ASMBS American Society for Metabolic & Bariatric Surgery

Updated Position Statement on Sleeve Gastrectomy as a Bariatric Procedure

Revised 10/28/2011

Preamble

The American Society for Metabolic and Bariatric Surgery (ASMBS) has previously published two position statements on the use of sleeve gastrectomy (SG) as a bariatric procedure.[1, 2] These position statements were developed in response to inquiries made to the society by patients, physicians, hospitals, health insurance payers, the media, and others regarding new procedures or issues within our specialty that require close evaluation and evidence-based scrutiny. In the evolving field of bariatric surgery, it is periodically necessary to provide updated position statements based on a growing or changing body of evidence. The Clinical Issues Committee and Executive Council have determined that since the 2009 position statement on SG was issued, there have been substantial changes to the published literature regarding SG and that the number and quality of the publications evaluating SG warrant publication of an updated statement. Specifically, multiple studies evaluating comorbidity improvement after SG, comparative studies with other accepted bariatric procedures, and long-term outcome data have emerged since the 2009 position statement. Recommendations are made based on published, peer-reviewed scientific evidence and expert opinion. The statement is not intended as and should not be construed as stating or establishing a local, regional, or national standard of care for any bariatric procedure.

The Data

The bariatric procedure commonly referred to as “sleeve gastrectomy” is a left partial gastrectomy of the fundus and body to create a long, tubular gastric conduit constructed along the lesser curve of the stomach. This procedure has evolved from a larger gastric component of the duodenal switch with biliopancreatic diversion. While SG is generally considered a restrictive procedure, the mechanisms of weight loss and improvement in comorbidities seen after SG may also be related to neurohumoral changes related to gastric resection or expedited nutrient transport into the small bowel. The metabolic mechanisms of action of SG continue to be an active area of research.

The recommendations of the 2009 position statement regarding the use of SG as a bariatric procedure were primarily based on a systematic review of the literature completed at that time which included two randomized controlled trials, one non-randomized matched cohort analysis, and thirty-three uncontrolled case series. At that time, the reported overall mean per cent excess weight loss (%EWL) after SG was 55% (average follow-up less than three years) and complication rates in large single center series (n>100) ranged up to 15%. The reported leak, bleeding, and stricture rates in the systematic review (which included high risk patients) were 2.2%, 1.2%, and 0.63%, respectively, and the post-operative 30-day mortality rate was 0.19% in the published literature.

An updated search of the literature using the same search strategy (Medline search using key words "bariatric, sleeve, gastrectomy, vertical gastrectomy") was conducted for this updated statement. Case reports or small case series (< 10 patients), review articles, and studies including adolescents or combining SG with other procedures were not included in this analysis. This updated search revealed 69 studies published since the last position statement that provide relevant outcome data to support updated recommendations. [3-50,51-71] This new literature includes several randomized controlled trials that generally show equivalence or superiority of the LSG to currently accepted procedures (Roux-en-Y gastric bypass, RYGB, and laparoscopic adjustable gastric banding, LAGB) with short and medium-term follow-up periods. **Table 1** lists the randomized controlled trials, the reported weight loss outcomes, and a summary of the conclusions from these studies. In addition to the randomized trials listed, there are several matched cohort, prospective, and case control studies that demonstrate weight loss outcomes, diabetes remission rates, improvements in inflammatory markers and cardiovascular risk, and improvements in a variety of obesity-related comorbidities after SG that are equivalent to or exceed RYGB and LAGB procedures.[12, 13, 51, 55] Remission rates of type 2 diabetes after SG are typically reported between 60% and 80% depending on the patient population and length of follow-up.[3, 9, 24, 33, 45, 55, 58, 61, 67, 69] A systematic review of diabetes remission rates after SG included 27 studies and 673 patients.[33] At a mean follow-up of 13 months, diabetes had resolved in 66% of patients and improved in 27%. There was a mean decrease in blood glucose of -88 mg/dL and a mean decrease in HbA1c of -1.7%.

In addition to improvement in many clinical parameters, several studies have also demonstrated significant improvements in quality of life after SG.[6, 19, 26, 41, 44, 65]

While there are several case control and retrospective series that have demonstrated superiority of RYGB over SG with regards to weight loss, comorbidity reduction, or diabetes remission[22, 31, 39] randomized studies have demonstrated superiority or equality to RYGB[42, 72] and superiority of LSG over LAGB in terms of weight loss (EWL 66% vs 48%), comorbidity reduction, or diabetes remission.[73]

Review of published complications after SG demonstrates major complication rates that are equal to or less than those reported in the 2009 statement and no new safety concerns have emerged. Staple line leaks and bleeding after SG continue to be the most serious complications and occur in 1-3% of patients in large published series.[8, 11, 29, 54, 60, 68]

The development of gastroesophageal reflux (GERD) after sleeve gastrectomy is reported in several publications[20, 37, 43, 48], but a recent systematic review evaluating the effect of SG on GERD reported inconsistent outcomes.[21] Further studies of the long-term effects of SG on GERD symptoms and the role of SG for patients with hiatal hernia are necessary in order to draw more definitive conclusions. There are also studies that report SG results in fewer nutritional deficiences than those reported after gastric bypass,[32, 35] but there is insufficient evidence to draw any definitive conclusions and more evidence is needed regarding the effect of SG on long-term vitamin, mineral, and nutritional deficiencies.

