

Prevalence of Atrial Fibrillation in Spain: OFRECE Study Results

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Abstract

Introduction and objectives. Atrial fibrillation is associated with substantial morbidity and mortality and both its incidence and prevalence are high. Nevertheless, comprehensive data on this condition in Spain are lacking. The aim of this study was to estimate the prevalence of atrial fibrillation in Spain.

Methods. A cross-sectional study was conducted in the general Spanish population older than 40 years. Two-stage random sampling was used, in which first-stage units were primary care physicians randomly selected in every Spanish province and second-stage units were 20 randomly selected persons drawn from each participating physician's assigned population. The reported prevalence was standardized for the age and sex distribution of the Spanish population. The electrocardiogram recordings were read centrally.

Results. Overall, 8343 individuals were evaluated. The mean age was 59.2 years (95% confidence interval, 58.6-59.8 years), and 52.4% of the participants were female. The overall age-adjusted prevalence of atrial fibrillation was 4.4% (95% confidence interval, 3.8-5.1). Prevalence was similar in both sexes, men 4.4% (3.6-5.2) and women 4.5% (3.6-5.3), rising with increasing age older than 60 years. In patients older than 80 years, the prevalence was 17.7% (14.1-21.3). In 10% of patients an unknown atrial fibrillation was diagnosed.

Conclusions. The prevalence of atrial fibrillation in the general Spanish population older than 40 years is high, at 4.4%. The prevalence is similar in both sexes and rises steeply above 60 years of age. It is estimated that there are over 1 million patients with atrial fibrillation in the Spanish population, of whom over 90 000 are undiagnosed.

Resumen

Introducción y objetivos. La fibrilación auricular se asocia con elevadas morbilidad y mortalidad, y tanto su incidencia como su prevalencia son altas. No obstante, hay escasos datos poblacionales sobre su epidemiología en España. El objetivo de este estudio es estimar la prevalencia de fibrilación auricular en España.

Métodos. Estudio transversal en población española de 40 o más años. Se realizó un muestreo en dos etapas, una primera selección aleatoria de médicos de atención primaria de cada provincia española y, en segundo lugar, se seleccionó aleatoriamente a 20 individuos de la población asignada a cada médico participante. La prevalencia se ponderó por edad, sexo y área geográfica. Se realizó una lectura centralizada de los registros electrocardiográficos.

Resultados. Se evaluó a 8.343 personas (media de edad, 59,2 [intervalo de confianza del 95%, 58,6-59,8] años; el 52,4% mujeres). La prevalencia total de fibrilación auricular fue del 4,4% (intervalo de confianza del 95%, 3,8-5,1). La prevalencia fue similar en varones (4,4% [3,6-5,2]) y mujeres (4,5% [3,6-5,3]) y se incrementa progresivamente a partir de los 60 años de edad. En los mayores de 80 años, la prevalencia fue del 17,7% (14,1-21,3). En un 10% de pacientes se diagnosticó una fibrilación auricular no conocida.

Conclusiones. La prevalencia de fibrilación auricular en la población general española mayor de 40 años es elevada, del 4,4%. La prevalencia es similar en varones y mujeres y se incrementa escalonadamente a partir de los 60 años. Se estima en más de 1 millón de pacientes con fibrilación auricular en la población española, de los que más de 90.000 están sin diagnosticar.

