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 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 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 a bridge to transplantation at 36 centers in North America between March 2005 and August 2008. The post-trial commercial use study enrolled more than 7,000 patients within those 36 centers, including 5,000 in the US.

The HeartMate II has been approved for bridge to transplantation and has been implanted in patients with a history of severe congestive heart failure (CHF) in whom traditional medical therapy has failed. FDA approval was based on the results of the STAR–CHF (Study of the HeartMate II: A Randomized Evaluation of assist Circulatory Support Therapy in Congestive Heart Failure) trial, which was conducted at 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.

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The percentage of patients transplanted by plant decreased from 48% in the original trial to 39% in the post-trial, while the percentage of patients receiving ongoing support increased from 32% to 67% 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 re-exploration was 2%, while the incidence of driveline infections increased 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 driveline infections (20% vs. 13%, respectively), right heart failure requiring right ventricular assist device (7% vs. 1%), and the need for device replacement (3% 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 portion 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, with 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 are essential for monitoring outcomes and providing feedback needed to improve results.”