Clinical outcome of gastric banding and gastric bypass in morbidly obese patients

Wouter te Riele

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Clinical outcome of gastric banding and gastric bypass in morbidly obese patients

Klinische resultaten van maagband plaatsing en maagomleiding bij patiënten met morbide obesitas

(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Utrecht op gezag van de rector magnificus, prof.dr. G.J. van der Zwaan, ingevolge het besluit van het college voor promoties in het openbaar te verdedigen op woensdag 21 december 2011 des middags te 2.30 uur

door

Wouter Wim te Riele

geboren op 22 februari 1977 te Hilversum

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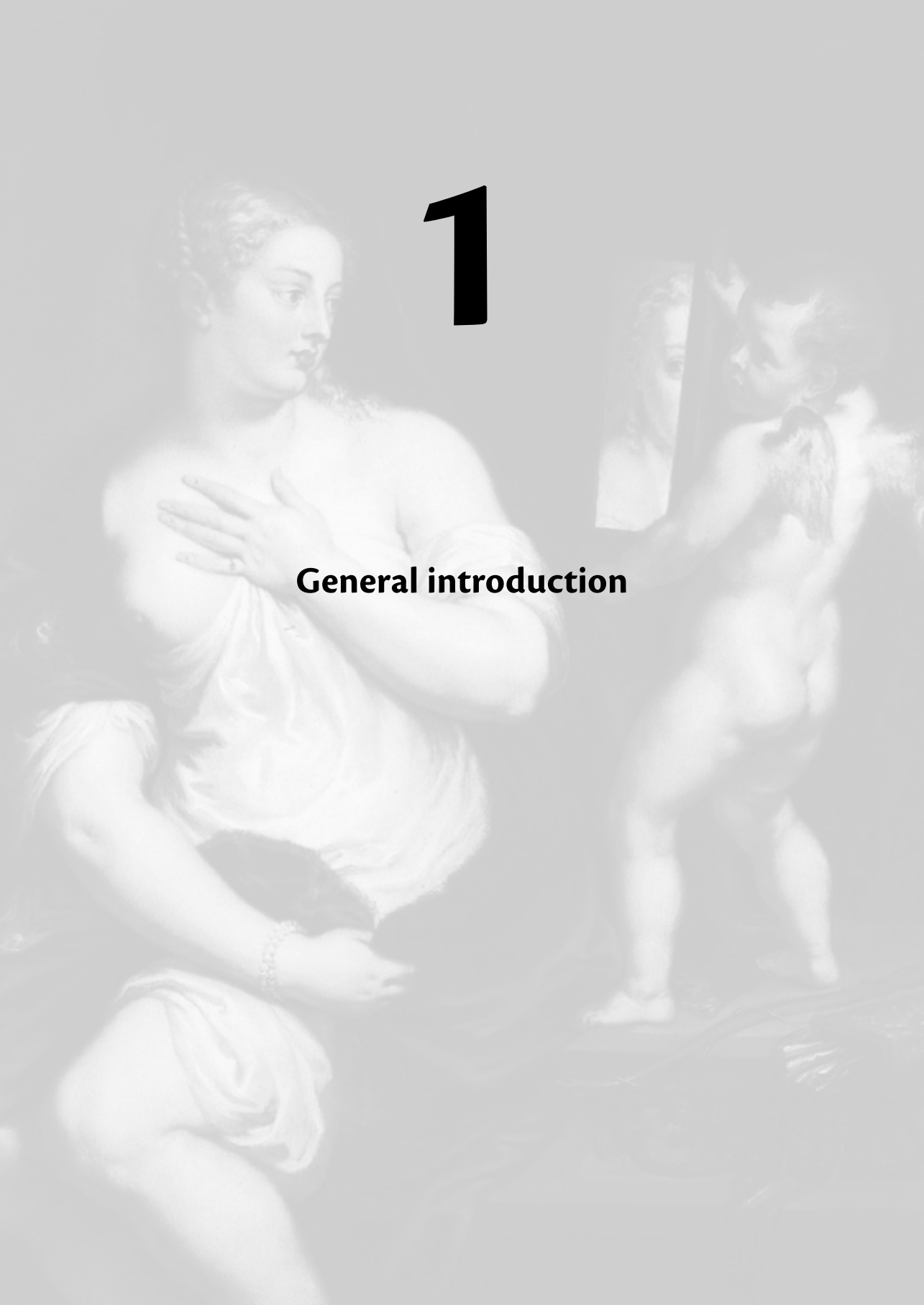

1

General introduction

Obesity: the problem

Since the 1960's obesity has become a global problem and an obesity epidemic has risen. Except for the African continent, obesity has spread around the world and is not limited to Western society. In the year 2000 obesity was officially declared a chronic disease by the World Health Organization.[1]

Obesity is classified by means of the body mass index (BMI: weight/(height^2). Normal weight is defined as a BMI 20-25 kg/m^2, overweight as a BMI 25-30 kg/m^2, obesity as a BMI 30-40 kg/m^2 and morbid obesity as a BMI > 40 kg/m^2.

The International Obesity Task Force estimates that at present at least 1,2 billion adults are overweight (BMI > 25), including 312 million who are obese (BMI > 30).[2] The National Health and Nutrition Examination Survey, showed prevalences of obesity in the U.S. of 34%.[3] Forecasts of Stewart and Wang suggest that if past trends continue, almost half the U.S. adult population will meet the WHO criteria for obesity by 2020.[4,5] On the other hand, there are some indications that the obesity epidemic is levelling off since the late '90's. A very recent systematic literature review by Rokholm et al. resulted in 52 studies from 25 different countries, which supported an overall levelling off since the late 90's of the epidemic in children and adolescents from Australia, Europe, Japan and the USA.[6]

The increasing prevalence of obesity is a public health threat as it is related to medical, physical, psychological, social and economic chronic comorbidities and disabilities. Overweight and obesity are associated with hypertension, glucose intolerance, dyslipidemia, and obstructive sleep apnea. Moreover, obesity is associated with an increased risk of death from cardiovascular disease, diabetes, kidney disease, and obesity-related cancers (colon, breast, esophageal, uterine, ovarian, kidney, and pancreatic).

Overweight and obesity are directly associated with increased all-cause mortality.[7] Estimates suggests that obesity accounts for 5-15% of deaths each year in the U.S. The number of deaths per year attributable to obesity is roughly 30.000 in the United Kingdom and 300.000 in the United States, where obesity is set to overtake smoking as the main preventable cause of illness and premature death.[8]

Cause of obesity

Traditionally recognized causes of obesity are behaviour and environmental causes such as diet, exercise, cultural practices and stress. More recently it has been suggested that the causes of obesity are heterogeneous and genetic inheritance and possibly viral infections may also contribute to the increasing incidence of obesity.[9]

The main causes of the obesity epidemic seems clear: overeating, especially of foods rich in fats or sugars and a progressive decline in physical activity. A modern lifestyle favouring sedentary

behaviour and easy access to low-cost energy dense food supply is held responsible. This possible cause is stated in the energy balance equation which indicates that energy input equals energy output, so that the balance is zero. A positive imbalance implies that the surplus of energy is stored as tissue mass.[10]

Data from recent large studies in twins suggest a strong genetic influence on obesity, regardless of the force of the obesogenic environment.[11] It seems that obesity has it roots in the interaction between the environment and a number of genetic factors. Very recently two genetic variations have been revealed that are closely associated with obesity and may contribute to the general predisposition to obesity.[12,13] The concept of genetic influence implies that carrying this particular gene set leads to an increased likelihood of developing obesity. The magnitude of the obesity then depends on particular environmental conditions.

In recent years viral infections have also been recognized as possible cause of obesity. Over the last ten years an experimental group from Los Angeles (USA) demonstrated that a human adenovirus, adenovirus-36 (Ad-36), is capable of inducing adiposity in experimentally infected chickens and mice.[14] In rats increased adiposity was observed due to Ad-36 infection. Recent studies have shown that, in the USA, antibodies to Ad-36 were more prevalent in obese subjects (30%) than in non-obese subjects (11%).

Treatment of obesity

The primary goal of the treatment of obesity is reducing comorbidity by long term weight loss. A weight reduction of 10% already results in a significant decrease in comorbidity. The most frequently used outcome measure for weight reduction is excess weight loss (EWL: amount of kilograms lost since baseline / excess weight). Excess weight is defined as the difference between the patient's weight and the theoretical ideal medium-frame bodyweight. Ideal bodyweight is determined according to Metropolitan Life Insurance Company 1983 height/weight tables.[15]

The first treatment options for morbid obesity are dietary strategies.[16,17] Dietary strategies can be broadly divided into five types: low-fat diets, low-calorie diets, very low-calorie diets, carbohydrate-restricted diets and low-glycemic-index diets. In patients with morbid obesity, reported weight loss after dietary strategies varies from 3-7 kg after 4 years of follow-up.[18,19] Long term data are very limited. The major problem with the first treatment option for obesity is the long term maintenance of weight loss. It seems obvious that weight loss among participants in diet trials will at best average 3 to 6 kg after 2 to 4 years. Although for some people a diet and exercise can lead to reduction in weight gain, for many people this is not enough and weight loss can not be maintained.

The second treatment option for morbid obesity is medical therapy. The aim of therapeutic agents is to reduce food consumption or increase energy utilization. This treatment modality focuses on central neuronal circuits involved in energy homeostasis and the opportunities these offer for

pharmacological intervention to reduce feeding behaviour and reduce weight gain. One of the most used therapeutic agents is sibutramine. Sibutramine is a serotonin/noradrenaline reuptake inhibitor. It acts by increasing noradrenaline and serotonin levels in cerebral regions associated with energy homeostasis.[20] Rucker et al. performed a meta-analysis of 30 weight-loss drug trials of 1–4 years in duration.[21] The meta-analysis contained 10 studies of sibutramine (n = 2,623). Compared with placebo, sibutramine reduced weight by 4.2 kg (3.6–4.7 kg). Sibutramine-induced weight loss was accompanied by a significant reduction in high-density lipoproteincholesterol and triglycerides, but raised heart rate and blood pressure.

Clinical experience with existing medical treatments suggests that weight loss produced by any one agent is limited and rarely exceeds 10% of the starting weight. Based on animal data, novel approaches targeting specific neuronal pathways within the hypothalamus, offer an opportunity for weight reduction.[22] However, these approaches are at an early stage and clinical studies will be needed to determine if these approaches lead to clinically meaningful weight loss and improvements in comorbid conditions such as diabetes and cardiovascular disorders.

The third treatment option for morbid obesity is bariatric surgery. In 1991, the National Institute of Health Consensus Panel on Gastric Surgery for Severe Obesity defined the population who would most likely benefit from bariatric surgery. These same criteria continue to be used nowadays to determine which patients should undergo weight loss surgery. These recommendations include patients who have a BMI greater than 35 kg/m^2 with significant comorbid conditions such as diabetes, hypertension or obstructive sleep apnea and patients who have a BMI greater than 40 kg/m^2 with or without any significant comorbid conditions.[23]

The effect of bariatric surgery is based on two principles: restriction or malabsorption. Restrictive procedures decrease the reservoir function of the stomach which leads to a limited possibility of food intake. Malabsorptive procedures generate a decrease of enteric digestion of food. This is accomplished by bypassing a part of the small bowel and hereby diminishing the working of digestion enzymes.

The two most performed bariatric procedures worldwide nowadays are laparoscopic adjustable gastric banding (LAGB) and the (laparoscopic) gastric bypass (GB). The working of the gastric band is based on the principle of restriction. The adjustable gastric band was first developed by Kuzmak in the early '90's and soon after the introduction, the procedure was performed completely by laparoscopy.[24] It includes a saline-filled bladder within a band that encircles the upper portion of the stomach. The saline-filled bladder is attached to tubing that is connected to a reservoir which is fixated in the subcutaneous tissue. The band that encircles the stomach creates a small proximal gastric pouch. The inflatable bladder is adjusted through accessing the reservoir. The outflow through the band is adjusted through adding saline through the subcutaneous reservoir. The band hereby limits the possibility of food intake. The (laparoscopic) gastric bypass is a procedure that combinese a slight malabsorption with restriction. The restrictive component entails creating a 20-30 ml gastric pouch just below the gastroesophageal junction. This pouch is divided from

the lower remnant stomach. The jejunum is then divided 30 to 50 cm distal to the ligament of Treitz, and the distal side of this division brought into the upper abdomen and anastomosed to the gastric pouch. The proximal jejunal limb is then anastomosed back to the jejunum 75 to 150 cm from the gastrojejunal anastomosis. This technique provides the malabsorptive component of the operation by preventing the mixing of food and digestive enzymes as food or drink traverses the Roux limb. The effect of the gastric bypass is partially caused by the duodenal bypass effect: excluding the duodenum from nutrients improves glucose homeostasis. There is also a positive effect on weight loss by the delivery of undigested nutrients to the more distal bowel.

The primary goal of bariatric surgery is reducing comorbidity by long term weight loss. Buchwald et al performed a systematic review and meta-analysis describing the results of the different bariatric procedures.[25] An excess weight loss of 48% (41%-54%) for patients who underwent gastric banding and 62% (57%-67%) for patients who underwent gastric bypass was reported.

After LAGB and GB, resolution or significant improvement of diabetes was reported in 48% and 84%, resolution of hypertension in 43% and 68%, improvement of hyperlipidemia in 71% and 94%, and resolution or improvement of sleep apnea in 56% or 94% of the patients, respectively. The Swedish Obese Subjects (SOS) study prospectively followed 2010 patients undergoing bariatric surgery and 2037 matched patients receiving conventional obesity treatments.[26] After 10 to 15 years, the surgical patients had a 24% reduction in mortality, as compared with the control subjects.

In general, LAGB has less severe complications compared to gastric bypass. Most important complication after LAGB is herniation of the distal stomach through the band (fundus herniation, 3-15%) for which a reoperation is often required. The treatment consists of rebanding (repositioning or replacement of the band) or conversion to a secondary malabsorptive procedure. Most important complication after GB is leakage of the gastrojejunal anastomosis which can be treated by stenting of the leakage and/or drainage of the leakage percutaneously or by laparotomy. Buchwald et al. found operative mortality (<30 days) of 0.1% for LAGB and 0.5% for GB.

The work by Buchwald is the most frequent cited data on results of bariatric surgery. However, the follow-up period for the different procedures was unclear. Long term reports on the outcome of the different bariatric procedures are scarce. In general, weight loss seems better and more durable after malabsorptive procedures, to the extent of more severe complications because of the more invasive character of these procedures. A continuing debate is going on which procedure is preferable for the obese patient. Some surgeons strongly prefer LAGB because of the safety and the reversibility of the procedure. Others argue for gastric bypass because they believe long term outcomes fall short in patients who undergo LAGB and there is a high reoperation rate and the need to conversion of banding to a malabsorptive procedure.

In 1995 bariatric surgery was introduced in the Sint Antonius Hospital, Nieuwegein, the Netherlands. LAGB was started in 1995. In 2002 open gastric bypass was introduced, and from

2005 the laparoscopic gastric bypass has been performed. This cohort of patients over a 15 year period has been the basis of the studies presented in this thesis.

Aims of this thesis

The central theme of this thesis is the safety and effectiveness of laparoscopic adjustable gastric banding and (laparoscopic) gastric bypass. The studies presented in this thesis were guided by the following questions:

- What are the results of laparoscopic adjustable gastric banding in terms of weight loss and complications? *(Chapter 2)*
- What are the results of laparoscopic adjustable gastric banding in patients who are not attending regular follow-up? *(Chapter 3)*
- Is continuing of band therapy in case of band slippage after laparoscopic adjustable gastric banding associated with failure in therapy? *(Chapter 4)*
- What are the results of gastric bypass in terms of weight loss and complications? *(Chapter 5)*
- How many patients are treated successfully and what is the morbidity after laparoscopic adjustable gastric banding compared to gastric bypass? *(Chapter 6)*
- Is secondary gastric bypass after failed primary laparosopic adjustable gastric banding as safe and effective as primary gastric bypass? *(Chapter 7)*
- What are the results of reconstructive surgery following succesful bariatric surgery in terms of physical and psycho-social well-being and quality of life? *(Chapter 8)*

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2

Sustained weight loss 2 years after laparoscopic adjustable gastric banding for morbid obesity

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Ned Tijdschr Geneeskd, 2007

Abstract

Objective

To analyse the results of the laparoscopic adjustable gastric banding (LAGB) procedure for morbid obesity retrospectively.

Methods

From November 1, 1995 to May 31, 2005, laparoscopic adjustable gastric banding was performed in St. Antonius Hospital, Nieuwegein, the Netherlands, in 411 patients. Inclusion criteria were BMI ≥ 40 kg/m^2 or BMI ≥ 35 kg/m^2 and severe comorbidity with > 2 attempts at weight loss in the past. Selection, inclusion and follow-up were performed in a specialised, multidisciplinary setting. Weight, and complications were prospectively recorded and retrospectively analysed. In 1995-2000 the perigastric method was used and in 2000-2005 the pars flaccida method.

Results

The study group consisted of 350 (85%) women and 61 (15%) men with a median age of 38 years (range 17 - 60). Out of these 411 patients, the median weight was 133,4 kg, the median overweight, 69,6 kg and the median BMI 46,3 kg/m^2. Two years after surgery, data was known for 267 patients where 206 (77%) had an excess weight loss > 30%, and 7 patients (3%) a weight gain. The median BMI difference was -10,2 kg/m^2 (range +4,7 - -26,4). The median loss of overweight was 46,3% (range +10,0 - -97,8). The weight loss remained stable in the following years. The most commonly seen complications were fundus slippage (13%) and port-a-cath related complications (7%). These occurred more often after the perigastric method than in the pars flaccida method.

Conclusion

Seventy-seven percent of the patients with morbid obesity who underwent LAGB with a follow-up of > 2 years were succesfully treated. The pars flaccida method resulted in fewer complications than the perigastric method.

Introduction

Obesity is an increasing threat to public health. Approximately half of all Dutch people have overweight (defined as body mass index (BMI) > 25 kg/m^2). Severe overweight or obesity (BMI > 30 kg/m^2) has a prevalence of approximately 10% for men and 11% for women and shows a rising trend over time (National Compass Public Health 2005; www.rivm.nl).[1] The prevalence of overweight children has doubled in recent decades to about 10%.[2]

Obesity is associated with an increased mortality risk (relative risk (RR): 1,8 and 2,5 with a BMI of 35 and 40 kg/m^2, respectively) and severe co-morbidity. This includes cardiovascular disease, diabetes mellitus type 2, dyslipidemia, symptomatic cholelithiasis, gastroesophageal reflux, sleepapnoe syndrome, osteoarthritis and low backpain.[3-6] These co-morbidities may lead to a reduced quality of life.[3]

The treatment of patients with morbid obesity (BMI > 40 kg/m^2) focuses primarily on reducing co-morbidity. A weight reduction of 10% already results in a significant decrease in co-morbidity.[7,8] Because of the limited results of conservative therapy, an increasing attention to bariatric surgery (i.e. the surgical treatment of patients with morbid obesity) has been reported.[9,10] Bariatric surgery has been proven effective for decreasing body weight, thereby reducing risk factors and co-morbidity with improving the quality of life.[11,12] Patients with a BMI > 40 kg/m^2 or BMI > 35 kg/m^2 with serious co-morbidities, with > 2 attempts to lose weight through dietary changes and drug therapy are eligible for bariatric surgery.[6,13]

A frequently used procedure in laparoscopic bariatric surgery is the placement of a gastric band. The initial experience with this surgery was reported in 1991.[14] A Dutch study of 30 patients with a short follow-up of 10 months was already published in 1994 in this journal.[15] In 1995 the laparoscopic adjustable gastric banding (LAGB) procedure was introduced in our hospital. We describe the results of 411 patients who underwent LAGB in a period of 10 years.

Methods

Patients

All patients in the St. Antonius Hospital in Nieuwegein, in the period from November 1995 till May 2005, who underwent a gastric band placement were included in the study. The patients were selected by a multidisciplinary team (internist, psychologist, dietician and surgeon) on the basis of international guidelines for surgical treatment of morbid obesity.[6] These patients fulfilled the inclusion criteria of a BMI > 40 kg/m^2 or BMI > 35 kg/m^2, serious co-morbidities and > 2 prior attempts to weight reduction through dietary changes or drug therapy. The main exclusion criteria were portal hypertension and severe psychiatric co-morbidity.

Surgery

The silicone gastric band is placed laparoscopically near the gastro-esophageal junction. Because the band is on the inside equipped with a balloon, which is connected to a tube and a subcutaneous located port-a-cath system, it is possible to adjust the band diameter by filling or emptying the balloon (Figure 1). During the study period two different gastric bands with similar mechanism of action were used.[16] The first 210 banding procedures were carried out by the perigastric technique, the last 201 according to the pars-flaccida technique.[17] All interventions were performed by one surgeon (BvR).

Figure 1. *Silicone gastric band which is placed near the gastro-esophageal junction. The inside of the band consists of a balloon, which is connected to a tube and a subcutaneously located port-a-cath system. By filling or emptying the balloon, the diameter of the balloon is adjusted.*

Follow-up and data collection

Body weight and complications were recorded in a prospective database. Postoperatively follow-up visits were scheduled every 2-3 months in the first year, every 3 months in the second year, twice yearly for up to 5 years and yearly thereafter.

Outcome Measures

The percentage of successfully treated patients was calculated based on the number of patients with a postoperative follow-up > 2 years. Ideal bodyweight was determined according to Metropolitan Life Insurance Company 1983 height/weight tables.[18] Excess weight was defined as the difference between the patient's weight and the theoretical ideal medium-frame bodyweight.

Successful obesity treatment was defined as an excess weight loss > 30%. We also looked at complications that occurred < and > 30 days after surgery.

Statistical analysis

The Mann–Whitney U test was used to compare continuous variables between groups. The Kruskal-Wallis test was used to compare continuous variables between more than two groups. Categorical variables were compared using the $\chi 2$ test. $P < 0,05$ was considered to indicate statistical significance. Analysis of data was performed using standard software SPSS® version 12.0 for Windows® (SPSS, Chicago, Illinois, USA).

Results

Study Population

In the study period laparoscopic adjustable gastric banding was carried out in 411 patients. The patient characteristics are listed in Table 1. The median stay in hospital of the patients was 2 days (range 1-10).

Table 1. *Preoperative data of patients who underwent LAGB (n=411).*

Female gender	350 (85%)
Age (yrs)	38 (17-60)
Weight (kg)	133 (88-230)
Excess weight (kg)	70 (32-113)
BMI (kg/m^2)	46 (36-84)

Data are presented as N (%) or median (range).

LAGB: laparoscopic adjustable gastric banding. Yrs: years. Kg: kilogram.

BMI: body mass index.

Follow-up

Fifty-two of the 411 patients (13%) did not complete follow-up: in the period 1995-1999 41/210 patients (20%) were lost to follow-up, in the period 2000-2005 8/201 patients (4%). Three patients died due to a non-surgery related cause (2 with a malignancy and 1 by suicide). The median follow-up time of the other 359 patients was 39 months (range 3-108). There were 267 patients with a follow-up time > 2 years. Out of this group, 26 patients (10%) were lost to follow-up.

Excess weight loss

Of the 267 patients with follow-up data of > 2 years in 206 (77%) an excess weight loss > 30% was found at 2 years follow-up (Figure 2). In 7 (3%) patients the weight increased. The median BMI reduction 2 years after laparoscopic gastric banding BMI was 10,2 points (Table 2). The median

excess weight loss was 46,3% (Table 2). The decrease was almost stable during the following years (Figure 3). In the subgroups with a lower preoperative BMI, the percentage excess weight loss after gastric banding was higher than in the groups with a higher baseline value of BMI (Table 3).

