

Special article

Spanish Implantable Cardioverter-Defibrillator Registry. Eighth Official Report of the Spanish Society of Cardiology Working Group on Implantable Cardioverter-Defibrillators (2011)

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Article history:

Available online 21 September 2012

Keywords:

Arrhythmia
Registry
Defibrillator

ABSTRACT

Introduction and objectives: To summarize the findings of the Spanish Implantable Cardioverter-Defibrillator Registry for 2011 compiled by the Electrophysiology and Arrhythmia Section of the Spanish Society of Cardiology.

Methods: Each implantation team voluntarily and prospectively recorded data on a data collection form, which was then sent to the Spanish Society of Cardiology.

Results: Overall, 4481 device implantations were notified, representing 83.6% of the estimated total number of implantations. The notified implantation rate was 97 per million population and the estimated total implantation rate was 116.2 per million. First implantations accounted for 70.2% of the total notified. Data were collected from 167 hospitals (22 more than in 2010). Most implantable cardioverter-defibrillator implantations took place in men (82.1%). The mean age was 62.4 (14.1) years. Most patients had severe or moderate-to-severe ventricular dysfunction and were in New York Heart Association functional class II. The most frequent underlying cardiac condition was ischemic heart disease, followed by dilated cardiomyopathy. The number of indications for primary prevention increased over the previous year and accounted for 70.6% of first implantations. Overall, 78.4% of implantable cardioverter-defibrillators were implanted by cardiac electrophysiologists.

Conclusions: The 2011 Spanish Implantable Cardioverter-Defibrillator Registry includes data on almost 84% of all implantations of these devices performed in Spain. This was the first year in which the number of implants decreased slightly from the previous year, as also occurred in the rest of Europe. The percentage of implants for primary prevention continued to increase.

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Registro Español de Desfibrilador Automático Implantable. VIII Informe Oficial del Grupo de Trabajo de Desfibrilador Automático Implantable de la Sociedad Española de Cardiología (2011)

RESUMEN

Introducción y objetivos: Se presentan los resultados del Registro Español de Desfibrilador Automático Implantable de 2011 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 comunicado fue 4.481 (el 83,6% del total de implantes estimado). El número de implantes por millón de habitantes fue 97 y el estimado, 116,2. Los primoimplantes fueron el 70,2%. Se obtuvieron datos de 167 hospitales (22 más que en 2010). La mayoría de los implantes (82,1%) se realizaron en varones. La media de edad fue 62,4 ± 14,1 años. La mayoría de los pacientes presentaban disfunción ventricular severa o moderada-severa 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 seguido aumentando respecto a años anteriores y son ya el 70,6% de los primoimplantes. Los implantes realizados por electrofisiólogos también han seguido aumentando y ahora son el 78,4%.

Conclusiones: El Registro de Desfibrilador Automático Implantable recoge información de casi el 84% de los implantes que se realizan en España. Es el primer año de nuestra serie en que el número de implantes ha disminuido ligeramente respecto al año anterior, como también ha ocurrido en el resto de Europa, aunque el número de implantes por prevención primaria ha seguido incrementándose.

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Palabras clave:

Arritmias
Registro
Desfibrilador

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Abbreviations

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

INTRODUCTION

Implantable cardioverter-defibrillators (ICDs) have proven effective for primary and secondary prevention of sudden cardiac death. The results of several published studies have enabled the main indications for ICD implantation to be established and presented in clinical guidelines for the management of patients with ventricular arrhythmia or a risk of sudden cardiac death.^{1,2} Nonetheless, the increased use of these devices has raised questions on their effectiveness outside the setting of clinical trials, the proper selection of patients for ICD implantation, access to this therapy, and its safety and cost-effectiveness.³ There is little information in the literature on these aspects or on the application of clinical guidelines in unselected patient populations. Thus, related health registries can be of great value in clarifying these issues.

This study presents the 2011 data on ICD implantation compiled by the Spanish Implantable Cardioverter-Defibrillator Registry. Most of the centers that carry out ICD implantation in Spain have collaborated with this registry. As is the case of the official reports describing the activity of previous years,^{4–10} the present report was written by members of the Electrophysiology and Arrhythmia Section (*Sección de Electrofisiología y Arritmias [SEA]*) of the Spanish Society of Cardiology (*Sociedad Española de Cardiología [SEC]*).

The main objective of the registry is to gain information on current ICD use in Spain, with a focus on the indications for this treatment, the clinical characteristics of the patients, implantation data, types of devices, the ICD programming used, and complications during the procedure.

METHODS

Data for the registry were collected on a data acquisition form available on the SEC web site.¹¹ ICD implantation teams directly filled out the form during or following the procedure on a voluntary basis, in collaboration with personnel from the ICD manufacturer. The forms were then sent by fax or electronic mail to the SEC.

The information was entered in the Spanish Implantable Cardioverter-Defibrillator Registry database by a technician engaged for this purpose with the help of a computer specialist from the SEC and a member of the SEA. Data were filtered by the SEC technician and the SEA member. The authors of the present article performed the data analysis and are responsible for the contents of this report.

The census data for the country as a whole and for each autonomous community and province used to calculate the rates per million population were obtained from estimates provided by

the Spanish National Institute of Statistics, referring to the period up to 1 January 2011.¹²

To estimate the representativeness of the registry, the percentage of notified implantation and replacement procedures with respect to the total number of implantations and replacements carried out in Spain in 2011 was calculated. The total number was based on the data for 2011 reported to the European Medical Technology Industry Association (EUCOMED)¹³ by the companies marketing ICDs in Spain. When more than 1 clinical presentation form or type of arrhythmia was recorded on the data collection form in the same patient, the most serious condition was used in the analysis.

For each variable analyzed, percentages were calculated based on the total number of notified implantations with information on the particular variable.

Statistical Analysis

The numerical results are expressed as the mean (standard deviation) or the median [interquartile range], depending on the distribution of the variable. Comparisons between continuous quantitative variables were performed with ANOVA or the Kruskal-Wallis test. Qualitative variables were compared with the chi-square test. The relationships between the number of implantations and the number of implantation centers per million population and between the total number of implantations and the number of implantations for primary prevention in each center were evaluated using linear regression models. The statistical significance of the gradual increase in indications for primary prevention vs secondary prevention was also analyzed.

