Optimizing outcomes and treatment strategies in bariatric surgery

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'The Dutch Audit for Treatment of Obesity'

Erman Onur Akpinar

OPTIMIZING OUTCOMES AND TREATMENT STRATEGIES IN BARIATRIC SURGERY

The Dutch Audit for Treatment of Obesity

Erman Onur Akpinar

Colophon

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Optimizing outcomes and treatment strategies in bariatric surgery

The Dutch Audit for Treatment of Obesity

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Promotor

Prof. dr. J.W.M. Greve	Maastricht Universiteit Medisch Centrum

Copromotores

Dr. S.W. Nienhuijs	Catharina ziekenhuis
Dr. P.J. Marang – van de Mheen	Leids Universitair Medisch Centrum

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General introduction and thesis outline

General Introduction

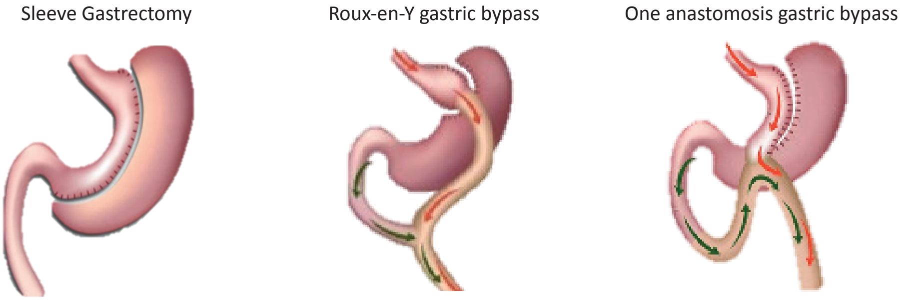
Obesity is a global epidemic defined as having a body mass index (BMI) of 30 or more, indicating excessive fat accumulation that presents a chronic health risk. Globally, there are 1.9 billion people with overweight and 650 million people with obesity.[1] In the Netherlands, approximately 51% of the population aged 20 years and older had overweight in 2020. The prevalence of obesity almost tripled in the last decades, from 5.3% in 1981 to 14.2% in 2020.[2]

Overweight and obesity are major risk factors for developing other chronic diseases. Numerous studies have shown that obesity is a risk factor for developing malignancies such as breast, liver, kidney, and colon cancer.[3,4] The most common obesity-related comorbidities are type 2 diabetes (T2D), dyslipidemia, hypertension (HTN), gastroesophageal reflux disease (GERD), obstructive sleep apnea syndrome (OSAS), and musculoskeletal disorders or osteoarthritis.[5–12] In addition, obesity is independently associated with cardiovascular diseases, the leading cause of death worldwide.[13,14] All these risk factors and comorbidities associated with obesity further increase the overall mortality risk and negatively impact the quality of life.[15,16]

Bariatric surgery is well established worldwide and is an effective and sustainable treatment for obesity.[17] Clinical trials have shown that weight loss is more effective and sustainable for bariatric surgery patients than non-surgical patients with obesity.[18,19] In addition to the weight loss, patients undergoing surgery also benefit from better metabolic outcomes, lowered incidence of cardiovascular diseases, and lower mortality compared with non-surgical patients.[20–22]

There is a variety of bariatric procedures available at the surgeon's disposal. In the Netherlands, the most performed techniques are Sleeve Gastrectomy (SG), Roux-en-Y gastric bypass (RYGB), and one-anastomosis gastric bypass (OAGB).[23] Other procedures included in the arsenal of bariatric surgeons but performed less often, consist of the laparoscopic adjustable gastric band (LAGB), single anastomosis duodenal-ileal bypass with sleeve gastrectomy (SADI-s), and duodenal switch. Each bariatric technique has its own set of (dis) advantages. While one technique may result in better comorbidity resolution, the other technique results in higher (long-term) weight loss.

The primary outcome of bariatric surgery is expressed as % total weight loss (TWL), with the cut-off at 20% to define adequate weight loss.[24,25] Regardless of the arbitrary threshold at 20%, the success of bariatric surgery is not only determined by weight loss but by a combination of long-term weight loss, pre-and postoperative complications, comorbidity reduction, and quality of life.



Clinical auditing

Ernest Amory Codman (1869-1940) was a Boston surgeon and the founding father of clinical auditing.[26] He believed that individual outcome evaluation was necessary to improve outcomes. Hence, he made an effort to follow up with all his patients years after treatment and recorded the diagnostic and treatment errors, also known as the end result system.[27] This process would be repeated annually, providing physicians with feedback and an opportunity to improve the quality of care and outcomes. This concept of repeatedly evaluating outcomes to improve the quality of healthcare served as a stepping stone to what is known as clinical auditing today.

The Dutch Audit for Treatment of Obesity

To improve the quality of healthcare, the Dutch Institute for Clinical Auditing (DICA) was founded to facilitate and organize the initiation of nationwide audits. In 2015, the Dutch Audit for Treatment of Obesity was launched by the Dutch Society for Metabolic and Bariatric Surgery (DSMBS) to monitor the quality of bariatric surgery across all hospitals and improve the quality of care and patient outcomes.[28] All hospitals in the Netherlands are required to register all bariatric procedures in the DATO. The DATO aims to provide hospitals with nationwide benchmarked feedback on a weekly basis, therewith providing insight in real world (real-time) data and a stimulus for improvement initiatives. Graphical methods are used to provide the benchmarked feedback to hospitals, in particular using funnel plots. These plots identify outliers (under- or excellent performers) by using predefined 95% control intervals (CI). If a hospital exceeds the control interval this means it has outlier performance on the outcome of interest, eventually providing underperforming centers the opportunity to learn from excellent performing centers.

The audit runs an annual plan-do-check-act (PDCA) cycle which consists of the systematic process of (1) identifying the problem, (2) defining standards, (3) collecting and (4) analyzing data, (5) implementing changes to improve outcomes, and (6) re-auditing.[29] This PDCA cycle is applied to quality indicators which are determined annually by the scientific committee of the DATO. These quality indicators consist of insight in the process of care, the structure of care and clinical outcomes. This systematic framework has shown that improvements in the structure of care will lead to improvement in the clinical process, eventually resulting in improving patient outcomes.[30] The audit cycle of the DATO is used to assess nationwide variation between hospitals based on these quality indicators with the purpose of improving bariatric surgical care in the Netherlands. As this is an ongoing process, it continuously strives to achieve higher quality of bariatric care, eventually improving patient outcomes.

Real-world data

Randomized controlled trials (RCT) are the gold standard for comparing the effectiveness of treatments between groups. However, they can present challenges such as ethical problems, financial costs, and insufficient sample size or power.[31] In addition, RCT's only investigate a selected group of patients and are therefore not generalizable to the whole population receiving a certain treatment in daily practice. Due to the strict in- and exclusion criteria in trials, the population characteristics can differ from routine clinical practice by including only healthy or high-risk patients while the real world setting contains a heterogenous population. These differences between trials and real-world patient characteristics result in contradictory findings in scientific literature, where patients in routine practice may have poorer clinical outcomes compared with trial patients. To treat patients effectively and give realistic treatment expectations, it is imperative to estimate real-world effectiveness of bariatric surgery. The DATO, which prospectively collects nationwide real world data in the process of bariatric care can be utilized for research and add valuable evidence to current literature.

Thesis Outline

Literature remains contradictory when comparing outcomes after different bariatric procedures. Recent RCTs have shown no difference in weight loss outcomes between SG and RYGB up to 5-years of follow-up.[32,33] Another RCT showed no difference in weight loss when comparing RYGB and OAGB.[34] However, systematic reviews and meta-analyses suggest differences in outcomes between these treatments which can benefit specific patient groups.[10,17,35] Since these meta-analyses mainly comprise retrospective studies that may be prone to bias, this calls for higher-quality evidence in comparing outcomes between procedures and larger cohorts with longer follow-up duration. However, the controlled setting in which RCTs are conducted cannot always be extrapolated towards daily practice given the selected group of patients. In addition, rapid changes in bariatric surgical care require prompt real-world evidence, leading to timely and essential changes in clinical practice without awaiting trials and compromising patient outcomes. Therefore, this thesis will aim to provide guidance for surgeons in daily practice by comparing outcomes between bariatric techniques and hospitals, including all patients receiving these procedures using the population-based DATO.

Metabolic effects of bariatric surgery

Several factors play a role in decision-making around the type of bariatric procedures, such as costs, outcomes, or comorbidity reduction, e.g., type 2 diabetes (T2D).[36] Bariatric surgery is increasingly performed in patients with obesity and T2D as metabolic surgery can lead to complete remission.[22] However, the resolution of T2D remission remains contradictory between the two most frequently performed procedures: RYGB and SG. A recent meta-analysis shows favorable outcomes for patients with RYGB,[37] whereas RCTs show no difference between the two treatments.[22,33] However, these studies do not utilize nationwide real-world data and thus may not reflect daily practice. The outcomes of T2D remission between RYGB and SG were compared in **Chapter 2**, using a propensity score-matched comparison in a nationwide cohort to adjust for confounding by indication.

Weight loss and weight recurrence

Obesity is a chronic disease that may need multiple sequential treatment strategies over a longer time period. The success of bariatric surgical treatment is defined as having a total weight loss of ≥20% after bariatric surgery.[24] The majority of patients undergoing bariatric surgery will achieve this weight loss goal. However, around 20% of the patients undergoing bariatric surgery will show non-response or weight recurrence.[38] Although the definition of weight recurrence is still up for debate, with arbitrary thresholds showing a wide variety of results,[39] patients with significant weight recurrence are potential candidates for revision surgery, making it important to identify such high-risk patients. Weight recurrence is multifactorial and associated with lifestyle, hormonal, genetic, and metabolic factors, but also with the type of bariatric procedure.[40,41] However, studies comparing the outcomes of weight recurrence between RYGB and SG remain scarce, in particular among patients initially achieving adequate weight loss. Hence, it is essential to require prompt real-world evidence to inform patients about the long-term outcomes regarding weight recurrence between bariatric procedures. In **Chapter 3**, weight recurrence defined as ≥10% weight increase from Nadir conditional to achieving ≥20%TWL at 1-year follow-up, were compared between SG and RYGB using matched cohorts from the DATO.

Revision bariatric surgery

Patients presenting with non-response after primary laparoscopic adjustable gastric banding (LAGB) are increasing, with failure rates up to 50%.[42,43] The gold standard for conversion surgery after failed LAGB is RYGB. However, the OAGB, which has one anastomosis less than the RYGB, has been performed more frequently in recent years.[44] The long-term outcomes of a trial comparing the weight loss outcomes and comorbidity reduction between RYGB and OAGB are still awaited.[45] Therefore, the three-year outcomes of patients undergoing a conversion OAGB or conversion RYGB after a failed primary LAGB were investigated in **Chapter 4** reflecting current practice.

Bariatric procedures

Bariatric surgery has a history of trends with frequent changes in techniques and procedures.[46,47] These trends and changes have led to different physician preferences among countries, regions, and hospitals.[44,48] Although bariatric procedures have proven to give sustained weight loss and comorbidity reduction, it is still unclear which procedure(s) give better (long-term) weight loss outcomes.[49,50] Theoretically, a high volume center specialized in one specific technique would have more experience with that technique which could result in better overall hospital outcomes. However, a one-size-fits-all policy may also result in worse outcomes for some patients who would be better off with a different type of bariatric procedure. The study described in **Chapter 5** therefore aimed to investigate each hospital's preference for a bariatric technique and evaluated if such a preference is associated with better overall weight loss performance.

International comparison of audits

In a world where digital innovation is expanding rapidly, big data from quality registries have proven to be valuable in improving quality of care and in research. Comparing outcomes with quality registries on a national level is of great value to daily practice and surgeons as they utilize real-world data. The DATO in the Netherlands has the purpose of auditing and monitoring with a PDCA cycle that continuously strives to improve outcomes after bariatric surgery.[29] This principle is adopted in many countries, and currently, there are 18 countries with a nationwide bariatric quality registry. Several national quality registries are compared in **Chapter 6**, and the discrepancies between recorded variables and definitions are described. Awareness of registering the same variables with identical definitions and standardized reporting of outcomes will enable comparing treatment effects on an international level, adding significant real-world evidence to current literature.[51]

Risk prediction tools are increasingly developed to translate evidence based medicine into daily practice. Clinicians use these risk prediction tools to guide their doctor-patient (shared) decision-making and inform patients about the risks of surgery. However, these risk prediction models are often used in the setting in which they were developed, which is known to perform less accurate in a new setting with geographical differences. This can result in over- or underestimation of individual risks eventually compromising clinical outcomes. In this context, in **Chapter 7** the Michigan Bariatric Surgery Collaborative (MBSC) risk prediction model for severe postoperative complications after bariatric surgery was externally validated using the DATO.[52] This project also highlights the possibilities of collaborating quality registries combining data for research purposes and could provide a useful generalizable risk prediction tool for surgeons in daily practice.

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2

Metabolic effects of bariatric surgery on patients with type 2 diabetes: a population-based study

Erman O. Akpinar, Ronald S.L. Liem, Simon W. Nienhuijs,
Jan Willem M. Greve, Perla J. Marang- van de Mheen, and
on behalf of the Dutch Audit for Treatment of Obesity Research Group

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Abstract

Background Bariatric surgery among patients with obesity and type 2 diabetes (T2D) can induce complete remission. However, it remains unclear whether Sleeve Gastrectomy (SG) or Roux-en-Y Gastric Bypass (RYGB) has better T2D remission within a population-based daily practice.

Objective To compare patients undergoing RYGB and SG on the extent of T2D remission at the 1-year follow-up.

Settings Nationwide population-based study including all 18 hospitals in the Netherlands providing metabolic and bariatric surgery

Methods Patients undergoing RYGB and SG between October 2015 and October 2018 with 1 year of complete follow-up data were selected from the mandatory nationwide Dutch Audit for Treatment of Obesity (DATO). The primary outcome is T2D remission within 1-year. Secondary outcomes include ≥20% Total Weight Loss (%TWL), obesity-related comorbidity reduction, and postoperative complications with a Clavien-Dindo (CD) grade ≥III within 30 days. We compared T2D remission between RYGB and SG groups using propensity score matching to adjust for confounding by indication.

Results A total of 5015 patients were identified from the DATO, and 4132(82.4%) had completed a 1-year follow-up visit. There were 3350 (66.8%) patients with a valid T2D status who were included in the analysis (RYGB=2623, SG=727). RYGB patients had a lower body mass index (BMI) than SG patients, but were more often female, with higher gastroesophageal reflux disease (GERD) and dyslipidemia rates. After adjusting for these confounders, RYGB patients had increased odds to achieve T2D remission (odds ratio [OR], 1.54; 95% confidence interval [CI], 1.14–2.1; $P < .01$). Groups were balanced after matching 695 patients in each group. After matching, RYGB patients still had better T2D remission (OR, 1.91; 95% CI, 1.27–2.88; $P <.01$). Also, significantly more RYGB patients had ≥20%TWL (OR, 2.71; 95% CI, 1.96–3.75; $P <.01$) and RYGB patients had higher dyslipidemia remission rates (OR, 1.96; 95% CI, 1.39–2.76; $P < .01$). There were no significant differences in CD ≥III complications.

Conclusions Using population-based data from the Netherlands, this study shows that RYGB achieves better T2D remission rates at 1-year follow-up and better metabolic outcomes for patients with obesity and T2D undergoing bariatric surgery in daily practice.

Introduction

Bariatric surgery is well established in the Netherlands as in other countries, and has proven to be safe and effective in weight loss and obesity related comorbidity reduction[1]. It is increasingly performed in patients with obesity and Type 2 Diabetes (T2D) as metabolic surgery can lead to complete remission[2]. Sleeve Gastrectomy (SG) is currently the most frequently performed technique worldwide as studies are showing that it results in less morbidity and similar comorbidity reductions compared with Roux-en-Y gastric bypass (RYGB). Nevertheless, a recent study describes that surgeon factors and expertise are highly associated with the decision for a specific bariatric technique and shows a higher likelihood for patients with T2D to undergo RYGB[4].

Patient characteristics are known to be associated with the likelihood of diabetes remission. For instance, a longer duration of T2D is negatively associated with T2D remission[5]. On the other hand, profound weight loss is associated with higher chances of T2D remission[6,7]. There are systematic reviews and meta-analysis that show a more favorable outcome after RYGB in terms of T2D remission and weight loss compared with SG[8–10]. However these reviews mostly contain retrospective and observational studies, which may be prone to bias if there is an underlying reason why patients get one treatment or the other. Recent randomized controlled trials (RCTs) like the Swiss Multicenter Bypass or Sleeve Study (SM-BOSS), the Sleeve vs Bypass (SLEEVEPASS), and Surgical Therapy And Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE) trials all show similar outcomes for RYGB versus SG, with no significant difference in T2D remission after 5 years[11–13]. But even though these studies are RCTs, some of them are underpowered and include only a selected group of patients not generalizable to the whole population in daily practice. With the increasing prevalence of obesity-related T2D worldwide and surgeons' desire to choose the bariatric treatment with the best chances for T2D remission, the need for guidance and population-based results is increasing[14].

Population-based data are valuable as they include all patients treated in daily clinical practice, rather than a selected group of patients. However, the estimated treatment effect from observational studies may be biased if there is an underlying reason for getting one treatment over the other (confounding by indication), whereas this is not a problem in trials due to randomization[15]. Propensity score matching (PSM) is a statistical pseudo-randomization technique that adjusts for confounding by indication, to ensure comparing patients with the same chance of receiving a treatment[16]. This study therefore aims to compare patients undergoing RYGB and SG on the extent of T2D remission at 1 year follow-up using population-based data from the Netherlands while adjusting for confounding by indication using PSM.

Methods

Study Design

This is a population-based cohort within the Dutch Audit for Treatment of Obesity (DATO). The DATO is a mandatory registry containing patient data from all hospitals performing bariatric surgery in the Netherlands[17]. The Dutch surgical association for bariatric and metabolic surgery has a minimum volume standard of 200 primary procedures annually with a minimum of 2 dedicated bariatric surgeons. Every 2 years, a third independent party conducts an on site validation of the data provided by the bariatric centers[17]. The scientific committee of the DATO unanimously approved using the data to perform this study. Every DATO year runs from October until October of the next year, so that in practice, all operated patients can reasonably have a 1 year follow-up appointment at the outpatient clinic by the end of December in the year following their surgery. The mandatory follow-up program in the Netherlands has a duration of 5 years. The post-operative follow-up visits at the surgical outpatient clinic for the first year are planned at approximately 3, 6, 9 and 12 months. To determine the T2D status at 1 year, patients need an outpatient clinic visit between 9-15 months post-operatively. This is a nationally predefined interval for comorbidity status and weight loss, from now on referred to as the 1-year follow-up.

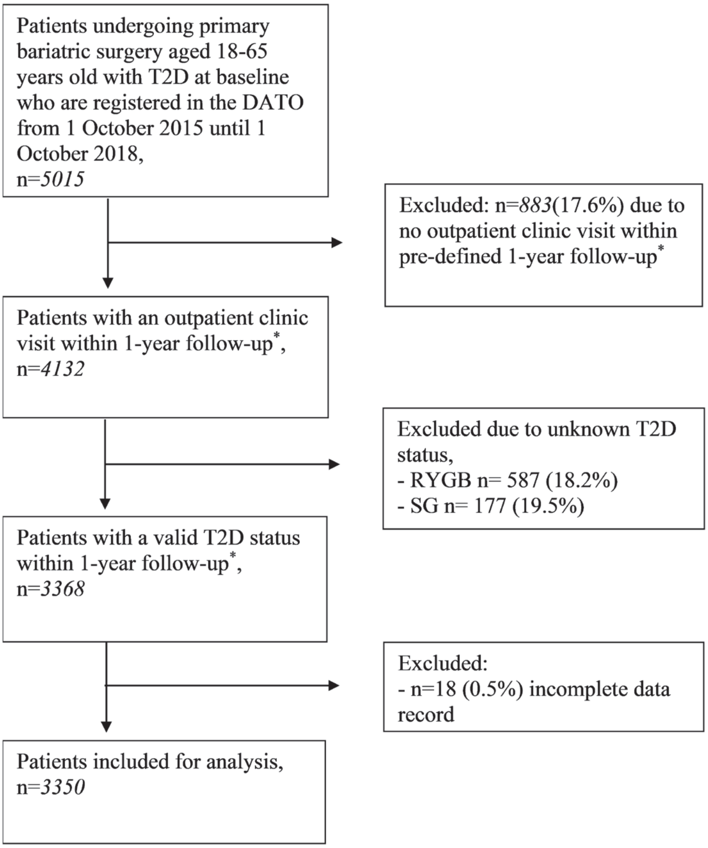
Patient selection

All patients with T2D undergoing primary bariatric surgery in the Netherlands from 1 October 2015 until 1 October 2018 were eligible for this study if they had a surgical outpatient clinic visit within the first year and before 1 January, 2020. Further inclusion criteria were having T2D present at baseline, being 18–65 years old on the day of surgery, and having an outpatient clinic visit between 9 and 15 months postoperatively to determine the T2D status. T2D at baseline is defined as glycated hemoglobin (HbA1C) ≥53 mmol HbA1c/mol HbA and classified by surgeons as being either without medication or with medication (e.g., oral antidiabetic agent or insulin-dependent) regardless of HbA1c. To determine the estimated treatment effect on T2D remission, we only included complete cases with a valid T2D status at 1-year follow-up, Figure 1.

Outcome parameters

The primary outcome is T2D remission at the 1-year follow-up after bariatric surgery. The status of T2D at the 1-year follow-up is compared with the status at the pre-operative screening and classified by bariatric surgeons as either complete remission, partial remission/ improvement, unchanged or deteriorated. Complete remission is defined as HbA1c (<53 mmol HbA1c/mol HbA) in absence of diabetic medication as stated in the International guidelines[18]. Partial remission is defined as a decrease in HbA1c (≤69 mmol HbA1c/mol HbA) and/or a decrease in diabetic medication. Deterioration denotes a significant increase in HbA1c (>69 mmol HbA1c/mol HbA), and/or increase in diabetic medication. Unchanged means no remission, improvement or deterioration as described above. For the present study, remission of T2D is defined as complete or partial remission, with no remission defined as unchanged or deterioration.

Figure 1. Flowchart of included patients.



*Patients with an outpatient clinic visit between 9 and 15 months post-operatively
T2D = type 2 diabetes; DATO = Dutch Audit for Treatment of Obesity; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy.

Secondary outcomes include: hypertension, dyslipidemia, gastroesophageal reflux disease (GERD), musculoskeletal pain, and obstructive sleep apnea syndrome (OSAS). These obesity-related comorbidities were also compared with their respective status at the pre-operative screening and reported as having complete remission, having improvement, being unchanged, deteriorating, de novo, or not being applicable (meaning not present/ unknown status at 1 year follow-up). The definitions of all comorbidity statuses are listed in Figure 2. Other secondary outcomes include ≥20% Total Weight Loss at 1-year follow-up (TWL = (pre-operative weight – follow-up weight) / pre-operative weight), prolonged length of stay (LOS) >2 days, and any severe postoperative complications defined as those having a Clavien-Dindo (CD) Classification of Surgical Complications grade ≥III within 30 days[17].

Statistical analysis

To compare baseline characteristics between the RGYB and the SG group, the Chi-square test was used for categorical variables and the Student *t* test was used for parametric continuous variables. The paired Student *t* test was used to compare continuous variables at baseline and postoperatively. A p-value <0.05 is considered as statistically significant. To compare patients undergoing RGYB and SG on T2D remission at the 1-year follow-up, a multivariable logistic regression is performed adjusting for confounders (before matching). Based on literature[2,19,20] and clinical experience all the following covariates were included in our multivariable model: sex, age, year of operation, baseline Body mass index (BMI), T2D with or without medication, American Society of Anesthesiologists (ASA) classification, hypertension, dyslipidemia and OSAS. Musculoskeletal pain and GERD are known not to be associated with T2D remission[21].

Propensity score matching (PSM) was conducted to adjust for confounding by indication, so that patients with the same likelihood of undergoing a bariatric technique were compared. Patients are matched on the following baseline variables: sex, age, year of operation, pre-operative BMI, T2D with or without medication at baseline, ASA classification, hypertension, dyslipidemia, GERD, musculoskeletal pain, and OSAS. The nearest neighbor method is used to match patients 1:1 with a caliper of 0.20. A standardized mean difference <0.1 was considered to show balanced groups. A logistic regression analysis was performed, relating the outcome to the bariatric procedure group and adjusting for the propensity score[16]. This PSM analysis was conducted for the primary and secondary outcomes. We also conducted and additional analysis using PSM with the primary outcome T2D remission defined as complete remission, and no remission defined as partial remission, unchanged, or deterioration to see whether this affected the results. Analysis were performed in R version 3.4.2 using the “MatchIt” 3.0.2 package.

Figure 2. Definitions of outcomes for obesity related comorbidities after bariatric surgery

Outcome	Type 2 Diabetes	Dyslipidemia	Hypertension	GERD	OSAS	Musculoskeletal pain
Complete remission	HbA1c (<53 mmol HbA1c/ mol HbA) in absence of diabetic medication.	Normal lipid spectrum (LDL, HDL, Triglycerides) without use of cholesterol lowering drugs	Normotensive (<120/80 mmHg) without use of antihypertensive drugs	Absence of symptoms, no medication use and a normal physiological test (by 24-48 hours pH measurement or by gastro-duodenoscopy)	No symptoms after preoperative diagnosis of OSAS by means of poly(somno) graphs (PSG), in combination with apnea-hypopnea index (AHI) <5 and no (more) use of CPAP/BiPAP	No symptoms after pre-operative diagnosis of joint complaints, without the use of any analgesics
Improvement/ partial remission	Decrease in HbA1c (≤69 mmol HbA1c/ mol HbA) and/ or decrease in diabetic medication (i.e. when stopping insulin use or stopping at least one oral tablet or halving dose)	Reduction of cholesterol lowering drugs while maintaining or improving the lipid spectrum / or improvement in lipid spectrum with same amount of drugs	Dose reduction and/or reduction in use of antihypertensive drugs or a decrease in systolic and diastolic blood pressure using the same drugs	Reduction of symptoms or reduction of medication use / or improvement with physiological test (by 24-48 hours pH measurement or by gastro-duodenoscopy)	Decrease in symptoms after pre-operative diagnosis of OSAS with reduction in CPAP/BiPAP pressure, improvement of AHI and/ or improvement of PSG	Decrease in symptoms of joint complaints and/ or reduction/ decrease in use of analgesics
Unchanged	Absence of improvement or deterioration	Absence of improvement or deterioration	Absence of improvement or deterioration	Absence of improvement or deterioration	Absence of improvement or deterioration	Absence of improvement or deterioration
Deterioration/ recurrence	Deterioration denotes significant increase in HbA1c (>69 mmol HbA1c/ mol HbA), increase in diabetic medication and/or (re) starting diabetic medication	Deterioration of the lipid spectrum and/ or increase in medication and/or (re) starting cholesterol lowering drugs after period of absence	The need to (re) start and / or increase antihypertensive drugs with increasing systolic and / or diastolic blood pressure	Worsening of symptoms and/ or increase in medication and/or (re) starting medication after period of absence	Worsening of symptoms and/ or (re) starting (increase) in CPAP/BiPAP pressure	Worsening of symptoms and/ or increase in medication and/ or (re) starting the use of analgesics
De novo	-	New diagnosis	New diagnosis	New diagnosis	New diagnosis	New diagnosis

GERD, Gastroesophageal reflux disease; OSAS, Obstructive Sleep Apnea Syndrome; CPAP, continuous positive airway pressure; BiPAP, Bilevel positive airway pressure

Sensitivity analysis

There may be several reasons for the unknown/missing T2D status at the 1 year follow-up, and these patients were excluded from the primary analysis. In the Netherlands patients prefer the nearest outside laboratory for venipuncture samples for HbA1c or have a venipuncture after a visit to the outpatient clinic. Also, using the predefined interval of between 9 and 15 months postoperatively to determine the T2D status will exclude any patient with an HbA1C assessment 1 day outside this period. Another reason is that endocrinologists refer patients with adequate glycemic control back to primary care. All these reasons make it logistically challenging for surgeons to retrieve the results from HbA1c samples to define the actual T2D status. With comparable missing percentages between groups and aforementioned reasons, the unknown T2D status at 1 year follow-up is likely to be missing at random. To gain insight into the extent to which unknown T2D status could influence our results, we conducted a sensitivity analysis. For this analysis we assumed all the unknown/missing T2D status (Figure 1) to be either improved or not improved at the 1-year follow-up. The same procedure of propensity-score matching and subsequent analysis was then conducted. Comparing patient characteristics for patients with and without missing T2D at 1-year shows that those with missing data on average are healthier subjects (Supplementary Table A), which could suggest that those patients are more likely to have improvements.

Results

Study population

Between 1 October 2015 and 1 October 2018, a total of 5015 patients with obesity and T2D who underwent bariatric surgery were eligible for this study, and 4132 (82.4%) completed the pre defined 1-year follow-up. Of these, a total of 3350 (81.1%) patients with complete data and known T2D status were included in the analysis. Table 1 shows that patients who received RYGB were significantly more likely to be female compared with SG patients (69.1% vs 59%), had GERD more often (15.1% vs 10.7%) and had dyslipidemia more often (36.5% vs 30.1%). However, on average RYGB patients had a lower BMI (42 [standard deviation, 5.0] versus 45 [standard deviation, 7.0], respectively) and were less likely to be ASA III (52.8% versus 66%, respectively) than SG patients. A total of 695 patients could be matched in each group resulting in balanced groups with no significant differences in baseline characteristics as shown in Table 1.

Table 1. Patient Characteristics for Roux-en-Y Gastric Bypass and Sleeve Gastrectomy before and after matching.

Characteristic	Before Matching				After Matching			
	RYGB (n = 2623)	SG (n = 727)	*p* Value	SMD	RGYB (n = 695)	SG (n = 695)	*p* Value	SMD
Sex, No. (%)								
Male	810 (30.9)	298 (41.0)	<0.001	0.212	284 (40.9)	279 (40.1)	0.827	<0.1
Female	1813 (69.1)	429 (59.0)			411 (59.1)	416 (59.9)		
Age, mean(SD)	51 (9)	51 (9)	0.141	0.060	51 (9)	51 (9)	0.648	<0.1
BMI, mean(SD), kg/m^2	42 (5)	45 (7)	<0.001	0.525	44 (6)	45 (6)	0.354	<0.1
Year of operation, No. (%)								
2016	909 (34.7)	204 (28.1)	0.002	0.149	178 (25.6)	199 (28.6)	0.430	<0.1
2017	902 (34.4)	262 (36.0)			259 (37.3)	244 (35.1)		
2018	812 (31.0)	261 (35.9)			258 (37.1)	252 (36.3)		
ASA classification, No. (%)								
I	10 (0.4)	0 (0.0)	<0.001	0.297	0 (0.0)	0 (0.0)	0.902	<0.1
II	1204 (45.9)	236 (32.5)			240 (34.5)	232 (33.4)		
III	1385 (52.8)	480 (66.0)			444 (63.9)	452 (65.0)		
IV	24 (0.9)	11 (1.5)			11 (1.6)	11 (1.6)		
T2D, No. (%)								
Present	691 (26.3)	229 (31.5)	0.007	0.114	217 (31.2)	216 (31.1)	>0.99	<0.1
With medication*	1932 (73.7)	498 (68.5)			478 (68.8)	479 (68.9)		
Hypertension, No. (%)								
Not present	980 (37.4)	260 (35.8)	0.001	0.152	232 (33.4)	251 (36.1)	0.558	<0.1
Present	397 (15.1)	152 (20.9)			148 (21.3)	140 (20.1)		
With medication	1246 (47.5)	315 (43.3)			315 (45.3)	304 (43.7)		
Dyslipidemia, No. (%)								
Not present	1245 (47.5)	385 (53.0)	0.005	0.137	358 (51.5)	363 (52.2)	0.964	<0.1
Present	420 (16.0)	123 (16.9)			119 (17.1)	117 (16.8)		
With medication	958 (36.5)	219 (30.1)			218 (31.4)	215 (30.9)		
GERD, No. (%)								
Not present	2109 (80.4)	616 (84.7)	0.010	0.132	571 (82.2)	587 (84.5)	0.453	<0.1
Present	117 (4.5)	33 (4.5)			33 (4.7)	32 (4.6)		
With medication	397 (15.1)	78 (10.7)			91 (13.1)	76 (10.9)		
OSAS, No. (%)								
Not present	1922 (73.3)	506 (69.6)	0.129	0.084	494 (71.1)	487 (70.1)	0.918	<0.1
Present	362 (13.8)	110 (15.1)			99 (14.2)	102 (14.7)		
With medication	339 (12.9)	111 (15.3)			102 (14.7)	106 (15.3)		
Musculoskeletal pain, No. (%)								
Not present	1375 (52.4)	362 (49.8)	0.412	0.056	353 (50.8)	348 (50.1)	0.964	<0.1
Present	1222 (46.6)	356 (49.0)			333 (47.9)	338 (48.6)		
With medication	26 (1.0)	9 (1.2)			9 (1.3)	9 (1.3)		

*Patients with T2D using oral antidiabetic agents, insulin or a combination therapy of insulin and oral antidiabetic agents.

