



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

Bjørn Hofmann ^{a,b,*}, Jøran Hjelmesæth ^{c,d}, Torgeir Thorson Søvik ^e

^a Department of Health, Technology and Society, University College of Gjøvik, Norway

^b Center for Medical Ethics, University of Oslo, Norway

^c Morbid Obesity Center, Vestfold Hospital Trust, Norway

^d Institute of Clinical Medicine, University of Oslo, Norway

^e Department of Gastrointestinal Surgery, Oslo University Hospital Ullevål, Oslo, Norway

ARTICLE INFO

Article history:

Received 11 April 2013

Received in revised form 29 July 2013

Accepted 29 July 2013

Available online 9 September 2013

Keywords:

Ethics

Evidence

Informed consent

Discrimination

Justice

Risk

Harm

Moral

Bariatric surgery

Type 2 diabetes

Obesity

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/m², 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/m² 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.

© 2013 The Authors. Published by Elsevier Inc. All rights reserved.

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/m² (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/m² (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/m² to those with BMI < 35 kg/m² (Dixon et al., 2012). The long-term effects on glucose control and surrogate endpoints such as albuminuria, lipid

☆ This is an open-access article distributed under the terms of the Creative Commons Attribution-NonCommercial-No Derivative Works License, which permits non-commercial use, distribution, and reproduction in any medium, provided the original author and source are credited.

☆☆ Conflicts of interest: One of the authors (JH) heads a public obesity resource center in Norway, and one of the authors (TS) is a surgeon with experience from bariatric surgery. BH has no conflict of interest to declare. Bjørn Hofmann is the guarantor of this work and takes full responsibility for the work as a whole, including the study design, access to data, and the decision to submit and publish the manuscript.

* Corresponding author. Center for Medical Ethics, Faculty of Medicine, PO box 1130, N-0318 Oslo, Norway. Tel.: +47 22 84 46 45.

E-mail address: b.m.hofmann@medisin.uio.no (B. Hofmann).

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/m² (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/m² 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/m², 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/m² 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/m². 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/m². 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/m² to BMI < 35 kg/m² 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/m² 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

Download English Version:

<https://daneshyari.com/en/article/5902755>

Download Persian Version:

<https://daneshyari.com/article/5902755>

[Daneshyari.com](https://daneshyari.com)