National Clinical Guideline Centre

Draft for consultation

Obesity

Identification, assessment and management of overweight and obesity in children, young people and adults

Update of CG43

Appendix H

July 2014

Draft for Consultation

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Royal College of Physicians

The Royal College of Surgeons of England

RCGP Royal College of General Practitioners

Royal College of Nursing

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H.1 Very-low-calorie diets (VLCD)

There were no included studies for this review

H.2 Bariatric surgery in people with type 2 diabetes

Table 1: Pollock 2013

Pollock RF, Muduma G, Valentine WJ. Evaluating the cost-effectiveness of laparoscopic adjustable gastric banding versus standard medical management in obese patients with type 2 diabetes in the UK. Diabetes, Obesity and Metabolism. 2013; 15(2):121-129.				
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA (health outcome: QALYs) **Study design:** Probabilistic decision analytic model **Approach to analysis:** The study used the CORE diabetes model to simulate the effects of a LAGB on patients who have early onset type 2 diabetes. The CORE diabetes model comprises of seventeen inter-dependent semi-	**Population:** Obese patients with early onset type 2 diabetes **Cohort settings:** Start age: 46.9 years Male:46.5% BMI (mean): 37.1 kg/m^2 **Intervention 1:** Standard medical management **Intervention 2:** Laparoscopic Adjustable Gastric Band	**Total costs (mean per patient):** Intervention 1: £20,263 Intervention 2: £23,562 Incremental (2−1): £3298 (95% CI: £1837 - £4647; p=NR) **Currency & cost year:** 2010 UK pounds **Cost components incorporated:** Diabetic complications[(b)], diabetes medication (Metformin, insulin, other	**QALYs (mean per patient):** Intervention 1: 9.14 Intervention 2: 10.05 Incremental (2−1): 0.92 (95% CI 0.59 – 1.25; p=NR)	**ICER (Intervention 2 versus Intervention 1):** £3602 per QALY gained (pa) 95% CI: NR Probability Intervention 2 cost-effective (£20K/30K threshold): 100%/100% **Analysis of uncertainty:** One way sensitivity analyses were conducted under 21 different scenarios. The ICER only increased above £20,000 to £36,377 in 1 scenario in which Hb1A1c, SBP and BMI benefits were lowered to 1 standard deviation below the mean.

Markov sub models, each modelling a diabetes related complication. **Perspective:** UK NHS **Time horizon/Follow-up:** 40 year time horizon **Treatment effect duration**[(a)]**:** unclear **Discounting:** Costs: 3.5%; Outcomes: 3.5%		hypoglycaemic treatment), and surgical costs including gastric band placement, dietician visits, clinical psychology consultations, GP visits, outpatient visits and post-surgical complications		
Data sources				
Health outcomes: baseline treatment effect data was taken from Dixon et al[19,20]; data used to model subsequent health outcomes was taken from Palmer et al[27,27]. **Quality-of-life weights:** EQ-5D from published literature[5,5]; population and tariff not stated. **Cost sources:** Costs of diabetes complications were taken from Beaudet et al[7,7]; costs of diabetic and other comorbidity medication were taken from 'the health and social care information centre'[22] and NHS prescription services drug tariff[25]; diabetes pharmacy use was taken from Dixon et al[19,20]; gastric band placement costs were taken from the NHS reference costs 2010[17]; the cost of post-surgical complications was taken from Salem et al[31,31]; dietician visits, clinical psychology consultations, GP visits and outpatient visits were based on resource use assumptions from Picot et al[29,29].				
Comments				
Source of funding: Allergan Ltd provided consulting fees to the authors to perform the analysis and write the manuscript. **Limitations:** Unclear whether the model accounts for future weight re-gain. Mortality and loss of HRQoL from surgical complications are also not modelled.				
Overall applicability[(c)]: Directly applicable Overall quality[(d)]: Potentially serious limitations				

Abbreviations: 95% CI: 95% confidence interval; BMI: body mass index; CUA: cost–utility analysis; da: deterministic analysis; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; LAGB: laparoscopic adjustable gastric band; NR: not reported; pa: probabilistic analysis; QALYs: quality-adjusted life years

(a) For studies where the time horizon is longer than the treatment duration, an assumption needs to be made about the continuation of the study effect. For example, does a difference in utility between groups during treatment continue beyond the end of treatment and if so for how long.

