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ORIGINAL ARTICLE

Propensity-Score-Matching Sleeve Gastrectomy vs. Gastric Bypass with 3 Years of Follow-Up

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Abstract

Background: From 1 January 2005, cases of bariatric surgery were examined with the help of the Quality Assurance Study for operative medicine. All data were registered and analyzed prospectively in cooperation with the Institute of Quality Assurance in Surgery at the Otto-von-Guericke University Magdeburg, Germany. The focus of the comparative study is on perioperative morbidity and complications.

Methods: Data collection includes people of full age who underwent Sleeve Gastrectomy or Gastric Bypass surgery between 2005 and 2017. The bougie is limited to 33-40 French for Sleeve Gastrectomy. Furthermore, the Roux-en-Y length for RYGB is set to 120-180 cm and the biliodigestive length is set to 40-60 cm.

Results: Between 2005 and 2017, 64349 patients were enrolled in GBSR. At this time 56328 primary operations were performed including 24146 RYGB and 24085 SG procedures. A matching was realized for n = 1,161 (81.7%) patients based on age, BMI, gender, ASA and comorbidities. The mean BMI reduction was 15.58 for gastric bypass and 14.80 for sleeve gastrectomy, consequently higher for RYGB (p = 0.004) in the third year of follow-up. For remission of NIDDM, IDDM, hypertension and sleep apnea, no significant differences were found at this time.

Conclusion: The number of obesity surgeries in Germany is continuously rising. Sleeve Gastrectomy and Roux-en-Y Bypass are well established interventions. The results of the study show significant findings for BMI reduction and gastroesophageal reflux. In terms of complications, no significant differences between both treatments were found. There is a need for further evaluations in order to be able to optimize patient selection in the next years.

Keywords

Obesity, Bariatric surgery, Sleeve gastrectomy, Gastric bypass, Morbidity, Complications, Comorbidities

Introduction

Obesity poses a worldwide challenge for the global population. Obesity is the biggest global chronic health issue [1]. Since the 1980s, it´s prevalence has tripled, and there are now over 1.9 billion obese people worldwide. Especially among children and adolescents, obesity has increased significantly in recent years [2]. Obesity impairs numerous organ systems. Comorbidities and secondary diseases result in rising morbidity and mortality as well as in an increasing loss of quality of life. Roux-en-Ygastric bypass and sleeve gastrectomy have been established as standards of surgical treatment. In 2013, altogether 468,609 bariatric interventions were performed worldwide, most frequently RYGB with 45%, followed by SG with 37%. Because of easy operability as well as the lower postoperative complication rate compared to RYGB, sleeve gastrectomy has been performed more frequently in the last years [3,4]. Unfortunately, there are only few long-term results or evidence-based studies. Still, reliable data are needed that make it possible to identify risk factors, prognostic indicators, and long-term complications in order to provide high standards. The aim of the present study was to compare SGs and RYGB with respect to perioperative morbidity and

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comorbidity based on data from the German Bariatric Surgery Registry (GBSR). The study aims to contribute to the evaluation of operative risks and suitable selection criteria for patients for both surgical treatments.

Method

From 1 January 2005, in total 64,349 bariatric procedures were registered in the GBSR, prospectively. In our study, we analyzed and retrospectively evaluated the data in cooperation with the Institute of Quality Assurance in Surgery at the Otto-von-Guericke University Magdeburg, Germany.

This is a multicenter observational study in which all hospitals performing bariatric surgery were included.

Between 2005 and 2017, a total of 229 institutions took part. Out of the 64,349 operations 56,328 primary procedures were performed including 24,146 RYGB procedures and 24,085 SG. SG were operated in 166 hospitals and RYGB in 155 of them.

For data selection the inclusion criteria were age over 18 years, bougie size limited to 33-40 French for primary SG, Roux-en-Y length for primary RYGB limited to 120-180 cm and the biliodigestive length limited to 40-60 cm as well as a complete 3 year follow-up. The statistical analysis was performed by an independent statistics consulting firm (Stat Consult GmbH, Magdeburg, Germany). All computations of this explorative analysis were performed using SAS® 9.4, SAS Institute, Cary (USA) and intentionally calculated to a full significance level of 5%, that is, they were not corrected with respect to multiple testing, and each $p \leq 0.05$ represents a significant result.

