Obesity Comorbidity/Treatment

Impact of laparoscopic adjustable gastric banding on type 2 diabetes

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Summary

Bariatric surgery is becoming an accepted option for obese people with type 2 diabetes. Our aim was to assess the impact of laparoscopic adjustable gastric banding (LAGB) through a systematic review of the literature. Data was sourced from Scopus, MEDLINE and EMBASE published from 2000 through May 2011, and five unpublished studies that were performed by industry for regulatory approval were also included. Studies were selected on the basis that they provide some detail of diabetes status before and after LAGB. There were 35 studies meeting the inclusion criteria. There was considerable heterogeneity in study design, sample size, length of follow-up, attrition rates and classification of diabetes status. Weight loss was progressive over the first 2 years with a weighted average of 47% excess weight loss at 2 years. Remission or improvement in diabetes varied from 53% to 70% over different time periods. Results were broadly consistent, demonstrating clinically relevant improvements in diabetes outcomes with sustained weight loss in obese people with type 2 diabetes following LAGB surgery. However, there were significant shortcomings in the reviewed literature with few high-quality studies, inconsistent reporting of diabetes outcomes and high attrition rates. Long-term studies that address these limitations are needed.

Keywords: Diabetes, gastric band, obesity, weight loss.

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Introduction

Obesity has become a global epidemic. Currently, an estimated 1.1 billion people worldwide are overweight or obese (1). Obesity prevalence rates in several countries now exceed 30% (2). The obesity epidemic is of particular concern because it increases risk for several adverse health conditions. One of the primary health hazards of obesity is diabetes. Approximately half of those diagnosed with type 2 diabetes are obese, and among the obese, risk for developing diabetes increases dramatically with increasing weight (3,4).

Although obesity is the primary cause of diabetes, research has shown that losing as little as 5–10% of body weight can prevent the onset of diabetes or result in improvements or even resolution post occurrence. Moreover, larger decreases in weight generate even greater benefits (5). However, large weight losses among the severely obese population (those with a body mass index [BMI; kg/m^2] over 35) have proven difficult to sustain through lifestyle modification. Bariatric surgery, which includes gastric bypass surgery and gastric banding, has been shown to be far more effective than medications and/or lifestyle interventions at sustaining weight loss.

A meta-analysis by Buchwald *et al.* (6) showed that persons with diabetes undergoing gastric bypass surgery lost an average of 60% of excess body weight (EWL) and that 80% of diabetes cases fully resolved. Although much of the improvements in diabetes resolution are due to the weight loss, there is likely to be an additional metabolic explanation given that many patients had their glucose levels improve even before the weight loss began to accrue

(7,8). Gastric banding generates smaller weight losses than gastric bypass and the improvements in diabetes status are also slower to materialize. Yet Buchwald *et al.* (6) reported that 57% of diabetes cases fully resolved with average weight losses of 46% EWL.

Many review articles have focused on the health improvements resulting from bariatric surgery, including diabetes resolution rates (6,9–14). However, to date, no review article has specifically focused on diabetes resolution rates for obese individuals with diabetes who undergo laparoscopic adjustable gastric banding (LAGB), which is the current standard for band placement. This article fills that gap. We review information from prior studies and review articles specifically related to improvements in diabetes status among obese individuals with diabetes who undergo LAGB.

A current review specifically targeting improvements in diabetes status resulting from LAGB is important given that many obese individuals with diabetes (and many payers) may prefer LAGB over gastric bypass surgery as long as the potential for improvements in diabetes status is relatively high, even if not as high as gastric bypass surgery. This follows because banding is reversible and has lower complication rates than gastric bypass surgery (14–16). This study provides a single source for accessing that information.

Methods

Literature search and inclusion criteria

We conducted a comprehensive review of recent literature and controlled clinical studies to ascertain the effect of LAGB on type 2 diabetes. We searched for articles in Scopus, MEDLINE and EMBASE published from 2000 through May 2011 that included the terms 'laparoscopic band' 'lap-band' 'laparoscopic adjustable gastric banding' or 'gastric band' in combination with 'diabetes'. The initial search revealed 119 studies. Bibliographic citations were reviewed to identify additional literature for consideration. Exclusion criteria consisted of articles that did not present data on improvements in diabetes status post banding, articles that only discussed gastric bypass surgery, articles that did not include the follow-up period for which diabetes improvement was reported and those in a language other than English. Case reports and abstracts were not included in order to avoid duplication of results with published studies.

