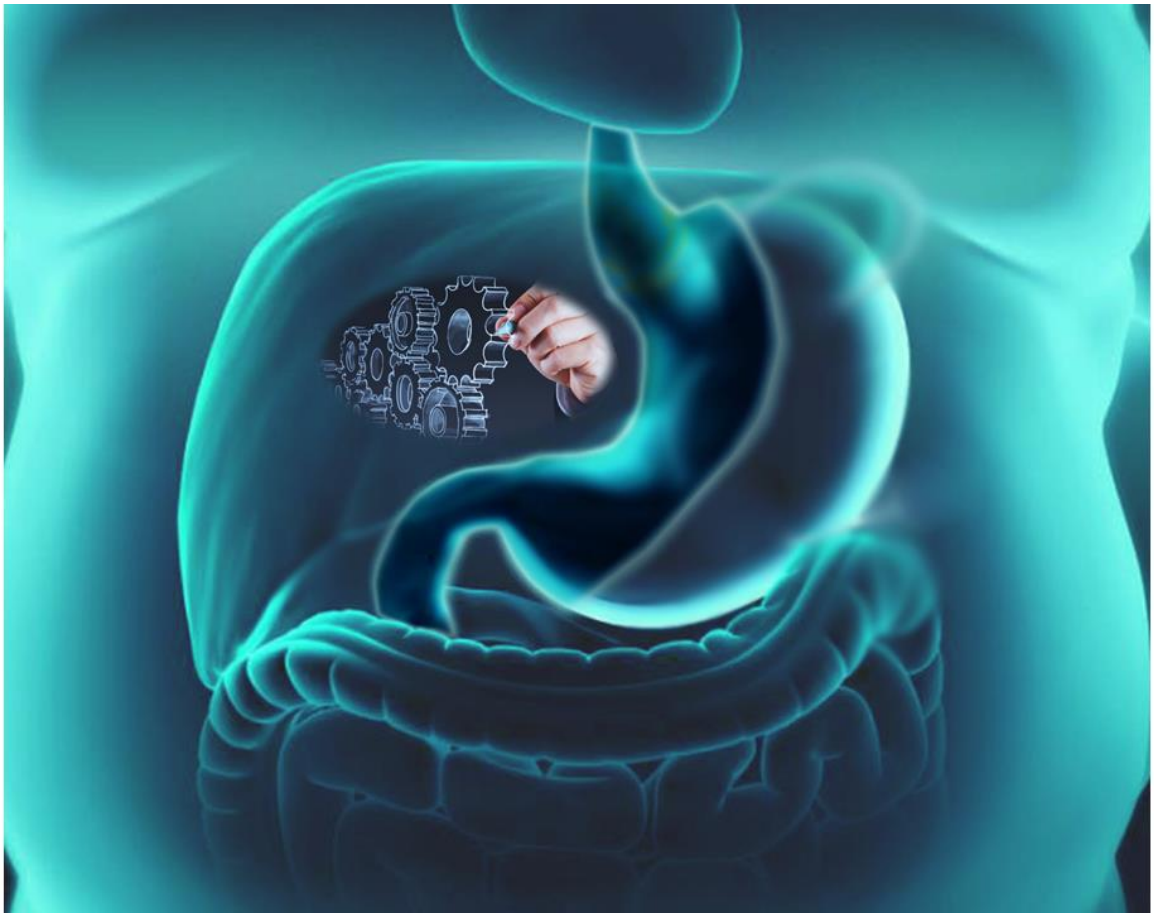
Process Improving In Sleeve Gastrectomy



Pim Wilhelmus Johannes van Rutte

PROPOSITIONS

1. The success of bariatric surgery is achieved by regarding it as a process consisting of a screening phase, the surgical procedure and postoperative follow-up – *This thesis*
2. The Sleeve Gastrectomy is the next Top Model in bariatric surgery – *This thesis*
3. Process Improvement strategies, originating from business management, also lead to improvements in bariatric surgery – *This thesis*
4. In order to improve surgical performance, the surgeon should review his own procedures and learn from the recognition and acknowledgement of pitfalls, shortcomings, hitches and errors – *This Thesis*
5. Obesity is preventable – *World Health Organisation*
6. The name Bariatric Surgery should be replaced by Metabolic Surgery – *Francesco Rubino*
7. Great things are not done by impulse, but by a series of small things brought together – *Vincent van Gogh*
8. Every scientific work can be regarded as a piece of art; there should be room for creativity and imagination to come up with particular ideas - *own conviction*
9. Music gives a soul to the universe, wings to the mind, flight to the imagination and life to everything – *Plato*
10. Voâhal goed kauwe, dat ut etuh gelèkmatig in je bloed komp –*Van Kooten en De Bie*

Process Improving In Sleeve Gastrectomy

Pim Wilhelmus Johannes van Rutte

Process Improving In Sleeve Gastrectomy

PROEFSCHRIFT

ter verkrijging van de graad van doctor
aan de Technische Universiteit Delft,
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voorzitter van het College voor Promoties,
in het openbaar te verdedigen op
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door

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Doctor of Medicine, Master of Science
Geboren te Helmond, Nederland

Dit proefschrift is goedgekeurd door:

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Chapter 1.2 SUMMARY IN ENGLISH

The world health organisation has declared obesity as one of the most serious public health issues of the 21st century.[1] The treatment of morbid obesity should be regarded as a process and it has been shown that it necessitates a multidisciplinary approach.[2,3] Bariatric surgery can be considered as the cornerstone for most morbid obese patients in this process as it is the only treatment modality with proven effective endurance, but it must however, be supported by psychological, dietary and physical counselling.[4] This encompasses a careful patient selection after screening and a follow-up program of at least five years.

Despite its effectiveness, there is ongoing debate on what surgical technique is best for which patient. A possible explanation can be the lack of knowledge about the actual mechanisms by which bariatric surgery acts, as the traditional principles of food restriction and malabsorption appear to be only of little importance.[5–7] Another explanation might be the fact that long-term results are still scarce. So far, these results have shown that the Roux-en-Y gastric bypass (RYGB) can be regarded as the gold standard. Of the available alternatives, the sleeve gastrectomy (SG) seems to approach this standard. The majority of the capacity of the stomach is resected with this technique without any additional small bowel reconstruction. The SG is performed increasingly worldwide. Particularly during the past 3 years, literature about this procedure has increased exponentially. Nevertheless, there is still a need for reviewing both the advantages and the disadvantages and thus the feasibility of this procedure in order to be able to acknowledge and use it as a principal option. In this thesis, the SG is regarded as a part of the treatment process for the morbid obese patient. The aim of the studies was to evaluate its' results considering the epidemiological, technical, nutritional, physiological, and innovative aspects, in order to optimise the procedure and improve the process.

