Obesity Facts
The European Journal of Obesity

Obes Facts 2017;10:261–272
DOI: 10.1159/000475842
Received: September 28, 2016
Accepted: April 13, 2017
Published online: June 10, 2017

Original Article

Cost-Utility Analysis of Bariatric Surgery in Italy: Results of Decision-Analytic Modelling

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Keywords

Bariatric surgery · Cost-Benefit analysis · Italy

Abstract

Objective: To evaluate the cost-effectiveness of bariatric surgery in Italy from a third-party payer perspective over a medium-term (10 years) and a long-term (lifetime) horizon. ***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 obtained from the Italian and international literature. Three types of surgeries were considered: gastric bypass, sleeve gastrectomy, and adjustable gastric banding. A base-case analysis was performed for the population, the characteristics of which were obtained from surgery candidates in Italy. ***Results:*** In the base-case analysis, over 10 years, bariatric surgery led to cost increment of EUR 2,661 and generated additional 1.1 quality-adjusted life years (QALYs). Over a lifetime, surgery led to savings of EUR 8,649, additional 0.5 life years and 3.2 QALYs. Bariatric surgery was cost-effective at 10 years with an incremental cost-effectiveness ratio of EUR 2,412/QALY and dominant over conservative management over a lifetime. ***Conclusion:*** In a comprehensive decision analytic model, a current mix of surgical methods for bariatric surgery was cost-effective at 10 years and cost-saving over the lifetime of the Italian patient cohort considered in this analysis.

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Obes Facts 2017;10:261–272
DOI: 10.1159/000475842

Introduction

Obesity is a serious disease and a risk factor for diabetes [1, 2], cardiovascular [3–5] and musculoskeletal diseases [6], gynecological problems [7, 8], and cancer [9]. When conservative methods of treatment for obesity fail, bariatric surgery remains the only effective method of weight loss.

Indications for bariatric surgery in Italy include BMI of more than 40 kg/m^2 or BMI of 35–40 kg/m^2 and the presence of comorbidities that can improve after surgery (metabolic, cardiopulmonary, and mental diseases as well as joint problems) [10]. According to the registry of the Società Italiana di Chirurgia dell'Obesità e delle Malattie Metaboliche (SICOB), 8,787 procedures were performed in Italy in 2014 [11]. The number of surgeries increased by 47% from 2008 to 2014. Overall, bariatric surgery was performed in 83 hospitals.

To acknowledge the increasing cost of bariatric surgery in Italy, evaluation of the economic and clinical impact of this treatment is essential for appropriate resource allocation and informed decision-making. 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 an either cost-saving or cost-effective alternative to conventional methods for managing obesity [12–21].

Health economic data are not transferable between geographies due to differences in healthcare systems, payment mechanisms, healthcare policies, and stakeholder interests. Thus, the local economic analysis is necessary to inform decision-makers about cost and projected clinical outcomes of a treatment method. Existing evidence regarding the cost-effectiveness of bariatric surgery in an Italian setting is presented by a single study [20]. However, this study had several significant limitations: the analysis considered a short time horizon (5 years) and included only two of the three available surgery methods into the analysis, and besides did not account for the effect of the potential delay of surgery. Due to limited evidence regarding the cost-effectiveness of bariatric surgery in Italy, it is essential to conduct a study assessing incremental cost and clinical benefits of bariatric surgery compared to conventional methods of obesity management.

The objective of this study was to evaluate the cost-effectiveness of bariatric surgery in Italy from a third-party payer perspective over the medium term (10 years) and long term (lifetime horizon).

Material and Methods

We used a state-transition decision analytic Markov model [22] to evaluate the cost-effectiveness of bariatric surgery compared with optimal medical treatment. Full details of the modeling approach, data inputs, and validation activities are reported elsewhere [23]. 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 (fig. 1). During each cycle, which is equal to 1 month, patients may progress from one state to another or remain in the previous state. The probability of moving from one state to another was obtained from literature sources on incidence and/or relative risks for each specific model state. Cost-effectiveness was evaluated over a 10-year and a lifetime perspective.

