Fifteen Years after Sleeve Gastrectomy: Gastroscopies, Manometries, and 24-h pH-Metries in a Long-Term Follow-Up: A Multicenter Study

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Keywords
Sleeve gastrectomy · Gastroesophageal reflux disease · Esophagitis · Barrett’s esophagus · Gastroscopy · Manometry · 24-h pH-metry

Abstract

Introduction: Sleeve gastrectomy (SG) is the most common bariatric operation with over 340,000 procedures per year. There are only few studies presenting follow-up results >10 years in the literature today. The aim of this study was the objective evaluation of long-term outcomes of at least 15 years after SG in non-converted patients. Methods: This study (multicenter cross-sectional; university-hospital based) includes all non-converted patients with primary SG before December 2005 at participating bariatric centers. The following methods were used: gastroscopy, esophageal manometry, 24-h pH-metry, and Gastrointestinal Quality of Life Index (GIQLI). Results: After removing converted patients, patients with bariatric procedures before SG, and deceased patients from the cohort, 20 of 53 participants have met the inclusion criteria. Of this group, 55% are suffering from symptomatic gastroesophageal reflux disease (GERD); 45% are without GERD. Esophagitis, hiatal hernias, Barrett’s esophagus, and enlarged sleeves were found in 44%, 50%, 13%, and 69% of patients during gastroscopy. Mean lower esophageal sphincter pressure was normal at 20.2 ± 14.1 mm Hg during manometry. Reflux activity in 24 h, number of refluxes, and DeMeester score were increased at 12.9 ± 9.7%, 98.0 ± 80.8, and 55.3 ± 36.3 during 24-h pH-metry. Patients with GERD scored significantly lower in the GIQLI than patients without GERD: 107.6 ± 18.4 versus 127.6 ± 14.4 (p = 0.04). Discussion/Conclusion: Fifteen years after primary SG, objective testing has shown that GERD, esophagitis, and Barrett’s esophagus are major issues for these patients. Surveillance endoscopies at 5-year intervals in all SG patients and 3-year intervals in patients with Barrett’s esophagus are recommended.

Introduction

Obesity is a disease that continually increases in numbers worldwide. It is strongly associated with numerous comorbidities of the metabolic syndrome [1]. Today, several bariatric/metabolic operations are available, and the global number of performed procedures increases each...
year [2]. Since 2014, sleeve gastrectomy (SG) has been the most frequently executed operation for obese patients worldwide. In 2018, 386,096 patients had an SG, which is 55.4% of all bariatric procedures [3].

SG is a procedure which involves the resection of a major part of the stomach, leaving only a narrow gastric sleeve [4]. Patients with a SG experience an early feeling of satiety after food intake. Additionally, altered levels of gut hormones such as ghrelin and glucagon-like-peptide 1 play an important role for achieved weight loss [5].

Physically, the gastric sleeve with the pylorus muscle as a physiological stenosis at the sleeve’s exit renders the sleeve a high-pressure system. Often the acid fluid emerging in the sleeve can only elude up to the esophagus leading to symptoms of gastroesophageal reflux disease (GERD) [6]. In the first years after the SG, a decreasing intra-abdominal pressure caused by weight loss can compensate this effect [7], but a few studies have exposed that GERD becomes a major side effect of SG in the long-term follow-up [7–9].

The aim of the current study, which in fact provides the longest follow-up (>15 years) after SG published so far, was to perform objective testing using gastroscopy, manometry, 24-h pH-metry, and a questionnaire for gastrointestinal quality of life in a multicenter setting. As the same collective of patients were assessed after a follow-up of 10 years, this study also qualifies to demonstrate a trend in the long-term follow-up.

### Patients and Methods

All patients that underwent SG for obesity before December 31, 2005, in one of the three participating Austrian bariatric centers were initially included in this multicenter study. The participating centers were the Medical University of Vienna, Klinik Landstraße, and Landesklinikum Hollabrunn.

#### Patient Cohort

A total of 53 patients met the inclusion criteria of 15 years follow-up after SG. Outcome of weight loss, conversion to Roux-en-Y gastric bypass, remission of comorbidities, and general quality of life in these 53 patients have recently been reported in a previous study [10]. The current study focuses only on patients that were not converted within the 15 years’ follow-up period, ergo patients still living with their SG today. Twenty-six of the original 53 patients (49.1%) were converted within the 15-year follow-up period. Three of the remaining 27 patients died within the follow-up period and were therefore not included in the following analysis. Their deaths were not related to the bariatric procedure. Additionally, patients with previous bariatric operations (gastric banding, gastric stimulation) before the SG were excluded as these operations may influence the outcomes in terms of GERD and esophageal functional testing (Table 1).

