The diagnostic accuracy of smartphone applications to detect atrial fibrillation: a head-to-head comparison between Fibricheck and AliveCor

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Abstract

Background

Atrial fibrillation (AF) often presents on paroxysmal basis, which makes it challenging to detect and record. Smartphone applications with built in algorithms that provide an immediate interpretation of the ECG make intermittent recordings possible and might facilitate the chance to detect AF. This study was performed to compare the diagnostic accuracy and clinical benefit of the Fibricheck and AliveCor application to detect AF in general practice.

Methods

A multi-centered diagnostic accuracy study in 17 general practices in Flanders. A convenience sample of 242 participants aged 65 and older underwent Fibricheck and AliveCor recordings followed by a 12 lead electrocardiogram. Sensitivity and specificity as well as net benefit and net reclassification index were calculated.

Results

After the exclusion of technical errors (n=5), uninterpretable ECG (n=1), active pacemakers (n = 18) and bad quality Fibricheck measurements (n = 28), 190 patients remained. The mean age was 77.3±8.0 years and 57.4% were women. The Fibricheck and AliveCor app showed an equally high sensitivity (98% (95%CI 92-100)) and a small difference in specificity (88% (95%CI 80-94) and 85% (95%CI 76-91), respectively) when undiagnosable AliveCor results were considered as AF positive. The NRI did not show a significant result and the net benefit was, for estimated prevalences of 2%, 6%, 8% and 15%, slightly in favour of the Fibricheck.

Conclusion

Both Fibricheck and AliveCor showed promising results for AF screening in patients aged 65 or older in general practice. Only small differences in performance could be found, and net benefit slightly favoured Fibricheck.

Keywords

Atrial fibrillation, screening, general practice, smartphone applications, AliveCor, Fibricheck

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Background

Atrial fibrillation (AF) is the most common cardiac arrhythmia encountered in clinical practice.[1] The prevalence rises with age.[2] A recent study in Flanders showed numbers around 6.4% in people aged 60 and older.[3] AF is associated with increased morbidity and mortality especially due to the 5-fold higher risk of stroke.[4,5] At least one third of patients is asymptomatic and many remain undiagnosed prior to an event.[6] Due to aging of the population we are facing a condition with epidemic proportions.[7,8] Given the burden of AF for both quality of life as medical costs, AF will become a major public health problem wherefore we need to make a change.[8,9]

Preventive strategies to reduce the risk are increasingly important.[3] Screening for AF could detect people who would benefit from prophylactic anticoagulation therapy and prevent two-third of AF related strokes.[10-13]. The European society of cardiology recommends opportunistic screening in patients aged 65 or older by pulse palpation followed by an electrocardiogram (ECG) if the pulse is irregular.[1] Pulse checks may be sensitive but are not specific. Furthermore, the possibility AF only presents on paroxysmal basis makes it challenging to detect and record. [14,15] The recent 'stroke stop' study showed a significantly higher sensitivity for AF diagnosis by multiple short ECG measurements compared with a single time point measurement. With 4 times as many cases diagnosed we need to look for a tool that is accurate and can be operated regularly by patients at home. [16]

Recent technological innovations have changed health care and its opportunities. Multiple screening tools for AF have been introduced and showed promising accuracy numbers: *the MyDiagnostick* (Applied Biomedical systems BV, Maastricht, The Netherlands) [17,18,19], *Watch BP* blood pressure monitor (Microlife WatchBP AG, Widnau, Switzerland)[20], *Omron heart scan* (OMRON healthcare Europe BV, Hoofddorp, The Netherlands)[21]. However, none of these devices are widespread used in general practice and all these devices need external hardware, which may form an obstacle. In this perspective smartphone applications could be a splendid way to bridge the gap. Smartphone ownership is growing fast, also among the elderly.[22] It is estimated that more than 27% aged 65 or older owns a smartphone.[23] AliveCor (AliveCor. Inc. , San Francisco, U.S.A) and Fibricheck (Qompium, Hasselt, Belgium) are both smartphone applications with built in algorithms that provide an immediate interpretation of the ECG. This would make intermittent recordings possible and facilitate the chance to detect AF before stroke occurs.

The aim of this study is a head-to-head comparison of both methods against a standard 12 lead ECG. Our objective is finding the application with superior diagnostic performance and clinical benefit that would be best to implement in general practice.

Methods

Study Design and study population

The ethical review board of the Medical Faculty of KU Leuven, Belgium, approved this multicenter screening study and all participants gave informed consent. The study design, sample size calculation and sampling methods have been described in detail previously.[24] In summary, 17 general practices in the Northern part of Belgium were recruited. A convenience sample of patients aged 65 or older with a history of (paroxysmal or permanent) AF was invited between October 2015 and March 2016. In addition, patients without cardiac arrhythmia were asked to participate. Each patient was asked questions about his/her medical history and chronic medication. Weight, height, systolic and diastolic blood pressure were measured, presence of cardiac murmurs and pulse palpation were clinically checked by one of the investigators.

Index test

For this study, both applications were installed and used on iPhone 5S (Apple, Cupertino, USA).

