REPORT NUMBER 15

The Gastric Banding Procedure
An Evaluation

A Technology Assessment

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This analysis was prepared for the Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC).
by

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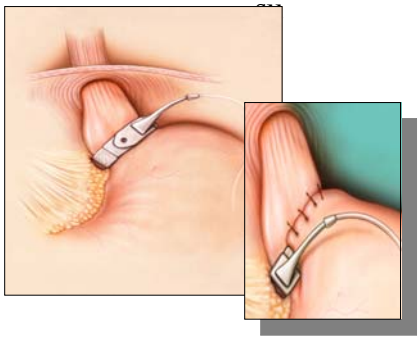


Executive Summary

This report has been prepared in response to a request by the Director of Professional Services of the MUHC to carry out an evaluation of the Laparoscopic Adjustable Gastric Banding (LAGB) procedure for morbid obesity, giving particular attention to its efficacy and safety, the quality of the evidence on which these evaluations are based, the costs, and how the cost compares with that of the most used alternative procedure.

Data on outcomes of the LAGB procedure were derived from a systematic review published in 2002, of 121 studies involving a total of 5,780 LAGB procedures for morbid obesity, and a review of 19 subsequent reports involving 10,913 such procedures. Outcomes of the LAGB procedure were compared with those of the current "standard" procedure, the Roux-en-Y gastric bypass (R-en-Y), an operation, which is also performed laparoscopically at this time (LR-en-Y).

Outcomes. No randomized controlled comparisons of these two procedures are available. The evidence concerning both is derived from numerous cohort follow-up studies of varying quality, and duration, and with extremely variable results. Conclusions based on average outcomes are as follows:

- **Weight loss. The evidence suggests that the LAGB procedure produces a satisfactory weight loss, averaging 50% of the excess weight by the third year. The weight loss following the R-en-Y (open) procedure is comparable, and possibly slightly superior (average excess weight loss 60%), and there is no reason to think that the weight loss following the laparoscopic procedure (LR-en-Y) would be different. Following both LAGB and R-en-Y procedures weight loss is sustained, at least up to five years (the limits of present follow-up). The slightly greater weight loss following the R-en-Y procedure is probably real but the data are inadequate to be certain of this.**

- **Conversion rate. Intraoperative complications cause conversion to open surgery in 2.2% of both procedures.**

- **Surgical Mortality rate. Estimates of the operative mortality rate associated with the LAGB procedure range from 0.02% to 0.11%. The estimated rate for LR-en-Y is 0.23%. The lack of direct comparative trials does not permit firm conclusions regarding the observed differences in mortality between the two procedures.**

- **Surgical Morbidity rate. Post-operative complication rates associated with the two procedures are fairly comparable. Complications necessitating intra-abdominal surgery occurred with 6.55% of the LAGB procedures and with 4.73% following LR-en-Y. The frequency of complications requiring local surgical intervention in the abdominal wall following LAGB (4.57%) were matched by the need to undertake stomal dilatation via gastroscopy following LR-en-Y (4.73%). However, such figures do not reflect the fact that following LAGB, corrective intra-abdominal surgery is usually simple and uncomplicated, whereas when it follows LR-en-Y it is usually more serious, resulting from intestinal obstruction or leakage at the site of**

anastomosis. Follow-up is insufficiently long to determine the long-term (> 5 years) problem free duration of the gastric band implant.

- **Comorbidity. Associated pathology. The weight loss resulting from bariatric surgery, regardless of the technique, is associated with substantial reduction in cardiovascular risk factors (hypertension, diabetes, lipid profile), and improvement in comorbidities such as obstructive sleep apnea, asthma, reflux esophagitis, and degenerative joint disease.**

- **Quality of life. The quality of life following LAGB is usually significantly improved following surgery, with a return to near normal population values of the Rand SF-36 quality of life index. Some subjects experience difficulty with the necessary change in diet, and approximately 1.3% of patients cannot tolerate the band. Approximately one third of patients require fairly extensive plastic surgery to eliminate redundant skin. Psychological problems are not necessarily diminished by the procedure. In one non-randomized comparative study patients treated with LAGB had significantly less positive evaluation of the surgery compared to those treated by R-en-Y. There was no significant difference between the two groups in self-esteem or depression.**

- **Costs. Based on the use of the Swedish Band the average cost to the MUHC of the LAGB procedure, including two years follow-up and the costs of complications, is estimated to be $7,771. The equivalent cost for the LR-en-Y is estimated to be $5,582. From the point of view of the provincial health care system the direct costs of the LAGB and the LR-en-Y procedures were approximately $9,418 and $7,064, respectively. Thus, apart from the cost of the gastric band device, the costs of the two operations were fairly comparable.**

Budget Impact. At present approximately 150 bariatric surgical procedures, mostly LR-en –Y, are carried out at the MUHC each year. If all operations were carried out using the LR-en-Y procedure the direct cost to the MUHC (including two years of follow-up) would be approximately $837,353 per year. If all 150 were carried out by the LAGB procedure (using the Swedish band), the cost would be $1,165,673 per year. The difference between using the LAGB and the LR-en-Y procedures, $328, 320, is the equivalent of 59 additional operations with LR-en-Y.

There are at present approximately 1,700 patients on the MUHC waiting list for bariatric procedures. To double the present turnover (to 300/year) using the LAGB procedure and Swedish Band would therefore cost the MUHC approximately $2.3 million, or $1.7 million using LR-en-Y.

Conclusion

There is sufficient evidence to support the conclusion that the Laparoscopic Adjustable Gastric Band (LAGB) operation is an effective procedure with an adequate safety record for up to five years. It is widely used in North America and in Europe.

Both the weight loss experienced, and the rates of mortality and morbidity associated with LAGB are fairly comparable to (or possibly lower than) the most commonly used procedure at this time, the Roux-en-Y gastric bypass.

There are no randomized comparisons of the two procedures, and there is insufficient evidence on which to decide whether LAGB is a superior procedure, or not. However, according to expert opinion there are some occasions on which it would be a significantly safer procedure than LR-en-Y. Accordingly, it should become an accepted bariatric option within the MUHC, and the Québec Healthcare system.

However, until it is recognized by Québec, neither the professional nor hospital costs for the procedure can legally be recovered from the Ministry.
For these reasons the MUHC should approach the Ministry to request that they consider recognition of the LAGB procedure for such exceptional cases.

In view of the fact that an effective alternative procedure exists, the TAU Committee therefore recommends that until the LAGB procedure has been approved by Québec it should not be routinely carried out at the MUHC.
It should only be carried out in exceptional circumstances, when in the opinion of the Surgeon it would carry a significantly lower risk than the LR-en-Y procedure.

Even if LAGB does receive provincial approval, in view of the fact that it costs approximately 39% more than the present laparoscopic Roux-en-Y procedure, it will be necessary to demonstrate clinically meaningful superiority over a longer follow-up before it is accepted as the operation of choice at the MUHC.

THE GASTRIC BANDING PROCEDURE. AN EVALUATION.

FOREWORD

In the fall of 2003 the Director of Professional Services, Dr. Françoise Chagnon, requested the Technology Assessment Unit (TAU) to undertake a review of Laparoscopic Adjustable Gastric Banding (LAGB) for the treatment of morbid obesity. In particular, she requested that TAU develop answers to the following questions:

- Is this an effective and reasonably safe procedure?
- Is the evidence of effectiveness and safety sufficiently good to justify its inclusion as a hospital service?
- What are the costs of this procedure, from the point of view of the MUHC compared to other surgical techniques used for obesity?

At its meeting on January 20, 2004, the Committee of the TAU approved the preparation of this review.

DEFINITIONS

BMI Classification of the NIH [1]: Normal weight: 18.5-24.9, Overweight: 25-29.9,
Obesity (Class 1): 30-39.9, Obesity (Class 2): 35-39.9.
Extreme Obesity (Morbid Obesity): ≥ 40, Superobesity: > 50.

Body Mass Index (BMI)[2]**:** Body weight (kg)/ height^2 (m).

% Excess Weight Loss (%EWL)[2]*:* [(initial wt - follow up wt) / initial wt - ideal wt] x 100.

Ideal weight[2]: the mid-point of the range of weights for medium frame, based on the Metropolitan Insurance height and weight tables. Can be estimated as follows: Adult female 5 ft. tall = 119 lbs. For each additional inch add 3 lbs. Adult male 5'3" tall = 135 lbs. For each additional inch add 3 lbs. (1 ft. = 50.4 cm, 1 in. = 2.54 cm, 1 lb/ 2.2 = kg).

INTRODUCTION

Morbid obesity is a serious and increasing health problem in Western countries. In its 1998 report the Conseil d'évaluation des technologies de la santé du Québec estimated that in 1992 there were between 116,000 and163,000 morbidly obese individuals age 16 years and over in the province, and that their treatment, including the treatment of related secondary morbidities was costing the health service over $250 million [2]. Its management with diet, behaviour modification, and medication has had only very limited success [3], and a reviewer in 2002 concluded that "there are no published studies demonstrating significant weight loss by diet therapy, exercise, or behaviour modification in morbidly obese patients" [4].