RYGB, Roux-en-Y Gastric Bypass; SG, Sleeve Gastrectomy; BMI, Body Mass Index; ASA, American society of anesthesiologists; T2D, type 2 diabetes; GERD, Gastro-esophageal Reflux Disease; OSAS, Obstructive Sleep Apnea Syndrome; SMD, standard mean difference; NA, not applicable.

Primary and secondary outcomes

For the primary outcome, Table 2 shows that patients undergoing a RYGB had higher odds of achieving complete or partial T2D remission at 1 year after adjusting for confounders (OR 1.54, 95%-CI[1.14-2.1] ;P<0.01). The same significant effect remained after PSM to adjust for confounding by indication (OR 1.91, 95%-CI[1.27-2.88] ;P<0.01) (Table 3), meaning that the results were still favorable for RYGB when comparing patients that were equally likely to receive either procedure.

Table 2. Multivariable logistic regression adjusting for confounders to determine the effect of RYGB and SG on T2D remission at 1-year follow-up

Multivariable analysis in T2D remission	T2D Complete or Partial remission		
	No. (%)*	OR [95% CI]	*p* Value
Type of procedure			
SG	727(21.7%)	ref.	
RYGB	2623(78.3%)	1.54 [1.14-2.1]	0.005
Sex			
Male	1108(33.1%)	ref.	
Female	2242(66.9%)	0.96 [0.72-1.27]	0.770
Age, mean (SD)	51(9)*	0.98 [0.96-1.0]	0.013
BMI, mean (SD)	43(6)*	0.99 [0.97-1.01]	0.246
Year of operation			
2016	1113(33.2%)	ref.	
2017	1164(34.7%)	0.97 [0.72-1.3]	0.826
2018	1073(32%)	1.76 [1.23-2.53]	0.002
ASA Classification			
I/ II	1450(43.3%)	ref.	
III+	1900(56.7%)	2.07 [1.57-2.71]	<0.001
T2D			
Present	920(27.5%)	ref.	
With medication	2430(72.5%)	0.41 [0.27-0.61]	<0.001
Hypertension			
Not present	1240(37%)	ref.	
Present	549(16.4%)	0.83 [0.53-1.3]	0.418
With medication	1561(46.6%)	0.95 [0.7-1.28]	0.722
Dyslipidemia			
Not present	1630(48.7%)	ref.	
Present	543(16.2%)	1.44 [0.92-2.26]	0.111
With medication	1177(35.1%)	1.13 [0.84-1.51]	0.424
OSAS			
Not present	2428(72.5%)	ref.	
Without CPAP	472(14.1%))	1.28 [0.84-1.96]	0.247
With CPAP	450(13.4%)	0.9 [0.63-1.28]	0.550

T2D, type 2 diabetes mellitus; SG, Sleeve Gastrectomy; RYGB, Roux-en-y Gastric Bypass; BMI, body mass index; ASA, American society of anesthesiologists; OSAS, Obstructive Sleep Apnea Syndrome; OR, odds ratio; CI, confidence interval.
*The absolute number and percentage are shown for categorical variables and the mean (SD) for continuous variables.

The secondary outcomes listed in Table 3, show that patients undergoing RYGB also had higher odds of achieving ≥20%TWL (OR 2.71, 95%-CI[1.96-3.75] ;$P<0.01$) and dyslipidemia remission at 1-year follow-up (OR 1.96, 95%-CI[1.39-2.76] ;$P<0.01$). After matching, the BMI was significantly decreased at 1 year compared to baseline for both groups, RYGB (Δ BMI 1 year = -13.4, 95%-CI[-13.1 to -13.7] ;$P<0.01$) and SG (Δ BMI 1 year = -11.8, 95%-CI[-11.5 to -12.2] ;$P<0.01$). The decrease in BMI on average was significantly higher after 1 year in the RYGB group compared with SG, -13.4 ± 4.5 versus -11.8 ± 4.2, respectively (*P<.001)*. There were no significant differences in CD ≥III complications (*P=0.083*) and no deceased patients in either group.

The analysis including only complete remission showed similar results with RYGB still having a favorable effect after PSM (OR 1.35, 95%-CI[1.09-1.69] ;$P<0.01$).

Table 3. Propensity score matched comparison of RYGB and SG on secondary outcome measures at the 1 year follow up (Sleeve Gastrectomy = reference).

	OR [95% CI]	*p* Value
Primary outcome*		
T2D Remission	1.91 [1.27-2.88]	<0.01
	OR [95% CI]	***p* Value**
Secondary outcomes*		
≥20% TWL	2.71 [1.96-3.75]	<0.01
≥50% EWL	3.12 [2.33-4.18]	<0.01
Hypertension remission	1.33 [0.96-1.84]	0.088
Dyslipidemia remission	1.96 [1.39-2.76]	<0.01
GERD remission	1.71 [0.67-4.35]	0.258
OSAS remission	1.09 [0.65-1.84]	0.733
Musculoskeletal pain remission	1.39 [0.92-2.09]	0.115
Clavien Dindo ≥III	0.57 [0.3-1.08]	0.083
ICU Admission	0.32 [0.03-3.14]	0.331
Length of Stay >2 days	0.72 [0.48-1.06]	0.099

*Analysis after matching results in balanced groups and is only adjusted for confounding by indication using the propensity score, thereby comparing patients with the same chance of receiving a procedure.
Comorbidity remission is defined as complete remission or partial remission.
T2D, type 2 diabetes; TWL, Total weight loss; EWL, Excess weight loss; GERD, gastro-esophageal reflux disease; OSAS, Obstructive sleep apnea syndrome; ICU, intensive care-unit; OR, odds ratio; CI, confidence interval.

Sensitivity analysis

The sensitivity analysis included patients with missing/unknown T2D status (n=764) despite having had a 1-year follow-up outpatient clinic visit, resulting in a total of 4132 patients (Figure 1). We assumed all the unknown/missing T2D status for the RYGB n=587 (18.2%) and SG n=177 (19.5%) as either improved or not improved at the 1-year follow-up, to gauge the impact of these missing data on the results (Table A). When defining all unknown/

missing T2D status at 1 year follow-up as improved, the RYGB remained associated with better T2D remission compared with SG (OR 1.48, 95%-CI[1.01-2.16];$P<0.05$). When defining all unknown/missing T2D status at 1 year follow-up as not improved, the RYGB still was associated with better T2D remission compared with SG (OR 1.26, 95%-CI [1.02-1.57];$P<0.05$).

Discussion

This nationwide study shows that patients undergoing RYGB are more likely to have T2D remission at 1 year follow-up when compared with SG in a population-based matched cohort. To our knowledge, this study is the largest matched population-based study concerning patients with obesity and T2D, presenting strong evidence because of using PSM while still including unselected patients treated in daily practice. RYGB was also associated with more favorable weight loss outcomes (≥20%TWL) and better metabolic effects regarding dyslipidemia.

There have been several previous retrospective studies comparing T2D remission between bariatric surgical procedures[22–24]. Brethauer et al. showed that RYGB has significantly better T2D remission rates compared with SG or Adjustable gastric banding (AGB)[23]. In contrast Jimenez et al. found that RYGB and SG have comparable T2D remission rates[24]. The contrasting findings between these studies can be due to the fact that they come with pitfalls such as selection bias, heterogeneity in groups and treatment by indication bias. To adjust for this bias, we used PSM and obtained balanced groups with comparable characteristics. Thus, similar to what would be seen with randomization, the measured baseline covariates are similar between treated and untreated subjects, making it possible to obtain an unbiased estimate of the average treatment effect[16]. The analysis of a PSM cohort can mimic that of an RCT as direct comparison between outcomes is possible. Our results show statistically significant difference in favor of RYGB compared with SG in terms of T2D remission and are thus a valuable addition to available evidence.

Among 134 patients completing a 5-year follow-up, Schauer et al. showed in the STAMPEDE trial that bariatric surgery was more effective than intensive medical therapy alone, but there was no significant difference in T2D remission between SG and RYGB[13]. However, their study was limited in the sample size within the bariatric surgery group as their study was not powered to detect differences in outcome between the two techniques. We also have to consider that this is a selected group of patients participating in a trial in a certain region due to the fact that it is a single-center trial. The SLEEVEPASS trial and the SM BOSS trial confirmed the aforementioned results among 193 and 205 patients completing 5 year follow-up, respectively[11,12]. Both these trials were underpowered to detect a difference in T2D remission, as their primary outcome was weight loss. Also, they were subject to a selected group of patients which may not be generalizable to the entire population. This emphasizes the need for well-designed trials with larger sample sizes, but also results that can be generalized on a population level. The current matched study with a large cohort of 695 patients in each surgical technique group shows that RYGB results in more favorable metabolic remission at 1 year in patients with obesity and T2D. The short term results for the recently published Oseberg trial were similar among 109 patients[25], supporting that patients with T2D undergoing RYGB may be more likely to achieve T2D remission.

Profound weight loss is known to be associated with higher T2D remission rates[6,7]. In this study the RYGB group had 2.71 times better odds to achieve ≥20%TWL at 1 year follow-up. Furthermore, others have shown that similar weight loss for the two treatments will still result in better glycemic control for RYGB[26]. This might be due to the metabolic effects of the gastric bypass on multi-organ insulin sensitivity, β-cell function and increased metabolic activity of brown adipose tissue, making it less likely for the SG technique to give the same results[27-29].

Together with the favorable metabolic effects of the gastric bypass on T2D, it has also been shown to be associated with higher remission rates in hypertension and dyslipidemia[30-32]. Our study confirms these findings in the matched cohort with more favorable dyslipidemia remission in the RGYB group.

Despite the risks for severe post-operative complications, bariatric surgery is mostly performed for sustainable weight loss and the beneficial metabolic effects, resulting in lower cardiovascular risks, lower mortality and improved quality-of-life for the patients in the long run[14,33]. In this study, patients receiving RYGB had similar severe post-operative complications defined as those with a CD grade ≥III (P=0.083) in the matched groups. The similar complication rates after RYGB and SG are in line with international findings about postoperative complications in countries with well-established bariatric surgery programs[1,34]. Only 1 patient in the matched SG group had a reoperation for stricture within 1-year follow-up, whereas the RYGB group had no major complications within 1-year. Several studies have shown that RYGB and SG have similar long term-complications within 5-year after bariatric surgery [11,12]. However, as mentioned before, the DATO is an ongoing data collection initiative, and longer term follow-up data will be collected to examine the overall and longer term outcomes.

Even though PSM is a strength, there are also several limitations that should be noted. First, 82.4% patients had an outpatient clinic visit between 9 and 15 months post-operatively, meaning 17.6% did not have data for this interval Figure 1. The national audit is mandatory and the quality of the data improves over the years, but values missing due to being outside predefined intervals, deceased patients, or logistical reasons (such as health insurance costs) remain challenging for data collection in bariatric surgery. Despite continuous efforts from hospitals to individually contact patients, missing outpatient clinic visits between predefined intervals remain. Secondly, this study could not adjust for unmeasured confounders such as surgeon preference, disease severity or disease duration, where previous studies have shown that these are negatively correlated with T2D remission and differ between RYGB and SG [4,35,36], thus, some residual confounding could remain. Although a trial would exclude the aforementioned, this would include a selected group of patients not generalizable to the whole population. Thirdly, our study only has evaluated short-term results up to 1 year follow-up. Since obesity is a chronic disease, the impact of bariatric surgery has to be studied across a longer duration of follow-up to draw conclusions on sustainability of comorbidity control[37]. As the DATO is an ongoing data collection initiative, the number of patients will increase and longer term follow-up results will be collected to examine whether the favorable short-term metabolic effects will be sustained.

Conclusion

Using population-based data from the Netherlands, this study shows that RYGB is associated with more favorable T2D remission and weight loss at the 1-year follow-up compared with SG. In addition, RYGB shows favorable metabolic effects compared with SG and has similar outcomes in terms of postoperative complications up to 1 year. Future research should investigate the longer term outcomes of comorbidity control in patients with obesity and T2D.

Collaborators

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Supplementary Table A. Comparing patient characteristics of patients with a complete vs. missing T2D status at 1-year follow-up

T2D status within 1-year follow-upa	Completed (n = 3368)	Missing (n = 764)	*p* Value	SMD
Characteristics				
Type of procedure, No. (%)				
RYGB	2638 (78.3)	587 (76.8)	0.394	0.036
SG	730 (21.7)	177 (23.2)		
Sex, No. (%)				
Male	1111 (33.0)	227 (29.7)	0.088	0.071
Female	2257 (67.0)	537 (70.3)		
Age (mean(SD))	51 (9)	50 (10)	<0.001	0.141
BMI (mean(SD))	43 (6)	43 (6)	0.318	0.039
Year of operation, No. (%)				
2016	1126 (33.4)	355 (46.5)	<0.001	0.269
2017	1164 (34.6)	216 (28.3)		
2018	1078 (32.0)	193 (25.3)		
ASA classification, No. (%)				
I	10 (0.3)	6 (0.8)	0.004	0.151
II	1442 (42.8)	375 (49.1)		
III	1868 (55.5)	373 (48.8)		
IV	35 (1.0)	6 (0.8)		
Na	13 (0.4)	4 (0.5)		
Type 2 diabetes, No. (%)				
Present	928 (27.6)	327 (42.8)	<0.001	0.323
With medication	2440 (72.4)	437 (57.2)		
Hypertension, No. (%)				
Not present	1248 (37.1)	270 (35.3)	<0.001	0.155
Present	554 (16.4)	172 (22.5)		
With medication	1566 (46.5)	322 (42.1)		
Dyslipidemia, No. (%)				
Not present	1639 (48.7)	417 (54.6)	<0.001	0.192
Present	547 (16.2)	146 (19.1)		
With medication	1182 (35.1)	201 (26.3)		
GERD, No. (%)				
Not present	2742 (81.4)	594 (77.7)	0.063	0.092
Present	150 (4.5)	43 (5.6)		
With medication	476 (14.1)	127 (16.6)		
OSAS, No. (%)				
Not present	2443 (72.5)	586 (76.7)	0.006	0.135
Present	474 (14.1)	108 (14.1)		
With medication	451 (13.4)	70 (9.2)		

Supplementary Table A. Continued

T2D status within 1-year follow-upa	Completed (n = 3368)	Missing (n = 764)	*p* Value	SMD
Musculoskeletal pain, No. (%)				
Not present	1745 (51.8)	381 (49.9)	0.220	0.093
Present	1587 (47.1)	380 (49.7)		
With medication	35 (1.0)	3 (0.4)		
Na	1 (0.0)	0 (0.0)		

[a]Note: Patients with missing T2D status show that they are healthier subjects on average, with younger age, less comorbidities at baseline and lower ASA classification.
T2D, type 2 diabetes; RYGB, Roux-en-Y Gastric Bypass; SG, Sleeve Gastrectomy; BMI, Body Mass Index; ASA, American society of anesthesiologists; GERD, Gastro-esophageal Reflux Disease; OSAS, Obstructive Sleep Apnea Syndrome; SMD, standard mean difference; NA, not applicable.

3

Weight recurrence after Sleeve Gastrectomy versus Roux-en-Y gastric bypass: a propensity score matched nationwide analysis

Erman O. Akpinar, Ronald S.L. Liem, Simon W. Nienhuijs,
Jan Willem M. Greve, Perla J. Marang- van de Mheen, and
on behalf of the Dutch Audit for Treatment of Obesity Research Group

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Abstract

Background Literature remains scarce on patients experiencing weight recurrence after initial adequate weight loss following primary bariatric surgery. Therefore, this study compared the extent of weight recurrence between patients who received a Sleeve Gastrectomy (SG) versus Roux-en-Y gastric bypass (RYGB) after adequate weight loss at 1-year follow-up.

Methods All patients undergoing primary RYGB or SG between 2015 and 2018 were selected from the Dutch Audit for Treatment of Obesity (DATO). Inclusion criteria were achieving ≥20% total weight loss (TWL) at 1-year and having at least one subsequent follow-up visit. The primary outcome was ≥10% weight recurrence (WR) at the last recorded follow-up between 2-5 years, after ≥20% TWL at 1-year follow-up. Secondary outcomes included remission of comorbidities at last recorded follow-up. A propensity score matched logistic regression analysis was used to estimate the difference between RYGB and SG.

Results A total of 19.762 patients were included, 14.982 RYGB and 4.780 SG patients. After matching 4.693 patients from each group, patients undergoing SG had a higher likelihood on WR up to 5-year follow-up compared with RYGB [OR 1.98, 95% CI (1.77–2.21), $p < 0.01$] and less often remission of type 2 diabetes (T2D) [OR 0.69, 95% CI (0.56–0.86), $p < 0.01$], hypertension (HTN) [OR 0.75, 95% CI (0.65–0.87), $p < 0.01$], dyslipidemia [OR 0.44, 95% CI (0.36–0.54), $p < 0.01$], gastroesophageal reflux (GERD) [OR 0.25 95% CI (0.18–0.34), $p < 0.01$], and obstructive sleep apnea syndrome (OSAS) [OR 0.66, 95% CI (0.54–0.8), $p < 0.01$]. In subgroup analyses, patients who experienced WR after SG but maintained ≥20%TWL from starting weight, more often achieved HTN (44.7% vs 29.4%), dyslipidemia (38.3% vs 19.3%), and OSAS (54% vs 20.3%) remission compared with patients not maintaining ≥20%TWL. No such differences in comorbidity remission were found within RYGB patients.

Conclusion Patients undergoing SG are more likely to experience weight recurrence, and less likely to achieve comorbidity remission than patients undergoing RYGB.

Introduction

Bariatric surgery is effective in achieving sustained weight loss, comorbidity reduction, and improved quality of life for patients with morbid obesity.[1–4] However, some patients will experience weight recurrence after initially achieving adequate weight loss following bariatric surgery.[5–7]

Weight recurrence is known to be associated with poor clinical outcomes such as comorbidity deterioration and worsened quality of life.[6,8–10] Although the definition of weight recurrence is still up for debate,[11] with arbitrary thresholds showing a wide variety of results,[12,13] patients with significant weight recurrence are potential candidates for revision surgery which makes it important to identify such high-risk patients. Weight recurrence is multifactorial and associated with lifestyle, hormonal, genetic, metabolic factors, and the type of bariatric procedure.[6,8] Literature has shown that around 25% of patients undergoing Roux-en-Y gastric bypass (RYGB) will show inadequate weight loss (non-response) or weight recurrence in the long term.[7,14] A recent retrospective study showed that patients undergoing Sleeve Gastrectomy (SG) more often have weight recurrence than patients undergoing RYGB.[5] However, this recent study did not adjust for confounding by indication, even though there may be underlying factors why some patients receive SG or RYGB, which makes it prone to bias as it does not enable fair comparison by balancing out the measured confounders on average between treatment groups.[15] In addition, studies that compare the results of weight recurrence between RYGB and SG remain scarce in the literature, in particular among patients initially achieving adequate weight loss. More evidence is imperative for surgeons to consider the risks of weight recurrence depending on the type of primary bariatric procedure, particularly for high-risk patients.

Therefore, this nationwide study will compare patients undergoing primary RYGB or SG on the extent of weight recurrence up to 5 years of follow-up after initial adequate weight loss at 1 year and assess the associated effect on remission of comorbidities.

Methods

Study design

This population based study used data from the Dutch Audit for Treatment of Obesity (DATO). The DATO is a mandatory nationwide audit in which all bariatric procedures are registered since 2015. Previous verification of the DATO data has shown the validity of the data.[16] In accordance with the Dutch Institute for Clinical Auditing (DICA) regulations and following the ethical standards as stated in Dutch law, no informed consent from patients was needed as this is an opt-out registry. This study was approved by all the scientific committee members of the DATO (reference number 2022-16).

Patient selection

Patients who underwent a primary Sleeve Gastrectomy or Roux-en-Y Gastric Bypass between 2015 and 2018 were identified. Inclusion criteria were achieving ≥20% Total Weight loss (TWL) at the first year of follow-up and having at least one subsequent follow-up measurement between 2 up to 5 years. Patients undergoing revision surgery during the 2-5 year follow-up were excluded. The time frame to determine weight loss in the DATO consists of the follow-up year with a range of ± 3 months, meaning that patients could have e.g. their 1-year follow-up visit between 9 and 15 months after the primary surgery.

Outcome parameters

The primary outcome of this study was 'weight recurrence (WR)', defined as ≥10% weight increase from Nadir during the last recorded follow-up between 2-5 years. Nadir (lowest recorded weight) was determined in the 1^{st} year of follow-up, conditional on achieving ≥20% TWL given inclusion criteria. Secondary outcomes included achieving ≥20% TWL or ≥50% Excess Weight Loss (EWL) at last recorded follow-up, WR without maintaining 20% TWL at last recorded follow-up, and comorbidity remission for hypertension (HTN), gastroesophageal reflux disease (GERD), type 2 diabetes (T2D), dyslipidemia, obstructive sleep apnea syndrome (OSAS), and osteoarthritis at last recorded follow-up.

Statistical analysis

Baseline characteristics between the two treatment groups were compared using the Chi-square test for categorical variables and depending on the distribution the *t*-test or Mann-Whitney *U* test for continuous variables. To evaluate the association between WR and type of procedure, all variables with a p-value <0.10 in univariable analyses were included in the multivariable logistic regression model to compare RYGB and SG on WR, adjusted for baseline characteristics and year of follow-up. Baseline characteristics were gender, age, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, T2D, HTN, GERD, OSAS, dyslipidemia, and osteoarthritis. In addition, year of follow-up was included because the duration of follow-up is described to be associated with weight recurrence.[17] Multicollinearity was assessed in all models with the Variance Inflation Factor not exceeding 2. Additionally, the two treatments were matched to adjust for confounding by indication as the patient-mix undergoing the two procedures has been shown to be systematically different.[18] Patients were matched 1:1 on all aforementioned characteristics and year of follow-up, using the nearest neighbor method with a caliper of 0.20.[15] A standardized mean difference <0.1 was considered to indicate balanced groups. After matching, propensity score matched analysis were conducted to evaluate the association between RYGB and SG on WR, adjusted for the propensity score. Similar analyses were done to compare the secondary outcomes between the matched groups.

Secondary outcomes were further explored within treatment groups among patients experiencing WR. The chi-square test was utilized to analyze differences within the (un) matched RYGB group by comparing patients who experienced WR without maintaining 20% TWL with patients who maintained 20% TWL from starting weight. The same analysis was done for the SG group. All statistical analyses were performed in R version 3.4.2. A *p*-value <0.05 was considered statistically significant in all analyses.

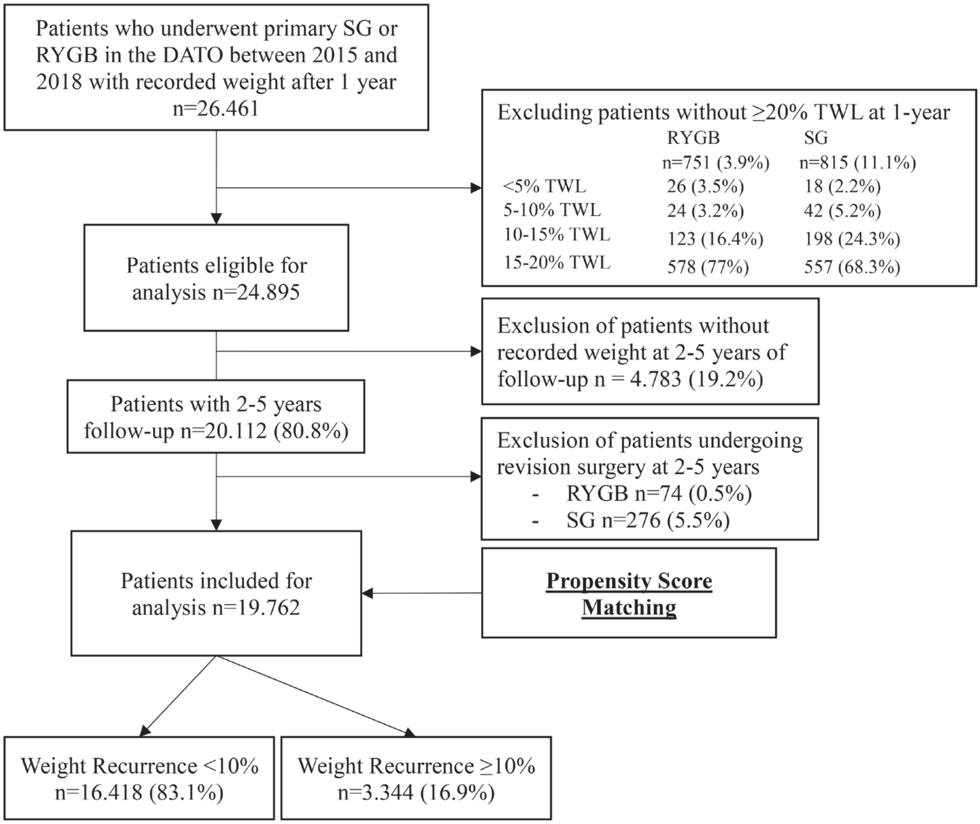
Results

Between 2015 and 2018 a total of 24.895 patients undergoing primary RYGB or SG who achieved ≥20%TWL at 1-year follow-up were eligible for analysis. Of these, 19.762 (79.4%) patients were included as they had an additional follow-up measurement between 2-5 years and did not undergo revision surgery, with 4780 patients undergoing primary SG and 14982 patients undergoing primary RYGB (Figure 1). The follow-up percentages for the 2nd, 3rd, 4th, and 5th year among eligible patients given their year of operation were 89.3%, 70%, 58%, and 44.6%, respectively. Baseline characteristics between the two treatment groups are shown in Table 1. Patients undergoing SG on average were younger and had a higher BMI. In addition, patients undergoing SG were more often male and had higher ASA classification but less often had T2D, HTN, dyslipidemia, GERD, OSAS and osteoarthritis at baseline than patients undergoing RYGB.

Primary Outcome

Adjusted for differences in baseline characteristics, Table 2 shows that patients who underwent SG had a higher likelihood to experience WR compared with patients who underwent RYGB [OR 2.07, 95% CI (1.89–2.27), $p < 0.01$]. Additional factors associated with a higher likelihood on WR were longer follow-up, with the 5th year having the highest likelihood [OR 10.9, 95% CI (9.49–12.51), $p < 0.01$]. On the other hand, older patients and those with a higher BMI at primary surgery were less likely to experience WR [OR 0.99, 95% CI (0.98–0.99), $p < 0.01$] and [OR 0.99, 95% CI (0.98–1.00), $p < 0.01$], respectively.

Figure 1. Flowchart of included patients



DATO, Dutch Audit for Treatment of Obesity; RYGB, Roux-en-Y Gastric Bypass; SG, Sleeve Gastrectomy; TWL, Total Weight Loss.

After matching 4693 patients from both treatment groups, there were no significant differences in baseline characteristics with all standardized differences below 0.1 indicating balanced groups (Table 1). In these matched groups, patients who underwent SG still had a higher likelihood to experience WR compared with RYGB [OR 1.98, 95% CI (1.77–2.21), $p < 0.01$] (Table 3).

Table 1. Patient characteristics of patients undergoing primary RYGB or SG between 2015 and 2018

Characteristics	Before matching				After matching			
	RYGB	SG	*p* Value	SMD	RYGB	SG	*p* Value	SMD
n	14982	4780			4693	4693		
Sex, No. (%)								
Male	2612 (17.4)	1169 (24.5)	<0.01	0.17	1115 (23.8)	1122 (23.9)	0.88	<0.01
Female	12370 (82.6)	3611 (75.5)			3578 (76.2)	3571 (76.1)		
Age, mean (SD)	45.45 (10.69)	41.96 (12.30)	<0.01	0.30	42.26 (11.14)	42.11 (12.29)	0.53	0.01
BMI mean (SD)	43.22 (4.89)	45.33 (6.36)	<0.01	0.37	45.08 (5.61)	45.08 (5.97)	0.96	<0.01
ASA classification, No. (%)								
I-II	8837 (59.0)	2163 (45.3)	<0.01	0.28	2168 (46.2)	2149 (45.8)	0.71	0.01
≥ III	6145 (41.0)	2617 (54.7)			2525 (53.8)	2544 (54.2)		
T2D, No. (%)								
Not Present	11762 (78.5)	4087 (85.5)	<0.01	0.18	4008 (85.4)	4008 (85.4)	1.00	<0.01
Present	3220 (21.5)	693 (14.5)			685 (14.6)	685 (14.6)		
Hypertension, No. (%)								
Not present	9483 (63.3)	3243 (67.8)	<0.01	0.10	3110 (66.3)	3175 (67.7)	0.16	0.03
Present	5499 (36.7)	1537 (32.2)			1583 (33.7)	1518 (32.3)		
Dyslipidemia, No. (%)								
Not present	11696 (78.1)	4002 (83.7)	<0.01	0.14	3866 (82.4)	3918 (83.5)	0.16	0.03
Present	3286 (21.9)	778 (16.3)			827 (17.6)	775 (16.5)		
GERD, No. (%)								
Not present	12596 (84.1)	4230 (88.5)	<0.01	0.13	4169 (88.8)	4147 (88.4)	0.50	0.01
Present	2384 (15.9)	550 (11.5)			524 (11.2)	546 (11.6)		
OSAS, No. (%)								
Not present	12089 (80.7)	3925 (82.1)	0.03	0.04	3851 (82.1)	3855 (82.1)	0.94	<0.01
Present	2893 (19.3)	855 (17.9)			842 (17.9)	838 (17.9)		
Osteoarthritis, No. (%)								
Not present	7528 (50.2)	2678 (56.0)	<0.01	0.12	2594 (55.3)	2622 (55.9)	0.57	0.01
Present	7452 (49.7)	2101 (44.0)			2099 (44.7)	2071 (44.1)		
Weight recurrence, No. (%)								
<10%	12687 (84.7)	3731 (78.1)	<0.01	0.17	4097 (87.3)	3655 (77.9)	<0.01	0.25
≥10%	2295 (15.3)	1049 (21.9)			596 (12.7)	1038 (22.1)		

RYGB, Roux-en-y Gastric Bypass; SG, Sleeve Gastrectomy; BMI, body mass index; ASA, American society of anesthesiologists; T2D, type 2 diabetes mellitus; GERD, gastro esophageal reflux disease; OSAS, obstructive sleep apnea syndrome; SMD: standardized mean differences

Table 2. Multivariable logistic regression analyses of weight recurrence between 2-5 years of follow-up

Multivariable analyses	**Weight recurrence between 2 up to 5 years of follow-up**		
(n=19.762)	**No. (%)a**	**aOR [95% CI]**	***p* Value**
Type of procedure			
RYGB	14,982 (75.8%)	ref.	
SG	4780 (24.2%)	2.07 (1.89-2.27)	<0.01
Sex			
Male	3781 (19.1%)	ref.	
Female	15,981 (80.9%)	0.92 (0.83 – 1.02)	0.13
Age	19,762 (100%)	0.99 (0.98 – 0.99)	<0.01
BMI	19,762 (100%)	0.99 (0.98 – 1.00)	<0.01
ASA			
I/ II	11,000 (55.7%)	ref.	
≥III	8762 (44.3%)	0.8 (0.74-0.88)	<0.01
Hypertension			
Not present	12,726 (64.4%)	ref.	
Present	7036 (35.6%)	0.93 (0.85-1.02)	0.14
GERD			
Not present	16,826 (85.1%)	ref.	
Present	2934 (14.9%)	0.97 (0.86-1.1)	0.63
Dyslipidemia			
Not present	15,698 (79.4%)	ref.	
Present	4064 (20.6%)	0.97 (0.87-1.08)	0.55
Follow-up (T0 = 1-year)[b]			
2-year (n=19,762)	17,649 (89.3%)	Ref.	
3-year (n=14,593)	10,225 (70%)	3.91 (3.46 – 4.43)	<0.01
4-year (n=9482)	5502 (58%)	7.59 (6.69 – 8.6)	<0.01
5-year (n=4460)	1990 (44.6%)	10.9 (9.49-12.51)	<0.01

RYGB, Roux-en-y Gastric Bypass; SG, Sleeve Gastrectomy; BMI, body mass index; ASA, American society of anesthesiologists; GERD, gastro esophageal reflux disease; aOR, adjusted odds ratio; CI, confidence interval.

[a] The absolute number and percentage are shown for categorical variables and the mean (SD) for continuous variables.

[b] Read horizontally; No. and percentage follow-up are calculated based on year of surgery, e.g.: patients with surgery in 2017 could have a recorded follow-up at 3-years, but are not included for year 4 or 5.

Secondary Outcomes

Within the matched groups, patients who underwent SG were significantly less likely to maintain 20% TWL [OR 0.36, 95% CI (0.31–0.42), $p < 0.01$] or 50% EWL [OR 0.43, 95% CI (0.38–0.49), $p < 0.01$] at their last recorded follow-up compared with RYGB. Furthermore, patients undergoing SG were less likely to achieve comorbidity remission for T2D, HTN, dyslipidemia, GERD, OSAS, and osteoarthritis (Table 3).

