

Special article

# Spanish Implantable Cardioverter-defibrillator Registry. Eleventh Official Report of the Spanish Society of Cardiology Electrophysiology and Arrhythmias Section (2014)



Javier Alzueta,\* Antonio Asso, and Aurelio Quesada

Sección de Electrofisiología y Arritmias, Sociedad Española de Cardiología, Madrid, Spain

Article history:

Available online 9 October 2015

Keywords:

Arrhythmias  
Registry  
Defibrillator

ABSTRACT

**Introduction and objectives:** We present the results of the Spanish Implantable Cardioverter-defibrillator Registry for 2014, 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 4911 (82% of the estimated total number of implantations). The implantation rate was 106 per million population while the estimated rate was 128. First implantations comprised 72.2%. Data were obtained from 162 hospitals (8 more than in 2013). Most implantations (82%) were performed in men. The mean patient age was  $61.8 \pm 13.7$  years. Most patients showed severe or moderate-to-severe ventricular dysfunction and were in New York Heart Association functional class II. The most frequent cardiac condition was ischemic heart disease, followed by dilated cardiomyopathy. Implantations for primary prevention indications comprised 58.5%. Electrophysiologists performed 85.6% of the implantations.

**Conclusions:** The 2014 Spanish Implantable Cardioverter-defibrillator Registry received information on 82% of the implantations performed in Spain. The number of implantations has increased from previous years and the percentage of implantations for primary prevention indications has increased from the previous year.

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## Registro Español de Desfibrilador Automático Implantable. XI Informe Oficial de la Sección de Electrofisiología y Arritmias de la Sociedad Española de Cardiología (2014)

RESUMEN

**Introducción y objetivos:** Se presentan los resultados del Registro Español de Desfibrilador Automático Implantable de 2014, 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 4.911 (el 82% del total de implantes estimado). La tasa de implantes fue 106 por millón de habitantes y la estimada, 128. Los primoimplantes fueron el 72,2%. Se obtuvieron datos de 162 hospitales (8 más que en 2013). La mayoría de los implantes (82%) se realizaron en varones. La media de edad fue  $61,8 \pm 13,7$  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 58,5%. Los implantes realizados por electrofisiólogos fueron el 85,6%.

**Conclusiones:** El Registro Español de Desfibrilador Automático Implantable de 2014 recoge información del 82% 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 aumentado con respecto al registro anterior.

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Palabras clave:

Arritmias  
Registro  
Desfibrilador

\* Corresponding author: Unidad de Arritmias, Servicio de Cardiología, Área del Corazón, Hospital Universitario Virgen de la Victoria, Campus de Teatinos s/n, 29010 Málaga, Spain.

E-mail address: [jalzueta@telefonica.net](mailto:jalzueta@telefonica.net) (J. Alzueta).

## Abbreviations

CRT: cardiac resynchronization therapy  
 EUCOMED: European Medical Technology Industry Association  
 ICD: implantable cardioverter-defibrillator  
 SEC: Spanish Society of Cardiology (*Sociedad Española de Cardiología*)

## INTRODUCTION

Implantable cardioverter-defibrillators (ICD) 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 arrhythmia or at risk of sudden cardiac death.<sup>1–3</sup> 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.<sup>4</sup> Thus, considering the little 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 implantation reported to the Spanish Implantable Cardioverter-defibrillator Registry in 2014. Most Spanish centers implanting ICD have contributed to the registry. As in the previous official reports on this activity in Spain,<sup>5–13</sup> this report has been prepared by the members of the Electrophysiology and Arrhythmia Section of the Spanish Society of Cardiology (SEC, *Sociedad Española de Cardiología*).

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.<sup>14</sup> 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 1 January, 2014.<sup>15</sup>

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 2014. This number was based on the data for 2014 reported to the European Medical Technology Industry Association (EUCOMED) by the suppliers of ICD in Spain.<sup>16</sup>

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  $\pm$  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 99.6% for the name of the implanting hospital to 12.6% for QRS width.

### Implanting Centers

In total, 162 hospitals performing ICD implantations reported their data to the registry (154 in 2013). The data from 152 hospitals are shown in [Table 1](#); 10 centers were excluded due to errors in the data collection sheet. As in the previous year, 90 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 2014, only 13 centers implanted more than 100 devices; 79, fewer than 10; and 32, only 1.

### Total Number of Implantations

The total number of implantations (first implantations and replacements) in 2014 was 4899, more than in 2013 (total number, 4722). Because the EUCOMED data<sup>16</sup> showed a total number of devices of 5980, this figure represents 82% of the total. The total number of implantations reported to the registry and those estimated by the EUCOMED in the last 12 years are shown in [Figure 2](#).

The overall rate of recorded implantations was 106 per million population; according to the EUCOMED data, the rate was 128 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 number of implantations performed in each province and the corresponding rate per million population by autonomous community are shown in [Table 2](#).

The implanting hospital was recorded in 99% of cases. Most implantations, 4506 (92.4%) were performed in public health care centers.

### First Implantations vs Replacements

This information was available in 4741 forms sent to the SEC (96.8%). There were 3446 first implantations, representing 72.6% of