To be included, the studies needed to contain some LAGB patients diagnosed with diabetes prior to surgery. In several cases, although the overall sample was large, the subsample of LAGB patients with diabetes at the time of surgery was small. Moreover, in studies that enrolled patients both with and without diabetes, enrolment, attrition and weight loss outcomes were not always reported separately for each subgroup. Therefore, for each study, we present data on the target population, study design, number of diabetes cases in the sample at baseline, average age, percent female, starting BMI, length of follow-up, attrition rates and excess weight lost from baseline (EWL) for the diabetes sample if available or for the overall sample if not. However, we only present improvements in diabetes status among those patients with diabetes at baseline.

Unpublished clinical studies

In addition to our search of the existing literature, we also included previously unpublished results from five clinical trials conducted by Allergan both in the USA and internationally that were undertaken as part of the regulatory review and approval process for the USA and other countries. The five Allergan trials represent all of their completed LAP-BAND® studies that collected diabetes outcomes data. They are briefly summarized below. We were unable to identify unpublished data from other band manufacturers for inclusion.

1. LAGB-001-B was a US-based, multi-centre 1 year study approved by the US Food and Drug Administration (FDA) in 1998 as a continuing and expanded access study to develop and maintain surgical skills at investigational sites and to increase access of the LAP-BAND® for patients. A primary objective was to assess changes in comorbid conditions associated with obesity post surgery. A total of 193 subjects were enrolled at 12 investigational sites, with 15 of these subjects diagnosed with type 2 diabetes prior to implantation.

2. LAGB-001-C was a US-based multi-centre 1 year study approved by the FDA in 2000 to allow obesity surgeons to develop LAP-BAND® surgical skills at new investigational sites and to expand access of the device to patients while FDA review was ongoing. An additional goal was to collect data on the band's influence on comorbid conditions. A total of 220 subjects were enrolled at 17 investigational sites, including 22 with type 2 diabetes diagnosed prior to implantation.

3. Following FDA approval in 2001, another US-based multi-centre study, LAGB-PM-001-D, was undertaken as a condition of approval to obtain longer term follow-up after implantation for subjects who had been enrolled in the pre-approval studies. A total of 109 subjects were evaluated at year 3, including 17 with type 2 diabetes prior to implantation.

4. LAGB-INT-MOB-9802 was a retrospective study at six international sites, including Australia, France, Italy, Mexico and two sites in Belgium. Reduction in obesity-related comorbid conditions was one of the primary outcomes studied. A total of 441 subjects were included in this retrospective study including 46 who had type 2 diabetes prior to surgery. The LAP-BAND® surgeries were performed between November 1993 and November 1998, with primary outcomes, including changes in diabetes status, measured at 1, 2 and 3 years post surgery.

5. LAGB-INT-MOB-9801 was a prospective data collection effort from three international investigational sites (Australia, Italy and Mexico) on subjects implanted with the LAP-BAND® System between November 1998 and June 2000. As with the other international study, one of the primary outcomes studied was reduction in comorbid conditions. A total of 225 subjects were enrolled, including 32 who were diagnosed with type 2 diabetes prior to surgery.