Table 3. Propensity score matched comparison of SG versus RYGB at 2 up to 5 years follow-up, with RYGB as a reference.

	aOR [95% CI]	*p* Value
Primary outcomea		
≥10% Weight Recurrence	1.98 [1.77 – 2.21]	<0.01
	aOR [95% CI]	***p* Value**
Secondary outcome(s)a		
≥10% WR and <20% TWL *(2 up to 5-years)*	1.99 [1.6 – 2.46]	<0.01
≥20% TWL *(2 up to 5-years)*	0.36 [0.31 – 0.42]	<0.01
≥50% EWL *(2 up to 5-years)*	0.43 [0.38 – 0.49]	<0.01
Comorbidity remissiona[β]		
T2D	0.69 [0.56 – 0.86]	<0.01
HbA1c (<53 mmol HbA1c/mol HbA)		
Hypertension	0.75 [0.65 – 0.87]	<0.01
Normotensive (<120/80 mmHg)		
Dyslipidemia	0.44 [0.36 – 0.54]	<0.01
Normal lipid spectrum (LDL, HDL, Triglycerides)		
GERD	0.25 [0.18 – 0.34]	<0.01
Absence of symptoms and a normal physiological test (by 24-48 hours pH measurement or by gastro-duodenoscopy)		
OSAS	0.66 [0.54 – 0.8]	<0.01
No symptoms after preoperative diagnosis of OSAS by means of poly(somno) graphs (PSG), in combination with apnea-hypopnea index (AHI) <5 and no (more) use of CPAP/BiPAP		
Osteoarthritis	0.48 [0.41 – 0.55]	<0.01
No symptoms after pre-operative diagnosis of joint complaints		

[a]Analysis after matching results in balanced groups and is only adjusted for confounding by indication using the propensity score, thereby comparing patients with the same chance of receiving a procedure.
RYGB, Roux-en-Y Gastric Bypass; SG, Sleeve Gastrectomy; WR, weight recurrence; TWL, Total Weight Loss; EWL, Excess Weight Loss; T2D, type 2 diabetes; GERD, gastro esophageal reflux disease; OSAS, obstructive sleep apnea syndrome; aOR, adjusted odds ratio; CI, confidence interval
[β]Remission is defined as no medication use in combination with the criteria as stated in the table above

Within the matched groups, a total of 596 (12.7%) patients had WR after RYGB and 1038 (22.1%) patients after SG. In addition, patients undergoing SG had a higher likelihood to experience WR without maintaining 20% TWL from starting weight than patients undergoing RYGB [OR 1.99, 95% CI (1.6–2.46), $p < 0.01$]. Matched patients undergoing SG with WR who maintained 20% TWL from starting weight, more often showed comorbidity remission for HTN (44.7% vs 29.4%), dyslipidemia (38.3% vs 19.3%), and OSAS (54% vs 20.3%) than patients who did not maintain 20%TWL after SG (Table 4). Among matched RYGB patients, such a difference in comorbidity remission was not found.

Table 4. Concomitant effect of weight recurrence on comorbidity remission between RYGB and SG

4a. Before propensity score matching

Secondary outcomes$^{\beta}$ at last recorded follow-up	<20% TWL	≥20% TWL	p-value
	No. (%)	No. (%)	
Unmatched SG patients with WR ≥10%	**N=461**	**N=588**	
T2D remission	33 (44)	44 (61.1)	0.06
HTN remission	42 (29.2)	80 (44.2)	0.01
Dyslipidemia remission	16 (19.3)	41 (38.3)	0.01
GERD remission	7 (12.7)	9 (11.7)	1.00
OSAS remission	16 (20.3)	54 (52.9)	0.01
Osteoarthritis remission	26 (11.9)	43 (16.8)	0.17
Unmatched RYGB patients with WR ≥10%	**N=678**	**N=1617**	
T2D remission	92 (51.7)	160 (52.5)	0.94
HTN remission	97 (38.2)	256 (51)	<0.01
Dyslipidemia remission	61 (43.9)	148 (49.3)	0.34
GERD remission	26 (32.5)	55 (29.7)	0.76
OSAS remission	62 (37.8)	153 (50.2)	0.01
Osteoarthritis remission	53 (16.9)	183 (23.3)	0.03

4b. After propensity score matching

Secondary outcomes$^{\beta}$ at last recorded follow-up	<20% TWL	≥20% TWL	p-value
	No. (%)	No. (%)	
Matched SG patients with WR ≥10%	**N=459**	**N=579**	
T2D remission	33 (44)	44 (61.1)	0.06
HTN remission	42 (29.4)	80 (44.7)	0.01
Dyslipidemia remission	16 (19.3)	41 (38.3)	0.01
GERD remission	7 (12.7)	9 (11.7)	1.00
OSAS remission	16 (20.3)	54 (54)	<0.01
Osteoarthritis remission	26 (11.9)	43 (16.9)	0.16
Matched RYGB patients with WR ≥10%	**N=171**	**N=425**	
T2D remission	16 (55.2)	25 (44.6)	0.49
HTN remission	18 (33.3)	63 (50.8)	0.05
Dyslipidemia remission	10 (38.5)	34 (50)	0.44
GERD remission	8 (50)	5 (18.5)	0.07
OSAS remission	22 (47.8)	39 (56.5)	0.47
Osteoarthritis remission	11 (13.6)	47 (25.4)	0.05

RYGB, Roux-en-Y Gastric Bypass; SG, Sleeve Gastrectomy; WR, Weight Recurrence; TWL, Total Weight Loss; T2D, type 2 diabetes; HTN, hypertension; GERD, gastro esophageal reflux disease; OSAS, obstructive sleep apnea syndrome. Calculations of remission percentages are made for patients in whom the comorbidity was present prior to surgery.
Analysis after matching results in balanced groups, thereby comparing patients with the same chance of receiving a procedure.
$^{\beta}$Remission is defined as no medication use in combination with the criteria as stated in the table above.

Discussion

Knowledge on differences in risks for weight recurrence between bariatric procedures is crucial during pre-operative consultation of patients. The current nationwide study including 19.762 patients, showed that patients who achieved at least 20%TWL at 1-year follow-up after SG had an increased likelihood on weight recurrence, were less likely to maintain 20%TWL and less likely to achieve comorbidity remission at their last follow-up to 5-years compared with similar patients after RYGB. In addition, matched patients with weight recurrence after SG who maintained ≥20% TWL more often showed comorbidity remission compared with those who did not maintain 20% TWL.

Weight recurrence has been described to result in lowered quality of life and comorbidity deterioration.[19–21] Factors associated with weight recurrence identified in this study are age, BMI, and longer follow-up, which are in line with current literature.[5,17,22] It has to be noted that BMI was not associated with increased weight recurrence, which has been shown to be more likely for patients with a baseline BMI ≥50.[23] The matched patients in this study on average had a BMI of 45, meaning that the difference in weight recurrence between both surgery groups is estimated among patients with mostly BMI <50. In addition, a previous systematic review showed that patients undergoing SG more often have significant weight recurrence compared with RYGB, although the majority of the included studies had small sample sizes.[24] The current study had much larger sample size due to the nationwide character and used propensity score matching, often referred to as pseudo-randomization, so that it provides stronger evidence for the higher likelihood of patients undergoing SG to experience weight recurrence up to 5-years of follow-up than after RYGB.

Less postoperative weight loss has been described to be associated with higher risks on weight recurrence.[17,25] Since studies have shown better short-term weight loss results after RYGB than after SG,[26] our study included only patients who initially achieved ≥20%TWL at 1-year to ensure the same starting point so that we could attribute any difference in outcome to the different procedure rather than the initial difference in weight loss. Despite initially achieving 20%TWL, weight recurrence occurred in 12.7% of patients after RYGB and 22.1% after SG. This suggests that even in patients who initially achieved adequate weight loss, longer follow-up is required to detect weight recurrence in a timely manner. In addition, it suggests that patients may require multiple sequential or parallel treatment strategies such as additional surgery[18] or medical treatment[27] to prevent or treat weight recurrence, as a single bariatric procedure may not always suffice.[28–31]

Comparative studies between RYGB and SG in achieving T2D remission remain controversial. Previous studies have shown that RYGB has better T2D remission than SG at 1 year,[32] whereas the difference after 5-years was not significantly different in one study[33], but in favor of RYGB in another study.[34] The latter results are consistent with our finding of a higher likelihood on T2D remission after RYGB among patients with initial adequate weight loss, as well as a lower likelihood on weight recurrence. However, the current study also shows that among patients with weight recurrence there is no difference in T2D remission between patients who maintained the ≥20%TWL compared with their starting weight or not, for either treatment groups. A possible explanation could be the initial effect of achieving 20% TWL on T2D remission, as a previous study showed that patients within similar weight change classes show no differences in T2D remission between different procedures.[35] In summary, there is need for larger studies with longer follow-up to confirm the association between weight recurrence and different likelihood of T2D remission between these treatment groups.

The current results support the findings of previous studies showing that RYGB achieves better comorbidity control when compared with patients undergoing SG.[36–38] In addition it suggests that patients undergoing RYGB may be less affected by ≥10% weight recurrence and its concomitant effect on comorbidity remission, regardless of maintaining 20% TWL, suggesting more favorable metabolic effects after RYGB compared with SG. Furthermore, these results show that maintaining adequate weight loss after weight recurrence less likely affects comorbidity control. Future studies are needed to investigate when patients will benefit the most of sequential (surgical) treatments when weight recurrence is evaluated in combination with TWL from starting weight and comorbidity control.

There are some limitations that should be noted. First, not all patients completed the 5-year follow-up as this is an ongoing registry, meaning that these estimates may be less precise and that results may be different if all patients have completed the 5-year follow-up. However, since both treatments groups were matched on follow-up in subsequent years, this has not affected the comparison between treatment groups. Second, this study did not include patients who eventually underwent revision surgery, which most likely are patients with the worst outcomes including weight recurrence. In addition, the postoperative complications were not included, which should be taken into account for high risk patients during shared decision making. Finally, matching cannot adjust for unmeasured confounders such as surgeon preference, which are assumed to be balanced by matching on the measured confounders. Despite the limitations, this is the first nationwide study on weight recurrence after initially achieving 20%TWL for patients undergoing SG and RYGB. Taking into account the likelihood of weight recurrence, maintaining ≥20%TWL, and comorbidity remission, the RYGB could be favored in terms of lower frequency of weight recurrence and more frequent comorbidity remission compared with SG. However, other factors have to be taken into account during shared decision making for a particular type of procedure, such as complication risks and revision surgery.

Conclusion

Patients undergoing SG are more likely to experience weight recurrence, and less likely to achieve comorbidity remission than patients undergoing RYGB. In addition, patients with weight recurrence after SG who maintained 20%TWL from starting weight more often showed comorbidity remission than patients not maintaining 20%TWL, suggesting that this should be taken into account when evaluating weight recurrence.

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4

Conversion to Roux-en-Y gastric bypass versus one-anastomosis gastric bypass after a failed primary gastric band: a matched nationwide study

Erman O. Akpinar, Simon W. Nienhuijs, Ronald S.L. Liem,
Jan Willem M. Greve, Perla J. Marang- van de Mheen, and
on behalf of the Dutch Audit for Treatment of Obesity Research Group

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Abstract

Background Primary laparoscopic adjustable gastric band (LAGB) has high rates of patients not achieving the desired weight loss, and it remains unclear which bariatric conversion procedure gives better results.

Objective To compare weight loss among patients undergoing conversion one anastomosis gastric bypass (cOAGB) and conversion Roux-en-Y gastric bypass (cRYGB) after a failed LAGB.

Setting Nationwide population-based study including all 18 hospitals providing metabolic and bariatric surgery

Methods Patients with a failed primary LAGB who underwent a cRYGB or cOAGB between 1 January 2015 and 31 December 2019 were selected from the Dutch Audit for Treatment of Obesity (DATO). The primary outcome was defined as not achieving ≥20% total weight loss (TWL) at 1 up to 5 year follow-up. Secondary outcomes included postoperative complications, defined as Clavien Dindo (CD) ≥III within 30 days, and comorbidity remission. A propensity score matched logistic and Poisson regression model was used to estimate the difference in patients not achieving ≥20% TWL between cRYGB and cOAGB.

Results A total of 615 (78.7%) patients underwent cRYGB, and 166 (21.3%) patients underwent cOAGB, with 163 patients successfully matched. Both groups had similar rates of patients not achieving ≥20% TWL at 1-year (odds ratio [OR] = .64, 95% confidence interval [CI]: .38-1.05). However, a sensitivity analysis showed that patients undergoing cOAGB had lower rates of patients not achieving ≥20% TWL up to 5 years follow-up (rate ratio = .69, 95% CI: .51-.95, $P < .05$). Patients undergoing cOAGB were less likely to achieve hypertension remission (OR = .22, 95% CI: .07-.66 , $P < .05$). There were no significant differences between groups in postoperative complications (OR = .39, 95% CI: .07-2.06, $P > .05$).

Conclusion This matched nationwide study suggests that the cOAGB has similar short-term weight loss outcomes but potentially better long-term weight-loss results than cRYGB. Therefore, cOAGB could provide a reliable alternative but needs to be substantiated in future long-term studies.

Introduction

The laparoscopic adjustable gastric band (LAGB) was one of the most commonly performed bariatric procedures at the end of the 20th century. Its early adoption was mainly due to the reduced number of short-term complications and acceptable weight loss results compared with the Roux-en-Y Gastric Bypass (RYGB).[1,2] However, a major disadvantage of this procedure has become clear in recent years, with long-term complications of LAGB increasing significantly, often resulting in either removal of the band alone or conversion to another procedure.[3–5]

In cases where a failed primary LAGB necessitated a conversion to another technique, RYGB has been considered the golden standard.[6] Conversion to Sleeve Gastrectomy (SG) was not preferred due to long term complications or not achieving the desired weight loss, often resulting in (another) conversion to RYGB.[7] An alternative to RYGB is the One Anastomosis Gastric bypass (OAGB).[8] The YOMEGA trial has shown lower short-term complication rates for primary OAGB compared with primary RYGB.[9–11] The OAGB also has similar to higher weight loss results and comorbidity remission, but at the cost of malnutrition.[8] The combination of higher weight loss and lower short-term complications compared with RYGB, have resulted in surgeons increasingly performing OAGB procedures, also after failed primary LAGB.[12–14]

Primary LAGB has been associated with high rates of patients not achieving the desired weight loss, ranging from 44% - 50%, making it likely to expect an increase in number of bandings requiring conversion in upcoming years[4,15]. This underlines the need for further evidence regarding which conversion technique has the best outcomes in terms of complications, comorbidity remission, and weight loss.[16,17] Current literature on this topic remains scarce[18], both for short and longer term results. The aim of this study therefore was to compare weight loss at 1 up to 5-year follow-up for patients undergoing a conversion RYGB (cRYGB) or conversion OAGB (cOAGB) after a failed primary LAGB.

Methods and Design

Study design

This is a population-based cohort study with data retrieved from the Dutch Audit for Treatment of Obesity (DATO). The DATO, a nationwide mandatory audit, started in 2015 and registers all bariatric procedures performed in the Netherlands. On-site data verification has shown the validity of the audit data.[19] This study was approved by all the scientific committee members (reference number 2021-132) of the DATO and has been performed following the ethical standards stated in Dutch law. In accordance with the Dutch Institute for Clinical Auditing (DICA) regulations, no informed consent from patients was needed as this is an opt-out registry.

Revision procedures

Revision surgery in the DATO is defined as receiving a second bariatric procedure after the previously performed primary bariatric procedure. Three groups of revision procedures are distinguished: conversion (converting the first bariatric technique in another bariatric technique), undo (restoring normal anatomy), and revision (revising the same bariatric technique). In addition to the type of revision procedure, the indication for the revision procedure is registered. For the present study these indications were categorized into (1) non-responders: primary non-responders in terms of weight loss (<5% Total Weight Loss (TWL) after primary bariatric surgery), secondary non-responders identified by weight regain (>10% weight regain = weight regain/nadir (lowest postoperative weight) *100%) or secondary comorbidity deterioration (recurrence of comorbidity or increase in medication for comorbidity e.g., diabetes), and (2) 'band related complications': food intolerance, band slippage, band erosion, gastroesophageal reflux disease (GERD), stenosis, dilated pouch, port infection, and other indications.

Patient selection

Patients were considered eligible if they underwent a conversion to Roux-en-Y Gastric Bypass (cRYGB) or conversion to One-Anastomosis Gastric Bypass (cOAGB) between 1 January 2015 and 31 December 2019, after a failed primary LAGB procedure. Since 2019, registering the indications for revision bariatric surgery has been obligatory in the DATO, so that procedures from all 18 hospitals were included in the analysis. For procedures carried out between 2015 and 2018, hospitals were included if they had complete data on indications for more than 85% of the revision procedures in the DATO.

Outcome parameters

The primary outcome was defined as not achieving ≥20% TWL at 1-year follow-up after conversion to RYGB or OAGB. To determine the % TWL at 1-year follow-up, patients need an outpatient clinic visit between 9 and 15 months postoperatively. The starting weight before primary bariatric surgery was used to calculate the weight loss. This was done to ensure fair comparison of groups, as it is possible that these differed in the extent to which patients initially did not achieve their desired weight loss but eventually complied with their goal to achieve ≥20% TWL. Secondary outcomes included comorbidity remission at 1 year follow-up for hypertension (HTN), GERD, type 2 diabetes (T2D), dyslipidemia, obstructive sleep apnea syndrome (OSAS), osteoarthritis, and postoperative severe complications within 30 days, defined as a Clavien Dindo (CD) classification grade ≥III.

Statistical analysis

Differences in characteristics of patients undergoing the two types of conversion procedures were analyzed using the χ^2 test for categorial variables and the *t* test or Mann-Whitney U test for continuous variables, depending on the distribution. Characteristics were gender, age, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, and obesity related comorbidities. A multivariable logistic regression model was used including variables with $p<0.10$ to compare the two treatment groups on the primary and secondary outcomes, adjusted for baseline characteristics. Multicollinearity was assessed in all models with the Variance Inflation Factor not exceeding 2.

Subsequently, propensity score matching was used to take into account possible confounding by indication between the two surgical conversion techniques. Patients were matched on gender, age, BMI, ASA classification, and obesity related comorbidities. The nearest neighbor method was used to match 1:1 with a caliper of .20.[20] A standardized mean difference <0.1 was considered to indicate balanced groups. All statistical analyses were performed in R version 3.4.2 (R Foundation for Statistical Computing). A *P*-value <.05 was considered statistically significant in all analyses.

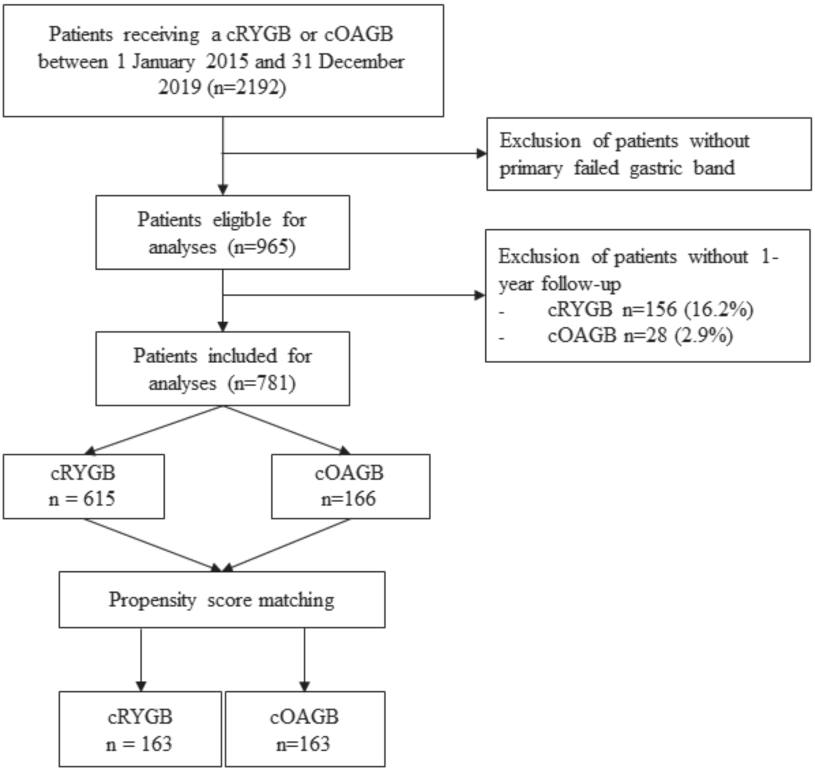
Sensitivity analysis

A longer follow-up time was available for patients who underwent conversion procedures in earlier years, which may provide important information on the reliability and sustainability after bariatric conversion surgery. We therefore conducted a sensitivity analyses to gain insight into the extent to which a longer duration of follow-up would affect the results. For all patients, the last known follow-up up to 5-years was taken to assess 20% TWL and calculate the time at risk since the conversion surgery. Patients were not required to have a 1-year follow-up in case a longer follow-up was registered, meaning that potentially a larger group of patients with longer follow-up could be available than for the primary analysis. For each treatment group, we calculated the rate of patients not achieving ≥20% TWL by dividing numbers of patients who did not achieve ≥20% TWL by the total patient time at risk. Multivariable Poisson regression analysis was then used to assess the difference in patients not achieving ≥20% TWL adjusted for baseline characteristics as above and including the logarithm of 'patient time at risk' as an offset variable. Propensity score matched analysis was conducted in the same manner as for the primary analysis.

Results

In addition to all revision procedures carried out in 2019, eleven out of 18 hospitals had sufficiently complete data for revision procedures between 2015 and 2018 to be included in the analysis. In total 781 patients were included having 1-year follow-up, with 615 (78.7%) undergoing conversion to RYGB and 166 (21.3%) undergoing conversion to OAGB (Figure 1).

Figure 1. Flowchart inclusion of patients



cRYGB, conversion Roux-en-y Gastric Bypass; cOAGB, conversion One Anastomosis gastric bypass.

Overall, 561 (71.8%) patients achieved their initially desired weight loss (≥20%TWL) after conversion surgery. However, from the patients who underwent cRYGB and cOAGB, respectively 184 (29.9%) and 36 (21.7%) patients did not achieve ≥20% TWL. Table 1 shows that patients undergoing cOAGB had a higher BMI on average, and less often osteoarthritis and GERD at baseline. There were no significant differences between the groups in age, gender, ASA classification, and other obesity related comorbidities. Patients undergoing cOAGB had a median biliopancreatic (BP) limb length of 180 cm (IQR [180-200]), and patients undergoing cRYGB had a median BP limb length of 80 cm (IQR [60-150]). The alimentary limb (AL) length of the cRYGB group had a median of 125 cm (IQR [100-150cm]).

Table 1. Patient characteristics of patients undergoing conversion RYGB or conversion OAGB after failed primary gastric band

Characteristics	Before matching		p Value	SMD	After matching		p Value	SMD
	cRYGB	cOAGB			cRYGB	cOAGB		
n	615	166			163	163		
Sex, No. (%)								
Male	90 (14.6)	21 (12.7)	0.60	<0.1	23 (14.1)	20 (12.3)	0.74	<0.1
Female	525 (85.4)	145 (87.3)			140 (85.9)	143 (87.7)		
Age, mean (SD)	48.39 (8.69)	48.19 (8.25)	0.79	<0.1	47.34 (8.48)	48.07 (8.25)	0.43	<0.1
BMI mean (SD)	43.07 (6.44)	46.99 (7.18)	<0.01	0.58	46.23 (6.35)	46.56 (6.41)	0.64	<0.1
Year of operation, No. (%)								
<2019	482 (78.4)	138 (83.1)	0.22	0.12	129 (79.1)	135 (82.8)	0.48	<0.1
≥2019	133 (21.6)	28 (16.9)			34 (20.9)	28 (17.2)		
ASA classification, No. (%)								
I-II	334 (54.3)	85 (51.2)	0.53	<0.1	79 (48.5)	82 (50.3)	0.82	<0.1
≥ III	281 (45.7)	81 (48.8)			84 (51.5)	81 (49.7)		
T2D, No. (%)								
Not Present	539 (87.6)	141 (84.9)	0.43	<0.1	133 (81.6)	138 (84.7)	0.55	<0.1
Present	76 (12.4)	25 (15.1)			30 (18.4)	25 (15.3)		
Hypertension, No. (%)								
Not present	448 (72.8)	120 (72.3)	0.96	<0.1	126 (77.3)	120 (73.6)	0.52	<0.1
Present	167 (27.2)	46 (27.7)			37 (22.7)	43 (26.4)		
Dyslipidemia, No. (%)								
Not present	537 (87.3)	151 (91.0)	0.25	0.12	147 (90.2)	148 (90.8)	1.00	<0.1
Present	78 (12.7)	15 (9.0)			16 (9.8)	15 (9.2)		
GERD, No. (%)								
Not present	500 (81.3)	151 (91.0)	<0.01	0.28	151 (92.6)	148 (90.8)	0.69	<0.1
Present	115 (18.7)	15 (9.0)			12 (7.4)	15 (9.2)		
OSAS, No. (%)								
Not present	561 (91.2)	156 (94.0)	0.32	0.11	153 (93.9)	153 (93.9)	1.00	<0.1
Present	54 (8.8)	10 (6.0)			10 (6.1)	10 (6.1)		
Osteoarthritis, No. (%)								
Not present	409 (66.5)	139 (83.7)	<0.01	0.41	139 (85.3)	136 (83.4)	0.76	<0.1
Present	206 (33.5)	27 (16.3)			24 (14.7)	27 (16.6)		
Indication conversion surgery, No. (%)								
Non responders	433 (70.4)	142 (85.5)	<0.01	0.37	140 (85.9)	139 (85.3)	1.00	<0.1
Band related complications	182 (29.6)	24 (14.5)			23 (14.1)	24 (14.7)		

cOAGB, conversion One Anastomosis Gastric bypass; cRYGB, conversion Roux-en-y Gastric Bypass; BMI, body mass index; ASA, American society of anesthesiologists; T2D, type 2 diabetes mellitus; GERD, gastro esophageal reflux disease; OSAS, obstructive sleep apnea syndrome; SMD: standardized mean differences

Indications for conversion surgery

The indication for conversion surgery in the cOAGB group was more often 'non-responders' rather than 'band related complications' compared with the cRYGB group. The group of non-responders included 21 (3.4%) patients in the cRYGB group and 6 (3.6%) patients in the cOAGB with primary non-response, 25 (4.1%) patients in the cRYGB and 1 (0.6%) patient in the cOAGB with secondary comorbidity deterioration, and 387 (62.9%) patients in the cRYGB and 135 (81.3%) patients in the cOAGB group with secondary non-responders as the indication for conversion surgery.

Primary and secondary outcomes

Adjusted for differences in patient characteristics, there were no significant differences between cRYGB and cOAGB in patients not achieving ≥20% TWL at 1 year follow-up (OR 0.82, 95%CI [0.53-1.27] p=0.38), indicating similar short-term results (Table 2).

Table 2. Multivariable logistic regression analyses of patients not achieving ≥20% TWL at 1-year follow-up after conversion bariatric surgery

Multivariable analyses	Patients not achieving ≥20% TWL at 1-year follow-up		
(n=781)	No. (%)*	aOR [95% CI]	*p* Value
Type of procedure			
cRYGB	615(78.7%)	ref.	
cOAGB	166(21.3%)	0.82 (0.53 – 1.27)	0.383
Sex			
Female	670(85.8%)	ref.	
Male	111(14.2%)	1.18 (0.75 – 1.85)	0.498
Age	48.4(8.6)*	1.04 (1.02 – 1.07)	<0.01
BMI	43.9(6.8)*	0.97 (0.94 – 0.99)	<0.01
Year of operation			
<2019	620(79.4%)	ref.	
≥2019	161(20.6%)	0.75 (0.49–1.13)	0.17
ASA			
I/ II	419(53.6%)	ref.	
≥III	362(46.4%)	0.74 (0.53–1.05)	0.088
GERD			
Not present	651(83.4%)	ref.	
Present	130(16.6%)	1.31 (0.86–2.00)	0.202
Indication conversion surgery			
Non-responders	575(73.6%)	ref.	
Band related complications	206(26.4%)	1.67 (1.17–2.39)	<0.01

TWL, Total Weight Loss; cOAGB, conversion One Anastomosis Gastric bypass; cRYGB, conversion Roux-en-y Gastric Bypass; BMI, body mass index; ASA, American society of anesthesiologists; GERD, gastro esophageal reflux disease; aOR, adjusted odds ratio; CI, confidence interval.
*The absolute number and percentage are shown for categorical variables and the mean (SD) for continuous variables.

Older age (OR 1.04, 95%CI [1.02 – 1.07] $p < 0.01$) and 'band related complications' as the indication for conversion surgery (OR 1.67, 95%CI [1.17–2.39] $p < 0.01$) had higher likelihood of not achieving ≥20% TWL at 1 year. In contrast, a higher BMI was associated with a significantly lower likelihood (OR 0.97, 95%CI [0.94–0.99] $p<0.01$) of not achieving ≥20% TWL, indicating better results

Regarding the secondary outcomes, the results in Table 3 show that a higher BMI at baseline was associated with a lower likelihood (OR 0.93, 95%CI [0.87–1.00]. $p < 0.05$) on severe postoperative complications within 30 days. Neither the technique cRYGB versus cOAGB (OR 0.36, 95%CI [0.08-1.60], p=0.18), nor other risk factors in the multivariable model were significantly associated with the occurrence of severe postoperative complications.

Table 3. Multivariable logistic regression analyses of severe postoperative complication within 30 days after conversion bariatric surgery

Multivariable analyses in CD ≥III (n=781)	Postoperative CD ≥III within 30 days		
	No. (%)*	aOR [95% CI]	*p* Value
Type of procedure			
cRYGB	615(78.7%)	ref.	
cOAGB	166(21.3%)	0.36 (0.08–1.6)	0.179
Sex			
Female	670(85.8%)	ref.	
Male	111(14.2%)	0.98 (0.33–2.85)	0.966
Age	48.4(8.6)*	1.03 (0.97–1.08)	0.33
BMI	43.9(6.8)*	0.93 (0.87–1.00)	<0.05
Year of operation			
<2019	620(79.4%)	ref.	
≥2019	161(20.6%)	0.92 (0.33–2.55)	0.867
T2D			
Not present	680(87.1%)	ref.	
Present	101(12.9%)	2.39 (0.9–6.37)	0.081
Hypertension			
Not present	568(72.7%)	ref.	
Present	213(27.3%)	1.8 (0.72–4.51)	0.212
Indication conversion surgery			
Non responders	575(73.6%)	ref.	
Band related complications	206(26.4%)	0.66 (0.24–1.82)	0.42

CD, Clavien Dindo Classification; cOAGB, conversion One Anastomosis Gastric bypass; cRYGB, conversion Roux-en-y Gastric Bypass; BMI, body mass index; T2D, type 2 diabetes mellitus; aOR, adjusted odds ratio; CI, confidence interval.
*The absolute number and percentage are shown for categorical variables and the mean (SD) for continuous variables.

Table 4. Propensity score matched comparison of cOAGB versus cRYGB after failed primary gastric band, with cRYGB as a reference.

	aOR [95% CI]	*p* Value
Primary outcome*		
Patients not achieving ≥20% TWL 1-year	0.64 [0.38-1.05]	0.08
Patients not achieving ≥50% EWL 1-year	0.46 [0.26-0.79]	<0.01
Secondary outcome(s)*		
Clavien Dindo ≥III within 30 days	0.39 [0.07-2.06]	0.27
Comorbidity remission*^β		
T2D	1.70 [0.52-5.58]	0.38
(HbA1c<53 mmol HbA1c/mol HbA)		
Hypertension	0.22 [0.07-0.66]	<0.01
(normotensive (<120/80 mmHg)		
Dyslipidemia	0.46 [0.08-2.59]	0.38
(Normal lipid spectrum (LDL, HDL, Triglycerides))		
GERD	0.73 [0.09-5.64]	0.76
(absence of symptoms with normal physiological test (by 24-48 hours pH measurement or by gastro-duodenoscopy))		

*Analysis after matching results in balanced groups and is only adjusted for confounding by indication using the propensity score, thereby comparing patients with the same chance of receiving a procedure.
cOAGB, conversion One Anastomosis Gastric bypass; cRYGB, conversion Roux-en-y Gastric Bypass; TWL, Total Weight Loss; EWL, Excess Weight Loss; CD, Clavien Dindo Classification; T2D, type 2 diabetes; GERD, gastro esophageal reflux disease; aOR, adjusted dds ratio; CI, confidence interval
^ Remission is defined as no medication use in combination with the criteria as stated in the table above
βObstructive sleep apnea syndrome and osteoarthritis are not included due to insufficient number of events

Sensitivity analysis

The sensitivity analysis included all patients with the last follow-up being registered in the DATO up to 5-years (n= 845 patients, 668(79.1%) conversion to RYGB, and 177(20.9%) conversion to OAGB). The completeness of follow-up among eligible patients depended on year of surgery, which varied between 92.4% for 1-year and 41.8% for 5-year follow-up (Supplementary Table A). From the patients undergoing cRYGB, a total of 235 did not achieve ≥20% TWL across 18492 patient months (i.e., a rate of 0.013 per month) compared with 46 patients who did not achieve ≥20% TWL in the cOAGB group across 5374 patient months (i.e., a rate of 0.009 per month). Adjusted for baseline characteristics, patients who underwent conversion surgery because of 'band related complications' had significantly higher rates of patients not achieving ≥20% TWL than 'non-responders' (rate ratio (RR) 1.3, 95%CI [1.11–1.53], $p<0.05$). In addition, patients undergoing cOAGB had lower rates of patients not achieving ≥20% TWL up to 5-years of follow-up (RR 0.76, 95%CI [0.58–0.99], p<0.05), indicating better long-term results. After matching 175 patients in each treatment group, this significant effect remained for patients undergoing cOAGB (RR 0.69, 95% CI [0.51–0.95], p <0.05).

