

Early Results of the Swiss Multicentre Bypass or Sleeve Study (SM-BOSS)

A Prospective Randomized Trial Comparing Laparoscopic Sleeve Gastrectomy and Roux-en-Y Gastric Bypass

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Objective: Laparoscopic sleeve gastrectomy (LSG) has been proposed as an effective alternative to the current standard procedure, laparoscopic Roux-en-Y gastric bypass (LRYGB). Prospective data comparing both procedures are rare. Therefore, we performed a randomized clinical trial assessing the effectiveness and safety of these 2 operative techniques.

Methods: Two hundred seventeen patients were randomized at 4 bariatric centers in Switzerland. One hundred seven patients underwent LSG using a 35-F bougie with suturing of the stapler line, and 110 patients underwent LRYGB with a 150-cm antecolic alimentary and a 50-cm biliopancreatic limb. The mean body mass index of all patients was 44 ± 11.1 kg/m², the mean age was 43 ± 5.3 years, and 72% were female.

Results: The 2 groups were similar in terms of body mass index, age, sex, comorbidities, and eating behavior. The mean operative time was less for LSG than for LRYGB (87 ± 52.3 minutes vs 108 ± 42.3 minutes; $P = 0.003$). The conversion rate was 0.9% in both groups. Complications (<30 days) occurred more often in LRYGB than in LSG (17.2% vs 8.4%; $P = 0.067$). However, the difference in severe complications did not reach statistical significance (4.5% for LRYGB vs 1% for LSG; $P = 0.21$). Excessive body mass index loss 1 year after the operation was similar between the 2 groups ($72.3\% \pm 22\%$ for LSG and $76.6\% \pm 21\%$ for LRYGB; $P = 0.2$). Except for gastroesophageal reflux disease, which showed a higher resolution rate after LRYGB, the comorbidities and quality of life were significantly improved after both procedures.

Conclusions: LSG was associated with shorter operation time and a trend toward fewer complications than with LRYGB. Both procedures were almost equally efficient regarding weight loss, improvement of comorbidities, and quality of life 1 year after surgery. Long-term follow-up data are needed to confirm these facts.

Keywords: comorbidities, gastric bypass, perioperative complications, randomized clinical trial, sleeve gastrectomy

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Bariatric surgery has been recognized as an effective and safe treatment option for morbid obesity and its related comorbidities.^{1–3} For the last 2 decades, Roux-en-Y gastric bypass has been considered as the treatment of choice for obesity World Health Organization grade III, with an acceptable complication rate, long-lasting weight control, and efficient reduction of comorbidities, especially type 2 diabetes (T2DM).^{4–6} The dramatically increasing prevalence of obesity has led to the development of alternative treatment strategies including new operative techniques, such as the laparoscopic sleeve gastrectomy (LSG), which was first described in 2003 by Regan et al⁷ in a staged concept. LSG is suggested to be a technically less demanding operation than laparoscopic Roux-en-Y gastric bypass (LRYGB), which offers some potential benefits over the LRYGB. Because the intestinal passage is still intact after LSG endoscopy of the remaining stomach and access to the duodenum is still possible, the risk of internal hernias is absent. In case of insufficient weight loss, LRYGB or biliopancreatic diversion with duodenal switch can be performed as a second-stage procedure. However, there has been some concern regarding onset or worsening of reflux and leakages after LSG, with the latter (although rare) being rather demanding to treat. LSG has gained popularity throughout the world, but there is still a lot of skepticism among bariatric surgeons regarding achievable long-term results in comparison with the established results of LRYGB. As a consequence, many studies in the past few years have been published assessing the midterm efficacy and safety of LSG. The excessive weight loss ranged from 53% to 69%, and the incidence of staple line leaks and bleeding ranged from 1% to 3%.^{8–12} In 2012, the American Society for Metabolic and Bariatric Surgery published a revised position statement, which proposed that LSG is a valid alternative operation technique to LRYGB.¹³ However, currently, the evidence for the superiority of either surgical technique is still weak.^{14–16} Only 3 (2 from the same institution) randomized clinical trials comparing LSG and LRYGB with small patient numbers (16–30 per group) and limited follow-up (12–35 months) have been published so far. Although bariatric operations are currently among the most frequently performed operative procedures in the United States and Europe,¹⁷ a potential outcome difference between LSG and LRYGB would therefore have a substantial impact on the health care systems worldwide. Therefore, we decided to conduct a large multicentric randomized clinical trial assessing the efficacy and safety of LSG and LRYGB to answer this important question.

