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Original article

Is selection bias toward super obese patients in the rationing of metabolic surgery justified?—A pilot study from the United Kingdom

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Abstract

Background: Recent evidence suggests that National Health Service (NHS) rationing of bariatric surgery is biased toward super-obese patients without scientific basis. The aim of this study was to compare health, quality of life, and employment outcomes in morbidly obese (MO) versus super-obese (SO) patients after laparoscopic Roux-en-Y gastric bypass (LRYGB) to provide a basis for rationing.

Methods: Consecutive patients undergoing LRYGB from January 2008–September 2009, with baseline body mass index (BMI) <45 kg/m^2 (MO) and BMI >60 kg/m^2 (SO) were identified from a prospective database. Seventy-six eligible patients were invited to complete a questionnaire comprising BAROS (bariatric analysis and reporting outcome system), EQ-5D (EuroQol – 5D), EQVAS (Euro-QoL visual analog score), and employment status preoperatively and postoperatively. Anthropometric, demographic, and clinical data were recorded.

Results: Fifty-one patients responded: 23 MO and 28 SO. Groups were matched for demographic characteristics and co-morbidities. The MO group had significantly higher percentage excess weight loss (%EWL) (82% versus 53%; *t* test: $P < .001$) and mean BAROS score (5.47 versus 4.21; *t* test: $P = .025$) than the SO group. EQ-5D improved significantly for both groups in 3 domains (self care, anxiety/depression, and pain/discomfort); there was no significant difference in improvement between groups. EQVAS was significantly higher for the MO group (90 versus 70; Mann-Whitney U: $P = .001$). Employment status changed for 8 patients postoperatively, but there was no significant difference between groups.

Conclusion: These results suggest that MO patients appear to benefit more than SO patients from LRYGB and yet seem to be disadvantaged in some NHS Trusts in the United Kingdom for access to bariatric surgery. This study provides a baseline framework for further research to generate evidence for more scientific rationing of bariatric surgery. (Surg Obes Relat Dis 2013;9:981–986.)

Keywords: Rationing of healthcare service; Morbid obesity; Super-obese quality of life; Employment

Bariatric surgery is known to improve obesity-related metabolic disorders such as type 2 diabetes mellitus, hypertension, hypercholesterolemia, and sleep apnea [1]. Bariatric surgery has also been proved to be a cost-effective treatment for morbid obesity [2–4].

Current guidelines suggest bariatric surgery should be offered to patients with a body mass index (BMI) 35–40 kg/m^2 with obesity related co-morbidities and with a BMI >40 kg/m^2 without co-morbidities [5]. However, with increased

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rationing of healthcare budgets in the National Health Service (NHS) in England and Wales, there is evidence that individual Primary Care Trusts (PCTs) are restricting access to bariatric surgery to patients with BMI >50 kg/m^2 or BMI >40 kg/m^2 with co-morbidity [6]. The criteria used by PCTs are not based on cost-benefit or quality-adjusted life year (QALY) calculations but appear to be based on arbitrary division at a higher BMI. With the well-described increases in obesity, both in the United Kingdom (UK) and worldwide [7], and the proven benefits of bariatric surgery, increased demand will inevitably ensue, placing further strain on already scarce healthcare resources. There is increasing interest in preoperative presence and postoperative changes in co-morbidities to be used for decision making [8]. Cost-benefit and QALY calculations for rationing of services can be complex, but improvement in health and quality of life (QOL) and employment status can be used as surrogate markers of direct and indirect benefits of bariatric surgery.

QOL has consistently been shown to improve after bariatric surgery [1,9]. There are few studies comparing outcome with regard to QOL between higher (super-obese) and lower BMI (morbidly obese) patients [10,11]. One study has shown that QOL was better in patients with lower preoperative BMIs compared with higher BMIs [11]. There is also evidence to show that patients in the super-obese category (BMI >50 kg/m^2) not only remain morbidly obese [10,12] but also that they are more likely to require longer-term care [13]. Bariatric surgery can enable patients to gain employment (indirect benefit) [4,14,15], but it is unknown which patient groups benefit most.