Discussion

In this nationwide study, we showed that 71.8% of patients after a failed primary LAGB did achieve their initially desired weight loss after conversion surgery. The matched comparison between cRYGB and cOAGB showed similar total weight loss at 1-year, but significantly lower rates of patients not achieving ≥20% TWL up to 5-years after cOAGB, suggesting potentially better long-term results. Furthermore, patients undergoing conversion surgery because of the indication 'band related complications' had less favorable weight loss results than 'non-responders'. Complications and remission of comorbidities were similar between both procedure groups, except for HTN remission with a lower likelihood for the cOAGB group.

Previous studies have shown that failed primary LAGB is best managed by converting to another bariatric technique such as OAGB or RYGB.[14,21] Furthermore, for primary procedures, previous studies have shown significantly greater weight loss for primary OAGB versus primary RYGB after a 5-year follow-up.[8–10,22,23] However, results for conversion procedures and particularly comparing the two techniques after a failed LAGB remain scarce. Therefore, the present study adds to available evidence showing similar total weight loss results at 1-year follow-up. Additionally, the sensitivity analysis results show significantly lower rates of patients not achieving the desired ≥20% TWL for the cOAGB group at 5-years compared with the cRYGB group, suggesting potentially better long-term results. Important to note in this context is that patients undergoing cOAGB in the current study had a median BP limb length of 180cm. These longer BP lengths (e.g., 180cm and 200cm) have been shown in previous studies to be associated with greater weight loss than shorter BP lengths.[9,22,24] One trial particularly showed that conversion to RYGB with longer BP lengths resulted in greater weight loss up to 4-years compared with standard BP lengths.[25] It is therefore possible that the OAGB, which commonly has a longer BP length than the RYGB, could partially explain the greater weight loss observed in patients up to 5-years in the current study, but this should be explored in future studies.

The OAGB has one anastomosis, resulting in less severe complication rates within 30 days compared with RYGB.[9,26] In the literature, reported severe complication rates within 30 days after conversion bariatric surgery range from 5.7% to 7%.[27,28] The severe complication rates within 30 days in the present study were 3.7% for the RYGB group and 1.2% for the OAGB group, without significant differences between the two groups after matching. The lower complication rate could be explained by the differences in the definition of severe complications in other studies[27,28] compared with the definition of the CD classification used in the current study.[29] Another explanation can be the centralization of bariatric surgery in the Netherlands, with only a few hospitals performing revision procedures.

Resolution of comorbidities was similar between the two treatments except for HTN, which shows a lower likelihood for remission at 1 year for the cOAGB group. A meta-analysis in 2019 showed no difference in HTN remission between the groups but better T2D remission for patients undergoing primary OAGB.[23] However, this meta-analysis was limited by the availability of literature, including relatively small retrospective cohorts. In addition, the current study assesses the results of patients undergoing conversion surgery after a failed primary LAGB, which could explain the different results in comorbidity resolution.

Considering long-term outcomes, OAGB results in more biliary reflux and nutritional complications, whereas the RYGB has more surgical reinterventions due to internal herniation[22,30]. Nevertheless, a potential concern arising from prolonged exposure to biliary reflux is the esophagogastric cancer risk.[31,32] Although bariatric surgery has been shown to reduce obesity-associated cancer risks, it is up to debate whether particularly OAGB gives increased risk in the development of esophagogastric cancer.[33]

To date, 'failure' is defined as inadequate weight loss or weight regain.[34] For the present study, failure is categorized into two distinct indications, i.e., 'non-responders' and 'band related complications'. The latter combines several different types of band related complications, such as band slippage, band erosion, band defect, tubing defect, and port infection, making it a heterogeneous group. In the current study, the patients with 'band related complications' had a lower BMI at baseline and showed less favorable weight loss results than 'non-responders'. Previous studies have described that a lower BMI at baseline is associated with lower weight loss.[35] It is therefore plausible that the less favorable weight loss results were due to a lower BMI at baseline rather than the type of band related complication.

There are limitations to this study. First, this study did not register complications beyond 30 days which is important to inform patients about long-term risks. Furthermore, we could not adjust for unmeasured confounders, such as surgeon preference, which remains an issue in observational studies. However, by using matching techniques, just as in randomization, the distribution of measured and unmeasured confounders will be balanced on average between the two treatment groups. Finally, although we used the offset of time at risk to compare patients with the same follow-up period, not everyone completed the 5-year follow-up, meaning that the estimates at longer follow-up may be less precise and that results might be different if all patients have completed the 5-year follow-up.

Conclusion

Patients undergoing cOAGB or cRYGB after failed primary LAGB have similar short-term total weight loss outcomes. Sensitivity analysis including follow-up to 5 years shows lower rates of patients not achieving the desired total weight loss for patients undergoing cOAGB compared with cRYGB, suggesting potentially better long-term results. Long term studies with higher completeness of follow-up are needed to confirm these findings.

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Supplementary table A. Percentage of follow-up completed among eligible patients according to year of surgery

Follow-up period	Year of surgery	Eligible patients who underwent cRYGB or cOAGB	Follow-up completed No. (%)
		N=845	N=845
1 year follow-up	2015-2019	845	781(92.4%)
2 year follow-up	2015-2018	680	440 (64.7%)
3 year follow-up	2015-2017	502	292 (58.2%)
4 year follow-up	2015-2016	336	170 (50.6%)
5 year follow-up	2015	177	74 (41.8%)

cRYGB conversion Roux-en-Y gastric bypass; cOAG, conversion one anastomosis gastric bypass;

5

Hospital variation in preference for a specific bariatric procedure and the association with weight loss performance: a nationwide analysis

Erman O. Akpinar, Ronald S.L. Liem, Simon W. Nienhuijs,
Jan Willem M. Greve, Perla J. Marang- van de Mheen, and
on behalf of the Dutch Audit for Treatment of Obesity Research Group

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Abstract

Purpose Hospitals performing a certain bariatric procedure in high volumes may have better outcomes. However, they could also have worse outcomes for some patients who are better off receiving another procedure. This study evaluates the effect of hospital preference for a specific type of bariatric procedure on their overall weight loss results.

Methods All hospitals performing bariatric surgery were included from the nationwide Dutch Audit for Treatment of Obesity. For each hospital, the expected (E) numbers of Sleeve Gastrectomy (SG), Roux-en-Y gastric bypass (RYGB), and One-anastomosis gastric bypass (OAGB) were calculated given their patient-mix. These were compared with the observed (O) numbers as the O/E ratio in a funnel plot. The 95% control intervals were used to identify outlier hospitals performing a certain procedure significantly more often than expected given their patient-mix (defined as hospital preference for that procedure). Similarly, funnel plots were created for the outcome of patients achieving ≥25% total weight loss (TWL) after 2-years, which was linked to each hospitals' preference.

Results A total of 34.558 patients were included, with 23.154 patients completing a 2-year follow-up, of whom 79.6% achieved ≥25%TWL. Nine hospitals had a preference for RYGB (range O/E ratio [1.09-1.53]), with 1 having significantly more patients achieving ≥25%TWL (O/E ratio [1.06]). Of 6 hospitals with a preference for SG (range O/E ratio [1.10-2.71]), one hospital had significantly fewer patients achieving ≥25%TWL (O/E ratio [0.90]), and from two hospitals with a preference for OAGB (range O/E ratio [4.0-6.0]), one had significantly more patients achieving ≥25%TWL (O/E ratio [1.07]). One hospital had no preference for any procedure but did have significantly more patients achieving ≥25%TWL (O/E ratio [1.10]).

Conclusion Hospital preference is not consistently associated with better overall weight loss results. This suggests that even though experience with a procedure may be slightly less in hospitals not having a preference, it is still sufficient to achieve similar weight loss outcomes when surgery is provided in centralized high-volume bariatric institutions.

Introduction

To effectively treat patients with morbid obesity, a variety of bariatric surgical procedures are available. Literature has extensively demonstrated the effectiveness of bariatric procedures in terms of weight loss and comorbidity reduction, but each procedure will have its own advantages considering some outcomes, while having disadvantages in terms of other outcomes.[1–5] This makes it crucial to tailor the best procedure to the characteristics of individual patients, e.g., performing a Roux-en-Y gastric bypass (RYGB) for patients with gastro-esophageal reflux disease (GERD).[6]

However, surgeon preference may also play a significant role in decision making around type of bariatric procedure.[7] Factors relevant for shared decision making are weight loss outcomes, patients' preference, and reduction of relevant comorbidities such as GERD or type 2 diabetes (T2D).[8] Furthermore, bariatric surgery has a history of trends with frequent changes in techniques and procedures.[9] Nowadays, the most frequently performed procedures are the one-anastomosis gastric bypass (OAGB), RYGB and the sleeve gastrectomy (SG), with SG being the world's predominant procedure due to lower long-term morbidity and similar weight loss results as RYGB.[2,9–12]

These trends and changes in bariatric surgery have led to different physician preferences, with many surgeons predominantly performing one procedure.[12] Previous studies have shown that high operative volume of a single procedure is associated with lower morbidity[13,14], consistent with the notion 'Practice makes perfect'. Having extensive experience with one specific technique in a high volume center could therefore result in better overall hospital outcomes. On the other hand, a one-size-fits-all policy may also result in worse outcomes for some patients who, based on their patient characteristics, would be better off with a different type of bariatric procedure.

Therefore, the present study will evaluate the extent to which hospitals perform some specific bariatric procedures more than expected given their patient-mix, and whether such hospital preference in high volume centers is associated with overall hospital performance on patients achieving 25% total weight loss (TWL) after 2-years.

Materials and Methods

Setting and Study design

In the Netherlands, bariatric surgical care is centralized in hospitals since 2010, using rather uniform peri-, and postoperative care protocols.[15] All hospitals perform bariatric surgery with a multidisciplinary team, including at least 2 dedicated bariatric surgeons and performing at least 200 procedures annually. This minimum number of annual procedures is based on the Dutch guidelines to ensure high surgeon experience on an institutional level. All included hospitals in the current study have at least 2 dedicated bariatric surgeons performing a minimal of 200 procedures annually for at least 5-years.[15]

Data were derived from the nationwide quality registry DATO (Dutch Audit for Treatment of Obesity).[16] The present study was approved by all scientific committee members of the DATO and has been performed following the ethical standards stated in Dutch law. The DATO is an opt-out quality registry with anonymized data which cannot be traced back to the individual patient, so that according to applicable Dutch regulations, no informed consent was needed for this study.

Patient selection

All patients who underwent a primary SG, RYGB or OAGB between 2015-2018 were included in the analysis. To evaluate the current Dutch situation, patients were excluded if they underwent bariatric surgery in hospitals that stopped performing bariatric surgery. Therefore, we included all 16 hospitals that performed bariatric surgery from 2015 to the present; 2 hospitals that stopped treating bariatric patients in this period were excluded. Patients with missing data on date of birth, weight, length, obesity related comorbidities during preoperative screening, or procedure type were excluded.

Definitions and outcome parameters

The choice for a specific bariatric procedure should be tailored based on the individual's patient characteristics. Therefore, hospital preference for a specific bariatric procedure was defined as performing significantly more of this specific procedure than would be expected based on the patient-mix treated in that hospital. The calculation of expected numbers is explained in more detail in the statistical analysis section. The following patient characteristics were taken into account: age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, year of operation, GERD, T2D, hypertension, obstructive sleep apnea syndrome (OSAS), dyslipidemia, and osteoarthritis, which were defined as described previously.[17]

The primary outcome is patients achieving ≥25% TWL (Total weight loss) i.e., for all patients in a hospital after 2-year follow-up. Although 20% TWL is a common threshold for successful weight loss, 25% TWL was chosen from the perspective of hospitals continuously improving their care, which is better supported by a threshold that is more discriminative as shown by a previous study.[18] The nationally predefined interval for a follow-up at 2 years is an outpatient clinic visit between 21-27 months postoperatively. Total weight loss at 2-year follow-up is defined as: $\frac{(preoperative\ weight - followup\ weight)}{preoperative\ weight}$ ** 100% = % TWL.* Secondary outcome was the composite measure Textbook Outcome, which is defined as: no mortality, no severe postoperative complications, no readmissions, no mild complications, and no prolonged length of stay (LOS) (>2days) within 30 days after primary bariatric surgery.[19] This was chosen because it provides additional insight in the direct postoperative quality of care delivered by the hospital, from the rationale that if practice makes perfect, hospitals with a preference for a specific type of procedure might have better Textbook Outcome.

Statistical analysis

Baseline characteristics were compared between patients undergoing different types of bariatric procedures, using descriptive statistics. Pearson Chi square test was used to compare categorical variables and the ANOVA for continuous variables.

Subsequently, nationwide hospital variation was evaluated in their preference to perform a specific bariatric procedure more often than would be expected given their patient-mix, using a funnel plot. First, multivariable logistic regression was performed using data from all patients in all hospitals, to estimate the extent to which certain characteristics made it more or less likely for the patient to undergo a specific bariatric procedure. All of the aforementioned patient characteristics were included as independent variables based on literature[20] and clinical relevance, and undergoing a specific bariatric procedure (yes/no) as the dependent variable. This was done separately for each of the three bariatric procedures. The coefficients from these models were used to estimate for each patient the expected probability to undergo each of the three bariatric procedures based on patient characteristics. These probabilities were summed across patients within each hospital to arrive at the aggregated expected number (E) of specific bariatric procedures performed in that hospital. The observed number (O) of specific bariatric procedures was then divided by the expected number for that hospital to calculate the O/E ratio.[21] Subsequently, we graphically plotted all hospitals with their O/E ratios in a patient-mix adjusted funnel plot along with 95% Control Intervals (CI). Hospitals above the upper 95%CI performed significantly more of a specific bariatric procedure than expected based on their patient-mix, and were defined as having a preference for that bariatric procedure. Hospitals under the lower 95%CI were significantly less likely to perform that particular procedure, which likely meant they had preference for another procedure and were therefore not further described. Hospitals in between the 95%CI were performing as expected given their patient-mix and were defined as having no specific preference. The funnel plot inherently takes into account differences in absolute numbers of procedures. This difference is shown by the funnel-shape of the control interval, which is broader for hospitals with lower numbers and narrower for hospitals with higher absolute numbers, meaning that a smaller preference can be identified as significantly different for hospitals with higher absolute numbers.

Similarly, patient-mix adjusted funnel plots were created for the primary outcome of patients achieving ≥25% TWL after 2 years, including the same patient characteristics. All hospitals were color coded depending on their preference for a specific bariatric procedure. If hospitals had a preference for more than one procedure, they were given a separate color to indicate preference for the combination rather than counted by both types of procedures. All statistical analyses were performed in R version 3.4.2.

Sensitivity analysis

Short-term weight loss results at 1-year follow-up have shown to be similar across bariatric procedures. Although 2-year follow-up was assessed, it may not have been long enough to show the impact on weight loss. Therefore, a sensitivity analysis was conducted including all patients undergoing bariatric surgery in 2015 with a complete 5-year follow-up to examine the association of hospital preference for a specific bariatric procedure and long-term weight loss. Hospital preference from the main analyses was used, based on all patients. Patient-mix adjusted funnel plots were created to show hospital performance on patients achieving ≥25% TWL after 5 years, including all aforementioned patient characteristics.

Results

Study Sample

Between 2015 and 2018, 34.866 patients underwent a primary bariatric procedure of whom 34.558 (99.1%) had complete data and were included for analysis. Hospitals had a median annual volume of 499 procedures (IQR 377-762). The follow-up at 2 year was 67% (n=23.154), with limited hospital variation (median 70.2% (IQR 63.5%-72.5%). Table 1. shows significant differences in all baseline characteristics between patients undergoing RYGB, SG, OAGB, or another procedure, which emphasizes the need for patient-mix adjustment when comparing hospitals on the extent to which they perform certain procedures and their performance on patients achieving ≥25% TWL after 2 years.

Hospital preference

The between-hospital variation in their patient-mix is shown in Figure 1. Hospitals varied significantly in distribution for all patient-mix variables, but in particular for the percentage of patients with ASA ≥3 (median of 47.8% [IQR=29.2-56.2%]), GERD (13% [(IQR=11.2-18.7%]), and osteoarthritis (51.6% [IQR=24.5-57.1%]) at baseline.

Table 1. Patient characteristics of patients who underwent a primary bariatric procedure between 2015 and 2018.

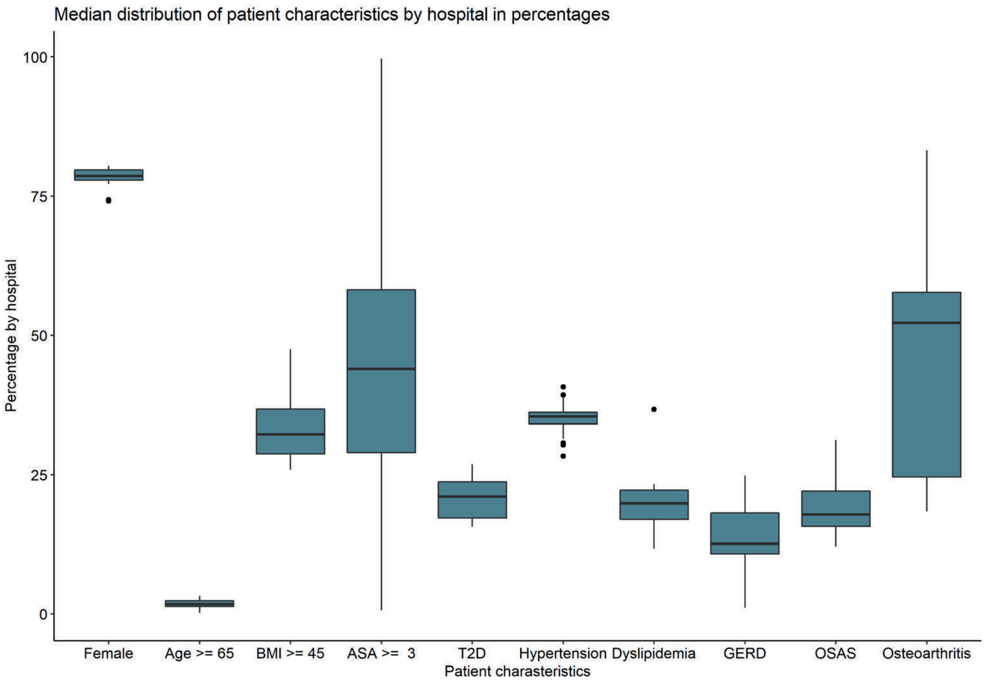
Characteristics	Type of procedure				*p* Value
	RYGB	SG	OAGB	Others*	
n	21971	8690	2885	1012	
Sex, No. (%)					
Male	4190 (19.1)	2230 (25.7)	736 (25.5)	249 (24.6)	<0.01
Female	17781 (80.9)	6460 (74.3)	2149 (74.5)	763 (75.4)	
Age, mean(SD)	44.66 (11.01)	41.77 (12.47)	45.66 (11.47)	44.39 (11.30)	<0.01
BMI mean (SD)	43.23 (4.89)	45.44 (6.48)	46.07 (6.01)	43.05 (5.82)	<0.01
ASA classification, No. (%)					
I-II	12620 (57.4)	3822 (44.0)	985 (34.1)	523 (51.7)	<0.01
>= III	9351 (42.6)	4868 (56.0)	1900 (65.9)	489 (48.3)	
T2D, No. (%)					
Not Present	17180 (78.2)	7265 (83.6)	2135 (74.0)	798 (78.9)	<0.01
Present	4791 (21.8)	1425 (16.4)	750 (26.0)	214 (21.1)	
Hypertension, No. (%)					
Not present	14166 (64.5)	5910 (68.0)	1726 (59.8)	654 (64.6)	<0.01
Present	7805 (35.5)	2780 (32.0)	1159 (40.2)	358 (35.4)	
Dyslipidemia, No. (%)					
Not present	17168 (78.1)	7225 (83.1)	2349 (81.4)	812 (80.2)	<0.01
Present	4803 (21.9)	1465 (16.9)	536 (18.6)	200 (19.8)	
GERD, No. (%)					
Not present	18528 (84.3)	7640 (87.9)	2510 (87.0)	871 (86.1)	<0.01
Present	3443 (15.7)	1050 (12.1)	375 (13.0)	141 (13.9)	
OSAS, No. (%)					
Not present	17812 (81.1)	7081 (81.5)	2289 (79.3)	874 (86.4)	<0.01
Present	4159 (18.9)	1609 (18.5)	596 (20.7)	138 (13.6)	
Osteoarthritis, No. (%)					
Not present	11312 (51.5)	4911 (56.5)	2066 (71.6)	390 (38.5)	<0.01
Present	10659 (48.5)	3779 (43.5)	819 (28.4)	622 (61.5)	

*The group of "Other" procedures consists of gastric banding n=91 (9%), BPD n=4 (0.4%), SADI n=32 (3.2%), banded gastric bypass n=851 (84%), and other procedures n=34 (3.4%).
RYGB, Roux-en-Y Gastric Bypass; SG, Sleeve gastrectomy; OAGB, One Anastomosis Gastric bypass; BMI, body mass index; ASA, American society of anesthesiologists; T2D, type 2 diabetes mellitus; GERD, gastro esophageal reflux disease; OSAS, obstructive sleep apnea syndrome; SD: standard deviation.

Figure 2. shows the extent to which hospitals performed more RYGB, SG or OAGB than expected based on their patient-mix, suggesting a preference for that specific procedure (depicted in green). Table 2 shows the extent to which patient characteristics influenced the odds to undergo a specific bariatric procedure. Female elderly patients with T2D, GERD, dyslipidemia,

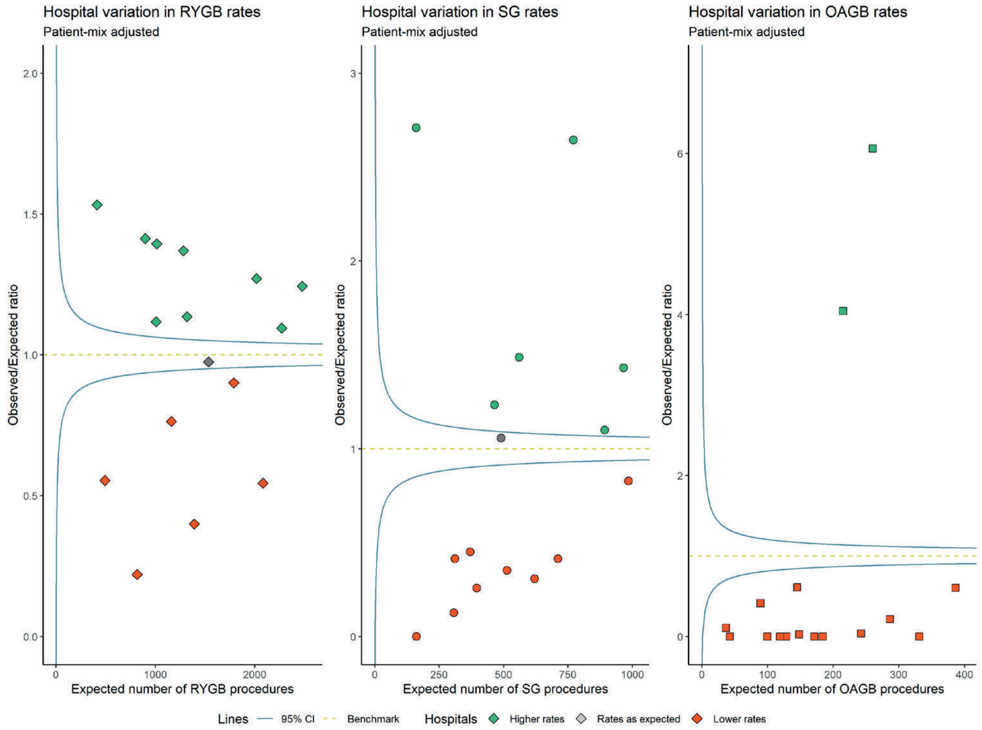
or osteoarthritis at baseline were more likely to undergo RYGB. Patients with higher BMI, higher ASA classification, and hypertension or osteoarthritis at baseline were more likely to undergo SG, and elderly patients with higher BMI, higher ASA classification, with T2D or hypertension at baseline were more likely to undergo OAGB. Nine hospitals performed significantly more RYGB (range in O/E ratio 1.09-1.53), six hospitals performed significantly more SG (range in O/E ratio 1.10-2.71), and 2 hospitals performed significantly more OAGB than expected given their patient-mix (range in O/E ratio 4.0-6.0). The hospitals indicated by a red color were significantly less likely to perform that type of procedure given their patient-mix, which could mean they had a preference for another type of procedure. Hospitals were indicated by a grey color if they performed as many procedures as would be expected given their patient-mix.

Figure 1. Boxplot showing the distribution of the median percentage (IQR) of patient characteristics by hospital in the Netherlands.



BMI, body mass index; ASA, American society of anesthesiologists; T2D, type 2 diabetes mellitus; GERD, gastro esophageal reflux disease; OSAS, obstructive sleep apnea syndrome; IQR: Inter Quartile Range

Figure 2. Patient-mix adjusted funnel plot showing hospital variation in preference for RYGB, SG, and OAGB procedures.



The color of the point shape (diamond (RYGB), circle (SG), and square(OAGB)) determines the rate; Green: denotes higher rates, Grey: denotes rates as expected, Red: denotes lower rates
RYGB, Roux-en-y Gastric Bypass; SG, Sleeve gastrectomy; OAGB, One Anastomosis Gastric bypass; CI, Control Intervals . Expected number given patient-mix.

Association of hospital preference with outcomes

Figure 3 shows how the preference for a particular type of bariatric surgery is associated with the overall hospital performance of patients achieving ≥25% TWL after 2-years. Most hospitals have a preference for one type of bariatric surgery, except for 1 hospital (in grey) without any preference, and 2 hospitals with a preference for both RYGB and SG. From the 9 hospitals with a preference for RYGB, one hospital had significantly more patients achieving ≥25% TWL after 2 years i.e., better overall outcomes (O/E ratio 1.06), and one of the two hospitals with a preference for OAGB (O/E ratio 1.07). On the other hand, from the 6 hospitals with a preference for SG, one hospital had significantly worse overall outcomes as fewer patients achieved ≥25% TWL after 2-years (O/E ratio 0.90). The hospital (grey) with no preference for either RYGB, SG or OAGB shows significantly better overall outcomes on ≥25% TWL after 2-years (O/E ratio 1.10). There were no significant differences between hospitals in the outcome ≥50% Excess Weight Loss (EWL) after 2-years (range O/E ratio 0.95-1.05).

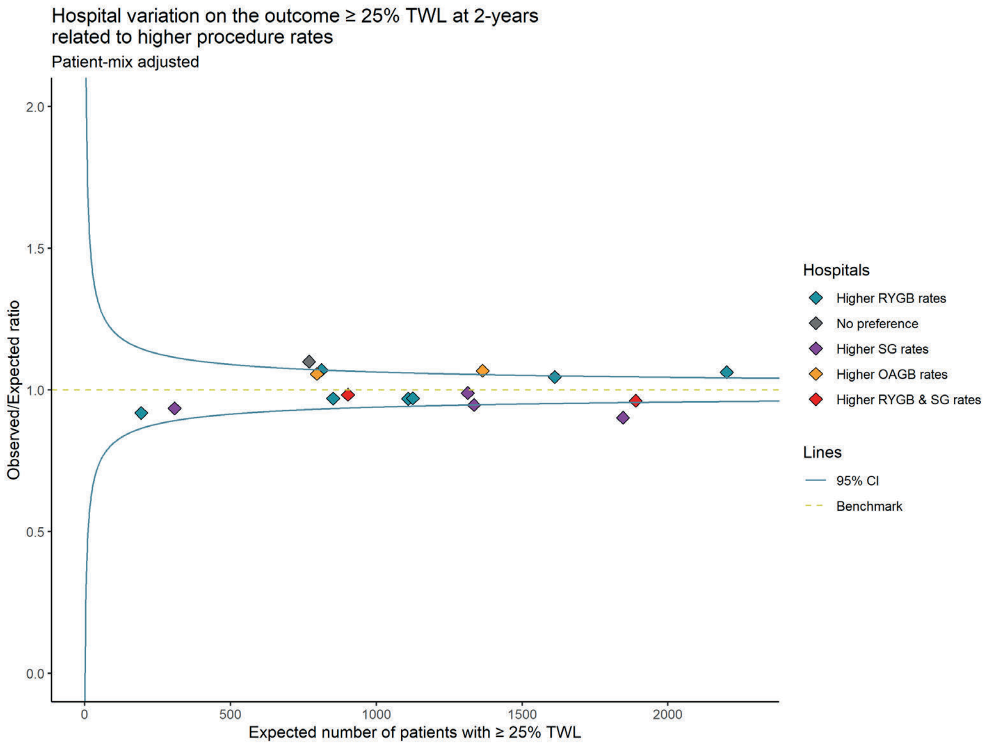
Table 2. Multivariable logistic regression analyses including all patients from all hospitals for undergoing a specific bariatric procedure based on patient-mix

Multivariable analyses	RYGB	SG	OAGB
	aOR [95% CI]	aOR [95% CI]	aOR [95% CI]
Sex			
Male	ref.	ref.	ref.
Female	1.54 [1.46-1.63]	0.66 [0.62-0.7]	0.9 [0.82-0.98]
Age	1.01 [1.01-1.02]	0.98 [0.97-0.98]	1.02 [1.01-1.02]
BMI	0.94 [0.94-0.94]	1.05 [1.05-1.06]	1.06 [1.05-1.06]
ASA			
I/ II	ref.	ref.	ref.
≥III	0.56 [0.54-0.59]	1.55 [1.47-1.63]	1.85 [1.71-2.01]
T2D			
Not present	ref.	ref.	ref.
Present	1.14 [1.07-1.21]	0.75 [0.7 -0.81]	1.23 [1.11-1.36]
Hypertension			
Not present	ref.	ref.	ref.
Present	0.9 [0.85-0.95]	1.09 [1.03-1.16]	1.12 [1.02-1.22]
GERD			
Not present	ref.	ref.	ref.
Present	1.16 [1.08-1.24]	0.85 [0.79-0.92]	1.00 [0.89-1.13]
Dyslipidemia			
Not present	ref.	ref.	ref.
Present	1.15 [1.07-1.22]	0.96 [0.9-1.04]	0.76 [0.68-0.85]
OSAS			
Not present	ref.	ref.	ref.
Present	1.04 [0.97-1.1]	1.04 [0.97-1.11]	0.99 [0.89-1.1]
Osteoarthritis			
Not present	ref.	ref.	ref.
Present	1.1 [1.05-1.15]	1.08 [1.03-1.14]	0.44 [0.41-0.49]

RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; OAGB, one-anastomosis gastric bypass; BMI, body mass index; ASA, American society of anesthesiologists; T2D, type 2 diabetes; GERD, gastro esophageal reflux disease; OSAS, obstructive sleep apnea syndrome; aOR, adjusted odds ratio; CI, confidence interval.

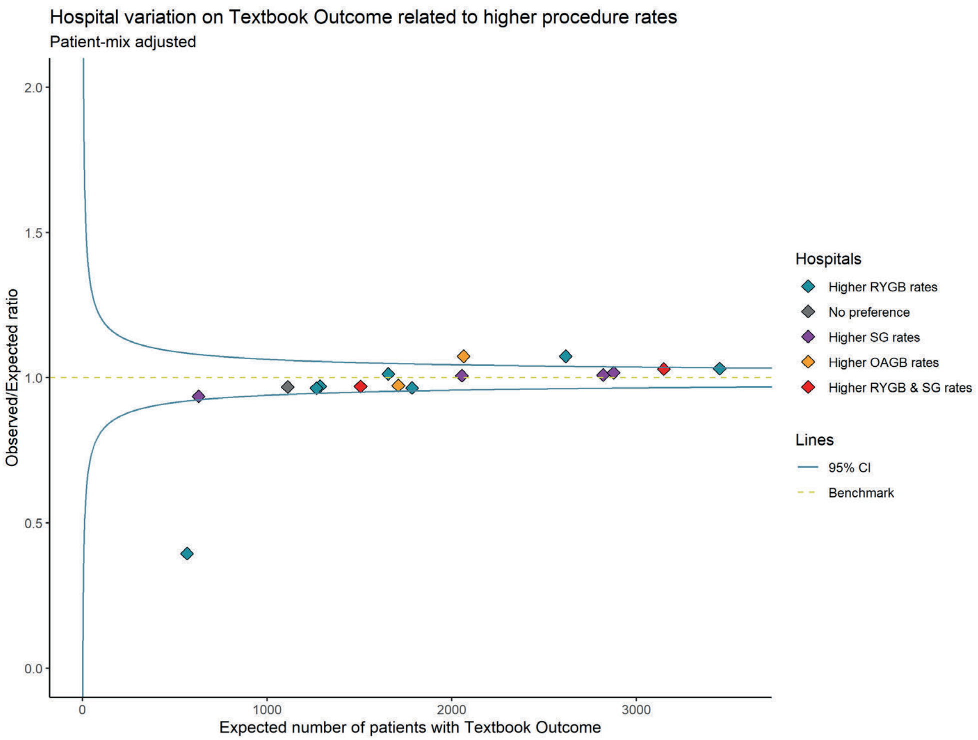
Figure 4. presents the between-hospital variation to achieve Textbook Outcome associated with hospital preference for a bariatric procedure. From the 9 hospitals with preference for RYGB, one hospital had significantly fewer patients achieving Textbook Outcome i.e. worse performance (O/E ratio 0.40), and one hospital had significantly better performance (O/E ratio 1.07). One hospital with preference for OAGB had significantly better overall performance in patients achieving Textbook Outcome (O/E ratio 1.07). The remaining 13 hospitals all had a performance as expected in patients achieving Textbook Outcome. Looking specifically at postoperative severe complications, there was no association between hospital preference for a specific procedure and the percentage of Clavien Dindo ≥III complications within 30 days (data not shown).