RESULTS

The response rates for the various fields on the data collection form ranged from 99.3% for the name of the participating hospital to 51% for the date of the previous implantation in replacement procedures.

Participating Centers

A total of 167 centers that perform ICD implantation in Spain participated in the registry (22 more than in 2010) (Table 1). Among them, 91 were public health care centers (5 more than in the previous year). The number of participating centers, the implantation rate per million population, and the total number of implantations performed in 2001 by autonomous community are shown in Figure 1.

Total Number of Implantations

Overall, 4481 implantations (first implants and replacement implants) were notified to the registry in 2011, a substantially lower number than in 2010 (4627). According to the EUCOMED¹³ data, 5361 devices were implanted in 2010; hence, 83.6% of the total were notified to the registry. The total number of implantations recorded in the registry and the number estimated by EUCOMED over the last 9 years are shown in Figure 2.

The implantation rate recorded in the registry was 97 per million population, whereas the rate according to the EUCOMED data was 116.2 per million population. The changes occurring in the implantation rates over the last 9 years according to the registry and EUCOMED data are shown in Figure 3. The numbers of implantations notified to the registry by participating centers are

Table 1
Number of Implantations by Autonomous Community, Province, and Center

<i>Andalusia</i>		
Granada	Hospital Ruiz de Alda	1
Almería	Hospital Torrecárdenas	19
Cádiz	Hospital de Jerez	11
	Hospital Universitario Puerta del Mar	42
Córdoba	Hospital de la Cruz Roja de Córdoba	2
	Hospital Reina Sofía	42
Granada	Hospital Clínico Universitario San Cecilio	16
	Hospital Universitario Virgen de las Nieves	97
Huelva	Hospital General Juan Ramón Jiménez	39
Málaga	Clínica El Ángel	5
	Clínica Parque San Antonio	7
	Hospital Internacional Xanit	6
	Hospital Regional Universitario Carlos Haya	2
	Hospital USP de Marbella	2
	Hospital Virgen de la Victoria	167
Seville	Clínica de Fátima	1
	Clínica Santa Isabel	6
	Hospital Infanta Luisa (Clínica Esperanza de Triana)	3
	Hospital Nisa Aljarafe	1
	Hospital Ntra. Señora de Valme	28
	Hospital Virgen del Rocío	71
	Hospital Virgen Macarena	63
<i>Aragon</i>		
Zaragoza	Hospital Clínico Universitario Lozano Blesa	48
	Hospital Miguel Servet	98
	Hospital Quirón Zaragoza	1
<i>Principality of Asturias</i>	Hospital Central de Asturias	166
<i>Balearic Islands</i>		
	Hospital Universitari Son Espases	49
	Clínica Juaneda	1
	Clínica Rotger Sanitaria Balear, S.A.	1
	Clinica USP Palmaplanas	4
	Hospital Son Dureta	1
	Hospital Son Llätzer	22
	Policlínica Miramar (Ameba S.A.)	1
<i>Canary Islands</i>		
Las Palmas	Clínica Santa Catalina S.A.	1
	Hospital Dr. Negrín	28
	Hospital Insular de Gran Canaria	35
	Hospital Ntra. Sra. del Perpetuo Socorro	1
	Hospiten Ramblas	4
Sta. Cruz de Tenerife	Clínica Santa Cruz	1
	Hospital Ntra. Sra. de La Candelaria	32
	Hospital Universitario de Canarias	42
<i>Cantabria</i>		
Santander	Hospital Universitario Marqués de Valdecilla	83
<i>Castile and León</i>		
Ávila	Hospital Ntra. Sra. de Sonsoles	31
Burgos	Complejo Asistencial de Burgos	4

Table 1 (Continued)
Number of Implantations by Autonomous Community, Province, and Center

	Hospital General Yagüe	69
León	Hospital de León	43
Salamanca	Complejo Hospitalario de Salamanca	65
Segovia	Hospital General de Segovia	2
Valladolid	Hospital Campo Grande	11
	Hospital Clínico Universitario de Valladolid	69
	Hospital Río Hortega	28
<i>Castile-La Mancha</i>		
Albacete	Hospital General de Albacete	29
	Sanatorio Santa Cristina	1
Ciudad Real	Hospital General de Ciudad Real	19
	Ntra. Sra. de Alarcos	2
Cuenca	Hospital Virgen de la Luz	12
Guadalajara	Hospital General y Universitario de Guadalajara	25
Toledo	Complejo Hospitalario de Toledo	6
	Hospital Ntra. Sra. del Prado	23
	Hospital Virgen de la Salud	87
<i>Catalonia</i>		
Barcelona	Capio Hospital General de Catalunya	13
	Centro Médico Teknon	2
	Clínica Corachan	1
	Clínica Delfos	1
	Clinica Dexeus	3
	Clínica Pilar Sant Jordi	17
	Clínica Quirón	6
	Clínica Sagrada Familia	2
	Hospital de la Santa Creu i Sant Pau	124
	Hospital Can Ruti	1
	Hospital Clínic de Barcelona	178
	Hospital de Barcelona	1
	Hospital de Bellvitge	71
	Hospital del Mar	17
	Hospital Germans Trias i Pujol	53
	Hospital Sant Joan de Déu	3
	Hospital Vall d'Hebron	88
Lleida	Hospital Universitario Arnau de Vilanova	17
Tarragona	Hospital Universitario de Tarragona Joan XXIII	15
<i>Valencian Community</i>		
Alicante	Clínica Benidorm	3
	Clínica Vistahermosa	3
	Hospital de Dènia	5
	Hospital de Levante	1
	Hospital de Torrevieja	27
	Hospital del Vinalopó	13
	Hospital General Universitario de Alicante	137
	Hospital General Universitario de Elche	7
	Hospital Marina Salud	3
	Hospital Universitari Sant Joan	28
	Sanatorio del Perpetuo Socorro	1

Table 1 (Continued)