CHAPTER 3

In **Chapter 3**, an overview is given of the current position of the SG. It became clear that still no consensus exists regarding the surgical technique. Traditionally, the size of the sleeve shaped stomach was believed to be the major indicator for weight loss. There has been a lot of debate on the right size of the gastric tube and the volume of the resected stomach. Latest studies move away from these thoughts as they proved that the restrictive effect of the SG is only of little importance.[8] The size of the gastric tube seems to have no effect on the volume of the resected stomach and latest studies show that it does not influence weight loss.[9–12] Moreover, evidence is

rising about the role of the gut hormones ghrelin, GLP-1 and Peptide-YY, the postoperative increase in bile acids and the changes in the gut microbiome. These findings are equal to the changes that occur after the RYGB, which underlines that the key elements of a bariatric procedure are not restriction and malabsorption, but are the hormonal, metabolic and microbiome changes.[13–15]

CHAPTER 4

During the past years, more results have been published regarding postoperative morbidity, Excess Weight Loss (EWL) and reduction of comorbidities. In **Chapter 4.1**, one of the largest series of SGs is presented. The mean age of the cohort was 42.5 years and the mean BMI 44.3 kg/m^2. Obesity related comorbidities are present in a considerable amount of patients. The mean duration of the procedure has decreased significantly during the study period to 41 minutes and so did the complication rates, while the surgical technique has been more or less consistent. Only two other studies have reported the results of >1,000 SG cases.[16,17] Interestingly enough, both show staple line leak rates lower than 1%, while a leak rate of 2.3% was found in our study. Postoperative bleeding was found in 2.6% of the cases. Mean %EWL was 68.4% after 1 year and 67.4% after two years, while maximum weight loss was achieved after 4 years. Complete remission of the obesity related comorbidities or improvement with reduction in medication occurred in nearly all patients. Sixty percent of the patients with diabetes showed complete remission after one year, in 53% hypertension disappeared, in 40% dyslipidaemia, and sleep apnoea disappeared in 62%. In a recent meta-analysis of 16 studies comparing the effect of the SG on diabetes with the effect of the RYGB, Zhang et al showed that remission of diabetes after SG is equal to the RYGB.[18] Again, hormonal changes, particularly increased levels of GLP-1, seem to play an important role in immediate postoperative improvement of glucose regulation, but long-term results are still scarce.[19–21] Remarkably, remission of all comorbidities occurs regardless the amount of weight loss. In Chapter 4.1, long-term results of the SG are given of a small group of 19 patients and 58.3% EWL was achieved after 5 years. Still, no large series of long-term effects of SG have been reported. Latest literature shows >50% EWL after 5-8 years, which is regarded successful and this supports the findings of our studies.[24] One of the revolutionary changes in surgery during the past years was the introduction of fast-track protocols. Fast-track surgery involves evidence-based techniques to enhance recovery and reduce surgical trauma and postoperative stress by minimising pain, reducing complications, improving outcomes and decreasing length of hospital stay while facilitating postoperative recovery after elective procedures. Fast-track protocols have been integrated in bariatric

surgery. The goal is to achieve high quality, safe and standardised surgical care with low morbidity and early patient discharge. There is a large role for the anaesthetist, who facilitates early postoperative recovery by adequate pain management.[25] In **Chapter 4.2**, a large retrospective comparative study is presented with the results of implementation of a fast-track protocol for the SG. It led to significant reduction of the duration of the procedure and length of hospital stay and moreover, significantly less early postoperative complications.

CHAPTER 5

Yet, in order to improve the learning curve of a surgical procedure, a proper description of its hazard zones and pitfalls is useful. In **Chapter 5.1**, a study is presented focussing on the commission of errors during the SG. Sixty surgical procedures were reviewed systematically by two independent observers according to the Observation Clinical Human Assessment (OCHRA) principles and the errors were scored as consequential or inconsequential. Human reliability assessment (HRA) originates from aviation and manufacturing in order to increase safety of the processes. The clinical value of OCHRA has been confirmed before by Tang et al, who applied the assessment on a laparoscopic cholecystectomy.[28] In the current study on the SG, thirteen critical steps were established by an expert panel and each step was assessed systematically for its implementation, which was to be according to the pre-agreed technique. The insertion of the liver retractor led to errors in 13% of the cases. It was found that the most errors are made during continuation of mobilisation of the greater curvature with the use of a sealing dissector and during transection of the stomach with the use of a stapler device. Furthermore, consequential errors during the start of the mobilisation of the greater curvature and repositioning of the stapler appeared to lead to longer duration of the procedure and were associated with a higher risk of postoperative complications. The OCHRA seemed a valuable tool for the assessment of performance of the surgeon, and helped to determine the crucial steps and the hazard zones of the SG.

Ergonomics have become an important topic in surgery during the past decades. For laparoscopic surgery, several dissection tools have been developed to facilitate the procedure. The feasibility of ultrasonic dissection during gastro-intestinal surgery has been reported before.[29–31] In bariatric surgery, dissection with ultrasonic devices is feasible and it is performed with a safety and effectivity profile equal to standard energised dissection.[32] Choice for one of the devices depends mostly on the surgeons' experience and preference. In **Chapter 5.2**, the latest ultrasonic dissectors are assessed for ergonomics, ease of use and dissection accuracy and a comparison is made between a cordless ultrasonic device and a wired dissector. No clinically

relevant differences were found in plume formation, dissector failures and procedure duration and surgeons found both devices equally effective. Both energised sealing devices and ultrasonic dissectors can be used for mobilisation of the greater curvature and when choosing for ultrasonic dissection, both devices are feasible. The next phase of the SG, transection of the stomach using a stapler, is a critical part of the procedure as inadequate stapling can lead to major complications. Too high a pressure of the staplers could lead to tissue ischaemia and too low a pressure to inadequate tissue compression, both with a risk of leakage of the staple line. Too much traction to the tissue could cause tearing and staple line bleeding. Latest staplers contain three rows of staples increasing in height outwardly. Overall, it is agreed that tissue type, tissue thickness and tissue compressibility must be considered by the surgeon when choosing a stapler and a cartridge. The study presented in **Chapter 5.3** is the first who measured the thickness of the gastric wall under optimal tissue compression. A thickness gauge was developed that could perform standardised and reproducible measurements of the thickness of the gastric wall and measurements were done on 5 points, as on average 5-6 staplers are used during the procedure. In this study, the gastric antrum was also significantly thicker than the fundus and this difference was more than 1 millimetre. Moreover, it was found that for tissue compression a 2.9 times lower pressure than applied by the standard stapler would be sufficient. Transection of the gastric antrum with Tri-staple™ technology with a cartridge with 3-, 3.5- and 4-mm staples and transection of the fundus with Tri-staple™ cartridges containing 2-, 2.5- and 3-mm staples is the advice, taking into consideration the other factors provoking complications. Staple line reinforcement remains controversial and the beneficial effects of waiting between stapling and firing have not yet been demonstrated. When reinforcement is used, the staple line becomes thicker and this must be taken into account for the choice of the staple size.[35–38] Major early postoperative complications often require extra care. Readmissions, diagnostic testing and management of these complications entail substantial expenses and as health-care costs are a major topic nowadays, insight is given into the costs of leakage and bleeding after SG in **Chapter 5.4**. Often, re-intervention was necessary. Median additional costs for the treatment of staple line leaks were €9,284 and for bleeds €4,267. Prolonged hospital stay accounted for 50.3% of these additional costs and ICU submission for 31.4% in case of a leak and in case of bleeding they comprised 42.0% and 34.8% respectively. Reduction of expenses can be achieved by minimising the risk of complications, aiming on early discharge and keeping readmission rates low. These strategies require optimal surgical performance, interdisciplinary collaboration, communication, logistics and outpatient accompaniment.