It is hypothesized that the cost-benefit ratio of bariatric surgery is greater in morbidly obese (MO) patients rather than super-obese (SO) patients. The aim of this study is to identify whether there is a difference in health and QOL outcome and change in employment status between MO and SO patients undergoing laparoscopic Roux-en-Y gastric bypass (LRYGB).

Methods

This was a questionnaire based and case note study. Consecutive patients who underwent primary LRYGB from January 2008–September 2009 in a single tertiary center were identified from a prospectively kept local database. Patients were divided into 2 groups according to baseline BMI at initial clinic visit. Those patients with a BMI <45 kg/m^2 were placed in the MO group, and those with a BMI >60 kg/m^2 were placed in the SO group. All patients were at least 1 year postsurgery.

Seventy-six patients fulfilled the criteria and were invited to participate in the study. Each was asked to complete the BAROS (bariatric analysis and reporting outcome system), EQVAS (Euro-QoL visual analog score), and EQ-5D (EuroQol – 5D) questionnaires. An additional EQ-5D questionnaire for their preoperative status was completed at the same time, in retrospect. Preoperative and postoperative employment status were also recorded. Patients that failed to respond to the initial postal invitation to participate in the study were sent a second invitation. Those who did not respond to the second cycle were contacted via telephone and questioned.

BAROS evaluates 3 parameters after surgery: weight loss, change in co-morbidities, and QOL; points are also deducted for reoperation and complications. A BAROS score ≤ 1 point was considered failure; >1 to 3 points, fair; >3 to 5 points, good; >5 to 7 points, very good; and >7 to 9 points, excellent [16,17]. The EQ-5D comprises 2 parts: the EQ-5D descriptive system, including questions on mobility, self-care, activity level, pain/ discomfort, and anxiety/depression, and the EQVAS, which asks the respondent to mark a scale of 0–100 regarding their perceived health state on that day [18]. EQ-5D is not specifically validated for bariatric surgery, but is used in other similar studies.

Demographic, anthropometric, and clinical details were collected from the local database as well as case note analysis for each patient responding to the study. Postoperative complications were also recorded. Data were analyzed using IBM SPSS (Statistical Package for the Social Sciences) Statistics version 19 (IBM, Armonk, NY). Mann-Whitney U, χ^2, and t tests were used to derive statistical significance.

This was a service evaluation study, so ethical approval was not required.

Results

Out of 76 eligible patients, 51 (68%) completed the study. There were 23 patients in the MO group, and 28 patients in the SO group. The female to male ratio was 3:1 in the overall study population. Other than preoperative BMI, no significant difference was noted in demographic characteristics between the 2 groups (Table 1).

There was no mortality in either group. Two patients from each group required a reoperation for complications within 48 hours of surgery. Mean BMI in the MO group at 1 year was 28 kg/m^2 (range 22–32) and in the SO group was 45 kg/m^2 (range 32–64). The mean percentage excess weight loss (%EWL) at 1-year follow-up in the MO group was 82% (61–123) compared with 53% (24–82) in the SO group; this difference was significant $P < .001$ (t test). The mean weight loss was significantly more for the SO group (59.0 kg: range 27–90 kg) compared with the MO group (42.8 kg: range 30–106 kg); this was statistically significant $P < .001$ (t test). There was no significant difference in the mean %BMI loss for the MO group (33%; range 22.56%–42.99%) compared with the SO group (33.1%; range 15.52%–50%) ($P = .960$ [t test]).

