ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

Bariatric Surgery for Adults With Class I Obesity and Difficult-to-Manage Type 2 Diabetes

A Health Technology Assessment

DECEMBER 2023

Ontario Health

Key Messages

What Is This Health Technology Assessment About?

Type 2 diabetes is a chronic metabolic condition in which the body is either unable to make enough insulin or it becomes resistant to the insulin it makes, resulting in elevated blood glucose levels – which is called *hyperglycemia*. Current treatments for adults with type 2 diabetes are designed to help them prevent hyperglycemia with medical management (medication, exercise, and nutritional counselling), but for some people who also have class I obesity (a body mass index between 30 and 35 kg/m^2), keeping blood glucose levels within a healthy range can still be challenging.

Bariatric surgery is any procedure that modifies the stomach or intestines to limit the amount of food that can be consumed or restrict the digestion of food, with the purpose of helping the person to lose weight to reduce health risks.

This health technology assessment looked at how safe, effective, and cost-effective bariatric surgery is for adults with class I obesity and difficult-to-manage type 2 diabetes. It also looked at the budget impact of publicly funding bariatric surgery in this population and at the experiences, preferences, and values of people with obesity and difficult-to-manage type 2 diabetes.

What Did This Health Technology Assessment Find?

Bariatric surgery may help adults with class I obesity and difficult-to-manage type 2 diabetes lose weight, depend less on (or no longer require) medication to control their blood glucose level, and have a better quality of life compared with medical management alone. While bariatric surgery carries additional risk of postsurgical complications, the risks are similar to those observed in people with class II and III obesity who undergo bariatric surgery.

Although bariatric surgery costs more than current usual care – medical management – it may be cost-effective in the long term because it improves quality-adjusted life-years. The cost-effectiveness of bariatric surgery is sensitive to whether the clinical benefits of weight loss and diabetes remission are achieved. We estimate that publicly funding bariatric surgery for people with class I obesity and difficult-to-manage type 2 diabetes in Ontario over the next 5 years would cost an additional $7.63 million.

People with obesity and type 2 diabetes who had undergone bariatric surgery reported improved physical health, mental health, and quality of life. People with obesity and type 2 diabetes saw bariatric surgery as a positive treatment option but also felt that equitable access should be a requirement of implementation.

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Abstract

Background

Many individuals with type 2 diabetes are classified as either overweight or obese. A patient may be described as having difficult-to-manage type 2 diabetes if their HbA1c levels remain above recommended target levels, despite efforts to treat it with lifestyle changes and pharmacotherapy. Bariatric surgery refers to procedures that modify the gastrointestinal tract. In patients with class II or III obesity, bariatric surgery has resulted in substantial weight loss, improved quality of life, reduced mortality risk, and resolution of type 2 diabetes. There is some evidence suggesting these outcomes may also be possible for patients with class I obesity as well. We conducted a health technology assessment of bariatric surgery for adults with class I obesity and difficult-to-manage type 2 diabetes, which included an evaluation of effectiveness, safety, cost-effectiveness, the budget impact of publicly funding bariatric surgery, and patient preferences and values.

Methods

We performed a systematic clinical literature review. We assessed the risk of bias of each included study, using the Cochrane Risk of Bias tool for randomized controlled trials, the Risk of Bias in Non-randomized Studies – of Interventions (ROBINS-I) tool for cohort studies, and the Risk of Bias in Systematic Reviews (ROBIS) tool for systematic reviews; we assessed the quality of the body of evidence according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. We performed a systematic economic literature review and conducted a cost–utility analysis of bariatric surgery in comparison with nonsurgical usual care over a lifetime horizon from a public payer perspective. We also analyzed the budget impact of publicly funding bariatric surgery for adults with class I obesity and difficult-to-manage type 2 diabetes in Ontario. To contextualize the potential value of bariatric surgery, we spoke with people with obesity and type 2 diabetes who had undergone or were considering this procedure.

Results

We included 14 studies in the clinical evidence review. There were large increases in diabetes remission rates (GRADE: Low to Very low) and large reductions in body mass index (GRADE: Low to Very low) with bariatric surgery than with medical management. Bariatric surgery may also reduce the use of medications for type 2 diabetes (GRADE: Low) and may improve quality of life for people with class I obesity and difficult-to-manage type 2 diabetes compared with medical management. (GRADE: Low)

Our economic evidence review included 5 cost-effectiveness studies; none were conducted in a Canadian setting, and 4 were considered partially applicable to our research question. Most studies found bariatric surgery to be cost-effective compared to standard care for patients with class I obesity and type 2 diabetes; however, the applicability of these results to the Ontario context is uncertain due to potential differences in clinical practice, resource utilization, and unit costs.

Our primary economic evaluation found that over a lifetime horizon, bariatric surgery was more costly (incremental cost: $8,151 per person) but also more effective than current usual care (led to a 0.339 quality-adjusted life-year [QALY] gain per person). The cost increase was driven by costs associated with surgery (before, after, and during surgery), and the QALY gain was due to life-years

gained. Results were sensitive to the bariatric surgery cost and assumptions regarding its long-term benefits with respect to weight loss and diabetes remission.

Publicly funding 50 bariatric surgeries in year 1, and gradually increasing to 250 surgeries in year 5, for people with class I obesity and difficult-to-manage type 2 diabetes would lead to budget increases of $0.55 million in year 1 to $2.45 million in year 5, for a total of $7.63 million over 5 years.

The people with obesity and type 2 diabetes with whom we spoke reported that bariatric surgery was generally seen as a positive treatment option, and those who had undergone the procedure reported positively on its value as a treatment to manage their weight and diabetes.

Conclusions

For adults with class I obesity and difficult-to-manage type 2 diabetes, bariatric surgery may be more clinically effective and cost-effective than medical management. Compared with medical management in people with class I obesity and difficult-to-manage type 2 diabetes, bariatric surgery may result in large increases in diabetes remission rates, large reductions in BMI, and reduced medication use for type 2 diabetes, improved quality of life. Over a lifetime horizon, bariatric surgery led to a cost increase and QALY gain. Bariatric surgery can result in postsurgical complications that are not faced by those receiving medical management. The cost-effectiveness of bariatric surgery depends on its long-term impacts on obesity-related and diabetes-related complications, which could be uncertain.

Our budget impact analysis suggests that publicly funding bariatric surgery in Ontario for people with class I obesity and difficult-to-manage type 2 diabetes would lead to a budget increase of $7.63 million over 5 years.

For people with obesity and type 2 diabetes, bariatric surgery was seen as a potential positive treatment option to manage their weight and diabetes.

Table of Contents

List of Tables

List of Figures

Objective

This health technology assessment evaluates the effectiveness, safety, and cost-effectiveness of bariatric surgery for adults with class I obesity and difficult-to-manage type 2 diabetes. It also evaluates the budget impact of publicly funding bariatric surgery in this population and the experiences, preferences, and values of people with class I obesity and type 2 diabetes.

Background

Health Condition

Obesity

Obesity is a chronic health condition in which excess fat accumulates – influenced by genetic, environmental, metabolic, and behavioural factors – in a person's body to the point of increasing their health risks.[1] Obesity is associated with higher risk of several chronic conditions, including hypertension, cardiovascular disease, certain types of cancer, and type 2 diabetes. People living with obesity also face increased stigma and poorer mental health.[2]

Body mass index (BMI) is a commonly used measure to estimate body fat that is calculated using the ratio of a person's weight in kilograms to height in metres squared. In 1995, the National Institutes of Health (NIH) convened an expert panel on the identification, evaluation, and treatment of overweight and obesity in adults and published clinical practice guidelines that are still widely used today.[3] They adopted the World Health Organization's BMI classification criteria (Table 1), which defines obesity as a BMI of 30 kg/m^2 or greater.[3]

Table 1: Body Mass Index Classification

Classification	BMI, kg/m^2
Underweight	< 18.5
Normal	18.5–24.9
Overweight	25.0–29.9
Obesity	≥ 30
Class I obesity	30.0–34.9
Class II obesity	35.0–39.9
Class II obesity	≥ 40

Abbreviations: BMI, body mass index.
Source: Expert Panel on the Identification, Evaluation, and Treatment of Overweight in Adults, 1998.[3]

Type 2 Diabetes

Type 2 diabetes is a chronic metabolic condition in which the body is either unable to make enough insulin or becomes resistant to the insulin it makes, resulting in elevated blood glucose levels (which is called *hyperglycemia*).[4]

Type 2 diabetes and obesity are linked to one another. Risk factors for type 2 diabetes include obesity, physical inactivity, lower socioeconomic status, increased age, family history, and ethnicity. Many people with type 2 diabetes have BMI values that are classified as either overweight or obese. Obesity is associated with a 7-fold increase in the risk of developing type 2 diabetes.[5] Fat distribution is a better predictor of type 2 diabetes than BMI, and an increased waist-to-hip ratio can indicate impaired fat storage. Fat deposits in the liver, muscles, and pancreas can contribute to developing type 2 diabetes, by impairing islet beta-cell function, which results in lower insulin production and insulin resistance.[5,6] Weight loss restores insulin sensitivity and beta-cell function, because less fat is stored in the liver, muscles, and pancreas.[7] While the mechanisms linking obesity and type 2 diabetes are not fully understood, it is believed to be associated with the development of insulin resistance caused by the increased circulation of fatty acids, glycerol, hormones, and proinflammatory cytokines from adipose tissue due to impaired fat storage capacity from weight gain, with possible contribution from increased associated inflammation.[5,8]

Type 2 diabetes is diagnosed using a hemoglobin A1c (HbA1c) test, which measures the proportion of glycated hemoglobin – a good estimate of blood glucose levels over the previous 2 to 3 months. An adult is diagnosed with type 2 diabetes if their HbA1c level is 6.5% or higher.[9] A patient's type 2 diabetes may be described as *difficult-to-manage* if their HbA1c level exceeds the recommended target level , despite efforts to treat it with lifestyle changes and medication. The recommended target level for HbA1c is 7%.[10]

Clinical Need and Population of Interest

Approximately 1 in 4 Canadians are living with obesity.[11] Although data from Statistics Canada and the Canadian Community Health Survey showed that the prevalence of class I obesity (BMI 30–35 kg/m^2) in Canada increased from 5% in 1985 to 14% in 2016, Twells et al[12] noted that the estimates were likely low because they were based on self-reported data, and people tend to underreport their weight. For example, obesity rates calculated using self-reported data were approximately 5% lower than those calculated using measured data, both in 2005 and 2016.

Approximately 3.1 million Canadians were estimated to have class I obesity in 2014. Of these, 60% reported having 1 or more obesity-related comorbidities (including type 2 diabetes).[13] However, the prevalence of class I obesity with difficult-to-manage type 2 diabetes in Canada is unclear.

In Ontario, the prevalence of diabetes overall is estimated to be 8%, with type 2 diabetes comprising 90% of these cases. The complications associated with diabetes account for an estimated 39% of heart attacks, 35% of strokes, 53% of renal failure, and 69% of limb amputations in Ontario.[4,14] The prevalence of class I obesity with difficult-to-manage type 2 diabetes in Ontario is also unclear.

Current Treatment Options

Standard care for people with obesity and type 2 diabetes is broadly referred to as *medical management* – the aim is to help people with obesity and type 2 diabetes reduce future health risk by keeping their blood glucose levels within a healthy range and by reducing their body fat percentage. Elevated HbA1c levels may be managed through health behaviour or lifestyle interventions that can help them modify their diet and be more active in order to lose weight.[15] Psychological and behaviour change interventions can also be used alongside lifestyle interventions.[16] These types of supports involve a collaborative approach between the physician and patient, allowing the patient to choose realistic goals, self-monitor behaviours, and problem-solve through setbacks to ensure that sustainable changes are being made. These initial medical management approaches would be facilitated by the patient's primary care physician.

Primary care physicians may consider prescribing medication to lower blood glucose levels to patients whose HbA1c levels are very high, who cannot lose weight, whose blood glucose levels are difficult to keep within a healthy range with diet and exercise, or who have increased cardiovascular risk factors. Both antidiabetic and antiobesity medications may be prescribed. Typically, metformin is the first-line therapy, but other agents such as glucagon-like peptide 1 receptor (GLP1R) agonists, sodium-glucose co-transporter 2 (SGLT2) inhibitors, and insulin may also be considered. Obesity medications such as liraglutide, naltrexone/bupropion combinations, and orlistat are used less frequently due to their high cost. Obesity medications do not usually help patients achieve the level of weight loss achieved by bariatric surgery and, therefore, do not usually help to improve glycemia and other obesity-related comorbidities, though some newer obesity medications (such as semaglutide and tirzepatide) have shown promise.[17,18]

Patients with difficult-to-manage type 2 diabetes may be referred to an endocrinologist, if blood glucose levels remain high despite medication, changes to diet, and exercise. In Ontario, patients may also be referred to a bariatric medical program, which involves a year-long intensive program led by an interdisciplinary team of clinicians, social workers, nurses, and dieticians. The focus of these programs is providing nonsurgical treatment for obesity and obesity-related health conditions, safe weight management, and healthy lifestyle changes.

Bariatric surgery is only considered after all other nonsurgical treatment options have been exhausted. Currently, if a patient with class I obesity and difficult-to-manage type 2 diabetes would like to consider bariatric surgery, it is only available to them through private clinics in Ontario where they must pay out of pocket to access alternative procedures that are not publicly funded.

Health Service Under Review

Bariatric surgery refers to various elective surgical weight loss procedures that involve modifications to the gastrointestinal tract.[13] It is also commonly referred to as metabolic surgery, given that it can be used to treat metabolic conditions like type 2 diabetes by inducing changes in glycemic control and appetite that are independent of weight loss.[19,20]

Numerous studies have demonstrated that bariatric surgery has resulted in substantial weight loss, resolution of comorbidities (particularly type 2 diabetes), improved quality of life, and reduced mortality risk in patients with class II or III obesity, with some evidence supporting this for class I obesity as well.[13,21-24] There are multiple mediators thought to be linked to the beneficial effects of bariatric surgery on type 2 diabetes. Weight loss associated with significant caloric restriction after surgery largely explains this effect.[25,26] Some weight loss–independent factors may also contribute to improved glycemia.[27] After bariatric surgery, when undigested food moves from the stomach to small intestine, it can lead to improved insulin sensitivity through a rapid increase of incretin levels, which may result in increased insulin production and improved beta-cell function.[27,28] Additionally, some believe that postsurgery changes to bile acid composition, gut microbiota, and metabolic activity of brown adipose tissue may also contribute to the beneficial effects that lead to type 2 diabetes remission.[27,28] Based on 1991 NIH guidelines, bariatric surgery is recommended in patients with class III obesity or class II obesity with comorbidities.[29] However, a 2023 statement from the American Society for Metabolic and Bariatric

Surgery and the International Federation for the Surgery of Obesity and Metabolic Disorders recommends considering bariatric surgery for people with class I obesity and metabolic disease (including type 2 diabetes) who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.[30] This is in agreement with the 2020 Obesity Canada guidelines,[31] which also recommend considering bariatric surgery in patients with poorly controlled type 2 diabetes and class I obesity despite optimal medical management.

There are several types of bariatric surgery, and the techniques and procedures used have evolved considerably over time.[31] The choice of surgery for a patient is made in consultation with a multidisciplinary team after an extensive work-up process.[32] Surgeries can be restrictive (i.e., limiting the volume of food intake), malabsorptive (i.e., limiting the absorption of nutrients), or both. Most bariatric procedures are now done laparoscopically (96% in 2012–2013), unless the complexity of the case does not allow for this.[13,31] In Ontario, surgeries that are currently publicly funded for people with class III obesity or people with class II obesity and comorbidities are Roux-en-Y gastric bypass, sleeve gastrectomy, biliopancreatic diversion with duodenal switch, and single anastomosis duodeno-ileal bypass with sleeve gastrectomy.

Roux-en-Y Gastric Bypass

The Roux-en-Y gastric bypass is both restrictive and malabsorptive in nature. It involves creating a small pouch using the top of the stomach to limit the volume of food and connecting it directly to the lower portion of the small intestine, so that food bypasses most of the stomach and the first part of the small intestine, minimizing the amount of nutrients absorbed.[31]

Sleeve Gastrectomy

Sleeve gastrectomy (also known as gastric sleeve) is mainly a restrictive procedure. It involves removing approximately 80% to 85% of the stomach, leaving only a sleeve-like tube from the esophagus to the duodenum.[31]

Biliopancreatic Diversion With Duodenal Switch

Biliopancreatic diversion with duodenal switch is a more complex, 2-part procedure that is both restrictive and malabsorptive in nature. The first part of the procedure is a sleeve gastrectomy, which is then followed by connecting the end of the intestine to the duodenum, bypassing the majority of the intestines.[31] Due to its complexity, this procedure is less commonly performed.

Single Anastomosis Duodeno-ileal Bypass With Sleeve Gastrectomy

Single anastomosis duodeno-ileal bypass with sleeve gastrectomy is a simplified version of the biliopancreatic diversion with duodenal switch procedure, which involves creating only 1 surgical connection in the intestines instead of 2 surgical connections.

Ontario, Canadian, and International Context

Ontario

In Ontario, bariatric surgery is publicly funded for patients with BMI 40 kg/m^2 or greater or with BMI 35 kg/m^2 or greater and 1 or more diagnosed comorbidities.[32] The provincial government currently funds up to 4,000 bariatric surgeries in Ontario per year. The Ontario Bariatric Network is a collaborative network that provides comprehensive medical and surgical bariatric services across the province. It comprises 10 bariatric Centres of Excellence (Thunder Bay, Sudbury, Ottawa, Kingston, Hamilton, Guelph, London, and 3 in Toronto) and 1 regional testing and assessment centre (Windsor).

Currently, eligibility criteria for bariatric surgery in Ontario is as follows[32]:

- Physician referral required
- Aged 18 years or older
- BMI 40 kg/m^2 and greater or BMI between 35 and 39.9 kg/m^2 with 1 or more of the following comorbidities: type 2 diabetes, coronary artery disease, hypertension, sleep apnea, or gastroesophageal reflux disease

Patients are ineligible for bariatric surgery in Ontario if they have[32]:

- Current drug or alcohol dependency (within 6 months of referral)
- History of smoking (within 6 months of referral)
- Recent life-threatening cancer (within last 2 years), or
- Untreated or inadequately treated psychiatric illness
- Class I obesity (BMI 30–34.9 kg/m^2)

The Roux-en-Y gastric bypass is the primary surgery used in the public health care system in Ontario (85% of bariatric surgeries in 2014). Sleeve gastrectomy is typically only performed in very specific scenarios (14% of bariatric surgeries in 2014), when Roux-en-Y bypass is not feasible (i.e., BMI > 60 kg/m^2, and presence of intraabdominal adhesions from previous surgery).[13,33] Similarly, biliopancreatic diversion is not commonly performed (1% of bariatric surgeries in 2014) due to its complexity and increased risk of complications.[13,33] Single anastomosis duodeno-ileal bypass with sleeve gastrectomy is currently being considered as a new surgical option in Ontario (D. Harris, email communication, June 2022).

Prior to 2009–2010, adjustable gastric banding was a commonly offered procedure in Ontario. Adjustable gastric banding involves the placing of an adjustable band around the upper portion of the stomach, which is tightened to restrict the amount of food intake. However, this procedure has fallen out of favour due to evidence of increased complications and weight regain after long-term follow-up compared with other bariatric surgeries.[31]

In 2019, wait times for publicly funded bariatric surgery in Ontario were estimated to be up to 2 years from referral to initial consultation, then 6 to 12 months from consultation to surgery.[34]

Patients can also access bariatric surgery through private clinics in Ontario for approximately $16,000 to $20,000 out of pocket. Procedures offered include sleeve gastrectomy, mini gastric bypass, and adjustable gastric banding, which are not publicly funded in Ontario. These clinics can offer bariatric surgery to patients with class I obesity because this type of surgery is not currently publicly funded for this population. Private clinics tend to have shorter wait times compared to the public health care system. However, patients with postsurgical complications from procedures done at private clinics may require treatment in the public system.

Canada

Bariatric surgery is currently available in all 10 provinces but not in the 3 territories for patients with class III obesity or class II obesity with comorbidities.[13,34,35] From point of referral to bariatric surgery, there may be lengthy wait-times in Canada – anywhere from 1.5 to 9 years (depending on the province), including the time needed to complete the surgical work-up process.[34]

International

Internationally, bariatric surgery is a widely accepted treatment for class III obesity and class II obesity with comorbidities.[35] In 2016, the second Diabetes Surgery Summit convened to review evidence and developed consensus guidelines that suggest considering bariatric surgery for the treatment of difficult-to-manage type 2 diabetes in patients with class I obesity.[19] These guidelines[19] have been endorsed by more than 45 professional medical and surgical societies across the world and are also consistent with recently published Obesity Canada guidelines.[31]

In 2023, the American Society for Metabolic and Bariatric Disorders and the International Federation for the Surgery of Obesity and Metabolic Disorders published a statement recommending that bariatric surgery be considered for people with class I obesity and type 2 diabetes, who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.[30]

Equity Context

The use of BMI alone to define obesity and obesity-related health risks has faced criticism[1]; BMI is not an accurate measure of adiposity as it cannot differentiate between body fat and muscle mass, leading to the misclassification of individuals who are athletes, body builders, pregnant, nursing, or older than 65 years. In addition, BMI-based obesity cut-offs were developed based on evidence from primarily White populations. Studies have shown that these cut-offs tend to underestimate the health risks faced by different races and ethnicities (such as East Asian, South Asian, Indigenous, and Black populations) because of biological differences in where individuals carry their weight.[36,37] Importantly, because the BMI threshold at which fat is abnormally deposited in the liver, muscles, and pancreas, resulting in risk of type 2 diabetes, is lower in people of South Asian and East Asian descent, recent recommendations from the American Society for Metabolic and Bariatric Surgery and the International Federation for the Surgery of Obesity and Metabolic Disorders to update NIH guidelines advocate for considering bariatric surgery if BMI is 27.5 or higher for Asian populations.[30] The National Institute for Health and Care Excellence (NICE) clinical guidelines on management of obesity also recommend the use of lower BMI cut-offs for individuals with type 2 diabetes and Asian family background (i.e., BMI 27.5–32.5 kg/m^2 for class I obesity), when considering eligibility for bariatric surgery.[38] Adjusted BMI-based cut-offs for bariatric surgery may support equitable treatment outcomes for people who face increased health risks at lower BMIs and who may benefit from it.

Expert Consultation

We engaged with experts in the specialty areas of bariatric surgery, endocrinology, internal medicine, and family medicine to help inform our understanding of aspects of the health technology and our methodologies and to contextualize the evidence.

PROSPERO Registration

This health technology assessment has been registered in PROSPERO, the international prospective register of systematic reviews (CRD #42022352537), available at crd.york.ac.uk/PROSPERO.

Clinical Evidence

Research Question

What are the clinical effectiveness and safety of bariatric surgery compared with medical management in adults with class I obesity and difficult-to-manage type 2 diabetes, with or without other comorbidities?

Methods

Clinical Literature Search

We performed a clinical literature search on July 4, 2022, to retrieve studies published from January 1, 2012, until the search date. Relevant studies published before 2012 were identified through a systematic review conducted by the Agency for Healthcare Research and Quality (AHRQ).[39] We used the Ovid interface in the following databases: MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and the National Health Service Economic Evaluation Database.

A medical librarian developed the search strategies using controlled vocabulary (e.g., Medical Subject Headings) and relevant keywords. Methodological filters were used to limit retrieval to systematic reviews, meta-analyses, health technology assessments, and randomized controlled trials. We also applied an observational studies filter.[40] The final search strategy was peer-reviewed using the PRESS Checklist.[41]

We created database auto-alerts in MEDLINE and Embase and monitored them until November 21, 2022. We also performed a targeted grey literature search of the International HTA Database, health technology assessment organizations and regulatory agencies websites, and clinical trial and systematic review registries, following a standard list of sites developed internally. See Appendix 1 for our literature search strategies, including all search terms.

Eligibility Criteria

Studies

Inclusion Criteria

- English-language full-text publications
- Studies published since January 1, 2012, for the database search (studies published before 2012 were identified using the AHRQ systematic review)
- Randomized controlled trials, comparative observational studies, health technology assessments, systematic reviews

Exclusion Criteria

- Animal and in vitro studies
- Nonsystematic reviews, narrative reviews, conference abstracts, editorials, letters, case reports, and commentaries
- Noncomparative observational studies

Participants

Inclusion Criteria

- Participants included adults (≥ 18 years of age) with class I obesity and difficult-to-manage type 2 diabetes (with or without other obesity-related comorbidities):
  - Difficult-to-manage type 2 diabetes is defined as having elevated glycated hemoglobin (HbA1c) levels (> 7%) despite optimal medical management efforts (medication and lifestyle changes)
  - Class I obesity is defined as:
    - Having a body mass index (BMI) of 30 to 34.9 kg/m^2, or
    - Individuals with BMI less than 30 kg/m^2 who may be eligible for surgery if they face higher health risks at lower BMIs based on their race or ethnicity

Exclusion Criteria

- Adults with class II or III obesity (BMI ≥ 35 kg/m^2), adults with class I obesity without type 2 diabetes, and individuals under the age of 18 years

Interventions

Inclusion Criteria

- One of the following bariatric surgeries:
  - Roux-en-Y gastric bypass
  - Sleeve gastrectomy
  - Biliopancreatic diversion with duodenal switch
  - Single anastomosis with duodeno-ileal bypass with sleeve gastrectomy

Exclusion Criteria

- Any nonsurgical interventions and any bariatric surgery procedures not currently conducted within the public health system in Ontario, including gastric band, adjustable laparoscopic gastric banding, mini gastric bypass, gastroplasty, jejuno-ileal bypass

Comparators

- Medical management of type 2 diabetes with class I obesity (i.e., nonsurgical interventions), which can include 1 or more of the following:
    - Dietary modification
    - Increased physical activity
    - Medications for diabetes
    - Medications for obesity

Outcome Measures

- Complete diabetes remission (as defined by study authors)
- Partial diabetes remission (as defined by study authors)
- Weight loss over time (change in BMI)
- Medication use for type 2 diabetes
- Quality of life
- Reduction in other obesity-related comorbidities (e.g., remission of hypertension, cardiovascular disease, gastroesophageal reflux disease, sleep apnea, etc.)
- Complications (e.g., readmission to hospital, reoperation, anastomotic leak, mortality, malnutrition, marginal ulcer, anastomotic stenosis, internal hernia, chronic pain)

Literature Screening

Two reviewers independently screened 20% of the titles and abstracts using Covidence[42] and resolved any conflicts through discussion. A single reviewer then completed the remaining title and abstract screening and obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. Next, a single reviewer examined the full-text articles and selected studies eligible for inclusion. A single reviewer also examined reference lists for any additional relevant studies not identified through the search.

Data Extraction

We used a data form to extract relevant data on study characteristics and risk-of-bias items including:

- Source (e.g., citation information, study type)
- Methods (e.g., study design, study duration and years, participant allocation, allocation sequence concealment, blinding, reporting of missing data, reporting of outcomes, whether the study compared 2 or more groups)
- Outcomes (e.g., outcomes measured, number of participants for each outcome, number of participants missing for each outcome, outcome definition and source of information, unit of measurement, upper and lower limits [for scales], timepoints at which the outcomes were assessed)

Equity Considerations

We planned to use PROGRESS-Plus,[43] a health equity framework recommended by the Campbell and Cochrane Equity Methods Group, to explore potential inequities for this health technology assessment, if subgroup analyses on the relevant variables were available. Factors that may lead to disadvantage or inequities in the framework include place of residence, race or ethnicity, culture or language, gender or sex, disability, occupation, religion, education, socioeconomic status, social capital, and other key characteristics that stratify health opportunities and outcomes.

Statistical Analysis

We did not undertake a meta-analysis due to the clinical heterogeneity of the included studies, and summarized the results descriptively using tables.[44,45] Mean change from baseline and the associated standard deviations were calculated if they were not reported in the primary studies.

Critical Appraisal of Evidence

We assessed risk of bias using the Cochrane Risk of Bias tool[46] for randomized controlled trials, the Risk of Bias in Non-randomized Studies – of Interventions (ROBINS-I)[47] for observational cohort studies, and the Risk of Bias in Systematic Reviews (ROBIS)[48] for the systematic review.

We evaluated the quality of the body of evidence for each outcome according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Handbook.[49] The body of evidence from observational studies was assessed according to guidance on the use of ROBINS-I when conducting GRADE assessments,[50] based on the following considerations: risk of bias, inconsistency, indirectness, imprecision, and publication bias. The overall rating reflects our certainty in the evidence.

Results

Clinical Literature Search

The database search of the clinical literature published between January 1, 2012, and July 4, 2022, yielded 3,485 citations after duplicates were removed, including grey literature searches. We identified no additional eligible studies from other sources, including database alerts (monitored until November

21, 2022). In total, we identified 15 studies (4 randomized controlled trials,[51-54] 2 companion reports,[55,56] 8 comparative observational studies,[57-64] and 1 systematic review[39]) that met our inclusion criteria.

We leveraged the systematic review by the AHRQ[39] to identify any studies published before 2012 that met our inclusion criteria. While overall this review explored a broader scope than that of our health technology assessment, their second key question aligned with our criterion of identifying studies directly comparing bariatric surgery to nonsurgical treatments for type 2 diabetes in patients with class I obesity. They included 3 randomized controlled trials; however, they noted that none of these randomized controlled trials enrolled patients exclusively with class I obesity (i.e., they expanded their inclusion criteria) and 2 assessed gastric banding procedures. Therefore, none of these randomized controlled trials met our eligibility criteria. They also included 2 small comparative observational studies[63,64] that did meet our eligibility criteria and were included in our clinical review. (Appendix 3 contains a list of selected studies excluded after full-text review; Figure 1 presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses [PRISMA] flow diagram for the clinical literature search.)

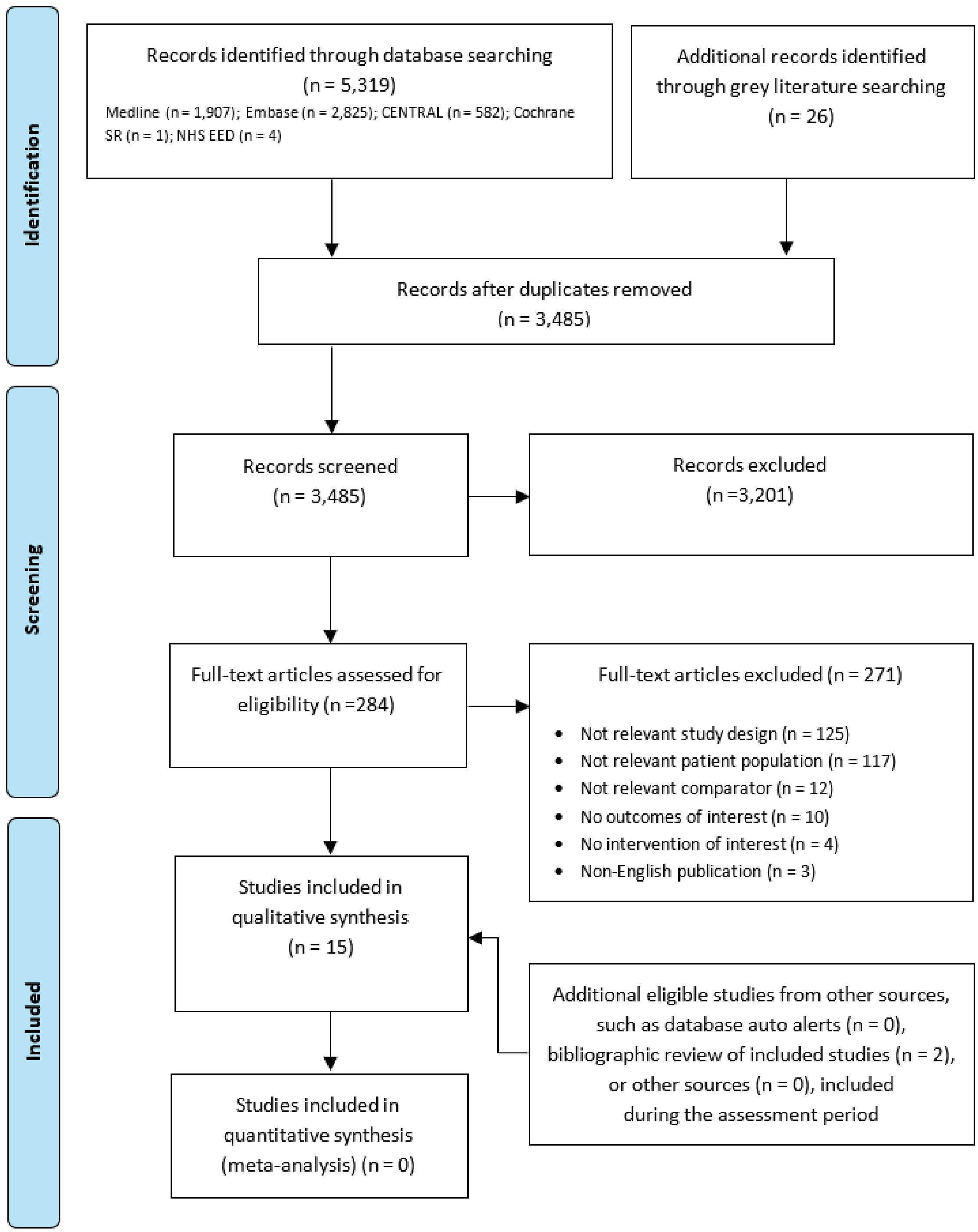

Figure 1: PRISMA Flow Diagram – Clinical Search Strategy

PRISMA flow diagram showing the clinical search strategy. The database search of the clinical literature yielded 5,319 citations published between January 1, 2012, and July 4, 2022. We identified 26 additional eligible studies from other sources. After removing duplicates, we screened the abstracts of 3,485 studies and excluded 3,201. We assessed the full texts of 284 articles and excluded a further 271. In the end, we included 15 articles in the qualitative synthesis.

Abbreviations: NHS EED, National Health Service Economic Evaluation Database; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses; SR, systematic review.

Source: Adapted from Page et al.[65]

Characteristics of Included Studies

The included studies comprised 4 randomized controlled trials[51-54] and 8 comparative observational studies,[57-64] in addition to 1 systematic review[39] (Table 2). The studies were conducted in Brazil, China, India, Italy, Portugal, Singapore, Taiwan, and the United States. Of the included studies, 7 assessed Roux-en-Y gastric bypass alone (3 randomized controlled trials[52,53,54] and 4 observational studies[57,59,61,64]), and 3 studies assessed bariatric surgery as a combination of Roux-en-Y gastric bypass and sleeve gastrectomy (1 randomized controlled trial,[51] which also had a small proportion of gastric banding, and 2 observational studies[58,62]), and 2 studies[63,60] assessed biliopancreatic diversion with duodenal switch. We found no studies assessing single anastomosis duodeno-ileal bypass with sleeve gastrectomy in patients with class I obesity and difficult-to-manage type 2 diabetes. None of the included studies conducted subgroup analyses using PROGRESS-Plus variables.

Our comparator of medical management was defined differently across the included studies. Some studies reported more intensive medical management programs, which could involve starting and adjusting medications, tailored counseling for diet and meal planning, and physical activity, while other studies reported various forms of standard medical management or usual care. Across the observational studies, the comparator group was often identified by matching different variables, including BMI, age, gender, and diabetes duration.

