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Systematic Review of Medium-Term Weight Loss after Bariatric Operations

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Background: Although bariatric surgery is known to be effective in the short term, the durability of that effect has not been convincingly demonstrated over the medium term (>3 years) and the long term (>10 years). The authors studied the durability of weight loss after bariatric surgery based on a systematic review of the published literature.

Methods: All reports published up to September, 2005 were included if they were full papers in refereed journals published in English, of outcomes after Roux-en-Y gastric bypass (RYGBP), and its hybrid procedures of banded bypass (Banded RYGBP) and long-limb bypass (LL-RYGBP), biliopancreatic diversion with or without duodenal switch (BPD±DS) or laparoscopic adjustable gastric banding (LAGB). All reports that had at least 100 patients at commencement, and provided ≥3 years of follow-up data were included.

Results: From a total of 1,703 reports extracted, 43 reports fulfilled the entry criteria (18 RYGBP; 18 LAGB; 7 BPD). Pooled data from all the bariatric operations showed effective and durable weight loss to 10 years. Mean %EWL for standard RYGBP was higher than for LAGB at years 1 and 2 (67 vs 42; 67 vs 53) but not different at 3, 4, 5, 6 or 7 years (62 vs 55; 58 vs 55; 58 vs 55; 53 vs 50; and 55 vs 51). There was 59 %EWL for LAGB at 8 years, and 52 %EWL for RYGBP at 10 years. Both the BPD±DS and the Banded RYGBP appeared to show better weight loss than standard RYGBP and LAGB, but with statistically significant differences present at year 5 alone. The LL-RYGBP was not associated with improved %EWL. Important limitations include lack of data on loss to follow-up, failure to identify numbers of patients measured at each data point and lack of data beyond 10 years.

Conclusions: All current bariatric operations lead to major weight loss in the medium term. BPD and Banded RYGBP appear to be more effective than both RYGBP and LAGB which are equal in the medium term.

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Introduction

Obesity is a chronic disease that requires lifelong therapy. In seeking effective treatments, we should take particular note of the duration of the effect. There is little value and possibly some harm, in achieving only short-term weight loss.[1] Yet, for most reports of medical and surgical treatments, we are provided with documentation of effectiveness for 12 months most commonly and, less often, for up to 3 years. Longer follow-up data are relatively rare.

Although it is generally agreed that non-surgical therapies do not solve the problem of obesity, there is little doubt that, with a well constructed and supervised medical program, many people will lose a substantial amount of weight. The challenge has always been to keep that weight off. For bariatric surgical therapies to claim superior effectiveness over medical programs, the durability of the weight loss after surgery needs to be confirmed.

Bariatric surgical treatments have been available for more than 50 years, and it would be a reasonable expectation that by 2006 we would have documented effectiveness of bariatric surgery over two or more decades. Gastric bypass is now approaching the 40th anniversary of its introduction. Yet, for this operation, the longest follow up data come from the 1995 report of Pories et al[2] of weight loss outcomes out to 14 years. Only 10 patients were included at that data point. Biliopancreatic diversion was introduced 30 years ago and there is also only a single report, by Scopinaro and coworkers[3] in 1998, which gives outcome data >10 years.

In the absence of significant long-term data (>10 years), we have chosen to perform a systematic review of the medium-term outcomes (3-10 years) of bariatric operations to find if durability of effectiveness in maintaining weight loss has been achieved. Systematic review permits an objective appraisal of all relevant existing evidence, synthesis of the findings of multiple studies and often, the demonstration of an effect from the pooled data that was not evident from individual studies.[4] There have been three major systematic reviews of bariatric surgery to date, each of which provides us with short-term outcome data only.

The first of these, by Chapman et al,[5] was commisioned by the Australian Department of Health and Ageing and undertaken by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S). This is an evidence-based medicine group funded by the Federal government and the Royal Australasian College of Surgeons to measure the safety and efficacy of new operations. They provided a comprehensive review of all data available to September 2001 on laparoscopic adjustable gastric banding, gastric bypass and gastroplasty, with data extending up to 4 years after surgery. They provided a full listing of the papers used in preparing the report.[5]

The second systematic review has been undertaken by MetaWorks (Medford, MA, USA), a commercial provider of evidence-based medicine reviews, under commission from Ethicon EndoSurgery (Cinncinati, OH, USA). To date, only a single selective report of their findings has been presented, by Buchwald et al.[6] In this report, only those papers having outcome data on four common co-morbidities of obesity were included in the analysis, and the outcomes at the single early time point of 12 months after operation were reported. There was no listing of the papers selected to be used, so that a check for completeness of search or validity of analyses was not possible.[6] An additional area of the overall systematic review has thus far been published as an abstract only.[7]

The third review, by Maggard et al,[8] was prepared by a collaboration of three academic evidence-based medicine groups in Southern California. They have provided a comprehensive review of weight loss outcomes at 1 year and a less complete review at ≥3 years. The listing of the included reports was provided.

