Costs and outcomes of increasing access to bariatric surgery for obesity: cohort study and cost-effectiveness analysis using electronic health records

Martin C Gulliford,[1,2]* Judith Charlton,[1] Helen P Booth,[1] Alison Fildes,[1] Omar Khan,[3] Marcus Reddy,[3] Mark Ashworth,[1] Peter Littlejohns,[1] A Toby Prevost[1,2] and Caroline Rudisill[4]

[1]Department of Primary Care and Public Health Sciences, King's College London, London, UK
[2]National Institute for Health Research (NIHR) Biomedical Research Centre, Guy's and St Thomas' NHS Foundation Trust, London, UK
[3]Department of Surgery, St George's University Hospital NHS Foundation Trust, London, UK
[4]Department of Social Policy, London School of Economics and Political Science, London, UK

*Corresponding author

Declared competing interests of authors: A Toby Prevost was a member of National Institute for Health and Care Excellence Public Health Advisory committees during the period of this research and has been a member of the National Institute for Health Research Public Health Research funding board since January 2014.

Published May 2016
DOI: 10.3310/hsdr04170

Scientific summary

Bariatric surgery for obesity: costs and outcomes of access increase
Health Services and Delivery Research 2016; Vol. 4: No. 17
DOI: 10.3310/hsdr04170

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Severe and morbid obesity are increasing rapidly in the UK. Bariatric surgery, the use of surgical procedures for treatment of obesity, is considered to be an effective intervention for severe and morbid obesity but most clinical trials have been of short duration (less than 2 years' follow-up) and have often evaluated intermediate outcome measures, including body weight. In 2006, the National Institute for Health and Care Excellence (NICE) recognised that there is a large gap between population need, measured in terms of the prevalence of obesity, and service delivery within the NHS. The National Obesity Observatory reported that there were fewer than 7000 inpatient bariatric surgical procedures performed in England in 2009/10, but more than 1 million patients are potentially eligible for this form of intervention. NICE recommended a gradual expansion of bariatric surgery utilisation for patients with morbid obesity, as well as for patients with severe obesity when comorbidity is present. The International Diabetes Federation recently advocated more widespread use of bariatric surgery in the management of obese patients with poorly controlled type 2 diabetes mellitus (T2DM).

Definitions

In this report, 'bariatric surgery' refers to surgical procedures for obesity including laparoscopic-adjustable gastric banding (LAGB), gastric bypass (GBP) and sleeve gastrectomy (SG). 'Morbid obesity' refers to persons with body mass index (BMI) ≥ 40 kg/m^2. 'Severe obesity' refers to persons with BMI between 35.0 and 39.9 kg/m^2.

Objectives

This study aimed to inform decision-makers of the costs and outcomes of increasing, or not increasing, access to bariatric surgery for severe and morbid obesity.

Setting

The setting for the study was the general population with obesity, aged ≥ 20 years, in the UK.

Perspective

The research took the perspective of the NHS. Health service costs were included. Wider societal costs, including changes in productivity, which are hard to estimate precisely, were not included. The research adopted a lifetime time horizon. Utilisation of bariatric surgical procedures in the private sector was not explicitly considered.

Outcomes

The primary outcome was quality-adjusted life-years (QALYs), after taking into account the incremental costs associated with intervention. Net health benefits were estimated at a threshold value of £30,000 per QALY. Secondary outcomes included incidence of T2DM, remission of T2DM, prevalence of depression and years lived with diabetes, coronary heart disease (CHD), stroke, cancer or depression.

Data source

The UK Clinical Practice Research Datalink (CPRD) provided the source of electronic health records (EHRs) for this study. The CPRD is the world's largest primary care database comprising anonymised longitudinal patient records from UK family practices. Data held within CPRD are considered to be broadly representative of the UK population.

Ethical and scientific approval

Scientific and ethical approval of the protocol for the study was given by the CPRD Independent Scientific Advisory Committee (ISAC protocol 13_089).

Methods

A health economic model was designed. Empirical data inputs to the model were provided through analysis of EHRs for a large population registered in primary care, derived from the CPRD. Estimates for the clinical effectiveness of bariatric surgery were derived from CPRD data analysis and updated systematic reviews. Probabilistic simulations, run using the model, provided estimates of lifetime incremental costs and health outcomes aggregated across the population at risk.

