Stepwise Screening of Atrial Fibrillation in a 75-Year Old Population:
Implications for Stroke Prevention

Running title: Engdahl et al.; Screening of Atrial Fibrillation

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[193] Clinical studies; [121] Primary prevention; [64] Primary and Secondary Stroke Prevention;
[70] Anticoagulants
Abstract:

**Background**—Atrial fibrillation (AF) is a frequent source of cardiac emboli in patients with ischemic stroke. AF may be asymptomatic and therefore undiagnosed. Screening for silent AF seems suitable in risk populations, little is however known on the yield and cost-effectiveness of such screening.

**Methods and Results**—All inhabitants in the municipality of Halmstad, Sweden age 75-76 were invited to a stepwise screening program for AF. As a first step, participants recorded a 12-lead ECG and reported their relevant medical history. Those with sinus rhythm on 12-lead ECG, no history of AF and at least two risk factors according to CHADS2 were invited to a 2 week recording period using a hand-held ECG asked to record 20 or 30 seconds twice daily and if palpitations occurred. 1330 inhabitants were invited of whom 848 (64%) participated. Previously undiagnosed silent AF was found in 10 (1%) among 848 individuals who recorded 12-lead ECG. Among 81 patients with known AF, 35 (43%) were not on OAC treatment. Among 403 persons with at least two risk factors for stroke, who completed the hand-held ECG event recording, 30 (7.4%) were diagnosed with paroxysmal AF. Thus 75/848 (9%) of the screened population were candidates for new OAC treatment, of those 57 actually started OAC treatment.

**Conclusions**—Stepwise risk factor-stratified AF screening in a 75-year old population yields a large share of candidates for OAC treatment on AF indication.

**Key words:** atrial fibrillation, screening, anticoagulation, stroke prevention
Introduction

Atrial fibrillation (AF) is the most common clinical arrhythmia with a prevalence steeply increasing with age. The prevalence of AF is often reported to be 6-8% in patients aged 75 years\textsuperscript{1,2}. AF is also a frequent source of cardiac emboli and a common etiology of ischemic stroke. The risk of ischemic stroke is increased in patients with AF\textsuperscript{3,4}. This risk can effectively be reduced by oral anticoagulation treatment (OAC)\textsuperscript{5}.

AF is sometimes symptomatic, but the correlation with symptoms is weak, thus AF can be present with a lack of symptoms\textsuperscript{6-8}. Often, an ischemic stroke is the first clinical sign of AF. Ischemic stroke associated with AF is known to be particularly severe and more frequently fatal than other ischemic strokes\textsuperscript{9,10}. AF is present in 25-30% of patients sustaining an acute ischemic stroke\textsuperscript{9,11,12}.

The aim of this study was to explore, by stepwise ECG screening, the prevalence of previously not diagnosed asymptomatic AF, suitable for OAC treatment in a population aged 75-76 years and to study to what extent they started OAC treatment.

Methods

Population

Halmstad is a municipality in the south-west part of Sweden with 92 000 inhabitants.

All individuals born in 1934 and 1935 were invited to participate by mail. If there was no response in 4-6 weeks, a reminder was sent. If there was no response or an active declination, no further contacts were made.

Index visit

At the index visit, all participants had to sign an informed consent and were asked to report their
medical history including presence of AF, antithrombotic treatment and thromboembolic risk factors according to the CHADS2 risk classification. If a patient reported a diagnosis of AF, this had to be confirmed by ECG recordings in the medical records.

The accuracy of the self-reported medical history was confirmed only in patients with AF. However, a random subset of 80 out of 727 patients with the questionnaire as the sole source of medical history was cross-checked against medical records in hospital, in primary care and against prescriptions. One of the 80 patients had erroneously omitted that he was treated for hypertension, in the remaining 79 cases, medical history was reported correctly.

The index visit also included recording of a 12-lead ECG. The first 100 12-lead ECGs were interpreted by a study nurse and a cardiologist; the following were interpreted by a study nurse who consulted a cardiologist on demand. The ECG interpretations were also checked by random samples viewed by a cardiologist. ECGs were interpreted only regarding rhythm and rate. Patients who had atrio-ventricular block grade II or III or a heart rate below 40/min or above 140/min were referred for further evaluation.

