Clinical outcomes in bariatric surgery

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CLINICAL OUTCOMES IN

BARIATRIC SURGERY

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Colophon
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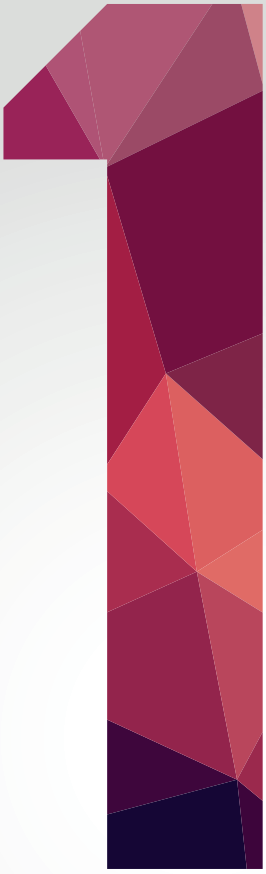

Introduction and Outline of This Thesis

"Every hospital should follow every patient it treats long enough to determine whether the treatment has been successful, and then to inquire 'if not, why not' with a view to preventing similar failures in the future."
— Ernest Codman, 1914

INTRODUCTION AND OUTLINE OF THIS THESIS

In the past decade, the prevalence of obesity has increased significantly in populations worldwide. Obesity, which is disproportionally more weight in relation to body height, is quantified by the body mass index (BMI). A BMI of >30 kg/m^2 represents obesity, ≥30.0 kg/m^2 severe obesity, and ≥40.0 kg/m^2 morbid obesity.[1]

Obesity is a complex, multifactorial, chronic disease that decreases health-related quality of life (QoL) and overall life expectancy.[2-4] Furthermore, several studies have demonstrated a strong association between BMI and development of life-impairing obesity-related comorbidities such as type 2 diabetes mellitus, hypertension, dyslipidemia, gastroesophageal reflux disease, obstructive sleep apnea syndrome, and musculoskeletal pain.[5-10] This thesis discusses the formation of a nationwide registry, the first short-term outcomes, and the interpretation of hospital comparison on a national and international level.

NON-OPERATIVE TREATMENT

Several strategies for weight loss have been proposed over the past few decades, with most consisting of first-line non-operative interventions.[11] Non-operative therapy for obesity carries the least risk and consists of diet, exercise, and behavioral modification. The diet programs appear to achieve weight loss by reducing calorie intake below energy expenditure combined with an increase in physical activity. Behavioral therapy is based on learning principles and is meant to assist in overcoming barriers to compliance with dietary therapy or increased physical activity. The results, however, often reveal a limited effect in terms of long-term weight management, whereas modest weight reduction is insufficient for significant improvement.[2, 12] Furthermore, there are currently no published studies describing significant sustained weight loss by diet therapy, exercise, or behavior modification in morbidly obese patients.[13]

SURGICAL TREATMENT

Surgical treatment is noted to be a more successful approach. In the "Consensus Conference on Gastrointestinal Surgery for Severe Obesity,"[14] long-term data on safety and efficacy of medical and surgical weight loss were reviewed. A panel of experts concluded that bariatric surgery has proven to be a long-term effective treatment option for morbid obesity and should be offered to obese patients unresponsive to non-operative therapy.[9, 15-17] In addition to sustained weight loss, surgical treatment provides additional benefits to people with obesity-related comorbidities.[9, 16, 18-21] According to the consensus-guidelines, patients are eligible for bariatric surgery if they have failed attempts at non-operative weight loss and have a BMI of ≥35.0 kg/m^2 with

obesity-related comorbidities or a BMI of ≥40.0 kg/m^2 with or without comorbidity. In the past decade, there has been a strong increase in acceptance of bariatric surgery, resulting in increased number of (bariatric) procedures and development of new surgical approaches.

BARIATRIC TECHNIQUES

Presently, bariatric surgery is predominantly performed laparoscopically. Traditionally bariatric surgery is categorized into three groups on the basis of the mechanism by which weight loss is induced: malabsorptive, restrictive, and a combination of the two.

The most frequently performed bariatric procedures in The Netherlands are the Roux-en-Y gastric bypass (RYGB) and the sleeve gastrectomy (SG).[22] The RYGB combines the restrictive and the malabsorptive components by decreasing the stomach size and by inducing nutrient malabsorption.[23, 24] The procedure is based on a gastrectomy with a Billroth II gastrojejunostomy.[21] The SG, however, consists solely of a restrictive component by decreasing the stomach size. Traditionally, SG serves as a bridge to a second-stage procedure, such as a gastric bypass.[22] Therefore, this type of surgery is mostly performed as an alternative to patients with extreme obesity (≥50.0 kg/m^2) or if RYGB is technically not feasible. Nowadays, the SG is mainly performed as a single-stage procedure and no longer exclusively for patients with extreme obesity.

THE NEED TO KNOW

Simultaneously with the exponentially increased numbers of bariatric procedures performed in the past decade, an increasing demand for reliable data on the effectiveness and safety of healthcare has emerged. This demand for more information was noted after the publication of a ground-breaking report "To Err is Human: Building a Safer Health System" in 2006.[25] The report stated that the current level of healthcare safety in the United States appeared to be far behind other high-risk industries. The goal of the report was to break the cycle of inaction regarding medical errors by advocating a comprehensive approach to improving patient safety.[25] In response to public and government demands to minimize these medical errors and improve patient care, there was a growing interest among Dutch medical professionals to define and understand their own outcomes.[26]

Clinical auditing is a powerful tool for understanding clinical outcomes in healthcare. Evidence for these outcomes is provided by collecting data, followed by ongoing review and assessment of performance and outcomes. One of the first audits was undertaken by Florence Nightingale in 1854. Nightingale was appalled by the unsanitary conditions and high mortality rates among soldiers. By keeping track of the mortality rates among

wounded soldiers, she demonstrated that strict hygiene contributed to significantly better survival rates of her patients. Her methodical approach is recognized as one of the earliest programs in outcome management.

Another pioneer advocating clinical auditing was Ernest Codman, a former surgeon from Massachusetts General Hospital (MGH). In 1912, he proposed that physicians should not only measure what they did but also track their results over time. He proposed the "end result idea." By measuring clinical outcomes of individual surgeons, surgical errors could be identified on specific patients. This provided physicians with the opportunity to identify clinical misadventures that could serve as the foundation for improving the care for future patients.[27, 28] MGH, however, refused his plan for evaluating the competence of their surgeons and therefore he lost his staff privileges.

In contrast to Nightingale's more epidemiological approach, Codman's idea was that each individual physician should participate in his or her own quality improvement by measuring individual outcomes. By measuring these outcomes, valuable data are generated for systematic critical analysis of the quality of medical care.

Clinical auditing can be described as a cycle of different stages that follows a systematic approach: (#1) identify the problem, (#2) define criteria and standards, (#3) collect data, (#4) compare outcomes with criteria and standards, (#5) implement changes, and (#6) re-audit. As the process continues, each cycle aspires to a higher level of quality. A successful example, and also the first Dutch surgical clinical audit, is the Dutch Surgical Colorectal Audit (DSCA).[29] The aim of this nationwide registry is to evaluate and improve surgical outcomes for patients with colorectal cancer.

CLINICAL AUDITING

The external validity of case series, observational studies, and randomized controlled trials may not reflect everyday practice and outcome.[30] With the registration of "real-world" data by clinical auditing, a more reliable insight into everyday practice can be provided.[31, 32] Auditing provides healthcare personnel reliable benchmarked information on structure, process, and outcome parameters based on nationwide data. These parameters are based on the Donabedian model[28], a systematic framework for examining and evaluating the quality of care provided. According to Donabedian's healthcare quality model, improvements in the structure of care should lead to improvements in clinical processes, which should in turn improve patient outcomes.[28, 29]

After the initiation of the DSCA (nowadays called DCRA), the Dutch Institute for Clinical Auditing (DICA) was founded with the objective to facilitate and organize the initiation

of nationwide audits in a uniform matter. With a secured web-based data collection system and a weekly benchmarked online feedback report, DICA provides structural insights into the care provided.

DUTCH AUDIT FOR TREATMENT OF OBESITY

In collaboration with DICA, the Dutch Society for Metabolic and Bariatric Surgery decided to begin a nationwide bariatric registry in 2013. The main purpose of Dutch Audit for Treatment of Obesity (DATO) was to provide insights and improve the quality of bariatric care by providing reliable, nationwide, benchmarked information on process and outcome parameters. The registry had to cover and include data on all bariatric procedures provided in all Dutch bariatric centers. The DATO was successfully initiated in 2015 and the first results were published in 2016. Currently, all 18 bariatric centers mandatorily participate and register data on all bariatric procedures. The initiation, implementation, and first short-term results of DATO are described in **Chapter 2**.[26]

The registry provides a nationwide overview of all bariatric procedures conducted in the Netherlands. A collaboration of the DATO's scientific committee, medical professionals, and other external healthcare providers formulates an annual list of structure, process, and outcome indicators. These results are published yearly and are publicly accessible.

To guarantee the quality, reliability, and applicability, extensive methodological support is provided by DICA. The support can be used to determine whether the treated patient population in each hospital differs significantly from each other. If differences are found, case-mix corrections are applied to provide reliable comparisons between individual hospitals. However, the published results from DATO do not require any case-mix adjustments at the moment. More information is provided in **Chapter 1** of this thesis.

By correct interpretation of the results, positive and negative outliers could be identified to stimulate healthcare professionals to improve perioperative bariatric care with actable information. One of the most common graphical methods to identify outliers is by using funnel plots. These plots show the outcome of interest (vertical axis) per hospital by using predefined control limits. The horizontal axis shows the number of interventions or the expected number of events, depending on the application of case-mix correction. If a hospital falls outside the predefined control limits, it is identified as a positive or negative outlier. This information could be used to initiate quality improvements.

INTERNATIONAL COMPARISON

In the first few years of DATO, the most process and outcome indicators revealed little to no variation between individual healthcare providers. To provide further insights into the quality of bariatric care, the demand for international comparison and evaluation increased.[30] A reliable comparison, however, can only be made with data from nationwide high-quality registries containing detailed clinical information about patients with obesity treated using bariatric surgery.

During the past decade, several nationwide European bariatric registries have been established to monitor the variety of procedures and their outcomes.[31, 33, 34] Only a few registries contain essential clinical information to such a degree that a meaningful comparison with DATO can be made. After extensive preliminary research that we conducted in 2016, addressing all technical and content issues, it appeared that the "Scandinavian Obesity Surgery Registry" (SOReg) was the only suitable registry for reliable international comparison of short-term surgical outcomes. SOReg is a Swedish nationwide mandatory bariatric surgery registry that started collecting data from 2007. In 2014, Norway joined SOReg and started to register bariatric patients from 2015.[35] In **Chapter 3**, a comparison has been made between demographics and the short-term results after primary surgery from DATO and SOReg.[36]

ROUX-EN-Y GASTRIC BYPASS OR SLEEVE GASTRECTOMY

Recent scientific literature explains the crucial role of gastrointestinal (GI) tract-derived signals in energy and hormone regulation.[37] RYGB and SG both alter the GI anatomy and nutrient flow in patients with obesity.[19, 38, 39] These procedures affect the GI signals, ultimately leading to weight loss and metabolic improvements. However, postoperative outcomes are highly variable between individual patients, with a large proportion of patients experiencing poor long-term outcomes.[22-24] RYGB and SG are markedly different anatomically and thus differentially impact on GI signaling and bodyweight regulation. To identify patients who may benefit the most from surgery and to tailor the surgical procedure to the individual is an extremely important topic that remains unanswered. This question could be answered in the near future by examining the data from multiple registries. The first question that needs to be answered is which bariatric technique is the most effective procedure. An attempt has been made in **Chapter 4**, describing a nationwide comparison study reflecting the short-term surgical outcomes after primary surgery between the two mainly performed bariatric procedures in the Netherlands, Norway, and Sweden.[36]

COMPOSITE OUTCOME MEASURE

Quality measurements in bariatric surgery mainly focus on readily available and easily understandable parameters.[31, 40] These parameters provide only insights into single outcomes and not necessarily into the entire care process. However, not only are different outcome parameters most likely related to each other, also the occurrence of individual parameters, such as complications and mortality, are relatively rare after bariatric surgery.[36, 41] Combining multiple single outcome parameters could provide more power, by providing a higher number of events, to detect significant and clinically relevant hospital differences.[42-44] Therefore, these outcomes will less likely differ due to chance variation alone.[45] **Chapter 5** describes a detailed composite outcome measure (ordered textbook outcome) consisting of multiple postoperative single outcome parameters for bariatric surgery.

QUALITY OF LIFE

Most outcomes in nationwide registries are standard clinical outcomes, such as weight loss, mortality, and postoperative complications.[26, 29, 42-44, 46, 47] These outcomes generate quantitative data that are convenient for the most commonly performed analyses. This may be one of the reasons that these outcomes have been most often used in international literature to measure the success rate for bariatric surgery.[5, 19, 20, 30, 48] Particularly, weight loss and reduction of obesity-related comorbidities were used as the most important indicators to calculate the success rate of bariatric surgery. However, by using these quantitative data the, also important, psychological and social consequences of morbid obesity and the impact of bariatric surgery are missed.

It is important to include QoL assessments in the evaluation of health interventions of bariatric surgery as the patient perspective can provide valuable information on the efficacy of bariatric surgery that cannot be obtained from clinical outcome measures alone.[18, 49, 50] A comparison study between the two most used bariatric techniques and the improvement in QoL after primary bariatric surgery is described in **Chapter 6**.

OBESE PATIENTS IN OTHER REGISTRIES

Obesity is a complex, multifactorial, chronic disease. Epidemiologic studies have demonstrated the association between obesity and an increased risk of developing certain cancers, such as colorectal, breast, kidney, pancreatic, liver, and endometrial cancer.[51]

Currently, data from DATO consist of the information solely entered by bariatric surgeons. However, the multifactorial aspect of obesity also covers several other disciplines. Some of these disciplines register their outcomes in their own registry. By combining data from these registries, existing data from a single registry can be

enriched. Enriched data can be used to test new hypotheses and prefill matching data points from different registries. For example, the weight and height of a patient only need to be entered once, providing higher reliability of the entered data and reducing the registration burden for individual healthcare providers.

With the support of DICA, 21 registries have been established in the Netherlands. Because of the uniformity and corresponding structure of each audit, a pseudo-randomized and irreversibly anonymized cross-linking between different registries could be possible in the near future. Meanwhile, it seemed worthwhile to conduct research on obese subjects with data collected by other registries. By using data from other registries, we can check the usability and validity of the provided data to examine whether data from other registries are of added value. Potentially, data from DATO can be enriched with data from other registries in the future.

Obese patients with colorectal cancer were identified as a specific patient group by using data from the DSCA. This offered the opportunity to evaluate the influence of obesity on perioperative and short-term postoperative outcomes in patients surgically treated for colorectal cancer. In addition, a comparison can be made between bariatric specialized hospitals and hospitals that only perform colorectal cancer surgery. The results of the perioperative and postoperative outcomes could identify the relationship between obesity and treatment-related morbidity after colorectal cancer surgery, as is described in **Chapter 7**.

DISCUSSION AND SUMMARY

Chapter 8 provides the general discussion and future perspectives of the main findings and implications of this thesis, followed by the English and Dutch summary in **Chapter 9**.

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A Dutch Nationwide Bariatric Quality Registry: DATO

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ABSTRACT

INTRODUCTION

In the Netherlands, the number of bariatric procedures increased exponentially in the 90s. To ensure and improve the quality of bariatric surgery, the nationwide Dutch Audit for Treatment of Obesity (DATO) was established in 2014. The audit was coordinated by the Dutch Institute for Clinical Auditing (DICA). This article provides a review of the aforementioned process in establishing a nationwide registry in the Netherlands.

MATERIALS AND METHODS

In collaboration with the DATO's scientific committee and other stakeholders, an annual list of several external quality indicators was formulated. This list consists of volume, process, and outcome indicators.

In addition to the annual external indicators, the database permits individual hospitals to analyze their own data. The dashboard provides several standardized reports and detailed quality indicators, which are updated on a weekly base.

RESULTS

Since the start, all 18 Dutch bariatric centers participated in the nationwide audit. A total of 21,941 cases were registered between 2015 and 2016. By 2016, the required variables were registered in 94.3% of all cases. A severe complicated course was seen in 2.87%, and mortality in 0.05% in 2016. The first-year follow-up shows a > 20% TWL in 86.1% of the registered cases.

DISCUSSION

The DATO has become rapidly a mature registry. The well-organized structure of the national audit institution DICA and governmental funding were essential. However, most important were the bariatric teams themselves. The authors believe reporting the results from the registry has already contributed to more knowledge and acceptance by other health care providers.

INTRODUCTION

Bariatric surgery has already been proven as the only long-term effective treatment option for morbid obesity in terms of weight loss and comorbidities reduction.[1-4] Although this effect is nowadays embedded in several guidelines and accepted by most practitioners, still some resistance exists.[5, 6] Especially for bariatric surgery, showing outcome transparently by clinical auditing is of utmost importance.[7] This should not only consist of the clinical outcomes, but also process indicators and patient-reported outcomes should be included as well.[8, 9] For this purpose, a registry was necessary for structured evaluation of bariatric surgical care.

HISTORY

In the Netherlands, the number of bariatric procedures increased exponentially in the 90s.[10] To deal with this increase, various health insurers started to keep track of their own individual quality indicators. The result was a fragmented and incomparable list of outcomes between various healthcare providers.

In order to define comparable outcomes, healthcare professionals took the initiative themselves. In 1996, the bariatric institutions of Belgium, the Netherlands, and Luxembourg united into the BeNeLux Association of Bariatric Surgeons (BABS). This was an improvement for scientific research. However, for the improvement of quality in healthcare, the differences between countries seemed to be a burden.

This led to the formation of a national working group for bariatric surgeons in the Netherlands, initiated by the Dutch Society for Gastrointestinal Surgery (DSGS), which was a subsidiary association of the Association of Surgeons of the Netherlands (ASN). This working group continued in April 2011 as the Dutch Society for Metabolic and Bariatric Surgery (DSMBS) and is now also the official national chapter of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO).

REGISTRIES

At the end of the 90s, only a few local initiatives were launched echoing various European registries. A commonly used system in the early 2000's was the Patients Outcome Measurement Tool (POMT), originally co-funded by a medical device supplier. Some users regarded the interference of industry as a restriction, others experienced some technical drawbacks. Due to the large input of international incomparable data, the results were difficult to interpret for each individual hospital.

Most bariatric centers, not using POMT, had their own hospital ICT system or used Microsoft Excel as a database management system. Derived from POMT or homemade systems, data could be used for iBAR (International BAriatric Registry). This European registry was launched in 2008 by the European Accreditation Council for Bariatric Surgery (EAC-BS). The aim of this registry was the creation of guidelines that could be applied to different global areas and define surgeon's credentials and institutional requirements for safe and efficient management of morbidly obese patients. The implementation of these guidelines would be applied by IFSO regional chapters in collaboration with the national bariatric and metabolic societies. In Europe, Middle East, and Africa, the IFSO European Chapter (IFSO-EC) was authorized to approve these "Centers of Excellence" (COE) in collaboration with the European Accreditation Council for Bariatric Surgery (EAC-BS).

Despite the promising start, the international data were too difficult to interpret and comparison between countries was complicated by European laws. In addition, the mandatory set contained too many variables. Due to this large number of variables, there was an insufficient focus on the processes and outcomes of the delivered care. Therefore, this registry was not suitable for a nationwide mandatory registry (**Fig. 1**).

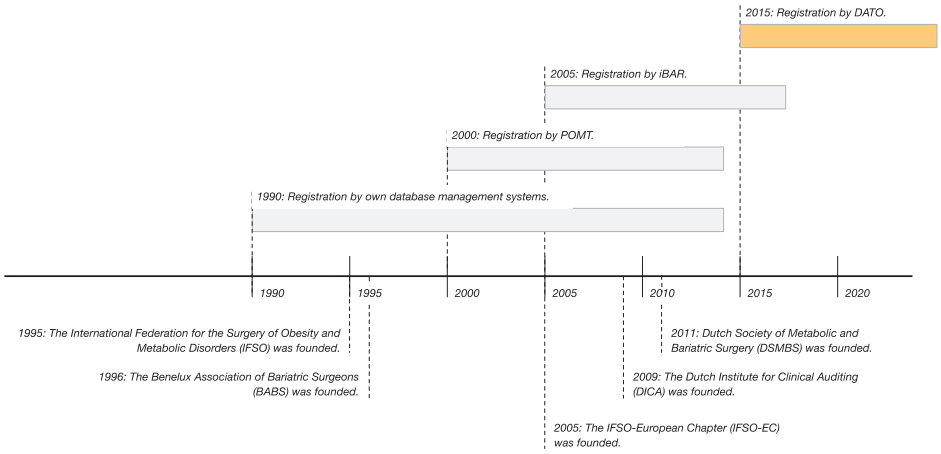

Figure 1: A timeline about the DATO's origin. Abbreviations: POMT, Patients Outcome Measurement Tool; iBAR, international BAriatric Registry; DATO, Dutch Audit for Treatment of Obesity.

DICA

A successful Dutch example of clinical auditing was the Dutch Surgical Colorectal Audit (DSCA), born from the demand for national quality registries in the surgical field.[11] From this initiative, the Dutch Institute for Clinical Auditing (DICA) was founded in

2009. DICA now has 23 national registries, which facilitates clinical audits for 15 surgical and non-surgical societies. DICA consists of a directional board, management board, methodological board providing supervision of applied methodology, privacy committee providing supervision on privacy issues, and a scientific bureau facilitating a sound board for the registries (**Fig. 2**).

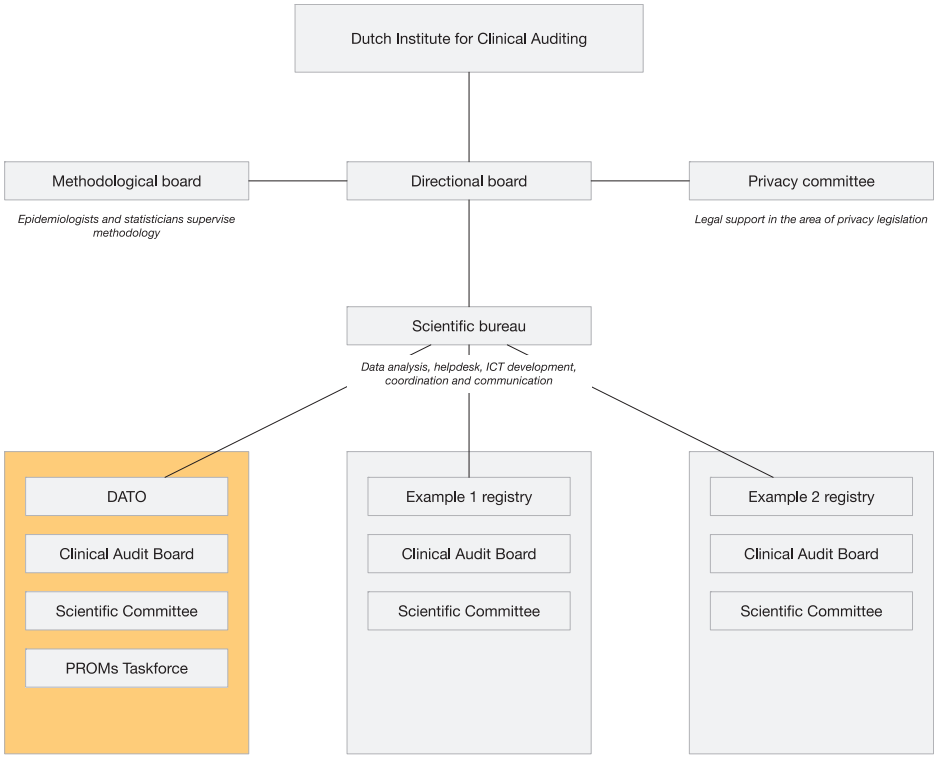

Figure 2: Organisational structure of the Dutch Institute for Clinical Auditing (DICA). Abbreviations: DATO, Dutch Audit for Treatment of Obesity.

AIM

The aim of this manuscript was to provide a review of the aforementioned process in establishing a nationwide registry in the Netherlands, with the Dutch Audit of Treatment of Obesity (DATO) as a result.

METHODS

FUNDING

One of the important goals of the DSMBS was to establish a nationwide registry. In 2012, the DSMBS announced the start of a new nationwide mandatory registry. The funding arose from a special quality improvement grant from the umbrella organization of nine health insurers in the Netherlands, called "Zorgverzekeraars Nederland" (ZN). ZN offered a financial structure to establish and maintain this nationwide audit. In co-operation with DICA, the Dutch Audit for Treatment of Obesity (DATO) was established in 2014. Structural funding is currently provided by the same umbrella organization. The audit has officially started on January 1, 2015.

SCIENTIFIC COMMITTEE

A scientific committee and a clinical audit board (CAB) was put in charge of overseeing its long-term goals and monitoring the quality of the registry.

The scientific committee represents all 18 bariatric centers and all members are mandated from the practicing hospital where they are employed. As a result, all practicing hospitals have an influence on the decision making within the scientific committee. In addition, the scientific committee has the task of assessing the quality and feasibility of (international) scientific applications.

The scientific committee provides three mandated deputies for the CAB. The CAB consists of a chairman, a secretary, and a treasurer and is responsible for day-to-day running of the registry. Any decision taken by the CAB must be officially reported to the scientific committee.

PATIENT SELECTION

The nationwide database covers all bariatric procedures in the Netherlands. The inclusion criteria for primary bariatric surgery in the Netherlands are linked to stringent requirements which are bundled in the Dutch Morbid Obesity Directive.[12] These inclusion criteria were defined by international literature and expert opinions.[4, 13, 14]

Patients must be 18 years or older and must be sufficiently healthy to undergo general anesthesia and surgery. In addition, they must have a body mass index (BMI) of ≥ 40.0 kg/m^2, or a BMI ≥ 35.0 kg/m^2 in combination with at least one of the 6 major obese-related comorbidities: diabetes mellitus [1, 2, 15], hypertension [1, 15], dyslipidemia [15], obstructive sleep apnea syndrome (OSAS) [16], gastroesophageal reflux disease (GERD) [17] and musculoskeletal pain [18]. Weight loss as a result of intensive treatment prior to surgery

(in patients who reached a weight below the minimum BMI indication for surgery) is not a contraindication for planned bariatric surgery.

Bariatric surgery is contraindicated if patients suffer from severe psychological problems, been addicted to alcohol [19], drugs [20] or other substances, an active gastrointestinal disease, or a disease that is life threatening on short terms.

REGISTRATION

The surgical department is primarily responsible for all the data entry. Some hospitals decided to transfer the responsibility of screening and follow-up data to other institutions like the Dutch Obesity Clinics (NOK). An overview of parameters recorded in DATO was given in **Table 1**.

For identification of unique patients, social security number, surname, date of birth, and sex are mandatory and registered. This patient's traceable data is anonymized by a data processing company before analyzes taken place. Therefore, all data is anonymous for people outside the hospital.

SCREENING

The registration of the pre-operative comorbidities occurs when the specific condition is present on the day of screening. Comorbidity is thus given in the registry as a yes/no option. To predict the postoperative mortality, the Charlson Comorbidity Index (CCI) is registered.[21, 22] As for diabetes mellitus, hypertension, dyslipidemia, GERD, and OSAS, a few sub-items are registered like the use of medication and laboratory tests.

To chart the surgical history, 10 main surgical areas are specified: surgical interventions of hernias, stomach, duodenum, liver, biliary tract, pancreas, small intestine, appendix, colon, and rectum. In addition, a second item registers which bariatric procedure has taken place in the past.

PROCEDURE AND FOLLOW-UP

Registration of the operation date and type of procedure with corresponding details is mandatory. A maximum of 5 procedure-specific items are requested per procedure. Complications are scored using the Clavien-Dindo Classification of Surgical Complications (CDC).[23]

The follow-up consists of postoperative weight registration, monitoring of pre-operative registered comorbidities, and any (long-term) complications (**Table 1**). The follow-up

Table 1: Variables recorded in DATO. M: mandatory; R: recommended.

Section (dataset)	Variable	Baseline	Follow-up
Patient characteristics	Social security number	M	-
	Date of birth	M	-
	Sex	M	-
	Alive/dead status	M	M
Screening	Weight	M	M
	Highest weight	R	-
	Length	M	-
	Hypertension	M	M
	Diabetes mellitus	M	M
	Dyslipidemia	M	M
	GERD	M	M
	OSAS	M	M
	Musculoskeletal pain	M	M
	Charlson Comorbidity Index	R	-
Abdominal history	If yes - 8 subitems could be answered [a]	R	-
Bariatric history	If yes - 5 subitems could be answered [b]	R	-
Procedure	Date of operation	M	-
	Name/code of surgeon	R	-
	ASA score	M	-
	Type of surgical procedure	M	-
	Clavien-Dindo Classification of Surgical Complications	M	-
Follow-up	Evaluation comorbidities	-	M
	Complications during previous period [c]	-	M
PROMs	RAND-36	M	M

Legend: [a] surgical interventions of hernia's, stomach, duodenum, liver, biliary tract, pancreas, small intestine, appendix, colon and/or rectum by laparoscopy or laparotomy; [b] Year of operation, type of surgery, type of technique and/or hospital; [c] as defined by Clavien-Dindo Classification of Surgical Complications.
Abbreviations: ASA, American Society of Anesthesiologists.

will be recorded at 3, 6, 9, 12, 24, 36, 48, and 60 months depending on the hospital and the applicable protocol. Each patient must be seen at least once a year (**Table 2**).

RAND-36

Patient-reported outcomes (PROs) are measured with the RAND 36-item Health Survey (RAND-36). The RAND-36 has been developed within the framework of the RAND

Health Science Program in the USA. The questionnaire is identical to the MOS SF-36 questionnaire, but contains another scoring algorithm. The RAND-36 measures 8 health domains: physical functioning, role limitations caused by physical health problems, and

Table 2: Annual quality indicator DATO report.

Number	Indicator	2015			2016		
		N	D	%	N	D	%
	Process						
2	Percentage of complete registered patient records regarding primary and/or secondary surgery.	9,534	10,355	92.1%	10,922	11,586	94.3%
3	Percentage of primary operated patients, meeting the inclusion criteria on the basis of BMI and age.	8,371	8,756	95.6%	9,625	10,028	96.0%
4	Percentage of primary operated patients, who are lost to follow-up in the first year after primary surgery.	-	-	-	131	6,433	2.04%
	Outcome						
5	Percentage of primary and/or secondary operated patients, with severe complications (CDC grade 3 or higher) within 30 days after surgery.	305	10,355	2.92%	332	11,586	2.87%
6	Percentage of primary and/or secondary operated patients, with a postoperative intervention within 30 days after surgery.	294	10,355	2.84%	316	11,586	2.73%
7	Percentage of primary operated patients, with more than 50% Excess Weight Loss (%EWL) in the first year after primary surgery.	-	-	-	5,346	6,433	83.1%
8	Percentage of primary operated patients, with more than 20% Total Weight Loss (%TWL) in the first year after primary surgery.	-	-	-	5,538	6,433	86.1%

Abbreviations: N, numerator; D, denominator; CDC, Clavien-Dindo Classification of Surgical Complications; BMI, body mass index.

role limitations caused by emotional problems, social functioning, emotional well-being, vitality, pain, and general health perception.[24-26]

DATA ENTRY

There are two methods to provide the required data for DATO. The first method is by a so-called batch file, where the hospital itself extracts the necessary data from its own electronic health records software. A second option uses a secure web-based registration interface, offered by DICA. The PROs are measured in a separate database and can be cross-matched with the clinical database.

DATA QUALITY

To increase data quality, a clear definition is set for each data entry point with an additional explanation mark. If impracticable values or the data yields outside its predefined

range, an error message occurs. A second safety measure is an automatic generated alert list, with a list of all incomplete mandatory variables for each

patient record.

Once every 2 years, DICA facilitates monitoring of data quality by an external organization. Trained personnel randomly verify hospital data entered in DATO with their own electronic patient records. The results of all randomly chosen hospitals are discussed and assessed by an external quality committee. The results and recommendations will eventually be presented in an online accessible report.

