New evidence supports ablation for heart failure patients with atrial fibrillation

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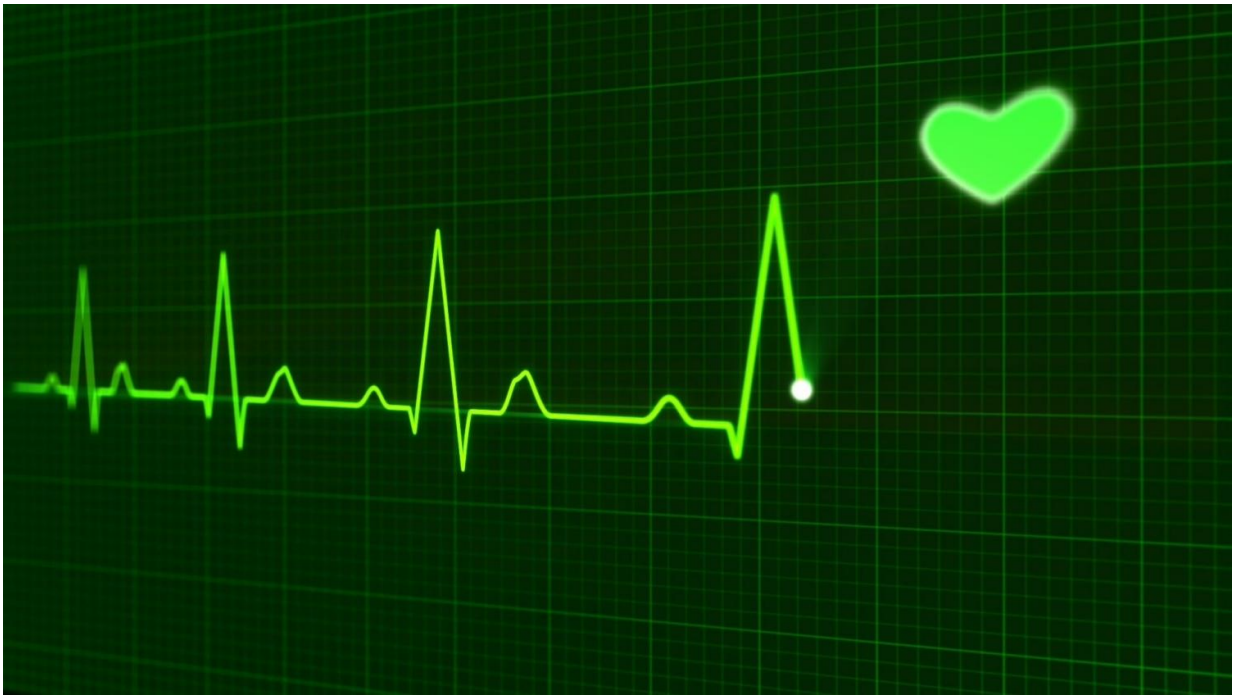

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Only 1 in 13 everyday patients could have participated in a pivotal international clinical trial looking at the use of catheter ablation to treat atrial fibrillation (AFib) among people with heart failure. However, new Mayo Clinic research provides evidence supporting the benefit of ablation, and shows what the outcomes might be for everyday patients. The Mayo study will be published in *Heart Rhythm* Journal.

The Catheter Ablation for Atrial Fibrillation with Heart Failure (CASTLE-AF) trial compared catheter ablation versus medical therapy alone for atrial fibrillation in patients with heart failure. In early 2018, the results of that trial were announced. Although the trial was fairly small with 363 participants, it showed an impressive 38% reduction in risk of death or hospitalization for worsening heart failure.

Xiaoxi Yao, Ph.D., a Mayo Clinic health services researcher, and Peter Noseworthy, M.D., a Mayo Clinic cardiologist, wanted to see if these findings would bear out across a broader population.

"Randomized clinical trials are the gold standard for evaluating new medical treatments or procedures," says Dr. Yao. "However, often their results are not necessarily applicable across a more heterogeneous group of people. Sometimes results cannot be replicated or are simply not as striking when interventions are tested across a broader population."

Why this study?

Heart failure affects about 6.5 million adults in the U.S., according to the Centers for Disease Control and Prevention. It leads to 1 in 8 deaths, and costs the nation tens of billions of dollars each year.

"Heart failure and AFib often go hand-in-hand," says Dr. Noseworthy. "The trouble is that one problem exacerbates the other. So, patients with heart failure often get much worse when they develop AFib and patients with AFib may go on to develop severe morbidity from heart failure. We need interventions for these patients to prevent the downward spiral."

Drs. Yao and Noseworthy, and their team, were able to use the OptumLabs Data Warehouse to determine what outcomes would hold true for a larger, more diverse group of people. The OptumLabs Data Warehouse is a longitudinal, real-world data asset with de-identified

administrative claims and electronic health record data.

"CASTLE-AF had very dramatic results—a nearly 40% mortality benefit of ablation in this population. We needed to see how this played out in everyday practice," says Dr. Noseworthy.

Their team identified 289,831 patients with both heart failure and atrial fibrillation between Jan. 1, 2008, and Aug. 31, 2018. This group was nearly 800 times larger than the CASTLE-AF trial.

Of these patients, less than 8% would have been fully eligible for the trial; whereas, only 15.5% would have met exclusion criteria.

"This discrepancy is one of the pitfalls of randomized clinical trials leading to less generalizable findings," says Dr. Yao. "There are many reasons why a person might not meet inclusion criteria, including some which introduce unintended bias."

Study size strengthens evidence

The Mayo team found that although less pronounced than in the CASTLE-AF trial, ablation was associated with a lower risk of death or hospitalization due to worsening heart failure across all patients, except those who would have met exclusion criteria.

"While our study validates this concept, the results are more modest in practice," says Dr. Noseworthy.

Among those who would have been eligible to participate, the current study showed an 18% reduction—much more modest than the results of the CASTLE-AF trial. People in the current study who received ablation and met exclusion criteria for the clinical trial did not reduce their risk of death. Rather, they showed an increased likelihood hospitalizations

related to heart failure.

"Our study is especially important because it provides complementary evidence in a case where very few clinical trials have been conducted," he says. "In addition, a large observational study provides a more realistic picture of treatment effects for our everyday patients."

Provided by Mayo Clinic