

Results of Sleeve Gastrectomy in Germany—Data on Nationwide Survey on Quality Assurance in Bariatric Surgery in Germany

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ABSTRACT

Background: Since January 1st of 2005, the situation of bariatric surgery is being analyzed in Germany. The data is registered prospectively in cooperation with the Institute of Quality Assurance in Surgery at the Otto-von-Guericke University Magdeburg. **Methods:** The data is registered through an online database which includes all information for primary and revision bariatric procedures as well as yearly follow-up. Participation in the quality assurance study is optional. All certificated centers have to participate at the survey. **Results:** From January 2006 to December 2009, 1478 sleeve gastrectomies (SG) were performed at 45 hospitals. The number of procedures has increased from 126 in 2007 to 933 in 2009. The main complication is leakage of the staple-line. Initial leakage rate was 7% in 2007. Leakage rate dropped down to 2.3% in 2008 and 2.5% in 2009. Mean age of patients was 43.1 years and mean BMI was 52.83 kg/m². Age and BMI were significantly higher in patients with SG than in all other patients undergoing bariatric surgery. **Conclusion:** SG is a common and hype bariatric procedure in Germany, but postoperative complication rate is high. Data on the long-term effect of SG on weight loss and amelioration of comorbidities need to be evaluated. More detailed analyzes are necessary to establish the position of SG in the bariatric surgery. Further studies should also include examinations on long-term complications and redo-procedure after SG.

Keywords: Bariatric Surgery; Sleeve Gastrectomy; German Multicenter Trial; Leakage; Complications

1. Introduction

In international comparison, Germany belongs to the countries with a high prevalence of obesity. Depending on age, overweight and obesity affect 25% to 70% of the population. The average body mass index (BMI) of the German population in 2009 was 25.7 kg/m², with 60.1% of men and 42.9% of women overweight [1].

Life expectancy is markedly shortened by obesity, in particular in young obese persons. The mortality risk rises to between six- and 12-fold of that of the normal population, with a 12-year reduction in life expectancy for overweight men and 9-year reduction for women.

Mortality risk increases 6 to 12 times compared to normal population. For grade III obesity a 20-year statistically corroborated reduction in life expectancy has been identified [2].

The results of the Swedish Obesity Subject Study (SOS study), which demonstrated the long-term effects of weight reduction on resolution of comorbidities, attest to the marked superiority of surgical treatment measures [3].

In terms of a bariatric treatment concept, sleeve gastrectomy (SG) has been the sole technique practiced since 2000. To date there are no long-term data on weight reduction or on regression of comorbidities. Complica-

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tion rate is considerably influenced by leakage of the staple line. Aim of these study is the comparison of the data on Nationwide Survey on bariatric surgery for SG in Germany with literature.

2. Methods

Data of primary bariatric procedures as well as revisional surgery has been evaluated since January 1st of 2005 using Nationwide Survey on quality assurance in bariatric surgery in Germany. Aim of Nationwide Survey is to improve quality on obesity surgery in Germany. Data registration is performed prospectively using an online database [4]. Participation on the Nationwide Survey is voluntary, but all certificated centers of bariatric surgery in Germany have to contribute at the survey. Survey was announced several times since 2005. Participation on the Nationwide Survey is open for all hospitals without any regulations of government or health insurance system. According this conditions number of participating hospitals has been increased from 66 (2005) to 114 in 2009. Patient's selection for bariatric surgery is based on guidelines of IFSO and German Guidelines on Bariatric Surgery [5]. In 2009 943 patient's data on SG were retrieved from 45 hospitals. The current report evaluates data of 1478 patients operated on SG from 2005-2009. Demographic and operative parameters as well as complication and mortality rate after SG were analyzed. The follow-up is collected by follow-up examinations, yearly. Weight loss and changes in comorbidities are gathered.

Data quality of German Nationwide survey is proven by experienced surgeons, control of plausibility and during certification of centers by the auditor as a site visit.

Review on literature was performed on PubMed and Cochrane Database using the keywords sleeve gastrectomy, leakage, staple line insufficiency, mortality and morbidity.

3. Results

1478 patients operated on SG has been analyzed using German Nationwide database on Quality assurance in Bariatric Surgery. Since 2005 number of bariatric procedures has been increased, beside the restrictions on health insurance system according obesity and bariatric surgery. In 2005 and 2006 RYGBP and GB were the most performed bariatric procedures in Germany. After introduction of SG in 2006 SG has been the hype procedure with 943 SG performed in 2009. **Figure 1** shows the distribution and changes of the different bariatric procedures from 2005 to 2009 (**Figure 1**).

3.1. Demographic Data

61.7% of patients with SG were female. Mean age of

patients undergoing SG was 43.2 years and mean BMI 52.8 kg/m². In comparison with all patients undergoing bariatric surgery in Germany age (41.0 vs. 43.2 years) and BMI (47.9 vs. 52.8 kg/m²) were significant higher in patients with SG ($p < 0.001$).

