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Laparoscopic Adjustable Gastric Banding for the Treatment of Clinically Sever (Morbid) Obesity in Adults: An Update

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25 YEARS OF EXCELLENCE

AHFMR
ALBERTA HERITAGE FOUNDATION FOR MEDICAL RESEARCH

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CONFLICT OF INTEREST

Conflict of interest is considered to be financial interest, either direct or indirect, that would be affected by the research contained in this report, or creation of a situation where an author's and/or external reviewer's judgment could be unduly influenced by a secondary interest such as personal advancement.

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EXECUTIVE SUMMARY

Background

Obesity is being identified as an epidemic worldwide affecting over 300 million adults. Clinically severe obesity is associated with a range of co-morbidities such as type 2 diabetes, hypertension, dyslipidemia, sleep apnea, and increased risk for cardiovascular diseases. Conventional treatments such as diet and exercise, behavioural modification regimens, and pharmacological interventions have been shown to be ineffective for this group of patients. Bariatric surgical procedures, such as Roux-en-Y gastric bypass (RYGB), adjustable gastric banding (AGB), or vertical banded gastroplasty (VBG), are considered as the last-resort therapy for severe obesity, but their long-term safety and clinical efficacy remains to be determined.

Objectives

To determine whether laparoscopic AGB (LAGB) is a safe and effective procedure compared with open and/or laparoscopic RYGB (LRYGB) and laparoscopic VBG (LVBG), especially in the longer term (≥ five years), for adult patients with clinically severe obesity.

Results

Three Health Technology Assessment (HTA) reports and 18 published primary studies, including one randomized controlled trial (RCT) comparing LAGB with LVBG, three non-randomized studies comparing LAGB with LRYGB, and 14 case series, met the inclusion criteria. These studies of variable methodological quality included adult patients with preoperative body mass index (BMI) ranging from 27 kg/m^2 to 87 kg/m^2. The follow-up periods available for comparison were up to three years in the RCT and up to two years in the comparative studies. Patients included in the 14 large case series (>500 patients) were followed for a period of longer than five years; however the numbers of patients available at five-year follow-up were small compared with the total number included in the entire case series.

Results from the RCT and two single-centre comparative studies suggested significantly shorter operating time and length of postoperative hospital stay associated with LAGB compared with LVBG or LRYGB.

Based on the RCT and three comparative studies, short-term mortality rates following LAGB were similar to those of LVBG or LRYGB with lower early postoperative complication rates. However, significantly higher long-term postoperative complications and associated re-operations following LAGB have caused safety concerns about the use of LAGB for patients with severe obesity.

Furthermore, although the length of hospital stay was shorter with LAGB, management of late complications, including re-operation, may result in an increased number of hospital days in the long run.

The RCT and three non-randomized comparative studies demonstrated that LAGB appeared to be effective in producing significant weight loss in patients with severe obesity. However, when compared with LRYGB, LAGB appeared to be less effective, with mean percent excess weight loss (%EWL) less than 50% at up to two years follow-up for patients with a wide range of preoperative BMIs (27 kg/m^2 to 81 kg/m^2). LAGB also appeared to be less effective than LVBG, with mean %EWL less than 50% at three years of follow-up for patients with preoperative BMIs between 40 kg/m^2 to 50 kg/m^2. Based only on the two large case series with follow-up rates available for each year, weight loss after LAGB gradually increased with careful band adjustment and achieved 47% to 54% EWL over one to five years after surgery, with 190 and 32 patients, respectively, attending five-year follow-up visit.

The improvement in co-morbidities and quality of life (QOL) was reported inconsistently. LAGB resulted in improvement of certain co-morbidities (such as diabetes and hypertension) and QOL. LRYGB appeared to yield more profound improvement of co-morbidities. Patients treated with RYGB tended to report higher scores on QOL measures than did patients who received LAGB or VBG. Nutritional deficiencies following bariatric surgery, particularly a concern with RYGB (open or laparoscopic), were not reported in most studies.

Conclusions and recommendations

Although the intent of this report was to look at long-term (greater than five years) safety and efficacy of LAGB, it is not possible at this stage to make definitive conclusions because of weak evidence (case series), with results available for a very small number of patients.

The greatest needs at present are long-term studies with systematic surveillance and minimal loss to follow-up that can better define the long-term weight loss and improvement in co-morbidities and QOL, as well as complications, following LAGB compared with LRYGB and LVBG. Future research needs to further classify patients according to their preoperative BMIs and perform subgroup analyses of results for each class of obesity according to the WHO/Canada body weight classifications. The main issue is to identify which patient group is most appropriate for which bariatric procedure.

Based on the current research evidence, guidelines, and position statements, all bariatric surgeries are effective in the treatment of morbid obesity but differ in the degree of weight loss and range of complications. The current evidence base supports the current practice (RYGB or VBG) for treating clinically severe obese

patients in Alberta. There is an opportunity to establish a registry that collects data on appropriate patient characteristics and links these data to meaningful outcome measures to answer the important clinical questions that the current research has failed to address.

Methodology

Systematic reviews, HTAs, clinical guidelines, and primary studies were identified by systematically searching The Cochrane Library, National Health Service Centre for Reviews and Dissemination database (Economic Evaluation Database, HTA, Database of Abstracts of Reviews of Effects), PubMed, EMBASE, and Web of Knowledge, as well as relevant library collections, practice guidelines, evidence-based resources, and other HTA agency resources from 2000 to March 2005 (for the search on systematic reviews, HTAs, clinical guidelines) and from 2002 to March 2005 (for the search on primary studies). Search was limited to English language, human studies in adults.

Reference

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GLOSSARY

Bariatric surgery: any gastric-intestinal surgery performed for the purpose of producing weight loss [1]

Body mass index (BMI): a mathematical calculation used to determine whether an individual is overweight. It is calculated by dividing a person's body weight in kilograms by his/her height in meters squared (kg/m^2) [1].

Clinically severe (or morbid) obesity: BMI >40 kg/m^2 or BMI >35 kg/m^2 with co-morbidities

Excess weight: total preoperative weight minus ideal weight [2]

Obese: BMI 30 kg/m^2 or over [3]

Obesity-related : a condition that is either caused or exacerbated by obesity [4]. In severely obese patients, the most common co-morbidities include diabetes, hypertension, hyperlipidemia, or sleep apnea.

Overweight [3]**:** BMI between 25 and 29.9 kg/m^2

Percentage of excess weight loss (%EWL) [2]**:** is the standard measure of weight loss in the bariatric surgery nomenclature. This calculation is derived from the formula %EWL = (weight loss/excess weight) × 100.

ABBREVIATIONS

AGB – adjustable gastric banding

AHFMR – Alberta Heritage Foundation for Medical Research

ASERNIP-S – Australian Safety and Efficacy Register of New Interventional Procedures - Surgical

BAROS – Bariatric Analysis and Reporting System

BCBS – Blue Cross and Blue Shield

BMI – body mass index

BPD – biliopancreatic diversion

CRD – Centre for Reviews and Dissemination

ECRI – formerly known as Emergency Care Research Institute

EWL – excess weight loss

FDA – Food and Drug Administration

IFSO – International Federation for the Surgery of Obesity

HTA – health technology assessment

LAGB – laparoscopic adjustable gastric banding

LRYGB – laparoscopic Roux-en-Y gastric bypass

LVBG – laparoscopic vertical banded gastroplasty

MSAC – Medical Services Advisory Committee

NHS – National Health Service

QOL – quality of life

RCT – randomized controlled trial

RYGB – Roux-en-Y gastric bypass

SAGB – Swedish Adjustable Gastric Band

SAGES – Society of American Gastrointestinal Endoscopic Surgeons

SOS – Swedish Obese Subjects

VBG – vertical banded gastroplasty

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INTRODUCTION

This report was prepared in response to a request from Alberta Health and Wellness for updated evidence on the use of laparoscopic adjustable gastric banding (LAGB) for the treatment of patients with clinically severe obesity. The project originated from requests by patients with severe obesity to add LAGB to the list of insured services. This report focuses on the safety and efficacy/effectiveness of LAGB.

Definition of obesity

Obesity is a complex, heterogeneous metabolic condition in which total body fat has accumulated to the extent that health may be affected [5, 6]. Currently, body mass index (BMI) is the most commonly used measure of obesity. According to the World Health Organization [7] and the Canadian Guidelines for Body Weight Classification in Adults [3], a normal BMI is considered to range from 18.5 to 24.9 kg/m^2. Overweight is defined by a BMI between 25 and 29.9 kg/m^2. A BMI above 30 kg/m^2 is considered obese, which can be further classified as Obese Class I (BMI between 30 and 34.9 kg/m^2), Obese Class II (BMI between 35 and 39.9 kg/m^2), and Obese Class III (BMI ≥40 kg/m^2). Clinically severe obesity (used interchangeably with the term "morbid obesity") is defined as a BMI ≥40 kg/m^2 or ≥35 kg/m^2 with serious co-morbid conditions [8]. Super-obesity is defined as a BMI ≥50 kg/m^2 [9].

Epidemiology

Obesity, because of its medical, physical, social, economic, and psychological co-morbid consequences, is considered a disease [9]. Obesity is a multi-factorial disease that results from an interaction of genetic, environmental, social and behavioural, psychological, and neurological factors [9]. Obesity is a chronic disease, which has become a challenging global public health issue.

The World Health Organization considers obesity to be an epidemic throughout both developed and developing countries, according to estimates that over 300 million adults are obese [10]. Clinically severe obesity occurs in 2% to 5% of the population in the Western world [11]. In the United States, more than 12 million people [12], or more than 5% of adults, are severely obese [13, 14].

In Canada, the overall national prevalence of adult obesity increased from 5.6% in 1985 to 14.8% in 1998, according to the National Population Health Surveys [15]. The Canadian Community Health Survey data revealed that, from 1994/95 to 2000/01, the number of obese Canadians aged 20 to 64 years increased by 24% [16]. By 2003, 14.9% of adult Canadians were considered obese and 33.3% were considered overweight [17]. Data from the Canadian Heart Health Survey (1986-1992) indicated that 3% of Canadian adults had a BMI greater than 35 kg/m^2 [18]. In 1985, all

provinces reported obesity rates of less than 10%, but in 1994, all provinces reported rates greater than 10% [18]. By 1998, all provinces except British Columbia and Quebec reported obesity rates greater than 15% [18]. Recently released longitudinal data from the National Population Health Survey showed that almost one-quarter of Canadians who had been overweight in 1994/95 had become obese by 2002/03. Women, young men, and members of low-income households were most likely to become obese [19].

Severe obesity is associated with a range of co-morbidities including type 2 diabetes, hypertension, dyslipidemia, osteoarthritis, sleep apnea, and certain cancers [20, 21]. It is also associated with an increased risk for cardiovascular diseases [18, 22]. In addition to the physical effects, there are significant psychosocial manifestations including depression, poor self-esteem, and sexual dysfunction [23].

Management of obesity

Various strategies, including low-calorie diets, physical exercises, behavioural modification regimens, pharmacological interventions, and surgical treatments, have been used to control obesity [24, 25]. Reported benefits have varied both in the short and long term.

Non-surgical treatments

First-line therapy for obesity consists of lifestyle changes such as diet, exercise, and behavioural modification. These strategies carry the least amount of risk [13]. For people with severe obesity, these strategies are usually ineffective in producing and maintaining significant weight loss [13].

Pharmacological therapy is considered second-line therapy and is recommended when lifestyle changes fail to yield significant weight loss. Increased risk is accepted for potentially enhanced weight loss [13]. Two drugs, sibutramine and orlistat, were approved by the US Food and Drug Administration (FDA) [13] and Health Canada [26, 27] for the treatment of severe obesity; however, the efficacy of these two drugs is very limited [24].

Generally, these non-surgical treatments have been unsuccessful in maintaining long-term weight loss for severely obese individuals [9, 25]; the failure rate of these conservative treatments is estimated to be 95% [28]. Optimal and continuous application of a combination of healthy eating, exercise, and behavioural modification, supplemented by drug therapy, can, at best, achieve and maintain a 5% to 10% loss of body weight [12] or a weight loss of up to 10 kg [6]. This amount of weight loss is usually insufficient for effective treatment of co-morbidities associated with obesity [6].

Surgical treatments

In response to the failure of conservative weight loss measures, several different bariatric surgical interventions have been developed. Bariatric surgery is considered major surgery in which a surgeon alters the patient's digestive tract in an attempt to induce weight loss [23]. The goals of bariatric surgery are to maintain a significant weight loss over time and to ameliorate co-morbid conditions [29].

After bariatric surgery, patients need to be followed by a multidisciplinary team of experts, including the operating surgeon, nutritionists, psychological counselors, health educators, and fitness experts [30]. This team helps patients adjust to new eating habits, increase or maintain weight losses, and improve their chances of living healthy lifestyles. It is important for severely obese patients to understand that, following bariatric surgery, a lifetime commitment of diligent follow-up is required [31].

Although surgical treatments are considered as the last-resort therapy for severely obese patients, they are the only treatments currently associated with documented, substantial, and maintained weight loss, as well as with the amelioration of obesity-related co-morbidities [14]. The investigators of the Swedish Obese Subjects (SOS) study, an ongoing multi-centre, prospective, non-randomized clinical trial that began in 1991, recently published the results of 1703 participants who were followed for 10 years [32]. Compared with conventional treatment, bariatric surgery was shown to be associated with more significant long-term weight loss, improved lifestyle, and improvement in co-morbidities such as hypertension, diabetes, and hyperglycemia [32].

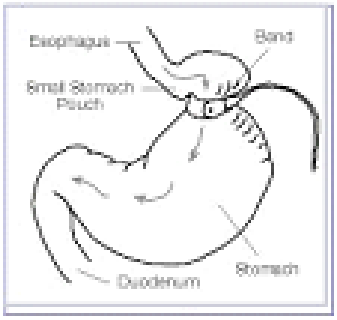
BARIATRIC SURGERY

Bariatric surgery is classified into three broad categories: gastric restrictive, mal-absorptive, or a combination of the two [23]. Restrictive procedures attempt to reduce the caloric intake by reducing gastric volume, slowing gastric emptying, and creating early satiety [11, 33]. Mal-absorptive procedures attempt to reduce the caloric uptake by bypassing various lengths of small intestine [11, 13].

Biliopancreatic diversion (BPD; with or without duodenal switch) and the distal gastric bypass are examples of mal-absorptive procedures. Adjustable gastric banding (AGB) and vertical banded gastroplasty (VBG) are purely restrictive, whereas Roux-en-Y gastric bypass (RYGB) is both restrictive and mal-absorptive (Figures 1-3, adapted from http://win.niddk.nih.gov/publications/gastric.htm).

AGB is a purely restrictive procedure, in which the surgeon places a silicone band around the entire upper portion of the stomach (see Figure 1). Because of the tiny pouch and the narrow channel through the band, patients feel satiated after only a small amount of food is eaten.

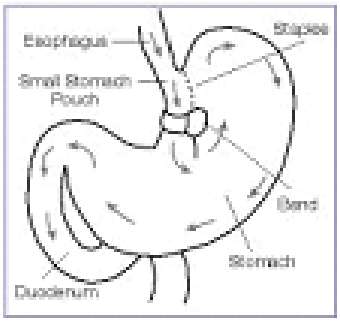
Figure 1: Gastric banding



Gastric restrictive bands were initially non-adjustable and designed for open placement. Refinement of these devices has resulted in an adjustable appliance, which can be placed laparoscopically [23]. By adjusting the diameter of the band, more or less food can be permitted to pass to the lower portion of the stomach. These adjustments permit some flexibility in treatment; the band can be narrowed if weight loss is insufficient, or it can be expanded if the patient experiences severe adverse effects.

