Mate for the heart: pulsatile or continuous?

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At the AHA meeting 2009 it was reported by the press media (and meanwhile published in the N Engl J Med by Slaughter et al., 3 December 2009), that a 'new type of device more than doubles the two-year survival rate among heart failure patients. The new device, called HeartMate II, improves survival, is more durable, and is linked to better quality of life. The device works by pumping blood continuously rather than simulating a heart beat as older pumps do. The pump is connected to equipment outside the body – a small computer and batteries that the patient wears in a belt pack or harness using a wire from the patient's abdomen. The FDA has approved the device only as a temporary bridge to transplant.'

The press was referring to the HeartMate II study entitled: Advanced Heart Failure Treated With Continuous-Flow Left Ventricular Assist Device. The goal of the trial was to compare treatment with a **continuous**-flow HeartMate II left ventricular assist device (LVAD) compared with a **pulsatile**-flow HeartMate XVE LVAD among patients with advanced heart failure not eligible for heart transplantation. The HeartMate II study was a randomised trial that enrolled patients in a 2:1 ratio, to a continuous-flow device (n=134) or the currently approved pulsatile-flow device (n=66). In the continuous-flow group, the mean age was 62 years, 19% were women, 66% had ischaemia as the cause of heart failure, and the mean cardiac index was 2.0 l/min/m². The primary composite endpoint was survival at two years without disabling stroke or reoperation to repair/replace the device. Secondary endpoints included actuarial survival, functional status, quality of life, and frequency of adverse events. Aspirin was recommended for all patients, and warfarin only for patients with a continuous-flow LVAD.

The primary outcome – survival free from stroke or reoperation to repair/replace the assist device – was 46% (62/134) in the continuous-flow group vs. 11% (7/66) in the pulsatile-flow group (p<0.001). Disabling stroke was 11 vs. 12%, reoperation to repair/replace the assist device was 10 vs. 36% (p<0.001), and death within two years was 33 vs. 41% (p=0.048). Rehospitalisation was reduced by 38% with the continuous-flow device. Functional class I or II at 12 months was 76 vs. 61% (p=0.22), respectively. It was concluded that a continuous-flow LVAD significantly improved the probability of survival free from stroke and device failure at two years compared with a pulsatile device. There was more than twofold improvement in survival at two years for the continuous-flow vs. the pulsatile-flow LVAD. Continuous-flow LVADs were associated with a reduction in clinically meaningful adverse event rates. Both devices significantly improved the quality of life and functional capacity, with a trend toward greater improvement with the continuous-flow LVAD. The smaller pump and percutaneous lead in the continuous-flow LVAD requires less surgical dissection for implantation, which reduces the potential for infection. Patients with a continuous-flow LVAD had a rate of device-related infection nearly 50% of that among patients with a pulsatile-flow device, which contributed to their reduced need for rehospitalisation.

Concerns persist that LVADs may predispose patients to thromboembolic and infectious events. The incidence of stroke did not differ significantly between the continuous-flow group (0.13 events per patient-year [stroke in 17% of patients]) and the pulsatile-flow group (0.22 events per patient-year [stroke in 14% of patients]). These might be high figures, but the rate of ischaemic stroke among patients with a continuous-flow LVAD is similar to that among patients with advanced heart failure who do not have device support and have other cardiovascular conditions such as atrial fibrillation. The rate of bleeding events associated with either type of LVAD was almost ten times the rate of thromboembolic events. This finding had also been observed in the HeartMate II bridge to transplant trial and has led many centres to reduce the targeted international normalised ratio to 1.5-2.5 for the continuous-flow LVAD.

The HeartMate II study underscores the use of continuous-flow LAVD destination therapy for long-term support in advanced heart failure. There is little doubt that this device is a viable option for patients with medically refractory advanced heart failure. Therefore, any patient in whom intravenous inotropic support is required should be considered a candidate for destination therapy. So, cardiac surgeons and cardiologists should make combined efforts to introduce the new device into clinical practice as soon as possible. ■

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