Clinical outcomes and adverse events of bariatric surgery in adults with severe obesity in Scotland: the SCOTS observational cohort study

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Disclosure of interests

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Primary conflicts of interest: Duff Bruce was the Chair of the charity Surgical Obesity Treatment Service from 2010 to 2016 (charity now closed); Julie Bruce is a current member of the NIHR Research for Patient Benefit – West Midlands Regional Advisory Committee; Jennifer Logue was a member of the NIHR Clinical Evaluation and Trials Committee from 2016 to 2020.

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Scientific summary

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Background

Bariatric surgery is a common procedure worldwide for the treatment of severe obesity and associated comorbid conditions but there is a lack of evidence as to medium-term safety and effectiveness outcomes in a UK setting.

Our aim was to establish the clinical outcomes and adverse events of different bariatric surgical procedures, their impact on quality of life (QoL) and the effect on comorbidities. In this observational cohort study, we established the physical and mental health, and social burden of severe obesity; the incidence of acute and chronic postoperative (postop) complications of bariatric surgery; the effect of the pre- and postop care pathway on complication rates and weight loss, for different bariatric surgical procedures; change in QoL, anxiety and depression, weight status, over time pre- and postoperatively for a mean of 3 years from date of bariatric surgery; the glycaemic control, lipids, blood pressure, medication prescription and rate of diabetes complications (microalbuminuria and renal disease, and retinopathy) in those who have pre-existing diabetes; and changes in socioeconomic factors (employment, benefit receipt, sick leave and healthcare use) for 3 years since bariatric surgery.

Methods

We conducted a prospective observational cohort study in National Health Service (NHS) secondary care and private practice in Scotland, UK. The study recruited participants from 10 NHS Hospitals and 4 private hospitals that were performing bariatric surgery. Adults (aged 16 and over) scheduled to undergo a primary bariatric surgery procedure were eligible for invitation to the study and were identified by their bariatric surgery clinical team. The only other inclusion criterion was residence in Scotland as that allowed study follow-up through electronic health records; those who had previous weight-loss surgery or were undergoing a repeat procedure were excluded from the study. Participants were asked for consent for health record data linkage (part one), postal and/or electronic follow-up (part two) and whether they were interested in future research. Those requiring a translator were asked for consent for clinical data linkage only.

Pre- and post surgery care pathways

To establish preoperative (preop) assessment and postop care pathways used in bariatric surgery, a questionnaire was distributed at each site. This covered pathways for referral, eligibility criteria, the different components of service delivery, the professionals involved and frequency and length of sessions and consultations. The questionnaire was distributed by e-mail and responses were collected over a 2-year period, which served as a consistency check for within-centre reporting over multiple years. Pathway costs were based on publicly available information for staff time. Unit costs were taken from the Personal Social Services Research Unit 2015 and the Information and Statistics Division Scotland tariffs 2015. Cost was calculated per person participating in the bariatric surgery care pathway by multiplying the salary costs of staff, according to grade or band, by the average number of annual sessions provided by that staff member and accounting for the length of session.

Outcomes

Outcomes were reported at 1 and 3 years after bariatric surgery. The main outcome measures using health record linkage were hospital length of stay, readmission and reoperation rate, mortality and diabetes

outcomes (HbA1c, medications, total cholesterol, systolic blood pressure, microalbuminuria and retinopathy). Change in weight was from clinical team report when available, and if not, patient self-report was used. Patient-reported outcome measures included Rand 12-item Short Form Survey (SF-12) and EuroQoL 5-level EQ-5D version (EQ-5D-5L) (both were health-related QoL); Impact of Weight on Quality of Life-Lite (IWQOL-Lite); Life Orientation Test (optimism); Generalised Anxiety Disorder Assessment; Patient Health Questionnaire (depression); International Prostate Symptom Score; Incontinence Questionnaire-Urinary Incontinence Short Form; erectile dysfunction (Massachusetts Male Ageing Study); Alcohol Use Disorders Identification Test; International Physical Activity Questionnaire – Short Form. Information on participants' comorbid conditions, smoking status, employment, social security status and healthcare utilisation was obtained using questionnaires specifically developed for this study.

