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Special article

Spanish Implantable Cardioverter-defibrillator Registry. 15th Official Report of the Spanish Society of Cardiology Electrophysiology and Arrhythmias Section (2018)

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A B S T R A C T

Introduction and objectives: This article presents the data corresponding to automated implantable cardioverter-defibrillator (ICD) implants in Spain reported to the Spanish Registry in 2018.
Methods: The data in this registry include both primary implants and generator replacements and were gathered from a data collection sheet voluntarily completed by implantation centers.
Results: In 2018, 6421 implant sheets were received compared with 7077 reported by Eucomed (European Confederation of Medical Suppliers Associations). This represents data on 90.7% of the devices implanted in Spain. Compliance ranged between 99.6% for the field "name of the implanting hospital" and 12.4% for "population of residence". A total of 173 hospitals reported their data to the registry, representing a slight decrease compared with hospitals participating in 2017 (n = 181).
Conclusions: After the reduction in ICD implants in 2017, the number of implants increased in 2018, with the highest number of ICDs implanted in Spain. The total number of implants remains much lower than the European Union average, with substantial differences between autonomous communities.

Registro Español de Desfibrilador Automático Implantable. XV Informe Oficial de la Sección de Electrofisiología y Arritmias de la Sociedad Española de Cardiología (2018)

Palabras clave:
Desfibrilador automático implantable
Muerte súbita
Registro nacional

R E S U M E N

Introducción y objetivos: Se presentan los datos correspondientes a los implantes de desfibrilador automático implantable (DAI) en España comunicados al Registro Español de Desfibrilador Automático Implantable en el año 2018.
Métodos: Los datos de este registro incluyen tanto los primoimplantes como los recambios de generador y se documentan a partir de una hoja de recogida de datos que voluntariamente cumplimentan los centros implantadores.
Resultados: En el año 2018 se recibieron 6.421 hojas de implante, frente a las 7.077 comunicadas por Eucomed *(European Confederation of Medical Suppliers Associations)*. Esto representa datos del 90,7% de los dispositivos implantados en España. El grado de cumplimiento osciló entre el 99,6% en el campo «nombre del hospital implantador» y el 12,4% en «población de residencia». Comunicaron sus datos al registro 173 hospitales, lo que supone una ligera disminución con respecto a los que participaron en 2017 (181).
Conclusiones: El Registro Español de Desfibrilador Automático Implantable del año 2018 recoge un crecimiento en el número de implantes de DAI después de la reducción observada en 2017 y es el año en que se ha implantado un mayor número de DAI en España. El número total de implantes en España sigue siendo muy inferior a la media de la Unión Europea, con importantes diferencias entre comunidades autónomas.

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Abbreviations

CRT: cardiac resynchronization therapy
Eucomed: European Confederation of Medical Suppliers Associations
ICD: implantable cardioverter defibrillator
SEC: Spanish Society of Cardiology

INTRODUCTION

Implantable cardioverter-defibrillator (ICD) placement is a highly effective treatment for controlling ventricular arrhythmias and the most effective treatment for preventing sudden cardiac death. ICDs continually monitor cardiac rhythm and administer a shock upon detection of tachycardia meeting the established heart rate and duration criteria. Various clinical practice guidelines list the indications for ICD therapy in patients with ventricular arrhythmias or at risk of developing them and include both primary and secondary prevention measures for sudden cardiac death.[1–3] Sudden cardiac death has a huge socioeconomic impact. Although its current incidence in Spain is unknown, the estimated incidence in Europe is 400 000 deaths per year,[4] with 40% occurring in individuals younger than 65 years.

The Electrophysiology and Arrhythmias Section of the Spanish Society of Cardiology (SEC) has published the Spanish Implantable Cardioverter-defibrillator Registry since 2005.[5–7] This report presents the data on ICD implantation corresponding to 2018. Most Spanish centers implanting ICDs have contributed to the registry. As in other years, this article reviews the patients' indications and clinical characteristics, implantation data, device type and programming, and procedure-related complications.

METHODS

The registry is based on information voluntarily collected by the participating centers during device implantation and concerns both first implantations and replacements. The information was entered in a database by a team comprising a technician, a SEC computer scientist, and a member of the Electrophysiology and Arrhythmias Section of the SEC. Data cleaning was performed by the technician and the first author, and all authors of this article analyzed the data and are responsible for this publication.

The census data for the calculation of rates, both national and by autonomous community and province, were obtained from the Spanish National Institute of Statistics as of January 1, 2019.[8] The data from the present registry were compared with those provided by the European Confederation of Medical Suppliers Associations (Eucomed).

The percentages of each of the variables analyzed were calculated by taking into account the total number of implantations with available information on the parameter. Only the most serious condition was included if various types of arrhythmias were recorded.

Statistical Analysis

Results are expressed as mean ± standard deviation or median [interquartile range], depending on the distribution of the variable. Continuous quantitative variables were analyzed using analysis of variance or the Kruskal-Wallis test, while qualitative variables were analyzed using the chi-square test. Linear regression models were used to analyze the number of implantations and devices implanted per million population, the total number of implantations, and the number of implantations for primary prevention in each center.

RESULTS

A total of 6421 implantation forms were received but 7077 procedures were reported by Eucomed; hence, data were collected on 90.7% of devices implanted in Spain. Compliance ranged from 99.6% for the field *name of implantation hospital* to 12.4% for the variable *town of residence*.

Implantation Centers

In total, 173 hospitals participated, which is a slight decrease vs 2017 (181). Data from the 173 hospitals are shown in table 1; 77 were publicly-funded health centers. Figure 1 shows the total number of implantation centers, the rate per million population, and the total number of implantations per autonomous community. In 2018, 19 centers implanted ≥ 100 devices; 82, ≤ 10; and 23, only 1.

Total Number of Implantations

In 2018, the total number of implantations (first and replacements) was 6421, representing an increase vs 2017 (6273). The total number of implantations reported to the registry and those estimated by Eucomed in the last 10 years are shown in figure 2. The data for 2018 show a marked increase in the number of ICD implantations in Spain vs the previous year (7077 in 2018 and 6429 in 2017 according to Eucomed data).

The overall implantation rate was 137/million population for the registry but 152/million population according to Eucomed data. This figure is similar to that of the previous year (135/million population in 2017) but much lower than the mean ICD implantation rate in Europe (306/million population in 2018); nonetheless, the rate in Europe has fallen for the first time. Changes in the implantation rate per million population during the last 10 years according to registry and Eucomed data are shown in figure 3.

