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By-Band-Sleeve Collaborative Group

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Scientific summary

Roux-en-Y gastric bypass, adjustable gastric banding or sleeve gastrectomy for severe obesity: The By-Band-Sleeve randomised controlled trial

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Scientific summary

Introduction

Bariatric surgery is an effective treatment for severe and complex obesity. When this study started (2011), adjustable gastric band (Band) and gastric bypass (Bypass) accounted for over 80% of procedures worldwide. By 2015, practice had changed. Sleeve gastrectomy (Sleeve) accounted for over 35% of procedures and Band use had declined. Well-designed randomised controlled trials (RCTs) comparing the procedures were lacking and considered difficult to do because of recruitment challenges. Additionally, outcome heterogeneity in bariatric trials hindered data synthesis.

Objectives

To compare the clinical and cost-effectiveness of Bypass, Band and Sleeve for the treatment of severe and complex obesity. To develop a core outcome set for bariatric surgery.

Methods

Study design

Open parallel-group RCT with an integrated internal pilot and QuinteT Recruitment Intervention (QRI). Initially a two-group trial (Bypass and Band), it was adapted to include Sleeve to ensure the trial remained relevant to clinical practice.

Settings and participants

Hospitals offering all 3 surgical procedures, with a minimum of 2 surgeons with experience of at least 100 Bypass, 50 Band and 50 Sleeve procedures were eligible. Adults referred for surgery according to National Institute for Health and Care Excellence (NICE) guidelines were eligible.

University of Bristol sponsored the trial, which was approved by the Research Ethics Committee Southwest-Frenchay (reference 11/SW/0248).

QuinteT Recruitment Intervention

The QRI was integrated throughout. Recruitment challenges were elicited through recruiter and patient interviews, audio-recordings of recruitment discussions, review of screening/eligibility information, charting recruitment pathways, and observing study meetings. Recruiter-training, site visits, with group and individual feedback on study presentation and equipoise issues, tips documents and newsletters were used.

Interventions

Surgical procedures were protocolised with minimal mandated and prohibited criteria and flexible components. Protocol adherence was monitored throughout.

Randomisation and blinding

Initially participants were randomised 1 : 1 to Bypass or Band. After the adaptation, participants were randomised to Bypass, Band or Sleeve, with the aim of achieving equal-sized groups at the end of recruitment. Randomisation was via a secure internet-based randomisation system, with stratification by site and cohort minimisation to ensure balance by diabetes status and baseline body mass index (BMI). The allocation ratio varied by site to account for site recruitment before the adaptation (i.e. higher site-specific probability of being allocated to Sleeve for sites that recruited to the two-group trial, 1 : 1 : 1 allocation for sites that opened after the trial was adapted). Randomisation was performed once eligibility was confirmed and consent given. Different postoperative care prevented blinding of study personnel or participants.

Follow-up

Participants were followed up at 4 weeks post surgery and 6, 12, 24 and 36 months post randomisation. Participants attended hospital for follow-up except during the pandemic when follow-up was conducted by telephone.

Outcomes

The two primary end points measured 3 years after randomisation were (1) loss of at least 50% excess weight (defined as change in BMI from baseline/BMI at baseline −25) and (2) the EQ-5D-5L utility score. Secondary outcomes were other weight loss measures (change in BMI over time, per cent total weight loss, %TWL), other aspects of quality of life [Short Form questionnaire-12 items physical and mental health component scores, EQ-5D visual analogue scale, Impact of Weight of Quality of Life-Lite (IWQOL-Lite) overall, self-esteem, sexual life and public distress domain scores, Gastrointestinal Quality of Life Index overall and gastrointestinal domain scores, Hospital Anxiety and Depression Scale (HADS) anxiety and depression scores], blood results assessing (1) metabolic control: glycated haemoglobin (HbA1c), fasting glucose, triglycerides, total cholesterol, high-density lipoprotein cholesterol (HDL-C); (2) safety bloods: haemoglobin, 25-hydroxyvitamin D, calcium, ferritin, folate, parathyroid hormone, serum iron and vitamin B12; and (3) liver and kidney function: alkaline phosphatase, alanine transaminase and creatinine, measures of dietary intake assessed using a validated interview process, binge eating behaviour, sleepiness, adverse health events, non-alcoholic fatty liver disease and resource use.

Sample size

We hypothesised that Bypass and Sleeve would have non-inferior weight loss and superior quality of life to Band and that Sleeve would have non-inferior weight loss and superior quality of life to Bypass. The expected proportion achieving least 50% excess weight loss at 3 years was 70% (based on registry data) and the non-inferiority margin (12%) was chosen by clinicians and patient representatives. The target standardised difference for the EQ-5D-5L utility score was 0.2, with correlations between pre- and post-randomisation measures and repeated post-randomisation measures of 0.5 and 0.75, respectively. The sample size was set at 447 per group, which was sufficient to test the two hypotheses with 90% power and 1% (one-sided) statistical significance for the non-inferiority hypothesis and 2% (two-sided) statistical significance for the superiority hypothesis, allowing for 15% loss to follow-up.

