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ECONOMICS AND POLICY IN DIABETES (AA BAIG AND N LAITEERAPONG, SECTION EDITORS)

Economics and Policy in Bariatric Surgery

Thomas J. Hoerger[1]

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Abstract
Purpose of Review The purpose of this review is to provide current synthesis of the evidence on the cost-effectiveness of bariatric surgery for persons with diabetes.
Recent Findings Virtually, every study that has evaluated the cost-effectiveness of bariatric surgery for persons who are obese and have type 2 diabetes has concluded that surgery is cost-effective. A few studies outside the USA found that surgery is cost-saving. Currently, most but not all US insurers cover bariatric surgery in persons with type 2 diabetes and BMI ≥ 35 kg/m^2.
Summary Bariatric surgery is a cost-effective treatment for persons with type 2 diabetes and BMI ≥ 35 kg/m^2. There is interest in extending surgery to persons with diabetes and lower BMI; the cost-effectiveness of treating these individuals with bariatric surgery should be explored. Despite the potential benefits, not all obese or overweight persons with diabetes will choose surgery.

Keywords Bariatric surgery · Diabetes · Cost-effectiveness

Introduction

Bariatric surgery is a common surgical approach, costing $15,000–$25,000, that produces significant weight loss in overweight and obese individuals. Beyond weight loss, the surgery may produce health benefits, including diabetes remission, reduction of cardiovascular events, and improved quality of life. Because of its costs and associated risks and the large number of obese Americans who are potentially eligible for bariatric surgery, researchers and policymakers are interested in whether and for whom bariatric surgery is cost-effective. This review evaluates the evidence on the cost-effectiveness of bariatric surgery for persons with diabetes, discusses implications for policy, and identifies remaining challenges.

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✉ Thomas J. Hoerger
tjh@rti.org

[1] Public Health Economics Program, RTI International, 3040 Cornwallis Road, Research Triangle Park, Durham, NC 27709, USA

What Is in a Name?

Bariatric surgery is formally defined as "surgical procedures performed on the stomach or intestines to induce weight loss" [1]. As the definition suggests, the original focus of the surgery was on weight loss, particularly for individuals who are severely obese. In recent years, many surgeons have preferred the term "metabolic surgery," focusing on the effects of surgery on diabetes and other metabolic conditions [2]. From one perspective, the choice of terminology may seem somewhat arbitrary because both terms cover the same set of surgical procedures. More subtly, "metabolic surgery" changes the emphasis from weight loss to avoiding diabetes complications and other disease outcomes, potentially opening the way for surgery in individuals at lower weights. Although the focus of this review is on diabetes, I will primarily use the more common "bariatric surgery" term in this review.

Types of Surgery and US Incidence

Currently, nearly all bariatric surgery is performed laparoscopically. In 2017, an estimated 228,000 bariatric surgeries were performed in the USA, with the most-common

procedures being sleeve gastrectomy (SG, 59.4%) and Roux-en-Y gastric bypass (RYGB, 17.8%). Laparoscopic adjustable gastric banding (LAGB), which was performed as frequently as RYGB in 2011, has become less popular, accounting for only 2.8% of procedures in 2017, whereas SG's share of procedures has more than tripled since 2011 [3].

Of the common US procedures, RYGB is the most complex, with a surgeon creating a small stomach pouch, bypassing the rest of the stomach, dividing the small intestine, and attaching the divided intestine to the small stomach pouch. SG is less complex; much of the stomach is removed, reducing its capacity, but the stomach's connection to the small intestine is untouched. In LAGB, an adjustable band is placed around the stomach and can be adjusted to restrict the flow of food into the stomach. Because it requires no physiological changes, LAGB is less complex than RYGB and SG and can be reversed. However, it produces lower weight loss than the other procedures, and the bands may need to be replaced.

