連続流LVADを用いることにより生存率が上昇する

HeartMate II：末期心不全患者において連続流左室補助装置はパルス波タイプのものと比較し生存率を改善する

HeartMate II: Continuous flow left ventricular assist device improves survival more than pulsatile type in end-stage heart failure

重症心不全患者において連続流左室補助装置（LVAD）は、現在使用されているパルス波タイプのものと比較し、2年生存率が良好であると2009年American Heart Association学会のレイトブレイキング臨床試験のセッションで発表され、New England Journal of Medicineに掲載された。HeartMate II最終的治療トライアルにおいて、末期心不全患者200人が連続流LVAD（HeartMate II）またはパルス流LVAD（HeartMate XVE）を植え込まれた。全ての患者が最大限の薬物治療でもコントロール不良で移植の適応ではなかった。複合一次エンドポイント（2年後に障害を残す脳卒中および再手術を必用とするデバイスの故障のない状態）に到達したのは、連続流LVAD患者においてパルス流LVAD患者と比較しはるかに多かった（46%対11%）。1年および2年生存率も連続流LVAD群において良好であった（1年生存率68%対55%、2年生存率58%対24%）。2年後の障害を残す脳卒中発現の割合は両群で同等であった（連続流群11%対パルス流群12%）。ポンプを修理または交換するために再手術を必用としたのは持続流群で10%であったのに対し、パルス流装置群においては36%であった。

Full Text

A new, continuous flow heart pump, or left ventricular assist device (LVAD), delivered better two-year survival in advanced heart failure patients than the current pulsatile model, researchers reported in a late-breaking clinical trial presentation at the American Heart Association's Scientific Sessions 2009.

In the HeartMate II Destination Therapy Trial, researchers tested a new device that helped heart failure patients who weren't responding to optimal medical therapy and weren't eligible for a heart transplant. They found significant improvement in outcomes of patients who received the continuous flow LVAD (HeartMate II) compared to those who received a pulsatile flow LVAD (HeartMate XVE), the only FDA-approved device for treating such patients.

"The results of this trial will alter the manner in which we provide mechanical circulatory support," said Joseph G. Rogers, M.D., co-author of the study and medical director of the Duke Heart Failure Program at Duke University Medical Center in Durham, N.C. "In the past, mechanical pumps delivered blood in a pulsatile manner; in other words, they beat like a human heart.

"The newer pump is smaller, operates quietly and has demonstrated superior durability. Interestingly, it also pumps blood continuously, which reduces the systolic blood pressure. We believe that in the future there will be little need for pulsatile blood pumps."

The study included 200 end-stage heart failure patients implanted at 38 U.S. medical centers between March 2005 and May 2007. All patients had failed optimal medical therapy and were ineligible for a heart transplant.

The primary endpoint was survival free from disabling stroke and device failure requiring re-operation at two years. Secondary endpoints included overall survival, adverse events, quality of life and functional capacity.

A greater proportion of continuous flow LVAD patients successfully reached the primary composite end-point compared to pulsatile flow (46 percent vs. 11 percent) - a highly significant finding, researchers said.

At one-year follow-up, 68 percent of the continuous flow LVAD patients had survived compared to 55 percent in the pulsatile flow group. At two years, survival was 58 percent for the continuous flow device vs. 24 percent with the pulsatile device.

Both groups experienced early and sustained improvements in their quality of life scores and functional capacity. The distance walked in six minutes (a common measure of functional abilities) increased from 182 to 318 meters in the continuous flow patients and from 172 to 306 meters in the pulsatile flow patients at one year, Rogers said.

Over the 24 months of the study, the rate of disabling stroke was similar in both study arms (11 percent for continuous flow LVAD vs. 12 percent for pulsatile flow LVAD).

In addition, 10 percent of the patients who received the continuous flow LVAD needed surgery to repair or replace the pump compared to 36 percent of patients with the pulsatile device.

Furthermore, other adverse events were less common in the continuous flow pump group than in the pulsatile one.

"Severe heart failure is associated with a very poor prognosis," Rogers said. "Patients diagnosed with advanced heart failure treated with optimal medical therapy have a 10 percent to 20 percent survival rate in the ensuing two years. Further, these patients are unlikely to experience significant improvement in their quality of life or functional abilities with routine medical or electrical therapies."

Transplantation is a standard treatment for patients with advanced heart failure. But an estimated 150,000 U.S. patients have advanced heart failure while the number of heart donors each year is about 2,100. "We believe that with improved technology and management strategies, LVADs will fill this important gap," Rogers said.

Thoratec Corporation, in Pleasanton, Calif., funded the study.

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Disclosures: Dr. Rogers has served as a consultant for Thoratec.

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