

ASMBS statements/guidelines

## Bariatric surgery in class I obesity (body mass index 30–35 kg/m<sup>2</sup>)

ASMBS Clinical Issues Committee\*

Received September 12, 2012; accepted September 13, 2012

### Preamble

The following position statement is issued by the American Society for Metabolic and Bariatric Surgery in response to numerous inquiries made to the society by patients, physicians, society members, hospitals, and others regarding the safety profile and efficacy of bariatric surgery for patients with class I obesity. In this statement, available data are summarized, and recommendations for treatment are made regarding bariatric surgery for patients with a body mass index (BMI) of 30–35 kg/m<sup>2</sup> based on current knowledge, expert opinion, and published peer-reviewed scientific evidence available at this time. The statement is not intended as, and should not be construed as, stating or establishing a local, regional, or national standard of care. The statement may be revised in the future as additional evidence becomes available.

### The Issue

Obesity is the major epidemic of our generation. The National Health and Nutritional Examination Survey (NHANES) suggests that obesity affects women (35.8%), men (35.5%), and children (2–19 years of age, 16.9%) [1,2]. Increasingly, data are accumulating that many of the metabolic problems that accompany obesity begin at a BMI of 30 or even earlier and increase early mortality [3,4]. Recently, the Food and Drug Administration voted to extend the use of a medical device, the LapBand, to people afflicted with class I obesity with  $\geq 1$  co-morbidities, and randomized prospective data from the STAMPEDE trial found the Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy in patients with a BMI of  $\geq 27$  kg/m<sup>2</sup> to be effective in the treatment of type 2 diabetes [5]. The current data support lowering the arbitrary BMI cutoff of 35 kg/m<sup>2</sup> established in 1991 by offering surgical therapy to patients

with class I obesity. The primary purpose of this review is to evaluate the evidence regarding the benefits and risks of all bariatric procedures in patients with BMI  $>30$  kg/m<sup>2</sup>.

**Class I obesity as a health problem.** Obesity is defined as a disease in which fat has accumulated to the extent that health is impaired. In the absence of a simple direct method for measuring total body fat, the BMI is the most common method for describing levels of obesity. For Western societies, the World Health Organization and the U.S. National Institutes of Health (NIH) have defined BMI  $>30$  kg/m<sup>2</sup> as being obese [6,7], primarily on the basis of associated mortality risk. In addition, the co-morbid conditions associated with obesity contributed substantially to the definition. Overweight and obesity can be divided into 4 levels of severity of co-morbidity and mortality risk (Table 1).

The morbidity and mortality risks of obesity have been subject to multiple systematic reviews. Some of these provide a global overview [8], but others are focused on specific weight-related diseases such as diabetes [9], cardiovascular disease [10], and various cancers [11–15]. A recent comprehensive systematic review and meta-analysis of the possible co-morbidity risks for both overweight and the classes of obesity has brought together the data from 89 individual studies [3], and the pooled relative risk for co-morbidities related to the severity of obesity was calculated. Significant associations were found between all classes of overweight/obesity and type 2 diabetes, coronary artery disease, hypertension, congestive heart failure, asthma, stroke, pulmonary embolism, gallbladder disease, 9 common cancers, osteoarthritis, and chronic back pain. Although class I obesity was not identified separately from overweight or the more severely obese, the findings were present for both the overweight and all 3 classes of obesity, confirming the effect of class I obesity in the pathogenesis of these diseases.

The mortality risk of obesity is best examined by following large populations over many years. The Prospective Studies Collaboration is an international consortium of 61 large, prospective epidemiologic studies mainly from North America and Europe and based at the University of Oxford. They analyzed 57 of these studies involving nearly 900,000 adults

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Table 1  
Classification of obesity

Classification	BMI range	Health and survival risk
Overweight	25–30	Mild
Class I	30–35	Moderate
Class II	35–40	Severe
Class III	>40	Very severe

BMI = body mass index.

for whom BMI was available [4]. They excluded the data from the first 5 years of follow-up and tracked outcomes for a mean of 8 years. They related BMI to cause-specific mortality and reported that, from a BMI of 25 kg/m<sup>2</sup>, mortality was approximately 30% greater for each additional 5 kg/m<sup>2</sup>. The risk status was largely independent of age. Also noted was an increased risk of stroke, myocardial infarction, and diabetes. Overall, for class I obesity, the life span was decreased by 3 years.

