Long-term Results of Laparoscopic Sleeve Gastrectomy for Obesity

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Objective: To determine the mid- and long-term efficacy and possible side effects of laparoscopic sleeve gastrectomy as treatment for morbid obesity.

Summary Background Data: Laparoscopic sleeve gastrectomy is still controversial as single and final treatment for morbid obesity. Some favorable short-term results have been published, however long-term results are still lacking.

Methods: In the period between November 2001 and October 2002, 53 consecutive morbidly obese patients who, according to our personal algorithm, were qualified for restrictive surgery were selected for laparoscopic sleeve gastrectomy. Of the 53 patients, 11 received an additional malabsorptive procedure at a later stage because of weight regain. The percentage of excess weight loss (EWL) was assessed at 3 and 6 years postoperatively. A retrospective review of a prospectively collected database was performed for evaluation after 3 years. Recently, after the sixth postoperative year, patients were again contacted and invited to fill out a questionnaire.

Results: Full cooperation was obtained in 41 patients, a response rate of 78%. Although after 3 years a mean EWL of 72.8% was documented, after 6 years EWL had dropped to 57.3%, which according to the Reinhold criteria is still satisfactory. These results included 11 patients who had benefited from an additional malabsorptive procedure (duodenal switch) and 2 patients who underwent a "resleeve" between the third and sixth postoperative year. Analyzing the results of the subgroup of 30 patients receiving only sleeve gastrectomy, we found a 3-year %EWL of 77.5% and 6+ year %EWL of 53.3%. The differences between the third and sixth postoperative year were statistically significant in both groups. Concerning long-term quality of life patient acceptance stayed good after 6 + years despite the fact that late, new gastro-esophageal reflux complaints appeared in 21% of patients.

Conclusions: In this long-term report of laparoscopic sleeve gastrectomy, it appears that after 6+ years the mean excess weight loss exceeds 50%. However, weight regain and de novo gastroesophageal reflux symptoms appear between the third and the sixth postoperative year. This unfavorable evolution might have been prevented in some patients by continued follow-up office visits beyond the third year. Patient acceptance remains good after 6+ years.

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Surgical treatment for morbid obesity has witnessed a significant evolution since the advent of laparoscopy. Numerous operations with a plethora of variations are presently advocated as method of choice to treat morbid obesity.

Laparoscopic sleeve gastrectomy (LSG) was originally intended as bridging procedure for super obese patients awaiting definitive bariatric intervention. Recently, after early promising results, sleeve gastrectomy was proposed as potential single and final treatment for morbid obesity by several authors.[1–3]

To our knowledge, long-term efficacy of the LSG procedure as intended final treatment for morbid obesity has not yet been demonstrated.

We present the 6+ years results after LSG.

METHODS

Study Design and Patients

A total of 53 consecutive patients selected for restrictive surgery underwent LSG as treatment for morbid obesity in the period between November 2001 and October 2002. Inclusion criteria for bariatric surgery followed 1991 NIH guidelines; the choice of a restrictive procedure was based on our personal algorithm.[4,5] Some individuals in our series had dropped under the limit of 35 body mass index (BMI) at the time of surgery as a result of a strenuous fat-free and carbohydrate poor diet in view of the operation.[4] All patients had been evaluated by a multidisciplinary team. Sleeve gastrectomy had been chosen amid an array of laparoscopic weight loss operations offered at our department (LSG, adjustable band, Roux-en-Y gastric bypass, biliopancreatic derivation by duodenal switch (DS) or according to Scopinaro). Choice was based on our empirically established algorithm.[5] In brief, all patients who were thought to be volume eaters and who were not diabetic nor subject to significant gastroesophageal reflux disease (GERD), benefited from LSG intended as final treatment. (At the time adjustable band gastroplasty was still performed for the same indication, but only as part of a specific study, unrelated to the present one. Therefore, this study does represent consecutive patients with no other form of selection.)

Patients were followed up postoperatively in the office on a regular basis until 3 years after operation. The patients were again contacted by telephone after the sixth postoperative year and were invited to fill out a questionnaire.

Procedures and Measures

LSG was performed following the technique described earlier using systematically a 34 Fr bougie.[6] With this technique, the antrum was spared, starting the gastric resection about 6 cm proximal to the pylorus.

This study was carried out in an effort to evaluate quality of life (QOL) and possible side effects as well as efficacy for weight loss at least 6 years after LSG.

