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Long-term Results, Late Complications and Quality of Life in a Series of Adjustable Gastric Banding

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Background: Adjustable gastric banding is currently the most common bariatric operation.This study is a retrospective analysis of the Finnish experience with this procedure over the last 10 years.

Methods: Between March 1993 and June 1999, 123 patients underwent either open (36) or laparoscopic (87) surgery for morbid obesity by the application of an adjustable gastric band. Data on preoperative clinical characteristics and postoperative outcome and weight-loss patterns up to 9 years (mean 55 months) are presented and also evaluated by the Bariatric Analysis and Reporting Outcome System (BAROS). Sex ratio was 31% males / 69% females, mean age 44 years and mean ± SD preoperative BMI 49 ± 8 kg/m² (range 33.6-85.1).

Results: During the evaluation period (March 1993 - December 2002), 54% of patients experienced postoperative complications requiring hospital treatment ≥7 days, and 52% underwent a reoperation. 33% of bands were removed.The most important late complications were esophagitis (30%), obstruction due to slippage / pouch dilatation (21%), incisional hernia (9%) and band erosion (9%). Mean excess weight loss at 1 and 2 year follow-up was 36% and 38%, which later stabilized to 30%. During the evalution period, there were 10 deaths, 2 of which were 30-day deaths, and the remainder were not associated with the band. According to BAROS, the outcome was regarded as "very good" in 3%, "good" in 7%, "fair" in 40% and "failure"in 50%.

Conclusion: Our long-term data found that weight reduction is acceptable, but the incidence of late complications and reoperations was high.

Key words: Morbid obesity, bariatric surgery, laparoscopy, gastric banding, long-term results, BAROS

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Introduction

Morbid obesity (body mass index (BMI) ≥40 kg/m²) occurs in 2-5% of the population of Western countries, and is associated with a high incidence of comorbidities.[1] Demographic studies have revealed an increasing incidence of morbid obesity[2,3] and indicate that this will be a major public health burden in the future. Treatment of morbid obesity by exercise, dietetic and pharmacological measures almost always results in failure,[4] and thus surgical options are increasingly being considered. Three categories of operations can be distinguished: 1) malabsorptive procedures, which reduce the caloric uptake; 2) restrictive techniques which reduce the caloric intake; and 3) combinations of these. Laparoscopic gastric banding is a restrictive operation, which has the advantages that it is readily performed by minimally invasive surgery, is adjustable and can be reversed if necessary.

Many reports of short-term results of adjustable silicone gastric bands have been published; however, there are only a few long-term studies.[5-9] In the long-term studies, the results (follow-up 1-7 years) have been favorable with respect to BMI decrease and number of complications and re-operation rates.[5-9] However, some other studies are less favorable, and report high rates of long-term (2 to 8 years) postoperative complications and side-effects, and indicate that there is a progressive loss in efficacy to maintain the decreased BMI.[10,11] Accordingly, the long-term outcome of gastric banding is still ambiguous. Since this procedure is

relatively expensive, it is important to assess its efficacy. Thus, we evaluated the long-term results of gastric banding with mean follow-up 55 months from our center in Finland, with the patients treated by a multidisciplinary team.

Patients and Methods

Patients

Between March 1993 and June 1999, 123 consecutive patients (38 males, 85 females) with morbid obesity underwent gastric banding in the Department of Surgery of Kuopio University Hospital. Mean age of the patients was 44 years (range 20-66 years), mean BMI 49 kg/m^2 (range 34-85 kg/m^2), and mean excess weight 67 kg (range 23-162 kg). Excess weight was defined as the difference between the patient's weight and the theoretical normal body weight. Normal body weight was determined according to BMI 25 kg/m^2. A total of 236 co-morbidity conditions related to obesity were recorded in 106 patients (86%); these included diabetes, hypertension, dyslipidemia, sleep apnea, osteoarthrosis and respiratory disease, and are listed in Table 1. Of the patients, 17 had no co-morbidity. None of the patients had been previously operated for obesity.

Preoperative Management and Evaluation

All patients had participated in long-term non-surgical weight reduction programs before undergoing surgery. They were evaluated preoperatively in the Division of Clinical Nutrition of Kuopio University Hospital by a multidisciplinary team, including surgeon, endocrinologist and clinical nutritionist. Criteria for the bariatric surgery included: age >18 years, BMI >40 or >35 with significant co-morbidities, being obese for ≥5 years, and no acute psychiatric illness or eating disorder. Preoperative evaluation included physical examination, laboratory investigations, gastroscopy and analysis of eating behavior by Bulimic Investigatory Test (Bite).[12] All patients were repeatedly informed about the importance of disciplined diet and eating habits. Information regarding the benefits, risks and side-effects of surgery was discussed in detail with the patients, and this information was also provided in written form. They were encouraged to meet previously-operated patients. The patients were informed of the necessity to undergo postoperative life-long follow-up and the importance to change dietary habits.