Similar findings had been derived from the Framingham database [16] and the NHANES [17]. In a Special Report in the *New England Journal of Medicine* [18], Olshansky et al. argued that the increasing problems of obesity and its comorbidities, particularly type 2 diabetes, will override the benefits of other health advances and a continued increase in life expectancy will not persist.

From these data, we conclude that class I obesity is a health problem that leads to additional serious co-morbidities and a shortened life expectancy. Therefore, class I obesity deserves effective treatment.

**Historic perspective for treatment recommendations.** The morbidity and mortality caused by the disease of obesity is well established and has long been recognized by all major advisory bodies. It was recognized by an NIH consensus conference in 1985. A subsequent separate consensus conference, held in March 1991, considered the role of bariatric surgery for these patients [19]. A synthesis of the views of the opinion leaders present at that time recommended that bariatric surgery should be considered for those patients who have BMI >40, BMI >35 in association with major co-morbidities such as severe sleep apnea, Pickwickian syndrome, obesity-related cardiomyopathy, or BMI >35 in association with obesity-induced physical problems with lifestyle, including joint disease or body size problems interfering with employment, family function, and ambulation.

Since the NIH consensus conference, new procedures have been introduced, the laparoscopic approach has largely replaced open surgery, and higher levels of scientific evidence are now available regarding the health hazards of obesity and the risks and benefits of bariatric surgery. Given the major changes that have occurred in this field, it is appropriate to review the data now available, and in the context of bariatric surgery as it is currently practiced, consider modification of the arbitrary recommendations established 20 years ago.

Despite attempts to update the recommendations of the original guidelines [20,21], private health insurers and Medicare continue to rely on the 1991 consensus conference guidelines to set a baseline for BMI above which bariatric surgery offers a favorable risk/benefit ratio. The correct placement of that baseline is of critical importance to the patient, the doctor, and the payor. In particular, the time has come to address the appropriate place for bariatric surgery for the treatment of patients with class I obesity. This discussion should consider whether class I obesity is a clinically relevant health problem, whether it is adequately managed by nonsurgical means, and whether there is evidence that bariatric surgical techniques provide a well-tolerated and cost-effective treatment approach.

### The data

**Nonsurgical treatment of class I obesity.** In the treatment algorithm for class I obesity, the most well-tolerated treatment that is effective should be the preferred option. All individuals seeking weight loss should begin with nonsurgical therapy and consider bariatric surgery only if they are unable to achieve sufficient long-term weight loss and co-morbidity improvement with nonsurgical therapies.

For most people with class I obesity, however, it is clear that the nonsurgical group of therapies will not provide a durable solution to their disease of obesity. Most will not lose a substantial amount of weight with these measures, and most who do lose weight will regain the weight within 1–2 years. Systematic reviews of the numerous randomized controlled trials (RCTs) of programs incorporating diets, exercise, pharmacotherapy, and behavioral therapy have reported a mean weight loss in the range of 2–6 kg at 1 year or less [22–26] with poor maintenance of that weight loss beyond that time [27].

However, within the total group of participants studied in these trials and within the general practice of bariatric medicine, there are individuals who have achieved substantial and durable weight loss and have been able to maintain that weight loss for several years. Therefore, before considering surgical treatment for obesity for any individual, an adequate trial of nonsurgical therapy should always be required. If, however, the attempts at treating their obesity and obesity-related co-morbidities have not been effective, we must recognize that the individual has a problem that threatens their health and life expectancy, and we must seek an effective, durable therapy such as bariatric surgery.

**Bariatric surgery for class I obesity.** There is a robust body of literature to support the safety profile and efficacy of bariatric surgery in patients who meet current NIH criteria. Many of the published articles demonstrate clear weight loss and co-morbidity benefits for patients who are at the low end of the currently accepted criteria. Although the data for patients with BMI 35–40 kg/m<sup>2</sup> who have

undergone bariatric surgery cannot be directly extrapolated to the 30–35 population, it is reasonable to expect the same beneficial effects of the surgery in this lower BMI group. Further data in the lower BMI group have been needed to better define the risk/benefit ratio for this patient population.

To date, there are 4 RCTs that include patients with BMI 30–35 kg/m<sup>2</sup> [5,28–30]. Three of these trials [5,28,29] also include patients with BMI outside of this range (as low as 25 and as high as 43). Because the overlap in BMI is large, the level of evidence is high, and the importance of optimal treatment of diabetes is critical, the data from these studies have been included in this analysis. Additionally, there are 16 observational studies [31–46] and 1 meta-analysis [47] examining the effects of bariatric surgery on diabetes in patients with BMI <35 kg/m<sup>2</sup>. A summary of these studies is provided in Tables 2 and 3.

