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Updated Position Statement on Sleeve Gastrectomy as a Bariatric Procedure

Clinical Issues Committee of the American Society for Metabolic and Bariatric Surgery

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The American Society for Metabolic and Bariatric Surgery (ASMBS) has previously published a position statement on the use of sleeve gastrectomy (SG) as a bariatric procedure [1]. These position statements have been developed in response to inquiries made to the Society by patients, physicians, hospitals, health insurance payors, the media, and others regarding new procedures or issues within our specialty that require close evaluation and evidence-based scrutiny. In the rapidly changing field of bariatric surgery, it is necessary to periodically review previously published statements and provide updated position statements from a growing or changing body of evidence. The Clinical Issues Committee and Executive Council have determined that, since the initial position statement on SG was issued, the published data have grown and the use of this procedure has become more widespread such that a revised position statement is warranted. Since the original position statement was published (15 studies, 775 patients, 3 years of follow-up), an additional 21 studies have been published with 1795 patients (excluding studies with duplicate patient groups) with follow-up data available for 5 years after SG for some patients. The purpose of the present updated statement is to review the currently available data regarding the safety, efficacy, and durability of the SG procedure as a primary or staged operation. Recommendations have been from 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.

SG as a bariatric procedure

The bariatric procedure commonly referred to as "sleeve gastrectomy" (SG) or "vertical gastrectomy" is a bariatric procedure involving subtotal gastric resection of the fundus and body to create a long, tubular gastric conduit along the lesser curve of the stomach. SG is the gastric component of the ASMBS-approved bariatric procedure of biliopancreatic diversion with duodenal switch. The mechanisms of weight loss and improvement in co-morbidities seen after SG might be related to gastric restriction, neurohumoral changes related to gastric resection or gastric emptying, or some other unidentified factor or factors.

A systematic review of the current data reporting either complications or weight loss outcomes after SG in adult human subjects was recently completed [2]. After removing studies with duplicate patient populations, the review included 36 studies and was the primary source of evidence for the present statement.

Included in these studies were 2 randomized controlled trials, 1 nonrandomized matched cohort analysis, and 33 uncontrolled case series. Three of the studies were multicenter trials, and the remaining studies were from single institutions. One study used an open approach, with the remaining reporting the results of laparoscopic SG (LSG). These 36 studies reported on a total of 2570 patients [3–38] (Table 1). Intermediate-term follow-up has been reported, with 3-, 4-, and 5-year follow-up periods. The number of patients reaching these follow-up periods in the published data was 123, 26, and 8, respectively. The reports described the treatment of patients with a preoperative body mass index of 35–69 kg/m^2. The percentage of excess weight loss was 33–85%, with an overall mean of 55%. A detailed description of the resolution or marked improvement in weight-related co-morbidities was reported in 10 studies and 754 patients, with follow-up to 5 years for a small number of patients. These studies demonstrated rates of

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Table 1
Outcomes of sleeve gastrectomy

Variable	High-risk patients/staged approach [6–18]	Primary procedure [3–5,8,19–38]	All patients
No. of studies* (no. of patients)	13 (821)	24 (1749)	36 (2570)
Preoperative BMI (kg/m^2)			
Range	49.1–69.0	37.2–54.5	37.2–69.0
Mean	60.0	46.6	51.2
Postoperative BMI (kg/m^2)			
Range	36.4–53.0	26.0–39.8	26.0–53.0
Mean	44.9	32.2	37.1
Follow-up (mo)	4–60	3–36	3–60
Excess weight loss (%)			
Range	33.0–61.4	36.0–85.0	33.0–85.0
Mean	46.6	60.7	55.4
Complication rate (%)			
Range	0–23.8	0–21.7	0–23.8
Mean	9.4	6.2	
Studies with >100 patients (%)	3.3–15.3	0–14.1	0–14.1
Leaks†	8/686 (1.2)	45/1681 (2.7)‡	53/2367 (2.2)
Bleeding†	11/686 (1.6)	7/1681 (1.0)§	28/2367 (1.2)
Strictures†	6/686 (0.9)	9/1681 (0.5)§	15/2367 (0.6)
Mortality¶	2/821 (0.24)	3/1749 (0.17)§	5/2570 (0.19)

BMI = body mass index.
Adapted, with permission, from Brethauer et al. [2].
* One study included clearly defined patients in both groups.
† Included studies with detailed complication data only.
‡ $P = .02$ compared with high-risk group.
§ P not significant compared with high-risk group.
¶ Thirty-day postoperative mortality.

improvement and remission of diabetes, hypertension, hyperlipidemia, and sleep apnea comparable to those seen with other restrictive procedures (Table 2). The major complication rates reported in these studies were relatively low. For all studies, the complication rates were ≤24% and, for the larger studies (n >100), ≤15%. The reported leak, bleeding, and stricture rate was 2.2%, 1.2%, and 0.63%, respectively, for all studies reporting detailed complication data (n = 2367). The postoperative 30-day mortality rate was 0.19% in the published data.

