Revisional and complicated bariatric surgery

Citation for published version (APA):

van Wezenbeek, M. R. (2020). *Revisional and complicated bariatric surgery*. [Doctoral Thesis, Maastricht University]. ProefschriftMaken. <https://doi.org/10.26481/dis.20200214mw>

Document status and date:

Published: 01/01/2020

DOI:

[10.26481/dis.20200214mw](https://doi.org/10.26481/dis.20200214mw)

Document Version:

Publisher's PDF, also known as Version of record

Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
- The final author version and the galley proof are versions of the publication after peer review.
- The final published version features the final layout of the paper including the volume, issue and page numbers.

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Revisional and complicated bariatric surgery

Colofon

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ISBN: 978-94-6380-686-2

Cover: Huib Dieltjens

Layout: Tiny Wouters

Production: ProefschriftMaken

The research presented in this thesis was conducted at CAPHRI Care and Public Health Research Institute, Department of Epidemiology, of Maastricht University. CAPHRI participates in the Netherlands School of Public Health and Care Research CaRe.

The printing of this thesis was financially supported by Maastricht University & Catharina Ziekenhuis Eindhoven.

Revisional and complicated bariatric surgery

PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Universiteit Maastricht,
op gezag van de Rector Magnificus, Prof. Dr. Rianne M. Letschert,
volgens het besluit van het College van Decanen,
in het openbaar te verdedigen
op vrijdag 14 februari 2020 om 14.00 uur

door

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geboren te Waalwijk op 16 november 1988

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CHAPTER 1

General introduction & outline of the thesis

GENERAL INTRODUCTION

1. Focus on revisions and complications

The consequences of the global obesity pandemic are enormous. They range from associated chronic diseases to premature deaths with a high impact on quality of life, health resources and costs. Treatment of obesity is challenging since it is a complex condition with serious social and psychological dimensions, which affects all ages and socioeconomic groups. Of the available options, a surgical intervention is the only long term effective treatment.¹ The transition towards laparoscopic surgery, concentrating care in high volume centers and improvements in anesthesiological approach have all attributed to the acceptance of bariatric surgery as a safe option. Even though it is the best available option in the treatment of (morbid) obesity, bariatric surgery remains associated with complications. Leakage and postoperative bleeding are short-term examples, dysphagia or weight regain necessitating a revisional procedure can occur on the long scale. The biggest challenge is to further reduce the risk of these adverse events. For this purpose, this manuscript focuses on these short- and long-term complications.

2. Obesity: Definition, epidemiology and etiology

Overweight and obesity are caused by an abnormal or excessive fat accumulation which impairs general health. Body Mass Index (BMI) is the most commonly used classification. It is a simple index that defines a person's weight in kilograms divided by the square of the height in meters (kg/m^2). Overweight is defined as a BMI greater than or equal to 25kg/m^2 and obesity describes a BMI greater than or equal to 30kg/m^2 .²

Obesity is an often preventable medical condition which increases the risk at developing various morbidities such as cardiovascular diseases, diabetes mellitus type 2, obstructive sleep apnea, depression, osteoarthritis and certain types of cancer.^{3,4} Furthermore, it is one of the leading preventable causes of death worldwide.⁵

Between 1975 and 2016, the incidence of worldwide obesity has nearly tripled. In 2016, 13% of the global adult population was obese, adding up to an astonishing 650 million obese adults worldwide.² Furthermore, in 2016, another 340 million children and adolescents between the age of 5 and 19 years old were either overweight or obese.² These numbers highlight the fact that obesity is a global burden which has been expanding over the last years. Consequently, this will greatly affect the health care costs both now as well as in the future.^{6,7}

According to the definitions of the World Health Organization, Caucasian people are considered obese when their Body Mass Index (BMI) is over 30 kg/m². Morbid obesity is considered in case of a BMI ≥ 40 kg/m² or a BMI ≥ 35 kg/m² while experiencing obesity-related health conditions. These conditions include diabetes mellitus type 2, hypertension, dyslipidemia, obstructive sleep apnea syndrome and osteoarthritis.

Major causes for obesity are excessive food intake and a lack of physical activity, making obesity a largely preventable disease through a combination of personal choices and social changes.² The high number of obese patients within a community with a low societal level may be caused by the low cost of energy-dense food. This hypothesis is likely enforced by the high palatability of sugar and fat.⁸ Only a minor part of the obese population has a genetic, medical or psychiatric illness as the primary cause for their obesity.⁹

The brain-gut axis has a major role in the control of food intake. During an empty stomach, the "hunger hormone" ghrelin is excreted to increase hunger by stimulation of the hypothalamus. This effect stops when the stomach wall is stretched, inhibiting the secretion of ghrelin.¹⁰ Other hormones such as leptin, peptide-YY, glucagon-like peptide and cholecystokinin also affect the central nervous system to regulate hunger and satiety and to control food intake.

Many contributing factors result in overweight and even obesity. These factors include genetic, behavioral, environmental, hormonal, social and cultural factors, which result in an energy imbalance and promote excessive fat deposition.¹¹ Studies show that behavioral and environmental factors play a predominant role in the current obesity epidemic.¹² In order to prevent weight regain, a common complication after bariatric surgery, it is of vital importance for patients to establish the necessary lifestyle changes.

3. Bariatric procedures

Bariatric surgery started in the 1950's with an intestinal bypass by laparotomy. Malabsorption of food was established by diverting a large portion of the small intestine, causing weight loss. Over the last decades, a number of different procedures have been developed to achieve even more weight loss. Figure 1.1 shows some of the highlights of the history of bariatric surgery. The procedures relevant to this manuscript will be reviewed below.

Figure 1.1 Important landmarks in the history of bariatric surgery.

3.1. Roux-en-Y gastric bypass (RYGB)

The original gastric bypass was introduced by dr. Mason in 1966.¹³ The first gastric bypass consisted of a small portion of the stomach along with a retrocolic loop gastrojejunostomy. Over the last decades, this procedure was further developed. Nowadays, the most performed type of gastric bypass is the Roux-en-Y gastric bypass. This procedure consists of a small gastric pouch from the upper stomach and a reconstruction of the gastro-intestinal tract to enable drainage of both gastric segments. Reconstruction of the intestinal tract is performed in many varieties, resulting in different lengths of the small intestine segments. There are three limbs: the alimentary limb (also known as the Roux limb; between the gastric pouch and the jejuno-jejunostomy), the biliopancreatic limb (the bypassed section including the stomach remnant, the duodenum and a portion of the proximal jejunum up to the jejuno-jejunostomy) and the common limb (originating distally from the jejuno-jejunostomy).

There are many varieties on the gastric bypass, such as the more recently introduced mini or omegaloop gastric bypass and the duodenojejunal bypass. Currently, RYGB is still considered the gold standard in bariatric surgery with good long-term results with a mean weight loss over 60%, a significant reduction of obesity-related comorbidities, a low revision rate and a high patient satisfaction rate.¹⁴

3.2. Adjustable Gastric Band (AGB)

The first gastric band was placed by Dr. Wilkinson, who aimed to achieve weight loss without disrupting the gastro-intestinal tract. His main goal was a restriction in food intake. The first band, a non-adjustable 2cm Marlex mesh, was placed in 1978.¹⁵ Later, in the mid 1980's, both Kuzmak and Hallberg separately developed the more modern version to the band. This was a silicone band which allowed for adjustments by the use of a subcutaneous port to

ensure comfort and effectiveness of the band. The band can be filled with a saline solution until the optimal restriction is achieved.¹⁶ Average long-term weight loss is reported to be close to 50% of all excess weight.¹⁷ In 2008, over 40% of all bariatric procedures consisted of a gastric band, however these percentages have quickly decreased over the last years.^{18,19}

3.3. *Vertical Banded Gastroplasty (VBG)*

This old restrictive procedure was first described by dr. Edward Mason in 1980.²⁰ In a VBG, a small gastric pouch is created by vertical stapling of the fundus and placing a band at the distal end of the pouch. The biggest downfall of this procedure was a high amount of gastro-gastric fistulae due to a high percentage of staple-line disruptions. Therefore, MacLean later altered the procedure by dividing this staple line.^{21,22}

Weight loss was obtained by restricting food intake due to a small gastric pouch. This in turn established early satiety while maintaining normal passage through the intestines, avoiding any malabsorption of nutrients and medication.

In the early days, VBG has proven to provide good short-term weight loss results and a low complication rate.²³⁻²⁶

3.4. *Sleeve gastrectomy*

A more modern restrictive procedure is the sleeve gastrectomy. It was first described by Marceau et al. in the late 1990's as part of a biliopancreatic diversion with duodenal switch (BPD/DS) and was later popularized by Gagner et al. as standalone procedure.²⁷⁻²⁹

This procedure reduces the stomach size to about 15-20% of its original size by surgically removing a large portion of the stomach along the greater curvature, the predominant area for the production of ghrelin, the hunger regulating peptide hormone.^{30,31}

Adequate long-term results are scarce, but SG is showing promising results in terms of weight loss and improvement of obesity related comorbidities in the short- and mid-term follow-up.^{32,33} Furthermore, it has quickly become one of the most performed procedures worldwide.¹⁹

3.5. *Single Anastomosis Duodenal bypass (SADI)*

One of the newest malabsorptive procedures which is quickly gaining in popularity is the single anastomosis duodenoileal bypass. It was first introduced by Torres et al. in 2007.³⁴ The SADI is a derivative of the primary procedure SADI-S (SADI with sleeve gastrectomy), which can be described as a simplified duodenal switch and has demonstrated to have satisfactory short- and

medium-term results.³⁵ Furthermore, it may be a valuable alternative to the technically more challenging biliopancreatic diversion. Even though the SADI appears to be a valid option since the first reported results are promising, more data is necessary to fully comprehend this new procedure.³⁴⁻³⁷ In 2018, the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), has marked SADI(-S) as a recognized bariatric procedure, but underlines the lack of long-term results and its potential unforeseeable long-term consequences such as nutrient deficiencies.³⁸

Important note:

As mentioned earlier, obesity is caused by a large range of factors. Proper treatment of the predominant behavioral and environmental risk factors does not only require a bariatric procedure, but also demands proper screening, pre-education and postoperative follow-up by a dedicated bariatric team including dieticians, psychologists, physical therapists, surgeons, internists, gastroenterologists and specialized nurses.

4. Benefits

An important benchmark in research on the results of bariatric surgery is the Swedish Obese Subjects (SOS) Registry, a large, long-term, prospective study comparing several bariatric procedures with the usual (conservative) treatment reporting on a wide range of outcome parameters.

Important results were an average long-term (total) weight loss between 16 and 23% with a reduction in the overall mortality rate (hazard ratio =0.71) in favor of bariatric surgery. Furthermore, bariatric surgery establishes favorable rates of recovery from diabetes, hypertriglyceridemia, low levels of high-density lipoprotein cholesterol, hypertension, and hyperuricemia. Finally, a reduction in cancer incidence was observed in female study subjects after surgery.^{1,39-41}

Other studies report an improvement of health-related quality of life and other psychological parameters.⁴²⁻⁴⁴

5. Complications in bariatric surgery and its provoking factors

Even though bariatric surgery appears to be largely beneficial, one of the biggest challenges is to prevent and limit any type of complication as much as possible. The term complication is a very broad conception, due to the large amount of different causes and the word complication can be interpreted in more than one way.

5.1. *Psychological factors*

Some of the factors that may affect the outcome after bariatric surgery are personal (social and psychological) patient factors and the commitment to make the necessary lifestyle changes after surgery. Important factors, such as eating behavior, socio-economic status and coping are known to affect these changes, thus affecting the outcome after bariatric surgery.⁴⁵⁻⁴⁷ In these cases, failure is often considered when an insufficient amount of weight loss is observed at the long-term.

The simple solution would be to identify these various factors and properly tackle them before and after surgery to ensure a good long-term result. This identification is impeded by the great diversity in results, outcome measures, diverse lengths of follow-up and small patient groups.⁴⁶ This in turn leads to a lack of consensus on which factors have a predictive value on the outcome after bariatric surgery.⁴⁸

5.2. *In-hospital care*

Obesity and its related anatomical changes create challenges for clinicians, as bariatric patients requires a different but still appropriate selection and dosing of medications for pain management and treatment of infectious complications, venous thromboembolisms, bleeding and other chronic diseases.⁴⁹ Inappropriate treatment of these obese patients may potentially lead to a different kind of failure: an increase in peri-operative complications, such as bleeding, anastomotic leakage, wound infection, venous thromboembolisms and cardiovascular events leading to increased mortality and readmission rate.⁵⁰

The annual number of performed bariatric procedures worldwide is currently over 500,000 and is still growing.⁵¹ Even though the complication rate for these type of procedures is relatively low, the high number of performed procedures still results in a high absolute number of complications. Due to these large numbers, associated costs will certainly impact health care economy.^{6,7} This calls for continuous efforts and research to reduce the number of complications. There are different areas to focus on, such as identifying risk factors associated with a higher postoperative complication rate.⁵² Even different intra-operative surgical techniques may affect the outcome. For example: usage of the pars flaccida technique versus the perigastric technique in AGB-placement or the choice of bougie caliber in sleeve gastrectomy.^{53,54} Nonetheless, it is unlikely that complications such as bleeding, anastomotic leakage and intra-abdominal abscesses are completely avoidable, which calls for a highly reliable treatment option. However, therapeutic options are diverse and can cause complications on their own.^{49,55,56}

With the continuous growing number of bariatric procedures, fast track protocols in hospitals have become more attractive, which in theory could have led to a negative effect on the perioperative outcome after bariatric surgery. Fortunately, fast track protocols have proven to be safe and effective in primary bariatric surgery.^{57,58} However, evidence on its positive effect in patients undergoing more challenging and less common revisional bariatric surgery is still very scarce. This seems relevant since the number of revisional procedures is expected to increase over the next years.

5.3. *Type of procedure*

Failure depends on many factors among which the type of procedure is important. For example: literature is increasingly showing that older (restrictive) procedures such as the AGB and the VBG are often not living up to expectations. Furthermore, the percentage of complications requiring revisional surgery is unacceptably high after VBG and AGB.⁵⁹⁻⁶¹ Recent literature reports a poor long-term outcome, mainly focusing on a variety of potential technical problems, weight loss and biomedical parameters.^{59,62,63} For these reasons, both procedures have been (largely) abandoned in the Netherlands for several years in favor of other bariatric techniques.⁶⁴

As mentioned before, sleeve gastrectomy appears to be a promising alternative to the older restrictive procedures. However, one of the major drawbacks of the sleeve gastrectomy is similar to the older procedures: development of complaints necessitating a revisional procedure (including insufficient weight loss and complaints of gastro-esophageal reflux disease). Proper long-term data is still scarce but the currently reported revision rates are lower than both the AGB and VBG.^{65,66} A recent study from Chang et al. reports a revision rate of almost 17%.⁶⁷

5.4. *Revisional surgery*

The most common option for revisional surgery after either failed ABG, VBG or sleeve gastrectomy is the RYGB, with a satisfactory outcome in terms of weight loss, morbidity and reduction in obesity-related comorbidities.⁶⁸⁻⁷⁰ Nonetheless, the first results of a revisional gastric bypass after sleeve gastrectomy are often disappointing in terms of (additional) weight loss. The failure of this type of revisional surgery has led to the search for a better alternative.⁷¹ Current alternatives are the biliopancreatic diversion, the duodenal switch and the more recently introduced single anastomosis duodeno-ileal bypass (SADI).^{36,72,73} Data on the outcome after SADI, especially as a revisional procedure, as well as comparison with other procedures is scarce.

OUTLINE OF THE THESIS

Different types of failure and complications will be highlighted in two main themes: revisional surgery and early postoperative complications. This thesis aims to contribute to the reduction of short- and long-term complications by analyzing current results of revisional surgery, finding predictors for failure and complications and assessing the effect of intra-operative techniques.

Part one

The first part of this thesis focuses on revisional bariatric surgery and its difficulties. Revisional procedures are used to treat several long-term complications such as weight regain, insufficient weight loss, gastro-esophageal reflux disease and dysphagia.

To fully understand the indications for revisional surgery, a proper understanding of the primary (failed) procedure is essential. Therefore, Chapter 2 focuses on the long-term medical outcome after primary VBG and its associated complications. To better understand the reason for these failures, a search for potential psychological and medical factors associated with failure has been conducted. The results will be discussed in Chapter 3.

When is revisional surgery indicated after failed VBG, what type of surgery provides the best (long-term) outcome? Chapter 4 attempts to answer these questions. Different revisional procedures after primary failed VBG are analyzed, including revision of the VBG, conversion to sleeve gastrectomy and conversion to RYGB.

As the number of revisional procedures is expected to rise over the next years, Chapter 5 evaluates the use of a fast track protocol in bariatric revisional surgery, which may increase the number of (revisional) procedures performed on a daily basis without an increase in early postoperative complications.

The thesis continues with Chapter 6, focusing on the conversion of both a failed AGB and a failed sleeve gastrectomy to RYGB. Current literature suggests RYGB is feasible as revisional procedure after almost every type of failed (primary) procedure. The comparison in Chapter 6 is made to evaluate whether this assumption is valid.

As mentioned before, new surgical techniques are arising. The first published results on the SADI are promising, however, much is unknown about this new procedure. Chapter 7 focuses on the use of SADI as a revisional procedure after primary sleeve gastrectomy to potentially find a better alternative to the RYGB. To further investigate the effects of the SADI as a revisional procedure, Chapter 8 describes a study protocol for a randomized controlled trial analyzing the outcome of SADI versus RYGB after sleeve gastrectomy.

Part two

The second part of the thesis focuses on early postoperative complications in bariatric surgery. Different aspects are reviewed. Chapter 9 focuses on the identification of potential risk factors leading to postoperative complications after primary RYGB. Chapter 10 assesses a technique to reduce the number of postoperative complications in primary RYGB. The final chapter of part two, Chapter 11, focuses on a new (endoscopic) treatment option for one of the most difficultly manageable complications: anastomotic leakage.

The thesis will be ended by a summary of the results with a general discussion and future perspectives.

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PART ONE

Revisions in bariatric surgery

CHAPTER 2

Long-term results of primary vertical banded gastroplasty

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Obesity Surgery. 2015;25(8):1425-30

ABSTRACT

Background

The vertical banded gastroplasty (VBG) used to be a common restrictive bariatric procedure, but has been abandoned by many due to a high failure-rate, a high incidence of long-term complications and the newer adjustable gastric band (AGB) and sleeve. However, potential favourable long-term results and the upcoming banded gastric bypass, with a similar mechanical outlet restriction and control of the pouch size, renewed our interest in the VBG. Therefore we investigated the long-term outcome of primary VBG at the Catharina hospital in the Netherlands.

Materials and methods

Patients that underwent a primary VBG between 1998 and 2008 were included. Patients' characteristics, operative details, evolution on weight and co-morbidities, complications and outcome of revisions were reviewed.

Results

A total of 392 patients (80% female) were reviewed with a mean age of 40 ± 9 years and Body Mass Index of 44 ± 5 kg/m². Mean follow-up after VBG was 66 ± 50 months and showed a mean excess weight loss (EWL) of $53 \pm 27\%$ and co-morbidity reduction of 54%. 152 patients (39%) out of 227 patients (58%) with long-term complaints underwent revisional surgery. Main reasons for revision were weight regain and vomiting/food intolerance. Analysis before revision showed an outlet dilatation (17%), pouch dilatation (16%) and outlet stenosis (10%). After revision, an additional EWL of 23% and 33% further reduction in co-morbidities was seen.

Conclusion

Primary VBG has an acceptable EWL of 53% and 55% of co-morbidities were improved. However, the high complication rate, often necessitating revision, underlines the limits of this procedure.

INTRODUCTION

Over the last decades, morbid obesity is an increasing problem worldwide and will continue to increase even further in the next years.¹ For obesity, there are many therapeutic options. The most efficacious therapy for morbid obesity is still bariatric surgery. One of the older techniques in bariatric surgery is the vertical banded gastroplasty (VBG), originally described by Mason in the early 1980s.² Later, this technique was altered by MacLean et al. due to a high rate of staple line disruptions in the original technique. In this altered technique, the vertical stapler line is completely divided to reduce the chance of a gastro-gastric fistula between the pouch and the gastric fundus.³

This gastroplasty establishes a restriction on food intake due to a small stomach pouch, which gives early satiety while maintaining passage of food through the further unaltered gastro-intestinal tract. This technique should avoid malabsorption of nutrients and medication.^{2,4} A VBG used to be a common restrictive procedure with good short-term results on excess weight loss and a low complication rate as shown in multiple studies.⁵⁻¹⁰ However, medium- and long-term results are more heterogeneous; from good long-term results^{6,9,11} to a high long-term complication rate up to 45% and a tendency for weight regain in the long-term follow-up, leading to revision rates between 21,4% and 65%.^{7,12-15} Due to the high rate of failure, this technique was abandoned in the Netherlands for several years in favor of other bariatric techniques.¹⁵

However, our interest in this old technique was renewed for two reasons. One is the recently published data by Bekheit et al.¹¹ showing good long-term results, a low revision rate and an acceptable late complication rate after VBG, with the remark of the authors that good patient-selection is an important factor for long-term success. The second reason is the upcoming tendency of placing bands around bypasses and sleeves, in which a band is placed around the gastric pouch. This resembles a similar mechanical restriction as introduced in the VBG.^{16,17}

The aim of the current study is to assess the long-term results of the Mason-MacLean VBG's as a primary bariatric procedure. Assessment will include excess weight loss (EWL) percentage, early and late complications, revision rates and evolution of comorbidities.

MATERIALS AND METHODS

Methods

Medical charts of all patients undergoing a primary VBG as described by Mason and MacLean^{2,3} between January 1998 and December 2008 at the Obesity Center, Catharina Hospital, the Netherlands, were retrieved. Data on patients' characteristics, operative details, evolution of excess weight loss and comorbidities, complications and outcome of revisions were collected and analyzed.

Excess weight was calculated as a percentage of the difference between the weight/BMI before surgery and the highest healthy weight ($\text{BMI}=25\text{kg/m}^2$), according to the method as reported by Deitel et al.¹⁸ EWL was expressed as a percentage of the amount of excess weight lost after surgery. Excess weight loss was categorized according to the Reinhold criteria. Using these criteria, an intervention is considered successful if patients lose at least 50% of their excess weight.¹⁹

Since late 2011, the postoperative follow-up in the Catharina hospital is a structured 5-year program. However, subjects in this study only had a 1-year structured follow-up at the outpatient clinic and thereafter additional visits in case of complications. Further follow-up was to be performed by the general practitioner. To update current follow-up, a postal questionnaire was sent to all patients to retrieve the latest outcome. Patients who did not respond received a phone call.

The postal questionnaire contained questions about current and lowest weight after surgery, about comorbidities and use of medication, revisional surgery if applicable and possible complaints. Pre-defined complaints were dysphagia, frequent vitamin deficiencies and incisional hernia. Other groups of complications were composed out of reported complaints.

Evolution on comorbidities was divided into resolved (treatment no longer needed), improved (diminished amount of medication and/or use of CPAP in case of sleep apnea), stable, worsened or de novo. In case of complaints, patients were invited for additional analysis at the Obesity Center's outpatient clinic. In case of non-response, the data of the latest visit at the outpatient clinic were used as final outcome.

Treatment

All patients were assessed pre-operatively for eligibility for bariatric surgery by a multidisciplinary team consisting of a surgeon, a psychologist and a dietitian. When necessary, patients received additional psychological or dietary advice as

preparation for the intervention and its consequences, aiming to increase the effect of the surgery.²⁰

Surgery was performed by hand-assisted (HA) laparoscopic approach in the earlier years and later by a pure laparoscopic approach. Using a CEEA21 stapler (Covidien, New Haven, CT, USA), a transgastric window is created about 6 cm distally from the gastro-esophageal junction along the lesser curvature. An oral gastric tube Ch34 is placed between the lesser curvature and the CEEA. Hereby, the pouch size is approximately 1.2 cm. Along this tube, the vertical staple line is created from the transgastric window towards the angle of His using an EndoGIA. (Covidien, New Haven, CT, USA) For the final step of this procedure, a polytetrafluoroethylene (PTFE) band (1.5 x7.5 cm) is wrapped around the distal end of the gastric pouch, using the gastric tube for calibration. At a circumference of 6 cm, the band is fixed using two non-absorbable sutures.

Statistical analysis

Data were retrospectively collected, managed and analyzed using SPSS version 22, for Windows (SPSS Inc, Chicago, IL, USA). Quantitative data are denoted as mean +/- standard deviation, whereas rates of complications, evolution on comorbidities are presented as a percentage. The Mann Whitney U test was used to determine any significance of the observed differences among subgroups. Statistical significance was identified when the *p* value was less than 0.05. Summative figures and tables were used where necessary.

A sub-analysis was performed for laparoscopic versus HA-laparoscopic procedures and for non-super obese versus super obese patients when clinically relevant. Super obesity was considered with a BMI over 50 kg/m² according to the IFSO-guidelines.

No ethical approval was required for this study.

RESULTS

Between January 1998 and December 2008, a total of 392 consecutive patients underwent a VBG according to the technique described by Mason and MacLean.^{2,3} Since January 2009, no more VBG's were performed in our operating rooms. Two concomitant cholecystectomies were performed (0.5%). In this population, 80.1% of patients was female. 155 laparoscopic and 235 HA-laparoscopic procedures were performed. One patient underwent a primary open procedure and one laparoscopic procedure was converted. Other baseline characteristics are displayed in Table 2.1. A total of 39 (9.9%) super obese patients were identified in this study population.

A total of 300 patients returned their completed questionnaires (76.5%). Of those that did not return the questionnaire, ten patients (2.6%) refused cooperation, 75 patients (19.1%) could not be reached on multiple occasions due to various reasons and seven patients (1.8%) died during the follow-up period, all due to causes unrelated to surgery. The average total follow-up of this population was 90 ± 49 months.

Intra-operative complications occurred in 17 patients (4.4%). An intra-operative bleeding occurred in seven patients, a gastro-intestinal perforation was seen in four patients and a liver injury was reported in five patients, in one case leading to conversion to laparotomy. One patient had a splenic injury for which splenectomy after conversion to laparotomy was necessary.

Table 2.1 Baseline characteristics (n=392)

	Mean $\pm$ SD
Age (years)	39.7 $\pm$ 9.3
Male : Female (n)	78 : 314
Body Mass Index (kg/m ²)	43.7 $\pm$ 4.7
Diabetes Mellitus type 2 (n, %)	58 (14.8%)
Diet only	12 (3.1%)
Oral medication	31 (7.9%)
Insulin dependent	15 (3.8%)
Hypertension (n, %)	76 (19.4%)
Dyslipidemia (n, %)	26 (6.6%)
Sleep apnea (n, %)	7 (1.8%)
Osteo-articular disease (n, %)	31 (7.9%)
Procedure (n, %)	
Laparoscopic	155 (39.5%)
Laparoscopic hand-assisted	235 (59.9%)
Open	1 (0.3%)
Laparoscopic converted to open	1 (0.3%)
Operative time (min)	95 $\pm$ 27
Length of hospital stay (days)	4 $\pm$ 2

SD: standard deviation

Thirty patients (7.7%) developed complications in the postoperative 30-day period of whom eight (1.9%) required a reoperation. Eight patients (1.9%) had postoperative bleeding, of which three were successfully treated conservatively. Four patients (1.0%) had postoperative leaking, treated by either surgical reintervention (three) or stenting (one). Three patients (0.8%) developed a sepsis based on an intra-abdominal abscess, all were managed conservatively with antibiotics and two patients needed additional CT-guided drainage for a successful treatment. Other complications were pneumonia or urinary tract infection (1.0%), pulmonary embolism (0.5%), post-operative AV-nodal re-entry tachycardia (0.3%), dehydration due to persistent vomiting with no proven evident cause (0.3%) and deep venous thrombosis (0.3%). One patient (0.3%)

developed necrosis of the stomach pouch, which necessitated debridement by reoperation and a prolonged admission at the intensive care unit. Her recovery was complicated by acute kidney failure and an ulcer in the recreated stomach pouch. Five patients (1.3%) were treated for a trocar site / wound infection. There was no postoperative mortality.

At last follow-up, a total of 227 (58.4%) patients have reported complaints after primary surgery. 152 patients (38.8%) necessitated revision of the VBG for various reasons, of which 146 were operated in the Catharina hospital and 6 in other medical centers. 16 patients underwent a second revisional procedure. Amongst the 227 patients, the most common complaints after primary VBG were either vomiting, dysphagia and/or food intolerance (47.3%), in eight patients caused by erosion of the band. Other common complaints were weight regain (28.8%) and insufficient weight loss (15.9%). Other complaints were severe reflux (2.7%), which in one case caused a Barrett esophagitis, and (recurrent) abdominal pain (2.7%). Six patients underwent revision in another hospital. Since no permission was given to retrieve their data, the complaints leading to revision of the primary VBG are unknown, but are taken into account in the total number of complaints. As mentioned before, seven patients deceased during follow-up; all due to causes unrelated to bariatric surgery.

Weight loss

The mean follow-up after VBG was 66.1 ± 50.3 months. The follow-up of patients necessitating revision was taken into account until revisional surgery was performed. The mean excess weight loss at last follow-up after a primary VBG was $51.2 \pm 27.4\%$.

When analyzing weight loss results in patients with persistent VBG-anatomy, this study showed a mean EWL of $54.9 \pm 27.7\%$. For patients who underwent revisional surgery, a significant lower mean %EWL of $45.4 \pm 25.8\%$ ($p=0.001$) was reported compared with the patients not necessitating revision.

According to Reinhold's 1982 criteria, only 48.2% of 392 patients achieved a successful long-term EWL-percentage ($\text{EWL} > 50\%$).⁽¹⁹⁾ Additional analysis of this study group shows that in patients without revisional surgery this percentage is 55.4% as opposed to only 36.8% of patients necessitating revision.

Comorbidities

Regarding the major obesity-related comorbidities, an improvement/resolvment rate for type 2 diabetes of 70.7% was found. The rates for

hypertension, dyslipidemia, sleep apnea and osteo-articular disease were respectively 40.8%, 46.1%, 71.4% and 54.8%. This means, that after primary VBG, 53.5% of the major obesity-related comorbidities were either improved or resolved, as shown in Table 2.2. The improvement/resolvment rate in patients with an intact VBG was 63.5% as opposed to 39.5% in the revision group.

Table 2.2 Results after primary VBG (n=392).

Mean follow-up (months)	66.1 ± 50.4			
Mean BMI (kg/m ²)	34.2 ± 6.0			
Mean EWL (%)	52.5 ± 26.5			
	Worse	Stabile	Improved	Resolved
Diabetes Mellitus type 2 (n)	6	11	20	21
Hypertension (n)	3	42	20	11
Dyslipidemia (n)	3	11	5	7
Sleep apnea (n)	0	2	1	4
Osteo-articular disease (n)	2	12	8	9
Total (%)	7.1	39.4	53.5	

SD: standard deviation; EWL: excess weight loss; BMI: body mass index.

Revisions

A total of 152 patients underwent revision, of which 16 patients eventually needed a second revision. Mean follow-up after revision was 56.5±37.8 months. Average time between primary VBG and revision was 41.1±34.0 months, ranging from 2-154 months. 21 patients underwent revision of the primary VBG, 16 patients were converted to a sleeve gastrectomy and in 115 patients, the primary VBG was converted to Roux-en-Y gastric bypass.

Total EWL after revisional surgery was 68.1±26.3% compared to the weight prior to primary bariatric surgery, which adds an additional excess weight loss of approximately 22.7% after revisional surgery. According to the Reinhold criteria, 77.0% of all patients had a good result after primary VBG combined with revisional surgery.¹⁹ Comorbidities showed a higher improvement/resolvment rate at last follow-up after revision of 72.8%

Additional analysis of the complaints before revision by means of either a stomach x-ray, gastroscopy or both showed various technical reasons for failure of the VBG. 26 patients showed a wide outlet (17.1%), pouch dilatation was seen in 24 patients (15.8%) and 15 patients showed an outlet stenosis (9.9%). Other technical reasons for failure were band erosion (5.3%), band luxation (2.0%), staple line dehiscence (2.7%), pouch rotation (0.7%) and band dehiscence (0.7%). In the other patients (45.8%), either no additional tests were performed or no evident technical cause for failure was found.

Subanalyses

Subanalysis for laparoscopic procedures versus HA-laparoscopic procedures showed no significant difference in terms of intra- and postoperative complications, weight loss in terms of %EWL, evolution of comorbidities and reasons for revision. Significantly more patients undergoing pure laparoscopy necessitated revision ($p=0.020$).

No significant differences were found between non-super obese and super obese patients in terms of intra- and postoperative complications, evolution of comorbidities and necessitation for revision. A significantly better %EWL was found in the group of non-super obese patients (52.4% vs. 40.0%, $p=0.001$). Reasons for revision did not differ significantly except insufficient weight loss. It was more often found in super obese patients ($p=0.024$).

DISCUSSION

Many studies have shown that a VBG is a good option for weight loss surgery in the short term, in terms of excess weight loss, reduction of co-morbidities and a low complication rate.^{2,5-10} The long-term results are heterogeneous. As mentioned before, good long-term results have been reported, however, various other studies have shown a high rate of long-term complications and a considerable revision rate.^{7,12,15,21} These results, in combination with the upcoming AGB and later also the gastric sleeve eventually led to the abandonment of this restrictive procedure in the Netherlands. Nevertheless, the study by Bekheit et al. recently reported good long-term results with a good EWL ranging between 58% and 62% over the years, a low rate of long-term complications and a low revision rate (5%).¹¹ These good results were one of the reasons to re-establish interest and assess this center's experience with this bariatric procedure.

This study showed an acceptable mean long-term EWL of 52.5% after a primary VBG, accompanied by a reduction in co-morbidities of 53.5% with a mean follow-up of 66.1 ± 50.4 months. These results are comparable with various studies showing good results after VBG.^{4,6-11,22}

The results of this study showed a comparable complication rate in the 30-day postoperative period of 7.7% as other studies analyzing results of laparoscopic VBGs have shown early complication rates of 4.2%-12.5%.^{8,9,12,23,24} These percentages are lower than those after open VBG as multiple studies show percentages over 15% after an open procedure, which can be explained by the higher incidence of wound infections.^{6,21,25} In this study population, a wound infection was found in only 5 patients (1.3%), even though almost 60% of all

patients underwent a hand-assisted laparoscopic procedure. In conclusion, in terms of weight loss, comorbidity improvement and/or resolvement and early complication rate, VBG is a good option as a restrictive bariatric procedure.

Be that as it may, a long-term complication rate of 58% was found. Furthermore, a number of patients showed a possible technical reason for failure which might explain some of the long-term complaints, such as a wide outlet, outlet stenosis and pouch dilatation. A low incidence of staple line dehiscence of only 2.7% was found in this study. This can be explained by the surgical technique that was used, which is complete transection of the vertical stapler line, first described by MacLean et al.³ A total of 152 (38.8%) necessitated revisional surgery after primary VBG. Analysis of the follow-up after revision showed an additional EWL of nearly 23% and an additional reduction in comorbidities of more than 33%. Revision of the primary VBG seems feasible, but additional analysis of these procedures is needed for making a better conclusion on the outcome.