CHAPTER 6

Literature has shown that bariatric surgery has some serious and debilitating complications in the longer term. At first, a considerable amount of patients complains of postprandial symptoms after SG, manifesting in dysphagia or reflux symptoms. The cause is either mechanical, e.g. stenosis or herniation, or functional. For the symptomatic patient in whom a mechanical problem is precluded by swallow X-ray, another cause should be found. The study presented in **Chapter 6.1** describes the application of a gastric emptying study in the search for the functional cause of postprandial symptoms. The study revealed that the SG leads to accelerated gastric emptying. However, the gastric emptying in symptomatic patients was not different from the asymptomatic, implicating that the cause of postprandial symptoms after SG does not lie in changes of the gastric emptying speed and therefore, the gastric emptying study is not a suitable diagnostic tool in these symptomatic patients.

Obesity is associated with several nutrient deficiencies.[39,40] This is confirmed in **Chapter 6.2**. Anaemia was found in 5% of the SG candidates, 7% had low serum ferritin and 38% of the patients had an iron deficiency. Low serum folate was found in a quarter of the patients and the majority (81%) had hypovitaminosis D. Deficiencies can be attributed to a non-varied, high-calorie and high-fat diet. One year after SG, anaemia was found in 6% of the patients and low ferritin in 8%. Only folate and vitamin D improved significantly, which is due to strict advices of supplementation. Recent studies comparing the nutrient status after RYGB and SG revealed that both procedures have a similar risk of developing postoperative deficiencies and they endorse the importance of postoperative monitoring and adequate supplementation.[41,42] It is important to have a general agreement on what needs to be supplemented. It is advised to take multivitamin tablets on a daily basis, containing the vitamins A, B1, B2, B3, B5, B6, B8, B12 and folate and also the vitamins C, D3, E and K and the minerals chrome, iron, magnesium, selenium and zinc in concentrations between 100% and 200% of the recommended daily intake.

Despite the good to excellent results of the SG in the majority of the patients, bariatric surgery fails in some of them. A treatment failure is defined as insufficient weight loss or weight regain but also fails if no remission of comorbidities occurs or if patients suffer from long-term morbidity. It is important to have an escape for those bariatric patients in whom the treatment fails. The major indications for revision are insufficient weight loss, weight regain or reflux complaints. In case of failure of a SG, two procedures are suggested; the biliopancreatic diversion/duodenal switch (BPD/DS) and a RYGB. Two recent small retrospective studies compared the results of both revision options and concluded that both are feasible procedures after failure of the SG. In cases of reflux complaints, RYGB would be the best option and in cases of insufficient weight loss, it would be the BPD/DS, at the cost of more complications and

nutrient deficiencies.[43,44] In **Chapter 6.3**, the indications for revisional surgery are reviewed. The total revision rate in this cohort was 5.5%. In all patients, the SG was converted to a RYGB. A subdivision was made between patients with a planned second procedure because of very high BMI, patients with failure of the SG which was performed after prior bariatric surgery and patients with failure of a primary sleeve gastrectomy. It was concluded that conversion of the SG to a RYGB in a two-step procedure in the patient with very high BMI is safe and effective in terms of additional weight loss and perioperative complications. Revision surgery after failure of a primary SG shows a relatively high complication rate but achieves significant remission of comorbidities and additional weight loss.

Since the past decades, the health care has been dealing with global ageing and this phenomenon also occurs amongst the obese population. As older patients with morbid obesity carry an extra risk for surgery, it is important to have a safe and effective bariatric procedure for this group. In **Chapter 6.4** the feasibility of the SG is studied in patients older than 55 years. It is shown that SG in the older obese leads to significant and excellent weight reduction in the first postoperative year in all age groups. All patients profit from a considerable reduction in comorbidities at the cost of an acceptable low complication rate. One can conclude that the SG is a viable option for the treatment of morbid obesity in the older patient.

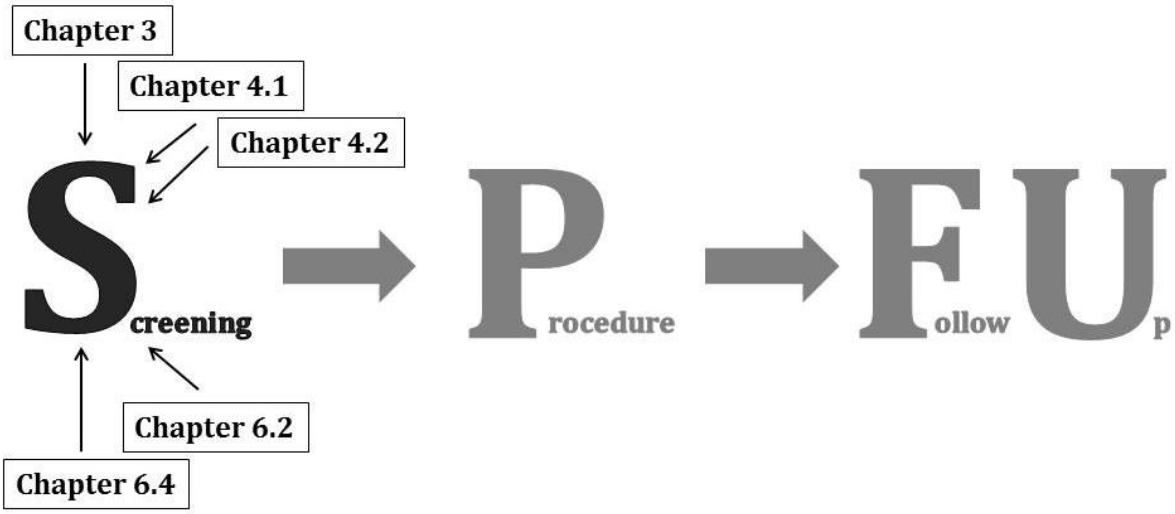
CONCLUSION

In this thesis, the sleeve gastrectomy is regarded as a part of a process that involves three successive phases; preoperative screening, the surgical procedure and postoperative follow-up. During the past years, several adjustments have been made to all phases in order to develop a standardised, safe, efficient, reproducible and learnable process with excellent results regarding weight loss and reduction of comorbidities. Further attention should be paid to the reduction of complications and revision options. The sleeve gastrectomy is the new top model in the treatment of morbid obesity. However, a morbid obese patient will always remain a morbid obese patient, despite excellent weight loss and remission of comorbidities after surgery and this requires a lifetime commitment to the life style changes.

