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Clinical Study

Fourteen- Year Long-Term Results after Gastric Banding

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Background. Gastric banding (GB) is a common bariatric procedure that is performed worldwide. Weight loss can be substantial after this procedure, but it is not sufficient in a significant portion of patients. Long-term rates for associated complications increase with every year of follow up, and only a few long-term studies have been published that examine these rates. We present our results after 14 years of postoperative follow up. *Methods*. Two hundred patients were operated upon form 01.02.1995 to 31.01.2009. Data collection was performed prospectively. In retrospective analysis, we analyzed weight loss, short- and long-term complications, amelioration of comorbidities and long-term outcome. *Results*. The mean postoperative follow up time was 94.4 months (range 2–144). The follow up rate was 83.5%. The incidence of postoperative complications for slippage was 2.5%, for pouch dilatation was 9.5%, for band migration was 5.5% and 12.0% for overall band removal. After 14 years, the reoperation rate was 30.5% with a reoperation rate of 2.2% for every year of follow up. Excess weight loss was 40.2% after 1 year, 46.3% after 2 years, 45.9% after 3 years, 41.9% after five years, 33.3% after 8 years, 30.8% after 10 years, 33.3% after 12 years and 15.6% after 14 years of follow up. *Conclusion*. The complication and reoperation rate after GB is high. Nevertheless, GB is still a therapeutic option in morbid obese patients, but the criteria for patient selection should be carefully evaluated.

1. Introduction

Demographic studies worldwide have shown a recent increase in the incidence of morbid obesity, and this condition has been identified as a major public health problem. Nonoperative treatments for weight loss offer limited success and have a high rate of failure. Currently, a Swedish obese subject study has shown that operative treatment of morbid obesity is the only effective therapy [1]. Besides weight reduction, the amelioration of obesity-associated comorbidities is an important consequence of surgical treatment of morbid obesity. Among the variety of restrictive and malabsorptive bariatric procedures, gastric banding has been performed in most countries worldwide. In Germany, GB (besides RYGBP) is the most performed bariatric procedure according to data from a nationwide survey [2].

Because GB has the advantages of being less invasive and a reversible procedure, it has been the procedure of choice for the treatment of morbid obesity for several years in Europe. In 2009, it was the most performed bariatric procedure in the USA.

The aim of our study was to analyze long-term results after GB from 1995 to 2009 and to assess the efficacy of GB for weight loss, improvement of comorbidities, and the incidence of complications.

2. Materials and Methods

2.1. Patients. Between February 1st 1995 and January 31st 2009, in 200 morbid obese patients, GB was performed at the Municipal Hospital in Gera, Germany. All patients were carefully selected according to IFSO-Guidelines [3].

Data collection was performed prospectively and analyzed retrospectively.

Preoperative characteristics of the patients are listed in Table 1. The operation was performed in 41 (20.5%) men and 159 (79.5%) women with a mean age of 41.5 years. The preoperative BMI was 47.9 kg/m^2. The mean BMI in men was

Table 1: Demographic data.

	Gender (%)	Age (years)	BMI (kg/m^2)
Men	20.5	41.5	52.0
Women	79.5	41.7	46.8
Total	100.0	41.5	47.9

Table 2: Operation data.

		Patients total	Mean operation time (min)
Total	(n)	200	128.1
Open surgery	(n)	39	117.7
Conversion rate	(n)	12	253.3
Laparoscopic approach	(n)	161	126.1
Perigastric approach	(n)	137	141.3
Pars flaccida technique	(n)	63	99.5

52.0 kg/m^2, which was significantly higher than in women (46.8 kg/m^2).

2.2. Operative Technique and Data. Between February 1st 1995 and June 15th 1997, 39 (19.5%) procedures had been performed by one surgeon using open approach technique.

In June 1997, we started the GB procedure with a laparoscopic technique used in 80.5% of operations (Table 2). From June 1997 to February 2001, all Lap Bands were placed using perigastric approach. This technique was used in 68.5% of patients. Conversion rate of laparoscopic technique was 7.4% during the first 100 laparoscopic operations. After introduction of the pars flaccida technique in March 2001, we performed all GB procedures (31.5%) with the pars flaccida technique by a standardized laparoscopic approach to avoid posterior slippage. The space between the left crus and the band was closed to avoid lateral slippage by a stitch between the greater curvature and the left crus. We formed a small pouch of less than 20 cc. The pouch was secured by 3 to 5 gastrogastric stitches to avoid anterior slippage.