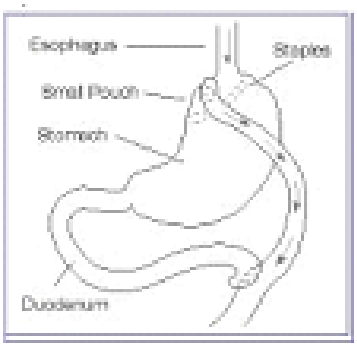
VBG is a simple gastric restrictive procedure that aids the management of body weight by limiting the amount and rate of solid food ingestion [34]. In this procedure, the surgeon creates a small gastric pouch in the upper portion of the stomach using vertically aligned staples. The pouch is drained through a narrow band (stoma) into the rest of the stomach. Made of polypropylene mesh, this band is intended to prevent the channel from widening over time. To allow placement of the band, the surgeon creates a circular "window" of staples connecting the front and back walls of the stomach (see Figure 2). VBG maintains the anatomical and functional continuity of the gastrointestinal tract [34].

Figure 2: Vertical banded gastroplasty



RYGB has both restrictive and mal-absorptive features, but the primary mechanism of weight loss is believed to be restrictive. The RYGB procedure involves the creation of a small stomach pouch by sealing off the majority of the stomach with a staple line or surgical division and then bypassing the distal stomach using a Y-shaped segment of the small intestine (see Figure 3). This procedure induces mal-absorption of ingested food, which reduces the number of calories absorbed, but also limits the uptake of essential nutrients such as vitamins and minerals [23]. Patients who receive RYGB are at risk for developing iron, vitamin B_{12}, folate, and calcium deficiencies [35].

Figure 3: Roux-en-Y gastric bypass



Laparoscopic techniques

A laparoscopic approach applied to traditional open bariatric procedures has resulted in laparoscopic bariatric surgery becoming one of the most rapidly growing fields [36]. Because of the significant co-morbidities associated with open bariatric procedures, severely obese patients are generally at increased risk for postoperative cardiopulmonary and wound-related complications. A laparoscopic approach might be of greater benefit to this group of patients than those considered to be not clinically obese [33, 37]. The goals of the laparoscopic approach are to reduce the length of hospitalization and minimize the morbidity associated with open bariatric surgery. Assessments of open and laparoscopic procedures demonstrated that laparoscopic procedures were associated with longer operating times, fewer serious complications, reduced time in the intensive care unit and shortened hospital stays, and earlier return to activities of daily living and work [38].

Laparoscopic techniques have recently been introduced for AGB, VBG, and RYGB. Adjustable silicone gastric banding was the first bariatric procedure to be performed by a laparoscopic approach in 1993 [37]. LAGB, unlike VBG and RYGB, involves no stapling of the stomach wall, no cutting or opening of the stomach, and no alteration of the gastrointestinal tract [33]. The major benefits of LAGB include adjustability, reversibility, and minimal invasiveness [6, 37].

- ***Adjustability:*** The degree of restriction can be adjusted by injecting or withdrawing saline through a port under the skin. This allows the size of the stoma (opening between the upper and lower stomach) to be changed to fit each patient's nutritional and weight loss needs [33]. With the option of adjustability, LAGB is able to induce a less severe rate of weight loss over a two-to-three-year period followed by maintenance of that weight loss [6].

- ***Reversibility:*** The band can be removed and normal stomach anatomy restored should it become necessary [6].
- ***Minimal invasiveness:*** The band can be placed laparoscopically in almost all patients who have not had previous gastric surgery.

The LAGB procedure is clearly an easier laparoscopic procedure than the laparoscopic gastric bypass [39]. However, concern persists regarding the long-term efficacy of LAGB, the incidence of adverse events and the requirement for re-operation in a proportion of patients [23].

Current status and practice

Worldwide, the number of bariatric surgical operations increased from 40,000 in 1998 to 146,301 in 2003 [40]. According to a 2003 worldwide survey, 37% of all bariatric surgeries performed were open procedures and 63% were laparoscopic procedures; in other words, about two-thirds of the world's bariatric surgery is performed laparoscopically [40]. The three most commonly performed procedures were laparoscopic gastric bypass (26%), LAGB (24%), and open gastric bypass (23%) [40]. When open and laparoscopic approaches are combined, gastric bypass was the most commonly performed procedure worldwide (65%), followed by gastric banding (24%), VBG (5.4%), and BPD/duodenal switch (4.9%) [40].

In Canada, the annual number of bariatric surgeries (excluding Quebec and rural Manitoba) increased from 78 in 2000/01 to over 1,100 procedures in 2002/03 [41]. In the United States, two major trends in the past decade have been observed. First, the most frequently performed procedure is RYGB, performed 70% of the time, compared with restrictive procedures (including gastroplasty and gastric banding), which are performed in 16% of cases [13]. Mal-absorptive procedures, represented by BPD, are performed in 12% of cases [13]. The second major trend is that the use of laparoscopic procedures increased from 5% in 1986 to 10% in 2001 [30]. Currently, 9% of bariatric procedures in the United States/Canada are LAGB [40]. The patient population has also changed; the mean preoperative BMI has increased from 45 kg/m^2 to 50 kg/m^2, the mean age at the time of surgery has increased from 37 to 41 years, and the percentage of male patients has increased from 11% to 15% [30].

The RYGB procedure has proven long-term weight loss and acceptable short- and long-term complication rates [33]. VBG, however, is the most common variety of gastroplasty and formerly the most commonly performed bariatric procedure in the United States [13]. It is performed less frequently today, perhaps for the following stated reasons: (1) poor patient compliance with eating behaviour modifications, (2) dehiscence of the vertical stapled partition, (3) less effective than gastric bypass procedure for control of type 2 diabetes mellitus, (4) requirement for implantation of a foreign body (e.g., polypropylene mesh or silastic ring), (5) less sustained weight

loss over time compared with RYGB procedure, and 6) side effects including gastro-esophageal reflux and solid food intolerance [13, 34].

Although gastric bypass and duodenal switch currently represent 80% of laparoscopic bariatric procedures in the United States and Canada, laparoscopic gastric restrictive procedures (VBG and AGB) represent the majority of bariatric procedures in Europe [42]. It has been observed, however, that although LAGB has been increasingly performed in the United States and Canada, Europe and countries outside of the United States/Canada have become more receptive to laparoscopic gastric bypass [40].

Both open VBG and open RYGB procedures are performed in Alberta with the RYGB procedure being more commonly performed. The LAGB procedure is not currently provided in Alberta (personal communication, Dr Davey, Dr Nohr, November 2004).

Regulatory status

Health Canada issued licenses for the marketing of the device Lap-Band to INAMED Health, Santa Barbara, CA, [43] and for the Swedish Adjustable Gastric Band (SAGB) to Obtech Medical, Baar, Switzerland [44].

The Lap-Band system is indicated for use in weight reduction for severely obese adult patients with a BMI of 35 kg/m^2 or higher who have failed more conservative weight reduction alternatives such as supervised diet, exercise, and behaviour modification programs. Patients who elect to have this device must make the commitment to accept significant and permanent changes in their eating habits (personal communication, Ms K Savage, Health Canada, October 2004). The SAGB is indicated for adult patients who have morbid obesity with a BMI above 40 kg/m^2 or above 35 kg/m^2 if complications or co-morbidities are present that threaten the vital or functional prognosis (personal communication, Ms K Savage, Health Canada, October 2004).

The Lap-Band system received pre-market application approval by the US FDA in June 2001 [45] and the indications were similar to that approved by Health Canada. The SAGB has not yet been approved by the US FDA.

OBJECTIVES AND SCOPE

In 2000, the Health Technology Assessment (HTA) unit at the Alberta Heritage Foundation for Medical Research (AHFMR) undertook an assessment of LAGB [46]. On the basis of one systematic review prepared by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) [47] and nine primary studies, the AHFMR assessment report concluded the following:

- The safety and/or efficacy of the LAGB procedure cannot be determined at the present time as a result of an incomplete and/or poor quality evidence base. It is recommended that further research be conducted to establish safety and/or efficacy.
- Whether LAGB surgery will replace the current standard of care (RYGB) or become part of the mainstream treatment for severe obesity can only be determined by well- designed studies reporting outcomes for more than five years.

An updated literature search found that a number of systematic reviews and HTA reports on bariatric surgery were published since the AHFMR report [28, 30, 38, 48-52]. Four of these reviews specifically compared the LAGB procedure with RYGB and/or VBG [48-50, 52]. Two of these reviews [48, 49] compared LAGB with both RYGB and VBG, whereas the other two reviews [50, 52] only compared LAGB with RYGB. The review by the ASERNIP-S group was prepared in 2002 [23] and was published in a peer-reviewed journal in 2004 [48]. This review was included in the other three more recent reviews [49, 50, 52] and the most recent McGill report [50] was built on this review. Thus, the present report will focus on the three most recent reviews [49, 50, 52] and update the Medical Services Advisory Committee (MSAC) review [49] that presented the findings from the ASERNIP-S review in terms of comparing LAGB with both RYGB and VBG.

It is important that patients be followed for at least five years to properly evaluate the safety and effectiveness of the bariatric procedures [29] for two reasons. First, maximum weight loss usually occurs during the first one or two years, with a gradual weight regain during the next two to five years following bariatric surgery. Second, many complications take several years to develop [53].

The objective of this report is to assess the most recent evidence on the long-term (five years or more) safety and efficacy of the LAGB procedure compared with open and laparoscopic RYGB and VBG. The open RYGB procedure is most commonly performed in North America and both open RYGB and open VBG are performed in Alberta. Evidence from systematic reviews or HTA reports published since 2000

(search date for AHFMR 2000 HTA report [46]) and evidence from primary studies published since 2002 (search date for MSAC 2003 [49]) will be used in this report.

The following primary question is addressed in this report:

Is LAGB a safe and effective procedure compared with open and/or laparoscopic RYGB and VBG, especially in the longer term (≥ five years), for adult patients with clinically severe obesity?

SAFETY AND CLINICAL EFFICACY OF LAGB

Evidence from HTA reports

Three HTA reports [49, 50, 52] identified by searching the HTA database met the inclusion criteria (see study selection in Appendix A: Methodology). The objectives, included studies, and conclusions of these reviews are summarized in Table 1. Details regarding search strategy, study selection, quality appraisal, and results from each of these reviews are presented in Appendix B.

HTA reports that mainly focused on non-surgical treatments (such as diet, exercise, behavioural therapy, or pharmacological treatments) or reviews that assessed bariatric surgery but did not compare LAGB with RYGB or VBG, or did not contain any information on LAGB, were excluded (see exclusion criteria in Appendix A: Methodology). The excluded reviews and reasons for exclusion are tabulated in Appendix C.

Similarity and variation of the included reviews

Patient selection

The three HTA reports included data for patients with preoperative BMIs >35 kg/m^2 or >40 kg/m^2, or >35 kg/m^2 with obesity-related co-morbidities.

Intervention

The MSAC review [49] compared the LAGB procedure with open RYGB and VBG, whereas the other two reviews [50, 52] only compared LAGB with RYGB. The McGill report [50] compared LAGB with LRYGB for safety profile but compared LAGB with open RYGB for efficacy on weight loss. The Blue Cross and Blue Shield (BCBS) report [52] attempted to compare LAGB with open RYGB in terms of efficacy and adverse events. However, data regarding open RYGB were extracted from background information, whereas data on LRYGB came from included primary studies.

Outcome measures

In the three reports, outcome measurements for safety included mortality, conversion from laparoscopic to open surgery, perioperative and postoperative complications, and re-operation rates. Measurements for efficacy included weight loss (expressed as reduction in absolute weight, BMI, or percent excess weight loss (%EWL), resolution or improvement of co-morbidities, and quality of life (QOL). Because %EWL is the standard measure of weight loss in bariatric surgery nomenclature [2], mean %EWL is used throughout this report when available.

Table 1: HTA reports that compared LAGB with RYGB and/or VBG

Study	Research question	Included study	Conclusion
MSAC 2003 [49] Australia **Follow-up:** up to 7 years	What is the value of LAGB in the treatment of morbidly obese patients (BMI ≥35 kg/m^2) who have failed to lose weight through non-surgical means compared with **VBG**? What is the value of LAGB in the treatment of morbidly obese patients (BMI ≥35 kg/m^2) who have failed to lose weight through non-surgical means compared with **open RYGB**?	**HTA reports:** NICE 2001 [54] ASERNIP-S 2002 [23] AHFMR 2000 [46] **Other published systematic reviews:** Gentileschi et al. 2002 [55] **Primary study:** 170 primary studies published prior to July 2002	LAGB is at least as safe as VBG and open RYGB. LAGB is less efficacious than RYGB but as efficacious as VBG in terms of weight loss. Limited evidence suggests that weight loss may be maintained up to 7 years after LAGB and may be maintained longer following LAGB than VBG. There is no evidence that any of the three procedures are significantly better at resolving co-morbidities than the other.
Chen and McGregor 2004 [50] McGill University HTA Unit, Canada **Follow-up:** up to 5 years	Is LAGB an effective and reasonably safe procedure (compared with **RYGB***)? Is the evidence of effectiveness and safety sufficiently good to justify its inclusion as a hospital service?	**HTA reports:** ASERNIP-S 2002 [23] Cochrane review 2003 [56] NICE 2002 [57] AHFMR 2000 [46] NHS CRD 1997 [58] SBU 2002 [59] SAGES guidelines 2000 [60] CCOHTA pre-assessment 2003 [61] **Primary study:** 19 primary studies published between June 2001 and February 2004	There is sufficient evidence to support that LAGB is an effective procedure with an adequate safety record up to 5 years. Weight loss and the rates of mortality and morbidity associated with LAGB are fairly comparable to that of RYGB. There is insufficient evidence to determine whether LAGB is a superior procedure or not.

Table 1: HTA reports that compared LAGB with RYGB and/or VBG (cont'd)

Study	Research question	Included study	Conclusion
BCBS 2003 [52] BlueCross BlueShield Association, USA **Follow-up:** up to 5 years	Are outcomes for LAGB as good as outcomes for **open RYGB** in patients with morbid obesity, as judged by the amount of weight loss and adverse events?	**HTA reports:** Not included **Primary study:** One comparative study (LAGB versus open RYGB), 8 case series on LRYGB and 32 case series on LAGB, published between 1985 and 2003	A large number of clinical series suggest that substantial weight loss occurred following LAGB, but the %EWL at 1 year may be less than that seen with RYGB. Short-term adverse event rates were low with LAGB, and probably less than those seen with RYGB. Longer-term adverse events following LAGB, however, occurred more frequently and may include serious complications such as erosion of the band through the gastric wall.

* LAGB was compared with open RYGB for efficacy on weight loss and compared with LRYGB for safety profile.

AHFMR: Alberta Heritage Foundation for Medical Research; ASERNIP-S: Australian Safety and Efficacy Register of New Interventional Procedures-Surgical; BCBS: Blue Cross and Blue Shield; BMI: body mass index; CCOHTA: Canadian Coordinating Office for Health Technology Assessment; EWL: excess weight loss; HTA: health technology assessment; LAGB: laparoscopic adjustable gastric banding; LRYGB: laparoscopic Roux-en-Y gastric bypass; MSAC: Medical Services Advisory Committee; NHS CRD: NHS Centre for Reviews and Dissemination; NICE: National Institute for Clinical Excellence; RYGB: Roux-en-Y gastric bypass; SAGES: Society of American Gastrointestinal Endoscopic Surgeons; SBU: The Swedish Council on Technology Assessment in Health Care; VBG: vertical banded gastroplasty

Findings

Methodological quality

The three HTA reports identified a number of methodological flaws in the primary studies when analyzed in terms of study design, sample size, follow-up, and reporting; these flaws are summarized in Appendix D.