The remaining 20 patients were specifically invited to the Medical University of Vienna for this study to undergo the following examinations: gastroscopy, 24-h pH-metry, manometry, and the Gastrointestinal Quality of Life Index (GIQLI) questionnaire [11]. Follow-up was as follows: 16/20 patients agreed to have gastroscopy (80%), 11/20 had 24-h pH-metry and manometry (55%), and 17/20 completed the GIQLI questionnaire (85%). Additionally, all patients were assessed for GERD-related symptoms. Due to the fact that the same collective of patients was evaluated in a previous study [12], the 15-year outcome of this study can be compared to the 10-year outcome.

#### Surgical Technique

The surgical technique of SG was similar in the three participating bariatric centers: after creating a cephnopertitoneum with 15 mm Hg, the lesser sac is entered and opened from the pylorus to the angle of His at the greater curvature of the stomach, preserving the gastro-epiploic arcade. The left crus of the hiatus is visualized to detect any undiagnosed hiatal hernias. A 14–16-mm (42–48 French) Bougie is used to resect a major part of the stomach using five to seven cartridges. The starting point is at about 6 cm distance proximal from the pylorus, and stapling ends at the angle of His. Belsey’s fat pad is removed to increase vision of the angle of His. The gastrocolic ligament is then reattached to the staple line with single-knot sutures.

The technique described above was common at the time (early 2000s) and has, in fact, only slightly changed until now. Currently, we use a slightly smaller Bougie size of 12 mm (36 French) and start the resection slightly closer to the antrum (2–3 cm from the pylorus). The entire fundus has always been resected completely [4].

#### Weight Loss, Remission of Comorbidities, Conversions

History of weight and BMI as well as the remission of comorbidities and conversion rates to other bariatric procedures of this patient cohort have been reported recently [10].

### Table 1. Patients’ characteristics

|                                  | All patients (SG) (n = 53) |
|----------------------------------|-----------------------------|
| Sex (female) (n = 42)            | 79%                         |
| Bariatric procedures before SG (n = 12) | 22.6%                      |
| Gastric banding (n = 10)         | 18.8%                       |
| Gastric stimulation (n = 1)      | 1.9%                        |
| Gastric balloon (n = 1)          | 1.9%                        |
| Converted patients (n = 26)      | 49.1%                       |
| RYGB (n = 25)                    | 47.2%                       |
| Duodenal switch (n = 1)          | 1.9%                        |
| Dead patients (n = 4)*           | 7.5%                        |
| Non-converted (n = 3)            | 5.6%                        |
| Converted (n = 1)                | 1.9%                        |

SG, sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass. * Dead patients within the 15-year follow-up period. Their deaths were not associated with a bariatric surgical procedure.
Gastrointestinal Quality of Life

Results of the GIQLI, which was developed by Eypasch et al. [11] as an interesting quality of life score for patients with GERD, are reported in the results section of this paper. The questionnaire contains 36 questions about gastrointestinal symptoms with five response categories and therefore a maximum score of 180 points [11].

Gastroscopy

Gastroscopy was performed to look for gastritis and ulcers in the sleeve, columnar lined esophagus at the gastroesophageal junction, and esophagitis at the distal esophagus. Biopsies were taken from the antrum and corpus of the sleeve as well as from the gastroesophageal junction for the diagnosis of Barrett’s esophagus (BE). In accordance with the Seattle protocol, a minimum of four quadrant biopsies at every centimeter with additional biopsies from areas of mucosal abnormalities were taken [13]. Additionally, the size of the sleeve (inversion possible with a gastroscope equaling a 40 mm diameter) was evaluated and checked for hiatal hernias and remnant fundus.

24-h pH-Metry and Manometry

The lower esophageal sphincter pressure (LESP) was evaluated during manometry. The total number of refluxes and acid exposure time of the distal esophagus within 24 h were measured during 24-h pH-metry. Data gained from this examination were also used to calculate the DeMeester score for each patient [14].

Statistical Analysis

The number of patients in this retrospective study with prospective examinations is limited by the sum of patients having had SG before 2005 in the 3 participating centers. In this study, descriptive statistics was used as it is based on quite a small patient collective. Data are presented within the mean and standard deviation or median and range or as percentages (where appropriate). Comparison of groups of data were performed by χ² tests or Mann-Whitney U tests (nonparametric). Statistical calculations were performed using SPSS® v24 for Windows® (IBM Corporation, Armonk, NY, USA).

