

# Surgical treatment of morbid obesity

An update

SUMMARY

AGENCE D'ÉVALUATION DES TECHNOLOGIES  
ET DES MODES D'INTERVENTION EN SANTÉ



# **Surgical treatment of morbid obesity**

## **An update**

Report prepared for AETMIS  
by Raouf Hassen-Khodja and Jean-Marie R. Lance

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The mission of the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) is to contribute to improving the Québec health-care system and to participate in the implementation of the Québec government's scientific policy. To accomplish this, the Agency advises and supports the Minister of Health and Social Services as well as the decision-makers in the health care system, in matters concerning the assessment of health services and technologies. The Agency makes recommendations based on scientific reports assessing the introduction, diffusion and use of health technologies, including technical aids for disabled persons, as well as the modes of providing and organizing services. The assessments take into account many factors, such as efficacy, safety and efficiency, as well as ethical, social, organizational and economic implications.

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## FOREWORD

### SURGICAL TREATMENT OF MORBID OBESITY: AN UPDATE

Obesity is now considered a major public-health problem and has even been declared a “global epidemic” by the World Health Organization (WHO). This chronic disease, which results from numerous biological, environmental and behavioural factors, leads to several health conditions, including hypertension, dyslipidemia, diabetes and some cardiovascular disorders. Québec has not been spared from this epidemic, with a rate of obesity that reached 21.8% in 2004.

In practice, obesity is defined as a body mass index (BMI) greater than 30 kg/m<sup>2</sup>. A more critical threshold is attained when the BMI reaches 40, or even only 35 if it is associated with co-morbidities. This is referred to as morbid obesity. In such cases, behavioural and medical therapy fail to achieve long-term weight reduction and, according to the WHO, surgery is the only effective treatment. However, owing to the expanding range of surgical techniques and the recent introduction of laparoscopic approaches, legitimate questions have been raised about the efficacy and risks of these major procedures.

As early as 1998 the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) had produced a report on the surgical treatment of morbid obesity, or bariatric surgery. At that time some techniques had been classified as accepted technologies, but another, performed in a Québec hospital, was still considered experimental. The rapid evolution of bariatric surgery and of the scientific evidence on this topic has prompted the need for an update. Moreover, faced with the growing prevalence of morbid obesity and concerned about the efficacy of the different techniques and the need to provide effective management for those affected by this health problem, the *Ministère de la Santé et des Services Sociaux* (MSSS) asked AETMIS to assess this surgical treatment.

This report examines the efficacy and risks of complications pertaining to the four major types of procedures, including those performed in Québec. It also compares abdominal-incision approaches with laparoscopic approaches, and deals with the economic aspects of this treatment. The primary sources for this analysis were scientific articles and health-technology assessment reports published since 1998.

Results confirm the long-term efficacy of surgical treatment in terms of maintaining weight loss and reducing co-morbidities. The different techniques available in Québec are considered efficacious and safe. Some have proven efficacy, while others continue to require close follow-up so that patient indications and eligibility may be better identified. In conclusion, AETMIS recommends that an action plan be developed to clearly define the needs for bariatric surgery and establish the means to meet those needs; that key conditions be determined to ensure that hospital centres offer high-quality bariatric treatment; and that a registry on morbid obesity and its management be established.

In submitting this report, AETMIS hopes to contribute to improving the health and quality of life of people with morbid obesity.

**Dr. Luc Deschênes**  
President and Chief Executive Officer

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### CONFLICTS OF INTEREST

None declared.

## SUMMARY

### MORBID OBESITY

Since 1998, in the wake of a report by the World Health Organization (WHO), obesity has been considered a major public-health problem and has even been declared a “global epidemic.” The WHO even calls it a chronic disease requiring long-term strategies for effective prevention and management. Obesity is the result of complex interactions of metabolic, endocrine, genetic, socioeconomic, environmental, cultural, psychological and behavioural factors. It causes many diseases, including hypertension, hyperlipidemia, diabetes, some cardiovascular disorders, sleep apnea, osteoarthritis and some cancers, and even death.

#### *Definition*

Obesity is characterized by excess body fat and is generally defined by the body mass index (BMI), which takes into account weight and height. This index is expressed in kilograms per square metre ( $\text{kg}/\text{m}^2$ ). The term obesity applies when the BMI is greater than or equal to  $30 \text{ kg}/\text{m}^2$ . A BMI between 25 and  $29.9 \text{ kg}/\text{m}^2$  is called overweight. Morbid obesity refers to a BMI that is greater than or equal to 40, or  $35 \text{ kg}/\text{m}^2$  if associated with co-morbidities.

