



# Are There Risk Factors That Increase the Rate of Staple Line Leakage in Patients Undergoing Primary Sleeve Gastrectomy for Morbid Obesity?

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## Abstract

**Background** Laparoscopic sleeve gastrectomy (LSG) is currently being performed with increasing frequency worldwide. It offers an excellent weight loss and resolution of comorbidities in the short term with a very low incidence of complications. However, the ever present risk of a staple line leak is still a major concern.

**Methods** Since 2005, data from obese patients that undergo bariatric procedures in Germany are prospectively registered in an online database and analyzed at the Institute of Quality Assurance in Surgical Medicine. For the current analysis, all patients that had undergone primary sleeve gastrectomy for morbid obesity within a 7-year period were considered.

**Results** Using the GBSR, data from 5,400 LSGs were considered for analysis. Staple line leak rate decreased during the study period from 6.5 to 1.4 %. Male gender, higher BMI, concomitant sleep apnea, conversion to laparotomy, longer operation time, use of both buttresses and oversewing, and the occurrence of intraoperative complications were associated with a significantly higher leakage rate. On multivariate

analysis, operation time and year of procedure only had a significant impact on staple line leak rate.

**Conclusions** The results of the current study demonstrated that there are factors that increase the risk of a leakage which would enable surgeons to define risk groups, to more carefully select patients, and to offer a closer follow-up during the postoperative course with early recognition and adequate treatment. All future efforts should be focused on a further reduction of serious complications to make the LSG a widely accepted and safer procedure.

**Keywords** Sleeve gastrectomy · Risk factors · Staple line leakage · German multicenter trial

## Introduction

Morbid obesity is steadily increasing worldwide. It promotes the development of various diseases, such as cardiovascular disease and type 2 diabetes, which greatly increase mortality. According to the German Health Interview and Examination Survey for Adults, the prevalence of obesity in Germany has risen substantially during the last years, especially among men. Currently, 22.3 % of the male and 23.9 % of the female population are obese [1].

For patients with morbid obesity, surgical management remains the only evidence-based approach to achieving clinically important and sustainable weight loss, but results greatly vary depending on the procedure [2].

Analysis of the literature suggests that laparoscopic sleeve gastrectomy (LSG) alone is efficacious in the short term and may offer certain advantages when compared to the existing options of laparoscopic adjustable gastric banding (LAGB) and laparoscopic Roux-en-Y gastric bypass (RYGB) [3–5].

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LSG has been shown to produce excellent excess weight loss in the short term comparable with RYGB and superior to LAGB with a low incidence of major complications and death [3, 6].

The most frequent and most feared complication after LSG is a gastric leak, most commonly occurring at the upper staple line near the gastroesophageal junction [7, 8]. This complication, although appearing in a low percentage of patients (0.74–1.7 %), may lead to abdominal sepsis and multiorgan failure or chronic gastric fistula increasing morbidity and hospital stay [3, 9, 10]. There is little evidence on factors that increase the risk of a staple line leak. However, in the light of the growing popularity of SG, it would be of high interest to clarify if those factors exist and, thus, if the risk can be reduced by a more differentiated preoperative patient selection and perioperative management, respectively.

The aim of this study was to analyze demographic, clinical, and perioperative factors that may impact the risk of a staple line leak following primary LSG.

## Methods

Within the German multicentered observational study—“German Bariatric Surgery Registry (GBSR)”—data for obese patients undergoing a bariatric procedure are prospectively acquired in an online database and analyzed by the Institute of Quality Assurance in Operative Medicine at the Otto-von-Guericke University of Magdeburg, Germany. The study was conducted in accordance to the principles of the Declaration of Helsinki for biomedical research. Participation was voluntary, evaluation was based on anonymous data, and the study involved observation only—i.e., it had no influence upon the choice or course of therapy.

