

Sicurezza ed efficacia del catetere PFA circolare a nove elettrodi per l'ablazione della Fibrillazione Atriale

Dr. Danilo Ricciardi
**Fondazione Policlinico Campus Bio-
Medico di Roma**



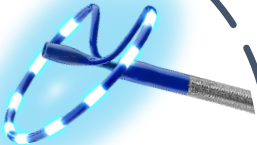
Anatomical Based PVI PFA Technologies on the market

Boston Scientific



FaraWave
2021

Medtronic



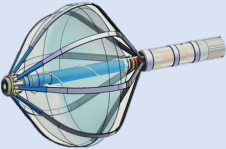
PulseSelect
March 2024

J&J



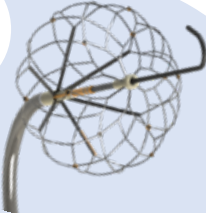
VariPulse
March 2024

Abbott



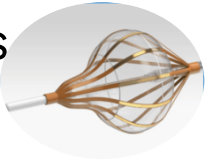
VOLT
April 2025
End 2025

Medtronic



Sphere-360
July 2026
Beginning 2026

CARDIO FOCUS



HeartLight X4

Kardium



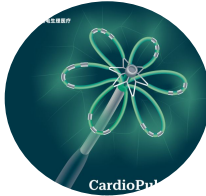
Kardium Globe

Adagio MEDICAL



iCLAS

DiNOVA



CardioPulse

Pulse Biosciences



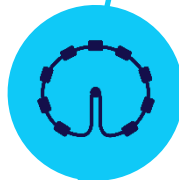
Nanosecond

OTHERS Start-Up
Expected

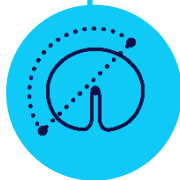


PulseSelect™ PFA catheter

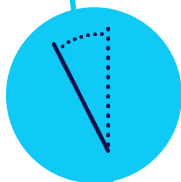
9 electrodes built to
sense, ablate, and pace



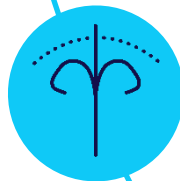
25 mm diameter loop



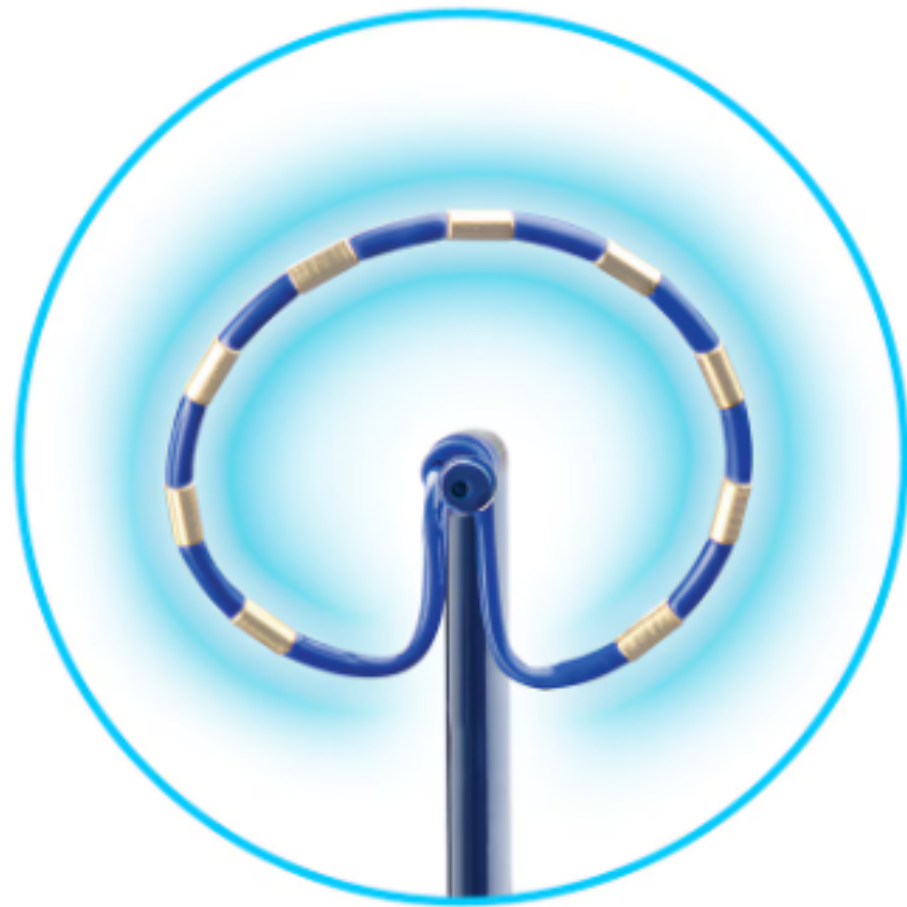
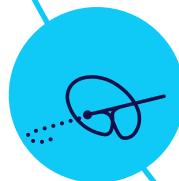
20° forward tilted array