Fibricheck

Patients were asked to adopt a standard sitting position (Figure 1). Three consecutive measurements were performed. If the finger was removed too early from the camera, an extra (fourth) measurement was carried out. The Fibricheck application measures the rhythm of the heart through the technique of photoplethysmography (PPG). PPG waveforms were acquired using the iPhone's LED flash to illuminate a patient's finger. The software calculates the blood volume pulse variation in the local arterioles, depending on the amount of reflected light on the camera. This way, each heartbeat is recorded and the rhythm is determined based on the RR-interval. During our study, the application was configured in a data-recording mode with only raw data collection. The app disposes of a software filter to score the quality of the PPG signal based on the ability to detect and differentiate heartbeats. If heart beat detection was compromised with noise, or if heartbeats were absent, these measurements were filtered out as bad quality and the results were not included in the analysis.

If more than one measurement was defined as a good signal, opportunistic selection took place, based on the quality of the PPG trace. All of the results were blinded for the investigators till after the entire screening procedure.

AliveCor

Next the AliveCor app was opened and simple instructions were given so fingers of both hands were covering the grey electrodes. (Figure 2) When the right position was obtained the measurement was started automatically. The record was wirelessly transmitted to a secure server, processed to remove noise and interpreted by a validated automated algorithm. This is based on the criteria of P-wave absence and R-R interval irregularity to diagnose AF. After 30s of recording the result was immediately shown: 'normal', 'possible AF', 'undiagnosable' or 'error'. When the result was 'undiagnosable' or 'error' an extra measurement took place and the process was repeated. All recordings were stored on a web-based software platform with recording time, date and automated algorithm diagnosis. (Figure 4) The investigator also manually noted all data.

Reference test

Immediately after the index tests, a 12-lead electrocardiogram was performed by the same investigator. The used digital ECG-devices were: CardiMax FCP-7101 (Fukuda Denshi, Tokyo, Japan), CP 50 (Welch Allyn, New York, USA), Universal ECG (QRS Diagnostic, Plymouth MN, USA) and ECG-1150 (Nihon Kohden Corporation, Tokyo, Japan). The 12 lead ECG's were protocolled for the presence of AF (Minnesota code 8-3-1) by two independent and double-blinded cardiologists. In case of inconsistent results, the ECG was reviewed by a third and fourth cardiologist and a final diagnose was made.

Statistical analysis

Our total study population got divided into subgroups for further analysis. Study population A was composed by removing all technical errors, non-interpretable ECG and active pacemakers; study population B by further eliminating bad quality Fibricheck measurements.

For the current study, study population B seems most relevant. In daily practice undiagnosable AliveCor results are not filtered out and AliveCor Inc. advises patients with this result to consult their physician.

As both applications are positioned as a screening tool the most logic consequence for further analyses is to consider an undiagnosable result the same as 'possible AF' because we would rather prefer a false positive result then missing a patient due to a false negative result. However, as the interpretation of these undiagnosable results may be considered as subjective we did calculate the results for both interpretations ('possible AF' and 'no AF'). Moreover, to avoid the necessity of interpretation we further excluded all undiagnosable AliveCor results and became study population C.

Sensitivity, specificity and their 95% confidence interval were calculated using 2x2 tables in all different subgroups for both applications. Positive and negative predictive values were estimated based on an expected prevalence of 6% in the general population aged 65 or older.[3]

To examine the possible improvement or deterioration of the Fibricheck application over the AliveCor application, the net reclassification improvement (NRI) was calculated by using the formula of Pencina.[25] To evaluate and to compare the different apps, the net benefit was calculated.[26-28] Decisions curves were constructed by plotting net benefit against the threshold probability (range 0.05 – 0.25). The curves show the expected net benefit per patient when referred for further investigations (like holter) according to both apps relative to no referral at all. The net benefit for a given threshold probability can be interpreted as the equivalent of the increase in the proportion of true positives for a given approach (Fibricheck or AliveCor) relative to ''refer none'' without an increase in false positives.[26-28] We calculated the net benefit for different prevalence settings, 2% as in the general population, 6% as in the general population aged 65 and older, 8% and 15% in high risk settings.[2,3]

All analyses were performed with MedCalc Version 17.4.4 (MedCalc Statistical Software, Mariakerke, Belgium) and SPSS 23.0 (SPSS Inc., Chicago, IL, USA).

Results

Study population

In total, 242 subjects agreed to participate in this study. Study population A consisted of 218 patients and study population B of 190 patients (Figure 5).

