BMJ Open

Opportunistic screening of atrial fibrillation by automatic blood pressure measurement in the community

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To cite: Omboni S, Verberk WJ. Opportunistic screening of atrial fibrillation by automatic blood pressure measurement in the community. *BMJ Open* 2016;**6**:e010745. doi:10.1136/bmjopen-2015-010745

▸ Prepublication history for this paper is available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2015-010745).

Received 2 December 2015
Revised 17 February 2016
Accepted 24 February 2016

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ABSTRACT

Objective: Timely detection of atrial fibrillation (AF) may effectively prevent cardiovascular consequences. However, traditional diagnostic tools are either poorly reliable (pulse palpation) or not readily accessible (ECG) in general practice. We tested whether an automatic oscillometric blood pressure (BP) monitor embedded with an algorithm for AF detection might be effective for opportunistic screening of asymptomatic AF in the community.

Setting: A community-based screening campaign in an unselected population to verify the feasibility of AF screening with a Microlife WatchBP Office BP monitor with a patented AFIB algorithm. When possible AF was detected (≥2 of 3 BP measurements reporting AF), a doctor immediately performed a single-lead ECG in order to confirm or exclude the presence of the arrhythmia. The main demographic and clinical data were also collected.

Participants: 220 consecutive participants from an unselected sample of individuals in a small Italian community.

Primary and secondary outcome measures: Number of patients detected with AF and diagnosed risk factors for AF.

Results: In 12 of 220 participants, the device detected possible AF during the BP measurement: in 4 of them (1.8%), the arrhythmia was confirmed by the ECG. Patients with AF were more likely to be older (77.0±1.2 vs 57.2±15.2 years, p=0.010), obese (50.0 vs 14.4%, p=0.048) and to suffer from a cardiovascular disease (50.0 vs 10.6%, p=0.014) than patients without AF. Participants with a positive BP AF reading and non-AF arrhythmias (n=8) did not differ in their general characteristics from participants with a negative BP AF reading and were younger than patients with AF (mean age 56.4±14.8, p=0.027; 5 of 8 participants aged <65 years).

Conclusions: Opportunistic screening of AF by BP measurement is feasible to diagnose this arrhythmia in unaware participants, particularly in those older than 65 years, who are the target patient group recommended by current AF screening guidelines.

Strengths and limitations of this study

- A blood pressure (BP) monitor with an atrial fibrillation (AF) detecting algorithm was tested in an unselected population resident in the community: each case of AF found was immediately verified with an ECG device by an experienced cardiologist.
- Additional demographic and clinical data were collected to verify risk factors for AF.
- The screening tool unmasked four unaware cases of AF in the community, corresponding to 1.8% of the screened population: the main risk factor for AF was advanced age followed by a positive medical history of cardiovascular disease or obesity.
- Five of the eight participants with positive BP AF readings with non-AF arrhythmia were younger than 65 years of age. All of the true positive patients with AF were older than 65 years of age, indicating that the screening would have been more efficient if only those older than 65 years would have been considered.
- Screening of AF by BP measurement, confirmed by ECG monitoring, in participants older than 65 years where possible AF is detected is useful for diagnosing AF in unaware participants.

INTRODUCTION

Atrial fibrillation (AF) is the most common form of sustained arrhythmia in clinical practice.[1] Its prevalence in developed countries approximates 1.5–2% in the general population and varies with age and sex: it is present in <0.5% of participants younger than 50 years, 3–4% of those aged 60–70 years and 5–15% of those aged 80 years or older.[2 3] However, recent insights indicate that this is most likely an underestimation as improved screening with innovative tools leads to a significant increase in detection of patients with AF.[4 5] This arrhythmia is associated with a fivefold increased risk of stroke and threefold increased incidence of congestive heart failure, and high mortality.[2 6 7] Usually, AF progresses from short, rare episodes (paroxysmal) to longer and more stable forms (persistent, long-standing persistent and permanent): in 25–40% of patients, it remains silent for long before diagnosis.[8 9] Since AF is often asymptomatic, stroke is the

initial dramatic presentation that leads to its detection in up to 25% of participants.[10–12]

Early detection and treatment of patients with asymptomatic AF before the first complications occur is a recognised priority for the prevention of strokes by all major guidelines.[11 13–17] In particular, the European Society of Cardiology recommends pulse-taking in all participants aged ≥65 years, followed by an ECG in case of irregular beats, to allow timely detection of AF.[15] However, pulse palpation has a low specificity and is much less reliable than ECG.[18] Moreover, despite the fact that most guidelines recommend it, pulse palpation is often not performed by doctors or nurses in clinical practice.[19]