Table 2: Characteristics of Studies Included in the Clinical Literature Review

Author, year, country; intervention and comparator	Study design: Class I obesity BMI, range, kg/m²	Study design: Follow-up, mo	Participants: Sample size, N or n	Participants: BMI, mean (SD), kg/m²	Participants: Age, mean (SD), y	Participants: Sex, % female
Randomized controlled trials						
Cheng et al, 2022,[54] Singapore	27.5–32.5[a]	60	26	—	—	—
I: Bariatric surgery – RYGB			12	29.1 (1.6)	40.0 (10.0)	50
C: Best medical treatment (diabetes medication adjustment and introduction of newer classes of glucose-lowering drugs, tailored meal planning, and diet counselling, advice to increase physical activity)			14	29.7 (1.6)	48.0 (9.0)	30
Cohen et al, 2020,[52] Brazil	30–35	24	100	—	—	—
I: Bariatric surgery – RYGB			51	32.5 (1.9)	52.5 (7.6)	45
C: Standard medical management (according to ADA and EASD guidelines)			49	32.6 (2.1)	50.2 (7.5)	45
Lau et al, 2021,[53] Portugal	30–34.9	12	20	—	—	—
I: Bariatric surgery – RYGB			10	33.6 (1.8)	53.4 (8.8)	50
C: Standard medical management (lifestyle guidelines by ADA and drug therapy)			10	32.0 (1.6)	58.2 (4.7)	30
Parikh et al, 2014,[51] United States	30–35	6[b]	57[c]	—	—	—
I: Bariatric surgery – sleeve, 55%; RYGB, 24%; band, 17%			20	32.8 (1.7)	46.8 (8.4)	79
C: Intensive medical weight management (6 mo of tailored diet counselling, physical activity, self-monitoring, and goal setting; diabetes medication adjustment; physical activity), followed by usual care			24	32.4 (1.8)	53.9 (8.4)	79
Prospective cohort						
Bhandari et al, 2017,[57] India	30–35	12	90	—	—	—
I: Bariatric surgery – RYGB			30	34.2 (0.8)	41.3 (2.3)	50
C1: Liraglutide (GLP1R agonist)			30	32.7 (1.2)	41.8 (3.3)	46.7
C2: SGLT2 inhibitors			30	31.3 (0.9)	41.2 (3.6)	50
Chiellini et al, 2009,[63] Italy	26–33	1	12	—	—	—
I: Bariatric surgery – BPD (using open technique)			5	30.9 (1.1)	48.0 (3.0)	40
C: Low-energy diet (daily energy deficit of 2,090–4,180 kJ/day, calculated as resting energy expenditure × 1.4)			7	30.0 (1.7)	51.0 (3.0)	42.9
Retrospective cohort						
Hsu et al, 2015,[58] Taiwan	27–35	60	351	—	—	—
I: Bariatric surgery – RYGB, 63.5%; sleeve, 36.5%			52	31.0 (2.4)	44.2 (9.5)	78.8
C: Medical treatment (matched based on age, diabetes duration, and baseline BMI)			299	29.1 (2.4)	51.2 (6.4)	51.2

Author, year, country; intervention and comparator	Study design: Class I obesity BMI, range, kg/m²	Study design: Follow-up, mo	Participants: Sample size, N or n	Participants: BMI, mean (SD), kg/m²	Participants: Age, mean (SD), y	Participants: Sex, % female
Ling et al, 2022,[59] China	27.5–32.5[a]	24	213	—	—	—
I: Bariatric surgery – RYGB			71	28.9 (1.7)	47.8 (8.8)	36.7
C: Standard medical treatment (patients received antidiabetic medication according to guidelines for medical treatment; propensity score matching used BMI, gender, age, weight, type 2 diabetes duration, Hba1c, blood pressure, and fasting blood glucose, fasting insulin, fasting C-peptide, and lipid levels)			142	28.5 (2.3)	47.3 (9.9)	30
Papadia et al, 2022,[60] Italy	30–35[d]	120	60	—	—	—
I: Bariatric surgery – BPD			30	28.9 (1.7)	47.8 (8.8)	50
C: Medical treatment (matched based on age, gender, BMI, type 2 diabetes duration)			30	28.5 (2.3)	47.3 (9.9)	30
Scopinaro et al, 2014,[61] Italy	30–34.9	36	47	—	—	—
I: Bariatric surgery – RYGB			20	32.9 (1.5)	57 (42–69)[e]	25
C: Treatment not specified. Type 2 diabetes controls (matched based on gender, age, BMI, diabetes duration, Hba1c level)			27	33.0 (1.6)	57 (50–64)[e]	25.9
Serrot et al, 2011,[64] United States	30–34.9	12	34	—	—	—
I: Bariatric surgery – RYGB			17	34.0 (1.0)	62.0 (12.0)	35.5
C: Medical management (patients receiving care in primary care center may receive counselling for nutrition, weight management, and exercise, in addition to medications for type 2 diabetes)			17	34.6 (0.8)	56.0 (7.0)	76.5
Zhang et al, 2021,[62] China	27.5–32.5	12	99	—	—	—
I: Bariatric surgery – RYGB, 85%; sleeve, 15%			21	29.0 (0.4)	44.2 (9.5)	47.6
C1: Medical management (conventional antidiabetic medication)			32	29.6 (0.2)	51.2 (6.4)	34.4
C2: High-BMI bariatric surgery[f]			46	—	—	—

Abbreviations: ADA, American Diabetes Association; BMI, body mass index; BPD, biliopancreatic diversion; C, comparator; EASD, European Association for the study of diabetes; GLP1R, glucagon-like peptide receptor; HbA1c, glycated hemoglobin; I, intervention; RYGB, Roux-en-Y gastric bypass; SGLT2, sodium-glucose co-transporter 2.

[a]People with BMI = 25–27.5 kg/m² were included if waist circumference ≥ 90 cm (men) or if waist circumference ≥ 85 cm (women).

[b]Horwitz et al, 2016,[56] and Horwitz et al, 2020,[55] were also included for their long-term follow-up data (36 months and 60 months, respectively) for this study.

[c]Authors reported a 23% dropout rate.

[d]People with BMI = 25–30 kg/m² were also included.

[e]Mean (range).

[f]This treatment arm was excluded because it was not an eligible population of interest.

Risk of Bias in the Included Studies

The overall risk of bias in the systematic review[39] was assessed as being high due to concerns about study eligibility criteria, data collection, and quality appraisal (Appendix 2, Table A1). Maggard-Gibbons et al[39] reported that they expanded their prespecified eligibility criteria to include studies that included patients with BMI values greater than 35 kg/m^2, and they did not report whether a quality appraisal was conducted by 2 independent reviewers.

For the 4 randomized controlled trials (Appendix 2, Table A2), there were no concerns related to adequate sequence generation and allocation concealment; while blinding was not possible, it is unlikely to introduce bias for our outcomes of interest. In general, the randomized controlled trials had small sample sizes, which ranged from 20 to 100 participants. There were some concerns about incomplete outcome reporting because 2 of the 4 trials reported dropouts that did not appear to be balanced across groups and the reasons for withdrawal were unclear. One trial was partially supported by funding from a pharmaceutical company, which may be a source of bias. Two long-term follow-up studies broke the initial randomization from the original 6-month randomized controlled trial, as 10 participants crossed over to the bariatric surgery arm.

For the 8 observational studies (Appendix 2, Table A3), there was moderate risk of bias for confounding and study participation selection due to how the comparator group was identified. Many of the studies identified controls through a convenience sample that was matched to the bariatric surgery group based on a few variables such as age, gender, and BMI.

Diabetes Remission

The outcome of diabetes remission was reported by most of the included studies. We found that studies reported complete or partial diabetes remission but used different definitions with different HbA1c or fasting glucose cut-offs that overlapped in some cases. In this report, we have presented the outcomes of complete diabetes remission and partial diabetes remission separately, using the definitions that were reported by the studies.

Complete diabetes remission was reported in 4 randomized controlled trials and 6 observational studies; however, the definition of *diabetes remission* used varied across the included studies (Table 3). In general, 3 of the randomized controlled trials found significantly higher remission rates in those receiving bariatric surgery compared with those receiving various forms of medical management. Remission rates in the studies ranged from 65% at the 6-month follow-up to 38%–42% at the 5-year follow-up for bariatric surgery, compared with 0% at both timepoints in the comparator. The remaining randomized controlled trial[52] reported a difference in diabetes remission between Roux-en-Y gastric bypass and medical management that was not statistically significant (44.5% vs. 24.4%, P = .05). In the observational studies, complete diabetes remission rates ranged from 25% to 100% for bariatric surgery compared with 0% to 3.5% for medical management (Table 3).

The quality of evidence (GRADE) from randomized controlled trials for complete diabetes remission was rated as Low at 6 months, 2 years, and 4 years, downgraded for risk of bias and imprecision, and Very low at 1 year, 3 years, and 5 years, downgraded for risk of bias, indirectness, and imprecision (Appendix 2, Table A4). The quality of evidence from observational studies for complete diabetes remission was rated as Very low at 1 year, downgraded for risk of bias, inconsistency, and indirectness, and Low at 2 years, 3 years, 5 years, and 10 years, downgraded for risk of bias and imprecision (Appendix 2, Table A5).

Table 3: Comparison of Complete Diabetes Remission Rates at Follow-up in Studies With Adults With Class I Obesity and Difficult-to-Manage Type 2 Diabetes – Bariatric Surgery vs. Medical Management

Follow-up timepoint and author, year	Definition of complete type 2 diabetes remission	Remission rate, n/N (%)		
		Bariatric surgery	Medical management	*P* value
Randomized controlled trials				
At 6 mo				
Parikh et al, 2014[51]	Hba1c < 6.5% without the use of glucose-lowering medication	13/20 (65)	0/24 (0)[b]	<.0001
At 1 y				
Lau et al, 2021[59]	Hba1c < 6.5% without the use of glucose-lowering medication	5/8 (62.5)[a]	0/10 (0)	.007
Cheng et al, 2022[54]	Hba1c ≤ 6% (≤ 42 mmol/mol) without the use of glucose-lowering medication	6/12 (50)[a]	0/14 (0)	
At 2 y				
Cohen et al, 2020[52]	Hba1c ≤ 6% (≤ 42 mmol/mol)	23/51 (44.5)[a,c]	12/49 (24.4)[d]	.051
Cheng et al, 2022[54]	Hba1c ≤ 6% (≤ 42 mmol/mol) without the use of glucose-lowering medication, since 1 y timepoint	3/12 (25)[a]	0/14 (0)	NR
At 3 y				
Horwitz et al, 2016[56]	Hba1c < 6.5% without the use of glucose-lowering medication	19/30 (63)	0/14 (0)	NR
Cheng et al, 2022[54]	Hba1c ≤ 6% (≤ 42 mmol/mol) without the use of glucose-lowering medication, since 1 y timepoint	4/12 (33.3)[a]	0/14 (0)	
At 4 y				
Cheng et al, 2022[54]	Hba1c ≤ 6% (≤ 42 mmol/mol) without the use of glucose-lowering medication, since 1 y timepoint	5/12 (41.7)[a]	0/14 (0)	NR
At 5 y				
Horwitz et al, 2020[55]	Definition not specified	11/29 (38)	0/14 (0)	.0081
Cheng et al, 2022[54]	Hba1c ≤ 6% (≤ 42 mmol/mol) without the use of glucose-lowering medication	5/12 (41.7)[a]	0/14 (0)	NR
Observational studies				
At 1 y				
Scopinaro et al, 2014[61]	Hba1c ≤ 6%	5/20 (25)[a]	0/27 (0)	<.05
Bhandari et al, 2017[57]	Hba1c < 6.5%	30/30 (100)[a]	NR[e]	NR
Zhang et al, 2021[62]	Hba1c < 6.5% and FBG < 5.6 without the use of glucose-lowering medication for 1 y	7/21 (33.3)	0/32 (0)	.002
	Hba1c < 6.5% without the use of glucose-lowering medication for 1 y	15/21 (72.2)	0/32 (0)	<.001
Ling et al, 2022[59]	Hba1c < 6% and FPG < 5.6 without medication for 1 y	30/71 (42.3)	5/142 (3.5)	<.001

Follow-up timepoint and author, year	Definition of complete type 2 diabetes remission	Remission rate, n/N (%)		
		Bariatric surgery	Medical management	*P* value
At 2 y				
Scopinaro et al, 2014[61]	Hba1c ≤ 6%	7/20 (35)[a]	0/27 (0)	<.01
At 3 y				
Scopinaro et al, 2014[61]	Hba1c ≤ 6%	4/20 (25)[a]	0/27 (0)	<.05
At 5 y				
Hsu et al, 2015[58]	Hba1c < 6% without the use of glucose-lowering medication	18/50 (36)	3/250 (1.2)	<.001
At 10 y				
Papadia et al, 2022[60]	Serum FBG concentration steadily lower than 125 mg/mL, with free diet and without the use of glucose-lowering medication	14/30 (48)[f]	0/30 (0)	NR

Abbreviations: FBG, fasting blood glucose; FPG, fasting plasma glucose; HbA1c, glycated hemoglobin; NR, not reported.

[a]Roux-en-Y gastric bypass.

[b]Intensive medical management.

[c]95% CI 29.6–59.2.

[d]95% CI 12.3–36.7.

[e]Remission rate not reported for comparator arms (liraglutide and sodium-glucose co-transporter 2 inhibitor groups); it is only stated that remission was better in the bariatric surgery groups.

[f]Biliopancreatic diversion.

Partial diabetes remission was reported in 1 randomized controlled trial[52] and 2 observational studies[58,59]; definitions of *partial diabetes remission* varied across studies (Table 4). At 2 years of follow-up, Cohen et al[52] reported partial remission in 70.9% of patients randomly assigned to Roux-en-Y gastric bypass surgery compared with 24.4% of patients receiving standard medical management, but this difference in percentages was not statistically significant. However, in both observational studies, partial remission rates were significantly better for the bariatric surgery groups (range 18.3%–28.0%) than those for the medical management groups (range 1.6%–4.2%) at 1 and 5 years of follow-up.

The quality of evidence (GRADE) from the randomized controlled trial was rated as Low at 2 years, downgraded for risk of bias and imprecision (Appendix 2, Table A4). The quality of evidence (GRADE) from the observational studies was rated as Low at 1 and 5 years, downgraded for risk of bias and imprecision (Appendix 2, Table A5).

Table 4: Comparison of Partial Diabetes Remission Rates at Follow-up in Studies With Adults With Class I Obesity and Difficult-to-Manage Type 2 Diabetes – Bariatric Surgery vs. Medical Management

Follow-up timepoint and author, year	Definition of partial type 2 diabetes remission	Remission rate, n/N (%)		
		Bariatric surgery	Medical management	*P* value
Randomized controlled trial				
At 2 y				
Cohen et al, 2020[52]	Hba1c < 6.5%	36/51 (70.9)[a,b]	12/49 (24.4)[c]	.05
Observational studies				
At 1 y				
Ling et al, 2022[59]	Hba1c < 6.5% and FPG < 6.9 without medication for 1 y	13/71 (18.3)[a]	6/142 (4.2)	<.001
At 5 y				
Hsu et al, 2015[58]	Hba1c = 6%–6.5% without medication	14/50 (28)	4/250 (1.6)	<.001

Abbreviations: FPG, fasting plasma glucose; HbA1c, glycated hemoglobin.
[a]Roux-en-Y gastric bypass.
[b]95% CI, 57.8–84.0.
[c]95% CI, 36.4–64.8.

Change in Body Mass Index

Change in BMI from baseline was reported in 4 randomized controlled trials and 8 observational studies (Table 5). Overall, in the randomized controlled trials, there were reductions in BMI ranging from −5 to −9 kg/m^2 for bariatric surgery and from −0.8 to −3.4 kg/m^2 for medical management. Notably, reductions in BMI appeared to remain after up to 5 years of follow-up. Similarly, in the observational studies, reductions in BMI ranged from −1 to −8.8 kg/m^2 for bariatric surgery and from 2.4 to −1.8 kg/m^2 for medical management at 1 month to 10 years of follow-up.

The quality of evidence (GRADE) from randomized controlled trials was rated as Low at 6 months and 4 years, downgraded for risk of bias and imprecision (Appendix 2, Table A6), and Very low at 1, 2, 3, and 5 years, downgraded for risk of bias, indirectness, and imprecision. The quality of evidence (GRADE) from observational studies at 1, 3, 5, and 10 years was rated as Low, downgraded for risk of bias, imprecision, or indirectness, and 2 years was rated as Very low, downgraded for risk of bias, indirectness, and imprecision (Appendix 2, Table A7).

Table 5: Comparison of BMI and Change in BMI at Follow-up in Studies With Adults With Class I Obesity and Difficult-to-Manage Type 2 Diabetes – Bariatric Surgery vs. Medical Management

Follow-up timepoint and author, year	BMI at follow-up, mean (95% CI), kg/m²			Change in BMI from baseline, mean (95% CI), kg/m²		
	Bariatric surgery	Medical management	*P* value	Bariatric surgery	Medical management	*P* value
Randomized controlled trials						
At 6 mo						
Parikh et al, 2014[51]	25.9 (23.4 to 28.4)	31.4 (28.8 to 34.0)[a]	<.0001	−7.0 (−9.6 to −4.4)	−1.0 (−2.5 to 0.5)[a]	<.0001
At 1 y						
Lau et al, 2021[53]	24.6 (21.7 to 27.5)[b]	30.5 (28.9 to 32.1)	<.001	−9.0 (−12.4 to −5.6)[b]	−1.5 (−4.5 to 1.5)	NR
Cheng et al, 2022[54]	NR	NR	NR	−6.0 (−5.4 to −6.6)[b]	−0.8 (−1.1 to −0.5)[a]	<.001
At 2 y						
Cohen et al, 2020[52]	24.3 (23.5 to 25.0)[b]	31.2 (30.5 to 32.0)	<.001	−8.2 (−10.3 to −6.2)[b]	−1.4 (−3.6 to 0.9)	NR
Cheng et al, 2022[54]	NR	NR	NR	−5.1 (−5.7 to −4.4)[b]	−1.0 (−1.3 to −0.7)[a]	<.001
At 3 y						
Horwitz et al, 2016[56]	26.6 (NR)	31.1 (NR)[a]	<.0001	−6.2 (NR)	−1.3 (NR)[a]	NR
Cheng et al, 2022[54]	NR	NR	NR	−5.0 (−5.5 to −4.4)[b]	−1.4 (−1.7 to −1.1)[a]	<.001
At 4 y						
Cheng et al, 2022[54]	NR	NR	NR	−5.0 (−5.6 to −4.5)[b]	−1.3 (−1.5 to −1.0)[a]	<.001
At 5 y						
Horwitz et al, 2020[55]	25.8 (22.7 to 28.9)	28.6 (25.0 to 32.2)[a]	NR	−7.0 (−10.2 to −3.8)	−3.4 (−6.0 to −0.8)[a]	.0007
Cheng et al, 2022[54]	NR	NR	NR	−5.4 (−6.4 to −4.4)[b]	−1.8 (−2.6 to −1.1)[a]	<.001
Observational studies						
At 1 mo						
Chiellini et al, 2009[63]	30.0(29.2 to 30.8)[c]	29.2 (27.4 to 31.0)[d]	NR	−1.0 (−2.4 to 0.4)[c]	−0.8 (−3.3 to 1.7)[d]	NR
At 1 y						
Serrot et al, 2011[64]	25.8 (23.3 to 28.3)[b]	34.3 (32.2 to 36.4)	<.001	−8.8 (−11.4 to −6.2)[b]	0.3 (−2.0 to 2.6)	NR
Scopinaro et al, 2014[61]	24.7 (22.6 to 26.8)[b]	32.6 (30.9 to 34.3)	<.05	−8.2 (−10.8 to −5.6)[b]	−0.4 (−2.7 to 1.9)	NR
Bhandari et al, 2017[57,]	27.4 (26.1 to 28.7)[b]	30.88 (29.7 to 32.0)[e]	NR	−6.7 (−8.1 to −5.2)[b]	−1.8 (−3.4 to −0.2)[e]	NR
	—	31.26 (30.6 to 32.0)[f]	—	—	−0.11 (−1.1 to 0.9)[f]	—
Zhang et al, 2021[62]	22.5 (22.1 to 22.9)	29.6 (29.3 to 29.9)	<.001	−6.5 (−7.1 to −5.9)	0 (−0.4 to 0.4)	NR

Follow-up timepoint and author, year	BMI at follow-up, mean (95% CI), kg/m^2			Change in BMI from baseline, mean (95% CI), kg/m^2		
	Bariatric surgery	Medical management	*P* value	Bariatric surgery	Medical management	*P* value
Ling et al, 2022[59]	24 (21.5 to 26.5)[b]	28.1 (25.6 to 30.6)	<.001	−4.9 (−7.9 to −1.9)[b]	−0.4 (−3.8 to 3.0)	NR
At 2 y						
Scopinaro et al, 2014[61]	25.2 (22.9 to 27.5)[b]	26.0 (23.8 to 28.2)	<.05	−7.7 (−10.4 to −5.0)[b]	−0.3 (−2.6 to 2.0)	NR
Ling et al, 2022[59,b]	25.3 (23.2 to 27.4)[b]	28.0 (25.3 to 30.7)	NR	−3.6 (−6.3 to −0.9)[b]	−0.5 (−4.0 to 3.0)	NR
At 3 y						
Scopinaro et al, 2014[61]	26.0 (23.8 to 28.2)[b]	32.6 (31.2 to 34.0)	<.05	−6.9 (−9.6 to −4.2)[b]	−0.4 (−2.5 to 1.7)	NR
At 5 y						
Hsu et al, 2015[58]	24.5 (21.8 to 27.2)	28.8 (26.2 to 31.4)	NR	−6.5 (−10.1 to −2.9)	−0.3 (−3.8 to 3.2)	<.001
At 10 y						
Papadia et al, 2022[60]	24.9 (22.5 to 27.3)[c]	31.6 (29.0 to 34.2)	NR	−5.7 (−9.5 to −1.9)[c]	2.7 (−1.5 to 6.9)	NR

Abbreviations: BMI, body mass index; CI, confidence interval; NR, not reported.
[a]Intensive medical management.
[b]Roux-en-Y gastric bypass.
[c]Biliopancreatic diversion.
[d]Diet.
[e]Liraglutide.
[f]Sodium-glucose co-transporter 2 inhibitor.

Medication Use for Type 2 Diabetes

Medication use for type 2 diabetes was reported in 3 randomized controlled trials and 6 observational studies (Table 6); however, the definition of *medication use* differed across studies. In the randomized controlled trials, significantly more patients (58%–80%) who underwent bariatric surgery no longer required diabetes medications at 6-month[55] and 5-year[55] follow-ups compared with patients in the medical management group (0%–12%). In addition, at the 3-year[56] follow-up of the former,[51] the mean number of diabetes medications used by patients who had undergone bariatric surgery was significantly lower than that for patients in the medical management group; at the 5-year follow-up insulin use was also lower in the bariatric surgery group than in the medical management group. Cohen et al[52] reported significant differences between Roux-en-Y gastric bypass and standard medical management in the proportions of patients using thiazolidinediones, incretin mimetics, SGLT2 inhibitors, and insulin after 2 years of follow-up.

Three of the observational studies reported that the proportion of patients using any diabetes medication ranged from 20% to 40% in the bariatric surgery group compared with 90.4% to 100% for medical management (with matched control groups) at 1, 5, and 10-year follow-ups.[58,59,60] The proportion of patients not using diabetes medications was significantly higher for bariatric surgery compared with standard medical management (72.2% vs. 0%),[62] and in another study, the proportion of patients using fewer type 2 diabetes medications at 1-year follow-up was significantly higher for Roux-en-Y gastric bypass compared with medical management.[61]

The quality of evidence (GRADE) from the randomized controlled trials was rated as Low, downgraded for risk of bias and imprecision (Appendix 2, Table A8), and the quality of evidence (GRADE) from the observational studies was rated as Low, downgraded for risk of bias and indirectness (Appendix 2, Table A9).

Table 6: Comparison of Diabetes Medication Use at Follow-up in Studies With Adults With Class I Obesity and Difficult-to-Manage Type 2 Diabetes – Bariatric Surgery vs. Medical Management

Follow-up timepoint and author, year	Diabetes medication use definition and group	Baseline	Follow-up	*P* value[a]
Randomized controlled trial				
At 6 mo				
Parikh et al, 2014[51]	Using diabetes medication, n/N (%)			
	Surgery	20/20 (100)	4/20 (20.0)	<.0001
	IMM	24/24 (100)	21/24 (88.0)	
At 2 y				
Cohen et al, 2020[52]	Using biguanides, n/N (%)			
	RYGB	40/51 (78.4)	39/51 (76.1)	.004
	SMM	45/49 (91.8)	48/49 (97.8)	
	Using thiazolidinediones, n/N (%)			
	RYGB	2/51 (3.9)	10/51 (19.6)	<.001
	SMM	4/49 (8.2)	33/49 (67.4)	
	Using incretin mimetics, n/N (%)			
	RYGB	23/51 (45.0)	21/51 (41.3)	<.001
	SMM	13/49 (27.0)	49/49 (100)	
	Using SGLT2 inhibitors, n/N (%)			
	RYGB	2/51 (3.9)	23/51 (45.7)	<.001
	SMM	2/49 (4.1)	44/49 (89.1)	
	Using insulin, n/N (%)			
	RYGB	20/51 (39.2)	6/51 (10.9)	<.001
	SMM	12/49 (24.5)	27/49 (54.3)	
	Using secretagogues, n/N (%)			
	RYGB	21/51 (41.2)	0/51 (0.0)	.495
	SMM	20/49 (40.8)	2/49 (4.3)	
At 3 y				
Horwitz et al, 2016[56]	Number of medications used, mean change			
	Surgery	NA	−1.33	<.0001
	IMM	NA	0.13	
At 5 y				
Horwitz et al, 2020[55]	Using insulin, n/N (%)			
	Surgery	NA	3/29 (10)	.007
	IMM	NA	7/14 (50.0)	
Cheng et al, 2022[54]	Using diabetes medication, n/N (%)			
	RYGB	12/12 (100)	5/12 (42.0)	—
	IMM	14/14 (100)	14/14 (100)	
Observational				
At 1 y				
Serrot et al, 2011[64]	Using fewer type 2 diabetes medications, n/N (%)			

Follow-up timepoint and author, year	Diabetes medication use definition and group	Baseline	Follow-up	*P* value[a]
	RYGB	NA	12/17 (71.0)	<.001
	SMM	NA	1/17 (6.0)	
Ling et al, 2022[58]	Using at least 1 hypoglycemic agent, n/N (%)			
	RYGB	62/71 (87.8)	24/71 (34.1)	<.001
	SMM	137/142 (96.3)	138/142 (97.5)	
Bhandari et al, 2017[57]	Using 1 medication for type 2 diabetes, n/N (%)			
	RYGB	19/30 (63.3)	3/30 (10.0)	—
	Liraglutide	21/30 (70.0)	23/30 (76.6)	
	SGLT2 inhibitors	23/30 (76.6)	19/30 (63.3)	
Zhang et al, 2021[62]	Using diabetes medications, n/N (%)			
	Surgery	18/21 (86)	6/21 (29)	.001
	SMM	32/32 (100)	32/32 (100)	
At 5 y				
Hsu et al, 2015[59]	Using any diabetes medication, n/N (%)			
	Surgery	42/50 (84.6)	10/50 (20.0)	<.001
	Matched control	243/250 (97.3)	226/250 (90.4)	
At 10 y				
Papadia et al, 2022[60]	Using diabetes medications, n/N (%)			
	BPD	30/30 (100)	12/30 (40.0)	<.01
	Matched control	30/30 (100)	30/30 (100)	

Abbreviations: BPD, biliopancreatic diversion; IMM, intensive medical management; NA, not applicable; RYGB, Roux-en-Y gastric bypass; SGLT2, sodium-glucose co-transporter 2; SMM, standard medical management.
[a]Between baseline and follow-up.

Quality of Life

Quality of life was reported in 1 randomized controlled trial that used the Medical Outcome Study 36-item Short-Form survey (Table 7). There were greater improvements in general health, emotional well-being, physical health, physical role functioning, and vitality scores in the Roux-en-Y gastric bypass group than in the standard medical management group after 2 years.[52] The quality of evidence (GRADE) was rated as Low, downgraded for risk of bias and imprecision (Appendix 2, Table A8).

Table 7: Comparison of Quality of Life After 2 Years in Studies With Adults With Class I Obesity and Difficult-to-Manage Type 2 Diabetes – Bariatric Surgery vs. Medical Management

Study	Quality-of-life domain[a]	Score,[b] mean difference between groups (95% CI)	*P* value
Cohen et al, 2020[52] (RCT)	General health	17.9 (10.0–25.7)	<.001
	Emotional well-being	8.9 (0.7–17.2)	.03
	Physical health	19.9 (3.5–36.4)	.02
	Physical role functioning	14.2 (5.1–23.2)	.002
	Vitality	14.4 (6.1–22.7)	.001

Abbreviations: CI, confidence interval; RCT, randomized controlled trial.
[a]Measured using the Medical Outcomes Study 36-item Short-Form Health Survey.
[b]The range for the total possible score for each domain is 0–100.

Other Obesity-Related Comorbidities

Remission of albuminuria and early-stage chronic kidney disease was reported in 1 randomized controlled trial, with higher remission rates in the Roux-en-Y gastric bypass group compared with the standard medical management group at 2 years (Table 8). The quality of evidence was rated as Low, downgraded for risk of bias and imprecision (Appendix 2, Table A8). One observational study reported a reduction in the proportion of patients with hypertension at 5 years; another study reported an increased hypertension remission rate at 1 year (Table 8). The quality of evidence (GRADE) was rated as Low, downgraded for risk of bias and imprecision (Appendix 2, Table A8).

Table 8: Impact on Other Obesity-Related Comorbidities – Bariatric Surgery vs. Medical Management

Author, year (study type)	Measure and group	Estimate	*P* value	Follow-up timepoint
Early-stage chronic kidney disease				
Cohen et al, 2020[52] (RCT)	Remission rate, % (95% CI)		.002	2 y
	RYGB, n=51	81.9 (71.8–92.1)		
	SMM, n=49	48.2 (32.2–64.1)		
Albuminuria				
Cohen et al 2020[52] (RCT)	Remission rate, % (95% CI)		.002	2 y
	RYGB, n=51	81.9 (71.8–92.1)		
	SMM, n=49	48.2 (32.2–64.1)		
Hypertension				
Hsu et al, 2015[58] (observational)	With hypertension, n/N (%)		.001	5 y
	Surgery (baseline; follow-up)	11/50 (21.2); 5/50 (10)		
	Matched control (baseline; follow-up)	62/250 (24.8); 97/250 (38.8)		
Ling et al, 2022[59] (observational)	Remission rate, adjusted OR (95% CI)		.005	1 y
	RYGB, n=71	4.25 (1.48–12.16)		
	SMM, n=142	Reference		

Abbreviations: CI, confidence interval; OR, odds ratio, RCT, randomized controlled trial; RYGB, Roux-en-Y gastric bypass; SMM, standard medical management.

Complications

Across the included randomized controlled trials, the most commonly reported postsurgical complications were readmission or reoperation, dumping syndrome, bezoar gastrojejunostomy (i.e., an obstruction in the digestive tract caused by built-up undigested food material, which is bypassed by creating a direct connection between the stomach to the jejunum), anemia requiring transfusion, and nonspecific abdominal pain (Table 9). Across the included observational cohort studies, the most commonly reported postsurgical complications were unspecified adverse events, bleeding, ulcer, anemia, reoperation, and nutrition and vitamin deficiency (Table 10). No intervention-related deaths were reported across the majority of included studies; however, 1 observational study[60] noted a significantly higher mortality rate after biliopancreatic diversion compared with the matched control group. GRADE assessment on complications was not conducted due to the variability in the types of complications reported across studies for different surgical procedures.

Table 9: Complication Rates for Bariatric Surgery and Medical Management in Studies With Adults With Class I Obesity and Difficult-to-Manage Type 2 Diabetes – Randomized Controlled Trials

Complication	Parikh et al, 2014,[51] n/N (%)		Cohen et al, 2020,[52] n/N (%)		Lau et al, 2021,[53] n/N (%)		Cheng et al, 2022,[54] n/N (%)	
	Surgery	IMM	RYGB	SMM	RYGB	SMM	RYGB	IMM
Intraperitoneal sepsis	NR	NR	NR	NR	NR	NR	1/12 (8.3)	0/14 (0)
Bezoar gastrojejunostomy	NR	NR	NR	NR	NR	NR	2/12 (16.7)	0/14 (0)
Dehydration	1/20 (5)	0/24 (0)	NR	NR	NR	NR	1/12 (8.3)	0/14 (0)
Anemia requiring transfusion	NR	NR	NR	NR	NR	NR	2/12 (16.7)	0/14 (0)
Nonspecific abdominal pain	NR	NR	NR	NR	NR	NR	2/12 (16.7)	0/14 (0)
Dumping syndrome	NR	NR	9/51 (17.6)	0/49 (0)	NR	NR	1/12 (8.3)	0/14 (0)
Dialysis	NR	NR	NR	NR	NR	NR	1/12 (8.3)	0/14 (0)
Mortality	0/20 (0)	0/24 (0)	0/51 (0)	0/49 (0)	NR	NR	0/12 (0)	0/14 (0)
Enterorrhagia	NR	NR	1/51 (2.0)	0/49 (0)	NR	NR	NR	NR
Anastomotic stricture	NR	NR	1/51 (2.0)	0/49 (0)	NR	NR	NR	NR
Gastric pouch leak	NR	NR	1/51 (2.0)	0/49 (0)	NR	NR	NR	NR
Trocar site abscess	1/20 (5)	0/24 (0)	NR	NR	NR	NR	NR	NR
Food impaction causing nausea/vomiting and dehydration/abdominal pain	3/30 (10)[a]	0/14 (0)	NR	NR	NR	NR	NR	NR
Readmitted or underwent reoperation	11/29 (37.9)[a]	0/14 (0)	NR	NR	NR	NR	NR	NR

Abbreviations: IMM, intensive medical management; NR, not reported; RYGB, Roux-en-Y gastric bypass; SMM, standard medical management.

[a]Reported from 2 follow-up studies to this randomized controlled trial – Horwitz 2016[56] and Horwitz 2020.[55]

Table 10: Complication Rates for Bariatric Surgery and Medical Management in Studies With Adults With Class I Obesity and Difficult-to-Manage Type 2 Diabetes – Observational Studies

Complication	Scopinaro et al, 2014,[61] n/N (%)		Hsu et al, 2015,[58] n/N (%)		Bhandari et al, 2017,[57] n/N (%)		Zhang et al, 2021,[62] n/N (%)		Ling et al, 2022,[59] n/N (%)		Papadia et al, 2022,[60] n/N (%)	
	RYGB	MC	Surgery	SMM	RYGB	Liraglutide; SGLT2	Surgery	SMM	RYGB	SMM	BPD	MC
Bleeding	3/20 (15)	0/27 (0)	—	—	—	—	—	—	1/71 (1.4)	0/142 (0)	—	—
Intestinal obstruction due to hernia	1/20 (5)	0/27 (0)	—	—	—	—	—	—	—	—	—	—
Mortality	0/20 (0)	0/27 (0)	1/50 (2)	9/250 (3.6)	—	—	0/21 (0)	0/32 (0)	—	—	2/30 (6.7)[a]	0/30 (0)
End-stage renal disease	—	—	1/50 (2)	2/250 (0.8)	—	—	—	—	—	—	—	—
Ulcer	—	—	—	—	—	—	—	—	8/71 (11.3)	1/142 (0.7)	—	—
Major complications	—	—	—	—	0/30 (0)	0/30 (0); 0/30 (0)	—	—	—	—	—	—
Cholelithiasis	—	—	—	—	—	—	1/21 (4.8)	1/32 (3.1)	—	—	—	—
Anemia	—	—	—	—	—	—	2/21 (9.5)	0/32 (0)	10/71 (14.1)	4/142 (2.8)	—	—
Ferritin deficiency	—	—	—	—	—	—	2/21 (9.5)	0/32 (0)	—	—	—	—
Osteoporosis	—	—	—	—	—	—	2/21 (9.5)	1/32 (3.1)	—	—	—	—
Adverse events	—	—	—	—	—	—	7/21 (33.3)	2/32 (6.3)	36/71 (50.7)	22/142 (15.5)	—	—
Trocar site infection	—	—	—	—	—	—	—	—	2/71 (2.8)	0/142 (0)	—	—
Small bowel obstruction	—	—	—	—	—	—	—	—	2/71 (2.8)	1/142 (0.7)	—	—
Dumping syndrome	—	—	—	—	—	—	—	—	1/71 (1.4)	0/142 (0)	—	—
Cardiovascular (stroke/MI)	—	—	—	—	—	—	—	—	1/71 (1.4)	5/142 (3.5)	—	—
Reoperation for BPD-related complications	—	—	—	—	—	—	—	—	—	—	10/30 (33.3)	0/30 (0)
Incisional hernia	—	—	—	—	—	—	—	—	—	—	2/30 (6.7)	0/30 (0)
Nutrition and vitamin deficiency	—	—	—	—	—	—	—	—	—	—	8/30 (26.7)	0/30 (0)

Abbreviations: BPD, biliopancreatic diversion; MC, matched control; NR, not reported; RYGB, Roux-en-Y gastric bypass; SMM, standard medical management.

[a]Mortality rate was significantly higher in BPD group compared with the matched control (*P* < .001).

Ongoing Studies

We are aware of an ongoing pilot study being conducted in Hamilton, Ontario, that is assessing the effectiveness and safety of bariatric surgery adults with class I obesity and type 2 diabetes.[66]

Discussion

We found evidence from 4 randomized controlled trials (203 participants) assessing the effectiveness and safety of bariatric surgery compared to medical management in individuals with class I obesity and difficult-to-manage type 2 diabetes. However, some comparative evidence from observational cohort studies (n = 8) was also identified. While previous systematic reviews broadened their inclusion criteria to include studies of patients with higher BMI values, we chose to remain consistent with our pre-specified eligibility criteria.[39,67,68] In addition, we chose not to conduct meta-analyses, due to the clinical and methodological heterogeneity in the patient population, follow-up periods, definitions of medical management (i.e., the comparator used), and outcome definitions (diabetes remission, medication use).