QUALITY INDICATORS

In collaboration with the DATO's scientific committee, professional societies, hospital organizations, Dutch Patient Federation (DPF), and the health insurance companies, an annual list of external quality indicators is formulated. Indicators were derived from the international literature or written on a consensus-based development process within the scientific committee. The list is annually approved and accredited by various stakeholders. In relation to quantity and quality, the minimum volume was set by DSMBS at 100 procedures per individual hospital in 2015 and 2016.

To analyze the different aspects of the surgical process, there are three types of quality indicators. The structure indicator provides information about the amount of bariatric procedures. The process indicators provide information about the completeness of registered (mandatory) variables to calculate all other indicators, correctness of the individual indication for bariatric surgery, and the lost to follow-up. The outcome indicators focus on clinical outcomes after bariatric surgery and possible surgical and non-surgical complications.

The lost to-follow-up indicator provides insight into the number of patients who are no longer visiting the outpatient clinic in their own hospital. The registration year for indicators with follow-up data runs from September to September. In these cases, there are no patients wrongly considered missing when their appointment falls within 12 to 14.5 months after the primary surgery date. This also applies to the indicator excess weight loss (EWL) and total weight loss (TWL).

Excess weight loss (EWL) is calculated using the formula $\frac{initial\ weight - postoperative\ weight}{initial\ weight - a}$, with reference point a as an ideal BMI of 25 kg/m^2. Total Weight Loss (TWL) is calculated with the formula $\frac{initial\ weight - postoperative\ weight}{initial\ weight}$.[5, 27]

BENCHMARK

The database permits individual hospitals to analyze their own data. The dashboard provides several standardized reports and detailed quality indicators, which are updated on a weekly basis in a secured web-based environment, called myDATO. Participating hospitals recognize their own results in these funnel plots from a highlighted dot. The results of any other hospital are shown with an anonymous gray dot (**Fig. 3**).

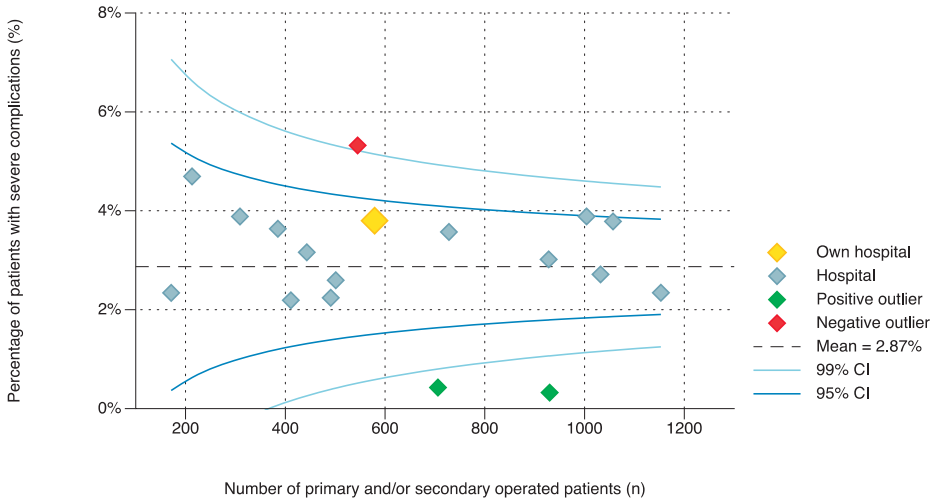

Figure 3: Percentage of primary operated patients in 2016, registered in the Dutch Audit for Treatment of Obesity (DATO), with severe complications (Clavien-Dindo grade 3 or higher) within 30 days after surgery, as reported per hospital.

ANALYSIS

Differences between patient and treatment characteristics were described using frequency tables. Categorical variables were compared using the chi-square trend test. Results of quality indicators and outcomes were presented concerning patients who had primary and/or secondary surgery from January 1, 2015, until December 31, 2016. Differences in quality indicator results over time were calculated with the chi-square trend test.

R version 3.4.1 is used for statistical analysis in combination with the "Companion to Applied Regression"-package (car 2.1–5) and "A Grammar of Data Manipulation"-package (dplyr 0.7.2).

RESULTS

Between 2015 and 2016, a total of 21,634 unique patients were registered in the DATO, with a total record count of 21,941. Of these, 18,784 (85.6%) operations were primary procedures. The mean age was 43.8 years (± 11.2 SD), with a median of 44 years. The mean BMI was 43.3 kg/m^2 (± 5.4 SD) and median of 42.3 kg/m^2.

The largest group of procedures involved patients with a Roux-en-Y gastric bypass (RYGB) (72.4%; n = 15,889), followed by gastric sleeve (GS) (17.7%; n = 3885), one anastomosis gastric bypass (OAGB) (5.9%; n = 1298) and other procedures (4.0%; n = 869).

STRUCTURE INDICATOR

All 18 bariatric centers met the quality indicator regarding a minimum of 100 bariatric procedures per individual hospital, with a range of 171 to 1,153 procedures.

PROCESS INDICATORS

The process indicator defined as completeness of the registered patient, which means all mandatory variables were registered in DATO to calculate the indicators, revealed a 92.1% (n = 9534) completeness in 2015, which increased in 2016 to 94.3% (n = 11,586).

In 2015, 95.6% (n = 8371) of the cases met the requirements for bariatric surgery, which increased in 2016 to 96.0% (n = 9625). In 0.8% (n = 169) of all registered cases, the BMI were unknown, 2.0% (n = 431) had an unknown presence of any comorbidity, and in 0.02% (n = 5), the age could not be calculated.

In 2016, the lost to-follow-up percentage was 2.04% (n = 131) of the 6433 primary bariatric procedures performed from January to October 2015.

OUTCOME INDICATORS

The first measured outcome indicator was mortality, also measured as CDC grade 5, within 30 days after surgery or during the same hospital stay. In 2015, 10 patients (0.1%) died after surgery; whereas, 6 patients (0.05%) died in 2016.

The postoperative complicated course within 30 days after surgery or during the same hospital stay was measured by CDC grade 3 or higher. Grade 4 was described as life-threatening complications requiring intensive care admission, which occurred 65 times (0.6%) in 2015 and 91 times (0.8%) in 2016. Requiring surgical, endoscopic, or radiological intervention (grade 3) had to take place 230 times (2.2%) in 2015 and 235

times (2.0%) in 2016. Added together, any complication during admission occurred in 3.0% (n = 305) of the cases in 2015 and 2.8% (n = 322) in 2016.

In 2016, 83.1% (n = 5346) of the operated patients from January 2015 till October 2015 had reached more than 50% EWL after primary surgery. The group with the highest percentage of > 50% EWL was OAGB (86.8%; n = 275), followed by RYGB (85.0%; n = 4218), GS (72.3%; n = 825), and other procedures (34.5%; n = 29).

From January 2015 till October 2015, 86.1% (n = 5538) of the operated patients succeeded more than 20% Total Weight Loss (TWL) after primary surgery at the first-year follow-up in 2016. The highest percentage of >20% TWL, was measured at OAGB (90.2%; n = 286), followed by RYGB (87.2%; n = 4325), GS (78.8%; n = 899) and other procedures (34.5%; n = 29).

DISCUSSION

This manuscript provided an extensive and complete overview of the aforementioned process in establishing a nationwide registry in the Netherlands, with the Dutch Audit of Treatment of Obesity (DATO) as a result.

DATO was mandatory for all bariatric centers, and therefore it was required to register all bariatric procedures. This was a requirement of the insurance companies to carry out bariatric surgery. DATO provided a nationwide transparent overview and results of bariatric procedures. By identifying positive outliers based on benchmarked indicators, DATO can provide healthcare professionals with actable information to improve their care and patients with valid information to choose a hospital of their preference.

CLINICAL AUDITING

The cornerstone of effective auditing is to provide high quality standards for entering data in an online accessible tool, using uniform international definitions, and producing interactive feedback charts for individual healthcare centers to improve care where necessary. Only when all surgeons and healthcare centers are participating in the registry, valid conclusion can be drawn from the provided benchmark information.[11, 28, 29] In the first years of registration, DATO succeed in the mission of high quality data, national coverage, and providing useful benchmark information for the individual clinic.[30]

COMPLICATED COURSE

Bariatric procedures were considered relatively safe, regarding to other surgical interventions, where mortality and morbidity were considered acceptable.[1, 4, 31, 32] With 16 deaths out of 21,634 unique patients in the past 2 years, bariatric surgery in the Netherlands can be considered relatively safe. A severe complication during admission was characterized by CDC grade 3 or higher. This occurs in 2.9% of patients. It is remarkable that in about 0.8% of cases, the "complication" involved a diagnostic laparoscopy. In bariatric surgery, however, this is considered a valuable diagnostic tool. When compared to international literature, the number of serious complications was significantly lower in DATO [4, 31]

LIMITATIONS

The DATO dataset contains a large set of data points to cover a wide variety of bariatric treatment characteristics. This is associated with a substantial administrative burden, because bariatric surgeons are responsible for providing their own surgical and follow-up data. Nevertheless, the dataset is limited and needs careful evaluation on a yearly base to prevent adverse grow. Technological innovation will contribute to higher data quality and smoother registration processes. In addition, it will be possible to get more useful information from other sources of registration to improve patient care.

Because the data provided by hospitals is self-reported, data fraud is a possible adverse effect. Therefore, an independent third-party visits bariatric centers and produces discrepancy reports to validate the data of individual centers. Bariatric centers receive the report and use it to improve the quality of data entry by their bariatric surgeons or trained personnel. A third limitation concerns the content of the DATO. From the start, the audit aimed to work together with paramedics and post-bariatric care providers. However, there are some privacy issues, and therefore it has been decided to focus primarily on bariatric surgery for now.

FUTURE PERSPECTIVES

DATO was designed with the idea that registering clinical information is not sufficient to give a total view of the outcomes of the treatment of bariatric surgery. It was immediately decided by the scientific bureau to measure PROs as well. Because these two instruments could technically not directly be linked, the PROs are measured in a separate database. A cross-matching with the clinical database is planned. For further improvement, initiatives are currently being undertaken for comparison with other European registries.

CONCLUSION

The Dutch Audit for Treatment of Obesity has become rapidly a mature registry. The well-organized structure of the national audit, the cooperation with DICA, and governmental funding are essential. However, most importantly were the bariatric surgeons themselves: unconditional nationwide participation including very high response for PROMs. The authors believe reporting the results from the registry has already contributed to more knowledge and acceptance by other health care providers, improved quality as each center got feedback about its performance, and improved discussion with health organizations such as insurance companies about quality and indicators. This provides enthusiasm for the future.

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Perioperative Outcomes of Primary Bariatric Surgery in North-Western Europe: A Pooled Multinational Registry Analysis

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ABSTRACT

INTRODUCTION

The global prevalence of obesity has increased in recent decades, and bariatric surgery has become a part of the treatment algorithm of obesity. National high-quality registries enable large-scale evaluations of the use and outcome of bariatric surgery and may allow for improved knowledge. The main objective was to evaluate the rate and type of complications after primary bariatric surgery in three North-Western European countries using nationwide registries.

MATERIALS AND METHODS

Data from three registries for bariatric surgery were used (January 2015–December 2016). All registries have nationwide coverage with data on patient characteristics, obesity-related diseases, surgical technique, complications, grading of complications, reinterventions, readmissions, and mortality. Eligibility criteria for bariatric surgery were similar and included body mass index of ≥ 40.0 or ≥ 35.0 kg/m^2, with one or more obesity-associated diseases.

RESULTS

A total of 35,858 procedures (32,177 primary) were registered. The most common procedure was gastric bypass in the Netherlands (78.9%) and Sweden (67.0%), and sleeve gastrectomy in Norway (58.2%). A total of 904 (2.8%) patients developed major complications after primary surgery and 12 patients (0.04%) died within 30 days. Total number of complications between the registries were comparable ($p = 0.939$). However, significant differences were seen for Clavien-Dindo Classification grades IIIb and IV ($p < 0.001$). Pooled readmission rates were 4.3% ($n = 1386$).

DISCUSSION

Bariatric surgery is safely performed in the three evaluated countries. Standardization of registries and consensus of variables are essential for international comparison and may contribute to improved quality of treatment across nations.

INTRODUCTION

The global prevalence of obesity and associated diseases has increased considerably in recent decades. Bariatric surgery has become a part of the treatment algorithm of obesity as significant and sustained weight loss, improvements of related diseases, and health-related quality of life can be assured.[1-5] On an individual basis, the indication for surgery should be balanced against the risk for postoperative complications and side effects.

Laparoscopy has contributed to the increased use of bariatric surgery worldwide.[6-8] Perioperative mortality is generally low at 0.08–0.35%, although perioperative morbidity range from 10 to 17%.[3] A shift towards high-volume hospitals may have contributed to a reduced risk of procedure related complications.[9]

National high-quality registries enable large-scale evaluations of the use and outcome of bariatric surgery and may allow for improved knowledge. Such registries have been established in several countries. The validity of the registries relies to a large extent on the quality of data retrieved and on high coverage rates.[10, 11]

The primary aim of this study was to evaluate the rate and type of complications after primary bariatric surgery in three North-Western European countries using nationwide registries. Findings could guide focus for adjustments that may improve the standard of bariatric care and may act as a benchmark analysis for comparison of outcome.

MATERIALS AND METHODS

Data from three nationwide registries for bariatric surgery were used. The Swedish registry started in 2007 as the Scandinavian Obesity Surgery Registry (SOReg) and was extended to Norway in 2014 (SOReg-N for Norway and SOReg-S for Sweden).[10] SOReg-N received status as a nation registry in June 2015 and the two registries were coordinated to allow for common use of data. The variables registered have the same definitions and the database platform is the same. An identical system for auditing of data to improve quality has been developed in the Netherlands. The Dutch Society for Metabolic and Bariatric Surgery (DSMBS) started a mandatory nationwide clinical audit in January 2015, called the Dutch Audit for Treatment of Obesity (DATO).[11]

All three registries have a nationwide coverage and include data on patient characteristics, obesity-related diseases, surgical technique, perioperative complications, grading

of the complications, reinterventions, readmissions, and mortality. Reporting to DATO is mandatory, and for this type of study, formal consent was not required under Dutch law. Reporting to SOReg-S and SOReg-N is not mandatory but "expected". The Swedish law allows patient inclusion in SOReg-S without the need of formal consent from the patient, while for SOReg-N, a written and informed consent from the patient is obligatory according to Norwegian legislation. Each country has a validated system by an external third party providing an onsite audit on a randomly selected number of patients. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Characteristics of the three registries are stated in **Table 1**.

Table 1: Characteristics of participating countries and data sets.

	Netherlands	**Norway**	**Sweden**
Inhabitants (x 10^6)	16.9	5.2	9.8
Numer of bariatric procedures per 100,000 inhabitants	65.1	55.6	61.4
Minimum required procedures per hospital	2015: 100/year 2016: 200/year	2015: not defined 2016: not defined	2015: not defined 2016: not defined
Registry			
Registry	DATO	SOReg-N	SOReg-S
Registry active since	2015	2015	2007
Registry organization	18 hospitals 1 central database	20 hospitals 1 central database	42 hospitals 1 central database
Data availability*			
Patient characteristics	+	+	+
Obesity related diseases	+	+	+
Surgical technique	+	+	+
Perioperative complications	+	+	+
Re-interventions	+	+	+
IC/ICU-admission	+	+	+
Hospital stay	+	+	+
Readmission	+	+	+
Mortality	+	+	+

Legend: *is obligatory in all registries.
Abbreviations: DATO, Dutch Audit for Treatment of Obesity; SOReg, Scandinavian Obesity surgery Registry; IC, intensive care; ICU, intensive care unit.

As DATO and SOReg-N first received nationwide status in 2015, it was chosen to compare the data from January 1, 2015 till December 31, 2016. Revisions and secondary bariatric procedures were excluded from the analysis; thus, the focus was on primary

bariatric surgery. Bariatric procedures were presented in three main groups: sleeve gastrectomy, gastric bypass (including Roux-en-Y, mini/one anastomosis and banded variations), and other bariatric procedures.

Since contributing to DATO is compulsory, the estimated national coverage rate for the number of bariatric procedures performed in the Netherlands in 2015 and 2016 was 100%. Based on data from the National Patient Registries in Sweden and Norway, supplemented with data from the Norwegian Association for Bariatric Surgery, the estimated coverage rate for SOReg-S was 98% for both years while for SOReg-N, the coverage rate was 18% (531 out of 2900) for 2015 and 48% (1353 out of 2846) for 2016.

Eligibility criteria for bariatric surgery were similar in the three countries. Patients with a body mass index (BMI) of ≥ 40.0 or ≥ 35.0 kg/m^2, with one or more obesity-associated diseases were eligible for bariatric surgery.[12-14] Indication for surgery and the type of the bariatric procedure was based on the experience of the surgeon, the multidisciplinary team, and on shared decision making together with the patient. "Fast-track" principles were considered standard in the postoperative care in all three countries.[15]

DEFINITION OF OBESITY ASSOCIATED DISEASES

Demographics and obesity-related diseases were uniformly defined and registered in the three registries. An obesity-associated disease was recorded as present if the patient reported receiving pharmacological treatment for the actual disease. Diseases recorded are type 2 diabetes mellitus (T2DM), hypertension, hyperlipidemia, gastro-esophageal reflux disease (GERD), musculoskeletal pain, and obstructive sleep apnea syndrome (OSAS) with ongoing continuous or bilevel positive airway pressure (CPAP/BiPAP) treatment.[2, 16-20]

Musculoskeletal pain was defined as daily use of pain-controlling medication or pain resulting in severe limitations of daily activity (e.g., unable to work).[21, 22] This definition was fairly similar for the three registries.

CLASSIFICATION OF COMPLICATIONS

Complications within the first 30 days after surgery were registered and categorized according to the Clavien-Dindo Classification of Surgical Complications (CD).[23] A severe complicated course is defined as CD grade IIIb or higher. A CD grade IIIb denotes a complication requiring intervention under general anesthesia, while CD grade IV was a complication requiring intensive care management and involving either single-organ dysfunction (CD grade IVa) or multiple-organ failure (CD grade IVb). Mortality is defined as CD grade Vand includes death from any cause within 30 days after surgery or during

the same hospital admission. Patients with multiple complications were counted only once, and the complication with the highest grade was used for analysis.

STATISTICAL ANALYSIS

Univariate analysis was performed to discriminate between countries and severe 30-day complications (CD grade ≥ IIIb). Categorical variables were compared with the χ^2 test with Yates' correction, and continuous variables with a t test. Statistical significance was set at a threshold of 0.05.

Statistical analyses were performed with R version 3.4.2 in combination with the "Companion to Applied Regression"-package (car 2.1-5) and "A Grammar of Data Manipulation"-package (dplyr 0.7.4).

RESULTS

A total of 35,858 unique cases were registered during the study period (**Table 2**). Of these, 21,941 (61.2%) were operated in the Netherlands, 1884 (5.2%) in Norway, and 12,033 (33.6%) in Sweden. There were 3681 (10.3%) revisional procedures which were not included in subsequent analyses.

Of the 32,177 primary interventions, 25,245 (78.5%) were performed in women. In the Netherlands, Norway, and Sweden, age and BMI distribution were fairly similar, 43.8, 42.4, and 41.0 years and 43.3, 42.7, and 41.2 kg/m2, respectively (**Table 2**). In conclusion, Dutch patients were significantly older, had a higher BMI, and had a higher number of registered obesity-related disease, compared to both Scandinavian countries.

Gastric bypass procedures were the most common procedures in the Netherlands and in Sweden (79.8 and 67.0%, respectively), while in Norway, sleeve gastrectomy was more common (58.2%, $p < 0.001$). There were significantly more preoperative obesity associated diseases registered in the Netherlands compared to Norway and Sweden ($p < 0.001$). The most frequent diseases were hypertension, T2DM, and musculoskeletal pain (**Table 2**).

COMPLICATIONS

In 2095 patients (6.5%), a perioperative complication was noted. A total of 904 (2.8%) patients developed a major complication after primary surgery (**Table 3**) and 12 patients (0.04%) died within 30 days. In the pooled analysis, the most common complications after primary bariatric surgery were bleeding, leakages, and intestinal occlusion/obstruc-

Table 2: Preoperative patient characteristics according to country.

	Netherlands		Norway		Sweden		All		*p-value**
	N	%	N	%	N	%	N	%	
Total number of procedures	21,941		1,884		12,033		35,858		-
Primary procedures	18,784	85.6%	1,790	95.0%	11,603	96.4%	32,177	89.7%	<0.001
> sleeve gastrectomy	3,652	19.4%	1,042	58.2%	3,631	31.2%	8,315	25.8%	<0.001
> gastric bypass	14,988	79.8%	747	41.7%	7,778	67.0%	23,513	73.1%	<0.001
> other procedures	144	0.8%	1	0.1%	204	1.8%	349	1.1%	<0.001
Revisional procedures	3,157	14.4%	94	5.0%	430	3.6%	3,681	10.3%	<0.001
Patient characteristics**									
Age (mean, years, SD)	43.8	± 11.2	42.4	± 11.1	41.0	± 11.5	42.4	± 11.3	<0.001
BMI (mean, kg/m^2, SD)	43.3	± 5.4	42.7	± 5.2	41.2	± 5.7	42.4	± 5.4	<0.001
Male	3,863	20.6%	417	23.3%	2,652	22.9%	6,932	21.5%	<0.001
Female	14,921	79.4%	1,373	76.7%	8,951	77.1%	25,245	78.5%	<0.001
Preoperative co-morbidities**									
Type 2 diabetes mellitus	4,122	21.9%	229	12.8%	1,405	12.1%	5,756	17.9%	<0.001
Hypertension	6,497	34.6%	523	29.2%	2,849	24.6%	9,869	30.7%	<0.001
Dyslipidemia	3,660	19.5%	214	12.0%	1,013	8.7%	4,887	15.2%	<0.001
GERD	2,078	11.1%	246	13.7%	1,175	10.1%	3,499	10.9%	<0.001
OSAS	3,374	18.0%	235	13.1%	1,131	9.8%	4,740	14.7%	<0.001
Musculoskeletal pain	8,209	43.7%	521	29.1%	2,426	20.9%	11,156	34.7%	<0.001
Other	8,626	45.9%	360	20.1%	2,873	24.8%	11,859	36.9%	<0.001

Legend: **p*-values compared all three different countries together, **calculated on unique patients after primary bariatric surgery. All *p*-values between the different countries were <0.001.
Abbreviations: SD, standard deviation.

tion. There was no significantly difference in the total number of complications between the registries (p = 0.939). However, a significant difference was seen in both CD grades IIIb and IV (p < 0.001) (**Table 3**). The Norwegian figures should be interpreted with care due to a lower coverage rate.

DISCUSSION

This study showed similarities in measuring patient's demographics, obesity-associated diseases, and perioperative outcomes, such as complications, in all three registries. The definitions of the variables also corresponded in the three compared countries.

Variation in annual hospital volumes for bariatric procedures was seen in the three analyzed European countries, with the highest volumes in the Netherlands (**Table 1**). Compared to the 2014 worldwide survey by the International Federation for the Surgery of

Table 3: Morbidity and mortality after primary bariatric surgery.

	Netherlands		Norway		Sweden		All		p-value*
	N	%	N	%	N	%	N	%	
Total number of procedures	18,784		1,790		11,603		32,177		-
Total number of complications	1,199	6,4%	162	9,1%	734	6,3%	2,095	6.5%	0.939
Perioperative complications									
Gastrointestinal perforation	105	0.6%	14	0.8%	89	0.8%	208	0.6%	0.067
Bleeding	89	0.5%	N/A		18	0.2%	107	0.3%	<0.001
Spleen injury	32	0.2%	8	0.4%	24	0.2%	64	0.2%	0.041
Hepatic injury	36	0.2%	N/A		12	0.1%	48	0.1%	0.059
Major vascular injury	2	0.0%	N/A		2	0.0%	4	0.0%	0.626
Postoperative complications									
Bleeding	263	1.4%	27	1.5%	147	1.3%	437	1.4%	0.530
Leakage	103	0.6%	20	1.1%	87	0.8%	210	0.7%	0.004
Intra-abdominal infection	26	0.1%	13	0.7%	58	0.5%	97	0.3%	<0.001
Wound infection	26	0.1%	13	0.7%	83	0.7%	122	0.4%	<0.001
Intestinal obstruction	46	0.2%	7	0.4%	95	0.8%	148	0.5%	<0.001
Cardiac complications	34	0.2%	4	0.2%	9	0.1%	47	0.1%	0.049
Pulmonary complications	58	0.3%	4	0.2%	37	0.3%	99	0.3%	0.794
Thrombotic complications	5	0.0%	2	0.1%	10	0.1%	17	0.1%	0.048
Bowel injury	18	0.1%	14	0.8%	89	0.8%	121	0.4%	<0.001
Other	356	1.9%	36	2.0%	175	1.5%	567	1.8%	0.033
Overall									
Re-intervention *CD-grade IIIb*	361	1.9%	41	2.3%	340	2.9%	742	2.3%	<0.001
IC/ICU admission *CD-grade IV*	128**	0.7%	4	0.2%	18	0.2%	150	0.5%	<0.001
Mortality *CD-grade V*	11	0.1%	0	0.0%	1	0.0%	12	0.0%	0.096
Length of stay & readmission									
Readmissions (<30 days)	492	2.6%	104	5.8%	790	6.8%	1,386	4.3%	<0.001
Hospital stay (mean, days, SD)	1.7	± 3.0	1.9	± 2.1	2.1	± 4.9	-	-	<0.001

Legend: *p-values compared all three different countries together, ** the DATO-registry only registers ICU-admission, but does not distinguish whether an admission is due OSAS observations or not. Therefore some ICU-admission are not categorized as CD grade-IV.
Abbreviations: N/A, not available; IC, intensive care; ICU, intensive care unit; CD, Clavien-Dindo Classification.

Obesity and Metabolic Disorders (IFSO), the present annual number of procedures for the total population in the three studied countries (0.06%) is higher than the estimated amount for all IFSO counties as well the European region (0.02 and 0.03%, respectively), but lower than in the USA and Canada (0.08%).[24] In the same survey, sleeve gastrectomy was found to have reached 45.9% of all procedures, followed by gastric bypass (39.6%)

and adjustable gastric banding (7.4%). This contrasts with the present use of gastric bypass in the Netherlands and Sweden (79.8 and 67.0%, respectively).

The overall rate for severe postoperative complications was 2.8% (n = 904), which is consistent with previous studies.[3, 25, 26] The associated factors for major postoperative complications have been shown to include laparoscopic versus open surgery, older age, surgeon experience, preoperative comorbidities, and BMI.[2, 13, 27, 28] The perioperative mortality was low and well below earlier reports.[27] The mean days of postoperative hospital stay were respectively 1.7 days (NL), 1.9 days (NO), and 2.1 days (SW). Pooled 30-day readmission rates were 4.3% (n = 1386) (Table 3). Combined, this large series reflecting an unselected practice in the three countries underlines the safety of the bariatric programs evaluated. Our findings could be used as indicators of expected outcome of bariatric surgery in this region of Europe.

As stated in the IFSO report, close to 100% of the elective bariatric surgical procedures are performed by laparoscopy worldwide.[29] Laparoscopy has significantly reduced morbidity and mortality after bariatric surgery.[6-8] To further improve outcome, a minimum annual hospital volume of 200 bariatric procedures has been established in the Netherlands. National guidelines in Sweden recommend 100 procedures annually, but are not required, while such numbers are not applied in Norway. One of the reasons is the demographics of the compared countries. The Netherlands has a population density of 409 inhabitants per km^2, compared to 13 per km^2 in Norway, and 20 per km^2 in Sweden. This could influence the number of procedures done annually in remote areas of the Nordic countries. It may also influence the readmission rate of the patients living in remote parts of the country and their access to bariatric experienced emergency facilities

Some studies suggest an inverse relationship between surgical caseload and severe postoperative complications.[3, 25, 26, 30, 31] This relationship remains unclear, and accreditation on quality outcomes may be greater than that of volume. Experience with handling and outcome of treatment of complications may be influenced by hospital volume but also remains undefined.

To facilitate comparison of international accreditation and quality outcome data, the IFSO Global Registry was founded in 2013.[32] The first IFSO Global Registry report in 2014 and a second report in 2016 demonstrated a widespread variation in access to surgery and baseline patient characteristics in the countries submitting data to the IFSO Global Registry.[29, 32] There are currently no standardized rules for countries participating in the registry. This results in participating countries with only one registering hospital

and countries where the registry is nationally mandatory. It appears that only a selected number of hospitals in few countries, audited by independent third parties, ensure the data quality in large audits. The future may show whether an internationally organized registry offers added value over a nationwide external audited mandatory registry.

Studies on postoperative outcomes are commonly based on data from clinical trials or patient cohorts from single hospitals. Owing to selection, these series may not always reflect the daily practice in general and the external validity may be restricted. Comparing outcome across nations based on such data may thus be inappropriate.[33, 34] Nationwide clinical audits provide detailed information on patient characteristics, treatment and hospital details. This information is easily available and can be used for monitoring of quality indicators. These indicators can be used for individual hospitals to compare their performances nationally and internationally.

This article focuses on short-term complications. However, the observed differences in patient selection, type of bariatric procedure, and postoperative courses may affect the long-term outcomes. Such analysis will take place when data is available. The design of the present study entails several limitations. In merging data from two different registries (DATO and SOReg), it is important that definitions and other variables are identical. The present use of pharmacological treatment in comorbid diseases, the Clavien-Dindo classification in evaluating complications facilitates this. The overall coverage, i.e., not missing any procedures in the registry, is continuously validated against official statistics. The accuracy of entered data is checked by a special trained nurse from the SOReg head office by comparing all entries to the patients' medical charts at regular site visits. In the Netherlands, it is done by an auditing team from the DICA. [11]

The major strength of this study is the international, population-based design, the use of data from three high quality registries including in-depth information and almost complete coverage of all patients who had bariatric surgery in the Netherlands and Sweden. Internal auditing measures are used in all three registries to improve data quality. Standardization of all registries, together with international consensus on definitions used in the registries, allow for easier comparisons between different countries and therefore international quality improvement. To our knowledge, this is the first multinational pooled registry analysis of national bariatric surgery programs in the world.

CONCLUSION

Bariatric surgery is safely performed in the three evaluated countries. Standardization of registries, together with international consensus on definitions used in the registries, allow for easier comparisons between countries and therefore international quality improvement across nations.

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Gastric Bypass Versus Sleeve Gastrectomy: Patient Selection and Short-Term Outcome of 47,101 Primary Operations from the Swedish, Norwegian, and Dutch National Quality Registries

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ABSTRACT

OBJECTIVE

The aim of this study was to compare the use and short-term outcome of Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) in Sweden, Norway, and the Netherlands.

BACKGROUND

Although bariatric surgery is performed in high volumes worldwide, no consensus exists regarding the choice of bariatric procedure for specific groups of patients.

METHODS

Data from 3 national registries for bariatric surgery were used. Patient selection, perioperative data (severe complications, mortality, and rate of readmissions within 30 days), and 1-year results (follow-up rate and weight loss) were studied.

RESULTS

A total of 47,101 primary operations were registered, 33,029 (70.1%) RYGB and 14,072 (29.9%) SG. Patients receiving RYGB met international guidelines for having bariatric surgery more often than those receiving SG (91.9% vs 83,0%, $P < 0.001$). The 2 procedures did not differ in the rate of severe complications (2.6% vs 2.4%, $P = 0.382$), nor 30-day mortality (0.04% vs 0.03%, $P = 0.821$). Readmission rates were higher after RYGB (4.3% vs 3.4%, $P < 0.001$).

One-year post surgery, less RYGB-patients were lost-to follow-up (12.1% vs 16.5%, $P < 0.001$) and RYGB resulted in a higher rate of patients with total weight loss of more than 20% (95.8% vs 84.6%, $P < 0.001$). While the weight-loss after RYGB was similar between hospitals, there was a great variation in weight loss after SG.

CONCLUSIONS

This study reflects the pragmatic use and short-term outcome of RYGB and SG in 3 countries in North-Western Europe. Both procedures were safe, with RYGB having higher weight loss and follow-up rates at the cost of a slightly higher 30-day readmission rate.