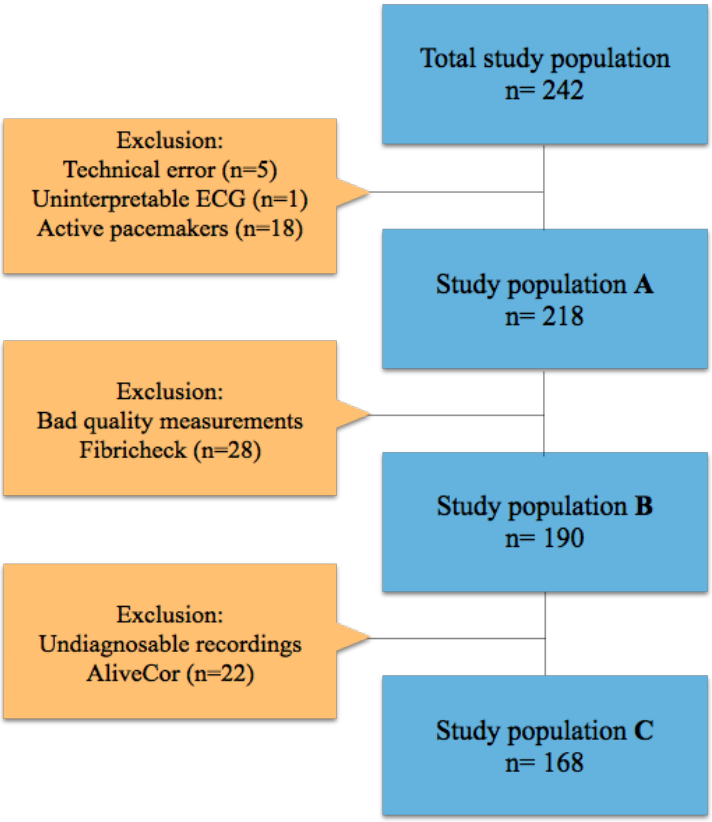

Figure 5: Flowchart study population

The baseline characteristics of study population B are shown in table 1. The mean age was 77.3 ± 8.0 years and 57.4% were women. There was a high burden of comorbid cardiovascular diseases like arterial hypertension (84.2%) and vascular disease (36.8%), and the mean BMI was elevated (26.2 ± 4.8). Based on chart review 116 patients (61.1%) had a history of AF, but at the moment of the study only 92 patients (48.4%) showed AF on their 12 lead ECG. In the AF population, the median CHA_2DS_2-VASc-score was 5 (IQR: 3-6) and all had a score ≥2. In total, 8 AF patients (8.7%) received a platelet aggregation inhibitor and 83 (90,2%) received anticoagulation.

Table 1. Characteristics of the study population (n = 190)

	All (n = 190)	AF present (n = 92)	AF absent (n = 98)	*P* value*
Age, mean ± SD	77.3 ± 8.0	78.8 ± 8.0	75.9 ± 7.9	0.013
Male gender, n (%)	81 (42.6)	45 (48.9)	36 (36.7)	0.090
Risk score				
CHA_2DS_2-VASc-score,median(IQR)	4 (3 – 6)	5 (3 – 6)	4 (3 – 5)	<0.001

	CHA_2DS_2-VASc-score ≥ 2, n (%)	189 (99.5)	92 (100)	97 (99.0)	0.33
Comorbidities					
	History of AF, n (%)	116 (61.1)	85 (92.4)	31 (31.6)	<0.001
	Diabetes mellitus type II, n (%)	41 (21.6)	25 (27.2)	16 (16.3)	0.069
	Vascular disease, n (%)	70 (36.8)	41 (44.6)	29 (29.6)	0.032
	TE, TIA or CVA, n (%)	43 (22.6)	30 (32.6)	13 (13.3)	0.001
	Congestive heart failure, n (%)	55 (28.9)	37 (40.2)	18 (18.4)	0.001
	Pacemaker, n (%)	5 (2.6)	4 (4.3)	1 (1.0)	0.15
	Arterial hypertension, n (%)	160 (84.2)	85 (92.4)	75 (76.5)	0.003
Clinical characteristics					
	BMI, mean ± SD	26.2 ± 4.8	26.0 ± 4.4	26.4 ± 5.1	0.62
	Systolic blood pressure (mmHg), mean ± SD	130 ± 16	130 ± 16	130 ± 16	0.81
	Diastolic blood pressure (mmHg), mean ± SD	74 ± 9	75 ± 11	73 ± 7	0.14
	Heart rate at rest (bpm), mean ± SD	76 ± 17	82 ± 19	71 ± 14	<0.001
	Cardiac murmur, n (%)	46 (28.9)	34 (37.0)	12 (12.2)	<0.001
Antithrombotic treatment					
	No antithrombotic treatment, n (%)	50 (26.3)	2 (2.2)	48 (49.0)	<0.001
	Platelet aggregation inhibitors, n (%)	37 (19.5)	8 (8.7)	29 (29.6)	<0.001
	Anticoagulants, n (%)	105 (55.3)	83 (90.2)	22 (22.4)	<0.001
	Vitamin K antagonists, n (%)	46 (24.2)	39 (42.4)	7 (7.1)	<0.001
	New oral anticoagulants, n (%)	58 (30.5)	43 (46.7)	15 (15.3)	<0.001
	Low-molecular-weight heparins, n(%)	3 (1.6)	3 (3.3)	0 (0)	0.072

*, Student's *t* test, Mann-Whitney U test or Chi^2 test.

AF: atrial fibrillation; SD: standard deviation; IQR: inter-quartile range; TE: thrombo-embolism; TIA: transient ischaemic attack; CVA: cerebrovascular accident; BMI: body mass index; bpm: beats per minute; ACE: angiotensin converting enzyme.

Fibricheck versus 12-lead ECG

The Fibricheck application showed a positive AF result in 102 subjects and a negative result in 88 participants. The PPG results matched the diagnosis of the cardiologists 176 times (93%). Of the 14 inconsistent results, 12 were found to be false positive and 2 were false negative. The false positive results were caused by atrial (n = 7) or ventricular (n = 1) extra systoles and by failure of the quality filter of the application to recognize a poor and unreliable signal (n = 4). The false negative results followed wrong peak detection (n = 1) and misinterpretation of an atrial flutter (n = 1).

On the basis of these results a sensitivity of the PPG measurement and interpretation of the Fibricheck app of 98% (95% CI 92-100) and a specificity of 88% (95% CI 80-94) was obtained. In this study population, the positive predictive value was 88% (95% CI 82–93) and the negative predictive value 98% (95% CI 92-100). Based on an expected prevalence of 6% in the general population aged 65 or older, a positive predictive value of 34% and a negative predictive value of 99.9% were estimated.[2,3]

If we would not have excluded the bad quality measurements and would have considered them all as positive results, the sensitivity would stay the same (98%), only the specificity would reduce to 74% (study population A).

