Long-Term Outcomes After Bariatric Surgery

Fifteen-Year Follow-Up of Adjustable Gastric Banding and a Systematic Review of the Bariatric Surgical Literature

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Objective: To describe the long-term outcomes after laparoscopic adjustable gastric banding (LAGB) and compare these with the published literature on bariatric surgery.

Background: Because obesity is a chronic disease, any proposed obesity treatment should be expected to demonstrate long-term durability to be considered effective. Yet for bariatric surgery, few long-term weight loss data are available. We report our 15-year follow-up data after LAGB and provide a systematic review of the peer-reviewed literature for weight loss at 10 years or more after bariatric surgical procedures.

Methods: We performed a prospective longitudinal cohort study of LAGB patients using an electronic database system (LapBase) to track progress, measure weight changes, and document revisional procedures. The evolution of the LAGB procedure was recognized, and revisional rates for 3 separate periods between September 1994 and December 2011 were described. In addition, we performed a systematic review of the peer-reviewed published literature collecting all reports that included weight loss data at or beyond 10 years.

Results: A total of 3227 patients, with a mean age of 47 years and a mean body mass index of 43.8 kg/m^2, were treated by laparoscopic adjustable gastric band placement between September 1994 and December 2011. Seven hundred fourteen patients had completed at least 10 years of follow-up. Follow-up was intact in 81% of patients overall and 78% of those beyond 10 years. There was no perioperative mortality for the primary placement or for any revisional procedures. There was 47.1% of excess weight loss (% EWL) at 15 years [n = 54; 95% confidence interval (CI) = 8.3] and 62% EWL at 16 years (n = 14; 95% CI = 13.6). There was a mean of 47.0% EWL (n = 714; 95% CI = 1.3) for all patients who were at or beyond 10 years follow-up. Revisional procedures were performed for proximal enlargement (26%), erosion (3.4%), and port and tubing problems (21%). The band was explanted in 5.6%. The need for revision decreased as the technique evolved, with 40% revision rate for proximal gastric enlargements in the first 10 years, reducing to 6.4% in the past 5 years. The revision group showed a similar weight loss to the overall group beyond 10 years. The systematic review of all bariatric procedures with 10 or more years of follow-up showed greater than 50% EWL for all current procedures. The weighted mean at maximum follow-up for LAGB was 54.2% EWL and for Roux-en-Y gastric bypass was 54.0% EWL.

Conclusions: The LAGB study from 1 center demonstrates a durable weight loss with 47% EWL maintained to 15 years. This weight loss occurred regardless of whether any revisional procedures were needed. A systematic review shows substantial and similar long-term weight losses for LAGB and other bariatric procedures.

Keywords: 15-year follow-up, gastric bypass, LAGB, long-term outcomes, RYGB

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Obesity is a chronic disease. Any weight loss therapy should be shown to be durable before it can be judged to be effective. However, studies of nonsurgical options for the treatment of obesity rarely extend beyond 12 months. Bariatric surgical procedures are known to achieve substantial weight loss and major secondary health benefits, but the durability of these effects remains to be firmly established. There has been ample time to generate long-term follow-up data. Bariatric procedures began more than 50 years ago with the introduction of the jejunoileal bypass. Roux-en-Y gastric bypass (RYGB) was introduced 44 years ago in 1967,[1] biliopancreatic diversion (BPD) was introduced 35 years ago,[2] and laparoscopic adjustable gastric banding (LAGB) 17 years ago.[3] Yet, most of the bariatric surgical literature contains data on short-term follow-up only (<3 years). One prominent systematic review included only 12-month follow-up data,[4] whereas others have provided data up to 4 years[5,6] and 1 extends to 8 years.[7] In a systematic review of bariatric surgical reports with medium-term follow-up (3–10 years), which we published in 2006,[7] a total of only 43 reports were identified.

There is a need for long-term follow-up (>10 years) data if we are to assure our patients, medical colleagues, and payers that bariatric surgery offers an effective sustainable treatment option for obesity. An assurance of at least a 10-year effect for any bariatric procedure should be a requirement for its eventual broad acceptance.

We commenced the LAGB procedure in September 1994 and have attempted to track all patients treated since that time by using a dedicated bariatric surgery database (LapBase). In this report, we seek to define the long-term outcomes after LAGB with respect to weigh loss and the need for revisional surgery or reversal of the procedure by examining our experience with this group of patients. The study period commenced soon after the introduction of the LAGB, and so the study also serves to illustrate the evolution of our knowledge regarding the procedure, its techniques, and optimal patient advice and care during the follow-up period.

