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Review article

Systematic review of sleeve gastrectomy as staging and primary bariatric procedure

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Sleeve gastrectomy (SG) is gaining popularity worldwide as a bariatric procedure both as a first-stage procedure in high-risk or super obese patients and as a primary operation. The potential advantages of the SG are that it confers immediate restriction of caloric intake, does not require placement of a foreign body or require adjustments, and can generally be performed in less time than required for bypass procedures. The possible disadvantages of the SG include the irreversibility, increased operative risk compared with other restrictive procedures, and unproved durability. The purpose of the present systematic review was to evaluate the current evidence regarding weight loss, complication rates, postoperative mortality, and co-morbidity improvement after SG.

Methods

The present review was conducted according to published recommendations, and the reports were selected using 2 levels of study screening [1]. PubMed was searched for citations that included SG using the keywords "bariatric surgery," "sleeve gastrectomy," "vertical gastrectomy," and "Magenstrasse and Mill." English language citations for human studies reported from 1996 to January 31, 2009 were included in the search. After an initial review of titles and abstracts, a review of 103 reports was conducted and the full text reviewed when appropriate. Additional citations were obtained by manually reviewing the bibliographies of the reports selected for review. Prospective and retrospective series reporting on SG as a primary or staging procedure for weight loss in adult patients were included if they included data on either postoperative complications or weight loss outcomes. Case reports (<5 patients), review articles, and studies reporting on technique only were not included. Substudies of larger series by the same group (or duplicate patient populations) were not included in our analysis of the total procedures performed, but these were included in our discussion when appropriate. In cases in which we were uncertain regarding duplicate patient groups (same group or institution reporting outcomes for a similar period without clear indications that the smaller report was a substudy or interim results), a consensus was reached among the authors regarding its inclusion or exclusion.

The indications for SG broadened during the review period. Therefore, the extracted studies were classified according to the indications for SG (high-risk patients/staged approach or primary procedure). The series were included in the high-risk/staged group if the investigators had clearly stated that the procedure was being used as a risk reduction strategy or as part of a planned staged approach. The series were categorized as primary procedures if no intention had been stated for a planned second procedure or if the investigators had explicitly reported that the SG was intended as a primary procedure.

Statistical analysis

Statistical analyses were performed only on the extracted data from the selected studies. Basic descriptive statistics (simple counts and means) were used to summarize the patient, study, weight loss, and complication data. Average unweighted values were calculated for the weight loss and complication data across all studies and for the high-risk and primary subgroups. As listed in Table 1 [2–37], no uniformity was present across studies for the method of reporting weight loss data. Additionally, an inverse variance mean was calculated for the percentage of excess weight loss (EWL) within each group of patients (high risk, primary) and for all patients combined. The estimates of variance were available for few studies; thus, a pooled estimate was calculated and

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Table 1
Sleeve gastrectomy outcomes