This series is not the first to report on the poor long-term results after VBG. Multiple studies have shown poor an outcome with high rates of revision, underlining the shortcomings of this type of procedure.^{7,12,15}

In the present series, almost 8% of all patients' complaints necessitating revision were caused by problems with the band of the VBG (erosion, luxation or dehiscence). It is well-known that the VBG is not the only bariatric procedure in which a band is used to achieve long-term excess weight loss. The commonly used adjustable gastric band (AGB) and the more recently introduced banded gastric bypass and banded sleeve are other applications of a band in bariatric surgery. When regarding the upcoming banded bypass, certain anatomical similarities can be found between this new technique and the VBG. In both procedures, a band is placed at the end of a gastric pouch, with the aim of restricting food intake and thereby reaching a feeling of satiety faster. Buchwald et al. recently published a systematic review and meta-analysis on the outcome after banded gastric bypass. This review reported a weighted mean late complication rate of 20% after banded Roux-en-Y gastric bypass. These recently published data, along with previous, mostly poor, long-term experiences after VBG and especially the similar anatomy between the VBG and the banded gastric bypass, should be taken into consideration when weighing the advantages and disadvantages of a banded gastric bypass.

Additional subanalyses showed no significant differences between laparoscopic and HA-laparoscopic procedures, except more revisions after laparoscopic procedures. Possible explanations might be better follow-up or psychologically more high-risk patients. Super obese patients showed a significant lower EWL and significantly more insufficient weight loss as reason for revision. Recent literature however shows significant variation in EWL and initial BMI: the higher

the initial BMI, the lower the eventual EWL, explaining the lower EWL in this study and the higher incidence of insufficient weight loss in revisional procedures.²⁶

An underexposed topic in this study is hit when discussing the possible failure of the patients. In some patients, an evident technical cause was found for failure. Nevertheless, a large number of patients failed without a technical cause. A possible explanation could be the learning curve of the surgeons performing the VBGs, however the number of procedures performed make this unlikely. An unassessed topic in this study are the psychosocial factors and predictors which could influence weight loss and possibly the risk of failure after bariatric surgery. All patients underwent psychological screening preoperatively to exclude apparent psychological contra-indications. When necessary, patients received psychological treatment as preparation for the intervention and its consequences, aiming to increase the effect of the surgery.²⁰ In the present study of 392 patients, a total of 101 patients returned to the outpatient clinic with complaints of either weight regain or insufficient weight loss. In some patients with these complaints, no evident technical cause was found or no additional analysis of these complaints was performed. Vallis et al. reported that if patients experience any psychological difficulties after surgical treatment with gastroplasty, these difficulties appear to be more related to the nature of morbid obesity than to the character of the individual.²⁷ Furthermore, it is known that bariatric patients can develop an eating disorder after bariatric surgery which may eventually lead to a regain of weight.²⁸ To acknowledge postoperative psychological difficulties, good follow-up is necessitated. This once again underlines the disadvantages of limited follow-up and might have left patients inadequately prepared to face the consequences of bariatric surgery. The limited follow-up of the patients in this study may be considered as a weak point towards the long-term outcome after VBG in this study. Better long-term results are mainly found in studies with a more intensive and extended follow-up period.^{6,9-11}

Intensive follow-up will certainly improve long-term outcome, however a significant amount of patients in this study necessitating revision due to a technical failure of the primary VBG underlines the limitations of this old restrictive bariatric procedure. Nowadays, more effective and safe procedures have passed the VBG in the pecking order, due to a higher percentage EWL and a lower early complication rate.^{29,30}

In conclusion: Although this study shows that VBG achieves an acceptable long-term EWL and a reduction in (the severity of) comorbidities, a high long-term complication rate, a high rate of failure and newly introduced bariatric surgery underline the limits of this old restrictive technique and strengthens the reason for abandoning this bariatric procedure in the Netherlands.

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CHAPTER 3

Medical and psychological predictors for long-term bariatric success using primary vertical banded gastroplasty as a model

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Bariatr Surg Pract Patient Care. 2016;11:110-115

ABSTRACT

Introduction

Bariatric surgery requires patients to implement permanent lifestyle changes which are affected by several factors. Psychological assessment seems to be essential for optimal weight loss and maintenance. The burden remains in identifying potential psychosocial predictors which might influence the long-term outcome. Therefore, this study was designed to identify those predictors for the long-term outcome after primary Vertical-Banded Gastroplasty (VBG).

Methods & Design

Patients undergoing primary VBG between 2001 and 2004 completed a number of psychological questionnaires. Additional postal questionnaires were sent to retrieve the latest medical outcome. Patients were categorized as failed or successful based on their excess weight loss at last follow-up.

Results

This study identified a number of potential predictors. Failed patients showed more esthetic expectations, a more dominant character, more work absenteeism before surgery and depend more on the procedure than successful patients. Successful patients showed that positive emotions are an inhibitory factor for eating and less underwent revisional surgery.

Conclusion

This study shows a number of possible predictors, mainly found in the patient's character. The best way to prevent these predictors seems to be early recognition in the preoperative phase and a structured postoperative psychological follow-up to tackle any potential problems at an early stage.

INTRODUCTION

Bariatric surgery has become an increasingly popular treatment option for morbid obesity. In 2011, over 340,000 procedures were performed, a number which is currently still growing.¹ These days, bariatric surgery is not solely performed to achieve long-term weight loss anymore, as more patients are operated for metabolic diseases like diabetes mellitus type 2.^{2,3} Bariatric surgery requires patients to implement permanent lifestyle changes to achieve long-term successful outcomes.⁴ These lifestyle changes are affected by several non-surgical factors such as eating behavior, personality, socio-economic status and coping.⁵⁻⁷

Psychological assessment both pre- and postoperative appears to be essential to guarantee an optimal weight loss and weight loss maintenance after bariatric surgery.⁸ However, there are still countries in which the role of the mental health providers is not well defined and the psychological support is not standard in the current postoperative standard package of care.⁹

Results are contradictory and far from conclusive and there is no general consensus on which psychological factors may predict the outcome after bariatric surgery. The challenge remains in identifying these potential psychological factors which might influence the long-term outcome.¹⁰ An important impediment is the overall methodological weakness, the different outcomes measures for success, small patient groups and diverse lengths of follow-up of the current literature to find reliable and valid predictors for the outcome of various bariatric procedures.⁶ There are various bariatric procedures. Malabsorptive procedures like Roux-en-Y gastric bypass (RYGB) and duodenal switch and restrictive procedures like adjustable gastric banding (AGB), sleeve gastrectomy (SG) and vertical-banded gastroplasty (VBG). The VBG is an old restrictive procedure, originally invented by Mason et al, later altered by MacLean.^{11,12} Studies on this procedure show good short-term results, however long-term results were more heterogeneous, which eventually led to the abandonment of this procedure in the Netherlands some years ago.¹³⁻¹⁵

Research on early postoperative predictors were published by a part of the current group.^{6,16,17} The current study was designed to identify potential psychosocial predictors for the long-term outcome after primary VBG.

METHODS AND DESIGN

Methods

Between January 2001 and November 2004, bariatric patients undergoing VBG at the Obesity Center, Catharina hospital, Eindhoven, the Netherlands, were included and asked to complete several questionnaires pre-operatively and six months, one year and two years postoperatively. All patients undergoing primary VBG were included. The questionnaires included questions to assess personality, eating behavior, obesity-related beliefs, health-related quality of life (HRQoL), body attitude, psychological and somatic symptoms and coping. All questionnaires are displayed in Table 3.1. Furthermore, patients were asked to complete questions on motivation, expectations, the history of their obesity, eating behavior and several eliciting and inhibitory factors with regard to eating.

Table 3.1 Psychological Questionnaires

Symptom Checklist	SCL-90 ¹⁸
Dutch Personality Questionnaire	DPQ ¹⁹
Dutch Eating Behavior Questionnaire	DEBQ ²⁰
Body Attitude Test	BAT ²¹
RAND-36 Health Survey	RAND-36 ²²
Amsterdam Biographical Questionnaire	ABQ ^{* 23}
Eating Disorder Inventory II	EDI-II ^{* 24}
Utrecht Coping List	UCL ^{* 25}
Multidimensional Health Locus of Control scale	MHLC ^{* 26}
Multidimensional Health Locus of Control-obesity	MHLC-obesity ^{* 27}
Overweight Cognition Questionnaire	OCG ^{* 28}

* Questionnaires only administered pre-operatively.

Since the end of the year 2011, follow-up is a structured five-year program at this center. However, patients participating in the current study underwent limited follow-up during one year in the hospital, after which they were referred back to the general practitioner in case of no complaints after one year. To retrieve all medical outcome and the latest follow-up, all medical charts were reviewed and all patients that underwent primary VBG in this center received a postal questionnaire. Non-responding patients received a phone call. In case of non-response, the last known follow-up out of the medical charts was used. The postal questionnaire was designed to retrieve the current and the lowest weight after surgery, current status of obesity-related comorbidities and use of medication, revisional surgery when applicable and long-term complaints.

Complaints were categorized into dysphagia, frequent vitamin deficiencies, incisional hernia and other complaints with an open text field.

The comorbidities were categorized into resolved (treatment no longer needed), improved (diminished amount of medication and/or use of CPAP in case of sleep apnea), stable, worsened or de novo. Patients reporting complaints were invited for additional analysis at the outpatient clinic.

Based on their last follow-up data, patients were categorized, depending on the percentage of excess weight loss (%EWL), as failed patient (<50%) or successful patient ($\geq 50\%$). These percentages are used in the Reinhold criteria, which state that a bariatric procedure is considered successful when a %EWL is achieved of at least 50%.¹⁸ Patients necessitating revision were considered failed patients, unless there was an evident technical cause for failure. In case of technical failure, patients were considered failed or successful based on the %EWL at last follow-up after VBG.

For this study, analysis of all pre-operative questionnaires was performed to identify possible predictors for long-term success after primary VBG. Long-term results after VBG were completed with the use of the additional postal questionnaires.

Treatment

All patients were evaluated at the outpatient clinic for eligibility for bariatric surgery by a dietitian, a bariatric nurse and a psychologist. When eligible for surgery, patients were asked to fill in all pre-operative questionnaires. Surgery was performed by hand-assisted (HA) laparoscopic approach. A transgastric window was created, using a CEEA21 stapler (Covidien, New Haven, CT, USA), about 6cm distally from the gastro-esophageal junction along the lesser curvature. An oral gastric tube Ch34 was placed between the lesser curvature and the CEAA. Hereby, the pouch size is approximately 1.2cm in length, measured from the gastro-esophageal junction. Along this tube, a vertical staple line was created from the transgastric window towards the angle of His using an EndoGIA. (Covidien, New Haven, CT, USA) For the final step of this procedure, a polytetrafluoroethylene (PTFE) band (1.5 x7.5cm) was wrapped around the distal end of the gastric pouch, using the gastric tube for calibration. At a circumference of 6cm, the band is fixed using two non-absorbable sutures.

Statistical analysis

Collection, management and analysis of all data was done retrospectively using SPSS version 22, for Windows (SPSS Inc, Chicago, IL, USA). Quantitative data are

denoted as mean $\pm$ standard deviation, whereas nominal data is denoted as a percentage. The Mann Whitney U-test was used to determine any significance of the observed differences among groups. Statistical significance was identified when the p value was less than 0.05. Summative figures and tables were used where necessary.

No ethical approval was required for this study and this study was performed according to the principles of the Declaration of Helsinki. Informed consent was obtained from subjects.

RESULTS

A total of 98 patients were eligible for inclusion for this study. 70 patients (71.4%) completed and returned their postal questionnaires. The other 28 patients did not complete the questionnaire after postal non-response. 18 phone numbers were out of order, one patient refused cooperation and nine patients could not be reached on multiple occasions. The total group showed an average total follow-up of 106.9 ± 49.3 months with an average total %EWL of $52.9 \pm 27.8\%$ at last follow-up after VBG. When classifying patients as described in the Methods, 62 failed patients (FP) and 36 successful patients (SP) were identified. Table 3.2 displays the baseline characteristics.

Table 3.2 Baseline characteristics (n=98).

	Failed patients n=62 (63.3%) Mean $\pm$ SD	Successful patients n=36 (36.7%) Mean $\pm$ SD	p-value
Age (years)	39.4 $\pm$ 8.5	39.3 $\pm$ 7.7	0.836
Male : Female (n)	9 : 53	2 : 34	0.319
Body Mass Index before VBG (kg/m ²)	46.4 $\pm$ 5.3	44.3 $\pm$ 4.4	0.039
Pre-operative comorbidities			
Diabetes Mellitus type 2 (n)	7	4	1.000
Hypertension (n)	15	9	0.929
Dyslipidemia (n)	3	1	1.000
Sleep apnea (n)	1	0	1.000
Osteo-articular disease (n)	6	1	0.256
Operative time (min)	94.4 $\pm$ 24.2	90.3 $\pm$ 18.5	0.599
Length of hospital stay (days)	3.1 $\pm$ 1.2	3.1 $\pm$ 1.0	0.906
Number of patients with ≥ 1 comorbidity (n)	24	13	0.798

VBG: vertical banded gastroplasty; SD: standard deviation.

Medical results

Shown in Table 3.3 are the medical results at last known follow-up after VBG and after revision, including follow-up, %EWL, number of revisional procedures and the presence of any comorbidities. Furthermore, the table shows the %EWL as expected preoperatively by the patients. Patients who underwent revision, had either a revision of the primary VBG (n=3), conversion to sleeve gastrectomy (n=2) or conversion to Roux-en-Y gastric bypass (n=18). Main reason for revision in the entire study population was weight regain (47.8%), which in one case was caused by an evident technical cause (band dehiscence). Mean %EWL of the total population at last known follow-up including any necessitated revision was $60.7 \pm 20.8\%$.

Table 3.3 Medical results at last follow-up (n=98).

	Failed patients n=62 (63.3%) Mean $\pm$ SD	Successful patients n=36 (36.7%) Mean $\pm$ SD	p-value
Mean follow-up without revision (months)	95.7 $\pm$ 48.3	87.4 $\pm$ 58.0	0.527
Mean EWL without revision (%)	30.4 $\pm$ 18.0	74.1 $\pm$ 25.1	<0.001
Number of revisions (n)	20	3	0.007
Mean total follow-up (months)	115.1 $\pm$ 42.4	92.9 $\pm$ 57.2	0.143
Mean EWL at last follow-up (%)	39.0 $\pm$ 23.0	77.5 $\pm$ 15.8	<0.001
Number of patients with ≥ 1 comorbidity	10	3	0.362
Expected EWL before surgery (%)	79.3 $\pm$ 22.7	84.3 $\pm$ 26.2	0.369

SD: standard deviation; EWL: excess weight loss

Questionnaires

Results of all questionnaires mentioned in the Methods were reviewed for potential predictors.

Table 3.4 shows the clinically relevant and the significantly different parameters of the various questionnaires. No significant differences were seen between the two groups in the SCL-90 subcategories, the UCL, the EDI (assessing the level of emotional eating), the MHLC, the NVE and the OCL-25.

Table 3.4 Results Psychological Questionnaires (n=98).

		Failed patients n=62 (63.3%) Mean $\pm$ SD	Successful patients n=36 (36.7%) Mean $\pm$ SD	p-value
SCL-90	<i>Psychoneuroticism</i>	139.0 $\pm$ 39.4	145.5 $\pm$ 45.2	0.611
DPQ	<i>Dominance</i>	14.8 $\pm$ 6.5	12.1 $\pm$ 5.8	0.049
ABV	<i>Work absenteeism (days)</i>	24.3 $\pm$ 58.4	18.8 $\pm$ 65.9	0.025
LAV	<i>Total score</i>	65.5 $\pm$ 15.2	63.9 $\pm$ 17.1	0.622
RAND-36	<i>Role limitations (emotional)</i>	5.5 $\pm$ 1.0	5.0 $\pm$ 1.2	0.032
RAND-36	<i>General perception of health</i>	15.0 $\pm$ 3.9	14.9 $\pm$ 3.8	0.804
MHLC-Obesity	<i>Doctor as locus of control</i>	11.4 $\pm$ 2.5	12.7 $\pm$ 3.0	0.038

SD: standard deviation

Motivation

Patients were presented a number of options on what motivated them to lose weight and what motivated them to choose for a bariatric procedure. These questionnaires were answered in a yes/no-format. Options on motivations to lose weight were health, limitations in movement, social reasons, esthetic reasons, condition, dissatisfaction with body and other psychic reasons. Motivations on choosing a bariatric procedure were insufficient results with other weight-losing methods, lasting weight reduction, the ability to eat less, surgery acting as a driving force and faster satiety.

No significant differences were found in any of the options between the two groups. Regrouping the motivations did not change the outcome between the two groups.

Expectations

The questions on expectations were similar to those for motivation. Options on expectations of the effects of the bariatric procedure were faster satiety, change of eating pattern, a happier life, lasting weight reduction, procedure acting as a driving force, increased activity, the ability to buy new clothes and other expectations. The study showed that patients in the FP group significantly more often expected to be able to buy new clothing ($p=0.004$). No significant differences were seen with respect to the other expectations.

History of patients' obesity

All patients were asked about their weight status (underweight, normal weight, overweight) during various life phases. No significant differences were found between the two groups. Furthermore, no significant differences were seen in the causes for the obesity, such as pregnancy, a medical reason, eating pattern or genetic predisposition.

Eliciting and inhibitory factors

There can be many eliciting as well as inhibitory factors for eating more than normal. Several eliciting factors were reviewed, however, no factors were significantly different between the two groups. A few only showed a trend to occur more often in the FP group, such as social activities ($p=0.074$) and the confrontation with food ($p=0.088$). Other factors reviewed were emotions, boredom, social control, watching television, time to eat and appetite. Inhibitory factors were positive and negative emotions, dieting, social control and work. A significant difference was seen in the positive emotions ($p=0.024$)

in favor of the SP group. No significant differences were seen for the other inhibitory factors.

Eating behavior

No significant difference was seen in the occurrence of binge eating or grazing between the two groups. Furthermore, no differences were seen between two groups when assessing number of meals, number of snacks and the amount of calories. Eating has many functions. This study assessed eating to attenuate (negative) emotions, to maintain positive emotions, satiety, distraction, habit, sociability, to stay alive and as a reaction to problems. No significant differences were seen between groups on incidence of these various functions.

DISCUSSION

This study was designed to find potential predictors for long-term success after primary vertical-banded gastroplasty, an old restrictive procedure achieving an average %EWL of up to 60%.¹⁹ Of all patients, 63.2% were considered a failed patient, underlining the inferiority of this procedure as shown in other studies before.¹³⁻¹⁵ Partly, failure may be imputed to the limited follow-up these patients had postoperatively, even though literature suggests a high long-term complication rate after VBG and a high rate of revision. As stated before, identifying predictors on the outcome after bariatric surgery remains a burden. Therefore, this study was set up to find either medical or psychosocial predictors on the long-term success after a primary bariatric procedure.

Considering the medical results, it is noteworthy that the pre-operative BMI is significantly higher in the FP group. This might suggest that a higher BMI compared to a lower BMI within the group of eligible bariatric patients may increase the chance of failure in terms of long-term %EWL, supporting multiple previously reported results.^{20,21} Even though the initial BMI influences the amount of excess weight and thus the percentage of %EWL, this study shows far better results in the SP group.²² %EWL at last follow-up was nearly twice as much in the SP group as opposed to the FP group. This study shows more revisional procedures in the FP group, which is explained by the occurrence of failure and the way of categorizing patients. The best option for failed procedures is a revisional procedure, so it seems only logical that the revision rate is higher in the FP group.

Other medical and demographic parameters such as comorbidities, gender, excess weight, length of hospital stay and operating time do not seem to be a predictor for the long-term results in this study population.

Considering the patients' pre-operative motivation for losing weight and choosing for a bariatric procedure, no significant differences were found. This suggests that various reasons for losing weight or for choosing a bariatric procedure are no predictor for the outcome after primary VBG in this study. Previous studies however, have shown that a poor health as motivation can be a potential predictor for long-term success.²³ It remains to what extend the reason for losing weight is related to the cause of the developed obesity. This study showed no differences between the groups in terms of reasons for obesity.

In terms of pre-operative expectations, the only potential predictor may be the fact that patients in the FP group significantly more often expected to buy new clothing in the postoperative phase, a pure esthetic expectation of the procedure. This supports old data published on esthetic expectations after bariatric surgery, stating that patients with a lower %EWL more often have high esthetic expectations as opposed to successful patients.²⁴ No differences were seen in expected %EWL before surgery between the two groups.

The studied population showed a similar weight history. The phase in which the overweight developed did not differ significantly between the FP group and the SP group. Furthermore, no differences were seen in terms of various options or number of weight loss attempts, which strengthens previous results on weight loss attempts before bariatric surgery.²⁰

There are many known eliciting factors for (excessive) eating, with emotions being a common factor. Multiple studies have shown that emotional eating has either no effect or a negative effect on postoperative weight loss.²⁰ This study showed that emotions as a eliciting factor for eating had no influence on the long-term success after primary VBG.

A significant difference was found for the predictive value of positive emotions as an inhibitory factor for eating in favor of the patients in the SP group. It may be expected that the vast majority of patients have more positive emotions after bariatric surgery, since bariatric procedures haven shown to improve quality of life, body dissatisfaction, depression and anxiety symptoms and eating disorders.^{16,25-27} It furthermore can be expected that patients will be confronted with more positive emotions post-bariatric surgery and thus, in patients reporting positive emotions as an inhibitory factor, might lead to a higher percentage of %EWL.

This study showed no predictive value in any of the parameters regarding eating behavior. Eating behavior, in terms of amount of calories, number of meals per day, binge eating, grazing and function of eating, will have a no predictive value on the percentage of long-term %EWL after primary VBG based on the results from this study. The literature is diverse on the effect of mainly eating and grazing. Some studies report a negative relation between

binge eating and %EWL, others do not report binge eating as a negative predictive value.^{28,29} This study supports the latter conclusion of the two.

Several questionnaires were used in this study. Only a few potential predictors can be pointed out with the current results. These results suggest that a more dominant character according to the DPQ leads to an inferior percentage of long-term %EWL. A dominant character is confident, authoritarian and likes to make its own decisions. Earlier studies showed no predictive value for short-term %EWL, using the same questionnaire.²¹

Patients in the FP group showed a higher rate of work absenteeism one year prior to bariatric surgery. A possible explanation for this outcome may be a poorer physical or mental state of the patient before surgery, however this hypothesis is not supported by the other results on physical and mental health in this study and extensive research showed no previous data on this specific subject.

Multiple studies have shown that an emotional eating pattern is a possible negative predictor for weight loss, while others support the current results, in which no predictive value on weight loss was found for emotional eating.²⁰

A striking finding is the fact that successful patients in this study believe that the VBG is significantly more responsible for long-term success as opposed to the FP group, according to the MHCL-obesity questionnaire. A result suggesting that successful patients place the long-term outcome more in the hands of the doctor and thus appear to be more receptive to lifestyles changes necessitated for long-term successful weight loss. It is strongly suggested that postoperative weight loss is largely dependent on making and sustaining changes in eating and physical activity.³⁰ This finding strengthens the believe that psychological follow-up is important for the long-term success after bariatric surgery. Furthermore, it appears of the utmost importance that patients are well informed pre-operatively that lifestyle changes are a key factor in achieving a successful long-term excess weight loss.

Results from this study should be interpreted with caution when translating them to current practice. A VBG is an old procedure, only a few are performed nowadays since this procedure is surpassed by newer options like the adjustable gastric band and the sleeve gastrectomy.¹ Even though, it is the authors' believe that this group of bariatric patients is not different to any other patient group undergoing a more modern restrictive procedure. Disadvantages of this study are the limited number of patients, the retrospective design of the study and the low frequency follow-up after surgery, which may have influenced the results. More intensive follow-up might have improved the long-term success rate and thereby have changed the categorization of patients in this study. An advantage of this study is the fact that it is not a controlled trial and it might thereby be a better reflection on everyday practice.

Nowadays, psychological assessment has found a permanent place in both the preoperative and the postoperative phase of a bariatric procedure. Be that as it may, it remains a burden to find potential hazards for poor long-term outcome after bariatric surgery.

When analyzing the possible predictors for long-term success it seems that predictors for successful %EWL can mainly be found in the patient's character. This study showed more than five possible psychosocial predictors and it seems impossible to tackle all of them preoperatively. Obviously, preoperative psychological screening remains inevitable for identifying known contraindications for bariatric surgery and possible predictors for the long-term outcome, but structured psychological follow-up seems more important to improve the rate of long-term success after bariatric surgery. Evidence on predictors remains limited and more elaborate research and prospective studies are necessitated to gain more evidence on this subject.

Conclusions

This study shows a number of possible predictors, mainly found in the patient's character and the best way to prevent these predictors seems to be early recognition in the preoperative phase and a structured postoperative psychological follow-up to tackle any potential problems at an early stage.

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CHAPTER 4

Long-term results after revisions of failed primary vertical banded gastroplasty

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World J Gastrointest Surg. 2016;8(3):238-45

ABSTRACT

Background & Objectives

Vertical banded gastroplasty (VBG) was a popular restrictive bariatric procedure however, has been abandoned due to a high long-term complications rate in many cases leading to the necessitation of revisional surgery. As a number of these revisions can be expected, this study reports and compares the results after revision of the primary VBG (Re-VBG), conversion to sleeve gastrectomy (cSG) and conversion to Roux-en-Y gastric bypass (cRYGB).

Setting & Methods

In this retrospective single-center study, all patients with a failed VBG who underwent revisional surgery were included. Medical charts were reviewed and additional postal questionnaires were sent to update follow-up.

Results

A total 152 patients were included in this study, of which 21 underwent Re-VBG, 16 underwent cSG and 115 patients underwent cRYGB. 16 patients necessitated a second revisional procedure. No patients were lost-to-follow-up. Two patients deceased during the follow-up period, 23 patients did not return the questionnaire. Main reasons for revision were dysphagia/vomiting, weight regain and insufficient weight loss. Excess weight loss (%EWL) after Re-VBG, cSG and cRYGB was, respectively, 45%, 57% and 72%. Eighteen patients (11.8%) reported postoperative complications and 27% reported long-term complaints.

Conclusion

In terms of additional weight loss, postoperative complaints and reintervention rate, Roux-en-Y gastric bypass seems feasible as a revision for a failed VBG. Furthermore, the high number of complications after VBG and complications due to revisional procedures underline that VBG should be excluded as a primary option in bariatric surgery.

INTRODUCTION

Obesity is a growing global problem, associated with morbidity, health care costs and even an increased mortality rate.¹ For the treatment of obesity, bariatric surgery is very effective in achieving significantly more long-term weight loss and an improved lifestyle compared with conventional therapy.^{2,3} In 2011, over 340,000 bariatric procedures were performed worldwide. Among those procedures, around 2,300 procedures were a vertical banded gastroplasty (VBG), first described by Mason and later altered by MacLean et al.⁴⁻⁶ Aim of this procedure was to establish a restriction on food intake with a small stomach pouch, without compromising passage of food through the entire gastro-intestinal tract and thereby avoiding malabsorption of nutrients and medication.⁷ This procedure has shown in earlier reports to have good short-term results in terms of weight loss and reduction in comorbidities.⁸⁻¹¹ However, there are many studies reporting on the poor long-term results after VBG, showing a tendency for weight regain and other complications resulting in a high revision rate.¹²⁻¹⁴ Various options are available for revisional surgery after VBG, such as revision of the VBG (Re-VBG), conversion to sleeve gastrectomy (cSG) and conversion to Roux-en-Y gastric bypass (cRYGB), in which re-VBG appears to have the poorest outcome and cRYGB has the best short- and long-term results.¹⁵⁻¹⁹ However, data on the comparison between the revisional options remains scarce.

Although VBG had been abandoned some years ago in the Netherlands, still a number of patients can be expected to return with complaints after VBG. In the current series, all three mentioned options for revision have been performed. The aim of this study is to compare the outcome after these revisional procedures.

MATERIALS AND METHODS

Methods

This is a single-center retrospective study. A total of 392 patients underwent primary VBG, between January 1998 and December 2008. Since 2009, VBG was not performed anymore. Only patients undergoing primary VBG at the current center were included to reduce heterogeneity. Medical charts as well as additional postal questionnaires were reviewed. Included parameters were patient's characteristics, operative details of primary and secondary procedures, evolution of weight and comorbidities following both operations, findings at

additional imaging, reason for revision, short-term complications and long-term complaints after revisional surgery.

The postal questionnaire contained questions on weight and comorbidities, on complaints dysphagia, vitamin deficiencies and incisional hernia. In case of insufficient weight loss, weight regain or complaints and without participation the follow-up program, the patient was invited to the outpatients department. In case of non-response, patients received a phone call and when there was no response at all, the data of the latest visit at the outpatient clinic were used as final outcome.

Excess weight was defined as the difference between the weight before surgery and the highest healthy weight, which is at a Body Mass Index (BMI) of 25kg/m^2 . Total excess weight loss (%EWL) was defined as a percentage of the amount of excess weight lost after surgery, as described by Deitel et al.²⁰ The weight before the primary VBG was used as baseline value to calculate %EWL.

Weight loss was categorized according to the criteria described by Reinhold et al.²¹ These criteria consider a bariatric procedure successful when a %EWL of at least 50% is achieved. Furthermore, change in BMI and % total body weight loss (TBWL) was calculated. The evolution of any present comorbidities was categorized in stable, improved (reduced amount of medication used and/or a lower setting of a Continuous Positive Airway Pressure-device (CPAP)), resolved (no treatment), worse and de novo.

Treatment

Before primary VBG, all patients underwent assessment at our outpatient clinic by a surgeon, a psychologist and a dietitian to consider whether or not they were qualified for a bariatric procedure according to the standard IFSO guidelines for bariatric surgery. There was no specific algorithm for choosing the operative technique if they were approved for a bariatric procedure. There was a tendency for the option of a gastric bypass in case of more comorbidities, otherwise a vertical banded gastroplasty was chosen at the time. All patients underwent Mason-MacLean VBG, a standard VBG first described by Mason et al with transection of the vertical staple line as described by MacLean.^{4,5}

Follow-up for these patients consisted of one year guidance by a psychologist, dietitian and surgeon. Thereafter, a GP continued care unless weight loss problems or complaints were an issue. In such case patients underwent an analysis by all three disciplines and/or by means of a stomach x-ray and/or a gastroscopy. If considered eligible for revision the options were a re-VBG, cSG or cRYGB.

The Re-VBG technique meant in essence one of the 2 following adjustments. If the pouch was too large, a reshaping of the pouch was performed. The other option was an adjustment of the primarily placed band at the end of the gastric pouch.

A cSG meant a division of the lower part of the stomach 6cm from the pylorus up to the transgastric window to remove the gastric fundus and part of the corpus and antrum.²² All sleeve gastrectomies were performed using a 34-Fr intraluminal boogie and stapled by use of the Endo GIA™ (Covidien, New Haven, CT, USA).

A cRYGB started with identification of the polytetrafluoroethylene (PTFE) band. Then the stomach was transected horizontally at the proximal side of the band. The band was removed in most cases. The pouch was resized with use of the endoscopic stapler up to the angle of His. Then, an end-to-side gastro-jejunostomy was constructed by a linear stapler and closed using Polysorb™ sutures before 2009 and V-Loc™ sutures after 2009 (Covidien, Mansfield, MA, USA). The alimentary limb, measuring 150-180 cm, was pulled up in an antecolic position. Finally, a side-to-side jejuno-jejunostomy was constructed, also using a linear stapler and closing the defect again with either Polysorb™ or V-loc™ sutures. Mostly, the procedure was finished by closing the mesenteric defects.

Statistical analysis

All data were collected retrospectively. Management and analysis as performed by using SPSS version 22, for Windows (SPSS Inc, Chicago, IL). Quantitative data are denoted as mean +/- standard deviation, whereas rates of complications and evolution on comorbidities are presented as a percentage. The student *t*-test, linear regression analysis and logistic regression analysis were used to determine any significance of the observed differences among subgroups. Statistical significance was identified when the *p* value was less than 0.05. An Odds Ratio (OR) was provided when applicable and considered significant when OR (95% CI) ≠ 1. Summative figures and tables were used when necessary.

No ethical approval was required for this study.

RESULTS

392 patients who underwent primary VBG were identified. According to the medical charts and questionnaires a total of 152 revisional procedures (38.7%) were performed between April 1999 and June 2014, of which six patients

underwent revision in another hospital. Necessary data of these patients was retrieved. Furthermore, these six patients did complete the postal questionnaire, so they were included in the analysis, together with the rest of the study population. Baseline characteristics are shown in Table 4.1.

Table 4.1 Baseline characteristics (n=152).

	Re-VBG n=21 (13.8%)	cSG n=16 (10.5%)	cRYGB n=115 (75.7%)	p-value
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	
Age (years)	42.3 $\pm$ 8.6	41.6 $\pm$ 11.4	43.0 $\pm$ 8.9	0.828
Male : Female	5 : 16	3 : 13	19 : 96	0.674
Body Mass Index before VBG (kg/m ²)	42.6 $\pm$ 5.4	43.6 $\pm$ 5.0	44.1 $\pm$ 4.9	0.445
Preoperative comorbidities				
Type 2 Diabetes Mellitus (n)	4	2	13	0.538
Hypertension (n)	4	2	25	0.790
Dyslipidemia (n)	0	3	11	0.111
Sleep apnea (n)	1	1	2	0.249
Osteo-articular disease (n)	5	0	9	0.038
Patients with 1 or more comorbidity	10	5	41	0.512
Operative time (min)	77.0 $\pm$ 39.2	100.6 $\pm$ 19.6	130.7 $\pm$ 47.3	<0.001
Length of hospital stay (days)	3.1 $\pm$ 2.9	3.8 $\pm$ 2.2	4.1 $\pm$ 5.8	0.761
Interval between VBG & Revision (months)	12.3 $\pm$ 10.7	30.7 $\pm$ 26.5	47.8 $\pm$ 34.8	<0.001
Average %EWL after VBG (%)	61.7 $\pm$ 27.0	38.7 $\pm$ 22.9	43.5 $\pm$ 25.0	0.007

Re-VBG: revision of the vertical banded gastroplasty; cSG: conversion to sleeve gastrectomy; cRYGB: conversion to Roux-en-Y gastric bypass; %EWL: percentage of excess weight loss; SD: standard deviation.

The initial 392 patients showed an average %EWL of 51.2 $\pm$ 27.4% and 54% of all known comorbidities were either improved or resolved. The resolved comorbidities were not taken into account in the current study. The patients necessitating revision showed a significantly lower %EWL of 45.4 $\pm$ 25.8%, compared to those not necessitating revision (54.9 $\pm$ 27.7%, $p=0.001$). At last follow-up, 58.4% (n=229) of the total of 392 patients reported long-term complaints, which in 152 patients led to a revisional procedure.

