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ORIGINAL CONTRIBUTIONS

Cost-Utility of Gastric Bypass Surgery Compared to Clinical Treatment for Severely Obese With and Without Diabetes in the Perspective of the Brazilian Public Health System

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Abstract

Purpose Obesity is associated with increased morbidity and mortality. Weight loss due to gastric bypass (GBP) surgery improves clinical outcomes and may be a cost-effective intervention. To estimate the cost-effectiveness of GBP compared to clinical treatment in severely obese individuals with and without diabetes in the perspective of the Brazilian public health system.

Materials and Methods A Markov model was developed to compare costs and outcomes of gastric bypass in an open approach to clinical treatment. Health states were living with diabetes, remission of diabetes, non-fatal and fatal myocardial infarction, and death. We also included the occurrence of complications related to surgery and plastic surgery after the gastric bypass surgery. The direct costs were obtained from primary data collection performed in three public reference centers for obesity treatment. Utility values also derived from this cohort, while transition probabilities came from the international literature. A sensitivity analysis was performed to evaluate uncertainties. The model considered a 10-year time horizon and a 5% discount rate.

Results Over 10 years, GBP increased quality-adjusted life years (QALY) and costs compared to clinical treatment, resulting in an incremental cost-effectiveness ratio (ICER) of Int$1820.17/QALY and Int$1937.73/QALY in individuals with and without diabetes, respectively. Sensitivity analysis showed that utility values and direct costs of treatments were the parameters that affected the most the ICERs.

Conclusion The study demonstrated that GBP is a cost-effective intervention for severely obese individuals in the Brazilian public health system perspective, with a better result in individuals with diabetes.

Keywords Cost-utility · Obesity · Gastric bypass surgery

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Introduction

The prevalence of obesity reaches global epidemic levels. In 2014, more than 640 million individuals were obese worldwide and almost 180 millions of these were severely obese. If these trends continue, by 2025 the global prevalence will reach 18% in men and more than 21% in women [1]. In Brazil, obesity prevalence increased by 7.5% between 2006 and 2016, reaching 53.8% and 18.9% of overweight and obesity, respectively [2].

Obesity and its comorbidities represent a very important public health problem worldwide regarding clinical and economic consequences. The impact in the global economy was estimated at US$2 trillion or 2.8% of the global gross domestic product (GDP) in 2014 [3]. In the perspective of the Brazilian public health system, the annual costs of obesity and associated diseases were estimated to be US$2.1 billion in 2010 [4].

In the Brazilian public health system (SUS), the number of Bariatric surgeries (BS) increased by 45% between 2010 and 2013, and BS health expenditures by 56%, totaling Int$20.5 million in 2013 [5]. At this time, only laparotomy surgeries were performed in the SUS [6]. In 2013, an overview of global estimates for BS placed Brazil in the second position in the number of surgeries performed per year (n = 86,840) [7]. Although there is a huge discrepancy between the number of individuals operated in the public and in the private systems, this large number of surgeries allows improvements in the learning curve and, consequently, better results.

Evidence indicates that bariatric surgery is the most effective intervention for the treatment of obesity. In several studies, the weight loss difference between the surgical and clinical groups was approximately 20%, besides allowing the control and/or remission of diseases associated with obesity, such as hypertension, type 2 diabetes mellitus, and cardiovascular diseases [8–16]. Furthermore, bariatric surgery has also been proven as a cost-effective treatment for obesity and its complications [17–19]. It has been suggested that patients with diabetes will present even better health outcomes compared with patients without diabetes [20, 21]. Given the current discussion about obesity management, surgical options, and its inclusion in diabetes treatment algorithms [22, 23], possible differences in patients' baseline status are worth noting.

Since data on costs of severe obesity and bariatric surgery are still limited, the objective of this study was to develop a cost-utility model comparing the GBP surgical treatment of severely obese individuals with and without diabetes to clinical treatment.