(b) Diabetic complications include: myocardial infarction, angina, congestive heart failure, stroke, stroke death within 30 days, peripheral vascular disease, annual haemodialysis cost, annual peritoneal dialysis cost, renal transplant cost, cataract operation, cataract operation follow up cost, annual cost of blindness, annual cost of neuropathy, amputation, prosthesis, gangrene treatment, infected ulcer, standard uninfected ulcer
(c) Directly applicable / Partially applicable / Not applicable
(d) Minor limitations / Potentially serious limitations / Very serious limitations

Table 2: Picot 2012

Picot J, Jones J, Colquitt JL, Loveman E, Clegg AJ. Weight loss surgery for mild to moderate obesity: a systematic review and economic evaluation. Obesity Surgery. United Kingdom 2012; 22(9):1496-1506.				
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA (health outcome: QALYs) **Study design:** Probabilistic decision analytic model **Approach to analysis:** Markov model comprising of six states (no comorbidity, remission of comorbidity, type 2 diabetic, stroke, CHD, dead). Relative treatment effect applies to the probability of moving between states. **Perspective:** UK NHS **Time horizon/Follow-**	**Population:** Obese patients with early onset type 2 diabetes **Cohort settings:** Start age: 46.9 Male: 46.5% BMI (mean): 37.1 kg/m2 **Intervention 1:** Non-surgical weight loss program **Intervention 2:** Laparoscopic Adjustable Gastric Band	**Total costs (mean per patient):** Intervention 1: £33,262 Intervention 2: £35,055 Incremental (2−1): £1792 (95% CI: NR; p=NR) **Currency & cost year:** 2010 UK pounds **Cost components incorporated:** Bariatric surgery: Time in theatre, surgeons operating time, anaesthetists time, high-cost consumables, days on ward, days in HDU, specialist dietician, physiotherapy, re-operations. Non-surgical weight loss program: Contact with	**QALYs (mean per patient):** Intervention 1: 10.39 Intervention 2: 11.49 Incremental (2−1): 1.10 (95% CI NR; p=NR)	**ICER (Intervention 2 versus Intervention 1):** £1634 per QALY gained (pa) 95% CI: NR Probability Intervention 2 cost-effective (£20K/30K threshold): 100%/100% **Analysis of uncertainty:** One way sensitivity analyses were run but results were not reported. The analysis was also run using a 2 and 5 year time horizon. At a £20,000 threshold LAGB was not cost effective at 2 years with an ICER of £20,159 but was cost effective at 5 years with an ICER of £4969. At a 2 year time horizon LAGB had an 11% probability of being cost effective at a £20,000 per QALY threshold. At a 20 year time horizon LAGB had a 100% probability of being cost effective at a £20,000 per QALY threshold

up: 20 year time horizon **Treatment effect duration:** Weight regain begins after 2 years, and at ten years post-surgery the patient returns to their pre-operative state **Discounting:** Costs: 3.5%; Outcomes: 3.5%		physician, optifast, Orlistat.		
Data sources				
Health outcomes: baseline systolic blood pressure; total cholesterol to high-density lipoprotein ratio data; percentage weight loss and resolution of type 2 diabetes were taken from Dixon et al[19,20]. Estimated hazards for acute myocardial infarction and stroke incidence were taken from the Framingham Heart Study accelerated failure time equations[1,1]. **Quality-of-life weights:** Data on HRQoL was taken from published literature[21,21] which measured health state preferences using visual analogue scale (VAS) scores and converted them to time trade-off (TTO) scores. **Cost sources:** for LAGB: cost of theatre time and staff costs were taken from Southampton University Hospital NHS trust finance department; costs related to days on ward and HDU were taken from NHS reference costs 2006-07[16]; specialist dietician and physiotherapy costs were taken from PSSRU 2007[14,15]. For non-surgical weight loss program: costs for physician contact were taken from NHS reference costs 2006-07[16] and inflated to 2009/10 prices using HCHS pay and price index[14,15]; cost of Orlistat was taken from US prices and converted to UK pounds. For health state costs: chronic diabetes costs were taken from Williams et al[18,20]; acute and chronic AMI costs were taken from Southampton CHD treatment model; acute and chronic stroke costs were taken from Ward et al[34,34].				
Comments				
Source of funding: NR. **Limitations:** Does not look at mortality and loss of HRQoL associated with surgical complications. The study does not measure HRQoL using EQ-5D. A lack of long run clinical data has necessitated long term extrapolation of clinical data based on assumptions.				
Overall applicability[(a)]: Directly applicable Overall quality[(b)]: Potentially serious limitations				

