Proceedings Supplement from the
Second International Consensus Summit
on Sleeve Gastrectomy

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Dear Readers,

After a successful First International Consensus Summit for Sleeve Gastrectomy in New York City in October 2007, I believed that 18 months later another summit was necessary. The necessity of another summit was in part due to rapid emergence of new knowledge about this operation, and also because its adoption in every continent of the world has caught like wildfire.

The Second International Consensus Summit for Sleeve Gastrectomy was held March 19-21, 2009, at the renovated and recently revived Fontainebleau Hotel in Miami Beach, Florida. The meeting had 375 participants who traveled from more than 30 countries, and was partitioned into three segments over three days—a live surgery session of nine technically different cases, a full day of oral presentations, and a half-day of debates. The oral presentations sessions featured invited speakers and presenters who submitted abstracts and, due to the abundance of accepted material, was broken out into several rooms simultaneously. These sessions focused on discussions of mechanisms of action; cohorts with five-year data; the effect of sleeve gastrectomy on type 2 diabetes; special cohorts (low BMI, adolescents, elderly patients, high-risk patients, and quality of life); new emergent technology surrounding sleeve gastrectomy; and complications and revisions.

*Bariatric Times* has assembled some highlights of this meeting from experts who submitted summaries of their presentations for purposes of this educational supplement.

Enjoy, and thank you for reading!

Sincerely,

Michel Gagner, MD, FRCSC, FACS
Is It Time to Bypass the Bypass? Should Pyloric Preservation Become an Important Principle in Bariatric Surgery?

by MITCHELL S. ROSLIN, MD

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The vertical sleeve gastrectomy has recently become an increasingly popular surgical option for the treatment of obesity. However, many bariatric surgeons have questioned its long-term efficacy and have promoted Roux-en-Y gastric bypass (RYGB) as a gold standard.

With an extensive experience with RYGB and a practice with thousands of post-RYGB patients, we commonly encounter patients with weight regain. It is our group’s impression that weight regain following RYGB is more common than discussed. Supporting this speculation are the results of two recent trials that compared RYGB to either banded bypass or duodenal switch. Both demonstrated weight regain of approximately 15 percent in the bypass-only group between the first and third postoperative years. In a randomized trial comparing banded bypass to standard bypass, Dr. Bessler concluded that banding the bypass preserves weight loss after the first year. In his study, the banded group maintained a 70-percent excess weight loss, whereas at the three-year mark, the bypass only was under 60-percent excess weight loss. These results were statistically significant. Similarly, three years postoperative, duodenal switch patients continued to lose weight, whereas the bypass group in a trial conducted at University of Chicago regained 17 percent of their total excess weight loss.

Our participation in several endoscopic trials, including the RESTORE trial (Randomized Evaluation of Endoscopic Suturing Transorally for Anastomotic Outlet Reduction) and the ROSE trial (Revision Obesity Surgery, Endoscopic), provided additional insight. The goal of these trials was to retighten the stoma or stoma and pouch with endoscopic suturing devices. During these trials, patients reported similar experiences. They still were eating a smaller quantity of food during each meal. However, they felt hungry shortly after eating. As a result, we studied glucose tolerance testing (GTT) on 36 post-RYGB patients. The mean age of the patients was 49 years old; average BMI at time of surgery was 48. They were a mean of 40 months post-bypass, and average weight regain was 17 pounds. We found that six patients were diabetic based on GTT, and 26 of 30 had reactive hypoglycemia, two hours post-glucose administration. Reactive hypoglycemia was defined as glucose less than 60 or a greater than 100mg/dL drop in one hour. Perhaps, more importantly, 16 of 26 had severe hypoglycemia where the ratio of maximum to minimum glucose was greater than 3 to 1.

We speculate that there is rapid gastric emptying, and that when a glycemic load is presented to the small bowel, there is an abrupt rise in insulin levels. This is consistent with the experience of tympany, bloating, and regurgitation post-Y-Gastric bypass. The rapid emptying is consistent with the findings of the gastric pouch injection or the fundoplication used in the Pennsylvania experience. The overall conclusion is that rapid emptying and meal insensitivity are the hallmarks of both RYGB and sleeve gastrectomy. Perhaps pyloric preservation will become an important principle in bariatric surgery.
It is our contention that the best valve is the biologic valve that is already present—the pylorus. and fall in glucose level. The combination of empty pouch and low sugar causes hunger. We feel that this cycle is contributory in the weight regain and maladaptive eating pattern that develops. Few patients in our study had pathologic insulin levels, suggesting neosidioblastosis is not the primary etiology.

Since the comparative trials between vertical banded gastroplasty and RYGB that were performed in the late 1980s and early 1990s, many have suggested that gastric bypass is the procedure of choice for sweet eaters. As 60 percent of calories consumed in the United States are simple carbohydrates, this group in all probability includes the majority of bariatric patients. The primary explanation given for the improved early results with bypass was that carbohydrate ingestion would cause gastrointestinal symptoms of dumping. This would act as negative reinforcement. However, what happens in patients who do not experience gastrointestinal symptoms associated with dumping. With time, do they become increasingly tolerant, and does the bypass no longer challenge the desire to eat simple carbohydrates?

Our data suggest that reactive hypoglycemia is far more common than previously reported. Additionally, our histories seem to indicate that this response, combined with rapid emptying, is somewhat responsible for weight regain following bypass. In other words, the dumping created by performing the bypass may not be helpful, as many have speculated.

Many readers will state how successful bypass procedures have been in their practices. It is important to highlight that this is one of many variables. Certain patients may scar and maintain a restrictive opening. There is variation on the amount and type of food eaten. Activity levels will be different. However, it is clear that the banded bypass patients have less weight regain. Thus, we feel that future versions of these procedures will incorporate a valve that regulates emptying. The valve can be synthetic, like a silastic ring, marlex mesh, or laparoscopic band; but this can lead to different issues. It is our contention that the best valve is the biologic valve that is already present—the pylorus. As opposed to mechanical products, the pylorus, the narrowest part of the gastrointestinal tract, can relax, open, and control the outflow of solid food. We believe that this is far more preferential than a synthetic band.