The name of the hospital performing the procedure was recorded in 99.6% of forms (table 1). Most procedures (5693, 92%) were performed in publicly-funded health centers.

First Implantations vs Replacements

This information was available in 5451 forms (83%). First implantations comprised 3899, representing 71.5% of the total (71.4% in 2017, 66.8% in 2016, 71.8% in 2015, and 72.6% in 2014). The rate of first implantations per million population was 83.4 (76.5 in 2017, 65.5 in 2016, 75.1 in 2015, and 79.0 in 2014).

Age and Sex

The mean age of all patients was 62.4 ± 13.55 (7-97) years in 2018 vs 62.6 ± 13.4 (6-90) years in 2017, 62.7 ± 13.4 (6-90) years in 2016, 62.8 ± 13.3 (6-89) years in 2015, and 61.8 ± 13.7 (7-94) years in 2014. The mean patient age was 61.2 ± 13.3 years for first implantations. Most patients were men: they represented 82.0% of all patients and 82.4% of first implantation patients.

Table 1
Implantations by Autonomous Community, Province, and Hospital

Andalusia		
Almería	Hospital Torrecárdenas	32
	Hospital Vithas Virgen del Mar	2
Cádiz	Clínica Nuestra Señora de la Salud	3
	Hospital de Jerez	45
	Hospital Quirón Campo de Gibraltar	1
	Hospital San Carlos	7
	Hospital Universitario de Puerto Real	9
	Hospital Universitario Puerta del Mar	70
Córdoba	Hospital de la Cruz Roja de Córdoba	4
	Hospital Universitario Reina Sofía de Córdoba	66
Granada	Hospital Campus de la Salud	10
	Clínica Nuestra Señora de la Salud	17
	Hospital Clínico Universitario San Cecilio	7
	Hospital Universitario Virgen de las Nieves	97
Huelva	Hospital Costa de la Luz	6
	Hospital General Juan Ramón Jiménez	48
Jaén	Complejo Hospitalario de Jaén	44
Málaga	Clínica El Ángel	4
	Clínica Parque San Antonio	7
	Hospital Internacional Xanit	7
	Hospital Quirón de Málaga	2
	Hospital Quirónsalud Marbella	7
	Hospital Virgen de la Victoria	238
Sevilla	Clínica HLA Santa Isabel	7
	Hospital de San Juan de Dios	1
	Hospital Nisa Aljarafe	2
	Hospital Nuestra Señora de Valme	45
	Hospital Quirónsalud Sagrado Corazón	5
	Hospital San Agustín	1
	Hospital Virgen del Rocío	93
	Hospital Virgen Macarena	62
Aragon		
Zaragoza	Hospital Clínico Universitario Lozano Blesa	49
	Hospital Miguel Servet	174
	Hospital Quirónsalud Zaragoza	2
Principality of Asturias	Hospital de Cabueñes	22
	Hospital Universitario Central de Asturias	198
Balearic Islands	Clinica Quirón Palmaplanas	7
	Clínica Rotger Sanitaria Balear, S.A.	4
	Hospital Son Llàtzer	22
	Hospital Universitari Son Espases	76
	Policlínica Miramar	1
Canary Islands		
Las Palmas	Clínica Santa Catalina	1
	Hospital Dr. Negrín	51
	Hospital Insular de Gran Canaria	79
	Hospital Nuestra Señora del Perpetuo Socorro	2
	Hospital La Paloma	1
Santa Cruz de Tenerife	Hospital San Juan de Dios (Tenerife)	6
	Hospital Nuestra Señora de la Candelaria	66
	Hospital Universitario de Canarias	47
Cantabria	Clínica Mompía	2
	Hospital Universitario Marqués de Valdecilla	130
Castile and León		
Ávila	Clínica Santa Teresa	1
	Hospital Nuestra Señora de Sonsoles	31
Burgos	Hospital Recoletas Burgos	3
	Hospital Universitario de Burgos (HUBU)	60
León	Hospital de León	62
Salamanca	Complejo Hospitalario de Salamanca	80
Segovia	Hospital General de Segovia	2
Valladolid	Hospital Campo Recoletas Grande	9
	Hospital Clínico Universitario de Valladolid	88
	Hospital Universitario Río Hortega	17
Castile-La Mancha		
Albacete	Hospital General de Albacete	59
	Hospital Quirónsalud Albacete	1
	Sanatorio Santa Cristina	2
Ciudad Real	Hospital General de Ciudad Real	56
	Quirón Ciudad Real	5
Cuenca	Hospital Virgen de la Luz	15
Guadalajara	Hospital General y Universitario de Guadalajara	32
Toledo	Hospital Nuestra Señora del Prado	38
	Hospital Virgen de la Salud	116
Catalonia		
Barcelona	Centro Médico Teknon	5
	Clínica Delfos	1
	Clínica Quirónsalud Barcelona	2
	Hospital Clínico de Barcelona	228
	Hospital de Bellvitge	160
	Hospital de la Santa Creu i Sant Pau	141
	Hospital de Sabadell Parc Taulí	19
	Hospital del Mar	30
	Hospital El Pilar (Quirónsalud)	18
	Hospital General de Catalunya	6
	Hospital Germans Trias i Pujol	52
	Hospital Sant Joan de Déu	9
	Hospital Vall d'Hebron	129
Girona	Clínica Girona	2
	Hospital Universitario de Girona Dr. Josep Trueta	66
Lleida	Hospital Universitario Arnau de Vilanova	25
Tarragona	Hospital de Sant Pau i Santa Tecla	2
	Hospital Universitario de Tarragona Joan XXIII	35
Valencian Community		
Alicante	Centro Medico Salus Baleares	1
	Clínica Glorieta	1
	Clínica Vistahermosa	7
	Hospital General Universitario de Alicante	168
	Hospital General Universitario de Elche	2
	Hospital IMED de Levante	5
	Hospital Mediterráneo	2
	Hospital Universitari Sant Joan d'Alacant	56
	Sanatorio del Perpetuo Socorro	1
Castellón	Hospital General Universitari de Castelló	26
Valencia	Hospital Arnau de Vilanova de Valencia	3
	Hospital Clínico Universitario de Valencia	65
	Hospital de Manises	44
	Hospital Francesc de Borja de Gandía	1
	Hospital General Universitario de Valencia	78
	Hospital Nisa 9 de Octubre	1
	Hospital Quirónsalud Valencia	4
	Hospital Universitari de la Ribera	52
	Hospital Universitario Dr. Peset	30
	Hospital Universitario La Fe	122

