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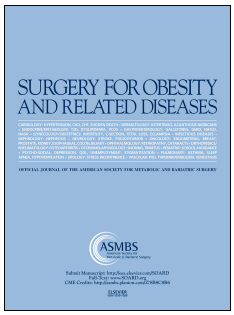

Bariatric surgery provision in response to the COVID-19 pandemic: retrospective cohort study of a national registry

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Title page

Title:

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

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Short title:

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Author contribution:

Conceptualisation: ERM, AC, KM, RW, ARA, CP, PS, OAK; Methodology: IC, ERM, OAK, PS; Formal analysis: IC, ERM; Data curation: IC, ERM, RW, ARA, CP, PS; Writing – original draft: ERM, OAK; Writing – review and editing: all authors; Funding acquisition: ERM, OAK

Title:

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

Abstract

Background:

When surgery resumed following outbreak of the COVID-19 pandemic, guidelines recommended the prioritization of patients with greater obesity-related comorbidity and/or higher Body Mass Index (BMI).

Objectives:

The aim of this study was to record the effect of the pandemic on total number, patient demographic and peri-operative outcomes of elective bariatric surgery in the United Kingdom.

Setting and Method:

The United Kingdom National Bariatric Surgical Registry was used to identify patients that underwent elective bariatric surgery during the pandemic (one year from 1st April 2020). Characteristics of this group were compared with a pre-pandemic cohort. Primary outcomes were case volume, case-mix and provider. National Health Service (NHS) cases were analyzed for baseline health status and peri-operative outcomes. Chi-square, Fisher's exact or Student's t-test were used as appropriate.

Results:

Total number of cases reduced to one third of pre-pandemic volume (8615 to 2930). Operating volume reduction varied, with thirty-six (45%) hospitals experiencing a 75-100% reduction. Cases performed in the NHS fell from 74% to 53% (p<0.0001). There was no change in baseline BMI (45.2 kg/m^2 ± 8.3 from 45.5 kg/m^2 ± 8.3; p=0.228) or prevalence of Type 2 Diabetes Mellitus (26% from 26%; p=0.999. Length of stay (median 2 days) and surgical complication rate (1.4% from 2.0%; RR 0.71 (95% CI 0.45 – 1.12); p=0.133) were unchanged.

Conclusions:

In the context of a dramatic reduction in elective bariatric surgery due to the COVID-19 pandemic, patients with more severe comorbidity were not prioritized for surgery. These findings should inform preparation for future crises.

Keywords

Bariatric Surgery; COVID-19 Pandemic; Guideline Adherence; Type 2 Diabetes Mellitus; Obesity

Main text

1. Introduction

At the onset of the COVID-19 pandemic there was an abrupt and unprecedented cessation of elective surgery services, in publicly funded (National Health Service) and private settings [1-3]. As services resumed to a growing backlog [4, 5], there were multiple ongoing barriers to resumption of normal service including ringfencing of specialist resources (e.g. intensive care beds) for patients with COVID-19 infection, and staff shortages [6]. There were also competing considerations regarding prioritization of elective caseload both between and within specialisms.

In May 2020, experts from the Diabetes Surgery Summit (DSS) issued guidelines to attempt to assist service providers as they stratified and prioritized elective bariatric surgery cases [6]. These guidelines can be summarized as recommending expedited surgery (within 90 days) for 1/ patients with Type 2 Diabetes Mellitus (T2D) and poor glycemic control, insulin use, or prolonged duration (> five years); 2/ patients with cardiovascular disease or two or more comorbidities increasing cardiovascular risk; 3/ patients requiring surgery as a bridge to other time-sensitive treatments including organ transplant; and 4/ patients with Body Mass Index (BMI) >60 kg/m^2. Soon after, the Federation of Surgical Specialty Associations (FSSA) (who were commissioned by NHS England at the start of the pandemic to establish relative surgical priorities) also recommend expedited bariatric surgery (within 90 days) for those with significant or multiple end-organ failure and these findings were endorsed by the Royal College of Surgeons of England [7]. The impact of the changes in health care policy during the pandemic

on patients awaiting bariatric surgery in the UK has not to date been quantified; neither has the extent to which contemporaneous guidelines were followed. It is important to analyze and reflect on health care policy during the pandemic, to assist with the management of future similar crises of resource limitation.