#### *Prevalence*

The prevalence of obesity ( $\text{BMI} \geq 30$ ) in the household population aged 18 and older (excluding women who are pregnant) is growing steadily. Whereas obese people accounted for only 13.8% of Canada’s population in 1978–1979, this proportion rose to 23.1% in 2004; these figures are based on directly measured height and weight. The gap between men and women is small: 22.9% vs 23.2%. The situation is comparable in Québec, which has an overall rate of 21.8% (20.9% for men and 22.7% for women). Morbid obesity ( $\text{BMI} \geq 40$ ) has also risen dramatically in Canada, from 0.9% in 1978–1979 up to 2.7% in 2004,

with women being more affected by this problem (3.8% vs 1.6% for men). This figure is not available for Québec.

#### *Consequences*

Obesity gives rise to a considerable epidemiological and economic burden. According to studies in the United States, where the rate of obesity during the 1999–2002 period reached 31.1% among people aged 20 to 74, this problem caused at least 112 000 deaths per year, although other estimates combining overweight and obesity yielded more than 300 000 deaths. Controversy persists over the magnitude of this burden. From an economic viewpoint, in 1997, Canada’s direct medical costs attributable to adult obesity were estimated to be \$1.8 billion, or 2.4% of total direct medical costs. One study estimated that obesity in Québec led to expenditures totalling \$700 million, or 5.8% of the province’s health-care budget (1999–2000 fiscal year), and to productivity losses in excess of \$800 million.

### ROLE OF SURGICAL TREATMENT IN THE THERAPEUTIC APPROACH TO OBESITY

The therapeutic approach to obesity is multifaceted and complex. It requires a specially adapted treatment structure and the availability of a multidisciplinary team.

#### *Management of obesity*

Obesity management is based on a minimum of three key measures:

- 1) intensive patient education on improving food patterns;
- 2) counselling on the need for regular physical activity; and
- 3) behavioural approaches designed to help people better regulate the lifestyle habits needing to be modified.

Weight-loss objectives must be clearly defined with the patient. Physicians may suggest drug therapy for patients unable to meet their target objectives through diet and physical activity.

### *Management of morbid obesity*

The multi-dimensional approach described above is not effective for treating morbid obesity. According to the WHO, the only effective treatment is bariatric surgery (from the Greek word *baros*, which means weight).

Bariatric surgery currently encompasses a range of techniques that can be classified into two main types of procedures:

- gastric-restriction techniques, which decrease food intake by reducing gastric capacity:
  - gastroplasty: a pouch or partition is created by horizontal or vertical stapling or banding (vertical banded gastroplasty),
  - gastric banding: a fixed or adjustable band is inserted to form a small-volume gastric reservoir;
- hybrid techniques, which combine gastric restriction with the principle of intestinal malabsorption by creating either a bypass or a diversion system:
  - gastric bypass techniques, including Roux-en-Y, the most common variant performed worldwide,
  - biliopancreatic diversion with distal gastrectomy or duodenal switch.

Although all these surgical techniques were developed for the abdominal-incision, or open-surgery, approach (laparotomy), surgeons continued to explore new ways of performing this procedure, chiefly in terms of the surgical approach. As a result, laparoscopic techniques appeared in the mid-1990s and soon became widely used in several countries. In fact, according to an international survey, 62.85% of the procedures performed worldwide in 2003 were

done laparoscopically, especially gastric bypass and adjustable gastric banding.

Although the efficacy and safety of each of these techniques, whether open or laparoscopic, are established to varying degrees, they still raise legitimate questions.

## ASSESSMENT OBJECTIVES

In 1998, the *Conseil d'évaluation des technologies de la santé* (the predecessor of AETMIS) published a report on the surgical treatment of morbid obesity. The need to clarify the status of biliopancreatic diversion with duodenal switch (the procedure used in Québec), the rapid expansion of laparoscopic techniques and the growing prevalence of morbid obesity are the reasons for this update. This report also responds to a request from the MSSS asking AETMIS to examine the evolving efficacy of bariatric-surgery techniques and the best conditions for managing people with severe obesity. Lastly, this assessment explores the economic aspects of this treatment.

## METHODOLOGY

This report is based on a review of the scientific literature and health-technology assessments published between 1998 (publication date of the previous report) and April 2005. Standard databases—Medline, Cochrane Library and HTA Database—were searched on the following keywords: *obesity, morbid obesity, surgical treatment, bariatric surgery, gastroplasty, gastric bypass, gastric banding*.

The search retrieved a large number of studies published since 1998. However, given the scarcity of comparative trials, whether randomized or not, and the predominance of case series, studies were selected by means of a simplified grid containing the following elements: study design, publication date, number of patients treated, length of follow-up, and relevance of clinical outcome measures.