We used 11 SAGB (SAGB; Obtech, Ethicon Endo-Surgery) and 189 Lap-Band bands (INAMED Health, Santa Barbara, CA).

2.3. Postoperative Management. The patients were followed in our hospital. The first consultation and clinical examination was performed six weeks postoperatively and then every three months for the first two years of followup. Followup examinations were performed twice a year or whenever needed after the second postoperative year.

A liquid diet was recommended for the first 5 days postoperatively. A normal diet was introduced thereafter. During each visit, a standardized fup was performed with documentation of weight, eating behavior, and a short clinical examination. Band adjustments were very rare. The band was adjusted only in cases of weight loss less than 2 kg per month or a less than 25% change in the EBWL after 3 months. In the case of discomfort from a normal diet or reflux symptoms, the filling of the band was reduced. The injection volume depended on the weight loss and the patient's tolerance as well as his or her eating behaviors.

Table 3: Reasons for band removal.

Patients	(n)	24
Overall removal rate	(%)	12.0
Discomfort	(n)	5
Excellent excessive weight loss	(n)	1
Migration	(n)	11
Slippage	(n)	2
During cholecystectomy (at out-of-town hospitals)	(n)	2
Peritonitis	(n)	1
Stomach wall necrosis	(n)	1
Epiphrenic esophageal diverticula	(n)	1

3. Results

3.1. Followup. Followup data were available from 83.5% of patients. The mean followup time was 94.4 (6–144) months.

3.2. Slippage. The slippage rate was 2.5% ($n = 5$). After an open approach in 3 patients, slippage occurred with a mean followup time of 10.3 (1–24) months. After laparoscopy in 2 patients, slippage occurred with a mean followup time of 18 (12–24) months. The operation was performed in all patients in perigastric approach. After introduction of pars flaccida technique, slippage rate decreased to zero.

3.3. Pouch Dilatation (PD). During the postoperative course, the great majority of our patients developed PD (9.5%, $n = 19$). A total of 12 patients were operated on by an open technique, and 7 patients underwent a laparoscopic technique. After introduction of the pars flaccida technique, pouch dilatation no longer occurred.

3.4. Band Migration. Band migration occurred in 5.5% ($n = 11$) of cases. In all patients, the operation was performed using a perigastric placement of the band.

3.5. Band Removal. Band removal was performed in 24 (12%) patients. Five patients wished to have the band removed due to discomfort. In one patient, the band was removed due to her excellent excessive weight loss. In 18 patients, the band had to be removed in case of long-term complications such as band migration in 11 cases and slippage in 2 cases. In 2 cases, the band was removed at an out-of-town hospital without any described reason after a cholecystectomy. Epiphrenic esophageal diverticula, gastric wall necrosis, and acute peritonitis were the reasons for band removal among the other patients (Table 3).

3.6. Reoperation. Among the above-mentioned complications, 61 (30.5%) patients required reoperation. In 5

Table 4: Overall reoperation rate

	(n)	(%)
Removal rate without slippage and migration	9	4.5
Slippage	5	2.5
Pouch dilatation	19	9.5
Migration	11	5.5
Disconnection	9	4.5
Reoperation due to failure	8	4.0
Patients in total	61	30.5
Reoperation rate per year of FUP		2.2

patients, the band was explanted without any substitution. The total number of patients requiring reoperation was significantly higher in the open approach group (31.3%, $n = 43$) versus the pars flaccida group (3.2%, $n = 3$). Data for reoperation are shown in Table 4. The reoperation rate was 2.2% per year.

3.7. Weight Loss after Gastric Banding. Weight loss after gastric banding is summarized in Table 5.

3.8. Changes in Comorbidities. During the postoperative period, 85.7% of patients who had previously suffered from diabetes prior to bariatric surgery could significantly reduce their insulin doses. In 14.3% of patients, diabetes was resolved, completely. Amelioration of hypertension was observed in 82.2% of patients.

3.9. Postoperative Mortality. There was no early postoperative mortality.

During the followup period, four patients (3 female and 1 male) died. The mean age of these patients was 64.1 (range 50.5–70) years. Two patients died due to their severe comorbidities 6 months and 96 months after GB. One patient died due to gastric cancer 36 months after GB [4]. Another woman died after repair of an abdominal wall hernia 132 months after band implantation.

