# クライオアブレーションは高周波アブレーションに匹敵する (LBCT 410-10)

FIRE and ICE：発作性心房細動におけるクライオアブレーションの安全性および有効性は高周波アブレーションと同等である

FIRE and ICE: Cryoablation comparable in safety and efficacy as RF ablation in paroxysmal atrial fibrillation

発作性心房細動（PAF）の治療において、クライオバルーンアブレーションの有効性および安全性は高周波カテーテル（RFC）アブレーションと同等である、とのFIRE and ICEトライアルの結果が示された。クライオバルーンはRFアブレーション治療群に比べ施術時間が短く（平均=124分対141分；p=0.0001）、透視時間はRFカテーテルの方が短かった（RFで平均17分；クライオバルーンで平均22分；p=0.0001）。このスタディ結果は第65回American College of Cardiology年次集会Late Breaking Clinical Sessionで発表され、同時に*New England Journal of Medicine*に掲載された。

## Full Text

Cryoballoon ablation efficacy and safety was equivalent to radiofrequency catheter (RFC) ablation for the treatment of paroxysmal atrial fibrillation (PAF), results of the FIRE and ICE trial show.

The positive results from the landmark FIRE AND ICE clinical trial, demonstrated comparable safety and effectiveness for the Arctic Front® Cryoballoon Catheter Family compared to the ThermoCool® line of radiofrequency (RF) ablation catheters for the treatment of symptomatic paroxysmal atrial fibrillation (AF). The study, presented in a late-breaking session at the American College of Cardiology's 65th Annual Scientific Sessions and published simultaneously in *The New England Journal of Medicine*, provides further clinical validation that Cryoballoon ablation is a safe and effective option for ablation treatment, with shorter and more consistent procedure times.

"Through this rigorously designed trial, we found that Cryoballoon catheter technology is not only comparable to RF ablation - the current standard of care - but also delivered key procedural efficiencies," said Prof. Karl-Heinz Kuck, M.D., director of cardiology at Asklepios Klinik St. Georg, Hamburg, Germany, and principal investigator of the trial. "The simple, straightforward cryoablation procedure may allow us to treat more patients with AF."

The trial met its primary efficacy endpoint of showing non-inferiority for the Arctic Front Cryoballoon catheters without 3D mapping compared to ThermoCool® RF ablation catheters using 3D mapping (p=0.0004) in reducing arrhythmia recurrence and the need for antiarrhythmic drug therapy and/or re-ablation.  It also met its primary safety endpoint of time to first all-cause death, all-cause stroke/TIA, or treatment-related serious adverse events (p=0.24); both technologies had similarly low complication rates. The Cryoballoon demonstrated shorter procedure times (mean=124 minutes) compared to the RF ablation treatment arm (mean=141 minutes; p=0.0001), and fluoroscopy times were shorter with the RF catheter (mean=17 minutes with RF; mean=22 minutes with cryoballoon; p=0.0001).

Isolating the pulmonary veins (pulmonary vein isolation, or PVI), which are a source of erratic electrical signals that cause AF, is a standard approach for treating AF patients: the Cryoballoon uses coolant to create contiguous, circumferential lesions to achieve PVI; RF ablation uses heat (RF energy) and requires 3D mapping as well as point-by-point application to achieve PVI.

A total of 769 patients from 16 medical centers throughout Europe were enrolled in the trial. All subjects were diagnosed with paroxysmal AF, had failed at least one antiarrhythimic drug and were followed for up to 33 months (mean = 1.54 years) following initial ablation. A non-inferiority design is often used to demonstrate that a newer technology is comparable to the currently accepted and existing technology.

"As the largest head-to-head study comparing these two technologies to treat AF, the FIRE AND ICE results provide important clinical insights on safety and effectiveness, and also show Cryoablation with more consistent procedure times, which benefits both patients and physicians," said Colleen Fowler, vice president and general manager of the AF Solutions business, part of the Cardiac and Vascular Group at Medtronic. "As the world's population continues to age, the demand for safe, clinically effective and efficient advanced treatment options will only increase. Today's findings further support the rapid global adoption of Cryoablation and serve as a significant milestone in helping guide optimal patient care."

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