Investigator	Patients (n)	Preoperative BMI (kg/m^2)	Follow-up (mo)	Postoperative BMI (kg/m^2)	%EWL	Complication rate	Bougie size (F)	Postoperative mortality* (%)
Regan et al. [2], 2003	7	63	11	50	33	(3/7)	60	0
Almogy et al. [3], 2004	21	57.5	18	NR	61.4	23.8%	NR	0
Moon Han et al. [4], 2005	60	37.2	12	28	83.3	2.9%	48	1
Baltasar et al. [5], 2005	7	61–74	4–27	NR	56.1	6.7% (2/30)	32	1
	7	>40	4–16	NR	33.6–90†			
	16	35–43	3–27	NR	62.3			
Milone et al. [6], 2005	20	69	6	53	35	5%	60	0
Mognol et al. [7], 2005	10	64	12	41	51	0%	32	0
Cottam et al. [8], 2006	126	65.3	12	49	46	13%	46–50	0
Hamoui et al. [9], 2006	118	55	24	NR	47.3	15.3%	NR (97% open)	1
Silecchia et al. [10], 2006	41	57.3	12	40.8	NR	12.1%	48	0
Himpens et al. [11], 2006	40	39	36	Median decrease 27.5	66	5%	34	0
Lee et al. [12], 2007	216	49	24	27.7 (2 yr)	59 (1 yr)	7.4%	32	0
Nocca et al. [13], 2007	163	45.9	24	31.6	61.5	7.4%	36	0
Tucker et al. [14], 2007	148	43.4	3	NR	NR	2.7%	44–52	0
Weiner et al. [15], 2007	120	60.7	60	45	NR	3.3%	32, 44	0
Braghetto et al. [16], 2007	50	37.9	12	26	85	2%	32, 40	0
Dapri et al. [17], 2007	40	42.5	12	NR	49	2.5%	32	0
Melissas et al. [18], 2007	23	47.2	12	31.1	NR	21.7%	34	0
Gan et al. [19], 2007	21	52.8	11.4	NR	36	4.7% (1/21)	32–40	0
Ou Yang et al. [20], 2008	138	50.6	24	39.8	46	5.15%	36	0
Parikh et al. [21], 2008	135	60.1	12	44.3	47.3	NR	40, 60	0
Felberbauer et al. [22], 2008	126	48.1	19	36	NR	3.2%	48	0
Rubin et al. [23], 2008	120	43.5	11	33.9	NR	0%	48	0
Skrekas et al. [24], 2008	93	48.9	12	32.9	58.3	4.3%	36	0
Mui et al. [25], 2008	70	40.7	12	28.4	63.5	2.9%	38	0
Gagner et al. [26], (2008	63	68	12	50	46	6.3%	NR	0
Kasalicky et al. [27], 2008	61	41.8	18	29.7	NR	3.2%	38	0
Vidal et al. [28], 2008	39	51.9	12	32.7	31‡	NR	NR	0
Frezza et al. [29], 2008	53	53.5	18	NR	59.2	9.4%	29, 38	0
Hakeam et al. [30], 2008	29	50.9	6	35.1	59.4	NR	34	0
Karamanakos et al. [31], 2008	16	45.1	12	28.9	69.7	0%	NR	0
Quesada et al. [32], 2008	15	54	6	NR	44	6%	38	0
Tagaya et al. [33], 2008	30	49.1	18	37.6	NR	13.3%	45	0
Takata et al. [34], 2008	8	49.1	12	36.4	24–75†	13% (2/15)	44	0
Uglioni et al. [35], 2009	41	46.3	36	36	60§	9.8%	35	0
Fuks et al. [36], 2009	135	48.8	12	39.8	49.4	5.1%	NR	0
Stroh et al. [37], 2009	144	54.5	24	NR	NR	14.1%	32	2
Summary (36 studies)	**2570**	**37.2–69.0 (51.2)¶**	**3–60**	**26.0–53.0 (37.1)‖**	**33.0–85.0 (55.4)¶**	**0–24% 0–15.3% for studies with n >100**	**32–60**	**5/2570 (.19)**

BMI = body mass index; %EWL = percentage of excess weight loss; NR = not reported.
* Thirty-day postoperative mortality.
† Mean %EWL not reported.
‡ Total weight loss.
§ Excess BMI lost.
¶ Unweighted mean.
‖ Inverse variance weighted mean.

