

Quality validation of different ECG leads, and an automatic P-wave detection algorithm for AF, based on real-world data

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BACKGROUND

Single-lead ECG has shown in research to be affected by artifacts leading to lower diagnostic yield of Atrial Fibrillation (AF). Use of multiple ECG leads and algorithms for detection of AF has shown to increase detection accuracy and reduce false positives.

METHODS

A novel RR- and P-wave based automatic algorithm implemented in the 2-lead Coala Heart Monitor (Coala) was evaluated for detection accuracy and quality by the comparison to blinded manual ECG interpretation. Evaluation was conducted on 100 consecutive anonymous printouts of chest- and thumb-ECG waveforms, where both an irregular RR-rhythm and strong P-waves in either chest or thumb recording were detected.

The recordings, without exclusions, were generated from 5,512 real-world data recordings from actual Coala users in Sweden (both OTC and Rx users) during the period of March 5 to March 22, 2019, with no control or influence by the researchers or any other organization or individual. The prevalence of cardiac conditions in the user population was unknown.

The blinded recordings were each manually interpreted and assessed for quality by a trained cardiologist. The manual interpretation was compared with the automatic analysis performed by the cloud-based detection algorithm to determine the detection quality of the respective ECG leads.

RESULTS

Strong P-waves were detected more often in the chest ECG as compared to the thumb ECG (90 vs 32 recordings). The assessed quality of the ECG tracings was higher in the chest ECGs as compared to the thumb ECGs (4.61 vs 3.88). Irregular RR-rhythms were detected in 569 recordings (10 % of a total of 5,512 recordings), the 100 non-AF recordings containing both irregular RR-rhythms and strong P-waves thus constituted 18% of all recordings with irregular RR-rhythms.

Non-pathological rhythm (normal) was present in 84% of the recordings although all of these recordings contained irregular rhythm disturbances (respiratory sinus arrhythmia, PAC/PVC etc). Respiratory sinus arrhythmia was the single most prevalent condition and found in 47% of the recordings with irregular RR-rhythms with strong detected P-waves.



Coala Heart Monitor is an FDA cleared and CE approved medical device system that is developed and validated in Sweden. For more information, please visit coalaife.com

PARAMETER	CHEST ECG		THUMB ECG	
	Algorithm	Cardiologist	Algorithm	Cardiologist
Strong P-waves detected	90	88	32	75
Weak P-waves detected	2	9	19	16
No P-waves detected	8	1	49	4
Poor quality for manual interpretation		2		1
ECG quality (1= barely readable, 5=excellent)	4.62		3.88	

Table 1. ECG quality and P-wave detection performance for chest and thumb recordings.

CONCLUSION

The combination of chest and thumb ECG for detection of AF by an automatic P-wave based algorithm is shown to be more than 300% superior to thumb ECG alone with the majority of automatically detected P-waves and highest assessed ECG quality in the chest recordings.