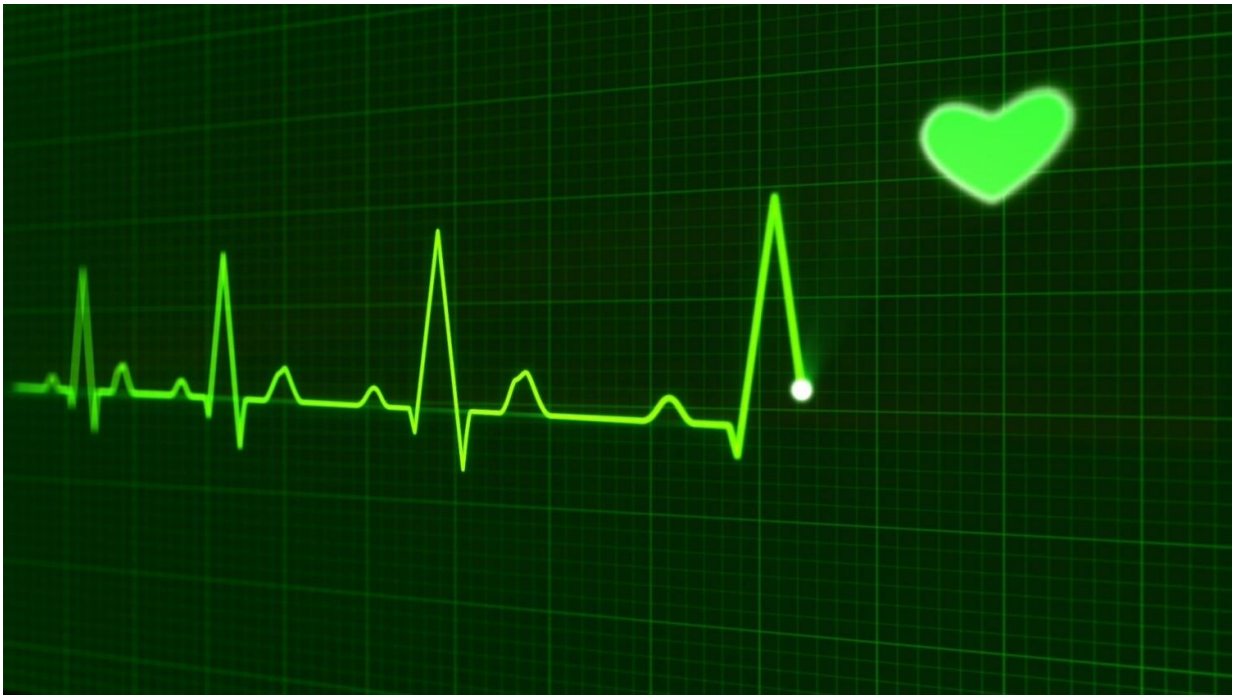
Study of patients on heart pumps debunks myths about categories and outcomes

January 15 2020



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A new analysis provides evidence that may change the current thinking around categorizing patients with heart failure prior to implanting a left-ventricular assist device (LVAD). Currently, clinicians and regulatory agencies divide patients who receive LVADs into two distinct categories: those receiving a device as a bridge to transplant (BTT) and those for whom the device is considered a destination therapy (DT). For BTT

patients, the device is intended to extend survival until they can receive a heart transplant. For DT patients, the device is intended for long-term use. Not all patients fit neatly into these categories—many are stuck in a gray zone known as bridge to transplant candidacy (BTC). But regardless of category and the intended goal of therapy, patients who received an LVAD known as the HeartMate 3 had a similarly low rate of disabling stroke of reoperations and their outcomes were significantly better compared to patients who received an older generation LVAD. These findings, led by investigators at Brigham and Women's Hospital, call into question the current practice of dividing patients into categories, suggesting that a single treatment goal may suffice: to extend survival and improve quality of life for patients with heart failure who haven't responded to therapy. The team's findings are published in *JAMA Cardiology*.

"This is an important analysis that could lead to a major change in thinking around adjudication of LVADs into discrete categories," said corresponding author Mandeep Mehra, MD, Executive Director of the Brigham's Center for Advanced Heart Disease. "We often fear that the focus on categorizing patients based on the goal of therapy, especially for patients who fall into the gray zone, may cause significant delays in decision making. Our data indicate that with the new generation LVAD, important clinical outcomes are relatively similar between these groups, suggesting that our attention should be on the patient's journey, not the destination. We should be focused on the patient's characteristics and identifying those who are transitioning into advanced heart failure for whom an LVAD may improve quality of life."

The current study leverages data from the Multicenter Study of MagLev Technology in PatientsUndergoing Mechanical Circulatory Support Therapy with HeartMate 3 (MOMENTUM 3), a randomized clinical trial sponsored by Abbott Laboratories, the manufacturer of HeartMate 3. MOMENTUM 3 enrolled patients irrespective of their intended goal

of therapy. Patients were randomized to receive either the HeartMate II—an older generation axial flow pump—or the HeartMate 3—a magnetically-levitated, continuous centrifugal-flow circulatory pump. The trial evaluated how many participants, two years after receiving their device, had not suffered a disabling stroke or had an operation to replace or remove a malfunctioning device.

A total of 1,020 patients received an LVAD. Of these patients, 396 (39 percent) were initially categorized by their clinicians as BTT or BTC and 624 (61 percent) were DT. Patients who received the HeartMate3 had a significantly lower rate of disabling stroke or reoperation than those who received the HeartMate II than those who received the HeartMate II in both the BTT/BTC group (77 percent versus 67 percent) and DT group (73 percent versus 59 percent). There were no differences in rates of pump thrombosis or stroke.

"The use of these designations based on current or uncertain future transplant eligibility is not necessary," said Mehra. "Patients with medically refractory heart failure can be successfully treated under a single preimplant strategy with the goal of extending survival and improving quality of life."

More information: Goldstein, DJ et al. "Association of Clinical Outcomes With Left Ventricular Assist Device Use by Bridge to Transplant or Destination Therapy Intent The Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HeartMate 3 Randomized Clinical Trial" *JAMA Cardiology* DOI: 10.1001/jamacardio.2019.5323

Provided by Brigham and Women's Hospital