Data collection

Clinical teams at sites reported height and weight at start of the weight-management programme, allowing body mass index (BMI) to be calculated. Date of surgery, operation type, weight at operation and American Society of Anaesthesiologists grade were reported using the web-based electronic case report form. Weight at routine clinical follow-up visits and any revisional bariatric surgery procedures were also recorded using this method.

At the end of the study, participant's relevant records were obtained from national electronic health records (Scottish Morbidity Record 01, Scottish Care Information Diabetes, National Records Scotland, Prescription Information System) and linked to their clinical and self-reported data.

Recruited participants completed questionnaires preoperatively and 3 years postoperatively. Completion of questionnaires could be either by post or electronically via a secure link sent by e-mail. Two reminders were sent by the participant's chosen method and a third reminder, if required, was sent by post to all participants.

Results

There was nearly a five fold difference in costs per patient for preop services (range £226–£1071) and more than a three fold difference for postop services (range £259–£896). The provision of services was variable regarding the format of delivery of sessions (group or as one-to-one sessions), and frequency and length of access to psychology and dietetics before and after surgery.

Between December 2013 and February 2017, 548 eligible patients were approached and 445 participants were enrolled in the study. Of those, 335 had a complete record for a primary bariatric surgery procedure and 1 withdrew from the study. Mean age was 46.0 (9.2) years, 74.7% were female and the median BMI was 46.4 (42.4; 52.0) kg/m^2, 4%.

At baseline pre-surgery, for each 10 kg/m^2 higher BMI, there was a change of −5.2 [95% confidence interval (CI) −6.9 to −3.5; $p < 0.0001$] in Rand 12-item Short Form Survey Physical Component Summary (SF-12 PCS), −0.1 (95% CI −0.2 to −0.1; $p < 0.0001$) in EuroQoL 5-level EQ-5D version index score and 14.2 (95% CI 10.7 to 17.7; $p < 0.0001$) in IWQOL-Lite Physical Function Score. We observed a 3.1 times higher use of specialist aids and equipment at home (odds ratio 3.1, 95% CI 1.9 to 5.0; $p < 0.0001$). Broadly, similar results were seen for each 10-year higher age, including a change of −2.1 (95% CI −3.7 to −0.5; $p < 0.01$) in SF-12 PCS.

The cohort that did not progress to surgery ($n = 92$) had a higher proportion of males, a higher proportion of participants aged 55 years or older, a higher proportion of participants in the lowest Scottish Index of Multiple Deprivation (SIMD) quintile and a higher median BMI at the start of the weight-management programme than those who progressed to surgery. The main reasons reported by sites for non-progression to surgery for Surgical Obesity Treatment Study (SCOTS) participants were patient decision (37%) followed by failure to achieve pre-surgical goals (31.5%).

Privately funded bariatric surgery was performed on 4% (n = 15) of participants. That cohort had a lower median BMI at the start of the weight-management programme but lower weight change pre-surgery, resulting in similar median BMIs at the time of surgery; they only resided in areas in SIMD quintiles 3–5 (more affluent areas) (all $p < 0.05$).

Sleeve gastrectomy was the most common procedure (49.3%), followed by Roux-en-Y gastric bypass (RYGB) (38.2%) and laparoscopic adjustable gastric banding (12.5%). Weight outcomes at 3 years were available for 129/335 of the operated cohort. The mean change in weight 3 years from the operation was −19.0% (±14.1) and −24.2% (±12.8) from the start of the preop weight-management programme, with RYGB resulting in the largest weight loss at 3 years post surgery. Median length of stay in hospital after surgery was 3.0 days (2.0, 4.0), admission to high-dependency or intensive care was experienced by 100 (33.4%) of the operated cohort and 139 (41.4%) of participants were readmitted to hospital in the same or subsequent 35 months post surgery. However, only 18 (5.4% of the operated cohort) had a reoperation or procedure considered to be related to bariatric surgery gastrointestinal (GI) complications or revisions and fewer than five participants died during follow-up.

