

NYPH/COLUMBIA: PAVING THE WAY IN MECHANICAL CIRCULATORY ASSISTANCE

The Center for Heart Assist Devices at New York-Presbyterian Hospital/Columbia University Medical Center is a recognized world leader in the field of mechanical circulatory assistance. To date, Columbia surgeons have performed over 500 implants, including the Thoratec® HeartMate® pneumatic and vented electric devices, the Thoratec ventricular assist device and other temporary assist devices.

NYPH/Columbia participated in the initial clinical evaluation of the Thoratec HeartMate pneumatic and vented electric devices leading to their FDA approval in 1994 and 1998. NYPH/Columbia was the principal investigating site for the multicenter REMATCH trial (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure), using the vented electric HeartMate LVAD. This \$7 million NIH-funded study was the first comprehensive assessment of mechanical circulatory assistance as a form of destination therapy. The study found that use of the implanted heart pump more than doubled the likelihood that terminally ill heart failure patients would be alive at the end of the year. As a result of the REMATCH trial, LVADs were approved as destination therapy for nontransplantable patients by the Centers for Medicare and Medicaid Services (CMS) in October 2003.



Columbia physician-scientists stand at the forefront of clinical research in the area of mechanical circulatory support systems. They are currently leading several clinical trials on the heels of the REMATCH trial that aim to offer patients remarkable advances in these devices. Currently, investigators are testing one of the next-generation left ventricular assist devices—the Thoratec HeartMate II. The device is a small axial flow pump, which is quieter than other devices and aims to provide patients with greater comfort and mobility. The Thoratec HeartMate II can be theoretically much less invasive, so that it causes less perioperative and long-term complications. In a separate clinical trial, investigators are testing a fully implantable left ventricular assist device—the Arrow LionHeart. The device has no percutaneous line, thus eliminating a potential source of infection. Other clinical research includes the investigation of the use of a novel pressor agent, arginine vasopressin, for the treatment of vasodilatory shock following LVAD insertion. In a randomized, prospective clinical trial, Columbia physician-scientists demonstrated that vasopressin is a potent agent to reverse vasodilatory shock accompanying congestive heart failure.

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mission

The Heart Hope™ Initiative

is a collaboration

between leading heart

centers committed to

advancing clinical outcomes

associated with mechanical

circulatory assist devices and

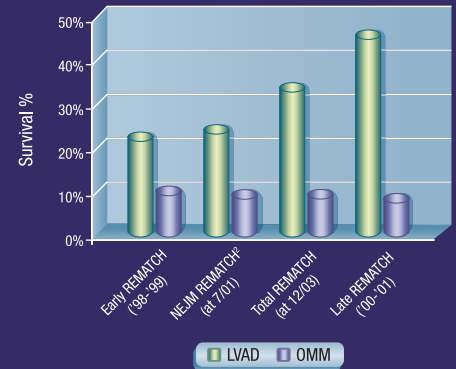
other advanced therapies in

the treatment of heart failure.



REMATCH UPDATE While cardiac transplantation remains the most effective treatment for NYHA Class IV (Stage D) heart failure, not all potential patients are candidates for transplantation. Data from early REMATCH, a study on the use of LVADs in patients ineligible for transplantation, showed 21% survival at 2 years compared to late-REMATCH patient 2-year survival of 43% with LVAD therapy. Late-REMATCH therapy data from 2000 and 2001 now indicate a 5-fold improvement in 2-year survival versus Optimal Medical Management (43% vs 8%).¹

Improved Outcomes in 2-Year LVAD Survival



DESTINATION THERAPY: AN EMERGING OPTION IN THE CONTINUUM OF HEART FAILURE TREATMENT

Cardiac transplantation remains the most effective treatment for New York Heart Association (NYHA) Class IV (Stage D) patients. The continuing dilemma for most physicians caring for NYHA Class IV heart failure patients, however, is how to treat those patients that are not transplant candidates.

Data from all phases of the REMATCH trial indicate that patients who no longer benefit from optimal medical management (OMM), and who are ineligible for a transplant, derive measurable and meaningful benefits from the implantation of a left ventricular assist device (LVAD) as Destination Therapy (DT). The benefits of DT compared with OMM and continuous IV inotrope therapy for this population of patients is measurable both in terms of increased survival and improved quality of life. Based on an analysis of mortality and survival rates, the absolute benefit from LVADs used in DT was shown to be greater than other device and drug therapies.³

QUALITY-OF-LIFE IMPROVEMENT

According to updated late REMATCH data, twice as many DT patients survive at 1 year when compared with OMM therapy (53.5% vs 26.5%). Almost 4 times as many DT patients survive to 2 years with LVADs vs OMM (43% vs 8.2%).¹

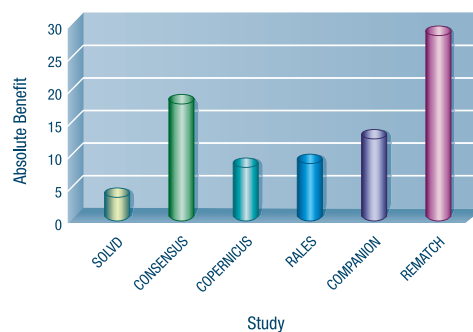
In addition to increased survival, quality of life for NYHA Class IV heart failure patients with an LVAD is vastly improved. In a study of REMATCH LVAD

recipients, preoperative Minnesota Living With Heart Failure (MLHF) Quality-of-Life Scores for patients receiving an LVAD averaged 77—the most severe condition of any heart failure patient group studied. At an interval of 6 months post-LVAD therapy, the MLHF Quality-of-Life Scores had improved to 41 (compared with a baseline of 59 and 44 at 6 months after biventricular pacing).⁴ These improvements in quality of life, while dramatic, are reflective of results garnered with the device and procedure regimens from the REMATCH trial. Results do not reflect improvements made to the LVAD or perioperative and postoperative technique in the past 3 years.