Abbreviations: 95% CI: 95% confidence interval; BMI: body mass index; CUA: cost–utility analysis; da: deterministic analysis; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death);HRQoL: health related quality of life; ICER: incremental cost-effectiveness ratio; LAGB: laparoscopic adjustable gastric band; NR: not reported; pa: probabilistic analysis; QALYs: quality-adjusted life years

(a) Directly applicable / Partially applicable / Not applicable

(b) Minor limitations / Potentially serious limitations / Very serious limitations

Table 3: Keating 2009

Keating CL, Dixon JB, Moodie ML, Peeters A, Bulfone L, Maglianno DJ et al. Cost-effectiveness of surgically induced weight loss for the management of type 2 diabetes: modeled lifetime analysis. Diabetes Care. 2009; 32(4):567-574.				
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA (health outcome: QALYs) **Study design:** Probabilistic decision analytic model **Approach to analysis:** Markov model comprising of three states (remission of diabetes, persistent/relapsed diabetes and dead). Relative treatment effect applies to the probability of moving between states with a one year cycle length. **Perspective:** Australian healthcare system **Time horizon/Follow-up:** lifetime **Treatment effect duration**[(a)]**:** lifetime	**Population:** Obese patients with early onset type 2 diabetes **Cohort settings:** Start age: 46.9 Male: 46.5% **Intervention 1:** Conventional therapy **Intervention 2:** Laparoscopic Adjustable Gastric Band	**Total costs (mean per patient):** Intervention 1: £45,112 Intervention 2: £44,024 Incremental (2−1): -£1,088 (95% CI: NR; p=NR) **Currency & cost year:** 2006 Australian dollars[(a)] **Cost components incorporated:** Surgical patients: Outpatient medical consultations, medical investigations (barium meal, gastroscopy), surgical therapy complications. Type 2 diabetes remission monitoring: Outpatient medical consultation, pathology. Other costs: ophthalmic assessment (tests), prescription medication	**QALYs (mean per patient):** Intervention 1: 14.5 Intervention 2: 15.7 Incremental (2−1): 1.2 (95% CI NR; p=NR)	**ICER (Intervention 2 versus Intervention 1):** Intervention 2 dominated intervention 1 (more effective at a lower cost) 95% CI: dominant to £21,538 Probability Intervention 2 cost-effective (£20K/30K threshold): NR **Analysis of uncertainty:** One way sensitivity analysis was conducted. LAGB remained dominant or cost effective in all but the following scenario: The relative risk of diabetes remission was reduced to the lower 95% CI reported from the Dixon study and annual probability for relapse to type 2 diabetes increased. Under this scenario the ICER increased to £21449

Discounting: Costs: 3%; Outcomes:3 %		(antihypertensive, debates, lipids, other), type 2 diabetes health care costs		
Data sources				
Health outcomes: the relative risk of diabetes remission in surgical therapy relative to conventional therapy was taken from Dixon et al[19,20]; the probabilities of diabetes remission and diabetes remission relapse were taken from studies by Pories et al[30,30] and Sjostrom et al[32,32] respectively; annual mortalities for patients with diabetes and patients with relapsed diabetes were taken from a study by Magliano et al[24,24]. **Quality-of-life weights:**.EQ5D from published literature[2]; elicited from Australian patients however tariff used not stated. **Cost sources:** costs for surgical therapy maintenance were taken from MBS 2006[4]; surgical therapy complication costs were taken from a private hospital; type 2 diabetes remission monitoring costs were taken from MBS 2006[4]; outpatient medical investigation costs were taken from MBS 2006[4]; prescription medicine costs taken from PBS 2006[3].				
Comments				
Source of funding: Allergan Ltd, the manufacturer of the LAP-BAND LAGB product. **Limitations:** The study employs a basic model structure, which ignores obesity co-morbidities other than T2D and mortality associated with surgery. Also the model does not take into account the effects of potential weight re-gain years after surgery.				
Overall applicability[(b)]: Partially applicable Overall quality[(c)]: Potentially serious limitations				