METHODS

From January 2007 to November 2011, we enrolled 217 patients at 4 bariatric centers in Switzerland. The study protocol was reviewed and approved by the local ethical committees of each participating bariatric center and registered at the clinical trials registry of the National Institutes of Health (NCT 00356213). All patients

were informed in detail about the potential risks and benefits of both operations and provided written informed consent for the participation of the study. Additional consent was obtained for the surgical procedure once the patient was randomized. The patients were evaluated by a multidisciplinary team (including an endocrinologist/physician, a psychiatrist, a nutritionist, and a bariatric surgeon) and were included in the study if they fulfilled the criteria for bariatric surgery in Switzerland [body mass index (BMI) >40 or >35 kg/m² with the presence of at least 1 comorbidity, age between 18 and 65 years, and failure of conservative treatment over 2 years].

In addition to general contraindications for major abdominal surgery, exclusion criteria were severe symptomatic gastroesophageal reflux disease (GERD) despite medication, large hiatal hernia, expected dense adhesions at the level of the small bowel, the need for endoscopic follow-up of the duodenum, and patients with inflammatory bowel disease.

The primary end point of the study was weight loss, which was defined by excessive BMI loss (EBMIL), over a period of 5 years. To detect a 10% difference, we calculated a study size of 200 patients to reach a 94% power. This is an interim analysis at 1 year. Secondary end points were the rate of perioperative morbidity and mortality, the remission rates of the associated comorbidities, and the change in quality of life (QOL) in the 2 patient groups.

Randomization

Patients were assigned to either the LSG or LRYGB group, using a computer-based randomization with sealed envelopes after informed consent has been obtained in the outpatient clinic. Using this strategy, a total of 225 patients were eligible and randomized. Eight patients were excluded because of the following reasons: 1 patient crossed over from the LRYGB to LSG group because of unexpected dense adhesions of the jejunum, and 7 patients were operated on after November 2011 when the recruitment phase was closed. This resulted in a total of 217 patients who were included in the study.

Operation Techniques

All patients were operated on using standardized operation techniques. For LSG, we used a 35-Fr bougie along the lesser curvature for calibration of the gastric tube; the longitudinal resection of the stomach was done from approximately 3 to 6 cm orally of the pylorus to the angle of His. The staple line was routinely oversewn with an absorbable running suture. Hiatal hernias were explored and repaired with posterior closure of the crura. LRYGB was performed with a 150-cm antecolic Roux-limb with either a linear stapled or circular stapled (25-mm) gastrojejunostomy according to the preference of the bariatric center. A 50-cm long biliopancreatic limb was chosen.

Assessment

All patients underwent complete evaluation before the operation (including endoscopy, esophageal manometry, upper gastrointestinal series, and abdominal ultrasonography). Additional investigations were performed according to the risk profile of each individual patient. Synchronous cholecystectomy was performed according to the center policy for patients with gallstones. Patients were followed at each center according to a protocol, 4 times during the first postoperative year and yearly intervals thereafter. Eating behavior, comorbidities, anthropometric parameters, clinical parameters including blood samples, and QOL using the Gastrointestinal Quality of Life Index (GIQLI) were routinely assessed.¹⁸ Vitamin supplementation and postoperative thrombosis prophylaxis were performed according to the center policy. Comorbidities were defined using international standard criteria (hypertension: systolic blood pressure 140 mm Hg or more and/or diastolic blood pressure ≥ 90 mm Hg or antihypertensive