**Table 1**  
Implantations by Autonomous Community, Province, and Hospital

<i>Andalusia</i>		
Almería	Hospital Torrecárdenas	15
Cádiz	Hospital de Jerez	20
	Hospital Universitario de Puerto Real	12
	Hospital Universitario Puerta del Mar	44
Córdoba	Hospital de la Cruz Roja de Córdoba	3
	Hospital Reina Sofía de Córdoba	54
Granada	Hospital Clínico Universitario San Cecilio	9
	Hospital Clínico de Granada	2
	Hospital Universitario Virgen de las Nieves	96
Huelva	Hospital General Juan Ramón Jiménez	50
Jaén	Complejo Hospitalario de Jaén	34
Málaga	Clínica El Ángel	6
	Clínica Parque San Antonio	11
	Hospital Internacional Xanit	13
	Clínica Quirón de Málaga	2
	Clínica Quirón de Marbella	8
	Hospital Virgen de la Victoria	212
	Hospiten Estepona	1
Seville	Clínica Sagrado Corazón, S.A.	1
	Clínica San Juan de Dios	2
	Hospital Infanta Luisa (Clínica Esperanza de Triana)	7
	Hospital Nisa Aljarafe	1
	Hospital Viamed Santa Ángela de la Cruz	1
	Clínica Santa Isabel	7
	Hospital Nuestra Señora de Valme	60
	Hospital Virgen Macarena	75
	Hospital Virgen del Rocío	84
<i>Aragon</i>		
Zaragoza	Hospital Quirón Zaragoza	3
	Hospital Clínico Universitario Lozano Blesa	34
	Hospital Miguel Servet	94
<i>Principality of Asturias</i>	Hospital Central de Asturias	150
<i>Balearic Islands</i>		
	Clínica Juaneda	1
	Clínica Quirón Palmaplanas	5
	Hospital Son Llàtzer	23
	Hospital Universitari Son Espases	61
	Clínica Rotger Sanitaria Balear, S.A.	1
	Policlínica Miramar (AMEBA S.A.)	2
<i>Canary Islands</i>		
Las Palmas	Hospital Dr. Negrín	26
	Hospital Insular de Gran Canaria	36
Sta. Cruz de Tenerife	Clínica Santa Cruz	1
	Hospital Nuestra Señora de la Candelaria	40
	Hospital Universitario de Canarias	68
	Hospiten Ramblas	1
	USP Hospital La Colina	2
<i>Cantabria</i>	Hospital Universitario Marqués de Valdecilla	75
	Igualatorio de Cantabria	1
<i>Castile and León</i>		
Ávila	Hospital Nuestra Señora de Sonsoles	12
Burgos	Hospital Universitario de Burgos, S.A. (HUBU)	68
Leon	Hospital de León	57
Salamanca	Complejo Hospitalario de Salamanca	76

**Table 1 (Continued)**  
Implantations by Autonomous Community, Province, and Hospital

Valladolid	Hospital Campo Grande	5
	Hospital Río Hortega	28
	Hospital Sagrado Corazón de Jesús	2
	Hospital Clínico Universitario de Valladolid	82
<i>Castile-La-Mancha</i>		
Albacete	Clínica Recoletas de Albacete	1
	Hospital General de Albacete	35
	Sanatorio Sta. Cristina	1
Ciudad Real	Hospital General de Ciudad Real	39
Cuenca	Hospital Virgen de la Luz	9
Guadalajara	Hospital General y Universitario de Guadalajara	31
Toledo	Hospital Nuestra Señora del Prado	14
	Hospital Virgen de la Salud	117
<i>Catalonia</i>		
Barcelona	Centre Cardiovascular Sant Jordi, S.A.	1
	Centro Médico Teknon	3
	Clínica Delfos	1
	Clínica Pilar Sant Jordi	6
	Clínica Quirón	1
	Clínica Sagrada Familia	2
	Hospital Clínic de Barcelona	199
	Hospital de Bellvitge	104
	Fundació de G.S. de l'Hospital de la Santa Creu i Sant Pau	130
	Hospital del Mar	20
	Capio Hospital General de Catalunya	13
	Hospital Germans Trias i Pujol	51
	Hospital Sant Joan de Déu	2
	Hospital Vall d'Hebron	76
Lleida	Hospital Universitario Arnau de Vilanova	18
Tarragona	Hospital Universitario de Tarragona Joan XXIII	17
	Hospital de Sant Pau i Santa Tecla	8
<i>Valencian Community</i>		
Alicante	Clínica Benidorm	1
	Hospital General Universitari d'Alacant	152
	Hospital IMED de Levante	2
	Hospital Universitari Sant Joan d'Alacant	31
	Sanatorio del Perpetuo Socorro	1
Castellón	Hospital General de Castelló	26
	Hospital Rey Don Jaime	1
Valencia	Grupo Hospitalario Quirón, S.A.	1
	Hospital Arnau de Vilanova	2
	Hospital Clínico Universitario	71
	Hospital de Manises	7
	Hospital General Universitario	52
	Hospital Universitari de la Ribera	32
	Hospital Universitario Dr. Peset	40
	Hospital Universitario La Fe	121
<i>Extremadura</i>		
Badajoz	Clídeba. IDC SALUD	4
	Hospital Infanta Cristina de Badajoz	124
Cáceres	Clínica Quirúrgica Cacerreña	1
	Clínica San Francisco	1
	Complejo Hospitalario de Cáceres	32
	Hospital San Pedro de Alcántara	6

**Table 1 (Continued)**  
Implantations by Autonomous Community, Province, and Hospital

Galicia		
A Coruña	Complejo Hospitalario Universitario de Santiago	91
	Complejo Hospitalario Universitario A Coruña	127
	Hospital USP Santa Teresa	6
	Hospital HM Modelo	1
Pontevedra	Complejo Hospitalario Universitario de Vigo (CHUVI)	104
	Hospital Miguel Domínguez	3
	Hospital Povisa	1
	Hospital Provincial de Pontevedra	1
La Rioja	Hospital San Pedro	32
Community of Madrid	Clínica La Luz	3
	Clínica Moncloa ASIS	1
	Clínica Ruber	1
	Clínica Sanitas La Moraleja	2
	Fundación Hospital Alcorcón	13
	Fundación Jiménez Díaz. Clínica Nuestra Señora de la Concepción	42
	Grupo Hospital de Madrid (H. Norte y H. Montepíncipe)	11
	Hospital 12 de Octubre	70
	Hospital Central de la Defensa	17
	Hospital Clínico San Carlos	113
	Hospital de Fuenlabrada	7
	Hospital de Torrejón	16
	Hospital General Universitario Gregorio Marañón	86
	Hospital Infanta Cristina de Parla	3
	Hospital Infanta Elena de Valdemoro	2
	Hospital Infanta Leonor de Madrid	5
	Hospital Quirón de Madrid	5
	Hospital Ramón y Cajal	86
	Hospital Rey Juan Carlos	13
	Hospital Ruber Internacional	3
	Hospital San Rafael	3
	Hospital Sanitas La Moraleja	2
	Hospital Severo Ochoa	13
	Hospital Sur de Alcorcón	3
	Hospital Universitario de Getafe	14
	Hospital Universitario La Paz	86
	Hospital Universitario Puerta de Hierro de Majadahonda	129
	Hospital Virgen de la Paloma	5
	Hospital Virgen del Mar	3
	Hospital Vithas Nuestra Señora de América	7
	Sanatorio San Francisco de Asís	2
Region of Murcia	Hospital General Universitario Morales Meseguer	4
	Hospital General Universitario Reina Sofía	11
	Hospital General Universitario Santa Lucía	1
	Hospital Rafael Méndez	15
	Hospital Universitario Virgen de la Arrixaca	92