Surgical approaches that aim either to produce malabsorption by short circuiting portions of the gastrointestinal tract, or to produce early satiety through restricting access to the stomach, or both, have been in use for 50 years. In 1991 a National Institutes of Health Consensus Conference concluded that medical therapies generally fail to control severe obesity and that surgery should be considered for individuals with a BMI >40 kg/m2, or with a BMI >35 kg per m^2 in the presence of comorbidities such as diabetes or sleep apnea [5]. In 2000 a subsequent NIH conference qualified this recommendation by adding that "weight loss surgery should be reserved for patients in whom other methods of treatment have failed", and that "lifelong monitoring after surgery is a necessity"[1].

The first surgery for morbid obesity, a jejuno-colic bypass, was carried out at the Royal Victoria Hospital in 1963 [6]. Since that time the standard procedure has become the Roux-en-Y gastric bypass (R-en-Y). Since 1994 there has been increasing worldwide use of the adjustable gastric band procedure. In this operation an inflatable cuff is placed around the upper stomach to create a small pouch with a restricted outlet into the body of the stomach. The degree of restriction can be adjusted postoperatively by injection or withdrawal of fluid from a port buried subcutaneously in the anterior abdominal wall. Since 1998 this device has increasingly been inserted laparoscopically. The device has been approved in the U. S. since June 2001 and licensed in Canada since September 1999. However, the procedure is not recognized for reimbursement by any of the Canadian provinces. [D.Minogue, Minogue Medical, Montreal. Personal communication].

The efficacy of surgical interventions in general for the treatment of morbid obesity is well documented in an extensive literature summarised in 8 systematic reviews (see Appendix 1). The present report is specifically concerned with the efficacy and safety of *laparoscopic adjustable gastric banding (LAGB),* and except in so far as it is necessary for comparison, other surgical interventions will not be discussed here. The cost of this procedure will be compared to the cost of the Laparoscopic Roux-en-Y (LR-en-Y) gastric bypass procedure, which is at present the preferred procedure for bariatric surgery in North America [4] and at the MUHC.

In Canada there are three devices available for LAGB, the LapBand (INAMED Health, Santa Barbara, CA, costing approximately $4,500), the Swedish Adjustable Gastric Band (Obtech Medical, Baar, Switzerland, $4,000), and the MidBand (Medical Innovation Department, Villeurbanne, France, $2,000). The LapBand has been the most extensively used, and the data reported in the literature are mostly based on its use. At the MUHC the Swedish band is favoured.

METHODS

To arrive at estimates of the efficacy of the LAGB procedure, and to enable comparison of its efficacy and costs with the R-en-Y gastric bypass, we first searched for meta-analyses and systematic reviews of these procedures. We identified eight (see appendix I), of which the most recent was a systematic review produced in June 2002 by The Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIPS) [7] and recently published [8]. However, this review included no reports published later than June 2001. To access articles published since that date we carried out a systematic literature search (as described in Appendix 2) for individual reports published between May 2001 and February 2004, of which 19 were identified. This report is based on the Australian systematic review and these additional 19 studies.

RESULTS

Studies published before June 2001 (Australian report) [7]

The Australian report was a systematic review of 121 human studies, involving a total of 5,780 LAGB procedures in individuals with morbid obesity, defined as a Body Mass Index (BMI) >35 kg/m^2, accessed up to mid 2001. Comparison was also made with outcomes of 9258 R-en-Y Gastric Bypass procedures. The findings of this review can be summarized as follows:

Weight Loss. Since studies used different indices to report weight loss, a single meaningful estimate based on a large number of procedures cannot be arrived at. However, examination of the individual studies indicates that substantial weight loss can be expected to result from this procedure, with average values for different studies ranging from 31-105 kg at the second year of follow-up. Excess weight loss at 2 years following surgery in eight series varied between 36% and 67%, undoubtedly reflecting, in addition to differences in operative technique and case selection the effect of the learning curve, since four of these series consisted of fewer than 60 cases at enrolment.

Mortality. The average short-term mortality rate associated with 5,780 operations for LAGB was 0.05% (95% CI 0.01-0.11).

Morbidity. Vomiting, diarrhoea and weight regain were not included as morbidity in these reports, and apart from this, morbidity was undefined. Considering the data in these studies as case series, the median overall (early and late) morbidity for LAGB was approximately 11% (range 0-68). There was no difference between the morbidity rates reported with the Lap-band and the Swedish band (11.3% and 10.5%, respectively).

Learning Curve. This 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 hundred procedures than the first. In the Australian systematic review it can be seen that there was a clear association between the morbidity rate and the size of the series reported. Morbidity exceeded 15% in more than half of all series of fewer than 100 cases, but was less than 15% in all series of more than 200 procedures.

Specific Morbidities.: Excluding intraoperative complications, the more frequent procedure related postoperative complications (based on Table 4 of the Australian report) were:

- Band related problems (erosion, dilatation, displacement, leakage) 6.19%.
- Port and connecting tube related problems (port rotation, disconnection, painful port site) 1.8%.
- Infections (wound, band, other) 0.83%.
- Respiratory complications 0.28%. Pulmonary embolism 0.16%.
- Miscellaneous 1.4%.

Studies reported since June 2001.

In order to access studies published since the Australian review, and in particular to find reports with a longer follow-up, we reviewed all literature published between May 1, 2001 and Feb. 1, 2004. The search strategy is described in Appendix 2. Excluding series of fewer than 100 cases and one report in which only the radiological findings were reported, 18 studies were identified that reported effectiveness, and one other study that reported only complications (see table 1).

Reduction in BMI. (Table 2). The average body mass index (BMI) before surgery was above 40 in all series, but the lower range was less than 35 in some series and less than 30 in at least one. The BMI values reflect the average values of those individuals followed up in any one year. Thus, no precise estimate of weight loss from year to year can be derived from the BMI data.

% Excess weight loss. (Table 2). In 12 of these studies the percentage excess weight loss, (the initial weight less the actual weight x 100/initial weight less ideal weight), was also reported. In these the weighted average percent excess weight loss (%EWL) increased progressively, from 41% at the end of the first year, to 50%, 50%, 55%, and 56% from the second through the fifth year of follow-up.

It is important to note that the number of cases in each year of follow-up diminishes progressively, numbering only 268 (of 10,913 implants) by year five. In so far as this was due to the time factor, i.e. not all individuals having completed follow-up at the time of the study, it might not systematically bias results. However, it is also possible that in some studies follow-up may have been selective, with successful cases being followed up preferentially, while others

such as those who could not tolerate the band, became excluded. The extent of this potential error is unknown and results should accordingly be interpreted with considerable caution.

However, it can reasonably be concluded from these data that weight either continues to be lost during the first few years of follow-up, or at least is not regained. This is what would be expected following implantation of an adjustable device that allows for the degree of obstruction to be increased in any individual who starts to regain weight. The actual extent of weight loss is uncertain. Bearing in mind the uncertainty introduced by the limited numbers followed up, the results suggest that on average approximately 55% of excess weight is lost by the forth year and sustained through the fifth year of observation.

Mortality. (Table 3) The twelve procedure related deaths were experienced in three of the 18 studies, there being no reported mortality in the other 15. Most of these deaths were due to pulmonary embolism or myocardial infarction. In view of a presumably high comorbidity in such patients the weighted average mortality of 0.11% can be considered acceptable (In four of these studies the mortality was not specifically mentioned, and assumed to be zero. If these four studies are excluded the average mortality becomes 0.12%.) Note also that 10 of the procedure related deaths were in one report. If this report were considered to be an outlier and excluded from calculations, the mortality for the procedure would be 0.02%, a figure comparable to the estimate of 0.05% based on the earlier data reviewed by the Australian investigators [7].

Conversion. (Table 3). In 2.2% of operations the procedure was converted to open laparotomy.

Morbidity. (Table 3). It is difficult to estimate an annual average morbidity rate because the authors did not report adverse events by year of follow-up, while the duration of follow-up in these studies varied from one to five years. However, the majority of adverse events occur within the first year and almost all within the first two years, and to obtain an overall estimate we have averaged the adverse events reported in all studies irrespective of the length of follow-up.

In most of these studies the frequency of associated adverse effects diminishes markedly with experience, the so-called learning curve. For example, in an Italian study carried out at 27 different centres the number of gastric pouch dilatations (the commonest complication) falls progressively from 61 in the centre with the smallest turnover to 0 in the centres with the largest[9]. Similarly, in a single centre study carried out in Belgium the number of complications

fell from 20 in the first hundred operations, to 6 in the second hundred, and to less than 2 in the fourth hundred operations [10].

Specific Morbidity Rates (Table 4). As can be seen in table 3 the adverse events encountered following LAGB are numerous and varied. To arrive at a more meaningful estimate of morbidity we list below the weighted average frequency of these complications grouped into eight categories reflecting their severity. Events that occur during the course of surgery, and haemorrhage in the immediate perioperative period are excluded, since these can be corrected by measures such as transfusion or conversion to open surgery.