The main outcome measures for this analysis were:

- Clinical efficacy: excess weight loss (EWL), defined in relation to ideal weight, or, alternatively, weight loss and a decrease in body mass index;
- Safety: complications characterized by their onset (short, medium or long term), type and severity;
- Co-morbidity: reduction or not of associated conditions;
- Consumption of health goods or services or other resources: days of hospitalization, mean length of stay, operating time;
- Efficiency: resource costs or savings; cost-effectiveness and cost-utility ratios.

## RESULTS

### *Surgical treatment in general*

Despite the large number of primary studies on the surgical treatment of morbid obesity, most cover either treatments with established efficacy or new approaches, especially laparoscopic procedures. Few provide long-term outcomes, however. A single major study (Swedish Obese Subjects Intervention Study, or SOS) compares surgical treatment with the medical approach. It uses a prospective design with 18 subject-matching variables. The other comparative studies, some of which were randomized, examined either the effects of the surgical approach (open or laparoscopy) or variants of the same technique. The studies are therefore mostly retrospective case series, while a few are prospective.

Surgical treatment is currently recognized as being a more effective therapeutic option than non-surgical treatment for patients who are morbidly obese. Although most of the evidence refers to short-term outcomes, several studies are beginning to demonstrate long-term sustained weight loss. Moreover, the SOS (the best controlled study available) found that bariatric surgery achieved a sustained weight loss of 16.1% in people with BMIs of at least 40, or at least 35 if associated with co-morbidities, including

diabetes, hyperlipidemia and hypertension. Surgery itself has some potentially serious complications. Although these adverse effects are generally managed appropriately, they require continual assessment.

Bariatric surgery remains an expensive procedure because it requires a multidisciplinary team, a specialized technical platform and long-term follow-up. In return, the resulting weight loss decreases the prevalence of co-morbidities and their consequences (prescription drug spending), serving to reduce productivity losses caused by sick leave and disability, and improves quality of life. Nevertheless the favourable cost-effectiveness (or cost-utility) ratio and the efficiency suggested by the current state of the evidence need to be confirmed by longer-term well-designed economic studies.

### *Surgical techniques*

Although bariatric surgery relies on a wide range of techniques, current evidence does not yet favour any one over the others, owing to the variety of contexts in which they are performed, the diversity of patient profiles and the lack of well-designed controlled studies. Moreover, a single procedure may involve several techniques.

The choice of surgical technique depends on a number of factors:

- Patient profile: age, personality, BMI, eating patterns, personal understanding and commitment, co-morbidities, contraindications;
- Reversibility or non-reversibility of the technique;
- Risks linked to each technique (e.g., wound dehiscence, hernias, device slippage, staple-line failure);
- Potential effects of nutritional deficits;
- Availability of human and material resources;
- Support provided by the expertise of a multidisciplinary team; and
- Surgical team's experience in bariatric surgery and, where applicable, in lapa-

roscopy, which requires a lengthy learning curve.

**In terms of overall efficacy**, current evidence generally indicates that hybrid techniques combining gastric restriction and intestinal malabsorption are superior to those designed only to restrict gastric capacity. The following provides details regarding the main techniques under review, of which three are used in Québec.

*Roux-en-Y gastric bypass (RYGB)*: This technique has proven efficacy in terms of stable weight loss, low complication rates and reduction of co-morbidities. Considered the gold standard of weight-loss surgery, the RYGB is the most commonly used gastric-bypass technique.

*Vertical banded gastroplasty (VBG)*: Although this technique has established efficacy, it has achieved lower than expected weight loss and has lost favour with North American surgeons (including those in Québec). Combined with the RYGB, VBG yields good long-term results.

*Adjustable gastric banding (AGB)*: This technique is generally recognized as being effective in terms of both weight loss and low complication rates. It has the advantage of being reversible and is increasingly replacing VBG.

*Biliopancreatic diversion with duodenal switch (BPD-DS)*: Despite the fact that this technique is used only in a few centres because of its stringent requirements for post-operative patient management and follow-up, its long years in use (over 20 years), the cumulative number of procedures performed to date and its positive weight-reduction results mean that this procedure is no longer considered experimental. In addition, some studies suggest that BPD-DS would be appropriate for super-obese patients with BMIs over 50.

#### *Laparoscopic approach*

Laparoscopic procedures offer many advantages. For example, they reduce hospital stays and decrease, if not eliminate, compli-

cations associated with open surgery; however, they do have other types of complications. Surgeons must train in the best conditions to master this approach.

The two most advanced laparoscopic techniques are Roux-en-Y gastric bypass (LRYGB) and adjustable gastric banding (LAGB), and they are no longer considered experimental. They must nonetheless be introduced in an environment that permits the ongoing study of their effects. After one year of follow-up, the LRYGB achieves the same outcomes as the open version, and their early complications differ only slightly. However, it is still necessary to obtain longer-term comparative data.