3.2. Comorbidities

Comorbidities have been evaluated for all patients. At German Nationwide Database 71.6% of all patients suffer on comorbidities. Patients undergoing SG have significant more comorbidities (90.8%; $p < 0.001$). Distribution on comorbidities is shown in **Table 1**.

3.3. Operation Data

Since 2005 we evaluated 1478 at German Nationwide Database at 45 hospitals. Hospital volume ranges between 1 to 146 procedures per year.

For calibration of the stomach, in 2007 mean bougie size was 32.7 (range 22 - 40 Charr) Charrriere and in 2009 35.3 (range 20 - 50 Charr). In 2009, 95.5% of SG procedures were performed laparoscopically and 3.4% in open approach. Conversion rate was 1.1% in 2009. Mean operation time was 96.2 minutes (range 26 - 394) with an intraoperative complication rate of 2.4%. Operative data are shown in **Table 2**.

3.4. General and Specific Postoperative Complications

The frequency of general complications such as pneumonia, urinary infection or cardiac complications, pulmonary embolism and fever was in 2007 14.1% and decreased to 7.9% in 2008 and 7% in 2009.

Specific complications are leakage of the staple line, intraabdominal abscess, bleeding and wound infection

Table 1. Distribution of comorbidities.

Years	2005-2009 all patients	2005-2009 patients with SG	Significance
Comorbidities	[%]	[%]	
Without comorbidities	18.4	9.2	<0.001
Hypertension	54.3	70.1	<0.001
Cardiac comorbidities	8.4	15.0	<0.001
IDDM	9.2	12.7	<0.001
NIDDM	17.4	22.4	<0.001
Respiratory comorbidities	16.6	21.6	<0.001
Sleep apnoea	16.8	25.8	<0.001
Gall stones	5.3	5.8	0.386
GERD	15.5	13.5	0.051
Varicosis	5.5	9.3	<0.001
Skeletal disease	41.5	52.1	<0.001

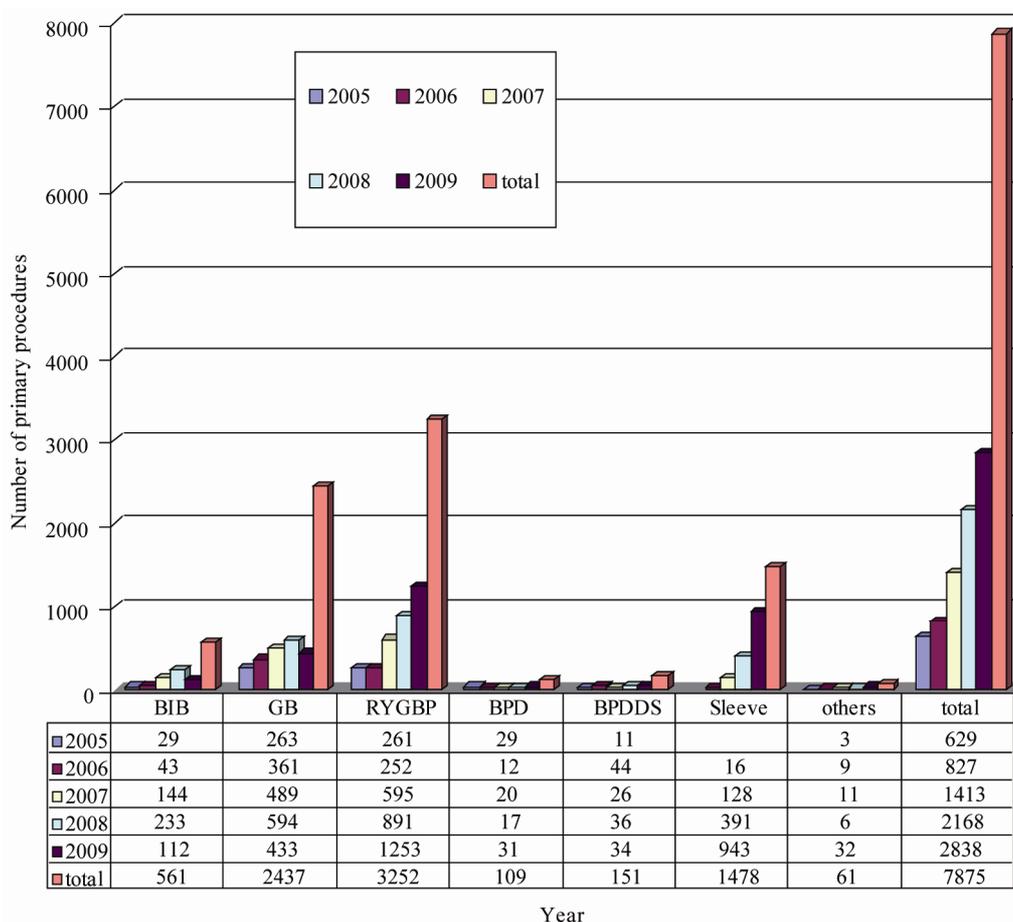


Figure 1. Distribution on primary bariatric procedures in Germany 2005-2009.