Material and Methods

We carried out a cost-utility analysis of gastric bypass (GBP) surgery compared to clinical treatment for severely obese patients in the perspective of the public health system, taking into consideration a 10-year time horizon. We designed a Markov model for two target populations: (i) severely obese with diabetes and (ii) severely obese without diabetes. On this basis, the main questions explored were whether GBP surgery would be more cost-effective compared to clinical treatment, and if so, which target population would beneficiate the most. Our study complied with national [24] and international [25, 26] guidelines for economic evaluation. We also used the CHEERS checklist for reporting our cost-utility analysis [27].

Cost and Utility Data

We conducted a multicentric, cross-sectional study assessing health-related quality of life and costs of treatment of severely obese patients. Severe obesity was defined as BMI greater than 40 kg/m^2 or greater than 35 kg/m^2 associated with one or more obesity-related comorbidities [28]. The population was recruited in three reference hospitals, authorized by the Ministry of Health for the treatment of obesity. The patients who underwent gastric bypass surgery were selected in Hospital São Lucas (HSL) of the Pontifícia Universidade Católica do Rio Grande do Sul (PUC/RS). Patients undergoing clinical treatment were selected in Policlínica Piquet Carneiro of the Universidade do Estado do Rio de Janeiro (UERJ) and at the Instituto Estadual de Diabetes e Endocrinologia Luiz Capriglione (IEDE) in Rio de Janeiro.

We developed a standard questionnaire for collecting information on costs, including direct medical costs such as health professionals' visits, laboratory tests, medications, hospital admissions, treatment of surgical complications, and the bariatric surgery. Non-medical direct costs (patient transportation, caregiver payment) and indirect costs (absenteeism) were included. The complete description of the micro-costing approach was previously published elsewhere [29].

For health-related quality of life, we used the Portuguese version of the EuroQol questionnaire (EQ-5D-3L), which was validated in Brazil in 2016 [30]. The EQ-5D-3L instrument was applied in 140 individuals with severe obesity submitted to gastric bypass (GBP) in open approach and 134 individuals undergoing clinical treatment. Utility values were generated based on the Brazilian value set for EQ-5D-3L results [30]. Subsequently, utility values were used to estimate the change in quality-adjusted life years (QALYs).

Comparators

Bariatric surgery strategy considered only patients who underwent the technique of Roux-en-Y gastric bypass by laparotomy, because the laparoscopic approach was not performed at public centers at the moment the study was carried out. Patients were grouped according to the time since surgery (up to 1 year, 1–2 years, 2–3 years, and > 3 years).

Clinical treatment is defined for the most updated guideline from the Brazilian Ministry of Health, which includes effective weight reduction (changes in lifestyle through diet and exercise education), public health strategies for prevention and health promotion, multidisciplinary assistance in primary health care services, nutritional follow-up, and referral for specialized assistance while waiting for surgical treatment when medically recommended [31].

Time Horizon, Discount Rate, Currency, Price Date, and Conversion

We adopted a 10-year-period horizon, considering the duration of the main randomized clinical trials for the treatment of severe obesity with the outcomes of interest. We used a 5% discount rate, which is recommended by the methodological guidelines published by the Brazilian Ministry of Health [24]. Costs were obtained in local currency (R$) related to 2015 prices, and converted to international dollars (Int$) using the purchasing power parity (PPP) of 1 Int$ = R$1.859 (World Bank, 2015) [32].

The Analytical Model

We developed a hybrid Markov decision tree model to compare the gastric bypass in open approach with the clinical treatment for severely obese individuals with and without diabetes. Figure 1 shows the rationale for each model. The health states considered into the models were living with diabetes, remission of diabetes, non-fatal and fatal myocardial infarction, and death for all causes. For the GBP arm, we included also the occurrence of complications related to surgery in the first year and the possibility to perform plastic surgery after the GBP. We included 10 Markov cycles of 1 year each, totaling 10-year time horizon.

The model was constructed using TreeAge software 2017 (Williamstown, MA, USA) and Microsoft Excel 2013 (Microsoft Corp., Redmond, WA, USA).

Clinical Effectiveness and Safety Data

The outcomes considered in the model were diabetes mellitus, fatal and non-fatal myocardial infarction, and death. We obtained transition probabilities from international literature [8, 9, 11–14] with the exception of mortality data that came from national registries [15, 16].

