

Qualitative and quantitative definitions of failure in bariatric surgery from published studies (2012-2013).

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Background

Obesity is one of the main public health issues for developed countries (*Bhatt et al., 2006*) with a prevalence of 40-50 in most European countries and over 65% in the US (WHO data). Treatment of obesity is necessary to reduce the risk of complications, such as type 2 diabetes, hypertension and dyslipidaemia, which lead to excess morbidity and mortality (*Allender et al., 2007*).

Management of obesity aims to achieve: weight loss without malnutrition, improvement of body composition and reduce risk of complications. 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 (*Gloy et al., 2013*). Currently 1% of patients with morbid obesity undergo bariatric surgery (*Elder et al, 2007*), including: adjustable gastric banding (AGB) and Roux-en-Y gastric bypass (RYGB).

The procedures are associated with a small mortality but 7-8% of patients undergo revision procedures (*Gloy et al., 2013; Chang et al., 2013*). Some of these are for mechanical faults (e.g. band migration or erosion) whereas others are for failure of weight loss.

There is no uniform or internationally recognised definition for what constitutes failure of bariatric surgery. Some authors have used excess BMI loss (EBMIL) to describe the loss achieved (*Deitel et al., 2003*) whilst others use percentage of total body weight, or simply change in BMI. 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/m², with sleeve gastrectomy (SG) giving the greatest weight loss and AGB providing the least (*Chang et al., 2013*).

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 advantages to have standardised criteria against which to judge their weight loss.

Aims:

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

Methods

Data sources & search terms

All articles from Obesity Surgery [journal] from 1/1/2012 to 31/12/2013 will be screened. If insufficient numbers of articles (<50) are obtained then a second journal may be selected to have all articles screened from the same time period. Alternatively, a MEDLINE search may utilised with key words "bariatric surgery" OR "obesity surgery" AND "revision".

Exclusion criteria:

- Abstracts, reviews, case reports, comments, letters, editorials
- Animal studies

Inclusion criteria:

- Title contains one of the following: "failure", "revision(al)", "repeat"

- Must state how failure was defined, or reason for repeat procedures (e.g. mechanical failure, surgical complication, inadequate weight loss). Qualitative and quantitative measures will be recorded.

Two reviewers (JM & AJ) will assess articles against these criteria; any disagreements will be resolved between the 4 reviewers.

Quality assessment

If sufficient articles have comparable, quantitative definitions that would be suitable for meta-analysis then a quality assessment of all articles would be performed using a defined method.

Data collection

If available, data will be collected on:

- Article reference
- Number of patients, and patient demographics
- Surgical procedure(s) performed
- Whether data is regarding 1st, 2nd or subsequent revision surgical procedures
- Pre-operative BMI, weight or equivalent
- Reason(s) for revision procedure
- How failure had been described, including details of figures or calculations for weight loss
- Post-operative BMI, weight or change
- Follow-up duration

Statistical analysis

Analysis will be performed for only studies that meet the above criteria. Descriptive statistics will be produced for individual studies and, if meta-analysis is to be performed, pooled data. Qualitative data will be reported using a table of representative examples.

References

Allender S, Rayner M. The burden of overweight and obesity-related ill health in the UK. *Obes Rev* 2007;8:467-73.

Bhatt DL, Steg PG, Ohman EM, Hirsch AT, Ikeda Y, Mas JL, et al. International prevalence, recognition, and treatment of cardiovascular risk factors in outpatients with atherothrombosis. *JAMA* 2006;295:180-9.

Chang SH, Stoll CR, Song J, Varela JE, Eagon CJ, Colditz GA. The Effectiveness and Risks of Bariatric Surgery: An Updated Systematic Review and Meta-analysis, 2003-2012. *JAMA Surg.* 2013 Dec 18. [Epub ahead of print]

Deitel M, Greenstein RJ. Recommendations for reporting weight loss. *Obes Surg.* 2003;13(2):159-160.

Elder KA, Wolfe BM. Bariatric surgery: a review of procedures and outcomes. *Gastroenterology* 2007 May;132(6):2253-71

Gloy V, Biel M, Bhatt DL, Kashyat SR, Schauer PR, Mingrone G, Bucher HC, Nordmann AJ. Bariatric surgery versus non-surgical treatment for obesity: a systematic review and meta-analysis of randomised controlled trials. *BMJ* 2013;347:f5934

World Health Organization. WHO global database on body mass index. <http://apps.who.int/bmi/index.jsp>.