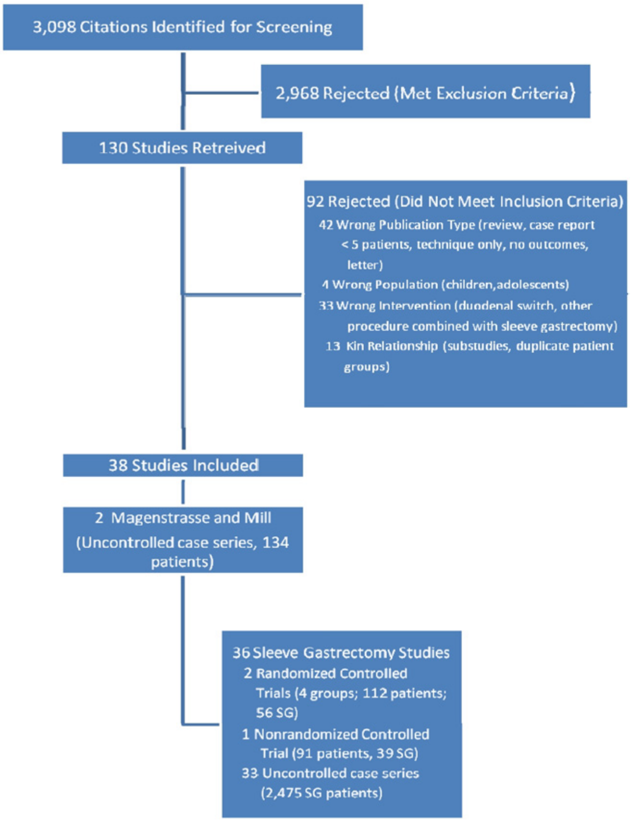

Fig. 1. Study flow chart.

the weights for the inverse variance weighted means were determined by the sample size. Comparisons of the complication and mortality rates were performed using the chi-square test and Fisher's exact test for the pooled data across all studies.

Results

Data retrieval

Fig. 1 shows the flow process for study selection. After the initial screening of titles and abstracts, 2968 citations were excluded, and 130 studies were reviewed to determine whether they the met inclusion criteria. Of the 130 studies, 92 were excluded during this phase of the review. Of the 92 excluded studies, 13 were kin studies, substudies of larger series, or duplicate patient groups from the same institution or group. After removing the Magenstrasse and Mill citations, 36 SG studies, including 2570 patients, were included in the present analysis. The Magenstrasse and Mill studies were not included in the SG analysis; however, given the similarities between these 2 procedures, the results from 2 series of the Magenstrasse and Mill procedure have been reported separately (Table 2) [38,39]. The other 6 Magenstrasse and Mill citations we found were substudies of a larger series [38] or included duplicate patient groups.

Study characteristics

A total of 36 studies were extracted for the present review. Of the 36 studies, 16 were from Europe, 11 were from the United States, 3 were from Asia, 2 were from Australia, 2 were from South America, and 1 each was from Israel and Saudi Arabia. The study design included 2 randomized controlled trials, 1 nonrandomized matched cohort analysis, and 33 uncontrolled case series. Also, 3 of the studies were multicenter trials and 33 from a single institution. Of the 36 studies, 13 clearly stated that the SG was used as a staged procedure or as a management strategy for a high-risk patient population, and 24 reported the results of the SG used as a primary operation with no intent of a second-stage procedure (1 study had clearly defined patients in both groups). Of the 36 studies, 1 reported on the open technique and 35 were laparoscopic. Each of the extracted studies included ≥1 of the outcomes of interest (i.e., weight loss data or detailed complication data).

Patient characteristics

Of the 36 studies, 32 reported the patient gender (n = 2135), and 64.5% of the patients were women. The mean patient age among all studies was 42.0 years (33 studies, n = 2381). In the high-risk/staged patient groups, 54.5% of the patients were women (11 studies, n = 672), and the average age was 45.0 years (11 studies, n = 669). For the primary SG group, 69.8% of the patients were women (21 studies, n = 1463), and the average age was 40.5 years (22 studies, n = 1712). The mean preoperative body mass index (BMI) in all 36 studies was 51.2 kg/m^2. The mean baseline BMI for the high-risk and primary SG patients is listed in Table 3.

Table 2
Magenstrasse and Mill outcomes

Investigator	Patients (n)	Preoperative BMI	Follow-up (yr)	Postoperative BMI	%EWL	Complication rate (%)	Bougie size (F)	Perioperative mortality (n)
Johnston et al. [2], 2003	100	46.3	5	NR	61	4	NR	0
Vassallo et al. [41], 2007	34	48	2	29	NR	2.9	36	0

Abbreviations as in Table 1.