Number of Implantations by Autonomous Community, Province, and Center

Castellón	Consorcio Hospital Provincial de Castellón	1	
	Hospital de La Plana	8	
	Hospital General de Castelló	42	
	Hospital Rey Don Jaime	4	
Valencia	Grupo Hospitalario Quirón, S.A.	3	
	Hospital Clínico Universitario	96	
	Hospital de Manises	20	
	Hospital General Universitario	50	
	Hospital Lluís Alcanyís	6	
	Hospital Universitari de la Ribera	5	
Extremadura	Hospital Universitario Dr. Peset	27	
	Hospital Universitario La Fe	107	
	Badajoz	Clideba	2
		Hospital Infanta Cristina de Badajoz	57
Cáceres	Clínica San Francisco	2	
	Complejo Hospitalario de Cáceres	2	
	Hospital San Pedro de Alcántara	17	
Galicia	A Coruña	Complejo Hospitalario Universitario A coruña	97
		Complejo Hospitalario Universitario de Santiago	81
	Hospital Clínico de Santiago	7	
	Hospital USP Santa Teresa	4	
	Ourense	Centro Médico El Carmen	1
Pontevedra	Complejo Hospitalario Universitario	48	
	Hospital do Meixoeiro	20	
	Hospital Povisa	2	
La Rioja	Hospital San Pedro	27	
	Hospital Viamed Los Manzanos	1	
Community of Madrid	Clínica San Camilo	3	
	Clínica La Luz	3	
	Clínica Ntra. Sra. de América	6	
	Clínica Ruber, S.A.	1	
	Fundación Hospital Alcorcón	10	
	Fundación Jiménez Díaz. Clínica Ntra. Sra. de la Concepción	38	
	Hospital 12 de Octubre	95	
	Hospital Central de la Defensa	17	
	Hospital Clínico San Carlos	94	
	Hospital de Fuenlabrada	7	
	Hospital de Madrid-Montepíncipe	2	
	Hospital de Torrejón	3	
	Hospital del Henares	1	
	Hospital General Universitario Gregorio Marañón	100	
Hospital Infanta Cristina de Parla	2		
Hospital Infanta Elena	3		
Hospital Infanta Leonor	3		
Hospital los Madroños	1		
Hospital Madrid Norte/Sanchinarro	7		
Hospital Nisa Pardo de Aravaca	1		

Table 1 (Continued)

Number of Implantations by Autonomous Community, Province, and Center

Region of Madrid	Hospital Quirón Madrid	6	
	Hospital Ramón y Cajal	96	
	Hospital Ruber Internacional	2	
	Hospital San Rafael	2	
	Hospital Sanitas La Moraleja	1	
	Hospital Severo Ochoa	14	
	Hospital Sur Alcorcón	1	
	Hospital Universitario de Getafe	11	
	Hospital Universitario La Paz	96	
	Hospital Universitario Madrid	1	
	Hospital Universitario Puerta de Hierro	142	
	Hospital USP San Camilo	1	
	Region of Murcia	Clínica Virgen de la Vega	4
		Hospital General Universitario Morales Meseger	4
Hospital General Universitario Sta. Maria del Rosell		2	
Hospital Rafael Méndez		3	
Chartered Community of Navarre	Hospital Universitario Virgen de la Arrixaca	57	
	Clínica Universitaria de Navarra	33	
	Hospital de Navarra	53	
Basque Country	Álava	Hospital Universitario de Araba	1
		Hospital Txagorritxu	47
	Vitoria	Hospital de San José	1
	Guipúzcoa	Hospital de Donostia	11
	Vizcaya	Clínica Vicente San Sebastián	1
	Hospital de Basurto	48	
	Hospital de Cruces	35	
Hospital de Galdakao-Usansolo	16		
No data	Hospital Quirón Vizcaya	1	
		33	

shown in Table 1. The number of implantations carried out in each province and the rate per million population of the corresponding autonomous community are shown in Table 2. The name of the hospital in which the device was placed was reported in 99.2% of the cases; most procedures (s—4216 (94.5%))—were carried out in public health institutions.

First Implantations vs Replacement Procedures

This information was available in 4207 of the data forms sent (93.8%). There were 2954 first implantations, representing 70.2% of the total (73.8% in 2010). The rate of first implantations in 2011 was 64 per million population (69.7 in 2010).

Age and Sex

The mean age (standard deviation) (range) of patients receiving an ICD or replacement device was 62.4 (14.1) years (6–94). The age of those receiving only first implants was 61.5 (13.9) years. Most patients were men, who accounted for 82.1% of the total treated and 81.8% of patients receiving a first implant.

