Support Device Enhances MV Surgery Outcomes

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SAN FRANCISCO — Mitral valve surgery in patients with mitral regurgitation and advanced systolic heart failure induces reverse ventricular structural remodeling, a major benefit that's further augmented by implantation of the CorCap cardiac support device at the time of the valve operation, Michael A. Acker, M.D., reported at the annual meeting of the American Association for Thoracic Surgery.

A new secondary analysis of a 300-patient multicenter randomized trial of the Acorn Cardiovascular Inc. CorCap cardiac support device similarly showed that while mitral valve (MV) surgery alone also improved patient symptoms and enhanced quality of life scores, the extent of these benefits was substantially greater when the MV procedure was combined with placement of the cardiac support device (CSD) designed to directly target the ventricle, he added.

"Improvement in symptoms and left ventricular function along with a very low mortality risk justifies strong consideration to offering mitral valve surgery in combination with a CSD to nonischemic heart failure patients who've been medically optimized yet remain symptomatic with significant mitral insufficiency," said Dr. Acker, professor of surgery and chief of the division of cardiothoracic surgery at the University of Pennsylvania, Philadelphia.

The overall results of the Acorn CSD trial were presented last fall at the annual scientific sessions of the American Heart Association. The data showed that the CSD—a synthetic mesh bag surgically placed around the heart to provide passive ventricular restraint—resulted in reduced left ventricular (LV) volume and a transformation from the dysfunctional spherical-shaped heart characteristic of advanced heart failure to a more mechanically efficient and electrically stable elliptical one. This translated into improved cardiac function; a marked reduction in heart transplantation or need for an LV assist device during follow-up; and significant quality-of-life gains, compared with optimal medical management in this population of patients with mainly New York Heart Association class III heart failure of nonischemic etiology.

Dr. Acker's subanalysis focused on the 193 trial participants with severe mitral regurgitation who underwent MV surgery plus randomization to the CSD or medical therapy alone: 84% of the MV operations were valve repairs, and the rest were replacements. In-hospital mortality was 1.6%. The 1- and 2-year survival rates were 86.5% and 85%, respectively, with no significant difference between patients who got the CSD and those who had MV surgery alone.

At 2 years' follow-up, patients who received MV surgery alone had a highly significant mean 27.8-mL reduction in LV end-diastolic volume, compared with baseline. However, patients who had MV surgery and got a CSD showed an even more impressive 45.7-mL reduction.

Similarly, patients who got MV surgery alone showed a significantly improved heart sphericity index, compared with baseline—but the improvement in sphericity score was nearly threefold greater in those who also got a CSD. Patients who underwent MV surgery alone also showed a significant reduction in LV end-systolic volume, a benefit that was substantially larger in the group that received a CSD. Two years following MV surgery, nearly 90% of patients had either no, or only mild, mitral regurgitation.

The traditional view has been that the MV functions as a sort of pop-off valve for the failing ventricle. The belief has been that the increase in afterload following surgical correction of the severe mitral regurgitation that commonly accompanies advancing heart failure would result in prohibitive mortality and, at best, only short-term improvement in MV function.

This view was first challenged a decade ago by Steven Bolling, M.D., who famously proposed what he described as an annular solution for what he argued was essentially a ventricular problem. The Bolling hypothesis held that using an undersized ring in the repair of the MV annulus would fix the abnormal annular geometry, alleviate excessive LV workload, improve LV geometry, and boost ventricular function. The Acorn CSD study provides the first definitive proof in the form of prospective multicenter clinical trial data.

Valve surgery reduced symptoms, but the benefits were substantially greater when the CorCap device was also placed.

DR. ACKER

Discussant D. Craig Miller, M.D., professor of cardiovascular surgery at Stanford (Calif.) University, said many Stanford cardiologists were skeptical of the initial Acorn CSD findings presented at the AHA. They thought the observed benefits were simply due to the MV surgery and doubted the CSD added anything. "When our heart failure cardiologists see these new data, it's going to open their eyes," Dr. Miller predicted.

Another important finding in the new subanalysis, Dr. Miller continued, is that the benefits don't wane with time. In fact, the additional 6 months of follow-up included in the secondary analysis demonstrated that the improvement is progressive. "Clearly the device is inducing some uncharacterized biologic signal which is good for these folks," he added.

But Dr. Miller also offered a note of caution: "This is a study involving idiopathic or valvular cardiomyopathy, not ischemic cardiomyopathy. I don't want the audience going home and trying it for the ischemic mitral regurgitation patients. That's a totally different kettle of fish."