The most common postoperative surgical complications (cholecystectomy and hernioplasties), occurring in the first year post surgery, were included in the model using data from medical records of patients coming from a major center for surgical treatment of obesity in the public health system [6, 33].

Based on the total number of plastic surgeries performed in 1 year in the public health system after GBP surgeries (n = 1065) and the total number of GBP surgeries in 2014 (n = 7003), we assumed a proportion of individuals of 15.2% who would undergo at least one plastic surgery in 10 years (mammoplasty and abdominal, crural, and brachial dermolipectomy) [34].

Resource Utilization and Cost Data

Annual health resource utilization was obtained from the previous study with primary data collection of obese individuals undergoing clinical or surgical treatment [29].

The cost of GBP surgery was defined as Int$3409.08 (R$6337.48) and was obtained from the official

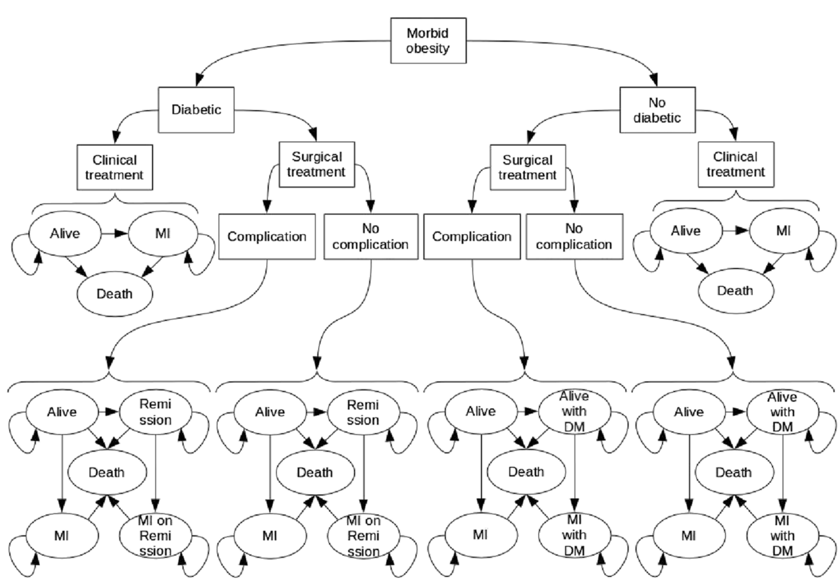

Fig. 1 Structure of the Markov model

reimbursement table of procedures of the Brazilian Public Health System for 2015 [35]. The costs of the four most common types of plastic surgery performed after bariatric surgery were also obtained from the official reimbursement table, and the weighted average value was considered for the model Int$498.46 (R$926.65) [35]. The average hospitalization cost of myocardial infarction was estimated at Int$2155.99 (R$4008) [36]. Table 1 presents the key parameters used in the models.

Analysis

The analysis was performed from the public payer perspective over a 10-year time horizon, and a 5.0% discount rate was applied to all variables considering Brazilian recommendations [24]. The incremental cost-effectiveness ratio (ICER) was calculated by dividing the difference in total *costs* (*incremental cost*) by the difference in quality-adjusted life years (QALY) (*incremental* effect) among group comparisons

