HeartMate 3: Better...but not perfect

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Central Message

The HeartMate 3 represents an engineering advance relative to the current generation of ventricular assist devices; however, the device is still associated with an undesirable adverse event rate.

See Article page 173.

The HeartMate 3 left ventricular assist device (LVAD; Abbott Laboratories, Lake Bluff, Ill) was introduced clinically in 2014 as part of a CE Mark clinical evaluation.^{1,2} Schmitto and colleagues¹ reported the first-in-human experience with this exciting new technology, and in this issue of the *Journal*, the same group (Hanke and colleagues³) report their experience with the first 27 patients supported with this fully magnetically levitated LVAD.

In the CE Mark report, considerable optimism was raised in response to the lack of pump thrombosis and the lower rates of gastrointestinal bleeding than seen in historical reports.⁴ The recent short-term report from the Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3 (MOMENTUM3) trial confirmed the favorable effect of the pump design on thrombosis, although it failed to show any meaningful improvement in stroke, gastrointestinal bleeding, or survival relative to the HeartMate 2 LVAD.^{5,6}

In comparing the two reports, one notes that the CE Mark study cohort was a slightly younger group of patients who were more likely to be in Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile 3 or 4 at the time of LVAD implantation, as opposed to the MOMENTUM3 population, in which a third of the patients were in INTERMACS profile 2 at the time of implantation. Nevertheless, the INTERMACS registry report has suggested that the risk profile at the time of implantation does not influence the rate of adverse events after implantation.⁴ Therefore, apart from age (which may be a significant confounding variable), one must look at other variables that may influence clinical outcomes after LVAD support.

In this regard, smaller, single-center reports provide value because they reflect outcomes that are based on an institution's management protocol. In this report, Hanke and colleagues³ present a 6-month survival greater than 83%, with no suspected pump thrombosis, no strokes, and only a single patient with a gastrointestinal bleeding event.

Assuming that these results in a relatively small sample size reflect the true underlying performance of the pump,

one must ask why the European results tend to be better than the American data. The mean age in this study was 56 years, slightly lower than that reported in the CE Mark study (59 years) or the MOMENTUM3 trial (60 years). It is likely, however, that these clinically insignificant differences in age are overshadowed by differences in patient management.

Unfortunately, these details are not completely described in the text; however, one may note that aspirin was administered to all patients at a dose of 100 mg/day. Previously, there has been some reluctance to use aspirin for the recipients of continuous-flow LVADs because of the adverse effects on von Willebrand factor.⁷ A recent analysis by Netuka and colleagues,⁸ however, demonstrated that use of the HeartMate 3 device does not result in degradation of von Willebrand factor, and antiplatelet therapy with aspirin is therefore recommended. Despite the use of aspirin, gastrointestinal bleeding was less prevalent in this report and the overall CE Mark trial than in the MOMENTUM 3 results.

Aortic valve opening has been proposed as a mechanism to protect against gastrointestinal bleeding, and certainly the pulsatility algorithm inherent in the HeartMate 3 may play a role here.⁹ Another key to these favorable results may lie in the strict blood pressure management.

Hanke and colleagues³ describe a target mean arterial pressure of 60 mm Hg. Previous studies with various devices have shown that higher blood pressures (mean arterial pressure >90 mm Hg) are associated with higher rates of stroke and pump thrombus formation.^{10,11}

Despite these encouraging results from Germany, one must acknowledge that this study and even the CE Mark trial enrolled a relatively small number of patients. The complete MOMENTUM 3 trial will enroll more than 1000 patients and will provide more definitive data with respect to the biocompatibility of this pump. At present, one can reliably conclude only that the HeartMate 3 represents a better, albeit imperfect, device. As such, continued efforts are needed to design better pumps that can be used to treat a wider range of patients with lower adverse event rates.

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