

HEART FAILURE

New centrifugal-flow pump for advanced heart failure

“an incremental benefit in clinical outcomes was associated with the use of the new centrifugal-flow pump”

Implantation of a new fully magnetically levitated centrifugal-flow pump in patients with advanced heart failure is associated with improved clinical outcomes compared with implantation of the currently approved axial continuous-flow pump. This finding was presented at the AHA Scientific Sessions 2016 by the MOMENTUM 3 investigators, and simultaneously published in *NEJM*.

Current left ventricular assist devices, such as the axial continuous-flow pump HeartMate II (St. Jude Medical, USA), have been shown to increase the rate of survival and improve the quality of life of patients with advanced heart failure who are refractory to standard medical therapy. However, the use of these devices is also associated with increased risk of infection and bleeding in addition to pump thrombosis. “HeartMate 3 (St. Jude Medical, USA) is a centrifugal pump that is designed to overcome the problem of pump thrombosis by virtue of three engineering attributes: a frictionless rotor

that is based on a fully magnetically levitated platform; wide blood-flow passages that reduce red cell destruction; and an artificial intrinsic pulse that prevents stasis of blood within the pump,” explains Mandeep Mehra, lead investigator of MOMENTUM 3.

MOMENTUM 3 was a non-blinded, randomized trial designed to compare the safety and efficacy of the new centrifugal-flow pump HeartMate 3 with the commercially available axial-flow pump HeartMate II in patients with advanced heart failure. The primary end point of the study was a composite of survival free of disabling stroke and need for surgical reoperation to replace or remove the pump.

In total, 152 (52%) patients received the centrifugal-flow pump, and 142 (48%) the axial-flow pump. Event-free survival at 6 months was observed in 86.2% of the patients in the centrifugal-flow pump group and in 76.8% of patients in the axial-flow pump group. The centrifugal-flow pump was both noninferior (absolute difference 9.4%, 95% lower confidence boundary -2.1 , $P < 0.001$ for noninferiority) and superior (HR 0.55, 95% CI 0.32–0.95, two-tailed $P = 0.04$ for superiority) to the axial-flow pump. The rates of death or disabling

stroke were not significantly different between the two groups, but the reoperation rate for pump malfunction was lower in the centrifugal-flow pump group than in the axial-flow pump group (0.7% versus 7.7%, HR 0.08, 95% CI 0.01–0.60, $P = 0.002$). Functional status (assessed by NYHA class and 6-min walk test) improved equally in the two treatment groups. With regard to adverse events, no suspected or confirmed cases of pump thrombosis were noted in the patients implanted with the centrifugal-flow pump, whereas 18 cases of pump thrombosis were observed in the axial-flow pump group ($P < 0.001$). The rate of other adverse events such as bleeding, sepsis, and drive-line infection were not significantly different between the two groups.

To conclude, an incremental benefit in clinical outcomes was associated with the use of the new centrifugal-flow pump that is largely attributable to the reduced need for reoperations for pump malfunction. These encouraging 6-month outcomes will be confirmed in a larger cohort of patients followed up for 2 years. “This future analysis will define the durability of these early important findings,” explains Mehra. “We anticipate that this device will become the predicate device for our patients in the near term; however, progress in this field will need to continue to eliminate other complications such as infection”.

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