AliveCor versus 12 lead ECG

The AliveCor showed 0 errors and 42 undiagnosable results in the total study population . In study population A and B still 30 and 22 'undiagnosable results' respectively remained. When the undiagnosables were considered as positive results, the AliveCor app showed an AF positive result in 105 subjects and a negative result in 85 participants of study population B. The app matched the diagnosis of the cardiologists 173 times (91%). Of the 17 inconsistent results, 15 were found to be false positive and 2 were false negative. On the basis of these results a sensitivity of 98% (95% CI 92 - 100) and a specificity of 85% (95% CI 76 - 91) was obtained. In this study population, the positive predictive value was 86% (95% CI 79 – 91) and the negative predictive value 98% (95% CI 91- 99). Based on an expected prevalence of 6% in the general population aged 65 or older, a positive predictive value of 29% and a negative predictive value of 99.8% were estimated

When the 'undiagnosables' were considered as 'non-AF', this led to an increase of 107 negative results, and only 83 positives. The app would match the diagnosis of the cardiologists only 163 times (86%) with an increase of 26 inconsistent results, 9 false positive and 19 false negative. In this case a sensitivity of 80% (95% CI 71 - 88) and a specificity of 91% (95% CI 83 - 96) was obtained.

In study population C we only had 11 inconsistent results, 9 false positives and 2 false negatives. Both sensitivity and specificity increased to a maximum, 97% (95%CI 91 – 100) and 90% (95%CI 82 – 95) respectively.

Fibricheck versus AliveCor

For study population B, both applications showed an equal sensitivity of 98% (95% CI 92 - 100) but Fibricheck had a slightly higher specificity 88% (95% CI 80 - 94) versus 85% (95% CI 76 – 91). (Table 2)

A positive NRI indicates reclassification improvement of the Fibricheck app over the Alivecor app in AF detection. NRIs were not statistically significant except for study population B with the undiagnosable AliveCor results considered as 'no AF'. In this situation Fibricheck would be an improvement.

Because the AF prevalence rises with age we calculated the net benefit decision curve for multiple prevalences and plotted both applications against 'referral' and 'no referral'. Both apps showed a bigger net benefit compared to 'no referral' or 'referral' in the whole population. This observation counts for the different prevalence settings and all corresponding probability thresholds. Head to head, Fibricheck had a higher net benefit then AliveCor. A small positive difference was observed at the lower probability thresholds but clearly increased for the higher probability thresholds. (figure 6)