### Randomized trials

There are 2 randomized trials evaluating the use of laparoscopic adjustable gastric bands (LAGB) in patients with lower BMI. In the first study by O'Brien et al., 80 patients with class I obesity were randomly assigned to a program of optimal nonsurgical weight loss therapy or to gastric banding and followed for 2 years [48]. The participants in the gastric banding group had an 87.2% excess weight loss (EWL) (95% CI, 78–97) at 2 years. BMI was reduced from a mean of 33.7 to 26.4 kg/m<sup>2</sup>. In comparison, the nonsurgical group had 21.8% EWL (12–32) at 2 years. Notably, 35% of the nonsurgical group had lost >25% of excess weight at 2 years, indicating that a worthwhile outcome can be achieved with nonsurgical therapy for a subgroup of patients. The principal reported co-morbidity in this RCT was metabolic syndrome, which was defined by the Adult Treatment Panel III (ATP III) criteria [49] and was present in 38% of each group at the commencement of the study. At 2 years, there was a highly significant reduction to 3% in the surgical group. Reduction from 38% to 24% in the control group was not significant. Additionally, the short-form health survey (SF-36) was used to compare changes in the 8 domains of both groups over the 2 years of study. The gastric banding group had significant improvement in all 8 domains of the SF-36, with significantly greater improvement than the nonsurgical group for physical functioning, vitality, and mental health. No major adverse events were reported, but 4 patients in the surgical group required a late revisional procedure for posterior prolapse. Four patients in the nonsurgical group required cholecystectomy, possibly linked to very-low-calorie diet therapy.

The second LAGB trial by Dixon et al. randomly assigned 60 patients with recent-onset type 2 diabetes (<2 years' duration) to surgery versus conventional diabetes therapy with emphasis on weight management [28]. The surgical group achieved significantly greater weight loss at 2 years (20% total weight loss versus 1.4%;

$P < .001$ ) and had a 73% rate of diabetes remission (fasting glucose level <126 mg/dL [7.0 mmol/L] and glycated hemoglobin (HbA<sub>1c</sub>) value <6.2% while taking no glycemic therapy) compared with 13% of the medical treatment group ( $P < .001$ ). There was a significant reduction in the use of pharmacotherapy for glycemic control in the surgical group at 2 years and no decrease in the medically managed group. No serious adverse events were reported in either group.

In a trial by Lee et al., 60 patients with poorly controlled diabetes were randomly assigned to receive laparoscopic gastric bypass or laparoscopic sleeve gastrectomy [29]. The bypass procedure used in this trial was the loop mini-gastric bypass, and there was no medical treatment arm in this study. The primary endpoint was diabetes remission (fasting glucose <126 mg/dL and HbA<sub>1c</sub> <6.5% without glycemic therapy) at 1 year. All patients completed follow-up, and overall, 70% achieved diabetes remission. Remission occurred in significantly more patients who had received bypass than those who received sleeve gastrectomy (93% versus 47%;  $P < .02$ ). Patients who had bypass achieved significantly lower BMI and greater improvements in lipids and metabolic syndrome in this study. Minor complications occurred in 10% of patients, and no major adverse events were reported in either group.

Schauer et al. randomly assigned 150 patients to receive intensive medical therapy (IMT) for their diabetes versus IMT plus gastric bypass versus IMT plus sleeve gastrectomy [5]. The primary endpoint for this study was the proportion of patients with a HbA<sub>1c</sub> <6% at 1 year. The study did include patients with BMI up to 43 kg/m<sup>2</sup> but 34% of the patients had a BMI <35 kg/m<sup>2</sup>, and it is therefore included in this analysis. Patients in this study had poorly controlled diabetes with a mean preoperative mean HbA<sub>1c</sub> of 9.2%, and despite improvements in glycemic control for all groups, the surgical groups achieved significantly greater glycemic control than the medical group. Mean HbA<sub>1c</sub> decreased to 7.4%, 6.6%, and 6.4% for the IMT, sleeve gastrectomy, and gastric bypass groups, respectively. The surgical groups also had significantly greater weight loss and significant reductions in cardiovascular medication compared with medical therapy. Additional surgical interventions were required in 4 patients in the surgery groups. These included 1 laparoscopic evacuation of a hematoma, 1 diagnostic laparoscopy to assess persistent nausea and vomiting, laparoscopic jejunostomy for feeding access after staple line leak after sleeve gastrectomy, and 1 laparoscopic cholecystectomy after gastric bypass. There were no deaths, episodes of serious hypoglycemia requiring intervention, malnutrition, or excessive weight loss among the 3 groups.

