

Editorial

First, Let's See Where We Stand. Then, Let's See How Far We Can or Want to Go



Primero conocer la realidad. A partir de ahí, hasta donde queramos o podamos

Julián Pérez-Villacastín*

Unidad de Arritmias, Hospital Clínico San Carlos, Madrid, Spain

Article history:

Available online 11 March 2014

In 2005, the Spanish Society of Cardiology—under the presidency of Eduardo de Teresa—decided to establish its own research agency in order to coordinate, foster, and facilitate both basic and applied research in the field of cardiovascular disease. At the very first meetings, it was decided that, as well as facilitating external projects (proposed by members), the Research Agency of the Spanish Society of Cardiology should provide leadership in constructing registries or designing nationwide studies of prevalent diseases like arterial hypertension, atrial fibrillation (AF), or coronary disease. One direct consequence was the OFRECE study, the main objective of which was to estimate the prevalence of AF in the adult Spanish population. The results appear in the article by Gómez-Doblas et al published in *Revista Española de Cardiología*.¹

A team of nearly 500 physicians collaborated in OFRECE, together with an unknown but presumably very high number of nursing staff. One hospital in each of Spain's 50 provinces was invited to participate, and 47 hospitals were included. One reference cardiologist was chosen at each hospital. At random, 10 primary care physicians were selected from each hospital's service area. For each physician, 20 individuals aged ≥ 40 years were randomly selected, using health care registration data, and invited to participate. A total of 8400 individuals (76% accepted, and 8343 made up the final study sample (54 were excluded because of noninterpretable electrocardiogram and 4 due to a lack of information). All participants were invited to a clinic visit and underwent an electrocardiogram, which were analyzed at a single center by at least 2 independent cardiologists. AF was diagnosed from the electrocardiogram or from well-documented antecedents in the patient's clinical history. Other clinical variables were analyzed and every effort was made to ensure a representative sample of the Spanish population. The researchers avoided any possible bias, such as that potentially arising from the probability of selection based on geographic area (statistical analysis).

The OFRECE results are highly interesting. AF was identified in 411 patients (41 new and 369 known cases); 75% had a clinical history of arterial hypertension, almost half had obesity, and one in four had been diagnosed with diabetes mellitus. Total estimated prevalence of AF was 4.4% (95% confidence interval, 3.8%–5.1%),

rising markedly in patients older than 60 years. In patients aged between 40 and 49 years, prevalence of AF is 0.5% in men and 0.2% in women. Prevalence doubles in patients aged between 50 and 59 years, but in the 60 to 69 age range, these figures multiply by 10 in men, reaching 5.3%, and by 20 in women, reaching 4%. In patients aged > 80 years, estimated prevalence was 17.7%. Overall, prevalence of AF was similar in men (4.4%) and women (4.5%). Significantly, in 10% of patients diagnosed with AF, the condition was previously unknown. Based on the current Spanish population, the authors calculate that > 1 million patients have AF in Spain, and $> 90\,000$ of them are undiagnosed.

In Spain, the epidemiology of AF has been analyzed in several studies.² Without wishing to fuel the controversy over numbers—although the OFRECE estimates would probably be closer to the truth than the others—these epidemiologic studies warn us that prevalence of AF is very high. Recently, data from a representative sample of Spanish emergency room services have shown that 2.2% of all patients present with AF in the electrocardiogram.³ The ESFINGE study analyzed prevalence of AF in patients of both sexes, aged ≥ 70 years, and hospitalized in internal medicine or geriatric units.⁴ Total prevalence of AF in this group was 31.3%. The Val-FAAP study estimated the proportion of individuals with AF among patients attended in primary care over a period of 5 days. The study included 119 526 participants (age, 52.9 years [standard deviation, 15.2 years]); 40.9% men); 6.1% had AF and this percentage increased with age, arterial hypertension, and male sex.⁵

If OFRECE estimates that, in Spain, 1 025 846 people could have AF in a population of 46 815 916 inhabitants, the gross percentage amounts to 2.2%. This is even higher than the maximum cited in recent European guidelines, which discuss figures of between 1% and 2%.⁶ Moreover, all the analyses agree that current demographic trends could lead to an increase in these figures in the coming years.⁶