If the participant had a pacemaker or ICD implant, medical records were studied with regard to the presence of atrial high rate episodes (mode switch) caused by AF. If present and lasting more than 30 seconds, EGM recordings were studied.

If a 12-lead ECG revealed previously undiagnosed AF the patient was offered a work-up consisting of blood pressure measurement, blood samples of fasting plasma glucose and thyroid stimulating hormone at a study nurse visit and an echocardiogram at a cardiologist visit. Serum glucose was not analysed in previously known individuals with diabetes. Patients with a previously diagnosed AF without OAC treatment were offered this work-up if not previously performed. After this work-up, the patient was recommended anticoagulation treatment unless
there were contraindications. OAC treatment was managed within routine health care and
initiated in our OAC clinic.

**Extended ECG recording**

Participants with at least one additional risk factor beside their age (i.e. CHADS₂ –score ≥2), no
history of AF and sinus rhythm on the 12-lead ECG at the index visit, were asked to make
additional ECG recordings. These were made by a handheld unit, recording ECG via lead I by
application of the users’ thumbs (Zenicor Medical Systems AB, Sweden. www.zenicor.se). Via
an in-built mobile phone, the ECG is transmitted to a website. The participant was instructed to
record 20 or 30 seconds of ECG twice daily during two weeks. The duration of the recording was
decided by a study nurse who judged the participants ability to handle the ECG recorder. All
handheld ECGs were interpreted by a cardiac research nurse and a cardiologist. AF was defined
as 30 seconds or at least two separate recordings with at least 10 seconds each of irregular
rhythm without visible p-waves. The Zenicor ECG system has been validated in previous
reports¹⁴,¹⁵. Patients with AF were offered a work-up and offered treatment as described above.

In cases where interpretation of handheld ECGs was hampered by poor signal quality, the
participants were offered an additional 48-hour Holter recording. In participants who displayed
runs of suspected AF on event recording not qualifying according to the definition above,
another two-week period of event recording were offered according to the judgement of the
investigating cardiologist. A study flow chart is depicted in **figure 1**.

Medical records from inhabitants who did not participate in the screening process were
analysed with respect to AF diagnosis, presence of anticoagulation treatment and risk factors
according to CHADS₂. Both hospital and primary care records were studied.

**Ethics**
The study was approved by the regional health research ethics board at Lund University and conducted according to the declaration of Helsinki. Inhabitants who did not participate in the screening procedure were informed via letter and newspaper advertising that we intended to study their medical records in order to characterise this subgroup. They were given the possibility to withdraw their participation also in this part of the study.

**Statistical methods**

Continuous variables are reported as mean and range. Selected proportions are reported with a 95% confidence interval. For continuous variables, student t-test was used. For proportions, Fishers exact test was used. Two-tailed tests were applied. A p-value of < 0.05 was regarded as significant. In the tables, p-values of < 0.05 are listed.

**Results**

Of 1330 inhabitants invited to participation, 848 (64%) attended the index screening visit. The cardiac research nurse spent 30 minutes at index visit per patient including 12-lead ECG registration and 40 minutes at handheld ECG recording including ECG interpretation per patient. The cardiologist spent 5-10 minutes per patient for second opinion on handheld ECG recordings and 60 minutes per visit including echocardiography among patients with newly diagnosed AF.

Characteristics including prevalence of AF among attending and not attending inhabitants are described in Table. A previous diagnosis of AF was confirmed in 81/848 (9.6%, 95% CI 7.8-11.7). In the group who did not attend the screening, the prevalence of AF was 39/352 (11.1%, 95% CI 8.2-14.8) (n.s.). Non-attendants had a higher prevalence of diabetes, heart failure and previous stroke (Table).