In addition, the requirement for revisional procedures and the weight loss outcomes after these revisions has been studied. In previous studies, we have reported on techniques,[8] perioperative outcomes,[9,10] short-term (<3-year follow-up) outcomes,[9] and

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medium-term (<10-year follow-up) outcomes.[10] We have previously reported changes in comorbidities in 3 randomized controlled trials (RCTs)[11–13] and several observational studies.[14] We have also documented improvement both in quality of life[11] and in survival.[15] As these important issues have been comprehensively examined in earlier studies using robust research methodology, we will not consider them in this observational study.

We further aim to compare these outcomes with existing published reports of long-term follow-up after bariatric surgery through a systematic review of the literature.

METHODS

Longitudinal Cohort Study

Study Design and Setting

We performed a prospective longitudinal cohort study of all patients having the LAGB procedure by 2 surgeons (P.E.O'B. and W.A.B.) through the Centre for Bariatric Surgery in Melbourne, Australia, during a 17-year period between September 1994 and December 2011. All follow-up data available at November 30, 2011, were included.

Participants

Patients were selected for the LAGB program if they fulfilled each of the following 4 criteria: They were obese [body mass index (BMI) >30 kg/m^2]; they were suffering medical, physical, or psychosocial problems due to obesity; they had tried for several years to control their obesity by lifestyle changes; they showed an understanding of the potential benefits and risks of the LAGB procedure and they agreed to fulfill their part in a partnership. This required that they endeavor to follow the rules regarding eating, exercise and activity, and commit to returning permanently to the aftercare program. Patients having LAGB as a revisional procedure for failure or side effects of another bariatric procedure have not been included in the present study. Ethical approval to carry out this research was obtained from The Avenue Hospital Ethics Committee in accordance with the National Health and Medical Research Council guidelines.

Data Sources

At the time of laparoscopic adjustable gastric band placement, each patient was entered onto an electronic medical record (LapBase; LapBase Pty Ltd, Melbourne, Australia) developed specifically for the optimal tracking and aftercare of bariatric surgical patients. At each visit, weight was measured and change in weight, change in BMI, and percentage of excess weight lost (% EWL) were calculated and stored. Other clinical data, barium swallows, letters, and reports were also stored. Aftercare visits occurred mainly through the principal clinic of the Centre for Bariatric Surgery or at 4 satellite clinics that the Centre for Bariatric Surgery operates across Melbourne. Some patients from rural areas of Victoria were followed up by a panel of trained rural general practitioners. Patient data were entered contemporaneously into the Web-based LapBase from all clinical centers. We defined loss to follow-up as an absence from the clinic for more than 24 months. All patient data were included up to the last recorded visit. No values were carried forward to replace missing data.

Outcome Measures

The principal end points were weight loss and revisional surgery. Weight was measured in kilograms to 1 decimal point at each clinic visit, using a calibrated electronic scale. Height was measured on entry into the program, using a stadiometer. No self-reported weight data were included. BMI and % EWL were calculated within LapBase. Excess weight was taken as the weight in kilograms above the weight at BMI of 25 kg/m^2. Revisional surgery included all procedures for correction of proximal enlargements above the band, including anterior and posterior prolapse and symmetrical enlargements, erosions of the band into the stomach, and all procedures for access port and tubing defects. All revisional procedures were recorded within LapBase.

Evolution of Technique and Impact on Revisional Surgery

All procedures undergo evolution as the techniques become refined, the understanding of mechanisms improves, and as we learn from and adjust our technique based on observation of early unfavorable outcomes. LAGB began in the early 1990s. Key changes have occurred in the band itself, the surgical placement technique, and the aftercare process during the 17-year period. These are listed in Table 1. Three distinct periods of development can be identified. To analyze the effect of this evolution over time, the measurement of revisional procedures was divided into 3 groups: the first, group 1, is the "perigastric era," which began with the introduction of the LAGB in 1993 (Ref. 3) and continued until 2000. Group 2, the "pars flaccida era," which commenced with a change in 2001 to this pathway, based on the findings of a RCT that showed almost complete avoidance of posterior prolapse by the new approach.[16] The final period was the "AP band era," which commenced in 2006 with the introduction of the LAP-BAND AP system and continues to the present time.

Systematic Review of the Literature

Search Strategy

The review was conducted and reported according to MOOSE (Meta-analysis of observational studies in epidemiology) guidelines.[17] Relevant literature was identified by searching electronic databases (including PubMed, EMBASE, Cochrane Database, and Ovid MEDLINE) up to November 1, 2011. Search terms used were as follows: laparoscopic adjustable gastric banding, LAGB, Swedish adjustable gastric banding, SAGB, gastric bypass, Roux-Y gastric bypass, Roux-en-Y, GBP, biliopancreatic diversion, BPD, duodenal switch, and bariatric. Additional search terms (10 years, longitudinal, 10-year follow-up, and long term) were also added to each of these main search terms in order to ascertain the most relevant research for our purposes. Furthermore, journals that are relevant to bariatric surgery research, such as *Obesity Surgery*, *Surgery for Obesity and Related Disorders*, and *International Journal of Obesity*, were searched directly. No attempt was made to contact authors directly.

