**WHY EARLY REFERRAL FOR CATHETER ABLATION OF DRUG REFRACTORY RECURRENT PAF MATTERS**

**Stroke Risk**

In a secondary analysis of the AFFIRM Trial, the presence of sinus rhythm is associated with a 50% lower risk of death in patients with Atrial Fibrillation (AF). However, the use of antiarrhythmic drugs to achieve sinus rhythm was associated with a 50% increased risk of death.

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**Sinus Rhythm**

Associated with 50% Decreased Mortality Risk

p < 0.0001 (HR 0.53; CI 0.39 - 0.72)

**Rhythm Control Drug Use**

Associated with 50% Increased Mortality Risk

p < 0.0005 (HR 1.49; CI 1.11 - 2.01)

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**The Intermountain Health Study (n = 4,535)**

The earlier patients are referred for stroke risk to a cardiologist, the sooner those patients may be identified as a potential candidate for catheter ablation. Treating PAF patients earlier with catheter ablation has shown the potential for improved outcomes.

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**Catheter ablation is a safe and effective alternative after AADs**

Multiple randomized studies have shown, through direct comparison, that catheter ablation is significantly more effective than AADs in patients with symptomatic PAF.

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**References**


There are two primary tools and techniques to achieve pulmonary vein isolation (PVI) with catheter ablation.

**Cryoballoon Technology:**
- The cryoballoon removes heat from the pulmonary vein tissue in a continuous application, efficiently scarring and disabling irregular electrical signals.
- The cryoballoon is an anatomical approach for PVI, creating long contiguous circumferential lesions surrounding the pulmonary vein.
- No 3D mapping required

**Radiofrequency Technology:**
- Several point-by-point applications of the catheter to achieve PVI
- Creates lesions using heating technology
- Use of 3D mapping is required

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**More Consistent and Reproducible Outcomes with Cryoballoon Ablation**

Among centers with varying annual ablation volume, cryoballoon ablation resulted in more consistent outcomes and procedure times compared to RF.

![Graph showing cryoballoon and radiofrequency ablation outcomes](image)

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**Better Outcomes with Cryoballoon**

**Fire and Ice™ Trial Predefined Secondary Analyses**

The FIRE AND ICE AF Ablation Clinical Trial is the largest prospective, 1:1 randomized, noninferiority study (762 patients from 16 sites in 8 countries) that compared the efficacy and safety of PVI using cryoballoon vs. radiofrequency (RF) ablation with the CARTO® 3D mapping system in patients with paroxysmal atrial fibrillation (PAF). Primary Efficacy Endpoint: Time to first all-cause death, all-cause stroke/TIA, prescription of AAD, or repeat ablation. Primary Safety Endpoint: Freedom from AF/AFL, prescription of AAD, or repeat ablation. Primary Safety and Efficacy Endpoints. Endpoint: Time to first all-cause death, all-cause stroke/TIA, prescription of AAD, or repeat ablation. Primary Safety and Efficacy Endpoints. Endpoint: Time to first all-cause death, all-cause stroke/TIA, prescription of AAD, or repeat ablation.

**Cryoballoon Ablation**
- Freedom from AF/AFL (%)
- Follow-up duration (months)
- 100-150/yr

**Radiofrequency Ablation**
- Freedom from AF/AFL (%)
- Follow-up duration (months)
- 100-150/yr

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**34% Fewer Cardiovascular Hospitalizations (including AF hospitalizations)**

**Cryo:** 139 events in 89 subjects (89/374; 23.8%)
**RF:** 203 events in 135 subjects (135/376; 35.9%)

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**33% Fewer Repeat Ablations**

**Cryo:** 49 events in 44 subjects (44/374; 11.8%)
**RF:** 70 events in 66 subjects (66/376; 17.6%)

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**Potential Complications**

- Potential complications/adverse events from cryoballoon ablation include:
  - Urinary infection
  - Vasovagal reaction
  - Visual impairment
  - Injury
  - Pericardial effusion
  - Pulmonary vein stenosis
  - Myocardial infarction
  - Nausea/vomiting
  - Nerve injury
  - Esophageal damage (including esophageal fistula)
  - Fatigue
  - Headache
  - Hysterectomy
  - Hypertension
  - Hypertension
  - Light-headedness
  - Myocardial infarction
  - Nausea/vomiting
  - Nerve injury
  - Pulmonary embolism
  - Pulmonary vein stenosis
  - Shivering
  - Shortness of breath
  - Sore throat
  - Tachycardia
  - Transient ischemic attack
  - Urinary infection
  - Vasovagal reaction
  - Visual changes

- Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events.
- For further information, please call Medtronic at 1-800-328-2918 and/or consult the Medtronic website at medtronic.com.

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**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.