Table 3
Outcomes of sleeve gastrectomy in high-risk/staged versus primary group

Variable	High-risk patients/ staged approach [2,3,5–10,15, 20,21,26,34]	Primary procedure [4,5,11–14,16–19, 22–25,27–33,35–37]
Studies* (patients)	13 (821)	24 (1,749)
Preoperative BMI (kg/m^2)		
Range	49.1–69.0	37.2–54.5
Mean	60.0	46.6
Postoperative BMI (kg/m^2)		
Range	36.4–53.0	26.0–39.8
Mean	44.9	32.2
Follow-up (mo)	4–60	3–36
%EWL		
Range	33.0–61.4	36.0–85.0
Mean	46.9	60.4
IVW mean (range)	46.6 (43.8–49.5)	60.7 (55.1–66.3)
Complication rate (%)		
All studies		
Range	0–23.8	0–21.7
Mean	9.4	6.2
Studies n >100	3.3–15.3	0–4.1
Complications		
Leak†	8/686 (1.2)	45/1,681 (2.7)‡
Bleeding†	11/686 (1.6)	17/1,681 (1.0)§
Stricture†	6/686 (.9)	9/1681 (.5)
Mortality	2/821 (.24)	3/1749 (.17)

IVW = inverse variance weighted; other abbreviations as in Table 1.
* One study included clearly defined patients in both groups.
† Including studies with detailed complication data only.
‡ P = .02 compared with high-risk group.
§ P value not significant compared with high-risk groups.

Weight loss

The mean %EWL after SG was reported in 24 studies (n = 1662) and was 33–85%, with an overall mean %EWL of 55.4%. The mean postoperative BMI was reported in 26 studies (n = 1940) and decreased from a baseline mean of 51.2 kg/m^2 to 37.1 kg/m^2 postoperatively. Those studies that did not include the %EWL reported the weight loss in terms of the BMI decrease, the percentage of BMI lost, or the percentage of the total weight lost (Table 1), and all had significant reductions in weight from the baseline values. The follow-up period for the weight loss data was 3–60 months. The weight loss data for the high-risk/staged and primary subgroups are listed in Table 3.

Co-morbidity reduction

Ten studies provided detailed postoperative co-morbidity data (n = 754) with a follow-up period of 1–5 years (Table 4). More than 70% of patients in these series had improvement or remission of type 2 diabetes. Also, significant improvements were seen in the other components of the metabolic syndrome (i.e., hypertension and hyperlipidemia), as well as in sleep apnea and joint pain.

Complications and operative mortality

The major postoperative complication rate ranged from 0% to 23.8%. For studies with >100 patients, the major postoperative complication rates ranged from 0% to 15.3%. Of the 36 studies, 33 (n = 2367) provided detailed complication data. In these 33 studies, 53 leaks (2.2%), 28 bleeding episodes requiring reoperation or transfusion (1.2%), and 15 postoperative strictures requiring endoscopic or surgical intervention (.6%) were reported. All extracted studies reported mortality data (n = 2570), with 5 postoperative deaths (within 30 days of surgery) reported, for an overall mortality rate of .19%. The mortality and complication rates for the high-risk/staged and primary groups are listed in Table 3.

Discussion

SG has increasingly gained acceptance among bariatric surgeons during the past 5 years. The initial reports of SG included high-risk patients who underwent laparoscopic SG (LSG) as a staged approach to bariatric surgery. Of the 36 published series included in the present analysis, 13 included patients who were considered by the investigators to be at high risk or who underwent LSG as a planned staged procedure before Roux-en-Y gastric bypass (RYGB) or biliopancreatic diversion/duodenal switch. These studies included a greater percentage of men and a greater preoperative BMI than the series using SG as the primary procedure. Many of these super obese and high-risk patients underwent second-stage RYGB or duodenal switch within 2 years of SG after improvement of their co-morbidities and surgical risk status. This staged approach limited the long-term follow-up in this group mainly to those who refused a second-stage operation or those with sufficient weight loss and co-morbidity reduction with SG alone. Despite the high surgical risk of this patient population, the reported rates of postoperative leaks, bleeding, and stricture have been acceptably low. Most of the early reports of SG were performed by bariatric surgeons who had had extensive experience performing the laparoscopic duodenal switch and gastric bypass procedures before implementing the SG into their practice. The low complication and mortality rates reported in this high-risk group might be a reflection of that experience or might reflect some degree of publication bias.