Abbreviations

AF, atrial fibrillation; ECG, electrocardiogram; PC, primary care

Keywords

Atrial fibrillation; Prevalence; Epidemiology

Palabras clave

Fibrilación auricular; Prevalencia; Epidemiología

Introduction

Atrial fibrillation (AF) is the most common arrhythmia in Western countries and is associated with high mortality and morbidity.^{1 and 2} It is the leading cause of embolic events and is also associated with episodes of heart failure, cognitive impairment, and decreased quality of life.^{3, 4, 5 and 6} The most common embolic event is stroke, which is associated with severe disability and dependence, involving significant increases in costs and in the use of health care systems.⁷ Identifying these patients is important because anticoagulation therapy is effective in preventing embolic events in patients at high risk. Study of the population prevalence of AF, using homogeneous criteria, provides valuable information for planning appropriate strategies for the prevention and treatment of this disease. In Spain, there is a lack of epidemiological data that would allow the prevalence rates of AF to be determined in the general population. In general, previous studies were conducted in groups of patients or in selected populations that were not representative of the Spanish general population, such as patients from specific areas not representative of the whole country, patients attending health centers or cardiology clinics, which introduced bias, or patients within narrow age ranges.^{8, 9, 10 and 11}

The aim of this population-based study was to estimate the prevalence of AF in the Spanish population older than 40 years by age (decades) and sex groups.

Methods

Design and Definitions

A cross-sectional study was conducted in primary care (PC) among the general Spanish population older than 40 years assigned to a PC physician. One hospital from each Spanish province (2 in the case of Barcelona and Madrid) was invited to participate in the study, as well as a referral cardiologist from each hospital. In total, 46 provinces and 47 hospitals and cardiologists participated. Four provinces and the second hospital in Madrid were excluded or did not participate due to a variety of logistic problems. Based on this, a 2-stage random sampling procedure was used.

In each hospital, the number of PC physicians and their assigned population was determined and the participating physicians were selected using simple random sampling. Ten PC physicians were selected from each hospital. Each cardiologist was responsible for coordinating the work of these 10 physicians in his or her center. At this time, the participating hospitals had almost 8000 PC physicians assigned to them. A further 769 physicians were invited to participate, of whom 425 (55.2%) participated (Fig. 1).

For each participating PC physician, simple random sampling based on the national health card of the assigned population older than 40 years was performed, so that 20 patients were selected per physician. Selected individuals were invited to participate by the PC physician. At this stage, a 76% (n=8400) participation rate was achieved. All participants gave their informed consent to participate in the study. The study began in March 2010 and ended in October 2012.

Overall, 57 people were excluded due to the lack of key information (n=4) or because the electrocardiogram (ECG) could not be evaluated (n=53), and thus the final sample consisted of 8343 participants (Fig. 1).

All patients were examined by their PC physician, an ECG was performed on the day of the visit, and the patients were referred to the coordinating cardiologist for fast tracking according to the protocol (newly diagnosed or uncertain diagnosis). All ECGs were read centrally by at least 2 cardiologists (Fuenlabrada University Hospital) as described below. All the ECGs were initially evaluated by 1 cardiologist and subsequently by another cardiologist. If there was a discrepancy between the 2 diagnoses, a third cardiologist was consulted and a final diagnosis was reached by consensus between the second and third cardiologists. Of the total number of ECGs analyzed, a consensus was reached in 99.9% of the patients, of which 98.1% were classified as having AF (262 of 267) by 1 observer; thus, in 1.9% of the patients, there was disagreement between the 2 cardiologists who specifically analyzed the ECGs for the presence of AF. In total, the 15 patients who were not diagnosed during their examination by the PC physician were diagnosed when their ECGs were read centrally. These diagnoses were reported to the PC physicians in order for them to take any appropriate action.

