Are There Gender-Specific Aspects in Obesity and Metabolic Surgery? Data Analysis from the German Bariatric Surgery Registry

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Bariatric surgery · Gastric banding · Sleeve gastrectomy · Roux-en-Y gastric bypass · Gender-specific aspects

Summary

\textbf{Background:} Since January 2005, the status of bariatric surgery in Germany has been examined in conjunction with a quality assurance study of the German Bariatric Surgery Registry (GBSR). All data are registered prospectively in cooperation with the Institute for Quality Assurance in Surgical Medicine at the Otto-von-Guericke University Magdeburg, Germany. \textbf{Methods:} Data are registered in an online database. Data collection on obesity and metabolic surgery is voluntary, and was started in 2005. In addition, follow-up data are collected once a year. \textbf{Results:} Since 2005, 8,293 sleeve gastrectomies, 10,330 Roux-en-Y gastric bypass procedures, and 3,741 gastric banding procedures have been performed in Germany, according to the data of the GBSR. Mean age and mean body mass index of female patients with gastric banding, sleeve gastrectomy, or Roux-en-Y gastric bypass were significantly lower than those of male patients. The incidence of relevant comorbidities was significantly higher in male than in female patients. \textbf{Conclusion:} Metabolic and obesity surgery is becoming more and more popular in Germany. Data from the GBSR study show significant differences in preoperative comorbidities and postoperative complications and mortality rates between male and female patients. There is a need for further evaluation of gender-specific aspects to optimize patient selection and reduce specific postoperative complications.
Introduction

Obesity is one of the greatest health-related challenges of the 21st century. According to data of the International Association for the Study of Obesity (IASO), Germany ranks first for prevalence of obesity in both sexes [1]. The German Federal Office of Statistics revealed that in 2009 51.4% of the population were overweight or obese. 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 [2]. Life expectancy is markedly shortened by obesity, in particular in young obese persons. The mortality risk rises to between 6- 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. For grade III obesity, a 20-year statistically corroborated reduction in life expectancy has been identified [3]. Surgical measures were compared in studies with conservative treatment. The results of the Swedish Obesity Subject (SOS) Study, which demonstrated the long-term effects of weight reduction on resolution of comorbidities, attest to the marked superiority of surgical treatment measures [4, 5]. Gender-specific aspects have implications for the complication rate, weight reduction, and resolution of comorbidities. The aim of the present study was to compare the data available from the German Bariatric Surgery Registry (GBSR) with international data with regard to gender-specific aspects.

Material and Methods

The data from the GBSR have been registered prospectively in an online database since January 1, 2005 at the Institute for Quality Assurance in Surgical Medicine of the Otto-von-Guericke University Magdeburg, Germany [6]. This paper evaluates the data on the main performed operations, gastric banding (GB), sleeve gastrectomy (SG), and Roux-en-Y gastric bypass (RYGB), collected between 2005 and 2012, in terms of gender-specific aspects. This study is part of an ongoing multicenter observational study initiated on January 1, 2005 for quality assurance in obesity surgery. All hospitals conducting bariatric surgery in Germany are encouraged to register with the study and enter prospective patient data in an online database. Indication and surgical approach are based on the individual center’s clinical practice. Information on the type of surgery (primary or secondary), surgical technique, anthropometric measures, vital and biochemical parameters, comorbidities, and short- and long-term complications is collected at the time of procedure and at annual follow-ups by the individual institutions in a standardized fashion. Short-term complications are classified as: i) intraoperative (injury of the spleen, liver, choledochus or vasculature, pneumothorax, gastric perforation, bleeding, or others), ii) general postoperative (urinary tract infection, renal complications, cardiac events, pulmonary complications, fever, thrombosis, or others), and iii) specific postoperative (bleeding requiring transfusion, bleeding requiring surgical revision, need for gastroscopy, insufficiency of anastomosis, stenosis of anastomoses, mechanical ileus, sepsis, peritonitis, intra-abdominal abscess, wound dehiscence, aseptic wound healing disorder, or others).

To ascertain completeness of data entry, participation in the study is a prerequisite to an institution’s certification as a center for bariatric surgery, and reported case numbers are verified against a hospital’s clinical and billing documentation. The anonymized data is provided to the institution’s quality assurance (ANOVA) (weight, BMI).

All computations were performed using SAS® 9.2 (SAS Institute, Cary, NC, USA) with a type 1 error rate of \( p < 0.05 \). Baseline and individual time-point data were compared by robust t-test for continuous variables (weight, BMI, age), or by chi-square test for nominal data (presence of comorbidities, gender). Intra-subject comparisons of pre- and postoperative data were performed by paired t-test (weight, BMI). Outcomes of surgical procedures were compared by one-way analysis of variance (ANOVA) (weight, BMI).

The study was conducted according to the Recommendations of the Declaration of Helsinki for Biomedical Research and the Guidelines and Standards of the Institutional Review Boards. All patients provided informed consent prior to entering the study. Aspects studied included demographic data, surgical parameters, complications, mortality, weight loss, and amelioration of comorbidities following GB, SG, and RYGB with respect to incidence in men and women. A comparison of the results with the literature was performed.