The initial report by Regan et al. [2] demonstrated proof of concept for this strategy, which has proved to be safe and effective in several other large series [8,9,20]. Cottam et al. [8] reported the outcomes of a high-risk group of patients with an average BMI of 65.3 kg/m^2. In their series, 94% of patients had an American Society of Anesthesiologists score of 3 or 4 before undergoing SG, with an average of 9 co-morbidities per patient. At 12 months after LSG, the mean BMI was 49 kg/m^2, only 44% of the patients had an American Society of Anesthesiologists score of ≥3, and the

Table 4
Co-morbidity remission and improvement after sleeve gastrectomy

Investigator	Patients (n)	Follow-up (mo)	Remission/Improvement rate (%)							
			T2DM	HTN	Hyperlipidemia	Sleep apnea	DJD/joint pain	GERD	Peripheral edema	Depression
Cottam et al. [8], 2006	126	12	81/11	78/7	73/5	80/7	85/6	70/8	91/3	67/9
Hamoui et al. [9], 2005	118	24	47/22	15/16	—	—	—	—	—	—
Moon Han et al. [4], 2005	60	12	100/0	93/7	45/30	100/—	76/24	80/20	—	—
Silecchia et al. [10], 2006	41	18	79.6/15.4	62.5/25	—	56.2/31.2	—	—	—	—
Weiner et al. [15], 2007	120	60	14/86	42/55	5/77	39/61	—/36	57/43	—	—
Gan et al. [19], 2007	21	11.4	14/81	—	—	—	—	—	—	—
Ou Yang et al. [20], 2008	138	24	39/49	29/48	48/39	52/33	—	—	—	—
Kasalicky et al. [27], 2008	61	18	71/—	65/23	—	45/—	—	—	—	—
Vidal et al. [28], 2008	39	12	84/—	50/—	50/—	—	—	—	—	—
Tagaya et al. [33], 2008	30	18	67/33	56/44	33/33	—	—	—	—	—

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

average number of co-morbidities per patient had decreased to 6. The 36 patients who underwent second-stage RYGB within the first year after LSG had an acceptable rate of major complications (11%; 3 cases of bleeding and 1 case of a leak, all managed nonoperatively), no mortality, and continued weight loss and co-morbidity resolution.

Another study by Ou Yang et al. [20] evaluated 138 high-risk patients with a mean BMI of 50.6 kg/m^2. In their series, the %EWL was 54% at 12 months and 46% at 24 months, and the mean BMI at 2 years had decreased to 39.8 kg/m^2. These weight loss findings were similar to those of other studies of this group of super obese patients. Only 6 patients (average %EWL of 35.4% at 15 months) underwent conversion to gastric bypass in their series, and these patients went on to achieve a %EWL of 63.9% at 8 months after RYGB.

Since 2006, most studies have reported the results of the SG as a primary operation. Although several patients in these series did undergo a second-stage operation for inadequate weight loss, the intention of the investigators had been to provide a primary weight loss procedure. The preoperative BMI was lower in this group of patients than that in the high-risk group, with a correspondingly greater %EWL. The complication rates reported in this lower risk group of patients was also low. The bleeding and stricture rates were lower than those in the high-risk group. The leak rate of 2.7% among primary operations was greater than the overall leak rate for the high-risk group, and this might have resulted from surgeon experience with this procedure. Several primary LSG series reported their initial experience with this procedure or the implementation of LSG as a part of a new bariatric program.

The largest series of LSG for the primary procedure group was by Lee et al. [12], who reported the outcomes of 216 patients. In their series, the average BMI for the LSG patients was 49 kg/m^2, greater than that of the nonrandomized comparative groups undergoing laparoscopic adjustable gastric banding, gastric bypass, or duodenal switch. Despite this greater BMI, the LSG group had a rate of weight loss similar to that of the RYGB and duodenal switch groups and a mean BMI of 27.7 kg/m^2 at 2 years. Of all 4 groups, the LSG patients had the greatest average total weight loss at 1 and 2 years (129 and 213 lb, respectively), and only 4.2% of LSG patients had a plateau in their weight loss at follow-up.