Input Data

Clinical Effectiveness and Safety Data

The risk of complications of obesity in the model depends on age, gender, smoking status, BMI, the level of systolic blood pressure (SBP), and the presence of T2DM. Bariatric surgery, by reduction of levels of BMI and SBP and reduction of prevalence and incidence of T2DM, leads to a reduction of obesity-associated complications rates and mortality. By modeling the risk in the surgery arm and in a patient cohort that did

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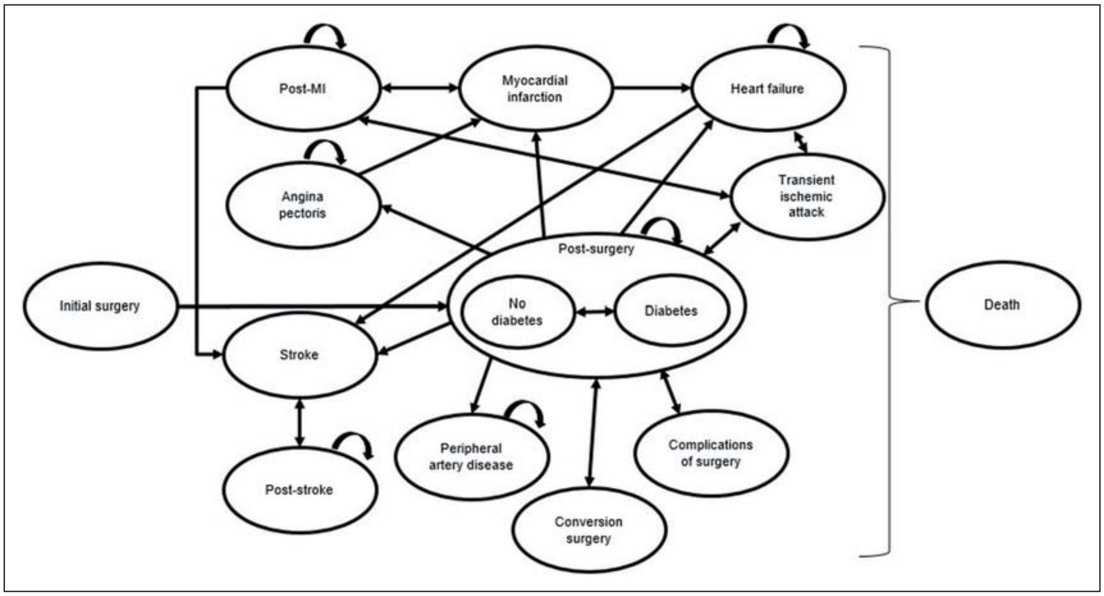

Fig. 1. Structure of the model (reproduced from [23]). MI = Myocardial infarction.

not undergo surgical weight reduction, it is possible to quantify the impact of the surgery on the rate of long-term negative events. Risk prediction models, derived from the Framingham Heart Study were used to calculate the 10-year risk of cardiovascular events [24, 25]. The incidence of diabetes was dependent upon BMI level and was obtained from Picot et al. [12], based on calculations from Colditz et al. [26]. Remission of diabetes was obtained from 2- and 10-year data from Swedish Obesity Subjects (SOS) study [27].

Three common surgical techniques which were in use in Italy were included in the analysis: gastric bypass (GBP), sleeve gastrectomy (SG), and adjustable gastric banding (AGB). The impact of different surgical methods on BMI in the base-case analysis was based on the Scandinavian Obesity Surgery Registry (SOReg) [28]. After the latest observation at 2 years, the impact on BMI was extrapolated using BMI change data from the SOS study [29]. After 15 years, BMI was assumed to be stable. Any change in BMI in the optimal medical management arm was based on the change in BMI of the conservative management arm of the SOS study [29]. Change in SBP was obtained from the SOS study for non-diabetic patients [27] and from Ikramuddin et al. [30] for diabetic patients. For analysis in different individual cohorts of patients, BMI change was obtained from individual studies [30–39].

The risk of short-term (30-day) mortality was obtained from an annual report of the Italian Society for Bariatric Surgery and Metabolic Disorders (SICOB) [40]. The risk of 30-day serious adverse events and reoperations in the base-case analysis was obtained from the SOReg [28]. SOReg 2011 data were also used to estimate the 2-year risk of complications of surgery (including cholecystectomy, abdominal hernia repair, leakage and abscess, gastric stricture, and gastric ulcer) [28]. The rate of conversion surgery was obtained from a controlled study of gastric bypass and adjustable gastric banding over 4.2 and 3.6 years of follow-up, respectively [32]. Conversion probability for SG was assumed to equal to one for GBP.