In the present study, we have applied the strict criteria of systematic review to examine the reported weight loss effects of bariatric surgical procedures >3 years and up to 10 years after operation.

Methods

Bariatric Procedures Reviewed: We have restricted the review to the three groups of bariatric procedures which are currently in broad clinical use. The three primary surgical procedures were laparoscopic adjustable gastric banding (LAGB), standard Roux-en-Y gastric bypass (RYGBP) and biliopancreatic diversion (BPD). The hybrid procedures of banded gastric bypass (Banded RYGBP) and long-limb gastric bypass where the Roux limb length was >250 cm (LL-RYGBP) were also included and analyzed as individual procedures. Gastroplasty procedures were not included, because the use of this group of operations has diminished following demonstration by multiple randomized controlled trials of an inferior outcome in comparison to RYGBP[9,10] and the introduction of the laparoscopic approach to bariatric surgery. The use of the duodenal switch variant of BPD was noted and data related to BPD was analyzed as pooled data and separately.

Search Strategy: Original published studies on LAGB, RYGBP, Banded-RYGBP and LL-RYGBP, and BPD were identified by searching Medline, Current Contents, Embase, ScienceDirect, PubMed and the Cochrane database up to September 1, 2005. The following search terms were used: laparoscopic adjustable gastric banding, LAGB, Swedish adjustable gastric banding, SAGB, gastric bypass, Roux Y gastric bypass, Roux-en-Y, RYGBP, GBP, biliopancreatic diversion, BPD, duodenal switch, bariatric. Journals directly relevant to obesity research, such as *Obesity Surgery*, *Obesity Research* and *International Journal of Obesity and Related Metabolic Disorders* were checked electronically or manually.

Study Inclusion Criteria: Only peer-reviewed full papers in English were included. Each paper had to include at least 100 patients at entry and had to provide weight loss data of ≥3 years duration from operation. The requirement for 100 patients was placed to avoid overestimating the confounding effect of the learning curve. Reports which included variants of a primary procedure totaling >100 were also accepted. Reports of different primary procedures were only accepted for those primary procedures which exceeded 100 patients.

For multiple publications of the same data or cumulative data, the last publication which fulfilled the inclusion criteria was used. Abstracts and unpublished data were not included.

Data Extraction: All papers were appraised by one of two independent reviewers trained in systematic review (TMcP, TC). Weight loss was recorded as %EWL and, when available, as change in body mass index (BMI). Other measures of weight loss, such as absolute values in kg, or % of initial weight lost were used infrequently and therefore not recorded. All reports were separated into those that provided a value for the number of patients at each data point, and those that did not, because pooled weighted mean values could not be calculated from the latter reports. There were various definitions for ideal weight used to calculate %EWL.[11] Most commonly used "ideal weight" measures are based on the "ideal weight" of the Metropolitan life tables or weight at BMI 25 kg/m^2. Most reports did not define which "ideal weight" is used.

Assessment of Heterogeneity: We noted the individual variations of technique within the principal groups, with separation of the hybrid groups such as the banded gastric bypass from the standard RYGBP and variations in methods of reporting of weight loss. Two important elements of heterogeneity that could not be measured were the percent of patients originally treated who were not available for follow-up (loss to follow-up) and the methods for measuring weight, directly in investigators' offices, at remote sites by another practitioner or by patient reporting by phone or letter.

For duplicate or repeated publications, the last report was included. Sub studies which were not representative of the obese population, e.g. reports only including patients with type 2 diabetes, were not included.

Data Synthesis and Analysis: The mean %EWL, number of patients and time of follow-up were recorded from each study. A fixed effect model was used because of inconsistent reporting of standard deviations. The pooled mean and pooled weighted mean values were calculated for each time point, and pair-wise comparisons of surgical techniques at specific time points were made using the Mann Whitney-U non-parametric test.

