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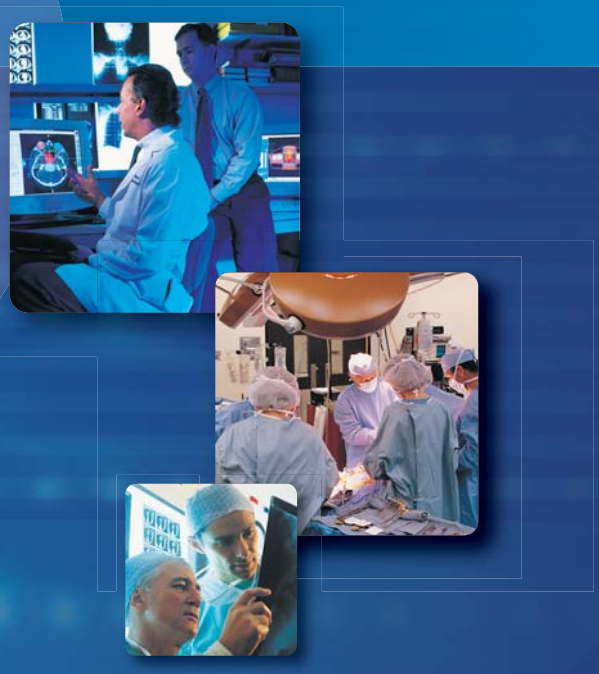
Laparoscopic Adjustable Gastric Banding for Weight Loss in Obese Adults: Clinical and Economic Review



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Canadian Agency for Drugs and Technologies in Health

Laparoscopic Adjustable Gastric Banding for Weight Loss in Obese Adults: Clinical and Economic Review

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September 2007

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Health technology assessment (HTA) agencies face the challenge of providing quality assessments of medical technologies in a timely manner to support decision making. Ideally, all important deliberations would be supported by comprehensive HTA reports, but the urgency of some decisions often requires a more immediate response.

The Health Technology Inquiry Service (HTIS) provides Canadian health care decision makers with HTA information, based on the best available evidence, in a quick and efficient manner. Inquiries related to the assessment of health care technologies (drugs, devices, diagnostic tests, and surgical procedures) are accepted by the service. Information provided by the HTIS is tailored to meet the needs of decision makers, taking into account the urgency, importance, and potential impact of the request.

Consultations with the requestor of this HTIS assessment indicated that a review of the literature would be beneficial. The research question and selection criteria were developed in consultation with the requestor. The literature search was carried out by an information specialist using a standardized search strategy. The review of evidence was conducted by one internal HTIS reviewer. The draft report was internally reviewed and externally peer-reviewed by two or more peer reviewers. All comments were reviewed internally to ensure they were addressed appropriately.

Reviewers

CADTH takes sole responsibility for the final form and content of this bulletin. The statements and conclusions in this bulletin are those of CADTH and not of the reviewers.

Reviewers who agreed to be acknowledged include:

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Dr. Nicolas Christou received an unrestricted education grant from Ethicon Endosurgery Canada and was the principal investigator for the North American Allergan GOAL Trial (telemetric band).

The Health Technology Inquiry Service (HTIS) is an information service for those involved in planning and providing health care in Canada. HTIS responses are based on a limited literature search and are not comprehensive, systematic reviews. The intent is to provide a list of sources and a summary of the best evidence on the topic that CADTH could identify using all reasonable efforts within the time allowed. HTIS responses should be considered along with other types of information and health care considerations. The information included in this response is not intended to replace professional medical advice, nor should it be construed as a recommendation for or against the use of a particular health technology. Readers are also cautioned that a lack of good quality evidence does not necessarily mean a lack of effectiveness, particularly in the case of new and emerging health technologies for which little information can be found, but which may in future prove to be effective. While CADTH has taken care in the preparation of the report to ensure that its contents are accurate, complete, and up-to-date, CADTH does not make any guarantee to that effect. CADTH is not liable for any loss or damages resulting from use of the information in the report.

EXECUTIVE SUMMARY

Context and Policy Issues

Laparoscopic adjustable gastric banding (LAGB) is a surgical option for obese patients. Other surgery options include the Roux-en-Y gastric bypass (RYGB) and vertical banded gastroplasty (VBG). Both these options can be performed laparoscopically or as open surgery.

Bariatric surgery is typically recommended for obese adults with a body mass index (BMI) of $\geq$35 kg/m^2 and risk factors, or a BMI $\geq$40 kg/m^2. Bariatric surgery induces weight loss. All bariatric surgery candidates have failed to achieve significant and sustainable weight loss through lifestyle modification.

Weight loss in obese patients can reduce obesity-related comorbidities such as hypertension, type 2 diabetes, and heart disease, and produce improvements in quality of life outcomes such as self-reported depression symptoms.

LAGB is becoming more common, especially in parts of Europe and Australia, where it is a publicly funded medical service. This procedure is being considered as an option in Canada. As a result, the question whether it should be publicly funded is arising. To help answer this question, recent published clinical and cost information must be synthesized.

Overview

This report investigates evidence on the clinical effectiveness and cost-effectiveness of LAGB as compared to RYGB (open and laparoscopic), VBG (open and laparoscopic), lifestyle modification, or control groups.

Research Question

What is the evidence for the clinical effectiveness and cost-effectiveness of LAGB in obese patients when it is compared to VBG or RYGB?

Methods

Published literature was obtained by cross-searching PubMed, BIOSIS Previews, EMBASE, MEDLINE, and PreMEDLINE. Regular alerts were established on PubMed, BIOSIS Previews, EMBASE, MEDLINE, and PreMEDLINE. The information retrieved via alerts is current to April 9, 2007. A parallel search was performed on the Cochrane Library (Issue 1, 2007) database. Publication language limits were not applied. Filters were applied to limit the retrieval to systematic reviews, health technology assessments, trials (including primary research), and economic studies. Retrieval was limited from 2004 to 2007 for the primary clinical and economic studies, and from 2005 to 2007 for the systematic reviews and health technology assessments.

The web sites of regulatory agencies, and health technology assessment and related agencies, were searched, as were specialized databases, such as those of the University of York Centre for Reviews and Dissemination. The Google™ search engine was used to search for information on the Internet. Efforts were made to find international funding information on the LAGB procedure. These searches were supplemented by hand searches of the bibliographies of selected papers.

Two external reviewers provided comments on this report.

Findings

Clinical Effectiveness of LAGB

Patients who undergo LAGB lose a lot of excess weight. This is generally not as much weight as is lost by patients who undergo RYGB (open or laparoscopic) or VBG (open or laparoscopic) procedures. The excess weight that is lost in all surgical groups is enough to reduce obesity-related comorbidities. In general, very low mortality rates are associated with all bariatric surgeries. LAGB consistently produced fewer short-term complications than RYGB or VBG. Re-operation or conversion to a different bariatric technique may be needed to correct lap band issues (e.g., band erosion).

Limitations of the evidence on LAGB include the lack of long-term studies, the lack of randomized controlled trials, and the poor or not reported follow-up participation rates.

Cost-effectiveness of LAGB

The economic research, while limited, suggests that investment in LAGB may lower total future health care costs by lowering the severity and incidence of obesity-related comorbidities and the associated costs. The initial set-up costs, long-term costs, and costs of surgeons' learning curves must be considered in these calculations.

Conclusions

LAGB has been shown to produce a significant loss of excess weight while maintaining low rates of short-term complications and reducing obesity-related comorbidities. LAGB may not result in the most weight loss but it may be an option for bariatric patients who prefer or who are better suited to undergo less invasive and reversible surgery with lower perioperative complication rates.

One caution with LAGB is the uncertainty about whether the low complication rate extends past three years, given a possibility of increased band-related complications (e.g., erosion, slippage) requiring re-operation.

ABBREVIATIONS

AETMIS	Agence d'évaluation des technologies et des modes d'intervention en santé
AGB	adjustable gastric banding
AHFMR	Alberta Heritage Foundation for Medical Research
BAROS	Bariatric Analysis and Reporting Outcome System
BCBS	Blue Cross Blue Shield
BMI	body mass index
BPD	biliopancreatic diversion
CADTH	Canadian Agency for Drugs and Technologies in Health
CCHS	Canadian Community Health Survey
CI	confidence interval
GB	gastric bypass
HTA	health technology assessment
ICER	incremental cost-effectiveness ratio
ICSI	Institute for Clinical Systems Improvement
RCT	randomized controlled trial
RYGB	Roux-en-Y gastric bypass
LAGB	laparoscopic adjustable gastric banding
LOS	(hospital) length of stay
LRYGB	laparosopic Roux-en-Y gastric bypass
LVBG	laparoscopic vertical banded gastroplasty
QALY	quality-adjusted life-year
QOL	quality of life
SR	systematic review
T2DM	type 2 diabetes mellitus
VBG	vertical banded gastroplasty
%EWL	per cent excess weight loss
%FFML	per cent fat-free mass lost

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Title: Laparoscopic Adjustable Gastric Banding for Weight Loss in Obese Adults: Clinical and Economic Review

Date: June 2007

1 CONTEXT AND POLICY ISSUES

The World Health Organization (WHO) considers obesity to be a global epidemic and a disease that requires long-term strategies aimed at prevention and management.[1] The health consequences that are associated with obesity include hypertension, type 2 diabetes (T2DM), heart disease, gallbladder disease, osteoarthritis, psychosocial problems, and premature death.[2,3] Such consequences are called obesity-related comorbidities.