Definitions and data presentation

The terminology used to define diabetes improvements, which included terms such as remission, resolution or cured, and ranges considered normal for glycosylated haemoglobin (HbA1c) differed across studies. Therefore, consistent with the terminology adopted by the Diabetes Surgery Summit (International Conference on Gastrointestinal Surgery to Treat Type 2 Diabetes, Rome, Italy, March 29–31, 2007), the term *remission* was adopted to describe improvements to normal levels among those who were considered to have diabetes at baseline, where normal is as defined in the original manuscript. Using this terminology, diabetes improvements are presented as the percentage of those with diabetes at baseline who were in remission, improved but not in remission, or who showed no change/worsening. In some cases, we were unable to differentiate improvements from remissions. In these cases, we conservatively placed the percentages in the improvements column and a zero in the remission column to ensure the totals added up to 100%. These cases are noted in the table. Using this approach, we then combined results across studies to present weighted average improvements at each time period, with weights based on sample sizes of the included studies. Based on data from those studies that report laboratory values, we also present a separate table that includes changes in HbA1c or fasting plasma glucose (FPG) among the subset of cases with diabetes at baseline. For each table, we also present weighted averages of the variables included in the table with weights based on the number of diabetes cases included in each study. To ease interpretation, we present results in separate tables based on the average length of follow-up post banding: 6 months, roughly 1 year, 15–24 months or 2–5 years.

Results

Thirty-five studies, representing 13 countries, met the initial inclusion criteria. These studies included 23 case series from the published literature and the five Allergan trials that followed LAGB patients post surgery, two retrospective data analysis of LAGB patients, four non-randomized case-control studies that compared LAGB patients to either non-surgical patients or to bariatric surgery patients and one randomized controlled trial. Three types of bands were represented in the data, including LAP-BAND® (Allergan, Santa Barbara, CA, USA), Swedish Band (Ethicon Endo-Surgery, Cincinnati, OH, USA) and Easyband® (Allergan, Lausanne, Switzerland) although the vast majority of studies reported results based on patients who received the LAP-BAND®.

6 months

Table 1 presents results for the three studies with 6-month assessments. All three studies were case series. For these studies, the weighted average baseline age was 46, 76% were female and baseline BMI was 45.0. Remission of diabetes varied considerably across the three studies; the weighted average rate of 62% was largely driven by the large sample size of the Dolan *et al.* (17) study. Based on the weighted average, an additional 8% showed improvements in diabetes status that fell short of full remission, while 30% saw no change or a worsening of diabetes. Mean EWL was far more consistent, with each study reporting a value between 25% and 31%, leading to the overall weighted mean EWL of 30%.

12 months

Ten published studies and four Allergan studies provided results with average follow-up of 12–13 months. The 10 published studies presented in Table 2 included seven case series, two retrospective data analysis and one non-randomized case-control study. For these studies, the weighted average baseline age was 45.4, 72% were female and average baseline BMI was 45.2. The weighted average remission rate for diabetes was 52.3%. An additional 16.8% of diabetes cases improved but were not resolved. At least 50% of participants showed improvements/resolution in each of the published studies except for the one by DeMaria *et al.* (23). Improvements in EWL from the studies ranged from 22% to 62%, with a weighted average of 34.8%. The results of the published literature were, on average, more favourable than the results of the Allergan trials in terms of diabetes improvements and excess weight lost.

15–24 months

Table 3 presents the results of five published case series, two of the unpublished Allergan studies and one published randomized controlled trial (RCT) with follow-up data averaging between 15 and 24 months. The weighted average baseline age for participants in these studies was 39.4 years,

Table 1 Baseline and follow-up values for studies with 6 months post-LAGB follow-up

First author (country – year)	Target population (surgical system used)	Study design	No. of diabetes cases	Age	% Female	Starting BMI	Length of follow-up	Attrition (%)	Remission (%)	Improvement (%)	No change/ worse (%)	Mean EWL lost (%)
Dolan *et al.*, 2003 (17) – Australia	T2DM or history of gestational diabetes with at least 6 months follow-up (Lap-Band)	Case series	88	47.5	74	45.0	6.5 months average (max of 19 months)	Not clear but all 49 seem to be followed up for 12 months	65	4	31	30.60
Spivak *et al.*, 2004 (18) – USA	T2DM with BMI >35 (Lap-Band)	Case series	14	40*	87*	45.3*	6 months	63*	29	36	35	25
Weiner *et al.*, 2007 (19) – Germany	T2DM with BMI >35 (Easy Band telemetrically adjustable gastric band)	Case series	5	36*	81*	43.3*	6 months	3*	100	0	0	28.40
Weighted average			107 total cases	46.0	76	45.1		64.8*	62	8	30	30

*Based on overall population not diabetes population

BMI, body mass index; EWL, excess body weight; T2DM, type 2 diabetes mellitus.