Figure 2. *Excess weight loss after 2 years in 267 patients who underwent a gastric banding procedure.*

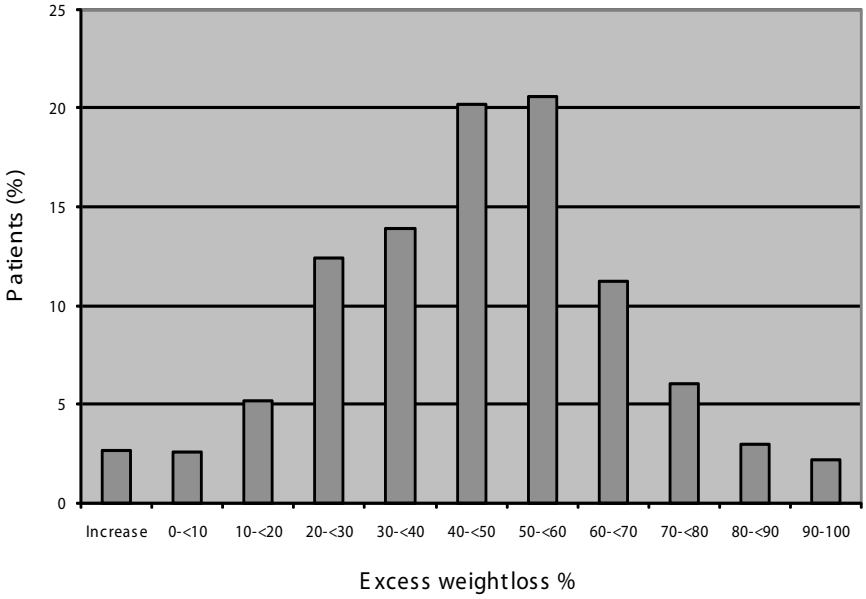

Table 2. *Weight loss 2 years after LAGB (n=267).*

	Total (n=267)	Women (n=228)	Men (n=39)
BMI pre LAGB (kg/m^2)	45 (36-69)	45 (36-69)	46 (36-60)
BMI difference	-10 (+5 - -26)	- 10 (+5 - -26)	-10 (-2 - -22)
EWL (%)	-46 (+10 - -98)	-45 (+10 - -98)	-46 (-9 - -80)

Data are presented as median (range).

LAGB: laparoscopic adjustable gastric banding. BMI: body mass index. EWL: excess weight loss.

Figure 3. *Weight loss for 411 patients after laparoscopic gastric banding (LAGB) expressed as (a) BMI and (b) excess weight loss (EWL).*

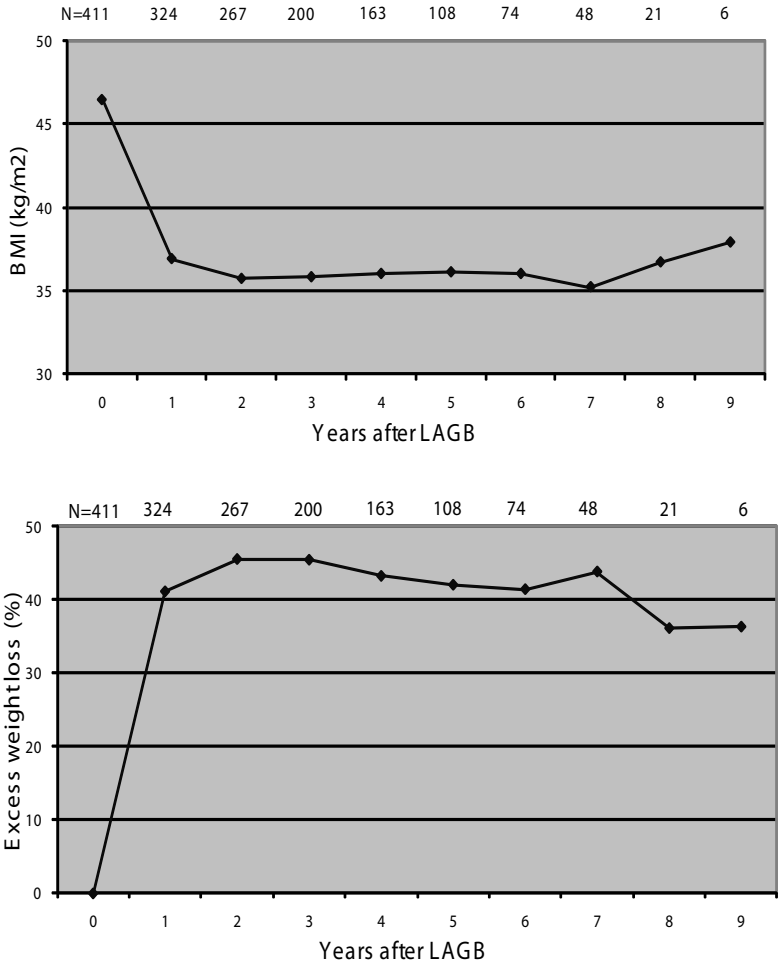

Table 3. *Weight loss after LAGB for subgroups of start BMI.*

	BMI 35-<40	BMI 40-<45	BMI 45-<50	BMI 50-<55	BMI >55	*P*
Patients (n)	25	102	70	38	32	
BMI diff.	-9 (-1 - -24)	-9 (-1 - -20)	-11 (-2 - -22)	-13 (-3 - -26)	-14 (+5 - -23)	P < 0,01
EWL (%)	54 (-9 - -90)	46 (-8 - -80)	43 (-5 - -60)	45 (-9 - -78)	38 (+10 - -98)	P < 0,01

Data are presented as N or median (range).

LAGB: laparoscopic adjustable gastric banding. BMI: body mass index.

BMI diff.: BMI difference. EWL: excess weight loss.

Complications

In 19 of the 411 patients (5%) a conversion to an open procedure was performed due to a hypertrophic liver lobe, bleeding or complex anatomy. Early complications were wound infections, gastric perforation and laceration of the liver (Table 4). Late complications were herniation of the fundus through the band, problems related to the port-a-cath system (leakage, infection and dislocation) and gastric erosion. Fundus herniation was seen more often after the perigastric than after the pars flaccida technique (Table 4). The complications did not affect the final weight loss (data not shown). The surgically related mortality rate was zero. In 90 of the 411 patients (22%) a reoperation was carried out (fundus herniation (n = 55), revision of the port-a-cath system (n = 30) and removal of the gastric band (n = 5).

Table 4. *Complications after LAGB.*

	Perigastric (n=210)	Pars flaccida (n=201)	Total (n=411)	*P*
<u><30 days postoperative</u>				
Wound infection	3	3	6 (1,5%)	0,96
Gastric perforation	2	1	3 (0,7%)	0,59
Liver laceration	1	0	1 (0,2%)	0,33
<u>>30 days postoperative</u>				
Slippage †	50	5	55 (13,4%)	< 0,01
Port-a-cath ‡	18	12	30 (7,3%)	0,31
Gastric erosion	1	0	1 (0,2%)	0,33

LAGB: laparoscopic adjustable gastric banding

† The median time to occurrence of slippage was 20 months (range: 1-87)

‡ The median time to occurrence of a port-a-cath problem was 25 months (range: 4-82)

Discussion

In contrast to our neighboring countries, in our country there is only little experience with the surgical treatment of obesity. Our report includes the first mid term results of LAGB in the Netherlands and shows a reduction of > 30% overweight in 77% of the patients with a follow-up duration > 2 years. The reported median BMI decrease of 10,2 points and the median excess weight loss of 46,3% correspond with the results reported in the literature.[11,19-21] Buchwald found in a meta-analysis, a mean decrease in BMI of 10,4 points and an excess weight loss of 47,5%.[22]

The advantages of the laparoscopic placement of the gastric band are the minimally invasive character of surgery and the rapid clinical recovery. A randomized study in our department already showed that surgery is safe and cost effective and is possible as day care surgery.[23] Other advantages are the possibility of calibration of the band with a controlled food intake and finally, the reversibility of the operation. If there is insufficient effect of the band or insufficient adherence of the patient, the band can be removed leaving the integrity of the gastro-intestinal tract undisturbed.

After switching to the pars flaccida technique by placing the band just below the gastro-oesophageal junction the rate of fundus herniation decreased significantly.[24] Other complications were mainly related to the port-a-cath reservoir and were treated in the outpatient clinic or day care surgery. The complications did not affect the final weight loss.

In the literature, long term results are often expressed as patients in follow-up. Shen showed a clear relationhip between an adequate follow-up and weight loss in patients after LAGB.[25] Usually, an excess weight loss > 30% is considered as a measure of successful obesity treatment.[26] The maximum weight loss in the majority of patients has been achieved 1,5 to 2 years postoperatively. In our study 77% of the patients with a follow-up time > 2 years showed an excess weight loss > 30% (Figure 2). If we consider the patients lost after 2 years as failures (n = 26 of 206), the success rate decreased to 67% (180 / 267).

The success of the surgical treatment of morbid obesity should not only be measured in terms of weight loss, but also expressed in decrease of co-morbidity and increase in quality of life. In previous studies, we already reported a statistically significant improvement in the quality of life after LAGB.[12,27] The effect of surgery on the co-morbidities in this group have not been analyzed till now. However, it is known from the literature that a weight loss of 10% is already associated with a significant reduction of comorbidity.[7,8] Buchwald et al. showed in a meta-analysis a significant decrease of diabetes mellitus, hyperlipidemia, hypertension and sleep apnoe syndrome after bariatric surgery.[22]

In the analysis of the subgroups, classified according to BMI at the start of the study, we found a greater effect of treatment for patients with lower baseline BMI (excess weight loss 54%) compared to patients with a higher value (excess weight loss 38%). The indication for bariatric surgery in patients with a BMI > 50 is still subject of discussion.[28] In contrast with the practice in Europe

and Australia, the preferred surgical procedure in the United States is the laparoscopic gastric bypass procedure. This operation results in a greater weight loss within a shorter time and gives a higher percentage of successfully treated patients than the gastric banding procedure. However, the price is a significantly increased morbidity and mortality.[29] Randomized comparative studies of the results of the gastric bypass procedure and laparoscopic gastric banding are lacking so far, but would respond to the question which operation is the best for patients with (severe) morbid obesity.

Conclusion

Seventy-seven percent of the patients with morbid obesity who underwent LAGB with a follow-up of > 2 years were succesfully treated. The pars flaccida method resulted in fewer complications than the perigastric method.

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3

Long term results of laparoscopic adjustable gastric banding in patients lost to follow-up

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Br J Surg, 2010

Abstract

Background

The aim of the study was to evaluate the results of laparoscopic adjustable gastric banding (LAGB) in patients lost to follow-up.

Methods

Patients lost to follow-up were retrospectively identified from a consecutive cohort of 495 patients who underwent LAGB between November 1995 and September 2006. These patients were asked to return to follow-up and their actual weight was assessed.

Results

Of 93 patients lost to follow-up, 73 were motivated to reattend the outpatient clinic. Of these, 60 per cent (44 patients) had lost less than 25 per cent of excess weight, compared with 16 per cent ($P < 0{,}001$), 27 per cent ($P < 0{,}001$) and 42 per cent ($P = 0{,}026$) of patients after 2, 4 and 8 years of regular follow-up.

Conclusion

Patients lost to follow-up are more likely to have poor weight loss, emphasizing the importance of follow-up after LAGB. Outcome after surgery for morbid obesity should include patients lost to follow-up as a measure of overall success.

Introduction

Laparoscopic adjustable gastric banding (LAGB) was introduced in the early 90's as a reversible method for achieving significant weight loss in the morbidly obese.[1] The procedure has gained popularity around the world, with good mid term results.[2-13]

Obesity is a chronic disorder that requires a continuous care model of treatment. Follow-up after surgical treatment should ideally be lifelong.[14,15] Compliance with a well structured postoperative management plan seems as important as good surgical technique in achieving long term success. Failures after gastric restriction have been attributed to motivational and/or psychological factors.[16] The only study on the effect of follow-up on weight loss after LAGB
showed a statistically significantly greater weight loss in patients followed regularly (more than six visits a year) than in patients who had less than optimal follow-up of six or fewer visits per year (50 versus 42 per cent excess weight loss (EWL), respectively).[17]

In many studies on LAGB, the percentage of patients in follow-up is often not reported or is poorly defined.[18-25] When described, the proportion of patients lost to follow up tends to increase with the length of follow-up.

The aim of this study was to evaluate the results of LAGB in patients lost to follow-up and the impact of patients lost to follow-up on long term outcome figures in morbidly obese patients.

Methods

Patients

The study group included consecutive patients undergoing LAGB between November 1995 and September 2006 at St Antonius Hospital, Nieuwegein. Inclusion criteria for surgery were a body mass index (BMI) greater than 35 kg/m^2 with co-morbidity, or a BMI above 40 kg/m^2 with or without co-morbidity, according to the National Institutes of Health consensus development panel report of 1991.[26] All patients had previously failed on conservative therapy and received extensive multidisciplinary (medical, nutritional, psychological, surgical) screening and education before surgery. The study was approved by the hospital's institutional review board.

Surgery

LAGB was performed as described previously.[27] During the first 210 procedures, the perigastric technique was used for band placement. The pars flaccida technique was adapted in the last 294 procedures.[28] All operations were performed by one surgeon. Postoperative follow-up visits were scheduled every 2–3 months in the first year, every 3 months in the second year, twice yearly for up to 5 years and yearly thereafter. From January 1999 onwards, follow-up was supported by specialized nurse-practitioners. Band adjustments were carried out in the outpatient clinic, based on weight loss and clinical presentation of the patient.

Data collection and outcome measures

Data for each patient were collected in a prospectively created database. The percentage of EWL and BMI were used to evaluate weight loss. Ideal bodyweight was determined according to Metropolitan Life Insurance Company 1983 height/weight tables.[29] Excess weight was defined as the difference between the patient's weight and the theoretical ideal medium-frame bodyweight. Result of therapy was defined as excellent (EWL more than 75 per cent), good (EWL 50–75 per cent), fair (EWL 25–50 per cent) or poor (EWL less than 25 per cent).[30] A poor result was considered a failure. Patients who underwent a secondary gastric bypass or had the band removed during follow-up were also considered treatment failures. Patients lost to follow-up were identified from the database. Patients were considered lost when they failed to attend for scheduled follow-up visits for a consecutive period of more than 18 months. At the time of analysis, patients lost to follow-up were contacted by telephone and asked to return to the outpatient clinic. For those who agreed, actual weight and reasons for non-compliance were assessed.

Statistical analysis

The Mann–Whitney U test was used to compare continuous variables between groups. Categorical variables were compared using the $\chi 2$ test. $P < 0{,}050$ was considered to indicate statistical significance. Analysis of data was performed using standard software SPSS® version 12.0 for Windows® (SPSS, Chicago, Illinois, USA).

Results

Between November 1995 and September 2006, 495 consecutive patients (417 women and 78 men) underwent LAGB. Median age was 38,6 (range 20 – 61) years, median preoperative weight was 130,0 (88,4 – 230,0) kg, median preoperative BMI 45,0 (36,2 – 71,7) kg/m^2 and median preoperative excess weight 65,9 (32,1 – 145,5) kg.

Nine patients were excluded from the analysis: five patients died during follow-up (one each from breast carcinoma, colonic carcinoma, pulmonary embolism, myelodysplastic syndrome and pneumonia) and four patients were followed up elsewhere. Of the remaining 486 patients, 393 (80,9 per cent) were in regular follow-up and 93 (19,1 per cent) met the criteria for lost to follow-up. Preoperative characteristics of patients of the two groups were comparable (Table 1).

Table 1. *Characteristics of patients before LAGB.*

	LOST (n=93)	IN (n=393)	*P*
Age (years)	38 (22-60)	39 (20-61)	0,22
Female gender	82 (88%)	329 (84%)	0,34
Weight (kg)	132 (98-230)	133 (88-210)	0,36
BMI (kg/m^2)	46 (36-63)	46 (36-72)	0,91
Excess weight (kg)	68 (42-146)	69 (32-142)	0,60

Data are presented as N (%) or median (range).

LAGB: laparoscopic adjuatable gastric banding, Kg:kilogram.

Median follow-up of patients in the regular follow-up group was 44,7 (range 3,0 – 127,2) months, compared with 37,4 (3,7 – 88,8) months in the lost group. In the regular follow-up group, 48 patients underwent a secondary gastric bypass because of insufficient weight loss, and in six others the band was removed. Follow-up data for these patients were included up to the time of secondary surgery. Thereafter, they were considered as band therapy failures.

Of 93 patients lost to follow-up, 73 (78 per cent) were motivated to return to follow-up. The remaining 20 patients could not be traced and were excluded from weight analysis. The median interval between operation and return to follow-up for the 73 patients who returned was 78,9 (range 24,9 – 129,8) months. Reasons for non-compliance with follow-up were generally non-specific (inability or unwillingness to make an appointment) in 61 (84 per cent) of the 73 patients. Twelve patients (16 per cent) indicated 'other health problems' as the reason for non-compliance.

The outcome after LAGB for the total group of 486 patients is shown in Figure 1. After 2, 4 and 8 years, treatment results were fair, good or excellent (EWL > 25%) in 78,3, 60,7 and 32,0 per cent of patients respectively. Treatment failure (EWL < 25%) occurred in 15,4, 22,3 and 28,7 per cent of these patients at the above time periods. The percentage of patients lost to follow-up gradually increased at a median annual rate of 5,3 (mean 4,9) percent, reaching 39,3 percent at 8 years.

The median weight loss after LAGB in the two groups until last follow-up is shown in Figure 2. Of those who returned to follow-up after being lost, significantly more patients had treatment failure and significantly fewer showed a fair, good or excellent result compared with patients attending regular follow-up. After a median follow-up of 78,9 months, 60 per cent (44 of 73) of the patients in the lost group had failed therapy versus 16,3 per cent (59 of 362; $P < 0,001$), 27,0 per cent (66 of 244; $P < 0,001$) and 42 per cent (31 of 74; $P = 0,026$) after 2, 4 and 8 years respectively in the regular group.

Median BMI, BMI difference and EWL of patients lost to follow-up were significantly different between the time of the last scheduled follow-up visit and the return visit following contact (Table 2). At their last visit in scheduled follow-up, 68 per cent (50 of 73) of the patients had a fair, good or excellent result compared with 40 per cent (29 of 73) at return to follow-up ($P < 0,001$) (Figure 3).

Figure 1. *Results for laparoscopic adjustable gastric banding categorized into four groups: lost to follow-up, treatment failures, EWL 25 – 50% or EWL > 50%.*

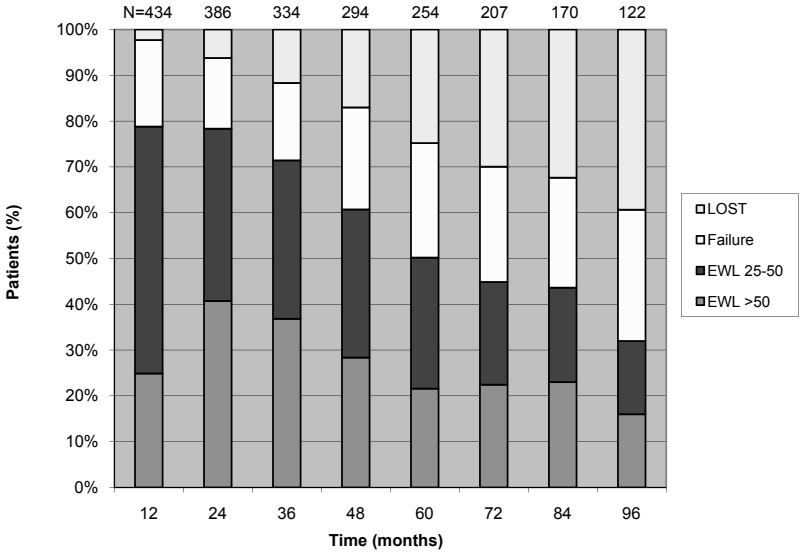

Figure 2*. Body mass index (BMI) after laparoscopic adjustable gastric banding in patients attending regular follow-up and patients lost to follow-up.*

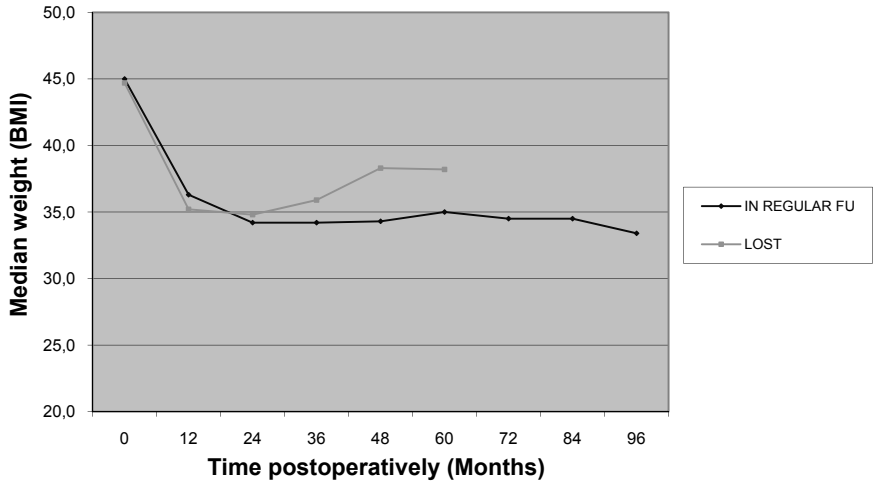

Figure 3. *Comparison of excess weight loss (EWL) before and after lost to follow-up after laparoscopic adjustable gastric banding.*

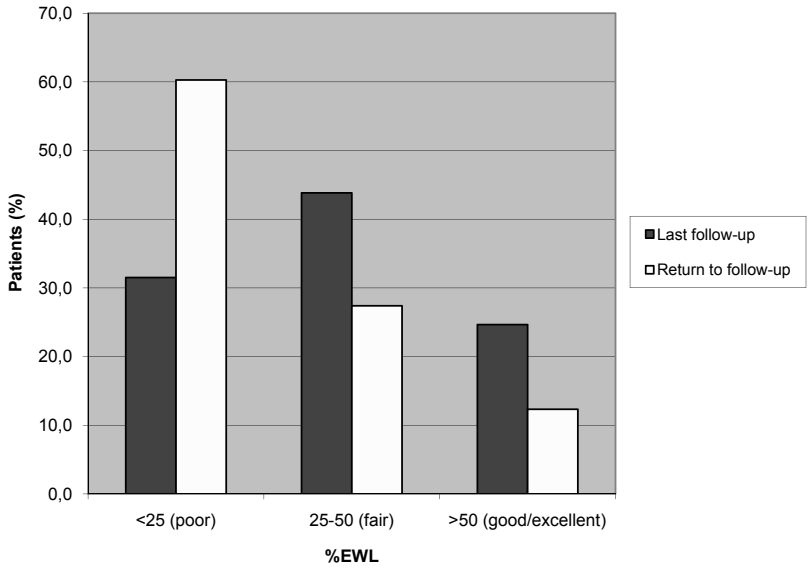

Table 2. *Weight at last follow-up and return to follow-up visits in 73 patients lost to follow-up*

	Last follow-up	Return to follow-up	*P*
BMI (kg/m^2)	37 (27-55)	41 (26-61)	<0,01
BMI difference (kg/m^2)	-8 ([+6]-[-22])	-4 ([+16]-[-26])	<0,001
EWL (%)	34 ([-26]-[77])	17 ([-70]-[77])	<0,001

Data are presented as median (range).

BMI: body mass index. EWL: excess weight loss.

Discussion

This is the first study to report on the outcome of patients lost to follow-up after laparoscopic adjustable gastric banding. In this follow-up study some important observations are made. The study shows a fair, good or excellent result of gastric banding after 8 years of follow-up in 32,0% of the patients. The percentage of therapy failures of patients in follow-up is stable after 4 years to 28,7% after 8 years of follow-up. The study shows a gradual increase over time of the percentage of patients lost to follow-up to 39,3% after 8 years despite the institution of a special bariatric care program. The majority (60,3%) of patients lost to follow-up have a poor weight outcome and should be considered as therapy failures.

In the literature the reported percentage of patients in regular follow-up in the largest series on long term outcome after LAGB varies widely, if reported at all. A clear definition of lost to follow-up is often not provided. In one series of 830 patients a follow-up percentage of 97 was reported, but 20% of the patients had lost compliance with the dietary, psychological and surgical advice and the operation was considered a failure in these patients.[3] Another series of 1265 patients reports that the percentage of patients observed at a follow-up time point is more than 60%, but the other 40% of patients are not defined.[19] Many other studies report the number of patients available or eligible for follow-up at one time point. The patients not available for follow-up at a specific time point are likely to be patients who were lost to follow-up or who received revisional surgery. Our study shows that despite an intensive bariatric care program including specialized nurse-practitioners in charge of the out-patient follow-up, the percentage of patients lost to follow-up increases yearly with an average of 4,9% to a total of 39,3% at 8 years follow-up. As the majority of these patients prove to be therapy failures they have a significant negative influence on the overall outcome of LAGB in the total patient group. This observation emphasizes the importance to include the percentage of patients lost to follow-up in studies reporting long term outcome of bariatric procedures and the need to include and endorse this criterium in the reporting standards of bariatric surgery worldwide.