A meta-analysis by Li et al. [47] evaluated 13 studies that assessed the effects of bariatric surgery on diabetes for patients with BMI <35 kg/m<sup>2</sup>. This review included a variety of bariatric procedures (Table 2), including

Table 2  
Randomized trials and meta-analysis of bariatric surgery trials including patients with body mass index <35 kg/m<sup>2</sup>

Study	Type	BMI range	Procedure	N	Duration	Follow-up	Weight loss	BMI change	Health outcomes
O'Brien 2006 [30]	RCT	30–35	LAGB versus medical therapy	80	2 years	97%	87.2% EWL versus 21.8% EWL ( <i>P</i> < .001)	33.7 to 26.4 versus 33.5 to 31.5 ( <i>P</i> < .001)	Metabolic syndrome 38% to 3% ( <i>P</i> < .001) versus 38% to 24% (N.S.)
Dixon 2008 [28]	RCT	30–40	LAGB versus medical therapy for T2DM	60	2 years	92%	20.7% TWL versus 1.7% TWL ( <i>P</i> < .001)	36.9 to 29.5 versus 37.1 to 36.6 ( <i>P</i> < .001)	Remission of diabetes: 22 of 30 (73%) versus 4 of 30 (13%)
Lee 2011 [29]	RCT	25–35	MGB versus LSG	60	1 year	100%	MGB 94% EWL LSG 76% EWL	MGB 30 to 22.8 LSG 30 to 24.4	HbA <sub>1c</sub> MGB 9.9% to 5.4% LSG 10.2% to 7.2% Higher rates of remission for MGB compared with LSG
Schauer 2012 [5]	RCT	27–43 (34% of patients with BMI <35)	LRYGB versus LSG versus IMT for T2DM	150	1 year	93%	LRYGB 88% EWL LSG 81% EWL IMT 13% EWL ( <i>P</i> < .001 surgical groups compared with IMT)	LRYGB –10.2 LSG –8.9 IMT –1.9 ( <i>P</i> < .001 surgical groups compared with IMT)	% of patients with HbA <sub>1c</sub> <6.0: LRYGB 42% LSG 37% IMT 12% ( <i>P</i> < .008 surgery versus IMT); significant reduction in cardiovascular medication in surgery groups versus IMT
Li 2012 [47]	Meta-analysis	<35 with T2DM	RYGB (4 studies) DJB (3 studies) BPD (3 studies) MGB (2 studies) SG (1 study)	357 (13 studies)	6 months to 18 years (mean 27 months)	NR	–17 kg ( <i>P</i> < .0001)	–5.8 ( <i>P</i> < .0001)	FPG –4.4 mmol/L HbA <sub>1c</sub> –2.59% Triglycerides –56.7 mg/dL Total Cholesterol –48.4 mg/dL (All changes <i>P</i> < .01)

BMI = body mass index; RCT = randomized controlled trial; T2DM = type 2 diabetes mellitus; LAGB = laparoscopic adjustable gastric band; LSG = laparoscopic sleeve gastrectomy; IMT = intensive medical therapy; LRYGB = laparoscopic Roux-en-Y gastric bypass; RYGB = Roux-en-Y gastric bypass; DJB = duodenal-jejunal bypass; BPD = biliopancreatic diversion; N.S. = not significant; MGB = mini-gastric bypass; SG = sleeve gastrectomy; NR = not reported; EWL = excess weight loss; TWL = total weight loss; FPG = fasting plasma glucose; HbA<sub>1c</sub> = glycated hemoglobin.

Table 3  
Observational studies including patients with body mass index <35 kg/m<sup>2</sup>

