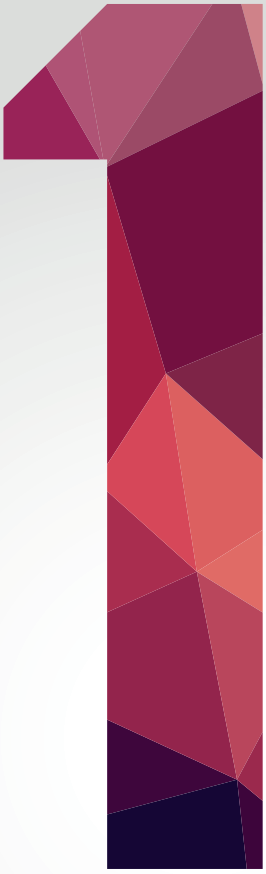
Clinical outcomes in bariatric surgery

Poelemeijer, Y.Q.M.



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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