

insurer [University of Pennsylvania Medical Center Health Plan] and the providers of bariatric surgical services). There is a similar program in Washington state, which is a joint venture of commercial insurers, state purchasers of health care, and Medicaid.<sup>16</sup> This “power of the payer” is currently being used to fund registries of bariatric surgical care aimed at assessing quality of care, but may some day be used to address some of the more fundamental questions in the arena of bariatric surgery.

Only through a better understanding of both the mechanism of these procedures and their overall effect on patients and the health care system will physicians and the public come to appreciate the appropriate role of bariatric surgery in the care of patients with morbid obesity and those living with the complications of obesity.

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#### REFERENCES

1. Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. *JAMA*. 2004;292:1724-1737.
2. Sugerman HJ, Londrey GL, Kellum JM, et al. Weight loss with vertical banded gastroplasty and Roux-Y gastric bypass for morbid obesity with selective versus random assignment. *Am J Surg*. 1989;157:93-102.
3. Randomised trial of jejunoileal bypass versus medical treatment in morbid obesity: the Danish Obesity Project. *Lancet*. 1979;2:1255-1258.
4. O'Brien PE, Laurie C, Skinner S, Proietto J, Strauss B. A randomised controlled trial of medical versus surgical therapy in the management of obesity. *Obes Res*. 2004;12:A33.
5. Kral JG, Dixon JB, Horber FF, et al. Flaws in methods of evidence-based medicine may adversely affect public health directives. *Surgery*. 2005;137:279-284.
6. Fierro M, Lightsey D; for the Council of State Governments' Healthy States Initiative. Beyond cost containment: state policies that support health care solutions for obesity. Available at: <http://www.healthystates.csg.org/NR/rdonlyres/02D483E7-583D-433C-9E30-DAA2E429E38E/0/aobeyondcosts.pdf>. Accessibility verified September 30, 2005.
7. Zingmond DS, McGory ML, Ko CY. Hospitalization before and after gastric bypass surgery. *JAMA*. 2005;294:1918-1924.
8. Meguid MM, Ramos EJ, Suzuki S, et al. A surgical rat model of human Roux-en-Y gastric bypass. *J Gastrointest Surg*. 2004;8:621-630.
9. O'Brien PE, Dixon JB, Brown W. Obesity is a surgical disease: overview of obesity and bariatric surgery. *ANZ J Surg*. 2004;74:200-204.
10. Sjostrom L, Lindroos AK, Peltonen M, et al; Swedish Obese Subjects Study Scientific Group. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. *N Engl J Med*. 2004;351:2683-2693.
11. Schauer P, Ikramuddin S, Hamad G, Gourash W. The learning curve for laparoscopic Roux-en-Y gastric bypass is 100 cases. *Surg Endosc*. 2003;17:212-215.
12. Grady D. Exchanging obesity's risks for surgery's. *New York Times*. October 17, 2000;Health section.
13. Gastrointestinal surgery for severe obesity: Proceedings of a National Institutes of Health Consensus Development Conference. *Am J Clin Nutr*. 1992;55(2 suppl):487S-619S.
14. Belle S. The NIDDK Bariatric Surgery Clinical Research Consortium. *Am Soc Bariatric Surg*. 2005;1:145-147.
15. Longitudinal Assessment of Bariatric Surgery Web site. Available at: <http://www.edc.gsph.pitt.edu/labs/>. Accessibility verified September 29, 2005.
16. Surgical Clinical Outcomes Assessment Program (SCOAP). Available at: <http://www.wsha.org/meetings/presentations/SCOAPFinal.ppt>. Accessibility verified September 27, 2005.

#### EDITORIALS

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## Weighing In on Bariatric Surgery Procedure Use, Readmission Rates, and Mortality

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**I**N RECENT YEARS, THERE HAS BEEN A DRAMATIC INCREASE in the number of bariatric surgical procedures performed in the United States and worldwide.<sup>1-4</sup> This increase in bariatric surgery has occurred as a consequence of multiple factors. First, the increased prevalence of obesity among both children and adults in the United States has received much publicity in the medical community, media, government, and the population in general. Despite this attention and multiple calls for action at various levels, the obesity epidemic is progressive.<sup>5</sup> Of particular concern is the alarming increasing prevalence of obesity among chil-

dren,<sup>5</sup> suggesting that the epidemic will worsen before it improves. Furthermore, it is estimated that at least 5% of the adult population in the United States experiences severe obesity, defined as a body mass index (BMI) greater than 40.<sup>5</sup>