INTRODUCTION

To ensure and improve the quality of bariatric surgery, assessment of outcome is required.[1-5] The external validity of case series, observational studies, and randomized controlled trials may not reflect everyday practice and outcome.[6] The Rome Diabetes Surgery Summit achieved consensus for a need of standard national registries to collect "real-world" data.[6, 7] In recent years, several national bariatric registries have been established in Europe and early results have been published.[3, 6, 8, 9]

Although bariatric surgery has been performed in high volumes worldwide for several decades [10], no consensus exists in regard to the choice of procedure for specific groups of patients.[11, 12] Two procedures dominate at present, Roux-en-Y gastric bypass (RYGB) [13] and sleeve gastrectomy (SG).[14, 15]

Nationwide registries, suitable for international benchmarking, have been developed in Sweden, Norway, and the Netherlands.[3, 16] A main reason for using data from national registries is to reduce the risk of selection bias and intention-to-treat confounders from individual hospitals. However, selection biases may still impact findings such as choice of surgical procedure for the individual patient, which may to some extent rely on the surgeon's preference or institutional practice. Moreover, individual countries apply clinical protocols incorporating differences that may impact outcome after bariatric surgery. National differences between individual hospitals may thus be small, while differences in outcome between nations may be more easily found. A recent study showed an extended overview of the registered variables in both registries and also showed that the definitions used for perioperative measures in the registries were comparable thus facilitating evaluation of surgical and outcome indicators between registries.[17] The 30-day morbidity and mortality following primary bariatric surgery in Sweden, Norway, and the Netherlands documented comparable outcome in these countries.[17]

The aim of this study was to compare the use and short-term outcome of RYGB and SG in Sweden, Norway, and the Netherlands during 2015 to 2017.

METHODS

DATA REGISTRIES

Patients receiving a primary RYGB or a primary SG from January 2015 till December 2017 were included. Perioperative data included a 30 days follow-up period after primary surgery. Evaluations of 1-year follow-up outcome included patients operated from January

2015 till December 2016. Patients operated in Sweden, Norway, and the Netherlands were registered in the respective national registries. Patient data were retrieved during the preoperative consultations, during hospital stay, and from follow-up consultations by direct plotting the information into the online-based registries by responsible health care providers. Further details on the design of these registrations have been described previously.[3, 16-19] All procedures open or laparoscopic were included in the registries and analyzed in the present study.

SOREG

SOReg (Scandinavian Obesity Surgery Registry) was initiated in 2007 in Sweden,3 and is supported by the National Board of Health and Welfare, a government agency under the Ministry of Health and Social Affairs. In the last 5 years, more than 98% of all patients who underwent bariatric surgery in Sweden have been registered in SOReg-Sweden (SOReg-S). In 2014, Norway joined SOReg and received status as a nationwide register in June 2015. The coverage rate based on public hospitals was 64% in 2016 and 73% in 2017.

All variables in SOReg-Norway (SOReg-N) and SOReg-S apply the same definitions and the database platform is identical. An identical system for auditing of data to improve quality has been developed. Both the SOReg-N and SOReg-S registries performed external data verification, indicating high quality of data.[20]

DATO

The nationwide DATO (Dutch Audit for Treatment of Obesity) registry includes all Dutch bariatric patients. Information is collected through an online survey for all patients. The registry officially started on January 1, 2015, and covers over 99.9% of all patients who undergo bariatric surgery in the Netherlands. Nationwide coverage is enforced via the Association of Surgeons of the Netherlands, the umbrella organization of Dutch health insurers, and the Dutch National Health Care Institute.[16, 18] Recent third-party data verification showed an inclusion rate of 100% for all bariatric hospitals in the Netherlands.

The variables have an overlap of more than 90% between the SOReg and DATO registries.[17] For all the variables used in this study, the definitions of DATO correspond to those of SOReg.[17]

MAIN OUTCOME MEASURES AND DEFINITIONS

Six indicators were used to compare the use and outcome of RYGB and SG; patient eligibility for surgery, severe complications, mortality, readmissions, rate of follow-up

at 1 year, and 1-year weight loss. Analyses were performed on merged data as well as on national basis.

ELIGIBILITY CRITERIA FOR BARIATRIC SURGERY

The National Institutes of Health Consensus Development Conference Statement [21], recognized as IFSO-guidelines for bariatric surgery, were practiced in all 3 countries.[7, 22-26] To make a distinction between whether or not patients were operated in agreement with these guidelines, a process indicator was established. The patient had to be between 18 and 65 years at the time of surgery, with a body mass index (BMI) of ≥ 40.0 kg/m^2 or a BMI of 35.0–40.0 kg/m^2 in combination with at least 1 of the 6 major obesity-related diseases: type 2 diabetes mellitus (T2DM), hypertension, dyslipidemia, obstructive sleep apnea syndrome, gastroesophageal reflux disease, and musculoskeletal pain. These diseases were defined by continuous use of medication and with continuous positive airway pressure in sleep apnoea. [25, 27, 28] Currently, patients with BMI of ≥ 30.0 kg/m^2 and T2DM may be offered metabolic surgery on an individual basis, but this criterion was not incorporated in the guidelines during the entire study period.[28]

PERIOPERATIVE RESULTS

Postoperative complications were categorized according to the Clavien-Dindo Classification of Surgical Complications (CD) and represent complications within 30 days after primary surgery or during the same hospital stay.[29] CD-grade IIIb or higher was classified as a severe complication. CD-grade IIIb represents a complication for which a surgical, endoscopic, and/or radiological intervention was performed under general anesthesia. CD-grade IV is described as life-threatening complications requiring intensive care (IC) admission. CD-grade V reflects the 30-days mortality rate.[29] Readmissions within 30-days after surgery were studied.

ONE-YEAR RESULTS

Patients without a registered 1-year follow-up after primary surgery were considered as lost-to follow-up. Postoperative weight loss is presented by percentage total weight loss (%TWL), which was defined as: $\frac{preoperativeweight - postoperativeweight}{preoperativeweight} \times 100$.[5, 30]

STATISTICAL ANALYSIS

RYGB and SG were analyzed separately. Differences in regard to patient and treatment characteristics were described using frequency tables. Categorical variables were compared using the χ^2 test with Yates' correction. Statistical significance was set at $P < 0.05$. The use of case-mix adjusted outcomes are controversial and not applied.[31, 32]

Results for all 6 process and outcome indicators were presented using funnel plots with 95% control limits that vary in relation to total number of hospital procedures in the above specified study period.[17, 33]

The funnel plots provide information regarding specific process or outcome measures for individual hospitals in relation to the overall average and in relation to results of other anonymized hospitals. The Y-axis shows the percentage of primary bariatric procedures indicated on the X-axis that met the binomial result as the specific indicator indicates. The Y-axis shows the absolute percentage per hospital (dot) and the number of patients operated, as shown on the x-axis.

R version 3.4.3 (Copyright (C) The R Foundation for Statistical Computing Platform) was used for statistical analysis in combination with the 'Companion to Applied Regression'-package (car 2.1–6), and "A Grammar of Data Manipulation"-package (dplyr 0.7.4).

This study was approved by the regional ethical committee of Stockholm, Sweden (2013/535–31/5) for SOReg-S. The Regional Committee for medical and health research ethics in South East Norway approved the study (reference number: 2018/1631) for SOReg-N. For this study, no ethical approval or informed consent was required under Dutch law for DATO.[16]

RESULTS

From January 2015 till December 2017, a total of 47,101 primary bariatric procedures (>99% laparoscopic cases) were registered. Of these, 33,029 (70.1%) were RYGB and 14,072 (29.9%) were SG procedures. Patient characteristics per country and combined are given in **Table 1**.

RYGB was the most commonly applied procedure in Sweden (64.0%) and the Netherlands (77.0%), while in Norway, SG was more common (57.0%, $P < 0.001$). Patients who underwent RYGB had more preoperative comorbidities (73.5% vs 64.3%, $P < 0.001$) than patients receiving SG. Patients operated in the Netherlands had more comorbidities than both Sweden and Norway ($P < 0.001$). Moreover, in Norway and Sweden, gastroesophageal reflux disease was about twice as common in RYGB patients, while no difference between the 2 procedures was seen in the Netherlands (**Table 1**).

Table 1: Preoperative patient characteristics according to country and combined data.

	Netherlands				Norway				Sweden				All				*p*-value*
	Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
Number of procedures	21,055	77.0%	6,292	23.0%	1,365	43.0%	1,809	57.0%	10,609	64.0%	5,971	36.0%	33,029	70.1%	14,072	29.9%	<0.001
Patient characteristics																	
Age (mean, years, SD)	44.5	± 10.9	41.9	± 12.4	42.9	± 10.8	42.1	± 11.1	40.7	± 11.8	41.0	± 10.9	43.2	± 11.2	41.5	± 11.6	<0.001
BMI (mean, kg/m^2, SD)	43.5	± 5.0	45.6	± 6.6	43.3	± 5.2	41.9	± 5.4	41.7	± 5.6	39.5	± 5.4	42.9	± 5,2	42,5	± 5.9	<0.001
Female	17,064	81.0%	4,684	74.4%	1,045	76.6%	1,395	77.1%	2,188	77.8%	4,834	80.1%	26,171	79.2%	10,913	77.6%	<0.001
Comorbidities	17,139	81.4%	5,017	79.7%	890	65.2%	1,109	61.3%	6,256	59.0%	2,917	48.9%	24,285	73.5%	9,043	64.3%	<0.001
T2DM	4,521	21.5%	1,058	16.8%	199	14.6%	196	10.8%	1,456	13.7%	502	8.4%	6,176	18.7%	1,756	12.5%	<0.001
Hypertension	7,312	34.7%	2,016	32.0%	453	33.2%	475	26.3%	2,791	26.3%	1,208	20.2%	10,556	32.0%	3,699	26.3%	<0.001
Dyslipidaemia	4,260	20.2%	1,060	16.8%	228	16.7%	178	9.8%	1,046	9.9%	408	6.8%	5,534	16.8%	1,646	11.7%	<0.001
GERD	2,705	12.8%	784	12.5%	293	21.5%	175	9.7%	1,322	12.5%	341	5.7%	4,320	13.1%	1,300	9.2%	<0.001
OSAS	3,841	18.2%	1,205	19.2%	223	16.3%	226	12.5%	1,113	10.5%	412	6.9%	5,177	15.7%	1,843	13.1%	<0.001
Musculoskeletal pain	9,519	45.2%	2,843	45.2%	462	33.8%	545	30.1%	2,337	22.0%	877	14.7%	12,318	37.3%	4,265	30.3%	<0.001

Legend: **p*-values compared all three countries together.
Abbreviations: BMI, body mass index; T2DM, type 2 diabetes mellitus; GERD, gastroesophageal reflux disease; OSAS, obstructive sleep apnoea syndrome; N/A, not available.

ELIGIBILITY CRITERIA FOR BARIATRIC SURGERY

In total, 89.2% (n = 42,030) of patient met the eligibility criteria for bariatric surgery, 91.9% for the RYGB and 83.0% for SG patients, respectively (P < 0.001) (Fig. 1). Twenty-three of 59 (39.0%) hospitals [Sweden (SE): 19/28; Norway (NO): 4/13; Netherlands (NL): 0/18] operated significantly more RYGB patients (**Fig. 1B**), and 18 of 61 (29.5%) hospitals (SE: 13/28; NO: 5/16; NL: 0/17) operated significantly more SG patients (**Fig. 1A**), not meeting the eligibility criteria for bariatric surgery compared to the overall average.

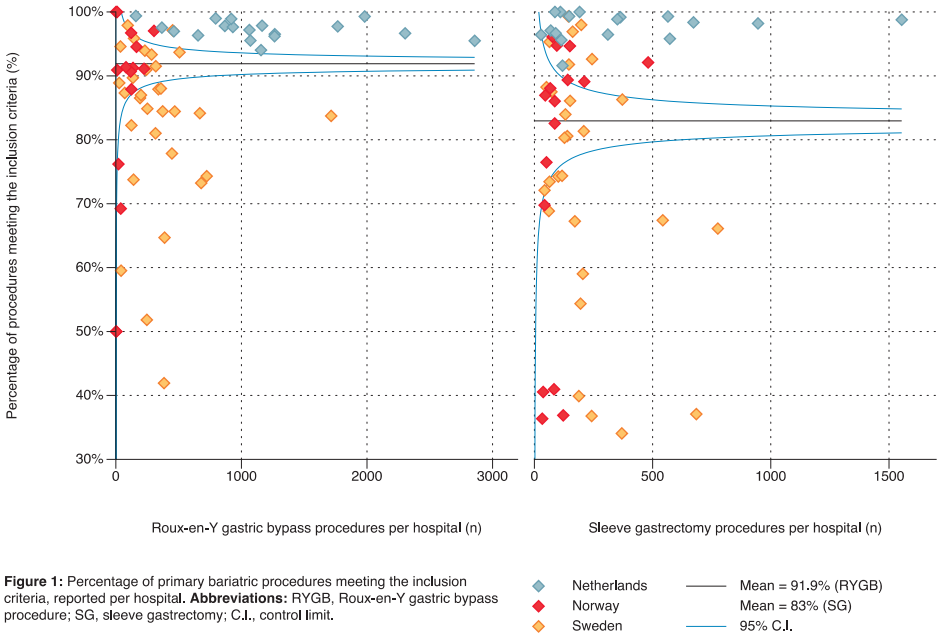

Figure 1: Percentage of primary bariatric procedures meeting the inclusion criteria, reported per hospital. **Abbreviations:** RYGB, Roux-en-Y gastric bypass procedure; SG, sleeve gastrectomy; C.I., control limit.

COMPLICATED POSTOPERATIVE COURSE

Severe complications (CD-Grade ≥IIIb) were registered in 2.6% (n = 846) patients after RYGB and 2.4% (n = 341) patients after SG (P = 0.382). Reinterventions due to severe complications were performed in 2.0% (n = 667) patients after RYGB and 2.1% (n = 290) patients after SG (P = 0.771). The overall number of patients registered with a CD-grade IV complication was 0.5% (n = 170) for RYGB and 0.3% (n = 47) after SG (P = 0.008) (**Table 2**). In the RYGB group, 4 of 59 (6.8%) hospitals (SE: 1/28; NO: 0/13; NL: 3/18) registered significantly lower rate of complications than the average. In contrast, a higher rate of severe complications was seen for SG in 9 of 61 (14.8%) hospitals (SE: 6/28; NO: 1/16; NL: 2/17) (**Fig. 2**). Thirty-day mortality was 0.04% (n = 13) after RYGB and 0.03% (n = 4) after SG (P = 0.821).

Table 2: Morbidity and mortality after primary sleeve gastrectomy and gastric bypass procedure.

	Netherlands				Norway				Sweden				All				*p*-value*
	Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
Number of procedures	21,055	77.0%	6,292	23.0%	1,365	43.0%	1,809	57.0%	10,609	64.0%	5,971	36.0%	33,029	70.1%	14,072	29.9%	< 0.001
Perioperative complications	420	2.0%	131	2.1%	66	4.8%	32	1.8%	284	2.7%	57	1.0%	770	2.3%	220	1.6%	< 0.001
Gastrointestinal perforation	135	0.6%	7	0.1%	24	1.8%	1	0.1%	121	1.1%	3	0.1%	280	0.8%	11	0.1%	
Bleeding	64	0.3%	44	0.7%	5	0.4%	0	0.0%	10	0.1%	12	0.2%	79	0.2%	56	0.4%	
Spleen injury	31	0.1%	21	0.3%	4	0.3%	8	0.4%	11	0.1%	17	0.3%	46	0.1%	46	0.3%	
Hepatic injury	44	0.2%	11	0.2%	0	0.0%	0	0.0%	16	0.2%	8	0.1%	60	0.2%	19	0.1%	
Major vascular injury	1	0.0%	1	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.0%	1	0.0%	
Postoperative complications	1,046	5.0%	347	5.5%	80	5.9%	94	5.2%	753	7.1%	309	5.2%	1,879	5.7%	750	5.3%	< 0.001
Bleeding	314	1.5%	129	2.1%	25	1.8%	25	1.4%	123	1.2%	66	1.1%	462	1.4%	220	1.6%	
Leakage	109	0.5%	46	0.7%	9	0.7%	16	0.9%	80	0.8%	30	0.5%	198	0.6%	92	0.7%	
Intra-abdominal infection	29	0.1%	15	0.2%	5	0.4%	11	0.6%	64	0.6%	22	0.4%	98	0.3%	48	0.3%	
Wound infection	28	0.1%	11	0.2%	4	0.3%	11	0.6%	54	0.5%	45	0.8%	86	0.3%	67	0.5%	
Intestinal obstruction	63	0.3%	10	0.2%	16	1.2%	0	0.0%	113	1.1%	7	0.1%	192	0.6%	17	0.1%	
Cardiac events	38	0.2%	12	0.2%	0	0.0%	5	0.3%	6	0.1%	3	0.1%	44	0.1%	20	0.1%	
Pulmonary events	71	0.3%	22	0.3%	5	0.4%	1	0.1%	33	0.3%	17	0.3%	109	0.3%	40	0.3%	
Thrombotic events	8	0.0%	4	0.1%	1	0.1%	2	0.1%	9	0.1%	2	0.0%	18	0.1%	8	0.1%	
Other	427	2.0%	115	1.8%	40	2.9%	46	2.5%	327	3.1%	164	2.7%	794	2.4%	325	2.3%	
Overall	506	2.4%	205	3.3%	29	2.1%	31	1.7%	315	3.0%	105	1.8%	850	2.6%	341	2.4%	< 0.001

Table 2: Morbidity and mortality after primary sleeve gastrectomy and gastric bypass procedure. (continued)

	Netherlands				Norway				Sweden				All				*p*-value*
	Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		Roux-en-Y gastric bypass		Sleeve gastrectomy		
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
Re-intervention *CD-grade IIIb*	346	1.6%	163	2.6%	27	2.0%	28	1.5%	294	2.8%	99	1.7%	667	2.0%	290	2.1%	
IC/ICU admission *CD-grade IV*	148	0.7%	38	0.6%	2	0.1%	3	0.2%	20	0.2%	6	0.1%	170	0.5%	47	0.3%	
Mortality *CD-grade V*	12	0.1%	4	0.1%	0	0.0%	0	0.0%	1	0.0%	0	0.0%	13	0.0%	4	0.0%	
Length of stay & readmission																	
Readmissions (<30 days)	572	2.7%	158	2.5%	87	4.6%	87	4.8%	752	7.1%	240	4.0%	1,411	4.3%	485	3.4%	< 0.001
Hospital stay (mean, days, SD)	1.6	± 2.9	1.6	± 2.7	1.7	± 3.4	2.0	± 2.2	1.5	± 4.6	1.6	± 2.3	1.6	± 3.5	1.7	± 2.5	< 0.001

Legend: **p*-values compared all three different countries together.

Abbreviations: N/A, not available; IC, intensive care; ICU, intensive care unit; CD, Clavien-Dindo Classification.

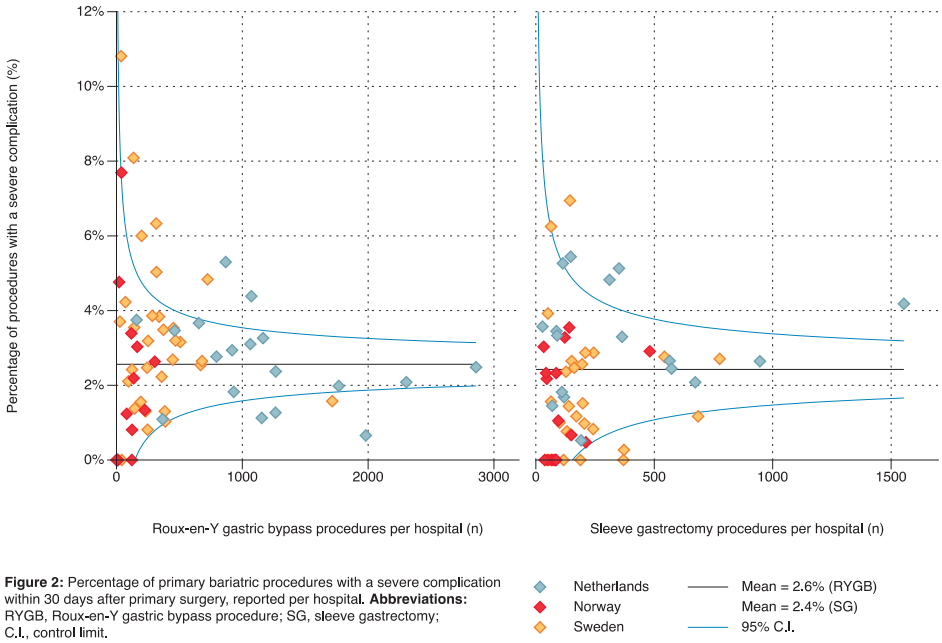

Figure 2: Percentage of primary bariatric procedures with a severe complication within 30 days after primary surgery, reported per hospital. **Abbreviations:** RYGB, Roux-en-Y gastric bypass procedure; SG, sleeve gastrectomy; C.I., control limit.

The 3 most common complications after RYGB and SG combined were bleeding (1.6%), leakage (0.7%), and wound infection (0.5%), with no statistical difference between the 2 procedures (**Table 2**).

LENGTH OF HOSPITAL STAY AND READMISSIONS

The length of stay was shorter after RYGB than SG, 1.6 days (SD ± 3.5) and 1.7 days (SD ± 2.5), respectively ($P < 0.001$) (**Table 2**). In the Netherlands, the length of hospital stay after RYGB and SG was comparable, while in Norway and Sweden, hospital stay was somewhat shorter after RYGB than SG in the same country ($P < 0.001$).

The readmission rate was 4.3% (n = 1411) after RYGB and 3.4% (n = 485) after SG ($P < 0.001$). Readmission rates were lowest in the Netherlands. Significantly more Swedish hospitals registered a readmission after RYGB (7.1%) than the overall average ($P < 0.001$) (**Table 2**).

LOST TO FOLLOW-UP AFTER 1 YEAR

On average, the 1-year lost to follow-up was lower after RYGB than SG, 12.1% (n = 2712) and 16.5% (n = 1433), respectively ($P < 0.001$). The largest difference between the 2 procedures was seen in Sweden, 11.9% for RYGB versus 20.1% for SG, respectively ($P < 0.001$). (**Fig. 3**).

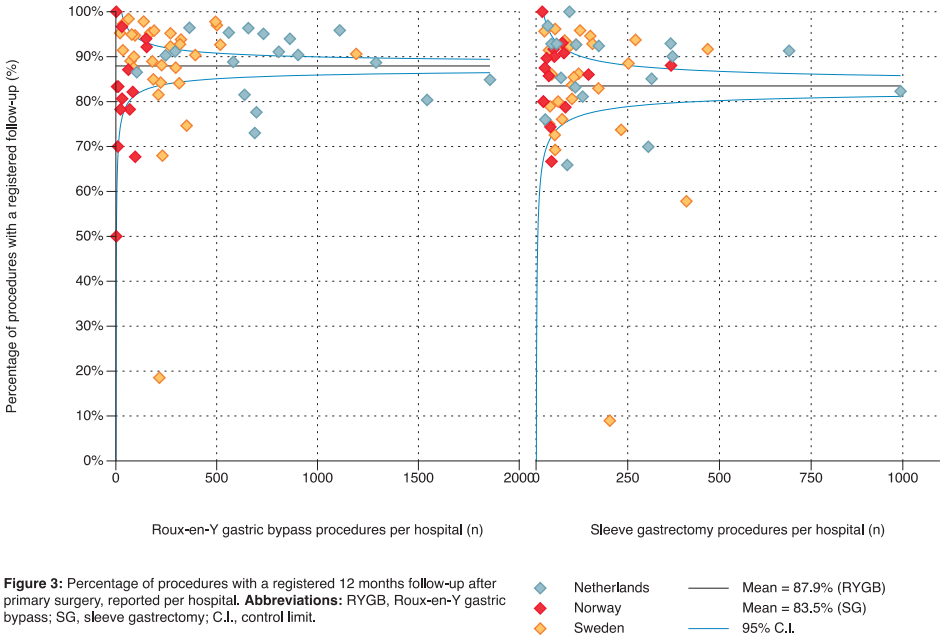

Figure 3: Percentage of procedures with a registered 12 months follow-up after primary surgery, reported per hospital. **Abbreviations:** RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; C.I., control limit.

After RYGB, 12 of 59 (20.3%) (SE: 5/28; NO: 2/13; NL: 5/18) and after SG 8 of 61 (13.1%) (SE: 5/28, NO: 1/16; NL: 2/17) centres had significantly higher rates of lost to follow-up up than the overall average, respectively.

TOTAL WEIGHT LOSS (%TWL)

ATWL percent (%TWL) of more than 20% the first year after surgery was reached more often after RYGB than SG, 95.8% and 84.6% of the patients, respectively ($P < 0.001$) (Fig. 4). In total, after RYGB, 6 of 59 (10.2%) (SE: 4/28; NO: 1/13; NL: 1/18) hospitals and after SG 18 of 61 (29.5%) (SE: 16/28; NO: 0/16; NL: 2/17) hospitals scored significantly lower than the overall average.

There is a significant difference in 20%TWL after SG in Sweden (75.2%), Norway (93.4%), and the Netherlands (90.8%) ($P < 0.001$), while the difference is much smaller after RYGB (SE: 94.9%; NO: 95.0%; NL: 96.3%; $P < 0.001$). The considerable spread in outcomes between hospitals after SG compared with RYGB is easily noticeable in the funnel plot.

DISCUSSION

This study describes the pragmatic everyday outcome of RYGB and SG in 3 Northwest-European countries based on a standard platform of 6 quality indicators. RYGB was

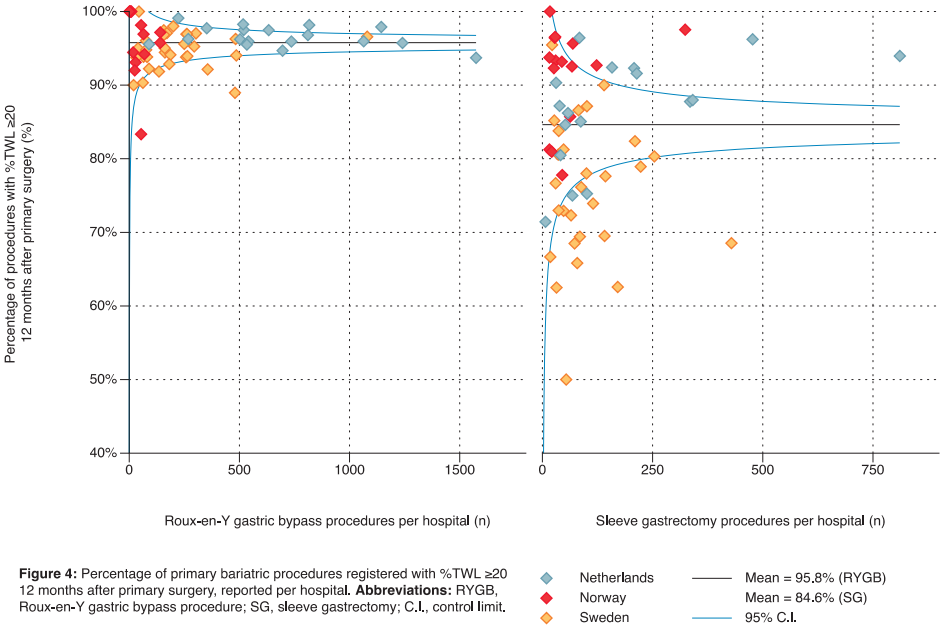

Figure 4: Percentage of primary bariatric procedures registered with %TWL ≥20 12 months after primary surgery, reported per hospital. **Abbreviations:** RYGB, Roux-en-Y gastric bypass procedure; SG, sleeve gastrectomy; C.I., control limit.

more often used in adherence to commonly accepted guidelines for eligibility to bariatric surgery. Postoperative severe complications (2.6% vs 2.4%) and mortality rates (0.04% vs 0.03%) did not differ between RYGB and SG, but readmission rates were higher after RYGB (4.3% vs 3.4%). In RYGB-patients, however, 1-year results were superior, with lower lost-to follow-up (12.1% vs 16.5%) and higher rate of %TWL ≥ 20% (95.8% vs 84.6%). These benchmarking findings may act as guidelines for expected early outcome of bariatric surgery in Northwest-Europe and elsewhere.

Most patients were operated in adherence to internationally used IFSO-guidelines for eligibility to bariatric surgery. Indications for bariatric surgery differ among European countries despite agreement on the international clinical guidelines.[34] At the moment, the BMI inclusion criteria in the Netherlands, Sweden, and Norway have been set at a BMI of 40.0 kg/m^2 or a BMI of 35.0 kg/m^2 for patients with obesity-related disease. Interestingly, we found that more RYGB patients were operated according to international guidelines for bariatric surgery than SG patients. This could be due the fact that there are some Swedish private clinics performing SG on patients with a BMI of 30 to 35 kg/m^2 or 35 to 40 kg/m^2 without any obesity-related comorbidity.

Comparing the 3 countries, the annual hospital case load was highest in the Netherlands. In all countries, mostly females were operated at a rate of about 75% or higher. Dutch patients were significantly older, had a higher BMI, and a higher number of

preoperative comorbidities. The mean age and BMI in the present study is lower than reported in most American series.[35] Overall, as well as in Sweden and the Netherlands, RYGB was the most common primary procedure, whereas in Norway, SG has reached 57% based on registered data. In the United States, SG surpassed RYGB in 2013 [36] and was estimated by ASMBS to constitute of 53% to 59% of all bariatric procedures during the present study period (2015 to 2017).[37] Interestingly, the findings indicate that there may be between-country differences in regarding to the use of SG in patients with gastroesophageal reflux disease (**Table 1**).

The present overall rates of severe postoperative complications were in line with results presented in the international literature. In a recent review on 107,874 patients [35], the leak rate was 1.1% in RYGB and 1.2% in SG. The associated factors for severe postoperative complications are laparoscopic versus open surgery, older age, surgical procedural experience, preoperative comorbidities, and BMI.[38-41] In Sweden, more postoperative complications were registered for RYGB surgery than SG (7.1% vs 5.2%). As significant outliers from all 3 countries were visible in all measured process and outcome indicators, this may provide insight to areas in need of improvements.

The present mortality of 0.03% to 0.04% compares favorably to others; Gribsholt et al [42] presenting 0.04% in 9,895 Danish RYGBs and the 0.20% to 0.22% presented in a large American cohort (n = 43,354) of RYGB and SG [43] and a recent meta-analysis on 69,494 patients [44]. These results underline the safety of RYGB an SG in these patients.

The overall hospital stay was short for both procedures (1.6 and 1.7 days, respectively), while Norway and Sweden had a significantly higher percentage of readmissions, especially after RYGB (4.6% and 7.1%, respectively). This could partly be explained by demographic differences between countries, where people often live closer to a (bariatric) hospital in the Netherlands. However, it could also be explained by centralization in the Netherlands, where hospitals perform a higher volume of bariatric procedures per year per clinic as demostrated in **Figs. 1 to 4**, and therefore have a higher number of procedures per surgeon per year. This could also explain the lower postoperative complication ratio described earlier.

Although it is generally not recommended to report weight loss with less than 2-year follow up, the present 1-year weight loss after RYGB is similar and more predictable between institutions, although there is a great variation in weight loss after SG. This can reflect the need for high technical quality in both procedures, as patients receiving large pouches and sleeves are known to have inferior weight loss. According to our data, it thus seems more difficult to achieve a technical perfect SG. The presented weight loss

is in line with the literature as well as earlier results from SOReg-S on patients operated before 2014 in Sweden.[17, 19] Interestingly, the 1-year %TWL outcome in RYGB seems more uniform and predictable across hospitals and nations than that of SG.

Currently, almost 98% of elective bariatric surgical cases are managed worldwide by laparoscopy.[12] The increased use of laparoscopy in bariatric surgery has reduced postoperative morbidity and mortality.[45-47] In an attempt to further improve quality, a minimum annual procedural volume per hospital of 200 cases has been established in the Netherlands and 100 in Sweden. In Norway, no formal minimum annual procedural hospital volume exists, although most centers perform close to 100 or more procedures annually. Although numerous studies suggest an inverse relation between hospital case load volume and postoperative severe complicated course, recent studies show no significant benefits for choosing a high-volume hospital compared with a low-volume hospital.[38-40, 48, 49] This remains a topic of discussion and accreditation on quality outcomes may be of greater value than that of volume.