In general, bariatric surgery may result in an increase in complete and partial diabetes remission when compared with medical management. Of note, the included studies used different definitions of diabetes remission based on different HbA1c cut-offs, fasting plasma glucose levels, and whether medications were still being used. Bariatric surgery may also result in a reduction in BMI and medication use compared with medical management. These effects seemed to persist with longer periods of follow-up (5 years from 2 randomized controlled trials, and 10 years from an observational study). Quality of life was only reported in 1 study, which demonstrated an improvement after bariatric surgery.

Equity Considerations

A potential equity concern exists with respect to the use of BMI cut-offs to determine eligibility for bariatric surgery. Current cut-offs were developed based on evidence from primarily White populations and tend to underestimate the health risks faced by other ethnicities, including Eastern and South Asian, Indigenous, and Black populations, with lower BMI values (i.e., not classified as obese by current BMI cut-offs [Table 1]) but with increased risks related to their weight and difficult-to-manage type 2 diabetes.[4,36,37,69,70] For example, in 2002, the World Health Organization convened an expert consultation on BMI classifications and acknowledged that having a BMI of 27.5 kg/m^2 or greater in Asian populations could be considered class I obesity.[37]

In our clinical review, 1 randomized controlled trial and 3 observational cohort studies were conducted in East Asian populations, using lower BMI cut-offs for class I obesity, and demonstrated similar improvements in diabetes-related outcomes and BMI to populations using the standard 30–34.9 kg/m^2 BMI cut-off. The current recommendations from the National Institute for Health and Care Excellence (NICE) clinical guidelines on management of obesity indicate that lower BMI cut-offs should be used for individuals with type 2 diabetes and an "Asian family background" (i.e., BMI 27.5–32.5 kg/m^2 for class I obesity), when considering eligibility for bariatric surgery.[38] In addition, a recent statement from the American Society for Metabolic and Bariatric Surgery and the International Federation for the Surgery of Obesity and Metabolic Disorders also recommends the use of lower BMI thresholds in Asian populations (i.e., offer bariatric surgery to those with a BMI of 27.5 kg/m^2 or higher).[30]

Strengths and Limitations

This clinical review was conducted by leveraging an existing systematic review[39] conducted in 2013 to identify studies published before 2012, then conducting a search from 2012 onward, in order to minimize research duplication.

The 4 included randomized controlled trials were each limited by small sample sizes ($N \leq 100$) and risk of bias due to unbalanced attrition across treatment arms, which raised concerns about incomplete outcomes data; 1 study also received partial support from industry funding. In addition, while the randomized controlled trial by Parikh et al[51] had 2 long-term follow-up studies (reporting 3- and 5-year follow-up data), it is important to note that randomization was broken after the initial 6-month trial and some participants from the medical management group crossed over to receive bariatric surgery.

The included observational cohort studies were also limited by small sample sizes (6 of 8 studies had a sample size of less than 100 participants each) and risk of bias concerns due to confounding and study participation selection, which is inherent to this study design.

The small sample sizes limited the ability of these studies to capture the occurrence of rare but severe adverse events after surgery, such as perioperative death and bowel obstruction.

Another limitation was the variability in the definition of medical management, with some studies using more intensive medical management programs (involving tailored management of medications, diet, and physical activity), while other studies reported various forms of standard medical management or usual care.

In addition, we did not identify any published studies comparing bariatric surgery to newer obesity medications such as semaglutide and tirzepatide. While evidence comparing some of these newer options to other obesity medications has shown promise in terms of weight loss and reductions in waist circumference,[17] further research is needed on long-term outcomes and their effectiveness when directly compared with bariatric surgery.

None of the studies was conducted in Ontario or Canada, and therefore it may be difficult to generalize the findings to an Ontario population.

Conclusions

Compared with medical management in people with class I obesity and difficult-to-manage type 2 diabetes, bariatric surgery:

- May result in a large increase in complete diabetes remission rates (GRADE: randomized controlled trials – Low to Very low; observational studies – Low to Very low)
- May result in a large reduction in BMI (GRADE: randomized controlled trials – Low to Very low; observational studies – Low to Very low)
- May result in a reduction in medication use for type 2 diabetes (GRADE: randomized controlled trials – Low; observational studies: Low)
- May result in improved quality of life (GRADE: randomized controlled trials – Low)

- May result in improved remission of obesity-related comorbidities (e.g., albuminuria, early-stage chronic kidney disease, and hypertension) (GRADE: randomized controlled trials – Low; observational studies – Low)
- Bariatric surgery can result in postsurgical complications, which are not faced by those receiving medical management (GRADE not assessed)

Economic Evidence

Research Question

What is the cost-effectiveness of bariatric surgery compared with medical management in adults with class I obesity and difficult-to-manage type 2 diabetes, with or without other comorbidities?

Methods

Economic Literature Search

We performed an economic literature search on July 5, 2022, to retrieve studies published from database inception until the search date. To retrieve relevant studies, we developed a search using the clinical search strategy with an economic and costing filter applied (Appendix 1).

We created database auto-alerts in MEDLINE and Embase, and we monitored them until May 1, 2023. We also performed a targeted grey literature search following a standard list of websites developed internally, which includes the International HTA Database and the Tufts Cost-Effectiveness Analysis Registry.

Eligibility Criteria

Studies

Inclusion Criteria

- English-language full-text publications
- Cost–benefit analyses, cost-effectiveness analyses, cost-minimization analyses, cost–utility analyses, or cost–consequence analysis

Exclusion Criteria

- Studies where the outcomes of interest are not reported or cannot be extracted
- Nonsystematic reviews, editorials, case reports, commentaries, conference abstracts, letters, and unpublished studies
- Noncomparative costing studies and feasibility analyses

Population

Inclusion Criteria

- Adults (≥ 18 years of age) with class I obesity and type 2 diabetes (with or without other obesity-related comorbidities)

- Class I obesity is defined as having a body mass index (BMI) of 30 to 34.9 kg/m^2, or people with a BMI less than 30 kg/m^2 who may be eligible for surgery if they face higher health risks at lower BMIs based on their ethnicity (such as East Asian, South Asian, Indigenous, and Black populations)

Exclusion Criteria

- Adults with class II or III obesity (BMI ≥ 35 kg/m^2), adults with class I obesity without type 2 diabetes, individuals under the age of 18 years

Interventions

Inclusion Criteria

One of the following bariatric surgeries:

- Roux-en-Y gastric bypass
- Sleeve gastrectomy/gastric sleeve
- Biliopancreatic diversion with duodenal switch
- Single anastomosis with duodeno-ileal bypass with sleeve gastrectomy

Exclusion Criteria

- Any nonsurgical interventions and any bariatric surgery procedures not currently conducted within the public health system in Ontario, including gastric band, adjustable laparoscopic gastric banding, mini gastric bypass, gastroplasty, and jejuno-ileal bypass

Outcome Measures

- Costs
- Health outcomes (e.g., quality-adjusted life-years)
- Incremental costs
- Incremental effectiveness
- Incremental cost-effectiveness ratios

Literature Screening

Two reviewers conducted an initial screening of titles and abstracts using Covidence[42] and obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. The 2 reviewers then examined the full-text articles and selected studies for inclusion. Any disagreements between reviewers during screening were resolved by consensus. Reference lists of included studies were also examined for any additional eligible studies not identified through the search.

Data Extraction

We extracted relevant data on study characteristics and outcomes to collect information about the following:

- Sources (e.g., citation information, study type)
- Methods (e.g., study design, analytic technique, perspective, time horizon, population, intervention[s], comparator[s])
- Outcomes (e.g., health outcomes, costs, incremental cost-effectiveness ratios)

Study Applicability and Limitations

We determined the usefulness of each identified study for decision-making by applying a modified quality appraisal checklist for economic evaluations originally developed by the National Institute for Health and Care Excellence (NICE) in the United Kingdom to inform the development of clinical guidelines.[71] We modified the wording of the questions to remove references to guidelines and to make it specific to Ontario. We then assessed the applicability of each study to the research question (directly, partially, or not applicable).

Results

Economic Literature Search

The database search of the economic literature yielded 612 citations published from database inception until July 5, 2022, including grey literature searches and after duplicates were removed. We identified 1 additional eligible study from other sources, including database alerts (monitored until May 1, 2023). In total, we identified 5 studies (4 cost–utility analyses and 1 cost–consequence analysis) that met our inclusion criteria. (Appendix 3 contains a list of selected studies excluded after full-text review. Figure 2 presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses [PRISMA] flow diagram for the economic literature search.)

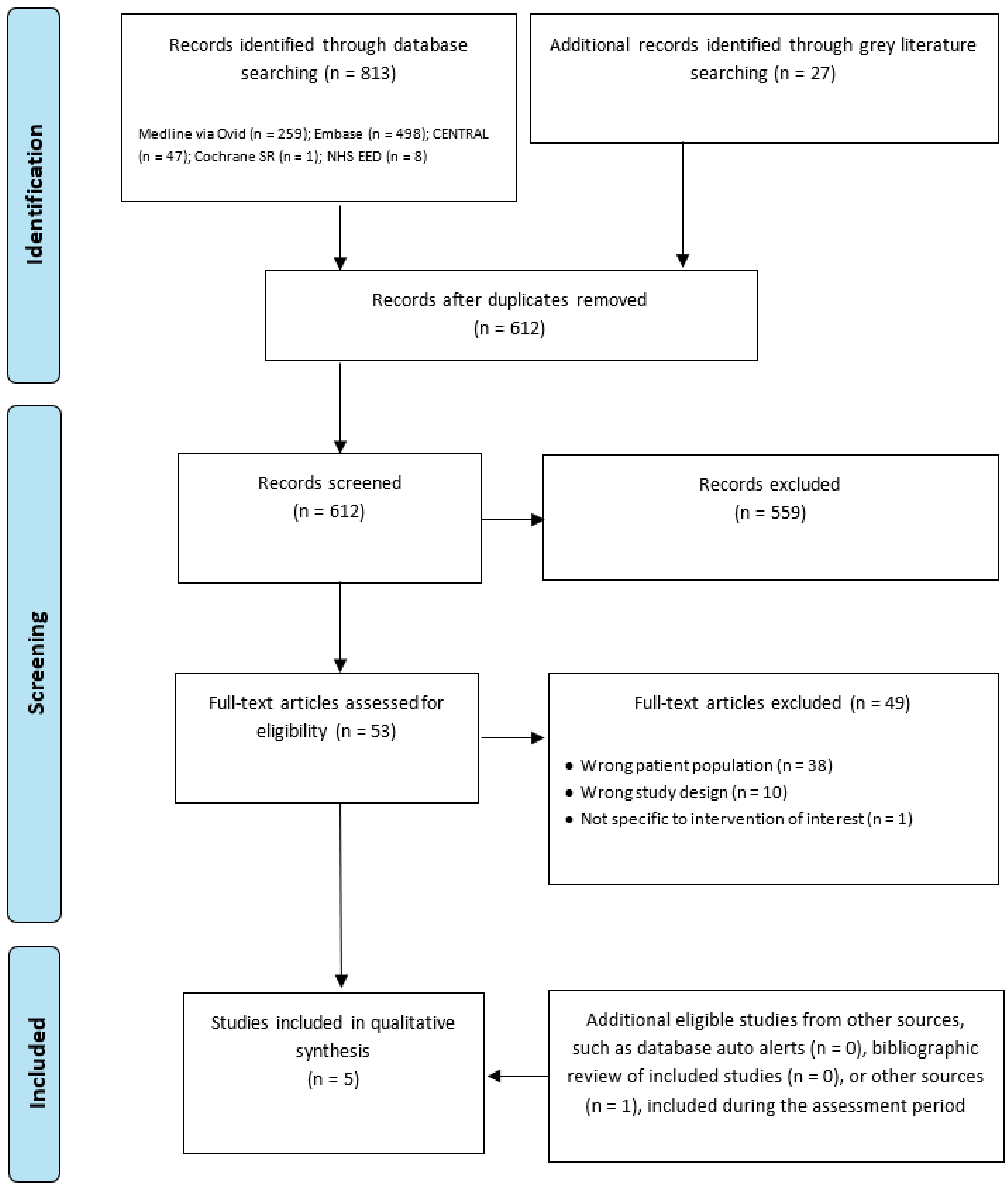

Figure 2: PRISMA Flow Diagram – Economic Search Strategy

PRISMA flow diagram showing the economic review process. The database search of economic literature yielded 813 citations published from database inception until July 5, 2022. After removing duplicates, we screened the abstracts of 612 studies and excluded 559. We assessed the full text of 53 articles and excluded a further 49. We identified 1 additional eligible study from other sources. In the end, we included 5 articles in the qualitative synthesis.

Abbreviation: NHS EED, National Health Service Economic Evaluation Database; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses; SR, systematic review.

Source: Adapted from Page et al.[65]

Overview of Included Economic Studies

We identified 5 studies (Table 11) that met our inclusion criteria.[54,72-75] Of these 5 studies, 4 were cost–utility analyses,[72-75] and 1 study was a trial-based cost–consequence analysis.[54] Wan et al,[75] Tu et al,[74] and Cheng et al conducted their studies specifically in a population with type 2 diabetes, while Rognoni et al[73] and Kim et al[72] considered subgroups with type 2 diabetes. Only Tu et al[74] explicitly described the study population as "poorly controlled type 2 diabetes," with a baseline HbA1c of 8.6%. No studies were conducted in Canada. Of the 5 studies, 2 were conducted in China,[74,75] 1 was conducted in Singapore,[54] 1 was conducted in Italy,[73] and 1 was conducted in the United States.[72]

Of the 5 included studies, 3 were model-based economic evaluations, all of which used cohort-level state transition models.[72,73,75] Rognoni et al[73] and Wan et al[75] used Markov models, while Kim et al[72] used an existing model called the bariatric outcomes and obesity modeling (BOOM) model. All 3 model-based studies used long-term time horizons (> 40 years). Wan et al[75] defined 3 health states (a type 2 diabetes remission state, a type 2 diabetes state, and a death state), and the model extrapolated outcomes from the end of a previous 2-year retrospective study.[76] Kim et al[72] also applied a long-term model after a decision-tree model for the first 5 years after surgery. Rognoni et al[73] developed a model with 3 diabetes-related health states (no diabetes, diabetes, and diabetes remission) and additional health states for amputation, nephropathy, retinopathy, hyperglycemic event, hypoglycemic event, stroke, myocardial infarction, and cancer.

The other 2 studies[54,74] used cost and clinical data from a single trial (a trial-based economic evaluation). Tu et al[74] conducted a cost–utility analysis based on data from a 4-year observational study in China and Cheng et al[54] conducted a cost–consequence analysis alongside a 5-year randomized controlled trial in Singapore.

All 5 studies compared the cost-effectiveness of bariatric surgery with medical management (medical therapy or other nonsurgical intervention); 3 cost-effectiveness analyses focused solely on patients with type 2 diabetes, and medical management included the use of oral antidiabetic medications and insulin.[72,73,75] The 2 trial-based economic evaluations also included newer diabetes medications (e.g., GLP1R agonists).[54,74] Additionally, Cheng et al[54] mentioned people in the medical treatment arm were assessed by a multidisciplinary medical team, including a dietitian, endocrinologist, and physiotherapist, and had clinic visits with a diabetologist every 3 months. Patients also received individualized meal planning and counselling on best dietary practices and advice to engage in moderate-intensity physical activity (minimum of 150 minutes/week).[8] Rognoni et al[72,73] described their usual care comparator as diet with physical exercise. Kim et al[72] did not describe the nonsurgical comparator in detail.

Tu et al,[74] Wan et al,[75] and Cheng et al[54] only considered laparoscopic Roux-en-Y gastric bypass as the type of bariatric surgery,[54,74,75] while Kim et al[72] also included open gastric bypass, and laparoscopic adjustable gastric banding. Rognoni et al[73] used a mix of 3 surgical procedures (adjustable gastric banding, 16.8%; gastric bypass, 24.6%; sleeve gastrectomy, 58.6%), weighted by the percentage of use in Italy at the time of the study.

Table 11: Characteristics of the Studies Included in the Economic Literature Review

Author, year, country	Analysis: Technique	Analysis: Design [model]	Analysis: Approach or perspective	Analysis: Time horizon (discount rate)	Study population: Age, range or mean, y	Study population: BMI-related criteria, kg/m²	Study population: Type 2 diabetes–related criteria	Intervention: N	Intervention: Bariatric surgery type	Comparator: N	Comparator: Medical management
Cheng et al, 2022,[54] Singapore	Cost–consequence	—	Trial-based, out-of-pocket expenditures	5 years (NR)	21–65[a]	27–32	Duration ≤ 10 y	12	LRYGB	14	Best medical treatment (diabetologist visit every 3 mo, glucose-lowering medications)
Kim et al, 2018,[72] United States	Cost–utility	Cohort-level state-transition modelling [BOOM]	Private payer and public health care payer (Medicare)	5 years, lifetime (3%)	Mean, 53	30–34.9, 35–39.9, 40–44.9, 45–49.9, and > 50	With and without complications (2 groups for each BMI range)	—	LRYGB, ORYGB, LAGB	—	Unclear
Rognoni et al, 2020,[73] Italy	Cost–utility, net monetary benefit	Cohort-level state-transition [Markov]	Italian health care payer perspective and societal perspective	Lifetime (3%)	Mean, 43	30–35, > 40 with complications, > 35 without complications[b]	With and without complications[b]	—	LAGB, 16.8%; gastric bypass, 24.6%; sleeve gastrectomy, 58.6%	—	Diet and exercise
Tu et al, 2019,[74] China	Cost–utility	Economic evaluation of observational study	Health care payer	4 years (NR)	18–65	≥ 27.5	Poorly controlled, duration ≤ 15 y, ≥ 2 symptoms of metabolic syndrome	106	LRYGB	106	Oral antidiabetic therapy, insulin, and/or GLP1R agonist
Wan et al, 2019,[75] China	Cost–utility	Cohort-level state-transition [Markov]	Third-party payer (Chinese health insurance)	40 years, lifetime (5%)	18–65	≥ 28	Recently diagnosed (< 2 y)	41	LRYGB	41	Metformin, sulfonylurea, and insulin

Abbreviations: BMI, body mass index; BOOM, bariatric outcomes and obesity modeling; GLP1R, glucagon-like peptide-1 receptor; LAGB, laparoscopic adjustable gastric band; ORYGB, open gastric bypass; LRYGB, laparoscopic Roux-en-Y gastric bypass; NR, not reported.

[a]Multiethnic Asian cohort.

[b]Categories: 30–35 kg/m² and type 2 diabetes, > 40 kg/m² type 2 diabetes with complications, > 35 kg/m² type 2 diabetes without complications.

Most studies considered type 2 diabetes status (e.g., changes in HbA1c and type 2 diabetes remission) or changes in BMI values as the measure of effect of bariatric surgery. One study also considered systolic blood pressure and lipid levels in predicting the risk of type 2 diabetes–related complications.[73] Wan et al[54,72,74,75] defined remission of diabetes as a fasting glucose level below 5.4 mmol/L (97.2 mg/dL) and an HbA1c value less than 6.0% without medication; they found that after 2 years, 53.6% of bariatric surgery patients and 2.6% of medical management patients in their propensity score–matched cohort were in a type 2 diabetes remission state. Tu et al[73] defined remission after Roux-en-Y gastric bypass as an HbA1c value less than 6.5% and no medications 1 year after surgery; they observed a remission rate of 64.9% 2 years after surgery.

The utility values used to inform analyses varied between the included studies. Tu et al[74] noted that a limitation of their study was that utility values were assigned to each HbA1c, using a US time trade-off valuation of the EQ-5D for type 1 diabetes, which were assumed to change linearly as HbA1c increased or decreased (per 1% change). In the study by Wan et al,[75] utility weights reflected the presence or absence of type 2 diabetes alone, irrespective of BMI change. Due to insufficient data on quality-adjusted survival associated with remission from type 2 diabetes, Wan et al[75] assumed that the utility of type 2 diabetes individuals in the remission state was the same as that of the general population.

Of the 5 studies, 4 focused on direct medical costs.[54,72,74,75] For the bariatric surgery groups, direct costs often included the cost of bariatric procedures, hospitalization costs, and outpatient consultations. For the comparator, the costs of outpatient medical consultations and prescription medications were often included. Rognoni et al[73] conducted their analysis from both the local payer perspective and a broader societal perspective, including out-of-pocket costs and productivity losses. This study also quantified patients' improved quality-adjusted life-years (QALYs) but converted them to a monetary value using the willingness-to-pay (WTP) threshold of €30,000 per QALY.[73]

Overall, studies found bariatric surgery for people with class I obesity and type 2 diabetes to be cost-saving or cost-effective (Table 12). Tu et al[74] and Kim et al[72] found similar incremental cost-effectiveness ratios (ICERs) for laparoscopic Roux-en-Y gastric bypass 5 years after surgery compared with medical management (from $19,359 [2013 USD] to $21,482 [2014 USD]/QALY). Over a lifetime horizon, Kim et al[72] found the ICER for laparoscopic Roux-en-Y gastric bypass decreased to $8,565 [USD]/QALY for female and $8,800 [2014 USD]/QALY for male. Tu et al[74] and Kim et al,[72] however, did not report uncertainty or the results of sensitivity analysis for individuals with class I obesity and type 2 diabetes.

Wan et al[75] focused their analysis on people with obesity and recently diagnosed type 2 diabetes and found that bariatric surgery was less costly and more effective compared to medical therapy (¥26,869.39 CNY [China yuan] less and 2.51 additional QALYs per individual) over a 40-year time horizon from a Chinese health insurance payer perspective. Their results remained stable in sensitivity analysis when varying parameters including utility values of health states, costs, and discount rate.[75] Rognoni et al[73] also found bariatric surgery to be cost-saving over a lifetime horizon across all sensitivity analysis. Considering both a payer perspective and a societal perspective using the WTP threshold of €30,000 EUR (euro), the net monetary benefit of bariatric surgery compared to a dietary intervention was positive. Finally, Cheng et al[54] estimated that the total 5-year health care cost incurred by Roux-en-Y gastric bypass group was 2.9 times lower compared with that of the best medical treatment group ($9,686 SGD [Singapore dollar] vs. $28,136 SGD, year not reported), while also resulting in better glycemic control and weight reduction.

We did not include several studies in our review for some common reasons (Appendix 3). Many studies have conducted analysis with a population that falls partially within our inclusion criteria. For example, in some studies, patients with a BMI between 30 and 40 kg/m^2, or patients with BMI over 32.5 kg/m^2 were included. Studies in which the mean BMI of the population fell outside of the 30 to 35 kg/m^2 range were excluded.[24,76-81] Additionally, studies in which the primary research question did not include our population of interest or in which the cost outcomes of interest were not reported were excluded.[82,83]

Table 12: Outcomes of the Studies Included in the Economic Literature Review

Author, year, country	Health outcome	Cost	Cost-effectiveness
Cheng et al, 2022,[54] Singapore			
Measure	Percent change from baseline to 5 y (SD)	Mean over 5 y, SGD[a]	—
Outcomes	Hba1c	Annual	—
	LRYGB: −27.8 (5.0)	LRYGB: $328	
	Medical treatment: −15.4 (4)	Medical treatment: $4,229	
	BMI	Total[b]	
	LRYGB: −18.6 (3.5)	LRYGB: $9,686	
	Medical treatment: −6.1 (2.5)	Medical treatment: $28,136	
	Weight		
	LRYGB: −15.7 (4.8)		
	Medical treatment: −4.5 (2.3)		
	Waist circumference		
	LRYGB: −13.5 (5.7)		
	Medical treatment: −2.7 (5.6)		
	SBP		
	LRYGB: −12.5 (5.6)		
	Medical treatment: −0.8 (4.3)		
Kim et al, 2018,[72] United States			
Measure	Mean QALYs gained, over 5 y (over lifetime horizon)	Mean over 5 y (mean over lifetime horizon), 2014 USD	5 y (lifetime horizon), USD per QALY
Outcomes	LRYGB	LRYGB	LRYGB vs. nonsurgical
	Female: 4.54 (15.19)	Female: $55,623 ($209,330)	Female: $19,907 ($8,565)
	Male: 4.70 (14.80)	Male: $55,119 ($193,224)	Male: $21,482 ($8,800)
	ORYGB	ORYGB	ORYGB vs. nonsurgical
	Female: 4.53 (15.18)	Female: $70,390 ($224,097)	Female: $35,352 ($15,343)
	Male: 4.69 (14.79)	Male: $69,692 ($207,797)	Male: $36,322 ($14,812)
	LAGB	LAGB	LAGB vs. nonsurgical
	Female: 4.49 (14.94)	Female: $51,488 ($206,609)	Female: $16,568 ($8,253)
	Male: 4.65 (14.53)	Male: $51,056 ($190,481)	Male: $18,401 ($8,652)
	Nonsurgical	Nonsurgical	
	Female: 3.56 (12.99)	Female: $36,117 ($190,466)	
	Male: 3.69 (12.35)	Male: $33,462 ($171,663)	

Author, year, country	Health outcome	Cost	Cost-effectiveness
Rognoni et al, 2020,[73] Italy			
Measure	Mean QALYs gained	Mean, 2018 EUR	Net monetary benefit
Outcomes	Bariatric surgery: 12.42 Diet: 11.01 Difference (in monetized values of QALY), EUR Societal perspective: €42,211 Payer perspective: €42,211	Societal perspective Bariatric surgery: €422,167 Diet: €522,336 Payer perspective Bariatric surgery: €98,257 Diet: €110,693	Societal perspective 142,380 (95% CI 110,747–176,199) Payer perspective 54,647 (95% CI 49,317–60,569)
Tu et al, 2019,[74] China			
Measure	Mean QALYs gained (95% CI)	Mean per patient over period, 2013 USD	Mean per patient, 2015 CNY
Outcomes	LRYGB: 3.756 (3.744–3.767) Medical management: 3.594 (3.580–3.608)	1 year LRYGB: $8,483 ($3,181) Medical management: $1,995 ($380) 2 years: LRYGB: $672 ($163) Medical management: $1,884 ($379) 3 years: LRYGB: $938 ($425) Medical management: $2,060 ($382) 4 years: LRYGB $1,046 ($328) Medical management: $1,976 ($363)	LRYGB: ¥86,366.55 Medical management: ¥113,235.94
Wan et al, 2019,[75] China			
Measure	Mean QALYs gained	Mean per patient, 2015 CNY	—
Outcomes	LRYGB: 13.46 Medical management: 10.95	LRYGB: ¥86,366.55 Medical management: ¥113,235.94	LRYGB vs. medical management: dominant

Abbreviations: BMI, body mass index; CNY, China yuan; EUR, euro; LAGB, laparoscopic adjustable gastric band; ORYGB, open gastric bypass; QALYs, quality adjusted life-years; LRYGB, laparoscopic Roux-en-Y gastric bypass; SBP, systolic blood pressure; SGD, Singapore dollars; NMB, net monetary benefit.

[a]Year not reported.

[b]The mean difference was 2.9 times higher in medical treatment group than that in the LRYGB group.

Applicability and Limitations of the Included Studies

One study was not applicable,[54] and 4 studies were partially applicable to the research question.[72-75] Concerns related to applicability (Appendix 4, Table A10) mainly arise from 3 sources: broader study populations than population of interest (class I obesity and difficult-to-manage type 2 diabetes), variability in standard care practices, and costs and resource utilization estimates sourced from jurisdictions that are likely to be different when compared with those of Ontario.

We did not assess the limitations of these studies as they were not deemed to be directly applicable.

Discussion

Our economic evidence review suggests that bariatric surgery may be cost-effective compared with standard care for patients with class I obesity and type 2 diabetes. Bariatric surgery has the potential to improve health outcomes in patients with less severe obesity but and type 2 diabetes. However, the applicability of these results to an Ontario context remains uncertain due to potential differences in clinical practice, resource utilization, and unit costs.

There is also an evidence gap regarding the population of interest in Ontario of adults with class I obesity and difficult-to-manage type 2 diabetes (defined as having elevated HbA1c levels [> 7%] despite optimal medical management efforts (medication and lifestyle changes). The populations in the included studies were generally broader than our inclusion criteria. Wan et al[75] focused on individuals with a BMI of 28 kg/m^2 and higher and recently diagnosed type 2 diabetes (duration < 2 years), while Tu et al[74] included individuals with a BMI of 27.5 kg/m^2 and higher and "poorly controlled" diabetes (duration ≤ 15 years). Additionally, compared to the conventional medical management group, individuals in the bariatric surgery group also had to have more than 2 symptoms of metabolic syndrome. Cheng et al[54] included individuals with BMIs between 27 and 32 kg/m^2 and an established diagnosis of type 2 diabetes (duration ≤ 10 years; HbA1c ≥ 8%). The remaining 2 studies did not specify the initial disease severity of the cohorts with diabetes analyzed in their models.[72,73]

The rate of diabetes remission following treatment is also an important determinant of the evaluation, as a higher remission rate would result in more favourable outcomes for the intervention. The definition of remission of diabetes and, subsequently, the proportion of patients who fall in the remission of diabetes state varied between studies. There were also limitations in the applicability of utility values used to inform analyses across the included studies. For instance, a study derived patients' utility values by assigning 1 to each HbA1c value,[54] while another study[72,74] used a linear model that linked change in BMI to utility gain. It is unclear how applicable these rates of remission and utility values would compare with those in Ontario.

Additionally, usual care comparators varied and were not fully described in most studies. Kim et al[72] included both patients with and without diabetes in their analysis and referred to the comparator broadly as "nonsurgical interventions." The 2 cost–utility analyses, which focused the patients with type 2 diabetes, referred to "conventional medical management" as the comparator and mentioned the use of diabetes management medications, but it is not clear if additional lifestyle interventions were used.[74,75] It is possible that country-specific clinical practice guidelines for nonsurgical management of type 2 diabetes may differ. There are also likely differences in clinical practices between those jurisdictions and Canada.

Strengths and Limitations

Our economic evidence review is bound by the limitations and applicability of included studies. All the included studies supported the cost-effectiveness of bariatric surgery compared with standard medical management. However, because most of the studies considered a broader study population the generalizability of their findings may not apply to our narrower population of interest. One strength, however, was that because the literature was searched since database inception and reference lists were reviewed, it is unlikely that studies were missed.

Conclusions

Our systematic review of the economic evidence suggested that bariatric surgery is likely cost-effective compared to usual care in people with class I obesity and difficult-to-manage type 2 diabetes; however, there is some uncertainty because the evidence was not directly applicable to our research question. Findings from the studies were considered not directly applicable, because these studies considered study population, practices, and costs and resource utilization from jurisdictions (China, Italy, Singapore, and the United States) where these are likely to be different when compared with Ontario. To determine the cost-effectiveness of bariatric surgery in people with class 1 obesity and difficult-to-manage type 2 diabetes in Ontario, it is necessary to conduct de novo analysis that examines Canadian or Ontario practices and incorporates the latest evidence about the treatment decision, disease progression, and long-term health outcomes.

Primary Economic Evaluation

Research Question

What is the cost-effectiveness of bariatric surgery compared with medical management in adults with class I obesity and difficult-to-manage type 2 diabetes, with or without other comorbidities, from the perspective of the Ontario Ministry of Health?

Methods

The information presented in this report follows the reporting standards set out by the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement.[84] We adapted the United Kingdom Prospective Diabetes Study Outcomes Model 2 (UKPDS-OM2), a microsimulation model that replicates the natural history of people with diabetes, to estimate the cost-effectiveness of bariatric surgery compared with that of nonsurgical usual care – medical management. The content of this report is based on a previously developed economic project plan.

Type of Analysis

We conducted a cost–utility analysis, as recommended by the Canadian Agency for Drugs and Technologies in Health (CADTH) guidelines for economic evaluation. The effectiveness outcome is quality-adjusted life-years (QALYs), which considers both a person's survival and health-related quality of life. A generic outcome measure such as the QALY allows decision-makers to make comparisons across different conditions and interventions. We also conducted a cost-effectiveness analysis with the following effectiveness outcomes:

- Life-years
- Number of individuals with diabetes remission, defined as no longer meeting the American Diabetes Association type 2 diabetes criteria – (1) fasting glucose ≥ 7.0 mmol/L (126 mg/dL), (2) glucose ≥ 11.0 mmol/L (200 mg/dL) 120 minutes after 75 g oral glucose load, or (3) glycated hemoglobin (hemoglobin A1c or HbA1c) ≥ 6.5%, and no longer needing medications for diabetes
- Number of diabetes-related complications including fatal or non-fatal myocardial infarction, fatal or nonfatal stroke, congestive heart failure, other ischemic heart disease, amputation, renal failure, and eye disease measured in terms of blindness in 1 eye

Study Population

Our study population was adults (≥ 18 years of age) with class I obesity and difficult-to-manage type 2 diabetes. Difficult-to-manage type 2 diabetes was defined as having elevated HbA1c levels (> 7%) despite optimal medical management (medication and lifestyle changes). Class I obesity was defined as having a BMI between 30 and 34.9 kg/m^2.

We are not aware of any reports with the characteristics of the study population in an Ontario or Canadian context. Thus, our modelled cohort's characteristics – demographic characteristics (e.g., age, sex), clinical risk factors (e.g., BMI and HbA1c levels), and history of complications – were based on those of 3,712 patients with class I obesity and type 2 diabetes from a UK General Practices retrospective cohort study.[85] We also used this cohort study to define type 2 diabetes duration, HbA1c, systolic blood pressure, low-density lipoprotein (LDL), high-density lipoprotein (HDL), estimated glomerular filtration rate (eGFR), history of peripheral artery disease, and smoking status (i.e., proportion of smokers). We used Ontario-specific race and ethnicity information, which suggested that 70.7% of Ontario's total population were White, 6.2% were Afro-Caribbean, and 19.8% were Asian.[86]

For other characteristics, we used data from large epidemiological studies as baseline values for the risk factors (Table 13). We used an atrial fibrillation prevalence of 12.7% – the mean value of the diabetes case series of included case-control studies in a systematic review that examined the association between diabetes and risk of atrial fibrillation.[87] Using results from a cross-sectional survey on predictors of anemia with 820 patients with diabetes who were followed up in a single clinic,[88] we used hemoglobin level for male and female patients as baseline level in our model. We also calculated the proportion of individuals with microalbuminuria and macroalbuminuria as 28.1% (based on Renal Insufficiency and Cardiovascular Events Italian Multicenter Study data,[89] which included 4,062 type 2 diabetes patients with 2 or 3 measurements of urinary albumin excretion in a 3- to 6-month period). Heart rate information was based on data from a cohort study[90] that assessed the relationship between heart rate and mortality in 11,140 patients with type 2 diabetes. We assumed that our study population had not previously experienced events of stroke, congestive heart failure, ischemic heart disease, amputation, blindness, or foot ulcer.

Table 13: Baseline Characteristics of the Study Population

Model parameter and data source	Value
Demographic[a]	
Sex,[85] %	
Women	51.7
Men	48.3
Age,[85] mean (SD), y	58.7 (13.6)
Clinical risk factors[b]	
Diabetes duration,[85] mean (SD), y	3.9 (5.0)
Atrial fibrillation,[87] %	12.7
BMI,[85] mean (SD), kg/m^2	32.5 (1.4)
eGFR,[85] mean (SD), mL/min/1.73 m^2	65.1 (21.1)
Hemoglobin,[88] mean (SD), g/dL	
For women	12.90 (0.07)
For men	13.93 (0.03)
Hba1c level,[85] %	8.7 (1.8)
HDL cholesterol level,[85] mean (SD), mmol/L	1.3 (0.4)
LDL cholesterol level,[85] mean (SD), mmol/L	2.4 (1.1)
Micro and macroalbuminuria,[89] %	28.1
Resting heart rate,[90] mean (SD), beats per min	74 (12)
White blood cell count,[91] mean (SD), 1×10^6 mL	7.78 (0.23)
Systolic blood pressure,[85] mean (SD), mmHg	135.8 (23.0)
Peripheral vascular disease,[85] %	7.1
Current smoker,[85] %	14.2
Event history[c]	
Stroke	No history
Congestive heart failure	No history
Ischemic heart disease	No history
Amputation	No history
Blindness	No history
Foot ulcer	No history

Abbreviations: BMI, body mass index; CHF, congestive heart failure; eGFR, estimated glomerular filtration rate; HbA1c, hemoglobin A1c or glycated hemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SD, standard deviation.

[a]Factors do not vary with time.

[b]Time-variant risk factors, for which we need the progression information in model inputs.

[c]Event history information would update as the individuals enter the model and go through the analysis. We assumed that the individuals in our model have no event history at the beginning, but the microsimulation process would collect and update event history information and use the event history information in the calculation.

