



# Systematic Review of Definitions of Failure in Revisional Bariatric Surgery

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## Abstract

**Background** There are no agreed definitions as to what constitutes a ‘failure’ of the primary bariatric procedure in relation to weight loss.

**Methods** The MEDLINE database for primary research articles was searched using obesity [title] or bariatric [title] and revision [title] or revisional [title].

**Results** The MEDLINE search retrieved 174 studies. After duplicates and exclusions were removed, 60 articles underwent analysis. Fifty-one studies included inadequate weight loss or weight regain as an indication for revision: 31/51 (61 %) gave no definition of failure, 7/20 quoted <50 % of excess weight loss at 18 months and 6/20 used <25 % excess weight loss.

**Conclusions** The majority of published studies do not define failure of bariatric surgery, and <50 % excess weight loss at 18 months was the most frequent definition identified.

**Keywords** Bariatric surgery · Obesity · Revisional surgery · Failure

## Introduction

Obesity is one of the main public health issues for developed countries with a prevalence of 40–50 % in most European countries and over 65 % in the USA.

Management of obesity aims to achieve weight loss without malnutrition, improvement of body composition and comorbidities and reduce the risk of complications (e.g. type 2 diabetes mellitus). A recent meta-analysis found bariatric surgery to be more effective than non-surgical measures for achieving weight loss and remission of type 2 diabetes [1]. However, currently, as few as 1 % of patients with morbid obesity undergo bariatric surgery [2], including adjustable gastric banding (AGB), roux-en-y gastric bypass (RYGB) and duodenal switch (DS), which is the most effective operation in terms of weight loss.

The procedures are associated with a low mortality but 7–8 % of patients undergo revision procedures [2]. Some of these are for mechanical faults (e.g. band migration or erosion or gastro-gastric fistula) whereas others are for inadequate weight loss.

There is no uniform or internationally recognised definition for what constitutes failure of bariatric surgery. Some authors have used excess body mass index (BMI) loss (BMIEL) to describe the loss whilst others use percentage of total body weight, or simply change in BMI. Expected BMI Loss (EBMIL) is generally regarded as the most accurate method, particularly if corrected for the patient’s initial (pre-operative) BMI and operation type [3]. There is also variation in the expected weight loss depending on the operation performed; a recent meta-analysis found the mean reduction in BMI was 12–17 kg/m<sup>2</sup> for a sleeve-forming gastrectomy (SFG), giving the greatest weight loss, and AGB providing the least [4]. There is, however, sufficient doubt over the outcomes for this to be tested in England by a nationally funded

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randomised study comparing AGB and RYGB, which may be expanded to include SFG [5].

Establishing a clear definition for failure is necessary for the allocation of services where resources are finite. Where it is necessary to select patients for repeat procedures, it would be advantageous to have standardised criteria against which to judge their weight loss. In this study, we aimed to describe how failure of weight loss is defined in published studies of patients undergoing revisional bariatric procedures.

## Objectives

1. Describe how failure of bariatric surgery is defined in the current literature.
2. Produce evidence-based suggestions for how failure may be categorised and defined.

## Methods

### Protocol and Registration

This systemic review was registered on the PROSPERO International prospective register of systemic reviews, registration no. CRD42014007514. The protocol is accessible at [http://www.crd.york.ac.uk/PROSPEROFILES/7514\\_PROTOCOL\\_20140111.pdf](http://www.crd.york.ac.uk/PROSPEROFILES/7514_PROTOCOL_20140111.pdf).

### Eligibility Criteria

Included studies were primary research articles concerning revisional bariatric surgery in humans. Only published full articles were eligible because the investigators were interested in the reporting in published studies, rather than abstracts and other work. All articles must be accessible and available in English. Animal studies, reviews, editorials, letters and case reports were excluded.

### Information Sources and Selection

The MEDLINE database was searched using the terms obesity [title] or bariatric [title] and revision [title] or revisional [title] for all papers before February 2014. MEDLINE was screened using the above term. Articles were then assessed for eligibility criteria. Duplicate articles were excluded. All articles that were fully available were included in the review. There was no assessment of bias in individual studies.

