Expect to see more scrutiny of bariatric surgery

After rapid growth, obesity surgery is facing questions about costs and complications. Are too many hospitals doing bariatric surgery without enough patient follow-up? Are some surgeons performing procedures before they have enough experience?

A New Mexico newspaper reported in April on three lawsuits against the University of New Mexico Medical Center in Albuquerque because of weight-loss surgery. One involved a 500-pound former football player who died after surgery at age 25. In another case, a 51-year-old nurse with rheumatoid arthritis died after surgery to help her lose some of her 429 pounds.

The May 4 *New York Times* tells about Linda Culpepper, who sought care at Vanderbilt after weight-loss surgery left her with life-threatening malnutrition. Her hair was falling out, her skin was flaking, and her muscles were so wasted she could hardly walk. A lung specialist later said Culpepper should not have been cleared for surgery because of the state of her lungs. She said the small hospital in Georgia where she had her operation did not offer a support group, and she had only one meeting with specialists before her procedure.

Among other issues:
- growing skepticism by insurers
- the high cost of the surgery and related care, which runs from $20,000 to $50,000
- whether patients can keep the weight off long term.

More than 140,000 obesity procedures are expected to be performed this year, up from about 30,000 in 1998.

**Pullback by payers**

UnitedHealthcare, the nation's largest health insurer, has stopped paying for weight-loss operations, as has Humana, according to the March 29 *Los Angeles Times*. Blue Cross and Blue Shield of Florida said it will stop in January. Without insurance, few patients could afford the cost.

A spokeswoman for America's Health Insurance Plans, a trade group, said companies are concerned about the high costs of surgery and the fact that some hospitals and doctors are performing it without the proper qualifications and equipment.

In response, advocates of obesity surgery are lobbying state legislatures to pass bills mandating coverage for weight-loss surgery.

**Demand for data**

Though surgery has proven to be the most effective therapy for morbid obesity, there's a call for more evidence on the risks and long-term weight control. Patients who don't get the proper follow-up may learn to out-eat the surgery, negating its benefits.

On the plus side, there is strong evidence that surgery can cure diabetes. A 5-year follow-up study of 1,160 patients who had laparoscopic gastric bypass found 83% of the 190 patients with Type 2 diabetes had their disease resolved.

There are also benefits for improving sleep apnea, hypertension, and joint problems.

But the complication rate is also high. The National Institutes of Health reports that after obesity surgery:
- 10% to 20% of patients require further operations to correct complications, the most common being abdominal hernia, which laparoscopic surgery has helped to resolve.
- Nearly 30% of patients develop nutritional deficiencies such as anemia, osteoporosis, and metabolic bone disease. These usually can be avoided if vitamin and
mineral intakes are high enough after surgery.

In a review of 3,464 cases by Podnos et al, the most common perioperative complications for laparoscopic gastric bypass were wound infection, anastomotic leaks, and GI tract hemorrhage. (See chart, p 11.)

**What’s the learning curve?**

A big determiner of patient outcomes—surgeon experience.

According to a report of 188 cases by Perugini et al, the learning curve was 120 cases, and the complication rate did not go down until the surgeon had performed that many cases. The finding was somewhat higher than the 100-case learning curve found by Schauer et al and the 75 cases found by Oliak et al.

Volume also makes a difference.

Surgeons who performed fewer than 10 bariatric procedures a year had twice the risk of adverse outcomes as high-volume surgeons—28% versus 14%, in a study of 4,685 patients from Pennsylvania’s discharge database.

The death rate was also much higher—5% for surgeons doing 10 or fewer cases versus 0.3% for high-volume surgeons. Overall, the mortality rate was 0.6% and rate of adverse outcomes was 17%.

Most dangerous of all is the low-volume surgeon (10 to 50 weight-loss operations a year) operating in a low-volume hospital—a situation with a 55% risk of adverse outcomes.

**A better handle on outcomes**

With the growing skepticism, expect more focus on outcomes.

The University of Pittsburgh has received a $6 million grant from NIH to lead a 6-center study on long-term effects of bariatric surgery. The study will look at quality of life; morbidity and mortality; and the effect of surgery on cardiovascular disease, congestive heart failure, and diabetes.

**Expert guidelines**

New guidelines on obesity surgery are coming from professional societies and public health agencies.

The Association of periOperative Registered Nurses (AORN) published a comprehensive bariatric surgery guideline in May, outlining clinical aspects as well as program planning.

Over the next few months, expert panels are expected to weigh in.

In Massachusetts, the state appointed an expert panel to study the safety of weight-loss surgery after several patients died. A report was expected in late May.

Louisiana is enrolling 40 state employees in a study to see if weight-loss surgery keeps insurance costs down over the long run by preventing other health problems.

**References**


---

**Are you monitoring outcomes?**

Every bariatric surgery program should have a database for monitoring outcomes, advises the administrator of the surgical weight-loss program at Medical Center East, Birmingham, Ala. The hospital expects to perform 1,000 weight-loss surgeries this year.

“This will help you understand who your maximum-risk patient is,” says DeNene Cofield, RN, BSN, CNOR, Medical Center East’s director of surgical services. Medical Center East monitors:

- reoperations within 30 days
- hospital readmissions within 30 days
- mortality
- complications (leakage, hernias, and strictures).

Each of these is sorted by open or laparoscopic cases, and these in turn are subdivided by:

- age
- sex
- body mass index (BMI).

Commercial databases for monitoring bariatric surgery outcomes are available but so far are designed for surgeons. One example is the Minnesota Bariatric Database from Exemplo Medical, LLC, Eden Prairie, Minn (www.exemplomedical.com; 612-702-5817). A database that includes hospital data is under development.
Centers of Excellence in bariatric surgery

Bariatric surgeons are rolling out a Center of Excellence program, which is scheduled to start taking applications in July. Criteria are expected to include a target for annual procedure volume, a comprehensive program for patient selection and follow-up, and reporting of outcomes data.

The program will be voluntary and have two steps:
• provisional approval after reviewers document that resources are in place to conduct a bariatric program
• full approval based on outcomes data verified in a site visit.

Reviews will be conducted by a panel of bariatric surgeons. Surgeon leaders say they believe a program designed by bariatric surgeons is needed. Though some insurance companies have centers of excellence programs, surgeons say the companies do not share the basis for their selections and do not share outcomes data.

The Center of Excellence program is sponsored by the American Society for Bariatric Surgery and will be administered by an independent entity, the Surgical Review Corporation. Information is at www.asbs.org.