Eligibility Criteria

We included only peer-reviewed full-text articles published in English. To be included, studies had to provide data on weight loss outcomes at 10 years or more after the initial procedure. The articles were also required to report the number of patients at the relevant final follow-up time point and to have at least 10 patients at that point. For example, if a report had only 3 patients at 14 years and 25 patients at 12 years, the 12-year data would be included. The weight loss data had to be expressed as % EWL, or the article had to provide sufficient data, such as weight and BMI, for the % EWL to be calculated. For this calculation, excess weight was defined as the weight in kilograms above BMI 25 kg/m^2.

In addition, the following data were sought in each article: the number of patients initially treated, the number of patients at the final follow-up time point, the percentage of patients lost to follow-up, and the reversal and revision rates. However, articles were not excluded if 1 or more of these elements were missing. For multiple publications of the same data, only the most recent report was included. Two reviewers, each experienced in systematic analysis of the literature, reviewed each study and resolved disagreements by consensus.

TABLE 1. The Evolution of the Adjustable Gastric Banding Procedure

	Initial	Current
The band	Incomplete encirclement of cardia	Complete encirclement of cardia
	Creases form with higher volumes	Noncreasing with higher volumes
	Narrow "footprint"	Wide "footprint"
	High pressure	Low pressure
	Basal volume: 0 mL	Basal volume: ~ 3 mL
	Could not be easily reopened	Easily reopened if required
Concept of mechanism	Restrictive with food stasis above the band generating "fullness"	Satiety induced by esophagus squeezing each bite through. No restriction with optimal eating
Site of the band	3 cm below E-G junction	1 cm below E-G junction
	Measured with a measuring rod	Measured with a calibrating balloon
	X-ray: true pouch present	X-ray: virtual pouch present
Diaphragmatic esophageal hiatus	Rarely dissected	Commonly dissected, hernia reduced, and crura approximated
Greater curve dissection	Just above the highest short gastric vessel	At the angle of His
Lesser curve dissection	Perigastric pathway	Pars flaccida pathway
Anterior fat pad	Band overlays fat pad	Fat pad undercut or excised
Anterior fixation	Designed to create a 15- to 25-mL pouch	Designed to create a "virtual" pouch
	2–3 sutures centrally	3 sutures from greater curve plus lesser curve suture
Initial band volume	Based on gastrostenometer	Semistandard initial volume
		3.0–4.5 mL for APS band.
Access port	Placed within rectus abdominis	Fixed to anterior rectus sheath
Postoperative length of stay	2–3 d	2–3 h
Aftercare process	Focus on "fills"	Clinical consultation ± adjustments
Patient education	Very limited	Extensive
		Partnership concept
		Based on achieving satiety
Band adjustments	Performed with x-ray control	Performed in office
	Volume determined by barium swallow appearance	Volume determined by weight loss, appetite, and symptoms

APS indicates Lap-Band AP system; E-G, esophagogastric.

Data Analysis

Patient data for weight loss (kg), change in BMI, and % EWL were summarized using descriptive statistics and expressed as means ± 95% confidence intervals (CIs). In the cohort study, hypotheses were not tested and thus inferential statistics were not required. However, weight loss at 2 years was compared between those who had revisional surgery and the background group, using a 2-sided *t* test. A *P* value of less than 0.05 was accepted as significant.

For the systematic review, the methodological limitations and incomplete reporting of data in identified articles prohibited the use of meta-analyses. Instead relevant were summarized in tables, and weighted means were calculated to provide a summary estimate of % EWL for each surgical technique.

RESULTS

Longitudinal Cohort Study

Participants

In total, 3227 patients were treated by primary laparoscopic adjustable gastric band placement. They had a mean age of 47.1 years and 78% were women. The mean initial weight was 121.7 kg, a mean height of 167 cm, and mean initial BMI was 43.8 kg/m^2 (range, 30.1–91.2 kg/m^2).

Loss to Follow-Up

There was a longer than 24-month interval since last follow-up visit for 620 patients (19%), and they were classified as lost to follow-up. Their weight loss and revisional surgery data are included up to their last visit. The number lost to follow-up increased with duration of follow-up. In total, 919 patients had completed 10 or more years of follow-up, and data beyond 10 years were available for 714 (78%) of these patients. However, as the frequency of visits is fewer, 73% were seen in the last 36 months and 62% were seen in the past 24 months.