Table 2. Operation data.

Year		2007	2008	2009
Number of operations	[n]	126	388	933
Number of hospitals	[n]	17	36	45
Hospital volume	[n]	1 - 67	1 - 108	1 - 146
Mean operative time	[min]	93.1	46.1	96.2
Laparoscopy	[%]	97.6	96.1	95.5
Open approach	[%]	2.4	2.1	3.4
Conversion rate	[%]	0	1.8	1.1
Mean sleeve volume	[ml]	99.3	103.2	108.8
Mean bougie size	[Charr]	32.7	34.4	35.3
Mean resected volume	[ml]	851.4	894.8	981.2
Staple line buttresses	[%]	42.6	51.3	41.9
Oversewing	[%]	51.1	31.2	46.9
Without buttresses or oversewing	[%]	6,3	22.2	11.2

occurred in 9.4% in 2007 and 5.1% in 2008 and 2009. In particular, the leakage rate of the staple-line dropped from 7.1% in 2007 to 2.3% in 2008 and 2.5% in 2009. The frequency of specific complications is listed in Ta-

ble 3.

3.5. Mortality Rate

From January 1st of 2006 until December 31st of 2009, 9 patients died after primary SG, the overall mortality after SG is therefore 0.6%. 8 of the patients died during the first 30 days and one patient at 72 day due to severe pulmonary infection. Mean BMI of these 6 men and 3 women was 56.5 kg/m². All of them suffered on comorbidities of metabolic syndrome (hypertension (n = 8 patients); diabetes mellitus (n = 4 patients); sleep apnea (n = 6 patients)).

Table 3. Postoperative complications after SG.

Year	Number of operations	Bleeding	Leckage of staple line	Stenose Sleeve	Bowel obstruction
2006-2007	[n]	1.6	7.0	0.8	0
2008	[n]	2.1	2.3	0	0
2009	[n]	1.8	2.5	0.1	0.1

3.6. Weight Reduction

For 477 patients, follow-up dates are available 18 months after SG and for 71 patients over 30 months. The detected demographic data shows no difference between surgery- and follow-up. The results of the BMI reduction and weight loss are listed in **Table 4**.

4. Discussion

Data of primary bariatric procedures as well as revisional surgery is gathered since January 1st of 2005 through the Nationwide Survey on quality assurance in bariatric surgery in Germany in order to improve care quality [4]. Number of patients undergoing SG is higher in the Nationwide Survey than in BOLD registry published by DeMaria 2010 [6].

After SG reduction of morbidity and mortality is still in discussion, especially due to the risk of leakage of staple line. Most discussed facts, influencing leakage rate are bougie size, resection of the antrum, using staple line reinforcement or oversewing of the staple line [7]. Leakage and subsequent fistulas near the staple-line especially at the gastro-esophageal junction are the main complications after SG [8-10]. The leakage rate is indicated at 0 to 5.5% [10,11]. The effect of bougie size on the leakage rate has not been examined using randomized controlled studies, but bougie size influences the leakage rate [7,11]. Some authors recommend overstitching the staple-line [9]. Literature has shown a decreased bleeding risk using staple line buttresses [13,14]. A protective effect from staple-line reinforcement to the advantage of leakage reduction could not be shown in randomized controlled studies. However, shorter surgery times and less blood loss have been described with its use.

In the study, the overall postoperative complication rate after SG is 14.1% (2007), 7.9% (2008) and 7.0% (2009). Leakage rate at the staple line was reduced from 7.0% (2007) to 2.5% (2009). Report on BOLD registry does not discuss complication rate after SG. Only data on complication rate of the BOLD registry in totally has been published until now [6].

Literature shows an overall complication rate of up to 24% with a median mortality rate of 0.37% [12,15]. In the quality assurance study the mortality rate is 0.6%. Major issue of this procedure is the possibility of surgical

complications due to insufficiency/leakage of the stapler line with or without fistulas. Such insufficiency accounts for morbidity (up to 80%) and mortality. Even though there are many approaches to resolving the stapler insufficiency (including reinforcement of the stapler with several foreign materials), it is an ongoing issue and might be one of the serious downsides of SG.

Influence of the higher BMI and age of patients undergoing SG in Germany on leakage rate, morbidity and mortality has to be investigated further on. Cohorts with more than 5000 patients are necessary to evaluate these facts from the statistical point of view.

