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ORIGINAL CONTRIBUTIONS

Is a One-Step Sleeve Gastrectomy Indicated as a Revision Procedure After Gastric Banding? Data Analysis from a Quality Assurance Study of the Surgical Treatment of Obesity in Germany

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Abstract
Background Since 1 January 2005, the outcomes of bariatric surgeries have been examined in Germany. All data are registered prospectively in cooperation with the Institute of Quality Assurance in Surgery at Otto-von-Guericke University Magdeburg.
Methods Data are collected in an online data bank. Data collection began in 2005 for the results of gastric banding (GB) and in 2006 for sleeve gastrectomies (SGs). In addition to primary bariatric operations, data regarding the complications of revision procedures and redo operations have been analyzed. Participation in the quality assurance study is required for all certified centers in Germany.
Results SGs are a popular redo operation after failed gastric banding. Using the German Bariatric Surgery Registry, we analyzed data from 137 SGs that were used in a one-step approach after GB and 37 SGs that were used in a two-step approach. Leakage rates for primary SGs dropped to 1.9 %. The incidence of leakage after a one-step SG after GB is significantly higher (4.4 %) than for a two-step approach (0 %).
Conclusion SGs are popular procedures after failed GB in Germany, but the complication rates for one-step band removal are higher than for a two-step approach. After examining the data, we suggest performing band removal and SG as a two-step procedure. Further analysis is necessary to evaluate the optimal time period between band removal and SG. Follow-up investigations must be performed to determine if SG is an effective and safe option after GB.

Keywords Redo operations · Gastric banding · Sleeve gastrectomy · German multicenter trial

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Introduction

Obesity is one of the greatest challenges to health in the twenty-first century. According to data from the International Association for the Study of Obesity (IASO), Germany ranks first in the prevalence of obesity for both genders [1]. The Federal Office of Statistics revealed that in 2011, 67.1 % of men and 53 % of women were overweight [2].

Laparoscopic gastric banding (GB) was introduced in Germany in the mid-1990s [3]. The long-term durability of GB remains controversial, and the number of GB procedures, especially in Europe, has decreased rapidly in recent years. The effects of long-term follow-up over a period of more than 10 years and long-term outcomes after GB have recently been published in a systematic review [3, 4].

If major complications or weight regain occur after GB, a redo operation is considered and may be performed. Indications

and surgical methods for redo procedure depend on the surgical experience.

The problem of how to select the best bariatric procedure for each patient has not yet been completely addressed. We have previously published gender-specific issues that influence short-term complications after sleeve gastrectomy (SG) and GB [5, 6].

The following paper investigates outcomes and complications for patients undergoing sleeve gastrectomy as a redo operation after failed GB based on an analysis of data from the German Bariatric Surgery Registry (GBSR). The primary goal of the study was the comparison of short-term complication rates of primary SG, band removal, and SG as a one- or two-step procedure.

Method

Since 1 January 2005, data from a quality assurance study of the surgical treatment of obesity in Germany have been registered prospectively in an online database at the Institute of Quality Assurance in Surgical Medicine of the Otto-von-Guericke University Magdeburg [7]. This paper evaluates the outcomes of SGs as redo operations after failed gastric banding for data collected between 2005 and 2011. Aspects studied include demographic data, surgical parameters, complications, and mortality following SG after failed GB with respect to the incidence of leakage, short-term morbidity, and mortality. The results are compared with other findings in the literature.

Statistical Analysis of Data

Statistical analysis was performed by StatConsult GmbH using SAS® 9.2 software program. Descriptive statistical analysis was specified by presentation of absolute and relative frequencies for nominal values and mean, standard deviation, minimum, and maximum values for continuous variables. Median was considered for high variation. Descriptive statistics were extended by frequency tests for several values and variables. For further verification of differences between the as used, for rare events, the Fisher's exact test was applied. p values were determined for two-sided tests, with a value of $p<0.05$ indicating a significant difference. Continuous variables of two groups were compared with two-sample t test. Multivariable analysis of influence parameters for a dependent variable was performed by logistic regression.

Results

There were 174 SGs performed as redo procedures after GB between 2005 and 2011. In 137 cases, band removal was performed simultaneously with the SG. The operation was carried out as a two-step procedure in only 37 cases.