Perioperative and Late Mortality

There were no deaths associated with either the primary laparoscopic adjustable gastric band placement or any subsequent revisional procedure. There have been no late deaths attributable to the procedure. A detailed analysis of late mortality for all patients older than 37 years was published in 2007.[15] There was ascertainment of vital status in 98.6% of patients. There were 4 deaths in 966 patients who had been followed up for a total of 3478 patient-years. These were due to cancer (n = 2), suicide (n = 1), and heart disease (n = 1).

Weight Loss

The weight loss over time, expressed as % EWL, is shown in Table 2 and Figure 1. There was 50.5% EWL at 3 years (n = 2596), 49.6% EWL at 5 years (n = 1983), 47% EWL at 10 years (n = 714), 47.5% EWL at 12 years (n = 343), 47.2% EWL at 15 years (n = 54), and 62% EWL at 16 years (n = 14). At 15-year follow-up, 26 patients (48%) had lost more than 50% of their excess weight, 15 had lost 25% to 50%, and 13 had lost less than 25%. The calculations of % EWL were based on kilograms of weight above BMI 25 kg/m^2 as excess weight.

The 95% CIs widen markedly as the sample size falls (Table 2). To reduce the dependence on the variability for a small number of patients at longest follow-up, the final weight loss data on all patients who had completed between 10 and 15 years of follow-up

TABLE 2. % EWL to 16 Years for the Total Group of Patients and for the Subgroup of Patients Who Had a Revisional Procedure

	Total Group			Revisional Surgery Group		
Years of Follow-Up	No. Patients	% EWL	95% CI	No. Patients	% EWL	95% CI
0.5	3132	35.3	0.70	724	39.1	1.3
1	3017	46.1	0.82	722	53.7	1.5
1.5	2941	49.9	0.90	721	58.8	1.7
2	2784	51.8	1.04	720	59.5	1.8
3	2596	50.5	1.12	717	56.6	1.9
4	2312	50.5	1.30	701	54.5	2.1
5	1983	49.6	1.41	677	53	2.3
6	1671	47.9	1.53	626	52.1	2.5
7	1372	47.9	1.59	549	50.4	2.5
8	1122	48.0	1.76	477	48.8	2.7
9	887	46.7	1.84	386	48.3	2.7
10	714	47.2	2.20	329	49.1	3.0
11	522	46.0	2.66	252	46.7	3.7
12	343	47.5	3.49	183	48.2	5.2
13	234	47.0	3.84	135	47.1	4.9
14	129	48.6	5.52	86	46.3	6.3
15	54	47.2	8.27	41	47.1	9.8
16	14	62.2	13.62	13	58.8	17.9
17	4	60.0	8.3	4	51.2	29.4

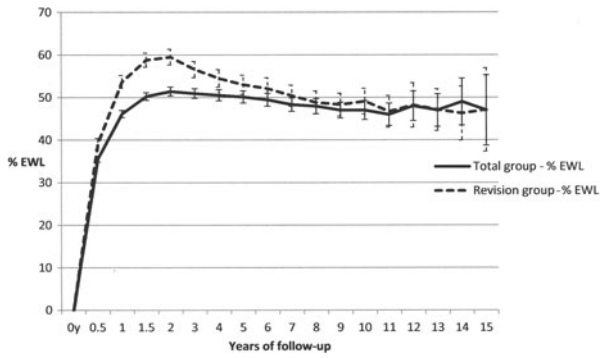

FIGURE 1. The % EWL with 95% CIs for the 15-year period of follow-up after LAGB. The continuous line shows the pattern of weight loss for the complete group. The dotted line shows the weight loss for those within that group who had revisional surgery.

were calculated. The mean weight loss for this long-term follow-up period (≥10 years) was 25.5 kg, which represents 47.1% EWL with 95% CI of 1.31. This weight loss value agrees closely with the values shown in Figure 1 for each of the follow-up years 10 to 15.

Revisional Surgery

Table 3 provides data on all band-related revisional procedures throughout the study period. The incidence of revision has decreased most clearly with the introduction of AP series of bands. Although change to the pars flaccida approach virtually removed the posterior slip, the total number of proximal enlargements remained constant until introduction of the new form of band in the third era. The mean time to revision had been 36.5 months. Erosions occurred in 8.5% of group 1, 2.2% of group 2, and 0.8% of group 3. The clinical features and outcomes in the erosion group are detailed in a recent publication.[18]

The long-term weight loss of the patients who had revisional procedures for proximal enlargements or erosions was not different from that of the overall study group (Fig. 1 and Table 2), indicating that revision with replacement of the band rather than conversion to another procedure does not seem to compromise the ongoing weight loss status. The 95% CIs listed in Table 2 indicate that a significantly greater weight loss occurred during years 1 to 4 of the follow-up from the primary procedure in those who had a revision than in the overall group. Most revision patients had removal and replacement of the LAGB. We could identify 23 patients who were converted by ourselves or other surgeons to an alternate bariatric procedure. Additional conversions may have occurred in the group that we have lost to follow-up.