SG patients were attributed to similar patients undergoing RYGB in a 1:1 Propensity-Score-Matching using greedy algorithm and a caliper of 0.2 standard deviations. The variables used for matching were as follows: Age (years), BMI (kg/m²), sex (male/female), ASA status (I/II/III-IV), comorbidities. The balance of the matched sample was assessed using standardized differences, which should not exceed 10% (< 0.1) after creating matched pairs. Categorical data were compared using McNemar's test. Continuous variables were compared using the t-test for paired samples. The outcomes of the matched pairs were analyzed for BMI reduction, intraoperative, general and special postoperative complications, and remission on comorbidities hypertension, IDDM and NIDDM, gastroesophageal reflux and sleep apnea.

The study was conducted according to the Recommendations of the Declaration of Helsinki for Biomedical Research.

Results

Propensity-Score-Matching for the 1,421 sleeve gastrectomies was compared to 1,963 patients with gastric bypass. A matching was realized for n = 1,161 (81.7%) patients. The standardized differences are illustrated in Table 1 and Table 2 before (original sample) as well as after (matched sample) the matching (Table 1 and Table 2). Well-balanced variables were indicated by a standardized difference of under 10% (< 0.1). All matching variables showed standardized differences of < 10% after matching which suggests well-balanced variables.

BMI reduction

Concerning BMI reduction, a significant difference of

Table 1: Standardized differences of metric variables both before (original sample) and after matching (matched sample).

		Operation		Operation	
		Roux-en-Y-Gastric Bypass	Sleeve Gastrectomy	Matched Sample	Original Sample
Age	Mean Value ± SD	45.3 ± 10.9	45.2 ± 11.3	0.009	0.054
BMI	Mean Value ± SD	49.6 ± 7.6	49.4 ± 8.2	0.016	0.282
Number of comorbordities	Mean Value ± SD	3.6 ± 2.4	3.6 ± 2.2	0.022	0.044

Table 2: Standardized differences of categorial variables both before (original sample) and after matching (matched sample).

	Roux-en-Y-Gastric Bypass		Sleeve Gastrektomy		Standardized Differences	
	[n]	[%]	[n]	[%]	Matched Sample	Original Sample
Male	324	27.91	320	27.56	0.008	0.229
Comorbidities	1050	90.44	1074	92.51	0.074	0.088
Comorbidity diabetes	333	28.68	332	28.60	0.002	0.009
Comorbidity sleepapnea	302	26.01	303	26.10	0.002	0.126
Comorbidity hypertension	779	67.10	794	68.39	0.028	0.046
ASA I	36	3.10	36	3.10	< 0.001	0.043
ASA II	481	41.43	477	41.09	0.007	0.155
ASA III	620	53.40	630	54.26	0.017	0.151
ASA IV	23	1.98	16	1.38	0.047	0.048

Table 3: Results of matched pair analysis: BMI reduction (paired t-test).

	Operation			
BMI Reduction	**Roux-en-Y-Gastric Bypass**	**Sleeve Gastrecktomie**	**RGYB-SG**	
Number [N]	1150	1146	1135	
Missing values	11	15	26	
Mean STD	15.58	14.8	0.8	
STD	6.33	6.76	9.39	
Minimum	-4.7	-13.9	-31.0	p = 0.004
Maximum	48.8	44.6	44.9	

Table 4: Results of matched pair analysis: Complications.

Roux-en-Y-Gastric Bypass		**Sleeve Gastrectomy**				**p-value**
		Yes		**No**		
		[n]	**[%]**	**[n]**	**[%]**	
Cumulatedcomplications	Yes	14	1.21	107	9.22	0.639
	No	115	9.91	925	79.67	
Intraoperative complications	Yes	0	0.00	19	1.64	0.542
	No	24	2.07	1118	96.39	
General postoperative complications	Yes	5	0.43	59	5.08	0.852
	No	56	4.82	1041	89.66	
Special postoperative complications	Yes	4	0.34	57	4.91	1.000
	No	58	5.00	1042	89.75	

Table 5: Results of matched pair analysis: Remission of comorbidities.