Table 1 Clinical utilities and costs of model inputs

Probabilities	Median	Minimum	Maximum	Distribution	Reference
GBP with diabetes					
DM remission	79.4807	57.91	87.777	Normal	Sjöström L, 2014 [13]
MI	0.0311	0.0119	0.0638	Normal	Romeo S, 2012 [12]
Fatal MI	0.0102	0.0007	0.029	Normal	Eliasson B, 2015 [14]
Fatal GBP complications	0.0105	0.0083	0.0112	Normal	Kelles SMB, 2014 [15]
Death of any cause	0.049	0.0007	0.1511	Normal	Eliasson B, 2015 [14]
GBP without diabetes					
DM incidence	0.01	0.0016	0.077	Normal	Sjöström L, 2004 [8]
MI	0.0173	0.0058	0.0335	Normal	Sjöström L, 2012 [11]
Fatal MI	0.0031	0.0011	0.0051	Normal	Sjöström L, 2012 [11]
Fatal GBP complications	0.0105	0.0083	0.0112	Normal	Kelles SMB, 2014 [15]
Death of any cause	0.0359	0.004	0.0583	Normal	Kelles SMB, 2014 [16]
CT with diabetes					
DM remission	0.1616	0.0875	0.1708	Normal	Sjöström L, 2014 [13]
MI	0.0527	0.0097	0.1059	Normal	Romeo S, 2012 [12]
Fatal MI	0.0347	0.0025	0.073	Normal	Eliasson B, 2015 [14]
Death of any cause	0.1817	0.0082	0.4991	Normal	Eliasson B, 2015 [14]
No DM, CT					
DM incidence	0.0978	0.0562	0.2437	Normal	Sjöström L, 2004 [8]
MI	0.0213				Sjöström L, 2012 [11]
Fatal MI	0.0044	0.0006	0.0099	Normal	Sjöström L, 2012 [11]
Death of any cause	0.0182	0.0025	0.0443	Normal	Sjöström L, 2007 [9]
Utilities					
DM, GBP	0.7432	0.7095	0.8216	Normal	Zubiaurre PR, 2017 [29]
No DM, GBP	0.7754	0.7476	0.8423	Beta	Zubiaurre PR, 2017 [29]
DM, GBP, MI	0.6477				Zubiaurre PR, 2017 [29]
No DM, GBP, MI	0.6027				Zubiaurre PR, 2017 [29]
DM, CT	0.5832			Beta	Zubiaurre PR, 2017 [29]
No DM, CT	0.5983			Beta	Zubiaurre PR, 2017 [29]
No DM, MI, CT	0.5792				Zubiaurre PR, 2017 [29]
Costs (Int dollar 2015)					
DM, GBP	1102.19	789.06	4410.93	Gamma	Zubiaurre PR, 2017 [29]
No DM, GBP	969.66	827.32	4414.25	Gamma	Zubiaurre PR, 2017 [29]
DM, CT	1714.72			Gamma	Zubiaurre PR, 2017 [29]
No DM, CT	1131,78			Gamma	Zubiaurre PR, 2017 [29]
Obesity, MI	2155.99				Bahia LR, 2018 [36]

GBP gastric bypass, *DM* diabetes mellitus, *MI* myocardial infarction, *CT* clinical treatment

[24]. The willingness-to-pay threshold related to per capita GDP/QALY (GDP Brazil 2015 = Int$15,565.26) was assumed to identify the intervention as cost-effective [37].

Sensitivity Analysis

In order to evaluate the impact of the uncertainties of the variables included in the model, we performed both deterministic and probabilistic sensitivity analyses. For deterministic analysis, variability arbitrated was around the central measure of 25% for cost, utility, and probabilities in accordance with the recommendations of the Brazilian Economic Analysis Guidelines of the Ministry of Health [24]. For the probabilistic analysis, the Tornado diagram selected 10,000 Monte Carlo simulations with the most important variables. Gamma distribution was applied to costs, and beta distribution was applied to probabilities and utilities.

Results

Gastric bypass surgery was associated with higher costs (Int$10,481.25 (R$19,484.66)) and an additional 1.26 QALY, which resulted in an ICER of Int$1937.99 per QALY (R$3602.73) when compared to clinical treatment in the non-diabetic cohort.

In the diabetic cohort, an incremental cost of Int$3432.43 (R$6381.21) and an incremental effectiveness of 1.88 QALY were obtained, resulting in an ICER of Int$1820.17 per QALY (R$3383.70) for surgical treatment compared to clinical treatment at 10 years. Table 2 represents the results of the cost-effectiveness analysis.

Considering the willingness-to-pay (WTP) threshold related to per capita GDP, GBP surgery was a cost-effective intervention with ICER below the World Health Organization (WHO) threshold value of one GDP [38]. ICER in the diabetic group and non-diabetic group were 12.45% and 11.69% of per capita GDP, respectively.