Table 1. Preoperative co-morbidity of patients (n=123, males=38, females=85)

	Male n (%)	Female n (%)	All n (%)
Diabetes type 2	15 (40)	25 (29) ns	40 (33)
Hypertension	26 (68)	29 (34) *	55 (45)
Dyslipidemia	21 (55)	50 (59) ns	71 (58)
Sleep apnea	21 (55)	14 (17) *	35 (29)
Osteoarthrosis	2 (5)	14 (17) ns	16 (13)
Asthma	5 (13)	15 (18) ns	20 (16)
Psychiatric diagnosis	4 (11)	12 (14) ns	16 (13)
Hypothyroid (treated)	1 (3)	9 (11) ns	10 (8)

Student's t-test, *P<0.0001 between males and females.

Operative Technique

The surgical procedure was performed according to the technique described by Kuzmak[13] and later by Belachew et al.[14] The first 36 patients were operated by laparotomy. In early years, the adjustable gastric band of Bioenterics from Kuzmak was used. The laparoscopic operation with the 9.75-cm Lap-Band® (Inamed Health, Santa Barbara, CA, USA) was started in August 1995. At the same time, because of high rate of slippages, the technique was modified by starting the dissection above the equator of the inflated (15-20 ml) calibration balloon.[14] The greater curvature was opened just proximal to the first short gastric vessels, tunnelization was perigastric, and at least 4 anterior gastrogastric sutures were used. In 5-10% of patients, the lesser sac was situated so high that we went through the sac. Until 1995, the stoma was first calibrated during the operation by the electronic sensor of the calibration tube. Later, 2 ml of saline was first instilled 6 weeks after the operation and thenafter on demand.

Postoperative Treatment

Patients were asked to eat only liquid food for about 6 weeks after the operation, after which they could carefully return to normal food. All patients were

asked to attend the outpatient clinic 6 and 12 months postoperatively, and thereafter annually or every second year for a check-up by a physician and for nutritional counselling by a nutritionist. Percentage of excess weight loss (%EWL), complication- and reoperation-rates, and changes in co-morbidity were recorded at each visit. The analysis of improvement in medical conditions was made according to the BAROS system,[15] so that the disorder was "recovered" when controlled without medication and "improved" when controlled by reduced doses of medication.

Additional filling of the band was based on clinical evaluation of symptoms and weight loss at follow-up. Until 1999, the patients underwent gastroscopy only when they were symptomatic. Since 2000, all patients have been gastroscoped annually because of the high rate of long-term complications.

Predictors of Outcome

Age, gender, preoperative BMI, the presence of type 2 diabetes, and results of the Bite questionnaire were considered as potential predictors of outcome and were associated with the %EWL and with the presence of major complications.

BAROS System

Changes in excess weight loss, obesity-related co-morbidities, and quality of life (QoL) were also assessed by the Bariatric Analysis and Reporting Outcome System (BAROS).[15] To assess the changes in QoL after surgery, the questionnaire evaluated five variables: self-esteem, physical condition, social life, working ability and sexual activity. Points were deducted for reoperations and defined complications. The system defined five outcome possibilities: failure, fair, good, very good and excellent. A postal BAROS questionnaire was sent to all patients who still had a functioning band in October 2002.

Statistical Analyses

Data are expressed as mean ±SD. Differences between repeated measures were evaluated with paired t-test. Differences between the groups were evaluated by Student's t-test, and categorial parameters were compared using chi-square. Some variables were correlated with %EWL (Pearson's two-tailed). Statistical significance was set at $P<0.05$.

Results

The evaluation period was from 1993 to 2002, ranging from 8 to 108 months (mean 55 months). During the evaluation period, there were 10 deaths, two of which were 30-day deaths, one from gastric perforation and one from respiratory insufficiency. The remaining 8 deaths were not related to surgery (myocardial infarction, stroke, traffic accident, breast cancer, alcoholic and narcotic abuse). Forty bands (33%) were removed. Thus, at the end of the follow-up period, 73 subjects still had a functioning band. BMI and %EWL are reported only for those subjects with functioning bands. Follow-up data were obtained in 120, 108, 91, 86, 63, 44, 32, 16 and 3 patients at 1, 2, 3, 4, 5, 6, 7, 8, 9 years, respectively. Five patients were lost to follow-up.