9 Fr shaft with bidirectional
steering

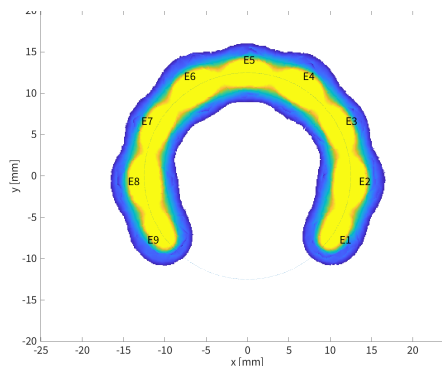


0.032" over-the-wire design

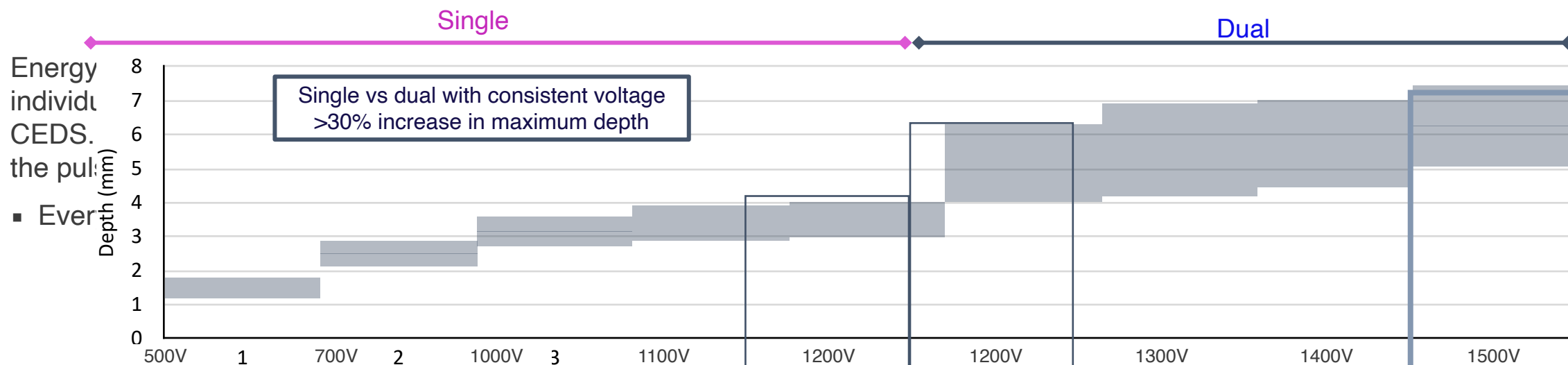
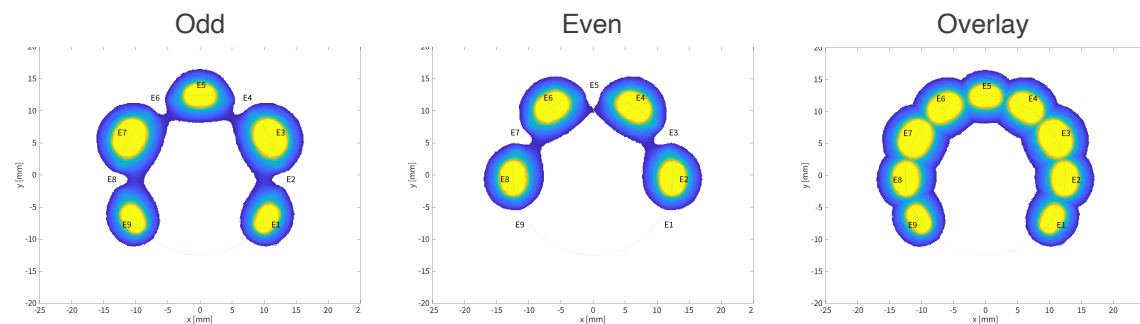


Vectoring technology enhances field depth while limiting required voltage

Single field mode



Dual field mode

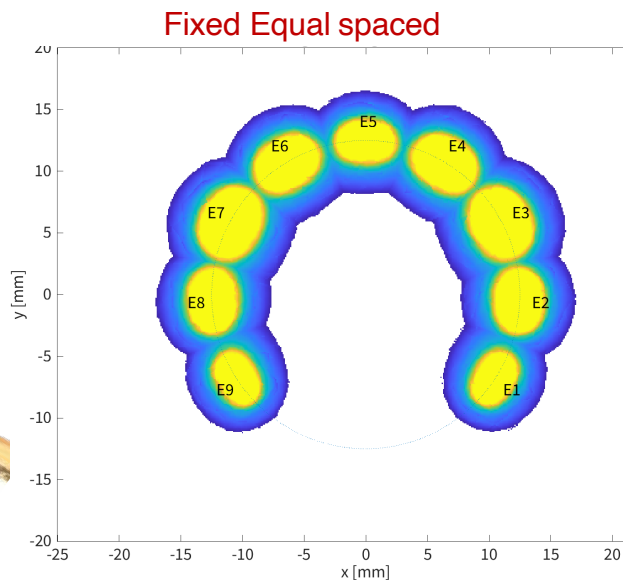
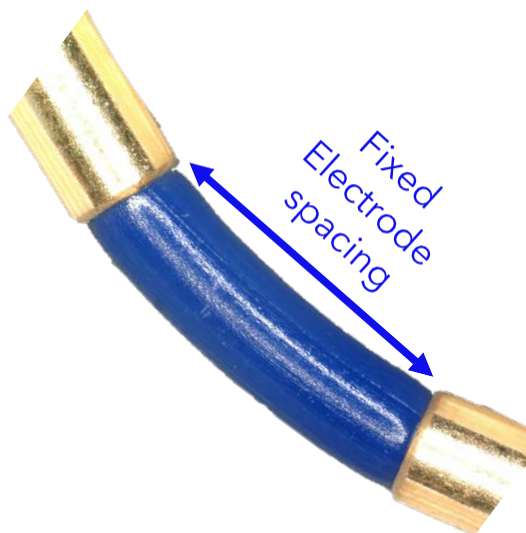


Shape & design - electrode spacing

What does it matter?

Fixed Electrode Spacing

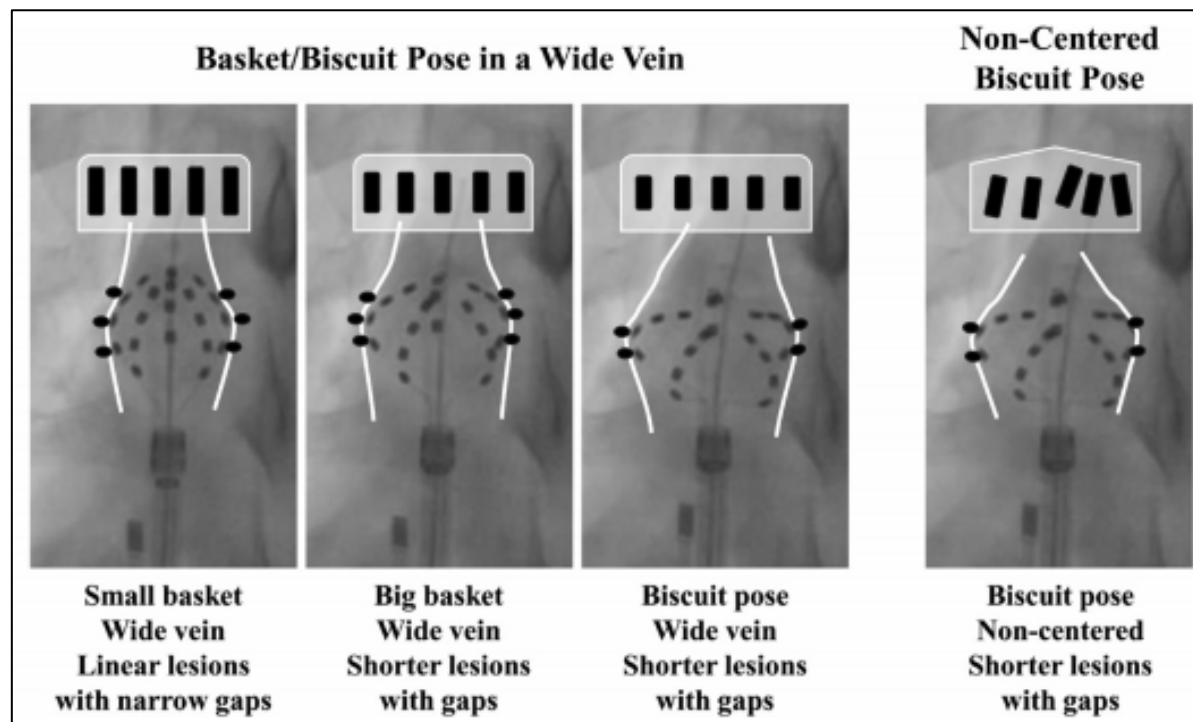
Consistent field regardless of catheter position¹