**Table 1 (Continued)**  
Implantations by Autonomous Community, Province, and Hospital

Chartered Community of Navarre	Hospital de Navarra	41
	Clínica Universitaria de Navarra	42
Basque Country		
Álava	Hospital Universitario de Araba	43
Guipúzcoa	Hospital Universitario Donostia	8
Vizcaya	Hospital de Basurto	32
	Hospital de Cruces	42
	Hospital de Galdakao-Usansolo	23
No data		23

the total (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 79.0 in 2014 (63.8 in 2013; and 64 in 2012).

### Age and Sex

The mean age ± standard deviation [interval] of patients receiving an ICD implantation or replacement was 61.8 ± 13.7 [7–94] years. In first implantation patients, the age was 60.9 ± 13.4 years. Most patients were men, who represented 82.00% of all patients and 81.57% of first implantation patients.

### Underlying Heart Disease, Left Ventricular Ejection Fraction, Functional Class, and Baseline Rhythm

The most frequent underlying cardiac condition in first implantation patients was ischemic heart disease (53.6%), followed by dilated cardiomyopathy (27.3%), hypertrophic (7.1%), the group of primary conduction abnormalities (Brugada syndrome, idiopathic ventricular fibrillation, and long QT syndrome) (2.6%), and, at lower percentages, valve diseases and arrhythmogenic dysplasias (Figure 4).

Left ventricular fraction was < 30% in 53.8% of first implantation patients, 30% to 40% in 24.6%, 41% to 50% in 6.6%, and > 50% in 15%. Patients who underwent ICD replacement showed a similar distribution (Figure 5). These data were recorded in 80.7% of the data collection sheets of the registry.

With respect to the New York Heart Association (NYHA) functional class, most patients were in NYHA II (48.7%), followed by NYHA III (32.6%), NYHA I (16.7%), and NYHA IV (2.1%). For this parameter, the distribution was also similar between total implantations and first implantations (Figure 6), and these data were reported in 58.6% of the data collection sheets.

The baseline rhythm, reported in 85.3% of the patients, was largely sinus (79.3%), followed by atrial fibrillation (16.5%) and pacemaker rhythm (3.9%); the remaining patients had other rhythms (atrial flutter and other arrhythmias).

### Clinical Arrhythmia Prompting Device Implantation, Its Form of Presentation, and the Arrhythmia Induced in the Electrophysiological Study

These data were contained in 80.7% of the registry forms. For first implantations, most patients had no documented clinical arrhythmias (54.7%), followed by those with sustained monomorphic ventricular tachycardia, nonsustained ventricular tachycardia, and ventricular fibrillation (18.7%, 13.8%, and 11.2%, respectively). In total, patients with no documented clinical arrhythmia comprised



Figure 1. Distribution of activity by autonomous community in 2014: number of implanting centers/rate per million population/total number of implantations.

54.7% (Figure 7). The differences in the type of arrhythmia between the first implantation group and the total were significant for patients with polymorphic ventricular tachycardia ( $P < .001$ ). There were no significant differences in the other categories. The most frequent clinical presentation in both the total implantation group and the first implantation patients (62.2% and 68.9% of completed

responses) was asymptomatic, followed by syncope, cardiac arrest, and “other symptoms” (Figure 8).

Data on electrophysiological studies were available for 1525 first implantation patients (44.3%). Such studies were performed in only 244 patients (13.8%). Sustained monomorphic ventricular tachycardia was the most common induced arrhythmia

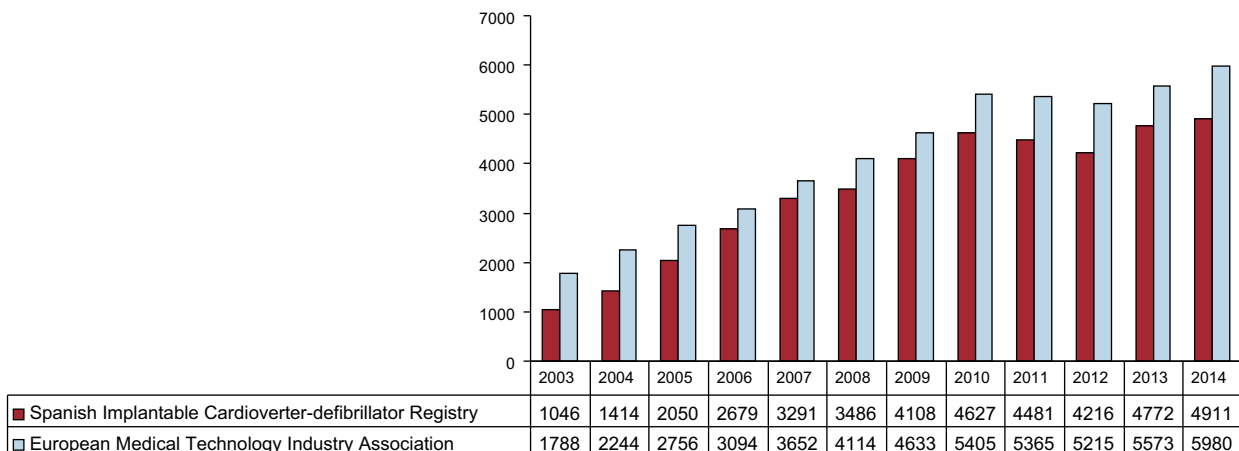
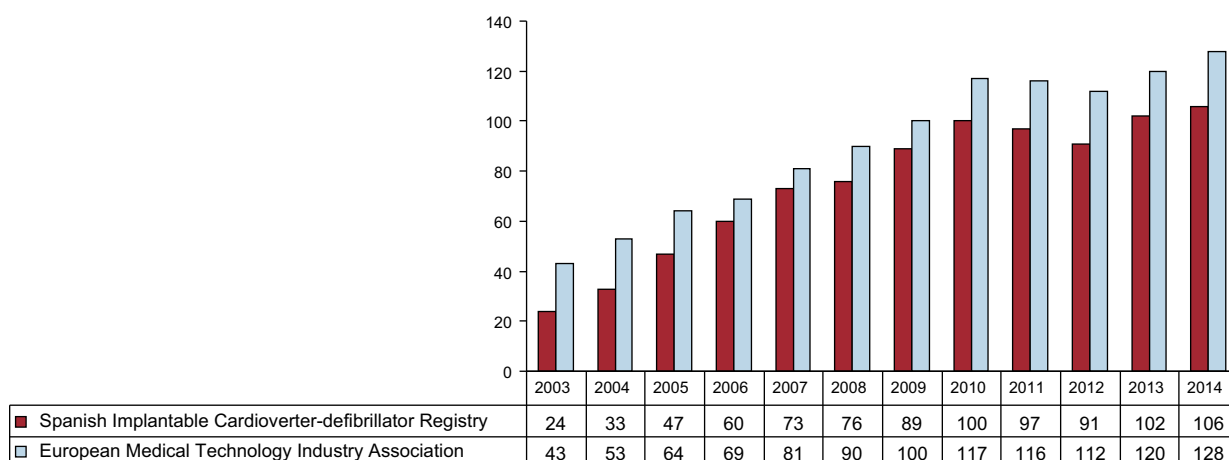