Second, multiple epidemiologic studies have demonstrated that increasing BMI is a causative factor in many life-threatening comorbidities, including type 2 diabetes, cardiovascular disease, and cancer. Body mass index has been established as an independent risk factor for premature mortality.<sup>6</sup> As a result of these convincing studies, calculation of all patients' BMI as a part of their health maintenance is

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**See also pp 1903, 1909, and 1918.**

recommended, with institution of weight loss therapy for all patients who have a BMI of more than 25.<sup>7</sup>

Third, combinations of diet therapy, behavior modification, prescribed exercise programs, and pharmacotherapy in various combinations are widely used and generally accomplish some degree of weight loss. Unfortunately, the weight loss is generally transient, particularly in patients with severe obesity.<sup>8,9</sup> The typical patient who presents for surgical evaluation has participated in multiple combinations of these interventions with variable success, with weight regain commonly occurring after treatment cessation. In contrast, several reports of bariatric surgical patients with follow-up for 10 years or longer have demonstrated sustained weight loss sufficient to favorably affect the occurrence of obesity-related comorbidities, particularly type 2 diabetes.<sup>8,10</sup>

Fourth, the emergence of Internet communication among patients who have undergone bariatric surgery has widely disseminated information regarding their successful outcomes.<sup>11</sup> In addition, the advent of the laparoscopic approach to bariatric surgery has led to more rapid recovery, and the development of multiple high-volume bariatric surgical centers has been associated with improved patient safety.<sup>12-14</sup> Highly publicized successful laparoscopic bariatric surgery in celebrities has also contributed to public interest in these procedures.

Despite this exponential increase in the performance of bariatric surgical procedures, current estimates indicate that as little as 0.6% of patients who qualify for bariatric surgery undergo a bariatric surgical procedure in any given year.<sup>15</sup> Thus, the vast majority of adult patients in the United States with morbid obesity do not undergo this treatment. On a practical level, patients who present to their primary care physician with a breast mass or symptomatic gallstones are routinely referred for surgical consultation. In contrast, patients who present to their primary care physician with severe obesity are routinely entered into medical treatment programs even if such programs have failed on multiple previous occasions.

The explanation for the disparity between the recognition of the health consequences of severe obesity and the application of the only effective intervention or treatment may include several factors. For instance, until fairly recently, only a relatively small number of surgeons were routinely performing bariatric procedures. However, the surgical community has responded with the development of multiple surgical training programs for both practicing surgeons and surgical trainees. As a result, surgical capacity has greatly increased and is no longer the limiting factor in some environments. In addition, health care funding and reimbursement issues constitute a barrier to access for many severely overweight patients who desire evaluation for possible bariatric surgery, especially those who are uninsured and have low income. Moreover, both physicians and patients are aware of the potential for adverse events following elective bariatric surgical procedures, which may pro-

duce disability, mortality, and high cost. The same communication system that informs patients of the success achieved by bariatric surgery also provides anecdotal cases of adverse outcomes to both physicians and patients and their families.<sup>11</sup> Also, the widespread perception that weight loss achieved by bariatric surgery may be transient, as is weight loss with medical therapy, is perpetuated by poor long-term results for certain bariatric surgical procedures used in the past; some of these procedures have largely been abandoned. However, weight loss following currently used procedures, predominantly gastric bypass, may occasionally result in weight regain despite the favorable outcomes shown for the majority of the surgical population.<sup>10</sup>

Three reports<sup>1-3</sup> in this issue of *JAMA* address many of these issues. These studies present data from population-based administrative databases to examine many important questions surrounding bariatric surgery.

Using the Nationwide Inpatient Sample (NIS) database, Santry and colleagues<sup>1</sup> estimate the national changes in bariatric surgery that occurred in 1998-2003. Gastric bypass remains the predominant bariatric surgical procedure despite the increasing popularity of new procedures, such as laparoscopic adjustable gastric banding and sleeve gastrectomy. While the number of bariatric surgery procedures has increased almost 10-fold during this interval, the length of stay and complications have declined and inpatient mortality has remained stable. The mortality using the NIS database was 0.1% to 0.2%; this remarkably low mortality rate presumably underestimates total postoperative mortality, as this database detects only deaths that occurred during the hospitalization in which the operative procedure was performed.

