

Original article

Current Antiarrhythmic Therapy for Nonvalvular Atrial Fibrillation in Spain. Data From the FANTASIIA Registry



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ABSTRACT

Introduction and objectives: Recently, there have been many developments in the management of nonvalvular atrial fibrillation, antiarrhythmic and anticoagulant therapy, and nonpharmacological treatment, but these developments are not applied immediately in clinical practice. The aim of this study was to identify the overall management and antiarrhythmic therapy used in the current general population of patients with nonvalvular atrial fibrillation in Spain.

Methods: A prospective, observational study of 1318 consecutive anticoagulated patients with nonvalvular atrial fibrillation, recruited between June 2013 and March 2014. We analyzed the patients' general characteristics, management, and antiarrhythmic therapy.

Results: Mean age was 73.8 ± 9.4 years; 42.5% were women. Atrial fibrillation was paroxysmal in 28% of the patients, permanent in 50%, persistent in 17.6%, long-standing persistent in 4.5%, and new-onset in 66 patients (5%). A rhythm control strategy was chosen in 39.4% of the patients and rate control in 60.6%. Beta-blockers were prescribed in 60.2% of the patients, digoxin in 19.5%, and calcium channel antagonists in 10.7%. The antiarrhythmic agents used were amiodarone (12.6%), flecainide (8.9%), propafenone (0.4%), sotalol (0.5%), and dronedarone (2.3%). Cardioversion had been performed previously in 41.9% of the patients, ablation in 3.4%, and atrial appendage closure in 0.2%.

Conclusions: Currently, patients with nonvalvular atrial fibrillation in Spain are managed mainly with rate control, and beta-blockers in particular. They receive few antiarrhythmic agents and only a very small number of these patients undergo nonpharmacological treatments.

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Tratamiento antiarrítmico actual de la fibrilación auricular no valvular en España. Datos del Registro FANTASIIA

RESUMEN

Introducción y objetivos: Recientemente se han producido numerosas novedades en el manejo de la fibrilación auricular no valvular y el tratamiento antiarrítmico, anticoagulante y no farmacológico empleado, pero su aplicación a la clínica no es inmediata. El objetivo del trabajo es conocer las características generales de manejo y tratamiento antiarrítmico de una población general de pacientes con fibrilación auricular no valvular actualmente en España.

Métodos: Estudio observacional y prospectivo de 1.318 pacientes consecutivos con fibrilación auricular no valvular, anticoagulados y reclutados entre junio de 2013 y marzo de 2014. Se analizan sus características generales, el manejo y el tratamiento antiarrítmico utilizado.

Resultados: La media de edad era $73,8 \pm 9,4$ años; eran mujeres el 42,5%. La fibrilación auricular fue paroxística en el 28% de los casos, permanente en el 50%, persistente en el 17,6%, persistente de larga duración en el 4,5% y *de novo* en 66 pacientes (5%). Se eligió control del ritmo en el 39,4% de los casos y de frecuencia en el 60,6%. Tomaron bloqueadores beta el 60,2%, digoxina el 19,5% y antagonistas del calcio el 10,7%. Los antiarrítmicos empleados fueron amiodarona (12,6%), flecainida (8,9%), propafenona (0,4%), sotalol (0,5%) y dronedarona (2,3%). Se realizó cardioversión previa en el 41,9%, ablación en el 3,4% y cierre de orejuela en el 0,2%.

Palabras clave:

Fibrilación auricular no valvular

Tratamiento antiarrítmico

Cardioversión

Ablación

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Conclusiones: Actualmente en nuestro país se maneja a los pacientes con fibrilación auricular no valvular preferentemente con control de frecuencia, sobre todo con bloqueadores beta, reciben pocos antiarrítmicos y se los somete en muy baja proporción a tratamientos no farmacológicos.