Three cohorts of participants were selected from CPRD.

Bariatric surgery cohort

This comprised a cohort of adult obese patients, aged ≥ 20 years, with first bariatric surgery procedures performed, including all participants with LAGB, GBP or SG recorded before 30 April 2014. The earliest procedure was performed in 2002.

Reliability study

A sample of 102 participants who had bariatric surgery recorded in their CPRD records was selected for a reliability study in which EHR data were compared with general practitioner-reported information.

General population cohort stratified by body mass index category

We sampled a second cohort of participants from CPRD to act as a general population comparison sample. The sample was drawn from the list of all acceptable patients who were registered with CPRD practices that contributed to the data linkage scheme at any time between 1 January 2008 and 31 December 2014. A stratified random sample was taken of up to 50,000 participants in each category of BMI, including normal weight (18.5–24.9 kg/m^2); overweight (25.0–29.9 kg/m^2); obese (30.0–34.9 kg/m^2), severe obesity (35.0–39.9 kg/m^2); morbid obesity (40.0–44.9 kg/m^2) and super-obesity (≥ 45.0 kg/m^2). Participants with bariatric surgery recorded who were excluded from the sample leaving 257,187 patients for further analysis. There were 247,537 participants eligible for linkage of Hospital Episode Statistics (HES) and deprivation data.

Sample for analysis of the probability of attaining normal body weight

In order to conduct in-depth analysis of BMI transitions, we drew a sample that enabled analysis over a longer period of time, with the inclusion of participants with a larger number of BMI records. The cohort comprised a stratified random sample of participants with at least three BMI values recorded between 1 November 2004 and 31 October 2014, with 278,982 participants for analysis.

Statistical analysis

Analyses were conducted to estimate mortality and the incidence and prevalence of comorbidity for BMI categories ranging from normal weight to morbid obesity. Health-care utilisation was estimated from EHRs in CPRD with linked HES data. Unit costs from reference sources were used to estimate health-care costs, using a two-part econometric model.

Markov model

A probabilistic Markov model was employed to conduct a cost–utility analysis comparing discounted costs and QALYs for bariatric surgery against standard non-surgical management for obesity. Model states included 'at risk' with no morbidity, diabetes mellitus, CHD, stroke and cancer. Each state was further subdivided into 'depressed' and 'not depressed'. Each state was stratified by BMI category, as well as by gender and single year of age. Death was included as an absorbing state. There were therefore 101 states in the model. Costs and outcomes were compared under conditions in which no patients received bariatric surgery or all patients received bariatric surgery. Costs and QALYs were discounted at 3.5%. A wide range of sensitivity analyses was conducted.

Results

Weight changes in the absence of bariatric surgery

We analysed data for 76,704 obese men and 99,791 obese women who did not receive bariatric surgery. During a maximum of 9 years' follow-up, 1283 men and 2245 women attained normal body weight. In simple obesity, the annual probability of attaining normal weight was 1 in 210 for men and 1 in 124 for women, increasing to 1 in 1290 for men and 1 in 677 for women with morbid obesity. The annual probability of achieving a 5% weight reduction was 1 in 8 for men and 1 in 7 for women with morbid obesity. Among participants who lost 5% body weight, 52.7% [95% confidence interval (CI) 52.4% to 53.0%] at 2 years and 78.0% (95% CI 77.7% to 78.3%) at 5 years had BMI records that indicated weight gain to values above the 5% weight loss threshold.

Obesity and the costs of health-care utilisation

There was a general trend of increasing cost as BMI category increased but 'normal' weight was sometimes associated with greater costs than overweight. Analysis showed that physical comorbidities, which were more frequent in obese patients, were the greatest predictors of annual health-care costs (adjusted mean additional cost £1366, 95% CI £1269 to £1463) followed by depression (£1044, 95% CI £973 to £1115). At a given level of comorbidity, morbid obesity was associated with mean additional costs of £456 (95% CI £344 to £568) higher than normal weight.

