Bariatric Risks Higher at Centers of Excellence

BY DAMIAN McNAMARA

VITALS

Major Finding: Risk-adjusted rates of serious complications in bariatric surgery were 4.0% at designated Centers of Excellence, compared with 2.7% at other hospitals.

Data Source: Study of prospective registry of 7,504 bariatric surgeries in Michigan in 2006-2008.

Disclosures: Dr. Dimick had no relevant disclosures.

SAN ANTONIO — The risk-adjusted rate of serious complications associated with bariatric surgery was paradoxically higher at hospitals designated as a Center of Excellence in Michigan, compared with other centers, a study of more than 7,500 procedures indicates.

"I'm going to cause major controversy," lead investigator Dr. Justin B. Dimick said at the annual Academic Surgical Congress, where he presented prospective data from the Michigan Bariatric Surgery Collaborative (MBSC) population-based clinical registry.

"The use of bariatric surgery has basically skyrocketed. This operation is not easy …and there is some variability," said Dr. Dimick of the surgery faculty at the University of Michigan, Ann Arbor.

Dr. Dimick, Nancy Birkmeyer, Ph.D., director of the collaborative, and their colleagues studied all 7,504 patients undergoing laparoscopic or open gastric bypass, sleeve gastrectomy, and other bariatric surgery procedures from 2006 to 2008. Excluded from the study were patients who had had Lap-Band procedures.

They found the lowest risk-adjusted rate of serious complications at a high-volume hospital that was not a designated bariatric Center of Excellence. But even when this institution was removed from the analysis, patients at a designated center did not fare significantly better in terms of reoperation, anastomotic leak, or infectious and medical complication rates, compared with other hospitals.

A total of 5,121 patients (68%) had bariatric surgery at a Center of Excellence. They had a 4.0% risk-adjusted rate of serious complications, compared with 2.7% for the 2,383 patients treated at other hospitals. Outcomes included death or disability, complications, and hospitals readmission. "For all three of these, the Centers of Excellence had worse outcomes," Dr. Dimick said.

There was no significant difference at 1 year in resolution of comorbidities by institution type, he said. One-year weight loss was not significantly different; patients at designated centers lost an average of 106 pounds versus 100 pounds at other hospitals. Also, improvements from baseline in health-related quality of life did not differ significantly; the Bariatric Quality of Life Index improved 12.4 points in patients at a Center of Excellence versus 11.8 among those treated elsewhere.

Dr. Dimick emphasized that he was not suggesting the Center of Excellence designation is bad. Indeed, he praised professional societies such as the American College of Surgeons and the American Society for Metabolic and Bariatric Surgery for creating standards. Blue Cross and Blue Shield, he added, also designates hospitals as Distinction Centers for Bariatric Surgery using their own criteria. Blue Cross Blue Shield of Michigan funds the MBSC via a pay-for-participation system; hospitals are paid to participate, and bariatric surgeons are required to attend quarterly quality improvement meetings to share best practices.

The lack of significant difference in his study between Centers of Excellence and other facilities could be a result of all hospitals striving to improve because the criteria exist, Dr. Dimick suggested. Still, he added, "Patients seeking bariatric care, at least in Michigan, should not rely only on Centers of Excellence designation."

The findings may not be generalizable to hospitals outside of Michigan because the surgeons in the study participated in a quality improvement collaboration, a meeting attendee said; Dr. Dimick agreed. In a follow-up video interview, he said, "The story here may be more about the success of quality improvement collaboratives statewide, than the lack of success of the Centers of Excellence program." In the last two quarters, for example, there were no deaths associated with the approximately 3,000 bariatric procedures performed within that state.

Another meeting attendee pointed out that a study by Dr. Edward H. Livingston and his colleagues at the University of Texas Southwestern Medical Center at Dallas found equivalent outcomes at Centers of Excellence versus other hospitals (Arch. Surg. 2009;144:319-25). These researchers used bariatric surgery data from the 2005 National Inpatient Survey and found no significant differences despite a higher volume of procedures at institutions designated as a Center of Excellence.

"I know Dr. Livingston's study is controversial as well …because he used an administrative database, which has a limited ability to ascertain complications. Our study had the limitation of generalizability beyond Michigan." Dr. Dimick said.

"The next obvious study is to see if Centers of Excellence have better outcomes outside of this unique quality collaborative," Dr. Dimick said. "The problem with that is we don't really have population-based data sources outside of the State of Michigan." ■

To see a video with Dr. Dimick explaining more about the study, including reactions from colleagues, go to www.youtube.com/ClinicalEndoNews.

