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Updated position statement on sleeve gastrectomy as a bariatric procedure

ASMBS Clinical Issues Committee

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Preamble

The American Society for Metabolic and Bariatric Surgery (ASMBS) has previously published 2 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 ASMBS 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, substantial changes have been published regarding SG and that the number and quality of the publications evaluating SG warrant publication of an updated statement. Specifically, multiple studies evaluating co-morbidity 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, peerreviewed 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. Although SG is generally considered a restrictive procedure, the mechanisms of weight loss and improvement in co-morbidities seen after SG could 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 published data completed at that time. These included 2 randomized controlled trials, 1 nonrandomized matched cohort analysis, and 33 uncontrolled case series. At that time, the reported overall mean percentage of excess weight loss (%EWL) after SG was 55% (average follow-up of <3 yr), and the complication rates in large single-center series (n >100) ranged ≤15%. The reported leak, bleeding, and stricture rate in the systematic review (which included high-risk patients) was 2.2%, 1.2%, and .63%, respectively, and the postoperative 30-day mortality rate was .19% in the published studies.

An updated search of the published data using the same search strategy (MEDLINE search using key words "bariatric, sleeve, gastrectomy, vertical gastrectomy") was conducted for the present updated statement. Case reports or small case series (<10 patients), review articles, and studies that included adolescents or combined SG with other procedures were not included in the present analysis. The updated search revealed 69 studies published since the previous position statement that provide relevant outcome data to support updated recommendations [3-71]. These new data include several randomized controlled trials that generally show equivalence or superiority of the laparoscopic SG (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. The randomized controlled trials, the reported weight loss outcomes, and a summary of the conclusions from these studies are listed in Table 1. In addition to the randomized trials listed, several matched-cohort, prospective, and case-control studies have demonstrate weight loss outcomes, diabetes remission rates, improvements in inflammatory markers and cardiovascular risk, and improvements in a variety of obesity-related co-morbidities after SG

Table 1 Randomized trials evaluating sleeve gastrectomy

Investigator	Procedures (n)	Mean preoperative BMI (kg/m ²)	Follow-up (mo)	Weight loss	Conclusions
Woelnerhanssen et al. [71]	LSG (11) LRYGB (12)	LSG: 45 LRYGB: 47	12	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	LSG: 68% EWL LRYGB: 62% EWL	No differences in weight loss; LSG and LRYGB equally safe and effective in amelioration of co-morbidities; LSG associated with fewer postoperative metabolic deficiencies
Lee et al. [74]	LSG (30) Mini-GB (30)	LSG: 30 LRYGB: 30	12	LSG: 76% EWL Mini-GB: 94% EWL*	GB patients more likely to achieve remission of T2DM (HbA1c <6.5%, 93% versus 47%, $P = .02$)
Karamanakos et al. [72]	LSG (16) LRYGB (16)	LSG: 45 LRYGB: 46	12	LSG: 69% EWL LRYGB: 60% EWL†	Greater weight loss with SG at 1 yr; PYY levels increased similarly after either procedure; greater ghrelin reduction and appetite suppression after LSG than after LRYGB
Himpens et al. [73]	LSG (40) LAGB (40)	LSG: 39 LAGB: 37	36	LSG: 66% EWL LAGB: 48% EWL*	Weight loss and loss of feeling of hunger after 1 yr and 3 yr better after LSG than LAGB; GERD more frequent at 1 yr after LSG and 3 yr after LAGB
Peterli et al. [58]	LSG (14) LRYGB (13)	LSG: 46 LRYGB: 47	3	LSG: 39% EBMIL LRYGB: 43% EBMIL†	Both procedures markedly improved glucose homeostasis; insulin, GLP-1, and PYY levels increased similarly after either procedure

BMI = body mass index; LSG = laparoscopic sleeve gastrectomy; LRYGB = laparoscopic Roux-en-Y gastric bypass; TBW = total body weight; mini-GB = mini-gastric bypass; EWL = excess weight loss; T2DM = type 2 diabetes mellitus; HbA1c = glycosylated hemoglobin; PYY = peptide YY; LAGB = laparoscopic adjustable gastric band; GERD = gastroesophageal reflux disease; EBMIL = excess BMI loss; GLP-1 = glucagon-like peptide-1. * P = NS.

that are equivalent to or exceed those of RYGB and LAGB [12,13,51,55]. The 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 glycosylated hemoglobin 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].

Although several case-control and retrospective series that have demonstrated superiority of RYGB over SG with regard to weight loss, co-morbidity 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% versus 48%), co-morbidity reduction, or diabetes remission [73].