Among the 81 patients who were previously diagnosed with AF in the screened group, 35
(43%) were not receiving anticoagulation treatment at study entry. The corresponding figure of the non-screened group was 56% (n.s.). Of these 35 patients with previously known AF, 17/35 (52%) started anticoagulation treatment.

**ECG recording – 12-lead ECG**

Previously unknown AF was diagnosed in 10 patients (1.2%, 95% CI 0.5-1.9) with a 12-lead ECG. The mean heart rate among these 10 patients was 83/min ranging from 64/min to 102/min. Their mean CHADS2–score was 1.8.

One participant of 848 was diagnosed with newly detected AV block III on 12-lead ECG and received a pacemaker implant.

**Extended handheld ECG recording**

Among the 848 participants there were 419 (49%) with no previous AF, sinus rhythm on 12-lead ECG at index visit and a CHADS2–score of at least 2. Of these participants 16 declined further participation or deceased, leaving 403 who underwent ECG event recording with the hand-held ECG. These 403 participants in total recorded 12 380 ECG tracings lasting 20 or 30 seconds. The mean number of recordings per patient was 31. 40 patients recorded less than 28 times but only six patients recorded less than 20 times. All patients with ambulatory ECG recordings were included in the final analysis. Ten of the 403 recordings had to be completed with a 48 hour-Holter recording due to difficulties in interpreting the hand-held ECG recording and most often with a suspicion of AF. Six of these ten recordings revealed paroxysmal AF. Due to short episodes of irregular heart rhythm on hand-held ECG raising suspicion of AF but not fulfilling our criteria, 4 participants undertook another period of two weeks ECG event recording. One of these four recordings revealed paroxysmal AF.

Thus, 30/403 (7.4%, 95% CI 5.2-10.4) were diagnosed with AF previously unknown. The
mean CHADS<sub>2</sub>-score of these 30 patients was 2.5 including 6 patients with previous stroke. A description of patient flow and ECG diagnostics is shown in figure 2.

Most patients with newly detected silent paroxysmal AF were diagnosed during the first days of their two-week ECG registration period and 22 of the 24 patient diagnosed with AF on handheld ECG had multiple recordings with AF runs. The duration of ECG recording necessary for detection of AF is shown in figure 3.

The yield of different methods to identify patients with an indication for OAC treatment and the proportion actually starting OAC treatment is shown in figure 4.

**Prevalence of AF**

At baseline, 81/848 (9.6%, 95% CI 7.6-11.6) of participants had a previously confirmed diagnosis of AF. Another 10 patients with AF diagnosed with 12-lead ECG and 30 were diagnosed on handheld or Holter ECG, thus the total prevalence in the screened population was 121/848 (14.3%, 95% CI 12.1-16.8). Among participants without a previously known AF diagnose, 40/767 (5.2%, 95% CI 3.8-7.7) were diagnosed with new AF. However, only 403 of these 767 participants were examined with extended handheld ECG recording.

**Work-up in patients with newly diagnosed and previously diagnosed AF**

Among the 40 patients with newly diagnosed AF, 38 underwent echocardiography. Left ventricular Ejection Fraction (LVEF) was slightly reduced (48%) in one patient and normal (> 50%) in the remaining patients. Mean LVEF was 60%. A majority (26/38) of these patients had enlarged left atria, defined as an area in apical four-chamber view of 24 cm<sup>2</sup> or larger. Mean left atrium area was 29 cm<sup>2</sup> None of these patients revealed significant valvular disease.

Among patients leaving blood samples for glucose, 7/41 (17%) displayed elevated fasting glucose levels, ranging from 6.4 to 7.4 mmol/l. No patients were diagnosed with previously
unknown abnormal level of thyroid stimulating hormone.

**Discussion**

In this study, stepwise risk factor-stratified AF screening in a 75-76 year old population identified a total prevalence of 14%, of which 62% had no OAC treatment. Among participants who were examined with extended handheld ECG recording, 30/403 were diagnosed with previously unknown paroxysmal AF. The amount of OAC treatment on AF indication more than doubled among the screened participants. Screening for AF might become an effective method to prevent stroke by initiation of OAC treatment.