QOL was evaluated using the Bariatric Analysis and Reporting Outcome System (BAROS) score. The BAROS evaluates the results of obesity treatments by analyzing 3 psychomedical aspects: weight loss, changes in comorbidities, and QOL. Up to 3 points are allowed for each category, points are deducted for complications and reoperations.[7] The QOL evaluation included symptoms of GERD as well. GERD was considered significant when the patient mentioned regular use of prescription-proton pump inhibiting agents.

Weight assessment that had been recorded after 3 years was now re-evaluated after 6+ years. Weight loss was registered as change in BMI and % excess weight loss (EWL). Data were analyzed using MedCalc statistical software. Comparison of means from continuous variables was performed using paired 2-tailed Student *t* test. Results are represented as mean ± standard deviation (SD), ±95% confidence interval. Statistical significance was defined as $P < 0.05$.

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TABLE 1. Difference Between Mid- and Long-Term Effect of LSG on %EWL and BMI

	0 yr	3 yr	6 yr	P
Stand alone LSG (n = 30)				
Mean BMI (±SD)	39.9 (±5.9)	26.6 (±4.3)	31.1 (±6.2)	0.0001*
95% CI	37.7–42.1	25.0–28.2	28.8–33.4	
Mean % EWL (±SD)		77.5% (±19.8)	53.3% (±28.3)	<0.0001*
95% CI		70.1–84.9	42.7–63.9	
LSG + duodenal switch (n = 11)				
Mean BMI (±SD)	38.4 (±4.0)	29.3 (±6.4)	26.7 (±6.2)	0.3490*
95% CI	35.7–41.1	24.9–33.6	21.9–31.5	
Mean % EWL (±SD)		59.9% (±34.9)	70.8% (±29.5)	0.5680*
95% CI		63.4–83.4	48.1–93.4	
Stand alone LSG and LSG + duodenal switch (n = 41)				
Mean BMI (±SD)	39.5 (±5.5)	27.3 (±5.0)	30.1 (±6.5)	0.0050*
95% CI	37.7–41.2	25.7–28.9	27.9–32.2	
Mean % EWL (±SD)		72.8% (±25.6)	57.3% (±29.1)	0.0017*
95% CI		64.7–80.9	47.9–66.8	

*Comparison of means using paired 2-tailed student t test.
LSG indicates laparoscopic sleeve gastrectomy; EWL, excessive weight loss; BMI, body mass index; SD standard deviation; CI, confidence interval.

RESULTS

Patient Characteristics

A total of 53 consecutive patients who were qualified for restrictive surgery, according to our personal algorithm we used at that time, underwent LSG for weight reduction in the period between November 2001 and October 2002.[5] All relevant data, gathered from the responses to the questionnaire, were collected by one of the authors (J.D.) between December 2008 and January 2009. Full evaluation was possible in 41 patients (30 women and 11 men, 3/1 ratio), meaning a follow-up at 6+ years in 78% of the patients. Four patients (3 women and 1 man) refused to cooperate, 8 patients could not be traced. All 12 patients who could not be evaluated were included in the data in an effort to provide intention-to-treat results.

Median age at surgery was 44 years (range, 28–71; SD, 11.0). Median preoperative BMI was 39.0 kg/m^2 (range, 31–57; SD, 5.4). Five patients suffered from arterial hypertension, 1 patient was diabetic type II. One patient had mentioned preoperative GERD symptoms.

Of the 41 patients, 11 underwent completion of a DS procedure because of weight regain some time between the third and sixth postoperative year. These latter patients were included in the study according to the intention-to-treat regimen.

Two other patients needed a resleeve operation because of weight regain combined with pouch dilatation as demonstrated on upper gastrointestinal (GI) series, and were included as well (intention-to-treat).

Data were analyzed in the over all patient groups, thus including patients with completion of DS, as well as in the subgroup of patients who were treated by LSG alone.

Efficacy

At 3 years postoperatively, an over all mean EWL of 72.8% had been recorded in our series (Table 1, Fig. 3). After the sixth postoperative year weight regain was observed in 31 cases (75.6%), resulting in a residual over all mean EWL of 57.3% (Table 1, Figs. 1–4). The difference in weight loss, expressed as EWL, between the third and sixth postoperative year was statistically significant for the entire group as well as for the subgroup of patients where LSG was the sole procedure (Table 1).

