The term "evidence-based medicine" was first coined by Sackett and colleagues as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."[1] The key to practicing evidence-based medicine is to apply the best current knowledge to decision-making for individual patients. Medical knowledge is continually and rapidly expanding and it is impossible for an individual clinician to read all the medical literature. For clinicians to practice evidence-based medicine, they must have the skills to read and interpret the medical literature so that they can determine the validity, reliability, credibility, and utility of individual articles. These skills are known as critical appraisal skills. Generally, critical appraisal requires that the clinician have some knowledge of biostatistics, clinical epidemiology, decision analysis, economics, and clinical knowledge.

Beginning October 2005 the American College of Surgeons will join with the Canadian Association of General Surgeons to sponsor a program entitled "Evidence Based Reviews in Surgery (EBRS)," supported by an educational grant from Ethicon Inc. and Ethicon Endo Surgery Inc. The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. During the academic year, 8 clinical articles are chosen for review and discussion. They are selected not only for their clinical relevance to general surgeons but also because they cover a spectrum of issues important to surgeons; for example, causation or risk factors for disease, naturally history or prognosis of disease, how to quantify disease (measurement issues), diagnostic tests and the diagnosis of disease, and the effectiveness of treatment. Both methodologic and clinical reviews of the article are performed by experts in the relevant areas and posted on the EBRS website. As well, a listserve discussion is held where participants can discuss the monthly article. Fellows and candidates of the College can access Evidence Based Reviews in Surgery through the American College of Surgeons website (www.facs.org). All journal articles and reviews are available electronically through the website. Currently we have a library of 40 articles and reviews that can be accessed at any time. Beginning in October, a new set of articles will be available each month until May. Surgeons who participate in the current (modules) packages can receive CME credits by completing a series of MCQ. For further information about EBRS the reader is directed to the ACS website or should email the administrator, Marg McKenzie at mmckenzie@mtsinai.on.ca.

In addition to making the reviews available through the ACS and CAGS websites, 4 the reviews are published in condensed versions in the *Canadian Journal of Surgery* and the other 4 will be published in the *Journal of the American College of Surgeons* each year. This month's article by Lindsay and colleagues entitled "A Randomized Controlled Trial of Fibrin Glue versus Conventional Treatment for Anal Fistula" is the first in the series for JACS. There are 13 articles that have been published previously in the *Canadian Journal of Surgery*. We hope readers will find EBRS useful in improving their critical appraisal skills and also keeping abreast new developments in general surgery. Comments about EBRS may also be directed to mmckenzie@mtsinai.on.ca.

REFERENCE

Evidence Based Medicine Working Group. Evidence-based medicine. JAMA 1992;268:2420–2425.

SELECTED ARTICLE

A Comparison of Diet and Exercise Therapy Versus Laparoscopic Roux-en-Y Gastric Bypass Surgery for Morbid Obesity: A Decision Analysis Model

Patterson EJ, Urbach DR, Swanstrom LL. J Am Coll Surg 2003;196(3):379–384.

Reviewed by

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ABSTRACT

Question: Does medical therapy (diet and exercise) or surgical treatment (laparoscopic Roux-en-Y gastric bypass) result in a longer life expectancy for morbidly obese individuals?

Design: A Markov decision analysis model.

Patient: A 45 years old woman with a body mass index (BMI) of 40Kg/m^2.

Treatment Alternatives: Diet and exercise therapy versus laparoscopic gastric bypass surgery.

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Outcome: Life expectancy.

Sources of Estimation for Probabilities and Utilities: Baseline mortality data were derived from published tables of vital statistics. The relative risks of death associated with obesity (relative to normal weight) were taken from a large cohort study. Other probabilities were derived from a limited number of patient series and randomized controlled trials. Utilities for all alive states were assumed to be 1.

Results: The undiscounted life expectancy after surgery was 69.7 years compared with 67.3 years from diet and exercise program (absolute increase in life expectancy of 2.4 years a relative increase in life expectancy of 10.8%). With 5% discontinuing, the increased survival decreased to .8 a year.

Sensitivity Analysis: One way sensitivity analyses were performed. The model was robust across all plausible ranges. Unless the risk of postoperative death was $>$ 10% and probability of successful weight loss was $<$ 4%, surgery was the dominant strategy.

Conclusions: Laparoscopic gastric bypass surgery for morbid obesity was associated with a substantially longer survival than diet and exercise therapy.

Commentary: There are few effective treatment options for morbid obesity. The likelihood of an obese patient achieving durable weight loss through dietary modifications and lifestyle changes is estimated to be 5% to 10%. Currently, bariatric surgery procedures based on restriction of caloric intake or induction of malabsorption appear to offer the highest probability of effective longterm weight loss. The laparoscopic Roux-en-Y bypass procedure is one of the most widely used procedures today, and was an appropriate choice for this analysis.

Although a prospective randomized trial of surgery versus diet and exercise is desirable, such a longterm study will likely not be completed. Most patients who come to be considered for surgery have already failed multiple attempts at dieting and may be unmotivated to participate in such a trial. Many patient series have demonstrated the effectiveness of bariatric surgery in achieving improved health-related outcomes. A recent retrospective study showed that obese patients with noninsulin dependent Type II diabetes mellitus managed with medical and dietary means had a 28% 6 years mortality although those treated with gastric bypass had a 9% mortality, including perioperative deaths. Although short and medium term health outcomes favor surgery at this time, there are currently insufficient data on longterm outcomes.