Roux-en-Y-Gastric Bypass		**Sleeve Gastrectomy**				**p-value**
		Yes		**No**		
		[n]	**[%]**	**[n]**	**[%]**	
IDDM	Yes	5	0.43	68	5.89	0.675
	No	74	6.41	1008	87.27	
NIDDM	Yes	3	0.26	49	4.24	0.767
	No	53	4.59	1050	90.91	
Hypertension	Yes	170	14.72	255	22.08	0693
	No	265	22.94	465	40.26	
Sleepapnoea	Yes	25	2.16	127	11.0	0.609
	No	118	10.22	885	76.62	

0.8 BMI points was found between both surgery techniques (p = 0.004). The mean BMI reduction was 15.58 for gastric bypass and 14.80 for sleeve gastrectomy, consequently higher for RYGB (Table 3).

Complications

Cumulative complications: A cumulative complication rate was assumed in cases where there was at least one complication, or more. In 14 pairs both matched patients developed at least one complication, in 925 pairs no patient developed any complications. 115 of the complications occurred after SG but not after RYGB, and 107 complications occurred exclusively after gastric bypass. Considering the p-value (p = 0.639), these difference is not significant (Table 4).

Intraoperative complications: Evaluation of intraoperative complication rate has shown no significant difference in comparison of SG and RYGB (p = 0.542) (Table 4).

General postoperative complications: With a p-value of 0.852 comparison of general postoperative complication rate has also shown no significant difference (Table 4).

Special postoperative complications: With a p-value of 1.000, these results are not significant (Table 4). Among the 62 cases in the SG group, frequent complications were secondary bleeding (18 cases) necessitating reoperation as well as anastomotic leaks (25 cases). These findings correspond with the bypass group (18 and 10 cases).

Remission on comorbidities and follow up data

Diabetes mellitus type II: Remission rate on insulin

dependent Diabetes mellitus type II has shown no significant differences after 3 years of follow up in comparison of patients after SG with patients after RYGB (p-value of 0.675) (Table 5).

For non-insulin dependent data did also shown no significant difference in comparison of both procedures (p-value 0.767) (Table 5).

Hypertension: Remission rate of hypertension was with a p-value of 0.693 not statistically significant in between SG and RYGB (Table 5).

Sleep apnea: Propensity Score analysis has also not evaluated anystatistically significant difference for reduction on sleep apnea (p-value of 0.609) (Table 5).

Gastroesophageal reflux during follow-up: In 21 pairs, both matched patients developed gastroesophageal reflux within three years of follow-up, in 771 pairs none of the patients did. Looking at the secondary diagonal, this comorbidity occurred in 292 pairs in the SG group but did not occur in the RYGB group. By contrast, just 71 pairs of gastroesophageal refluxes were recorded in the bypass group. This result is statistically significant ($p < 0.001$) (Table 6).

For a better overview, the results of the secondary diagonal including odds-ratio evaluations are summarized in (Table 7). A confidence interval (CI) of 1 is indicative of similar groups. Nearly all outcome variables are in the CI of 1, thus no systematic deviation between both surgery interventions was found. A systematic difference was detected only for gastroesophageal reflux. There was a high-significant deviation (6.2% vs. 25.3%, $p < 0.001$) for the benefit of gastric bypass. According to this, there is a four times higher risk of contracting gastroesophageal reflux after a sleeve-gastrectomy surgery compared to a gastric-bypass surgery (1: OR = 1: 0.243 = 4.115).

Discussion

With 78.45% (Roux-en-Y gastric bypass) and 86.40% (sleeve gastrectomy), women decided to undergo a surgical intervention more frequently than men. After matching, this difference was not noted anymore. A study by Stroh, et al. [5] found that more female than male patients underwent a bariatric surgery, especially GB, SG and RYGB. These findings correspond with other studies [6]. Gender-specific aspects have consequences with regards to complication rate, weight loss and improvement of comorbidities. It was shown that for men there is a significantly higher complication rate as well as mortality due to a higher BMI and a higher incidence of comorbidities compared to women [5]. A significantly differing age distribution was not detected, neither in the present study nor in international comparative studies. In Thymitz, et al., the mean age was 42.3 years for gastric bypass, and in van Rutte, et al., it was 42.3 years for sleeve gastrectomy [7,8]. The BMI after matching is nearly similar in both groups so there is no difference between both surgery techniques for this variable. In a study by Peterli, et al., the mean BMI represented 43.6 kg/m^2 in the SG group and 44.2 kg/m^2 in the RYGB group, hence, as in the present study, too, there was no significant difference found between both interventions in this respect [9]. In terms of weight loss, a significant difference of 0.8 BMI points was detected ($p = 0.004$). BMI reduction after gastric bypass

Table 6: Results of matched pair analysis: Sleep apnea and gastroesophageal reflux during follow-up.

