

Optimizing outcomes and treatment strategies in bariatric surgery

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General discussion, summary and future perspectives

Clinical auditing has proven to be a powerful tool in improving the quality of care through a Plan-Do-Check-Act (PDCA) cycle. The annual PDCA cycle provides physicians with feedback on their outcomes and thereby stimulates initiatives to improve them.¹ The Dutch Audit for Treatment of Obesity (DATO) was initiated for this purpose and records data on variables related to care structure, care process, and patient outcomes.² Improvements in the structure and process of care will eventually improve clinical outcomes.³ In addition, the data from DATO can be utilized for clinical research to compare patient outcomes after treatment in daily practice and thereby provide new knowledge about how to optimize and improve care. Although randomized trials provide the highest-quality evidence, selection criteria limit applicability to selected patient groups rather than providing evidence for the entire patient population. Therefore, the aim of this thesis is to optimize treatment strategies and provide guidance in bariatric surgical care by using the DATO database to present population-based evidence regarding scientific questions in bariatric literature.

Bariatric surgery is known to have beneficial metabolic effects and can induce complete remission in type 2 diabetes (T2D) for patients with morbid obesity.⁴ Previous studies reporting on metabolic outcomes comparing Roux-en-Y Gastric Bypass (RYGB) and Sleeve Gastrectomy (SG) had conflicting results.⁵⁻⁷ The results reported in **Chapter 2** add to this evidence base by matching population-based patient cohorts undergoing primary RYGB and SG to adjust for confounding by indication. Matching cohorts enables fair comparison of patient outcomes by balancing out the measured confounders between treatment groups similar to randomization.⁸ This study showed that patients undergoing primary RYGB had better weight loss and more favorable metabolic effects in T2D and dyslipidemia remission compared with SG up to 1-year follow-up. These findings are supported by several studies showing better short-term metabolic effects for the RYGB group, possibly due to weight loss independent effects of RYGB.⁹⁻¹¹ Longer-term studies with 5-year follow-up on the other hand, showed similar outcomes for patients who underwent RYGB and SG in terms of T2D remission, with similar weight loss results.¹²⁻¹⁴ This would suggest that the effect on T2D remission is weight dependent. However, another study using national data and a follow-up duration of 5-years showed significantly more weight loss and better T2D remission for RYGB compared with SG.¹⁵ These contradicting long-term findings could be due to the relatively small sample sizes and the controlled setting of trials compared with the large national cohort reflecting real-world practice.^{12,13,15} Although the latter study used population-based data, patients from 2005-2015 were included with no matching of treatment groups which makes it prone to bias as a possible explanation for the contrasting findings. In addition, bariatric surgery is rapidly changing with frequent technique modifications so that

comparing treatment effects in more recent patient populations with up to date techniques remains important. The findings reported in **Chapter 2** add to this debate by including more recent patients and by matching these patients. In the future these research results may help surgeons and patients choose the optimal procedure in favor of those benefitting from more metabolic control on the short-term. As the audit is ongoing, longer follow-up data will be collected to conduct future research with long term outcomes.

While short term outcomes give guidance for the initial treatment effect, evidence on long-term outcomes after bariatric surgery is essential as this reflects the patency of the treatment effect. Following bariatric surgery, most patients will initially achieve the desired weight loss goal, defined as $\geq 20\%$ Total Weight Loss (TWL).¹⁶ However, around 20% of the patients undergoing bariatric surgery will experience weight recurrence or is a nonresponder.¹⁷ Weight recurrence is multifactorial and associated with lifestyle, genetic and metabolic factors, and the type of bariatric procedure.^{18,19} Although the definition of weight recurrence is still up for debate, with arbitrary thresholds showing a wide variety of results, the key issue is to identify patients at high risk, as obesity is a chronic condition.¹⁸ However, to identify patients with progression or deterioration, standardized terminology for weight recurrence is needed.²⁰ Different terminology is used in current literature including the term failure, which enhances the stigma on obesity, and may result in depression, low self-esteem and anxiety in patients, eventually worsening eating behaviors.¹⁹ Another term frequently used is weight regain, also withholding arbitrary cutoff points. Several studies tried to define weight regain, using definitions such as weight regain from maximum weight loss (nadir weight).²¹ Currently, there is no consensus on the definition while the clinical implications between thresholds differ. These different thresholds can lead to over-diagnosing people when the cutoff point is very low (e.g.: $>5\%$ weight regain) whilst the treatment effect may still be sufficient in terms of comorbidity remission or health related quality of life (HRQoL).^{22,23} Another term used is (primary) non-response, which can be either those not achieving adequate weight loss or those gaining weight and not experiencing comorbidity improvement. The term secondary non-response is then used to identify patients who successfully achieved their initial weight loss goal but have a recurrence or progression of the disease in the longer term, thereby distinguishing them from patients who initially did not respond to the treatment.²⁴ The POWER task Force of the American Society for Metabolic and Bariatric Surgery (ASMBS) has published a review suggesting a standardized definition for patients by introducing the terms 'weight recurrence' and 'nonresponder'.²⁰ Overall, the suggested terminology emphasizes that obesity is a chronic disease that may need multiple sequential or parallel treatment strategies to prevent or treat weight recurrence and comorbidity deterioration.^{25,26}

