Special article

Spanish Implantable Cardioverter-defibrillator Registry. Twelfth Official Report of the Spanish Society of Cardiology Electrophysiology and Arrhythmias Section (2015)

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A B S T R A C T

Keywords:
Arrhythmias
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Introduction and objectives: We present the results of the Spanish Implantable Cardioverter-defibrillator Registry for 2015, as compiled by the Electrophysiology and Arrhythmia Section of the Spanish Society of Cardiology.
Methods: Data collection sheets were voluntarily completed by each implantation team and prospectively sent to the Spanish Society of Cardiology.
Results: The number of reported implantations was 5465 (85% of the estimated total number of implantations). The implantation rate was 118 per million population while the estimated rate was 138. First implantations comprised 71.8%. Data were obtained from 169 hospitals (7 more than in 2014). Most implantations (82.7%) were performed in men. The mean patient age was 62.8 ± 13.3 years. Most patients showed severe or moderate-to-severe ventricular dysfunction and were in New York Heart Association function class II. The most frequent cardiac condition was ischemic heart disease, followed by dilated cardiomyopathy. Implantations for primary prevention indications comprised 58.2%. Electrophysiologists performed 79.6% of the implantations.
Conclusions: The 2015 Spanish Implantable Cardioverter-defibrillator Registry received information on 85% of the implantations performed in Spain. The number of implantations has grown from previous years. The percentage of implantations for primary prevention indications has slightly decreased from the previous registry.

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Registro Español de Desfibrilador Automático Implantable. XII Informe Oficial de la Sección de Electrofisiología y Arritmias de la Sociedad Española de Cardiología (2015)

R E S U M E N

Palabras clave:
Arritmias
Registro
Desfibrilador

Introducción y objetivos: Se presentan los resultados del Registro Español de Desfibrilador Automático Implantable de 2015, elaborado por 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 voluntariamente por cada equipo implantador.
Resultados: El número de implantes comunicados fue 5.465 (el 85% del total de implantes estimado). La tasa de implantes fue 118 por millón de habitantes y la estimada, 138. Los primoimplantes fueron el 71,8%. Se obtuvieron datos de 169 hospitales (7 más que en 2014). La mayoría de los implantes (82,7%) se realizaron en varones. La media de edad fue 62,8 ± 13,3 años. La mayoría de los pacientes presentaban una disfunción ventricular grave o grave-moderada y clase funcional II de la *New York Heart Association*. La cardiopatía más frecuente fue la isquémica, seguida de la dilatada. Las indicaciones por prevención primaria han sido el 58,2%. Los implantes realizados por electrofisiólogos fueron el 79,6%.
Conclusiones: El Registro Español de Desfibrilador Automático Implantable de 2015 recoge información del 85% de los implantes realizados en España. El número de implantes ha crecido respecto a los datos de los últimos años. El porcentaje de indicación por prevención primaria ha disminuido ligeramente con respecto al registro anterior.

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INTRODUCTION

Implantable cardioverter-defibrillators (ICDs) are useful for the primary and secondary prevention of sudden cardiac death. The main indications for ICD implantation have been derived from numerous studies and have been included in the successive clinical management guidelines of patients with ventricular arrhythmias or at risk of sudden cardiac death.[1–3] However, the increased use of ICD has raised questions about their effectiveness outside the setting of clinical trials, about the real-world selection of patients for implantation, and about the availability, safety, and cost-effectiveness of this therapy.[4] Thus, given the scarcity of information in the medical literature on these aspects and the application of the clinical guidelines to unselected patient populations, health care registries could be extremely useful.

The current study presents the data on ICD implantations reported to the Spanish Implantable Cardioverter-defibrillator Registry in 2015. Most Spanish centers implanting ICDs have contributed to the registry. As in the previous official reports on this activity in Spain,[5–14] this report has been prepared by the members of the Electrophysiology and Arrhythmia Section of the Spanish Society of Cardiology (*Sociedad Española de Cardiología* [SEC]).

The main aim of the registry is to determine the current implantation situation in Spain, with special emphasis on indications, patients' clinical characteristics, implantation data, types of devices, programming, and procedural complications.

METHODS

The registry data were obtained using a data collection form available at the SEC website.[15] Each implantation team directly and voluntarily completed this form during or after the procedure with the help of the technical staff of the ICD manufacturer.

A specially appointed technician introduced the information into the database of the Spanish Implantable Cardioverter-defibrillator Registry, with the help of a computer technician of the SEC and a member of the Electrophysiology and Arrhythmia Section. The computer technician and section member also performed data cleaning. The authors of this article analyzed the data and are responsible for this publication.

The census data for the distinct calculations of rates per million population, both national and by autonomous community and province, were obtained from the estimations of the Spanish National Institute of Statistics as of Friday, January 1, 2016.[16]

To estimate the representativeness of the registry, the proportion of implantations and replacements recorded in the registry was calculated with respect to the total number of implantations and replacements performed in Spain in 2015. This number was based on the data for 2015 reported to the European Confederation of Medical Suppliers Associations (Eucomed) by the suppliers of ICDs in Spain.[17]

If the data collection sheet recorded various clinical presentations or arrhythmias in the same patient, only the most serious condition was included in the analysis.

The percentages of each of the variables analyzed were calculated by taking into account the total number of implantations including information on the analysis variable.

Statistical Analysis

Numerical results are expressed as mean ± standard deviation or median [interquartile range], according to the distribution of the variable. Continuous quantitative variables were compared using analysis of variance or the Kruskal-Wallis test. Qualitative variables were compared using the chi-square test. The relationships between the number of implantations and the devices implanted per million population and the total number of implantations and the number of implantations for primary prevention in each center were studied using linear regression models.

RESULTS

The response rates to the distinct fields of the data collection sheet ranged from 99.4% for the field "name of the implanting hospital" to 25.3% for the field "hospital of origin".

Implanting Centers

A total of 169 hospitals performing ICD implantations reported their data to the registry (162 in 2014). The data from the 169 hospitals are shown in Table 1; 32 forms were excluded due to errors in the center records; 99 hospitals were public centers. The total number of implanting centers, rate per million population, and total number by autonomous community according to the data sent to the registry are shown in Figure 1. During 2015, only 14 centers implanted more than 100 devices; 85, 10 or fewer; and 33, only 1.

Total Number of Implantations

The total number of implantations (first implantations and replacements) in 2015 was 5465, more than in 2014 (total number, 4899). Because the Eucomed data[17] showed a total number of devices of 6406, the registry figure represents 85% of the total. The total number of implantations reported to the registry and those estimated by Eucomed in the last 12 years are shown in Figure 2.

The overall rate of recorded implantations was 118 per million population; according to the Eucomed data, the rate was 138 per million population. The change in the implantation rate per million population during the last 12 years according to the registry and Eucomed data is shown in Figure 3. Implantations reported per implanting center are shown in Table 1.

The implanting hospital was recorded in 99.4% of cases. Most implantations (4958, 90.7%) were performed in public health care centers.

First Implantations vs Replacements

This information was available in 4853 forms sent to the SEC (88.8%). There were 3487 first implantations, representing 71.8% of the total (72.6% in 2014, 68.8% in 2013, 69.4% in 2012, 70.2% in 2011, and 73.8% in 2010). The rate of first implantations per million population was 75.1 in 2015 (79.0 in 2014, 63.8 in 2013, and 64.0 in 2012).