1. Band Problems requiring intra-abdominal surgical intervention (Band intolerance. Band leakage. Gastric pouch problems. Band slippage) 6.55%.
2. Tube/Port Problems requiring regional local surgical correction. (Leakage. Breaks. Misplacement) 4.57%.
3. Erosion to Stomach requiring removal by gastroscopy 0.22%.
4. Pneumonia/pulmonary embolism 0.20%.
5. Other infections 0.17%.
6. Other 0.15% (gas embolism, hernia, gastric necrosis)

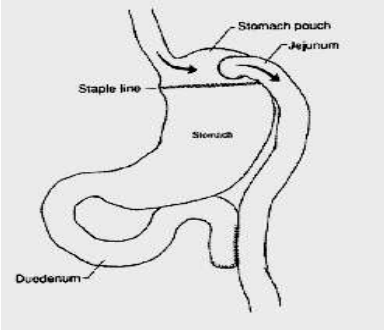
Total events = 11.86%

Summary: From these data it is reasonable to conclude that this procedure can be carried out in an institution such as the MUHC with an expected mortality rate of less than 0.11% (possibly 0.02%) and an expected overall morbidity (excluding intraoperative events) of less than 11.9 %. We can anticipate that on average approximately 55% of excess weight will be lost by the fourth year, and sustained for at least five years, the extent of available follow-up data. Thus, this is an effective and reasonably safe procedure. The evidence of its safety and effectiveness is sufficiently good to justify its inclusion as a hospital service. However, the possibility of complications due to late band failure or other complications occurring later than five years cannot be ignored.

Comparator Procedure. The Laparoscopic Roux-en-Y Gastric Bypass (LR-en-Y)

As a comparator we will use the accepted Roux-en-Y gastric bypass procedure. In this operation a small portion of the upper stomach is isolated and connected with a Roux-limb as an

enterostomy to the jejunum. Until 1999 this procedure was carried out via open laparotomy, but since then it has been increasingly carried out laparoscopically.



Though the outcome in terms of weight loss is presumably the same whether this procedure is carried out via laparotomy or laparoscopy, the morbidity profile is different [11]. Accordingly, we will estimate its efficacy (weight loss) based on the open R-en-Y operation which has a long history allowing for long follow-up observation, but we will base estimates of mortality and morbidity on the currently used laparoscopic R-en-Y procedure (LR-en-Y) for which long follow-up is not yet available.

Weight Loss. The R-en-Y gastric bypass procedure has a long history in which its efficacy has been firmly established. For example, in 2000 MacLean and colleagues published a long-term (average 5.5 years) follow-up of 243 patients undergoing this procedure at the MUHC. In 134 initially morbidly obese patients, results were ranked as: excellent in 60%(BMI< 30), good in 33% (BMI 30-35), and as a failure 7% (BMI > 35). However, in 96 super obese patients results were only considered excellent in 26%, good in 31%, and a failure in 43%[12].

To obtain an overall estimate of the weight loss to be expected from the R-en-Y procedure we will rely on the Australian systematic review of 21 studies in which the percent excess weight loss is reported [7]. Five of these included series of 100 or more cases and reported follow-up at three years [13-17] The average percent excess weight loss weighted by number of patients at the time of each follow-up was 69%. In 3 that reported a five-year follow-up [14;15;17] the average excess weight loss was 62 %. (Note however, that no more than 32% and 15% of patients were followed up at three and five years respectively, and it is unlikely that these truly reflected the average of operated cases).

Adverse Events. Estimates of the frequency of adverse events associated with the laparoscopic procedure are based on a systematic review of the complications of LR-en-Y reported in 10 studies involving 3,464 patients, published by Podnos et al in September 2003 [11].

Conversion. In that review, the average conversion rate from LR-en-Y to open laparotomy in nine studies was 2.2% [11]. We found four additional studies [18-21]not included in the Podnos systematic review, involving 2042 LRY procedures. In these the weighted average conversion rate was 3.1%.

Mortality. The weighted average mortality associated with 3,464 LRY operations was 0.23% [11].

Specific Morbidity Rates. (Table 5). The frequency of specific adverse events (based on the data reported by Podnos et al [11]), grouped according to the corrective interventions involved, are shown below and in table 5. (Intraoperative events and immediate perioperative GI bleeds excluded):

1. Stomal stenosis, requiring dilatation via gastroscopy 4.73%
2. Bowel Obstruction, requiring abdominal surgery 2.92%.
3. Anastomotic Leak, requiring abdominal surgery 2.05%.
4. Wound Infection, requiring antibiotic 2.98%.
5. Incisional Hernia, requiring surgical repair, 0.47%.
6. Pneumonia 0.14%. Pulmonary Embolism 0.41%.

Total events 13.7%.

Summary of Outcomes (Table 6). These results suggest that the weight lost with the LAGB procedure may be slightly less than that following the LR-en-Y (based on follow-up of the open procedure) by the third year of follow-up. However, the limited evidence available also suggests that following the former procedure some weight may continue to be lost in subsequent years. The mortality rate, the frequency of complications, and their severity all appear to be comparable or slightly higher following LR-en-Y, but the fact that these are not direct comparisons and the uncertainty surrounding the collection of some of these data must be remembered. Furthermore, according to expert opinion, intra-abdominal surgery following LAGB is usually less complicated than following LR-en-Y, when it is usually the result of acute intestinal obstruction or leakage at the anastomotic site.

Obesity Comorbidities

The beneficial effect of bariatric surgery on cardiovascular risk factors has been clearly demonstrated. For example, in a Swedish study[22] 845 surgically treated patients (BMI 41.0, SD+/- 4.6) were compared with 845 non-randomly matched control subjects receiving conventional obesity treatment. By two years the adjusted odds ratios and 95%CI for the surgically treated group versus the controls were: Hypertension 0.38 (0.22, 0.65). Diabetes, 0.02 (0.00, 0.16). Hyperinsulinemia, 0.10 (0.04, 0.25). Hypercholesterolemia 1.24 (0, 1.8).

An Austrian study [7] that followed up 454 patients for an average three years following LAGB found post operative "improvement" in: Hyperlipidemia (n 265) 95%, Insulin-dependent diabetes (n 24) 96%, Pulmonary disease (n 85) 95%, Degenerative joint disease(n 105) 91%, Hypertension (n 235) 75%, Gastritis (n 62) 58%), Reflux Disease (n 51) 67%. Many other before/after studies have found similar improvement in hypertension, lipid profile, and diabetes [23-28] in asthma [24;29], in reflux esophagitis [23;24], in obstructive sleep apnea [24;26;30] and in degenerative joint disease [23;26;31].

In a recent study published by the Bariatric Surgery Division of General Surgery of the MUHC, the five-year outcome of 1,035 surgical patients was compared to that of 5746 non-randomized age and gender matched severely obese patients who had not undergone weight reduction surgery, identified from the Québec provincial health insurance database. The risk ratios (95%CI) were: Mortality 0.11 (0.04-0.27). Morbidities; Respiratory 0.24(0.17-0.36). Musculoskeletal 0.41 (0.32-0.55). Infectious diseases 0.23 (0.17-0.25). Endocrine 0.35 (0.32-0.38). Cardiovascular 0.18 (0.12-0.22) [32].

Quality of life following LAGB

Numerous studies have evaluated quality of life following LAGB. Almost all report significant and sustained improvement. The Rand SF-36 quality of life index has been found to be significantly improved in all eight subscales in several studies [33-35], and in two this index had returned to [36], or close to [33] community normal values by one year. Studies based on the Moorhead-Ardelt quality of life index [37] and the gastrointestinal quality of life index [38] have also reported significant improvement.

However, there are clearly some negative results of this procedure. Some subjects experience difficulty with the necessary change in diet (slow eating of small quantities) and in one study

13% of patients experienced significant amounts of vomiting [39]. Reported effects on psychological status are variable. In the previously mentioned study of O'Brien and colleagues [24] 336 (of an original 700) patients followed up for 24 months showed an improvement in the Beck Depression Index from 18 to 7.8. By contrast a study of the psychological status of 128 post-LAGB patients using the Minnesota Multiphasic Personality Inventory (MMPI), found that there was no improvement following surgery unless patients also received psychotherapy. "Patients without psychotherapy showed a long-standing or even an increase in susceptibility to anxiety and depression, even though they found benefit from improvement in the body image" [40].
In one study a comparison was made between the psychological impact of the LAGB (N=80) and R-en-Y (N=27) procedures [41]. Selection was not random, and inquiry was carried out by written questionnaire, after follow-up of nine to twelve months. The patients treated with LAGB had lost less weight, and had a significantly less positive evaluation of the surgery compared to the group treated by R-en-Y. There was no significant difference between the two groups in self-esteem or depression. The average self-esteem score for both groups was comparable to population norms and the mean depression score was not in the depressed range.