Study	Type	BMI range	Procedure	N	Duration	Follow-up	Weight loss	BMI change	Health outcomes
Abbatini 2012 [36]	Prospective cohort matched for severity of T2DM	30–35	Sleeve gastrectomy (n = 9) versus standard medical therapy for T2DM (n = 9)	18	1 year	100%	NR	LSG 32.7 to 21.1 MT 32.9 to 31.7	DM Remission: LSG 8/9 MT 0/9  HbA <sub>1c</sub> : LSG 8.1% to 5.9% MT 7.5% to 8.2%
Gianos 2012 [37]	Retrospective review	30–35	LSG (n = 24) LRYGB (n = 8) LAGB (n = 10)	42	14 months	95%	Mean 41.4 lb weight loss	33.9 to 26.5	25 patients with T2DM: 20% remission 48% improvement 27 patients with HTN: 33% remission 52% improvement 25 patients with Dyslipidemia: 20% remission 52% improvement 28% no change
Cohen 2012 [31]	Prospective observational study	30–35	LRYGB	66	Median 5 year f/u (range 1–6)	100%	36% total weight loss	NR	DM remission 88% DM improvement 11% HbA <sub>1c</sub> 9.7% to 5.9% significant improvements in SBP, DBP, total cholesterol, LDL, HDL, triglycerides and predicted 10-year CV risk
Huang 2011 [38]	Prospective observational study	25–35	LRYGB	22	1 year	100%	NR	30.8 to 23.7	T2DM: HbA <sub>1c</sub> 9.2% to 5.9% FPG 204 to 103 mg/dL Remission 63.6% Improvement 36.4%
Serrot 2011 [39]	Retrospective review	30–35	LRYGB (n = 17) versus MT (n = 17) for T2DM	34	1 year	100%	LRYGB 70% EWL (–57 lbs) MT no change	LRYGB –8.8 MT no change	HbA <sub>1c</sub> : LRYGB 8.2% to 6.1% (P < .001) CMT no change
Frenken 2011 [43]	Retrospective review	26–34.5	BPD, DS, RYGB	16	1 year	94%	NR	32 to 25	HbA <sub>1c</sub> : BPD, DS 8.8% to 5.2% RYGB 7.8% to 6.7%
Scopinaro 2011 [44]	Prospective study	25–30 30–35	BPD	15 15	2 years	100%	25–30: 80.4 to 70.9 kg 30–35: 89.2 to 73.7 kg	25–30: 28.1 to 24.6 30–35: 33.1 to 27.4	HbA <sub>1c</sub> : 25–30: 9.1% to 6.9% 30–35: 9.5% to 5.9% Higher remission rates of T2DM in obese versus overweight patients

Table 3 Continued.

Study	Type	BMI range	Procedure	N	Duration	Follow-up	Weight loss	BMI change	Health outcomes
Lee 2010 [45]	Prospective study	25–35	LSG	20	1 year	100%	69.10%	31.0 to 24.6	DM remission in 10/20 (50%) of patients Preop C-peptide > 3 predicted DM remission
DeMaria 2010 [46]	Retrospective review multicenter database (BOLD)	30–35	RYGB	109	1 year	69% at 1 year 62% at 1 year	NR	RYGB 33.7 to 27.1	% patients off T2DM Meds:
			LAGB	109				LAGB 33.9 to 30.9	RYGB 55.2% LAGB 27.5%
Shah 2010 [40]	Prospective observational study	22–35	LRYGB	15	9 months	100%	–16 kg weight  –16.9 cm waist circumference	28.9 to 23.0	FPG: 233 to 89 mg/dL ( $P < .001$ ).  HbA <sub>1c</sub> : 10.1% to 6.1% ( $P < .001$ ).  Significant reduction in HTN, dyslipidemia, predicted CV risk
Choi 2010 [35]	Observational study	30–35	LAGB	22	18 months	100%	42% EWL		Improvement or resolution of co-morbidities
Sultan 2009 [32]	Prospective observational study	28–35	LAGB	53	2 year	81%	69.7% EWL at 2 years	33.1 to 25.8 at 2 years	Resolution or improvement in hypertension, depression, diabetes, asthma, lipid profile, sleep apnea, osteoarthritis
Kakoulidis 2009 [34]	Prospective observational study	30–35	Sleeve gastrectomy	23	6 months	NA	100% EWL at 6 months	33.8 to 25.0	Significantly improved or resolved in most patients
Cohen 2006 [42]	Observational study	<35	RYGB	37	6–48 months	100%	81% EWL		36 patients had total remission of their co-morbidities
Parikh 2006 [41]	Prospective observational study	30–35	LAGB	93	Up to 8 years	89%	Excess weight loss: 57.9%, 57.6, and 53.8% at 1, 2, 3 years, respectively	32.7 to 27.2 at 1 year, 27.3 at 2 years, and 27.6 at 3 years	Improvement or resolution of co-morbidities
Angrisani 2004 [33]	Prospective observational study	30–35	LAGB	210	5 years	72%	61.30% EWL at 2 years 71.9% EWL at 5 years	33.9 to 29.7 at 1 year, 28.2 at 45 years	Co-morbidities resolved at 1 year in 89.1% of patients

