Performance evaluation of dual vs. single lead automatic, real-world arrhythmic ECG recordings

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BACKGROUND

Detection of treatment-demanding paroxysmal arrhythmias can be difficult. Use of single lead ECG recordings for detection of Atrial Fibrillation (AF) has shown to lead to high false positive discovery rates, and requirements of additional manual clinical interpretation or 12-lead ECG to reach satisfactory diagnostic precision. Use of sequential, dual-lead ECG recordings for detection of AF has indicated significant clinical improvement in detection yield of AF and reduction of false positive discovery rates as compared to single lead-ECG.

METHODS

The Coala Heart Monitor ("Coala", Coala Life AB, Stockholm Sweden) system was evaluated by manual interpretation of 1,000 consecutive anonymous printouts of chest- and thumb-ECG waveforms, without any exclusion. The anonymized printouts contained three 10 s. strips of ECG at 25 mm/s, including mean heart rate, RR median and any user-provided annotation but with personal identification and algorithm analysis results removed (blinded), apart from gender and age within a 10-year span. The recordings were derived from actual Coala users in Sweden with no training, control or influence, under a defined time period. The prevalence of cardiac conditions in the user population was unknown.

The blinded recordings were manually interpreted by a trained cardiologist. The interpretation was compared with the automatic analysis performed by an enhanced algorithm in the Coala Cloud to evaluate ECG signal performance and to calculate performance metrics of a combination of sequential dual chest- and thumb-ECG measurements as compared to the clinical performance metrics of singe lead ECG measurements only.

The Coala Heart Monitor is a CE-approved Class IIa medical device solution approved for home and professional use. It's a wireless and cloud-based service developed and produced in Sweden by Coala Life AB. The 2-lead, 1-channel ECG and synchronous heart sound recording system analyzes for 10 different arrhythmias, and to help detect for murmurs. For more info, see www.coalalife.com.

RESULTS

METRIC	RESULT USING DUAL CHEST- AND THUMB-ECG AND P-WAVE DETECTION ALGORITHM	RESULT BASED ON SINGLE LEAD THUMB-ECG ONLY
Prevalence of AF in the recordings	14.4 % (143 of 990 recordings)	14.4 % (143 of 990 recordings)
% of recordings with ECG quality good enough to permit manual interpretation	99.2% (8 of 998 non-readable)	98.7% (13 of 998 non-readable)
Negative predictive value (NPV) for detecting AF	0.992	0.995
Positive predictive value (PPV) for detecting AF	0.872	0.647
False positive discovery rate	12.8%	35.3%
Sensitivity for detecting AF	0.951	0.972
Specificity for detecting AF	0.976	0.909
Accuracy	0.973	0.919

CONCLUSION

Based on 1,000 real-world recordings the sequential combination of dual chest- and thumb-ECG with P-wave detection yielded significantly higher Positive Predictive Values (PPV) as compared to single lead ECG measurements. Dual chest- and thumb-ECG reduced false positive AF indications from 35.3% for single lead-ECG to 12.8% using combined chest- and thumb-ECG with P-wave detection.