Figure 2. Total number of implantations recorded and those estimated by the European Medical Technology Industry Association from 2003 to 2014.



**Figure 3.** Total number of implantations recorded per million population and those estimated by the European Medical Technology Industry Association from 2003 to 2014.

(43.0%), followed by ventricular fibrillation (17.6%) and, to a lesser extent, nonsustained ventricular tachycardia (11.5%) and others (3.3%). No arrhythmia was induced in 24.5% of the electrophysiological studies. Most of these studies were performed in patients with ischemic heart disease or dilated cardiomyopathy.

### Clinical History

Data on the clinical history of patients have only been available since 2011 because such data were not previously recorded.

Responses to questions on clinical history were obtained for between 66.8% and 82.1% of first implantation patients, with the following findings: hypertension, 58.8%; hypercholesterolemia, 51.2%; smoking, 36.9%; diabetes mellitus, 31.8%; history of atrial fibrillation, 25.0%; kidney failure, 13.6%; history of sudden cardiac death, 7.3%; and stroke, 5.0%.

The QRS width was recorded in 37.1% of the forms (mean, 122.6 ms ± 37 ms). In 33.4% of the patients, the recorded width was > 140 ms. Of these patients, 83.3% of the first implantation patients and 83.7% of the total had a defibrillator-resynchronization device (ICD-CRT [cardiac resynchronization therapy]) device.

### Indications

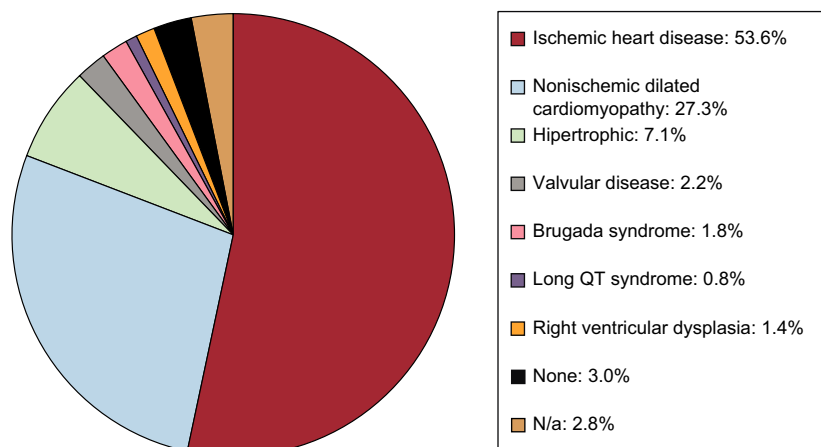
The changes in the type of heart disease and presentation in first implantation patients from 2010 to 2014 are shown in Table 3.

Data on this parameter were recorded in 85% of the registry collection sheets. For ischemic heart disease, the most frequent indication was prophylactic prevention (45.5%), representing a slight decrease from the previous year (48.8%). For dilated cardiomyopathy, the main indication was also prophylactic (47% vs 52.1% in 2013 and 62.3% in 2012). For less common heart diseases, the most frequent indication was primary prevention of hypertrophic cardiomyopathy, valve diseases, congenital diseases, and Brugada syndrome. For long QT syndrome, secondary prevention was the most common indication.

The implantation indication was reported in 65% of the records. Most first implantations were indicated for primary prevention (58.5%), reversing the decreasing trend of the previous 2 years. This variability has been growing, and was statistically significant until 2008, in 2009 and 2010, and in 2013 and 2014 ( $P < .02$ ) (Table 4).

### Implantation Setting and Attending Specialist

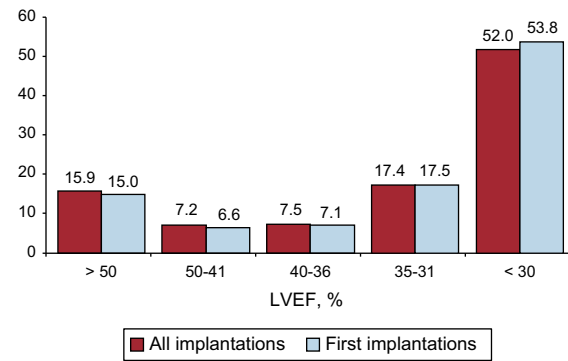
There was an 87.4% response rate to these questions. In 83.4%, the main implantation location was the electrophysiology laboratory (79.8% in 2013, 81.4% in 2012, and 76.4% in 2011), followed by the operating room (15.0%). Electrophysiologists performed 81.7% of implantations (80.7% in 2013; 81.0% in 2012; and 78.4% in 2011); surgeons, 11.0% (13.8% in 2013; 14.0% in 2012; and 15.5% in 2011); both specialist types, 4.6%; and other specialists and intensivists, 1.4% and 1.3%, respectively.