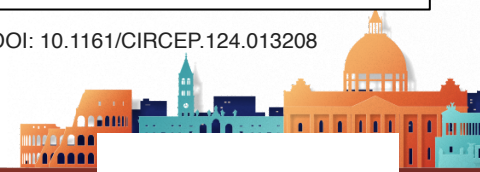
- 500V/cm threshold visualized
- Voltage controlled delivery at 1500V

Variable Electrode Spacing

Changing fields depending on electrode position



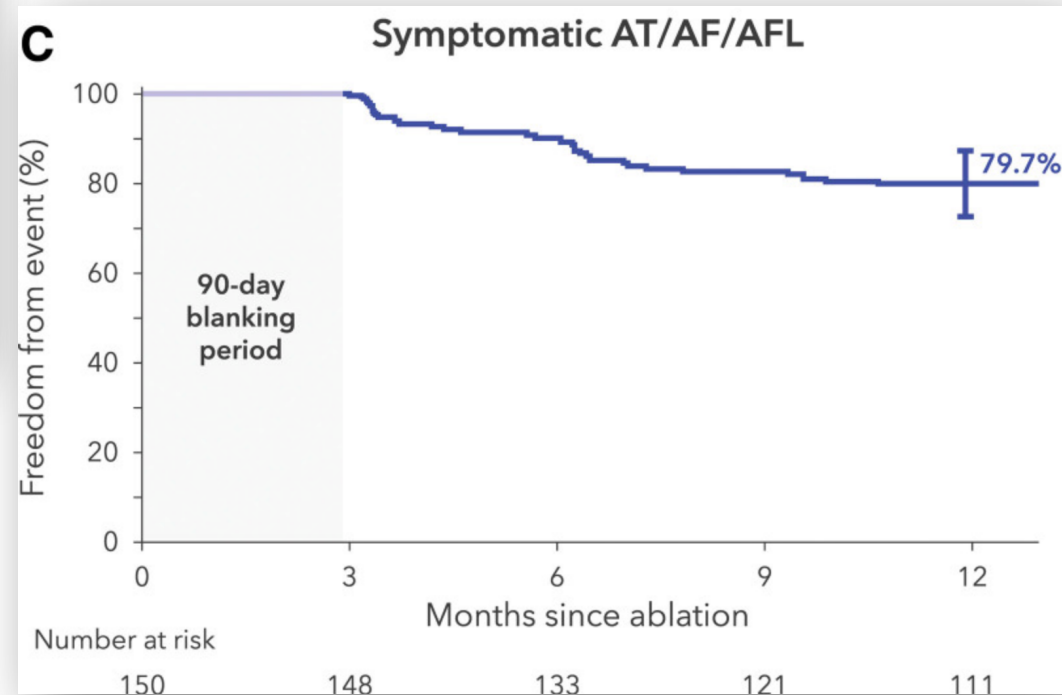
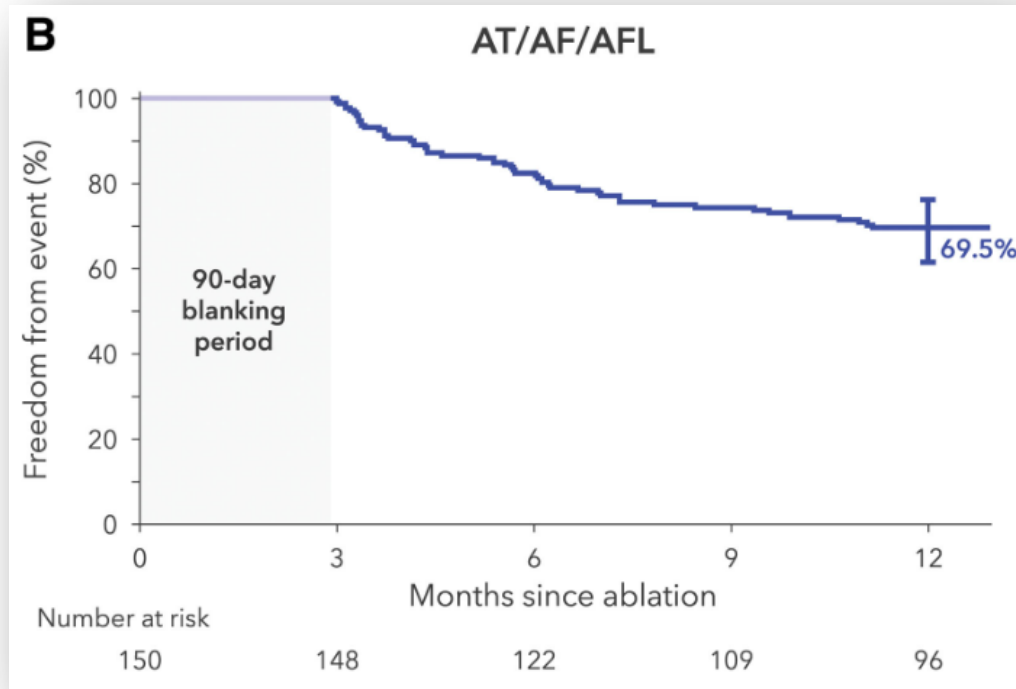
Watanabe et al. Circ Arrhythm Electrophysiol. 2024;17:e013208. DOI: 10.1161/CIRCEP.124.013208