Several large registries have also reported weight loss and complication data after SG. The American College of Surgeons Bariatric Surgery Center Network longitudinal database (n=28,616) recently reported 30-day, 6-month, and 1-year outcomes of LSG, LAGB, and RYGB including morbidity and mortality, readmissions, and reoperations as well as reduction in body mass index (BMI) and weight-related comorbidities. This study reported that the LSG has higher risk-adjusted morbidity, readmission and reoperation/intervention rates compared to the LAGB, but lower reoperation/intervention rates compared to the LRYGB and open RYGB. There were no differences in mortality between groups. However, LSG patients had a higher BMI and higher risk profile than LAGB patients. Reduction in BMI and most of the weight-related comorbidities after the LSG also lies between those of the LAGB and the RYGB.[38] The Michigan Bariatric Surgery Collaborative (MBSC) evaluated 30 day complication rates for 62 bariatric surgeons in 25 hospitals and reported the risk of serious complication after LSG to be 2.2% compared to 0.9% for LAGB and 3.6% for RYGB.[15] Another publication from MBSC used a registry of 25,469 bariatric patients to develop a risk prediction model for serious complications after bariatric surgery and found the risk of SG to fall between LAGB and RYGB.[27] A large prospective national registry in Spain reported outcomes of 540 SG patients from 17 centers. Morbidity rate was 5.2% and mortality rate 0.36%. Complications were more common in superobese patients, males, and patients >55 years old. Mean percent excess BMI loss (EBL) was 72.4 +/- 31% at 24 months and Bougie caliber was an inverse predictive factor of %EBL at 12 and 24 months. In this patient population, diabetes remitted in 81% of the patients and hypertension improved in 63.2%. A second-stage surgery was performed in 18 patients (3.2%).[63]

Data from the 3rd International Summit for Sleeve Gastrectomy was recently published and included questionnaire results from 88 surgeons who had performed 19,605 SG procedures. Among this group of patients, a second-stage procedure became necessary in 2.2% of patients. The mean percentage of excess weight loss reported by the surgeons at 1, 2, 3, 4, and 5 years was 62.7%, 64.7%, 64.0%, 57.3%, and 60.0%, respectively. Proximal staple line leaks occurred in 1.3% of cases (range 0-10%) and distal staple line leaks occurred in .5%. Intraluminal bleeding occurred in 2.0% of cases and the mortality rate was .1% +/- .3%.[25]

Durability of SG in has been an important concern over the last five years. There are currently five studies that report the long-term (≥ 5 years) weight loss results after SG and one paper that reports the long-term results of a non-resectional vertical sleeve (Magenstrasse and Mill procedure). A summary of these publications is shown in **Table 2**.

Sarela et al. reports their long-term experience with their initial 20 patients who underwent LSG as a primary procedure.[64] The overall %EWL for this group was 68% at ≥8 years. During the follow-up period, three patients were lost to follow-up after two years and four patients underwent a revisional procedure (three RYGB, one duodenal switch) for insufficient weight loss. Of the 13 SG-only patients who had long-term follow-up, the median %EWL was 68% and 11 of the 13 patients had > 50% EWL.

Bohdjalian et al. reported 5 year follow-up on their initial 26 SG patients. Mean %EWL at 5 years was 55% (not converted, n = 21). Weight regain of more than 10 kg from nadir was observed in five (19.2%) of the 26 patients in this series and four of the patients (15.4%) were converted to gastric bypass due to severe reflux (n = 1) and weight loss failure (n = 3). Additionally, Bohdjalian and colleagues demonstrated long-term suppression of ghrelin in a subset of these patients.[17] Himpens et al. reported their long-term experience with 41 patients who underwent LSG as a primary procedure. During the six year follow-up period, 11 patients underwent conversion to duodenal switch and that group had 71% EWL at six years (up from 60% EWL at three years). The 30 patients who had LSG only had 77% EWL at three years and 53% EWL at 6 years. Despite some weight increase in this group, patient acceptance of LSG remained high. [36] This and other studies demonstrate that there is a tendency for some weight regain after SG, perhaps similar to that seen after RYGB.

Summary and Recommendations.

