

## Moral challenges with surgical treatment of type 2 diabetes☆☆

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### ABSTRACT

**Aim:** To review the most important moral challenges following from the widespread use of bariatric surgery for type 2 diabetes for patients with BMI <35 kg/m<sup>2</sup>, although high quality evidence for its short and long term effectiveness and safety is limited.

**Methods:** Extensive literature search to identify and analyze morally relevant issues. A question based method in ethics was applied to facilitate assessment and decision making.

**Results:** Several important moral issues were identified: assessing and informing about safety, patient outcomes, and stakeholder interests; acquiring valid informed consent; defining and selecting outcome measures; stigmatization and discrimination of the patient group, as well as providing just distribution of health care. The main sources of these challenges are lack of high quality evidence, disagreement on clinical indications and endpoints, and the disciplining of human behavior by surgical interventions.

**Conclusion:** A lack of high quality evidence on the effect of bariatric surgery for the treatment of T2DM in patients with BMI < 35/kg/m<sup>2</sup> poses a wide variety of moral challenges, which are important for decisions on the individual patient level, on the management level, and on the health policy making level. Strong preferences among surgeons and patients may hamper high quality research.

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### 1. Introduction

Type 2 diabetes mellitus (T2DM) is one of the most challenging health problems in the world (UN General Assembly, 2006), affecting more than 300 million people worldwide, a figure which is expected to increase by more than 50% in the next decade (Danaei et al., 2011; World Health Organization, 2006). Many types of treatments exist, but some surgical procedures in morbidly obese subjects appear to have dramatic beneficial effects on T2DM. According to a 1991 National Institutes of Health consensus statement, bariatric surgery may potentially improve T2DM (Consensus Development Conference

Panel, 1991), whilst international conferences on bariatric surgery for T2DM have concluded that bariatric surgery is an effective treatment of T2DM in morbidly obese subjects (Rubino, Kaplan, Schauer, Cummings, & Delegates, 2010). Recently, bariatric surgery has been launched as an attractive treatment alternative for patients with T2DM and a body-mass index (BMI) <35 kg/m<sup>2</sup> (Dixon, Pories, O'Brien, Schauer, & Zimmet, 2008; Rubino, 2008; Rubino et al., 2010; Mingrone et al., 2012; Varela, 2011; Spanou, 2013; Walton & Date, 2011). Several observational and some randomized controlled studies demonstrate that such surgical procedures may help patients to achieve a substantial weight loss, ameliorate glucose control and even induce remission of T2DM in a large proportion of patients (Buchwald et al., 2009; Dixon et al., 2008; Lautz, Halperin, Goebel-Fabbri, & Goldfine, 2011).

However, there is still debate on the limited evidence on the effect and safety of bariatric surgery in persons with BMI < 35 kg/m<sup>2</sup> (Colquitt, Picot, Loveman, & Clegg, 2009; Institute of Health Economics, 2011; Lautz et al., 2011; Pinkney & Kerrigan, 2004), particularly in those with T2DM. Some critics argue that the remission of T2DM after surgery is often transient (Pinkney, Johnson, & Gale, 2010). Even with high quality evidence for morbidly obese persons, we cannot uncritically extrapolate results on T2DM from persons with BMI ≥ 35 kg/m<sup>2</sup> to those with BMI < 35 kg/m<sup>2</sup> (Dixon et al., 2012). The long-term effects on glucose control and surrogate endpoints such as albuminuria, lipid

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profiles, hypertension, markers of inflammation, and other cardiovascular risk factors of the various bariatric procedures are still not fully understood (Lautz et al., 2011; Varela, 2011). Hence, it is still controversial whether bariatric surgery is a justified treatment strategy for T2DM in patients with BMI < 35 kg/m<sup>2</sup> (Lautz et al., 2011).

Moreover, bariatric surgery modifies otherwise healthy organs with partly irreversible methods, and may forcefully alter people's everyday behavior. Some patients feel guilt and shame after bariatric surgery (Groven & Raheim, and Engelsrud). Bariatric surgery itself has been considered by some to be a part of the medicalization of modern life, transforming physical states into diseases, persons into patients, and behavioral problems into surgical tasks (de Vries, 2007). Furthermore, some have argued that bariatric surgery is governed by overtly strong professional and commercial interests (Pinkney, 2010a) launching value laden terms, such as “metabolic surgery” and “diabetic surgery.” History bears witness to a series of futile surgical procedures, including within the field of bariatric surgery (Pinkney et al., 2010). Jejunoileal bypass, for example, was performed for many years before severe procedure-related complications were recognized (MacDonald, 2003).

These circumstances all pose substantial moral questions to those who care for and advice persons with diabetes. Accordingly, the objective of this review is to highlight the most pertinent moral questions with bariatric surgery for patients with T2DM and BMI < 35 kg/m<sup>2</sup> so that health professionals, decision makers, and health policy makers can make sound and transparent decisions on which treatment strategies should be offered, to which patients and patient groups in order to help them in the *best possible way*.

## 2. Method

A question based (Socratic) approach in ethics is used where a set of 32 questions is posed in order to highlight moral issues connected to bariatric surgery for diabetes. The method is described in detail elsewhere (Hofmann, 2005a) and has been implemented in models addressing ethical issues in Health Technology Assessment (HTA) (HTA core model for medical & surgical interventions v 1). The approach has been applied to other analyses of ethical aspects of a wide range of health technologies as well as to other surgical procedures (Hofmann, 2010).

The core of the question based approach is to identify moral issues and reveal underlying or hidden moral assumptions in order to stimulate critical thinking and sound decision making. Rather than analyzing bariatric surgery for T2DM within a particular ethical framework and providing specific recommendations, the method aims at presenting the norms, values, viewpoints, and ethical arguments that are relevant for recommendations and decisions in context. Hence, the method is not a tool for producing clear-cut answers to all challenging questions from an ethics ivory tower, but provides norms, values, and arguments that health professionals and decision makers may need to take into account when selecting the best treatment option for this group of patients.