One method to categorize obesity is to use body mass index (BMI). BMI is calculated by dividing an individual's body weight (in kilograms) by his or her height (in meters) squared (kg/m^2). Statistics Canada provides the following BMI values and corresponding weight categories:[2]

- BMI <18.5 kg/m^2= underweight
- BMI between 18.5 kg/m^2 and 24.9 kg/m^2= normal weight
- BMI between 25.0 kg/m^2 and 29.9 kg/m^2= overweight
- BMI between 30.0 kg/m^2 and 34.9 kg/m^2= Obese Class I
- BMI between 35.0 kg/m^2 and 39.9 kg/m^2= Obese Class II
- BMI ≥40 kg/m^2=Obese Class III (or morbidly obese).

The three classes of obesity represent the escalating risk of developing obesity-related comorbidities.[2]

The prevalence of obesity is increasing in Canada and in other countries. According to the 2004 Canadian Community Health Survey (CCHS), approximately 5.5 million (~23.1%) adult Canadians had a BMI of ≥30 kg/m^2.[2,3] This is ~10.0% higher than was reported in a similar survey conducted in 1978-1979[2] and represents a significant change over the 25-year timeframe ($p<0.05$).[2] Over this period, the median BMI increased from 24.4 kg/m^2 to 26.1 kg/m^2.[2]

Drawing on the 2004 CCHS data, a positive correlation can be seen between obese categories and the prevalence of comorbidities such as high blood pressure, diabetes, and heart disease in adults.[2]

- The prevalence of high blood pressure for those of normal weight is 8.7% compared to 23.7% for those in Obese Class I, 30.1% for Obese Class II, and 29.5% for Obese Class III.
- The prevalence of diabetes for those of normal weight is 2.2% compared to 9.9% for those in Obese Class I and 12.0% for Obese Classes II and III combined.
- The prevalence of heart disease for those of normal weight is 3.0% compared to 7.2% for Class I and 6.7% for Obese Class II and III combined.

The cost of obesity is considerable given the increasing number of Canadians who are obese and the correlation of obesity to serious comorbidities. In 1997, the direct medical costs that were attributable to adult obesity were estimated to be C$1.8 billion, which is 2.4% of all direct medical costs in Canada.[4] Many weight-loss interventions for obesity exist, including lifestyle modification, pharmaceuticals, and bariatric surgery. Bariatric surgery may be the only strategy that results in a significant loss of excess weight in morbidly obese adults.[4]

The 2006 Canadian clinical practice guidelines on the management and prevention of obesity in adults recommend bariatric surgery as an option for adults with BMI ≥35 kg/m^2 and risk factors, or a BMI ≥40 kg/m^2 after lifestyle modification (i.e., a combination of improved nutrition, increased physical activity, and cognitive behaviour therapy) has failed.[3]

Bariatric surgery refers to surgical procedures that can be restrictive, malabsorptive, or a

combination of techniques.[3] Bariatric procedures can be performed as open or laparoscopic surgery.

Gastric-restrictive procedures reduce gastric capacity, which in turn reduces food intake. Gastroplasty involves making a smaller stomach pouch from the existing stomach by stapling or banding a new gastric pouch or partition. This approach is used in bariatric surgery such as adjustable gastric banding (AGB) or vertical banded gastroplasty (VBG). In AGB, an adjustable ring is used to constrict the size of the stomach and limit food intake. The ring is adjustable through an inflatable balloon in the lining. The balloon can be inflated or deflated with saline. This adjustment controls the amount of food that can be held in the stomach.[5,6] In VBG, the patient's stomach is divided into two with a surgical stapler. The reduced capacity of the small, upper section induces satiety with a reduction in food capacity. The section then slowly empties through a gap into the rest of the digestive system.[5,6]

The gastric malabsorptive technique involves inducing malabsorption via a bypass or diversion system. This technique is used in bariatric surgery such as biliopancreatic diversion (BPD).

The combined technique involves gastric restriction from creating a gastric pouch that becomes the patient's new, smaller stomach, coupled with malabsorption via a bypass or diversion system. These techniques are called gastric bypass (GB). The Roux-en-Y gastric bypass (RYGB) involves the creation of a gastric pouch (the new stomach) with a surgical stapler and the shortening of the alimentary path via a Roux limb.[5,6]

Laparoscopic GB, open GB, and laparoscopic adjustable gastric banding (LAGB) are the three most common bariatric operations performed today.[7] Open RYGB is considered to be the gold standard of open bariatric surgery and is the most common in North America.[4] These operations have similar goals: to reduce excess weight and maintain the loss in the long term. The results depend not only on the surgery, but also on the patient's commitment to responsible eating habits (i.e., eating smaller amounts of food more slowly) and lifestyle choices (i.e., daily exercise).

LAGB is becoming more common, especially in parts of Europe and Australia where it is a publicly funded medical service.[4,8] This procedure is receiving greater consideration as an option for bariatric surgery in Canada.[5] The question whether it should be publicly funded is arising. To provide evidence and inform decision making, recent published clinical and cost information must be synthesized.

2 RESEARCH QUESTION

What is the evidence for the clinical effectiveness and cost-effectiveness of LAGB in obese patients when it is compared to VBG or RYGB?

3 METHODS

Published literature was obtained by cross-searching PubMed, BIOSIS Previews, EMBASE, MEDLINE, and PreMEDLINE. Regular alerts were established on PubMed, BIOSIS Previews, EMBASE, MEDLINE, and PreMEDLINE. The information retrieved via alerts is current to April 9, 2007. A parallel search was performed on the Cochrane Library (Issue 1, 2007) database. Publication language limits were not applied. Filters were applied to limit the retrieval to systematic reviews (SRs), health technology assessments (HTAs), trials, and economic studies. Retrieval was limited from 2004 to 2007 for the primary clinical and economic studies, and from 2005 to 2007 for the SRs and HTAs.

The web sites of regulatory agencies, and HTA and related agencies, were searched, as were specialized databases, such as those of the University of York Centre for Reviews and Dissemination. The Google™ search engine was

used to search for information on the Internet. Efforts were made to find international funding information on LAGB. These searches were supplemented by hand searches of the bibliographies of selected papers.

3.1 Eligibility Criteria for Inclusion

Originally, included studies had to examine LAGB in a case series or compare LAGB to RYGB, laparoscopic RYGB (LRYGB), VBG, laparoscopic vertical banded gastroplasty (LVBG), or control groups (e.g., intensive diet regime). A scoping search, however, revealed an overwhelming amount of literature. Because of HTIS's rapid turnaround, a decision was made to exclude all reports that were based on case series designs. This produced a more manageable amount of information and ensured that only the highest quality research available (i.e., with a comparison group) was considered.

Also excluded were reports that compared LAGB to AGB and studies that compared different bands for LAGB or different surgical techniques for LAGB. Reports that contained information on other operations such as BPD were excluded because they were outside the scope of this report.

The quality of the included HTAs and SRs was assessed by two research officers using Oxman and Guyatt's Index of the Scientific Quality of Research Overviews.[9] If a consensus could not be achieved through discussion, a third reviewer was consulted. No kappa statistics were calculated to quantitatively assess inter-rater reliability (because a consensus was required to finalize a score) nor were the reviewers blinded to any aspect of the papers being evaluated. The highest score of 7 indicates that a report has minimal flaws. The lowest score of 1 indicates the presence of extensive flaws. Scores of 3 and 5 indicate major and minor flaws respectively.

For this CADTH report, if the surgery was not specified as laparoscopic or open, it was considered to be open. All data are presented as mean (standard deviations) unless otherwise specified. The confidence intervals (CI) are 95% CI, unless otherwise noted.

4 FINDINGS

Three HTAs and four SRs were identified in the literature search. Two randomized controlled trials (RCTs) and five non-randomized comparative studies were included for the clinical section. Three primary economic studies were included with the economic sections of the clinical reports. This paucity of primary clinical and economic trials reflects the fact that most of the primary clinical studies published since 2004 were case series that were excluded from this CADTH report (Appendix 2). The primary clinical and economic trials that had been considered in the three HTAs and four SRs were not individually summarized. Instead, their contributions were noted in the context of the respective HTAs or SRs.

4.1 Clinical Effectiveness

The clinical efficacy of bariatric surgery can be reported in several ways. A common outcome is per cent excess weight loss (%EWL) where a patient's excess weight is divided by his or her ideal weight (often the benchmark weight is taken from the Metropolitan Height and Weight tables[10]). The success of bariatric surgery is considered to be excellent if %EWL>75.0%, good if between 50.0% and 75.0%, and fair if between 25.0% and 50.0%.[4] A second common outcome is change in BMI from baseline.

This CADTH report focuses on the clinical outcome of %EWL because it is commonly reported and it provides an informative marker for success after bariatric surgery and a measure that is comparable across studies. When %EWL was not reported, the change in BMI or BMI reduction was used as a measure of clinical effectiveness. It is clinically informative and commonly reported. The resolution or improvement of obesity-related comorbidites is examined when data are reported.

4.1.1 HTAs

The Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) has published a HTA on bariatric surgery.[4] The literature search spanned 1988 to April 2005. The authors included several study designs that ranged from SRs to retrospective, non-comparative studies. There was no statistical pooling of the outcomes from the included studies. They examined LAGB, laparoscopic and open RYGB, and laparoscopic and open BPD.

The authors summarized the evidence on RYGB, LAGB and VBG.

- RYGB was established in its clinical effectiveness because it provided stable weight loss, was associated with a low complication rate, and was associated with resolution or improvement of obesity-related comorbidities.
- VBG led to lower than expected weight loss. This procedure has been losing popularity with North American surgeons and is increasingly being replaced by LAGB.
- LAGB seemed to be safe and effective in terms of %EWL. There were rare occurrences of major complications, and acceptable complication and re-operation rates. Reports with longer follow-up periods are needed. The reversibility of LAGB provided an added advantage over RYGB and VBG.
- Laparoscopic approaches to RYGB and AGB were no longer considered to be experimental.