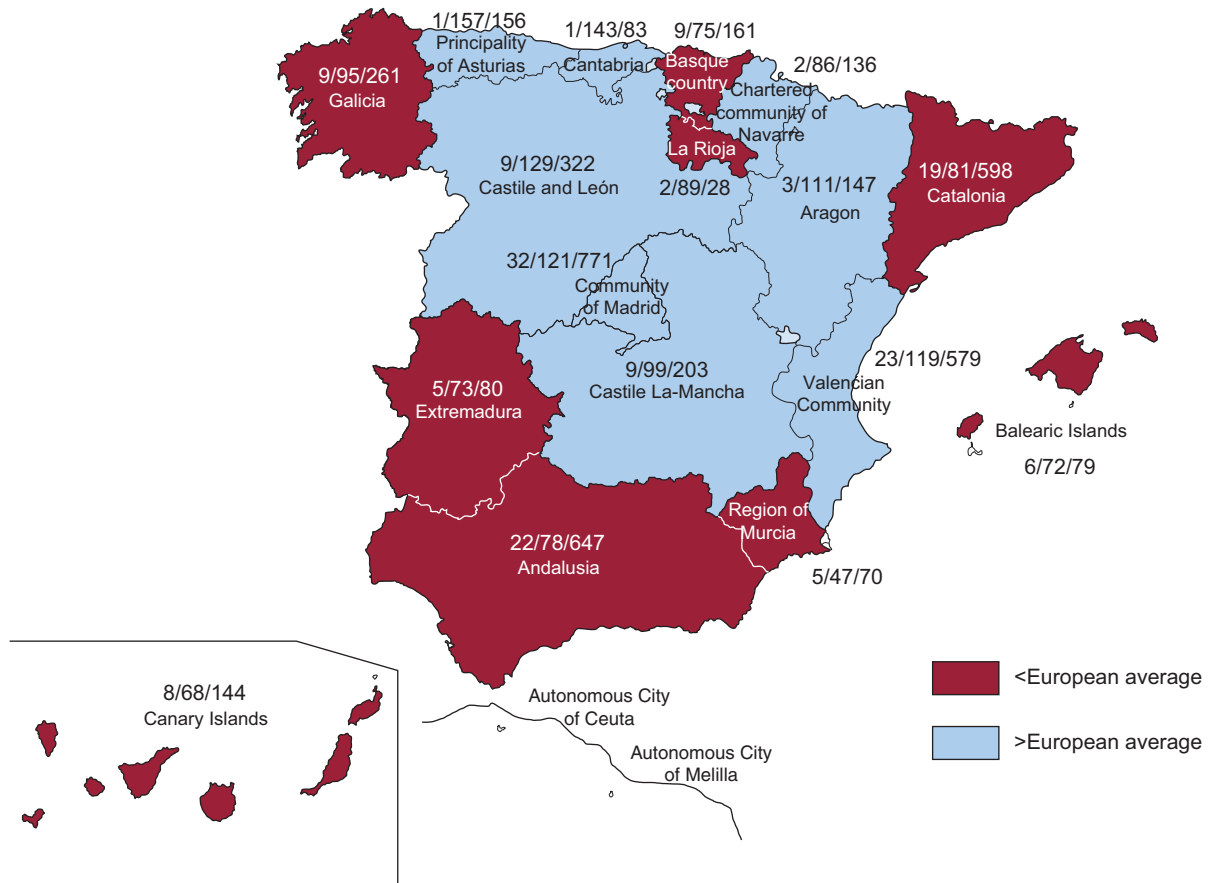


Figure 1. Distribution of the 2011 implantation activity by autonomous community: number of implantation centers/implantation rate per million population/total number of implantations.

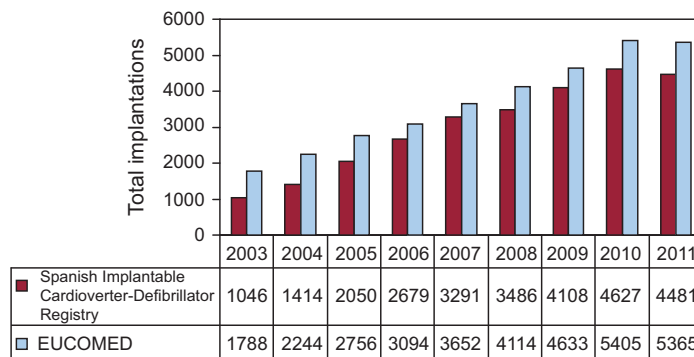


Figure 2. Total number of implantations notified to the registry and total number estimated by European Medical Technology Industry Association (2003-2011). EUCOMED, European Medical Technology Industry Association.

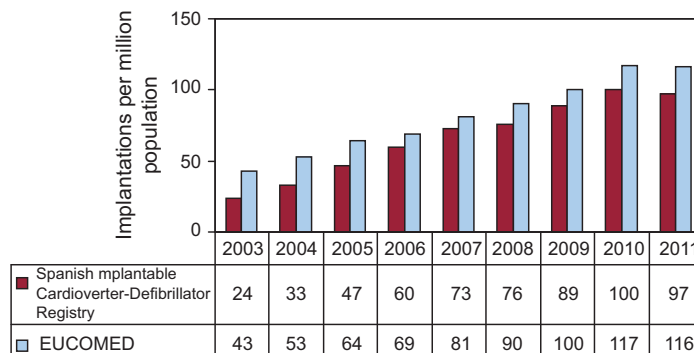


Figure 3. Total number of implantations per million population as recorded in the registry and as estimated by European Medical Technology Industry Association (2003-2011). EUCOMED, European Medical Technology Industry Association.

Table 2
Implantations Performed by Autonomous Community and Province

Autonomous community	Rate per million population	Province	Implants, n		
Andalusia	78.4	Almería	19		
		Cádiz	53		
		Córdoba	44		
		Granada	114		
		Huelva	39		
		Málaga	189		
		Seville	173		
		Zaragoza	147		
Aragon	111.8	Zaragoza	147		
Principality of Asturias	157.3	Asturias	166		
Canary Islands	68.6	Las Palmas	65		
		Sta. Cruz de Tenerife	4		
Cantabria	68.6	Tenerife	75		
		Santander	83		
		Castile and León	126.2	Ávila	31
				Burgos	73
				León	43
Castile-La-Mancha	99.2	Salamanca	65		
		Segovia	2		
		Valladolid	108		
		Albacete	30		
		Ciudad Real	21		
		Cuenca	12		
		Guadalajara	25		
Catalonia	81.5	Toledo	116		
		Barcelona	582		
		Lleida	17		
		Tarragona	15		
		Valencian Community	119.3	Alicante	228
Castellón	55				
Valencia	314				
Extremadura	73.9			Badajoz	59
		Cáceres	21		
		Galicia	65.4	A Coruña	189
Ourense	2				
Pontevedra	70				
Balearic Islands	72.6			Baleares	79
		La Rioja	28		
Community of Madrid	121	Madrid	770		
Region of Murcia	47.7	Murcia	70		
Chartered Community of Navarre	86	Navarra	86		
Basque Country	161	Álava	49		
		Guipúzcoa	11		
		Vizcaya	101		
No data			33		

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

The most frequent underlying cardiac condition was ischemic heart disease (51%), followed by dilated cardiomyopathy (33.9%), hypertrophic cardiomyopathy (6.9%), and primary conduction abnormalities (Brugada syndrome, idiopathic ventricular fibrillation, and long QT syndrome, 3.9%), and in small percentages, valvular heart disease, and arrhythmogenic dysplasia (Fig. 4).

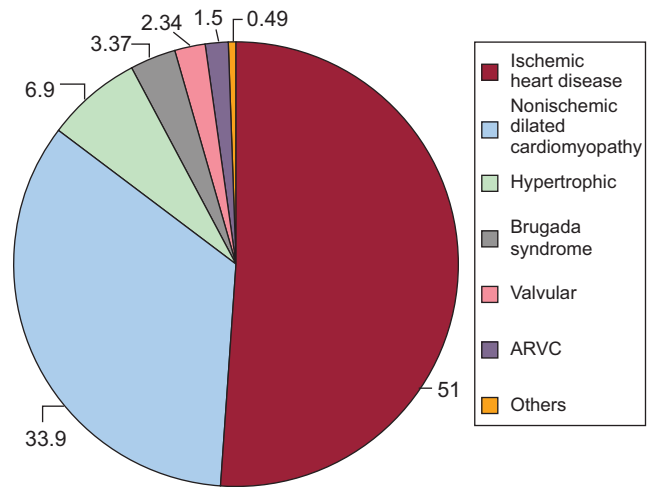


Figure 4. Type of heart disease prompting device implantation (all implantations) ARVC, arrhythmogenic right ventricular dysplasia. Data are expressed as percentages.