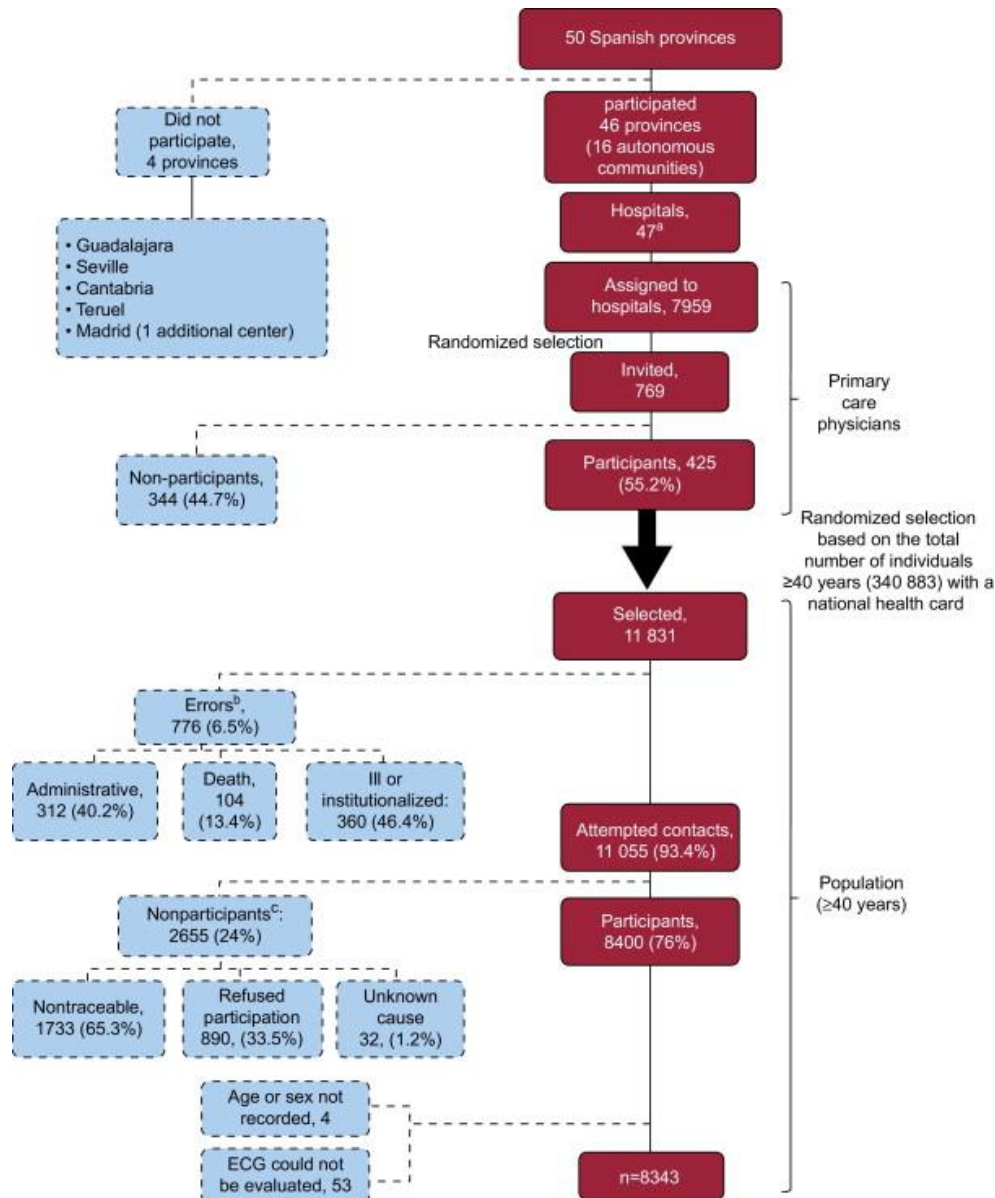


Figure 1. Flowchart of participation in the OFRECE study. ECG, electrocardiogram.

^aBarcelona: 2 hospitals participated. ^bErrors. Administrative: no longer a patient of the physician (does not belong to the center or the quota assigned), language difficulty; ill or institutionalized: institutionalized, acute or chronic disease preventing visits to the center, hospitalization, terminal process, bedridden, dementia, Alzheimer disease, mental disability, mental retardation or cognitive impairment. ^cReasons for not participating. Unreachable: after repeated attempts to contact by mail and/or telephone; participant refusal: refusal to participate or initial acceptance but failure to attend the center, various personal or business reasons preventing attendance at the center; unknown: unspecified cause.