Chapter 7. DISCUSSION

One of the biggest advances in surgery of the past decades has been the shift to a minimally invasive approach. The advantages of minimally invasive surgery have been proven extensively in bariatric procedures, making this approach standard of care. As the prevalence of morbid obesity is increasing rapidly, there is a need for a minimally invasive surgical procedure with high safety, efficacy, efficiency and sustainability. The procedure should be technically easy to perform, reproducible, easy to learn, it should have a low risk of complications, lead to optimal weight loss and reduction of comorbidities and its results should last as long as possible. The laparoscopic sleeve gastrectomy (SG) has become an important pillar in the treatment of obesity. As is summarised in **Chapter 3**, there is enough evidence to conclude that the SG can be offered as a stand-alone treatment. A recently published meta-analysis confirms once again, that the SG has a safety profile comparable to the gold standard, the Roux-en-Y-gastric bypass (RYGB).[1] Moreover, it achieves similar results in terms of weight loss and reduction of the obesity-related comorbidities.[2,3] The SG has evolved from a step-up procedure, preceding the duodenal switch, to a stand-alone procedure that is now preferred in the treatment of morbid obesity in the university hospitals in the United States of America.[4,5] The aim of this thesis was to study the results of the SG as a stand-alone procedure. The focus was on safety and efficiency and it was studied what crucial parts of the process could be improved or optimised. Therefore, we divided the process into three phases (see illustration 1) to create a clinical pathway. The first phase is the screening of the morbid obese patient. We would like to discuss the findings of the reported studies that have contributed to or will lead to improvement of the screening phase. The next phase is the surgical procedure itself. The studies that reported the results of the procedure and the adjustments that have contributed to increased safety and efficiency will be discussed in this chapter. Furthermore, recommendations for further improvement of the procedure and future research will be given based on the studies reported in this thesis. The last phase is the follow-up phase. The studies concerning evaluation of and adjustments to this final phase of the process will be discussed.

7.1 SCREENING



Careful patient selection is believed to be of major importance in bariatric surgery.[6] Since the SG has been implemented as a stand-alone bariatric procedure, all patients were screened by a multidisciplinary team consisting of a bariatric surgeon, an obesity nurse, a psychologist and a dietician. Patients were selected for an SG based on the same selection criteria as for RYGB, which are reported in the introduction of this thesis. By using this multidisciplinary approach, only motivated, conscious and mentally stable patients are operated on. This is essential to prevent or reduce early relapse and weight regain after surgery.[7,8] Patients with a psychological disorder or an eating disorder do not directly receive approval for the operation. Psychological counselling is offered to them first, in order to achieve a stable situation and increase the success of the life style changes and surgical outcome. Those patients with unhealthy dietary habits are educated in making the right choices with the goal to achieve a consistent and healthy diet which should be maintained postoperatively.

As is summarised in **Chapter 3**, patients with a history of gastro-oesophageal reflux symptoms should not be offered an SG. This is confirmed in a recent meta-analysis comparing the SG to the RYGB, which reported increased rates of reflux after SG and significant reduction of pre-existing reflux symptoms after the RYGB.[9] The study reported in **Chapter 4.1** shows that de novo postoperative development of reflux occurs in 11.7% of the patients. In order to facilitate the exclusion of patients with gastro-oesophageal reflux for SG, standardised diagnosing is necessary. A standard questionnaire, systematically scoring preoperative reflux symptoms, is a valuable tool for preoperative assessment and decision making.[10] A point of discussion is the value of preoperative endoscopic evaluation of the stomach and based on recent literature, it seems to have no additional value. Abnormalities are found in a high amount of patients, but

without any consequences for further treatment in the majority of them.[11–13] Besides, several studies revealed that the presence of Helicobacter Pylori (H. Pylori) preoperatively is not associated with major postoperative complications or ulceration.[14–17] This implicates that preoperative endoscopic screening and treatment for H. Pylori are not indicated. The exact cause and the late effects of gastro-oesophageal reflux after SG are still under investigation. Long-term data on reflux related complications are awaited to draw definitive conclusions on the effect of the SG on reflux. Unless these long-term results prove differently, it is recommended to perform a RYGB in those patients reporting reflux symptoms in the questionnaire during preoperative screening.

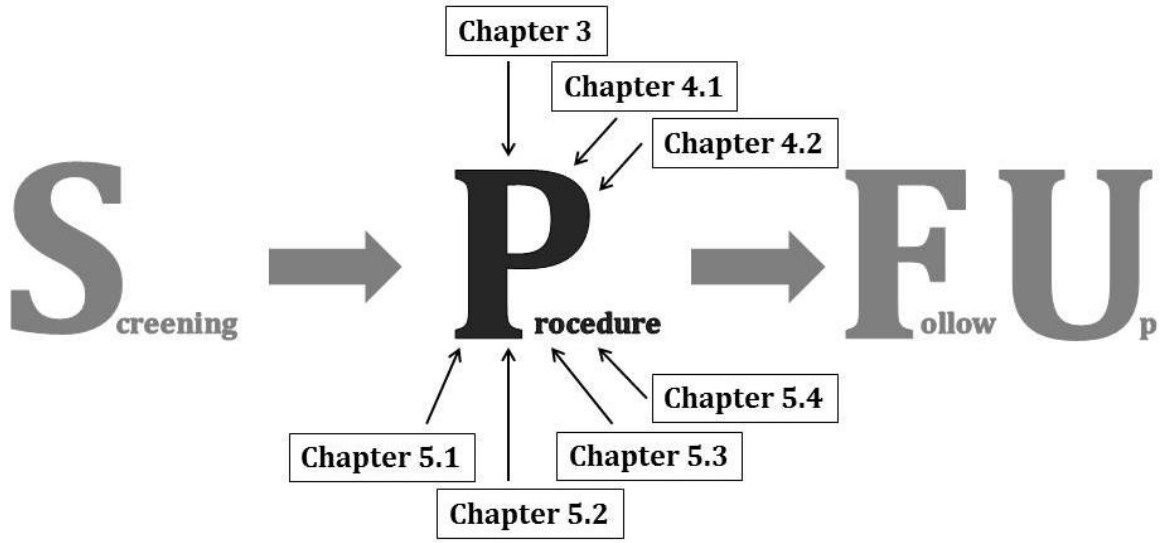
Another point of discussion is the age limit for bariatric surgery. Global ageing is also a major issue according to the world health organisation and obesity is seen increasingly under the elderly population. The upper age limit for bariatric surgery has been set at 65 years. Older patients carry higher risks for surgery and in this population safety of the procedure is of major importance. Recent literature shows that in the older morbidly obese patient, the SG is a safer procedure than an RYGB or gastric banding as it shows lower readmission and reoperation rates.[18] These findings are in agreement with the study in **Chapter 6.4** reporting the feasibility of the SG in the older obese patient and concluding that in this population the SG should be the first choice. The primary goal of the SG in the elderly should be to reduce their comorbidities and improve the quality of life.[19–21] As a result, health insurers have started to reimburse the treatment in this older population and lately, the age limit has been reset to 68 years for primary treatment of obesity and 69 years for patients that need a revision because of severe postprandial complaints or gastro-oesophageal reflux.