The main aims of this study were, therefore, to document elective bariatric surgery activity in the UK in one year from the outset of the pandemic; and compare this to a pre-pandemic 'control' period. Specific aims were as follows: firstly, to describe the effect of the pandemic on total number of elective bariatric operations, case mix and provider in the United Kingdom (UK); secondly, to examine demographic of patients undergoing elective bariatric surgery within the NHS during the pandemic and see how well this corresponded to contemporaneous recommendations; and thirdly, to record perioperative outcomes for patients undergoing elective bariatric surgery within the NHS during the pandemic in the UK.

2. Methods

2.1. Study design and sample description

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 with the unique identifier NCT05532891 and can be accessed here: https://clinicaltrials.gov/ct2/show/NCT05532891. It was conducted

in accordance with the principles of the Declaration of Helsinki [8] and has been reported in line with STROBE criteria [9].

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 [10]. 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.

All adult 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) were included in the study. The pre-pandemic period was chosen to ensure that there would be no cases of COVID-19 in this period nor in the 30-days afterward (during which peri-operative complications are recorded). Fully-anonymized data were extracted for the purposes of analysis.

2.2. Patient consent and ethics statement

Patient consent for NBSR data collection and usage of anonymized data for research purposes is routinely taken as part of the standard process for surgical consent, as per NHS commissioning guidelines. 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).

2.3. Study variables

The main predictor variable was the time-period during which patients underwent elective bariatric surgery: one year from 1st April 2020 or one year from 1st September 2018. Outcome variables were case volume, case-mix and provider (NHS or private hospitals). Since FSSA and RCS guidelines were specifically aimed at NHS providers, we then focused on NHS cases to study further outcome variables comprising demographic and baseline health status of patients; and peri-operative variables: presence of a second consultant during the operation; surgical approach to operation – completed laparoscopically or not; length of hospital stay; surgical complications; reoperation within 30 days and mortality within 120 days.

2.4. Data collection and statistical analysis

Diabetes status is recorded pre-operatively and at each follow up visit as follows: no indication of T2D; impaired glycemia or diet-controlled; oral hypoglycemics or insulin treatment (insulin with or without additional hypoglycemic medications). For the purposes of analysis we grouped the latter two categories as 'on treatment' and thus have three groups for the outcome variable 'T2D status': T2D on treatment; pre-T2D; and no T2D.

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.

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 analyze categorical or ordinal values. Student's t-test was used for continuous parametric data. Relative risk was calculated for peri-operative outcomes, with Koopman asymptotic score for 95% confidence interval. $P<0.05$ is considered statistically significant.

3. Results

3.1. Case mix and provider

Total number of cases recorded in NBSR decreased from 8615 in the first reporting period, to 2930 in the year from 1st April 2020 (Table 1). Revision cases as a proportion of total increased (9% to 11%; $p = 0.0006$) and this was driven by an increase in the NHS (9% to 13%; $p<0.0001$), with no change in the private sector (Table 1). There was a much greater reduction in cases performed in the NHS than in the private sector, with the proportion of private cases increasing from 25% in the pre-pandemic period to 46% during the pandemic (2084/8615 to 1356/2930; $p<0.0001$; Figure 1A). Elective bariatric surgery began to resume in June 2020 and increased until October 2020. In the NHS it then dropped off over the winter months during the second national lockdown, whilst remaining relatively constant in the private sector (Figure 1B). In terms of primary surgery caseload, in the pre-pandemic period there was a greater proportion

of Roux-en-Y gastric bypass (RYGB) in the NHS than in private settings [11]. Following outbreak of the pandemic, changes in primary caseload were most pronounced in the private sector with a decrease in adjustable gastric bands (AGB) from 18% to 6% and an increase in sleeve gastrectomy (SG) from 46% to 53% (Figure 1C).

3.2. Caseload by hospital

There was high variability in the bariatric surgery workload between different hospitals in the UK, with the majority experiencing a profound reduction in bariatric cases performed during the COVID-19 pandemic. A small proportion of hospitals experienced no change or an increase the number of cases and this was more commonly observed in the private sector (27% versus 6% in the NHS; p=0.005) (Figure 2).

3.3. Demographic of patients undergoing bariatric surgery in the NHS

There was no difference in baseline heath status for patients undergoing bariatric surgery during the pandemic when compared to pre-pandemic (Table 2). Notably patients were no more likely to be higher BMI, nor have T2D or other obesity-related comorbidities.

3.4. Peri-operative outcomes for NHS patients

There were no statistically significant differences in peri-operative outcomes for patients treated during the pandemic (Table 3). One mortality was recorded: this occurred in an NHS patient in July 2020, 48 days post-operatively and cause of death was recorded as ‘chronic multi organ failure’.