The changing incidence of revision for proximal gastric dilatation is shown in Table 3, which shows the proportion of patients needing revision for each of the 3 eras. This includes procedures for posterior prolapse, anterior prolapse, and symmetrical enlargements. There has been a progressive decrease, with the most prominent reduction associated with the introduction of the LAP-BAND AP system after 2006. There has been no revision required to date for any of the patients treated in the past 3 years. The weight loss pattern during 15 years for the revision group is compared with that of the total group, as shown in Figure 1. The revision group (n = 1116) showed better weight loss in the early years after the band placement with a mean (SD) of 56.1 (24.6) % EWL at 2 years (n = 1116) than 51.4 (25.3) in the total group (N = 3125). This difference is significant ($t_{4239} = 5.3$; $P < 0.001$). Beyond 4 years, there was no difference.

Explantation of the band was reported in 181 (5.6%) of the patients. The commonest reason was patient request (n = 57; 31%), usually associated with symptoms of reflux or heartburn without evidence of obstruction or delay (n = 35). In addition, there was a group of 22 patients who sought removal because they were content with their current status and confident of the future without the band. In 38 patients (21%), there had been an erosion of the band and they chose not to have it replaced. Recurring symptoms of proximal gastric enlargement led to explantation in 25 patients (15%). Other reasons included infection at the band or access port site (n = 13) and poor weight loss (n = 27). No reason could be identified in our record in 21 patients who had their band removed by another surgical group.

TABLE 3. Total Revisional Procedures During the Follow-Up Period

	Total Period (1994–2011; N = 3227)	Perigastric Era (1994–2000; N = 931)	Pars Flaccida Era (2001–2005; N = 926)	LAP-BAND AP Era (2006–2011; N = 1370)
Enlargements	840 (26%)	375 (40%)	377 (41%)	88 (6.4%)
Erosions	110 (3.4%)	79 (8.5%)	20 (2.2%)	11 (0.8%)
Port/tubing	666 (21%)	281 (30%)	304 (33%)	81 (5.9%)
Explantations	181 (5.6%)	92 (9.9%)	59 (6.4%)	30 (2.2%)

The patients having explantation could also be represented in the enlargements or erosion values if the adverse event led to the explantation. Patients with erosion who had explantation and later replacement of the band are not included in the explantation numbers.

Systematic Review

The flow diagram of the screening process is shown in Figure 2. From a total of 36,132 articles drawn from the search, the duplication of findings by the different search engines was deleted and 5913 articles of the initial group were screened by their titles. Further screening of the abstract and then of the full-text article led to a final inclusion of 19 articles that provided 24 sets of eligible data relating to specific bariatric procedures. This included 6 sets relating to LAGB[19–24] (Table 4). The present study is also included in Table 4 for comparison. There are 9 sets relating to RYGB[25–33] (Table 5). There are 5 sets relating to gastroplasty,[19,25,30,32,34] 3 sets relating to BPD and/or duodenal switch,[35–37] and 1 set relating to fixed open gastric banding.[32] These are shown in Table 6. A summary of the reasons for exclusion is provided in Figure 2. The most common reason was the absence of weight loss outcome data at 10 or more years and the duplication of data from another study. Only 2 sets of data were excluded by having fewer than 10 patients in the final study group.[38,39] Three studies were excluded on the basis of having weight loss data that could not be expressed as % EWL.[40–42]

There were no RCTs. The Swedish Obese Subjects (SOS) study was a prospective, nonrandomized, matched, interventional study. All other studies were observational and were either prospective or retrospective cohort studies.

All studies had deficiencies in data reporting. For most articles, there was inadequate information regarding patient selection and data management. The methods for obtaining follow-up data were usually not mentioned or were acknowledged to be by remote means such as a telephone call rather than direct clinic measurement. The method for estimating % EWL was not defined in 12 reports and was based on the Metropolitan Life scale in 5 reports, and other methods were used for 4 reports. A definition for lost to follow-up was generally not provided, and although the total loss to follow-up was usually provided, no study informed specifically about the lost to follow-up rate of those at 10 or more years. The reported percentage of follow-up varied widely from a lowest value of 29% at 10 years in 1 US data set[33] to a level of 97% at 14 years claimed in another US data set.[27]

Some qualifications of the data in Table 5 are required. Two studies did not provide % EWL data but expressed the weight loss as BMI[26] or as percentage of total weight lost and kilograms of weight loss.[32] To compare these outcomes with the present study and others, conversion to % EWL was performed using the published initial BMI, weight, and height data. The gastric banding procedure of the SOS study,[32] as shown in Table 6, was not the LAGB but a different operation that was used briefly during the 1980s in which a fixed band was placed to create an hour-glass stomach.[43] The LAGB was introduced later in the SOS study and their follow-up has not exceeded 10 years. The RYGB reported by White et al[29] was a banded bypass that involves placing a nonadjustable band around the mid portion of the proximal gastric pouch.[44] Although the methods for calculating the % EWL were generally not provided, depending on the patient