The major methodological limitations of research on LAGB included lack of comparative studies, small sample sizes, and significant decrease in numbers of patients at longer follow-up times (e.g., at five years of follow-up). The majority of studies were case series. In general, longer follow-up data were available for RYGB or VBG but not for LAGB, which needs to be taken into account when comparing these three procedures from case series studies.

Safety

The safety profiles of the three procedures (LAGB, VBG, RYGB/LRYGB) were compared in terms of mortality, conversion from laparoscopic to open procedure, morbidity (peri- or postoperative complications), and/or re-operation rates (Table 2). The reporting of these results varied across the three HTA reports. The MSAC review [49] combined results from primary comparative studies, or case series, or both. The safety data reported in the McGill review [50] were derived from the ASERNIP-S review [23], 19 primary studies on LAGB, one review of 3463 cases on LRYGB, and other additional studies. In the BCBS report [52], the safety data for LAGB and LRYGB were derived from primary studies. The results on open RYGB provided in the BCBS report were primarily based on the findings from two systematic reviews and a number of comparative studies that were summarized in the background section, and these data are not presented in Table 2.

Table 2: Safety of LAGB compared with RYGB and/or VBG

Study	Procedure	Mortality	Conversion	Morbidity	Re-operation
MSAC 2003 [49]	LAGB	Average 0.3%	Range 0%-10.5%	Procedure-specific complication rates: 1.3%-28%	Range 0%-22.4%
	Open RYGB	Average 1.7%	Not relevant	Procedure-specific complication rates: 1%-20%	Range 0%-47.4%
	Open VBG	Average 0.5%	Not relevant	Procedure-specific complication rates: 1.5%-15.8%	Range 0%-66.6%
McGill 2004 [50]	LAGB	Short-term: average 0.05% (95%CI 0.01-0.11)* Procedure-related mortality: average 0.11% or 0.12%	2.2%	**Specific morbidity rates:** Band problems requiring intra-abdominal surgical intervention (band intolerance, band leakage, gastric pouch problems, band slippage): 6.55% Tube/port problems requiring regional local surgical correction (leakage, breaks, misplacement): 4.57% Erosion to stomach requiring removal by gastroscopy: 0.22% Pneumonia/pulmonary embolism: 0.20% Other infections: 0.17% Other (gas embolism, hernia, gastric necrosis): 0.15% Total events: 11.86%	NA
	LRYGB	Average 0.23%†	2.2%†-3.1% (based on an additional 4 studies not included in the review [62])	**Specific morbidity rate:**† Stomal stenosis requiring dilatation via gastroscopy: 4.73% Bowel obstruction requiring abdominal surgery: 2.92% Anastomotic leak requiring abdominal surgery: 2.05% Wound infection requiring antibiotic: 2.98% Pneumonia: 0.14% Pulmonary embolism: 0.41% otal events 13.7%	NA
BCBS 2003 [52]	LAGB	Average 0.1%	0%-5%	**Early complication rates:** <5% **Late complication rates:** Slippage, and/or dilation of the band, problems at the port sites: 4%-10% Erosion of the band through the gastric wall: 1.1%	4%-10%
	LRYGB	Range 0%-0.9%	1.1%-6.9%	Overall rate not available	2.3%-9%

Data were derived from primary studies unless indicated otherwise. * Based on ASERNIP-S review 2002 [23] † Based on a review of 3,464 cases [62]
BCBS: Blue Cross and Blue Shield; CI: confidence interval; LAGB: laparoscopic adjustable gastric banding; LRYGB: laparoscopic Roux-en-Y gastric bypass; MSAC: Medical Services Advisory Committee; NA: not available; RYGB: Roux-en-Y gastric bypass; VBG: vertical banded gastroplasty

The average mortality rates reported in the three reports ranged from 0.05% to 0.3% for LAGB, 1.7% for open RYGB and 0.23% for LRYGB, and 0.5% for open VBG. The mortality rates for LAGB derived from primary studies were similar in the three reports, 0.1% [52], 0.11% or 0.12% [50], and 0.3% [49]. The McGill report noted a mortality rate of 0.05%, which was taken from the ASERNIP-S review [23]. One of the reasons for this discrepancy may be that these reviews included different primary studies and they derived overall mortality rates in different ways.

Based on the available data from primary studies, the MSAC review reported procedure-specific complication rates of 1.3% to 28% for LAGB, 1% to 20% for open RYGB, and 1.5% to 15.8% for open VBG.

The MSAC assessment report [49] found that LAGB was at least as safe as open RYGB and VBG. LAGB appeared to have lower rates of mortality and re-operation than open RYGB and VBG, but this could be attributed to the shorter follow-up period available for the LAGB patients.

The McGill report [50] concluded that, at up to five years of follow-up, the rates of mortality and morbidity associated with LAGB were fairly comparable to LRYGB.

The BCBS report [52] found that short-term (less than one year) complication rates were low following LAGB and may be lower than those following RYGB. Longer term (over one year) complications occurred more frequently following LAGB and these may include serious complications such as erosion of the band through the gastric wall. No data were available to compare longer-term complications of LAGB with open RYGB.

Nutritional deficiency rates of 16% for open RYGB and 24% for LRYGB were reported in the MSAC [49] and the BCBS reports [52], respectively.

In summary, based on the information presented in the three HTA reports, it appears that LAGB was safer than, or at least as safe as, open RYGB or open VBG in terms of short-term (up to five years) mortality and morbidity. The mortality rates associated with LAGB appeared to be lower than those of LRYGB, but the overall postoperative complications and conversion rates were comparable for both LAGB and LRYGB.

Efficacy/effectiveness

Clinical efficacy of the three procedures (LAGB, VBG, RYGB/LRYGB) was compared in terms of weight loss, improvement of co-morbidity, and QOL (Table 3). The McGill [50] and the BCBS reports [52] provided overall mean %EWL or

ranges of mean %EWL. The MSAC report [49] presented data from each of the primary studies in a number of tables but did not provide ranges or an overall mean %EWL. Thus, the mean %EWLs presented in Table 3 are from the ASERNIP-S review [23] that was summarized in the MSAC report.

Table 3: Efficacy of LAGB compared with RYGB and/or VBG

Study	Procedure	Weight loss (No. of studies)	Improvement of co-morbidity	Quality of life
MSAC 2003 [49]	LAGB	**4 yrs:** mean %EWL 44%-68%*	Some improvement in obesity-related co-morbidities, with the possible exception of GORD	Improved in the majority of patients
	Open RYGB	**4 yrs:** mean %EWL 50%-67%*	Some improvement in obesity-related co-morbidities, with the possible exception of GORD	Improved in the majority of patients
	VBG	**4 yrs:** mean %EWL 40%-77%*	Some improvement in obesity-related co-morbidities, with the possible exception of GORD	Improved in the majority of patients
McGill 2004 [50]	LAGB	**1 yr:** weighted mean %EWL 40.8% (range 29.5%-75%) (12 studies) **3 yrs:** weighted mean %EWL 50.4% (range 3%-72%) (9 studies) **5 yrs:** weighted mean %EWL 55.9% (range 53%-57.1%) (3 studies)	**3 yrs:** improvement in hyperlipidemia in 95% of patients*, insulin dependent diabetes in 96% of patients*, pulmonary disease in 95% of patients*, reflux disease in 67% of patients*	Significant and sustained improvement (based on some studies not included as primary studies)
	Open RYGB	**3 yrs:** weighted mean %EWL 69% (5 studies) **5 yrs:** weighted mean %EWL 62% (3 studies)	NA	NA
BCBS 2003 [52]	LAGB	**1 yr:** mean %EWL 35%-58% (14 studies) **3 yrs:** mean %EWL 36%-77% (8 studies)	NA	NA
	LRYGB	**1 yr:** mean %EWL 56%-77% (8 studies) **3 yrs:** mean %EWL 62%-75% (2 studies)	NA	NA

Data derived from primary studies unless indicated otherwise. * Based on ASERNIP-S review [23]

BCBS: Blue Cross and Blue Shield; EWL: excess weight loss; GORD: gastroesophageal reflux disease; LAGB: laparoscopic adjustable gastric banding; LRYGB: laparoscopic Roux-en-Y gastric bypass; MSAC: Medical Services Advisory Committee; NA: not available; No.: number; RYGB: Roux-en-Y gastric bypass; VBG: vertical banded gastroplasty; yr(s): year(s)

Weight loss

The MSAC assessment report [49] concluded that, based on the evidence from all available studies, LAGB was as efficacious as VBG but less efficacious than RYGB in terms of mean %EWL at up to seven years of follow-up. The ASERNIP-S review [23] included in the MSAC report suggested that LAGB was effective, at least up to four years, as were RYGB and VBG in terms of %EWL.

The McGill report found that the %EWL experienced with LAGB was comparable to RYGB at five years of follow-up [50].

The BCBS report concluded that, at one year of follow-up, %EWL following LAGB was less than that after LRYGB. Data on %EWL beyond one year were limited by incomplete follow-up data.

In summary, research evidence suggests that LAGB can produce significant mean %EWL at up to seven years of follow-up. When compared with VBG or RYGB, the LAGB procedure seems to be as effective as VBG, but it may be less effective than RYGB. Longer follow-up data are needed to determine the long-term efficacy of LAGB.

Resolution or improvement of co-morbidity

According to the MSAC report [49], all three procedures (LAGB, open RYGB, open VBG) led to improvements of some obesity-related co-morbidities, such as diabetes, hypertension, hyperlipidemia, and sleep apnea. It appears that there were no significant differences among LAGB, VBG, or open RYGB in terms of improvement of co-morbidities.

Improvement of QOL

According to the MSAC report [49], QOL was improved in the majority of patients following all three procedures. Overall, patients who received RYGB reported higher scores on QOL measures than did patients treated with LAGB or VBG. There seems to be no significant differences between LAGB and VBG in terms of improvement of QOL.

Evidence from primary studies

Eighteen primary studies [11, 12, 42, 63-77] met the inclusion criteria (see Appendix A: Methodology). Identified from the search were one randomized controlled trial (RCT), three non-randomized comparative studies, and 14 large case series (≥500 cases).

The RCT [42] compared LAGB with LVBG. There was another RCT [78] that compared AGB with VBG, which was cited widely in the literature. However, both procedures evaluated in the RCT were performed as open procedures; thus, this RCT [78] was

excluded. No RCTs were found that directly compared LAGB with LRYGB, but three non-randomized studies [64-66] compared LAGB with LRYGB.

Of the 14 case series, there were 12 studies on LAGB and two studies on RYGB. No large case series was found for VBG. Ten case series [11, 12, 63, 67-72, 77] reported long-term (≥ five years) results on safety and/or clinical efficacy of LAGB or RYGB, and the other four case series only reported on a single postoperative complication (such as band erosion or leakage).

Ten of the 18 studies [11, 12, 63, 66-70, 72, 79] included in this report overlapped with the primary studies identified by the recently published McGill report [50]. Nine studies assessed in the McGill report were not included in this report because these studies had either a smaller sample size (<500) or a shorter follow-up period (less than five years).

Operating time and postoperative hospital stay

It is clinically important to compare the operating time and length of postoperative hospital stay among the different procedures, especially using laparoscopic approaches. Information in this regard provided in the RCT and the three comparative studies is summarized in Table 4.

Table 4: Operation data from RCT or comparative studies

	Morino et al. 2003 [42] RCT LAGB vs**. LVBG** (N=100; LAGB: n=49, LVBG: n=51)	**Weber et al. 2004 [64]** LAGB vs. **LRYGB** (N=206; LAGB: n=103, LRYGB: n=103)	**Mognol et al. 2005 [65]** LAGB vs. **LRYGB** (N=290; LAGB: n=179, LRYGB: n=111)	**Biertho et al. 2003 [66]** LAGB vs. **LRYGB** (N=1261; LAGB: n=805, LRYGB: n=456)
Operating time	65 (35-120) vs. 94 (40-270) minutes (p<.05)	145 vs. 190 minutes (p<.001)	70±20 vs. 180±60 minutes (p<.01)*	NA
Hospital stay	3.7 vs. 6.6 days (p<.05)	3.3 vs. 8.4 days (p<.001)	2 vs. 8 days (p<.01)	5±2.4 (2-22) vs. 3±10.3 (2-9) days (p<.05)†

Data expressed as mean±SD (range) unless otherwise stated. * Not clear if the value is mean or median † Median±SD
LAGB: laparoscopic adjustable gastric banding; LRYGB: laparoscopic Roux-en-Y gastric bypass; LVBG: laparoscopic vertical banded gastroplasty; N: total number; n: subgroup number; NA: not available; RCT: randomized controlled trial; SD: standard deviation

The RCT [42] showed a significantly longer operating time and hospital stay associated with LVBG compared with LAGB. Two single-centre comparative studies indicated a similar pattern that LAGB was associated with significantly shorter operating time and hospital stay compared with LRYGB. The other study that was undertaken in two centres showed longer hospital stays following LAGB compared with LRYGB. However, as the author pointed out, this may be related more to the differences in the health system in the two countries rather than to the operation itself [66].

Safety

Information regarding clinical safety extracted from the RCT and the three comparative studies is presented in Table 5 and details of these studies are summarized in Appendix B. The findings on safety from the 10 large case series are presented in Table 6. Information from the other four case series that only reported the incidence of one single postoperative complication is summarized in Appendix B.

Table 5: Safety data from RCT or comparative studies

	Morino et al. 2003 [42] RCT LAGB vs**. LVBG** (N=100; LAGB: n=49, LVBG: n=51)	**Weber et al. 2004 [64]** LAGB vs. **LRYGB** (N=206; LAGB: n=103, LRYGB: n=103)	**Mognol et al. 2005 [65]** LAGB vs. **LRYGB** (N=290; LAGB: n=179, LRYGB: n=111)	**Biertho et al. 2003 [66]** LAGB vs. **LRYGB** (N=1261; LAGB: n=805, LRYGB: n=456)
Mortality	0% vs. 0%	0% vs. 0%	0.6% vs. 0.9% (NS)	0% vs. 0.44% (NS)
Conversion	0% vs. 0%	0% vs. 1 %	0% vs. 3.6%*	3% vs. 2% (NS)
Early complication	6.1% vs. 9.8% (NS)	17% (18)† vs. 20% (21)† (p=.36)	2.8% vs. 10% (p<.01)	1.7% vs. 4.2% (p=.02)
Early re-operation	NA	1% (1)† vs. 6.8% (7)† (p=.033)	NA	NA
Late complication	32.7% vs. 14% (p<.05)	44% (45)† vs. 14% (14)† (P<.001)	26% vs.15.3% (p<.05)	9.25% vs. 8.1% (NS)
Late re-operation	24.5% vs. 0% (p<.001)	25% (26)† vs. 3.9% (4)† (p<.001)	26% vs. 4.5%*	NA

* p-value was not reported. The leading author was contacted but no information was obtained. † Only absolute numbers (in brackets) of complications were reported in the study; the leading author was contacted for rates of complications but no information was obtained. Rates of complications were then calculated from absolute numbers of complications and total number of patients.

LAGB: laparoscopic adjustable gastric banding, LRYGB: laparoscopic Roux-en-Y gastric bypass; LVBG: laparoscopic vertical banded gastroplasty; N: total number; n: subgroup number; NA: not available; NS: not significant; RCT: randomized controlled trial

Mortality

In the RCT [42], no deaths occurred after LAGB or LVBG. Among the three studies that compared LAGB with LRYGB, one study [64] reported no deaths in either group, and the other two found no significant difference in the early mortality rates between the two groups (0.6% for LAGB versus 0.9% for LRYGB [65], and 0% for LAGB versus 0.44% for LRYGB [66]).

The perioperative mortality rates for LAGB reported in the case series ranged from 0% to 0.16%. No deaths occurred in four large case series [12, 63, 67, 70] with total patient numbers ranging from 709 to 1000. An overall postoperative mortality rate of 0.53% following LAGB was reported in a multi-centre case series study involving 1893 patients [69].

