ORIGINAL ARTICLE

Does atrial fibrillation still increase the risk of death? One-year follow-up results of the NOMED-AF study

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KEY WORDS

atrial fibrillation, oral anticoagulation, risk of death

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ABSTRACT

INTRODUCTION Although atrial fibrillation (AF) is a well-known risk factor for ischemic stroke and hospitalization, its effect on mortality has not been clearly established.

OBJECTIVES We aimed to assess whether AF is an independent risk factor for death. A secondary objective was to evaluate the role of oral anticoagulation in the prevention of stroke and death in 1-year follow-up of patients included in the NOMED-AF (Noninvasive Monitoring for Early Detection of Atrial Fibrillation) study.

PATIENTS AND METHODS The NOMED-AF study included 3014 patients. The participants underwent continuous long-term electrocardiographic monitoring using a wearable vest for up to 30 days. The present analysis involved 2795 patients who completed the 1-year follow-up. The median (interquartile range) follow-up time was 365 (365–365) days. AF was diagnosed in 617 participants.

RESULTS Independent risk factors for death in the patients who completed the 1-year follow-up were AF, age equal to or above 65 years, and chronic kidney disease. The individuals with diagnosed AF had an almost 2-fold higher risk of death (odds ratio [OR], 1.7; 95% CI, 1.18–2.44; P <0.001) and a 2.5-fold higher risk of stroke (OR, 2.53; 95% CI, 1.41–4.44; P <0.001), as compared with those without an AF diagnosis. The participants with AF who received oral anticoagulants had an almost 5-fold lower risk of death than those who were not on anticoagulation (2.9% vs 14.2%, respectively; P <0.001).

CONCLUSIONS AF is an independent risk factor for death and cardiovascular hospitalization. The risk of death and stroke in patients with AF is significantly higher than in the patients without this arrhythmia. Oral anticoagulation in patients with AF significantly reduces the rates of death and stroke; however, its use is suboptimal in this group of patients.

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INTRODUCTION Atrial fibrillation (AF) is the most common sustained arrhythmia worldwide, and is strongly associated with high mortality and morbidity from stroke, heart failure, and dementia, as well as with increased risk of hospitalization.[1-3] AF is also often associated with deterioration of exercise capacity and quality of life. The incidence of AF increases with age. It is currently estimated to affect approximately 19% of individuals aged 65 years or older, with higher incidence in men.[4] Recently, we have established that in patients aged 65 years or above there are some main risk factors for "silent" (asymptomatic) AF; for example, male sex, age, chronic kidney

WHAT'S NEW?

The results of our study clearly show that atrial fibrillation (AF) is an independent risk factor for death and cardiovascular hospitalization. Oral anticoagulation significantly reduces the risk of death in patients with de novo AF. Thromboembolism prophylaxis still needs improvement, especially in the patients who are at a very high risk for stroke.

disease (CKD), heart failure, diabetes, previous stroke, or obesity.[5]

Nevertheless, the impact of AF on mortality has not yet been conclusively confirmed, and previous studies may have underestimated this association.[6]

The current study aimed to report the 1-year follow-up results of the NOMED-AF (Noninvasive Monitoring for Early Detection of Atrial Fibrillation) study in order to assess the impact of AF on mortality, stroke, and cardiovascular hospitalization incidence. Secondly, we aimed to evaluate the impact of oral anticoagulation (OAC) use on mortality and stroke in patients aged 65 years or older during 1-year follow-up.

PATIENTS AND METHODS NOMED-AF was a cross-sectional study based on a nationwide sample of adults aged 65 years or older (n = 3014; mean [SD] age, 77.5 [7.9] years; 50.9% men). The study was approved by the local bioethical committee (26/2015) and registered at ClinicalTrials.gov (NCT03243474). A complete description of the study design and methodology has been published elsewhere.[7] Briefly, all patients included in the study were selected randomly. Similar numbers of men and women were selected in each age category in each municipality. A trained nurse interviewed the study participants at home using a standardized questionnaire, measured basic parameters, and collected a blood sample for laboratory assessment. Long-term electrocardiographic (ECG) monitoring was performed using a wearable ECG vest equipped with 2 recorders and a docking station that had been developed and manufactured specifically for this study.[8] The current substudy was a cohort study analyzing the health status, pharmacotherapy, and occurrence of adverse events at 1-year follow-up, based on the information obtained from the participants or their family members via a telephone call.