A literature search method developed to identify relevant moral issues was applied. MEDLINE, EMBASE, EURETH, Cochrane, BIOSIS, CINAHL, and PSYCINFO were included in this search. Search command and strategy building followed thereafter (Droste, Dintsios, & Gerber, 2010). Search words were: bariatric surgery, type 2 diabetes, ethic\*, moral\*, patient autonomy, consent, assent, conflict, interest, self determination, health disparities, discrimination, mental capacity, mental competency, parental, perceptive discrimination, beneficence, utility, effectiveness, efficacy, effectiveness, safety. Due to limited results for BMI < 35 kg/m<sup>2</sup>, searches were performed without this limitation and the literature was assessed manually for BMI-ranges. Some results (moral issues) from literature without BMI-limitations were found relevant also for BMI < 35 kg/m<sup>2</sup> and were included.

An initial literature search, informal interviews with experts, and scanning of patient interest groups' web-pages helped us identify 13 (of 32) questions as morally relevant. Then literature searches were performed to address these 13 questions. On closer scrutiny, 5 were excluded, as they were not considered to be special to bariatric surgery for T2DM with BMI < 35 kg/m<sup>2</sup>. Duplicates of moral issues or arguments were excluded. So were studies only mentioning ethical issues, but without any substantiation of these.

## 3. Results

232 articles and reports were identified. 68 articles were included in the analysis on the basis that they provided information on a series of moral issues related to the following questions Q1–8. Fig. 1 illustrates the results from the search strategy.

### 3.1. Q1. Is bariatric surgery a safe and effective means of treating T2DM?

Despite the overwhelming number of studies, it is argued that the evidence is of too poor a quality (Colquitt et al., 2009; Institute of Health Economics, 2011; Lautz et al., 2011; Picot et al., 2009; Pinkney & Kerrigan, 2004). Several meta-analyses of the effects of bariatric surgery have been excluded from systematic reviews and health technology assessments because they include only case series and studies of poor and mediocre quality (Colquitt et al., 2009; Institute of Health Economics, 2011). Although several studies have indicated that bariatric surgery is effective in the treatment of diabetes (Lee et al., 2011; Mingrone et al., 2012; Schauer et al., 2012) and can provide “complete disease remission” (Rubino, Moo, Rosen, Dakin, & Pomp, 2009), most studies are case series or retrospective cohort studies. Only a few randomized trials exist (Dixon et al., 2008; Ikramuddin et al., 2013; Keidar et al., 2013; Mingrone et al., 2012; Schauer et al., 2012), of which most are small and report short-term outcome (Colquitt et al., 2009; Institute of Health Economics, 2011; Lautz et al., 2011; Picot et al., 2009), particularly for patients with BMI < 35 kg/m<sup>2</sup>. A recent meta-analysis is based on a restricted number of small-scale short-term trials, with a substantial risk of publication bias (Li et al., 2012). In addition, few studies have included control groups which are offered an appropriate standardized intensive lifestyle intervention program (Hofso et al., 2010). High quality long-term studies on safety are lacking, so that studies on cost effectiveness provide uncertain results. Studies call attention to the risk of serious adverse events (Keidar et al., 2013). Accordingly, extrapolating results from bariatric surgery for patients with BMI ≥ 35 kg/m<sup>2</sup> to BMI < 35 kg/m<sup>2</sup> may not be warranted (Dixon et al., 2012). Moreover, the mechanisms by which gastrointestinal surgery may ameliorate T2DM, and whether they are independent of their effects on food intake and body weight, are still largely unknown (Lautz et al., 2011).

The lack of long-term high quality evidence for the effects of bariatric surgery on T2DM makes it difficult to answer the question of whether it is effective, safe and efficient, making decision-making demanding. It may well be morally commendable to treat individual overweight or obese patients with T2DM at centers that can document good results in long-term case series studies. However, whether bariatric surgery should be implemented and funded as a general method to treat T2DM for persons with BMI < 35 kg/m<sup>2</sup> is a difficult moral question. Therefore there is a moral imperative to provide high quality evidence on the efficacy, effectiveness, safety, and cost-effectiveness of bariatric surgery before wider access to this treatment strategy can be given (Hofmann, 2012).

### 3.2. Q2. What is the goal of the treatment?

Which endpoint to select, monitor, and report is a scientific question, but it is also a moral question, as the endpoints indicate the goal of the treatment, and what is considered to be a *good life*. A

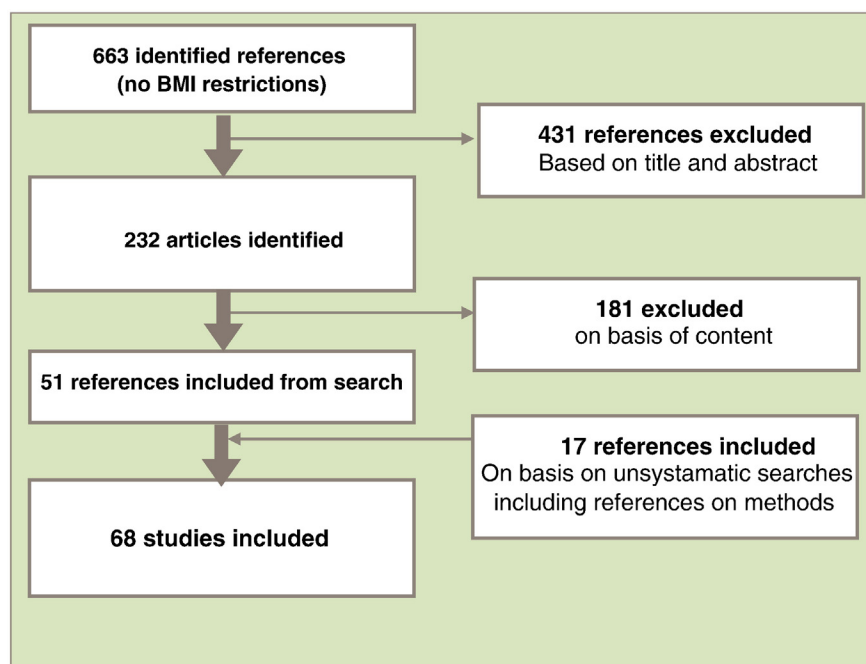


Fig.1. Results from literature search.