The next important element of preoperative screening is laboratory testing. Apart from standard determination of haemoglobin levels, renal and hepatic functioning and the inflammation and coagulation status, assessment of the preoperative micronutrient status has gained interest. Many studies have already proven that morbid obesity is associated with higher prevalence of vitamin and mineral deficiencies.[22–25] It is of major importance to detect these deficiencies preoperatively for early supplementation and as a basis for postoperative evaluation of the effect of the surgery on the micronutrient status. As is presented in **Chapter 6.2**, deficiencies of the vitamins B12 and D, folic acid and the mineral iron are frequently found in SG candidates and they persist or occur de novo after surgery. Other studies have shown the beneficial effects of supplementation.[26–29] These findings have led to the development of a standard laboratory test which is taken on each obese patient during the screening phase, measuring the levels of serum haemoglobin, leukocytes, C-reactive protein, electrolytes and the renal function, but also the vitamins A, B1, B6, B12, folic acid (B11) and D3, iron, ferritin, calcium, magnesium, phosphate,

zinc and Parathyroid Hormone (PTH). Based on a recent study, determination of methylmalonic acid has been added to the test, as it detects more functional vitamin B12 deficiencies. Besides, adequate intramuscular supplementation of vitamin B12 leads to normalisation of the values in all deficient patients.[30] All patients are instructed to take multivitamin tablets daily and specifically, the deficiencies of vitamin B1, B12 and D, calcium, folic acid or iron are supplemented in case of preoperative deficiency. However, the study in **Chapter 6.2** revealed that despite prescription of supplements, deficiencies persist or occur newly after surgery. It is not clear if the cause lies in inadequate dosing of the supplements or in patient compliance. This should be investigated to achieve better control on the nutrient status of the SG patient.

To conclude the screening phase, approval for surgery is given by the surgeon in a multidisciplinary consultation. Then the next step is preoperative instruction and preparation. Patients are instructed to follow a crash diet two weeks prior to surgery, in order to reduce the size of the liver and create a larger and safer operation field for the surgeon.[31,32] Furthermore, preoperative clarification of the surgical procedure and the direct postoperative course have become part of the fast-track protocol and contribute to enhanced recovery and better outcome, as is shown in **Chapter 4.2**. Fast-track principles provide uniformity for both patients and the caregivers. Since the implementation of fast-track, identical protocols have been used for SG and RYGB, except for the surgical procedures themselves. Even revision surgery is now being performed according to fast-track principles. As a result, all patient groups are informed about the process simultaneously in group sessions and the one-on-one patient contacts can be reduced. These adjustments have led to enhanced efficiency of the screening phase.

7.2 PROCEDURE



It is believed that optimisation and improvement of the procedure can be achieved by creating a standardised and reproducible process. This starts with the identification of the key elements of the procedure. There has been a lot of debate on the surgical technique of the SG during the past decade.

As is reported in **Chapter 3**, there is an ongoing discussion on the size of the gastric tube. Prior studies concluded that the size of the sleeve shaped stomach was the major indicator of weight loss. Latest studies refute these thoughts as they proved that the restrictive effect of the SG is only of little importance. Initial BMI is a predictor of postoperative weight loss, but the volume of the resected stomach and thus the remaining sleeve size appears not to be.[33] The size of the tube seems to have no effect on the volume of the resected stomach and does not influence weight loss.[34–37] In the cohort presented in **Chapter 4.1**, a 34 French (Fr) gastric tube was used during all procedures. The size has not been changed as satisfying results were achieved with the use of these tubes. Assuming the fact that excess weight loss is not directly influenced by the volume of the sleeve shaped stomach, a question might arise if a larger gastric tube would achieve the same results with reduced incidence of early complications and dysphagia symptoms. So far, only one randomised controlled trial has studied the effect of the gastric tube size and compared the results between a 27 Fr and a 39 Fr tube. The authors concluded that there was no significant difference in weight loss and morbidity.[34] Ruiz-Tovar and his group reported excellent weight loss and remission of comorbidities 5 years after SG with the use of a 50 Fr gastric tube.[35] A meta-analysis of almost ten thousand SG procedures suggests that the use of ≥40 Fr gastric tubes would reduce the risk of staple line leaks.[38] In order to draw any definite conclusions on the right size of the gastric tube, we call for a proper controlled trial, randomising

SG procedures for the use of 3 different types of gastric tubes, 30Fr, 40Fr and 50Fr. Outcome measures should be excess weight loss, remission of comorbidities, staple line leaks and bleedings, reflux, dysphagia and vomiting. In this proposed study, all other factors influencing the outcome of the procedure should be taken into account.

A second important element of the procedure is the optimal use of laparoscopic instruments. Evaluation and assessment of precision ease of use and ergonomics help to choose the most appropriate instrument. High usability and precision would reduce the occurrence of errors and good ergonomics would facilitate the performance of the surgeon, both potentially increasing the safety of the process. One of the major steps of the SG is mobilisation of the greater curvature of the stomach by division of the omentum majus. In the cohort presented in **Chapter 4.1**, a standard energised sealing device (Ligasure Atlas™, Covidien, Mansfield, MA, USA) has been used during all SG procedures. This device contains a cord and uses electrical energy to seal the tissue. A potentially suitable alternative is the ultrasonic dissection tool, using ultrasonic energy.[39,40] So far, no superiority has been found for either standard energised dissectors or ultrasonic dissectors.[41,42] Ultrasonic dissectors, however, do not generate electric energy and these tools can be used in all patients. For instance, in those with a pacemaker, disabling of the pacemaker is not necessary during the operation, which in turn leads to lower risk of cardiac arrhythmias. The use of wireless energised instruments could facilitate the surgical procedure as the operating field is cleaner and the instrument can be used with better manoeuvrability without the presence of cables. In **Chapter 5.2** the possible advantages of wireless ultrasonic dissection were studied for SG. During a comparative study, the wireless Sonicision™ (Covidien, Mansfield, MA, USA) was compared to the Harmonic ACE+® (Ethicon Endo-Surgery Inc., Cincinnati, OH, USA). In this study, objective measures were scored to assess the safety and efficiency of the procedure. Additionally, subjective measures have been taken into account. Not only the experience and opinion of the surgeon were scored, but the scrub nurses were also involved in the assessment of both dissectors. For an optimal course of the procedure, both preparation and installation and the actual dissection should proceed undisturbedly. Hence, both the scrub nurse and the surgeon should be satisfied with the instrument. Installation of the wireless Sonicision™ appeared significantly faster. However, the mean duration of the operation was not significantly reduced by any of the dissectors. Scrub nurses found the Sonicision™ clearer and easier to set up. Concerning ergonomics, surgeons found the manoeuvrability of the wireless dissector significantly better, but found no difference in precision, safety or speed. Overall, one can conclude that both wireless and cord-containing ultrasonic dissection are equally safe, and effective, but in terms of installation and ergonomics the wireless ultrasonic dissector could be preferred. The use of a wireless dissector could have an additional value if all surgical tools (camera and suction device) were wireless. When the operating field would be

clean and free of cables, manoeuvrability would further improve and the space around the operation table would increase. However, the development and use of wireless devices will presumably increase the costs of the instruments. When the use of these tools does not lead to a faster procedure or a reduction in complications and hospital stay, the cost-efficiency of the process is not increased and the use of wireless dissectors cannot be recommended.