**Figure 4.** Type of heart disease prompting implantation (first implantations). Sole diagnosis.

**Table 2**  
Implantations by Autonomous Community and Province

Autonomous community	Rate per 10 <sup>6</sup> inhabitants	Province	Implantations, no.
Andalusia	98.9	Almería	15
		Cádiz	76
		Córdoba	57
		Granada	107
		Huelva	50
		Jaén	34
		Málaga	253
		Seville	238
		Aragon	98.4
Principality of Asturias	138.8	Asturias	150
Balearic Islands	83.3	Balearics	93
		Las Palmas	62
Canary Islands	82.3	Sta. Cruz de Tenerife	112
Cantabria	124.2	Cantabria	75
Castile and León	132.2	Ávila	12
		Burgos	68
		Leon	57
		Salamanca	76
		Valladolid	117
Castile-La-Mancha	119.9	Albacete	37
		Ciudad Real	39
		Cuenca	9
		Guadalajara	31
		Toledo	131
Catalonia	87.9	Barcelona	609
		Lleida	18
		Tarragona	25
Valencian Community	109.2	Alicante	186
		Castellón	27
		Valencia	327
Extremadura	153.2	Badajoz	128
		Cáceres	40
Galicia	121.2	A Coruña	225
		Pontevedra	109
La Rioja	101.5	La Rioja	32
Community of Madrid	120.1	Madrid	766
Region of Murcia	48.1	Murcia	123
Chartered Community of Navarre	130.4	Navarra	83
Basque Country	70.6	Álava	53
		Guipúzcoa	8
		Vizcaya	97
No data			23



**Figure 5.** Left ventricular ejection fraction of the registry patients (total and first implantations). LVEF, left ventricular ejection fraction.

### Device Type

This information was available in 94.9% of the records and is summarized in Table 5. Single-chamber devices comprised 48.8% of implanted ICD (48.2% in 2013 and 49.4% in 2012), dual-chamber devices comprised 17.4% (18.9% in 2013 and 18.0% in 2012), and ICD-CRT devices comprised 33.7% (32.9% in 2013 and 32.5% in 2012).

In patients with ischemic heart disease, 76.8% of implants (74.8% in 2013 and 72.3% in 2012) were single- or double-chamber devices and 23.1% (25.5% in 2013 and 27.7% in 2012) were ICD-CRT devices. In patients with dilated cardiomyopathy, ICD-CRT devices comprised 53.7% (51.7% in 2013 and 56.5% in 2012).

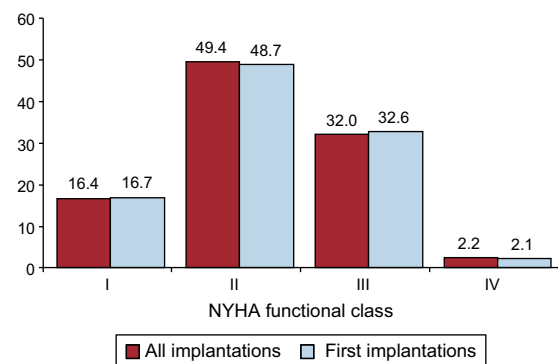
### Reasons for Device Replacement, Need for Lead Replacement, and Use of Additional Leads

Of the 1282 replacements, information was available on 976 (76.1%). The most frequent reason for replacement was battery depletion (83.5%); complications motivated 7.9% (same as in 2013) and a change of indication prompted 8.6%. Of the latter, 84 replacements or 9.62% (11.6% in 2013) were required before 6 months.

Information was available on the status of the leads in 70.8% of the replacements; 9.3% were malfunctioning (85 records) and they were extracted in 46% of the patients reporting this problem.

### Device Programming

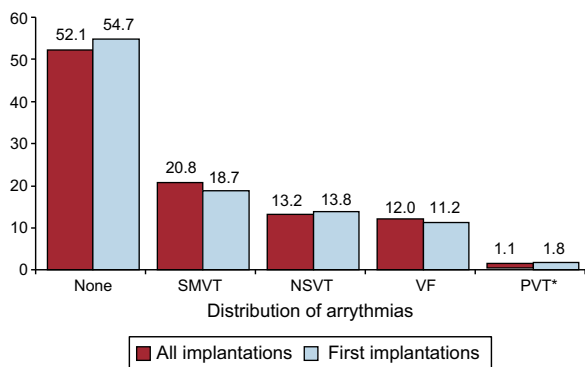
Information on this parameter was provided in 73.5% of records. The most widely used programming was VVI (54.1%), followed by



**Figure 6.** New York Heart Association functional class of the total and first implantation patients in the registry. NYHA, New York Heart Association.

### Generator Placement Site

Information on the placement of first implantations was provided in 2906 forms (87.8%). Placement was subcutaneous in 95.2% of patients and subpectoral in the remaining 4.8%. The figures were also 95.2% and 4.8% for all devices implanted, respectively.



**Figure 7.** Distribution of arrhythmias prompting implantation (first implantations and total). NSVT, nonsustained ventricular tachycardia; PVT, polymorphic ventricular tachycardia; SMVT, sustained monomorphic ventricular tachycardia; VF, ventricular fibrillation. \**P* < .001.

DDD (31.6%), VVIR (6.4%), DDDR (5.1%), and other modes, largely algorithms to prevent ventricular pacing (2.3%).

Induction of ventricular fibrillation was tested in 128 patients, 2.9% (5.1% in 2013 and 6.7% in 2012) of the 4385 records providing this information. The mean threshold was  $19.7 \pm 6.8$  ( $20.4 \pm 6.5$  in 2013 and  $20.5 \pm 7.1$  in 2012) and the mean number of shocks was 1.3.