The mean BAROS score was significantly higher in the MO group compared with the SO group, 5.47 and 4.21,

Table 1
Preoperative characteristics of the study population

Patient Characteristic	MO (n = 23)	SO (n = 28)	*P*
Female: male	16:7	22:6	.373*
Age	48	44	.58†
Co-morbidities			
Diabetes	18	15	.094*
Sleep apnea	7	14	.107*
HTN	18	16	.145*
Hypercholesterolaemia	13	6	.015*
Employment	16	13	.097*
Preoperative weight (kg)	123 (91–161)	179 (147–294)	.135†
Preoperative BMI (kg/m^2)	42 (36–45)	67 (60–92)	.003†

BMI = body mass index; HTN = hypertension; MO = morbidly obese; SO = super obese;
*χ^2.
†*t* test.

respectively ($P = .025$; *t* test). Fig. 1 shows distribution of BAROS scores in the 2 groups. When analyzing the QOL element of the BAROS score, there was no significant difference in mean Moorehead-Ardelt quality of life (MAQL) score between the 2 groups: 1.57 versus 1.12 (*t* test: $P = .160$). Co-morbidities improved for 39 of 51 patients, but there was no significant difference in improvement in co-morbidity score between the 2 groups (χ^2: $P = .243$; Fig. 2).

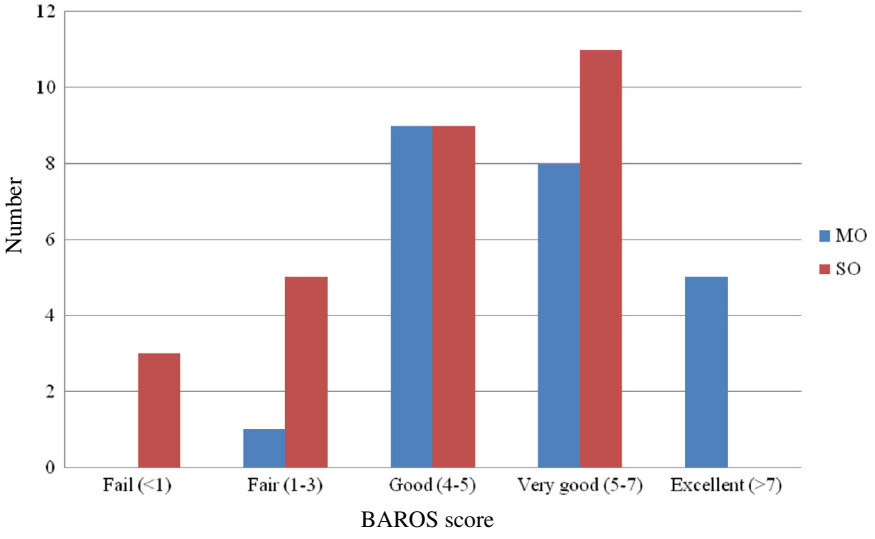
Median EQVAS scores were 90 (range 31–100) and 70 (range 30–95) for the MO and SO groups, respectively. This difference was statistically significant $P = .001$ (Mann-Whitney *U* test).

On subgroup analysis of EQ-5D, there were significant improvements in self-care (χ^2: $P < .001$), pain/discomfort (χ^2: $P = .020$), and anxiety (χ^2: $P = .033$) for all patients when comparing the preoperative and postoperative EQ-5D scores. Although there were improvements in mobility and ability to perform usual activities, they were not significant (Table 2). There was no significant difference in the change in EQ-5D score (preoperatively compared with postoperatively) between the MO and SO groups (Table 3).

Preoperatively, 16 of 23 patients in the morbidly obese group were employed compared with 13 of 28 in the super-obese group. There was no significant difference in preoperative employment status between the 2 groups (Fisher's exact: $P = .155$). Postoperatively, 17 of 23 in the MO group and 16 of 28 in the SO group were employed. Employment status changed in 8 patients. Three patients in each group gained employment, and 2 patients from the MO group were unable to return to work due to chronic pain. There was no significant difference in post-operative employment status between the MO and SO groups (Fisher's exact: $P = .251$).