Overall, in addition to elimination or improvement of such comorbidities as asthma, bone and joint disabilities, sleep apnea, and reflux esophagitis, the effect of bariatric surgery on quality of life is clearly positive.

Costs

Costs of the LAGB procedure. (Appendix 3, Table A1) The costs of the uncomplicated procedure and the routine follow-up costs for the first two postoperative years are shown in detail in table A 1. The direct cost per procedure to the MUHC for LAGB (Swedish Adjustable Gastric Band, $4,000) is $7,344 and for LR-en-Y $5,261. Also shown in the table are the direct costs to the Québec healthcare system (which include professional fees), $8,876 for LAGB and $6,670 for LR-en-Y.

Cost of complications of LAGB. (Appendix 3, Table A2) The frequency and the costs of the interventions resulting from post operative complications, including conversion, of the LAGB procedure are shown in table A2. The estimated average direct cost to the MUHC resulting from these complications is $427, and to the healthcare system $542.

Cost of complications of LR-en-Y. (Appendix 3, Table A3) this table shows the frequency of the complications and the principal cost generating interventions, including conversion, following the LR-en-Y procedure. The estimated direct cost of these events to the MUHC is $321 and to the healthcare system $394.

In summary, it is estimated that the direct cost per LAGB procedure to the MUHC (operation, conversion, follow-up, complications) would be $7,771, and for the LR-en-Y $5,582. The equivalent costs to the Québec healthcare system would be $9,418 and $7,064 for the LAGB and LR-en-Y procedures, respectively.

Budget Impact.

Currently, the Bariatric Surgery Section of the Division of General Surgery, MUHC, performs both LR-en-Y and LAGB procedures for the treatment of severe and morbid obesity, as well as operations to treat complications of the "older" procedures, such as Bilio-pancreatic bypass or Vertical Banded Gastroplasty. The R-en-Y gastric bypass has been carried out laparoscopically since February 2002. To date, 18 LAGB procedures and 248 LR-en-Y procedures have been done at the MUHC.

Demand . The total bariatric surgery volume at the MUHC is currently 150 procedures per year and there are approximately 1,700 patients on the waiting lists for weight loss surgical procedures (Dr. N. Christou, MUHC).

Potential budget impact. For purposes of estimating the potential budget impact of increased use of the LAGB procedure we will consider the following scenarios. Use of the LAGB procedure, using the Swedish Band for all of the present 150 primary bariatric surgical interventions would involve the MUHC in direct costs to the value of $1,165,673 per year. The cost to the Québec healthcare system would be $1,412,678 (See Appendix 3, Table A4). For purposes of comparison, the use of LR-en-Y for all of the present 150 procedures would cost the institution $837,353 per year, and the Québec Healthcare system $1,059,578 (See Appendix 3, Table A5)

Ethical and Legal Issues.

Should this procedure be carried out at the MUHC?

The ethical and legal issues surrounding the gastric banding procedure are complex. The following points should be considered:

- There is sufficient evidence of the safety and efficacy of the LAGB procedure to justify its approval in the hospital and in the province. However, it is not yet approved in other Canadian provinces.
- There is insufficient evidence on which to decide whether LAGB is superior to the LR-en-Y procedure. However, it is widely practiced in the USA and in Europe, and the devices are licensed for use in Canada. There is no obvious clinical reason why it should not be an option at the MUHC. For certain quite rare cases it may be considered to be significantly safer than the LR-en-Y procedure.
- However, since Québec does not yet recognize the procedure, neither professional nor hospital charges could legally be recoverable from the Ministry.

Accordingly, in view of the evidence of its efficacy and safety, the MUHC should request the Ministry to consider approval of the LAGB procedure, at least for limited use when it is considered to be the safest available operation.

In the meanwhile, since hospital costs would not be recoverable, and since a reasonable alternative bariatric procedure is available, the TAU committee recommends that this procedure not be routinely carried out at the MUHC at this time, except under the special aforementioned circumstances.

Furthermore, since it costs approximately 39% more than the standard LR-en-Y procedure, even when it is approved by Québec there should be a clear demonstration of its superiority before accepting it as the principal bariatric operation at the MUHC.

Table 1. Summary of studies of laparoscopic adjustable gastric banding for morbid obesity (published between May 2001-February 2004).

Study	Author Place, Year	Study Design	Device	Study Period	Patients N (Female %)	Mean Age (SD) (Range)
1	Angrisani, et al. Italy, 2003 [9]	Retrospective	Lap-Band	Jan.96 –Jan.02	1893 (81%)	37.8 (10.9)
2	Weiner et al. Germany, 2003 [42]	Prospective	Lap-Band (952) Swedish-Band(2) Heliogast-band (30)	May.94-Jun.02	984 (79%)	37.9 (18-65)
3	Mittermair et al. Austria, 2003 [23]	Prospective	Swedish-band	Jan.96-Dec.01	454 (85%)	38
4	Favretti et al. Bruxelles, 2002 [10]	Prospective	Lap-Band	Sep.93-Nov.00	830 (81%)	37.9 (15-65)
5	Pontiroli et al. Italy, 2002 [43]	Prospective	Not report	Jun.96	143 (83%)	42.9 (0.83)
6	Szold et al. Israel, 2002 [44]	Retrospective	Lap-Band	Nov.96-May.99	715 (77%)	38.1 (15-72)
7	Biertho et al Switzerland, 2003 [45]	Prospective	Swedish-Band	Jan.97-Jul.01	805 (79%)	41.7 (10.9)
8	Ceelen et al. Switzerland, 2003 [25]	Prospective	Swedish Band	Jan, 98 –Oct.01	625 (80%)	36 (Median)
9	Dukhno et al. Israel, 2003 [31]	Prospective	Lap-Band	Sep.99-Aug.01	250 (78%)	36 (16-62)
10	Zinzindohoue et al. France, 2003 [26]	Prospective	Lap-band	Apr.97-Jun.01	500 (83%)	40.4 (16.3-66.3)
11	Fox et al. Mexico, 2003 [46]	Retrospective	Lap-Band	Aug.96-Dec.01	105 (85%)	44.8 (11.17)
12	Steffen et al. Switzerland, 2003 [47]	Prospective	Swedish-Band	Apr.96-Nov.00	824 (745) (81%)	43
13	Belachew et al. Belgium, 2002 [48]	Prospective	Lap-Band	Jan.95-	763 (78%)	34
14	O'Brien et al Australia, 2002 [24]	Prospective	Lap-Band	Jaul.94-May.00	709 * (84%)	41 (16-71)
15	Vertruyen et al. Belgium, 2002 [49]	Retrospective	Lap-Band	Oct.93-Dec.00	543 (76%)	41 (18-65)
16	Victorzon et al. Finland, 2002 [50]	Prospective	Swedish-Band	96-01	110 (90%)	42 (21-64)
17	Chevallier et al. Paris, 2002 [51]	Prospective	Lap-Band	Apr.97-Nov.00	400 (88%)	40.2 (16.3-66.3)
18	Busetto et al. Italy, 2002 [52]	Retrospective	Lap-Band	Jan.96-Dec.97	260 (not reported)	37.6 (10.8) (17-65)
19	Mortele et al Belgium, 2001[53]	Prospective	Swedish-band	Oct.97-Nov.99	218 (80)	Not report

*: Among 709 patients, 61 implants were made via laparotomy..

Table 2. Weight loss reported in the studies of laparoscopic adjustable gastric banding for morbid obesity (published between May 2001-February 2004).