4. Discussion

GB is beside RYGBP the most frequently performed bariatric operation worldwide. According to the data of a meta-analysis study, this procedure has been carried out in 95% of countries performing bariatric surgery [5].

When GB was introduced, the results were excellent in comparison with other restrictive bariatric procedures.

In the literature, only a few prospective randomized studies have been reported. These studies compared GB with RYGBP or/and SG. In addition, randomized trials comparing different kinds of bands (low- and high-pressure bands) were also performed. Single center studies report data with low evidence on the complication rates, outcome, and amelioration of comorbidities. In general, patient's outcome after GB is influenced by the incidence of long-term complications. These include slippage, pouch dilatation, and band migration as well as port-site complications and esophageal dilatation. Nevertheless, there are only a few studies examining long-term results with a time period longer than 10 years available in the literature.

In our clinical experience, the results obtained after 14 years show a high complication rate and a weight regain after the 5th year of followup. These data are comparable with data published by Lanthaler et al. [6]. In their data describing young patients, weight loss was very successful within the first 4 years postoperatively [6]; thereafter, the BMI increased slowly. However, the reason for weight regain after that time was not described in detail. In our experience, most of the patients change their eating behaviors to liquids and sweets leading to a high calorie intake.

Nevertheless, an improvement in obesity-related comorbidities was observed in most patients. However, complete resolution of diabetes was less than reported in a published meta-analysis [4]. Reasons for this difference may have been the high BMI of our patients and the early onset of diabetes prior to surgery.

In our retrospective examination with preoperative data collection, the majority of our patients were female, which is consistent with data from the literature [5, 6]. The BMI (47.5 kg/m^2) in our patients was higher than in most published studies due to the reimbursement problems of bariatric surgeries in Germany.

4.1. Slippage and Pouch Dilatation. Over time, the complication rates for incidences of slippage and pouch dilatation decreased. The drop in the complication rate was the result of a switch from the perigastric to a pars flaccida technique as well as the introduction of next generation bands and the development of band devices especially made for the connecting tube and the port system.

In fact, there was a decrease in the slippage rate from 3.6% in the perigastric approach to 0% in the pars flaccida technique [7].

Pouch dilatation is a long-term complication after GB. The incidence of pouch dilatation is influenced by the surgical approach (open versus laparoscopic) and the technique (perigastric versus pars flaccida). Opening the lesser sac during open band placement leads to a higher incidence of pouch dilatation than the laparoscopic approach, which creates a small retrogastric channel. Data in the literature examining the incidence of pouch dilatation are mostly heterogeneous because most studies include different approaches and techniques. Otherwise, there are only a few reports with a followup period of more than 5 years.

4.2. Band Migration. Intragastric band migration is characterized by a "silent" migration of the band into the stomach [8, 9]. Peritonitis symptoms are usually absent, and there are limited retrospective data obtained from long-term studies available [10, 11]. The incidence of band migration ranges from 0.6% to 14.4% according to the literature [10–13]. In a few studies, band migration has been considered as a complication associated with the first 2 postoperative years, which is caused by intraoperative gastric perforation [6, 14–16].

Table 5: Excess body weight loss in comparison with literature.

Author	Year	n	EWL in %							
Years of FUP			1	2	3	5	8	10	12	14
Belachewet al. [24]	2002	763	40	50.0				50		
O'Brien and Dixon[25]	2002	706	47	52	53.0	57.0				
Weiner et al. [26]	2003	984					59.3			
Martikainen et al. [27]	2004	123	36	38		30.0				
Biagini and Karam [28]	2008	591	66.7	72.6			82.3			
Strohet al. [2]	2009	200	40.2	46.3	45.9	41.9	33.3	30.8	33.3	15.6
			$n = 175$	$n = 157$	$n = 147$	$n = 122$	$n = 80$	$n = 53$	$n = 15$	$n = 1$

In our data, most patients with band migration had an uncritical uptake of nonsteroidal antirheumatic agents, bronchospasmolytic drugs, and anticoagulant substances. Specifically, 26.6% of patients were treated with nonsteroidal antirheumatic substances, 20.2% with anticoagulant substances, and 0.6% with bronchospasmolytic drugs. Therefore, in our opinion, these medications should be considered as potential causes of band migration. Chronic inflammation at the tissue area covered by the band could be a further reason for developing erosion. In our experience, band migration occurs by 30–86 months postoperatively [17]. In addition, the erosion rate has been shown to increase over the long-term followup period [18].

