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Special article

Spanish Implantable Cardioverter-Defibrillator Registry. Seventh Official Report of the Spanish Society of Cardiology Working Group on Implantable Cardioverter-Defibrillators (2010)

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ABSTRACT

Introduction and objectives: The authors summarize the findings of the Spanish Implantable Cardioverter-Defibrillator Registry for 2010 compiled by the Spanish Society of Cardiology Working Group on Implantable Cardioverter-Defibrillators.
Methods: Members of the Spanish Society of Cardiology were prospectively surveyed; data were recorded voluntarily by each implantation team on one-page questionnaires.
Results: In total, 4627 device implantations were reported, comprising 85.6% of the overall estimated number of implantations. The reported implantation rate was 100.61 per million population and the estimated total implantation rate was 117.50 per million. The proportion of first implantations was 73.87%. We collected data from 143 hospitals (9 more than in 2009). The majority of the implantable cardioverter-defibrillator implantations were performed in men (81%). The mean age was 62.5±13 years. Most of the patients had severe or moderate-to-severe ventricular dysfunction and were in New York Heart Association functional class II. Ischemic heart disease was the most frequent underlying cardiac condition, followed by dilated cardiomyopathy. The number of implantable cardioverter-defibrillator implantations indicated for primary prevention increased over the previous year and now accounts for 65.6% of first implantations. In all, 76.1% of the implantable cardioverter-defibrillator implantations were performed by cardiac electrophysiologists.
Conclusions: The 2010 Spanish Implantable Cardioverter-Defibrillator Registry includes data on almost 86% of all the implantable cardioverter-defibrillator implantations performed in Spain. Although the number has continued to increase, it still remains far lower than the European average. There has been a significant increase in the number of implantations indicated for primary prevention.

Registro Español de Desfibrilador Automático Implantable. VII Informe Oficial del Grupo de Trabajo de Desfibrilador Automático Implantable de la Sociedad Española de Cardiología (2010)

Palabras clave:
Arritmias
Registro
Desfibrilador

RESUMEN

Introducción y objetivos: Se presentan los resultados del Registro Español de Desfibrilador Automático Implantable de 2010 elaborado por el Grupo de Trabajo de Desfibrilador Automático Implantable de la Sección de Electrofisiología y Arritmias de la Sociedad Española de Cardiología.
Métodos: Se envió de forma prospectiva a la Sociedad Española de Cardiología la hoja de recogida de datos cumplimentada de forma voluntaria por cada equipo implantador.
Resultados: El número de implantes comunicados fue de 4.627 (el 85,6% del total estimado de implantes). El número de implantes por millón de habitantes comunicados fue 100,6 y el estimado, 117,5. Los primoimplantes fueron el 73,87%. Se obtuvieron datos de 143 hospitales (9 más que en 2009). La mayor parte de los desfibriladores automáticos implantables se implantaron en varones (81%). La media de edad fue 62,5 ± 13 años. La mayoría de los pacientes presentaban disfunción ventricular severa o moderada a severa y estaban en clase funcional II de la *New York Heart Association*. La cardiopatía más frecuente fue la isquémica, seguida de la miocardiopatía dilatada. Las indicaciones por prevención primaria han aumentado con respecto al año previo y constituyen el 65,6% de los primoimplantes. El 76,1% de los implantes los realizaron electrofisiólogos.
Conclusiones: El Registro Español de Desfibrilador Automático Implantable de 2010 recoge información de casi el 86% de los implantes de desfibriladores automáticos implantables que se realizan en España. El

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número de estos ha continuado aumentando, aunque sigue alejado de la media europea. Es significativo el incremento de las indicaciones por prevención primaria.

