Gastric Bypass Cuts Left Atrial Size, Heart Failure

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BY MITCHEL L. ZOLER Philadelphia Bureau

NEW ORLEANS — Good outcomes from bariatric surgery in morbidly obese patients continue to accumulate.

In a series of 12 patients with severe systolic heart failure at one center, bariatric surgery was safe and led to improved left ventricular function, Dr. Gautam V. Ramani said at the annual meeting of the American College of Cardiology. An independent report showed that gastric bypass surgery led to a significant reduction in left atrial size in a randomized, prospective study with 409 patients, Dr. Sheldon E. Litwin reported in a poster at the meeting.

"Left atrial volume is a powerful, longterm prognostic factor for survival; it's considered the hemoglobin A_{1c} of the heart," Dr. Litwin said in an interview. "Our findings suggest that gastric bypass surgery may lead to improved cardiovascular outcomes. So far, no one has proven that gastric bypass surgery leads to fewer deaths, but we think that reduced left atrial volume is a harbinger of a mortality effect." Another significant aspect of this study was that it's the largest prospective study reported to date of bariatric surgery for morbid obesity, said Dr. Litwin, professor of medicine and director of noninvasive imaging at the

University of Utah, Salt Lake City. His study enrolled patients with a BMI of more than 40 kg/m², or more than 35 if they also had secondary complications from obesity. About 85% of the pa-

tients were women, and their average BMI was about 45. The patients were randomized to either gastric bypass with Roux-en-Y surgery or no surgery. Follow-up after 2 years showed that patients who had surgery lost an average of 96 pounds and had an average drop in BMI of 15.5. There was no significant change in weight or BMI in the patients who did not have surgery. At baseline, the average left atrial size in all patients was about 57 mL, measured by echocardiography. Two years after surgery, left atrial volume fell by an average of 2.5 mL in the surgery patients and increased by an average of 4 mL in control patients.

The second study reviewed 12 patients with severe systolic heart failure who underwent bariatric surgery at the University of Pittsburgh during 2001-2006. Their average BMI was 53, and their average age was 41

years. All patients had a left ventricular ejection fraction of less than 45%, with an average ejection fraction of 22%. Three patients had New York Heart Association class II heart failure, seven patients had class III heart failure, and two patients had class IV heart failure.

Eight patients had laparoscopic Rouxen-Y surgery, two had a gastric sleeve placed laparoscopically, one had gastric banding placed laparoscopically, and one underwent gastric bypass by open surgery (after initial laparoscopic surgery wasn't successfully completed).

The average postoperative length of hospitalization was 3 days. By 1 month after surgery, the only complications were pulmonary edema in one patient and acute renal failure in another; both conditions resolved after 1 month.

At 1 year after surgery, the average BMI was 40 and the average left ventricular ejection fraction was 35%, a statistically significant improvement over baseline. At follow-up, nine patients had class II heart failure, and three had class III.

"Despite the small study size and retrospective data, bariatric surgery was safe in patients with severe, systolic heart failure," said Dr. Ramani, a cardiologist at the University of Pittsburgh. "Bariatric surgery should be offered to obese patients with heart failure before they develop end-organ dysfunction and renal failure."

Consider ICDs for Transplant Patients With Ejection Fractions Below 40%

BY SHERRY BOSCHERT San Francisco Bureau

SAN FRANCISCO — Patients with transplanted hearts face a higher risk of sudden cardiac death if they have left ventricular ejection fractions below 40%, a retrospective study of 208 patients found.

The risk for sudden cardiac death is compounded if the patient also has cardiac allograft vasculopathy of any severity, Dr. Michelle Montpetit and her associates reported at the annual meeting of the International Society for Heart and Lung Transplantation.

"It would be reasonable to consider implantation of defibrillators in heart transplant patients with an ejection fraction of less than 40% and cardiac allograft vasculopathy of any severity," said Dr. Montpetit of Loyola University, Maywood, Ill.

Identifying these patients early is important, she said, because 73% of patients in the study who died of sudden cardiac death did so within the first 5 years after heart transplantation.

Implantable cardioverter defibrillators (ICDs) are recommended for nontransplant patients with heart failure to prevent sudden cardiac death. Previous studies have shown that defibrillators improve survival in nontransplant patients with a history of MI and an ejection fraction below 30%, and in nontransplant patients with cardiomyopathy and an ejection fraction below 35%.