Pulsed Field Ablation for the Treatment of Atrial Fibrillation: PULSED AF Pivotal Trial

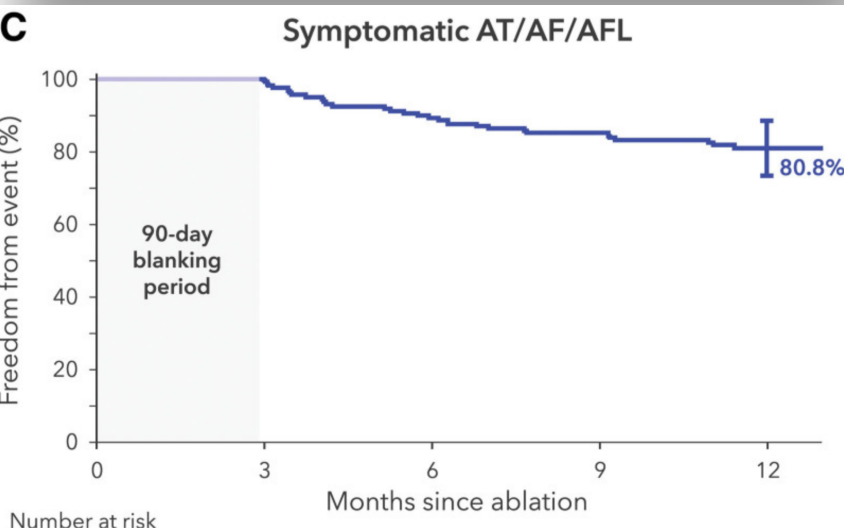
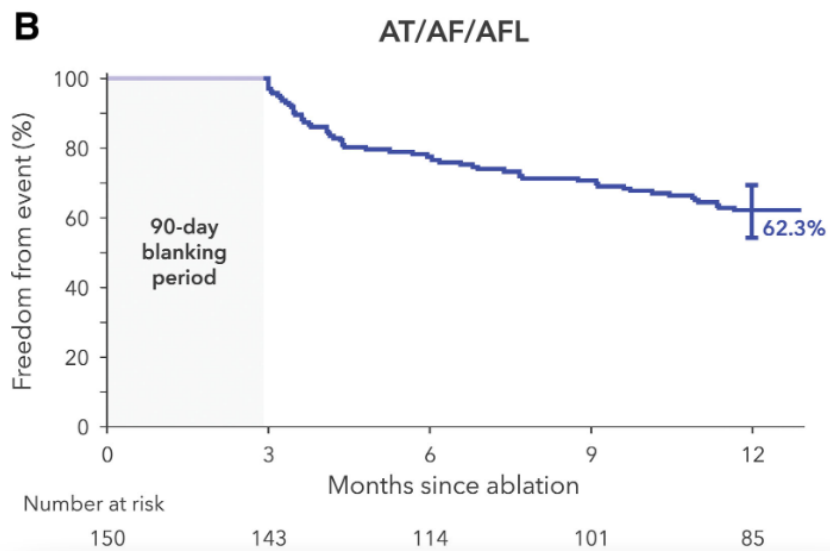
Treatment success* at 12 months for paroxysmal atrial fibrillation.

Any atrial tachyarrhythmia found on a Holter, ECG, or transtelephonic monitor after the blanking period is considered an event.

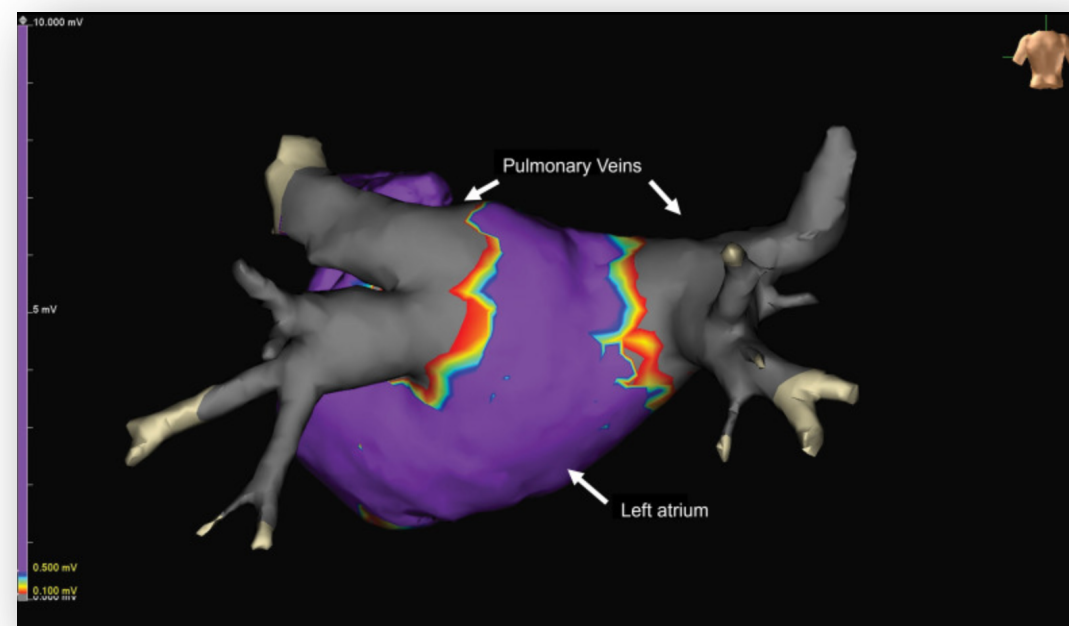


**Freedom from chronic failure (arrhythmia recurrence, escalation of antiarrhythmic drugs, or repeat ablation)*

Pulsed Field Ablation for the Treatment of Atrial Fibrillation: PULSED AF Pivotal Trial



Treatment success* at 12 months for persistent atrial fibrillation
Any atrial tachyarrhythmia found on a Holter, ECG, or transtelephonic monitor after the blanking period is considered an event



**Freedom from chronic failure (arrhythmia recurrence, escalation of antiarrhythmic drugs, or repeat ablation)*

Unmatched safety



0 Esophageal events



0 PV stenosis



0 Phrenic nerve injury



0 Coronary artery spasm

PULSED AF demonstrated a low rate of primary safety adverse events (0.7%) and provided effectiveness consistent with established ablation technologies using a novel irreversible electroporation energy to treat patients with AF.

