Health & Medicine

New Hope for Heart Failure Patients

A Columbia study shows that patients with heart failure can live longer and better lives with an implanted mechanical device that assists the heart—instead of replacing it.

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A portable implantable pump formerly used primarily to sustain patients awaiting heart transplants could in fact extend the lives of as many as 100,000 people a year as a long-term treatment for heart failure, according to a landmark study led by Columbia's Eric A. Rose, M.D. '71C '75P&S.

The study, published last November 15 in The New England Journal of Medicine, shows that end-stage heart failure patients who received an implantable left ventricular assist device (LVAD) lived significantly longer than patients who received medical therapy only. The majority of "terminal" heart failure patients receiving the HeartMate LVAD lived for over a year, half of those lived for two years or more, and eighteen patients receiving the HeartMate are still alive today, nearly five years later. Compare this to end-stage heart failure patients receiving medical therapy only: Only a quarter of that group in the trials lived for a year, and only 8 percent made it to the two-year mark.

In fact, the study was the first of its kind to show a substantial improvement in quality of life for patients who received mechanical devices. Each patient was monitored for pain, energy level, mental outlook, and ability to perform routine activities; while a five-point increase is considered meaningful, patients receiving the implant showed a seventeen-point increase.

This makes the findings of the study all the more astounding. If patients about to die could be given an extra year, let alone three or more, with improved function and

quality to boot, implantable LVADs may well prove a viable alternative to heart transplants.

As medical technology has advanced, more patients survive heart attacks to live longer lives, which means that more of them eventually suffer heart failure. In the last two decades, the number of people dying of heart failure has more than doubled. So implantable LVADs could have a potentially enormous impact. “I foresee that it will become like hemodialysis is to kidney disease,” says Rose. “Currently 300,000 patients receive hemodialysis. That’s larger than the population of Kansas City.”

Rose’s study is called REMATCH—for Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure. The trials were designed by Columbia’s International Center for Health Outcomes and Innovation Research—a collaboration between the College of Physicians and Surgeons and the Mailman School of Public Health—which coordinated the trials at twenty different transplant centers around the country. Rose, chairman of Columbia’s Department of Surgery, was the principal investigator for the entire study and lead author of the article.

It’s not the first breakthrough in pioneering surgical interventions for Rose, who celebrated his twentieth anniversary at Columbia last fall. In 1984, he performed the world’s first cardiac transplant on a child. (That patient graduated from college this year.) Since then, Rose has built Columbia’s cardiac transplant center into the world’s largest while shifting the focus of his own research toward mechanical cardiac assist devices.

The REMATCH study took four years to complete and involved 129 patients nationwide, fourteen of whom were treated at Columbia, where Mehmet Oz, M.D., associate professor of surgery at the College of Physicians and Surgeons, managed the clinical trials. All of the patients suffered from end-stage heart failure, a condition in which the heart becomes too weak to supply the body with enough oxygenated blood. End-stage heart failure patients are generally too debilitated to move freely; their lungs and extremities can fill with fluids, and they are so short of breath that even speaking becomes difficult. The REMATCH trials took only those end-stage heart failure patients who were ineligible for transplants—because they were too old or their conditions were complicated by other diseases such as diabetes, kidney failure, or cancer. In REMATCH, Rose and his colleagues used the HeartMate LVAD. The device consists of a pump the size of a portable CD player

inserted into the abdomen and connected to the left ventricle, the main pumping chamber of the heart, and the aorta, the main outflow vessel from the left ventricle. The pump pulls blood out of the left ventricle and pumps it into the aorta (a function normally carried out by the left ventricle itself) at a rate of fifty pulses per minute—higher if the pump senses a greater need, say, from exercise. The pump is powered by a relatively compact battery pack that the patient wears on a shoulder harness.

LVADs are smaller and simpler than the artificial hearts designed to replace the heart altogether, and the study results lead Rose and others to question the "hype" surrounding artificial hearts. "The role for artificial hearts is going to be relatively small," says Rose. "Most of these patients with end-stage heart failure don't need total heart replacement—plus, the remaining heart serves as backup for the mechanical device. Indeed, after REMATCH, it may be unethical to offer a patient an artificial heart that may only prolong their life by sixty days or so."

Rose and his colleagues at Columbia are also working on combining LVAD implantation with promising experimental therapies. "It's possible that LVADs may someday offer us a bridge to recovery while new stem cells injected into the heart muscle replace damaged heart muscle," he predicts.

Based on the results of REMATCH, the HeartMate is expected to win FDA approval soon for primary treatment of end-stage heart failure in patients not qualifying for heart transplant. For Rose, REMATCH represents "a point of inflection" in the development of mechanical devices to support the heart. "For the first time," he says, "we have rigorous evidence that using machines to keep heart failure patients alive is no longer a dream; it's a reality."

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