74.2% were female and baseline BMI was 44. Rates of diabetes remission varied between 20% and 100%, although 4 of the 8 studies (including most of the observations) were in the 50–75% range. The weighted average remission rate was 51%, with 4% showing improvements that fell short of remission. Weighted average EWL was 47%, with nearly identical values in both the studies from the literature and those from the unpublished Allergan trials. The RCT published by Dixon *et al.* (32) presents results that are more favourable than the Allergan trial data or the non-randomized studies.

≥24 months follow-up

Thirteen studies, including eight published case series, two of the Allergan studies and three non-randomized case-control studies provided results with greater than 24 months of follow-up. These are presented in Table 4. The weighted average baseline age for these studies was 43.9 years, 70.8% were female and baseline average BMI was 46.1. For nearly all of the published studies, the rate of diabetes remission was between 40% and 75%. The three exceptions that were well outside of this range had small sample sizes. The Fielding *et al.* (39) study, which only had four participants with diabetes, reported 100% remission. Rubenstein *et al.* (44), which had a sample of six people with diabetes only reported diabetes improvements, so no remission information was available. The study by Boza *et al.* (36) had 11 people with diabetes and reported an improvement rate of 28.6%. The unpublished Allergan trials reported slightly lower rates of diabetes remission with rates of 34–35% though the LAGB-PM-001-D study also reported an 18% improvement rate. Across all of the studies, weighted averages were 37.6% for diabetes remission and 23.1% for improvements. Overall, the weighted average EWL was 44.8%. Figure 1 displays diabetes remission and improvement rates alongside %EWL over time from 6 months to >24 months.

Changes in clinical values

Table 5 reports improvements in clinical biochemical values for the 10 studies that provide this information for those with diabetes at baseline. At 6 months, Weiner *et al.* (19) showed a clinically and statistically significant improvement from a baseline mean level of 7.5 mmol L^{-1} to a 6-month mean level of 5.0 mmol L^{-1}. At 12 to 13 months, four studies provided data on lab values related to diabetes improvements. Dixon and O'Brien (24) showed that HbA1c values improved from 7.8% on average at baseline to 6.2% at 12 months. Singhal *et al.* (28) found smaller improvements of HbA1c from 8.2 to 7.4% and FPG from 9.1 to 6.9 mmol L^{-1}. Brancatisano *et al.* (21) found an improvement from baseline to 12.5 months of 8.0% to

Table 2 Baseline and follow-up values for studies with 12–13 months post-LAGB follow-up