The study was initiated in January 2005 and is still ongoing. For the current investigation, all obese subjects that underwent primary sleeve gastrectomy for morbid obesity within a 7-year period were considered for analysis (1 January 2005 until 31 December 2011). Patients that underwent SG as a revisional or redo operation were excluded. The main goal of the study was to investigate factors that increase the risk of a postoperative staple line leakage. The following variables were considered for analysis:

- *Demographic/clinical aspects* (age, gender, BMI, comorbidities, *Helicobacter pylori* status)
- *Surgical aspects* (operation time, surgical approach, antibiotic prophylaxis, management of staple line, bougie size, volume of removed stomach)
- *Perioperative complications*

## Statistical Analysis

Statistical analysis was performed by StatConsult GmbH using SAS® 9.2 software program. For descriptive statistical analysis, absolute/relative frequencies were used for nominal values. Continuous data are expressed as mean, minimum, and maximum. Median and standard deviation were considered for high variation. Frequency testing for categorical variables was conducted by standard methods, and continuous variables were compared by using the robust *t* test. Differences found in the two-dimensional cross-comparison (contingency table analysis) were tested statistically by Pearson's  $\chi^2$  test. Differences between the groups were to be regarded as significant if  $p < 0.05$  was found in a two-sided test. A multivariate analysis of influence parameters was performed by logistic regression using both stepwise forward and backward analyses.

## Results

Within the study period (from 2005 until 2011), 5,400 patients underwent LSG as primary procedure for morbid obesity. Table 1 demonstrates the annual increase of LSG performed in Germany within the study period.

### Demographic Data

There was a higher proportion of female patients (63.6 %). LSG was performed in 1,965 male obese (36.4 %). This female preponderance was confirmed for each year of the study period.

Mean age at the time of surgery was 43.6 years (range 18–74) with a slightly higher mean age for male patients (44.7 vs. 42.9 years). Female obese had a mean BMI of 51.5 kg/m<sup>2</sup> which was marginally lower compared to male subjects (53.2 kg/m<sup>2</sup>).

Comorbidities were present in the majority of patients (89.7 %) in this study with hypertension being the most frequent diagnosis (65.9 %) followed by sleep apnea

**Table 1** Annual increase of sleeve gastrectomies in Germany within the study period

Year	Sleeve gastrectomy (n)
2005	1
2006	21
2007	154
2008	421
2009	1,073
2010	1,710
2011	2,020
Total	5,400

(26.9 %) and type 2 diabetes (insulin-dependent 13.2 %, non-insulin dependent 21.6 %).

Before surgery, *H. pylori* infection was histologically proven in 14.6 % of all patients analyzed in this study.

### Operative Data

Mean operative time in was 85 min (SD 42.3 min). LSG was completed by laparoscopy in 96.6 % of all cases. Primary laparotomy was performed in 2.1 %, and a conversion to the open approach was necessary in 0.9 %. Perioperative antibiotic prophylaxis was administered in the vast majority of patients (90.8 %).

Oversewing of the staple line was applied in 40.2 % of all LSG; staple line buttressing materials were used in 31.9 %. In 2.9 % of all patients, staple line buttressing and oversewing were performed simultaneously.

The mean bougie size used in this study was 35.8 (20–50) Charriere. Mean resected gastric volume was 1.035.9 mL.

### Perioperative Complications

Intraoperative complications occurred in 111 (2.1 %) LSGs, with injuries to the spleen (0.57 %) and the liver (0.11 %) and bleeding (0.15 %) being the most frequent events. During the postoperative course, 6.2 % of all patients developed general complications. Surgical complications were observed in 4.8 % of the cases and are listed in Table 2. Mortality decreased within the study period from 1.3 % in 2007 to 0.2 % in 2011.

### Staple Line Leakage

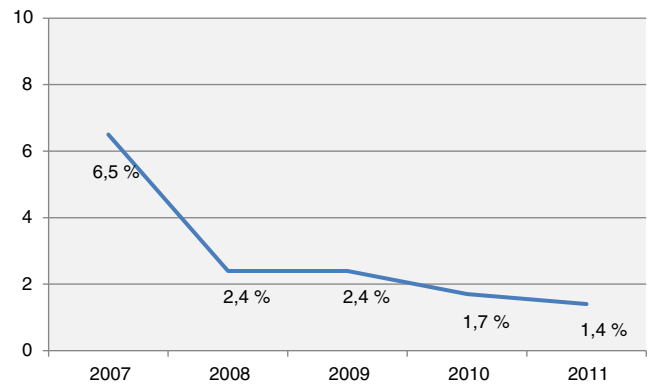
Staple line leakage following primary sleeve gastrectomy was observed in 103 (1.9 %) patients. Leakage rate decreased during the study period from 6.5 % in 2007 to 1.4 % in 2011 (Fig. 1).