One limitation of the AETMIS report was that the sample size at each follow-up period was not reported. This limits the conclusions that can be drawn, because it can be presumed that patients who were successfully followed-up were those with successful surgeries, were the most committed to the after-surgery care, experienced the least severe morbidities, and perhaps even experienced the greatest %EWL. Because the follow-up population was unknown across many studies, the generalizability and strength of the results in those studies were limited.

There were wide variations in each surgical group for re-operation rates, early complication rates, and late complication rates. In general, the authors stated that laparoscopic procedures were reported to have lower rates of mortality and wound-related complications such as infections and hernias, but were associated with increased rates of complications (such as intestinal obstruction and gastrointestinal tract bleeding) that were rarely seen in open surgery.

Several included studies showed a reduction in obesity-related comorbidities after bariatric surgery. These comorbidities included diabetes, hypertension, cardiovascular disease, sleep apnea, asthma, and arthritis.

The quality score for the AETMIS HTA was 2 (major flaws), mainly because of the uncertainty about whether the literature search was reasonably comprehensive and whether the selection bias was minimized.

An HTA update was published in 2005 by the Alberta Heritage Foundation for Medical Research (AHFMR) Health Technology Assessment Unit.[11] A previous AHFMR HTA[12] concluded that the safety and efficacy of LAGB could not be determined because of insufficient evidence. The objective of the updated report was to determine whether LAGB was a safe and effective procedure compared to open or laparoscopic RYGB or laparoscopic VBG with particular emphasis on longer term (i.e., >5 years) follow-up. The findings were based on three HTAs, one RCT, three comparative non-randomized trials, and 10 case series. The authors of the 2005 AHFMR report made several conclusions.

- RYGB (open) and VBG (open) could be supported as bariatric operations in Alberta. While all three procedures were effective in treating morbid obesity, the degree of weight loss and range of complications differed. In addition, there was no sufficient evidence based on a period of >5 years for LAGB, making it difficult to determine its long-term efficacy and safety.
- The evidence relating to long-term follow up (i.e., ≥5 years) was in a case series, and only

a small number of patients were followed for this length of time.
- LAGB produced %EWL of <50.0%. This was less %EWL than was produced by LRYGB or LVBG at follow-up periods of 24 and 36 months.
- The short-term mortality rates were similar across LAGB, LVBG, and LRYGB, with lower rates of early post-operative complications, and shorter operating time and length of post-operative hospital stay compared to the open surgery counterparts. Compared to LVBG and LRYGB, LAGB had higher rates of long-term post-operative complications and re-operations, which may have offset the initial advantage in reduced duration of hospital stay.
- LAGB and LRYGB were found to improve obesity-related comorbidities, although the information was reported infrequently and inconsistently.

The AHFMR report based several conclusions on the three HTA reports that it included in its review.
- When comparing %EWL, LAGB was as effective as LVBG, but less effective than RYGB (open).
- Based on the evidence for health outcomes and safety between one and five years, no significant differences in comorbidity resolution or improvement were found.
- The primary studies had methodological flaws, including a lack of comparators, small sample sizes, and short follow-up times (e.g., <5 years), which was especially apparent in the case of LAGB.
- The average mortality rates were between 0.05% and 0.3% for LAGB, 0.23% for RYGB (open), and 0.5% for VBG (open).

For the case series reports, there were wider ranges of %EWL for LAGB patients than was seen in the comparative studies. The case series also had higher %EWL values. The reported complication rates in the case series studies were presented inconsistently. The early complications occurred less often than the late complications.

One comparative study reported the rates of comorbidities and noted that LRYGB patients, compared to LAGB patients, experienced significantly lower frequencies of hypertension and dyslipidemia, but no difference in the frequency of diabetes. Three case series on LAGB and the one case series on RYGB reported improvement in comorbidities. The absence of control or comparison groups and large variances in reporting limit the meaningfulness of these results.

Because of the variation of data across all included studies, it was difficult to form conclusions from the AHFMR HTA, especially regarding findings from the case series data. It was also difficult to summarize the early and late complication data because of the variation across studies. The quality score given to this HTA was 2 (major flaws), because the report was judged to have inadequately minimized the potential for selection bias.

In 2005, the Institute for Clinical Systems Improvement (ICSI) produced a technology assessment report on bariatric surgery.[6] The committee made several conclusions.
- In large studies, RYGB patients experienced %EWL between 60.0% and 70.0%. This, combined with the low morbidity results, made RYGB the preferred bariatric surgery over VBG and LAGB.
- LAGB patients experienced %EWL between 40.0% and 60.0%. It was less effective than RYGB. LAGB resulted in significant morbidity. For example, 12.0% to 19.0% of patients may have required re-operation as a result of band slippage. There was also a paucity of studies with follow-up periods >48 months.
- VBG resulted in substantial weight loss and was associated with high morbidity rates. For example, VBG patients had a re-operation rate of up to 30.0% from stoma obstruction and staple-line disruption. The high morbidity rates led to the conclusion that VBG was inferior to RYGB.
- Perioperative morbidity was low for LAGB, VBG, and RYGB, with rates around 1.0%.
- To perform laparoscopic bariatric surgery,

specialist training is required.
- Comparable weight loss occurred with LAGB and LRYGB when compared to their open surgery counterparts

Some key information was missing in the report, such as the baseline differences between treatment groups, other than BMI; the %EWL rates at 12 months and 24 months; and the definitions of short- and long-term complications. The quality score given to this report was 1, indicating extensive flaws, largely because the methods used to locate evidence, the criteria with which study eligibility was determined, and the criteria for assessing the validity of included studies were not reported.

4.1.2 Systematic reviews

The Blue Cross Blue Shield (BCBS) Technology Evaluation Center published a report in 2007.[13] A report from this institution published in 2003 concluded that LAGB did not meet their criteria for coverage. The updated report has concluded otherwise. The current BCBS report reviewed the evidence on LAGB compared to open or laparoscopic GB. The literature was searched between 1980 and September 2006, with eight comparative trials and 57 case series meeting the inclusion criteria.

The authors of the 2007 BCBS report made several statements.
- There was enough evidence to allow a patient to make an informed choice between GB and LAGB. Either was a reasonable choice for a patient considering bariatric surgery.
- LAGB patients lost less weight than GB patients. There were conflicting reports about whether this difference disappeared over time. Attrition bias may have skewed the results because the LAGB patients who had their bands removed or deflated were excluded from the analyses, thereby potentially contributing to an overestimate of LAGB's effectiveness.
- LAGB was considered to be a less invasive procedure than GB; and associated with fewer procedural complications, decreased hospital stay, and earlier return to usual activities. The long-term outcomes of LAGB were uncertain.
- The long-term complications were not reported systematically or consistently. This resulted in variable reporting that was partly due to poor follow-up and the absence of a systematic surveillance system for reporting adverse events.

Eight comparative studies (n=4,191) were included. Three comparative studies matched patients on key characteristics, and the remaining five compared patients at two institutions. It was unclear whether the three studies matched patients in one facility, and whether the remaining five studies tried to match patients in different groups. Appendix 1 Table 1 details the results of these studies. Overall, the 12-month %EWL ranged between 32.0% and 54.0% for LAGB compared to 52.0% to 76.0% for laparoscopic GB. At 24 months, the %EWL for LAGB was between 45.8% and 55.0% compared to 54.0% and 80.0% for laparoscopic GB (p value not reported). While 57 case series papers were included initially in the BCBS report, only those with >50.0% of the patients available for 24-month follow-up for weight loss outcomes (nine studies) and for complications (eight studies) were included in their analyses. In these studies, the %EWL ranged between 35.0% and 45.0% at 12 months (six studies) and between 36% and 56.0% at 24 months (five studies).

There were no reports of death in the LAGB group compared to 0.3% in the laparoscopic GB group among the comparative studies. For the case series, the mortality rates for LAGB and GB ranged between 0.0% and 0.8%.

In the comparative studies, LAGB patients and laparoscopic GB patients experienced wound infection as the most common short-term complication (1.0% median LAGB versus 2.5% median laparoscopic GB). Also, the perioperative (or short-term) complication rates were lower (medians across complications ≤1.0%) with LAGB than with laparoscopic GB. The LAGB and laparoscopic GB groups

experienced re-operation as the most common long-term complication (23.8% LAGB versus 16.4% laparoscopic GB, medians across complications ≤2.5%). It was not reported whether this difference was statistically significant nor was it clear as to how many studies reported complications.

In the case series for LAGB, the most common perioperative complication was wound infection (approximately 5.8%, five studies reported) and re-operation for long-term complications (approximately 13.0%, eight studies reported). The reporting of long-term complication rates across the case series was variable. For example, complications related to the placement of laparoscopic ports varied between 2.8% and 20.2%.

The quality of the studies varied, making it difficult to draw conclusions, especially for case series where the absence of a comparison group complicates the interpretation of results. In addition, most comparative studies compared one group of patients receiving one intervention to another group of patients receiving another intervention in a different facility. The conclusions from studies comparing across facilities was limited because variables, such as surgeons' experience and hospital protocols, were not considered. Thus, the observed differences in outcomes could be due to different interventions, different surgeons, different hospital protocols, or a combination thereof. Of the seven syntheses noted in this CADTH report, this review by BCBS received the second highest quality score of 4 (a rank between minor and major flaws). This was mainly because of the uncertainty surrounding the avoidance and minimization of selection bias.