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

Extremadura		
Badajoz	Hospital Infanta Cristina de Badajoz	142
	Hospital Quirón Clideba	4
Cáceres	Clínica San Francisco de Cáceres	3
	Complejo Hospitalario de Cáceres	32
Galicia		
A Coruña	Complejo Hospitalario Universitario A Coruña	163
	Complejo Hospitalario Universitario de Santiago	105
	Hospital Modelo	2
	Hospital Quirónsalud A Coruña	8
Lugo	Hospital Universitario Lucus Agusti	25
Ourense	Complejo Hospitalario de Ourense	17
Pontevedra	Complejo Hospitalario de Pontevedra	2
	Hospital Álvaro Cunqueiro (CHUVI)	89
	Hospital Montecelo	1
	Hospital Nuestra Señora de Fátima	4
	Hospital Povisa	19
La Rioja	Hospital San Pedro	28
Community of Madrid	Clínica La Luz	9
	Clínica La Milagrosa	1
	Clínica Moncloa	16
	Clínica Ruber	1
	Clínica Universitaria de Navarra de Madrid	1
	Fundación Hospital Alcorcón	22
	Fundación Jiménez Díaz	73
	Grupo Hospital de Madrid	11
	Hospital 12 de Octubre	99
	Hospital Central de la Defensa	27
	Hospital Clínico San Carlos	132
	Hospital de Fuenlabrada	25
	Hospital de Torrejón	10
	Hospital del Henares	9
	Hospital General de Villalba	1
	Hospital General Universitario Gregorio Marañón	71
	Hospital Infanta Leonor	37
	Hospital Universitario La Zarzuela	1
	Hospital Los Madroños	2
	Hospital Nisa Pardo de Aravaca	3
	Hospital Quirón Madrid	4
	Hospital Quirón San Camilo	3
	Hospital Quirónsalud Sur Alcorcón	1
	Hospital Ramón y Cajal	100
	Hospital Rey Juan Carlos	19
	Hospital Ruber Internacional	1
	Hospital San Rafael	7
	Hospital Severo Ochoa	15
	Hospital Universitario de Getafe	14
	Hospital Universitario La Paz	122
	Hospital Universitario Puerta de Hierro Majadahonda	156
	Hospital Virgen de la Paloma	2
	Hospital Virgen del Mar	2
	Hospital Vithas Nuestra Señora de América	2
	Sanatorio San Francisco de Asís	2
Region of Murcia	Hospital General Universitario Morales Meseguer	8
	Hospital General Universitario Reina Sofía Murcia	15
	Hospital General Universitario Santa Lucía	33
	Hospital La Vega-HLA	4
	Hospital Rafael Méndez	21
	Hospital Universitario Virgen de la Arrixaca	63
Chartered Community of Navarre	Clínica Universidad de Navarra	29
	Hospital de Navarra	63
Basque Country		
Álava	Hospital Universitario de Áraba	44
Guipúzcoa	Hospital Universitario de Donostia	150
Vizcaya	Hospital de Basurto	59
	Hospital de Cruces	55
	Hospital de Galdakao-Usansolo	15
	IMQ Zorrotzaurre	1
Not defined		51

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 (52.9%), followed by dilated cardiomyopathy (26.1%), hypertrophy (7.1%), primary conduction abnormalities (Brugada syndrome and long QT syndrome) (2.9%), valve diseases (1.6%), and arrhythmogenic right ventricular cardiomyopathy (1.1%) (figure 4).

Systolic function data were provided in 66.5% of forms. In this group, left ventricular ejection fraction was $>$ 50% in 18.2% of patients, from 41% to 50% in 9.3%, from 36% to 40% in 9.2%, from 31% to 35% in 18.6%, and $\leq$ 30% in 44.8% (figure 5). The distribution was similar when it was grouped by first implantations and by replacements.

The New York Heart Association (NYHA) functional class was recorded in 45.2% of forms. Most patients were in NYHA class II (55.7%), followed by NYHA III (27.9%), NYHA I (15.3%), and NYHA IV (1.1%). The distribution for this variable was also similar in the overall and first implantation groups (figure 6).

Based on data from 69.4% of forms, the baseline cardiac rhythm was primarily sinus rhythm (77.1%), followed by atrial fibrillation (18.0%) and pacemaker rhythm (4.4%). The remaining patients had other rhythms (eg, atrial flutter and other arrhythmias).

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

The clinical arrhythmia prompting device implantation was reported in 69.9% of forms submitted to the registry. For first implantations, most patients had no documented clinical arrhythmia (63.7%), while 14.5% showed sustained monomorphic ventricular tachycardia, 9.8% had nonsustained ventricular tachycardia, and 10.6% had ventricular fibrillation. In total, patients with no documented clinical arrhythmia comprised 63.7% (figure 7). The most frequent presentation in both the total implantation group and the first implantation patients (56.1% of completed responses) was asymptomatic, followed by syncope, sudden cardiac death, and other symptoms (figure 8).