1/300 Cerebrovascular accident

1/300 Tamponade

0/300 Transient ischemic attack

0/300 Major bleeding

0/300 Myocardial infarction

0/300 Pericarditis

0/300 Vagal nerve injury

0/300 Systemic pulmonary embolism

0/300 Pulmonary edema

0/300 Vascular access complications

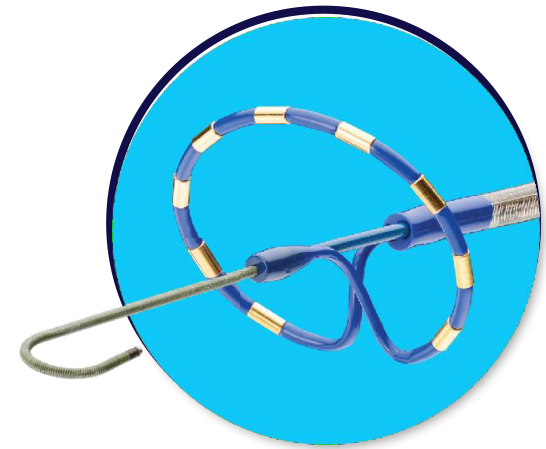
0/300 Cardiovascular hospitalization

0/300 Death



Pulsed field ablation (PFA) durability research^{1,2}

Reproducible durability^{1,2} in paroxysmal (PAF) and persistent (PsAF) patients using the PulseSelect PFA system



Nair, et al.¹

25

PAF and PsAF patients

Remapped at
~60 days

Durable PVI confirmed

98%

per vein

102/104 pulmonary veins durably isolated

96%

per patient

24/25 patients all PVs durably isolated



15

PAF and PsAF patients



Remapped at
~75 days



Durable PVI confirmed

95%

per vein

52/55 pulmonary veins durably isolated

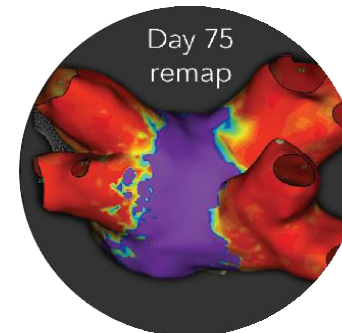
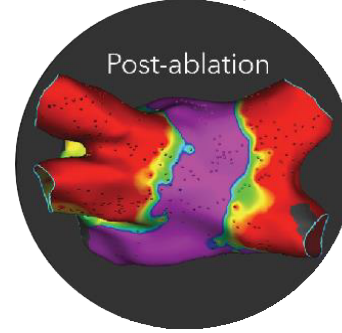
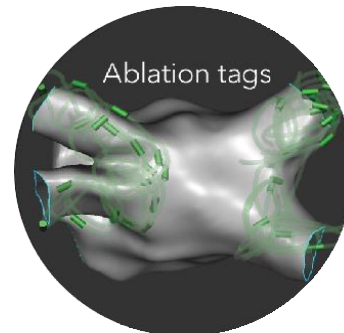
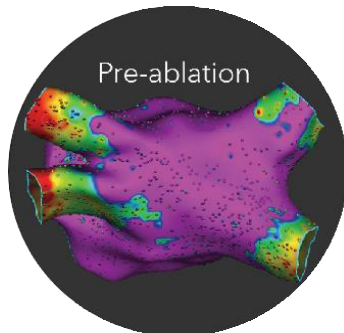
93%

per patient

14/15 patients all PVs durably isolated

Reproducible durability

with the
PulseSelect PFA system



Verma, et al.²

1. Nair, et al. First Invasive remapping to assess long term durability of pulmonary vein isolation using a circular pulsed field ablation catheter. Presented at APHRS 2024.

2. Verma A, et al. Chronic Durability of Pulmonary Vein Isolation using the PulseSelect Pulsed Field Ablation Catheter Integrated with a Novel Mapping and Navigation System. AF Symposium, 2025

Acute outcomes and learning curve from the initial patients treated with the PulseSelect system: a real-world multicenter experience of pulsed field ablation

Giulio Molon¹  · Stefano Nardi² · Gianfranco Mitacchione³ · Antonio Dello Russo⁴ · Danilo Ricciardi⁵ · Roberto Mantovan⁶ · Luca Bontempi⁷ · Alessandro Costa¹ · Luigi Argenziano² · Edoardo Casali⁸ · Vincenzo Turco⁸ · Giuseppe Boriani⁸

- Multicenter study
- Enrollment included the **first consecutive patients treated with pulmonary vein isolation (PVI) using the PulseSelect™** pulsed field ablation system.
- The study population consisted of **patients diagnosed with (symptomatic) atrial fibrillation (AF)**.

paroxymal

persistent

Journal of Interventional Cardiac Electrophysiology
<https://doi.org/10.1007/s10840-025-02036-5>

Acute outcomes and learning curve from the initial patients treated with the PulseSelect system: a real-world multicenter experience of pulsed field ablation

One Shot to Pulmonary Vein Isolation (1STOP) project



N=131

Paroxysmal &
Persistent
Atrial fibrillation



N=6

European Centers

Procedure:

Pulmonary vein
isolation (PVI) using
the PulseSelect System



Procedure time: 55.0 minutes
Fluoroscopy time: 16.0 minutes



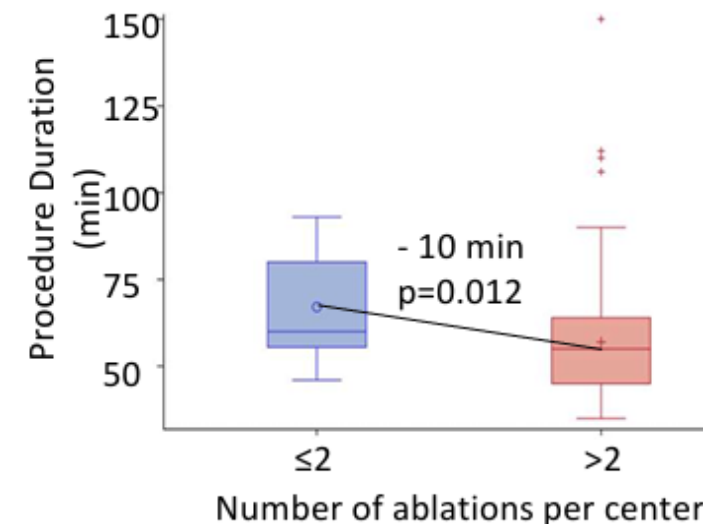
General anesthesia: 75.5 %
Moderate sedation: 24.5%
• 15.1% w/o anesthesiologist