Information on demographic variables, personal details, and general variables were collected, as well as clinical variables using a specific questionnaire for AF. The various clinical variables were defined according to the guidelines of the American College of Cardiology/American Heart Association for AF¹² as follows: obesity, body mass index greater than or equal to 30; overweight, body mass index greater than or equal to 25; central obesity, waist circumference greater than or equal to 102 cm for men and greater than or equal to 88 cm for women; hypercholesterolemia, previous diagnosis and treatment with lipid-lowering drugs; diabetes mellitus, previous diagnosis and treatment with oral diabetic agents or insulin; and previous diagnosis of documented ischemic heart disease, such as previous myocardial infarction, unstable angina or revascularization. Hypertension was defined as the presence of any of the following criteria: *a*) previous diagnosis of hypertension and treatment with medication, diet or exercise, and *b*) systolic blood pressure greater than or equal to 140 mmHg or diastolic blood pressure greater than or equal to 90 mmHg on at least 2 occasions on the day of examination.

A diagnosis of AF was based on 2 criteria: *a*) the presence of AF on ECG performed on the day of examination, and/or *b*) a documented clinical history of nonpermanent AF (paroxysmal or persistent).

Statistical Analysis

Given the nature of the sampling process, in which individuals in the population had different probabilities of being selected, each participant in the final sample was assigned a weight representing the number of people in the Spanish population (with the exception of Ceuta, Melilla, and Cantabria, which did not provide participants), for the same age, sex, and geographical area as those represented by the patient.¹³ Thus, the sum of all the weights of the sample was equal to the size of the Spanish population older than 40 years.

Weighting was done in 2 stages. In the first stage of the 2-stage sampling design, the weights were calculated as the inverse of the probability of selecting each individual in each stage of the sampling process. In the first stage (physician selection), the probability of selection in each province was calculated by using the number of PC physicians in the province as the denominator. In the second stage (participant selection), the number of people older than 40 years assigned to each physician was used as the denominator. In the second stage, a reweighting procedure was performed to adjust the sample distribution to the population distribution for variables related to the outcome of the analysis and not considered in the sampling procedure (age and sex). A third variable (geographical area) was included in case it was decided to present the data disaggregated by area. The data by autonomous community was not presented because the sample size calculated would provide inaccurate estimates. The reweighting procedure was performed using the method proposed by Deville and Särndal¹⁴ using the *calibrate* instruction in the Stata v10.1 statistical software package. The municipal population census of 2011 was used to adjust or calibrate for sex, age, and geographic area. We considered 5 geographic areas defined by autonomous community grouping: north (Aragón, Principality of Asturias, Galicia, Chartered Community of Navarre, Basque Country, La Rioja); central (Castile and León, Castile-La Mancha, Community of Madrid); east (Catalonia, Valencian Community, Region of Murcia, Balearic Islands); south/south-West (Andalusia, Extremadura); and the Canary Islands.

All the analyses took into account the sampling design of the study. In the case of AF, specific prevalences were calculated by age and sex, as well as total prevalence and their 95% confidence intervals (95% CI).

Age- and sex-adjusted odds ratios were estimated using logistic regression models in order to identify cardiovascular risk factors and antecedents associated with the presence of AF. Subsequently, a multivariate model was adjusted for the variables with $P < .01$ in the bivariate analysis

Results

The study included 8343 participants (mean age, 59.2 [95% CI, 58.6-59.8] years; 52.4% women). Table 1 shows the general characteristics of the study population and, for purposes of comparison, the same population disaggregated into those with a diagnosis of AF and those without AF. In the study population, AF was diagnosed in 410 patients (204 men and 206 women). Of these, 267 had a diagnosis of AF on ECG on the day of examination. The remaining 143 patients had a documented history of AF but did not have AF on the day of examination (nonpermanent AF, 34.9% of all patients with AF).