82.2% of the current study population was female. Follow-up of patients necessitating second revision was taken into account until second revision. A total of 127 patients (83.6%) successfully completed last follow-up by either returning the postal questionnaire or answering the questions on the phone. This resulted in a mean follow-up after revisional surgery of 56.5 $\pm$ 37.9 months. In total, 25 patients did not return the postal questionnaire and could not be reached despite repeated attempts. Of these 25 patients, two patients deceased during follow-up due to a cause unrelated to bariatric surgery. Of these patients, the unreturned questionnaires were considered as missing data and

the data of last known follow-up was used as final outcome so patients could be included in the analysis.

Reasons for revision

Complaints leading to revisional surgery are shown in Table 4.2. Six patients have had their revisional procedure in another center and therefore the complaints remained unknown. A possible surgically technical cause for failure of the VBG was found in 54.2% of all patients in this study.

Table 4.2 Complaints before revision (n=152).

	Re-VBG n=21 (n)	cSG n=16 (n)	cRYGB n=115 (n)	Total (%)	p-value
Vomiting/Dysphagia/Food intolerance	17	8	36	40.2	<0.001
Weight regain	1	4	42	30.8	0.007
Insufficient weight loss	3	4	25	21.1	0.665
Unknown	0	0	6	3.9	0.792
Severe GERD	0	0	4	2.6	1.000
Decline comorbidities	0	0	1	0.7	1.000
Excessive weight loss	0	0	1	0.7	1.000

Re-VBG: revision of the vertical banded gastroplasty; cSG: conversion to sleeve gastrectomy; cRYGB: conversion to Roux-en-Y gastric bypass; GERD: Gastro esophageal reflux disease.

Additional tests, in this study a stomach x-ray and/or a gastroscopy, were performed for additional analysis when necessary. The three main technical problems in this study population were a wide outlet, allowing faster passage of food through the pouch (17.1%), pouch dilatation (15.8%) and outlet stenosis (9.9%). Other technical reasons for failure were band erosion (5.3%), band luxation (displacement of the PTFE-band from its original position) (2.0%), staple line dehiscence resulting in a fistula (2.7%), pouch rotation (0.7%) and band dehiscence (0.7%).

Intra- and postoperative complications

126 procedures (82.9%) were performed laparoscopically, 15 procedures (9.9%) had a primary open approach and 11 (7.2%) procedures were converted from a laparoscopic to an open approach. One conversion was due to an intra-operative gastro-intestinal perforation which could not be managed laparoscopically, the other procedures were converted because of an unacceptable laparoscopic overview due to extensive intra-abdominal adhesions. Only 2 intra-operative complications (1.4%) occurred during surgery, both being an iatrogenic gastro-intestinal perforation.

Complications in the 30-day postoperative period were seen in a combined total of 18 patients (11.8%). No complications were seen after revision of the primary VBG (0/21). After cSG, three complications were objectified (3/16 = 18.8%): one pneumonia, one patient suffering from persistent vomiting after surgery causing dehydration. No evident cause was found for the persistent vomiting. The third patient had an ileus. In the group of patients who underwent cRYGB, 15 complications were registered (15/115 = 13.0%). Reoperation was necessary in two out of three patients with bleeding and in all patients with anastomotic leakage (n = 3). All leakages were found at the gastro-jejunoanastomosis. Other complications included intra-abdominal abscesses (n = 3), wound infection (n = 2), pneumonia (n = 1), urinary tract infection (n = 1), ileus (n = 1) and deep venous thrombosis (n = 1). The intra-abdominal abscesses all necessitated re-admission to the hospital for intravenous antibiotic treatment combined with either CT- or ultrasound-guided drainage. In total, eight patients were admitted for appropriate treatment of the complication, three patients did not necessitate readmission and seven complications occurred during primary admission. No significant difference was found in the total number of complications between the groups.

Weight loss & evolution of comorbidities

When not including the follow-up after any secondary revisional procedure, the mean total %EWL at last follow-up after primary revisional surgery was $66.4 \pm 25.8\%$. In terms of change in BMI, this meant an average reduction of $12.5 \pm 5.6 \text{ kg/m}^2$. Mean TBWL was $28.1 \pm 11.2\%$. When including the 16 patients that underwent a second revisional procedure, %EWL was $68.2 \pm 26.4\%$. Change in BMI was $12.7 \pm 5.4 \text{ kg/m}^2$ and TBWL was $28.7 \pm 11.1\%$.

At baseline, a total of 82 comorbidities were found amongst 56 patients. The separate improvement/resolution percentages for the three different procedures were 71.4%, 77.8% and 67.8% for respectively Re-VBG, cSG and cRYGB when considering each comorbidity as a separate entity. Figure 4.1 shows the improvement/resolution rates divided between the three groups. Table 4.3 shows the results after primary revisional surgery, stratified for each procedure.

Long-term complaints

At last follow-up after revisional surgery, 41 patients (27.0%) reported complaints, which in 16 cases necessitated a second revisional procedure. All long-term complaints are displayed in Table 4.4. In one patient after Re-VBG, DVFI was caused by band erosion.

Table 4.3 Results after primary revision at last follow-up (n=152).

	Re-VBG N=21 Mean ± SD	cSG N=16 Mean ± SD	cRYGB N=115 Mean ± SD	Corrected p-value*	
				Re-VBG vs cSG	cRYGB vs Re-VBG
Follow-up (months)	39.1 ± 48.7	49.3 ± 17.6	50.0 ± 33.3		
Average %EWL after VBG (%)	61.7 ± 27.0	38.7 ± 22.9	43.5 ± 25.0		
Additional %EWL	-14.6 ± 19.9	17.9 ± 32.7	27.9 ± 28.2		
Total %EWL (%)	45.4 ± 25.5	56.6 ± 24.4	71.7 ± 23.8	0.614	0.006
Total body weight loss (%)	18.4 ± 11.1	24.1 ± 11.6	30.4 ± 10.1	0.049	<0.001
Change Body Mass Index (kg/m ²)	8.1 ± 5.8	10.8 ± 5.8	13.5 ± 5.1	0.119	<0.001
				Odds Ratio (95% CI)**	
Reinhold (%EWL > 50%) (%)	47.6	56.3	82.6	0.791 (0.211 ; 2.972)	0.342 (0.125 ; 0.934)
Long-term complications (%)	61.9	62.5	15.7	0.833 (0.214 ; 3.244)	10.105 (3.600 ; 28.367)
2 nd revisional procedure (n, %)	10 (47.6%)	5 (31.3%)	1 (0.9%)	n/a	n/a
Improvement/resolution in patients with 1 or more comorbidities (%)	80 (8/10)	60 (3/5)	92.7 (38/41)	0.375 (0.081 ; 1.738)	1.247 (0.476 ; 3.265)
					0.468 (0.126 ; 1.740)

* Corrected for operative time, time between VBG & revision, osteo-articular disease and mean EWL after VBG; ** No correction possible in logistic regression analysis due to limited events and group sizes; Re-VBG: revision of the vertical banded gastroplasty; cSG: conversion to sleeve gastrectomy; cRYGB: conversion to Roux-en-Y gastric bypass; SD: standard deviation; %EWL: excess weight loss.

Figure 4.1 Improvement /resolution rates comorbidities. DM: type 2 diabetes mellitus; HT: hypertension; DL: dyslipidemia; SA: sleep apnea; OAD: osteo-articular disease; VBG: vertical banded gastroplasty.

Table 4.4 Long-term complaints after revision (n=152).

	Re-VBG n=21 (n)	cSG n=16 (n)	cRYGB n=115 (n)	Total (%)
Vomiting/Dysphagia/Food intolerance	4	4	6	9.2
Weight regain	6	4	4	9.2
Insufficient weight loss	2	1	0	2.0
Petersen's hernia	n/a	n/a	4	2.6
Incisional hernia	0	0	3	2.0
Recurrent abdominal pain	1	1	1	2.0
None	8	6	97	73.0

Re-VBG: revision of the vertical banded gastroplasty; cSG: conversion to sleeve gastrectomy; cRYGB: conversion to Roux-en-Y gastric bypass.

Subgroups based on reason for revision

Since the reason for revision may affect the outcome of the total weight loss, the evolution of comorbidities and potentially also the early postoperative course, additional analysis was performed. Patients undergoing revision for either weight regain or insufficient weight loss (WR/IWL) were compared to the other reasons given earlier in this manuscript. Results are shown in Table 4.5.

Table 4.5 Subgroup analysis (n=152) (WR / IWL vs. Other complaints).

	WR / IWL n=79 Mean ± SD	Other n=73 Mean ± SD	p-value
Age (years)	41.6 ± 7.4	43.9 ± 10.7	0.121
Male : Female (n)	13 : 66	14 : 59	0.661
Body Mass Index before VBG (kg/m ²)	44.7 ± 5.0	42.8 ± 4.8	0.016
Operative time (min)	128.2 ± 46.3	109.7 ± 48.6	0.020
Length of hospital stay (days)	4.3 ± 6.8	3.4 ± 2.0	0.858
Type of revision			
Re-VBG	4	17	
cSG	8	8	0.004
cRYGB	67	48	
Average %EWL after VBG (%)	31.3 ± 19.0	61.2 ± 23.1	< 0.001
Postoperative complications <30 days (n, %)	12 (15.2%)	6 (8.2%)	0.184
Total %EWL (%)	67.5 ± 23.7	65.2 ± 28.1	0.583
Reinhold (%EWL >50%) (%)	79.7	74.0	0.398
Long-term complications (%)	22.8	28.8	0.399
2 nd revisional procedure (n)	5	11	0.079
Improvement/Resolution rate (% , n)			
Type 2 Diabetes Mellitus	90 (9/10)	55.6 (5/9)	n/a
Hypertension	76.9 (10/13)	44.4 (8/18)	n/a
Dyslipidemia	100 (9/9)	100 (5/5)	n/a
Sleep apnea	0 (0/1)	66.7 (2/3)	n/a
Osteo-articular disease	57.1 (4/7)	57.1 (4/7)	n/a

WR: weight regain; IWL: insufficient weight loss; %EWL: excess weight loss; VBG: vertical banded gastroplasty; Re-VBG: revision of the vertical banded gastroplasty; cSG: conversion to sleeve gastrectomy; cRYGB: conversion to Roux-en-Y gastric bypass.

Second revisional procedures

A total number of 16 patients underwent a second revisional procedure. 10 patients underwent conversion from a revised VBG to RYGB, five patients had their sleeve converted to RYGB. One patient necessitated revision due to persistent vomiting after RYGB. Additional analysis showed a stenosis of the gastrojejunostomy. The most common reasons for second revision were weight regain (43.7%) and DVFI (31.3%). Other reasons were insufficient weight loss (18.7%) and band erosion (6.3%).

DISCUSSION

The absolute number of performed bariatric procedures is still increasing and therefore the number of revisional procedures can be expected to rise as well. Combined with the known poor long-term outcome after VBG, this fact strengthens the belief that more revisional procedures of failed VBG can be

expected in the future. This study is the first to report on the comparison between Re-VBG, cSG and cRYGB after failed primary VBG.

The revision rate of VBG was almost 39% (152 patients out of a total of 392 primary VBGs). The average %EWL after failed VBG was $45.4 \pm 25.8\%$ at last follow-up before revision. Patients who underwent Re-VBG had a noticeable better %EWL after VBG at baseline. This can be explained by the much shorter average interval of only 12 months between the VBG and the revision, making follow-up too short to start noticing weight regain, a common reason for revision.¹⁷

The main reasons for revision overall were similar to many other studies assessing either the long-term follow-up after VBG or the results after revision of the failed VBG.^{12,15,17,19,23} However, there is a difference in the type of complaints leading to the different revisional procedures in this study. Furthermore, the number of procedures differed between the groups in this study. These facts can be explained by various reasons. First of all, the indication for Re-VBG was limited (mainly band-related problems). In the early years, when a patient had complaints of DVFI, a Re-VBG was performed, especially when the DVFI was caused by band erosion. As more reports became available over the years, showing that cRYGB is a better revisional option than Re-VBG, that latter procedure was abandoned at an early stage and cRYGB has proven to be a better option and has been for quite some years, explaining the low number of VBGs.^{15,16,18} The last Re-VBG was performed in 2006. The second group, representing the cSGs, appears to have a more similar pattern of reasons for revision as seen in the cRYGB group, compared to the Re-VBG group. The size of the cSG group however is small, mainly due to early abandonment of this procedure, because there are very limited reports on the outcome of cSG over the last years and the larger experience with cRYGB, which had already proven to be a reliable procedure.^{16,17,22} The last cSG after VBG was performed in January 2010. Since then, all revisional procedures after failed VBG were cRYGB.

The results in this study show that, although no early postoperative complications were seen in this group and the improvement/resolution rate of comorbidities is comparable with the other groups, Re-VBG is not the preferred revisional procedure after failed primary VBG. The reasons are a low total %EWL, high long-term complication rate and a high revision rate at long-term follow-up. Considering %EWL, this study actually showed an average decrease after Re-VBG, resulting in patients regaining nearly 15% of their initial excess weight. This result may be biased by the already available experience that cRYGB appeared superior to Re-VBG and the limited indication for Re-VBG.¹⁸

The second group in this study were the cSGs. The long-term results after cSG are acceptable, with a significant better additional excess weight loss compared

to Re-VBG and an improvement/resolution rate of comorbidities comparable with cRYGB. Although cSG appears to give a lower chance on postoperative complications compared to cRYGB, a significant higher long-term complication rate compared to cRYGB and a high second revision rate are showing the limits of this revisional procedure after failed primary VBG.

Although cSG appears to be superior compared to Re-VBG, this study confirms that cRYGB seems to be the best option of these three procedures. At last follow-up, patients showed an average %EWL of almost 72%, improvement or even resolution of comorbidities in 92.8% patients familiar with one or more obesity-related comorbidities. Furthermore, the chance of developing long-term complications after cRYGB is significantly lower compared to the other two revisional procedures. In contrast of these good results, we noticed a high postoperative complication rate of 13.0% after cRYGB. However, this rate is comparable with many previously published results showing postoperative complication rates of 6.5-25%.^{15,23-25} In terms of %EWL, these results are comparable with previously reported data after both revisional RYGB for failed VBG as well as after primary RYGB.²⁴⁻²⁷ The current good results may be affected by the used alimentary limb length of 150-180 cm, on the other hand, this seems unlikely, since previous studies have shown that a limb length of 150 cm did not produce a better %EWL compared to a limb length of 75-100 cm.^{28,29}

Considering the subgroup analysis performed to differentiate between weight loss-related complaints and other complaints, an expected significant difference was found in terms of %EWL. Furthermore, a difference was found in the number of different revisional procedures between the two groups, which can be explained by the earlier reported difference in reason for revision between procedures. This may also explain the difference in operative time, since a Re-VBG takes a significant shorter time than a cRYGB. After revisional surgery, no significant differences were found in terms of %EWL, postoperative complications and number of long-term complications and number of performed 2nd revisional procedures.

The reported high revision rate and previously published unfavorable results underline the limits of this old restrictive procedure.^{12,13} These rates also strengthen the expectation that a number of patients will necessitate revision in the future, since VBG is currently still performed as a primary procedure.⁶ Although revisional surgery seems feasible, the high number of complications after revision should be taken into account.

These results should be interpreted with caution due to a number of limitations in this study. First of all, the unequal distribution of groups, mainly due to a bias caused by the center's greater experience with cRYGB, thereby explaining the small number of Re-VBGs and cSGs. Furthermore, the retrospective design

limits the reliability of the reported outcome. Since not all patients responded to our question to update the last known follow-up, a number of long-term complaints might have been missed, as well as potential revisional procedures performed in other hospitals. Not only the distribution between groups is unequal, also total time of follow-up is unequal, since Re-VBGs were performed only in the early and cRYGBs are still performed nowadays. The mean follow-up appears to be similar, but it should be kept in mind that Re-VBG showed a higher second revision rate as opposed to cSG and cRYGB and follow-up of the primary revision was taken into account until second revision. Keeping these limitations in mind, this study still suggests that Roux-en-Y gastric bypass is the superior choice for revisional surgery after failed primary VBG due to a good long-term %EWL, a high improvement rate of comorbidities, a low long-term complication rate and a low percentage of necessitated second revisional procedures.

In conclusion: In terms of additional weight loss, number of postoperative complaints and necessitation of a second revision, the Roux-en-Y gastric bypass seems feasible as a revision for a failed VBG. Furthermore, the high number of complications after VBG and complications due to revisional procedures underline that VBG should be excluded as a primary option in bariatric surgery and other restrictive should be considered instead.

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CHAPTER 5

Conventional versus fast track anesthesia protocol in an unselected group of patients undergoing revisional bariatric surgery

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International Journal of Surgery Open. 2015;1:22-27

ABSTRACT

Introduction

Fast track care has proven to be safe and effective in primary bariatric procedures. The number of more complex revisional procedures is expected to rise over the next years. The aim was to evaluate the potential benefits and safety of a fast-track protocol in an unselected group of patients undergoing Roux-en-Y Gastric Bypass (rRYGBP) as revision.

Method

For this retrospective study, all patients undergoing rRYGBP between January 2005 and December 2013 were included and categorized between conventional care (CC) and fast track care (FT). Patient characteristics, operative details and intra- and early postoperative complications < 30 days were analysed.

Results

A total of 407 patients were included for analysis. 303 patients (74.4%) received peri- and postoperative treatment according to the fast track protocol. Mean age of the study population was 44.0 ± 8.9 years; mean pre-primary procedure BMI was 45.7 ± 7.0 kg/m². A total of 54 (13.3%) postoperative complications were registered (CC 19.2% vs. FT 11.2%; $p=0.038$). Both operative time (CC 135.3 ± 42.6 minutes vs. FT 79.3 ± 29.3 minutes; $p<0.001$) as well as hospital stay (CC 5.1 ± 6.3 days vs. FT 3.1 ± 5.3 days; $p<0.001$) were significantly shorter in the FT group. A multivariate analysis on postoperative complications showed that fast track was not predictive for the occurrence of complications (OR=0.853; 95% CI [0.403–1.804]; $p=0.677$).

Conclusion

Fast track care appears to be safe and efficient for patients undergoing revisional Roux-en-Y gastric bypass, but postoperative outcome may be highly dependent on surgical experience.

INTRODUCTION

Over the last years, a high number of bariatric procedures have been performed worldwide.¹ Therefore, it is expected that the number of revisions will increase over the next years. High revision rates up to 50% are found after either adjustable gastric banding (AGB) or vertical banded gastroplasty (VBG). Reported revision rates after sleeve gastrectomy (SG) are lower, keeping in mind that proper long-term follow-up after SG is scarce.²⁻⁷

A frequently performed revision for these failed restrictive bariatric procedures is conversion to Roux-en-Y gastric bypass (RYGBP).^{5,6,8} In the early days of bariatric surgery, revisions were questioned for their safety and additional benefit.⁹ Nowadays, for a specific group of patients with either complications of the primary bariatric procedure or weight regain, revisional bariatric surgery can be beneficial.

Currently, the morbidity rate after revisional RYGBP is found to be similar compared to primary RYGBP.¹⁰ Due to the high demand of bariatric procedures, fast track care is becoming increasingly popular for bariatric surgery. It is known to increase the efficiency and thereby the productivity on a daily basis, without increasing the risk of postoperative complications.^{11,12}

Since revisional bariatric surgery has become a lot safer over the last years, the demand for revisional bariatric surgery is expected to increase and the implementation of fast-track protocols in bariatric surgery is growing worldwide, the question is raised whether a fast track protocol would be safe to implement in revisional bariatric surgery.

This study aimed to evaluate the potential benefits and safety of a fast-track protocol in an unselected group of patients undergoing conversion to RYGBP bypass after VBG, AGB or SG.

METHODS

For this retrospective analysis, medical charts of all patients undergoing revisional bariatric surgery between January 2005 and December 2013 at the Obesity Centre of the Catharina Hospital Eindhoven, a national referral center for revisional bariatric surgery were reviewed.

This study has been approved by the Institutional Review Board of the Catharina Hospital and has been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki. All patients undergoing revisional Roux-en-Y gastric bypass (rRYGBP) after either adjustable gastric banding (AGB), sleeve gastrectomy (SG) or vertical banded gastroplasty (VBG, either Mason or

Mason-MacLean approach) were included. Other revisional procedures (such as conversion to sleeve gastrectomy) were excluded.

This study was conducted according to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement.

Before January 2011, all bariatric patients were treated according to the hospital's conventional care (CC) protocol. Since January 2011, all patients, including those submitted to revisional procedures, at the Catharina hospital undergo bariatric surgery according to the new center-adjusted fast track care (FT) protocol.

Fast track versus conventional care anaesthesia

Table 5.1 gives an overview of the FT and CC protocol. Furthermore, the CC protocol from this hospital has been described in detail before [13]. The screening and preoperative work-up program was identical for the FT and CC group.

Many differences are found between CC and FT. Premedication in the CC protocol consisted of acetaminophen 1000 mg and diazepam 5 mg. No premedication was included in the FT protocol. In both groups, patients received thrombosis prophylaxis by 5000 units of FraxiparinR (low-molecular weight heparin (LMWH)) and compression stockings. In both protocols, patients received standard hemodynamic monitoring (electrocardiography, pulse oximetry and non-invasive blood pressure measurement). In both groups, bispectral index monitoring and neuromuscular monitoring were routinely used to diminish the chance of awareness in the totally paralyzed patient and to antagonize the muscle relaxant properly. Medication used for induction of the anaesthesia and for perioperative anesthetic maintenance and postoperative analgesia are shown in Table 5.1.

At the end of the procedure, after antagonizing muscle relaxation with sugammadex, patients from the CC group were transferred from the operating room (OR) table to a normal ward bed by the OR personnel. In the FT protocol, desflurane and remifentanyl were discontinued upon notification from the surgeon so the patients could be extubated immediately after the procedure and thus were able to move from the operation table to their bed themselves.

Following to the CC protocol, all male patients with a Body Mass Index (BMI) over 45 kg/m² and all female patients with a BMI over 50 kg/m² were transferred to the intensive care unit (ICU) for respiratory monitoring due to a higher risk developing atelectasis, respiratory dysfunction and complications in combination with the postoperative use of morphine. In the FT group, all patients were admitted to the recovery and transferred to the short-stay surgical ward after 1–2 hours. Furthermore, in the FT group, revisional

procedures were normally performed during regular bariatric programs between primary bariatric procedures, whereas in the CC group, revisional patients were planned on a separate operating program.

Table 5.1 Anaesthesia protocols.

Conventional Care	Fast Track Care
<i>Premedication</i>	<i>Premedication</i>
Acetaminophen 1000mg	None
Diazepam 5mg	
<i>Thrombosis prophylaxis</i>	<i>Thrombosis prophylaxis</i>
Low molecular weight heparins (5000 IU)	Low molecular weight heparins (5000 IU)
Compressed stockings	
<i>Induction</i>	<i>Induction</i>
Sufentanil 0.2-0.7 µg/kg	Piritramide 0.2-0.3 mg/kg
Propofol 2 mg/kg	Propofol 2 mg/kg
Rocuronium 0.6 mg/kg	Suxamethonium 1.0-1.5 µg/kg/hr
	Granisetron 3 mg
	Dexamethasone 8 mg
<i>Maintenance</i>	<i>Maintenance</i>
Remifentanyl 5-15 µg/kg/hr	Remifentanyl 5-15 µg/kg/hr
Sevoflurane or propofol 2-10 mg/kg/hr	Desflurane (6.0% vol.)
Rocuronium 0.4 mg/kg/hr	Bispectral index monitoring
Bispectral index monitoring	
<i>Postoperative analgesia</i>	<i>Postoperative analgesia</i>
Patient controlled analgesia (PCA)	Parecoxib 40 mg
with 1 mg morphine and droperidol	Acetaminophen 4dd 1000 mg
	Tramadol 3dd 100 mg
	Piritramide 0.2-0.3 mg/kg when indicated
<i>Postoperative care</i>	<i>Postoperative care</i>
Intensive Care Unit (ICU) or	Surgical ward
Surgical ward	
<i>Additional concerns</i>	<i>Additional concerns</i>
High labour for personnel (transfer of the patient)	Direct mobilization
Liberal intravenous fluid administration	Restricted intravenous fluid administration (max. 1L perioperative, max. 1L postoperative)
	Liberal oral fluid intake

Surgical procedure

The technique of the rRYGBP differed between the different primary procedures. The main difference is found in the preparation before the construction of the gastric pouch. After SG, no additional preparations were necessitated except any potential adhesiolysis.

In case of rRYGBP after AGB, the band had to be removed first and the created wrap had to be undone. This was performed in one procedure, unless there was band erosion present. In that case, the band was removed in a separate

laparoscopic procedure and at least three months later, the rRYGBP was performed. In case of an earlier VBG, procedure was started with the identification of the band. After identification, the stomach was transected horizontally at the proximal side of the band. The VBG-pouch was then resized with use of an endoscopic stapler (Endo GIA™ (Covidien, New Haven, CT, USA)), up to the angle of His.

After the creation of the pouch, an end-to-side antegastric gastrojejunostomy was constructed by a linear stapler (EndoGIA™ (Covidien, New Haven, CT, USA)) and closed using a running suture. The alimentary limb measured an estimated 150–180 cm. The limb was pulled up in an antecolic position in all procedures. The procedure was finished by constructing the jejuno-jejunostomy, again by using a linear stapler and running suture. Mostly, the procedure was finished by closing the mesenteric defect. The alimentary limb length and the closure of the mesenteric defects were not taken into account for the current analysis.

Outcome

Patients were followed at the bariatric outpatient clinic, as part of our center's follow-up protocol. To assess the safety of fast track care in bariatric revisional surgery, the primary outcome measurements for this study were intra- and postoperative complications less than 30 days after surgery. Included postoperative complications were bleeding, anastomotic leakage, gastrointestinal perforation, various infectious complications (e.g. abscess, pneumonia, and wound infection), any major cardiovascular event and venous thromboembolisms. Additionally, all postoperative complications were categorized according to the Clavien–Dindo scale.¹⁴ A multivariate analysis was performed to find potential predictors for postoperative complications after rRYGBP. Other outcome measurements were length of hospital stay, duration of the surgical procedure and the rate of readmissions.

Statistical analysis

All data for the current study were prospectively collected and analysed retrospectively. Data management and analysis was performed using SPSS version 22 for Windows (IBM Corporation, Armonk, NY, USA). Continuous variables were presented as mean $\pm$ standard deviation (SD). Complications and rate of readmissions are presented as a percentage.

Dependent on the distribution and type of variable, either student's *t*-test, Mann–Whitney U-test, Chi-square test or Fisher's exact test was used to determine any statistical significance between the observed differences among

groups. Differences were considered significant in case of a p value less than 0.05.

Covariates showing a trend towards significance for developing a postoperative complication ($p < 0.1$) were considered for multivariable logistic regression analysis. Odds ratio (OR) and 95% confidence intervals (CI) were provided when applicable and considered significant when OR (95% CI) $\neq 1$. No ethical approval was required for this study. The Institutional Review Board for this retrospective study granted permission.

RESULTS

Between January 2005 and December 2013, a total of 407 patients (84% female) with a mean BMI of 37.6 ± 6.6 kg/m² were included for analysis. A total of 112 VBGs (27.5%), 174 AGBs (42.0%) and 124 SGs (30.5%) were converted to RYGBP. Mean age of the study population was 44.0 ± 8.9 years, the mean BMI before the primary bariatric procedure was 45.7 ± 7.0 kg/m².

A total of 104 (25.6%) patients were treated according to the CC protocol and 303 patients (74.4%) were treated according to the FT protocol. Patient characteristics of the two groups are shown in Table 5.2. No missing data were reported in the current study.

Table 5.2 Patient characteristics (n=407).

	CC n=104 (25.6%) Mean $\pm$ SD	FT n=303 (74.4%) Mean $\pm$ SD	p-value
Age (years)	41.9 $\pm$ 8.9	44.7 $\pm$ 8.8	0.007
Male : Female (n)	15 : 89	50 : 253	0.618
Body Mass Index (BMI) (kg/m ²)	37.6 $\pm$ 6.5	37.6 $\pm$ 6.6	0.977
BMI before previous bariatric procedure (kg/m ²)	45.6 $\pm$ 7.0	45.8 $\pm$ 7.0	0.732
Pre-operative comorbidities (n, %)			
Diabetes mellitus type 2	15 (14.4%)	40 (13.2%)	0.753
Hypertension	31 (29.8%)	77 (25.4%)	0.381
Dyslipidaemia	4 (3.8%)	38 (12.5%)	0.012
Sleep apnoea	3 (2.9%)	22 (7.3%)	0.109
Osteo-articular disease	4 (3.8%)	30 (9.9%)	0.054
Type of previous bariatric procedure (n, %)			
Adjustable Gastric Banding (AGB)	23 (22.1%)	148 (48.8%)	<0.001
Sleeve Gastrectomy (SG)	26 (25.0%)	98 (32.3%)	
Vertical Banded Gastroplasty (VBG)	55 (52.9%)	57 (18.8%)	
ASA classification (n, %)			
I	8 (7.7%)	12 (4.0%)	0.277
II	92 (88.5%)	274 (90.4%)	
III	4 (3.8%)	17 (5.6%)	
Primary open approach (n, %)	20 (19.2%)	3 (1.0%)	<0.001

CC: conventional care; FT: fast track care; SD: standard deviation.

A total of 23 procedures employed an open approach and 384 procedures of laparoscopic approach. 11 procedures (2.8%) were converted to an open approach during surgery (CC group 6/84 vs. FT group 5/300). Seven procedures were converted due to extensive adhesions of the previous procedure; three conversions were due to an intra-operative bleeding and one due to a large incisional hernia. All postoperative complications, including the stratification according to the Clavien–Dindo scale and the readmission rate are shown in Table 5.3.

Mean operating time was 135.3 ± 42.6 minutes in the CC group vs. 79.3 ± 29.3 minutes in the

FT group; ($p \leq 0.001$) and the mean length of hospital stay was 5.1 ± 6.3 days in the CC group vs. 3.1 ± 5.3 days in the FT group; ($p \leq 0.001$).

Following the criteria as described in the Methods section, a total of 54 patients (13.3%) developed a postoperative complication <30 days after rRYGBP, of which 22 patients (5.4%) necessitated a surgical reintervention (11 anastomotic leaks, four bleedings, four gastro-intestinal perforations and three intra-abdominal abscesses).

Table 5.3 Peri- and postoperative outcome (n=407).

	CC n=104 (25.6%) Mean $\pm$ SD	FT n=303 (74.4%) Mean $\pm$ SD	p-value
Intra-operative complications (n, %)	5 (4.8%)	3 (1.0%)	0.029
Postoperative complications (n, %)	20 (19.2%)	34 (11.2%)	0.038
Surgical complications (n, %)	13 (12.5%)	19 (6.3%)	0.042
Anastomotic leakage	8 (7.7%)	11 (3.6%)	0.106
Bleeding	5 (4.8%)	5 (1.7%)	0.132
Gastro-intestinal perforation	1 (1.0%)	3 (1.0%)	1.000
Infectious complications (n, %)	11 (10.6%)	25 (8.3%)	0.471
Intra-abdominal abscess	7 (6.7%)	19 (6.3%)	0.868
Pneumonia	2 (1.9%)	6 (2.0%)	1.000
Urinary tract infection	1 (1.0%)	0	0.256
Wound infection	2 (1.9%)	3 (1.0%)	0.606
Cardiovascular complications (n, %)	0	0	n/a
Venous thromboembolism	0	0	n/a
Readmissions (n, %)	10 (9.6%)	24 (7.9%)	0.590
Clavien-Dindo classification (n, %)			
Clavien-Dindo I	0	0	n/a
Clavien-Dindo II	8 (7.7%)	8 (2.6%)	0.036
Clavien-Dindo III	10 (9.6%)	25 (8.3%)	0.668
Clavien-Dindo IV	2 (1.9%)	1 (0.3%)	0.162
Clavien-Dindo V	0	0	n/a
Serious adverse events (Clavien-Dindo $\geq$ 3a) (n, %)	12 (11.5%)	26 (8.6%)	0.371

CC: conventional care; FT: fast track care; SD: standard deviation

Multivariate analysis

A multivariate analysis was conducted on the occurrence of postoperative complications after rRYGBP. Type 2 diabetes mellitus ($p=0.015$), operative time ($p=0.005$), an open procedure ($p<0.001$), conversion to open procedure ($p=0.008$), ASA risk classification ($p=0.055$) and conventional care protocol ($p=0.038$) were found to be significant factors ($p<0.1$) for developing postoperative complications after revisional RYGBP in this study after univariate analysis. Although significant between groups, age, dyslipidemia and type of previous bariatric procedure were not found to be univariate significant predictors for the occurrence of postoperative complications ($p>0.1$). After multivariate analysis, a primary open procedure was found to be a significant independent risk factor for postoperative complications (OR=9.155; 95% CI [3.064–27.359]; $p<0.001$).

DISCUSSION

Fast track anaesthesia protocols have shown to be efficient in optimizing and standardizing perioperative care and result in a reduction in hospital stay and postoperative morbidity. Our study showed a decrease in hospital stay (from 5.1 ± 6.3 days in the CC group to 3.1 ± 5.3 days in the FT group) and a decrease in postoperative complications (from 19.2% in the CC group to 11.2% in the FT group). A primary open procedure was found to be an independent predictor for postoperative complications. Also operative time significantly decreased from 135.3 ± 42.6 minutes to 79.3 ± 29.3 minutes (CC and FT group, respectively).

Multiple studies have assessed the safety and efficiency of fast track care in both bariatric as well as in other abdominal procedures.^{11,12,15} Be that as it may, all fast track studies in a bariatric population focused on patients undergoing a primary bariatric procedure, leaving out the more complex and difficult revisional procedures.^{11,12,16,17} Therefore, this study assessed an unselected group of patients undergoing revisional RYGBP. Results may contribute to fast track implementation in revisional bariatric surgery. Potentially, current results may contribute to the consideration of a fast track protocol in other abdominal re-do procedures. The results show significant reduction in postoperative complications <30 days and less surgical complications since the implementation of the fast track protocol. Furthermore, less minor complications (Clavien–Dindo ≤ 2) were observed in the FT group, and both operative time and hospital stay were significantly reduced.

Few differences were found between the CC group and the FT group. Patients in the FT group were on average a few years older. Previous research has shown that patient with a higher age have an increased risk at postoperative complications.¹⁸ Nonetheless, age turned out not to be a significant predictor after univariate analysis on postoperative complications in the current study. The type of previous bariatric procedure differed between groups, which might be explained by the time lapse. VBG used to be a commonly performed procedure but was abandoned some years ago and replaced by the newer AGB and SG.¹⁹ The number of primary open procedures differed significantly between groups and has shown to be an independent factor in the occurrence of postoperative complications.

Noticeable is the significantly smaller number of Clavien–Dindo 1 or 2 complications. Although an ultrasound or CT-scan was not performed routinely, none of the patients suffered from a clinically obvious venous thromboembolism, which might suggest that stockings are not necessitated in these revisional procedures and low molecular weight heparins in the proper dose suffice. In current literature, there is still no consensus on the proper dose of low molecular weight heparins.

The postoperative complication rate significantly decreased from 19.2% in the CC group to 11.2% in the FT group. These rates are very comparable to previously published results on revisional RYGBP after failed VBG, AGB or SG.^{6,20–22} The complication rate of the FT group is even comparable with some studies on the outcome after primary RYGBP.^{23,24} Whether the reduction in rate of complication is caused purely by this implementation is arguable, as many factors may have influenced the occurrence of postoperative complications.

