CorCap Helps Even Without Mitral Valve Surgery

BY MITCHEL L. ZOLER
Philadelphia Bureau

PHILADELPHIA — Surgical placement of the CorCap cardiac support device led to significant but modest improvements in heart failure patients who did not undergo concurrent mitral valve surgery.

The moderate benefit in patients with severe heart failure who were not otherwise scheduled for heart surgery left it unclear exactly which types of patients would benefit most from having a CorCap mesh bag surgically placed around their heart, Mariell L. Jessup, M.D., said at the annual meeting of the International Society for Heart and Lung Transplantation.

Further studies are needed to better define the best candidates for placement of the cardiac support device (CSD), said Dr. Jessup, medical director of the heart failure/transplant program at the University of Pennsylvania, Philadelphia.

Last November, at the annual scientific sessions of the American Heart Association, researchers presented the results from a randomized, controlled study that compared the safety and efficacy of this CSD with conventional therapy in a total of 300 patients with severe heart failure. In the overall group, which included 193 patients who had concurrent mitral valve repair or replacement and 107 patients who did not undergo a mitral valve procedure, placement of the CorCap was associated with significant reductions in the need for subsequent cardiac procedures, improved left ventricular shape and function, and improved quality of life during a median follow-up of 22 months. The study was sponsored by Acorn Cardiovascular, the company that makes the CorCap.

Dr. Jessup and the other investigators in the study are paid consultants to Acorn. On the basis of these findings, Acorn has submitted an application to the Food and Drug Administration to approve the CorCap for use in patients with advanced heart failure.

Additional analyses of the results broke the study into its two parts: the patients who also had mitral valve repair, and those who did not. Dr. Jessup presented the substudy results for patients who did not have concurrent mitral valve treatment, the subgroup that provides "a more obvious way to test the efficacy of the cardiac support device," she said, because the absence of additional procedures provides "the purest test of efficacy." In this subgroup, 57 patients who were on optimal medical therapy underwent cardiac surgery to place the CSD, while a group of 50 control patients continued on optimal medical therapy only.

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The effect of the cardiac support device in patients without mitral valve repair was very similar to the results seen in the entire study. In this subgroup, placement of the CorCap led to an improvement in a composite efficacy index in 35% of patients, compared with 19% who improved in the control arm, a statistically significant difference.

This composite, the primary end point for the study, included death, changes in heart failure severity, and the need for cardiac procedures such as heart transplant, placement of a ventricular assist device, or placement of a cardiac resynchronization pacemaker. In this substudy, as in the entire study group, the difference in this end point between the control and intervention arms was mostly due to differences in the need for subsequent cardiac procedures. There was no difference seen in survival.

Treatment with the CSD also led to favorable changes in left ventricular size in this subgroup, although the changes were smaller than in the patients who also had mitral valve repair.

In this subgroup, the heart surgery used to place the CSD led to an acute increase in mortality: five patients died within the first 30 days in the CorCap group, compared with no deaths in the control group. But this difference disappeared during longer follow-up. The initial surgery also led to an early surge in serious adverse events, but again these balanced out during longer follow-up, Dr. Jessup said. ■

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