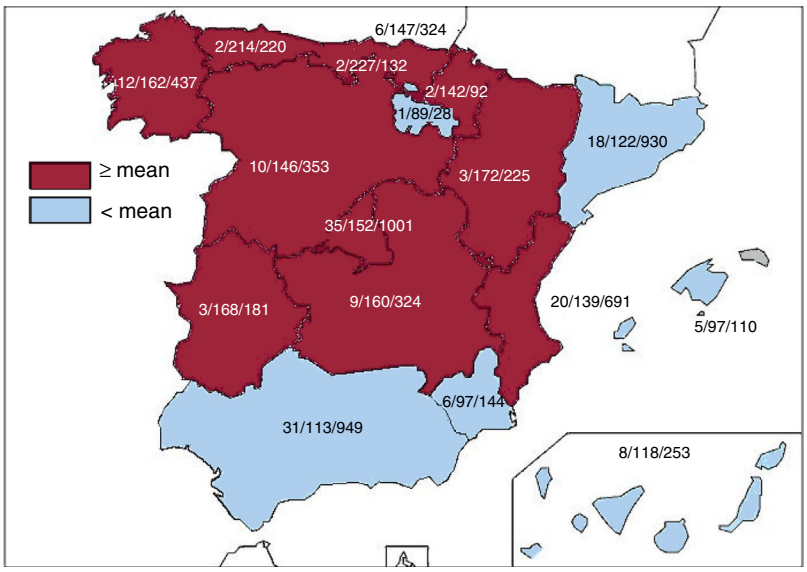
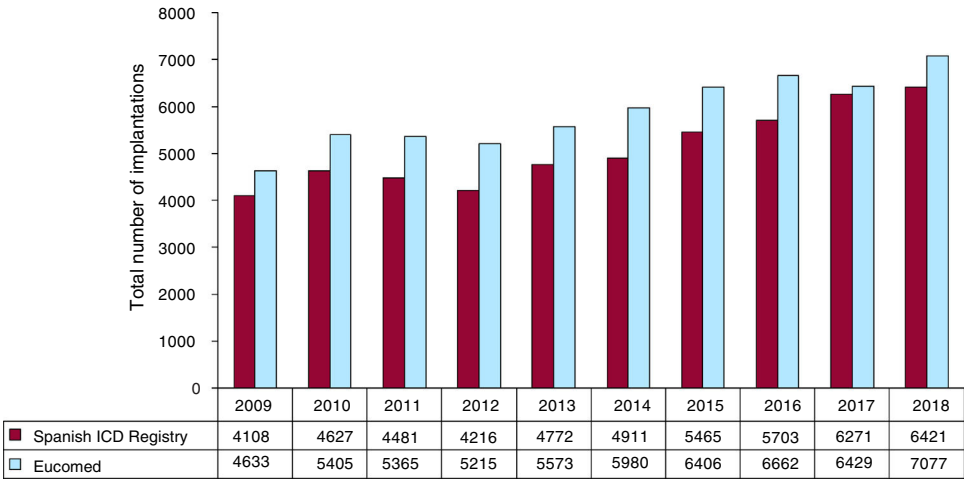


Figure 1. Distribution of implantation activity by autonomous community in 2018: number of implantation centers/rate per million population/total number of implantations. Mean rate = 137 implantations/million population.



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Spanish ICD Registry	4108	4627	4481	4216	4772	4911	5465	5703	6271	6421
Eucomed	4633	5405	5365	5215	5573	5980	6406	6662	6429	7077

Figure 2. Total number of implantations notified and number estimated by Eucomed from 2009 to 2018. Eucomed, European Confederation of Medical Suppliers Associations; ICD, implantable cardioverter defibrillator.

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Spanish ICD Registry	89	100	97	91	102	106	118	122	135	137
Eucomed	100	117	116	112	120	128	137	143	138	152

Figure 3. Total number of implantations notified per million population and number estimated by Eucomed from 2009 to 2018. Eucomed, European Confederation of Medical Suppliers Associations; ICD, implantable cardioverter defibrillator.

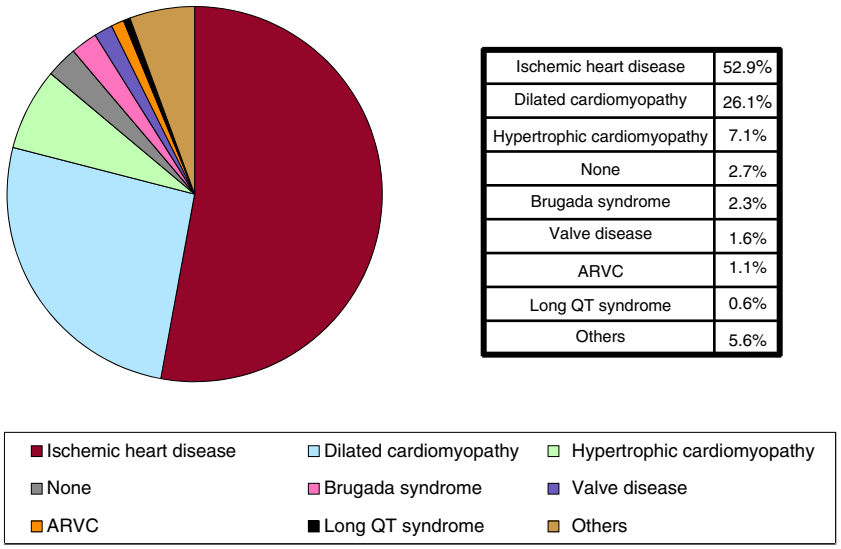


Figure 4. Type of heart disease prompting implantation (first implantations). ARVC, arrhythmogenic right ventricular cardiomyopathy; Others, patients with more than 1 diagnosis.

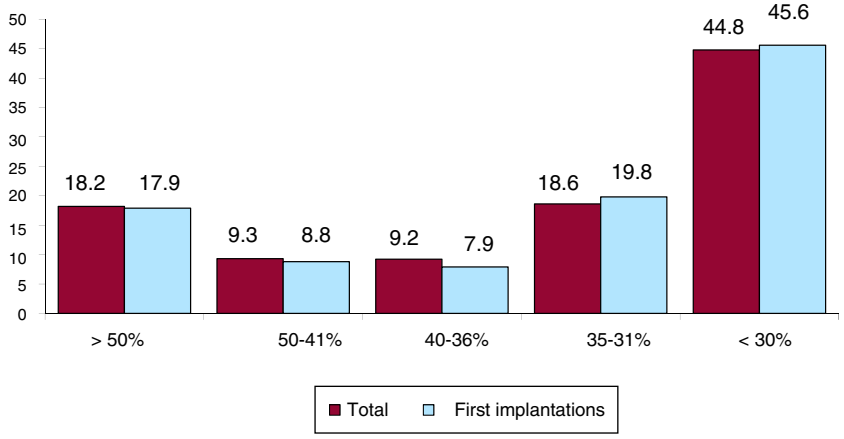


Figure 5. Left ventricular ejection fraction of patients in the registry (total and first implantations).