drug therapy; diabetes mellitus type 2 (T2DM): fasting plasma glucose ≥ 126 mg/dL or 2-hour plasma glucose ≥ 200 mg/dL during oral glucose tolerance test or antidiabetic drug with or without insulin therapy; impaired glucose tolerance: 2-hour plasma glucose ≥ 140 and ≤ 200 mg/dL during oral glucose tolerance test; dyslipidemia: fasting high-density lipoprotein <40 mg/dL for men, <50 mg/dL for women, and/or triglycerides >150 mg/dL and/or low-density lipoprotein >100 mg/dL or the use of statins; obstructive sleep apnea syndrome: repeated upper airway occlusions during sleep with or without sleepiness and high apnea/hypopnea index and the need for continuous positive airway pressure during sleep; and GERD: need for proton pump inhibitor agents and/or esophagitis diagnosed on endoscopy and/or abnormal manometry; athralgia: clinical and radiological findings). Remission and improvement of comorbidities were defined by the endocrinologist/physician responsible for the follow-up. The definitions for remission of diabetes from the International Diabetes Association were not published yet at the time of the submission of the protocol. Perioperative complications were defined using a standardized complication classification system, which has been shown to be very reliable.¹⁹ In brief, the Clavien-Dindo classification for grading the severity of complications by the therapy used to correct a specific complication. Grade I complications include minor deterioration from the normal postoperative course. Grade II complications can be treated by drugs, blood transfusion, physiotherapy, or nutritional support. Grade III complications require interventional (IIIa) or operative (IIIb) treatment. Grade IV complications are life-threatening complications with the need of intensive care unit management. Grade V is defined as death of the patient. If a patient had more than 1 complication, only the highest ranked complication was used for the analysis.

Statistical Analysis

Data analysis was performed using IBM SPSS for Windows (version 21; IBM, Armonk, NY). Values are reported as means \pm SD. Descriptive statistics were used for demographic variables such as age, weight, and BMI. The Student *t* and Fisher exact 2-sided tests were used where appropriate. A *P* value of less than 0.05 was considered as statistically significant.

RESULTS

Patient Characteristics

A total of 217 patients with a BMI between 35 and 61 kg/m² were randomized to either LSG (107 patients) or LRYGB (110 patients). The follow-up rate was 100% at 1 year. One hundred twelve patients completed the 2-year follow-up and 70 patients the 3-year follow-up at the time of analysis (median follow-up of 2 years). The 2 groups were similar in terms of sex distribution, age, weight, BMI, and QOL (Table 1). There were no differences regarding eating disorder/behavior. The rate of comorbidities, such as diabetes, hypertension, hyperlipidemia, obstructive sleep apnea syndrome, and others, were almost identical in both groups (Table 1).

Perioperative Data/Complications

The mean operative time was less for LSG than for LRYGB (87.2 \pm 52.3 minutes vs 108 \pm 42.3; *P* = 0.003). The conversion rate was 0.9% in both groups. In the LSG group, 1 patient had to be converted to an open procedure because of technical difficulty with extreme intra-abdominal fat and enormous liver size. In the LRYGB group, 1 patient was converted to an open procedure to control bleeding at the gastric remnant. Additional operations have been performed in 36 of 107 patients in the LSG group and 26 of 110 patients in the LRYGB group (*P* = 0.09). Among these, the main operations were cholecystectomies (15 in the LSG group and 19 in

the LRYGB group) and hiatal hernia repair (13 in the LSG group and 1 in the LRYGB group; $P = 0.001$).

The perioperative complication rate (<30 days) assessed by the Clavien-Dindo classification was higher in the LRYGB group than in the LSG group (17.2% vs 8.4%; $P = 0.067$). The grading of the complications is given in Table 2. The rate of severe complications requiring a reoperation was 4.5% (5/110) in the LRYGB group versus 0.9% (1/107) in the LSG group ($P = 0.21$). The reason for the reoperation in the LSG group was obstruction of the gastric sleeve. The reasons for the 5 revisions in the LRYGB group were as follows: 1 leakage at the gastrojejunostomy, 1 obstruction of the biliopancreatic limb, 2 intra-abdominal abscesses, and 1 pleural empyema.

The different complications stratified into minor and major complications are given in Table 2. One patient had an early leakage at the gastrojejunostomy after LRYGB, with a complicated course including aspiration, acute respiratory distress syndrome, multiorgan failure, and finally an episode of intracerebral bleeding, which eventually led to the death of the patient.

TABLE 1. Patient Descriptives

	LSG (n = 107)	LRYGB (n = 110)	P
Age, mean ± SD, yr	43.0 ± 11.1	42.1 ± 11.2	NS
Female, n (%)	77 (72)	79 (72)	NS
Weight, mean ± SD, kg	123.5 ± 19.4	124.8 ± 19.8	NS
BMI, mean ± SD, kg/m ²	43.6 ± 5.3	44.2 ± 5.3	NS
QOL (GIQLI score), mean ± SD	99.0 ± 20.5	98.8 ± 17.4	NS
Hypertension, %	63	59	NS
Diabetes, %	24	26	NS
Dyslipidemia (%)	67	51	NS
OSAS, %	48	42	NS
GERD, %	44	46	NS
Back/joint pain, %	61	68	NS
Depression, %	20	11	NS

Patient descriptives and the rate of comorbidities.