Statistical analyses

The analysis population was all randomised participants, excluding withdrawals who were unwilling for their data to be used. Primary analyses were by intention to treat. Analyses were adjusted for diabetes and BMI at baseline and baseline values of the outcome where available. For longitudinal continuous outcomes, hierarchical mixed models with participant nested by site and gradients allowed to vary across time for each participant were fitted. Time was modelled with treatment-specific restricted cubic splines. Generalised linear models were used to assess treatment effects for binary and count outcomes. Pre-specified subgroup analyses and sensitivity analyses were carried out for the primary outcomes. Missing data for the primary weight outcome were imputed. Results are presented as treatment effects with 98% confidence intervals. Analyses were performed using Stata, version 18.0 (StataCorp LP, College Station, TX, USA).

Economic evaluation

The primary objective was to compare the cost-effectiveness of Bypass, Band and Sleeve to 3 years. Costs for the surgical procedures were taken from a micro-costing study. Other healthcare resource use was costed using national UK reference costs. Quality-adjusted life-years (QALYs) were estimated using the EQ-5D-5L utility score, assuming quality of life changed linearly between follow-up points and imputing missing questionnaires. Costs and outcomes after the first year of follow-up were discounted at an annual rate of 3.5%. The cost-effectiveness of the three procedures was compared using the incremental net monetary benefit. The probability of each intervention being the most cost-effective option was calculated. A range of subgroup and sensitivity analyses were carried out.

Results

Patient screening and recruitment

Between December 2012 and September 2019, 6961 patients from 12 NHS hospitals were assessed for eligibility. Overall, 1351 (28.5% of eligible, 32.6% of approached) were recruited and randomised; 463 to Bypass, 468 to Band and

420 to Sleeve. Recruitment was achieved with over 30 interviews, 77 individual and 27 group feedback sessions and 29 training sessions. Sites opening later benefitted from lessons learnt earlier in the trial.

Withdrawals

Ninety participants withdrew, 55 before surgery and 35 after surgery. The most cited reason (when given) was declining surgery. Five participants (one Bypass, four Band) withdrew consent for their data to be used.

Protocol deviations

Overall, 163/1346 (12.1%) participants did not undergo surgery within 3 years of randomisation. Of the remaining 1183, 115 did not receive the allocated surgery and two operations were abandoned. Most crossovers were from Band to Bypass or Sleeve, with few crossovers from Sleeve to another procedure.

Patient follow-up

Overall, 1159 (85.7%) participants remained in follow-up at 3 years.

Numbers analysed

The analysis population consisted of 1346 randomised participants. All participants were included in analyses of the primary weight outcome and 1284 (95.4%) were included in analyses of the primary quality-of-life outcome.

Baseline data and operative characteristics

Baseline characteristics were similar in the three groups. The mean age was 47.3 years and 1020/1344 (75.9%) were women. The mean BMI at recruitment was 46.4 kg/m^2. Most participants were White (1140/1344, 84.8%) and fewer than half (561/1343, 41.8%) were in full time employment. Almost a third had type 2 diabetes (407/1344, 30.3%), and most were on medication (1232/1346, 91.5%).

The median waiting time to surgery was 5 months; 389 participants had a Bypass, 363 Band and 429 Sleeve. All prohibited aspects of surgery were avoided, but in 31/1181 (2.6%) cases not all of the mandated components were adhered to, the most common surgery-specific deviations were not closing mesenteric defects and not reflecting the fad pad. Most participants (1099/1181, 93.1%) had an uneventful (normal) postoperative recovery (Clavien–Dindo grade 0). The median postoperative stay was 2 days.

Primary outcome: percentage excess weight loss at 3 years

In total, 276/405 (68.1%) participants randomised to Bypass achieved at least 50% excess weight loss at 3 years, compared to 97/383 (25.3%) participants in the Band group and 141/342 (41.2%) participants in the Sleeve group [adjusted risk differences: Bypass minus Band + 40.7% 98% confidence interval (+ 33.9% to + 47.5%); Sleeve minus Band + 14.7% (+ 5.2% to + 24.2%), Sleeve minus Bypass −26.0% (−35.8% to −16.3%)]. Sensitivity analyses provided consistent results. There was no evidence to suggest subgroup differences (diabetic status at baseline, $p = 0.90$; baseline BMI, $p = 0.30$).

Primary outcome: EQ-5D utility score at 3 years

The mean utility score was significantly higher in the Bypass group compared to Band [mean difference 0.079 (0.040 to 0.117)] and in the Sleeve group compared to Band [0.045 (0.006 to 0.085)]. The difference between Sleeve and Bypass was not statistically significant [−0.033 (−0.072 to 0.006)]. Comparisons involving Bypass were robust to the sensitivity analyses, with an increase in the difference between Sleeve and Bypass in favour of Bypass when excluding participants who did not have surgery [−0.043 (−0.084 to −0.003)]. All sensitivity analyses favoured Sleeve over Band, some were statistically significant at the 2% level and others were not. No subgroup differences were found (diabetes $p = 0.79$, baseline BMI $p = 0.31$).