STUDY	AUTHOR, YEAR	YEAR 0		YEAR 1			YEAR 2			YEAR 3			YEAR 4			YEAR 5		
		BMI (mean) (range)	n 0	BMI (mean)	EWL (%)	n 1	BMI (mean)	EWL (%)	n 2	BMI (mean)	EWL (%)	n 3	BMI (mean)	EWL (%)	n 4	BMI (mean)	EWL (%)	n 5
1	Angrisani, 2003	43.7±6.2 (30.4-83.6) [1]	1893	33.7	-	1325 [2]	34.8	-	1325 [2]	34.1	-	1325 [2]	32.7	-	1325 [2]	34	-	1325 [2]
2	Weiner, 2003	46.8 ± 7.2	984	34.0	-	-	32	-	-	-	-	-	-	-	-	-	-	-
3	Mittermair, 2003	46.7 (median) (35-78)	454	32.8	-	-	28.8	-	-	27.6	72	-	-	-	-	-	-	-
4	Favretti, 2002	46.4 ± 7.2	830	37.3	-	660	36.4	-	479	36.8	-	305	36.6	-	185	36.4	-	74
5	Pontiroli, 2002	44.9 ± 0.53	143	36.9	-	143	36.7	-	94	37.0	-	56	-	-	-	-	-	-
6	Szold, 2002	43.7 (35-66)	715	33	-	-	33	-	-	32.1	-	-	-	-	-	-	-	-
7	Biertho, 2003	42.2±4.9 (29-64) [1]	805	-	33.3	664	-	-	-	-	-	-	-	-	-	-	-	-
8	Ceelen, 2003	40 (Median) (40.2-41.3)	625	31.6	45.8	588	31.8	49.9	588	32	47.4	588	-	-	-	-	-	-
9	Dukhno, 2003	44 (35-76)	250	25	72	250	-	-	-	-	-	-	-	-	-	-	-	-
10	Zinzindohoue, 2003	44.3 (35-65.8)	500	34.2	42.8	343	32.8	52	185	31.9	54.8	45	-	-	-	-	-	-
11	Fox, 2003	46.71 (SD=11.17)	105	33.6	75	37	31.5	75	37	29.8	72	24	32	60	7	-	-	-
12	Steffen, 2003	42.4 ± 0.2 (31-69) [1]	824	35.8	29.5	821	33.2	41.1	744	31.5	48.7	593	30.0	54.5	380	29.2	57.1	184
13	Belachew, 2002	42 (35-65)	763	32	40	687 [2]	30	50	687 [2]	30	-	687 [2]	30	55 [3]	687	-	-	-
14	O'Brien, 2002	45.0 ± 7	709	-	47	492	-	53	336	-	53	273	-	52	112	-	54	32
15	Vertruyen, 2002	44 (35-67)	543	33.2	38	405	31.3	61	372	30.1	62	261	31.4	58	123	31.2	53	52
16	Victorzon, 2002	44 (median) (35-76)	110	35	45	71	34	52	59	33	53	26	-	-	-	-	-	-
17	Chevallier, 2002	43.8 (35.1-65.8)	400	34.3	42.1	168	32.7	52.7	33	-	-	-	-	-	-	-	-	-
18	Busetto, 2002	46.6 ± 7.1 (34.9-70.2)	260	36.8	39.7	252	-	-	239	-	43.0	229	-	-	-	-	-	-
Weighted average % excess weight loss (%EWL) [3]					**40.8**			**50.0**			**50.4**			**54.9**			**55.9**	
Number of patients (N) (=Σ n)			N=10913			N1=4778			N2=3041			N3=2039			N4=1309			N5=268
Studies included in weighted % EWL calculation				7-18			8, 10-17			8, 10-12, 14-16, 18			11-15			12,14-15		

[1]: According to the guideline, bariatric surgery is only recommended to patients with morbid obesity. Morbid obesity defined as BMI of 40 or over, or a BMI of 35 in the presence of comorbidities.
[2]: Not reported the number of patients at the each year of follow-up. But the number of patients at the end of the follow-up was reported.
[3]: Weighted average % EWL at year n of follow-up= Σ(%EWL x n at that follow-up year) divided by total N at that follow-up year.

Table 3: Mortality, conversion rate and morbidity in the studies of laparoscopic adjustable gastric banding for morbid obesity (published between May 2001-February 2004).

Author, Year Patients (N)	Mortality N (%)	Conversion N (%)	Post-operative morbidity (early)		Post-operative morbidity (delayed)		Total Morbidity (%)
			N (%)	Total (%)	n (%)	Total (%)	
Angrisani, 2003 1893	10 (0.53) [1]	59 (3.1)		0.0	Gastric pouch dilation: 93(4.8) Tube port failure: 79(4.1) Gastric erosion: 21(1.1)	10.2	10.2
Weiner, 2003 984	0	0	Gastric perforation: 1(0.1) Slippage: 1(0.1)	0.2	Band slippage: 32 (3.3) Band migration: 3 (0.3) Band rupture: 1(0.1) Port problems: 25(2.5)	6.2	6.4
Favretti, 2002 830	0	22(2.7)	Gastric perforation: 1(0.1) Gastric slippage: 1(0.1)	0.2	Stomach slippage: 17(2.0) Malpositioning: 9(1.1) Erosions: 4(0.5) Psychological intolerance: 3(0.4) HIV: 1(0.1) Reservoir leakage: 91(11.3)	15.1	15.3
Steffen, 2003 824	1 (0.12) [2]	43(5.2)	Gas embolism: 1(0.1)	0.1	Port problems: 18(2.2) Band intolerance: 58(7%)	9.2	9.3
Biertho, 2003 805	0	24(3.0)	Pneumonia: 8(1.0) Pulmonary embolism: 2(0.2) Port hematoma: 2(0.2) Acute abdomen: 1(0.1) Port infection: 1(0.1)	1.7	Band slipping: 11(1.4) Band leakage: 4(0.5) Band migration: 4(0.5) Band infection: 1(0.1) Band stenosis: 2(0.3) Band intolerance: 26(3.2) Tube port failure: 23(2.9) Gastrointestinal bleeding: 1(0.1) Incisional hernia: 3(0.5)	9.3	11.1
Belachew, 2002 763	1(0.1) [3]	10(1.3)		0.0	Tube port failure: 20(2.6) Gastric erosion: 7(0.9) Total food intolerance: 59(7.7) Pulmonary embolism 1(0.1)	11.4	11.4
Szold, 2002 715	0	6 (0.8)	Trocar site bleeding: 1(0.1) Band malposition and outlet obstruction: 5(0.7)	0.8	Band slippage or pouch dilation: 53 (7.4) Band erosion: 3(0.4) Port problems: 18(2.5) Wound infection: 3((0.4)	10.8	11.6
O'Brien, 2002 709 [4]	0	7 (1)	Port infection: 7(1.0) DVT: 1(0.1)	1.1	Slippage: 87(12.3) Tube problems: 26(3.7) Erosion into stomach: 20(2.8) Band leak: 1(0.1)	18.9	20.0
Ceelen, 2003 625	0	5(0.8)	Early slipping: 3(0.5) Wound infection: 12(1.9) Wound abscess: 2(0.3) Parietal hematoma: 6(1.0) Pneumothorax: 1(0.2) Urinary retention: 1(0.2) Severe allergic reaction: 2(0.3)	4.3	Acute dysphasia: 10(1.6) Slipping or pouch dilatation: 35(5.6) Incorrectly placed band: 2(0.3) Band leakage: 2(0.3) Fluid reservoir reoperations: 16(2.5) Incision hernia: 5(0.8) Esophagitis: 15(2.4) Esophageal dilatation: 7(1.1) Food impaction: 3(0.5)	15.2	19.5
Vertruyen, 2002 543	0? [5]	6(1.2)		0.0	Food intolerance: 24(4.6) Pouch dilation: 20(3.7) Psychological intolerance: 2(0.4) Band erosion: 5(1) Tube disruption: 15(2.8) Port leakage: 1(0.2)	12.3	12.3

Table 3: (Continued) Mortality, conversion rate and morbidity in the studies of laparoscopic adjustable gastric banding for morbid obesity (published between May 2001-February 2004).

Author, Year Patients (N)	Mortality N (%)	Conversion N (%)	Post-operative morbidity (early)		Post-operative morbidity (delayed)		Total Morbidity (%)
			N (%)	Total (%)	n (%)	Total (%)	
Zinzindohoue, 2003 500	0	12(2.4)	Perforation: 4(0.8) ARDS: 2(0.4) Slippage: 3(0.6) Atelectasis: 5((1)	2.8	Gastric necrosis: 1((0.2) Slippage: 40(8) Incision hernia: 3(0.6) Tube disruption: 3 (0.6) Port dysfunction: 33((6.6)	16.0	18.8
Mittermair, 2003 454	0	0	Pouch dilatation: 3(0.7)	0.7	Port disconnection: 28(6.2) Port infection: 5(1.1) Band leakage: 11(2.4) Pouch dilation: 6(1.3) Pouch hemorrhage: 1(0.2) Stomach perforation: 4(0.9) Band migration: 14(3.1)	15.2	15.9
Chevallier, 2002 400	0	12 (3)	Gastric perforation: 2(0.5) Pulmonary complications: 7(2.7) Slippage: 3(0.75)	3.0	Gastric necrosis: 1(0.25) Slippage: 31(7.75) Incisional hernia: 2(0.5) Port problems: 30(7.5)	16.0	19.0
Busetto, 2002 260	0	11(4.2)		0.0	Port problems: 62(23.8) Band related problems: 11(4.2)	28.1	28.1
Dukhno, 2003 250	0	10 (4)	Gastric perforation: 2(0.8) Bleeding: 5(2)	2.8	Band slippage: 13(5.2) Band erosion: 3(1.2) Tube disconnection: 5(2) Port infection: 4(1.6) Band problems: 1(0.4)	10.4	13.2
Mortele, 2001 218	0?[5]	Not reported	Misplacement of the band: 5(2.3)	2.3	Band slippage: 17 (7.8) Inversion of the access port: 3(1.4) Device leakage: 2(0.9) Gastritis: 7(3.2) Esophagitis: 11(5) Trapping of food in the stoma: 4(1.8)	20.2	22.5
Pontiroli, 2002 143	0?[5]	4(2.8)	0	0.0	Port disconnections: 4(2.8) Gastric slippages: 8(5.6)	8.4	8.4
Victorzon, 2002 110	0	2(1.8)	Fever: 3(2.7) Pneumonia: 2(1.8) Wound infection: 1(0.9) Urinary infection: 1(0.9) Unclear hypotonia: 1(0.9) Obstipation: 1(0.9) Hemorrhage: 1(0.9)	9.1	Slippage: 3(2.7) Band or port leaking: 5(4.5) Band erosion: 2(1.8) Infection: 1(0.9)	10.0	19.1
Fox, 2003 105	0?[5]	5(4.8)		0.0	Band slippage and dilatation: 3(2.9) Erosion: 3(2.9) Port tubing leakage: 3(2.9) Port infection: 4(3.8) Band removal: 5(4.8)	17.1	17.1
Weighted average [6] N=11131	**0.11 (0.02) [7]**	**2.18**		**1.0**		**12.5**	**13.5**