Results

The numbers of GB, SG, and RYGB as well as the gender distribution are illustrated in figure 1.

Demographic Data

With regard to gender distribution for bariatric procedures, and in particular for GB, SG, and RYGB, the proportion of women was higher. The mean age of women compared to that of men was significantly lower for all procedures. Female patients had a significantly lower BMI. Table 1 shows the demographic data for all GB, SG, and RYGB patients as well as those comparing men and women. Figures 2 and 3 show the distribution of age and BMI for patients in relation to the three bariatric procedures.

Comorbidities

Comorbidities were recorded for all patients. Patients with SG and RYGB had a greater number of comorbidities than all other patients undergoing obesity surgery and registered in the GBSR. In the entire study, 79.5% of patients with GB, 89.9% of patients with SG, and 86.7% of patients with RYGB suffered from comorbidities. The percentage of comorbidities in men compared to women was higher if SG or RYGGB were performed. Independent of the type of operation, male patients generally had a significantly higher incidence of hypertension, non-insulin-dependent diabetes mellitus type II (NIDDM), and sleep apnea. Incidence of hypertension was 59.4% in male GB patients, 73.1% in male SG patients, and 69.6% in male RYGB.
Gender-Specific Aspects in Obesity and Metabolic Surgery

Cant gender-specific differences were detected for the occurrence of skeletal diseases and pulmonary embolism. The gender-specific proportions of comorbidities are given in table 2.

Data on Surgical Technique

Since 2005, data have been recorded for GB and RYGB, and since 2006 for SG. GB is currently performed in 45, SG in 93, and RYGB in 85 of the participating hospitals. More than 98% of all primary bariatric procedures were performed using laparoscopy. No gender-specific differences were noted in terms of the access route. Clinically not relevant was the 8-min significantly longer operation time for male patients (p < 0.001).

General Postoperative Complication Rates

The overall general complication rate for GB was 1.66% (n = 62) with a gender-specific difference. Male patients developed more general complications than females. This included cardiac complications and fever lasting longer than 2 days. The overall general postoperative complication rate for patients with SG was 6.10% (n = 506) without any gender-specific difference. Besides urinary infection, there was no significant difference in the general postoperative complication rate between men and women (table 3). Patients with RYGB developed significantly more complications than patients with GB (p < 0.001). The gen-

Table 1. Demographic data – mean age and BMI

<table>
<thead>
<tr>
<th>Operation</th>
<th>Sex</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>female</td>
<td>male</td>
</tr>
<tr>
<td>Gastric banding</td>
<td>2,860</td>
<td>881</td>
</tr>
<tr>
<td>Mean age, years</td>
<td>40.1</td>
<td>42.6</td>
</tr>
<tr>
<td>Mean BMI, kg/m²</td>
<td>44.8</td>
<td>46.4</td>
</tr>
<tr>
<td>Sleeve gastrectomy</td>
<td>5,322</td>
<td>2,971</td>
</tr>
<tr>
<td>Mean age, years</td>
<td>42.9</td>
<td>44.7</td>
</tr>
<tr>
<td>Mean BMI, kg/m²</td>
<td>51.6</td>
<td>53.1</td>
</tr>
<tr>
<td>Roux-en-Y gastric bypass</td>
<td>8,013</td>
<td>2,317</td>
</tr>
<tr>
<td>Mean age, years</td>
<td>41.3</td>
<td>43.9</td>
</tr>
<tr>
<td>Mean BMI, kg/m²</td>
<td>48.1</td>
<td>48.6</td>
</tr>
</tbody>
</table>
Specific Severe Postoperative Complications

As specific severe complications, leakage or gastric perforation, bleeding, wound infection, and stenosis were considered. Special complications occurred in 43 out of 3,741 (1.15%) patients with GB. There was no gender-specific difference in the special complication rate ($p = 0.101$) (table 4). The incidence of postoperative severe complications after SG was 4.87% ($n = 404$). A gender-specific aspect was detected for the incidence of bleeding necessitating reoperation, leakage, as well as sepsis and peritonitis. For RYGB, the overall specific complication rate was 5.30%. Specific complications...
occurred in 547 out of 10,331 patients. The specific complication rate was significantly higher in men (6.34%, n = 147) than in women (4.99%, n = 400) (p = 0.0011). Significant differences were detected for leakage or insufficiency of gastrojejunual anastomosis, sepsis, and peritonitis (table 4).

Mortality

Between January 1, 2005 and December 31, 2012, no patient died following primary GB. However, the mortality rate was 0.35% (n = 29) for SG and 0.27% (n = 28) for RYGB. For SG and RYGB, we found a higher mortality rate for men than for women (table 5).