Elsewhere at the meeting, however, Dr. Bolling, a coinvestigator in the Acorn trial, said he thinks the CSD ought to be able to induce favorable reverse LV remodeling in patients with ischemic, as well as in those with dilated, cardiomyopathy.

"Now that we really understand that this [functional mitral regurgitation] is a ventricular disease, I think we should change our mantra for these patients. It should be: 'Find mitral regurgitation in patients with cardiomyopathy, fix mitral regurgitation, but more importantly, fix the left ventricle.' … I think any treatment directed at the ventricle itself is going to be better than mitral valve surgery alone," said Dr. Bolling, professor of surgery at the University of Michigan, Ann Arbor.

Having personally implanted the CSD, however, he's not convinced it's the answer. "The Acorn procedure is somewhat technically difficult and unfamiliar to the surgeon," he said, adding that he sees the CSD as having only "limited potential" as an LV remodeling device.

Dr. Bolling holds a financial interest in the GeoForm MV repair ring, a silicone and titanium device he coinvented and has licensed to Edwards Lifesciences Corp. The GeoForm has already received Food and Drug Administration approval for MV repair. At the thoracic surgeons' meeting, he presented initial prospective data in 10 patients—half with ischemic and half with dilated cardiomyopathy—indicating a 26- or 28-mm GeoForm ring not only improved mitral regurgitation but also reversed LV remodeling.

The ring's unique three-dimensional shape encourages alignment of heart muscle in a way that promotes remodeling, he explained, adding that larger multicenter studies are underway. ■

Poor Kidney Function Portends Anemia in Heart Failure Patients

NEW ORLEANS — Poor kidney function is the strongest indicator for anemia in heart failure patients, according to the results of a large study of HMO patients.

A reduced glomerular filtration rate emerged as the strongest risk factor for developing anemia in 41,754 heart failure (HF) patients free of anemia at baseline, Alan S. Go, M.D., reported at the annual scientific sessions of the American Heart Association.

Anemia was a common occurrence in this HMO population with HF, with an incidence of 9% per year, according to Dr. Go of Kaiser Permanente of Northern California, Oakland. The study featured nearly 83,000 person-years of follow-up.

Chronic renal impairment is extremely common among HF patients. Roughly 40% of patients had a baseline glomerular filtration rate (GFR) of less than 60 mL/min per 1.73 m^2. The risk of developing anemia during follow-up was proportionate to their degree of baseline renal impairment. Heart failure patients with an estimated GFR of 45-59 mL/min per 1.73 m^2 were 34% more likely to become anemic than were those with a GFR of 60 or more. Those with a GFR of 30-44 had a more than twofold increased incidence of anemia, while patients with a GFR of 15-29 were at more than fourfold increased risk.

Among those patients with a baseline GFR less than 15 mL/min per 1.73 m^2 who weren't on dialysis, the incidence of anemia during follow-up was more than eight times greater than in patients with a GFR of at least 60. In those on dialysis, the rate increased nearly fivefold.

Other independent predictors of the development of anemia in a multivariate analysis included cirrhosis, with an adjusted 2.3-fold relative risk, compared with noncirrhotic patients, and HIV infection, which conferred an 80% increase in risk. African descent and age greater than 70 years were each associated with a 40% increased risk of becoming anemic, Dr. Go said. ■

Use of BNP to Guide Heart Failure Tx Reduced Deaths

ORLANDO, FLA. — Use of serial plasma B-type natriuretic peptide levels to guide medical therapy for systolic heart failure was linked to significant reductions in heart failure–related deaths and hospitalizations, Patrick Jourdain, M.D., reported at the annual meeting of the American College of Cardiology.

Half of the 220 patients in this 21-center French randomized trial received state-of-the-art, clinically guided medical therapy in accord with heart failure (HF) practice guidelines. The other half underwent monthly B-type natriuretic peptide (BNP) measurement for 3 months, then three times per year thereafter.

The goal in the BNP group was to titrate doses of ACE inhibitors, β-blockers, and diuretics until the plasma BNP dropped below 100 pg/mL.

During a median 15 months of follow-up, the BNP group had three HF-related deaths and the clinically managed group had nine. The primary end point in this unsponsored trial—HF-related death or hospitalization for HF—occurred in 25 patients in the BNP arm and 57 in the control group. This translates to a highly significant 54% reduction in relative risk when BNP was used to optimize medical management, noted Dr. Jourdain of Hôpital Rene Dubos, Pointoise, France. ■