Several aspects of long-term outcomes can be monitored in Sweden and Norway by registering the unique identification number given at birth, which allows cross-linking with other nationwide registrations. All Dutch citizens have a similar identification number, but cross-linking between different registries may be more challenging due to legal restrictions. However, the national bariatric registries can learn from one another and allow for international comparison. The SOReg registries include more pre- and postoperative laboratory values, which allow comorbidities to be measured more objectively. On the contrary, registration in DATO is mandatory, whereas registration in SOReg-N is on voluntary basis. In addition, the Netherlands offers a weekly benchmark feedback, while SOReg presents a selection of quality outcomes online and publish annual figures.

Case-mix adjusted outcomes are still controversial in the international literature [31, 32] and deliberately not applied in this study and could imply a possible selection bias as does the heterogeneity of the data, which reflects real-world data. This could be a limitation of this study in a narrower sense of the word.

Nationwide clinical audits provide detailed information on patient characteristics, treatment, and individual hospitals. This information is quickly available for monitoring of quality indicators. These indicators can be used for hospitals to compare their performances relative to a national and an international benchmark analysis. A disadvantage of national clinical audits is that data may not always be complete and directly validated.

The major strength of this study is the international, population-based design, the use of pooled data from 3 high-quality registries including in-depth information, and almost complete coverage of all patients who had bariatric surgery in the Netherlands and Sweden. Standardization of registries and consensus of definitions of measures included facilitate comparisons between countries that may impact quality of the treatment given on an international level.

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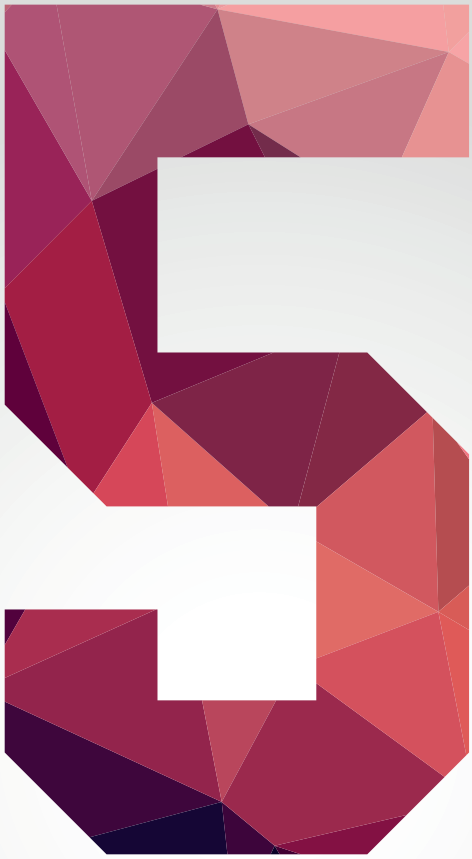

Textbook Outcome: an Ordered Composite Measure for Quality of Bariatric Surgery

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ABSTRACT

INTRODUCTION

Textbook outcome (TO) studies have previously shown that a composite measure can provide additional information on the overall quality of surgical care. However, these were binominal outcomes which do not give individual hospitals the required information on how to improve their performance. The aim of this study is to create an ordered TO consisting of multiple outcome parameters for bariatric surgery to assess the extent of hospital variation.

METHODS

Patients who underwent a primary bariatric procedure in the Netherlands were included for analyses. The outcomes were ordered as mortality, severe postoperative complications, readmission, mild complications and prolonged length of stay (LOS) within 30 days after primary surgery with TO defined as none of these outcomes occurring. Hospitals were identified with a significantly higher or lower observed/expected ratio than expected based on case-mix and the extent of hospital variation was expressed as the median and interquartile range (IQR).

RESULTS

From a total of 27,360 patients on average, 88.7%reached TO (range 35.5–96.9%). Two hospitals had less than expected TO due to more prolonged LOS (57.6%) in one hospital and more mild complications in another (17.1%). Hospital variation was much smaller for TO (median OR 0.91 IQR [0.62–1.06]) than for an ordered TO (median POR 0.66 IQR [0.55–0.96]).

CONCLUSION

Using the ordered TO for bariatric surgery, more hospital variation was captured thereby enabling individual hospitals to identify which outcomes and specific groups need improvement. This could attribute to the ongoing effort to improve the quality of the outcome of bariatric surgery.

INTRODUCTION

Several studies have shown that bariatric surgery can be considered safe, with a low postoperative mortality event rate of less than 1.0%.[1-5] The results from the Dutch Audit for Treatment of Obesity (DATO) showed similar results.[6] Despite these positive results, between-hospital differences are still visible which offer opportunities for quality improvement. To achieve these improvements, several outcome indicators are established by DATO.[6] However, these outcome indicators provide insight into single outcome parameters, but do not necessarily provide insight into the entire care process in which different outcome parameters could be related to each other.[7, 8]

In the field of gastrointestinal cancer surgery and elective aneurysm surgery, a composite measure has been illustrated to give insight in the entire care process and make hospital comparison possible.[9-11] This composite measure has been described as textbook outcome (TO) and since TO covers the most desirable surgical outcomes, it gives a better impression of the overall quality of surgical care for the patient.[12-14] The indicator estimates the overall chance for a successful hospital admission and thus providing relevant information for the patient. In addition, event rates may be low for single outcome parameters, so that small differences between hospitals could be due to chance alone. Combining multiple outcome parameters provides more power to detect hospital differences and outcomes will be less likely different due to chance alone.[7] Ultimately, this results in a quality stimulus focused on all outcomes relevant for the patient and not only on single surgical outcome indicators.

Previous TO studies have shown that such a composite measure could provide additional information on the overall quality of surgical care from a patient's perspective.[9-11] However, the disadvantage of the earlier described TO indicator refers to combining all single outcome parameters into one binominal outcome. This binominal outcome does not give individual hospitals information where and how to improve if their performance is significantly worse than the national average. Ordering the different individual outcome parameters would make the composite measure more useful for quality improvement by professionals as well as suitable for the patient's perspective.

The aim of this study is to create a new ordered textbook outcome measure consisting of multiple postoperative outcome parameters for bariatric surgery and to assess whether this measure is more distinctive than individual parameters to estimate hospital differences.

METHODS

PATIENT SELECTION

The study was designed as an observational study and unanimously approved by the scientific committee of DATO. Data were obtained from the national bariatric registry, a specific nationwide audit in which all 18 Dutch bariatric centres participate.[6] All patients undergoing a primary bariatric procedure between 1 January 2015 and 1 January 2018 were included for the analyses. Minimal data requirements were date of operation, type of surgery, bariatric technique and date of discharge. In addition, the parameters readmission, postoperative complications and mortality should be registered, up to 30 days after the primary surgery.

DEFINITIONS

Postoperative complications within 30 days after primary surgery were recorded by Clavien-Dindo Classification of Surgical Complications (CD).[15] A mild complication was defined as CD-grade I or II and a severe complication was defined as CD-grade III or IV. Postoperative mortality, also registered as CD-grade V, was defined as mortality during the initial hospital stay or within 30 days after primary surgery.

Readmission was defined as the first readmission after discharge, but within 30 days after the initial intervention. A readmission is seen as a complication and therefore minimally marked as a mild complication.[16-18] Prolonged length of stay (LOS) was defined as discharge more than 2 days after primary procedure.[19, 20]

PARAMETERS

An ordinal composite outcome measure has been developed in previous research taking into account mutual relationships between mortality, readmission and prolonged length of stay.[7, 8] For the present study, members of the DATO scientific committee selected internationally described and relevant outcome parameters for desirable patient outcome after bariatric surgery.[17, 21-24] The measured outcome parameters were mortality, severe and mild postoperative complications, readmission and prolonged LOS, defined as hospital admission >2 days after primary surgery.

ORDERING OF PARAMETERS

Given possible relationships between the indicators, the hospital may be a positive outlier on one indicator and a negative outlier on another, thus requiring ordering to create an integral picture of quality of care. Ordering of individual parameters was based on expert advice and evidence from literature regarding what patients considered as better quality of care.[8] Previous research showed that patients considered complica-

tion after discharge (resulting in readmission) as worse quality of care compared to a complication during the same admission (resulting in prolonged LOS).[8, 25] Thereby, the ordering was defined as worst to best: mortality, severe complications, readmission, mild complications and prolonged LOS. Different combinations of these five quality indicators are possible within a single patient.

As readmission is considered as a mild complication, the combination of readmission and no mild complication is not possible. Similarly, a severe complication, which requires an intervention (CD-grade III) or intensive care observation (CD-grade IV) will exclude a normal LOS, unless this severe complication was the reason for a readmission. This results in 10 different groups in which all patients can be uniquely classified with the best group being similar to the textbook outcome in previous research (**Table 1**).

Table 1: Ordinal composite outcome, ordered from worst to best.

Group	Description
1	Death;
2	Alive, severe complications, readmission, prolonged-LOS after primary surgery;
3	Alive, severe complications, readmission, no prolonged-LOS after primary surgery;
4	Alive, severe complications, no readmission, prolonged-LOS after primary surgery;
	~~Alive, severe complications, no readmission, no prolonged-LOS after primary surgery;~~
5	Alive, only mild complications, readmission, prolonged-LOS after primary surgery;
6	Alive, only mild complications, readmission, no prolonged-LOS after primary surgery;
7	Alive, only mild complications, no readmission, prolonged-LOS after primary surgery;
8	Alive, only mild complications, no readmission, no prolonged-LOS after primary surgery;
	~~Alive, no severe or mild complications, readmission, prolonged-LOS after primary surgery;~~
	~~Alive, no severe or mild complications, readmission, no prolonged-LOS after primary surgery;~~
9	Alive, no severe or mild complications, no readmission, prolonged-LOS after primary surgery;
10	Alive, no severe or mild complications, no readmission, no prolonged-LOS after primary surgery;

VALIDATION

The selection of parameters and ordering of the TO parameters were subsequently discussed in various forums, such as the Dutch national indicator days. During these days, the health insurers, national health care institute, patient federation and health-care professionals meet to discuss the validity of different quality indicators. All parties have agreed to the proposed ordered parameters and official approval was given to continue and carry out the analyses.

ANALYSIS

First, the percentage was calculated of patients for whom each individual outcome quality indicator was met. In addition, the proportion was calculated of patients for whom the conditional on all parameters listed above, in the ordered composite outcome, were met with the final (best) group being the TO. The group of patients is subsequently subdivided into one of the 10 ordered TO groups to assess the variation between hospitals in reasons why TO is not met, explaining which individual indicator is mainly responsible.

Second, a univariate logistic regression model was applied to study the associations between selected patient and procedure characteristics and achieving TO. The following characteristics were tested: age, gender, weight, height, BMI, procedure type (sleeve gastrectomy, gastric bypass or other procedure), type 2 diabetes mellitus (T2DM) (yes/no), hypertension (yes/no), dyslipidaemia (yes/no), gastro oesophageal reflex disease (GERD) (yes/no), obstructive sleep apnoea syndrome (OSAS) (yes/no) and musculoskeletal pain (yes/no). All variables with $p < 0.05$ were included in the multivariate logistic regression analysis. Variables that remain independently associated with TO in multivariate analyses are relevant for fair hospital comparisons while considering potential differences in these patient and procedure characteristics.

Third, we estimated hospital differences in achieving TO using funnel plots with 95% control limits (C.I.). These plots were adjusted for those case-mix variables independently associated with TO in multivariate analyses. Casemix adjusted funnel plots show the actual observed (O) number of events divided by the expected (E) number of events on the y-axis (O/E ratio). The expected (E) number of events is displayed on the x-axis. A ratio greater than 1.0 indicates that more events have occurred than would have been expected based on case-mix of the hospital, while a ratio less than 1.0 indicates less events has occurred than would have been expected. We expressed the extent of hospital variation by calculating the median O/E ratio with the interquartile range (IQR). The same was done for the ordered TO but using an ordinal logistic regression analysis to assess which case-mix variables were significantly associated (expressed as a proportional odds ratio (POR)).

Finally, to assess whether the ordered TO had better statistical properties in terms of identifying hospital differences, the relative efficiency of the TO versus each individual indicator was defined. To express the relative efficiency, the median SE of the coefficient of the hospital variable was used from a fixed effect logistic regression including hospital in addition to the statistically significant case-mix variables, as the SE reflects how precise hospital differences are estimated. This was done both for the ordered TO

and the individual indicators and then compared to assess the efficiency of the ordered TO in relation to the individual indicators.

Analyses were performed using R version 3.5.1 in combination with the "Companion to Applied Regression"-package (car 3.0-2), "A Grammar of Data Manipulation"-package (dplyr 0.7.6), "Tidy Data Functions"-package (tidyr 0.8.1), "Table 1 Baseline Characteristics"-package (tableone 0.9.3), "Convert Statistical Analysis Object"-package (broom 0.5.0) and "Support Functions and Datasets"-package (MASS 7.3-50).

RESULTS

A total of 27,360 unique patient records regarding primary bariatric surgery were entered by 18 Dutch hospitals. Twenty-seven thousand, two hundred seventy-three (27,273; 99.7%) of these records contained complete data and were used for detailed analyses.

Table 2 shows the number and proportion of patients for whom each desired health outcome was realised. A total of 88.7% (n = 24,201) patients reached TO after primary bariatric surgery. Looking at the differences between each conditional step in **Table 2** mild postoperative complications (2.6%; n = 720) and prolonged LOS (4.4%; n = 1182) had the greatest effect on achieving TO for the individual patient.

Table 2: Population: percentage of patients for whom the outcome quality indicator was met; Conditional: percentage of patients for whom the outcome quality indicator, but also all outcome quality indicators listed above were met.

	Population		Conditional	
	N	%	N	%
Patients	27,273			
No mortality	27,258	99.9%	27,258	99.9%
No severe complications	26,573	97.4%	26,558	97.4%
No readmission	26,534	97.3%	26,103	95.7%
No mild complications	26,098	95.7%	25,383	93.1%
No prolonged-LOS	25,410	93.2%	24,201	88.7%
Textbook Outcome			24,201	88.7%

To gain insight into the variation between hospitals, each patient was assigned to one category of the ordered TO group. The last group, the most favourable group, was defined as TO. **Fig. 1** shows a simple group classification and the variation between hospitals, with the emphasis on TO, prolonged LOS, mild complications, severe com-

plications and mortality. On average, 4.3% (range 0.2%–17.1% between hospitals) of the patients had only a mild postoperative complication, and 2.6% (range 0.6%–4.5%) had severe postoperative complications. It should be noted that the average for mild post-operative complications was heavily influenced by one hospital (B) that scored 17.1%. In **Fig. 1**, the individual parameter 'readmission' is not included, because a readmission was by definition considered as a mild complication.

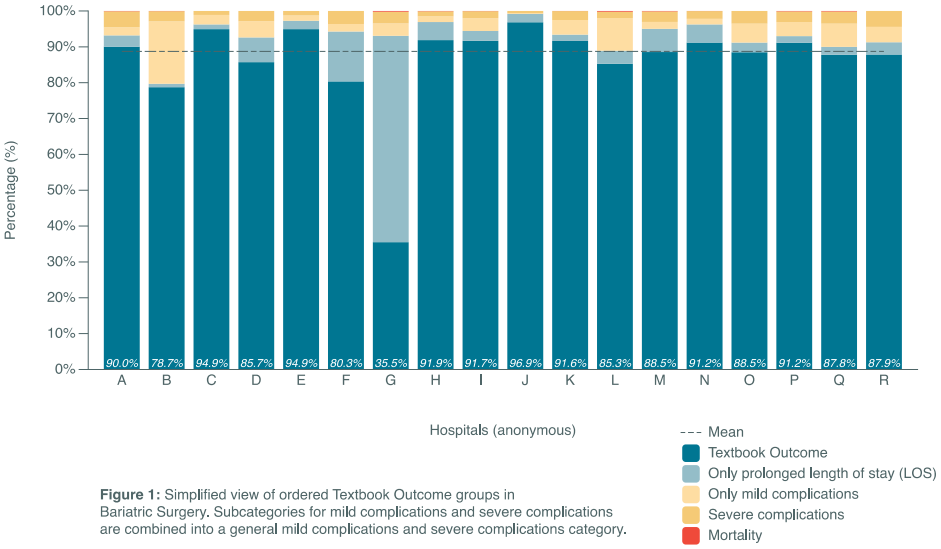

Figure 1: Simplified view of ordered Textbook Outcome groups in Bariatric Surgery. Subcategories for mild complications and severe complications are combined into a general mild complications and severe complications category.

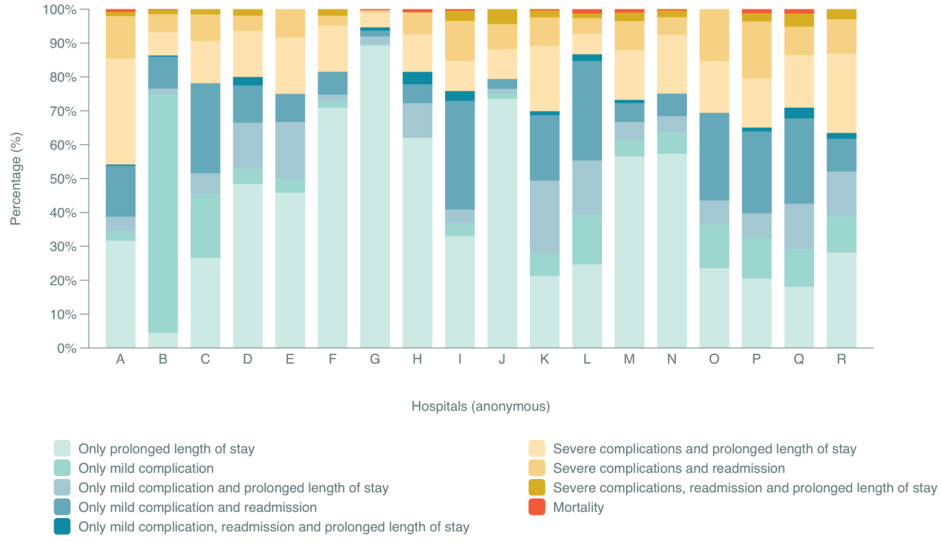

Figure 2: Detailed view of ordered non-Textbook Outcome groups in bariatric surgery.

For a clear overview, **Fig. 2** shows the distribution of parameters for not achieving TO. The figure is a detailed representation of all ordered TO groups of patients who have not achieved TO. The outlier of mild postoperative complications in **Fig. 2** (hospital B) is visible. Another significant outlier is hospital G with 57.6% of the postoperative patients with a prolonged LOS. The national average was 4.2% (range 1.0%–57.6%). In addition, particularly **Fig. 2** shows the added value of the ordered TO groups above only having the binomial TO, thereby showing hospitals for which exact combination of outcomes they perform not as good as other hospitals do. For instance, patients with only a mild complication or readmission but with a normal LOS might be patients discharged too early and require a different type of intervention comparing to patients with also a prolonged LOS which might represent more complex patients.

IMPACT OF PATIENT AND PROCEDURE CHARACTERISTICS

Age, procedure type, T2DM, hypertension, dyslipidaemia, GERD and OSAS were factors associated with achieving TO in univariate logistic regression (**Table 3**). All factors remain significant in multivariate logistic regression, except for dyslipidaemia. Factors associated with a significantly effect on achieving TO were included in the case-mix model. **Table 3** shows the same case-mix factors remaining significant for both the binomial and the ordered TO.

Table 3: Patient characteristics.

	Non-Textbook Outcome		Textbook Outcome			Uni-/multivariate logistic regression		Ordinal logistic regression	
	N	%	N	%	*p*-value	OR	95% C.I.	OR	95% C.I.
Number of patients	3,072	11.3%	24,201	88.7%	-	-	-	-	-
Age (mean, years, SD)	45.0	± 11.3	43.8	± 11.3	**<0.001**	**0.99***	**0.99 – 0.99**	**0.99**	**0.99 – 1.00**
Gender (female)	2,407	78.4%	19,281	79.7%	0.092	1.08	0.99 – 1.19	-	-
Weight (mean, kg, SD)	126.3	± 21.0	126.5	± 20.2	0.549	1.00	1.00 – 1.00	-	-
Length (mean, cm, SD)	169.3	± 9.2	169.4	± 8.9	0.536	1.14	0.75 – 1.74	-	-
BMI (mean, kg/m^2, SD)	44.0	± 5.7	44.0	± 5.5	0.855	1.00	0.99 – 1.01	-	-
Sleeve gastrectomy	822	26.8%	5,457	22.5%	-	REF	-	REF	-
Gastric bypass	2,250	73.2%	18,744	77.5%	**<0.001**	**1.25***	**1.15 – 1.37**	**1.28**	**1.18 – 1.40**
T2DM	777	25.3%	4,803	19.8%	**<0.001**	**0.73***	**0.67 – 0.80**	**0.82**	**0.74 – 0.90**
Hypertension	1,201	39.1%	8,150	33.7%	**<0.001**	**0.79***	**0.73 – 0.85**	**0.90**	**0.82 – 0.98**
Dyslipidaemia	695	22.6%	4,637	19.2%	**<0.001**	**0.81**	**0.74 – 0.89**	-	-
GERD	403	13.1%	3,079	12.7%	0.555	0.97	0.86 – 1.08	-	-
OSAS	674	21.9%	4,361	18.0%	**<0.001**	**0.78***	**0.71 – 0.86**	**0.85**	**0.77 – 0.94**
Musculoskeletal pain	1,425	46.4%	10,944	45.2%	0.229	0.95	0.88 – 1.03	-	-

Abbreviations: N, number; OR, odds ratio; SD, standard deviation; CI, confidence intervals; T2DM, type 2 diabetes mellitus; GERD, gastroesophageal reflux disease; OSAS, obstructive sleep apnoea syndrome.
* factor remains significant after multivariate logistic regression and ordinal logistic regression analyses.

The variation between hospitals for the individual indicators is shown in **Fig. 3** which again show the outlier hospitals B (on mild complications) and G (on prolonged LOS). It also shows that for each individual indicator, other hospitals scored significantly worse compared to the national average. A total of 12 out of 18 hospitals performed significantly worse on one or more single outcome parameters after case-mix correction, suggesting integration of these indicators in the ordered TO.

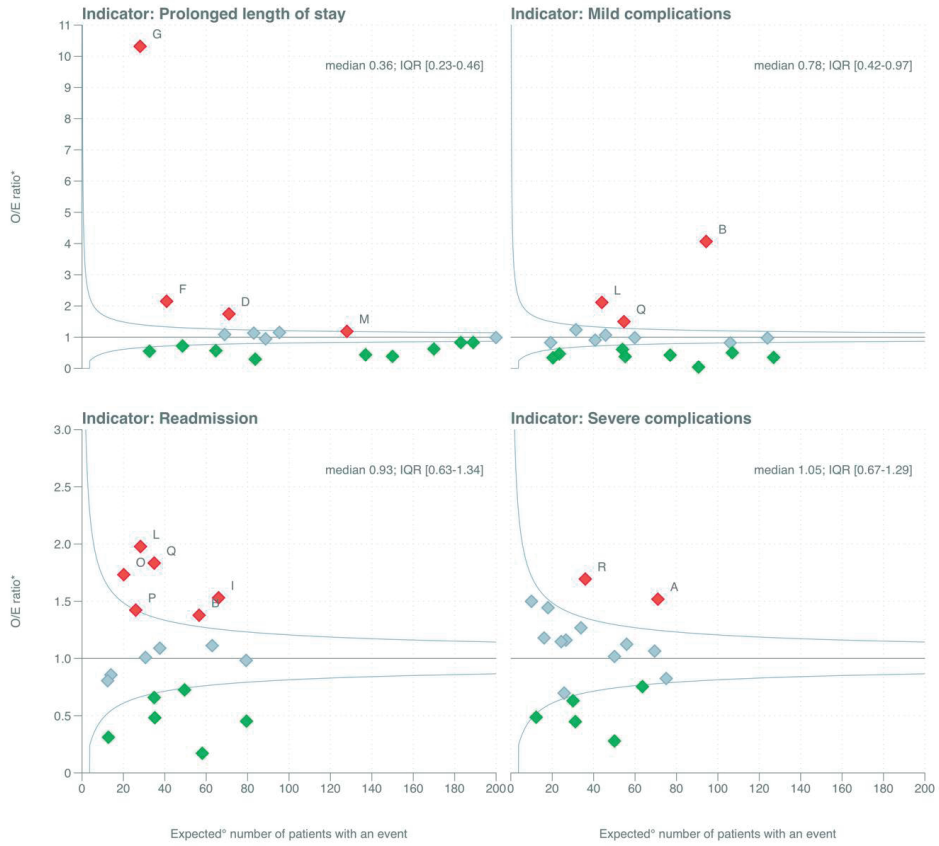

Figure 3: Funnel plot of between-hospital variation for a specific single indicator after bariatric surgery (2015-2017). *O/E ratio: observed number of events devided by expected° number of events. ** O = E: the observed number equals the expected° number of events. °Expected based on population characteristics.

The case-mix adjusted funnel plot for achieving TO shows the variation between hospitals (**Fig. 4**). Two hospitals scored significantly lower compared to the nationwide average and two hospitals had significant better scores. Comparing the extent of hospital variation in **Figs. 3** and **4**, the IQR is clearly smaller when using the TO and thus smaller

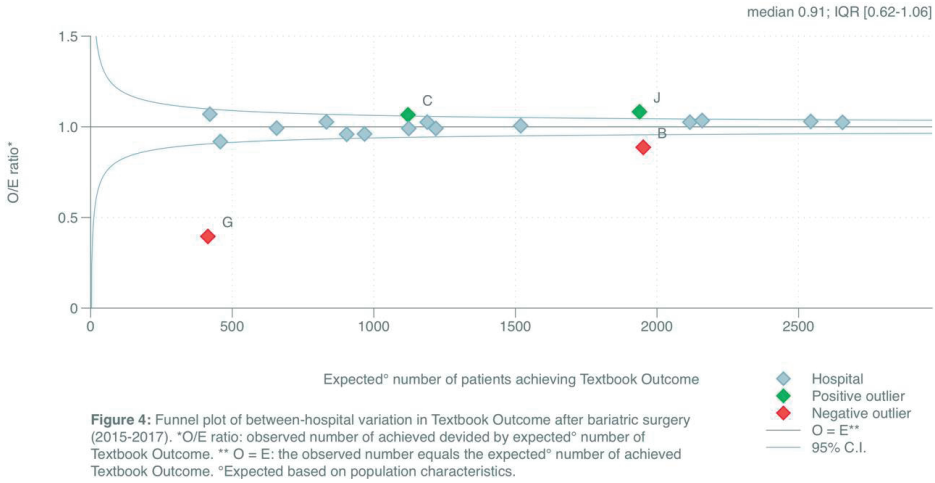

Figure 4: Funnel plot of between-hospital variation in Textbook Outcome after bariatric surgery (2015-2017). *O/E ratio: observed number of achieved devided by expected° number of Textbook Outcome. ** O = E: the observed number equals the expected° number of achieved Textbook Outcome. °Expected based on population characteristics.

hospital variation. In comparison, the ordered TO had a median 0.66 [IQR 0.55–0.96], thereby showing the full extent of hospital variation which in part is cancelled out in the TO as different hospitals are outliers on the different indicators.

To express the relative efficiency of detecting hospital differences, **Fig. 5** shows that using the ordered TO it is 11 times as likely to detect hospital differences when compared to mortality alone, about twice as likely compared to complications or readmissions and 1.2 times as likely compared to prolonged LOS. The relative efficiency of the ordered TO is comparable to that of the classic TO but with the advantage of capturing the full hospital variation as well as showing hospitals on which indicator they are an outlier.

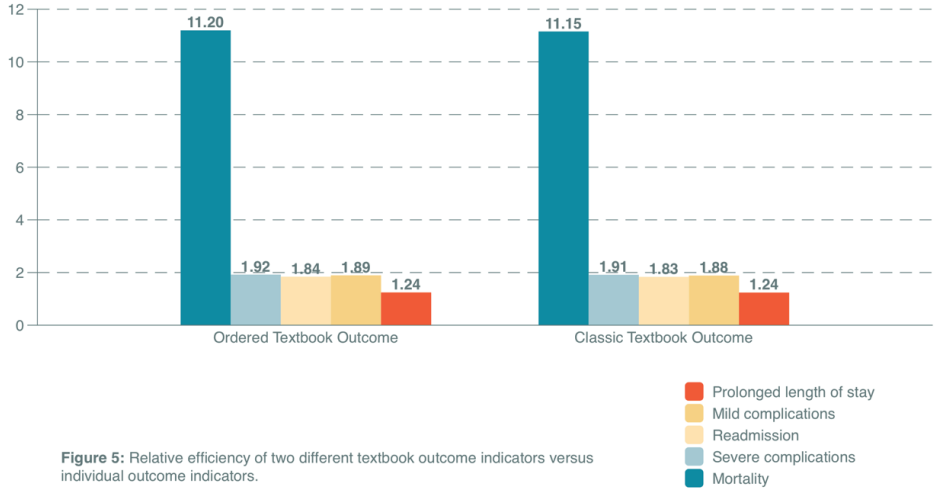

Figure 5: Relative efficiency of two different textbook outcome indicators versus individual outcome indicators.

DISCUSSION

The present study uses existing previously developed composite outcome measure for other indications representing the percentage of patients with TO and added significant detail by ordering the different individual outcome parameters after primary bariatric surgery to make the TO more useful for quality improvement. The new composite measure (an ordered TO for bariatric surgery) still has the same properties as a composite measure for postoperative outcome quality measurements, not only from a patient's perspective, but also providing more detailed information for the care giver.

It was shown, that for almost 90% of all primary bariatric patients, all desired health outcomes were realised. The binomial outcome indicator for achieving TO has smaller between-hospital variation as different hospitals were outliers for different indicators which cancelled out in the TO but were fully captured in the ordered TO. Besides, quality improvement of bariatric care has been primarily focused on mortality and morbidity rates alone and does not reflect the quality of care completely.[26-28] Thus, a hospital can score above average on a single indicator mortality, but score poorly on other processes regarding postoperative care like prolonged LOS [9, 11, 27] as was also seen in the present study. Another statistical pitfall is seen when the incidence and/or variation in mortality and morbidity is lacking, it hampers the discriminative ability of a single outcome indicator which is why either outcomes or multiple years are combined to improve this.[28, 29] Finally, outcomes parameters are often related to each other [7, 8, 25] so that different hospitals are outliers on different indicators which are cancelled out in the dichotomous TO. Therefore, an ordered TO indicator was created to provide a tool in distinguishing hospitals, capturing the full extent of the hospital variation, and provide additional information for the individual care giver.

This ordered TO provides a good insight in different individual process indicators who influence the postoperative outcome. Because each patient can only be classified into one of the predetermined categories, there is a clear insight into the differences between hospitals for different combination of indicators thereby informing quality improvement initiatives. The ordered TO indicator identified hospitals who choose to hospitalise patients longer than the recommended 2 days. There were also hospitals that discharged their patients within 2 days after primary surgery but had a relatively higher percentage of readmissions related to a postoperative complication within 30 days after primary surgery. Despite the fact that the percentages differed little in achieving TO, there seem enough opportunities for hospitals to improve on individual indicators and their combinations given the variation.

Non-influential factors such as patient characteristics are often decisive for the type of procedure.[30] These factors can have an influence on achieving TO, while this has no direct relation with surgical expertise or team effort by the hospital. It is remarkable that the present study showed that a gastric bypass is associated with a higher likelihood (OR) of achieving TO compared to sleeve gastrectomy, while recent literature claims the opposite.[31, 32] This is most probably due to the large number of RYGB procedures in the Netherlands and the associated experience gained with this procedure.

STUDY LIMITATIONS

Previous data verification by an independent third party showed no overall differences in patient, procedure and outcome data.[6] Therefore, it is unlikely that the results would have been influenced by the missing of almost 1% of the patient's data.

The present study indicated more than 10% of the primary operated patients did not achieve TO. The indicators 'mild complication' and 'prolonged LOS' were found to have the largest impact on achieving TO but were not associated with a reintervention or permanent morbidity. Therefore, these indicators may be considered as a 'minor morbidity' and it could be a point of discussion whether these indicators should be included in the definition of 'textbook outcome' as earlier discussed by Kolfschoten et al.[9] However, previous studies have shown that patients are willing to travel further for better quality of care.[33] Therefore, they were included in our suggested ordered TO for bariatric surgery.