GERD indicates gastro esophageal reflux disease; GIQLI, Gastrointestinal Quality of Life Index; OSAS, obstructive sleep apnea syndrome; NS, nonsignificant.

TABLE 2. Perioperative Morbidity

	LSG (n = 107)	LRYGB (n = 110)	P
Major complications			
Leak		1*	
Bleeding		2	
Obstruction	1*	1*	
Infection	1	7*	
Minor complications			
Dysphagia	3	2	
Surgical	1	1	
Nonsurgical	3	5	
Complication grade			
I	5	8	
II	3	6	
III	1	4	
IV	0	0	
V	0	1	
Total	8.4%	17.2%	0.067

Perioperative morbidity stratified into minor and major and according to the Clavien-Dindo classification.

*reoperation (0.9% vs 4.5%; $P = 0.21$).

Weight Loss at 1, 2, and 3 Years

There was a significant weight loss at 1 year in both groups. In LSG patients, the weight loss was from 123.5 ± 19.4 to 86.9 ± 16.9 kg compared with the weight loss in LRYGB patients from 124.7 ± 19.8 to 84.7 ± 16.8 kg. There was no difference regarding weight loss or EBMI between the 2 groups after 1 year (Figs. 1A, B), and there was no further weight loss in patients who completed the follow-up at 2 (n = 112) and 3 (n = 70) years. We observed a tendency toward a lower EBMI at 3 years in the LSG group (n = 38) than in the LRYGB group (n = 32) [63.3% vs 72.8% (NS)].

Resolution of Comorbidities

The rate of comorbidities improved dramatically in both groups 1 year after the operation. Figure 2 displays the percentage of patients who were cured or showed improvement in their comorbidities. For patients with T2DM, 57.7% in the LSG group and 67.9% in the LRYGB group were not taking medication. Except for the remission of GERD, there was no difference between the LSG group and the LRYGB group regarding the remission of comorbidities or improvement rate. Patients undergoing LSG experienced a slightly higher rate of new-onset GERD (12.5% vs 4%; $P = 0.12$), and among those who already presented with GERD before the operation, the rate of

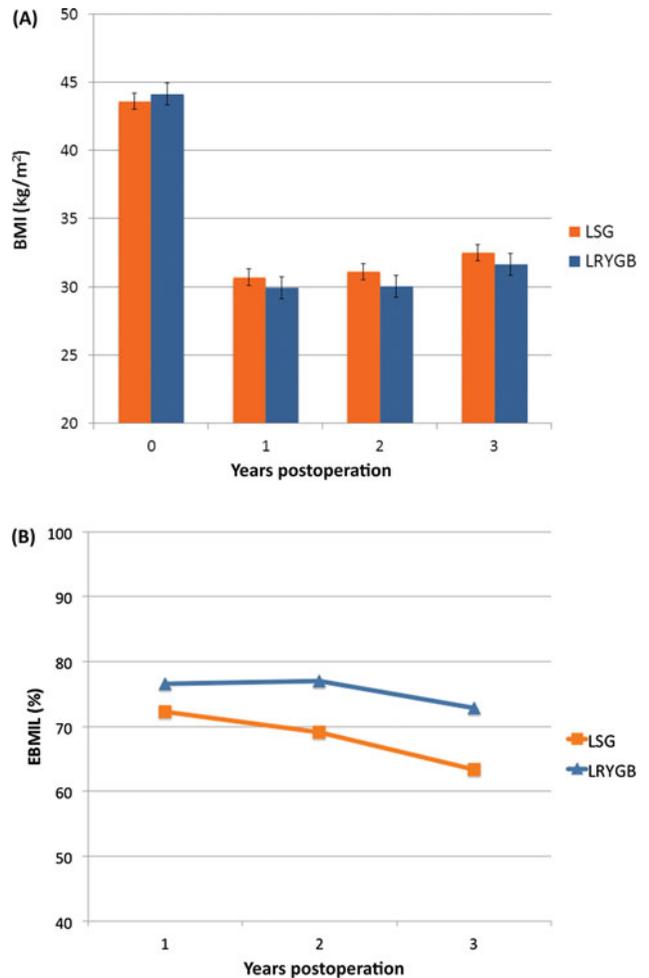


FIGURE 1. A, Change in BMI (means ± standard error). B, EBMI (means).