In this context, a recent systematic review suggested that further research with larger cohorts and longer follow-up was needed for (secondary) non-responders, while also recommending comparing outcomes between bariatric procedures.¹⁸ The matched population-based study reported in **Chapter 3** responds to this call by showing that patients who receive SG are more likely to experience $\geq 10\%$ weight recurrence up to 5 years of follow-up compared with patients receiving RGYB, after $\geq 20\%$ initial TWL at 1 year. Another study supports this finding by showing a higher percentage of patients experiencing weight recurrence in the SG group.²² Also, studies have shown lower sustained weight loss outcomes for SG compared with RYGB, which most likely persists even after initial weight loss, resulting in more patients experiencing weight recurrence in the SG group.^{27,28} This thesis (**Chapter 3**), therefore, adds valuable new knowledge on 19,762 patients utilizing rigorous methods to allow fair comparison between treatment groups. The main finding was that SG has a higher likelihood of weight recurrence compared with RYGB. Furthermore, it was shown that patients undergoing SG were less likely to achieve comorbidity remission compared with RYGB, which is in line with a previous study.²⁹ In addition, matched patients with $\geq 10\%$ weight recurrence after SG who maintained $\geq 20\%$ TWL from starting weight more often showed comorbidity remission than those not maintaining 20% TWL. Among matched RYGB patients, such a difference in comorbidity remission was not found. These results suggest that RYGB patients may be less affected by $\geq 10\%$ weight recurrence and its concomitant effect on comorbidity remission. However, selecting the most suitable procedure for the individual patient remains important, as RYGB can result in higher long-term complication rates compared with SG.¹² The stringent threshold of $\geq 10\%$ weight recurrence in this study was related to a recent systematic review correlating risk factors with weight recurrence.¹⁸ One can argue whether weight recurrence should be defined using an arbitrary threshold. Even though the majority of literature uses a measure of body weight to define weight recurrence, in an ideal situation, all key outcomes have to be included such as HRQoL, complications, and comorbidity remission. Such a composite outcome measure will aid in investigating which patients will benefit the most from sequential (surgical) treatments when the 'significance' of weight recurrence is evaluated. Therefore, future research is needed to utilize a standardized definition of clinically significant weight recurrence, taking all key outcomes into account, such as TWL from starting weight, comorbidity control, complications, and HRQoL.

Literature remains scarce regarding revision surgery, both in terms of the best procedure and patient outcomes. Patients experiencing complications after Laparoscopic Adjustable Gastric Band (LAGB) such as band slippage, erosion, or stenosis, are potential candidates for revision surgery. Conversion to RYGB (cRYGB) is the procedure of choice after a failed LAGB, followed by SG, which is also frequently performed. However, conversion to One-

