

Cost analysis of bariatric surgery in Denmark made with a decision-analytic model

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ABSTRACT

INTRODUCTION: Bariatric surgery offers effective obesity treatment. The aim of this study was to evaluate the cost-effectiveness of bariatric surgery in Denmark from a third-party payer perspective in the mid- (ten years) and long-term (lifetime).

METHODS: A state-transition Markov model was developed in which patients may experience surgery, post-surgery complications, diabetes mellitus type 2, cardiovascular diseases or die. Transition probabilities, costs and utilities were informed by the literature. Three types of surgery were included: gastric bypass, sleeve gastrectomy and adjustable gastric banding. The impact of different surgical methods on BMI level was informed by the Danish Obesity Surgery Registry (Dansk Fedmekirurgiregister).

RESULTS: In the ten-year base-case analysis, bariatric surgery led to a cost increment of 19,332 DKK and generated an additional 1.1 quality-adjusted life years (QALYs). In the course of a lifetime, surgery leads to savings of 36,403 DKK, an additional 0.7 life years and 2.9 QALYs. Bariatric surgery was cost-effective at ten years with an incremental cost-effectiveness ratio of 17,818 DKK per QALY and was dominant over conservative management in the course of a lifetime. Up to three years of delay in the provision of surgery resulted in a reduction of life years, a lower QALY gain and a minor decrease in healthcare costs.

CONCLUSIONS: In Denmark, bariatric surgery is cost-effective at ten years and may produce a significant reduction in healthcare costs over the course of a lifetime in persons with severe obesity.

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TRIAL REGISTRATION: not relevant.

Obesity is a serious disorder and a risk factor for diabetes, cardiovascular and musculoskeletal diseases, gynaecological problems and cancer. Compared with having a normal weight, extreme obesity with a BMI in the 40-59 kg/m² range is associated with an estimated loss of 6.5-13.7 years of life. When conservative obesity treatment methods (drugs, diet and exercise) fail, bariatric surgery remains the only effective weight reduction method.

Evaluation of the economic and clinical impact of bariatric surgery is essential for appropriate resource al-

location and informed decision making. However, to our knowledge within the Danish setting, no economic evaluations of bariatric surgery have been published. The objective of this study was to evaluate the cost-effectiveness of bariatric surgery in Denmark from a third-party payer perspective in the mid (ten years) and long term (lifetime).

METHODS

A state-transition decision analytic Markov model [1] was used to evaluate the cost-effectiveness of bariatric surgery compared with optimal medical treatment. Full details of the modeling approach, data input and validation activities are reported elsewhere [2]. In brief, obese patients may undergo surgery or continue optimal medical management, experience post-surgery complications or have no complications, develop type 2 diabetes mellitus (T2DM) or cardiovascular diseases (angina, myocardial infarction, stroke, heart failure and peripheral artery disease), recover from T2DM or die (**Figure 1**). During each cycle, lasting one month, patients may progress from one state to another or remain in the previous state. The risk of obesity complications in the model depend on age, gender, smoking status, BMI level, the level of systolic blood pressure (SBP) and the presence of T2DM. Bariatric surgery, by reduction of BMI and SBP, and reduction of the prevalence of T2DM, leads to a decrease in the risk of obesity complications and mortality. By modelling the risk in the surgery arm and a hypothetical cohort of patients who do not undergo surgical weight reduction, it is possible to quantify the impact of the surgery on the rate of long-term negative events. Gender-specific Danish life tables provided information about mortality in the general population; non-ischaemic heart disease mortality in a normal population was calculated by subtraction of mortality due to ischaemic heart disease from all-cause mortality. The presence of one of the cardiovascular events or diabetes influences the risk of having associated conditions (e.g. risk of stroke is higher in patients who have heart failure) and mortality, which was informed by information from a number of epidemiological studies.