An SR published by O'Brien *et al*.[14] analyzed %EWL after LAGB and RYGB. This review included 18 reports on LAGB and 18 reports on RYGB (Appendix 1 Table 2). RYGB patients had significantly greater weight loss (67.0% versus 53.0%, $p<0.05$) compared to LAGB patients in the first two years. This difference disappeared at three years, as LAGB patients continued to experience increased %EWL while RYGB patients experienced a stabilized if not decreased %EWL after 24 months. This lack of significant difference continued until eight years post-surgery – the last time-point at which LAGB outcomes were available (53.1%EWL for LAGB versus 56.6%EWL for RYGB). Two limitations of the review were that no follow-up rates were reported and no information was provided on the total patient populations. The authors also stated that %EWL was only one outcome of clinical importance. The authors concluded that LAGB and RYGB induced major and sustainable weight loss after eight years. The quality score for this SR was 2 (reflecting major flaws), mainly because it was judged to have inadequately minimized bias when selecting the articles for inclusion.

The Medical Advisory Secretariat (MAS) of the Ontario Ministry of Health and Long-Term Care has produced a health technology literature review.[5]

The report identified HTAs and SRs between April 2004 and December 2004, and primary studies from 1994 and onward. Five HTAs and SRs made conclusions about LAGB. The consensus was that there was a lack of high-quality, long-term evidence to consider LAGB equal to GB (Appendix 1 Table 3).

The report had one main conclusion.

- RYGB and BPD techniques were better than other banding techniques for weight loss and resolution of comorbid diseases. There were no published prospective, long-term, direct comparisons available.

No conclusions were made regarding LAGB.

The MAS review was given a quality score of 2 (major flaws), largely because the assessors could not find adequate evidence that selection bias was minimized.

The Cochrane Collaboration has published an SR on surgery for morbid obesity.[7] This review included 23 RCTs and three non-randomized studies.

The authors of the Cochrane review made several conclusions.

- GB resulted in greater weight loss; better quality of life (QOL); and fewer revisions, operations, and conversions than gastroplasty, but produced more adverse events.
- LVBG resulted in more patients with excellent or good results and fewer late complications than LAGB.
- The weight loss was similar when open and laparoscopic procedures were compared. Fewer serious complications occurred with laparoscopic surgery.
- In general, laparoscopic surgery took longer operative time, reduced the blood loss, and led to a quicker recovery.
- Bariatric surgery was more effective than non-surgical procedures for weight loss. The comparative benefit and harm associated with different surgical procedures were unclear.
- The overall quality of the trials was poor; for example, few had adequate allocation concealment.

The review received a top quality score of 7 (minimal flaws), suggesting that the results can be viewed with confidence.

4.1.3 Primary clinical trials

Seven comparative trials, two of which were RCTs, were included in this CADTH report[15-21] (Appendix 1 Table 4). These primary clinical trials were excluded in the HTAs and SRs.

The first RCT[15] compared 40 LAGB patients to 40 non-surgical patients (i.e., behavioural modification, very low-calorie diet, pharmacotherapy, and education and professional support on eating and exercise behaviour). All patients had a BMI between 30 kg/m^2 and 35 kg/m^2, and had at least one obesity-related comorbidity. The average baseline BMI was 33.7±1.8 kg/m^2 for LAGB versus 33.5±1.4 kg/m^2 for the non-surgical patients. Patients in both groups were followed every four to six weeks throughout the 24 months of the study.

The LAGB patients experienced a significantly greater %EWL at 24 months than their non-surgical counterparts [87.2% (range 77.7% to 96.6%) versus 21.8% (range 11.9% to 31.6%), p<0.001)]. The adverse events were recorded by physicians at each follow-up session. The surgical group (n=39) experienced seven adverse events, including five patients with operative interventions (13%), one infection (2.6%), and four patients with prolapse requiring a revision surgery (10.0%). The non-surgical group (n=31) experienced 18 adverse events, including one patient with an intolerance to a very low-calorie diet (3.0%), eight patients with intolerance to orlistat (26.0%), and four patients with operative interventions (13.0%). No deaths occurred in either group.

The study had proper randomization and reported withdrawals, but it was not blinded and it was unclear whether the allocation concealment was adequate. The follow-up participation at 24 months for the LAGB group was 98.0% and 83.0% for the non-surgical group, which could skew the results (most likely in a favourable manner) for the non-surgical group.

A second RCT[16] compared 50 LAGB patients to 50 VBG patients. The baseline BMI was similar for both groups (46.7±6.1 kg/m^2 for LAGB versus 46.6±6.4 kg/m^2 for VBG). The age and number of comorbidities were also similar.

VBG patients had significantly greater %EWL at 24 months than LAGB patients (70.1±25.5% for VBG versus 54.9±23.3% for LAGB, p≤0.001). The LAGB group had three reported early adverse events, compared to the 12 reported adverse events in the VBG group (p value not reported). All three adverse events in the LAGB group were conversion surgeries. Two of the adverse events in the VBG group were deaths. The long-term complications included 20 re-operations for LAGB patients compared to 18 for VBG patients.

Before the surgery, 78.0% of LAGB patients and 82.0% of VBG patients suffered from a minimum of one obesity-related comorbidity. After the surgery, this significantly decreased in

both groups to 40.0% and 47.9% for the LABG and VBG groups respectively. Three comorbidities significantly improved or resolved in both LAGB and VBG groups: joint problems, pulmonary problems, and diabetes.

The authors concluded that on the basis of adverse events, LAGB was superior to VBG. This study properly randomized the patients and reported the withdrawals. At the 24-month follow-up, no patients dropped out (excluding the two deaths). The study did not report blinding and it was unclear whether there was adequate allocation concealment.

Miller *et al.*[17] prospectively compared LAGB to VBG (n=1,117) over a minimum of five years in a non-randomized comparative trial. The initial decision to use LAGB or VBG was based on referral and patients' preference. Patients' characteristics such as age and BMI were similar between groups. The authors concluded that LAGB and VBG were effective surgical techniques, but that LAGB resulted in a significantly lower re-intervention and re-operation rate, and improved health status and QOL with similar results in %EWL and loss of comorbidities. The authors reported that they would not recommend VBG based on the advantages in the LAGB group. This study had a 92.0% follow-up rate, and the mean duration of the follow-up period was 92 months (range 60 to 134).

The %EWL at 24, 60, and 120 months for the LAGB group was 59.0±13.0%, 68.0±16.0%, and 62.0±18.0% respectively, compared to 61.0±16.0%, 69.0±18.0%, and 59.0±21.0% respectively for the VBG group, p values not reported. Relative to baseline, both groups experienced a significant ($p<0.0001$) decrease in hypertension, T2DM, osteoarthritis, and pulmonary disease. The statistics for LAGB and VBG were not reported. The perioperative mortality was similar between the two groups, with two dying in the LVBG group and one dying in the LAGB group (0.4% for VBG and 0.2% for LAGB, p=1.0). There were significantly more wound infections in the VBG group (3.4% for VBG versus 0.0% for LAGB, $p<0.0001$). There were no differences in the other reported perioperative complications. The long-term complications (undefined) were not significantly different or were in favour of LAGB. For example, LAGB patients incurred significantly fewer incidences of bolus obstruction, outlet stenosis, and incisional hernia. Significantly fewer LAGB patients needed re-operation (49.7% for VBG versus 8.5% for LAGB, $p<0.0001$).

Another prospective comparative study[18] compared LAGB to LRYGB in 898 patients. Physicians' referrals determined the surgery group. An examination of baseline characteristics revealed that LRYGB patients were significantly younger (44±10 years for LRYGB patients versus 47±11 years for LAGB patients, $p<0.001$) and had significantly lower BMI values (49±8 kg/m^2 for LRYGB patients versus 51±9 kg/m^2 for LAGB patients, $p<0.05$), indicating a possible selection bias.

LRYGB patients lost significantly more excess weight than LAGB until the fifth year, when the advantage disappeared. Attrition in the sample occurred over time with 1.3% LRYGB patients (n=5) and 0.7% (n=3) LAGB patients retained at five years. The %EWL for LRYGB patients was 64.9% and 67.4%, compared to 34.0% and 38.6% for LAGB patients at 12 and 24 months respectively. One death (0.2%) occurred in each group. LAGB patients experienced significantly fewer complications than LRYGB patients (24.0% versus 32.0%, p=0.002). The most common early complication in both groups was wound infection, and the most common late complication for LRYGB patients was internal hernia. For LAGB patients, it was chronic band slippage or pouch dilation.

A retrospective comparative study examined 470 LAGB and 120 LRYGB patients over 36 months.[19] Females dominated the study in both groups. The baseline differences in BMI and age were not significant. The %EWL for LAGB patients was significantly less ($p<0.001$) at all points of follow-up (which ended at 36 months). The %EWL was 39.0%, 45.0%, and 55.0% for LAGB patients at 12, 24, and 36 months

respectively. This compared to 65.0%, 67.0%, and 63.0% for LRYGB patients. Over half of all LAGB and LRYGB patients experienced resolution or improvement of their comorbidities (including hypertension and T2DM). No significant differences emerged. In both groups, 21.0% of patients experienced complications. The most frequent complication for LAGB patients was acute obstruction within the first 30 days of the operation and pouch enlargement later. LRYGB patients most often experienced marginal ulcer and small bowel obstruction in the first 30 days after the operation. The authors stated that the learning curve for LRYGB was longer than the curve for LAGB and that complications decreased with experience. The authors concluded that LAGB was a simpler, less invasive, and safer procedure compared to LRYGB, and that while LAGB resulted in less %EWL, it was just as effective in reducing comorbidities. These reasons compelled the authors to state that LAGB might be considered to be the first option offered to morbidly obese patients.

