From California Technology Assessment Forum

Sleeve Gastrectomy as a Stand alone Bariatric Procedure for Obesity: *A Technology Assessment*

Judith Walsh, MD, MPH

Professor of Medicine, Division of General Internal Medicine, Department of Medicine, University of California San Francisco

Abstract

The California Technology Assessment Forum (CTAF) has been requested to review the scientific evidence for the use of sleeve gastrectomy (SG) also known as vertical sleeve gastrectomy (VSG) or laparoscopic sleeve gastrectomy (LSG) as a stand alone surgical treatment for the treatment of obesity. There are several surgical procedures commonly performed for the treatment of morbid obesity. VSG is promoted as a less invasive alternative to Roux-en-Y gastric bypass, the bariatric surgery most frequently performed in the U.S. CTAF recently assessed the evidence for laparoscopic adjustable silicone gastric banding for obesity, but has not previously reviewed this topic

Background

Epidemiology and Definitions of Obesity

The prevalence of obesity is increasing worldwide and in the United States. The degree of obesity is described using body mass index (BMI) which is calculated by using weight (in kilograms) divided by height in meters squared. Class I obesity is defined as a body mass index >30 kg/m^2; class II obesity is a BMI >35 kg/m^2; class III (severe or morbid) obesity is >40 kg/m2; and class IV (super morbid) obesity is defined as >50 kg/m^2.

Data from the Centers for Disease Control and Prevention (CDC) show that the prevalence of obesity in the U.S. has been increasing from 1985 to 2008 [www.cdc.gov/obesity/data/trends.html]. More than 33% of adults in the U.S. are obese.[1]

Obesity, weight loss and health outcomes

Obesity is associated with premature mortality as well as many other chronic conditions, including hypertension, type II diabetes mellitus, heart disease, stroke, osteoarthritis, obstructive sleep apnea, some cancers and depression. Increasing adiposity is associated with an increased risk of these diseases, while weight loss is associated with a decreased risk of developing these diseases. In the Nurses' Health Study, a cohort study of over 100,000 women aged 30–55, weight loss of 5 kg or more was associated with a graded decrease in the risk of diabetes mellitus.[2] In another study of 28,388 overweight women aged 40–64, intentional weight loss of >9.1 kg was associated with a 25% decrease in all cause, cardiovascular and cancer mortality.[3] Weight loss is also associated with a reduction in blood pressure in more than half of treated individuals.[4] Blood pressure decreases approximately 0.3–1.0 mm/Hg for every kilogram of weight loss. Individuals who maintain weight loss maintain lower blood pressure than those who regain weight.[5] Weight loss is also associated with a decreased risk of osteoarthritis. Among 800 women in the Framingham study, a BMI decrease of 2 kg/m^2during the previous ten years was associated with a decreased odds of developing osteoarthritis of 50%.[6] Obesity has also been associated with social stigma and decreased quality of life. Weight loss has been shown to improve social functioning and quality of life.[7,8]

Treatment of Obesity

Diet, exercise and behavior modification are the primary recommended treatments for obesity. Therapy with medications (orlistat, sibutramine) may be indicated for some individuals who have medical complications of obesity, but the associated weight loss is generally modest and there are side effects associated with the medications. Although many individuals may lose weight, most regain it over time. Systematic reviews of the effects of behavioral and drug therapies of obesity report an average long term weight loss of between four and seven kilograms.[8,9]

Surgery for Obesity

Surgical treatment is another option for individuals at high risk for complications from obesity. Bariatric surgery was first performed in the 1960s and its use has been increasing. Between 1998 and 2004, the number of bariatric surgeries performed annually increased from about 13,000 per year to about 121,000 per year.[10] In a systematic review and meta-analysis of the efficacy of bariatric surgery, effective weight loss was achieved and most patients had improvement or resolution of diabetes, hypertension, hyperlipidemia or obstructive sleep apnea.[11] Bariatric surgery has also been shown to reduce overall and cause specific mortality.[12,13]

Surgery has the theoretic advantage of being a long term treatment for a chronic health problem. Surgery has also been shown to be associated with more weight loss than behavioral or medical therapy.[14] However, surgery is a major intervention and is associated with complications and perioperative mortality.

