

Screening For Atrial Fibrillation In The Community Using A Novel ECG Recorder

Irma Battipaglia, MD, Katrina Gilbert, BSc, Andrew J. Hogarth, MD, PhD, Muzahir H. Tayebjee, MD

The West Yorkshire Arrhythmia Service, Leeds Teaching Hospitals NHS, Leeds, West Yorkshire, UK.

Abstract

Aims: MyDiagnostick (MDK) is a novel portable ECG recorder. We conducted this study to evaluate its role in screening for atrial fibrillation (AF).

Methods: The device is a cylindrical rod with metallic electrodes at both ends recording electrocardiogram (ECG) when both electrodes are held. Individuals were requested to hold the device for approximately 15 s, the device was then connected to a laptop (with proprietary software downloaded) and analysed. Anonymised ECGs were stored for further analysis. A total of 855 ECGs were recorded and analysed offline by two arrhythmia specialists assessing ECG quality, in particular the level of noise. A noise score (NS) was devised regarding ECG quality.

Results: Seven individuals were found with unknown AF (0.8%). In general ECG quality was good and rhythm diagnosis was certain with total interobserver agreement.

Conclusion: The MDK provided a rapid and accurate rhythm analysis and has potential implications in preventing ischaemic cardio-embolic stroke.

Introduction

Atrial fibrillation (AF) is the most frequently occurring arrhythmia, with a prevalence ranging from 0.7% in the age group 55–59 years to 17.8% in those aged ≥ 85 years.¹ More than 30% of patients with AF are asymptomatic.²⁻³ These patients are at increased risk of heart failure and ischaemic thromboembolic stroke. In particular, the annual stroke risk in AF patients not treated with anticoagulants is 5%, which is two to seven times as high compared with non-AF patients.⁴ Furthermore, a stroke registry by Pisters et al. demonstrated that 45% of all AF-related strokes occurred in patients with asymptomatic and unknown AF.⁵ For this reason, screening for AF and initiation of anticoagulation in patients at risk is key to reducing the total number of embolic strokes as well as heart failure hospitalizations. For the diagnosis of AF an ECG showing the arrhythmia is mandatory, since pulse analysis is not accurate enough. Recently a new diagnostic device, the MyDiagnostick (MDK) (Applied Biomedical Systems BV, Maastricht, The Netherlands), has been validated enabling quick ECG recordings and easy detection of AF.⁶

Two recent studies⁶⁻⁷ have shown the accuracy of MDK in detecting AF through 60 s recordings using the automatic algorithm. The hypothesis of our study was that shorter rhythm strips (15 s) obtained through MDK and analysed by experienced personnel would allow quick and reliable mass screening for AF. This is the first use of MDK for AF screening via this method.

Material and Methods

The MDK is a cylindrical rod (length 26 cm, diameter 2 cm) with metallic electrodes at both ends that are held onto to record an ECG in lead I configuration (Figure 1). Using this novel device we screened a large population for AF during a single-day campaign for rhythm awareness in a busy shopping centre in Leeds (UK). Four MDK sticks and 2 laptops with proprietary software for the device were used. A total of 855 people were screened from 9 am to 7 pm. People of both sex and all ages were enrolled after signing a consent form. Individuals with known AF or pacemaker implanted were excluded. People enrolled were asked to hold MDK with both hands at the ends of the stick. Being a portable device people could have their rhythm checked with great simplicity, holding the device in front of them for only 15 s, until the first flashing light, corresponding to an ECG strip recorded, stopped flashing. In this way we obtained a large number of ECG lead I strips in an easy and quick manner. For people who could not keep their arms steady while standing, we asked them to have a sit and put their arms on their knees while holding the stick. Individuals were given access to their results immediately, in fact specialists or cardiologists, who were attending the AF screening campaign, plugged the device into the laptop, downloaded and

Key Words:

Atrial fibrillation, Screening, MyDiagnostick.

Disclosures:
None.

Corresponding Author:
MH Tayebjee,
West Yorkshire Arrhythmia Service,
Department of Cardiology, Leeds General Infirmary,
Leeds, LS1 3EX, UK.



Figure 1: MyDiagnostick

analysed the ECG at all times, for each patient they had enrolled, soon after obtaining the ECG recording. Anonymous ECGs were stored electronically. Two arrhythmia specialists analysed the ECGs offline to describe and classify quality of the ECG strips despite such a short recording. Noise on ECG was described according to a noise score (NS) where NS 1 was a completely clear ECG, NS 2 was an ECG with noise but where a good interpretation was possible, NS 3 was borderline ECG for noise (analysis based on RR regularity), NS 4 was a not interpretable ECG (Figure 2). This NS was validated through an evaluation of agreement between the operators about score of noise on ECGs. A sample of 50 ECGs were analysed by two arrhythmia specialists, independently, to validate interpretation.