Outcomes

Risks

Like all invasive procedures, bariatric surgery carries a small risk of death and a higher probability of complications. The overall risk of dying during bariatric surgery is 0.1 to 0.5% [4••]. This risk is small enough to have a relatively small effect in cost-effectiveness analyses; doubling the risk does not appreciably change the cost-effectiveness ratio. Other complications are more common, including infection and blood clots (all procedures), poor nutrition (all procedures), leaking of the sleeve (SG), dumping syndrome (RYGB), and replacement or removal (LAGB). Revisional surgery is sometimes needed, accounting for 14% of bariatric surgeries in 2017. Because revisional surgery is costly, these surgeries should be accounted for in cost-effectiveness studies.

Weight Loss

Weight loss associated with bariatric surgery may be reported as change in weight (in pounds or kilograms), reduction in body mass index (BMI), percent total weight loss, or percent excess weight loss. Reporting all measures can help account for differences in patients' weight before surgery [5]. A recent systematic review of bariatric surgery studies with at least 10 years of patient follow-up reported excess weight loss of 56.7% for RYGB (17 studies), 45.9% for LAGB (17 studies), and 58.3% for SG (only two studies) [6••].

Diabetes Remission

In patients with diabetes, bariatric surgery may lead to complete remission (normal glucose measurements in the absence of antidiabetic medications), partial remission (absence of antidiabetic medications with elevated, but still subdiabetic glucose), and improvement (reductions in medication), based on standardized definitions [5]. Recurrence of diabetes may occur over time. Remission and recurrence should be incorporated within cost-effectiveness modeling. Remission will lead to cost savings for medications and may delay progression of diabetes complications, whereas recurrence will put an end to those savings and delays.

A meta-analysis comparing diabetes remission/improvement rates between surgery and medical/lifestyle interventions in randomized (non-blinded) clinical trials reported an odds ratio of 8.45 in favor of surgery. Remission/improvement rates for the surgical groups in the studies ranged from 28 to 90%, with a median of 50%, whereas the highest rate for the medical/lifestyle groups was 23% [4••]. Mean HbA1c in the surgical groups was 1.14 percentage points lower than in the medical/lifestyle groups. Long-term recurrence rates may occur in 34 to 50% of persons who initially achieve remission [7].

Improvements in Other Diseases

A pair of studies on a large matched cohort found that patients with severe obesity (BMI > 35) and diabetes who underwent bariatric surgery experienced significantly lower rates of microvascular (diabetic retinopathy, neuropathy, or nephropathy) and macrovascular (coronary artery disease or cerebrovascular events) events than matched patients who did not receive surgery. The hazard rates for bariatric surgery were 0.41 for microvascular events and 0.60 for macrovascular events [8•, 9•].

Costs

In a review of 23 cost analyses, the average cost of an initial bariatric surgery procedure was $14,389 in 2016 U.S. dollars [10, 11]. Limiting the sample to US studies increased the average cost to $15,772. The review noted that the analyses did not apply a uniform cycle of care, so it was difficult to ascertain whether the estimates included pre-surgery costs (e.g., participation in a supervised weight loss program, psychological testing) or post-surgery costs for nutritional supplements or complications. In a study that included costs 1 month before and 2 months after surgery, the total cost was estimated at $20,000 to $24,000 [12].

Cost-Effectiveness

Most cost-effectiveness studies of bariatric surgery in persons with diabetes model the short- and long-term impacts of surgery on costs and outcomes. Modeling is necessary because the health benefits from delaying or preventing diabetes complications and the cost savings from reduced antidiabetic medications accrue slowly over time compared with the immediate, high cost of surgery. Modeling requires making assumptions about the long-term impact of surgery, usually by extrapolating from short-term clinical studies. For example, in a cost-effectiveness study of newly diagnosed diabetes patients, Hoerger et al. [13] assumed that gastric bypass led to an 80.3% diabetes remission rate and an annual recurrence rate of 8.3%, small reductions in blood pressure and cholesterol, and a large reduction in BMI. Costs of RYGB in the year of the surgery were assumed to be $23,000, with subsequent surgery-related costs declining from $3000 in year 2 to $600 by year 6. The model simulated diabetes complications, assuming that progression of diabetes complications was slowed during diabetes remission. The model projected complications, costs, and quality-adjusted life years (QALYs) over patients' remaining lifetime. The incremental cost-effectiveness ratio (ICER) was calculated as the incremental cost of surgery divided by the incremental QALYs associated with surgery.