PALLIATIVE CARE

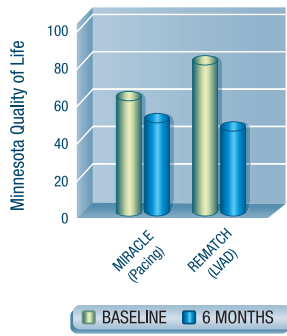
In addition to LVAD improvements in survival and quality of life, other recent studies have prompted physicians caring for heart failure patients to reconsider the continuum of care. Prior to LVAD therapy, the most common option for patients that did not improve after 60 days of OMM and were not candidates for transplantation was palliative care. Continuous infusions of IV inotropes were once considered to be a treatment option. Today, however, IV inotrope therapy has been shown to be effective for palliative care but provides little or no therapeutic benefit. According

Meaningful Benefits in End-Stage Disease: Absolute Benefit?



to the COSI study (continuous outpatient support with inotropes), mortality for patients on continuous IV inotropes is 74% at 6 months. In this study of 36 consecutive patients, the median survival was 3.4 months. These patients were discharged from the hospital on continuous outpatient support with IV inotropes from 1993 through 2001. The 3-, 6-, and 12-month Kaplan Meier survival was 51%, 26%, and 6%, respectively.⁵

Improvement in Quality of Life: Minnesota Living With Heart Failure Score³



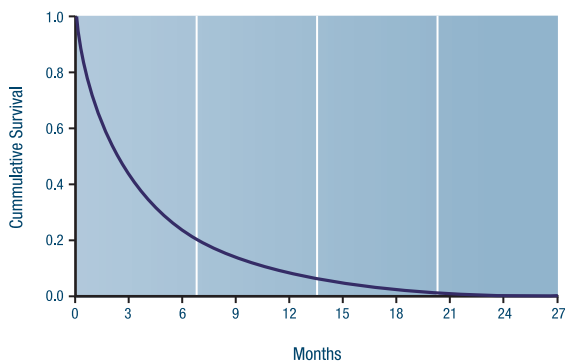
REMATCH LVAD patients showed a greater change in quality of life from baseline to 6-month follow-up when compared with patients after biventricular pacing. (Lower scores = less limitation.)

PROCEDURE SELECTION CRITERIA

As pharmacologic and device therapies for heart failure proliferate, the continuum of heart failure treatment becomes more promising, and more complex, for physicians. DT patient selection criteria is as follows:

- NYHA functional Class IV heart failure
- Declining condition with OMM for 60 of the last 90 days
- Ineligible for cardiac transplantation
- Ineligible for Cardiac Resynchronization Therapy (CRT)
- Nonresponsive to CRT
- Intolerance to ACEIs, ARB, or beta-blocker drugs
- Possible malignant (life-threatening) ventricular arrhythmias
- Repeated hospitalization
- Unable to be weaned from inotropic therapy
- Life expectancy < 2 years

Continuous Inotropic Infusions



Hershberger RE, et al. *J Card Fail*. 2003;9(3):180-187.

1. REMATCH UPDATE as of April 2004 - Thoratec Registry.
 2. Rose EA, et al. *N Engl J Med*. 2001;345(20):1435-1443.
 3. LW Stevenson 6/04.
 4. Stevenson LW. *Circulation*. 2004;110(8):975-981.
 5. Hershberger RE, et al. *J Card Fail*. 2003;9(3):180-187.

CRITERIA FOR SUCCESSFUL DESTINATION THERAPY DISCHARGE

As more DT patients are discharged back to their communities, the criteria for successful discharge are continually refined. Some of the criteria that the VAD team uses to ensure a successful discharge are shown below. As always, 24 hours a day, 7 days per week, support is available to all discharged patients and their support system.

HOME

- Ability to perform activities of daily living
- Proof of patient and companion competency
- Emergency contact list
- Grounded 3-prong outlets

COMMUNITY

- Education and training of:
 - Patient and companion
 - First responders
 - Emergency room staff
- Placement on power company "first to restore" list

- Mission
- Columbia University Medical Center
- REMATCH Update
- Destination Therapy: An Emerging Option in the Continuum of Heart Failure Treatment
- Criteria for Successful Destination Therapy Discharge



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NYPH/Columbia regularly conducts training for surgeons establishing new ventricular assist programs. Columbia surgeons have successfully trained over 250 cardiothoracic surgeons in 100 centers worldwide in LVAD implantation. The educational programs at NYPH/Columbia, including the recent Society of Thoracic Surgeons Fifth International Conference on Circulatory Support Devices, continue to highlight the facility as a center of excellence in the field of ventricular assist devices.

To complement its extensive clinical activity, NYPH/Columbia has developed multiple research programs in physiology, immunology, vascular biology, hematology, cellular and molecular biology, each having a specific focus on the effect of long-term implantable devices.

The Program for Heart Assist Devices at NYPH/Columbia assumes an active role in both clinical and basic science evaluation of mechanical circulatory support. Educational programs spearheaded by Columbia surgeons have strengthened ties with LVAD centers in the United States and around the world, making it the premier center in the field of mechanical circulatory assistance.