AF is not a benign arrhythmia of the type that only affects quality of life. AF increases mortality, as it can lead to heart failure, cerebral embolism, peripheral embolism, acute myocardial infarction, and sudden death.^{7,8} The after-effects of AF can be catastrophic. Moreover, it is a “treacherous” arrhythmia, as it can be asymptomatic and intermittent, and therefore go unnoticed by both physician and patient. Hence, despite the surprisingly high figures, OFRECE has probably underestimated prevalence of AF in the general population.⁹

In clinical guidelines, one of the first decisions to be made when dealing with a patient with AF concerns the need for anticoagulation therapy. We do not know how long AF must continue

SEE RELATED ARTICLE:

<http://dx.doi.org/10.1016/j.rec.2013.07.014>, Rev Esp Cardiol. 2014;67:259–69.

* Corresponding author: Unidad de Arritmias, Hospital Clínico San Carlos, Profesor Martín Lagos s/n, 28040 Madrid, Spain.

E-mail address: jvillacastin@secardiologia.es

in order to produce an embolism. Although traditionally it seems accepted that episodes of fewer than 48 h rarely provoke embolism, the existence of other risk factors probably means shorter episodes can generate atrial thrombus. Recent studies suggest this is the case.⁹ Hence, the need for anticoagulation therapy is based on existing embolic risk factors but not on AF type—paroxysmal, persistent, or permanent. The European clinical practice guidelines¹⁰ recommend anticoagulation, except when contraindicated, for all patients with CHA₂DS₂-VASc (congestive heart failure, hypertension, age \geq 75 [doubled], diabetes, stroke [doubled]-vascular disease and sex category [female]) \geq 2. In addition to anticoagulation therapy, the treatment of patients with AF includes the management of concomitant diseases and strategies aimed at avoiding symptoms onset. These strategies include electrical cardioversion, the administration of antiarrhythmic drugs to maintain sinus rhythm or control the rate, ablation of the arrhythmia, or the implantation of devices to close the left atrial appendage. Faced with so many therapeutic options, it is only logical to think that many patients do not receive the treatment they need, whereas others are treated unnecessarily.¹¹ This lack of adherence to clinical practice guidelines has been seen to associate with increased morbidity and mortality.¹² Consequently, new units that are specifically dedicated to treating AF are being designed to adapt the available resources to meet these patients' needs.¹³ In Spain, following the OFRECE results, the next step could involve analyzing these issues.

AF is a highly expensive disease. In Europe, the mean cost of each patient with AF has been estimated at between €450 and €3000 per year.¹⁴ The greater part of this expenditure is related to hospitalization. In the Netherlands, the total cost of AF has been estimated to be 1.3% of the entire health care budget.¹⁵ In Spain, we do not have access to reliable data about the socioeconomic and health care impact of AF. If we want to be able to plan solutions, the first thing we require is reliable information. This is why we believe we must congratulate the Research Agency of the Spanish Society of Cardiology and the authors of OFRECE for successfully completing a difficult task and gathering very important information. It has been difficult, and has taken time, but they have broken new ground. And they have achieved this with the cooperation of many physicians and nurses working in different specialties, and in collaboration with the Spanish Ministry of Health, health care departments in the autonomous communities, and the pharmaceutical and technology companies, too: a truly excellent example of team work.

The success of a clinical study can be measured in terms of the volume and quality of the content required to populate the data base, the reliability and accessibility of the information, and above all, by its practical value. We hope the design, work habits, and data obtained through OFRECE serve as an example for the Spanish health care system. And that similar studies and top quality registries proliferate. We need access to reliable information that enables us to plan and deploy our resources appropriately so we can later achieve whatever is necessary or possible in attending our patients. New forms of research are emerging. Thanks to the digitization of information, the well-designed and executed analysis of prevalence, activity, or results is gaining ground and could become a reliable source of information for decision-making—above all, for the man in the street.^{16–18} In this context,

we sincerely hope that our health care authorities will look favorably on future studies like OFRECE. We believe that if the Spanish authorities want to do things properly, they need studies like this.

CONFLICTS OF INTEREST

None declared.