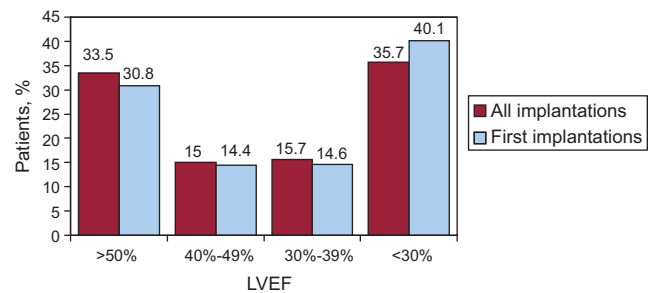


Figure 5. Left ventricular ejection fraction in registry patients (all implantations and first implantations). LVEF, left ventricular ejection fraction. Data are expressed as percentages.

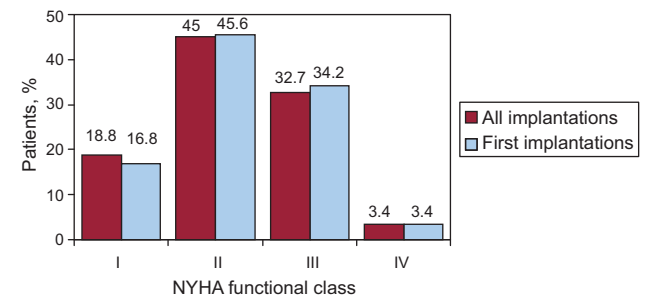


Figure 6. New York Heart Association functional class in registry patients (all implantations and first implantations). NYHA, New York Heart Association.

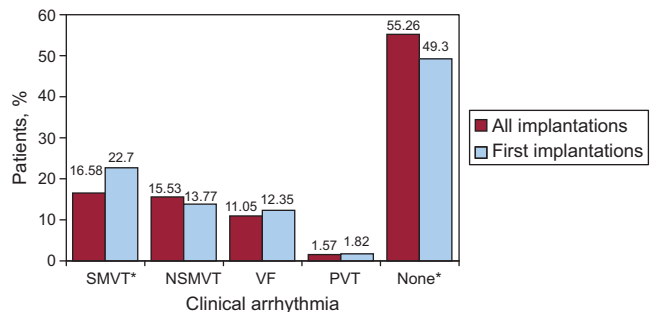


Figure 7. Arrhythmia prompting device implantation (all implantations and first implantations), expressed as percentage. NSMVT, nonsustained monomorphic ventricular tachycardia; PVT, polymorphic ventricular tachycardia; SMVT, sustained monomorphic ventricular tachycardia; VF, ventricular fibrillation. *P<.001.

Table 3
Number of First Implantations According to the Type of Heart Disease, Type of Clinical Arrhythmia, and Form of Presentation (2008–2011)

	2008	2009	2010	2011
<i>Ischemic heart disease</i>				
Aborted SCD	93 (9.3)	111 (7.9)	154 (10.0)	150 (10.85)
SMVT associated with syncope	126 (10.2)	117 (8.4)	132 (8.6)	199 (14.4)
SMVT without syncope	176 (14.3)	201 (14.4)	317 (20.7)	197 (14.2)
Syncope without arrhythmia	138 (11.2)	121 (8.7)	68 (4.4)	95 (6.8)
Prophylactic implantation	607 (49.3)	637 (45.9)	642 (42.0)	623 (45.0)
Missing/unclassifiable	92 (7.5)	202 (14.5)	212 (13.9)	120 (8.7)
Subtotal	1231	1389	1525	1384
<i>Dilated cardiomyopathy</i>				
Aborted SCD	38 (6.6)	53 (5.5)	49 (6)	47 (5.9)
SMVT associated with syncope	33 (5.7)	61 (6.4)	58 (7.1)	57 (7.1)
SMVT without syncope	43 (7.4)	69 (7.2)	136 (16.8)	157 (19.6)
Syncope without arrhythmia	74 (12.8)	102 (10.7)	34 (4.2)	37 (4.6)
Prophylactic implantation	337 (58.3)	440 (46.1)	393 (48.7)	427 (53.4)
Missing/unclassifiable	53 (9.2)	228 (23.9)	136 (16.8)	74 (9.3)
Subtotal	578	953	806	799
<i>Valvular heart disease</i>				
Aborted SCD	11 (12.5)	8 (9.3)	9	16 (10.8)
SMVT	25 (28.4)	27 (31.3)	29	47 (31.8)
Syncope without arrhythmia	8 (9.1)	8 (9.3)	4	5 (3.4)
Prophylactic implantation	39 (44.3)	28 (23.5)	50	66 (44.6)
Missing/unclassifiable	5 (5.7)	15 (17.4)	16	14 (9.6)
Subtotal	88	86	108	148
<i>Hypertrophic cardiomyopathy</i>				
Secondary prevention	29 (19.9)	24 (14.9)	90 (54.5)	127 (68.8)
Prophylactic implantation	99 (67.8)	97 (60.2)	53 (32.1)	52 (28.0)
Missing/unclassifiable	18 (12.3)	40 (24.8)	22 (13.2)	7 (3.8)
Subtotal	146	161	165	186
<i>Brugada syndrome</i>				
Aborted SCD	7 (10.4)	11 (8.4)	17 (24.6)	7 (13.5)
Prophylactic implantation in syncope	27 (40.4)	36 (27.6)	18 (26.6)	25 (40.8)
Prophylactic implantation without syncope	28 (41.2)	52 (40)	23 (33.3)	15 (28.8)
Missing/unclassifiable	5 (7.8)	31 (23.8)	11 (15.9)	5 (9.6)
Subtotal	67	130	69	52
<i>ARVC</i>				
Aborted SCD	2 (6.96)	1 (3.8)	4 (15.9)	2 (4.6)
SMVT	12 (41.4)	16 (61.2)	23 (71.8)	21 (48.8)
Prophylactic implantation	12 (41.4)	5 (19.2)	4 (12.5)	17 (39.5)
Missing/unclassifiable	3 (10.3)	4 (15.3)	1 (3.1)	3 (6.98)
Subtotal	29	26	32	43
<i>Congenital heart disease</i>				
Aborted SCD	2 (11.1)	4 (19)	3 (8.1)	4 (12.5)
SMVT	5 (27.8)	1 (4.7)	15 (40.5)	8 (25.0)
Prophylactic implantation	10 (55.6)	9 (42.8)	16 (43.2)	15 (46.8)
Missing/unclassifiable	1 (5.5)	7 (33.3)	3 (8.1)	5 (15.4)
Subtotal	18	21	37	32
<i>Long QT syndrome</i>				
Aborted SCD	3 (15.8)	9 (50)	18 (60)	11 (50)
Prophylactic implantation	16 (84.2)	3 (16.6)	6 (20)	9 (40.9)
Missing/unclassifiable	0	6 (33.3)	6 (20)	2 (9.1)
Subtotal	19	18	30	22