Discussion

This study has shown that at 1-year follow-up LRYGB improved co-morbidities and QOL in both the groups on both BAROS and EQ-5D scoring. Postoperative employment status was also better in both the groups, suggesting



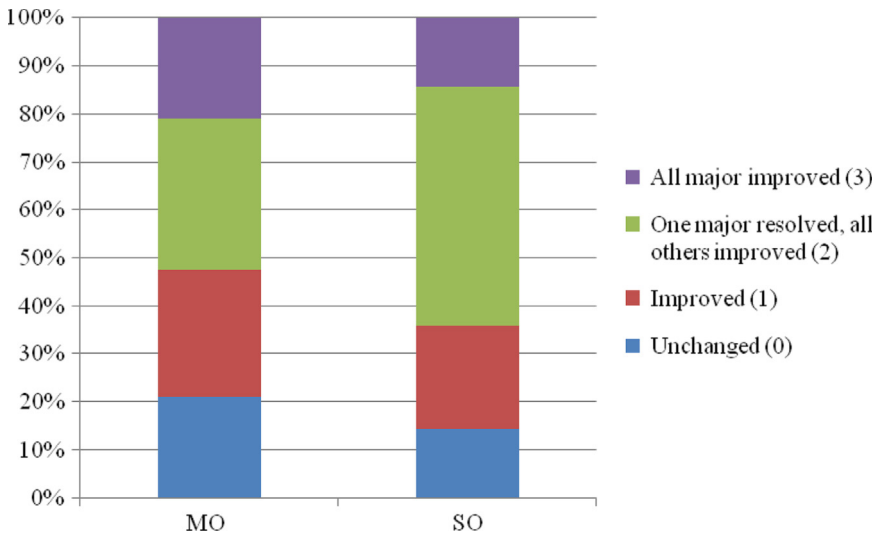
BAROS: Bariatric Analysis and Reporting Outcome System

BMI: Body Mass Index

MO: morbidly obese

SO: super obese

Fig. 1. Distribution of BAROS category with BMI. BAROS = Bariatric Analysis and Reporting Outcome System; BMI = body mass index; MO = morbidly obese; SO = super-obese.



BMI: Body Mass Index

MO: morbidly obese

SO: super obese

Fig. 2. Improvement in co-morbidities with BMI. BMI = body mass index; MO = morbidly obese; SO = super-obese.

Table 2
Combined EQ-5D results for both patient groups

Quality of Life Parameters	Preoperative	Postoperative	P (χ^2)
Mobility			
I have no problems in walking about.	5	37	.23
I have some problems in walking about.	42	14	
I am confined to bed.	4	0	
Self care			
I have no problems with self-care.	18	44	<.001*
I have some problems with washing and dressing myself.	31	6	
I am unable to wash or dress myself.	2	1	
Usual Activities			
I have no problems with performing my usual activities.	7	37	.164
I have some problems with performing my usual activities.	37	13	
I am unable to perform my usual activities.	7	1	
Pain/discomfort			
I have no pain or discomfort.	8	26	.02*
I have moderate pain or discomfort.	22	20	
I have extreme pain or discomfort.	21	5	
Anxiety/depression			
I am not anxious or depressed.	10	34	.033*
I am moderately anxious or depressed.	23	15	
I am extremely anxious or depressed.	18	2	

EQ-5D = EuroQol – 5D.
*Statistically significant.

indirect benefits of surgery. This is in keeping with previous literature.

The overall BAROS score was significantly higher in the MO compared with the SO group. The MO group also achieved a greater %EWL than the SO group. There was a significant difference in EQ VAS between the MO and SO groups. Improvements in co-morbidities were not significantly different between the 2 groups. Although there was no significant difference between the 2 groups in terms of improvement in QOL as measured with EQ-5D or QOL component of BAROS, there was a significant difference in their EQVAS scores suggesting that perception of QOL was better in the MO group.

The SO group had significantly worse results with regard to %EWL, BAROS score, and EQVAS compared with the MO group. These findings have not been reported previously. This may be because even after surgery, many of these patients remain morbidly obese, as shown in this and previous studies [10,12]. One other study has shown better BAROS scores in MO compared with SO patients in the early postoperative period; however, these differences became less apparent after 18 months follow up [11]. However, it should be noted that this study used a single cut-off point of BMI 50 kg/m^2 to divide patients into 2 groups, thus contributing to less apparent differences.