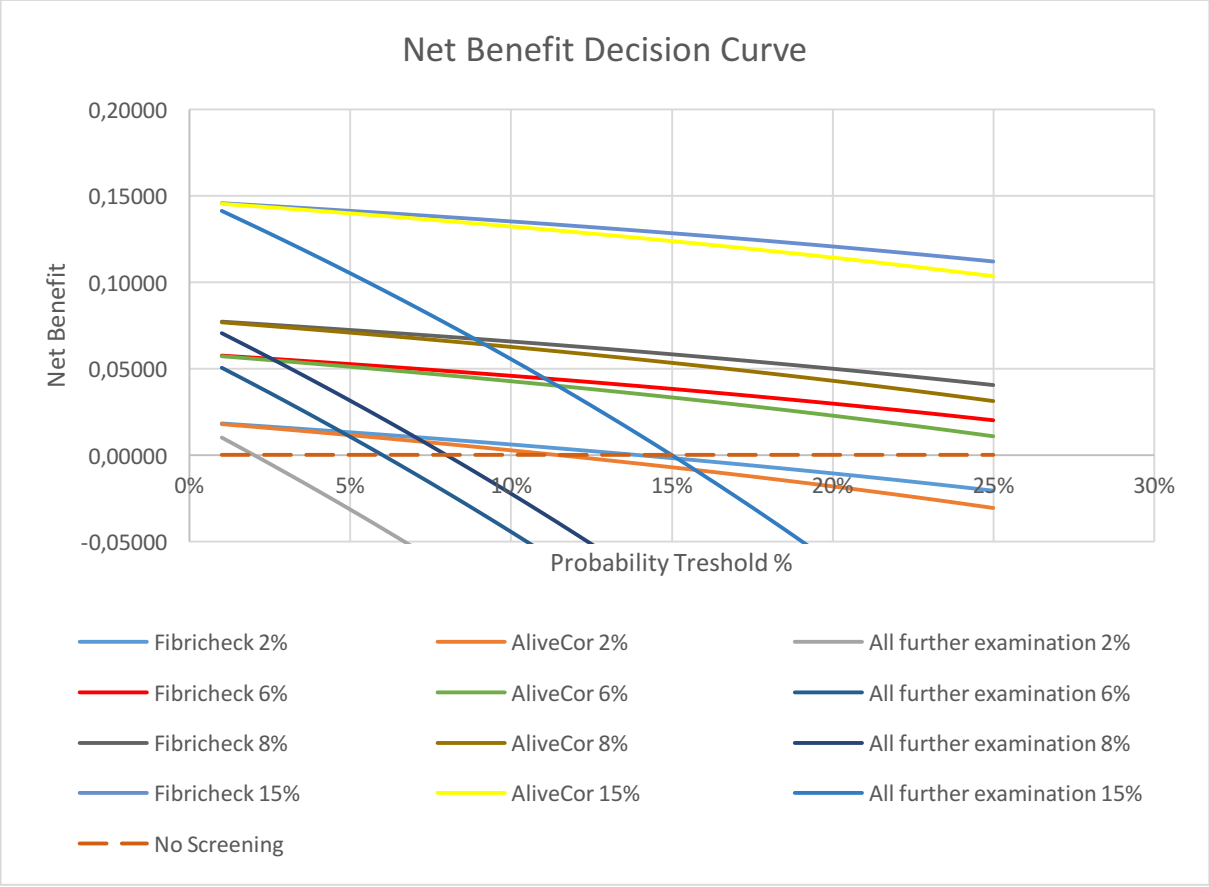

Figure 6: Net benefit decision curve

Table 2: Diagnostic accuracy and net reclassification improvement										
Study population	**Sensitivity** (95% CI)	**Specificity (95% CI)**	**Positive Predictive Value (95% CI)**		**Negative Predictive Value (95% CI)**		**Net Reclassification Index**			
			Study population	*General population*	*Study population*	*General population*	*Event*	*Non-event*	*Total*	*P-value*
A (n=218)										
Fibricheck	98% (93-100)	74% (65- 81)	76% (70-81)	19%	98% (92- 99)	100%	0	0,086	0,086	0,056
Alivecor x=1	98% (93-100)	82% (74- 89)	83% (76- 87)	26%	98% (92- 99)	100%				
B (n=190)										
Fibricheck	98% (92-100)	88% (80-94)	88% (82-93)	34%	98% (92-99)	100%	0	-0,031	-0,031	0,42
Alivecor x=1	98% (92-100)	85% (76-91)	86% (79-91)	29%	98% (91-99)	100%				
Alivecor x=0	80% (71-88)	91% (83–96)	89% (81-94)	36%	83% (76-88)	99%	0,174	0,031	0,205	<0,001
C (n=168)										
Fibricheck	100% (95-100)	90% (82-95)	89% (82-94)	39%	100%	100%	0,026	0	0,026	0,42
Alivecor	97% (91-100)	90% (82-95)	89% (82-94)	36%	98% (91-99)	100%				

CI: confidence interval; x=1: interpretation undiagnosable records Alivecor as possible AF; x=0 interpretation undiagnosable records AliveCor as no AF.
Event NRI: atrial fibrillation present; non-event NRI: atrial fibrillation absent

Discussion

Main results

The purpose of this study was to investigate whether the Fibricheck or the AliveCor application showed a superior performance in detecting AF in a primary healthcare setting. For screening the sensitivity is crucial. Both applications showed an equally excellent sensitivity in all subpopulations studied. Furthermore, both applications showed an acceptable specificity, which could reduce the number of ECG's compared to current screening through pulse palpation.[14] The results for AliveCor were in line with previously found sensitivity and specificity numbers. [29,30]

However, sensitivity and specificity alone do not provide a full answer for our objective. Screening involves trade-offs between diagnosing patients versus unnecessary additional testing for those who are healthy. Therefore, the net reclassification index was calculated to check whether Fibricheck would perform better compared to Alivecor.[25] The current study was not able to find a significant NRI that would favour Fibricheck, unless all undiagnosable AliveCor results were considered as 'no AF'.

Moreover, the net benefit of both applications was measured, in which benefits and harms were put on the same scale so they could be compared directly.[26-28] To calculate this, an exchange rate was defined by considering the number of patients a clinician is willing to screen to find one new AF patient. Both applications tested are non-invasive so the possible harm would be low. Decision curves for reasonable prevalences and exchange rates were calculated and showed Fibricheck to be slightly superior compared to Alivecor, as to screening nobody or pursue further examinations by everyone.

Difference in practical use of both applications

Although we did not formally evaluate the user-friendliness, both devices were easy to use and only few recordings were interrupted. Bad contact between the finger and the camera caused some problems for the PPG measurements and tremor could influence this. A small advantage of Alivecor is that it stops automatically once the fingers are moved from the electrodes and restarts when a good position is obtained. Another difference is recording time, 60 seconds for Fibricheck compared to 30 seconds for AliveCor. Furthermore, AliveCor does require additional hardware; initially the electrodes were embedded in a smartphone cover, but now a separate patch with electrodes is on the market.[35] Both applications are linked to a web-based platform, so clinicians can review the recordings (figures 3,4).

To date, no application is integrated with the electronic health record of the clinician. In the future this would facilitate the selection of eligible patients and monitoring and supervision of the measurements.

Implementation in daily practice

Previous studies have shown that AF screening using handheld devices could cost-effectively save lives. [33,36] A recent study demonstrated the willingness and capacity to use mobile health devices by older persons.[37] Furthermore, the current increase in smartphone use is majorly due to elderly. Given that 64% of the American adults own a smartphone, the majority already has the potential hardware for apps such as Fibricheck.[23] The current study tested both applications only in people aged 65 and older because the effectiveness of screening in a younger population is thought to be low.[38] This due to low prevalence and often CHA_2DS_2-VASc scores beneath 2 thus no benefit of preventive anticoagulation in case of AF.[37] Studies investigating the effect of screening in younger population are lacking and caution needs to be taken when extrapolating our study results to younger subjects.[12] During this study all measurements were performed under medical supervision. It remains unclear whether these applications would achieve the same accuracy in an unsupervised situation. Repetitive measurements at home might increase the chance of identifying a new, paroxysmal, AF.[16]

Both applications are already available in the app store. Fibricheck works with a monthly subscription system and is only purchasable after doctor's prescription. AliveCor is accessible for everybody.