The quality assurance trial insures a detailed data-collection as it is described in the methods. Latest recommendations for leakage rate reduction are on the one hand associated with the lack of mobilization of the periesophageal fat with the aim to preserve a minimum of one centimeter of stomach-wall lateral of the Hiss angle and the avoidance of stenosis in the area of the angulus fold on the other hand [16].

Table 5 reflects current data from literature on stapler-line insufficiency rates, perioperative morbidity and mortality in comparison with data from the quality assurance study (**Table 5**).

A systematic literature research shows an overweight reduction after SG of 33% to 85% [17]. Studies have proven a correlation between bougie size and the extent of weight loss [15,18].

Patients with a BMI > 60 kg/m² profit from SG in the bariatric therapy concept as long as this procedure is chosen as the initial surgery [19]. It is however, gaining value as a single procedure [20,21]. Long-term results of follow-up data of more than 5 years are only available in few studies [18,23,24].

5. Conclusions

According to literature and data on German Nationwide Survey the following operative technical details should be registered and evaluated in further studies such as through detailed data collection in the quality assurance study:

- Diameter of the calibration tube;
- Use of staple-line reinforcement;
- Use of the stapler with the fewest leakage rate;

Table 4. Reduction of BMI.

OP	Months after operation [months]	Number of patients [n]	BMI		
			OP [kg/m ²]	Follow up [kg/m ²]	BMI-Reduction [kg/m ²]
SG	0 - 6	105	55.6	47.9	-7.7
	6 - 18	477	53.8	39.7	-14.1
	18 - 30	71	54.1	39.0	-15.2

Table 5. Complications after SG-Review in literature.

Author	Year	Number of patients [n]	Follow up [mo]	BMI [kg/m ²]	Bougie [Charr]	Overall complication rate [%]	Mortality
Regan [25]	2003	7	11	63	60	42.8	0
Almogly [26]	2004	21	18	57.5		23.8	0
Baltazar [15]	2005	31	27	35 - 74	32	6.7	1/31
Langer [27]	2005	10	6	43.3		0	0
Milone [28]	2005	20	6	69	60	5	
Mognol [29]	2005	10	12	64		0	0
Moon [30]	2005	130	12	37.2	48	2.9	1/130
Cottam [31]	2006	126	12	65.4	46 - 50	13	
Himpens [20]	2006	40	36	39	34	5	0
Hamoui [32]	2006	118	24	55		15.3	1/118
Langer [33]	2006	23	18	48.5			
Roa [34]	2006	30	6	41.2	52	13.3	
Silecchia [35]	2006	41	12	57.3	48	12.1	0
Braghetto [36]	2007	50	12	37.9	32 - 40	2	0
Dapri [37]	2007	40	12	42.5	32	2.5	0
Givon-Madhala [38]	2007	25	4	44			
Lalor [11]	2007	164	29	42	44		0
Lee [39]	2007	216	24	49	32	7.4	0
Melissas [40]	2007	23	12	47.2	34	21.7	0
Serra [9]	2007	993		35-51		9.4	< 1
Tucker [41]	2007	148	3	45.9	36	7.4	0
Weiner [19]	2007	120			32 - 44	17.5	1/120
Parikh [42]	2008	120	12	60.1	40 - 60		0
Felberhauer [43]	2008	126	19	48.1	48	3.2	0
Rubin [44]	2008	120	11	43.5	48	0	0
Srekas [45]	2008	93	12	48.9	36	4.3	0
Mui [46]	2008	70	12	40.7	38	2.9	0
Gagner [47]	2008	63	12	68		6.3	0
Kasalicky [48]	2008	61	18	41.8	38	3.2	0
Frezza [49]	2008	53	18	53.5	29 - 38	9.4	0
Uglioni [50]	2009	41	36	46.3	35	9.8	0
Fuks [51]	2009	135	12	48.8		5.1	0
Stroh [22]	2009	144	24	54.5	32	14.1	2
Himpens [24]	2010	41	72	39.9		12.2	
German Survey 2006-2009		1478	36	52.8	32.7	7.5	9/1478

- Influence on comorbidities on leakage rate;
- Influence on gender on leakage rate.

The aim is to define the importance of SG in the bariatric therapy concept by gathering a high number of patients and a detailed data collection through the quality assurance trial [22].

6. Conflict of Interests

The German Nationwide Survey is supported by: Johnson & Johnson MEDICAL GmbH, Ethicon Endo-Surgery Germany, Norderstedt; Covidien Germany GmbH, Neustadt/Donau; Lamed GmbH, Oberhaching/München, Germany; Pharm-Allergan GmbH, Ettlingen, Germany; Sanofi-Aventis Germany GmbH, Berlin; W. L. Gore Associates GmbH, Putzbrunn, Germany.

A conflict of interests or any connection to products mentioned in this report does not exist.

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