This rapid growth in bariatric procedure use and improvement in outcomes was achieved in a steadily sicker population, as demonstrated by the Charlson Comorbidity Index scores. However, given the high proportion of clinically demonstrated comorbidities in the morbidly obese population, it is apparent that the Charlson index does not accurately reflect the degree of comorbidity in the NIS study population, in which 64% had no comorbidity.<sup>16</sup> This time-trend analysis also notes that fewer men and Medicaid beneficiaries underwent bariatric surgery. Morbid obesity is somewhat less common in men than in women, and men may not seek surgical intervention as frequently as women due to sex disparities of access to care and greater social acceptance of obesity in men. In addition, impaired quality of life from obesity appears to affect women to a greater extent than men.<sup>17</sup> Medicaid utilization is presumably low due to decreased reimbursement for these patients as well as due to higher risk of complications, which may make surgeons reluctant to provide surgical care.<sup>18</sup>

In the second study in this issue, Zingmond and colleagues<sup>2</sup> used a California database that tracks all hospitalizations and has sufficient identifiers to allow cross-reference with the California death statistical master file.<sup>2</sup> Thus, data regarding all hospitalizations including rehospitaliza-

tions following Roux-en-Y gastric bypass surgery and postoperative deaths from all causes and settings were identifiable. Zingmond et al reported a total mortality rate at 30 days of 0.33% for gastric bypass patients. This figure closely corresponds to the 0.5% mortality rate for gastric bypass surgery recently reported in a review by Buchwald et al.<sup>19</sup> These data contrast with the 1.9% mortality at 30 days for Washington State reported by Flum et al using similar methods.<sup>20</sup> The explanation for the differential mortality rate reported for these 2 states is not known but presumably involves the relatively higher number of cases performed in California and possibly a greater tendency to concentrate the caseload in centers that perform high volumes of bariatric procedures.<sup>12,20</sup>

Zingmond et al also report a substantial increase in the frequency of hospitalizations in the first year following gastric bypass surgery compared with the year prior to gastric bypass surgery (19.3% vs 7.9%, respectively). Among patients with complete 3-year follow-up, a mean of 8.4% were admitted the year before gastric bypass surgery, whereas 20.2% were admitted the year after, 18.4% in the second year, and 14.9% in the third year after gastric bypass. Analysis of the reasons for these hospitalizations suggests that hospitalizations prior to gastric bypass were generally for treatment of obesity-related disease, whereas following gastric bypass, early and late complications of the procedure accounted for rehospitalization. The requirement for such rehospitalizations is concerning because it reflects postoperative complications and indicates that total costs of health care among patients undergoing bariatric procedures may be increased following operation.

Several factors may have contributed to increased rates of postoperative hospitalization that may not be sustained in the future. Zingmond et al note that patients undergoing operation by high-volume surgeons experience fewer postoperative rehospitalizations. Another ameliorating factor includes technical innovations such as division of the stomach resulting in fewer gastric revisions, as well as the laparoscopic approach that reduces wound infections, pulmonary complications, and incisional hernias.<sup>21</sup> Many of the complications that necessitate rehospitalization, such as early postoperative dehydration, anastomotic stricture, or ventral hernia are closed-ended events that have definitive resolution. This is reflected by a progressively lower rate of readmission in each of the 3 years following operation. The need to resolve these complications often does not affect the long-term result with regard to weight loss, diminished comorbidities, lower mortality risk, and associated long-term cost savings. Another factor that can influence preoperative and postoperative admission rates may be improved postoperative access to care for morbidly obese patients, who often do not receive necessary care preoperatively.<sup>22</sup>

In the third article in this issue, Flum and colleagues<sup>3</sup> report the mortality among Medicare beneficiaries undergoing bariatric surgery. Their finding of a 30-day mortality rate of 2.0% and a 1-year mortality rate of 4.6% is higher than has been reported for the general population.<sup>19</sup> The 30-day

mortality is presumably predominantly related to postoperative complications. The 1-year mortality rate is less clearly related to the operative procedure because the "all-cause" rate of death at 1 year may be related to preexisting disease or an unrelated cause. Nevertheless, the mortality risk in Medicare beneficiaries is clearly increased, indicating that this patient population is at increased risk. Approximately 90% of these Medicare beneficiaries were younger than 65 years of age, indicating that their Medicare eligibility most likely arose from a declaration of permanent and total disability. It is therefore reasonable to assume that this population has a greater burden of associated disease that contributes to this mortality rate. To date, a method for measuring the disease burden of morbidly obese patients specifically and for relating these obesity-related comorbidities to operative mortality has not been developed but is clearly needed. Of greater methodologic concern in the study by Flum et al is the inability of the Charlson index to detect comorbidity in the disabled or elderly population.