Thus we believe that pyloric preservation will become an important principle in bariatric surgery. Success with sleeve gastrectomy has shown that severe malabsorption does not need to be part of the duodenal switch. An increasingly popular option in our practice is a laparoscopic duodenal switch with a sleeve done over a 38 bougie with a 125 to 150cm common channel. With this approach, we have not had to lengthen any common channel for protein malnutrition, and patients report 1 to 3 bowel movements daily. None have complained of spillage or poor control. We believe that sleeve and this type of duodenal switch or pyloric preserving bypass will become common. We also speculate that this approach will improve long-term outcomes by increasing initial weight loss and preventing recidivism after the first postoperative year.

**REFERENCES**


**KEY POINTS**

- Weight regain is common after gastric bypass.
- Reactive hypoglycemia is far more common than expected after gastric bypass.
- The combination of rapid emptying of the pouch and hypoglycemia causes hunger between meals.
- For the best results, the pouch needs a valve—and the pylorus is the ideal valve.
- Pyloric preservation will become a principle in bariatric surgery and the new gold standard procedure may be a modified duodenal switch with pouch similar to sleeve and common channel of 125 to 150cm.
Sleeve Gastrectomy and the SILS™ Procedure: The Texas Endosurgery Institute Experience

by JOHN J. GONZALEZ, JR., MD

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BACKGROUND

Laparoscopic sleeve gastrectomy (LSG) is one of the newest bariatric procedures in our surgical armamentarium. It likely works as a result of gastric restriction, with removal of 70 to 80 percent of the stomach proximal to the antrum, as well as an associated hormonal component. There have been excellent results in multiple centers and the technique has been described in detail elsewhere. There is little variation in the described techniques of LSG except with respect to the appropriate size gastric pouch, ranging anywhere from 32 to 50 Fr. Typically, the procedure requires 5 to 6 skin incisions for working trocars and a liver retractor. The advent of the Covidien SILS™ laparoscopic procedure using a single incision has now allowed for an even more enhanced minimally invasive experience and the ability to decrease the number of skin incisions to one or two. Single incision surgery has exploded in the United States and has been performed for such procedures as appendectomy, cholecystectomy, colectomy, nephrectomy, hysterectomy, hiatal hernia repair, gastric banding, and gastric bypass. The LSG seems tailor-made for the SILS™ procedure because of the straightforward nature of the procedure itself and the ability to operate in a single quadrant of the abdomen. The following is our experience at the Texas Endosurgery Institute.

METHODS

Twenty-four consecutive patients underwent attempted SILS™ sleeve gastrectomy between June 2008 and April 2009. All patients that were eligible for the standard LSG were considered for the SILS™ procedure. Because this was a new technique for the author, the body mass index (BMI) was limited to 50 and below. Presence of a known hiatal hernia was an absolute contraindication for the single access technique.

OPERATIVE TECHNIQUE

The technique is similar to that described by Saber et al with some very minor modifications. The patient is placed in the supine position on a split leg table (Figure 1). The surgeon stands between the legs, which provides the most ergonomically advantageous position for access to the upper abdomen when working from the umbilicus. The camera holder is on the patient’s left side. A 2.5cm curvilinear incision is then made at the upper half of the umbilicus, taking care to stay within the outer rim so as to preserve cosmesis. The subcutaneous tissues are separated down to the anterior fascia. Small skin flaps are often necessary to get as much room as possible through this small incision. A Veress needle is then introduced into the peritoneal cavity and pneumoperitoneum is achieved with a pressure of 15mm/Hg. A 5mm, low-profile Dexide™ (Autosuture™, Covidien, Norwalk, Connecticut) trocar is then inserted in the upper left portion of the incision, just to the right of the linea alba. A long, 5mm, 30-degree laparoscope is then inserted and the abdominal cavity is carefully inspected. A 15mm, bladeless trocar is then inserted through the center of the umbilical wound and a second 5mm Dexide™ port is introduced through the lower right portion of the incision, just left of the linea alba (Figure 2). The trocars are offset as much as possible within the single incision and each trocar has a separate fascial defect, which is important to prevent leakage and maintain pneumoperitoneum. The patient is then placed into a steep reverse Trendelenburg position. A Nathanson liver retractor is then inserted through a separate, 5mm stab wound in the mid-epigastrium to elevate the liver cephalad and expose the esophageal hiatus and angle of His.

The remainder of the surgery is essentially identical to a standard LSG. Some critical differences are the length of the instruments, which should always be bariatric length, and the ability of the graspers and dissectors to roticulate, which is essential to avoid “sword fighting” and maintain triangulation. As with the standard technique, the lesser sac is entered with an AutoSonix™ (Autosuture™, Covidien, Norwalk, Connecticut) device and the greater curvature is mobilized beginning approximately 6cm proximal to the pylorus. The mobilization is continued all the way up to the short gastric vessels around the spleen and through the angle of His. Once the fundus is completely
mobilized, the gastric resection is begun 6cm proximal to the pylorus with two firings of a laparoscopic articulating 45mm Endo GIA™ stapler with a green 4.8mm cartridge. The stapler is angled away from the incisura angularis to avoid narrowing at this point. Once past the incisura, a 34 Fr bougie dilator is passed along the lesser curvature and into the antrum by the anesthesiologist under direct laparoscopic vision. The remainder of the transection is then accomplished by firing a series of laparoscopic articulating Endo GIA™ staplers with blue 3.5mm cartridges. This shorter staple height seems to limit intraluminal bleeding without any increase in sheering forces in most stomachs in our experience. Seamguard® Bioabsorbable Staple Line Reinforcement (W. L. Gore & Associates, Flagstaff, Arizona) is used on the final firing around the angle of His. Furthermore, the uppermost firing of the stapler is angled off to the left of the left crural pillar to avoid encroachment on the esophagus and to prevent a leak here, which can be very difficult to deal with in the postoperative period. The relevant portion of the procedure is then concluded with the evaluation of the integrity of the staple line and intraluminal hemostasis by intraoperative endoscopy.

All patients undergo gastrograffin swallow evaluation on postoperative day (POD) 1 and are begun immediately on a clear liquid diet if normal. Most patients are discharged the afternoon of POD 1, though occasionally patients will stay an additional day primarily secondary to nausea.