The importance to stimulate follow-up compliance is also illustrated by the weight loss results of patients who were in regular follow-up compared to those lost to follow-up, as has been reported by others.[31] The multidisciplinary follow-up team should make an effort to minimize the rate of patients who are lost to follow-up and thereby probably increase the rate of successfully treated patients after LAGB. In this perspective, early identification of patients who will be lost to follow-up would be useful. No preoperative differences in patient characteristics were found between patients in regular follow-up and patients who were lost to follow-up. The postoperative weight loss curve in patients lost to follow-up shows a normal decline until 12 months follow-up, and then turns to ascend (Figure 2) contrary to the pattern seen in patients in regular follow-up. This inclining trend in weight loss could be indicative of treatment failure, and may warrant an increased surveillance of these patients.

The cause of the high failure percentage in the lost to follow-up group is unknown. Regular follow-up is essential for several reasons to achieve long-term success after LAGB. First, band adjustments have a specific role in the follow-up of LAGB patients. A gastric band that is not properly adjusted may be ineffective, because optimal restriction may not be attained. Close follow-up with step-by-step band inflation improves weight reduction.[32] Secondly, patients should be supported to drastically change their eating habits. Some patients tend to drink high-calorie liquids postoperatively, resulting in failure of weight loss. Other patients may show binge-eating problems that are associated with unsatisfactory postoperative results.[33] Thirdly, psychological factors play a role in weight loss after LAGB. Patients who attend support groups or psychotherapy have more weight loss and a better quality-of-life than non-attenders.[34,35]

This study teaches two important lessons. First, the fact that bariatric surgery is more than surgery alone, and requires besides a strong commitment from the patient to comply with follow-up protocols, the dedication of the surgeon to perform long-term follow-up and his involvement to implement and maintain the follow-up program. Second, the management of the bariatric patient should ideally take place in the setting of a multidisciplinary team approach, which besides surgery should include dietary care, psychological counselling, eating behaviour intervention and exercise programs. This approach should motivate patients maximally to comply with the follow-up program. Every effort should be made to minimize the rate of patients who are lost to follow-up, thereby increasing the rate of successfully treated patients after laparoscopic adjustable gastric banding.

In conclusion, our study emphasizes the importance of patient follow-up after LAGB. The majority (60,3%) of patients lost to follow-up are therapy failures. Long term follow-up results of gastric banding may be improved by identifying patients who are non-compliant and intensify their follow-up frequency. Hereby trying to minimize the percentage of patients lost to follow-up. Long-term follow-up reports of bariatric procedures should include the percentage of patients lost to follow-up at all time points; both as a measure of the effectiveness of the follow-up program and as a truthful indication of the overall success rate of bariatric surgery.

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4

Rebanding for slippage after gastric banding: should we do it?

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Submitted

Abstract

Background & aims

Laparoscopic adjustable gastric banding (LAGB) is a commonly performed bariatric procedure worldwide. LABG is frequently complicated by band slippage. A suggested treatment for slippage is rebanding, but its long term effects on weight loss are unknown. The aim of this study was to investigate whether rebanding after gastric band slippage is associated with weight loss failure.

Methods

This was a retrospective analysis of a prospectively collected database of 627 consecutive patients who underwent LABG. Rebanding for band slippage was performed in 81 patients. Weight loss was defined as good (excess weight loss (EWL) > 50%), fair (EWL 25 – 50%) or as a failure (EWL < 25%). Weight loss was compared before and after rebanding in the subgroups of patients in whom the primary LABG was successful or unsuccessful with regard to weight loss. Rebanded patients were matched to patients without slippage for important prognostic variables and compared for weight loss failure. To assess whether slippage was independently associated with weight loss failure multivariate logistic regression was performed.

Results

The chance of a fair result of rebanding for patients following primary successful (n = 34) and unsuccessful LAGB (n = 22) was 62% and 27% after a median follow-up of 113 and 97 months, respectively. There was no difference in weight loss failure between the 81 rebanded patients and the 81 matched patients: 54% versus 59% (P = 0,43). In multivariate analysis rebanding was also not significantly associated with weigh loss failure: adjusted odds ratio 1,42; 95%-confidence interval: 0,85 - 2,38; P = 0,18.

Conclusion

In general, rebanding after LABG has no negative effect on weight loss therapy. However, patients in whom LAGB was unsuccessful prior to rebanding have poor long term weight loss results.

Introduction

At least 5% of the people in the western world is morbidly obese. According to the Centers for Disease Control, every 90 seconds an American dies from an illness related to obesity, which adds up to nearly 400.000 deaths in the U.S. each year.[1,2] Young adults with morbid obesity may lose 20 years of life expectancy if they do not lose weight.[3]

Bariatric surgery is currently the best treatment for morbid obesity and directly decreases mortality.[4,5] A commonly performed bariatric operation is laparoscopic adjustable gastric banding (LAGB). This procedures has rapidly gained popularity in the U.S. after approval by the Food and Drug Administration in 2001 and accounted for 44% of yearly performed bariatric procedures in the U.S in 2008.[6] LAGB is characterized by low procedure associated morbidity and mortality, the potential of reversibility and good mid term weight loss results.

In the last decade, over 500.000 gastric bands have been placed worldwide. With the increase of LAGB new procedure related complications have been introduced, of which the most common complication is band slippage. The incidence of slippage after LAGB is estimated to be 5% - 10%.[7] The best treatment of slippage remains unknown. Some authors favor explantation of the band followed by a secondary bariatric procedure, but others suggest rebanding (i.e. continuation of band treatment by repositioning or replacement of the band). No randomized or case-matched studies have been performed on this topic. There are only some cohort studies on rebanding, but these were small series and did not report on long term outcome in terms of weight loss.

The aim of this study was to describe the long term effects on weight loss in a large prospective cohort of patients who underwent rebanding for slippage following LABG. We investigated whether rebanding is independently associated with failure of weight loss by means of a case-matched comparison and multivariate logistic regression.

Methods

Patients

This was a post-hoc analysis of a prospectively collected database which included all consecutive patients who underwent LAGB between November 1995 and October 2008 at Sint Antonius Hospital, Nieuwegein, a large non-university, teaching hospital in the Netherlands. Indications for LAGB were a body mass index (BMI) greater than 35 kg/m^2 with comorbidity or a BMI above 40 kg/m^2 with or without comorbidity, according to the National Institutes of Health consensus development panel report of 1991.[8] All patients had previously failed on conservative therapy and underwent extensive multidisciplinary screening (medical, nutritional, psychological and surgical) and education.

Surgery

The technique of LABG was performed as described previously.[9] From 1995 to 2000, the perigastric technique was used, from 2001 onwards the pars flaccida technique was adopted.[6] Rebanding for slippage was performed with an open or laparoscopic approach. Adhesions were dissected, the tubing of the band was identified and followed to the band. Both anterior and posterior aspects of the band were released. Adhesions between the pouch and surrounding structures were lysed and the pouch was reduced downward through the band by gentle traction. The band was repositioned 2 cm below the gastro-esophageal junction to create a small gastric pouch. Multiple nonabsorbable gastrogastric sutures were placed on both anterior and posterior aspects of the band to secure its position.

Data collection and definitions

Data for each patient before and after the operation were prospectively collected. Regular postoperative follow-up visits were scheduled every 2 – 3 months in the first year, every 3 months in the second year, twice yearly for up to 5 years and yearly thereafter. From January 1999 onwards, follow up was supported by specialized nurse-practitioners.

Ideal bodyweight was determined according to Metropolitan Life Insurance Company 1983 height/weight tables.[10] Excess weight was defined as the difference between the patient's weight and the theoretical ideal medium-frame bodyweight. Weight loss was defined as good (excess weight loss (EWL) > 50%), fair (EWL 25 – 50%) or as a failure (EWL < 25%). Patients who had the band removed or underwent a secondary procedure during follow-up were also considered band treatment failures.

The diagnosis of band slippage was made on the basis of clinical and radiological evaluation. Patients with symptoms of occasional chest pain, regurgitation, nausea and vomiting, persisting after deflating the band, had an gastrografine X-ray of oesphagus. Band slippage was considered when dilatation of the pouch with or without outflow obstruction was present on imaging.

Subgroups and case-matching

From the entire cohort of patients undergoing LABG, patients who underwent rebanding for slippage were identified from the prospective database. Patients were divided into two subgroups: 1) patients with initial good weight loss, >1 year following primary LAGB (EWL > 50%) and 2) patients with less than good weight loss, >1 year following primary LAGB (EWL < 50%).

To reduce potential selection bias, each patient who underwent rebanding was matched with one patient who underwent LAGB and did not have slippage for all of the following known prognostic criteria: (1) year and month of operation (± 1 month), (2) BMI before LAGB (± 6 kg/m^2), (3) gender (M/F), (4) age (± 10 yr) and (5) technique of LABG (perigastric or pars flaccida). Patients who underwent LAGB and did not have slippage were consecutively enrolled in reversed order: if more than one 'non slippage' patient could be matched with a patient in the slippage group,

the patient operated on most recently was selected. Groups (i.e. rebanding and non slippage patients) were compared for weight loss.

Statistical analysis

Analyses were performed using standard software (SPSS 12.0 for Windows). The Kolmogorov-Smirnov test was used to assess whether continuous data were normally distributed ($P > 0,05$). Normally distributed data are presented as means (± standard deviation) and non normally distributed data as medians (range). Differences tested with Student's *t* test or Mann-Whitney *U* test, respectively. For categorical variables, the $\chi 2$ test or Fischer's exact test were used as appropriate.

Weight loss was compared before and after rebanding in the subgroups and in the case-matched cohorts. To assess whether rebanding was independently associated with failure of weight loss we performed logistic regression. As the main interest was the effect of rebanding, we identified confounding factors associated with weight loss in the entire cohort of patients undergoing LAGB (i.e. patient and operation characteristics). These prognostic criteria were entered into a univariate regression model: age, gender, BMI, operation technique, and length of follow-up. The outcome was *failure* of band therapy (EWL < 25%). All factors associated with failure ($P < 0.02$) were entered as covariates into a multivariate regression model with rebanding as the main factor. Age and gender were included in the model regardless of univariate association. Results of logistic regression are shown as odds ratios and 95% confidence intervals (CI). A two-tailed $P < 0,05$ was considered statistically significant.

Results

Patients

During the study period, 627 consecutive patients (514 women and 113 men) underwent LAGB. Mean age was 39,7 yrs (± 9,3), mean preoperative BMI 45,5 kg/m^2 (± 5,4) and mean preoperative excess weight 67,0 kg (± 16,9). Median follow-up after LAGB was 104 months (range 14 - 176 months). The first 210 procedures were performed by the perigastric technique, the last 417 procedures by the pars flaccida technique.

Rebanding

During follow-up, 88 of 627 patients (14%) were diagnosed with slippage at a median of 23 months (range 0 - 112 months) after LAGB (perigastric 63/210 = 30%, pars flaccida 25/417 = 6%). Sixty-three of 88 patients (72%) had late slippages (i.e., > 1 yr after LAGB) and 25 of 88 patients (28%) had early slippages (i.e., < 1 yr after LAGB). Seven of the 88 patients (8%) with slippage had their band removed and were excluded from further analysis. The remaining 81 patients underwent

rebanding and formed the cohort for further analysis. Median follow-up after rebanding was 68 months (range 1 - 170 months).
Seventy-seven patients underwent rebanding for slippage once and 4 patients were rebanded twice due to recurrent slippage. Of these 85 reoperations, 79 were performed open, 6 laparoscopic and 1 was converted from laparoscopic to open. In patients with primary slippage, 72 bands were repositioned, 6 were replaced by a new band and 3 bands were removed. The latter 3 patients were rebanded 3, 4 and 5 months later. In the patients with recurrent slippage, all 4 bands were repositioned.

Weight loss before and after rebanding
Figure 1 shows the outcome of rebanding for slippage following LAGB. The chance of a fair result (EWL > 25%) for patients who underwent rebanding (n = 81) was 81% and 78% after follow-up of 1 and 2 years, respectively. At a median follow-up of 110 months after primary LAGB (range 14 - 176 months), the chance of a fair result was 43%.
Figure 2 shows the outcome for the subgroup of patients with initial good weight loss (EWL > 50%) > 1 year following primary LAGB (n = 34). The chance of a fair result for these patients after follow-up of 1 and 2 years was 97% and 88%, respectively. At a median follow-up of 113 months (range 47 - 165 months) after primary LAGB, the chance of a fair result was 62%.
Figure 3 shows the outcome for the subgroup of patients with initial less than good result (EWL < 50%) > 1 year following primary LAGB (n = 22). The chance of a fair result for these patients after follow-up of 1 and 2 years was 68% and 65%, respectively. At a median follow-up of 97 months (range 30 - 165) after primary LAGB, the chance of a fair result was 27%.

Figure 1. *Weight loss after rebanding for slippage following LAGB (n = 81).*

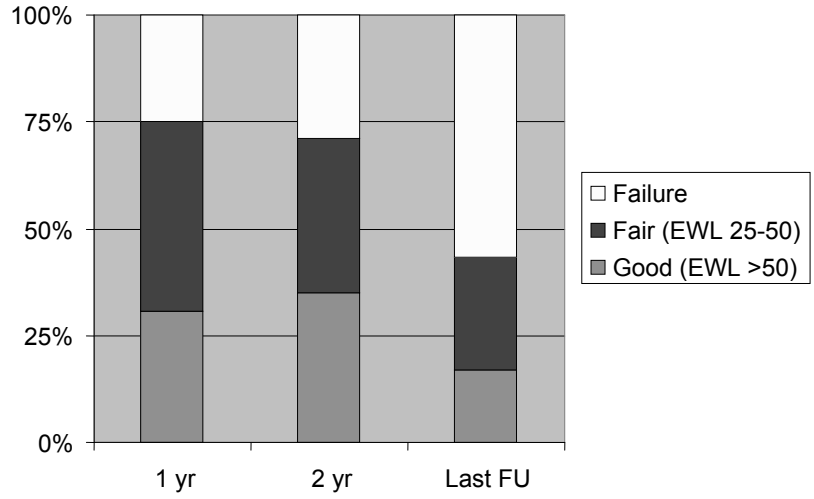


Figure 2. *Weight loss in the subgroup of patients with rebanding for slippage after initial succesful LAGB (n = 34).*

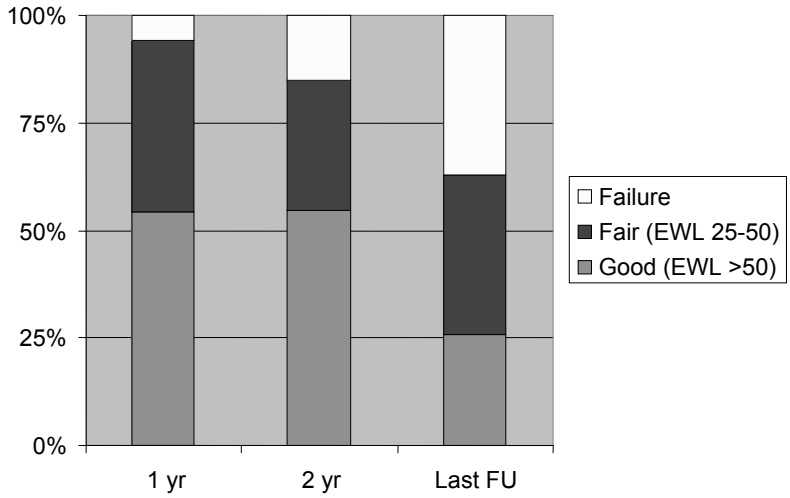
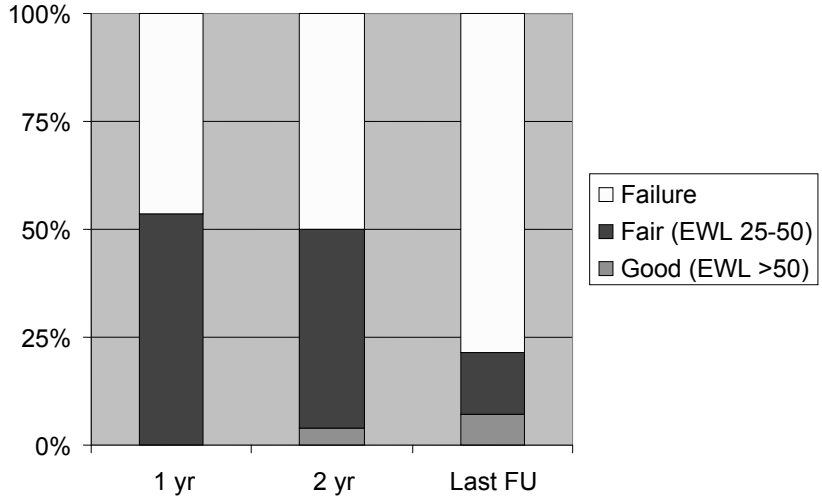


Figure 3. *Weight loss in the subgroup of patients with rebanding for slippage after initial unsuccesful LAGB (n = 22).*



Case matched comparison of rebanding for slippage with no slippage

The characteristics of 81 patients undergoing rebanding for slippage and the 81 matched patients without slippage are presented in Table 1. There was no difference in the percentage therapy failure (EWL < 25%) between the rebanding group and the case matched group without slippage: 54% (n = 44) versus 59% (n = 48) (*P* = 0,43), after a median follow-up of 110 and 100 months, respectively.

Table 1. *Characteristics of 81 patients with rebanding versus 81 matched patients without rebanding.*

	Cases (n = 81)	Matched patients (n = 81)	*P*
Female gender	74 (91%)	73 (90%)	0,79
Age (yr)	37,3 (±9)	37,2 (±9)	0,86
BMI pre LAGB (kg/m^2)	45,7 (±6)	45,9 (±6)	0,79
EW before LAGB (kg)	66,6 (±15)	66,9 (±16)	0,98
Operation: PG/PF	62/19	54/27	0,16
FU after LAGB (mnths)	110 (14-176)	100 (22-172)	0,67

Data are presented as N (%), mean (±SD) or median (range).

Yr: years. Kg: kilogram.

BMI: body mass index. LAGB: laparoscopic adjustable gastric banding. EW: excess weight.

PG: perigastric, PF: pars flaccida.

FU: follow-up.

Multivariate regression analysis

The results of univariate logistic regression analysis of prognostic factors for weight loss failure (EWL < 25%) are given in Table 2. Rebanding was not associated with failure: OR 1,07; 95% - CI: 0,67 - 1,71; *P* = 0,77 in univariate analysis. The factors significantly associated with failure were BMI before LAGB and length of follow-up. When adjusting for potential confounders in multivariate analysis (i.e. including co-variates gender, age, BMI before LABG and length of follow-up) there was still no association between rebanding and failure: adjusted OR 1,42; 95% - CI: 0,85 - 2,38; *P* = 0,18.

Table 2. *Predictors of failure of LAGB in logistic regression analysis.*

	Univariate			Multivariate		
Predictor	OR	95% CI	*P*	OR	95% CI	*P*
Rebanding	1,07	0,67-1,71	0,77	1,42	0,85-2,38	0,18
Gender	0,94	0,63-1,42	0,78	0,96	0,63-1,47	0,86
Age	0,99	0,97-1,01	0,27	0,99	0,98-1,01	0,53
BMI before LAGB	0,93	0,90-0,96	< 0,001	0,93	0,90-0,96	< 0,001
Length of FU	1,01	1,00-1,01	0,004	1,01	1,00-1,01	0,003
Technique LAGB	1,23	0,88-1,72	0,23			

LAGB: laparoscopic adjustable gastric banding

OR: Odds ratio

CI: confidence interval

BMI: body mass index. FU: follow-up

Discussion

This is the first study evaluating the long term effect (i.e., > 5 yr follow-up) on weight loss after rebanding for slippage in a large prospective cohort of patients after LAGB. Our main finding is that there was no independent association between rebanding and weight loss failure in a case matched comparison and in logistic regression adjusting for potential confounders. However, the subgroup of patients with unsuccessful LAGB prior to rebanding tended to have a poor long term outcome compared to the subgroup of patients with succesful LAGB prior to rebanding.

The literature on long term outcome following rebanding for band slippage is scarce and contradictory. An evidence-based decision making algorithm was recently presented based on a systematic review of 11 reports describing refixation and/or replacement of a gastric band after failed LAGB, with a total patient group of 281 patients (range 10 - 55 patients per study).[11] Median follow-up was considerably shorter than the present study: 27 months versus 68 months. Moreover, only 4 out of 11 studies reported postoperative weight loss after rebanding for slippage (range 16 - 29 patients per study). Nevertheless, the author concluded that patients with good weight loss after LAGB may benefit from rebanding. Other authors have recommended against rebanding, based on a review, of 4 studies with a total of 193 patients that did not show adequate weight loss after rebanding.[12]

In the literature a distinction is made between anterior slippage, posterior slippage and pouch dilatation.[13] These three entities can have an acute or chronic clinical presentation. Anterior slippage means an upward prolapse of the stomach's inferior, anterior portion with caudal slippage of the band. Inadequate anterior fixation is thought to be the most important predisposing factor for anterior slippage. Posterior slippage means upwards herniation of the posterior stomach wall through the band such that the band moves in a caudal direction. This type of slippage is almost

completely limited to patients operated by the perigastric technique. Opening of the lesser sac during the initial operation is thought to be the most important predisposing factor to posterior slippage. Pouch dilatation means an enlarged gastric pouch above a normally placed gastric band. This may be caused by excessive eating resulting in high pressures in the proximal gastric pouch. In our study, indication for rebanding was persistence of symptoms of occasional chest pain, regurgitation, nausea and vomiting after band deflation and pouch dilatation on X-ray. No distinction was made between anterior, posterior slippage or pouch dilatation and the method of rebanding was decided during operation. The overall 14% slippage rate in our study is relatively high as compared to the literature.[14] This may be explained by the high slippage rate of 30% rate in the 210 patients treated by the perigastric LABG technique in the period from 1995 until 2001. The 6% slippage in the period from 2001 onward is comparable to other recent reports

Our findings are clinically relevant because LAGB has become a very popular bariatric procedure in the last decade, and slippage is a common complication for which the best treatment is yet unknown. Prospective data on the effect of rebanding on long term weight loss were lacking. Our data show that rebanding is not a prognostic factor for failure of weight loss. Therefore, a slipped gastric band should not necessarily lead to a change in bariatric therapy (i.e., conversion to another operation such as a gastric bypass procedure). In patients successfully treated by LAGB, rebanding for band slippage should be considered, as good long term success was found in 62% of the subgroup of patients with initial successful LABG. However, in patients with initial unsuccessful LABG, long term success was only 27%. This low success rate justifies band removal and conversion to another bariatric procedure in case of band slippage after initial unsuccessful LABG. Other authors have also discussed that rebanding is an appropriate procedure for slippage, however for those with inadequate weight loss conversion to a secondary bariatric procedure might be a better option. In line with our findings, Schouten concludes that patient selection is crucial for considering rebanding for slippage and that patients with good weight loss after LAGB would benefit from rebanding. Patients with poor weight loss with slippage after LAGB might do better with conversion to another bariatric procedure.[11]

There are some possible limitations to our study. Firstly, this was a non randomized study which may have led to selection bias in the comparison of rebanded patients with patients without slippage. This was, however, well compensated for by the case-matched analysis using a large prospective database of over 500 patients and multivariate logistic regression analysis adjusting for potential confounders. Secondly, the majority of rebanding procedures were performed by an open procedure, whereas currently all re-operations in our intitute are performed laparoscopically. It is not very likely that this has influenced our main results. Although there are no comparative studies between open or laparoscopic rebanding, a randomized trial has demonstrated equal effectiveness in terms of weight loss between open gastric banding and LABG.[15] Finally, we used excess weight loss as the measure of success regarding weight loss therapy. This is currently the most widespread used measure in surgical bariatric literature but it has recently been

questioned.[16] Besides weight loss, resolution of comorbidities and improvement of quality of life are also important factors that should be taken into account when evaluating the success of bariatric treatment. These outcomes after rebanding must be studied in the future.

In conclusion, the results of this study show that, in general, rebanding for slippage has no effect on long term weight loss. A slipped gastric band is therefore not necessarily an indication for band explantation and conversion to another bariatric procedure. The treatment decision should be individualized, which takes into account the initial success after LABG. Patients with successful initial LABG who develop slippage can be rebanded with a good change of successful long term weight loss.

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5

Gastric bypass surgery is an effective treatment for morbid obesity

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Ned Tijdsch Geneeskd, 2010

Abstract

Aim

Evaluating the results of the gastric bypass for morbid obesity.