Table 1. Characteristics of the Population With and Without Atrial Fibrillation

	All (n=8343)	With AF (n=410)	Without AF (n=7933)	P
<i>Women, %</i>	52.4	52.8	52.4	.890
<i>Age group, %</i>				
40-49 years	31.2	2.3	32.5	
50-59 years	24.6	5.7	25.4	
60-69 years	19.3	20.2	19.2	<.001
70-79 years	14.9	31.4	14.1	
≥80 years	10.1	40.4	8.7	
<i>Cardiovascular risk factors</i>				
Obesity, %	33.8	47.8	33.2	<.001
Overweight, %	42.1	36.9	42.3	.140
Central obesity, %	55.7	74.4	54.9	<.001
BMI, average	28.4	29.6	28.4	<.001
Waist circumference, average	96.6	101.4	96.4	<.001
Hypercholesterolemia, %	25.4	45.6	24.5	<.001
Diabetes mellitus, %	12.2	24.5	11.6	<.001
Smoking, %	22.3	4.7	23.2	<.001
Hypertension, %	45.3	76.0	43.9	<.001
SBP (mmHg), mean	130.9	134.8	130.7	.001
DBP (mmHg), mean	77.8	76.7	77.9	.226
<i>Medical history</i>				
Stroke, %	3.8	16.6	3.2	<.001
Peripheral artery disease, %	2.4	7.9	2.1	<.001
Chronic pulmonary disease, %	6.3	18.1	5.8	<.001
Thyroid disease, %	6.9	10.6	6.8	.009
Pacemaker implantation, %	0.7	7.4	0.4	<.001
ICD implantation, %	0.7	7.4	0.4	<.001
Ischemic heart disease, %	4.9	17.9	4.3	<.001
Previous diagnosis of HF, %	3.1	29.4	1.8	<.001

AF, atrial fibrillation; BMI, body mass index; DBP, diastolic blood pressure; HF, heart failure; ICD, implantable cardioverter-defibrillator; SBP, blood pressure.

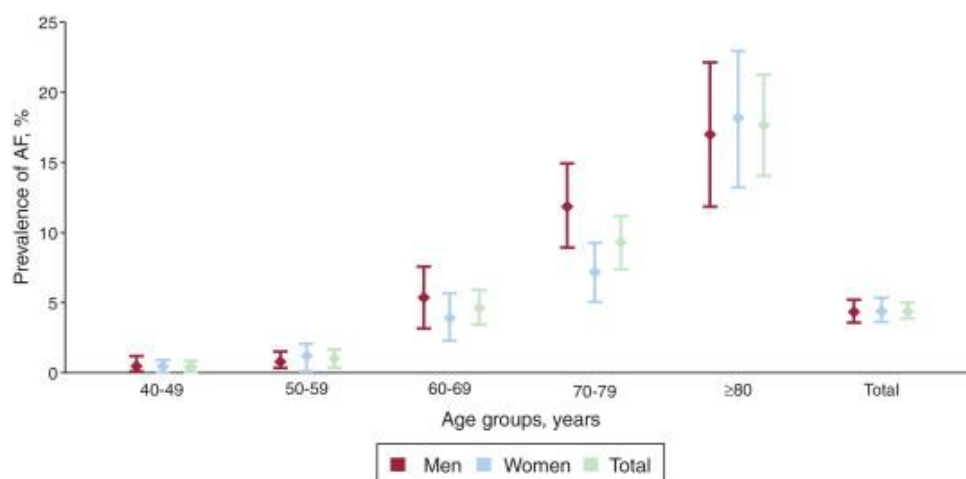
The overall prevalence of AF was 4.4% (95%CI, 3.8-5.1). The prevalence was similar in men (4.4% [3.6-5.2]) and women (4.5% [3.6-5.3]), rising with increasing age older than 60 years. The prevalence of AF by age and sex is presented in Table 2 and Figure 2.