Surgical versus Medical Treatment of Obesity

The Swedish Obese Subjects (SOS) study is the largest prospective study on the effects of operative treatment for obesity. A total of 1000 patients who were allocated to one of the three surgical procedures (gastric banding; vertical banded gastroplasty; or gastric bypass) and 1000 controls (matched for age, sex, BMI, clinical site, and co-morbidities) are being followed for ten years.[15,16] As compared with a control group of patients of similar weight at baseline, the two-year incidence rates of diabetes mellitus and hypertension were lower in the surgically treated patients, and they had less hyperinsulinemia and hypertriglyceridemia and higher serum high-density-lipoprotein (HDL) cholesterol concentrations.[17] Most importantly, after a median follow-up of 11 years with 99.9% complete follow-up, there was a statistically significant 29% reduction in all cause mortality for the patients in the surgical group compared with the control group. Other studies have reported reductions in total mortality in surgically treated patients ranging from 40% to 89%.[2,3,18,19]

Recommendations for Surgical Treatment of Obesity

The National Institute of Health Consensus Conference on obesity surgery recommends that surgery be considered for individuals who meet the following criteria:[20]

- Individuals with a BMI of 40 kg/m^2 or greater
- Individuals with a BMI of 35 kg/m^2 or greater and who also have serious medical conditions (diabetes, obstructive sleep apnea) that would improve with weight loss.

In addition, patients must have failed sustained weight loss programs, must have an acceptable operative risk and they must be committed to long term follow-up.

Clinical practice guidelines from the American College of Physicians emphasize that a doctor-patient discussion of surgical options for appropriate patients should include the long-term side effects, such as possible need for reoperation, gall bladder disease and malabsorption.[21]

Although these are the current recommendations, there is ongoing interest in expanding the use of procedures to other patient populations, especially those with diabetes mellitus.[22–24]

There are two major categories of surgery- restrictive or malabsorptive, based on the primary mechanism by which they induce weight loss. In addition, some procedures include components of both.

Restrictive Procedures Restrictive procedures limit caloric intake by decreasing the size of the stomach's reservoir capacity, so that only small amounts of food can be taken in at any one time. Eating large amounts of food results in discomfort and nausea. Vertical banded gastroplasty (VBG) and laparoscopic adjustable gastric banding (LAGB) are purely restrictive procedures and the resulting anatomy is similar. Food intake is limited because of the size of the stomach, but the absorptive ability of the intestine remains intact. These procedures are simpler to perform than procedures that result in malabsorption, but the resulting weight loss is more gradual.

Malabsorptive Procedures Malabsorptive procedures interfere with nutrient absorption by shortening the length of the functional small intestine. Examples of procedures that result in malabsorption are jejunileal bypass (JIB), biliopancreatic diversion (BPD) and duodenal switch (DS). More dramatic weight loss can occur with these procedures, but because of the malabsorption there can be metabolic complications including deficiencies of micronutrients as well as protein calorie malnutrition.

Roux-en-Y gastric bypass (RYGB) The RYBG procedure is both restrictive and malabsorptive. First a small gastric pouch is created to restrict food intake. Then, part of the jejunum is attached to the pouch so that food bypasses the distal stomach, duodenum and proximal jejunum. The bypass of the jejunum results in some malabsorption. The length of the Roux limb (portion of the jejunum from the new stomach pouch the point where it joins up with the segment from the remainder of the stomach) is usually between 50 cm and 150 cm. The length of the common limb where absorption can occur is usually more than 300 cm in length. Shorter common limbs may be associated with greater malabsorption, though comparative studies between short and long limb gastric bypasses have demonstrated equivalent weight loss.[4,5] Complications associated with gastric bypass include failure of the gastric partition, leaks at the junction of the stomach and small intestine, marginal ulcers and strictures at the gastrojejunostomy and acute gastric dilatation either spontaneously or secondary to a blockage at the Y-shaped anastomosis. Other complications following surgery include vomiting, incisional hernias, obstruction, nutrient deficiencies (poor absorption of iron, vitamin B12, vitamin D, folate, and calcium) and the dumping syndrome. Rapid gastric emptying, or dumping syndrome, happens when the jejunum fills too quickly with undigested food from the stomach. Symptoms include nausea, vomiting, bloating, diarrhea, sweating, palpitations, and shortness of breath. This happens most commonly when the patient consumes refined carbohydrates and concentrated sweets. Thus, some surgeons consider this a desirable side effect as the symptoms reinforce compliance with a healthier diet. Patients with dumping syndrome can minimize symptoms by eating several small meals a day that are low in carbohydrates and drinking liquids between meals, not with them. The symptoms are thought to aid weight loss by conditioning the patient against eating sweets, though they can have a dramatic impact on a patient's quality of life.