BMI = body mass index; T2DM = type 2 diabetes mellitus; LAGB = laparoscopic adjustable gastric band; LSG = laparoscopic sleeve gastrectomy; LRYGB = laparoscopic Roux-en-Y gastric bypass; MGB = mini-gastric bypass; BPD = biliopancreatic diversion; DS = duodenal switch; RYGB = Roux-en-Y gastric bypass; EWL = excess weight loss; TWL = total weight loss; FPG = fasting plasma glucose; DM = diabetes mellitus; HTN = hypertension; CV = cardiovascular; MT = conventional medical therapy; HbA<sub>1c</sub> = glycated hemoglobin.

investigational procedures such as duodenal-jejunal bypass. There were 357 patients included in the analysis, which had a small number of patients with long-term follow-up and most with short- and medium-term follow-up. According to the weighted mean difference calculation, bariatric surgery in this population led to 5.18 kg/m<sup>2</sup> of BMI lowering (95% CI, 3.79–6.57;  $P < .00001$ ), 4.8 mmol/L decrease in fasting plasma glucose (FPG) (95% CI, 3.88–5.71 mmol/L;  $P < .00001$ ), 2.59% decrease in HbA<sub>1c</sub> (95% CI, 2.12–3.07%;  $P < .00001$ ), 56.67 mg/dL decrease of triglyceride levels (95% CI, 11.53–101.82;  $P = .01$ ), and 48.38 mg/dL of total cholesterol reduction (95% CI, 21.08–75.68;  $P = .0005$ ). Overall, 80.0% of the patients achieved adequate glycemic control (HbA<sub>1c</sub> <7%) without antidiabetic medication. The studies reported a low incidence of major complications (3.2%) with no mortality. The authors conclude that bariatric surgery is effective and well tolerated for diabetic patients with BMI <35 kg/m<sup>2</sup>.

### Observational studies

The 16 observational studies included in this review were single-institution prospective or retrospective analyses of patients with lower BMI. There was 1 retrospective multicenter review of patients with BMI <35 that used the Bariatric Outcomes Longitudinal Database (BOLD). These studies reported weight loss results and co-morbidity reduction consistent with what has been reported for class II obesity, and most included changes in glycemic control as a primary or secondary endpoint. These studies contained the range of methodological deficiencies typical of single-institution case series (lack of control data, propensity to bias, and lack of information on completeness of follow-up). Most are limited by small numbers of patients and short-term follow-up. There was also variability in the method of weight and co-morbidity reporting. Laparoscopic adjustable gastric banding, sleeve gastrectomy, gastric bypass, and biliopancreatic diversion are all represented in the current literature (Table 3) [31–46].

**Weight loss.** The various observational studies reported a range of weight loss for different follow-up periods. Parikh [41] reported 57.9% EWL at 1 year and 53.8% at 3 years. Sultan [32] followed 53 patients after gastric banding and reported a 69.7% EWL at 2 years. The Italian Collaborative study [33] reported 71.9% EWL in 96 patients who had been followed-up at 5 years after gastric banding. Choi et al. reported results for patients with BMI 30–35 and co-morbidities, as well as BMI 35–40 without co-morbidities, and had an overall EWL of 42% at 18 months, which was no different than their cohort of band patients who meet the current NIH criteria [35].

Kakoulidis et al. reported 100% EWL in 23 patients who had reached 6 months of follow-up after sleeve gastrectomy [34]. Three other studies with small numbers of patients who received sleeve gastrectomy reported significant weight loss

[36,37,45], including a study by Lee et al. that reported 69% EWL 1 year after laparoscopic sleeve gastrectomy.

Cohen et al. reported his experience with 37 class I obese patients who underwent Roux-en-Y gastric bypass (RYGB) [42]. There was 77% EWL in 20 patients at 36 months and 81% EWL in 9 patients at 48 months. Data collected from the BOLD registry included 109 RYGB patients with BMI <35 kg/m<sup>2</sup> who had 69% EWL 1 year after surgery. Other studies of weight loss after RYGB in this patient population consistently report BMI reduction to the mid-20s 1 year after surgery [37,38].

Two small studies have reported excellent weight loss after biliopancreatic diversion or duodenal switch in patients with BMI <35 kg/m<sup>2</sup>. Importantly, patients did not have excessive weight loss after these procedures, and weight stabilized at a BMI around 25 kg/m<sup>2</sup> within a year after surgery [43,44].

