Screening of unknown atrial fibrillation through handheld device in the elderly

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Abstract

Objective To estimate the prevalence of unknown atrial fibrillation (AF) in the elderly population of the Veneto Region, Italy. Methods 1820 patients aged ≥ 65 years with no history of AF and not anticoagulated were enrolled in primary-care settings. They underwent an opportunistic electrocardiogram screening with a handheld device (MyDiagnostick) designed to specifically detect AF. The electrocardiogram recordings were reviewed by the researchers, who confirmed the presence of AF. Results The device detected an arrhythmia in 143 patients, which was confirmed as AF in 101/143 (70.6%), with an overall prevalence of AF of 5.5% (101/1820). Prevalence of unknown AF resulted in 3.6% in patients aged 65–74 years, and 7.5% in patients age 75 or older, and increased according to CHA2DS2-VASc score: 3.5% in patients with a score of 1 or 2, 5.6% in patients with a score of 3, 7.0% in patients with a score of 4, and 7.2% in patients with a score ≥ 5. The detection rate was significantly higher in patients with mild symptoms compared to asymptomatic counterparts (24.1% vs. 4.0%, P < 0.0001). At multivariate analysis, congestive heart failure and age ≥ 75 years-old were independent predictors for screen-detected AF. Conclusions An opportunistic screening with handheld device revealed an unexpectedly high prevalence of unknown AF in elderly patients with mild symptoms. Prevalence increased with age and CHA2DS2-VASc score.

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1 Introduction

The prevalence of atrial fibrillation (AF) increases with advancing age, and the burden of AF is predicted to grow rapidly with the ageing of the global population.[1,2] The AF more than quadruples the risk of ischemic stroke, being associated with almost 20% of such events; when caused by AF, cerebral impairment tends to be more severe.[3-6] In one-fourth to almost half of the patients admitted with an ischemic stroke in presence of AF, the arrhythmia was unknown.[7,8] These data may be explained by the fact that AF patients are frequently asymptomatic (i.e., silent AF), and, as consequence, the arrhythmia is underdiagnosed.[9] Early detection of AF together with adequate anticoagulation can help to prevent ischemic strokes.[10] Currently, the European Society of Cardiology recommends opportunistic screening for AF in patients older than 65 years by the pulse palpation or electrocardiogram (ECG) rhythm strip.[11] By contrast, the American guidelines do not suggest any recommendation.[11] Given the importance of identifying and treating AF, several studies have examined the use of both opportunistic (offered as part of a routine medical evaluation) and systematic screening (general or targeted screening of a high-risk population). In the Screening for Atrial Fibrillation in the Elderly (SAFE) study, both methods of screening performed similarly and identified more cases of AF than did the routine care.[12] Use of handheld devices may facilitate the opportunistic
screening for AF. The SEARCH-AF study reported the screen-detected AF in 1.5% of the 1000 unselected subjects age 65 or older who attended local pharmacies, by using AliveCor™ handheld ECG device.[13] Another recent study, which utilized the MyDiagnostick™ handheld bar device to screen for AF, detected AF in 1.1% of patients visiting the general practitioner for influenza vaccination.[14]

The aim of this study was to estimate the prevalence of unknown AF in in a large-scale, elderly population of the Veneto Region, Italy with no previous diagnosis of AF and anticoagulation therapy.

2 Methods

2.1 Study population

Patients aged ≥ 65 years old with no known AF and anticoagulation therapy were enrolled in five primary care settings in the Veneto Region, Italy and were invited to hold the MyDiagnostick bar device (Applied Biomedical Systems BV, Maastricht, The Netherlands), during a regular visit with their general practitioner (GP). Before handling the device, medical history was obtained, including stroke/transient ischemic attack, heart failure, hypertension, diabetes mellitus, myocardial infarction, vascular disease, and antiplatelet therapy utilization. The GPs received both a training about the MyDiagnostick device and screening procedures.

The MyDiagnostick is an easy-to-apply device that registers and automatically analyses a single-lead I rhythm strip after holding the device with both hands for one minute. It signals a red light in case of rhythm irregularity suspicious for AF, and a green light in case of absence of AF. The algorithm of the MyDiagnostick for AF is based on an irregular R-R interval, which must be present during > 75% of the one-min recording.

