



ASMBS Summary and Implications of Long-term Mortality Studies for Bariatric Surgery in NEJM Aug 23, 2007

Two landmark studies published in Thursday's New England Journal of Medicine showed a significant survival benefit for people who have bariatric surgery. These studies, along with many others, should resolve any lingering questions about the benefits and risks of bariatric and metabolic surgery. Health care policy that restricts access to bariatric surgery, in light of these studies and what we have seen in our own practices for years, has deadly consequences. Insurers can no longer deny this lifesaving surgery and we believe we now have the momentum and the irrefutable evidence to force reconsideration of outdated and dangerous health care policy.

Below is a summary of these important studies.

Sjöström L, Narbro K, Sjöström CD, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. *N Engl J Med* 2007;357:741-52.

Adams TD, Gress RE, Smith SC, et al. Long-term mortality after gastric bypass surgery. *N Engl J Med* 2007;357:753-61.

Sjöström et al. conducted a prospective, controlled study of bariatric surgery, the Swedish Obese Subjects (SOS) study in which severely obese patients (male > BMI 34 and female BMI > 38) desiring surgery were matched with equally obese patients not desiring surgery. There were 2010 patients who had surgery including vertical banded gastroplasty (68%), gastric banding (19%) and Roux-en-Y Gastric Bypass (13%) and 2037 who had no surgery but standard medical weight loss treatment. At 10 years, weight loss ranged from 14 to 25% of initial weight in the surgery group compared to 2% in the control group. In the surgery group there was a 29% reduction in the adjusted hazard ratio for death after an average follow up of 10.9 years with a 99.9% follow-up rate.

Adams et al. conducted a retrospective cohort study with controls obtained from driver's license records that were matched to patients who had undergone gastric-bypass surgery. In this study, deaths from all causes were reduced by 40%, from diabetes 92%, from coronary artery disease by 56%, and from cancer by 60%.

Significance of Studies

1) Both studies are well designed with appropriate control groups. The SOS study is the only prospective, controlled study in the literature with sufficient power to determine mortality reduction. Both studies are among the most important studies in bariatric surgery literature because they address the most important outcome –long-term survival.

2) Both studies corroborate findings of retrospective studies by Pories, Flum and Christou that demonstrated significant mortality reduction associated with bariatric surgery (gastric bypass). These previous studies were criticized by some authorities because of inadequate control groups or flaws in study design. The high quality of the Sjostrom and Adams studies should dispel any major criticism in design or methodology.

3) Both studies provide extremely strong evidence of health improvement and mortality reduction after bariatric surgery. Furthermore, both studies predated major advances in bariatric surgery, especially the advent of laparoscopic surgery. Survival benefit may likely be even greater today.

4) The 29-40% mortality reduction resulting from bariatric surgery is comparable to or exceeds major advances in cardiology over the last decade including the introduction of statins, antihypertensive agents and aspirin.

5) The most notable reductions in mortality included diabetes related mortality reduction (92%) and cancer (60%) and coronary artery disease (56%).

6) Although obesity has been linked to many cancers including breast, colon, prostate, and esophageal cancer, the Adams study and the Christou study are the first to show a reduction in cancer mortality with bariatric surgery.

Impact of Studies

- 1) Both studies support the concept adopted by CMS that obesity (100 million Americans) and particularly severe obesity (15 million Americans) is a disease and a lethal disease.
- 2) Both studies dispel the notion that bariatric surgery is cosmetic surgery– it saves lives. Even though CMS mandated coverage in Feb 2006, most insurance companies today still do not cover bariatric surgery as part of the standard benefit package. Many insurance carriers that do cover bariatric surgery place non-evidence-based barriers to discourage or delay patients from acquiring surgical treatment. The results of these 2 studies suggest that more health insurance companies are likely to cover bariatric surgery. The weight of evidence of these 2 studies and other supportive evidence must support the contention that it is unethical for insurance carriers to deny patient access to bariatric surgery.
- 3) Both studies dispel the notion that weight loss is temporary. The SOS study in particular indicates significant long-term weight loss up to 15 years with 99.9% follow-up.
- 4) Both studies dispel the notion that bariatric surgery is dangerous. With operative mortality rates below 1%, obesity is far more dangerous than bariatric surgery. The AHRQ report of Jan 2007 indicated that mortality rates for bariatric surgery between 1998 and 2004 fell by 78%. The ASMBS quality initiative known as Bariatric Surgery Center of Excellence has set high quality standards for hospitals and surgeons performing bariatric surgery. To date, this effort has resulted in certification of over 250 hospitals and nearly 500 surgeons nation-wide as participating members of a Bariatric Center of Excellence.

- 5) The significant mortality reduction identified in these studies raises the issue of potential mortality benefit of surgery in patients with BMI < 35. A reassessment of standard indications for bariatric surgery based primarily on BMI and exclusion of patients with BMI < 35 should be conducted by a multidisciplinary panel of experts.
- 6) Both studies raise many unanswered and relevant clinical questions:
 - a. How much weight needs to be lost to achieve a significant mortality reduction?
 - b. Are there factors other than weight loss that might account for the survival benefit?
 - c. How do these operations cause long-term weight loss?
 - d. What are the relative risks and benefits of each operation and what guides should surgeons use to match specific operations with patient goals?
- 7) More government-supported research, specifically well designed clinical trials, should commence to address the important issues raised by these 2 studies. The US government has invested relatively very little in evaluation of obesity treatment in general and even less for bariatric surgery.
- 8) Prevention: Although bariatric surgery has been proven to be effective treatment for severe obesity, the U.S. government, health care providers, civic leaders, and policy makers must place more focus on prevention in order to reduce the impending burden of obesity for generations to come.