Demographic Data

In 137 patients, band removal and SG were performed as a one-step operation. There was a higher proportion of women in these patients (74.5 %).

The mean age of these patients was 45 years (24–68 years), and the mean BMI was 45.4 kg/m^2 (range 20.6–82.0 kg/m^2).

GB removal and SG were performed as a two-step procedure in 37 patients. In this group, 78.4 % of the patients were female. The mean age at the time of redo surgery was 43.3 years (25–59 years). Patients undergoing the two-step procedure were younger, but this result was not statistically significant ($p=0.266$). The BMI of patients undergoing two-step band removal and SG was 46.9 kg/m^2 (range 25.4–72.6 kg/m^2). Demographic data from all groups are shown in Table 1.

Comorbidities

Comorbidities were recorded for all patients in the study. In addition to the fact that all patients had already undergone GB at the time of redo surgery, 75.7 % suffered from other comorbidities.

Data Comparing Surgical Techniques

Since 2005, data from GB procedures have been recorded in the GBSR. The GB procedure is currently performed in 88 participating hospitals. Overall, each hospital performs between 1 and 145 procedures per year. For the 6 years that data have been collected, the number of GB surgeries performed has ranged from 1 to 304 for several participating hospitals. Data from SGs have been recorded in the GBSR since 2006.

The mean operation time for patients having a one-step band removal and SG was not significantly longer than that

Table 1 Demographic data—mean age and BMI

		Primary SG	One-step procedure	Two-step procedure	p value
Number of operations	[n]	5,400	137	37	
Mean age	[years]	43.6	45.0	43.3	0.266
Mean BMI	[kg/m^2]	52.1	45.4	46.9	0.463
Women	[%]	63.6	74.5	78.4	0.675
Men	[%]	36.4	25.5	21.6	
Incidence of comorbidities	[%]	89.7	75.2	75.7	0.951

for patients having a two-step operation (133 vs. 116 min, $p = 0.103$).

Operations were performed using a laparoscopic approach in 97.1 % of two-step procedures and in 97.0 % of one-step procedures. The conversion rates from a laparoscopic to open procedure were not significantly different between one- and two-step approaches (3.0 vs. 2.9 %, $p = 0.957$).

Compared to the mean operation time for SG as a primary approach (94.1 min), the operation time for a one- or two-step band removal and SG is significantly longer. The conversion rate also increases for redo operations from 0.9 % for a primary SG to 3.0 % for a one-step or 2.9 % for a two-step revision of GB to SG.

Leakage of the staple line is the "Achilles' heel" of SG; we observed a significant difference in oversewing of the staple line for one-step operations (52.6 %) vs. two-step operations (27.8 %, $p = 0.008$). Staple-line buttresses were used in 16.3 % of one-step operations and in 41.7 % of two-step procedures ($p = 0.003$). Operative data are shown in Table 2.

Intraoperative Complication Rates

Intraoperative complication rates were not statistically significantly higher in two-step redo operations than in one-step operation (5.4 vs. 4.4 %, $p = 0.678$). In two-step operations, injuries of the spleen were observed in all cases with intraoperative complications, whereas in one-step procedures, spleen injuries were not reported. Complications in one-step operations were liver injuries and gastric perforations.

General Postoperative Complication Rates

The general postoperative complication rate was 5.1 % for one-step operations. Most complications were pulmonary complications. For two-step procedures, there were no general complications described.

Specific Postoperative Complication Rates

There was no relevant difference in the total incidence of surgery-specific postoperative complications between one- and two-step band removal and sleeve gastrectomy (6.6 vs. 5.4 %, $p = 0.789$).

Patients who underwent band removal and SG in one operation had a higher risk of leakage with a leakage rate of 4.4 vs. 0 % in two-step operations ($p = 0.344$). Data are shown in Table 3.

Mortality

For operations between 1 January 2005 and 31 December 2011, the mortality rate was zero.

Univariate Analysis and Comparison to SG as a Primary Approach

Gender-specific differences in leakage rates were analyzed for primary SGs. For patients with SG after GB, we could not find any gender-specific differences ($p = 0.610$).