At this moment, we have not applied a weighting for each parameter in this ordered TO, in the absence of evidence in the current literature of what the weight for each step or parameter

should be. There is however evidence on ordering of the different parameters, which was the rationale of developing an ordered TO.

Another possible limitation of this study could be the absence of long-term follow-up results. However, long-term follow-up results reflect the quality of care given 5 years earlier. Short-term information reflects recently delivered care and is therefore more suitable and actionable for performance measures and inducing quality improvement cycles.

IMPLICATIONS FOR THE FUTURE

Now, the new indicator can be embedded in the current audit cycle, enhancing the insight of short-term postoperative complications per institute, whereby hospitals re-

ceive information on the short-term postoperative outcomes in a composite measure. In addition, different process parameters will be identified for each individual hospital in order to (further) improve the quality of care.

Furthermore, long (er)-term outcomes will have to be analysed to assess whether these are associated with the existing TO indicator. This will outline a completer picture of the full postoperative bariatric care process in each individual hospital.

CONCLUSION

An ordered textbook outcome for bariatric surgery is suggested as a composite measure for short-term postoperative outcome after bariatric surgery. Most importantly, individual hospitals can identify differences in outcome indicators using this ordered TO, whereas these may remain hidden in the previously developed binomial TO. This between-hospital variation may initiate an improvement cycle that will result in hospital and surgical quality improvements and therefore improve the clinical outcome of bariatric surgery.

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Measuring Quality of Life in Bariatric Surgery:
A Multicentre Study

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ABSTRACT

BACKGROUND

Current studies mainly focus on total weight loss and comorbidity reduction. Only a few studies compare Quality of Life (QoL) after sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB). This study was conducted to examine the extent of improvement in QoL on different domains after primary bariatric surgery and compare these results to Dutch reference values.

METHODS

The study included prospectively collected data from patients who underwent primary bariatric surgery in five Dutch hospitals. The RAND-36 questionnaire was used to measure the patient's QoL; preoperatively and twelve months postoperatively. Postoperative scores were compared to Dutch reference values, standardized for age, using t-test. A difference of more than 5% was considered a minimal important difference. A multivariate linear regression analysis was used to compare SG and RYGB on the extent of improvement, adjusted for case-mix factors.

RESULTS

In total, 4864 patients completed both the pre- and postoperative questionnaire. Compared with Dutch reference values, patients postoperatively reported clinically relevant better *physical functioning* (RYGB + 6.8%), *physical role limitations* (SG + 5.6%; RYGB + 6.2%) and *health change* (SG + 77.1%; RYGB + 80.0%), but worse *general health perception* (SG − 22.8%; RYGB − 17.0%). Improvement in QoL was similar between SG and RYGB, except for *physical functioning* (β 2.758; p-value 0.008) and *general health perception* (β 2.607; p-value < 0.001) for which RYGB patients improved more.

CONCLUSIONS

SG and RYGB patients achieved a better postoperative score in *physical functioning*, *physical role limitations*, and *health change compared* to Dutch reference values, and a worse score in *general health perception*.

INTRODUCTION

International literature provides evidence that bariatric surgery can contribute to substantial weight loss and a positive effect on obesity-related comorbidities.[1, 2] On the other hand, bariatric surgery may also lead to severe postoperative complications, as well as endocrine and metabolic complications.[1, 3-5] Psychological consequences of bariatric surgery were also described as complex and not always entirely understood.[6-9] Therefore, bariatric surgery requires a detailed evaluation of its impact on a patients level and is best assessed with a Quality of Life (QoL) assessment.[10]

Standard clinical outcomes, such as weight loss and resolution of comorbidities, are mostly objectively measured in registries, resulting in quantitative data, which are convenient for analyses. QoL assessments, however, are primarily patient-reported measurements and may be more challenging to interpret. On the other hand, it is essential to include QoL assessments in the evaluation of health interventions of bariatric surgery as the patient perspective can provide valuable information on the effectiveness of bariatric surgery that cannot be obtained from clinical outcome measures alone.[10-12] QoL could be measured by using questionnaires reflecting the patient's perspective on the effects of the provided healthcare or treatment given to the patient in their daily lives.[10, 11] Literature showed that the Short Form 36-item Health Survey® (SF-36) is the most commonly used QoL measurement in bariatric surgery.[10] A nearly identical questionnaire is the RAND 36-item Health Survey (RAND-36) that evaluates the same domains as the SF-36. The difference between these two questionnaires mainly consists of the commercial fees required for using the questionnaire.[13, 14] The RAND-36 is also the standard QoL measuring tool offered to patients in all Dutch bariatric hospitals.

Recent studies mainly focussed on clinical outcomes such as total weight loss and obesity-related comorbidity reduction.[15, 16] The few initial studies which compared

QoL after sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB) did not use the RAND-36 and included a low sample size (range 50–1703) with only two studies of more than 1000 patients.[17, 18] Another pitfall in previously conducted studies is the low volume of postoperative respondents as well as single-centre studies, making the results on improvement after bariatric surgery less reliable and also not generalizable to other settings in daily practice.[19] Furthermore, a recent study comparing RYGB and SG in three different European countries showed differences in preoperative characteristics, which may have been the reason for a different surgical approach but could also affect the outcomes including postoperative QoL after bariatric surgery.[20] We therefore com-

pared changes between these procedures, not only looking at statistical significance but also considering clinically relevant differences.

The aim of this study is to compare improvement in QoL after primary bariatric surgery for the two mainly performed primary bariatric procedures in the Netherlands: SG and RYGB. In addition, the study compares postoperative values with reference values for the general Dutch population. A multicentre study design is chosen for a better representation across multiple sites.

MATERIALS AND METHODS

QoL-data were prospectively collected from all patients undergoing a primary RYGB or SG in the five participating hospitals in the Netherlands between 1 January 2015 and 1 January 2017. QoL-data were linked to the national bariatric DATO-registry covering all centres providing bariatric surgery.[21]

The scientific committee, which coordinates the national DATO-registry, represents all participating bariatric centres and all members are mandated by the practising hospital where they practice. This committee approved the research proposal for the present study and manuscript for publication. A more in depth description about the scientific committee is given in an earlier scientific article.[21]

PATIENTS

In the Netherlands, patients with a body mass index (BMI) ≥ 40.0 kg/m2 or with a BMI ≥ 35.0 kg/m2 and one or more obesity associated comorbidities were eligible for bariatric surgery during the study period.[21, 22] These obesity associated comorbidities were type-2 diabetes mellitus (T2DM), hypertension (HT), dyslipidaemia, gastroesophageal reflux disease (GERD), obstructive sleep apnoea syndrome (OSAS) and musculoskeletal pain. Further treatment strategies, including the choice for SG or RYGB, were determined by a multidisciplinary team and by shared decision making with the patient.

Baseline characteristics in patients undergoing SG or RYGB were compared using the mean ± standard deviation (SD) for normally distributed variables and the median with interquartile range for non-normally distributed variables. The Mann–Whitney *U* test was performed for continuous variables and $\chi 2$ for categorical variables. The threshold for significance has been set at 0.05.

QUALITY OF LIFE (QOL)

During the development process of the nationwide DATO registry, several questionnaires were considered including the Bariatric Analysis and Reporting Outcome System (BAROS) [23, 24], SF-36 and RAND-36 questionnaires. Given the controversy surrounding BAROS a generic QoL questionnaire was preferred. The RAND-36 and SF-36 are identical, except for different scoring algorithms for the *pain* and *general health perception* scales, resulting in the choice for the RAND-36 questionnaire.[13, 14, 25, 26].

RAND-36

The Dutch version of the RAND-36 is a validated and standardized translation of the original RAND-36 questionnaire.[13, 14] The questionnaire contains 36 questions within nine scales. These scales are *physical functioning*, *social functioning*, *physical role limitations*, *emotional role limitations*, *mental health*, *vitality*, *pain*, *general health perception* and *health change perception*. Previous studies have shown this to be a valid tool for the measurement of QoL among obese patients undergoing bariatric surgery.[25, 27, 28]

Each patient undergoing bariatric surgery in one of the five participating bariatric centres was included in the study. The preoperative questionnaire was completed during the initial screening for bariatric surgery. The postoperative questionnaire was administered 12 months (range 9–15) after primary surgery. The questionnaires were part of the standard given care in the five participating centres.

ANALYSING THE QUESTIONNAIRE

All completed questionnaires were analysed by a predefined algorithm, provided by the RAND-36 research group and included in the original article.[13, 14] A brief summary is given below.

All scores were recoded following the provided algorithm: a high score indicates a more favourable health state (or outcome) of the patient.[14, 26] Each item was scored on a 0 to 100 range. An average of all scores in each of the nine individual scales has been calculated. Missing values were replaced with the personal mean of the specific scale if at least half of the answers on the questions of the scale were provided.[13, 14, 26]

COMPARING TO THE DUTCH REFERENCE POPULATION

First, postoperative RAND-36 scores were divided into six age groups (18–24, 25–34, 35–44, 45–54, 55–64 and 65 +). Second, the extent of improvement after surgery was calculated by subtracting preoperative RAND-36 scores from the postoperative RAND-36 scores, providing the delta separately for SG and RYGB. Third, the postoperative

RAND-36 scores were compared with the Dutch reference values [13], in order to see if patients experience the same QoL postoperatively as the Dutch reference group.

Finally, for a valid comparison, the age distribution of the Dutch reference population [13] was applied to the age-specific QoL-values of the SG or RYGB patients to prevent overall values being different because of a difference in age distribution. The age-standardized QoL scores for each of the nine scales were compared for SG and RYGB patients with the Dutch population using the *t*-test.

POSTOPERATIVE INFLUENCES ON THE QOL OUTCOMES

The Clavien–Dindo classification (CD) is used to determine whether a patient had experienced a severe postoperative complication.[29, 30] All patients with a CD grade ≥ 3, within 30 days after primary surgery, were registered as severe. Due to the low number of severe complications, both operative techniques have been combined and the *t*-test compared the severe complicated group with the uncomplicated group.

A distinction has also been made to see whether the achievement of Total Weight Loss (TWL) influences the QoL outcomes.[21, 31] All patients were subdivided into patients who reached 20% TWL within 12 months postoperatively and patients who did not. There were no patients in this cohort missing preoperative or postoperative weight scores. Both groups are compared using the *t*-test.

COMPARISON BETWEEN SG AND RYGB

In order to compare between SG and RYB, we compared the extent of improvement between SG and RYGB patients adjusted for patient variables that differed at baseline using multivariate linear regression analysis reporting the β estimate and *p*-value.

Analyses were performed using R version 3.5.1 and the R-packages "Companion to Applied Regression"-package (car 3.0-2), "A Grammar of Data Manipulation"-package (dplyr 0.7.8) and "Table 1"-package (tableone 0.9.3)' were used.

RESULTS

A total of 5574 unique patients underwent a primary SG or RYGB. Patients who were operated and who did not complete both questionnaires (n = 710) were excluded. A total of 4864 (87.3%) patients were eligible for analyses, having completed both a preoperative and postoperative questionnaire. Baseline characteristics were shown in **Table 1** and correspond to the national bariatric benchmark in the Netherlands.[21]

Table 1: Baseline characteristics showing preoperative measurements and prevalence of obesity-related comorbidities.

	Sleeve gastrectomy		Roux-en-Y gastric bypass		
	N	%	N	%	*p*-value
Number of patients	965	19.8%	3,899	80.2%	
Gender (female)	745	77.2%	3,152	80.8%	**0.013***
Weight (median, kg, IQR)	133.9	(119.4 – 155.0)	123.9	(113.0 – 136.4)	**<0.001***
BMI (median, kg/m^2, IQR)	45.8	(42.0 – 52.7)	43.0	(40.4 – 46.7)	**<0.001***
Waist circumference (median, cm, IQR)	133	(123 – 145)	127	(120 – 136)	**<0.001***
Age (mean, years, SD)	39.3	± 12.5	45.6	± 10.3	**<0.001***
Type 2 diabetes mellitus	170	17.6%	1,160	29.9%	**<0.001***
Hypertension	297	30.8%	1,593	40.9%	**<0.001***
Dyslipidaemia	128	13.3%	902	23.1%	**<0.001***
GERD	49	5.1%	233	6.0%	0.317
OSAS	200	20.7%	812	20.8%	0.965
Musculoskeletal pain	430	44.6%	2,294	58.8%	**<0.001***

Abbreviations: N, number; SD, standard deviation; IQR, interquartile range; GERD, gastroesophageal reflux disease; OSAS, obstructive sleep apnoea syndrome. * statistically significant difference measured.

Patients with a SG were significantly heavier ($p < 0.001$), reflected in both higher BMI and higher waist circumference ($p < 0.001$). Statistically significant differences in obesity-related diseases were seen for T2DM, hypertension, dyslipidaemia and musculoskeletal pain. All these obesity-related diseases were seen significantly more often in the RYGB group ($p < 0.001$) compared to SG.

SLEEVE GASTRECTOMY

For patients undergoing SG, the best postoperative QoL scores were seen in relatively young bariatric patients (**Table 2a**). However, the older bariatric patients showed a larger positive delta score and therefore showed a bigger improvement compared to the younger and middle-aged patients (**Table 2b**). For example, the youngest patients scored postoperatively better on *physical functioning* and *physical role limitations*. On the other hand, the delta scores for these domains are slightly lower for the younger patients compared to the oldest group (**Table 2a**, **b**).

ROUX-EN-Y GASTRIC BYPASS

For RYGB patients, especially the three youngest categories showed better postoperative scores in almost all RAND-36 domains except for the domain *vitality* and *general health perception* (**Table 3a**). However, the largest improvement (delta) was seen in the oldest group (65 +). This applies to all domains except *physical role limitations*,

Table 2a & Table 2b: Postoperative unadjusted scale scores & pre- and postoperative change in scale scores (delta) per age group after **sleeve gastrectomy**, measured with RAND-36. Abbreviations: SD, standard deviation.

Age (n)	18-24 (n=135)		25-34 (n=257)		35-44 (n=211)		45-54 (n=226)		55-64 (n=124)		65+ (n=12)		Overall (n=965)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Physical functioning	91.26	± 13.90	90.42	± 18.33	88.39	± 19.81	83.03	± 20.76	75.27	± 25.79	58.33	± 37.77	85.92	± 20.92
Social functioning	84.68	± 21.38	86.04	± 21.47	87.30	± 19.74	84.03	± 21.48	82.00	± 23.28	77.00	± 34.12	85.03	± 21.46
Physical role limitations	88.79	± 26.07	87.57	± 27.46	85.97	± 27.93	81.65	± 32.00	79.30	± 33.30	70.83	± 45.87	84.63	± 29.69
Emotional role limitations	85.37	± 31.27	86.35	± 30.38	90.28	± 26.63	85.49	± 31.24	83.04	± 31.02	83.33	± 40.82	86.42	± 30.08
Mental health	76.37	± 17.76	78.21	± 17.53	81.29	± 15.41	79.08	± 18.03	80.99	± 15.50	72.67	± 31.94	79.21	± 17.15
Vitality	61.44	± 20.74	62.91	± 18.73	67.90	± 17.58	67.25	± 19.69	68.60	± 18.44	61.67	± 32.20	65.68	± 19.20
Pain	82.68	± 24.76	84.39	± 21.85	80.48	± 26.79	75.79	± 26.33	73.16	± 27.44	61.00	± 39.18	79.44	± 25.72
General health perception	55.68	± 15.15	56.80	± 15.96	56.44	± 15.90	55.42	± 16.03	51.53	± 18.00	51.33	± 24.45	55.48	± 16.26
Health change	93.68	± 16.27	93.44	± 14.83	92.90	± 17.74	92.49	± 19.10	93.82	± 13.11	95.83	± 10.21	93.18	± 16.56
Age (n)	18-24 (n=135)		25-34 (n=257)		35-44 (n=211)		45-54 (n=226)		55-64 (n=124)		65+ (n=12)		Overall (n=965)	
	Delta	SD	Delta	SD	Delta	SD	Delta	SD	Delta	SD	Delta	SD	Delta	SD
Physical functioning	28.51	± 19.94	30.50	± 23.68	30.81	± 26.11	33.61	± 24.77	33.98	± 23.26	19.17	± 42.12	31.46	± 24.24
Social functioning	8.56	± 26.69	17.37	± 29.25	15.64	± 26.54	14.57	± 26.20	14.12	± 25.78	29.33	± 55.09	14.85	± 27.48
Physical role limitations	19.54	± 41.84	28.07	± 43.76	29.03	± 42.97	32.66	± 45.62	27.42	± 46.63	29.17	± 62.08	28.28	± 44.38
Emotional role limitations	0.78	± 36.75	7.85	± 40.84	6.45	± 36.14	10.60	± 38.88	4.67	± 42.51	17.00	± 18.62	6.99	± 38.94
Mental health	3.17	± 17.48	10.50	± 20.20	7.77	± 17.68	7.68	± 17.74	6.49	± 16.02	2.00	± 28.48	7.65	± 18.32
Vitality	8.16	± 19.96	10.61	± 21.36	14.74	± 21.50	18.79	± 20.83	19.09	± 22.44	0.00	± 28.28	14.31	± 21.64
Pain	13.03	± 25.40	18.66	± 26.66	18.05	± 29.37	17.42	± 26.64	20.12	± 26.03	26.33	± 42.07	17.77	± 27.17
General health perception	18.94	± 16.61	21.54	± 17.02	19.38	± 17.73	19.54	± 17.42	18.41	± 17.09	15.33	± 14.40	19.76	± 17.20
Health change	54.02	± 27.72	55.03	± 29.44	51.94	± 32.30	53.61	± 32.98	56.72	± 30.87	70.83	± 36.80	54.22	± 31.02

Table 3a & Table 3b: Postoperative unadjusted scale scores & pre- and postoperative change in scale scores (delta) per age group after **Roux-en-Y gastric bypass**, measured with RAND-36. Abbreviations: SD, standard deviation.

Age (n)	18-24 (n=84)	25-34 (n=537)	35-44 (n=1,040)	45-54 (n=1,427)	55-64 (n=741)	65+ (n=70)	Overall (n=3,899)
	Mean SD	Mean SD	Mean SD	Mean SD	Mean SD	Mean SD	Mean SD
Physical functioning	94.42 ± 10.54	92.90 ± 13.67	91.94 ± 15.58	88.19 ± 18.80	82.17 ± 22.11	84.44 ± 20.23	88.75 ± 18.35
Social functioning	88.42 ± 16.77	83.89 ± 22.03	87.05 ± 21.24	85.07 ± 22.61	84.12 ± 23.07	89.06 ± 20.19	85.40 ± 22.14
Physical role limitations	90.42 ± 24.83	86.17 ± 29.91	87.23 ± 28.79	84.45 ± 31.37	82.22 ± 31.89	87.50 ± 29.44	85.18 ± 30.49
Emotional role limitations	88.82 ± 27.28	83.14 ± 33.50	90.07 ± 26.37	86.61 ± 31.17	87.60 ± 30.28	94.43 ± 20.28	87.44 ± 29.96
Mental health	81.93 ± 12.64	78.02 ± 17.83	81.41 ± 15.96	80.37 ± 17.64	80.36 ± 17.16	85.26 ± 15.90	80.45 ± 17.06
Vitality	62.50 ± 20.14	63.20 ± 19.89	67.19 ± 19.74	67.49 ± 20.30	68.81 ± 19.77	74.54 ± 18.31	67.11 ± 20.04
Pain	87.42 ± 20.75	82.60 ± 23.44	82.76 ± 23.22	79.84 ± 24.59	76.44 ± 25.89	78.56 ± 28.79	80.48 ± 24.45
General health perception	57.47 ± 11.38	57.71 ± 15.01	60.42 ± 14.81	60.14 ± 14.84	59.44 ± 14.79	62.81 ± 15.59	59.75 ± 14.82
Health change	95.42 ± 13.41	94.17 ± 16.92	95.37 ± 15.17	94.61 ± 16.13	94.47 ± 16.59	95.83 ± 15.16	94.77 ± 16.01
Age (n)	18-24 (n=84)	25-34 (n=537)	35-44 (n=1,040)	45-54 (n=1,427)	55-64 (n=741)	65+ (n=70)	Overall (n=3,899)
	Delta SD	Delta SD	Delta SD	Delta SD	Delta SD	Delta SD	Delta SD
Physical functioning	24.17 ± 20.34	30.66 ± 22.87	31.75 ± 23.31	34.54 ± 23.14	36.76 ± 24.36	41.85 ± 24.73	33.61 ± 23.50
Social functioning	8.45 ± 24.03	13.03 ± 26.80	14.20 ± 28.57	13.99 ± 27.51	15.88 ± 28.40	16.13 ± 29.31	14.20 ± 27.84
Physical role limitations	16.25 ± 39.82	23.57 ± 43.65	27.49 ± 44.97	29.19 ± 45.80	33.11 ± 47.96	35.19 ± 47.71	28.57 ± 45.73
Emotional role limitations	4.47 ± 43.26	-0.97 ± 39.34	6.24 ± 36.86	3.60 ± 40.44	12.83 ± 45.57	9.93 ± 34.10	5.56 ± 40.55
Mental health	7.07 ± 13.77	7.54 ± 18.36	8.44 ± 17.88	6.84 ± 18.46	7.99 ± 18.36	7.26 ± 20.46	7.59 ± 18.23
Vitality	3.75 ± 22.71	12.47 ± 22.74	16.68 ± 23.02	16.98 ± 22.39	18.38 ± 22.89	18.89 ± 22.12	16.32 ± 22.82
Pain	11.58 ± 28.36	17.95 ± 31.18	18.92 ± 27.69	20.99 ± 28.07	20.98 ± 27.36	21.57 ± 33.49	19.85 ± 28.42
General health perception	15.47 ± 18.15	21.40 ± 18.11	22.53 ± 17.34	23.53 ± 17.23	22.89 ± 16.30	23.93 ± 18.13	22.70 ± 17.28
Health change	42.50 ± 30.64	51.49 ± 30.40	55.08 ± 29.28	57.62 ± 28.81	58.16 ± 29.34	57.87 ± 24.68	55.91 ± 29.34

emotional role limitations and *health change*. For these domains, the second-oldest group (55–64) showed the largest improvement (**Table 3b**).

OVERALL QUALITY OF LIFE

The comparison of the Dutch reference values with both the postoperative SG and RYGB values were standardized to the age distribution of the Dutch reference group.[13] As suggested in recent scientific literature, a statistical significant QoL-score difference of > 5% is considered a minimal important difference (MID).[32, 33]

Results showed a MID in the domains *physical functioning* (for RYGB), *physical role limitations* and *health change* (for both SG and RYGB) compared to Dutch reference values. Especially, for the domain *health change*, a large difference was observed (**Table 4a**). However, patients postoperatively still report lower scores on the domain *general health perception*. In addition, the SG scores were slightly lower than the RYGB in all RAND- 36 domains (**Table 4a**).

COMPLICATIONS AND TOTAL WEIGHT LOSS

Hypothetically, a postoperatively complicated course has a negative influence on the postoperative QoL outcomes. To make reliable calculations, both operative techniques were combined and the postoperative complicated group was compared with the uncomplicated group. **Table 4b** shows that the positive effects in the domains *physical functioning* and *physical role limitations* have disappeared (shown in **Table 4a**). A MID was seen in the domain of *social functioning*, *physical role limitations*, *emotional role limitations*, *vitality* and *pain*. Patients postoperatively still report lower scores on the domain *general health perception*, while they still report a significant *health change* (**Table 4b**).

SG VS. RYGB

Comparing the extent of improvement between SG and RYGB patients on each domain, a significant difference was seen in the domains *physical functioning* and *general health perception* when adjusted for differences in baseline characteristics; T2DM, hypertension, dyslipidaemia and musculoskeletal pain. These significant differences were mostly seen in the RYGB group (**Table 5**).

DISCUSSION

Current studies on bariatric surgery particularly focus on weight loss and improvement of obesity-related diseases but do not sufficiently take the patient's perspective into

Table 4a & Table 4b: Table 4a represents the postoperative adjusted baseline scale scores for sleeve gastrectomy and Roux-en-Y gastric bypass. Table 4b represents the postoperative scale scores for patients with a postoperative severe complication (Clavien-Dindo grade ≥3) and scale scores for patients with a successful postoperative total weight loss (>20 %TWL) after 1 year. All outcomes are measured with RAND-36. Percentage difference (%) and p-value are comparisons to the Dutch benchmark.

	Sleeve gastrectomy				Roux-en-Y gastric bypass				Dutch reference group	
	n = 965				n = 3,899					
	Mean	SD	%	p-value	Mean	SD	%	p-value	Mean	SD
Physical functioning	86.02	± 19.66	+3.5	<0.001	88.76	± 17.69	**+6.8***	**<0.001***	83.09	± 20.39
Social functioning	85.02	± 21.32	-2.7	0.002	85.40	± 22.05	-2.2	<0.001	87.35	± 19.74
Physical role limitations	84.73	± 29.21	**+5.6***	**<0.001***	85.19	± 30.36	**+6.2***	**<0.001***	80.24	± 34.84
Emotional role limitations	86.41	± 29.90	+1,9	0.128	87.43	± 29.72	+3.1	<0.001	84.79	± 31.46
Mental health	79.12	± 17.01	+2.8	<0.001	80.44	± 16.96	+4.5	<0.001	77.00	± 18.66
Vitality	65.53	± 18.98	-3.0	0.002	67.09	± 19.92	-0.7	0.241	67.59	± 19.82
Pain	79.55	± 25.15	-2.0	0.072	80.49	± 24.27	-0.8	0.217	81.14	± 24.37
General health perception	55.50	± 16.11	**-22.8***	**<0.001***	59.74	± 14.76	**-17.0***	**<0.001***	71.95	± 21.60
Health change	93.21	± 16.29	**+77.1***	**<0.001***	94.76	± 15.97	**+80.0***	**<0.001***	52.63	± 18.50
	Postoperative complication				Unsuccessful %TWL				Dutch reference group	
	n = 119				n = 696					
	Mean	SD	%	p-value**	Mean	SD	%	p-value**	Mean	SD
Physical functioning	80.58	± 27.29	-3.0	<0.001	82.42	± 21.50	-0.8	<0.001	83.09	± 20.39
Social functioning	77.90	± 30.93	**-10.8***	**0.003***	81.11	± 23.50	**-7.4***	**0.001***	87.35	± 19.74
Physical role limitations	75.64	± 39.88	**-5.7***	**0.005***	79.43	± 33.80	-1.0	0.002	80.24	± 34.84
Emotional role limitations	83.71	± 33.91	-1.27	0.292	79.16	± 36.18	**-6.6***	**<0.001***	84.79	± 31.46
Mental health	78.90	± 18.81	+2.5	0.500	76.38	± 17.57	+0.8	<0.001	77.00	± 18.66
Vitality	61.92	± 22.48	**-8.4***	**0.027***	63.47	± 19.98	**-6,1***	**0.004***	67.59	± 19.82
Pain	70.51	± 30.66	**-13.1***	**<0.001***	76.72	± 25.51	**-5.4***	**0.015***	81.14	± 24.37
General health perception	55.74	± 16.02	**-22.5***	**0.060***	53.46	± 16.37	**-25.7***	**<0.001***	71.95	± 21.60
Health change	88.46	± 23.73	**+68.1***	**0.001***	89.72	± 21.88	**+70.5***	**<0.001***	52.63	± 18.50

Abbreviations: SD, standard deviation; %, percentage. * statistically significant and clinically relevant difference measured. ** p-value measured with the post-operative uncomplicated and the successful %TWL group.

Table 5: Postoperative delta scale scores of sleeve gastrectomy and Roux-en-Y gastric bypass, measured with RAND-36. Beta's were estimated using linear regression and adjusted for T2DM, hypertension, dyslipidaemia and musculoskeletal pain. Compared with a multivariate logistic regression analysis.

	Sleeve gastrectomy		Roux-en-Y gastric bypass			
	n = 965		n = 3,899			
	Delta mean	SD	Delta mean	SD	Beta estimate	p-value
Physical functioning	31.46	± 24.24	33.61	± 23.50	2.758	**0.008***
Social functioning	14.85	± 27.48	14.20	± 27.84	-0.821	0.509
Physical role limitations	28.28	± 44.38	28.57	± 45.73	-1.352	0.505
Emotional role limitations	6.99	± 38.94	5.56	± 40.55	-2.650	0.141
Mental health	7.65	± 18.32	7.59	± 18.23	0.483	0.544
Vitality	14.31	± 21.64	16.32	± 22.82	0.919	0.361
Pain	17.77	± 27.17	19.85	± 28.42	1.148	0.360
General health perception	19.76	± 17.20	22.70	± 17.28	2.607	**<0.001***
Health change	54.22	± 31.02	55.91	± 29.34	-0.072	0.957

Abbreviations: SD, standard deviation; T2DM, type 2 diabetes mellitus. * statistically significant and clinically relevant difference measured.

account.[21, 34-38] It is important to focus more on postoperative outcomes from a patient's perspective, because of the enormous increase in bariatric procedures worldwide.[22, 39-41]

There were a few initial studies comparing QoL after SG and RYGB, but these studies had mostly a low sample size and did not use the RAND 36-item Health Survey (RAND-36).[17, 18] In addition, these studies were almost all single-centre studies and most of them reported low postoperative response rates.[19]

However, there were two larger population-based studies comparing postoperative QoL after bariatric surgery. The first study from Waljee et al. had a larger sample size comparing to the previous noted studies, but does not distinguish between SG and RYGB and has a poor follow-up rate.[42, 43] The second study from Sarwer et al. focused on the QoL and sexual functioning of patients with obesity and looked specific on the changes in these domains, but does not made a distinction between RYGB and SG either.[44] As a result, the question remained which postoperative differences in QoL could be measured between the two most commonly used surgery techniques and how these changes relate to the Dutch population. Therefore, the first multicentre study has been conducted comparing QoL between SG and RYGB with a large sample size and a postoperative response rate of more than 85%.

Results showed that bariatric patients had meaningful higher postoperative scores on *physical functioning*, *physical role limitations* and *health change* for both SG and RYGB compared to Dutch reference values, but meaningful lower scores on *general health perception*. It may be concluded that patients feel better postoperatively, but not yet fully healthy. These results could be a prelude to focus more on these domains, so that bariatric patients do not end up in social isolation and feeling healthier, similar to the national average.

Table 4b clearly showed that a postoperatively severe complicated course or failure to achieve the desired weight loss influences the QoL outcomes. Where first a meaningful positive postoperative score in *physical functioning* and *physical role limitations* was seen (**Table 4a**), a significant negative score was now seen in the severe complicated group and the unsuccessful %TWL group. In addition, a negative trend is also observed in almost all other domains. This argues for better psychological postoperative support for patients where the outcomes do not meet Textbook Outcome.[45]

The two bariatric surgical techniques showed a similar QoL improvement in all domains except for *physical functioning* and *general health perception* for which RYGB patients showed a higher postoperative improvement. This difference could be explained by the underlying indication for treatment. Particularly for patients with a high BMI (> 50 kg/m^2) a SG is preferably, so a second stage procedure may follow.[46] The use of the SG for morbid obese patient stems from the use of this procedure as a modification to the duodenal switch. Later on, it was used as a first part of a two-stage gastric bypass procedure on morbid obese patients. In the beginning of this century multiple studies have been published with a laparoscopic sleeve gastrectomy as an isolated bariatric procedure, with promising results. [47, 48] During the time when this study was conducted, the RYGB was often used as a second-stage procedure in Dutch bariatric hospitals. In recent years and increase in the use of the "one anastomosis gastric bypass" (OAGB) and the "single anastomosis duodeno-ileal bypass with sleeve gastrectomy" (SADI-s) was seen. In addition, minor modifications have been applied to the existing RYGB. This makes the RYGB more successful in patients with a higher BMI. This has led to a decrease in the number of SG procedures nowadays.

Patient with a SG could experience a worse health perception compared to patients with a single RYGB operation. Despite the fact that BMI is added in the case-mix model, also the weight loss in both groups can be experienced differently.

Another significant difference was seen in the preoperative registered obesity-related diseases in the RYGB-group. Several studies suggest that the RYGB has a greater

beneficial effect on obesity-related diseases after surgery compared to SG.[49-52] This also could have an effect on the surgeon's choice for the type of bariatric surgery and therefore the differences in experienced QoL.