RESULTS

During the 11-month study period, 24 sleeve gastrectomies were attempted by SILS™ technique. There were 17 females and 7 males with a mean preoperative BMI of 44 (range 37–48). The procedure was successfully performed in 19 patients, with five conversions to a standard five-port LSG because of the presence of hiatal hernias not identified on preoperative barium swallow. There were no conversions to open procedure. Mean operative time was 72 minutes (range 58–94 min.) and mean blood loss was less than 30cc. Mean hospital stay was 1.3 days (range 1–3 days). There were no intraoperative or postoperative complications and no mortality.

DISCUSSION

The introduction of natural orifice surgery (NOTES) has been an exciting development in minimally invasive surgery. However, it is reserved for a handful of academic centers with specialized equipment and research protocols. The SILS™ procedure provides a more enhanced minimally invasive surgery experience to the “average” advanced laparoscopic surgeon with little to no additional capital investment in new equipment. New technology, including roticulating, bariatric-length instruments (Figure 3), single access ports (Figure 4A, 4B), and improved, angulated optics, has caused an explosion in the application of single incision surgery. SILS™ sleeve gastrectomy is a natural offshoot of this new laparoscopic surgical evolution and appears to be a perfect fit for this technique. It is important to note that there is no compromise in surgical technique when using the SILS™ procedure. It is clearly safe, technically feasible, and not prohibitively expensive for the community laparoscopic bariatric surgeon. The learning curve is not terribly steep but does require the ability to use both hands equally well and the ability to operate in line with the optical port. Technological advances in instrumentation and optics will make this operation easier and even more accessible in the years to come.

REFERENCES


KEY POINTS

• Sleeve gastrectomy is tailor-made for the SILSTM technique.
• There is no compromise in surgical technique with respect to a standard laparoscopic sleeve gastrectomy.
• SILS™ sleeve gastrectomy is safe, feasible, and not prohibitively expensive.
Reducing Risk in Bariatric Surgery: Rationale for Sleeve Gastrectomy

by ERIC J. DEMARIA, MD

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Sleeve gastrectomy is a component part of the duodenal switch procedure (DS) for obesity treatment, which also resembles the Morganstrasse-Mill procedure (M&M) developed in England, although the M&M procedure does not involve a gastric resection. Gagner first noted that the DS procedure carried a high prohibitive morbidity and mortality risk when performed laparoscopically in high-risk patients and suggested dividing the complex laparoscopic DS procedure into two component parts performed laparoscopically—the sleeve gastrectomy (LSG) followed by the laparoscopic Roux-en-Y ileoduodenostomy to create malabsorption at a later time. Thus was born the first generally accepted proposal to stage bariatric surgery in an effort to reduce the risks of the surgical procedure in the field of bariatric surgery. It is clear that the evolution of sleeve gastrectomy to the current time has been closely linked to the concept of reducing surgical risk in bariatric patients.

The evolution of LSG as a risk reduction strategy should be no surprise to those familiar with the history of bariatric surgery, which can be viewed as a steady march forward in development of surgical procedures to optimize the benefits while minimizing the risks of surgical intervention. The very earliest bariatric procedures were intestinal bypass operations (like the jejunoileal bypass), which produced extreme levels of gut malabsorption in order to accomplish massive weight loss in bariatric patients. Such procedures progressively fell into disfavor due to concerns about risk and were ultimately replaced in the 1970s with gastric bypass due to its lower overall risk profile. Subsequently, in the 1980s, Dr. Ed Mason advocated the vertical banded gastroplasty procedure as a risk reduction strategy, and this procedure became widely accepted and adopted. One can argue that adjustable gastric banding, increasing in popularity in the US in recent years, provides a lower risk of life-threatening complications, and this is often cited by patients as the primary reason for choosing the adjustable band operation for their obesity treatment.

It is interesting that this progressive march toward safer bariatric surgical interventions has been undertaken without good tools available to clinicians to assess surgical risk in the bariatric population. In fact, understanding the risk of bariatric surgery has been a neglected area of study for decades, primarily because the overall risk of mortality has been reported in large case series to be small, mandating tremendous numbers of patients to be studied in order to draw any valid conclusions. The available data demonstrating low overall mortality risk have also perpetuated the inaccurate concept that the risk is equally small for all patients undergoing bariatric surgery—if it were, it would be like no other procedural intervention in medicine. Identifying certain specific factors that increase bariatric surgery risk is an

KEY POINTS

- Evolution of bariatric surgery procedures over decades has been characterized by progressive adoption of risk reduction strategies.
- Risk stratification systems are key to identifying patients who could benefit from risk reduction strategies such as medical optimization and pre-op weight loss.
- Sleeve gastrectomy introduced the concept of staged intervention into bariatric surgery, an approach demonstrated to have value for risk reduction.
- A growing body of evidence suggests sleeve gastrectomy may be an appropriate primary bariatric surgical procedure primarily due to low risk and ease of surgical revision when required.
One of the truly fascinating phenomena found in the current LSG literature is the apparent low risk for morbidity and mortality in the presence of a high-risk patient population. Some pioneering surgeons have clearly selected only high-risk patients in the early development of their sleeve gastrectomy procedure. To date, very few surgical mortalities have been reported in the cumulative surgical literature on sleeve gastrectomy despite the high-risk group selection bias. Many of these patients likely are in the OS-MRS Class C category, although to date no author has formally classified his or her sleeve patients according to this risk stratification system to confirm the high-risk status.

A number of questions remain regarding LSG. Similar to other commonly performed bariatric procedures including RYGB, the mechanism of effectiveness for sleeve gastrectomy as a bariatric treatment is not known. Restriction of oral intake, neurohumoral changes in the gastrointestinal tract as a result of the gastric resection component of the procedure, changes in gastric emptying, or other unidentified factors may explain the success of sleeve gastrectomy as a weight loss intervention. Another major unanswered question is how often will patients fail the sleeve procedure and require revisional procedures? Admittedly the available reports suggest this to be a less frequent phenomenon than many had predicted. A potential advantage of sleeve gastrectomy as a primary bariatric procedure is the reported ease of surgically revising a sleeve. When it comes to sleeve revision, some surgeons are re-sleeving patients when the sleeve segment dilates over time, while others recommend conversion to another form of bariatric surgery. Most appealing for these latter cases is conversion to DS since the sleeve represents a component part of that operation and therefore revision does not usually require any revision of the previously operated gastric portion of the procedure, which likely reduces risks such as leak. Another approach has been to convert the sleeve to a Roux-en-Y gastric bypass (RYGB) by transecting the sleeve segment to create an appropriately small gastric pouch, followed by bringing up a Roux limb using standard techniques. It is premature to determine the risk associated with conversion of sleeve to RYGB since only small series have been reported to date; however, those who have performed this procedure testify that it is technically easier than many other revisions of previous gastric surgery for obesity, such as conversion of vertical banded gastroplasty to gastric bypass.