## Data Collection Process

Two reviewers (JM & AJ) independently extracted data from all articles and then discussed each article together. The following data were collected: patient demographics, primary and revisional bariatric procedures performed, proportion of primary cases that required revision, whether consecutive cases were listed, indications for revision, follow-up period, and definitions used for each indication. In some cases, it was not possible to extract data (e.g. patient demographics) due to its presentation in multiple tables in the primary article.

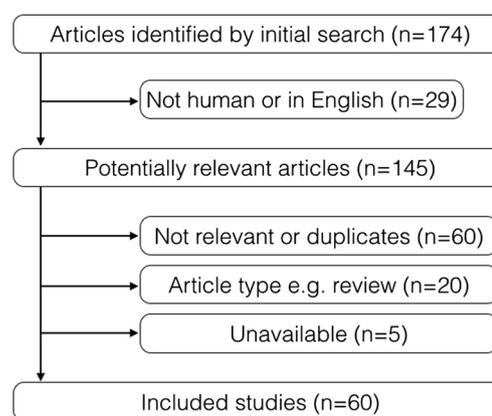
## Summary Measures

Descriptive statistics were produced from the dataset. There was no comparative statistical analysis.

## Results

Screening of MEDLINE database identified 174 articles, of which 145 articles were in English and studies of human subjects. After removal of duplicates and articles not concerning revisional bariatric surgery, 85 remained. Five articles were not available through University of Leeds, NHS Athens or BMA Library journal access. A further 20 were excluded due to their article type (reviews, case reports, technical reports, editorials, comments, letters). The remaining 60 articles were included for analysis (Fig. 1).

The total number of revisional procedures performed was 4148. The indication was provided in 2741 cases. The reason for surgery was for inadequate weight loss or weight regain in 1614 (59 %), for mechanical complications in 832 (30 %), for intolerance or other patient factors in 211 (8 %) and for nutritional deficiencies in 84 cases (3 %). Eight out of 60 (13 %) articles did not list the indications for the revisional



**Fig. 1** Pathway for identification of relevant papers

**Table 1** Studies that listed inadequate weight loss or renewed weight gain as an indication for revisional surgery, and offered a definition for how failure of primary procedure was defined

Article	Inadequate weight loss	Renewed weight gain	Definition
Fronza et al., Am J Surg 2010	32		Loss of <50 % EWL
Brolin et al., Ann Surg 2008	151		Loss of <50 % EWL
Himpens et al., Obes Surg 2012	13	45	Loss of <50 % EWL, or BMI of >35 kg/m <sup>2</sup>
Heylen et al., Obes Surg 2011	–	–	Gain of 10 % of more 2 years post-operatively
van Rutte et al., Obes Surg 2012	7		Loss of <25 % EWL
Burton et al., Obes Surg 2010	–	–	Loss of <25 % EWL at 12 months post-operatively
Hamza et al., Obes Surg 2010	21		Loss of <25 % EWL
Iannelli et al., Obes Surg 2009	41		Persistent obesity (BMI >30 kg/m <sup>2</sup> )
Bessler et al., Obes Surg 2005	8		Loss of <50 % EWL, or BMI of >35 kg/m <sup>2</sup>
Yimcharoen et al., Surg Endosc 2011		51	Gain after nadir was reached
Cohen et al., Surg Endosc 2005	14		Loss of <25 % EWL at 24 months post-operatively
Slegtenhorst et al., Surg Obes Relat Dis 2013	42		Loss of <25 % EWL
Meesters et al., Surg Obes Relat Dis 2012	6		Loss of <25 % excess BMI loss
Lee et al., Surg Obes Relat Dis 2011		8	Loss of <15 % weight, or gain of >20 % weight
Radtka et al., Surg Obes Relat Dis 2010	43		Loss, and maintenance, of <50 % EWL
Foletto et al., Surg Obes Relat Dis 2010	27		Loss of <20 % EWL
Patel et al., Surg Obes Relat Dis 2010	34		Loss of <25 % EWL at 24 months post-operatively
Bessler et al., Surg Obes Relat Dis 2010	22		Loss of <50 % EWL, or BMI of >35 kg/m <sup>2</sup>
Coakley et al., Surg Obes Relat Dis 2008	9	19	Loss of <40 % EWL
Nesset et al., Surg Obes Relat Dis 2007	97		Loss of <50 % EWL

*EWL* Excess weight loss

surgery. The mean age of revisional cases was 44 years (standard deviation  $\pm 4.9$  years), and 82 % of patients were female. Four out of 52 studies listed no demographics.