The next essential element of the SG is stapling and transection of the gastric wall along the gastric tube. The most feared complication of the procedure is leakage of the staple line. Several laparoscopic staplers have been developed to facilitate transection of the gastric wall. In the cohort studied for this thesis, one of the first adjustments to the procedure was the transition of stapling with a 3 rows of staples with equal heights to the Tri-Staple™ technique in 2010. It was believed that optimal tissue compression is achieved when three rows of staples, increasing in height outwardly, are positioned. The high outer row of staples serve for tissue compression, the low inner row for vessel occlusion. This would lead to a reduction in staple line leaks and bleedings. As is shown in **Chapter 4.1**, the total complication rate has decreased significantly after 2010. However, despite transition to Tri-staplers, major complications still occur and staple line leaks are found in 2.3% of the cases. It was questioned if the right staple height has been used. Prior studies reported that the wall of the gastric antrum is thicker than the wall of the cardia.[43,44] This was, however, measured under a set pressure comparable to the grasping force of the stapler. It was hypothesised that for optimal tissue compression a lower pressure would be sufficient. Results of the study presented in **Chapter 5.3** show that the grasping force of the stapler could be reduced by 2.9 times. As the majority of the staple line leaks are found proximally, too large staples might be used at this site. A thickness gauge was developed that could perform standardised and reproducible measurements of the wall of the excised gastric specimen. The measurements revealed that the walls of the gastric fundus and cardia are significantly thinner than the antral wall and the difference was more than one millimetre. For stapling of the gastric antrum Tri-stapling with 3-, 3.5- and 4-mm staples should be done and for stapling of the fundus Tri-Staple™ cartridges containing 2-, 2.5- and 3-mm staples are advised, taking into consideration the other factors provoking complications. Another point of interest is the actual firing of the stapler as this has not been standardised yet. It is done manually and the force and speed of firing vary between the surgeons. Besides, it is suggested to wait between grasping and firing, although the optimal waiting time has not been studied yet.[45] The use of a powered stapler could contribute to the standardisation of staple firing. In this device the optimal grasping force could be adjusted based on feedback of the tissue, waiting time could be set before firing and the staples could be fired with controlled speed under optimal stability of the device. The iDrive™ (Covidien, Mansfield, MA, USA) is a powered stapler that was developed by Covidien. So far, no studies have been performed comparing this device to the manually

controlled staplers, so the feasibility of powered stapling still needs investigation. Concerning the safety of the procedure and the aim to further reduce the risk of leaks, Gagner recently called for a thickness calibration device that can determine the right stapler size.[46] This device should be used intra-operatively by measuring the thickness of the gastric wall and giving an advice for the staple size before firing a stapler. Ideally, these features should be combined with a standardised powered stapler. The development of such a device could contribute to the reduction of leaks. The aim of the intra-operative measurements and directly adjusted standardised staple firing should be to obtain optimal tissue contact and compression while avoiding tissue ischaemia.

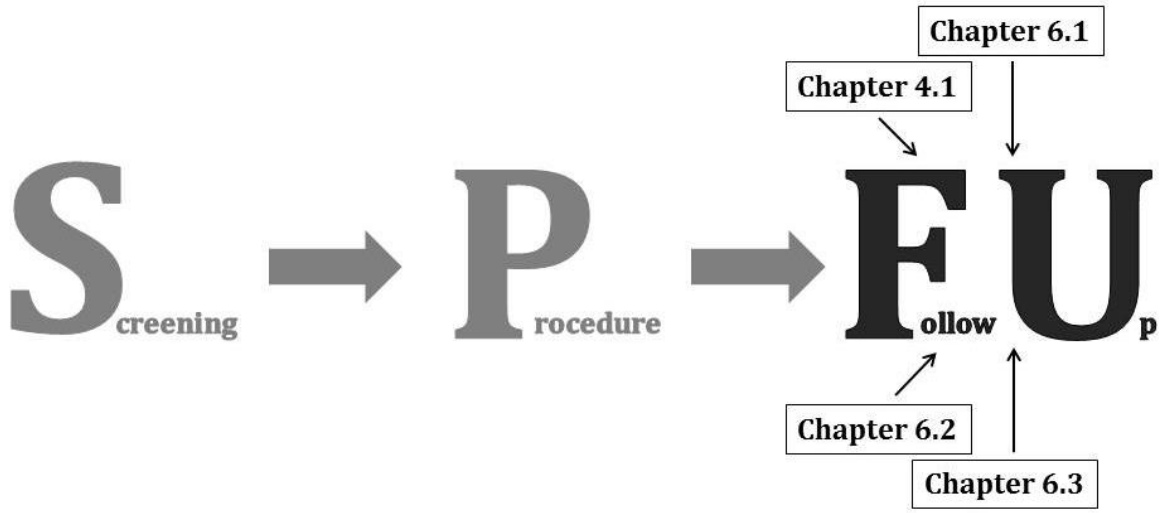
However, there are other important factors that contribute to the reduction of complications. One of these factors, which appeared to be one of the major adjustments to the process, was the implementation of a fast-track protocol in 2011. As is reported in **Chapter 4.2**, the conventional anaesthesia, postoperative analgesia and recovery protocols were replaced by a protocol avoiding premedication, intra-operative administration of muscle relaxants and opioids and early postoperative mobilisation. This also led to a significant reduction in overall early complications and, interestingly enough, staple line leaks and bleedings decreased significantly. Implementation of this new protocol not only involved adjustments made to anaesthesia. By creating a bariatric team, consisting of a bariatric surgeon, dedicated OR-personnel and anaesthesiologists, it became possible to perform 6 to 7 bariatric procedures a day. This has been achieved by the standardisation of the major aspects of the SG. As is shown in **Chapter 5.1**, the procedure was divided into 13 key steps. Each surgeon performed these steps similarly and with the use of the same instruments. Prior to each procedure, instruments were laid out by the OR-personnel as written in the protocol and during the procedure the instruments were handed out fluently according to each consecutive step. The duration of the surgery has decreased significantly by 20 minutes and the changeover times between the procedures became shorter. Even ergonomic circumstances improved by the new protocol as the patients awaken faster from anaesthesia and transfer themselves from the operation table back into their beds. Furthermore, the standardisation made it possible to train new OR-personnel properly. At first, the team only consisted of specialised bariatric anaesthesiologists and OR-personnel. Now, other personnel could be trained rapidly and the teams have expanded during the past years. The number of bariatric surgeons has also increased from three to six. Nowadays, it is feasible to perform 18 to 20 bariatric procedures in 3 operation rooms simultaneously in one day. Strict postoperative nursing care by trained nurses and a postoperative visit by the bariatric physician assistant contributed to enhanced recovery, which has led to a significant reduction in mean hospital stay from 4 to 2 days.