LSG has become established as a low-risk surgical option for high-risk bariatric surgery patients. Should the need for reoperation and revision/conversion to another bariatric procedure remain low over time, it is likely that sleeve gastrectomy will continue to increase as a primary bariatric surgical intervention around the world, similar to its evident growth in popularity in Europe.

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**REFERENCES**

Laparoscopic Sleeve Gastrectomy: Mid-term Weight Loss Results

by GREGG H. JOSSART, MD, FACS, AND PAUL T. CIRANGLE, MD, FACS

BACKGROUND
The sleeve gastrectomy as a solo procedure (independent of the duodenal switch) has been performed as early as 2000. The operation was offered either as a first stage for higher body mass index (BMI) patients or as a single stage to mainly lower BMI patients. Due to the variations in risk, starting BMI, and technique, weight loss results beyond the first year have been limited. Indeed, the ASMBS position statement reviewed 35 publications representing 2,410 patients, and there were essentially no significant results reported beyond 24 months. However, weight loss at 24 months was quite acceptable and ranged from 50 to 90 percent.

DISCUSSION
The authors started performing the procedure in 2002 as a first stage for higher BMI patients. We were very cautious in implementing the procedure initially and only performed 93 procedures from 2002 to 2005. During this time, we saw a dramatic weight loss of 84 percent at 24 months postoperative. We also began to realize that some of these patients would start to regain after the first 12 months. It was this weight regain that prompted us to become more aggressive with smaller pouch volumes starting in 2005 (Figure 1). We started to staple close to the 32 Fr bougie and resect the fundus by starting within 2cm of the pylorus. Early problems with nausea and dehydration increased, but our 30-day emergency room (ER) visit rate in 2006 for these problems was only three percent, and now decreased to 1.7 percent in 2008. Our leak rate increased as well. It had been zero percent in the first 75 patients, then increased to two percent until we changed to green staple cartridges and started using buttress materials or suture inversion of the superior staple line. Our current leak rate has now stabilized at 0.3 percent. The leaks that do occur in this narrow pouch are very difficult to manage. We also started to see some of our early patients develop reflux and hiatal hernias (Figure 2) beyond one year and thus became more aggressive about dissecting posterior hernias and performing a posterior hiatal hernia closure. In 2008, 30 percent of our patients underwent simultaneous hernia repairs. The early results have shown resolution of reflux symptoms.

We now have 93 patients that are beyond four years postoperative. The mean BMI for
KEY POINTS

- Laparoscopic sleeve gastrectomy five-year results are limited and vary from 40 to 80 percent.

- The surgical technique and calibration of the pouch has improved to yield better weight loss.

- Smallest pouch may be necessary to achieve durable weight loss but may also yield a higher complication rate.
Sleeve Gastrectomy and Diabetes: Early Clinical and Hormonal Changes

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Sleeve gastrectomy (SG) was originally conceived as a first stage of biliopancreatic diversion-duodenal switch (BPD-DS) for achieving weight loss and reducing comorbidities in superobese patients. Recently it has been proposed that SG could also be considered as a potential single restrictive bariatric procedure. Furthermore, Moon Han et al showed that SG without the second-stage operation was associated with an excess weight loss of 71 percent and 100-percent resolution rate of type 2 diabetes mellitus (T2DM) at six months after surgery. Lacy et al reported that SG is associated with a high resolution of T2DM at short term (4 months after surgery), and this resolution rate was comparable to that in Roux-en-Y gastric bypass (RYGB) (51.4% and 62%, respectively, $p=0.332$). At 12 months, T2DM had resolved, respectively, in 33 out of 39 (84.6%) SG patients and in 44 out of 52 (84.6%) of the RYGB subjects ($p=0.618$). Neither the weight loss nor the degree of descent in the waist circumference was associated with T2DM resolution following SG or RYGB. The aim of the study was to elucidate the clinical and hormonal effects of SG in T2DM patients in the early postoperative phase.

MATERIALS AND METHODS

Between October 2002 and December 2008, 200 obese patients underwent SG in our institution. Forty-eight patients (31:17 female to male ratio; mean age 50.2 years; mean BMI 50.8) had an altered glucose homeostasis (32 T2DM and 16 impaired glucose tolerance [IGT]). Evaluations were performed as follows:

- **Group A (20 pts):** BMI, fasting glycemia (FPG), HbA1c, HOMA-IR were evaluated preoperatively and at 3, 6, 12, 24, and 36 months postoperative; euglycemic hyperinsulinemic clamp at 12 months postoperative.
- **Group B (22 pts):** FPG and basal insulinemia, HOMA-IR were evaluated preoperatively and at 5, 15, 30, 60 days postoperative. In 10 of these patients, FPG and insulinemia were evaluated on postoperative Days 1, 2, 3, and 4.
- **Group C (6 pts):** Insulin sensitivity and secretion by intravenous glucose tolerance test (IVGTT), ghrelin, and GLP-1 values were evaluated preoperatively and 60 hours postoperative. At one

**KEY POINTS**

- Sleeve gastrectomy is effective on T2DM independent of weight loss.
- An additional non-weight loss-related mechanism contributes to changes in insulin resistance following SG.
- Modifications of ghrelin and GLP-1 after SG may play a role in T2DM resolution.
month postoperative, we evaluate ghrelin and GLP-1 values after meal. The total number of SG procedures and the effect on diabetic patients were evaluated in the Italian registry.

RESULTS

In Group A, cure was obtained in 80 percent. The antidiabetic therapy was discontinued 3.3 months postoperatively (EWL 36.3±7.2%, FPG 125.5±15.5 mg/dL and HbA1c 59±0.4%). The BMI at the time of discontinued therapy was not significantly different from preoperative value. Paradoxically, in not cured patients we observed a statistically significant reduction of BMI at three months after procedure. These data may be explained by the longer duration of the diabetes in this group. Twelve months after surgery, in patients who had stopped antidiabetic medications, hyperinsulinemic euglycemic clamp was performed. Insulin sensitivity was restored into normal range in all patients.