Normal mortality was based on gender-specific Italian life tables; normal non-ischemic heart disease mortality was calculated by subtraction of mortality due to ischemic heart disease from all-cause mortality. The presence of any cardiovascular event or diabetes influences the risk of having associated conditions (e.g,. risk of myocardial infarction is higher in patients who have heart failure) and mortality which was obtained from a number of epidemiological studies.[41–52].

Clinical inputs are presented in table 1.

Resource Utilization and Cost Data

Evaluation of the resource utilization and cost data was performed using Italian sources (table 1). Only direct medical costs were included in the analysis.

The cost of bariatric surgery procedures with or without complications were based on the Italian national DRG tariff from 2013 (DRG 288 for GBP, SG, and AGB). Post-surgery care was based on single expert

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Table 1. Clinical and cost inputs

Parameter	Value	Range	Distribution for PSA	Source
Patients baseline characteristics				
Age, years	40.6	21–56	normal (SD = 4.5)	[40]
Gender, males, %	24.64	N/A	beta	[40]
BMI, kg/m^2	46.2	23–58	normal (SD = 5.8)	[40]
Diabetes mellitus, %	20	N/A	beta	assumption
Systolic blood pressure, mm Hg	140.1	125–200	gamma (α = 55.53, λ = 2.52)	[27]
Smoking, %	14.3	N/A	beta	[62]
Distribution of surgery types				
Gastric bypass banding	0.282			[40]
Sleeve gastrectomy	0.346			[40]
Adjustable gastric banding	0.372			[40]
Absolute BMI reduction from SOREG 2011				
GBP, 1 year, males	12.7	8.7–37.7	normal (SD = 2.2)	[28]
GBP, 2 years, males	12.6	8.6–37.4	normal (SD = 2.2)	
SG, 1 year, males	9.7	5.9–25.5	normal (SD = 1.7)	
SG, 2 years, males	9.4	5.7–24.7	normal (SD = 1.6)	
AGB, 1 year, males	5.6	3.9–16.9	normal (SD = 1.0)	
AGB, 2 years, males	6.9	4.8–20.9	normal (SD = 1.2)	
GBP, 1 year, females	13.5	9.5–41.1	normal (SD = 2.4)	
GBP, 2 years, females	13.5	9.5–41.2	normal (SD = 2.4)	
SG, 1 year, females	12.5	7.5–32.8	normal (SD = 2.2)	
SG, 2 years, females	14.7	8.9–38.0	normal (SD = 2.6)	
AGB, 1 year, females	5.5	3.9–17.0	normal (SD = 0.9)	
AGB, 2 years, females	5.1	3.6–15.7	normal (SD = 0.9)	
Cost inputs, EUR				
Cost of index surgery	5 681	4,544–6,817	N/A	G.U. 2013, DRG 288
Cost of abdominal hernia procedure	1 807	1,446–2,168	–	G.U. 2013, DRG 159-160; [71]
Cost of cholecystectomy	2 834	2,071–3,106	–	G.U. 2013, DRG 494
Cost of leakage and abscess	6 566	5,252–7,879	–	G.U. 2013, DRG 155
Cost of obstruction	6 566	5,252–7,879	–	G.U. 2013, DRG 155
Cost of stricture	6 566	5,252–7,879	–	G.U. 2013, DRG 155
Cost of gastric ulcer	29	23–34	–	8-week course of 40 mg omeprazole. AIFA
Annual cost of diabetes type II	3,325	2,660–3,990	gamma (α = 100; λ = 33.25)	[60]
Cost of acute stroke (30 days)	4,502	3,601–5,402	gamma (α = 100; λ = 45.02)	[56]
Annual cost of post-stroke during 1st year	9,975	7,980–11,970	gamma (α = 100; λ = 99.75)	[56]
Annual cost of post-stroke during 2nd year	7,422	5,938–8,907	gamma (α = 100; λ = 74.22)	[56]
Cost of transient ischemic attack (30 days)	7,789	6,231–9,347	gamma (α = 100; λ = 77.89)	[56]
Cost of acute myocardial infarction (30 days)	6,503	5,203–7,804	gamma (α = 100; λ = 65.03)	[59]
Annual cost of post-myocardial infarction state	6,110	4,888–7,332	gamma (α = 100; λ = 61.10)	[59]
Annual cost of heart failure	11,647	9,318–13,977	gamma (α = 100; λ = 116.47)	[58]
Annual cost of peripheral artery disease	3,945	3,156–4,734	gamma (α = 100; λ = 39.45)	[57]
Annual cost of angina	6,503	5,203–7,804	gamma (α = 100; λ = 65.03)	[59]

