

Two atrial fibrillation ablation techniques equal on efficacy and safety

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Two established techniques for correcting the root cause of the heart rhythm disorder atrial fibrillation show similar effects and safety outcomes, according to research presented at the American College of Cardiology's 65th Annual Scientific Session.

The study, called FIRE AND ICE, is the largest randomized trial to compare radiofrequency and cryoballoon [ablation](#), two techniques designed to treat [atrial fibrillation](#) by disabling small portions of the heart that generate out-of-sync electrical signals. Radiofrequency ablation uses heat energy to disable the targeted heart tissue, while the cryoballoon, a newer technique, uses extreme cold to achieve the same effect. The trial revealed no differences between the two techniques for the study's primary outcomes—the recurrence of an irregular heart rhythm or the need for medication or subsequent procedures to address atrial fibrillation. It was funded in part by Medtronic, which makes the cryoballoon device.

"The FIRE AND ICE trial demonstrated that the cryoballoon, a newer, easier-to-use ablation catheter, worked as well as the established technology, which ultimately means that more patients can be treated for atrial fibrillation without having [to go to a] specialized cardiac center," said Karl-Heinz Kuck, M.D., Ph.D., head of cardiology at St. Georg Hospital in Hamburg, Germany, and the study's lead author. "In addition, there was, in general, a low risk of procedural complications in both groups, demonstrating that catheter ablation has become much safer over the years."

Atrial fibrillation, estimated to affect more than 33 million people worldwide, is an irregular heart rhythm that can cause fatigue, lightheadedness, shortness of breath, chest pain and an increased risk for stroke. Although medications and lifestyle changes can help manage the condition's risk factors and symptoms, about 30 percent of patients do not benefit from available medications or cannot take them due to side effects or other reasons. Ablation is one option for treating these patients. During ablation, a physician threads a small medical device through a vein in the groin to kill a small number of cells around the heart's pulmonary veins, preventing them from issuing electrical signals that are out of sync with the rest of the heart.

The trial, conducted in eight European countries, enrolled 769 patients needing ablation for intermittent atrial fibrillation. Patients were randomly assigned to receive either the radiofrequency or cryoballoon technique; both patients and physicians were aware of which technique was being used. The two groups were similar in terms of demographic factors, such as age and gender, as well as health status, based on parameters such as body mass index, blood pressure and various measures of heart function.

In addition to using different methods for disabling the target [heart tissue](#), the two techniques involved different procedures to help the physician locate the target tissue. For radiofrequency procedures, physicians were guided by 3-D electroanatomical mapping to create tissue lesions in a point-by-point ablation approach. For cryoballoon procedures, physicians used a type of X-ray imaging known as fluoroscopy to create tissue lesions in a single-step ablation approach.

Outcomes were assessed through in-person patient visits conducted three months after the procedure, six months after the procedure and every six months thereafter. Each visit included an electrocardiogram test to assess heart rhythm and function, as well as the use of a Holter monitor, in

which the patient wears a monitor for 24 hours to check for any abnormal heart rhythm. Patients were tracked for just over 18 months, on average.

The results revealed no significant difference in the rates of recurrence of an [irregular heart rhythm](#) or the need for medication or subsequent procedures to address atrial fibrillation, outcomes that collectively occurred in 64.1 percent of patients receiving radiofrequency ablation and 65.4 percent of cryoballoon patients within 12 months after the procedure.

There were also no significant differences in the overall safety profile of the two techniques. Safety was assessed with a composite endpoint of death, stroke and procedure-related serious adverse events; 87.2 percent of patients receiving radiofrequency ablation and 89.8 percent of cryoballoon patients had not experienced any of these safety endpoints by 12 months after the procedure.

In both groups, there was generally a low rate of procedure-related complications such as infection, dangerous [heart rhythms](#) or accumulation of fluid in the heart. However, patients receiving cryoballoon ablation were significantly more likely to experience injury to the phrenic nerve, which can affect the functioning of the diaphragm and require patients to use an artificial ventilator. Such injuries occurred in 2.7 percent of cryoballoon patients and zero patients receiving radiofrequency ablation. In all but one of these cases, functioning was restored by 12 months post-operation.

The study revealed some significant procedural differences between the two techniques. Because it involved 3-D anatomical mapping, [radiofrequency ablation](#) required about five minutes less fluoroscopy time and, thus, exposed patients and physicians to radiation for a shorter period of time, though Kuck said that the overall usage of fluoroscopy

was relatively limited in both groups, at 21.7 minutes and 16.6 minutes total on average for the cryoballoon and radiofrequency procedures, respectively. Cryoablation was associated with a shorter overall procedure time by 18 minutes per procedure, on average, and a similarly reduced amount of time in which the catheter was present inside the heart's left atrium while the ablation was carried out.

"The procedure time was interesting because there are more cost pressures on the healthcare system for more efficient tools that keep procedures short and predictable," Kuck said.

Kuck said the findings could help inform future medical guidelines on the use of different [catheter ablation](#) techniques for treating atrial fibrillation. One limitation of the study is that it did not investigate ablation for treating [patients](#) with more advanced stages of atrial fibrillation. A separate trial would be needed to assess the ablation techniques' effectiveness and safety for that patient population, he said.

More information: Karl-Heinz Kuck et al. Cryoballoon or Radiofrequency Ablation for Paroxysmal Atrial Fibrillation, *New England Journal of Medicine* (2016). [DOI: 10.1056/NEJMoa1602014](https://doi.org/10.1056/NEJMoa1602014)

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