Secondary outcomes

Mean BMI and mean %TWL followed the same pattern as the primary weight outcome; the Bypass group had greater weight loss compared to the Sleeve group, which in turn had greater weight loss compared to the Band group.

Scores measuring overall quality of life and physical function mirrored the primary EQ-5D-5L utility score, Bypass and Sleeve were superior to Band; Bypass and Sleeve were not different statistically, but the differences favoured Bypass. Scores measuring mental well-being were similar in the three groups, except for the HADS depression score which was higher (worse) in the Band group compared to the Bypass group. Mean IWQOL-Lite scores with Bypass and Sleeve were superior (better) compared with Band statistically across all domains; scores for Bypass and Sleeve were similar except for self-esteem which was higher with Bypass [+ 6.7 (+1.0 to +12.30)]. The gastrointestinal subscale favoured Bypass over Band, with similar scores for comparisons involving Sleeve.

Metabolic control (mean HbA1c and fasting glucose) was lower with Bypass and Sleeve compared to Band, with no difference between the Bypass and Sleeve. At 3 years, 244/291 (83.8%) of the Bypass group, 200/268 (74.6%) of the Band group and 190/230 (82.6%) of the Sleeve group had a HbA1c < 48 mmol/mol without antidiabetic medication. Triglycerides, total cholesterol and HDL-C followed similar trends; additionally, mean triglyceride and total cholesterol levels were higher in the Sleeve group compared to Bypass. Differences in safety bloods between groups varied, with most differences being between Bypass and Band. The only differences between Bypass and Sleeve were for ferritin and calcium, both of which were higher with Sleeve. Mean vitamin B12 and vitamin D were notably lower in the Band group compared to Bypass and Sleeve, which were similar. At 3 years, 76/285 (26.7%) of the Bypass group, 106/256 (41.4%) of the Band group and 70/238 (29.4%) of the Sleeve group had vitamin D ≤ 50 nmol/l. Alkaline phosphatase and alanine transaminase levels were lower in the Sleeve group compared to the Bypass group.

No differences in dietary intake were found. Mean binge eating scores were consistent with non-binge eating behaviour in all groups. Sleepiness was most common in the Band group. In all groups, most participants had moderate or severe non-fatty liver disease, with < 3% having none or mild disease.

Adverse events

There were 11 deaths, 4 before surgery and 7 following surgery; 1 death could be attributed to Band. Overall, 1905 adverse events were reported, with fewest post-surgery events in participants who had Sleeve (39.3/100 years compared to 51.4 and 57.1/100 years after Bypass and Band, respectively [rate ratio Sleeve : Bypass 0.74 (0.55 to 0.99)]). Post-surgery morbidity was rare with 15 internal hernia repairs after Bypass, 3 leaks from the staple line following Sleeve, and 52 corrective surgeries, removals and/or revisions following Band.

Economic evaluation

The mean costs per participant over the 3 years in the trial, including the costs of the surgery, were £8268 for Bypass; £7695 for Sleeve; and £7357 for Band. Participants randomised to Bypass accrued on average more QALYs over the 3 years than those allocated to Band and Sleeve (2.02 for Bypass; 1.82 for Band, 1.95 for Sleeve). Combining the costs and QALYs, Bypass was the most cost-effective option at the cost-effectiveness thresholds applied by NICE, with probabilities < 0.3 that Sleeve or Band is the most cost-effective option.

Core outcome set

A nine-item core set was developed.

Discussion

Main findings

Bypass and Sleeve were superior to Band, with non-inferior weight loss and superior quality of life. Sleeve was inferior to Bypass in terms of weight loss. Quality of life, while not statistically different, favoured Bypass, with a mean difference that exceeded the 0.03 threshold for clinical significance. Higher proportions of recipients in all three groups achieved a HbA1c of < 48 mmol/mol than is achieved with the new drugs for treating obesity. Rates of adverse events were highest in the Band group followed by Bypass, then Sleeve; serious surgical complications occurred at rates in line with registry reports. Bypass was found to be the most cost-effective surgical option from a UK NHS perspective.

Strengths and limitations

By-Band-Sleeve is the largest multicentre trial to date to assess the impact of the three most common bariatric operations on weight loss, quality of life, comorbidities and cost-effectiveness. The findings are generalisable to the wider NHS.

Despite recruitment challenges, the introduction of Sleeve and decline in Band, the recruitment target was met. Adherence to intervention protocols was high. COVID-19 impacted follow-up, but loss-to-follow-up for the primary outcomes was in line with the power calculation.

Percent excess weight loss is no longer the weight metric of choice, %TWL is preferred. The trial was not blinded. Completeness of data for some secondary outcomes was low. Current internationally recognised definitions of comorbidity resolution, which changed since the trial was designed, could not be applied.

Conclusion

Bypass and Sleeve resulted in significantly more weight loss and better quality of life than Band. Bypass resulted in more weight loss and a higher mean quality-of-life score than Sleeve. These differences between groups were mirrored in most secondary end points. There were fewest adverse events after Sleeve. Bypass was the most cost-effective operation, followed by Sleeve.

Trial registration

The trial is registered as ClinicalTrials.gov: NCT02841527 and ISRCTN00786323.

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