Acute PVI success was 100%
No major complications

Procedural Efficiency

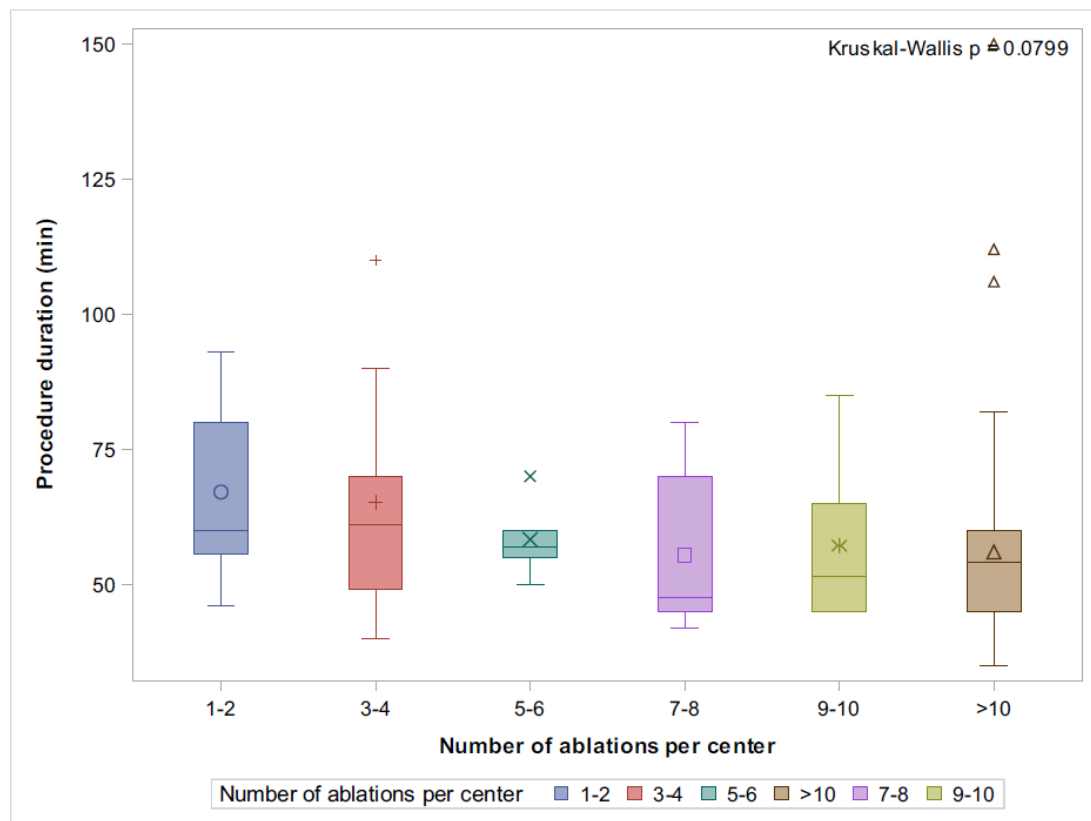
Learning Curve



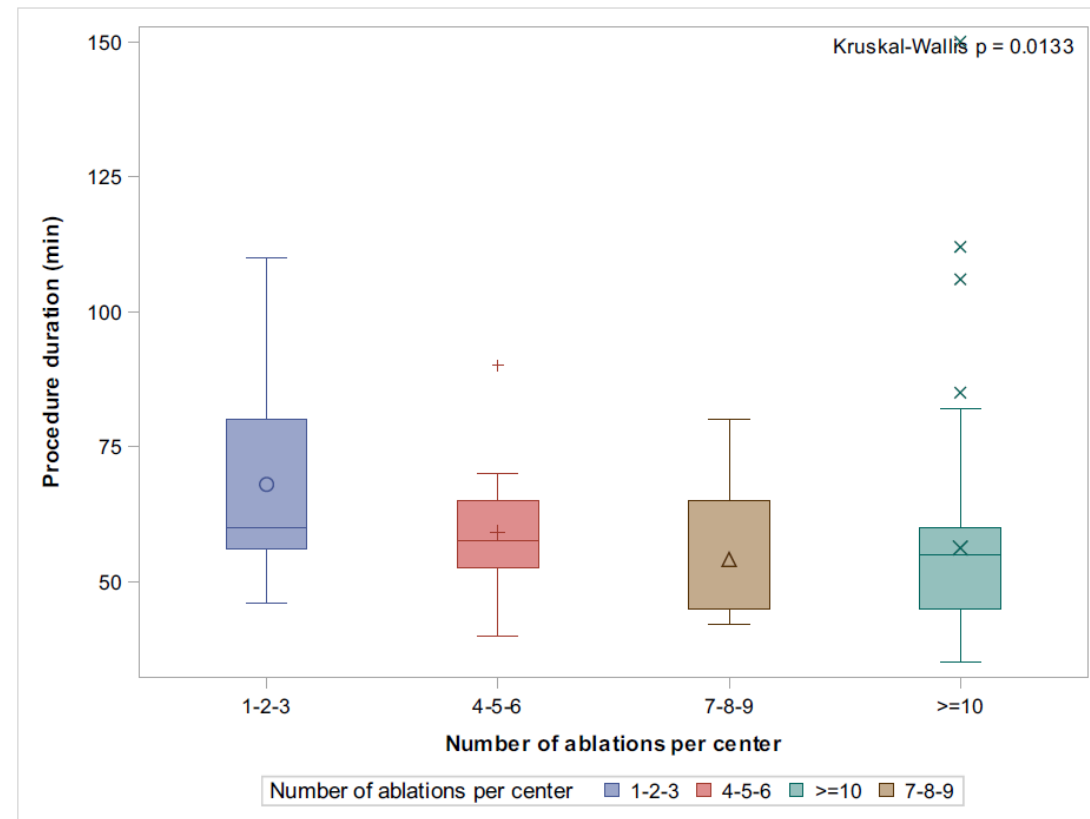
Significant reductions in procedural
times after 2-3 cases



Acute outcomes and learning curve from the initial patients treated with the PulseSelect system: a real-world multicenter experience of pulsed field ablation



Reduction in procedural times when procedures are grouped in pairs.



More pronounced decrease in procedural durations when procedures are grouped in sets of three.