opinion. The unit cost for outpatient physician visits was set to zero because general practitioners are paid on capitation basis and the marginal cost of extra visit approaches zero. Using a conservative approach, it was assumed that patients who do not undergo surgery require no annual visits to a general practitioner or any other obesity-related care. The scope of conventional treatment was obtained from the SOS study [27]. These data are in line with results of systematic literature reviews and meta-analyses [12, 53–55], where conventionally treated patients received the unstandardized nonsurgical treatment for obesity, ranging from sophisticated lifestyle intervention and behavior modification to no treatment whatsoever. No cost was assumed for the conventional treatment.

Distribution of different surgical methods (GBP 28.21%, SG 34.63%, AGB 37.15%) was obtained from the annual report of the SICOB [40]. The costs of the end-stage organ damage health states were obtained from the Italian literature and international studies when no local cost was available [56–60]. Cost data are presented in 2015 in EUR. Inflation adjustment was performed using the Italian consumer price index.

Utility Data

Utilities (health-related quality of life) were estimated using EuroQol-5D (EQ-5D). Utilities were dependent on BMI level and presence of diabetes [13]. In addition, the disutility of having cardiovascular disease was obtained from data from UK adaptations of US Medical Expenditure Panel Survey EQ-5D mapping study [61].

Cohort Description

First, the base-case (primary) analysis included summary characteristics of candidates being considered for bariatric surgery in Italy. These so-called 'multiple cohorts' were extracted from the SICOB patient registry [40], the SOS study [27], and the Organisation for Economic Co-Operation and Development's data about the proportion of the smoking population [62]. This analysis was performed in a cohort of 41-year-old patients with a mean BMI of 46 kg/m^2 and a mean SBP of 140 mm Hg; 25% were male, , 20% had T2DM, and 14% were smokers. Patient characteristics were extracted from the SICOB registry [40].

Second, cost-effectiveness of bariatric surgery was evaluated in 16 cohorts of 41-year-old non-smoking males and females with moderate (start BMI 33 kg/m^2), severe (start BMI 37 kg/m^2), morbid (start BMI 42 kg/m^2), and super obesity (start BMI 52 kg/m^2) with and without presence of T2DM.

Sensitivity and Scenario Analysis

Validation of the data inputs was performed using deterministic (varying each model's parameters individually while holding other variables fixed at base-case values) and probabilistic (when each variable has random value within pre-determined distribution during 1,000 Monte Carlo simulations) sensitivity analyses. One-way sensitivity analysis was performed using the mean patient characteristics (41-year-old non-smoking male, with a BMI of 43.7 kg/m^2, a SBP of 140 mm Hg and absence of diabetes). Cost drivers (variables with a major input to the costs) were identified, and results are presented by means of a Tornado diagram. Specific conditions were applied to the binary input parameters (gender, smoking, and diabetes status). For the 'gender' parameter, 'male gender' was considered as max input, 'female gender' as minimum input. For diabetes and smoking, their presence was considered as max input, their absence as minimum input.

A probabilistic sensitivity analysis was performed using beta distribution for the probabilities as well as gamma distributions for the longitudinal data, the cost data with descriptive statistics available, and the utility data. Lognormal distributions were used for the relative risks. Uniform distributions were used for parameters based on expert or analyst assumptions and for parameters where descriptive statistics were not available in the original publications. Reimbursement tariffs were not tested in probabilistic analysis.