Many studies have estimated the cost-effectiveness of bariatric surgery in severely obese patients. In a systematic review of economic evaluations of bariatric surgery, lifestyle interventions, and medications, Avenell and colleagues examined 43 analyses in 27 studies that looked at bariatric surgery; some of the studies considered more than one type of surgery [14••]. The calculated ICERs were compared to a threshold of £20,000 (approximately $26,000) per QALY often applied in the UK in the assessment of new drugs. There is no formal threshold for cost-effectiveness in the USA; $50,000 per QALY is often cited as the cutoff for cost-effectiveness, although some economists have argued that this cutoff is too low [15].

In the Avenell review, bariatric surgery was considered cost-effective in all 43 analyses and was cost-saving (reduced costs and increased QALYs) in ten of the analyses. None of the analyses that found cost savings were based on the US. costs and utilization. Avenell and colleagues note that the reviewed studies may understate the cost of surgery-related complications and fail to account for weight regain after surgery. To address these issues, they construct their own cost-effectiveness model of bariatric surgery in the UK. They calculate that bariatric surgery has an ICER of £11,648 per QALY. Although not cost-saving, this estimate falls within the range of ICERs in the review and provides further evidence that bariatric surgery is cost-effective.

A pair of US studies not included in the review by Avenell and colleagues concluded that bariatric surgery in obese patients would reduce expenditures within 2–4 years [16] or 5–10 years [12]. Unlike modeling studies, these studies focused on observed expenditures for individuals who did or did not receive bariatric surgery. The challenge in these expenditure-based studies was matching a group of bariatric surgery patients with a comparison group of similar individuals who were eligible for but did not undergo bariatric surgery. Subsequent studies using the expenditure approach and arguably more-appropriate matching methods did not find that bariatric surgery reduced spending [17, 18]. In some ways, discussion about whether bariatric surgery ultimately reduces health expenditures (i.e., is cost-saving) distracts from the more-relevant issue of cost-effectiveness. Most health interventions increase overall health expenditures; the relevant question is whether the resulting health benefits—lowered mortality, reduced morbidity, and improved quality of life—are worth the added expenditures.

The systematic review by Avenell and colleagues includes analyses for all persons with severe obesity (BMI of ≥ 35 kg/m^2), not just individuals with diabetes. Several studies have focused exclusively on persons with diabetes (Table 1). The table also includes diabetes subgroup analyses from two recent studies that focused on severely obese patients.

In the three US studies, the ICERs range from $7000 to $22,000 per QALY; outside the USA, bariatric surgery may be cost-saving, possibly because the costs of surgery are lower than in the USA. In the Table 1 studies, the ICERs were most sensitive to the direct improvement in quality of life per unit of BMI reduction, follow-up surgery costs, the cost of diabetes medications, the duration of diabetes remission, and the time horizon for the study. The ICERs were not sensitive to changes in the perioperative mortality rate.

Notably, one of the studies estimates the cost-effectiveness of LAGB for persons with diabetes and BMI between 25.0 and 29.9 kg/m^2 [25••]. This weight category represents a new target for metabolic surgery, focusing more on the benefits from diabetes remission than on the weight loss that is achievable for overweight (as opposed to obese) individuals. The study finds that the ICER depends on how long the surgery's effects on weight, HbA1c, blood pressure, and cholesterol persist. The ICERs are greater than $90,000 if the health benefits persist for 2 years, $52,000 for 5 years, $29,000 for 10 years, and $22,000 for 15 years. The study has limitations; it does not model gradual relapse to diabetes, and it assumes that the direct effects of a 1-BMI point weight loss on quality of life are the same for overweight individuals and for obese individuals. Nevertheless, the study raises the possibility that bariatric surgery may be cost-effective for overweight persons with diabetes. More research on this issue is needed.