Weight Loss

Postoperative reduction in BMI after 1 year was 8.1 ± 5.4, after 2 years 8.7 ± 6.8, after 3 years 7.5 ± 5.8 and after 9 years 4.7 ± 1.1 kg/m^2, respectively. Average weight losses and gains are shown in Table 2. The largest average weight loss achieved during the follow-up period was 30 kg, representing a 44.6 %EWL. After 1-3 years, most patients started to regain weight, and the final average weight decrease from baseline was 19.5 kg. Postoperative %EWL (Figure 1) varied from 36 ± 24% 1 year postoperatively, to 21 ± 5% at 9 years, respectively. At the end of the evaluation period, 11 patients (9%) achieved a 75 %EWL, 16 patients (13%) 50-75 %EWL, 36 patients (29%) 25-50 %EWL and 49 patients (40%) 0-25 %EWL. Eleven patients (9%) gained weight in spite of a functioning band. In two patients, the operation was converted to a gastric bypass, and the further weight loss was excellent.

Outcome of Co-morbidities

Table 3 demonstrates the outcomes of co-morbidities in patients with follow-up ≥1 year, except the

Table 2. Weight losses and gains in 120 patients after gastric banding (follow-up ≥1 year)

	Preoperative value	Lowest postoperative value	Most recent value
Average body weight (kg)	138.0 ± 26.0	108.3 ± 24.8*	118.5 ± 29.7*
Range	90.5 - 229.0	57.2 - 179.7*	67.1 - 234.0*
Body Mass Index (kg/m^2)	48.8 ± 8.6	38.3 ± 8.3*	42.0 ± 10.3*
Range	33.6-85.1	21.3 - 64.7*	26.2 - 87.0*
Average Excess weight (kg)	67.2 ± 24.2	37.6 ± 23.3*	47.7 ± 28.7*
Range	23.3-161.8	-10.0 - 106.8*	3.1 - 166.8*

Mean ± SD. *Paired samples t-test, $P<0.0001$ from preoperative value

incidences of asthma and arthrosis for which data were missing. There were a total of 199 co-morbidities in 106 patients preoperatively. Of these conditions, 75 (38%) were improved or recovered, but 87 (44%) remained unchanged. In 34 patients (17%), the co-morbidity conditions worsened.

Complications

During the follow-up time, 74 of 123 patients (63%) experienced complications (Table 4). Early (during hospitalization) postoperative complications occurred in 19 patients, including gastric perforation (four cases), pneumonia (four cases), pulmonary emboli (two cases), wound infections (five cases), intra-abdominal bleeding (one case), peripheral deep venous thrombosis (one case), respiratory insufficiency in one patient and two cases of dehiscence. After the open operation, five patients needed early postoperative intensive care.

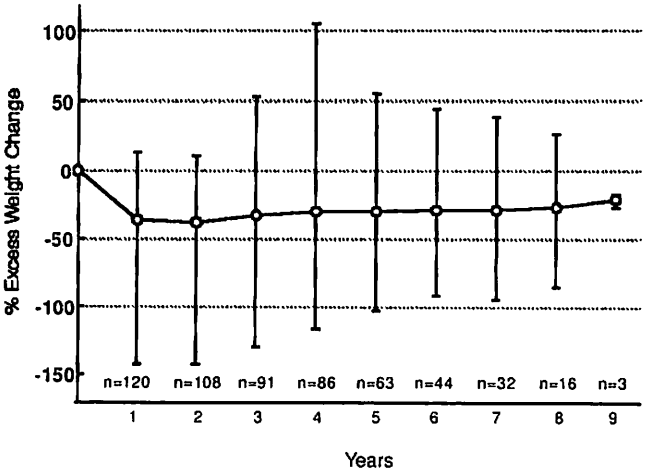

Figure 1. Excess weight loss (%) from 1 to 9 years (mean and range). Includes only patients with a functioning band.

With respect to major complications, band erosion occurred in 9% of the patients (Table 4). In addition, slippage occurred in one-fifth of the patients. The change in suturing technique did not decrease the rate of slippages. Also, 11 incisional hernias were found, all after laparotomy. Esophageal dilatation was detected in 4 patients, and 6 patients suffered recurrent pneumonias due to aspiration. Two patients experienced vitamin / mineral deficiency, vitamin B deficiency and potassium imbalance due to persistent vomiting.