The outcomes of SG have been compared with those after other bariatric procedures that have been accepted as primary procedures by the ASMBS. Two randomized comparison trials have recently been published. The first prospective randomized trial compared LSG and laparoscopic adjustable gastric banding (n = 16 in each group) and reported a greater percentage of excess weight loss (66% versus 48%, $P = .025$) after LSG at 3 years [3]. The second prospective randomized trial compared LSG and Roux-en-Y gastric bypass (n = 40 in each group) and reported better weight loss with LSG at 1 year (percentage of excess weight loss of 70% versus 61%, respectively, $P = .05$) [4]. A matched cohort analysis comparing LSG and Roux-en-Y gastric bypass reported similar weight loss (31% of initial weight) and remission of diabetes and metabolic syndrome (84% and 62%, respectively) at 1 year postoperatively [5].

Some have considered SG to be a resectional form of the Magenstrasse and Mill procedure, an unbanded long lesser curve gastroplasty that is different from SG in that no gastric resection is performed. A comparison of the SG and the Magenstrasse and Mill procedure is controversial, because many have theorized that the extensive gastric resection characterizing SG provides an additional mechanism for weight loss owing to a reduction in the secretion of gastric hormones such as ghrelin. However, the 5-year outcomes of the Magenstrasse and Mill procedure have been published and have demonstrated durable weight loss (61% excess weight loss) and a reduction of obesity-related co-morbidities.

SG is the gastric component of the ASMBS-approved bariatric procedure of biliopancreatic diversion with duodenal switch and began its evolution as a primary operation with the observation that a single-stage laparoscopic duodenal switch in super obese patients with major co-morbidities demonstrated a high risk of complications and mortality. Thus, the performance of the SG as the first stage of the laparoscopic procedure emerged as a risk reduction strategy for high-risk patients. As determined from the investigators' stated intentions or description of the patient population, 13 studies used SG in high-risk patients or as a planned staged approach (n = 821) and 24 studies used SG as a primary procedure (n = 1749; one study had clearly defined patients in both groups). The differences in

Table 2
Co-morbidity remission and improvement after sleeve gastrectomy

Investigator	Patients (n)	Follow-up (mo)	T2DM (%)	HTN (%)	Hyperlipidemia (%)	Sleep apnea (%)	DJD/joint pain (%)	GERD (%)	Peripheral edema (%)	Depression (%)
Cottam et al. [9], 2006	126	12	81 R 11 I	78 R 7 I	73 R 5 I	80 R 7 I	85 R 6 I	70 R 8 I	91 R 3 I	67 R 9 I
Hamoui et al. [10], 2005	118	24	47 R 22 I	15 R 16 I	—	—	—	—	—	—
Moon Han et al. [19], 2005	60	12	100 R	93 R 7 I	45 R 30 I	100 R	76 R 24 I	80 R 20 I	—	—
Silecchia et al. [14], 2006	41	18	79.6 R 15.4 I	62.5 R 25 I	—	56.2 R 31.2 I	—	—	—	—
Weiner et al. [6], 2007	120	60	14 R 86 I	42 R 55 I	5 R 77 I	39 R 61 I	36 I	57 R 43 I	—	—
Gan et al. [26], 2007	21	11.4	14 R 81 I	—	—	—	—	—	—	—
Ou Yang et al. [18], 2008	138	24	39%R 49 I	29 R 48 I	48 R 39 I	52 R 33 I	—	—	—	—
Kasalicky et al. [31], 2008	61	18	71 R	65 R 23 I	—	45 R	—	—	—	—
Vidal et al. [5], 2008	39	12	84 R	50 R	50 R	—	—	—	—	—
Tagaya et al. [36], 2008	30	18	67 R 33 I	56 R 44 I	33 R 33 I	—	—	—	—	—

T2DM = type 2 diabetes mellitus; HTN = hypertension; DJD = degenerative joint disease; GERD = gastroesophageal reflux disease; R = remission; I = improved.