Three surgical techniques commonly used in Denmark were included in the analysis: gastric bypass (GBP), sleeve gastrectomy (SG) and adjustable gastric

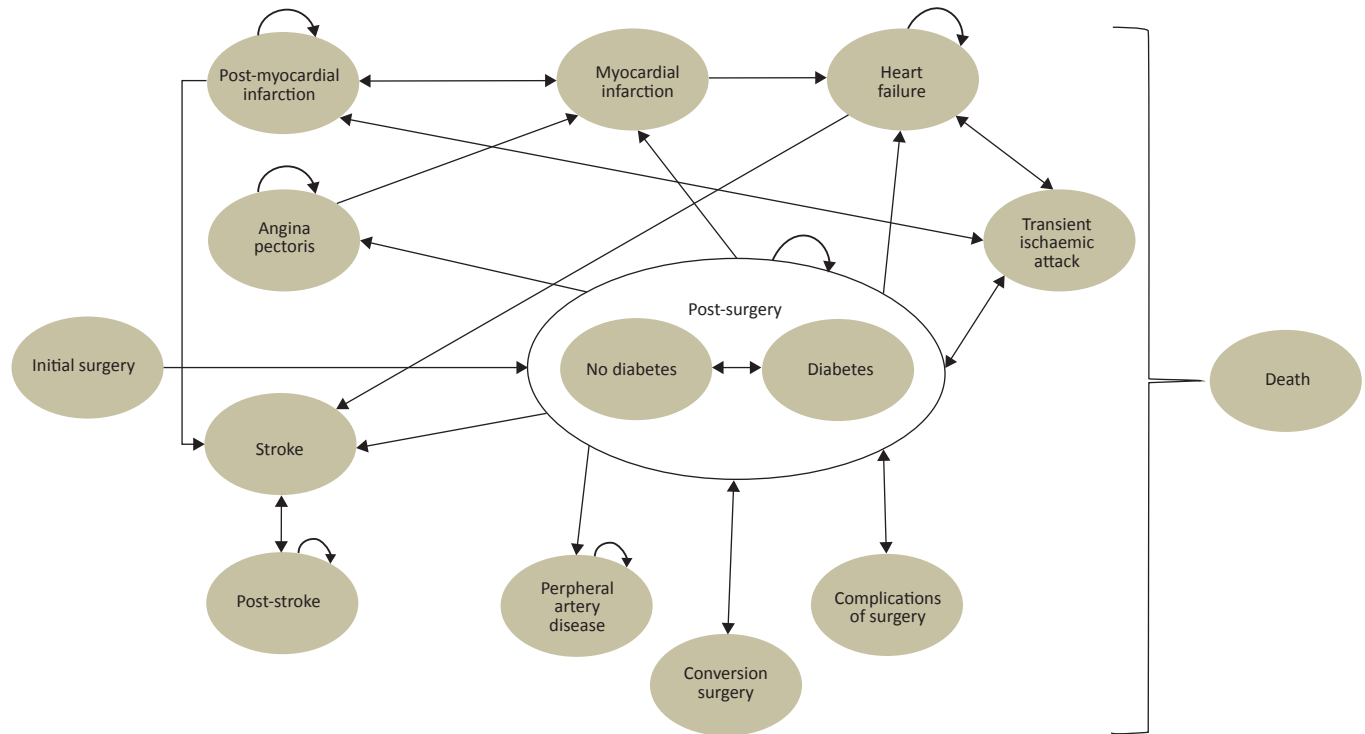
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FIGURE 1

Structure of the model [2].



banding (AGB). The impact of different surgical methods on the BMI level in the base-case analysis was informed by information from the Danish Obesity Surgery Registry [3]. After the latest observation at one year, the impact on BMI was extrapolated using BMI change data from the SOS study [4]. After 15 years, the BMI level was assumed to be stable for the rest of the patient's life. Change of BMI in the optimal medical management arm was informed by information about the change of BMI in the control arm of the SOS study [4]. Change in SBP was derived from the SOS study for non-diabetics [5] and from the study by Ikramuddin et al [6] for diabetic patients. For analysis in different individual cohorts of patients, BMI change was informed by individual studies. Where the standard deviation was not reported, it was obtained from Nguyen et al [7]. Clinical input is presented in **Table 1**.