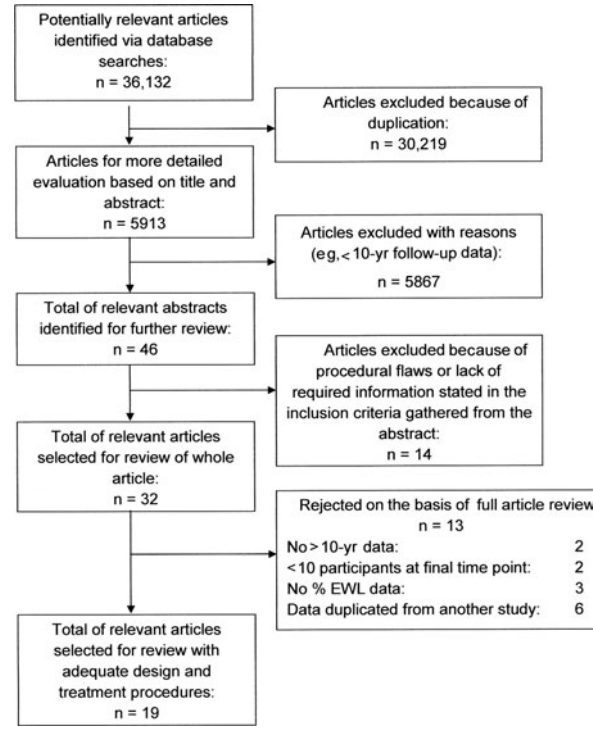

FIGURE 2. The flow diagram for the systematic review.

characteristics, a lower value for % EWL may be obtained if the Metropolitan Life scale was used.

The systematic review confirmed the safety of LAGB, with 1 death in a total of 6177 patients. A summary of the pooled data from the systematic review is provided in Table 7. The weighted mean weight loss reported in these series was 54.2% EWL, with a range of 33% to 60%. The mean reported follow-up rate was 84% of patients. In comparison, the 6 RYGB series that provided perioperative mortality figures reported 21 deaths in 2684 patients (0.8%). All deaths occurred in series using open surgery. The RYGB studies reported a weighted mean weight loss of 54.0% EWL (range, 27%–68%) and a mean follow-up rate of 71%. Although definitive comparison is not possible because of the numerous defects within most studies and the heterogeneity of the data, there is marked similarity in the long-term weight loss effect of the RYGB and LAGB. However, perioperative mortality was significantly greater with RYGB ($P < 0.001$; χ^2 with the Yates correction), all deaths being associated with open surgery.

The need for revisional procedures was not different between RYGB and LAGB. The median rate for the 6 RYGB sets that provided data was 22%, with a range of 8% to 38%. All of the LAGB reports

TABLE 4. Long-Term Studies (>10 Years) of Weight Loss After LAGB From Systematic Review

Author, Reference, and Year of Publication	Initial No. Patients	Perioperative Mortality	% Follow-Up Achieved	Longest Follow-Up, y	No. Patients at Maximum Years	Weight Loss at Maximum Years (% EWL)	Revision or Reversal, %
Miller et al[19] (2007)	554	1 (0.2%)	92	10	154	59	8
Favretti et al[20] (2007)	1791	0	91	11	28	38	19
Lanthaler et al[21] (2010)	276	0	80	10	NR	60	53
Naef et al[22] (2010)	167	0	94	10	28	49	20
Himpens et al[23] (2011)	154	0	54	12	36	48	60
Stroh et al[24] (2011)	200	0	84	12	15	33	26
O'Brien et al, present study	3227	0	81	15	54	47	43

NR indicates not recorded.

TABLE 5. Long-Term Studies (>10 Years) of Weight Loss After RYGB

Author, Reference, and Year of Publication	Initial No. Patients	Surgical Approach	Perioperative Mortality	% Follow-Up Achieved	Longest Follow-Up, y	No. Patients at Maximum Years	Weight Loss at Maximum Years (% EWL)	Revision or Reversal, %
Fobi[25] (1993)	100	Open	NR	NR	10	46	55	12
Wolfel et al[26] (1994)	143	Open	NR	71	10	83	49*	NR
Pories et al[27] (1995)	608	Open	9 (1.5%)	97	14	10	49L	38
Sugerman et al[28] (2003)	1025	Open	9 (0.9%)	37	10–12	135	52	NR
White et al[29] (2005)	342	Open	0	88	14	NR	58	27
Günther et al[30] (2006)	195	Open	2 (0.5%)	69	25	72	27	8
Christou et al[31] (2006)	274	Open	1 (0.4%)	84	12	161	68	NR
Sjostrom et al[32] (2007)	265	Open	NR	NR	15	10	66*	17
Higa et al[33] (2011)	242	Laparoscopic	0	29*	10	65	57	32

*The % EWL was calculated using BMI, weight, and height values provided in the report and excess weight being kilograms of weight above BMI of 25 kg/m^2.
NR indicates not recorded.