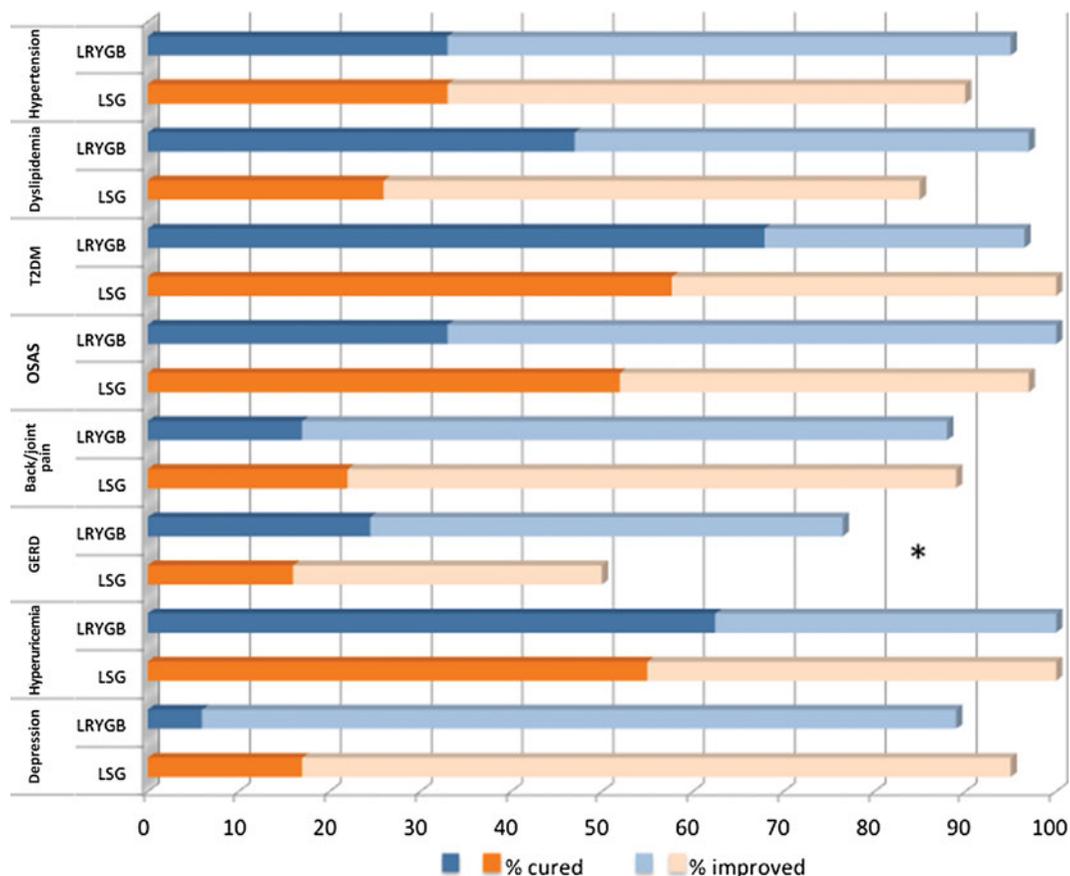


FIGURE 2. Reduction in comorbidity 1 year after surgery. No significant difference in cure or improvement of comorbidities between LSG and LRYGB except for GERD (* $P = 0.008$). GERD indicates gastro esophageal reflux disease; OSAS, obstructive sleep apnea syndrome; T2DM, type 2 diabetes.

improvement was significantly lower than those who underwent LRYGB (50% vs 75%; $P = 0.008$). The QOL assessed at 1 year was equal between patients undergoing LSG and those undergoing LRYGB, with 127 and 128 points, respectively, at 1 year (NS). Patients from both groups experienced a significant improvement in QOL compared with baseline ($P < 0.0001$) and even exceeded that of healthy individuals who reach a score of 121 points ($P < 0.01$).¹⁸

Complications During the First Postoperative Year

In the LRYGB group, there was 1 anastomotic ulcer at the gastroenterostomy and 1 stricture that needed endoscopic dilatation. Up to 1 year postoperatively, no patient had to be reoperated on for either insufficient weight loss or internal hernia in both groups. Two patients of the LSG group experienced severe GERD symptoms, but until 1 year after the operation, none of them agreed to have undergone conversion to LRYGB. Both patients were asymptomatic and not receiving proton pump inhibitor therapy before the operation. The incidence of micronutrient deficiency was equal in both groups (LSG: $n = 28$ patients; LRYGB: $n = 27$ patients), with vitamin D deficiency being the most frequent deficiency, followed by vitamin B₁₂ deficiency (LSG: $n = 7$; LRYGB: $n = 15$; $P < 0.12$). Iron, folic acid, and zinc were rarely deficient.