Roux-en-Y-Gastric Bypass		Sleeve Gastrektomy				p-value
		Yes		No		
		[n]	[%]	[n]	[%]	
Gastroesophageal reflux during follow-up	Yes	21	1.82	71	6.15	< 0.001
	No	292	25.28	771	66.75	

Table 7: Odds ratio evaluation.

	Disadvantage			OR Formatched Samples		
	Roux-en-Y-Gastric Bypass	Sleeve Gastrektomy	p-value	OR	Lower Limit	Upper Limit
Cumulatedcomplications	9.22	9.91	0.639	0.930	0.708	1.221
Intraoperative complications	1.64	2.07	0.542	0.792	0.410	1.508
General postoperative complications	5.08	4.82	0.852	1.054	0.718	1.547
Special postoperative complications	4.91	5.00	1.000	0.983	0.670	1.442
IDMM during follow-up	5.89	6.41	0.675	0.919	0.651	1.295
NIDDM during follow-up	4.24	4.59	0.767	0.925	0.614	1.390
Hypertension during follow-up	22.08	22.94	0.693	0.962	0.807	1.147
Sleep apnea during follow-up	11.00	10.22	0.609	1.076	0.831	1.395
Gastroesophageal reflux during follow-up	6.15	25.28	< 0.001	0.243	0.185	0.316

was 15.58 on average, and after sleeve gastrectomy it was 14.80. The average BMI reduction was higher after RYGB. Although several studies show comparable results between gastric bypass and sleeve gastrectomy with regards to weight loss [9-11], most studies suggest that postoperative weight loss is significantly higher after combined treatments like the Roux-en-Ygastric bypass [12-14]. According to Lager, et al., one year after surgery, patients had lost 40.4 kg after RYGB and 34.3 kg after SG ($p < 0.0001$), and four years after surgery, they had lost 34.4 kg after gastric bypass and 26.7 kg after sleeve gastrectomy ($p < 0.0001$). There was a recovery of weight in both groups over time. These findings support Peterli, et al., who detected a discreet recovery of weight in year three [9].

In literature, complications like bleeding, stenosis as well as insufficiency appear most frequently with both surgery techniques [13,15,16]. In other studies, there is a classification into intraoperative, general and special postoperative complications seldom. Wang, et al. found no significant difference between SG and RYGB [11]. Intraoperative complication rates did not differ significantly ($p = 0.542$). These findings were also evaluated in comparative studies. Melissas, et al. found, the general perioperative complication rate was 1.2% for SG and 1.04% for RYGB [13]. These findings were not significant. Wang, et al. concluded the same [11]. General complication rates in both patient groups did not differ significantly ($p = 0.852$). In contrast to this, results of literature show statistically significant differences after early (< 30 days) and late (> 30 days) postoperative complications. Melissas, et al., detected an early complication rate of 3.02% for gastric bypass and 2.12% for sleeve gastrectomy ($p = 0.0006$). More patients from the RYGB group had complications within 30 days after surgery (3.03% RYGB vs. 0.97% SG, $p < 0.0001$) [13]. Husain, et al. found similar results with complication rates of 5.5% for SG and 10.7% for RYGB, the complication rate was significantly higher after RYGB ($p = 0.008$) [17]. Peterli, et al. found significant results (17.2% RYGB vs. 8.4% SG, $p = 0.067$) [18]. Some factors play an important role for the incidence of special postoperative complications. The ability of the surgeon, their participation in special training programs as well as their cooperation in interdisciplinary teams should be prerequisites for bariatric treatments [15,19]. Stroh, et al. examined leakage, perforation of the stomach, bleeding, infected wound as well as stenosis. Special complications occurred in 4.87% of patients after SG and in 5.30% of patients after RYGB. All in all, the number of special complications was significantly higher in men than in women ($p = 0.0011$) [5]. The present study detected secondary bleedings and anastomotic leaks necessitating reoperation. With a p-value of 1.000, the results of kinds of operations were not significant. Over 90% of the patients in both groups had at least one comorbidity. This number is comparable to international data [12] in the present study, most of the operated patients were classified with ASA III [20,21].

For the parameters IDDM, NIDDM, hypertension as well as sleep apnea within three years of follow-up, no significant differences between RYGB and SG were found.