TABLE 6. Long-Term Studies of Weight Loss After Other Bariatric Procedures From Systematic Review

Author, Reference, and Year of Publication	Operative Procedure	Initial No. Patients	Perioperative Mortality	% Follow-Up Achieved	Longest Follow-Up, y	No. Patients at Maximum Years	Weight Loss at Maximum Years (% EWL)	Revision or Reversal, %
Fobi[25] (1993)	VBG	100	NR	NR	10	43	44	12
Hess et al[35] (2005)	BPD/DS	1300	8 (0.6%)	92	10	167	75	3.4
Scopinaro et al[36] (2005)	BPD	312	NR	78	10	243	73	NR
Günther et al[30] (2006)	G/P	33	0	79	20	18	−10	NR
Sjostrom et al[32] (2007)	VBG	1369	NR	NR	15	108	44*	21
Sjostrom et al[32] (2007)	Fixed open banding†	376	NR	NR	15	10	32*	31
Miller et al[19] (2007)	VBG	563	2 (0.4%)	92	10	154	62	40
Larrad-Jiménez et al[37] (2007)	BPD	343	3 (0.3%)	68	10	65	70	NR
Scozzari et al[34] (2010)	VBG	266	0	70	10	150	60	10

*The % EWL was calculated using BMI, weight, and height values provided in the report and excess weight being kilograms of weight above BMI of 25 kg/m^2.
†All patients at long-term follow-up treated as gastric banding were of the fixed band placed at open surgery.
DS indicates duodenal switch; G/P, gastroplasty; NR, not recorded; VBG, vertical banded gastroplasty.

TABLE 7. Pooled Data From Systematic Review With Weighted Mean % EWL for the Principal Procedures

Procedure	No. Reports	Weighted Mean % EWL	Range of % EWL	Revision Range, %
RYGB	9	54.0	28–68	8–38
LAGB	7	54.2	33–64	8–60
Gastroplasty	5	52.9	−10 to 62	10–40
BPD/DS	3	73.3	70–75	—

DS indicates duodenal switch.

provided data on revisional surgery. The median value was 26%, with a range of 8% to 60%. Almost no details of the type of revisional procedures have been provided so that a more detailed analysis is not possible.

DISCUSSION

The longitudinal cohort study of the LAGB patients shows that they have achieved and maintained a loss of nearly half of their excess weight to 15 years. The validity of 15-year figure of 47% of EWL (n = 54) is reinforced by the pooling of all long-term data (≥10 years) and finding the same weight loss of 47% EWL for the much larger group (n = 714; data on 78% of original group available) with narrow CIs. After reaching a peak weight loss at 2 years, there is a high degree of stability of the weight loss status through the next 13 years, a possible reflection of the benefit of continued ability to achieve satiety through adjustability by the compression of the gastric cardia.[45]

This effect has been achieved safely, with no perioperative mortality for the primary procedure or for any revisional procedures. From the systematic review, the relative safety of LAGB versus RYGB is confirmed and supports existing published data.[5,6,46]

The systematic review serves to emphasize the clinical value of all current bariatric procedures. With a weighted mean of more than 50% EWL at 10 or more years, bariatric surgery far exceeds the effectiveness of nonsurgical weight loss programs in terms of long-term effectiveness, a key requirement for treating a chronic disease such as obesity.

It is inevitable that there will be small numbers at the outermost follow-up point in any longitudinal study of a clinical practice. The potential bias linked to this should be recognized and managed. We have tried to manage this by providing 95% CI values, by providing data on loss to follow-up, specifically for the long-term follow-up group, and by showing the weight loss pattern for each of the years. With pooling of the data for all patients beyond 10 years, we can see whether the group data differ from annual data. This latter analysis showed consistent pattern of weight loss until the 16th year when just 14 patients were included and a 62% EWL was present but with 95% CIs of 13.6.

The greatest potential cause for bias when estimating long-term outcomes is through losing to follow-up those patients with the poorest responses. This bias is particularly sensitive to small numbers. Two studies from the systematic review quoted their longest follow-up at 14 and 15 years as isolated values and included just 10 patients.[27,32] One provided the 95% CI that illustrated the low level of confidence that could be attached to the data. The other provided no measure of dispersion of the data. The addition or subtraction of a single patient with 100% EWL or no weight loss would shift the mean by 10%. Furthermore, no specific data had been provided on the loss to follow-up for their long-term groups. The combination of small numbers of patients followed up, the lack of data on the denominator (the total number actually treated for that time period with the rest having been lost to follow-up), and the lack of some measure of variance of the data leaves a low reliability to any evidence of effect.