Fifty-one studies listed inadequate weight loss or weight regain as an indication for surgery. Of these, 20 (39 %) offered a definition for the indication. Whereas 7/20 quoted the 1991 National Institute of Health criterion (<50 % of excess weight loss at 18 months [6]) and 6/20 used the <25 % excess weight loss (Table 1). In the remaining 7/20, a wide variety of absolute values and units were used.

Overall, 31/60 (52 %) of articles were not compliant with CONSORT trial openness [7]. This was most frequently due to lack of clear description for the selection and eligibility of participants (in 21/60) but also due to the absence of patient demographics or details of the procedures performed.

## Conclusion

These results demonstrate two main points: the inconsistency in reporting and defining the reasons for failure of a primary bariatric procedure, and that the majority of studies concerning revisional operations do not report their selection criteria.

The most frequently cited (7/20 studies) definition for failure of the primary operation was <50 % of excess weight lost (EWL), with or without BMI of greater than 35 m/kg<sup>2</sup>, at 18 months post-operation. In contrast, the second most frequent definition was <25 % of excess weight lost (without a time-frame specified). In several papers, these two figures are attributed to the 1991 NIH consensus guidelines [6] and the 1982 Reinhold criteria [8]; however, neither of these gives the exact definitions. However, given the variation in expected weight loss between different surgical procedures, it is not surprising that different thresholds are reported for failure.

It must also be considered that there have been significant changes in surgical techniques over the last 20 years, i.e. vertical band gastroplasty is now rarely performed, whilst AGB and SFG have become much more common. This is reflected in the degree of weight loss that may be expected from the primary procedure [4], and the definition of inadequate weight loss should be derived from this. Courcoulas et al. [9] also demonstrated that patients may be split into distinct groups based upon their weight loss after a primary procedure. Using this method, it would be possible to describe failure as a statistical outlier; however, this would not take into account reversal of co-morbidities.

None of the articles in this review listed failure of remission of type 2 diabetes or hypertension as an indication for re-

operation. Whilst obesity per se is a major health risk, it is known that 20–30 % are the ‘metabolically healthy obese’. Therefore, it could be suggested that revisional procedures for inadequate weight loss may be reserved for those with the metabolic syndrome who are at greatest risk of complications.

There have been previous calls for standardisation in the reporting of bariatric surgery [10] that note the complexity of calculations and the variability in units. For these reasons, comparison between studies is difficult. None of the definitions used ‘percentage weight change’, which is reported in major prospective studies [9]. However, using weight (as % EWL or percentage weight change) does not take into account the patient’s height and therefore cannot accurately describe their obesity. Equally, BMI should be corrected for initial (pre-operative) BMI (IBMI) as BMI 25 kg/m<sup>2</sup> is not a feasible target for patients with IBMI >50 kg/m<sup>2</sup>[3].

Arguably more concerning was that 52 % (31/60) of studies did not meet CONSORT trial openness because they did not describe how they had selected their patient group. Many went on to describe their weight loss post-surgery, which is difficult to interpret without a definition of the inclusion criteria. Given that current evidence does support reoperative bariatric surgery, it is important that such studies are of high quality with detailed reporting.

### Summary

We conclude that there is an urgent need for a universal agreement on how obesity surgery is described as having failed, in terms of weight loss and metabolic criteria.

**Statement of Informed Consent** Does not apply.

**Statement of Human and Animal Rights** This article does not contain any studies with human participants or animals performed by any of the authors.

**Conflict of Interest** The authors declare that they have no conflict of interest.

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