During the telephone conversation, the following information was collected: survival status, any hospitalization, stroke, myocardial infarction (MI), unscheduled ambulatory visit, and New York Heart Association functional class. Additionally, in patients with AF, we gathered data regarding symptoms on the European Heart Rhythm Association scale, type of AF, necessity to perform cardioversion or ablation, hospitalization for AF, and type of OAC. The patients with diagnosed AF were contacted by a cardiologist, whereas in those without AF, the telephone call was performed by a trained paramedic.

The study complies with the Declaration of Helsinki. The locally appointed ethics committee approved the research protocol, and informed consent was obtained from all participants.

Statistical analysis All statistical analyses were performed using the SPSS package v.19 (IBM Corp., Armonk, New York, United States). The risk factor analysis was conducted on a sample weighted to the Polish population, considering the complex sampling scheme taking into account age, sex, and place of residence (voivodeships, districts, and municipalities). Sample weights were computed taking into account selection probability and poststratification weights. The distribution of risk factors with 95% CI was obtained for the follow-up group. Risk factors associated with death and hospitalization were first identified using a univariable logistic regression; subsequently, a multivariable model was built. Odds ratios (ORs) were calculated, along with their significance and 95% CIs. The impact of AF on death and stroke was assessed by the Pearson χ^2 test, and the impact of OAC use was evaluated using the Fisher exact test. The Kaplan–Meier curves were used to illustrate the probability of survival and freedom from stroke. Data on the time of a given event (death or stroke) were obtained during the telephone interview.

RESULTS Among the 3014 participants of the NOMED-AF study, a total of 2795 patients (92.7%) completed the 1-year follow-up. The median (interquartile range) follow-up duration was 365 (365–365) days, and AF was diagnosed in 617 individuals (22.1%). Clinical characteristics of the patients are presented in TABLE 1.

Among the patients with AF, 204 (33.1%) did not receive OAC, 168 (27.2%) received vitamin K antagonists (VKAs), and 245 (39.7%) were treated with non-VKA oral anticoagulants (NOACs).

During follow-up, 4 risk factors for cardiovascular hospitalization were identified: AF (OR, 2.73; 95% CI, 1.61–4.61), MI (OR, 1.54; 95% CI, 1.06–2.23), peripheral artery disease (OR, 1.82; 95% CI, 1.25–2.63), and diabetes mellitus (OR, 1.4; 95% CI, 1.02–1.92) (TABLE 2). The main risk factors for all-cause hospitalization were lower extremity arterial disease (OR, 1.44; 95% CI, 1.12–1.86) and CKD (OR, 1.34; 95% CI, 1.09–1.63) (TABLE 2). The independent risk factors for death were AF (OR, 2.42; 95% CI, 1.4–4.18), age greater than or equal to 65 years (OR, 2.85; 95% CI, 1.65–4.92), and CKD (OR, 2.55; 95% CI, 1.7–3.84) (TABLE 2). OAC was determined as a protective factor against death (OR, 0.29; 95% CI, 0.14–0.58) (TABLE 2). A detailed description of the independent risk factors for hospitalization and death is presented in TABLE 2.

Mortality and stroke Among the patients with diagnosed AF, 41 individuals (6.7%) died, and in the group without AF there were 85 deaths

TABLE 1 Clinical characteristics of the study population

Parameter		Value
Age group	65–69 y	539 (19.3)
	70–74 y	584 (20.9)
	75–79 y	552 (19.7)
	80–84 y	487 (17.4)
	85–89 y	408 (14.6)
	≥90 y	225 (8.1)
Women		1373 (49.1)
Body mass index, kg/m^2, mean (SD)		27.1 (4.788)
Hypertension		2261 (80.9)
Heart failure		623 (22.3)
NYHA class	I	1657 (59.3)
	II	667 (23.9)
	III	283 (10.1)
	IV	19 (0.6)
Chronic kidney disease		922 (33)
Glomerular filtration rate	<15 ml/min/1.73 m^2	5 (0.2)
	15–29 ml/min/1.73 m^2	41 (1.7)
	30–59 ml/min/1.73 m^2	696 (28.7)
	≥60 ml/min/1.73 m^2	1684 (69.4)
Diabetes mellitus		804 (28.8)
Stroke	Any type	256 (9.2)
	Ischemic cerebral	192 (6.9)
	Intracranial hemorrhage	13 (0.5)
	Unclassified	51 (1.8)
Transient ischemic attack		336 (12)
Coronary heart disease		622 (22.3)
Previous myocardial infacrtion		408 (14.6)

Data are presented as number (percentage) of patients unless indicated otherwise.