We assumed normal distribution for continuous variables (e.g., BMI, HbA1c), binomial distribution for binary outcomes (e.g., peripheral vascular disease, current smoker), and a multinomial distribution for ethnicity. We ensured that BMI was within the range of 30 to 35 kg/m^2 and that HbA1c was equal to or above 7.0%. Using R, we randomly generated a hypothetical cohort with 1,000 patients characterized by the clinical characteristics described in Table 13.[92]

We did not use the clinical characteristics from the trials in our clinical evidence review to characterize the study population because, in general, they had small sample size and did not represent the Ontario population. For example, Parikh et al[51] recruited a study population from a public health care system in New York City, and 87.8% of the study population were Hispanic. The trials also did not report sufficient details about risk factors (e.g., cholesterol level, smoking status, etc.) that are necessary for our model-based economic evaluation.

Perspective

We conducted this analysis from the perspective of the Ontario Ministry of Health.

Interventions and Comparators

We compared bariatric surgery with usual care (medical management) (Table 14).

Bariatric Surgery

There are different types of bariatric surgery available in Ontario, with the Roux-en-Y gastric bypass as the primary surgery used in the public health care system (estimated to be 85% of bariatric surgeries in 2014).[13,33] In our reference case, we considered the Roux-en-Y gastric bypass as the intervention of interest. We did not consider other types of bariatric surgeries in our economic evaluation.

Usual Care (Medical Management)

In our clinical evidence review, usual care (medical management) for type 2 diabetes with class I obesity can include 1 or more of the following: dietary modification, increased physical activity, medications for diabetes, and medications for obesity. In this economic evaluation, usual care means medical management that does not include medications for obesity but that does include medications for diabetes. Compared with usual care, bariatric surgery is an add-on therapy for weight management for the study population.

We conducted a scenario analysis in which the comparator to bariatric surgery was not usual care but an intensive medical bariatric program in Ontario (Table 14). The intensive medical bariatric program in Ontario provides medical care that includes intensive lifestyle interventions with protein meal replacement, psychology and behavioral coaching and counselling, dietetics support, and medication.[93] Eligible people are assigned to a Bariatric Centre of Excellence or Regional Assessment and Treatment Centre. The treatment plan may vary and is determined by the interdisciplinary team. In the scenario analysis, bariatric surgery is a replacement for the intensive medical bariatric program.

Table 14: Disease Interventions and Comparators Evaluated in the Primary Economic Model

Intervention	Comparator	Population	Outcomes
Bariatric surgery with Roux-en-Y gastric bypass	Usual care No surgery (reference case) Intensive medical bariatric program, including meal replacement and behavioral modification program (scenario)	Adults with class I obesity and difficult-to-manage type 2 diabetes	Quality adjusted life-years Life-years Costs Number of diabetes-related complications including fatal or nonfatal MI, other IHD, stroke, CHF, amputation, renal failure, and eye disease measured in terms of blindness in 1 eye Number of diabetes remission

Abbreviations: CHF, congestive heart failure; IHD, ischemic heart disease; MI, myocardial infarction.

Time Horizon and Discounting

We used a lifetime horizon (50 years) in our reference case to account for long-term costs and outcomes including complications relevant to diabetes and obesity management. We also used a shorter time horizon (5 years) in a scenario analysis to match the clinical data available. In accordance with CADTH guidelines,[94] we applied an annual discount rate of 1.5% to both costs and QALYs. All costs are expressed in 2023 Canadian dollars.

Model Structure

We used a decision tree to calculate the proportion of patients who are in diabetes remission, have complications, or have died 1 year after bariatric surgery or nonsurgical treatment. Individuals would then enter the adapted UKPDS-OM2 to estimate long-term costs and effectiveness. We chose to use the UKPDS-OM2 because it is a microsimulation model, which considers different patient characteristics at an individual level and better represents the clinical pathways of people with type 2 diabetes.

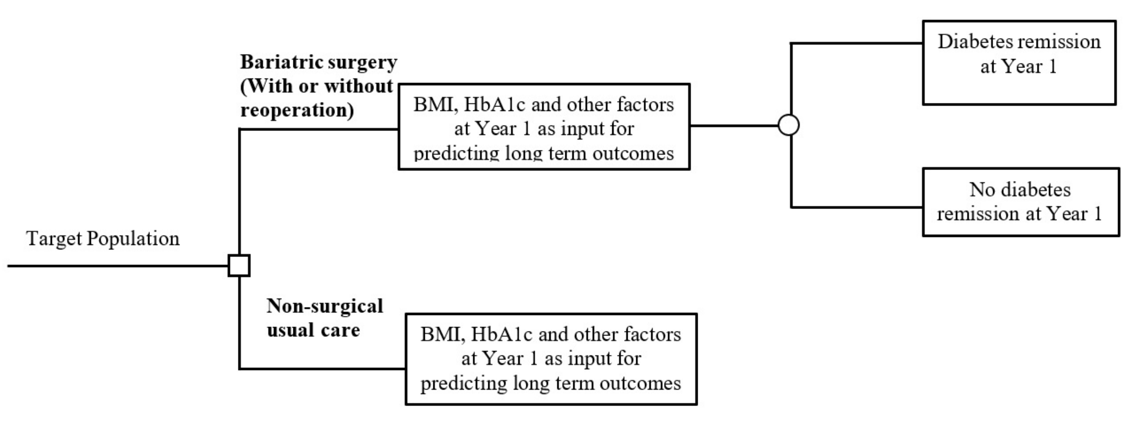

Figure 3: Structure of the Decision Tree for the First Year After Initial Treatment

People receiving bariatric surgery or usual care may have weight loss (and experience a BMI reduction), achieve diabetes remission (no longer requiring diabetes care), both, or neither. People who receive bariatric surgery may experience complications that require reoperating.
Abbreviations: BMI, body mass index; HbA1c, hemoglobin A1c or glycated hemoglobin.

Decision Tree for the First Year After Bariatric Surgery or Medical Management

We used a decision tree to simulate the BMI change, type 2 diabetes remission, and postsurgical complications within the first year. Figure 3 shows the structure of the decision tree. People receiving bariatric surgery or usual care may have weight loss (and experience a BMI reduction); achieve diabetes remission (no longer requiring diabetes care); or neither. Those who receive bariatric surgery may experience complications that require reoperating. The outcomes (diabetes remission, weight loss, complications) were not exclusive to one another.

The outputs of the decision tree included QALYs, costs, BMI, and HbA1c levels 1 year after the intervention. Patients could gain utility due to weight loss and diabetes remission or lose utility due to complications. Diabetes remission led to cost savings, while reoperation due to complications incurred additional costs. The BMI and HbA1c levels 1 year after the intervention were used as inputs for the long-term model.

UKPDS-OM2 for Long-Term Outcomes

The UKPDS-OM2 is a patient-level microsimulation model that estimates the long-term impact of health interventions for people with type 2 diabetes.[95] The model uses 13 risk equations to determine the first occurrence of 8 diabetes-associated complications (ischemic heart disease, chronic heart failure, first amputation, blindness in 1 eye, renal failure, first stroke, first myocardial infarction, and ulcer) and second event occurrence of amputation, stroke or myocardial infarction, as well as death.[95] Factors such as smoking status, HDL cholesterol, LDL cholesterol, systolic blood pressure, HbA1c, peripheral vascular disease, atrial fibrillation, weight, albuminuria, heart rate, white blood cell count, hemoglobin, and estimated glomerular filtration rate, were included as covariates in risk equations (Appendix 5).

For this analysis, we adapted the UKPDS-OM2 by modifying the components in the following manner:

- For risk factors, we assumed that compared with usual care, bariatric surgery only impacts BMI and HbA1c over 5 years. We modified the parameters for these 2 factors within the first 5 years of the model analysis and populated the UKPDS-OM2 accordingly (see section *Impact of Bariatric Surgery and Nonsurgical Treatment on Natural History*)
- For risk factors other than BMI and HbA1c, we used the baseline characteristics of the hypothetical patient cohort, and the risk factor progression equations reported by Leal et al[96,97] to populate UKPDS-OM2 risk factor worksheets

Main Assumptions

- We assumed that the bariatric surgery program included Roux-en-Y gastric bypass and postsurgical follow-up care for 1 year. After the first year, individuals are transferred to primary care
- We assumed that there are no new surgical or nonsurgical treatments that may incur costs or influence outcomes of interest
- We assumed that bariatric surgery and nonsurgical treatment would only impact HbA1c and BMI. In the reference case, we did not consider the impact of bariatric surgery and nonsurgical treatment on cholesterol levels or blood pressure, which is a conservative assumption (it may underestimate

the benefits of bariatric surgery). We conducted scenario analyses in which other risk factors, including cholesterol levels and blood pressure, can also be impacted by bariatric surgery and nonsurgical treatment

- We assumed that after the first 5 years, HbA1c and BMI would progress according to UKPDS-OM2 risk factor progression equations.[97] We evaluated this assumption with scenario analyses, where HbA1c and BMI bounce back to baseline-level prior intervention (worst case scenario) or stay stable (best case scenario, in which we have year-5 values for the remainder of the time horizon)

Clinical Outcomes and Utility Parameters

We used several input parameters to populate the model:

- Baseline levels of risk factors for people with class I obesity and type 2 diabetes
- Changes in risk factors associated with nonsurgical treatment and bariatric surgery to account for the effects of nonsurgical treatment and bariatric surgery on BMI and diabetes remission
- Variables on progression of risk factors
- Risk equations of macrovascular and microvascular events, and death in the UKPDS–OM2
- Health-state utilities (i.e., health-related quality of life)

Risk Factors at Baseline

The UKPDS–OM2 simulates the occurrence of macrovascular and microvascular events and death according to demographic characteristics (sex, age, ethnicity), clinical risk factors (diabetes duration, atrial fibrillation, BMI, eGFR, hemoglobin, HbA1c, HDL, LDL, albuminuria, heart rate, white blood cell count, systolic blood pressure, peripheral vascular disease, and smoking), and event history (stroke, congestive heart failure, ischemic heart disease, amputation, blindness, foot ulcer). The baseline levels of these risk factors are determined with data from large epidemiological studies (Table 13).[85,87-90]

Risk Factor Progression

UKPDS-OM2 requires risk factor progression information on a year-by-year basis to update the individual risk of complications and death. However, there was limited information on long-term data (how the risk factors would progress for people with class I obesity and difficult-to-manage type 2 diabetes). We used risk factor progression equations[97] to update the progression over the lifetime horizon for risk factors other than HbA1c and BMI and the progression after year 5 for HbA1c and BMI. Table A11 summarizes the functional forms and risk factors considered in the risk factor progression equations.[95,97]

Impact of Bariatric Surgery and Medical Management on Natural History

Our reference case assumed that bariatric surgery led to differences in BMI and HbA1c from nonsurgical treatment, which further cause differences in long-term outcomes and costs. This assumption is conservative regarding the benefits of bariatric surgery because it examines the narrow impact of bariatric surgery on weight change and diabetes management, ignoring the impact on other metabolic parameters that could also modify the risk of events (macrovascular and microvascular) and death.

The effect estimates of different types of bariatric surgery and nonsurgical treatment on BMI, HbA1c, HDL and LDL cholesterol, and systolic blood pressure were based on data from the studies included in our clinical evidence review. Table 15 presents the model parameters on clinical effects of bariatric surgery or comparison, including continuous variables for BMI and HbA1c and dichotomous variables such as probabilities of reoperation, diabetes remission, and death. We considered the further impact on HDL, LDL, and systolic blood pressure in a scenario analysis. Our clinical evidence review included 4 randomized controlled trials. Nevertheless, due to heterogeneity in the study populations and results, we did not conduct meta-analyses to pool the effect estimates. For the model-based cost-effectiveness analysis, we chose the trial by Parikh et al[51] because we considered the context (i.e., study population) to be similar to the Canadian context; for this trial, there were subsequent reports on diabetes and BMI outcomes until 5 years after the intervention.[55,56]

Table 15: Summary Estimates Used in the Economic Model

Intervention and variable	Change value from baseline		
	Month 6	Year 3	Year 5
Roux-en-Y gastric bypass[55,56,56]			
BMI, mean (SD),[b] kg/m^2	−7.0 (2.6)	−6.2[a]	−7.0 (3.2)
Hba1c, mean (SD),[b] %	−1.2 (1.1)	−0.79[a]	−0.57 (1.40)
HDL level, mean (SD),[b,c] kg/m^2	2.6 (12.5)	NR[d]	9.6 (11.3)
LDL level, mean (SD),[b,c] kg/m^2	20.0 (44.5)	NR[d]	4.36 (51.4)
SBP, mean (SD),[b,c] mmHg	−0.4 (19.7)	NR[d]	3.75 (23.8)
Diabetes remission proportion, n/N[e] (%)	13/20 (65)	19/30 (63.3)	11/29 (37.9)
Death[51,e]	0	NA	NA
Complication,[98] n/N[e] (%)	1,185/10,499 (10.14)		
Reoperation,[99] n/N[d] (%)	1,850/96,538 (1.92)		
Usual care			
BMI, Hba1c, HDL, LDL, and SBP	Progression following UKPDS risk factor progression equations[97]		
Diabetes remission[f]	0	0	0
Death[e]	0		
Intensive medical bariatric treatment[51, 55,56]			
BMI, mean (SD)[b]	−1.0 (1.5)	−1.3[a]	−3.4 (2.6)
Hba1c, mean (SD)[b]	0.1 (1.5)	0.47[a]	0.81 (1.47)
HDL, mean (SD)[b,c]	6.0 (27.6)	NR[d]	5.8 (10.2)
LDL, mean (SD)[b,c]	−10.2 (52.5)	NR[d]	−28.9 (43.7)
SBP, mean (SD)[b,c]	2.5 (19.1)	NR[d]	6.7 (25.3)
Diabetes remission proportion	0	0	0
Death[e]	0	NA	NA

Abbreviations: BMI, body mass index; HbA1c, hemoglobin A1c or glycated hemoglobin; HDL, high-density lipoprotein, LDL; low-density lipoprotein; NA, not applicable; NR, not reported; SBP, systolic blood pressure; SD, standard deviation.

[a]No standard deviations reported.

[b]We estimated normal distribution in probabilistic analysis for this parameter, with mean and standard errors (estimated as standard deviation divided by the square root of the sample size).

[c]Impact of surgeries and non-surgical treatment on HDL and LDL cholesterol, and blood pressure are assessed only in a scenario analysis.

[d]We assumed that the change value from baseline to year 3 was the same as that of year 5.

[e]We estimated beta distribution in probabilistic analysis for this parameter, using the number of events and sample size.

[f]Assumption.

Parameters for the Decision Tree (Year 1)

We used a decision tree to simulate the changes in BMI and HbA1c, as well as the occurrence of diabetes remission and reoperation. For BMI and HbA1c, we applied the baseline levels (Table 13) as the values for the first 3 months in the decision tree, and the levels measured at 6 months (Table 16) for the next 9 months in the decision tree. According to Parikh et al,[51] 6 months after surgery, BMI decreased 7.0 kg/m^2 (SD 2.6) and HbA1c level decreased 1.2% (SD 1.1%) from baseline.[51] This trial also reported impacts of bariatric surgery on cholesterol and blood pressure levels, which were considered in the scenario analysis.[51] We used the proportion of patients who received bariatric surgery and reached diabetes remission 6 months after surgery (65%) as the probability of diabetes remission in the last 9 months within the first year after surgery. According to the American College of Surgeons–National Surgical Quality Improvement Program, 1.92% of patients (1,850 of 96,538) needed reoperation.[99] We assumed that the reoperation happened within the first 3 months after the initial surgery and had no impact on diabetes remission, BMI, and HbA1c outcomes.

BMI and HbA1c outcomes with usual care followed the risk factor progression equations.[97] For our scenario analysis that included a comparison with the intensive medical bariatric program, BMI decreased by 1.0 kg/m^2 (SD 1.5) and the HbA1c increased by 0.1% (SD 1.5%) from baseline at 6 months.[51] There was no diabetes remission or reoperation within the first year of the model for either nonsurgical scenario.

No death event was reported in this trial,[51,55,56] so we assumed that the death probability in the decision tree for short-term outcomes was 0.

Parameters for UKPDS-OM2 After the First Year

According to 2 subsequent reports of outcomes after bariatric surgery by Horwitz et al,[52,53] for people receiving bariatric surgery, BMI decreased by 6.2 kg/m^2 (SD not reported) and 7.0 kg/m^2 (SD 3.2) at 3 years and 5 years after the surgery, respectively.[51,55,56] Bariatric surgery also led to decrease in HbA1c (3 years: mean 0.79% [SD not reported]; 5 years: mean 0.57% [SD 1.40])[51,55,56]; however, the proportion of people who reached diabetes remission decreased to 37.9% at 5 years (11 of 29 patients, including 9 patients who switched from the intensive medical bariatric program to surgery).

We used the risk factor progression equations[97] to simulate the prognoses receiving usual care.

For the scenario analysis that included the intensive medical bariatric program comparator, BMI decreased by 1.3 kg/m^2 (SD not reported) and by 3.4 kg/m^2 (SD 2.6) and the HbA1c increased by 0.47% (SD not reported), 0.81% (SD 1.47), and 0.1% (SD 1.5) for the changes from baseline to 3 years and from baseline to 5 years after initiation of intensive bariatric program.

Because the trials only reported the mean change values for BMI and HbA1c at 3 years, and the mean and SDs at 5 years after the initiation of treatment, we used the SDs at 5 years for the same outcome as the SDs for values at 3 years. We further applied the values for BMI and HbA1c at 3 years after treatment for the second and the third years, and the values at 5 years for the fourth and the fifth years in this model.

Year 5 and beyond: In our reference case, we used the risk factor progression equations reported by Leal et al[97] to simulate the change of risk factors after 5 years for all people in our hypothetical cohort.

However, due to limited long-term outcomes, we made different assumptions for the long-term effects of bariatric surgery on BMI and HbA1c, including 1 scenario in which we assumed that BMI and HbA1c would return to baseline levels at 6 years (worst case scenario) and another scenario in which we assumed that BMI and HbA1c would be the same at 5 years.

Risk Equations for Health Events

The UKPDS-OM2 uses 17 risk equations that are used to predict the occurrence of events, including 7 equations for macrovascular events, 6 for microvascular events, and 4 for death.[95] Tables A11 and A12 summarize the functional forms and risk factors considered in the risk equations, as well as the risk factor progression equations.[95,97]

Health State Utilities

A health state utility value represents a person's preference for, or the value they place on, a certain health state or outcome. Utilities are often measured on a scale ranging from 0 (death) to 1 (full health). Disutility values were applied if patients experience complications. In the first year after treatment, we assumed that people could have utility gains following diabetes remission or meaningful weight loss. We applied disutility values associated with complications in our analysis (Table 16), using Ontario- or Canada-specific utility values when available, or values from other sources that were considered most relevant.

In our model, an initial utility value was set for individuals without complications. Boye and colleagues[100] reported health-state utilities elicited through time trade-off analysis from 405 people from the United Kingdom with obesity (202 with type 2 diabetes and 203 without); the current utility value was 0.797 (SD 0.184) for people with obesity and diabetes and 0.817 (SD 0.191) for those without. We assumed an initial utility value of 0.797 and estimated the utility gain as 0.020 (SD 0.270). Boye and colleagues[100] also found that the utility gains were 0.011 (SD 0.029), 0.023 (SD 0.050), 0.042 (SD 0.068), 0.053 (SD 0.087), and 0.060 (SD 0.093) for people with obesity and type 2 diabetes who could lose less than 2.5%, 2.5% to 5%, 5% to 10%, 10% to 15%, and more than 15% weight, respectively, in the first year after the treatment. We applied the utility gains in the first year after the treatment.[100] We could not find any utility values that were directly applicable on surgical complications. We applied a disutility of −0.320 (SD 0.280), which was estimated to be the disutility value for surgical site infections following joint or spine surgery, based on a time to trade-off evaluation by the UK participants.

We used an initial utility value of 0.797 for individuals with class I obesity and difficult-to-manage type 2 diabetes entering the UKPDS-OM2. O'Reilly et al[101] reported EQ-5D utility values for patients with type 2 diabetes and related complications. In this study, the EQ-5D instrument was administered to 1,147 patients in Ontario, and utility was estimated by converting health states from the study population into EQ-5D preference weights elicited from a sample of the general population. This study reported disutility values of −0.059, −0.046, −0.063, and −0.102 for myocardial infarction, stroke, amputation, and renal failure, respectively.[101] A study[102]conducted in the United States reported utility values for a type 2 diabetes patient population from a multivariate regression model: disutility values were −0.042 for people with congestive heart failure and −0.019 for people with other heart diseases (which we applied as disutility for ischemic heart disease).

For other microvascular events, Sharma and colleagues[103] conducted a cross-sectional study to assess the utility values for 221 Canadian patients with diabetic retinopathy, using a time trade-off technique. Of all 43 patients with visual acuity between counting finger to no light perception, the disutility value was estimated as −0.312.[103] Hayes et al[104] conducted an exploratory regression analysis based on data from a randomized controlled trial of hyperbaric oxygen therapy in patients with chronic, nonhealing diabetic foot ulcer. The estimated disutility value was −0.0531.

In the first year, we applied the utility gain due to diabetes remission or weight loss for the last 9 months. For surgical complication, we applied the utility loss for a duration of 3 months. For other complications, we assumed the same disutility values for years of onset and subsequent years.

Table 16: Utility Values Associated With Health States in the Economic Model

Health state	Value, mean (SD)
Baseline utility[100,a]	0.797 (0.184)
Utility gain[a]	
Diabetes remission[100,b]	0.020 (0.270)
Weight loss[100]	
< 2.5%	0.011 (0.029)
2.5% to 5%	0.023 (0.050)
5% to 10%	0.042 (0.068)
10% to 15%	0.053 (0.087)
15% and more	0.060 (0.093)
Utility loss (disutility)	
Reoperation[105,a,c]	−0.320 (0.280)
MI[101]	−0.059
Stroke[101]	−0.046
Amputation[101]	−0.063
Renal injury[101]	−0.102
CHF[102]	−0.042
IHD[102]	−0.019
Blindness[103]	−0.312
Ulcer[104]	−0.053

Abbreviations: CHF, congestive heart failure; IHD, ischemic heart disease; MI, myocardial infarction.

[a]We estimated beta distribution in probabilistic analysis for this parameter, using mean and standard error (estimated as standard deviation divided by the square root of the sample size).

[b]Mean difference calculated based on reported values.

[c]Assumed to be equal to disutility due to surgical site infections that needed reoperation.

Cost Parameters

Cost inputs were obtained from standard Ontario sources, published literature, and clinical experts. The fees for professional visits and procedures were obtained from the Ontario Schedule of Benefits for Physician Services and Ontario Schedule of Benefits for Laboratory Service.[106,107] All costs were reported in 2023 Canadian dollars. When costs from 2023 not available in Canadian dollars, the Statistics Canada Consumer Price Index was used to adjust the costs to 2023 Canadian dollars.[108]

We considered the following costs in this model:

- Bariatric surgery and surgical complications
- Nonsurgical management of people with class I obesity and difficult-to-manage type 2 diabetes
- Outcome-related costs, including those related to myocardial infarction, congestive heart failure, other ischemic heart disease, stroke, amputation, blindness, renal failure, and ulcer

Before bariatric surgery, we assumed there would be 1 preoperative medical management appointment for the bariatric surgery patient in a Bariatric Regional Assessment Treatment Centre, 8 outpatient case conferences, 1 psychiatric evaluation, and 1 education session before surgery. We estimated the costs of the preoperative education sessions as that of 4 hours of nursing work. We also assumed the patient need comprehensive lab testing: gastroscopy, colonoscopy, imaging test, cardiovascular and sleep apnea evaluations. The estimated subtotal cost at preoperative stage to be $2,298.36 (Table 17).

Table 17: Costs Used in the Economic Model

Variable	Unit cost, $	Quantity	Total cost, $	Reference
Surgery, total cost (excluding reoperation)	11,646.67[a]			
Preoperative				
Preoperative medical management	100.00	1	100.00	SoB K090
Bariatric outpatient case conference	32.45	8[b]	259.60	SoB K702
Psychiatry consultation	222.50	1	222.50	SoB A195
Education (nutrition and preoperation classes)	38.92	4	155.68	Hourly wage for registered nurse in Ontario[109]
Lab testing[c]	167.92	1	167.92	SoB for laboratory services
Helicobacter pylori stool antigen test	189.00	1	189.00	Lifelabs[110]
Gastroscopy	82.90[d]	1	144.86	SoB Z527
Colonoscopy	175.85	1	175.85	SoB A415, A120
Chest x-ray	40.55	1	40.55	SoB X092
Pulmonary function tests	17.70	1	17.70	SoB J301
Cardiac imaging	215.15	1	215.15	SoB G570, G571
Cardiac stress test	108.00	1	108.00	SoB G315/319
Electrocardiogram	33.30	1	33.30	SoB G175, G301, G313
Sleep apnea study	468.25	1	468.25	SoB J896
During surgery				
Roux-en-Y gastric bypass	1350.00	1.25	1687.50	SoB S120, E793
Surgical assistant	12.51	19[e]	237.69	SoB S120, S114
Anesthesiologist	15.49	24[f]	371.76	SoB S120, S114
Operating room	973.00	1	973.00	Day care surgery cost[111]
Hospitalization	1,492.00	2	2,984.00	Per diem rate for ward[112]
Complication (excluding reoperation)	1,419.35	1[b]	1,419.35	Davis et al, 2020[113]
Postsurgical				
Peer group and education sessions				
First year after surgery				
Lab testing[c]	167.92	4[g]	671.68	
Bariatric outpatient case conference	32.45	8[b]	259.60	SoB K702
Postoperative monthly management of a patient in a Bariatric RATC	25.00	24[h]	600.00	SoB K091
Second to fifth years after surgery				
Reoperation	14,667.25[a]	0.020	—	Davis et al, 2020[113]; Gribben et al, 2018[99]
Intensive bariatric medical program (scenario), total	3707.36[a]	—	—	
Bariatric outpatient case conference	32.45	8 (initial evaluation)	259.60	SoB K702; assuming 8 units
Lab testing[i]	167.92	3	503.76	
Meal replacement program	92.00	32	2944.00	Bariatric Medical Clinic – Optifast Program by St. Joseph Healthcare Hamilton[114]

Abbreviations: RATC, Regional Assessment Treatment Centre; RYGB, Roux-en-Y gastric bypass; SoB, schedule of benefits.

Notes for Table 17 continued

[a]We estimated the log-normal distribution by assuming the standard error was 20% of the mean.

[b]Assuming 8 units of case conference are applied.

[c]Lab testing cost is estimated based on the total of venipuncture (G489), blood glucose (L104, L111), lipid profile (total cholesterol – L055, HDL – L117, triglycerides – L243), urinalysis (L253), complete blood count (L393), electrolytes (sodium – L226, potassium – L204, chloride – L053, bicarbonate – L061), creatinine (L065), aspartate transferase (L222), parathyroid hormone (L330), prothrombin time (L445), blood type (L490), ferritin (L329), 25-hydoxyvitamin D (L606), vitamin B12 (L345), folate (L308).

[d]Assuming 4 anesthesiologist units ($15.49/unit) are applied.

[e]We assumed that the surgery lasts for 2 hours for both Roux-en-Y gastric bypass, so 7 basic units and 12 time units are applied for surgical assistant.

[f]We assumed that the surgery lasts for 2 hours for both Roux-en-Y gastric bypass, so 10 basic units and 14 time units are applied for anesthesiologist.

[g]We assumed that individuals would receive laboratory testing at months 1, 3, 6, and 12 after surgery.

[h]We assumed that individuals would visit physicians at months 1, 3, 6, and 12 after surgery, and for each visit, 6 units of postoperative management are applied.

[i]We assumed that individuals would receive laboratory testing at months 0, 6, and 12.

The professional fees for Roux-en-Y gastric bypass surgery were based on the Ontario Schedule of Benefits and Fees.[107] We assumed a laparoscopic surgery was conducted and applied an additional 25% to the unit cost of $1,350 (S120). Further, we assumed the surgery lasts for 2 hours and included 19 surgical assistant time units and 24 anesthesiologist time units accordingly. According to the estimates by the Interprovincial Health Insurance Agreements Coordinating Committee, the cost of operating room was estimated to be $973, and the unit cost for a ward stay was $1,492 (the median value of the split rate for wards of Ontario hospitals). The estimates included both the direct costs of providing care to inpatients as well as a portion of the indirect costs of the hospital. We assumed that patients would stay 2 days in hospital after surgery. In addition, based on the probabilities and unit costs of different types of complications reported by Davis et al[113] in 2020, we estimated the weighted average for complications, excluding reoperation, as $1,491.35, while the cost per reoperation was $14,667.25 (which has been necessary for 2.0% of individuals who have received the bariatric surgery [1,850 reoperations of 94,688 bariatric surgeries]).

Within the first year after surgery, follow-up care includes tests and clinical visits at 1 month, 3 months, 6 months, and 12 months. We assumed individuals would transfer to their primary care physician 1 year after the surgery. In sum, the unit cost for bariatric surgery was estimated at $11,646.67.

For people who receive nonsurgical usual care, health services included 1 clinical visit to their primary care provider and lab testing, which we assumed was included in the estimate for annual diabetes care costs. For the intensive medical bariatric program in scenario analysis, we assumed the initial evaluation by a group of interdisciplinary experts cost 8 units of a bariatric outpatient case conference. The weekly cost of a meal replacement program was reported to be $92.[114] We assumed that it included the cost of a 1-to-1 education program, weight measurement, and formula purchase. In the first 6 months of this program, we assumed weekly costs of $92, and in the following 6 months, we assumed monthly costs of $92.

For people receiving diabetes care, we used cost estimates from the Ontario Diabetes Database. This database captures all the relevant costs from the perspective of the Ontario Ministry of Health, including inpatient hospitalizations, emergency department visits, clinic visits, physician and nonphysician services, prescription medications (the proportion that was covered by government funded drug benefit programs), laboratory tests, complex continuing care, long-term care and home care services, same-day surgery, dialysis, mental health, and medical devices. Based on the incident cases between 2004 and 2012 in this database, Rosella and colleagues[115] estimated the annual attributable costs in Canadian dollars in 2012. They reported the annual costs were $1,219 for women with diabetes and $996 for men in the second year after index date (diagnosis of diabetes) in the database. We used the sum of OHIP costs and these estimates as the annual cost for type 2 diabetes care. We then inflated the costs to 2023 Canadian dollar amounts and estimated the annual diabetes care cost for the hypothetical cohort as $1,431. According to Horwitz et al,[55] 37.9% of patients with type 2 diabetes would reach type 2 diabetes remission after bariatric surgery. For people entering the UKPDS-OM2, we applied 62.1% of the annual care cost ($887) to people who received surgery and 100% for people who did not as their unit therapy cost from year 2 to year 50 in our model.

Furthermore, Goeree et al[116] calculated the attributable costs to diabetes complications in Canadian dollars in 2007, based on the same database. We used the costs in the first year and the second year after the index events (myocardial infarction, ischemic heart disease, stroke, heart failure, amputation, blindness, and renal injury) as the costs for the first year and subsequent years of the complications (Table 18).

Table 18: Values and Annual Costs Used in the Economic Model

Variable	Value
Diabetes care,[115] mean $	
Women	1,565.28[a]
Men	1,278.94[a]
Probability of diabetes remission after surgery,[55] *P* (n/N)[b]	.379 (11/29)
Probability of diabetes remission with usual care, *P*	0
Diabetes complications	
MI,[116] mean $	
First year	16,438.94
Subsequent years	6,810.74
CHF,[116] mean $	
First year	22,591.90
Subsequent years	10,631.81
IHD,[116] mean $	
First year	9,889.34
Subsequent years	5,879.12
Stroke,[116] mean $	
First year	24,316.00
Subsequent years	20,351.00
Amputation[116]	
First year	51,755.98
Subsequent years	10,492.07
Blindness,[116] mean $	
First year	5,490.94
Subsequent years	4,418.16
Renal injury,[116] mean $	
First year	29,987.02
Subsequent years	20,982.73
Ulcer,[117] mean $	
First year	27,623.29
Subsequent years	15,130.82

Abbreviations: CHF, congestive heart failure; IHD, ischemic heart disease; MI, myocardial infarction.
[a]We estimated the log-normal distribution by assuming the standard error was 20% of the mean.
[b]We estimated the beta distribution based on number of events and sample size.

Internal Validation

Formal internal validation was conducted by the secondary health economist. This included checking for errors, and checking the accuracy of parameter inputs and equations that were varied during the adaptation of the model, and checking results. The UKPDS model has also been extensively validated by the model developer (reference; and you can give examples of how they validated if you like, e.g., comparing projected health outcomes with what's observed in studies).

Analysis

Our reference case and sensitivity analyses adhered to CADTH guidelines[94] when appropriate. The reference case represents the analysis with the most likely set of input parameters and model assumptions.

We set distributions for risk factor variables and used these distributions to randomly generate 1,000 hypothetical people with class I obesity and difficult-to-manage type 2 diabetes. We applied a microsimulation approach for both the decision tree for outcomes in the first year and the UKPDS-OM2 for the long-term outcomes.

To account for uncertainties, we allowed each individual to enter the model 1,000 times, thus accumulating QALYs and cost within the first year after the intervention 1,000 times, each time using a different random set of parameters. We calculated the expected total costs and QALYs as the average values of the 1,000 simulations for each hypothetical individual, and the mean costs and QALYs and the credible intervals, the incremental costs and QALYs and their credible intervals for the hypothetical cohort with 1,000 patients over a 1-year time horizon. We also calculated the ICERs (incremental cost-effectiveness ratios) for bariatric surgery versus usual care (medical management).

For long-term outcomes, we calculated the reference case of this analysis by running 1,000 inner loops and 1,000 bootstrap iterations to simultaneously capture the uncertainty. The number of loops represents the time it takes for each individual to run through a Monte Carlo simulation. We ran 1,000 simulations, 1 for each individual. In this model, per-patient outcomes are calculated by dividing the total simulated number of events (e.g., myocardial infarction) by the total number of loops. The UKPDS-OM2 software contains 5,000 full sets of model equation parameters and, with bootstrapping, the model examined the impact of uncertainties within the model equation parameters. However, we were unable to vary the parameters related to the costs (e.g., diabetes care or complication costs), effectiveness (e.g., change in BMI and HbA1c), and risk factor progression equations (e.g., cholesterol, blood pressure) and examine the impact of these uncertainties (of costs, effectiveness, and risk factor progression equations) using a conventional probabilistic sensitivity analysis approach in our analysis. We calculated the mean costs and QALYs for the bariatric surgery group and medical management group, respectively. We also calculated the mean incremental costs and QALYs with credible intervals and ICERs for bariatric surgery versus nonsurgical treatment over a time horizon from year 2 to year 50.

Further, we calculated the total costs and QALYs over the 50-year time horizon by adding the total costs and QALYs of the 2 stages and estimated the ICERs.

Scenario Analyses

Our sensitivity analyses explored how the results would be affected by varying input parameters and model assumptions. We conducted one-way sensitivity analyses on key model inputs such as age, BMI, baseline HbA1c, and cost parameters. We examined the robustness of cost-effectiveness results through the following scenario analyses (Table 19).

Table 19: Variables Varied in Scenario Analyses

Scenario	Parameter	Reference case	Scenario analysis
Short time horizon	Time horizon	Lifetime	5 years
Impact on SBP and HDL and LDL cholesterol	Baseline levels and progression for SBP, and HDL and LDL levels	No impact caused by bariatric surgery	Lower risk levels for bariatric surgery
Assumptions related to Hba1c and BMI			
Recurrence of obesity and diabetes	Hba1c and BMI after 5 years	Hba1c and BMI estimated through risk factor progression equations	Hba1c and BMI return to baseline levels
Stable Hba1c and BMI	Hba1c and BMI after 5 years	Hba1c and BMI estimated through risk factor progression equations	Hba1c and BMI remain the same as year 5
Intensive medical bariatric program	Comparison	Nonsurgical usual care with only medication for diabetes	Intensive medical bariatric program (with weight management)
Calibration of UKPDS-OM2 outputs	Occurrence of death events	Output from UKPDS-OM2	Scaling down the output from UKPDS-OM2 by 20%

Abbreviations: BMI, body mass index; HbA1c, hemoglobin A1C; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure; UKPDS-OM2, United Kingdom Prospective Diabetes Study Outcome Model 2.

Scenario 1 – Shorter Time Horizon

The reference case evaluates the cost-effectiveness over a lifetime horizon. This scenario analysis uses a 5-year time horizon.

Scenario 2 – Impact of Risk Factors Including Systolic Blood Pressure and Cholesterol

The reference case considers the effect of bariatric surgery and usual nonsurgical care on HbA1c and BMI but does not consider their impact on systolic blood pressure and cholesterol and the risk modifications of the latter. This scenario analysis examined the robustness of cost-effectiveness results to the assumption.