### Demographic Factors

Male gender was associated with a significantly higher leakage rate (2.5 vs. 1.6 %;  $p=0.02$ ). Patients with a staple line leak were significantly younger than those without leakage

**Table 2** Surgical complications following primary sleeve gastrectomy

Type of complication	Frequency (%)
Leakage	1.9
Bleeding	
Transfusion	0.8
Reoperation	1.1
Abscess	0.8
Wound infection	0.9



**Fig. 1** Annual decrease of leakage rate during study period

(41.5 vs. 43.6 years;  $p=0.046$ ). However, when the entire patient cohort was subdivided into age groups, a significant difference was no longer confirmed ( $p=0.46$ ). Interestingly, the lowest leak rate was observed in patients beyond 60 years. None of the patients aged 70 years and older experienced a leakage. However, these results may have been influenced by the low number of subjects in these age groups (Table 3).

### BMI

Patients with a staple line leak had a higher preoperative BMI (53.1 vs. 52.1 kg/m<sup>2</sup>). This difference was not statistically significant ( $p=0.26$ ). When analyzing BMI groups separately, a significant variation of the leak rate was observed with the highest rate for patients with a BMI between 50 and 59.9 kg/m<sup>2</sup> ( $p<0.01$ ) (Table 4).

### Antibiotic Prophylaxis

The administration of antibiotic prophylaxis had no influence on leakage rate ( $p=0.12$ ).

**Table 3** Influence of patient's age on staple line leakage

	Leakage	Control
Age (mean)	41.5 years	43.6 years
$p=0.046$		
Age groups (in years)	Leakage (n/%)	Control
<21	3/3.1	93/96.9
21–34	21/1.9	1,100/98.1
35–49	52/2.1	2,414/97.9
50–59	23/1.77	1,275/99.2
60–69	3/0.8	377/99.2
≥70	0/0	31/100
$p=0.46$		

**Table 4** Influence of preoperative BMI on staple line leakage

BMI—groups (kg/m <sup>2</sup> )	<i>n</i>	Leakage rate (%)
<35	87	1.2
35–39.99	318	1.9
40–49.99	2,064	1.2
50–59.99	1,800	2.8
≥60	1,131	1.8

*p*<0.01

### Comorbidities

The presence of at least one comorbidity did not significantly increase the risk of a leak in the present study (1.98 vs. 1.3 %; *p*=0.24). However, when analyzing each comorbidity separately, a significant association could only be demonstrated for a concomitant sleep apnea (2.6 vs. 1.8 %; *p*=0.04). None of the other comorbidities increased significantly the risk of a leak (Table 5).

### *H. pylori*

An infection of the gastric mucosa with *H. pylori* does not significantly increase the risk of a staple line leak (1.9 vs. 1.91 %; *p*=0.99).

### Surgical Variables

The results of the current study clearly demonstrated that the surgical approach has an impact on the leak rate. For all procedures completed laparoscopically, the lowest leak rate was observed (1.7 %). In patients with primary laparotomy, leak rate increased up to 4.4 %. The highest proportion of staple line leaks was demonstrated for procedures with conversion to open approach (14.6 %; *p*<0.01). Similarly, operative time significantly impacts likelihood of a leakage with a positive correlation between longer operative time and higher rate of staple line leak (116.9 vs. 93.7 min; *p*<0.01). By

**Table 5** Association between comorbidities and risk of staple line leak

Comorbidity	Significance ( <i>p</i> )
Sleep apnea	0.04
Hypertension	0.19
T2DM	
Insulin dependent	0.19
Non-insulin dependent	0.76
Cardiovascular	0.19
Smoking	0.97
Osteoarthritis	0.88

contrast, no significant association was found for the bougie size (35.8 vs. 35.3 Charr; *p*=0.19) and the volume of the removed stomach (*p*=0.4).

