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Carving out success: identifying factors associated with metabolic and bariatric surgery outcomes

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Citation

Jacobs, A. (2025, March 26). *Carving out success: identifying factors associated with metabolic and bariatric surgery outcomes*. Retrieved from https://hdl.handle.net/1887/4209450

Version:	Publisher's Version
License:	Licence agreement concerning inclusion of doctoral thesis in the Institutional Repository of the University of Leiden
Downloaded from:	https://hdl.handle.net/1887/4209450

Note: To cite this publication please use the final published version (if applicable).

IV

Overarching framework

7

General discussion and summary

Over the past decades, the global prevalence of overweight and obesity has reached epidemic proportions. Consequently, effective interventions such as metabolic and bariatric surgery (MBS) are essential for achieving substantial weight loss and reducing the elevated health risk associated with obesity. Nonetheless, it is important to acknowledge the significant variability in weight loss outcomes among individuals after these surgical procedures. This thesis presents a comprehensive exploration and analysis of various factors that could potentially affect weight loss after MBS. We have shown that predicting postoperative weight loss after MBS based on preoperative factors remains very difficult. In this concluding chapter, we take a closer look at the results presented in previous chapters, place them in a broader perspective and try to translate the results into daily practice and discuss possible directions for future research.

Weight loss after metabolic and bariatric surgery

Weight loss after MBS of course depends on the time at which it is measured after surgery. The data presented in **Chapters 4 and 5** show that nadir weight occurs at the 18-month follow-up moment, with an average percent total weight loss (%TWL) of about 33%. After nadir is reached, it is not unusual for patients to experience recurrent weight gain and then stabilize. Three years after surgery, the average %TWL in our study was approximately 31%, as detailed in **Chapters 4 and 5**. These findings are consistent with existing literature, which reports that maximum weight loss occurs within one to two years after surgery, with an average %TWL of 32% for Roux-en-Y gastric bypass (RYGB) [1]. The weight then stabilizes and an average %TWL of 25% is reached, up to more than ten years after RYGB, as shown by the key results from the Swedish Obese Subject study, which is the largest non-randomized observational study in this field [1].

Identification of factors that could impact outcomes after surgery

– PART I –

Psychological factors

As outlined in the introduction, psychological problems are commonly observed in individuals who undergo MBS, particularly eating disorders such as binge eating disorder, depression and anxiety. Despite recent guidelines, the impact of preoperative psychological issues on postoperative weight loss remains a topic of debate,

with research yielding inconsistent findings. This inconsistency makes it difficult for clinicians to accurately predict patient outcomes and to determine the best treatment plan. To address this uncertainty, we conducted a systematic review and meta-analysis, detailed in **Chapter 2**, aiming to bring together multiple studies examining how psychological factors affect weight loss following MBS. Additionally, the study described in **Chapter 3** evaluated the predictive ability of a preoperative psychological assessment tool, the Cleveland Clinic Behavioral Rating System (CCBRS), in determining weight loss and compliance to follow-up after MBS.

The systematic review and meta-analysis in **Chapter 2** evaluated the following factors: compliance to follow-up, physical activity, binge eating, depressive symptoms, anxiety, body image, and quality of life (QoL). It revealed that preoperative depressive symptoms and binge eating, problems that are often a reason to refuse patients for surgery, did not significantly impact weight loss after MBS. Although no meta-analysis was feasible for anxiety symptoms due to data limitations, the review also suggests no substantial association between preoperative anxiety and weight loss after MBS. However, postoperatively, individuals with symptoms of binge eating disorder and those who showed up less often for a follow-up appointment, had less weight loss.

As detailed in **Chapter 3**, psychologists in this study assessed patients with the CCBRS, alongside the standard preoperative screening. The CCBRS consists of nine psychological domains: consent, expectations, social support, adherence, coping/stressors, mental health, substance use/abuse/dependence, eating behaviors, and overall impression. The findings revealed that none of these domains were predictive of weight loss or compliance up to five years after MBS.

Outline of (international) guidelines

A critical aspect to take into mind when interpreting the results from **Chapter 2 and 3**, is that there are certain psychological contra-indications for MBS according to international guidelines as well as the Dutch guideline.