Anastomosis Gastric Bypass (cOAGB) is gaining ground in frequency and is the primary procedure of choice in certain countries.³⁰ In **Chapter 4**, we matched both cRYGB and cOAGB procedures and compared them on weight loss, showing similar outcomes after failed LAGB up to 1-year follow-up. These results echo the findings from the YOMEGA-trial that compared the efficacy and safety between primary RYGB and primary OAGB, showing no significant difference in weight loss at 2 years.³¹ However, the sensitivity analysis (**Chapter 4**) up to 5-year follow-up shows a higher rate of patients not achieving the desired weight loss goal after cRYGB, which suggests potentially better long-term outcomes for cOAGB and thereby supporting findings of a similar study.³² The most likely explanation for these findings is the longer biliopancreatic (BP) limb lengths for the cOAGB group, which has been described to be associated with additional weight loss.^{33,34} Although achieving significant weight loss is important in bariatric surgery, it is not the only consideration when choosing a procedure; the short and long term complications are also essential elements in such a choice. With regard to short-term complications reported in **Chapter 4**, there was no significant difference between cRYGB and cOAGB in postoperative complications within 30 days, defined as Clavien Dindo (CD) \geq III. However, long term complications play an important role in morbidity after bariatric surgery. RYGB long term complications consist, among others, of marginal ulcer, internal herniation, and postoperative malnutrition, whereas the OAGB long term complications mainly consist of internal herniation, bile reflux and postoperative malnutrition. A recent meta-analysis showed mixed results regarding the bile reflux after revisional OAGB, with some studies reporting no bile reflux whilst others reported a higher incidence.³⁵ Another meta-analysis showed a higher incidence of postoperative malnutrition after primary OAGB compared with primary RYGB, which was mainly observed in OAGB with long BP lengths (\geq 200cm).³⁶ However, these studies mainly consisted of retrospective cohorts, making it difficult to translate into daily practice. Additional studies with long-term outcomes are needed to gain insight into the consequences of bile-reflux and the extent of postoperative malnutrition, which have been reported to develop more often in patients undergoing OAGB.³⁷ The long-term results of a randomized controlled trial comparing the safety and efficacy of RYGB and OAGB (the RYSA-trial) are awaited to gain evidence regarding weight loss outcomes and long term complications.³⁸

Metabolic and bariatric surgery rapidly changes with frequent technique modifications and as a result, physicians may have changing preferences for specific procedures that can be more pronounced in some hospitals, regions, and nations.^{30,39} The extent to which hospital preference for a bariatric procedure is associated with weight loss performance was reported in **Chapter 5**. To acknowledge that patients with certain characteristics may be more likely to receive one procedure over another, we defined hospital preference as performing a specific procedure more often than expected, based on the patient-mix in that hospital.

The study showed that hospitals predominantly performing one procedure may have better results with that procedure, but having such a preference did not consistently result in better overall weight loss outcomes. Instead, one hospital having no preference for any procedure was outperforming others in terms of weight loss, suggesting that this hospital has successfully tailored the procedure to individual patients rather than being specialized in one procedure and applying that procedure to most patients. Previous research in bariatric surgical care underlined the benefit of such a patient-tailored approach.^{40,41} This supports and implies that bariatric surgeons need to be proficient in various procedures and that it remains essential to select the most suitable procedure for individual patients given their characteristics. Moreover, similar complication rates and textbook outcome results were found comparing RYGB, SG and OAGB. These similar postoperative outcomes between procedures are probably due to effects of a high annual case load in centralized bariatric care centers.^{42,43} The Dutch guidelines state that bariatric surgery has to be performed in a centralized hospital within a multidisciplinary team having at least 2 dedicated bariatric surgeons who collectively perform more than 200 procedures annually. The Dutch guidelines most likely result in surgeons performing sufficiently various procedures such as RYGB, SG and OAGB leading to similar results regardless of their preference.⁴⁴ Irrespective of the choice for a bariatric procedure, patients undergoing bariatric surgery have shown to achieve sustained weight loss for up to 2-years (**Chapter 5**) and even longer as reported in literature.^{16,27} As the DATO continues to follow these patients, longer-term outcomes will become available in the future.