Reoperations

Removal of the band was performed due to slippage /pouch dilatation /obstructive problems in 24 patients. The reasons for the other band removals were erosion (11 cases), problems concerning band function (2 cases), and infections (3 cases). In 27 of the 123 patients (22%), the band had to be repositioned, and in 5 patients (4%), it had to be replaced. Access-port problems (displacement or rupture) occurred in 23 patients (19%). In all, 52% of patients had to undergo a new operation.

Predictors of Outcome

Age, gender, preoperative BMI, the presence of type 2 diabetes or points in the Bite questionnaire showed no significant correlations with %EWL. Gender was the only predictive factor for complication- and reoperation-rates. Males had significantly fewer major postoperative complications, and underwent few reoperations (10/8, 29%) than females (44/45, 64%, $P<0.001$).

Table 3. Outcome of co-morbidity symptoms (follow-up = 1 year, n=106 patients)

Variables	Number of preoperative co-morbidities n (%)	Recovered† n (%)	Improved†† n (%)	Stable n (%)	Worsened n (%)
Diabetes	40	8 (20)	4 (10)	13 (33)	15 (38)
Hypertension	55	7 (13)	12 (22)	23 (42)	13 (24)
Dyslipidemia*	71	20 (28)	10 (14)	30 (42)	6 (8)
Sleep Apnea**	35	5 (14)	9 (26)	21 (60)	-
All diagnoses	200	40 (20)	35 (18)	87 (44)	34 (17)

†Controlled without medication.
††Controlled with reduced doses of medication.
*Follow-up data is missing in five cases.
**1 year after operation.

Evaluation by BAROS

A postal BAROS questionnaire was sent to all patients still having a functioning band in October 2002. Out of these 73 patients, 62 (85%) returned the questionnaire. The outcome by the BAROS is shown in Table 5. Concerning the quality of life questionnaire, 42 (68%) considered that their QoL was improved, whereas for the other 20 (32%), QoL was similar to (8) or had worsened (12) after surgery. QoL did not differ between genders.

Table 4. Postoperative complications (n=123 patients)

Complications	n (%)
- severe wound / access-port infection	7 (5)
- dehiscence	2 (1)
- gastric perforation/intraperitoneal hemorrhage	4 (3)
- incisional hernia	11 (9)
- band erosion (requiring reoperation)	11 (9)
- pneumonia	10 (8)
- pulmonary embolism	2 (2)
- seroma, minor wound/skin infection	7 (6)
- gastro-gastric fistula	3 (2)
- slippage	26 (21)
- pouch dilatation (without slippage)	10 (8)
- esophageal dilatation	4 (3)
- esophagitis, peptic ulcer*	36 (29)
- electrolyte imbalance, vitamin-deficiency	2 (2)
Total number of complications	135 (100)
Patients without any complications	43 (35)

*new cases

Discussion

Weight loss after restrictive operations is usually less than after malabsorptive operations. In comparison with other recent long-term studies,[5,7] our weight loss results were modest. In the short-term (e.g. follow-up 1 year), weight loss was impressive (36 ± 24 %EWL), but later, only 50 patients (40%) maintained the weight loss, in agreement with other studies.[5-9] Many patients started to regain in spite of our regular follow-up protocol and nutritional counselling.

A number of unfavorable prognostic factors have been identified in the literature. These include increasing age, increasing preoperative BMI and diseases associated with insulin resistance and type 2 diabetes.[16] However, a number of co-existing conditions have been found to have no relation with the weight loss, e.g. sex, several co-morbidities and previous bariatric surgery.[16] In this study, age, gender, preoperative BMI or type 2 diabetes had no relation to weight loss after surgery, nor to the scores in the

Table 5. BAROS scores (n = 62)

	n (%)	Scores	Outcome
Failure	31 (50)	-4.45 - 1.00	Failure 50%
Fair	24 (39)	1.10 - 3.00	
Good	4 (6)	3.50 - 5.00	Success 50%
Very Good	3 (5)	5.30 - 6.80	
Excellent	-	-	

Bite questionnaire. In comparison with other long-term studies,[5-9] our patients were older (mean age 44 compared to 34-40 years) and the preoperative co-morbidity rate was markedly higher. Accordingly, these results suggest that young subjects without any or with only a few co-morbidities may benefit from gastric banding. However, morbidly obese patients with co-morbidities constitute the target population for bariatric surgery. Therefore, pros and cons of bariatric surgery should be carefully evaluated.