Median BAROS quality of life score after 6+ years was 5 (range, −2–9; SD, 2.7; 95% confidence interval, 4–6).

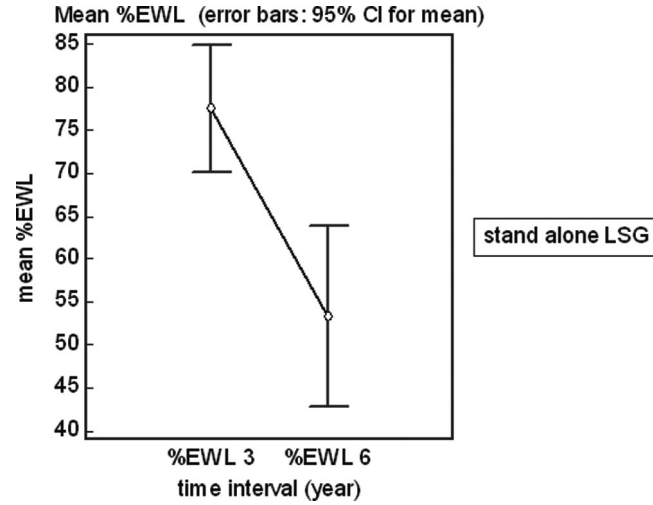

FIGURE 1. Difference in mean %EWL between 3 and 6 years postoperatively for stand-alone sleeve gastrectomy.

One patient suffering from diabetes type II had resolution of the disease. Of 5 patients, 2 with arterial hypertension became and stayed normotensive.

Of 53 patients, 23 (43.4%) either were lost for follow-up or refused to respond to our questionnaire (n = 12) or needed another procedure, and should be considered dissatisfied with the sleeve gastrectomy procedure. These 23 patients combined with those who did not reach 50% excess weight loss, according to Reinhold criteria, were considered objective failures.[8] At 3 years, an objective failure rate of 47% was noted, which reached up to 64% after the sixth postoperative year (Tables 2, 3).

Postoperative Morbidity

Major morbidity, meaning leakage, stenosis, bleeding, or incisional hernia occurred in 12.2% of all patients (Table 4). There were no surgery-related deaths. One patient died of colon cancer 4 years after LSG. Gastroesophageal complaints were reported after

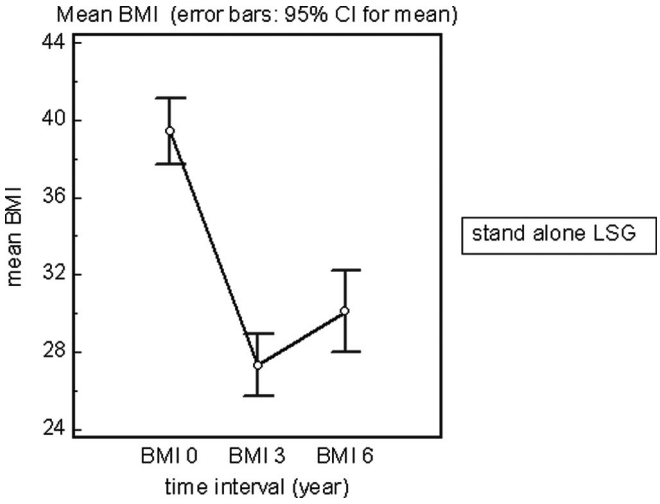

FIGURE 2. Difference in mean BMI between 3 and 6 years postoperatively for stand-alone sleeve gastrectomy.

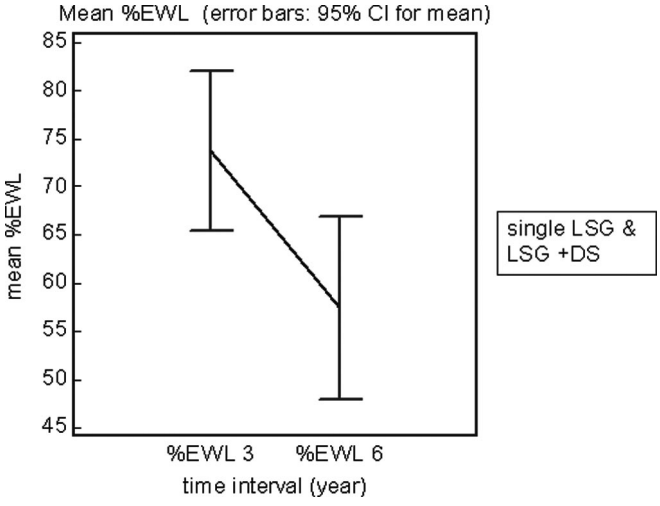

FIGURE 3. Difference in mean %EWL between 3 and 6 years postoperatively for over all population (stand-alone LSG and LSG + DS).