The choice for a primary open procedure has shown to be an independent predictive factor for the occurrence of complications in this study. Nevertheless, the total number of open procedures is still quite low, which makes it unlikely that this is the only explanation for the decrease in complications. Surgical experience should also be taken into account, as the CC group includes the first 100 revisional RYGBP procedures. Shikora et al. Previously showed a large reduction in complications between the first 100 patients and the following 650 patients undergoing primary RYGBP.²³ This may be applicable in the current study as well, however, primary RYGBP has been performed for many years by experienced surgeons at this center and the surgical technique of a revisional RYGBP is essentially similar to the one of a primary RYGBP.

The use of fixed operating room teams during the day will have a contributing factor as well.²⁵ These fixed teams were implemented at the same time as the use of the fast track protocol in this hospital. The truth on the reduction of the postoperative complication rate is most likely found somewhere in the middle,

meaning that expertise, laparoscopic approach, fixed teams and fast track care are all likely to be a contributing factor.

The reduction in percentage minor complications (Clavien–Dindo ≤ 2) may be caused by the fast track protocol, by promoting faster mobilization of patients, the decreased operating time and improved health care over the years.

The readmission rates in the CC group and the FT group were 9.6% and 7.9%, respectively. These percentages are found to be similar to previous results in studies on fast track implementation in primary RYGBP surgery.^{12,16} Moreover, this study confirms the reduction in both operative time and length of hospital stay. Operative time decreased with a mean of more than 55 minutes, which can be explained by a combination of a reduced number of open procedures, increased surgical expertise and the use of fixed teams during the day. Fast track care has shown to significantly reduce the length of hospital stay.^{12,26} This result can be confirmed by the current study, in which the mean hospital stay was reduced by 2 days, implying a substantial reduction in health care costs.²⁷

Whether this solely caused by the implementation of fast track is arguable, since primary open approach (possibly resulting in a longer postoperative recovery) and a lower rate of complications during primary admission will have an influence on the average length of hospital stay.

Limitations

There are some limitations to the current study design, but this study showed that revisional bariatric procedures may benefit from a center-specific fast track protocol. First, the retrospective approach is limiting since results are dependent on the accuracy with which the medical charts were managed. Second, the design also limits the means to firmly objectify the predictive value of a learning curve in this study on revisional RYGBP. The combination of maturation of the surgical team, the high volume (currently still increasing) of revisional bariatric surgery in this center and the increased anesthesiological experience may bias the results of the fast track group. Drawback of the current study may be the fact that groups were not matched and that there were differences in performed operations during time. Our center is an expert center on revisional bariatric surgery; therefore our patient population is very diverse. This makes our patient population different from other centers. Our study did not stratify complications on their occurrence during primary admission or readmission, which might have been of clinical interest. Also our fast track anaesthesia protocol is center-adjusted and there might be few differences with other bariatric centers in terms of the used anesthetic agents.

Finally, our results might be biased by the course of time. As mentioned earlier, there is a combined influence of the implementation of the fast track

anaesthesia protocol, the maturation of surgical experience and the use of fixed teams at the operating room. In our opinion, the effect of the surgical learning curve is very difficult to eliminate from our study results. Also the fact that the CC group and FT group differ in primary open procedures is a result of time and the emerging expert status of our center for revisional bariatric surgery. Despite these limitations and the fact that further research is needed to substantiate the current results, fast track care appears to be safe and efficient for patients undergoing revisional Roux-en-Y gastric bypass and may be beneficial in other abdominal revisional procedures.

Conclusion

Fast track care appears to be safe and efficient for patients undergoing revisional Roux-en-Y gastric bypass, but postoperative outcome may be highly dependent on surgical experience.

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CHAPTER 6

Conversion to gastric bypass after either failed gastric band or failed sleeve gastrectomy

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Obes Surg. 2017;27(1):83–89

ABSTRACT

Background

Roux-en-Y gastric bypass (RYGB) is still considered the gold standard in bariatric surgery. Before, adjustable gastric banding (AGB) was regarded as an alternative, nowadays, sleeve gastrectomy (SG) is a more favorable alternative. In case of unsatisfactory results, RYGB is often performed as secondary procedure. Conversion of an AGB is associated with a high risk at complications, the hypothesis was that this would be less after conversion of an SG.

Methods

All patients undergoing conversion to RYGB after AGB or SG between 2005 and 2012 were included for retrospective analysis. Patient characteristics, operative details, postoperative complications, the relief of complaints, weight loss, reasons for failure and evolution of known comorbidities up to two years were analyzed.

Results

A total of 178 patients were included (79.8% female): AGB 110 (61.8%) vs. SG 68 (38.2%). Main reasons for conversion were weight regain/insufficient weight loss (48.4%) or dysphagia/reflux complaints (39.9%). Surgical complications were found in 19 patients (AGB 13 vs. SG 6; $p=0.530$). Infectious complications occurred in 13 patients (AGB 11 vs. SG 2; $p=0.135$). Total body weight loss was equal between groups after two years (AGB $31.6\pm11.0\%$ vs. SG $31.6\pm12.0\%$; $p=0.998$). Similar results were found in a subgroup analysis on patients undergoing conversion for additional weight loss (AGB $31.7\pm11.7\%$ vs. SG $27.0\pm13.1\%$; $p=0.173$).

Conclusions

Conversion to RYGB after failed AGB or SG showed comparable short-term results in terms of postoperative complications and weight loss.

INTRODUCTION

For the treatment of morbid obesity, Roux-en-Y gastric bypass (RYGB) has been considered the gold standard for many years. Not long ago, adjustable gastric banding (AGB) was considered a feasible alternative as it showed a low postoperative complication rate and acceptable weight loss percentages.¹ Drawback to this procedure are the reported high long-term complication rates, often necessitating removal of the band or conversion to RYGB.^{2,3} The more recently introduced sleeve gastrectomy (SG) poses a reliable alternative to both the AGB and the RYGB, showing similar short- and mid-term results between RYGB and SG in terms of morbidity rate, weight loss and obesity-related comorbidity improvement.⁴⁻⁶

The drawback of the SG can be similar to the AGB resulting into long-term complaints requiring a second bariatric procedure. Even though proper long-term studies after SG are not yet available, current literature reports a much lower re-do percentage after SG compared to AGB.⁷⁻⁹

In case of failure necessitating a surgical reintervention of either AGB or SG, the most feasible option is currently still RYGB, however other options are emerging such as the mini gastric bypass, duodenal switch and the recently introduced single anastomosis duodeno-ileal bypass (SADI).⁹⁻¹⁴ Conversion of a failed AGB is risky, as multiple studies have shown postoperative complications rates of over 10%.^{11,15,16} The new gastric pouch of the RYGB has to be created in the same area where the band was placed, which hypothetically can lead to more complications. Since this is not the case after SG, the complication rate may be lower after conversion of a failed SG to RYGB. Furthermore, data on bariatric re-do surgery after sleeve gastrectomy is currently still scarce. Therefore, the aim of this study was to compare the short-term-results after secondary RYGB for failed AGB versus failed SG.

METHODS AND DESIGN

All patients undergoing conversion to Roux-en-Y gastric bypass (cRYGB) between January 1st 2007 and December 31st 2012 were analyzed. For this study, all patients undergoing cRYGB after either failed primary adjustable gastric banding (AGB) or failed primary sleeve gastrectomy (SG) were included for analysis. A planned secondary procedure was regarded as insufficient weight loss.

Patient demographics, operative details, postoperative complications and follow-up until 2 years after surgery were included in the analysis. During

follow-up postoperative weight and the evolution of any known obesity-related comorbidities were evaluated. The obesity-related comorbidities included type 2 diabetes mellitus, hypertension, dyslipidemia, sleep apnea and osteo-articular disease.

Primary outcome for this study were postoperative surgical complications <30 days. Anastomotic leakage, bleeding, incidental gastrointestinal perforation and intra-abdominal abscess were considered surgical complications.

Secondary outcomes were infectious complications such as pneumonia, urinary tract infection and wound infection were scored. Intra-abdominal abscesses were also taken into account for the infectious complications. All complications were stratified according to the Clavien-Dindo scale.¹⁷

Other secondary outcome measurements were additional weight loss and the evolution of any known obesity-related comorbidities. An additional analysis on weight loss and evolution of comorbidities was performed between the different reasons for the secondary procedure.

Weight loss was denoted as percentage excess weight loss (%EWL), percentage of total body weight loss (%TBWL) and change in body mass index (cBMI). The highest weight before the primary bariatric procedure was considered the starting weight for calculating weight loss. %EWL was defined as percentage of excess weight lost after surgery, in which excess weight was defined as the difference between the weight before surgery and the highest healthy weight ($BMI=25 \text{ kg/m}^2$).¹⁸

The evolution of comorbidities was categorized as stable, improved, resolved, worse and de novo. Improved would indicate a reduced amount of medication, improved lab results and/or a lower setting of a Continuous Positive Airway Pressure-device (CPAP). Resolved meant no medication or treatment necessary and/or normalized lab results.

Surgical treatment

The cRYGB technically differed between patients, depending on the primary bariatric procedure. Main difference was found in the preparation for constructing the gastric pouch. After primary SG, except adhesiolysis, no additional preparations had to be made.

In case of primary AGB, the band had to be removed and the created wrap had to be undone prior to the creation of the new pouch. Until 2010, this was done in the same procedure as the Roux-en-Y gastric bypass. Since then, the band was removed during a separate laparoscopic procedure and around at least three months later, the cRYGB was performed.

The gastric pouch was created by using an endoscopic stapler (EndoGIA™ (Covidien, New Haven, CT, USA)). Next, a jejunal limb was pulled up in an antecolic position after which an antegastric end-to-side gastrojejunostomy was created by linear stapling and sutures using Polysorb™ sutures before 2010 and V-Loc™ (Covidien, Mansfield, MA, USA) sutures since then. Until 2010, the alimentary limb measured an estimated 100-150cm. Since 2010, the alimentary limb measured an estimated 150-180cm. Often, the procedure was ended by closure of the mesenteric defect.

Statistical analysis

Data were collected and analyzed retrospectively. Data management and analysis was performed using SPSS version 22 for Windows (IBM Corporation, Armonk, NY, USA). Quantitative data are denoted as mean +/- standard deviation (SD). Complications and rate of readmissions are presented as a percentage.

Either student *t*-test, Mann Whitney U-test or Chi-square-test was used to determine any statistical significance between the observed differences among groups depending on distribution. Differences were considered significant in case of a *p* value less than 0.05. Odds Ratio (OR) and 95% confidence intervals (CI) were provided when applicable and considered significant when OR (95% CI) ≠ 1.

Summative figures and tables were used when applicable.

No ethical approval was required for this study. Permission was granted by the Institutional Review Board for this retrospective study.

All procedures performed in study involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, formal consent was not required.

Informed consent was obtained from all individual participants included in the study.

RESULTS

A total of 178 patients (79.8% female) underwent cRYGB after either primary AGB or primary SG between January 2007 and December 2012. Patient characteristics are presented in Table 6.1, divided between the group of patients with AGB as primary procedure (n=110; 61.8%) and the group with SG as primary procedure (n=68; 38.2%).

Average operating time was 86.3 ± 37.3 minutes (AGB 92.7 ± 39.3 vs. SG 75.9 ± 31.3 ; $p < 0.001$). Mean hospital stay was 3.8 ± 5.9 days after surgery (AGB 4.3 ± 7.0 vs. SG 3.0 ± 3.5 ; $p = 0.143$). A total of six procedures (3.4%) were converted from laparoscopic to open procedure (AGB $n = 5$ vs. SG $n = 1$; $p = 0.409$). One patient underwent conversion due to persistent bleeding of the omentum, one procedure was converted due to splenic hemorrhage and four procedures were converted because of an insufficient view due to extensive adhesions. 30-day mortality rate was zero. No patients died during the 2-year follow-up of the study.

Table 6.1 Patient characteristics ($n = 178$).

	AGB n=110 (61.8%) Mean $\pm$ SD	SG n=68 (38.8%) Mean $\pm$ SD	p-value
Age (years)	44.1 ± 8.8	44.7 ± 11.1	0.735
Male : Female (n)	91:19	51:17	0.212
Body Mass Index (BMI) (kg/m^2)	39.4 ± 6.2	36.1 ± 7.7	0.002
Highest registered BMI (kg/m^2)	45.9 ± 6.3	50.6 ± 10.5	0.003
Starting BMI (before primary surgery) (kg/m^2)	44.9 ± 6.0	49.3 ± 10.7	0.010
Pre-operative comorbidities (n, %)			
Diabetes Mellitus type 2	17	14	0.380
Hypertension	23	24	0.034
Dyslipidemia	9	10	0.171
Sleep apnea	6	8	0.129
Osteo-articular disease	8	7	0.481
ASA classification (n, %)			
I	3	3	
II	102	60	0.595
III	5	5	
Conventional care : fast track care	23:87	17:51	0.525

AGB: adjustable gastric band; SG: sleeve gastrectomy; SD: standard deviation.

(Technical) reasons for conversion

Table 6.2 describes the reasons which led to the conversion of the primary bariatric procedure. Main reasons were either weight regain (33.7%) or dysphagia (30.3%).

Four patients had other complaints after AGB. One patient had persisting pain complaints, one patient had a leaking band with no weight regain until that moment, and one patient had many complaints after AGB which eventually necessitated removal of the band and one patient necessitated cRYGB for a better regulation of the known type 2 diabetes mellitus.

Patients often underwent additional imaging (often swallow test or gastroscopy) to further analyze the complaints of the patient. Additional analysis showed band slippage in 19 (17.3%) patients after AGB, late infection

of the AGB in three patients (2.8%), pouch dilatation above the AGB in two patients (1.8%) and a leaking band or band erosion in two patients each (1.8%). In 82 patients (74.5%) after AGB, either no evident technical cause for failure was found or no additional analysis was performed.

After SG, additional analysis showed dilatation of the sleeve in three patients (4.4%), kinking/torsion of the sleeve (causing persistent dysphagia or reflux complaints) in four patients (5.9%) and stenosis of the sleeve in nine patients (13.2%). In 52 patients (76.5%), no evident technical cause was found or patients did not undergo additional analysis of complaints.

Table 6.2 Reasons for conversion (n=178).

	AGB n=110 (61.8%)	SG n=68 (38.8%)	p-value
	n	n	
Weight regain	56 (50.9%)	4 (5.9%)	<0.001
Insufficient weight loss	17 (15.5%)	11 (16.2%)	0.898
Dysphagia	27 (24.5%)	27 (39.7%)	0.033
Reflux/GERD	6 (5.5%)	11 (16.2%)	0.018
Planned 2 nd bariatric procedure	0	15 (22.0%)	<0.001
Other	4 (3.6%)	0	0.112

AGB: adjustable gastric band; SG: sleeve gastrectomy; GERD: Gastro esophageal reflux disease.

Intra- and postoperative complications <30 days

Intra-operative complications occurred in a total of six patients (3.4%): five after failed AGB (4.5%) versus one after failed SG (1.5%), $p=0.409$.

Early postoperative surgical and/or infectious complications occurred in a total of 21 patients (11.8%), 15 after AGB and 6 after SG. These complications are displayed in Table 6.3.

Weight loss and comorbidity evolution

Weight loss was evaluated after, six months, one year and two years. Weight loss parameters (%EWL, %TBWL and cBMI) are shown in Table 6.4. The percentages of the obesity-related comorbidities which either were improved or resolved after two years were 91.3%, 87.5%, 86.7%, 72.7% and 69.2% for respectively diabetes mellitus type 2, hypertension, dyslipidemia, sleep apnea and osteo-articular disease in this study population.

Table 6.3 Postoperative outcome (n=178).

	AGB n=110 Mean ± SD	SG n=68 Mean ± SD	p-value
Patients with surgical complications (n, %)	13 (11.8%)	6 (8.8%)	0.530
Leakage gastrojejunostomy (n, %)	6 (5.5%)	3 (4.4%)	1.000
Leakage enteroenterostomy (n, %)	0	0	n/a
Bleeding (n, %)	4 (3.6%)	3 (4.4%)	1.000
Gastro-intestinal perforation (n, %)	3 (2.7%)	0	0.288
Patients with infectious complications	11 (10%)	2 (2.9%)	0.135
Intra-abdominal abscess (n, %)	8 (7.3%)	2 (2.9%)	0.322
Pneumonia (n, %)	3 (2.7%)	0	0.288
Urinary tract infection	0	0	n/a
Wound infection	1 (0.9%)	0	1.000
Clavien-Dindo 1 (n, %)	0	0	n/a
Clavien-Dindo 2 (n, %)	4 (3.6%)	0	0.299
Clavien-Dindo 3a/3b (n, %)	10 (9.1%)	6 (8.8%)	0.952
Clavien-Dindo 4a/4b (n, %)	1 (0.9%)	0	1.000
Clavien-Dindo 5 (n, %)	0	0	n/a
Serious Adverse Events (Clavien-Dindo ≥3) (n, %)	11 (10%)	6 (8.8%)	0.795

Missing Data: n=0. AGB: adjustable gastric band; SG: sleeve gastrectomy; SD: standard deviation.

Table 6.4 Weight loss after cRYGB (n=178).

	AGB n=110 Mean ± SD	SG n=68 Mean ± SD	p-value	Missing data n (%)
Weight loss after 6 months				
Change in BMI (kg/m ²)	13.3 ± 5.9	16.5 ± 6.9	0.001	44 (24.7%)
% Total Body Weight Loss (%TBWL)	28.3 ± 9.6	33.4 ± 10.3	0.004	44 (24.7%)
% Excess Weight Loss (%EWL)	63.7 ± 19.1	74.3 ± 27.3	0.014	44 (24.7%)
Weight loss after 1 year				
Change in BMI (kg/m ²)	14.4 ± 6.0	17.1 ± 7.5	0.021	42 (23.6%)
% Total Body Weight Loss (%TBWL)	31.1 ± 9.6	33.8 ± 11.9	0.144	42 (23.6%)
% Excess Weight Loss (%EWL)	71.7 ± 19.0	73.2 ± 29.2	0.735	42 (23.6%)
Weight loss after 2 years				
Change in BMI (kg/m ²)	14.5 ± 6.5	15.7 ± 7.0	0.373	62 (34.8%)
% Total Body Weight Loss (%TBWL)	31.6 ± 11.0	31.6 ± 12.0	0.998	62 (34.8%)
% Excess Weight Loss (%EWL)	73.1 ± 23.1	68.3 ± 28.6	0.324	62 (34.8%)

cRYGB: conversion to Roux-en-Y gastric bypass; AGB: adjustable gastric band; SG: sleeve gastrectomy; SD: standard deviation.

Subgroup analysis

Subgroup analysis was performed to assess differences in complications and weight loss after two years between the two groups with the primary aim to obtain additional weight loss (weight regain, insufficient weight loss or planned second bariatric procedure). A total of 103 (57.9%) were included (AGB: n=73

vs. SG: $n=30$). No differences were found at baseline except starting BMI (AGB $45.0 \pm 6.1 \text{ kg/m}^2$ vs. SG $55.1 \pm 11.3 \text{ kg/m}^2$; $p < 0.001$). No differences were found in terms of both postoperative complications (AGB 15.1% vs. SG 6.7%; $p = 0.337$). Out of the 103 patients included in this subgroup, 66 (64.1%) attended the 2-year follow-up. Weight loss was not different in terms of cBMI (AGB $14.9 \pm 7.2 \text{ kg/m}^2$ vs. SG $15.0 \pm 8.1 \text{ kg/m}^2$; $p = 0.951$) or %TBWL (AGB $31.7 \pm 11.7\%$ vs. SG $27.0 \pm 13.1\%$; $p = 0.173$), however it did differ in terms of %EWL (AGB $71.1 \pm 21.6\%$ vs. SG $50.8 \pm 23.0\%$; $p = 0.002$).

Furthermore, patients undergoing conversion for relief of complaints were analyzed (AGB: $n=37$ vs. SG: $n=38$). Differences at baseline were a higher prevalence of type 2 diabetes mellitus ($p = 0.007$), hypertension ($p = 0.017$) and dyslipidemia ($p = 0.047$) in SG patients. Furthermore, the pre-operative BMI was different (AGB $36.7 \pm 6.5 \text{ kg/m}^2$ vs. SG $31.8 \pm 5.7 \text{ kg/m}^2$; $p = 0.001$).

Results showed no difference in postoperative complications (AGB 10.8% vs. SG 10.5%; $p = 1.000$). Out of the 75 patients included, 50 (66.7%) attended the 2-year follow-up. No differences were found in weight loss after two years in terms of cBMI (AGB $13.8 \pm 4.9 \text{ kg/m}^2$ vs. SG $16.2 \pm 6.3 \text{ kg/m}^2$; $p = 0.951$) and %TBWL (AGB $31.4 \pm 9.9\%$ vs. SG $34.8 \pm 10.3\%$; $p = 0.173$), whereas %EWL differed significantly. (AGB $76.9 \pm 25.8\%$ vs. SG $80.7 \pm 25.9\%$; $p = 0.002$). Pre-operative complaints improved in 100% in the failed AGB group and in 71% in the failed SG group ($p < 0.001$).

DISCUSSION

This is the first study to compare the short-term outcome of cRYGB after failed AGB and SG. Main differences between the two groups were the starting BMI and the reasons for conversion. In terms of postoperative complications, weight loss and comorbidity-improvement, results were similar between conversion to AGB and conversion to SG.

At baseline, both current BMI, as well as starting BMI before primary procedure differed significantly. Taking a closer look at the current study population, the results suggest a better initial weight loss effect after SG compared to AGB, as SG patients started off at a higher BMI and ended up at a lower BMI after primary surgery. Caution is needed when discussing the effect of the primary procedures, as the time between the primary and secondary procedure is an important factor, but is unknown in many patients of the current study population. Many of these patients were referred from different hospitals which compromised some of these data.

Operative time was longer in the AGB-group, which may be caused by the longer time needed in patients in which band removal and cRYGB were performed sequentially in the same procedure. Another explanation may very well be the fact that cRYGB after failed AGB is more challenging than cRYGB after failed SG.

No differences were found in both total as well as individual postoperative complications between the two groups, making the hypothesis that cRYGB after failed SG may lead to less postoperative complications unlikely. On the other hand, these complication rates do emphasize the complexity of secondary bariatric procedures, as they are higher compared to reported complication rates after primary RYGB.^{19,20} Nevertheless, they are comparable with previous reports on secondary procedures.^{8-10,21} The majority of the AGB patients was operated in two stages; first the removal of the band and after approximately three months the RYGB. This did not decrease the amount of postoperative complications as similar results were found after one-step conversion.^{22,23}

In this study, when considering the BMI before primary surgery as reference point, average weight loss two years after conversion was similar between the two groups. Weight loss differed six months after surgery, which is most likely still explained by the large difference in mean BMI before secondary surgery.

The most essential differences are found in the reason for conversion and its associated subgroup analyses, since the majority of the failed AGB-patients underwent conversion for additional weight loss, whereas the distribution between the aim for additional weight loss and complaint relief was more equal in SG patients. Conversions aiming to establish additional weight loss showed a higher percentage of complications after conversion of a failed AGB, although not significant. In terms of weight loss, cBMI and %TBWL were similar. The %EWL was significantly higher in failed AGB patients, however recent literature suggested that %EWL may not be the best way to describe weight loss.⁽²⁴⁾ On the other hand, the large absolute difference in %EWL, while taking the starting BMI of both groups into account, may suggest that cRYGB as additional weight loss procedure after SG might not be the best option for achieving additional weight loss after failed SG. Looking at newly available literature, for example duodenal switch or single anastomosis duodeno-ileal bypass appear to have the upper hand over RYGB in terms of additional weight loss, however serious postoperative deficiencies and other (unknown) long-term complications have to be taken into account when considering these procedures.^{13,14} The results after failed AGB are good when comparing them to several other studies, confirming that RYGB is a good re-do option after failed AGB for additional weight loss.²⁵

When analyzing the patients undergoing conversion for relief of complaints, SG-patients showed a significant lower pre-operative BMI. The therapeutic mechanism however is very different between the two groups. Complaints of patients in the AGB group are usually relieved after removal of the band since the anatomic state is returned to normal, whereas in SG-patients, the cRYGB is the therapeutic procedure, since return to normal anatomy is impossible. After band removal, weight regain seems inevitable for which cRYGB appears to be a good option to prevent that when looking at the current results, as it even achieves additional weight loss. Furthermore, cRYGB is a valuable option for SG-patients with complaints as it achieves relief of complaints in many patients and establishes good short-term weight stabilization in the current study.

These findings do suggest that the effect of the RYGB as a secondary procedure is dependent on the combination of the reason for which a conversion is performed and the primary bariatric procedure. A thorough assessment of these patients is advisable to make a clear distinction between these different groups. In terms of weight loss, RYGB seems feasible after failed AGB. In terms of relief of complaints, RYGB seems feasible after either AGB or SG.

However, in terms of weight loss, RYGB may not be the best option after SG, especially since other procedures such as SADI seem preferable in terms of (additional) weight loss after SG.^{14,26} Further research is needed to substantiate these assumptions.

The current study design is subject to limitations, since the retrospective design makes the results subjective to bias and sometimes incomplete when looking at the follow-up. Furthermore, the follow-up, especially the 2-year follow-up, shows a high number of missing which compromises the impact and the credibility of the current results. Despite these limitations, it can be concluded that RYGB as secondary procedure after failed AGB or failed SG shows comparable short-term results in terms of postoperative complications and weight loss. Nonetheless, these results are susceptible to the reason that necessitates conversion.

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CHAPTER 7

Matched short-term results of SADI versus GBP after sleeve gastrectomy

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Obes Surg. 2018;28(12):3809-14

ABSTRACT

Background

The Gastric Bypass (GBP) is the most popular revisional technique after Sleeve Gastrectomy (SG). However, the results after revision are not always satisfactory in terms of additional weight loss and complications. The Single Anastomosis Duodenal Ileal Bypass (SADI) could be a valuable alternative.

Objective

This study is a retrospective matched-control study reviewing short term results in terms of weight loss and comorbidities reduction of both SADI and GBP as a revisional procedure after primary sleeve gastrectomy. Complications and vitamin deficiencies will be evaluated as well.

Methods

Patients with a SADI procedure after a primary sleeve gastrectomy (SG) with a minimum follow-up of one year, were included. Their results were retrospectively reviewed and matched with a cohort of GBP patient on age, BMI and gender. Comparison was on comorbidities, weight loss, complications and blood markers.

Results

A total of 64 patients were included, 32 SADI procedures and 32 matched gastric bypasses with no significant differences on baseline. No differences were found in terms of (additional) total weight loss. The operating time of the SADI was significantly longer ($p=0.007$). No clinically relevant differences were found concerning comorbidities or blood markers. In the SADI group, more defecation problems were reported and fewer vitamins deficiencies were encountered.

Conclusion

Based on a small group and short-term results, the SADI could be regarded as a safe alternative to a GBP following SG with a similar amount of additional weight loss and fewer post-operative early complications. Longer follow-up and larger studies are needed to determine its full potential.

INTRODUCTION

Obesity is still a globally expanding problem and is even called an epidemic. In the Netherlands alone, almost 14% of all the citizens is obese.⁽¹⁾ The risk at disease increases as the Body Mass Index (BMI) or waist circumference increases.^{1,2} Bariatric surgery is currently the most effective therapy for obesity with good long-term results. A multitude of studies showed significant weight loss and substantial improvement of comorbidities after bariatric surgery.³ Weight loss is achieved by multiple standard procedures such as a laparoscopic sleeve gastrectomy (SG), a Roux-en-Y gastric bypass (GBP) or a duodenal switch (DS).

Patients suffering from a more severe form of morbid obesity (BMI>60), benefit the most from bariatric surgery. Those patients may even qualify for a two-step procedure. This often includes a SG as primary bariatric procedure and conversion to a GBP as revisional procedure.⁴ However, earlier research showed that the combination of SG and GBP surgery often shows insufficient results compared to the combination of SG and DS.⁵ The drawback of the DS may be a technically more challenging operation. For this reason, the Single Anastomosis Duodenal Bypass (SADI) was developed by Torres et al.⁶ It can be regarded as a technically less demanding procedure with presumably a similar amount of weight loss.^{6,7} The first clinical results of the SADI as a primary procedure, with a follow-up period of three years showed an excess weight loss of almost 100% after three years. Nonetheless, a comparison with other procedures is missing.⁶ Therefore, this study will present the clinical results concerning the differences between the results of the SADI and what is currently considered the gold standard; GBP following a SG. Results of both surgery types will be defined by means of comorbidities, weight loss, complications and blood markers.

METHODS

This is a retrospective matched-cohort study, for which medical charts were reviewed to retrieve the necessary data. Informed consent was obtained from all individual participants. A total of six follow-up moments were included in the study: 1. Before sleeve gastrectomy (baseline characteristics), 2. One year after sleeve gastrectomy, 3. Before revisional surgery, 4. Three months after revision, 5. Six months after revision, 6. One year after revision. During these follow-up moments, a number of parameters were measured and reviewed. The primary outcome for this study is weight loss after revisional surgery, expressed in percentage of total weight loss (%TWL). %TWL is calculated as (initial weight –

current weight) / (initial weight) * 100%. %TWL was chosen to report weight loss since it appears to be less influenced by preoperative BMI in comparison to the percentage of excess weight loss (%EWL).^{8,9}

Secondary parameters are %TWL after revision, the evolution of any known obesity-related comorbidities, various blood markers, operating time and postoperative complications.

To calculate the weight loss effect of the conversion alone, %TWL after conversion is calculated: (weight at revision – weight at follow-up) / (weight at revision) * 100%.

All known obesity-related comorbidities (diabetes mellitus type 2, hypertension, dyslipidemia, obstructive sleep apnea syndrome (OSAS), joint complaints and gastro-esophageal reflux disease (GERD)) are scored at baseline. The evolution of these comorbidities is categorized as either stable, improved, resolved, worse, de novo or not applicable.

The presence and potential improvement of diabetes mellitus type 2 will be assessed by the amount of antidiabetic medication used and the HbA1c-level. When the HbA1c-level is lower than 42 mmol/mol and no antidiabetic medication is necessary, the diabetes is considered resolved. An improvement is considered when a reduction in use of medication is achieved or a lower HbA1c-level is measured. A decline is considered when the opposite occurs.

The presence and potential improvement of hypertension will be assessed by measuring the blood pressure and evaluating the current use of medication. Hypertension is considered resolved when measuring a normal blood pressure (120-140/80-89 mmHg) without the use of medication. Improvement is considered with a 50% reduction in medication dose, stopping one or more medicines or achieving a normal tension with the current medication. A decline is considered when the opposite occurs.

The presence and potential improvement of hypercholesterolemia will be assessed by LDL/HDL ratio and potential changes in the use of medication.

The presence and potential improvement obstructive sleep apnea is assessed by the use of a continuous positive airway pressure (CPAP) device and the evolution of complaints (subjective improvement or decline).

Joint complaints are only assessed by the subjective amount of complaints of the patient and the use of pain medication for joint complaints.

Blood markers include cholesterol (mmol/L), LDL (mmol/L), HDL (mmol/L), HbA1c (mmol/mol), C-peptide (ng/mL), insulin (pmol/L), creatinine (μmol/L), iron (μmol/L), ferritin (g/L), vitamin B12 (pmol/L) and vitamin D (nmol/L).

The postoperative complications include postoperative bleeding, internal herniation, anastomotic leakage, vitamin B12 and vitamin D deficiencies, defecation complaints (either obstipation; no defecation for at least 3 days, diarrhea; Bristol stool scale 7 or fatty stools; bulky stools, difficult to flush, pale

and oily appearance, foul-smelling), emergency care visits and emergency surgery. Vitamin B12 and D deficiencies are determined by use of reference values.

Study population

All patients who underwent conversion from sleeve gastrectomy to SADI between January 2016 and June 2017 with an available minimum amount of follow-up of 6 months will be considered for inclusion in the current study. Patients who had surgery before 2013 were not included, due to changes in pre- and postoperative protocol. These patients will be used to match the included SADI-patients on age, sex and BMI. The BMI had a range of maximum 10 kg/m² per individual match and the maximum age difference was 10 years. Before surgery, patients were screened for physical and mental condition using interviews and tests with an obesity nurse, psychologist, dietician, and physiotherapist. Based on the opinions of the mentioned professionals, a multidisciplinary consultation concluded whether the patient was appropriate to undergo revisional surgery. Measurements during this screening were used as baseline characteristics.

Surgical procedures

The pouch of the gastric bypass procedure was created by dissecting the prior sleeve using the Endo-GIA™ stapler (Medtronic, New Haven, CT, USA). The antecolic and antegastric gastrojejunal and jejuno-jejunostomy anastomosis were created, using an EndoGIA™ and V-loc™ stitching. The alimentary limb measured approximately 150-180cm and the biliopancreatic limb is 60-80 cm. Both internal openings were closed. A leak test was performed to test the gastrojejunostomy. The SADI procedure encompassed a Maryland dissection along the sleeve up to the level of the gastroduodenal artery, under the pylorus, preserving the vascularization at the lesser curvature. The duodenum was divided with an Endo-GIA™. The ileocecal junction was identified and measured proximally up to around 250 cm. The loop was ascended antecolic and a side-to-side duodenoileal anastomosis was created with 2 V-loc™ stitches. A leak test was performed.

All subjects followed the same postoperative protocol including a liquid diet for two weeks, the use of low-molecular weight heparins (Fragmin™) for four weeks to prevent thrombo-embolic events and the use of pantoprazole for three months, to reduce complaints of gastric acid. Finally, life-long vitamin supplementation is advised.

Statistical analysis

The results were presented as mean $\pm$ standard deviation (SD). A p -value <0.05 was considered to be statistically significant. Data management and analysis was performed using SPSS version 23 for Windows (IBM Corporation, Armonk, NY, USA).

One-way ANOVA's were performed to test differences between groups concerning the percentage TWL, BMI, blood markers, operating time, highest and lowest weight. When the Levene's test for homogeneity of variance proved that the assumption of equal variances was not met, the Brown-Forsythe for testing the equality of means was performed. Concerning dichotomous variables, chi-square tests or, when indicated, Fischer's exact tests were performed per variable.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

RESULTS

In total, 42 patients underwent a conversion to SADI between January 2016 and June 2017. Nine patients were excluded due to an insufficient follow-up period. One patient was excluded since the procedure considered a conversion from GBP to SADI. A total of 86 patients were selected from all patients who underwent a revisional GBP between 2013 and 2016. Thirty-two out of them were matched to the SADI-patients.

Demographics of the study population at baseline are shown in Table 7.1. No cases of intraoperative complications were reported in this study population. The mean operating time of the SADI was significantly higher than the operating time of the GBP (66.6 min vs. 56.9 min; $p=0.006$).

The indication for conversion to SADI was a planned secondary procedure to achieve additional weight loss after primary SG in patients with a high initial BMI. All conversions from SG to GBP were due to either insufficient weight loss or weight regain after primary SG.

Table 7.1 Demographics.