Gastric bypass with Roux-en-Y anastomosis has been considered the bariatric surgery of choice in the US. In addition, there is increasing evidence supporting the evidence of laparoscopic adjustable silicon banding. Thus any new procedure must be carefully compared with an established bariatric procedure such as Roux-en-Y gastric bypass or laparoscopic adjustable banding.

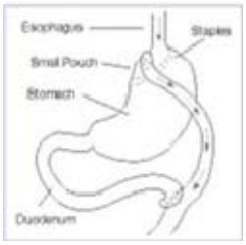

Figure 1.

: Roux-en-Y gastric bypass

(Enlarge Image)

Sleeve gastrectomy Sleeve gastrectomy was initially offered to patients with super severe obesity as the first part of a two part surgical procedure, which was later followed by a gastric bypass or a duodenal switch.[25,26] However, the weight loss associated with sleeve gastrectomy may be enough for some individuals.

The procedure is performed laparoscopically- a partial gastrectomy is done in which most of the greater curvature of the stomach is removed and a "tubular" stomach is created. The stomach capacity is reduced to about 25% of its prior capacity, and is therefore restrictive. The pyloric valve is left intact, which means that digestion is not changed. Without the fundus, it is more resistant to stretching. Also the cells producing Ghrelin (a gut home involved in regulating food intake) are absent.

After 6–12 months, the stomach can expand and intake may be less restricted. Gastric bypass can then be added if necessary. Sleeve gastrectomy is not a reversible procedure.

Figure 2.

http://www.wellsphere.com/digestive-health-article/laparoscopic-sleeve-gastrectomy/696643

(Enlarge Image)

Sleeve gastrectomy is technically easier than gastric bypass, avoids multiple anastomoses, preserves access to the pylorus, duodenum and ampulla of Vater, can be performed in the presence of intra-abdominal adhesions, reduces postoperative risk of internal herniation and protein and mineral malabsorption and is proposed to be safer.[27,28] However, it is associated with increased gastric pressure and may be associated with an increase in gastroesophageal reflux disease (GERD) as well as an increase in staple line leaks. Thus an important question is how VSG compares to other established bariatric procedures for the treatment of obesity?

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies

Sleeve gastrectomy is a procedure and therefore is not subject to FDA approval.

TA Criterion 1 is met

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database and Database of Abstracts of Reviews of Effects (DARE) were searched using the key words vertical gastrectomy or vertical sleeve or sleeve gastrectomy and also with the term obese or weight or overweight or bariatric. The search was performed for the period from 1966 to July, 2010. The bibliographies of systematic reviews and key articles were manually searched for additional references. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full.

Inclusion Criteria were that the study had to compare VSG with another treatment, had to report at least 12 month follow-up, had to report clinical outcomes, had to include humans and had to be published in English.

Studies were excluded if they did not report clinical outcomes, if they were case series or if the follow-up was less than 12 months. Articles that focused on surgical methods or instrumentation were excluded.

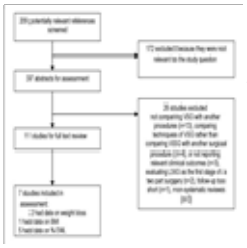

Figure 3.

Study Selection

(Enlarge Image)

A total of 209 potentially relevant articles were identified. 172 were excluded for not addressing the research question. A total of 37 abstracts were evaluated. 26 were excluded. Reasons for exclusion included not comparing VSG with another procedure (n=13), comparing techniques of VSG rather than comparing VSG with another surgical procedure (n=4), or not reporting relevant clinical outcomes (n=3), evaluating LSG as the first stage of a two part surgery (n=2), follow-up too short (n=1), non-systematic reviews (n=3). The remaining studies (n=11) were included. Of these, seven studies compared VSG with at least one other surgical procedure, evaluated clinical outcomes and are included in this review. In addition, two systematic reviews and two registry studies were included and evaluated.