Flum et al also report that the volume of surgery performed is directly correlated with mortality risk. Thus, surgeons with a higher procedure volume among Medicare patients appeared to have lower postoperative mortality rates. While it is unlikely that any of the specific surgeons limited their activity to Medicare beneficiaries, the number of Medicare beneficiaries cared for by a given surgeon is probably a reflection of the total bariatric surgical experience of that surgeon. In addition, the fact that these Medicare patients present the highest risk of postoperative mortality should not be taken as a statement that bariatric surgery should not be offered to such higher-risk patients. These patients may also represent the potential greatest benefit associated with major lasting weight loss given their associated disease burden.<sup>18</sup>

These studies contribute important information regarding morbid obesity and its treatment. Morbid obesity is a significant health concern and bariatric surgery offers a potentially effective and enduring treatment for weight reduction. Bariatric surgery results in long-term weight loss, helps resolve comorbidities, provides a survival benefit,<sup>8,10,23</sup> and has increased substantially as a direct consequence of its success in treating morbid obesity. These studies demonstrate that there are vulnerable patient populations and potential additional costs associated with surgery but suggest that surgical volume helps mitigate these risks and costs. Bariatric surgery may be a potentially life-saving intervention in the right patients and in the right surgeons' hands. The studies presented in this issue indicate that experience and technique count.

These 3 studies also demonstrate both strengths and weaknesses of administrative claims data. Even though large numbers of patients are available, some needed information is simply not present in these claims data sets. These articles underscore the compelling need to have a validated bariatric-specific severity of illness scale to fully define patient surgical risk. Prospective, clinically derived databases for bariatric surgical outcomes are also required to provide a vehicle for qual-

ity improvement, much like current systems for coronary artery bypass graft surgery established by the Society for Thoracic Surgeons.<sup>24</sup> Surgical societies including the American Society for Bariatric Surgery, the American College of Surgeons, and the Society of American Gastrointestinal Endoscopic Surgeons all have recognized the need for data collection and quality improvement with programs in place.<sup>25-27</sup> These data collection efforts will require effort, dedication, financial support, and cooperation to fulfill these goals.

Given that obesity is a societal concern, there must be societal solutions and perspective. Prevention initiatives, medical alternatives, and new technologies may emerge in the future to help combat obesity. However, bariatric surgery today remains a fundamental therapy for morbidly obese patients. The studies by Santry et al, Zingmond et al, and Flum et al must be seen as opportunities for improvement in bariatric surgery, not as support for exclusionary practices by payors for patients in dire need. Instead, bariatric surgeons must meet the challenge of safely and efficiently providing this essential therapy for the most imperiled patients.