One limitation of this study is that the number of patients at each stage of follow-up was not reported. The study follow-up period was only 36 months, which limits the generalizability of the results for long-term effectiveness and safety.

Quebbemann *et al.*[20] published a retrospective comparative trial of 27 patients >65 years old who underwent LRYGB or LAGB. At 12 months follow-up, the LRYGB patients had higher %EWL, 72.0%% compared to 32.0% for LAGB patients, p values not reported. The average number of obesity-related comorbidities decreased significantly in the LRYGB group (4.1 versus 2.2, p=0.001) whereas no significant differences were seen in the LAGB group (3.9 versus 2.8, p>0.05). No between-group differences emerged in terms of mortality and complication rate.

The authors concluded that bariatric surgery could be performed safely in patients >65 years old and that LRYGB was more effective than LAGB for this patient population. The small sample size, combined with poor statistical reporting (e.g., on the selected sample, statistical analyses performed, number of surgeons conducting the surgeries), limits the confidence with which one can interpret the results.

A retrospective trial compared the outcomes of LAGB patients to those of control patients (patients who were eligible for bariatric surgery but who refused).[21] The study included 122 patients, 73 of whom underwent LAGB and 49 of whom refused surgery. After 48 months, the patients in the LAGB group reduced their BMI values by an average of 8 kg/m^2 , whereas the control group experienced an average BMI increase of 1.3 kg/m^2 (statistical significance not reported). The LAGB group was significantly less likely to develop T2DM (0.0% versus 17.2%, p=0.0001) and significantly more likely to experience a reduction in already present T2DM (45.0% versus 4.0%, p=0.0052) when compared to the control group. The same pattern emerged in prevention (1.4% versus 25.6%, p=0.0001) and remission of hypertension (20.5% versus 2.3%, p=0.0001). The authors stated that there was an impressive reduction of fat mass and a non-significant reduction of fat-free mass. No data were provided on this measure.

The study was small. While the authors did not think that there were any confounding factors that could account for the large differences between the groups, it is logical to assume that patients who refuse bariatric surgery differ systematically from those who undergo bariatric surgery. The authors concluded that LAGB can successfully prevent T2DM and hypertension for a minimum of four years.

4.2 Economic Information

4.2.1 HTAs

The authors of the AETMIS report made several conclusions regarding cost-effectiveness.[4]

- Bariatric surgery was cost-effective because it was comparable to other medical treatment and health care services provided in Canada.
- While surgery, resulting complications, and annual follow-ups were expensive compared

to other medical treatment and health care services provided in Canada, the overall cost was lowered through the savings incurred by reducing the prevalence of comorbidities such as cardiovascular disease and diabetes (i.e., decreased resource utilization in hospitalizations, drug costs, and productivity losses from sick leave and disability).
- More economic research was needed to evaluate the long-term results of the bariatric surgery techniques (e.g., LAGB, RYGB) and approaches (e.g., open versus laparoscopic surgery).
- Well-designed, long-term economic studies were required to assess efficacy, QOL, and resource-utilization costs and savings.

The conclusions were partly based on two economic modelling studies: a British study and a US study. The British study reported the cost per quality-adjusted life-year (QALY) gained to be £6,289 for gastric banding (GB) (mainly RYGB), £8,527 for adjustable gastric banding (AGB), and £10,237 for VBG. The model predicted costs 20 years post-surgery, with a discount of 6.0%. Sensitivity analyses were performed on different hospital lengths of stay (LOS), pre- and post-admission costs, weight loss, surgical learning curve, costs associated with diabetes (the only comorbidity used in the model), and utility gains. The results of the sensitivity analyses were not reported. The British study seemed to have limited its analyses by excluding non-medical costs. It was unclear whether they included only direct medical costs.

The US study evaluated GB compared to no treatment for obesity and reported that the cost per QALY ranged between US$5,000 and US$16,000 for women, and between US$10,000 and US$35,600 for men. The differences were accounted for by differences in age and initial BMI. Sensitivity analyses using less obese, older men resulted in a cost per QALY>US$50,000. The US study used a payer perspective (thus omitting non-medical costs such as lost wages) and did not take comorbidities into account.

The generalizability of these results to Canada may be limited based on the differences in health care systems, especially in the US study.

A retrospective Canadian study presented in the AETMIS report[4] found that bariatric surgery patients had higher direct health care costs and payments for medical services in the first year, compared to a surgical control group (the type of surgery that was performed was not reported). The pattern changed when the numbers were analyzed five years post-surgery, with the mean cumulative costs being nearly C$6 million less (in 1996 dollars) for every 1,000 bariatric patients. These figures included direct hospital costs (e.g., nursing care, medications, physiotherapy, operating room) and medical service costs (e.g., outpatient visits, consultations).

The AETMIS HTA stated that the direct costs of bariatric surgery were estimated to range between C$4,968 and C$10,870 in countries where public health care systems predominated.[4] The variation depended on the insured costs of hospital care, physicians' fees, general hospital-service charges, the type of surgery, whether the follow-up period was included, and whether potential complications were included. The McGill University Health Centre's Technology Assessment Unit estimated that the direct costs of LAGB and LRYGB were $9,418 and $7,064 respectively.[4] The currency unit was unclear but can be assumed to be Canadian. These costs included those of the surgical procedure, conversion, follow-up, complications, and physicians. Much of the cost data did not specify the year in which the estimate applied.

The AETMIS HTA[4] included nine LAGB studies that reported average operation time or hospital LOS. The operation time ranged between 35 minutes and 120 minutes, and the LOS ranged between 1.2 days and 4.0 days. No costs were associated with these variables. The HTA prepared by the Institute for Clinical Systems Improvement[6] reported a hospital LOS ranging from one day (for some LAGB patients) to six to eight days for open procedures.

One HTA included in the AHFMR HTA[11] reported that RYGB patients had higher QOL

scores. No further information was presented, and no other economic information was noted.

4.2.2 Systematic reviews

The Medical Advisory Secretariat (MAS) of the Ontario Ministry of Health and Long-term Care (MOHLTC) estimated the cost of the GB or gastroplasty procedure to be C$6,185 (in 2003 dollars).[5] This figure excluded the costs of pre-operative consultations, follow-up, surgery revisions, and hospitalizations due to surgery-related complications.

The MAS review[5] also reported that the annual health care costs of treating morbidly obese patients and their comorbid conditions often exceeded C$10,000 per year, per person. It was estimated that Ontario funded 508 procedures per year (283 were performed in Ontario and 225 were performed outside Canada). The authors estimated that approximately 10.0% of Ontario's population could qualify for bariatric surgery by 2010.

In a 2003 report, the Medical Services Advisory Committee in Australia estimated that AGB costs A$912 (Australian dollars) more than bypass procedures. This is equivalent to ~C$800. This additional cost may become negligible when the savings in hospital and other health care system costs are factored into the costs of LAGB. The likely incremental cost for Ontario will be the cost of the device, which was estimated to be C$3,000. The authors projected that if 100.0% of the surgeries were AGB, the incremental annual budget impact would be $58.0 million for the estimated 3,500 procedures. These compared to an incremental annual budget impact of C$47.5 million if no surgeries were AGB, but were GB instead. It is unclear whether this figure consisted primarily of laparoscopic procedures. This analysis excluded the one-time start-up capital costs for the new bariatric surgery centres that would be required.

The cost experience in Australia was cited by the Medical Services Advisory Committee.[5] LAGB was reported to have a net clinical benefit when it was compared with open VBG. The initial costs (initially, LAGB costs A$3,665 more than VBG) were offset because LAGB patients experienced lower rates of revisions and complications. LAGB costs A$4,912 more than RYGB. The LAGB costs are not offset by the shorter hospital stay and lower intensive care.

The Cochrane SR[7] reported on operative time and LOS (from one RCT[22]). The operative time was significantly shorter for LAGB patients compared to LVBG patients [65.4 minutes (35 to 120) versus 94.2 minutes (40 to 270), $p<0.05$]. The same pattern was seen for LOS [3.7 days (2 to 6) versus 6.6 days (3 to 58), $p<0.05$], with LAGB patients having shorter hospital stays. No costs were associated with operation time or LOS.

4.2.3 Clinical trials

Of the seven clinical trials, six contained information about QOL, operation time, or LOS in the hospital.[15-20]

Three studies found that LAGB patients experienced enhanced QOL after surgery[15,17,20] compared to baseline scores.

One study measured QOL with the Bariatric Analysis and Reporting Outcome System (BAROS). When compared to VBG patients, LAGB patients had a significantly higher combined rating of "good," "very good," and "excellent" [83.9% versus 57.8%, $p<0.0001$, odds ratio 3.797, CI 2.072 to 7.125].[17]

One study used the SF-36™ survey (a generic health survey with 36 questions on such issues as pain, emotional health, and mental health, and which groups the items into eight domains) to assess patients' QOL.[15] This RCT compared LAGB patients to non-surgical patients.[15] At baseline, no differences existed between the two groups.[15] At 24 months, the LAGB patients experienced significant improvements in all eight domains of the SF-36 compared to the non-surgical patients who experienced significant improvements in three domains.