4. Discussion

After a complete cessation in activity during the first lockdown from late March to April 2020, bariatric surgery began to resume in the UK around June-July 2020. Guidelines issued by the DSS and FSSA and endorsed by the Royal College of Surgeons of England clearly stated that patients with more severe obesity-related comorbidity and greater BMI ought to be prioritized. This analysis of the NBSR suggests that these guidelines were not followed.

The rationale for such recommendations were two-fold. Firstly, there is a dose-dependence in terms of BMI and mortality for patients contracting COVID-19, and patients with poorly controlled T2D are more likely to die than those with well-controlled T2D [12, 13]. Given the likelihood that more COVID-19 variants would arise, putting more vulnerable people at risk, it was important to prioritize bariatric surgery in patients with highest risk so that they would be protected in future outbreaks. The guidelines issued by DSS and FSSA were consistent with government drives to prioritize weight reduction as one of the few modifiable risk factors for severe COVID-19 infection [14]. Secondly, patients with more severe comorbidities or more advanced T2D have increased all-cause mortality, therefore have the most to lose by a delay in their surgery [15, 16]. This approach of stratifying bariatric patients and prioritizing those in greatest metabolic need was also supported by UK surgeons (based on evidence from contemporaneous surveys) [3]. Indeed, the original FSSA guidelines for prioritization of elective surgery published in April 2020 did not mention bariatric surgery at all [17]; in response to lobbying by the Bariatric Obesity and Metabolic Surgical Society (BOMSS) on behalf of the

community of bariatric surgeons, elective bariatric surgery was included from July 2020 onwards [7].

It is therefore surprising that our research identifies a startling discrepancy between guidelines and real-world practice. This discrepancy was also seen in the USA, where patients undergoing bariatric surgery during the pandemic had fewer comorbidities than pre-pandemic [18]. One reason for not recommencing surgery on high-risk patients could be to counter the potential deskilling of surgeons following a period of not operating - a rationale which in part led to some countries advocating prioritizing lower risk patients following recommencement of bariatric surgery [19]. If this were a concern, however, one approach would be to employ two-consultant operating [20]. Interestingly our study shows the proportion of two-consultant operations performed during the pandemic did not change. This could potentially be a strategy for future similar periods of decreased operating, to allay any concerns regarding operating on higher risk patients after a period of inactivity. Another potential rationale for avoiding bariatric surgery in high-risk patients would be fears of high peri-operative risk for patients with extensive comorbidities undergoing bariatric surgery and contracting COVID-19 in the peri-operative period. Results from this present study, and others [18, 21, 22], however, show good peri-operative outcomes for patients undergoing elective bariatric surgery during the pandemic, which would suggest that the DSS and FSSA guidelines were appropriate. Nonetheless, there are likely to be multiple complex obstructions to fulfilling the DSS and FSSA guidelines on prioritization and these must be examined and addressed in future work [23, 24].

The overall reduction of bariatric surgery caseload to around two-thirds in the UK was much greater than that seen in the USA, where there was a 12% reduction in total cases during 2020 when compared to surgery in previous years [18]. Private practice saw a much more modest reduction in bariatric operating than NHS services. Many bariatric cases are performed in private facilities that do not have intensive care units, so one possible explanation for the difference was a lack of competition for these services. However, staff shortages would be expected to impact both sectors to a similar degree. Close examination of the strategies of private bariatric surgery providers in keeping services running will assist NHS managers as they deal with the bariatric surgery backlog. We observed a relative increase in the proportion of revisional surgery, and an increase in prevalence of primary sleeve gastrectomy; however, these findings are both in line with longer-term evolving international trends [25, 26].

Our study has some limitations. In terms of data-completeness, entry of elective bariatric surgery cases to NBSR is mandatory for all NHS cases and strongly recommended for private providers. Hospital Episode Statistic (HES) data records all NHS episodes and listed 6460 episodes of 'primary bariatric surgery' in the year from 1st April 2018 [27]. Although monthly counts are not publicly available, this gives external validity to our figure of 6384 for the year commencing 1st September 2018. Additionally, NBSR does not have the granularity to identify for example patients waiting time-sensitive treatments, such as transplants, who may have been approximately prioritized in line with recommendations; however, this will have accounted for a tiny fraction of cases. A further limitation of the NBSR is that some conditions may be investigated to different degrees in different centers, for example liver disease which is

likely to be diagnosed based on screening liver blood tests and/or ultrasound. Nonetheless, there is no reason to suspect that this would introduce systemic bias when comparing the two time-periods. It is also worth noting that the surgical complication rate is so low for elective bariatric surgery in the UK that our study may have been unable to detect a statistically significant difference between the two time-periods.