variety of endpoints are reported in studies of diabetes surgery: improvements in multiple metabolic measures (such as glucose tolerance, percent glycosylated hemoglobin, insulin sensitivity, beta-cell function), short-term reductions in the use of antidiabetic drugs, remission of T2DM, weight loss, cardiovascular events, and mortality (Buchwald et al., 2009; Dixon et al., 2008; Lautz et al., 2011; Pinkney et al., 2010). Other surrogate endpoints are changes in albuminuria, blood lipids, blood pressure, inflammation markers, and other cardiovascular risk factors (Lautz et al., 2011). Weight-loss might be an unreliable surrogate endpoint for improved glucose control in diabetes (Pinkney et al., 2010), for as surgery advocates argue, diabetes can be cured before weight loss after surgery (Rubino et al., 2009). How endpoints are defined is also important. The definition of remission of T2DM, for example, has important implications for the effect size (Buse et al., 2009; Pournaras et al., 2012).

Some studies have shown stable improvements in health-related quality of life (Tayyem, Ali, Atkinson, & Martin, 2011), while others have shown that initial mental health benefits tend to either dissipate after 3 years (Pinkney et al., 2010) or be closely related to long-term weight loss outcome (Karlsson, Taft, Rydén, Sjöström, & Sullivan, 2007). The same variety in goals exists for the monitoring of complications. The potential beneficial effects of surgery on T2DM might be offset by short and long-term complications. Clinically important long-term results after surgery, such as changes in levels of micronutrients, bone mineral density and fracture risk, microvascular and macrovascular complications, (Lautz et al., 2011), are largely unknown. Further, postprandial hypoglycemia ranging from moderate to severe, has been increasingly recognized after bariatric surgery (KE, 2011), particularly following gastric bypass. Symptomatic hypoglycemia requiring hospitalisation was nearly 3-fold higher among patients who had undergone gastric bypass than a matched control group from the general population (Marsk, Jonas, Rasmussen, & EN, 2010). A Norwegian study of 64 patients undergoing gastric bypass showed that 1 out of 4 had postchallenge hypoglycemia 1 year after the GB procedure (Hofsø et al., 2011). A morally relevant question is therefore whether this limited knowledge is due to a lack of complex research design, research funding, ignorance, or limited interest in such issues. The definition and selection of an appropriate endpoint are therefore both moral as well as professional issues, as is the selection of inclusion criteria.

Additionally, the question of *who* decides the endpoints is as morally important, as the endpoints express the goal of treatment and what is considered to be good and healthy. Patients should have a say in decisions on endpoints, especially when evidence is poor.

### 3.3. Q3. What are the interests of the stakeholders?

Both professionals and patients have strong and partly coinciding interests, and it is argued that there are professionals “who perform surgery for personal profit within a largely unregulated environment” (Pinkney et al., 2010). Conflicts of interest may arise as surgeons and scientists hold positions in or are paid by commercial companies providing products for bariatric surgery. Private for profit bariatric centers may let non-medical motives interfere with medical intentions. Moreover, enthusiasm sometimes exceeds evidence, and may compromise the search for high quality scientific evidence.

Differences in professional standards and preferences between funding systems, nations, and regions indicate that professional interests vary. E.g., gastric banding techniques dominate in Australia, while gastric bypass is frequently performed in the United States. The variability of procedures also appears to have substantial moral consequences. Learning and handling a large variety of procedures may expose patients to inferior quality treatment (Ballantyne et al., 2005). On the other hand, restricting the number of procedures may limit the possibility to adjust treatment to the individual patient.

Patients are active on the Internet and patient organizations may influence the medical industry (Jones, 2008; Oliver, 2006), although it is not obvious that it serves the best interest of the individual (and vulnerable) patient (Meier, 2009). Some diabetes associations have greeted bariatric surgery with caution (American Diabetes Association, 2010; International Diabetes Federation, 2011). Hence, stakeholder interests should be open and transparent to promote sound and accountable decisions.

### 3.4. Q4. Are there moral challenges connected to informed consent?

#### 3.4.1. Lack of knowledge to support information

As the evidence for the long-term effectiveness and safety of bariatric surgery for T2DM in patients with BMI <35 kg/m<sup>2</sup> is limited,

it is challenging to inform persons before surgery and to obtain a valid informed consent. Information pertaining to disease etiology, mechanisms and outcomes from various interventions is complex, even to specialists caring for patients undergoing bariatric treatment, and is difficult to communicate to patients (Pinkney et al., 2010). In particular, it is difficult to inform patients about the risk, side-effects and expected consequences, such as long-term nutritional, medical, and psychological consequences (Pinkney et al., 2010), e.g., micronutrient depletion requiring meticulous monitoring and lifelong replacement (Mechanick et al., 2008) or the need to balance freedom from insulin injections after gastric bypass surgery against the risks of alternative treatment (Pinkney et al., 2010). Health illiteracy and poor comprehension of the benefits and risks of surgery can result in unrealistic expectations and poor decision making (Wee et al., 2009) which challenge informed consent and result in potential litigation (Kaufman, McNelis, Slevin, & La Marca, 2006).

