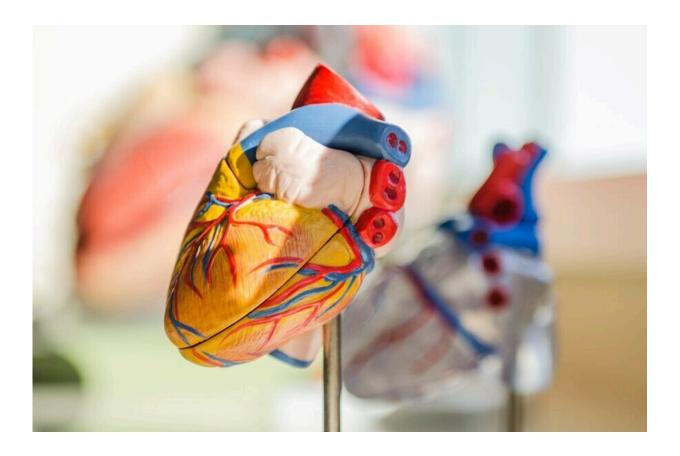


New ablation technology found safe, effective for atrial fibrillation

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A new ablation technology known as pulsed field ablation was successful at eliminating episodes of abnormal heart rhythms for 12 months in up to two-thirds of patients, according to a study being presented at the



American College of Cardiology's Annual Scientific Session Together With the World Congress of Cardiology.

The study is the first prospective, global clinical trial for the use of pulsed field <u>ablation</u>, which issues <u>electrical pulses</u>, for treating the <u>heart rhythm disorder atrial fibrillation</u> (AFib). Ablation is a minimally invasive catheter-based procedure that disables portions of heart tissue that cause irregular heart rhythms.

Pulsed field ablation is different from thermal ablation—which has stood as the standard ablation method for AFib for decades—in that it disables cardiac cells using electricity rather than extreme temperatures. The technology allows ablation procedures to be performed in less time and with a lower risk of damage to surrounding tissues than thermal ablation, according to researchers.

"The efficacy of the procedure is similar to what we see in thermal ablation, but we're getting it much faster and with much more safety," said Atul Verma, MD, head of cardiology at McGill University Health Centre in Montreal, Canada, and the study's lead author. "That is a major development for the field of electrophysiology."

AFib, the most common type of heart rhythm disorder, causes a variety of symptoms including fast or chaotic heartbeat, fatigue, shortness of breath and chest pain and increases a person's risk of stroke. Ablation is one of several procedural and medical interventions used to control AFib symptoms and reduce stroke risk.

In standard thermal ablation procedures, a physician threads tiny instruments to the heart via a vein or artery. Heat (radiofrequency energy) or extreme cold (cryoablation) is then applied to create small scars in specific portions of the atria. However, thermal ablation carries the risk of damaging other nearby tissues and structures, such as the



esophagus and nerves.

By contrast, pulsed field ablation uses electrical fields to create tiny holes in the membranes of heart muscle cells. This causes the targeted cells that contribute to irregular heart rhythms to die without altering the overall structure of the tissue or affecting other cell types. Pulsed field ablation has been used to treat cancer by killing tumor cells for about a decade; however, the technology has only recently been applied to the heart.

The study, PULSED AF, was conducted at 41 sites in nine countries (U.S., Canada, Australia, Austria, Belgium, France, Japan, the Netherlands and Spain) and enrolled patients who continued to experience AFib despite taking medicines to improve heart rhythm regulation.

For the trial, physicians first treated one patient each to gain experience with the technique, in a total of 60 patients. They then continued to enroll patients and perform pulsed field ablations up to an additional 300 procedures between all sites. Researchers analyzed final outcomes from these 300 procedures.

Half of the patients had paroxysmal AFib (in which episodes of irregular heartbeat end on their own and do not last more than a week) and half had persistent AFib (in which episodes continue for at least a week and do not end on their own).

Sixty-six percent of patients with paroxysmal AFib and 55% of those with persistent AFib experienced no AFib episodes between three months and 12 months after their procedure (the trial's primary endpoint), as measured by weekly and symptomatic self-reports, electrocardiograms and 24-hour Holter monitoring. These rates of efficacy are on par with outcomes from thermal ablation procedures,



according to researchers.

In addition, all patients reported significant and meaningful improvements in quality of life. Only one adverse event occurred in each of the two patient cohorts, for an adverse event rate of 0.7%. Researchers said that most pulsed field ablation procedures were completed in less than an hour, making them substantially faster than thermal ablation procedures, which typically take two hours or more.

"There's been a huge amount of enthusiasm over this technology in the electrophysiology community," Verma said. "Many physicians feel that pulsed field ablation will become the dominant way of doing ablation moving forward, so in that sense, it's really a paradigm shift."

Study researchers said that the trial was limited by its lack of a control group. In addition, larger studies will be needed to provide more definitive evidence of the procedure's safety since adverse events are generally rare with cardiac ablation. Researchers said that the success rates and safety of pulsed field ablation could improve further as the technology continues to advance.

More information: Conference:

www.expo.acc.org/ACC23/Public/Enter.aspx

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