[1]: Perioperative: MI (5), Pulmonary embolism (2). Postoperative: Pulmonary embolism (1), bleeding (1), perforation (1).
[2]: Post-operative: Septic (1).
[3]: Perioperative: Pulmonary embolism (1).
[4]: Among 709 patients, 61 implants were made via laparotomy.
[5]: Presumed but not specifically recorded.
[6]: Weighted average mortality = Σ (mortality in each study x n of that study) divided by total N.
[7]: Weighted average mortality with exclusion of data of Angrisani.

Table 4. Complications (excluding intraoperative) of LAGB, grouped according to similarity of cost generating interventions in each of the reviewed studies (published between May 2001-February 2004).

Author (N)	Band Problems [1]	Tube/Port Problems [2]	Erosion to Stomach	Pneumonia /Pulmonary Embolism	Other infection	Gas Embolism	Hernia	Gastric Necrosis
Angrisani, 2003 1893	29	48	0	0	0	0	0	0
Weiner, 2003 984	38	25	0	0	0	0	0	0
Favretti, 2002 830	36	91	0	0	0	0	0	0
Steffen, 2003 824	61	56	0	0	0	1	0	0
Biertho, 2003 805	48	26	0	10	0	0	1	0
Belachew, 2002 763	80	20	0	1	0	0	0	0
Szold, 2002 715	70	0	0	0	3	0	2	0
O'Brien, 2002 709	88	33	20	1	0	0	0	0
Ceelen, 2003 625	51	18	0	0	14	0	5	0
Vertruyen, 2002 543	13	16	0	0	0	0	0	0
Zinzindohoue, 2003 500	58	28	0	0	0	0	3	1
Mittermair, 2003 454	38	33	4	0	0	0	0	0
Chevallier, 2002 400	36	30	0	7	0	0	2	1
Busetto, 2002 260	11	62	0	0	0	0	0	0
Dukhno, 2003 250	19	9	0	0	0	0	0	0
Mortele, 2001 218	23	3	0	0	0	0	0	0
Pontiroli, 2002 143	8	4	0	0	0	0	0	0
Victorzon, 2002 110	11	0	0	3	2	0	0	0
Fox, 2003 105	11	7	0	0	0	0	0	0
Total (N=11131)	**729 (6.55%)[3]**	**509 (4.57%)[3]**	**24 (0.22%)[3]**	**22 (0.20%)[3]**	**19 (0.17%)[3]**	**1 (0.01%)[3]**	**13 (0.12%)[3]**	**2 (0.02%)[3]**

[1]: Includes band intolerance, leak, pouch problem and slippage.
[2]: Includes leakage, breaks and misplacement.
[3]: %=n/N*100.

Table 5. Complications of LR-en-Y, grouped according to similarity of cost generating interventions in the review of Podnos [11] (excluding intraoperative events and perioperative haemorrhage).

Complications	Procedures (N1)	Complications (N2)	% (N2/N1x100)
Stomal stenosis	3464	164	4.73
Leak	3464	71	2.05
Bowel obstruction	3464	101	2.92
Ventral hernia	2958	14	0.47
Wound infection	3258	97	2.98
Pulmonary embolism	2651	11	0.41
Pneumonia	2075	3	0.14
Total	**21334**	**461**	**13.71**

Table 6. Comparison of outcomes of the LABG and LR-en-Y procedures.

OUTCOME	LABG (%)	LR-en-Y(%)
% EWL at 3 years	50.4[a]	69.0[b]
Mortality rate (procedure related)	0.11[d] (0.02[g], 0.05[b])	0.23[c]
Conversion rate	2.18[d]	2.2[c]
Complications requiring abdominal surgery [e]	6.55[f]	4.95 [c]
Complications requiring local surgery [e]	4.57 [f]	0.47
Complications requiring gastroscopy [e]	0.22 [f]	4.73 [c]
Infection	0.17 [f]	2.98[c]
Pneumonia/Pulmonary embolism	0.20 [f]	0.55 [c]
Other	0.15 [f]	

[a]: Based on weighted average of studies reported since May 2001 listed in table 2.
[b]: Based on Australian review [7].
[c]: Based on Podnos et al.[11]
[d]: Based on weighted average of studies reported since May 2001 listed in table 3.
[e]: Excluding intra-operative events and perioperative bleeding.
[f]: Based on weighted average of studies reported since May 2001 listed in table A1.
[g]: Weighted average excluding one outlier .See table 2.

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Appendix 1

Summary of HTA reports and most updated Cochrane review (listing assessments that included, or focused on, laparoscopic adjustable banding for severe obesity):

TITLE OF REPORT	AGENCY	DATABASES AND DATES SEARCHED	OBJECTIVE OF REVIEW	FINDINGS
Surgery for morbid obesity (Cochrane Review) [54].	Cochrane Library (Issue 1, 2003). Apr.2003	Data extracted by Cochrane report was up to Cot.2001. 18 randomized controlled trials involving 1891 peoples were included.	To assess the effects of surgery for morbid obesity on weight, comorbidities and quality of life.	There was only one randomized controlled trial (Nilsell 2001 [55]) comparing adjustable gastric banding with vertical banded gastroplasty and one RCT study (de Wit 1999 [56]) comparing open versus laparoscopic placement of adjustable silicone gastric banding.
Systematic review of laparoscopic adjustable gastric banding for the treatment of obesity [7]	Australian safety and efficacy register of new interventional procedures – surgical: June 2002	Medline: 1988-2001 Aug. EMBASE: 1988-2001 Aug. HealthStar: 1988-2001 Jun. Cochrane library: 2001 Issue 2 Current contents: 1993-2001 Aug.	"To assess the literature regarding the procedure of laparoscopic adjustable gastric banding for the treatment of obesity and make recommendations on the safety and efficacy of this technique"	"the evidence base was of average quality up to 4 years for laparoscopic adjustable gastric banding. Laparoscopic gastric banding is safer than vertical banded gastroplasty and Roux-en-Y gastric bypass, in terms of short-term mortality rates. Laparoscopic gastric banding is effective, at least up to 4 years, as are the comparator procedures. Up to 2 years the laparoscopic gastric band results in less weight loss than Roux-en-Y gastric bypass; from 2-4 years there is insufficient evidence to conclude that Roux-en-Y remains more effective than laparoscopic gastric banding. Long-term efficacy of laparoscopic gastric banding remains unproven and further evaluation by randomised controlled trials is recommended to define its merits relative to the comparator procedures."
The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation [57].	Health Technology Assessment NHS R&D HTA program July. 2002	BIOSIS Cochrane review Current controlled trials DARE EConLIT EMBASE Medline MRC trials database NHS EED AND HTA database	"To systematically review the clinical effectiveness and cost-effectiveness of surgery for the management of morbid obesity and to develop a cost-effectiveness model using the best available evidence to	"When compared with conventional treatment, surgery resulted in a significantly greater loss of weight (23-37 kg more weight), which was maintained at 8 years. As a consequence, there were improvements in QoL [quality of life] and co-morbidities associated with the loss of weight from surgery. Comparison of the different types of surgery showed that gastric bypass appeared more beneficial, with a greater weight loss (6-14 kg more weight) and/or improvements in co-morbidities and complications than either gastroplasty or jejunoileal bypass. Assessment of open versus laparoscopic gastric bypass and adjustable silicone gastric banding showed fewer serious complications with laparoscopic placement. Laparoscopic surgery had a longer operative time compared with open surgery, but

		PubMed National research register Science citation Index Searches up to 2001 Nov.	determine cost-effectiveness in a UK setting"	resulted in reduced blood loss, proportion of patients requiring intensive care unit stay, length of hospital stay, days to return to activities of daily living and days to return to work." - The authors caution that the costs in the report are based on several assumptions, that the evidence of clinical effectiveness varies between the different procedures, and that the costs reflect the UK setting. They concluded that "The total net costs of treating morbid obesity (over 20 years) through surgical procedures varied from £9,626.90 for vertical banded gastroplasty to £10,795.16 for silicone adjustable gastric banding…"
Laparoscopic adjustable gastric banding for clinically severe (morbid) obesity [58].	Alberta Heritage Foundation for Medical Research Dec. 2000	Medline EMBASE HTA EED DARE Health STAR National Guideline clearinghouse Cochrane reveiew Searches restricted to 1993-1999. Aug.	"Highlight evidence from published scientific literature regarding the safety, efficacy and effectiveness of the laparoscopic adjustable gastric band procedure" "Address issues of training, patient selection criteria and post-operative patient care" "Inform a decision whether LAGB surgery can safely be performed in this patient population outside a hospital setting"	"Whether LAGB [laparoscopic adjustable gastric banding] will replace current standard of care (Roux-en-Y gastric bypass) or become part of mainstream treatment for morbid obesity can only be determined by well designed studies reporting greater than five year outcomes of patients who have had the procedure."