#### 3.4.2. Information or marketing?

Information disclosure terminology may become directive: terms like “diabetes surgery”, “diabetes cure”, “metabolic surgery”, “diabetes remission”, “resolution”, “quelling”, and “biochemical remission” (Buchwald et al., 2009; Goldfine, Shoelson, & Aguirre, 2009; Pinkney et al., 2010; Purnell & Flum, 2009; Rubino et al., 2010; Varela, 2011; Walton & Date, 2011) are not value neutral. Correspondingly, the scientific literature is full of claims that bariatric surgery has “dramatic effects” on diabetes, that it is a “success”, and is a “therapeutic tool” that “reverses the disease” (Rubino, 2008; Rubino et al., 2010). Failing to disclose that these claims are still controversial undermines valid consent. There is an important difference between informing patients that bariatric surgery is “diabetes treatment” to that it is a form of “enforced behavioral therapy” which can “require many years of psychiatric support in behaviour modification” (James & Morgan, 2010), where exact indications and contraindications to surgery are yet not defined (Rubino et al., 2010).

#### 3.4.3. Risk perception and lack of understanding

Studies show that patients undergoing bariatric surgery do not remember information on potential complications provided to them before surgery (Madan, Tichansky, & Taddeucci, 2007). Internet information on bariatric treatment is of variable content and quality (Nichols & Oermann, 2005). Some forms of bariatric surgery may change the life of the person substantially: eating habits and other daily life routines may be altered. Risk related to the surgeon's experience and the institution's procedural volume (Ballantyne et al., 2005), as well as surgeons' relationship with industry, is not always disclosed. Hence, to inform patients about bariatric surgery for T2DM in an adequate and balanced way seems to be at least as challenging as in other types of treatment (Sarwer et al., 2004).

#### 3.4.4. Lack of competence to consent

Additionally, a substantial proportion of bariatric surgery candidates have psychological/psychosocial co-morbidity (Roski, 2005; Sarwer et al., 2004) which may reduce the persons' decision making competence. Some studies have identified that as many as 50%–80% of candidates for bariatric surgery have psychiatric disorders (James & Morgan, 2010; Roski, 2005; Sarwer et al., 2004). Obtaining a valid informed consent prior to surgery may therefore be challenging due to a lack of information and understanding, reduced voluntariness, and diminished decision making capacity. Existing guidelines may be valuable for ascertaining valid informed consent (Wee et al., 2009).

#### 3.5. Q5. Does surgery alter the conception of diabetes or diabetic patients?

Surgery appears to change the conception of diabetes: “Whereas diabetes is traditionally viewed as a chronic, relentless disease in which delay of end-organ complications is the major treatment goal,

GI surgery offers a novel end point: the concept of complete disease remission” (Rubino et al., 2009). With bariatric surgery, T2DM has gone from the ingrained notion of being a medical (metabolic) chronic disease to become a “surgical disease” (Lautz et al., 2011), which can be resolved by “metabolic surgery” (Rubino, 2008; Rubino et al., 2010). T2DM is frequently referred to as a “lifestyle disease,” i.e., being a behavioral disease with low prestige and subject to stigma. It is often considered to be self-inflicted resulting from lack of self-control, and is, as such, subject to prejudice (Puhl & Heuer, 2009). Therefore, surgery may make T2DM more “biological,” enhance its prestige, and reduce prejudice, discrimination, and stigma.

On the other hand, bariatric surgery has been described as “surgically induced starvation by malabsorption or gastric restriction.” (Pinkney et al., 2010) with social and esthetical significance (James & Morgan, 2010). It may therefore be regarded as *a surgical solution to the medical implications of a social problem*. In this perspective bariatric surgery may support (or even enhance) the stigmatization of a vulnerable group of people.

The terms diabetes resolution or remission are often based on surgeons' clinical judgment and have seldom been precisely defined in the literature. Recently, however, a consensus statement was published suggesting that remission is defined as achieving glycaemia below the diabetic range in the absence of active pharmacologic (anti-hyperglycemic medications, immunosuppressive medications) or surgical therapy (ongoing procedures such as repeated replacements of endoluminal devices) (Buse et al., 2009). Partial remission is sub-diabetic hyperglycemia (A1C not diagnostic of diabetes [ $<6.5\%$ ], fasting glucose 100–125 mg/dl [5.6–6.9 mmol/l]) of at least 1 year's duration in the absence of active pharmacologic therapy or ongoing procedures. Complete remission is a return to “normal” measures of glucose metabolism (A1C in the normal range, fasting glucose  $<100$  mg/dl [5.6 mmol/l]) of at least 1 year's duration in the absence of active pharmacologic therapy or ongoing procedures (Buse et al., 2009).

Hence, bariatric surgery may change the biological and social conception of T2DM. When surgery enhances the biological aspect of T2DM, this is morally relevant and may avoid prejudice, stigmatization, and discrimination.

#### 3.6. Q6. Should there be limits to bariatric surgery for diabetes?

Where should limits be set with respect to patient BMI, age, family history of diabetes, duration, and severity of disease and risk profile? These are morally relevant questions which reach beyond the competence of scientists and surgeons. Other morally challenging questions are: should we use surgery for the prevention of T2DM in obese asymptomatic persons or to use it only after some other intervention has failed (diet, behavioural treatment, or drug regime) (Institute of Health Economics, 2011)? Should bariatric surgery be used for children and when can we use it for adolescents?

More knowledge may be obtained by high quality empirical studies with subgroup analyses. However, even with such knowledge available, there are no absolute limits in nature. Inclusion criteria and limits (of age, severity) are based on social aspects including moral norms and values. We set limits from what we believe can help people. Accordingly, such moral issues cannot be answered by professionals alone. Collaborations between patient organizations, professionals, and health care providers can elaborate guidelines to be used in individual deliberations in clinical practice.