Results

A total of 1,703 reports were identified on initial review. Only 43 reports fulfilled the selection criteria. There were 18 reports on LAGB, 18 reports on RYGBP and 7 reports on BPD or its DS variant. These are listed in Tables 1-4. Of the LAGB reports, 12 gave data on the Lap-Band® (Inamed, Allergan, Santa Barbara, CA) alone, 5 on the Obtech® band (Ethicon EndoSurgery, Cincinatti, OH) alone, and 1 included both devices. Of the RYGBP, 12 reports were of standard RYGBP, 3 were of the Banded RYGBP and 3 were of the LL-RYGBP. Of the 7 reports of BPD, 4 were of the standard form and 3 were of the duodenal switch variant.

Pooled data from all reports are shown in Figure 1. This shows the %EWL over the 10-year period and graphically demonstrates the overall effectiveness and durability of bariatric surgery with mean %EWL in the range of 54-67% and no evidence of loss of effect at 10 years. The %EWL from all the subgroups is shown in Tables 1-4 and Figures 2-4. The data for the Lap-Band® and Obtech® band and for BPD and the duodenal switch variant are pooled, because there were no significant differences between the procedures.

Figure 2 shows the changes in %EWL for Standard RYGBP, LAGB and BPD. Standard RYGBP achieves strong weight loss in the first 2 years, but begins fading after 2 years and falls to

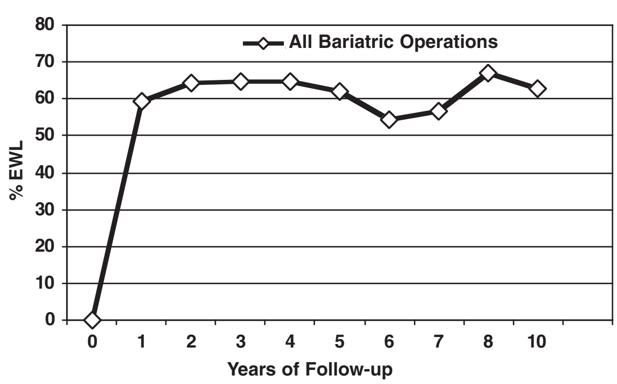

Figure 1. Pooled data of %EWL for all bariatric procedures within the review.

Table 1. %EWL after RYGBP

Author year, n	Time (years) of follow-up (n) 1	2	3	4	5	6	7	10
Balsiger 2000, n=191[12]	68 (113)	72 (88)	66 (72)	63 (55)				
Capella 2001, n=652[13]					77 (72)			
Gleysteen 1987, n=133[14]	63.1 (133)	61.9 (130)	58.6 (121)	56.8 (101)				
Higa 2001, n=497[15]	69 (572)	69 (51)	62 (19)					
Jones 2000, n=352[16]	48 (103)				43 (92)			43 (36)
Linner 1982, n=227[17]	63	63	59					
Oh 1997, n=189[18]	68.7 (90)	69.5 (47)	65.3 (29)	57.4 (14)				
Pories 1995, n=608[2]	68.9 (506)			57.7 (317)				54.7 (158)
Rabkin 1998, n=138[19]	61	74	74	69				
Smith 1997, n=205[20]	72.2 (110)	70.1 (69)	65.8 (44)	56.3 (22)	61.9 (12)	53.3 (7)	55 (2)	
Sugerman 1989, n=182[21]	58	57	57					
Wittgrove 2000, n=500[22]	77	80	75	75	83			
Mean	65.2	68.5	64.7	62.2	66.2	53.3	55.0	48.9
Sum of N	1627	385	285	509	176	7	2	194
Weighted mean	**67.3**	**67.5**	**62.5**	**58.0**	**58.2**	**53.3**	**55.0**	**52.5**
No. of studies reporting, n	7	5	4	4	3	1	1	2

Table 2A. %EWL after LL-RYGBP

Author year, n	Time (years) of follow-up (n) 1	2	3	4	5
Brolin 2002, n=199[23]	61 (103)	64 (40)		55.5 (53)	
Choban 2002, n=105[24]	53.3 (105)	56 (105)	57 (105)		
Rabkin 1998, n=138[19]	61	74	74	69	
Mean	57.2	63.7	64.3	69.0	55.5
Sum of N	105	208	160	0	54
Weighted mean	**53.3**	**58.5**	**60.3**		**55.5**
No. of studies reporting, n	1	2	2	0	1