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

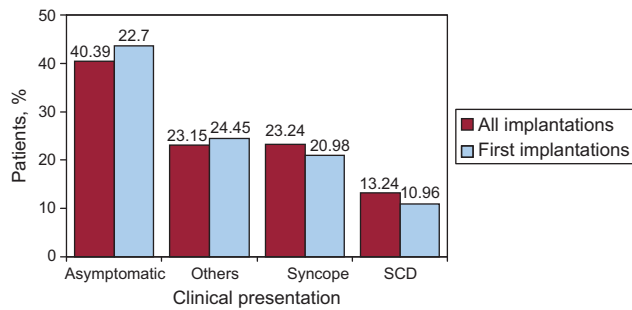


Figure 8. Clinical presentation of arrhythmia in registry patients (all implantations and first implantations). SCD, sudden cardiac death.

With regard to left ventricular function in patients with first implants, the left ventricular ejection fraction was <30% in 40.1% of patients, 30–39% in 14.6%, 40–49% in 14.4%, and >50% in 30.8% of patients. In patients with replacement ICDs, the distribution of values was similar (Fig. 5).

New York Heart Association (NYHA) functional class in patients with a first ICD was mainly NYHA II (45.5%), followed by NYHA III (32.2%), and NYHA I (18.8%); a small percentage of patients were in NYHA IV (3.4%). In this case, the distribution of values between first implants and replacement implants was also very similar (Fig. 6).

The baseline cardiac rhythm, recorded in 84.5% of patients, was sinus rhythm (76.8%), atrial fibrillation (19%), paced rhythm (3.9%), and other rhythms (atrial flutter and other arrhythmias) in the remaining patients.

Clinical Arrhythmia Prompting Device Placement, Presentation, and Electrical Stimulation-Induced Arrhythmia

Related data were available in 80.9% of notified cases. In first implants, the largest group comprised patients who did not have documented clinical arrhythmia (55.2%), followed by those with sustained monomorphic ventricular tachycardia and those with nonsustained monomorphic ventricular tachycardia (16.5% and 15.5%, respectively). Among the total of implantation procedures performed, 49.3% of devices were placed in patients without documented clinical arrhythmia (Fig. 7). Percentage differences in the type of arrhythmia between patients receiving first implants and the total were statistically significant for those without arrhythmia and those with sustained monomorphic ventricular tachycardia ($P<.001$), but not for the remaining patients.

The most common clinical presentation in the overall population and in the group with a first implant was an absence of symptoms, followed by “other symptoms”, and syncope. Statistically significant differences between patients with a first implant and the overall group were found for sudden cardiac death and asymptomatic status ($P<.01$), but not for syncope or other presentations (Fig. 8).

Information regarding whether electrophysiological study had been performed was available in 2357 notifications of first implantations (79.7%); these studies were carried out in 278 cases (11% of notifications provided this information). The most frequently recorded induced arrhythmia was sustained monomorphic ventricular tachycardia (49%), followed by ventricular fibrillation (18.8%), and less frequently nonsustained monomorphic ventricular tachycardia (10%), and others (4.2%). Arrhythmia was not induced at electrophysiological study in 18.8% of patients undergoing this test. The studies were mainly performed in patients with ischemic heart disease and dilated cardiomyopathy.

Table 4

Changes in the Main Indications for Implantable Cardioverter Defibrillator Placement (First Implantations, 2003–2011)

Year	SCD	SMVT	Syncope	Primary prevention
2003	13.7	2.8	14	29
2004	14.8	37	16	32.2*
2005	11.1	34.8	14.6	39.5*
2006	9.5	27	13.2	50.3*
2007	9.9	25	14.1	50.7*
2008	9.3	21.4	12.3	57*
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

SCD, sudden cardiac death; SMVT, sustained monomorphic ventricular tachycardia.
* Significant difference with respect to the previous year ($P<.01$).

Clinical History

In keeping with a suggestion from the SEC Working Group on Implantable Cardioverter-Defibrillators, several new fields related to the patients' medical history that had not been included in previous years were incorporated in the 2011 data form.¹¹ These were filled out in 60% of the notifications with the following results: hypertension, 53.6%; hypercholesterolemia, 45.2%; smoking, 32.3%; history of atrial fibrillation, 29.8%; diabetes mellitus, 26.8%; renal failure, 15%; and family history of sudden cardiac death, 8.7% and stroke, 6.4%. The QRS interval was documented in 48.9% of notifications and yielded a mean value of 128.3 (67.1) ms.

Indications

The indication for a first ICD implantation was for primary prevention in most cases (59.4%), with a notable increase since 2003, when 29%⁴ were indicated for this reason. This increase was statistically significant ($P<.01$) between all successive years of the registry, with the exception of a decrease from 2008 to 2009 and an increase from 2010 to 2011, in which the difference was not statistically significant.