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#### REFERENCES

- Santry HP, Gillen DL, Lauderdale DS. Trends in bariatric surgical procedures. *JAMA*. 2005;294:1909-1917.
- Zingmond DS, McGory ML, Ko CY. Hospitalization before and after gastric bypass surgery. *JAMA*. 2005;294:1918-1924.
- Flum DR, Salem L, Brockel Elrod J, Dellinger EP, Cheadle A, Chan L. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. *JAMA*. 2005;294:1903-1908.
- Steinbrook R. Surgery for severe obesity. *N Engl J Med*. 2004;350:1075-1079.
- Hedley AA, Ogden CL, Johnson CL, et al. Prevalence of overweight and obesity among US children, adolescents, and adults, 1999-2002. *JAMA*. 2004;291:2847-2850.
- Calle EE, Thun MJ, Petrelli JM. Body-mass index and mortality in a prospective cohort of US adults. *N Engl J Med*. 1999;341:1097-1105.
- US Preventive Services Task Force (USPSTF). Screening for obesity in adults. Available at: <http://www.ahrq.gov/clinic/uspstf/uspsobes.htm>. Accessed September 18, 2005.
- Sjostrom L, Lindroos AK, Peltonen M, et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. *N Engl J Med*. 2004;351:2683-2693.
- Li Z, Maglione M, Tu W, et al. Meta-analysis: pharmacologic treatment of obesity. *Ann Intern Med*. 2005;142:532-546.
- Pories WJ, MacDonald KG Jr, Morgan EJ, et al. Surgical treatment of obesity and its effect on diabetes: 10-y follow-up. *Am J Clin Nutr*. 1992;55:582S-585S.
- Hamoui N, Lake J, Beart R, et al. Patterns of Internet use: bariatric versus colorectal patients in a private institution *J Am Coll Surg*. 2004;199:223-228.
- Liu JH, Zingmond D, Etzioni DA, et al. Characterizing the performance and outcomes of obesity surgery in California. *Am Surg*. 2003;69:823-828.
- Courcoulas A, Schuchert M, Gatti G, Luketich J. The relationship of surgeon and hospital volume to outcome after gastric bypass surgery in Pennsylvania: a 3-year summary. *Surgery*. 2003;134:613-621.
- Nguyen NT, Paya M, Stevens CM, Mavandadi S, Zainabadi K, Wilson SE. The relationship between hospital volume and outcome in bariatric surgery at academic medical centers. *Ann Surg*. 2004;240:586-593.
- Encinosa WE, Bernard DM, Steiner CA, Chen CC. Use and costs of bariatric surgery and prescription weight-loss medications. *Health Aff (Millwood)*. 2005;24:1039-1046.
- Schauer PR, Ikramuddin S, Gourash WC, Ramanathan R, Luketich J. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. *Ann Surg*. 2000;232:515-529.
- Friedman MA, Brownell KD. Psychological correlates of obesity: moving to the next research generation. *Psychol Bull*. 1995;117:3-20.
- Martin LF, Tan TL, Holmes PA, et al. Preoperative insurance status influences postoperative complication rates for gastric bypass. *Am J Surg*. 1991;161:625-634.
- Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. *JAMA*. 2004;292:1724-1737.
- Flum DR, Dellinger EP. Assessing the impact of bariatric surgery on survival. *J Am Coll Surg*. 2004;199:543-551.
- Puzziferri N, Austrheim IT, Wolfe BM, et al. Three-year follow-up of a prospective randomized trial comparing laparoscopic versus open gastric bypass. *Ann Surg*. In press.
- Yancy WS, Olsen MK, Curtis LH. Variations in coronary procedure utilization depending on body mass index. *Arch Intern Med*. 2005;165:1381-1387.
- Christou NV, Sampalis JS, Liberman M, et al. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. *Ann Surg*. 2004;240:416-423. discussion 423-414.
- Ferguson TB, Coombs LP, Peterson ED. Preoperative  $\beta$ -blocker use and mortality and morbidity following cabg surgery in North America. *JAMA*. 2002;287:2221-2227.
- Surgical Review Corporation. Bariatric Surgery Centers of Excellence Program. Available at: <http://www.surgicalreview.org/>. Accessed September 18, 2005.
- American College of Surgeons. Bariatric Surgery Center Network Accreditation Program. Available at: <http://www.facs.org/cqi/bscn/>. Accessed September 18, 2005.
- Society of American Gastrointestinal Endoscopic Surgeons. SAGES Outcomes Initiative. Available at: <http://www.sages.org/outcomes.html>. Accessed September 18, 2005.

## Antipsychotic Drugs in Dementia What Should Be Made of the Risks?

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THE INTRODUCTION OF THE FIRST ANTIPSYCHOTIC DRUG, chlorpromazine, into clinical practice more than 50 years ago revolutionized psychiatry and neurology.<sup>1</sup> The efficacy of this drug and other drugs in the phenothiazine class demonstrated that a disease considered a "mental illness" could respond to a biologically mediated

therapy and heralded the introduction of other neuromodulating therapies such as levodopa for Parkinson disease.

However, since their introduction, the phenothiazines and other antipsychotic neuroleptic agents have raised challenging questions about their adverse effects and toxic effects. Skeptics of the effectiveness of antipsychotic drugs in schizophrenia suggested that sedation rather than a direct

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See also p 1934.