Strengths and limitations

This study is the first that evaluated a head-to-head comparison of two smartphone applications for the detection of atrial fibrillation. An important strength is that the study was performed in general practice. Participants were representative of those who may benefit the most from screening. Almost all patients had a CHA_2DS_2-VASc-score higher than 2. This implies that early detection of AF would lead to anticoagulation and so direct prevention of stroke. Furthermore, a 12 lead ECG was recorded in every participant as the gold standard for AF diagnosis.[1] Not many previous studies have done this.[32,33] However, a few limitations should be noted. First, different ECG devices, instead of one standardized device, were used for practical reasons.

Second, although time delay between all measurements was kept as short as possible, the presentation of short-term rhythm differences, such as paroxysmal AF, could not be fully excluded. Third, the interpretation of bad quality measurements and undiagnosable results should be made with caution. In previous studies the undiagnosable results of AliveCor were interpreted as no AF or the interpretation was not mentioned. [30-32] Fourth, the extrapolation of these results to populations with a different prevalence of AF should be made with caution. Fifth, a combination of three recordings was used to make a diagnosis for Fibricheck instead of one for AliveCor. If more than one measurement was defined as a good signal, opportunistic selection took place, based on the quality of the PPG trace of Fibricheck.

Conclusion

Both Fibricheck and AliveCor showed promising results for AF screening in patients aged 65 or older in general practice. Only small differences in performance could be found, and net benefit slightly favoured Fibricheck. Moreover, the fact no additional hardware is required, widespread smartphone use is present and the fact it is only purchasable through prescription by a clinician, makes Fibricheck at this point the favoured choice for further implementation in general practice.

Sources of Funding

None. Qompium Inc. provided 2 IPhone 5S in AliveCor case with both Fibricheck as AliveCor applications installed.

Abbreviations

AF: Atrial fibrillation/ ECG: Electrocardiogram / APP: application

PPG: photoplethysmography/ CI: confidence interval;/ PPV: positive predictive value

