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Usability of Handheld Electrocardiogram Devices to detect Atrial Fibrillation in a Cardiology Ward Setting

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Abstract

Keyword(s): electrocardiogram, recording, atrial fibrillation, mobile devices

1. INTRODUCTION

Atrial fibrillation (AF) is the most common arrhythmia, associated with an increased mortality and morbidity. This heart rhythm disorder is a major public health concern since its prevalence is estimated to be 1-2%. AF prevalence is increasing in an ageing population with multiple cardiovascular chronic conditions that are associated with its development (1). An electrocardiogram (ECG) is needed for diagnosis of AF. In about 30% of patients, AF episodes are asymptomatic. Nevertheless, they have the same risks. Therefore, it is important to capture AF as early and as reliably as possible with simple diagnostic screening tools, especially in populations with risk factors. Even in hospitals, there is no uniform detection strategy. Therefore, some AF patients will not receive optimal treatment (2, 3). A fast, cost-effective, efficient and accurate screening tool is needed to optimize the current situation of detection and management of AF. Since AF is normally diagnosed with an ECG there is a focus on screening with mobile devices or single lead handheld ECG devices. This study evaluated two such devices, MyDiagnostick and AliveCor, and tested their ability to detect AF in hospitalized patients.

2. METHODS AND MATERIALS

In total, 216 patients hospitalized at the department of cardiology of Jessa Hospital received a 12-lead ECG, immediately followed by recordings with two single lead handheld ECG devices (Figure 1). The study was approved by the hospital ethical committee.

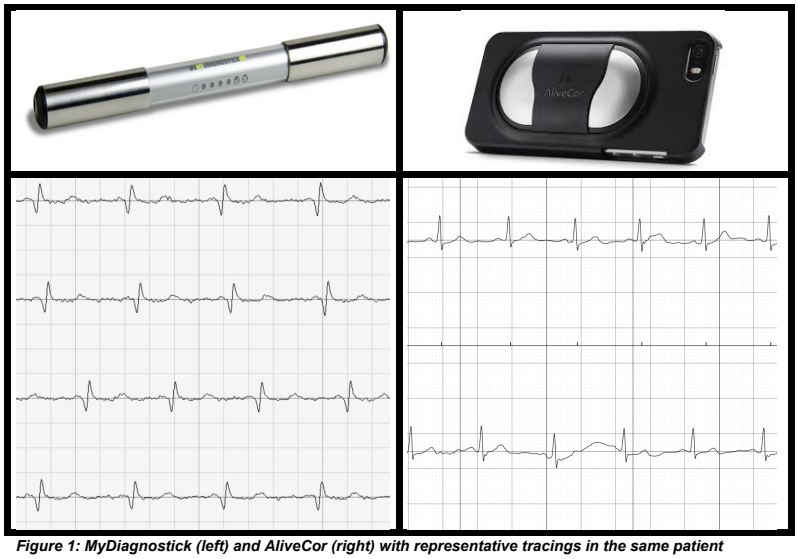

Figure 1: MyDiagnostick (left) and AliveCor (right) with representative tracings in the same patient

The MyDiagnostick (Applied Biomedical Systems, Maastricht, The Netherlands) screening tool is a dedicated rod-like device that needs to be held with two hands. Recordings cannot be seen at the time of registration, but can be uploaded later to a computer for manual reading. Immediately after recording, the device may blink a green or red light to indicate presence of AF. For the purpose of this study, that feature was turned off and

the automatic interpretation was reviewed after uploading to the PC. This device can be programmed for one specific patient. When used in a screening setting, as performed in this study, all the recordings can be linked to the patients' name and date of birth when uploading them to a PC. In case of a screening setting, the investigator should however carefully pay attention to the order of measurements to not mix up patients' recordings.

The AliveCor Heart Monitor (AliveCor, San Francisco, CA, USA) is embedded in an iPhone case, allowing recording by the AliveECG application while placing fingertips on the mobile device. Recordings can be seen live on the iPhone screen and patient data can be entered directly after each measurement to identify each ECG. The recordings can also be sent wirelessly to the investigator for later review. An alternative recording method of the AliveCor, i.e. by placing the device on the chest, was not used in this study after a pilot phase showed recordings of insufficient quality.

Specialized nurses recorded the 12-lead ECGs with a Schiller CARDIOVIT AT-10 plus (Schiller, Belmont, Australia) ECG device. Immediately after this recording and after oral consent by the patient for the study, patients were asked by a biomedical student to hold the AliveCor device for 30 seconds, followed by holding the MyDiagnostick for one minute. All recordings were reviewed offline by an electrophysiologist, interpreting each of the three tracings independently from the others. Patient data, manual interpretation of the recordings and the automatic analysis by each device were entered in a database and statistically processed with SPSS (SPSS Inc., Chicago, IL, USA). The 12 lead ECGs were used as a 'gold standard' to calculate the feasibility, accuracy, specificity and sensitivity of each of the handheld devices as a screening tool for AF.