Table 1 ICER of bariatric surgery for persons with diabetes

First author (year)	Country	Type of surgery	Diabetes population	Year, currency	Published ICER (per QALY)
Hoerger (2010) [13]	USA	RYGB, adjustable bands	BMI ≥ 35, newly diagnosed or established	2005 $US	RYGB, new patients $7000 RYGB, established patients $11,000 Banding, new patients $11,000 Banding, established patients $13,000
Ackroyd (2006) [19]	France, Germany, UK	RYGB or adjustable band		2005 pounds	£1517 (UK), cost-saving in France, Germany
Anselmino (2009) [20]	Austria, Italy, Spain	RYGB or adjustable band	BMI ≥ 35, newly diagnosed or established	2009 euros	€1246 (Italy), 2664 (Spain), cost-saving in Italy
Ikramuddin (2009) [21]	USA	RYGB	BMI ≥ 30	2007 $US	$21,973
Keating (2009) [22]	Australia	Adjustable band	BMI ≥ 30	2006 $AU	Cost-saving; 1 AU = 0.74 USD
Pollock (2013) [23]	UK	Adjustable band	BMI ≥ 30	2012 pounds	£3602
Borisenko (2015) [24]	Sweden	RYGB, adjustable band, or sleeve gastrectomy	BMI ≥ 33 (diabetes subgroup)	2012 euros	Cost-saving
Wentworth (2017) [25••]	USA	Adjustable band	Overweight, not obese (BMI 25 to 30 kg/m^2)	2015 $US	$22,000
Gulliford (2017) [26]	UK	RYGB, adjustable band, sleeve gastrectomy	BMI ≥ 40 (diabetes subgroup)	2013 pounds	£6176

Guidelines for Bariatric Surgery

Based on evidence of the effectiveness of bariatric surgery in persons with diabetes, a global consortium of diabetes, surgical, and medical organizations has ratified and endorsed guidelines for bariatric/metabolic surgery in patients with type 2 diabetes. The key guidelines state the following:

> Metabolic surgery is recommended as an option to treat T2D in patients with the following conditions:
>
> - Class III obesity (BMI > 40 kg/m^2), regardless of the level of glycemic control or complexity of glucose-lowering regimens.
> - Class II obesity (BMI 35.0–39.9 kg/m^2) with inadequately controlled hyperglycemia despite lifestyle and optimal medical therapy.
>
> Metabolic surgery should also be considered to be an option to treat T2D in patients with class I obesity (BMI 30.0–34.9 kg/m^2) and inadequately controlled hyperglycemia despite optimal medical treatment by either oral or injectable medications (including insulin) [4••].

From a cost-effectiveness perspective, the guidelines raise several questions for future research. First, is bariatric surgery cost-effective for individuals with inadequately controlled diabetes who have class-1 obesity (BMI 30.0–34.9 kg/m^2) or are overweight (BMI 25.0–29.9 kg/m^2)? Most previous cost-effectiveness studies (with the exception of Wentworth and colleagues [25••]) have focused on individuals with higher BMI and a good share of the modeled QALY benefit in these individuals comes from a direct improvement in quality of life associated with a reduction in BMI. If individuals have a lower pre-surgery weight, their absolute change in BMI—and the resulting direct quality of life effect—will likely be smaller. Surgery may still lead to diabetes remission and fewer diabetes complications in the future, but will the resulting long-run improvements be enough for surgery to be cost-effective?