Methods

All patients who underwent gastric bypass surgery at the St. Antonius Hospital in Nieuwegein from 2002 to 2008 were retrospectively analyzed. Indications for surgery were a body mass index (BMI) ≥ 40 kg/m^2 or a BMI ≥ 35 kg/m^2 with severe co-morbidity. Main outcome measures were excess weight loss after at least 1 year of follow-up, surgery-related morbidity, and mortality.

Results

290 patients with a median age of 42,5 years (range 21 – 66) underwent a gastric bypass (233 open, and 57 laparoscopic). The median excess weight before surgery was 78,7 kg (range 30,1 – 190,3) and the median BMI was 49,5 kg/m^2 (range 33,2 – 84,9). In 35,5% patients (n= 103/290) this was a secondary intervention after previous unsuccessful bariatric surgery. 189 patients were followed longer than one year. The surgery was successful (EWL > 50%) in 71,4% of these patients (n = 135/189). The median excess weight loss was 58,6% (range 7,7 – 102,4). The median BMI reduction was 16,2 kg/m^2 (range 0,9 – 42,9). Patients for whom the gastric bypass was their primary bariatric surgery lost more weight than those for whom it was a secondary procedure (median EWL 61,4% versus 53,5%, and median BMI reduction 17,8 kg/m^2 versus 11.9 kg/m^2). The most common early complications (within 30 days after surgery) were anastomotic leakage (n = 15) and wound infections (n = 11). Late complications consisted mainly of anastomotic strictures (n = 18) and cicatrical hernias (n = 15). Mortality was 0,7% (n = 2).

Conclusion

Gastric bypass surgery is an effective treatment for morbid obesity and has acceptable surgery-related morbidity and mortality.

Introduction

A patient with morbid obesity (BMI ≥ 40 kg/m^2 or BMI ≥ 35 kg/m^2 with severe co-morbidity) is eligible for bariatric surgery.[1] Bariatric surgery is the most effective therapy for both short and long term reduction of body weight.[2-5] Weight loss decreases co-morbidity and mortality, and improves the quality of life.

The gastric bypass is one of the most frequently implemented bariatric surgical procedures.[6, 7] It is primarily performed in the malignantly obese (BMI ≥ 50 kg/m^2). Bariatric surgery has been performed at the St. Antonius Hospital in Nieuwegein since 1995, starting with laparoscopic gastric band placement, and including gastric bypass surgery since 2002. This paper describes the results of the patients (n = 290) who underwent gastric bypass surgery during the first six years since implementation at our center.

Methods

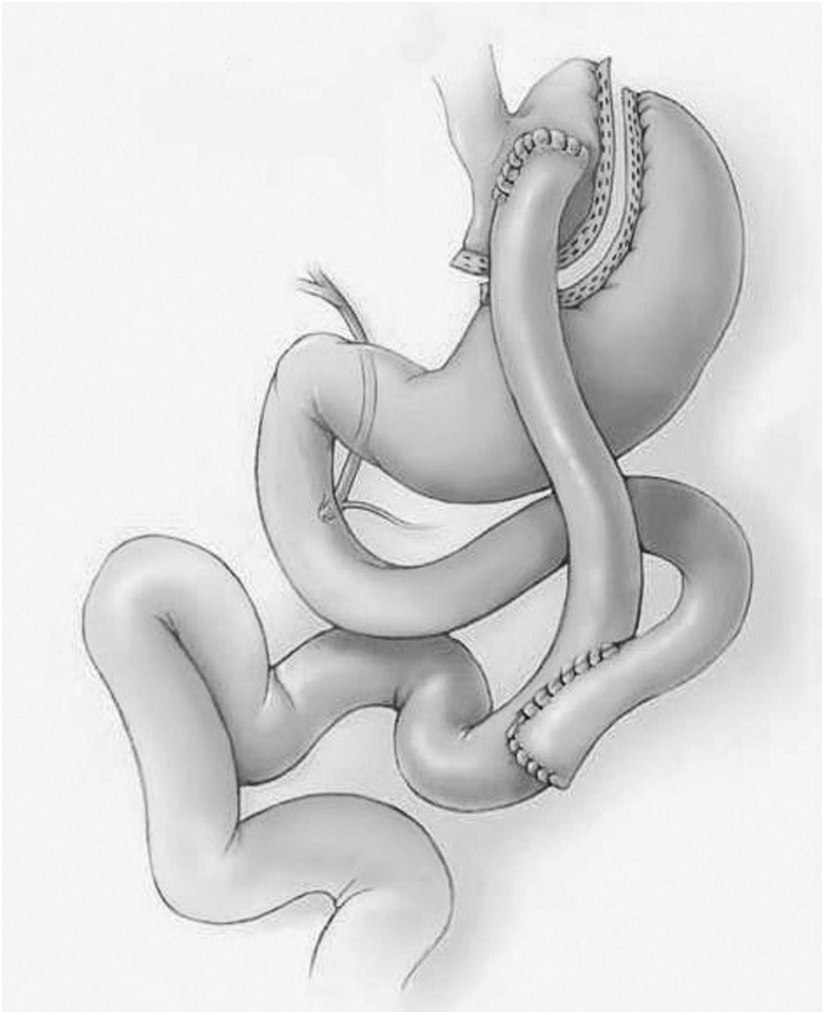
Patients

We analyzed data from all consecutive patients who underwent a gastric bypass procedure from 2002 to 2008. A multidisciplinary team determined the indication for surgery in accordance with the international criteria listed in the 'National Institutes of Health consensus development conference draft statement for surgical treatment of morbid obesity.'[1] Only patients with a BMI ≥ 40 kg/m^2 or a BMI ≥ 35 kg/m^2 and severe co-morbidity who had undertaken two or more serious attempts at weight loss were eligible for bariatric surgery. Malignantly obese patients (BMI ≥ 50 kg/m^2) had a primary indication for gastric bypass surgery. Secondary gastric bypass surgery was indicated in patients with insufficient weight loss after previous bariatric surgery (laparoscopic gastric band placement, vertical gastric sleeve, or previous gastrointestinal bypass surgery) or in those who suffered complications from a previously placed band. Portal hypertension and severe psychiatric co-morbidity and instability were the most important exclusion criteria.

Surgery

During gastric bypass surgery a small proximal stomach pouch (about 20-30 ml) is formed by employing a stapling technique (Figure 1). The jejunum is dissected 50 cm distal to the suspensory duodenal ligament (Treitz), and a 75-150 cm long roux-loop is created. This loop is positioned antecolicly and anastomosed to the pouch using either a linear or circular stapling technique. Gastro-intestinal continuity is restored with a side-to-side jejuno-jejunostomy. When we performed a secondary bypass surgery, the previously placed gastric band was always removed. Two bariatric surgeons (BvR and MJW) performed all surgeries.

Figure 1. *The Roux-and-Y gastric bypass for patients with morbid obesity.*



Follow-up and data collection

Follow-up after surgery was conducted by a specialized nurse-practitioner and consisted of consultation every 2-3 months the first year after surgery, every 3 months the second year, twice yearly for up to 5 years and yearly thereafter. Patients who did not return for follow-up for over 18 months were considered lost to follow-up. All data was recorded in a database.

Outcome measures

Weight loss was only evaluated in patients who were followed-up for a minimum of one year. Weight loss was expressed as the percentage of excess weight lost (EWL) and the amount of BMI reduction. The magnitude of obesity was determined using the 'Metropolitan Life Insurance Company 1983 height/weight tables.'[8] For patients who underwent secondary bypass surgery, the weight loss attained at the most recent follow-up was compared to the patients' weights before both the primary and the secondary bariatric procedures. We classified the success of the surgery: EWL ≥ 75% was considered an excellent result, EWL ≥ 50% good, EWL ≥ 25% acceptable, and EWL < 25% poor.[9] Treatment was considered successful when the results were excellent or good. Early (<30 days postoperatively) and late (≥ 30 days postoperatively) complications in the overall study population were analyzed. We compared weight loss and morbidity after primary or secondary bypass surgery and after open or laparoscopic surgery. We used Statistical Package for the Social Sciences (SPSS Inc., Chicago, USA) version 12.0 for Windows for the data analysis.

Results

Study population

A total of 290 patients (231 women, 59 men) underwent a gastric bypass surgery (Table 1). In the secondary gastric bypass group were significantly more women than in the primary gastric bypass group (88% versus 75%, $P < 0,05$). The median preoperative BMI of the overall study population was 49,5 kg/m^2 (range 33,2 – 84,9 kg/m^2).

Most of the bypasses were created using an open approach (n = 233 open, n = 57 laparoscopic). The median hospital length of stay for all patients was 3 days (range 1 - 60). The operative time was longer for the laparoscopic approach than for the open approach (median 120 minutes for laparoscopic surgery, and 80 minutes for open surgery). The surgery was a secondary bariatric procedure in 103 patients (35,5%).The median preoperative BMI of the patients undergoing bypass surgery as their primary bariatric surgery (n = 187) was 51,2 kg/m^2 (range 39,0 – 84,9) (Table 1). Most of these patients underwent an open procedure (131/187 = 70,1%).

Among the patients for whom the gastric bypass was their secondary bariatric surgery, the median preoperative BMI was 45,5 kg/m^2 (range 33,2 – 68,0) (Table 1). The patient with the lowest BMI (33,2 kg/m^2) was below the lower BMI limit meriting an indication for bariatric surgery (35 kg/m^2), but underwent a secondary procedure because of complaints after previous laparoscopic gastric band placement. The lower BMI had been attained following placement of the gastric band. Secondary bariatric surgery was only performed laparoscopically in one patient.

Table 1. *Characteristics of patients who underwent gastric bypass (n=290).*

Variable	Total (n=290)	Primary GB (n=187)	Secondary GB (n=103)
Female gender	231 (80%)	140 (75%)	91 (88%)
Age (yrs)	43 (21-66)	42 (21-66)	43 (27-64)
Weight (kg)	145 (91-260)	150 (96-260)	125 (91-230)
BMI (kg/m^2)	50 (33-85)	51 (39-85)	46 (33-68)
Follow-up (months)	19 (0-77)	17 (0-67)	20 (0-77)
Lost to follow-up	31 (11%)	13 (7%)	18 (18%)
Technique			
Open	233	131	102
Laparoscopic	57	56	1

Data are presented as N (%) or median (range).

GB: gastric bypass. Yrs: years. Kg: kilogram.

Follow-up

All 290 patients were followed for at least 30 days. Thirty-one patients (10,7%) were subsequently lost to follow-up for at least 18 months (median 21 months, range 2 – 39). The median follow-up time of the remaining 259 patients was 19 months (range 0 – 77), 189 of which were followed for ≥ 1 year, and 111 of which were followed for ≥ 2 years. The median follow-up time of patients undergoing gastric bypass surgery as their primary bariatric surgery was 17 months (range 0 – 67); 7,0% of these patients were lost to follow-up. Within the group undergoing secondary gastric bypass surgery the median follow-up time was 20 months (range 0 – 77); 17,5% of these patients were lost to follow-up.

Weight loss

Of the 189 patients with ≥ 1 year follow-up (117 primary surgeries, 72 secondary surgeries), 135 (71,4%) attained EWL ≥ 50% (Figure 2), with a median EWL of 58,6%, and a median BMI reduction of 16,2 kg/m² (Table 2). Subgroups with a higher preoperative BMI achieved greater BMI reductions (Table 3).

At maximum follow-up, patients for whom the gastric bypass was their primary bariatric surgery attained a median EWL of 61,4% (range 15,1 – 102,4%) and a median BMI reduction of 17,8 kg/m² (range 5,4 – 42,9) (Table 2). Of these 117 patients, 92 (78,6%) attained a successful outcome (EWL ≥ 50%) (Figure 2).

At maximum follow-up, patients who underwent secondary gastric bypass surgery attained a median EWL of 53,5% (range 7,7 – 98,3%) and a median BMI reduction of 11,9 kg/m² (range 0,9 – 25,7) (Table 2). Secondary gastric bypass surgery was successful (EWL ≥ 50%) in 40 of these 68 patients (58,8%) (Figure 2).

The median BMI reduction and the median EWL were greater after a primary than after a secondary bypass surgery (Table 2). Likewise, more primary than secondary procedures were successful (EWL ≥ 50%) (Figure 2). However, when the EWL was calculated using the weight before the primary procedure in the group undergoing the gastric bypass as a secondary procedure, the median excess weight loss at maximum follow-up did not differ from those who only underwent a primary gastric bypass.

Table 2. *Weight loss 1 year after gastric bypass (n=189)*

	Total (n=189)	Primary GB (n=117)	Secundary GB (n=72)
BMI pre GB (kg/m^2)	50	51	46
BMI difference	-16	-18	-12
EWL (%)	59	61	54

GB: gastric bypass. BMI: body mass index. EWL: excess weight loss

Figure 2. *Excess weight lost after a primary (PGB) and secondary (SGB) gastric bypass surgery, >1 year follow-up*

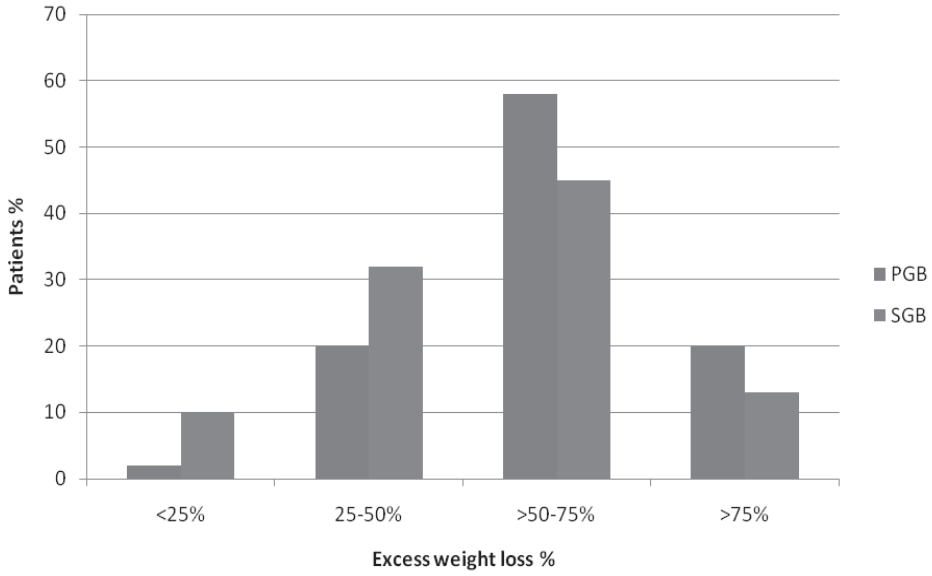


Table 3. *Weight loss after gastric bypass for subgroups of start BMI (n=189)*

	BMI < 45 (n=45)	BMI 45-55 (n=105)	BMI > 55 (n=39)
BMI pre GB	42 (33-45)	50 (44-55)	59 (55-85)
BMI difference	-11 (-1- -20)	-17 (-2 - -29)	-22 (-10 - -43)
EWL (%)	57 (8-98)	59 (10-102)	61 (29-91)

Data are presented as median (range).

BMI: body mass index. GB: gastri bypass. EWL: excess weight loss.

Complications

Within 30 days after surgery, complications occurred in 14,5% of patients (n = 42/290). Anastomotic leakage (5,2%) and wound infection (3,8%) were the most common early complications (Table 4). In 17 patients (5,9%), the early complications resulted in re-operation. Late complications occurred in 21% of patients (n= 61/290), including mainly anastomotic strictures (6,2%) and cicatrical hernias (5,2%) (Table 4). The anastomotic strictures were all treated by endoscopic dilation. The median number of dilations performed to remove the strictures was 4,6 (range 1 – 25). Patients who underwent open surgery had both more early and late complications than those who underwent laparoscopic surgery (16,7 versus 7,0% early complications, and 24,5% versus 7,3% late complications). Anastomotic strictures and cicatrical hernias occurred more frequently after the open technique (Table 4). During the follow-up period 2 patients deceased; both within 30 days after surgery. One patient died of a myocardial infarction. A second patient died with multi-organ failure and sepsis following anastomotic leakage.

Table 4. *Complications after GB (n=290).*

	Total (n=290)	Open (n=233)	Laparoscopic (n=57)
<30 days postoperative			
anastomotic leakage	15 (5,2%)	14 (6,0%)	1 (1,8%)
wound infection	11 (3,8%)	11 (4,7%)	0 (0%)
anastomotic stenosis	6 (2,1%)	6 (2,6%)	0 (0%)
abscess	5 (1,7%)	5 (2,1%)	0 (0%)
bleeding	2 (0,7%)	1 (0,4%)	1 (1,8%)
fascie dehiscence	1 (0,3%)	1 (0,4%)	0 (0%)
other	10 (3,4%)	8 (3,4%)	2 (3,5%)
reoperation	17 (5,9%)	15 (6,4%)	2 (3,5%)
>30 days postoperative			
anastomotic stenosis	18 (6,2%)	18 (7,7%)	0 (0%)
cicatrical hernia	15 (5,2%)	15 (6,4%)	0 (0%)
wound infection	4 (1,4%)	3 (1,3%)	1 (1,8%)
abscess	2 (0,7%)	2 (0,9%)	0 (0%)
anastomotic leakage	1 (0,3%)	0 (0%)	1 (1,8%)
other	31 (10,7%)	28 (12,0%)	3 (5,3%)

Discussion

Our study is the first report on the outcome of gastric bypass surgery in the Netherlands. After a follow-up period of at least one year, 71,4% of our patients had an EWL > 50%. The median BMI reduction of 16,2 kg/m² and the median EWL of 58,6% is similar to results reported by other centers.[10, 11]

Worldwide, gastric bypass and laparoscopic gastric band placement are currently the most commonly performed bariatric surgeries.[6,7] The main benefits of the gastric bypass compared to gastric banding are the greater percentage of successfully treated patients, and greater weight loss in a shorter time.[2, 12, 13] However, the gastric bypass procedure is associated with more surgery-related morbidity than gastric banding, as we have also shown in an earlier comparative study.[12,14,16] The loss of integrity of the digestive tract and the irreversibility of the bypass procedure may be considered drawbacks.

Patients who underwent primary bariatric surgery attained greater weight loss than those who underwent secondary surgery. For more than one-third of the patients who underwent gastric bypass surgery, this was a secondary procedure after a previous unsuccessful bariatric surgery. When the weight loss after the initial unsuccessful procedure was added to the weight loss after the secondary gastric bypass, the total excess weight loss did not differ between the groups undergoing primary and secondary bariatric surgery. This observation supports the idea that morbid obesity may initially be treated with the less invasive gastric band, especially in patients in

the lower BMI groups (BMI < 45 kg/m^2) without important co-morbidity. The morbidity of both procedures must be added, but in experienced hands, the morbidity of gastric band placement is very low. When gastric banding is unsuccessful, a secondary gastric bypass results in similar weight loss.

The 30-day morbidity of the open and laparoscopic approaches in our series (16,7% versus 7,0%) is similar to that reported by other centers (13,0% versus 7,4%).[17] The percentage of early complications was lower in the group treated laparoscopically, confirming a previous report that the laparoscopic approach results in lower morbidity.[17]

The higher complication rate in the group that underwent open procedures may partly be attributed to the learning curve in performing the bypass technique. We introduced the laparoscopic approach after gaining several years of experience with the open approach. The influence of the bypass technique learning curve on morbidity has previously been addressed.[18]

The percentage of anastomotic leakages (5,2%) was higher in our series than reported in an earlier review (3 - 4%).[15] With the advent of laparoscopy and the effect of the learning curve, the percentage of anastomotic leakages has decreased 9,5% in the 6 years that we have performed gastric bypass surgery (10,5% in 2002 and 1,4% in 2008).

Anastomotic strictures were the most common and the most burdensome late complication. Multiple dilations were often required to eliminate the strictures. This complication is related to the technique used to make the anastomoses. With the laparoscopic approach, we made part of the gastro-jejunostomy with a linear stapler and closed the remaining defect with sutures. In the open approach, we usually used the circular stapling technique which carries a higher risk of anastomotic strictures.[19, 20] Following laparoscopy, anastomotic strictures are also more common when the circular stapling technique is used than when a linear stapler is employed.[21] Our use of the circular stapling technique during the open approach explains our higher incidence of anastomotic strictures (6,2%) compared to studies reporting only on patients operated on laparoscopically with a linear stapling technique (range 0,8 - 4.7%).[11, 14, 15, 22]

More frequent use of the laparoscopic approach in the future should cause the number of wound infections and cicatrical hernias to decline. Both complications are associated with the open approach.[14, 17, 23] Two patients deceased during the follow-up period (2/290 = 0,7%), both within 2 months after surgery. This is acceptable when compared to similarly sized studies (0,23; 0,87; and 1% mortality).[14, 24]

Successful outcome of the surgical treatment of morbid obesity should be measured not only in excess weight loss, but also in decreased co-morbidity and improved quality of life. A longer follow-up time is needed to determine the effect of the bypass procedure on co-morbidity. This is the subject of a future study.

Conclusion

The gastric bypass is a complex procedure which is conducted on a population with higher surgical risk based on its obesity and co-morbidities. The mortality risk is evident and it is very important that patients are well-informed. The procedure is an effective treatment for morbid obesity, whether conducted primarily or secondarily following an earlier unsuccessful bariatric surgery. In experienced hands, the surgery is associated with acceptable morbidity. The laparoscopic approach seems to be preferable.

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6

Comparison of weight loss and morbidity after open gastric bypass and laparoscopic gastric banding. A single center European experience

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Obes Surg, 2008

Abstract

Background

Gastric bypass and gastric banding are widely used to treat morbid obesity and both procedures offer certain advantages. The indication for these two treatment options continue to be subject to debate.

Methods

A retrospective single-center case-controlled matched-pair cohort study was performed. Fifty-three primary gastric bypass patients (GB) operated between January 2002 and May 2005 were matched by gender, age, race, and initial bodyweight to 53 patients who underwent laparoscopic adjustable gastric banding (LAGB) in the same time period.

Results

Both groups were comparable regarding age, race, gender, preoperative body mass index, and excessive weight. Severe early complications occurred in six patients (11,3%) in the GB group and were not seen in the LAGB group. Severe late complications occurred in three patients (5,7%) in the GB group and one patient (1,9%) in the LAGB group. No mortality occurred in either group. Weight loss was significantly lower in the LAGB group than in the GB group at all time points during the followup. Significantly more patients were treated successfully (excess weight loss > 50%) in the GB group than in the LAGB group. After 2 years, 76% of the patients in the GB group were treated successfully versus 40% of the patients in the LAGB group (P = 0,03).

Conclusion

Gastric bypass and gastric banding are safe and with low mortality. Gastric bypass is more effective in terms of weight loss and the number of successfully treated patients. Gastric banding is a procedure with less severe complications.

Introduction

Obesity is an increasing concern in Western countries and its prevalence has reached epidemic proportions.[1] The association between obesity and comorbid diseases such as hypertension, diabetes mellitus type II, dyslipidemia, and sleep-apnea syndrome makes reduction of body weight in selected patients imperative. Bariatric surgery has proven to be the most effective long term treatment in morbidly obese patients.[2-4]

Laparoscopic adjustable gastric banding (LAGB) and (laparoscopic) gastric bypass (GB) are the two procedures most commonly performed.[5-12] The two techniques each have their own advantages and procedure-related complications. The gastric bypass procedure results in increased weight loss compared to gastric banding, which is reached earlier after operation, whereas banding has the advantage of complete reversibility. The gastric bypass might be associated with a higher incidence of short term surgical complications.[10,13] However, increasing experience with laparoscopic gastric banding has shown a high incidence of long term complications and reoperations.[14]

The indication for these two treatment options continue to be subject to debate over the years.[15] The choice of operation is often primarily based on the preference of the patient or the experience and familiarity of the physician with a certain procedure rather than on evidence. No prospective randomized trials are available to compare the results of both procedures and to establish the superiority of one procedure above the other. In the absence of such trials, a case-controlled matched-pair cohort study is second best to compare the results of both procedures. We performed this study in a single center to compare the efficacy of laparoscopic adjustable gastric banding and open gastric bypass in morbidly obese patients in terms of the percentage of patients treated successfully and to evaluate the morbidity of both procedures.

Methods

Patients

Bariatric surgery was introduced in our department in 1995. Potential candidates for surgery were screened by a multidisciplinary team, consisting of a physician, a surgeon, a psychologist, and a dietician. Patient inclusion was according to criteria proposed by the National Institutes of Health Development Panel.[16] These criteria included a BMI > 40 kg/m^2 or a BMI > 35 kg/m^2 with severe related comorbidity. All patients had previously failed on conservative treatment. All bariatric procedures were performed by a single surgeon (BvR). Follow-up after surgery was conducted by a specialized nurse-practitioner and consisted of consultation every 2-3 months the first year after surgery, every 3 months the second year, twice yearly for up to 5 years and yearly thereafter.