The LAGB techniques appear to be safe and effective (in terms of excess weight loss) and have the extra advantage of being reversible. Furthermore, major complications are rare, and complication and re-operation rates are acceptable. Yet these effects have been measured only in the short term and need to be confirmed by longer studies.

The other laparoscopic techniques are still classified as experimental, owing to the uncertainty surrounding their effects.

Lastly, in addition to offering no comparisons, the evidence on the surgical treatment of adolescents and children with morbid obesity is insufficient to draw valid conclusions. Although this assessment has not examined the consequences of substantial weight loss (e.g., the need for reconstructive plastic surgery), this aspect must not be overlooked in the therapeutic treatment plan because it has a potentially significant psychological impact.

## **COST EFFECTIVENESS OF BARIATRIC SURGERY**

According to the current state of evidence, even if the published economic studies and models have their limitations, the surgical treatment of morbid obesity would appear to be a cost-effective procedure. Although this type of surgery is relatively expensive,

mostly because of the costs incurred by the procedure itself and by the management of early or late complications that can result, and because of the requirement for annual follow-ups and possible need for plastic surgery, the positive effects linked to weight reduction would appear to compensate for these costs. Indeed, bariatric surgery lowers the prevalence of co-morbidities (e.g., cardiovascular diseases and diabetes) and their impact on resource utilization (hospitalizations, drug expenditures). It also reduces productivity losses caused by sick leave and disability, and improves quality of life.

These initial results must nevertheless be confirmed by more well-designed economic evaluations based on factual data on long-term effectiveness and resource utilization and on valid comparisons of the different surgical techniques and approaches (laparoscopy or open surgery).

## CHALLENGES FOR QUÉBEC'S MEDICAL PRACTICE

Different bariatric-surgery techniques are currently being used in Québec by highly experienced surgeons in the field. Yet there is a lack of data on the quality and effectiveness of these procedures and on the population of treated patients. The supply of services also appears insufficient, given the steady growth of waiting lists and wait times. In such a context:

- it is crucial to know and share all the different information about the treated population and the outcomes achieved in bariatric-surgery centres;
- it is necessary to effectively measure the evolution and extent of bariatric-surgery needs resulting from the growing prevalence of morbid obesity;
- it is advisable to promote the development of practice guidelines on the management of patients with morbid obesity in order to ensure that service offerings are of high quality.

Québec's Association of General Surgeons (QAGS) has developed a policy on the surgical treatment of morbid obesity. The QAGS emphasizes the following points: need for an interdisciplinary team; designation of referral centres; information and training for surgical residents; and increased bariatric-surgery training opportunities. Furthermore, it would be advisable, in the management of any bariatric-surgery plan, to anticipate the potential need for reconstructive plastic surgery.

## RECOMMENDATIONS

- 1) It is recommended that the *Ministère de la Santé et des Services Sociaux* and other decision makers concerned with the problem of morbid obesity precisely identify current and future needs in bariatric surgery, establish an action plan to increase the capacity to provide this treatment, and ensure that patients in the different settings and regions have fair access to these services.
- 2) It is recommended that, at the organizational level, all hospital bariatric-surgery programs comply with the conditions listed below, which will be subject to a quality-assurance process. Such programs must:
  - Establish a strict patient-selection process (e.g., patients who have BMIs of 40 kg/m<sup>2</sup> or more, or 35 with co-morbidities, who have acceptable operative risks, who are motivated and well informed of the inherent risks of the procedure and of the need for lifelong follow-up) and a system for prioritizing patients on scheduled waiting lists.
  - Have available facilities and equipment adapted to the specific profile of the patients concerned (e.g., recovery rooms, intensive-care units, beds and furniture, diagnostic investigation tables, operating tables, and adapted surgical instruments).

- Have an experienced multidisciplinary team capable of supplying the full range of care and services tied to this type of treatment: surgical team, psychologist, nutritionist, medical specialists (e.g., diabetologists, cardiologists, pneumologists).
  - Provide closely monitored lifelong follow-up, and cover the physical and psychological dimensions of this treatment, which consequently includes consultations linked to the need for plastic surgery.
- 3) It is recommended that a Québec registry on morbid obesity and its management be established. This registry will offer key support in implementing a regional follow-up program for operated patients by linking the different health-care structures (hospitals, health centres) and by including specific patient education on nutritional approaches appropriate for this type of patients. This data source will make it possible to determine the prevalence and categorization of the different patients, to evaluate the surgical procedures that are currently being performed and to rule on the new bariatric-surgery approaches.

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