**Patient demographics**

More than 60% of our community’s inhabitants aged 75 and 76 participated in the study. Since our invitation process merely included an invitation by letter in combination with the fact that the study was not accompanied by a media campaign, we are pleased with the participation. In an AF prevalence study among 75-year old persons by Tveit et al., 82% of the population were examined. However, the Norwegian study used telephone reminders and even home visits for ECG recording.

Interestingly, inhabitants not attending the AF screening programme had a higher burden of cardiovascular risk factors than those attending since they had higher mean CHADS2-score, affected by higher prevalence of diabetes, heart failure and stroke. There was no significant difference in baseline AF prevalence among participants and non-participants.

**ECG recording**

A single 12-lead ECG-recording in a 75-year old population revealed only 1% of newly diagnosed persistent or permanent AF, a figure also reported from Tveit et al. Fitzmaurice et
al.\textsuperscript{17} found 2\% of new AF using this method.

Intermittent ECG recording yielded 7\% new AF diagnoses in our study, comparable to
the yield seen in extended ECG recordings in patients with ischemic stroke\textsuperscript{18,19}. This finding not
only underlines the importance of age in AF prevalence, but also that most patients with AF have
paroxysmal arrhythmia implicating that a single ECG recording with sinus rhythm has a low
negative predictive value in excluding a diagnosis of AF. Hence, among the total of 121 patients
with AF in this study, only 35 (29\%) had persistent or permanent arrhythmia.

There are plenty of data on different methods of intermittent ECG-recording to detect
paroxysmal AF, most of it derives from studies on patients with cryptogenic ischemic stroke, on
patients who underwent AF ablation or from studies on antiarrhythmic drugs i.e. patient
populations with previously diagnosed AF or patients with generally high cardiovascular risk.
Studies on ambulant intermittent ECG recordings in the general population are scarce.
Continuous ECG monitoring, which would be regarded as “Gold standard” for ECG screening,
reveal previously undiagnosed paroxysmal AF in as much as 20-30\% new AF diagnoses in
populations with high cardiovascular risk\textsuperscript{20,21}. The evidence for the elevated risk of ischemic
stroke in connection to brief AF episodes is mainly derived from device studies\textsuperscript{21,22}. The AF
episodes detected in this study are of larger recording proportion than the episodes detected in
device studies. Since the stroke risk is similar in paroxysmal and in permanent or persistent AF\textsuperscript{23,24},
we hypothesize that patients diagnosed with silent paroxysmal AF in this study has a stroke
risk similar to patients with clinical evident AF. Further long-term evaluation of our patients will
reveal the clinical course of their AF disease.

Technical development has provided several ways of ambulatory ECG recording. Short-
term Holter recordings of 24-48 h was previously the standard method but is hampered by low
diagnostic yield, particularly when looking for paroxysmal AF. In addition, Holter monitoring most often generate a large share of ECG information without diagnostic interest. The efficacy of detecting silent paroxysmal AF by different ambulant ECG monitoring strategies has been outlined by Kirchhof and colleagues. Event recorders and loop recorders on the other hand are activated by the patient when symptoms occur. They can also detect and store asymptomatic arrhythmias, particularly when the recorder is continuously monitoring which in turn requires continuously attachment of the recorder to the patient which might affect patient compliance during longer recordings. Event recorders not continuously attached to the patient, like the ones used in this study, must be activated and attached by the patient. Event and loop recorders with intermittent and continuously ambulatory ECG recording have demonstrated a better diagnostic yield in comparison to Holter recordings when it comes to detecting paroxysmal AF in stroke patients. Rizos et al. reported that automated analyze of continuous ECG recorded in a stroke unit among patients with ischemic stroke or TIA almost tripled the diagnostic yield with regard to detection of silent paroxysmal AF in comparison to 24-hour Holter recording. High diagnostic yield is demonstrated by Mobile Cardiac Outpatient Telemetry (MCOT) and implantable loop recorders in preliminary reports. These two modalities are however expensive and implantable loop recorder requires minor surgery. The optimal ambulatory ECG method is yet to be defined; the choice of this study is directed by patient compliance and cost effectiveness. Further screening studies will reveal if there are more suitable ambulatory ECG modalities.

