

the differences between these observational data sets might provide insights to further refine endoscopic-harvesting techniques. We look forward to seeing these data published in the peer-reviewed literature.

Our analysis has identified an important potential area for quality improvement in cardiac surgery, and further observational and randomized evaluations are called for. The medical community and regulatory agencies should continually assess whether technological changes in medical devices should be implemented only after an analysis of randomized outcome data or can be implemented on the basis of observational or anecdotal information. Data collected in professional registries³ and more efficient clinical trials should enable us to reduce the substantial uncertainty that currently exists regarding the balance of benefit and risk of many therapies.⁴ Further research on endoscopic harvesting should focus on improving the technique so that patients can benefit from the short-term advan-

tages without any detriment to long-term clinical outcomes.

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Perioperative Safety and Bariatric Surgery

TO THE EDITOR: Flum and colleagues (July 30 issue)¹ report on the Longitudinal Assessment of Bariatric Surgery (LABS) consortium study (LABS-1) in which the rate of the composite adverse outcome by 30 days after bariatric surgery was greater among the patients who underwent laparoscopic Roux-en-Y gastric bypass than among the patients who underwent laparoscopic adjustable gastric banding, after controlling for coexisting conditions. However, there is a potential for confounding by indication inherent in nonrandomized studies. Given the beneficial effects of Roux-en-Y gastric bypass on the remission of diabetes, patients with more severe diabetes are probably more likely to undergo Roux-en-Y gastric bypass than laparoscopic adjustable gastric banding. The mechanism of adjustment for diabetes in this study seems vulnerable to residual confounding by indication (or, as some authors have suggested, “confounding by severity”²). The stratum of “insulin use” encompasses a wide range of diabetes severity, and among patients

receiving insulin, those with more severe diabetes may be more likely to undergo Roux-en-Y gastric bypass than laparoscopic adjustable gastric banding. Given the important role that glycemic control plays in determining postoperative outcomes,³ both investigators and the medical community should be cautious in interpreting these results as representing inherent risks of the procedures themselves.

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TO THE EDITOR: Flum et al. report a low 30-day perioperative rate of death (0.3%) among patients undergoing bariatric surgery. The composite end point of the study was death, deep-vein thrombosis or venous thromboembolism, reintervention, or failure to be discharged by 30 days after surgery. Patients with obesity are at significant risk for the development of coronary artery disease,¹ possibly due, in part, to the increased prevalence of concomitant risk factors for atherosclerosis (such as hypertension, dyslipidemia, and diabetes mellitus) in this population. Therefore, it would be of interest to know the prevalence of cardiac end points, particularly myocardial infarction and heart failure, during the perioperative period in this patient population. Second, it would be important to know whether there were any differences in these events between patients undergoing gastric banding and those undergoing a Roux-en-Y gastric bypass procedure. This information would be of benefit for physicians and patients when considering the safety of bariatric surgery and would help in the selection of the differing available techniques.

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THE AUTHOR REPLIES: The aim of LABS-1 was to characterize early postoperative safety events in bariatric surgery by describing the outcome and by exploring the relationship of these events to patient characteristics. Vetter and colleagues appropriately note that nonrandomized studies such as LABS-1 have the potential of bias due to confounding, including confounding by indication. Our results show that patients undergoing differing operations have a mixed-risk profile; some higher-risk characteristics were more common in patients who underwent the more invasive procedure (Roux-en-Y gastric bypass), whereas other

characteristics were more common among those who had the less invasive procedure (laparoscopic adjustable gastric banding). Multivariable regression was used to account for these differences. Vetter et al. note that patients with more severe diabetes might have been more likely to undergo Roux-en-Y gastric bypass than laparoscopic adjustable gastric banding, and adjusting for the severity of diabetes by adjusting for insulin use might not have been adequate. Although we found no significant difference ($P=0.11$) in the percentage of patients with diabetes who received insulin and underwent Roux-en-Y gastric bypass (83%) as compared with those who did not (79%), we agree that confounding remains a possibility. We feel that LABS-1 contributes to the literature on the safety of bariatric surgery as a rigorous multicenter study describing rates and generating hypotheses about associations. It is not our intention to overinterpret the results, and we trust that the discerning reader will also avoid this.

Bhattacharyya and Kaddoura inquire about the prevalence of cardiac end points after bariatric surgery. Of the 15 deaths among the 4776 patients assessed, 13 were associated with a known cause and 4 were due to cardiac events (2 myocardial infarctions, 1 cardiac failure, and 1 cardiomyopathy or fatal arrhythmia). Although LABS-1 did not explicitly focus on cardiac end points (there were too few events to conduct a proper statistical analysis), a substudy of the comprehensive health outcomes of approximately 2500 patients undergoing bariatric surgery (LABS-2) is under way and addresses this issue. LABS-2 also includes functional metrics, longer-term safety outcomes, weight-loss durability, patient-reported outcomes and quality of life, and information about health care utilization. The LABS study was recently extended to increase longitudinal follow-up, and we look forward to sharing information as it develops over the next several years.

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