	SADI	Gastric bypass	p-value
Participants (n)	32	32	n/a
Male (n)	6 (18.8%)	6 (18.8%)	n/a
Female (n)	26 (81.3%)	26 (81.3%)	n/a
Age (mean, range)	46.9 (21-66)	48.2 (29-63)	0.597
Mean BMI $\pm$ SD (kg/m ²)	57.5 ($\pm$ 7.6)	53.7 ($\pm$ 7.0)	0.030

BMI: body mass index; SD: Standard deviation.

Complications

Postoperative complications and long-term complications are displayed in Table 7.2.

The largest difference was found in defecation problems, which was a 21.9% difference between the two groups ($p=0.037$). Vitamin B12 and D deficiencies were defined for multiple follow-up moments (Table 7.3).

Table 7.2 Early and late complications after surgery.

	SADI n (%)	Gastric bypass n (%)	p-value
Anastomotic leak	1 (3.1)	3 (9.4)	0.306
Bleeding	1 (3.1)	0 (0)	0.500
Emergency care visits	5 (15.6)	8 (25)	0.268
Emergency operations	2 (6.3)	3 (9.4)	0.500
Defecation problems	11 (34.4)	4 (12.5)	0.037
Internal herniation	0 (0)	2 (6.3)	0.246

Table 7.3 Vitamin deficiencies.

	Measuring moment	SADI n (%)	Gastric bypass n (%)	p-value
Vitamin B12 deficiency	Baseline	4 (12.5)	7 (21.9)	0.171
	1 year after sleeve	1 (3.8)	7 (21.9)	0.053
	3 months after revision	0 (0)	4 (12.5)	0.105
	6 months after revision	0 (0)	6 (18.8)	0.058
Vitamin D deficiency	Baseline	23 (71.9)	18 (56.3)	0.415
	1 year after sleeve	7 (21.9)	12 (37.5)	0.295
	3 months after revision	2 (6.3)	9 (28.1)	0.062
	6 months after revision	6 (18.8)	19 (59.4)	0.067

Weight loss

The %TWL is presented Figure 7.1. Although weight loss appears slightly higher in the SADI-group, no significant differences were found ($p>0.05$). Furthermore, no significant differences concerning BMI were found before and after revision. Weight regain was observed in three patients from the SADI group and nine patients in the Bypass group.

Figure 7.1 Differences in %Total Weight Loss after revision.

SADI/GBP after revision = Weight loss after revision; SADI/GBP total = Total weight loss including the effect of the primary sleeve gastrectomy.

Comorbidities

Table 7.4 shows the evolution of the obesity-related comorbidities between baseline and the last moment of follow-up. Only patients who experienced an improvement or even resolution of the comorbidity during follow-up were taken into account. Both variables include 'de novo' patients as well. No significant results were found.

Table 7.4 Reduction of comorbidities.

	Incidence at baseline (%)	Remissions (%)	Improvement (%)	p-value
DM				
SADI	9/32 (28.1%)	2 (22.2)	1 (11.1)	0.564
Bypass	6/32 (18.8%)	1 (16.6)	3 (50)	
HT				
SADI	14/32 (43.8%)	6 (42.9)	4 (28.6)	0.066
Bypass	10/32 (31.3%)	1 (10)	7 (70)	
DL				
SADI	19/32 (59.4%)	7 (36.8)	7 (36.8)	0.505
Bypass	17/32 (53.1%)	7 (41.2)	6 (35.3)	
OSAS				
SADI	7/32 (21.9%)	3 (42.9)	1 (14.3)	0.471
Bypass	11/32 (34.4%)	7 (63.6)	2 (18.2)	
GERD				
SADI	4/32 (12.5%)	2 (50)	1 (25)	0.273
Bypass	0/32 (0%)	0 (0)	0 (0)	
JC				
SADI	14/32 (43.8%)	4 (28.8)	7 (50)	0.206
Bypass	14/32 (43.8%)	7 (50)	3 (21.4)	

DM: diabetes mellitus; HT: hypertension; DL=dyslipidemia/hypercholesterolemia; OSAS=obstructive sleep apnea syndrome; GERD: gastroesophageal reflux disease; JC: joint complaints; SADI: single anastomosis duodenoileal bypass.

DISCUSSION

This retrospective matched cohort study compared the results of SADI and GBP as revisional procedure after primary sleeve gastrectomy to achieve additional weight loss. It appeared that SADI leads to an equal remission of comorbidities, fewer vitamin deficiencies, fewer complications and a similar amount of additional weight loss compared to the GBP. Nonetheless, SADI has a longer operating time with more patients suffering from defecation problems.

Results revealed that the operating time of the SADI was significantly longer than the operating time of the GBP. This operating time may be prolonged due to the fact that these SADI-procedures were the first performed in this hospital. A completed learning curve may have a positive effect on the operating time.¹⁰

Probably the most remarkable finding is the fact that the effect of both GBP and SADI after primary sleeve gastrectomy are equal. This is remarkable since already published literature would suggest a superiority in favor of the SADI.¹¹⁻¹³ Similar results were found in the mean BMI of both groups. Be that as it may, follow-up is limited to only one year and a higher number of patients in the Bypass group already showed weight regain. Since the follow-up in earlier studies is a few years longer, it is possible that a difference may reveal itself after a longer period of follow-up.¹¹⁻¹³ A higher weight loss is hypothesized by the longer alimentary limb of the SADI, which may stimulate an enhanced secretion of the hormones Peptide YY and Glucagon-like Peptide-1 which are associated with increased satiety and decreased food intake.^{6,14,15} This hypothesis could not be reproduced in the current study, showing similar weight loss results.

The weight loss after revision is approximately one third of the total achieved weight loss, which strengthens the indication for secondary surgery after sleeve gastrectomy in certain cases.

These results contrasted with the results of comparisons between BMI per group. The SADI did not lead to significantly lower BMI values. However, results showed that subjects of the SADI group had a slightly higher initial weight. This can be explained by the indication for second surgery, which is additional weight loss. Patients of the SADI group started the project with the approach of a two-step surgery. This in contrast to patients in the Bypass group, who started assuming that the sleeve gastrectomy alone would be sufficient.

The evolution of comorbidities was similar in both groups, which indicates that both procedures (including the effect of the sleeve gastrectomy) have a comparable positive effect on the improvement of these comorbidities. This is comparable with previous literature suggesting SADI maintains a similar improvement of comorbidities as GBP.^{7,16,17} Nonetheless, these data should be interpreted cautiously. Due to some missing data, sums of outcome per

variable were not consistent with their previous frequencies and the absolute number of comorbidities is low.

When analyzing the blood markers, both groups show an improvement in the lipid spectrum, without a difference between the two groups. This suggests that SADI has a similar positive effect on the lipid spectrum as GBP after primary sleeve gastrectomy, which is in accordance with previous literature.¹⁸

Significant higher levels of vitamin B12 were found in the SADI-group, which may be caused by the increased availability of intrinsic factor (IF) compared to GBP, as a larger portion of the stomach is still available to produce this glycoprotein. This consequently led to a larger amount of vitamin B12 deficiencies in the Bypass group. It should be notified that vitamin B12 levels were already significantly lower before revisional surgery, which may suggest a more aggressive supplementation regime during the SADI period compared to the GBP period in this study population.

When considering the complications after surgery, fewer anastomotic leaks, emergency care visits and emergency operations were observed in the SADI group. Meanwhile, a lot more patients complained of problems with their stools after SADI. This could be explained by the fact that the alimentary limb is longer in the SADI.⁶ Other studies implicate intestinal bacterial overgrowth with increased inflammation after bariatric surgery. This could possibly have more effect after a SADI procedure. Nonetheless, mechanisms are still poorly understood. Furthermore, complaints can be worse due to more malabsorption causing diarrhea due to the longer alimentary limb. Though, these symptoms are likely to disappear within months after surgery.¹⁹

Regarding the vitamin D deficiency, earlier research shows that patients who underwent GBP were often noncompliant in taking the regular vitamin supplementation.²⁰ Furthermore, the Roux-anastomosis causes malabsorption of fat-soluble vitamins due to insufficient mixing with bile salts.²⁰ More noncompliance and deficiencies in the Bypass group can be explained by the fact that patients who underwent surgery between 2013 and 2016 were included and the SADI was only performed from 2016 onwards. As time passed, more strict check-ups were introduced, and patients were better informed regarding vitamin supplementation. Furthermore, the SADI was considered a new surgical procedure in the Catharina hospital and results in contrast to the gold standard were not known. Therefore, the importance of supplements in this group was emphasized.

Both groups ended the follow-up period with approximately the same BMI and had an equal remission of comorbidities.

Nonetheless, this study has some considerable limitations. The first limitation is the retrospective nature of this study. Some results may be distorted due to selection bias. However, the retrospective nature also has a positive aspect,

because true clinical circumstances are investigated and therefore, results reflect a non-research setting.¹⁷

Second limitation is the size of the study population and the duration of the follow-up. It was discussed earlier that a longer follow-up would possibly lead to more significant differences in %TWL between groups. Furthermore, a larger study population would make it possible to give value to differences in outcome such as postoperative complications. Many of these limitations would be tackled by setting up a prospective and randomized trial.

Conclusively, SADI appears to be a promising surgical method. It seems to be a safer procedure in terms of complications considering it to be advanced bariatric surgery. The results are good (equal or better than the GBP at some points) in a short-term follow-up, however, a longer follow-up period and larger study population are needed to determine its full potential. Therefore, preferably prospective, randomized research is required.

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CHAPTER 8

Single Anastomosis duodenoileal bypass or GAstric bypass after primary sleeve gastrectomy (SAGA-trial): a randomized controlled trial (Study protocol)

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ABSTRACT

Background

To achieve additional weight loss after primary sleeve gastrectomy, Roux-en-Y gastric bypass (RYGB) is the most performed procedure, however results are disappointing. New procedures such as the Single Anastomosis Duodeno-Ileal bypass (SADI) appear to be a better alternative, however there is only limited evidence to support this assumption. This article describes the study protocol of a randomized controlled trial comparing the outcomes of the RYGB and SADI after primary sleeve gastrectomy.

Methods & Design

This is a single-centre, prospective, randomized controlled, clinical study. The trial is conducted as a superiority trial to demonstrate that SADI is better than RYGB after primary sleeve gastrectomy. The primary endpoint of this study will be the additional weight loss in terms %EWL after 2 years. Secondary outcome measurements for this study will be weight loss expressed with different parameters, the comparison of peri- and postoperative complications, reduction of obesity-related comorbidities, biochemical changes, gut flora changes, convalescence, adherence to the bariatric program, dumping syndrome complaints and quality of life. Total follow-up of the study will be two years. The aim is to include fifty patients (age between 18 and 65), with a body mass index between 35 and 60 kg/m² for whom a secondary procedure after primary sleeve gastrectomy is indicated.

Discussion

This study aims to provide important data on the impact of RYGB and SADI after primary sleeve gastrectomy in terms of weight loss and many other parameters.

BACKGROUND

Morbid obesity remains a global burden, for which bariatric surgery still appears to be the most effective therapy. It is known to achieve long-term weight loss, a risk reduction of cardiovascular morbidity and an improvement in both lifestyle and any known obesity-related comorbidities such as diabetes mellitus type 2 and hypertension.¹⁻³

Bariatric has become increasingly popular over the last years. In 2011, over 340,000 bariatric procedures were performed worldwide of which adjustable gastric banding (AGB), sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB) were performed most frequently.⁴ AGB has been decreasing in popularity over the last years due to poor long-term results.⁵ The RYGB is currently still considered the best surgical option for the treatment of morbid obesity, although seems to be surpassed by the SG in numbers.⁶ The sleeve gastrectomy was first described by Marceau et al. in the late 1990's as part of a biliopancreatic diversion with duodenal switch (BPD/DS) and was later popularized by Gagner et al. as standalone procedure.⁷⁻⁹ SG is a bariatric procedure based on a restriction of food intake by removal of the gastric fundus, which is the predominant area for the production of ghrelin.¹⁰ Ghrelin has been described as a hunger regulating peptide hormone.¹¹ SG is known to achieve good short- and medium term weight loss results, however long-term results are scarce.¹² Nevertheless a long-term drawback of SG is weight regain, of which recently reported percentages are between 5.4-29.5%, often necessitating another bariatric procedure to achieve additional weight loss or prevent further weight regain.¹³⁻¹⁶ Current revision rates of SG are between 5.5-11%, taking into account that these rates are not only for weight regain, but also other complications such as gastroesophageal reflux disease, dysphagia and insufficient weight loss.¹⁵⁻¹⁷ These rates are expected to increase over the next years.

There are several options for secondary surgery after SG: re-sleeve gastrectomy, mini gastric bypass, RYGB, BPD/DS or single anastomosis Duodenoileal bypass (SADI). RYGB and BPD/DS appear to be the most preferable as secondary procedure.^{14,16-19} However, the more recently introduced SADI also appears to have promising results in terms of weight loss.²⁰ The SADI is a derivative of the primary procedure SADI-S, which can be described as a simplified duodenal switch and has demonstrated to have satisfactory short- and medium-term results.²¹

In a SADI, a duodenojejunal anastomosis is created, keeping the pyloric valve intact. The common loop is measured from Bauhin's valve (approximately 250 cm).

In a RYGB, the pyloric valve is excluded from the food trajectory. By creating a small gastric pouch, after which a gastrojejunostomy is created. Keeping the pyloric valve intact reduces the occurrence of dumping syndrome but may potentially maintain complaints such as reflux or dysphagia. Therefore, RYGB is preferred as secondary procedure for complaints of gastro-esophageal reflux or dysphagia.²²

In case of insufficient weight loss or weight regain, SADI appears to achieve more additional weight loss compared to RYGB, however may be associated with more nutritional deficiencies and complaints such as fatty diarrhea and (persisting) complaints of reflux or dysphagia.

Evidence on which of these two procedures is preferred for achieving the most additional weight loss after sleeve gastrectomy is scarce. Results provided are of a retrospective nature with small groups, long-term results are lacking and thus conclusions lack hard evidence.

In the recently published study by Torres et al., conversion to SADI appears to produce similar results as conversion to BPD/DS, however the intra- and postoperative complication rate is lower.^{19,20} Again, evidence is scarce but the first results appear promising and deserve further investigation. Furthermore, no comparison was made between the SADI and any other bariatric procedure as secondary procedure after sleeve gastrectomy.

Therefore, this randomized controlled trial aims to determine whether SADI is a feasible alternative to the RYGB, the current gold standard, as secondary procedure for achieving additional weight loss after SG.

Indications for inclusion will be either weight regain, insufficient weight loss or a planned secondary procedure after primary sleeve gastrectomy.

Primary outcome of this study will be weight loss in terms of percentage excess weight loss (%EWL) 2 years after surgery.

Secondary outcome measurements for this study will be other weight loss parameters, peri- and postoperative complications, reduction of obesity-related comorbidities, biochemical changes, gut flora changes, adherence to the bariatric program, dumping syndrome complaints and quality of life.

METHODS AND DESIGN

This single-centre, prospective, randomized controlled, clinical study will be conducted at the Catharina Hospital, in Eindhoven, the Netherlands in both a clinical and an outpatient clinic setting. In- and exclusion criteria for all participants are displayed in Table 8.1. Total follow-up of participants will be two years.

Table 8.1 Inclusion and exclusion criteria.

<ul style="list-style-type: none"> - Age ≥ 18 years - Prior sleeve gastrectomy as primary bariatric procedure at least 18 months ago. - Patients must meet the criteria of morbid obesity at least 18 months after the primary sleeve gastrectomy: <ul style="list-style-type: none"> • Body mass index (BMI) ≥ 40 kg/m² • BMI ≥ 35 kg/m² with persistent obesity-related comorbidities: <ul style="list-style-type: none"> ◦ Diabetes Mellitus type 2 ◦ Hypertension ◦ Hypercholesterolemia ◦ Sleep apnea ◦ Osteo-articular disease - Patient is found eligible for secondary surgery after screening by a dietitian, a psychologist, a bariatric nurse, a bariatric surgeon and a physical therapist. - Written informed consent is obtained. 	<ul style="list-style-type: none"> - Patients with complaints of dysphagia or therapy-resistant gastro-esophageal reflux requiring conversion to RYGB. - Severe concomitant disease (e.g. carcinoma, neurodegenerative disorders) - American Society for Anaesthesiologists (ASA) classification $\geq$ IV - Incapability to participate due to a language problem, illiteracy or financial problems - History of alcohol or drug abuse - Pregnant or lactating female (Women of child bearing potential must take a pregnancy test prior to surgery) - Contra-indication to general anesthesia - The inability to read, understand and/or fill out the questionnaires - Disapproval by the psychologist or the dietician to undergo a secondary procedure due to non-compliance to the bariatric program.
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Primary objective

The primary endpoint of this study will be weight loss, which will be expressed by the percentage of total excess weight loss (%EWL) after a minimal follow-up period of 2 years. Total excess weight is defined as the difference between the weight before primary surgery and the highest healthy weight, which is at a body mass index (BMI) of 25 kg/m². %EWL is calculated as (pre-sleeve BMI – current BMI) / (pre-sleeve – 25) * 100%.

Secondary objectives

There will be a number of secondary endpoints which are listed below:

1. To compare the operative time and textbook-outcome (discharge <2 days and no complications per-operative and in the first 30-days).
Included postoperative complications are surgical complications (anastomotic leakage, bleeding, incidental gastrointestinal perforation), infectious complications (intra-abdominal abscess, pneumonia, urinary tract infection, wound infection, gastroenteritis), major cardiovascular events, venous thromboembolism, anastomotic stenosis, marginal ulcer and postoperative ileus. All postoperative complications are also scored according to the Clavien-Dindo scale.²³ A complication is considered a serious adverse event when the Clavien-Dindo equals 3a (A complication

requiring surgical, endoscopic or radiological intervention not under general anesthesia) or higher.

2. Since several parameters are used worldwide to express the amount of weight loss after bariatric surgery of which some are used to further evaluate additional weight loss:
 - Percentage excessive weight loss after conversion (%EWL after conversion): $(\text{BMI at revision} - \text{BMI at follow-up}) / (\text{BMI at revision} - 25) * 100\%$
 - Total change in BMI (cBMI): pre-sleeve BMI – current BMI
 - Change in BMI after conversion (cBMI after conversion): BMI at revision – current BMI
 - Percentage total weight loss (%TWL): $(\text{pre-operative weight} - \text{current weight}) / (\text{pre-operative weight}) * 100\%$
 - Percentage total weight loss after conversion (%TWL after conversion): $(\text{weight at revision} - \text{weight at follow-up}) / (\text{weight at revision}) * 100\%$
3. To evaluate the improvement or even resolution of any present obesity-related comorbidities (diabetes mellitus type 2, hypertension, dyslipidemia, sleep apnea, osteo-articular disease). All medication use and changes in medication doses will be documented every follow-up moment. Furthermore, laboratory findings will be obtained and analyzed pre-operatively and every 6 months after surgery to ensure they are in normal range.
4. To evaluate any biochemical changes after surgery by means of drawing blood. (Hemoglobin, hematocrit, MCV, ASAT, ALAT, bilirubin, creatinine, sodium, potassium, calcium, phosphate, albumin, lipid spectrum, HbA1c, insulin, C-peptide, methyl malonic acid, vitamin B12, iron, ferritin, folic acid, magnesium, vitamin D, vitamin A, vitamin B1, vitamin B6).
5. To evaluate complaints and/or complications >30 days including dysphagia, gastro-esophageal reflux disease (GERD), defecation problems, the need for re-do surgery for either weight regain, insufficient weight loss or medical complaints, vitamin deficiencies using the biochemical results, and internal herniation GERD will be evaluated by using the Frequency Scale for Symptoms of GERD (FSSG) and dysphagia will be evaluated using a questionnaire designed by Suter et al. assessing food tolerance after bariatric surgery.^{24,25} Patients will be asked to complete this questionnaire on a yearly basis during the study period.
In addition, patients will report on their defecation pattern including frequency and consistency of the stool using the Bristol Stool Chart. All diagnoses and frequencies of internal herniation, vitamin deficiencies, and weight loss complaints will be scored.

6. To evaluate (changes in) quality of life (QoL), objectified by the Research and Development-36 (RAND-36) questionnaire. Additionally, convalescence after surgery will be evaluated with the Surgical Recovery Scale (SRS) questionnaire to evaluate the general postoperative recovery.
7. To evaluate the adherence of the included patients to the bariatric program by keeping records of attendance to the outpatient clinic visits. Furthermore, a record of the number of unscheduled visits will be kept.
8. To evaluate the occurrence of dumping syndrome (DS) complaints. DS will be diagnosed using the Dumping Syndrome Rating Scale (DSRS).
9. To evaluate the possible postoperative changes in the gut flora, providing new opportunities to understand the relationship of the gastrointestinal tract to obesity as well as new therapeutic strategies. Stools will be investigated at four different moments: 1. Before surgery, 2. Four weeks after surgery 3. Three months after surgery and 4. One year after surgery.

Interventions

All procedures will be performed by experienced bariatric surgeons who perform at least 100 bariatric procedures every year.

All patients will be treated peri-operatively according to the hospital-adjusted fast track protocol as earlier described in another manuscript.²⁶ Patients will undergo either conversion from primary sleeve gastrectomy to SADI or RYGB.

Laparoscopic conversion of sleeve gastrectomy to single anastomosis duodenoileal bypass

After achieving pneumoperitoneum by placing a Veress needle in the left upper quadrant of the abdomen, trocars (normally between five and seven) are placed according to the preference of the surgeon.

The procedure is initiated by any adhesiolysis when necessitated using a dissection device. Then, the duodenum is identified, stapled and transected about 2 cm distal to the pyloric valve at the level of the gastroduodenal artery. The ileocecal valve is identified and proximal of it, 300 cm of small intestine are measured backwards, making the common channel. The loop is ascended antecolically and an end-to-side duodeno-ileal anastomosis is constructed using a linear stapler (EndoGIA, Covidien) followed by a running suture (V-Loc, Covidien). The length of the alimentary loop will be measured. The mesenteric defects will not be closed routinely. A leak test of the anastomosis is performed by applying methylene blue over a gastric tube. The procedure is finished by removal of the trocars under sight and closure of the skin.

Laparoscopic conversion of sleeve gastrectomy to Roux-en-Y gastric bypass

After achieving pneumoperitoneum by placing a Veress needle in the left upper quadrant of the abdomen, trocars (normally between five and seven) are placed according to the preference of the surgeon.

The procedure is initiated by any adhesiolysis when necessitated using a dissection device. Then the procedure continues with perigastric dissection of the lesser curvature to enter the omental bursa. Next, a linear 45 mm endostapler (EndoGIA, Covidien) is inserted in the created opening to horizontally transect the stomach to create a gastric pouch. In case of sleeve dilatation, the pouch is resized vertically towards the angle of His, along a 34 Fr gastric tube. The small bowel is brought up towards the newly created gastric pouch at a length of 60-80 cm from the point of Treitz. At this point, a gastrojejunostomy is constructed using a linear stapler (EndoGIA, Covidien) followed by a running suture (V-Loc, Covidien). Next, an enteroenterostomy is created using a linear stapler (EndoGIA, Covidien) and a running suture between the small bowel proximal to the gastrojejunostomy and a point of small bowel 150 cm distally from the gastrojejunostomy. The length of the common channel will be measured. The mesenteric defect will be closed routinely. A leak test of the proximal anastomosis is performed by applying methylene blue over a gastric tube.

The procedure is finished by removal of the trocars under sight and closure of the skin.

Allocation

When it is not technically possible to perform SADI during surgery, RYGB will be performed instead and vice versa. These patients will remain in their initial allocated group for statistical analysis in accordance with the intention-to-treat principle.

When neither a SADI nor RYGB is technically possible, another bariatric procedure will be performed or the procedure will be cancelled as the surgeon's wishes and the patient will be excluded from the study.

Participant timeline

An overview of the enrolment, interventions, assessments and visits for participants is shown in Figure 8.1. Most of the assessments are during the visits at the outpatient clinic.

Sample size and recruitment

Results on %EWL for SADI after primary sleeve gastrectomy or SADI-S are still scarce, but are currently reported to be between 72% and 98%.^{20,27} According to a recent report by Carmeli et al comparing BPD/DS and RYGB as secondary procedure after sleeve gastrectomy, the mean %EWL after SADI is 80% and the mean %EWL after RYGB is 65.5%.¹⁸

Combining these findings combined with the fact that the SADI is considered a simplified version of the BPD/DS, it is hypothesized that the mean %EWL after SADI will be approximately 80%.²⁸ Mean %EWL after RYGB is set at 65.5%, based on the reports by Carmeli et al.

Current sample size was calculated according to a continuous outcome superiority design. The significance level (alpha) was set at 0.05 and the power (1-beta) was set at 0.90. Mean outcomes are 65.5% in the control group and 80% in the experimental group. The standard deviation was set at 15%. Using these settings, sample size calculation shows that a total sample size of 46 patients is required, which means 23 patients per group. Taking a 10% dropout into account, the aim is to include 50 patients.

In this, well over 3,000 primary sleeve gastrectomies have been performed up to 2017 and the annual number is still increasing. A number of these patients are expected to return over the next years with complaints of either weight regain, insufficient weight loss or to assess the indication for a planned secondary procedure.¹³⁻¹⁵ These patients will be considered for inclusion in the current study when revisional surgery is indicated to achieve additional weight loss.

Considering the weight regain percentages reported in previous literature (5.4%-29%) within five years, it can be expected that at least 50-100 patients will return annually. An inclusion period of 24 months should be sufficient to include the number of patients needed. A ten percent dropout rate is taken into account.

Randomisation

Patients willing to enter the bariatric program as well as the current study, will be randomized at the outpatient clinic by the attending physician. Computerized randomization for allocation of the treatment group will take place through the trial website after verification that all inclusion criteria and none of the exclusion criteria have been met. Then, written informed consent will be obtained by the attending physician.

	Enrollment	Allocation	Post-Allocation									Close-out	
	Preoperative Screening	Preoperative Consult	Surgery T ⁰	1 m T ¹	2 m T ²	3 m T ³	4 m T ⁴	10 m T ⁵	12 m T ⁶	16 m T ⁷	22 m T ⁸	24 m T ⁹	
ENROLLMENT													
Study information	X												
Eligibility screening	X												
Informed consent		X											
Allocation		X											
INTERVENTIONS													
Sleeve to SADI			◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	
Sleeve to Gastric bypass			◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	
ASSESSMENTS													
Outpatient clinic visit	X	X		X	X		X	X	X	X	X	X	
Weight registration	X	X		X	X		X	X	X	X	X	X	
Complication registration		X		X	X		X	X	X	X	X	X	
Medication registration		X		X	X			X	X	X	X	X	
Physical examination		X		X	X			X	X	X	X	X	
Assessment comorbidities		X			X				X	X		X	
RAND-36		X							X	X		X	
DSRS		X					X		X			X	
SRS				X			X						
FSSG		X							X			X	
Food tolerance questionnaire		X							X			X	
Blood tests		X								X	X		
Stool sample		X		X		X				X			

Figure 8.1

Randomisation will take place at the moment of the scheduling of the procedure and the patient will be informed immediately on the outcome of the randomization. Randomization will be performed by one of the bariatric surgeons, who will be the only ones who will have access to the trial website besides the main investigators. Participants will be given as much time as they desire to consider their decision. In case of extra questions, an independent doctor is available to answer them. Patients are also asked for their consent to keep record of their medical data after the 2-year study period. This is already a standard procedure at the Obesity Centre. These data can then be used for long-term follow up studies.

No blinding is performed.

Adherence

To evaluate the adherence of the included patients to the bariatric program, records will be kept of whether or not patients have attended the outpatient clinic visits. Reminders will be sent to patients both by phone and by mail to increase the adherence to the study protocol.

It is believed that proper follow-up of patients after bariatric surgery will increase the likelihood of sufficient weight loss. Therefore, a record will be kept of the number of missed outpatient clinic appointments.

Statistical analyses

All data will be handled confidentially and anonymously. All patients are given a subject identification code which will be linked to the data of the subject in case it is found necessary to trace data to an individual subject. The code is not based on the patient's initials or birth date. The code is based on the order in which the patient is enrolled in the study.

The key to the code is safeguarded by the principal investigator. The handling of personal data is done in accordance with the Dutch Personal Data Protection Act.

All data will be stored on CCM, the study section of the eHealth environment of BePatient, an online patient platform used by the Catharina hospital's Obesity Center. This section is not accessible by any of our patients. All data is stored securely and can only be accessed with one code which is only available to the principal investigator. One file with a unique study number will be provided per patient.

SPSS version 24, for Windows (SPSS Inc, Chicago, IL, USA), will be used for the management and analysis of all data.

The data of the randomized patients are analysed according to the intention-to-treat principle. Total follow-up will be two years after surgery. The regular post bariatric program will be continued after two years up till five years after surgery.

Continuous variables that are normally distributed will be presented as a mean with standard deviations. Skewed continuous variables will be presented as median with interquartile ranges (IQR). Variables measured on a nominal or ordinal scale are summarized as an amount (n) with a percentage as total of the investigated group.

Differences in baseline characteristics, as well as differences in operative time, hospital stay will be univariately tested. Continuous, normally distributed variables are tested with the unpaired Student's *t*-test. Non-parametric Mann-Whitney U test is performed in case of skewed continuous variables. In case of nominal or ordinal variables, Chi-square test (or Fisher's exact test, when appropriate) is performed. Differences in overall mortality rates and disease-specific mortality rates over time between RYGB and SADI will be evaluated with Kaplan-Meier analysis and tested with the log rank test. Differences in continuous measurements over time (SRS outcome, DSRS outcome and RAND-36 outcome), %TWL, %EWL, cBMI and biochemical changes between RYGB and SADI will be expressed as mean ($\pm$ standard deviation) or median (IQR).

Differences in rates or proportions over time (proportion of patients with %EWL ≥ 50 , peri- and postoperative morbidity rates, readmission rates, short- and long-term complication rates, improvement/resolution rates of obesity-related comorbidities and the need for re-do surgery between RYGB and SADI are expressed as (cumulative) incidence rates or (cumulative) incidence density rates. Reasons/causes for secondary surgery are analysed in a similar way (e.g. psychological reason, technical reasons).

A subgroup analysis is performed similarly to the method as described above. Subgroups will be patients with weight regain versus patients with insufficient weight loss after primary SG.

Monitoring

The investigator will submit a summary of the progress of the trial to the accredited Medical Ethics Research Committee (MERC) once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

When a serious adverse event (SAE) occurs, the principal investigator will be notified within 24 hours by email or telephone. The investigator will report the

SAEs through the web portal *ToetsingOnline* to the accredited MERC that approved the protocol, within 15 days after the investigator has first knowledge of the serious adverse events.

An SAE not listed above will be recorded in an overview list that will be submitted periodically to the MERC (once every 6 months).

All involved physicians will periodically be asked to report any adverse events caused by the current study protocol. These events will be listed and discussed.

The monitoring board can ask for a full report on any adverse event in order to discuss a specific event. A copy of this report will be sent to the central ethics board and to the involved physicians.

All deceased patients will be evaluated by the safety board for cause of death and possible trial related serious adverse effects. Every death will be reported to the central ethics board and the local ethics board.

Ethical considerations

The current study will be conducted according to the principles of the Declaration of Helsinki (eighth version, October 2013) and in accordance with the Medical Research Involving Human Subjects Act.

In accordance with the legal requirements in the Netherlands an insurance policy is closed. This insurance provides cover for damage to research subjects through injury or death caused by the study.

All patients will be properly informed and a written informed consent is obtained before they will be included in the trial. They all consent to the fact that their medical data will be used anonymously for publication.

An approval of the hospital's MERC is currently in progress.

DISCUSSION

As discussed earlier, sleeve gastrectomy is currently one of the most performed procedures with good long-term results.²⁹ The downfall is an increasing amount of failure in terms of acceptable weight loss. Often, patients show weight regain and a great portion of those patients undergo revision.^{13,14,16}

There is very limited data on the long-term follow-up after sleeve gastrectomy, but since the absolute number of sleeve gastrectomies is rapidly increasing, it is expected that the number of patients necessitating revisional surgery will increase too. Nowadays, RYGB is considered the golden standard for revision of a failed sleeve gastrectomy, however more data with disappointing results have recently been published.^{30,31}

Therefore, new alternatives are being explored. The first data on the SADI appear promising, but require further investigation.²⁰

This trial aims to answer whether SADI achieves superior weight loss (in terms of percentage total body weight loss) results compared to RYGB after primary sleeve gastrectomy. Furthermore, this study aims to clarify a number of other outcomes as described in the Methods section of this manuscript.

For example, there is very little known about the biochemical changes after SADI. Since SADI is a malabsorptive procedure, vitamin deficiencies are likely to occur.

Standard issues such as postoperative complications, improvement of obesity-related comorbidities, convalescence and quality of life are investigated as well. An issue important to patients may be functional complaints such as dumping syndrome, which is one of the functional concerns after RYGB. It is expected that these complaints will be significantly less after SADI, mainly due to the preservation of the pyloric sphincter, but to our knowledge, no evidence is currently available on this issue.

More and more evidence shows that good postoperative support is associated with an increase in weight loss and an improvement in comorbidities.^{32,33}

Therefore, adherence to the program will be taken into account in this study as well.

A relative new field within weight reduction therapy are changes in the gut microbiota. It has been shown that the gut microbiome may change after bariatric surgery and affect weight loss, but more data is needed on this subject and data on changes after a revisional bariatric procedure is scarce.³⁴

In conclusion, the aim of this study is to investigate whether SADI is a superior alternative to RYGB as revisional procedure after primary sleeve gastrectomy in terms of additional weight loss. Additionally, this study attempts to further discover many unknown elements of the SADI.

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PART TWO

**Early complications in
bariatric surgery**

CHAPTER 9

Predictors for the occurrence of major complications after primary Roux-en-Y gastric bypass surgery

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Minerva Chirurgica. 2016;71(5):286-92

ABSTRACT

Background

The risk of developing postoperative complications after primary Roux-en-Y gastric bypass (RYGB) is relatively low. Nevertheless, postoperative complications can have serious consequences in terms of severe morbidity and health care costs. Identification of potential predictors is useful for further reduction of the postoperative complication rate.

Methods

This retrospective study included all patients undergoing primary RYGB between January 2010 and December 2013, using data from a prospectively collected database. Patients' characteristics, operative details and perioperative outcome were analyzed.

Results

A total of 773 patients (14.5% male) were included for analysis, with a mean age of 42.1 ± 10.4 years and a mean Body Mass Index of 42.8 ± 4.3 kg/m². A total of 66 (8.5%) direct postoperative complications occurred. Clavien-Dindo grade 3a and higher occurred in 55 patients. Univariate analysis identified age ($p=0.013$), gender ($p=0.017$), BMI over 50 kg/m² ($p=0.096$), hypertension ($p=0.099$), chronic obstructive pulmonary disease ($p=0.002$) and previous upper gastrointestinal surgery ($p=0.095$) as potential predictors. Multivariate logistic regression analysis showed that male gender (OR 2.412; 95%CI [1.212-4.797]) and chronic obstructive pulmonary disease (COPD) (OR 3.716; 95%CI [1.543-8.949]) were found to be independent predictors for the occurrence of major complications after primary RYGB.