#### 3.7. Q7. How does bariatric surgery affect the distribution of health care?

Bariatric surgery is costly, but it may save money on a societal level in several countries (Dixon, Zimmet, Alberti, & FR, 2011; Keating et al., 2009). There are substantial inequalities in the access to bariatric surgery (Socioeconomic disparities in eligibility & access to bariatric surgery: a national population-based analysis). In private health care



systems, only a small fraction of eligible persons are offered bariatric surgery for T2DM, and those who gain access to bariatric surgery are not always those who are most in need (Flum, Khan, & Dellinger, 2007; Purnell & Flum, 2009). Men, black and Hispanic individuals with low income are less likely to undergo bariatric surgery in the United States (Flum et al., 2007), where 85%–90% of operations are performed on white women with higher income levels (Flum et al., 2007).

In a publicly funded health care system, bariatric surgery for T2DM may drain resources from other health needs. Professionals fight for “their patients” sometimes ignoring other professionals’ and patients’ health problems. However, as T2DM is likely to afflict ethnic minorities and those of lower socio-economic status, bariatric surgery could reduce inequalities and discrimination.

There may be many reasons for the unjust distribution of bariatric surgery. Too strict inclusion criteria and guidelines, unbalanced advertisement, and discrimination of gender, fitness, age and ethnicity by the use of BMI are but three of these. Hence, the issue of justice is important when offering bariatric surgery for T2DM, and the solutions may vary with health care system.

### 3.8. Q8. Is it morally right to ask for further bariatric surgery studies?

As already indicated there is a request for more high quality studies (Colquitt et al., 2009; Institute of Health Economics, 2011). “There is currently little or no scientific or ethical justification for offering bariatric surgery to patients with a BMI < 35 kg/m<sup>2</sup> outside the context of a controlled clinical trial.” (Pinkney et al., 2010) On the other hand, is it right to conduct and wait for results from randomized controlled trials when existing studies are convincing, the “success” is “dramatic” and the operation is “strikingly safe” (Pinkney, 2010b; Rubino et al., 2010; Rubino et al., 2009)? Consensus statements argue that bariatric surgery should be offered to those with BMI ≥ 30 kg/m<sup>2</sup> and with T2DM inadequately controlled by lifestyle interventions and medication (Rubino et al., 2010).

As high quality randomized controlled trials are resource demanding and time consuming, there is a danger that many vulnerable patients will be deprived of a treatment which is documented to be effective by a large number of case series. On the other hand, it has been argued that most published (positive) research findings based on small short-term observational studies are false (Ioannidis, 2005). New methods are introduced into clinical practice before evidence is available (Ross et al., 2008) and there are double standards for evidence: “If surgery were a pill, it would be monitored much more carefully.” (Pinkney et al., 2010). Studies from centers with a homogeneous patient group (e.g. private centers) may lack external validity.

There is therefore a danger of putting a futile or even a detrimental treatment into clinical practice that later cannot be verified by randomized studies because this would be considered unethical (Hofmann, 2012). Limited understanding of the effects of bariatric surgery is therefore an ethical problem. History shows that we too often have been overly optimistic.

## 4. Discussion

We have identified several moral challenges related to bariatric surgery to T2DM for persons with BMI < 35 kg/m<sup>2</sup>. Some of the most prominent moral issues are how to: 1. assess the safety and outcome of bariatric surgery, 2. decide on proper endpoints, 3. obtain informed consent when information is complex or uncertain or when the competence is reduced, 4. handle strong stakeholder interests, 5. handle changes in conceptions of the disease and the patient group, 6 to set limits, 7. provide just distribution of health care, and 8. handle the lack of knowledge. These challenges seem to result from a lack of high quality evidence, from disagreement on clinical indications, from prejudice against persons with “lifestyle diseases,” but also from

trying to discipline human behavior through surgery. Moreover, several surgical procedures are available, and strong preferences among surgeons and patients may hamper high quality research. Although there are strong and opposing opinions on many of these issues, there is a large degree of consensus in the literature that these issues are morally challenging.

Though many morally relevant questions have been identified, the current study is not exhaustive, and other relevant questions remain: Should bariatric surgery be offered to adolescents with T2DM and BMI < 35 kg/m<sup>2</sup> or even children? What is the opportunity cost of bariatric surgery, and which health services will receive less attention if bariatric treatment receives more? Which surgical procedures should be recommended for which patient groups? How should the various values, interests and perspectives outlined here be balanced? How should we perform ethically sound research? These and other morally pertinent questions are beyond the scope of this study and its method, and should be addressed in the decision making context. The aim of this study has been to highlight the moral issues relevant for deliberations on bariatric surgery for T2DM so that informed advice and sound justifications can be given and accountable decisions can be made. Arguments have to be assessed, values weighted and alternatives appraised *in the context* of decision making.

Although the selection of questions and moral challenges posed in this study may not be value neutral (Hofmann, 2005a; Hofmann, 2005b), this review does not represent specific interests, such as patient interest groups, surgeons, industry, health insurers, health policy makers or HTA-agencies. Moreover, other than the selected moral questions (Q1–8) may be relevant. Of the 32 questions of the Socratic approach, only those which are reflected in the literature, or which are considered to be controversial by the stakeholders need to be addressed. Initially 13 questions were identified as morally relevant. The literature search did not reveal additional questions, which indicates that the initial selection was adequate. A second round of discussion eliminated 5 questions, as they were not considered to be special to bariatric surgery for T2DM with BMI < 35 kg/m<sup>2</sup>. Would other methods have achieved the goals of this study more effectively? Obviously other approaches to address ethical issues within and without a health technology assessment setting could have been applied. Nevertheless, the method applied here is well established for assessing health technologies and is able to highlight many of the challenges that are identified in the literature. It has also been applied previously to bariatric surgery (Hofmann, 2010).

How good are the sources reviewed in this study? Other sources of data could have been used, e.g., primary studies with interviews of eligible persons for bariatric treatment, their relatives, health care personnel, the health care industry, health insurers and health policy makers. However, primary research was beyond the scope of this review. Moreover, as high quality evidence is scarce, studies of inferior quality have been included in this review. This can of course result in bias in assessing safety, efficacy, effectiveness, and efficiency. However, these concerns are not that crucial to the review of other moral challenges and ethical arguments, as relevant challenges and important and sound arguments may occur in journals and publications of lower quality.