Type 2 diabetes mellitus (T2DM) was present pre-surgery in 182 participants. For those with available outcomes, bariatric surgery was associated with a 5.72 mmol/mol (±16.71) reduction in HbA1c (p = 0.001) (data available for 93/182), and a 4.6 mmHg (±16.6) reduction in systolic blood pressure after 3 years (p = 0.01). There was a decrease in prescribed diabetes medication (data available for 139/182) in 84.9% of participants, with 65.5% stopping all diabetes medications ($p < 0.001$). The proportion prescribed insulin decreased from 13.6% to 4.0% ($p < 0.001$). Change in the prevalence of microalbuminuria could not be calculated as only 30 participants had a urine microalbumin result reported within 27–45 months of their primary bariatric surgery. In the 18 months prior to surgery, 124 participants with T2DM had a urine microalbumin result reported (58 missing) and 33 (26.6%) had a raised albumin : creatinine ratio. Retinal screening showed observable or referable retinopathy preoperatively in 19.4% of participants with available data; however, there was no difference in the proportion having an improvement or worsening of retinopathy (8.6% in both groups). The proportion with retinal screening outcomes available at 3 years post surgery was low (58/182; 31.9%).

Physical QoL improved in the 3 years post surgery, with a mean change in SF-12 PCS of 8.32 (±8.95; $p < 0.001$) based on available change data from 101/336; however, there was no change in the prevalence of anxiety or depression. The only other significant changes observed between preop to 3 years post-surgery time points were incontinence, where the proportion with symptomatic incontinence (ICIQ-UI SF score ≥ 6) decreased from 38.0% to 20.3% at 3 years (p = 0.003), and physical activity, where there was a decrease in the proportion reporting having undertaken ≥1 of walking or moderate or vigorous physical activity in the last 7 days (92.8% to 83.1%; p = 0.005) yet conversely an increase in reported physical activity of 918.0 (−655.0; 2194.5) metabolic equivalent of tasks (MET) minutes per week (p = 0.02).

Limitations

Recruitment was stopped and follow-up reduced from 10 to 3 years due to low numbers of bariatric surgery procedures in Scotland making recruitment of the intended 2000 participants impossible. Completion of baseline and year-3 questionnaires by participants was much lower than anticipated, leading to a high proportion of missing data.

Conclusions

Bariatric surgery is a safe and effective treatment for obesity. However, there are differences between the selection and care of patients undergoing bariatric surgery recruited to this study (and therefore within Scotland) and those having bariatric surgery in other countries and that may be resulting in the decreased effectiveness, and therefore cost-effectiveness, of bariatric surgery. The older, higher-BMI

cohort in SCOTS had poor physical and mental QoL at baseline compared to other reported cohorts. While physical QoL improved 3 years post-surgery, the high prevalence of comorbid mental health conditions did not. Those with T2DM, on average, had fair glycaemic control prior to surgery and the majority stopped all diabetes medications 3 years after surgery. However, they did not appear to be getting full diabetes care with annual review and screening and therefore benefits from improved diabetes management may be negated by poor preventive care.

The immediate post-surgery management for participants in SCOTS showed a longer hospital stay and a high high-dependency unit (HDU) / intensive-therapy unit (ITU) admission rate with no evidence of high complication rates in the form of subsequent operative procedures. We have speculated that the low volume of bariatric surgery performed in SCOTS sites may have led to cautious practice, especially as the median ITU/HDU stay was only 1 day. Subsequent readmissions over 3 years were also high though also with low amounts of operative procedures suggestive of bariatric surgery complications. Potentially these may have been avoided or manageable as an outpatient were a specialist bariatric team available to review urgently. This combination of practice could mean higher costs for bariatric procedures while the decreased effectiveness, possibly due to restricting surgery to those with higher BMI and multiple comorbidities, may have implications for the cost-effectiveness of bariatric surgery.

Future research

Future research should consider the selection and pathways of care for people undergoing bariatric surgery. There should be consideration of a balance of outcomes and clarity around which non-surgical interventions, if any, should be considered prior to surgery for which groups. Randomised trials of pre- and post-surgery multidisciplinary interventions are required to ascertain the optimal care pathway to support safe and effective surgery. Standardisation of outcomes in bariatric surgery is key within future research to allow comparisons and meta-analysis, as is research to improve participant response rates to patient-reported outcome measures within efficient study designs.

Study registration

This study is registered as ISRCTN47072588.

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