A systematic review of the interventions for the prevention and treatment of obesity, and the maintenance of weight loss [59]	Center for reviews and dissemination: Research and development division of the department of health	Medline, EMBASE, DHSS-Data and other relevant data source. Searches up to the end of 1995	"To systematically assess the effectiveness of interventions designed to prevent and treat obesity/overweight, and maintain weight loss".	Does not include an analysis of the laparoscopic banding procedure.
Obesity – problems and interventions: a systematic review [3]. (only English summary available):	Swedish Council on Technology Assessment in Health Care. 2002.			The English summary does not include a detailed analysis of the laparoscopic banding procedure, but makes the following general conclusions: "Of the surgical methods used in Sweden, gastric bypass has the strongest scientific documentation and the best effect on weight reduction…In people with severe obesity, surgical treatment has positive, well-documented long-term effects on weight, quality of life, and morbidity from diabetes."
SAGES guidelines for laparoscopic and conventional surgical treatment of morbid obesity [60].	Society of American Gastrointestinal Endoscopic Surgeons, American Society for Bariatric Surgery. 2000.			"Bariatric surgery currently provides the only significant, sustained weight loss. Laparoscopic techniques, based on their "open" counterparts, are available. When performed by appropriately trained surgeons, laparoscopic approaches appear to hasten the patient's recovery and return to normal function. Experience and training in bariatric surgery, advanced laparoscopic surgery skills, and a commitment to long-term patient management are required."
Laparoscopic adjustable gastric banding for clinically severe obesity [61].	Canadian Coordinating Office for Health Technology Assessment (CCOHTA) Apr.2003	Pubmed Cochrane Library (Issue 1, 2003) CRD databases (HTA, DARE and NHS EED) (March 2003) HTA agencies (reports published since 1998)	Pre-assessment of the literature.	Long-term outcomes data on the effectiveness and safety of the laparoscopic adjustable gastric banding procedure is needed. The NICE guidance document recommends that hospitals wanting to offer surgery for morbid obesity maintain databases of outcomes and complications associated with the different procedures, and assessments of their impact on patient quality of life. There are a number of HTA agencies currently assessing this technology, and several have recently published assessments on surgical interventions for morbid obesity, therefore CCOHTA will not conduct an assessment on this topic at present

Appendix 2

Literature Search strategies

First step.

We searched the following websites using keywords

Obesity, morbid obesity, treatment for obesity, gastric banding.

- **Mexican Society of Obesity Surgery A.C.**
http://www.smco.org.mx/
- **Mexican Association of Laparoscopic Surgery**
http://www.amce.com.mx
- **American Society for Bariatric Surgery (ASBS)**
http://www.asbs.org/
- **International Federation for the Surgery of Obesity (IFSO)**
http://www.obesity-online.com/ifso/
- **Society of American Gastrointestinal Endoscopic Surgeons (SAGES)**
http://www.sages.org/
- **American College of Surgeons (ACS)**
http://www.facs.org/
- **European Association for Endoscopic Surgery (EAES)**
http://www.eaes-eur.org/
- **Society of Laparoendoscopic Surgeons (SLS)**
http://www.sls.org/
- **Obesity Online**
http://www.obesity-online.com/
- **American Diabetes Association (ADA)**
http://www.diabetes.org
- **American Obesity Association (AOA)**
http://www.obesity.org
- **American Society of Bariatric Physicians (ASBP)**
http://www.asbp.org
- **North American Association for the Study of Obesity (NAASO)**
http://www.naaso.org
- **The N.E.W. Program**
http://www.thenewprogram.com
- **Weight For Life**
http://www.weightforlife.com
- **Obesity Law and Advocacy Center**
http://obesitylaw.com
- **National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health**
http://www.nhlbi.nih.gov/
- **National Library of Medicine (NLM), National Institutes of Health**
http://www.nlm.nih.gov

Second step.

The following database or websites were searched using the following keywords individually or combined, without language restriction.

Keywords:

1. Gastric banding
2. Obese
3. Roux-en-Y gastric bypass
4. Lap-band
5. Quality of life
6. Efficacy
7. Complications

Databases

The Cochrane Library

DARE (http://www.york.ac.uk/inst/crd/)

DEC reports (http://www.doh.gov.uk/)

Trip database (http://www.tripdatabase.com/)

Medscape (http://www.medscape.com/px/urlinfo)

NHS – National Horizon Scanning Center

N.I.C.E. – National Institute for Clinical Excellence

Health Technology Assessment (HTA) websites:

CHSPR – Centre for Health Services and Policy Research (UBC) British Columbia

HSURC – Health Services Utilization and Research Commission (Saskatchewan)

ICES – Institute for Clinical Evaluative Sciences

MCHP – Manitoba Centre for Health Policy

INAHTA database – International Network of Agencies for Health Technology Assessment

AÉTMIS - Agence d'évaluation des technologies et des modes d'intervention en santé

AHFMR - Alberta Heritage Foundation for Medical Research

ASERNIP-S– Australian Safety & Efficacy Register of New Interventional Procedures - Surgery

ANAES - L'agence nationale d'accréditation et d'évaluation en santé

CAHTA - Catalan Agency for Health Technology Assessment and Research

CCOHTA – Canadian Coordinating Office for Health Technology Assessment

CÉDIT – Comité d'évaluation et de diffusion des innovation technologiques

CMT – Center for Medical Technology Assessment (Sweden)

DACEHTA – Danish Centre for Evaluation and Health Technology Assessment

DIMDI – German Institute of Medical Documentation and Information

DSI – Danish Institute for Health Services Research

FinOHTA – Finnish Office for Health Care Technology Assessment

ITA – Institute of Technology Assessment ((Austria)

MSAC – Medical Services Advisory Committee (Australia)

NCCHTA - National Coordinating Centre for Health Technology Assessment

NHS QIS - NHS Quality Improvement Scotland

SBU – The Swedish Council on Technology Assessment in Health Care

SNHTA – Swiss Network for Health Technology Assessment

TA-SWISS – Center for Technology Assessment

Third step.

We then searched the literature for individual articles published between May 2001 and February 2004 using the same keywords as above through PubMed and CISTI (National research council Canada).

Forth step.

Lastly, we carried out a manual search of certain journals listed below for publications between May 2001 and February 2004, again using the same key words.

Am J Clin Nutr	Am J Epidemiol
BMJ	Eur J Clin Nutr
Eur J Endocrinol	Int J Obes Relat Metab Disord
J Clin Endocrinol Metab	Lancet
N Engl J Med	Nutr Rev
Obes Res	Obes Surg

Appendix 3

Table A1. Costs related to operation and follow-up visits for laparoscopic adjustable gastric banding and laparoscopic Roux-en-Y gastric bypass (costs of complications excluded).

	LAGB (Unit Cost, $ x time)	**LR-en-Y (Unit Cost, $ x time)**
Operating[1]	1041 ($694 x 1.5h)	1388($694 x 2hs)
Recovery room[1]	124 ($31/h x 4hs)	124 ($31/h x 4hs)
Hospitalization[1]	420.34 ($420.34/day x 1day)	840.68 ($420.34/day x 2days)
Hotel and facility [2]	62.21 ($62.21/day x 1day)	124.42 ($62.21/day x 2days)
Lab (X-ray, blood test, etc) [3]	150	150
Pharmaceutical (drug cost only)[3]	80	80
Device [3]	4000 (Swedish band)	0
Disposables [4]	800	2000 [4]
Dietetics consultations [4]	500 ($100X5hs)	500 ($100X5hs)
Surgeon [3]	*(1,162)*	*(1,162)*
Anaesthetist [5]	*(120.5)*	*(120.5)*
Costs of operation to MUHC	**7,177.55**	**5,207.1**
Costs of operation (including professional)	**8,460.05**	**6,489.6**
2-year Follow-up		
Routine visit [6]		
Surgeon [7]	*(25.2) ($18X7X20%)*	*(126) ($18X7)*
Nursing	10.85 ($31X15m/60X7X20%)	54.25 ($31X15m/60X7)
Inflation adjustment in surgeon's office [6]		
Surgeon [7]	*(75.6) ($18X7X60%)*	
Nursing	32.55 ($31X15m/60X7X60%)	
Disposables [3]	84 ($20X7X60%)	
Inflation adjustment in radiology [6]		
Surgeon [7]	*(25.2) ($18X7X20%)*	
Radiologist [8]	*(123.2) ($88X7X20%)*	
Lab (technician)	11.2 ($32X15m/60X7X20%)	
Disposables [3]	28 ($20X7X20%)	
Costs of follow-up to MUHC	166.6	54.25
Costs of follow-up (including professional)	415.8	180.25
Total costs to MUHC	**7,344**	**5,261**
Total costs (including professional)	**8,876**	**6,670**

Professional charges, not paid by MUHC, shown in the italics.