There was 82% agreement with regards to noise classification. However there was 100% agreement on rhythm diagnosis.

Results

Using MDK 855 people were screened in only 10 hours in a busy suburban shopping centre. We found 7 individuals with unknown AF (0.8%). Globally, the MDK showed good quality lead I strips (Table 1). Twenty-eight percent of ECG strips were completely clear and only in 7% of cases the level of noise was so high that it was impossible to interpret the ECG. In 80% of the recordings we had a NS of 1 or 2.

Discussion

For the first time we used MDK to obtain 15 s ECG recordings to screen for AF in a large population. Our results proved that short rhythm strips obtained through MDK and analysed by experienced people provided good quality ECG data, with low NS. We found 7 individuals with unknown AF (0.8%). Previous studies have shown the accuracy of MDK in AF detection through 60 s ECG recordings and using an automatic algorithm (see above). In one of these studies general practitioners screened for AF in 191 patients in primary care⁶ using MDK. They compared the results with 12 lead ECG recordings and showed good diagnostic accuracy of the device (high sensitivity and specificity for atrial fibrillation (94% (95% CI 87-98) and 93% (95% CI 85-97) respectively). In another study MDK was used to screen a population of 676 patients attending their general practitioner for influenza vaccination: in 1.6% of patients AF had never been diagnosed before (all patients with CHA₂DS₂-VASc score >1).⁷ In our study we showed high rhythm diagnostic accuracy with shorter records time. This has implication as it can allow a large number of people to be screened quickly.

The Importance Of AF Detection: Available Technologies And Addressed Populations

In almost half of the patients with an AF-related stroke, AF has been previously undiagnosed.⁸ Two large randomized trials, CRYSTAL-AF⁹ and EMBRACE,¹⁰ have compared standard of

care monitoring in cryptogenic stroke patients to invasive and non-invasive monitoring strategies, respectively, documenting a higher detection of AF in the intervention group and subsequently a higher rate of anticoagulant treatment.

Clearly, as the method of detecting AF has been heterogeneous, the optimal approach is still debated.¹¹ Several strategies for detection of this arrhythmia in patients with a previous stroke include: in-hospital monitoring,¹² serial ECGs,¹³⁻¹⁴ ECG Holter monitoring,¹⁵ monitoring with the use of external event or loop recorders,¹⁶ long-term outpatient monitoring,¹⁷ and monitoring by means of implantable cardiac monitors.¹⁸

Other technologies to screen for AF on a large scale and assess people with silent AF exist. An automatic oscillometric sphygmomanometer incorporating an algorithm for detecting AF was tested in a study enrolling 405 unselected outpatients seen in two cardiology clinics. This device showed a sensitivity of 95% and a specificity of 86% for AF detection at each blood pressure measurement.¹⁹ A recent study, 'SEARCH-AF', screened 1000 pharmacy customers aged ≥65 years using an iPhone electrocardiogram, identifying 1.5 % people with undiagnosed atrial fibrillation.²⁰

Of course, dealing with screening addressed to large populations, cost-effectiveness of the devices used must be considered.

Recently, the CADTH (Canadian Agency for Drugs and Technologies in Health) conducted a systematic review (36 studies) about very topic issues: the clinical effectiveness and cost-effectiveness of outpatient cardiac monitoring devices for AF monitoring after an ischemic stroke/TIA. They showed that to ensure cost-effective use of cardiac monitoring, the incremental cost compared with standard practice must be relatively small, the diagnostic yield must be substantial, the patient cohort must be relatively healthy and the initiation of OAC in newly diagnosed patients must be high. To achieve a high diagnostic yield, the patient cohort must be one with a high expected prevalence of AF based on their medical history, type of stroke and stroke symptoms, their recent discharge after their stroke and few investigations for AF in hospital.²¹

Also in terms of costs MDK can be considered a convenient technology, likely to be offered to a larger population.

