LVAD: CLINICAL AND BIOENGINEERING IMPLICATIONS

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Congestive heart failure affects nearly 4.7 million Americans each year, with over 550,000 cases newly diagnosed annually. Over 40,000 persons per year are in the severest form of heart failure, with only 1800 to 2000 donor hearts available for definitive therapy. Perhaps the single most significant contribution to care of such patients has been the bioengineering advances in mechanical left ventricular and total heart support.

Recently the results of a $25 million NIH randomized trial, the REMATCH trial, attracted national media, newspaper and scientific acclaim. This three year landmark multicenter study reported by lead investigator Dr. Eric Rose demonstrated in 68 of the 129 patients studied, that implanted LVAD's (specifically the Thoratec HeartMate) can extend life and improve the quality of life of terminally ill heart failure patients.

The LVAD device is implanted into the upper part of the abdominal wall, and connected to cannulae that drain blood from the left ventricle into the device, and then pump blood back into the aorta. Drive lines exit the body, and are attached to a control system and battery pack.

The results of the REMATCH trial documented a statistically significant twofold improvement in survival at one year (52.1% vs. 24.7%) versus patients who were medically supervised and managed with drugs alone. The survival at two years was 22.9% versus 8.1%. Patients on the pump reported an improved quality of life, with less depression and an overall feeling of being better. Nevertheless, there were serious adverse events for patients treated with the LVAD device, including predominantly infection, bleeding and device malfunction. Overall, the frequency of occurrence was 2.35 times that of the medical therapy group.

These encouraging results with a mechanical heart pump have spurred national controversy over the management of congestive heart failure patients, and the associated cost both financially and physiologically for such therapy. Bioengineering advances in pump design, materials and control circuitry that reduce major morbidity and extend survival will clearly drive this field. Newer smaller devices that require less energy, are easier to surgically implant, and solve the problems of blood component damage and infection will greatly enhance the application of artificial pumping devices in the care of such desperately ill congestive heart failure patients. It will be the translational research goals of surgeons and bioengineers to bring this highest level of technology to the large number of patients suffering from the nation's number one killer, heart disease.

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