The Canadian guidelines state contraindications for MBS are unstable psychiatric illness, (changes in psychiatric medications in the last six months), recent substance abuse (alcohol or drugs) or an inability to adhere to long-term follow-up, due to a high risk of short- and long-term complications [2, 3].

The guideline from the European Association for Endoscopic Surgery (EAES) states that psychological evaluation can be considered before MBS and that a previous diagnosis of binge eating or depression is no absolute contraindication for MBS [4]. Most mental disorders (mood, anxiety, bipolar disorder, eating disorders etcetera) might be considered as a contraindication for MBS if severe and undertreated [4].

The Dutch guideline states that individuals who are not willing to adhere to lifestyle changes and patients with unstable, chronic psychiatric psychopathology, such as bipolar disorder or psychotic episodes, should not be considered for MBS [5]. Additionally, anyone showing signs of certain psychiatric conditions needs further evaluation and possibly treatment by a psychologist or psychiatrist. These conditions include severe depression with vital signs or suicidal thoughts, severe anxiety disorder lasting at least six months, acute post-traumatic stress disorder lasting more than a month, and current or recent (within the past year) alcohol addiction. However, if a patient has been free from addiction for over a year, it does not exclude them from surgery. The guideline is stricter about psychological issues and requires that anyone with a suspected or confirmed eating disorder, depression, problems with impulse control or emotional instability, should be referred to a psychologist for assessment and treatment before undergoing MBS [5].

The overlap between the guidelines lies in the importance of assessing psychiatric conditions such as depression, anxiety disorders, substance abuse, and eating disorders before proceeding with surgery. All guidelines agree that unstable, severe or undertreated mental illnesses are a contra indication for MBS. Recent alcohol/substance abuse are described as contra indications in the Dutch and Canadian guidelines. However, differences exist in the specific criteria and thresholds for exclusion. For instance, the Canadian and Dutch guidelines highlight challenges with long-term follow-up as contraindication. The Dutch guideline outlines a specific exclusion criterion: a suspected or confirmed eating disorder, depression, problems with impulse control or emotional instability, referral and treatment by a psychologist must also precede surgery. Meanwhile, the European guideline suggests that previous diagnoses of binge eating, or depression may not be absolute contraindications, but can be if untreated or severe.

Clinical implications before surgery

The clinical implications of the findings from **Chapters 2 and 3**, as compared to existing guidelines, suggest a more nuanced approach to assessing and managing psychological factors in patients undergoing MBS. Firstly, our research indicates

that not all preoperative psychological symptoms are necessarily predictive of adverse weight loss outcomes after surgery. Contrary to the stricter point of view taken in some guidelines, particularly the Dutch guideline requiring treatment for any eating disorder and depression before surgery, our findings are more in line with the European guideline. This guideline not immediately disqualifies patients for MBS if they have such symptoms. Since our studies found no association between preoperative psychological factors and weight loss after MBS, the Dutch guideline could describe these conditions as contraindications only if severe or untreated. This approach could provide more personalized care and help ensure that patients who may not face negative outcomes after MBS due to their psychological symptoms are not denied surgery.

Clinical implications after surgery

As described in **Chapter 2**, our results underscore the importance of postoperative monitoring and early detection of binge eating disorder symptoms in bariatric care. Individuals diagnosed with binge eating disorder tended to experience less weight loss after surgery. Therefore, we strongly advise bariatric care providers to be attentive to signs of postoperative binge eating and to address them to optimize weight loss outcomes. This is already described in the guidelines on postoperative monitoring [5, 6].

The relationship between attendance to follow-up and weight loss remains somewhat unclear. It is uncertain whether attendance to follow-up appointments leads to more significant weight loss or if patients who experience greater weight loss are more likely to attend these appointments. While the direct impact on weight loss may be uncertain, consistent follow-up remains important for overall patient outcomes, including monitoring for potential complications such as vitamin deficiencies, adjusting medications, and addressing any issues related to changes in weight [5, 6]. Therefore, we recommend that both bariatric centers and patients prioritize attending follow-up appointments to the best of their abilities.