But the proper interpretation of these results remains a point of discussion. As has been shown for other type of surgeries and diseases, the RAND-36 is a generic questionnaire and may not be specific enough to fully analyse the QoL in bariatric patients.[53, 54] For example, when looking at *physical functioning*, the score was calculated on the basis of ten questions. These questions relate to typical activities during the day and may be one of the key items for patients with obesity, but can only be answered with a limited number of options; limited a lot, limited a little, or not limited at all which is likely to capture only the very severe physical limitations e.g. induced by severe obesity. More subtle differences may not be measured adequately, while this is essential for obese and bariatric patients. Using a bariatric-specific quality of life questionnaire may detect more clinically relevant differences. However, as already mentioned in the introduction, there were currently no suitable bariatric questionnaires that could be applied in current scientific research.

Another point of debate is calculating and reporting the MID. Not only the baseline scores may vary by population and context, but also the differences experienced and noticed by the patient may vary. Therefore the proper interpretation of these results remains a point of discussion.[55] This means, for example, that an increase of 10 points should be interpreted differently if the baseline values differ. And also, an individual rise from 10 to 20 on a 100-point scale can be interpreted differently than a rise from 60 to 70.

As mentioned earlier in the discussion, other studies have not shown differences between SG and RYGB in QoL, while different outcomes following these two operations can be hypothesised.[17, 18] For example, the indication for the type of bariatric surgery is mainly based on the choice and expertise of the specific surgeon. There were some studies that suggest that the RYGB has a more beneficial effect on metabolic obesity-related diseases.[46] We tried to correct this by adding these baseline differences (**Table 1**) in the case-mix model.

There are some limitations, despite the accuracy of this study. A possible response bias could be generated by excluding patients from the study without postoperative measurements. However, this study offers a high response rate, whereby it can be assumed that the influence will be very small. In addition, this study didn't focus on statistically significant differences alone but also described whether these differences

were clinically relevant (minimal important difference; MID) which at the same time will also safeguard against finding chance differences. This study does not have specific data to make a comparison between patients who participate in a multidisciplinary postoperative coaching program and patients who did not. These coaching programs could consist of participating in support groups, appointments with a dietician and psychological follow-up by trained professionals.

There is still no consensus, whether to correct for multiple testing or not. Current statements say, an adjustment is particularly required in confirmatory analyses with multiple analyses stating one final conclusion.[56] This study, on the other hand, has an exploratory meaning with the aim of not missing potentially important findings by a standard adjustment of multiple testing.[57] Therefore, the results in this study were not corrected for multiple testing.

The strength of this study was the large sample size, high response rate and the prospective study design. Most other studies collecting patient-reported outcome data struggle to get a sufficiently high response rate as a part of daily routine clinical care. Therefore, the number of requested items has been kept to a minimum, but at the cost of having limited other data to e.g. adjust for patient characteristics. Furthermore, this was a multicentre study including hospitals located in different geographic areas, therefore a representative group from the population was obtained. A limitation of the current study was the availability of only one-year follow-up data. When all Dutch hospitals have implemented the PROMs registration, the follow-up will be extended to an annual follow-up up to five years after the primary surgery in the national DATO-registry. This will further substantiate the current outcomes of this study.

CONCLUSIONS

This study showed that bariatric patients achieve better postoperative *physical functioning*, *physical role limitations*, and *health change* for both SG and RYGB compared to Dutch reference values, but worse general health perception. In addition, a larger improvement in *general health perception* was seen in patients who underwent RYGB compared to SG. Further studies are needed to develop a specific QoL-questionnaire, which focuses on the different aspects of the bariatric patient and the different inclusion criteria for a specific procedure.

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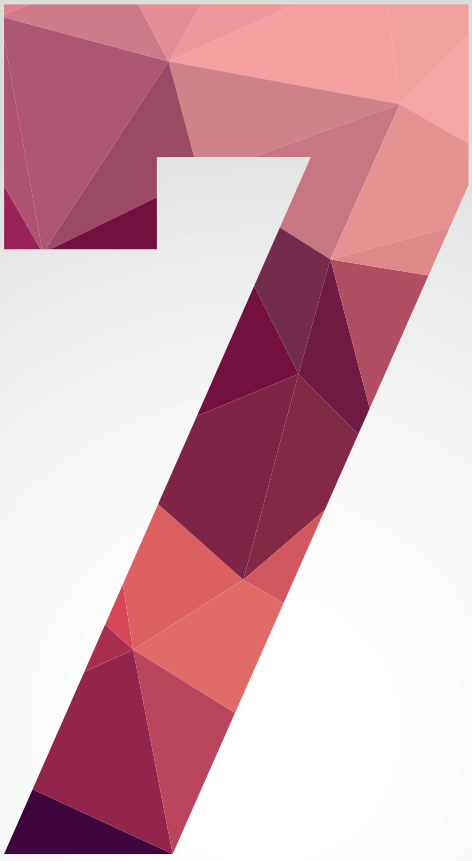

Obesity as a determinant of perioperative and postoperative outcome in patients following colorectal cancer surgery: A population-based study (2009-2016)

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ABSTRACT

BACKGROUND

Obesity is an increasing problem worldwide that can influence perioperative and post-operative outcomes. However, the relationship between obesity and treatment-related perioperative and short-term postoperative morbidity after colorectal resections is still subject to debate.

STUDY

Patients were selected from the DCRA, a population-based audit including 83 hospitals performing colorectal cancer (CRC) surgery. Data regarding primary resections between 2009 and 2016 were eligible for analyses. Patients were subdivided into six categories: underweight, normal weight, overweight and obesity class I, II and III.

RESULTS

Of 71,084 patients, 17.7% with colon and 16.4% with rectal cancer were categorized as obese. Significant differences were found for the 30-day overall postoperative complication rate ($p < 0.001$), prolonged hospitalization ($p < 0.001$) and readmission rate (colon cancer $p < 0.005$; rectal cancer $p < 0.002$) in obese CRC patients. Multivariate analysis identified BMI 30 kg/m2 as independent predictor of a complicated postoperative course in CRC patients. Furthermore, obesity-related comorbidities were associated with higher postoperative morbidity, prolonged hospitalization and a higher readmission rate. No significant differences in performance were observed in postoperative outcomes of morbidly obese CRC patients between hospitals performing bariatric surgery and hospitals that did not.

CONCLUSION

The real-life data analysed in this study reflect daily practice in the Netherlands and identify obesity as a significant risk factor in CRC patients. Obesity-related comorbidities were associated with higher postoperative morbidity, prolonged hospitalization and a higher readmission rate in obese CRC patients. No differences were observed between hospitals performing bariatric surgery and hospitals that did not.

INTRODUCTION

The World Health Organization (WHO) has recognized obesity as a pandemic disease that contributes to rising healthcare costs worldwide.[1, 2]. Up to one-third of the Western population is currently overweight or obese.[3-5]

Not only is obesity considered to be of growing concern in the aetiology of colorectal cancer (CRC), but there is also a rising awareness of possible treatment-related morbidity and mortality after colorectal resections in obese patients.[6, 7] One study, which included almost 12,000 rectal cancer patients, showed a significant association between obesity and postoperative morbidity.[8] However, findings in the international literature are often contradictive and inconclusive, due to limited study populations.[9, 10]

The aim of this population-based study was to evaluate the influence of obesity on perioperative and short-term postoperative outcomes in patients surgically treated for primary CRC in a nationwide registry. In addition, hospitals performing both bariatric and colorectal surgery and those performing only colorectal surgery were compared to test a possible association between surgical experience with obese patients and the outcomes of these CRC patients.

MATERIAL AND METHODS

DATA SOURCE

Data were derived from the Dutch ColoRectal Audit (DCRA), formerly known as the Dutch Surgical Colorectal Audit (DSCA). The DCRA collects information on patients, tumours, treatment, perioperative and short-term outcome characteristics (<30 days) of all patients undergoing surgical resection for primary CRC in the Netherlands.[6]

PATIENT SELECTION

For this study, no ethical approval or informed consent was required under Dutch law. All patients registered in the DCRA undergoing primary colorectal tumour resection between 1 January 2009 and 31 December 2016, were evaluated. Minimal data requirements were date of birth, body mass index (BMI), date of operation, type of surgery, tumour specifications and 30-day morbidity. All patients were examined preoperatively by an anaesthesiologist no more than 2 working days before the elective operation. Body weight and height were measured by the anaesthetist as standard procedure by all elective operations.

In addition to demographics and the American Society of Anesthesiologists (ASA) classification [11], an extensive set of comorbidities were registered in the DCRA. The Charlson Comorbidity Index (CCI) [12] was used as a composite comorbidity score.[13, 14]

OUTCOME PARAMETERS

The primary endpoint of this study was a severe adverse postoperative event captured by a composite measure: complicated postoperative course. A complicated postoperative course was defined as prolonged hospitalization (>14 days postoperative) or Clavien-Dindo Classification of Surgical Complications (CD) grade III or higher.[15] It includes complications requiring surgical, endoscopic and/or radiological interventions (CD grade III), life-threatening complications requiring admission to an intensive care unit (CD grade IV) or death (CD grade V).[16]

Secondary endpoints included any perioperative and postoperative complications, defined as a surgical or non-surgical complication occurring within 30 days after the primary resection, not classified as CD grade III or higher. In the DCRA, perioperative complications, postoperative complications, wound infections, wound dehiscence and intra-abdominal complications, such as postoperative bleeding, ileus, infection, abscess or anastomotic leakage, were registered when a re-intervention was performed. Non-surgical complications were defined as cardiac, thromboembolic, pulmonary, infectious, neurological or other.

STATISTICAL ANALYSIS

Patients were subdivided into different weight categories, as defined by the World Health Organization: underweight (BMI < 18.5 kg/m^2), normal weight (BMI 18.5 – 24.9 kg/m^2), overweight (BMI 25.0 – 29.9 kg/m^2), obesity class I (BMI 29.9 – 34.9 kg/m^2), obesity class II (BMI 35.0 – 39.9 kg/m^2), obesity class III (BMI ≥ 40.0 kg/m^2).[17]

Differences in patient and treatment characteristics for the different weight categories were assessed using Mann-Whitney *U* test for categorical variables and an independent sample t-test for continuous variables. Obese patients (BMI ≥ 30.0 kg/m^2) were compared with normal-weight patients (BMI 18.5 – 24.9 kg/m^2).

To evaluate hospital outcomes, a multivariate logistic regression was performed. The regression included gender, age, comorbidity-related scores (CCI score, ASA score), tumour location, pathological tumour stage, surgery setting (elective or urgent/emergency), preoperative tumour complications, additional resection due to tumour

invasion or to metastases as single factors. The variable BMI has been left out of the standard case-mix correction.[6]

The risk of postoperative complication was calculated using multivariate logistic regression analysis. Comorbidity-related scores and BMI were entered in the multivariate analysis to evaluate the effects of obesity and its associated comorbidities on postoperative outcome. Next to the p-values calculated with the Mann-Whitney *U* test, are the odds ratios (OR) stated. An OR is a measure of association between an exposure and an outcome.[18]

Comparisons were made between hospitals performing both bariatric and colorectal surgery and those performing only colorectal surgery. Analyses were performed to identify whether obese patients with CRC were more frequently referred to hospitals performing bariatric surgery and if patients were equally distributed (with regard to patient characteristics) among both types of hospitals.

R version 3.4.2 was used for statistical analysis in combination with the "Companion to Applied Regression"- package (car 2.1-5), "A Grammar of Data Manipulation"-package (dplyr 0.7.4), "Data Visualization for Statistics"-package (sjmisc 2.6.2) and "Labelled Data Utility Functions"-package (sjlabelled 1.0.4).

RESULTS

BASELINE CHARACTERISTICS

A total of 83 participating hospitals entered 77,819 unique patient records, including 55,892 (71.8%) colon cancer and 21,595 (27.8%) rectal cancer patients. The 332 (0.4%) patients with an unknown tumour, were excluded. In total, 50,876 (91.0%) colon cancer and 20,208 (93.6%) rectal cancer patients for whom a computable preoperative BMI could be calculated, were eligible for final analysis. **Table 1a** and **Table 1b** show the baseline characteristics of CRC patients in the different weight categories, during the study period (2009 – 2016).

OBESE COLON CANCER (OCC) PATIENTS

Of the 50,876 colon cancer patients, 9016 (17.7%) patients were obese as shown in **Table 1a**. OCC patients were significantly younger (mean 69.4 years; SD ± 9.9, $p < 0.001$) compared with normal-weight colon cancer (NCC) patients (mean 70.5 years; SD ± 11.5, $p < 0.001$) and overweight colon cancer patients (mean 70.6 years; SD ± 10.2, $p < 0.001$) (**Table 1a**).

Table 1a: Patient, tumour and treatment characteristics of colon cancer patients combined with postoperative complications. Legend: *Mortality is shown as Clavien-Dindo classification grade V; **Clavien-Dindo classification grade ≥III combined with prolonged hospital stay; red values are column percentage values; green values are row percentage values. Abbreviations: ASA, American Society of Anesthesiologists risk score.

		Total		Normal weight 18.5 – 24.9 kg/m^2		Overweight 25.0 – 29.9 kg/m^2		Obesity > 30.0 kg/m^2		
		N	%	N	%	N	%	N	%	*p*-value
Number of colon cancer patients		50,876	100.0	20,755	40.8	20,212	39.7	9,016	17.7	<0.001
Patient characteristics										
Gender	Female	23,759	46.7	10,690	45.0	7,987	33.6	4,431	18.6	<0.001
Age	< 60 years	7,297	14.3	3,289	45.1	2,580	35.4	1,276	17.5	<0.001
	60 – 70 years	15,424	30.3	5,762	37.4	6,248	40.5	3,171	20.6	<0.001
	70 – 80 years	17,522	34.4	6,736	38.4	7,336	41.9	3,166	18.1	<0.001
	≥ 80 years	10,613	20.9	4,958	46.7	4,045	38.1	1,396	13.2	<0.001
ASA score	I - II	37,944	74.6	16,005	42.2	15,409	40.6	5,909	15.6	<0.001
	III	11,898	23.4	4,307	36.2	4,445	37.4	2,904	24.4	<0.001
	IV - V	897	1.8	372	41.5	313	34.9	184	20.5	<0.001
Charlson score	1	11,755	23.1	4,323	36.8	4,721	40.2	2,558	21.8	<0.001
	≥2	13,692	26.9	4,721	36.5	5,535	40.4	2,901	21.2	<0.001
Body mass index	18.5 – 24.9 kg/m^2	20,755	40.8	-	-	-	-	-	-	-
	25.0 – 29.9 kg/m^2	20,212	39.7	-	-	-	-	-	-	-
	30.0 – 34.9 kg/m^2	6,881	13.5	-	-	-	-	-	-	-
	35.0 – 39.9 kg/m^2	1,603	3.2	-	-	-	-	-	-	-
	≥ 40.0 kg/m^2	532	1.0	-	-	-	-	-	-	-
Abdominal surgical history	Yes	17,590	34.6	7,131	40.5	6,727	38.2	3,423	19.5	<0.001
Tumour characteristics										
Tumour location	Right colon	22,272	43.8	9,461	42.5	8,553	38.4	3,795	17.0	<0.001
	Transversum / left colon	8,584	16.9	3,487	40.6	3,421	39.9	1,502	17.5	0,191

Table 1a: Patient, tumour and treatment characteristics of colon cancer patients combined with postoperative complications. Legend: *Mortality is shown as Clavien-Dindo classification grade V; **Clavien-Dindo classification grade ≥III combined with prolonged hospital stay; red values are column percentage values; green values are row percentage values. Abbreviations: ASA, American Society of Anesthesiologists risk score. (continued)

		Total		Normal weight 18.5 – 24.9 kg/m^2		Overweight 25.0 – 29.9 kg/m^2		Obesity > 30.0 kg/m^2		
		N	%	N	%	N	%	N	%	*p*-value
	Sigmoid	20,020	39.4	7,807	39.0	8,238	41.1	3,719	18.6	<0.001
Preoperative tumour complications	Bleeding	8,159	16.0	3,274	40.1	3,302	40.5	1,454	17.8	0.284
	Obstruction/ileus	5,953	11.7	2,971	49.9	2,067	34.7	730	12.3	<0.001
	Abscess	467	0.9	209	44.8	186	39.8	61	13.1	0.034
	Other	2,891	5.7	1,494	46.7	1,149	35.9	461	14.4	<0.001
Pathological T classification	(y)pT0-1	4,321	8.5	1,456	33.7	1,847	42.7	983	22.7	<0.001
	(y)pT2	8,317	16.3	3,108	37.4	3,457	41.6	1,645	19.8	<0.001
	(y)pT3	29,222	57.4	12,050	41.2	11,659	39.9	5,019	17.2	0.001
	(y)pT4	8,208	16.1	3,826	46.6	2,926	35.6	1,214	14.8	0.001
	(y)pTx/unknown	808	1.6	315	39.0	323	40.0	155	19.2	0.635
Pathological N classification	pN0	29,304	57.6	11,707	40.0	11,693	39.9	5,386	18.4	<0.001
	pN1	12,485	24.5	5,226	41.9	4,947	39.6	2,106	16.9	0.006
	pN2	8,497	16.7	3,563	41.9	3,354	39.5	1,425	16.8	0.031
	pNx/unknown	590	1.2	259	43.9	218	36.9	99	16.8	0.244
Metastatic disease	Yes	5,962	11.7	2,773	46.5	2,189	36.7	865	14.5	<0.001
Lymph nodes	≥10 retrieved	45,351	89.1	18,514	40.8	18,036	39.8	8,010	17.7	0.169
Surgical characteristics										
Setting	Urgent	7,708	15.2	3,807	49.4	2,683	34.8	957	12.4	<0.001
Approach	Laparoscopic	29,249	57.5	11,206	38.3	12,107	41.4	5,575	19.1	<0.001
Conversion	Yes	3,749	7.4	1,205	32.1	1,498	40.0	991	26.4	<0.001
Complications										

Table 1a: Patient, tumour and treatment characteristics of colon cancer patients combined with postoperative complications. Legend: *Mortality is shown as Clavien-Dindo classification grade V; **Clavien-Dindo classification grade ≥III combined with prolonged hospital stay; red values are column percentage values; green values are row percentage values. Abbreviations: ASA, American Society of Anesthesiologists risk score. (continued)

		Total		Normal weight 18.5 – 24.9 kg/m^2		Overweight 25.0 – 29.9 kg/m^2		Obesity > 30.0 kg/m^2		
		N	%	N	%	N	%	N	%	*p*-value
Peroperative complications	Total	1,312	2.6	486	37.0	538	41.0	268	20.4	0.011
	Bleeding	205	0.4	73	35.6	80	39.0	50	24.4	0.080
	Bowel injury	351	0.7	124	35.3	150	42.7	69	19.7	0.196
	Ureter/urethral injury	89	0.2	36	40.4	28	31.5	22	24.7	0.112
	Bladder injury	61	0.1	23	37.7	25	41.0	12	19.7	0.926
Postoperative complications	Total	15,173	29.8	5,898	38.9	5,995	39.5	2,984	19.7	<0.001
	Surgical complications	7,595	14.9	2,847	37.5	3,029	39.9	1,579	20.8	<0.001
	Pulmonary complications	2,820	5.5	1,116	39.6	1,109	39.3	521	18.5	0.012
	Cardiac complications	1,791	3.5	698	39.0	684	38.2	373	20.8	0.507
	Thromboembolic complications	341	0.7	125	36.7	134	39.3	76	22.3	0.631
	Infectious complications	1,897	3.7	715	37.7	752	39.6	395	20.8	0.497
	Neurological complications	727	1.4	298	41.0	286	39.3	122	16.8	0.056
Postoperative re-interventions	Total	4,219	8.3	1,608	38.1	1,708	40.5	808	19.2	<0.001
	Anastomotic leakage	1,935	3.8	729	37.7	785	40.6	381	19.7	0.014
	Bleeding	241	0.5	113	46.9	90	37.3	33	13.7	0.167
Clavien-Dindo classification*	Grade III-IV	4,402	8.7	1651	37.5	1,737	39.5	923	21.0	<0.001
	Grade V	1,610	3.2	669	41.6	614	38.1	269	16.7	<0.001
Prolonged hospital stay	>14 days	8,740	17.2	3,531	40.4	3,408	39.0	1,590	18.2	<0.001
	Duration (mean/days/SD)	9.4	± 8.8	9.4	± 8.7	9.3	± 8.8	9.7	± 9.1	-
Severe complicated course**	Yes	11,228	22.1	4,491	40.0	4,380	39.0	2,096	18.7	<0.001
Readmission	Yes	2,604	5.1	1,000	38.4	1,032	39.6	522	20.0	0.005

This group also had a higher ASA-score and were associated with more preoperative comorbidities (OCC 87.3% vs NCC 71.6%, $p < 0.001$). In particular, cardiac, vascular, diabetes, and pulmonary comorbidities were recorded significantly more frequently (**Fig. 1**). Colon tumours were seen significantly more in the right colon and had a significantly lower pathological and clinical tumour stage. OCC patients were mostly operated using a laparoscopic approach (OCC 61.8% [5575 of 9016] versus NCC 54.0% [11,206 of 20,755], $p < 0.001$), but less frequently underwent an emergency procedure (OCC 10.6% [957 of 9016], NCC 18.3% [3807 of 20,755], $p < 0.001$). In 11.0% of OCC and 5.8% of NCC patients, a laparoscopic conversion was needed. Furthermore, more perioperative complications were seen in the OCC group (p ¼ 0.011), but for the specific complications bleeding, bowel injury, ureter/urethral and bladder injury, no significant differences were observed.

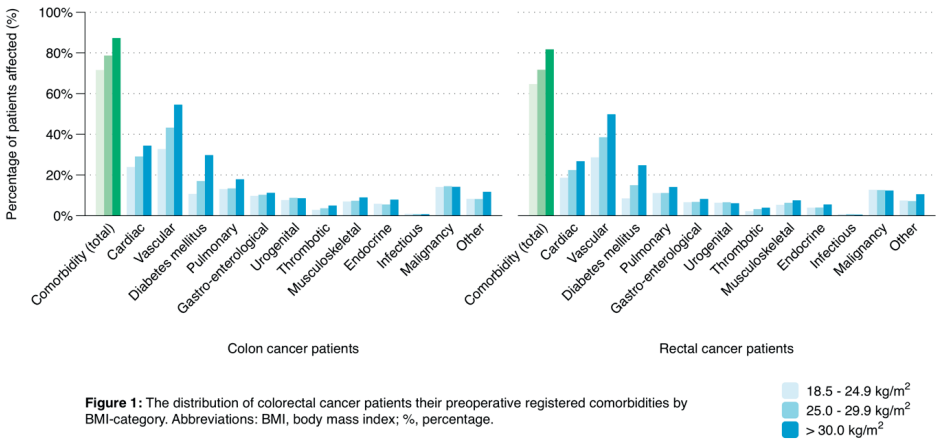

Figure 1: The distribution of colorectal cancer patients their preoperative registered comorbidities by BMI-category. Abbreviations: BMI, body mass index; %, percentage.

In total, 33.1% (n = 2984) of the OCC patients developed a postoperative complication compared with 28.4% (n = 5898) of the NCC patients. Significant differences in surgical complications ($p < 0.001$) and pulmonary complications ($p < 0.001$) were seen in the OCC group. Furthermore, significant differences were observed in postoperative re-interventions performed for anastomotic leakage ($p < 0.014$) and for severe complicated course in the OCC group ($p < 0.001$). The higher number of total postoperative and surgical complications in combination with a higher CD grade and prolonged hospitalization resulted in more OCC patients with a severe complicated postoperative course. Regarding the percentage of mortality (CD grade V), a slight but significant difference was seen in favour of the OCC group: 3.0% [269 of 9016] versus 3.2% [669 of 20,755] in the NCC group ($p < 0.001$).

Table 1b: Patient, tumour and treatment characteristics of rectal cancer patients combined with postoperative complications. Legend: *Mortality is shown as Clavien-Dindo classification grade V; **Clavien-Dindo classification grade ≥III combined with prolonged hospital stay; red values are column percentage values; green values are row percentage values. Abbreviations: ASA, American Society of Anesthesiologists risk score.

		Total		Normal weight 18.5 – 24.9 kg/m^2		Overweight 25.0 – 29.9 kg/m^2		Obesity > 30.0 kg/m^2		
		N	%	N	%	N	%	N	%	*p*-value
Number of rectal cancer patients		20,208	100.0	8,186	40.5	8,377	41.5	3,322	16.4	<0.001
Patient characteristics										
Gender	Female	7,426	36.7	3,305	44.5	2,560	34.5	1,357	18.3	<0.001
Age	< 60 years	4,429	21.9	1,903	43.0	1,725	38.9	700	15.8	<0.001
	60 – 70 years	7,001	34.6	2,637	37.7	2,967	42.4	1,298	18.5	<0.001
	70 – 80 years	6,286	31.1	2,500	39.8	2,663	42.4	1,038	16.5	0.088
	≥ 80 years	2,481	12.3	1,143	46.1	1,020	41.1	280	11.3	<0.001
ASA score	I - II	16,713	82.7	6,957	41.6	6,999	41.9	2,498	14.9	<0.001
	III	3,274	16.2	1,132	34.6	1,290	39.4	795	24.3	<0.001
	IV - V	152	0.8	74	48.7	51	33.6	22	14.5	0.046
Charlson score	1	4,158	20.6	1,479	35.6	1,787	43.0	827	19.9	<0.001
	≥2	4,440	22.0	1,646	37.1	1,866	42.0	857	19.3	<0.001
Body mass index	18.5 – 24.9 kg/m^2	8,186	40.5	-	-	-	-	-	-	-
	25.0 – 29.9 kg/m^2	8,377	41.5	-	-	-	-	-	-	-
	30.0 – 34.9 kg/m^2	2,684	13.3	-	-	-	-	-	-	-
	35.0 – 39.9 kg/m^2	488	2.4	-	-	-	-	-	-	-
	≥ 40.0 kg/m^2	150	0.7	-	-	-	-	-	-	-
Abdominal surgical history	Yes	6,096	30.2	2,396	39.3	2,445	40.1	1,133	18.6	<0.001
Tumour characteristics										
Distance anal verge	<5 cm	5,290	26.2	2,187	41.3	2,141	40.5	869	16.4	0.112
	5-10 cm	6,340	31.4	2,623	41.4	2,623	41.4	980	15.5	0.011

Table 1b: Patient, tumour and treatment characteristics of rectal cancer patients combined with postoperative complications. Legend: *Mortality is shown as Clavien-Dindo classification grade V; **Clavien-Dindo classification grade ≥III combined with prolonged hospital stay; red values are column percentage values; green values are row percentage values. Abbreviations: ASA, American Society of Anesthesiologists risk score. (continued)

		Total		Normal weight 18.5 – 24.9 kg/m^2		Overweight 25.0 – 29.9 kg/m^2		Obesity > 30.0 kg/m^2		
		N	%	N	%	N	%	N	%	*p*-value
	≥10 cm	8,040	39.8	3,126	38.9	3,433	42.7	1,380	17.2	<0.001
Preoperative tumour complications	Bleeding	2,448	12.1	985	40.2	997	40.7	421	17.2	0.513
	Obstruction/ileus	572	2.8	298	52.1	196	34.3	54	9.4	<0.001
	Abscess	107	0.5	56	52.3	27	25.2	18	16.8	<0.001
	Other	846	4.2	386	45.6	342	40.4	94	11.1	<0.001
Clinical T classification	cT1	649	3.2	242	37.3	284	43.8	119	18.3	0.044
	cT2	4,760	23.6	1,812	38.1	2,066	43.4	828	17.4	<0.001
	cT3	11,462	56.7	4,656	40.6	4,764	41.6	1,872	16.3	0.468
	cT4	1,923	9.5	896	46.6	676	35.2	279	14.5	<0.001
	cTx/unknown	1,414	7.0	580	41.0	587	41.5	224	15.8	0.933
Clinical N classification	cN0	8,119	40.2	3,286	40.5	3,365	41.4	1,343	16.5	0.943
	cN1	6,314	31.2	2,515	39.8	2,646	41.9	1,050	16.6	0.624
	cN2	4,059	20.1	1,660	40.9	1,655	40.8	673	16.6	0.673
	cNx/unknown	1,716	8.5	725	42.2	711	41.4	256	14.9	0.212
Pathological T classification	(y)pT0-1	1,854	9.2	712	38.4	809	43.6	316	17.0	0.012
	(y)pT2	6,252	30.9	2,481	39.7	2,620	41.9	1,078	17.2	0.001
	(y)pT3	9,389	46.5	3,814	40.6	3,883	41.4	1,534	16.3	0.805
	(y)pT4	944	4.7	455	48.2	323	34.2	126	13.3	<0.001
	(y)pTx/unknown	1,769	8.8	724	40.9	742	41.9	268	15.1	0.271
Pathological N classification	pN0	12,869	63.7	5,249	40.8	5,308	41.2	2,105	16.4	0.749
	pN1	4,675	23.1	1,860	39.8	1,962	42.0	781	16.7	0.668

Table 1b: Patient, tumour and treatment characteristics of rectal cancer patients combined with postoperative complications. Legend: *Mortality is shown as Clavien-Dindo classification grade V; **Clavien-Dindo classification grade ≥III combined with prolonged hospital stay; red values are column percentage values; green values are row percentage values. Abbreviations: ASA, American Society of Anesthesiologists risk score. (continued)

		Total		Normal weight 18.5 – 24.9 kg/m^2		Overweight 25.0 – 29.9 kg/m^2		Obesity > 30.0 kg/m^2		
		N	%	N	%	N	%	N	%	*p*-value
	pN2	2,325	11.5	926	39.8	972	41.8	391	16.8	0.885
	pNx/unknown	339	1.7	151	44.5	135	39.8	45	13.3	0.175
Metastatic disease	Yes	1,429	7.1	657	46.0	554	38.8	184	12.9	<0.001
Lymph nodes	≥10 retrieved	15,619	77.3	6,262	40.1	6,482	41.5	2,632	16.9	0.025
Surgical characteristics										
Setting	Urgent	294	1.5	139	47.3	108	36.7	34	11.6	0.002
Approach	Laparoscopic	12,796	63.3	5,150	40.2	5,385	42.1	2,105	16.5	<0.001
Conversion	Yes	1,323	6.5	341	25.8	602	45.5	372	28.1	<0.001
Complications										
Peroperative complications	Total	783	3.9	262	33.5	338	43.2	169	21.6	<0.001
	Bleeding	149	0.7	59	39.6	57	38.3	30	20.1	0.538
	Bowel injury	142	0.7	53	37.3	62	43.7	23	16.2	0.515
	Ureter/urethral injury	123	0.6	45	36.6	43	35.0	32	26.0	0.021
	Bladder injury	46	0.2	14	30.4	22	47.8	8	17.4	0.190
Postoperative complications	Total	7,604	37.6	2,874	37.8	3,159	41.5	1,452	19.1	<0.001
	Surgical complications	3,953	19.6	1,419	38.9	1,509	41.3	668	18.3	0.195
	Pulmonary complications	855	4.2	341	39.9	334	39.1	159	18.6	0.056
	Cardiac complications	540	2.7	204	37.8	211	39.1	117	21.7	0.409
	Thromboembolic complications	109	0.5	41	37.6	47	43.1	20	18.3	0.994
	Infectious complications	982	4.9	353	35.9	390	39.7	220	22.4	0.025
	Neurological complications	241	1.2	84	34.9	109	45.2	43	17.8	0.530

Table 1b: Patient, tumour and treatment characteristics of rectal cancer patients combined with postoperative complications. Legend: *Mortality is shown as Clavien-Dindo classification grade V; **Clavien-Dindo classification grade ≥III combined with prolonged hospital stay; red values are column percentage values; green values are row percentage values. Abbreviations: ASA, American Society of Anesthesiologists risk score. (continued)

		Total		Normal weight 18.5 – 24.9 kg/m^2		Overweight 25.0 – 29.9 kg/m^2		Obesity > 30.0 kg/m^2		
		N	%	N	%	N	%	N	%	*p*-value
Postoperative re-interventions	Total	2,162	10.7	847	39.2	896	41.4	386	17.9	0.252
	Anastomotic leakage	723	3.6	283	39.1	325	45.0	109	15.1	0.103
	Bleeding	99	0.5	41	41.4	40	40.4	17	17.2	0.990
Clavien-Dindo classification*	Grade III-IV	1,995	9.9	714	35.8	820	41.1	424	21.3	<0.001
	Grade V	386	1.9	180	46.6	127	32.9	66	17.1	<0.001
Prolonged hospital stay	>14 days	4,423	21.9	1,683	38.1	1,799	40.7	854	19.3	<0.001
	Duration	11.0	± 9.7	10.6	± 9.6	10.9	± 9.6	11.9	± 10.3	-
Severe complicated course**	Yes	5,509	27.3	2,087	37.9	2,242	40.7	1,080	19.6	<0.001
Readmission	Yes	1,963	9.7	746	38.0	812	41.4	379	19.3	0.002

Univariate analysis (**Table 2a**) showed a significantly increased risk of postoperative complications in each weight group compared with the NCC group. In particular, an increased risk of postoperative complications was found in class III (BMI ≥ 40.0 kg/m^2) OCC patients with an OR of 1.50 (95% confidence interval [CI] 1.26 – 1.78). This relationship remained statistically significant in class III OCC patients (BMI ≥ 40.0 kg/m^2) using a multivariate analysis. Factors such as gender, age, tumour location, tumour staging, urgency of operation, preoperative tumour complications, CCI and ASA were entered in the multivariate analysis (**Table 2a**).