The changes occurring in first implantations according to the type of heart disease, type of clinical arrhythmia and presentation form during the 2008 to 2011 period are shown in Table 3. Ischemic heart disease was the condition most often associated with ICD implantation in 2011, and the indication was mainly for primary prevention (59.6%), thereby continuing the growing trend seen in the last few years (58.5% in 2010 and 56.4% in 2009). The trend in primary prevention for dilated cardiomyopathy also increased (74.7%, vs 72.8% in 2010 and 69.4% in 2009). In 59.7% of implantations, 3-chamber pacemakers were combined with cardiac resynchronization therapy (CRT). In ischemic heart disease, CRT was used in 29.9% of patients. In the less common heart diseases, the predominant indication was primary prevention in hypertrophic cardiomyopathy, valvular disease, and Brugada syndrome, and secondary prevention in long QT syndrome, arrhythmogenic cardiac disease, and congenital heart disease.

The changes occurring in the indications related to the main types of heart diseases over the last 9 years are shown in Table 4.

Implantation Setting and Attending Specialist

The response rate for these items was 87%. The main setting in which ICD implantation was performed was the electrophysiology

Table 5
Types of Implantable Cardioverter-Defibrillators Placed

	2010, total	2011, total	2011, EUCOMED	2010, first implants	2011, first implants
Single-chamber	50.3	46.7	46.6	51.1	48.3
Dual-chamber	20.2	18.4	18.3	20.0	17.2
Resynchronizer	28.2	34.9	35.7	28.7	34.5

EUCOMED, European Medical Technology Industry Association.

laboratory in 76.4% of cases (70.3% in 2010 and 67% in 2009), followed by the operating room in 21.2%.

The procedure was carried out by electrophysiologists in 78.4% of cases (76.1% in 2010), surgeons in 15.5% (17.7% in 2010), both these specialists in 2%, and other specialists in 1.4%.

Generator Implantation Site

The generator was placed subcutaneously in a pectoral position in 91.6% and a subpectoral position in 8.4%. In first implants, the values were 96.6% and 6.4%, respectively.

Type of Device

This information was provided in 94.5% of notifications and is summarized in Table 5. Single-chamber ICDs, dual-chamber ICDs, and CRTs were used in 46.7%, 18.4%, and 34.9% of patients, respectively. In 2010, these values were 50.3%, 20.2%, and 28.2%, respectively.

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

Among the 1253 ICD replacement procedures, this information was provided in 81.48%. The most common reason was depletion of the battery, which occurred in 917 cases (89%), and complications in the remaining 105 cases (10.5%). Among the latter cases (early replacements), 20.27% were carried out within the first 6 months following the implantation procedure.

In 82.3% of replacement notifications, information was provided on the status of the leads: 8.7% were malfunctioning (90 entries), and lead extraction was carried out in 46.6% of the cases in which this information was recorded.

Implantable Cardioverter-Defibrillator Programming

Data on this item were included in 89.9% of entries. The antibradycardia pacing most often used was VVI mode (49%), followed by DDD mode (30.3%), VVIR mode (8.6%), DDDR mode (7.2%), and other pacing modes, mainly preventive algorithms for ventricular pacing (5%). Antitachycardia pacing was programmed in 92.9%.

Defibrillation thresholds were measured in 446 patients (12.4%). In the 3591 entries providing this information, the mean threshold was 22.6 J and a mean of 1.1 shocks were delivered.

Complications

In 2011, there were 6 deaths at implantation (0.1%), a rate similar to 2010, 15 dissections of the coronary sinus (0.3%), 9 cases of pneumothorax (0.2%), and 17 cases of various or unspecified complications.

DISCUSSION

The results of the 2011 ICD registry continue to show acceptable representativeness. The information contained in this registry is a reliable reflection of the situation in Spain regarding the number of implantations performed, the location and distribution of this activity by autonomous community, the type of implant placed, the indications for this treatment, clinical characteristics of the patients, programming of the devices, and complications.

Comparison With Registries of Previous Years

Since data from the Spanish Implantable Cardioverter-Defibrillator Registry were first published, 2011 was the first year in which a decrease occurred in the total number of implantations performed and in the percentage of implantations per million population. These data are consistent with the results published by EUCOMED¹³ and are similar to the trends observed in some other European countries. Nonetheless, despite this decrease, the percentage of ICD placements for an indication of primary prevention rose, mainly due to the increase in the use of CRT devices. Among the total, 66.2% of the devices implanted were single-chamber or dual-chamber ICDs (70.5% in 2010), whereas 34.4% were CRT devices (28.2% in 2010). Thus, there was a decrease in the indications for single- and dual-chamber ICDs, and an increase in CRT implantations, which partly counterbalanced the drop in conventional ICDs. It seems reasonable to consider that these data are a reflection of the effect of the economic crisis in Europe and that a continuation of this trend could be expected in 2012.

The most common indication for implantation of a first ICD was ischemic heart disease, at 51% (53% in 2010), and the second in frequency was dilated cardiomyopathy, at 33.9% (27.6% in 2010). More than half the implants in cases of dilated cardiomyopathy were CRT devices (59.7%), whereas the percentage was lower (29.9%) in ischemic heart disease patients.

Over the last 10 years, there has been a gradual increase in ICD use, which is likely linked to publication of several clinical trials that have provided reliable evidence supporting the benefits of this type of therapy. Following publication of the Multicenter Automatic Defibrillator Implantation Trial II¹⁴ in 2002, a significant increase in ICD procedures was observed from 2002 to 2003. The results of the Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure trial¹⁵ and the Sudden Cardiac Death in Heart Failure Trial,¹⁶ published between 2005 and 2006, confirmed previous data and supported the use of this therapy, with or without cardiac resynchronization, in heart failure patients. In 2011, this trend reversed and the total number of implants decreased, despite a 6.4% increase in CRT implants. This change may have been driven by publication of the Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy¹⁷ study in 2009, which included patients in NYHA functional class I and II.

Differences remain in the number of implantations recorded in the present registry and the EUCOMED data, and these differences have persisted over time in similar percentages. The number of participating centers has increased to 167 (22 more than in 2010); however, 70 of them notified less than 10 implantations each (and among these 23 centers notified only 1), whereas 11 centers reported more than 100 implantations over the year. There was no correlation between the number of implantations performed per hospital and the percentage of implantations of CRT devices ($r=0.013$; $P=.95$); nor was a correlation found between the number of implantations and the percentage of primary prevention indications ($r=0.003$; $P=.98$).