Training is a major element of surgery. As is discussed above, standardisation of the procedure facilitates the training process. Nowadays, surgical fellows and residents can be trained adequately in performing the SG. In order to teach them, we believe it is of major importance to gain knowledge of the key steps of the procedure and focus on the potential hazard zones. In **Chapter 5.1**, an observational study is presented that analysed the performance of the SG according to the Observational Clinical Human Reliability Assessment (OCHRA). The study showed no difference in major complications between the different levels of the surgeon's experience. All fellows and residents were supervised by an experienced bariatric surgeon. One can conclude that adequate supervision leads to similar results as performance by experienced surgeons. However, occurrence of errors during two of the 13 critical steps of the procedure was significantly associated with longer duration of the procedure and more postoperative complications. We believe that it is very important for a surgeon to record and review his own procedures. By reviewing, one can discover any hitches or even inadequate or unnecessary actions. Awareness and acknowledgement of these actions are basics for improvement. OCHRA seemed to be a valuable tool, not only for the assessment of the surgical performance but also for detection of the hazard zones of the SG procedure. It could even be used for standard monitoring of the surgeon's performance, by randomly conducting the assessment or it could also be deployed when the surgical results of any surgeon deteriorate. It might help to find the underlying cause of any complication in order to prevent recurrence in future procedures. In this way, it could contribute to increased safety. With regard to training, OCHRA is a very valuable tool for surgical fellows and residents. Once the key steps of the SG are determined and the hazard zones are known, a virtual training programme could be set up to let them train the SG on a simulator, practice different scenarios and learn how to deal with the potential errors, just like a pilot trains scenarios in a flight simulator. When the simulation training is completed successfully, trainees should perform an SG in real life under strict supervision. Again, reviewing the procedures, detecting technical errors and recognising the consequences form the fundaments for improvement. Then, OCHRA can also be used as an examination tool, to determine if a bariatric surgeon in training could perform the SG without supervision. The value of OCHRA in the examination of surgical performance has been proven before.[47] The assessment of a careful execution of the procedure without the occurrence of consequential errors would be an adequate determinant for solo performance of the SG.

At the present time in which health care costs are a major topic, adjustments to the process should also lead to a reduction of the costs. Postoperative complications increase the costs as patients have a longer hospital stay and require additional treatments. It was studied what the additional costs were in case of a major complication. **Chapter 5.4** shows that the median additional costs for the treatment of a staple line leak were €9,284 and for bleeding €4,267. In

case of a leak, prolonged hospital stay accounted for 50.3% of these additional costs and Intensive Care Unit (ICU) submission for 31.4%. When postoperative bleeding was found, 42.0% of the costs were assigned to prolonged hospital stay and 34.8% to ICU submission. Submission to the ICU could be reduced by adequate training in early detection of major complications. As is supported by several studies, the vital sign tachycardia appears to be the major clinical manifestation of both postoperative leak and bleeding. This can be supported by postoperative serum determination of haemoglobin, leukocyte and C-reactive protein levels.[48–50] Treatment of major complications has also been given a minimally invasive and, in particular, a multidisciplinary approach. When postoperative bleeding is suspected, based on tachycardia and a decreased haemoglobin level, administration of tranexamic acid and blood transfusion appeared to be an adequate first conservative treatment option.[51] Early detection and conservative treatment of this complication have led to a reduction in the numbers of direct surgical re-interventions. By standardisation of the bariatric care, complications can be managed on the ward and less ICU submissions are necessary. For leakage of the staple line, treatment has shifted to a non-surgical approach. By close cooperation with gastro-enterologists, surgical treatment of leaks can be avoided as endoscopic drainage has become an important modality.[49,52,53] Positioning of an endoscopic stent is the right treatment for leaks with a hole >1cm.[52,53] By involving the intervention radiologist in the development of a treatment protocol for gastric leaks, radiological drainage of intra-abdominal abscesses has become part of the treatment options. The ability to treat complications non-surgically, with as a consequence the omission of anaesthesia and postoperative recovery with intensive monitoring, will reduce the costs of the process. Moreover, by clear instructing in self-care and alarm symptoms, the patient can return home with an endoscopically or radiologically positioned drain and this in turn reduces the hospital stay. However, it is only possible when the clinical symptoms and the infectious status are showing improvement. It remains very important to keep focussing on the reduction of major complications. A current topic is the application of staple line reinforcement (SLR) in order to reduce the risk of leaks. In the cohort presented in **Chapter 4.1**, no SLR has been used and a leak rate of 2.3% has been achieved. The use of SLR remains controversial. Earlier studies could not demonstrate a reduction of leaks, but did show fewer bleedings.[54–56] When reinforcement is used, the staple line becomes thicker and this must be taken into account for the choice of the staple size.[57–60] We call for a proper randomised controlled trial in the near future, comparing a group of SG with SLR to a group of SG without SLR. Outcome measures should be staple line leaks and bleedings, re-interventions and hospital stay.

7.3 FOLLOW UP



The final phase of the process is the postoperative follow up. Early complications are detected and taken care of in the first 30 postoperative days. However, patients can develop serious complications in the longer term. The major late complaints after SG are gastro-oesophageal reflux, vomiting and postprandial epigastric pain. It is important to find the exact cause of these complaints. Prior studies believed that increased intra-gastric pressure would impede the function of the lower oesophageal sphincter, which would lead to gastro-oesophageal reflux.[61] However, Toro et al. observed a large variability in sleeve volume and compliance of the stomach wall and no correlation was found between the size of the sleeve shaped stomach and the intra-gastric pressure.[62] By applying High Resolution Impedance Manometry and volumetric Computed Tomography scanning in postoperative patients, Mion et al. found no correlation between the sleeve volume and the intra-gastric pressure either, and increased intra-gastric pressure did not appear to be an indicator for reflux symptoms. However, impedance reflux episodes were correlated with symptoms and a correlation was found between postprandial epigastric pain and increased intra-gastric pressure.[63] In **Chapter 6.1** the correlation between postprandial symptoms and gastric emptying was studied by performing a gamma scan measuring the lag phase, half emptying time and caloric emptying rate of the sleeve shaped stomach. In all patients, the gastric emptying was faster than in non-operated patients, but no statistically significant difference could be found between symptomatic and asymptomatic patients. It was concluded that postprandial symptoms cannot be explained by altered gastric emptying. A gastric emptying study is not the preferred method to assess upper digestive symptoms after SG, but High Resolution Impedance Manometry (HRIM) appears to be a valuable tool. The measurement of abnormal pressure and contraction waves during swallowing and an impaired food transport function quantify the upper digestive symptoms and this diagnostic test

serves to confirm the indication for revision to RYGB in case of severe postprandial symptoms. If future larger studies show the same results for HRIM as a diagnostic tool in patients with upper digestive symptoms after SG, this tool should be added to the protocol for treatment of late complications.

