

An Individualised Ablation Strategy to Treat Persistent Atrial Fibrillation: Core-to-Boundary Approach Guided by Charge-Density Mapping

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Objective

The aim of this study was to compare the outcome of an individualized approach to PVI plus Core-to-Boundary ablation (C-to-B) targeting repetitive activation pattern guided by Charge Density Mapping (CDM) (study group) versus Empirical PVI plus Posterior Wall Isolation (PWI) (control group) in patients (pts) with Persistent AF.

Patient Population

- *De novo* Persistent AF patients from Royal Brompton Hospital, London and John Radcliffe Hospital, Oxford (November 2016 - April 2018) were prospectively enrolled.
- **Study Group:** Individualized ablation strategy PVI + Core-to-Boundary (40pts) **vs.**
Control Group: PVI + Posterior Wall Isolation (80pts)
- Patient characteristics of study group: similar in both study and control groups
 - Age 62 ± 12 years, 29 males
 - Persistent AF duration 10 ± 5 months
 - 6pts with long-standing Persistent AF duration 18 ± 3 months
 - LA diameter was 43 ± 6 mm
 - LVEF $53 \pm 12\%$.

Key Outcomes and Findings

- 87.5% were free from AF in the absence of antiarrhythmics at 24mo after a single procedure
- 68% AcQMap vs 46% Carto: Freedom from AF/AT in the absence of antiarrhythmics medications at 24mo following a single procedure
- 77% of Conduction Pattern Cores identified in the Pre-PVI maps were still present Post-PVI
Anatomical Distributions:
 - Posterior wall in 32/32 pts
 - **Mid-anterior wall in 30/32 pts**
 - **Septal wall in 23/32 pts**
 - **Roof in 11/32 pts**

Terminology or Nomenclature:

- Conduction Pattern Core (CPC) the center or core of focal activation, localized irregular activation, localized irregular activation or the region in which 2 of 3 overlap or coalesce.
- Conduction Pattern Core Depletion:
 - Depletion: continue ablating until AF terminates or until no additional conduction patterns can be identified. If AF converts to AT, the tachycardia was mapped and ablated.
 - Once a mechanism is targeted and the conduction pattern core has been identified, elimination is the goal.
 - Elimination if defined as: local electrogram abatement/elimination. Re-map to confirm elimination of local phenomenon.

Methods

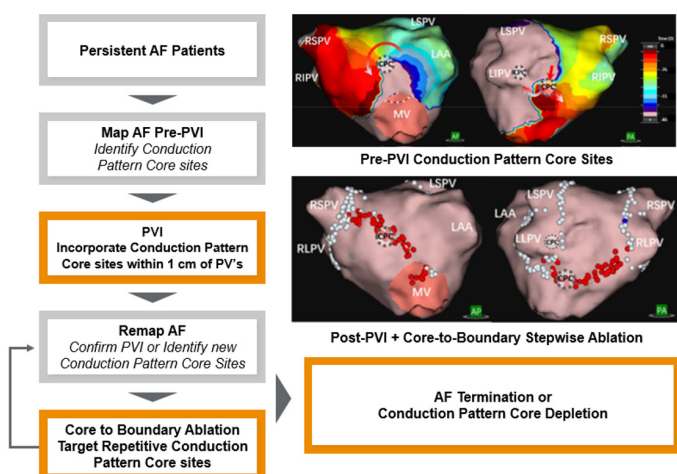
Core-to-Boundary Strategy - Acutus Study Arm (40pts)

- PVI plus conduction pattern core-to-boundary stepwise ablation until termination of AF or depletion of identified cores. If AF persisted after confirmation of Conduction Pattern Core depletion in the left atrium then the right atrium mapping was performed at the discretion of the operator.
 - PVI Strategy: When performing PVI, incorporate Conduction Pattern Cores within 1cm of the PVs.
 - Core-to-Boundary Ablation Strategy: Ablate the core (the center of focal, rotational, or irregular activity or at the location in which they overlap/coalesce) then anchor to the nearest anatomic or non-conductive boundary(s).

Empiric PVI + Posterior Wall Isolation - Carto Control Arm (80pts)

- Linear ablation across the roof and infero-posterior wall connecting the contralateral PVs antral lesions achieving Posterior Wall Isolation. Empiric CTI was performed at the discretion of the operator.
 - Posterior wall isolation confirmed with voltage mapping

Fig. 1: A stepwise individualised approach (PVI + C-to-B) to treat PerAF



Limitations

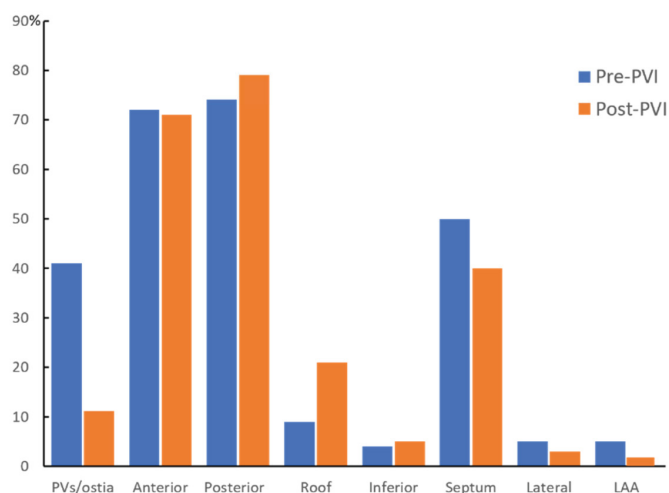
- Prospective observational study (not randomized)
- Post-procedure monitoring with 24hr continuous monitoring (a limitation in the majority of publications)
- Significance and hierarchy of each conduction pattern type was not compared
- Further studies are needed to demonstrate the spatio-temporal relations of different activation patterns and to characterize the respective contribution of each activation pattern in human AF.