Second, is bariatric surgery for adolescents with type 2 diabetes cost-effective? The prevalence of type 2 diabetes among adolescents in the USA has been rising [27]. A few studies that examined the effect of bariatric surgery in adolescents found promising results for weight loss and diabetes remission in the short-run [28, 29]. However, the studies have not been long enough to assess long-run outcomes. Consequently, citing the lack of evidence, the guidelines do not currently make a recommendation about bariatric surgery for adolescents with diabetes. If future studies show that weight loss and diabetes remission are as persistent for adolescents as for adults, cost-effectiveness models will likely show that ICERs for adolescents are at least as cost-effective as for adults, because adolescents have a longer time horizon to benefit from the surgery.

Third, which bariatric surgery procedure is most cost-effective for patients with type 2 diabetes? Although some studies have compared RYGB and LAGB, there has not yet been a conclusive cost-effectiveness analysis of RYGB and SG, which is now the most-common form of bariatric surgery in the USA. A relative lack of evidence on long-term outcomes of SG has limited comparisons of the two procedures. Because patients have heterogeneous preferences over the different characteristics of the two procedures, patients benefit from having more than one procedure to choose from. RYGB may offer slightly more weight loss than SG, but it is a more-complex procedure; it costs more, and it has a greater risk of surgical complications and nutritional shortfalls. Different patients will value these characteristics differently.

Fourth, if bariatric surgery is an effective and cost-effective treatment for patients with diabetes, does it have a role to play in preventing diabetes? Previous cost-effectiveness studies have not focused directly on this issue. Including prevention or delay of diabetes onset in cost-effectiveness models will improve the overall cost-effectiveness of bariatric surgery relative to usual care, but lifestyle interventions may be a less expensive and more cost-effective approach to diabetes prevention as a specific strategy. For example, the Diabetes Prevention Program (DPP) produces a diabetes risk reduction of 58% over 3 years in overweight and obese persons with impaired glucose tolerance and elevated fasting glucose [30]. Although bariatric surgery would produce larger weight loss and less weight regain than the DPP, it costs much more than a lifestyle intervention and, even in the high-risk DPP population, the annual probability of diabetes onset was only about 10%. Therefore, there is less immediate payoff in terms of averted diabetes costs and improved quality of life for prevention than there is for treatment of patients who already have diabetes.

Insurance Coverage for Bariatric Surgery

Currently, Medicare, Medicaid, and most but not all private US insurance companies cover bariatric surgery for individuals with BMI ≥ 40 kg/m^2 or with BMI ≥ 35 kg/m^2 and one or more obesity-related conditions, including diabetes. Beneficiaries need to meet additional conditions for coverage, typically including participation in a physician-supervised weight loss program for at least 3–6 months, psychological testing, and an understanding of and commitment to follow necessary nutrition and behavioral changes following surgery. Some surgeons have challenged the requirement for attendance in a weight-loss program, noting that few patients lose substantial amounts of weight in such a program and that attendance delays the benefits of surgery. From an economist's perspective, attending the program may demonstrate that a participant is serious about and committed to the behavioral changes necessary post-surgery.

Conclusion

The evidence strongly suggests that bariatric surgery is a cost-effective treatment for type 2 diabetes. With guidelines for diabetes treatment from major organizations such as the American Diabetes Association recommending bariatric surgery for obese individuals with diabetes [31•], the incidence of surgery will likely increase, and surgery may be performed at lower BMI levels. Although this will pose some budget challenges due to its costs, bariatric surgery will reduce the burden of diabetes at a reasonable cost.

Compliance with Ethical Standards

Conflicts of Interest The author declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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31.• American Diabetes Association. Obesity management for the treatment of type 2 diabetes: standards of medical care in diabetes-2019. Diabetes Care. 2019;42(Suppl 1):S81–S9. https://doi.org/10.2337/dc19-S008 **This publication includes the U.S. guidelines recommending bariatric surgery for obese persons with type 2 diabetes.**