3. RESULTS

The screening group consisted of 118 males and 98 females with an average age of 68.2 ± 13.1 years. Based on chart review, 31.5% of the study population was known with AF. The 12-lead recording showed a prevalence of AF in 4.6% of the population. It is known that not all AF is permanently present. Moreover, 10.7% of the study group comprised patients who recently underwent an ablation (4.2%) or cardioversion (6.5%) for AF.

Automatic analysis by MyDiagnostick reported unreadable recordings in 1.4%. Nevertheless, the device provided an automatic diagnosis of 'sinus rhythm' in these cases (Table 1). Manual reading considered 8 more tracings (11 in total, 5%) as unusable, with a higher proportion in patients with AF (Table 2). The built-in analysis of MyDiagnostick reported an automatic AF prevalence of 9.7% (21/216), but more than half of these (13/21) were false positives. Automatic MyDiagnostick screening had a sensitivity of 80.0% and a specificity of 93.7%. Based on manual review, the sensitivity decreased to 20.0% (mainly because a high proportion of AF patients had unreadable tracings), and the specificity increased to 94.2%. The diagnostic accuracy of automatic MyDiagnostick screening was 93.1%. After manual review it decreased to 90.7% due to exclusion of unreadable tracings.

Table 1: Automatic analysis of the handheld ECG recordings (n=216).

		12-lead ECG				
	(#)	**AF**	**SR**	**Total**	**(%)**	
MyDiagnostick	**AF**	8 [0]	13 [0]	21	**Sens.: 80.0**	**Spec.: 93.7**
["Unreadable"]	**SR**	2 [1]	193 [2]	195	**PPV: 38.1**	**NPV: 99.0**
	Total	10	206	216		
AliveCor	**AF**	1	12	13	**Sens.: 10.0**	**Spec.: 94.2**
	SR	9	194	203	**PPV: 7.8**	**NPV: 95.6**
	Total	10	206	216		

AF: atrial fibrillation, SR: sinus rhythm, sens..: sensitivity, spec.: specificity, PPV & NPV: positive & negative predictive value

The AliveCor did not have the feature to label recordings as unreadable at the moment of this study, but 10.6% of all recordings were manually judged to be unusable. The AliveCor device reported an automatic prevalence of 6.0% (13/216), but only one case was truly positive. Automatic analysis for the AliveCor device yielded a sensitivity of 10.0% and specificity of 94.2%. With manual reading, sensitivity and specificity became 40.0% and 88.3% respectively, with positive and negative predictive values becoming 57.1% respectively 97.8%. Automatic AliveCor analysis showed an accuracy of 90.2%. It was 86.1% with manual annotation of the recordings due to exclusion of unusable tracings.

Table 2: Manually reviewed handheld ECG recordings

		12-lead ECG				
	(#)	**AF**	**SR**	**Total**		**(%)**
MyDiagnostick	**Unreadable**	5	6	11		
	AF	2	6	8	**Sens.: 20.0**	**Spec.: 94.2**
	SR	3	194	197	**PPV: 25**	**NPV: 98.5**
	Total	10	206	216		
AliveCor	**Unreadable**	2	21	23		
	AF	4	3	7	**Sens.: 40.0**	**Spec.: 88,3**
	SR	4	182	186	**PPV: 57.1**	**NPV: 97.8**
	Total	10	206	216		

AF: atrial fibrillation, SR: sinus rhythm, sens..: sensitivity, spec.: specificity, PPV & NPV: positive & negative predictive value

For both devices, dry hands or poor electrode contact led to recordings of poor quality, often not even usable for interpretation, even after manual reading. Especially the AliveCor device is very sensitive to suboptimal contact and slight patient movements (e.g. tremor), explaining the higher proportion of 'unreadable' ECGs compared to MyDiagnostick (10.6% vs. 5.1%) Whether the recording would be usable remained largely unpredictable bedside, even after experience with a few hundred recordings. On the other hand, direct visualisation of the tracing on the AliveCor device allows for a repeat recording if needed, which is not possible with MyDiagnostick. A high proportion of the AF patients had an unreadable recording with MyDiagnostick than with Alivecor, leading to a decreased sensitivity after manual interpretation. Whether this is a matter of chance with small numbers needs further evaluation. Two patients in the study population had a pacemaker. MyDiagnostick reported an error measurement in one of these cases, while AliveCor recorded a usable ECG in both. Our experience is that both automatic and manual interpretation for AF was impossible in these pacemaker patients.
Overall, patients' acceptance of the handheld recordings was very high. Only 1% of the patients refused participation after a short explanation of the study, and 2.8% accepted the study but later gave up trying to record a full tracing. Recording with both devices never exceeded more than 5 minutes of patients' time.