Band erosion can lead to a life-threatening condition in cases of upper gastrointestinal bleeding and bowel obstruction. Therefore, finding a correct diagnosis is essential. In our study, we did not see any port infection in the first 3 postoperative months and after band filling. In the literature, port infection has been reported to be the first symptom of erosion [19]. However, our own data revealed varying intervals between the onset of port infection and the occurrence of erosion.

Thus, the treatment depends on symptomatology. We favor band removal in cases of complete erosion using gastroscopy and an AMI Band Cutter (CJ Medical, Buckinghamshire, Great Britain) [17].

In the literature, a correlation of erosion rate with the band type (high-pressure versus low-pressure bands) has not been described [20].

At the end of the 1990s, repositioning of the band in cases of slippage and pouch dilatation was widely performed. However, data from our study indicated a higher incidence of gastric band migration, and data in the literature have shown disappointing results [17, 18, 21]. Thus, in cases of slippage and pouch dilatation, most published results and our findings reveal no indication for rebanding [18]. We believe band removal in cases of erosion accompanied by a simultaneous "rebanding" should not be performed because there is a potential risk of infection of the new band. This conclusion is based on the different causes of band erosion, a significantly higher migration rate following intraoperative gastric perforation and the currently available data in the literature. In addition, because of the high failure rate after band revision, a conversion to a Roux-en-Y gastric bypass or biliopancreatic diversion needs to be considered.

4.3. Amelioration of Comorbidities. According to data from a German nationwide survey on bariatric surgery, our reported patients had a significantly higher age and BMI compared with data obtained in the meta-analysis on bariatric surgery patients [5]. In addition, significantly more patients suffered from type-II diabetes mellitus and arterial hypertension in our study. Thus, the consequential higher rate of comorbidities was due to the occurrence of a severe metabolic syndrome. However, the impact of a high preoperative BMI on weight reduction needs to be investigated through a long-term study.

4.4. Reoperation Rate. The reintervention rate per year of followup in our patients was 2.2%. These data correspond to the literature, which reports a reoperation rate between 3 and 4% per year of followup [18].

4.5. Excess Weight Loss. Concerning the EBWL, the literature reports an EBWL of 47.5% from a meta-analysis study. This meta-analysis reported a progression in weight loss for the first 3 years after GB, which was followed by a stable level of weight loss out to 8 years with no detectable regain of weight [22]. Data of long-term studies with a followup time of more than five years are shown in Table 5. Studies comparing weight loss after perigastric technique to pars flaccida approaches have not shown any influence of operation technique on EWL [23]. GB results in a continuous weight loss during the first 3 years and is sustained for up to 5 years. These results are in concordance with data from the Italian Band Group, but not with weight loss patterns observed in Australian data [14, 23]. We believe the patients in our study had a lower weight loss due to the higher preoperative BMI and the higher incidence of diabetes type II. For better long-term results, we suggest interdisciplinary teamwork to reduce long-term complication rates, increase weight loss, and ameliorate comorbidities.

5. Conclusion

GB has been shown to be a safe and efficient bariatric procedure when performed by an experienced surgeon

using a standardized operation technique. The importance of a close and standardized followup by an experienced multidisciplinary team and the surgeon can result in a decreased complication rate, increased weight loss, and reduced comorbidities.

Furthermore, there are no data in the literature addressing specific criteria, which allow the selection of patients for either restrictive or malabsorptive procedures so as to improve final outcome. To guarantee long-term success after bariatric surgery and to avoid complications, particularly when following combined procedures, lifelong postoperative care is required, which is a specific concern for obesity surgery. Moreover, there is a limited amount of long-term followup data available in the literature and these are from just a few single center studies. Thus, researchers and clinicians should prospectively enroll all patients as indicated by the German multicenter observational study for quality assurance in obesity surgery. This study annually registered parameters such as weight reduction, amelioration of comorbidities, and long-term complications. Subsequently, these data were used to assess the surgical treatment of morbid obesity in Germany [2].

Abbreviations

EWL: Excess weight loss
Fup: Followup
GB: Gastric banding
PD: Pouch dilatation
RYGBP: Roux-en-Y Gastric Bypass.

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