First author (country – year)	Target population (surgical system used)	Study design	No. of diabetes cases	Age	% Female	Starting BMI	Length of follow-up	Attrition (%)	Remission (%)	Improvement (%)	No change/ worse (%)	Mean EWL lost (%)
Bacci *et al.*, 2002 (20) – Italy	T2DM, BMI >35 with comorbidity (Lap-Band)	Case series	7	45 (wc)	92 (wc)	43.6 (wc)	12 months	62*	57	43	0	
Brancatisano *et al.*, 2008 (21) – Australia	T2DM, impaired glucose tolerance or metabolic syndrome (Swedish band)	Case series	78	52 (T2DM) 47 (IGT)	58 (T2DM) 83 (IGT)	47.0 (T2DM) 45.0 (IGT)	12.5 months	25% > 6 months*	51	30	19	37.8 (T2DM) 41 (IGT)
Busetto *et al.*, 2008 (22) – Italy	T2DM, age 60 or older (Lap-Band)	Retrospective data analysis	46	64.1*	85.2*	44.2*	12 months	7*	0	100	0	
DeMaria *et al.*, 2010 (23) – USA	T2DM with BMI 30- < 35 (not specified)	Retrospective	109	52.0	76.6*	33.9	6–12 months	63	27.5	NR	62.5	21.6
Dixon and O'Brien, 2002 (24) – Australia	T2DM, BMI >35 with comorbidities (Lap-Band)	Case series	50	–	34	48.2	12 months	2	64	26	10	38
Gan *et al.*, 2007 (25) – Australia	T2DM with BMI >35 undergoing LAGB compared to those undergoing Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy (not specified)	Case control-categorized by type of surgery	12	–	83	45.6	13 months average (max 36 months)	1	17	33	50	34.2*
Kasama, *et al.*, 2008 (26) – Japan	T2DM with BMI >35 (Lap-Band or Lap-Band VG)	Case series	4	43*	61.5*	37.5*	12 months	11	50	25	25	61.7*
LAGB-001-B	Multi-centre study of 193 patients (Lap-Band)	Prospective	15	41.5*	81.9*	46.6*	12 months	20	33.3	8.3	58.3	37.0*
LAGB-001-C	Multi-centre study of 220 patients (Lap-Band)	Prospective	22	41.0*	85.0*	47.4*	12 months	0	22.7	31.8	45.5	40.8*
LAGB-INT-MOB-9802	Retrospective study at six international sites in Australia, France, Italy, Mexico and Belgium of 441 patients (Lap-Band)	Retrospective	46	36.0*	87.0*	43.0*	12 months	2.2	24.4	NR	75.6	46.3*
LAGB-INT-MOB-9801	Multi-centre study with sites in Australia, Italy and Mexico of 225 patients (Lap-Band)	Prospective	32	36.0*	76.0*	45.0*	12 months	9.4	72.4	NR	27.6	41.0
Nadler *et al.*, 2007 (27) – USA	Adolescents with impaired glucose tolerance (Lap-Band or Lap-Band VG)	Case series	5	15.8*	74.0*	47.6*	12 months	36*	100	0	0	56.7*
Singhal *et al.*, 2008 (28) – UK	T2DM with BMI >35 undergoing banding surgery (Lap-Band VG, Lap-Band VG or Swedish band)	Case series	109	46.7	66.4	52.9	12 months	6.6	36.6 (insulin) 34.2 (metformin)	61 (insulin) 34.2 (metformin)	2.4 (insulin) 31.6 (metformin)	34.3
Weiner *et al.*, 2003 (29) – Germany	T2DM with morbid obesity undergoing LAGB (Lap-Band for all but two patients who received Swedish band)	Case series	161	37.9*	77.9*	46.4*	12 months	2*	92	0	8	
Weighted average			696 total cases	45.4	72	45.2		16.7	52.3	16.8	29.0	34.8

*Based on overall population not diabetes population.

BMI, body mass index; EWL, excess body weight; IGT, impaired glucose tolerance; LAGB, laparoscopic adjustable gastric banding; NR, not recorded; T2DM, type 2 diabetes mellitus; wc, with comorbidity.

Table 3 Baseline and follow-up values for studies with 15–24 months post-LAGB follow-up

First author (country – year)	Target population (surgical system used)	Study design	No. of diabetes cases	Age	% Female	Starting BMI	Length of follow-up	Attrition	Remission (%)	Improvement (%)	No change/ worse (%)	Mean EWL lost (%)
Abu-Abeid *et al.*, 2001 (30) – Israel	T2DM, over age 60 with BMI >35 (Lap-Band)	Case series	7	63.6*	72.2*	44.4*	21.9 months average	Not clear	71	29	0	
Busetto *et al.*, 2004 (31) – Italy	T2DM with BMI >35 (Lap-Band)	Case series	73	37.5*	–	46.6*	15.3 months average (12–18 months)	21.7*	55	0	45	
Dixon *et al.*, 2008 (32) – Australia	T2DM with BMI 30–40 randomized to LAGB and conventional therapy (Lap-Band)	RCT	30 to each intervention	46.6 (LAGB)	50 (LAGB)	37.0 (LAGB)	24 months	8.3	73	NR	27	62.5*
Kasza *et al.*, 2011 (33) – USA	T2DM with BMI >35 (Lap-Band)	Case series	31	43*	90.3*	45.6*	24 months	70.2*	20	12	68	34*
LAGB-INT-MOB-9802	Retrospective study at six international sites in Australia, France, Italy, Mexico and Belgium of 441 patients (Lap-Band)	Retrospective	46	36.0*	87.0*	43.0*	24 months	6.5	30.2	NR	69.8	50.9*
LAGB-INT-MOB-9801	Multi-centre study with sites in Australia, Italy and Mexico of Lap-Band for 225 patients (Lap-Band)	Prospective	32	36.0*	76.0*	45.0*	24 months	15.6	59.3	NR	40.7	44.9
Lee *et al.*, 2006 (34) – Taiwan	T2DM with BMI >35 (Lap-Band)	Case series	16	31.2*	48.4*	42.7*	24 months	0*	100	0	0	44.0*
Spivak *et al.*, 2005 (35) – USA	T2DM with BMI >35 (Lap-Band)	Case series	12	42*	–	45.2*	At least 18 months	67.4*	33	33	33	37
Weighted Average			247 total cases	39.4	74.2	44.0		23.4	51.0	3.9	45.0	47.0