Abbreviations: 95% CI: 95% confidence interval; BMI: body mass index; CUA: cost–utility analysis; da: deterministic analysis; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; LAGB: laparoscopic adjustable gastric band; MBS: medicare benefits schedule; NR: not reported; pa: probabilistic analysis; PBS: pharmaceutical benefits scheme; QALYs: quality-adjusted life years

(a) Converted using 2006 purchasing power parities[26]

(b) Directly applicable / Partially applicable / Not applicable

(c) Minor limitations / Potentially serious limitations / Very serious limitations

Table 4: Hoerger 2010

Hoerger TJ, Zhang P, Segel JE, Kahn HS, Barker LE, Couper S. Cost-effectiveness of bariatric surgery for severely obese adults with diabetes. Diabetes Care. 2010; 33(9):1933-1939.				
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA (health outcome: QALYs) **Study design:** Probabilistic decision	**Population:** Obese patients with early onset type 2 diabetes **Cohort settings:** Start age: 46.9	**Total costs (mean per patient):** Intervention 1: £45,251 Intervention 2: £55,134 Incremental (2−1): £9883 (95% CI: NR; p=NR)	**QALYs (mean per patient):** Intervention 1: 9.55 Intervention 2: 11.76 Incremental (2−1): 2.21 (95% CI NR; p=NR)	**ICER (Intervention 2 versus Intervention 1):** £4453 per QALY gained (pa) 95% CI: Dominant - £14,632 Probability Intervention 2 cost-effective (£20K/30K threshold): 98%/100%

analytic model **Approach to analysis:** Markov model comprising of five states (nephropathy, neuropathy, retinopathy, coronary heart disease and stroke). Relative treatment effect applies to the probability of moving between states with a one year cycle length. **Perspective:** US healthcare system **Time horizon/Follow-up:** lifetime **Treatment effect duration**[(a)]**:** lifetime **Discounting:** Costs: 3%; Outcomes:3 %	Male: 46.5% **Intervention 1:** Standard care for type-2 diabetics **Intervention 2:** Gastric bypass	**Currency & cost year:** 2005 US dollars[(a)] **Cost components incorporated:** Cost of the bypass surgery included: annual visits, supplements, revisional surgery, cholelithiasis, abdominoplasty, nonoperative leak. Both surgical and non-surgical costs include the costs of diabetic related medication.		**Analysis of uncertainty:** A variety of one way sensitivity analyses were conducted. These included reducing the quality of life gain from a BMI reduction to zero and doubling the relapse rate. The ICER did not increase above £20,000 per QALY in any of the one way sensitivity analyses.
Data sources				
Health outcomes: Diabetic remission rate was taken from Buchwald et al[8,10]; relapse rate was taken from Sjostrom et al.[32,32] Effect of surgery on systolic blood pressure, total cholesterol and HDL was taken from Batsis et al[6,6], Vogel et al[33,33], Buchwald et al[8,9] and Sjostrom et al.[32,32] Finally pre-operative mortality was taken from Buchwald et al[8,9]. **Quality-of-life weights:** QWB-SA elicited from a US cohort. **Cost sources:** yearly bypass surgery costs taken from Parikh et al[28,28], Craig and Tseng[12,13], Salem et al[31,31], Maggard et al[23,23] and CMS[11].				
Comments				

Source of funding: Centres for Disease Control and Prevention (CDC). **Limitations:** Model does not explicitly account for weight re-gain, however there is a probability that the patient could relapse after diabetes remission. Although the study is based on the US healthcare system the costs detailed in the study, such as the cost of bypass surgery and follow-up care, are far greater than UK costs. This means the study's results will bias away from the intervention. The study does not use EQ5D for HRQoL values.

Overall applicability[(b)]: Partially applicable Overall quality[(c)]: Potentially serious limitations

Abbreviations: 95% CI: 95% confidence interval; CUA: cost–utility analysis; da: deterministic analysis; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; MBS: medicare benefits schedule; NR: not reported; pa: probabilistic analysis; PBS: pharmaceutical benefits scheme; QALYs: quality-adjusted life years

(a) Converted using 2005 purchasing power parities[26]

(b) Directly applicable / Partially applicable / Not applicable

(c) Minor limitations / Potentially serious limitations / Very serious limitations

H.3 Follow-up care packages after bariatric surgery

There were no included studies for this review

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