The case series study on RYGB [77] reported a mortality rate of 0.9% within 30 days of surgery and 74 late deaths in a clinical series of 1025 patients.

Morbidity

Although the RCT and three comparative studies reported early or late postoperative complications, the early or late complications were either not defined [42, 65] or defined differently [64, 66]. Weber et al. [64] stated that early morbidity and mortality were reported up to 30 days after surgery as early complications and thereafter as late complications. Biertho et al. [66] defined early postoperative complication as complications appearing during the first postoperative week and late postoperative complications as complications occurring after the first postoperative week and during the first 18 postoperative months.

The RCT [42] reported similar conversion and early complication rates following both procedures (6.1% for LAGB versus 9.8% for LVBG). Higher rates of late complications (32.7% for LAGB versus 14% for LVBG) and late re-operations (24.5% for LAGB versus 0% for LVBG) were associated with LAGB when compared with LVBG.

Among the three comparative studies, no conversion to open procedure was necessary for LAGB in two studies [64, 65], and no difference in conversion rates was noted between the LAGB and LRYGB groups in one study [66]. Two studies [66, 65] reported higher early complication rates for LRYGB than for LAGB, whereas two studies [64, 65] showed significantly higher late complication and re-operation rates following LAGB compared with LRYGB.

Based on data from large case series on LAGB (Table 6), conversion rates ranged from 0% to 5.2% and re-operation rates ranged from 3.9% to 18.9%. Complications were grouped into perioperative, early postoperative, and late postoperative complications. The common perioperative and early postoperative complications

included digestive perforation, liver injury, hemorrhage, early slippage and dilation, respiratory disorders, and infection. Late postoperative complications included band-related (late slippage, band migration, band erosion, band rupture, band infection), port-related (port infection, port rotation, port penetration and port break), and tube-related (tube system leakages or rupture) complications.

The case series on RYGB [77] did not report re-operation rates. Postoperative complications included anastomotic leaks, severe or minor wound infections, marginal ulcer, pulmonary embolism, small bowel obstruction, and anastomotic stenosis.

In summary, three comparative studies [66, 64, 65] demonstrated similar postoperative mortality between LAGB (0% to 0.6%) and LRYGB (0% to 0.9%), with fewer early complications but significantly higher late complication and re-operation rates following LAGB compared with LRYGB. Based on one RCT [42], LAGB appeared to be as safe as LVBG in terms of short-term mortality and early complications. However, LAGB was associated with higher rates of late complications and re-operations compared with LVBG.

Table 6: Safety of LAGB/RYGB: evidence from large case series

Study	Mortality n (%)	Conversion n (%)	Re-operation n (%)	Intra-operative complications n (%)	Early postoperative complications n (%)	Late postoperative complications n (%)
LAGB						
Dargent 2004 [71] N=1180	2 (0.16%) (early)	5 (0.4%)	151 (12.7%)	Not available	Total: 27 (2.2%) Peritonitis: 6 (0.51%) Abscess: 4 (0.34%) Pulmonary complications: 6 (0.51%) Wound abscess: 3 (0.25%) Tromboembolism: 3 (0.25%) Other: 5 (0.42%)	Late slippage: 105 (8.8%) Band erosion: 22 (1.8%) Intolerance, esophageal dilatation: 24 (2.0%)
O'Brien et al. 2002 [12] N=709	0	7 (1%)	134 (18.9%)	Not available	Laparoscopic approach (n=648): Infection at reservoir site: 7 (1.1%) Deep venous thrombosis: 1 (0.1%) Open approach (n=61): Gastric perforation: 2 (3.3%) Infection at reservoir site: 5 (8.2%) Other wound infection: 12 (19.6%) Deep venous thrombosis and pulmonary embolism: 1 (1.6%) Respiratory failure: 5 (8.2%)	Prolapse/ slippage: 87 (12.5%) Reservoir/ tubing breaks: 26 (3.6%) Erosion into stomach: 20 (2.8%) Lap-Band Balloon leak: 1 (0.1%)

Table 6: Safety of LAGB/RYGB: evidence from large case series (cont'd)

Study	Mortality n (%)	Conversion n (%)	Re-operation n (%)	Intra-operative complications n (%)	Early postoperative complications n (%)	Late postoperative complications n (%)
LAGB (cont'd)						
Chevallier et al. 2004 [63] N=1000	0	12 (1.2%)	111 (11%)	Digestive perforations: 4 (0.4%) Liver injuries: 6 (0.6%)	Early slippage and dilation: 3 (0.3%) Respiratory disorders: 15 (1.5%)	Slippages: 101 (10.1%) Band migration: 3 (0.3%) Esophageal dilatation: 5 (0.5%) Port problems: 57 (5.7%)
Steffen et al. 2003 [68] N=824	0 (≤30 days) 3 (0.4%) (>30 days)	(5.2%)	26 (3.1%)	Total: 12 (1.4%) Liver hematoma: 5 (0.6%) Splenic hemorrhage: 3 (0.4%) Hemorrhage from gastroepiploic veins: 2 (0.2%) CO_2 embolism: 1 (0.1%) Esophageal perforation: 1 (0.1%)	Total: 25 (3%) Pulmonary atelectasis or pneumonia: 13 (1.5%) Prolonged sub-ileus: 2 (0.2%) Minor wound problems: 10 (1.2%)	Band-related: total 51 (6.3%) Band leakage: 14 (1.8%) Band infection: 2 (0.2%) Slippages: 22 (2.7%) Band erosion: 13 (1.6%) Access-port or tube-related total: 56 (6.8%)
Weiner et al. 2003 [67] N=984	0	0	36 (3.9%)	Not available	Gastric perforation: 1 (0.1%) Slippage: 1 (0.1%)	Band-related: Slippage: 32 (3.3%), Migration: 3 (0.3%), Band rupture: 1 (0.1%), Band dilatation: 1 (0.1%) Port-related: Port infection: 6 (0.6%) Port rotation: 14 (1.4%) Port penetration: 2 (0.2%) Port break: 3 (0.3%)
Angrisani et al. 2003 [69] N=1893	10 (0.53%) (overall)	59 (3.1%)	77 (4.1%)*	Not available	Pulmonary embolism: 2 (0.1%)	Gastric pouch dilation: 93 (4.8%) Intra-gastric migration (erosion): 21 (1.1%) Tube system leaks/ rupture: 79 (4.1%)

Table 6: Safety of LAGB/RYGB: evidence from large case series (cont'd)

Study	Mortality n (%)	Conversion n (%)	Re-operation n (%)	Intra-operative complications n (%)	Early postoperative complications n (%)	Late postoperative complications n (%)
LAGB (cont'd)						
Favretti et al. 2002 [70] N=830	0	22 (2.7%)	127 (15.3%)*	Not available	Major complications requiring re-operation: Gastric perforation: 1 (0.1%) Stomach slippage: 1 (0.1%)	Major complications requiring re-operation: Stomach slippage: 17 (1.8%) Mal-positioning: 9 (0.9%) Erosions: 4 (0.5%) Psychological intolerance: 3 (0.4%) HIV+: 1 (0.1%)
Belachew et al. 2002 [72] N=763	1 (0.1%) (early)	10 (1.3%)	80 (10.5%)	Not available	Gastric perforation: 4 (0.5%) Large bowel perforation: 1 (0.1%) Severe bleeding: 1 (0.1%) Port infection: 1 (0.1%)	Erosion: 7 (1%) Total food intolerance: 59 (8%) Access port problems: 20 (2.5%)
Vertruyen 2002 [11] N=543	Not available	6 (1.2%)	24 (4.4%)*	Gastric perforation: 1 (0.2%) Bowel perforation: 1 (0.2%) Gastric vessel hemorrhage: 1 (0.2%) Liver laceration: 5 (1%) Deep venous thrombosis: 1 (0.2%) Pneumonia: 2 (0.4%)	Not available	Total and irreversible food intolerance due to proximal pouch dilatation: 24 (4.6%) Psychological intolerance: 2 (0.4%) Gastric ulceration: 1 (0.2%) Band erosion: 5 (1%) Collecting tube disruption: 15 (2.8%) Port leakage: 1 (0.2%)

Table 6: Safety of LAGB/RYGB: evidence from large case series (cont'd)

Study	Mortality n (%)	Conversion n (%)	Re-operation n (%)	Intra-operative complications n (%)	Early postoperative complications n (%)	Late postoperative complications n (%)
RYGB						
Sugerman et al. 2003[77] N=1025	9 (0.9%) (<30 days) 74 (late)	Not applicable	Not available	Not available†	Not available†	Anastomotic leaks: (3%) Severe wound infections: (6%) Minor wound infections: (8%) Marginal ulcer: (9%) Pulmonary embolism: (1%) Small bowel obstruction: (4%) Anastomotic stenosis: (15%)

* Calculated based on the information provided in the study. † Complications were reported all together without further classification. Therefore, all reported complications are presented in the category of late postoperative complications.

CO_2: carbon dioxide; HIV: human immunodeficiency virus; LAGB: laparoscopic adjustable gastric banding; N: total number; n: subgroup number; RYGB: Roux-en-Y gastric bypass

Efficacy/effectiveness

One RCT [42] and three non-randomized studies [64-66] compared the clinical efficacy/effectiveness of LAGB with LRYGB or LVBG (Table 7). Because the follow-up periods of these studies were less than three years, large case series with follow-up longer than five years were used to supplement evidence on the longer-term efficacy of the three surgical procedures (Table 8).

Table 7: Efficacy data from RCT or comparative studies

		Morino et al. 2003 [42] RCT LAGB vs. **LVBG** (N=100; LAGB: 49 LVBG: 51)	**Weber et al. 2004 [64]** LAGB vs. **LRYGB** (N=206, LAGB: 103 LRYGB: 103)	**Mognol et al. 2005 [65]** LAGB vs. **LRYGB** (N=290, LAGB: 179 LRYGB: 111)	**Biertho et al. 2003 [66]** LAGB vs. **LRYGB** (N=1261, LAGB: 805 LRYGB: 456)
Baseline BMI ($kg/m^{2)}$		LAGB: 44.7 (40.1-50) LVBG: 44.2 (40-50)	LAGB: 48 (37-66) LRYGB: 47.8 (38.3-66.3)	LAGB: 54 (50-74) LRYGB: 59 (50-81)	LAGB: 42.2 (29-64) LRYGB: 49.4 (27-77)
Weight loss (%EWL)	1 mo	-	8.2% vs. 15.0% (p<.05)	-	-
	3 mos	-	16.4% vs. 32.8% (p<.05)	20% vs. 30% (p<.05)*	15% vs. 36% (p<.0001)
	6 mos	-	24.9% vs. 44.0% (p<.05)	30% vs. 47% (p<.05)*	22% vs. 52% (p<.0001)
	9 mos	-	30.7% vs. 52.0% (p<.05)	-	-
	1 yr	39.2% vs. 62.3% (p<.05)	35.1% vs. 54.8% (p<.05)	41% vs. 63% (p<.05)*†	33% vs. 67% (p<.0001) ‡
	18 mos	-	-	46% vs. 70%(p<.05)*†	40% vs. 75% (p<.0001) ‡
	2 yrs	41.4% vs. 63.5% (p<.05)	42.1% vs. 54.0% (p<.05)	46% vs. 73% (p<.05)*†	47% for LAGB§
	3 yrs	39% vs. 58.9% (p<.05)	-	-	56% for LAGB§
	4 yrs	-	-	-	58% for LAGB§
Co-morbidity	HT	-	62%→18% vs. 52%→13% (NS)	-	-
	DB	-	44%→18% vs. 37%→6% (p=.007)	-	-
	DL	-	62%→65% vs. 74%→37% (p=.001)	-	-

* p value was obtained through personal communication (Dr Mognol, April 2005) † Rates of follow-up for LRYGB are 49%, 25%, and 17%, respectively; rates for LAGB are 85%, 72%, and 65%, respectively ‡ Rates of follow-up for LRYGB are 57% and 37%, respectively; rates for LAGB are 97% for up to 18 months § Data for LRYGB after 2 years not available.

BMI: body mass index; DB: diabetes; DL: dyslipidemia; EWL: excess weight loss; HT: hypertension; LAGB: laparoscopic adjustable gastric banding, LRYGB: laparoscopic Roux-en-Y gastric bypass; LVBG: laparoscopic vertical banded gastroplasty; mo(s): month(s); N: total number; NS: not significant; RCT: randomized controlled trial; yr(s): year(s)

Weight loss

The RCT [42] demonstrated that LVBG was significantly more effective than LAGB in terms of weight loss at up to three years of follow-up. The magnitude of %EWL after LAGB remained similar when followed up for one (39%), two (41%), and three years (39%), which was similar to the pattern with LVBG at one (63%), two (64%), and three (59%) years.

In the two single-centre comparative studies [64, 65], the LRYGB procedure resulted in significantly higher %EWL than LAGB at up to two years of follow-up. The proportion of the patients available at each follow-up time was not reported in the studies; thus, the leading authors of the two studies were contacted for further information. Although the author of the study with a case-matched design did not respond, the other one indicated a higher follow-up rate for LAGB (e.g., 65% at two years) than for LRYGB (17% at two years) [65]. In the other study involving 1261 patients [66], the LRYGB procedure also yielded a significantly higher %EWL than LAGB at up to 18 months of follow-up. These results were applicable to 97% of the patients who received LAGB but only 57% and 37% of the patients following LRYGB at 12 and 18 months, respectively. The longer-term (after two years) follow-up data were not available for LRYGB, but the mean %EWL following LAGB seemed to increase gradually, from 40% at 18 months to 58% at four years. However, the proportions of patients available at two to four years of follow-up were not reported.

Based on the two case series in which the follow-up rates were available for each year [12, 71] (see Table 8), the mean %EWL for those who had LAGB ranged from 47% to 49% at one year with rates of attendance of 63% to 93%, respectively. At five years of follow-up, a mean %EWL of 54% was reported in both studies with rates of attendance of 74% (32 patients) to 84% (190 patients), respectively.