6+ years (Table 5). About 18% of patients in the stand-alone LSG group and 21% of patients in the over-all group mentioned occasional vomiting, and respectively 23% to 26% of patients reported frequent episodes of GERD.

DISCUSSION

Our patient group is representative for the average bariatric population in Belgium in 2001 to 2002.[9] Patients were selected according to the 1991 NIH guidelines.

Weight assessment was made after 3 and 6 years after sleeve gastrectomy. Data after the sixth postoperative year were derived from a telephone questionnaire. Telephone surveys are generally considered biased in the sense that patients tend to underestimate their weight. One should therefore be aware that the actual final BMI could be even higher than the ones we worked with in our database, meaning that true weight regain could be even more pronounced.

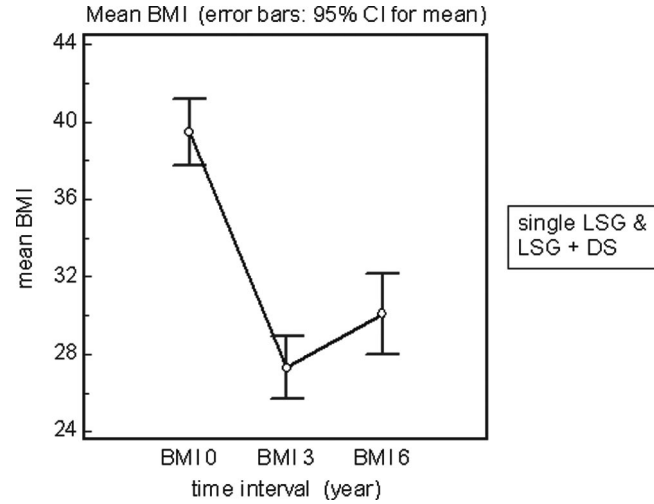

FIGURE 4. Difference in mean BMI between 3 and 6 years postoperatively for over all population (stand-alone LSG and LSG + DS).

TABLE 2. Objective Success After 3 yr, Intention-to-Treat After Stand-Alone Sleeve Gastrectomy

	Success	Failure
Evaluated patients; n = 41	n = 28; LSG: >50% EWL	n = 13; *LSG: <50% EWL: n = 2; *LSG + DS: n = 11
No evaluation possible; n = 12		n = 12; *Lost for follow-up: n = 4; *Refused cooperation: n = 8
Total: 53	28/53: 53%	25/53: 47%

LSG indicates laparoscopic sleeve gastrectomy; EWL, excessive weight loss; DS, duodenal switch.

TABLE 3. Objective Success After 6 yr, Intention-to-Treat After Stand-Alone Sleeve Gastrectomy

	Success	Failure
Evaluated Patients; n = 41	n = 19; LSG: >50% EWL	n = 22; *LSG: <50% EWL: n = 11; *LSG + DS: n = 11
No evaluation possible; n = 12		n = 12; *Lost for follow-up: n = 4; *Refused cooperation: n = 8
Total: 53	19/53: 36%	32/53: 64%

LSG indicates laparoscopic sleeve gastrectomy; EWL, excessive weight loss; DS, duodenal switch.

TABLE 4. Major Complications Related to Sleeve Gastrectomy

Complication	Patients (%)
Leak	2/41 (4.9%)
Stenosis	1/41 (2.4%)
Bleeding	1/41 (2.4%)
Incisional hernia	1/41 (2.4%)

TABLE 5. Gastro-esophageal Complaints at 6 yr Postoperatively

	Preoperative	Postoperative
Stand alone sleeve gastrectomy		
Gastroesophageal reflux	3.3%	23%
Vomiting	0%	18%
Stand alone sleeve gastrectomy and sleeve gastrectomy + duodenal switch		
Gastroesophageal reflux	0%	26%
Vomiting	0%	21%

Between 2001 and 2002, the only available long-term data about this type of restrictive procedure came from Johnston et al and concerned the Magenstrasse and Mill, an open "sleeve-like" procedure.[10] Since then, as far as we know, no long-term results of the currently performed LSG operation have yet been reported. Some reports with medium-term follow-up, including ours, showed a promising %EWL after 1 and 2 years. Ranges of respectively ±62% and ±72% have been reported.[1–3,6]

According to the present study, the mean long-term EWL at 6+ years after LSG remains above 50% both in the pure LSG as the LSG + DS group. Considering the Reinhold criteria, these results are considered satisfactory.[8] However, despite this acceptable final result, our series did show significant weight regain between the third and the sixth postoperative year.