Scenario 3 – Different Assumptions on the Progression of HbA1c and BMI

- Recurrence of obesity and diabetes: For the reference case, we assumed that the impacts on HbA1c and BMI of bariatric surgery last for 5 years. The reference case used the UKPDS-OM2 progression equations for HbA1c and BMI after 5 years. This scenario assessed the cost-effectiveness of the intervention in the scenario in which obesity and diabetes returned to the baseline levels at year 6
- Stable HbA1c and BMI from UKPDS-OM2: This scenario assumed that the HbA1c and BMI remain stable after year 5. We used year 5 values as the parameters from year 6

Scenario 4 – Intensive Medical Bariatric Program as Comparator

The reference case compared bariatric surgery with nonsurgical usual care, without weight management. This scenario analysis examined the cost-effectiveness of bariatric surgery compared with the intensive medical bariatric program.

Scenario 5 – Conservative Estimates of UKPDS-OM2 Mortality

Empirical evidence suggested that the UKPDS-OM2 overestimated all-cause mortality and cardiovascular mortality.[118,119] This scenario analysis scaled down the death events by 20% and evaluated the costs and outcomes accordingly.

Results

Reference Case Analysis

In our reference case, the average cost in year 1 was $1,401 and $12,400 for people who received nonsurgical usual care and bariatric surgery, respectively (Table 20; Tables A4–A6; Figures A1 and A2 show the trajectory of BMI and HbA1c levels over the lifetime horizon). The lifetime horizon analysis estimated that the total cost was $51,263 for nonsurgical usual care compared with $59,261 for bariatric surgery. In our reference case analysis, we found that bariatric surgery led to increased costs in year 1 but saved costs related to diabetes care compared with nonsurgical usual care from year 2 until the end of life. The incremental cost for bariatric surgery was estimated to be $7,998 over a lifetime horizon when compared with nonsurgical usual care. As for QALYs, bariatric surgery led to a 0.040 increase in QALYs in the first year (due to diabetes remission and weight loss) and a 0.294 increase in QALYs over a lifetime horizon of year 2 to year 50, with a total increase of 0.334 QALYs when compared with nonsurgical usual care. Examining the breakdown of outcomes, the difference in QALY was driven by the life-years gained after bariatric surgery in year 2 to year 50 (Table A5). The ICER was estimated to be $23,946 per QALY over a lifetime horizon and $271,484 per QALY in the first year.

Table 20: Reference Case Analysis Results

Strategy	Average total cost, $	Average total effects		
		Diabetes remission	Life-years	QALY
Usual care, mean (CrI)[a]	52,039	0	17.162	13.524
Year 1	1,429	0	1	0.797
Year 2 to year 50	50,610	NA	16.162	12.726
Bariatric surgery, mean (CrI)[a]	60,190	0.647	17.513	13.863
Year 1	12,626	0.647	1	0.838 (0.800–0.874)
Year 2 to year 50	47,564[b]	NA	16.513[b]	13.025[b]
Incremental[c,d,e]	8,151[d]	0.647[e]	0.351[e]	0.339[e]
ICER, $ per outcome unit	—	$12,598 per diabetes remission at year 1	$23,222 per life-year gained	$24,023 per QALY

Abbreviations: ICER, incremental cost-effectiveness ratio; NA, not applicable; QALY, quality-adjusted life-year.
[a]With the 2-stage model, we calculated the total by adding the estimates from 2 stages; thus, we were not able to estimate credible intervals.
[b]The UKPDS-OM2 was not able to consider the uncertainties related to cost parameters for diabetes care and complications, effectiveness parameters for BMI and HbA1c, and risk factor progressions.
[c]Results may appear inexact due to rounding.
[d]Incremental cost = average cost (bariatric surgery) − average cost (nonsurgical usual care).
[e]Incremental effect = average effect (bariatric surgery) − average effect (nonsurgical usual care).

Sensitivity Analysis

We conducted scenario analyses to examine structural model uncertainty regarding the key assumptions on the benefit of bariatric surgery. For the decision tree evaluating the costs and QALYs in the first year, people who received nonsurgical usual care had stable costs and QALYs. Therefore, differences in costs were driven by the surgery cost while the difference in QALYs was utility gains due to weight loss and diabetes remission after surgery. We conducted one-way sensitivity analysis (Table 21) on the utility parameters for weight loss and diabetes remission, and the effect of bariatric surgery on weight loss and diabetes remission. Our sensitivity analyses found that the incremental costs and incremental QALYs in the first year were robust to the values of diabetes remission and weight loss parameters.

Table 21: One-Way Sensitivity Analysis

Parameters	Range	Average incremental cost, $[a]	Average incremental effect, QALY[b]	ICER, $ per QALY
Reference case		11,197	0.041	271,484
Utility gain				
Type 2 diabetes remission	0–0.06	No impact	0.032–0.061[c]	183,761–359,094[c]
10%–15% weight loss	0–0.1	No impact	0.033–0.049[c]	229,016–340,075[c]
> 15% weight loss	0–0.1	No impact	0.015–0.058[c]	192,218–734,838[c]
Effectiveness				
Probability of type 2 diabetes remission	0.4–0.8	10,990–11,624[d]	0.038–0.044[d]	248,175–307,408[d]
BMI decrease	2–10	No impact	0.019–0.047[e]	239,735–581,887[e]

Abbreviations: BMI, body mass index; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.

[a]Incremental cost = average cost (bariatric surgery) − average cost (nonsurgical usual care).

[b]Incremental effect = average effect (bariatric surgery) − average effect (nonsurgical usual care).

[c]The larger utility gain was associated with a greater QALY gain and lower ICER value.

[d]The higher probability of type 2 diabetes remission was associated with the lower the incremental cost, more QALY gain, and lower ICER value.

[e]The larger BMI decrease was associated with more QALY gain and lower ICER value.

We conducted additional sensitivity and scenario analyses for long-term costs and QALY scores. Differences in cost in the long-term model were driven by the assumption that bariatric surgery would lead to cost savings due to diabetes remission. Our reference case assumed that 38% of patients who initially had diabetes would reach remission, which led to cost saving for diabetes care (annual diabetes care costs from a Ministry of Health perspective was estimated to be $887 for people who underwent bariatric surgery versus $1,431 for those who did not). When the annual diabetes care costs increased by 5% to 50% for individuals who underwent bariatric surgery ($936 to $1,335), the total therapy costs from year 2 to year 50 ranged from $7,044 to $10,063 (reference case: $6,709). We found that although incremental costs from year 2 to year 5 were driven by the assumption of cost savings due to diabetes remission, the incremental costs over the lifetime horizon, as well as the ICER estimates, were nevertheless relatively robust (ICER estimates ranging from $24,494 to $33,533 per QALY).

As our clinical evidence review shows, there is limited evidence on the long-term effects of bariatric surgery on weight and diabetes outcomes. Our reference case analysis was based on changes in BMI and HbA1c from a clinical trial over a 5-year period, and the assumption that the 2 factors would progress as per the risk factor progression equations by Leal et al.[95] This reference case was limited due to uncertainty of the trajectory of risk factors over the lifetime horizon. A scenario analysis with a 5-year time horizon found that the average incremental cost was $9,068; the average incremental QALY was 0.058; and the ICER was $157,504 per QALY (Table 22).

Table 22: Scenario Analysis Results: 5-Year Time Horizon

Strategy	Average total cost, $[a]	Average total effect, QALY[a]	ICER, $ per QALY
Usual care	14,167	3.802	—
Bariatric surgery	23,235	3.859	—
Incremental[b]	9,068[c]	0.058[d]	157,504

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.
[a]With the 2-stage model, we calculated the total by adding the estimates from 2 stages; thus, we were not able to estimate credible intervals.
[b]Results may appear inexact due to rounding.
[c]Incremental cost = average cost (bariatric surgery) − average cost (nonsurgical usual care).
[d]Incremental effect = average effect (bariatric surgery) − average effect (nonsurgical usual care).

When bariatric surgery led to changes on cholesterol levels and systolic blood pressure, the costs were similar to those in the reference case, but QALYs differed because of different risk levels due to changes in cholesterol and systolic blood pressure (Table 23). The incremental QALY was estimated to be 0.357, which was larger than that of the reference case (0.339 QALYs). The ICER was $22,505 per QALY over a lifetime horizon.

If we assumed that BMI and HbA1c values stay stable 5 years after the intervention and beyond, the incremental QALY of bariatric surgery compared with that of nonsurgical usual care decreased to 0.364 over the lifetime horizon. The ICER was $22,036 per QALY over the lifetime horizon. Assuming BMI and HbA1c values returned to baseline before surgery, gains would be 0.160 QALYs. The ICER was $44,457 per QALY over the lifetime horizon.

In all the scenario analyses on different assumptions about the benefits of bariatric surgery, bariatric surgery led to cost savings and QALY gains from year 2 to year 50. Over the lifetime horizon, the ICERs from these scenario analyses were similar to those of the reference case except for the scenario in which BMI and HbA1c return to baseline before surgery.

Table 23: Scenario Analysis Results for Different Assumptions of Benefits

Strategy	Average total cost, $[a]	Average total effect, QALY[a]	ICER, $ per QALY
Bariatric surgery impacting cholesterol and systolic blood pressure			
Usual care	52,090	13.533	—
Bariatric surgery	60,126	13.890	—
Incremental[b,c,d,e]	8,036	0.357	22,505
Hba1c and BMI stay stable after 5 years			
Usual care	51,612	13.562	—
Bariatric surgery	59,629	13.925	—
Incremental[b,c,d,e]	8,017	0.364	22,036
Hba1c and BMI return to baseline levels after 5 years			
Usual care	52,110	13.548	—
Bariatric surgery	59,244	13.708	—
Incremental[b,c,d,e]	7,134	0.160	44,457

Abbreviations: BMI, body mass index; HbA1c, hemoglobin A1c (or glycated hemoglobin); ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-years.
[a]With the 2-stage model, we calculated the total by adding the estimates from 2 stages; thus, we were not able to estimate credible intervals.
[b]Incremental cost = average cost (bariatric surgery) − average cost (nonsurgical usual care).
[c]Negative costs indicate savings.
[d]Results may appear inexact due to rounding.
[e]Incremental effect = average effect (bariatric surgery) − average effect (nonsurgical usual care).

One clinical trial[51] compared bariatric surgery with a medical weight management program; we assumed the effect was similar to that of the intensive medical bariatric program available in Ontario. The cost of intensive medical bariatric program was estimated to be $5,170 in year 1, and $56,643 over the lifetime horizon. The total QALY for the intensive medical bariatric program was 13.691 QALYs, larger than that of the nonsurgical usual care in the reference case but still smaller than the bariatric surgery. The ICER was $21,383 per QALY for bariatric surgery when compared with that for an intensive medical bariatric program over a lifetime horizon (Table 24).

Table 24: Sensitivity Analysis Results: Comparison of Bariatric Surgery With Intensive Medical Bariatric Program

Strategy	Average total cost, $[a]	Average total effect, QALY[a]	ICER, $ per QALY
Usual care—intensive medical bariatric program	56,643	13.691	—
Bariatric surgery	60,279	13.861	—
Incremental[b]	3,636[c]	0.170[d]	21,383

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-years.
[a]With the 2-stage model, we calculated the total by adding the estimates from 2 stages; thus, we were not able to estimate credible intervals.
[b]Results may appear inexact due to rounding.
[c]Incremental cost = average cost (bariatric surgery) − average cost (non-surgical usual care).
[d]Incremental effect = average effect (bariatric surgery) − average effect (nonsurgical usual care).

Assuming conservative outputs regarding all-cause deaths from the reference case, we estimated that average costs and QALYs would be larger for people who received nonsurgical usual care and bariatric surgery than those in the reference case over the lifetime horizon of year 2 to year 50. Over the lifetime horizon, the total costs and QALYs were estimated to be $53,930 and 16.705 for nonsurgical usual care, and $61,158 and 16.986 for bariatric surgery. The incremental cost and QALYs were $7,228 and 0.281 for bariatric surgery compared with nonsurgical usual care. The ICER was $25,746 per QALY over the lifetime horizon (Table 25).

Table 25: Sensitivity Analysis Results: Decreased Incidence of Death

Strategy	Average total cost, $[a]	Average total effect, QALY[a]	ICER, $ per QALY
Usual care	53,930	16.705	—
Bariatric surgery	61,158	16.986	—
Incremental[b]	7,228[c]	0.281[d]	25,746

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-years.
[a]With the 2-stage model, we calculated the total by adding the estimates from 2 stages; thus, we were not able to estimate credible intervals.
[b]Results may appear inexact due to rounding.
[c]Incremental cost = average cost (bariatric surgery) − average cost (nonsurgical usual care).
[d]Incremental effect = average effect (bariatric surgery) − average effect (nonsurgical usual care).

Discussion

We conducted a primary economic evaluation to determine the cost-effectiveness of bariatric surgery compared with usual care (medical management) for people with class I obesity and difficult-to-manage type 2 diabetes in the Ontario setting. We used an externally developed and publicly available microsimulation model, allowing for better incorporation of individual risk factors and event history in the long-term analysis. This is particularly important considering the complexity of the diabetes care pathway and both macrovascular and microvascular complications. The study population in this analysis consisted of 1,000 hypothetical patients with characteristics derived from previous epidemiological studies. With this hypothetical cohort, we were able to define the study population strictly as class I obesity and difficult-to-manage type 2 diabetes, which was rather different from other reports that included similar populations but with a mix of class I or class II obesity or a mix of with or without comorbidities. With a decision tree over a 1-year time horizon, our analyses considered the potential benefits of diabetes remission and weight loss incurred by bariatric surgery and their impact on quality of life (measured by QALYs). In the long term, we adapted the UKPDS-OM2 to examine the impact of bariatric surgery and nonsurgical usual care on macrovascular and microvascular events over a lifetime horizon. This model was internally valid over 25 years and predicts event rates for complications.[95] It has been used in a range of research and in clinical and commercial applications worldwide, including by NICE.[120,121]

Our clinical evidence review found Low- to Very low-quality evidence (GRADE) on the benefits of bariatric surgery for diabetes remission or weight loss. Nevertheless, our analysis found that bariatric surgery was both more costly (the incremental cost was $8,151) and more effective (the incremental QALY was 0.339) than usual care (medical management) over the lifetime horizon. Bariatric surgery may be cost-effective compared with nonsurgical usual care. Our results were similar to those from several other reports that included similar study populations.[54,72-75]

The cost difference between year 2 and year 50 was driven by diabetes care costs, but this had limited impact on the difference in the total costs over the lifetime horizon, which was mainly determined by the bariatric surgery costs. The QALY difference in the short term, which was attributed to the diabetes remission and weight loss, was small (0.041 QALY). The difference in the total QALYs over the lifetime horizon was driven by life expectations gained in the long-term. In sum, the cost-effectiveness of bariatric surgery depended on the bariatric surgery costs and its long-term benefits.

We conducted a further series of sensitivity and scenario analyses to examine uncertainty in model structure and parameters, including the assumptions on benefits of bariatric surgery for weight loss, for diabetes remission over the short-term and long-term horizons. The results from these sensitivity and scenario analyses were consistent with the reference case. In the short-term, the cost difference was relatively insensitive to the assumptions of diabetes remission and weight loss. The estimate of incremental QALYs was small but stable, except when we assumed there were no utility gains due to either diabetes remission or weight loss. In the long term, we conducted scenario analyses with different assumptions about BMI and HbA1c progression. However, our model-based analysis suggested that most of QALY gains (0.058 of 0.339 QALYs gained was accumulated over the first 5 years in our analysis) occurred beyond the 5-year time horizon. Results depended on the assumption over the long-term effectiveness of bariatric surgery. Our analysis was conducted from a public payer perspective, rather than from a societal perspective. However, we expected that an analysis from a societal perspective would be more in favour of bariatric surgery. From a societal perspective the saved costs attributable to diabetes treatment and the benefits in productivity gain (as a results of improved outcomes) for people who reach diabetes remission after bariatric surgery would be larger.

Our analyses assessed bariatric surgery from a cost-effectiveness perspective. Though our analysis suggested that bariatric surgery might be an economically attractive option, it should not be taken as a prescription for decision-making. In practice, clinical decisions about treatment for people with class I obesity and difficult-to-manage type 2 diabetes may take into account other factors, such as patient preferences, the benefits and risks of bariatric surgery versus those of alternative options, and individual clinical characteristics (such as risk of macrovascular or microvascular complications).

Strengths and Limitations

We examined the role of bariatric surgery in management of people with class I obesity and difficult-to-manage type 2 diabetes in Ontario. We filled an evidence gap by considering long-term costs and outcomes in the clinical pathway. Compared with existing decision-analytic models on relevant topics, our model has merits in terms of time horizon, model structure, and a focus on a clearly defined study population. First, we took a lifetime horizon approach, which was necessary to consider the long-term impact of obesity and type 2 diabetes in costs and outcomes. We considered the benefits of diabetes remission and weight loss in the short-term and adapted the UKPDS-OM2 to evaluate the impact of bariatric surgery on a variety of macrovascular and microvascular complications. This analysis focused on a clearly defined study population of individuals with class I obesity and difficult-to-manage type 2 diabetes, rather than a mixed population with various levels of obesity and varying degrees of type 2 diabetes. Furthermore, our analysis was based on the best available evidence and applied Canadian data where possible.

However, our analysis also had some limitations. First, our model was limited by the low quality of clinical evidence outcomes. Only limited clinical trial data were available to inform the change in BMI and HbA1c, and information about long-term outcomes contained even greater uncertainties. The clinical parameters were based on 1 clinical trial with reports of HbA1c and BMI outcomes at 6 months,[51] 3 years,[56] and 5 years[55] after the initial treatment. We chose this trial as the primary source of parameters based on the similarity in the clinical setting and completeness of HbA1c and BMI outcomes over the 5 years of follow up. Nevertheless, this clinical trial was not conducted in Ontario or Canada, and the effects of bariatric surgery on BMI and HbA1c may be different from those of the bariatric surgery program in the population of interest here in Ontario. We addressed this concern by conducting various scenario analyses with different assumptions on the effects and observed similar outcomes over the lifetime horizon. Nevertheless, higher quality of clinical evidence on the long-term outcomes may better inform the model-based analysis.

Second, we were unable to identify reports that could characterize the study population or nonsurgical usual care in either Ontario or Canadian settings. Our study population was 1,000 hypothetical patients who did not have the same clinical characteristics of real individuals who would have met the eligibility criteria of class I obesity and difficult-to-manage type 2 diabetes in Ontario or in Canada. This approach meant that we were able to focus on obesity and type 2 diabetes factors, but also that we were unable to examine the role of other risk factors (e.g., cholesterol levels, smoking history, resting heart rate, estimated glomerular filtration rate) in a manner that can best represent the risk profiles of the Ontario population. We addressed this concern by using large epidemiological studies on type 2 diabetes patients from similar settings (e.g., United Kingdom, Australia) to characterize our study population. However, there may be unknown meaningful differences between Ontario populations and the populations in these studies.

In addition, we were unable to examine the uncertainty over long-term effectiveness and cost parameters in a probabilistic approach with the UKPDS-OM2. This underestimated the uncertainty over the cost-effectiveness results and reported narrow credible intervals. Nevertheless, we conducted scenario analyses to examine the robustness of cost-effectiveness with different assumptions over the benefit of bariatric surgery. Our cost estimates may not reflect the emerging changes in clinical practice, such as shortened hospital stay after bariatric surgery, panniculectomy need (i.e., skin fold removal), new medications for obesity (i.e., tirzepatide), or change in definition of type 2 diabetes remission.[18]

There may be concerns over the applicability of the UKPDS-OM2, which was a model for people with newly diagnosed type 2 diabetes, while our population of interest is people with class I obesity and difficult-to-manage type 2 diabetes.[121]

Lastly, due to limited clinical data, we were unable to fully examine the cost-effectiveness of bariatric surgery for people of different ethnicities or consider the cost-effectiveness of bariatric surgery using a lower BMI cut-off value. Overall, our results were robust, but caution is necessary if generalizing the results of this model-based analysis to settings other than Ontario.

Conclusions

For people with class I obesity and difficult-to-manage type 2 diabetes, bariatric surgery may be more costly but it may also more clinically effective when compared with usual care (medical management). Over a lifetime horizon, bariatric surgery led to cost increases ($8,151); yet, it also led to a gain of 0.339 QALYs. The cost increase was driven by the surgery costs and the QALY gain by life-years gained. The cost-effectiveness results depend on the long-term outcomes of bariatric surgery, which are uncertain.

Budget Impact Analysis

Research Question

What is the potential 5-year budget impact for the Ontario Ministry of Health of publicly funding bariatric surgery in adults with class I obesity and difficult-to-manage type 2 diabetes, with or without other comorbidities?

Methods

Analytic Framework

We estimated the budget impact of publicly funding bariatric surgery using the cost difference between 2 scenarios (Figure 4): (1) current clinical practice without public funding for bariatric surgery (the current scenario) and (2) anticipated clinical practice with public funding for bariatric surgery (the new scenario).

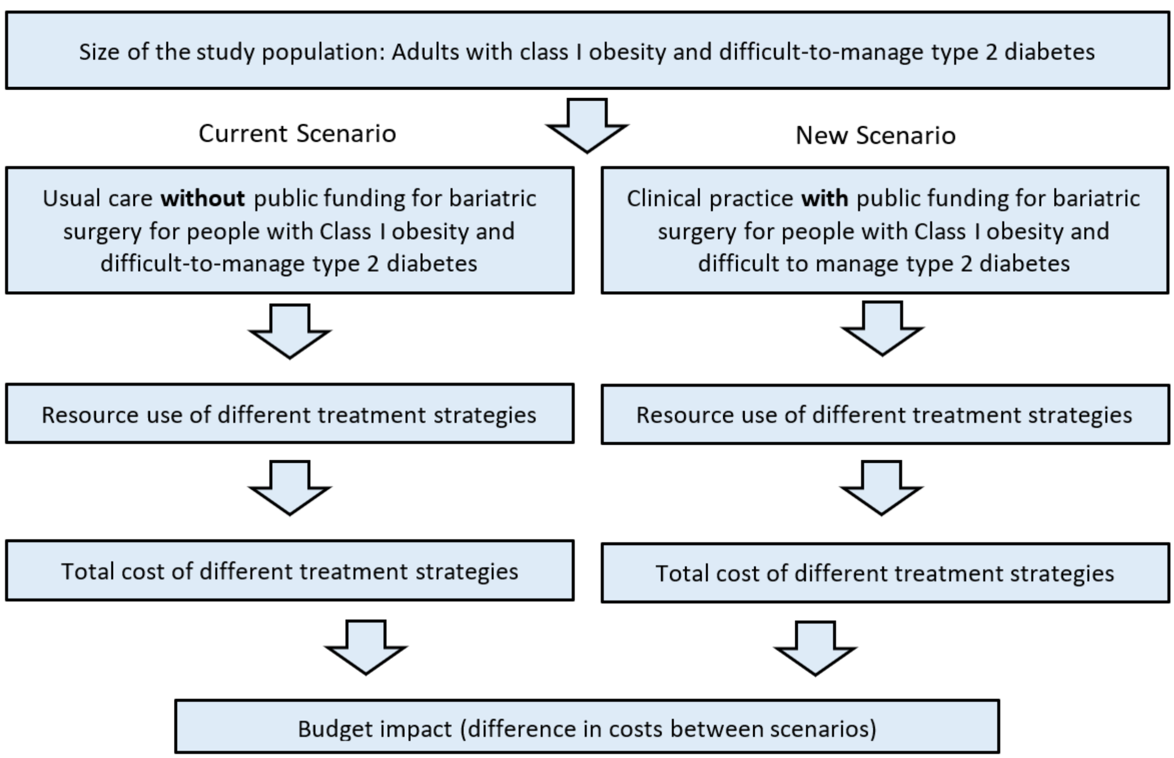

Figure 4: Schematic Model of Budget Impact

Flow chart describing the model for the budget impact analysis. Based on the size of the study population, we created 2 scenarios: the current scenario, which would explore the distribution of treatment strategies, resource use, and total costs without public funding for bariatric surgery; and the new scenario, which would explore the distribution of treatment strategies, resource use, and total costs with public funding for bariatric surgery. The budget impact would represent the difference in costs between the 2 scenarios.

Key Assumptions

This budget impact analysis is based on our model-based analysis. The assumptions in our cost-effectiveness analyses also applied to the budget impact analyses. In addition, we also assumed that:

- The eligibility of bariatric surgery would not change over the next 5 years
- The risk of health events (including macrovascular and microvascular events, and death) would remain stable over the next 5 years
- The procedure and costs of bariatric surgery and other nonsurgical treatment strategies would stay the same over the next 5 years
- If bariatric surgery is funded for people with class I obesity and difficult-to-manage type 2 diabetes in Ontario, the surgery would be Roux-en-Y gastric bypass
- If bariatric surgery is funded for people with class I obesity and difficult-to-manage type 2 diabetes in Ontario, there would be expanded capacity to meet the additional need. This funding recommendation would not take away the capacity for people who are currently eligible
- We did not consider the costs for people with class I obesity and difficult-to-manage type 2 diabetes who receive bariatric surgery from private clinics
- We assumed that once the surgery is publicly funded, the number of eligible individuals would exceed the current capacity, and the main driver of budget impact is the bariatric surgery program capacity

Study Population

Table 26 summarizes the estimates for the volume of eligible people in a new scenario with bariatric surgery being publicly funded for people with class I obesity and difficult-to-manage type 2 diabetes in Ontario. However, the prevalence of class I obesity with difficult-to-manage type 2 diabetes in Ontario is unknown. According to Diabetes Canada's projections, the total number of people with diabetes is projected to climb to 2,953,000 cases in 2032 from 2,346,000 in 2022.[122] Based on these projections, we calculate that in 2023, there are 1,501,119 diagnosed type 2 diabetes cases, and this will increase to 1,645,494 in 2027. Assuming 14% of these cases are in individuals with class I obesity (a conservative estimate, because this 14% estimate is from the general population, who are at a lower risk of obesity than people with type 2 diabetes), and 56.6% of the population with controlled diabetes, we estimate that the number of people with class I obesity and difficult-to-manage type 2 diabetes will increase from 89,106 in 2023 to 97,677 in 2027 (Appendix 7).

Table 26: Population in Ontario Who May Meet Eligibility Criteria

	2023	2024	2025	2026	2027
People with diabetes (type 1, diagnosed and undiagnosed type 2 diabetes)[a], n	2,400,481	2,456,228	2,513,268	2,571,634	2,631,355
People with diagnosed diabetes (type 1 and diagnosed type 2 diabetes)[b], n	1,681,155	1,720,197	1,760,145	1,801,021	1,842,846
People with diagnosed type 2 diabetes[c], n	1,501,119	1,535,980	1,571,650	1,608,148	1,645,494
People with class I obesity and difficult-to-manage type 2 diabetes[d], n	89,106	91,176	93,293	95,460	97,677

[a]Calculated based on 2,346,000 diabetes cases in 2022 and a 2.32% increase rate.[122]

[b]Calculated based on 1,643,000 type 1 and diagnosed type 2 diabetes cases in 2022 and an 2.32% increase rate.[122]

[c]Assuming 7.5% of all diabetes cases are type 1 diabetes, the number of type 1 diabetes cases is estimated based on the total number of diabetes cases. The number of people with diagnosed type 2 diabetes was estimated by subtracting the number of people with type 1 diabetes from the number of people with diagnosed diabetes (type 1 and diagnosed type 2 diabetes).

[d]Calculated based on a prevalence of 14% of class I obesity among individuals with type 2 diabetes, and a proportion of 56.6% with controlled diabetes.

Current Intervention Mix

Currently, in Ontario, bariatric surgery is publicly funded for adults with BMI greater than 40 kg/m^2, or with BMI equal to or greater than 35 kg/m^2 and 1 or more diagnosed comorbidities (type 2 diabetes, coronary heart disease, hypertension, sleep apnea, or gastroesophageal reflux disease).[123] Therefore, we assumed all people with class I obesity and difficult-to-manage type 2 diabetes who seek bariatric surgery currently receive nonsurgical treatment only, which means they receive medication for diabetes but no surgery to control or reduce weight as treatment.

Uptake of the New Intervention and New Intervention Mix

The current capacity funds up to 4,000 bariatric surgeries in Ontario per year. It means if the eligibility criteria expanded to include people with class I obesity and difficult-to-manage type 2 diabetes, the number of eligible people may far exceed the current capacity. Thus, we are assuming that the budget impact of publicly funding bariatric surgery for people with class I obesity and difficult-to-manage type 2 diabetes mainly depends on the increased capacity of bariatric surgery program. To predict the budget impact, it is critical to predict the program capacity. We assumed a capacity increase of 100 surgeries for the bariatric surgery program in Ontario per year. Nevertheless, the increased capacity may serve people who meet the eligibility criteria currently, and not all capacity would be applied to the study population for this health technology assessment. If bariatric surgery is public funded for people with class I obesity and difficult-to-manage type 2 diabetes, we assumed bariatric surgery for people with class I obesity and difficult-to-manage type 2 diabetes would take up 50% of the total increased capacity (Table 27).

Table 27: Uptake of Bariatric Surgery for Class I Obesity and Difficult-to-Manage Type 2 Diabetes

	Year 1	Year 2	Year 3	Year 4	Year 5
Increased total capacity for bariatric surgery, n	100	200	300	400	500
Potential uptake in people with class I obesity and difficult-to-manage type 2 diabetes,[a] n	50	100	150	200	250

[a]We assumed people with class I obesity and difficult-to-manage type 2 diabetes would take up 50% of the total increased capacity for bariatric surgery.

Resources and Costs

We used undiscounted, annual per-person costs associated with bariatric surgery and usual care for our cost-effectiveness analyses. We considered both resource use associated with health technology and health states, including costs incurred by bariatric surgery, treatment of diabetes with medical management, and complications. All costs were inflated if necessary and reported in 2023 Canadian dollars. We used Microsoft Excel for budget impact analysis.

According to the cost-effectiveness model (Table 28), the average unit cost per person who received usual care ranged from $1,432 in year 1 to $3,247 in year 5, while for people who received bariatric surgery the average unit cost per person ranged from $13,795 in year 1 to $2,746 in year 5. The main driving factor for the cost difference is the surgical cost in year 1 and medical management costs from year 2 to year 5.

Table 28: Undiscounted, Annual Per-Person Costs Associated With Bariatric Surgery and Usual Care for the Budget Impact Analysis

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
No bariatric surgery						
Medical management	$1,432	$1,456	$1,398	$1,379	$1,338	$7,003
Complications	$0	$1,910	$1,904	$1,934	$1,908	$7,657
Total	$1,432	$3,366	$3,302	$3,313	$3,247	$14,660
Bariatric surgery						
Surgery	$11,643	$0	$0	$0	$0	$11,643
Medical management	$733	$904	$870	$859	$835	$4,201
Complications	$0	$1,867	$1,870	$1,903	$1,910	$7,550
Total	$12,363	$2,771	$2,739	$2,762	$2,746	$24,813

Internal Validation

The secondary health economist conducted formal internal validation. This process included checking for errors and ensuring the accuracy of parameter inputs and equations in the budget impact analysis.

Analysis

We conducted a reference case analysis and sensitivity analyses. Our reference case analysis has the most likely set of input parameters and model assumptions. Our sensitivity analyses explored how the results are affected by varying input parameters and model assumptions. We further conducted sensitivity analyses regarding the bariatric surgery costs, costs for complications, and uptake of bariatric surgery. Furthermore, we conducted scenario analyses assuming higher or capacity increase in the new intervention mix.

Results

Reference Case

We estimated the budget impact per person according to Table 28. The unit cost for 1 surgery was estimated to be $11,643. Considering the diabetes care costs and macrovascular and microvascular complications, the budget increase would be $10,931 (the difference between bariatric surgery and no bariatric surgery in Table 28) in year 1. In the next few years, the budget impact per person would be a cost saving of $595, $562, $551, and $501 in year 2 to year 5, respectively, driven by the cost savings for diabetes care. The total budget impact per person was estimated to be $8,734 in 5 years.

Table 29 shows the budget impact of publicly funding bariatric surgery for people with class I obesity and difficult-to-manage type 2 diabetes. Assuming from year 1 to year 5 that the number of publicly funded bariatric surgery for people with class I obesity and difficult-to-manage type 2 diabetes increased from 50 to 250, publicly funding these surgeries would lead to a budget increase of $0.55 million in year 1 to $2.45 million in year 5, for a $7.63 million increase in total.

As the breakdown shows (Table 29), the budget increase was mainly driven by the costs of bariatric surgery. If we only consider the costs of bariatric surgery, the budget impact would be $0.58 million in year 1, and $2.91 million in year 5 if the number of surgeries increased from 50 to 250 over 5 years.

Table 29: Budget Impact Analysis Results

Scenario	Budget impact, $ million[a]					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total[b,c]
Current scenario	0.14	0.62	1.43	2.57	4.04	8.81
Medical management	0.14	0.43	0.86	1.43	2.13	4.99
Complications	0	0.19	0.57	1.15	1.91	3.82
New scenario	0.69	1.69	2.99	4.59	6.49	16.45
Bariatric surgery	0.58	1.16	1.75	2.33	2.91	8.73
Medical management	0.11	0.33	0.67	1.13	1.69	3.93
Complications	0	0.19	0.57	1.14	1.90	3.79
Budget impact[b,c]	0.55	1.06	1.55	2.02	2.45	7.63
Bariatric surgery	0.58	1.16	1.75	2.33	2.91	8.73
Medical management	-0.03	−0.10	−0.19	−0.41	−0.62	−1.06
Complications	0	−0.00	−0.01	−0.01	−0.02	−0.04

[a]In 2023 Canadian dollars.
[b]Negative costs indicate savings.
[c]Results may appear inexact due to rounding.

Sensitivity Analysis

Table 30 shows the scenarios with a higher number of bariatric surgeries conducted for people with class I obesity and difficult-to-manage type 2 diabetes. In the scenario of an annual increase of 100 surgeries, the annual budget increase would be $1.09 million in year 1, and $4.90 million in year 5, with a total of $15.27 million. When 200 additional surgeries were funded, the annual budget increase would be $2.19 million in year 1, and $9.81 million in year 5, with a total of $30.54 million.

Table 30: Budget Impact Analysis Results

Scenario	Budget impact, $ million[a]					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total[b,c]
Annual increase of 100 surgeries for class I obesity and difficult-to-manage type 2 diabetes						
Current scenario	0.14	0.62	1.43	2.57	4.04	8.81
New scenario	1.24	2.75	4.54	6.61	8.95	24.08
Budget impact[b,c]	1.09	2.13	3.11	4.03	4.90	15.27
Annual increase of 200 surgeries for class I obesity and difficult-to-manage type 2 diabetes						
Current scenario	0.29	1.25	2.87	5.15	8.08	17.63
New scenario	2.48	5.50	9.08	13.21	17.89	48.16
Budget impact[b,c]	2.19	4.26	6.22	8.06	9.81	30.54

[a]In 2023 Canadian dollars.
[b]Negative costs indicate savings.
[c]Results may appear inexact due to rounding.

Discussion

We conducted a model-based budget impact analysis to examine the range of costs related to publicly funding bariatric surgery for people with class I obesity and difficult-to-manage type 2 diabetes. For this population, we based the cost and resource estimates on outputs from the model in our primary economic evaluation. Assuming 50 additional bariatric surgeries were funded for this study population in year 1, increasing to 250 in year 5, publicly funding bariatric surgery for people with class I obesity and difficult-to-manage type 2 diabetes would lead to a budget increase of $0.55 million in year 1 and $2.45 million in year 5, for a total budget increase of $7.63 million over 5 years. The cost increase was driven by the surgical costs. In Ontario, bariatric surgery is publicly funded for patients with a BMI of more than 40 kg/m^2, or for those with a BMI of 35 kg/m^2 or greater, with 1 or more diagnosed comorbidities (type 2 diabetes, coronary heart disease, hypertension, sleep apnea, or gastroesophageal reflux disease). Our budget impact analysis may be used to help estimate the resources needed to adopt eligibility criteria of bariatric surgery for people with class I obesity (BMI between 30 and 35 kg/m^2) and difficult-to-manage type 2 diabetes in Ontario.

Considering the public funding that is available for bariatric surgery in Ontario, and there are about 4,000 surgeries funded by Ministry of Health annually, in the scenario of bariatric surgery publicly funded for people with class I obesity and difficult-to-manage type 2 diabetes, the availability or the capacity of the bariatric surgery program may be limited by factors that are beyond the scope of this analysis – for example, human resources, such as the availability of bariatric surgeons and clinicians. Therefore, we also reported the budget impact per person and the budget increase for the costs of bariatric surgery alone, to serve as guideposts for resource planning. According to our analysis, the unit cost for 1 surgery was estimated to be $13,345, and the budget impact per person over a 5-year period was $9,953 considering the potential cost savings due to decreased need in diabetes care.