Since hypertension is the most common risk factor associated with AF,[20] using an automatic blood pressure (BP) monitor to detect AF would benefit the large number of hypertensive patients who monitor their BP at home, in the doctor's office or in community pharmacies.[20] Recently, an automatic BP device with an algorithm that can detect AF has been proposed for opportunistic screening of AF when BP is measured. Such a device showed a very high sensitivity and specificity when compared with ECG monitoring (on average (95% CI), 0.98 (0.95 to 1.00) and 0.92 (0.88 to 0.96), respectively) and was expected to detect twice as many patients with AF as pulse palpation.[21–27] Following results from studies including approximately 2300 participants, National Institute for Health and Care Excellence (NICE) has now recommended the use of such technology to screen AF in primary care clinics.[28]

The objective of the present investigation was to evaluate the ability of such a validated electronic oscillometric BP monitor embedded with an algorithm for AF detection, to identify new cases of AF in an unselected population of a small community located in northern Italy, during a hypertension screening campaign.

METHODS

Study design and participants

A community-based screening campaign focusing on BP measurement and the collection of basic information on main cardiovascular risk factors was performed. It was carried out in an unselected population of participants aged ≥18 years, living in two small villages (Besnate and Solbiate Arno) in the Northern area of Italy, close to the city of Varese, in the Lombardy region. Visits took place in mobile units located in the villages' main squares. A questionnaire was administered to all participants and BP was measured by non-healthcare operators, previously trained by a physician who coordinated and supervised all the on-field activities. Information about the participant's age, gender, height, body weight and family history for cardiovascular diseases was collected. Also recorded were their habits in relation to smoking, drinking and personal clinical history for cardiovascular diseases, presence and treatment of arterial hypertension, diabetes mellitus and dyslipidaemia. Following the interview, BP was measured in triplicate at 1 min interval time with the patient in the sitting position having rested for at least 5 min, according to current recommendations, by a validated, automatic electronic upper-arm sphygmomanometer (Microlife WatchBP Office AFIB, Microlife AG, Switzerland). The oscillometric BP monitor is embedded with an algorithm that can identify pulse irregularities compatible with AF during the automatic BP measurement: if at least two of three measurements detected AF, the 'AFIB' symbol flashed on the display of the device, indicating a possible case of AF. In such a case, the doctor immediately performed a single-lead ECG recording with a hand-held ECG recorder (Cardio-A Palm ECG, Shenzhen Creative Industry Co Ltd, China), in order to check the patient's heart rhythm. The ECG was performed by the patient with the assistance of the doctor: he or she was asked to grab the device with the right hand (palm and fingers) and to press the left side of the device with the centre of the left hand palm. The ECG detected by such palm measurement is equivalent to a single-lead ECG signal. A 30 s recording was performed and, if considered of poor quality by the assisting physician (a cardiologist adequately trained and experienced in ECG interpretation), it was repeated. ECG tracings were visually inspected immediately and checked by the doctor who either confirmed or excluded the presence of AF. This arrhythmia was defined by the absence of distinct 'p' waves, an absolutely irregular RR interval and an atrial cycle length <200 ms (300 bpm) on the recorded 30 s ECG.

Since this was a health awareness campaign, no approval by any Ethics Committee was required, according to the Italian regulations. However, prior to the examination, all participants were asked to give written informed consent for the collection and analysis of their clinical data, according to the Italian Personal Data Protection Code. All visits took place between June 2013 and June 2015. The design of the study did not envisage any patients' follow-up.

All data collected at the time of the examination were recorded on a paper sheet. The individuals' data were then entered in an electronic database to allow pooled analysis. Patients were considered having AF when detection by the BP monitor was confirmed by the single-lead ECG.

Statistical analysis

Data analysis was performed by grouping the patients according to the presence or absence of AF. Given the observational nature of the study, no sample size estimation was done. All participants provided valid data, and thus no methodology for replacing missing data was implemented. The main demographic and clinical data of the two subgroups were summarised by calculating the mean (±SD) in case of continuous variables and the absolute (n) and relative (%) frequencies in case of

categorical variables. Differences across groups were evaluated by the analysis of variance or χ^2 test, depending on the type of variable. A p value of <0.05 was considered significant. Data analysis was performed using IBM SPSS Statistics V.20 for Windows.