**Health outcomes.** In the observational studies, all studies reported resolution or improvements of various co-morbidities, but the level of detail regarding specific co-morbidities was variable. Several studies focused primarily on the effects of surgery on type 2 diabetes and evaluated remission rates based on variable definitions. All the observational studies reported positive effects on glycemic control and diabetes remission rates consistent with reports of higher BMI patients. The majority of patient groups studied had poorly controlled diabetes with preoperative HbA<sub>1c</sub> values ranging from 8% to 10%. Other cardiovascular risk factors, when reported, improved after bariatric surgery in these observational studies.

One observational study [34] measured the quality of life score using BAROS, with 16 of 23 patients having an excellent or very good status. Kakoulidis et al. reported good to excellent quality of life in 22 of 23 patients 6 months after sleeve gastrectomy [34].

**Adverse events.** Several observational studies reported serious adverse events. In the Italian Collaborative study [33], 1 patient died at 20 months postoperatively from sepsis after gastric perforation in association with a dilated gastric pouch. This group also reported an 8% late reoperation rate for proximal gastric enlargements, leakage from the access port, or band erosion. In the report of 79 patients undergoing sleeve gastrectomy, 2 patients underwent reoperation for bleeding, and there was 1 gastric fistula with sepsis [34]. In a review of the BOLD database including 109 RYGB and 109 LAGB patients with BMI <35 kg/m<sup>2</sup>, complications rates were higher after gastric bypass (18%) compared with banding (3.3%;  $P < .05$ ). Most complications were minor (nausea, vomiting, stricture), but serious complications, including anastomotic leakage, intra-abdominal bleeding, and internal hernia, were reported in 1 patient each in the RYGB group. One LAGB patient developed a band slippage in this review [46].

The special case of type 2 diabetes. Among all the co-morbidities caused by obesity, type 2 diabetes deserves

special attention. Type 2 diabetes was estimated to be present in 36 million people in the United States in 2007 [50], and the prevalence is increasing annually. Type 2 diabetes is strongly linked to overweight and obesity. Two large epidemiologic studies, the Nurses' Health Study [51] and the Health Professionals Study [52], show a direct relationship between the risk of type 2 diabetes and weight. Type 2 diabetes is associated with major health problems, including micro- and macrovascular complications, premature death, and high costs to the healthcare system.

This chronic, unremitting disease has traditionally been treated with escalating regimens of medical therapy. Lifestyle interventions, including weight loss and exercise, is the initial mode of therapy for many patients, and when a closely monitored, intense intervention strategy is used, it can achieve modest improvements in weight loss (6.2% versus .9% in control group;  $P < .001$ ), glycemia (.4% reduction in HbA<sub>1c</sub> compared with .1% in control group;  $P < .001$ ), fitness, and some cardiovascular risk factors if intense lifestyle interventions are maintained [53]. Prevention of diabetes in high-risk adults has also been reported with intense lifestyle intervention as well as medication (metformin). In the Diabetes Prevention Program, diabetes incidence 10 years after randomization was reduced by 34% in the lifestyle group (who lost then regained some weight long term) and by 18% in the metformin group (who maintained some modest weight loss) compared with placebo [54]. These data support the use of intense lifestyle interventions to achieve long-term weight loss and glycemic control in a subset of patients who have class I obesity or are at risk for developing diabetes. Unfortunately, intense lifestyle and behavioral interventions are often not practical or sustainable in everyday practice outside of a clinical trial.

The aforementioned surgical RCTs consistently reported significant improvement in glycemic control and higher remission rates compared with standard or intensive medical therapy for diabetic patients with BMI  $< 35$  kg/m<sup>2</sup>. The follow-up for these RCTs is only 1 or 2 years, however. A recently published prospective study by Cohen et al. reported longer-term results in 66 severely diabetic patients (mean preoperative HbA<sub>1c</sub> of 9.7%; disease duration, 12.5 years) with BMI 30–35 who underwent laparoscopic gastric bypass. The median follow-up time was 5 years (30 patients had 6-year follow-ups), and no patients were lost to follow-up. This study reported an 88% diabetes remission rate (HbA<sub>1c</sub>  $< 6.5\%$  without diabetes medication) and 11% improvement rate (HbA<sub>1c</sub>  $< 7\%$ , decrease in dosage of oral medication, off insulin). No patient had excessive weight loss, and no patient who achieved remission had recurrence of their diabetes during the follow-up period [31].