Surgery

LAGB Group

Between September 1995 and May 2005, a total of 411 banding procedures were performed with either the Lap- Band® (Bioenterics, Inamed Health, Santa Barbara, California, USA) or the Swedish adjustable gastric band® (SAGB, Johnson & Johnson, New Brunswick, NJ, USA).[17] The first 210 procedures were carried out according to the perigastric technique.[18] Later on, the pars flaccida technique was adopted because of an unacceptable high rate of fundus slippages in the early group.[19] Six weeks after operation the gastric band was inflated in the office and during further follow-up adjusted, depending on the weight loss and according to each patient's individual need.

GB Group

Between January 2002 and May 2005, 53 primary open gastric bypass procedures were performed. The operation was performed through a supraumbilical laparotomy. The stomach was transected creating a small, proximal pouch. The jejunum was transected 50 cm distally to the duodenojejunal flexure. A gastro-jejunostomy was created using a circular stapler (CEA 25 mm, Tyco, Mansfield, MA) with an antecolic Roux limb of 75–125 cm. Continuity was established by a sutured laterolateral jejuno-jejunostomy. In the postoperative course, all patients got a contrast study of the esophagus and stomach after 3 days. Resumption of oral diet was started in the absence of a leakage. Patients were discharged as soon as sufficient oral fluid and soft food intake was possible.

Data Collection and Statics

Data for each patient were prospectively collected in a database. A case-controlled matched-pair cohort study was performed. Fifty-three primary gastric bypass (GB) patients operated between January 2002 and May 2005 were matched by gender, age, race, and initial bodyweight to 53 patients who underwent laparoscopic adjustable gastric banding in the same time period. To minimize bias, patients who underwent LAGB were consecutively enrolled in reversed order: if more than one LAGB patient could be matched with one GB patient, the patient operated on most recently was selected.

Demographic data, operation time, length of hospital stay, complications and weight loss were compared. Morbidity up to 30 days after surgery were defined as early complications, and adverse events thereafter as late complications. Complications were divided as minor or severe. The percentage of excess weight loss (EWL) and BMI were used to evaluate weight loss. Ideal body weight was determined according to the Metropolitan Life Insurance Company 1983 height/weight tables.[20] Excess weight was defined as the difference between the patient's weight and the theoretical medium frame ideal body weight. The effect of surgery was categorized: an EWL > 75% was defined as an excellent result, an EWL > 50% as a good result, an EWL > 25% as a fair result, and an EWL < 25% as a poor result.[21] Good and excellent results (EWL > 50%) were defined as successful treatment.

Data analysis was performed using standard software (SPSS 12.0 for Windows). Continuous variables were compared using the Mann–Whitney U test. Chi-square test was used to compare noncontinuous variables. Statistical significance was defined as $P < 0,05$.

Results

The LAGB and GB groups consisted of 44 women and nine men ($P = 1,0$) and 51 persons of the Caucasian race and two of the African race ($P = 1,0$). The median age for LAGB patients was 40,3 years compared with 38,0 years in the GB group ($P = 0,24$). Median preoperative BMI was 50,9 kg/m^2 for the LAGB group compared with 51,3 kg/m^2 for the GB group ($P = 0,66$). Median preoperative weight and excess weight were 147,0 kg versus 151,0 kg ($P = 0,08$) and 82,7 kg versus 88,7 kg ($P = 0,13$) for the LAGB versus the GB group. Median operation time was significantly shorter for the LAGB group than for the GB group: 60 minutes versus 75 minutes ($P < 0,001$). Median hospital stay was significantly shorter for the LAGB group than for the GB group: 2 days versus 5 days ($P < 0,001$). Median follow-up was 23 months for the LAGB group and 18 months for the GB group ($P = 0,02$). No patients were lost to follow-up. All data are shown in Table 1.

Table 1. *Patient characteristics*

	LAGB (n=53)	GB (n=53)	*P*
Sex (female/male)	44 / 9	44 / 9	1,0
Age (yrs)	40 (22-59)	38 (22-61)	0,2
Initial BMI (kg/m^2)	51 (41-66)	51 (41-85)	0,7
Weight (kg)	147 (99-210)	151 (106-260)	0,1
Excess weight (kg)	83 (48-142)	89 (51-190)	0,1
Operation time (min)	60 (35-120)	75 (55-150)	<0,001
Hospital stay (days)	2 (1-7)	5 (4-55)	<0,001
Follow-up (months)	23 (10-52)	18 (3-48)	0,02

Data are presented as N or median (range).

LAGB: laparoscopic adjustable gastric banding, GB: gastric bypass.

Yrs: years. BMI: body mass index. Kg: kilogram. Min: minutes.

Complications

Complications are listed in Table 2. Reoperations are shown in Table 3. No mortality occurred in either group. In the LAGB group, there were no conversions to an open procedure.

Table 2. *Complications*

	LAGB (n)	GB (n)
Early minor		
Obstruction	2	-
Wound infection	2	2
Total	**4 (7,5%)**	**2 (3,8%)**
Early severe		
Leakage of anastomosis	-	3
Intra-abdominal abscess	-	1
Infected hematoma	-	1
Pneumonia	-	1
Total	**-**	**6 (11,3%)**
Late minor		
Luxation reservoir	1	-
Stenosis anastomosis	-	1
Total	**1 (1,9%)**	**1 (1,9%)**
Late severe		
Incisional hernia	-	3
Band slippage	1	-
Total	**1 (1,9%)**	**3 (5,7%)**

Table 3. *Reoperations*

	LAGB (n)	GB (n)
Port revision	1	-
Band reposition	1	-
Leakage of anastomosis	-	2
Cicatrical hernia	-	3
Infected hematoma	-	3
Drainage abscess	-	1
Pneumonia	-	1
Total	**2 (3,8%)**	**10 (18,9%)**

Early Complications

Minor early complications occurred in four patients (7,5%) in the LAGB and two patients (3,8%) in the GB group. In the LAGB group, two patients had early obstruction caused by stomal edema

for which temporary tube feeding was necessary. In the LAGB and GB group, two patients had a wound infection. No reoperations as a result of early complications were necessary in either group. Severe early complications occurred in six patients (11,3%) in the GB group and were not seen in the LAGB group. In the GB group, three patients had leakage at the gastrojejunostomy. In two patients, the leakage was suspected because of the clinical condition of the patient, and a reoperation was performed. In one patient, without any symptoms, the leakage was found on the postoperatively performed contrast study. No reoperation was performed in this patient. Other severe early complications that also required reoperation in the GB group were an intra-abdominal abscess (n = 1) and an infected intra-abdominal hematoma (n = 1). One patient was reoperated under suspicion of an intra-abdominal infectious complication, but proved to have a pneumonia.

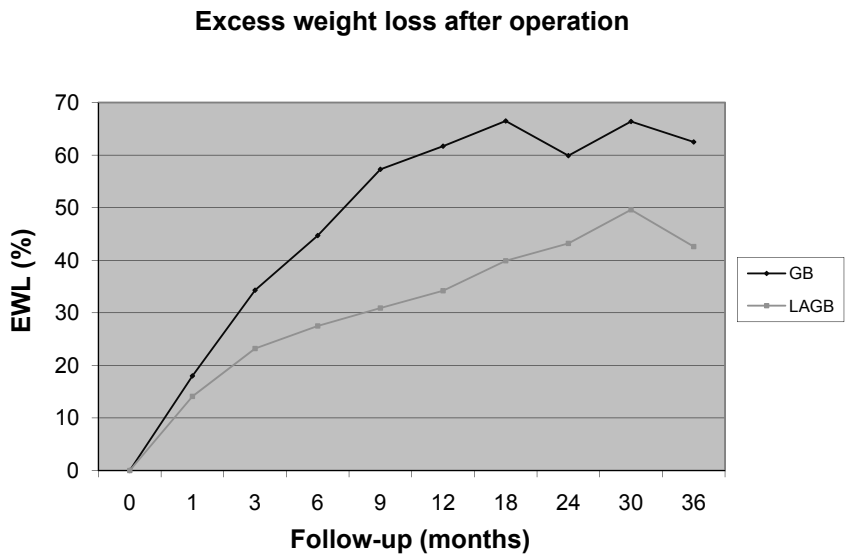
Large Complications

Minor late complications occurred in one patient (1,9%) in the LAGB and one patient (1,9%) in the GB group. In the LAGB group, one patient had a dislocation of the port-a-cath reservoir, which required a reoperation. In the GB group, one patient had stenosis at the gastro-jejunal anastomosis, which could be treated by endoscopic dilatation. Severe late complications occurred in one patient (1,9%) in the LAGB group and three patients (5,7%) in the GB group. In the LAGB group, one patient had a band slippage and required a reoperation. In the GB group, three patients had an incisional hernia, who were reoperated. Two of these three patients also had experienced an early infectious complication.

Weight Loss

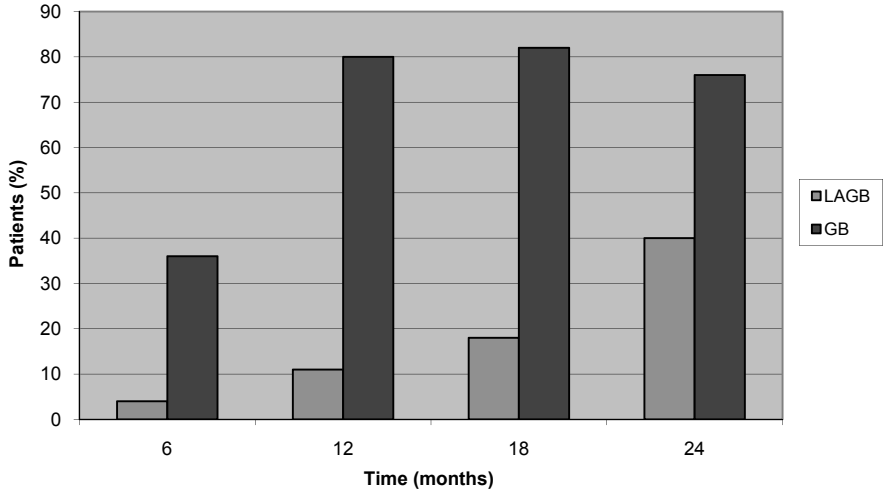
EWL was significantly lower in the LAGB group than in the GB group at all time points during the follow-up (Figure 1). Median EWL was 23,2% for the LAGB group versus 34,3% ($P < 0,001$) for the GB group at 3-month follow-up, 27,4% versus 44,7% at 6 months ($P < 0,001$), 34,4% versus 62,1% at 1 year ($P > 0,001$), and 43,4% versus 59,9% at 2 years ($P < 0,001$). The median BMI difference at 2 years follow-up in the LAGB group was from 50,9 to 38,3 kg/m^2 (-12,6 kg/m^2) and for the GB group from 51,3 to 34,0 kg/m^2 (-17,3 kg/m^2). According to the outcome classification, significantly more patients reached good/excellent results (EWL > 50%) in the GB group at all time points during follow-up (Figure 2). After two years, 40% of the patients in the LAGB group were treated successfully (EWL > 50%) versus 76% of the patients in the GB group ($P = 0,03$).

Figure 1. *Change in EWL (%) after GB and LAGB.*



Time (months)	0	1	3	6	9	12	18	24	30	36
GB (n)	53	49	48	47	39	45	28	17	10	5
LAGB (n)	53	51	35	47	45	47	39	25	17	9

Figure 2. *Percentage of patients treated succesfully (EWL > 50%) after GB and LAGB at 6, 12, 18 and 24 months postoperatively.*



Discussion

Several studies have shown the advantage of the gastric bypass operation over the gastric banding procedure in weight outcome.[22-24] This single-center study is the first to date to establish the superiority of gastric bypass over gastric banding in terms of the percentage of patients treated successfully defined as an EWL > 50% (76% versus 40%; *P* = 0,03). As in other series, the weight loss after gastric bypass in our series was more profound at all time points after operation compared to gastric banding. The gastric bypass procedure showed more severe early and late complications. Both procedures were safe and performed without mortality.
In the absence of prospective randomized trials, a case-controlled matched-pair cohort study is second best to compare both procedures. This study was performed in a single-center setting. The two groups we compared meet the requirements of similarity in demographics and the consistency of the surgical team (one surgeon, BvR). Two other case-controlled matched-pair cohort studies have compared gastric banding to gastric bypass. Weber et al. performed a study with comparable groups of 103 patients.[23] It was concluded that laparoscopic gastric bypass offers a significant advantage regarding weight loss and reduction of comorbidities. The higher incidence of early complications in the bypass group was found to outweight the significantly higher rate of late complications requiring reoperations in the banding group. Cottam performed a study with comparable groups of 181 patients.[24] They concluded that gastric bypass is better than gastric banding at 3 years follow-up with respect to weight loss and reduction of comorbidities. Major reoperation rates for both techniques were the same. The weight outcome in both studies was comparable to the present study, but the percentage of successfully treated patients was not reported. A limitation of all studies is the relative short follow-up period of 3 years. The difference in weight loss between the bypass and banding groups is reported to diminish after longer follow-up periods as the banding group continues to lose weight.[25] Longer follow-up studies are needed on this subject.

One limitation of our study might be the selection bias with regard to the procedure chosen. No preoperative criteria were defined for the selection of either a banding or a bypass procedure and the choice of operation was based on the preference of the patient and the surgeon. Assuming that patients with a worse expected outcome, based on eating pattern or previous history may have been selected for a bypass operation, would implicate more favourable results in the gastric banding group as compared to historical controls. For this reason, we compared the outcome of our patients undergoing gastric banding in the period 1995–2001 (n=265), when banding was the only procedure performed in our department, with the group of patients undergoing gastric banding in the study period 2002–2005 (n = 146), when patients were selected either for a banding or a bypass procedure.

There was no difference in weight outcome in this subanalysis of banded patients, which suggests a minimal influence of selection bias on the outcome in our study.
The sample size of our study did not allow further evaluation of the relation between the preoperative BMI and weight outcome between both procedures. Gastric banding might be more effective in lower BMI groups. The outcome of gastric banding would therefore compare more favorable to gastric bypass in lower BMI groups than in the present study, which included patients with a median BMI over 50.
Both gastric banding and gastric bypass proved safe procedures in our series, without mortality. Reported mortality rates for laparoscopic adjustable gastric banding and gastric bypass are around 0,05% versus 0,5%, respectively.[26] Comparing the two techniques, the type of complications are different. The most hazardous, but very rare (< 1%), early complication after LAGB is undiagnosed gastric perforation.[27] The most frequently encountered late complication in the LAGB procedure is band slippage. The reported incidence in early studies was 20–30%.[28,29] The high incidence of this complication and its need for reoperation has been pointed out as a limitation of this procedure. This complication was encountered frequently during use of the perigastric operative technique. After the introduction of the pars flaccida technique, this complication significantly decreased (1,9%, present series).[30-32] Another late complication of the LAGB is infection or leakage at the port site, which can often be resolved in ambulatory surgery.
The most serious early complication of the gastric bypass, with a reported incidence of 3–4%, is leakage of the gastro-jejunal anastomosis.[33] In our series, we had a 5,7% leakage rate, although without any mortality. Most encountered complication after gastric bypass is stenosis at the gastro-jejunal anastomosis, which is treated by endoscopic dilatation.[34] Our most frequent late complication was the occurrence of incisional hernia because of the fact that the gastric bypass operation was performed by laparotomy. The introduction of laparoscopic procedures will definitely reduce the incisional hernia rate.
To date there is no "gold standard" of surgical therapy in the morbidly obese patient. No selection criteria exist to tailor the most appropriate bariatric procedure to the individual patient. Neither is there a "gold standard" in the definition of successful surgical treatment. Although comorbidities are significantly reduced or cured by a minimal EWL of 10%, most surgeons still adhere to a body mass reduction below 30 kg/m^2 or an EWL > 50% in their definition of successful treatment.[35,36] One should appreciate that a change in the definition of successful treatment will dramatically change the outcome perspective as illustrated in our series. Defining successful treatment as EWL > 30%, would duplicate the percentage of successfully treated patients by laparoscopic gastric banding in our series to 80% at 2-year follow-up, compared to 40% of the patients if successful treatment was defined as EWL > 50%.

Conclusion

In conclusion, both laparoscopic gastric banding and gastric bypass proved safe procedures to establish weight loss in the morbidly obese patients. The number of patients treated successfully was significantly higher in the bypass group. Laparoscopic gastric banding has less severe complications. Consensus among bariatric surgeons with regard to "ideal" weight loss in combination with further studies to define success rates in different BMI cohorts should lead to guidelines to tailor the appropriate procedure to the individual patient.

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7

Conversion of failed laparoscopic gastric banding to gastric bypass as safe and effective as primary gastric bypass in morbidly obese patients

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Surg Obes Relat Dis, 2008

Abstract

Background

To determine whether the mid term outcome of secondary gastric bypass (SGB) after laparoscopic adjustable gastric banding (LAGB) is comparable to the outcome of primary gastric bypass (PGB) in morbidly obese patients in terms of complications and weight loss. Controversy exists among bariatric surgeons regarding the choice of primary operation for morbid obesity. Some prefer to start with LAGB as a low risk operation for all patients and perform revisional surgery in the case of failure. Others prefer to tailor the primary operation to the individual patient.

Methods

A total of 55 patients who had undergone SGB after failed LAGB from 2002 to 2006 were retrospectively compared with 81 patients who had undergone PGB for morbid obesity during the same period in our hospital by a single surgeon.

Results

The mean operative time in the PGB group was shorter (73 ± 22 min, range 50–100) compared with the SGB group (99 ± 32 min, range 55–180; $P < 0{,}001$). The median length of admission did not differ significantly between the PGB and SGB groups (4 ± 6,6 d, range 3–55, versus 4 ± 2,9 d, range 3–16, respectively; $P = 0{,}13$). No significant differences were found in the occurrence of complications between the PGB and SGB groups (29,6% versus 30,9%, respectively, $P = 0.87$). No patient died. At 2 and 3 years postoperatively, no significant difference was found in percentage of patients treated with good or excellent outcomes using the criteria of MacLean (2 years, PGB 60,0% versus SGB 58,8%, $P = 0{,}94$; 3 years, PGB 75,0% versus SGB 72,7%, $P = 0{,}91$).

Conclusion

In this series, gastric bypass as a secondary procedure after failed LAGB was as safe and effective as PGB. Conversion to gastric bypass appears to be the treatment of choice after failed LAGB.

Introduction

Obesity is a major health problem in Western countries.[1] Because of the strong association of weight-related co-morbidities with hypertension, diabetes mellitus, dyslipidemia, and obstructive sleep apnea syndrome, obesity not only affects the quality of life of morbidly obese patients, but also places an increasing burden on healthcare systems.[2,3] Currently, bariatric surgery is the most effective treatment of morbid obesity, achieving sustained weight loss, improving co-morbid conditions, and even reducing mortality rates.[4-6] Different surgical procedures have been applied. However, no consensus has yet been reached about the standard treatment of morbid obesity. A trend analysis performed by Samuel demonstrated a marked shift from restrictive procedures to a clear preference for combined restrictive-malabsorptive procedures in the past decade.[7] Gastric bypass as a primary procedure has been shown to be more effective than laparoscopic adjustable gastric banding (LAGB) in terms of weight reduction.[8] This could explain the current predominant preference for gastric bypass. Despite reported failure and complication rates of 40% and 50%, respectively, many patients still do very well after LAGB, which has the ultimate advantage of total reversibility without compromise to the gastro-intestinal tract.[9-12] To resolve the complication and to acquire additional and sustained weight loss, revisional surgery after LAGB might be required. Numerous studies have already shown that conversion to gastric bypass as a secondary procedure after failed LAGB results in improved weight control with acceptable morbidity.[13-15] However, the results of secondary gastric bypass (SGB) have been compared with other procedures such as refixation, replacement, or removal of the gastric band. Whether SGB after failed LAGB poses significant risks and results in similar weight loss compared with primary gastric bypass (PGB) remains unclear. Therefore, the purpose of this study was to determine whether the outcome of SGB after LAGB is comparable to the outcome of PGB in morbidly obese patients in terms of complications and weight loss.

Methods

Patients

Gastric bypass has been performed in our department since 2002. LAGB has been performed in our department since 1995 (n = 383, to November 2004, last SGB patient). The indications for bariatric surgery have been in accordance with the 1991 National Institutes of Health Consensus Development Conference Draft Statement.[16,17] Patients must meet the following criteria: body mass index BMI > 40 kg/m^2 or a BMI > 35 kg/m^2 with severe related comorbidity. Previous nonoperative treatment must have been unsuccessful.

From January 2002 to October 2006, 81 patients underwent PGB at our center. In the same period, 55 patients underwent SGB after failed LAGB for morbid obesity. The indications for SGB after LAGB included insufficient weight loss (excess weight loss (EWL) < 25%) in the presence

of a normal functioning band, band-related complications, or intractable symptoms. In these patients, primary LAGB had been performed from November 1995 to November 2004. All LAGB procedures had been performed at our hospital, except for those of 3 patients. Of these 55 patients, 40 had their band placed before 2001, when the perigastric method was used, and 12 had their band placed after January 2001, when the pars flaccida method was used. In the 3 patients who had undergone LAGB elsewhere, the perigastric method had been used.

Surgery

All gastric bypass (GB) procedures were performed through an upper midline laparotomy. In the case of conversion, the gastric band was removed. By dividing the stomach, a small proximal pouch was formed. The jejunum was divided 50 cm distal to the duodenojejunal flexion. A gastro-jejunostomy was created using a circular stapler (CEA 25 mm, Tyco, Mansfield, MA) with an antecolic Roux limb of 75–125 cm. Continuity was established by a sutured lateral-lateral jejunojejunostomy.

Postoperative management

During the postoperative course, all patients underwent an upper gastro-intestinal contrast study on the second postoperative day. If no leak or obstruction was demonstrated, the nasogastric tube was removed and a liquid diet initiated. The patients were discharged as soon as they had advanced to sufficient semiliquid intake, which was continued for 1 month. Follow-up after surgery was conducted by a specialized nurse-practitioner and consisted of consultation every 2-3 months the first year after surgery, every 3 months the second year, twice yearly for up to 5 years and yearly thereafter.

Data collection

The data for each patient were collected prospectively. The collected data included age, gender, preoperative weight and BMI, operative time, length of admission, early (< 30 days) and late (> 30 days) complications, reoperations, and follow-up weight. The interval between LAGB and SGB and the indication for revision were also included. The weight loss results are expressed as the change in the BMI. According to the criteria of MacLean, the result of therapy was considered a failure if the BMI was > 35 kg/m^2 and good/excellent if the BMI was < 35 kg/m^2.[18]

Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences, version 12.0 (SPSS, Chicago, IL). A comparison of the continuous variables was done using the Mann-Whitney U test and of categorical variables using the chi-square test or Fisher's exact test. *P* values < 0,05 were considered significant.

Results

All patients were followed up until November 2006. The median follow-up was 12,8 months (range 0,3 – 54). The patient characteristics are summarized in Table 1.

***Table 1**. Characteristics of patients with primary or secondary gastric bypass.*

	PGB (n=81)	SGB (n=55)	*P*
Age (yrs)	38 (21-62)	43 (28-65)	<0,01
Female gender	65 (80%)	49 (89%)	0,17
Weight (kg)	151 (106-260)	132 (91-230)	<0,001
BMI (kg/m^2)	51 (40-85)	47 (33-68)	<0,001
Excess weight (kg)	87 (51-190)	68 (30-146)	<0,001
Follow-up (months)	13 (1-37)	13 (1-54)	0,36
Operation time (min)	75 (50-150)	100 (55-180)	<0,001
Admission (days)	4 (3-55)	4 (3-16)	0,13

Data are presented as N (%) or median (range).

PGB: primary gastric bypass. SGB: secondary gastric bypass.

Yrs: years. Kg: kilogram. Min: minutes.