The rhythm strip can be visualized and analyzed by linking the device to a computer. A recent validation study showed that the sensitivity and the negative predictive value of green light signal was very good (both 100%), with a specificity of 97% in the subgroup of patients ≥ 65 years old.[15]

In case of red light alarm, a 12-lead ECG recording was suggested to confirm the presence of AF. The management of the newly detected cases of AF was at discretion of the GP. After the screening sessions, the MyDiagnostick rhythm registrations of all participants were analyzed independently by two cardiologists (E.B. and F.R.) for the presence of AF. Conflicting interpretations were judged by a third researcher (F.M.). The AF was defined as an irregular rhythm without visible P-waves. The study protocol was approved by the local Ethical Committee and all subjects gave written informed consent.

2.2 Statistical analysis

Categorical variables were expressed as n (%), whereas continuous variables were expressed as mean ± SD. Categorical variables were compared using the Pearson’s chi-squared or Fisher exact test as appropriate. Continuous data were compared using the unpaired t test. A P-value of < 0.05 was considered statistically significant. Binary logistic regression analysis was used to identify independent predictors of AF detection. Data were analyzed using STATA version 14.1 (STATA Corporation, College Station, TX, USA).

3 Results

From November 2017 to June 2019, a total of 1820 patients were screened. Demographic and clinical characteristics of the study population are shown in Table 1. Half of the participants were 65–74 years-old (915/1820, 50.3%), and the other 905 (49.7%) aged 75 or older, with a slight preponderance of women (53.4% vs. 46.6%). Mean CHA2DS2-VASc score was 3.29 ± 1.22. Mild symptoms were present in 137/1820 (7.5%) subjects: palpitations in 87, exertional dyspnea in 35, dizziness in 10, chest pain in 5.

Overall, MyDiagnostick showed a red signal in 143/1820 (7.9%) participants. Diagnosis of AF was confirmed in 101/143 (predictive positive value of 70.6%), which accounts for 5.5% of the screened population (Figure 1). In the remaining 42 red signal alarms, rhythm strips analysis...
showed premature atrial or ventricular complexes in 33 patients, sinus arrhythmia in two patients, artifacts in seven patients.

Detection rate of AF increased with age, ranging from 3.6% in the patients 65–74 years-old to 7.5% in those age 75 or older. Prevalence of unknown AF increased according to CHA2DS2-VASc score: 3.5% in 508 patients with a score of 1 or 2, 5.6% in 551 patients with a score of 3, 7.0% in 456 patients with a score of 4, and 7.2% in 305 patients with a score ≥ 5. The detection rate in patients with symptoms was significantly higher than in asymptomatic counterparts [33/137 (24.1%) vs. 68/1683 (4.0%), \( P < 0.0001 \)] (Figure 2).

Compared to subjects in sinus rhythm, those with AF were more frequently males, older, with more congestive heart failure and vascular disease, and with higher CHA2DS2-VASc score (Table 2). At linear regression univariate analysis, congestive heart failure, age > 75 years-old and vascular disease were associated with the AF detection, whereas female sex resulted protective (Table 3). At multivariate analysis, congestive heart failure (OR = 3.79, 95% CI: 1.86–7.71, \( P < 0.0001 \)) and age > 75 years-old (OR = 1.98, 95% CI: 1.28–3.07, \( P = 0.002 \)), but not vascular disease (OR = 1.29, 95% CI: 0.83–2.00, \( P = 0.257 \)) were independently associated with AF. By contrast, female sex showed an independent protective role (OR = 0.53, 95% CI: 0.35–0.82, \( P = 0.004 \)) for AF occurrence.

Table 2. Comparison of individuals with and without AF.

| Variable                          | Non-AF \((n = 1719)\) | AF \((n = 101)\) | \( P \)-value |
|-----------------------------------|------------------------|-----------------|--------------|
| Female                            | 934 (54.3%)            | 38 (37.6%)      | 0.001        |
| Age ≥ 75 yrs                      | 837 (48.7%)            | 68 (67.3%)      | < 0.0001     |
| Congestive heart failure          | 42 (2.4%)              | 11 (10.9%)      | < 0.0001     |
| Hypertension                      | 1183 (68.8%)           | 78 (77.2%)      | 0.075        |
| Diabetes                          | 424 (24.6%)            | 23 (22.7%)      | 0.667        |
| Stroke/Transient ischemic attack  | 85 (4.9%)              | 7 (6.9%)        | 0.376        |
| Vascular disease                  | 412 (23.9%)            | 35 (34.6%)      | 0.015        |
| CHA2DS2-VASc score                | 3.28 ± 1.22            | 3.57 ± 1.15     | 0.018        |

Data are presented as means ± SD or \( n \)% (AF: atrial fibrillation).