Epidemiology of bariatric surgery in the UK

There were 3045 adult obese patients with first bariatric surgery procedures recorded, including 3039 of defined type, between 2002 and 2014, including LAGB, 1297; GBP, 1265; and SG, 477. Annual procedures increased from one in 2002 to a maximum of 525 in 2010. Intervention rates were greatest among those aged 35–54 years, with a peak of 37 procedures per 100,000 population per year in women and 10 per 100,000 per year in men. The mean age and BMI of participants undergoing surgery increased during the period, as did the proportion of men and proportion with diabetes. Between 2002 and 2006, LAGB accounted for > 90% of procedures; in 2014, GBP accounted for 52% and SG accounted for 26%. Among patients initially receiving LAGB, rates of band removal were 1.6 (95% CI 1.3 to 2.0) per 100 patient-years; rates of a second procedure of a different type were 1.2 (95% CI 0.9 to 1.5) per 100 patient-years.

Bariatric surgery and Incidence of type 2 diabetes mellitus

During a maximum of 7 years of follow-up (median 2.8 years, interquartile range 1.3–4.5), 38 new diagnoses of diabetes were made in bariatric surgery patients and 177 were made in controls. By the end of 7 years of follow-up, 4.3% (95% CI 2.9% to 6.5%) of bariatric surgery patients and 16.2% (95% CI 13.3% to 19.6%) of matched controls had developed diabetes. The incidence of diabetes diagnosis was 28.2 (95% CI 24.4 to 32.7) per 1000 person-years in controls and 5.7 (95% CI 4.2 to 7.8) per 1000 person-years in bariatric surgery patients; the adjusted hazard ratio was 0.20 (95% CI 0.13 to 0.30; $p < 0.0001$). This estimate was robust after varying the comparison group in sensitivity analyses, excluding gestational diabetes, or allowing for competing mortality risk.

Bariatric surgery in the management of type 2 diabetes mellitus

There were 826 obese participants with T2DM who received bariatric surgery, including LAGB 220, GBP 449 and SG 153, with four procedures undefined. Mean glycated haemoglobin (HbA_{1c}) declined from 64 mmol/mol (8.0%) before bariatric surgery to 48 mmol/mol (6.5%) in the second postoperative year; the proportion with $HbA_{1c} < 48$ mmol/mol (< 6.5%) increased from 17% to 47%. The adjusted relative rate of remission over the first 6 postoperative years was 5.97 (95% CI 4.86 to 7.33; $p < 0.001$) overall; for LAGB 3.32 (95% CI 2.27 to 4.86); for GBP 7.16 (95% CI 5.64 to 9.08); and for SG 6.82 (95% CI 5.05 to 9.19). Rates of remission were maintained into the sixth year of follow-up.

Bariatric surgery and clinical depression

Before surgery, 36% of bariatric surgery participants, and 21% of controls, had clinical depression: between-group adjusted odds ratio (OR) 2.02 (95% CI 1.75 to 2.33; $p < 0.001$). In the second postoperative year 32% had depression: adjusted OR, compared with time without surgery, 0.83 (95% CI 0.76 to 0.90, $p < 0.001$). By the seventh year, the prevalence of depression increased to 37%: adjusted OR 0.99 (95% CI 0.76 to 1.29; $p = 0.959$).

Cost-effectiveness analysis

In persons with morbid obesity aged 20–74 years, bariatric surgery was associated with increased longevity and reduced time living with diabetes. Incremental costs associated with bariatric surgery were £15,258 (95% CI £15,184 to £15,330), including costs of bariatric surgical procedures of £9164 per participant. Incremental QALYs were 2.142 (95% CI 2.031 to 2.256) per participant. The estimated cost per QALY gained was £7129 (95% CI £6775 to £7506). Net monetary benefits valued at a threshold of £30,000 per QALY were £49,016 (95% CI £45,720 to £52,414) per participant. Estimates were similar across gender, age and deprivation subgroups. Bariatric surgery was slightly more cost-effective in patients with morbid obesity and diabetes at £6176 (95% CI £5894 to £6457) per QALY, and slightly less cost-effective in severe obesity, at £7675 (95% CI £7339 to £8037).

