

Evolving Technology

Initial United States experience with the Paracor HeartNet* myocardial constraint device for heart failure

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OBJECTIVE: This study was undertaken to review the initial results and surgical safety data for the US Food and Drug Administration safety and feasibility trial of the Paracor HeartNet (Paracor Medical, Inc, Sunnyvale, Calif.) myocardial constraint device.

METHODS: Patients with New York Heart Association functional class II or III heart failure underwent device implantation (n = 21) through a left minithoracotomy.

RESULTS: The average age was 53 years (31–72 years). There were 18 men and 3 women, and 17 patients had nonischemic etiology of heart failure. Mean heart failure duration was 8.3 years (1.4–18.8 years). Average ejection fraction was 22% (11%–33%), with an average left ventricular end-diastolic dimension of 74 mm (55–94 mm). Previous medical therapy included angiotensin-converting enzyme inhibitors, β -blockers, diuretics, digoxin, and aldosterone receptor blockers. At implantation, 17 patients had implantable electronic devices: 1 biventricular pacemaker, 11 biventricular pacemakers with cardioverter-defibrillators, and 5 implantable cardioverter-defibrillators. Patient comorbidities included hypertension in 10 cases, diabetes mellitus in 8, myocardial infarction in 1, and ventricular tachycardia in 8. Mean operative time was 68 minutes (42–102 minutes), and implantation time averaged 15 minutes (5–51 minutes). The average time to ambulation was 1.6 days (1–4 days). The intensive care unit stay averaged 3.3 days (1–16 days), and hospital stay averaged 6.3 days (4–16 days). Atrial fibrillation occurred in 2 patients, and there were 2 in-hospital deaths.

CONCLUSIONS: The Paracor device can be implanted in patients with heart failure and reduced left ventricular function with a high degree of success. Significant surgical complications were infrequent. The initial US experience supports the conduct of a randomized, controlled, pivotal trial.