Clinical outcomes reported by the identified studies included measures of weight change, fat content (e.g. body mass index) or fat distribution (waist-hip ratio), quality of life (ideally measured using a validated instrument) and resolution of obesity related co-morbidities (e.g. hypertension, diabetes)

Additional outcomes evaluated were mortality, adverse events and rates of revision.

TA Criterion 2 is met

TA Criterion 3: The technology must improve net health outcomes

Weight loss is typically the primary goal for surgical intervention. Weight loss is typically reported as the percentage of excess body weight lost (%EBWL). Other commonly reported outcomes include absolute weight loss, change in BMI and post-procedure BMI. Other ideally reported outcomes include changes in conditions related to obesity such as diabetes, hypertension, joint pain, sleep apnea and hyperlipidemia. All potential benefits should be weighed against potential harms. These harms can either occur peri-operatively or later. Potential peri-operative harms include surgical complications such as wound infections, leaking, bleeding, stricture or mortality. Complications that can occur later include GERD and nutrient malabsorption.

A systematic review of all current data on weight loss or complications after sleeve gastrectomy was recently published.[23] At least 36 studies have evaluated the use of sleeve gastrectomy as a bariatric procedure for the treatment of morbid obesity and 24 of these studies have evaluated SG as a stand alone procedure. The majority of these are case series- there are two randomized controlled trials and one nonrandomized prospective matched cohort analysis.

1749 patients were included in 24 studies that evaluated SG as a primary procedure.[27–49] Among patients in whom sleeve gastrectomy was used as the primary procedure, the number of patients in each study ranged from 15 to 216 and the length of follow-up ranged from 3 to 36 months. The range of the percent of excess weight loss was from 36%-85%, with a mean of 60.7%. Complications occurred in an average of 6.2% of individuals. In studies that had more than 100 patients, the complication rate ranged from 0%-4.1%. Among studies reporting detailed complication data, complications included leaks (2.7%), bleeding, (1.0%), strictures 90.5%) and 30 day post operative mortality (0.17%).[23] Short term morbidity was recently evaluated in 25.275 Michigan patients receiving one of three bariatric procedures (gastric bypass, sleeve gastrectomy and laparoscopic adjustable gastric banding) during 2006–2009. Overall 7.3% of patients had complications, most of which were wound problems or other minor complications. Serious complications were most common after gastric bypass (3.6%), followed by sleeve gastrectomy (2.2%) and laparoscopic adjustable gastric band (0.9%). Similarly, the risk of leak or perforation, infection and medical complications was intermediate between gastric bypass and LAGB for SG, suggesting that the overall complication rate for SG falls in between the other two procedures.[50]

Long term Outcomes: Benefits and Risks

The majority of studies of SG have published short term outcomes from 12 to 36 months. Five year follow-up data was recently published for a series of 26 consecutive patients who had VSG in Austria. A mean EWL of 55% was achieved, suggesting that the weight loss was stable. Eight patients (31%) had severe GERD requiring chronic proton pump inhibitor (PPI) use. One patient required a conversion to gastric bypass because of severe reflux symptoms and two other patients required conversion to gastric bypass because of a combination of regaining weight and severe GERD. Himpens et al recently reported six year outcomes of a consecutive series of 53 patients who had undergone sleeve gastrectomy. At six year follow-up, the mean excess weight loss exceeds 50% and 21% of patients had new gastroesophageal reflux complaints.[51]

In a Spanish registry, investigators reported outcomes of 17 centers for 540 patients who had undergone SG.[52] Median length of follow-up was 16.5 months, although 33 patients reached 36 months of follow-up. Overall, mean %EWL was 55.13 at 12 months, 63.83 at 24 months. Overall morbidity rate was 5.2% and mortality rate was 0.36%. A total of 3.3% of patients needed a second surgery, primarily for inefficacious weight loss, but some (n=3) required surgery for severe GERD. Complications were more common in the super-obese (BMI >50 kg/m2) and in patients over 55 years of age.