Abbreviations: NYHA, New York Heart Association

(3.9%). The patients with diagnosed AF had an almost 2-fold higher risk of death (OR, 1.7; 95% CI, 1.18–2.44; P <0.001), as compared with the non-AF group. The Kaplan–Meier curves of the survival probability in the groups with and without AF are shown in FIGURE 1. Stroke occurred in 32 patients without AF (1.5%) and in 23 individuals with AF (3.8%). The participants with diagnosed AF had a 2.5-fold higher risk of stroke (OR, 2.53; 95% CI, 1.41–4.44; P <0.001) (FIGURE 2).

In general, MI during the follow-up period was diagnosed in 1.1% (n = 30) and stroke in 2% (n = 55) of the patients. In the subgroup of patients with AF who received OAC, stroke occurred in 13 individuals (3.1%), and among the AF patients not treated with OAC, there were 10 cases of stroke (5.5%) (TABLE 3, FIGURE 3). The patients with AF who did not receive OAC had a 1.7-fold higher risk of stroke than the OAC users (OR, 1.77; P = 0.02). The patients with AF who received OAC had an almost 5-fold lower risk of death than those who did not receive OAC (2.9% vs 14.2%, respectively; P <0.001) (TABLE 3; Supplementary material, *Figure S1*). The occurrence of stroke and death in relation to OAC use is presented in detail in TABLE 3.

De novo atrial fibrillation In individuals with de novo AF (n = 140), the risk of stroke during the follow-up was significantly higher than in the patients without AF (10.8% vs 0.8%; P <0.001 for women, and 8.4% vs 2.3%; P = 0.006 for men; respectively) (TABLE 4). The risk of death during follow-up was significantly higher among women with de novo AF than in those without this arrhythmia (17.1% vs 3.3%; P = 0.001), but no significant differences were found between men with or without de novo AF (7.1% vs 4.6%; P = 0.2) (TABLE 4).

The patients with de novo AF who were treated with OAC had a significantly lower incidence of death (0% vs 19%; P = 0.001) than those who did not receive OAC (TABLE 5). OAC use did not significantly influence the stroke incidence (P = 0.75) (TABLE 5).

DISCUSSION The most important findings of the current study are that AF is an independent

TABLE 2 Independent risk factors for cardiovascular hospitalization, all-cause hospitalization, and death

