton Science Park
Southampton SO16 7NS, UK
Email: hta@hta.ac.uk
www.hta.ac.uk

ISSN 1366-5278