NPV: negative predictive value/ NRI: net reclassification improvement

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Attachments

Figures

Figure 1-2 : Correct position during Fibricheck – AliveCor measurement

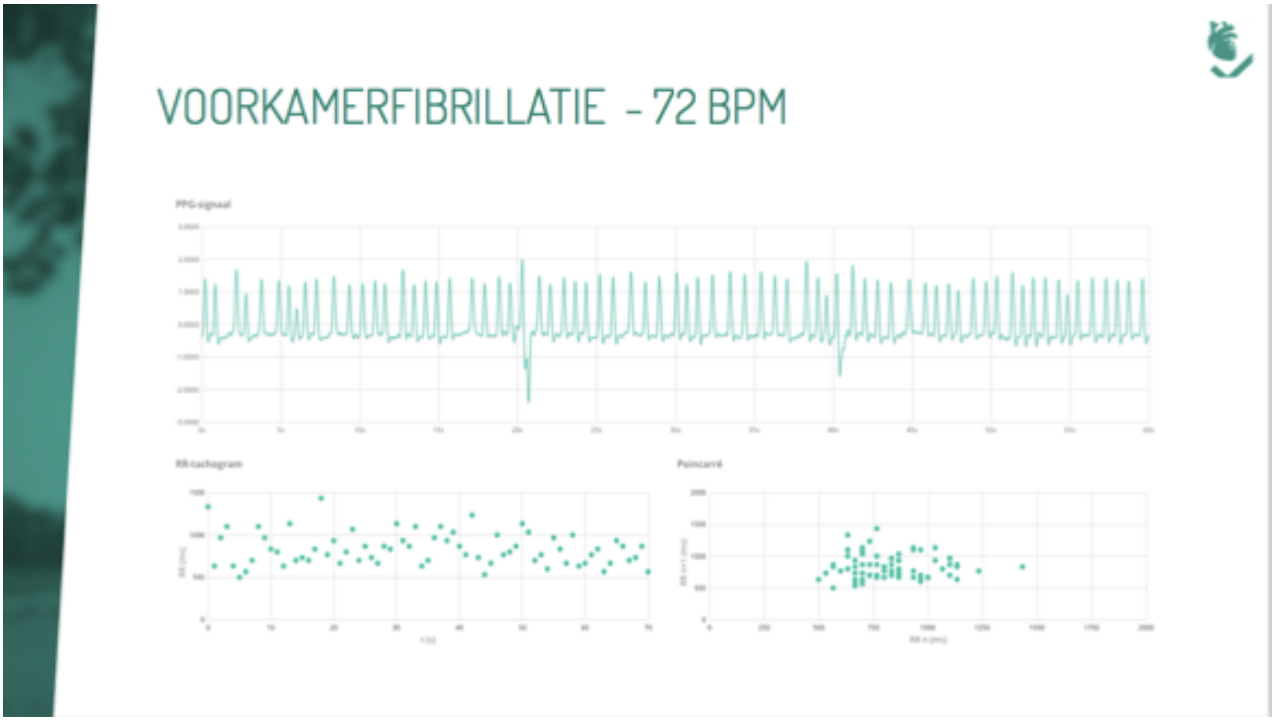

Figure 3: Online platform Fibricheck

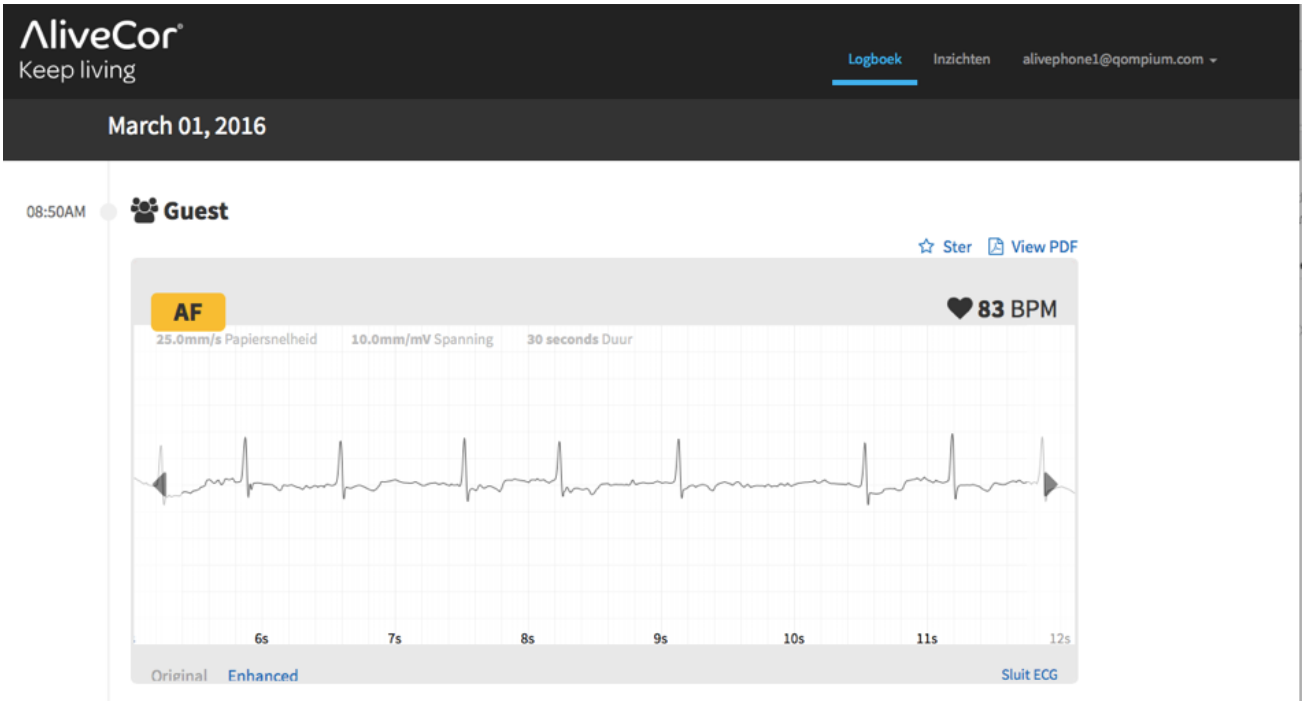

Figure 4: Online platform AliveCor

Dutch Abstract

Inleiding

Voorkamerfibrillatie (VKF) is een frequent voorkomende hartritmestoornis. De kans op een cerebrovasculair accident vervijfvoudigt met ernstige morbiditeit en mortaliteit tot gevolg. Gezien de prevalentie van voorkamerfibrillatie toeneemt met leeftijd en we in een periode van vergrijzing komen wordt screening, en zo nodig preventieve behandeling met anticoagulantia, cruciaal. Europese richtlijnen raden opportunistische screening via polspalpatie aan bij elke 65-plusser en bij een afwijkend ritme aansluitend een 12 afleidingen elektrocardiogram (ECG). Recent toonde de *strokestop*-studie dat meervoudige metingen de kans op detectie met factor 4 kunnen verhogen. Smartphones zijn anno 2017 alom aanwezig en meerdere applicaties voor VKF-screening zijn op de markt. Fibricheck gebaseerd op fotoplethysmorgafie en Alivecor gebaseerd op een 1 afleiding ecg via een gekoppelde smartphone cover, worden in deze studie rechtstreeks met elkaar vergeleken.

Methode

Tussen oktober 2015 en maart 2016 namen 17 Vlaamse huisartsenpraktijken deel aan de studie. Alle 65-plussers die zich aanboden voor routine consultatie werden gevraagd deel te nemen. Patiënten gekend met VKF werden actief uitgenodigd. In totaal werden 242 patiënten gescreend door beide applicaties gevolgd door afname 12 afleidingen ECG. Deze werden geïnterpreteerd door 2 onafhankelijke cardiologen en finale diagnose gebruikt als gouden standaard. Statistisch analyse werd uitgevoerd, net benefit en netto reclassificatie index berekend.

Resultaten

Na exclusie technische fouten (n=5), onleesbaar ECG (n=1), actieve pacemakers (n=18) en metingen van slechte kwaliteit Fibricheck (n=28) werden 190 patiënten weerhouden. De gemiddelde leeftijd was 77.3±8.0 jaar. Beide applicaties hadden eenzelfde sensitiviteit van 98% (95%CI 92-100) maar Fibricheck een iets hogere specificiteit van 88% (95%CI 80-94) versus 85% (95%CI 76-91)voor AliveCor. Netto reclassificatie index toonde geen significant resultaat. Net benefit werd berekend voor verschillende prevalenties van 2% tot 15%, Fibricheck was hierin voor alle cijfers superieur ten aanzien van screening via AliveCor, geen screening of verder onderzoek bij iedereen.