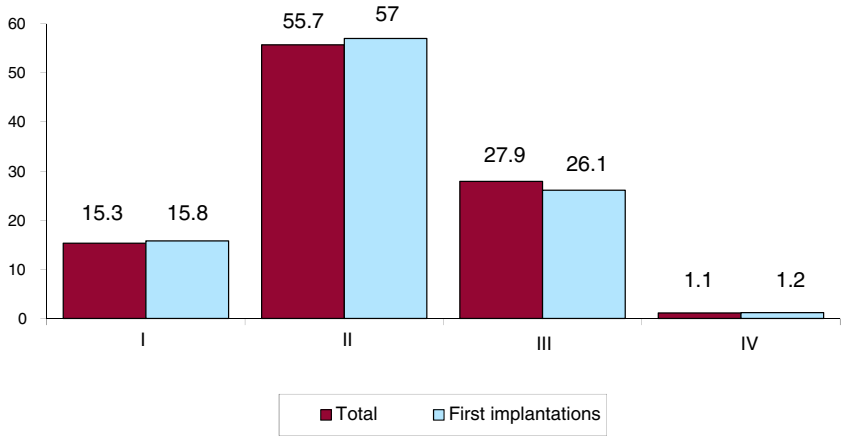


Figure 6. New York Heart Association functional class of total and first implantation patients.

Information on the electrophysiological studies performed was provided in 57.5% of forms. These studies were carried out in 312 patients (8.5%), mainly those with ischemic heart disease and dilated cardiomyopathy, and in 33.5% of patients with Brugada syndrome. Sustained monomorphic ventricular tachycardia was the most common induced arrhythmia (27.6%), followed by nonsustained ventricular tachycardia (16.8%), ventricular fibrillation (14.1%), and, to a lesser extent, other arrhythmias (4.6%).

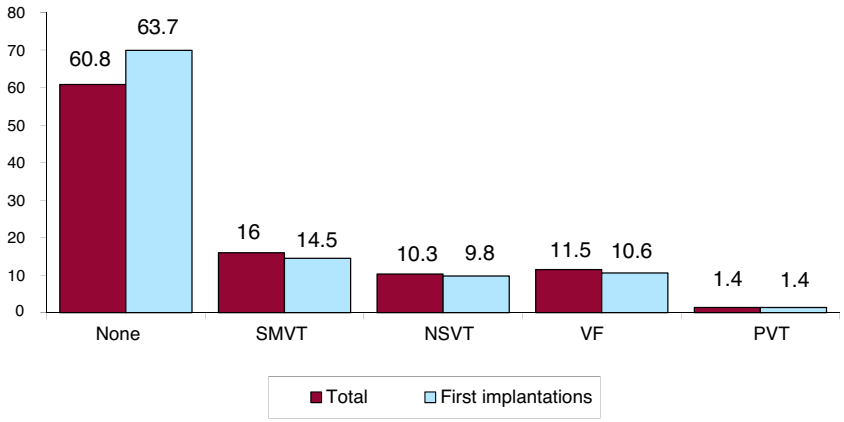


Figure 7. Distribution of the arrhythmias prompting implantation (total and first implantations). NSVT, nonsustained ventricular tachycardia; PVT, polymorphic ventricular tachycardia; SMVT, sustained monomorphic ventricular tachycardia; VF, ventricular fibrillation.

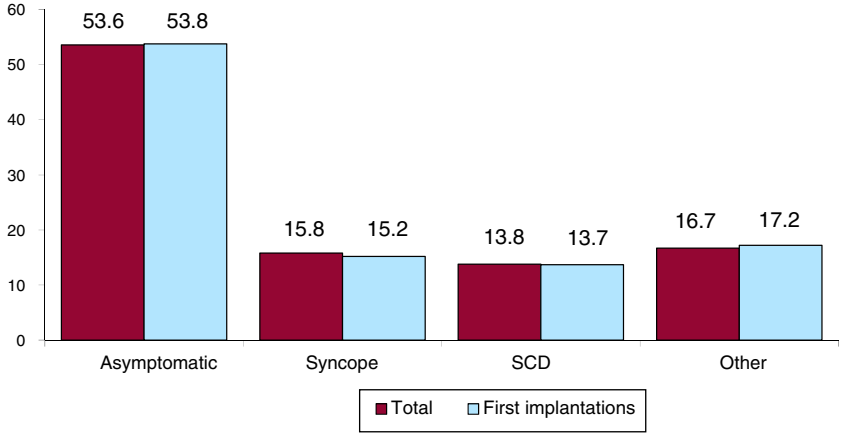


Figure 8. Clinical presentation of the arrhythmia in the registry patients (first implantations and total). SCD, sudden cardiac death.

No arrhythmia was induced in 36.9% of the electrophysiological studies.

Clinical History

Information on clinical history was provided in 38.6% of forms. Hypertension was present in 57% of patients, as well as hypercholesterolemia in 48%, smoking in 35%, diabetes mellitus in 30%, history of atrial fibrillation in 27%, family history of sudden cardiac death in 9%, renal failure in 15%, and history of stroke in 6%.

The QRS interval was reported for 43.5% of first implantations (mean, 124 ms). In 39% of the patients, it was $>$ 140 ms, and 88.7% of these patients had a resynchronization-defibrillator device (ICD-cardiac resynchronization therapy [CRT]).

Indications

Device indications in recent years are shown in table 2. These data were provided in 62.6% of forms in 2018. Ischemic heart disease was the most frequent reason for ICD implantation, accounting for 53.8% of first implantations in 2018. Among ischemic heart disease patients, the most common indication was primary prevention (39%). The second most common reason was dilated cardiomyopathy (29% of all first implantations). For the less common heart diseases, the most frequent indication was primary prevention.

The implantation indication was identified in 62.6% of forms. Most first implantations were indicated for primary prevention (65.7%), a proportion that has slowly been increasing throughout registry history (table 3).

Implantation Setting and Treating Specialist

The implantation setting and specialist performing the procedure were recorded in 69.4% of forms. In total, 82.4% of procedures were performed in electrophysiology laboratories and 14.3% in operating rooms. Cardiac electrophysiologists performed 77.9% of implantations, surgeons performed 9.3%, and both together performed 8.1%. Other specialists and intensivists were involved in 2.6% and 2.1% of procedures, respectively.

Generator Placement Site

Generator placement was recorded for 70.2% of first implantations. Placement was subcutaneous in 91.8% of patients and subpectoral in the remaining 8.2%. These figures were 91.3% and 8.7%, respectively, for all devices implanted.