Figure 3. Patient-mix adjusted funnel plot showing hospital variation in 25% TWL after 2 -years related to preference for type of procedure



RYGB, Roux-en-y Gastric Bypass; SG, Sleeve gastrectomy; OAGB, One Anastomosis Gastric bypass; CI, Control Intervals. Expected number given patient-mix.

Figure 4. Patient-mix adjusted funnel plot showing hospital variation on textbook outcome related to preference for type of procedure



RYGB, Roux-en-y Gastric Bypass; SG, Sleeve gastrectomy; OAGB, One Anastomosis Gastric bypass; CI, Control Intervals. Expected number given patient-mix

Sensitivity analysis

The follow-up at 5-years was 35.4% (n=2565) with limited hospital variation (median 33.2% [IQR =28.4-41.3%]). Even though the funnel plot has lower power to detect differences in hospital performance, as shown by wider control intervals, Supplemental Figure 1 shows a very similar pattern for 5-year weight loss results as shown in Figure 3 for 2-year weight loss results. Hospital preference for a specific bariatric procedure was not systematically associated with hospital performance on patients achieving ≥25% TWL after 5-years.

Discussion

This study demonstrates large variation between hospitals to perform specific bariatric procedures more often than would be expected given the patient-mix, suggesting a preference for that procedure. The largest number of hospitals had a preference for RYGB, only a few for OAGB. Furthermore, hospital preference for a specific type of bariatric procedure is not consistently associated with better overall weight loss outcomes for all patients treated in that hospital after 2 years; one hospital with a preference for RYGB, one hospital with a preference for OAGB, and one hospital with no preference at all had significantly more patients achieving ≥25% TWL after 2 years (adjusted for patient-mix). Notably, from the hospitals having a preference for SG, one hospital had significantly worse performance on achieving ≥25% TWL weight loss after 2-years, and one hospital with preference for RYGB performed significantly worse in patients achieving textbook outcome.

There are multiple factors that influence the choice for one bariatric procedure over another, e.g.: short term complications, long term complications, GERD, T2D, and expected long term weight loss.[7,8,22] The current study shows that patients with characteristics known to be associated with increased complications risks, such as higher ASA classification and higher BMI, were more likely to undergo SG. This is supported by literature showing lower short and long term complication risks after SG compared to RYGB, which has led to a worldwide increase of patients undergoing SG.[12] In contrast, female patients were less likely to undergo SG[23], which has shown to be less effective in weight loss for females than males.[24] Females at child bearing age could play an important role in the decision making process of females more often undergoing SG, given the lower postoperative complications rates compared with RYGB.[2,25] Nevertheless, the RYGB may still be preferred in patients with T2D and GERD due to higher remission rates compared with SG.[17,26,27] This is also shown in the current study results with a higher likelihood to undergo RYGB for patients with T2D and GERD at baseline, whereas OAGB was preferred for patients with T2D without GERD likely due to a higher prevalence of biliary reflux.[4] Although the current study adjusted for differences in all patient characteristics, the funnel plots show various preferences for specific type of bariatric procedures between hospitals. These preferences are most likely due to (shared) surgeon preferences, which is more strongly correlated with procedure selection than patient or hospital factors.[7]

Hospitals with high volume on specific bariatric procedures, are associated with lower morbidity, mortality, and improved outcomes after bariatric surgery.[28–31] It has been described that performing more than 100 laparoscopic RYGB results in 50% decrease of complications.[32] Furthermore, for every 10 cases performed annually, either on hospital or surgeon-level, the odds are in favor of lower major morbidity.[14] The current study shows an annual median hospital volume of 499 procedures, meaning these hospitals have procedure volumes associated with favorable outcomes. Hospitals having a preference for a specific procedure likely means they have relatively more experience with this procedure in the peri-, and postoperative care process, which would suggest improved outcomes.

However, the results from the present study do not show systematically better outcomes for hospitals having a preference for a specific procedure. One possible explanation could be that even though experience with a particular procedure may be slightly less in hospitals not having a preference for a specific procedure, it is still sufficient to achieve similar weight loss outcomes due to the centralized bariatric care in high volume institutions. This would also explain why hospital preference was not consistently associated with textbook outcome or CD ≥III complications within 30 days. Of note, one hospital with RYGB preference performed significantly worse on textbook outcome, which was not due to worse peri-operative complications within 30 days, but due to their extended LOS policy of 3 days. This emphasizes the importance of the entire care process surrounding the surgery.

Long term complications also have to be considered in shared decision making with patients to choose a specific type of bariatric procedure. After all, possible long-term complications are directly linked to the procedural technique, with possible internal herniations occurring after RYGB or OAGB, biliary reflux or malnutrition after OAGB, and GERD after SG.[33] The present study recorded 15 (0.28%), 23 (0.15%), and 2 (0.11%) complications (e.g. stricture, intestinal obstruction, gallstone, dysphagia, and internal herniation) after respectively SG, RYGB, and OAGB beyond 30 days up to 2-years of follow-up. The lower percentage complications after RYGB compared with SG is likely due to the relatively short-term follow-up as RYGB has shown to have more operative re-interventions for long-term complications up to 5-years[25].

The current study links the results of the decision-making process for procedure type to the overall hospital outcomes. A possible pitfall for hospitals with a preference could be that they also perform this procedure when perhaps another procedure might have advantages, thereby not tailoring the most suitable procedure to the clinical features of the patient as discussed previously.[34] The results for the hospital with no preference for any procedure (Figure 3.) support that bariatric patients are more likely to lose ≥25% of their total body weight if such a tailored choice of bariatric procedure is successful, rather than having a preference for (a) specific procedure(s) which is used on many patients.[34,35] This shows the importance of procedure selection for the individual patient and underlines that every bariatric surgeon should be proficient in various bariatric procedures.

This study has several strengths. It includes a nationwide registry reflecting daily practice and benchmarks the quality of care after adjustment for patient-mix differences in high-volume hospitals. However, there are also limitations. Data collected as part of daily practice may be subject to errors and incomplete data. However, the mandatory design of the DATO ensures completeness and participation of all hospitals, and data verification has previously shown that the quality of entered data is reliable.[36] Second, the follow-up after 2-years was only 67%, and a longer follow-up is needed to assess long-term weight loss. However, because there was limited variation between hospitals in percentage follow-up, this is unlikely to explain the results on variation in hospital preference and their overall outcomes at 2-year follow-up. Finally, this study could not adjust for surgeon volume or surgeon preference, as no distinction between surgeons can be made from the DATO dataset. However, it seems likely that hospital preference is the result of a shared preference and hospital policy given the importance of working in teams, particularly since surgeons are collectively responsible for the outcome of their patients in the Dutch setting, as well as that all surgeons in a hospital share the work load in performing a similar number of procedures.

Conclusion

Hospital preference for a specific bariatric procedure is not consistently associated with their overall performance on achieving ≥25% total weight loss for their patients after 2-years. This suggests that even though experience with a procedure may be slightly less in hospitals not having a preference, it is still sufficient to achieve similar weight loss outcomes when surgery is provided in centralized high-volume bariatric institutions.

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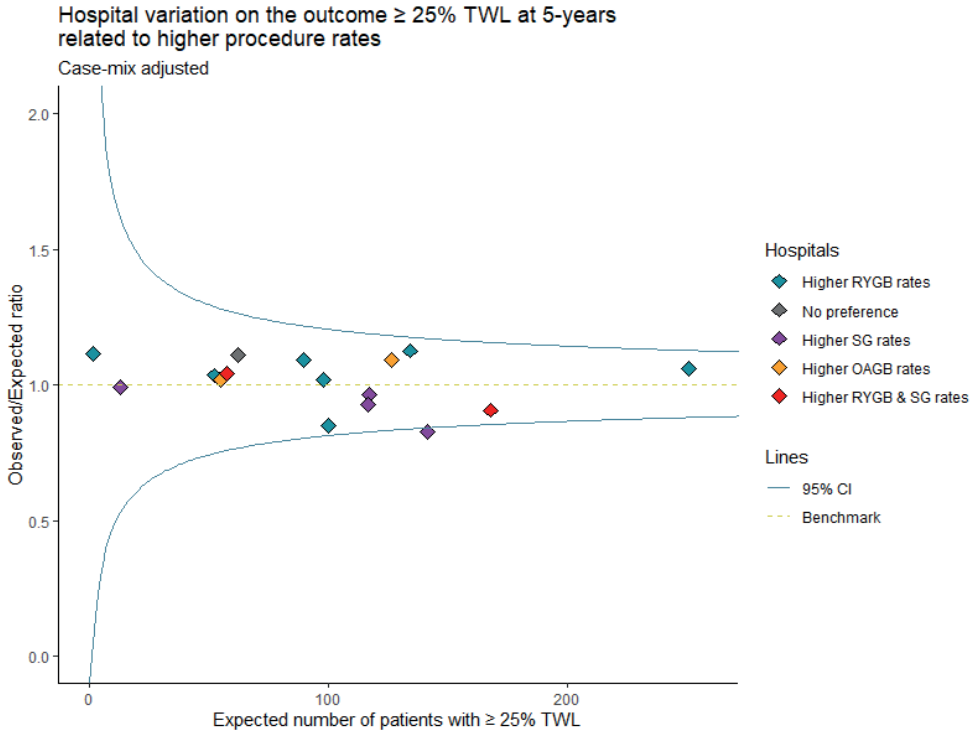
Supplemental figure 1. Patient-mix adjusted funnel plot showing hospital variation in 25% TWL after 5-years related to preference for type of procedure



RYGB, Roux-en-y Gastric Bypass; SG, Sleeve gastrectomy; OAGB, One Anastomosis Gastric bypass; CI, Control Intervals. Expected number given patient-mix

6

National bariatric surgery registries: an international comparison

Erman O. Akpinar, Perla J. Marang- van de Mheen, Simon W. Nienhuijs,
Jan Willem M. Greve, Ronald S.L. Liem

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Abstract

Introduction Pooling population-based data from all national bariatric registries may provide international real-world evidence for outcomes that will help establish a universal standard of care, provided that the same variables and definitions are used. Therefore, this study aims to assess the concordance of variables across national registries to identify which outcomes can be used for international collaborations.

Methods All 18 countries with a national bariatric registry who contributed to The International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Global Registry report 2019 were requested to share their data dictionary by email. The primary outcome was the percentage of perfect agreement for variables by domain; patient, prior bariatric history, screening, operation, complication and follow-up. Perfect agreement was defined as 100% concordance, meaning that the variable was registered with the same definition across all registries. Secondary outcomes were defined as variables having 'substantial agreement'(75%-99.9%) and 'moderate agreement'(50%-74.9%) across registries.

Results Eleven registries responded and had a total of 2585 recorded variables that were grouped into 250 variables measuring the same concept. A total of 25(10%) variables have a perfect agreement across all domains: 3(18.75%) for the patient domain, 0(0.0%) for prior bariatric history, 5(8.2%) for screening, 6(11.8%) for operation, 5(8.8%) for complications, and 6(11.8 %) for follow-up. Furthermore, 28(11.2%) variables have substantial agreement and 59(23.6%) variables moderate agreement across registries.

Conclusion There is limited uniform agreement in variables across national bariatric surgery registries. Further alignment and uniformity in collected variables are required to enable future international collaborations and comparison.

Introduction

National bariatric surgery registries ensure and improve the quality of care provided to the patient.[1–4] Pooling the datasets from all the national bariatric registries may provide international real-world evidence that will help establish a universal standard of care for the treatment of patients with morbid obesity[5–7].

The International Federation for the Surgery of Obesity and metabolic disorders (IFSO) global registry report 2019 includes a total of 833.687 operation records combining all bariatric registries.[8] The main goal of the global registry is to improve outcomes for bariatric patients. However, there is a structural lack of consistency in defining outcomes across national registries.[9–11] Most registries do not register the same variables, and even when they register the same variables, it only has a similar 'overall concept', rather than the same definition. For example, the same overall concept being measured with 'severe postoperative complications' may contain categories such as bleeding or leakage, but is defined differently in other registries where additional categories such as obstruction or stricture are also included.[12] A 'common language' in gathering and defining variables is required to address the issues mentioned above, resulting in Common Data Elements (CDE's) and eventually leading to standardized outcome reporting[13], but the extent of inconsistency across registries is currently unknown.

Therefore this study aimed to compare the degree of concordance in variables between national bariatric registries and to discuss the need for further alignment and uniformity in collecting variables for international collaborative and comparative studies.

Materials & Methods

Study design

The IFSO Registry Committee requested all 18 countries with an established national bariatric surgery registry in 2019 by email to share their data dictionary for this study.[11] The Committee requested countries that did not include the definition of variables in their data dictionary, to send a separate explanatory text guiding consistent data entry, e.g., appearing as part of hover prompts containing the definition of variables. A reminder was sent by email after 2-4 weeks to ensure a high participation rate.

Review of variables

Registries differ in whether they use one or more variable(s) to measure the same overall concept. For example, the variable 'Diabetes Mellitus diagnosis' with categories (1) 'no' (2) 'yes' (3) 'yes, with medication' can be followed by a second variable 'Details of the treatment' with the categories (1) oral hypoglycaemics (2) insulin treatment and (3) injectable other than insulin. These two variables measure the same overall concept as one variable with the categories (1) no indication of diabetes (2) pre-diabetes (3) oral hypoglycaemics (4) insulin treatment. Variables are registry specific and thus challenging to compare 1 on 1. To assess the degree of concordance for this study, variables were first grouped in variables that measure the same overall concept and then categorized into the following six domains: patient characteristics, prior bariatric history, screening, operation, complication, and follow-up. These domains are based on the chronological order of the care pathway that appears in most national registries. For each individual registry, their variables were mapped against the total list of grouped variables within the different domains. During the mapping of individual registries the following main points were taken into account: whether the content of the variable(s) occur in the registry (registered / not registered) and whether the variable(s) have a matching definition. Upon receiving the data dictionaries, a medical doctor (EA) listed all variables from all participating registries. Then, two reviewers, a medical doctor (EA) and expert bariatric surgeon (RL) had several meetings as part of the mapping process to review and discuss the assignment of variables in the different domains. A third independent expert bariatric surgeon (SN) was available to discuss until consensus was reached in case of disagreement. When the definition of variables was not available, the variables were reviewed to the best of our knowledge with the provided documents at hand.

Defining variables

Continuous variables, e.g. 'weight', and categorical variables, e.g. 'diabetes mellitus diagnosis' containing the categories 'yes' or 'no' were considered a match if they had the same definition. Categorical variables were also considered a match if they could be mapped to higher-level aggregated category e.g. 'postoperative myocardial infarct' or 'postoperative dysrhythmia' match the aggregated category 'cardiac complications'.

Outcome parameters

The primary outcome is the percentage of 'perfect agreement' across registries for variables by domain. Perfect agreement is defined as a 100% concordance for variables across all registries, meaning that the variable is recorded in all registries with the same definition or matches the mapping of a categorical variable with the same aggregated category. Secondary outcomes were a '75% - 99.9% concordance defined as 'substantial agreement' and '50% - 74.9% concordance defined as 'moderate agreement'.

Results

Participating registries

Eleven out of 18 national bariatric surgery registries responded and agreed to participate in the study, as shown in Table 1. The 18 national registries together comprise a total of 735.881 patients, from which the 11 participating registries included n=554.599 (75.4%) patients undergoing bariatric surgery according to the IFSO Global Registry report 2019. [8] Registries with definitions available for part of the variables were from Brazil, Kuwait, Mexico, Russia, Turkey, and the UK.

Table 1. Participating National Bariatric Surgery Registries (in alphabetical order)

Number	Country	Registration name	Participating	Country specific definition of variables
1	Australia/New Zealand[a]	ANZMOSS	Yes	Yes
2	Austria	OGA	Yes	No
3	Belgium	BeSOMS	**No**	-
4	Brazil	SBCBM	Yes	Yes (partially)
5	Egypt	ESBS	**No**	-
6	France	SOFFCO.MM	**No**	-
7	India	OSSI	**No**	-
8	Israel	ISMBS	**No**	-
9	Italy	SICOB	**No**	-
10	Japan	JSSO	**No**	-
11	Kuwait	KLOSS	Yes	Yes (partially)
12	Netherlands	DATO	Yes	Yes
13	Norway[b]	SOREG-N	Yes	Yes
14	Russia	BAREOREG	Yes	Yes (partially)
15	Sweden[b]	SOREG-S	Yes	Yes
16	Turkey	TOSS	Yes	Yes (partially)
17	United Kingdom	NBSR	Yes	Yes (partially)
18	United States of America	MBSAQIP	Yes	Yes

[a] Australia and New Zealand share an identical national registry and therefore counted as one registry.
[b] Norway and Sweden register independently and are counted as two registries, but use identical data dictionaries that are compatible when merging data.

Primary and secondary outcomes

A total of 2585 variables were assessed, which were grouped into 250 variables (Supplementary Table 1) measuring the same concept across the 6 domains. From these 250 variables 16 (6.4%) were in the patient domain, 14 (5.6%) in prior bariatric history, 61 (24.4%) in screening, 51 (20.4%) in operation, 57 (22.8%) in complication, and 51 (20.4%) in follow-up (Figure 1). The number of variables with perfect agreement by domain was: 3

(18.75%) for the patient domain, 0 (0.0%) for prior bariatric history, 5 (8.2%) for screening, 6 (11.8%) for operation, 5 (8.8%) for complications and 6 (11.8 %) for follow-up, meaning a total of 25 (10%) variables across all domains. Perfect agreement was found for the variables 'hospital ID' and 'Healthcare institution' that were part of the domains screening, operation, complications, and follow-up. Within the domain 'complications', perfect agreement was found for the 3 variables 'post-operative bleeding', 'leak' and 'surgical complication' with the first two having identical definitions and the latter mapped to the same aggregated category. Within the follow-up domain, the 4 variables with a perfect agreement were 'date of follow-up', 'weight', 'medical treatment of diabetes mellitus' with the categories (1)'insulin (2)'non-insulin medication' and 'diabetes mellitus status' with the categories (1) diabetes or (2) no diabetes.

Figure 2 shows the median percentage of agreement for variables by domain and the interquartile range (IQR) indicating the variation in agreement rather than only looking at perfect agreement: patient 63.6% [IQR=43.2-77.3%], prior bariatric history 45.5% [IQR=20.5-68.2%], screening 36.4% [IQR=18.2-63.6%], operation 54.5% [IQR=18.2-81.8%], complication 54.5% [IQR=27.3-72.7%] and follow-up 27.3% [IQR=13.6-63.6%].

A summary of the variables with a 'perfect', 'substantial' and 'moderate' agreement are shown in Table 2. A total of 28 (11.2%) variables have substantial agreement (75%-99.9%) and a total of 59 (23.6%) variables have moderate agreement (50% - 74.9%) across registries. Taken together, this means that from the total of 250 variables in all registries, 138 (55.2%) variables had less than 50% agreement across registries.

Figure 3. shows how these variables with perfect, substantial and moderate agreement are distributed across the 6 domains. The domains patient, operation and complication have 10(62.5%), 27(52.9%), and 32(56.1%) variables, respectively, with more than 50% agreement across registries.

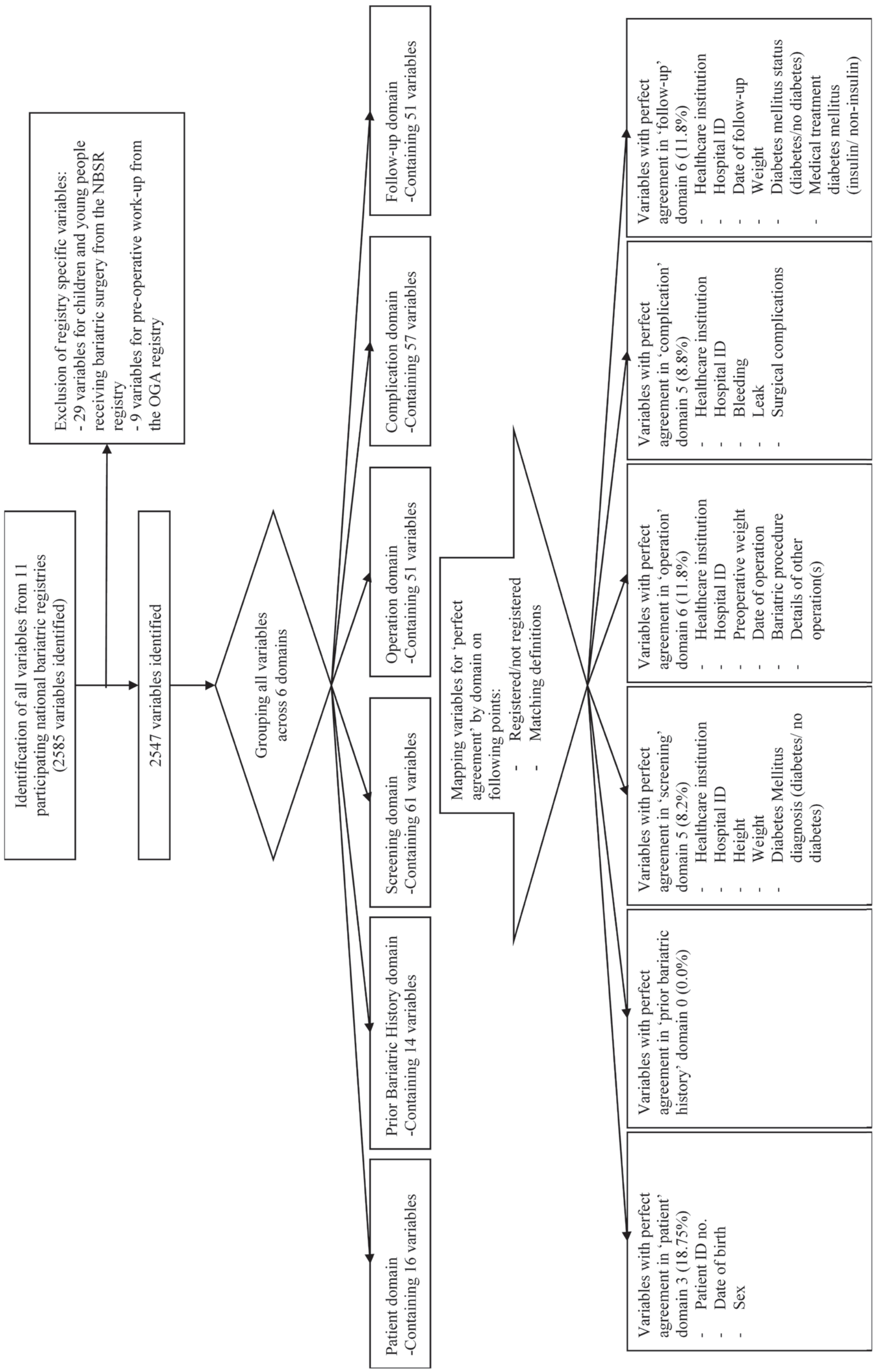

Figure 1. Flowchart for identifying perfect agreement in variables across 11 national bariatric registries

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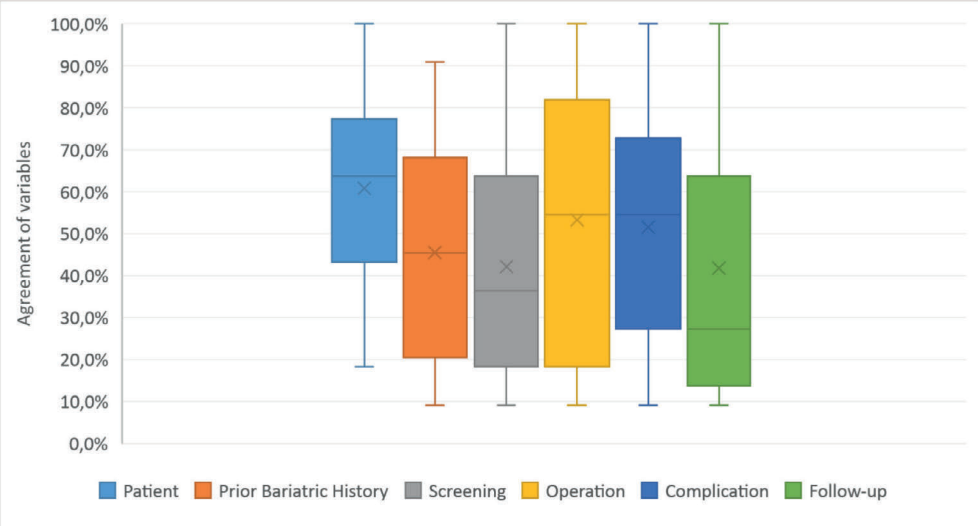
Figure 2. Boxplot for the median agreement rates of variables by domain



Boxplot showing the median percentage of agreement for variables by domain and the interquartile range (IQR) indicating the variation in agreement.

Table 2. Summary of variables divided into perfect-, substantial- and moderate agreement

Variables	Perfect agreement 100%	Substantial agreement 75% - 99.9%	Moderate agreement 50% - 74.99%
Patient characteristics			
Nationality			X
Patient ID no	X		
Healthcare institution			X
Hospital ID		X	
Initials			X
Prefix			X
Surname			X
Date of birth	X		
Sex	X		
Date of Death			X
Prior Bariatric History			
Hospital ID			X
Prior metabolic or bariatric procedure		X	
Prior type of gastric bypass			X
Prior type of malabsorptive procedure			X
Prior type of other bariatric procedure			X

Table 2. Continued

Variables	Perfect agreement 100%	Substantial agreement 75% - 99.9%	Moderate agreement 50% - 74.99%
Screening			
Healthcare Institution	X		
Hospital ID	X		
Date of consultancy		X	
Height	X		
Weight	X		
Hypertension (diagnosis)		X	
Diabetes mellitus (diagnosis)	X		
Details diabetes mellitus		X	
HbA1c (mmol/mol)			X
Dyslipidemia			X
GERD (diagnosis)			X
OSAS (diagnosis)		X	
Osteoarthritis (diagnosis)		X	
Peripheral vascular disease/ aneurysm aorta			X
Liver disease			X
Mobility			X
Increased risk Pulmonary Embolism			X
PCOS			X
Depression			X
Smoking			X
Operation			
Healthcare Institution	X		
Hospital ID	X		
Preoperative Weight	X		
ASA classification			X
Date of operation	X		
Surgical procedure (primary/two-stage/revision)		X	
Operative approach		X	
Bariatric procedure	X		
Surgeon ID			X
Date of discharge			X
Type of technique gastric band		X	
Fixation gastric band			X
Type malabsorptive		X	
Type gastric bypass		X	
Biliopancreatic limb length			X
Alimentary limb length			X
Closure Petersen's space		X	
Closure hernia jejuno-jejunostomy		X	
Type gastric band (brand)			X
Common limb length		X	

Table 2. Continued

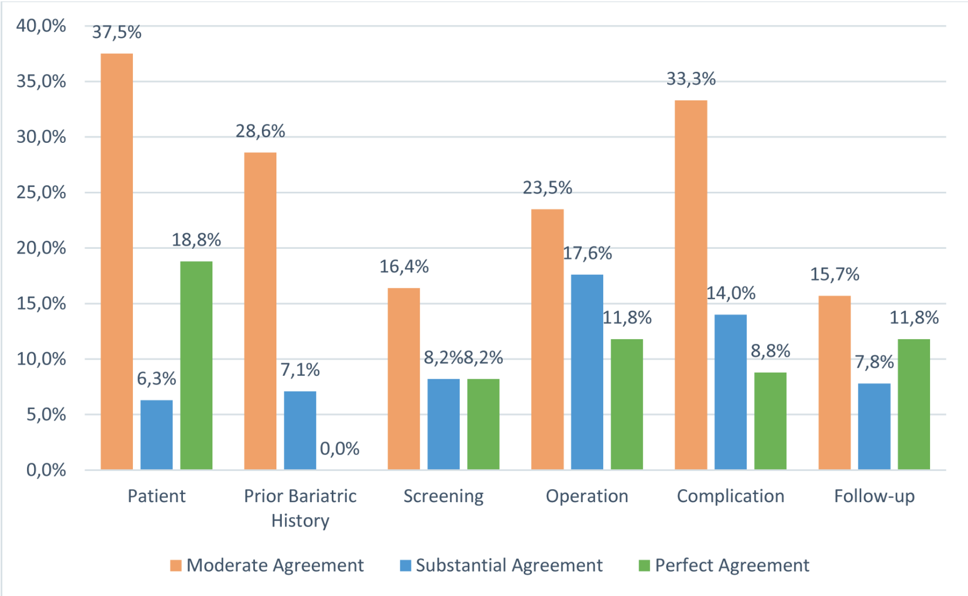
Variables	Perfect agreement 100%	Substantial agreement 75% - 99.9%	Moderate agreement 50% - 74.99%
Operation continued			
Bougie size		X	
Technique of pouch excision			X
Distance from pylorus			X
Details of other operation(s)	X		
Combined operation			X
Suture material			X
Ante-colic/retro-colic			X
Complication			
Healthcare Institution	X		
Hospital ID	X		
Date of complication		X	
Period the complication occurred		X	
Date of re-admission			X
Date of discharge after re-admission			X
Type of (re)intervention			X
Operative approach (re)intervention			X
Patient status at discharge		X	
Gastrointestinal perforation		X	
Bleeding	X		
Splenic injury			X
Source of bleeding			X
Surgical complications	X		
Leak	X		
Post-operative complications		X	
Gastric complication			X
Stricture			X
Electrolyte disorder			X
Hepatobiliary problems			X
CBD stones			X
Band problems			X
Pouch dilatation/band slippage			X
Band erosion			X
Port/band infection			X
Other complications (including cardiac, pulmonary and other)		X	
Incisional hernia		X	
Intestinal obstruction		X	
Petersen's hernia			X
Malnutrition/enteral feeding			X
Post-op vomiting/nausea			X
Patient discharge to (home/revalidation centre)			X

Table 2. Continued

Variables	Perfect agreement 100%	Substantial agreement 75% - 99.9%	Moderate agreement 50% - 74.99%
Follow-up			
Healthcare Institution	X		
Hospital ID	X		
Date of follow-up	X		
Weight	X		
Hypertension status		X	
Medical treatment hypertension			X
Diabetes mellitus status	X		
HbA1c (mmol/mol)			X
Medical treatment diabetes mellitus	X		
Dyslipidemia status		X	
GERD status		X	
Medical treatment GERD			X
OSAS status		X	
Medical treatment OSAS			X
Osteoarthritis			X
Medical treatment osteoarthritis			X
Clinical malnutrition			X
Vitamins and micro-elements intake			X

ID, Identity Document; HbA1c, Hemoglobin A1c; GERD, Gastroesophageal Reflux Disease; OSAS, Obstructive Sleep Apnea Syndrome;, PCOS, Polycystic Ovary Syndrome; ASA, American society of Anesthesiologists; CBD stones, common bile duct stones.
Adolescent section of the NBSR and the pre-operative work-up section of OGA are not included in the list of common data elements due to registration specific variables.

Figure 3. Percentage of variables with a Moderate-, Substantial- or Perfect agreement by domain.



Moderate agreement is 50%-74.9% consensus, Substantial agreement is 75% - 99.9% consensus, and Perfect agreement is 100% consensus.

Discussion

The present study aimed to assess the concordance in variables across participating national bariatric surgery registries. Even though participating registries in this study include a larger number of patients (n=554.599) than individual registries, data can only be pooled as part of a collaborative study if there is a common language on collected data between national registries. To our knowledge, this is the first comparison of variables between national bariatric surgery registries, showing that there is only limited 'perfect agreement' of variables. Suggesting that there is a need for better alignment and uniformity in collecting variables across national bariatric surgery registries.

Although this is the first comparison of variables between national registries, several limitations should be noted. First, not all national registries participated, meaning that the current agreement percentage could be an overestimation. Furthermore, not all participating registries had specific definitions for all variables available, resulting in some variables assessed to the best of our knowledge with the documents at hand. Additionally, there were registration specific variables such as the adolescent-specific variables of the UK registration and the pre-operative work-up variables in the Austria registration, which we did not include because the individual registries were the only ones collecting them. Including these domains would have led to even more discrepancy in the agreement between registrations and further support our findings of limited concordance. Finally, this study only looked at the concordance of variables currently collected in national registries, however this does not reflect importance, meaning that other (not yet reported) variables may be considered essential in decisions towards a bariatric common data element (CDE) set.

The BARIACT project has proposed a core outcome set including nine outcomes.[14] However, the core outcome set is developed in the UK, making it specific for the UK population rather than internationally applicable. Furthermore, it only contains outcomes and does not contain all essential variables across all domains. Our study compares on an international level and shows that perfect agreement on variables occurs across all six domains, showing the importance of variables such as patient characteristics, and operation details.

To assess the degree of concordance for this study, we grouped the variables that measure the same overall concept. Brethauer et al. recommend using standardized outcome reporting and encounter challenges when reporting, e.g. 'complete diabetes remission'.[15] Whereas the ASMBS recommends a lower HbA1c level <6% without the use of glucose-lowering medication[15], the International Diabetes Federation (IDF) target is HbA1c <7% with or without medication.[16,17] Our study also encountered these challenges, showing that there is a need to not only register these variables but also to define them identically.