RESULTS

A total of 220 participants were enrolled: all of them provided the relevant information and were included in the analysis. In 12 participants, the device detected possible AF during the BP measurement: in 4 of them (1.8% of the whole population), this arrhythmia was confirmed by the single-lead ECG, whereas for the remaining 8 participants sinus arrhythmia (n=1) or supraventricular ectopic beats (n=7) were diagnosed. All participants diagnosed for AF were apparently unaware of this arrhythmia.

Demographic, anthropometric and clinical data of the participants, grouped by the absence or presence of AF or other arrhythmias, are summarised in table 1. In the whole sample, participants' mean age was 57.5 ±15.3 years, and males were slightly more prevalent than females (51.4 vs 48.6%). A personal history for cardiovascular disease was recorded in 11.4% of participants. Hypertension was previously diagnosed in 36.4%, whereas an additional 17.2% of participants had elevated BP values (≥140/90 mm Hg) during the automatic measurement. Diabetes and dyslipidaemia were reported by 7.7% and 27.3% of participants, respectively. Obesity was documented in 15.0% of the sample.

Patients with AF were older (77.0±1.2 vs 57.2±15.2 years, p=0.010), were more often obese (50.0 vs 14.4%, p=0.048) and were more likely to display a positive history for cardiovascular disease (50.0 vs 10.6%, p=0.014) than those without this arrhythmia. None of the patients diagnosed with AF had a previous stroke, whereas one had a positive history for myocardial infarction and heart failure, and one for myocardial infarction and peripheral artery disease. Patients with AF also had higher levels of systolic BP than those free from AF, but the difference was not statistically significant (151.5±6.1 vs 133.9±18.5 years, p=0.059).

When participants with a positive BP AF reading with non-AF arrhythmias were removed from the pool of participants with no AF, a statistically significant difference between non-AF patients and patients with confirmed AF was still observed for age (p=0.010) and concomitant cardiovascular diseases (0.017) (table 1). The demographic and clinical features of these participants were superimposable over those of participants without any arrhythmia detected during BP measurement, suggesting that participants with a positive BP AF reading with non-AF arrhythmias have a lower risk than those with a positive BP AF reading with AF. As a matter of fact, they were younger (p=0.027), with five of eight participants aged <65 years, less frequently obese (p=0.028) and less likely to have a cardiovascular disease (p=0.028) or high BP (p=0.028).

DISCUSSION

Our community survey documented a 1.8% prevalence of AF in an unselected sample of the population. Although based on a limited number of participants, our results add a new piece of information to existing evidence from larger surveys. The estimated prevalence of AF in epidemiological studies carried out in Europe in the general population in the past decade ranged between 1.9% and 2.9%.[29] In a recent nationwide, retrospective, observational Italian study involving 233 general practitioners and screening almost 300 000 patients representative of the population, the prevalence of AF was 2.0%.[30] Population-based studies report the prevalence of mostly known AF, whereas in our study all participants in whom AF was detected were unaware of their condition. This may be possibly related to a sampling bias in that people with known AF may have decided not to be screened because they were already aware of their condition and regularly followed by their physician. Thus, our approach may be useful to detect unaware cases of AF, and our results suggest that the true prevalence of AF in the community may be higher than that reported in population studies.

In our study, consistent with previous evidence, age, obesity, previous cardiovascular diseases and hypertension were important independent risk factors for AF.[31–36] We did not find any significant relationship between other established cardiovascular risk markers, such as smoking, diabetes or dyslipidaemia, and the development of new-onset AF, but this may be related to the small sample of patients with AF included in our survey.

Interestingly, our study showed that participants who were falsely diagnosed as having AF during BP measurement had demographic and clinical characteristics similar to those of participants with a negative BP AF reading. Notably, they were younger than 65 years, which implies a lower need for treatment than for those who are older. Therefore, our results seem to suggest that, when a community screening approach based on BP measurement with the AFIB technique is followed, it would be more practical, economical and logistically affordable to seek AF confirmation by ECG only in participants older than 65 years of age. This is related to both the higher AF incidence, which increases the chance of true positivity, and the higher need for treatment among those older than 65 years of age as compared with those who are younger.