In the PGB group, the patients were significantly younger at gastric bypass (mean 39,2 ± 9.5 yr, range 21,1– 62,0) than the SGB group (mean 43,8 ± 9.1 yr, range 27,7– 64,7; $P < 0,01$). Also, the mean preoperative BMI of patients undergoing PGB (52,3 ± 7,2 kg/m^2, range 40,6 – 84,6) was significantly greater than that in the SGB group (47,7 ± 7,4 kg/m^2, range 33,2 – 68,1; ($P < 0,001$). However, no significant difference was present in the mean initial age (38,2 ± 8,9 yr, range 23,5 – 59,1, versus 39,2 ± 9,5 yr, range 21,1 – 62,0, respectively; $P = 0,50$) or mean preoperative BMI (50,1 ± 6,5 kg/m^2, range 42,1 – 71,7, versus 52,3 ± 7,2 kg/m^2, range 40,6 – 84,6, respectively; $P = 0,07$) of the SGB group before the primary LAGB procedure compared with the PGB group. Although the mean operative time in the PGB group was shorter (73 ± 22 min, range 50 – 100) than that for the SGB group (99 ± 32 min, range 55 – 180; $P < 0,001$), the median length of admission was not significantly different (6,6 ± 4 d, range 3 – 55, versus 4 ± 2,9 d, range 3 – 16, respectively; $P = 0,13$). The median follow-up for both groups was comparable at 12,8 and 13,4 months ($P = 0,36$). The median time between the LAGB and the SGB was 66,2 months (range 12,7 – 120,0). Insufficient weight loss in the presence of a functioning gastric band was the most common reason to convert to gastric bypass (n = 45; 78,6%). The mean EWL for these patients at SGB was 11,2% ± 6,9% (range [-21,6%] – [24,6%]). In 3 patients (5,5%), gastric perforation and band erosion was the indication for removal of the gastric band, and 4 patients (7,3%) had a dislocation of the stomach or slip of the band that resulted in removal of the gastric band. The other reasons for removal were band malfunction in 1 patient (1,8%) and intractable gastro-intestinal symptoms in 2 (3,6%). Band removal with immediate conversion to SGB was performed in 50 patients (90,9%);

5 patients had their gastric band removed as a separate procedure before SGB. The reasons were gastric perforation in 2, band erosion in 1, and pouch dilation in 2.

Complications

No significant differences were found in the occurrence of complications between the PGB and SGB groups (29,6% versus 30,9%, respectively, $P = 0,87$) (Table 2).

Early complications occurred in 11 patients (13,6%) in the PGB group and 8 (14,5%) in the SGB group. In the PGB group, 5 patients (6,2%) had a leak of the gastrojejunal anastomosis; 2 were treated conservatively and 3 underwent reoperation. In the SGB group, 2 patients (3,6%) had an anastomotic leak; in 1, the anastomotic leak was detected by the standard postoperative contrast study and was treated conservatively. The other patient initially had a negative contrast study, but 1 week postoperatively, he developed symptoms with a clinical suspicion of leak and required reoperation. One patient, who was clinically suspected of having a leak and an intra-abdominal infection, underwent reoperation but proved to have pneumonia.

Late complications occurred in 13 patients (16,0%) in the PGB group and 9 (16,4%) in the SGB group. In the PGB group, 6 patients (7,4%) developed stenosis of the gastrojejunal anastomosis versus 2 patients (3,6%) in the SGB group. All were successfully treated with (multiple) endoscopic dilation. Symptomatic cholelithiasis was seen in 3 patients (3,7%) in the PGB group and 3 patients (5,5%) in the SGB group.

In the PGB group, 11 patients (13,6%) underwent reoperation because of an early or late complication compared with 10 patients (18,2%) in the SGB group (Table 3). One patient died of breast carcinoma 13 months after the gastric bypass procedure. No patient died during the follow-up period.

Table 2. *Complications after primary or secondary gastric bypass.*

	PGB: n (%)	SGB: n (%)	*P*
Early			
Leakage anastomosis	5 (6,2)	2 (3,6)	0,51
Wound infection	2 (2,5)	1 (1,8)	0,80
Abscess	2 (2,5)	4 (7,3)	0,18
Pneumonia	2 (2,5)	-	0,24
Urinary tract infection	-	1 (1,8)	0,22
Total	**11 (13,6)**	**8 (14,5)**	**0,87**
Late			
Stenosis anastomosis	6 (7,4)	2 (3,6)	0,36
Incisional hernia	2 (2,5)	3 (5,5)	0,36
Cholelithiasis	3 (3,7)	3 (5,5)	0,63
Ulcer	2 (2,5)	1 (1,8)	0,80
Total	**13 (16,0)**	**9 (16,4)**	**0,96**
Total (early + late)	**24 (29,6)**	**17 (30,9)**	**0,87**

PGB: primary gastric bypass. SGB: secondary gastric bypass.

Table 3. *Reoperations after primary or secondary gastric bypass.*

	PGB: n (%)	SGB: n (%)	*P*
Leakage anastomosis	3 (3,7)	1 (1,8)	0,52
Abscess	2 (2,5)	4 (7,3)	0,18
Pneumonia	1 (1,2)	-	0,41
Incisional hernia	2 (2,5)	3 (5,5)	0,36
Cholecystectomy	3 (3,7)	2 (3,6)	0,98
Gastric banding	1 (1,2)	-	0,41
Total	11 (13,6)	10 (18,2)	0,17

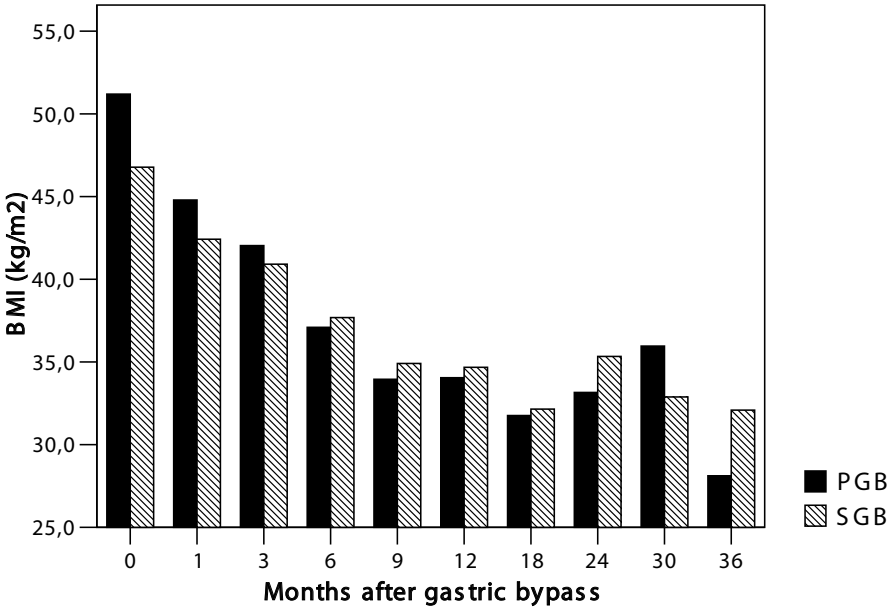
PGB: primary gastric bypass. SGB: secondary gastric bypass.

Weight loss

The mean BMI of the PGB group compared with the SGB group was significantly greater at 1 month postoperatively (46,5 ± 6,9 kg/m^2, range 36,4 – 81,1, versus 43,6 ± 6,9 kg/m^2, range 31,1 – 64,5, respectively; $P < 0,01$). However, after 3 months, no significant differences were noted between the PGB and SGB groups (42,9 ± 6,9 kg/m^2, range 33,5 – 71,3, versus 41,0 ± 6,0 kg/m^2, range 29,6 – 57,7, respectively; $P = 0,12$). At 2 years postoperatively, the mean BMI of the PGB and SGB groups was 33,3 ± 7,5 kg/m^2 (range 24,3 – 50,5) and 35,6 ± 5,7 kg/m^2 (range 27,5 – 48,0; $P = 0,43$), respectively (Figure 1).

At 2 and 3 years postoperatively, no significant difference was found in the percentage of patients with good/excellent outcomes, according to the criteria of MacLean, between the PGB (2 years, 60,0%; 3 years, 75,0%) and SGB (2 years, 58,8%; 3 years, 72,7%) groups (P = 0,94 and P = 0,91, respectively).[18]

Figure 1. *Body mass index (BMI) after primary and secondary gastric bypass.*



Follow-up (months)	1	3	6	9	12	18	24
PGB (n)	76	68	55	46	44	28	17
SGB (n)	45	47	42	31	31	24	14

Discussion

The results of our study have shown that SGB after failed LAGB is equally safe and effective as PGB. No differences were found in the complication rates. At 2 years of follow-up, no significant differences were found in the percentage of patients with good/excellent outcomes. Only a few studies have compared the safety and efficacy of SGB with PGB. Revisional surgery is a known risk factor for anastomotic leaks and other complications.[19,20]

Roller and Provost demonstrated that when converting to gastric bypass, patients with previous revisions are at a greater risk of developing complications (41,7%) than patients undergoing first-time revision (29,6%).[19] Sugerman and Wolper showed that conversion to GB after failed gastroplasty resulted in significantly more complications than when GB was performed as a primary procedure.[21] A more recent case-matched analysis by Martin demonstrated that resectional gastric bypass after a failed bariatric procedure achieved results comparable to those for patients undergoing an initial bariatric procedure, with equal complication rates.[22] The mean BMI was 28,1 kg/m^2 versus 28,4 kg/m^2 after 1 year in their PGB (n = 54) and SGB (n = 27) groups, respectively.[22] Most of these patients (74%) had undergone conversion after failed vertical banded gastroplasty; only 7% were after failed gastric banding.

The BMI achieved in our SGB group seems consistent with the results of other studies. In a series of 141 patients who had undergone conversion after failed gastroplasty, Jones found a mean BMI of 31,0 kg/m^2 at 5 years.[23] In the study by Mognol, 70 patients underwent conversion to GB after failed LAGB and had achieved a median BMI of 32,2 kg/m^2 at 18 months.[24]

The most common indication for conversion to gastric bypass in our study was inadequate weight loss, in accordance with other studies, in which the percentage was 49–89%.[10,25] The longer operative times in our SGB group could have resulted from gastric band removal, as well as correction of the complication. Also, scarring and adhesions make the SGB procedure technically more demanding than the PGB procedure. Some authors favour a time interval between band removal and the gastric bypass, in contrary to our one step technique. Van Nieuwenhove found decreased rates of anastomotic strictures (0 %) after a two step technique in a group of 14 patients, at the expense of an increased operating time and hospital stay.[26]

One limitation of our study was the relative short follow-up period. Nevertheless, the SGB was successful in 58,8% of the patients after 2 years. Also, the initial age and BMI before PGB and SGB were significantly different between the 2 groups. This difference was inherent to our study and can be explained by the interval between primary LAGB and SGB in the SGB group. The initial age and BMI were not significantly different between the PGB and SGB groups, before primary LAGB.

Bariatric surgery is currently the most effective treatment for morbid obesity, but not all bariatric operations are equally successful. LAGB was a popular procedure in the mid-90's mainly because of the relative simplicity of the procedure.[7] However, the high failure rate of LAGB in the long term has been reflected by the revision rate, which has ranged from 1,9% to 66,7%.[27,28] DeMaria

estimated that in their series, the overall need for band removal or gastric bypass after gastric banding would ultimately be > 50%.[10] Currently, gastric bypass is becoming the predominant primary treatment of morbid obesity, because it most successfully achieves sustained weight loss in the long term.[7,29,30] As a revisional procedure, the conversion to gastric bypass also appears to be superior in achieving weight loss compared with rebanding after failed LAGB or revision after vertical banded gastroplasty.[9,13-15,31] In our center, we consider conversion to GB for insufficient weight loss.

Conclusion

In this series, gastric bypass as a secondary procedure after failed LAGB was equally safe and effective as PGB. Conversion to gastric bypass appears to be the treatment of choice after failed LAGB.

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8

The impact of reconstructive procedures following bariatric surgery on patient well-being and quality of life

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Abstract

Background

Massive weight loss following bariatric surgery may lead to an excess of lax, overstretched skin, causing physical discomfort which may affect the patient's quality of life. Whereas the functional and aesthetic deformity is an expected result of massive weight loss, the role of the plastic surgeon in the multidisciplinary approach of the morbidly obese is still unclear. The purpose of the current study is to evaluate the results of reconstructive surgery following weight loss surgery, focusing on the impact on the physical and psycho-social well-being and quality of life of the patients.

Methods

Out of a group of 465 patients, 61 patients underwent reconstructive surgery following weight loss surgery. In 43 respondents, the quality of life after reconstructive surgery was retrospectively measured by the Obesity Psychological State Questionnaire. Patient satisfaction was evaluated.

Results

Reconstructive surgery resulted in a significant improvement in quality of life in patients at a mean interval of 42 months between weight loss and reconstructive surgery. The most frequent procedures were abdominoplasty and breast reconstruction. The relative high complication rate of 27,9% was of no influence on quality of life and the majority of the patients (67%) were satisfied with reconstructive surgery.

Conclusion

This study shows that reconstructive surgery following weight loss after bariatric surgery results in a significant improvement in overall quality of life. Reconstructive surgery should be incorporated in the multidisciplinary care programme following weight loss surgery in the morbidly obese patient.

Introduction

The worldwide obesity epidemic is becoming a major health problem. In recent years, a growing number of morbidly obese patients are seeking a surgical solution for their weight problem. Bariatric surgery is the only effective treatment for morbidly obese patients resulting in a substantial and long term weight reduction with a concomitant significant improvement in overall quality of life.[1-4]

Massive weight loss following surgery leads to an excess of lax, overstretched skin, causing physical discomfort and psycho-social problems, which may negatively affect the patients' quality of life.[5] The changes in physical appearance and functioning may also impede a further weight reduction or may even lead to weight regain.[6] Whereas the functional and aesthetic deformity is an expected result of massive weight loss, the role of the plastic surgeon in the multidisciplinary approach of the morbidly obese is still unclear.

The purpose of this study is to evaluate the role of reconstructive surgery following weight loss surgery in the treatment of morbid obesity, with special emphasis on its impact on the physical and psycho-social well-being and quality of life of the patients.

Methods

Patients

During the period November 1995 to April 2005, 465 patients underwent surgery for morbid obesity at the St. Antonius Hospital in Nieuwegein. Of these patients, 61 (13,1%) underwent body-contouring surgery in the same clinic following massive weight loss. These patients were included and asked to participate in the study.

Quality of Life Measurements

Following informed consent, the patients completed a questionnaire to analyse the effect of reconstructive surgery on quality of life. The actual and past psycho-social states were measured by the Obesity Psycho-social State Questionnaire (OPSQ; Table 1).[7] The questionnaire measures seven domains: 'physical functioning' (15 items), 'mental well-being' (six items) 'physical appearance' (nine items), 'social acceptance' (four items), 'self-efficacy toward eating and weight control' (three items), 'intimacy' (four items) and 'social network' (two items). Table 2 shows examples of every scale of the OPSQ. All scales have a moderate to high reliability. The questionnaire has a five-point rating scale, ranging from 1 (almost never) to 5 (almost always). A lower score on a psycho-social state reflects less problems on that domain and corresponds with a good quality of life. The pre-operative quality of life was measured retrospectively by asking the patients to what extent the items of the questionnaire applied to them at a time point 3 months prior to their reconstructive surgery. To assess the most invalidating problems of

excess skin, we asked for the patients' primary motivation to seek bodycontouring surgery, e.g. functional problems, aesthetical problems or complaints of dermatitis. Patients were asked for their satisfaction with the result of the reconstructive surgery and with the scar in particular. The satisfaction was documented on a scale ranging from 1 (very satisfied) to 4 (dissatisfied).

Table 1. *Example items of the Obesity Psychosocial State Questionnaire (OPSQ)*

Scales	Items
Physical functioning	To kneel or to duck easily
Mental well-being	To feel depressed (reversed score)
Physical appearance	To feel fatty when someone takes a picture (reverse score)
Social acceptance	To be discriminated because of my weight (reverse score)
Self-efficacy	To feel helpless toward my eating behaviour (reversed score)
Intimacy	To have sexual problems because of my weight (reversed score)
Social network	To visit friends and acquaintances

Note: respondents answer to what extent they agree with the proposition on a 5-point rating-format, ranging from 1 (almost never) to 5 (almost always)

Data Collection

The records of all patients were reviewed retrospectively for demographic data and pre- and post-operative weight data.

Statistical Analyses

All statistical analyses were performed using SPSS for Windows version 12.0 (SPSS Inc, Chicago, IL, USA). Student's t test and multivariate analysis were used for parametric variables; nominal variables were analysed with the Pearson chi-squared test. A two-sided *P* value of $< 0,05$ was considered statistically significant.

Results

Of the 61 patients who underwent reconstructive surgery, 43 patients (2 men, 41 women) agreed to participate in the study, i.e. response rate of 70,5% (Table 2).

The mean age of the patients was 41,5 years (range 23 - 60). The mean weight before the primary bariatric procedure was 138,2 kg (range 106 – 230) with a mean body mass index (BMI) of 48,2 kg/m² (35,8 – 79,5). Forty patients (93%) underwent laparoscopic adjustable gastric banding (LAGB); three patients underwent gastric bypass surgery as a primary procedure. Due to unsatisfactory results or band-related problems, 11 of the 40 LAGB patients underwent gastric bypass surgery as a redo operation.

The patients experienced a mean initial weight loss of 36,3% at a mean interval of 42,1 months (range 8 – 110) between their primary bariatric procedure and reconstructive surgery.
This results in a mean weight of 86,9 kg (range 57,0 – 177,0) and a BMI of 30,7 kg/m² (range 21,5 – 65,0) at the time of reconstructive surgery.
A total of 68 reconstructive operations were performed in 43 patients (Table 3); 24 patients (55,8%) underwent one operation; 13 (30,2%) underwent two operations and six (14%) of the patients underwent three operations. Almost all (94%) operations were single reconstructive procedures. Most patients had an abdominoplasty (61%) or breast reduction/augmentation (25%).

***Table 2**. Characteristics of patients with reconstructive surgery after bariatric surgery (n=43).*

Female gender	41 (95%)
Age (yrs)	42 (23-60)
Comorbidity	
Diabetes Mellitus II	4 (9%)
Hypertension	23 (54%)
Bariatric surgery type	
Gastric banding	40 (93%)
Gastric bypass (primary/secondary)	3/11 (7%/26%)
Weight pre bariatric surgery (kg)	138 (106-230)
BMI pre bariatric surgery (kg/m^2)	48 (36-80)
Weight pre reconstructive surgery (kg)	87 (57-177)
BMI pre reconstructive surgery (kg/m^2)	31 (21-65)
Interval bariatric – reconstructive surgery (months)	42 (8-110)

Data are presented as N (%) or median (range).

Yrs: years. Kg: kilogram. BMI: body mass index

***Table 3.** Reconstructive surgery procedures.*

Abdominoplasty	38 (56%)
Breast augmentation/reduction	15 (22%)
Liposuction legs	3 (4,4%)
Derma-lipectomy legs	4 (5,9%)
Derma-lipectomy arms	1 (1,4%)
Dog ear correction	3 (4,4%)
Abdominoplasty + breastreduction	2 (2,9%)
Abdominoplasty + liposuction tights	1 (1,5%)
Derma-lipectomy legs + dogear correction	1 (1,5%)
Total	68 (100%)

Data are presented as N (%).

Quality of Life

After reconstructive surgery, patients improved significantly on six of the seven psycho-social states of the Obesity Psychological State Questionnaire (Table 4).

The most significant improvement was seen in physical functioning and physical appearance. Reconstructive surgery improved physical functioning and patients felt healthier ($P < 0,001$). Patients also experienced less depressive symptoms ($P < 0,001$). Overall patients were more satisfied with their physical appearance ($P < 0,001$). In line with this, patients experienced less problems in intimacy and sexuality ($P < 0,001$). There was a significant difference in selfefficacy towards eating before and after reconstructive surgery ($P < 0,001$); patients had more problems to cope with their eating behaviour after the operation.

For 32 patients (74,4%), improvement in physical appearance was one of the most important motives to seek body-contouring surgery. For eight patients (18,6%), this was the only reason. Another important motive was problems patients experienced in physical functioning. For 27 patients (62,8%), this was one of the reasons. Approximately 50% of the patients experienced problems with personal hygiene and complained of intertriginous dermatitis (51,2%).

Table 4. *Obesity Psychological State Questionnaire score* before and after reconstructive surgery.*

Psychological states	Before rec.surgery	After rec.surgery	*P*
Physical functioning	3,58 (0,75)	2,34 (0,74)	<0,001
Mental well-being	3,42 (0,97)	2,48 (0,89)	<0,001
Physical appearance	3,92 (0,73)	2,63 (0,78)	<0,001
Social acceptance	3,42 (1,16)	2,28 (0,77)	<0,001
Self-efficacy toward eating	2,93 (1,40)	3,97 (0,74)	<0,001
Intimacy and sexuality	3,29 (1,13)	2,47 (1,02)	<0,001
Social network	2,79 (0,98)	2,22 (0,78)	<0,05

* Score varied from 1 (almost never) to 5 (almost always)

Data are presented as mean (SD)

Patient Satisfaction

Sixty-seven percent of the patients was satisfied with the overall result of the operation (Table 5, scores 1 and 2). Eight patients (18,6%) were dissatisfied (score 4). In the interview, we asked the patients to elucidate their dissatisfaction. Most patients were not satisfied with the proportions of their body after operation and with the occurrence of dog-ears in the scars in particular. Some patients had high expectations about the aesthetic result, based on examples from the internet, and were in the end disappointed with the result of their own operation.

Regression analysis was performed to determine factors influencing patient satisfaction. The occurrence of postoperative complications did not influence patient satisfaction (satisfaction score of 2,3 versus 2,5). Weight increase after reconstructive surgery was significantly associated

with patient satisfaction: patients with a stable weight after the operation were significantly more satisfied than those with an increase in body weight (satisfaction score 1,9 versus 2,6; $P < 0,05$). All other factors (number of operations, type of operation, hospital stay) failed to show any influence on patients' satisfaction.

Table 5. *Patient satisfaction after reconstructive procedure.*

Satisfaction	Score	
Result scar in specific	Very satisfied	15 (34,9%)
	Satisfied	16 (37,2%)
	Unsatisfied	6 (14,0%)
	Very unsatisfied	6 (14,0%)
Overall satisfaction	Very satisfied	9 (20,9%)
	Satisfied	20 (46,5%)
	Unsatisfied	6 (14,0%)
	Very unsatisfied	8 (18,6%)

Data are presented as N (%)

Discussion

This study shows that reconstructive surgery after succesful bariatric surgery leads to a significant improvement in quality of life. Irrespective of the occurrence of complications following the reconstructive procedures, the majority of patients were satisfied with the result of reconstructive surgery.

Morbid obesity is an increasingly common disease and its treatment is a challenge for many specialists. Weight loss surgery will lead to a long lasting and significant weight loss and improvement in quality of life.[1-4] In the literature, studies on subsequent reconstructive surgery focus on the complications associated with the procedures. Our study is unique by reporting on a large cohort of patients with a long term follow-up.

The overall complication rate was 27,9%, which is in accordance to the literature (20 – 50%).[8,9] Despite the relative high percentage of complications, this was of no influence on patients' satisfaction. A total of 67% of the patients were satisfied to very satisfied with the final result of reconstructive surgery. The positive results of reconstructive surgery apparently justify the complication rate and the sequential operations often required. Patients who were dissatisfied complained about the dog-ears after abdominoplasty or the post-operative contour deformities which sometimes occur after reconstructive procedures. Massive weight loss results in an excess redundant skin creating new problems, both psychological and functional.[5,6]

The loose hanging skin results in feelings of unattractiveness, embarrassment, limitations in activity, sexual problems and hygienic discomfort such as skin rash and infections.

Although some studies observe a stable long term quality of life after bariatric surgery, patients are normally not well prepared to the sequelae of massive weight loss which may lead to a decline in quality of life and increase the risk of weight regain.[10-13] It has been suggested that these new problems affect the patients' quality of life to almost the same degree as the problems of overweight prior to the bariatric operation.[5,14] In our study, patients point out that this new problems do cause a poor quality of life but not in the same degree as before bariatric surgery.

In a previous study of Larsen et al., the quality of life before and after bariatric surgery was measured and compared with the general Dutch reference population.[15] Preoperative scores of patients on all dimensions of quality of life were significantly lower than scores of the age norm group. This difference diminished 1 year after the operation but increased again in the long term on all dimensions. The exact cause of this decline is unclear, but one hypothesis might be that the functional and aesthetic deformity is a major factor of influence.

The role of reconstructive surgery following weight loss surgery is still underestimated by medical specialists. Currently, it is seen as a cosmetic adjunct to bariatric surgery. However, previous investigations have concluded that a positive effect on quality of life is also seen after other reconstructive procedures like reduction mammaplasty and cosmetic facial surgery.[16,17]

In our study, some 13% of the patient were scheduled for reconstructive surgery. This may be a conservative figure as some patients may have been operated outside our clinic. Most patients (93%) in our study underwent laparoscopic adjustable gastric banding. Compared to the gastric bypass procedure, the average weight loss following banding is substantially less. Therefore, in the bypass population, a higher percentage of patients may be in need of reconstructive surgery.