Conclusions

This study showed a number of potential predictors, of which male gender and (COPD) after multivariate regression analysis were found to be independent predictive factors for the occurrence of major complications after primary RYGB.

INTRODUCTION

For the treatment of morbid obesity, surgery has proven to be the most effective therapy as it results into long-term weight loss, an improved lifestyle and improvement of any obesity-related comorbidities.¹ Nowadays, there are many surgical options, of which Roux-en-Y Gastric Bypass (RYGB), Sleeve Gastrectomy and Adjustable Gastric Banding are performed most frequently.² Of these procedures, RYGB is currently still considered the gold standard. Even though the risk of serious postoperative complications following RYGB is relatively low, the high number of performed procedures results in a high absolute number of complications.³⁻⁵ Due to these large numbers, associated costs will certainly impact health care economy. Therefore, identifying potential predictors is important.

In 2011, the Michigan Bariatric Surgery Collaborative showed in a large retrospective that previous venous thromboembolism, mobility limitations, coronary artery disease, pulmonary disease, male gender, smoking history, age over 50 and procedure type are associated with an increased risk for the development of postoperative complications after bariatric surgery.³ Stenberg et al. have shown that age, additional operation, intraoperative adverse events and conversion to open surgery lead to a higher risk at serious postoperative complications. Furthermore, the complication risk was affected by the annual hospital volume to the prejudice of hospitals in a learning curve at the time of the operation.⁴

Other studies largely report on the same predictive factors, however results are sometimes contradictory.^{3,4,6-10}

Even though a number of studies have been published, this study aimed to identify potential risk factors for the development of major complications in the 30-day postoperative period after primary laparoscopic Roux-en-Y Gastric Bypass for further clarification of previous findings and possibly finding new predictive factors.

METHODS AND DESIGN

Since 2010, data on all patients undergoing bariatric surgery at the Catharina hospital, Eindhoven, the Netherlands, were collected prospectively in an online database. In this database, patient characteristics, operative details, complications and follow-up on weight loss and comorbidities were collected. For the current study, all patients undergoing primary Roux-en-Y gastric bypass (RYGB) between January 2010 and December 2013 were included. All early

postoperative complications <30 days after primary RYGB were registered. Postoperative complications included surgical complications (anastomotic leakage, bleeding, incidental gastrointestinal perforation), infectious complications (intra-abdominal abscess, pneumonia, urinary tract infection, wound infection, gastroenteritis), major cardiovascular events, venous thromboembolism, anastomotic stenosis, marginal ulcer and postoperative ileus. All postoperative complications were classified according to Clavien-Dindo.¹¹ Primary outcome of this study were all major complications. A complication was considered major when the Clavien-Dindo equaled 3a (A complication requiring surgical, endoscopic or radiological intervention not under general anesthesia) or higher. All complications were diagnosed by the physician in charge at the time of the complication. The event was registered into the hospital's electronic system as well as the severity of the complication and later checked by two of the authors. The Clavien-Dindo depended on the treatment administered according to the hospital's electronic files.

Demographic and intra-operative variables included for analysis were age, gender, Body Mass Index (BMI), smoking, use of any alcohol, obesity-related comorbidities (diabetes mellitus type 2, hypertension, dyslipidemia, sleep apnea and osteo-articular disease), gastroesophageal reflux disease, chronic obstructive pulmonary disease, cardiovascular disease, previously performed upper gastrointestinal surgery, American Society of Anesthesiologists (ASA)-classification, the use of a fast track protocol versus the conventional protocol, operative time and occurrence of intra-operative complications. Additionally, age ≥ 50 years and BMI ≥ 50 kg/m² were taken into account to separately analyze the older bariatric patient and the super-obese bariatric patient.

COPD is an obstructive lung disease including symptoms like shortness of breath, and coughing with the production of sputum and was considered when diagnosed by a general practitioner or a pulmonologist using a spirometry test. Cardiovascular disease was considered when the patient had a history myocardial infarction and/or underwent a percutaneous coronary intervention (PCI).

Treatment

All morbidly obese patients attending the outpatient clinic were screened and discussed by a multidisciplinary team, consisting of dietitians, nurse-practitioners, psychologists and surgeons. When necessary, patients underwent a preparatory course before bariatric surgery.

In earlier patients, follow-up was planned for one year after surgery, after which the patient was referred back to the general practitioner. Since the end of 2011, bariatric patients in this center undergo a structured five-year follow-up

program with multiple visits to the outpatient clinic every year, including appointments with dietitians, nurses-practitioners, psychologists and bariatric surgeons.

Procedure

Patients were planned for surgery when they met the international guidelines for bariatric surgery as provided by the International Federation for the Surgery of Obesity and metabolic disorders (IFSO).

All patients planned for a laparoscopic primary Roux-en-Y gastric bypass were selected in the current study. Since 2011, patients are treated according to an implemented fast track protocol and by fixed operating room teams.¹² Before then, patients received the conventional care. The surgery was performed by one of five expert bariatric surgeons, each performing well over fifty bariatric procedures per year.

Surgery was started by administering general anesthesia to the patient. The patient received thrombosis prophylaxis by 5000 units of low-molecular weight heparin. After adequate pre-oxygenation, induction is performed by the use of piritramide (0.2-0.3 mg/kg), Suxamethonium 1.0-1.5 µg/kg and propofol (2mg/kg) and the patient is intubated thereafter. During surgery, remifentanyl is administered at a constant rate of 5-15 µg/kg/hour for analgesic maintenance. Anesthetic depth is maintained with desflurane (6.0% vol.) in expired air. After completion of the anesthesia, the patient is placed in a reversed Trendelenburg position and the surgical procedure was initiated.

After insufflation of the abdomen using a Veress needle and the introduction of both the trocars and the camera, construction of the gastric bypass was initiated by creation of the gastric pouch using a stapler (EndoGIA; Covidien, New Haven, CT, USA). After completion of the pouch, the alimentary loop was pulled in an antecolic position, after which the antegastric end-to-side gastrojejunostomy was constructed by linear stapling (EndoGIA; Covidien, New Haven, CT, USA) and sutures using Polysorb™ sutures until 2010 and V-Loc™ (Covidien, Mansfield, MA, USA) since the beginning of 2011. The alimentary loop measured an estimated 150-180 cm. The created biliopancreatic loop was estimated 60-80cm. The end-to-side jejunojunctionostomy was created, also using a stapling device (EndoGIA; Covidien, New Haven, CT, USA) and sutures (Covidien, Mansfield, MA, USA). Closure of the mesenteric defects was not performed routinely. The procedure is finished by removal of the trocars under sight and closure of the skin.

Statistical analysis

Data was managed and analyzed using SPSS version 22 (Windows; IBM Corporation, Armonk, NY, USA). Univariate associations between major complications and demographic covariates were analysed using Chi-square test and Fisher's exact test or independent samples *t*-test or Mann Whitney U-test. Covariates showing a trend towards significance for developing a major complication ($p < 0.1$) were considered for multivariable logistic regression analysis. Covariates displaying more than 1% missing values were excluded for multivariable regression analysis. A *p*-value < 0.05 was considered significant. Quantitative data are denoted as mean $\pm$ standard deviation (SD). Complications and evolution of comorbidities are presented as a percentage. Odds Ratio (OR) and 95% confidence intervals (CI) were provided when applicable and considered significant when OR [95% CI] $\neq 1$. Summative figures and tables were used when applicable.

No ethical approval was required for this study. Permission was granted by the Institutional Review Board for this retrospective study. All patients gave their informed consent for the prospective registration of their data in a large registry and the use for this study.

The described work has been carried out in accordance with the guidelines of the Declaration of Helsinki for experiments involving human subjects.

RESULTS

A total of 773 patients (85.5% female) underwent primary laparoscopic Roux-en-Y gastric bypass. Mean age was 42.1 ± 10.4 years and the mean preoperative BMI was 42.8 ± 4.3 kg/m². The mean highest recorded BMI was slightly higher at 44.4 ± 4.7 kg/m². Obesity-related comorbidities were found in 423 patients (54.7%).

Sixty-six patients (8.5%) developed postoperative complications between day 0 and day 30 after surgery. Intra-operative complications occurred in nine patients (1.2%). Conversion rate was 0.3% ($n=2$) and was performed in both cases due to incidental perforations of the small intestine.

There was no 30-day mortality. The 90-day mortality rate was 0.1%; One patient died at day 70 day following RYGB due to an acute pulmonary hemorrhage after a complicated postoperative course due to a leakage of the jejunojejunostomy.

Major complications (Clavien-Dindo $\geq 3a$) were observed in 55 out of 66 complications (7.1%). Details of these events are shown in Table 9.1.

Table 9.1 Major complications <30 days (n=55).

	n (% of total group, n=773)
Anastomotic leakage	
Leakage gastrojejunostomy	15 (1.9%)
Leakage jejunojejunostomy	2 (0.3%)
Bleeding	16 (2.1%)
Gastrointestinal perforation	4 (0.5%)
Intra-abdominal abscess	22 (2.8%)
Pneumonia	3 (0.4%)
Wound infection	2 (0.3%)
Urinary tract infection	2 (0.3%)
Major cardiovascular event	1 (0.1%)
Anastomotic stenosis	4 (0.5%)
Marginal ulcer	2 (0.3%)
Gastro-enteritis	0
Postoperative ileus	0
Venous thromboembolism	0

Demographic and intra-operative parameters compared between patients with major complications and the patients with minor or no complications are shown in Table 9.2.

Multivariate analysis

A logistic regression analysis was performed using the factors (age, gender, BMI ≥ 50 , hypertension, COPD and previous upper gastrointestinal surgery) that were found to be significantly associated with occurrence of major complications in the univariate analysis (as is shown in Table 9.2). In this analysis, male gender (OR 2.412; 95%CI [1.212-4.797]) and COPD (OR 3.716; 95%CI [1.543-8.949]) were found to be independent predictors for the occurrence of major complications after primary RYGB, as is shown in Table 9.3. One-hundred and thirty two patients (17.1%) were identified with one of the two factors. Only seven patients were found to have both independent predictive factors (0.9%).

Learning curve

Learning curve may have been a confounder in the occurrence of major complications following RYGB. Therefore, the first cohort of 100 operated patients from the current study population were compared with the rest of the patients (n=673).

Mean operative time (83.2 ± 27.6 minutes vs 61.2 ± 14.0 minutes; $p < 0.001$) and mean hospital stay (3.7 ± 8.9 days vs 2.4 ± 3.3 days; $p < 0.001$) were significantly longer in the first 100 patients. The number of intraoperative complications

(3.0% vs. 0.9%; $p=0.099$) and postoperative major complications (6.0% vs. 7.3%; $p=0.642$) did not differ significantly between groups.

Table 9.2 Patient characteristics (n=773).

	MC (n=55) Mean $\pm$ SD n (%)	No MC (n=718) Mean $\pm$ SD n (%)	p-value	Missing values (n [%])
Age (years)	45.4 $\pm$ 9.8	41.8 $\pm$ 10.4	0.013	0
Age over 50 (n)	20 (36.4%)	176 (24.5%)	0.052	0
Gender (male : female)	14: 41	98 : 620	0.017	0
Body Mass Index (kg/m ²)	43.3 $\pm$ 4.7	42.8 $\pm$ 4.3	0.397	0
BMI over 50 kg/m ² (n)	7 (12.7%)	47 (6.5%)	0.096	0
Smoking (n, %)	16 (29.1%)	148 (20.6%)	0.130	9 (1.2%)
History of smoking	34 (61.8%)	305 (42.5%)	0.004	9 (1.2%)
Use of any alcohol (n, %)	14 (25.5%)	230 (32.0%)	0.479	23 (3.0%)
Pre-operative comorbidities (n, %)				
Type 2 Diabetes Mellitus	18 (32.7%)	165 (23.0%)	0.101	0
Hypertension	24 (43.6%)	235 (32.7%)	0.099	0
Dyslipidemia	15 (27.3%)	137 (19.1%)	0.141	0
Sleep apnea	7 (12.7%)	80 (11.1%)	0.720	0
Osteo-articular disease	8 (14.5%)	113 (15.7%)	0.815	0
Gastroesophageal reflux disease (n, %)	22 (40.0%)	242 (33.7%)	0.343	0
Chronic obstructive pulmonary disease (n, %)	8 (14.5%)	26 (3.6%)	0.002	0
Cardiovascular disease (n, %)	3 (5.5%)	44 (6.1%)	1.000	0
Previous upper gastrointestinal surgery (n, %)	12 (21.8%)	98 (13.6%)	0.095	0
ASA (n)				
I	1 (1.8%)	21 (2.9%)	1.000	0
II	47 (85.5%)	634 (88.3%)	0.530	0
III	7 (12.7%)	63 (8.8%)	0.327	0
Conventional Care : Fast track Care (n)	5 : 50	59 : 659	0.799	0
Operative time (min)	68.6 $\pm$ 27.7	63.7 $\pm$ 17.0	0.461	1 (0.1%)
Intra-operative complication	2 (3.6%)	7 (1.0%)	0.130	0
Polysorb suture : V-Loc suture	5 : 50	59 : 659	0.799	0

MC: major complication

Table 9.3 Results of logistic regression analysis (n=773).

	Beta (SE)	Significance	Odds ratio	95% CI for Odds Ratio	
				Lower	Upper
Age	0.022 (0.016)	0.171	1.022	0.991	1.054
Gender	0.880 (0.351)	0.012	2.412	1.212	4.797
Body Mass Index $\geq$ 50 kg/m ²	0.782 (0.454)	0.085	2.186	0.897	5.325
Hypertension	0.043 (0.322)	0.894	1.044	0.555	1.964
Chronic obstructive pulmonary disease	1.313 (0.448)	0.003	3.716	1.543	8.949
Previous upper gastrointestinal surgery	0.625 (0.361)	0.083	1.869	0.921	3.793
Constant	-3.985 (0.677)	< 0.001	0.019		

SE: standard error

DISCUSSION

The aim of this study was to identify risk factors that may be predictive for the occurrence of major complications (Clavien-Dindo $\geq 3a$) following RYGB. The international Clavien-Dindo classification for surgical complications was chosen to score the postoperative complications to create a better comparison tool for other studies.¹¹ The main finding in this study was that male gender and COPD are significantly associated with the occurrence of major complications after primary RYGB.

The fact that male gender was found to be an independent risk factor for major complications confirms results of previous reports while keeping in mind that the scoring of the postoperative complications differed between these reports and the current study.^{7,8} Be that as it may, Stenberg et al. showed no significant predictive value for gender after primary RYGB for serious postoperative complications (Clavien-Dindo $\geq 3b$).^{3,4,7}

Previous findings also support the current result that COPD was identified to be an independent predictive factor for the occurrence of major complications after primary RYGB.⁽³⁾ Be that as it may, the question remains to what extent this is caused by the actual COPD and what the involvement is of (history of) smoking, as it is one of the main risk factors for the development of COPD and is furthermore related to the occurrence of postoperative complications after RYGB.^{3,13} Besides that, assessment of collinearity between history of smoking and pulmonary diseases (including COPD) would have been important before including both parameters in the regression analysis. From a more practical point of view, it would be very interesting to see whether pre-operative cessation of smoking would decrease the risk of developing a major complication after surgery. Unfortunately, the current study was not designed to assess this hypothesis, so further research is necessitated.

In the current study population, postoperative complications were identified in only 8.5% of all patients, which is comparable with previous literature.^{3,4} A total of 55 major complications (7.1%) were identified, of which anastomotic leakage, bleeding and intra-abdominal abscesses were the most common. The in-hospital mortality rate (0.1%) was comparable with previous literature.^{3,4,6,9,14,15}

A number of demographic parameters were analyzed for their potential predictive value on the occurrence of major complications. In previous studies, age has shown to be an independent significant predictor for serious complications.^{3,4} The current study did not identify age as an independent predictive factor.

BMI was not found to be a risk factor for postoperative complications, however patients with a BMI ≥ 50 kg/m² showed a trend towards more major complications ($p=0.096$) in comparison to patients with a lower BMI. Previous

studies showed inconsistent results on the value of BMI towards postoperative complications.^{3,4,7}

The obesity-related comorbidities (type 2 diabetes mellitus, hypertension, dyslipidemia, sleep apnea and osteo-articular disease) had no predictive value in the occurrence of major complications. Hypertension was identified as potential predictor, but appeared to have no independent predictive value according to the regression analysis ($p=0.894$), however has been described before as risk factor for postoperative morbidity.⁷

The current study showed that patients who had previous upper gastrointestinal surgery show a trend towards more major complications. No previous studies were found on this matter. Data on the effect of previous upper gastrointestinal surgery (such as cholecystectomy) on the occurrence of (serious) postoperative complications after RYGB is scarce. Some studies show an increased need for adhesiolysis, potentially resulting in a prolonged operative time, conversion to open surgery, an increased incidence of wound infection and prolonged hospital stay.^{16,17} Further research is needed to delineate the effects of previous (upper abdominal) surgery on postoperative outcomes following RYGB.

The use of conventional care or fast track care was taken into account. Fast track care may be a protecting factor for the occurrence of postoperative complications as it aims to reduce the stress response and organ dysfunction and thereby shortening the time required for full recovery.¹⁸ This result was not reproduced by the current study. Furthermore, it remains the question whether fast track care may rather influence the speed of functional recovery and a faster return to work than the occurrence of postoperative complications.

Also other perioperative factors (operative time and intra-operative complications) showed no significant predictive value for the occurrence of major complications. Conversion to open procedure was not taken into account as a predictive factor as it was embedded in the intra-operative complications.

The occurrence of postoperative or even major complications events may very well be surgeon or hospital dependent due to an inadequate level of experience.^{4,19-21} It seems unlikely that the occurrence of complications in this study population is dependent on an individual learning curve, as all procedures were performed by experienced bariatric surgeons, each performing at least 50-100 procedures every year. Additional analysis was performed to assess the hospital's experience, which did not influence the occurrence of intra-or postoperative complications.

This study, among others, is necessary to identify factors that may increase the risk of complications so proper strategies can be implemented to reduce future postoperative complications to a minimum.

The most important limitation of the current study is relative small amount of patients. Even though a total of 773 patients were included for the current analysis, a larger number of patients is preferable in the search for predictors of major complications after RYGB, since the complication rate after RYGB is relatively low.^{3,4,20,21} Another limitation for the current study is the retrospective design, causing a limited registration of possible predictors. Coexisting conditions such as depression or hepatic conditions could not be scored due to insufficient registration.

In conclusion: This study showed a number of potential predictors, of which male gender and COPD after multivariate regression analysis were found to be independent predictive factors for the occurrence of major complications after primary RYGB.

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CHAPTER 10

Transection versus preservation of the neurovascular bundle of the lesser omentum in primary Roux-en-Y gastric bypass surgery

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Surg Obes Relat Dis. 2016;12(2):283-9

ABSTRACT

Background & Objectives

A gastric pouch in Roux-en-Y gastric bypass (RYGB) surgery can be created after transection of the perigastric neurovascular bundle or by preserving these structures. Some surgeons choose to transect the neurovascular bundle (NBT), containing branches of the vagus nerve, since this might be related to additional weight loss, others advocate preservation (NBP) to reduce postoperative complications. This study assessed the effect of both techniques after primary RYGB.

Setting & Method

All patients undergoing primary RYGB in a large bariatric center in the Netherlands between January 2010 and December 2013 were included. Patient demographics, operative details, postoperative complications and weight loss after one year were retrospectively analyzed.

Results

A total of 773 consecutive patients were included (85.5% female). NBT was performed in 407 patients (52.7%), whereas NBP was performed in 366 patients. There were no missing data and 81.2% of patients completed the 1-year follow-up.

Postoperative complications were found in 66 patients (8.5%). A total of 49 patients (6.3%) either had an anastomotic leakage, postoperative bleeding or intra-abdominal abscess (NBT 8.8% vs. NBP 3.6%, $p=0.003$). Percentage total body weight loss (NBT $34.5\pm6.9\%$ vs. NBP 33.4 ± 6.9 ; $p=0.011$) differed to a lesser extent between groups, although this was significant.

Neurovascular bundle transection was identified as independent factor amongst others for occurrence of leakage, bleeding and abscess development (OR 2.886; 95%CI [1.466–5.683]; $p=0.002$).

Conclusions

Transection of the neurovascular bundle in RYGB is associated with more complications. Furthermore, weight loss is not relevantly increased. Further research is necessitated to substantiate these findings.

INTRODUCTION

Roux-en-Y gastric bypass (RYGB) is preferred by many for the treatment of morbid obesity, as it results in good long-term weight loss and an improvement in obesity-related comorbidities.^{1,2} Even though the postoperative complication rate is low after primary RYGB, the absolute number of complications still has a serious effect on health care costs.^{3,4} To create the pouch, the omental bursa has to be exposed for placement of the stapler. This can be done by transecting the neurovascular bundle containing branches of the vagus nerve and the left gastric artery and vein.⁵ Alternatively, this bundle can be preserved by creating an entry point via perigastric dissection.

There are some potential benefits of vagotomy or vagal nerve blocking in the treatment such as enhanced satiety, reduced food intake and additional weight loss. However, these studies are performed in patients with normal abdominal anatomy or rats.⁶⁻⁸ The first studies mentioned the potential benefits of vagotomy as a treatment for morbid obesity.^{7,9,10} However, more recent studies showed no difference in percentage weight loss between transection and preservation after RYGB in humans, whereas earlier, a postoperative difference in weight loss in favor of vagus nerve preservation was found in rats.¹¹⁻¹⁴ No differences in postoperative complications were found.¹²⁻¹⁴ In terms of other effects lesser neurovascular bundle transection establishes a higher dumping symptomatology after RYGB compared to lesser omental preservation.¹²

It remains unclear how transection or preservation of the perigastric neurovascular bundle may affect the postoperative course and weight loss after RYGB-surgery. Therefore, the aim of this study is to assess the effect of neurovascular bundle transection (NBT) versus neurovascular bundle preservation (NBP) on the short-term course after RYGB.

METHODS AND DESIGN

All patients undergoing primary Roux-en-Y gastric bypass surgery for the treatment of morbid obesity between January 2010 and December 2013 were included. A prospective database containing patient's characteristics, operative details, postoperative complications and follow-up, including weight loss and the evolution of any present comorbidities was used. One-year follow-up was considered for all patients. Long-term complications were not taken into account in the current study due to the short period of follow-up. All patients underwent follow-up after six weeks, six months and one year. For each follow-up, weight loss and evolution of any known comorbidities were registered. For

the current study weight loss rates and the outcome of comorbidities after one year were included in the analysis.

Main outcome for this study was the occurrence of postoperative complications.

All complications were scored and additionally rated according to the Clavien-Dindo classification for surgical complications.¹⁵ A Clavien-Dindo score of 3a or higher was considered a serious adverse event. As the occurrence of gastrojejunal anastomotic leakage, postoperative bleeding or intra-abdominal abscesses may directly be related to the type of technique used (transection or preservation of the neurovascular bundle). Transection of gastric vessels may lead to an increase of postoperative bleeding and potentially compromise the blood supply to the newly created gastrojejunal anastomosis in certain cases. Furthermore, abscess formation may also be reflected minor leakage of the gastrojejunal anastomosis or represent an infected hematoma.. Therefore, these complications were combined and considered the primary outcome for this study. Patients with more than one complication were counted as one complication to prevent overrepresentation.

The obesity surgery mortality risk score (OS-MRS) was included for pre-operative assessment of the mortality risk.¹⁶

Postoperative weight loss was defined in three different ways: change in Body Mass Index (cBMI), percentage total body weight loss (%TBWL) and percentage excessive weight loss (%EWL). Total %EWL was defined as a percentage of the amount of excess weight lost, in which excess was defined as the difference between the weight before surgery and the highest healthy weight, which is at a Body Mass Index (BMI) of 25 kg/m².¹⁷

The evolution of the comorbidities was categorized into four different stages: stable, improved (reduced amount of medication used, improved lab results and/or a lower setting of a Continuous Positive Airway Pressure-device), resolved (no treatment and normalized lab results) and worse (opposite of improved). Any new comorbidities were registered, but were not taken into account in the analysis of the evolution of comorbidities.

Treatment

All patients underwent a preoperative screening at the outpatient clinic to assess whether or not they were qualified for a bariatric procedure. Every patient had to meet the standard IFSO guidelines for bariatric surgery. Patients were discussed in a multidisciplinary team consisting of a surgeon, a psychologist, and a dietitian.

Follow-up of the patients used to consist of one year guidance at the hospital by the bariatric team, containing a psychologist, a dietitian and a surgeon. After

one year, follow-up was performed by a general practitioner. At the end of 2011, follow-up changed to a structured 5-year program with multiple appointments at the outpatient clinic with the surgeon, obesity nurse, dietitian, psychologist and physical therapist.

Procedure

All patients were planned for a RYGB by laparoscopic approach. Nowadays, patients are treated according to the fast track anesthesia protocol care, which was started in 2011. Before 2011, patients received the conventional anesthesia protocol care. Fast track care aims to reduce stress response and organ dysfunction after surgery and thereby greatly shorten the time required for full recovery.^{18,19}

Surgery was performed by one of six different expert bariatric surgeons, each performing well over 50 bariatric procedures each year. The procedure started with creation of the gastric pouch using Endo GIA™ staplers (Covidien, New Haven, CT, USA).

Neurovascular bundle transection (NBT) included transection of the lesser omentum using a linear stapler (Endo GIA™ (Covidien, New Haven, CT, USA)). Preservation of the neurovascular bundle established by entering the omental bursa via perigastric dissection approximately 5-6 cm distal of the esophagogastric junction. The dissection was performed directly adjacent to the gastric wall until the omental bursa was entered, thereby taking care that the anterior and posterior nerves of Latarjet were preserved.²⁰ The two different techniques were simultaneously used over the inclusion period. Whether the neurovascular bundle was transected or preserved depended on the preference of the operating surgeon.

After creation of the pouch, an end-to-side antecolic, antegastric gastrojejunostomy was constructed by linear stapling (EndoGIA™ (Covidien, New Haven, CT, USA)) and running suture. The alimentary loop measured an estimated 150-180 cm. The biliopancreatic loop was between 60 and 80 cm. A jejunio-jejunostomy was created, also by linear stapling and running suture. Mostly, the procedure was finished by closing the mesenteric defect.

Statistical analysis

All data for the current study were collected prospectively and analyzed retrospectively. Management and analysis was performed using SPSS version 22 for Windows (IBM Corporation, Armonk, NY, USA). Quantitative data are denoted as mean +/- standard deviation (SD). Complications and evolution of comorbidities are presented as a percentage.

Dependent on the type of variable, either student *t*-test or Mann Whitney U-test was used to determine any statistical significance between the observed differences among groups. A multivariate analysis was performed to identify potential predictors for the occurrence of either anastomotic leakage, postoperative bleeding or an intra-abdominal abscess. Differences were considered significant in case of a *p* value less than 0.05. Odds Ratio (OR) and 95% confidence intervals (CI) were provided when applicable and considered significant when OR (95% CI) $\neq$ 1. Summative figures and tables were used when applicable. Permission was granted by the Institutional Review Board for this retrospective study. Informed consent was obtained for prospective registration in a large registry by all patients.

RESULTS

A total of 773 patients (85.5% female) were included in the current study with a mean age of 42.1 ± 10.4 years and a mean BMI of 42.8 ± 4.3 kg/m². In 407 (52.7%) patients, the neurovascular bundle was transected (NBT) and in 366 (47.3%) patients, the neurovascular bundle was preserved (NBP). Apart from gender (more men in the NBP group) and the distribution between conventional care and fast track care, patient characteristics did not differ significantly between the two groups, as shown in Table 10.1. All patients were planned for a laparoscopic approach. The conversion rate was 0.3%.

In the postoperative 30-day period, a total of 66 patients developed complications (8.5%). There was no 30-day mortality. Mortality rate after one year was 0.4%. Three patients died during this period, of which one was RYGB-related (0.1%). This patient died during hospital admission after 70 days after an acute pulmonary hemorrhage. The postoperative course was initially complicated by leakage of the jejuno-jejunostomy. One patient died due to severe sepsis caused by a combination of pneumonia and a urinary tract infection, almost eight months after surgery. The third patient died from the consequences of metastasized vaginal carcinoma.

A total of 18 anastomotic leaks (2.3%) occurred, requiring surgical reintervention in 15 cases (83.3%). Hemorrhage occurred in 16 patients (2.1%), of which 14 patients (87.5%) required a surgical reintervention. In three patients, active bleeding was identified (two at the gastrojejunal anastomosis, one at the minor omentum, all after NBT). In 11 patients, only blood clots were found around the gastrojejunal anastomosis along with a significant postoperative decrease in hemoglobin levels of more than 2.0 mmol/L. In the other two cases, active intraluminal bleeding at the site of the gastro-

jejunostomy was managed with clipping via gastroscopy. Fifty-five out of 66 postoperative complications were considered to be a serious adverse event. Details on the perioperative and postoperative complications, Clavien-Dindo classification and weight loss after 1 year is shown in Table 2, stratified between NBT and NBP.

Table 10.1 Patient characteristics (n=773).

	NBT n=407 Mean ± SD	NBP n=366 Mean ± SD	p-value
Age (years)	42.0 ± 10.5	42.2 ± 10.2	0.803
Age ≥ 50 (n, %)	103 (25.3%)	93 (25.4%)	0.974
Male : Female (n)	74 : 333	38 : 328	0.002
Body Mass Index (kg/m ²)	42.7 ± 4.3	42.9 ± 4.4	0.642
Body Mass Index ≥ 50 (n, %)	27 (6.6%)	27 (7.4%)	0.686
Highest Body Mass Index (kg/m ²)	44.3 ± 4.7	44.5 ± 4.8	0.348
Pre-operative comorbidities (n, %)			
Diabetes Mellitus type 2	101 (24.8%)	82 (22.4%)	0.431
Hypertension	137 (33.7%)	122 (33.3%)	0.923
Dyslipidemia	79 (19.4%)	73 (19.9%)	0.852
Sleep apnea	53 (13.0%)	34 (9.2%)	0.101
Osteo-articular disease	71 (17.4%)	50 (13.7%)	0.148
Gastro-esophageal reflux (n, %)	133 (32.7%)	131 (35.8%)	0.362
History of smoking (n, %)	183 (45.0%)	156 (42.6%)	0.631
Previous upper gastrointestinal surgery (n, %)	60 (14.7%)	50 (13.7%)	0.668
ASA-classification (n, %)			
I	12 (2.9%)	10 (2.7%)	
II	361 (88.7%)	320 (87.4%)	0.774
III	34 (8.4%)	36 (9.8%)	
Conventional Care vs. Fast track Care (n)	23 : 384	41 : 325	0.005

NBT: neurovascular bundle transection; NBP: neurovascular bundle preservation; ASA: American Society of Anesthesiologists

A total of 49 patients (6.3%) either had gastrojejunal anastomotic leakage, postoperative bleeding or an intra-abdominal abscess, of which 36 patients (8.8%) in the NBT group versus 13 patients (3.2%) in the NBP group ($p=0.003$). Six out of 16 patients (37.5%) with gastrojejunal anastomotic leakage also developed an intra-abdominal abscess. One patient with postoperative bleeding developed an intra-abdominal abscess. No patient developed a gastrojejunal anastomotic leakage after a postoperative bleeding in this study.

Table 10.2 Peri- and postoperative outcome (n=773).

	NBT n=407 Mean ± SD	NBP n=366 Mean ± SD	p-value	Missing data n (%)
Operative time (min)	67.7 ± 19.2	60.0 ± 15.5	0.001	1 (0.001%)
Hospital stay (days)	2.6 ± 3.2	2.5 ± 5.5	<0.001	0
Intraoperative complications (n, %)	7 (1.7%)	2 (0.5%)	0.183	0
Postoperative complications (n, %)	44 (10.8%)	22 (6.0%)	0.017	0
Anastomotic leakage (n, %)	13 (3.2%)	5 (1.4%)	0.092	0
Leakage gastrojejunostomy (n, %)	11 (2.7%)	5 (1.4%)	0.193	0
Leakage enteroenterostomy (n, %)	2 (0.5%)	0	0.501	0
Bleeding (n, %)	11 (2.7%)	5 (1.4%)	0.193	0
Gastro-intestinal perforation (n, %)	1 (0.2%)	3 (0.8%)	0.350	0
Intra-abdominal abscess (n, %)	18 (4.4%)	6 (1.6%)	0.026	0
Pneumonia (n, %)	4 (1.0%)	1 (0.3%)	0.377	0
Wound infection (n, %)	2 (0.5%)	0	0.501	0
Urinary tract infection (n, %)	0	2 (0.5%)	0.224	0
Gastro-enteritis (n, %)	0	1 (0.3%)	0.473	0
Major cardiovascular event (n, %)	0	2 (0.5%)	0.224	0
Anastomotic stenosis (n, %)	2 (0.5%)	2 (0.5%)	1.000	0
Marginal ulcer (n, %)	4 (1.0%)	1 (0.3%)	0.377	0
Postoperative ileus (n, %)	1 (0.2%)	0	1.000	0
Readmission (n, %)	31 (7.6%)	13 (3.6%)	0.015	0
Clavien-Dindo 1 (n)	0	1	0.473	0
Clavien-Dindo 2 (n)	7	3	0.348	0
Clavien-Dindo 3a/3b (n)	32	16	0.045	0
Clavien-Dindo 4a/4b (n)	4	2	0.689	0
Clavien-Dindo 5 (n)	1	0	1.000	0
Serious Adverse Events (Clavien-Dindo ≥3) (n, %)	37 (9.1%)	18 (4.9%)	0.024	0
Change in Body Mass Index (kg/m ²) after 1 year	14.8 ± 3.4	14.3 ± 3.4	0.010	145 (18.8%)
% Total Body Weight Loss (%TBWL) after 1 year	34.5 ± 6.9	33.4 ± 6.9	0.011	145 (18.8%)
% Excess Weight Loss (%EWL) after 1 year	85.7 ± 19.5	83.2 ± 20.3	0.123	145 (18.8%)

NBT: neurovascular bundle transection; NBP: neurovascular bundle preservation.

Comorbidities

Improvement/resolution rates after one year for the entire study population for diabetes mellitus type 2, hypertension, dyslipidemia, sleep apnea and osteo-articular disease were 99.3% (140/141), 88.7% (189/213), 84.7% (105/124), 97.0% (64/66) and 76.5% (78/102), respectively. The number of comorbidities differed from those at baseline, as 628 of 773 patients (81.2%) completed the 1-year follow-up. Comorbidities of the mentioned 628 patients were included for the 1-year improvement/resolution rates.

Operating surgeon

Table 10.3 presents the number of procedures per year for each surgeon. Besides the number of RYGBs, each surgeon performed at least an equivalent amount of sleeve gastrectomies and a number of bariatric re-do procedures (data not shown). Differences in number of complications are assessed per year between the surgeons and also shown in Table 10.3.

The occurrence of either gastrojejunal anastomotic leakage, bleeding or intra-abdominal abscess during the current study period was not different between the surgeons ($p=0.376$).

Table 10.3 Complications and procedures per surgeon (n=773).