Device Type

The types of device implanted are shown in table 4. This information was provided in 91.6% of forms submitted to the

Table 2
Number of First Implantations According to Type of Heart Disease, Type of Clinical Arrhythmia, and Form of Presentation From 2014 to 2018

	2014	2015	2016	2017	2018
Ischemic heart disease					
Aborted SCD	141 (6.7)	200 (11.9)	135 (10.4)	101 (6.5)	165 (10.6)
SMVT with syncope	173 (10.6)	243 (14.5)	142 (10.9)	135 (8.7)	92 (5.9)
SMVT without syncope	108 (6.6)	121 (7.2)	226 (17.3)	212 (13.7)	231 (14.9)
Syncope without arrhythmia	70 (4.3)	174 (10.4)	31 (2.4)	61 (3.9)	62 (3.9)
Prophylactic implantation	740 (45.5)	804 (48.9)	650 (49.9)	603 (39.0)	793 (50.8)
Missing/unclassifiable	393 (24.8)	158 (9.4)	121 (9.3)	434 (28.0)	217 (13.9)
Subtotal	1625	1672	1305	1546	1560
Dilated cardiomyopathy					
Aborted SCD	25 (6.8)	63 (6.5)	51 (5.9)	61 (7.3)	47 (5.6)
SMVT with syncope	72 (8.5)	67 (6.9)	43 (5.0)	65 (7.8)	39 (4.8)
SMVT without syncope	111 (13.4)	113 (11.7)	91 (10.5)	100 (12.0)	53 (6.6)
Syncope without arrhythmia	37 (4.3)	66 (6.8)	59 (6.8)	30 (3.6)	26 (3.3)
Prophylactic implantation	400 (47.0)	459 (47.6)	550 (63.5)	341 (41.0)	355 (44.2)
Missing/unclassifiable	173 (20.3)	196 (20.3)	72 (8.3)	233 (28.7)	283 (35.2)
Subtotal	851	964	866	830	803
Valve disease					
Aborted SCD	11 (9.0)	19 (14.4)	12 (10.5)	5 (5.3)	9 (9.8)
SMVT	38 (31.5)	33 (25.0)	28 (24.5)	22 (23.2)	24 (26.1)
Syncope without arrhythmia	7 (5.7)	13 (9.9)	9 (7.9)	5 (5.3)	5 (5.4)
Prophylactic implantation	46 (37.7)	55 (41.7)	52 (45.6)	46 (48.4)	37 (40.2)
Missing/unclassifiable	20 (16.4)	12 (9.9)	13 (11.4)	17 (17.9)	17 (18.5)
Subtotal	126	132	114	95	92
Hypertrophic cardiomyopathy					
Secondary prevention	62 (25.8)	60 (24.3)	49 (20.3)	49 (21.5)	48 (19.2)
Prophylactic implantation	166 (69.2)	179 (72.5)	176 (70.3)	166 (72.8)	198 (79.2)
Missing/unclassifiable	12 (5.0)	8 (3.2)	16 (6.6)	13 (5.7)	4 (1.6)
Subtotal	240	247	241	228	250
Brugada syndrome					
Aborted SCD	8 (13.7)	7 (15.9)	16 (24.2)	11 (15.5)	14 (18.9)
Prophylactic implantation in syncope	17 (29.3)	14 (31.8)	10 (15.2)	16 (22.5)	14 (18.9
Prophylactic implantation without syncope	22 (37.9)	12 (27.3)	35 (53.0)	38 (53.5)	14 (18.9)
Missing/unclassifiable	11 (18.9)	11 (25.0)	5 (7.6)	6 (8.4)	17 (23.0)
Subtotal	60	47	66	71	74
ARVC					
Aborted SCD	6 (13.3)	8 (20.5)	2 (4.3)	3 (12.5)	4 (10.3)
SMVT	16 (35.5)	17 (41.4)	25 (54.3)	7 (29.1)	16 (41.0)
Prophylactic implantation	16 (35.5)	14 (34.1)	18 (39.1)	10 (41.6)	14 (35.9)
Missing/unclassifiable	7 (15.5)	2 (4.8)	1 (2.2)	4 (16.6)	5 (12.8)
Subtotal	45	41	46	24	39
Congenital heart disease					
Aborted SCD	5 (13.9)	9 (27.3)	4 (12.1)	6 (12.0)	7 (15.2)
SMVT	7 (19.4)	9 (27.3)	10 (30.3)	10 (20.0)	14 (30.4)
Prophylactic implantation	15 (41.7)	12 (36.4)	12 (36.4)	29 (58.0)	21 (45.6)
Missing/unclassifiable	9 (25.0)	3 (36.4)	7 (21.2)	5 (10.0)	4 (8.7)
Subtotal	36	33	33	50	46
Long QT syndrome					
Aborted SCD	19 (70.4)	8 (38.1)	10 (30.3)	15 (48.4)	9 (24.3)
Prophylactic implantation	5 (18.5)	12 (54.5)	15 (45.5)	12 (38.7)	18 (48.6)
Missing/unclassifiable	3 (11.1)	2 (9.1)	8 (24.2)	4 (12.9)	10 (27.3)
Subtotal	26	22	33	31	37

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

Table 3
Changes in the Main Indications for Implantable Cardioverter-defibrillators (Percentages of First Implantations, 2009-2018)

Year	SCD	SMVT	Syncope	Primary prevention
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*
2015	11.2	13.6	16.9	58.2
2016	11.8	17.0	9.9	62.0*
2017	12.5	15.7	9.8	62.0
2018	13.3	13.5	7.4	65.7

SCD, sudden cardiac death; SMVT, sustained monomorphic ventricular tachycardia.
* Significantly different ($P < .02$) vs 2017.

registry. In 2018, first implantations of subcutaneous defibrillators comprised 6.0% (5.3% in 2017 and 6.4% in 2016).

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

The most frequent reason for replacement was battery depletion (79.3%); complications prompted 9.1% of replacements (10.5% in 2017 and 8.8% in 2016) and a change of indication prompted 11.5%. Of the 818 replacements providing this information, 2.4% were performed before 6 months.

Information was available on lead status in 56.1% of forms; 4.6% were malfunctioning (40 forms) and they were extracted in 12.5% of patients reporting this problem.

Device Programming

With data on 49.3% of implantations, the most common pacing mode was VVI (54.52%), following by DDD (28.5%), VVIR (6.3%), DDDR (4.7%), and others (6.0%).