Sensitivity Analysis

A base case scenario for deterministic one-way sensitivity analysis showed that utility values and direct costs of treatments were the parameters that affected the most the results. When taking into consideration the lower and upper limits of QALY, the ICER ranges from In$1938 to In$19,848.67 (Fig. 2).

Probabilistic sensitivity analysis indicated that GBP surgery was a cost-effective intervention in 99.5% of cases in patients with diabetes and in 93.4% of the patients without diabetes. (Figs. 3 and 4).

Conclusion

To the best of our knowledge, our study is the first study to investigate the cost-effectiveness of gastric bypass surgery in patients with severe obesity, with and without diabetes mellitus in the perspective of the Brazilian public health system. The results clearly showed that GBP surgery is a good value for money compared to clinical treatment, improving clinical outcomes at an affordable cost.

In our analysis, we developed a hybrid Markov model to evaluate the economic impact of GBP surgery in the context of the Brazilian Health Care System. Based on primary data collection at reference centers for obesity, this study especially estimated direct and indirect costs and utility data. Although based on only three reference centers, we performed a micro-cost analysis, considering the local setting. All utility and cost inputs used were obtained from the Brazilian population's data. Bariatric surgery clearly reduces the risk of the obesity-related adverse events significantly at 10 years, especially in a young and severe obese population with diabetes, as demonstrated in the present analysis [8, 9, 11–16].

Several studies have already shown that BS is a cost-effective intervention compared to clinical treatment, with significant gains in quality of life, in addition to future economic benefits despite a higher initial expenditure with the surgery [17–19, 39–42]. The results of our study are similar to those previously published studies in European countries [40–42] and in the USA [43]. Another interesting issue is that only two studies explicitly considered the difference between individuals with and without diabetes [17, 18]. In this sense, our study brings new contributions to the international literature, since our results indicate that GBP surgery is more cost-effective in patients who already had diabetes at the time of surgical procedure.

Table 2 Results of cost-effectiveness analysis

	Costs Int$	Incr costs, Int$	Total QALY	Incr QALY	ICER, Int$/QALY
CT	7073.75	–	0.5832	–	–
DM, BS	10,506.18	3432.43	0.7432	1.88	1820.17
No DM, BS	10,481.25	3407.50	0.7754	1.26	1937.99

GBP gastric bypass, *DM* diabetes mellitus, *CT* clinical treatment, *Incr* incremental, *QALY* quality-adjusted life years, *ICER* incremental cost-effectiveness ratio

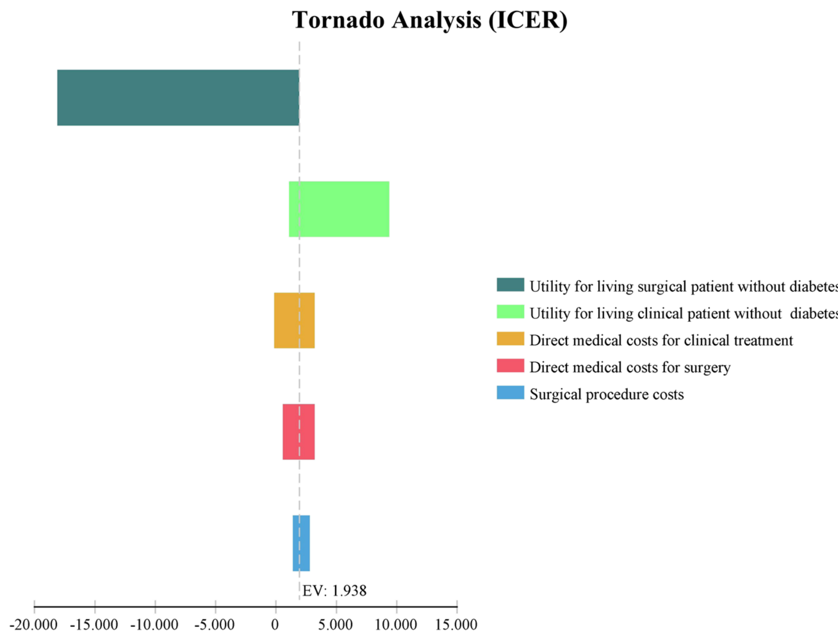

Fig. 2 Tornado diagram. The figure shows one-way sensitivity analysis and presents the five parameters that affect the most the ICER

It is worth noting the inclusion of plastic surgery costs in our model. It is the only study to show that surgery is cost-effective even including four types of plastic surgery (mammoplasty and abdominal, crural, and brachial dermolipectomy). Just one study assumed that only abdominoplasty was performed during the third year after bariatric surgery [41].