The third study was non-randomized. It compared LAGB to LRYGB patients and found that both groups experienced significant increases in QOL (e.g., physical function, general health, Beck Depression Inventory) when compared to the respective baseline values ($p<0.001$). No significant differences were observed between the groups at baseline or after surgery.[20]

Three studies examined operating time.[17-19] When compared to VBG, operating time did not differ significantly with LAGB. Both groups had operation times of approximately 60 minutes.[17] When compared to the LRYGB and RYGB groups, LAGB patients experienced less time in operation (LAGB, around 65 minutes; LRYGB, around 135 minutes; and RYGB, nearly 210 minutes).[18,19]

The LOS for LAGB patients was reported in four studies.[16-18,20] Two studies reported that LAGB patients had significantly shorter LOS compared to VBG patients (4.2±1.3 days versus 10.1±2.3 days, $p<0.0001$;[17] and 3.5±1.5 days versus 6.8±10.4 days, $p<0.001$[16]). LAGB patients also had shorter LOS compared to LRYGB patients (1.1±1.1 days versus 2.5±3.5 days, $p<0.05$).[18] One study, which did not report quantitative information, found that LAGB patients, on average, stayed in the hospital one fewer day than LRYGB patients.[20]

4.2.4 Primary economic studies

Data on the following three primary economic studies appear in Appendix 1 Table 5.

Van Mastrigt *et al.* published findings on the cost-effectiveness of LAGB and VBG, based on an RCT.[23] They concluded that costs and QOL were equal between LAGB and VBG, and therefore, the selection of bariatric procedures could be based on clinical factors.

The two primary outcomes used for the cost-effectiveness analysis were %EWL at 12 months post-surgery and a QOL score from a standardized, generic measure called the EQ-5D (a questionnaire that assesses a patient's ability in five categories: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression). At 12 months, VBG patients had significantly higher %EWL than LAGB patients (53.87±20.64 %EWL for LAGB versus 71.69±20.79 %EWL for VBG, $p=0.001$). No significant differences were observed between LAGB and VBG on the EQ-5D, so the QALY associated with LABG was the same as that for VBG.

The total cost for LAGB was €11,299 compared to €13,185 for VBG. The authors report that this difference was not significant (CI: −€5,999 to €1,765). The estimated incremental cost-effectiveness ratio (ICER) was calculated (the costs were combined over the difference in their effect) with the base case ICER for the cost per 1%EWL equalling €105.83. Thus, it would cost an additional €105.83 for every 1%EWL when the LAGB procedure is compared to the VBG procedure.

This study used a societal perspective in that it summed the direct medical costs (e.g., out-of-pocket expenses, surgery, consultations with physicians and dietitian, inpatient days, prescribed medication) and indirect non-medical costs (e.g., unpaid help and productivity losses). Real costs, rather than charged costs, were used in the analysis, because the charged costs in the Netherlands reflect what was agreed between the insurance company and the hospital.

One limitation to this study is the short-term follow-up. Some literature shows that LAGB patients continue to lose weight beyond 12 months. The issue of long-term complications was not considered. Furthermore, the sample size was small. This limits the ability to detect small differences in outcome measures (i.e., inadequate statistical power) and limits the study's generalizability to the average bariatric surgery candidate.

Wasowicz-Kemps *et al.*[24] analyzed the costs of LAGB as an outpatient procedure compared to those of an inpatient procedure with one night in hospital. The costs of the overnight stay were higher (€4,203 versus €3,609) based on an

intention-to-treat analysis. The outpatient group reported significantly worse postoperative pain (p=0.009) even with a similar use of pain medication in the two groups.

The third study[25] focused on QOL. It was a non-randomized trial that compared LAGB patients 36 months post-surgery to a control group who responded to a recruitment poster for a bariatric surgery study. All patients had baseline BMI values between 30 kg/m^2 and 35 kg/m^2, with the LAGB patients having a clinically small but significantly lower BMI than controls (33.0±1.4 kg/m^2 versus 33.4±1.6 kg/m^2, p=0.03). The LAGB patients had lost 32.8±17.6 kg after 36 months. Both groups of patients completed the SF-36 Health Survey and the Beck Depression Inventory. LAGB patients scored significantly better than control patients on all domains of the SF-36. LAGB patients also scored significantly fewer symptoms of depression as measured by the Beck Depression Inventory. While there was no difference between the two groups in the value placed on grooming and appearance, the LAGB patients scored their appearance evaluations more favourably than the control group. The comparisons controlled for the differences in BMI scores of the two groups.

The authors concluded that bariatric candidates should be advised that while surgery will help reduce the %EWL, the average patient will remain overweight. The authors also stated that while remaining overweight, the LAGB patients will experience greater QOL than other people of similar BMIs with no surgery. The authors concluded that LAGB has a positive impact on obesity-related comorbidities.

The limitations of this study included the fact that patients were recruited at different times and in a different manner, and that the LAGB group may not be representative of general LAGB patients because the included patients had not had their bands removed and had successfully completed a 36-month follow-up. In addition, the authors commented on reduction or obesity-related comorbidities. This was not a stated objective of their study nor was it referenced. No costs were associated with the QOL outcomes.

Limitations

- While there is a large quantity of research on the use of LAGB in obese adults, most of the research is in the form of case series, which cannot be used to draw confident conclusions because of several factors, including the fact that there is no control group.
- A limitation to the literature that is included in this CADTH report is the lack of long-term follow-up (i.e., ≥5 years) and low or unknown participation rates at follow-up. This may be one area where case series with high participation rates for ≥5 years can be of value until higher quality studies are published (i.e., well-designed, non-randomized or randomized comparative studies). Furthermore, case series reports should be consulted for a better picture of the less common adverse events after LAGB, LRYGB, and VBG.
- Another limitation is the variation and inconsistency in the reporting of complications, and the varying definitions of early and late complications.
- Only three RCTs were found: two compared LAGB to VBG,[16,22] and one compared LAGB to a non-surgical group.[15] One of the RCTs comparing LAGB to VBG was contained in HTAs and SRs.[22] None of the studies were long-term (two studies were 24 months and one was 36 months). No RCTs compared LAGB to LRYGB or RYGB.
- The topic of bariatric surgery is complex and several factors may affect weight loss. Efforts were made to capture the most relevant information in the literature, but there were areas that were excluded in this CADTH report.
    - This CADTH report did not investigate the clinical effectiveness and safety of different lap bands or different surgical techniques, nor did it address the variation in surgical techniques and lap bands in the included studies.
    - Studies were excluded when they focused solely on patients undergoing bariatric surgery after a previously failed surgery.
    - Studies that focused on specific subpopulations, such as those patients

who become pregnant after bariatric surgery, were excluded.
    - Studies that explored the effect of predictive factors (e.g., BMI, age, sweet eaters, binge eaters) on the success of bariatric surgery were excluded. This CADTH report was unable to compare the study results of patients who are recommended for bariatric surgery (according to 2006 Canadian clinical practice guidelines on the management and prevention of obesity in adults and children[3]) to those of patients who would not be recommended for bariatric surgery in Canada (e.g., BMI<35 kg/m^2). According to current guidelines, patients with a BMI<35 would not be recommended for bariatric surgery, but several studies that were included in this report included patients with BMI<35.
    - Studies addressing the effect of bariatric surgery on intermediate outcomes (e.g., cholesterol and glucose levels) were excluded. If the studies included in this report contained information on these outcomes, they were not reported.
- Primary studies that were excluded from this report may have been included in the HTAs and SRs summarized in this CADTH report, and may be part of the evidence base that was considered. Other differences exist in the stated inclusion and exclusion criteria for reports that were considered for this CADTH report, and the HTA and SRs that are included in this report.
- This CADTH report did not explore the effect of the surgeon's learning curve on patients' outcome (i.e., %EWL, mortality, morbidity, costs, etc.). The findings of many studies might be confounded because participating surgeons were at various points on the learning curve. This is relevant because some studies reported that adverse events and operating time decreased with surgeons' experience.
- The manner in which LAGB was adjusted or not adjusted after surgery and throughout the follow-up period was not addressed in this CADTH report. Not adjusting the lap band throughout the study may have resulted in diminished weight loss.
- While some economic information was presented for LAGB, VBG, and RYGB (open and laparoscopic), more studies are needed to assess the total cost of bariatric surgery over the long-term (≥5 years). More recent published information would help in determining the costs associated with LAGB and other bariatric surgeries.
- This report compared LAGB to VBG (open and laparoscopic), but the use of VBG is decreasing in Canada and VBG is considered by some to be outdated. As a result, it does not seem to be a viable alternative to LAGB, RYGB, or LRYGB.

5 CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

- Most of the literature is non-randomized and non-comparative. This leads to weak conclusions about the safety and effectiveness of LAGB. Most of the comparative studies had poor patient follow-up and follow-up periods were rarely ≥5 years.
- In general, very low mortality rates are associated with LAGB, VBG, LVBG, RYGB, and LRYGB. LAGB consistently had fewer short-term complications. There may be long-term complications that require re-operation or conversion to a different bariatric technique. This not only diminishes LAGB's safety profile of LAGB but also affects its economic profile.
- Open and laparoscopic RYGB lead to greater loss of excess weight in patients during the early years post-surgery. VBG patients may also lose more weight than LAGB patients. It is less clear whether this weight loss advantage persists over the long term as LAGB patients continue to lose (and maintain) their weight loss at a slower pace than RYGB, LRYGB, VBG, and LVBG patients. If the weight loss after LAGB is adequate to reduce or improve obesity-related morbidities, LAGB may be an effective and

viable option for some patients.

