

Targeting nonpulmonary vein sources in persistent atrial fibrillation identified by noncontact charge density mapping UNCOVER AF trial

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Objective

Identification and elimination of non-pulmonary vein targets may improve clinical outcomes in patients with persistent atrial fibrillation (AF). This multicenter, prospective, single arm study reported on the use of the novel AcQMap noncontact imaging and mapping system to guide ablation of these complex atrial arrhythmias.

Key Points

- First study evaluating the AcQMap system assisted treatment protocol for persistent AF.
- Achieved 73% single procedure freedom from AF at 12-months treating persistent AF patients.
- Ablation of 3-4 non-pulmonary vein (PV) targets resulted in 12-mo arrhythmia-free success by a 9.4x odds ratio.
- Ability to create non-contact, high definition full chamber maps enabled the system to discern 3 distinct non-PV patterns of interest; focal, localized rotational activation (LRA), and localized irregular activation (LIA).

Methods

- 13 clinical sites in Canada and Europe; 129 enrolled and 127 treated patients.
- De novo ablation of PersAF, defined as sustained AF lasting >7days and <1 year with electrical cardioversion.
- Primary safety outcome was freedom from device / procedural complications with 24 hours of procedure.
- Primary effectiveness outcome was freedom from AF >30 sec at 12-months with or without AADs.
- Ablation strategies were individualized per patient to address dynamic activation patterns identified in addition to PVI.

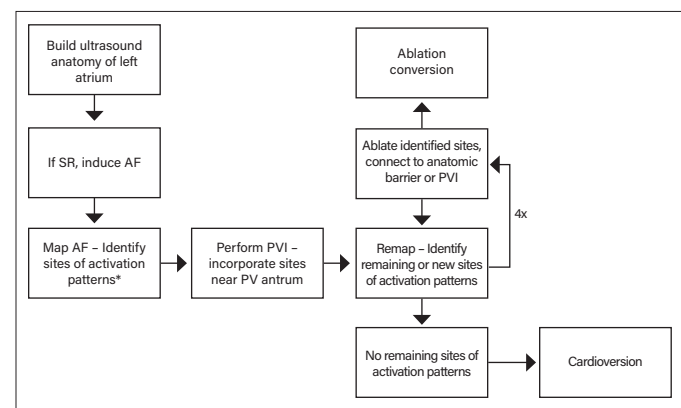


Fig. 1: Procedural flow (Map – Ablate – Remap)

“The efficiency with which maps are created encouraged iterative mapping to assess resultant changes in activation following each energy delivery.”

– Willems, et al. 2019

- Ablation therapy was a combination of contact force, non-contact force (including balloon-based cryotherapy) catheters.
- Clinical follow-up at 7 days, 1, 3, 6, 9, 12-months with standard 12-lead ECG and 24-hour continuous ECG monitoring.
- Patient QOL was assessed at each follow-up visit using AF Effect on Quality of Life (AFEQT) questionnaire.

Results

- Met safety objective of 98% with no device related major adverse events.
- Achieved 73% single procedure freedom from AF at 12-mo treating PersAF patients.
- After 1 or 2 procedures, >80% of the patients had no episodes of AF >30s based on 24-hr continuous ECG monitoring.

- Three distinct subcategories of abnormal conduction patterns with atrial origins were observed.
 - LIA was most prevalent (44.1%).
 - Focal activity was 2nd most prevalent (31%).
 - LRA prevalent a quarter of the time (24.9%).
- Procedural predictors of maintaining NSR at 12-mo included the ablation of 3-4 non-PV targets, presenting in SR for index procedure, and the ablation of at least 2-3 pattern types.
- The reduced levels of arrhythmia burden after CA were significantly associated with a clinically meaningful improvement in overall health status and quality of life as measured by the AFEQT.

Study Limitations

- Non-randomized.
- Post-procedure monitoring with 24-hour continuous ECG monitoring.

Conclusion

This clinical study reports on rapid, global iterative mapping to guide adaptive ablation therapy in a PersAF population. Procedural outcomes were based on durably ablating neither too little nor too much, suggesting that PVI plus ablation of patient-specific non-PV targets provides benefit to conventional approaches. Identification and characterization of such targets provides a platform for a greater understanding of disease pathophysiology and the possibility of positive impacts on the natural history of the disease.