Input data

Clinical effectiveness and safety data

The model operates with the prediction of risk of cardiovascular events, T2DM, surgery complications and mortality in the general population. The risk of cardiovascular events in the model is predicted by the patient-related prognostic characteristics: age, gender, SBP,

BMI, the presence of diabetes and smoking status. The risk equation from the Framingham Heart Study was used to determine the ten-year risk of cardiovascular events, which was re-stratified into monthly risk [8, 9]. Diabetes incidence was BMI-related and was determined by polynomial regression as reported by Picot et al [10] and based on estimates from Colditz et al [11]. Remission of diabetes was informed by two- and ten-year data from the Swedish Obesity Subjects study [5]. The risk of short-term (30-day) mortality and severe adverse events in the base-case analysis was informed by information from the Danish Obesity Surgery Registry [3]. Scandinavian Obesity Surgery Registry 2011 data were used to estimate the two-year risk of complications of surgery (cholecystectomy, abdominal hernia repair, leakage and abscess, gastric stricture and gastric ulcer) [12]. The rate of conversion surgery was obtained from a controlled study about gastric bypass and adjustable gastric banding with 4.2 and 3.6 years of follow-up, respectively [7]. The conversion probability for sleeve gastrectomy was assumed to be equal to the probability for gastric bypass.

Resource utilization and cost data

Cost data were obtained from Danish sources, except



TABLE 1

Clinical and cost inputs.

	Value	Range, 1-way sensitivity analysis	Distribution, probabilistic sensitivity analysis	Reference
<i>Patients' baseline characteristics</i>				
Age, yrs	40	22-57	Normal SD: ± 4.5	Danish Obesity Surgery Registry, Annual Report 2010 [15]
Gender, males, %	22.6	–	Beta	Danish Obesity Surgery Registry, Annual Report 2010 [15]
BMI, kg/m ²	42	20-68	Normal SD: ± 7	Danish Obesity Surgery Registry, Annual Report 2015 [3]
Diabetes mellitus, %	23.2	–	Beta	Danish Obesity Surgery Registry, Annual Report 2015 [3]
Systolic blood pressure, mmHg	140	89-201	Gamma: $\alpha = 100$; $\lambda = 1.4$	Sjöström et al, 2004 [5]
Smoking, %	18.5	–	Beta	Danish Obesity Surgery Registry, Annual Report 2015 [3]
<i>Absolute BMI reduction from Danish Obesity Surgery Registry, Annual Report 2015 [3]</i>				
GBP:				
1 mo.	2.2	–	–	–
3 mo.s	6.9	–	–	–
6 mo.s	9.0	–	–	–
1 yr	11.5	–	–	–
SG:				
1 mo.	1.0	–	–	–
3 mo.s	9.2	–	–	–
6 mo.s	7.9	–	–	–
1 yr	11	–	–	–
AGB:				
1 mo.	0.6	–	–	–
3 mo.s	+0.1	–	–	–
6 mo.s	4.6	–	–	–
1 yr	3.5	–	–	–
<i>Cost input</i>				
GBP:				
Without complications	42,715	34,172-51,258	–	Danish Interactive DRG (1004)
With complications	42,715	34,172-51,258	–	
SG:				
Without complications	36,931	29,544.8-44,317.2	–	Danish Interactive DRG (2601)
With complications	36,931	29,544.8-44,317.2	–	
AGB:				
Without complications	42,715	34,172-51,258	–	Danish Interactive DRG (1004)
With complications	42,715	34,172-51,258	–	
Removal/revision without complications	36,931	29,544.8-44,317.2	–	Danish Interactive DRG (2601)
Abdominal hernia procedure	30,376	24,300.8-36,451.2	–	Danish Interactive DRG (0624)
Cholecystectomy	23,443	18,754.4-28,131.6	–	Danish Interactive DRG (0708)
Leakage and abscess	41,173	32,938.4-49,407.6	–	Danish Interactive DRG (0631)
Obstruction	45,276	36,220.8-54,331.2	–	Danish Interactive DRG (0614)
Stricture	45,276	36,220.8-54,331.2	–	Danish Interactive DRG (0614)
Gastric ulcer	122	97.6-146.4	–	www.medstat.dk: 8-week course of 40 mg omeprazol
Diabetes type 2	15,427	12,341.6-18,512.4	Gamma: $\alpha = 100$; $\lambda = 154.27$	Danish Centre for Evaluation and Health Technology Assessment, 2005
Acute stroke	85,090	68,072-102,108	Gamma: $\alpha = 100$; $\lambda = 850.90$	Danish Interactive DRG (0114)
Post-stroke 1 yr	204,961	163,968.8-245,953.2	Gamma: $\alpha = 100$; $\lambda = 2,049.61$	Porsdal, 1999
Acute TIA	18,069	14,455.2-21,682.8	Gamma: $\alpha = 100$; $\lambda = 180.69$	Danish Interactive DRG (0124)
Acute AMI	40,428	32,342.4-48,513.6	Gamma: $\alpha = 100$; $\lambda = 404.28$	Tiemann, 2008
Post-MI state	6,003	4,802.4-7,203.6	Gamma: $\alpha = 100$; $\lambda = 60.03$	Lindgren 2007
Heart failure	51,473	41,178.4-61,767.6	Gamma: $\alpha = 100$; $\lambda = 514.73$	Blomström, 2008
PAD	40,328	32,262.4-48,393.6	Gamma: $\alpha = 100$; $\lambda = 403.28$	Levy, 2003
Angina	51,500	41,200-61,800	Gamma: $\alpha = 100$; $\lambda = 515.00$	Ballegaard, 2004

