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Accuracy of a smartwatch based single-lead electrocardiogram device in screening for atrial fibrillation

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Topic(s):
m-Health

Citation:

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Background: Wearable arrhythmia detection devices are the contemporary standard in personal cardiac monitoring. Despite the appeal of smartwatch-based integrated ECG devices, there is a paucity of data evaluating their accuracy in arrhythmia screening.

Objective: We aimed to evaluate whether a recent FDA approved smartwatch-based detection device for atrial fibrillation (AF) is an accurate and feasible screening tool when compared to the 12-lead ECG.

Methods: A prospective, multi-centre, validation study was conducted in a hospital population. The wearable arrhythmia device paired with a smartwatch was used (iECG) to generate an automated diagnosis (AF or sinus rhythm) which was compared to a simultaneously recorded 12-lead ECG and reviewed by an independent cardiologist. Where an unclassified or no-analysis tracing was generated, a repeat iECG was performed. Two electrophysiologists (EP) analysed all unclassified iECGs blinded to the 12-lead diagnosis.

Results: A total 439 ECGs (iECGs [n=239] and 12-lead ECG [n=200]) were recorded in 200 patients (56.5% male, age 67 ± 16 years), recruited from 3 tertiary centres. This identified 38 patients to be in AF (including 2 new diagnoses) and 162 patients in sinus rhythm. Sensitivity for AF and sinus rhythm using the KB was 89.5% and 92.9% respectively, this improved to 94.4% and 98.3% when excluding unclassified readings (Table 1). Overall agreement between 12-lead ECG and smartwatch ECG automated diagnosis when including unclassified readings was satisfactory (κ=0.78, p<0.001). Review of unclassified tracings by two blinded electrophysiologists revealed comparable testing parameters to the device automated diagnoses with an overall sensitivity of 87.8% (EP1: 3 false positives, 1 false negative) and 90.2% (EP2: 2 false positives, 1 false negative).

Conclusion: In an unselected patient cohort, a smartwatch based single-lead ECG demonstrated satisfactory accuracy with a high negative predictive value. Further studies are required to assess the utility of wearable devices as a cost-effective screening tool for AF.

<table>
<thead>
<tr>
<th>iECG vs 12-lead ECG</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>PLR</th>
<th>NLR</th>
<th>Accuracy (%)</th>
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<tbody>
<tr>
<td>Atrial Fibrillation</td>
<td>89.5</td>
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<td>96.7</td>
<td>16.0</td>
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UC = Unclassified; PPV = Positive predictive value; NPV = Negative predictive value; PLR = Positive likelihood ratio; NLR = Negative likelihood ratio
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