Abstract: P1457

Preliminary results of the FLASH-AF: Validation of the device independent nature of a pulse deriving smartphone application for the detection of atrial fibrillation

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Topic(s):
Remote Patient Monitoring and Telemedicine

Citation:
European Heart Journal (2019) 40 (Supplement), 765

Background: Smartphone applications using photoplethysmography (PPG) technology through their camera are becoming an attractive alternative for atrial fibrillation (AF) screening due to their low cost, convenience, and broad accessibility. However, some important questions concerning their diagnostic accuracy, robustness and device independent nature remain to be answered.

Purpose: This study evaluated the diagnostic accuracy of a PPG-based pulse-deriving smartphone application with respect to handheld single-lead ECG and 12-lead ECG. In addition, the device dependent nature and robustness of the performance of the application was assessed.

Methods: 300 Patients who are scheduled for a regular consultation or procedure (i.e. ablation or cardioversion) will be recruited from the cardiology ward. Additionally, patients hospitalized for continuous cardiac monitoring will be recruited to enrich the database with AF measurements. After obtaining written informed consent, the patients fill in a questionnaire collecting demographic and medical information.

The pulse-deriving application will be tested on total of 14 different smartphones, 7 iOS devices and 7 Android devices. In total, each device will be measured with 150 times. The patients will additionally perform a single-lead ECG measurement with a handheld device. Subsequently, a 12-lead ECG will be recorded to obtain the reference diagnosis.

Results: A total of 164 patients already participated in the study. The mean age was 64 (±19) years, 58% was male. The AF-prevalence was 37%. On average, patients in AF had a higher CHA2DS2-VASc score; 3.93 (±1.80) compared to 2.02 (±1.63) for non-AF patients.

The amount of insufficient quality measurements recorded with the pulse-deriving smartphone application ranged from 4% (iOS) to 13% (Android). Averaged for all the smartphone devices, the pulse-deriving application scored 81.2% (±5%) sensitivity, 97.1% (±1%) specificity, 88.8% (±2%) NPV, 95.0% (±1%) PPV, and 90.9% (±2%) accuracy. The handheld single-lead ECG device had 78.2% sensitivity, 95.5% specificity, 87.6% NPV, 91.5% PPV, and 88.9% accuracy.

The same calculations were preformed after excluding regular atrial flutter measurements. On average, the pulse-deriving application scored 90.1% (±2%) sensitivity, 97.1% (±1%) specificity, 95.2% (±1%) NPV, 94.0% (±1%) PPV, and 94.8% (±1%) accuracy. The handheld single-lead ECG device had 90.2% sensitivity, 97.7% specificity, 97.7% NPV, 95.1% PPV, and 96.9% accuracy.

Conclusion: The diagnostic accuracy of the pulse-deriving smartphone application and the handheld single-lead ECG device was strongly influenced by the presence of regular atrial flutters, stressing the importance of further thorough validation. For the pulse-deriving smartphone application, there was no significant influence from device type in terms of diagnostic accuracy for the detection of AF. Insufficient quality measurements were more frequently performed on Android devices.