A national registry in Germany was created to collect data on all bariatric procedures performed in Germany.[49] Among 3,122 patients who had bariatric surgery, 144 SG procedures were performed at 17 hospitals. So far, two year follow-up has been reported. Weight loss outcomes have not yet been reported for the SG patients, but the overall rate of major complications was 9.4%. Leakage occurred in 7%, bleeding in 1.6% and stenosis in 0.8%. The reoperation rate for complications was 4.16%. Repeat laparoscopy was performed for bleeding at the staple line, and repeat laparotomy was performed for leakage at the staple line. Two patients (1.4%) died. One died from pneumonia after a complicated post-operative course and one patient died after staple line rupture postoperatively.

In summary, even in the registry studies, relatively few individuals have been followed for more than two years. Among those who have been followed, the weight loss appears to be overall relatively stable. However, GERD is very common post-operatively and in some cases can be severe, requiring chronic PPI use or even requiring surgery. Complications also occur in a significant number of patients. Since there are also significant complications with the other commonly used bariatric procedures, it will ultimately be important to understand how these long term complications compare across bariatric procedures. Thus, although SG can improve weight loss and associated obesity related conditions, it is currently not known whether or not SG improves net health outcomes especially over the long term.

TA Criterion 3 is not met

TA Criterion 4: The technology must be as beneficial as any established alternatives.

Since RYGB or laparoscopic gastric banding (LGB or GB) are the bariatric surgeries of choice, any new bariatric procedure must be compared to one of them. Seven studies have compared SG to one or more other established surgical procedures (Table 1). Of these, only two have been randomized trials that have assessed the efficacy of SG compared with another surgical procedure. Thus far, the two randomized trials comparing LSG with another procedure have published 12 month outcome data for 112 patients and 36 month outcome data for 80 patients. Himpens at al conducted a trial with 80 patients who were randomized to either laparoscopic gastric banding or laparoscopie isolated sleeve gastrectomy. Outcomes were measured after one and three years of follow-up. At one year, median weight loss was 14 kg for LGB and 26 kg for SG; after three years it was 17 kg for BG and 29.5 kg for SG. Percent of excess weight loss was consistently better for SG than for LGB both at one and three year follow-up. At one year follow-up, GERD occurred in more patients with SG than with LGB, but at three years it occurred in more patients with LGB than with SG. Complications were divided into postoperative complications, late complications and inefficacy. Post-operative complications requiring reoperation were necessary for two patients after SG (intraperitoneal bleeding leading to re-laparoscopy and gastric ischemia leading to total gastrectomy). There were no postoperative complications in the individuals who underwent GB. Late complications in the GB group included pouch dilation, gastric erosion and disconnection. There were no late complications in the SG group. Inefficacy occurred in two individuals in each group. Two patients in the GB group required conversion to RYGB and two patients in the SG group required conversion to DS. Although there were a higher number of complications in the GB group, the complications in the SG group were more severe Table 2.[30]

In the second randomized trial, 32 patients were randomized to either RYGB or LSG. Follow up occurred for 12 months. At 12 months, excess weight loss was greater with LSG than with LRYGB (69.7% vs. 60.5%). BMI at 12 months decreased significantly in both groups but was not significantly different between groups. The authors report that there were no intraoperative or postoperative complications. Outcomes beyond one year have not been reported.

Five other studies have compared LSG to other procedures including GB, RYGB and DS procedures. None of these studies have been randomized- one was prospective and the other four were retrospective analyses. In the prospective study, 271 patients who underwent one of four surgical procedures, including SG (n=30) were followed for varying durations of time. Individuals in the SG group had a higher baseline (BMI (61.4) vs. 44.3–53.2 for the other three procedures), probably reflecting that SG is often offered to higher risk individuals. Mean length of follow-up was shortest for SG (16.7 months) and longest for BPD/DS (27.5 months). The mean change in BMI at follow-up ranged from 7. kg/m^2 to 24 kg/m^2, with SG falling in between at 18 kg/m^2. All procedures resulted in weight loss and body composition changes. Complication rates were not reported.[54]