### Complications

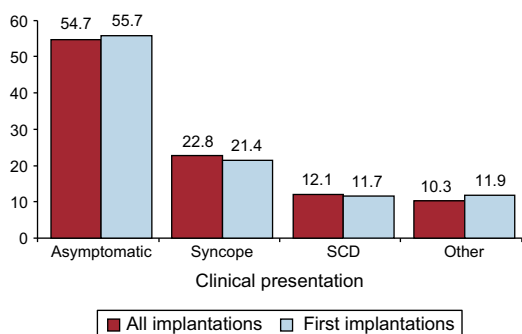
With a response rate of 83.6%, 27 complications were reported: 6 coronary sinus dissections, 5 pneumothoraces, 3 tamponades, 2 deaths, and 11 unspecified complications. The mortality rate was 0.05%, the same as in the previous year (0.05%).

### DISCUSSION

The 2014 data of the Spanish Implantable Cardioverter-defibrillator Registry continue to adequately reflect the implantation situation in Spain. The registry information is pertinent, particularly the number of implants, type of implant, indications, and patients' clinical characteristics.

### Comparison With Registries of Previous Years

The Spanish Implantable Cardioverter-defibrillator Registry was first published in 2005 with the results of 2002 to 2004.<sup>4</sup> The number of implanted ICD increased each year until 2010,<sup>5–10</sup> with 2011 and 2012 then showing a decreased total number of implantations, in both the registry<sup>11,12</sup> and EUCOMED data. In



**Figure 8.** Clinical presentation of the arrhythmia in the registry patients (first implantations and total). SCD, sudden cardiac death.

2013, the number of implantations rose again, exceeding the figures of the 2010 registry, and the number of implanted devices has increased further in 2014. A continual increase was also seen in Europe, in both the number of ICD and the number of ICD-CRTs.<sup>16</sup>

In contrast to 2013,<sup>13</sup> when a decrease was seen in the percentage of implantations for primary indications, the current registry found an increase (58.3% vs 53.0%), with the percentage now exceeding that of 2012 (58.1%).<sup>12</sup>

There was a slight increment in the percentage of ICD-CRT implantations (33.7% vs 32.9% in 2013 and 32.5% in 2012). The percentage of single-chamber ICD stabilized (48.8% vs 48.2% in 2013 and 49.4% in 2012). There were practically no variations in the use of dual-chamber ICD (17.4% vs 18.9% in 2013 and 18.0% in 2012). The resynchronization rate has slightly increased in recent years, and no major changes are expected, unless the resynchronization indications are updated.

The most frequent indication in 2014 continued to be ischemic heart disease (53.6%), followed by dilated cardiomyopathy (27.3%). As in previous years,<sup>13</sup> more than half of the implantations in patients with dilated cardiomyopathy were of ICD-CRT devices (53.7%). The incidence was lower in patients with ischemic heart disease (23.1%).

The progressive increase in the number of ICD implantations stopped in 2011 and 2012. The 2013 results showed somewhat of a recovery with the total number of implantations slightly surpassing the rate per million population of 2010 (102 vs 100).<sup>13</sup> This increase was confirmed by the data for 2014, with an implantation rate of 106 in our registry.

No recent studies have modified the ICD implantation indications. In 2002, the Multicenter Automatic Defibrillator Implantation Trial II<sup>17</sup> study was published, followed by the Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure<sup>18</sup> in 2005 and the Sudden Cardiac Death in Heart Failure Trial<sup>19</sup> in 2006, which established the current indications in primary prevention and cardiac resynchronization and triggered a progressive increase in the number of implantations during that decade. The indications for ICD and CRT implantation are well supported in clinical practice guidelines.<sup>20–25</sup> However, the implantation rate per million population does not correspond with that expected from the clinical evidence, both in Spain and in other European countries,<sup>26</sup> a tendency that has become consolidated with time in these countries.

As in previous registries, the 2014 registry represents 82% of the implantations reported to the EUCOMED (85% in 2013). Most of the hospitals implanting ICD provided the registry with data but 100% participation of the implanting centers remains to be reached. In addition, some data are lost while being sent and processed. All of these factors can explain the differences from the EUCOMED data.

The number of implanting centers slightly increased from 2013. One hospital reported more than 200 implantations; 11 hospitals (14 in 2013 and 8 in 2011) reported more than 100 implantations, and 68 centers, mainly private, reported less than 10 implantations. Some studies have shown an inverse relationship between the implantation volume and the number of complications.<sup>27</sup>

There were no changes from previous registries in the epidemiological characteristics of the patients. Patients with severe ventricular dysfunction and in NYHA II and III continue to predominate. The growing tendency for implantations to be performed in the electrophysiology laboratory continues (83.4% vs 79.8% in 2013 and 81.4% in 2012), as well as those performed by electrophysiologists (81.7% vs 80.7% in 2013 and 81% in 2012).

### Differences Among Autonomous Communities

Differences among autonomous communities continue to be evident. The implantation rate was 106 per million population and



**Table 3**

Number of First Implantations According to the Type of Heart Disease, Type of Clinical Arrhythmia, and Form of Presentation From 2009 to 2014