*Based on overall population not diabetes population.
BMI, body mass index; EWL, excess body weight; LAGB, laparoscopic adjustable gastric banding; NR, not recorded; RCT, randomized controlled trial; T2DM, type 2 diabetes mellitus.

Table 4 Baseline and follow-up values for studies with >24 months post-LAGB follow-up

First author (country – year)	Target Population (surgical system used)	Study design	No. of Diabetes Cases	Age	% Female	Starting BMI	Length of follow-up	Attrition (%)	Remission (%)	Improvement (%)	No Change/ Worse (%)	Mean EWL Lost (%)
Boza *et al.*, 2011 (36) – Chile	T2DM (36% Lap-Band, 64% Swedish band)	Case series	11	37.8*	70.4%*	36.0*	48 months (median)	57.8*	0	28.6		
Caiazzo *et al.*, 2010 (37) – France	T2DM choosing to undergoing gastric banding (Swedish band)	Case series	23	44.9	65	45.3	60 months	4.3	27	NR	73	25
Cottam *et al.*, 2006 (38) – USA	T2DM undergoing banding matched with those undergoing gastric bypass surgery (Lap-Band)	Case control-categorized by type of surgery	44	42*	80*	47.2*	Most followed for 36 months	77* at 3 years	50	34	15.8	51*
Fielding, 2003 (39) – Australia	T2DM with BMI >60 undergoing (not specified)	Case series	4	39*	64.5*	69*	Up to 60 months	83	100	0	0	61*
Frigg *et al.*, 2004 (40) – Switzerland	T2DM (Lap-Band)	Case series	59	41*	79*	45*	44 months average	6	75	8	17	54*
Korenkov *et al.*, 2007 (41) – Germany	T2DM with BMI >34 (Lap-Band)	Case series	14	37.5*	72.4*	48.5*	36–96 months (average 5 years)	5	57	43	0	61.9*
LAGB-PM-001-D	Multi-centre study of 109 patients from the pre-approval studies (Lap-Band)	Prospective	17	41.2*	83.2*	47.4*	36 months	0	35.3	17.6	47.1	40.0*
LAGB-INT-MOB-9802	Retrospective study at six international sites in Australia, France, Italy, Mexico and Belgium of 441 patients (Lap-Band)	Retrospective	46	36.0*	87.0*	43.0*	36 months	23.9	34.3	NR	65.7	48.7*
Pontiroli *et al.*, 2002 (42) – Italy	T2DM or IGT with BMI >35 (not specified)	Case control- LAGB matched to diet group	66	42.9*	81.1*	44.9*	36 months	17	NR	80	20	
Pontiroli *et al.*, 2005 (43) – Italy	T2DM with BMI >35 undergoing banding matched with those refusing to undergo surgery (Lap-Band)	Case control- LAGB matched to those who refused surgery	17	53.3	77	48.3	36 months	0 (LAGB) 12 (No LAGB)	45%	NR	55	
Rubenstein *et al.*, 2002 (44) – USA	T2DM with BMI >35 (Lap-Band)	Case series	6	40.8*	88.9*	48.8*	Up to 36 months	79* at 3 years	NR	84	16	53.6*
Segato *et al.*, 2011 (45) – Italy	T2DM and morbidly obese (Lap-Band)	Case series	52	47.6	57.7	49.1	36 months (median)	30.8	36.5	32.7	30.8	24.1
Sultan *et al.*, 2010 (46) – USA	T2DM with BMI >35 (Lap-Band)	Case series	102	49.3	52	46.3	60 months	14.7	39.7	NR	60.3	45.7
Weighted Average			461 total cases	43.9	70.8	46.1		23.2	37.6	23.1	39.2	44.8

