

Bariatric surgery provision in response to the COVID-19 pandemic: retrospective cohort study of a national registry

NCT05532891

11th September 2022

Study protocol and statistical analysis plan

1. Methods

1.1. Study design

This is a nationwide cohort study, involving retrospective analysis of prospectively collected data.

The study design, including subgroup analysis of NHS patients, was planned at the time of study conception, although no formal prospective analysis plan was recorded. The study has been retrospectively registered on ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT05532891>.

1.2. Data source and study population

The National Bariatric Surgical Registry (NBSR) is a bespoke database for the prospective collection of data pertaining to all patients undergoing elective bariatric surgery for weight loss in the UK. Emergency cases are not recorded in NBSR, and neither are revision procedures unless the aim of surgery is to induce further weight loss (for example, removal of gastric band for dysphagia or conversion of sleeve to bypass for reflux are not recorded). At each visit, demographic, perioperative and clinical outcome data are recorded by the health care provider. Diabetes status is recorded pre-operatively and at each follow up visit as follows: no indication of T2DM; impaired glycaemia or diet-controlled; oral hypoglycaemics or insulin treatment. For the purposes of analysis we grouped the latter two categories as 'on treatment'.

The NBSR was used to identify all patients that underwent elective bariatric surgery during the pandemic (one year from 1st April 2020) or prior to the pandemic (one year from 1st September 2018). Fully-anonymised data were extracted for the purposes of analysis. Where a variable was 'not recorded' this point was excluded from analysis. For age, gender, procedure type and provider the records were 100% complete, for BMI at time of surgery there was 5% missing data and for other variables the missing value rate was 2% or lower.

1.3. Ethics statement

The data holder NBSR complied with local ethics guidelines. Use of this dataset for research purposes conformed with UK legislation and was approved by the Health Research Authority (17/CAG/0023).

1.4. Study outcomes

Outcomes recorded and compared between the two time periods included caseload, case-mix, provider, demographic and baseline health status of patients, and peri-operative outcomes.

1.5. Statistical analysis

Statistical analysis was performed using Prism 9.3.1 for MacOS (GraphPad Software, San Diego, USA). Chi-square, chi-square for trend or Fisher's exact tests were used to analyse categorical or ordinal values. Student's t-test was used for continuous parametric data. $P<0.05$ is considered statistically significant.