Acute outcomes and learning curve from the initial patients treated with the PulseSelect system: a real-world multicenter experience of pulsed field ablation

- ❖ 100% acute PVI success with no major complications.
- ❖ Efficient workflow: median procedure time 55 min.
- ❖ Procedures feasible under moderate sedation in selected patients.
- ❖ Rapid adoption, with a learning curve of only 2–3 cases per center.

7 Conclusions

This evaluation focused on implementation of the PulseSelect system in real-world practice of AF ablation, showed short procedural times, with a rapid learning curve, and high acute procedural efficiency. In 1 out of 4 cases general anesthesia was not applied and no major complications were observed.



New Evidence on the Horizon: Comparative Outcomes with Cryoballoon and Medtronic PFA

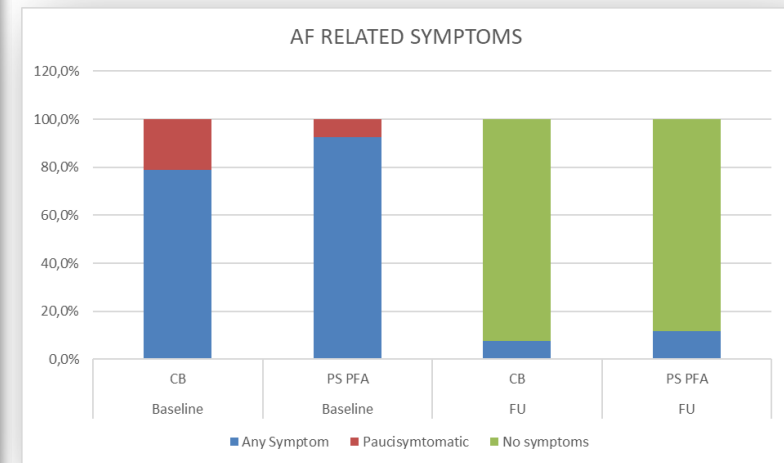
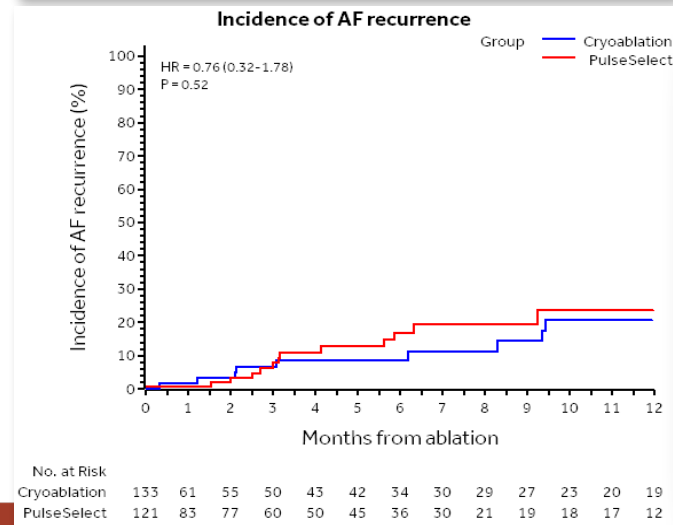
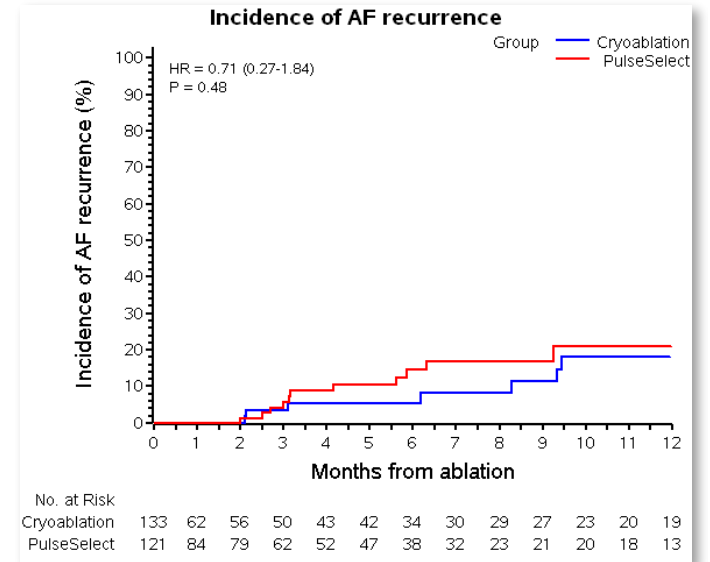
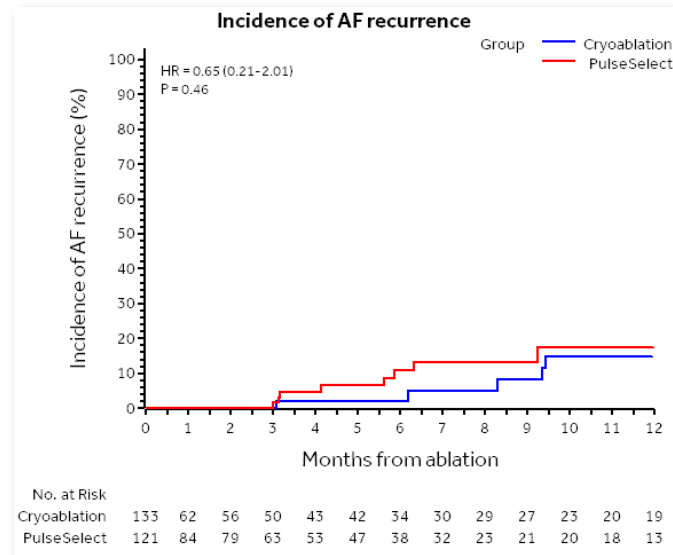


Single-Shot Ablation for AF: Real-World Procedural and One-Year Outcomes with PulseSelect PFA vs Cryoballoon

Manuscript accepted for publication on JCE

Aim: acute and one-year outcomes of PulseSelect PFA and fourth-generation cryoballoon (CB4) ablation, both performed in the same medium-volume centers as part of routine clinical practice, were compared

Methods: 254 consecutive patients undergoing **first-time PVI** were **included: 121 treated with PulseSelect and 133 with CB4**, across 10 Italian centers between January 2024 and February 2025



Single-Shot Ablation for AF: Real-World Procedural and One-Year Outcomes with the Newly Adopted PulseSelect PFA Compared with Cryoballoon from the 1STOP Project