Analysis

The present analysis was performed from a third-party payer perspective over 10 years and a lifetime horizon. All costs and outcomes beyond the first year were discounted by 3.0% annually according to the recommendations of Italian Association of Health Economics (AIES) [63]. Surgery was considered cost-effective if the incremental cost-effectiveness ratio (ICER), which is calculated by dividing difference in cost between two arms by difference in quality-adjusted life years (QALYs, was below the societal willingness-to-pay threshold of EUR 50,000/QALY [64]. Clinical effectiveness was evaluated by analyzing the cumulative rates of adverse events and the relative risk of adverse events over a 10-year period and over a lifetime. The model was constructed using Microsoft Excel 2013 (Microsoft Corp., Redmond, WA, USA).

In addition to standard evaluation of cost-effectiveness between two technologies, analysis of the impact of delay in surgery provision (watchful waiting) on clinical and economic outcomes in non-diabetic patients was performed. Patients were initially included in the optimal medical management arm, with a move to the surgical arm after 1, 2 or 3 years. Results were compared with the analysis in which patients had received surgery immediately.

Finally, a scenario analysis was conducted with 100% utilization of each surgery method to differentiate the results by technique.

Table 2. Base-case results of cost-effectiveness analysis

	Cost, EUR	Δ cost	LYG, years	Δ LYG	QALY	Δ QALY	ICER, EUR/QALY
10 years							
OMM arm	8,334	–	8.7	–	3.6	–	–
Surgical arm	11,010	2,661	8.7	0.0	4.7	1.1	2,412
Lifetime							
OMM arm	41,307	–	22.0	–	8.9	–	–
Surgical arm	32,671	–8,649	22.5	0.5	12.0	3.2	dominates

ICER = Incremental cost-effectiveness ratio; LYG = life years gained; OMM =optimal medical management; QALY = quality-adjusted life years.

Table 3. Absolute and relative risks in the model

	Angina	MI total non-fatal	MI fatal	Stroke total non-fatal	Stroke fatal	TIA	HF	PAD	Diabetes
10 years									
Absolute risk in surgical arm	2%	3%	0.05%	2%	0.36%	0.27%	2%	2%	11%
Absolute risk in OMM arm	3%	4%	0.07%	3%	0.49%	0.37%	3%	2%	22%
Relative risk	0.72	0.73	0.67	0.73	0.73	0.74	0.73	0.73	0.49
Lifetime									
Absolute risk in surgical arm	12%	22%	2%	19%	3%	2%	15%	10%	29%
Absolute risk in OMM arm	14%	27%	3%	24%	4%	2%	19%	11%	48%
Relative risk	0.85	0.82	0.75	0.82	0.82	0.86	0.83	0.86	0.61

HF = Heart failure; MI = myocardial infarction; PAD = peripheral artery disease; TIA = transient ischemic attack.

Model Validation

The model underwent a previously reported extensive three-step validation process [23].

Results

Base-Case Results

Multiple-Cohort Analysis

In the base-case analysis, bariatric surgery increased the cost compared to optimal medical management by EUR 2,661 and generated additional 1.1 QALYs, resulting in an incremental cost-effectiveness ratio of EUR 2,412 per QALY at 10 years. In the analysis over the lifetime of the patient cohort, bariatric surgery led to cost savings of EUR 8,649 and generated an additional 0.5 years of life and 3.2 QALYs (table 2). Surgery is, therefore, more effective and less expensive than conservative weight management. Also, surgery showed the potential to significantly reduce the risk of negative events, both for 10 years and lifetime horizon (table 3).

Single-Cohort Analysis

The analysis shows that over 10 years, bariatric surgery was cost-saving in all eight cohorts considered as diabetic (moderately, severely, morbidly, and super obese males and females). In the non-diabetic cohorts, surgery was cost-effective in all groups, namely in moderately obese males (ICER EUR 7,198/QALY) and females (ICER EUR 7,710/QALY),