Limitations

The MDK has shown to be an easy and accurate technology to screen large populations for AF. However this technology has some limitations. First of all it provides a single lead ECG and in some patients with a very vertical cardiac axis, distinguishing a p wave can be difficult. Secondly, ECG interpretation can be affected by muscle tremor. Furthermore, the automatic algorithm could not identify



Figure 2: Examples of lead I ECG recordings for noise score

Table 1: Results of MDK use for AF screening

| | MDK ECG recordings | % |
|------|--------------------|-----|
| AF | 7/855 | 0.8 |
| NS 1 | 240/855 | 28 |
| NS 2 | 446/855 | 52 |
| NS 3 | 107/855 | 13 |
| NS 4 | 62/855 | 7 |

sinus arrhythmia or very frequent extra beats, erroneously classifying those rhythms as AF. However we were not affected by this limitation because we did not rely on the automatic algorithm. Moreover, as QRS regularity is used as a surrogate of sinus rhythm when it is not possible to clearly distinguish a p wave, in patients with AF with little RR interval variation, sinus rhythm could be misdiagnosed. Finally, although a 15 s ECG recording is shorter than the usual 60 s, it is longer than the 10 s conventional 12 lead ECG.

Conclusions

During a single-day screening for AF in a large population, MDK resulted to be an easy-to-use new technology, with very good diagnostic accuracy for AF detection. We obtained clear ECG recordings in only 15 s, with a low interobserver variability, supporting the reliability of this novel device. Using MDK general practitioners could regularly screen all patients >65 years, at higher risk for ischaemic thromboembolic stroke, more frequently. This easy to use and portable device has a potentially important role in population screening for AF.

References

- Heeringa Jan, van der KuipDeirdre A M, HofmanAlbert, KorsJan A, van HerpenGerard, StrickerBruno H Ch, StijnenTheo, LipGregory Y H, WittemanJacqueline C M. Prevalence, incidence and lifetime risk of atrial fibrillation: the Rotterdam study. *Eur. Heart J.* 2006;27 (8):949–53.
- Miyasaka Yoko, BarnesMarion E, GershBernard J, ChaStephen S, BaileyKent R, SewardJames B, IwasakaToshiji, TsangTeresa S M. Coronary ischemic events after first atrial fibrillation: risk and survival. *Am. J. Med.* 2007;120 (4):357–63.
- Wang Thomas J, LarsonMartin G, LevyDaniel, VasanRamachandran S, LeipEric P, WolfPhilip A, D'AgostinoRalph B, MurabitoJoanne M, KannelWilliam B, BenjaminEmelia J. Temporal relations of atrial fibrillation and congestive heart failure and their joint influence on mortality: the Framingham Heart Study. *Circulation.* 2003;107 (23):2920–5.
- Lip Gregory Y H, LarocheCécile, PopescuMircea Iaochim, RasmussenLars Hvilsted, Vitali-SerdozLaura, DanGheorghe-Andrei, KalarusZbigniew, CrijnsHarry J G M, OliveiraMario Martins, TavazziLuigi, MaggioniAldo P, BorianiGiuseppe. Improved outcomes with European Society of Cardiology guideline-adherent antithrombotic treatment in high-risk patients with atrial fibrillation: a report from the EORP-AF General Pilot Registry. *Europace.* 2015;17 (12):1777–86.
- Pisters Ron, van OostenbruggeRobert J, KnottnerusIris L H, de VosCees B, BoreasAnita, LodderJan, PrinsMartin H, CrijnsHarry J G M, TielemanRobert G. The likelihood of decreasing strokes in atrial fibrillation patients by strict application of guidelines. *Europace.* 2010;12 (6):779–84.
- Tieleman R G, PlantingaY, RinkesD, BartelsG L, PosmaJ L, CatorR, HofmanC, HoubenR P. Validation and clinical use of a novel diagnostic device for screening of atrial fibrillation. *Europace.* 2014;16 (9):1291–5.
- Vaes Bert, StalpaertSilke, TavernierKaren, ThaelBritt, LapeireDaphne, MullensWilfried, DegryseJan. The diagnostic accuracy of the MyDiagnostick to detect atrial fibrillation in primary care. *BMC Fam Pract.* 2014;15.
- Ben Freedman S, LowresNicole. Asymptomatic Atrial Fibrillation: The Case for