Table 3. Logistic regression analysis.

| Variable                          | Univariable analysis |          | Multivariable analysis |          |
|-----------------------------------|----------------------|----------|------------------------|----------|
|                                   | OR (95% CI)          | \( P \)-value | OR (95% CI)           | \( P \)-value |
| Congestive heart failure          | 4.88 (2.43–9.80)     | < 0.0001 | 3.79 (1.86–7.71)      | < 0.0001 |
| Hypertension                      | 1.54 (0.95–2.47)     | 0.077    |                        |          |
| Age ≥ 75 yrs                      | 2.17 (1.42–3.33)     | < 0.0001 | 1.98 (1.28–3.07)       | 0.002    |
| Diabetes                          | 0.90 (0.56–1.45)     | 0.67     |                        |          |
| Stroke/Transient ischemic attack  | 1.43 (0.64–3.18)     | 0.38     |                        |          |
| Vascular disease                  | 1.68 (1.10–2.57)     | 0.016    | 1.29 (0.83–2.00)       | 0.257    |
| Female                            | 0.51 (0.34–0.77)     | 0.001    | 0.53 (0.35–0.82)       | 0.004    |
4 Discussion

4.1 Main findings

In an elderly population of the Veneto Region with unknown AF, aged ≥ 65 years-old, an AF prevalence of 5.5% was found. The detection rate in patients with mild symptoms (24.1%) was significantly higher compared to asymptomatic subjects (4.0%). Patients with screen-detected AF had a mean CHA2DS2-VASc score of 3.29, meaning that the large majority would require anticoagulation.

4.2 Previous studies

The MyDiagnostick device, similar to other hand-held device (e.g., AliveCor Kardia Mobile, Zencor-ECG, Omron Heartscan HCG-801) used in several studies, had a large diffusion in the last few years and have shown a good capability in detection new AF-cases that may be benefit by a prompt initiation of anticoagulant therapy. Several clinical trials used these devices in various settings with different screening methods, from opportunistic single-time to systematic multiple-time screening; the new AF rate ranged from 0.7% to 9.5% (Table 4). In trials where multiple recordings were performed, the detection rate was higher. The prevalence described in our study is comparable to that found in a Canadian primary care setting by Godin, et al.[16] (6.2%) and in a Dutch geriatric setting by Zwart, et al.[17] (5.5%). By contrast, a recent meta-analysis showed that the average detection rate of new AF using single-lead ECG devices was 1.7% (95% CI: 1.4%–2.1%).[18] The difference is probably due to the inclusion of not completely asymptomatic patients in our study. Indeed, in our population almost one out of four patients with mild symptoms (palpitations, dizziness, chest pain, asthenia) had AF. It is more likely that, these patients developed in the past a form of persistent AF, that did not prompt them to the Emergency Room, because well tolerated. This finding strengthens the importance of taking an accurate clinical history in older patients with risk factors for AF.

Table 4. Previous studies on AF screening through handheld device.