Table 2B. %EWL after Banded-RYGBP

Author year, n	Time (years) of follow-up (n) 1	2	3	4	5	6	7	8	9	10
Capella 2002, n=652[13]				77 (72)						
White 2005, n=342[25]	79.2 (265)	80.3 (203)	74.6 (166)	72.4 (115)	67.4 (72)	65.6 (55)	60 (35)	65.1 (37)	55.3 (24)	61.5 (26)
Fobi M 2005, n=514[26]	73.5 (514)	78.2 (475)	77.7 (450)	77.0 (401)	75.7 (354)	74.7 (327)	73.7 (299)	72.5 (194)	72.2 (64)	
Mean	76.4	79.3	76.2	74.7	73.4	70.2	66.9	68.8	63.8	61.5
Sum of N	779	678	616	516	498	382	334	231	88	26
Weighted mean	**75.4**	**78.8**	**76.9**	**76.0**	**74.7**	**73.4**	**72.3**	**71.3**	**67.6**	**61.5**
No of studies reporting, n	2	2	2	2	3	2	2	2	2	1

Table 3. %EWL after Lap-Band® (LAGB*) and Obtech band (SAGB*)

Author year, n, operation	Time (years) of follow-up (n) 1	2	3	4	5	6	7	8
Belachew 2002, n=763, LAGB[27]	40	50	55					
Biertho 2005, n=824, SAGB[28]	29	41.5	47 (593)	51 (380)	55 (184)			
Ceelen 2003, n=625, LAGB-SAGB[29]	45.8	49.9	47.4					
Dargent 2004, n=1180, LAGB[30]	49 (696)	56 (573)	57 (434)	57 (321)	54 (190)	49 (86)	50 (14)	
Fox 2003, n=105, LAGB[31]	61 (50)	75 (37)	72 (24)	60 (7)				
Frigg 2004, n=295, LAGB[32]	40 (243)	46 (200)	47 (155)	54 (98)				
Greenslade 2004, n=273, SAGB[33]	42.9	53.7	60.15	64.0	48.0			
Holloway 2004, n=504, LAGB[34]	50 (489)	61 (469)	65 (469)					
Jan 2005, n=154, LAGB[35]	36	45	57					
Mittermair 2003, n=454, SAGB[36]			72					
O'Brien 2002, n=709, LAGB[37]	47 (492)	52 (333)	53 (264)	54 (108)	57 (30)	57 (10)		
Ponce J 2005, n=1014, LAGB[38]	40.5 (668)	52.9 (240)	62.0 (68)	64.3 (12)				
Steffen 2003, n=824, SAGB[39]	29.5 (821)	41.1 (744)	48.7 (593)	54.5 (380)	57.1 (184)			
Suter 2005, n=180, SAGB[40]	45.0 (178)	57.1 (171)	63.9 (172)					
Vertruyen 2002, n=543, LAGB[41]	38 (405)	61 (372)	62 (261)	58 (123)	53 (52)		52 (15)	
Victorzon 2002, n=110, LAGB[42]	45 (71)	52 (59)	53 (26)					
Weiner 2003, n=984, LAGB[43]								59.3 (100)
Zinzindohoue 2003, n=500, LAGB[44]	42.8 (343)	52 (185)	54.8 (45)	62.1 (6)				
Mean	42.6	52.9	57.5	57.9	54.0	53.0	51.0	59.3
Sum of N	4456	3383	3104	1435	640	96	29	100
Weighted mean	**42.0**	**52.7**	**54.8**	**54.5**	**55.2**	**49.8**	**51.0**	**59.3**
No of studies reporting, n	11	11	12	9	5	2	2	1

*LAGB = Lap-Band; SAGB = Obtech band.

Table 4. %EWL after BPD and the DS variant

Author year, n	Time (years) of follow-up (n) 1	2	3	4	5	6	7	8	9	10
Anthone 2003, n=701[45]	69 (333)		73 (71)		66 (50)					
Bajardi 2000, n=142[46]	65	62	61		63		60			
Baltasar 2001, n=125[47]	70.1 (96)	75 (75)	75 (64)	81.2 (54)	81.4 (32)					
Dolan 2004, n=134[48]	64.1	71	72.1							
Hess 2005, n=440[49]	73.5 (345)	80.5 (264)	78.5 (187)	77.5 (132)	74.5 (92)	62 (51)	69 (29)	68 (11)		
Scopinaro 1998, n=1356[3]	74 (1284)		75 (1092)		75 (785)		76 (394)		77 (122)	
Nanni 2005, n=122[50]	76 (122)		75 (88)							
Mean	69.6	72.5	72.4	77.9	71.2	68.5	69.0	72.0		77.0
Sum of N	896	1623	410	1278	174	836	89	405	0	122
Weighted mean	**71.8**	**75.1**	**76.3**	**75.5**	**73.3**	**74.2**	**69.0**	**75.8**		**77.0**
No of studies	4	3	4	3	3	2	1	2		1