Several previous small studies suggest that 6%-37% of patients after heart transplantation die of sudden cardiac death. The only previous study of ICD use in patients after heart transplant found that 3 of 10 patients were cardioverted appropriately during 13 months of follow-up. They had received ICDs for indications including low ejection fraction and coronary disease, syncope, or symptomatic ventricular tachycardia.

The current study examined data on 208 of 617 patients who underwent heart transplantation at Loyola University Medical Center from 1984 to 2005. The 208 died during those 2 decades, 27% of them from sudden cardiac death, which was defined as a witnessed arrhythmic death or a sudden death at home or in the hospital with no known cause.

Patients with sudden cardiac death were more likely to have undergone heart transplantation for ischemic cardiomyopathy (64%), compared with 46% of patients who died of other causes. Other clinical and demographic characteristics were similar between groups.

The only single factor associated with sudden cardiac death in multivariate analysis was left ventricular ejection fraction. Among the entire cohort, 40% of patients with ejection fractions below 40% died of sudden cardiac death, compared with 22% of patients with greater ejection fractions. Of the 56 patients with sudden cardiac death, 23 (41%) had ejection fractions below 40%.

Cardiac allograft vasculopathy by itself was not associated with risk of sudden cardiac death, but when combined with a low ejection fraction, it increased the risk of sudden cardiac death to 52%, Dr. Montpetit said.

Among a subset of patients who underwent coronary angiography near the time of death, 4 had mild cardiac allograft vasculopathy (defined as any lesion less than 50% of a major vessel) and 13 had severe vasculopathy (lesions greater than 50%). The severity of vasculopathy did not appear to affect the risk of sudden cardiac death.

The findings were limited by the retrospective nature of the study, its small size, and the lack of autopsy data to confirm the cause of death, Dr. Montpetit said. Not all patients had coronary angiography or ejection fraction measurements near the time of death. The records may have been skewed by the fact that "we tend to collect more data on patients with acute rejection," she said.

A posttransplant history of at least one episode of severe rejection was significantly more common in patients who later died of sudden cardiac death (64%) than in patients who died of other causes (46%).

Heart Pump to Be Studied as Bridge and Destination Tx

BY SHERRY BOSCHERT San Francisco Bureau

SAN FRANCISCO — Results from three small, foreign trials of an experimental heart pump were good enough to prompt a U.S. feasibility study, and two U.S. trials are planned, Dr. Donald S. Esmore said at the annual meeting of the International Society for Heart and Lung Transplantation.

In the three foreign studies, the VentrAssist left ventricular assist device was implanted either as destination therapy or as a bridge to transplant. In the U.S. feasibility study, which began in 2005, 10 patients out of a planned total of 30 have had the device implanted as a bridge to transplant, he said.

Dr. Esmore is a cardiothoracic surgeon at Alfred Hospital, Melbourne, and a consultant to Ventracor, the company that makes the heart pump. Ventracor plans to begin separate U.S. pivotal trials for destination therapy and for bridge to transplant this year, he said.

The initial pilot trial in Australia found no device-related deaths and a low rate of adverse events in nine patients who received the device, four as destination therapy and five as a bridge to transplant. The mean length of support on the device was 297 days.

A subsequent phase II trial in 33 patients who received the heart pump as a bridge to transplant at multiple centers outside the United States showed that 27 (82%) survived and either underwent heart transplantation within 154 days or were alive and capable of being transplanted, reported Dr. Esmore and his associates.

The median time to transplant for those who got new hearts was 95 days (range 32-306 days). The bridge time on the heart pump was a median of 167 days, reaching 486 days.

Five patients died during the study—two of them (6%) within 30 days of transplanta-tion—for an overall survival rate of 85%.

The rate of serious adverse events was similar to rates seen with other heart pumps, Dr. Esmore said. There were 10 local infections, 8 cases of systemic sepsis, and 6 device malfunctions. Two patients died of a cerebrovascular accident; 14 had neurologic embolic events but experienced no major disability and progressed to successful transplantation.

The third foreign trial has enrolled 12 of an expected 15 patients to get the device as destination therapy. The mean time on the pump has been 378 days. Seven patients remain alive on the pump, and one has had a heart transplant.

The combined results from these studies show that close to 60% of patients survived in the 2 years after getting the pump, he said.