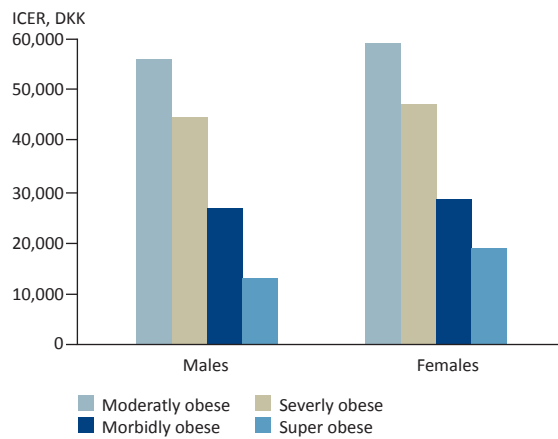
AGB = adjustable gastric banding; AMI = acute myocardial infarction; DRG = diagnosis-related groups; GBP = gastric bypass; MI = myocardial infarction; PAD = peripheral arterial disease; SD = standard deviation; SG = sleeve gastrectomy; TIA = transient ischaemic attack.

the cost of peripheral arterial disease (PAD), which was not available in Denmark: therefore, a value from a

Swedish study was used. Only direct medical costs were included in the analysis.

FIGURE 2

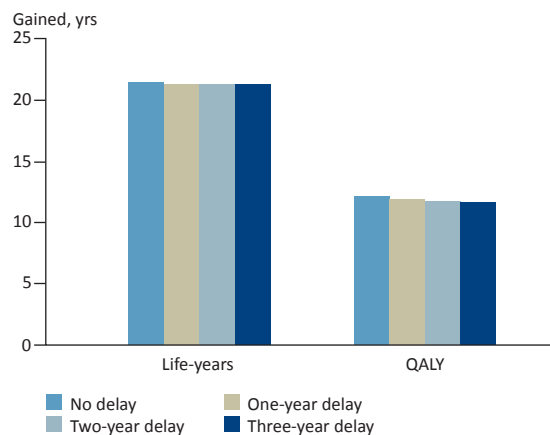
Incremental cost-effectiveness ratio estimates for different cohorts of non-diabetic patients.



ICER = incremental cost-effectiveness ratio.

FIGURE 3

Life-years and quality-adjusted life years (QALY) gained by performing surgery immediately and with a delay up to three years, respectively.



The cost of the bariatric surgery procedure with or without complications was informed by Danish diagnosis-related groups (DRG) data from 2012 (DRG 1004 for GBP and AGB, and DRG 2601 for SG). Post-surgical care utilization was informed by expert opinion and a study by Picot [10]. The model accounted for two follow-up visits to the surgeon in the first post-operation year and single visits to the surgeon and out-patient physician in the second year. It was assumed that surgery candidates who do not undergo surgery do not consume any resources in relation to the management of obesity.