In Group B, 66 percent of patients did not resume postoperative antidiabetic medications. In all patients, a sharp (5 days) and significant reduction of serum glucose and insulin concentration and HOMA-IR values remained substantially unchanged despite a greater weight loss (EWL 23.6% and 32.3%, respectively).

In Group C, postoperatively (60 hours), in IVGTT the insulin curve showed a restored normal shape with marked improvement of insulin secretion and sensitivity (Figure 1). Moreover, we observed a significant modification of ghrelin (Figure 2) and GLP-1 values (Figure 3).

In the Italian registry, the total number of SG was 562 (448 in 2008; 14% T2DM patients). T2DM resolution was observed in 3 to 6 months postoperative. In 80% of patients, a sharp (5 days) and remarkable improvement of insulin action after SG was observed. The results of the present study strongly suggest that an additional non-weight loss-related mechanism contributes to changes in insulin resistance following SG. Modifications of ghrelin and GLP-1 after SG may play a role in T2DM resolution. Further studies are needed to confirm the role of ghrelin and GLP-1 in T2DM resolution after sleeve gastrectomy.

CONCLUSION

These data confirm that sleeve gastrectomy is effective on T2DM independent of weight loss. We observed a marked reduction in HOMA-IR findings, thus indicating a rapid (3–5 days) and remarkable improvement of insulin action after SG unrelated to weight loss. The results of the present study strongly suggest that an additional non-weight loss-related mechanism contributes to changes in insulin resistance following SG.

SUGGESTED READINGS

Sleeve gastrectomy (SG) has recently become popular both as primary operation as well as staged operation in the super morbidly obese. It has similar outcomes to other restrictive procedures and a risk profile that is superior to other bariatric operations for the super morbidly obese. SG can be performed quickly and safely and, like other restrictive procedures, offers immediate caloric restriction. There are, however, several reasons to practice caution in advocating SG—irreversibility (unlike a band), major complications (e.g. leak), and lack of data beyond five years. Within this short article, SG will be evaluated based on the current evidence regarding weight loss, complication rates, postoperative mortality, and comorbidity improvement. This article is meant to summarize a recent systematic review submitted to Surgery for Obesity and Related Diseases.

Recently, the indications for SG have begun to broaden, and there has been a surge in interest evidenced by numerous published reports, the authors' feedback, and presentations at national and international conferences (several of which are devoted to SG). Our review was conducted in accordance with published recommendations and is under review at this time. Several thousand citations were reviewed with a resultant 36 SG studies with 2,570 patients. Studies took place all over the world, including one each from Israel and Saudi Arabia. Although there were only two randomized controlled trials, three of the studies were multicenter trials and the remaining single institution studies had large cohorts. After reviewing these studies, several clearly state that SG was being used as a staged procedure or as a management strategy for a high-risk patient population; however, some studies reported results of the SG used as a primary operation with no intent of a second-stage procedure.

The mean preoperative BMI among all 36 studies was 51kg/m², 65 percent of patients were female, and mean patient age was 42 years. When the staged/high risk subset was examined, 55 percent were female and the average age was 45 years. For those articles that clearly point toward a primary SG group, 70 percent of patients were female and the average age was just over 40 years. Ten studies showed 70 percent of patients examined had improvement or remission of type 2 diabetes within follow-up periods ranging from 1 to 5 years. There were also significant improvements in hypertension, hyperlipidemia, sleep apnea, and joint pain.

The mean excess weight loss (EWL) after SG was reported in 24 studies and ranged from 33 to 85 percent, with an overall mean EWL of 55 percent. Mean postoperative BMI was reported in 26 studies and decreased from a baseline mean of 51kg/m² to 37kg/m² postoperatively. The follow-up periods for weight loss data ranged from 3 months to 60 months. Within subgroups, weight loss data for the staged/high risk patients was EWL 33 to 61% (mean 47%) at a followup of five years and as a primary procedure EWL 36 to 85% (mean 60%) with only a three-year followup.

One of the most important factors to take into consideration when offering this procedure to patients is the risk profile. Significant complications commonly include leaks (2.2%), bleeding requiring reoperation (1.2%), and postoperative strictures requiring endoscopic or surgical intervention (0.6%). All studies reported mortality data with five postoperative deaths (within 30 days of surgery) for an overall mortality rate of 0.19 percent.

The trend toward SG as a primary procedure has gained momentum since 2006 when the first large series started to appear. Initially, SG studies included high-risk patients who underwent LSG as a staged approach.
There is ample data to make a case for SG as a primary as well as a staged procedure.
Sleeve Gastrectomy, Glucose Tolerance, and GLP-1

by JOSEP VIDAL, MD, PhD

INTRODUCTION

Bariatric surgery is known to be a highly effective and long-lasting treatment for morbid obesity and many related conditions, including type 2 diabetes mellitus (T2DM) and metabolic syndrome (MS).1,2 Data suggest that the resolution of obesity-associated metabolic disturbances is more common following the predominantly malabsorptive and the mixed malabsorptive-restrictive procedures, compared to the purely restrictive operations.3 However, data on the resolution rates of T2DM and MS following sleeve gastrectomy suggest this bariatric technique is an exception to this rule.

In a prospective study, we demonstrated that at four months after surgery, the resolution rate of T2DM in subjects undergoing laparoscopic sleeve gastrectomy (LSG) was comparable to that in subjects with T2DM undergoing laparoscopic Roux-en-Y gastric bypass (LRYGB) matched for DM duration, type of DM treatment, and glycemic control.4 Moreover, the clinical features associated with the early resolution of T2DM were similar between the two surgical groups. Likewise, in a subsequent study we showed that at longer followup (12 months), LSG is as effective as LRYGB in inducing remission not only of T2DM, but also of MS.5 At one year after surgery, T2DM had resolved in approximately 85 percent of the participants in both surgical groups. The rate of resolution of MS was 62.2 percent and 67.3 percent (p=0.392) following LSG and LRYGB, respectively. The amelioration and the resolution rate of the different MS components at 12 months after surgery was not significantly different between the two study groups. A younger age and a greater weight loss relative to baseline were associated with the resolution of MS following the two surgical procedures.

Since changes in gastrointestinal hormones have been implicated in the resolution of T2DM following bariatric surgery, we aimed to compare the changes in glucose tolerance and GLP-1 following LSG and LRYGB.