*Based on overall population not diabetes population.
BMI, body mass index; EWL, excess body weight; IGT, impaired glucose tolerance; LAGB, laparoscopic adjustable gastric banding; NR, not recorded; T2DM, type 2 diabetes mellitus.

6.1% and Gan *et al*. (25) showed an improvement from 8.9% to 7.2% from baseline to 13 months. Thus, each of these studies showed roughly a clinically important 1.5 point improvement in HbA1c. Dixon *et al*. (32) found that weight loss with LAGB lowered HbA1c from 7.8 to 6.0 at 24 months. Pontiroli *et al*. (43) reported a decline in HbA1c from 9.4 to 8.0 at 36 months and Korenkov *et al*. (41) reported a decline in HbA1c from 7.3 to 6.3 with duration lasting between 36 and 96 months post surgery. Finally, Sultan *et al*. had the longest follow-up of 60 months and found a decline in HbA1c from 7.53 to 6.58 and in fasting glucose from 8.1 to 6.6 mmol L^{-1}.

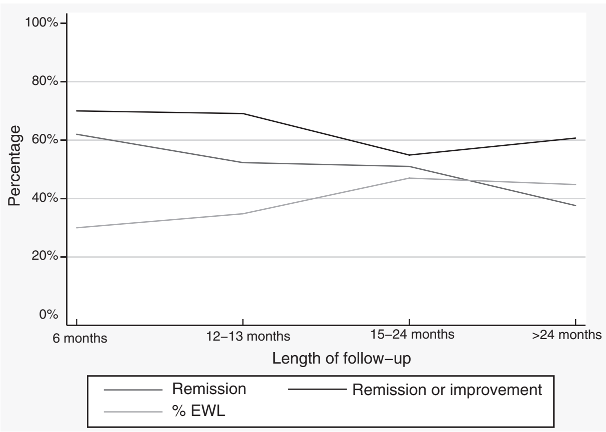

Figure 1 Diabetes remission/improvement rates and %EWL at each time point.

Discussion

This review suggests clinically important improvements in diabetes outcomes and sustained weight loss post LAGB. Although rates of diabetes remission/improvement remained high at all time points, diabetes remission rates trended downward over time. The published data and unpublished Allergan studies show that on average, diabetes remission rates decreased from roughly 62% at 6 months to 55% at 12–24 months and finally to 38% beyond 24 months. This downward trend is consistent with data from the Swedish Obese Subjects study (47) and recent reports from gastric bypass surgery (48), and indicative of the progressive nature of type 2 diabetes. Although remission rates trended downward, when combined with diabetes improvements, the longest term studies reveal remission or improvements occurred for over 60% of LAGB patients. The early, unpublished LAGB trials showed lower rates of diabetes remission than the published studies, although, due to their small sample size, combining their data with results from the literature did not have large effects on the overall weighted averages. The smaller remission rates may have been due to more rigorous criteria for defining remission or the fact that physicians had limited LAGB experience. Moreover, some of these studies did not have a classification for diabetes improvements that fell short of remission; patients were coded as 'in remission' or 'not in remission'.