Parameter	β	SE	Wald	*P* value	OR	95% CI
Independent risk factors for cardiovascular hospitalization						
Any atrial fibrillation	1	0.27	14.06	<0.001	2.73	1.61–4.61
Male sex	0.26	0.16	2.64	0.1	1.3	0.95–1.77
Age ≥65 y	0.03	0.18	0.03	0.87	1.03	0.73–1.45
Myocardial infarction	0.43	0.19	5.23	0.02	1.54	1.06–2.23
Coronary artery disease	0.27	0.17	2.47	0.12	1.31	0.94–1.84
Pulmonary diseases	–0.07	0.23	0.08	0.78	0.94	0.60–1.47
Thromboembolism	0.24	0.24	0.95	0.33	1.27	0.79–2.05
Lower extremity arterial disease	0.6	0.19	9.98	<0.001	1.82	1.25–2.63
Ischemic stroke/transient ischemic attack	–0.02	0.21	0.01	0.94	0.98	0.65–1.5
Diabetes mellitus	0.34	0.16	4.41	0.04	1.4	1.02–1.92
Chronic kidney disease	0.16	0.17	0.95	0.33	1.18	0.85–1.63
Oral anticoagulation	0.37	0.27	1.79	0.18	1.44	0.84–2.47
Independent risk factors for all-cause hospitalization						
Any atrial fibrillation	0.3	0.19	2.49	0.11	1.35	0.93–1.97
Male sex	0.04	0.09	0.15	0.7	1.04	0.86–1.25
Age ≥65 y	0.06	0.1	0.29	0.59	1.06	0.87–1.29
Myocardial infarction	–0.04	0.13	0.09	0.77	0.96	0.74–1.24
Coronary artery disease	0.21	0.11	3.43	0.06	1.23	0.99–1.53
Pulmonary diseases	0.21	0.14	2.44	0.12	1.24	0.95–1.62
Thromboembolism	0.2	0.16	1.58	0.21	1.23	0.89–1.69
Lower extremity arterial disease	0.36	0.13	7.95	<0.001	1.44	1.12–1.86
Ischemic stroke/transient ischemic attack	0.11	0.14	0.63	0.43	1.12	0.85–1.46
Diabetes mellitus	0.18	0.1	3.16	0.08	1.2	0.98–1.46
Chronic kidney disease	0.29	0.1	8.1	<0.001	1.34	1.09–1.63
Oral anticoagulation	0.17	0.21	0.64	0.42	1.18	0.78–1.78
Independent risk factors for death						
Any atrial fibrillation	0.88	0.28	9.92	<0.001	2.42	1.4–4.18
Male sex	0.14	0.2	0.5	0.48	1.15	0.78–1.69
Age ≥65 y	1.05	0.28	14.06	<0.001	2.85	1.65–4.92
Myocardial infarction	–0.22	0.28	0.64	0.42	0.8	0.47–1.38
Coronary artery disease	0.16	0.23	0.48	0.49	1.17	0.75–1.83
Pulmonary diseases	0.32	0.27	1.41	0.23	1.37	0.81–2.32
Thromboembolism	–0.72	0.44	2.71	0.1	0.48	0.2–1.15
Lower extremity arterial disease	0.29	0.26	1.27	0.26	1.34	0.81–2.21
Ischemic stroke/transient ischemic attack	0.47	0.25	3.45	0.06	1.59	0.97–2.61
Diabetes mellitus	–0.07	0.21	0.11	0.74	0.93	0.61–1.42
Chronic kidney disease	0.94	0.21	20.24	<0.001	2.55	1.70–3.84
Oral anticoagulation	–1.24	0.36	12.14	<0.001	0.29	0.14–0.58

Risk factors associated with cardiovascular hospitalization, all-cause hospitalization, and death were identified using a multivariable logistic regression analysis. *P* values below 0.05 were considered significant.

Abbreviations: OR, odds ratio

risk factor for death or cardiovascular hospitalization, and that OAC use is associated with reduced incidence of all-cause mortality and stroke. A Swedish registry of 272 186 patients with AF aged up to 85 years also showed that AF was an independent risk factor for all-cause death, and that the risk was additionally increased by comorbidities, such as CKD or chronic obstructive pulmonary disease.[9]

Our results clearly show that in the patients with AF aged 65 years or older, the risk of death and stroke increased almost 2-fold. Although these patients are supposed to receive OACs, this treatment is initiated in only two-thirds of them. The current study, performed in a real-life setting, showed that 33% of the patients do not take appropriate medication to prevent thromboembolism. This finding may be related

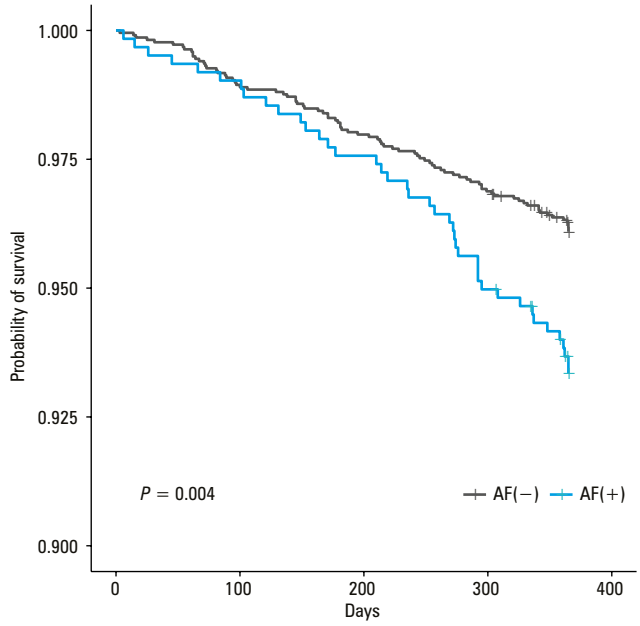

FIGURE 1 Kaplan–Meier curve of the probability of survival in the groups without and with atrial fibrillation (AF)