Cost-effectiveness considerations. Demonstration of the clinical needs and the clinical effectiveness of bariatric surgery cannot be the sole determinant for advocacy of bariatric surgery for class I obesity. An evaluation of the

economic effects is also needed. Cost/benefit analyses of obesity and of bariatric surgery are now becoming available [55,56], and the economic value of more active intervention is being debated [57–59].

Data from a level 2 study supports the claims of cost-effectiveness. The RCT addressing diabetes [28] was subjected to careful analysis of cost-efficacy [60] and cost-effectiveness [61]. For cost-efficacy assessment, all within-trial costs were measured, including gastric banding surgery, mitigation of complications, outpatient consultations, investigations, weight loss therapies, and medications. The mean 2-year intervention cost was Australian dollar (AUD) \$13,400 for the gastric banding group and AUD\$3,400 for the conventional therapy group. Relative to conventional therapy, the incremental cost-effectiveness ratio (ICER), which is a measure of the additional cost to achieve an additional benefit, was AUD\$16,600 per case of diabetes remitted. As the mean annual costs for maintaining a patient with type 2 diabetes in Australia and including all levels of severity and complexity is estimated to be AUD\$10,900 [62], an early cost saving can be anticipated. The analysis was extended to a modeled lifetime [61] and assumed that the mean number of years of remission was 11.4 for surgical therapy and 2.1 for conventional therapy. It was estimated that the surgical group had increased quality-adjusted life years (15.7 versus 14.5) at lesser lifetime costs (AUD\$98,900 versus AUD\$101,400). The authors concluded that surgically induced weight loss as a therapy for type 2 diabetes was a “dominant” intervention in that it provided health benefits with a reduced long-term healthcare costs.

A recent systematic review and economic evaluation of bariatric surgery for different BMI groups found that bariatric surgery was a clinically effective and cost-effective intervention for moderately to severely obese people compared with nonsurgical interventions. Specifically, this analysis found that bariatric surgery for patients with BMI 30–35 produced incremental cost-effectiveness ratios that were within the cost-effective range [55].

Which bariatric surgical procedure is preferred for class I obesity? The decision regarding the choice of bariatric procedures must take into account the risk/benefit analysis for a particular patient as well as their preferences. In the BMI 30–35 group and for bariatric surgery in general, there is currently no predictive method to match a particular patient with a particular operation to achieve the optimal outcome. We must therefore have frank discussions with our patients and reach a mutually agreeable option. Currently, high-level data support the use of laparoscopic adjustable gastric banding, gastric bypass, and sleeve gastrectomy in this population. Compared with gastric bypass and sleeve gastrectomy, LAGB has a lower rate of early, severe postoperative complications [63,64]. The effectiveness of gastric banding, however, is clearly more dependent on the quality of follow-up than other bariatric surgical procedures and may therefore be unsuitable if good aftercare is not assured and funded [65]. Additionally, there



are no weight loss independent effects of gastric banding that can influence metabolic improvement, and many bariatric practices may not be able to achieve the excellent weight loss results with LAGB that are reported in the literature [66]. Finally, some patients are averse to having a foreign body placed around their stomach. Therefore, RYGB and sleeve gastrectomy should also be considered as acceptable options for this patient population, particularly for patients with poorly controlled type 2 diabetes who may benefit from the additional metabolic effects these procedures provide in addition to weight loss. The presence of other specific co-morbidities, such as severe gastroesophageal reflux, may also influence the choice of procedures toward gastric bypass [67]. In the final analysis, it remains up to the judgment of the treating physicians and the patient to choose the option they feel is in the patient's best interest.

### Summary and recommendations

1. Class I obesity is a well-defined disease that causes or exacerbates multiple other diseases, decreases the duration of life, and decreases the quality of life. The patient with class I obesity should be recognized as deserving treatment for this disease.
2. Current options of nonsurgical treatment for class I obesity are not generally effective in achieving a substantial and durable weight reduction.
3. For patients with BMI 30–35 who do not achieve substantial and durable weight and co-morbidity improvement with nonsurgical methods, bariatric surgery should be an available option for suitable individuals. The existing cutoff of BMI, which excludes those with class I obesity, was established arbitrarily nearly 20 years ago. There is no current justification on grounds of evidence of clinical effectiveness, cost-effectiveness, ethics, or equity that this group should be excluded from life-saving treatment.
4. Gastric banding, sleeve gastrectomy, and gastric bypass have been shown in RCTs to be well-tolerated and effective treatment for patients with BMI 30–35 in the short and medium term.

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