Unlike diabetes remission, EWL consistently increased with length of follow-up for both the published studies and

Table 5 Changes in diabetes lab values following LAGB

Study	Length of follow-up (months)	Lab measure	Change in diabetes lab value	% change
Weiner *et al.* (19)	6	FPG	–3.0 mmol L^{-1}	–40.0
Dixon and O'Brien (24)	12	HbA1c	–1.6%	–20.5
		FPG	–3.2 mmol L^{-1}	–34.0
Singhal *et al.* (28)	12	HbA1c	–0.8%	–9.8
		FPG	–2.2 mmol L^{-1}	–24.2
Brancatisano *et al.* (21)	12.5	HbA1c	–1.9%	–23.8
		FPG	–3.9 mmol L^{-1}	–40.6
Gan *et al.* (25)	13	HbA1c	–1.7%	–19.1
Busetto *et al.* (31)	15.3	FPG	–0.6 mmol L^{-1}*	–7.2%*
Dixon *et al.* (32)	24	HbA1c (surgery)	–1.8%	–23.1
		HbA1c (no surgery)	–0.39%	–5.1
Pontiroli *et al.* (43)	36	HbA1c	–1.4%	–14.9
Korenkov *et al.* (41)	36–96 (average of 60)	HbA1c	–1.0%	–13.7
Sultan *et al.* (46)	60	HbA1c	–0.95%	–12.6
		FPG	–1.5 mmol L^{-1}	–18.8

*Based on overall population not diabetes population.
FPG, fasting plasma glucose; HbA1c, haemoglobin.

for the Allergan trial data. Combined, EWL increased from 34.8% at 12 months to 47.0% at 24 months before levelling off at 44.8% in studies with data greater than 24 months. This is consistent with other reviews of LAGB weight outcomes for those without diabetes (10). These results are encouraging as those with type 2 diabetes have been reported to have a poorer response to non-surgical weight loss programs (49–51).

The review also revealed significant shortcomings of the current literature. The included studies varied along many dimensions, including study design, duration, reporting measures, outcomes and attrition rates. Concerning attrition, Tables 1–4 reveal it varied from 16.7% on average at 12 months to 23.1% for the longest term studies. Quality varied from a single randomized controlled trial to retrospective cohort audits with no control groups. Two studies included data from individuals with BMIs less than 35 kg m^{-2}. Although these studies are important given the recent FDA approval to expand LAP-BAND® to lower BMI groups, it is unclear whether these results would generalize to those with higher BMIs (52,53). Moreover, the majority of studies provided no biochemical evidence of glycemic control and vague or poorly defined definitions for diabetes improvement or remission. When in doubt, we conservatively assumed no improvements; therefore, our estimates are conservative in this regard. Although the inconsistent reporting may surprise those familiar with managing type 2 diabetes, this is indicative of the broader literature regarding bariatric surgery (6). There is clearly a need for standardized terminology and reporting of relevant outcome measures for those with type 2 diabetes (54).

This review was limited to weight and diabetes outcomes. It did not include short- or long-term complications as this information was not available in nearly all of the studies reviewed. However, safety of the LAGB, albeit not specifically for those with diabetes, has been well described in recent large cohort and registry studies (55–57). These confirm that LAGB surgery provides the lowest post-operative mortality, fewer complications in the first year and the shortest hospital stay of all bariatric surgical procedures. Longer term issues such as proximal pouch dilatation (58), erosion of the band into the stomach (58,59) and port and tubing issues have also been reviewed (60). In large series, reoperation rates for all complications combined are in the order of 10–15% at 5 years, and removal of the band without replacement is roughly 5%, although many early series had higher reoperation rates (61).

Many of the studies also had very small sample sizes for individuals with type 2 diabetes. We account for this by pooling data across studies and calculating weighted averages, although in some cases, data unique to those with diabetes was not available. Moreover, because the longer term studies may suffer from attrition bias, we cannot be sure whether study dropouts might have shown less favourable weight and health outcomes. If so, our estimates would be biased. An additional limitation is that many studies did not report HbA1c values, so our estimates of the effect of LAGB on improvement in HbA1c is represented by only a subset of the included studies. Although longer term studies that address these limitations are needed, the studies to date provide compelling evidence that LAGB leads to both short and longer term clinically relevant improvements in diabetes status primarily attributed to sustained EWL among diabetes patients who undergo the procedure.

Potential conflicts of interest

Dr Dixon, Dr Finkelstein and Mr Segel are consultants to Allergan, and Ms Murphy is an Allergan employee and stockholder.

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