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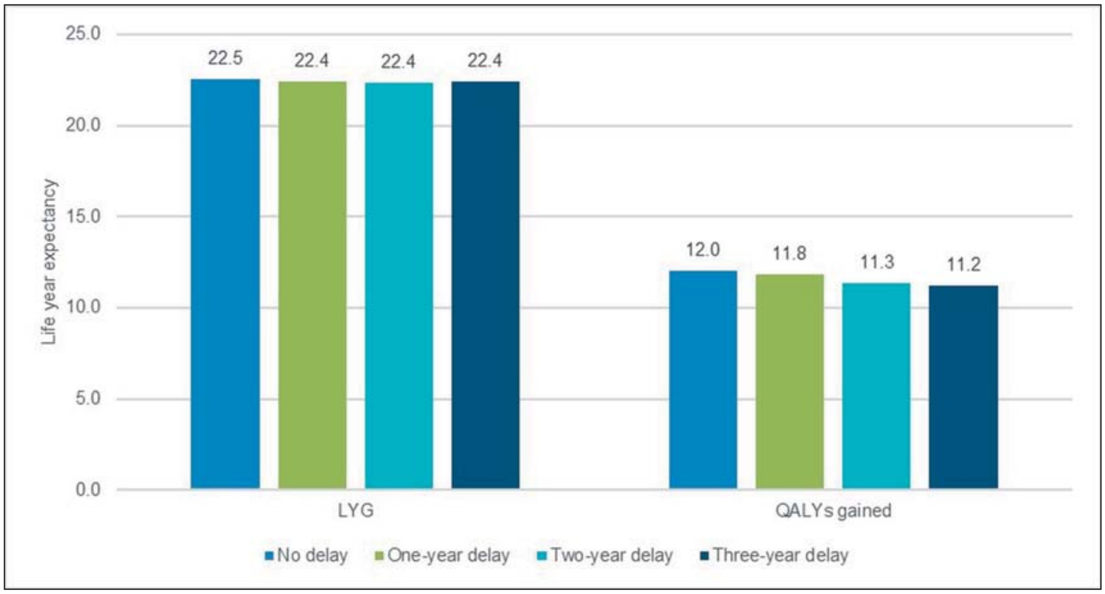

Fig. 2. Life years expectancy and QALYs expectancy performing surgery immediately and with a delay.

severely obese males (ICER EUR 6,659/QALY) and females (ICER EUR 7,026/QALY), morbidly obese males (ICER EUR 2,873–3,447/QALY) and females (ICER EUR 3,133–3,698/QALY), and super obese males (ICER EUR 1,030/QALY) and females (ICER EUR 1,177/QALY). The cost-effectiveness of surgery increased with the increase of baseline BMI of the cohort.

The analysis shows that over the lifetime horizon, bariatric surgery is cost-saving in all eight cohorts considered as diabetic. In the non-diabetic cohorts, surgery was cost-saving in all groups, except for moderately obese males (ICER EUR 155/QALY).

Analysis of Delay in Provision of Surgery

Our analysis revealed that there was a significant reduction of clinical benefits when surgery was delayed for 3 years. There was a difference in performance of 0.1 life years gained and 0.8 QALYs between the immediate operation and watchful waiting with the 3-year delay in the provision of surgery (fig. 2). Additionally, the cost for provision of surgery increased with the delay of surgery provision, except for the 1st year: the cost of the surgery over the lifetime horizon accounted for EUR 32,398 with the immediate operation, EUR 31,736 with a 1-year delay, EUR 36,704 with a 2-year delay, and EUR 35,493 with a delay of 3 years.

Scenario Analysis per Each Surgery Method

All surgery techniques were dominant compared to conventional treatment at lifetime horizon and cost-effective at the 10-year horizon. GBP was the most beneficial treatment option as it was associated with the highest savings of EUR 9,434 and QALY gains of 3.4 years at lifetime horizon, while at a shorter run of 10 years it was also the most cost-effective alternative to optimal medical management. GBP increased the cost compared to optimal medical management by EUR 3,039 and generated additional 1.4 QALYs, resulting in an incremental cost-effectiveness ratio of EUR 2,228.