Are the moral challenges reviewed in this paper specific to bariatric surgery for T2DM with BMI < 35 kg/m<sup>2</sup>? No, but bariatric surgery is of particular interest, because it uses medical intervention to alter organs and processes that otherwise appear healthy, and because we do not know whether it addresses the causes of T2DM. T2DM is of specific interest, as it associated with lifestyle and human behavior. Bariatric surgery has been viewed as an “attempt to combat an excess of food by cutting out parts of their stomachs and intestines, and consider this a rational solution” (Pinkney et al., 2010). Surgery offers symptoms relief, prevents disease progression, but is still controversial in terms of whether it provides a cure or not (Pinkney, 2010a). Moreover, T2DM is often considered to be a self-inflicted

disease resulting from lack of self-control, and is, as such, subject to prejudice. Many of the moral challenges with BMI < 35 kg/m<sup>2</sup> are also relevant for BMI ≥ 35 kg/m<sup>2</sup>, but they are more outspoken for the first. Hence, bariatric surgery for T2DM poses moral challenges that are known from other fields of health care, but the combination of uncertain mechanisms, weak evidence, broad range of endpoints, complex and uncertain information to patients, as well as the mixture of behavior and biology is unique.

Again, many of the arguments presented in this study have to be assessed in detail when deciding on bariatric surgery in particular contexts. This review highlights the moral issues that are pertinent in the literature and that may be relevant in order to make transparent and sound decisions.

## 5. Conclusions

We have identified several important moral issues with bariatric surgery for T2DM for BMI < 35 kg/m<sup>2</sup>: assessing and informing about safety and patient outcomes, defining and selecting endpoints, assessing stakeholder interests, acquiring valid informed consent, stigmatization, discrimination and just distribution of health care. These moral challenges are important both on the individual (micro) level, on the management (meso) level, and on the health policy making (macro) level. Thus they are relevant for all who advise and treat persons with T2DM. Many of the identified challenges result from the lack of high quality evidence. More high quality evidence is therefore important to reduce the moral challenges and to make accountable decisions in diabetes care and in health policy making. In this review our calling has been “to ask questions, not to give answers”, to paraphrase the poet Henrik Ibsen.