OBESE RECTAL CANCER (ORC) PATIENTS

Of the 20,208 rectal cancer patients, 3322 (16.4%) patients were obese as shown in **Table 1b**. ORC patients were significantly younger (mean 66.7 years; SD ± 9.8) ($p < 0.001$) and had higher ASA and CCI scores compared with normal-weight rectal cancer (NRC) patients (mean 67.1 years; SD ± 11.4) (**Table 1b**).

Fig. 1 shows the distribution of comorbidities in the ORC group. ORC patients were associated with more preoperative comorbidities (ORC 81.7% vs NRC 64.7%, $p < 0.001$). Looking at tumour characteristics, the ORC patients were diagnosed with a higher located rectal tumour of >10 cm from the anal verge (ORC 41.5% [1380 of 3322] vs NRC 38.2% [3126 of 8186], $p < 0.001$), and had more preoperative tumour complications: obstruction/ileus ($p < 0.001$) and abscesses ($p < 0.001$). Significant differences in pathological and clinical tumour stage were seen: more cT2 ($p < 0.001$) and cT4 tumours ($p < 0.001$) and (y)pT2 ($p < 0.001$) and (y)pT4 tumours ($p < 0.001$). For surgical characteristics, ORC patients were mostly operated using a laparoscopic approach (ORC 63.4% [2105 of 3322] versus NRC 62.9% [5150 of 8186]). Also, in ORC patients (11.2%) more laparoscopic conversion was needed compared to NRC patients (4.2%). On the other hand, the ORC group less frequently underwent an emergency procedure (ORC 1.0% [34 of 3322]; NRC 1.7% [139 of 8186], $p < 0.001$). Furthermore, more perioperative complications were seen in the ORC group ($p < 0.001$), but for the specific complications bleeding, bowel injury, ureter/urethral and bladder injury, no significant differences were observed, in contrast to the NRC patients.

Of all the ORC patients, 43.7% (n = 1452 of 3322) developed a postoperative complication. This was significantly higher in ORC compared with NRC patients (35.1%; n = 2874 of 8186). The ORC group developed more postoperative surgical complications ($p = 0.195$), and a significant difference in infectious complications ($p = 0.025$) was seen. Furthermore, no significant difference was observed in postoperative re-interventions performed for anastomotic leakage ($p = 0.103$) and bleeding ($p = 0.988$) in the ORC group, but a significant difference was seen for a severe complicated course ($p < 0.001$).

The increased postoperative complication rate and the higher CD grade in combination with a significantly prolonged hospitalization for the ORC group resulted in more ORC patients with a prolonged hospital stay (ORC 32.5% vs NRC 25.5%).

Univariate analysis (**Table 2b**) showed a significantly increased risk of postoperative complications in each weight group compared with the NRC group. In particular, an increased risk of postoperative complications was found in class II ORC patients with an OR of 1.92 (95% CI 1.60e2.31), remaining significant in the multivariate analysis (standard) (OR 1.96; CI 1.62e2.39).

The same comorbidity-associated factors, as mentioned for the colon cancer patient group, were entered in the multivariate analysis (**Table 2b**).

HOSPITALS PERFORMING AND THOSE NOT PERFORMING BARIATRIC SURGERY

There was a wide variation between hospitals in the number of obese CRC patients treated during the study period. Colon cancer patients were treated in 83 individual hospitals with a range of 49 – 1600 surgical procedures per hospital between 2009 and 2016. This was between 11 and 346 per hospital for OCC patients, with a total of 9016 procedures (**Fig. 2**). All 19 hospitals performing bariatric surgery treated a lower total volume (29.6%) of OCC patients compared with hospitals that do not perform bariatric surgery (2668 vs 6,348, respectively). Besides the number of treated patients, there were no statistically significant differences in preoperative characteristics and postoperative outcomes in OCC patients treated in hospitals offering bariatric surgery and those that do not offer bariatric procedures ($p = 0.754$).

Similar results were seen for rectal cancer patients. The 83 hospitals were jointly responsible for 3322 surgical procedures (range 2 – 132 per hospital) for ORC patients. Fig. 2 shows the distribution in volume and the number of complicated postoperative courses. The 19 hospitals performing bariatric surgery were responsible for 1004 surgical procedures for ORC patients (range 6 – 132 per hospital, 30.2%). No significant difference was seen between treatment in hospitals offering bariatric surgery and hospitals that did not with regard to a complicated postoperative course ($p = 0.149$).

Table 2b: Univariate and multivariate analyses of rectal cancer patients for a complicated postoperative course. *Multivariate analysis was calculated with CCI-score and ASA-score. Abbreviations: N, number; SD, standard deviation; CI, confidence interval; OR, odds ratio; BMI, body mass index; CCI, Charlson Comorbidity Index; ASA, American Society of Anesthesiologists risk score.

	Normal postoperative course		**Complicated postoperative course**				
	N	**%**	**N**	**%**	***p-value***	**Odds ratio**	**95% CI**
Rectal cancer patients	11,225	55.5	8,983	44.5	-	-	-
Univariate analysis							
BMI (mean, kg/m^2, SD)	26.0	± 4.1	26.5	± 4.4	<0.001	-	-
18.5 – 24.9 kg/m^2	4,780	23.7	3,406	16.9	<0.001	REF	REF
25.0 – 29.9 kg/m^2	4,643	23.0	3,734	18.5	0.780	**1.13**	**1.06 – 1.20**
30.0 – 34.9 kg/m^2	1,350	6.7	1,334	6.6	<0.001	**1.39**	**1.27 – 1.51**
35.0 – 39.9 kg/m^2	206	1.0	282	1.4	<0.001	**1.92**	**1.60 – 2.31**
≥ 40 kg/m^2	69	0.3	81	0.4	0.023	**1.65**	**1.19 – 2.45**
Comorbidities	7,608	37.6	6,624	32.8	<0.001	**1.33**	**1.26 – 1.42**
Cardiac	2,115	10.5	2,217	11.0	<0.001	**1.41**	**1.32 – 1.51**
Vascular	3,839	19.0	3,459	17.1	<0.001	**1.20**	**1.14 – 1.28**
Diabetes mellitus	1,416	7.0	1,373	6.8	<0.001	**1.25**	**1.15 – 1.35**
Pulmonary	1,156	5.7	1,220	6.0	<0.001	**1.37**	**1.26 – 1.49**
Gastro-enterological	721	3.6	690	3.4	0.001	**1.21**	**1.09 – 1.35**
Urogenital	615	3.0	676	3.3	<0.001	**1.40**	**1.25 – 1.57**
Thrombotic	284	1.4	304	1.5	<0.001	**1.35**	**1.15 – 1.59**
Musculoskeletal	662	3.3	572	2.8	0.175	1.09	0.97 – 1.22
Endocrine	478	2.4	370	1.8	0.648	0.97	0.84 – 1.11
Infectious	73	0.4	75	0.4	0.148	1.29	0.93 – 1.78
Malignancy	1,332	6.6	1,226	6.1	<0.001	**1.17**	**1.08 – 1.28**
Other	817	4.0	772	3.8	0.001	**1.20**	**1.08 – 1.33**
Multivariate analysis*							
BMI (mean, kg/m^2, SD)	26.0	± 4.1	26.5	± 4.4	<0.001	-	-
18.5 – 24.9 kg/m^2	4,780	23.7	3,406	16.9	<0.001	REF	REF
25.0 – 29.9 kg/m^2	4,643	23.0	3,734	18.5	0.780	**1.11**	**1.04 – 1.18**
30.0 – 34.9 kg/m^2	1,350	6.7	1,334	6.6	<0.001	**1.39**	**1.26 – 1.52**
35.0 – 39.9 kg/m^2	206	1.0	282	1.4	<0.001	**1.96**	**1.62 – 2.39**
≥ 40 kg/m^2	69	0.3	81	0.4	0.023	**1.72**	**1.23 – 2.42**

Table 2a: Univariate and multivariate analyses of colon cancer patients for a complicated postoperative course. *Multivariate analysis was calculated with CCI-score and ASA-score. Abbreviations: N, number; SD, standard deviation; CI, confidence interval; OR, odds ratio; BMI, body mass index; CCI, Charlson Comorbidity Index; ASA, American Society of Anesthesiologists risk score.

	Normal postoperative course		Complicated postoperative course				
	N	**%**	**N**	**%**	***p-value***	**OR**	**95% CI**
Colon cancer patients	33,005	64.9	17,871	35.1	-	-	-
Univariate analysis							
BMI (mean, kg/m^2, SD)	26.2	± 4.4	26.5	± 4.7	<0.001	-	-
18.5 – 24.9 kg/m^2	13,724	27.0	7,031	13.8	<0.001	REF	REF
25.0 – 29.9 kg/m^2	13,168	25.9	7,044	13.8	0.294	**1.04**	**1.00 – 1.09**
30.0 – 34.9 kg/m^2	4,311	8.5	2,570	5.1	<0.001	**1.16**	**1.10 – 1.23**
35.0 – 39.9 kg/m^2	964	1.9	639	1.3	<0.001	**1.30**	**1.17 – 1.44**
≥ 40 kg/m^2	301	0.6	231	0.5	<0.001	**1.50**	**1.26 – 1.78**
Comorbidities	24,487	48.1	14,782	29.1	<0.001	**1.66**	**1.59 – 1.74**
Cardiac	8,111	15.9	5,986	11.8	<0.001	**1.55**	**1.49 – 1.61**
Vascular	12,769	25.1	7,916	15.6	<0.001	**1.26**	**1.21 – 1.31**
Diabetes mellitus	5,055	9.9	3,338	6.6	<0.001	**1.27**	**1.21 – 1.33**
Pulmonary	4,013	7.9	3,190	6.3	<0.001	**1.57**	**1.49 – 1.65**
Gastro-enterological	3,058	6.0	2,161	4.2	<0.001	**1.35**	**1.27 – 1.43**
Urogenital	2,409	4.7	1,788	3.5	<0.001	**1.41**	**1.32 – 1.51**
Thrombotic	1,040	2.0	758	1.5	<0.001	**1.36**	**1.24 – 1.50**
Musculoskeletal	2,337	4.6	1,473	2.9	<0.001	**1.18**	**1.10 – 1.26**
Endocrine	1,966	3.9	1,121	2.2	0.160	1.06	0.98 – 1.14
Infectious	269	0.5	169	0.3	0.141	1.16	0.96 – 1.41
Malignancy	4,249	8.4	3,022	5.9	<0.001	**1.38**	**1.31 – 1.45**
Other	2,714	5.3	1,811	3.6	<0.001	**1.26**	**1.18 – 1.34**
Multivariate analysis*							
BMI (mean, kg/m^2, SD)	26.2	± 4.4	26.5	± 4.7	<0.001	-	-
18.5 – 25.0 kg/m^2	13,724	27.0	7,031	13.8	<0.001	REF	REF
25.0 – 30.0 kg/m^2	13,168	25.9	7,044	13.8	0.294	**1.07**	**1.02 – 1.11**
30.0 – 35.0 kg/m^2	4,311	8.5	2,570	5.1	<0.001	**1.21**	**1.14 – 1.28**
35.0 – 40.0 kg/m^2	964	1.9	639	1.3	<0.001	**1.38**	**1.24 – 1.54**
≥ 40 kg/m^2	301	0.6	231	0.5	<0.001	**1.50**	**1.25 – 1.79**

DISCUSSION

This population-based study on the influence of obesity on perioperative and post-operative outcome in patients during and after CRC resection gives a comprehensive overview of the perioperative and short-term postoperative outcomes of colorectal surgery in obese CRC patients.

Independent analyses and a multivariate logistic regression model, including all obesity-related comorbidities, showed a significantly increased risk factor (OR) in developing a complicated postoperative course for obese CRC patients. This study suggests that obesity and the comorbidities associated with obesity are associated with a higher risk of adverse clinical postoperative outcome, prolonged hospitalization and a higher readmission rate.

Obesity is seen as a potential risk factor for postoperative morbidity, but conflicting results are described in the international literature.[9, 19] A study by Amri et al. showed no significant association between obesity and complications after colon cancer surgery.[10] Our study, however, confirms the results described in the STARSurg Collaborative study and offers additional perioperative and short-term postoperative information of all CRC hospitals in the Netherlands. Including all Dutch academic, teaching and non-teaching hospitals.[6] These results are supported by the findings of Smith et al. which showed a significant association between obesity and postoperative complications after rectal cancer resection in a population of almost 12,000 rectal cancer patients.[8] Also, a recent large, international, multicentre, prospective, cohort study, discussing BMI and postoperative complications after gastrointestinal surgery showed an increased risk of major postoperative complications in overweight and obese patients compared with normal-weight patients.[20]

Furthermore, various scientific articles suggest a so-called "obesity paradox" for pre-obese and mildly obese surgical patients.[2, 21, 22] However, this clinical finding is still a point of discussion and such a paradox was not found in this large population-based study.[23, 24]

Obese CRC patients were generally operated using an open approach, but the literature describes laparoscopic CRC surgery as feasible and safe.[25] In the Netherlands, obese CRC patients are mostly operated laparoscopically. Findings in the international literature confirm the association of obese CRC patients with more emergency procedures and laparoscopic conversions.[26] Also, significantly more postoperative re-interventions were performed for anastomotic leakage in the OCC group, which was described as an

essential determining factor in a recent observational study.[27] Several hypotheses are described in the international literature as a reason for the higher anastomotic leakage rate in the OCC group, e.g. impaired anastomotic microcirculation due to increased abdominal pressure.

As obesity is on the increase, evaluation of care processes in best performing hospitals is of great interest.[28] Although, in our study, the experience in the treatment of obese patients, reflected by hospitals offering bariatric surgery, did not result in better postoperative outcomes. Moreover, because participation in the DCRA is mandatory for Dutch hospitals, it was possible to explore hypotheses regarding the underlying mechanisms explaining the observed variation in outcome of obese patients between hospitals. For example, hospitals performing bariatric surgery could have had more experience in the (surgical) treatment of, as well as perioperative care for, obese patients. Although, the analyses did not show different results for CRC surgery between hospitals performing and hospitals not performing bariatric surgery. More in-depth studies are needed to reveal differences in the care processes that lead to better or worse outcomes for obese patients undergoing CRC resection.

The strength of this study was the advantage of population-based data, which reflect daily general practice in the Netherlands. However, some limitations of this population-based study need to be addressed. The combination of the primary inclusion criteria and missing data caused exclusion of 5016 (9.0%) colon cancer and 1387 (6.4%) rectal cancer patients. External third-party data verification showed that weight and height are not typically missing data in patients with an unfavourable postoperative outcome.[6] Therefore, it can be assumed that the missing data occurred randomly.

Furthermore, the DCRA only provides short-term postoperative surgical and oncological outcomes (<30 days). The content of the DCRA is not only based on mandatory indicators, but also on a dynamic process led by a multidisciplinary team, including colorectal surgeons, oncologists and pathologists, which can lead to new registration of topics based on the team's increasing insights. Information on, e.g. ERAS (enhanced recovery after surgery) and fast-track protocols is currently not registered in the DCRA, but may be added over time. The quality of reported data in the DCRA was influenced over time due to better registration and training of the registrars.[6] In addition, the start of the national colorectal screening programme in 2014, could have influenced the study results.

The effect of disease-related weight loss was difficult to evaluate. Weight and height of the patient were registered on the day of admission, which was no more than two

working days before the colorectal resection. However, significant weight loss before the primary colorectal resection could be expected due to the disease itself, which is known to be associated with worsened postoperative outcomes.[29]

We also took bariatric surgery as a proxy for experience in the surgical treatment of obese patients. The development of more specialized hospitals for optimized care, already showed improvement in several quality outcomes, due to increased operative volumes and more specialized care.[30-32] Surgeons experienced in both bariatric surgery and colorectal surgery might have a better postoperative outcome for (severely) obese patients.[33] It could, therefore, be expected that hospitals performing bariatric surgery could have better results for this specific patient category. However, this study did not find a relationship between experience in the field of bariatric surgery and a favourable postoperative outcome. The assumption in this article, that colorectal surgeons in hospitals offering bariatric surgery by definition have a better experience with obese patients was not sufficient.

CONCLUSIONS

Using real-life data reflecting daily practice in the Netherlands, we identified obesity as an important risk factor in the care process of CRC patients. Obesity-related comorbidities were associated with higher postoperative morbidity, prolonged hospitalization and a higher readmission rate in obese CRC patients. No differences were observed between hospitals performing bariatric surgery and hospitals that did not.

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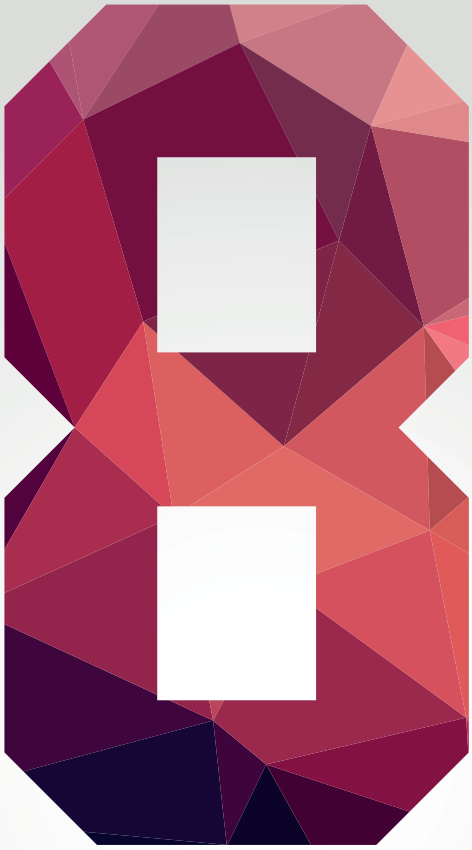

General Discussion and Future Perspectives

Obesity is a complex, multifactorial, chronic disease with a globally increasing prevalence.[1] Typically, comorbidities associated with excess body weight include increased incidence of cardiovascular diseases, type 2 diabetes mellitus (T2DM), hypertension (HT), dyslipidemia, gastroesophageal reflux disease (GERD), obstructive sleep apnea syndrome, musculoskeletal pain, and cancer.[2, 3] The 2008 intercountry comparable estimates revealed that 52.5% of the adult population in the Netherlands were overweight and 18.8% were obese.[4]

Obesity can be treated either surgically or non-surgically. Non-surgical treatment is usually a multicomponent approach comprising behavioral therapy, dietary changes, increase in physical activity, and prescription of pharmacotherapeutic agents.[5] However, non-surgical treatment is generally ineffective in long-term weight management.[1, 6]

Surgical treatment, on the other hand, seems to be a more successful approach. In addition to sustained weight loss, surgical treatment is associated with additional benefits in patients with obesity-related diseases.[7-12] Therefore, the demand for bariatric surgery has increased dramatically in recent years.[13-15] Presently, the Roux-and-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) are the most frequently performed bariatric procedures worldwide.

Although clinical trials, observational studies, and randomized controlled trials have provided data on specific bariatric surgical procedures for different sets of patients and evaluating their outcomes, general questions on the effectiveness of bariatric surgery and the best surgical procedure for obesity remain unclear.[9] Moreover, there is an increasing demand for healthcare personnel to consistently provide the highest possible care according to today's science and clinical standards. The use of real-life nationwide data is an absolute necessity to investigate not only the effectiveness of specific bariatric procedures but also to improve the quality of patient care.[16-22]

The Dutch Society for Metabolic and Bariatric Surgery has developed a core set of data points to be measured by individual (bariatric) hospitals and initiated a nationwide clinical audit: the Dutch Audit for Treatment of Obesity (DATO).[23]

CLINICAL AUDITING

A nationwide clinical audit is a quality-improvement tool that provides healthcare personnel with reliable benchmarked information on the structure, process, and outcome parameters based on the Donabedian model.[24] The Donabedian model is a systematic framework used to examine and evaluate the quality of care provided to patients. Ac-

cording to this model, improvements in the structure of care should lead to improvements in clinical processes, which, in turn, will improve patient outcomes.[18, 24]

In 1966, Donabedian first described the three elements of his model in "*Evaluating the Quality of Medical Care*."[25] However, that study was based on the results obtained by Dr. Ernest Codman in the early 20th century. Ernest Codman, a surgeon from Boston, proposed that physicians should measure what they do but also track their care results over a period. He proposed the "end result idea" to know the status of a patient after a long period of time. This model provides the physician with the opportunity to identify clinical errors that could serve as learnings to improve care for future patients.[24, 25] Donabedian's work is significant even to this day, commonly known as the international healthcare quality movement. Many clinical audits have been initiated internationally since, especially in the surgical domain.[20, 23]

Recent literature reveals that auditing and benchmarked feedback appear to have a positive effect on the quality of surgical care.[18, 23, 26-33] Providing feedback information enables performance monitoring and increases awareness of the care provided by individual physicians. This feedback information helps improve structure and/or process parameters that could improve patient outcomes, as aforementioned in the Donabedian model. Measuring the structure, process, and outcome parameters in bariatric surgery is now typically included in the hospital guidelines.[22, 34]

Clinical auditing not only improves care quality but also is cost effective. Treatment of undesired patient outcomes, such as complications or reinterventions, involves high cost, but it is plausible to reduce these costs by improving outcomes.[35, 36]

DUTCH AUDIT FOR TREATMENT OF OBESITY

Since its introduction in 2015, DATO has been shown to be an important quality-improvement tool for bariatric surgery in the Netherlands. In the first year of DATO launch, all 18 Dutch bariatric hospitals participated and the case ascertainment approached >99% for all bariatric procedures **(This thesis)**.[23, 29] Quality improvement is measured by weekly online benchmarking and discussion of audit results in meetings by the scientific committee.

For any quality improvement to succeed, it is important that all physicians endorse the results provided by the audit. Physicians are most likely to use these results if the provided data are of high standard and complete. To achieve this, all structure, process, and outcome indicators are reviewed on a yearly basis by the scientific committee in consultation with other healthcare providers. Each indicator is examined whether or not

it is relevant, reliable, useful, understandable, distinctive, and feasible. In addition, outcomes are investigated for the presence of a clinically relevant inter-hospital variation. Indicators that do not meet these requirements are removed from the dataset, giving the opportunity to develop new indicators and improve the quality of care given. This approach also ensures removal of non-essential data points from the audit, reducing the administrative burden.

For further quality incentive, the results are published online every year.[29] These results provide patients, payors, and other healthcare providers' insights into the care provided by each hospital. To check these published results for validity and accuracy, random data samples are analyzed by an independent third-party service provider. Inaccuracies are reported and published online.[37] The Association of Surgeons in the Netherlands also provides counseling to avoid negative outliers to ensure further quality improvements.

In the first 2 years after implementing the audit, the percentage of bariatric patients with a severe complication and number of patients with reintervention within 30 postoperative days decreased from 2.8% to 2.3% and from 2.7% to 2.2%, respectively. After 1 year of implementing the audit, the percentage of patients with a follow-up increased significantly from 96.9% to 97.9% ($p < 0.001$) **(This thesis)**.

INTERNATIONAL COMPARISON

International literature reveals a large variation in severe complications and mortality rates of about 4.1% and 0.3%, respectively.[38] However, the averages reported in DATO demonstrated significantly better results: severe complications and mortality rates of 2.3% and <0.1%, respectively, in 2017. These low percentages could be attributed to the high-quality bariatric care in the Netherlands. Another plausibility could be a more applied form of the wait-and-see policy in cases of mild or moderate complications. Also choosing not to intervene can lower the number of severe complications than that reported in international literature. For example: if an intervention is postponed or even canceled and no ICU admission is required, the maximum complication score will be Clavien-Dindo grade II or lower. Therefore, the complication will be marked as a mild or moderate complication instead of a severe complication. Such cases could also demonstrate that a significant number of 'severe' complications does not necessarily require an intervention. These unnecessary interventions could cause a higher chance in developing new complications, ICU admissions or even mortality.

Also, the follow-up rate was significantly better than that reported in international literature, with a 1-year follow-up of 97.9% in 2017 versus approximately 85%, respectively.[38]

Further improvements in postoperative outcomes resulted in considerable decrease in hospital variation in the past few years. To further stimulate the quality incentives, we had to compare our results with those of other countries **(This thesis)**.

An European registry called the international bariatric initiative (iBAR) was already in place. iBAR served as the basis for most European counterparts that later developed their own registries. Despite considerable similarities between these initiatives, we carefully analyzed all data points for any differences in definitions in the selected registries. This extended comparison revealed the possibility of a comparison study between registries in The Netherlands, Norway and Sweden, as is described in **Chapter 3**. The comparison study demonstrated similarities between these registries in measurement of patient characteristics, obesity-associated diseases, surgical techniques, perioperative complications, reinterventions, intensive care admissions, length of hospital stay, readmissions, and mortality.

The study revealed that Dutch patients were significantly older, had a higher body mass index (BMI), and were more frequently female subjects than Norway and Sweden patients. Regarding the use of surgical techniques, Norway (NO) appeared to prefer SG (58.2%), whereas the Netherlands (NL) (79.8%) and Sweden (SE) (67.0%) preferred RYGB. Preoperative comorbidities were most frequently reported in the Netherlands, especially T2DM (NL: 21.9%; average: 17.9%), HT (NL: 34.6%; average: 30.7%), and musculoskeletal pain (NL: 43.7%; average: 34.7%) **(This thesis)**.[39]

Postoperative complications and mortality rates were comparable among the countries and did not differ significantly. However, the percentage of reinterventions (NL: 2.6%; average: 2.8%), readmissions (NL: 2.6%; average: 4.3%), and length of hospital stay (NL: 1.7 days; NO: 1.9 days; SE 2.1 days) were significantly lower in the Netherlands **(This thesis)**. These reported outcomes cover all bariatric procedures and do not distinguish between different bariatric techniques. To investigate the effectiveness of bariatric surgery and the most preferred and effective surgical technique, a more in-depth analysis is necessary.

RYGB VERSUS SG

A comparison study between DATO and the Scandinavian Obesity Registry (SOReg) was conducted to examine the most preferred bariatric techniques. Outcomes of this second international comparison study are described in **Chapter 4**. An earlier comparison study, described in **Chapter 3**, demonstrated that the RYGB (73.1%) and SG (25.8%) were the most frequently performed procedures in the Netherlands, Norway, and Sweden. This second international comparison study used six quality indicators to

compare the postoperative outcomes of the two most performed bariatric procedures in North-Western Europe: (1) eligibility criteria for bariatric surgery, (2) complicated postoperative course, (3) length of hospital stay, (4) readmissions, (5) lost-to follow-up after 1 year, and (6) total weight loss (%TWL).

Most patients were operated in accordance with the internationally used IFSO-guidelines (RYGB 91.9%; SG 83.0%).[40] However, a significantly larger percentage of Swedish hospitals (13 out of 28) did not meet the international criteria for both RYGB and SG. Overall incidence of severe postoperative complications were 2.6% for RYGB and 2.4% SG ($p < 0.001$).[41] Pooled analysis revealed the most common complications after primary bariatric surgery as bleeding (1.6%), leakage (0.7%), and wound infection (0.5%). Factors associated with severe postoperative complications were laparoscopic versus open surgery, older age, surgical procedural experience, preoperative comorbidities, and BMI **(This thesis)**.[3, 42-44]

Regarding overall hospital stay, a significantly lower length of hospital stay was observed in the Netherlands for both RYGB (1.6 days) and SG (1.6 days) than Norway and Sweden. Additionally, a significantly lower percentage of readmissions (RYGB: 2.7%; SG: 2.5%) was noted in the Netherlands. This could be explained in part by demographic and geographic differences between the countries, with people in the Netherlands often living closer to a (bariatric) hospital. In addition, the patient volume per hospital is larger in the Netherlands, often resulting in more efficient care paths for patients receiving bariatric surgery. Moreover, an overall high percentage of 1-year follow-up after RYGB (87.9%) and SG (83.5%) was noted. The %TWL after 12 months demonstrated a success rate of 95.8% after RYGB and 84.6% after SG **(This thesis)**. In conclusion, both procedures appear to be safe, with RYGB having higher %TWL at the cost of a slightly higher 30-day readmission rate.

INTERPRETATION OF INTERNATIONAL COMPARISONS

Patient population usually differs across hospitals and case-mix adjustment is applied when specific patient populations are overrepresented in selected hospitals. However, the use of case-mix adjustment remains controversial and could be considered suboptimal in specific cases. For example, fluctuations and differences between hospitals could be based on chance variation and, therefore, should not be adjusted for case-mix. This is largely compensated by the use of the population-based study design. A larger sample size implies a more precise estimate and, therefore, more confidence and a narrower confidence interval.[45, 46]

Another challenge for hospital comparison is the use of anonymized healthcare data between different countries, as each country has its own privacy laws. To perform an international comparative study, aggregated data should be used. The loss of details in aggregated data makes it impossible to identify specific outcome predictors. Therefore, the outcomes of the international comparison studies in this thesis could not be case-mix adjusted and a possible selection bias could not be ruled out. Even after case-mix correction, unmeasured confounding will remain. Therefore, outcome rates, adjusted or not, should always be interpreted with caution. At the time of this thesis, the online published outcome indicators from both DATO and SOReg were not case-mix adjusted.

COMPOSITE OUTCOME MEASURE

During the development of new quality indicators, there is a growing demand for new indicators that reveal the overall quality of care in a well-organized manner. In surgeries for gastrointestinal cancer and elective aneurysm, such a composite measure has been described. This composite measure, called Textbook Outcome (TO), provides insights into the entire care process, enabling the possibility of hospital comparison.[26, 30, 31], which in turn could provide a better impression of the overall quality of surgical care provided to the patient.[29, 47, 48]

However, the disadvantage of TO indicator lies in combining all single outcome parameters into one binominal outcome. This binominal outcome does not provide individual hospitals information where and how to improve if their performance is significantly worse than the national average. Ordering different individual outcome parameters could make the composite measure more useful for quality improvement by professionals and suitable in terms of patient perspective.

The ordered TO consists of multiple postoperative outcome parameters for bariatric surgery. By using the ordered TO for bariatric surgery more hospital variation was captured. Through the ordered outcomes, individual hospitals could directly identify the outcomes and specific parameters that needed improvement. The results are therefore both useful from a patient's perspective and provides more detailed information for the individual hospital **(This thesis)**.

PATIENT-REPORTED OUTCOMES

Published studies on bariatric surgery have particularly focused on weight loss and improvement of obesity-related diseases, but have not considered the patient's perspective.[22, 23, 34, 49-51]. In recent years, several quality of life (QoL) questionnaires or patient-reported outcome measures (PROMs) have been introduced to elicit essential patient

information enabling physicians to improve quality of care for their patients. However, these questionnaires are prone to confounding factors such as socioeconomic status and are difficult to integrate in daily practice. Most bariatric hospitals have initiated the implementation of these questionnaires in daily practice by offering them on a tablet or other electronic device during the waiting period in the outpatient clinics.