Table 2. Prevalence of Atrial Fibrillation by Sex and Age Group and Estimated Number of Patients in the Spanish Population

Age	Men (n=3829)		Women (n=4514)		Total (n=8343)	
	%	95%CI	%	95%CI	%	95%CI
40-49 years	0.5	0.0-1.2	0.2	0.0-0.4	0.3	0.0-0.7
50-59 years	0.9	0.3-1.6	1.1	0.1-2.1	1.0	0.4-1.7
60-69 years	5.3	3.1-7.5	4.0	2.3-5.7	4.6	3.4-5.9
70-79 years	11.9	8.9-14.9	7.2	5.1-9.3	9.3	7.4-11.2
≥80 years	17.0	11.9-22.1	18.1	13.3-22.9	17.7	14.1-21.3
Total	4.4	3.6-5.2	4.5	3.6-5.3	4.4	3.8-5.1

Age	Total (in thousands)	95%CI	Total (in thousands)	95%CI	Total (in thousands)	95%CI
40-49 years	17.3	0.0-43.6	6.30	0.0-14.0	23.6	0.0-50.9
50-59 years	26.7	9.26-44.2	31.6	0.49-62.6	58.3	21.4-95.2
60-69 years	114.6	64.6-164.7	92.7	52.1-133.3	207.4	145.3-269.4
70-79 years	183.0	131.8-234.1	138.9	97.5-180.3	321.8	252.9-390.9
≥80 years	142.3	99.9-184.7	272.4	193.8-351.1	414.7	326.2-503.3
Total	483.9	394.9-572.9	541.9	437.4-646.5	1025.8	879.1-1172.6

95%CI, 95% confidence interval.

**Figure 2.** Prevalence of atrial fibrillation by sex and age group (95% confidence intervals). AF, atrial fibrillation.

Regarding cardiovascular risk factors, patients with AF had a higher percentage of obesity (47.8% vs 33.2%; $P<.001$), hypercholesterolemia (45.6% vs 24.5%; $P<.001$), diabetes mellitus (24.5% vs 11.6%; $P<.01$), and hypertension (76% vs 43.9%; $P<.01$), and a lower percentage of smoking (4.7% vs 23.2%; $P<.001$) than patients without AF. Patients with AF more often had a history of cerebrovascular disease (16.6% vs 3.2%; $P<.001$), peripheral arterial disease (7.9% vs 2.1%; $P<.001$), pulmonary disease (18.1% vs 5.8%; $P<.001$), ischemic heart disease (17.9% vs 4.3%; $P<.001$) and a history of heart failure (29.4% vs 1.8%; $P<.001$) (Table 1).

Multivariate analysis showed that age, male sex, central obesity, not smoking, a history of heart failure, thyroid disease, and having a pacemaker were independently associated with the presence of AF (Table 3). Although no differences were found in the prevalence of AF by sex, differences were found by decade, with a higher prevalence in men less than 80 years of age and in women more than 80 years of age. These data are in line with those of other studies, except for the finding of a higher prevalence in women in their eighties. Of the 410 patients with AF, 41 (10%) were diagnosed on the day of the examination (unknown AF).

Table 3. Age- and Sex-adjusted Odds Ratios of Having Atrial Fibrillation for Each Cardiovascular Risk Factor, Previous History, and Final Multivariate Model

