

Validation of dipole density mapping during atrial fibrillation and sinus rhythm in human left atrium

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Objective

Validate the accuracy of noncontact electrograms obtained by the AcQMap® mapping system against conventional contact electrograms obtained from a circular catheter in the human left atrium during sinus rhythm and atrial fibrillation.

Methods

- 20 patients with persistent atrial fibrillation.
 - Mean AF duration 9 months \pm 6 months;
 - Mean LA parasternal long-axis diameter was 43mm \pm 5mm.
- EPS followed by AF ablation guided by the AcQMap noncontact charge density mapping system.
- Morphology and timing difference were analyzed in SR and AF from simultaneous recordings of noncontact and contact unipolar electrograms obtained from seven pre-specified locations in the LA.
 - Reconstructed EGMs were post-processed from inversely-derived charge density by the AcQMap mapping system.

Results

- This novel noncontact charge density mapping system provides comparable reconstructed atrial electrogram measurements in SR or AF in human left atrium when the anatomical site of interest is \leq 40mm from the mapping catheter.

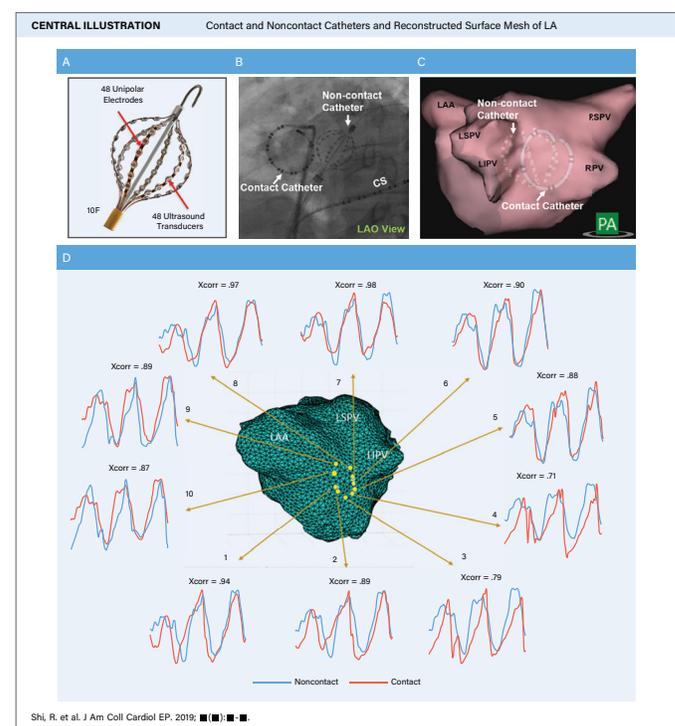


Fig. 1: (A) Depiction of the noncontact catheter with 6 splines, each carrying 8 ultrasound transducers and 8 high-fidelity unipolar electrodes. (B) Noncontact catheter and circular contact catheter in the left atrium (LA) (left anterior oblique [LAO] view). (C) LA anatomy constructed by the noncontact catheter mapping system (poster- o-anterior [PA] view). The noncontact mapping catheter is shown in the center of the LA chamber and the contact circular mapping catheter is positioned on the posterior wall. (D) Morphology comparison, cross-correlation (Xcorr), of 10 noncontact reconstructed and contact electrogram pairs. The yellow dots represent 10 locations of the circular contact mapping electrodes with the relevant paired contact (red)/noncontact (blue) electrogram. CS $\frac{1}{4}$ coronary sinus; LAA $\frac{1}{4}$ left atrial appendage; LIPV $\frac{1}{4}$ left inferior pulmonary vein; LSPV $\frac{1}{4}$ left superior pulmonary vein; RIPV $\frac{1}{4}$ right inferior pulmonary vein; RSPV $\frac{1}{4}$ right superior pulmonary vein.

Study Limitations

- Although charge density cannot be directly measured, charges and voltages are inherently linked.
 - Consequently, post-processed voltage-based electrograms (reconstructed from the derived charge density) were compared to corresponding contact electrograms measured at the same location on the chamber wall.
 - Reconstructed noncontact electrograms have limitations associated with mathematical calculation, as well as the intrinsic reproduction of far-field blending.
- Validation analysis was limited to segments within the R-R intervals to avoid interference from the QRS and T waves.
 - The short duration of compared sample sets (30s) would impose some limitation on evaluation of activation stability in both the time domain and phase space.
- LAA and PV-structure represent the outer limits of the AcQMap range of noncontact reconstruction.
 - The best way to account for this limitation is to have the AcQMap catheter placed in the center of the chamber, this was not a requirement in this validation study.

Conclusion

This is the first study comparing charge density-based reconstructed unipolar electrograms with contact electrograms in the human LA, using physically comparable measurements.

- The results of this study show that charge density mapping offers similar electrogram morphology and timing when compared to contact mapping.
- Morphology correlation and timing difference values were significantly improved at radial distances $\leq 40\text{mm}$, with most of the comparison sites located within this range.

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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.

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M E D I C A L

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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