Validation of diagnostic accuracy of Coala Heart Monitor

Validation of diagnostic accuracy of a handheld, smartphone-based rhythm recording device

Aims

Evaluation of the diagnostic accuracy of a rhythm recording device, for detection of atrial tachyarrhythmia (ATA) and atrial fibrillation (AF) compared to 12-lead-electrocardiogram (12-L-ECG).

Methods

Two hundred 12-L-ECGs (reference standard) and Coala Heart Monitor recordings (index test) were collected from 189 patients. Two electrophysiologists independently performed manual review of all 12-L-ECGs and Coala Heart Monitor recordings in random order.

The Coala Heart Monitor recordings were also analyzed by the integrated automatic algorithm. Algorithm results were compared to the results of the reference standard..

Results

Manual analysis for AF had a sensitivity of 100% (95% confidence interval (CI): 95.3–100) and a specificity of 97.5% (CI: 93.0–99.5).

Automatic analysis for AF showed a sensitivity of 97.4% (CI: 91.0–99.7) and a specificity of 86.1% (CI: 78.6–91.7).

Manual analysis of Coala Heart Monitor for ATA, including both AF and Atrial Flutter (AFL), showed a sensitivity of 98.9% (CI: 94.0–100) and a specificity of 100% (CI: 96.6–100).

Automatic analysis for ATA showed a sensitivity of 93.5% (CI: 86.3–97.6) and a specificity of 92.6% (CI: 85.9–96.7).

Conclusion

Coala Heart Monitor has a very high accuracy for ATA and AF in manual analysis and a high accuracy for ATA and AF in automatic analysis, making the device suitable for screening.

Study highlights

- Clinical validation of Coala Heart Monitor accuracy for AF and ATA against gold standard 12-lead-ECG
- The study confirms that Coala Heart Monitor ECG shows similar accuracy as standard clinical 12-lead-ECG for diagnosis of AF.
- The automatic analysis had 100% sensitivity for AF in individual ECG leads, as presented to the clinician, and 97.4% sensitivity as determined by combined thumb and chest analysis for presentation in the patient app.

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Q&A with Dr Astrid Paul Nordin

Dr. Nordin, tell us about your study and why the findings are important.

– There is increasing evidence that screening for atrial fibrillation (AF) can help prevent ischemic stroke, as early detection of AF means that these individuals can be prescribed anticoagulation therapy before symptoms manifest.

So there is an increasing need for screening and new devices, such as Coala Heart Monitor. The Coala Heart Monitor, to our knowledge, has not prior to our study been validated against standard reference 12-lead-ECG screening.

So, the purpose of the study was to validate the diagnostic reliability of the Coala Heart Monitor, for atrial arrhythmias and atrial fibrillation, compared to a 12-lead ECG.

> *“So our conclusions are that Coala has a high diagnostic reliability for both atrial arrhythmias and atrial fibrillation*

What do you see as the most important conclusions from your study?

– We concluded that Coala Heart Monitor has a high diagnostic reliability for both Atrial [Tachy] Arrhythmias (ATA) and Atrial Fibrillation (AF). The manual interpretation was significantly better than the automatic algorithm. It is the recommendation from the guidelines to interpret registrations from this type of device manually.

Both the sensitivity and specificity of the manual interpretation have very good values, for both ATA and AF.

In this study, we assisted the patient in performing the Coala registration. However, I would like to think that the Coala is just as good for screening purposes.

The device shows very good results with a high reliability.

How do you plan to use the results?

– We are using the Coala Heart Monitor in another study, IDEAL-AF, a randomized trial where we randomize patients to two different types of atrial fibrillation ablation procedures and then follow them for 2 years.

All patients in the study are offered a Coala Heart Monitor for the entire follow-up period of 2 years and asked to do ECG recordings if they get symptoms but also before each scheduled follow-up visit.

We wanted to do this validation study as to ensure we have chosen a reliable tool to follow up with our patients in IDEAL-AF.

The study was led by Dr Astrid Paul Nordin, MD, Karolinska Institute and Cardiologist at Karolinska University Hospital, Stockholm, Sweden.

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