Limitations

Intervention effects were estimated from non-randomised studies because there have not been sufficient clinical trials that evaluated substantive clinical outcomes over more than a few years of follow-up. It is uncertain whether or not benefits from surgery will be maintained in the long-term. We modelled scenarios in which benefits from surgery declined rapidly over time and showed that conclusions were robust to varying assumptions. The health economic model included diabetes, cardiovascular disease, cancer and depression but did not include other forms of obesity-related comorbidity that might also benefit from bariatric surgery. The study only considered NHS health-care costs. Data were analysed for bariatric surgery patients who are presently highly selected and outcomes may differ if bariatric surgery is more widely utilised. EHRs contain frequent missing values and recording of data may be biased in relation to outcomes of interest.

Conclusions

For patients with morbid obesity, the chance of attaining normal weight or maintaining clinically relevant weight loss is very low. Present obesity treatment frameworks grounded in community-based weight management programmes appear to be ineffective. Health-care costs are increased in obesity, primarily because of the greater burden of comorbidity.

Bariatric surgery is associated with reduced incidence of clinical diabetes in obese participants without diabetes at baseline, and remission of diabetes in obese patients with diabetes. Psychological comorbidity is frequent among individuals selected to undergo bariatric surgery, but any modest improvement over the initial postoperative years is not maintained.

Bariatric surgery is cost-effective relative to standard weight management across a wider range of BMI levels than currently recommended, and is more cost-effective in diabetes mellitus, with results robust to gender, age and deprivation differences.

In a primary care organisation with a population of 250,000 adults aged 20–75 years, there may be 7000 people with morbid obesity. This number may be as high as 11,000 in a deprived area or as low as 4500 in an affluent area. There may be 1500 with morbid obesity and diabetes. If 1000 bariatric surgical procedures are commissioned over a period of time, the immediate financial cost will be approximately £9.2M. Total additional NHS costs may be £15.3M over the patients' lifetime, as a result of increased longevity. If bariatric surgery procedures are allocated equally to people with and without diabetes, there will be 112 fewer patients developing diabetes over the next 10 years, while 200 patients with diabetes may experience remission of the condition. The expected health gain over the patients' lifetime is 2142 QALYs, from reduced mortality, reduced incidence of diabetes, cardiovascular disease and cancer, and increased well-being. Valued at a threshold of £30,000 per QALY, these benefits amount to £64M, with a net monetary benefit of £49M. Based on equitable patient selection, health gains will generally be directed to more deprived groups but diverse population groups have capacity to benefit from increased access to bariatric surgery at acceptable cost.

Funding

Funding for this study was provided by the Health Services and Delivery Research programme of the National Institute for Health Research (NIHR). Martin C Gulliford and A Toby Prevost were supported by the NIHR Biomedical Research Centre at Guy's and St Thomas' Hospitals. Peter Littlejohns was supported by the South London Collaboration for Leadership in Applied Health Research and Care. The funders did not engage in the design, conduct or reporting of the research.

Health Services and Delivery Research

ISSN 2050-4349 (Print)

ISSN 2050-4357 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HS&DR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hsdr. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Services and Delivery Research* journal

Reports are published in *Health Services and Delivery Research* (HS&DR) if (1) they have resulted from work for the HS&DR programme or programmes which preceded the HS&DR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

HS&DR programme

The Health Services and Delivery Research (HS&DR) programme, part of the National Institute for Health Research (NIHR), was established to fund a broad range of research. It combines the strengths and contributions of two previous NIHR research programmes: the Health Services Research (HSR) programme and the Service Delivery and Organisation (SDO) programme, which were merged in January 2012.

The HS&DR programme aims to produce rigorous and relevant evidence on the quality, access and organisation of health services including costs and outcomes, as well as research on implementation. The programme will enhance the strategic focus on research that matters to the NHS and is keen to support ambitious evaluative research to improve health services.

For more information about the HS&DR programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hsdr

This report

The research reported in this issue of the journal was funded by the HS&DR programme or one of its preceding programmes as project number 12/5005/12. The contractual start date was in October 2013. The final report began editorial review in October 2015 and was accepted for publication in February 2016. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HS&DR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).