If surgical treatment of obesity fails due to failure to maintain the achieved weight, reconstructive surgery may have an important role.[18] In previous studies analysing predictors of weight loss and control, it is suggested that quality of life is positively associated with long term outcomes of weight management.[19-21] As reconstructive surgery results in an improvement in quality of life, it may contribute to the management of weight control.

In the interview, patients explicitly mention the great influence of high expectations. The expectations regarding the outcome of reconstructive surgery of most patients are based on examples and success stories on the internet, which often turn out not to be realistic. Patients are generally not prepared for the marked scarring following surgery. It is of great importance therefore to inform patients pre-operatively and outline realistic expectations.[5]

Our study has some limitations as it concerns a retrospective evaluation. Only patients who actually had undergone reconstructive surgery were included. In our study, we used the Obesity Psycho-social State Questionnaire, a self-developed questionnaire. The psychometric characteristics of the OPSQ were established in a previous study and, although not validated, proved to be satisfactory.[7] The pre-operative quality of life was measured retrospective, which

may have given some bias to the results. In future, prospective studies with obesity-related questionnaires should verify the current results.

Conclusion

The contribution of the reconstructive surgeon to the multidisciplinary treatment of morbid obesity is substantial and beneficial in the care for these patients. Dissatisfaction was mainly due to technical factors. As these are correctable factors, overall satisfaction could be improved. Reconstructive surgery should be included in the continuum of care and may improve the long term weight outcome in the surgical treatment of morbid obesity.

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9

Summary

The increasing popularity of bariatric surgery gives rise to vital questions, concerning the safety and efficacy of the most frequently performed procedures. The findings of the studies from this thesis and the answers to the central questions are summarized here.

What are the results of laparoscopic adjustable gastric banding in terms of weight loss and complications?

After introduction of laparoscopic adjustable gastric banding in 1991, it was introduced in 1995 in the Sint Antonius Hospital, Nieuwegein, the Netherlands. In *Chapter 2* the first mid term results of laparoscopic adjustable gastric banding (LAGB) in the Netherlands are described in terms of weight loss and complications. In 77% of the patients a statistically significant excess weight loss > 30% was reached after a minimum follow-up duration of 2 years. The median difference in body mass index (BMI) before and after LAGB, after 2 years of follow-up, was -10 kg/m^2. The median excess weight loss (EWL) was 46%. A greater effect of treatment was found for patients with lower baseline BMI (35 - 40 kg/m^2) (EWL 54%) compared to patients with a higher baseline BMI value (> 55 kg/m^2) (EWL 38%). The introduction of laparoscopic adjustable gastric banding was not associated with in hospital mortality (0%). In 22% of the patients a reoperation was carried out. Most found complications were fundus herniation (13%) and port-a-cath related problems (7%). All of these patients underwent a reoperation. After switching to the pars flaccida technique by placing the band just below the gastro-oesophageal junction the rate of fundus herniation decreased significantly (24 to 2%).
In conclusion, laparoscopic adjustable gastric banding has shown to be a safe procedure, with good mid term weight loss results in the majority (77%) of the patients, but with a high reoperation rate. It has the advantage of the minimally invasive character of laparoscopic surgery and rapid clinical recovery. Other advantages are the possibility of calibration of the band with a controlled food intake and finally, the reversibility of the operation. If there is insufficient effect of the band or non compliance of the patient, the band can be removed leaving the integrity of the gastro-intestinal tract undisturbed.

What are the results of laparoscopic adjustable gastric banding in patients who are not attending regular follow-up?

Obesity is a chronic disorder which requires a continuous care model of treatment. The exact role of follow-up after bariatric surgery is unknown. Compliance with a well structured postoperative management plan seems as important as good surgical technique in achieving long term success. Failures after bariatric surgery even have been attributed to motivational and/or psychological factors. In *Chapter 3* we describe the results of a study which evaluated the outcome of gastric banding in patients who did not attend the postoperative care program and were lost to follow-

up. The percentage of patients lost to follow-up after gastric banding gradually increased at a median annual rate of 5%, reaching 39% at 8 years follow-up. Of these patients, 78% could be motivated to return to the outpatient clinic and actual weight could be assessed. Median BMI, BMI decline and EWL of patients lost to follow-up were significantly different between the time of the last scheduled follow-up visit and the return visit. In the group of patients who were lost to follow-up after LAGB significantly more patients had treatment failure and significantly fewer showed a fair result compared with patients attending regular follow-up. After a median follow-up of 79 months, 60% of the patients in the lost group had failed therapy versus 16% ($P < 0{,}001$), 27% ($P < 0{,}001$) and 42% ($P = 0{,}026$) after 2, 4 and 8 years in the regular follow-up, respectively.
This study shows that, despite an intensive bariatric care programme, the percentage of patients lost to follow-up increases yearly at a median rate of about 5 percent. After 8 years of follow-up, 39% of the patients were lost to follow-up and the majority of these patients (60%) were therapy failures. Long term follow-up of the total LAGB group resulted in a fair outcome in 32% of patients after 8 years follow-up. Every effort should be made to minimize the rate of patients lost to follow-up after LAGB, thereby increasing the chance of success after LAGB. As a consequence, long term follow-up reports of bariatric procedures should always include the percentage of patients lost to follow-up at all time points, both as a measure of the effectiveness of the follow-up programme and as a truthful indication of the overall success rate of bariatric surgery.

Is continuation of band therapy in case of band slippage after laparoscopic adjustable gastric banding associated with failure in therapy?

In *Chapter 2* we showed LAGB to be a safe and effective procedure with good mid term weight loss, but at the expense of a high reoperation rate. The most frequent complication and reason for reoperation after LAGB is slippage of the gastric band. Uncertainty exists of the best treatment of a slipped band. Some authors favour continuation of band treatment (rebanding), others favour conversion to a malabsorptive procedure. In *Chapter 4* we present the largest series in literature with weight loss results of patients who underwent rebanding for a slipped gastric band. In our cohort of LAGB patients we found a slippage rate of 14%. Patients who underwent rebanding for slippage had a chance of a fair result (EWL > 25%) after a median follow-up of 110 months of 43%. Subgroups of patients who underwent rebanding for slippage following succesful and unsuccesful LAGB had a chance of a fair result of 62% and 27% after a median follow-up of 113 and 97 months, respectively. In a case matched comparison between patients who underwent rebanding for slippage and patients without slippage, no difference in therapy outcome in terms of weight loss was found. Finally, logistic regression showed a significantly association with therapy failure of initial BMI before LAGB and length of follow-up after LAGB. However, rebanding for slippage was not significantly associated with therapy failure.

In the literature, no guidelines are set for the selection of the appropriate procedure to manage slippage after LAGB. The study presented above provides important information for clinical decision making in case of band slippage following LAGB. The assumption of a slipped gastric band being a point of application of change in bariatric therapy because of expected weight loss failure seems wrong according to our data. Our findings show that rebanding for slippage is not a prognostic factor for inadequate weight loss. In patients successfully treated by LAGB, rebanding for band slippage should be considered, as good long term success was found in 62% of these patients. Our data show a poor long term success rate (27% of the patients) of rebanding for slippage in the subgroup of patients with unsuccessful weight loss after primary LAGB. This low success rate justifies band removal and conversion to another bariatric procedure in case of band slippage after unsuccessful primary band therapy.

What are the results of gastric bypass in terms of weight loss and complications?

In *Chapter* 5 the safety and efficacy of the (laparoscopic) gastric bypass (GB) is studied after the introduction in 2002 in the Sint Antonius Hospital, Nieuwegein, the Netherlands. It is the first publication on the clinical outcome of gastric bypass in the Netherlands. The study group consisted of patients who underwent a gastric bypass as a primary procedure (65%) or as a secondary procedure (35%) after failed primary bariatric surgery. In 71% of the patients, an EWL > 50% was reached after 1 year of follow-up, with a median EWL of 59%, and a median BMI reduction of 16 kg/m^2. Subgroups with a higher preoperative BMI achieved greater BMI reductions. Patients who underwent gastric bypass as a primary bariatric procedure attained a succesful outcome (EWL > 50%) in 79%, compared to 59% of the patients after a gastric bypass as a secondary procedure. However, when the EWL was calculated using the weight before the primary procedure in the group undergoing the gastric bypass as a secondary procedure, the median EWL at maximum follow-up did not differ from those who underwent a primary gastric bypass.
The in hospital mortality for the gastric bypass procedure was 0,7% (2 / 290). Short term complications occurred in 15% of patients, with anastomotic leakage (5%) as the most common early complication. In 6% of the patients early complications resulted in re-operation. Late complications occurred in 21% of patients, including mainly anastomotic strictures (6%) and cicatrical hernias (5%). Patients who underwent open surgery had both more early and late complications than those who underwent laparoscopic surgery, confirming reports that the laparoscopic approach results in lower morbidity.
The main benefits of the gastric bypass are the high percentage of successfully treated patients, and the higher percentage of weight loss in the short term. However, the gastric bypass procedure is associated with surgery related mortality and morbidity. The loss of integrity of the digestive tract and the irreversibility of the bypass procedure may be considered drawbacks. The laparoscopic gastric bypass seems to compare favorably to the open gastric bypass due to less morbidity.

How many patients are treated successfully and what is the morbidity after laparoscopic adjustable gastric banding compared to gastric bypass?

As described in *Chapter 2* and *Chapter 5*, laparoscopic adjustable gastric banding and (laparoscopic) gastric bypass are the two bariatric procedures most commonly performed. The indication for these two treatment options continues to be subject to debate over the last decade. In the absence of prospective randomized trials, in *Chapter 6* we describe the results of a case-controlled matched-pair cohort study to compare the results of both procedures.
EWL was significantly higher in the GB group than in the LAGB group at all time points during the follow-up. Median EWL was 60% for the GB group versus 43% ($P < 0,001$) for the LAGB group at 2 years follow-up. The median BMI decrease at 2 years follow-up in the GB group was 17 kg/m^2 versus 12 kg/m^2 for the LAGB group. After two years follow-up, significantly more patients had good treatment results (EWL > 50%) in the GB group compared to the LAGB group (76% versus 40%, $P = 0,03$).
In terms of complications, the most obvious difference existed in severe early complications after GB compared to LAGB (11% vs 0%). These complications mainly consisted of leakage at the gastro-jejunostomy which required reoperation. No mortality occurred in either group.
In conclusion, the gastric bypass compared to gastric banding results in increased weight loss, in a higher number of patients, but is associated with a higher incidence of severe early complications. In the absence of consensus among bariatric surgeons on the definition of successful surgical treatment in terms of weight loss, definite conclusions about superiority of a specific procedure can not be drawn. For example, defining successful treatment as an EWL > 30%, instead of > 50%, would duplicate the percentage of successfully treated patients by laparoscopic gastric banding from 40% to 80% in our series. Future studies and consensus should lead to guidelines to tailor the appropriate procedure to the individual patient.

Is secondary gastric bypass after failed primary laparosopic adjustable gastric banding as safe and effective as primary gastric bypass?

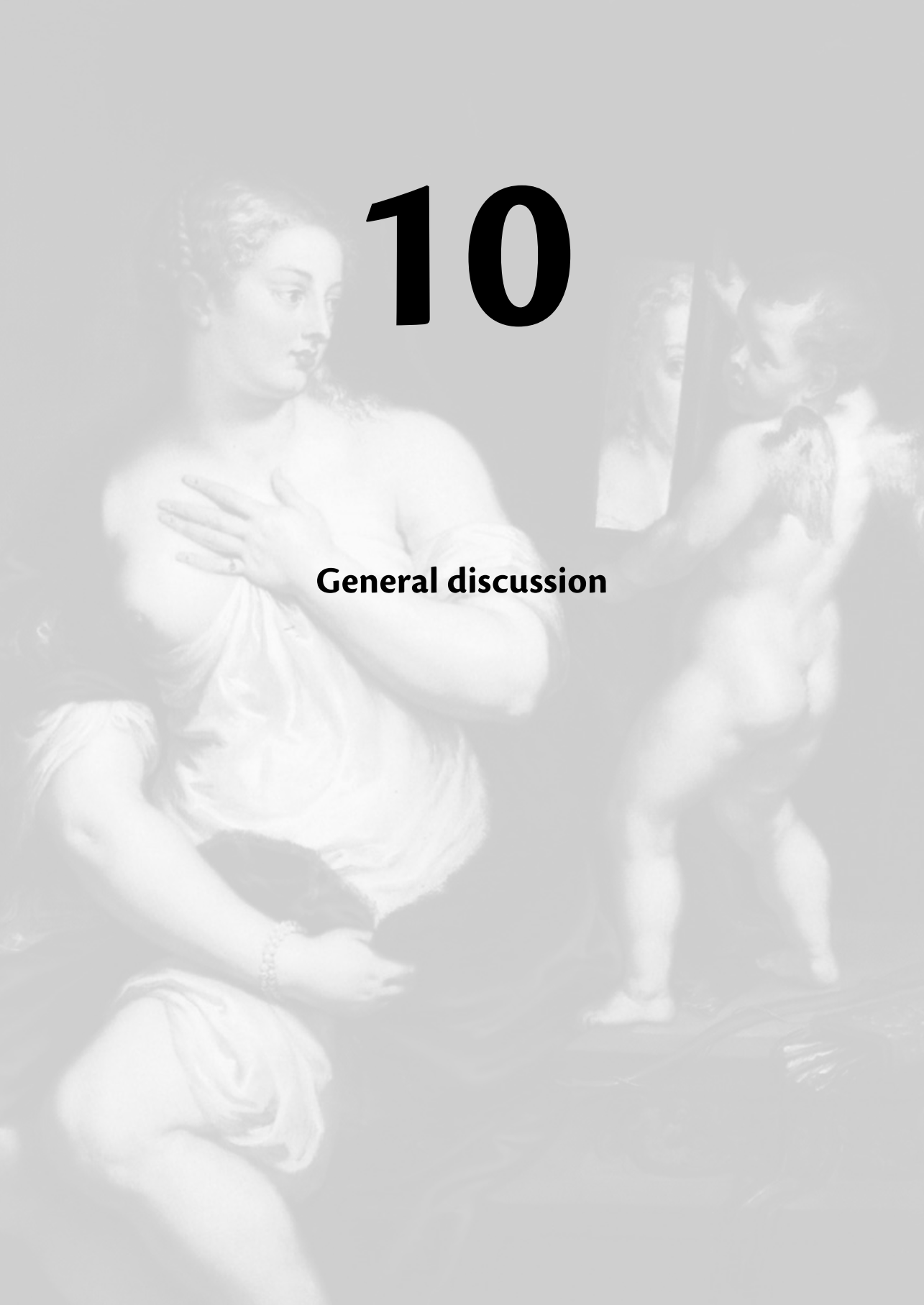
Long term failure rates of laparoscopic adjustable gastric banding have recently been reported to be 40-50% (*Chapter 3*). Despite these failure rates, laparoscopic adjustable gastric banding is at increased interest, most likely because of the ultimate advantage of total reversibility without compromise to the gastrointestinal tract. In the US, the rate of gastric banding procedures of all bariatric procedures increased from 9% to 44% between 2003 and 2008. Many surgeons prefer gastric bypass as a salvage procedure in case of failed gastric banding. This gives rise to the question of safety and efficacy of gastric bypass after failed gastric banding (secondary gastric bypass) compared to primary gastric bypass. The aim of the study presented in *Chapter 7* was to determine whether the outcome of secondary gastric bypass is comparable to the outcome of

primary gastric bypass in terms of complications and weight loss. The weight loss after secondary gastric bypass and primary gastric bypass turned out to be similar. After 3 years of follow-up, 73% and 75% of the patients had a BMI < 35 kg/m^2 after secondary and primary gastric bypass, respectively. In terms of complications, no significant differences were found in the occurrence of complications between the primary and secondary groups (30% versus 31%, respectively, *P* = 0,87). Leakage of the gastro-jejunal anastomosis occurred in 6% and 4% of the patients, respectively. Reoperation rates were 14% and 18% (*P* = 0,17) for the primary and secondary gastric bypass group, respectively. No patient died during the follow-up period.
A secondary gastric bypass procedure after failed gastric banding is a technically more demanding procedure than primary gastric bypass because of scarring and adhesions. Our study presented in *Chapter 7* shows that it can be performed equally safe and effective as a primary gastric bypass. In our center, we consider conversion to gastric bypass for insufficient weight loss after gastric banding.

What are the results of reconstructive surgery following succesful bariatric surgery in terms of physical and psycho-social well-being and quality of life?

Bariatric surgery proved to be the only effective treatment for morbidly obese patients resulting in a substantial and long term weight reduction. After successful bariatric surgery, the weight loss leads to an excess of overstretched skin causing physical discomfort and a possible negative effect on the quality of life. It has even be suggested that these new problems affect the patients quality of life to almost the same degree as the initial problems of overweight. In *Chapter 8* we present the results of a study on the impact of reconstructive surgery after successful bariatric surgery on the patients quality of life. During the study period of 10 years, body-contouring surgery was performed after a successful bariatric procedure (gastric banding or gastric bypass) in 13% of the patients. After reconstructive surgery, patients improved significantly on six of the seven domains of quality of life: physical functioning, mental well being, physical appearance, social acceptance, self-efficacy towards eating and intimacy. The overall result of reconstructive surgery was satisfying for 67% of patients and dissatisfactory in 19%. Dissatisfaction was mainly caused by technical factors like dog ears in the scars or due to high expectations based on unrealistic examples from the internet. In regression analysis performed to determine factors influencing patient satisfaction, weight increase after reconstructive surgery proved to be the only factor significantly associated with patient satisfaction.
The surgical treatment of obesity fails in a significant proportion of patients due to recurrent weight gain. Reconstructive surgery may even have an important role to maintain the achieved weight loss after bariatric surgery. It has been suggested that quality of life is positively associated with long-term outcome of weight management. As reconstructive surgery results in an improvement in quality of life, it may contribute to the management of weight control. The

contribution of reconstructive surgery is not limited to a cosmetic adjunct to bariatric surgery but plays a substantial role in the multidisciplinary treatment of the morbidly obese patient.



10

General discussion

The studies presented in this thesis provide answers to several important questions regarding bariatric surgery. Gastric banding and gastric bypass proved effective and safe procedures. Revisional surgery proved safe and quality of life was good after reconstructive procedures. These results were in accordance with major findings in the literature. Bariatric surgery has proven to be the most effective treatment for morbid obesity, producing durable weight loss, improvement or remission of comorbid conditions, and longer life. The studies presented in this thesis support these important conclusions for the outcome of bariatric surgery in the Netherlands.

However, if we broaden our outlook on obesity, some new and pivotal questions arise. Which bariatric operation has to be chosen for each individual patient? Which operation is the best? Various appropriate treatment modalities exist for each patient, and the surgeon has to select from among feasible treatment options. Is a pure restrictive procedure as laparoscopic adjustable gastric banding appropriate for patients with low BMI of 40 - 45 kg/m^2 or do we have to select these patients for a combined restrictive/malabsorptive procedure as gastric bypass? Are the heavier patients with BMI > 50 kg/m^2 only suitable for combined procedures as gastric bypass or does restriction work as well? No selection criteria exists to tailor the most appropriate bariatric procedure to the individual patient. In the 2009 SAGES guidelines for patient selection, the authors concluded that patients who undergo gastric bypass experience 60 - 70% EWL compared to 45 - 50% EWL for gastric banding.[1] Gastric bypass has 75% remission of comorbidities compared to 60% for gastric banding. Mortality rates are approximate 0,1% for gastric banding and 0,5% for RGB. Finally no conclusions are presented on the selection of patients for both procedures.

These incomplete guidelines for patient selection for different types of bariatric surgery are the consequence of the most important, unanswered question about the treatment of obesity: what is the definition of successful treatment of a morbidly obese patient?

Over the last decades, excess weight loss is used as the main surgical outcome parameter of bariatric surgery. Standard criteria for the percentage of weight loss to be defined as a successful outcome have never been developed. The lack of such standard criteria for success impedes the choice of the best bariatric treatment for the individual morbidly obese patient. It is well known that surgery for obesity reduces mortality, even after modest weight loss.[2] However, how much weight loss is necessary to reach good outcomes? Many authors have created their own definition of success. Reinhold proposed criteria of which other author's have deducted the following definition: EWL < 25% is defined as a failure, 25 - 50% as fair and > 50% as success.[3] These criteria are twice as stringent as those of Mason: EWL > 25% is succesful.[4] Pories defined success as a loss of 25% of the operative weight, while Freeman only required a loss of 15%.[5,6] MacLean used only the BMI and defined BMI < 35 kg/m^2 as a success and BMI > 35 kg/m^2 as a failure.[7] Consensus on the ideal weight loss for morbid obesity is crucial for the selection of the right procedure. The rate

of success after LAGB duplicates if an EWL > 25% is accepted as successful therapy instead of an EWL > 50%. In addition, can we define our treatment successful if comorbidities and quality of life reach acceptable levels with an EWL > 25%, but the cosmetic result does not satisfy the patient? Bariatric surgeons will have to define an unambiguous answer to these kind of questions.

The ideal weight loss for morbidly obese patients to cure comorbidities is unknown. Kuhlmann found that 10 kg weight loss in the morbidly obese already reduced diabetes associated mortality by 30%. In a recent review, Buchwald found diabetes resolution in 78% of 135246 patients undergoing bariatric surgery.[8] A progressive relationship was found between diabetes resolution and weight loss achieved. Weight loss and diabetes resolution were greatest for patients undergoing biliopancreatic diversion/duodenal switch, followed by gastric bypass, and least for banding procedures. On the other hand, recent evidence suggest that weight and type 2 diabetes are not in a direct cause-and-effect relationship.[9] The manifestations of type 2 diabetes can totally clear within days after gastric bypass, before there is any significant weight loss.

Besides weight loss, the ultimate goal of bariatric surgery is to improve the quality of life by patients' health and pschychological and socioeconomic well-being. For this reason, it's mandatory to incorporate patient-perceived quality of life and obesity related comorbidities in the definition of successful treatment of morbid obesity. An evaluation of the results of obesity treatment should include weight loss, reduction of these comorbidities and quality of life. In 1998, Oria introduced a system to report the outcome of obesity treatment: Bariatric Analysis and Reporting Outcome System (BAROS).[10] It can be used to present results of surgical and nonsurgical treatment of obesity. The BAROS scoring system analyzes the 3 parameters mentioned above as well as the occurrence of complications and reoperations after primary surgery. The final classification exists of 5 outcome groups, from failure to excellent.
After the introduction of BAROS in 1998 it has been used incidently, rather than widespread. Nguyen used BAROS to compare results in a randomized trial of 155 patients who underwent laparoscopic or open gastric bypass.[11] The outcome scores were classified as good or better in 82% of the open operations and 97% in the laparoscopic operations. Favretti used BAROS in 1998 to evaluate the success of LAGB in 180 patients and found good or better results in 48% of the patients.[12] The reasons why BAROS has not been accepted worldwide remains unclear. Possibly its cumbersome manner of presenting results has been an impediment. In 2009 a modified BAROS was introduced by Oria, with improvement of the quality of life measurement, analysis of comorbidities by updated diagnostic criteria and 2 options for reporting weight changes (% EWL and the percentage of excess body mass index loss).[13] This modified BAROS does not resolve the problem of complexity but can be interpreted as an encouragement for surgeons to reach consensus on the definitions of successful outcome of obesity treatment in the near future.

Bariatric surgery has proven to be safe and the most effective answer to the obesity epidemic worldwide in the last decades. The prospect is that in the near future bariatric surgery will increase from 344.000 to 500.000 procedures annually worldwide. It should be the objective for the officers of treatment of obesity to reach consensus on the definition of failure and success of this treatment. The definition of successful bariatric treatment should include weight loss, comorbidities and quality of life. Once this consensus has been reached, the different types of bariatric procedures can be evaluated and compared. Success for subgroups of obese patients according to these new formulated criteria can be discovered and bariatric treatment can become patient tailored. This evaluation should be the purpose of future studies and lead to the selection of the appropriate bariatric procedure for the individual obese patient.

