進行した心不全において新たなLVADは転帰をより良好にする(Abstract 19-LB-20223)

MOMENTUM-3：最大規模の LVAD トライアルの結果、最新世代のデバイスの臨床的有意性が示された

MOMENTUM-3: Largest LVAD trial demonstrates the clinical superiority of the newest generation device

進行した心不全で、新型の左心補助人工心臓（LVAD）を装着された患者は、旧型で既存の心臓ポンプを使用された患者に比べ、2 年後の脳卒中、ポンプ血栓症および出血エピソードが有意に少なかった、と American College of Cardiology's 68th Annual Scientific Session で発表され、*New England Journal of Medicine* に掲載された。2 年後、主要エンドポイント（後遺症を伴う脳卒中、または再装着あるいは装置の不具合による除去がないこと）に達したのは HeartMate 3 を装着された患者の 74.7% であり、HeartMate II を装着された患者では 60.6% であった。リスクは 40% 低下した。

Full Text

Severely ill patients with advanced heart failure who received a novel heart pump—the HeartMate 3 left ventricular assist device (LVAD)— suffered significantly fewer strokes, pump-related blood clots and bleeding episodes after two years, compared with similar patients who received an older, more established LVAD, according to research presented at the American College of Cardiology's 68th Annual Scientific Session and simultaneously published online in the *New England Journal of Medicine* at the time of presentation.

Based on these final findings, the HeartMate 3 LVAD should now be considered the standard of care for patients with advanced heart failure who do not respond to guideline-directed medical therapy, said Mandeep R. Mehra, MD, medical director of the Heart and Vascular Center, Brigham and Women's Hospital in Boston and lead author of the study.

"These final results from what is by far the largest LVAD trial ever conducted demonstrate the clinical superiority of the HeartMate 3 compared with its predecessor, the HeartMate II," Mehra said. "We have shown a decrease in adverse events that uniquely occur due to the interface between the patient and the mechanical pump. These include a consistent and reliable reduction in strokes of all kinds and severity with the HeartMate 3 but also a remarkable reduction in the rate of pump-related blood clots and significant reductions in all types of bleeding, especially gastrointestinal bleeding. In addition to having significantly lower rates of adverse events, patients who received the HeartMate 3 had a lower rate of readmission to the hospital and spent fewer days in the hospital when they were readmitted."

The HeartMate 3 is the first implantable mechanical heart pump to use fully magnetic levitation technology—which makes the pump frictionless without mechanical bearings—to push blood through the device and into the aorta, the body's central artery.

The trial, known as MOMENTUM-3, enrolled 1,028 patients at 69 centers in the U.S. Patients' median age was 60 years and 78 percent were men. All had severe heart failure that left them unable to engage in usual physical activity without discomfort. Most had symptoms of fatigue or shortness of breath even when resting. Most (85 percent) were receiving intravenous heart failure medication because pills alone no longer worked or caused intolerable adverse effects.

Some patients in the study needed an LVAD to sustain them until they were able to receive a heart transplant. Others, because of age or other health problems, were not candidates for a transplant and relied on an LVAD as lifelong therapy. Patients were randomly assigned to have either a HeartMate 3 or a HeartMate II surgically implanted. All patients received blood-thinning medications following surgery and were also taking 81 to 325 mg of aspirin daily. The trial was designed to include two pre-specified interim analyses and then a final analysis. The first interim analysis reported six-month outcomes in the first 294 patients and the second analyzed two-year outcomes for the first 366 patients enrolled; this data was presented at ACC's 2018 Annual Scientific Session.

The primary endpoint for the final analysis was survival at two years free of disabling stroke or reoperation to replace or remove a malfunctioning device. The principal secondary endpoint was the rate of device replacement at two years.
At two years, 74.7 percent of patients who received the HeartMate 3 met the primary endpoint, compared with 60.6 percent of those who received the HeartMate II, a 40 percent reduction in risk favoring the HeartMate 3. The rate of pump replacement at two years was 2.3 percent for patients receiving the HeartMate 3 and 11.3 percent for those who received the HeartMate II.

Pump clotting occurred in 1.4 percent of HeartMate 3 patients compared with 13.9 percent of HeartMate II patients. Five percent of HeartMate 3 patients experienced a disabling stroke compared with 7.5 percent of HeartMate II patients. Significantly fewer HeartMate 3 patients experienced episodes of any type of bleeding (43.7 percent) or gastrointestinal bleeding (24.5 percent) compared with HeartMate II patients (55 percent for any type of bleeding, 30.9 percent for gastrointestinal bleeding).

HeartMate 3 patients spent more days on LVAD support outside of hospital (a median of 48 more days in the Heartmate 3) and spent fewer days in the hospital after being readmitted (a median of 13 days, compared with a median of 18 days for HeartMate II patients).

Patients continued to be at increased risk for infections at two years of follow-up, Mehra said. He said that he and his colleagues are engaging with infectious disease experts to try to find ways of reducing susceptibility to infection in patients with advanced heart failure.

The research team plans to continue to follow the MOMENTUM-3 patients for at least another three years to monitor their long-term survival. Additionally, they are developing a new trial that will examine how to optimize medical therapy for patients with advanced heart failure—for example, whether bleeding episodes might be further reduced by discontinuing daily aspirin or switching from the traditional blood thinner warfarin to newer blood-thinning medications.

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