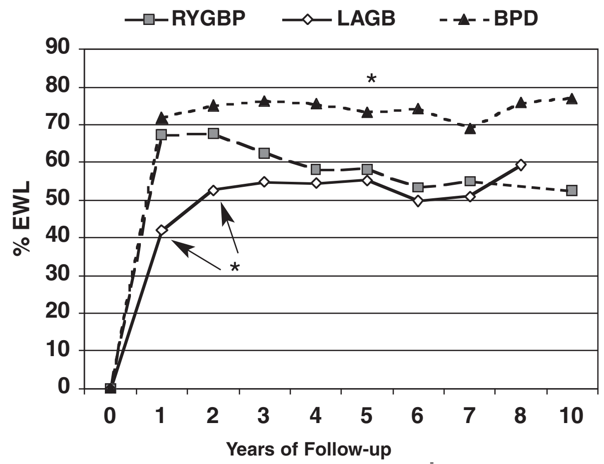

Figure 2. %EWL for LAGB, standard RYGBP and BPD and its DS variant (* P<0.05).

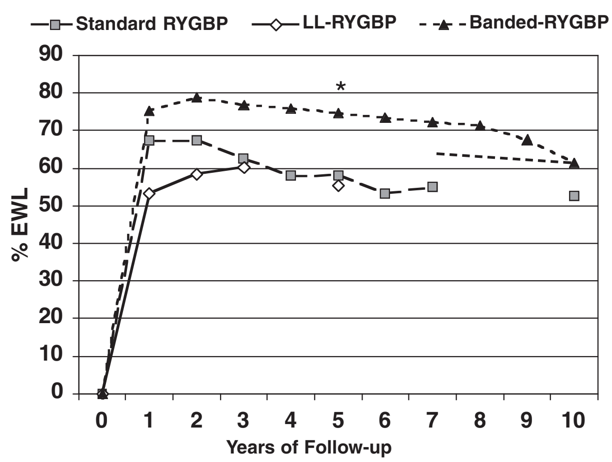

Figure 3. %EWL for standard RYGBP and its two hybrid forms of LL-RYGBP and Banded RYGBP (* P<0.05).

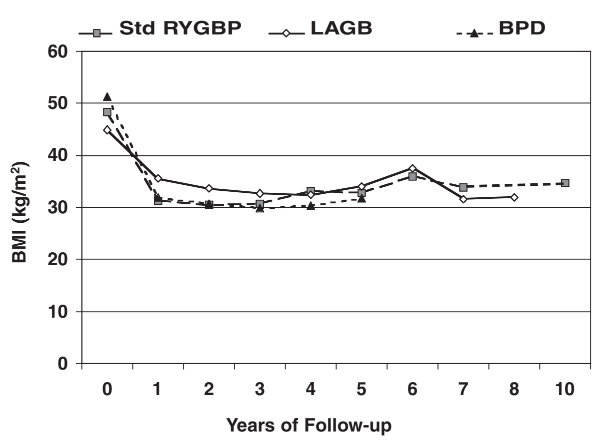

Figure 4. Changes in BMI for LAGB, standard RYGBP and BPD.

around 50 %EWL by 10 years. After LAGB placement there is a gradual progression of weight loss for the first 3 years followed by stable levels of weight loss out to 8 years (Table 3). No fading of effectiveness is evident. There were fewer studies of the Obtech® band than the Lap-Band®, and they only provide data up to 5 years but show no differences in effect (Table 3). RYGBP has generated statistically significantly more weight loss at 1 and 2 years compared with LAGB (P<0.05). However, by 3 years there is no difference, and this lack of difference persists through 8 years.

Table 4 shows the weight lost after BPD and its DS variant. There are no differences at any time point between the two, and so the data are pooled in Figure 2 which shows their effect in comparison to Std RYGBP and LAGB. The weight lost is statistically significantly greater for BPD at 5 years but at no other point.

Figure 3 shows the changes in %EWL for standard RYGBP (Table 1) and its hybrid forms – Banded RYGBP and LL-RYGBP (Tables 2A and 2B). The LL-RYGBP is not different from the RYGBP in the first 5 years. No further data are available for this option after 5 years. The Banded RYGBP appears to retain effectiveness better than the RYGBP, with the %EWL being significantly greater at 5 years for this group (P<0.05). There are no statisically significant differences beyond the 5-year time point. As each point beyond 5 years is based on data from two or one study (Table 1), more data are required to confirm that Banded RYGBP generates more weight loss in the medium term than standard RYGBP.