Work-up

Work-up in patients with newly detected AF yielded a low prevalence of pathological findings with the exception of 12% elevated fasting glucose levels. No patient had newly detected thyroid
disease or structural heart disease besides the more or less expected finding of enlarged left atria. Since we only measured blood pressure at one visit, no patient was diagnosed with hypertension in the work up.

**Initiation of OAC**

Patients with a newly diagnosed AF were more inclined to initiate OAC treatment than patients with a known diagnosis of AF. Some of the patients with known AF without OAC treatment had previously been treated with OAC in connection to a cardioversion, after which the OAC treatment was withheld if sinus rhythm seemingly persisted. Patients with known AF without symptoms seemed less declined to restart OAC treatment after its termination. The change in 2010 AF guidelines\(^{28}\) to recommend long-term OAC after cardioversion if there are thromboembolic risk factors present was not always applied in patients treated according to previous recommendations. Patients with newly diagnosed AF were on the other hand easily motivated to commence OAC treatment, despite that most of them were without symptoms.

Undertreatment with OAC in patients with AF and thromboembolic risk factors is very common. Among patients with known AF in our study, 43% were not receiving OAC at study entry. According to nationwide Swedish inpatient-statistics, half of patients with AF are never treated with OAC\(^{29}\). Similar figures are reported from Go et al.\(^{30}\) and Waldo et al.\(^{31}\). A markedly better guideline adherence with 85% of patients with AF and risk factors treated with OAC was reported from Tveit et al.\(^{16}\). Thus, the widespread OAC undertreatment in patients with AF contributes to an unnecessary high stroke incidence.

**AF prevalence**

The baseline prevalence of AF the 75-year old population in this study (9.6%) is higher than reported from most other studies. A prevalence of 6-8% is often reported in this age group\(^1,2,32\),
but higher prevalence figures are reported from Nordic countries \textsuperscript{16,33} and from the UK \textsuperscript{17}. After including the share of patients who underwent extended ECG recording, the prevalence of AF rose to 14\% in our study. Since only half of the screened population was examined with handheld ECG recorder, it is not controversial to speculate that such ECG recording in the entire screened population would have further increased the prevalence.

Screening programmes for AF, mainly in the primary care setting, have been reported from the UK \textsuperscript{17,34}. In a large randomised UK study\textsuperscript{17} in patients aged above 65, primary care centres were randomized to systematic or opportunistic screening which was compared to routine care. In patients invited to systematic screening, 53\% registered ECG and a new AF diagnosis was noted in 52/2357 (2\%). The UK study from Fitzmaurice et al. lack data on OAC treatment, both in patients with known AF and in patients newly diagnosed with AF. Data on OAC is of importance for calculations of cost effectiveness since the majority of costs for AF stem from stroke care. \textsuperscript{35} Furthermore, single recordings of 12-lead ECG, as used in the UK study, have severe limitations in detecting paroxysmal AF.

Whether screening for AF in patients with risk factors and initiation of OAC treatment will significantly reduce the incidence of stroke and be cost effective remains to be shown in further studies. However, based on the study from the UK\textsuperscript{17}, both American Heart Association and American Stroke Association Primary Prevention of Stroke Guidelines from 2011\textsuperscript{36} and the 2012 Focused Update of AF Guidelines from the European Society of Cardiology\textsuperscript{37} recommend opportunistic screening of AF in individuals at least 65 years of age in the primary care setting by pulse palpation followed by ECG recording in case of irregular pulse.

As proposed by our study, systematic screening with extended ECG recording in a 75-year-old population detect a considerable share of high-risk patients with untreated silent AF,
partly due to the higher prevalence of AF at age 75 years rather than 65 years and partly due to the extended ECG recording. The most favourable and cost-effective method for screening of AF is subject to further studies.

Limitations

This study has several limitations. Since our study was carried out in a single community, the results are probably not reproducible in all populations. The generalizability to individuals of other ages, races/ethnicity is uncertain.