Results

Fifty-three patients received SG as a bariatric procedure before December 2005 in one of the three participating centers and therefore have a follow-up of at least 15 years. After removing patients converted to other bariatric procedures, patients with bariatric procedures before the SG, and deceased patients, 20 individuals were eligible to participate in the examinations performed for this study. The results of all examinations were divided into two groups: patients suffering from symptomatic GERD and patients without GERD.

GERD and the GIQLI Questionnaire

Eleven (55%) of this study’s 20 participants are suffering from symptomatic GERD with a daily need of symptomatic therapy (proton pump inhibitors), and nine (45%) are without GERD symptoms today. A total of 17 patients completed the GIQLI questionnaire. Nine patients with symptomatic GERD scored significantly lower at 107.6 ± 18.4 than 8 patients without GERD; 127.6 ± 14.4 (p = 0.04).

Gastroscopy

Gastroscopy results are highlighted in Table 2. Nine patients with GERD symptoms and seven without GERD were evaluated 15 years after SG. Remnant fundus was only found in 19% (n = 3/16) of the patients. Hiatal hernias were found in 67% (n = 6/9) of the symptomatic patients and 29% (n = 2/7) of the asymptomatic patients (p = 0.08). Bile in the sleeve was only found in 43% (n = 3/7) of the patients without GERD. The sleeve was enlarged in 69% (n = 11/16) of the patients (89% (n = 8/9) GERD

| Table 2. Endoscopic and histologic results of gastroscopy at 15 years after SG |
|---------------------------------|---------------------------------|---------------------------------|-------------------------------|
| All non-converted patients (n = 16) | Non-converted patients with symptomatic GERD (n = 9, 57%) | Non-converted patients without GERD (n = 7, 43%) | p value |
| Fundus residual, % | 19 | 11 | 29 | 0.39 |
| Hiatal hernia, % | 50 | 67 | 29 | 0.08 |
| Bile in the sleeve, % | 19 | 0 | 43 | 0.05 |
| Enlarged sleeve, %* | 69 | 89 | 43 | 0.15 |
| CLE (GE junction), % | 44 | 44 | 43 | 0.77 |
| Active gastritis, % | 75 | 78 | 71 | 0.89 |
| Esophagitis, % | 44 | 56 | 29 | 0.14 |
| BE, % | 13 | 11 | 14 | 0.84 |
| HP, % | 0 | 0 | 0 | N/A |

CLE, columnar lined esophagus; GE, gastroesophageal; GERD, gastroesophageal reflux disease. * Enlarged sleeve was defined as inversion possible with a gastroscope equaling a 40 mm diameter.
group; 43% (n = 3/7) no-GERD group; p = 0.15). An inversion with the endoscope was easily possible in these patients, which is equal to a diameter of at least 40 mm. Columnar lined esophagus was found in 44% (n = 7/16) of the patients; no difference was found between patients with or without GERD.

The biopsies revealed active gastritis in 78% (n = 7/9) of the patients in the GERD group and in 71% (n = 5/7) of the group without GERD. Esophagitis was found in 56% (n = 5/9) and 29% (n = 2/7) (p = 0.14), respectively, in the GERD and no-GERD group. Two of 16 patients (13%) were suffering from BE, one in each group (GERD and no GERD). *Helicobacter pylori* (HP) was not detected in any of the patients.

**Table 3. 24-h pH-metry and manometry results 15 years after SG**

|                      | All non-converted patients | Non-converted patients with symptomatic GERD | Non-converted patients without GERD | p value |
|----------------------|-----------------------------|---------------------------------------------|------------------------------------|---------|
| **Manometry**        |                             |                                             |                                    |         |
| LESP, mm Hg (normal 10–35 mm Hg) |                      |                                             |                                    |         |
| Patients increased, % | 20.2±14.1 (n = 11)          | 22.1±18.6 (n = 6, 55%)                      | 19.1±9.1 (n = 5, 45%)             | 0.71    |
| Patients decreased, % | 9                           | 17                                          | 0                                  |         |
| **24-h pH-metry**    |                             |                                             |                                    |         |
| Acid exposure, % (normal <4.2%) |                      |                                             |                                    |         |
| Patients increased, % | 12.9±9.7 (n = 11)           | 14.7±10.2 (n = 6, 55%)                      | 10.3±9.1 (n = 5, 45%)             | 0.22    |
| Reflux activity, n (normal <73) |                      |                                             |                                    | 0.18    |
| Patients increased, % | 98.0±80.8 (n = 11)          | 112.0±81.3 (n = 6, 55%)                     | 87.0±0.79.7 (n = 5, 45%)          |         |
| DeMeester score (normal <14.72) |                      |                                             |                                    |         |
| Patients increased, % | 55.3±36.3 (n = 11)          | 65.3±42.4 (n = 6, 55%)                      | 42.3±33.1 (n = 5, 45%)            | 0.15    |

LESP, lower esophageal sphincter pressure; GERD, gastroesophageal reflux disease; SG, sleeve gastrectomy.