To conclude, our data demonstrates that not only was there a dramatic reduction in bariatric surgery in the UK during the pandemic, but that patients were not prioritized for the available surgery slots as recommended. More studies are warranted to better understand the reasons for failure to appropriately prioritize patients. This is essential to guide policymakers and stakeholders in future periods of severe resource limitation, so that as surgeons we protect our most vulnerable.

Conflict of interest statement

Declaration of interests: none

Figure legends

Figure 1: Caseload in the NHS and private sectors prior to and during the COVID-19 pandemic

A: Total number of cases occurring in the pre-pandemic and pandemic period under NHS and private providers; compared by chi-square; B: Cases per month during the pandemic period; breakdown between NHS and private providers illustrated; C: Case mix of primary surgery. NHS: National Health Service; AGB = adjustable gastric band; OAGB = single anastomosis gastric bypass; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy.

Figure 2: Elective bariatric surgery volume in individual hospitals prior to and during the pandemic Trajectories of individual hospital volume for A: NHS and B: Private cases (limited for ease of viewing to those hospitals recording 20 cases in total in either one of the time-periods); C: Summary table to illustrate number of hospitals (with percentage of total number) experiencing different degrees of change in volume of cases during the pandemic.

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Table 1: Total number and number of revisions prior to and during the COVID-19 pandemic. Cases performed by 'All', National Health Service (NHS) and private providers are illustrated. Funding category was missing in 147 cases in the pre-pandemic period and 8 cases in the pandemic period. Revisions are expressed as a percentage (%) of total in each category. Chi-square test was used to compare revision with non-revision between pre-pandemic and pandemic for each provider type.

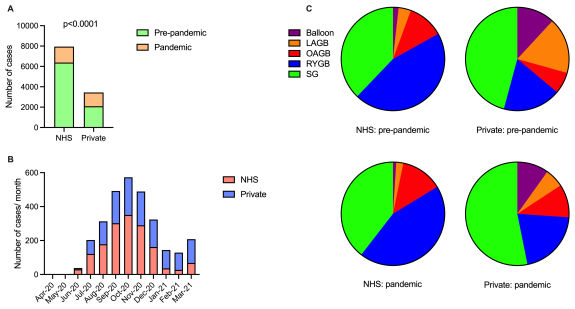
		Pre-pandemic	Pandemic	p value
All	Total	8615	2930	0.0006
	Revision	746 (9%)	316 (11%)	
NHS	Total	6384	1566	<0.0001
	Revision	567 (9%)	202 (13%)	
Private	Total	2084	1356	0.952
	Revision	174 (8%)	114 (8%)	

Table 2: Demographics of National Health Service (NHS) patients undergoing bariatric surgery prior to and during the COVID-19 pandemic. BMI = body mass index; T2D = Type 2 Diabetes Mellitus; % = % of total in each category

	Pre-pandemic	Pandemic	p value
Age in years; mean ± standard deviation	45.8 ± 11.4	46.3 ± 11.6	0.095
Female/ male; n (%)	5058 (79), 1326 (21)	1266 (81), 300 (19)	0.162
BMI at time of surgery kg/m^2; mean ± standard deviation	45.5 ± 8.3	45.2 ± 8.3	0.228
T2D on treatment/ pre-T2D/ no T2D; n (%)	1635 (26)/242 (4)/ 4393 (70)	397 (26)/ 72 (5)/ 1077 (70)	0.999
Duration of T2D less than 5 years/ 5-10 years/ more than 10 years; n (%)	904 (57)/ 314 (20) / 364 (23)	202 (53)/ 83 (22)/ 100 (26)	0.106
On treatment for hypertension n (%)	2192 (35)	550 (35)	0.718
Diagnosed with cardiovascular disease n (%)	307 (5)	66 (4)	0.284
Obstructive sleep apnoea treated/ untreated/ no indication	1402 (22)/ 358 (6)/ 4511 (72)	400 (26)/ 63 (4) / 1090 (70)	0.953
Liver disease n (%)	449 (7)	110 (7)	0.931