In fact, although the number of our patient cohort is rather small, difference in % EWL after 3 and 6 years appears to be statistically highly significant. Moreover, weight regain is probably even higher than our results indicate. Indeed, 11 of our patients (26%) did benefit from a complementary DS procedure between the fourth and sixth postoperative year, and hence no longer presented LSG as stand-alone procedure. In accordance with the intention to treat principle, these patients were included in the 6+ year results, which avoided selecting out the patients with favorable results (the ones who did not need an additional weight loss procedure). However, even in the latter subgroup with favorable results, the difference in EWL at 3 and 6+ years still reached statistical significance. Of 53 patients, 23 either were lost for follow-up or refused to respond to our questionnaire (n = 12) or needed another procedure (n = 11). This means that 43.4% of our patients were not satisfied with the procedure of simple sleeve gastrectomy. Objective failure rates at 3 and 6+ years were 47% and 64%, respectively (Tables 2, 3). These results should be compared with the numbers after other bariatric procedures as gastric bypass, vertical banded gastroplasty, or gastric banding.

Thus, LSG appears to be subjected to weight regain after more than 3 years. This is similar to what has been reported earlier in other purely restrictive bariatric surgical procedures.[11–15] Recently, Scozzari et al reported excess weight loss after adjustable gastric banding of 42% at 3 years, 33% at 5 years, and 30% at 7 years. The same study reported an EWL after vertical banded gastroplasty (VBG) of 61%, 57%, and 53%, respectively.[11] Thus, long-term results of VBG are quite similar to our long-term findings after LSG. This is interesting because short-term results seem to be better after LSG than after VBG. This difference may partly be explained by suppression of ghrelin obtained by the resection of the gastric fundus in LSG but not in VBG.[16–19] However, the hope that removal of the ghrelin-producing fundus could guarantee long-lasting weight loss, appears to be vain. Most likely, hyperactivity of previously silent ghrelin-producing cells, scattered over the gastrointestinal tract, annihilates the early effect of fundic resection which at least partly could explain weight regain after LSG.[16] This loss of "appetite suppression effect" of LSG in long-term follow-up had been predicted before.[17]

Another issue intervening in early weight loss after LSG is increased gastric emptying which, combined with decreased gastric acid secretion, causes incomplete digestion after LSG.[17,20,21] Increased gastric emptying is associated with higher levels of glucagon-like-peptide-1, a glucose-regulating insulin-enhancing agent, which has been linked to weight loss and resolution of type II diabetes mellitus.[22–26] This salutary effect on gastric emptying is however likely to diminish after time, once the sleeved stomach regains compliance which will permit the patient to ingest larger volumes more frequently.[17]

Late weight regain can be induced by purely dietary factors as well, like changes in eating behavior by shifting toward "easy" highly caloric food stuffs. Purely dietary flaws can probably be detected and possibly could have been treated by frequent follow-up visits aiming at repeated patient education and motivation. This issue has been demonstrated before in other restrictive procedures, especially adjustable gastric banding.[27–29] It is noteworthy that in our series weight regain coincided with the interruption of the office visits after 3 years.

This confirms that loss of continuous support and control is likely to play an important role in weight regain. Consequently, continued office visits should be strongly encouraged.

There is general apprehension that, rather than regaining normal compliance, the sleeved stomach might dilate over time. Dilatation of the stomach allows the patient to consume larger volumes of food, hence induces weight regain. On late postoperative barium upper GI series, performed because of weight regain, some patients presented "neo-fundus" formation (Fig. 5). Actually, 2 patients in our series successfully benefited from a resleeve procedure for "fundus regeneration" as proposed by Baltasar et al (Fig. 5).[30]

In our opinion, neofundus formation can be caused by leaving too much fundus at the time of operation in an effort to avoid fistulas. During sleeve gastrectomy, the critical point is at the angle of His. When at this point the surgeon for safety reasons decides to staple away from the left crus this might result in a sleeve-tube with a conical rather than a cylindrical shape. Following Laplace′s law (combined with a relative distal downstream stenosis), this might result in proximal dilatation and "neofundus" formation. This neofundus issue could be important as it causes both weight regain and GERD. Further investigation is warranted for this specific issue.