Sensitivity Analysis

In deterministic one-way sensitivity analysis, the most sensitive parameters were presence of T2DM (surgery is less cost-effective in the absence of diabetes), age (surgery is less cost-

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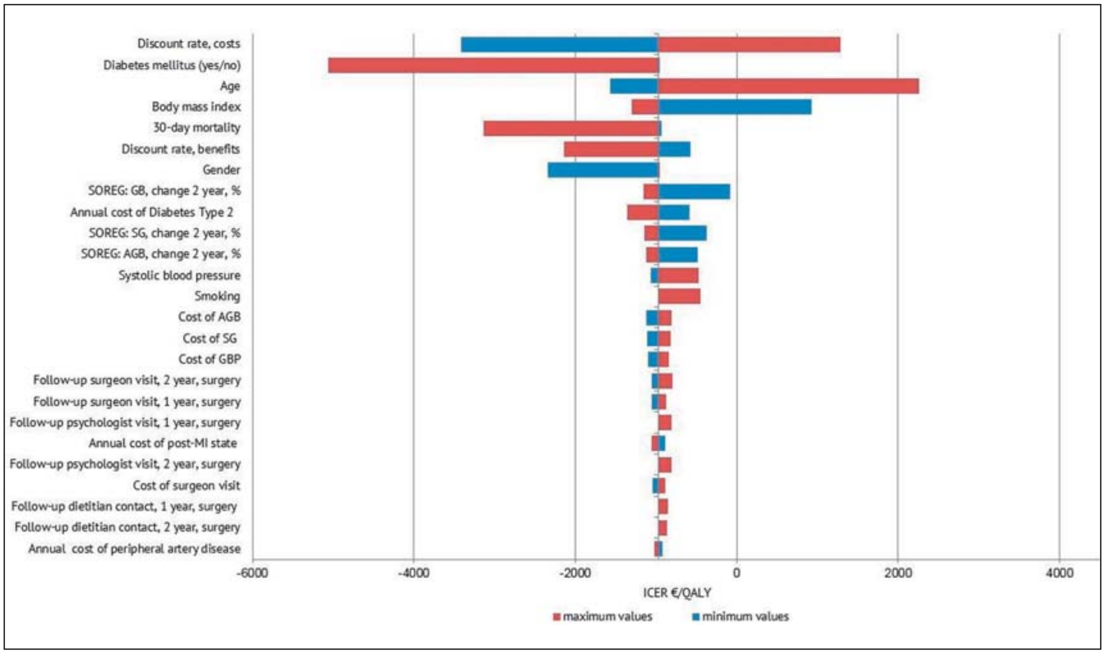

Fig. 3. Tornado diagram. One-way sensitivity analysis was produced for a single cohort of a 41-year-old non-smoking male with BMI of 43.7 kg/m^2.

effective in older patients), discount rate for costs (surgery is less cost-effective with a higher discount rate), and baseline BMI (surgery becomes more cost-effective with increase in BMI) (fig. 3). Probabilistic sensitivity analysis demonstrated that bariatric surgery produced clinical benefits (defined as additional QALYs) and was cost-saving in 100% of the patients and had cost-saving effects in 99.9% of cases, while in the remaining 0.1% it was cost-effective (fig. 4).

Discussion

Our analysis of currently used surgical techniques in Italy indicates that bariatric surgery is cost-effective in the medium term and can save the healthcare system money over a longer time horizon. When the demonstrated lifetime clinical and economic benefits are extrapolated to the patient cohort, which received surgery during 2014 in Italy (n = 8,787), it would result in savings of about EUR 76 million and generate an additional 4,393 person-years or 28,118 person-QALYs over the lifetime of the operated cohort. Furthermore, a cost-saving effect was also demonstrated over lifetime for all patients except for moderately obese males without the presence of diabetes.

Our results have originated from decision analytic modeling, which has inherent limitations of being a simplification of reality. Several empirical studies, performed mainly in Sweden and the US, did not demonstrate a reduction in cost when applying bariatric surgery, although they shared common limitations of short time horizon, reporting data for discontinued/outdated surgical techniques (e.g. vertical banded gastroplasty in the SOS study), and extensive use of the open surgical approach [65, 66]. Due to delays in publication and the regular development of surgical techniques, empirical economic evidence may not reflect current safety and efficacy of bariatric procedures. Decision analytic modeling can complement empirical data and bridge knowledge gaps in a timely manner.