A review of published complications after SG demonstrated 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 disease after SG has been reported in several publications [20,37,43,48], but a recent systematic review evaluating the

[†] $P \leq .05$.

effect of SG on gastroesophageal reflux disease reported inconsistent outcomes [21]. Additional studies of the long-term effects of SG on gastroesophageal reflux disease symptoms and the role of SG for patients with hiatal hernia are necessary to draw more definitive conclusions. There are also studies that report SG results in fewer nutritional deficiencies than those reported after gastric bypass [32,35]; however, 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 reductions in body mass index (BMI), and weightrelated co-morbidities. That study reported that LSG has greater risk-adjusted morbidity, readmission, and reoperation/intervention rates compared with the LAGB but lower reoperation/intervention rates compared with laparoscopic RYGB and open RYGB. No differences were seen in mortality between groups. However, LSG patients had a greater BMI and a greater risk profile than LAGB patients. The reduction in BMI and most of the weight-related co-morbidities after the LSG are also between those of LAGB and RYGB [38]. The Michigan Bariatric Surgery Collaborative evaluated the 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 with .9% for LAGB and 3.6% for RYGB [15]. Another publication from the Michigan Bariatric Surgery Collaborative 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 be between LAGB and RYGB [27]. A large prospective national registry in Spain reported outcomes of 540 SG patients from 17 centers. The morbidity rate was 5.2% and the mortality rate .36%. The complications were more common in superobese patients, men, and patients >55 years old. The mean percentage of excess BMI loss was $72.4\% \pm 31\%$ at 24 months, and the bougie caliber was an inverse predictive factor of the percentage of excess BMI loss 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 Third 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 secondstage 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 $.1\% \pm .3\%$ [25].

The durability of SG in has been an important concern during the past 5 years. Currently, 5 studies have reported the long-term (≥5 yr) weight loss results after SG and 1 study has reported the long-term results of a nonresectional vertical sleeve (Magenstrasse and Mill procedure). A summary of these publications is listed in Table 2.

Sarela et al. [64] reported their long-term experience with their initial 20 patients who underwent LSG as a primary procedure. The overall %EWL for their group was 68% at ≥8 years. During the follow-up period, 3 patients were lost to follow-up after 2 years and 4 patients underwent a revisional procedure (3 RYGB and 1 duodenal switch) for insufficient weight loss. Of the 13 LSG-only patients with long-term follow-up, the median %EWL was 68%, and 11 of the 13 patients had >50% EWL.

Bohdjalian et al. [17] reported the 5-year follow-up data from their initial 26 SG patients. The mean %EWL at 5 years was 55% (not converted, n = 21). Weight regain of >10 kg from nadir was observed in 5 (19.2%) of the 26 patients in their series, and 4 of the patients (15.4%) underwent conversion to gastric bypass because of severe reflux (n = 1) or weight loss failure (n = 3). Additionally, Bohdjalian et al. [17] demonstrated long-term suppression of ghrelin in a subset of these patients. Himpens et al. [36] reported their long-term experience with 41 patients who underwent LSG as a primary procedure. During the 6-year follow-up period, 11 patients underwent conversion to du-

Table 2 Long-term follow-up after sleeve gastrectomy

Investigator	Patients (n)	Preoperative BMI (kg/m²)	Follow-up (yr)	Weight loss
Johnston et al. [75] (M+M procedure)	16	46	5	61%EWL
Weiner et al. [76]	8	62	5	-17 BMI
Himpens et al. [36]	41	39	6	53%EWL
Bohdjalian et al. [17]	26	48	5	55%EWL
Sarela et al. [64]	20	46	8–9	69%EWL*
D'Hondt et al. [26]	23	39	6	56%EWL

BMI = body mass index; M+M = Magenstrasse and Mill; EWL = excess weight loss; LSG = laparoscopic sleeve gastrectomy.

^{*} Included 13 LSG-only patients; 4 patients underwent revision to gastric bypass or duodenal switch, 2 patients were lost to follow-up after 2 years.

odenal switch and that group had 71% EWL at 6 years (up from 60% EWL at 3 yr). The 30 patients who underwent LSG only had 77% EWL at 3 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 have 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 have now been published in peer-reviewed studies demonstrating durable weight loss, improved medical co-morbidities, 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 a part of a planned staged approach.

From the current published data, SG has a risk/benefit profile between LAGB and laparoscopic RYGB.

As with any bariatric procedure, long-term weight regain can occur and, in the case of SG, this can be managed effectively with reintervention. Informed consent for SG used as a primary procedure should be consistent with the 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 their outcome data in the peer-reviewed scientific studies.

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 the 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. 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 a 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 according to current knowledge, the available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of the present position statement is to assist practitioners in achieving this objective.

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