Several randomized trials have recently compared LSG and other bariatric procedures. Karamanakos et al. [31] compared LSG and RYGB and reported better weight loss with LSG at 1 year (%EWL of 69.7% versus 60.5%, respectively; $P = .05$). Both procedures resulted in marked increases in fasting and postprandial peptide YY levels, and the investigators attributed the improved weight loss with the LSG to lower levels of ghrelin and greater appetite suppression compared with RYGB. Himpens et al. [11] compared LSG and laparoscopic adjustable gastric banding in a randomized controlled trial and, at 3 years postoperatively, reported a greater %EWL (66% versus 48%, $P = .025$), greater loss of hunger (46.7% versus 2.9%), and greater loss of craving for sweets (23.3% versus 2.9%) after LSG. Two patients in that series (5%) had insufficient weight loss 3 years after LSG and underwent a duodenal switch [11]. Another small randomized trial also demonstrated superior weight loss and decreased ghrelin levels after LSG compared with after laparoscopic adjustable gastric banding [40].

In a nonrandomized study by Vidal et al. [28], LSG and RYGB patients were matched for various diabetes parameters (e.g., age at diagnosis, treatment type, and fasting glucose and glycosylated hemoglobin levels). At 1 year after surgery, the weight loss was similar for the 2 groups (31% of initial weight) and both groups had an 84% rate of remission of diabetes and comparable rates of resolution of the metabolic syndrome (62% for SG and 67% for RYGB) [28].

Lalor et al. [41] reported on the complications of SG when performed as a primary procedure. For 148 patients with an average preoperative BMI of 44 kg/m^2, the major complication rate was 2.9% [41]. That series included 16 patients in whom LSG was used as a revisional procedure after failed laparoscopic adjustable gastric banding or jejunoileal bypass. SG has also been reported as a revisional procedure for inadequate weight loss after laparoscopic adjustable gastric banding by others [13,22,23,35].

An important issue regarding the SG is durability. Most published series have reported their 1- or 2-year results; however, several studies have demonstrated durable weight loss 3–5 years after surgery. One of the potential factors contributing to the durability of this operation is the size of calibration used to create the sleeve. No clear consensus has been reached regarding sleeve calibration or bougie size in the published data. Several investigators have reported weight regain when a larger bougie size was used early in their experience with the SG [15,38]. More recent reports have used smaller bougie sizes (32–44F), particularly when the operation was intended as a primary procedure.

The 5-year follow-up data are available for the Magenstrasse and Mill procedure, with the %EWL maintained at 61%, although this duration of follow-up has been reported for a relatively small number of patients [38]. Weiner et al. [15] evaluated the influence of the gastric sleeve size on long-term weight loss after LSG and found significantly greater weight loss in patients who underwent LSG with tube calibration and a slight weight gain at 5 years for patients who underwent LSG with a larger sleeve volume or in whom the measured volume of the resected stomach was <500 cm^3 [15]. The randomized trial by Himpens et al. [9] and a study by Uglioni et al. [35] reported the 3-year results after LSG with durable weight loss effects.

The primary effect of LSG on co-morbidity reduction is most likely secondary to the immediate caloric restriction and rapid weight loss, although some studies have suggested other mechanisms such as rapid gastric emptying that might result in gut hormone changes [18,31]. Additional study is required to establish the effects of LSG on gut hormone interactions and the effects on glucose metabolism.

Conclusion

From the current evidence, including 36 studies and 2570 patients, LSG is an effective weight loss procedure that can be performed safely as a first stage or primary procedure. From this large volume of case series data, a matched cohort analysis, and 2 randomized trials, LSG results in excellent weight loss and co-morbidity reduction that exceeds, or is comparable to, that of other accepted bariatric procedures. The postoperative major complication rates and mortality rates have been acceptably low. Long-term data are limited, but the 3- and 5-year follow-up data have demonstrated the durability of the SG procedure.

Disclosures

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