Society Mum on Gastric Banding in Mild Obesity

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FROM THE ANNUAL MEETING OF THE AMERICAN SOCIETY FOR METABOLIC AND BARIATRIC SURGERY

ORLANDO – The American Society for Metabolic and Bariatric Surgery has opted to defer making recommendations on the use of the laparoscopically placed gastric band for class I obesity patients, according to Dr. Stacy A. Brethauer, chair of the society's clinical issues committee.

The stage was set for the position statement after the Food and Drug Administration's approval last February of a laparoscopically placed gastric band for patients with class I obesity and a related comorbidity. The society opted to wait, pending availability of level I evidence on the safety and efficacy of at least one alternative surgical option, such as laparoscopic gastric bypass.

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"We decided to wait until we had adequate data on at least the bypass," which should take about another 2 years, given the status of controlled trials now in progress, he said. Safety and efficacy data from randomized, controlled trials of the gastrectomy sleeve will likely take even longer, he added.

"We could issue a statement based just on the band data. There are enough data to say that it's safe and effective. The FDA has spoken, and approved bands for patients with a body mass index (BMI) of 30-34 kg/m^2 and at least one obesity-related comorbidity. But the society's committee seeks to produce a broader assessment of the treatment options, said Dr. Brethauer, a surgeon in the Bariatric and Metabolic Institute of the Cleveland Clinic.

His committee's decision to wait parallels the slow approach that Dr. Brethauer and many of his colleagues have taken on placing bands in the expanded population after the agency's decision last February. This cautious approach reflects both medical insurance coverage issues and the skeptical view of bariatric surgery that many physicians still have, which limits patient referrals.

Despite the FDA's action, class I obesity patients with an obesity-related comorbidity generally still do not receive insurance coverage for band placement, so the only patients of this type getting bands are those who pay for the procedure themselves. "At the Cleveland Clinic, about 5% of our practice is self-pay. We don't see many patients who say, 'I have a BMI of 33 [kg/m^2], here is $15,000, please put in a band.' That may happen elsewhere, but not in our practice," Dr. Brethauer said in an interview.

Also, "primary care physicians … still see bariatric surgery as carrying a lot of risk, even for patients with a BMI of more than 35." As a result, most patients Dr. Brethauer sees about bariatric surgery are self-referred or sent by endocrinologists.

At least some endocrinologists "have realized that there are benefits to patients from bariatric surgery that they can't offer. The endocrinologists will be the [linchpin] for changing the paradigm and getting patients to surgery sooner. The primary care physicians will hopefully follow. Our job [as bariatric surgeons] is to give [these physicians] the evidence so that they can feel comfortable making referrals. Right now, we only see patients with a BMI of 30-35 for entry into trials. We work with endocrinologists" as co-principal investigators of studies in this BMI group.

"The FDA's approval of bands for these patients was based on evidence, but many physicians either don't believe the evidence or don't pay attention to it."

Dr. Brethauer said that he has received consulting fees from Bard/Davol, Baxter Healthcare, Cardinal Health, Ethicon Endo-Surgery, and Stryker Endoscopy. He also has received honoraria and served on an advisory committee for Ethicon Endo-Surgery, has been a proctor for Bard/Davol, and had received teaching honoraria from Covidien. ■