	A	B	C	D	E	F	<i>p</i> -value
2010	1/41	1/8	1/15	0	0	0	0.164
2011	2/76	0/31	5/60	0	0	5	0.295
2012	3/63	3/53	12/69	0/12	2/37	13	0.093
2013	3/82	1/25	7/64	4/50	3/50	19	0.473
NBT	0	116	205	13	55	18	
NBP	261	1	1	50	34	19	

Surgeon D: Started at end of 2012; Surgeon E: Started 2012; Surgeon F: Started at end of 2011, also performs bariatric procedures at another hospital; NBT: neurovascular bundle transection; NBP: neurovascular bundle preservation

Multivariate analysis

A univariate analysis (shown in Table 10.4) on the occurrence of anastomotic leakage, postoperative bleeding or intra-abdominal abscess, showed Age ($p=0.011$), Age ≥ 50 ($p=0.026$), presence of dyslipidemia ($p=0.006$), a history of smoking ($p=0.009$), neurovascular bundle transection ($p=0.003$) and OS-MRS ($p=0.021$) as potential predictor. OS-MRS, Dyslipidemia, History of smoking and neurovascular bundle transection were included in the multivariate analysis. Even though operating surgeon was not predictive for these complications ($p=0.376$), this was also included in the analysis to further assess the influence of the operating surgeon on the occurrence of either gastrojejunal anastomotic leakage, bleeding or intra-abdominal abscess.

The multivariate analysis is shown in Table 10.5, which identified transection of the neurovascular bundle (OR 2.983; 95% CI [1.442–6.171]; $p=0.003$) and History of smoking (OR 2.115; 95% CI [1.147–3.903]; $p=0.016$) as independent predictive factors for occurrence of anastomotic leakage, or postoperative bleeding or intra-abdominal abscess after primary RYGB.

Table 10.4 Univariate analysis (n=773).

	Complications n=49 Mean $\pm$ SD	No complications n=724 Mean $\pm$ SD	p-value
Age (years)	45.7 $\pm$ 9.6	41.9 $\pm$ 10.4	0.011
Age $\geq$ 50 (n, %)	19 (38.8%)	177 (24.4%)	0.026
Male : Female (n)	10 : 39	102 : 622	0.224
Body Mass Index (kg/m ²)	43.1 $\pm$ 5.0	42.8 $\pm$ 4.3	0.626
Body Mass Index $\geq$ 50 (n, %)	7 (14.2%)	47 (6.5%)	0.072
Highest Body Mass Index (kg/m ²)	44.2 $\pm$ 4.9	44.4 $\pm$ 4.7	0.637
Pre-operative comorbidities (n, %)			
Diabetes Mellitus type 2	17 (34.7%)	166 (22.9%)	0.061
Hypertension	22 (44.9%)	237 (32.7%)	0.081
Dyslipidemia	17 (34.7%)	135 (18.6%)	0.006
Sleep apnea	5 (10.2%)	82 (11.3%)	0.810
Osteo-articular disease	9 (18.4%)	112 (15.5%)	0.589
Gastro-esophageal reflux (n, %)	22 (44.9%)	242 (33.4%)	0.101
History of smoking (n, %)	30 (61.2%)	309 (42.7%)	0.009
History of thrombo-embolic events	0	10 (1.4%)	1.000
Previous upper gastrointestinal surgery (n, %)	11 (22.4%)	99 (13.7%)	0.089
ASA-classification (n, %)			
I	1	21	
II	41	640	0.376
III	7	63	
Conventional Care vs Fast track Care (n)	4 : 45	60 : 664	1.000
Obesity surgery mortality risk score (n)			
Class A	26	516	
Class B	23	207	0.021
Class C	0	1	
Neurovascular bundle transection vs preservation	36 : 13	371 : 353	0.003

Table 10.5 Results of logistic regression analysis (n=773).

	Beta (SE)	Significance	Odds ratio	95% CI for Odds Ratio	
				Lower	Upper
Obesity surgery mortality risk score	0.523 (0.331)	0.114	1.687	0.881	3.229
Dyslipidemia	0.546 (0.354)	0.123	1.727	0.862	3.458
Neurovascular bundle transection	1.093 (0.371)	0.003	2.983	1.442	6.171
Operating surgeon	-0.059 (0.120)	0.624	0.943	0.746	1.192
History of smoking	0.749 (0.312)	0.016	2.115	1.147	3.903
Constant	-4.491 (0.592)	<0.001	0.011		

CI: Confidence Intervals; SE: Standard error.

Post-hoc power analysis

Due to the retrospective and exploratory nature of this study, a post-hoc power analysis was conducted to calculate the power in accordance to the primary outcome measure. Primary outcome was the incidence of either gastrojejunal

anastomotic leakage, postoperative bleeding or intra-abdominal abscess. A type I error rate (α) was set at 0.05. This calculation showed a statistical power of 90.8%.

DISCUSSION

Until now, impact of neurovascular bundle transection or preservation in primary Roux-en-Y gastric bypass surgery was elusive. Some studies claim that transection is safe and efficient because it does not influence clinical, functional and laboratory results or even affect weight loss in an early stage and may technically alleviate gastric pouch formation.^{8,14,21} Other studies show that vagus nerve preservation is associated with less postoperative dumping and reduced food intake.^{11,12} However, the impact on the early postoperative course was often unclear.

Current results showed that neurovascular bundle transection was an independent predictive factor for anastomotic leakage, postoperative bleeding or intra-abdominal abscess formation after RYGB. Additionally, a small significant difference was seen in %TBWL and change in BMI after one year in favor of neurovascular bundle transection. A potential explanation may be the transection of both the left gastric artery and the left gastric vein. Hypothetically, transection of these vessels may compromise the blood supply to the newly created gastrojejunostomy, thereby increasing the risk of an anastomotic leakage. Furthermore, transection of these large blood vessels may hypothetically increase the chance at postoperative bleeding.

Male gender was significantly different between groups but did not influence the occurrence of anastomotic leakage, postoperative bleeding or intra-abdominal abscess development. This is in contrast with previous studies showing that male gender is a predictor for postoperative complications after primary RYGB.^{3,4} Operative time was marginally increased in the NBT group. This may be either explained by the higher number of intra-operative complications, even though this was not significant, or it may reflect the fact that transection of the neurovascular bundle is a more time-consuming procedure than preservation of this anatomical structure. Furthermore, hospital stay was longer in the NBT group, most likely explained by the higher number of postoperative complications in this group.

Nonetheless, the exact mechanism underlying the observed differences in the postoperative complication rate between patients undergoing neurovascular bundle transection and patients in which the neurovascular bundle was preserved remains uncertain.

When observing the results in Table 10.2, an increased occurrence of intra-abdominal abscesses is observed in the NBT group. Besides the technical aspects that may lead to an increased abscess formation in patients undergoing neurovascular bundle transection, activity of the (abdominal) vagus nerve also is involved in regulating local and systemic inflammation.^{22,23} Interestingly, recently published data showed that the vagus nerve has an important regulatory role in inflammation during liver abscess formation in hamsters. Vagotomy disrupted the inflammatory response in this study and increased abscess formation in these hamster livers.²⁴ To what extent this will be similar in the human body is unclear and further research is necessitated to substantiate these findings.

A possible confounding factor may have been the operating surgeon's experience. However, as all operating surgeons perform well over 50 bariatric procedures (including gastric bypasses, sleeve gastrectomies and bariatric redo procedures) every year in this large bariatric center, this seems unlikely. A univariate analysis showed that the operating surgeon was not predictive for the occurrence of postoperative complications in this study population ($p=0.376$). Furthermore, Table 10.5 shows that in a multivariate analysis, operating surgeon is not predictive for the occurrence of gastrojejunal leakage, postoperative bleeding or intra-abdominal abscess.

The number of readmissions was higher in the NBT group, but can be explained by the higher number of postoperative complications in this group since not all complications occur during primary admission.

The rationale for transection of the neurovascular bundle is mainly based on the idea that it may provide some additional weight loss and that this technique may support a more straightforward method of gastric pouch creation.^{6,7,21,25,26} Both %TBWL and cBMI were significantly higher in the NBT group. Since the groups showed a comparable BMI at baseline, this study supports the idea that vagotomy induces additional weight loss after primary RYGB. Be that as it may, the difference between the two groups, although significant, seems clinically irrelevant since the difference only involves one or two kilograms of additional weight loss after one year. Furthermore, the exact effect of limb lengths in this population remains unclear since the limb lengths differed between 150 and 180 cm and were estimated, not measured. This also applies for gastric pouch size.

There are some caveats to the current study design. First, this study is prone for bias due to the retrospective setup. Selection or randomization bias may have occurred, since the technique for gastric pouch creation depended on the operating surgeon. On the other hand, this is less likely since patients were not selected to be seen by a specific surgeon, but received an appointment with the first surgeon available. Secondly, due to the current study design, it remains

unclear what factor of neurovascular bundle transection causes the increase in postoperative complications. A number of potential factors have been discussed, but further research is necessary to substantiate the actual impact of these factors.

Conclusions

Transection of the neurovascular bundle in RYGB is associated with more complications. Furthermore, weight loss is not relevantly increased. Further research is necessitated to substantiate these findings.

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CHAPTER 11

A specifically designed stent for anastomotic leaks after bariatric surgery: Experiences in a tertiary referral hospital

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Obesity Surgery. 2016;26(8):1875-80

ABSTRACT

Background

Management of anastomotic leakage after either laparoscopic Roux-en-Y Gastric Bypass (LGBP) or laparoscopic Sleeve Gastrectomy (LSG) remains a burden. Various options are available for the treatment of these leaks. A newer and less invasive option for the treatment of leaks is the use of endoluminal stents. The main drawback for this treatment is stent migration. The current study describes the outcome of a new, specifically designed stent for the treatment of anastomotic leaks after bariatric surgery.

Methods

For this retrospective observational study, medical charts of patients undergoing bariatric surgery between October 1, 2010 and July 1, 2013 were reviewed. All patients with anastomotic leakage, treated with the bariatric Hanarostent, were included.

Results

Twelve patients were included out of a total of 1702 bariatric patients in the described period. Seven had a leakage after LSG, five after LGBP. An average of 2.4 endoscopic procedures and 1.25 stents were used per patient. Successful treatment was seen in nine out of 12 patients (75%). Most common complication was dislocation or migration of the stent, occurring in eight patients (66.7%).

Conclusions

The ECBB Hanarostent®, which was specifically designed for post bariatric leakages, shows equal but not favorable success rates in this small series compared to previous reports on other types of stenting techniques. Despite the stent design, the complication rate is not reduced and the main future goal should be to target the high stent migration rate.

INTRODUCTION

Obesity remains a global burden. For the treatment of morbid obesity, bariatric surgery has been the superior option for many years as it achieves good long-term weight loss, reduction of cardiovascular risk factors, improvement of obesity-related comorbidities and improved lifestyle.¹⁻³

With an increasing number of procedures worldwide, it can be expected that the absolute number of complications after bariatric surgery will increase as well, even though these are relatively safe interventions. A recently published large study by Sanni et al. showed an average morbidity rate after laparoscopic gastric bypass (LGBP) of 5.1% and 1.4% after laparoscopic sleeve gastrectomy (LSG).⁴ The occurrence of anastomotic leakage, a major complication after either LGBP or LSG is, respectively, 1.6-4.8% and 1.7-2.4% as reported in more recent literature.⁵⁻⁸ Various options are available for the treatment of these leaks, such as conservative management (e.g. luminal suction via stomach-pump, antibiotic treatment or external drainage), early surgical reintervention, fibrin glue treatment, over-the-scope-clipping and endoluminal stents.⁹⁻¹¹ Until recently, surgical or radiological drainage, dismantling the anastomosis and resuturing of the leakage was the gold standard in case of anastomotic leakage. Be that as it may, performing surgery in a recently operated and infected area remains difficult and may contribute to the occurrence of complications.¹² A less invasive method might be endoscopic stenting, which has its own disadvantages such as stent migration, obstruction, perforation or disintegration.^{13,14} Nevertheless, an increasing number of studies are reporting good results.¹⁵⁻²⁰

More recently, repositionable and removable covered self-expandable metal stents (RReCoMSeS) have been developed, which appear feasible for temporary stenting of fistulae or leaks, however, results after bariatric surgery are still very limited.^{13,14,18,21}

This article describes the results in a series of bariatric patients with anastomotic leakage after either LGBP or LSG treated with the bariatric Hanaro® ECBB stent, a new repositionable and removable stent specifically designed for the treatment of anastomotic leaks after bariatric surgery.

MATERIALS AND METHODS

Patients

For this retrospective observational study, medical charts were reviewed of all patients undergoing bariatric surgery between October 1, 2010 and July 1,

2013. All patients underwent treatment at the Catharina Hospital, Eindhoven, the Netherlands; a tertiary referral center for bariatric surgery.

All patients meeting the official IFSO guidelines for bariatric surgery underwent preoperative screening for eligibility by a multidisciplinary team, consisting of a dietician, a psychologist, a bariatric nurse and a surgeon. Those eligible for surgery were planned for either LGBP or LSG, based on the patients' screening data and their personal preference. All patients undergoing treatment with the new covered Hanaro[®] (M.I. Tech, Seoul, South Korea) ECBB bariatric stent for the treatment of either staple line leakage after sleeve gastrectomy or gastrojejunostomy leakage after gastric bypass surgery were included. The choice for stenting was made when other treatment options had not been successful in closure of the defect.

Materials

Bariatric surgery was performed by laparoscopic approach. The LSG has been described in detail before.⁽⁶⁾ In case of LGBP, a standard Roux-en-Y gastric bypass was performed with an average biliopancreatic loop of 60-80 cm and an estimated alimentary loop of 150-180 cm. An antecolic and antegastric approach was used to create the gastrojejunostomy. All anastomoses were created by a combination of stapling (EndoGIA[®] Covidien, New Haven, CT, USA) and V-loc[®] stitching (Covidien, New Haven, CT, USA).

In case of a suspected anastomotic leakage, the choice was made between additional imaging and a laparoscopic reintervention, mainly based on the clinical presentation of the patient (fever, tachycardia, elevated inflammation parameters, decreasing hemoglobin levels). Either a laparoscopic reintervention or radiological drainage was usually performed before endoscopic stenting was considered.

All patients undergoing endoscopic stent placement received monitored analgosedation using intravenous midazolam and/or fentanyl or propofol. The stent catheter was inserted over a guidewire in the upper gastrointestinal tract next to the endoscope and then released under direct endoscopic view. All patients were primarily treated with the Hanaro[®] ECBB bariatric stent with a length of 24 cm and a width of 30 mm (REF: ECBB-30-240-090). This is a long silicone covered nitinol stent, designed with a bottle-like shaped neck with a narrow lumen for the esophagus (20 mm), a shoulder to a wider lumen of 30 mm to bypass the wide gastric lumen and lassos at both ends to reposition or remove the stent (Figure 11.1).

Figure 11.1 Hanaro® ECBB bariatric stent.

Primary outcome for this study was closure of the defect after stent removal. Secondary outcome were stent-related complications and fistula or stent-related mortality, the number of endoscopies, the number of stents used, number of repositions and the differences in outcome between LSG and LGBP.

Statistical analysis

Data was collected retrospectively using Microsoft Excel 2010 for Windows. SPSS 22 for Windows was used for analysis of the data (SPSS Inc, Chicago, IL, USA).

Quantitative data are denoted as mean (range), whereas mortality rate and complications are presented as a percentage.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Since this is a retrospective study, a formal consent is not required.

Informed consent was obtained from all individual participants included in the study.

RESULTS

Between October 2010 and July 2013, a total of 1702 bariatric procedures were performed. Among this number, a total of 826 sleeve gastrectomies were performed of which 21 (2.5%) were a revisional procedure after earlier bariatric intervention, such as adjustable gastric banding (AGB). Furthermore, 874 gastric bypass procedures were performed, of which 264 (30.2%) were a revisional procedure.

A total of 12 patients (0.7% of all operated patients from that period) were treated with the ECBB bariatric type Hanarostent because of post-surgical leakage. Five were male and seven were female, with a mean age of 43.1 years (range 22-57). Further patient details are shown in Table 11.1.

Table 11.1 Patient characteristics.

Patient (No)	Gender	Age (years)	BMI before surgery (kg/m ²)	Comorbidities*	ASA	Smoking	Previous procedure
1	M	40	54.5	2, 4, 5	3	Yes	No
2	F	48	43.7	1	2	No	VBG
3	M	41	43.7	4	2	Yes	No
4	F	45	40.4	1, 2	2	No	No
5	F	57	56.2	1, 2, 4	2	Yes	No
6	M	39	53.7	None	2	No	No
7	F	56	45.5	1, 3	2	No	No
8	M	22	42.5	None	2	No	No
9	F	43	41.8	1	2	Yes	AGB
10	F	43	36.3	1, 3	2	No	No
11	M	43	47.7	1, 3, 4, 5	2	Yes	No
12	F	40	57.9	None	2	No	No
Mean (range)		43.1 (22-57)	46.99 (36.3-57.9)				

*1: diabetes mellitus type 2; 2: hypertension; 3: dyslipidemia; 4: sleep apnea; 5: osteo-articular disease. BMI: body mass index; ASA: American Society of Anesthesiologists; VBG: vertical banded gastroplasty; AGB: adjustable gastric band

Seven patients had a leakage of the staple line after LSG and five patients had a leakage of the proximal anastomosis after LGBP (two as revisional procedure). The leak was diagnosed after a mean of 8.75 days after surgery (range 3-15) and the stent was placed after an average of 8 days (range 0-24) after diagnosis. All details on the outcome are shown in Table 11.2. All leaks in patients after LSG were found on the proximal side of the staple line, near the angle of His and the esophagogastric junction. Before stent insertion, most patients were treated with another, unsuccessful technique: five patients underwent a second laparoscopic intervention, seven patients underwent CT-guided external drainage and one patient was first treated with over-the-scope-clipping (OTS®, Ovesco, Tübingen, Germany). Only one patient was immediately treated by means of a stent.

The Hanaro® bariatric stent was successful in closing the defect in nine out of 12 patients (75%). A total of 29 stent-related endoscopic procedures were performed and a total of 15 stents were used, resulting in an average of 2.4 procedures per patient (range 1-3) and a mean number of 1.25 stents (range 1-2) used per patient. Successful treatment of the leak was seen in six out of seven LSG patients (85.7%) and in three out of five LGBP patients (60%). Stent-related complications were seen in nine out of 12 patients (75%) involving ten stents (66.7%). The most common complication was migration of the stent, occurring in eight out of 12 patients (66.7%) including 9 out of 15 stents (60%).

Table 11.2 Patient's outcome.

No.	Surgical procedure	Reintervention	Interval diagnosis and stenting	Length/Width (mm)	Clips used (OTSC)	Outcome*	No. of procedures	No. of stents	Stent-related complications	Insertion-removal (days)
1	Sleeve Gastrectomy	Yes	1	240/30	No	I, III, R	3	1	Migration	36
2	VBG to Gastric Bypass	No	1	240/30	No	I, R	2	1	-	40
3	Sleeve Gastrectomy	No	3	240/30	No	I, R	3	1	Migration	45
4	Sleeve Gastrectomy	No	3	240/30	No	I, R	2	1	-	35
5	Gastric Bypass	Yes	16	240/30	No	I, II	2	2	Small bowel perforation	-
6	Sleeve Gastrectomy	No	4	240/30	No	I, II, R	3	2	Migration + Stent rupture	45
7	Gastric Bypass	Yes	0	240/30	No	N, R	1	1	Small bowel perforation	6
8	Sleeve Gastrectomy	No	1	240/30	Yes	I, III, R	3	1	Migration	14
9	AGB to Gastric Bypass	No	21	240/30	No	I, R	2	1	-	28
10	Gastric Bypass	Yes	7	240/30	No	II, N, R	3	2	Migration (2x)	8
11	Sleeve Gastrectomy	No	24	240/30	No	N, R	2	1	Migration	1
12	Sleeve Gastrectomy	Yes	21	240/30	Yes	I, III, R	3	1	Migration	35
Mean (range)			8.75 (3-15)				2.4 (1-3)	1.25 (1-2)		26.6 (1-45)

* I: Overall stenting successful; II: More than one stent necessary; III: Repositioning of the stent; N: Stenting unsuccessful; R: Stent removed; OTSC: Over-the-scope-clipping; VBG: Vertical banded gastroplasty; AGB: Adjustable gastric band.

Three stents were repositioned, six stents were removed and one stent-in-stent technique was used to resolve the stent-related problem. Stent removal was performed by either endoscopy (five) or surgery (one). All migrated stents moved distally, in one case all the way to the terminal ileum. Mean time between placement and removal of a dislocated stent was 2.8 days (range 1-6 days). A small bowel perforation due to the stent was seen in two patients (16.7%), in one case necessitating additional revisional surgery. LSG patients showed more stent-related complications than LGBP patients 85.7% vs 60%). Dislocation of the stent was seen in six out of seven LSG patients (85.7%) and in one out of five LGBP patients (20%). Both small bowel perforations occurred in LGBP patients (40%).

No leakage or stent-related mortality was seen in this study. One patient died six months after surgery due to severe septic shock caused by a pneumonia. Leakage was resolved (confirmed by gastroscopy), however the stent was not yet removed by the time the patient deceased and was taken into account as successful treatment in this analysis.

Stent removal in case of successful and uncomplicated closure of the defect was performed after a mean of 37.8 days (range 28-49).

Four stents showed a technical malfunction (26.7%). Two stents unfolded only partially at the proximal side, one stent showed a 90-degree kinking and one stent was found to be partially ruptured.

DISCUSSION

Anastomotic leakage remains a serious and difficult to treat complication after bariatric surgery, with reported percentages of 1.6-4.8%.⁵⁻⁸ Even higher percentages are reported after revisional surgery (2.8-11.8%).²²⁻²⁴ During the study period, the overall anastomotic leakage rate in this center was around 4%, mostly after revisional procedures. With the development of modern endoscopic devices, such as the newly created Hanaro bariatric ECBB stent®, new alternatives have risen for the treatment of leaks. However, clinical experience with these new devices is limited.

The current study population is too small to make a solid statement of the possible predictive value of the given baseline characteristics on the occurrence of leakage and the influence on the success rate of the Hanaro stent®. The most important is the fact that these patients have to be compared to the general population undergoing bariatric surgery in the current bariatric center and that is not the goal of this manuscript.

Multiple studies have described the effect of stenting for the treatment of leaks after bariatric surgery. The current success percentage of 75% is quite comparable to previously reported percentages between 78-94%.^{11,25-28} The current stent migration percentage of 58% is also similar to the upper limit of previously reported percentages 5-58%.^{11,25-28}

A trend to a higher rate of successful closing of the defect was seen after LSG compared with LGBP in this study as might be expected. Remarkably, LSG patients showed more stent-related complications (all being stent migration) as opposed to LGBP patients, an unexpected finding because the bariatric Hanarostent® was specifically designed for LSG associated leaks.²⁹ No evident explanation was found for the high migration rate.

The main difference between previous studies and the current study, besides the design, appears to be the length and the width of the applied stent. Leenders et al. suggested that stent length may be a risk factor for stent migration, with a longer stent being related to a higher risk, possibly due to pronounced effect of peristaltic movements.²¹ The current report seems to confirm this. Furthermore, the current results show that the use of large-diameter stents does not prevent stent migration in nonstenotic gastrointestinal tract segments. Many other solutions have been tried to reduce the stent migration rate in the past, such as a partially covered design, deployment of multiple stents, anti-migration struts and additional over-the-scope clipping of the stent, but none posed as the definite solution for the prevention of migration.^{15,21,30,31} A partially covered ECBB stent may prevent migration, but stent removal is often more difficult. Stent migration is a problem for which a definite solution remains unclear and keeps necessitating more research.

The results in terms of number of endoscopic procedures, number of used stents and successful removal percentages are in accordance with, but not in favor of previously reported studies about endoscopic stenting of postsurgical fistulae or leaks, including the previously reported data of this center.^{17,21,25,26,28}

Even though LGBP patients showed stent migration in only one out of five patients, two patients showed a small bowel perforation caused by the stent, a serious adverse event with possible severe clinical consequences.

Even though designed for leaks after sleeve gastrectomy, the ECBB Hanarostent® may be beneficial in the future for the treatment of leakage after Roux-en-Y gastric bypass. The reported bowel perforations may be caused by the stent's specific design. Length, diameter and material may have an influence, possibly by kinking of the stent and thereby applying additional pressure to the intestinal wall, increasing the chance of perforation.

This study contains a number of limitations. First of all, this study describes a relatively small series of 12 patients, but is currently the largest to report on the

outcome of the bariatric ECBB Hanarostent[®]. Larger, preferably prospective studies are needed. Another limitation is the heterogeneity of the group, since patients with leakage after either LSG or LGBP were included for analysis. Statistical analysis of LSG versus LGBP was not possible due to the small and heterogeneous group. A third limitation is that the stent was not the first treatment option of the leak in these patients, possibly influencing the outcome of the stent.

Furthermore, the first treatment varied between patients.

Nevertheless, this study shows the potential usefulness of the bariatric ECBB Hanarostent[®] in case of leakage after sleeve gastrectomy with the downfall of a high migration rate. No advantage is seen overall over other types of RReCoMSeS.

Furthermore, this study shows a potential benefit in the use of the bariatric Hanarostent[®] in the treatment of leakage of the gastrojejunostomy after LGBP, with the remark that the occurrence of bowel perforations has to be properly addressed first.

Improvements of the stent's design such as changes in length, diameter, shape and materials appear necessary and should lead to at least a lower migration rate of the stent. A biodegradable and (partially) covered stent, making stent removal unnecessary, may also be favorable.

In conclusion: The ECBB Hanarostent[®], which was specifically designed for post bariatric leakages, shows equal but not favorable success rates (75%) in this small series compared to previous reports on other types of stenting techniques. Despite the stent design, the complication rate is not reduced and the main goal for the future should be to target the high migration rate (58%) after stenting.

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CHAPTER 12

Summary, discussion & future perspectives

12

SUMMARY & DISCUSSION

As stated in the introduction, bariatric surgery is the best therapeutic option for the treatment of morbid obesity in terms of weight loss and a reduction of obesity-related comorbidities, while reducing the lifetime health care costs and elevating the postoperative quality of life.¹⁻⁴

Although the majority of bariatric patients benefit from these positive outcomes, a small but significant amount of patients is confronted with some type of complication. The aim of this thesis was to contribute to the reduction of before mentioned complications by analyzing current results of revisional surgery, finding predictors for complications and assessing the effect of different intra-operative techniques.

Part one

To develop a notion on treating complications in the future, it is essential to have a proper understanding of the past. Therefore, Chapter 1 described the long-term outcome of primary vertical banded gastroplasty (VBG) in 392 patients. With a mean follow-up of 66 months, VBG provided an acceptable mean excess weight loss of 53%, with a 55% improvement of obesity-related comorbidities. Nonetheless, this chapter underlined the major disadvantage of this procedure, with a reported complaint rate of 58% and a total revision rate of nearly 40%. These numbers are similar to previously reported statistics and strengthen the belief to abandon this old restrictive bariatric procedure.⁵⁻⁹ Nowadays, sleeve gastrectomy appears more suitable, as the first reported results are superior to those of the VBG.¹⁰

Even though VBG is abandoned in the Netherlands, an interest should be taken in its anatomical similarities with the more modern banded gastric bypass. The main difference between the two procedures is the presence or absence of the pyloric valve. The results of the older VBG may be helpful in improving the banded gastric bypass, as literature is already reporting a complication rate up to 20%.¹¹

It is becoming more and more clear that the success of bariatric also depends on many psychological factors such as eating behavior.¹² Chapter 2 attempted to find more of these predictors for success or failure. Among others, it identified that successful patients depend less on the procedure than patients who failed. This supports the results presented by Mitchell et al. that proper lifestyle changes may be more important than the bariatric procedure itself for achieving sufficient long-term weight loss.¹³ This chapter showed a few other potential predictors. Unfortunately, the outcome of this study does not provide

the solution for a standard pre- and postoperative psychological evaluation. On the contrary, psychological guidance before and after bariatric surgery needs to be individualized, while keeping track of the major (psychosocial) risk factors associated with failure. Unfortunately, the conclusion remains similar to the majority of other psychological bariatric publications: more (high quality) research is highly needed and current results are inconsistent.¹³⁻¹⁷

After developing an understanding of the primary VBG, the next task was understanding its revisional procedures. Chapter 3 described the results of different revisional procedures after primary failed VBG. Even though the groups in this study were skewed and some of the groups were small, the results were still very clear. The best revisional option after failed VBG is a Roux-en-Y gastric bypass (RYGB) when compared to revision of the VBG or conversion to a sleeve gastrectomy. This study proved a superiority for conversion to RYGB in terms of (additional) weight loss, improvement of obesity-related comorbidities, the occurrence of long-term complaints or complications and the need for additional revisional surgery.

Revision of the VBG or conversion to sleeve gastrectomy should be not be considered as revisional option for failed primary VBG based on these results. These statements are supported by other studies on this subject.^{9,18-20} Therefore, if revision of a failed primary VBG is indicated, it is suggested to only perform a revision to RYGB unless this is technically not possible.

As shown in Chapter 3, RYGB appears to be a feasible and effective option as revisional procedure after VBG. Can this statement be extended to other restrictive procedures such as the adjustable gastric banding (AGB)? The suggestion is supported by previously published literature, which shows good results of RYGB as revision after failed AGB. Furthermore, conversion to RYGB appears to be superior after failed AGB when compared to band revision or conversion to sleeve gastrectomy.²¹⁻²⁴ A drawback is a high postoperative complication rate after revision, as a gastric pouch is created around the old location of the AGB.^{24,25}

Chapter 4 hypothesized that the complication rate may be lower when converting a failed sleeve gastrectomy to RYGB. The thought behind this hypothesis was to further strengthen the believe that AGB should be abandoned as a primary bariatric procedure, besides the high long-term failure rate of this procedure.^{23,26,27} Furthermore, this study investigated the effectiveness of RYGB as revisional procedure after either failed AGB or sleeve gastrectomy (SG).

The results did not support the believe that conversion to RYGB after sleeve is a safer procedure when compared to RYGB after failed AGB as it reported a

similar postoperative complication rate (8.8% vs. 11.8%; $p=0.530$). Although these results suggested a similar effectiveness of RYGB as revisional procedure after either AGB or SG, they should be interpreted with caution. During follow-up, a slight decrease in total weight loss was observed in the SG group compared to an increase in the AGB group. The results in this chapter confirmed that RYGB is a valuable option as revisional procedure after failed AGB, however, it cannot be irrefutably stated that it is as valuable after failed sleeve gastrectomy for achieving additional weight loss.

Keeping the high failure rate of the AGB and the high complication rate after revision in mind, AGB should not be performed routinely as a primary bariatric procedure until reliable selection criteria are developed.^{23,26-28} Nowadays, both SG and RYGB are considered longer lasting and safer bariatric procedures.²⁹⁻³¹

Recently, fast track protocols were introduced to counterattack the increasing demand for bariatric surgery and have proven to be safe and effective.^{32,33}

It is expected that many revisional procedures will be performed over the next years when considering the amount of performed VBG's, AGB's and SG's in the last decades. With the increasing demand for revisional surgery, the question rises whether fast track surgery would be safe in this challenging group of patients. The main goal would be to stabilize or even decrease the significant complication rate. Despite being comparable with previous literature, Chapter 3 and 4 reported a high complication rate between 8-13%.³⁴⁻³⁸

Chapter 5 reported on the results of the use of a fast track protocol in revisional bariatric surgery. This study reported a significant decrease of the postoperative complication rate after implementing the fast track protocol. Based on these results, fast track care is safe to implement in bariatric revisional surgery, potentially reducing health care costs by lowering hospital stay and increasing logistics without increasing the complication rate.^{32,33}

Even though a significantly lower complication rate is reported (19.2% vs. 11.2%; $p=0.038$), caution should be taken in assuming that fast track care decreases the complication rate. Strong confounding factors such as an increased experience of the operating team, the surgeon's learning curve or improved surgical equipment may also be the cause of the reduced complication rate over the years.^{39,40}

When aiming for relief of reflux complaints, RYGB appears to be effective, but the value of RYGB as revision after failed sleeve gastrectomy to achieve additional weight loss, is debatable.⁴¹ Casillas et al. reported similar results as shown in Chapter 4, which is a decline in (additional) weight loss over time after RYGB as revisional for failed primary sleeve gastrectomy.⁴² Yorke et al. reported on the lowest BMI after revision of primary sleeve gastrectomy to RYGB. A

mean BMI of 36.4 kg/m² is reported. Despite the fact that this is lower than the reported BMI after primary sleeve gastrectomy, this is well within range to be called morbid obesity.⁴³ Even though some studies do report good results on RYGB as revisional procedure after failed primary SG, the search for a potentially better alternative has started.

Homan et al. and Carmeli et al. have explored the potentials of the biliopancreatic diversion compared with Roux-en-Y gastric bypass. Even though a higher weight loss is reported, a drawback is that this type of procedure is technically more challenging and may lead to an even higher rate of postoperative complications.^{44,45} Therefore, the single-anastomosis duodenoileal bypass (SADI) was chosen to investigate as an alternative for RYGB after sleeve gastrectomy in Chapter 6. Even though the knowledge on this relatively new procedure is limited, the first results seem promising.^{46,47}

After 12 months, this study showed a slightly higher weight loss and less early postoperative complications in the SADI group, which were not significantly different when compared to the RYGB group. Biggest drawbacks were the limited group sizes and the total follow-up. Based on these limited results, SADI appears to be safer compared to a biliopancreatic diversion in terms of postoperative complications.

Recent studies do support the hypothesis that SADI is a valuable alternative to achieve additional weight loss after sleeve gastrectomy.⁴⁸⁻⁵⁰ The biggest drawback of these results are the retrospective nature of the studies. Good prospective, preferably randomized controlled trials are necessary to place current results into perspective. With the current knowledge of the SADI and the results from Chapter 6 in mind, Chapter 7 reported on a study protocol for a prospective, randomized controlled trial.

Part two

As mentioned before, part two of this thesis focused on postoperative complications after bariatric surgery. Obviously, prevention is the best way to lower the postoperative complication rate. Prevention is based on knowing the risk factors. Chapter 8 reported on predicting factors for the occurrence of major complications (Clavien-Dindo $\geq 3a$) after primary RYGB. Even though the study population was small (only 773 patients), this study identified two independent risk factors: male gender and chronic obstructive pulmonary disease.

It seems unlikely that the male gender itself is a risk factor for the occurrence of postoperative complications, however, the male bariatric population are more often diagnosed with metabolic syndrome. This in turn is correlated to an

increased risk at postoperative complications in bariatric surgery.⁵¹ Is it an option to stabilize or even treat this syndrome before performing bariatric surgery so the postoperative complication rate may be lowered? Recent literature reports on the interactions between gut microbiota, host genetics and the development of metabolic syndrome and even obesity.^{52,53} This knowledge could be used to create a successful dietary treatment, which may even have the potency to transcend the current results of bariatric surgery. To our knowledge, no such treatment is currently available.

The other independent factor found in Chapter 8 was chronic obstructive pulmonary disease (COPD). Since COPD is highly correlated with smoking, it is unknown which of the two caused the increased risk for postoperative complications. Be that as it may, it is always smart to stop smoking. Furthermore, a pulmonologist should be consulted more routinely to diminish any unnecessary risks intra- and postoperatively.