Screening for AF in people over the age of 65 years leads to improved detection of AF as compared with routine clinical practice. However, in a large randomised trial, the effect on overall AF diagnosis rate for systematic and opportunistic screening was comparable (OR and 95% CI: 1.57 (1.08 to 2.26) and 1.58 (1.10 to 2.29), respectively). The number of participants needed to be screened in order to detect one additional case compared with routine practice was 172 participants (95% CI: 94 to 927) for systematic screening and 167 (92 to 806) for opportunistic screening.[37 38]

The present study reported that one of three participants who were positively diagnosed for AF with the BP

Table 1 Demographic and clinical characteristics of the participants enrolled in the study

	Patients with no AF (n=216)	Patients without AF or any other arrhythmia (n=208)	Patients with positive BP AF readings with non-AF arrhythmias (n=8)	p Value patients without AF or any other arrhythmia vs patients with positive BP AF readings with non-AF arrhythmias	Patients with AF (n=4)	p Value patients with AF vs patients with no AF	p Value patients with AF vs patients without AF or any other arrhythmia	p Value patients with AF vs patients with positive BP AF readings with non-AF arrhythmias	All patients (n=220)
Age (years)	57.2±15.2 (20–84)	57.2±15.3 (20–84)	56.4±14.8 (32–74)	0.880	77.0±1.2 (76–78)	0.010	0.010	0.027	57.5±15.3 (20–84)
Male/female (%)	111/105 (51.4)/(48.6)	106/102 (51.0)/(49.0)	5/3 (62.5)/(37.5)	0.522	2/2 (50.0)/ (50.0)	0.956	0.970	0.679	113/107 (51.4)/(48.6)
Height (cm)	166.7±9.3	166.6±9.3	169.5±8.2	0.383	170.3±8.2	0.447	0.434	0.895	166.8±9.3
Weight (kg)	71.6±15.0	71.7±15.1	67.1±11.0	0.397	80.8±17.5	0.226	0.235	0.140	71.7±15.0
BMI (kg/m^2)	25.6±4.3	25.7±4.3	23.3±3.1	0.122	27.7±4.5	0.337	0.357	0.096	25.7±4.3
Obesity (BMI≥30 kg/m^2)	31 (14.4)	31 (14.9)	0 (0.0)	0.238	2 (50.0)	0.048	0.055	0.028	3.3 (15.0)
Current smokers (%)	37 (17.1)	34 (16.3)	3 (37.5)	0.119	1 (25.0)	0.680	0.644	0.665	38 (17.3)
Alcohol drinkers (%)	94 (43.5)	91 (43.8)	3 (37.5)	0.726	1 (25.0)	0.459	0.454	0.665	95 (43.2)
Cardiovascular diseases (%)	23 (10.6)	23 (11.1)	0 (0.0)	0.320	2 (50.0)	0.014	0.017	0.028	25 (11.4)
Hypertension (%)	78 (36.1)	78 (37.5)	0 (0.0)	0.053	2 (50.0)	0.567	0.609	0.028	80 (36.4)
Diabetes (%)	17 (7.9)	17 (8.2)	0 (0.0)	0.400	0 (0.0)	0.559	0.551	–	17 (7.7)
Dyslipidaemia (%)	60 (27.8)	60 (28.8)	0 (0.0)	0.074	0 (0.0)	0.216	0.205	–	60 (27.3)
SBP (mm Hg)	133.9±18.5	133.8±18.4	136.4±22.2	0.697	151.5±6.1	0.059	0.058	0.182	134.2±18.5
DBP (mm Hg)	81.0±12.0	80.4±10.0	82.8±10.5	0.524	88.3±12.0	0.233	0.125	0.372	81.1±12.1
HR (bpm)	72.9±11.3	73.2±11.4	67.0±5.9	0.129	72.3±3.6	0.905	0.873	0.445	72.9±11.2

p Values refer to the statistical significance of the difference across the different study subgroups.
AF, atrial fibrillation; BMI, body mass index; BP, blood pressure; DBP, diastolic blood pressure; HR, heart rate; SBP, systolic blood pressure.

monitor actually had the disease as was confirmed with ECG. This result is worse than a previous study performed among 1000 primary care patients which found a positive predictive value of 44% with the Microlife WatchBP Home A device.[25] However, this study was performed among participants 75 years and older. If, for our study, only patients older than 65 years would have been considered, this would have led to a positive predictive value of 57% obtained with the BP monitor. In any case, the result of this study seems to be an improvement in comparison to pulse palpation as demonstrated in the SAFE trial where one in 5.7 ECG referrals led to a positive AF detection.[38] In addition, since pulse palpation generally has a lower sensitivity value (87%)[38] for detecting AF than the BP monitor (98%),[27] it is not unlikely that the latter has led to the detection of more patients with AF.