The benefit from OAC treatment in patients with AF is so far studied among patients diagnosed on standard (i.e. 12-lead) ECG recordings and the benefit in patients diagnosed with shorter episodes of AF in single-lead ECG recordings remains less studied. However, the following data suggest that these short AF episodes carry a risk similar to permanent and persistent AF:

- An increased risk for stroke in device patients with short episodes of AF is reported\(^{21, 22}\).
- Short episodes of AF is a common finding in patients suffering from “cryptogenic” stroke\(^{38-41}\).

Since handheld ECG recording was intermittent, episodes of AF may have remained undiagnosed. Data on risk factors according to CHADS\(_2\) was self-reported in participants without a diagnosis of AF and collected from medical records in non-participants. Both methods of data collection have limitations.

A more comprehensive invitation procedure might have increased participation further. Persons might have been more willing to take part in an established and routinely performed screening programme rather than taking part in a clinical study.
For instance, 83% of invited 65-year old men accepted to participate in aortic abdominal aneurysm screening in the Uppland region in Sweden. 

**Implications**

Undiagnosed AF is often the aetiology behind “cryptogenic” stroke. It is a challenge of considerable proportions to diagnose patients with silent AF and offer them OAC treatment. Unfortunately, OAC is withheld among half of patients with already known AF and risk factors. This study implies than patients with previously diagnosed and not yet diagnosed AF can get better stroke prevention within a screening programme.

**Conclusions**

Stepwise risk factor-stratified AF screening in a 75-year old population yields a large share of candidates for OAC treatment on AF indication. Persons not participating had more cardiovascular risk factors than those participating. Patients with paroxysmal AF constitute the majority of the AF population. Repeated handheld ECG recording detected new AF in 7% of participants, and the total prevalence of AF was 14% in the population who participated in the screening programme. Most patients with newly diagnosed AF were willing to commence OAC treatment.

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**References:**


Table 1. Clinical Characteristics n, (%)

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<th>Non-participating n=352</th>
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<tr>
<td>Male gender</td>
<td>364 (43%)</td>
<td>149 (42%)</td>
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<tr>
<td>Previously diagnosed AF</td>
<td>81 (9%)</td>
<td>39 (11%)</td>
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<td>Heart Failure</td>
<td>30 (4%)</td>
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<td>Hypertension</td>
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<td>Diabetes Mellitus</td>
<td>91 (11%)</td>
<td>60 (17%)</td>
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<td>Previous Stroke/TIA</td>
<td>80 (9%)</td>
<td>49 (14%)</td>
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<td>CHADS₂—score (mean)*</td>
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</table>

* CHADS₂—score was calculated regardless of diagnosis of AF

Figure Legends:

**Figure 1.** Study design and flow of participants.

**Figure 2.** Study flow with regard to ECG diagnostics.
Figure 3. Duration of ECG registration needed to diagnose paroxysmal AF. Graph shows number of patients still undiagnosed as a function of ECG recording days. The six patients that remained undiagnosed after 14 days were later diagnosed by Holter recording.

Figure 4. Yield of different methods of identifying patients with an indication for OAC treatment and the proportion actually commencing OAC treatment. Black bars indicate the proportion commencing OAC treatment, they grey bar denotes the proportion of patients who did not.
Known AF in medical history n=81 (9.6%)

Individuals deceased or declining further participation n=16

New AF on 12-lead ECG n=10 (1.2%)

Individuals with sinus rhythm n=757

New AF on Event recorder ECG n=30 (7.4%)

Individuals with sinus rhythm and CHADS2-score = 1 n=338 (45%)

Individuals with sinus rhythm and CHADS2-score >1 n=419 (55%)

No AF on Handheld ECG n=373

Invitation n=1330

Participation Declined n=482

Index visit 12-lead ECG n=848 (64%)

Individuals with sinus rhythm n=757

Figure 2
Stepwise Screening of Atrial Fibrillation in a 75-Year Old Population: Implications for Stroke Prevention
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