- Screening to Prevent Stroke. *JAMA.* 2015;314 (18):1911–2.
- Sanna Tommaso, DienerHans-Christoph, PassmanRod S, Di LazzaroVincenzo, BernsteinRichard A, MorilloCarlos A, RymerMarilyn Mollman, ThijsVincent, RogersTyson, BeckersFrank, LindborgKate, BrachmannJohannes. Cryptogenic stroke and underlying atrial fibrillation. *N. Engl. J. Med.* 2014;370 (26):2478–86.
 - Gladstone David J, SpringMelanie, DorianPaul, PanzovVal, ThorpeKevin E, HallJudith, VaidHaris, O'DonnellMartin, LaupacisAndreas, CôtéRobert, SharmaMukul, BlakelyJohn A, ShuaibAshfaq, HachinskiVladimir, CouttsShelagh B, SahlasDemetrios J, TealPhil, YipSamuel, SpenceJ David, BuckBrian, VerreaultSteve, CasaubonLeanne K, PennAndrew, SelchenDaniel, JinAlbert, HowseDavid, MehdiratManu, BoyleKarl, AvivRichard, KapralMoira K, MamdaniMuhammad. Atrial fibrillation in patients with cryptogenic stroke. *N. Engl. J. Med.* 2014;370 (26):2467–77.
 - Kishore Amit, VailAndy, MajidArshad, DawsonJesse, LeesKennedy R, TyrrellPippa J, SmithCraig J. Detection of atrial fibrillation after ischemic stroke or transient ischemic attack: a systematic review and meta-analysis. *Stroke.* 2014;45 (2):520–6.
 - Rizos Timolaos, GüntnerJanina, JenetzkyEkkehart, MarquardtLars, ReichardtChristine, BeckerRüdiger, ReinhardtRoland, HeppThomas, KirchoffPaulus, AleynichenkoElena, RinglebPeter, HackeWerner, VeltkampRoland. Continuous stroke unit electrocardiographic monitoring versus 24-hour Holter electrocardiography for detection of paroxysmal atrial fibrillation after stroke. *Stroke.* 2012;43 (10):2689–94.
 - Douen Andre G, PageauNicole, MedicSejla. Serial electrocardiographic assessments significantly improve detection of atrial fibrillation 2.6-fold in patients with acute stroke. *Stroke.* 2008;39 (2):480–2.
 - Kamel Hooman, LeesKennedy R, LydenPatrick D, TealPhilip A, ShuaibAshfaq, AliMyzoon, JohnstonS Claiborne. Delayed detection of atrial fibrillation after ischemic stroke. *J Stroke Cerebrovasc Dis.* 2009;18 (6):453–7.
 - Manina Giorgia, AgnelliGiancarlo, BecattiniCecilia, ZingariniGianluca, PaciaroniMaurizio. 96 hours ECG monitoring for patients with ischemic cryptogenic stroke or transient ischaemic attack. *Intern Emerg Med.* 2014;9 (1):65–7.
 - Higgins Peter, MacFarlanePeter W, DawsonJesse, McInnesGordon T, LanghornePeter, LeesKennedy R. Noninvasive cardiac event monitoring to detect atrial fibrillation after ischemic stroke: a randomized, controlled trial. *Stroke.* 2013;44 (9):2525–31.
 - Flint Alexander C, BankiNader M, RenXiushui, RaoVivek A, GoAlan S. Detection of paroxysmal atrial fibrillation by 30-day event monitoring in cryptogenic ischemic stroke: the Stroke and Monitoring for PAF in Real Time (SMART) Registry. *Stroke.* 2012;43 (10):2788–90.
 - Hindricks Gerhard, PokushalovEvgueny, UrbanLubos, TaborskyMilos, KuckKarl-Heinz, LebedevDmitry, RiegerGuido, PürerfellnerHelmut. Performance of a new leadless implantable cardiac monitor in detecting and quantifying atrial fibrillation: Results of the XPECT trial. *Circ Arrhythm Electrophysiol.* 2010;3 (2):141–7.
 - Wiesel Joseph, FitzigLorenzo, HerschmanYehuda, MessineoFrank C. Detection of atrial fibrillation using a modified microlife blood pressure monitor. *Am. J. Hypertens.* 2009;22 (8):848–52.
 - Lowres Nicole, KrassInes, NeubeckLis, RedfernJulie, McLachlanAndrew J, BennettAlexandra A, FreedmanS Ben. Atrial fibrillation screening in pharmacies using an iPhone ECG: a qualitative review of implementation. *Int J Clin Pharm.* 2015;37 (6):1111–20.
 - Gino De Angelis, KarenCimon, LaurenCipriano, KellyFarrah, SarahGarland, JohnCairns, AdrianBaranchuk. Monitoring for Atrial Fibrillation in Discharged Stroke and Transient Ischemic Attack Patients: A Clinical and Cost-Effectiveness Analysis and Review of Patient Preferences.No. 5.2a . CADTH Optimal Use Reports. 2016.