In the present study, the incidence of a leakage was reduced by reinforcing the staple line from 2.5 % (no reinforcement) to 1.5 % (oversewing) and 1.6 % (use of buttressing material). The highest leak rate could be demonstrated when using both oversewing and buttressing (5 %; *p*<0.01) (Table 6).

### Perioperative Complications

The incidence of intraoperative complications was associated with a significantly higher rate of postoperative staple line leakage (9.9 vs. 1.7 %; *p*<0.01). It can be assumed that the occurrence of complication during the procedure frequently necessitated a conversion to laparotomy which has been demonstrated to significantly increase the rate of a staple line leak. Similarly, there was a significant correlation between the incidence of general postoperative complications and the risk of a leakage (18.4 vs. 0.8 %; *p*<0.01). However, these results must be interpreted with caution. It is very likely that patients with a staple line leak consecutively developed complications due to a prolonged hospital stay and the need of reinterventions and parenteral nutrition. Thus, it must be suggested that both parameters are inversely correlated.

### Multivariate Analysis

To further clarify the influence of all variables investigated in the study on the incidence of staple line leakage following primary LSG, a multivariate analysis was performed. To minimize the impact of patients with incomplete data sets and in order to improve statistical quality, the following inclusion criteria were determined:

- Period 2007–2011
- Laparoscopic procedures only
- Hospital with >100 procedures/year (>25 LSG/year)

Furthermore, the variables general/surgical postoperative complications were excluded from analysis. A total of 3.643

**Table 6** Influence of surgical variables on the risk of staple line leak

Variable	Significance ( <i>p</i> )
Conversion	<0.01
Operation time	<0.01
Bougie size	0.19
Volume of removed stomach	0.4
Use of both buttressing and oversewing	<0.01
Intraoperative complications	<0.01

patients were eligible for multivariate analysis. A significant influence on leakage rate was observed for operation time and year of procedure only. For the latter, a significant decrease of staple line leaks over time during the study period could be demonstrated.

## Discussion

Laparoscopic sleeve gastrectomy has become a common surgical procedure, and it is increasingly being done as a potentially stand-alone bariatric operation. LSG has been shown to produce an excellent weight loss and resolution of comorbidities in the short term and midterm [3–6]. In a review by Buchwald and Oien, it was demonstrated that the rate of LSG has dramatically increased within the last years, currently being the second most bariatric procedure worldwide [11]. In GBSR, the remarkable increase of LSG was confirmed, with a rate comparable to RYGB [12]. Mistakenly, LSG has been considered as a technically simple procedure which has led to its adoption by a large number of surgeons [13]. However, LSG is associated with potentially serious complications, and one of the most feared is a leakage of the staple line. The incidence is probably multifactorial and includes a local ischemia, an increased intraluminal pressure, and extensive lateral traction during resection [13]. The key factors in case of a leak are the early detection and the adequate management. Early reintervention is associated with better results and prompt cure [14]. Therapeutic options vary, mainly depending on the timing and the clinical presentation of the leak and most importantly on the patient's condition.

In a recent publication by Weiner et al., early postoperative complication rate was compared between patients who had undergone LSG with those who had undergone RYGB. Although leak rate was comparable, patients following LSG experienced significantly more often early complications. Specifically, postoperative bleeding rate was significantly higher in the LSG group [15]. By contrast, a study comparing procedure-related morbidity in the short term and midterm follow-up including leakage, readmission, and reoperation rate revealed that LSG appears to have the lowest procedure-related morbidity when compared with RYGB and LAGB [16].

Despite the fact that gastric leak is still the most feared complication following LSG, little is known about factors that may influence the risk of a staple line leakage. Thus, the main focus of the current study was to investigate whether there are factors that increase the incidence of a leak in patients who underwent primary LSG for morbid obesity. For the study, data from the GBSR were used. All patients operated between 2005 and 2011 were considered for analysis.

The leak rate constantly decreased throughout the study period with an estimated risk for a leak of 1.4 % in 2011. This

steady decline can be attributed to the growing experience of surgeons and centers with LSG. The most important finding of the study is that there are factors which significantly increase the risk of a staple line leak following primary LSG. It was demonstrated that male gender, a higher BMI, and a concomitant sleep apnea are associated with a higher leak rate. In addition, conversion to laparotomy, longer operative time, use of both suture and buttresses for staple line reinforcement, and the occurrence of intraoperative complications also have a significant impact on staple line leak rate. However, on multivariate analysis, only operative time and year of the procedure remained statistically associated with an increased rate of a gastric leak.