	2010	2011	2012	2013	2014
<i>Ischemic heart disease</i>					
Aborted SCD	154 (10.0)	150 (10.8)	134 (9.9)	135 (10.5)	141 (6.7)
SMVT with syncope	132 (8.6)	199 (14.4)	110 (8.1)	160 (11.9)	173 (10.6)
SMVT without syncope	317 (20.7)	197 (14.2)	148 (10.9)	179 (13.3)	108 (6.6)
Syncope without arrhythmia	68 (4.4)	95 (6.8)	77 (5.7)	43 (3.2)	70 (4.3)
Prophylactic indication	642 (42.0)	623 (45.0)	682 (50.5)	657 (48.8)	740 (45.5)
Missing/unclassifiable	212 (13.9)	120 (8.7)	200 (14.8)	169 (12.6)	393 (24.8)
Subtotal	1525	1384	1351	1343	1625
<i>Dilated cardiomyopathy</i>					
Aborted SCD	49 (6.0)	47 (5.9)	50 (6.6)	46 (6.0)	25 (6.8)
SMVT with syncope	58 (7.1)	57 (7.1)	44 (5.8)	79 (10.4)	72 (8.5)
SMVT without syncope	136 (16.8)	157 (19.6)	46 (6.0)	81 (10.7)	111 (13.4)
Syncope without arrhythmia	34 (4.2)	37 (4.6)	38 (5.0)	49 (6.5)	37 (4.3)
Prophylactic indication	393 (48.7)	427 (53.4)	473 (62.3)	395 (52.1)	400 (47.0)
Missing/unclassifiable	136 (16.8)	74 (9.3)	108 (14.2)	108 (14.2)	173 (20.3)
Subtotal	806	799	759	758	851
<i>Valvular heart disease</i>					
Aborted SCD	9 (8.3)	16 (10.8)	15 (13.4)	11 (10.2)	11 (9.0)
SMVT	29 (26.8)	47 (31.8)	24 (21.6)	41 (37.9)	38 (31.5)
Syncope without arrhythmias	4 (3.7)	5 (3.4)	12 (10.8)	4 (3.7)	7 (5.7)
Prophylactic indication	50 (46.2)	66 (44.6)	48 (43.2)	38 (35.2)	46 (37.7)
Missing/unclassifiable	16 (14.8)	14 (9.6)	12 (10.8)	14 (12.9)	20 (16.4)
Subtotal	108	148	111	108	126
<i>Hypertrophic cardiomyopathy</i>					
Secondary prevention	90 (54.5)	52 (27.9)	53 (26)	58 (29.9)	62 (25.8)
Prophylactic indication	53 (32.1)	127 (68.8)	140 (68.6)	131 (67.5)	166 (69.2)
Missing/unclassifiable	22 (13.2)	7 (3.8)	11 (5.3)	5 (2.8)	12 (5.0)
Subtotal	165	186	204	194	240
<i>Brugada syndrome</i>					
Aborted SCD	17 (24.6)	7 (13.5)	11 (14.1)	9 (13.6)	8 (13.7)
Prophylactic implantation in syncope	18 (26.6)	25 (40.8)	22 (28.2)	28 (42.4)	17 (29.3)
Prophylactic implantation without syncope	23 (33.3)	15 (28.8)	42 (53.8)	18 (27.2)	22 (37.9)
Missing/unclassifiable	11 (15.9)	5 (9.6)	3 (3.8)	11 (16.7)	11 (18.9)
Subtotal	69	52	78	66	60
<i>ARVC</i>					
Aborted SCD	4 (15.9)	2 (4.6)	1 (3.3)	5 (12.2)	6 (13.3)
SMVT	23 (71.8)	21 (48.8)	11 (33.3)	14 (34.5)	16 (35.5)
Prophylactic implantation	4 (12.5)	17 (39.5)	13 (39.4)	14 (34.5)	16 (35.5)
Missing/unclassifiable	1 (3.1)	3 (6.9)	8 (24.4)	8 (19.5)	7 (15.5)
Subtotal	32	43	33	41	45
<i>Congenital heart disease</i>					
Aborted SCD	3 (8.1)	4 (12.5)	6 (20.0)	4 (17.4)	5 (13.9)
SMVT	15 (40.5)	8 (25.0)	7 (23.3)	6 (26.1)	7 (19.4)
Prophylactic implantation	16 (43.2)	15 (46.8)	12 (40.0)	10 (43.5)	15 (41.7)
Missing/unclassifiable	3 (8.1)	5 (15.4)	5 (16.6)	3 (13.4)	9 (25.0)
Subtotal	37	32	30	23	36
<i>Long QT syndrome</i>					
Aborted SCD	18 (60.0)	11 (50.0)	10 (41.6)	19 (48.7)	19 (70.4)
Prophylactic implantation	6 (20.0)	9 (40.9)	10 (41.6)	18 (46.1)	5 (18.5)
Missing/unclassifiable	6 (20.0)	2 (9.1)	4 (16.6)	2 (5.3)	3 (11.1)
Subtotal	30	22	24	39	26

ARVC, arrhythmogenic right ventricular cardiomyopathy; SCD, sudden cardiac death; SMVT, sustained monomorphic ventricular tachycardia. Data are expressed as No. (%).

**Table 4**  
Changes in the Main Indications for Implantable Cardioverter-defibrillators (First Implantations, 2003–2014)

Year	SCD	SMVT	Syncope	Primary prevention
2003	13.7	42.8	14.0	29.0
2004	14.8	37.0	16.0	32.2*
2005	11.1	34.8	14.6	39.5*
2006	9.5	27.0	13.2	50.3*
2007	9.9	25.0	14.1	50.7*
2008	9.3	21.4	12.3	57.0*
2009	9.4	20.8	13.9	55.9
2010	10.9	20.6	11.1	57.1*
2011	10.7	15.1	14.6	59.4
2012	12.5	10.2	19.1	58.1
2013	13.5	11.1	22.4	53.0*
2014	13.2	17.9	10.2	58.5*

SCD, sudden cardiac death; SMVT, sustained monomorphic ventricular tachycardia.  
\* Significant difference compared with the previous year ( $P < .02$ ), the previous year.

128 according to the EUCOMED data; both databases showed an increase from 2012 (102 and 120). Several autonomous communities showed higher rates than the average: Extremadura (153 implantations per million), Principality of Asturias (138), Castile and León (132), the Chartered Community of Navarre (130), Galicia (121), Cantabria (124), Community of Madrid (120), Castile-La-Mancha (119), and the Valencian Community (109). The following were below the average: Andalusia (99), Aragon (98), Catalonia (88), the Region of Murcia (84), the Balearic Islands (83), the Canary Islands (82), and the Basque Country (71). Although the difference between communities with the highest and lowest rates of implantations is currently more than double (153 vs 71), it is lower than in the previous registry (186 vs 71). The number of implantations markedly increased in the Community of Madrid and in Castile-La-Mancha and Castile and León. There was a decrease in the Principality of Asturias and slight decreases in Extremadura, the Chartered Community of Navarre, the Basque Country, and the Valencian Community.