[1]: Nursing cost only, does not include hotel cost and pharmacy cost. Department of Finance, MUHC.

[2]: Including housekeeping, food services, laundry and central supply room.

[3]: Dr. N. Christou.

[4]: "Proposal and business case to expand resources available to the bariatric surgery program of the division of general surgery, MUHC", appendix A.

[5]: "Medical Specialist's Manual", Regie de l'assurance maladie, Quebec. March. 2003. Code 5355.

[6]: Routine follow-up visits at 2wk, 4wk, 3mth, 6mth, 12mth, 18mth and 24mth. Total 7 visits within the first 2 years. 20% of these visits require no band adjustment, 60% require band adjustment carried out in the surgeon's office and 20% require band adjustment in Radiology (Dr. N. Christou, MUHC).

[7]: $18 for Quebec patient. $150 for non-Quebec patients.

[8]: "Medical Specialist's Manual", Regie de l'assurance maladie, Quebec. March. 2003. Code 8158.

Table A2: Cost-generating interventions related to conversion and complications (intra-operative excluded) of laparoscopic adjustable gastric banding.

Items	Intervention	Frequency (%)	Unit Cost (MUHC) ($)	Unit Cost (Including Professional) ($)	Total Costs (MUHC)[1] ($)	Total Costs (Including Professional) ($)
Conversion	Open laparotomy	2.18 [2]	1794.65 [4]	1818.75[4]	39.12	39.65
Band problems (Band intolerance, leak, pouch problem, and slippage)	Laparoscopic intra-abdominal surgical intervention	6.55[3]	5177.55[5]	6460.05 [5]	339.13	423.13
Tube/port problems (leakage, breaks, and misplacement)	Regional local surgical correction	4.57[3]	891.55 [6]	1527.8 [6]	40.74	69.82
Erosion to stomach	Endoscopic removal	0.22 [3]	15.5 [7]	113.7 [7]	0.03	0.25
Pneumonia/Pulmonary embolism	Hospitalization (assumed 4 days)	0.20 [3]	2080.2 [8]	2191.3 [8]	4.16	4.38
Gas embolism	Hospitalization (assumed 3 weeks)	0.01 [3]	10283.55 [9]	10717.55 [9]	1.03	1.07
Hernias	Surgical repair	0.12 [3]	891.55 [10]	1588.05 [10]	1.07	1.91
Gastric necrosis	Laparoscopic intra-abdominal surgical intervention	0.02 [3]	7177.55 [11]	8460.05 [11]	1.44	1.69
Total					**427**	**542**

[1]: Total cost = unit cost x frequency (%).
[2]: See table 3.
[3]: See table A1.
[4]: Assume: additional operating room 30 minutes ($694/h) and additional anaesthetist time 30 minutes ($12.05/unit x2units). Additional 3 days hospitalization (Dr. N. Christou, MUHC). [($420.34+$62.21) x 3 days].
[5]: Assume: cost the same as costs of operation listed in table 5, except that 50% of the interventions require a new device. (Dr. N. Christou, MUHC).
[6]: Assume: operation room 30m ($694/h). Recovery room 2hrs ($31/h). Hospitalization 1day ($420.34+$62.21). Surgeon ($576, code 5355). 50% of these require local aesthetic and 50% general Anaesthetist ($12.05/unit x 10units, code 5355).
[7]: Carried out in the endoscopy suit. No medication. One nurse, $31/hr. Procedure duration 15 min + 15 min preparation. No post-procedure care. Specialist ($50, code 0691). Anaesthetist ($12.05/unit x 4 units, code 0691).
[8]: Assume: average 4 days hospitalization [($420.34+$62.21) x 4 days]. Medication ($150), physician ($111:1main visit $54/visit code 0034, follow-up visits:3x$19/visit code 0039). Post discharge medication is not a hospital cost.
[9]: Assume: 3 weeks hospitalization [($420.34+$62.21) x 21 days]. Medication ($150). physician ($434: 1main visit $54/visit code 0034, follow-up visits: 20x$19/visit code 0039).
[10]: Operating room 30m ($694/h). Recovery room 2hrs ($31/h). Hospitalization 1day ($420.34+$62.21). Surgeon ($576, code 5355). Anaesthetist ($12.05x10, code 5355).
[11]: Assume cost same as costs of operation (see table 5).

Table A3. **Cost-generating interventions related to conversion and complications (intra-operative excluded) of laparoscopic Roux-en-Y gastric bypass.**

Items	Intervention	Frequency (%) (See Table A2)	Unit Cost (MUHC) ($)	Unit Cost (Including Professional) ($)	Total Costs (MUHC)[1] ($)	Total Costs (Including Professional) ($)
Conversion	Open laparotomy	2.2	1794.65 [2]	1818.75[2]	39.48	40.01
Stomal stenosis	Endoscopic dilatation	4.73	15.5 [3]	62.55 [3]	0.73	2.96
Leak/bowel obstruction	Abdominal surgical intervention via laparotomy	4.97	5207.1 [4]	6489.6 [4]	258.79	322.53
Ventral hernia	Correction, general anaesthesia	0.47	1856.65 [5]	2553.15 [5]	8.73	12.00
Wound infection	Outpatient	2.98	46.5 [6]	154.5 [6]	1.39	4.60
Pneumonia/Pulmonary embolism	Hospitalization (assumed 4 days)	0.55	2080.2 [7]	2191.3 [7]	11.44	12.05
Total					**321**	**394**

Frequency data from review paper by Podnos (et al. 2003)[11].

[1] Total cost = unit cost x frequency (%).

[2]: Assume: additional operating room 30 minutes ($694/2) and additional anaesthetist time 30 minutes ($12.05X2). Additional 3 days hospitalization [($420.34+$62.21) x 3 days] (Dr. N. Christou, MUHC).

[3]: Carried out in the endoscopy suit. No medication. One nurse, $31/hr. Procedure duration 15 min + 15 min preparation. No post-procedure care. Specialist ($35, code 0874). Anaesthetist ($12.05, code 0874).

[4]: Cost the same as operation cost listed in table A2. (Dr. N. Christou, MUHC).

[5]: Operation room 1h ($694/h). Recover room 2hrs ($31/h). Hospitalize 3day [($420.34+$62.21) x 3 days]. Surgeon ($576, code 5355). Anaesthetist ($120.5, code 5355). (Dr. N. Christou, MUHC).

[6]: Assume: 6 additional follow-up visits. Cost the same as cost of follow-up in table A2. (Dr. N. Christou, MUHC). Medication (antibiotic drug) for outpatients is not a hospital cost.

[7]: Assume: average 4 days hospitalization [($420.34+$62.21) x 4 days]. Medication ($150), physician ($111:1main visit $54/visit code 0034, follow-up visits:3x$19/visit code 0039). Post discharge medication is not a hospital cost.

Table A4 . The budget impact analysis of implanting laparoscopic adjustable gastric banding ($).

Items	Cost /Procedure		150 Procedures		300 Procedures		450 Procedures	
	MUHC	Including Professional	MUHC	Including Professional	MUHC	Including professional	MUHC	Including professional
Operation [1]	7,177.55	8,460.05	1,076,633	1,269,008	2,153,265	2,538,015	3,229,898	3,807,023
Follow-up [1]	166.6	415.8	24,990	62,370	49,980	124,740	74,970	187,110
Conversion & Complications [2]	427	542	64,050	81,300	128,100	162,600	192,150	243,900
Total costs	**7,771**	9,418	**1,165,673**	1,412,678	**2,331,345**	2,825,355	**3,497,018**	4,238,033

[1]: See table A1.
[2]: See table A2.

Table A5. The budget impact analysis of implanting laparoscopic Roux-en-Y gastric bypass ($).

Items	Cost /Procedure		150 Procedures		300 Procedures		450 Procedures	
	MUHC	Including Professional	MUHC	Including Professional	MUHC	Including professional	MUHC	Including professional
Operation [1]	5,207.1	6,489.6	781,065	973,440	1,562,130	1,946,880	2,343,195	2,920,320
Follow-up [1]	54.25	180.25	8,138	27,038	16,275	54,075	24,413	81,113
Conversion & Complications [2]	321	394	48,150	59,100	96,300	118,200	144,450	177,300
Total costs	**5,582**	7,064	**837,353**	1,059,578	**1,674,705**	2,119,155	**2,512,058**	3,178,733

[1]: See table A1.
[2]: See table A3.