Giuseppe Boriani¹, Giulio Molon², Stefano Nardi³, Gianfranco Mitacchione⁴, Danilo Ricciardi⁵, Enrico Chieffo⁶, Roberto Mantovan⁷, Luca Bontempi⁸, Matteo Ziacchi⁹, Edoardo Casali¹, Michela Casella¹⁰

1. Cardiology Division, Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Policlinico di Modena, Modena, Italy; 2. IRCCS Sacro Cuore Don Calabria, Negrar di Valpolicella, Italy; 3. Pineta Grande Hospital, Castel Volturno; 4. Department of Electrophysiology and Cardiac Pacing, ASST Spedali Civili, Department of Medical and Surgical Specialties, Radiological Sciences and Public Health, University of Brescia, Brescia, Italy; 5. Fondazione Policlinico Campus Biomedico, Roma; 6. Ospedale Maggiore, Crema; 7. ULSS 2 Marca Trevigiana, Ospedale di Conegliano; 8. Ospedale Bolognini, Seriate; 9. Policlinico S.Orsola Bologna, 10. Azienda Ospedaliero Universitaria delle Marche, Ancona

Introduction: Pulmonary vein isolation (PVI) is an established treatment for symptomatic atrial fibrillation (AF). Over the past decade, single-shot technologies have simplified ablation workflows, with cryoballoon (CB) representing the standard “anatomical approach.” Recently, pulsed field ablation (PFA) has emerged as a non-thermal alternative designed to selectively ablate myocardial tissue while minimizing collateral injury. The PulseSelect system is a PFA technology specifically designed for PVI, with growing clinical experience supporting its safety and efficacy

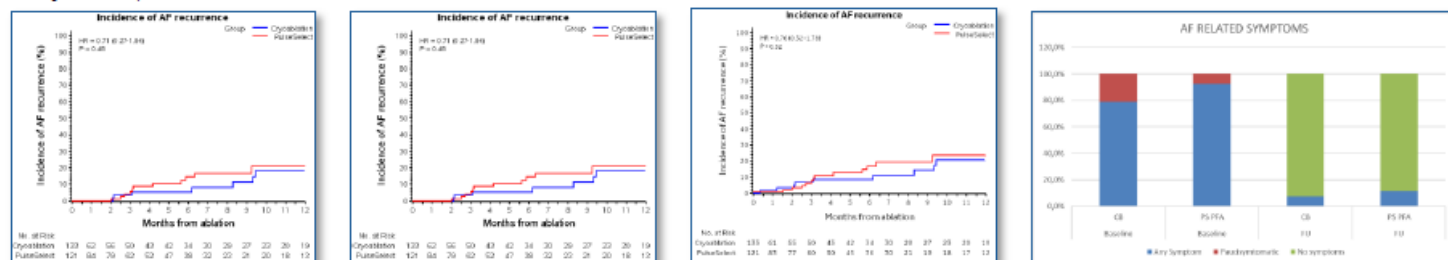
Purpose: In this analysis, acute and one-year outcomes of PulseSelect PFA and fourth-generation cryoballoon (CB4) ablation, both performed in the same medium-volume centers as part of routine clinical practice, were compared.

Methods: A total of 254 consecutive patients undergoing first-time PVI were included: 121 treated with PulseSelect and 133 with CB4, across 10 Italian centers between January 2024 and February 2025. Baseline clinical and echocardiographic data were prospectively collected. Procedural workflow, anesthesia type, procedure duration, fluoroscopy time, and periprocedural complications were analyzed. Follow-up included scheduled clinical visits and 12-month monitoring to assess arrhythmia recurrence, evaluated using Kaplan–Meier survival analysis.

Results: Among 254 patients, 28.3% were women, with a mean age of 62 ± 9 years; and paroxysmal AF accounted for 76.4% of cases. **Baseline clinical and echocardiographic characteristics were comparable** between the two groups. General anesthesia was more frequently used with PulseSelect than with CB4 (74.4% vs 16.5%). Mean skin-to-skin procedure duration **was shorter with PulseSelect** (62.4 ± 18 min) compared with CB4 (71.4 ± 30 min; $p = 0.005$), while fluoroscopy time was modestly longer with PulseSelect. **No acute complications occurred in the PulseSelect group.** In contrast, three transient phrenic nerve palsies were observed with CB4 (all resolved before discharge). At 12 months, arrhythmia recurrence was comparable between groups across all analytical approaches, including different blanking period, confirming high efficacy for both single-shot ablation modalities. Figure 1-2-3. A marked and consistent improvement in AF-related symptoms was observed irrespective of the ablation technology used. Figure 4

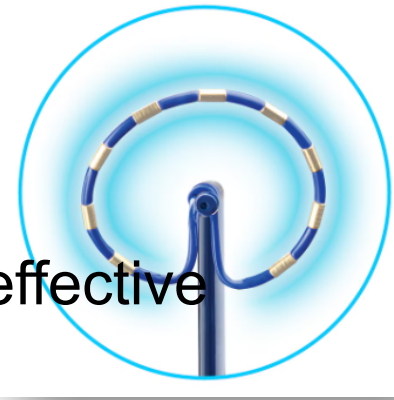
Kaplan–Meier estimates of cumulative incidence of AF recurrence after pulmonary vein isolation with fourth-generation cryoballoon (CB4) versus PulseSelect pulsed field ablation (PFA). Fig 1: 90-day blanking period. Fig 2: 60-day blanking period. Fig 3: no blanking period. No significant differences in event incidence were observed between ablation strategies across analyses.

Fig 4: Change in symptom burden from baseline to last follow-up



Conclusions: In this real-world multicenter experience, PulseSelect pulsed field ablation and fourth-generation cryoballoon ablation for pulmonary vein isolation were found to have comparable efficacy at one-year follow-up in patients with atrial fibrillation. Rhythm outcomes remained consistent across different analytical approaches, including varying blanking period definitions, supporting the robustness of the observed results. Both technologies were associated with substantial and clinically meaningful symptom improvement.

Take Home Messages



- Pulsed Field Ablation (PFA) is emerging as a safe, fast, and clinically effective energy source.
- The PulseSelect™ system represents a valid alternative to cryoballoon ablation for PVI.
- The circular catheter design, combined with electroporation, provides enhanced versatility for ablation in both the left and right atria, extending beyond standard PV lesions.
- Cryoballoon ablation remains a cornerstone for widespread PVI procedures, offering standardized workflows, denervations and homogenized clinical outcomes.

