

Amelioration of Diabetes Mellitus Type II after Sleeve Gastrectomy—Data on Nationwide Survey on Quality Assurance in Bariatric Surgery in Germany*

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ABSTRACT

Introduction: Sleeve Gastrectomy (SG) is becoming more popular due to its weight reducing effect and promising anti-diabetic efficacy. However, long term results are still lacking. **Methods:** The study focuses on anti-diabetic efficacy of SG through retrospective analysis of data for patients who underwent SG in Germany from 2005 to 2011. Anti-diabetic efficacy was assessed at 1, 2 and up to 4 years after surgery. **Results:** 5400 morbidly obese patients underwent SG. Of these 5400 patients 13.2% (n = 712) were insulin treated (IT) and 21.6% (n = 1165) were non-insulin treated (NIT). Total follow-up was accomplished in 41.24% of patients. Percentage of remission and improvement (RI) at 1 year was 83.8% (80.2% for insulin treated (IT) vs. 85.1% for non-insulin treated (NIT)). RI% at 2 years dropped to 77.6% (76.9% for IT vs. 77.9% for NIT patients). With late follow up (up to 4 years), RI% was 65.9% (58.8% for IT vs. 66.7% for NIT patients). Difference between IT and NIT patients was insignificant. **Conclusion:** SG shows promising anti-diabetic efficacy at 1 year, 2 years and up to 4 years after surgery. This efficacy gradually drops with prolonged time interval after surgery and seems to be insignificantly higher among NIT vs. IT patients.

Keywords: Sleeve Gastrectomy; Diabetes Mellitus Type II; Diabetes Remission; Metabolic Surgery

1. Introduction

Sleeve Gastrectomy (SG) was initially described as the first step of biliopancreatic diversion with duodenal switch in super obese patients [1]. Recently, stand-alone SG is gaining worldwide popularity, being a relatively non-technically demanding procedure with excellent results, in terms of substantial weight loss. Accordingly, SG is now approved as a definitive treatment in patients with a body mass index (BMI) >40 kg/m² or BMI >35 kg/m² in diabetic patients [2-4]. This is due to the fact

that SG has an extended spectrum of action which covers additional satisfactory improvement of diabetic state [2-4]. It has also been proposed with encouraging results for diabetic non-morbidly obese patients with optimistic outcome [2-4]. Being a relatively recent technique, long term effect of SG is currently under research. This nationwide survey demonstrates long term anti-diabetic efficacy of SG in morbidly obese Germans who underwent SG from 2005 to 2011.

2. Patients and Methods

Patient selection: This data pool includes morbidly obese Germans who underwent SG between 2005 and 2011 in 107 hospitals cooperating with the German Bariatric Surgery Registry (GBSR), Institute of Quality Assurance in

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Surgery at the Otto-von-Guericke University of Magdeburg [5]. Data were collected in a prospective manner. That is to say, every year a new sample of population is added to the already existing cohort. After complete data collection, retrospective statistical analysis was done. Inclusion criteria conformed to the National Institutes of Health Consensus criteria [6]. The term (diabetes) refers to a clinical status with a fasting plasma glucose level of more than 126 mg/dl [7].

Assessment of diabetic profile was done at 1, 2 and up to 4 years after SG. Accordingly, patients fell into one of four presentations, namely: remission, improvement, no change and deterioration. Remission, which can be either partial (improvement) or complete, was defined as achieving glycaemia below the diabetic range (126 mg/dl) in the absence of active pharmacologic (anti-hyperglycemic medications, immunosuppressive medications) or surgical (ongoing procedures such as repeated replacements of endoluminal devices) therapy [8].

3. Statistical Analysis of Data

Statistical analysis was performed by Stat Consult 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 the differences between the variables χ^2 -test was used. Significant differences are shown if $p < 0.05$. Continuous variables of two groups were compared with two sample t-Test.