Besides weight regain, patients with neofundus can experience the effects of relative midstomach stenosis. This stenosis causes stasis of food whereas the growing surface of acid producing mucosa increases acid production. Both conditions are known to cause GERD. Actually, we did observe increased GERD complaints after 6 + years as compared with the 3 years results we reported earlier. GERD diagnosis was made based on the regular use of proton pump inhibiting agents. In general clinical practice, GERD is mostly diagnosed by GERD-bases complaints.[31] Ambulatory pH measurement obviously would have been preferable for evaluating GERD, however this was difficult to arrange in our study because of local reimbursement issues. We demonstrated earlier a 22% incidence of post-LSG GERD after 1 year which came down to 3% after 3 years.[6] From the present study, it appears that GERD presents a biphasic pattern after LSG. The first peak develops during the first postoperative year and disappears before the third postoperative year, most likely thanks to increased gastric compliance and improved gastric emptying.[17,20,21,32] A second peak of GERD shows up

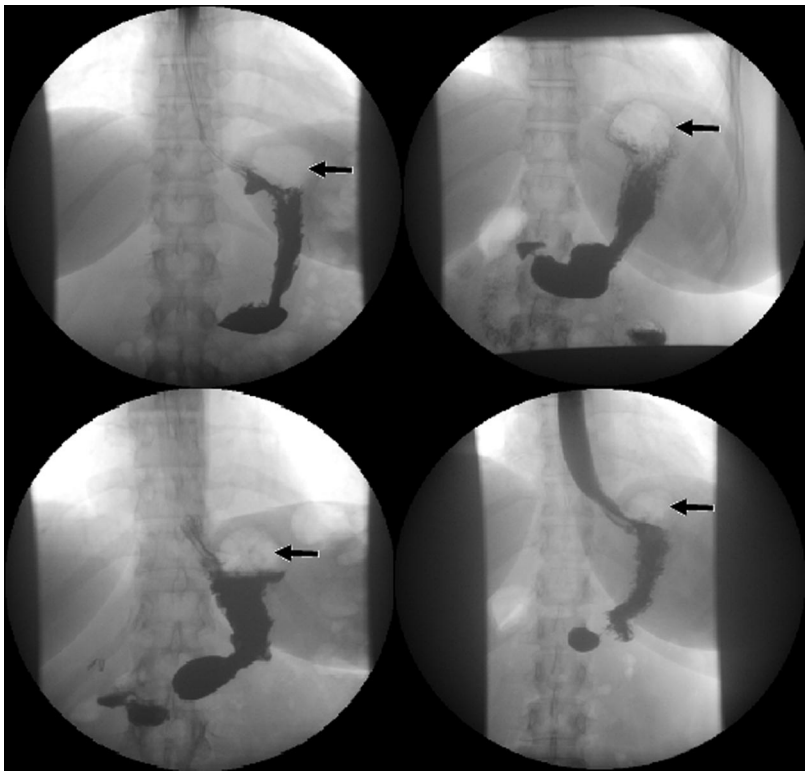

FIGURE 5. Upper GI series showing "neo-fundus" formation. Four different cases of neo-fundus formation (black arrow) illustrated on upper GI series. The 2 cases above presented neo-fundus during the study and underwent a resleeve procedure. The other 2 cases (beneath) were diagnosed with neo-fundus in later follow-up, respectively 7 and 8 year after LSG.

later on and might be linked with the appearance of a neofundus. As far as treatment options is concerned, DS is not very helpful because in our series GERD occurred after full DS as well.

Despite the relatively high incidence of postoperative persistent GERD and vomiting, patient acceptance of LSG is still quite good as indicated by a mean BAROS of 5, which testifies a good QOL even more than 6 years postoperatively.

To conclude, LSG is a safe, effective, and by the patients well accepted bariatric procedure, but it appears to be associated with weight regain and quite often with reflux symptoms in long-term follow-up. Weight regain could probably be at least partly avoided by tighter follow-up. Weight regain, but not GERD after LSG can be managed successfully by completion of a DS procedure at a later stage.

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