Standardised laboratory tests are done during follow up; three times in the first postoperative year and annually afterwards. In collaboration with the clinical endocrinologist, standard dosage regimens have been developed to treat the micronutrient deficiencies. In case of severe deficiencies the endocrinologist is consulted for further analysis. The study presented in **Chapter 6.2** shows that deficient iron and ferritin levels persist after SG and vitamin deficiencies occur de novo in a considerable amount of patients postoperatively. Based on this study, all patients are instructed to take multivitamins on a daily base, for the rest of their lives. These supplements are not covered by the insurance company and patients have to buy them themselves. The fact that deficiencies occur de novo implicates that the SG also causes a certain degree of disturbance in nutrient absorption. On the other hand, the finding that deficiencies persist after surgery in a considerable amount of patients despite supplementation, implicates either disturbed uptake of supplements or inadequate patient compliance with regard to supplement intake. It is hard to control patient compliance as patients buy the supplements in drugstores or order them online. Registration of the purchases is not possible and concrete intake of the supplements cannot be monitored. The only way to monitor the purchases of multi-vitamins is to sell them at the clinic or get access to the registration of online orders. This privacy issue should be discussed critically in the near future. Education and enlargement of the responsibility of the patient in terms of self-management may increase patient compliance. The patient must realise that he himself plays the most important role in the success of the process instead of attributing all advantages to proper management by the bariatric team. All patients are told that the surgical procedure is just a tool to break the vicious circle and start to lose weight, with all the additional effects. In order to maintain weight loss and remission of comorbidities, the patient needs to stick to the life style changes for the rest of their lives. Besides, it is of major importance to make the patient aware of the possible risks of nutrient deficiencies. As a result of agreements with health insurance companies, the duration of the outpatient follow up has been set at five years. Over the years, a standardised follow up programme has been developed to improve patient care and postoperative outcome (See the flow chart in the introduction of this thesis). It involves six visits to the outpatient bariatric clinic during the first postoperative year and two annual visits afterwards. After 5 years, the clinical follow up ends and by this time, patients should have achieved a stable weight after a period of significant weight loss. **Chapter 4.1** reveals that 8.2% of the patients need a revision in the first 5 years after SG. It is important to detect the cause of failure of the SG. A differentiation should

be made between insufficient weight loss or weight regain and severe reflux or postprandial symptoms. As is shown in **Chapter 6.3**, the major indications for revision of an SG are postprandial symptoms and reflux. Reflux symptoms should be reduced by offering patients with preoperative gastro-oesophageal reflux an RYGB. Postprandial symptoms seemed to have an anatomical cause. Occurrence of a gastric stenosis after an SG should be avoided by correct positioning of the staplers and as is discussed before, a larger gastric tube might help to prevent stenosis. Weight regain is the indication for revision in 22.2% of the cases. Again, the cause of weight regain should be found. In case of relapse into old unhealthy dietary habits, consultation of a dietician is essential. In case of lack of physical exercise, psychological consultation and physical coaching should prevent further weight regain. Concerning the economics and the attempts to reduce the health care costs, the question should be answered if it is possible to shorten the duration and reduce the costs of the outpatient follow up after SG. The emergence of technical innovations in communication could facilitate in the development of "telecare". An example is the development of the online programme "Be patient". This programme makes the patient's responsibility part of the process. E-learning modules provide support programmes regarding the surgical procedure, dietary advices and other instructions regarding the life style changes. Furthermore, patients can connect to companions through a bariatric social network. More importantly, patients can be monitored remotely by for instance iHealth weight scales and activity trackers. This way, the patient manages his own process and professionals are directly informed about the consequences and results. By implementation of telecare, the follow up might be extended to more than five years. The efficiency, efficacy and sustainability of Telecare and E-health are still under investigation and the feasibility in bariatric surgery should be proved soon.

Despite all the efforts, revision surgery is still necessary for 8% of the patients. For them it is of major importance to find a revision procedure with high safety and effectivity. This is still a topic that requires further investigation. The study presented in **Chapter 6.3** shows the results of the revision from an SG to an RYGB. It leads to significant additional weight loss and comorbidities, but at the cost of a relatively high risk of major complications. During the past years, alternative procedures have been developed for failed SG. The Biliopancreatic diversion and Duodenal Switch (BPD-DS), which was originally preceded by the SG in a two-stage procedure, can still be performed in case of failure. Only small studies compared the results of RYGB and the BPD-DS. They concluded that the BPD-DS achieves more additional weight loss, but at the cost of more complications and nutrient deficiencies.[64,65] In the search for other less invasive procedures, the following procedures have been suggested for revision surgery; The relatively new single anastomosis gastric-bypass (Omega loop) might be a good option, as it only requires one anastomosis, but reflux symptoms are also reported after this procedure.[66] The latest alternative

is the single-anastomosis duodenal-ileal bypass (SADI), which seems to be a promising revision option. Early results show minimal complications and significant additional weight loss and remission of comorbidities.[67] In both procedures, only one anastomosis is made, which would reduce the risk of leaks. However, as these procedures are relatively new, larger studies should be done to draw any definite conclusions on their feasibility.

7.4 CONCLUSIONS AND FUTURE PERSPECTIVES

In this thesis, the laparoscopic sleeve gastrectomy was regarded as a process, involving three successive phases. In the past years, several adjustments have been made to all three phases in order to achieve a standardised, safe, efficient, reproducible and learnable process with excellent results in terms of weight loss and remission of comorbidities. There is still room for improvement with regard to reduction of the major complications leaks and bleedings and to treatment options in case of failure of the process. Non-surgical causes of complications should be further investigated, such as smoking and intra-operative haemodynamic changes. The sleeve gastrectomy has the potentials to become the new gold standard in the treatment of morbid obesity. In a next summit on sleeve gastrectomy, supported by this thesis, a global consensus should be reached on the use of the instruments to reach a uniform procedure. Once the procedure has been optimised, the focus should shift to the postoperative phase. Larger studies on long-term results of the sleeve gastrectomy are awaited. Besides, the metabolic and physiological causes of weight loss and weight regain after surgery should be further studied. At last, patient accompaniment and the psychological aspects of the process should obtain attention. A morbid obese patient will always remain a morbid obese patient, despite excellent weight loss and remission of comorbidities after surgery and this requires a lifetime commitment to the life style changes. The psychological aspects of the process must become subject to further research.

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