- Several areas remain unaddressed. For example, patient selection criteria need to be explored because success may depend on factors such as baseline BMI, obesity-related comorbidities, psychological differences, and food habits. Patients who undergo RYGB and LRYGB procedures may be more prone to nutritional deficiencies than patients undergoing LAGB. This is rarely reported in the research, however, and remains understudied.
- The economic research, while limited, suggests that the cost of LAGB is reasonable. The total health care costs may be lowered with lower severity and incidence of obesity-related comorbidities and the associated costs. The initial set-up costs, long-term costs, and costs of the learning curve for surgeons (the outcomes of LAGB and other laparoscopic surgeries are worse for the first 100 patients on whom a surgeon operates[11]) must be considered in these calculations. One paper[26] provides Canadian economic data regarding the impact of bariatric surgery on health care costs. This paper was not selected for inclusion in this CADTH report because it did not report economic information for LAGB separately. Instead, it reported on bariatric surgery as a whole.
- Another Canadian study did not meet the inclusion criteria for this CADTH report.[27] This paper did not look specifically at LAGB. Instead, it examined bariatric surgery more globally.
- A recent RCT[28] was retrieved after this CADTH report went to external peer review. The authors of the trial concluded that LRYGB was superior to LAGB for weight loss and that it produced significantly longer operative time and more life-threatening complications. It is the first RCT to directly compare LAGB and LRYGB, and it provides a five-year follow-up. Its sample size is small: 27 LAGB patients and 24 LRYGB patients.
- While several questions remain unanswered, LAGB has been consistently shown to produce a significant loss of excess weight while maintaining low rates of short-term complications and improving or resolving obesity-related comorbidities. Among the bariatric options, LAGB may not result in the most weight loss but it may be an option for those who prefer or who are better suited to a less invasive, reversible surgery with lower perioperative complication rates.
- If LAGB is to become a universal benefit, the proper infrastructure (e.g., operating rooms, hospital beds, outpatient clinics) must be in place. Training programs are needed to ensure that bariatric surgeons are fully trained to perform surgery, treat the postoperative complications that may arise (e.g., band erosion), and perform the surgical conversion that may be required if a patient does not achieve the weight-loss goal.
- One caution with LAGB is the uncertainty about whether the low complication rate extends past three years, given the possibility of increased band-related complications (e.g., erosion, slippage) requiring re-operation. LAGB has been funded and is the bariatric surgery of choice in at least one country (Australia).[4] As a result, the findings from long-term research may become available, permitting adequate assessment of the long-term implications of LAGB as a surgery option on its own and in comparison to other surgeries such as LRYGB.

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APPENDIX 1

Table 1: Clinical Effectiveness Outcomes from Blue Cross and Blue Shield Association Technology Evaluation Center[13]					
Study Design and Intervention(s)	**Sample Size**	**Follow-up (Mean Months)**	**Baseline Characteristics**	**Outcomes**	
comparative studies (8 studies) LAGB LGB	90 to 1,261	12 to 39	BMI kg/m^2 40.2 to 55.4 47.2 to 56.7	%EWL Mortality Most common long-term complication Most common short-term complication	LAGB 12 months 32.0 to 54.0 (7 studies) LAGB 24 months 45.8 to 55.0 (3 studies) LGB 12 months 52.0 to 76.0 (7 studies) LGB 24 months 54.7 to 80.0 (3 studies) 0.0% LAGB versus 0.3% LGB (7 studies) LAGB re-operation 23.8% LGB re-operation 16.4% LAGB wound infection 1.0% median LGB wound infection 2.5% median
single-arm series (57 studies) LAGB	123 to 830	32 to 74	BMI kg/m^2 34 to 74	%EWL BMI (kg/m^2) reduction Mortality rate Most common perioperative complication Re-operation	12 months 35.0 to 45.0 (6 studies) 24 months 36.0 to 56.0 (5 studies) 36 months 33.0 to 53.0 (5 studies) 60 months 31.0 to 56.0 (2 studies) 12 months 8.0 to 14.7 (8 studies) 24 months 8.2 to 15.6 (8 studies) 36 months 7.5 to 11.0 (7 studies) 60 months 8.0 to 10.0 (2 studies) 0.0 to 0.8 (7 studies) wound infection, approximately 5.8% (5 studies) approximately 13.0% (8 studies)

BMI=body mass index; LAGB=laparascopic adjustable gastric banding; LGB=laparascopic gastric banding

Table 2: Clinical Outcomes from O'Brien *et al.*[14]		
Clinical Outcome	**Surgery**	
	LAGB (18 studies)	**RYGB (18 studies)**
%EWL (mean) 12 months 24 months 36 months 60 months	 42 53 55 55	 67 67 62 58
Mean follow-up (months)	not reported	not reported
Baseline BMI range (kg/m^2)	not reported	not reported
Sample size (range)	10,041 (105 to 1,014)	5,824 (105 to 652)

BMI=body mass index; LAGB=laparascopic adjustable gastric banding; RYGB=Roux-en-Y gastric bypass

Table 3: Conclusions from HTAs and SRs Included in Medical Advisory Secretariat, Ministry of Health and Long-Term Care[5]	
Report	**Conclusions**
Blue Cross Blue Shield Association Technology Evaluation Center, 2003	• insufficient evidence to make any conclusions on LAGB or laparoscopic gastric bypass • evidence is mainly case series that contains variability in patient populations, surgeons, and hospitals • lack of consistency in reporting health outcomes and adverse events; few studies that have follow-up periods >3 years • crude comparisons of weight loss can be made at 1 year, but that is extent of information available • LAGB weight loss at 1 year less than gastric bypass; more limited evidence at 3 years suggests that difference may narrow over time • early adverse event rates low after LAGB and probably lower than gastric bypass; higher rate of long-term adverse events; several potentially serious long-term adverse events such as band slippage or erosion; incidences of which increase over time and can result in visceral organ damage, abdominal pain, and intestinal obstruction; these adverse events cannot be confidently determined • insufficient evidence to conclude that LAGB or LGB can improve net health outcomes or are as beneficial as current established surgery (open RYGB) • improved health outcomes from LAGB or LGB yet to be shown in investigational settings; based on these conclusions, Blue Cross Blue Shield Technology Evaluation Center deems that LAGB and LGB do not meet their criteria

Table 3: Conclusions from HTAs and SRs Included in Medical Advisory Secretariat, Ministry of Health and Long-Term Care[5]	
Report	**Conclusions**
Australian Medical Services Advisory Committee (MSAC) , 2003	• LAGB had lowest re-operation rates; 9.9% compared to 11.6% for RYGB and 16.6% for VBG; LAGB follow-up periods shorter • no difference in mortality across LAGB, RYGB or VBG; weight loss for LAGB comparable to VBG but less than RYGB • based on level III and IV evidence (no RCTs of LAGB versus open RYGB or VBG were found), authors concluded that regarding weight loss, LAGB is less effective than RYGB and as effective as VBG • LAGB patients experience shorter hospital stays and operative times than RYGB patients, but no difference compared to VBG patients; variation across studies in length of stay and operation time, likely reflecting various techniques and surgeons' experience • no evidence that RYGB, LAGB, or VBG significantly better than one another
Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S), 2002.	• comparative studies suggest that RYGB produces more weight loss than LAGB and VBG at least up to 2 years; after 2 years, advantage only seen between RYGB and VBG • all 3 procedures resulted in considerable weight-loss up to 4 years post-surgery • LAGB found to be safer in terms of short-term mortality rates
Technology Assessment Unit of McGill University Health Centre, 2004	• enough evidence to indicate that LAGB is effective procedure with adequate safety record of up to 5 years • while there is insufficient evidence to determine whether LAGB is a superior procedure to LRYGB, there are incidences where it is safer
Alberta Heritage Foundation for Medical Research (AHFMR), 2000	• concluded that RYGB was gold standard to treat morbid obesity • early attempts at LAGB show high rate of complications and re-operations • well-designed studies with at least 5-years follow-up will determine if LAGB will become more mainstream • LAGB should become accepted option

BMI=body mass index; LAGB=laparascopic adjustable gastric banding; LGB=laparascopic gastric banding; RCT=randomized controlled trial; RYGB=Roux-en-Y gastric bypass; VGB=vertical banded gastroplasty

Table 4: Clinical and Economic Drivers of Included Clinical Trials						
Author	**Design Intervention**	**Sample Size**	**Follow-up (Months)**	**Baseline Characteristics**	**Outcomes**	
van Dielen *et al.*[16]	RCT LAGB VBG	100 50 50	24	Age (years): 37.2±9.7 39.0±8.5 BMI (kg/m^2): LAGB 46.7±6.1 VBG 46.6±6.4	12 month %EWL (mean±SD) 24 month %EWL (mean±SD) Immediate adverse events Late adverse events LOS Comorbidities (preoperative versus postoperative):	LAGB 53.3±21.2, VBG 71.1±24.0 LAGB 54.9±23.3, VBG 70.1±25.5 3 versus 12 (LAGB versus VBG) 20 versus 33 (LAGB versus VBG group) 3.5±1.5 days versus 6.8±10.4 days, p<0.001 (LAGB versus VBG group) with comorbidity, LAGB (78.0% versus 40.0%, p<0.001), VBG (82.0% versus 47.9%, p<0.001) with T2DM, LAGB (10.0% versus 2.0%, p<0.05), VBG (14.0% versus 2.0%, p<0.05) with hypertension, LAGB (14.0% versus 10.0%), VBG (20.0% versus 14.6%)
O'Brien *et al.,*[15]	RCT LAGB non-surgical	80 40 40	24	Age (years): 41.8±6.4 40.7±7.0 BMI (kg/m^2): LAGB 33.7±1.8	12 month %EWL (CI) 24 month %EWL (CI) Adverse events (LAGB versus non-surgical group)	LAGB 78.6 (69.2 to 88.1), p<0.001 non-surgical 41.1 (31.2 to 50.9) LAGB 87.2 (77.7 to 96.6), p<0.001 non-surgical 21.8(11.9 to 31.6) 7 (18.0%) versus 18 (58.0%)
Miller *et al.*[17]	prospective, comparative LAGB VBG (laparotomy)	1,117 554 563	92 mean (60 to 134) Lost to follow up: LAGB 8.0% VBG 6.0%	Age (years): LAGB 35±10.6 VBG 34±9.6 BMI (kg/m^2): LAGB 46.7±0.78 VBG 46.9±09.9 Overall female to male ratio: 4:1	24 month %EWL (mean±SD) 60 month %EWL (mean±SD) 120 month %EWL (mean±SD) Comorbidity (pre-operatively, 10-year follow-up): Hypertension T2DM Pulmonary disease Osteoarthritis Mortality (perioperative) Wound infection (perioperative)	LAGB 59.0±13, VBG 61.0±16 LAGB 68.0±16, VBG 69.0±18 LAGB 62±18, VBG 59±21 LAGB 71.0%, 20.0% (p<0.0001) VBG 86.0%, 34.0% (p<0.0001) LAGB 27.0%, 4.0% (p<0.0001) VBG 32.0%, 6.0% (p<0.0001) LAGB 69.0%, 6.0% (p<0.0001) VBG 89.0%, 14.0% (p<0.0001) LAGB 82.0%, 8.0% (p<0.0001) VBG 94.0%, 13.0% (p<0.0001) LAGB 0.2% (p=1.0) VBG 0.4% LAGB 0.0% (p<0.0001), VBG 3.4%