The next step that should be re-evaluated to reduce the risk of postoperative complications, is the surgical procedure itself. In Chapter 9, the primary RYGB was evaluated. More specifically, the transection or preservation of the neurovascular bundle at the lesser curvature of the stomach was evaluated. The results of this study showed that transection of this neurovascular bundle is associated with an increased risk at major postoperative complications (Clavien-Dindo $\geq 3b$) after primary RYGB. As shown in Chapter 9, these results seemed to be independent of the operating surgeon.

Theoretically, these complications are most likely caused by transection of the vein and the artery in the lesser curvature then the abdominal branches of the vagus nerve. Transecting blood vessels does not only mean an increased bleeding risk, but may also contribute to anastomotic ischemia of the gastrojejunostomy, which in turn may cause anastomotic leakage.

It may be quite interesting to know what effect the transection or preservation of these abdominal branches of the vagus nerve will have. Several studies suggest more weight loss in patients undergoing vagotomy or vagal blockade by achieving a faster satiety and reduced calorie intake.⁵⁴⁻⁵⁶ Will this affect the long-term outcome of (primary) RYGB or can proper lifestyle changes prevent this from happening? To our knowledge, there is no available evidence on this subject in 2018. Long-term follow-up of the current study population may provide some of these results.

To prevent every single postoperative complication after bariatric surgery is an illusion. One of most difficult treatable complications is leakage. To make it even more complex, there is a wide variety of treatment options. A more

modern and less invasive method is the use of endoluminal stents, however these stents are confronted with their own limitations such as migration.⁵⁷⁻⁵⁹ Chapter 10 reported on the use of a specifically designed for the treatment of anastomotic leakage after bariatric surgery. Despite the specific design, this study showed comparable results when compared to previous literature.⁶⁰⁻⁶² The treatment of anastomotic leakages after bariatric surgery remains a challenge. Based on current results when compared to other techniques, stenting should remain an option for the treatment in the future, as 75% of all leakages was successfully treated. The main goal in stent treatment is to target the high migration rate which was observed in 8 out of 12 patients in the current study. An option might be the more recently introduced lumen apposing stents.⁶³

FUTURE PERSPECTIVES

Bariatric surgery does not only have many clinical and psychological benefits. It can also lead to significant cost savings to health care systems.¹ Complications after bariatric surgery are known to give a significant increase in health care costs.^{64,65} Reducing the number of complications logically reduces the total health costs.

Not only postoperative complications, but also long-term complications of procedures such as VBG or AGB leads to an increase in total costs. These health care costs are formed by a plurality of components: Properly diagnosing the cause of failure including a proper screening to identify any psychological factors, the increased use of medication to treat complaints, the performance of revisional bariatric surgery when indicated (which in turn has an increased risk at postoperative complications) and many more. In conclusion, the high costs are an additional argument to reduce the number of complications.

Even though many factors have already been identified to contribute to complications in bariatric surgery, new problems could be developing as we speak. Even though the first results of weight loss after primary sleeve gastrectomy seem promising, it is still unknown what the number of long-term complications such as gastroesophageal reflux disease, dysphagia or weight regain will be.^{29,35,66}

As more primary RYGB's are performed every year, it is possible that we will be confronted with more patients reporting long-term failure of the current gold standard, the RYGB.⁶⁷ The next challenge will then be to find the most effective treatment depending on the type of failure: Resizing the pouch, banding of the

gastric bypass, alterations in the limb length or in some cases reversal of the procedure.⁶⁸⁻⁷¹

Furthermore, new procedures such as the SADI may create new cases of failure in the future, which again require the proper treatment.

In conclusion: The search for the perfect bariatric procedure (No complications, sufficient weight loss, no weight regain, no functional complaints, etc.) continues.

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CHAPTER 13

Nederlandse samenvatting

13

NEDERLANDSE SAMENVATTING

De gevolgen van (morbide) obesitas zijn enorm. Obesitas heeft een grote impact op iemands leven en kan leiden tot vroege sterfte, chronische ziekten en hoge gezondheidskosten. Er wordt gesproken over obesitas indien de Body Mass Index (BMI) groter is dan 30 kg/m^2 . Er wordt zelfs gesproken van een pandemie. De laatste cijfers van de World Health Organization (WHO) rapporteren dat 13% van de wereldbevolking obees was in 2016, wat neerkomt op ongeveer 650 miljoen mensen wereldwijd.¹ Een substantieel deel van deze groep mensen heeft zelfs morbide obesitas. Er wordt gesproken van morbide obesitas bij een BMI ≥ 40 of een BMI ≥ 35 met klachten van een of meerdere obesitas gerelateerde aandoeningen. Deze aandoeningen zijn onder andere: diabetes mellitus type 2 (suikerziekte), hypertensie (hoge bloeddruk), hypercholesterolemie (hoog cholesterol), obstructief slaap apnoe syndroom (OSAS, adempauzes tijdens de slaap) en gewrichtsklachten.

Er bestaan veel behandelmogelijkheden voor morbide obesitas, maar momenteel is bariatrische chirurgie (chirurgie met gewichtsverlies als doel) de enige effectieve behandeling op de lange termijn.² Op de lange termijn zorgt het voor een totale gewichtsafname van 16-23% en in een groot deel van de gevallen voor de genezing van obesitas gerelateerde aandoeningen.²⁻⁵

Om uiteenlopende redenen kan een operatie niet het gewenste effect hebben. Er wordt dan gesproken van een complicatie op de lange termijn. Deze complicaties zijn divers; zo kan een patiënt te veel zijn afgevallen, te weinig zijn afgevallen (ook wel een primaire non-responder genoemd) of na goed af te zijn gevallen weer aankomen in gewicht (secundaire non-responder). Daarnaast kan er sprake zijn van blijvende functionele problemen, zoals slikproblemen, maagzuurklachten of voedselintolerantie. In een deel van deze gevallen dient de eerdere procedure te worden omgezet door middel van een nieuwe operatie. Dit wordt ook wel revisiechirurgie of redo-chirurgie genoemd. Als een oude operatie wordt omgezet, wordt er tegenwoordig ook wel gesproken van een conversie. Bijvoorbeeld: Er is een maagband geplaatst met aanvankelijk een goed resultaat. Na een aantal jaar komt de patiënt toch terug omdat er complicaties zijn van de maagband. Er kan dan voor gekozen worden om de band te verwijderen en een gastric bypass uit te voeren. In andere gevallen kan ervoor gekozen worden de bestaande ingreep te reviseren (herzien).

Naast de zojuist genoemde nadelen op de lange termijn (waarbij in een deel van de gevallen revisiechirurgie noodzakelijk is), kunnen er ook complicaties optreden vlak na de operatie. Vaak zijn dit complicaties binnen 30 dagen na de operatie. Zo kan er bijvoorbeeld een nabloeding, een wondinfectie of een naadlekkage optreden.

Dit proefschrift richt zich op deze verschillende complicaties. Het proefschrift is opgesplitst in twee delen. Het eerste deel richt zich op de revisiechirurgie als behandeling van de lange termijncomplicaties na eerdere bariatrische chirurgie. Er wordt meer inzicht verkregen in zowel de gefaalde oude operaties met hun lange termijn complicaties, als in de uitkomsten en veiligheid van de hierop volgende revisieoperaties. Het tweede deel richt zich op de korte termijncomplicaties na een gastric bypass (maagomleiding), waarbij gepoogd is om met diverse methoden de complicaties te verminderen en te behandelen.

Deel een

Revisiechirurgie wordt vooral uitgevoerd als behandeling van een lange termijncomplicatie van een eerdere maagverkleinende ingreep. Om de redenen voor revisiechirurgie beter te kunnen begrijpen, is het essentieel om te begrijpen wat de effecten van de originele bariatrische ingreep zijn. In **Hoofdstuk 2** worden de lange termijnresultaten besproken van de vertical banded gastroplasty (VBG), ook wel bekend als Mason-gastroplastiek, een oudere vorm van obesitaschirurgie welke in de jaren '80 is geïntroduceerd. Met gemiddeld 53% verlies van het overtollige gewicht (ook wel bekend als excess weight loss; EWL) en een verbetering bij 55% van obesitas gerelateerde aandoeningen (diabetes mellitus type 2, hypertensie, hypercholesterolemie, obstructief slaap apnoe syndroom en gewrichtsklachten) zijn de resultaten na een VBG acceptabel te noemen. Het grote nadeel van de VBG wordt echter ook aangetoond in dit hoofdstuk. Maar liefst 58% van de patiënten heeft klachten ontwikkeld na de operatie. Bijna 40% van de onderzochte populatie heeft uiteindelijk een revisieoperatie ondergaan. Dit hoge percentage aan lange termijncomplicaties onderstreept waarom de VBG momenteel niet meer wordt uitgevoerd in Nederland.

De afgelopen decennia is het in toenemende mate duidelijk geworden dat het succes van bariatrische chirurgie ook afhankelijk is van verschillende psychologische factoren, zoals het eetgedrag van een patiënt.⁶ **Hoofdstuk 3** is erop gericht om factoren te identificeren die een goede of juist een slechte uitkomst voorspellen. De uitkomst wordt bepaald door de hoeveelheid gewichtsverlies, waarbij minder dan 50% verlies van het overtollige gewicht als een slechte uitkomst wordt beschouwd. In deze populatie worden een aantal factoren geïdentificeerd als voorspeller van een slechte uitkomst na bariatrische chirurgie. Zo blijkt in de onderzochte populatie dat patiënten met esthetisch hogere verwachtingen minder goed afvielen op de lange termijn. Daarnaast was de hoeveelheid werkverzuim vóór de operatie hoger in deze groep en werd er een hogere afhankelijkheid gezien van de operatie. Dit houdt in andere

woorden in dat deze patiënten meer vertrouwen op het effect van de operatie dan het effect van de leefstijlveranderingen die noodzakelijk zijn.⁷

Zoals al eerder gemeld is het revisiepercentage hoog na een VBG. Omdat de literatuur verschillende opties beschrijft als revisieoperatie van een eerdere VBG, wordt in **Hoofdstuk 4** gekeken welke optie het beste lijkt te zijn in een retrospectieve analyse. De 3 opties die werden onderzocht zijn het herzien van de originele operatie (revisie van de VBG), omzetting naar een sleeve gastrectomie (SG) of een Roux-en-Y gastric bypass (RYGB). De resultaten in deze studie laten duidelijk zien dat de beste revisieoperatie de conversie naar een RYGB is. Deze optie laat namelijk het hoogste gewichtsverlies op de lange termijn, de meeste verbetering van obesitas gerelateerde aandoeningen en de laagste incidentie lange termijncomplicaties zien in vergelijking met de andere twee opties. Gebaseerd op de resultaten uit deze studie wordt dan ook geadviseerd om in het geval van een gefaalde VBG te kiezen voor een omzetting naar RYGB, tenzij dit technisch niet mogelijk blijkt te zijn.

In **Hoofdstuk 5** wordt de hypothese onderzocht of omzetting van een gefaalde maagband, ofwel adjustable gastric band (AGB), naar een RYGB gepaard gaat met een hoger percentage postoperatieve complicaties in vergelijking de omzetting van een gefaalde SG naar een RYGB. Dit zou een extra argument kunnen zijn om de AGB als primaire bariatrische ingreep te verlaten, naast de bekende hoge percentages lange termijncomplicaties.⁸⁻¹⁰ De resultaten laten echter vergelijkbare resultaten zien tussen de twee groepen (omzetting AGB naar RYGB versus omzetting SG naar RYGB). Zo is er een vergelijkbaar percentage postoperatieve complicaties (8.8% versus 11.8%; $p=0.530$), gewichtsverlies en verbetering van obesitas-gerelateerde aandoeningen. Wordt er extra zorgvuldig naar deze resultaten gekeken, dan valt op dat het totale gewichtsverlies in de SG-groep op de lange termijn iets afneemt, in tegenstelling tot de AGB-groep, waar dit juist licht toeneemt. De conclusie uit Hoofdstuk 5 is dat conversie naar een RYGB een goede revisieprocedure is voor een gefaalde AGB. Dit statement kan niet zo hard gemaakt worden voor de omzetting van een gefaalde SG naar RYGB op basis van deze resultaten. Op basis van (extra) gewichtsverlies lijken er andere opties de voorkeur te krijgen, zoals de biliopancreatic diversion met duodenal switch (BPD-DS) of een single anastomosis duodenoileal bypass (SADI, omleiding door middel van één aansluiting van de dunne darm op de twaalfvingerige darm), twee nieuwe types van bariatrische operaties.^{11,12}

Het aantal bariatrische ingrepen neemt wereldwijd nog steeds toe, waarbij de behoefte aan een fast track protocol (programma gericht op een versneld herstel na een operatie) ook steeds verder toeneemt.¹³ Onderzoek heeft aangetoond dat dit veilig is in primaire bariatrische chirurgie.¹⁴⁻¹⁶ Met in 2016

bijna 51.000 verrichte revisieprocedures wereldwijd, een aantal dat nog steeds toeneemt, kan dit echter ook voordelen bieden bij revisiechirurgie.¹³ Daarom wordt in **Hoofdstuk 6** de veiligheid onderzocht van een fast track protocol bij patiënten die een technisch veel lastigere bariatrische revisieprocedure ondergaan. Dit retrospectieve onderzoek rapporteert een significant lager complicatiepercentage sinds de invoer van het fast track protocol bij bariatrische revisiechirurgie. Hierbij moet de kanttekening gemaakt worden dat deze percentages niet alleen beïnvloed zullen zijn door het fast track protocol, maar mogelijk ook door een toegenomen ervaring van het operatieteam, de leercurve van de chirurg en verbeterde chirurgische apparatuur. Desalniettemin mag geconcludeerd worden dat de implementatie van een fast track protocol bij bariatrische revisiechirurgie veilig is.

Zoals reeds vernoemd in Hoofdstuk 5, is het extra gewichtsverlies na een omzetting van een gefaalde SG naar RYGB beperkt. Er lijken betere alternatieven beschikbaar waaronder de BPD-DS en de SADI, maar het bewijs in de literatuur is beperkt.^{11,12,17} In **Hoofdstuk 7** worden in een matched cohort studie de uitkomsten van de SADI als alternatieve revisieprocedure na een gefaalde SG vergeleken met die van de RYGB. Getalsmatig toont dit een iets hoger gewichtsverlies en minder postoperatieve complicaties in de SADI groep wanneer deze vergeleken wordt met de RYGB groep, maar deze verschillen zijn niet statistisch significant. Op basis van deze resultaten kan wel voorzichtig gesteld worden dat de SADI als revisieprocedure minder complicaties lijkt te geven in vergelijking met de beschikbare percentages na BPD-DS. Andere studies suggereren ook een gunstig effect van de SADI als revisieprocedure na een gefaalde SG.¹⁸⁻²⁰ Het grootste nadeel van deze resultaten is het retrospectieve karakter van de studies. Goed prospectief, gerandomiseerd onderzoek is nodig om de kennis van de SADI als revisieprocedure na een gefaalde SG uit te breiden. Mede daarom wordt in **Hoofdstuk 8** een protocolvoorstel voor een prospectieve randomized controlled trial die de effecten vergelijkt tussen de SADI en de RYGB als revisieprocedure na een eerdere SG.

Deel twee

De focus van deel twee van dit proefschrift lag op de vroege complicaties na bariatrische chirurgie. Er wordt over het algemeen gesproken van een vroege complicatie indien deze binnen 30 dagen na de operatie optreedt. Veel onderzoek is al uitgevoerd om het percentage vroege complicaties tot een minimum te beperken, maar er is nog steeds ruimte voor verbetering. Preventie is van belang, omdat bij (morbide) obesitaspatiënten het beloop van een complicatie veel ernstiger kan zijn.

Deze vroege complicaties worden vaak gegradeerd naar ernst van de complicatie met behulp van de Clavien-Dindo classificatie.²¹ Deze classificatie beschrijft de ernst van de complicatie van graad I (simpele wondinfectie) tot aan graad V (dood van een patiënt). Hoofdstukken 9 en 10 zullen zich focussen op de complicaties van graad IIIa (complicatie waarvoor een radiologische, endoscopische of chirurgische interventie zonder algehele narcose noodzakelijk is) en hoger; ook wel serieuze complicaties of 'serious adverse events' genoemd.

Om de hoeveelheid serieuze complicaties te verlagen lijkt preventie het beste middel. Voor een adequate preventie is het identificeren van risicofactoren noodzakelijk. **Hoofdstuk 9** beschrijft een aantal van deze risicofactoren die gerelateerd zijn aan het ontstaan van serieuze postoperatieve complicaties waarvoor minstens een re-interventie (radiologisch, endoscopisch of chirurgisch) noodzakelijk is (classificatie volgens Clavien-Dindo $\geq 3a$). In een populatie van 773 patiënten waarbij een primaire RYGB werd uitgevoerd zijn 2 onafhankelijke risicofactoren geïdentificeerd: het mannelijk geslacht (Gemiddeld een 2,4 keer hogere kans op een complicatie ten opzichte van het vrouwelijk geslacht) en COPD (chronic obstructive pulmonary disease; gemiddeld een 3,7 keer hogere kans op een complicatie ten opzichte van patiënten zonder COPD).

Een van de hypothesen waardoor deze complicaties ontstaan, in dit geval specifiek een naadlekkage, is het doornemen van de neurovasculaire bundel bij de maag, bestaande uit de bloedvoorziening en aftakkingen van de nervus vagus (een van de 12 zogenaamde hersenzenuwen). Dit doornemen is noodzakelijk om de gastrojejunostomie te creëren; de aansluiting tussen de nieuwe (kleinere) maag en de darm. Hierdoor zou een verhoogd bloedingsrisico kunnen ontstaan. Ook zou dit kunnen leiden tot een verhoogd risico op ischemie van de nieuw aangelegde gastrojejunostomie, wat vervolgens weer kans geeft op een naadlekkage. In **Hoofdstuk 10** wordt in een retrospectieve analyse het effect vergeleken van twee technieken: het sparen van deze neurovasculaire bundel versus het doornemen van deze neurovasculaire bundel. De resultaten laten een statistisch significant lager percentage serieuze complicaties zien (Clavien-Dindo $\geq 3a$) in de groep patiënten waarbij de neurovasculaire bundel wordt gespaard. In deze studie lijkt dit resultaat niet af te hangen van de opererend chirurg. In deze studie is niet onderzocht wat het effect van deze twee technieken heeft op de lange termijn in het kader van mogelijke passageklachten, dumpingklachten en het gewichtsverlies.

Een van de lastigst te behandelen korte termijncomplicaties is een naadlekkage. Het is een complicatie die maakt dat patiënten ernstig ziek kunnen worden (sepsis), gaat regelmatig gepaard met het ontstaan van abcessen in de

buikholte en vraagt eigenlijk altijd om een re-interventie (chirurgisch, endoscopisch of radiologisch). De aanpak van dit probleem wordt bemoeilijkt door de grote variatie aan behandelopties. Een modernere en minder invasieve methode voor de behandeling van een naadlekkage is het gebruik van endoluminale stents (stents die geplaatst worden aan de binnenzijde van maag of darmen). Een belangrijk nadeel van deze stents is migratie. **Hoofdstuk 11** beschrijft de resultaten van een specifiek ontworpen stent om dit probleem te voorkomen. De resultaten tonen echter dat ook dit specifieke ontwerp het probleem van stentmigratie (66.7%) niet kan voorkomen en dat het succesvol behandelpercentage van 75% vergelijkbaar is met eerdere literatuur.²²⁻²⁴

In dit proefschrift zijn zowel korte als lange termijncomplicaties onderzocht en daarbij behorende behandelopties. De gevonden resultaten en conclusies leiden tot meer inzicht in welke factoren invloed hebben op de uitkomsten na bariatrische chirurgie. Zij dragen daarmee hopelijk bij aan een betere behandelstrategie welke zal moeten zorgen voor betere uitkomsten na bariatrische (revisie)chirurgie met een verlaging van het aantal korte en lange termijncomplicaties.

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PART THREE

Appendices

VALORISATION

This thesis describes the outcome and safety of revisional surgery as treatment option for long-term complications after primary bariatric surgery, while gaining more knowledge on the older bariatric procedures. Furthermore, this thesis describes some methods to reduce and properly treat short-term complications such as anastomotic leakage. Bariatric surgery is still gaining in popularity, as is shown by the increasing number of bariatric procedures performed annually worldwide.¹⁻⁴

In 2018 in the Netherlands, a total of 11,468 procedures were performed, of which roughly 10% were revisional procedures. At the end of 2018, Angrisani et al. published the global numbers of 2016, describing a total number of 685,784 procedures of which 7.4% (n=50,977) were revisional procedures. This was the first manuscript to separately describe the worldwide number of revisional procedures, which strengthens the believe that revisional surgery is obtaining a larger part in the diverse world of bariatric surgery.¹⁻³

More knowledge is becoming available on the large amount of long-term complications after bariatric surgery, which often required revisional surgery. Even though the older procedures and their complications are rapidly decreasing in volume, a lot is still unknown about these long-term complications in terms of the mechanism of origin, the proper treatment and the risk factors contributing to the occurrence of these complications. Furthermore, more data is needed on the effects and safety of revisional bariatric procedures and all the gathered data will be useful for any future complications in modern or future bariatric procedures. The first part of this thesis provides some support on these issues, which will be discussed below.

Even though bariatric surgery is relatively safe, the high number of performed procedures worldwide results in a high absolute number of complications.⁵⁻⁷

The second part focuses on the challenging issue of lowering the early serious complication rate after primary Roux-en-Y gastric bypass (RYGB) surgery to an all-time low.

Below, the value of this thesis is discussed in separate sections.

Social and economic relevance

Bransen et al. have reported on the additional health care costs of leaks and bleedings after sleeve gastrectomy.⁸ This study reported high costs after a serious complication. These costs were especially high due to prolonged hospitalization and additional interventions.

These numbers should be taken into account when looking at the total number of annually performed bariatric procedures. In case of these large numbers,

even less than one percent reduction in serious complications will cause a significant reduction in total health care costs. Therefore, this thesis has provided data on how to further reduce these serious complications.

The amount of long-term complications is largely dependent on choosing the right primary bariatric procedure. Even though this thesis does not provide a definitive answer on what the best procedure is, it supports abandoning VBG as primary procedure and speculates on the indication of AGB as primary procedure, as it shows a high number of long-term complications. This thesis seems to support the choice for conversion to RYGB in case of failed VBG or AGB, although new alternatives should be explored as well.

Such information has to be taken into account in the decision-making process for the revisional-technique of choice. This in turn will help reducing health care costs as the patient is becoming healthier.⁹

Finally, this thesis has proven that the implementation of a fast track protocol is safe. This protocol potentially reduces health care costs by lowering hospital stay and improving logistics without increasing the complication rate.^{10,11}

Target audience

This thesis targets a broad audience as it contains valuable information for bariatric surgeons, obesity teams, general practitioners (who will eventually perform follow-up of these patients) and other specialists such as endocrinologists and gastroenterologists. This thesis attempts to provide some unity to bariatric experts in treating long-term complications which necessitate revisional bariatric surgery.

All patients currently experiencing complications after restrictive procedures such as primary vertical banded gastroplasty (VBG) or adjustable gastric banding (AGB) can be helped more accurately with the use of the results in this thesis, as it provides some guidelines for clinicians who are being challenged by long-term complications after VBG or AGB.

In case of failed VBG or AGB, this thesis advises to perform a conversion to RYGB when revisional surgery is deemed necessary. Furthermore, VBG should be completely abandoned as primary bariatric procedure. In case of a failed sleeve gastrectomy, more research is required, since this thesis challenges the gold standard of performing conversion to RYGB after failed SG and provides a potentially better alternative which is the Single Anastomosis Duodenal bypass (SADI).

Furthermore, this thesis urges all clinicians to always preserve the neurovascular bundle of the lesser gastric curvature in primary RYGB surgery if technically possible, as it reduces the number of serious adverse events after surgery.

Activities

This results of multiple chapters thesis has been fundamental for the new study design on the effects of SADI vs RYGB as revisional procedure after failed sleeve gastrectomy. It will add valuable information to the draft of a model which may be helpful in easy decision making to choose the correct revisional procedure when indicated.

Innovation

This thesis has shown that VBG is inferior as primary bariatric procedure, supporting previous research. New insights are provided on pre-operative factors that predict long-term success after a bariatric procedure, in this case primary VBG.

This thesis encompasses a study to compare revisional RYGB after either primary AGB or primary sleeve gastrectomy. Furthermore, it includes the first study to prove the safe use of a fast track protocol in the more complicated revisional bariatric procedures and proves that preserving the neurovascular bundle significantly reduces postoperative complications after primary RYGB.

The future

The search for the perfect bariatric procedure is still ongoing, however the focus is slowly turned towards screening, selection of patients and the proper follow-up. With this search, new procedures are bound to be developed, which can cause short- and long-term complications, which in turn may require new treatment strategies.

Currently, the quest for finding the best revisional procedure after SG to achieve additional weight loss is still ongoing. This thesis has suggested a prospective, randomized controlled trial to investigate the effect of SADI after failed SG in the near future. SADI was suggested as a better alternative to achieve additional weight loss, however, present day practice has already caught up with the future. Nonetheless, future research on the SADI is necessary, as the first published results are very promising.¹²

The main aim for future research on long-term complications after failed bariatric procedures should be to provide consensus and hopefully even guidelines on how to treat these challenging complications. This will be challenging nonetheless, as patient characteristics will be very diverse.

Finally, the main aim for bariatric surgery in general may demand more focus on the screening of the patients and the perfect postoperative follow-up.

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DANKWOORD

Een promotieboekje schrijven gaat niet over een nachtje ijs. Daar gaat, of je dat nou wil of niet, veel tijd in zitten. Dat is niet alleen je eigen tijd, maar ook tijd van vele anderen! Er zijn veel mensen die direct en/of indirect een bijdrage hebben geleverd aan de totstandkoming van dit boekje en die wil ik graag bedanken.

Dr. S.W. Nienhuijs

Geachte copromotor, beste Simon, zonder andere mensen tekort te doen ben jij verreweg de belangrijkste persoon in mijn promotietraject geweest. Puur toevallig had je mijn CV uit een stapel getrokken, zo kwamen wij met elkaar in contact. Onze samenwerking begon augustus 2013 en ging van simpel databasewerk naar opzetten van een promotieonderzoek naar samenwerken in de kliniek. Jouw passie voor de wetenschap is bewonderenswaardig, maar ik heb vooral respect voor jouw vermogen om hier 110% voor te geven zonder dat je je andere taken als chirurg, opleider, vader, enz. daarmee tekort doet. Enorm bedankt voor je betrokkenheid, je tomeloze inzet en je grote vertrouwen in mij als onderzoeker en later ook als arts-assistent!

Prof. Dr. J.A.W. Teijink

Geachte promotor, beste Joep. Net na mijn sollicitatie voor de opleiding in september 2017 raakten wij aan de praat over mijn boekje en kwam van het een het ander. Een vaatchirurg als promotor van een boekje over bariatrische chirurgie, daar had ik mijn geld in ieder geval niet op ingezet van tevoren. Gelukkig is de link tussen "Integrated Care" en bariatrische chirurgie groot. Mijn oprechte dank voor de energie die jij samen met Nicole erin hebt gestoken en voor je vertrouwen in mijn boekje.

Prof. dr. Bouvy, prof. dr. Jansen, prof. dr. Greve, prof. dr. Hazebroek en dr. van Dielen

Ik wil jullie, als leden van de beoordelingscommissie, bedanken voor jullie tijd en inzet die jullie in de kritische beoordeling van mijn proefschrift hebben gestoken en voor de deelname aan de verdediging.

Maatschap Chirurgie en Intensive Care Catharina Ziekenhuis

Dank voor de prettige samenwerking en begeleiding in de jaren die ik in het Catharina Ziekenhuis heb door morgen brengen. Ik heb het genoeg gehad veel van jullie te mogen leren.

Bariatrische chirurgen Catharina Ziekenhuis

Jullie wil ik apart bedanken: *Frans Smulders, Jean-Paul de Zoete, Misha Luyer en Gust van Montfort*. Jullie hebben allen een belangrijke bijdrage aan dit boekje als medeauteurs! Dank voor jullie kritische visie en opmerkingen bij de verschillende onderzoeken, ze hebben me enorm geholpen!

Maatschap Chirurgie Viecuri Medisch Centrum

Bedankt voor jullie inzet en zeer fijne samenwerking in het (ruime) jaar dat ik bij jullie als ANIOS heb mogen werken. Dank voor jullie vertrouwen in mij als arts-assistent in aanloop naar de sollicitatieronde voor de opleiding. Mede door jullie reed ik dagelijks met veel plezier van Eindhoven naar Venlo!

Maatschap Chirurgie Máxima Medisch Centrum

Dank voor de leerzame eerste 1½ jaar van mijn opleiding. Jullie laagdrempeligheid, expertise en gezelligheid maken mijn opleiding een feest. Ik kijk ernaar uit om, na een uitstapje naar het MUMC, nog jaren samen te kunnen werken.

In het bijzonder dank aan de bariatrische chirurgen. Jullie betrokken mij al snel bij het lopende onderzoek in jullie kliniek en zijn altijd te porren voor een inhoudelijke discussie, ook over mijn boekje.

Arts-assistenten Catharina Ziekenhuis, Viecuri, Máxima & MUMC+

Ik heb inmiddels de halve regio aan ziekenhuizen gehad, maar dat boekje was de rode draad door al deze ziekenhuizen. Ik wil alle assistenten enorm bedanken met wie ik over de afgelopen jaren in de bovengenoemde ziekenhuizen met veel plezier heb mogen werken.

Obesitascentrum Catharina Ziekenhuis

Aan de werksfeer heeft het zeker niet gelegen tijdens mijn onderzoek. Lieve mensen van het Obesitascentrum, wat zijn jullie fijne collega's om mee te werken en wat hebben jullie mij fijn opgevangen als broekie in 2013. Miranda, Trea, Claudette en Bianca. Dank voor al jullie inzet voor de poli, maar zeker ook voor mijn onderzoek met alle brieven en telefoontjes. Mohammed, Kim, Femke, Marieke A, Willem, Eva, en Bea, jullie hebben fulltime het allerbeste voor met iedere patiënt die het Obesitascentrum binnenloopt, bewonderenswaardig! Dat geldt ook voor alle diëtisten die zich iedere dag inzetten voor een gezond leven. Dan de vele psychologen dit het centrum rijk is, waarvan ik Gerbrand speciaal ga noemen. Dank voor het mogen gebruiken van jouw database en jouw kritische visie bij het artikel over psychologische factoren!

Onderzoekers Catharina Ziekenhuis

Een gezellige werksfeer is cruciaal en daar hebben jullie maximaal aan bijgedragen. Thijs, held. Ook al lagen onze promotieonderwerpen ver uit elkaar, ik ben blij dat wij elkaar hebben gevonden in het stappen op vrijdagavond, eindeloos veel bijnamen, le Bask en het schrijven van een paar van mijn artikelen. Respect voor de manier waarop jij de publicaties er doorheen knalt. Pieter en Yannick, de vaatboys. Dank voor al jullie gezelligheid, collegiale visie en bijdrage aan alle niet-onderzoek gerelateerde activiteiten, zoals de uitjes naar de AH, de bitterballen en de presentaties. Geert, zowel als onderzoeker als arts-assistent een goede collega. Jij hebt net als Thijs je boekje er doorheen geknald. Respect. P.S. Bedankt voor het meebrengen van die drone... Sjaak, mijn bariatriebuddy. Dank je voor jouw wetenschappelijke input en jouw onmisbare bijdrage als 'partner in crime' bij de bezoeken aan al die verschillende congressen. Wenen gaat ons niet vergeten.

Bedankt Teus, Emmeline, Maikel, Emiel, Lindy, David, Saskia en alle andere onderzoekers (en semi-artsen).

Alle overige medeauteurs

Dankjewel voor al jullie inzet voor de verschillende artikelen, deze was onmisbaar. Dr. Gilissen, beste Lennard, bedankt dat ik een van jouw gevorderde onderzoeken af heb mogen maken, ik ben trots op het resultaat.

De Juppies

Bedankt mannen. Jullie zijn als team zowel op het veld als buiten het veld een welkome afleiding naast al die medische zaken!

Vrienden

Dank jullie wel allemaal. Ik ga er een aantal noemen: Jeroen, Gijs, Luco en Huib. Dank voor al die fantastische stapavonden (tenminste, voor zover ik me ze nog herinner...) en de geweldige vakanties! Jeroen, jij speciaal bedankt dat een technisch ingenieur als jij als paranimf wil fungeren bij deze medische promotie, echt top maat! Huib, jij bedankt voor je creatieve geest die ervoor heeft gezorgd dat dit boekje er zo gelikt uit ziet!

Schoonfamilie

Lieve familie Mooren, wij kennen elkaar nu al bijna 13 jaar en ik kom nog steeds met enorm veel plezier bij jullie over de vloer. Dank voor jullie interesse in mijn onderzoek en werk de afgelopen jaren.

Familie

Lieve mama, beste Peter. Dank voor al jullie interesse in mijn onderzoek de afgelopen jaren, dat werkte erg motiverend. Bedankt ik altijd op jullie kan rekenen en dat jullie altijd voor mij klaar staan, dankjewel! Lieve opa (en oma, ook al ben je niet meer onder ons), deze woorden gelden voor jullie net zoveel! Stefan, mijn kleine (maar toch niet zo kleine) broertje. Wat hebben wij af en toe elkaar het leven zuur gemaakt. Bedankt dat jij desondanks mijn paranimf wil zijn bij deze promotie.

Iris

Lieve Iris, mijn allerbeste maatje. Wat een avontuur weer hè! Het is zo fijn om thuis te komen en daar iemand te hebben waarop je blindelings kan vertrouwen. Dankjewel voor jouw steun door dik en dun en jouw kritische blik waar ik hem nodig heb. Het is goed dat jij me met beide benen op de grond houdt. Ik hou van je, dat er nog maar heel veel mooie avonturen mogen volgen!

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CURRICULUM VITAE

Martin Richard van Wezenbeek was born on November 16, 1988, in Waalwijk, the Netherlands. He grew up in Sprang-Capelle in a family of 2 children. After graduating from high school (Gymnasium, Willem van Oranje College) in Waalwijk in 2007, he started his Medicine study at Maastricht University. After internships in several hospitals in the Netherlands and in Ayr, Scotland, he spent his final year at the trauma surgery department in Maastricht. When he received his medical degree in 2013, he started working at the bariatric surgery department in the Catharina Hospital in Eindhoven. From August 2013 until April 2015, he worked as a full time PhD candidate under the direct supervision of dr.

S.W. Nienhuijs, working on the current thesis and database management. From May 2015 until August 2015, he worked as a resident at the intensive care department, before transferring as a resident to the surgical department, still at the Catharina Hospital. In November 2016, he took on a new challenge as resident at the surgical department in the VieCuri Medical Center in Venlo.

January 2018, he started his specialization in general surgery at the Máxima Medical Center in Veldhoven and the Maastricht University Medical Center+, under the supervision of dr. R.M.H. Roumen and prof. dr. L.P.S. Stassen. During this period, he finished the current thesis.