Ventricular fibrillation induction was tested in 249 patients, 5.8% of the 4322 records providing this information (5.3% in 2017 and 4.1% in 2016). The mean number of shocks delivered was 1.1. Thus, the threshold was not calculated in most patients.

Complications

Complication data were recorded in 77.2% of forms. There were 25 complications: 10 coronary sinus dissections, 2 tamponades, 9 deaths, and 4 unspecified. The mortality rate was 0.2%, representing an increase vs the 3 previous years (0.09% in 2017 and 0.02% in 2016), although the number remains quite low.

DISCUSSION

In 2018, information was obtained on the vast majority of implantations performed in Spain, with over 90% of those being performed according to Eucomed data. This is at least partly due to the efforts of the SEC but is mainly due to the contribution of the implantation centers.

Comparison With Registries of Previous Years

The SEC excels at the publication of activity data and has systematically published registry data since 2005.[5] In 2018, there was another slight uptick in the number of devices, whereas the number remained stable in Europe.[9] This situation reduced, albeit slightly, the difference vs our neighboring countries. The overall implantation rate per million population was 152 in 2018 (vs 138 in 2017) while it dropped from 311 in 2017 to 306 in 2018 in Europe.

There was also a slight increase in implantations for primary prevention in 2018, which reached 65.7% (table 3); this figure also brings Spain closer (again, only slightly) to the European level.[10]

Finally, the percentage of subcutaneous ICDs was 6.0% in 2018; this represents a slightly increase vs 2017 (5.3%) but is still lower than that of 2016 (6.4%). This figure seems low for a therapy with so many potential advantages.[11]

The most frequent underlying heart disease in 2018 continued to be ischemic heart disease (52.9%), followed by dilated cardiomyopathy (26.1%). In 2018, implantations for primary prevention of dilated cardiomyopathy appeared to have slightly recovered since the marked reduction in this therapy in Spain after the publication of the DANISH study.[12] This phenomenon was also seen to a greater or lesser extent in other European countries.[13] In our opinion, this reduction is not justified by the available data. First, the only guidelines published after the results of the DANISH trial maintained the indication for ICD implantation for primary prevention in patients with dilated cardiomyopathy (class I, level of evidence A).[3] Second, the results of the DANISH study should not be applied to patients who have no indication for cardiac resynchronization (less than half of the patients included in the study). Third, the benefit to patients younger than 70 years of age is clear in the DANISH trial, and most implantations for primary prevention are in patients younger than that age.[14] Finally, the results of 2 meta-analyses again showed a benefit of ICDs in this patient population, with a 25% reduction in the relative risk of death.[15,16]

The 2018 data are generally consistent with those of previous years. Given the scientific evidence, the implantation rate in our country remains lower than expected. In 2010, the implantation rate per million population in Spain was about half the European

Table 4
Percent Distribution of Implanted Devices by Type

Device type	Total					First implantations				
	2014	2015	2016	2017	2018	2014	2015	2016	2017	2018
Subcutaneous			3.6	3.8	4.4		2.4	6.4	5.3	6.0
Single-chamber	48.8	48.6	45.4	45.7	46.6	48.8	50.4	48.4	49.4	50.1
Dual-chamber	17.4	14.5	13.7	15.0	15.0	17.4	13.2	13.0	14.1	13.4
Resynchronization device	33.7	35.7	37.3	35.7	34.0	33.7	33.9	32.1	31.5	30.6

rate (116 vs 248); in 2017, the gap slightly decreased to 152 vs 306 implantations per million.[9] This is a positive development, but we should not forget the magnitude of the difference in implantation rates vs our neighboring countries.

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 continued to predominate. There were no changes either in the type of specialist performing the implantation.

Differences Among Autonomous Communities

As in previous years, the data from the 2018 registry showed large differences in the implantation rates of the various autonomous communities. Overall, the implantation rate in Spain in 2018 was 137 per million population according to the registry and 152 according to Eucomed data, a slight increase vs previous years. Several autonomous communities showed higher rates than the average: Cantabria (227), Principality of Asturias (214), Extremadura (168), Galicia (162), Castile-La Mancha (160), Community of Madrid (152), the Basque Country (147), Castile and León (146), Chartered Community of Navarre (142), and the Valencian Community (139). Below average were Catalonia (122), the Canary Islands (118), Andalusia (113), the Region of Murcia (97), and La Rioja (89). The analysis by autonomous community highlighted the major difference between the highest and lowest rates, which is difficult to explain in terms of a theoretically homogeneous health system. These differences are not explained by income level or population density. Also striking is the case of Andalusia, which, despite the general rise throughout Spain, failed to recover the implantation rate it had in 2016 (124).

Comparison With Other Countries

In all of the countries participating in Eucomed, the implantation rate dropped from 311 per million population in 2017 (320 in 2016) to 306 in 2018. This figure includes ICDs and ICD-CRTs. Germany continued to lead with 485 devices, whereas Spain (152 implantations/million) was the country with the lowest number of implantations. Several countries showed higher than average rates: Italy (414), the Netherlands (385), the Czech Republic (381), Denmark (359), and Poland (332). Below the average were Ireland (273), Sweden (247), Belgium (235), Finland (235), Norway (225), France (224), Switzerland (220), Portugal (219), the United Kingdom (207), Greece (186), and, in last position, Spain (152). The difference in the implantation rate in Spain from the European average was maintained in 2018 (152 vs 306 compared with 138 vs 311 in 2017, 144 vs 320 in 2016, and 138 vs 315 in 2015). We are thus still far from the nearest country in terms of rate (152 vs 186).

The ICD-CRT implantation rate in Europe was 119 per million population (124 in 2017, 119 in 2016, 126 in 2015, 119 in 2014, and 113 in 2013). Germany (195 implantations per million population) continued to be first, whereas Spain (50) had the lowest implantation rate.

The proportion of ICD-CRTs with respect to the total varied from 39% in Denmark to 87% in the Czech Republic. The European average was 58%. Above the average were France, Portugal, the Netherlands, the United Kingdom, Germany, Italy, Sweden, and the Czech Republic. Below the 58% line were Denmark, Belgium, Finland, Norway, Switzerland, Greece, Ireland, and Poland. Spain had a proportion of 49%.