Table 8: Effectiveness of LAGB/RYGB on weight loss: evidence from large case series

Study		Mean %EWL and /or mean BMI						Improvement in co-morbidities	Quality of life
		1 yr	3 yrs	5 yrs	6 yrs	7 yrs	10-12 yrs		
LAGB									
Dargent 2004 [71] N=1180 Baseline BMI=43.3	n of pts	696/1105*	434/873*	190/225*	86/290*	14/111*	-	Improved in every patient with an EWL >25%	NA
	%EWL	49	57	54	49	50	-		
	BMI	-	-	30.4†, 37.3‡	-	-	-		
O'Brien et al. 2002 [12] N=709 Baseline BMI=45	n of pts	492/537*	273/288*	32/43*	10/18*	-	-	Improvement in diabetes, asthma, dyslipidemia, hypertension, and disturbed sleep	Improvement in Beck Depression Index and Rand SF-36 (all 8 scales)
	%EWL	47	53	54	57	-	-		
	BMI	-	-	-	-	-	-		
Steffen et al. 2003 [68] Baseline BMI=43	n of pts	821§	593§	184§	-	-	-	NA	BAROS scores higher in pts with co-morbidities than in patients without co-morbidities
	%EWL	29.5	48.7	57.1	-	-	-		
	BMI	35.8	31.5	29.2	-	-	-		
Weiner et al. 2003 [67] Baseline BMI=46.8	n of pts	-	-	-	-	-	-	Most co-morbid conditions resolved by 1 yr post-surgery. 92% of patients with DB no longer required medications.	At 2 and 8 yrs, a stable improvement was found using BAROS and modified QOL-Index.
	%EWL	-	-	-	-	59.3	-		
	BMI	34	32	-	-	-	-		
Angrisani et al. 2003 [69] Baseline BMI=43.7	n of pts	-	-	-	-	-	-	NA	NA
	%EWL	-	-	-	-	-	-		
	BMI	33.7	34.1	34.8	32	-	-		
Favretti et al. 2002 [70] Baseline BMI=46.4	n of pts	660§	305§	76§	24§	3§	-	NA	NA
	%EWL	-	-	-	-	-	-		
	BMI	37.3	36.8	36.4	39.9	29.4	-		
Belachew et al. 2002 [72] Baseline BMI=42	n of pts	-	-	-	-	-	-	NA	NA
	%EWL	40	-	50-60	-	-	-		
	BMI	32	30	<30	-	-	-		

Table 8: Effectiveness of LAGB/RYGB on weight loss: evidence from large case series (cont'd)

Study	Mean %EWL and /or mean BMI							Improvement in co-morbidities	Quality of life
		1 yr	3 yrs	5 yrs	6 yrs	7 yrs	10-12 yrs		
LAGB (cont'd)									
Vertruyen 2002 [11]	n of pts	405[§]	261[§]	52[§]	-	15[§]	-	NA	NA
Baseline BMI=44	%EWL	38	62	58	-	53	-		
	BMI	33.2	30.1	31.2	-	32.1	-		
RYGB									
Sugerman et al. 2003 [77]	% FL	91	-	50 (342/683)			37 (135/361)	Improvement in DB and HT at 1-2 and 5-7 yrs	NA
N=1025	%EWL	66	-	59			52	Improvement in other co-morbidities	
Baseline BMI=51	BMI	33	-	35			36		

The unit for BMI: kg/m^2 * Denominators were obtained from the authors (personal communication) † For patients with baseline BMI <50 kg/m^2 ‡ For patients with baseline BMI >50 kg/m^2 § Number of patients on whom the results were based. The total number of patients eligible for follow-up (i.e., time elapsed since surgery ≥follow-up period) were not reported. BAROS: Bariatric Analysis and Reporting System; BMI: body mass index; DB: diabetes; EWL: excess weight loss; FL: follow-up; HT: hypertension; LAGB: laparoscopic adjustable gastric banding; N: total number; n: subgroup number; NA: not available; QOL: quality of life; RYGB: Roux-en-Y gastric bypass; yr(s): year(s)

The BMIs at five years were reported in four of the five case series. They ranged from 29 kg/m^2 to 37 kg/m^2. Only one [11] of five case series reported all three variables (number of patients, %EWL, and BMI) at seven years of follow-up; only 15 patients were available, with a mean %EWL of 53% and a mean BMI of 32 kg/m^2 (baseline BMI 44 kg/m^2). The other three case series [67,69,72] on LAGB did not even report the number of patients who attended the follow-up sessions and hence their results are grossly biased and not useful.

The one case series on RYGB [77] reported a mean %EWL of 66% and BMI of 33 kg/m^2 at one year of follow-up; 91% of the patients were available. At five years of follow-up, only 50% of the patients were available, with a mean %EWL of 59% and a mean BMI of 35 kg/m^2. It is important to note that the mean baseline BMI was 51 kg/m^2, and 37% of the patients were available at 10 to 12 years of follow-up, with a reported mean %EWL of 52% and BMI of 36 kg/m^2.

Taking into account the heterogeneity of the studies, the following statements should be cautiously interpreted:

- On the based of one RCT, patients had a significantly higher mean %EWL following LVBG at three years compared with those patients who underwent LAGB.
- On the basis of three comparative studies, patients who had LAGB had significantly less weight loss (%EWL 33% to 41%) at one year follow-up compared with those who had LRYGB (%EWL 55% to 67%). However, these results were based on the comparison of patients with a higher follow-up rate for LAGB (85% to 97%) and the patients with lower follow-up rates for LRYGB (49% to 57%). Results for LAGB tend to be less biased than those for LRYGB.
- On the basis of two case series with small numbers of patients (ranging from 190 to 32) available for assessment at five years, mean %EWLs reported were in the range of 54% to 58% following LAGB.
- On the basis of one case series with 50% of the patients available at the five-year follow-up period, a mean %EWL of 59% was reported following RYGB.

Improvement of co-morbidities

The comparative study by Weber and colleagues [64] found that both LAGB and LRYGB reduced the frequency of co-morbidities such as hypertension and diabetes. LRYGB resulted in significantly lower frequencies of diabetes and dyslipidemia compared with LAGB (see Table 7). The RCT [42] and the other two comparative studies [65, 66] did not report the change in co-morbidities after surgery.

Three case series on LAGB [12, 67, 71] reported improvement of co-morbidities (diabetes, asthma, hypertension, dyslipidemia and disturbed sleep) in most patients. The one case series on RYGB [77] reported improvement of diabetes and hypertension in the majority of patients at five to seven years following the procedure. However, most case series did not report improvement or resolution of co-morbidities.

Improvement of QOL

The RCT [42], three comparative studies [64-66], and most case series did not report on the change in QOL after surgery. Three case series studies [12, 67, 68] evaluated changes in QOL after surgery, using the Bariatric Analysis and Reporting System (BAROS), Rand SF-36, or modified QOL-Index. All three studies reported improvements of QOL in patients who received LAGB over two to eight years of follow-up.

In summary, the mean %EWL following the LAGB procedure was significantly less than that reported in the RCT for LVBG or in the comparative studies for LRYGB over a period of two to three years of follow-up. The numbers of patients available at five years of follow-up were not reported in the majority of the case series studies (through personal communication with all of the authors, only two [12, 71] replied and provided follow-up rates of 84% and 74% with 190 and 32 patients, respectively). In other words, the long-term effectiveness of LAGB was based on a relatively small number of patients. The long-term effectiveness remains to be determined.

CLINICAL GUIDELINES/POSITION STATEMENT/EXPERT OPINION

Clinical guidelines

The European Association for Endoscopic Surgery recently published evidence-based guidelines on obesity surgery [80], with intention to define the comparative effectiveness and surrounding circumstances of the various types of obesity surgery. The guidelines recommended that obesity surgery should be considered in adults with a documented BMI greater than or equal to 35 kg/m^2 and related co-morbidity, or a BMI of at least 40 kg/m^2. AGB, VBG, RYGB, and BPD are all effective in the treatment of morbid obesity, but differ in degree of weight loss and range of complications. Because obesity surgery has various competing aims such as weight loss, adjustability, reversibility, and safety, it is difficult to draw universally valid conclusions about the optimal bariatric procedure. The choice of procedure therefore should be tailored to the patient's BMI, perioperative risk, metabolic situation, co-morbidities, and preference, as well as to the surgeon's expertise.

The National Institutes of Health and the National Heart, Lung, and Blood Institute published guidelines for all treatment options for obesity (including bariatric surgery) in 2000 [8]. The guideline stated that "weight loss surgery is an option in carefully selected patients with *clinically severe* obesity (BMI ≥40 kg/m^2 or ≥35 kg/m^2 with co-morbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity or mortality." It also stated that RYGB and VBG result in substantial weight loss. The guidelines recommended that patients be followed after bariatric surgery by a multidisciplinary team of experts, including medical, behavioural, and nutritional experts.

The Society of American Gastrointestinal Endocrinologists and the American Society for Bariatric Surgery also published a guideline in 2000 that specifically focused on bariatric surgery [60]. Patient selection criteria included the standard BMI restriction, and that patients "can show that dietary attempts at weight control have been ineffective." The guideline mentioned various surgical procedures, including RYGB, VBG, BPD, and various gastric banding procedures, but did not discuss the relative efficacy of each of these procedures. It emphasized that advanced laparoscopic skills as well as a well-trained operating team familiar with the equipment, instruments, and techniques of bariatric surgery are required in order to perform bariatric surgical procedures laparoscopically.

The Society of American Gastrointestinal Endoscopic Surgeons (SAGES) published a guideline in 2003 entitled "Guidelines for the Clinical Application of Laparoscopic Bariatric Surgery" [81]. The guideline recommended a multidisciplinary approach to patient care after surgery. Patient selection criteria were the same for open and

laparoscopic surgical approaches, and the guideline stated that virtually all bariatric procedures can be done laparoscopically. However, it noted that sufficient training for the use of the laparoscopic approach was mandatory.

The Association of Perioperative Registered Nurses published a bariatric surgical guideline in 2004 [1]. This guideline described the advantages and disadvantages of several bariatric surgical procedures, including BPD, VBG, AGB, and RYGB. The guideline stated that bariatric surgical procedures can result in long-term weight loss, resolution of co-morbidities, and QOL improvement.

Position statement

SAGES at their 2003 Conference made the following statements on appropriateness of restrictive procedures and RYGB [82]:

Statements on gastric bypass

1. LRYGB affords improved short-term recovery from surgery and a lower incidence of incision hernias than open RYGB. Long-term follow-up for LRYGB is unavailable.
2. LRYGB produces similar short-term weight loss and improvement in co-morbid medical conditions as in open RYGB.
3. There is no standard technique for RYGB; therefore, it is difficult to compare widely varying approaches for the same operation.
4. There are no high-grade evidence studies from which to make decisions about the role of other weight loss procedures compared with the gastric bypass.

Statements on restrictive procedures

1. In the United States, VBG and other fixed gastroplasty-type operations produce less weight loss compared with RYGB.
2. LAGB can be performed with lower average mortality than either RYGB or any of the mal-absorptive operations, and it produces variable weight loss in short-term follow-up studies.
3. LAGB produces reduction of obesity-associated co-morbidities based on short-term follow-up data.
4. Prospective randomized trials comparing LAGB with LRYGB are needed.

Overall, future research is required to determine the "optimal" procedure that is safe in terms of mortality and effective on the bases of weight loss and improvement in co-morbidities in the long term.

Expert opinion

Advice on the use of LAGB and other surgical procedures for obesity in Alberta was obtained from provincial experts (November 2004).

There is no particular set of clinical practice guidelines that clinicians in Alberta would apply in the treatment of patients with clinically severe obesity. In Alberta, there is no standard treatment for patients with clinically severe obesity. A 6% to 8% success rate in terms of weight loss would be expected with the best non-surgical treatment plan. The quality of bariatric surgery varies with support, technique, and volumes but a success rate of 60% to 80% would be expected.

RYGB and VBG are currently performed in Alberta, with RYGB being more commonly performed. LAGB is not currently provided in Alberta. According to current expert opinion, LAGB is becoming the standard of care worldwide and Canada and Alberta have been slow to adopt this procedure of care.

LAGB, being minimally invasive with a very short hospital stay, would be cost-effective per unit care. It could help to address the problem of increasing numbers of morbidly obese people on waiting lists and the demands of their obesity-related co-morbidities on the provincial health care system.

DISCUSSION

Safety and efficacy of LAGB

Currently, LAGB and open or laparoscopic RYGB are the most commonly performed procedures worldwide, and VBG is only performed in a very small proportion of obese patients. Therefore, the major debate within the bariatric surgery community is which procedure, LAGB or RYGB (open or laparoscopic), is most appropriate for which patient group [64].

The ideal study design to identify the best procedure would be a prospective RCT. However, such a study may not be feasible because of the significant difference in the invasiveness and irreversibility of the two procedures [64]. To date, no RCT has been published that compared LAGB with open or laparoscopic RYGB.

Three comparative studies [64, 65, 66] were found that compared LAGB with LRYGB with follow-up available for both procedures up to two years. One study [64] used a matched-pair study design and compared the two procedures in patients with similar demographics who received either procedure at a high-volume centre. However, the follow-up rates for both groups were not available. Another single-centre study [65] mainly involved super-obese patients (i.e., BMI >50 kg/m^2) but the LRYGB group included more males and significantly heavier patients. Furthermore, the rates of follow-up were different between the two groups (e.g. 65% for LAGB versus 17% for LRYGB at two years).

The results from the study by Biertho and colleagues [66] need to be interpreted with caution. Although this study is the largest comparative study (involving 1261 patients) to date, it had several significant methodological flaws. First, the study involved two separate facilities, each one using only one procedure. The centre in New York City provided patients with LRYGB and the centre in Switzerland provided patients with LAGB. Second, there were biases in patient selection and no attempts were made to adjust for differences in patient care, culture, and follow-up care. The mean preoperative BMI was significantly higher in the LRYGB group (49.4 kg/m^2) than in the LAGB group (42.2 kg/m^2). Third, band adjustments were not made "*if a 1-kg weight loss had been noted in the past three months*". Furthermore, the rates of those attending follow-up visit in the LRYGB group were significantly lower than those in the LAGB group at 12 months (57% for LRYGB versus 97% for LAGB) and 18 months (37% for LRYGB versus 97% for LAGB). All of these factors will affect the validity of the results.

Results from the three comparative studies were consistent in terms of mortality and %EWL following LAGB and LRYGB. All three studies showed similar mortality rates associated with the two procedures (maximum 0.6% for LAGB versus 0.9% for

LRYGB), but significantly lower %EWL following LAGB compared with LRYGB. Both single- centre studies [64, 65] indicated higher late complication and re-operation rates following LAGB LRYGB. LRYGB appeared to be associated with higher early complications.

A recently published US state-wide population study involving 3328 patients undergoing gastric bypass reported a 30-day mortality of 1.9% [83]. Whether the surgery was performed as an open procedure or laparoscopically was not reported in this study, but presumably the majority of the procedures would be open RYGB. The early mortality rate of 1.9% was higher than those reported in the comparative studies and the large case series included in our report. This discrepancy may reflect surgical inexperience and varying approaches for the same procedure.

According to the European Association for Endoscopic Surgery guidelines, outcome assessment after surgery should include weight loss and maintenance, nutritional status, co-morbidities, and QOL [80]. Although weight loss and maintenance was reported in the majority of the studies included in our report, reporting of the other three aspects was insufficient.

Long-term nutritional deficiency following the RYGB procedure is an important clinical problem. Two HTA reviews [49, 52] reported nutritional deficiency rates of 16% for open RYGB and 24% for LRYGB. However, none of the three comparative studies and large case series reported nutritional status following laparoscopic or open RYGB.

Only one comparative study [64] and four case series reported changes in co-morbidities following LAGB or RYGB. The results from the comparative study suggested a greater effect of LRYGB on the improvement of co-morbidities.

The MSAC report [49], based on two comparative studies and one consecutive case series on LAGB, found that the majority of patients who received LAGB, VBG, or RYGB reported improvements in their QOL. The different results may be attributed to study sample size, patient preoperative co-morbidity, and different instruments used to measure QOL (e.g., SF-36 versus BAROS). Patients who received RYGB seemed to report higher scores on the QOL measurement compared with LAGB. Improvement in QOL following surgical procedures was reported in three case series but not in any of the comparative studies included in this report.

Given different early and late complications and re-operation rates, as well as different magnitudes of weight loss, improvement in co-morbidity, and QOL associated with LAGB and LRYGB, it is too early to draw any conclusion as to whether LAGB is safer and more efficacious/effective in treating severely obese patients compared with LRYGB beyond five years. There seems to be a trend in Europe that LRYGB has recently gained more acceptances and some clinics have

been changing their practice from LAGB to LRYGB (personal communication, Dr Dargent, April 2005).

Patient selection and follow-up

Specific patient selection criteria have not yet been agreed upon for laparoscopic bariatric surgery. Several clinical guidelines recommended that bariatric surgery be provided for carefully selected patients whose BMIs are greater than 40 kg/m^2 or greater than 35 kg/m^2 with obesity-related co-morbidities. Almost all included studies applied these criteria for patient inclusion; however, the preoperative BMIs reported in the primary studies ranged from 27 kg/m^2 to 87 kg/m^2. The RCT [84] only included patients with preoperative BMIs between 40 kg/m^2 to 50 kg/m^2, whereas one comparative study [65] only included super-obese patients (i.e., BMIs ≥ 50 kg/m^2). Overall, the three comparative studies [64, 65, 66] included patients with a wide range of preoperative BMIs (27 kg/m^2 to 81 kg/m^2). Most studies did not conduct separate analyses for patients with different ranges of BMIs, for example, for patients whose BMIs were greater than 50 kg/m^2 or 60 kg/m^2. Furthermore, results for patients who had previously had bariatric surgery were not analyzed separately from those patients who were undergoing surgery for the first time.