The 2014 data confirm the general increase in Spanish implantation activity seen in the previous registry, which was more acute in the communities with rates below the average. There was no association between the gross domestic product of the community and the number of implantations. Curiously, most high-income communities incomes were below the mean. The communities above the mean are the least populated, except for the Community of Madrid and the Valencian Community. There was also no relationship between the incidence of ischemic heart disease and heart failure in the various communities. There are other possible explanations for these differences, such as the health care organization of each community, the number of arrhythmia units, and the distribution of the referral hospitals.

### Comparison With Other Countries

Including ICD and ICD-CRT, the implantation rate in the countries participating in the EUCOMED was 302 per million population

(289 in 2013). Germany, with 555 devices per million population, is still the country with the highest number of implantations. Spain (126 implantations per million) was the country with the lowest number of implantations. Above the average are the Netherlands (377 implantations per million), Italy (394), Denmark (313), and the Czech Republic (358). Below the average are Poland (296), Austria (278), Ireland (242), Belgium (235), Sweden (226), Norway (221), France (208), Switzerland (226), Finland (215), the United Kingdom (195), Portugal (148), Greece (144), and Spain (126). The difference in the implantation rate in Spain from the European mean continues to grow (126 vs 302 in 2014 and 120 vs 289 in 2013). The difference between Spain and the second-last country persists (126 vs 144).

The ICD implantation rate was 183 per million population in 2013 (176 in 2012). Germany (340 implantations per million population) had the highest number of implantations, whereas Spain (84) had the lowest.

The ICD-CRT implantation rate was 119 per million population (113 in 2013). Germany (215 implantations per million population) continued to be first, whereas Spain (44) had the lowest implantation rate.

The proportion of ICD-CRT with respect to the total varies from 29% in Ireland and Poland to 45% in the Czech Republic and United Kingdom. The European average is 39%. Above the average are Austria, France, Switzerland, the United Kingdom, Italy, and the Czech Republic, whereas Ireland and Poland are below 30%. Spain has a proportion of 35%.

These countries had the same regional differences<sup>28,29</sup> seen in the Spanish registry, for unknown reasons. One possible explanation is the number of available arrhythmia units, but that does not explain the relationship, at least in Spain, because communities with the highest number of available units had lower implantation rates. Other explanations, such as per capita income, also fail to show a correlation, with countries such as Ireland, the Czech Republic, and Poland showing much greater implantation rates than Spain. The prevalence of cardiovascular diseases, access to the health care system and its organization, and the degree of acceptance of and adherence to the clinical practice guidelines could be related to the rate and variability of implantations in Spain.

### Limitations

The registry included 82% of implantations performed in Spain according to the EUCOMED data. This figure is lower than that of the previous year (85.6%) but higher than that of 2012 (80.8%). The percentage has decreased from 2007, when the representativeness was 90%. Nonetheless, the number of registered implantations continues to accurately reflect the situation in Spain and the number of participating centers has remained practically unchanged in the last 2 years.

The true number of implantations in some hospitals differs from that reported to the registry, given that the registry only includes the data collection sheets received. Because data can now be sent in various ways, some sheets were not received or correctly registered. Indeed, 2015 will be a year of transition as the registry data will be collected in 2 ways, on paper and via the Internet. From 2016, all data will be collected via the website, which should

**Table 5**  
Distribution (%) of the Types of Devices Implanted

	2010, total	2011, total	2012, total	2013, total	2013, first implantations	2014, total	2014, first implantations
Single-chamber	50.3	46.7	49.4	48.2	50.9	48.8	53.4
Dual-chamber	20.2	18.4	18.0	18.9	19.5	17.4	16.3
Resynchronization device	28.2	34.9	32.5	32.9	29.5	33.7	30.3

improve the results and minimize the differences between the data obtained and those provided by the EUCOMED.

There is excessive variability in the percentage of responses to the various questions in the ICD registry sheet, ranging from 99.6% for the implanting hospital to 37.1% for QRS width. Finally, the percentage of complications reported to the registry fails to reflect reality because these data are provided during or immediately after the implantation, meaning that most subacute complications are not recorded.

### Future Prospects of the Spanish Implantable Cardioverter-defibrillator Registry

This registry is the XI official report. The durability of this registry is a credit to all of the participating members of the Section of Electrophysiology and Arrhythmias of the SEC. The continued modernization of the registry will allow more and better information to be obtained with less effort on the part of the staff involved in its maintenance. The quality of the information will improve with further computerization of the registry, and the completion of certain fields will be obligatory. In the future, it may permit more ambitious clinical objectives and include parameters such as death, shocks, and complications that provide relevant clinical information.

### CONCLUSIONS

The 2014 Spanish Implantable Cardioverter-defibrillator Registry collected information on 82% of all implantations performed in Spain and continues to be representative of the activity and current indications of this therapy in Spain. After 2 years of decreases in the number of implantations, a recovery was seen in 2013, which was confirmed this year with a figure of 106 per million population. As in previous years, the total number of implantations in Spain continues to be much lower than the average for the European Union, with the difference continuing to grow, and the autonomous communities continue to show considerable variability.

### ACKNOWLEDGMENTS

We would like to thank all of the health care professionals involved in ICD implantation in Spain who have voluntarily and selflessly contributed to the ultimate success of the registry. We also thank José María Fernández, an SEC fellow who maintains the database of the Spanish Implantable Cardioverter-defibrillator Registry, for his enthusiastic work in maintaining the database and his participation in its development. Our thanks also go to the personnel at the ICD manufacturers (Medtronic, Boston Scientific, St. Jude Medical, Biotronik, and the Sorin Group) for their help in collecting and sending datasheets to the SEC for most of the implantations. Finally, we thank the SEC for its work in receiving the information, particularly Gonzalo Justes and José María Naranjo.

### CONFLICTS OF INTERESTS

J. Alzueta has participated in research projects with St. Jude Medical, Medtronic, Boston Scientific, Biotronik, and the Sorin Group. A. Aso has participated in research projects sponsored by Medtronic, St. Jude Medical, and Boston Scientific. A. Quesada has participated in talks and round tables sponsored by Medtronic and the Sorin Group.

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