HeartMate II Outcomes Continue to Improve

BY DOUG BRUNK

FROM THE ANNUAL MEETING OF THE SOCIETY OF THORACIC SURGEONS

SAN DIEGO – Survival rates of patients implanted with the HeartMate II ventricular assist device have improved significantly, according to a long-term multicenter analysis designed to compare outcomes from the time of the clinical trial to those in the post–Food and Drug Administration approval period.

Excellent outcomes have been maintained and the incidence of adverse events has trended downward with the HeartMate II, a continuous-flow left ventricular assist device (LVAD) for bridge to heart transplantation, Dr. Ranjit John said at the meeting.

A multicenter trial of the HeartMate II, manufactured by Thoratec Corp., was conducted from 2005 to 2008 and led to FDA clearance of the device for bridge to transplantation. Since FDA clearance in April 2008, more than 1,400 additional patients implanted with the device for bridge to transplantation have been tracked by the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), which is funded by the National Institutes of Health.

The HeartMate II, also cleared for destination therapy, has been implanted in more than 6,000 patients worldwide, with more than 5,000 patient years of support, according to Dr. John, of the department of cardiothoracic surgery at the University of Minnesota, Minneapolis.

The original trial of the device enrolled 486 bridge to transplantation patients at 36 centers in North America between March 2005 and April 2008. The post-trial commercial use study enrolled

1,496 patients at 83 centers between April 2008 and September 2010. The study's primary end point was survival. Secondary end points included frequency of adverse events and complications, functional status as assessed by the 6-minute walk, and quality of life as assessed by the Kansas City Cardiomyopathy Questionnaire in the original trial and the EuroQol (EQ-5D) instrument in the post trial.

Dr. John reported that the 1-year survival rate improved significantly from 76% in the original trial to 85% in post trial. "With every era of the trial, there was a stepwise incremental improvement in survival, probably from all lessons learned from the early phases of the original trial," he commented.

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DR. JOHN

The percentage of patients transplanted by 1 year decreased from 48% in the original trial to 39% in the post trial, while the percentage of patients receiving ongoing support increased from 32% in the original trial to 45% in the post trial.

The overall incidences of bleeding and infection in the post trial were 36% and 38%, respectively. Specifically, the incidence of bleeding requiring surgical reexploration was 7%, while the incidence of driveline infections was 13%.

The incidence of adverse events trended downward in the post trial, compared with the original trial. For example, the incidence of bleeding requiring reexploration was 21% in the original trial vs. 7% in the post-trial group. Similar declines were seen in the incidence of percutaneous lead infections (20% vs. 13%, respectively), right heart failure requiring right ventricular assist device (7% vs. 1%), and the need for device replacement (5% vs. 1%).

At baseline, only 13% of patients in the original trial and 16% of patients in the post trial could complete the 6-minute walk test. At 6 months, the proportion of patients who could complete the test improved to 92% and 94%, respectively.

Dr. John also reported that quality of life measures improved in up to 6 months in the original trial and up to 12 months in the post trial.

The invited discussant, Dr. Michael A. Acker, said that the results of the post trial demonstrate "that new VAD technology that utilizes continuous flow – a disruptive concept compared to pulsatile flow – can be taught, along with appropriate patient selection, and can be disseminated to a broad range of clinical centers. If similar successful dissemination occurs after the destination therapy approval, small continuous-flow pumps will constitute a paradigm shift for the treatment of end-stage heart failure."

Dr. Acker, who heads the cardiovascular surgery division at the University of Pennsylvania Medical Center, Philadelphia, noted that the trial also demonstrates "that mandatory prospective databases such as INTERMACS are essential for monitoring outcomes and providing feedback needed to improve results." ■

VITALS

Major Finding: The 1-year survival rate improved significantly from 76% in the original HeartMate II trial to 85% in a commercial use trial of the device.

Data Source: A study of 1,496 patients at 83 centers who received the device between April 2008 and September 2010 for bridge to transplantation.

Disclosures: Dr. John disclosed that he received a research grant from Thoratec Corp. to conduct the study. One of the study investigators is employed by the company.