It was observed from large case series studies that the number of patients available at longer-term follow-up (e.g., at five years) was very small compared with the overall total number of cases. One limitation of this report is that inclusion of such studies with longer duration but lower rates of follow-up does not provide useful results. Studies with shorter periods of follow-up but higher rates of follow-up may provide better results. However, the aim of this report was to look at the longer-term (≥ five years) safety and clinical efficacy of LAGB compared with open or laparoscopic RYGB or VBG. Given the lack of longer-term follow-up data in the HTA reports and primary comparative studies, large case series with follow-up longer than five years were included.

These studies did not report the characteristics, the safety and efficacy outcomes, and other treatment opportunities for the other patients who did not present at follow-up. It is important to know whether these patients were better or worse off following surgery and what the reasons were for not being available for monitoring, whether they looked for other treatment options, and how the management of these patients will impact the entire health care system.

Following bariatric surgery, a commitment to significant lifestyle changes is essential and hence patient compliance is vital. Weight loss success following bariatric surgery is highly variable, even within the patient population receiving the same procedure. These variations have been attributed to psychological differences

among groups of patients, higher prevalence of eating disorders, and existing psychopathologies [85].

It is noted that the success of any bariatric surgical procedure depends upon a diligent long-term commitment to lifestyle changes by patients choosing to have the surgery. Hence, providing results only from quantitative clinical studies only is too narrow a focus for this intervention. Because of the timelines allocated to the completion of this report, only a cursory search was conducted with the view of looking for qualitative research (search strategy and selection criteria available upon request).

A systematic review by Herpertz and colleagues [86] focused on psychosocial outcomes such as psychiatric co-morbidity, psychopathology, psychosocial functioning, econometric data, and general QOL at least one year after VBG, BPD, RYGB, and LAGB. MEDLINE and PSYCHLIT were searched for studies in German or English published between 1980 and 2002. One of their exclusion criteria was studies with dropout rates exceeding 50%. In all, 40 studies were reviewed and these studies were graded by the authors based on their methodological design. The majority of the studies were classified as prospective or retrospective cohort studies with a mean sample of 89 patients and a mean follow-up of 35 months. The authors came to the following conclusions:

- Bariatric surgery has a positive effect on affective and anxiety disorders, with no effect on personality disorders;
- Improvement in eating disorders depends on the surgical procedure for example, gastric restrictive procedures make it physiologically more difficult to binge eat;
- Improvement occurs in self-esteem and social functioning;
- Improvement occurs in educational and occupational status; and
- With the exception of patients with severe personality disorders, the concern that obesity surgery reinforces psychic symptoms and leads to a reduction of QOL was not supported.

Correlation analyses did not produce consistent results for weight loss and a single psychosocial outcome variable. There seemed to be a positive relationship between weight loss and QOL.

This systematic review did not answer the questions of why patients did not attend follow-up sessions and how these patients differed from those who did attend. Well- designed qualitative studies are needed to learn more about the characteristics, preferences, and expectations of those patients who seemed to be lost to follow-up assessments.

Learning curve

The International Federation for the Surgery of Obesity (IFSO) issued guidelines regarding the training and qualification of surgeons performing bariatric surgery [87]. The IFSO recommends that, prior to independently performing primary bariatric surgery, each surgeon should be a "fully-trained, qualified, certified general or gastrointestinal surgeon who has completed a recognized general/gastrointestinal surgery program "with additional training in" all aspects of bariatric surgery, including patient education, support groups, operative techniques and post-operative follow-up with an IFSO or IFSO Affiliate Society-designated bariatric surgeon or one who has performed at least 200 bariatric surgical procedures and has five or more years experience in the field of bariatric surgery." In addition, the IFSO recommends certain written approvals of expertise, course attendance, membership in an obesity surgery society, continuing medical education, and other criteria.

LAGB appears to be a difficult procedure that takes time and experience to carry out effectively. Many authors reported a steep learning curve effect, with markedly lower morbidities for the second 100 procedures performed [50]. Serious complications can arise if surgeons are not well trained in bariatric and laparoscopic procedures [28].

It was noted by some authors that morbidity rates tended to be higher and have wider confidence intervals in smaller case series compared with larger case series [49]. This observation may be attributed to the surgeons' learning curve and wide confidence intervals are usually a result of small sample sizes.

In general, during the initial stages of the learning curve, the procedure will be lengthier and costlier, and usually associated with higher mortality rates, simply because surgical staff are not familiar with the procedure [49]. For this reason, it has been argued that the assessment of a new surgical procedure during the initial stages of the learning curve does not provide an accurate picture of its safety and efficacy. Hence, this report chose to include only case series of 500 or more patients. Once practitioners have gained enough experience, they often feel that a rigorous evaluation such as an RCT is unwarranted and potentially unethical, especially if it involves withholding the technique from patients who may benefit from the procedure. This could account for the relatively few published RCTs.

Postoperative care

Severe obesity is a chronic condition requiring lifelong treatment and follow-up. Unlike many other surgeries, bariatric surgery is not a cure, nor is it a one-time fix. The care of patients following bariatric surgery needs to be comprehensive and of long-term duration [88]. Patients need to know that a commitment to permanent lifestyle changes following the operation is essential.

Training and commitment is required to achieve optimal outcomes with LAGB. It is important for a multidisciplinary team to have knowledge about band adjustment, appropriate investigation and management of postoperative complications, care for obesity-related co-morbidities, and application of the art of general bariatric care, which includes nutritional, movement and exercise, and behavioural therapies.

CONCLUSION

A bariatric surgical procedure should be safe and effective, have a low revision rate, be well accepted by patients, and have minimal side effects on other organs. Worldwide, open or laparoscopic RYGB is the most commonly performed procedure (65%), followed by LAGB (24%) and VBG (5%). LAGB has recently gained popularity because of its adjustable, reversible, and minimal invasive features.

Health Canada issued licenses for the marketing of both the Lap-Band system and SAGB. These devices are indicated for use in weight reduction for severely obese adult patients with a BMI above 40 kg/m^2 or above 35 kg/m^2 with serious co-morbidities who have failed more conservative weight reduction alternatives such as supervised diet, exercise, and behaviour modification programs.

No bariatric procedure is standardized and the same procedure varies by facility, technique, and equipment used. As well, patient selection criteria are not specific and formalized in relation to defining which patient is appropriate for which procedure.

Several recent clinical guidelines stated that the role of bariatric surgery was in the treatment of severely obese patients (BMI >40 kg/m^2 or >35 kg/m^2 with serious obesity-related co-morbidities) who failed non-surgical treatments. According to the most recent European Association for Endoscopic Surgery guidelines, RYGB, AGB, and VBG are all effective in the treatment of morbid obesity but differ in degree of weight loss and range of complications. The choice of procedure should be tailored to the patient's situation. These guidelines emphasized the importance of sufficient training for surgeons in both bariatric and laparoscopic procedures and the need for comprehensive postoperative care by a multidisciplinary team.

Evidence on the safety and efficacy of the LAGB procedure was mainly derived from three very recently published HTA reports and 18 recently published primary studies of variable quality that included adult patients with BMIs ranging from 27 kg/m^2 to 87 kg/m^2.

No RCT was found that directly compared LAGB with open or laparoscopic RYGB or open VBG. One RCT was found that compared LAGB with LVBG. Three non-randomized studies compared LAGB with LRYGB. The follow-up periods available for comparison were up to three years in the RCT and up to two years in the comparative studies. Fourteen large case series (>500 patients) were found, with 12 studies on LAGB, two studies on RYGB, and no study on VBG.

Results from the RCT and two single-centre comparative studies suggested significantly shorter operating time and length of postoperative hospital stay associated with LAGB compared with LVBG or LRYGB.

Based on the RCT and three comparative studies, short-term mortality rates following LAGB were similar to those of LVBG or LRYGB with lower early postoperative complication rates. However, significantly higher long-term postoperative complications and associated re-operations following LAGB have caused safety concerns about the use of LAGB for patients with severe obesity. Furthermore, although the length of hospital stay was shorter with LAGB, management of late complications including re-operation may result in an increased number of hospital days in the long run.

The RCT and three non-randomized comparative studies demonstrated that LAGB appeared to be effective in producing significant weight loss in patients with severe obesity. However, when compared with LRYGB, LAGB appeared to be less effective, with mean %EWL less than 50% at up to two years of follow-up for patients with a wide range of preoperative BMIs (27 kg/m^2 to 81 kg/m^2). LAGB also appeared to be less effective than LVBG, with mean %EWL less than 50% at three years of follow-up for patients with preoperative BMIs between 40 kg/m^2 to 50 kg/m^2. Based only on the two large case series with follow-up rates available for each year, weight loss after LAGB gradually increased with careful band adjustment and achieved 47% to 54% EWL over one to five years after surgery, with 190 and 32 patients, respectively, attending five-year follow-up visit. However, when BMIs were presented as outcome measures, most patients would still be defined as obese following bariatric surgery. Thus, the focus should be on improvement in associated co-morbidities, but this outcome was reported inconsistently.

It is the improvement or resolution of co-morbidities related to obesity that should be the goal of bariatric surgery. However, only some of the included studies reported outcomes on improvement of co-morbidity and QOL. Based on the limited evidence, LAGB results in improvement of certain co-morbidities (such as diabetes and hypertension) and QOL. LRYGB appeared to yield more profound improvement of co-morbidities. Patients treated with RYGB tended to report higher scores on QOL measures than did patients who received LAGB or VBG.

Nutritional deficiency following bariatric surgery, particularly a concern with RYGB (open or laparoscopic), is a serious long-term complication. This aspect, however, was not reported in most studies.

Although the intent of this report was to look at long-term (greater than five years) safety and efficacy of LAGB, it is not possible at this stage to make definitive conclusions as a result of weak evidence (case series), with results reported on a very small number of patients.

The greatest need at present is long-term studies with systematic surveillance and minimal loss to follow-up that can better define the long-term weight loss and improvement of co-morbidities and QOL, as well as complications following LAGB. Future research needs to further classify patients according to their preoperative BMIs and perform subgroup analyses of results for each class of obesity according to the WHO/Canada body weight classifications.

From the currently available evidence, guidelines, and position statements, all bariatric surgeries are effective in the treatment of morbid obesity but differ in the degree of weight loss and range of early or late postoperative complications. Defining the appropriate patient population for each of the bariatric surgical procedures remains a challenge. The current evidence base supports the current practice (RYGB or VBG) for treating clinically severe obese patients in Alberta. There is an opportunity to establish a registry that collects data on appropriate patient characteristics and links these data to meaningful outcome measures to answer the important clinical questions that the current research has failed to address.

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APPENDIX A: METHODOLOGY

Search strategy

The literature searches were conducted in September and October 2004, with an update search in March 2005. The searches were divided into two parts: the first part covered systematic reviews, HTAs and guidelines published from 2000 to March 2005, and the second part sought to update an earlier review and looked for primary clinical studies on LAGB, RYGB, and VBG published from 2002 to March 2005.

Major electronic databases used included: The Cochrane Library, NHS Centre for Reviews and Dissemination (CRD) databases (Economic Evaluation Database, HTA, Database of Abstracts of Reviews of Effects), PubMed, EMBASE, and Web of Knowledge (Science Citation Index and Social Sciences Citation Index). In addition, relevant library collections, practice guidelines, evidence-based resources and other HTA agency resources (Agence d'évaluation des technologies et des modes d'intervention en santé, Canadian Coordinating Office for Health Technology Assessment, McGill University Health Centre Technology Assessment Unit, ECRI, ASERNIP-S, Succinct and Timely Evaluated Evidence Reviews, UK National Coordinating Centre for Health Technology Assessment, UK National Institute for Clinical Excellence, Hayes Inc., Aetna, BCBS, Institute for Clinical Evaluative Sciences) were searched. A recently updated bibliography of HTA reports on bariatric surgery, compiled by the US Veterans Affairs Technology Assessment Program, was also used. Published assessment reports by Hayes Inc. and ECRI were purchased, and reports from other agencies were also used to identify further information. Health Canada provided information on the licensed indications for LAGB.

Medical Subject Headings (MeSH) related to the topic are gastric bypass, gastroplasty, obesity, and morbid/surgery.

Limits (applied where available): English language, human studies

Population age: adults

Publication Year: 2000 – March 2005 (for the search on systematic reviews, HTAs, etc.); 2001 – March 2005 (for the search for primary studies). The original literature searches were run in September and October 2004, and update searches were run on the major databases (PubMed, The Cochrane Library, the UK NHS CRD databases, and EMBASE), on March 29, 2005.

Database	Platform	Edition/Date	Search terms and results
CORE DATABASES			
The Cochrane Library (Database of Systematic Reviews (CDSR), Central Register of Controlled Trials (CENTRAL))	Wiley InterScience http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME	Issue 3, 2004 Update search: Issue 1, 2005	1. gastric bypass or obesity morbid or gastroplasty or gastric band* 2. gastroplasty or gastric bypass or gastric band* or lapband or adjustable band*
UK NHS Centre for Reviews and Dissemination (CRD) (Health Technology Assessment Database, NHS Economic Evaluation Database, Database of Reviews of Effects)	http://nhscrd.york.ac.uk/welcome.htm	Sept 5, 2004 Update search: March 29, 2005	gastric-bypass OR obesity-morbid OR gastroplasty OR gastric band*
PubMed National Library of Medicine (MEDLINE, Pre-MEDLINE, HealthSTAR)	http://www.pubmed.gov	1.Sept 5, 2004 Update search: March 29, 2005	gastric bypass OR obesity, morbid/surgery OR gastroplasty OR "lap band*" OR "laparoscopic gastric band*" OR lapband OR "gastric band" OR "stomach stapling" OR "stomach bypass" OR "banded gastroplasty" AND systematic [sb] Limit: 2000-2004
		2. Oct 7, 2004 Update search: March 29, 2005	gastroplasty OR gastric bypass OR "vertical banded gastroplasty" OR "stomach stapling" OR "adjustable gastric banding" OR "laparoscopic adjustable gastric band*" OR lapband OR "lap band" OR "laparoscopic band*" OR "gastric band*" OR "banded gastroplasty" OR ((LAGB OR VBG) AND obesity, morbid) OR "vertical banded" OR "vertical gastroplasty" AND randomized controlled trial [pt] OR clinical trial [pt] OR meta-analysis [pt] OR practice guideline [pt] OR cohort studies OR case reports OR case series OR comparative study Limit: 2001-2004, English language, human studies

Database	Platform	Edition/Date	Search terms and results
CORE DATABASES (cont'd)			
Web of Knowledge (Science Citation Index, Social Sciences Citation Index)	http://isiwebofknowledge.com/	1. Sept 5, 2004 2. Oct 8, 2004	gastric band* AND (assessment or review or systematic or meta-analysis) laparoscopic adjustable band* or lapband or lagb or vbg or (adjustable band or gastric bypass) AND obesity AND (trial or comparative study or cohort or RCT)
EMBASE	Ovid	1. Sept 5, 2004 (1996 to 2004 Week 36) 2. Oct 7, 2004 (1996 to 2004 Week 40) Update search: March 29, 2005 (1996 to 2005 Week 13)	gastric bypass.mp. or exp stomach bypass/ or exp gastroplasty/ or gastric banding.mp. or exp gastric banding/ AND exp morbid obesity/ or exp obesity/ AND systematic review.mp. or exp "systematic review"/ Limit: 2000-2005 exp gastroplasty/ or exp stomach bypass/ or exp gastric banding/ AND randomized controlled trial/ or controlled study/ or exp cohort analysis/ or exp comparative study OR (lapband or LAGB OR VBG or adjustable band$).mp AND obesity/su Limit: human studies, English language, 2001-2004
CINAHL	Ovid	(1982 to October Week 1)	exp gastroplasty/ or exp gastric bypass/ or (lapband or LAGB or VBG or adjustable band$).mp AND randomized controlled trial.mp. or exp clinical trials/ or controlled trial.mp. or cohort study.mp. or exp prospective studies/ or comparative study.mp. or exp comparative studie/ or case series.mp. Limits: English language, 2001-2004