Age ($p = 0.082$) and BMI ($p = 0.600$) also had no influence on leakage for patients with one-step SG as a reoperation after GB. Further investigations have also not shown any influence of BMI on the leakage rates for patients with redo operations.

Data from the GBSR showed that patients with SG and sleep apnea had a higher incidence of leakage. In patients with one-step SG following GB, we did not see a correlation with the incidence of sleep apnea ($p = 0.839$) or any other investigated comorbidity influencing the complication rate.

Operation time ($p = 0.743$), use of an open or laparoscopic approach ($p = 0.817$), or bougie size ($p = 0.701$) had no influence on leakage rates when the SG and band removal were performed as a one-step procedure.

For one-step operations, the highest incidence of leakage was observed if staple-line buttresses were used (9.1 %). The incidence of leakage for a pure staple line was 4.9 and 2.8 %

Table 2 Operative data

		Primary SG	One-step procedure	Two-step procedure	*p* value
Staple-line buttresses	[%]	31.9	16.3	41.7	0.006
Oversewing	[%]	40.2	52.6	27.8	
Staple line with oversewing	[%]	2.6	0.7	0.0	
Pure staple line	[%]	25.3	30.4	30.6	
Bougie size	[charr]	36	36	35	0.199
Operation time	[min]	94	133	116	0.103
Intraoperative complication	[%]	2.1	4.4	5.4	0.678

Table 3 Specific complication rates for one- and two-step band removal and SG

		Primary SG	One-step procedure	Two-step procedure	*p* value
Sepsis	[%]	0.5	2.2	0.0	1.000
Abscess	[%]	0.8	2.2	0.0	1.000
Bleeding					
- Transfusion	[%]	0.8	0.8	5.4	0.115
- Reoperation	[%]	1.1	0.8	0.0	1.000
Leakage	[%]	1.9	4.4	0.0	0.344
Total	[%]	4.8	6.6	5.4	0.789

for patients with oversewing, which was not statistically significant ($p=0.653$).

When SG was used as a primary approach, the incidence of intraoperative complications had no significant effect on leakage (16.7 vs. 3.8 %, $p=0.13$). Patients with general complications had a higher leakage rate than patients without leakage or staple-line insufficiency (28.6 vs. 3.1 %, $p=0.031$).

Discussion

Since 1 January 2005, primary and repeat bariatric procedures have been recorded within the framework of a quality assurance study of the surgical treatment of obesity by the Institute for Quality Assurance in Surgical Medicine at the Otto-von-Guericke University Magdeburg with the aim of improving the quality of care [7, 8].

GB is still one of the most often performed bariatric operations worldwide. Due to experiences with GB and its long-term effects, the operation rate in Europe and worldwide has decreased since 2008.

Meta-analysis data showed no relevant long-term differences in excess weight loss when comparing GB and Roux-en-Y-gastric bypass (RYGBP) [3]. The high frequency of adverse events in the perigastric area could be reduced with the introduction of the pars flaccida technique and new soft bands. These results show that GB is still a safe and effective treatment for obesity over the long term.

Long-term complications, as well as insufficient weight loss or failed amelioration of comorbidities, are indications for redo operations after GB. Because SG is a popular procedure in Germany, conversion of GB to SG is an interesting option for redo surgeries.

GBSR data from 2005 to 2011 have shown an increasing number of reoperations after GB, especially a SG after a prior GB (Table 4). This redo operation can be performed either as a one-step or two-step operation. Evaluated data from the GBSR have shown that the one-step procedure is the most common in Germany, but data have also found a higher incidence of certain specific complications. Because staple-line insufficiency is the Achilles' heel of SG, we analyzed data from the GBSR to determine if it has an influence on incidence of leakage after one- or two-step operations. Our investigation detected a higher incidence of leakage for the one-step procedure. A literature review of these results is difficult because most published reports include a mix of patients after GB and vertical banded gastroplasty (VBG) or a mix of reoperations as one- or two-step procedures without any comparison of both types of intervention (Table 5) [9–13].