REFERENCES

- Gómez-Doblas JJ, Muñoz J, Alonso Martín JJ, Rodríguez-Roca G, Lobos JM, Awamleh P, et al. Prevalence of Atrial Fibrillation in Spain. OFRECE Study Results. *Rev Esp Cardiol*. 2014;67:259–69.
- Pérez-Villacastín, Pérez Castellano N, Moreno J. Epidemiología de la fibrilación auricular en España en los últimos 20 años. *Rev Esp Cardiol*. 2013;66:561–5.
- Martín Martínez A, Sánchez López J, Malagón Caussade F, Del Arco Galán C, Suero Méndez C, Coll-Vinent i Puig B, et al. Impacto de la fibrilación auricular en la práctica diaria de la fase aguda: ¿la epidemia del siglo XXI? (Estudio Hermes-AF) *Rev Esp Cardiol*. 2012;65 Supl 3:363.
- López Soto A, Formiga F, Bosch X, García Alegría J. Prevalencia de la fibrilación auricular y factores relacionados en pacientes ancianos hospitalizados: estudio ESFINGE. *Med Clin (Barc)*. 2012;138:231–7.
- Barrios V, Calderón A, Escobar C, De la Figuera M. Pacientes con fibrilación auricular asistidos en consultas de atención primaria. Estudio Val-FAAP. *Rev Esp Cardiol*. 2012;65:47–53.
- Camm AJ, Kirchhof P, Lip GY, Schotten U, Savelieva I, Ernst S, et al. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). *Eur Heart J*. 2010;31:2369–429.
- Chen L, Sotoodehnia N, Buzkova P, Lopez F, Yee L, Heckbert S, et al. Atrial fibrillation and the risk of sudden cardiac death. The Atherosclerosis Risk in Communities Study and Cardiovascular Health Study. *JAMA Intern Med*. 2013;173:29–35.
- Soliman EZ, Safford MM, Muntner P, Khodneva Y, Dawood FZ, Zakai NA, et al. Atrial fibrillation and the risk of myocardial infarction. *JAMA Intern Med*. 2014;174:107–14.
- Healey IS, Connolly SJ, Gold MR, Israel CW, Van Gelder I, Capucci A, et al. Subclinical atrial fibrillation and the risk of stroke. *New Engl J Med*. 2012;366:120–9.
- Camm AJ, Lip GY, De Caterina R, Savelieva I, Atar D, Hohnloser SH, et al; ESC Committee for Practice Guidelines (CPG). 2012 focused update of the ESC Guidelines for the management of atrial fibrillation: an update of the 2010 ESC Guidelines for the management of atrial fibrillation. Developed with the special contribution of the European Heart Rhythm Association. *Eur Heart J*. 2012;33:2719–47.
- Clua-Espuny JL, Lechuga-Duran I, Bosch-Princep R, Roso-Llorach A, Panisello-Tafalla A, Lucas-Noll J, et al. Prevalencia de la fibrilación auricular desconocida y la no tratada con anticoagulantes. Estudio AFABE. *Rev Esp Cardiol*. 2013;66:545–52.
- Nieuwlaat R, Prins MH, Le Heuzey JY, Vardas P, Aliot E, Santini M, et al. Prognosis, disease progression, quality of life and treatment of atrial fibrillation patients during 1 year follow up of the Euro Heart Survey on atrial fibrillation. *Eur Heart J*. 2008;29:1181–9.
- Hendriks J, Tomini F, Asselt T, Crijns H, Vrijhol H. Cost effectiveness of a specialized atrial fibrillation clinic versus usual care in patients with atrial fibrillation. *Europace*. 2013;15:1128–35.
- Wolowacz SE, Samuel M, Brennan VK, Jasso Mosqueda JG, Van Gelder IC. The cost of illness of atrial fibrillation: a systematic review of the recent literature. *Europace*. 2011;10:1375–85.
- Heemstra HE, Nieuwlaat R, Meijboom M, Crijns HJ. The burden of atrial fibrillation in the Netherlands. *Neth Heart J*. 2011;19:373–8.
- Ryan TJ. Large cardiac registries: the path to higher quality and lower cost in our healthcare system. *Circulation*. 2010;121:2612–4.
- Hickey G, Grant S, Cosgriff R, Dimarakis I, Pagano D, Kappetein A, et al. Clinical registries: governance, management, analysis and applications. *Eur J Cardiothorac Surg*. 2013;44:605–14.
- Eichler HG, Pétavy F, Pignatti F, Rasi G. Access to patient-level trial data—a boon to drug developers. *N Engl J Med*. 2013;369:1577–9.