Database	Platform	Edition/Date	Search terms and results
CORE DATABASES (cont'd)			
PsycINFO	Ovid	(2000 to September Week 3 2004)	gastroplasty.mp. or gastric bypass.mp. or gastric banding.mp. or (lapband or LAGB or VBG or adjustable band$ or laparoscopic adjustable or vertical adjustable).mp or (obesity and surgery).mp. Limits: human studies, English language, 2001-2004
HealthSTAR	Ovid	1987 to Sept 2004	exp gastroplasty/ or exp gastric bypass/ OR (lapband or LAGB or VBG or adjustable band$).mp. and obesity.mp. Limits: human studies, English language, NonMedline, 2001-2004
ECRI (HTAIS database)	www.ecri.org	Sept 5, 2004	Banding
CLINICAL PRACTICE GUIDELINES			
AMA Guidelines (Alberta Medical Assoc.)	http://albertadoctors.org	Sept 15, 2004	scanned guidelines
CMA Clinical Practice Guidelines InfoBase Database (Canadian Medical Assoc.)	http://mdm.ca/cpgsnew/cpgs/index.asp	Sept 15, 2004	bariatric
National Guideline Clearinghouse	www.guideline.gov	Sept 15, 2004	bariatric
REGULATORY AGENCIES/LICENSING AGENCIES/COVERAGE AGENCIES			
Health Canada	http://www.mdall.ca/	Oct 26, 2004	gastric band
LIBRARY CATALOGUES			
NEOS (Central Alberta Library Consortium Catalogue)	http://www.neoslibraries.ca/	Sept 5 2004	gastric banding

Note: * is a truncation character that retrieves all possible suffix variations of the root word: e.g., surg* retrieves surgery, surgical, surgeon, etc. In databases accessed via the Ovid platform, the truncation character is $.

Study selection

Inclusion criteria

For HTA reports

Studies were included if they fulfilled the following criteria:

- HTA reports identified through HTA databases had to have the following components: clear research question, comprehensive literature search, clear study selection criteria, quality assessment (at least provided a study design), synthesis of the results. The HTA reports could be systematic reviews (see Cook et al. 1997 [89] for definition) or less comprehensive assessments.
- Published from 2000 onward, in English, full text
- Focused on LAGB or bariatric surgeries for adult patients
- LAGB compared with RYGB or VBG
- Results for LAGB were reported separately

For primary studies

Studies were included if they fulfilled the following criteria:

- RCTs, non-randomized comparative studies that compared safety and/or efficacy of LAGB with RYGB and/or VBG; or
- Case series that reported long-term results of safety and/or efficacy of LAGB, RYGB, or VBG (total patient number ≥ 500, follow-up ≥ five years)
- Patient BMI ≥40 kg/m^2 or ≥35 kg/m^2 with obesity-related co-morbidities
- Outcome measures included at least one of the following: rates of mortality, morbidity or complications, weight loss (reduction in %EWL, BMI, or kg), change in obesity-related co-morbidities (diabetes, hypertension, hyperlipidemia, or obstructive sleep apnea), or QOL
- Published from 2002 onward, in English, full text

Exclusion criteria

Studies were excluded if they met any of the following criteria:

- Pre-assessments and protocols, conference abstracts, case reports, letters, comments, English summary without full text in English
- Mainly focused on non-surgical treatments for obesity
- Assessed bariatric surgeries for adolescents with obesity

- Focused on the technical variation of LAGB (e.g., Lap banding versus Swedish banding) but did not compare LAGB with other procedures
- Focused on non-adjustable gastric banding
- Compared open bariatric surgery with all laparoscopically performed procedures rather than compared one procedure with another procedure
- Case series that reported surgery outcomes in a special subgroup of patients (e.g., patients with severe venous stasis disease)
- Case series that focused on using a special diagnosis technique (e.g., radiological contrast) to detect postoperative complications
- Case series that only reported postoperative complications after open RYGB or open VBG

Data extraction

For systematic review/HTA report

- Study (author, year of publication, country)
- Objective
- Quality appraisal
- Search (database searched, search results)
- Study selection (inclusion/exclusion criteria)
- Intervention (procedure, device, comparator, follow-up)
- Result/conclusion (safety, efficacy)

For primary studies

RCT or non-randomized comparative trials

- Study (author, year of publication, country)
- Objective
- Participant (total number and sub-group number, age, gender distribution, preoperative BMI)
- Intervention (procedures, comparators, follow-up)
- Outcomes
    - Operating time, length of hospital stay
    - Safety: mortality, morbidity (early and late complications), re-operation rate, conversion rate

- Efficacy: weight loss, improvement of co-morbidities, QOL

Case series

- Study (author, year of publication, country)
- Objective
- Participant (total number, age, gender distribution, preoperative BMI)
- Intervention (procedures, follow-up)
- Outcomes
  - Safety: mortality, morbidity (early and late complications), re-operation rate, conversion rate
  - Efficacy: maintained weight loss, improvement of co-morbidities, QOL

Methodological quality appraisal

No formal methodological quality assessment was conducted for included systematic reviews/HTA reports, or for the included primary studies because of the tight timelines. The level of evidence for comparative studies was assigned to each of the primary studies using the criteria developed by the National Health and Medical Research Council 2000 [90]. The issues related to methodological quality was also mentioned and discussed. One researcher selected the studies and abstracted the data. Two researchers synthesized the results for presentation in the report.

APPENDIX B: SAFETY AND EFFECTIVENESS OF LAGB FOR THE TREATMENT OF CLINICALLY SEVERE OBESITY

Table B1: Summary of evidence from HTA reports

Search	Study selection	Quality appraisal	Results
MSAC 2003 [49]			
Databases searched: Medline (prior to July 2002) Embase (prior to July 2002) The Cochrane library NICE CRD Databases (DARE, HTA, EED) 19 HTA agency websites **Search results:** Three HTA report/briefs, one SR, and 170 primary studies (seven non-randomized comparative studies; 27 studies describing 19 RCTs that included an open RYGB, open VBG, or LAGB arm; 136 case series on LAGB)	**Inclusion criteria:** Study design: RCTs, non-randomized controlled clinical trials, or consecutive case series of LAGB, published in English Intervention: LAGB vs. open RYGB or open VBG Patients: BMI >35 kg/m^2 Outcome measures: Weight loss, quality of life, changes in magnitude and prevalence of co-morbidities, conversion/re-operation rate, procedural mortality, procedural morbidity, other adverse effects/complications **Exclusion criteria:** Animal study or laboratory study Case reports and LAGB case series <10 patients Conference abstracts of case series	**Quality appraisal:** HTA reports were assessed using the NICE CRD Quality Assessment Scales for Systematic Reviews. Evidence from primary studies was assessed and classified using the dimension of evidence (strength of evidence, size of the effect, and relevance of the evidence) defined by the National Health and Medical Research Council [90]. **Methodological limitations:** No RCTs or SRs of RCTs directly compared LAGB with either RYGB or VBG Generally small sample size (<100 patients) Lack of baseline information Retrospective study design Short follow-up period or substantial loss to follow-up	**Safety:** Mortality rates: 0.3% for LAGB, 0.5% for VBG, and 1.7% for RYGB Morbidity rates: Procedure-specific complication rates: 1.3%-28% for LAGB, 1%-20% for RYGB. Nutritional deficiency rates: 16% for RYGB, not reported for VBG and LAGB Most commonly reported complications: port complications (5.5%-28%) for LAGB, dumping (20%) and ulcers (12.1%) for RYGB, and herniation (15.8%) and stenosis (9.3%) for VBG **Efficacy:** Weight loss: Patients undergoing RYGB lost significantly more weight than patients with LAGB. The weight loss achieved with VBG and LAGB was similar. Weight loss may be maintained up to 7 yrs after LAGB. Limited evidence suggests that weight loss is maintained longer following LAGB than VBG. Change in co-morbidities: All three procedures result in some improvement. There was no evidence that any of the three procedures were significantly better than the other. Quality of life: Most patients had improvement after any of the three procedures. Patients with RYGB may be happier with their results than those with LAGB. No significant differences between quality of life measures in patients with VBG or LAGB.

Table B1: Summary of evidence from health technology assessment reports (cont'd)

Search	Study selection	Quality appraisal	Results
Chen and McGregor 2004 [50]			
Databases searched: 18 websites (associations/societies of obesity, diabetes, bariatric surgery, physician/surgeons, NLM/NIH, etc.) The Cochrane library, DARE, DEC reports, Trip database, Medscape, NHS Centre, NICE 24 HTA agency websites PubMed (May 2001-Feb 2004) CISTI (National Research Council Canada) (May 2001-Feb 2004) A manual search of 12 relevant journals (May 2001-Feb 2004) **Search results:** Eight HTA reports/SRs were identified, with the SR by the ASERNIP-S [23] being the most recent one. 19 primary studies published from May 2001 to Feb 2004	**Inclusion criteria:** Study design: SR/MA, primary studies (prospective, retrospective) Intervention: LAGB vs. RYGB Patients: BMI ≥40 kg/m^2 Outcome measures: Findings on effectiveness or complications **Exclusion criteria:** Cases <100 in case series Studies only reporting radiological findings	**Quality appraisal:** Study design was provided for each of the included primary studies. No formal quality appraisal was conducted for systematic reviews/ meta-analyses, or primary studies. **Methodological limitations:** No randomized controlled comparisons of LAGB and RYGB are available. The evidence is derived from numerous cohort studies of varying quality and duration, and with extremely variable results.	**Safety:** Surgical mortality rates: 0.02%-0.11% for LAGB vs. 0.23% for RYGB Morbidity rates: Postoperative complication rates and conversion rate (2.2% for both) are comparable for LAGB and RYGB. **Efficacy:** Weight loss: Mean %EWL 50% by the 3rd yr for LAGB vs. 60% for RYGB Change in co-morbidities: Weight loss resulting from both procedures was associated with substantial reduction or improvement in co-morbidity (hypertension, diabetes, lipid profile, obstructive sleep apnea, etc.). Quality of life: Usually significantly improved following LAGB. No significant difference between LAGB and RYGB in self-esteem or depression.

Table B1: Summary of evidence from health technology assessment reports (cont'd)

Search	Study selection	Quality appraisal	Results
BCBS 2003 [52]			
Databases searched: PubMed (Jan 1985-Aug 2003) Computerized searches supplemented by manual reviews of bibliographies of selected references, pertinent Cochrane reviews, and reviews of *Current Contents* **Search results:** 41 primary studies on LAGB or RYGB: one comparative study (LAGB vs. open RYGB), 32 case series on LAGB, eight case series on LRYGB	**Inclusion criteria:** Study design: comparative study with at least 25 patients per treatment arm, single-arm study with at least 100 patients, English full-length articles Intervention: LAGB vs. RYGB Patients: BMI ≥40 kg/m^2, or BMI ≥35 kg/m^2 with at least one serious co-morbidity, or >100% above ideal body weight Outcome measures: weight loss and /or adverse effects of surgery **Exclusion criteria:** Follow-up <1 yr	**Quality appraisal:** Study quality was formally assessed for comparative studies based on the quality assessment approach outlined by the United States Preventive Services Task Force [91]. **Methodological limitations:** Lack of high-quality clinical trials that directly compare outcomes among different procedures. The literature is dominated by single-arm studies. Variability in skill, expertise, and training of individual surgeons may affect both the beneficial and harmful outcomes of surgery. Lack of standardization in reporting outcomes (especially for adverse events) hinders the ability to compare outcomes between single-arm series. Other sources of variability (patient clinical characteristics, psychological factors, time periods for surgery being performed) may further bias comparisons among single-arm studies.	**Safety:** Surgical mortality rates: Average 0.1% for LAGB vs. 0%-0.9% for LRYGB Morbidity rates: Early completion rates: <5% for LAGB Conversion rates: 0%-5% for LAGB vs. 1.1%-6.9% for LRYGB Re-operation rates: 4-10% for LAGB vs. 2.3%-9% for LRYGB **Efficacy:** Weight loss: Mean %EWL 35%-58% for LAGB vs. 56%-77% for LRYGB at 1 yr 36%-77% for LAGB vs. 62%-75% for LRYGB at 3 yrs Change in co-morbidities: Not reported Quality of life: Not reported

ASERNIP-S: Australian Safety and Efficacy Register of New Interventional Procedures-Surgical; BCBS: Blue Cross and Blue Shield; BMI: body mass index; CISTI: Canadian Institute for Scientific and Technical Information; CRD: Centre for Reviews and Dissemination; DARE: Database of Abstracts of Reviews of Effects; DEC: Development and Evaluation Committee; EED: Economic evaluation Database; EWL: excess weight loss; HTA: health technology assessment; LAGB: laparoscopic adjustable gastric banding; LRYGB: laparoscopic Roux-en-Y gastric bypass; MA: meta-analysis; MSAC: Medical Services Advisory Committee; NHS: National Health Service; NICE: National Institute for Clinical Excellence; NIH: National Institute of Health; NLM: National Library of Medicine; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SR: systematic review; VBG: vertical banded gastroplasty; yr(s): year(s)

Table B2: Clinical trials that compared LAGB with LVBG or LRYGB

Study design	Patient characteristics	Intervention	Conclusion
Morino et al. 2003 [42] Italy **Design:** Single-centre RCT **Level of evidence:** II **Patient inclusion:** Age 18-60 yrs History of obesity ≥5 yrs BMI 40-50 kg/m^2 Previous weight loss attempt **Study period:** February 1999 – December 2000	**Total number:** N=100 LAGB: n=49 LVBG: n=51 **Mean age (yrs):** LAGB: 37 (20-50) LVBG: 38 (21-58) **Gender (F/M):** LAGB: 38/11 LVBG: 43/8 **Mean baseline BMI (kg/m^2):** LAGB: 44.7 (40.1-50.0) LVBG: 44.2 (40.0-50.0) Two groups were comparable in age, gender, mean weight, BMI, %EWL, and lab test results.	**Procedure:** LAGB **Device:** Lap-Band (Bioenterics, Carpinteria, CA) **Comparator:** LVBG **Length of follow-up:** mean 33.1 (range 24-46) mos **Rates of follow-up:** At 1 yr: 98% for LAGB vs. 90% for LVBG At 2 yrs: 94% for LAGB vs. 88% for LVBG At 3 yrs: 90% for LAGB vs. 95% for LVBG	This study demonstrates that, in patients with a BMI of 40-50 kg/m^2, LAGB required shorter operating time and hospital stay but was associated with significantly higher rate of re-operation. LVBG is more effective in terms of late complications, re-operations, and weight loss.
Weber et al. 2004 [64] Switzerland **Design:** Single-centre matched-pair comparative study **Level of evidence:** III-3 **Patient inclusion:** BMI >40 or >35 kg/m^2 with co-morbidity, history of obesity >5 yrs, failed conservative treatment >2 yrs, age between 18 and 60 yrs **Study period:** May 1995 – May 2003 (May 1995 – June 2000 mainly LAGB, after June 2000 mainly LRYGB)	**Total number:** N=206 LAGB: n=103 LRYGB: n=103 **Mean age (yrs):** LAGB: 39.6 (22-60) LRYGB: 40.1 (20-62) **Gender (F/M):** LAGB: 84/19 LTYGB: 84/19 **Mean baseline BMI (kg/m^2):** LAGB: 48 (37.01-66.0) LRYGB: 47.8 (38.3-66.3) Two groups were comparable in age, gender, and baseline BMI.	**Procedure:** LAGB **Device:** Lap-Band (Bioenterics, Carpinteria, CA) **Comparator:** LRYGB **Length of follow-up:** LAGB: mean 41.9 ±21.4 mos LRYGB: mean 17.6±8.3 mos **Rates of follow-up:** Not available (the leading author was contacted but no information was obtained)	LAGB and LRYGB are feasible and safe. Pouch dilatations after LAGB are responsible for more late complication compared with the LRYGB. LRYGB offers a significant advantage regarding weight loss and reduction of co-morbidities after surgery.