National quality registries have shown their value in improving healthcare quality by following a PDCA cycle, eventually improving patient outcomes. The International Federation for the Surgery of Obesity and Metabolic disorders (IFSO) global registry brings together all (national) bariatric surgery registries and reports on patient demographics and outcomes, striving to improve the surgical care for patients with morbid obesity.³⁰ However, enabling comparison in outcomes between international centers and giving feedback to stimulate improvement initiatives can only be achieved if all included registries share the same recorded variables and outcomes. In **Chapter 6** the degree of concordance between recorded variables in 11 bariatric surgery registries with nationwide coverage is reported. A total of 2585 recorded variables were grouped into 250 variables measuring the same concept. These variables were grouped into six domains: patient characteristics, history, screening, operation, complication, and follow-up. From all 250 variables assessed, only 25 (10%) had a perfect agreement among participating registries, meaning they all recorded the same variable with identical definition. The remainder of these variables had different definitions or were not recorded across all registries. Contrasting findings in the literature could be explained by differences in definitions of outcomes such as complications,

which have previously been shown to give discrepant results.⁴⁵ In addition, the relatively large discrepancies in recorded variables may explain part of the contrasting findings in bariatric literature when comparing bariatric procedures in weight loss and comorbidity outcomes.^{22,46} Overall, these 11 registries together included 554,599 patients, which could be helpful to gain evidence particularly with regard to relevant bariatric research questions and the treatment effect of various operative procedures. Moreover, it can be used to develop risk and outcome prediction tools to guide shared decision-making in daily practice. Further alignment and uniformity are needed across registries with identical definitions of variables and consistency in reported outcomes. Also, continuous data verification remains essential as the reported outcomes only present strong evidence when data are reliable and valid. Efforts have been made to standardize outcome reporting but has not been adopted consistently by the entire bariatric society.^{46,47} Initiatives endorsed by IFSO such as the development of a core outcome set (COS) or the Standardized Quality of life measures in Obesity Treatment (SQOT) are awaited.^{48,49} Ultimately, standardized recording of variables and outcomes will enable international collaborations with large population-based cohorts to improve the quality of bariatric surgical care on an international level.

As we move to clinical care offering individualized treatments, surgeons need individualized information about the likely benefits and risks associated with specific types of surgery, to guide doctor-patient decision-making in daily practice. Although it is possible to use average estimates from the literature, these estimates of risk and benefit are preferably based on the population from their own rather than another country. In addition, these estimates should preferably be tailored to the individual patient rather than the average in a patient group. Risk prediction tools may be useful in this context, and the Michigan Bariatric Surgery Collaborative (MBSC) risk prediction model was developed for this purpose to predict severe postoperative complications within 30 days after primary bariatric surgery.⁵⁰ It is known that prediction models perform well in the setting in which they are developed but perform less accurately in a new geographical setting, meaning they can overestimate or underestimate risks in a new population, which may affect decision-making and compromise clinical outcomes.⁵¹ Therefore, a prediction model must be externally validated, assessing its performance in the new setting which will also enhance its generalizability.^{52,53} The MBSC model was therefore externally validated for the Dutch setting using the DATO data (**Chapter 7**). Assessing the performance of a prediction model should include both its discriminative ability (using the Area Under the Curve (AUC)) and a calibration plot. The former is the ability to distinguish between patients with and without a postoperative complication (i.e. the extent to which patients with complications have a higher predicted risk than those without). The latter predicts the extent to which the absolute predicted risk is similar to the actual observed risk, which can be used by physicians and patients during shared