Most,[5-9] but not all[10,11] studies indicate good short- and long-term results with only a few complications and need for reoperation, and in most cases, there is no mortality. The overall complication / reoperation rate has been 19%.[8,17] In this study, about 60% of all patients experienced major or minor complications, and 52% needed some kind of reoperation. One in every three of all 123 inserted bands had to be removed. These figures are greater than in most previous studies with short follow-ups. In spite of the high overall complication rate in the present study, the early postoperative morbidity was not very high. Age, preoperative BMI, the presence of type 2 diabetes or Bite score value did not affect the complication and reoperation rates. However, males had fewer complications and reoperations than females, in spite of the fact that they had significantly more preoperative co-morbidities (sleep apnea and hypertension) than women.

Band erosion is a serious late complication after gastric banding and requires band removal. It occurs usually between the first and second year after the surgery, and the incidence has varied from 0.3 to 11%.[10,17,18] In our study, the number of erosions was comparable to most previous studies.[5-7] Most of the erosions occurred in patients operated during the first 3 years of this study, but they occurred later than in the previous studies, even 4-8 years after banding. Because of the high rate of erosions, all patients need to be followed with annual gastroscopies, which adds substantial cost to this procedure in the long term.

Band slippage and pouch enlargement are the most frequent complications after gastric banding, but improvement in surgical technique (suturing and high band placement) and better patient selection have made it possible to decrease the rate of this complication.[19] In some studies, the reoperation rate due to slipping or pouch enlargement has been only 5-6%.[5,8] Late band slippage was also the most important complication in our study. However, the change in suturing technique did not decrease the amount of slippages. Almost all slippages occurred in females (23/26), but we could not find any variable to account for this gender difference. It could be argued that a high score in the Bite questionnaire indicating bulimic eating could be a predictor of a high slippage rate, but there was no connection between these variables. All patients were repeatedly instructed to eat slowly and to take regular small meals to avoid pouch dilatation and slippage. The newer techniques, higher retrogastric tunneling and the learning curve may decrease slippage. However, in two of our dorsal slippages, the bands were situated proximal to the bursal reflection.

In addition to weight loss, rate of complications and reoperations, and changes in co-morbidities, the QoL is also an important variable when evaluating outcome. BAROS is an evidence-based, unbiased and easily performed scoring system with a disease-specific instrument to analyze QoL.[15,20] According to the QoL questionnaire in the present study, 42 patients (68%) indicated that their QoL had improved and 20 (32%) that their QoL was similar to (8) or worsened (12) after surgery. When considering the marked preoperative obesity and the large number of co-morbidities and the complications with the procedure, this outcome can be deemed as favorable.

According to BAROS, 50% of our treatments were "failures", and only one of 10 operations resulted in a good or very good result. We did not have any excellent outcomes. This result is very different from previous results published.[7,21] In a prospective study, Zinzindohoue et al[8] investigated 500 Lap-band® patients for up to 4 years, and failure was found in only 6%, a fair result in 18%, good in 49% and excellent in 27%. Also in other studies, the scores have been markedly higher.[21,22] In our study, the complications and reoperations in the long-term are the most important reasons for the poor result in the BAROS questionnaire.

BAROS is a valuable tool to evaluate bariatric treatments. It allows one to compare the results of different procedures by different surgeons in different countries. However, there is the problem that Oria and Moorehead did not define the "normal" or

"ideal" weight. In our study, the ideal body weight was determined according to BMI 25 kg/m^2. Zinzindohoue et al[8] used the Metropolitan Life Insurance Tables (1983), and in some studies the authors do not define "ideal weight" at all. If the ideal weights differ, the BAROS scores may not be comparable.

The scoring system does not fully replace clinical evaluation. An example for the scoring bias from the present study is presented as follows: *The patient is young, does not have any co-morbidities, and QoL before surgery is good. Five years postoperatively, the patient has a 48% EWL (1 point), the medical condition is unchanged (0 point) and QoL is still good (0 point). Postoperatively, there was one major complication (deduct 1 point). Thus, the final score is 0 point, which means that the result is classified as a failure.*

Most gastric banding studies indicate good short- and long-term results with only a few complications and need for reoperation. In the others, including the present study, the result is poor. More long-term studies are needed to evaluate the efficacy of this procedure.

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