We used %EWL as one of the criteria for comparing 2 groups. This concept was challenged recently, as excess weight depends on initial "ideal weight" of the patient [19]. "Ideal weight" used in many surgical reports, including this

Table 3
Changes in EQ-5D scores preoperatively and postoperatively in the morbidly and super-obese groups

	MO	SO	P (χ^2)
Mobility			
Better	15	19	.538
Worse	0	0	
No change	8	9	
Self-care			
Better	10	16	.245
Worse	0	0	
No change	13	12	
Usual activities			
Better	14	20	.453
Worse	1	0	
No change	8	8	
Pain/discomfort			
Better	13	17	.953
Worse	1	1	
No change	9	10	
Anxiety/depression			
Better	14	0	.230
Worse	2	7	
No change	7	21	

EQ-5D = EuroQol – 5D; MO = morbidly obese; SO = super obese.

one, refers to "ideal weight" of medium frame individuals according to the Metropolitan Life Insurance Company's height-weight tables. Ideal weight for small and large frame individual of the same gender and height could vary by approximately 18 kg or 6 BMI points [20]. For this reason, we have also reported actual weight loss and %BMI loss. The actual weight loss was, in fact, higher for the SO group compared with the MO group, although percentage change in BMI was very similar for both groups.

As shown in 2 previous studies [14,15], employment status improved for the entire study group, but improvement in employment status was not significantly different between the 2 groups. Overall, LRYGB does not appear to have had a significant impact on employment status in this study, but this may improve with longer follow-up as patients lose more weight and become more active.

The 2 groupings used in this study (BMI <45 kg/m^2 and BMI >60 kg/m^2) were selected to allow differences between patients at either end of the BMI spectrum to be identified if they were present. There are no accepted categories of BMI >40 kg/m^2. The World Health Organization classification of BMI classes BMI 30.0–34.9 kg/m^2 as obesity I, 35.0–39.9 kg/m^2 as obesity II, and ≥ 40.0 kg/m^2 as obesity III, but does not subdivide patients with BMI >40 kg/m^2 [21]. Had a single cut-off point (e.g., BMI 50 kg/m^2, as used by many PCTs to determine eligibility for bariatric surgery [6]) been used, the differences between the groups would not be highlighted.

BAROS measures postoperative QOL but does not compare it with preoperative status, thus limiting its use in showing the improvement in QOL from preoperative status. Therefore the EQ-5D questionnaire was used as a preoperative and postoperative assessment of QOL. The preoperative EQ-5D was measured retrospectively, thus relying on patients' recall of previous health states, and this may question the accuracy of the preoperative EQ-5D scores. However, it was thought that the simplicity of the questionnaire would make it reliable even for assessing preoperative health status retrospectively. To the best of our knowledge pre and postoperative QOL along with BAROS score has not been examined before.

The center performs more than 200 LRYGB per year; however, the number of cases at extremes of BMI was relatively small, accounting for the small sample size of this study. The other main limitation was relatively short follow up. With larger sample size and longer follow up, the differences between the 2 groups may become more apparent.

Conclusion

In summary, this study shows that MO patients benefit more from LRYGB in terms of both %EWL and BAROS score than SO patients. In addition, MO patients have a better perception of QOL than SO patients. Improvement in QOL and employment status was seen in both groups, although it was not significantly different between them, as initially hypothesized. The results presented here suggest that if bariatric surgery in the NHS is to be rationed in an evidence-based manner, MO patients should not be disadvantaged. In fact, the cost benefits may be greater in this group of patients. Larger studies with longer follow up and more detailed health economic analyses are required to further investigate the findings of this study. The recently proposed/introduced Edmonton scoring system may be more useful in evaluating the cost-effectiveness of surgery for rationing purposes [8].

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Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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