decision making. The validated model with the best performance reported in **Chapter 7** showed an AUC of 0.602 with a good calibration. Although the calibration is good, the model's discriminative ability remains moderate, as the ideal model should have a higher AUC (preferably >0.8). Several reasons could explain the moderate AUC, which makes the model less suitable e.g. to identify high-risk patients. First, the DATO population is rather homogenous with relatively little variation in bariatric patient mix, making it difficult for the model to discriminate between patients with and without severe complications.⁵⁴ Moreover, due to centralization and high annual case load, the relatively low complication rates make it challenging to predict the occurrence of serious complications. Finally, the model may discriminate better for specific complications such as anastomotic leakage or death rather than all complications combined. This hypothesis is supported by the ASMBS calculator and the Obesity Surgery-Mortality Risk (OS-MRS) score, that have high discriminative ability for specific complications, but lower AUC when predicting all severe complications combined.^{55,56} Moreover, specific complications after bariatric surgery especially mortality are low (<0.1%)⁵⁷, meaning that the clinical relevance to predict one specific complication or only mortality is up for debate. Also, the relevant information for patients likely relates to the overall risk to experience a complication, rather than information about multiple specific complication risks. This emphasizes the need for a model which not only predicts the likelihood of all major postoperative complications but also in combination with outcomes relevant for patients such as weight loss and comorbidity remission. The MBSC outcome calculator has responded to this call and updated their model predicting outcomes such as weight loss and comorbidity remission. The study described in **Chapter 7** shows that the externally validated MBSC model may be a useful adjunct in clinical practice for the Dutch population by accurately predicting individual risks. Although it has a moderate discriminative ability to identify e.g. high-risk patients for inclusion in trials, the accurately predicted risk shown by the good calibration can be communicated to the patient during shared decision-making. Future studies are needed to continuously update and improve the model adding relevant prediction outcomes such as weight loss and comorbidity remission. Finally, studies are needed to show whether the predictions from this model e.g. as an outcome calculator, will be accepted by surgeons and influence their decision-making in daily practice.

Future Perspectives

In this thesis, the first long-term results from the DATO up to 5-years have been presented. As is the case in every bariatric registry, the percentage of patients with missing follow-up data remains a challenge, particularly at longer follow-up.⁵⁸ The DATO has a prespecified time frame for recording outcomes during follow-up to ensure accurate measurements. This time frame has a window of $-/+ 3$ months for each follow-up year. The narrow timeframe may partially explain the missing percentage in outcomes during follow-up. Another explanation is that patients cannot be linked between centers due to Dutch privacy regulations. For example, any referral to another hospital or change of hospital by the patient results in loss of follow up, as the registry data cannot link back to the patients' primary data. In addition, it remains a challenge for patients to be compliant in the postoperative follow-up care after bariatric surgery. Several initiatives have been taken by bariatric centers to improve the percentage of follow-up such as reaching out to patients by phone or reminders through email, however, without satisfactory results. Patient-centered registration with cross-linking of patient information across all bariatric caregivers and different outcome registries using a unique patient identifier to connect all different medical records, could enhance the follow-up percentage.

A higher percentage of patients with complete long-term follow-up data will give more reliable insight into long-term outcomes and guide us towards better treatment strategies. However, even if the follow-up record is available, it remains important to also register outcomes in a complete and consistent manner such as long-term complications, which could be treated in another hospital and cannot link back to the patients primary data. Another important long-term outcome is the comorbidity status, where information such as blood tests are not always available during an outpatient clinic visit so that only the use of medication or status of the comorbidity is registered. A possible explanation could be the distance to the hospital and the recent COVID-19 pandemic resulting in more E-health consultations where patients were less likely to undergo blood tests due to the restrictions. Furthermore, it is common for Dutch patients to get treatment by other specialized healthcare providers for their comorbidities such as T2D, who likely will have more information at their disposal, but register these data elsewhere i.e.; in the Dutch Pediatric and Adult Registry of Diabetes (DPARD). Since the Dutch institute for Clinical Auditing (DICA) also facilitates the DPARD, linking the DATO to the DPARD would improve the completeness of data during follow-up and result in additional details regarding the comorbidity status, such as HbA1c, insulin dependency, and duration of diabetes. Eventually, this additional information can be utilized to gain evidence in complex relevant bariatric research questions. Furthermore, by combining the DATO with the Dutch Gastrointestinal Endoscopy Audit (DGEA) for endoscopic

bariatric treatments and DICA Medicines program (including pre-and post-bariatric pharmaceutical treatments) it would help the DATO registry to become a multidisciplinary registry, reflecting current healthcare practice that increasingly focuses on multidisciplinary approaches to treat patients with morbid obesity. The ultimate registry would be one that is linked with all other registries providing complete data. Moreover, the registry can be linked to the health cost database and provide insight in the cost-effectiveness of bariatric treatments. However, Dutch privacy regulations are strict and cross-linking registries will require ongoing collaborative efforts from the national health care institute, government officials, and healthcare providers.