Gastric Banding Improves Weight, Health, QOL in Teens

BY MARY ANN MOON

Gastric banding allowed extremely obese adolescents to achieve a more substantial and durable weight loss than did an intensive lifestyle modification program, based on results of a prospective clinical trial.

The bariatric procedure improved overall health better than did lifestyle intervention, resolving all cases of metabolic syndrome and insulin resistance. It also improved the adolescents' quality of life to a greater degree, according to Dr. Paul E. O'Brien of the Centre for Obesity Research and Education at Monash University, Melbourne, and his associates.

They compared the two approaches in subjects aged 14-18 years with a body mass index of greater than 35. All individuals had related medical complications, including hypertension, metabolic syndrome, asthma, and back pain, as well as physical limitations such as the inability to play sports and problems performing activities of daily living. They also reported psychosocial problems including isolation, low self-esteem, and victimization by bullies.

The subjects were randomly assigned to undergo laparoscopic adjustable gastric binding with follow-up education and guidance or to participate in an intensive nonsurgical intervention program.

The program focused on reduced energy intake (800-2,000 kcal per day, depending on age and weight); increased physical activity (more than 10,000 steps per day as measured by pedometry), which included structured exercise for at least 30 minutes per day; and behavior modification. The subjects were advised to limit sedentary pursuits to 2 hours per day, and to participate in bike rides, hiking trips, kickboxing events, and bowling parties with other patients. They received 6 weeks of instruction from a personal trainer and met with a physician, dietitian, or exercise consultant every 6 weeks.

Twenty-four of the 25 subjects in the surgery group completed the full 2 years of follow-up, compared with 18 of the 25 in the lifestyle group. Twenty-one subjects in the surgery group but only three subjects in the lifestyle group achieved the primary outcome measure of a loss of at least 50% of excess weight.

At 2 years, surgery group subjects had lost a mean of 35 kg, which represents a mean loss of 28% of total body weight. Those in the lifestyle group lost a mean of 3 kg, which represents a mean loss of 3% of total body weight, wrote Dr. O'Brien and his colleagues (JAMA 2010;303:519-26).

At the study's inception, 9 subjects in the surgery group and 10 in the lifestyle group had metabolic syndrome. By the study's end, this had resolved in all surgery subjects and in six of the lifestyle subjects. Similarly, insulin resistance was abnormally high in more than half of the subjects at baseline. The problem resolved in all subjects in the surgery group but persisted in three subjects in the lifestyle group.

Those who underwent gastric banding also showed significant improvements in quality of life in the domains of physical functioning, general health, self-esteem, and family activities, whereas those who participated in the nonsurgical intervention did not.

There were no operative or postoperative complications, and the rates of adverse events were similar between the two groups. Two girls in each group became pregnant during follow-up, an unexpectedly high rate that "suggests sexual counseling may be appropriate in association with weight-loss programs" in adolescents, the researchers said.

Since "the need for revisional procedures for enlargement of the stomach above the band or injury to the tubing is intrinsic to the gastric banding procedure," it was not surprising that seven patients in the surgery group required such revisions, they noted. "The need for a revisional procedure did not compromise the weight loss outcome or lead to additional adverse events," the investigators stated.

However, compared with adults, adolescents may have more difficulty understanding and complying with instructions to eat only small meals and to eat very slowly to avoid the need for revisional procedures. Therefore, additional education and supervision of eating may be helpful for this age group, they added.

In an editorial, Dr. Edward H. Livingston of the University of Texas Southwestern Medical Center, Dallas, said the study provides another randomized controlled trial comparing bariatric surgery with nonsurgical treatments, culminating in more level 1 evidence. This is crucial because the quality of the current evidence in support of bariatric surgery is "poor," he said (JAMA 2010;303:559-60).

Dr. Livingston cited the importance of the 28% rate of revisional procedures in the study "because O'Brien et al. are among the most experienced group in the world with these operations, suggesting that these complication rates will probably be higher in actual community practice."

The study was supported in part by Allergan Inc., which provided the gastric bands. Dr. O'Brien reported no conflicts of interest. One of his associates is a consultant for Allergan, Bariatric Advantage, Scientific Intake Ltd., SP Health Co., Optifast, Abbott Australasia, Eli Lilly Australia, Merck Sharp & Dohme Australia, Nestle Australia, and Roche Products Australia. Dr. Livingston reported no conflicts. ■