The first short-term results of a large multicenter study are described in **Chapter 6**, with a response rate of >85%. The study compared the 1-year postoperative QoL results after RYGB and SG with the Dutch reference group. A significant improvement was noted in postoperative patients in physical functioning, physical role limitations, and health status, although the general health perception was significantly worse. These outcomes could be a prelude to focus more on these domains such that patients receiving bariatric surgery are not socially isolated or have a persisting worsened health perception. However, the results in **Chapter 6** also demonstrated that RAND-36 may not be an ideal questionnaire to measure QoL after bariatric surgery. This may have an impact on the outcomes that have been measured.

OBESE PATIENTS IN OTHER REGISTRIES

Data from DATO now consist of only the information entered by bariatric surgeons. However, the multifactorial aspect of obesity also covers several other disciplines. Some of these disciplines register their outcomes in their own registries. Existing data from a single registry can be enriched by combining data from these registries. The enriched data could be used to not only test new hypotheses but also prefill matching data points from different registries. For example, the weight and height of a patient needs to be entered only once, providing higher reliability of the entered data and reducing the registration burden for individual healthcare providers.

With recent technological advantages, it could be possible to cross-link different quality registries without violating any privacy legislation. This offers the likelihood to isolate specific patient groups and perform analyses using the enriched data. The usability and validity of the provided data can be analyzed using data from other registries to examine whether data from other registries are of added value. Potentially, DATO data can be enriched with information from other registries in future.

Considering obesity as a growing concern in the etiology of colorectal cancer, there is also a rising awareness of possible obesity-related postoperative morbidity after colorectal surgery. Therefore, obese patients with colorectal cancer were identified as a specific patient group by using data from the DSCA.

Chapter 7 endorses obesity as an important risk factor for patients with colorectal cancer (CRC). Obesity-related comorbidities were noted to be associated with significantly higher postoperative morbidity, length of hospital stay, readmission rate. Multivariate analysis identified BMI > 30 kg/m^2 as an independent predictor of a complicated postoperative course. Importantly, these are the first results obtained following the identification of obese patients from other registries. Future studies must examine whether more extensive and in-depth analyses are possible by cross-linking multiple audits and enriching current datasets.

As DATO is still a surgical and not a multidisciplinary audit, there is no information about patients with (morbid) obesity undergoing non-surgical treatment or no treatment at all. The audit could, therefore, not provide an overview of the overall effectiveness of bariatric surgery. Moreover, the impact of surgery on obesity-related diseases compared to that of conservative treatments could not be addressed. This thesis does not contain information about the long-term follow-up, including, for example, contour restoring surgery or late complications such as malnutrition, as noticed by other disciplines.

FUTURE PERSPECTIVES

Evaluation and improvement of quality of care are crucial. The DATO is one of the first nationwide mandatory bariatric registries in Europe. Now that the first short-term results have been published, it is important for the registry to evolve and further improve bariatric care. Furthermore, other (new) nationwide registries can be used in the future for international comparisons.[13]

LONG-TERM OUTCOMES

Outcomes such as postoperative morbidity and mortality are often used to evaluate hospital performance. However, these outcomes only provide information on short-term surgical outcomes, which means that the multidimensional aspect of the whole bariatric care pathway is not fully evaluated. More information is needed on the long-term durability of comorbidity control and complications after bariatric procedures. The Enhanced Recovery After Surgery (ERAS) program is a multimodal approach to improve perioperative care in colon surgery.[52] Presently, it may be assumed that ERAS is also embedded in bariatric surgery. Whether this leads to the desired quality improvements and whether ERAS needs to be adjusted for bariatric surgery remain points of discussion. Additionally, medical and nutritional monitoring are essential in managing dietary adequacy and the deficiencies that may occur.

PATIENT-CENTERED REGISTRATION

Currently, 'patient measured outcomes' (PROs) after bariatric surgery are often from the clinician's point of view. Including patient perspective can be used for not only screening purposes but also quality-of-care improvement by enhancing the physician–patient communication. These (PROs) can identify potentially important subjects during consultation and evaluation of bariatric surgery. For example, a patient who has achieved an enormous weight reduction can score significantly worse on questions on patient's perception of appearance and health status. The physician will notice this during the consultation and refer the patient to the plastic surgeon for body-contour surgery. The same could apply to patients with psychological complaints after bariatric surgery. Early identification and recognition can lead to quick and adequate referrals and therefore better quality of care and might even reduce costs.

In addition, PROMs can be an adequate alternative measurement to indicate the success of the bariatric surgery. Presently, reaching the postoperative target weight is the golden standard for measuring the success rate of bariatric surgeries. Softer outcome measures, however, can provide an additional insight into the current success rate, such as being able to re-participate in society again.

Currently, there is an ever-increasing list of PROMs. However, none of these meet the current quality requirements set for measuring patient outcomes after bariatric surgery.[53] A new disease-specific PRO for obesity and bariatric surgery should be designed to meet the current quality requirements. The combination of clinical outcomes and PROs are of great importance in the future for identifying the most appropriate procedure for a given patient and obtaining an actual informed consent.

REVISION SURGERY

Unfortunately, not all bariatric procedures are successful. A total of 3.157 (14.4%) revision surgeries were registered in 2016. However, the indication to perform a revision surgery appears to differ considerably between hospitals. In addition, there are major differences in the number of interventions and the technique used between hospitals.

In 2017, DATO started to register the indication for revision surgery and to obtain data regarding the surgical technique used by each hospital. A detailed analysis will reveal the type of surgical technique that is suitable for a specific patient group. The information provided by measuring these outcomes can be a prelude to develop new process and outcome indicators. The DATO data-dictionary of 2020 reveals new indicators that could measure these outcomes, hopefully resulting in further quality improvement.

INFORMATION AND COMMUNICATIONS TECHNOLOGY

Measuring adequate outcomes is accompanied by a rapidly increasing volume of data. As a result, there is a growth in various databases and initiatives, each measuring a different aspect with the use of the same data points. An example of this fragmented information is the existence of two separate databases in DATO: the clinical and the PROM database. The joint evaluation of these databases on a patient level may be the key to better interpretation of PROMs, with demographics and other confounding factors being available in the database to calculate case-mix adjusted PROMs.

Various initiatives need to be addressed to reduce the current administrative burden. First, healthcare data should be findable, accessible, interoperable, and reusable. This allows data to be used multiple times for different purposes. Second, simplifying data compilations by cross-linking different (public) databases needs to be stimulated. In addition, synoptic reporting could help physicians produce more complete, consistent, and valuable medical reports. Electronic synoptic reporting uses coded-value templates to quickly capture interoperable data in discrete fields.

The introduction of Internet and wireless technologies has allowed for an explosion of medical applications and new technologies. Especially, wearable technologies, such as smartwatches, are now being used for diagnostics and patient monitoring. This new source of information could be used for automatic and more accurate data collection.

If we can make maximum use of these technological possibilities, healthcare providers will no longer be saddled with a rising administrative burden and additional costs, which is at the expense of clinical patient care.

CONCLUSION

The DATO has rapidly become a mature registry. Bariatric surgery can be considered relatively safe. The Dutch results and our comparative studies with Norway and Sweden confirm this conclusion.

Individual and composite outcome measures, assessing the short-term postoperative outcome after bariatric surgery, enable the possibility to identify outliers. Most importantly, individual hospitals can identify differences in outcome, whereas these may remain hidden in daily practice. This between-hospital variation may initiate an improvement cycle. This will probably result in hospital and surgical quality improvements leading to improved outcomes in bariatric surgery.

Altogether, population-based data from clinical registries are a valuable addition to randomized controlled trials. In future, this could lead to algorithm development that supports clinical decision-making and personalized medicine.

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Dutch Summary / Nederlandse Samenvatting

SAMENVATTING

INTRODUCTIE

Er is lang aangenomen dat obesitas enkel het gevolg was van een ongezonde leefstijl. Obesitas wordt tegenwoordig echter erkend als een complexe, multifactoriële en chronische ziekte die samengaat met een verhoogd risico op zowel morbiditeit als mortaliteit. Volgens de definitie van de Wereldgezondheidsorganisatie (WHO) is er sprake van obesitas wanneer iemand een buitengewone ophoping van vetweefsel heeft dat daarbij een negatief effect kan hebben op de gezondheid van het individu. Om vast te stellen of iemand obesitas heeft wordt in de literatuur veelal gebruik gemaakt van de Body Mass Index (BMI), waarbij er van obesitas wordt gesproken bij een BMI van 30 kg/m^2 of hoger.

Sinds 1975 wordt bijna een verdrievoudiging gezien van obesitas tot circa 13% van de wereldbevolking in 2016.[1] Tevens is er een stijging van obesitas zichtbaar in de leeftijdsgroep van 5 tot 19 jaar met een percentuele stijging van 4 naar 18%.

Obesitas wordt voornamelijk veroorzaakt door een disbalans in de calorische intake via energierijke voeding enerzijds en de afname in activiteit van de mens anderzijds. Deze veranderingen in voedingspatronen en lichaamsbeweging zijn vaak het resultaat van veranderingen in de samenleving op het gebied van gezondheid, landbouw, transport en milieu, maar ook op het gebied van voedselverwerking, marketing en onderwijs. Andere oorzaken die invloed hebben op het ontwikkelen van obesitas zijn hormonale veranderingen, psychische gezondheid en erfelijke aanleg.

Obesitas is een chronische en progressieve ziekte die een belangrijke risicofactor is voor de ontwikkeling van obesitas-gerelateerde ziekten als diabetes mellitus[2], hart- en vaatziekten[3], obstructief slaapapneusyndroom[4], gastro-intestinale problemen[5], artrose en verscheidene vormen van kanker[6]. Daarnaast heeft obesitas een negatieve invloed op de kwaliteit van leven en zijn de maatschappelijke gevolgen enorm.[7]

In de laatste decennia zijn er verschillende pogingen gedaan om obesitas met niet-operatieve interventies te lijf te gaan. De eerste resultaten na conservatieve behandeling waren hoopvol, maar de lange(re)-termijnresultaten in termen van gewichtsverlies en obesitas-gerelateerde ziektereductie waren teleurstellend te noemen.

Een meer succesvolle benadering werd gevonden binnen het chirurgisch vakgebied met zowel effect op korte als op langere termijn. De meest uitgevoerde chirurgische ingreep in Nederland is op dit moment de Roux-en-Y-Gastric Bypass (RYGB), gevolgd

door de Sleeve Gastrectomy (SG). Om de kwaliteit en effectiviteit van deze ingrepen te meten heeft de "Dutch Society for Metabolic and Bariatric Surgery" (DSMBS) het voortouw genomen in de oprichting van een landelijke kwaliteitsregistratie met als doel om de kwaliteit van geleverde zorg inzichtelijk te maken. Centraal hierin staat het Donabedian-model met drie onderling verbonden domeinen: structuur, processen en uitkomsten.

Deze registratie is ondergebracht bij de "Dutch Institute for Clinical Auditing" (DICA). Jaarlijks worden deze uitkomstmaten samen met de "Inspectie Gezondheidszorg en Jeugd" (IGJ) en de Patiëntenfederatie Nederland geëvalueerd en openbaar gemaakt, zodat de uitkomsten voor iedereen inzichtelijk zijn.

Dit proefschrift geeft inzicht in de vorming van de landelijke bariatrische registratie met daarbij inzicht in de eerste korte-termijnresultaten en de interpretatie van ziekenhuis-vergelijking op nationaal en internationaal niveau.

DUTCH AUDIT FOR TREATMENT OF OBESITY

In 2015 is in Nederland de "Dutch Audit for Treatment of Obesity" (DATO) van start gegaan naar voorbeeld van de "Patients Outcome Measurement Tool" (POMT) en de "International BAriatric Registry" (iBAR). In het begin heeft de registratie zich gericht op proces- en uitkomstindicatoren die gestoeld zijn op internationale richtlijnen rondom bariatrische chirurgie. De indicatie voor bariatrische chirurgie is een BMI ≥ 40 kg/m^2 of BMI 35-40 kg/m^2 in combinatie met één van de bekende obesitas-gerelateerde ziekten. Daarnaast is de voorwaarde dat de patiënt voldoende gezond is om anesthesie te ondergaan met daarbij bereidheid tot een langdurige follow-up.

Het percentage postoperatieve follow-up, gewichtsverlies, optreden van ernstige complicaties en mortaliteit na primaire bariatrische chirurgie, is een greep uit enkele kwaliteitsindicatoren die binnen de DATO worden gemeten (**Hoofdstuk 2**). Tijdens het registratiejaar 2016 zijn van slechts 2,1%, van alle patiënten die een primaire bariatrische ingreep hebben ondergaan, geen follow-up-gegevens na één jaar aanwezig. Daarnaast wordt in 2016 2,3% van alle primaire ingrepen een ernstige complicatie binnen 30 dagen gerapporteerd. Wanneer deze resultaten worden vergelijken met de internationale literatuur (0-7%) kan men stellen dat bariatrische chirurgie in Nederland als relatief veilig beschouwd kan worden met daarbij nauwlettende follow-up door de zorgverlener.[8, 9]

Met de komst van DATO en de deelname van alle 18 bariatrische ziekenhuizen is het meten van deze structuur-, proces- en uitkomstparameters tegenwoordig ingebed in

individuele ziekenhuisrichtlijnen, door middel van normeringseisen en richtlijnen opgesteld vanuit Zorgverzekeraars Nederland. Vervolgens is vanuit elk bariatrisch ziekenhuis in Nederland een gemandateerd lid aangewezen die zitting heeft in de wetenschappelijke commissie om het ontwikkelingsproces van deze indicatoren te waarborgen.

INTERNATIONALE VERGELIJKING

Met uitkomstvergelijkingen tussen individuele ziekenhuizen en de kwaliteitsverbeteringen die hiervan het gevolg zijn, neemt de variatie over de tijd af. Om nieuwe kwaliteitsimpulsen te initiëren is getracht op landelijk niveau verschillende uitkomstmaten met elkaar te vergelijken, waarbij het belangrijk is dat definities binnen verschillende registraties met elkaar overeenkomen.

In samenwerking met de "Scandinavian Obesity Surgery Registry" (SOReg) zijn de registraties van Noorwegen, Zweden en Nederland met elkaar vergeleken (**Hoofdstuk 3**). De definities van verschillende gemeten datapunten binnen de registraties komen op het gebied van patiëntkenmerken, obesitas-gerelateerde ziekten, chirurgische technieken, perioperatieve complicaties, re-interventies, intensive care-opnames, opnameduur in het ziekenhuis, heropnames en mortaliteit met elkaar overeen.

Uitkomsten van de eerste vergelijkingsstudie toonden aan dat Nederlandse patiënten significant ouder zijn, preoperatief een hogere BMI hebben en vaker van het vrouwelijk geslacht zijn. Ook is een variatie zichtbaar tussen de verschillende bariatrische technieken, waarbij in Noorwegen vaker de SG (58,2%) wordt toegepast, terwijl dit in Nederland (79,8%) en Zweden (67,0%) de RYGB is. Preoperatieve co-morbiditeiten werden het meest geregistreerd in Nederland. Vooral T2DM (NL: 21,9%; overall gemiddelde: 17,9%), HT (NL: 34,6%; overall gemiddelde: 30,7%) en musculoskeletale pijn (NL: 43,7%; overall gemiddelde: 34,7%) zijn vaker preoperatief geregistreerd.

RYGB VERSUS SG

De RYGB en SG zijn de twee meest toegepaste bariatrische ingrepen in Nederland, Noorwegen en Zweden, waarbij reeds in **Hoofdstuk 3** is beschreven op welke vlakken de registraties met elkaar overeenkomen. Door de uitkomsten van de landelijke registraties met elkaar te vergelijken, kunnen belangrijke uitkomstindicatoren over een grotere groep patiënten berekend worden en mogelijke variaties geïdentificeerd worden. **Hoofdstuk 4** beschrijft de perioperatieve uitkomsten van de RYGB en SG in Noordwest-Europa.

Kijkend naar de indicatiestelling wordt het overgrote deel van de primair geopereerde patiënten geopereerd volgens de internationaal geldende richtlijnen (RYGB 91,9%; SG

83,0%). Daarbij was de incidentie van ernstige postoperatieve complicaties met 2,6% voor RYGB en 2,4% SG (p <0,001) laag te noemen. Een gepoolde analyse toonde aan dat de meest voorkomende complicaties na primaire bariatrische chirurgie bloeding (1,6%), lekkage (0,7%) en wondinfectie (0,5%) betroffen. Het totale ziekenhuisverblijf in Nederland vertoonde een significant kortere verblijfsduur voor zowel RYGB (1,6 dagen) als SG (1,6 dagen) in vergelijking met Noorwegen en Zweden. Ook werd in Nederland een significant lager percentage heropnames gezien (RYGB 2,7%; SG 2,5%). Over het algemeen werd er een hoog percentage 1-jaars follow-up gezien na RYGB (87,9%) en SG (83,5%). Het gewichtsverlies na 12 maanden liet een succespercentage zien van 95,8% na RYGB en 84,6% na SG. Concluderend kan gesteld worden dat beide bariatrische technieken veilig zijn en dat het postoperatief gewrichtsverlies hoger is na een RYGB ten koste van een iets hoger heropnamepercentage binnen 30 dagen.

SAMENGESTELDE UITKOMSTMAAT

Om kwaliteitsverbeteringen te stimuleren zijn er verschillende uitkomstindicatoren vastgesteld die onder andere worden gemeten in DATO. Deze uitkomstindicatoren geven inzicht in individuele uitkomstparameters, maar verschaffen niet noodzakelijkerwijs inzicht in het gehele zorgproces. Hierbij kan aangenomen worden dat verschillende afzonderlijke uitkomstmaten aan elkaar gerelateerd zijn en dus invloed op elkaar uitoefenen.

Textbook Outcome (TO)-studies hebben eerder aangetoond dat een samengestelde uitkomstmaat aanvullende informatie kan geven over de algehele kwaliteit van chirurgische ketenzorg. **Hoofdstuk 5** beschrijft een geordende uitkomstmaat, bestaande uit meerdere uitkomstparameters. Deze uitkomstmaat toont grote variatie in de gemeten ketenzorg tussen de deelnemende ziekenhuizen.

De uitkomstparameters die TO bepalen zijn vastgesteld tijdens een consensusmeeting binnen de wetenschappelijke commissie. De uitkomstparameters die zijn geselecteerd omvatten verlengde opnameduur (>2 dagen), heropname, ernstige postoperatieve complicaties, re-interventies, intensive care opname en mortaliteit. De uitkomsten zijn als gerangschikt naar ernst. Beginnende met mortaliteit als ernstigste complicatie, gevolgd door ernstige postoperatieve complicaties, heropname, milde complicaties en verlengde verblijfsduur (LOS) binnen 30 dagen na primaire operatie, met TO gedefinieerd als geen van deze uitkomsten.

In totaal zijn er 27.360 primaire operaties geregistreerd tussen 2015 en 2018 waarover TO berekend kon worden. Er wordt gesproken van TO als alle gewenste uitkomsten worden bereikt en ongewenste uitkomsten, voor de patiënt, worden voorkomen.

Bij 88,7% van de patiënten werd uiteindelijk TO bereikt (bereik 35.5 – 96.9%) na een primaire bariatrische operatie. Twee ziekenhuizen scoorden lager door een significant langere opnameduur (57,6%) en één ziekenhuis in verband met een hogere incidentie van milde complicaties (17,1%).

PATIËNT GERAPPORTEERDE UITKOMSTEN

Waar internationale studies zich de afgelopen decennia met name op gewichtsverlies en verbetering van obesitas-gerelateerde ziekten hebben gericht, wordt er de laatste jaren een toename gezien in het aantal studies waarbij de kwaliteit van leven centraal staat.

Om inzicht te kunnen krijgen in de door de bariatrische patiënt ervaren verandering in de kwaliteit van leven, worden sinds de oprichting van DATO "Patiënt Gerapporteerde Uitkomsten" (PRO's) geregistreerd. Hierbij wordt gebruik gemaakt van de RAND-36-vragenlijst. Binnen DATO wordt deze vragenlijst in ieder geval preoperatief en 12 maanden postoperatief ingevuld. De perioperatieve resultaten van de twee meest toegepaste bariatrische verrichtingen worden met elkaar vergeleken en tevens afgezet tegen het landelijk gemiddelde (**Hoofdstuk 6**).

In totaal hebben 4.864 patiënten, geopereerd in 5 ziekenhuizen, zowel de pre- als de postoperatieve vragenlijst ingevuld. Vergeleken met Nederlandse referentiewaarden rapporteerden deze patiënten postoperatief een beter *fysiek functioneren* (RYGB + 6,8%), minder *rolbeperkingen door fysieke problemen* (SG + 5,6%; RYGB + 6,2%) en een grotere *gezondheidsverandering* (SG + 77,1%; RYGB + 80,0%) ten opzichte van het Nederlands gemiddelde. Echter bariatrische patiënten ervoeren een slechtere *algemene gezondheidsbeleving* (SG -22,8%; RYGB -17,0%). Verbetering in kwaliteit van leven was over het algemeen vergelijkbaar tussen de twee technieken (RYGB en SG), behalve binnen de domeinen *fysiek functioneren* (P = 0.008) en *algemene gezondheidsbeleving* (P <0.001) waar RYGB-patiënten meer progressie toonden.

Resultaten vanuit het patiëntenperspectief laten zien dat bariatrische chirurgie een positieve invloed heeft op het welbevinden van de obese patiënt. Zowel de SG als de RYGB laten een significante positieve verbetering zien op verschillende domeinen.

ANDERE REGISTRATIES

In de internationale literatuur is reeds beschreven dat patiënten met morbide obesitas een verhoogde kans op darmkanker hebben. Met de hypothese dat morbide obesitas een onafhankelijke risicofactor is voor een postoperatief gecompliceerd beloop, is een nationale vergelijkingsstudie met de Nederlandse darmkankerregistratie (DCRA)

verricht. Hierbij is gekeken naar de postoperatieve uitkomsten van morbide obese patiënten na darmkankerchirurgie.

Hoofdstuk 7 onderschrijft obesitas als een belangrijke risicofactor voor patiënten met darmkanker. Obesitas-gerelateerde co-morbiditeiten werden geassocieerd met significant hogere postoperatieve morbiditeit, opnameduur en percentage heropnames. Multivariate analyse identificeerde BMI ≥ 30 kg/m^2 als een onafhankelijke voorspeller van een gecompliceerd postoperatief beloop.

Door in de toekomst meer gebruik te maken van verschillende registraties of databronnen is het mogelijk om huidige datasets binnen een registratie te verrijken. Hiermee kunnen uitgebreidere analyses uitgevoerd worden en beter inzicht verkregen worden in het het beloop van multifactoriële ziekten zoals morbide obesitas.

TOEKOMSTPERSPECTIEVEN

Evaluatie en verbetering van de kwaliteit van zorg is van cruciaal belang, zo ook binnen de bariatrische ketenzorg. Met de oprichting van DATO is een eerste belangrijke stap gezet om verdere kwaliteitsimpulsen te stimuleren. De landelijke registraties geven momenteel inzicht in de belangrijke proces- en uitkomstindicatoren binnen de bariatrische ketenzorg. Ook is een eerste stap gezet in het registreren van PRO's, waarbij er significante postoperatieve kwaliteitsverbeteringen worden gezien in vrijwel alle domeinen. Echter, de vragenlijst biedt op dit moment weinig onderscheidend vermogen binnen de specifieke domeinen, wat de vraag oproept of de huidige vragenlijst het best aansluit binnen de bariatrische ketenzorg.

Door het grote aanbod van verschillende vragenlijsten en de variatie in toepasbaarheid, is het lastig is om de juiste vragenlijst te kiezen om de hele bariatrische ketenzorg in kaart te brengen. Op dit moment zijn er verschillende vragenlijsten die in meer of mindere mate een gedeelte van de ketenzorg meten. De afstemming van de juiste vragenlijsten vraagt om verder onderzoek en het zal een kwestie van tijd zijn voordat deze barrières geslecht zullen worden. De combinatie van klinische resultaten en PRO's zal in de toekomst van groot belang zijn voor het identificeren van de juiste procedure voor specifieke patiëntgroepen en het op de juiste manier verkrijgen van 'informed consent'.

Resultaten zoals nu gepubliceerd en beschreven in dit proefschrift bieden over het algemeen informatie over chirurgische uitkomsten op korte termijn, wat betekent dat het multidimensionale aspect van de gehele bariatrische zorgketen nog niet volledig wordt geëvalueerd. In de loop van de komende jaren zal er meer informatie beschikbaar ko-

men over de langetermijnresultaten met betrekking tot co-morbiditeiten, complicaties en succesratio.

Want helaas niet elke bariatrische procedure is succesvol. In 2016 werden in totaal 3.157 (14,4%) revisieprocedures geregistreerd. De indicatie voor het uitvoeren van revisiechirurgie blijkt echter aanzienlijk te verschillen tussen ziekenhuizen. DATO is in 2017 gestart om de indicatie voor revisiechirurgie te registreren en om te zien welke chirurgische technieken door elk individueel ziekenhuis worden gebruikt. Bij verdere diepteanalyses zal uiteindelijk moeten blijken welk chirurgische techniek geschikt is voor elke specifieke patiëntengroep. De informatie die wordt verkregen door deze uitkomsten te meten, kan een opmaat zijn voor de ontwikkeling van nieuwe proces- en uitkomstindicatoren.

Het meten van adequate resultaten gaat gepaard met een snel toenemend gegevensvolume. Hierdoor is er een groei te zien in het aantal verschillende databases en initiatieven, die elk een ander aspect proberen te meten binnen de huidige ketenzorg. Deze verschillende registraties/databases maken echter veelal gebruik van dezelfde datapunten, zoals gegevens omtrent gewicht en co-morbiditeiten. Met (her)gebruik van bestaande gegevens uit verschillende (openbare) bronnen en koppeling van synoptische rapportages, kan de zorgverlener toegang krijgen tot completere, consistentere en waardevollere medische informatie. Door de bestaande technologische mogelijkheden maximaal te benutten en ervoor te zorgen dat geregistreerde gegevens vindbaar, toegankelijk, interoperabel en herbruikbaar zijn, kan men ervoor zorgen dat de zorgverlener niet wordt opgezadeld met toenemende administratieve lasten en extra kosten.

CONCLUSIE

De constante zoektocht naar verbetering is een belangrijke factor voor het behalen van klinisch goede uitkomsten, wat belangrijk is voor zowel de zorgverlener als de patiënt. Met behulp van een landelijke klinische registratie kunnen deze gegevens verzameld en objectief geanalyseerd worden. DATO is inmiddels een onmisbaar instrument om de kwaliteit van bariatrische chirurgie in Nederland te meten, maar ook om de kwaliteit van zorg op een transparante manier te kunnen blijven waarborgen.

Om verdere kwaliteitsverbeteringen te initiëren is het belangrijk om ook over de eigen landsgrenzen heen te kijken. Vergelijkingsstudies, zoals beschreven in dit proefschrift, hebben aangetoond dat DATO uitermate geschikt is voor internationale vergelijkingen op zowel landelijke als op ziekenhuisniveau. Door landelijke registraties te combineren is in dit proefschrift de grootste wetenschappelijke internationale audit-groep tot op

heden beschreven. De resultaten uit deze studie kunnen gebruikt worden om het zorgproces rondom de bariatrische chirurgie verder te verbeteren. Hiermee kan de zorg verder geoptimaliseerd worden, maar ze bieden ook nieuwe mogelijkheden om bijvoorbeeld verschillende bariatrische technieken op grote schaal met elkaar te vergelijken en toe te spitsen op de individuele patiënt, waardoor 'personalized' of 'tailored medicine' mogelijk is.

Uitkomsten uit landelijke registraties bestaan meestal uit individuele uitkomstparameters, waarbij het zorgproces niet altijd correct wordt weergegeven. Door gebruik te maken van een samengestelde uitkomstmaat kunnen verschillende facetten van het zorgproces weergegeven worden in één uitkomstmaat. Textbook Outcome is zo'n samengestelde uitkomstmaat die inzicht geeft in een eventueel ongunstig beloop na bariatrische chirurgie. Door gebruik te maken van een gecombineerde uitkomstmaat kunnen verschillende processen in de zorgketen, uit verschillende ziekenhuizen, inzicht geven in de geleverde bariatrische zorg.

Studies binnen de bariatrische chirurgie richtten zich de afgelopen decennia met name op gewichtsverlies en verbetering van obesitas-gerelateerde ziekten, maar houden onvoldoende rekening met het perspectief van de patiënt. Door gebruik te maken van gevalideerde 'kwaliteit-van-leven'-vragenlijsten is het mogelijk om de kwaliteitsverbetering in verschillende domeinen weer te geven. Wanneer deze uitkomsten worden gekoppeld aan klinische gegevens kan de effectiviteit van bariatrische chirurgie op de kwaliteit van leven gemeten worden op het niveau van de patiënt.

Wanneer in de toekomst gegevens uit andere bronnen gekoppeld kunnen worden, waardoor klinische data verder verrijkt kunnen worden, is het mogelijk om het zorgproces verder uit te diepen en nieuwe onderzoekverbanden te leggen. Het zal een uitdaging worden om in de toekomst slimmer te registreren, meer data te verzamelen, maar de registratielast te verminderen.

Concluderend kan gesteld worden dat de DATO een succesvolle landelijk dekkende registratie is, die inzicht geeft in de korte termijn uitkomsten tussen verschillende ziekenhuizen. Door vergelijkingen van proces- en uitkomstindicatoren op nationaal en internationaal niveau wordt getracht nieuwe kwaliteitsimpulsen te genereren om verdere kwaliteitsverbeteringen te realiseren.

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CURRICULUM VITAE

Youri Poelemeijer was born in Amsterdam on November 27th, 1987. The first years he lived in Amsterdam, until he moved to Hilversum at the age of 10. In 2006 he graduated from Comenius College Hilversum. Because of his special interest in biology and the human body he started his study Medicine at VU University Amsterdam that same year.

During his studies Youri decided to join the board of the medical study association 'M.F.V.U.' in 2008. As a secretary, he was able to contribute to the realization of various events during that year. His sporting career unfolded at the end of 2008 at A.A.S.R. 'Skøll'. That year he won the student's coxed four championship (EjC4+). A year later he joined R.S.V.U. 'Okeanos' in the heavyweight men's eight (Ej8+) and finished 3rd that year. The following years Youri rowed alternately in the eight, coxless four and coxless pair. Eventually he had the privilege in 2011 to participate in the 'Oude Vier' (128th Varsity); the main event of the oldest and most prestigious student rowing regatta in the Netherlands. That same year he also reached the semi-finals in the Temple Challenge Cup at the Henley Royal Regatta, the world's best-known and most prestigious rowing event.

In addition to his clinical rotations, which started in 2012, he began as a student researcher on the Trauma Surgery Department of the VU University Medical Center (Amsterdam) under the supervision of Dr. W.P. Zuidema. The subject concerned lateral clavicle fractures and the need for treatment, which resulted in his first scientific presentation at a medical conference. Due to the growing interest in trauma surgery, Youri performed a clinical internship in trauma and orthopaedics at Red Cross Children's War Memorial Hospital (Cape Town, South Africa).

In January 2015 he received his medical degree and started working for one year as a surgical resident at Haaglanden Medisch Centrum (The Hague). At the end of 2015 he got the opportunity to become part of the research team at Leiden University Medical Center (Leiden) and the Dutch Institute for Clinical Auditing (DICA). For three years Youri dedicated his time focused on clinical outcomes after bariatric surgery under the supervision of Prof. Dr. R.A.E.M. Tollenaar, Dr. S.W. Nienhuijs and Drs. R.S.L. Liem. The research project was the basis of this PhD thesis.

During this period, he was also able to combine his love for sports and medicine. For example, he was the venue medical officer during UEFA Women's EURO 2017, chief medical officer at the Alpe d'HuZes fundraising event and currently he is a certified diving physician in the Netherlands. In addition to sports, Youri has also been involved

in the education of (younger) colleagues. Together with five other PhD students, he organized a two-day masterclass for young healthcare professionals with the aim of creating more awareness about Value Based Healthcare.

In 2018 Youri returned to clinical health care and started as a surgical resident at Leiden University Medical Center. Currently he works as a surgical resident at the University Medical Center Groningen (UMCG) and is living together with his girlfriend Josine van Yperen and his son Alexander Poelemeijer in Amsterdam.

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Dubai, United Arab Emirates (UAE)

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