Table 4: Clinical and Economic Drivers of Included Clinical Trials						
Author	**Design Intervention**	**Sample Size**	**Follow-up (Months)**	**Baseline Characteristics**	**Outcomes**	
					Late complications (LAGB versus VBG)	Pouch dilation 1.1% versus 1.8% (p=0.451, odds ratio 0.605, CI 0.180 to 1.844) Band erosion 1.3% versus 1.1% (p=0.787, odds ratio 1.188, CI 0.339 to 4.307) Bolus obstruction 0.9% versus 9.8% (p<0.0001, odds ratio 0.084, CI 0.026 to 0.213)
					Reoperation (LAGB versus VBG)	8.5% versus 49.7% (p<0.0001, odds ratio 0.0937 CI 0.065 to 0.133)
					Operating time (LAGB versus VBG) (mean±SD)	57.4±28.3 minutes versus 60.2±29.8 minutes (p=0.932)
					Hospital stay LAGB versus VBG) (mean±SD)	4.2±1.3 versus 10.1±2.3, p<0.0001
					Good, very good, and excellent BAROS scores (quality of life)	LAGB 83.9%, VBG 57.8 (p<0.0001, odds ratio 3.797, CI 2.072 to 7.125)
Jan *et al.*[18]	Prospective, comparative LAGB LRYGB	898 406 492	up to 60 months	Age (years): LAGB 47±11 LRYGB 44±10 (p<0.001) BMI (kg/m^2): LAGB 51±9 LRYGB 49±8 (p<0.05)	12 month %EWL (mean) 24 month %EWL (mean) 60 month %EWL (mean) Mortality Complications (LAGB versus LRYGB) Reoperations (LAGB versus LRYGB) Operating time (LAGB versus LRYGB) (mean) Hospital stay (LAGB versus LRYGB) (mean)	LAGB 34.0, LRYGB 64.9 LAGB 38.6, LRYGB 67.4 LAGB 49.0, LRYGB 58.6 LAGB 0.2%, LRYGB 0.2% 24.0% versus 32.0% (p=0.002) 17.0% versus 17.0% 68±26 minutes versus 134±41, p<0.001 1.1±1.1 days versus 2.5±3.5 days, p<0.05
Galvani, *et al.*[19]	Retrospective, comparative LAGB	590 470	36	Age (years): LAGB 44±10 LRYGB 41±10 BMI (kg/m^2): LAGB 47±8	12 month %EWL (mean) 24 month %EWL (mean) 36 month %EWL (mean) Mortality Complications (LAGB versus LRYGB)	LAGB 39.0, LRYGB 65.0 LAGB 45.0, LRYGB 67.0 LAGB 55.0, LRYGB 63.0 LAGB 0.0%, LRYGB 0.8% 21.0% versus 21.0%

Table 4: Clinical and Economic Drivers of Included Clinical Trials						
Author	**Design Intervention**	**Sample Size**	**Follow-up (Months)**	**Baseline Characteristics**	**Outcomes**	
	LRYGB	120		LRYGB 36±5 Gender (female): LAGB 376/470 LRYGB 110/120	Reoperations (LAGB versus LRYGB) Operating time (LAGB versus LRYGB) (mean) Hospital stay (LAGB versus LRYGB) (mean)	8.0% versus 8.0% 66±26 versus 209±39, p=0.0001 9±2 hours versus 55±17 hours
Quebbe-mann, *et al*.[20]	Retrospective, comparative LAGB LRYGB	27 14 13	 19.6 mean 9.3 mean	Age (years): LAGB 68 LRYGB 68 BMI (kg/m^2): LAGB 48.78±5.7 LRYGB 45.8±8.6 Gender (female): LAGB 50% LRYGB 76.9%	12 month %EWL (mean) 24 month %EWL (mean) Minor complications (LAGB versus LRYGB) Major complications (LAGB versus LRYGB) Reoperations (LAGB versus LRYGB) Hospital stay (LAGB versus LRYGB) (mean) Total QoL score (preoperative versus postoperative)	LAGB 32.0, LRYGB 72.0 LAGB 35.0, LRYGB NR 1 versus 1 1 versus 0 0 versus 0 0.8 days versus 1.9 days LAGB 107.9±17.6 versus 207.9±15.9 (p<0.005) LRYGB 130.6±19.8 versus 213.2±17.7 (p<0.05)
Pontiroli *et al*.[21]	Retrospective, comparative LAGB Control (eligible patients refused surgery)	122 73 49 (43 by year 2)	48 months	Age (years): LAGB 46.1±1.48 control 44.4±2.12 BMI (kg/m^2): LAGB 45.2±1.07 control 45.2±1.61 Gender (female): LAGB 86.0%; control 83.0%	Developed T2DM (LAGB versus control) Remission diabetes (LAGB versus control) Developed hypertension (LAGB versus control) Remission hypertension (LAGB versus control) BMI change, baseline and 48 months (kg/m^2)	0.0% versus 17.2%, p=0.0001 45.0% versus 4.0%, p=0.0052 1.4% versus 25.6%, p=0.0001 20.5% versus 2.3%, p=0.0001 LAGB 45.9±0.89 to 37.7±0.71 control 45.2±1.04 to 46.5±1.3

BMI=body mass index; CI=confidence interval; LAGB=laparascopic adjustable gastric banding; LGB=laparascopic gastric banding; LRYGB=laparoscopic Roux-en-Y gastric bypass; RCT=randomized controlled trial; RYGB=Roux-en-Y gastric bypass; T2DM=type 2 diabetes mellitus; VGB=vertical banded gastroplasty

Table 5: Clinical and Economic Drivers of Included Economic Trials						
Author	**Study Design and Intervention(s)**	**Sample Size**	**Follow-up (Mean Months)**	**Baseline Characteristics**	**Outcomes**	
van Mastrigt *et al.*[23]	RCT LAGB VBG	 50 50	12	Age (years): LAGB 37.2±9.64 VBG 38.9±8.53 BMI: LAGB 46.7±6.12 VBG 46.5±6.42 LAGB 82.0% female VBG 78.0% female	%EWL 12 months (LAGB versus VBG) Total costs (€) Incremental cost per %EWL (moving from VBG to LAGB)	53.87±20.64 versus 71.69±20.79, p=0.001 LAGB 11,299, VBG 13,185 €105.83
Wasowicz-Kemps, *et al.*[24]	RCT LAGB LAGB	50 OP 25 OS 25	6 weeks	BMI kg/m$^{2:}$ OP 47 (37 to 61) OS 47 (39 to 60) Age: OP 37 (23 to 58) OS 41 (25 to 59) OP 23 females OS 21 females Operating time (minutes): OP 74 (45 to 180), OS 73 (45 to 120)	OP costs €3,609, OS costs €4,203 Hospital charge data from billing department; admission costs, operation costs (e.g., materials, facilities, operation time, personnel), and additional costs (e.g., consultations, laboratory tests)	
Dixon *et al.*[25]	Retrospective cohort LAGB Control (patients seeking bariatric surgery)	 158 79 79	36 months	Age (years): LAGB 39.4±7.8 control 39.5±7.6 LAGB 24% men control 24% men BMI (kg/m^2): LAGB 33.0±1.4 control 33.4±1.6, p=0.03	%EWL at 36 months SF-36 scores (LAGB versus control) Beck Depression Inventory Multidimensional body self-relations questionnaire	LAGB 51.5 mean±11.3 SD Physical function 85.3±18.3 versus 69.4±22.2, p<0.001 General health 78.0±18.7 versus 54.7±22.4, p<0.001 Mental health 75.7±17.5 versus 64.0±19.6, p<0.001 5.5±6.4 versus 13.4±8.3, p<0.001 Appearance orientation 3.66±0.68 versus 3.56±0.69, p=0.40 Appearance evaluation 2.72±0.70 versus 1.92±0.57, p<0.001

BMI=body mass index; LAGB=laparascopic adjustable gastric banding; OP=outpatient; OS=overnight stay; RCT=randomized controlled trial; VGB=vertical banded gastroplasty

APPENDIX 2

Excluded Studies: Case Series

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