

Title: Safety and Efficacy of Mitral Isthmus Isolation Using Focal Pulsed Field Ablation Within the Coronary Sinus

Brief title: Safety and Efficacy of PFA Within the Coronary Sinus for Mitral Isthmus Isolation

Document date: May 5, 2026

Brief summary:

This study evaluates the use of focal pulsed field ablation (PFA) inside the coronary sinus (CS) to help treat atrial fibrillation (AF). Standard heat-based treatments often fail to permanently block abnormal electrical signals in thick heart tissue like the mitral isthmus (MI). This research tests whether PFA—a technology that uses electrical pulses instead of heat—can safely and effectively create a complete electrical block in this area. We will monitor 30 patients to check for immediate procedural success and ensure the safety of nearby structures, such as the right coronary artery, using heart scans (CTA).

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Intervention Name: Focal Pulsed Field Ablation of the Coronary Sinus

Intervention Description:

The intervention involves the delivery of non-thermal, high-voltage electrical pulses within the coronary sinus using the AForcePlus PFA catheter (APT Medical). This is performed to achieve transmural lesions at the mitral isthmus (MI) that complement endocardial ablation. The procedure targets myocardial cells while minimizing thermal damage to adjacent structures, particularly the right coronary artery. Bidirectional conduction block is verified via differential pacing techniques.

Inclusion Criteria:

- Symptomatic paroxysmal or persistent atrial fibrillation documented by ECG or Holter monitoring.
- Age between 18 and 75 years.
- Willingness to comply with the post-procedural follow-up, including cardiac CTA scans.
- Requirement for substrate modification including linear ablation at the mitral

isthmus.

Exclusion Criteria:

- History of prior heart surgery or Left Atrial Appendage Occlusion (LAAO).
- Heart failure symptoms classified as NYHA Class III or IV.
- Advanced renal failure (eGFR < 30 mL/min/1.73m²).
- Presence of left atrial thrombus identified by transesophageal echocardiography (TEE).

Primary Outcome Measure

- **Title:** Acute Procedural Success of Mitral Isthmus Isolation.
- **Description:** The percentage of patients achieving acute bidirectional conduction block across the mitral isthmus line, confirmed by differential pacing from the left atrial appendage and distal coronary sinus.
- **Time Frame:** Intraoperative (immediately following the ablation procedure).

Study Protocol with Statistical Analysis Plan

- **Protocol:** Patients undergo standardized pulmonary vein isolation (PVI) followed by endocardial mitral isthmus (MI) ablation. If a complete block is not achieved endocardially, focal PFA is delivered within the coronary sinus. Safety is assessed via biomarkers (cTnT, LDH, Haptoglobin) and cardiac CTA at follow-up.
- **Statistical Analysis:** Quantitative variables will be expressed as mean ± standard deviation or median with interquartile range. Differences between pre- and post-ablation values will be analyzed using the paired t-test or Wilcoxon signed-rank test, depending on data normality (verified by Shapiro-Wilk test). Categorical data will be presented as frequencies and percentages. All statistical analyses will be performed using SPSS version 26.0.