Clinical outcomes in bariatric surgery

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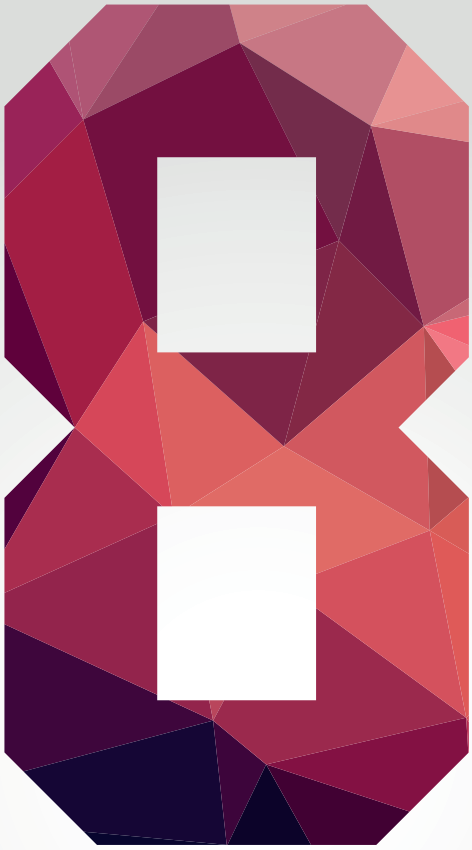

General Discussion and Future Perspectives

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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