Overall reported leakage rates after GB and SG ranged from 0 to 33 % [14]. In studies with more than 50 patients, leakage rates are still higher than for SG as a primary approach. Only a few studies have compared complication rates, especially leakage, for one- and two-step band removal and SG. These studies show a lower incidence of leakage for a two-step SG after band removal with a range from 0 to 2.8 % [13, 14]. Evaluated data from the GBSR also suggest a lower leakage rate for the two-step procedure. There were no reports of leakage after a two-step procedure in the GBSR, but there may be a bias because of the low number of patients. Obviously, the nonsignificantly higher leakage rate for one-step operations compared to primary SG is an important point for further discussions ($p=0.052$). Single-center results published by Yazbek et al. and Alqahtani et al. did not report a higher incidence of leakage of the staple line for SG after GB compared to SG as a primary approach [15, 16].

The Fourth International Consensus Conference on Sleeve Gastrectomy reported that high leaks at the angle of His occur in 89 % of cases. Data from the third summit consensus on SG detected a rate of high leaks in 1.3 % and of lower leaks in 0.5 % of cases. Intraluminal bleeding occurred in 2.0 % of cases [17]. A study reported at the fourth consensus meeting on SG and published by Parikh et al. that included 18,992 patients showed a leakage rate of 2.2 %, which is much lower than that reported with one-step band removal and SG in the literature and GBSR [18].

Table 4 One-step redo operations performed annually after GB from the GBSR

Year	2005	2006	2007	2008	2009	2010	2011	Total
Redo procedure	[*n*]	[*n*]	[*n*]	[*n*]	[*n*]	[*n*]	[*n*]	[*n*]
GB in RYGBP	1	2	14	24	39	68	53	201
GB in BPD		1	10	11	5	8	3	38
GB in sleeve			6	20	28	40	43	137
GB in BPDDS		2	0	3	1	0	0	6

Table 5 Data from the literature

Author	Year	Number of patients with GB [*n*]	Leakage rate [%]	EWL [%]
Acholonu [9]	2009	15 (13 one step)	6.7	20.3
Ianelli [10]	2009	36	12.2	–
Foletto [11]	2010	41 one step	5.7	40.6
Gagnière [12]	2011	102	16.1 (one step) vs. 2.8 (two step)	–
Goitein [13]	2011	46	6.6	–
Berende [14]	2012	28	33.0 vs. 0	–
Algahtani [15]	2013	65	5.5	80
Yazbek [16]	2013	90	5.5	–

Examinations have shown that GB leads to chronic inflammation of the gastric wall in the tissue under the band [19].This inflammation may be one reason for the higher leakage rates in one-step operations. Data comparing leakage rates of GB pars flaccida and perigastric techniques are not available in the literature. The GBSR could not be used to investigate this issue, because many patients underwent GB operations before 2005 in different hospitals.

Data from the GBSR and most publications show that overall morbidity was significantly higher in patients having undergone LSG after primary gastric banding compared with those undergoing primary LSG. Gastric leaks secondary to staple-line disruption also occurred statistically significantly more often in patients with primary gastric banding. The optimal waiting time between gastric band removal and performing LSG could not be determined from the GBSR or the literature. We suggest a waiting time of at least of 1 month, whereas the literature suggests a waiting time of 6 months. Due to the risk of leakage and the associated complications of leakage, an SG after band removal due to migration should be not performed.

Multivariable analysis of data from the GBSR revealed that of the factors analyzed (age, gender, comorbidities, body mass index, perioperative antibiotics, laparoscopy vs. laparotomy, oversewing vs. staple-line buttresses, bougie size, hospital experience, year of operation, primary gastric banding), the only independent risk factor for staple-line disruption was primary gastric banding.

Data regarding long-term weight loss and amelioration of comorbidities after SG as a redo operation after GB are rare in the literature. These data are necessary to further evaluate whether SG as a restrictive procedure is still a method of choice after failed GB.

Conclusions

Based on data from the GBSR on the surgical treatment of SG after failed GB and a review of the literature, SG and band removal as a one-step procedure have a significantly higher incidence of overall complications and especially of leakage of the staple line compared to a two-step procedure or prior SG. Based on this data, it seems that band removal and SG as a two-step procedure reduce the leakage rate, but further evaluations with a higher number of procedures are necessary to confirm these findings. In the literature, the suggested optimal waiting time for a two-step procedure is 6 months. The optimal waiting time between band removal and SG must be evaluated in further studies.

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