European Heart Journal (2024) 45 (Suppl 1)
Arrhythmias and Device Therapy – Atrial Fibrillation (AF), Treatment, Rhythm Control, Catheter Ablation

Atrial fibrillation ablation with temperature-controlled very high-power short-duration, with conventional-power, or with combined modes in clinical practice: 12-month outcomes from SECURE

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Funding Acknowledgements: Type of funding sources: Private company. Main funding source(s): Biosense Webster, Inc.

Background/Introduction: QDM is a contact force-sensing catheter optimized for temperature-controlled radiofrequency ablation in very high-power short-duration (vHPSD; 90 W/4 s), conventional-power (CP; ≤50 W), or vHPSD/CP combined modes.

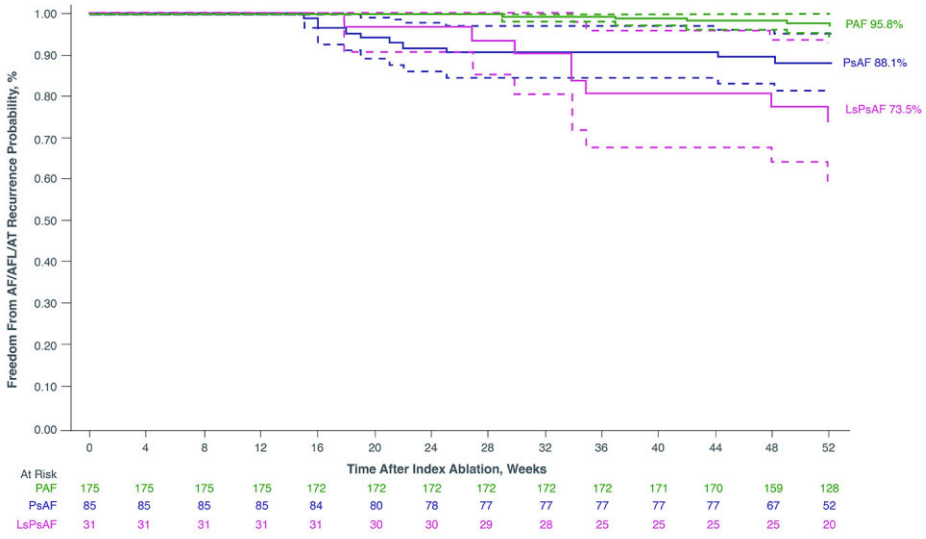
Purpose: Evaluate 12-month (M) safety and effectiveness of atrial fibrillation (AF) ablations performed with 3 different ablation modes using the QDM catheter, a frequently used single tip catheter in Europe.

Methods: SECURE is an observational, prospective, post-market study collecting data on procedures performed per standard-of-care with up to 12M follow-up, in 16 enrolling sites in 8 countries across Europe and Israel. Index pulmonary vein (PV) isolation procedures are reported here. The primary safety endpoint is the incidence of primary adverse events (PAEs); the primary effectiveness endpoint is PV isolation (entrance block) of targeted PVs. Additional endpoints include acute reconnections, incidence of char and steam pop, 12M recurrence, repeat ablation, and healthcare utilization (HCU). Ablation strategy, impedance drop, and catheter stability were analysed with a cloud-based data management and artificial intelligence-powered algorithm.

Results: Since Feb 2021, 291 patients (70% male, 61±11 yrs, CHA2DS2-VASc 1.9±1.5) completed 12M follow-up in 11 sites. Most patients (175 [60.1%]) were treated for paroxysmal (PAF), 85 (29.2%) for persistent (PsAF), and 31 (10.7%) for long-standing persistent (LsPsAF) AF, under general anaesthesia (44.0%) or sedation (55.7%). A combined workflow was used in 66.0% of ablations, while vHPSD-only and CP-only were used in 13.4% and 20.6% of cases, respectively. Four (1.4%) patients reported a PAE; all resolved, and none were catheter related. Acute effectiveness was achieved in all targeted veins; 5.0% of PVs had acute reconnections, with the most common being the left superior PV. No steam pops were reported; 2 counts of char were noted in PsAF ablations with combined modes. Freedom from documented recurrence were 95.8% for PAF, 88.1% for PsAF, and 73.5% for LsPsAF (Fig 1). Freedom from repeat ablation post-blanking and freedom from cardioversion were both 96.8%. Cardiovascular hospitalization and emergency room visits decreased by 65.3% and 76.5% from 12M pre- to 12M post-procedure, respectively. Application-level analyses showed larger impedance drop and greater catheter stability with vHPSD. In procedures using a combined workflow, vHPSD was used preferentially for most PV segments, except anteriorly on the left wide area circumferential ablation (Fig 2).

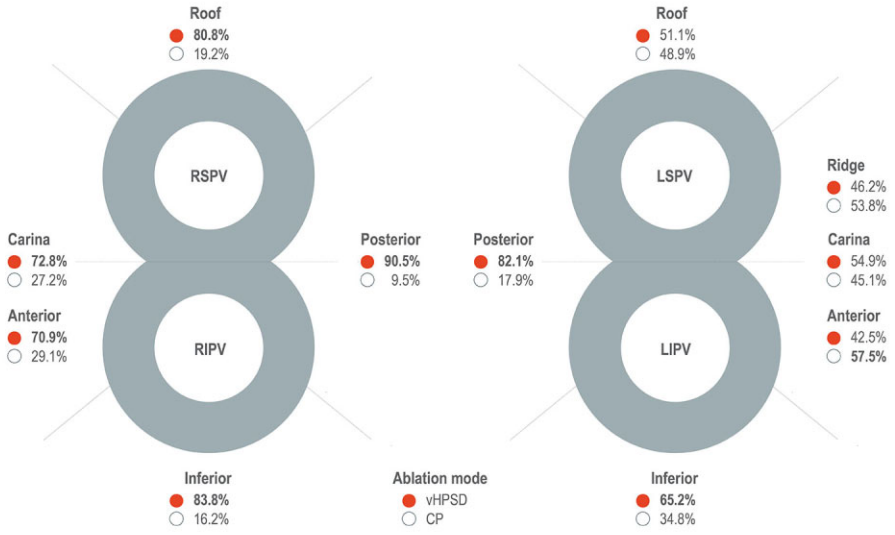
Conclusions: Real-world data demonstrates that AF ablation with the QDM catheter is safe and effective with a low PAE rate, high 12M effectiveness, and reduced HCU. Most procedures were done with combined modes, where vHPSD was used preferentially, except at left anterior thicker regions. Larger impedance drop and greater catheter stability were observed with vHPSD applications.

Fig 1. Freedom From Documented Recurrence



Reporting AF/AT/AFL recurrence episodes with duration ≥30 seconds documented by an electrocardiographic monitoring tool.
The two-sided 95% confidence interval of the survival probability is based on Greenwood's formula.
AF, atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia; PAF, paroxysmal AF; LSPsAF, long-standing persistent AF; PsAF, persistent AF.

Fig 2. Ablation Mode Used Per PV Segment in Patients Ablated With a Combined vHPSD/CP Workflow (n=192)



CP, conventional power; LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein; vHPSD, very high-power short-duration.