4. Results

The study included 5400 morbidly obese patients who underwent SG from 2005 through 2011. Their demographic data are demonstrated in **Table 1**. Of these 5400 patients who underwent SG 13.2% were insulin treated (IT) vs. 21.6% who were non-insulin treated (NIT). All these patients suffered on diabetes mellitus type II. Follow up was successfully accomplished in 34.7% patients after one year, 10.4% at two years and for 3.4% for patients up to 4 years. Those represent our cohort. This relatively low follow up rate is due to the fact that follow up program is not covered by the health insurance system in Germany.

Patients are divided in two major groups according to the anti-diabetic efficacy of SG: patients who show either remission or improvement of their diabetic status (RI) and those who show either no change of their diabetic status or deterioration (ND). Remission was defined of total loose of diabetes mellitus type II independent if the

patient was treated with insulin or oral anti-diabetics. Several categories were defined patients could have a reduction of insulin dose at all, a reduction of the oral doses as well as a change from insulin to non-insulin treated diabetes type II. Also some patients developed diabetes in spite of weight reduction in case of better medical examinations. **Table 2** illustrates all these changes as well as RI% among patients (total, IT and NIT) after SG at 1, 2 and up to 4 years (**Table 3**). RI% was higher, but statistically insignificant among NIT vs. IT patients at all follow up points.

Data on duration of diabetes prior to surgery were not available for these patients.

5. Discussion

Weight gain has always been referred to as a risk factor for impaired glucose tolerance. Moreover, anti-diabetic agents are usually associated with weight gain [9]. This twin association of diabetes and obesity was the corner stone for many studies centered upon simultaneous control of both metabolic disorders. Conservative methods proved to lack long-lasting efficacy [10]. Surgery seems therefore to be the most suitable alternative [10].

Among variable surgical options, SG has recently emerged as a possible remedy for both diabetes and obesity. Anti-diabetic effect of SG has even been proved to precede its weight reducing effect [11]. Being a relatively recent procedure, proper explanation of its mechanism of action is currently under research. It is suggested that SG is not simply an absolute restrictive maneuver. Fundus

Table 1. Demographic data of morbidly obese diabetics who underwent SG in Germany from 2005 through 2011 and incidence of associated co-morbidities.

– Gender:	
• Males	1965 (36.4%)
• Females	3435 (63.6%)
– Mean age in years:	
• Males	44.7
• females	42.9
– Mean BMI in kg/m ² :	
• Males	53.2
• Females	51.5
– Percentage of patients with associated co-morbidities (other than diabetes mellitus):	
• Hypertension	65.9%
• Skeletal diseases	49.8%
• Sleep apnea	26.9%

Table 2. Changes of diabetes mellitus type II at 1, 2 and up to 4 years after SG for IT, NIT patients and for the total cohort.

	At least one follow-up		At one year (0.5 - 1.5 years)		At two years (1.5 - 2.5 years)		Up to four years (>2.5 years)	
Patients with follow-up	N (%)		N (%)		N (%)		N (%)	
	2227 (41.2%)		1873 (34.7%)		559 (10.4%)		131 (2.4%)	
	After one year		After two years		Up to four years			
	(%)	BMI (kg/m ²)	(%)	BMI (kg/m ²)	(%)	BMI (kg/m ²)		
Reduction of insulin								
IT patients	40.9 (n = 99)	-12.95 (±5.24)	39.7 (n = 31)	-15.76 (±6.63)	17.7 (n = 3)	-19.81 (±4.48)		
Change from IT to NIT								
IT to NIT patients	4.6 (n = 11)	-13.80 (±3.70)	6.4 (n = 5)	-16.93 (±6.85)	-	-		
New onset of IT								
IT patients	2.1 (n = 5)	-7.65 (±10.75)	5.1 (n = 4)	-12.50 (±5.60)	-	-		
Reduction of oral anti-diabetics								
NIT patients	34.8 (n = 152)	-13.84 (±5.84)	18.0 (n = 22)	-13.28 (±5.85)	22.2 (n = 6)	-11.73 (±5.50)		
Change from NIT to IT								
NIT to IT patients	0.9 (n = 4)	-11.00 (±3.68)	0.8 (n = 1)	-5.93 (-)	-	-		
New onset of NIT								
NIT patients	0.7 (n = 3)	-8.22 (±4.19)	0.8 (n = 1)	-6.57 (-)	11.1 (n = 3)	-13.88 (±6.88)		
Remission and improvement (RI)								
Total diabetics	83.8	-14.48 (±5.71)	77.6	-16.17 (±7.01)	65.9	-15.40 (±6.41)		
IT patients	80.2	-14.15 (±5.96)	76.9	-16.03 (±6.51)	58.8	-20.18 (±6.72)		
NIT patients	85.1	-14.63 (±5.62)	77.9	-16.19 (±7.35)	66.7	-11.95 (±4.98)		

IT: insulin treated, NIT: non-insulin treated.

