First Clinical Validation of a 12-Lead ECG-Based Fully Automated Non-Invasive Electroanatomical Mapping System for Ventricular Arrhythmia Localization

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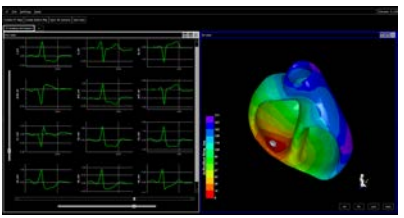
We performed an initial clinical validation of CorLector system, a fully automated 12-lead ECG-based non-invasive electroanatomical mapping system designed to localize arrhythmia origin without computed tomography or magnetic resonance imaging.



Twenty-one patients ECGs acquired at two clinical sites were analysed using Corlector system. Non-invasive epi-endocardial activation maps were independently reviewed by two electrophysiology physicians and compared with clinically confirmed arrhythmia origin. Accuracy was quantified using a prespecified 6-level anatomical concordance score: 0, different ventricle; 1, same ventricle; 2, same ventricular wall; 3, adjacent segment; 4, same segment; 5, exact localization. The prespecified feasibility criterion was at least 80% of cases with clinically acceptable concordance. A weighted accuracy index (WAI) was calculated to summarize overall ordinal performance.

The cohort included ventricular arrhythmias arising from left ventricular, right ventricular, outflow tract, papillary muscle, moderator band, fascicular, parahisian, mitral annular and aortic cusp regions. Score frequencies for 0/1/2/3/4/5 were 1/2/4/5/5/4 cases, corresponding to 4.8%, 9.5%, 19.0%, 23.8%, 23.8%, and 19.0%, respectively. Clinically acceptable concordance was achieved in 18/21 cases (85.7%), exceeding the prespecified 80% feasibility threshold. Higher-grade concordance was observed in 14/21 cases (66.7%) with scores 3-5 and in 9/21 cases (42.9%) with scores 4-5. The WAI was 61.9%, exceeding the predefined clinical benchmark. The highest accuracy was observed in anatomically standard locations susch as RV/LV lateral walls whereas lower scores occurred predominantly in papillary muscle, outflow tract and LV cusps.

This first clinical validation demonstrates that a fully automated 12-lead ECG-based non-invasive mapping system can provide clinically actionable localization of ventricular arrhythmia origin across RV and LV while identifying specific anatomically complex locations require further algorithmic refinement.