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Abbreviations

AF: atrial fibrillation
 HF: heart failure
 NVAf: nonvalvular atrial fibrillation
 OAC: oral anticoagulant

INTRODUCTION

Atrial fibrillation (AF) is the most common arrhythmia in Western countries. Prevalence, estimated at 1.5% to 2%,¹ increases with age, ranging from 1% in individuals younger than 60 years to 12% in the group aged 75 to 84 years. More than a third of patients with AF are aged 80 years or older.^{1,2} Recently, the Spanish OFRECE study estimated that AF prevalence in Spain was 4.4% in adults older than 40 years and 17.7% in those aged 80 or older.³ This arrhythmia is often associated with structural heart disease and other chronic conditions. It leads to significant morbidity and mortality (increased mortality and stroke risk, heart failure [HF], dementia, etc), and increased hospital admissions and economic burden.^{2,4–10}

Since 2010, European and US guidelines on AF have been published almost yearly, reflecting the major changes in the management of patients with this condition. This whirlwind of changes is the result of the successive introduction of more discriminative embolism and bleeding risk indices, the key role of implantable cardiac devices in silent AF, novel oral anticoagulants (OAC) and new antiarrhythmic agents, and the development of ablation. Recently, nonvalvular atrial fibrillation (NVAf) has been defined as AF in the absence of rheumatic mitral stenosis, heart valve prosthesis, or mitral valve repair.¹ Clinical practice guidelines show general consensus in their recommendations, which reflect these major changes in overall management, and pharmacological and nonpharmacological decisions (such as whether to follow a rhythm or rate control strategy in initial NVAf management, and indications for classic and new antiarrhythmic agents).¹¹ However, these guidelines are not immediately applied in routine clinical practice, despite their strong clinical trial-based evidence and high class of recommendation.

The aim of this study was to analyze the current management of NVAf, choice of rhythm or rate control strategies, and the use of antiarrhythmic therapy and nonpharmacological treatment in a general, unselected population of patients with NVAf in Spain.

METHODS

Study Data and Design

The data for this study were taken from the FANTASIIA Registry (Spanish acronym for Atrial fibrillation: Influence of anticoagulation level and type on stroke and bleeding event incidence), a prospective, observational, national, multicenter study that is collecting general information on the current situation and characteristics of the Spanish population with any type of NVAf, following the European AF guideline criteria.¹ The main aim of the registry is to evaluate the incidence of thromboembolic and

bleeding events in an unselected population of patients with NVAf over 3 years, specifically with reference to the use and type of antithrombotic agent, vitamin K antagonist (VKA) and direct OAC, as well as anticoagulation adjustment (in patients receiving VKA). The FANTASIIA Registry is designed as an initial enrolment visit and 3 follow-up visits at 1, 2, and 3 years. The patients' clinical and laboratory data are being collected in an electronic case report form.

In our study, we analyzed a cross-sectional baseline data set from the FANTASIIA enrolment visit, focusing on the secondary endpoints of the registry, which concern the general characteristics of NVAf management, initial AF control strategy, rhythm or rate control, treatment type, antiarrhythmic class, and nonpharmacological treatment.

Study Population

In this preliminary analysis, we studied 1318 consecutive patients, seen at 50 outpatient clinics, with a diagnosis of NVAf (excluding patients with rheumatic mitral valve disease or valvular prostheses), entered in the FANTASIIA Registry by 81 investigators (81% cardiologists, 11% primary care physicians, and 8% internists) between June 2013 and March 2014. The clinics were randomly selected, and located throughout Spain. Inclusion criteria were patients older than 18 years who had been receiving anticoagulant therapy (80% VKA and 20% direct OAC, ie, dabigatran, rivaroxaban or apixaban) for at least 6 months before enrolment. The patients were managed according to routine clinical practice. The FANTASIIA Registry complies with all the principles of the Declaration of Helsinki and the study protocol was approved by the Clinical Research Ethics Committee at *Hospital Universitario de Alicante* and by all the local ethics committees. All study participants signed the informed consent.

Statistical Analysis

Quantitative variables were described using the mean \pm standard deviation or median [interquartile range], depending on whether they followed a normal distribution, which we tested with the Kolmogorov-Smirnov method. For between-group comparisons, we used the Student *t* test for continuous variables and the chi-square test for qualitative variables. Statistical significance was defined as $P < .05$. Statistical analyses were performed with SPSS statistical package version 12.

RESULTS

Baseline Characteristics of Study Patients

We enrolled 1318 patients throughout Spain who met the aforementioned inclusion and exclusion criteria between June 2013 and March 2014. Baseline characteristics are shown in [Table 1](#). Mean age was 73.8 years (\pm 9.4 years) and 758 patients (57.5%) were men. The most prevalent risk factor was hypertension, which was observed in 1068 patients (81.0%), followed by hypercholesterolemia in 711 (54.0%), and diabetes mellitus in 386 (29.0%). Other notable comorbidities were ischemic stroke, in 210 patients

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