Table B2: Clinical trials that compared LAGB with LVBG and LRYGB (cont'd)

Study design	Patient characteristics	Intervention	Conclusion
Mognol et al. 2005 [65] France **Design:** Single-centre comparative study **Level of evidence:** III-3 **Patient inclusion:** BMI >50 kg/m^2 (super-obese patients) **Study period:** 1994-2004 (LAGB since 1994 and LRYGB since 1999)	**Total number:** N=290 LAGB: n=179 LRYGB: n=111 **Median age (yrs):** LAGB: 40±10 (20-59) LRYGB: 40±10 (18-63) **Gender (F/M):** LAGB: 149/30 LRYGB: 77/34 **Median baseline BMI (kg/m^2):** LAGB: 54±5 (50-74) LRYGB: 59±8 (50-81) No difference for age; more males (31% vs. 17%, p<.01) and higher baseline BMI in LRYGB group (p<.01).	**Procedure:** LAGB **Device:** Lap-Band® (Inamed, Santa Barbara, CA, USA) **Comparator:** LRYGB **Length of follow-up*:** LAGB: mean 30 mos LRYGB: mean 9 mos **Rates of follow-up*:** At 12 mos: 85% for LAGB vs. 49% for LRYGB At 18 mos: 72% for LAGB vs. 25% for LRYGB At 24 mos: 65% for LAGB vs. 17% for LRYGB	LRYGB results in significantly greater weight loss than LAGB in super-obese patients, but it is associated with a higher early complication rate. LRYGB gives the best long-lasting EWL, but is a challenging operation when performed by the laparoscopic approach, with potential life-threatening complications

Table B2: Clinical trials that compared LAGB with LVBG and LRYGB (cont'd)

Study design	Patient characteristics	Intervention	Conclusion
Biertho et al. 2003 [66] Switzerland, USA **Design:** Comparative study **Level of evidence:** III-3 **Patient inclusion:** BMI >40 or >35 kg/m^2 with obesity-related co-morbidity **Study period:** January 1997 – July 2001 (LAGB, in Switzerland) January 1998 – July 2001 (LRYGB, in USA)	**Total number:** N=1261 LAGB: n=805 LRYGB: n=456 **Mean age (yrs):** LAGB: 41.7±10.9 (15-70) LRYGB: 40.2±10.5 (15-68) **Gender (F/M):** LAGB: 636/169 LRYGB: 361/95 **Mean baseline BMI (kg/m^2):** LAGB: 42.2±4.9 (29-64) LRYGB: 49.4±8.3 (27-77) Patients in LRYGB group had significantly higher BMIs than patients in LAGB group (p=.0001).	**Procedure:** LAGB **Device:** Swedish Adjustable Gastric Band® (Obtech) **Comparator:** LRYGB **Length of follow-up:** up to 18 mos **Rates of follow-up:** At 3 mos: 97% for LAGB vs. 89% for LRYGB At 6 mos: 97% for LAGB vs. 88% for LRYGB At 12 mos: 97% for LAGB vs. 57% for LRYGB At 18 mos: 97% for LAGB vs. 37% for LRYGB	These data suggest that LRYGB provides a higher EWL at 18 mos, compared with LAGB, and this holds for all ranges of preoperative BMI. Both procedures can produce an EWL above 50%, but this criterion is met faster after LRYGB with an EWL that could be 10%-20% superior. LRYGB could be associated with higher intra-operative complication rates, early postoperative complication rates, and postoperative mortality rates. The best indication for the two procedures is still unclear and probably depends on the patient's preoperative BMI, eating habits, and associated morbidities. LAGB could be indicated for patients with a BMI between 30 and 40 kg/m^2 and LRYGB could be preferred for patients with a BMI between 40 and 50 kg/m^2.

Continuous data are expressed as mean (or median)±standard deviation (range). * Information regarding mean follow-up and follow-up rates was obtained through personal communication (Dr Mognol, April 2005).

BMI: body mass index; EWL: excess weight loss; F: female; LAGB: laparoscopic adjustable gastric banding; LRYGB: laparoscopic Roux-en-Y gastric bypass; LVBG: laparoscopic vertical banded gastroplasty; M: male; mos: months; N: total number; n: subgroup number; RCT: randomized controlled trial; yr(s): year(s)

Table B3: Summary of large case series on LAGB/RYGB

Study	Study period	Patient characteristics				Device	Follow-up
		Total number	Gender (F/M)	Age (yrs)	Baseline BMI (kg/m^2)		
LAGB							
Dargent 2004 [71] France	April 1995 - December 2003	1180	998/182	Mean 39.5 (range 17-66)	Mean 43.3 (range 35-87)	Lap-Band, SAGB	Up to 7 yrs
O'Brien et al. 2002 [12] Australia	July 1994 - May 2000	709	603/106	Median 41 (range 16-71)	Mean 45.0±7 (max.77)	Lap-Band	Up to 6 yrs
Chevallier et al. 2004 [63] France	April 1996 - June 2003	1000	896 /104	Mean 40.4 (range 16.3-66.3)	Mean 44.3 (range 35.0-65.8)	Lap-Band	Up to 7 yrs
Steffen et al. 2003 [68] Switzerland	April 1996 - February 2002	824	636/188	Mean 43±2	Mean 42.4±1*	SAGB	Up to 5 yrs
Weiner et al. 2003 [67] Multi-centre, Germany	May 1994 - June 2002	984	845/139	Mean 37.9 (range 18-65)	Mean 46.8±7.2*	Lap-Band, SAGB Heliogast	Up to 8 yrs
Angrisani et al. 2003 [69] Multi-centre, Italy	January 1996 - January 2002	1893	1534/359	Mean 37.8± 10.9 (range 17-74)	Mean 43.7±6.2 (range 30.4-83.6)	Lap-Band	Up to 6 yrs
Favretti et al. 2002 [70] Italy	September 1993 - November 2000	830	647/183	Mean 37.9 (range 15-65)	46.4±7.2*	Lap-Band	Up to 7 yrs
Belachew et al. 2002 [72] Multi-centre, Belgium	January 1995	763	595/168	Mean 34	Mean 42 (range 35-65)	Lap-Band	Up to 5 yrs
Vertruyen 2002 [11] Belgium	October 1993 - December 2000	543	487/ 56	Mean 41 (range 18-65)	Mean 44 (range 35-67)	Lap-Band	Up to 7 yrs

Table B3: Summary of large case series on LAGB/RYGB (cont'd)

Study	Study period	Patient characteristics				Device	Follow-up
		Total number	Gender (F/M)	Age (yrs)	Baseline BMI (kg/m^2)		
RYGB							
Sugerman et al. 2003 [77] Virginia	September 1981 - January 1999	1025	799/226	Mean 39±10 (range 12-69)	Mean 51±10*	Not applicable	Up to 12 yrs

* BMI range not reported.

BMI: body mass index; F: female; LAGB: laparoscopic adjustable gastric banding; M: male; max.: maximum; RYGB: Roux-en-Y gastric bypass; SAGB: Swedish Adjustable Gastric Band; yr(s): year(s)

Table B4: Incidence of postoperative complications identified from case series on LAGB or LRYGB

Study	Study period	Patient characteristics				Device	Complications
		Total number	Gender (F/M)	Age (yrs)	Baseline BMI (kg/m^2)		
LAGB							
Mittermair et al. 2003 [74] Austria	January 1996- December 2002	566	475 /91	Mean 43.1 (range 23-62)* and 40.4 (range 26-66)†	Mean 42.9 (range 38-52)* and 46.3 (range 40-55)†	SAGB	Band leakage: 25 in 22 patients (4.4%)
Abu-Abeid et al. 2003 [73] Israel	November 1996 - May 2001	1480		Mean 45 (range 24-53)	Mean 43 (range 35-59)	Lap-Band	Band erosion: 17 (1.1%)
Dargent 2003 [75] France	April 1995- October 2001	973	417/83	Mean 39.4 (range 17-63)	Mean 43.4 (range 30-60)	Lap-Band	Band slippage: 35 (6.8%)
LRYGB							
Champion and Williams 2002 [76] USA	1995- 2001	711	604/107	Mean 38 (range 16-64)	Mean 51 (range 38-80)	Not applicable	Small bowel obstruction: 13 (1.8%)

* For the group with early postoperative band leakages † For the group with late band leakages

BMI: body mass index; F: female; LAGB: laparoscopic adjustable gastric banding; LRYGB: laparoscopic Roux-en-Y gastric bypass; M: male; SAGB: Swedish Adjustable Gastric Band; yrs: years

APPENDIX C: EXCLUDED REVIEWS AND PRIMARY STUDIES

Study	Reason for exclusion
ASERNIP-S 2002 [23]. A systematic review of laparoscopic adjustable gastric banding for the treatment of obesity (update and re-appraisal)	This review was Included in the MSAC review [49] and the McGill review [50]
Avenell et al. 2004 [92]. Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement. Health Technology Assessment 2004;8(21)	Focused on diet, lifestyle change, and drugs but not on LAGB
BCBS 2003 [93]. Special report: the relationship between weight loss and changes in morbidity following bariatric surgery for morbid obesity	Compared bariatric surgery with non-surgical treatments. No information about LAGB
Buchwald et al. 2004 [2]. Bariatric surgery: a systematic review and meta-analysis	Did not report the results for LAGB separately
Colquitt et al. 2004 (Cochrane review) [56]. Surgery for morbid obesity	No information about LAGB
ECRI 2004 [30]. Bariatric surgery for obesity	Did not report the results for LAGB separately
Ferchak and Meneghini 2004 [94]. Obesity, bariatric surgery and type 2 diabetes – a systematic review	Did not meet the definition for systematic review (searched only one database, no methodological quality assessment, etc)
Fried et al. 2004 [95]. Literature review of comparative studies of complications with Swedish band and Lap-Band	Comparison of different devices
Gentileschi et al. 2002 [55]. Evidence-based medicine: open and laparoscopic bariatric surgery	Did not compare LAGB to other bariatric procedures. Included in the MSAC review [49]
HAYES Inc. 2003 [28]. Laparoscopic bariatric surgery	Focused on the comparison of open and laparoscopic approaches for the same procedure (e.g., VBG vs. LVBG)
HAYES Inc. 2004 [51]. Health outcomes after bariatric surgery	Did not compare LAGB to other bariatric procedures
ICSI 2000 [96]. Technology Assessment update: Gastric restrictive surgery for morbid obesity	Focused on VBG and RYGB. No information about LAGB
Maggard et al. 2005 [97]. Meta-analysis: surgical treatment of obesity	Information for LAGB was not reported separately
Mittermair et al. 2003 [79]. Laparoscopic Swedish adjustable gastric banding: 6-year follow-up and comparison to other laparoscopic bariatric procedures	No control group, only compared LAGB to other bariatric procedures based on the results derived from published literature
Monteforte and Turkelson 2000 [98]. Bariatric surgery for morbid obesity (Meta-analysis)	No information regarding LAGB

Study	Reason for exclusion
NICE 2001 [54]. Clinical and cost effectiveness of surgery for people with morbid obesity	Updated by NICE 2002 [57]
NICE 2002 [57]. The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation	No information about LAGB
NICE 2003 [38]. Clinical and cost effectiveness of surgery for morbid obesity: a systematic review and economic evaluation	A journal publication of NICE 2002 [57]
Nilsell et al. 2001 [78]. Prospective randomised comparison of adjustable gastric banding and vertical banded gastroplasty for morbid obesity	Compared open AGB with open VBG
SBU 2002 [59]. Obesity – problems and interventions: a systematic review	Only English summary is available
Shekelle et al. 2004 [99]. Pharmacological and surgical treatment of obesity	Mainly focused on non-surgical treatments
Sjostrom et al. 1992 [100]. Swedish obese subjects (SOS). Recruitment for an intervention study and a selected description of the obese state. **Sjostrom et al.** 2004 [32]. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery.	Main purpose was to compare bariatric surgery with conventional treatment for obese patients. Information on LAGB was not reported separately.
SMM report. 2003 [101]. Surgery for morbid obesity – systematic review	Only English summary is available. No information on LAGB available from the summary.
Steer 2001 [102]. Surgical interventions for morbid obesity	No information about LAGB

AGB: adjustable gastric banding; ASERNIP-S: Australian Safety and Efficacy Register of New Interventional Procedures-Surgical; ICSI: Institute for Clinical Systems Improvement; LAGB: laparoscopic adjustable gastric banding; LVBG: laparoscopic vertical banded gastroplasty; MSAC: Medical Services Advisory Committee; NICE: National Institute for Clinical Excellence; RYGB: Roux-en-Y gastric bypass; SBU: The Swedish Council on Technology Assessment in Health Care; SMM: Norwegian Centre for Health Technology Assessment; Steer: Succinct and Timely Evaluated Evidence Review; VBG: vertical banded gastroplasty

APPENDIX D: METHODOLOGICAL QUALITY

Methodological limitations identified by the HTA reports

The MSAC report [49] and the BCBS report [52] applied a set of previously developed criteria to assess the methodological quality of the included primary studies, whereas the McGill report [50] only provided study design for the included studies. The three reports identified a number of methodological flaws in terms of study design, sample size, follow-up, and reporting.

Study design

There was a lack of controlled studies that directly compare LAGB with other bariatric surgery [49]. Some studies relied on historical control groups or simply compared a series of patients from one centre to a series of patients from another centre or country [49]. Most relevant studies on LAGB were case series [49, 50, 52].

Comparison among studies was hampered by differences in equipment, surgeon's expertise or preference, patient selection criteria, and measurement of outcomes [49].

Sample size

The sample size of included studies was generally small, with fewer than 100 patients in each study [49].

Follow-up

Most studies had a short follow-up period (less than five years). In some studies with longer follow-up, a substantial number of patients were lost to follow-up as the study progressed [49].

Reporting

Some studies did not provide baseline information, or did not provide a measure of variance or perform statistical tests to ensure that there were no significant differences between the different intervention groups at baseline [49].

Methodological quality of primary studies

No formal quality assessment was conducted in this report. Some methodological limitations associated with the included primary studies were noted.

Study design

There is only one RCT [42] that compared LAGB with LVBG, with follow-up of less than four years. Three non-randomizedstudies [64-66] compared LAGB with LRYGB. These three studies are classified as level III-3 evidence based on the National Health and Medical Research Council designation of levels of evidence [90]. The majority of included studies are level IV case series.

Follow-up

The RCT [42] had a follow-up of three years and 90% or more of patients in the two groups were available for the evaluation at three years. In two comparative studies [65, 66], the percentages of patients available for follow-up in the two groups were considerably different, with 97% for the LAGB group versus only 37% for the LRYGB group at 18 months in one study [66] and 65% for the LAGB group versus 17% for the LRYGB group at two years in another study [65].

Some of the case series with a follow-up of five years or longer provided numbers of patients on whom results were reported at five years. These numbers, however, were very small compared with the overall noted sample size. The total number of patients eligible for follow-up (i.e., time elapsed since surgery ≥ follow-up period) was not reported.