DISCUSSION

This is the first multicentric randomized clinical trial including a large number of patients with 100% 1-year follow-up comparing

LSG versus LRYGB. We found that LSG and LRYGB are almost equally efficient regarding weight loss and reduction in comorbidities. There was a trend toward fewer perioperative complications in patients undergoing LSG. However, the difference was not statistically significant.

LSG can be considered a technically less demanding operation than the LRYGB, which is reflected by the shorter operation time and the lower complication rate in the LSG group. Our results of the perioperative morbidity are comparable with those of a recently published Finnish trial, which focused only on the perioperative complication rate between LSG and LRYGB.²⁰ That study reported a reduced operating time and a lower overall complication rate in the LSG group. The complication rate was slightly higher, with 13.2% for LSG and 26.5% for Roux-en-Y gastric bypass than ours. In line with our results, there was no difference regarding major complications. Despite the lower complication rate, it needs to be emphasized that LSG is not a harmless operation, because it can be associated with deleterious complications. Leakage at the gastroesophageal junction or (less frequently) in the antrum is known to be very unpleasant and cumbersome to treat.²¹ The leakage rate is between 1% and 3%²² but can be as high as 16% in reoperations.²³ Mild dysphagia after LSG can be observed frequently, but strictures or torsions of the gastric sleeve are complications that are difficult to treat and often result in the resection of the gastric sleeve at the end of the treatment line. Therefore, it is utmost important that this procedure is performed with the best standardized technique by experienced bariatric surgeons.

In the past, there has been skepticism regarding LSG and GERD, because the anatomical structure of the angle of His is no longer intact after LSG. Furthermore, there is still a large proportion of remaining parietal cells. Accordingly, the new-onset rate of GERD has been reported as high as 21% after LSG.¹⁰ In line with this, we observed a significantly lower rate of GERD remission and a clear trend of new-onset GERD after LSG compared with LRYGB. Therefore, we believe that patients with preexisting GERD are at a risk of deterioration after LSG and should rather undergo LRYGB. This is one result of our study that allows the bariatric surgeon to tailor the operative strategy for the patient according to his or her preoperative risk profile. We also propose that patients undergo LSG if they have expected major adhesions, need a staged concept, or suffer from Crohn disease. It is hoped that such a tailored approach will optimize the long-term results of bariatric surgery.

The strengths of this study are the standardized multicentric design and the complete follow-up of all included patients at 1 year, reflecting a representative patient population. Both groups were almost identical regarding the anthropometric values and the prevalence of comorbidities, and both procedures led to a similar and significant weight loss comparable with previous nonrandomized studies.¹⁴ At 3 years, EBMI after LSG was slightly lower than that of the LRYGB group. However, only a third of all patients reached this time point so far.

One of the main goals of bariatric surgery is the long-term remission of the obesity-associated comorbidities such as T2DM, hypertension, and dyslipidemia. In our study, the rate of remission/improvement of the comorbidities was very high in both treatment groups, confirming the metabolic effect of both LSG and LRYGB. The potential different mechanisms behind the 2 surgical techniques have been investigated by 2 participating centers of this article in the past.^{16,24–27} Interestingly, we did not observe a difference between the 2 procedures regarding T2DM resolution. T2DM was efficiently treated by both procedures, which is important because T2DM is one of the main health care cost factors in obese patients.²⁸ Further follow-up results of this study will have to be awaited for a firm statement regarding long-term remission rates of comorbidities and weight loss between the 2 procedures.

CONCLUSIONS

LSG can be performed faster than LRYGB and is associated with fewer perioperative complications. We could show that LSG and LRYGB are equally efficient regarding weight loss, reduction in comorbidities, and increase in QOL at 1 year. Therefore, we believe that LSG is a valuable surgical alternative for selected patients with morbid obesity. Long-term follow-up data are needed to confirm these results.