Limitations and future research

Determining the impact of severe or unstable preoperative depression, anxiety, or (binge) eating disorders on postoperative weight loss presents challenges as these patients are typically not included into research due to the psychological contraindications for surgery. This preoperative selection of patients may have led to a selection bias. Thus, the absence of associations between preoperative symptoms

and weight loss in our study, might also suggest effective preoperative selection and treatment, rather than the absence of effects on weight loss.

The exclusion of patients with severe psychological symptoms prevents us from concluding whether these individuals would also experience less weight loss. Therefore, we recommend that patients with severe psychological symptoms continue to undergo formal psychological screening and treatment before undergoing surgery. This recommendation is important not only for optimizing weight loss outcomes but also for addressing potential psychological complications following MBS.

However, beyond just screening, tailored care is crucial. Collaboration with the patient's psychiatrist is essential to determine the optimal timing for surgery. This process cannot be captured by a single questionnaire. Instead, it requires a good understanding of the patient's psychological and physical condition. Knowing the patient well enough to make informed decisions is key to ensure the best outcomes. Furthermore, it is important to consider whether slightly less weight loss should be a reason to withhold surgery. For example, a previous study from the Dutch Obesity Clinic found that patients with a current DSM IV Axis 1 or 2 diagnosis had only 3.7% lower maximum TWL compared to patients without such a diagnosis, and 6.5% lower TWL four years after surgery [7].

To overcome the limitation of excluding these patients, future research would have to include these populations to enable more accurate clinical decision-making and achieve a comprehensive understanding postoperative outcomes. However, one could argue about the ethical considerations involved, as including patients with severe psychological symptoms may raise concerns about their well-being. Research might address this by including patients with severe symptoms only if it is determined that their obesity significantly impedes their access to effective psychological support, thereby worsening their symptoms. This approach could ensure that the inclusion of such patients is justified by the potential benefits of addressing both their obesity and psychological distress.

Additionally for future research, when employing psychological screening tools for research purposes, doing retesting after psychological treatment would be insightful in distinguishing the effects of psychological treatment from those of the disorder itself. This approach could provide valuable insights into the effectiveness of interventions and help refine screening protocols for enhanced patient care.

– PART II –

Preoperative prerequisites

According to international guidelines, patients should undergo thorough screening prior to MBS [8]. Several preoperative prerequisites are implemented by guidelines, clinics and insurance companies to assess if patients are eligible for MBS. Examples of these criteria include mandatory preoperative weight loss or meeting the "last resort" criterion. The latter often involves completing a mandatory weight loss program (MWP) before MBS, as was formerly a standard requirement before reimbursement was approved by insurance companies [9]. This requirement was based on the assumption that they will induce preoperative weight loss, prepare patients for the necessary lifestyle changes, and therefore lead to greater postoperative weight loss [10]. However, there is ongoing discussion whether these preoperative prerequisites are beneficial and associated with better weight loss outcomes after MBS. To address this debate, the study reported in **Chapter 4** evaluated whether meeting the "last resort" criterion was associated with weight loss following MBS. Additionally, the study presented in **Chapter 5** describes whether preoperative weight loss related with weight loss outcomes after MBS.

The cohort study described in **Chapter 4** revealed no difference in weight loss outcomes after MBS between patients who qualified at screening according to the last resort criterion and those who did not meet this criterion initially, necessitating a MWP before MBS. Furthermore, the results showed that any weight lost during the MWP phase was typically regained before surgery, indicating that this preoperative weight loss had only short-term effects and did not contribute to substantial postoperative weight loss. Additionally, referring patients to a MWP after screening resulted in a significant delay in surgical treatment.

The study reported in **Chapter 5** assessed the association between preoperative weight change and weight loss outcomes after MBS. Five distinct groups were defined based on patients' preoperative weight changes, ranging from weight gain to weight loss. The analysis showed a positive association between weight loss prior to MBS and greater overall weight loss (from initial screening to follow-up). However, patients who experienced weight gain before surgery, did not have less postoperative weight loss (from surgery to follow-up).

Outline of (previous) guidelines

At the time of the study described in **Chapter 4**, MWPs were still a strict prerequisite for surgery, mainly due to insurance requirements [9, 11]. The previous Dutch "Guideline Morbid Obesity," established in 2011, recommended attempting weight loss prior to MBS, preferably within an intensive counseling program [12]. This recommendation was based on the potential benefits of reducing surgical risks such as blood loss, complications, conversions, and operating time, and possibly improving postoperative outcomes [13].