4. DISCUSSION AND CONCLUSION

Handheld heart monitors are an attractive method to screen larger groups of patients at risk for AF in a fast and simple manner. Both the MyDiagnostick and AliveCor devices allow recording of single lead ECGs that can be stored for later reviewing. Nevertheless, the recordings are prone to unusable recordings and incorrect automatic analysis. Therefore, automatic reporting is not reliable enough to trust upon without manual reading. Although MyDiagnostick had the highest sensitivity with automatic analysis, this was the result of a high proportion of AF patients having in fact unusable tracings, which

were interpreted by the device as “AF”. More data are required to evaluate whether this was a matter of chance or whether an AF population if truly at risk of more low-quality tracings.

The AliveCor results indicate that manual reading increases sensitivity, although it remained <50%. That is problematic in a population with a smaller a priori prevalence than in our testing group, but may be adequate in populations with a high risk like geriatric wards, diabetes clinics or neurology departments.

Other studies reported higher sensitivities of the devices. However, these studies screened much smaller numbers of patients, probably in more controlled conditions (4-7). Haberman et al. performed a comparably sized study with the AliveCor device in 381 patients showing a sensitivity of 72%, which is also lower than in most similar studies and more in line with the results of our study (8). Reducing the proportion of unreadable measurements and improving automatic analysis are needed.

We have no own data yet on the potential cost-effectiveness of the screening approach based on these devices. Prior research has shown that screening with handheld ECG monitors in a 75-year old population at risk for AF or in patients with a recent ischemic stroke, can be cost-effective by saving lives and improving quality of life (9, 10). If confirmed, this can definitely make these attractive tools for hospitals or general practitioners to quickly screen patients at risk and prevent unwanted outcomes.

References

1. Lloyd-Jones DM, Wang TJ, Leip EP, Larson MG, Levy D, Vasan RS, et al. Lifetime risk for development of atrial fibrillation: the Framingham Heart Study. Circulation. 2004;110(9):1042-6.
2. MacRae CA. Symptoms in atrial fibrillation: why keep score? Circulation Arrhythmia and electrophysiology. 2009;2(3):215-7.
3. Singh SN. Costs and clinical consequences of suboptimal atrial fibrillation management. ClinicoEconomics and outcomes research : CEOR. 2012;4:79-90.
4. Lau JK, LowresUsing a novel wireless system for monitoring N, Neubeck L, Brieger DB, Sy RW, Galloway CD, et al. iPhone ECG application for community screening to detect silent atrial fibrillation: a novel technology to prevent stroke. International journal of cardiology. 2013;165(1):193-4.
5. Tarakji KG, Wazni OM, Callahan T, Kanj M, Hakim AH, Wolski K, et al. Using a novel wireless system for monitoring patients after the atrial fibrillation ablation procedure: The iTransmit study. Heart rhythm : the official journal of the Heart Rhythm Society. 2015;12(3):554-9.
6. Tieleman RG, Plantinga Y, Rinkes D, Bartels GL, Posma JL, Cator R, et al. Validation and clinical use of a novel diagnostic device for screening of atrial fibrillation. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology. 2014;16(9):1291-5.
7. Vaes B, Stalpaert S, Tavernier K, Thaels B, Lapeire D, Mullens W, et al. The diagnostic accuracy of the MyDiagnostick to detect atrial fibrillation in primary care. BMC family practice. 2014;15:113.
8. Haberman ZC, Jahn RT, Bose R, Tun H, Shinbane JS, Doshi RN, et al. Wireless Smartphone ECG Enables Large Scale Screening in Diverse Populations. Journal of cardiovascular electrophysiology. 2015.
9. Levin LA, Husberg M, Sobocinski PD, Kull VF, Friberg L, Rosenqvist M, et al. A cost-effectiveness analysis of screening for silent atrial fibrillation after ischaemic stroke. Europace : European pacing, arrhythmias, and cardiac electrophysiology : journal of the working groups on cardiac pacing, arrhythmias, and cardiac cellular electrophysiology of the European Society of Cardiology. 2015;17(2):207-14.
10. Engdahl J, Andersson L, Mirskaya M, Rosenqvist M. Stepwise screening of atrial fibrillation in a 75-year-old population: implications for stroke prevention. Circulation. 2013;127(8):930-7.