The current study demonstrated that male obese have a significantly higher risk to develop a leak following primary LSG. However, it should be noted that the proportion of male patients investigated in the study was only 36.4 % which may have influenced the results. The increased risk can probably be attributed to the higher content of visceral fat in male subjects which makes the procedures and adequate exposure of anatomical structures more challenging. In addition, concomitant sleep apnea was also more frequent in male patients, and this condition was associated with a higher leak rate in this study. The correlation between male gender and increased leak rate was also confirmed in a multicenter study including 2,834 obese [17]. An analysis by Weiner et al. compared early postoperative complications in patients after LSG and RYGB, respectively. LSG was associated with a higher rate of adverse events during the early postoperative course. Interestingly, male gender percentage was significantly higher in the complicated LSG group compared with the complicated RYGB group. Consequently, the authors concluded that the higher rate of complications after LSG may be related to the predominance of males in this group [15].

The age at the time of surgery did not significantly impact the leak rate in the current study. Surprisingly, the highest leak rate was observed in patients younger than 21 years. None of the patients with an age of 70 and older experienced a leakage. However, these results have to be interpreted with caution as the number of obese subjects in these age groups was considerably low. Similarly, Sakran et al. found no significant differences regarding leak rate following LSG in their study with identical mean age in the leak and control group [17].

More experience exists in the literature regarding the influence of preoperative BMI on staple line leak rate. Most studies confirmed a negative correlation with higher BMI [17, 18]. In the current study, leak rate varied significantly among the defined BMI groups with the highest rate for patients with a preoperative BMI between 50 and 59.9 kg/m<sup>2</sup>. Interestingly, the risk of a staple line leak was considerably lower in patients with a BMI of 60 kg/m<sup>2</sup> or more. However, we believe that this result may be attributed to the fact that the number of super obese patients was much lower compared to those with



a BMI between 40 and 49.9 and 50 and 59.9, respectively. In a systemic analysis by Aurora et al. including 4,888 patients, BMI >50 kg/m<sup>2</sup> was associated with a higher leak rate although the difference was not statistically significant [14]. Weiner et al. demonstrated a higher complication rate following LSG compared with RYGB and found that mean BMI was significantly higher in the complicated LSG group. Thus, they concluded that higher BMI is probably a causative factor for the higher complication rate [15].

The administration of antibiotic prophylaxis and a *H. pylori* infection had no significant impact on staple line leak rate following primary LSG in the present study. However, one of the limitations of the current analysis is that appropriate preoperative eradication therapy was not documented. Thus, it can be assumed that the real infection rate at the time of surgery differed which may have influenced the results. Therefore, a more detailed analysis would be desirable to further investigate the influence of a persistent or untreated *H. pylori* infection on postoperative outcome after LSG.

One possible causative factor for a staple line leak is local ischemia. Thus, all medical conditions which deteriorate the local blood supply should increase the risk of a leak. Nevertheless, no correlation could be observed in the present study, especially for type 2 diabetes, cardiovascular disease, and smoking. Interestingly, concomitant sleep apnea was the only comorbidity that significantly increased the risk of a staple line leak. The reason for this association is not totally clear. It should be discussed that using a CPAP for treatment of sleep apnea may lead to an increased pressure in the sleeve. However, this was not further evaluated in the study. A second explanation is a chronic ischemia of gastric wall in patients with sleep apnea. However, these two explanations should be the focus of future studies. The influence of comorbidities on leak rate is poorly studied. There is only one analysis including 2,834 patients which found no significant correlation between all comorbidities investigated (hypertension, type 2 diabetes, dyslipidemia, sleep apnea) and the risk of a leak after primary and revisional LSG [17].

The present study clearly demonstrated that there are surgical variables which are associated with a higher risk of a staple line leak. Both conversion to laparotomy and a longer operative time significantly increase the leak rate. This has not been reported before. Possible explanations for these correlations can be technical difficulties during the procedure due to high BMI, male gender, or previous abdominal surgery. Similarly, the occurrence of intraoperative complications—which also significantly increased the risk of a staple line leak in the current study—may subsequently prolong operative time and cause conversion to laparotomy. Thus, a close relation between all these parameters can be assumed.