Table 3: Peri-operative outcomes of National Health Service (NHS) patients undergoing elective bariatric surgery prior to and during the COVID-19 pandemic % = % of total in each category

	Pre-pandemic	Pandemic	p value	Relative risk (RR) and 95% confidence interval (CI)
Presence of second consultant n (%)	289 (5)	56 (4)	0.099	0.79 (0.60 – 1.05)
Completed laparoscopically n (%)	6268 (99.8%)	1552 (99.9%)	0.485	0.87 (0.81 – 1.20)
Length of stay in days; mean (standard deviation) median (IQR; range)	 2.17 (3.84) 2 (1-2; 0-198)	 2.00 (3.43) 2 (1-2; 0-90)	 0.125 n/a	
Surgical complications; n (%)	126 (2.0)	22 (1.4)	0.133	0.71 (0.45 – 1.12)
Reoperation within 30 days; n (%)	57 (0.9)	8 (0.5)	0.159	0.57 (0.27 – 1.20)
Mortality within 120 days; n	0	1	n/a	



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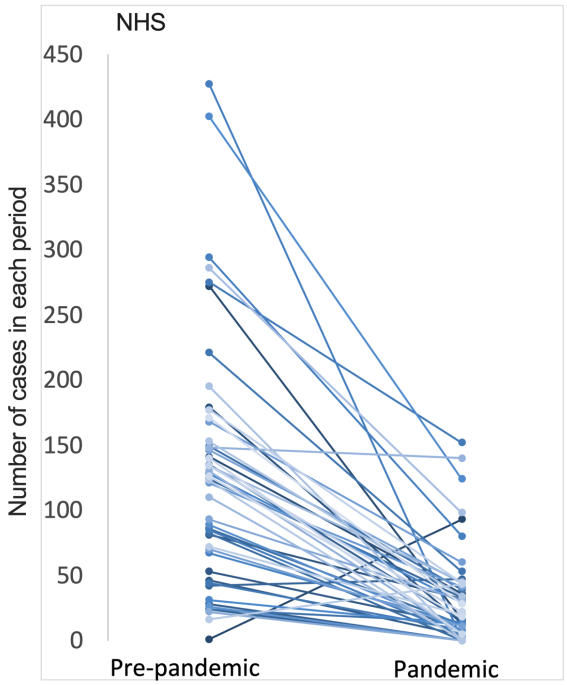

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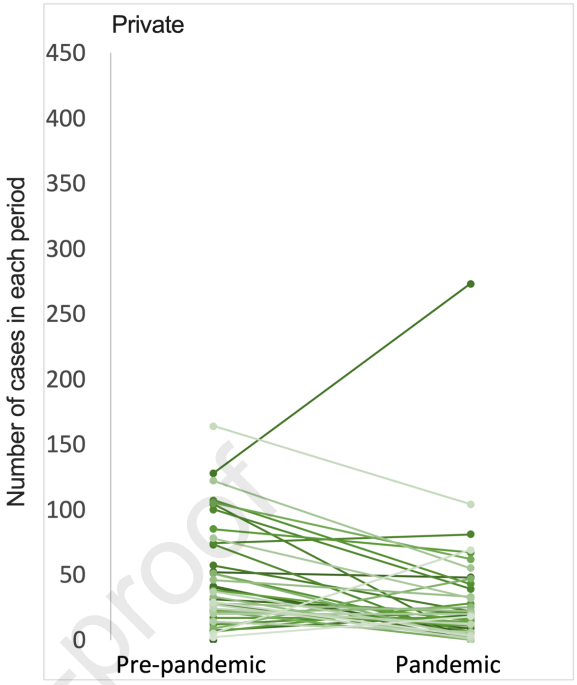

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	NHS	Private
No change or increase	3 (6)	11 (27)
>0 and ≤25% decrease	1 (2)	3 (7)
>25 and ≤50% decrease	2 (4)	5 (12)
>50 and ≤ 75% decrease	14 (29)	11 (27)
>75 and ≤100% decrease	29 (59)	11 (27)

Title:

Bariatric surgery provision in response to the COVID-19 pandemic: lessons from a national registry

Highlights:

- Analysing patterns of health care provision in time of severe resource limitation is important to aid planning for future crises
- UK national registry analysis demonstrates a dramatic reduction in volume of elective bariatric surgery following the COVID-19 outbreak
- Despite guidelines that recommended prioritisation of patients most severely affected by obesity, there were no changes in the baseline health status of patients undergoing surgery
- There were no significant changes in peri-operative outcomes