Considering distinctive features like health systems' structure and financing, outcomes assessment, and the type of surgery, comparisons should be made cautiously. Gastric bypass in open approach is reimbursed by SUS since 1999 [44], but only in 2017, the laparoscopic approach was incorporated by the public health system [45], an intervention that is mainly performed in high-income countries [43]. Another point is the cost-effectiveness threshold adopted by different countries. Although the Brazilian government does not have an established cost-effectiveness threshold to consider a cost-effective health intervention, the estimated incremental cost-effectiveness ratios of this analysis are well below those suggested by the World Health Organization for interventions for low- and middle-income countries [38].

Obesity is a growing public health problem in Latin America, and around 58% of the inhabitants of the region are overweight [46]. During 2013, Latin America accounted

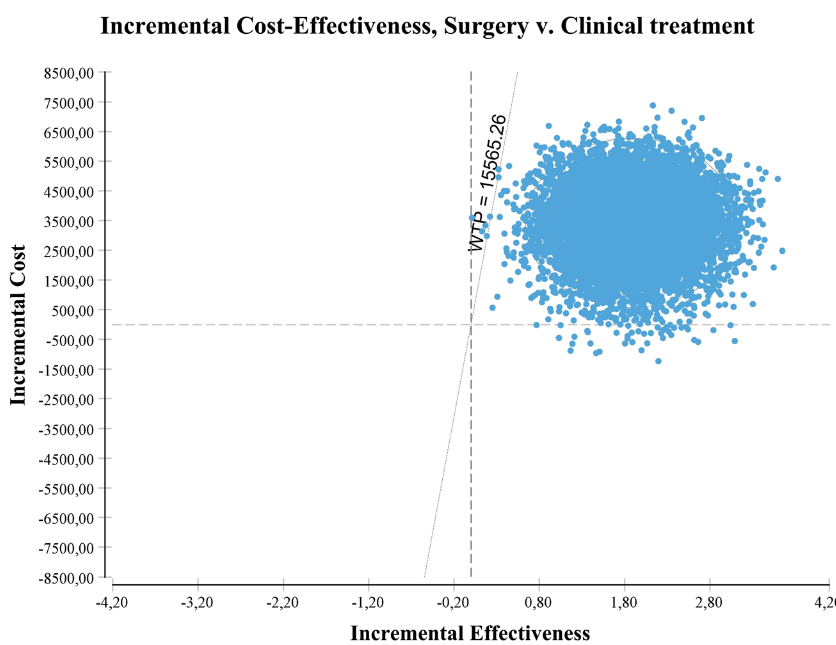

Fig. 3 Cost-effectiveness acceptability plan in severely obese patients with diabetes