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## References

- American Diabetes Association. (2010). Standards of medical care in diabetes. *Diabetes Care*, 33, S11.
- Ballantyne, G., Ewing, D., Capella, R., et al. (2005). The learning curve measured by operating times for laparoscopic and open gastric bypass: Roles of surgeon's experience, institutional experience, body mass index and fellowship training. *Obesity Surgery*, 15, 172–182.
- Buchwald, H., Estok, R., Fährbach, K., et al. (2009). Weight and type 2 diabetes after bariatric surgery: Systematic review and metaanalysis. *American Journal of Medicine*, 122, 248–256.
- Buse, J. B., Caprio, S., Cefalu, W. T., Ceriello, A., Del Prato, S., Inzucchi, S. E., McLaughlin, S., Phillips, G. L., 2nd, Robertson, R. P., Rubino, F., et al. (2009). How do we define cure of diabetes? *Diabetes Care*, 32(11), 2133–2135.
- Colquitt, J. L., Picot, J., Loveman, E., & Clegg, A. (2009). Surgery for obesity. *Cochrane Database of Systematic Reviews*, 2(Art. No.: CD003641), <http://dx.doi.org/10.1002/14651858.CD14003641.pub14651853>.
- Consensus Development Conference Panel. (1991). NIH conference. Gastrointestinal surgery for severe obesity. *Annals of Internal Medicine*, 115, 956–961.
- Danaei, G., Finucane, M. M., Lu, Y., Singh, G. M., Cowan, M. J., Paciorek, C. J., Lin, J. K., Farzadfar, F., Khang, Y. H., Stevens, G. A., et al. (2011). National, regional, and global trends in fasting plasma glucose and diabetes prevalence since 1980: Systematic analysis of health examination surveys and epidemiological studies with 370 country-years and 2.7 million participants. *Lancet*, 378(9785), 31–40.
- de Vries, J. (2007). The obesity epidemic: Medical and ethical considerations. *Science and Engineering Ethics*, 13(1), 55–67.
- Dixon, J. B., Chuang, L. M., Chong, K., Chen, S. C., Lambert, G. W., Straznicki, N. E., Lambert, E. A., & Lee, W. J. (2012). Predicting the glycemic response to gastric bypass surgery in patients with type 2 diabetes. *Diabetes Care*, 36(1), 20–26.
- Dixon, J., O'Brien, P., Playfair, J., et al. (2008). Adjustable gastric banding and conventional therapy for type 2 diabetes: A randomized controlled trial. *Journal of the American Medical Association*, 299, 316–323.
- Dixon, J., Pories, W., O'Brien, P., Schauer, P., & Zimmet, P. (2008). Surgery as an effective early intervention for diabetes. *Diabetes Care*, 28, 472–474.
- Dixon, J. B., Zimmet, P., Alberti, K. G., & FR (2011). Bariatric surgery: An IDF statement for obese type 2 diabetes. *Diabetic Med*, 28, 628–642.
- Droste, S., Dintios, C., & Gerber, A. (2010). Information on ethical issues in health technology assessment: How and where to find them. *International Journal of Technology Assessment in Health Care*, 26(4), 441–449.
- Flum, D. R., Khan, T. V., & Dellinger, E. P. (2007). Toward and rational and equitable use of bariatric surgery. *Journal of the American Medical Association*, 298, 1442–1444.
- Goldfine, A., Shoelson, S., & Aguirre, V. (2009). Expansion and contraction. *Nature Medicine*, 15(6), 616–617.
- Groven KS, Raheim M, Engelsrud G: “My quality of life is worse compared to my earlier life”: Living with chronic problems after weight loss surgery. *International Journal of Qualitative Studies on Health and Wellbeing*, 5: 5553.
- Hofmann, B. (2005a). Toward a procedure for integrating moral issues in health technology assessment. *International Journal of Health Technology Assessment*, 21(3), 312–318.
- Hofmann, B. (2005b). On value-judgements and ethics in health technology assessment. *Poiesis & Praxis: International Journal of Health Technology Assessment*, 3(4), 277–295.
- Hofmann, B. (2010). Stuck in the middle: The many moral challenges with bariatric surgery. *The American Journal of Bioethics*, 10(12), 3–11.
- Hofmann, B. (2012). Parachutes for diabetes: Bariatric surgery beyond evidence? *Diabetes Research and Clinical Practice*, 98(3), 406–407.
- Hofsø, D., Jenssen, T., Bollerslev, J., Ueland, T., Godang, K., Stumvoll, M., Sandbu, R., Røislien, J., & JH (2011). Beta cell function after gastric bypass surgery: A controlled clinical trial. *European journal of endocrinology/European Federation of Endocrine Societies*, 164(2), 231–238.
- Hofso, D., Nordstrand, N., Johnson, L. K., Karlsen, T. I., Hager, H., Jenssen, T., Bollerslev, J., Godang, K., Sandbu, R., Røislien, J., et al. (2010). Obesity-related cardiovascular risk factors after weight loss: A clinical trial comparing gastric bypass surgery and intensive lifestyle intervention. *European journal of endocrinology/European Federation of Endocrine Societies*, 163(5), 735–745.
- HTA core model for medical and surgical interventions v 1.
- Ikramuddin, S., Korner, J., Lee, W. J., Connett, J. E., Inabnet, W. B., Billington, C. J., Thomas, A. J., Leslie, D. B., Chong, K., Jeffery, R. W., et al. (2013). Roux-en-Y gastric bypass vs intensive medical management for the control of type 2 diabetes, hypertension, and hyperlipidemia: The Diabetes Surgery Study randomized clinical trial. *Journal of the American Medical Association*, 309(21), 2240–2249.
- Institute of Health Economics. (2011). Bariatric treatments for adult obesity. Edmonton, Canada: Institute of Health Economics.
- International Diabetes Federation. (2011). Bariatric surgical and procedural interventions in the treatment of obese patients with type 2 diabetes. A position statement from the International Diabetes Federation Taskforce on Epidemiology and Prevention. New York: International Diabetes Federation.
- Ioannidis, J. (2005). Why most published research findings are false. *PLoS Medicine*, 2(8), e124.
- James, R. J., & Morgan, J. F. (2010). Psychiatric needs must be considered. *BMJ*, 341, c5298.
- Jones, K. (2008). In whose interest? Relationships between health consumer groups and the pharmaceutical industry in the UK. *Sociology of Health & Illness*, 30, 929–943.
- Karlsson, J., Taft, C., Rydén, A., Sjöström, L., & Sullivan, M. (2007). Ten-year trends in health-related quality of life after surgical and conventional treatment for severe obesity: The SOS intervention study. *International Journal of Obesity*, 31, 1248–1261.
- Kaufman, A., McNeilis, J., Slevin, M., & La Marca, C. (2006). Bariatric surgery claims—a medico-legal perspective. *Obesity Surgery*, 16, 1555–1558.
- KE, F. -S. (2011). Hypoglycemia complicating bariatric surgery: Incidence and mechanisms. *Current Opinion in Endocrinology, Diabetes, and Obesity*, 18(2), 129–133.
- Keating, C. L., Dixon, J. B., Moodie, M. L., Peeters, A., Bulfone, L., Magliano, D. J., & PE, O. B. (2009). Cost-effectiveness of surgically induced weight loss for the management of type 2 diabetes: Modeled lifetime analysis. *Diabetes Care*, 32(4), 567–574.
- Keidar, A., Hershkop, K. J., Marko, L., Schweiger, C., Hecht, L., Bartov, N., Kedar, A., & Weiss, R. (2013). Roux-en-Y gastric bypass vs sleeve gastrectomy for obese patients with type 2 diabetes: A randomised trial. *Diabetologia*, 56(9), 1914–1918.
- Lautz, D., Halperin, F., Goebel-Fabbri, A., & Goldfine, A. B. (2011). The great debate: Medicine or surgery: What is best for the patient with type 2 diabetes? *Diabetes Care*, 34(3), 763–770.
- Lee, W. J., Chong, K., Ser, K. H., Lee, Y. C., Chen, S. C., Chen, J. C., Tsai, M. H., & Chuang, L. M. (2011). Gastric bypass vs sleeve gastrectomy for type 2 diabetes mellitus: A randomized controlled trial. *Archives of Surgery*, 146(2), 143–148.
- Li, Q., Chen, L., Yang, Z., Ye, Z., Huang, Y., He, M., Zhang, S., Feng, X., Gong, W., Zhang, Z., et al. (2012). Metabolic effects of bariatric surgery in type 2 diabetic patients with body mass index < 35 kg/m<sup>2</sup>. *Diabetes, Obesity & Metabolism*, 14(3), 262–270.
- MacDonald, K. J. (2003). Overview of the epidemiology of obesity and the early history of procedures to remedy morbid obesity. *Archives of Surgery*, 138, 357–360.
- Madan, A. K., Tichansky, D. S., & Taddeucci, R. J. (2007). Postoperative laparoscopic bariatric surgery patients do not remember potential complications. *Obesity Surgery*, 17(7), 885–888.
- Marck, R., Jonas, E., Rasmussen, F., & EN (2010). Nationwide cohort study of post-gastric bypass hypoglycaemia including 5,040 patients undergoing surgery for obesity in 1986–2006 in Sweden. *Diabetologia*, 53, 2307–2311.
- Mechanic, J., Kushner, R., Sugerman, H., et al. (2008). American Association of Clinical Endocrinologists, The Obesity Society and American Society for Metabolic & Bariatric Surgery medical guidelines for clinical practice for perioperative nutritional, metabolic and nonsurgical support of the bariatric surgery patient. *Endocrine Practice*, 14(Suppl 1), 1–83.
- Meier, B. (2009). *Diabetes case shows pitfalls of treatment rules*. New York: New York Times.