METHODS AND RESULTS

Following a standardized test meal (STM), the levels of GLP-1, insulin, and glucose were determined before and at six weeks after surgery in 12 normal-glucose tolerant obese subjects (BMI=53.81kg/m²) undergoing LSG (n=6) or LRYGB (n=6). The two groups were matched for gender distribution, age, and BMI. Insulin secretion and insulin sensitivity indices were derived from the STM (Δ insulin0-30 / Δ glucose0-30, AUC0-120 insulin/AUC0-120 glucose, insulin sensitivity composite index), and fasting samples (HOMA-S, HOMAB). Four non-operated morbidly obese subjects matched for the BMI attained at six weeks after surgery served as controls.

At six weeks after surgery, patients in both surgical groups had lost approximately 10 percent of their initial body weight (LSG: median, 9.51%; LRYGB: median, 10.2%; p=0.690). The GLP-1 response to a STM was larger than that prior to surgery following LSG (p=0.043) and LRYGB (p=0.028) (Figure 1). The AUC0-120 of GLP-1 changed to a similar

KEY POINTS

• The resolution rates of T2DM following LSG and LRYGB are similar.

• The resolution rates of metabolic syndrome following LSG and LRYGB are similar.

• LSG and LRYGB are associated with comparable changes in the GLP-1 response to meal intake.
Our data suggest that although LSG is considered a restrictive bariatric procedure, at least at short term, it is associated with changes in the GLP-1 response to meal intake, and glucose homeostasis comparable to those observed following LRYGB.

extent following the two surgical procedures (LSG: median, 493%; LRYGB: median, 725%; \( p = 0.343 \)), and was larger than that in the control group (\( p < 0.01 \)). Likewise, changes in fasting plasma glucose (LSG: median, -2%; LRYGB: median, -8%; \( p = 0.343 \)) and the AUC_{0-120} glucose in response to the STM (\( p = 0.268 \)) did not differ between the two surgical groups. As shown in Figure 2, the time course of the glucose response in the post-surgical examination was almost superimposable between the two groups. Changes in HOMA-S (\( p = 0.876 \)), insulin sensitivity composite index (\( p = 0.530 \)), and the indices of \( \beta \)-cell function adjusted for the prevailing insulin sensitivity changed comparably following LSG and LRYGB.

DISCUSSION

Our data suggest that although LSG is considered a restrictive bariatric procedure, at least at short term, it is associated with changes in the GLP-1 response to meal intake and glucose homeostasis comparable to those observed following LRYGB.

The data reported here is in addition to that reported by Karamanakos et al on the similarities in the gut hormone response to food intake between LSG and LRYGB. In their study, a marked reduction in fasting ghrelin levels and an increase in fasting PYY were observed following LSG (n=16). Fasting ghrelin did not change, and fasting PYY increased to a similar extent following LRYGB (n=16). At three months after surgery, meal intake induced a reduction in plasma ghrelin levels following LSG (n=6) but not following LRYGB (n=6). Both surgical procedures were associated with a marked increase in the prandial PYY response relative to prior to surgery.

Korner et al have recently reported a comparison of the ghrelin, GLP-1, and PYY response to meal intake following LRYGB and laparoscopic adjustable gastric banding (LAGB). In this prospective study, the degree of suppression of ghrelin levels post-meal did not differ significantly pre-surgery to Week 52 in either the LRYGB or the LAGB group. As previously reported, after LRYGB, the post-prandial response of GLP-1 and PYY was significantly increased relative to baseline. In contrast, in LAGB patients, the postprandial rise of GLP-1 measured at 30 minutes did not change after surgery. The AUC for PYY in response to the test meal increased threefold at 26 weeks after surgery in the LRYGB group. The AUC of PYY in the LAGB subjects was also increased, but to a lesser extent.

CONCLUSION

In summary, LSG does not appear to fit in the category of purely restrictive bariatric procedures. The changes in the GLP-1 secretion resemble those present following LRYGB and are in contrast with those reported in the literature following LAGB. Although our data suggest GLP-1 could play a role in the changes in glucose homeostasis following LSG, future studies are required addressing this question specifically in subjects with T2DM.

SUGGESTED READINGS

Laparoscopic Revisions of Sleeve Gastrectomy

by RAUL J. ROSENTHAL, MD, FACS

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BACKGROUND

The increasing implementation of laparoscopic sleeve gastrectomy (LSG) as a final or staged treatment option for morbid obesity has resulted in a new group of patients with the potential for revisional surgery.

Revisions of sleeve gastrectomy can result from acute complications, such as bleeding or leaks, and chronic complications, such as strictures or missed hiatal hernias, resulting in severe gastroesophageal reflux and pain. We must also distinguish two groups of complications, resulting when sleeve gastrectomy is used as a primary procedure or when sleeve gastrectomy is used as a secondary procedure or revisional approach to replace another failed bariatric surgery.

A different group of revisions of sleeve gastrectomy is those that result from failure of weight loss, those that result from weight regain, and those that are planned conversions to malabsorptive procedures, such as gastric bypass (RYGB) or biliopancreatic diversion with duodenal switch (BPD-DS).

To our knowledge, there are no literature reports of revisional surgery for failed sleeve gastrectomy implemented as a final approach for morbid obesity. There are several publications, however, reporting the results of conversion of sleeve gastrectomy to malabsorptive procedures.

Reoperative bariatric surgery can be the result of complications or failures. The latter can be divided into revisions and conversions. With the introduction of staged procedures, a new indication for conversions of LSG was introduced. Patients in this group of reoperative bariatric surgery will undergo an LSG followed by a BPD-DS or RYGB based on weight loss and resolution of comorbidities. Reoperative options for a failed LSG can be divided into revisions such as trimming or banding of the sleeve, or revisions such as BPD-DS or RYGB.

While the results of conversional surgery after LSG are well documented by Schauer and Gagner, there is minimal data of revisional or conversional surgery of LSG when performed as a final step.

At Cleveland Clinic Florida Bariatric and Metabolic Institute, LSG has been always performed as a final step. In close to 370 cases, only four patients underwent a conversion to a RYGB (1.08%). The reasons for failure were sleeve dilatation in all cases. All cases were performed laparoscopically, with no morbidity or mortality.