- Contact-force sensing catheters were used in all pts in the control group. This might have introduced bias in favor of the control group, yet the clinical outcome was better in the study group.
 - Study Group: 26pts TheraCool SF, Biosense Webster (non-contact force) and 14pts TactiCath, Abbott at 30-40 W

Additional Findings

- A mean of 3.7 ± 1.0 Conduction Pattern Cores was observed in Pre-PVI maps. Distributions varied across the PV/ostia, posterior wall, anterior wall, septal wall and LA roof.
- Focal activation was the dominant pattern near the PV/ostia (62%). PVI terminated to SR/AT in 8pts, however, the majority (86%) still had ≥ 3 Conduction Pattern Cores following PVI.
- 77% of Conduction Pattern Cores identified in Pre-PVI maps were still present after PVI. On average, an additional 2.2 ± 0.6 Conduction Pattern Cores were ablated following PVI. Given the frequency of Conduction Pattern Cores present after PVI on the anterior wall, septal wall and roof, an empiric PVI + Posterior Wall Isolation ablation strategy would have missed these potentially important sites.

Fig. 2: Distribution of LA sites with CPCs pre- and post-PVI

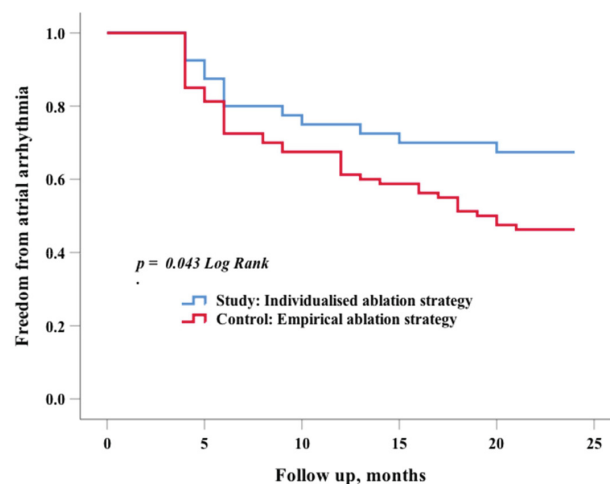


This figure shows the distribution of sites with CPCs in the left atrium pre and post PVI. The dominant cores were on anterior and posterior walls.

Conclusion

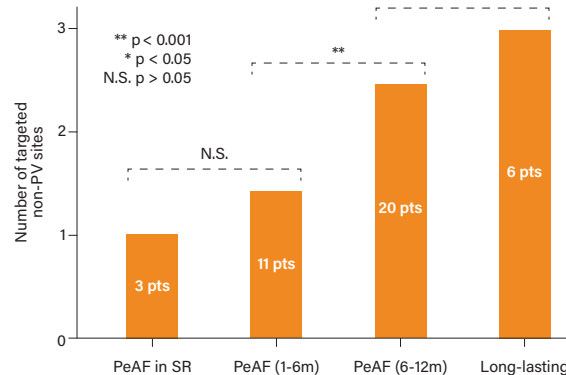
- The number of Conduction Pattern Cores correlated with the duration of Persistent AF.
- Spatiotemporal stability and occurrence of Conduction Pattern Cores did not change significantly after PVI.
- When compared to empiric PVI + Posterior Wall Isolation ablation strategy, the individualized ablation strategy targeting Conduction Pattern Cores had a high rate of acute procedural Persistent AF termination (73%) and a favorable 24-month outcome with 68% pts free from AF/AT in the absence of anti-arrhythmic medications after a single procedure. Despite contact force being used in all control patients, the clinical outcomes were better in the study group.
- In Persistent AF patients, 77% of triggers remain outside of the pulmonary veins even after PVI is complete. Pre- and Post- PVI mapping are vital to identifying remaining targets. Given the frequency of Conduction Pattern Cores on the anterior wall, an empiric PVI + Posterior Wall Isolation ablation strategy would have missed these potentially important sites.

Fig. 3: Freedom from atrial fibrillation/tachycardia following a single procedure



Cumulative freedom from persistent atrial fibrillation/tachycardia (AF/AT) following a single procedure in the study group (68%) and control group (46%) at 24-months, p=0.043.

Fig. 4: The average number of targeted CPCs before AF termination increased with the duration of persistent atrial fibrillation.



The average number of CPCs increased with the duration of perAF. CPC=conduction pattern core; perAF=persistent atrial fibrillation. (AF was induced with high frequency intra-atrial pacing at the beginning of the procedure in patients who were electively cardioverted prior to the procedure.)

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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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