- Mingrone, G., Panunzi, S., De Gaetano, A., Guidone, C., Iaconelli, A., Leccesi, L., Nanni, G., Pomp, A., Castagneto, M., Ghirlanda, G., et al. (2012). Bariatric surgery versus conventional medical therapy for type 2 diabetes. *The New England Journal of Medicine*, 366(17), 1577–1585.
- Nichols, C., & Oermann, M. H. (2005). An evaluation of bariatric web sites for patient education and guidance. *Gastroenterology Nursing*, 28(2), 112–117.
- Oliver, J. E. (2006). The politics of pathology: How obesity became an epidemic disease. *Perspectives in Biology and Medicine*, 49(4), 611–627.
- Picot, J., Jones, J., Colquitt, J. L., Gospodarevskaya, E., Loveman, E., Baxter, L., & Clegg, A. (2009). The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: A systematic review and economic evaluation. *Health Technology Assessment*, 13(41).
- Pinkney, J. (2010a). Big questions remain unanswered. *BMJ*, 341, c5304.
- Pinkney, J. (2010b). Bariatric surgery for diabetes: Gastric banding is simple and safe. *The British Journal of Diabetes & Vascular Disease*, 10, 139–142.
- Pinkney, J., Johnson, A., & Gale, E. (2010). The big fat bariatric surgery bandwagon. *Diabetologia*, 53, 1815–1822.
- Pinkney, J., & Kerrigan, D. (2004). Review: When should bariatric surgery be used in the treatment of type 2 diabetes? *British Journal of Diabetes & Vascular Disease*, 4(4), 232–237.
- Pournaras, D., Aasheim, E., Søvik, T., Andrews, R., Mahon, D., Welbourn, R., Olbers, T., & le Roux, C. (2012). Effect of the definition of type II diabetes remission in the evaluation of bariatric surgery for metabolic disorders. *British Journal of Surgery*, 99(1), 100–103.
- Puhl, R. M., & Heuer, C. A. (2009). The stigma of obesity: A review and update. *Obesity*, 17(5), 941–964.
- Purnell, J. Q., & Flum, D. R. (2009). Bariatric surgery and diabetes: Who should be offered the option of remission? *Journal of the American Medical Association*, 301(15), 1593–1595.
- Roski, C. H. (2005). Psychiatric symptoms among prospective bariatric surgery patients: Rates of prevalence and their relation to social desirability, pursuit of surgery, and follow-up attendance. *Obesity Surgery*, 15, 677–683.
- Ross, S., Robert, M., Harvey, M., Farrell, S., Schulz, J., Wilkie, D., Lovatsis, D., Epp, A., Easton, B., McMillan, B., et al. (2008). Ethical issues associated with the introduction of new surgical devices, or just because we can, doesn't mean we should. *Journal of Obstetrics and Gynaecology Canada*, 30(6), 508–513.
- Rubino, F. (2008). Is type 2 diabetes an operable intestinal disease? A provocative yet reasonable hypothesis. *Diabetes Care*, 31(Suppl 2), S290–S296.
- Rubino, F., Kaplan, L., Schauer, P., Cummings, D., & Delegates, D. S. S. (2010). The Diabetes Surgery Summit consensus conference: Recommendations for the evaluation and use of gastrointestinal surgery to treat type 2 diabetes mellitus. *Annals of Surgery*, 251(3), 399–405.
- Rubino, F., Moo, T., Rosen, D., Dakin, G., & Pomp, A. (2009). Diabetes surgery: A new approach to an old disease. *Diabetes Care*, 32(Suppl 2), S368–S372.
- Sarwer, D. B., Cohn, N. I., Gibbons, L. M., Magee, L., Crerand, C. E., Raper, S. E., Rosato, E. F., Williams, N. N., & Wadden, T. A. (2004). Psychiatric diagnoses and psychiatric treatment among bariatric surgery candidates. *Obesity Surgery*, 14, 1148–1156.
- Schauer, P. R., Kashyap, S. R., Wolski, K., Brethauer, S. A., Kirwan, J. P., Pothier, C. E., Thomas, S., Aboud, B., Nissen, S. E., & Bhatt, D. L. (2012). Bariatric surgery versus intensive medical therapy in obese patients with diabetes. *The New England Journal of Medicine*, 366(17), 1567–1576.
- Socioeconomic disparities in eligibility and access to bariatric surgery: A national population-based analysis.
- Spanou, M. K. T. (2013). Bariatric surgery as a treatment option in patients with type 2 diabetes mellitus. *World J Diabetes*, 4(2), 14–18.
- Tayyem, R., Ali, A., Atkinson, J., & Martin, C. R. (2011). Analysis of health-related quality-of-life instruments measuring the impact of bariatric surgery: Systematic review of the instruments used and their content validity. *The patient*, 4(2), 73–87.
- UN General Assembly. (2006). Resolution on diabetes. Wien: United Nation.
- Varela, J. E. (2011). Bariatric surgery: A cure for diabetes? *Current Opinion in Clinical Nutrition and Metabolic Care*, 14(4), 396–401.
- Walton, S. J., & Date, R. S. (2011). Surgical cure for type II diabetes: Myth or reality? *Annals of Surgery*, 254(1), 180–181.
- Wee, C. W., Pratt, J. S., Fanelli, R., Samour, P. Q., Trainer, L. S., & Paasche-Orlow, M. K. (2009). Updates for informed consent and patient education in weight loss surgery. *Obesity*, 17, 885–888.
- World Health Organization. (2006). World Health Organization fact sheet number 312. : World Health Organization.