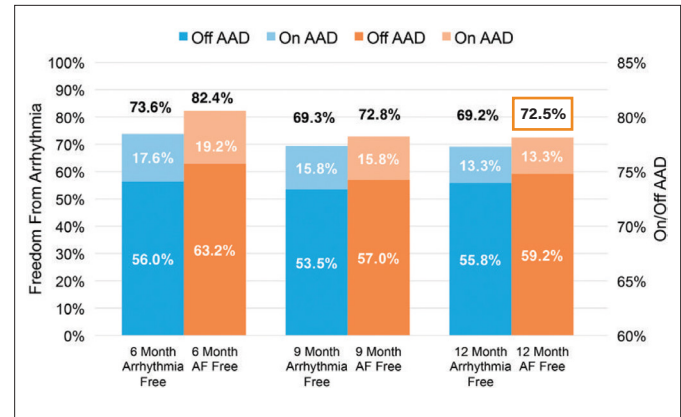


Fig. 2: Chronic efficacy outcome following a single procedure, on and off antiarrhythmic drug (AAD). Values based on 24-h continuous ECG monitoring. Retreatments were not allowed during the initial 3-mo blanking period. AF, atrial fibrillation.

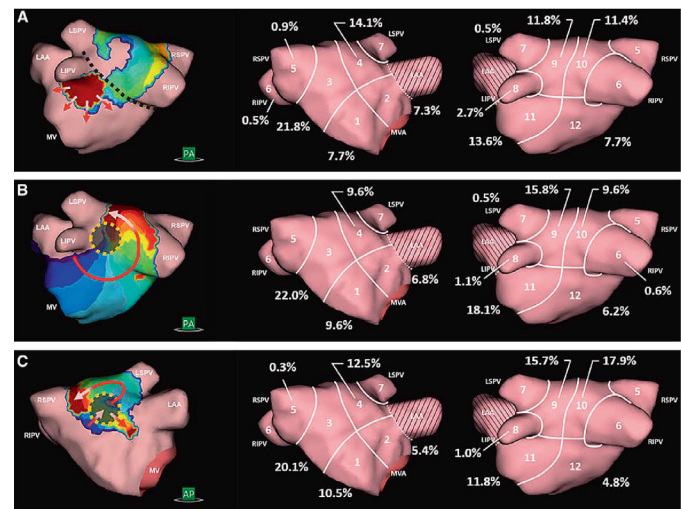


Fig. 3: Cardiac image and mapping.

The cardiac anatomy is partitioned into 12 quadrants. The quadrant and number of activation patterns of interest identified per location are displayed. A represents focal activity characterized by radial conduction from a single location; B shows localized rotational activation characterized by ≥ 270 degrees of conduction around a fixed, confined zone, whereas C shows localized irregular activation characterized by repetitive, multidirectional entry, exit, and pivoting conduction through and around a fixed, confined zone. AP indicates anteroposterior; LAA, left atrial appendage; LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; MV, mitral valve; MVA, mitral valve annulus; PA, posteroanterior; RIPV, right inferior pulmonary vein; and RSPV, right superior pulmonary vein.

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ABOUT ACUTUS MEDICAL

Acutus Medical is a dynamic arrhythmia care company focused on developing distinct, innovative technologies designed to provide physicians and patients with improved results. Founded in 2011, Acutus Medical, Inc., is based in Carlsbad, California.

U.S. Indication for Use:

The AcQMap System is intended for use in patients for whom electrophysiology procedures have been prescribed.

When used with the AcQMap Catheters, the AcQMap System is intended to be used to reconstruct the selected chamber from ultrasound data for purposes of visualizing the chamber anatomy and displaying electrical impulses as either charge density-based or voltage-based maps of complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

AND – When used with the specified Patient Electrodes, the AcQMap System is intended to display the position of AcQMap Catheters and conventional electrophysiology (EP) catheters in the heart.

OR – When used with conventional electrophysiology catheters, the AcQMap System provides information about the electrical activity of the heart and about catheter location during the procedure.

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