The number of surgical procedures, as well as the prevalence of different surgical methods (GBP: 68.8%, SG: 31%, AGB: 0.2%), was obtained from the annual report (2015) published by the Danish Obesity Surgery Registry [3]. The costs of the end-stage organ damage

health states were extracted from the Danish sources (except for the cost of PAD). Cost data are presented in 2012 DKK (Table 1). Inflation adjustment was performed using the Danish Consumer Price Index.

Utility data

Health-related quality of life was dependent on BMI and presence of diabetes [13]. In addition, the disutility of having cardiovascular disease was informed by data from UK adaptations of the US Medical Expenditure Panel Survey EQ-5D mapping study [14].

Cohort description

First, the base-case (primary) analysis included summary characteristics of real candidates for bariatric surgery in Denmark. Characteristics of the cohort were extracted from the Annual Reports (years 2010 and 2015) of the Danish Obesity Surgery Registry [3, 15] and SOS study [5] (Table 1). This analysis was performed for a cohort of 40-year-old patients, 22.6% of whom were males, with a mean BMI of 42 kg/m², a mean SBP of 140 mmHg, a prevalence of T2DM of 26% and a prevalence of smokers of 18.5%. Second, cost-effectiveness of bariatric surgery was calculated for 16 cohorts of 40-year-old non-smoking males and females with moderate (start BMI: 33 kg/m²), severe (start BMI: 37 kg/m²), morbid (start BMI: 42 kg/m²) and super obesity (start BMI: 52 kg/m²) with and without presence of T2DM.

Analysis

The present analysis was performed from a third-party payer perspective over ten years and a lifetime horizon. All costs and outcomes beyond the first year were discounted by 3.0% annually according to the Danish pharmacoeconomic recommendations. Surgery was considered cost-effective if the incremental cost-effectiveness ratio (ICER, which is calculated by dividing the difference in cost between the two arms by the difference in quality-adjusted life years (QALYs)) was below the societal willingness-to-pay threshold of 223,000 DKK per QALYs. In Denmark, there is no officially accepted and recognized willingness-to-pay threshold. Current practice suggests that the cost-effectiveness threshold might lie between 223,000 and 250,000 DKK per QALY, as in two recent studies [16, 17] in the field of diabetes and CVD, thresholds of 250,000 DKK and 223,000 DKK per QALY were applied. Another option would be to value each QALY by 1-3 times the local gross domestic product per capita as recommended by the World Health Organization [18], which exceeds estimates in Danish publications. The lowest reported willingness to pay a threshold of 223,000 DKK per QALY was used in the analysis. The model was constructed using Microsoft Excel 2013 (Microsoft Corp., Redmond, Washington,

USA). In addition to standard evaluation of cost-effectiveness between two technologies, we analysed the impact of delay in surgery provision on clinical and economic outcomes in non-diabetic patients. Patients were initially managed in the optimal medical management arm, with a move to the surgical arm after one, two and three years. Results were compared with the analysis in which patients receive surgery immediately. Clinical effectiveness was evaluated by analysing the cumulative rates of adverse events and the relative risk of adverse events in the course of a ten-year-period and a lifetime.

The model underwent an extensive three-step validation process. Details are reported elsewhere [2].

Trial registration: not relevant.

RESULTS

In the base-case analysis at ten years, bariatric surgery increased the cost compared with optimal medical management by 19,332 DKK and generated an additional 1.1 QALYs, resulting in an incremental cost-effectiveness ratio of 17,818 DKK. In the base-case analysis over the lifetime of patients' cohort, bariatric surgery produced cost savings of 36,403 DKK and generated an additional 0.7 years of life and 2.9 QALYs. Surgery was superior to conservative management by being a more effective and less expensive treatment strategy. Also, surgery showed potential to significantly reduce the risk of obesity-related conditions at ten years and in the course of a lifetime as follows: angina (relative risk (RR) = 0.71 and RR = 0.85; respectively), non-fatal myocardial infarction (RR = 0.71; RR = 0.83), fatal myocardial infarction (RR = 0.63; RR = 0.75), non-fatal stroke (RR = 0.72; RR = 0.82), fatal stroke (RR = 0.72; RR = 0.82), transient ischaemic attack (RR = 0.72; RR = 0.87), heart failure (RR = 0.72; RR = 0.84), PAD (RR = 0.72; RR = 0.86) and diabetes (RR = 0.46; RR = 0.61).