As more surgeons adopt the LSG as a primary procedure for weight loss, more cases of surgical management of failure will be reported, helping us understand the reasons and options for revisional or conversional surgery in this patient population.

DISCUSSION

Complications of sleeve gastrectomy are few, this being one of the most appealing characteristics of this procedure.

In a review of 149 sleeve gastrectomies performed as a single-stage approach for the treatment of morbid obesity, our group reported an overall morbidity of 2.9 percent. One patient had a staple-line disruption resulting in an abscess that required percutaneous drainage; one patient had a bleeding episode from a retractor liver injury requiring laparoscopic drainage; one patient had a bowel injury during access requiring conversion to an open procedure; and one patient developed a stricture requiring endoscopic dilatation. Long-term complications of sleeve gastrectomy in this report were related only to the development of choledocholithiasis. There was no mortality in this series.

When used as a revisional approach for failed gastric banding, the incidence of complications of sleeve gastrectomy is markedly increased. In the same publication, our group reported 14 patients that...
As more surgeons adopt the LSG as a primary procedure for weight loss, more cases of surgical management of failure will be reported, helping us understand the reasons and options for revisional or onversional surgery in this patient population.

underwent conversion of adjustable gastric banding to sleeve gastrectomy with an overall morbidity of seven percent. One patient developed staple-line disruption followed by formation of an abscess, requiring laparoscopic revision and drainage. There was no mortality in this series.

From a technical point of view, the laparoscopic approach when revising a complicated or failed sleeve gastrectomy is similar to the one utilized with other general surgical procedures. We recommend open access to the abdominal cavity via Hasson canula and the use of multiple trocars to allow wide access to the surgical site. We also mandate routine reinforcement of staple lines with oversewing or buttressing and drainage.

CONCLUSION

Laparoscopic sleeve gastrectomy can be performed with minor complications and low mortality. It has been demonstrated to be a safe and effective procedure in the short term. The laparoscopic approach to manage complications and revisions is feasible.

Meticulous attention to oversewing the staple line was the main factor contributing to our extended operative time, but we feel this time is well spent to achieve hemostasis and prevent a leak that could result in significant morbidity.

Prospective studies are required after laparoscopic sleeve gastrectomy to determine the long-term outcome and efficacy of maintenance of weight loss and resolution of comorbid conditions.

SUGGESTED READINGS


Table 1. Reasons for revisional surgery after sleeve gastrectomy

<table>
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<tr>
<th>1. COMPLICATIONS</th>
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<tr>
<td>A. Acute</td>
<td>Bleeding</td>
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<td>Leak</td>
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<td>B. Chronic</td>
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<td>Biliary tract disease</td>
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<td>GERD</td>
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<th>2. FAILURE OF WEIGHT LOSS OR WEIGHT REGAIN</th>
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<td>• Sleeve dilatation</td>
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<th>3. STEP APPROACH</th>
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<tr>
<td>• Conversion to RYGBP</td>
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<tr>
<td>• Conversion to BPD DS</td>
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KEY POINTS

• Open access to the abdominal cavity via Hasson canula and the use of multiple trocars to allow wide access to the surgical site is recommended.

• Routine reinforcement of staple lines with oversewing or buttressing and drainage is mandated (in author’s practice).

• Laparoscopic sleeve gastrectomy has been demonstrated to be a safe and effective procedure in the short term.
The Process of Reimbursement for Sleeve Gastrectomy

by GRANT BAGLEY, MD, JD

This summary focuses on the development and submission of a code for sleeve gastrectomy. This presentation includes information on the status of this particular code, how a code is developed, and what surgeons can do to assist in the process of obtaining the code.

As a practicing surgeon, I was having difficulty obtaining payment for innovative surgical procedures. Frustrated with the process, I decided to begin working within the government to assist in helping surgeons with reimbursement. I spent five years at the Centers for Medicare and Medicaid Services (CMS) working on physician fee schedule and coverage issues, and offer insight from that experience.

A consortium of surgeons from the American Society for Metabolic and Bariatric Surgery (ASMBS), the Society for American Gastrointestinal and Endoscopic Surgeons (SAGES), and the American College of Surgeons (ACS) have worked together on the creation of a CPT code for the sleeve gastrectomy procedure. The CPT Committee met in February, and the CPT code for the sleeve gastrectomy procedure was created.

Next, the process goes to the Relative Value Scale Update Committee (RUC). The American Medical Association (AMA)/Specialty Society Relative Value Scale Update Committee was established to ensure that physician
Local and private payers...need to hear the message about the efficacy of the sleeve gastrectomy procedure.

Carefully completed surveys are necessary for the involved specialty societies to present and defend values at the RUC meeting. We must also convince third party payers that this procedure is medically necessary. As a surgeon, what else can you do to assist in the process? If you have not done so already, begin speaking with local and private payers. They need to hear the message about the efficacy of the sleeve gastrectomy procedure. Surgeons need to bring information to the carriers, and eventually Medicare will cover it as well. As a community, the message needs to be about evidence-based decisionmaking, which supports this procedure. While the concept of evidence-based medicine was not envisioned as a way for insurers to create policy, it has become the standard for adding coverage for new procedures, and has evolved beyond the physician-patient discussion; therefore, we must use it in convincing third-party payers to cover new procedures. Often the level of evidence needed is directly proportional to the cost of the new technology. In presenting the case to medical directors for insurers, be knowledgeable about the studies—both the good and the bad. Third-party payers are particularly interested in how to formulate a policy with clear selection criteria from which patients are likely to benefit.

Both private payers and Medicare will worry about the cost of payment and the utilization of sleeve gastrectomy. A policy that is based on evidence and is clear in terms of proper patient selection criteria will result in more rapid coverage. Success depends on how well we convey the message of the benefits of sleeve gastrectomy and whether we can make it clear that utilization can be restricted to those patients most likely to benefit.

The new national coverage determination (NCD) of bariatric surgery for diabetes has been helpful. Groups need to work together to advocate for coverage change. More clinical studies have been conducted and long-term results have improved. Now, as a group, we need to convey the message to get coverage adequately defined.

KEY POINTS

- Surveys from the participating medical societies about the work involved in performing SG are critical to the process, and participation is encouraged.

- Local and private payers need to hear the message about the efficacy of the sleeve gastrectomy procedure.