**Fig. 1. 24-h pH-metry after 10 and 15 years in patients with and without GERD.**

**Manometry and 24-h pH-Metry**

The results of functional esophageal testing (manometry and 24-h pH-metry) are presented in Table 3. The LESP measured during manometry was not significantly different between patients with symptomatic GERD and without symptomatic GERD (22.1 ± 18.6 and 19.1 ± 9.1; p = 0.71). Only 2 patients were outside the normal range.

The results of the 24-h pH-metry have shown pathological values in both groups but patients without GERD showed slightly better (not significantly different) results. The acid exposure time in the distal esophagus, which should remain below 4.2% of 24 h, was 14.7% ± 10.2 in GERD and 10.3% ± 9.1 in no-GERD patients. Also, the total number of refluxes, which should be below 73 with-
in 24 h, was increased in both groups with 112 ± 81.3 (symptomatic GERD) and 87.0 ± 79.7 (no GERD). The calculated DeMeester score was increased in 82% of all patients (GERD group: 65.3 ± 42.4; no-GERD group: 42.3 ± 33.1; p = 0.15). Figure 1 highlights the development of the 24-h pH-metry results after 10 and 15 years in patients with and without GERD.

Discussion

This multicenter study presents results of gastroscopy, esophageal functional testing, and GIQLI in primary non-converted SG patients with a follow-up of least 15 years. Thus, it also presents the longest follow-up in objective testing after SG. Further, it is an update of exactly the same patient population described in a publication 5 years ago, reporting the results of gastroscopy, manometry, and 24-h pH-metry 10 years after SG [12]. Therefore, both timepoints can be compared to track a trend in objective findings in the long-term follow-up after SG.

GERD and GIQLI 15 Years after SG

Short-term studies, especially in the early years, claimed SG to be an anti-reflux procedure [15, 16]. This effect was justified by a decrease of the intra-abdominal pressure due to weight loss and a large distance between the first stapler and the pylorus. Nevertheless, mid- and long-term studies report a relatively high number of new onset and worsening of GERD, especially if weight regain occurs as well [8, 17]. In studies with a follow-up of more than 10 years, GERD rates between 21.4% and 58.5% have been reported [9, 18–21].

Comparing the 15-year results of the present study with the 10-year results of the same collective, the numbers would suggest a slightly increasing GERD rate: 55% at 15 years versus 50% GERD rate at 10 years, especially when considering that the conversion rate increases as well [10, 12]. However, a third of the converted patients of this collective had conversion due to severe GERD symptoms [10]. Thus, these patients should be born in mind when considering the GERD rate of the present study.

The results of the GIQLI in this study collective clearly show that GERD has a major impact on the quality of life as the score of patients with GERD was 20 points below that of patients with no GERD symptoms. Comparing these results to those of the previous study, both (GERD and no-GERD patients) scored slightly higher than they did 5 years ago. This must be attributed to the increased conversion rate to RYGB over the last 5 years [10].

Gastroscopy 15 Years after SG

The findings of this study showed that hiatal hernias, esophagitis, and an enlarged sleeve were found more often in the group of patients suffering from GERD. The difference was not significant; however, this may be due to the small patient collective of this study. Interestingly, bile in the sleeve was only found in the group without reflux, which indicates that GERD symptoms are not based on biliary fluid.

Another interesting fact is that BE was equally found in both the group of patients with and without symptomatic reflux. These results correspond with a study of endoscopic findings after SG by Genco et al. [22] who also failed to find significant correlations between GERD symptoms and gastroscopic results. Interestingly, Genco et al. [22] found biliary-like reflux in the endoscopy after SG in up to 76.5%, unrelated to the presence of GERD symptoms. Therefore, the authors recommended routine postoperative endoscopic surveillance, regardless of the presence or absence of GERD [22]. Also, Borbely et al. [23] in a study comparing endoscopic findings before and after SG reported that 17% of the patients had silent reflux without any GERD symptoms. The 13% BE rate of the present study is in line with other recent studies after SG; however, the total number of patients with BE in the current study was quite small [22, 24, 25]. To monitor the development of BE, the guidelines of the American Association of Gastroenterology recommend surveillance endoscopies every 3 years in patients without dysplasia [26].