Conclusie

Beide applicaties tonen veelbelovende cijfers voor voorkamerfibrillatie screening bij 65-plussers. Op basis van statistische analyse alleen kunnen we geen applicatie als superieur aanduiden. Gebaseerd op net benefit analyse is Fibricheck de te verkiezen applicatie voor screening in eerste lijn. Het feit dat de Fibricheck applicatie, in tegenstelling tot AliveCor, geen extra hardware nodig heeft is voor grootschalige implementatie ook een duidelijke meerwaarde.

Ethical committee

Application

KU LEUVEN **Biomedische Wetenschappen**
Ethische begeleiding masterproeven

mp11191	Smartphone applicaties voor diagnose voorkamerfibrillatie kritisch bekeken: Alivecor vs FibriCheck

Student(en):
Ruth Van Haelst
Christophe Mortelmans
Promotor:
Bert Vaes (bert.vaes@med.kuleuven.be - u0087897 - Acad. Centr. voor Huisartsgeneeskunde)
Hoofdonderzoeker:

Faculteit:
Geneeskunde
Opleiding:
Master in de huisartsgeneeskunde (Leuven e.a.)
Het onderzoek is:
multicentrisch
De opdrachtgever is:
academisch (universiteit,...)

Het onderzoek is:
Het onderzoek is onderdeel van een groter project waarvoor reeds goedkeuring van de Ethische commissie werd bekomen.
CTC s-nummer:
S03244

Het onderzoek valt volledig binnen het groter project.

Bijkomende gegevens:

Achtergrond:

Voorkamerfibrillatie is een frequent probleem bij ouderen (6% bij 65-plussers). Een deel van de patiënten (12-30% naargelang de bron) is asymptomatisch en zich niet bewust van deze hartritmestoornis. Aanwezigheid van VKF leidt tot een sterk verhoogd risico op complicaties, waaronder een CVA. Vroege detectie en preventie kunnen ernstige complicaties voorkomen en de levenskwaliteit van de patient verbeteren. Er zijn de laatste jaren nieuwe screeningsmethoden op de markt gekomen waaronder enkele medische telefoonapplicaties, welke rol deze kunnen spelen in de vlaamse huisartsenpraktijk vraagt verder onderzoek.

Vorig jeer schreef ik met 4 medestudenten reeds een stagwerk rond de haalbaarheid van de applicatie 'Cardimoni' binnen de huisartsenpraktijk.

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Christophe Mortelmans zette het onderzoek verder en werkt momenteel aan een validatiestudie.

Vraagstelling:

In dit ManaMa-onderzoek zullen twee smartphone applicaties voor de diagnose van voorkamerfibrillatie met elkaar vergeleken worden. De 'app' FibriCheck en AliveCor worden in de huisartsenpraktijk getest en vergeleken met een 12 afleiding ECG als gouden standaard. De vraagstelling is welke methode superieur is en hoe deze kan geïntegreerd worden in de eerste lijn. Dit onderzoek geldt als vervolg op de eerder uitgevoerde haalbaarheidsstudie (stagewerk KUL 2014-15) en validatiestudie van Fibricheck (ManaMa thesis Christophe Mortelmans 2016).

Methodologie:

Mijn Manama thesis zal gebaseerd worden op het onderzoek dat momenteel lopende is, en al werd goedgekeurd door de ethische commissie, in het kader van de Manama thesis van Christophe Mortelmans. Dit werd in overleg met onze promotor beslist gezien het grote aantal proefpersonen en controles en de hoeveelheid bekomen gegevens.

Referenties:

In bijlage:

1. Stagewerk 2014-2015

2. Aanvraag ethische commissie Christophe Mortelmans

Approval

Martine Goossens <martine.goossens@med.kuleuven.be> **Markeren als ongelezen**
do 24/03/2016 18:47
Inbox

English version below

Geachte Heer/Mevrouw

De Opleidingspecifieke Ethische Begeleidingscommissie van de opleiding "Master in de huisartsgeneeskunde (Leuven e.a.)" heeft uw voorstel tot Masterproef "Smartphone applicaties voor diagnose voorkamerfibrillatie kritisch bekeken: Alivecor vs FibriCheck" onderzocht en gunstig geadviseerd. Dit betekent dat de commissie van oordeel is dat de studie, zoals beschreven in het protocol, wetenschappelijk relevant en ethisch verantwoord is. Dit gunstig advies van de commissie houdt niet in dat zij de verantwoordelijkheid voor de geplande studie op zich neemt. U blijft hiervoor zelf verantwoordelijk. Indien u van plan bent uw masterproef te publiceren kan deze e-mail dienen als bewijs van goedkeuring.

Dear Mr/Ms

The Supervisory Committee on Medical ethics of the "Master in de huisartsgeneeskunde (Leuven e.a.)" programme has reviewed your master's thesis project proposal "Smartphone applicaties voor diagnose voorkamerfibrillatie kritisch bekeken: Alivecor vs FibriCheck" and advises in its favour. This means that the committee has acknowledged that your project, as described in the protocol, is scientifically relevant and in line with prevailing ethical standards. This favourable advice does not entail the committee's responsibility for the planned project, however. You remain solely responsible. If you intend to publish your master's thesis, this e-mail may be used as proof of the committee's consent.