Although in our study the use of a BP monitor with AF detector was shown to be useful, it needed confirmation by a single-lead ECG. The latter approach, coupled with cardiologist interpretation, has been successfully tested for screening AF in primary care practices or community pharmacies, and it is presently considered the first-choice method for screening programmes for detection of undiagnosed AF.[39–41]

Study limitations and strength

Our study suffers from some limitations. First, the diagnosis of AF was confirmed by a cardiologist using a 1-lead ECG device, whereas the gold standard is a 12-lead ECG. However, as mentioned previously, recent studies have shown high accuracy and feasibility, as well as cost-effectiveness, of AF screening with single-lead ECG devices with the physician's interpretation.[24 39–41] We are of the opinion that readings from a hand-held single-lead ECG recorder may have sufficient quality to make an appropriate diagnosis, particularly because in our case 30 s tracings were repeated several times in case of doubt and correct interpretation was immediately warranted by an experienced cardiologist. Second, at the present research setting, an experienced cardiologist verified the presence of AF when it was detected during the BP measurement and transmitted the results to the subject's general practitioner in order to initiate the therapy. Although this may seem to limit the application of this approach for community screening, as a matter of fact the presence of a cardiologist is not required for general community screening. Similar to other public health screening events (eg, BP measurement), creating awareness and referring people to their general practitioners (perhaps with an ECG printout) after an AF positive BP measurement can also have a positive healthcare effect.

Third, given the opportunistic nature of the screening campaign, we could not systematically check the possible presence of AF in all participants, including those apparently negative during the BP measurement. However, since several studies have shown a good specificity (89–92%) and a high sensitivity (97–100%) of the methodology of ≥2 of 3 measurements,[27] we may assume that the chance that participants with true AF could be diagnosed is reasonably high and much higher than that of missing a false negative. Fourth, AF usually occurs more frequently in males than in females,[2 29] gender representing one of the most powerful risk factors for AF together with age and cardiovascular comorbidities. However, this was not the case for our survey, where the proportion of men and women reporting AF was exactly the same. We cannot exclude that the observational nature of our study, the relatively unselected sample of the population and the small number of patients with AF, might have prevented an accurate estimation of the relative importance of various factors contributing to the genesis of the arrhythmia. Moreover, we must acknowledge that the prevalence of AF in our population, though very close to that observed in a large nationwide Italian survey,[30] might not be representative of the phenomenon in the whole country and also because undetermined selection bias related to the willingness of being screened cannot be excluded. In addition, we cannot rule out possible regional differences in the prevalence of AF, and consequent representation bias, particularly because data have been collected in a population resident in a highly developed area of the country.

The strength of the presented approach for the screening of AF is that screening is automatically performed during consecutive automatic BP measurements without extra effort. This means that the current finding of AF cases comes on top of the detection of hypertension which was present in 53.6% of the screened population, with 36.4% of them aware and 17.2% (approximately one-third) unaware of their condition.

CONCLUSIONS

In conclusion, our small-scale observational study indicates that opportunistic screening of AF by BP measurement, with confirmation by single-lead ECG monitoring if AF is detected, is feasible to diagnose this arrhythmia in unaware participants. Since the majority of the participants with a positive BP AF reading and non-AF arrhythmias were younger than 65 years of age and all of the AF-positive participants were older than 65 years, this study confirms validity of recommending opportunistic screening of AF by BP measurements in patients older than 65 years.[27]

Whether such an approach might have a positive impact on clinical, social and economic outcomes needs to be demonstrated in large, well-designed prospective studies.

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Acknowledgements The authors are grateful for the logistic support provided by the following volunteers who helped collect the data during the screening campaign: Lara Brianese, Armando De Falco, Edoardo Ghirardi, Daniela Ghiringhelli, Antonio Miranda, Andrea Niglia, Federica Pagliarin, Massimo Protasoni, Alberto Riganti, Andrea Zerbi.

Contributors SO wrote the first draft of the manuscript. WJV contributed to the writing and finalisation of the manuscript.

Funding This work was supported by Biotechmed Ltd which sponsored the campaign by providing for free the blood pressure monitors used in the study.

Disclaimer The sponsor had no role in the design and conduct of the study; collection, management, analysis and interpretation of the data; preparation, review or approval of the manuscript; and decision to submit the manuscript for publication.

Competing interests SO received lecture fees from Colpharma Ltd, the Italian distributor of Microlife AG, and is a scientific consultant for Biotechmed Ltd, provider of telemedicine services. WJV is an employee of Microlife AG.

Patient consent Obtained.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

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