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11

Nederlandse samenvatting

Doel van dit proefschrift

De centrale vraagstelling van dit proefschrift betreft de veiligheid en effectiviteit van de laparoscopische geplaatste maagband en de (laparoscopische) maagomleiding in de behandeling van morbide obesitas. De volgende vraagstellingen worden onderzocht in de verschillende studies:

- Wat zijn de resultaten van de laparoscopische geplaatste maagband in termen van gewichtsverlies en complicaties? *(Hoofdstuk 2)*
- Wat zijn de resultaten van de laparoscopische geplaatste maagband bij patiënten die zich onttrekken aan poliklinische follow-up? *(Hoofdstuk 3)*
- Is het behouden van een maagband in het geval van fundusherniatie gerelateerd aan het falen van de maagband op de lange termijn? *(Hoofdstuk 4)*
- Wat zijn de resultaten van een maagomleiding in termen van gewichtsverlies en complicaties? *(Hoofdstuk 5)*
- Hoeveel patiënten worden succesvol behandeld en wat is de morbiditeit na een laparoscopische geplaatste maagband vergeleken met een maagomleiding? *(Hoofdstuk 6)*
- Is de veiligheid en effectiviteit van een secundaire maagomleiding na gefaalde maagband therapie vergelijkbaar met de veiligheid en effectiviteit van een primaire maagomleiding? *(Chapter 7)*
- Wat zijn de resultaten van reconstructieve chirurgie na succesvolle bariatrische chirurgie in termen van fysiek en psychosociaal welzijn en kwaliteit van leven? *(Chapter 8)*

Samenvatting

De resultaten van de verschillende studies uit dit proefschrift zijn hieronder samengevat.

Wat zijn de resultaten van de laparoscopische geplaatste maagband in termen van gewichtsverlies en complicaties?

Na de wereldwijde introductie van de laparoscopisch geplaatste maagband in 1991, werd deze techniek in 1995 geïntroduceerd in het Sint Antonius Ziekenhuis te Nieuwegein, Nederland. In *Hoofdstuk 2* worden de eerste Nederlandse middellange termijn resultaten van de laparoscopisch geplaatste maagband gepresenteerd in termen van gewichtsverlies en complicaties. Bij 77% van de patiënten met een minimale postoperatieve follow-up duur van 2 jaar werd een overgewichtsverlies van > 30% bereikt. Na 2 jaar postoperatieve follow-up na het plaatsen van de maagband was het mediaan verlies in body mass index (BMI) 10 kg/m^2. Het mediaan overgewichtsverlies was 46%. Een groter overgewichtsverlies werd gevonden voor patiënten met een lager uitgangs-BMI (35 – 40

kg/m^2) ten opzichte van patiënten met een hoger uitgangs-BMI (> 55 kg/m^2): 54% versus 38%. De introductie van de laparoscopisch geplaatste maagband ging niet gepaard met mortaliteit (0%). Bij 22% van de patiënten was een re-operatie noodzakelijk. Meest voorkomende complicaties waren fundusherniatie (13%) en port-a-cath gerelateerde problemen (7%). Al deze patiënten ondergingen een re-operatie. Na verandering van operatietechniek waarbij de maagband meer naar proximaal, net onder de gastro-oesophageale overgang wordt geplaatst (pars flaccida in plaats van perigastrische techniek), daalde het percentage fundusherniaties van 24% naar 2%.
Concluderend kan gesteld worden dat de laparoscopisch geplaatste maagband een veilige procedure is gebleken met goede middellange termijn resultaten bij een meerderheid van de patiënten (77%), maar met een hoog re-operatie percentage. De procedure heeft het voordeel van de minimale invasiviteit van de laparoscopische techniek met snel klinisch herstel. Een tweede voordeel is de aanpasbaarheid van de diameter van de maagband met de mogelijkheid tot gecontroleerde voedsel inname. Ten slotte heeft de maagband het voordeel van complete reversibiliteit bij onvoldoende effect of therapieontrouw van de patiënt. De maagband kan verwijderd worden zonder dat de continuïteit van het maag-, darmstelsel is verstoord.

Wat zijn de resultaten van de laparoscopische geplaatste maagband bij patiënten die zich onttrekken aan poliklinische follow-up?

Morbide obesitas is een chronische aandoening welke een langdurige behandeling behoeft. De exacte mate van importantie van follow-up na bariatrische chirurgie is onbekend. Het lijkt erop dat voor een geslaagde behandeling op de lange termijn, een goed postoperatief begeleidingstraject net zo belangrijk is als goede chirurgische techniek. Het falen van de behandeling zou deels toe te schrijven zijn aan te geringe motivatie of andere psychologische factoren. In *Hoofdstuk* 3 beschrijven we een studie waarin de resultaten van maagband plaatsing beschreven worden bij patiënten die zich hebben onttrokken aan het postoperatieve begeleidingstraject. Het percentage patiënten dat zich onttrok aan de follow-up na maagband plaatsing nam jaarlijks toe met 5% tot 39% van de patiënten na 8 jaar postoperatieve follow-up. Van deze patiënten kon 78% gemotiveerd worden terug te keren in het begeleidingstraject en het actuele gewicht kon bepaald worden. De mediaan BMI, de BMI afname en het overgewichtsverlies van deze patiënten waren significant verschillend voor en na het onttrekken aan de poliklinische begeleiding. In de groep patiënten die zich onttrokken aan de begeleiding hadden significant meer patiënten een falende therapie en significant minder patiënten een acceptabel resultaat van behandeling vergeleken met patiënten in het begeleidingstraject (therapiefalen: 60% versus 16% [P < 0,001], 27% [P < 0,001] en 42% [P = 0,026] na 2, 4 en 8 jaar follow-up).
Deze studie laat zien dat ondanks een intensief gespecialiseerd postoperatief bariatrische begeleidingsprogramma, het percentage patiënten dat zich onttrekt aan dit programma jaarlijks oploopt met 5%. Na 8 jaar follow-up was 39% van de patiënten verloren gegaan in de follow-up

en bij het merendeel van deze patiënten (60%) bleek sprake te zijn van falende therapie. Voor de totale groep patiënten die een maagband plaatsing onderging werd na 8 jaar follow-up een acceptabel behandelresultaat gevonden van 32%. In het postoperatieve traject moet derhalve maximale inspanning geleverd worden patiënten te behouden voor follow-up, ten einde de slagingskans van de therapie te maximaliseren. Studies die resultaten van bariatrische procedures presenteren behoren altijd het percentage patiënten verloren in de follow-up te rapporteren om een betrouwbare indicatie te geven over het slagingspercentage van de bariatrische therapie.

Is het behouden van een maagband in het geval van fundusherniatie gerelateerd aan het falen van de maagband op de lange termijn?

In *Hoofdstuk 2* lieten we zien dat maagband plaatsing een veilige en effectieve procedure is met goede middellange termijn resultaten, maar met een hoog re-operatie percentage. De meest voorkomende complicatie die een re-operatie vereist is fundusherniatie, waarbij het distale deel van de maag hernïeert door het lumen van de maagband naar proximaal. Er bestaat onzekerheid over de beste behandelmethode van een fundusherniatie. Sommige experts bepleiten het behouden van de band ('reband ing'), anderen kiezen voor het verwijderen van de band en conversie naar een secundaire bariatrische ingreep. In *Hoofdstuk 4* presenteren we de resultaten van de grootste serie in de literatuur van patiënten die 'reband ing' ondergingen voor een fundusherniatie. In onze serie van patiënten die een maagband plaatsing ondergingen kreeg 14% een fundusherniatie. De patiënten die 'reband ing' voor een fundusherniatie ondergingen hadden een kans van 43% op een acceptabel behandelresultaat (overgewichtsverlies > 25%) na een mediaan follow-up van 110 maanden. Subgroepen van patiënten na een succesvolle of niet succesvolle maagband plaatsing die 'reband ing' voor een fundusherniatie ondergingen hadden een kans op een acceptabel behandelresultaat van respectievelijk 62% en 27% na een mediaan follow-up van 113 en 97 maanden. In een patiënt-controle-onderzoek werd geen verschil in gewichtsverlies gevonden tussen patiënten die 'reband ing' voor fundusherniatie ondergingen vergeleken met patiënten met een maagband zonder fundusherniatie. Ten slotte toonde logistische regressie analyse geen onafhankelijk significant verband tussen 'reband ing' voor fundusherniatie en therapie falen van de maagband.

In de literatuur zijn geen duidelijke richtlijnen voor de juiste keuze van behandeling van een fundusherniatie. De hierboven beschreven studie geeft richtlijnen voor het te volgen beleid in het geval van een geslipte maagband. 'Reband ing' voor fundusherniatie is geen prognostische factor voor inadequaat gewichtsverlies volgens onze data. De aanname dat een geslipte maagband verwijderd moet worden in verband met te verwachten therapie falen wordt derhalve niet ondersteund door deze studie. Bij patiënten met een goed functionerende maagband dient 'reband ing' overwogen te worden in het geval van een fundusherniatie (62% kans op succes). Bij patiënten met een slecht functionerende maagband dient verwijderen van de maagband en een

secundaire bariatrische ingreep overwogen te worden in het geval van een fundusherniatie (27% kans op succes bij 'rebanding').

Wat zijn de resultaten van een maagomleiding in termen van gewichtsverlies en complicaties?

In *Hoofdstuk 5* wordt de veiligheid en effectiviteit van een (laparoscopische) maagomleiding beschreven sinds de introductie van deze techniek in 2002 in het Sint Antonius Ziekenhuis te Nieuwegein, Nederland. Het betreft de eerste publicatie over de resultaten van de maagomleiding voor morbide obesitas in Nederland. De studiegroep betreft patiënten die een maagomleiding ondergingen als primaire procedure (65%) of als een secundaire procedure (35%) na eerdere insufficiënte primaire bariatrische chirurgie. Bij 71% van de patiënten werd een overgewichtsverlies > 50% bereikt na 1 jaar follow-up, met een mediaan overgewichtsverlies van 59% en een mediaan BMI verlies van 16 kg/m^2. Subgroepen met een hoger uitgangs-BMI bereikten een hoger BMI verlies. Patiënten die een primaire maagomleiding ondergingen hadden een kans van 79% op een succesvol resultaat (overgewichtsverlies > 50%), vergeleken met 59% van de patiënten die de maagomleiding als secundaire procedure ondergingen. Echter, als het overgewichtsverlies berekend werd aan de hand van de uitgangs-BMI voor de primaire bariatrische ingreep was er geen verschil tussen beide groepen.
De met de maagomleiding gepaard gaande mortaliteit was 0,7% (2 / 290). Korte termijn complicaties traden op bij 15% van de patiënten, waarbij naadlekkage de meest voorkomende was (5%). Bij 6% van de patiënten leidde een vroege complicatie tot een re-operatie. Late complicaties traden op bij 21% van de patiënten, waarbij strictuur van de proximale anastomose (6%) en littekenbreuken (5%) de voornaamste waren. Patiënten die een open maagomleiding ondergingen hadden meer vroege en late complicaties dan patiënten die een laparoscopische maagomleiding ondergingen, conform de literatuur.
Het belangrijkste voordeel van de maagomleiding is het hoge percentage succesvol behandelde patiënten en het hoge gewichtsverlies dat in korte tijd bereikt wordt. De maagomleiding gaat daarentegen gepaard met procedure gerelateerde mortaliteit en morbiditeit. Nadelen zijn de irreversibiliteit van de procedure en het verlies van continuïteit van het maag-, darmstelsel. De laparoscopische maagomleiding heeft de voorkeur boven de open maagomleiding.

Hoeveel patiënten worden succesvol behandeld en wat is de morbiditeit na een laparoscopische geplaatste maagband vergeleken met een maagomleiding?

De laparoscopische maagband plaatsing en de (laparoscopische) maagomleiding zijn de twee meest uitgevoerde bariatrische ingrepen wereldwijd. Met de opkomst van de bariatrische chirurgie blijft de indicatie voor de keuze tussen beide ingrepen onderwerp van discussie. Bij het ontbreken van prospectief gerandomiseerde studies, beschrijven wij in *Hoofdstuk 6* de resultaten

van een patiënt-gecontroleerde cohort studie om de resultaten van beide ingrepen te vergelijken. Het overgewichtsverlies was significant hoger in de maagomleidig groep dan in de maagband groep op alle tijdspunten in de follow-up. Na 2 jaar follow-up was het mediaan overgewichtsverlies 60% na een maagomleiding vergeleken met 43% na een maagband (P < 0,001) en het mediaan BMI verlies 17 kg/m^2 na een maagomleiding vergeleken met 12 kg/m^2 na een maagband (P < 0,001). Na 2 jaar follow-up hadden significant meer patiënten een goed behandelresultaat (overgewichtsverlies > 50%) na een maagomleiding dan na een maagband (76% versus 40%, P = 0,03).
Er werden significant meer ernstige, vroege complicaties na een maagomleiding gezien dan na een maagband (11% versus 0%). Deze complicaties bestonden voornamelijk uit lekkage ter plaats van de gastro-jejunostomie, welke vaak een re-operatie vereiste. In beide groepen werd geen mortaliteit gezien.
Concluderend kan gesteld worden dat een maagomleiding vergeleken met een maagband leidt tot een hoger gewichtsverlies, in een groter aantal patiënten tegen de prijs van een groter aantal ernstige, vroege complicaties. Bij het ontbreken van consensus onder bariatrisch chirurgen over een definitie van succesvolle behandeling van de morbide obese patiënt, kunnen geen duidelijke conclusies getrokken worden over de superioriteit van één van beide procedures. Als voorbeeld zou een definitie van een overgewichtsverlies van > 30% als goed behandelresultaat het aantal succesvol behandelde patiënten door een maagband verhogen van 40% naar 80% in onze serie. Toekomstige studies en consensus onder bariatrisch chirurgen over succesvolle therapie zouden moeten leiden tot een definitieve keuze van de juiste procedure voor de juiste patiënt.

Is de veiligheid en effectiviteit van een secundaire maagomleiding na gefaalde maagband vergelijkbaar met de veiligheid en effectiviteit van een primaire maagomleiding?

Recente series laten slechte behandelresultaten op de lange termijn na een maagband plaatsing zien van 40-50% (*Hoofdstuk 3*). Ondanks deze hoge percentages van slechte behandeling op de lange termijn staat de maagband plaatsing toch toenemend in de belangstelling. In de Verenigde Staten steeg het aantal geplaatste maagbanden als percentage van alle uitgevoerde bariatrische ingrepen tussen 2003 en 2008 van 9% naar 44%. Veel chirurgen kiezen in het geval van een gefaalde maagband voor een secundaire maagomleiding. Hiermee rijst de vraag of een secundaire maagomleiding net zo veilig en effectief is als een primaire maagomleiding. Het doel van de studie die in *Hoofdstuk 7* wordt beschreven was of de resultaten van een secundaire maagomleiding vergelijkbaar zijn met de resultaten van een primaire maagomleiding in termen van gewichtsverlies en complicaties. Het gewichtsverlies na een primaire of secundaire maagomleiding bleek niet verschillend. Na 3 jaren follow-up hadden respectievelijk 75% en 73% van de patiënten een BMI < 35 kg/m^2 na een primaire of secundaire maagomleiding. Er werden geen significante verschillen gevonden in het vóórkomen van complicaties na een primaire of secundaire maagomleiding

(30% versus 31%, *P* = 0,87). Het percentage lekkages ter plaatse van de gastro-jejunostomie was respectievelijk 6% en 4%. Het percentage re-operaties was respectievelijk 14% en 18% (*P* = 0,17). In beide groepen werd geen mortaliteit gezien.
Een secundaire maagomleiding na een gefaalde maagband is een technisch meer uitdagende procedure dan een primaire maagomleiding. De studie gepresenteerd in *Hoofdstuk 7* laat zien dat een primaire of secundaire maagomleiding met vergelijkbare effectiviteit en veiligheid uitgevoerd kunnen worden. In ons ziekenhuis wordt een secundaire maagomleiding overwogen in het geval van gefaalde maagband therapie.

Wat zijn de resultaten van reconstructieve chirurgie na succesvolle bariatrische chirurgie in termen van fysiek en psychosociaal welzijn en kwaliteit van leven?

Bariatrische chirurgie is in de laatste jaren de enige effectieve, duurzame therapie gebleken voor morbide obesitas. Na succesvolle bariatrische chirurgie kan het overgewichtsverlies leiden tot nadelige cosmetische bijverschijnselen zoals een spanningsloos huidsurplus. Deze verschijnselen kunnen fysieke ongemakken geven en tevens een verminderde kwaliteit van leven veroorzaken. Er is zelfs gesuggereerd dat deze nieuwe ongemakken de kwaliteit van leven in dezelfde mate negatief kunnen beïnvloeden als de oorspronkelijke morbide obesitas. In *Hoofdstuk 8* presenteren we de resultaten van een studie naar de uitwerking van reconstructieve chirurgie na succesvolle bariatrische chirurgie op de kwaliteit van leven. Gedurende de studieperiode van 10 jaar werd bij 13% van de patiënten reconstructieve chirurgie verricht na bariatrische chirurgie. Na reconstructieve chirurgie verbeterden patiënten significant op 6 van de 7 domeinen van kwaliteit van leven: fysiek functioneren, geestelijk welzijn, fysieke prestatie, sociale acceptatie, zelf beheersing ten aanzien van eten en intimiteit. Voor 67% van de patiënten was de reconstructieve chirurgie naar tevredenheid verlopen en voor 19% teleurstellend. Teleurstelling werd vooral veroorzaakt door technische factoren zoals 'dog ears' ter plaats van het litteken of door hoge verwachtingen ten gevolge van irrealistische voorbeelden op internet.
De chirurgische behandeling van morbide obesitas faalt in een significant deel van de patiënten door gewichtstoename. Reconstructieve chirurgie zou mogelijk een belangrijke rol kunnen spelen bij het behouden van het gewichtsverlies op de lange termijn. Een goede kwaliteit van leven is positief geassocïeerd met het behouden van gewichtsverlies op de lange termijn. Zoals uit onze studie blijkt verhoogt reconstructieve chirurgie in de meerderheid van de patiënten de kwaliteit van leven en daarmee mogelijk de kans op behoud van gewichstverlies. De bijdrage van reconstructieve chirurgie aan de multidisciplinaire behandeling van morbide obesitas is niet beperkt tot een cosmetisch aspect, maar van onmisbaar belang.

Discussie

De studies die in dit proefschrift gepresenteerd worden geven antwoord op belangrijke vragen over de chirurgische behandeling van morbide obesitas in Nederland. Maagband plaatsing en een maagomleiding blijken veilige en effectieve procedures te zijn. Revisie chirurgie blijkt veilig en reconstructieve chirurgie na succesvolle bariatrische chirurgie verhoogt de kwaliteit van leven. Deze bevindingen komen overeen met gegevens uit de literatuur: bariatrische chirurgie is de meest effectieve behandeling van morbide obesitas en kan veilig uitgevoerd worden.

Als we ons blikveld verruimen buiten de studies gepresenteerd in dit proefschrift ontstaan nieuwe vragen betreffende de behandeling van morbide obesitas. De belangrijkste vraag betreft de selectie van de juiste morbide obese patiënt voor de juiste bariatrische procedure. Er bestaan geen duidelijk criteria voor de selectie van morbide obese patiënten voor een restrictieve, een malabsorptieve of een gecombineerde procedure. In de SAGES richtlijnen gepresenteerd in 2009 worden geen duidelijke conclusies getrokken welke patiënt in aanmerking komt voor welke ingreep. De incomplete richtlijnen betreffende patiëntenselectie voor verschillende vormen van bariatrische chirurgie zijn het gevolg van de meest belangrijke, onbeantwoorde vraag over de behandeling van morbide obesitas: wat is de definitie van succesvolle behandeling?

Gedurende de laatste decennia is overgewichtsverlies de belangrijkste chirurgische uitkomstmaat geweest voor de behandeling van morbide obesitas. Standaard criteria voor het percentage overgewichtsverlies dat succesvolle obesitas behandeling representeert zijn nooit algemeen geaccepteerd. Het gebrek aan deze criteria bemoeilijkt de juiste keuze van behandeling voor de morbide obese patiënt. Verschillende auteurs hebben hun eigen definitie van succes ontwikkeld. Reinhold heeft een aantal criteria ontwikkeld waarvan andere auteurs de volgende definitie hebben afgeleid: overgewichtsverlies < 25% is gedefiniëerd als een slecht resultaat, 25-50% als een acceptabel resultaat en > 50% als een goed resultaat. Deze criteria zijn echter twee keer zo streng als die van Mason: een overgewichtsverlies van > 25% is een goed resultaat. Daarnaast heeft MacLean alleen de BMI gebruikt als uitkomstmaat: een BMI < 35 kg/m^2 is een succesvol resultaat en een BMI > 35 kg/m^2 is een slecht resultaat.

Een consensus over het te bereiken overgewichtsverlies is cruciaal voor de keuze van de juiste bariatrische procedure. Voor een maagband verdubbelt het succespercentage als een overgewichtsverlies van 25% succesvol wordt geacht in plaats van een overgewichtsverlies van 50%. Kunnen we onze behandeling bijvoorbeeld als succesvol bestempelen als de comorbiditeit en de kwaliteit van leven een acceptabel niveau bereiken bij een overgewichstverlies van 25%, maar het cosmetische resultaat is naar patiënt zijn of haar ontevredenheid?

Het is de taak van de behandelaars van obesitas in het algemeen en bariatrisch chirurgen in het bijzonder, deze vragen in de nabije toekomst te voorzien van duidelijke antwoorden.

Naast het verlies van overgewicht is het ultieme doel van bariatrische chirurgie het duurzaam verminderen van de comorbiditeit en het verbeteren van de kwaliteit van leven van de morbide obese patiënt. Daarom is het van essentïeel belang deze twee aspecten te betrekken in de definitie van succesvolle behandeling van morbide obesitas. Een volledige presentatie van de resultaten van obesitas behandeling betreft evaluatie van het overgewichtsverlies, de comorbiditeit en de kwaliteit van leven. In 1998 heeft Oria het BAROS (Bariatric Analysis and Reporting Ouctome System) geïntroduceerd. Het is een systeem dat gebruikt kan worden om de resultaten van chirurgische en niet-chirurgische behandeling van morbide obesitas te presenteren. Het BAROS analyseert de drie bovenstaand genoemde parameters: overgewichtsverlies, de comorbiditeit en de kwaliteit van leven. Na de introductie van dit systeem in 1998 is het helaas incidenteel gebruikt en heeft het geen wereldwijde navolging gevonden in het presenteren van de resultaten van obesitas behandeling. De redenen hiervoor zijn niet geheel duidelijk, doch liggen mogelijk in het feit dat het gebruik van het systeem omslachtig en tijdrovend is. In 2009 is door Oria een gemodificeerde versie geïntroduceerd die gebruiksvriendelijker zou zijn, doch deze versie lijkt nog te gecompliceerd voor wijdverbreid gebruik. Het presenteren van de resultaten van obesitas behandeling op de drie bovengenoemde parameters kan echter als een aanmoediging opgevat worden voor de behandelaars van obesitas om te komen tot een consensus betreffende de succesvolle behandeling van morbide obesitas.

Bariatrische chirurgie is het meest effectieve antwoord gebleken op de wereldwijde obesitas epidemie van de laatste decennia. De belangrijkste taak voor de behandelaars van obesitas is om te komen tot een consensus betreffende succesvolle en niet-succesvolle behandeling van morbide obesitas. Als deze consensus bereikt is kunnen de verschillende procedures met elkaar vergeleken worden voor subgroepen van patiënten en dan kan de behandeling van morbide obesitas afgestemd worden op de individuele patiënt.

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Dankwoord

Publicaties

Curriculum vitae

Review committee

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Curriculum vitae

Wouter te Riele was born on February 22, 1977, in Hilversum, the Netherlands. He graduated from the Gemeentelijk Gymnasium, Hilversum, in 1995. After not been selected for the study of Medicine, he studied Political Science for a year. In 1996 he was selected for Medicine and started his study on the University of Amsterdam. During his study period he functioned as a student assistant in the Department of Anatomy & Embryology and obtained his Medical Degree in 2004. In August 2004 he started as a resident at the Department of Surgery in the Sint Antonius Hospital Nieuwegein, until August 2006. In this period he started scientific research on the results of bariatric surgery which has become the basis for this thesis. From September 2006 until December 2006 he functioned as a full time researcher at the same department. In January 2007 he started surgical training in Nieuwegein for the first two years (Dr. P.M.N.Y.H. Go). From January 2009 the third and fourth year of surgical training were followed at the University Medical Center Utrecht (Prof. dr. I.H.M. Borel Rinkes). From January 2011 he is following the last two years of surgical training in Nieuwegein and is specialising in laparoscopic, gastro-intestinal/ bariatric surgery. He hopes to complete training in December 2012. He is a member of the European Obesity Academy from January 2010.

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