Four retrospective analyses have compared the outcomes of SG with other surgical interventions, but one of the studies only included six individuals who had SG [O'Keefe, 2010]. In one study 216 of 846 patients underwent SG, whereas the others underwent other surgical procedures.[31] Weight loss at 12 months with SG was comparable to that achieved with RYGB or DS. There were no deaths in any of the groups. The rate of major complications was comparable to that seen with banding (4.6% vs. 4.8%) and significantly less than that seen with RYGB (10.6%) or DS (39.3%). In another retrospective study, 20 patients underwent SG, whereas 24 had GB and 16 underwent RYGB. The main outcomes were the percentage of individuals who had complete resolution of type two diabetes over 36 month follow-up . Overall resolution was achieved in 80.9% of SG patients, 60.8% for GB patients and 81.2% for RYGB. Complications were not reported.[55] In the final registry study, 50 patients who underwent SG were compared with 50 patients who underwent LRYBG and they were followed for 12 months. Mean BMI at 12 months was 26.3 kg/m^2 in the SG group and 31 in the LRYGB group. Resolution of diabetes and hypertension were achieved in the vast majority of individuals in both groups. In the LSG group, a major complication requiring reoperation was a delayed leak from the gastroesophageal (GE) junction which was detected 21 days post surgery. In the LRYGB group, major complications included a pulmonary embolism and a leak from the gastrojejunostomy site. There were no deaths.

There are several ongoing clinical trials comparing sleeve gastrectomy with another surgical procedure. The French SLEEVE study will compare SG with laparoscopic gastric bypass and will compare complications, efficacy and quality of life in 280 participants randomized to one or the other surgery. This study is currently enrolling and is expected to be completed in 2013. A Swiss RCT is comparing SG with RYGB for the treatment of morbid obesity. This study is currently enrolling participants , will enroll 90 participants and follow them for five years. The primary outcomes will be effectiveness in terms of weight loss, reduction in co-morbidity and quality of life and will also evaluate complications. An Israeli study will randomize 150 eligible candidates to receive either SG or RYGB. Participants will be followed for five years for the primary outcome of weight loss. Secondary outcomes will include complication rates and resolution of common comorbidities. Finally a Brazilian study has recently been completed. In this nonrandomized study, 65 participants underwent either SG or banded ring gastric bypass (a modification of traditional RYGB which adds a silastic ring to the gastric bypass operation) and were followed for 12 months. The main outcomes were weight loss, reduction in BMI and waist circumference reduction. These results have not yet been published, but given the nonrandomized nature of the study and the relatively short follow-up, it is unlikely that these results will result in any major new information. The results of some of the randomized trials should hopefully provide more information about the long term comparative efficacy of SG compared with other bariatric procedures as well as more information about long term potential harms.

TA Criterion 4 is not met

TA Criterion 5: The improvement must be attainable outside the investigational settings.

Registry data would suggest that the results of the surgery (e.g. amount of weight lost and complication rates) seem to be comparable in non-investigational settings to that achieved in the investigational settings. However, since overall improvement compared with the established alternatives has not yet been shown in the investigational setting, it cannot be considered shown outside the investigational setting.

TA Criterion 5 is not met

Conclusion

Bariatric surgery might be indicated for individuals who are unable to control their weight with conservative measures. The current standards of care for bariatric surgery are the RYGB and LGB. SG was initially used as the first part of a two part procedure, but subsequent information has suggested that SG alone may be enough for some individuals. SG is technically easier than RYGB and so is an attractive surgical option especially in morbidly obese patients.

The results of multiple case series and retrospective studies have suggested that SG as a primary procedure is associated with a significant reduction in excess weight loss. The complication rate ranged from 0–4.1% and complications included leaks, bleeding, strictures and mortality.

Only two randomized controlled trials have compared SG to another surgical procedure. These trials included a total of 112 participants who were followed from one to three years. Among the 80 participants followed for three years, there were a similar number of complications in the SG and the RYGB groups, although the complications in the SG group were more severe. To date, long term outcomes from registry studies are relatively limited, but longer term follow-up will provide additional important information. Future studies will hopefully provide additional information on the relative efficacy and complication rates in larger number of individuals and also on the long term benefits and risks of the procedure. Some of the ongoing trials should hopefully answer some of these questions in the future.

Recommendation

It is recommended that the use of SG does not meet CTAF technology assessment criteria 3–5 for improvement in health outcomes for the treatment of obesity.

October 13, 2010

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