Future Perspectives

This study provides an overview of the currently collected variables from participating countries, and it could serve as a stepping stone in developing a CDE set on a broader scale. IFSO has ongoing efforts to compare and improve outcomes on an international level and developed a data dictionary set as the minimum to be reported in all bariatric registries. However, the outcomes presented in the IFSO global registry report 2019 show a lack of uniformity in gathered data points among contributing registries. One essential step in developing a CDE set is to assemble a task force[13,18], such as the Registry Committee which has been commissioned to develop a core outcome set.[8] They have the ideal platform to facilitate, develop, share, and recommend using a CDE set that can be implemented internationally as the minimum set to be reported to encourage international collaborative investigations.

Conclusion

There is only limited uniform agreement in variables across eleven of the 18 national bariatric surgery registries, emphasizing the ongoing inconsistency of reported outcomes and other characteristics in bariatric literature. Improving consistency by developing and implementing a common data element set in national registries will facilitate future international collaborative studies and international benchmarking.

Recommendations:

- Need for consistency in bariatric literature by reporting standardized outcomes using common data elements in national registries
- International implementation of a common data element set in existing and developing national bariatric surgery registries for future nested registry trials, international collaborations, international benchmarking and large population based studies
- Future work is needed for further alignment and uniformity in collected variables across registries with identical definition(s)

Disclaimer

The authors cannot take responsibility for variables misplaced due to the lack of a dictionary with specific definitions for variables.

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Supplementary table 1. Summary of all the 250 variables divided into separate domains

	Variables
Patient characteristics	
	Nationality
	Patient ID no
	Healthcare institution
	Hospital ID
	Initials
	Prefix
	Surname
	Date of birth
	Sex
	Date of Death
	Education status
	Employment status
	Phone number
	Funding
	Referral
	Ethnicity
Prior Bariatric History	
	Hospital ID
	Healthcare institution of prior bariatric procedure
	Prior existing comorbidities
	Date of prior bariatric procedure
	Prior metabolic or bariatric procedure
	Prior type of gastric bypass
	Prior type of malabsorptive procedure
	Prior type of other bariatric procedure
	Prior gastric band removal
	Prior gastric band revision
	Performed in bariatric healthcare centre
	Performed in other healthcare centre
	Prior gastric balloon
	Date of prior comorbidities
Screening	
	Healthcare Institution
	Hospital ID
	Date of consultancy
	Height
	Weight
	Highest measured weight
	Waist circumference
	Body Mass Index (BMI)
	Hypertension (diagnosis)
	Diabetes mellitus (diagnosis)

Supplementary table 1. Continued

	Variables
Screening continued	
	Details diabetes mellitus
	HbA1c (mmol/mol)
	Dyslipidemia
	LDL-cholesterol (mmol/L)
	HDL-cholesterol (mmol/L)
	Triglycerides (mmol/L)
	LDL/HDL-ratio
	GERD (diagnosis)
	OSAS (diagnosis)
	Osteoarthritis (diagnosis)
	Obesity Surgery Mortality Risk Score (OS-MRS)
	Myocardial infarction
	Congestive heart failure
	Peripheral vascular disease/ aneurysm aorta
	CVA/TIA
	Dementia
	Chronic pulmonary disease
	Gastrointestinal ulcer disease
	Liver disease
	Para-/hemiplegia
	Renal disease
	Malignancy (excluding cutaneous SCC, BCC)
	HIV/AIDS
	Connective tissue disease (including rheumatoid disease)
	Asthma
	Mobility
	Increased risk Pulmonary Embolism
	PCOS
	Depression
	Operation decision date
	Renal transplant
	Liver transplant
	Referral date
	Diabetes duration
	Creatinine
	PTH
	Vitamin D status
	Blood pressure (diastolic and systolic)
	Diarrhea
	Incontinence
	Menstrual cycle
	Panniculus

Supplementary table 1. Continued

	Variables
Screening continued	
	Other comorbidities
	Smoking
	Social activities
	Previous weight loss program
	Abdominal apronectomy
	Pre-operative endoscopy
	Abdominal ultrasound
	Helicobacter pylori
	pH measurement
Operation	
	Healthcare Institution
	Hospital ID
	Preoperative Weight
	ASA classification
	Date of operation
	Surgical procedure (primary/two-stage/revision)
	Main reason revision
	Type of revisional surgery (conversion/revision/undo)
	Type of revisional bariatric procedure
	Operative approach
	Bariatric procedure
	Surgeon ID
	First assistant ID
	Date of discharge
	Type of technique gastric band
	Dissection for band positioning
	Fixation gastric band
	Type malabsorptive
	Type gastric bypass
	Method measuring bowel length
	Biliopancreatic limb length
	Alimentary limb length
	Closure Petersen's space
	Closure hernia jejuno-jejunostomy
	Type gastric band (brand)
	Circumference ring of gastric band
	Common limb length
	Bougie size
	Technique of pouch excision
	Other techniques for pouch excision
	Distance from pylorus
	Pouch size

Supplementary table 1. Continued

	Variables
Operation continued	
	Details of other operation(s)
	Operation record status (incomplete/complete)
	Age at operation
	Aborted procedure
	Planned or unplanned revision
	Pre-operative Body Mass Index (BMI)
	Type inserted instrument
	Brand instrument
	Model instrument
	Producer instrument
	Serial number instrument
	Drainage
	Provocative test for leakage
	Time incision
	Time end of procedure
	Combined operation
	Suture material
	Ante-colic/retro-colic
	Blood loss
Complication	
	Healthcare Institution
	Hospital ID
	Date of complication
	Period the complication occurred
	Date of re-admission
	Date of discharge after re-admission
	Type of (re)intervention
	Clavien Dindo classification of surgical complications
	Operative approach (re)intervention
	Anesthesia
	ICU-admission
	Date ICU admission
	Date of discharge ICU
	Patient status at discharge
	Gastrointestinal perforation
	Bleeding
	Splenic injury
	Liver injury
	Source of bleeding
	Surgical complications
	Leak

Supplementary table 1. Continued

	Variables
Complication continued	
	Post-operative complications
	Esophageal complications
	Esophageal dilatation
	Esophageal dysmotility
	Gastric complication
	Gastric ulcer
	Marginal ulcer
	Stricture
	Delayed gastric emptying
	Motility disorder
	Metabolic disorder
	Early dumping
	Late dumping
	Other deficiencies
	Secondary hyperparathyroidism
	Peripheral neuropathy
	Electrolyte disorder
	Hepatobiliary problems
	Liver failure
	CBD stones
	Band problems
	Pouch dilatation/band slippage
	Band erosion
	Port/band infection
	Motility disorder due to gastric band
	Other complications (including cardiac, pulmonary and other)
	Incisional hernia
	Intestinal obstruction
	Intolerance of bariatric procedure
	Petersen's hernia
	Extended admission
	Malnutrition/enteral feeding
	Post-op vomiting/nausea
	Other procedure related complications
	Hospital discharge destination (home/revalidation centre)
	Acute renal failure
Follow-up	
	Healthcare institution
	Hospital ID
	Date of follow-up
	Weight

Supplementary table 1. Continued

	Variables
Follow-up continued	
	Hypertension status
	Medical treatment hypertension
	Diabetes mellitus status
	HbA1c (mmol/mol)
	Medical treatment diabetes mellitus
	Dyslipidemia status
	Medical treatment dyslipidemia
	GERD status
	Medical treatment GERD
	OSAS status
	Medical treatment OSAS
	Osteoarthritis
	Medical treatment osteoarthritis
	Diarrhea
	Depression
	Abdominal pain for no clinical reason
	How was follow-up conducted (hospital or by phone)
	Blood tests
	Clinical malnutrition
	Education status
	Asthma
	Mobility
	PCOS
	Urinary incontinence
	Menstrual function
	Pregnancy
	Estimated date of delivery
	Follow-up record status
	Follow-up period
	Patient called for follow-up
	Contact details patient
	Lost to follow-up
	Lost to follow-up date
	Self-reported weight
	Body Mass Index (BMI)
	Excess weight
	Ideal weight
	Lost weight
	Excess Weight Loss %
	Total Weight Loss %
	Email to surgeon

Supplementary table 1. Continued

	Variables
Follow-up continued	
	Age at primary operation (in case unknown at primary registration)
	Hunger feeling
	Vitamins and microelements intake
	Abdominal apron
	Endoscopy
	Abdominal ultrasound

ID, Identity Document; BMI, Body Mass Index; HbA1c, Hemoglobin A1c; LDL, Low-Density Lipoprotein; HDL, High-Density Lipoprotein; GERD, Gastroesophageal Reflux Disease; OSAS, Obstructive Sleep Apnea Syndrome; CVA, Cerebrovascular Accident; TIA, Transient Ischemic Attack; SCC, Squamous Cell Carcinoma; BCC, Basal Cell Carcinoma; HIV, Human Immunodeficiency Virus; AIDS, Acquired Immune Deficiency Syndrome; PCOS, Polycystic Ovary Syndrome; PTH, Parathyroid Hormone; pH, Pondus Hydrogenii; ASA, American society of Anesthesiologists; ICU, Intensive Care Unit; CBD stones, common bile duct stones.
Adolescent section of the NBSR and the pre-operative work-up section of OGA are not included in the list of common data elements due to registration specific variables.

7

Predicting serious complication risks after bariatric surgery: external validation of the Michigan Bariatric Surgery Collaborative risk prediction model using the Dutch Audit for Treatment of Obesity

Erman O. Akpinar, Amir A. Ghaferi, Ronald S.L. Liem,
Simon W. Nienhuijs, Aaron J. Bonham, Jan Willem M. Greve,
Perla J. Marang-van de Mheen, and on behalf of the Dutch Audit
for Treatment of Obesity Research Group

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Abstract

Background Risk prediction tools can support doctor-patient (shared) decision-making in clinical practice by providing information on complication risks for different types of bariatric surgery. However, external validation is imperative to ensure the generalizability of predictions in a new patient population.

Objective To perform an external validation of the risk prediction model for serious complications from the Michigan Bariatric Surgery Collaborative (MBSC) for Dutch bariatric patients using the nationwide Dutch Audit for Treatment of Obesity (DATO).

Setting Population-based study, including all 18 hospitals performing bariatric surgery in the Netherlands.

Methods All patients registered in the DATO undergoing bariatric surgery between 2015 and 2020 were included as the validation cohort. Serious complications included, among others, abdominal abscess, bowel obstruction, leak, and bleeding. Three risk prediction models were validated: 1) the original MBSC model from 2011; 2) the original MBSC model including the same variables but updated to more recent patients (2015-2020); 3) the current MBSC model. The following predictors from the MBSC model were available in the DATO: age, sex, procedure type, cardiovascular disease, and pulmonary disease. Model performance was determined using the Area Under the Curve (AUC) to assess discrimination (i.e., the ability to distinguish patients with events from those without events) and a graphical plot to assess calibration (i.e., whether the predicted absolute risk for patients was similar to the observed prevalence of the outcome).

Results The DATO validation cohort included 51,291 patients. Overall, 986 (1.92%) patients experienced serious complications. The original MBSC model, which was extended with the predictors 'GERD (yes/no),' OSAS (yes/no),' hypertension (yes/no), and renal disease (yes/no),' showed the best validation results. This model had a good calibration and AUC of 0.602, compared with an AUC of 0.65 and moderate-good calibration in the Michigan model.

Conclusion The DATO prediction model has a good calibration but moderate discrimination. To be used in clinical practice, good calibration is essential to accurately predict individual risks in a real-world setting. Therefore, this model could provide valuable information for bariatric surgeons as part of shared decision-making in daily practice.

Introduction

Clinicians increasingly use risk prediction tools to accurately estimate an individual's risk profile to guide their doctor-patient (shared) decision-making and inform patients about the risks of surgery as we move to clinical care offering individualized treatments, care, and monitoring.[1–3] For instance, a recent systematic review reported on 16 models developed to predict diabetes remission after bariatric surgery,[4] including 11 scoring systems and 5 logistic regression models. Clinicians caring for patients in other populations may use e.g. these scoring system, provided that the prediction model is correct for that patient population i.e. it needs external validation, as otherwise clinical decisions based on these (incorrect) prediction models may negatively influence patient outcomes. The above systematic review showed for instance that the ABCD score was validated in 9 studies and the Diabetes Remission score in 6 studies, showing different results depending on the population.

The Michigan Bariatric Surgery Collaborative (MBSC) developed a prediction model for serious postoperative complications after bariatric surgery within 30 days.[5] The MBSC model reported a moderate ability to discriminate between patients with and without serious complications (c-statistic 0.66) and good calibration, meaning that the model does not systematically over- or underestimate absolute complication risks.[6] When calibration is good, estimates from such prediction models can support shared decision-making by informing patients of their individualized risks of a serious complication. When discrimination is good, the estimates can also be used to support treatment decision making by identifying patients at high risk for serious complications who may benefit from less invasive treatment options.

Most prediction models are used in the setting in which they were developed and few are externally validated.[7] However, it is known that prediction models often perform less well outside the setting where they were developed, which can lead to systematically over-or underestimating risks,[8] particularly if the patient population is rather different, which may occur between countries or over time. For the MBSC model, it is unknown whether it is generalizable to other populations. Hence, external validation is needed to evaluate the performance of the model in a new setting before being used in clinical practice.[9,10] The benefit of externally validating a model is that it allows prior predictive data knowledge to be retained rather than discarding it, making the model more generalizable across new settings.[11] The ultimate predictive model would be a universal one that is highly accurate and widely applicable across all geographical settings.

In this context, a generalizable risk prediction model would be an important addition for bariatric surgeons to support their shared decision making in daily practice. Therefore, this study aims to perform an external validation of the MBSC risk prediction model in the Dutch population and assess its performance among bariatric patients treated in the Netherlands.

METHODS

Study Sample

Data were derived from the Dutch Audit for Treatment of Obesity (DATO). This audit has a nationwide coverage and has been mandatory since 2015, so that it reflects real-world practice among patients undergoing bariatric surgery in the Netherlands. The DATO collects detailed information on patient, comorbidity, treatment, follow-up, short term and long term outcome characteristics for patients undergoing bariatric surgery. Details of the DATO regarding data collection, quality and validation have been described elsewhere.[12]

The DATO's scientific committee unanimously approved the use of the data for this study (reference number DATO-2022-142) and was carried out in accordance to the regulations of the Dutch Institute for Clinical Auditing. No informed consent was required as this is an opt-out quality registry and is performed in accordance with the ethical standards of Dutch law.

A population-based validation cohort was created within the DATO, including all patients undergoing primary bariatric surgery in the Netherlands from 1 January 2015 until 31 December 2020. Similar to the original MBSC model, patients undergoing revisional bariatric surgery were excluded due to considerable heterogeneity in this group and associated increased risk for postoperative complications. Minimal data requirements for analysis were information on age, sex, type of procedure and short-term (≤30 days) complications.

Outcome

The DATO registers the same serious complications as the MBSC, i.e. complications categorized by the MBSC as grade 2 or 3.[5] Grade 2 complications include abdominal abscess, bowel obstruction, leak, bleeding, wound infection or dehiscence, respiratory failure, renal failure, venous thromboembolism, and band related problems requiring reoperation. Grade 3 complications include myocardial infarction or cardiac arrest, renal failure requiring long-term dialysis, respiratory failure requiring >7 days mechanical ventilation or tracheostomy, and death.

External validation approach

To validate and update the risk prediction model in a new setting, the following three steps were taken. First, we validated the original MBSC model (as published in 2011) for the DATO population. Secondly, the original MBSC model was updated using the same predictors but including patients undergoing bariatric surgery between 2015 and 2020. This was done as the original model was developed including patients undergoing bariatric surgery between

2006 and 2010, and outcomes may have improved over time given new scientific knowledge and improved surgical strategies. Subsequently, this updated MBSC model was validated for the DATO population. Finally, the current MBSC prediction model including potentially different predictors and patients undergoing bariatric surgery between 2015 and 2020, was validated for the DATO population.

Predictors

The predictors used in the original MBSC risk prediction model from 2011 remained the same for the updated MBSC model including patients undergoing bariatric surgery between 2015 and 2020.[5] The current MBSC model includes 9 predictors of which age, sex, ethnicity, and procedure type are forced into the model. The other predictors were added based on significantly improving the model: gastroesophageal reflux disease (GERD), cardiovascular disease (coronary artery disease, dysrhythmia, peripheral vascular disease, stroke, hypertension, hyperlipidemia), prior venous thromboembolism (VTE), mobility limitation (requiring ambulation aids, non-ambulatory, bed bound), and private insurance.[13] The predictors ethnicity, VTE, health insurance and mobility limitation are not registered in DATO and were therefore not included in the external validation. All the predictors registered in the DATO were coded according to the definitions and criteria as stated in the original publication of the MBSC model.[5]

Statistical analysis

Missing values

Missing data for predictor variables were imputed with multiple imputation techniques using all other available information of the patients, to prevent bias due to missing data and loss of statistical power. A total of 5 complete datasets with 5 iterations were derived and averaged using the mice package in R studio.

Predictive performance

Discrimination and calibration are assessed to study the performance of the model. Discrimination refers to the ability of the model to distinguish between patients with and without a serious postoperative complication (i.e. patients with a serious complication have higher predicted risks than without complications), quantified by the c-statistic or the Area Under the Curve (AUC). An AUC below 0.6 was defined as rather poor discrimination, above 0.6 as moderate discrimination, and above 0.7, and 0.8 as good and excellent discrimination respectively.[14] The calibration is evaluated using a visual calibration plot to assess how well the absolute predicted risk corresponds to the observed risk within subgroups of patients in daily practice. A calibration slope of 1 denotes a good fit between the observed and predicted risks, and a calibration slope above 1 or below 1 denotes miscalibration i.e., respectively systematic over- or underestimation of the predicted risk within subgroups of patients. The Brier score was used as a measure of overall model fit, with a significant score indicating a good fit.

Validation and updating methods

Several updating methods have been described for redeveloping a prediction model in case they perform poorly in a new setting. These consist of logistic calibration, re-estimating coefficients, and selectively adding predictors. These model revision and extension methods described by Steyerberg et al. were applied to update the models in the external validation set in case of poor initial performance.[15] All external validations and updating methods are graphically plotted using the val.prob function of the 'rms' package using R studio version 4.0.2

Sensitivity analysis

A new risk prediction model within the DATO population was developed and internally validated, including all patients between 2015 and 2020, and its performance was compared with the results from the external validation. All baseline characteristics showing a significant association ($p<0.1$) with the outcome serious complications in univariate logistic regression analysis were included in the multivariable model. Multivariable logistic regression modeling was used to identify significant predictors ($p<0.157$) using a stepwise backwards selection. Bootstrapping with 250 samples was conducted for internal validation of the model and to correct for optimism.[6,15] Diabetes was forced into the model as a clinically relevant predictor.

Results

A total of 51,219 patients underwent primary bariatric surgery in the Netherlands between 2015 and 2020 and were included in the validation cohort. Overall, 986 (1.92%) patients experienced serious complications. Patient characteristics are shown in Table 1 and compared to the patients included in the original MBSC model, showing a rather different case-mix. Patients from the DATO on average were younger, had a lower BMI, and more often had coronary artery diseases. Furthermore, patients from the DATO less often had type 2 diabetes (T2D), hypertension, dyslipidemia, GERD, obstructive sleep apnea syndrome (OSAS), and musculoskeletal pain. In addition, patients in the DATO population more often underwent a RYGB or SG rather than adjustable gastric band compared with the MBSC population.

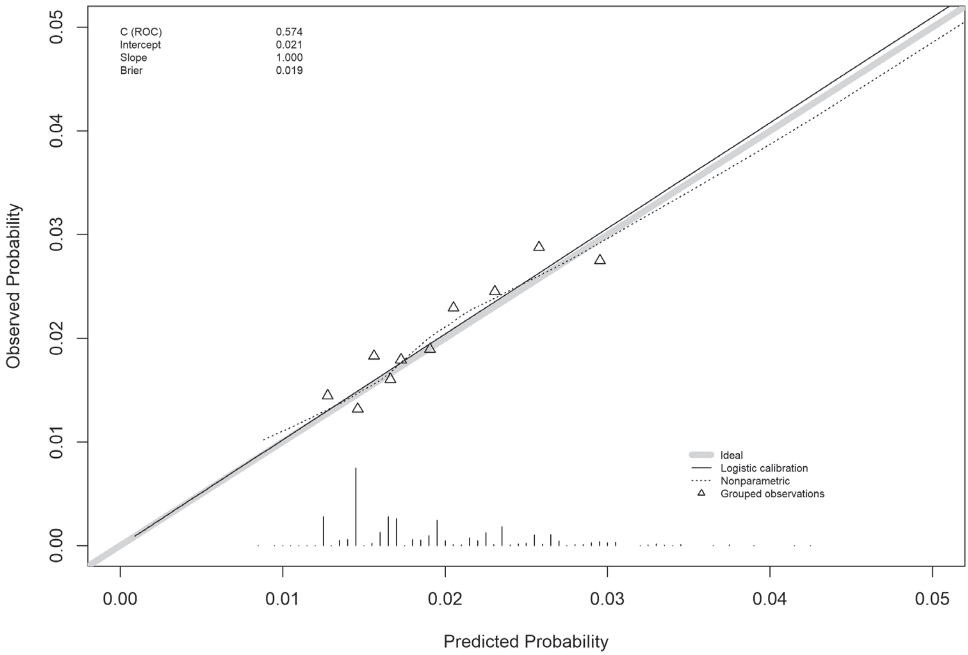
Table 1. Patient Characteristics from the DATO between 2015 and 2020

Patient Characteristics	DATO 2015-2020	MBSC^ 2006-2010
	N= 51,291	N=25,469
Sex, No. (%)		
Male	10801 (21.1)	5525 (21.7)
Female	40490 (78.9)	19944 (78.3)
Age (y), mean (SD)	44.0 (11.62)	45.7 (11.4)
BMI, mean (SD), kg/m^2	42.85 (5.26)	48.0 (8.5)
Procedure type, No. (%)		
Open RYGB	39 (0.1)	1092 (4.3)
RYGB	37955 (74.0)	13758 (54)
Adjustable gastric band	111 (0.2)	8015 (31.5)
Sleeve Gastrectomy	13180 (25.7)	2279 (8.9)
BPD/DS	6 (0.0)	325 (1.3)
T2D, No. (%)	9795 (19.1)	8540 (33.7)
Hypertension, No. (%)	17536 (34.2)	13544 (54.9)
Dyslipidemia, No. (%)	10161 (19.8)	12774 (50.2)
GERD, No. (%)	8007 (15.6)	12315 (48.4)
OSAS, No. (%)	9139 (17.8)	11374 (44.8)
Musculoskeletal pain, No. (%)	22302 (43.5)	19714 (77.4)
Pulmonary disease, No. (%)	10249 (20.0)	6588 (25.9)
Coronary artery disease, No. (%)	22351 (43.6)	1369 (5.4)
Previous venous thromboembolism, No. (%)	-	979 (3.8)
Any smoking history, No. (%)	-	9919 (39.0)
Mobility limitations, No. (%)	-	1360 (5.3)
Private insurance, No. (%)	-	18333 (72.0)

^=Characteristics of patients undergoing bariatric surgery in Michigan between 2006 and 2010 from Finks et al.
DATO, Dutch Audit for Treatment of Obesity; MBSC, Michigan Bariatric Surgery Collaborative; RYGB, Roux-en-Y Gastric Bypass; BPD, biliopancreatic diversion; DS, duodenal switch; BMI, Body Mass Index; T2D, type 2 diabetes; GERD, Gastro-esophageal Reflux Disease; OSAS, Obstructive Sleep Apnea Syndrome.

Figure 1. shows the calibration plot for the external validation of the original MBSC model for the DATO population. The coefficient for the variable ‘age’ was significantly different in the DATO population and was updated as recommended.[15] The model was extended by predictors that are significantly associated with serious complications in the DATO population: gastro esophageal reflux disease (GERD) (no GERD/ GERD with or without medication) and obstructive sleep apnea syndrome (OSAS) (no OSAS/ OSAS with or without medication). This model (Figure 1.) shows good calibration, as shown by the slope of 1.00 which indicates that predicted risk aligns good with the observed risk. However, the model had rather poor discrimination as shown by the AUC of 0.574. The Brier score was significant which indicates a good overall model fit.

Figure 1. Calibration plot: external validation of the MBSC model from Finks et al. (2011)

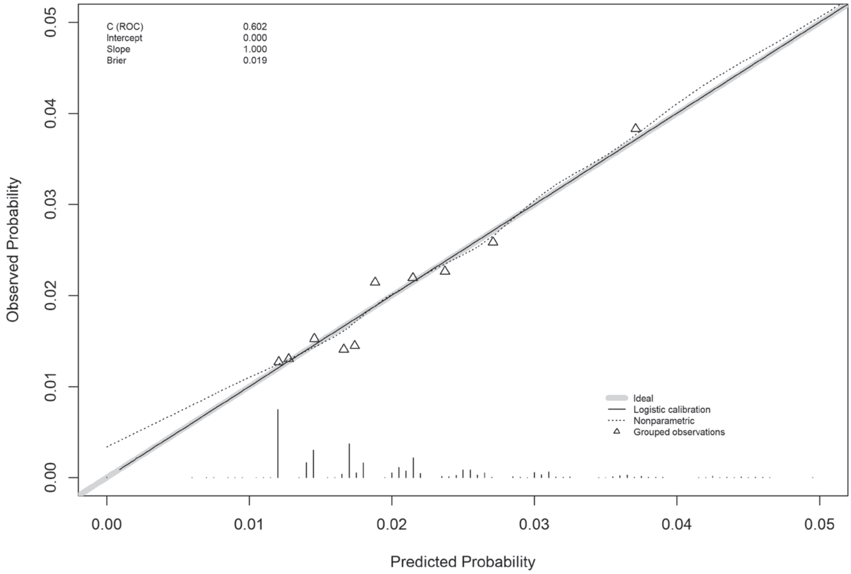


C (ROC) is the AUC of the model which is 0.574. The calibration slope is 1.0. The Brier score is significant which denotes a good model fit. MBSC, Michigan Bariatric Surgery Collaborative

The updated MBSC model including patients undergoing surgery between 2015 and 2020 again shows a good calibration with a slope of 1.00 and moderate discrimination shown by the AUC of 0.602 Figure 2. The coefficients for ‘age’ and ‘procedure type’ were significantly different in the DATO validation cohort and thus were updated for the new geographical setting. Additionally, the model was extended with the predictors ‘GERD’, ‘OSAS’, ‘hypertension’ (no hypertension/ hypertension with or without medication), and ‘renal disease’ (no renal disease/ chronic renal insufficiency, renal failure requiring dialysis, nephrotic syndrome, and other renal diseases). These predictors were significantly associated with the occurrence of serious complications in the DATO cohort. The Brier score showed good overall model fit.

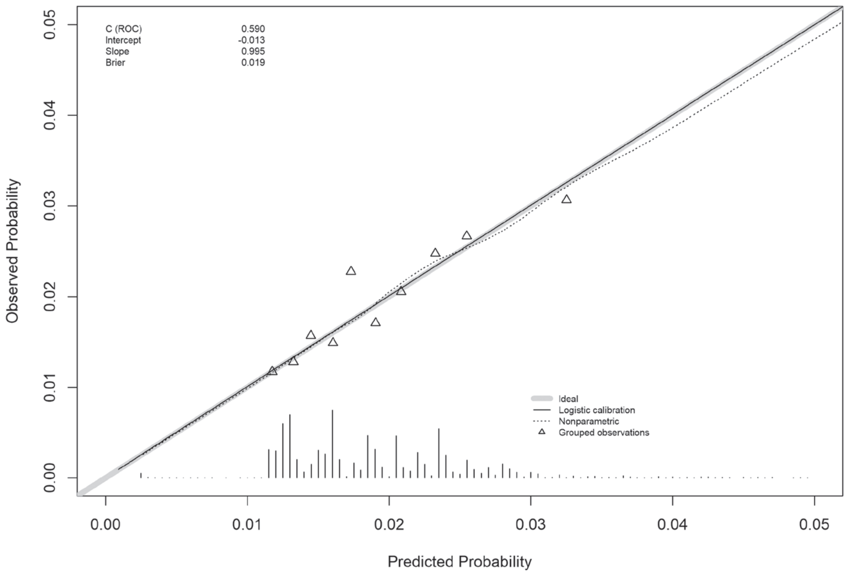
The current MBSC model has a calibration slope of 0.99 (Figure 3) with a rather poor discrimination shown by the AUC of 0.590. The coefficient for ‘age’ was significantly different in the DATO population and thus updated. This model was also extended with the predictors ‘GERD’, ‘OSAS’, ‘hypertension’ and ‘renal disease’. The Brier score showed a good overall model fit.

Figure 2. Calibration plot: external validation of the MBSC model from Finks et al. (2011) with a new population from 2015-2020



C (ROC) is the AUC of the model which is 0.602. The calibration slope is 1.0. The Brier score is significant which denotes a good model fit. MBSC, Michigan Bariatric Surgery Collaborative

Figure 3. Calibration plot: external validation of a newly fitted prediction model with MBSC data from 2015-2020



C (ROC) is the AUC of the model which is 0.590. The calibration slope is 0.995. The Brier score is significant which denotes a good model fit. MBSC, Michigan Bariatric Surgery Collaborative

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Table 2 shows the regression coefficients for all predictors included in the three MBSC models, as well as the coefficients for the best performing DATO model, i.e. the external validation of the updated MBSC model.

Table 2. Regression coefficients for predictors of the original MBSC prediction Model, the updated MBSC prediction model, current MBSC model, and external validated DATO risk prediction Model

Predictor	Original MBSC^	Updated MBSC*	Current MBSC~	Best performing DATO Model**
Intercept	-5.12	-2.0677	-2.8827	-3.8707
Age (yr) >50	0.3225	0.1288	-	0.4060
Age (yr) <20	-	-	Ref.	-
20 – 29	-	-	0.5948	-
30 – 39	-	-	0.808	-
40 – 49	-	-	0.9579	-
50 – 59	-	-	0.9173	-
≥60	-	-	0.9806	-
Male gender	0.2321	0.2335	0.2841	0.1669
Procedure type	-			
Adjustable gastric band	Ref.	-2.7925	-2.3007	-1.5805
Laparoscopic RYGB	1.2759	-1.6749	-1.6331	-0.9366
Sleeve Gastrectomy	0.8988	-2.5589	-2.4741	-0.5744
Open RYGB	1.2556	Ref.	Ref.	Ref.
BPD/Duodenal switch	2.2702	-1.0542	-1.4858	-11.9429
SADI-S/Gastric balloon	-	-11.3539	-11.1019	-11.6160
Ethnicity (White)	-	-	Ref.	-
Black	-	-	0.2192	-
Hispanic	-	-	0.0892	-
Other	-	-	-0.1149	-
Coronary artery disease	0.4260	0.2498	0.184	0.0043
VTE	0.6410	0.7172	0.7677	-
Pulmonary disease	0.3150	0.1353	-	0.0023
Smoking history	0.1797	0.0347	-	-
GERD	-	-	0.2075	0.1978
OSAS	-	-	-	0.1521
Hypertension	-	-	-	0.1845
Renal disease	-	-	-	0.4041
Mobility limitations	0.4784	0.474	0.4276	-
Private insurance	-	-	-0.2962	-
AUC	0.66	0.65	0.655	0.602

DATO = Dutch Audit for Treatment of Obesity; MBSC = Michigan Bariatric Surgery Collaborative; RYGB = Roux-en-y gastric bypass; BPD = biliopancreatic diversion; SADI-S = Single anastomosis Duodeno- ileal Bypass with Sleeve gastrectomy; VTE = venous thromboembolism; GERD = gastro esophageal reflux disease; OSAS = obstructive sleep apnea syndrome; AUC = Area Under the Curve.
^ Original MBSC model predicting serious postoperative complications patients between 2006 and 2010
* Updated MBSC model including patients undergoing bariatric surgery between 2015 and 2020
~ Current MBSC model including patients undergoing bariatric surgery between 2015 and 2020
** External validation of the DATO model (Figure 2.) including patients undergoing bariatric surgery between 2015 and 2020

Sensitivity analysis

The newly developed model on the DATO population of patients undergoing bariatric surgery between 2015 and 2020, included the variables 'procedure type', 'age', 'sex', 'GERD', 'hypertension', and 'renal disease' based on statistical significance in the stepwise backward selection. The variable 'diabetes' (no diabetes/ diabetes with or without medication) was forced into the model based on clinical relevance. This (internally validated) model had an AUC of 0.606 i.e. moderate discrimination with a calibration slope of 1.074 (Supplemental Figure 1), and the plot shows that the prediction model systematically underestimates the actual risks, particularly for those at higher predicted risk.

Discussion

This study provided an external validation of the MBSC risk prediction model for the Dutch population using the nationwide DATO as the validation cohort, which includes all patients receiving bariatric surgery in the Netherlands. The best performance was shown for the updated MBSC model (Figure 2), which showed a moderate discrimination slightly lower than the original model (0.60 versus 0.66), and a good calibration. Some predictors (age and procedure type) had significantly different effects in the validation cohort, and were therefore updated. In addition, the model was extended with significant predictors of serious complications in the DATO: 'GERD', 'OSAS', 'hypertension', and 'renal disease'. Although the ideal model would have higher discriminative ability (preferably AUC>0.8), this is likely not feasible given the moderate discrimination in the development cohort (AUC 0.66). For meaningful use in clinical practice the model needs good calibration, meaning that predicted risks are similar to the actual observed risks and therefore can be communicated to patients and physicians as part of shared decision making.