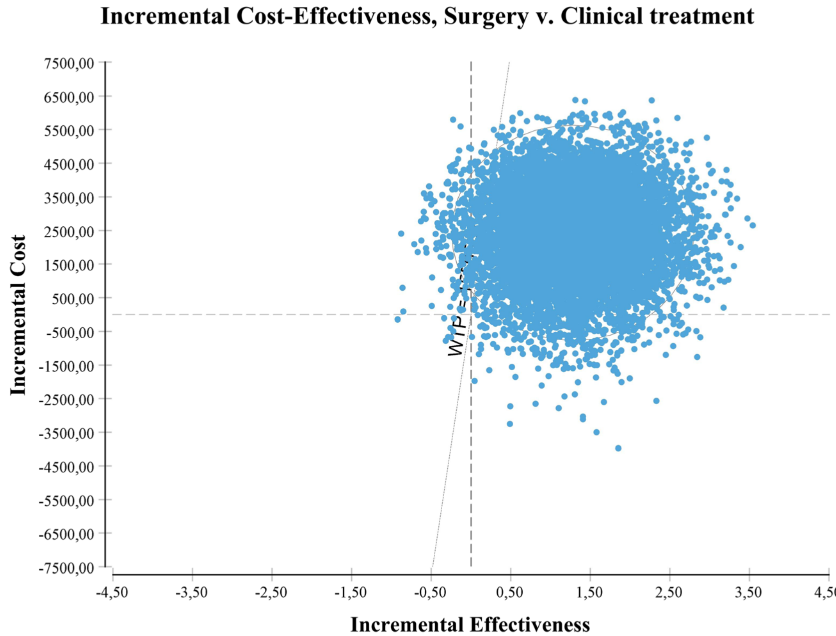

Fig. 4 Cost-effectiveness acceptability plan in severely obese patients without diabetes

for 30.5% of total procedures performed in four different regions in the world (USA/Canada, Europe, Latin/South America, and Asia/Pacific) [7]. Brazil is the country with the highest number of procedures in the region. Cost-effectiveness models are tools to decision-making and can further help to tackle with problems like obesity. Nevertheless, thus far, only developed countries have presented cost-effectiveness models of bariatric surgery for severe obesity [43].

It is worth mentioning the association between surgical skills and better or adverse outcomes after bariatric surgery. Hereupon, we have to consider the direct influence of the surgeon learning curve on operative outcomes [47]. In Brazil, high-complexity services are offered in a standardized manner, only in registered hospitals that develop specialized diagnostic and therapeutic support [48]. The results presented might be related to the years of experience and the growing number of bariatric surgeries performed by Brazilian specialized centers [5, 49].

Our study has some limitations. Every decision analytic model is a simplification of a health care system. The current surgical results may differ from the international study that provided the major outcomes inputs [8, 9, 11–13]. Compared to the private health care system, our conservative approach to estimating health care resources, such as lower medication prices and surgical costs according to the amounts reimbursed by the government, may underestimate the cost-effectiveness ratio. The analysis did not account for other obesity-related comorbidities such as stroke, heart failure, peripheral arterial disease, sleep apnea, cancer, and musculoskeletal disorders, and then it could undervalue the clinical benefits of surgery. Only two surgery complications (cholecystectomy and incisional hernia) were included in the model and did not consider for the possibility of other long-term surgery complications and clinical complications due to vitamin and iron deficiencies.

Brazil has no explicit value for a cost-effectiveness threshold in the public health system [50], which drives our choice for the WHO recommendations [38]. In addition, the current discussion about the use of GDP-based thresholds in decision-making processes [51] implies more conservative recommendations.

The development of this comprehensive decision analytic model for GBP surgery is a remarkable advance and can be further used for appropriate resources and decision-making processes. As many health care systems are operating under significant budget constraints, it is important to ensure that health interventions are cost-effective, i.e., reduce the cost of care or provide relevant clinical benefits for the money spent. Like all other health interventions, bariatric surgery must be evaluated from an economic perspective to support decision-making about the appropriateness of fund allocation for this service.

This economic evaluation demonstrated that GBP surgery is a cost-effective intervention for the treatment of severe obesity compared to clinical treatment in the perspective of public health system, showing a potential to reduce the risk of obesity-related conditions at 10 years at a reasonable cost, especially in the population with diabetes.

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Author Contribution LRB, DVA, and ENS conceived and designed the study; PRZ, MQR, and RPA performed the data collection and preliminary analysis; MGC developed the model and performed the statistical analysis; and LRB, RPA, and MQR wrote the draft manuscript. All authors revised and approved the manuscript.

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Compliance with Ethical Standards

Conflicts of Interest RPA received government grants to carry out the study. Authors RPA, LRB, DAV, MQR, RPA, ENS, PRZ, and CCM declare that they do not have any conflicts of interest. The study received funds for data monitoring and statistical analysis. The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The Research Ethics Committees of each institution approved this study and approved on the Brazil Platform for clinical trials with their related numbers: HSL/PUCRS (1.488.130), IEDE (855.012), and UERJ (731.209).

Consent Statement Informed consent was obtained from all individual participants included in the study.

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