However, in 2016, the American Society for Metabolic and Bariatric Surgery (ASMBS) released a position statement on insurance-mandated preoperative weight loss [11]. This document underscores the absence of solid evidence to support the effectiveness of these weight loss programs mandated by insurers. Consequently, it is advised that the decision to exclude patients from MBS based solely on their inability to lose weight through preoperative diets is not recommended. The statements argue that such requirements can lead to increased dropout rates prior to surgery, delay of receiving potentially life-saving treatments, worsening of obesity-associated medical conditions, and increased healthcare costs [11]. This practice is deemed unethical and is suggested to be discontinued. Personalized treatment is essential, with decisions adapted to each patient's specific circumstances, allowing treatment teams to choose the most suitable treatment options. The results from **Chapter 4** and personal communication with Dr. Mitchell Roslin, an associate editor of the ASMBS scientific journal, reinforced the ASMBS's position on this topic.

In addition, the updated Dutch guideline for the surgery of obesity, updated in 2020, now explicitly states that preoperative weight loss or multiple weight loss attempts are unnecessary requirements for undergoing MBS [5]. Instead, the guideline offers several options to assess the current lifestyle of patients seeking MBS. These criteria include undergoing a weight loss attempt under the guidance of a healthcare professional such as a general practitioner or dietitian, demonstrating a serious commitment to weight loss, and having obesity for at least five years [5]. However, these criteria are recommendations and are no longer mandatory prerequisites. The guideline also states that preoperative weight loss may help in reducing complications, but the impact is so minimal that it is not justifiable to require all patients to adhere to a preoperative diet [5].

Clinical implications

Despite updated guidelines, some clinics and insurance companies continue to prescribe preoperative MWPs as a criterion on their websites [14, 15]. We encourage those who continue to enforce preoperative weight loss or MWPs as a prerequisite for MBS to reevaluate this approach. Rather than considering it a requirement, clinics should follow existing guidelines which recommend using previously described factors such as previous weight loss attempts, duration of obesity and participation in a MWP as part of the personalized advice during screening [5]. There is insufficient scientific evidence to support this, as described in **Chapter 4**. Preoperative weight loss is still encouraged due to its association with greater overall weight loss, as detailed in **Chapter 5**. However, preoperative weight gain should not deny patients from surgery, as it is not associated with lower postoperative weight loss.

Limitations and future research

In research, it is important to differentiate between causation and association. Causation is a direct cause-and-effect relationship between two or more variables. Association is a statistical relationship without having direct causality. Different research designs affect the whether causation can be assumed. For example, randomized controlled trials can show causation because they are well-controlled and randomized, while observational studies generally only show associations. In this thesis, most studies were retrospective, which limits the ability to make causal conclusions. Despite these limitations, it is important to note that no significant associations were found between many preoperative factors -like psychological problems, preoperative weight loss and recently following a MWP- and weight loss after MBS. This lack of associations suggests that these preoperative factors might not play a significant role in predicting postoperative outcomes, although causality cannot be definitively determined because of the retrospective nature of these studies.

Another limitation of this thesis is that it only focuses on weight loss as an outcome after MBS. While many studies primarily use weight loss as main outcome, it is not the only important indicator. Other outcomes, such as the resolution or improvement of obesity-associated medical conditions, amount of medication usage, and quality of life, as well as societal outcomes like absenteeism and premature death, can be considered equally or maybe even more important. Therefore, it is crucial for future research to have more attention to these outcomes of MBS, preferably in large prospective trials so causal relationships can be studied.

– PART III –

Food and health literacy

Food literacy is defined as the combination of knowledge, skills, and behaviors necessary for planning, managing, selecting, preparing, and consuming food to meet dietary needs and determine food intake [16]. Health literacy refers to individuals' ability to locate, comprehend, and utilize information and services to make informed decisions and take actions concerning health, both for themselves and others [17]. Food and health literacy are frequently studied in the general population. However, research on food and health literacy in individuals undergoing MBS is limited. Therefore, **Chapter 6** of this thesis aimed to investigate food and health literacy among patients awaiting MBS, as well as to explore the factors associated with these literacies.