Table 3. Follow-up rate of patients at 1, 2 and up to 4 years after primary SG.

	At least one follow-up		At one year (0.75 - 1.25 years)		At two years (1.75 - 2.25 years)		Up to four years (>2.25 years)	
Patients with follow-up	N (%)		N (%)		N (%)		N (%)	
	2 227 (41.2%)		1 837 (34.7%)		599 (10.8%)		131 (2.4%)	

IT: insulin treated, NIT: non-insulin treated.

resection, with resultant reduction of orexigenic ghrelin hormone, results primarily in post-operative weight loss. However, ghrelin hormone proved as well to have diabetogenic effect [12]. This together with rapid gastric emptying, shorter bowel transit time and post-operative rise of serum incretins (glucagon-like-peptide-1 and peptide-YY) seem to augment its anti-diabetic effect [13,14]. These findings could partly explain the anti-diabetic effect of SG.

Although this potential to control diabetes seems to be higher with RYGB if compared to SG [15,16], SG seems however to have promising results. An efficacy of 88% was observed in less than one year after SG in diabetic patients [17]. This group of patients required only 6 months to achieve a mean HbA1C level of 6%. Our re-

sults go in accordance. Within one year after surgery, 83.8% of our patients had RI of their diabetic state.

Ruiz-Tovar *et al.* noticed that 83.3% of patients discontinued their hypoglycemic medications within one month after SG. These findings were maintained for 24 months after surgery [18]. In this survey, a more or less stationary RI% was noticed at midterm follow up intervals of 2 years after SG, where RI% dropped slightly to 79.5%.

SG is the newest member among all obesity procedures. Long-term efficacy of SG is therefore currently lacking. However, some reports in literature studied the anti-diabetic efficacy of SG five years after surgery and attributed normalization of fasting blood sugar and HbA1C encountered in 76.9% of their patients to SG

[19]. We noticed that 65.9% of our patients maintained their diabetes free state with long-term follow up interval (up to 4 years). Abbatini *et al.* in analysis of long term effects of SG noticed an anti-diabetic efficacy, starting by 87.8% one year after surgery, gradually decreasing to 84.6% at two years and further dropped to 76.9% at five post-operative years. Similarly our cohort showed that 83.8% of patients achieved RI within 1 year after SG. This percentage dropped gradually to 77.6% at 2 years and 65.9% up to 4years after operation respectively.

Reports about anti-diabetic efficacy of SG highlighted a clinical situation of persisting diabetes after operation. This could be encountered in type 1 insulin treated diabetics with autoimmune destruction of pancreatic beta cells. It is therefore recommended to exclude this condition before surgery to optimize surgical outcome [20]. Schauer *et al.* similarly noticed an 87% reduction in the number of patients requiring oral anti-diabetic medications after surgery vs. only 79% reduction among the insulin requiring group [21]. In the same way, NIT patients in our cohort showed a higher RI% than IT at all follow up intervals. This difference was statistically not significant.

Although this report demonstrates in our opinion long term outcome of a relatively recent surgical procedure, which is lacking in most published studies, our database lacks however accurate assessment of pre- and post-operative HbA1C levels. This is a limitation in this survey. Moreover, the follow up rate for our patients is relatively low. However, this is attributed to the fact that follow up of patients is not covered by health insurance service in Germany.

6. Conclusion

In conclusion, SG is rapidly expanding in Germany, due to its promising results in terms of post-operative weight loss. Its anti-diabetic efficacy, even in IT patients, seems also to play a role in its growing popularity. However, long term assessment of its anti-diabetic efficacy is currently under evaluation.

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