Substantial comparative and long-term data are now published in the peer-reviewed literature demonstrating durable weight loss, improved medical comorbidities, long-term patient satisfaction, and improved quality of life after SG.

The ASMBS therefore recognizes SG as an acceptable option as a primary bariatric procedure and as a first stage procedure in high risk patients as part of a planned staged approach.

Based on the current published literature, SG has a risk/benefit profile that lies between the laparoscopic adjustable gastric band and the laparoscopic Roux-en-Y gastric bypass.

As with any bariatric procedure, long-term weight regain can occur and, in the case of SG, this could be managed effectively with re-intervention. Informed consent for SG used as a primary procedure should be consistent with consent provided for other bariatric procedures and should include the risk of long-term weight gain.

Surgeons performing SG are encouraged to continue to prospectively collect and report outcome data in the peer-reviewed scientific literature.

Sleeve gastrectomy position statement and standard of care

This position statement is not intended to provide inflexible rules or requirements of practice and is not intended, nor should it be used, to state or establish a local, regional, or national legal standard of care. Ultimately, there are various appropriate treatment modalities for each patient, and surgeons must use their judgment in selecting from among the different feasible treatment options.

The ASMBS cautions against the use of this position statement in litigation in which the clinical decisions of a physician are called into question. The ultimate judgment regarding appropriateness of any specific procedure or course of action must be made by the physician in light of all the circumstances presented. Thus, an approach that differs from the position statement, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious physician may responsibly adopt a course of action different from that set forth in the position statement when, in the reasonable judgment of the physician, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology. All that should be expected is that the physician will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient in order to deliver effective and safe medical care. The sole purpose of this position statement is to assist practitioners in achieving this objective.

Table 1. Randomized Trials Evaluating Sleeve Gastrectomy

Author	Procedures (N)	Mean Preoperat5ive BMI (kg/m^2)	Follow-up	Weight Loss	Conclusions
Woelnerhanssen et al.[71]	LSG (11) LRYGB (12)	LSG 45 LRYGB 47	12 months	LSG 28% TBW LRYGB 35% TBW	No differences in weight loss, insulin sensitivity, or effects on adipokines (adiponectin, leptin),
Kehagias et al.[42]	LSG (30) LRYGB (30)	LSG 46 LRYGB 45	36 months	LSG 68% EWL LRYGB 62% EWL	No differences in weight loss. LSG and LRYGB are equally safe and effective in the amelioration of comorbidities. LSG is associated with fewer postoperative metabolic deficiencies
Lee et al.[74]	LSG (30) Mini-GB (30)	LSG 30 LRYGB 30	12 months	LSG 76 % EWL Mini-GB 94% EWL*	GB patients more likely to achieve remission of T2DM (HbA1c < 6.5%, 93% vs. 47%, p=0.02)
Karamanakos et al.[72]	LSG (16) LRYGB (16)	LSG 45 LRYGB 46	12 months	LSG 69% EWL LRYGB 60% EWL**	Greater weight loss with SG at one year PYY levels increased similarly after either procedure. Greater ghrelin reduction and appetite suppression after SG compared with LRYGB
Himpens et al.[73]	LSG (40) LAGB (40)	LSG 39 LAGB 37	36 months	LSG 66% EWL LAGB 48% EWL**	Weight loss and loss of feeling of hunger after 1 year and 3 years are better after SG than LAGB. GERD is more frequent at 1 year after SG and at 3 years after GB
Peterli et al.[58]	LSG (14) LRYGB (13)	LSG 46 LRYGB 47	3 months	LSG 39% EBMIL LRYGB 43% EBMIL*	Both procedures markedly improved glucose homeostasis: insulin, GLP-1, and PYY levels increased similarly after either procedure

*P =Not Significant, **P $\leq$ 0.05

BMI, body mass index, LSG, laparoscopic sleeve gastrectomy; LRYGB, laparoscopic Roux-en-Y gastric bypass, LAGB, laparoscopic adjustable gastric band; EWL, excess weight loss; EBMIL, excess body mass index loss; Mini-GB, Mini-gastric bypass

Table 2. Long-term follow-up after sleeve gastrectomy

Author	Patients (n)	Preoperative BMI (kg/m^2)	Follow-up	Weight Loss
Johnston et al.[75] (M+M procedure)	16	46	5 years	61% EWL
Weiner et al.[76]	8	62	5 years	-17 BMI
Himpens et al.[36]	41	39	6 years	53% EWL
Bohdjalian et al.[17]	26	48	5 years	55% EWL
Sarela et al.[64]	20	46	8-9 years	69% EWL*
D'Hondt et al.[26]	23	39	6 years	56% EWL

*13 LSG-only patients. 4 patients underwent revision to gastric bypass or duodenal switch, 2 patients lost to follow-up after two years. BMI, body mass index; EWL, excess weight loss

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