Follow-Up Data on Weight Reduction and Amelioration of Comorbidities

The mean BMI reduction for patients with GB 3 years after operation was 10.9 kg/m². The comparison between men and women showed a slightly higher mean BMI reduction for the female population, but the result was not statistically significant. Male patients were able to reduce their mean BMI from 49.0 kg/m² to 37.2 kg/m² (–11.8 kg/m²), and female patients from 45.6 kg/m² to 35.0 kg/m² (–10.6 kg/m²) (table 6). For patients with SG, the mean BMI reduction 3 years after operation was 15.1 kg/m² in male patients. This was slightly less than in female patients (16.1 kg/m²), without any statistical significance (table 6). Within 3 years of RYGB, male patients lost 15.8 kg/m² and female patients 16.1 kg/m² (table 6). Amelioration rates for IDDM, NIDDM, hypertension, and sleep apnea after GB, SG, and RYGB are shown in table 7.
Due to the experience with GB and the long-term effects, the operation rate in Europe and across the world has decreased [7]. In Germany, the number of GB procedures has decreased rapidly since 2005. Important reasons for this are the high BMI (overall mean BMI 49.9 kg/m²) and incidence of comorbidities in bariatric surgery patients in Germany. Less than 12% of all patients in Germany are free from comorbidities. In a literature review comparing GB, RYGB, and SG, the complication rate was 12.1% for SG, 9.5% for RYGB, and 6.5% for GB [8]. Long-term effects of GB have been reported in a systematic review which showed that 15 years after GB an almost 50% reduction in excess weight was maintained [9]. This review and the included reports did not contain information on gender-specific aspects of weight loss, amelioration of comorbidities, and reoperation rate. However, GB is a safe and less invasive technique showing no difference in long-term results when compared with RYGB [9]. There are no studies with follow-up data for more than 5 years concerned with gender-specific aspects after GB.

SG gained high popularity in Germany. Worldwide, 27.6% of all bariatric operations performed in 2011 were SGs [7]. This operation not only leads to a restriction of food intake but, due to resection of the fundus, also to less ghrelin production and hence a reduced feeling of hunger. In the bariatric treatment concept, SG is an effective procedure. It was first used as a first-stage procedure in high-risk patients in preparation for duodenal switch, and for patients with a BMI of more than 60 kg/m² [10]. However, SG is being increasingly performed as a stand-alone obesity surgery, especially as an alternative to RYGB [7, 11, 12]. However, there are only few studies with long-term follow-up data for more than 5 years [13–15]. To evaluate other factors influencing complications secondary to SG, data from the GBSR were analyzed in regard to gender-specific aspects. We evaluated a higher specific complication rate, especially for bleeding necessitating reoperation, leakage, and sepsis and peritonitis for male patients, as well as a significantly higher mortality rate. Because of their higher BMI and significantly higher incidence of comorbidities, men have a significantly higher overall complication rate and mortality. Therefore, in particular for men aged over 45 years, with a BMI above 55 kg/m², hypertension, and/or sleep apnea, the indication for bridging through implantation of a balloon system should be investigated before resorting to SG [16].

GBSR data for gender-specific aspects of RYGB have shown a significant difference for anastomotic insufficiency of gastroenteroanastomosis. The leakage rate for men was 2.37% (55/2,317) and for women 1.68% (135/8,013). Studies with multivariate analysis for RYGB revealed a higher mortality rate for patients with the following characteristics: male gender (odds ratio (OR) 2.80), BMI > 50 kg/m² (OR 3.60), hypertension (OR 2.78), pulmonary embolism (OR 2.62), and age above 45 years (OR 1.64) [17]. Because of the abdominal obesity prevalent in men, the operation often poses a techni-

| Table 7. Gender-specific amelioration rates of comorbidities after GB, SG, and RYGB |
|-------------|--------------|---|---|
| Sex, %      | Gastric banding | IDDM | NIDDM | Hypertension | Sleep apnea | Sleeve gastrectomy | Roux-en-Y gastric bypass |
| female      | Remission     | 59.1 | 68.9 | 63.0 | 67.5 | 76.9 | 81.2 |
| male        | Increase      | 12.5 | 3.4  | 5.0  | 3.1  | 7.4  | 10.3 |
|             | Without change| 28.4 | 27.6 | 41.4 | 34.8 | 15.7 | 8.4  |
|             | Remission     | 59.1 | 68.9 | 63.0 | 67.5 | 76.9 | 81.2 |
|             | Increase      | 12.5 | 3.4  | 5.0  | 3.1  | 7.4  | 10.3 |
|             | Without change| 28.4 | 27.6 | 41.4 | 34.8 | 15.7 | 8.4  |
|             | Remission     | 59.1 | 68.9 | 63.0 | 67.5 | 76.9 | 81.2 |
|             | Increase      | 12.5 | 3.4  | 5.0  | 3.1  | 7.4  | 10.3 |
|             | Without change| 28.4 | 27.6 | 41.4 | 34.8 | 15.7 | 8.4  |
Gender-Specific Aspects in Obesity and Metabolic Surgery

**References**


**Conclusion**

Based on the data of the GBSR study, it was possible to demonstrate that female gender has a protective effect against complications. Because of their higher BMI and significantly higher incidence of comorbidities, men have a significantly higher overall complication rate and mortality. There are no studies with follow-up data for more than 5 years regarding gender-specific aspects after the different bariatric operations. The aim of the GBSR is to evaluate these data and compare GB, SG, and RYGB over a time period of at least 10 years.

**Acknowledgement**

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**Disclosure Statement**

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