We further conducted sensitivity analyses to examine the robustness of our budget impact analysis. In the scenario of larger number of bariatric surgeries funded for people with class I obesity and difficult-to-manage type 2 diabetes, the total budget increase would be $17.40 million and $34.80 million, respectively, when 1,500 bariatric surgeries (100 in year 1 to 500 in year 5), or 3,000 bariatric surgeries (200 in year 1 to 1,000 in year 5) are funded for the study population.

Strengths and Limitations

Our budget impact analysis had several strengths. First, it was a model-based analysis that considered surgical costs, diabetes care costs, and complications costs. Second, we conducted sensitivity analyses to examine the budget impact of bariatric surgery. Our cost parameters were derived from Ontario or Canadian settings.

Our budget impact analysis was also limited by some uncertainties. First, it was based on the economic model used in our primary economic evaluation, so it contains the same structural uncertainties. Second, our analysis contained uncertainties related to clinical and cost parameters, particularly costs related to diabetes care or diabetes remission, and long-term outcomes. To overcome this limitation, we used a breakdown of the undiscounted bariatric surgery, and we reported the budget impact considering only surgical costs. Third, the capacity of bariatric surgery may be further limited by factors that are beyond the scope of this review. We reported the budget impact when different numbers of surgeries were funded, to serve as a guidepost for resource planning.

Conclusions

Our budget impact analysis suggests that publicly funding bariatric surgery in Ontario for people with class I obesity and difficult-to-manage type 2 diabetes would lead to a budget increase of $0.55 million in year 1 (50 surgeries funded) and $2.45 million in year 5 (250 surgeries funded), for a total increase of $7.63 million over 5 years. The estimated budget increase was mainly due to the surgical costs. If we only considered the surgical costs, the budget impact would be an additional $0.58 million in year 1 and $2.91 million in year 5, for a total of $8.73 million.

Preferences and Values Evidence

Discussion

Engaging with people directly through interviews allowed us to perform a robust examination of the preferences and values surrounding bariatric surgery. All those who participated had direct experience with obesity and trying multiple methods of weight loss options including using diet and exercise. This familiarity with multiple methods of weight loss options allowed for extensive discussion on their struggle to manage their weight with conservative options. In most cases, participants have been struggling with obesity from childhood. Those with type 2 diabetes spoke about the challenges they faced with managing their blood glucose levels despite lifestyle changes and, in some cases, being on medication.

All participants had been diagnosed with obesity, and all but 1 had undergone bariatric surgery.

Therefore, most participants were able to speak to the impact that bariatric surgery had on various aspects of their lives. Participants categorized these benefits as medical, physical, and mental health and provided many examples of each. Participants were able to speak to the barriers they have faced in accessing and choosing to undergo bariatric surgery.

We had broad geographic representation with representation from both southern and northern Ontario as well as rural and urban perspectives. In terms of limitations, firstly the low recruitment rate may be attributed to the stigma and discrimination faced by patients diagnosed with obesity as well as bariatric surgery being viewed as "cheating" or "the easy way out." There was low representation from people who have both obesity and diabetes and from those who pursued medical management for their obesity rather than bariatric surgery

Objective

The objective of this analysis was to explore the underlying values, needs, and priorities of those who have lived experience with obesity and difficult-to-manage type 2 diabetes. In addition, this analysis aimed to examine patient, family, and caregiver preferences and perceptions of bariatric surgery.

Background

Exploring patient preferences and values provides a unique source of information about people's experiences of a health condition and the health technologies or interventions used to manage or treat that health condition. It illuminates how the condition and its treatment impact the person with the health condition, their family and other caregivers, and the person's personal environment. Engagement also provides insight into how a health condition is managed by the province's health system.

Information shared from lived experience can also identify gaps or limitations in published research (e.g., outcomes important to those with lived experience that are not reflected in the literature).[124-126] Additionally, lived experience can provide information and perspectives on the ethical and social values implications of health technologies or interventions.

Because the needs, preferences, priorities, and values of those with lived experience in Ontario are important to consider in order to understand the effect of the technology on people's lives, we may speak directly with people who live with a given health condition, including those with experience of the technology or intervention we are exploring.

For this analysis, the preferences and values of people with lived experience with obesity and type 2 diabetes mellitus were examined via direct engagement. The initiative was led by the Patient and Public Partnering team at Ontario Health, and direct engagement with eligible participants was completed through telephone interviews.

Direct Patient Engagement

Methods

Partnership Plan

The partnership plan for this health technology assessment focused on consultation to examine the experiences of people who have been directly impacted by obesity and their family members or caregivers. We engaged with participants via telephone interviews.

We conducted qualitative interviews, as this method of engagement allowed us to explore the meaning of central themes in the experiences of people with obesity and type 2 diabetes, and their implications, as well as the experiences of their families and caregivers.[127] The sensitive nature of exploring people's experiences of a health condition and their quality of life further supported our choice of methodology.

Participant Outreach

We used an approach called purposive sampling to connect with participants,[128-131] which involved actively reaching out to people with direct experience of the health condition and health technology or intervention being reviewed. We approached a variety of community organizations, clinical experts, and community-based health programs in Ontario that support people affected by obesity and difficult-to-manage type 2 diabetes in an effort to increase the public's awareness of our engagement activity and to connect with people who would like to share their lived experiences.

Inclusion Criteria

We sought to speak with adults with lived experience with obesity and difficult-to-mange type 2 diabetes who had or who were planning to undergo bariatric surgery. Participants did not have to have direct experience with bariatric surgery to participate.

Exclusion Criteria

We did not set exclusion criteria for participants who otherwise met the inclusion criteria.

Participants

For this project, we spoke with 8 individuals with lived experience with obesity, 3 of whom were also diagnosed with type 2 diabetes. Of the 8 participants, 7 had undergone bariatric surgery.

Approach

At the beginning of the interview, we explained the role of our organization, the purpose of this health technology assessment, the risks of participation, and how participants' personal health information would be protected. We gave this information to participants both verbally and in a letter of information (Appendix 8), if requested. We then obtained participants' verbal consent before starting the interview. With the participants' consent, we audio-recorded then transcribed the interviews.

Interviews lasted approximately 20 to 60 minutes. The interview was semistructured and comprised a series of open-ended questions. Questions were based on a list developed by the Health Technology Assessment International Interest Group on Patient and Citizen Involvement in Health Technology Assessment.[132] Questions focused on the impact of obesity and type 2 diabetes on quality of life, experiences with bariatric surgery, and perceptions of the benefits or limitations of bariatric surgery (Appendix 9).

Data Extraction and Analysis

We used a modified version of a grounded-theory methodology to analyze interview transcripts. This approach allowed us to organize and compare experiences across participants. This method consists of a repetitive process of obtaining, documenting, and analyzing responses while simultaneously collecting, analyzing, and comparing information.[133,134] We used the qualitative data analysis software program NVivo[135] to identify and interpret patterns in the data. The patterns we identified allowed us to describe the effect obesity, type 2 diabetes, and their associated management had on those interviewed.

Results

Living With Obesity

Participants spoke about the physical challenges they faced when living with obesity and how obesity had impacted several aspects of their lives including their families and day to day lives. Everyday activities were challenging and tedious due to their decreased mobility, joint pain, fatigue, and other physical conditions, which they attributed to their obesity:

> *What the knee doctor told me, "Don't walk, don't run, don't jump, don't cycle." So it was a recipe for disaster too.*

> *I've been struggling with knee pain for the last couple years. I need knee replacement.*

> *It's affected everything in my life. It's affected the activities that I can do with my children. It's limited things like we don't travel because I don't feel comfortable on an airplane or a or a train.*

Participants spoke about the multiple medical conditions they had been diagnosed with that were associated with obesity and their struggle to manage these conditions:

> *I have multiple medical issues, including a history of high blood pressure, which over the last year has become more and more difficult to control. I have a history of type 2 diabetes in my family.*

> *I've had several specialist cardiologists, rheumatologist, endocrinologist, orthopedic.*

> *Turns out I had really bad sleep apnea.*

> *I saw it slowly, gradually coming back and becoming overweight to the fact that I was definitely obese. And then, I see the health issue start like the arthritis in my knees, my blood pressure, then the diabetes.*

A few spoke about their fear of transferring their negative behaviours when it comes to food choices to their children:

> *My children see me struggling, and I know that they are suffering because of that. I can see that one of my children is suffering from disordered eating.*

Patients discussed the impact that living with obesity had on their mental health. Participants spoke about their low self-esteem, body image issues, and the guilt they felt for being overweight. Their low self-esteem impacted several facets of their day to day lives; for example, participants would refrain from socializing or attending events with their families at times, leading to social isolation. This resulted in strained their relationships with their families and friends. A couple of participants also touched on their experiences with depression:

> *I'm afraid to show myself because how I look … No, my clothes don't fit properly. I might as well not put makeup on, I don't have a neck anymore. I'm not going to get a belt because I don't have my size. I can't afford to go get more new clothes, so all of those things are huge barriers just to everyday living.*

The low self-esteem and confidence also had a negative impact on their motivation to lead an active lifestyle, and they spoke about their struggles to go to the gym due to worry about how they may be perceived by others:

> *I would never go to the gym when I was overweight, I didn't feel comfortable in there. It wasn't a place that I felt welcome.*

> *I have tried various different types of gyms, private gyms, the gyms with the community centres and stuff like that, but a gym is an intimidating place to go for somebody who's overweight. It's awful.*

One participant spoke about the negative impact that their low self-esteem has had on their career trajectory where they felt they couldn't seek out other career opportunities due to their weight:

> *I felt like I couldn't go after a better job because of how I look or I won't be taken seriously because of my weight … And that puts a barrier up in terms of a career. And I thought of going back to school, but again I just thought then I still feel this. I would be kind of outcast. So what is the point?*

Stigmatization and Discrimination

The stigma and discrimination faced by people with obesity negatively impacted participants' mental health. Participants spoke about navigating the health care system when living with obesity. They reported being stigmatized and discriminated against by health care providers when trying to navigate the health care system. Some examples included being spoken to in a condescending tone and, in some cases, not being taken seriously, with their health concerns always being attributed to their weight. Participants emphasized there is a blaming culture and misconceptions around weight loss in that some health care professionals do not realize that obesity may not be in someone's control. Some reported having to self-advocate by pushing their primary care team for a referral for bariatric surgery:

> *First thing when they look at you and they see someone who's overweight.*

> *With obesity, we really need to continue the dialogue and to continue taking away that false belief that every single element is related to weight.*

> *[My doctor] started saying that unless I lost weight, I'm gonna die and this wasn't what I wanted from my doctor. I have tried and my self-esteem was very low from being so heavy.*

Journey to Find Weight Management Solutions

All participants spoke about their journey to find weight loss solutions and their frustrations with failing to lose weight. Many had been struggling with obesity since childhood and had been attempting to manage their weight since then. Participants spoke about exhausting all weight loss solutions, citing several commercial diets and different exercises they've attempted throughout their lives. Despite all these efforts, they were unable to lose weight:

> *I had been attempting to lose and manage my weight since childhood, so obesity has been part of my journey since I've been quite young.*

> *I did all those traditional ways of losing weight and was never successful.*

> *I just couldn't lose weight and I worked out 7 days a week. I ate healthy and still the scale was hard to move. So, it became quite frustrating.*

Several participants also spoke about the weight fluctuations that came with "yo-yo dieting," where they would experience temporary successes before putting the wight back on, in some instances gaining even more weight:

> *It was very frustrating, because you try every diet, you lose 50 pounds, and you gain 60.*

> *That's when I broke down and I said what's wrong with me like I am doing everything that I should be doing and instead of losing, I'm gaining.*

For some, pharmacological options were introduced by their health care providers, such as appetite suppressants.

A couple of participants mentioned the link between low socioeconomic status and difficulties being able to afford nutritious food.

> *When you don't have a lot of money, your choices for food are poor. They tend to be high calorie, but not high nutrition.*

Journey to Find Solutions to Control Diabetes

Participants reported a variety of circumstances that led to their diagnosis of type 2 diabetes. For some, the news of their condition came from routine bloodwork while others experienced symptoms of blurry vision and fatigue, which led them to seek out medical attention:

> *But for me, it was definitely the eyes like it was a drastic change was like even my eye doctor was surprised. When I say drastic, it was a huge change, like something even the ophthalmologist was quite surprised with the change of how drastic my vision changed.*

> *I became a true diabetic, not a prediabetic or not a potential one, but a true diabetic. At the time … I took 1 pill every morning up until the time of my surgery.*

> *I was tired all the time and I brought it up with my doctor.*

Following their diagnosis of type 2 diabetes, participants discussed various treatment methods they followed in an attempt to manage their blood sugar levels. These treatment methods typically involved active blood sugar monitoring, adjustment of food intake, changes to their diet, and increased exercise. Additional changes to lifestyle, such as quitting smoking, were suggested when needed. Participants reported that each step or adjustment to these treatment methods would be made in consultation with their health care providers and their blood sugar would continue to be monitored to track the effects of the treatment regimen.

Participants also reflected on their added burden to find a solution to manage their blood sugar along with managing their weight. They spoke about their struggle to control their diabetes even when making significant lifestyle modifications such as being diligent with their diet and exercise along with regular monitoring of their blood sugar levels. When lifestyle changes had no impact on their diabetes, their health care providers recommended they start on medication:

> *I was trying my best to keep my sugars around 25 grams a day. So if it was heavy in the morning, then later in the afternoon and keep the carbs under 50, the sugars under 25.*

> *I bought a book about diabetic cooking and it's very, very good for not so much the recipes as they're showing you but the glycemic value of different foods.*

> *The years of trying different diets that are out there, so many different things. I tried weight loss medication, which is kind of deals with both the diabetes and helps with a little bit of weight loss.*

In some cases, medication was not a sufficient solution to manage their diabetes:

> *I was on about 100 units of insulin or even more, but my endocrinologist worked with what he had.*

> *[The doctor] did more tests and more blood work. And my sugars were a bit high so [my doctor] put me on medication…So that and healthy eating and some exercise, that's what I'm trying now. But to be honest with you, I don't have a lot of hope because nothing's ever worked.*

Participants who were not diagnosed with diabetes but had a family history of it expressed concerns that it might impact them in the future:

> *I have a history of type 2 diabetes in my family so that was my biggest worry.*

> *My mother was a diabetic. My grandmother was a brittle diabetic. So I have seen those warning signs coming. And I didn't want to become a prediabetic. I didn't want to become a diabetic. I didn't want those health concerns for me.*

Perceptions of Bariatric Surgery

We asked participants about their perceptions of bariatric surgery. Prior to undergoing bariatric surgery, some viewed it as "cheating or the easy way out." These participants also spoke about the societal views around obesity and the misconception of obese people not trying hard enough to lose weight, an additional factor that added to the negative perceptions surround bariatric surgery and those who opt for that option:

> *It wasn't something that I had ever considered before because I thought it was cheating. Because there's that stigma around being overweight and not looking after yourself, and getting bariatric surgery is like a cheater's way of losing the weight.*

> *In my mind I thought bariatric surgery is for those who are too lazy to work out.*

This was contrasted by others who had very positive perceptions of bariatric surgery citing it as the only solution left for them to try after years of struggling to manage their weight. The participants with diabetes also perceived the surgery as a possible way to reverse their diabetes. These participants spoke about how the option to undergo bariatric surgery brought them hope, and they saw it as a road to becoming a healthier person. Additionally, they expressed the possibility of the avoidance of worsening comorbidities or even an early death:

> *I was headed towards hope. Maybe there is hope for me to be able to shed this heavier body so I can feel lighter, and I can feel better about myself.*

> *Maybe it could help with my diabetes and blood pressure. Maybe I would live longer.*

Decision-Making

When asked about decision-making, responses varied, with some participants citing their physician recommending bariatric surgery while others had to self-advocate to get a referral. A few participants had delayed undergoing bariatric surgery because they had the negative perception of it being seen as an "easy way out." All participants described bariatric surgery as being their "last resort" after exhausting all weight loss options, especially due to the invasiveness of the surgery:

> *I was getting very obese and through my family doctor, we decided I would like to try the bariatric program because I've tried every diet under the sun, and it just hadn't worked.*

> *I started to really look into the bariatric surgery myself and I'm the one who actually approached my doctor and was like, you know, I really think this is what I want to try. Everything else has been unsuccessful.*

Several participants spoke about conducting online research and speaking to others who had previously undergone bariatric surgery to be more informed prior to undergoing surgery:

> *I did my own research online. I talked to people who had bariatric surgery.*

> *I'm the type that's research oriented, so I was on the Internet as much as I could and read everything that I could on the bariatric surgeries.*

Some participants spoke about their fears when learning about how bariatric surgery is performed and the negative experiences of others that had prompted them to delay undergoing bariatric surgery:

> *During the info session, after they started talking about you know, where they make their incision – I forget what the technical names are, but part of your stomach stays there and then part of it gets cut off – I just blanked out. So this is what scared me.*

A participant who had undergone bariatric surgery years ago reflected on being told about the risks associated with bariatric surgery but still decided to go ahead with the surgery:

> *The risk of dying from the surgery was, I think 1 in 2. So it was like a 50% death, like there was a 50% death rate. So that was also discussed with us because they're saying this is a high-risk surgery.*

Participants also spoke about their fear of dying young and wanting to prevent that from happening:

> *My biggest my biggest fear is that I will die young. I'm [in in my 40s] and because I am obese. it is quite possible in my life, could be shortened and that frightens me.*

Bariatric Surgery Experience

Experience prior to surgery Those who underwent bariatric surgery spoke about their experience. Before their surgery, a majority had a positive experience with the education sessions and saw them as a setup for success. They reflected on the difficulties with being on a liquid diet in the weeks prior to surgery and their mindset going into surgery which in some cases participants felt nervous and feared the risk of surgical complications they may face while others were hopeful:

I had to go through what you call our teaching classes. They specifically would bring people in a room and who were candidates for the surgery, and they would teach us about various aspects. So first of all, diet and nutrition about exercise, reminding us that bariatric surgery was a tool, but not like an end all and be all solution. It wasn't a quick fix.

There was an education program and I think about a 40- or 50-page brochure pamphlet that the bariatric clinic did put together. And I reviewed it constantly. So I was very aware of the steps of what led up to it. What the lifestyle and that would be after the fact and the preparation, the food once again and everything else. It was well structured and well laid out.

I think I was very hopeful going into surgery. Nervous, yes. But I was hopeful on that day.

Recovery

We asked participants about their experience with recovery. They touched on their hospital stay which lasted about 3 to 5 days. Those from out of town spoke about staying at a hotel after discharge for a few days for their postoperative check-up:

I was in the hospital postsurgery for about 4 days.

I went to a hotel. I think I was told to stay around either 3 or 5 days and then I flew home.

All participants had positive experiences with the initial postsurgical supports that were offered to them by the bariatric program. These included dietitians, counsellors, and periodic weigh-ins:

I did find the support very helpful there. We see the counselor in there so that was good. And I really enjoyed meeting with the dietitians and talking to them and measuring my success that way.

The supports were good. I remember they were in person and being able to meet with the dietitian and then the nurse. And they were both very good.

Some participants stated there is a lack of long-term supports and needed the support to continue past the 5-year mark:

It was over and I couldn't believe this. There was no long-term aftercare or anything like this because they said, "Oh no, you're done with the program now. Thank you very much." And I said, "Well, this is when I need the help."

I need more than 5 years of support to overcome my lifelong struggle with obesity.

Impact of Bariatric Surgery

All participants reflected on the positive experience bariatric surgery had on their quality of life. They noted vast improvements in their day to day lives where they are now able to easily take part in everyday activities which were previously challenging due to their obesity. They cited their increased ability to take part in physical activities due to their increased mobility. They reported day to day routine tasks such as running errands, taking care of their children, and other routines are now easier for them to manage:

> *Being able to go with my kids to different things. I don't have to think about if I can fit in a chair if I'm going to go to the movie theater. There's so many little things that we take for granted when we're not overweight.*
>
> *It was great. Like I said, I believe I lost like 160 pounds and so I was a lot healthier. I was able to move around. I was able to sit in a regular plane seat. It's just. I didn't have the obesity with me, so I was in a much better health frame.*
>
> *It has impacted me beyond imagination. I wouldn't be able to play on the floor with my grandchildren. I wouldn't be able to have them have sleepovers at my house. I couldn't imagine doing that at 300-plus pounds.*

Those who were previously diagnosed with diabetes had their diabetes reversed or had a reduction in the severity of their diabetes:

> *Five years post–gastric sleeve, I was diabetes free.*
>
> *The one thing I just want to say is that most people that come off the surgery table are not diabetics anymore. That's because I've been a diabetic for so many years. I wasn't one of those ones. But right away my insulin was reduced a lot, which made a big difference for me.*
>
> *Health-wise, everything was cured. I didn't have any pain in my knees from the osteoarthritis; my blood pressure concerns my diabetes was fully gone.*

Participants perceived that undergoing bariatric surgery had reduced their risks of acquiring other chronic illnesses or other ailments associated with obesity. Furthermore, they perceived the surgery had prevented them from an early death:

> *I think it saved my life because being 320 pounds and diabetic You know, I can see the writing on the wall.*
>
> *I do believe without me having this bariatric surgery – 2 things – I would be dead. If I'm not dead, I would have drained this health care system because I would have had heart problems and lots of additional problems.*

Improved Mental Health

All reported significant and lasting impacts on their mental health. Participants reported on their improved confidence and self esteem and were finally able to have a positive outlook of the future. The positive impacts on their mental health also led to improvements in their quality of life where they are now able to socialize and enjoy everyday activities. It also provided participants the motivation to lose more weight:

> *I'd be more comfortable and more confident going places with them that involve activities that are physically active instead of sitting around at home. We watch a movie. We don't go for a hike. And you know, they're not keen on hike. But probably because I haven't been able to encourage that in them.*

> *I think they see that difference too where it's like I'm able to stand up for myself. So definitely I have more self-confidence after surgery.*

> *I'm more motivated. And it was a win-win. I've I lost 90 pounds altogether, half on my own, half with the surgery. And I've kept it off. I've not put any of it back on.*

Other Considerations

There were a couple of participants where bariatric surgery wasn't a sustainable weight loss solution. In one instance, a patient suffered from excess vomiting after undergoing bariatric surgery. Another participant gained the weight back due to the lack of long-term supports they needed to sustain their weight loss:

> *I was sick for 2 years after my bariatric surgery where at one point I was even throwing up water.*

> *Slowly over the last 10 years, the weight has crept back, little bit every year…I was lacking the supports and the things that would help me along and I think that's what caused me to gain the weight back.*

Another consideration that a couple of participants mentioned was the excess skin due to the substantial weight loss impacting their body image and participants looking at surgical options to address it:

> *The worst is like the skin hanging everywhere like. After the surgery, when I got to my lowest weight, I really hated my body so I would cover everything. I didn't wear shorts. I didn't wear tank tops.*

Barriers

There were several barriers noted by participants regarding accessing bariatric surgery. One was the stigma and discrimination faced by the obese population in the healthcare system. There was also the stigma around bariatric surgery, with the misconception of it being seen as an easy way out by some:

> *It wasn't something that I had ever considered before because I thought it was cheating. Because there's that stigma around being overweight and not looking after yourself and getting Bariatric surgery is like a cheater's way of losing the weight.*

Geography was another barrier reported by participants, with bariatric surgery being offered at hospitals in major city centers and the education sessions being held in person, though it is unclear if this has changed. The travel involved for some for their surgery, and also, the need to stay at a hotel (for the postsurgical appointment) after being discharged are additional barriers.

We are geographically challenged. [Name of city] is the biggest centre, everyone regionally had to come into the city to do the interview process…what bothered me most was the road conditions because often the highways would be closed, and they couldn't come through for their appointments. So that is a huge challenge, the geography up here.

Participants were asked if they were able to access bariatric surgery through a private clinic; all participants stated that they were unable to afford to bariatric surgery through a private clinic. An additional expense would also the time off work that needed to be taken to recover. Those who did not live in a major city centre or near a hospital with a bariatric clinic spoke about out-of-pocket costs such as hotel and transportation:

I'm on long term disability. I have 3 children. I can barely afford my own expenses…There's no way I could pay for bariatric surgery."

So 2 days plus the 5 days in a hotel at about $200 a night.

Additionally, the lack of consistent long-term support needed by some to sustain their weight loss was noted as a barrier:

Yes, after 5 years postsurgery. You get nothing. Absolutely nothing, no counselling. So then you're on completely on your own.

Conclusions

Participants emphasized the positive impact that bariatric surgery on their quality of life. Participants reported bariatric surgery helped with reducing their weight and in some cases eliminating their chronic conditions such as diabetes resulting in physical, social, and mental health benefits. The barriers mentioned include stigmatization of obesity, cost, and geography. Participants highlighted the importance of having access to long-term support to sustain weight loss results. Participants emphasized that implementation should require equitable access.

Conclusions of the Health Technology Assessment

Compared with medical management in people with class I obesity and difficult-to-manage type 2 diabetes, bariatric surgery may result in large increases in rates of complete diabetes remission (GRADE: randomized controlled trials – Low to Very low; observational studies – Low to Very low), large reductions in BMI (GRADE: randomized controlled trials – Low to Very low; observational studies – Low to Very low), and reduced medication use for type 2 diabetes (GRADE: randomized controlled trials – Low; observational studies – Low). Bariatric surgery may also result in improved quality of life (GRADE: randomized controlled trials – Low), and improved remission of obesity-related comorbidities such as albuminuria, early-stage chronic kidney disease, and hypertension (GRADE: randomized controlled trials – Low; observational studies – Low) in people with class I obesity and difficult-to-manage type 2 diabetes compared with medical management. While bariatric surgery can result in postsurgical complications that are not faced by those receiving medical management, the risks are similar to those observed in people with class II and III obesity who undergo bariatric surgery (GRADE not assessed).

For people with class I obesity and difficult-to-manage type 2 diabetes, our primary economic evaluation found that bariatric surgery may be more costly but also more effective clinically compared with usual care (medical management). Over a lifetime horizon, bariatric surgery led to cost increases ($8,151); yet, it also led to a gain of 0.339 QALYs. The cost-effectiveness results depend on the long-term outcomes (weight loss and diabetes remission) of bariatric surgery, which are uncertain.

Over 5 years, publicly funding bariatric surgery in Ontario for people with class I obesity and difficult-to-manage type 2 diabetes would lead to a budget increase of $0.55 million in year 1 (50 surgeries funded) and $2.45 million in year 5 (250 surgeries funded), for a total increase of $7.63 million over 5 years. The estimated budget increase was mainly due to the surgical costs.

People with obesity and type 2 diabetes with whom we spoke reported that they saw bariatric surgery as a positive option. Those who had undergone the procedure reported positively on its value as a treatment to manage weight loss and diabetes. They felt that equitable access should be a requirement of implementation.

Abbreviations

AHRQ: Agency for Healthcare Research and Quality

BMI: body mass index

CADTH: Canadian Agency for Drugs and Technologies in Health

CI: confidence interval

CNY: China yuan

eGFR: estimated glomerular filtration rate

EUR: euro

GLP1R: glucagon-like peptide 1 receptor

GRADE: Grading of Recommendations Assessment, Development, and Evaluation

HbA1c: hemoglobin A1c or glycated hemoglobin

HDL: high-density lipoprotein

ICER: incremental cost-effectiveness ratio

LDL: low-density lipoprotein

NICE: National Institute for Health and Care Excellence

NIH: National Institutes of Health

NOK: Norwegian kroner

OR: odds ratio

QALY: quality-adjusted life-year

ROBINS-I: Risk of Bias in Non-randomized Studies – of Interventions

ROBIS: Risk of Bias in Systematic Reviews

SD: standard deviation

SGD: Singapore dollar

SGLT2: sodium-glucose co-transporter 2

UKPDS-OM2: United Kingdom Prospective Diabetes Study Outcomes Model 2

WTP: willingness-to-pay

Glossary

Adverse event: An adverse event is an unexpected medical problem that happens during treatment for a health condition. Adverse events may be caused by something other than the treatment.

Base case: In economic evaluations, the base case is the "best guess" scenario, including any assumptions, considered most likely to be accurate. In health technology assessments conducted by Ontario Health, the reference case is used as the base case.

Budget impact analysis: A budget impact analysis estimates the financial impact of adopting a new health care intervention on the current budget (i.e., the affordability of the new intervention). It is based on predictions of how changes in the intervention mix will impact the level of health care spending for a specific population. Budget impact analyses are typically conducted for a short-term period (e.g., 5 years). The budget impact, sometimes referred to as the net budget impact, is the estimated cost difference between the current scenario (i.e., the anticipated amount of spending for a specific population without using the new intervention) and the new scenario (i.e., the anticipated amount of spending for a specific population following the introduction of the new intervention).

Cohort model: In economic evaluations, a cohort model is used to simulate what happens to a homogeneous cohort (group) of patients after receiving a specific health care intervention. The proportion of the cohort who experiences certain health outcomes or events is estimated, along with the relevant costs and benefits. In contrast, a microsimulation model follows the course of individual patients.

Cost–benefit analysis: A cost–benefit analysis is a type of economic evaluation that expresses the effects of a health care intervention in terms of a monetary value so that these effects can be compared with costs. Results can be reported either as a ratio of costs to benefits or as a simple sum that represents the net benefit (or net loss) of 1 intervention over another. The monetary valuation of the different intervention effects is based on either prices that are revealed by markets or an individual or societal willingness-to-pay value.

Cost–consequence analysis: A cost–consequence analysis is a type of economic evaluation that estimates the costs and consequences (i.e., the health outcomes) of 2 or more health care interventions. In this type of analysis, the costs are presented separately from the consequences.

Cost-effective: A health care intervention is considered cost-effective when it provides additional benefits, compared with relevant alternatives, at an additional cost that is acceptable to a decision-maker based on the maximum willingness-to-pay value.

Cost-effectiveness analysis: Used broadly, "cost-effectiveness analysis" may refer to an economic evaluation used to compare the benefits of 2 or more health care interventions with their costs. It may encompass several types of analysis (e.g., cost-effectiveness analysis, cost–utility analysis). Used more specifically, "cost-effectiveness analysis" may refer to a type of economic evaluation in which the main outcome measure is the incremental cost per natural unit of health (e.g., life-year, symptom-free day) gained.

Cost–utility analysis: A cost–utility analysis is a type of economic evaluation used to compare the benefits of 2 or more health care interventions with their costs. The benefits are measured using quality-adjusted life-years, which capture both the quality and quantity of life. In a cost–utility analysis, the main outcome measure is the incremental cost per quality-adjusted life-year gained.

Decision tree: A decision tree is a type of economic model used to assess the costs and benefits of 2 or more alternative health care interventions. Each intervention may be associated with different outcomes, which are represented by distinct branches in the tree. Each outcome may have a different probability of occurring and may lead to different costs and benefits.

Discounting: Discounting is a method used in economic evaluations to adjust for the differential timing of the costs incurred and the benefits generated by a health care intervention over time. Discounting reflects the concept of positive time preference, whereby future costs and benefits are reduced to reflect their present value. The health technology assessments conducted by Ontario Health use an annual discount rate of 1.5% for both future costs and future benefits.

Disease-specific preference-based measures: Disease-specific preference-based measures are instruments used to obtain the quality-adjusted weight (i.e., the utility value) of being in a particular health state or having a specific health condition. Disease-specific preference-based measures are often thought to be more sensitive than generic preference-based measures in capturing condition-specific health effects. Like generic preference-based measures, disease-specific preference-based measures typically consist of a self-completed questionnaire, a health-state classification system, and a scoring formula that calculates the utility value. The key difference is that health states in disease-specific preference-based measures are important for the health condition of interest but may not apply to all patient populations. Examples of disease-specific preference-based measures include the Diabetes Utility Index (DUI) and the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30).

Disutility: A disutility is a decrease in utility (i.e., a decrease in preference for a particular health outcome) typically resulting from a particular health condition (e.g., experiencing a symptom or complication).

EQ-5D: The EQ-5D is a generic health-related quality-of-life classification system widely used in clinical studies. In economic evaluations, it is used as an indirect method of obtaining health state preferences (i.e., utility values). The EQ-5D questionnaire consists of 5 questions relating to different domains of quality of life: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each domain, there are 3 response options: no problems, some problems, or severe problems. A newer instrument, the EQ-5D-5L, includes 5 response options for each domain. A scoring table is used to convert EQ-5D scores to utility values.

Generic preference-based measures: Generic preference-based measures are generic (i.e., not disease specific) instruments used to obtain the quality-adjusted weight (i.e., the utility value) of being in a given health state. Generic preference-based measures typically consist of a self-completed questionnaire, a health-state classification system, and a scoring formula that calculates the utility value. Examples include the Health Utilities Index Mark 3 (HUI3), the EQ-5D, and the Short Form–Six Dimensions (SF-6D). The quality-adjusted weights are obtained from the public or from patients, who are provided with a descriptive profile of each predefined health state and asked to fill out a questionnaire. The benefit of using a generic instrument is the ability to obtain utility values that are comparable across different health care interventions and diseases.

Health-related quality of life: Health-related quality of life is a measure of the impact of a health care intervention on a person's health. It includes the dimensions of physiology, function, social life, cognition, emotions, sleep and rest, energy and vitality, health perception, and general life satisfaction.

Health state: A health state is a particular status of health (e.g., sick, well, dead). A health state is associated with some amount of benefit and may be associated with specific costs. Benefit is captured through individual or societal preferences for the time spent in each health state and is expressed in quality-adjusted weights called utility values. In a Markov model, a finite number of mutually exclusive health states are used to represent discrete states of health.

Incremental cost: The incremental cost is the additional cost, typically per person, of a health care intervention versus a comparator.

Incremental cost-effectiveness ratio (ICER): The incremental cost-effectiveness ratio (ICER) is a summary measure that indicates, for a given health care intervention, how much more a health care consumer must pay to get an additional unit of benefit relative to an alternative intervention. It is obtained by dividing the incremental cost by the incremental effectiveness. Incremental cost-effectiveness ratios are typically presented as the cost per life-year gained or the cost per quality-adjusted life-year gained.

Markov model: A Markov model is a type of decision-analytic model used in economic evaluations to estimate the costs and health outcomes (e.g., quality-adjusted life-years gained) associated with using a particular health care intervention. Markov models are useful for clinical problems that involve events of interest that may recur over time (e.g., stroke). A Markov model consists of mutually exclusive, exhaustive health states. Patients remain in a given health state for a certain period of time before moving to another health state based on transition probabilities. The health states and events modelled may be associated with specific costs and health outcomes.

Microsimulation model: In economic evaluations, a microsimulation model (e.g., an individual-level or patient-level model) is used to simulate the health outcomes for a heterogeneous group of patients (e.g., patients of different ages or with different sets of risk factors) after receiving a particular health care intervention. The health outcomes and health events of each patient are modelled, and the outcomes of several patients are combined to estimate the average costs and benefits accrued by a group of patients. In contrast, a cohort model follows a homogeneous cohort of patients (e.g., patients of the same age or with the same set of risk factors) through the model and estimates the proportion of the cohort who will experience specific health events.

Ministry of Health perspective: The perspective adopted in economic evaluations determines the types of costs and health benefits to include. Ontario Health develops health technology assessment reports from the perspective of the Ontario Ministry of Health. This perspective includes all costs and health benefits attributable to the Ministry of Health, such as treatment costs (e.g., drugs, administration, monitoring, hospital stays) and costs associated with managing adverse events caused by treatments. This perspective does not include out-of-pocket costs incurred by patients related to obtaining care (e.g., transportation) or loss of productivity (e.g., absenteeism).

Monte Carlo simulation: Monte Carlo simulation is an economic modelling method that derives parameter values from distributions rather than fixed values. The model is run several times, and in each iteration, parameter values are drawn from specified distributions. This method is used in microsimulation models and probabilistic analysis.

Multiway sensitivity analysis: A multiway sensitivity analysis is used to explore uncertainty in the results of an economic evaluation. It is done by varying a combination of model input (i.e., parameter) values simultaneously between plausible extremes to observe the potential impact on the cost-effectiveness of the health care intervention of interest.

Natural history of a disease: The natural history of a disease is the progression of a disease over time in the absence of any health care intervention.

One-way sensitivity analysis: A one-way sensitivity analysis is used to explore uncertainty in the results of an economic evaluation. It is done by varying 1 model input (i.e., a parameter) at a time between its minimum and maximum values to observe the potential impact on the cost-effectiveness of the health care intervention of interest.

Probabilistic analysis: A probabilistic analysis (also known as a probabilistic sensitivity analysis) is used in economic models to explore uncertainty in several parameters simultaneously and is done using Monte Carlo simulation. Model inputs are defined as a distribution of possible values. In each iteration, model inputs are obtained by randomly sampling from each distribution, and a single estimate of cost and effectiveness is generated. This process is repeated many times (e.g., 10,000 times) to estimate the number of times (i.e., the probability) that the health care intervention of interest is cost-effective.

