

April 25, 2012  
Louis Jacques, MD  
Director, Coverage & Analysis Group  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services

Dear Dr. Jacques,

I am the Director of the Michigan Bariatric Surgery Collaborative. This statewide clinical registry and quality improvement program has the participation of virtually every bariatric surgery surgeon and program in the state of Michigan. Our externally audited registry now includes data on more than 35,000 consecutive bariatric surgery patients with 1 year follow-up for 12,000. Blue Cross and Blue Shield of Michigan funds our program which has improved the safety and quality of bariatric surgery across the state while saving millions in health care costs.

I'm writing regarding CMMS' initial National Coverage Decision memo limiting coverage of laparoscopic sleeve gastrectomy to procedures performed in the context of an approved randomized clinical trial. Our group is currently performing a comparative effectiveness analysis of the safety and effectiveness of laparoscopic sleeve gastrectomy, gastric bypass, and adjustable gastric band using data from our clinical registry. In this study we matched nearly 9,000 patients on preoperative risk factors and predictors of weight loss outcomes to deal with the issue of selection bias. Outcomes included complications occurring within 30 days, weight loss, comorbidity resolution, quality of life, and patient satisfaction at 1, 2, and 3 years follow-up.

We found that SG has outcomes that are between RYGB and LAGB . Overall complication rates among patients undergoing SG (6.3%) were significantly lower than for RYGB (10.0%,  $p<0.0001$ ) but higher than for LAGB (2.4%,  $p<0.0001$ ). Serious complication rates were similar for SG (2.4%) and RYGB (2.5%,  $p=0.736$ ) but higher than for LAGB (1.0%,  $p<0.0001$ ). Weight loss over time was greatest for RYGB, followed by SG, and then LAGB . Weight loss for all three procedures was steep during the first year and then leveled off or rebounded slightly over the subsequent two years. Excess body weight loss at 1-year was 13% lower for SG (60%) than for RYGB (69%,  $p<0.0001$ ) but was 77% higher for SG than for LAGB (34%,  $p<0.0001$ ). SG was similarly closer to RYGB than LAGB with regard to resolution of obesity-related comorbidities, quality of life, and patient satisfaction. Rates of complications increased with increasing age and rates of weight loss decreased with increasing age for all three procedures. Specifically, serious complications were approximately two times higher for patients in the 60+ age category than for patients in the <30 age category for all three procedures. Excess body weight loss at 1 year was 5.7%, 8.1%, and 13.5% lower for patients in the 60+ age category than for patients in the <30 age category for RYGB, SG, and LAGB, respectively.

We have provided CMMS with a pre-publication copy of this study. We believe that our study adds to a growing body of evidence regarding the safety and efficacy of sleeve gastrectomy and addresses a number of CMS's specific concerns with prior studies including the lack of comparison groups, selection bias, generalizability of single center studies, the lack of age-stratified results, and a lack of long-term outcomes. I'd be glad to speak with you about these issues at your convenience.

Sincerely,

Nancy Birkmeyer, PhD

Director, Michigan Bariatric Surgery Collaborative  
Senior Scientist, Center for Healthcare Outcomes and Policy, University of Michigan