The analysis in specific cohorts over ten years revealed that bariatric surgery was cost saving in all of the eight considered diabetic cohorts (moderately, severely, morbidly and super obese males and females). In non-diabetic cohorts, surgery was cost-effective in all cohorts, namely in moderately obese males (ICER 55,615 DKK per QALY) and females (ICER 58,838 DKK per QALY), severely obese males (ICER 44,543 DKK per QALY) and females (ICER 47,168 DKK per QALY), morbidly obese males (ICER 26,708 DKK per QALY) and females (ICER 28,435 DKK per QALY), and super obese males (ICER 12,952 DKK per QALY) and females (ICER 13,872 DKK per QALY). The cost-effectiveness of surgery increased with the increase of baseline BMI level of the cohort (Figure 2).

The analysis in specific cohorts over the course of a lifetime revealed that bariatric surgery is cost saving in

all eight considered diabetic cohorts. In non-diabetic cohorts, surgery was cost saving in all cohorts, except for moderately obese males (ICER 7,253 DKK per QALY) and females (ICER 3,488 DKK per QALY), as well as severely obese males (ICER 3,090 DKK per QALY).

Analysis of the consequences of different timing of surgery revealed that losses of clinical benefits might be observed with a delay of up to three years. Differences of 0.1 life-years and 0.4 QALYs were shown between the performance of the immediate operation and a three-year delay (Figure 3). Additionally, the cost of delayed provision of surgery was associated with a minor decrease in lifetime costs. The cost of the surgery over the course of a lifetime accounted for 197,123 DKK with the immediate operation, 195,336 DKK with a one-year delay, 194,199 DKK with two-year delay and 195,598 DKK with a three-year delay.

DISCUSSION

Our study evaluated potential long-term clinical and economic consequences of bariatric surgery in Denmark. To the best of our knowledge, this is the first published Danish cost-effectiveness analysis of bariatric surgery.

Global evidence suggests different estimates of the cost-effectiveness of bariatric surgery, depending on the country context, severity of obesity status and type of operation. The results indicate that bariatric surgery can be either a cost-saving or a cost-effective alternative to conventional methods for obesity management; e.g. in Germany [19] a lifetime (20-year) horizon, bariatric surgery was found to produce extra costs of 921 € and yield less clinical benefits (2.55 QALY). On the contrary, an analysis conducted in a Finnish setting [20] showed that within a ten-year horizon, bariatric surgery can be more effective and less costly than ordinary treatment and yields 0.58 incremental QALYs. Finally, in Sweden [2] over the course of a lifetime, bariatric surgery was associated with savings of 8,408 € and generated an additional 0.8 years of life and 4.1 QALYs per patient.

The study has a number of limitations, which were discussed elsewhere [2]. In brief, the analysis did not include all potential obesity-related complications and potentially underestimated cost benefits from the surgery. The model did not distinguish outcomes of the surgery for different populations of diabetic patients, which could affect the overall effectiveness of the therapy. Furthermore, the data on management of the patients after surgery or surgical candidates who do not receive surgery was based on assumptions.

The results of our analysis, which include a mix of currently used surgical techniques in Denmark, indicate that bariatric surgery is cost-effective in the mid-term and can save healthcare costs over a longer time horizon. If the demonstrated lifetime clinical and economic

benefits were extrapolated to the cohort that received surgery during the year 2015 in Denmark [3] (n = 580), it would produce savings of about 21 M DKK and generate an additional 410 person-years or 1,694 person-quality-adjusted years over the lifetime of the operated cohort. Furthermore, a cost saving effect was also demonstrated over a lifetime for all patients except for non-diabetic moderately obese males and females, and severely obese males.

The results of our study indicate that bariatric surgery is cost-effective (mid-term) and cost saving (over the course of a lifetime). Surgery is also associated with significant clinical benefits.

CONCLUSIONS

In a comprehensive decision-analytic model, the current mix of surgical methods for bariatric surgery was cost-effective at ten years and cost saving over the course of a lifetime in the cohort operated in Denmark.

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