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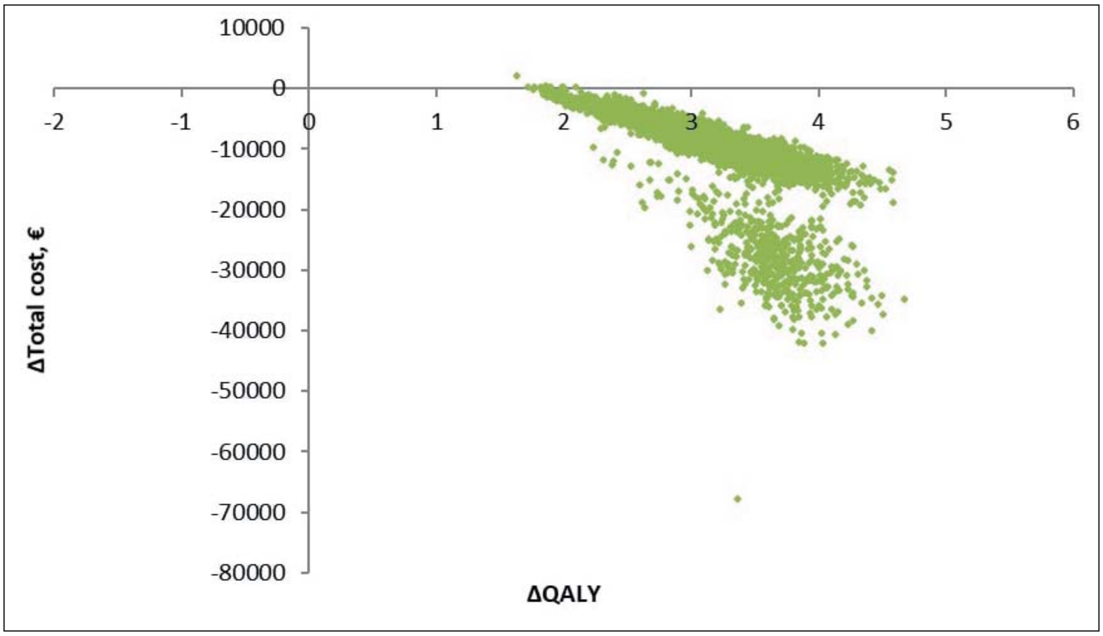

Fig. 4. Cost-effectiveness acceptability plane. The figure shows the distribution of 1,000 Monte Carlo simulations at a lifetime horizon.

The results of our study show that bariatric surgery is cost-effective (over the medium term) and cost- saving (over lifetime), and is associated with a significant clinical benefit. Bariatric surgery should, therefore, be prioritized in Italy to treat severely obese individuals. A recent analysis of utilization of bariatric surgery in seven European countries showed that Italy has one of the lowest rates of bariatric surgery interventions (128 procedures per 1 million population), compared with Europe's average (401 procedures per 1 million population) [68]. However, the frequency of bariatric surgery interventions in England and Germany is even lower, with 117 and 72 procedures per 1 million population, respectively [67].

This study has a number of limitations, as previously discussed [23]. In brief, the analysis did not include all potential obesity-related complications and potentially underestimated cost benefits of surgery. The model did not distinguish outcomes of surgery in different populations of diabetic patients, which could affect the overall effectiveness of the therapy. The data regarding management of patients after surgery or surgical candidates who do not receive surgery was based on assumptions. Risk equation from the Framingham Heart Study may lead to an overestimation of risk of cardiovascular events in Italy [68]. Additionally, using DRG tariffs as a proxy for modeling costs, is a well-known limitation of cost-effectiveness analyses under the common condition of insufficient or unavailable data from hospital-level cost studies. However, in reality, the DRG tariffs appear to a be a rigid estimate for procedure-related hospital expenses [69].

Using a broad utilities scoring system, not specific to any country, is a recognized issue and is a limitation in the domain of healthcare evaluation and modeling. However, using validated data sets is a common approach when there is limited or a complete lack of local data [70].

These limitations should be taken into account while interpreting the results of the study.

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Conclusion

In a comprehensive decision analytic model, the current mix of surgical methods for bariatric surgery available in Italy was cost-effective at 10 years and cost-saving over the lifetime of the treatment cohort.

Disclosure Statement

Oleg Borisenko, Daniel Adam, Elisabeth Burdukova, and Vasily Lukyanov are employees of the Synergus AB – MedTech consulting company, which received a grant from Covidien Inc. (now part of Medtronic Inc.) to perform the study. Other authors do not have any conflict of interest to disclose.

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