	OR (95%CI)	P
<i>Cardiovascular risk factors</i>		
Obesity	1.65 (1.22-2.23)	.001
Overweight	0.71 (0.51-0.98)	.038
Central obesity	1.78 (1.32-2.40)	<.001
Hypercholesterolemia	1.60 (1.17-2.19)	.004
Diabetes mellitus	1.42 (1.03-1.94)	.032
Smoking	0.44 (0.23-0.83)	.012
Hypertension	1.55 (1.05-2.29)	.029
<i>Previous history</i>		
Peripheral artery disease	1.81 (1.02-3.21)	.042
Chronic pulmonary disease	1.88 (1.21-2.92)	.005
Thyroid disease	1.90 (1.27-2.85)	.002
Pacemaker	9.31 (4.76-18.22)	<.001
Ischemic heart disease	2.59 (1.68-4.00)	<.001
Previous diagnosis of HF	8.73 (5.27-14.45)	<.001
<i>Multivariate model</i>		
Age	1.08 (1.06-1.10)	<.001
Female sex	0.61 (0.43-0.86)	.005
Central obesity	1.70 (1.24-2.33)	.001
Smoker	0.47 (0.24-0.92)	.028
Thyroid disease	1.69 (1.11-2.58)	.016
Pacemaker	5.50 (2.11-14.36)	.001
Previous diagnosis of HF	7.72 (4.44-13.41)	<.001

95%CI, 95% confidence interval; HF, heart failure; OR, odds ratio.

Table 4. Characteristics of the Population With New Atrial Fibrillation and Previously Diagnosed Atrial Fibrillation

	New AF	Known AF	P
<i>Participants, no.</i>	41	369	
<i>Sex, %</i>			
Men	59.8	45.9	.208
Women	40.2	54.1	
<i>Age (years), mean</i>	74.7	75.3	.782
<i>CVRF, %</i>			
Obesity	40.0	48.6	.401
Overweight	51.1	35.4	.101
Central obesity	73.9	74.5	.942
Hypercholesterolemia	42.3	45.9	.708
Diabetes mellitus	9.8	26.0	.016
Smoking	17.9	3.3	.004
Hypertension	77.1	75.9	.907
<i>Medical history, %</i>			
Stroke	17.9	16.5	.851
Peripheral artery disease	7.4	8.0	.911
Chronic pulmonary disease	10.6	18.9	.227
Thyroid disease	7.1	11.0	.494
Pacemaker	4.8	7.7	.473
Ischemic heart disease	23.5	17.3	.397
Previous diagnosis of HF	7.4	31.6	.007
<i>Previous visit for dizziness/palpitations, %</i>			
Previous visit	25.3	55.7	.007
Visit to PC physician	25.3	41.8	.476
Visit to the cardiologist	7.8	43.0	.036
Visit to hospital emergency service	9.6	37.1	.284

AF, atrial fibrillation; CVRF, cardiovascular risk factors; HF, heart failure; PC, primary care.

The Spanish 2011 census estimated the population to be 46 815 916 inhabitants; of these, 51.1% (23 922 933 people) were older than 40 years of age. By applying the specific prevalences for age and sex observed in the OFRECE study to the Spanish population, and taking into account the design, the number of patients with AF in the population older than 40 years in Spain (with the exception of Cantabria, Ceuta, and Melilla) was estimated to be 1 025 846 (95% CI, 879 077-1 172 614), of whom 94 546 (95% CI, 57 944-131 148) would be undiagnosed.

Discussion

This study is the first to provide estimates of the prevalence of AF in the Spanish population older than 40 years of age and shows that the prevalence of AF in this population increases with age. The strength of this study lies in the fact that it was conducted using the general population and that a highly representative sample was obtained by the random selection of PC physicians and the population assigned to each physician, thereby strengthening the validity of the results. Previous studies have been based on the records of patients with other cardiovascular diseases (eg, hypertension) or on specific geographical areas, which has led to widely varying estimates, with prevalences between 0.7% and 8.5%.^{8, 9, 10 and 11} The REGICOR study,⁹ the only study conducted in the general population rather than in patients from different areas, found a prevalence of 0.7%. However, that study was strongly limited by its exclusion of the population older than 74 years of age, precisely the age group with the highest prevalence of AF. In the PREV-ICTUS study,¹⁰ a population-based cross-sectional study that analyzed participants older than 60 years, the prevalence of AF was 8.5% (95% CI, 7.9%-9.2%), was higher in men (9.3% vs 7.9% in women), and increased from 4.2% in those aged between 60 and 64 years to 16.5% in those older than 85 years. The CARDIOTENS study,⁸ which was conducted in hypertensive patients, found a prevalence of AF of 4.8%, which increased with each decade of life (1.0% in those younger than 50 years and 11.1% in those older than 80 years). However, CARDIOTENS cannot be considered a population-based study because it included consecutive patients attending PC centers or cardiology services, which could have led to a selection bias that overestimated prevalence.