The best performing DATO model includes several predictors that are also reported in the literature to be significantly associated with serious complications. These predictors include age, male gender, procedure type, GERD, OSAS, hypertension, renal disease, and pulmonary disease.[3,5,16–18] Age, male gender, procedure type and pulmonary disease were also included in the original MBSC model, and GERD in the current MBSC model, whereas OSAS, hypertension and renal disease were not included in any of the MBSC models. The predictor BMI, which has been identified as a risk factor in previous studies,[19,20] did not have an independent significant association with serious complications in the current study, nor was it included in any of the MBSC models. Part of the explanation could be that patients with BMI above 50 are known to be at increased risk for 30-day morbidity whereas the DATO and MBSC cohort had a lower average BMI of 42.85 (SD=5.26) and 48 (SD=8.5), respectively.[21]

Further differences in predictors between the DATO and MBSC model are that the variables ethnicity, mobility limitations, VTE, and private insurance are not recorded in the DATO. It has to be noted that all patients in the Netherlands have health insurance by law, including coverage for bariatric surgery. Although national registries have the common purpose to assess and improve the quality of care, registries often differ in defining and collecting variables.[22] In addition, the need for mobility aids or being bed-bound is rarely the case in Dutch patients with morbid obesity, likely explained by the considerably lower average BMI compared with the MBSC population, making it redundant to record this predictor. Notably, mobility limitations seem to occur in 5% of the MBSC cohort (Table 1). The mobility limitations variable therefore most likely acts as a proxy to capture the risk of patients with extremely high BMI in the MBSC model, i.e., above 50 kg/m^2,who have increased risk for 30-day morbidity.[21]

Furthermore, the DATO does not register ethnicity. However, comorbidities such as diabetes or hypertension may act as a proxy as they occur more frequently in some ethnic groups and may have different associations with the outcome.[23,24] This would explain why hypertension was needed to extend the DATO model based on its significant association with serious complications and thereby may have captured part of what was covered by the ethnicity variable in the MBSC model. Diabetes, on the other hand, did not significantly add to the DATO model, most likely because it was already captured by the predictors cardiovascular disease and renal disease, both long-term consequences of diabetes.

The best performing DATO model shows good calibration. This means for instance that the individual risk prediction for a female, aged 55 years, with hypertension, undergoing a SG, who has a predicted risk of 2.1%, will accurately match the observed risk for patients with these characteristics. This is essential for using the prediction model in clinical practice, as making clinical decisions based on a mis-calibrated prediction model that systematically under- or overestimates the risks in some subgroups, could be harmful if e.g. a procedure carries a much higher serious complication risk for particular patients. The discriminative ability on the other hand is 0.602, which means that the model is consistent 60% of the time in predicting higher risks for patients who will experience serious complications. The serious complication rates after bariatric surgery in the DATO are consistent with the MBSC and current literature,[25,26] which is important as differences in outcome incidence will affect model performance and particularly induce miscalibration.[10,15] Nonetheless, the DATO population is relatively homogenous in its patient characteristics which makes it harder for the model to discriminate between patients with and without serious complications.[27] In addition, the relatively low complications rates, likely due to centralization and high annual volumes,[28,29] reflect the high quality of bariatric care in both cohorts, making the occurrence of serious complications a difficult to predict clinical problem. Finally, some predictors may discriminate better for specific complications such as leak, rather than all complications combined.[18,30]

Other risk prediction models include the bariatric surgical risk calculator, recently developed by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP).[31] This model also has a moderate discrimination for overall serious complications, but good discrimination for specific complications such as leak. To our knowledge, this model is merely used in the setting in which it is developed and provides information for patients of the MBSAQIP cohort, but no external validation has been reported which could lead to inaccurate risk predictions when used in a new patient population. Continued international collaboration with multiple national cohorts and external validations in diverse patient populations is likely needed to further enhance the generalizability and optimize existing prediction models, to ensure meaningful use in clinical practice.

It is imperative to conduct an external validation of a prediction model before it is implemented in clinical practice because the model generally performs not as good in a new setting. The results of the current study show a good calibration for the best performing DATO model, which can be used to inform patients and physicians about the absolute risks during shared decision making. This study also highlights the importance of external validation of prediction models to retain prior information and add information that is significantly important for the new setting, which in turn improves generalizability.[32] Also important is that the current model contains common non-invasive predictors which are relatively easy to retrieve during patient consultation.[33] Future studies are needed to show whether implementation of the current risk prediction model affects clinical decision making and is accepted by surgeons in daily practice. Overall, this study calls attention to online accessible bariatric surgery risk calculators, which are sporadically being utilized. It is a reminder that without external validation, a risk calculator may not always be accurate in a patient population different from the setting where it was developed, potentially compromising patient outcomes.

The strength of this study is that the DATO and the MBSC are both population-based registries that capture the whole population rather than a selection of patients. Furthermore, because the MBSC model was updated including patients treated between 2015 and 2020, possible differences over time in e.g. treatment were taken into account. Moreover, an external validation enhances the model's generalizability, retains prior information and given the good calibration, the risk prediction model can be implemented in clinical practice. Some limitations should be noted. First, this study only looked at serious complications occurring within 30 days and did not investigate the risk of any long-term outcomes after bariatric surgery, whereas these long-term outcomes may also influence decision making e.g. regarding type of bariatric procedure. Furthermore, we did not capture all the variables included in the MBSC model. However, as explained previously for the risk factor ethnicity (which was forced in the original MBSC model), it seems likely that this may have been captured by extending the model with the variables hypertension, cardiovascular disease and renal disease. Moreover, the model's discriminative ability is only moderate, so that the model seems less useful to identify high-risk patients e.g. for inclusion in a trial.

Conclusion

The external validation of the MBSC model for the Dutch bariatric population has good calibration, meaning that it adequately predicts individual risks in a real-world setting, but it has only moderate discrimination. This model could provide useful information for bariatric surgeons in daily practice to enable communicating individualized complication risks to patients as part of shared decision making.

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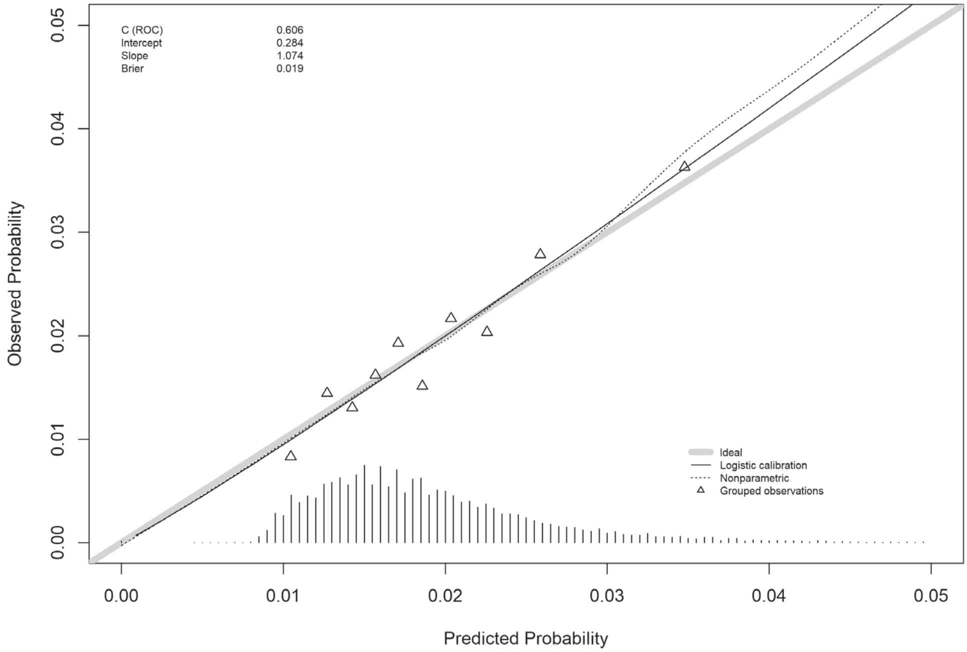
Supplemental figure 1. Calibration plot: internal validation of a risk prediction model using DATO population between 2015 and 2020



C (ROC) is the AUC of the model which is 0.606. The calibration slope is 1.074. The Brier score is significant which denotes a good model fit. DATO, Dutch Audit for Treatment of Obesity

8

General discussion, summary and future perspectives

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 ≥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 ≥10% weight recurrence up to 5 years of follow-up compared with patients receiving RGYB, after ≥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 ≥10% weight recurrence after SG who maintained ≥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 ≥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 ≥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) ≥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 (≥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-Q[60], 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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In the Netherlands, 14.2% of the population suffers from obesity.[1] Obesity is associated with a high risk for comorbidities such as diabetes, cholesterol, hypertension, reflux, cardiovascular diseases, and obstructive sleep apnea syndrome.[2] In combination, the conditions result in poor quality of life, chronic morbidity, or even mortality. Therefore, it is important to take action as there are several treatment options for these patients. Metabolic and bariatric surgery has proven to be superior compared with nonsurgical methods in treating obesity and reducing the risk of associated morbidity. In addition, abundant literature on bariatric surgery shows its safety and efficacy. However, the question which bariatric procedure will provide the best patient outcomes remains difficult to answer, because the different types of procedures each have their own advantages and disadvantages. In addition, randomized trials comparing outcomes between the different types of procedures typically have a selected patient population, which may not reflect the outcomes achieved in daily practice when including all patients. In the Netherlands, the data of all bariatric procedures are collected in the Dutch Audit for Treatment of Obesity (DATO) registry.[3] This provides the opportunity to leverage this population-based data to gain new knowledge, optimize treatment strategies, and further improve the quality of bariatric surgical care. Therefore, we used DATO data to compare outcomes of the most frequently performed surgical techniques in terms of weight loss, weight recurrence, complications, and remission of comorbidities.

Approximately 12,000 procedures are annually recorded in the DATO, with the Roux-en-Y Gastric Bypass (RYGB) and Sleeve Gastrectomy (SG) being the most frequently performed techniques. Even though Dutch hospitals differ in which procedure they perform more often, the results in this thesis show that their overall outcomes are similar in terms of weight loss after 2 years of follow-up and complications within 30 days after the procedure. Although the main outcome after bariatric surgery is weight loss, its success cannot solely be measured by one outcome. Ideally, all outcomes such as weight loss, comorbidity remission, complications, and quality of life have to be evaluated. The studies in this thesis show that the metabolic effects after RYGB with regard to comorbidity remission are more favorable than after SG. In addition, the RYGB showed better weight loss results up to 5 years of follow-up with a lower likelihood for weight recurrence than SG. Still, the choice for the procedure has to be evaluated case-by-case and tailored to each individual patient, as the RYGB has higher long-term complication risks including a higher risk for surgical intervention.

These long-term complications are a downside of bariatric surgery and may require conversion to another technique e.g., after primary gastric banding. As is the case for primary surgery, there is debate on which type of conversion surgery could achieve the best results for patients. In more recent years, the one-anastomosis gastric bypass (OAGB) is increasingly being performed as it requires one anastomosis less than the RYGB. Our study showed similar results in weight loss and comorbidity remission when the OAGB or the RYGB were performed as a conversion procedure after primary gastric banding. Future research is needed to evaluate the long-term complications after RYGB versus OAGB conversion procedures, which have to be considered when deciding which conversion technique achieves the best patient outcomes. Fortunately, complications do not frequently occur after bariatric surgery. However, this may present a challenge if the numbers in national registries such as DATO seem too limited to answer some research questions regarding complications. Combining data from multiple registries may solve this, provided that the same variables, outcomes, and definitions are used across registries. However, our research showed large discrepancies between national bariatric registries on the recorded data and the definitions, complicating the possibility for international collaborations. To illustrate the possibilities for such international collaboration when registries do have similar data, we validated the MBSC risk prediction tool to predict serious complications within 30 days in the Dutch DATO population. Dutch bariatric surgeons can use the information from this DATO prediction tool to support patient consultation and inform them about the benefits and individualized (complication) risks for a specific type of bariatric procedure.

These results are relevant for patients with morbid obesity and healthcare professionals involved in the multidisciplinary bariatric team to support their decision-making on what constitutes the optimal treatment strategy. Since previous studies have shown contrasting results, it is particularly important that these results add new population-based evidence including all types of patients treated in daily practice. In addition, it reiterates that all bariatric procedures in the Netherlands are safe and effective. Since most results have been presented during national and international conferences and are available onlinein scientific journals, this new knowledge can be utilized to build and guide future research and implemented as part of quality improvement projects. Dutch bariatric healthcare professionals are informed about the results through the scientific committee meetings of the DATO in which all bariatric institutions are represented. This enables them to apply the knowledge in relevant hospital-based policies and in doctor-patient consultations. However, informing patients with morbid obesity about relevant scientific developments currently depends on their treating healthcare professional, which might be improved by initiating a nationwide association.[4]

Even though metabolic and bariatric surgery is a safe and effective treatment for patients with morbid obesity, the field is rapidly changing with new techniques and treatments becoming available. These new techniques and treatments require evaluation on which strategy achieves the best outcomes, taking into account weight loss, weight recurrence, revision surgery, complications, and comorbidity remission. Morbid obesity should be considered a chronic disease that may require multiple sequential treatments. The nationwide DATO is well-suited as a tool for long-term follow-up of patients, as well as for evaluation of treatment strategies and to initiate quality improvement initiatives by benchmarking hospitals or surgeons. The research reported in this thesis has shown several examples of how DATO may contribute real-world scientific evidence to provide guidance to bariatric surgeons and to improve the overall bariatric care across all phases in the treatment of obesity.

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Appendices

Dutch summary / Nederlandse samenvatting

List of contributing authors

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PhD Portfolio

Acknowledgements / Dankwoord

About the author

Nederlandse samenvatting

Clinical auditing heeft bewezen effectief te zijn bij het verbeteren van de kwaliteit van zorg door middel van een Plan-Do-Check-Act (PDCA)-cyclus. De jaarlijkse PDCA-cyclus geeft artsen feedback op hun uitkomsten en stimuleert zo initiatieven om deze te verbeteren.[1] The Dutch Audit for Treatment of Obesity (DATO) is met dit doel voor ogen opgericht en registreert gegevens op het gebied van zorgstructuur, zorgproces en patiëntuitkomsten.[2] Verbeteringen in de structuur en het proces van de zorg zullen uiteindelijk leiden tot verbeteringen in klinische uitkomsten.[3] Daarnaast kunnen de gegevens uit de DATO worden gebruikt voor klinisch onderzoek om patiëntuitkomsten te vergelijken en zo nieuwe inzichten te geven over hoe de zorg verbeterd en geoptimaliseerd kan worden in de dagelijkse praktijk. Hoewel gerandomiseerde onderzoeken evidence van de hoogste kwaliteit leveren, beperken selectiecriteria de toepasbaarheid op de gehele patiëntenpopulatie. Dit proefschrift heeft zich met name gericht op het optimaliseren van behandelstrategieën in de dagelijkse praktijk en het bieden van handvaten binnen de bariatrische chirurgische zorg. Met behulp van de DATO-database werd onderzoek gedaan op populatieniveau met betrekking tot relevante wetenschappelijke vragen in de bariatrische literatuur.

Bariatrische chirurgie staat bekend om zijn gunstige metabolische effecten en kan complete remissie van type 2 diabetes (T2D) veroorzaken bij patiënten met morbide obesitas.[4] Eerdere studies die metabole uitkomsten vergeleken tussen Roux-en-Y Gastric Bypass (RYGB) en Sleeve Gastrectomy (SG) hadden tegenstrijdige resultaten.[5–7] De resultaten gerapporteerd in **hoofdstuk 2** dragen bij aan deze wetenschappelijke basis door patiënten die een primaire RYGB of SG ondergingen op populatieniveau te matchen om te corrigeren voor confounding by indication. Het matchen van cohorten maakt een eerlijke vergelijking van patiëntuitkomsten mogelijk door de gemeten confounders tussen behandelgroepen te balanceren, vergelijkbaar met randomisatie.[8] De studie in **hoofdstuk 2** toonde aan dat patiënten die een primaire RYGB ondergingen betere gewichtsverlies en gunstigere metabole effecten hadden in termen van T2D- en dyslipidemie-remissie tot 1 jaar in vergelijking met SG. Deze bevindingen worden ondersteund door verschillende onderzoeken die betere metabolische effecten op korte termijn laten zien voor de RYGB-groep, mogelijk als gevolg van de gewichtsverlies onafhankelijke effecten van RYGB.[9-11] Lange termijn onderzoeken met een follow-up van 5 jaar laten daarentegen vergelijkbare resultaten zien voor patiënten die RYGB en SG ondergingen in termen van T2D-remissie, met vergelijkbare resultaten in gewichtsverlies.[12-14] Dit zou suggereren dat het effect op T2D-remissie gewichtsafhankelijk is. Echter, een andere studie die gebruikmaakte van nationale gegevens en een follow-upduur van 5 jaar toonde significant meer gewichtsverlies en betere T2D-remissie voor de RYGB vergeleken met de SG.[15] Deze tegenstrijdige lange termijn bevindingen zouden te wijten kunnen zijn aan de relatief kleine patiënten groepen en de gecontroleerde setting van deze onderzoeken in vergelijking tot de grote nationale cohorten die de dagelijkse praktijk weergeeft.[12,13,15] Hoewel de laatste studie gegevens gebruikte van een landelijke database, werden patiënten uit 2005-2015 geïncludeerd en werd niet gematched tussen behandelgroepen. Deze tegenstrijdige bevindingen kunnen mogelijk verklaard worden door counfounding by indication. Bovendien verandert bariatrische chirurgie snel met frequente technische aanpassingen, zodat het vergelijken van behandeleffecten bij een meer recente patiëntenpopulatie met up-to-date technieken belangrijk blijft. De bevindingen gerapporteerd in **hoofdstuk 2** dragen bij aan dit debat door meer recente patiënten te includeren en te matchen. In de toekomst kunnen deze onderzoeksresultaten chirurgen en patiënten helpen bij het kiezen van de optimale procedure voor degenen die baat hebben bij meer metabole controle op de korte termijn. Aangezien de audit nog steeds gaande is, zullen er in de toekomst langere follow-up gegevens worden verzameld om onderzoek met lange termijn resultaten uit te voeren.

Hoewel korte termijn resultaten een indicatie geven van het initiële behandel effect, is evidence over de lange termijn resultaten na bariatrische chirurgie essentieel, aangezien dit de duurzaamheid van het behandeleffect weergeeft. Na bariatrische chirurgie bereiken de meeste patiënten aanvankelijk het gewenste gewichtsverlies, gedefinieerd als $\geq$20% Total Weight Loss (TWL).[16] Echter, ongeveer 20% van de patiënten die bariatrische chirurgie ondergaan, zal 'weight recurrence' ervaren of is een 'non-responder'.[17] Weight recurrence is multifactorieel en is geassocieerd met levensstijl, genetische en metabole factoren en het type bariatrische procedure.[18,19] Aangezien obesitas een chronische aandoening is, is het belangrijk om patiënten met een hoog risico op weight recurrence te identificeren. Dit ondanks het feit dat de definitie van weight recurrence nog steeds ter discussie staat met willekeurige afkapwaarden die een grote variëteit aan resultaten laten zien.[18] Om patiënten met progressie of verslechtering te identificeren, is een gestandaardiseerde terminologie voor weight recurrence nodig.[20] Verschillende terminologieën worden gebruikt in de huidige literatuur, waaronder het woord 'Failure', wat het stigma op obesitas vergroot en kan leiden tot depressie, een laag zelfbeeld en angst bij patiënten, wat uiteindelijk het eetgedrag kan verergeren.[19] Een andere term die vaak wordt gebruikt, is 'weight regain', waarbij ook willekeurige afkapwaarden worden gehanteerd. Verschillende studies hebben getracht weight recurrence te definiëren, waarbij definities worden gebruikt zoals gewichtstoename vanaf het punt van maximaal gewichtsverlies (nadirgewicht).[21] Momenteel bestaat er geen consensus over de definitie, terwijl de klinische implicaties tussen de afkapwaarden significant verschillen. Deze verschillende afkapwaarden kunnen leiden tot over diagnose bij mensen wanneer het afkappunt zeer laag is (bijv.: >5% gewichtstoename), terwijl het

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behandeleffect nog steeds voldoende kan zijn in termen van comorbiditeiten remissie of gezondheid gerelateerde kwaliteit van leven (HRQoL).[22 ,23] Een andere term die wordt gebruikt is (primaire) non-respons, wat kan betekenen dat patiënten geen adequate gewichtsverlies laten zien of dat ze aankomen en geen verbetering van comorbiditeiten ervaren. De term secundaire non-respons wordt gebruikt om patiënten te identificeren die hun initiële streefgewicht hebben bereikt, maar op de lange termijn een terugval of progressie van de ziekte hebben, waardoor ze worden onderscheiden van patiënten die aanvankelijk niet op de behandeling reageerden.[24] De POWER-taskforce van de American Society for Metabolic and Bariatric Surgery (ASMBS) heeft een overzicht gepubliceerd waarin een gestandaardiseerde definitie voor patiënten wordt voorgesteld door de termen ‘weight recurrence’ en ‘non-responder’ te introduceren.[20] Over het algemeen benadrukt de voorgestelde terminologie dat obesitas een chronische ziekte is die mogelijk meerdere sequentiële of parallelle behandelstrategieën nodig heeft om weight recurrence en verslechtering van comorbiditeiten te voorkomen of te behandelen.[25,26]

In deze context suggereerde een recente systematische review dat verder onderzoek met grotere cohorten en langere follow-up nodig was voor (secundaire) non-responders, en adviseerde ook om de uitkomsten tussen bariatrische procedures te vergelijken.[18] Het gematchte landelijke onderzoek dat in **Hoofdstuk 3** wordt gerapporteerd, voldoet aan deze oproep door te laten zien dat patiënten die een SG ondergaan, meer waarschijnlijk ≥10% weight recurrence ervaren tot 5 jaar follow-up in vergelijking met patiënten die RGYB ondergaan, na initieel ≥20% TWL op 1 jaar. Een andere studie ondersteunt deze bevinding door een hoger percentage patiënten te laten zien die weight recurrence ervaren in de SG-groep.[22] Ook hebben studies laten zien dat SG minder vaak tot aanhoudend gewichtsverlies leidt in vergelijking met RYGB, wat zelfs doorzet na het initiële gewichtsverlies en uiteindelijk resulteert in meer patiënten die weight recurrence ervaren in de SG-groep.[27,28] Dit proefschrift (**Hoofdstuk 3**) voegt daarom waardevolle nieuwe kennis toe over 19.762 patiënten door gebruik te maken van statistische methoden om een eerlijke vergelijking tussen behandelingen mogelijk te maken. De belangrijkste bevinding was dat SG een grotere kans heeft op weight recurrence in vergelijking met RYGB. Bovendien werd aangetoond dat patiënten die een SG ondergingen minder kans hadden op comorbiditeiten remissie dan patiënten die een RYGB ondergingen, wat in lijn is met een eerdere studie.[29] Daarnaast toonden gematchte patiënten met ≥10% weight recurrence na SG die ≥20% TWL vanaf het startgewicht behielden, vaker comorbiditeiten remissie dan degenen die geen 20% TWL behielden. Onder de gematchte RYGB-patiënten werd een dergelijk verschil in comorbiditeiten remissie niet gevonden. Deze resultaten suggereren dat RYGB-patiënten mogelijk minder worden beïnvloed door ≥10% weight recurrence en de bijbehorende effecten op comorbiditeiten remissie. Het blijft echter belangrijk om de meest geschikte procedure voor de individuele patiënt te selecteren, aangezien RYGB vaker kan leiden tot lange termijn complicaties in vergelijking met SG.[12] De drempel van ≥10% weight recurrence in deze studie hangt samen met een recente systematische review die risicofactoren correleerde met weight recurrence.[18] Men kan bediscussiëren of weight recurrence gedefinieerd moet worden met behulp van een arbitraire afkapwaarde. Hoewel de meerderheid van de literatuur een maat als lichaamsgewicht gebruikt om weight recurrence te definiëren, moeten in een ideale situatie alle belangrijke resultaten zoals HRQoL, complicaties en comorbiditeiten remissie worden meegenomen. Een dergelijke samengestelde uitkomstmaat zal helpen bij het onderzoeken welke patiënten het meest zullen profiteren van sequentiële (chirurgische) behandelingen wanneer de klinische 'significantie' van weight recurrence wordt geëvalueerd. Daarom is toekomstig onderzoek nodig om een gestandaardiseerde definitie te verkrijgen voor de klinisch significantie van weight recurrence, waarbij rekening wordt gehouden met alle essentiële resultaten zoals TWL vanaf het startgewicht, comorbiditeiten remissie, complicaties en HRQoL.

Literatuur over revisiechirurgie blijft schaars met betrekking tot de beste bariatrische procedure en de uitkomsten voor de patiënt. Patiënten die complicaties ondervinden na een Laparoscopische Adjustable Gastric Band (LAGB), zoals bandverschuiving, erosie of stenose, komen in aanmerking voor revisiechirurgie. Conversie naar RYGB (cRYGB) is de gouden standaard na een mislukte LAGB, gevolgd door SG, wat ook vaak wordt uitgevoerd. Conversie naar One-Anastomosis Gastric Bypass (cOAGB) wint echter aan populariteit en is de primaire procedure van keuze in sommige landen.[30] In **hoofdstuk 4** hebben we zowel cRYGB als cOAGB procedures gematcht en vergeleken op gewichtsverlies, waarbij vergelijkbare uitkomsten werden aangetoond tot 1 jaar follow-up na een LAGB. Deze resultaten weerspiegelen de bevindingen van de YOMEGA-trial die de effectiviteit en veiligheid vergeleek tussen primaire RYGB en primaire OAGB, waarbij geen significant verschil werd gevonden in gewichtsverlies na 2 jaar.[31] De sensitiviteitsanalyse (**hoofdstuk 4**) met een 5 jaar follow-up toonde echter een hoger percentage patiënten die het gewenste gewichtsverlies niet bereikten na cRYGB, wat wijst op potentieel betere langetermijnresultaten voor cOAGB en daarmee ondersteuning biedt aan bevindingen van een vergelijkbare studie.[32] De meest waarschijnlijke verklaring voor deze bevinding is de langere biliopancreatische (BP) darmlengte voor de cOAGB-groep, wat mogelijk geassocieerd is met extra gewichtsverlies.[33,34] Hoewel het bereiken van significant gewichtsverlies belangrijk is bij bariatrische chirurgie, is het niet de enige overweging bij het kiezen van een procedure; de korte- en lange termijn complicaties zijn ook essentiële factoren om mee te nemen in de keuze voor een ingreep. In **hoofdstuk 4** wordt beschreven dat er geen significant verschil is tussen cRYGB en cOAGB in postoperatieve complicaties binnen 30 dagen, gedefinieerd als Clavien Dindo (CD) ≥III. Echter spelen lange termijn complicaties een belangrijke rol in morbiditeit na bariatrische chirurgie. RYGB lange termijn complicaties bestaan onder andere uit marginal ulcer, inwendige herniatie en postoperatieve ondervoeding, terwijl de OAGB lange termijn complicaties voornamelijk bestaan uit inwendige herniatie, gallige reflux en postoperatieve ondervoeding. Een recente meta-analyse toonde verschillende resultaten met betrekking tot gallige reflux na revisie tot OAGB, waarbij sommige studies geen gallige reflux rapporteerden, terwijl anderen een hogere incidentie rapporteerden.[35] Een andere meta-analyse toonde een hogere incidentie van postoperatieve ondervoeding na primaire OAGB in vergelijking met primaire RYGB, wat voornamelijk werd waargenomen bij OAGB met langere BP lengtes (≥200 cm).[36] Echter bestonden deze studies voornamelijk uit retrospectieve cohorten, waardoor het moeilijk is om deze te vertalen naar de dagelijkse praktijk. Aanvullende studies met lange termijn uitkomsten zijn nodig om inzicht te krijgen in de gevolgen van gallige reflux en postoperatieve ondervoeding welke vaker vermeld werden bij patiënten die een OAGB ondergingen.[37] De lange termijn resultaten van een gerandomiseerde gecontroleerde trial die de veiligheid en effectiviteit van RYGB en OAGB vergelijkt (de RYSA-trial), worden afgewacht om evidence te verkrijgen met betrekking tot de verschillen in gewichtsverlies en lange termijn complicaties.[38]

Metabole en bariatrische chirurgie ontwikkelt snel met frequente technische aanpassingen. Als gevolg hiervan kunnen artsen voorkeuren ontwikkelen voor specifieke procedures welke meer uitgesproken zijn in sommige ziekenhuizen, regio's en landen.[30,39] De mate waarin de voorkeur van het ziekenhuis voor een bariatrische procedure gepaard gaat met prestaties op het gebied van gewichtsverlies werd gerapporteerd in **hoofdstuk 5**. Om te erkennen dat patiënten met bepaalde kenmerken eerder de ene procedure dan de andere ondergaan, definieerden we ziekenhuisvoorkeur als 'het vaker uitvoeren van een specifieke procedure dan verwacht op basis van de patiëntmix in dat ziekenhuis'. Het onderzoek toonde aan dat ziekenhuizen die voornamelijk één procedure uitvoeren betere resultaten kunnen behalen met die procedure, maar dat een dergelijke voorkeur niet consistent leidde tot betere algemene gewichtsverlies resultaten. In plaats daarvan overtrof een ziekenhuis zonder voorkeur voor een bepaalde procedure de andere ziekenhuizen in termen van gewichtsverlies, wat suggereert dat dit ziekenhuis de procedure succesvol heeft afgestemd op individuele patiënten in plaats van gespecialiseerd te zijn in één procedure en die toe te passen op de meeste patiënten. Eerdere onderzoeken in de bariatrisch chirurgische zorg benadrukten het voordeel van een op maat gemaakte aanpak voor de patiënt.[40,41] Dit ondersteunt en impliceert dat bariatrische chirurgen bedreven moeten zijn in verschillende procedures en dat het essentieel blijft om de meest geschikte procedure te selecteren voor de individuele patiënt afhankelijk van zijn of haar karakteristieken. Daarnaast zijn vergelijkbare complicatierisico's en uitkomstresultaten gevonden tijdens het vergelijken van RYGB, SG en OAGB. Deze vergelijkbare postoperatieve uitkomsten tussen procedures zijn waarschijnlijk te danken aan de effecten van een hoog jaarlijks caseload in gecentraliseerde bariatrische zorgcentra.[42,43] De Nederlandse richtlijnen stellen dat bariatrische chirurgie moet worden uitgevoerd in een gecentraliseerd ziekenhuis, binnen een multidisciplinair team met ten minste 2 toegewijde bariatrische chirurgen die gezamenlijk meer dan 200 procedures per jaar uitvoeren. De Nederlandse richtlijnen leiden waarschijnlijk tot chirurgen die voldoende verschillende procedures uitvoeren, zoals RYGB, SG en OAGB, wat leidt tot vergelijkbare resultaten ongeacht hun voorkeur.[44] Ongeacht de keuze voor een bariatrische procedure hebben patiënten die een bariatrische ingreep ondergaan aangetoond dat ze duurzaam gewichtsverlies behalen tot 2 jaar (**Hoofdstuk 5**) en zelfs langer zoals gerapporteerd in de literatuur.[16,27] Naarmate de DATO deze patiënten blijft volgen, zullen er in de toekomst langere termijn uitkomsten worden onderzocht.

Nationale kwaliteitsregistraties hebben hun waarde aangetoond in het verbeteren van de kwaliteit van de gezondheidszorg door het volgen van een PDCA-cyclus, wat uiteindelijk leidt tot betere patiëntresultaten. De wereldwijde International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) brengt alle (nationale) registraties voor bariatrische chirurgie samen en rapporteert over de patiëntkarakteristieken en resultaten, met als doel de chirurgische zorg voor patiënten met morbide obesitas te verbeteren.[30] Het mogelijk maken van vergelijkingen tussen internationale centra en het geven van feedback ter stimulering van verbeterinitiatieven kan echter alleen worden bereikt als alle opgenomen registraties dezelfde variabelen en uitkomsten registreren. In **hoofdstuk 6** wordt de mate van overeenstemming tussen geregistreerde variabelen in 11 bariatrisch chirurgische registraties met landelijke dekking gerapporteerd. Een totaal van 2585 geregistreerde variabelen werden gegroepeerd in 250 variabelen die hetzelfde concept meten. Deze variabelen werden gegroepeerd in zes domeinen: patiëntkarakteristieken, voorgeschiedenis, screening, operatie, complicaties en follow-up. Van alle 250 beoordeelde variabelen hadden slechts 25 (10%) een perfecte overeenkomst tussen de deelnemende registraties, wat betekent dat ze allemaal dezelfde variabele met een identieke definitie registreerden. De rest van deze variabelen had verschillende definities of werden niet in alle registraties geregistreerd. Tegenstrijdige bevindingen in de literatuur kunnen worden verklaard door verschillen in definities van uitkomsten zoals complicaties, die eerder hebben geleid tot uiteenlopende resultaten.[45] Bovendien kunnen de relatief grote verschillen in geregistreerde variabelen een deel van de tegenstrijdige bevindingen in de bariatrische literatuur verklaren bij het vergelijken van bariatrische procedures in termen van gewichtsverlies en comorbiditeiten remissie.[22,46] In totaal omvatten deze 11 registraties samen 554,599 patiënten, wat belangrijk kan zijn om evidence te verkrijgen, met betrekking tot relevante bariatrische onderzoeksvragen en het behandeleffect van verschillende operatieve procedures. Bovendien kan het gebruikt worden om een predictiemodel te ontwikkelen die risico's en uitkomsten kan voorspellen om gedeelde besluitvorming in de dagelijkse praktijk te begeleiden. Er is behoefte aan verdere afstemming tussen registraties om op een consistente en uniforme manier uitkomsten te rapporteren en variabelen te registreren met identieke definities. Ook blijft continue dataverificatie essentieel, aangezien gerapporteerde uitkomsten alleen sterke evidence leveren wanneer de gegevens betrouwbaar en valide zijn. Er worden inspanningen geleverd om de rapportage van uitkomsten te standaardiseren, maar dit wordt niet consistent door de gehele bariatrische gemeenschap aangenomen.[46,47] Initiatieven gesteund door IFSO, zoals de ontwikkeling van een core outcome set (COS) of de Standardized Quality of life measures in Obesity Treatment (SQOT), worden afgewacht.[48,49] Uiteindelijk zal gestandaardiseerde registratie van variabelen en uitkomsten meerdere internationale samenwerkingen mogelijk maken en onderzoeke initieren met grote landelijke cohorten om de kwaliteit van bariatrisch chirurgische zorg op internationaal niveau te verbeteren.