Only for gastroesophageal reflux, there was a significant difference ($p < 0.001$). The risk of developing gastroesophageal reflux within three years after sleeve gastrectomy is four times higher than after gastric-bypass surgery. Melissas, et al. asserted that the prevalence of the comorbidities diabetes and hypertension is significantly higher after RYGB [13]. Peterli, et al. found that comorbidities generally improve significantly after three years [9]. Nevertheless, different opinions exist with regards to the distribution and remission of comorbidities. In a study by Ruiz, et al., no significant differences were detected. Within the first year after surgery, type II diabetes improved 89.8% after bypass surgery compared to 86.9% after sleeve gastrectomy ($p = 0.305$), and five years after surgery, it was 86.4% vs. 82% respectively ($p = 0.027$). The results are similar for hypertension. One year after surgery, RYGB led to an improvement of 84.3% vs. 78.3% after SG ($p = 0.17$), and five years after surgery, the improvement was 73.5% vs. 63.8% respectively ($p = 0.006$) [22]. Wang, et al. remarked a stronger effect after gastric bypass, but analysis did not show any significant effect [11]. The problem with all these studies is their missing analysis of the correlation between remission of diabetes and preoperative diabetes duration as well as medication [23]. Melissas, et al. established that significantly more patients after RYGB experienced remission of hypertension than patients after SG. These were one year postoperative (48% vs. 44%, $p = 0.018$) and after two years (55% vs. 49%, $p = 0.023$). In the following years, no significant difference could be detected. For the remission of diabetes type II the improvement after RYGB was significantly higher (60.1% vs. 54.2%, $p = 0.005$) one year postoperative than in the following years. There was no difference between both surgical techniques. Sleep apnea showed similar results. The remission rate after RYGB one year after surgery was significantly higher than the one after SG (68% vs. 60%, $p = 0.0002$) but not in the following years. The authors concluded that RYGB can achieve significantly better results one year after surgery in terms of the remission of diabetes, hypertension and sleep apnea [13].

Gastroesophageal reflux disease is significantly increased in overweight and obese patients. While prevalence among people of normal weight ranks between 15 and 20%, prevalence is estimated at 50 to 100% in the obese population. Although bariatric surgery is the gold standard when it comes to the treatment of obesity, not all interventions seem appropriate for the treatment of GERD. Studies show conflicting results,

particularly regarding the influence of SG on reflux disease [24]. In a review by Gorodner, et al., eight studies were mentioned which support the negative influence of SG on GERD. For example, Himpens, et al. described an increasing percentage of reflux symptoms after surgery [25]. In contrast, Gorodner, et al. presented four studies with results to the contrary. In an analysis of Weiner, et al., there was an improvement of symptoms in 43% of cases as well as a decline in 57% of cases [24,25]. Concerning the differing influence of different techniques on GERD, Dupree, et al. analyzed the effect of SG on patients with gastroesophageal reflux disease and compared the results with those of RYGB. 44.5% of the patients suffered from GERD before surgery. 84.1% complained about persisting symptoms after surgery. Just 15.9% experienced a decline in symptoms. Of the patients without pre-existing GERD, 8.4% developed a new reflux disease. In contrast, after RYGB symptoms improved in 62.8% of patients within six months ($p < 0.001$) [26]. The results of this study underline the conclusion of the present study and support statements of several authors to treat patients with pre-existing GERD using RYGB. Considering the controversial results in the literature, more studies are needed to evaluate the difference of RYGB and SG on long term effect of comorbidities and weight loss.

Conclusions

The aim of the present study was to ensure the quality assurance of bariatric surgery, to evaluate operative risks, to provide criteria for the selection of patients for both SG and RYGB to supply evidence-based knowledge. We were able to demonstrate that the mean BMI reduction was significantly higher after gastric bypass ($p = 0.004$).

For the examined comorbidities, we found differences in gastroesophageal reflux. The risk for patients to develop reflux within three years after surgery was four times higher after SG than after RYGB. With regards to complications, no significant differences were found. General risk factors such as preoperative BMI, gender, ASA, risk classification as well as the existence of comorbidities were pointed out and used for propensity score matching. The selection of surgery techniques should be made considering BMI, age, gender as well as comorbidities, and should fit the patient's individual environment. Obesity, as a chronic disease, needs lifelong follow-up care. Due to a lack of long-term data, there is an increased need for further studies in order to improve the postoperative outcome and to reduce perioperative as well as postoperative morbidity and mortality.

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Conflict of Interest

There is no conflict of interest.

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