Adapted, with permission, from Brethauer et al. [2].

baseline data, weight loss, complications, and mortality rates between these 2 groups are listed in Table 1. The reported indications to use SG as a primary operation have included inflammatory bowel disease, severe small bowel adhesions from previous surgery, the necessity to continue specific medications (immunosuppressant or anti-inflammatory agents), pretransplant weight loss, and patient refusal to undergo anatomic rearrangement of their intestinal anatomy or placement of an implanted device. The high-risk subgroup, characterized by the accepted high-risk factors, including an average body mass index of 60 kg/m^2, has demonstrated a notably low rate of complications (overall 9.4%, including 1.2% for leakage and 1.6% for bleeding), and mortality within 30 days occurring in only 2 (0.24%) of 821 patients.

From a technical standpoint, no consensus has been reached regarding the optimal diameter of the indwelling bougie typically used to calibrate the sleeve segment during surgery; however, a general trend has been found in the published data toward smaller diameters. The bougie size in the reported data have ranged from 32F to 60F. Evidence has suggested that the volume of the resected stomach correlates with long-term weight loss and that dilation of the gastric sleeve might be a mechanism for long-term failure of weight loss maintenance [6]. However, concern exists regarding stricture formation when smaller diameter bougies have been used to calibrate the sleeve segment, and strictures can contribute to gastric leak and fistula after SG. Isolated SG strictures appear to respond to endoscopic management or surgical revision of the sleeve or conversion to gastric bypass. However, concern has been raised that the combination of persistent leak or fistula in the presence of a proximal stricture after SG might lead to total gastrectomy with esophagojejunostomy, carrying a high risk of morbidity and mortality, as the only definitive surgical option because of the extensive gastric resection that characterizes the SG procedure.

Summary and Recommendations

Limited intermediate-term (3–5-year) data have been published in peer-reviewed studies demonstrating durable weight loss and improved medical co-morbidities in patients treated for morbid obesity using the SG procedure. The long-term follow-up data at ≥5 years for high-risk and super-obese patients are limited, in part because some patients undergo a planned second operation (Roux-en-Y gastric bypass or duodenal switch) within 2 years of their SG, either as part of an overall staged treatment strategy or because of weight loss failure or weight regain. 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.

At present, the ASMBS recognizes that the concept of staged bariatric surgery using lower risk procedures as the initial treatment appears to have value as a risk-reduction strategy for high-risk patients. SG is uniquely positioned as a bariatric procedure because of its development as a risk-reduction initial treatment strategy with the intent that it

might be more easily converted to an alternative procedure after significant weight loss compared with the other available bariatric procedures. Much of the published data supporting SG as a bariatric procedure have described favorable outcomes in patients described as high risk, making it an acceptable option for this subgroup. Furthermore, a significant proportion of patients have demonstrated durable weight loss after SG and might not require conversion to another procedure. Therefore, it is justifiable to recommend SG as an ASMBS-approved bariatric procedure.

A deficiency of long-term follow-up data remains in the published surgical reports to confirm the effectiveness of SG as a stand-alone intervention at ≥5 years. Such long-term data might or might not ultimately confirm that the procedure should remain in the category of a staged treatment intervention. Furthermore, SG has the potential to cause long-term postoperative nutritional complications owing to the extensive gastric resection by decreasing the absorption of some vitamins and nutrients, such as vitamin B_{12} and iron. Similar to other bariatric procedures, long-term nutritional surveillance is recommended after SG.

Conclusion

Although the published intermediate-term 3–5-year follow-up data after SG are increasing, the data remain limited. The ASMBS has accepted SG as an approved bariatric surgical procedure primarily because of its potential value as a first-stage operation for high-risk patients, with the full realization that successful long-term weight reduction in an individual patient after SG would obviate the need for a second-stage procedure. Unanswered questions remain regarding how often patients will ultimately require conversion after SG to another procedure, the optimal strategies for revision of SG, a definitive assessment of the risks of bariatric surgical management using a staged procedure strategy, and issues of procedure selection for the many millions of morbidly obese patients who could benefit from bariatric surgical intervention.

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

Sleeve gastrectomy position statement and standard of care

The present 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, various treatment modalities are appropriate 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 have been 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 less than the standard of care. A conscientious physician can 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 would be 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 to deliver effective and safe medical care. The sole purpose of the present position statement is to assist practitioners in achieving this objective.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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