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DISCUSSANTS

M. Morino (Torino, Italy):

I would like to thank the Society for giving me the opportunity to discuss this article and Dr Peterli for giving me the opportunity to review the manuscript. Dr Peterli and coworkers have to be complimented on this RCT; it addresses one of the most interesting topics on bariatric surgery at present, the comparison between sleeve and bypass. In fact your study was designed and powered on the basis of long-term (5-year) excess weight loss. You did not mention that in this presentation, but this I think is quite important. You have already published twice on different aspects of the early results of this trial, and today you presented the results at 1, 2, and 3 years, but it is important to note that less than 30% of the patients have reached the 3-year end point and less than 50% have reached the 2-year end point.

Keeping in mind that the design of the study was powered at 5 years, my first question is whether you believe that the data that you presented today are sufficiently powered from a statistical point of view to sustain your conclusions?

The second point is that 200 patients randomized at 4 centers in 5 years means 10 patients per center per year. If you divide for 1 or 2 surgeons who probably perform this surgery in your group or maybe even 3, it makes 1 patient every 3 months. So, do you believe that this limited accrual is related to a limited rate of accrual or to a high exclusion rate?

My third question concerns the GERD. In the manuscript, it is a little bit confusing, as you state that the symptoms of GERD were an exclusion criterion and then you state that in the sleeve group, the rate of GERD improvement was lower than that in the bypass group. Could you please comment on this point?

Response From R. Peterli (Basel, Switzerland):

It is true that the study was designed for an end point at 5 years, but as the procedures are gaining such popularity, we believe that it is important to address these results at 1 year and it is only the weight loss results that we have presented at 2 and 3 years. There are very few randomized studies in bariatric surgery, and it is a general problem in surgery that we do not have randomized trials. In the United States, you often have only 1-year results and it is very rare to have more than 25% follow-up rate at 5 years. If you have 25% follow-up rate at 5 years, one does not know the majority of the results. So we thought that it was important to address these results because this operation is gaining such popularity.

It is true that it took us a long time to recruit. As the principal investigator, I have experience with duodenal switch, so I knew the technique. The sleeve gastrostomy technique had to be standardized

and the other centers started later on. So there was a certain delay until we had it standardized for the other centers, and ethical approval in the other centers also took time. That explains the differences: the small number per year, per center the other centers that started later on.

We did exclude severe GERD and big hiatal hernias, but many of these patients have some GERD symptoms; indeed, 48% of our patients did have intermittent reflux symptoms, so we did not exclude them, we excluded only severe GERD.

DISCUSSANTS

F. Pattou (Lille, France):

Thank you very much for this discussion and for this important randomized study in a field in which there are relatively few. This operation in France has become, as in many countries, the most performed operation and that raises concern, at least in France. You talked to us about the safety; I will not come back to the long-term concern, which is a major one, but come back to the safety. You concluded that this operation is safer than gastric bypass. I would like to ask you about a complication that is now being seen with increasing frequency, acute leak at the top of the suture line. It may occur in only a few percent of patients, perhaps the reason you did not mention it, but it is extremely worrisome in everyday clinical life. In France, a large national study showed that these patients have at least 2 months' mean hospital stay. Could you please comment on this specific point of safety and the specific complication of acute leak?

Response From R. Peterli (Basel, Switzerland):

Thank you, Prof Pattou, for this is a very important remark. It is true that the leak rate, in a consensus meeting last year, was 1% and good centers have 0% to 0.5%. However, that is not the issue, it is how do you perform the operation, what kind of staple is used. If you standardize the technique, you can decrease the leakage rate. But the problem is how do you manage a leak. Because it seems such an easy operation, many surgeons start doing it. However, they do not have experience in bariatric surgery and they start doing sleeves because they think it is easier to perform than a bypass and that is the danger. That is why I think it is important to give this message. I think it is true that if a leak occurs, it is a catastrophe and it has to be managed properly. The centers that start doing this type of surgery must work together with experienced people. They can start, but then they must have a contact, so if they have a leak, they know how to manage it.

It is an issue, and I say that the sleeve is safer in terms of frequency of complications and that is how we powered the study also, as a secondary end point. But obviously, the leak, if it occurs, is much easier to treat in the bypass patients; that is true.