In general, the success of bariatric surgery is measured by weight loss. However, other outcomes such as complications, comorbidity reduction and the quality of life are also relevant. For several years the RAND-36 was used as patient-reported outcomes measures (PROMs) for the DATO. However, this general questionnaire lacked the discriminative ability for obesity specific quality of life outcomes such as eating behavior.⁵⁹ Hence, DICA and the Dutch Society for Surgery taskforce developed and implemented the OBESI-Q⁶⁰, which is a more discriminative and accurate PROM for patients who undergo bariatric surgery.⁶¹ The first results on PROMs using the OBESI-Q will become available in 2023. Combining all the aforementioned key outcomes in the form of a long term composite outcome measure to define the success of bariatric surgery, may give more comprehensive insight into the postoperative care and follow-up process in daily practice.

As bariatric surgery is frequently being performed in the Netherlands, with an annual case load of 12,000 procedures, patients presenting with weight recurrence will also increase in coming years. In general, there is relatively little evidence on the outcomes after bariatric revision surgery, and the DATO is an excellent way to gain real-world evidence for this group of patients. However, obtaining such information about revision surgery also means the administrative burden for doctors will increase, as more variables will need to be recorded annually.⁶² There is a thin line in balancing a minimal essential amount to record variables and a high administrative burden. Currently, the DATO is recording a total of 206 variables. Accomplishing full electronic forwarding of data already routinely collected in hospitals' electronic medical records will decrease the administrative burden and provide more detailed information regarding the surgical procedure, e.g., stapling techniques, pouch sizes and used instruments. However, this remains a challenge as the restriction in data exchanges are different in various electronic health records. Furthermore, the manual entries in the DATO as well as the delivery of batch files are still prone to error and automating this process will further improve the already high quality of the data.⁶³ Therefore, critical evaluation of what variables need to be collected to make a reasonable assessment of the quality of

care delivered remains essential, particularly in the context of different stakeholders asking different questions.⁶⁴

In clinical auditing, providing feedback information on one's own performance is essential. DICA recognizes the feedback information as one of the key points for its registries and follows an annual PDCA cycle for their quality indicators. In addition, DICA provides an online dashboard where real time feedback is presented on already uploaded data that can serve hospitals to improve their quality of care. The interactive dashboard particularly gives the ability for clinicians to filter on subgroups of patients with specific comorbidities or procedure types, display trends over time, and even show results on regional and individual surgeon level. This tailored feedback information presented in the dashboard will serve as the basis for future improvement initiatives when outcomes may deteriorate, e.g., by stimulating the discussion for surgical care in specific patient groups at local, regional, and surgeon levels. Finally, during scientific committee sessions, the best practice centers can share their results and be transparent in their care process to facilitate learning opportunities for other hospitals.

Overall, the DATO has proven its value and is essential in continuously striving to improve healthcare outcomes. As the DATO continues to mature, more detailed information will be available covering longer follow-up periods, which can be utilized to gain real-world evidence in daily practice. Finally, using the PDCA cycle, improvement initiatives will repetitively be stimulated to offer safe and high-quality bariatric surgical care.

Conclusion

The DATO has become a mature surgical registry improving bariatric outcomes in Dutch healthcare and adding longer-term real-world clinical evidence to bariatric literature. This thesis utilized the nationwide DATO registry to compare outcomes after RYGB, SG and OAGB while adjusting for confounding by indication using matching techniques to provide new knowledge that may optimize surgical treatment strategies in daily practice. The results showed that the overall surgical care across bariatric centers in the Netherlands is of high quality and bariatric surgeons are proficient in various procedures on a national level, and therefore able to select the most suitable procedure for the individual patient. Furthermore, it suggests better outcomes for the RYGB group by reporting better weight loss outcomes and comorbidity remission compared with SG. While the postoperative complications within 30 days between SG, RYGB, and OAGB are similar, future studies are needed to assess the longer term complications as obesity is a multi-causal chronic condition which may require multiple sequential treatments. In an attempt to aid surgeons in shared decision-making, an international collaboration resulted in an externally validated risk prediction tool that can accurately estimate individual risks to be used by patients and physicians. In the future, the DATO could better serve bariatric centers by providing interactive, tailored feedback, decreasing the registration burden, and becoming a multidisciplinary audit to improve the overall metabolic and bariatric care across all phases in the treatment of obesity.

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