The prospective cohort study outlined in **Chapter 6** revealed that food literacy in patients awaiting MBS was comparable to that of the general population, while health literacy appeared to be even higher. Additionally, the study identified that women exhibited higher scores in both food and health literacy. Interestingly, no significant association was observed between BMI and either food or health literacy. These findings underscore the multifaceted nature of obesity as a condition influenced by various factors beyond mere knowledge and skills related to food and health. Additionally, behavior is influenced by various factors beyond just skills, such as attitudes, self-efficacy, and social influences, which collectively impact the ability to turn knowledge into effective actions and drive behavioral change, also in obesity treatment [18, 19].

Outline of guidelines

Both the Dutch guideline for obesity surgery and a Dutch clinic specializing in MBS recommend postponing surgery if a patient lacks sufficient knowledge of healthy eating [5, 20]. They then advise undergoing dietary sessions first to better prepare for the surgery. However, the guidelines do not specify the methods for assessing this knowledge or define what constitutes inadequate knowledge of healthy eating.

Clinical implications

Currently, formally assessing food and health literacy is not standard practice in clinical care, even though guidelines suggest that inadequate knowledge about healthy eating could prompt dietary counseling and postpone surgery. To improve this, it could be beneficial to incorporate validated questionnaires, like those used

in **Chapter 6**, into clinics' standard treatment protocols. This would create a consistent way to evaluate patients. It is important to clarify that the intention is not to introduce a new preoperative prerequisite. Instead, it would provide guidance to clinicians during preoperative screening and assessment and to enable them to offer personalized advice to each patient based on their individual needs.

Limitations and future research

It is crucial to recognize that the used questionnaires rely on patients reporting their own literacy. There is a potential bias where patients might feel pressured to provide overly positive responses, especially if they perceive it could impact their readiness for surgery, which could impact the reliability of the results. To address this, these questionnaires could be used as tools, similar to how clinics use surveys for psychology and physical activity, to guide conversations with patients during screening. This approach could enable more accurate assessments of food and health literacy among those being considered for MBS.

In **Chapter 6**, however, when the food and health literacy questionnaires were administered, patients were already screened and deemed eligible for MBS as part of the preoperative counseling program. Therefore, there may be less pressure on patients to provide socially desirable responses, because their readiness for surgery was not influenced by their questionnaire answers. However, it cannot be completely ruled out that patients still may have given more favorable responses and thus cause bias. It is important to note that these questionnaires remain self-reported, which reflects how patients perceive their own literacy levels and experiences.

The study described in **Chapter 6** is ongoing and will also explore the relationship between food and health literacy and weight loss after MBS. If an association is found between preoperative food or health literacy or changes in these literacies during perioperative counseling and subsequent weight loss, it would be worthwhile to investigate whether interventions aimed at enhancing these literacies could also improve weight loss outcomes. Additionally, future studies should include a larger sample of individuals with lower literacy levels, as **Chapter 6** had only a few participants from this group, making it challenging to draw definitive conclusions. Providing questionnaires in paper or verbal formats, in addition to digital ones, might help reduce selection bias and better represent patients with varying literacy levels.

The future of obesity care

This thesis has shown that predicting weight loss after MBS based on preoperative factors is very difficult. It raises the question whether preoperative screening in its current form remains the best method for determining surgical eligibility. Instead, a more holistic approach that considers the complex interplay of factors influencing both the development of obesity and weight loss after MBS may be more effective. Tailored care, rather than strict screening criteria, should guide decision-making.

Furthermore, it is important to move beyond weight loss as the primary outcome measure for MBS. Improvements of obesity-associated medical conditions, quality of life, and overall well-being should be equally important when evaluating the success of MBS. For instance, is a slightly lower expected total weight loss of 20-25% in a patient with psychological conditions a valid reason to deny treatment? Only when the risks, such as exacerbation of psychological conditions outweigh the benefits of surgery should it be considered. This exemplifies the importance of personalized, patient-centered care.

As we learn more about the mechanisms underlying obesity, including the roles of genetics and gut hormones, treatment strategies are expected to become more tailored to each person's needs. The development of new obesity management medications —though beyond the scope of this thesis— will also shape future obesity treatment options and influence the role of MBS.

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