Little experience exists in the literature regarding the influence of bougie size and management of the staple line on leak rate. In a review including 4,999 LSG, larger-sizing bougies

were associated with a significant decrease in incidence of leak with no change in weight loss [19]. Parikh et al. who analyzed 9,991 patients who had undergone LSG demonstrated that the risk of a leak significantly decreased with bougie size >40 French [18]. In contrast to the results of these studies, the current analysis failed to confirm a significant association.

The management of the staple line during LSG is still controversially debated. There are some surgeons who advocate to oversee the staple line; some prefer buttressing materials. In the present study, it was shown that the use of sutures and buttresses reduces the risk of a leak from 2.5 to 1.5 and 1.6 %, respectively, with no difference between both techniques. The significantly highest incidence of leaks was observed when using both sutures and buttressing materials (5 %). Consequently, the latter should always be avoided. Most of the studies agree that the use of buttressing material provides no advantages when compared with oversewing the staple line. In a prospective randomized trial by Albanopoulos et al., no significant difference was observed between both techniques, although all complications (two leaks, one bleeding) occurred in the buttressing group only [20]. In a review including 4,888 LSG, comparable leak rates were demonstrated [14]. A meta-analysis investigated 9,991 patients that had undergone LSG and confirmed that buttressing did not impact leak rate [18]. Choi et al. reviewed 1,335 obese that had undergone LSG and found that reinforcement decreased the risk of a leak with no significant difference between both techniques. However, oversewing seemed to increase the risk of a staple line hemorrhage [21].

In the GBSR, the occurrence of postoperative complications was significantly associated with an increased risk of a staple line leak. However, it must be assumed that there is an inverse correlation. Incidence of a leakage is associated with a prolonged hospital stay, repeated interventions, and necessity of parenteral alimentation which subsequently may cause secondary complications.

For multivariate analysis, further selection criteria were used. Procedures completed laparoscopically and hospitals with an annual bariatric operation load of >100 procedures were considered only. All LSG from the first 2 years of the study (2005/2006) and the variables general and surgical postoperative complications were excluded from analysis. These selection criteria were applied to improve statistical quality and to exclude both the influence of low-volume centers and the impact of the first years after introduction of LSG in Germany. The results of the multivariate analysis confirmed a significant negative effect only for a longer operation time on leak rate. Furthermore, the year of LSG was significantly associated with an increased leak rate. The latter finding can be explained by the growing experience of surgeons and centers in Germany which have made LSG a safer procedure. As demonstrated earlier, leak rate decreased considerably throughout the study period from 6.5 to 1.4 %.

This significant correlation between the operative year and leak rate was not confirmed by Daskalakis et al. in their analysis including 230 LSG. Complication and leak rate decreased within their study period but without statistical significance. However, a significant decrease in operative time was noted [22].

## Conclusion

The LSG is rapidly gaining in popularity worldwide, and it is currently the second most bariatric operation in Germany. One major concern is a postoperative leak of the staple line which still represents a challenge for bariatric surgeons. Due to the growing experience, a constant decrease of the leak rate is being observed. However, staple line disruption—especially when diagnosis and appropriate management is delayed—may still lead to abdominal sepsis, multiorgan failure, and increased mortality in young patients with a benign condition. The mechanisms resulting in staple line failure and the management principles are insufficiently understood. The results of the current study demonstrated that there are factors that increase the risk of a leakage following LSG for morbid obesity. Thus, these findings may help the surgeons to define risk groups and to carefully select patients. Moreover, it would enable a more differentiated patient counseling before surgery and a closer follow-up during the postoperative course in patients at risk. When a leakage is suspected, a prompt and consequent diagnostic workup should be initiated and if necessary, an early reintervention discussed. All future efforts should be focused on a further reduction of serious complications to make the LSG a widely accepted and safer procedure.

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**Conflict of Interest** All authors (Benedix F, Benedix DD, Knoll C, Weiner R, Bruns C, Manger T, Stroh C) declare that there is no conflict of interest.

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