

CLINICAL EVALUATION OF THE CORCAP CARDIAC SUPPORT DEVICE IN PATIENTS WITH DILATED CARDIOMYOPATHY

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BACKGROUND: Progressive left ventricular (LV) remodeling is part of the unfavorable natural history in patients with heart failure (HF). The CorCap™ Cardiac Support Device (CSD) is a mesh device that is implanted around the heart to reduce wall stress and the first therapy specifically designed to address LV remodeling. Early clinical studies have shown that the CSD is safe and associated with improvements in LV structure and function and patient symptoms.

DESIGN: This multicenter prospective trial enrolled 300 patients with NYHA Class III-IV HF and dilated cardiomyopathy. 193 patients underwent mitral valve repair/replacement (MVR) and were randomized to either MVR alone or MVR plus CSD. 107 patients were randomized to either continued optimal medical therapy alone or with the CSD. Patients were followed to a common closing date 12 months after the last patient was enrolled (median follow up 22 months).

RESULTS: The primary endpoint was a clinical composite with patients classified as improved, same or worsened based upon the occurrence of death, a major cardiac procedure indicative of HF progression and a change in NYHA class. Compared to the control group, the CSD group had more patients “improved” (38 percent vs. 27 percent) and fewer patients “worsened” (37 percent vs. 45 percent), yielding an odds ratio of 1.73 (1.07, 2.79; $p = 0.02$). The CSD group had fewer major cardiac procedures (e.g. transplant, LVAD) compared to controls (19 vs. 33; $p = 0.01$), a greater reduction in LV end diastolic ($p = 0.009$) and systolic volumes ($p = 0.026$) and a greater improvement in sphericity index ($p = 0.026$). Quality of life (Minnesota Living with HF and SF 36) was significantly improved in the CSD group ($p = 0.05$ and $p = 0.015$ respectively). Repeat hospitalizations and adverse events were not different between the two groups.

SUMMARY: In patients with progressive HF who are symptomatic despite optimal medical therapy, CSD implant reverses the natural history of HF, as indicated by an improvement in LV size and shape, an improved clinical score, fewer major cardiac procedures, and improvements in quality of life. This innovative therapy represents a new and effective approach for patients with enlarged hearts.

CAUTION: The CorCap CSD is an investigational device. Limited by USA law to investigational use.