Quality-adjusted life-year (QALY): The quality-adjusted life-year (QALY) is a generic health outcome measure commonly used in cost–utility analyses to reflect the quantity and quality of life-years lived. The life-years lived are adjusted for quality of life using individual or societal preferences (i.e., utility values) for being in a particular health state. One year of perfect health is represented by 1 quality-adjusted life-year.

Reference case: The reference case is a preferred set of methods and principles that provide the guidelines for economic evaluations. Its purpose is to standardize the approach of conducting and reporting economic evaluations, so that results can be compared across studies.

Risk difference: Risk difference is the difference in the risk of an outcome occurring between a health care intervention and an alternative intervention.

Scenario analysis: A scenario analysis is used to explore uncertainty in the results of an economic evaluation. It is done by observing the potential impact of different scenarios on the cost-effectiveness of a health care intervention. Scenario analyses include varying structural assumptions from the reference case.

Sensitivity analysis: Every economic evaluation contains some degree of uncertainty, and results can vary depending on the values taken by key parameters and the assumptions made. Sensitivity analysis allows these factors to be varied and shows the impact of these variations on the results of the evaluation. There are various types of sensitivity analysis, including deterministic, probabilistic, and scenario.

Societal perspective: The perspective adopted in an economic evaluation determines the types of costs and health benefits to include. The societal perspective reflects the broader economy and is the aggregation of all perspectives (e.g., health care payer and patient perspectives). It considers the full effect of a health condition on society, including all costs (regardless of who pays) and all benefits (regardless of who benefits).

Time horizon: In economic evaluations, the time horizon is the time frame over which costs and benefits are examined and calculated. The relevant time horizon is chosen based on the nature of the disease and health care intervention being assessed, as well as the purpose of the analysis. For instance, a lifetime horizon would be chosen to capture the long-term health and cost consequences over a patient's lifetime.

Time trade-off: In economic evaluations, time trade-off is a direct method of measuring people's preferences for various health states. In a time-trade off, respondents are asked about their preference for either (a) living with a chronic health condition for a certain amount of time, followed by death, or (b) living in optimal health but for less time than in scenario (a). That is, respondents decide how much time in good health they would be willing to "trade off" for more time spent in poorer health. Respondents are surveyed repeatedly, with the amount of time spent in optimal health varying each time until they are indifferent about their choice.

Uptake rate: In instances where 2 technologies are being compared, the uptake rate is the rate at which a new technology is adopted. When a new technology is adopted, it may be used in addition to an existing technology, or it may replace an existing technology.

Utility: A utility is a value that represents a person's preference for various health states. Typically, utility values are anchored at 0 (death) and 1 (perfect health). In some scoring systems, a negative utility value indicates a state of health valued as being worse than death. Utility values can be aggregated over time to derive quality-adjusted life-years, a common outcome measure in economic evaluations.

Willingness-to-pay value: A willingness-to-pay value is the monetary value a health care consumer is willing to pay for added health benefits. When conducting a cost–utility analysis, the willingness-to-pay value represents the cost a consumer is willing to pay for an additional quality-adjusted life-year. If the incremental cost-effectiveness ratio is less than the willingness-to-pay value, the health care intervention of interest is considered cost-effective. If the incremental cost-effectiveness ratio is more than the willingness-to-pay value, the intervention is considered not to be cost-effective.

Appendices

Appendix 1: Literature Search Strategies

Clinical Evidence Search

Search Date: July 4, 2022

Databases searched: Ovid MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and NHS Economic Evaluation Database

Database segments: EBM Reviews - Cochrane Central Register of Controlled Trials <May 2022>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to June 29, 2022>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2022 Week 26>, Ovid MEDLINE(R) ALL <1946 to July 01, 2022>

Search strategy:

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1 Obesity/ (697858)
2 Obesity, Abdominal/ (12001)
3 (obese or obesit*).ti,ab,kf. (922189)
4 Body Mass Index/ (644782)
5 (body mass ind* or BMI).ti,ab,kf. (893184)
6 Overweight/ (212792)
7 (over weight or overweight or "excess weight").ti,ab,kf. (237257)
8 or/1-7 (1807901)
9 Bariatric Surgery/ (51825)
10 (((bariatric or metabolic) adj3 (operat* or procedur* or surg*)) or diabetes surger*).ti,ab,kf. (73658)
11 Gastric Bypass/ (17523)
12 (gastric bypass* or gastric stapl* or gastric surger* or roux-en-y or RYGB).ti,ab,kf. (57828)
13 (stomach adj2 (bypass or stapl*)).ti,ab,kf. (257)
14 ((gastrectom* or gastric) adj3 sleeve*).ti,ab,kf. (26227)
15 (SADI-S or (single anastomosis adj3 (duoden* or sleeve* gastr*))).ti,ab,kf. (574)
16 Biliopancreatic Diversion/ (4894)
17 (((bilio pancreatic or biliopancreatic) adj3 (bypass* or diversion* or surg*)) or ((bilio pancreatic or biliopancreatic or BPD) and duodenal switch*) or BPD-DS).ti,ab,kf. (4051)
18 ((malabsorpti* or restrictive) adj2 (bypass or operat* or procedur* or surg*)).ti,ab,kf. (3666)
19 or/9-18 (124586)
20 8 and 19 (81097)
21 Obesity/su [Surgery] (18619)
22 ((obesity or antiobesity) adj3 (operat* or procedur* or surg*)).ti,ab,kf. (15821)
23 or/20-22 (90263)
24 exp Diabetes Mellitus, Type 2/ (481165)

25 ((adult onset or ketosis resistant or maturity onset or non insulin depend* or noninsulin depend* or slow onset or type 2 or type II) adj2 (diabet* or DM)).ti,ab,kf. (518991)
26 (DM2 or T2D or T2DM or NIDDM).ti,ab,kf. (150083)
27 or/24-26 (648289)
28 23 and 27 (15049)
29 (mild* obes* or class 1 obes* or class one obes* or "BMI 30-34.9 kg*" or "body mass index 30-34.9 kg*" or "BMI 30-35 kg*" or "body mass index 30-35 kg*").ti,ab,kf. (2582)
30 19 and 29 (327)
31 28 or 30 (15168)
32 exp Animals/ not Humans/ (16626958)
33 31 not 32 (10401)
34 Case Reports/ or Comment.pt. or Editorial.pt. or (Letter not (Letter and Randomized Controlled Trial)).pt. or Congress.pt. (6107170)
35 33 not 34 (9844)
36 limit 35 to english language [Limit not valid in CDSR; records were retained] (9375)
37 limit 36 to yr="2012 -Current" (7261)
38 37 use cctr,coch,cleed (587)
39 (Systematic Reviews or Meta Analysis).pt. (163897)
40 Systematic Review/ or Systematic Reviews as Topic/ or Meta-Analysis/ or exp Meta-Analysis as Topic/ or exp Technology Assessment, Biomedical/ (850065)
41 ((systematic* or methodologic*) adj3 (review* or overview*)).ti,ab,kf. (624697)
42 (meta analy* or metaanaly* or met analy* or metanaly* or meta review* or metareview* or health technolog* assess* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).ti,ab,kf. (597302)
43 (evidence adj2 (review* or overview* or synthes#s)).ti,ab,kf. (94857)
44 (review of reviews or overview of reviews).ti,ab,kf. (2203)
45 umbrella review*.ti,ab,kf. (2127)
46 GRADE Approach/ (1878)
47 ((pool* adj3 analy*) or published studies or published literature or hand search* or handsearch* or manual search* or ((database* or systematic*) adj2 search*) or reference list* or bibliograph* or relevant journals or data synthes* or data extraction* or data abstraction*).ti,ab,kf. (591057)
48 (medline or pubmed or medlars or embase or cinahl or web of science or ovid or ebsco* or scopus).ab. (665100)
49 cochrane.ti,ab,kf. (287367)
50 (meta regress* or metaregress*).ti,ab,kf. (28926)
51 (((integrative or collaborative or quantitative) adj3 (review* or overview* or synthes*)) or (research adj3 overview*)).ti,ab,kf. (35458)
52 (cochrane or (health adj2 technology assessment) or evidence report or systematic review*).jw. (74452)
53 ((comparative adj3 (efficacy or effectiveness)) or relative effectiveness or ((indirect or indirect treatment or mixed-treatment) adj comparison*)).ti,ab,kf. (62298)
54 or/39-53 (1690091)
55 37 and 54 (646)
56 55 use medall (279)
57 Clinical Trials as Topic/ (323075)
58 controlled clinical trials as topic/ (16839)
59 exp Randomized Controlled Trials as Topic/ (398136)
60 controlled clinical trial.pt. (188128)

61 randomized controlled trial.pt. (1130280)
62 Pragmatic Clinical Trial.pt. (4204)
63 Random Allocation/ (217580)
64 Single-Blind Method/ (99778)
65 Double-Blind Method/ (489357)
66 Placebos/ (373232)
67 trial.ti. (994791)
68 (random* or sham or placebo* or RCT*1).ti,ab,kf. (4722890)
69 ((singl* or doubl*) adj (blind* or dumm* or mask*)).ti,ab,kf. (745231)
70 ((tripl* or trebl*) adj (blind* or dumm* or mask*)).ti,ab,kf. (5368)
71 or/57-70 (5850329)
72 37 and 71 (1549)
73 72 use medall (498)
74 Epidemiologic Methods/ (215792)
75 exp Epidemiologic Studies/ (7149409)
76 Observational Studies as Topic/ (285957)
77 Clinical Studies as Topic/ (115858)
78 single-case studies as topic/ (376)
79 (Observational Study or Validation Studies or Clinical Study).pt. (136069)
80 (observational adj3 (study or studies or design or analysis or analyses)).ti,ab,kf. (512747)
81 cohort*.ti,ab,kf. (2121027)
82 (prospective adj7 (study or studies or design or analysis or analyses)).ti,ab,kf. (1366461)
83 ((follow up or followup) adj7 (study or studies or design or analysis or analyses)).ti,ab,kf. (440864)
84 ((longitudinal or longterm or (long adj term)) adj7 (study or studies or design or analysis or analyses or data)).ti,ab,kf. (800248)
85 (retrospective adj7 (study or studies or design or analysis or analyses or data or review)).ti,ab,kf. (1647814)
86 ((case adj control) or (case adj comparison) or (case adj controlled)).ti,ab,kf. (353856)
87 (case-referent adj3 (study or studies or design or analysis or analyses)).ti,ab,kf. (1326)
88 (population adj3 (study or studies or analysis or analyses)).ti,ab,kf. (559761)
89 (descriptive adj3 (study or studies or design or analysis or analyses)).ti,ab,kf. (250294)
90 ((multidimensional or (multi adj dimensional)) adj3 (study or studies or design or analysis or analyses)).ti,ab,kf. (9715)
91 (cross adj sectional adj7 (study or studies or design or research or analysis or analyses or survey or findings)).ti,ab,kf. (902379)
92 ((natural adj experiment) or (natural adj experiments)).ti,ab,kf. (6060)
93 (quasi adj (experiment or experiments or experimental)).ti,ab,kf. (45121)
94 ((non experiment or nonexperiment or non experimental or nonexperimental) adj3 (study or studies or design or analysis or analyses)).ti,ab,kf. (3802)
95 (prevalence adj3 (study or studies or analysis or analyses)).ti,ab,kf. (112742)
96 organizational case studies/ (46520)
97 or/74-96 (11076518)
98 37 and 97 (3954)
99 98 use medall (1568)
100 38 or 56 or 73 or 99 (2494)
101 obesity/ (697858)
102 abdominal obesity/ (20216)
103 (obese or obesit*).tw,kw,kf. (927233)

104 body mass/ (548316)
105 (body mass ind* or BMI).tw,kw,kf. (895390)
106 (over weight or overweight or "excess weight").tw,kw,kf. (237587)
107 or/101-106 (1796917)
108 bariatric surgery/ (51825)
109 (((bariatric or metabolic) adj3 (operat* or procedur* or surg*)) or diabetes surger*).tw,kw,kf,dv. (74020)
110 exp gastric bypass surgery/ (14542)
111 (gastric bypass* or gastric stapl* or gastric surger* or roux-en-y or RYGB).tw,kw,kf,dv. (58005)
112 (stomach adj2 (bypass or stapl*)).tw,kw,kf,dv. (428)
113 exp sleeve gastrectomy/ (17117)
114 ((gastrectom* or gastric) adj3 sleeve*).tw,kw,kf,dv. (26284)
115 (SADI-S or (single anastomosis adj3 (duoden* or sleeve* gastr*))).tw,kw,kf,dv. (580)
116 biliopancreatic bypass/ (4894)
117 (((bilio pancreatic or biliopancreatic) adj3 (bypass* or diversion* or surg*)) or ((bilio pancreatic or biliopancreatic or BPD) and duodenal switch*) or BPD-DS).tw,kw,kf,dv. (4092)
118 ((malabsorpti* or restrictive) adj2 (bypass or operat* or procedur* or surg*)).tw,kw,kf,dv. (3716)
119 or/108-118 (124787)
120 107 and 119 (81159)
121 obesity/su [Surgery] (18619)
122 ((obesity or antiobesity) adj3 (operat* or procedur* or surg*)).tw,kw,kf,dv. (17388)
123 or/120-122 (91196)
124 non insulin dependent diabetes mellitus/ (460569)
125 ((adult onset or ketosis resistant or maturity onset or non insulin depend* or noninsulin depend* or slow onset or type 2 or type II) adj2 (diabet* or DM)).tw,kw,kf,dv. (521451)
126 (DM2 or T2D or T2DM or NIDDM).tw,kw,kf,dv. (150152)
127 or/124-126 (647690)
128 123 and 127 (15193)
129 (mild* obes* or class 1 obes* or class one obes* or "BMI 30-34.9 kg*" or "body mass index 30-34.9 kg*" or "BMI 30-35 kg*" or "body mass index 30-35 kg*").tw,kw,kf,dv. (2590)
130 119 and 129 (332)
131 128 or 130 (15315)
132 (exp animal/ or nonhuman/) not exp human/ (11483376)
133 131 not 132 (14819)
134 Case Report/ or Comment/ or Editorial/ or (letter.pt. not (letter.pt. and randomized controlled trial/)) or conference abstract.pt. or conference review.pt. (12623285)
135 133 not 134 (10689)
136 limit 135 to english language [Limit not valid in CDSR; records were retained] (10078)
137 limit 136 to yr="2012 -Current" (8059)
138 137 use emez (4404)
139 Systematic review/ or "systematic review (topic)"/ or exp Meta Analysis/ or "Meta Analysis (Topic)"/ or Biomedical Technology Assessment/ (824552)
140 (meta analy* or metaanaly* or health technolog* assess* or systematic review*).hw. (847701)
141 ((systematic* or methodologic*) adj3 (review* or overview*)).tw,kw,kf. (639557)
142 (meta analy* or metaanaly* or met analy* or metanaly* or meta review* or metareview* or health technolog* assess* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).tw,kw,kf. (611966)
143 (evidence adj2 (review* or overview* or synthes#s)).tw,kw,kf. (97069)

144 (review of reviews or overview of reviews).tw,kw,kf. (2406)
145 umbrella review*.tw,kw,kf. (2156)
146 ((pool* adj3 analy*) or published studies or published literature or hand search* or handsearch* or manual search* or ((database* or systematic*) adj2 search*) or reference list* or bibliograph* or relevant journals or data synthes* or data extraction* or data abstraction*).tw,kw,kf. (600781)
147 (medline or pubmed or medlars or embase or cinahl or web of science or ovid or ebsco* or scopus).ab. (665100)
148 cochrane.tw,kw,kf. (291040)
149 (meta regress* or metaregress*).tw,kw,kf. (29855)
150 (((integrative or collaborative or quantitative) adj3 (review* or overview* or synthes*)) or (research adj3 overview*)).tw,kw,kf. (36526)
151 (cochrane or (health adj2 technology assessment) or evidence report or systematic review*).jw. (74452)
152 ((comparative adj3 (efficacy or effectiveness)) or relative effectiveness or ((indirect or indirect treatment or mixed-treatment) adj comparison*)).tw,kw,kf. (93857)
153 or/139-152 (1728220)
154 138 and 153 (513)
155 "clinical trial (topic)"/ (118655)
156 "controlled clinical trial (topic)"/ (12385)
157 "randomized controlled trial (topic)"/ (229309)
158 randomization/ (200709)
159 Single Blind Procedure/ (46518)
160 Double Blind Procedure/ (193297)
161 placebo/ (368512)
162 trial.ti. (994791)
163 (random* or sham or placebo* or RCT*1).tw,kw,kf. (4790540)
164 ((singl* or doubl*) adj (blind* or dumm* or mask*)).tw,kw,kf. (781790)
165 ((tripl* or trebl*) adj (blind* or dumm* or mask*)).tw,kw,kf. (5995)
166 or/155-165 (5443875)
167 138 and 166 (831)
168 observational study/ (407377)
169 cohort analysis/ (1173296)
170 longitudinal study/ (332945)
171 follow up/ (1849496)
172 retrospective study/ (2305829)
173 exp case control study/ (1557275)
174 cross-sectional study/ (927948)
175 quasi experimental study/ (10740)
176 prospective study/ (1406115)
177 (observational adj3 (study or studies or design or analysis or analyses)).tw,kw,kf. (517958)
178 cohort*.tw,kw,kf. (2131936)
179 (prospective adj7 (study or studies or design or analysis or analyses)).tw,kw,kf. (1399887)
180 ((follow up or followup) adj7 (study or studies or design or analysis or analyses)).tw,kw,kf. (502437)
181 ((longitudinal or longterm or (long adj term)) adj7 (study or studies or design or analysis or analyses or data)).tw,kw,kf. (807956)
182 (retrospective adj7 (study or studies or design or analysis or analyses or data or review)).tw,kw,kf. (1657049)

183 ((case adj control) or (case adj comparison) or (case adj controlled)).tw,kw,kf. (356960)
184 (case-referent adj3 (study or studies or design or analysis or analyses)).tw,kw,kf. (1326)
185 (population adj3 (study or studies or analysis or analyses)).tw,kw,kf. (579269)
186 (descriptive adj3 (study or studies or design or analysis or analyses)).tw,kw,kf. (256060)
187 ((multidimensional or (multi adj dimensional)) adj3 (study or studies or design or analysis or analyses)).tw,kw,kf. (9774)
188 (cross adj sectional adj7 (study or studies or design or research or analysis or analyses or survey or findings)).tw,kw,kf. (904977)
189 ((natural adj experiment) or (natural adj experiments)).tw,kw,kf. (6086)
190 (quasi adj (experiment or experiments or experimental)).tw,kw,kf. (46429)
191 ((non experiment or nonexperiment or non experimental or nonexperimental) adj3 (study or studies or design or analysis or analyses)).tw,kw,kf. (3908)
192 (prevalence adj3 (study or studies or analysis or analyses)).tw,kw,kf. (117334)
193 or/168-192 (9825997)
194 138 and 193 (2243)
195 154 or 167 or 194 (2825)
196 100 or 195 (5319)
197 196 use medall (1907)
198 196 use emez (2825)
199 196 use coch (1)
200 196 use cctr (582)
201 196 use cleed (4)
202 remove duplicates from 196 (3544)

Economic Evidence Search

Search Date: July 5, 2022

Databases searched: Ovid MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and NHS Economic Evaluation Database

Database segments: EBM Reviews - Cochrane Central Register of Controlled Trials <May 2022>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to June 29, 2022>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2022 Week 26>, Ovid MEDLINE(R) ALL <1946 to July 01, 2022>

Search strategy:

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1 Obesity/ (697858)
2 Obesity, Abdominal/ (12001)
3 (obese or obesit*).ti,ab,kf. (922189)
4 Body Mass Index/ (644782)
5 (body mass ind* or BMI).ti,ab,kf. (893184)
6 Overweight/ (212792)
7 (over weight or overweight or "excess weight").ti,ab,kf. (237257)
8 or/1-7 (1807901)
9 Bariatric Surgery/ (51825)

10 (((bariatric or metabolic) adj3 (operat* or procedur* or surg*)) or diabetes surger*).ti,ab,kf. (73658)
11 Gastric Bypass/ (17523)
12 (gastric bypass* or gastric stapl* or gastric surger* or roux-en-y or RYGB).ti,ab,kf. (57828)
13 (stomach adj2 (bypass or stapl*)).ti,ab,kf. (257)
14 ((gastrectom* or gastric) adj3 sleeve*).ti,ab,kf. (26227)
15 (SADI-S or (single anastomosis adj3 (duoden* or sleeve* gastr*))).ti,ab,kf. (574)
16 Biliopancreatic Diversion/ (4894)
17 (((bilio pancreatic or biliopancreatic) adj3 (bypass* or diversion* or surg*)) or ((bilio pancreatic or biliopancreatic or BPD) and duodenal switch*) or BPD-DS).ti,ab,kf. (4051)
18 ((malabsorpti* or restrictive) adj2 (bypass or operat* or procedur* or surg*)).ti,ab,kf. (3666)
19 or/9-18 (124586)
20 8 and 19 (81097)
21 Obesity/su [Surgery] (18619)
22 ((obesity or antiobesity) adj3 (operat* or procedur* or surg*)).ti,ab,kf. (15821)
23 or/20-22 (90263)
24 exp Diabetes Mellitus, Type 2/ (481165)
25 ((adult onset or ketosis resistant or maturity onset or non insulin depend* or noninsulin depend* or slow onset or type 2 or type II) adj2 (diabet* or DM)).ti,ab,kf. (518991)
26 (DM2 or T2D or T2DM or NIDDM).ti,ab,kf. (150083)
27 or/24-26 (648289)
28 23 and 27 (15049)
29 (mild* obes* or class 1 obes* or class one obes* or "BMI 30-34.9 kg*" or "body mass index 30-34.9 kg*" or "BMI 30-35 kg*" or "body mass index 30-35 kg*").ti,ab,kf. (2582)
30 19 and 29 (327)
31 28 or 30 (15168)
32 exp Animals/ not Humans/ (16626958)
33 31 not 32 (10401)
34 Case Reports/ or Comment.pt. or Editorial.pt. or (Letter not (Letter and Randomized Controlled Trial)).pt. or Congress.pt. (6107170)
35 33 not 34 (9844)
36 limit 35 to english language [Limit not valid in CDSR; records were retained] (9375)
37 economics/ (263754)
38 economics, medical/ or economics, pharmaceutical/ or exp economics, hospital/ or economics, nursing/ or economics, dental/ (989496)
39 economics.fs. (467111)
40 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf. (1166096)
41 exp "costs and cost analysis"/ (658714)
42 (cost or costs or costing or costly).ti. (314122)
43 cost effective*.ti,ab,kf. (417135)
44 (cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)).ab,kf. (272899)
45 models, economic/ (15353)
46 markov chains/ or monte carlo method/ (100711)
47 (decision adj1 (tree* or analy* or model*)).ti,ab,kf. (59625)
48 (markov or markow or monte carlo).ti,ab,kf. (166229)
49 quality-adjusted life years/ (51329)

50 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf. (101482)
51 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).ti,ab,kf. (171950)
52 or/37-51 (3145798)
53 36 and 52 (744)
54 36 use cleed,coch (9)
55 53 use medall,cctr (306)
56 or/54-55 (315)
57 obesity/ (697858)
58 abdominal obesity/ (20216)
59 (obese or obesit*).tw,kw,kf. (927233)
60 body mass/ (548316)
61 (body mass ind* or BMI).tw,kw,kf. (895390)
62 (over weight or overweight or "excess weight").tw,kw,kf. (237587)
63 or/57-62 (1796917)
64 bariatric surgery/ (51825)
65 (((bariatric or metabolic) adj3 (operat* or procedur* or surg*)) or diabetes surger*).tw,kw,kf,dv. (74020)
66 exp gastric bypass surgery/ (14542)
67 (gastric bypass* or gastric stapl* or gastric surger* or roux-en-y or RYGB).tw,kw,kf,dv. (58005)
68 (stomach adj2 (bypass or stapl*)).tw,kw,kf,dv. (428)
69 exp sleeve gastrectomy/ (17117)
70 ((gastrectom* or gastric) adj3 sleeve*).tw,kw,kf,dv. (26284)
71 (SADI-S or (single anastomosis adj3 (duoden* or sleeve* gastr*))).tw,kw,kf,dv. (580)
72 biliopancreatic bypass/ (4894)
73 (((bilio pancreatic or biliopancreatic) adj3 (bypass* or diversion* or surg*)) or ((bilio pancreatic or biliopancreatic or BPD) and duodenal switch*) or BPD-DS).tw,kw,kf,dv. (4092)
74 ((malabsorpti* or restrictive) adj2 (bypass or operat* or procedur* or surg*)).tw,kw,kf,dv. (3716)
75 or/64-74 (124787)
76 63 and 75 (81159)
77 obesity/su [Surgery] (18619)
78 ((obesity or antiobesity) adj3 (operat* or procedur* or surg*)).tw,kw,kf,dv. (17388)
79 or/76-78 (91196)
80 non insulin dependent diabetes mellitus/ (460569)
81 ((adult onset or ketosis resistant or maturity onset or non insulin depend* or noninsulin depend* or slow onset or type 2 or type II) adj2 (diabet* or DM)).tw,kw,kf,dv. (521451)
82 (DM2 or T2D or T2DM or NIDDM).tw,kw,kf,dv. (150152)
83 or/80-82 (647690)
84 79 and 83 (15193)
85 (mild* obes* or class 1 obes* or class one obes* or "BMI 30-34.9 kg*" or "body mass index 30-34.9 kg*" or "BMI 30-35 kg*" or "body mass index 30-35 kg*").tw,kw,kf,dv. (2590)
86 75 and 85 (332)
87 84 or 86 (15315)
88 (exp animal/ or nonhuman/) not exp human/ (11483376)
89 87 not 88 (14819)
90 Case Report/ or Comment/ or Editorial/ or (letter.pt. not (letter.pt. and randomized controlled trial/)) or conference abstract.pt. or conference review.pt. (12623285)
91 89 not 90 (10689)
92 limit 91 to english language [Limit not valid in CDSR; records were retained] (10078)

93 Economics/ (263754)
94 Health Economics/ or Pharmacoeconomics/ or Drug Cost/ or Drug Formulary/ (142846)
95 Economic Aspect/ or exp Economic Evaluation/ (526202)
96 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).tw,kw,kf. (1186349)
97 exp "Cost"/ (658714)
98 (cost or costs or costing or costly).ti. (314122)
99 cost effective*.tw,kw,kf. (426132)
100 (cost* adj2 (util* or efficac* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)).ab,kw,kf. (283757)
101 Monte Carlo Method/ (78449)
102 (decision adj1 (tree* or analy* or model*)).tw,kw,kf. (63023)
103 (markov or markow or monte carlo).tw,kw,kf. (169703)
104 Quality-Adjusted Life Years/ (51329)
105 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).tw,kw,kf. (104801)
106 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).tw,kw,kf. (192850)
107 or/93-106 (2694931)
108 92 and 107 (842)
109 108 use emez (498)
110 56 or 109 (813)
111 110 use medall (259)
112 110 use emez (498)
113 110 use coch (1)
114 110 use cctr (47)
115 110 use cleed (8)
116 remove duplicates from 110 (603)

Grey Literature Search

Performed on: Jul 7 - 15, 2022

Websites searched:

Alberta Health Evidence Reviews, Alberta Health Services, BC Health Technology Assessments, Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), Institute of Health Economics (IHE), Ontario Health Technology Assessment Committee (OHTAC), McGill University Health Centre Health Technology Assessment Unit, Centre Hospitalier de l'Universite de Quebec-Universite Laval, Contextualized Health Research Synthesis Program of Newfoundland (CHRSP), Health Canada Medical Device Database, Health Technology Assessment Database (INAHTA), Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers, Centers for Medicare & Medicaid Services Technology Assessments, Veterans Affairs Health Services Research and Development, Institute for Clinical and Economic Review, Oregon Health Authority Health Evidence Review Commission, Washington State Health Care Authority Health Technology Reviews, National Institute for Health and Care Excellence (NICE), Healthcare Improvement Scotland, Health Technology Wales, Ireland Health Information and Quality Authority Health Technology Assessments, Australian Government Medical Services Advisory Committee, Australian Safety and Efficacy Register of New Interventional Procedures -Surgical (ASERNIP-S), Italian National Agency for Regional Health Services, Belgian Health Care Knowledge Centre, Ludwig Boltzmann Institute for Health

Technology Assessment, Swedish Agency for Health Technology Assessment and Assessment of Social Services, Ministry of Health Malaysia Health Technology Assessment Section, Tuft's Cost-Effectiveness Analysis Registry, PROSPERO, EUnetHTA, clinicaltrials.gov

Keywords used:

bariatric, bariatric surgery, metabolic surgery, gastric bypass, roux en y, gastric sleeve, sleeve gastrectomy, biliopancreatic diversion, single anastomosis, malabsorption surgery, restrictive surgery, obesity surgery, obesity, obese, body mass index, BMI, mild obesity, class 1 obesity, BMI 30, BMI 34.9, BMI 35, bariatrique, obésité, gastrectomie, bypass gastrique, chirurgie métabolique

Clinical results (included in PRISMA): 26

Economic results (included in PRISMA): 27

Ongoing HTAs (PROSPERO/EUnetHTA/NICE/MSAC): 31

Ongoing clinical trials: 64

Appendix 2: Critical Appraisal of Clinical Evidence

Table A1: Risk of Bias[a] Among Systematic Reviews (ROBIS Tool)

Author, year	Phase 2				Phase 3
	Study eligibility criteria	Identification and selection of studies	Data collection and study appraisal	Synthesis and findings	Risk of bias in the review
Maggard-Gibbons et al, 2013[39]	High[b]	Low	High[c]	Low	High[b,c]

Abbreviation: BMI, body mass index; ROBIS, Risk of Bias in Systematic Reviews.

[a]Possible risk-of-bias levels: low, high, unclear.

[b]Authors specified in protocol that population of interest had BMI from 30–34.9 kg/m^2 and diabetes; however, when screening, they modified their criteria to include studies with a broader BMI range and impaired glucose tolerance (a precursor to diabetes).

[c]Authors do not report that risk of bias assessments were conducted by 2 reviewers.

Table A2: Risk of Bias[a] Among Randomized Controlled Trials (Cochrane ROB tool)

Author, year	Adequate sequence generation	Allocation concealment	Blinding	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Parikh et al, 2014[51]	Low	Low	Low[b]	High[c]	Low	Low
Horwitz et al, 2016[56,d]	Low	Low	Low[b]	Unclear[c,e]	Low	High[f]
Horwitz et al, 2020[55,d]	Low	Low	Low[b]	Unclear[c]	Low	High[f]
Cohen et al, 2020[52]	Low	Low	Low[b]	Low	Low	High[g]
Lau et al, 2021[53]	Low	Low	Low[b]	High[h]	Low	Low
Cheng et al, 2022[54]	Low	Low	Low[b]	Low[i]	Low	Low

Abbreviation: ROB, risk of bias

[a]Possible risk-of-bias levels: low, unclear, and high.

[b]Participants, personnel, and outcome assessors unblinded, but unlikely to introduce bias for outcomes of interest.

[c]Report overall dropout rate was 23%; and 27.5% of surgery group withdrew before receiving intervention, seems unbalanced across groups.

[d]These studies are long-term follow-up studies of Parikh, 2014 that are being assessed separately from the primary study due to increased risk of bias from broken randomization.

[e]Unbalanced dropout rate (at 3-year follow-up: bariatric surgery, 25%; medical management, 14%).

[f]After 6 months, 10 participants crossed over to the bariatric surgery arm, breaking the original randomization in Parikh et al, 2014.

[g]Study was partially supported by pharmaceutical industry funding.

[h]Unbalanced dropout rate (bariatric surgery, 20%; medical management, 0%).

[i]High dropout rate (55%) but appears balanced across treatment arms, and intention-to-treat analysis was used.

Table A3: Risk of Bias[a] Among Nonrandomized Trials (ROBINS-I Tool)

	Preintervention		Intervention		Postintervention		
Author, year	Confounding	Study participation selection	Classification of interventions	Deviations from intended intervention	Missing data	Measurement of outcomes	Selection of reported results
Chiellini et al, 2009[63]	Moderate[b]	Moderate[b]	Low	Low	Low	Low	Low
Serrot et al, 2011[64]	Moderate[c]	Moderate[c]	Low	Low	Low	Low	Low
Scopinaro et al, 2014[61]	Moderate[d]	Moderate[d]	Low	Low	Low	Low	Low
Hsu et al, 2015[58]	Moderate[e]	Moderate[e]	Low	Low	Low	Low	Low
Bhandari et al, 2017[57]	Moderate[f]	Moderate[f]	Low	Low	Low	Low	Low
Zhang et al, 2021[62]	Moderate[g]	Moderate[g]	Low	Low	Low	Low	Low
Ling et al, 2022[59]	Moderate[h]	Moderate[h]	Low	Low	Low	Low	Low
Papadia et al, 2022[60]	Moderate[i]	Moderate[i]	Low	Low	Low	Low	Low

Abbreviation: BMI, body mass index; HbA1c, hemoglobin A1c (or glycated hemoglobin); ROBINS-I, Risk of Bias in Non-randomized Studies – of Interventions.

[a]Possible risk-of-bias levels: low, moderate, serious, critical, and no information.

[b]Comparator group was matched to the bariatric surgery group, but variables used for matching were not reported.

[c]Medical management group matched to the bariatric surgery group based on BMI.

[d]Medical management group was matched to the bariatric surgery group based on gender, age, BMI, diabetes duration, and HbA1c level; but noted challenges in finding 2 matches for high HbA1c levels; authors also noted that all participants in the bariatric surgery group were recommended to be on insulin at baseline, but 50% refused which may be a source of imbalance across groups.

[e]Medical management group was matched based on age, diabetes duration, and BMI; at baseline, the bariatric surgery group was predominantly female, had longer diabetes duration, were younger, had higher BMI, and poorer glycemic control.

[f]Baseline BMI for the bariatric surgery group was higher than those for the medical management groups (GLP1R agonist and SGLT2 treatment groups).

[g]Control group was matched on age, sex, and duration of diabetes.

[h]Conducted propensity score matching but did not include use of hypoglycemic agents in matching conditions.

[i]Control group was matched on age, gender, BMI, and diabetes duration.

Table A4: GRADE Evidence Profile for the Comparison of Bariatric Surgery and Medical Management for Studies With Adults With Class I Obesity and Type 2 Diabetes for the Outcome of Diabetes Remission (Complete and Partial) – Randomized Controlled Trials

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Complete diabetes remission							
At 6 months							
1 RCT	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[b]	Undetected	None	⊕⊕ Low
At 1 year							
2 RCTs	Serious limitations (−1)[c]	No serious limitations	Serious limitations (−1)[d]	Serious limitations (−1)[b]	Undetected	None	⊕ Very low
At 2 years							
2 RCTs	Serious limitations (−1)[e]	No serious limitations	No serious limitations	Serious limitations (−1)[b]	Undetected	None	⊕⊕ Low
At 3 years							
2 RCTs	Serious limitations (−1)[f]	Serious limitations (−1)[g]	No serious limitations	Serious limitations (−1)[b]	Undetected	None	⊕ Very low
At 4 years							
1 RCT	No serious limitations	Unable to assess	No serious limitations	Very serious limitations (−2)[b]	Undetected	None	⊕⊕ Low
At 5 years							
2 RCTs	Serious limitations (−1)[f]	No serious limitations	Serious limitations (−1)[d]	Serious limitations (−1)[b]	Undetected	None	⊕ Very low
Partial diabetes remission							
At 2 years							
1 RCT	Serious limitations (−1)[e]	Unable to Assess	No serious limitations	Serious limitations (−1)[b]	Undetected	None	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.

[a]Unclear incomplete data reporting.

[b]Concern for imprecision due to small sample size.

[c]High risk of incomplete outcome data and unclear selective outcome reporting.

[d]Varying definitions of diabetes remission across studies.

[e]Unclear selective outcome reporting and other sources of bias due to pharmaceutical industry funding.

[f]High risk of bias due to patient crossover breaking randomization after 6-month trial period, and unclear incomplete outcome reporting.

[g]Varying magnitude of effects across studies.

Table A5: GRADE Evidence Profile for the Comparison of Bariatric Surgery and Medical Management for Studies With Adults With Class I Obesity and Type 2 Diabetes for the Outcome of Diabetes Remission (Complete and Partial) – Comparative Observational Studies

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Complete diabetes remission							
At 1 year							
4 observational	Serious limitations (−1)[a]	Serious limitations (−1)[b]	Serious limitations (−1)[c]	No serious limitations	Undetected	None	⊕ Very low
At 2 years							
1 observational	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[d]	Undetected	None	⊕⊕ Low
At 3 years							
1 observational	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[d]	Undetected	None	⊕⊕ Low
At 5 years							
1 observational	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[d]	Undetected	None	⊕⊕ Low
At 10 years							
1 observational	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[d]	Undetected	None	⊕⊕ Low
Partial diabetes remission							
At 1 year							
1 observational	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[d]	Undetected	None	⊕⊕ Low
At 5 years							
1 observational	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[d]	Undetected	None	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation.
[a]Moderate risk of bias through confounding and study participation selection.
[b]Varying magnitude of effects across studies.
[c]Varying medical management comparators and definitions of diabetes remission across studies.
[d]Concern for imprecision due to small sample size.

