Real-world data validation of a novel P-wave based automatic Atrial Fibrillation detection algorithm

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BACKGROUND

Automatic ECG algorithms using only RR-variability in ECG to detect AF have shown high false positive rates. By including P-wave presence in the algorithm, research has shown that it can increase detection accuracy for AF.

METHODS

A novel RR- and P-wave based automatic detection algorithm implemented in the Coala Heart Monitor (Coala) was evaluated for detection accuracy by the comparison to blinded manual ECG interpretation based on real-world data. Evaluation was conducted on 100 consecutive anonymous printouts of chest- and thumb-ECG waveforms, where the algorithm had detected both irregular RR-rhythms and strong P-waves in either chest or thumb recording (non-AF episodes classified by algorithm as Category 12).

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.
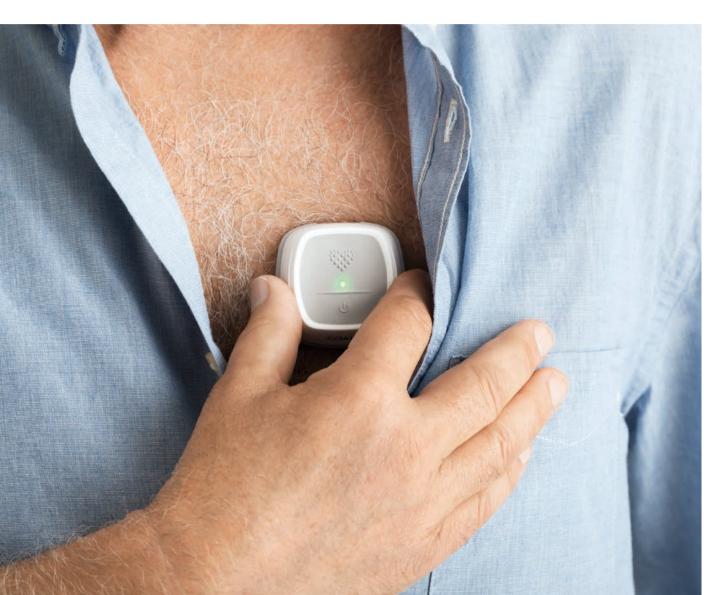
The blinded recordings were each manually interpreted by a trained cardiologist. The manual interpretation was compared with the automatic analysis performed by the detection algorithm to determine the number of additional false negative indications for AF as presented to the user.
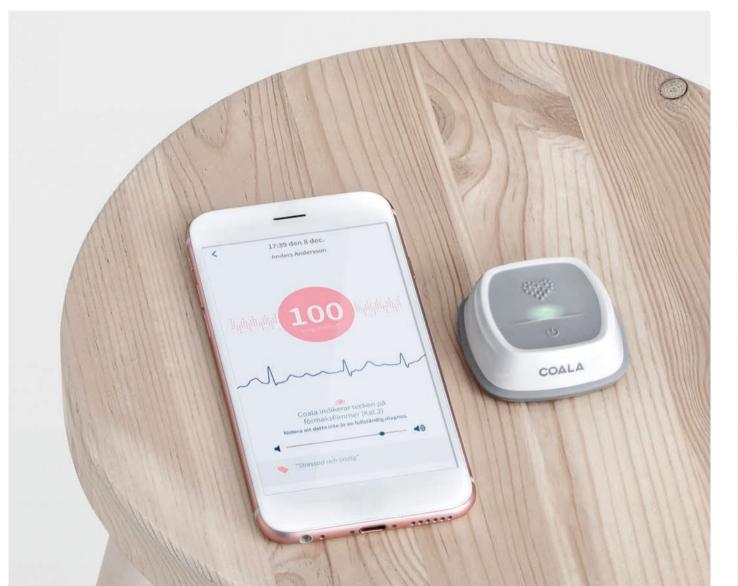
RESULTS

The trained cardiologist manually interpreted 0 of the 100 recordings as AF. Manual interpretation showed that the novel automatic AF algorithm yielded 0% False Negative error and 100% Negative Predictive Value (NPV) for detection of AF. 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 constituted 18% of all recordings with irregular RR-rhythms. Respiratory sinus arrhythmia was the single most prevalent condition and was found in 47% of irregular RR-rhythms with strong P-waves.

CONCLUSION

The novel, P-wave based automatic ECG algorithm used in the Coala, showed a zero percent False Negative error rate for AF detection in ECG recordings with RR-variability but presence of P-waves, as compared to manual interpretation by a cardiologist.

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 coalalife.com