Current studies have stated that the presence of BE is inversely associated with HP infection; in other words, an HP infection might have a protective effect countering the genesis of BE and esophageal cancer [27]. This finding may explain the high BE incidence in the present study as HP eradication was performed preoperatively in all infected patients. While some studies claim that preoperative eradication of HP is not necessary before SG any more [28], other studies emphasize the important effects of HP eradication in all bariatric patients before the procedure [29]. Hence, this issue will have to be assessed in future studies.

The comparison of endoscopic findings of this study to the results of the 10-year data reveals no significant differences, which means that no exacerbation of the esophageal findings was found after another 5 years [12]. Ergo,
some SG patients still have normal endoscopic results more than 15 years after SG.

**Esophageal Functional Testing 15 Years after SG**

The results of patients undergoing manometry 15 years after primary SG interestingly show a normal LESP. One might have expected the LESP to decrease after such a long follow-up as the sleeve represents a high-pressure system which could weaken the LESP and thus cause GERD symptoms. However, this theory cannot be sustained based on the results of this examination. De novo hiatal hernias may instead lead to acid backflow to the esophagus. There is no consensus to be found in the literature in this regard. While some studies report a decreased LESP after SG [30], other studies found it to have increased after SG [31]. It should also be mentioned that only manometry results of short-term studies are available at this point.

This study’s 24-h pH-metry results are increased in all categories (reflux exposure time of the distal esophagus, total number of refluxes in 24 h, and DeMeester score) 15 years after primary SG. Interestingly, values indicating acid reflux in the present study are increased in asymptomatic patients without GERD symptoms as well. This finding suggests that not only symptomatic GERD patients should have surveillance follow-up endoscopies but also asymptomatic patients after SG.

Compared to the results of the same collective 5 years ago, these values have slightly increased, especially in patients with symptomatic GERD [12]. Only a few other studies provide results of 24-h pH-metry in patients with a follow-up longer than 5 years. Dimbezel et al. [32] found a DeMeester score of 47 in ten symptomatic GERD patients 5 years after SG, which is in line with our results. Other studies reporting 24-h pH-metry only 6 months after SG (+/- hiatalplasty) have found normal DeMeester scores [33, 34]. This comparison shows that GERD may occur over time and is not present immediately after the SG.

**Limitations of the Study**

This study presents a rather small collective from the early days of SG. The operation technique has slightly changed over the follow-up period of this study. Plus, a commonly used worldwide standard does not exist, either. Especially the resection of the antrum, which is commonly done nowadays, could have a positive effect on GERD. So as not to affect the outcome, patients with previous operations were excluded from this study. Other bariatric centers with the same surgical technique before 2005 were included to increase the number of patients; however, this means various surgeons having performed the procedures.

In terms of functional esophageal testing and GIQLI, preoperative results are not available; nevertheless, a trend can be observed comparing the data of this study to our previous study presenting a 10-year follow-up of the same collective. Additionally, functional esophageal testing is very uncomfortable for the patients; therefore, only 55% were willing to participate in this examination, which may have affected the outcome as well.

**Conclusion**

Fifteen years after primary SG, objective testing has shown that GERD, esophagitis, and Barrett’s esophagus are major issues these patients have to deal with. Especially GERD has a negative impact on patients’ quality of life. Additionally, de novo hiatal hernias and enlarged sleeves were found in a majority of these patients. Thus, surveillance endoscopies every 5 years in all SG patients and every 3 years in patients with Barrett’s esophagus are recommended.

**Statement of Ethics**

Study approval statement: This study protocol was reviewed and approved by the research committee of the Medical University of Vienna, Austria; approval number: 2169/2019. Consent to participate statement: Written informed consent was obtained from participants to participate in the study. This study complies with the guidelines for human studies and is ethically in accordance with the World Medical Association Declaration of Helsinki.

**Conflict of Interest Statement**

The authors declare that they have no conflict of interest.

**Funding Sources**

No funding was required for this study.

**Author Contributions**

Daniel Moritz Felsenreich: study design and manuscript writing. Evi Artemiou: organizing examinations and manuscript writing. Lukas Wintersteller: organizing examinations and proofread-
ing. Julia Jedamzik, Jakob Eichelter, Lisa Gensthaler, and Christoph Bichler: examinations and proofreading. Christoph Speker and Philipp Beckerhinn: patients management and proofreading. Ivan Kristo: 24-h pH-metry evaluation and proofreading. Felix Benedikt Langer and Gerhard Prager: study design and proofreading.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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