- We must use evidence-based medicine in convincing third-party payers to cover new procedures.
Debates and Consensus: A Summary

by MICHEL GAGNER, MD, FRCSC, FACS

INTRODUCTION

The last day of the conference was dedicated to six debates coordinated with the participation of Dr. Scott Shikora, current president of the American Society for Metabolic and Bariatric Surgery (ASMBS). The six major topics debated are listed in Tables 1 and 2. For each debate, a panel of six experts was requested with a moderator that had prepared multiple choice questions, and included audience participation using a Meridia system. Each question was well deliberated for 30 minutes.

Question 1: What is the mechanism of action of the sleeve gastrectomy?

From the audience participation, nearly 80 percent judged that restriction was the main mechanism, and 20 percent answered primarily that sleeve gastrectomy had a hormonal action. Unfortunately, answer choices were not formulated with an association of both, which might have been the right answer ultimately. Concerning the effect of sleeve gastrectomy on gastric emptying, two-thirds of participants registered an answer which supposed that results are now contradictory and more studies are needed. Still, one quarter supported the idea that a faster gastric emptying resulted. Concerning hormonal studies and what was presented, a majority of the audience (90%) believed that sleeve gastrectomy had the most profound reduction of serum ghrelin (more than gastric bypass). There is therefore a consensus on this—that sleeve gastrectomy appears to be a restrictive procedure primarily, with a secondary hormonal action causing intense reduction of serum ghrelin.

Question 2: What is the best procedure for weight regain after sleeve gastrectomy?

The audience was divided on this issue. Where 50 percent would opt for a gastric bypass, 42 percent would favor a duodenal switch (DS). Perhaps this was because most participants were familiar with gastric bypass as opposed to DS. Nobody chose gastric banding, and some wanted to re-sleeve (6%). Weight regain after sleeve gastrectomy, similar to gastric bypass, appears after two years, and most authors do not have enough experience yet to engage in the matter.

Question 3: What is the best option for a patient with a BMI of 35 to 50 kg/m² with poorly controlled type 2 diabetes?

After debating different operations for these conditions, it appears that the literature is favoring gastric bypass, but this is primarily because sleeve gastrectomy is a recent option, with few published cohorts, while gastric banding and gastric bypass have had plenty of evidence, including randomized trials. Nevertheless, sleeve gastrectomy came as a better selection than gastric banding for type 2 diabetes, as the voters were 50 percent for gastric bypass, 34 percent for sleeve gastrectomy, six percent for DS, and only five percent for gastric banding. When the question was articulated for BMI group of 35 to 40 kg/m², then sleeve gastrectomy and gastric bypass were equal at 46 percent of the yes vote each. Consequently, this is almost tempting to conclude that for type 2 diabetes, sleeve gastrectomy can play a role, especially in smaller BMI patients.

Question 4: What will be the best future access to perform sleeve gastrectomy?

This session was debated by experts who perform sleeve gastrectomy using a single incision, or put all ports in the periumbilical area (NOTUS), or have a transvaginal approach (NOTES). The audience was not convinced that this approach is superior; most participants assumed that the future was still with conventional laparoscopy at more than 70 percent of the vote and only 31 percent pushing for single incision/port technology, and NOTES only garnered seven percent. When the question was asked about the patient perspective on this, most participants assumed that the future was still with conventional laparoscopy at more than 70 percent of the vote and only 31 percent pushing for single incision/port technology, and NOTES only garnered seven percent. When the question was asked about the patient perspective on this, most participants thought that patients would favor a NOTES approach to sleeve gastrectomy (49% of the vote). In terms of technique adoption, the shortest learning curve was seen with SILS™/NOTUS techniques, and the audience agreed with this statement overwhelmingly by 86 percent. Most participants thought that weight loss data would show a
One can conclude that sleeve gastrectomy can be considered a primary operation for adolescents (which gives similar weight loss results to that of young adults), patients with a high BMI, and patients with inflammatory bowel disease, especially Crohn’s disease.

failure or success from these approaches at two years (39%), and most agreed that these new approaches needed to demonstrate a 50-percent excess weight loss (EWL).

**Question 5: Yes or No—Should the sleeve gastrectomy be considered a primary operative procedure for the conditions listed in Table 2?**

Concerning these different questions, which were avidly debated, the voting results expressed resulted in a no vote by nearly 70 percent for portal hypertension, a yes vote by 60 percent for adolescents, a yes vote by 85 percent for high BMI groups, a no vote by nearly 90 percent for severe gastroesophageal reflux disease, a too close call (yes 54%) for diabetic gastroparesis, a no vote at nearly 60 percent for severe psychiatric illness, and a yes vote at 82 percent for Crohn’s disease. Therefore, one can conclude that sleeve gastrectomy can be considered a primary operation for adolescents (which gives similar weight loss results to that of young adults), patients with a high BMI, and patients with inflammatory bowel disease, especially Crohn’s disease.

**Question 6: In your opinion, is there currently enough published data to support the sleeve gastrectomy as a primary procedure to treat morbid obesity on par with adjustable gastric banding and Roux-en-Y gastric bypass?**

Several groups presented cohorts of patients with follow-up periods of 4 to 8 years the day before. Jossart and colleagues in San Francisco presented eight years’ experience, including 1,200 cases, whereas at more than four years, weight loss resulted in a similar curve to gastric bypass. At higher BMI (>55kg/m²) a plateau of nearly 40kg/m² demanded a second stage, but below a BMI of 55, the operation was terrific. Schauer and colleagues assessed the literature from 35 reports, studied more than 3,000 published sleeve gastrectomy cases, and found an extremely low mortality rate (near 0.12%). Results have shown excellent weight loss and comorbidity reduction that is comparable to or exceeds other bariatric operations, and that the sleeve gastrectomy is safe and efficacious. Himpens of Belgium analyzed his patients from 2001 through 2002 to attain six-year followup. Sixty-five percent of 46 patients were considered a “success” (%EWL>50) at two years. At six years, the success rate was maintained at 59 percent. Weiner from Frankfurt and MacMahon of Leeds, who started in 2000, also had similar results.

Certainly, the audience thought there was enough evidence published to support the sleeve gastrectomy as a primary procedure to treat morbid obesity on par with adjustable gastric banding and Roux-en-Y gastric bypass with a yes vote at 77 percent. This is perhaps the strongest contribution to this second consensus conference.

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