| Study                        | N   | Device used          | Type of screening                          | Median age | New AF rate |
|------------------------------|-----|----------------------|--------------------------------------------|------------|-------------|
| Lowres, et al.[13]           | 1000| AliveCor Kardia      | Opportunistic single-time                  | 76         | 1.5%        |
| Svennberg, et al.[20]        | 7173| Zenicor              | Intermittent twice-daily two weeks screening | 75         | 3.0%        |
| Proietti, et al.[22]         | 65747| Omron                | Opportunistic single-time                  | 58         | 1.1%        |
| Kaassenbrood, et al.[14]     | 3269| MyDiagnostick        | Opportunistic single-time                  | 64.1       | 1.1%        |
| Engdahl, et al.[23]          | 848 | Zenicor              | Intermittent twice-daily two weeks screening | 75         | 4.7%        |
| Hendricks, et al.[24]        | 928 | Zenicor              | Intermittent twice-daily four weeks screening | 69.8       | 3.8%        |
| Hendricks, et al.[25]        | 95 | Zenicor              | Intermittent twice-daily four weeks screening | 54.1       | 9.5%        |
| Chan, et al.[29]             | 1013| AliveCor Kardia      | Opportunistic single-time                  | 68.4       | 0.5%        |
| Doliwa Sobocinski, et al.[33] | 249 | Zenicor              | Intermittent twice-daily one month screening | 57         | 6.0%        |
| Doliwa Sobocinski, et al.[34] | 606 | Zenicor              | Opportunistic single-time                  | 64         | 1.0%        |
| Hendrickx, et al.[29]        | 201 | Zenicor              | Intermittent twice-daily two weeks screening | 56         | 6.5%        |
| Claes, et al.[30]            | 10758| Omron                | Opportunistic single-time                  | 59         | 1.6%        |
| Samol, et al.[31]            | 132 | Heartscan HCG-801    | Opportunistic single-time                  | 64         | 5.3%        |
| Battipaglia, et al.[32]      | 855 | MyDiagnostick        | Opportunistic single-time                  | NR         | 0.8%        |
| Chan, et al.[33]             | 13122| AliveCor Kardia      | Opportunistic single-time                  | 64.7       | 0.8%        |
| Chan, et al.[34]             | 10735| AliveCor Kardia      | Opportunistic single-time                  | 78.6       | 0.7%        |
| Halcox, et al.[35]           | 501 | AliveCor Kardia      | Intermittent weekly over twelve months     | 72.6       | 3.8%        |
| Orchard, et al.[36]          | 1805| AliveCor Kardia      | Opportunistic single-time                  | 75.7       | 1.1%        |
| Godin, et al.[39]            | 7585| AliveCor Kardia      | Opportunistic single-time                  | NR         | 6.2%        |
| Zwart, et al.[37]            | 439 | MyDiagnostick        | Opportunistic multi-time screening         | 78         | 5.5%        |

AF: atrial fibrillation.

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the green signal of MyDiagnostick based on an immediate 12-lead ECG as reference test. Tieleman, et al. reported a sensitivity of 100% (95% CI: 93%–100%) and a specificity of 95.9% (95% CI: 91.3%–98.1%) in a cohort of 192 patients: in the false-positive cases, the 12-lead ECG rhythm analysis showed frequent premature atrial or ventricular complexes with irregular coupling interval, or sinus arrhythmia or atrial flutter with an irregular ventricular response. In our study, we found a predictive positive value of 70.6%, with false positive due mostly to premature atrial or ventricular complexes.

The AF screening studies have been implemented in a variety of settings, including pharmacies, influenza vaccination encounters, primary care clinics and remotely in individuals’ homes. In Italy, Primary Care clinics are ideally suited for AF screening. These facilities are able to select a priori high-risk patients that would benefit from early detection of AF. In this setting, handheld single-lead ECG may be preferable to screening with 12-lead ECGs because of cost/efficiency advantage. In our study, patients with red signal were referred to confirmatory testing by 12-lead ECG and subsequent evaluation by a cardiologist. Anticoagulation therapy was initiated in the patients only in case of presence of AF at the 12-lead ECG and not solely on the basis of the recording by the device, which is not currently approved for this use.

4.4 Predictors of AF detection

The age > 75 years-old and congestive heart failure were independent predictors of screen-detected AF. These results are consistent with results of other screening trials and the Framingham study in which congestive heart failure resulted one of the most important risk factors for AF with a 4.5- and 5.9-fold increased risk in men and women, respectively.

4.5 Limitations

Our study presents some limitations, due to the observational design and potential selection bias. First of all, the GPs may have screened patients with more comorbidities and with symptoms, explaining, perhaps, the higher observed prevalence. On the other hand, our observations are based only on the results of one-lead ECG screening and on the subsequent manual analysis of ECG strips; data about confirmatory 12-lead ECG are not reported in our analysis since the subsequent management of patients with positive screening depends to GPs. Finally, the registrations of the MyDiagnostick were interpreted by the cardiologists, who were unblinded to the light alarms.

4.6 Conclusions

An opportunistic screening with handheld device revealed an unexpectedly high prevalence of unknown AF in a sample of elderly patients dwelling in the Veneto Region, Italy. Prevalence increased with age and CHA2DS2-VASc score. Moreover, one out of four patients with mild symptoms had AF. The use of handheld and other low-cost devices should be revised in future AF guidelines.

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