Naarmate we toewerken naar zorg die gepersonaliseerde behandelingen biedt, hebben chirurgen gepersonaliseerde informatie nodig over de waarschijnlijke voordelen en risico's van bepaalde operaties om de besluitvorming tussen arts en patiënt in de dagelijkse praktijk te ondersteunen. Hoewel het mogelijk is om gemiddelde risicoschattingen uit de literatuur te gebruiken, hebben deze schattingen vaak betrekking op een andere populatie. Daarnaast moeten deze schattingen bij voorkeur worden afgestemd op de individuele patiënt in plaats van het gemiddelde in een patiëntengroep. Risico voorspellende modellen kunnen hierbij nuttig zijn. Het Michigan Bariatric Surgery Collaborative (MBSC) risico predictiemodel is ontwikkeld met als doel om ernstige postoperatieve complicaties binnen 30 dagen na primaire bariatrische chirurgie te voorspellen.[50] Het is bekend dat predictiemodellen goed presteren in de setting waarin ze zijn ontwikkeld, maar minder nauwkeurig presteren in een nieuwe geografische setting. Dit kan ervoor zorgen dat ze risico's in een nieuwe populatie kunnen overschatten of onderschatten, wat de besluitvorming kan beïnvloeden en klinische resultaten kan compromitteren.[51] Daarom moet een predictiemodel extern gevalideerd worden om de prestaties ervan in de nieuwe setting te beoordelen, wat ook de algemene bruikbaarheid zal vergroten.[52,53] Het MBSC-model werd daarom extern gevalideerd voor de Nederlandse setting met behulp van de DATO-gegevens (**Hoofdstuk 7**). De prestaties van een predictiemodel worden beoordeeld op basis van het discriminatievermogen (met behulp van de 'area under the curve' (AUC)) en een kalibratieplot. Het eerste is het vermogen om onderscheid te maken tussen patiënten met en zonder een postoperatieve complicatie (dat wil zeggen de mate waarin patiënten met complicaties een hoger voorspeld risico hebben dan die zonder complicaties). Het laatste voorspelt in hoeverre het absolute voorspelde risico vergelijkbaar is met het daadwerkelijk waargenomen risico, wat kan worden gebruikt door artsen en patiënten tijdens gezamenlijke besluitvorming. Het gevalideerde model met de beste prestaties, gerapporteerd in **Hoofdstuk 7**, toonde een AUC van 0,602 met een goede kalibratie. Hoewel de kalibratie goed is, blijft het discriminerend vermogen van het model matig, aangezien het ideale model een hogere AUC zou moeten hebben (bij voorkeur >0,8). Er kunnen verschillende redenen zijn waarom de AUC matig is, waardoor het model minder geschikt is om bijvoorbeeld hoog-risicopatiënten te identificeren. Ten eerste is de DATO-populatie vrij homogeen met relatief weinig variatie in patiëntkarakteristieken, waardoor het moeilijk is voor het model om onderscheid te maken tussen patiënten met en zonder ernstige complicaties.[54] Bovendien maken de relatief lage complicatierisico's het vanwege de gecentraliseerde zorg en de hoge jaarlijkse caseload het uitdagend om de kans op ernstige complicaties te voorspellen. Tot slot kan het model beter onderscheid maken voor specifieke complicaties zoals naadlekkage of mortaliteit dan voor alle ernstige complicaties gecombineerd. Deze hypothese wordt ondersteund door de ASMBS-calculator en de Obesity Surgery-Mortality Risk (OS-MRS) score, die een hoge discriminerend vermogen hebben voor specifieke complicaties, maar een lagere AUC wanneer alle ernstige complicaties samen worden voorspeld.[55,56] Bovendien zijn specifieke complicaties na bariatrische chirurgie, met name mortaliteit, laag (<0,1%)[57], wat betekent dat de klinische relevantie om één specifieke complicatie of alleen mortaliteit te voorspellen ter discussie staat. Bovendien heeft de relevante informatie voor patiënten waarschijnlijk betrekking op het algehele risico om een complicatie te ervaren, in plaats van informatie over meerdere specifieke complicatierisico's. Dit benadrukt de noodzaak voor een model dat niet alleen de waarschijnlijkheid van alle belangrijke postoperatieve complicaties voorspelt, maar ook de resultaten die relevant zijn voor patiënten combineert, zoals gewichtsverlies en comorbiditeiten remissie. De MBSC outcome calculator heeft hierop geanticipeerd en hun model bijgewerkt om resultaten te voorspellen zoals gewichtsverlies en comorbiditeiten remissie. De in **hoofdstuk 7** beschreven studie toont aan dat het extern gevalideerde MBSC-model een nuttige aanvulling kan zijn in de klinische praktijk voor de Nederlandse populatie door individuele risico's nauwkeurig te voorspellen. Hoewel het een matig discriminered vermogen heeft om bijvoorbeeld hoog-risicopatiënten te identificeren, kan het nauwkeurig voorspelde individuele risico, wat wordt aangetoond door de goede kalibratie, worden gecommuniceerd naar de patiënt tijdens een gedeelde besluitvorming. Toekomstige studies zijn nodig om het model voortdurend te updaten en te verbeteren door relevante voorspellende uitkomsten zoals gewichtsverlies en comorbiditeiten remissie toe te voegen. Ten slotte zijn studies nodig om te laten zien of de voorspellingen van dit model, bijvoorbeeld als een online calculator, door chirurgen wordt geaccepteerd en of dit hun besluitvorming in de dagelijkse praktijk beïnvloedt

Toekomstperspectieven

In dit proefschrift zijn de eerste lange termijn resultaten van de DATO tot 5 jaar gepresenteerd. Zoals bij elke bariatrische registratie het geval is, blijft het percentage patiënten met ontbrekende follow-upgegevens een uitdaging, vooral bij een langere follow-up.[58] Om nauwkeurige metingen te garanderen heeft de DATO een vooraf gespecificeerd tijdsbestek voor het vastleggen van resultaten tijdens de follow-up. Dit tijdsbestek heeft een venster van -/+ 3 maanden voor elk follow-up jaar. Het korte tijdsbestek kan het ontbrekende percentage in uitkomsten tijdens de follow-up gedeeltelijk verklaren. Een andere verklaring is dat patiënten vanwege de Nederlandse privacyregelgeving niet kunnen worden gekoppeld tussen centra. Elke verwijzing naar een ander ziekenhuis of verandering van ziekenhuis door de patiënt kan leiden verlies van follow-up data, omdat de gegevens niet kunnen worden teruggekoppeld naar de primaire gegevens van de patiënt. Daarnaast blijft het een uitdaging voor patiënten om compliant te zijn in de postoperatieve nazorg na bariatrische chirurgie. Er zijn verschillende initiatieven genomen door bariatrische centra om het percentage follow-up te verbeteren, zoals het telefonisch bereiken van patiënten of herinneringen via e-mail te versturen. Dit heeft helaas niet tot positieve resultaten geleid. Het percentage follow-up zou wel verhoogd kunnen worden door een patiëntgerichte registratie met cross-linking van patiëntinformatie over alle bariatrische zorgverleners en verschillende uitkomstregistraties met behulp van een unieke patiëntidentificatie om alle verschillende medische dossiers met elkaar te verbinden.

Een hoger percentage van patiënten met een complete lange termijn follow-up geeft betrouwbaarder inzicht in lange termijn resultaten en kan ons leiden naar betere behandel strategieën. Echter, zelfs als de follow-up data beschikbaar is, blijft het belangrijk om uitkomsten op een complete en consistente manier te registreren, zoals lange termijn complicaties die behandeld kunnen worden in een ander ziekenhuis en niet kunnen worden gelinkt aan de primaire data van de patiënt. Een andere belangrijke lange termijn uitkomst is de comorbiditeiten status, waarbij informatie zoals de uitslag van een bloedonderzoek niet altijd beschikbaar is tijdens een polikliniekbezoek en alleen het gebruik van medicatie of de status van de comorbiditeit wordt geregistreerd. Een mogelijke verklaring hiervoor kan de afstand tot het ziekenhuis zijn en de recente COVID-19 pandemie die heeft geleid tot meer E-health consulten. Bovendien is het gebruikelijk dat Nederlandse patiënten behandeld worden door andere gespecialiseerde zorgverleners voor hun comorbiditeiten zoals T2D, die waarschijnlijk meer informatie tot hun beschikking hebben en deze data elders registreren, bijvoorbeeld in het Dutch Pediatric and Adult Registry of Diabetes (DPARD). Aangezien het Dutch Institute for Clinical Auditing (DICA) ook het DPARD faciliteert, zou het koppelen van de DATO aan de DPARD de volledigheid van de data tijdens follow-up verbeteren en resulteren in extra informatie met betrekking tot de comorbiditeiten status, zoals HbA1c, insuline afhankelijkheid en duur van diabetes. Uiteindelijk kan deze extra informatie worden gebruikt om onderzoek te doen naar complexe en relevante bariatrische onderzoeksvragen. Bovendien zou het combineren van de DATO met de Dutch Gastrointestinal Endoscopy Audit (DGEA) voor endoscopische bariatrische behandelingen en het DICA Medicines programma (inclusief pre- en post-bariatrische farmaceutische behandelingen) helpen om de DATO registratie een multidisciplinaire registratie te maken. Dit weerspiegelt de huidige gezondheidszorgpraktijk welke steeds meer gericht is op multidisciplinaire benaderingen om patiënten met morbide obesitas te behandelen. De ultieme registratie zou er één zijn die gekoppeld is aan alle andere registraties met complete data. Bovendien kan de registratie worden gekoppeld aan de database voor gezondheidskosten en kan dit inzicht bieden in de kosteneffectiviteit van bariatrische behandelingen. Nederlandse privacyregelingen zijn echter strikt en het koppelen van registraties vereist continue inspanningen en samenwerkingen tussen het nationale zorginstituut, zorgverzekeraars, overheidsfunctionarissen en zorgverleners.

Over het algemeen wordt het succes van bariatrische chirurgie gemeten aan de hand van gewichtsverlies. Andere uitkomsten, zoals complicaties, comorbiditeiten remissie en de kwaliteit van leven, zijn echter ook relevant. Jarenlang werd de RAND-36 gebruikt als patiënt reported outcome measurement (PROM) voor de DATO. Deze algemene vragenlijst ontbrak echter aan het onderscheidend vermogen voor obesitas-specifieke kwaliteit van leven uitkomsten, zoals eetgedrag.[59] Daarom hebben DICA en de Nederlandse Vereniging voor Heelkunde een werkgroep opgericht en de OBESI-Q[60] ontwikkeld en geïmplementeerd. De OBESI-Q is een meer onderscheidende en nauwkeurigere PROM voor patiënten die een bariatrische ingreep ondergaan.[61] De eerste resultaten van PROM's met behulp van de OBESI-Q zullen beschikbaar komen in 2023. Het combineren van al deze belangrijke uitkomsten in de vorm van een samengestelde lange termijn-uitkomst om het succes van bariatrische chirurgie te definiëren, kan uitgebreider inzicht geven in het postoperatieve zorg- en follow-up proces in de dagelijkse praktijk.

Aangezien bariatrische chirurgie vaak wordt uitgevoerd in Nederland, met een jaarlijks aantal van circa 12,000 procedures, zal het aantal patiënten met weight recurrence in de komende jaren toenemen. Over het algemeen is er relatief weinig evidence over de resultaten na bariatrische revisie chirurgie. De DATO is een uitstekende manier om real-world evidence te verkrijgen voor deze groep patiënten. Het verkrijgen van dergelijke informatie over revisie chirurgie betekent echter ook dat de administratieve lasten voor artsen zal toenemen, aangezien er jaarlijks meer variabelen moeten worden geregistreerd.[62] Het vinden van een balans tussen een minimaal noodzakelijk aantal te registreren variabelen en een hoge administratieve last is een uitdaging. Momenteel worden in de DATO in totaal 206 variabelen geregistreerd. Het volledig elektronisch doorsturen van gegevens die al routinematig worden verzameld in de elektronische patiëntendossiers (EPD's) van ziekenhuizen zal de administratieve last verminderen. Verder zal het meer gedetailleerde informatie bieden zoals de gebruikte stapler-technieken, de grootte van de pouch en de gebruikte instrumenten. Dit blijft echter een uitdaging, omdat de beperkingen in gegevensuitwisseling variëren in verschillende EPD's. Bovendien zijn handmatige invoeringen in de DATO en de levering van batchbestanden nog steeds vatbaar voor fouten en zal automatisering van dit proces de al hoge kwaliteit van de gegevens verder verbeteren.[63] Het blijft belangrijk om kritisch te evalueren welke variabelen moeten worden verzameld om de kwaliteit van de geleverde zorg goed te kunnen beoordelen. Met name in de context van verschillende belanghebbenden die verschillende relevante vragen stellen.[64]

Bij clinical audits is het essentieel om feedbackinformatie te verstrekken over de eigen prestaties. DICA erkent feedbackinformatie als een van de belangrijkste speerpunten voor haar registraties en volgt een jaarlijkse PDCA-cyclus voor haar kwaliteitsindicatoren. Bovendien biedt DICA een online dashboard waar real-time feedback wordt gepresenteerd op reeds geüploade gegevens, wat ziekenhuizen kan helpen om hun kwaliteit van zorg te verbeteren. Het interactieve dashboard geeft clinici in het bijzonder de mogelijkheid om te filteren op subgroepen van patiënten met specifieke comorbiditeiten of proceduretypes, trends in de loop van de tijd weer te geven en zelfs resultaten op regionaal en individueel chirurgisch niveau te tonen. Deze op maat gemaakte feedbackinformatie die wordt gepresenteerd in het dashboard, dient als basis voor toekomstige verbeterinitiatieven wanneer resultaten verslechteren. Hiermee kan de discussie over chirurgische zorg in specifieke patiëntengroepen op lokaal, regionaal en chirurgisch niveau worden gestimuleerd. Ten slotte kunnen de best practice-centra tijdens wetenschappelijke commissievergaderingen hun resultaten delen en transparant zijn in hun zorgproces om verbeterinitiatieven te stimuleren in andere ziekenhuizen.

Al met al heeft de DATO zijn waarde bewezen en is het essentieel om continu te streven naar betere bariatrische uitkomsten. Naarmate de DATO volwassener wordt, zal er meer gedetailleerde informatie beschikbaar komen over langere follow-up-periodes, welke gebruikt kunnen worden om real-world evidence te verkrijgen in de dagelijkse praktijk. Ten slotte zal met behulp van de PDCA-cyclus herhaaldelijk verbeterinitiatieven worden gestimuleerd om veilig en kwalitatief hoogwaardig bariatrisch chirurgische zorg te leveren.

Conclusie

De DATO is een volwassen chirurgische registratie geworden die de bariatrische uitkomsten in de Nederlandse gezondheidszorg verbetert en real-world lange termijn evidence toevoegt aan de bariatrische literatuur. Dit proefschrift maakte gebruik van de landelijke DATO registratie om de uitkomsten tussen RYGB, SG en OAGB te vergelijken, terwijl gecorrigeerd werd voor confounding by indication met behulp van matching technieken om chirurgische behandelstrategieën in de dagelijkse praktijk te optimaliseren. De resultaten toonden aan dat de algehele chirurgische zorg in Nederlandse bariatrische centra van hoge kwaliteit zijn en dat bariatrische chirurgen bekwaam zijn in verschillende procedures op nationaal niveau. Hierdoor zijn ze in staat om de meest geschikte procedure voor de individuele patiënt te selecteren. Bovendien toonden de resultaten van dit proefschrift dat de RYGB-groep betere uitkomsten heeft op het gebied van gewichtsverlies en remissie van comorbiditeiten in vergelijking met SG. De postoperatieve complicaties binnen 30 dagen tussen SG, RYGB en OAGB zijn vergelijkbaar, maar er zijn toekomstige studies nodig om de complicaties op langere termijn te onderzoeken. Obesitas is immers een multicausale chronische aandoening die mogelijk meerdere opeenvolgende behandelingen behoeft. Daarnaast heeft een internationale samenwerking aangetoond dat een extern gevalideerde predictiemodel de individuele postoperatieve risico's na bariatrische chirurgie nauwkeurig kan inschatten. Dit predictiemodel biedt handvaten voor chirurgen tijdens shared decision-making en kan gebruikt worden door artsen en patiënten. In de toekomst zou de DATO bariatrische centra beter van dienst kunnen zijn door interactieve, op maat gemaakte feedback te geven, de registratielast te verminderen en een multidisciplinaire audit te worden om de algehele metabole en bariatrische zorg in alle fasen van de behandeling van obesitas te verbeteren.

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List of Contributing Authors

A.J. Bonham. MSc

Department of Surgery, University of Michigan, United States of America

Assoc. Prof. A.A. Ghaferi, MD MSc

Department of Surgery, University of Michigan, United States of America

Prof. Dr. J.W.M. Greve, MD PhD

Department of Surgery, Zuyderland Medical Center, Heerlen, the Netherlands
Dutch Obesity Clinic South, Heerlen, the Netherlands
Department of Surgery, Maastricht University Medical Center, NUTRIM School for Nutrition and Translational Research in Metabolism, Maastricht, the Netherlands

Drs. R.S.L. Liem, MD

Department of Surgery, Groene Hart Hospital, Gouda, the Netherlands,
Dutch Obesity Clinic, The Hague & Gouda, the Netherlands

Dr. P.J. Marang – van de Mheen, PhD

Department of Biomedical Data Sciences, Medical Decision Making, Leiden University Medical Center, Leiden, the Netherlands

Dr. S.W. Nienhuijs, MD PhD

Department of Surgery, Catharina Hospital, Eindhoven, the Netherlands

Other contributing authors and members of the Dutch Audit for Treatment of Obesity

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List of Publications

Publications in this thesis

National Bariatric Surgery Registries: an International Comparison

Akpinar EO, Marang- van de Mheen PJ, Nienhuijs SW, Greve JWM, Liem RSL. *Obesity Surgery 2021 July*

Metabolic effects of bariatric surgery on patients with type 2 diabetes: a population-based study

Akpinar EO, Liem RSL, Nienhuijs SW, Greve JWM, Marang-van de Mheen PJ, Dutch Audit for Treatment of obesity Research group. *Surgery for Obesity and Related Diseases 2021 February*

Conversion to Roux-en-Y gastric bypass versus one-anastomosis gastric bypass after a failed primary gastric band: a matched nationwide study

Akpinar EO, Nienhuijs SW, Liem RSL, Greve JWM, Marang-van de Mheen PJ, Dutch Audit for Treatment of obesity Research group. *Surgery for Obesity and Related Diseases 2022 July*

Predicting serious complications risks after bariatric surgery: external validation of the Michigan Bariatric Surgery Collaborative risk prediction model using the Dutch Audit for Treatment of Obesity

Akpinar EO, Ghaferi AA, Liem RSL, Bonham AJ, Nienhuijs SW, Greve JWM, Marang-van de Mheen PJ, Dutch Audit for Treatment of obesity Research group. *Surgery for Obesity and Related Diseases 2022 September*

Hospital variation in preference for a specific bariatric procedure and the association with weight loss performance: a nationwide analysis

Akpinar EO, Liem RSL, Nienhuijs SW, Greve JWM, Marang-van de Mheen PJ, Dutch Audit for Treatment of obesity Research group. *Obesity Surgery 2022 September*

Weight Recurrence after Sleeve Gastrectomy versus Roux-en-Y gastric bypass: a propensity score matched nationwide analysis

Akpinar EO, Liem RSL, Nienhuijs SW, Greve JWM, Marang-van de Mheen PJ, Dutch Audit for Treatment of obesity Research group. *Surgical Endoscopy 2023 February*

Other Publications

Impact of the COVID-19 pandemic on surgical care in the Netherlands
Michelle R de Graaff, Rianne N M Hogenbirk, Yester F Janssen, Arthur K E Elfrink, Ronald S L Liem, Simon W Nienhuijs, Jean Paul P M de Vries, Jan Willem Elshof, Emiel Verdaasdonk, Jarno Melenhorst, Erman O Akpinar, Nienke Wolfhagen, Anne Loes van den Boom, Marieke J Bolster-van Eenennaam, Peter van Duijvendijk, David J Heineman, Michel W J M Wouters, Schelto Kruijff, the Dutch CovidSurg Collaborative Study Group. *British Journal of Surgery 2022 september*

Impact of preoperative weight loss on postoperative weight loss revealed from a large nationwide quality registry
Lodewijks Y, Akpinar EO, van Montfort G, Nienhuijs SW, Dutch Audit for Treatment of obesity Research group. *Obesity Surgery 2022 January*

Prognostic Tools for hypertrophic scar formation based on fundamental differences in systemic immunity
de Bakker E, van der Putten MAM, Heymans MW, Spiekstra SW, Waaijman T, Butzelaar L, Negenborn VL, Beekman VK, Akpinar EO, Rustemeyer T, Niessen FB, Gibbs S. *Experimental Dermatology 2021 January*

"Can we please stop calling them missions?": An assessment of a needs-driven and collaborative surgical training model in a resource-limited setting
Botman M, Hendriks TCC, Mtui GS, Nuwass EQ, Akpinar EO, Niemeijer AS, Nieuwenhuis MK, van Zuilen PPM, Winters HAH. *Submitted*

A

A Standard Set of Patient Reported Outcome Measures to measure Quality of Life in Obesity Treatment Research: outcomes of the S.Q.O.T. consensus meetings
Phillip J. Dijkhorst, Claire E.E. de Vries, Caroline B. Terwee, Ignace M.C. Janssen, Ronald S.L. Liem, Bart A. van Wagensveld, Johan Ottoson, Bruno Halpern, Liesbeth F.C. van Rossum, Alend Saadi, Lisa West-Smith, Mary O'Kane, Jason C.G. Halford, Karen D. Coulman, Salman Al-Sabah, John B. Dixon, Stuart W. Flint, Wendy A. Brown, Ximena Ramos Salas, Maarten M. Hoogbergen, Sally Abbott, Alyssa J. Budin, Jennifer F. Holland, Lotte Poulsen, Richard Welbourn, Bernardo Rea, Ronette L. Kolotkin, John M. Morton, Francois Pattou, Erman O. Akpinar, Stephanie Sogg, Jacques M. Himpens, Vanessa Osborne, Natasja Wijling, Laura Divine, Nadya Isack, Susie Birney, Bernadette Keenan, Joe Nadglowski, Jacqueline Bowman, Ken Clare, Riccardo Meloni, Sandra de Blaeij, Theodore K. Kyle, Melanie Bahlke, Andrew Healing, Ian Patton, Valerie M. Monpellier. *Submitted*

PhD Portfolio

Item	Year
Courses	
R-course, DICA	2018
PhD Days NUTRIM	2019
R-Advanced Course	2019
Mendeley hands-on training	2019
PG course; Creating good quality research in Bariatric/Metabolic surgery: How to plan, write and publish | Obesity Surgery supported course	2019
BROK: Legislation and Organization for Clinical researchers	2019
R-advanced course 2	2020
Statistic part 2 - regression analysis	2020
Cursus klinische predictiemodellen - predM	2020
Academic writing for PhD candidates and research masters students (PhD-1)	2021
Repeated Measurements NIHES	2021
Seminars, Workshops and master classes	**Year**
Weekly research meetings, DICA, Leiden, the Netherlands	2018-2021
Journal club LUMC, Leiden, the Netherlands	2019-2021
Data verification masterclass, DICA, Leiden, the Netherlands	2020
Annual NUTRIM Symposium	2018-2021
Oral Presentations	**Year**
IFSO, 24th world congress Madrid. National Bariatric Surgery Registries: an International Comparison	2019
IFSO-EC Praag. (cancelled due to COVID-19). Metabolic effects of bariatric surgery on patients with type 2 diabetes in the Netherlands a propensity score matched comparison of RYGB vs SG	2020
Expert meeting bariatrische chirurgie. (cancelled due to COVID-19) Lange termijn uitkomsten van de Dutch Audit for Treatment of Obesity	2020
Dutch Society for Metabolic and Bariatric Surgery (DSMBS). Evaluating the association of hospital preference for type of bariatric procedure and patients' weight loss.	2021
IFSO, 25th world congress Miami. (cancelled due to COVID-19). Predicting serious complications after bariatric surgery: an external validation of the MBSC model using DATO	2021
IFSO, 25th world congress Miami. (cancelled due to COVID-19). Four-year survival after bariatric surgery; evaluating the association with textbook outcome in a national cohort	2021
IFSO, European Chapter Praag. Conversion to RYGB versus OAGB after failed primary gastric band: matched nationwide study	2021
IFSO, 12th Frankfurter meeting. Metabolic effects of bariatric surgery on patients with type 2 diabetes: a population-based study	2021
Zoom Forward 22, IFSO-EC & EASO. Predicting severe complications risks after bariatric surgery. *External validation of the Michigan Bariatric Surgery Collaborative prediction model using the Dutch Audit for Treatment of Obesity*	2022
The Future of Obesity Treatment symposium. Real world data in obesity treatment	2022
Dutch Society for Metabolic and Bariatric Surgery (DSMBS). Weight recurrence after sleeve gastrectomy vs roux-en-y gastric bypass: a propensity score matched nationwide analysis (presentation given by F. Bruinsma)	2023

Item	Year
Poster Presentations	**Year**
ICHOM. A generic PROM used for bariatric surgery in the Dutch Audit for Treatment of Obesity (DATO): responsiveness of the RAND-36 to detect clinical outcomes?	2019
Conferences	**Year**
NVvH Chirurgendagen – Voorjaarsdag, Veldhoven	2019
NVvh Chirurgendagen – Najaarsdag, Ede	2019
International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), World Congress, Madrid	2019
Dutch Society for Metabolic and Bariatric Surgery (DSMBS), Veenendaal	2020
International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), European Chapter, Praag	2020
NUTRIM Webinar Symposium	2020
International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), 11th Frankfurther meeting, Frankfurt	2020
International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), World Congress, Virtual	2020
Samenwerkende kwaliteitsregistraties (SKR) impact conference, Amsterdam	2021
Dutch Society for Metabolic and Bariatric Surgery (DSMBS), Veenendaal	2021
International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), 12th Frankfurther meeting, Frankfurt	2021
International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), TOSS, Antalya	2021
Zoom Forward 22, IFSO-EC & EASO, Maastricht	2022
NVvH Chirurgendagen – voorjaarsdag, Den Haag	2022
The Future of Obesity Treatment symposium. Real world data in obesity treatment, Maastricht	2022
Other	
Steering committee member Codman Dashboard Explorative	2021
Steering committee member Nederlandse Vereniging voor Overgewicht en Obesitas (NVOO)	2021-2023
Teaching	
Lectures	
DICA PhD Candidates	2018-2021
Supervising	
J. de Graaf, student master thesis	2021
Invited peer-reviews	
British Journal of Surgery	2020-2021

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Dankwoord

Eindelijk is het zo ver, mijn proefschrift! Het resultaat van jarenlang onderzoek en toewijding. Dit avontuur zou niet mogelijk zijn geweest zonder de steun en bijdrage van mijn familie, vrienden en collega's. Het was een bijzondere en mooie tijd waarvoor ik een ieder wil bedanken, in het bijzonder een aantal personen.

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Beste dr. S.W. Nienhuijs, mijn copromotor en dagelijkse begeleider. Beste Simon, vanaf dag 1 heb jij gezorgd dat ik mij thuis voel in jullie onderzoeksteam. Je betrokkenheid en niet te stoppen doorzettingsvermogen stimuleren elke onderzoeker net dat extra stapje te doen. Wat een bijzondere wetenschapper en chirurg ben jij. Je was altijd bereikbaar en ook als er weer een deadline voor revisions gehaald moest worden, was jij altijd de eerste om te reageren. Je deskundigheid, voortdurende begeleiding en vermogen om complexe vraagstukken te vereenvoudigen waren van onschatbare waarde. Bij elke praatje op een congres was jij aanwezig in de zaal om mij te steunen. Ik kon alles met jou bespreken en ik zal onze avondjes uit na een IFSO congres niet vergeten. Hartelijk dank Simon, voor je voortdurende steun en inspiratie.

Beste dr. P.J. Marang – van de Mheen, mijn copromotor en dagelijkse begeleidster. Beste Perla, mijn dagen in het LUMC bij jou zullen mij altijd bijblijven. Je regelde een kamertje voor mij zodat ik mij volledig kon richten op mijn promotie. Je vermogen om complexe concepten helder uit te leggen, om de statistiek verder uit te diepen, om mij aan te moedigen origineel te zijn in mijn benadering naar onderzoek heeft dit proefschrift naar een hoger niveau getild. De analyses die we wekelijks in 'R-studio' aan het doorspitten waren om de matching goed te krijgen, de journal clubs waarin we kritisch leerden zijn, onze wekelijkse gesprekken onder het genot van een koffie, maar ook de rood gemarkeerde documenten met je feedback die de artikelen extra diepgang gaven zal ik koesteren als mooie momenten. Bedankt voor je begeleiding, betrokkenheid en onuitputtelijke steun.

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Lieve secretaresses van DICA, Cunera (tante Q), maar later ook Ingeborg en Elly. Wat een gezelligheid weer elke ochtend. En de lekkernijen op jullie kamer ontbraken niet. Ik wist me weg altijd wel naar jullie te vinden voor een praatje (en stiekem gesnoep). Bedankt voor de leuke gesprekken en al jullie ondersteuning met betrekking tot DICA werkzaamheden. PS Ik geniet nog steeds elke dag van mijn echte Cunera aan de muur. Bedankt voor de tijd en passie die je erin hebt gestopt.

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Olivier, maat, collega, bro, je liefde voor Ajax liet je al snel merken door Arden gelijk in een tenue te zetten. Onze pauzes samen zal ik niet vergeten en je was altijd wel in om naar de patatzaak te lopen. Lekker pondjes bij eten.

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About the Author

About the Author

Erman Akpinar was born on the 3rd of May 1992 in Amsterdam, the Netherlands. He grew up with his Mother in the Transvaalstraat in Amsterdam. Most of his time he was active in sports playing football for AVV Zeeburgia and loved to play videogames. In 2009, he graduated from secondary school at the Pieter Nieuwland College. In the same year he was accepted for Medical school at the Vrije Universiteit Medical Center (VUmc).

During his clinical rotations his interest for the surgical professions bloomed, in particular for the general surgery. He extended this period by doing a rotation abroad in Tanzania for 3 months at the Haydom Lutheran Hospital. Here he participated in a surgical mission called 'Operatie Glimlach' which was initiated by 'Dokters van de Wereld' to help people with burn and traumatic injuries. His activities consisted of intakes, assisting during surgery, and doing the follow-up care at the outpatient clinic. His Master thesis was an extension of his interest for burn injuries, which consisted of investigating the development of hypertrophic scar formation after surgery at the department of plastic and reconstructive surgery in the VUmc. During this period his scientific interest sparked.

After graduating Medical school in 2016 he started as a surgical resident not in training at the department of surgery at the Maasstad Hospital. During his residency his interest for bariatric surgery began to grow. This period was marked by building clinical experience in the surgical field and his marriage in 2018.

At the end of 2018 he became part of the clinical researcher team at the Dutch Institute for Clinical Auditing and started his PhD trajectory on bariatric surgery at the Department of Surgery at the Maastricht University, under the supervision of his promotor prof. dr. J.W.M. Greve, and copromotores dr. S.W. Nienhuijs and dr. P.J. Marang - van de Mheen.

As a PhD candidate, he simultaneously coordinated the Patient Reported Outcome Measures after bariatric surgery for the Dutch Audit for Treatment of Obesity (DATO). During this time, he became interested in the perception of the patient's health status, level of impairment and health-related quality of life. After some research, he found out that there was no national association for patient representation and advocacy after bariatric surgery. Therefore, together with Omrum Aydin and Floris Westerink, he founded the Nederlandse Vereniging voor Overgewicht en Obesitas (NVOO). Currently he holds a position in the steering committee of the NVOO and supervises the scientific branch of the patient association.

In 2022 Erman returned to the clinic and started as a surgical resident not in training at the Amphia Hospital. He lives together with his wife Funda Albostanli and his son Arden Akpinar in Amsterdam.

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