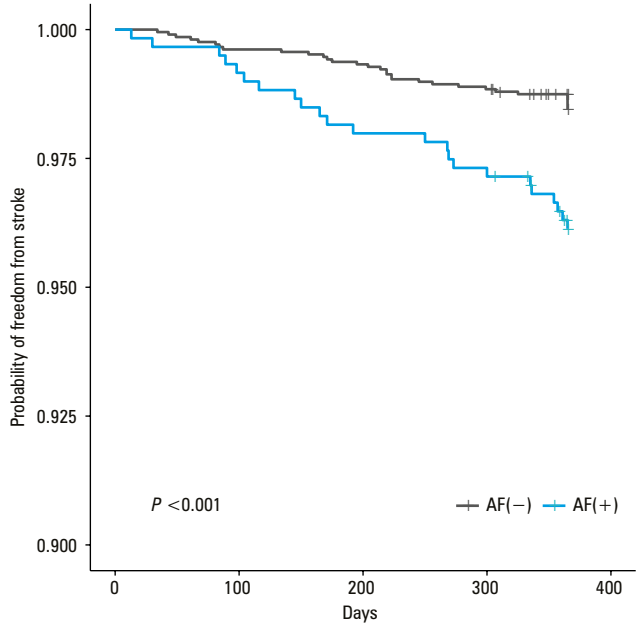

FIGURE 2 Kaplan–Meier curve of the probability of freedom from stroke in the groups without and with atrial fibrillation (AF)

to the fear of side effects (eg, bleeding) associated with the use of several medications, possibly affecting elderly people with many comorbidities, as well as to taking different medications that might impact the pharmacokinetics of OACs. These results are similar to those obtained in the EORP-AF (Eurobservational Research Programme in Atrial Fibrillation) study, which showed that OACs alone (VKAs or NOACs) were used by 75% of patients with AF, whereas 12% used them in combination with antiplatelet drugs. The remaining patients either did not receive anticoagulant treatment (6%) or were treated only with antiplatelet drugs (7%).[10]

The results of the current study also confirm the benefits of OAC use in patients with AF, showing that this treatment allowed for a significant reduction in the incidence of stroke and death, as compared with the patients who did not receive such medications in long-term follow-up. Among the individuals without thromboembolic prophylaxis, 5.5% had stroke, and 14% died. Our results strengthen the previous evidence, highlighting the importance of OAC use and confirming its association with stroke and mortality rate reduction in AF patients.[11]

Interestingly, in the group of patients with de novo AF, OAC contributed mainly to the reduction of all-cause mortality, and had no effect on the occurrence of stroke. This may be due to the fact that AF itself has a procoagulant effect; hence, it leads to a greater number of serious

TABLE 3 Occurrence of stroke and death in relation to oral anticoagulation use

Group	Event		Patients	*P* value
	No	Yes		
Stroke				
AF (–)	2042 (98.5)	32 (1.5)	2074	0.02
AF (+) on OAC	400 (96.9)	13 (3.1)	413	
AF (+) not on OAC	173 (94.5)	10 (5.5)	183	
Whole population	2615 (97.9)	55 (2.1)	2670	
Death				
AF (–)	2093 (96.1)	85 (3.9)	2178	<0.001
AF (+) with OAC	401 (97.1)	12 (2.9)	413	
AF (+) without OAC	175 (85.8)	29 (14.2)	204	
Whole population	2669 (95.5)	126 (4.5)	2795	

Data are presented as number (percentage) of patients.

The χ^2 test was used for statistical analysis. *P* values below 0.05 were considered significant.