Multidisciplinary obesity management groups providing comprehensive dietary and lifestyle support for patients are desirable for all morbidly obese patients, but are often not available. Although many do well after surgery without a comprehensive obesity management team, there are data demonstrating that optimal weight loss and improvement in quality of life are achieved with a system based approach. The recent NIH funded multi-institutional collaborative group to study the disease of obesity and to develop and test treatment options for this condition should provide important new evidence based guidelines for management of these common and complicated patients in the years ahead.

Decision analysis is often performed when there are two competing treatment options and where are insufficient data from randomized controlled trials available on which to base treatment decisions. This decision analysis compared two strategies aimed at prolonging the lives of morbidly obese: a strategy of diet and exercise was compared to laparoscopic Roux-en-Y gastric bypass for a hypothetical 45 years old woman with a body mass index of 40. The strategy that they predicted would result in the longest life was considered to be the "best." They first estimated the probability of a body mass index (BMI) reduction from 40 to 30 for each strategy, and estimated average life-expectancy from US vital statistics tables. The risk of death from obesity was based on the population analysis summarized in the 1991 NIH consensus conference on gastrointestinal surgery for severe obesity.

In all computer modeling exercises, assumptions are made to simplify the analysis. It is important for the reader to carefully consider whether the assumptions seem reasonable because the modelers can obtain the desired result by the choice of their assumptions. It is preferable if data are drawn from multiple sources in the literature and then the data are synthesized. A number of assumptions in this decision analysis are concerning. An operative mortality of .4% was assumed which is the reported mortality in many series from high volume centers. Actual mortality rates based on hospital discharge data suggest annualized first year mortality rates in excess of 1% and mortality rates during a surgeon's initial learning curve may in fact be higher. Nonfatal complications of surgery were not considered to have any impact on quality of life, and the longterm

side effects of the surgery were assumed to have no effect on life-expectancy. It was assumed that a woman who went from a BMI of 40 to a BMI of 30 would have the same life expectancy as a woman who had a BMI of 30 throughout her life. These assumptions may or may not be true, and the authors made no attempt to justify them.

The authors also assumed that a weight loss of 60% of excess weight would be achieved by 80% of patients. This may not be achieved in all practices. The article does note that most reported bariatric surgery series are from academic medical centers where multidisciplinary bariatric surgery support services are available. The results from these series may not be generalizable to surgeons who practice in less structured programs or in those with lower numbers of patients operated on an annual basis.

The most troubling assumption in this study was that the utility for each health state other than death is 1. Utility measures are a way of assigning a quality-adjusting factor to raw survival data. In general, a year in perfect health is considered to have a value of 1, and death has a value of zero. It is hard to accept that any morbidly obese patient who undergoes surgery has a perfect quality of life. Although many patients undoubtedly prefer the quality of their lives after surgery than before, the requirement to eat frequent very small quantities and the inability to eat solid food for a prolonged period after surgery may make their quality of life less than perfect.

A Markov process, in which individuals cycle through the model every month, was used and is appropriate. The details are not important, but patients were defined as being in one of three health states: morbidly obese, not morbidly obese, or dead. Patients could be in either of the first two states in each cycle, but obviously could switch only once into the dead state. The baseline analysis predicted substantial improvement in life expectancy for the surgically treated patients. The gain in life expectancy was not trivial – approximately 2.4 years or 10.8% relative increase in life expectancy for this relatively youthful, low risk obese cohort (ie, 24.7 versus 22.4 years). But, when this was discounted to account for the fact that present health is valued above future health, the improvement in life-expectancy was 0.8 years. The problem with the assigned utility scores noted above becomes very important. If the utility for the surgical patients was .9 instead of the assumed 1.0, the quality-adjusted survival would be 22.2 years in the surgically treated group rather than 24.7 which are less than the non-surgical group, unless of course the utility scores for those patients were less than 1.0. In fact, it would take just a very small decrease in the utility score of the surgical group to completely change the outcomes of the analysis.

For the baseline analysis, the authors recognized that there is some uncertainty about the relative risk of death between those who lose weight and those who do not. They looked at the effect of varying the relative risk of death between 2 and 4. These values were derived from tables comparing the risk of death for the morbidly obese to that of individuals of ideal body weight. The model considered only weight reduction to a BMI of 30, which is well above ideal body weight, and thus, these rates may not be correct. It would have been better to use data concerning the age-specific relative risk of death of women who had a BMI of 40 compared to a BMI of 30 but these data may not be available.

The impact of uncertainty with regard to some variables was examined through the process of sensitivity analysis. In this process, the value of each variable is changed one at a time and the calculations repeated. For example, the authors explored whether an increase in the operative mortality would change the outcomes of the analysis. They found that surgery was the best option unless the operative mortality was greater than 10%, or if the probability of weight loss after surgery was less than 4%. Both of these are well outside clinically probable values, so the result favoring surgery is robust to a one-way sensitivity analysis. Unfortunately, a sensitivity analysis was not performed varying the utility values. It is hard to understand why this was not done because, as noted previously, it appears that a small change in the utilities could alter the results of the analysis.

This study demonstrates how decision analysis can be used to help us answer questions that cannot be readily answered using randomized trials. Results from many existing patient series can be used systematically to develop computer models to predict the relative merits of alternative treatment options. The results of this study demonstrate that laparoscopic Roux-en-Y bypass is probably superior to any other option reasonably available today for the treatment of morbid obesity. The significant limitations of the analysis are the failure to model the short and long-term complications of the surgery, and the assump-

tion that all morbidly obese patients who are not dead are in perfect health.

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