There were no significant changes in the patients' epidemiologic characteristics, and similar data were recorded for age and sex. Patients with severe ventricular dysfunction and patients in NYHA functional class II or III continued to predominate. The increase in implantation of ICD-CRTs persisted, with a rate of 34.4% in 2011 (27.8% in 2010 and 25.2% in 2009). There were no substantial changes regarding the implantation site or specialist performing the procedure. The 2011 data were very similar to those of 2010, with a slight increase in the percentage of implantations performed by electrophysiologists (78.4% in 2011 and 76.1% in 2010).

Differences Between Autonomous Communities

The differences in ICD implantation rates among the various autonomous communities held steady. The overall average implantation rate in Spain in 2011 was 97 per million population, 116.2 per million population according to EUCOMED data. Several autonomous communities showed rates above this average: the Principality of Asturias (157), Cantabria (143), Castile and León (129), the Community of Madrid (121), the Valencian Community (119) and Castile-La-Mancha (99). The autonomous communities with activity below the average included Galicia (95), La Rioja (89), the Chartered Community of Navarre (86), Catalonia (81), Andalusia (78), the Basque Country (75), Extremadura (73), the Balearic Islands (72), the Canary Islands (68), and the Region of Murcia (47). Except in the case of the Chartered Community of Navarre (179 in 2010), which showed a considerable decrease with respect to the previous year, there was a slight, uniform drop in the implantation rate per million population in most autonomous communities, particularly those with the largest populations. In the Principality of Asturias, Cantabria, and La Rioja, however, an increase in the implantation rate was documented with respect to 2010. There is no clear justification for these large differences among autonomous communities, although they may be explained in part by the number and level of development of the arrhythmia units in the different communities.

Comparison With Other Countries

The implantation rate in Europe including ICDs and ICD-CRTs was 269 per million population. Germany, with 498 implants per million population, remained the country with the highest rate, and Spain, with 120 according to the EUCOMED data, was the country with the lowest rate. The following countries were above the European average: Germany (498), Italy (353), the Netherlands (345), and Denmark (318). Countries below the average include Austria (229), the Czech Republic (227), Poland (222), Belgium (206), France (191), Switzerland (188), Sweden (188), the United Kingdom (164), Norway (184), Finland (158), Portugal (127), and Spain (120). We do not have data for Greece or Iceland.

The rate of ICD implantations in Europe was 162 per million population (156 in 2010). The number of implantations performed

increased in Germany, Denmark, France, Norway, Ireland, Italy, and Portugal. The ICD-CRT implantation rate was 107 per million (99 in 2010). Regarding these devices, the number of implantations increased in all countries with the exception of the Czech Republic, Sweden, and Portugal, which showed a slight decrease. As in previous registries, Germany (177) and Italy (176) had the highest rates of ICD-CRT implantation in Europe, whereas Spain (42) had the lowest rate.

Although there were some slight changes with respect to previous years, the 2011 data were fairly similar to those in the previous registries. The difference between Spain and the European average was maintained: the implantation rate in our country was half that of the European average and one-third that of Germany. In previous registries this difference was attributed to several causes,¹⁰ such as the degree of difficulty in accessing the health care system, the social perception of sudden death, the incidence of ischemic heart disease and sudden death in our setting, the degree to which clinical trials and clinical practice guidelines are accepted, and the lack of a sufficient number of arrhythmia and electrophysiology units, etc. However, such large differences in the number of implantations in Spain relative to countries such as Poland and the Czech Republic, in which *per capita* incomes are lower, do not seem reasonable.

Limitations

According to the EUCOMED data, 83.6% of implantations performed in Spain were notified to the registry. This value is lower than the 86% notified in 2010 and the 90% in 2007 but is still representative of the situation in Spain. In the 2011 registry, a new data collection form containing additional fields related to clinical items was used for the first time and the response rates varied according to the specific item. In some hospitals, the true number of implantations performed differed from the number notified. This is because only implantations recorded on the data form were included, and some cases may not have been notified correctly or may have been lost in the process. Lastly, the complications recorded do not accurately reflect the true situation because the data form was completed during or immediately after the procedure. Therefore, subacute complications such as lead displacements, hematomas, and pneumothoraces appearing after the data form had been filled out and sent would not be recorded.

Future Prospects of the Spanish Implantable Cardioverter-Defibrillator Registry

The current Registry is the VIII Official report of this activity in Spain. Over the years, maintenance of the registry and its updating have been made possible by the collaboration and work of all the participating members. Continuation of the registry in the future will rely on the efforts of all those involved to prevent the gradual decrease in the percentage of implantation notifications that has occurred since 2007.

Modernization of the registry, with the possibility of using the currently available online data collection form, may improve the results. This format will enable basic longitudinal follow-up to be performed, with information on parameters such as mortality, shocks delivered, prescribed therapies, and complications, thus enhancing the value of the registry.

CONCLUSIONS

The 2011 Spanish Implantable Cardioverter-Defibrillator Registry is a compilation of 83.6% of the ICD implantations carried out

in Spain and continues to be representative of the use of and indications for this therapy in our country. This is the first year that the number of implantations has decreased with respect to previous registries, with a rate of 97 implantations per million population. The primary prevention indications have continued to increase and account for 70.6% of the total in first implantations. As in previous years, the implantation rate in our country in 2011 was lower than the European Union average, and considerable differences were seen to persist among the autonomous communities.

ACKNOWLEDGEMENTS

We thank all the health care professionals involved in ICD implantation in Spain, who have voluntarily and generously contributed to the success of this registry.

We are also grateful to the personnel from the ICD manufacturers (Medtronic, Boston Scientific, St. Jude Medical, Biotronik, and Sorin Group), who collaborated in collecting and sending data to the SEC in the majority of implantations.

We would also like to thank the SEC for their invaluable work in entering data and maintaining the registry database, in particular Gonzalo Justes and José María Naranjo.

CONFLICTS OF INTEREST

J. Alzueta has participated in research projects with Medtronic, St. Jude and Boston and in round tables sponsored by Biotronik, St. Jude and Boston.

J.M. Fernández received a grant from SEC to cover maintenance of the Spanish Implantable Cardioverter-Defibrillator Registry database.

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