Table A6: GRADE Evidence Profile for the Comparison of Bariatric Surgery and Medical Management for Studies With Adults With Class I Obesity and Type 2 Diabetes for the Outcome of Change in Body Mass Index – Randomized Controlled Trials

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Mean change in body mass index							
At 6 months							
1 RCT	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[b]	Undetected	None	⨁⨁ Low
At 1 year							
2 RCTs	Serious limitations (−1)[c]	No serious limitations	Serious limitations (−1)[d]	Serious limitations (−1)[b]	Undetected	None	⨁ Very low
At 2 years							
2 RCTs	Serious limitations (−1)[e]	No serious limitations	Serious limitations (−1)[d]	Serious limitations (−1)[b]	Undetected	None	⨁ Very low
At 3 years							
2 RCTs	Serious limitations (−1)[f]	No serious limitations	Serious limitations (−1)[d]	Serious limitations (−1)[b]	Undetected	None	⨁ Very low
At 4 years							
1 RCT	No serious limitations	Unable to assess	No serious limitations	Very serious limitations (−2)[b]	Undetected	None	⨁⨁ Low
At 5 years							
2 RCTs	Serious limitations (−1)[f]	No serious limitations	Serious limitations (−1)[d]	Serious limitations (−1)[b]	Undetected	None	⨁ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.

[a]Unclear incomplete data reporting.

[b]Concern for imprecision due to small sample size.

[c]High risk of incomplete outcome data and unclear selective outcome reporting.

[d]Varying definitions of medical management as comparator across studies.

[e]Unclear selective outcome reporting and other sources of bias due to pharmaceutical industry funding.

[f]High risk of bias due to patient crossover breaking randomization after 6-month trial period, and unclear incomplete outcome reporting.

Table A7: GRADE Evidence Profile for the Comparison of Bariatric Surgery and Medical Management for Studies With Adults With Class I Obesity and Type 2 Diabetes for the Outcome of Change in Body Mass Index – Comparative Observational Studies

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Mean change in body mass index							
At 1 month							
1 observational	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[c]	Undetected	None	⊕⊕ Low
At 1 year							
5 observational	Serious limitations (−1)[a]	No serious limitations	Serious limitations (−1)[b]	No serious limitations	Undetected	None	⊕⊕ Low
At 2 years							
2 observational	Serious limitations (−1)[a]	No serious limitations	Serious limitations (−1)[b]	Serious limitations (−1)[c]	Undetected	None	⊕ Very low
At 3 years							
1 observational	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[c]	Undetected	None	⊕⊕ Low
At 5 years							
1 observational	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[c]	Undetected	None	⊕⊕ Low
At 10 years							
1 observational	Serious limitations (−1)[a]	Unable to assess	No serious limitations	Serious limitations (−1)[c]	Undetected	None	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation.
[a]Moderate risk of bias from confounding and study participation selection.
[b]Varying definitions of medical management as comparator across studies.
[c]Concern for imprecision due to small sample size.

Table A8: GRADE Evidence Profile for the Comparison of Bariatric Surgery and Medical Management in Studies With Adults With Class I Obesity and Type 2 Diabetes for Secondary Outcomes – Randomized Controlled Trials

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Diabetes medication use							
2 RCTs	Serious limitations (−1)[a]	No serious limitations	No serious limitations	Serious limitations (−1)[b]	Undetected	None	⊕⊕ Low
Quality of life							
1 RCT	Serious limitations (−1)[c]	Unable to assess	No serious limitations	Serious limitations (−1)[b]	Undetected	None	⊕⊕ Low
Albuminuria remission							
1 RCT	Serious limitations (−1)[c]	Unable to assess	No serious limitations	Serious limitations (-1)[b]	Undetected	None	⊕⊕ Low
Early-stage chronic kidney disease remission							
1 RCT	Serious limitations (−1)[c]	Unable to assess	No serious limitations	Serious limitations (−1)[b]	Undetected	None	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; RCT, randomized controlled trial.
[a]Risk of bias due to patient crossover breaking randomization after 6-month trial period, and incomplete outcome reporting.
[b]Concern for imprecision due to small sample size.
[c]Risk of bias due to pharmaceutical industry funding.

Table A9: GRADE Evidence Profile for the Comparison of Bariatric Surgery and Medical Management in Studies With Adults With Class I Obesity and Type 2 Diabetes for Secondary Outcomes – Comparative Observational Studies

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Diabetes medication use							
6 observational	Serious limitations (−1)[a]	No serious limitations	Serious limitations (−1)[b]	No serious limitations	Undetected	None	⊕⊕ Low
Hypertension							
2 observational	Serious limitations (−1)[a]	No serious limitations	No serious limitations	Serious limitations (−1)[c]	Undetected	None	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation.
[a]Moderate risk of bias from confounding and study participation selection.
[b]Varying definitions of medical management as comparator across studies.
[c]Concern for imprecision due to small sample size.

Appendix 3: Selected Excluded Studies

Clinical Evidence

For transparency, we provide a list of studies that readers might have expected to see but that did not meet the inclusion criteria, along with the primary reason for exclusion.

Citation	Primary reason for exclusion
Dixon JB, O'Brien PE, Playfair J, et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. *JAMA*. 2008;299(3):316–323.	Intervention (gastric banding)
Schauer PR, Bhatt DL, Kirwan JP, et al. Bariatric surgery versus intensive medical therapy for diabetes—5-year outcomes. *N Engl J Med*. 2017;376:641–651.	Population (not limited to class I)
Courcoulas AP, Goodpaster BH, Eagleton JK, Belle SH, Kalarchian MA, Lang W, Toledo FG, Jakicic JM. Surgical vs medical treatments for type 2 diabetes mellitus: a randomized clinical trial. *JAMA Surg*. 2014;149(7):707–715.	Population (not limited to class I)
Cummings DE, Arterburn DE, Westbrook EO, et al. Gastric bypass surgery vs intensive lifestyle and medical intervention for type 2 diabetes: the CROSSROADS randomised controlled trial. *Diabetologia*. 2016 May;59:945–953.	Population (not limited to class I)
Ikramuddin S, Korner J, Lee WJ, et al. Roux-en-Y gastric bypass vs intensive medical management for the control of type 2 diabetes, hypertension, and hyperlipidemia: the Diabetes Surgery Study randomized clinical trial. *JAMA*. 2013 Jun 5;309(21):2240–2249.	Population (not limited to class I)
Halperin F, Ding SA, Simonson DC, et al. Roux-en-Y gastric bypass surgery or lifestyle with intensive medical management in patients with type 2 diabetes: feasibility and 1-year results of a randomized clinical trial. *JAMA Surg*. 2014;149(7):716–726.	Population (not limited to class I)
Rao WS, Shan CX, Zhang W, Jiang DZ, Qiu M. A meta-analysis of short-term outcomes of patients with type 2 diabetes mellitus and BMI≤ 35 kg/m^2 undergoing Roux-en-Y gastric bypass. *World J Surg*. 2015 Jan;39:223–230.	No comparator
Müller-Stich BP, Senft JD, Warschkow R, et al. Surgical versus medical treatment of type 2 diabetes mellitus in nonseverely obese patients: a systematic review and meta-analysis. *Ann Surg*. 2015;261(3):421–429.	Population (not limited to class I); meta-analysis of heterogeneous studies

Economic Evidence

For transparency, we provide a list of studies that readers might have expected to see but that did not meet the inclusion criteria, along with the primary reason for exclusion.

Citation	Primary reason for exclusion
Banerjee S, Garrison LP Jr, Flum DR, Arterburn DE. Cost and health care utilization implications of bariatric surgery versus intensive lifestyle and medical intervention for type 2 diabetes. *Obesity (Silver Spring)*. 2017;25(9):1499–1508. DOI: 10.1002/oby.21927	Missing full results on class I obesity and type 2 diabetes subgroup
Celik A, Asci M, Celik BO, Ugale S. The impact of laparoscopic diverted sleeve gastrectomy with ileal transposition (DSIT) on short term diabetic medication costs. *Springerplus*. 2015 Aug 14;4:417. DOI: 10.1186/s40064-015-1216-z	Missing full intervention costs
Keating CL, Dixon JB, Moodie ML, et al. Cost-effectiveness of surgically induced weight loss for the management of type 2 diabetes: modeled lifetime analysis. *Diabetes Care*. 2009;32(4):567–574. DOI: 10.2337/dc08-1749	Missing full results on class I obesity and type 2 diabetes subgroup
Keating CL, Dixon JB, Moodie ML, Peeters A, Playfai' J, O'Brien PE. Cost-efficacy of surgically induced weight loss for the management of type 2 diabetes: a randomized controlled trial. *Diabetes Care*. 2009;32(4):580–584. DOI: 10.2337/dc08-1748	Missing full results on class I obesity and type 2 diabetes subgroup
Picot J, Jones J, Colquitt JL, et al. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. *Health Technol Assess*. 2009 Sep;13(41):1–190,215–357,iii–iv. DOI: 10.3310/hta13410	Missing full results on class I obesity and type 2 diabetes subgroup
Picot J, Jones J, Colquitt JL, Loveman E, Clegg AJ. Weight loss surgery for mild to moderate obesity: a systematic review and economic evaluation. *Obes Surg*. 2012;22(9):1496–1506. DOI: 10.1007/s11695-012-0679-z	Missing full results on class I obesity and type 2 diabetes subgroup
Seki Y, Kasama K, Yokoyama R, et al. Bariatric surgery versus medical treatment in mildly obese patients with type 2 diabetes mellitus in Japan: Propensity score-matched analysis on real-world data. *J Diabetes Investig*. 2022;13(1):74–84. DOI: 10.1111/jdi.13631	Missing full intervention costs
Tang Q, Sun Z, Zhang N, et al. Cost-effectiveness of bariatric surgery for type 2 diabetes mellitus: a randomized controlled trial in China. *Medicine (Baltimore)*. 2016 May;95(20):e3522. DOI: 10.1097/MD.0000000000003522	Missing full results on class I obesity and type 2 diabetes subgroup
Wu T, Wong SKH, Law BTT, et al. Bariatric surgery is expensive but improves co-morbidity: 5-year assessment of patients with obesity and type 2 diabetes. *Br J Surg*. 2021;108(5):554–565. DOI: 10.1002/bjs.11970	Missing full results on class I obesity and type 2 diabetes subgroup

We excluded studies in which the primary research question and main analysis were not concerned with our population of interest. Some of these studies did conduct sensitivity analyses for diabetic cohorts with lower BMI levels (e.g., 30–34 kg/m^2); 8 studies analyzed males and females with type 2 diabetes and a BMI of 33 kg/m^2 in separate scenario analyses,[136-142] while 2 studies analyzed people with type 2 diabetes and an initial BMI between either 30–34 kg/m^2 or 30–35 kg/m^2.[143,144] All studies were conducted using state-transition Markov modelling to evaluate the cost-effectiveness of bariatric surgery compared with that of optimal medical treatment. Most studies also analyzed bariatric surgery using a mix of surgical methods that were usually reflective of the clinical practice in the country of interest. For example, Senchez-Santos et al[142] included a weighted mix of 3 procedures (gastric bypass, 76%; sleeve gastrectomy, 22%; adjustable gastric banding, 2%), with proportions representative of the routine clinical practice in Spain. In all studies, bariatric surgery was cost-saving or cost-effective in patients with type 2 diabetes class I obesity when considering 10-year and lifetime horizons.

Additionally, health technology assessments on bariatric surgery in patients with diabetes and BMI from 30 to 35 kg/m^2 that include primary economic analysis components have been conducted by *Folkehelseninstituttet* (the Norwegian Institute of Public Health) in 2019[145] and the *Zorginstituut*

Nederland (Netherlands Healthcare Institute) in 2014.[146] Neither have been published in full in English and, as such, were not included in economic evidence review.

The assessment published by *Zorginstituut Nederland*[146] included a budget impact analysis estimating the cost of bariatric surgery at €5,000 to €15,000 EUR depending on hospital and type of operation. They also estimated the resulting savings, from successful operations in the form of decreased medication use, at approximately €1,000 to €5,000 per patient per year. The overall budget impact in this patient group was estimated as €200 to €600 million, while the medication savings would be €40 to €200 million per year.

The assessment published by *Folkehelseninstituttet*[145] concluded that the clinical evidence available at the time was insufficient for a reliable and valid cost-effectiveness model that would reflect Norwegian clinical practice. Instead, they performed a cost analysis. They estimated that the cost of bariatric surgery with a 1-year follow-up would be between 83,500 NOK (Norwegian kroner) and 118,000 NOK per patient, which included surgery costs, consultations, examinations, and patient training before and after surgery. The estimated cost for standard treatment – an intensive lifestyle intervention – would be between 23,400 NOK and 52,200 NOK per patient, which included outpatient consultations (physician, nutritionist, and sports teacher) and group-based teaching in physical activity, diet, and motivation.

Appendix 4: Results of the Applicability Checklist for Studies Included in the Economic Literature Review

Table A10: Assessment of the Applicability[a] of Studies That Evaluated the Cost-Effectiveness of Bariatric Surgery for People With Class I Obesity and Difficult-to-Manage Diabetes

Author, year, country	Is the study population similar to the question?	Are the interventions similar to the question?	Is the health care system studied sufficiently similar to Ontario?	Were the perspectives clearly stated? If yes, what were they?	Are all direct effects included? Are all other effects included where they are material?	Are all future costs and outcomes discounted? If yes, at what rate?	Is the value of health effects expressed in terms of quality-adjusted life-years?	Are costs and outcomes from other sectors fully and appropriately measured and valued?	Overall judgment[b]
Cheng et al, 2022; Singapore	Yes	Yes	Partially	Yes, patient perspective	No	NA	No	No	Not applicable
Rognoni et al, 2020; Italy	Partially	Partially (Combined with gastric banding)	Yes	Yes, Italian payer perspective and societal perspective	Partially	Yes, 3%	Yes	Partially	Partially applicable
Kim et al, 2018; United States	Partially	Yes	Partially	Yes, health care sector and private payer perspective	No	Yes, 3%	Yes	No	Partially applicable
Tu et al, 2019; China	Partially	Yes	No	Yes, health care sector	No	NA (Trial-based)	Yes	No	Partially applicable
Wan et al, 2019; China	Partially	Yes	No	Yes, Chinese health insurance (third-party payer) perspective	No	Yes, 5%	Yes	No	Partially applicable

Abbreviations: NA, not applicable.

[a]Response options for all items were yes, partially, no, unclear, or not applicable.

[b]Overall judgement may be directly, partially, or not applicable.

Appendix 5: Introduction to the United Kingdom Prospective Diabetes Study Outcome Model 2

The United Kingdom Prospective Diabetes Study Outcome Model (UKPDS-OM) 2 is a patient-level microsimulation model that estimates the long-term impact of health interventions for people with type 2 diabetes.[95] The model uses risk equations to determine the first occurrence of 8 diabetes-associated complications (ischemic heart disease, chronic heart failure, first amputation, blindness in 1 eye, renal failure, first stroke, first myocardial infarction, and ulcer); second event occurrence of amputation, stroke, or myocardial infarction; and death.[95] Thirteen factors were included as covariates in risk equations – smoking status, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, systolic blood pressure, HbA1c, peripheral vascular disease, atrial fibrillation, weight (or BMI), albuminuria, heart rate, white blood cell count, hemoglobin, and estimated glomerular filtration rate.[95] This model has a cycle length of a year, and in each cycle, the probability of death or of experiencing 1 or more complications is calculated for each patient according to the appropriate risk equation. Each probability is compared with a random number drawn from a uniform distribution ranging from 0 to 1 to determine whether an event occurs for this patient. Probability of death is based on whether complications have occurred, and which complications have occurred in the current annual cycle. If the model predicts that an individual dies, their total years lived and quality-adjusted life-years are calculated, and the individual exits the simulation; if an individual survives that cycle, their age, years of diabetes, clinical risk factor values and event histories are updated and carried forward to the next annual cycle.

The model has been extensively validated. This model is based on patient-level data from the United Kingdom Prospective Diabetes Study, which was a multicentre, prospective, randomized trial that recruited approximately 5,100 people newly diagnosed type 2 diabetes and has 30 years of follow-up data.[147] The first UKPDS OM was developed primarily to assess the lifetime benefits of diabetes-related interventions, particularly to facilitate economic evaluations by estimating changes in outcomes based on changes in key risk factors including blood glucose level, blood pressure, lipid profile and smoking status.[95,148] The model uses data from all 5,102 patients who entered the trial and from the 4,031 surviving patients at the 10-year posttrial monitoring period.[95] The model was internally valid over 25 years and predicts event rates for complications. However, caution should be applied if model results are extrapolated to populations that differ significantly from that included in the study or that include race or ethnicities other than White Caucasian, Afro-Caribbean, or Asian-Indian.[95] The model has been used in a range of research, clinical and commercial applications worldwide, including by NICE.[120,121]

For the analysis, we used Version 2.1, which was released in January 2020. Here we briefly introduce the model structure and its outputs, risk factors and their progression, and risk equations. For more details on the calculation process, please refer to the original publication.[95]

Model structure and its outputs: The model has a maximum time horizon of 70 years. The main outputs are estimates of life expectancy, quality-adjusted life-years, costs of therapies, and costs of complications. Quality-adjusted life years can also be listed for each year simulated for each subject. The model also outputs cumulative event rates by simulated year and Kaplan-Meier event-free survival.[95,96]

Risk factors and their progression: The model includes a set of variables to predict the outcomes. We can classify the variables as:

- Demographic factors including sex, age of diabetes diagnosis, ethnicity
- Clinical risk factors, including atrial fibrillation, BMI, eGFR, hemoglobin, HbA1c, HDL and LDL cholesterol, heart rate, micro and macro albuminuria, white blood cell count, systolic blood pressure, peripheral vascular disease, and smoking history.
- Event history, including disease history of stroke, congestive heart failure, ischemic heart disease, amputation, blindness, and ulcer.

In real life, risk factors may change over an individual's lifetime, which would require that risk factor levels be updated on a year-by-year basis in the model. However, the current version of model did not include equations for updating risk factor time paths. In 2021, Leal et al reported risk factor progression equations for the model.[95-97] This study[95] estimated equations for prognosis of 13 clinical risk factors used the data with 20-year follow up of 5,102 UKPDS participants and 10-year posttrial follow up of the 4,031 survivors.

There are 13 worksheets, with 1 for each risk factor.[95,96] Users can paste in their own data or use one of the built-in methods to populate the values.[95,96]

Table A11: Risk Factor Progression Equations from UKPDS-OM2[95]

Risk factors	Functional form	Influential factors
Continuous variables		
Hba1c	Panel	Sex, age of diabetes diagnosis, ethnicity Value in the previous year, first recorded value
SBP	Panel	Sex, age of diabetes diagnosis, ethnicity Value in the previous year, first recorded value
LDL	Panel	Sex, age of diabetes diagnosis, ethnicity Value in the previous year, first recorded value
HDL	Panel	Sex, ethnicity Value in the previous year, first recorded value
BMI	Panel	Sex, age of diabetes diagnosis, ethnicity Value in the previous year, first recorded value
Heart rate	Panel	Sex, age of diabetes diagnosis, ethnicity Value in the previous year, first recorded value
WBC	Panel	Sex, age of diabetes diagnosis, ethnicity Value in the previous year, first recorded value
Hemoglobin	Panel	Sex, age of diabetes diagnosis, ethnicity First recorded value
Binary variables		
Urine albumin	Weibull	Sex, age of diabetes diagnosis, ethnicity Smoking history, SBP, Hba1c, BMI, HDL
Peripheral vascular disease	Weibull	Age of diabetes diagnosis Smoking history, SBP, Hba1c, BMI, LDL
Atrial fibrillation	Exponential	Age of diabetes diagnosis BMI
Smoking history	Logistic	Sex, age of diabetes diagnosis, age now Smoking history (in the previous year and the first recorded value)
eGFR < 60[a]	Weibull	Sex, age of diabetes diagnosis, ethnicity SBP, BMI, HDL, LDL, eGFR

Abbreviations: BMI, body mass index; CHF, congestive heart failure; eGFR, estimated glomerular filtration rate; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; IHD, ischemic heart disease; LDL, low-density lipoprotein; MI, myocardial infarction; SBP, systolic blood pressure; WBC, white blood cell count.

Risk equations for health events: The transitions between health states are determined by the model's risk equations. This model includes 7 equations for macrovascular outcomes (first myocardial infarction for men, first myocardial infarction for women, second myocardial infarction, first stroke event, second stroke, congestive heart failure, ischemic heart disease), 6 for microvascular outcomes (first amputation without prior ulcer, first amputation with prior ulcer, second amputation, blindness, ulcer, and renal failure), and 4 for death (probability for people without history or events, people in the first year of events, people with history but no events, people in subsequent years of events). Hayes et al[95] used proportional hazards models for complications and death to select significant covariates from the candidate risk predictors, then examined the parametric forms of the hazard models graphically and chose survival analysis models by considering the Akaike information criteria for exponential, Weibull, and Gompertz parametric forms. Users can specify values for each risk factor for each patient at a given year. UKPDS-OM2 risk equations for these have events have been validated. [95,96] We did not make changes to the risk equations.

The UKPDS-OM2 software contains 5,000 full sets of equation parameters derived from bootstrap samples (sampling with replacement) of the UKPDS trial population.[96] The users can set the number of bootstraps, and each bootstrap run will use a different set of model equation parameters from those available.[96]

Table A12: Risk Equations From UKPDS-OM2[95]

Outcome	Functional form	Risk factors
Macrovascular events		
First MI for men	Exponential	Sex, age of diabetes diagnosis, ethnicity Hba1c, HDL cholesterol, LDL cholesterol, micro- and macro-albuminuria, peripheral vascular disease, smoking history, SBP, white blood cell Amputation history, CHF history, IHD history, stroke history
First MI for women	Weibull	Sex, age of diabetes diagnosis, ethnicity eGFR, Hba1c, LDL cholesterol, micro- and macro-albuminuria, peripheral vascular disease, smoking history, SBP, white blood cell CHF history, IHD history
Second MI	Exponential	LDL cholesterol, micro- and macro-albuminuria
CHF	Weibull	Age of diabetes diagnosis Atrial fibrillation, BMI, eGFR, LDL cholesterol, micro- and macro-albuminuria, peripheral vascular disease Amputation history, ulcer history
IHD	Weibull	Sex, age of diabetes diagnosis eGFR, HDL cholesterol, LDL cholesterol, peripheral vascular disease, SBP Amputation history, CHF history
First stroke	Weibull	Sex, age of diabetes diagnosis Atrial fibrillation, hba1c, LDL cholesterol, micro- and macro-albuminuria, smoking history, SBP, white blood cell Amputation history, IHD history
Microvascular events		
First amputation, no prior ulcer	Weibull	Sex, age of diabetes diagnosis Atrial fibrillation, Hba1c, HDL cholesterol, micro- and macro-albuminuria, peripheral vascular disease, SBP, white blood cell Stroke history
First amputation, prior ulcer	Exponential	Age of diabetes diagnosis Peripheral vascular disease
Second amputation	Exponential	Hba1c
Blindness	Exponential	Age of diabetes diagnosis Hba1c, SBP, white blood cell CHF history, IHD history
Renal failure	Exponential	Sex, age of diabetes diagnosis, ethnicity BMI, eGFR, hemoglobin, LDL cholesterol, micro- and macro-albuminuria, SBP, white blood cell Amputation history, blindness history

Outcome	Functional form	Risk factors
Death		
Death in years with no history or events	Gompertz	Sex Smoking history
Death in 1st year of event(s)	Logistic	Age of diabetes diagnosis, ethnicity Peripheral vascular disease, smoking history Amputation event, IHD event, MI event, stroke event, renal injury event
Death in years with history but not events	Gompertz	BMI, micro- and macro albuminuria, white blood cell, smoking history Amputation history, CHF history, renal injury history, stroke history
Death in subsequent years of event(s)	Logistic	Age Atrial fibrillation, HDL cholesterol, peripheral vascular disease, white blood cell Amputation event (first and second), amputation history, IHD event, IHD history, MI event, MI history, stroke event, renal injury history

Abbreviations: BMI, body mass index; eGFR, estimated glomerular filtration rate; CHF, congestive heart failure; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; IHD, ischemic heart disease; LDL, low-density lipoprotein; MI, myocardial infarction; SBP, systolic blood pressure.

Appendix 6: Cost-Effectiveness Results

Table A13: Reference Case Analysis Results: Risk of Events[a,b] for Diabetes Complications (From Year 2 to Year 50)

Strategy	IHD	MI	Heart failure	Stroke	Amputation	Blindness	Renal failure	Ulcer
Usual care	0.3653	0.4458	0.2522	0.2982	0.2706	0.1550	0.0527	0.0884
Bariatric surgery	0.3661	0.4478	0.2005	0.2997	0.2701	0.1533	0.0620	0.0721
Incremental[c]	−0.0008	0.0020	−0.0516	0.0015	−0.0005	−0.0017	0.0092	−0.0162

Abbreviations: IHD, ischemic heart disease; MI, myocardial infarction
[a]Negative values indicate lower risk.
[b]Results may appear inexact due to rounding.
[c]Incremental effectiveness = average effectiveness (bariatric surgery) − average effectiveness (nonsurgical usual care).

Table A14: Reference Case Analysis Results: Cost Breakdown (From Year 2 to Year 50)

Strategy	Average costs, $		
	Total	Intervention	Complications
Usual care	50,610	10,741	39,868
Bariatric surgery	47,564	6,709	40,855
Incremental cost[a,b,c]	−3,046	−4,032	985

[a]Incremental cost = average cost (bariatric surgery) − average cost (nonsurgical usual care).
[b]Negative costs indicate savings.
[c]Results may appear inexact due to rounding.

Table A15: Reference Case Analysis Results: Differences[a,b] in Total Quality-Adjusted Life-Years Due to Diabetes Complications (From Year 2 to Year 50)

Strategy	IHD	MI	Heart failure	Stroke	Amputation	Blindness	Renal failure	Ulcer
Usual care	0.000	−0.006	-0.047	−0.091	−0.079	0.000	−0.020	−0.072
Bariatric surgery	0.000	−0.006	−0.034	−0.096	−0.081	0.000	−0.027	−0.057
Incremental[c]	0.000	0.000	0.014	−0.005	−0.002	0.000	−0.007	0.015

Abbreviations: IHD, ischemic heart disease; MI, myocardial infarction
[a]Negative values indicate quality-adjusted life-year losses.
[b]Results may appear inexact due to rounding.
[c]Incremental effectiveness = average effectiveness (bariatric surgery) − average effectiveness (nonsurgical usual care).

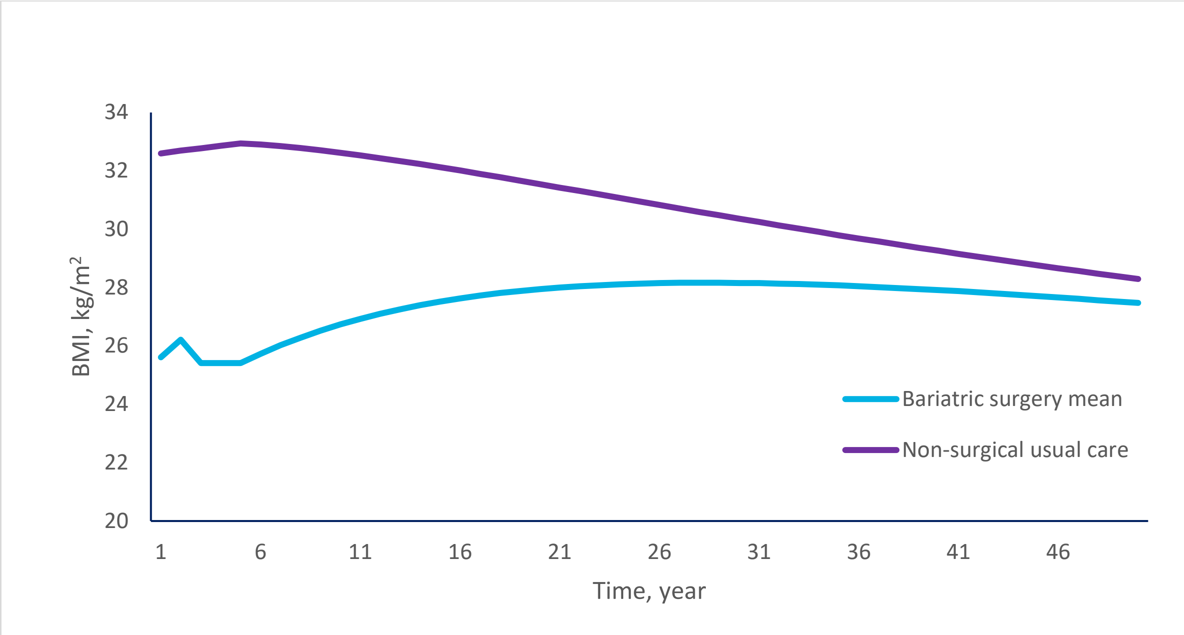

Figure A1: BMI Progression Over the Lifetime Horizon

The BMI level is lower for individuals who received bariatric surgery in the first few years after the bariatric surgery compared with those who received usual care. However, the difference between groups decreases over the lifetime horizon.
Abbreviations: BMI, body mass index.

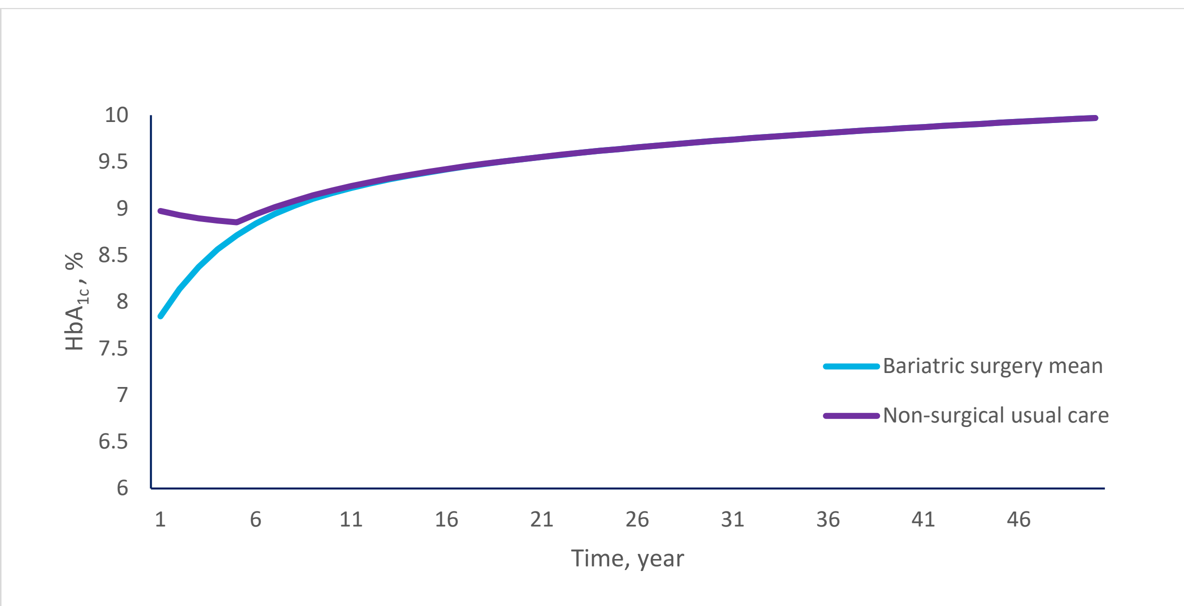

Figure A2: HbA1c Progression Over the Lifetime Horizon

The HbA1c level is lower for individuals who received bariatric surgery in the first few years after the bariatric surgery but becomes similar 10 years after the surgery compared with those who received usual care.
Abbreviations: HbA1c, hemoglobin A1c (glycated hemoglobin).

Appendix 7: Volume of Population of Interest in the Budget Impact Analysis

Based on data from Statistics Canada and the Canadian Community Health Survey, the prevalence of self-reported class I obesity in Canada was about 14% in 2016. Of this, 60% reported having 1 or more obesity-related comorbidity (including type 2 diabetes).

According to Diabetes Canada, approximately 15% of people in Ontario have type 1 or type 2 diabetes (diagnosed or undiagnosed), and by 2022, there would be 2,346,000 people with diabetes; with people with type 2 diabetes accounting for 90%–95% of number.

Nevertheless, the prevalence of class I obesity with difficult-to-manage type 2 diabetes in Ontario is unknown; we do not have the prevalence of class I obesity with difficult-to-manage type 2 diabetes to estimate the number of people who would seek bariatric surgery. According to Diabetes Canada, the total number of people with diabetes – type 1, diagnosed type 2, and undiagnosed type 2 diabetes – is projected to climb to 2,953,000 cases by 2032.[122] Thus, we estimate a 2.32% annual increase.

According to Diabetes Canada's projection, we estimated that there were 1,643,000 people with type 1 diabetes and diagnosed type 2 diabetes in Ontario in 2022. Assuming 7.5% of all diabetes cases are type 1 diabetes, we calculate that in 2022, there were 1,467,050 diagnosed type 2 diabetes cases, which would increase to 1,645,494 in 2027. Assuming 14% of them are with class I obesity (a conservative estimate because this 14% estimate is from general population, who are at a lower risk of obesity than people with type 2 diabetes), we estimate that the number of people with type 2 diabetes and class I obesity ranges from 205,387 in 2022 to 230,369 in 2027.

A cross-sectional study by Weisman et al[149] reported that of 83,273 adults in a Canadian population based primary care electronic medical record database, 10,473 individuals with type 2 diabetes were treated with insulin and 71,316 were not treated with insulin, 24.9% and 62.4% of people met the HbA1c target of ≤ 7.0%. This leads to an estimate of diabetes control rate of 56.6% (10,473*24.9% + 71,316*62.4% = 47,109 individuals having diabetes control; 56.6% = 47,109/83,273). So, we estimate that the number of people with class I obesity and difficult-to-manage type 2 diabetes increases from 89,106 in 2023 to 97,677 in 2027.

Appendix 8: Letter of Information

LETTER OF INFORMATION

Ontario Health

Ontario Health is conducting a review of bariatric surgery for people with obesity and uncontrolled type 2 diabetes. The purpose is to understand whether public funding should be expanded to this surgery.

An important part of this review involves gathering perspectives of patients and caregivers of those who have been diagnosed with obesity and uncontrolled type 2 diabetes who may or may not have experience with bariatric surgery.

WHAT DO YOU NEED FROM ME

- ✓ Willingness to share your story
- ✓ 30-40 minutes of your time for a phone
- ✓ Permission to audio- (not video-) record the interview

WHAT YOUR PARTICIPATION INVOLVES

If you agree to share your experiences, you will be asked to have an interview with Ontario Health staff. The interview will last about 30-40 minutes. It will be held over the telephone and with your permission, the interview will be audio-taped. The interviewer will ask you questions about your or your loved one's condition and your perspectives on bariatric surgery in Ontario.

Participation is voluntary. You may refuse to participate, refuse to answer any questions or withdraw before or at any point during your interview. Withdrawal will in no way affect the care you receive.

CONFIDENTIALITY

Please ensure to avoid providing any identifiable information throughout the interview as there may be opportunity for inadvertent collection personal health information via our auto-recording and transcription process.

All information you share will be kept confidential and your privacy will be protected except as required by law. The results of this review will be published, however, no identifying information will be released or published. Any records containing information from your interview will be stored securely until project completion. After the project's completion, the records will be destroyed.

If you are sending us personal information by email, please be aware that electronic communication is not always secure and can be vulnerable to interception.

RISKS TO PARTICIPATION

There are no known physical risks to participating. Some participants may experience discomfort or anxiety after speaking about their experiences.

Appendix 9: Interview Guide

Bariatric Surgery Interview Guide

Lived-Experience
Health care journey involving obesity and diabetes
What treatment options were you offered prior to bariatric surgery?

Diabetes
Journey to find solution for controlling diabetes
Treatment options offered for diabetes
What's worked, what hasn't?

Decision-Making
Information about bariatric surgery
Decision-making surrounding bariatric surgery
Access/barriers? Cost

Bariatric Surgery Experience
How did you feel going into surgery? Concerns?
Procedure itself
Recovery—length of stay, postdischarge (discharge information), readmission
Postsurgery recovery
Impact of surgery

Any equity/ethical concerns? (theoretically)

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