Other European countries also show regional differences in the ICD implantation rate.[16–18] The reasons are difficult to identify and do not seem to be economic because the rates of countries with lower income than Spain, such as Ireland and Poland, far exceed ours, even in more disadvantaged regions. Nor can these differences be explained by the prevalence of cardiovascular diseases. It seems that electrophysiologists working in Spain have not been able to convince their clinical colleagues, responsible for device indication, of the virtues of ICDs and their ability to reduce the rates of overall and sudden cardiac death in at-risk patients.

Limitations

Although the 2018 ICD registry included more than 90% of the implantations reported to Eucomed, the information was often incomplete. Data were not available for all fields of the implantation form and its completion was uneven.

In addition, data collection was limited to the periimplantation period and there are no follow-up data; thus, the complication records may underestimate the actual percentage.

Future Prospects of the Spanish Implantable Cardioverter-defibrillator Registry

During 2018, it was possible to collect information on more than 90% of the devices reported to Eucomed, a satisfactory figure but nonetheless a decrease vs 2017. Throughout 2019, a website for the online completion of the implantation form has been developed by the SEC in collaboration with the Spanish Agency for Medicines and Health Products.[19] This website will allow real-time registration of both pacemakers and ICDs. We hope that this change will boost the quality of the registry and its degree of completion. We also hope that the new platform will allow us to conduct prospective studies and improve the safety of patients affected by any possible safety alerts.

CONCLUSIONS

The 2018 Spanish Implantable Cardioverter-defibrillator Registry received information on 90% of the implantations performed in Spain. In 2018, the number of devices increased and the difference vs other European countries decreased, albeit slightly. The total number of implantations in Spain is still much lower than the average for the European Union and the autonomous communities continue to show considerable variability.

CONFLICTS OF INTEREST

I. Fernández Lozano has participated in clinical studies sponsored by Medtronic, Abbott, Biotronik, and Sorin and has fellowship grants from the SEC and the Cardiovascular Research Foundation. J. Osca Asensi has participated in clinical studies sponsored by Abbott, Boston, and Biotronik. J. Alzueta Rodríguez has participated in presentations sponsored by Boston and has received fellowship grants from the FIMABIS Foundation.

REFERENCES

1. Priori SG, Blomström-Lundqvist C, Mazzanti A, et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. *Eur Heart J.* 2015;36:2793–2867.
2. Zipes DP, Camm AJ, Borggrefe M, et al. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: A report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Com. *Europace.* 2006;8:746–837.

3. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation.* 2018;138:e210–e271.
4. Mendis SPP, Norrving B. *Global atlas on cardiovascular disease prevention and control*. Geneva: World Health Organization; 2011.
5. Peinado R, Arenal A, Arribas F, et al.Spanish Implantable Cardioverter-Defibrillator Registry. First Official Report of the Spanish Society of Cardiology Working Group on Implantable Cardioverter-Defibrillators (2002-2004). *Rev Esp Cardiol.* 2005;58:1435–1449.
6. Alzueta J, Fernandez-Lozano I. Spanish Implantable Cardioverter-Defibrillator Registry. 13th Official Report of the Spanish Society of Cardiology Electrophysiology and Arrhythmias Section (2016). *Rev Esp Cardiol.* 2017;70:960–970.
7. Fernández Lozano I, Osca Asensi J, Alzueta Rodríguez J. Spanish Implantable Cardioverter-Defibrillator Registry. 14th Official Report of the Spanish Society of Cardiology Electrophysiology and Arrhythmias Section (2017). *Rev Esp Cardiol.* 2018;71:1047–1058.
8. Instituto Nacional de Estadística. Datos poblacionales [nota de prensa 11 abril 2019]. Available at: https://www.ine.es/prensa/pad_2019_p.pdf. Accessed 15 Jun 2019.
9. MedTech Europe. Statistics for Cardiac Rhythm Management products, 2013-2017. Available at: http://www.medtecheurope.org/index.php/node/801. Accessed 24 Jun 2019.
10. John Camm A, Nisam S. European utilization of the implantable defibrillator: has 10 years changed the'enigma'? *Europace.* 2010;12:1063–1069.
11. Boersma LVA. The subcutaneous ICD. Ready to conquer everyone's heart? *Rev Esp Cardiol.* 2018;71:886–887;
Køber L, Thune JJ, Nielsen JC, et al. DANISH Investigators. Defibrillator implantation in patients with nonischemic systolic heart failure. *N Engl J Med.* 2016;375:1221–1230.
12. Haugaa KH, Tilz R, Boveda S, et al. Implantable cardioverter defibrillator use for primary prevention in ischaemic and non-ischaemic heart disease-indications in the post-DANISH trial era: results of the European Heart Rhythm Association survey. *Europace.* 2017;19:660–664.
13. Elming MB, Nielsen JC, Haarbo J, et al. Age and outcomes of primary prevention implantable cardioverter-defibrillators in patients with nonischemic systolic heart failure. *Circulation.* 2017;136:1772–1780.
14. Al-Khatib SM, Fonarow GC, Joglar JA, et al. Primary prevention implantable cardioverter defibrillators in patients with nonischemic cardiomyopathy: a meta-analysis. *JAMA Cardiol.* 2017;2:685–688.
15. Golwala H, Bajaj NS, Arora G, Arora P. Implantable cardioverter-defibrillator for nonischemic cardiomyopathy: an updated meta-analysis. *Circulation.* 2017;135:201–203.
16. Proclemer A, Zecchin M, D'Onofrio A, et al. The Pacemaker and Implantable Cardioverter-Defibrillator Registry of the Italian Association of Arrhythmology and Cardiac Pacing - Annual report 2016. *G Ital Cardiol.* 2018;19:119–131.
17. Freeman JV, Wang Y, Curtis JP, Heidenreich PA, Hlatky MA. Physician procedure volume and complications of cardioverter-defibrillator implantation. *Circulation.* 2012;125:57–64.
18. Lazarus A, Biondi N, Thebaut JF, Durand-Zaleski I, Chauvin M. Implantable cardioverter-defibrillators in France: practices and regional variability. *Europace.* 2011;13:1568–1573.
19. Agencia Española de Medicamentos y Productos Sanitarios y Sociedad Española de Cardiología. Plataforma de Registros Nacionales de Marcapasos y DAIs. Available at: http://cardiodispositivos.es. Accessed 15 Jun 2019.