Abbreviations

CRT: cardiac resynchronization therapy
ICD: implantable cardioverter-defibrillator
LVEF: left ventricular ejection fraction
NSMVT: nonsustained monomorphic ventricular tachycardia
SCD: sudden cardiac death
SEC: Spanish Society of Cardiology
SMVT: sustained monomorphic ventricular tachycardia
VF: ventricular fibrillation

INTRODUCTION

The implantable cardioverter-defibrillator (ICD) has been shown to be effective in the primary and secondary prevention of sudden cardiac death (SCD). The results of a number of published studies have made it possible to establish the main indications for ICD implantation, compiled in the clinical guidelines for the management of patients with ventricular arrhythmias or at risk for SCD.[1,2] However, the increased use of these devices has raised questions concerning their efficacy outside the context of clinical trials, the appropriate selection of patients for ICD implantation, access to this therapy, its safety, and its cost-effectiveness.[3] In this respect, given the limited information in the literature concerning these issues and the application of the clinical guidelines in unselected patient populations, health registries may prove to be highly useful.

The present report brings together data on ICD implantation from the Spanish ICD Registry for 2010. It is the result of the collaboration of most of the Spanish centers that implant these devices. Like the official reports that described the activity of the previous years,[4–9] this report has been prepared by members of the Working Group on ICD (GTDAI) of the Electrophysiology and Arrhythmia Section (SEA) of the Spanish Society of Cardiology (SEC).

The main objective of the registry is to enable the examination of key aspects of the current use of the ICD in Spain such as indications, clinical characteristics of the patients, implantation parameters, types of devices and their programming, and procedural complications.

METHODS

The registry data were obtained from a data collection form that is available at the SEC web page (http://www.secardiologia.es/images/stories/file/arritmias/registros-arritmias-hoja-datos-dai.pdf). The form was completed directly and voluntarily by each implantation team, with the collaboration of personnel from the manufacturer of the ICD, during or after implantation of the device and was sent by fax or e-mail to the SEC.

The information was entered into the Spanish ICD Registry by a person engaged for that purpose, with the aid of a computer specialist from the SEC and a member of the GTDAI, who were also in charge of data cleaning. The authors of this article were responsible for data analysis and the preparation of this manuscript.

The census data used to calculate the rates per million population, for the country as a whole and for each autonomous community and province, were obtained from the estimates reported by the Spanish National Institute of Statistics for the period up to 1 January 2010.[10] For the populations of the European countries included, the figures of the U.S. Census Bureau were employed.[11]

To estimate the representativeness of the registry, we calculated the proportion of implantations and replacement procedures reported in relation to the total number of implantations and replacement procedures performed in Spain in 2010. This number was based on the data for that year provided to the European Medical Technology Industry Association (EUCOMED) by the commercial ICD suppliers in Spain.[12]

When more than one type of medical condition or clinical arrhythmia was reported for the same patient, only the most serious condition was included in the analysis.

The percentages for each of the variables analyzed were calculated on the basis of the total number of implantations for which information on that variable was available.

Statistical Analysis

The numerical results are expressed as the mean ± standard deviation or median [interquartile range], depending on the distribution of the values of the variable. The comparison of the continuous quantitative variables was performed using ANOVA or the Kruskal-Wallis test. The qualitative variables were compared by means of the χ^2 test. The relationships between the number of implantations and the number of implantation centers per million population and between the total number of implantations and the number of implantations for primary prevention in each center were assessed using linear regression analysis. The statistical significance of the progressive increase in the proportion of ICD implantations indicated for primary versus secondary prevention was also analyzed.

RESULTS

The response rate for the different items in the data collection form ranged between 57.6% (functional status of the original electrodes in the case of replacements) and 99% (name of implantation center), although for most of the items the response rate was higher than 80%.

Implantation Centers

In all, 145 centers in which ICD implantation was performed made their data available to the registry (9 more than in 2009) (Table 1). Of these, 86 were public hospitals or clinics (6 more than in 2009). Figure 1 shows the total number of ICD implantation centers in each Spanish autonomous community and the number of implantations per million population performed in those centers that provided data to the registry in 2010.