Fewer reports provided information on change in BMI. The changes in BMI reflect the changes described for %EWL, but there are no significant differences in the initial BMI or subsequent levels between the three principal groups of procedures. No operation has achieved a sustained reduction below 30 kg/m^2 (Figure 4).

Discussion

The most important single observation to be drawn from these meta-analyses is that pooled data of all operations demonstrates that bariatric surgery can achieve a major reduction in weight which is sustained for at least 10 years (Figure 1). Each of the principal groups of procedures show at least 50% of excess weight lost. No other therapy for obesity in use today could approach this degree of weight loss over such a period of time.

BPD appears to have the most effect on weight, with a mean weight loss for the 8-year period from year 3 to years 10 of 74.4 %EWL. Mean weight loss for RYGBP for the same 8 years and for LAGB for the 5 years available are 56.6 and 53.1 %EWL respectively. When compared with LAGB, RYGBP caused significantly greater weight loss at years 1 and 2 but there were no differences during the 3-10 year period which was the focus of this study. The amount of weight lost after RYGBP shows a fading pattern from year 2 onwards, and longer follow-up will be important to confirm that it does not become significantly less than the other two groups of procedures beyond 10 years. It is possible that the hybrid procedure of Banded RYGBP is more effective than either the band alone or RYGBP. Certainly, there is a significantly greater effect at year 5 but not at other data points. Additional data will be valuable in clarifying this possibility.

There are several important limitations to this study. First, and of greatest concern, is the general lack of information on the percent of patients lost to follow-up. With effort, follow-up of 98% can be achieved after 7 years.[37] Loss to follow-up has been regarded as an indicator of failure in both randomized controlled trials and observational studies.[9,37] When an unknown but potentially large number of the initial group are missing, the interpretation of final outcome is very difficult. If authors provide the percent of patients who are lost to follow-up, at least some approximate estimate of impact on available data can be made. Provision of data on loss to follow-up should be a strict editorial requirement for bariatric surgical reports on outcomes.

Secondly, the number of reports available for inclusion in this study was disappointingly low. RYGBP has been in use in its standard form for nearly 40 years and yet only 12 published papers have fulfilled the inclusion criteria. Six additional papers were available on the hybrid forms of RYGBP. BPD has been in use for 30 years and 7 papers were available. In contrast, LAGB has been in clinical use for just over 10 years and yet contributed 18 refereed papers to the review. The lack of medium-term data may reflect increasingly serious loss to follow-up with time or a bias towards reporting positive rather than negative findings.

Thirdly, the single outcome measure of this study has been weight lost, as reflected in %EWL or change in BMI. Weight loss is a sum of fat loss and loss of fat-free mass, principally through loss of muscle. In a study by Valera-Mora et al,[51] fat-free mass was shown to comprise >50% of the weight loss in men after BPD. Similarly, a study of RYGBP patients showed that fat-free mass loss comprised 40% of weight lost,[52] and in a study of LAGB patients 33% of weight lost was fat-free.[53] The variation in the proportion of weight loss consisting of fat-free mass after bariatric surgery suggests that if the results of loss of fat mass alone were used, there may be no significant differences between the interventions. In reporting the beneficial effects of bariatric surgery, we should seek to express these benefits as accurately as possible. The documentation of ratio of change in fat mass to muscle mass should ideally become a standard part of reporting weight loss. There are other important outcomes of bariatric surgery, including early complications and deaths, late revisional surgery, nutritional deficiencies, improvements in health and quality of life, and increased survival associated with weight loss. This review has not sought to include those end-points.

A further limitation is the frequent lack of information of the number of patients at each data point. Without such information, our ability to understand, interpret or conduct meta-analyses is blocked. It should be an editorial requirement that, when providing a mean of a group of observations, the number of observations be stated.

Because of these limitations, we have to be guarded in the conclusions drawn from this systematic review. We can state that all current bariatric operations achieve a major and durable weight loss in the medium term. When compared with RYGBP and LAGB, it is probable that BPD achieves greater weight loss and it is possible that the hybrid procedure of Banded RYGBP achieves greater weight loss also. RYGBP achieves greater weight loss than LAGB at years 1 and 2, but there is no difference beyond 2 years. The fading effectiveness of RYGBP during the medium term is of particular concern.

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