The preferred method for calculating % EWL, with excess weight defined as the number of kilograms of weight above BMI 25 kg/m^2,[47] differs from some of the studies included in the systematic review where the Metropolitan Life scale was used. The latter generates a range of "desirable" that vary according to sex, height, and BMI between the BMI values of 20 and 27 and, on average, a lower values for % EWL will be obtained.

In the 15-year study of LAGB, there has been a notable need for additional surgery due to late adverse events, with nearly half of the patients requiring 1 or more revisional procedures during the follow-up period. The systematic review indicates that the overall rate of revision may not be different between RYGB and LAGB. In treating a chronic disease such as obesity during a lifetime, it is inevitable that something will need to be corrected at some time in some patients, a fact accepted in other surgery for chronic diseases such as with joint replacements or coronary artery surgery. Although we should be attempting to minimize this need, it is realistic to expect that some revisional procedures may be required, especially in the medium or long term. Importantly, for the LAGB study group, those who had revisional surgery did not have an inferior long-term weight loss outcome when compared with the overall group. An approach in LAGB patient care that regards the need for revision as an indication to reverse the LAGB and possibly proceed with another type of bariatric procedure[48] would therefore not be supported by these findings and another recent report.[49]

For the LAGB study, there has been a notable decrease in the need for revisional procedures during the 15-year period, particularly evident in group 3 (the LAP-BAND AP era). In part, this will represent a lead time bias and the incidence of revision can be expected to increase for this group in due course. However, comparison of the time rate of presentation indicates a marked reduction. This reduced rate could be attributed to improvements in the band itself, the technique of band placement, the quality of patient education, or the improved understanding of how the band works as detailed in Table 1. All have improved with time and experience and attributing the relative contributions would not possible without specific trials. Most probably, the combination of improvements has driven the better outcome.

The quality of the literature available for the systematic review was disappointing. RYGB has been the dominant bariatric procedure for most of the last 44 years and yet only 9 reports are available providing outcome data beyond 10 years. All of these reports lacked important detail, making confident description of the real long-term effect problematic. Similar criticism could be leveled at BPD with or without duodenal switch with its 35-year history, but, as the BPD group of procedures now represent less than 2% of bariatric surgery, long-term outcome data are becoming less relevant. Five reports are available on gastroplasty, but, as this is now of historical interest only, further data are not expected.

Both the study of the LAGB cohort and the systematic review suffer from several limitations. Perhaps, most important is the potential bias from loss to follow-up. This creates a particular challenge in assessing bariatric surgical outcome, as it is likely that the bariatric surgery patients who are not doing well are the most hesitant to return for follow-up. For this reason, in our RCTs, beginning with a trial of RYGB and other stapling procedures in the 1980s,[50] we have included loss to follow-up as a part of the definition of failure. To minimize the loss to follow-up in the present study, all patients were provided with their next appointment at each visit. If this appointment was missed, another appointment was set and an attempt was made to contact these patients and/or their family members. However, if this failed, further follow-up was often dependent on the patient restoring contact. The rate of 81% in the present study is a generally accepted as good. In the systematic review, reported rates varied from 29% to 97%, the latter figure being surprisingly high for a US population during 14 years.

It was not possible to perform meta-analyses of the studies identified by systematic review because of the absence of RCTs and the heterogeneity of the observational studies. All studies contained differences of design, rates of loss to follow-up or lacking key information on follow-up, differences in or nonreporting of the characteristics of the study subjects, and differences in the types of surgical interventions and detail of their application.

The generalizability of the LAGB outcomes needs to be considered. Is the present study showing a particular outcome unique to Australia? We do not believe it is. All reports included in the

systematic review are derived from European groups, and the Australian data are in the mid-range of all of these data. Because the LAGB was not introduced to the United States until 2001, no 10-year data can be expected from US groups at this time. However, an earlier systematic review of medium-term outcomes reported equivalent rates of weight loss were achieved in the United States, Europe, and Australia.[7]

In conclusion, the present study of LAGB shows that, at 15 years after gastric banding, nearly half the excess weight remains lost. The earlier high frequency of late adverse events has been reduced markedly. Gastric banding is a safe and effective treatment option for obesity in the long term. The systematic review shows that all current procedures achieve substantial long-term weight loss. It supports the existing data that LAGB is safer than RYGB and finds that the long-term weight loss outcomes and needs for revisional surgery for these 2 procedures are not different.

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