Abbreviations: AF, atrial fibrillation; OAC, oral anticoagulation

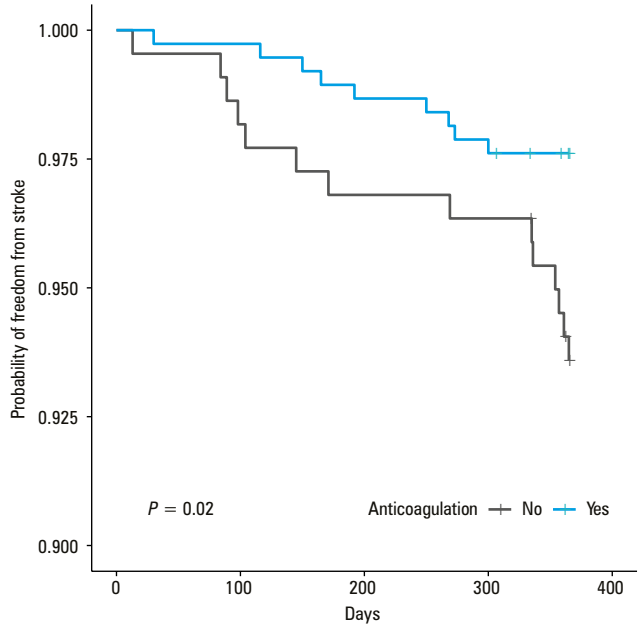

FIGURE 3 Kaplan–Meier curve of the probability of freedom from stroke in the groups without and with oral anticoagulation

cardiovascular events, and anticoagulant treatment contributes to their reduction and indirectly influences the mortality rate in this group of patients.[12,13] In addition, patients with AF require frequent consultations with a physician, which allows for carrying out diagnostics and therapy in such a way so as to focus on the most pressing clinical problems, and to adjust the treatment to the patient's current clinical status.

Based on the 1-year follow-up results of the EORP-AF study, OAC use (NOAC and VKA) is associated with a lower risk of all main adverse outcomes, and a lower risk for cardiovascular and all-cause death.[10] The follow-up data from many worldwide registries also showed that OAC was closely associated with a lower risk for stroke and death.[14,15] Thus, our data support the concept that the use of OAC allows for reducing the risk of death, independently of the known predictors of mortality in AF patients.

Limitations The main limitation of the study is the lack of complete follow-up data, which may have resulted in an underestimation of the stroke prevalence (information on stroke occurrence was not available for 125 patients [4.5%]). Although OAC was recommended to the patients with de novo AF, we have no data on whether they received or continued this therapy. We advised them to inform their physician about the diagnosis to start the recommended anticoagulant treatment.

Conclusions AF is an independent risk factor for death and cardiovascular hospitalization. The risk

TABLE 4 Incidence of stroke and death in women and men with de novo atrial fibrillation

Event		De novo AF, n (%)		*P* value	OR	95% CI
		Yes	No			
Stroke						
Women	Yes	4 (10.8)	9 (0.8)	0.001	14.46	4.24–49.37
	No	33 (89.2)	1074 (99.2)			
Men	Yes	7 (8.4)	23 (2.3)	0.006	3.88	1.61–9.32
	No	76 (91.6)	968 (97.7)			
Death						
Women	Yes	7 (17.1)	37 (3.3)	0.001	6.07	2.53–14.59
	No	34 (82.9)	1091 (96.7)			
Men	Yes	6 (7.1)	48 (4.6)	0.2	1.61	0.67–3.87
	No	78 (92.9)	1002 (95.4)			

The Fisher exact test was used for statistical analysis. *P* values below 0.05 were considered significant.

Abbreviations: see **TABLES 2** and **3**

TABLE 5 Incidence of stroke and death depending on oral anticoagulation use in patients with de novo atrial fibrillation

Event	De novo AF			*P* value
	On OAC	Not on OAC	Whole population	
Stroke				
No, n (%)	50 (89.3)	59 (92.2)	109 (90.8)	0.75
Yes, n (%)	6 (10.7)	5 (7.8)	11 (9.2)	
Total, n (%)	56 (100)	64 (100)	120 (100)	
Death				
No, n (%)	56 (100)	56 (81.2)	112 (89.6)	0.001
Yes, n (%)	0	13 (18.8)	13 (10.4)	
Total, n (%)	56 (100)	69 (100)	125 (100)	

The Fisher exact test was used for statistical analysis. *P* values below 0.05 were considered significant.

Abbreviations: see **TABLE 3**

of death and stroke in patients with AF is significantly higher than in patients without this arrhythmia. OAC use in individuals with AF significantly reduces the number of deaths and strokes. Even though access to anticoagulation is wide, one-third of patients with AF still do not receive proper thromboembolism prophylaxis.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/paim.

ARTICLE INFORMATION

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CONTRIBUTION STATEMENT KM conceived the concept of the study. KM, BS, ZK, TZ, TG, GO, and JK contributed to the design of the research. All authors were involved in data collection. KM, ZK, and AS analyzed the data. ZK coordinated funding for the project. All authors edited and approved the final version of the manuscript.

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