European studies have also reported wide variability in prevalences in the general population, with estimates ranging from 0.2% to 1.2% and, for people older than 50 years of age, from 1.5% to 5.5%.^{2, 15, 16, 17, 18 and 19} Most of the studies that have investigated the prevalence of AF are not strictly comparable for 2 reasons: *a*) the characteristics of the study population and their distribution by age and sex, and *b*) the method used to diagnose AF. Studies that based the diagnosis of AF on ECG alone, and not on a history of AF, found lower prevalences than those that based the diagnosis on ECG and a clinical history of AF.¹⁵ Another aspect that may influence the prevalence of AF in different series, as confirmed in this study, is the risk profile of the populations analyzed (prevalence of hypertension, diabetes mellitus, obesity, etc). In the case of the Spanish population, recent studies have demonstrated a high prevalence of variables associated with AF, which are not always well adjusted.^{20 and 21} In this study, all ECGs were read centrally by 2 cardiologists, which increased the quality of the information by enhancing diagnostic certainty and reducing variability and misclassification problems.

Interestingly, 10% of patients with AF at the time of examination were unaware of having AF. This figure is slightly different from that described by Labrador et al.¹¹ or Wheeldon et al.,¹⁶ who found that 8.6% and 7.7% or more of patients had undiagnosed AF, respectively. However, both these studies only analyzed the general population aged 65 years and older, and therefore the data are not directly comparable.^{11 and 16} It should be noted that there were higher percentages of men, patients without diabetes, smokers, and patients without a history of heart failure in the population of patients with previously undiagnosed AF (an arrhythmia that may cause few symptoms). This finding is very important because patients with AF have a 5-fold higher risk of a stroke²² and because effective treatment is available using classical or novel anticoagulants to prevent these embolic events.^{23 and 24}

Limitations

The hospitals studied within each province were not randomly selected. This probably had very little impact on the study as it is unlikely that the prevalence of AF varies significantly between adjacent areas. Of more importance, the randomized selection of the physicians and particularly of the patients assigned to each physician was considered to add strength to the results of this study. The high number of sampling points improved the representativeness of the sample, which is sometimes difficult to evaluate. A limitation inherent to this type of general population study is that the participants may differ from nonparticipants. Although it is impossible to completely rule out potential bias due to selective participation and to determine its direction, it should be emphasized that any such bias cannot be very

large, since there was a very good participation rate for this type of study (76% of those invited to participate in the study) and, of the nonparticipants, only one-third did not participate due to refusal. Another limitation is that the patients without a known history of paroxysmal AF and with a normal ECG at the time of examination by the family physician were not diagnosed with AF; however, this limitation is common to all published studies on the prevalence of AF and is difficult to avoid. Furthermore, when AF was diagnosed on the basis of clinical history alone, a centralized reading of the previous ECG was obviously not possible; nevertheless, a diagnosis of AF was only included in the study if such a reading was recorded in a medical record or the clinical history in PC.

Conclusions

The prevalence of AF in the general Spanish population older than 40 years is high (4.4%). The overall prevalence is similar in men and women, but differs according to the decade of age analyzed and increases steeply above 60 years of age. There are over 1 million patients with AF in the Spanish population, of whom more than 90 000 are undiagnosed. This has important implications for public health due to the frequency and severity of complications caused by this arrhythmia in the absence of treatment.

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Conflicts of interest

None declared.

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Appendix. Steering Committee, coordinators, researchers, collaborators, and reading center

Steering Committee

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