SPECIAL ARTICLE

Spanish Implantable Cardioverter-Defibrillator Registry. Sixth Official Report of the Spanish Society of Cardiology Working Group on Implantable Cardioverter-Defibrillators (2009)

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Introduction and objectives. This article describes the findings of the 2009 Spanish Implantable Cardioverter-Defibrillator (ICD) Registry compiled by the Working Group on Implantable Cardioverter-Defibrillators of the Spanish Society of Cardiology's Electrophysiology and Arrhythmias Section.

Methods. Each implantation team voluntarily sent prospective data recorded on a single-page document to the Spanish Society of Cardiology.

Results. In total, 4108 device implantations were reported, which comprised 88.6% of the estimated total number of implantations carried out. The number of implants reported corresponded to 89 per million population and the estimated total number was 100.2 per million. The proportion of first implantations among those reported was 71.3%. Data were received from 134 centers, 17 more than in 2008. There continued to be significant regional variations between the various Spanish autonomous regions. The highest implantation rate (81%) was in men (mean age 62 years) who had severe or moderate-to-severe ventricular dysfunction and were in New York Heart Association functional class II. The most common heart condition was ischemic heart disease, followed by dilated cardiomyopathy. Indications for primary prevention accounted for 55.9% of first implantations; this figure was lower than the previous year's for the first time since 2003. The most significant increase observed was in patients with ischemic heart disease.

Conclusions. The 2009 Spanish ICD registry included data on almost 89% of all ICD implantations performed in the country. Although the number of implantations has continued to increase, it still remains far from the European average. The percentage of implantations performed for primary prevention was observed to have stabilized.

Key words: *Defibrillator. Registry. Arrhythmia.*

Registro Español de Desfibrilador Automático Implantable. VI Informe Oficial del Grupo de Trabajo de Desfibrilador Automático Implantable de la Sociedad Española de Cardiología (2009)

Introducción y objetivos. Se presentan los resultados del Registro Español de Desfibrilador Automático Implantable (DAI) de 2009 elaborado por el Grupo de Trabajo de Desfibrilador Automático Implantable de la Sección de Electrofisiología y Arritmias de la Sociedad Española de Cardiología (SEC).

Métodos. Se envió de forma prospectiva a la SEC la hoja de recogida de datos cumplimentada de forma voluntaria por cada equipo implantador.

Resultados. El número de implantes comunicados fue de 4.108 (el 88,6% del total de implantes estimado). El número de implantes por millón de habitantes fue 89 y el estimado, 100,2. La tasa de primoimplantes supuso el 71,3% de los registros. Se obtuvieron datos de 134 centros (17 centros más que en 2008). Sigue habiendo diferencias regionales importantes entre las distintas comunidades autónomas. Existe una mayor tasa de implante en varones (81%), con una media de edad de 62 años, disfunción ventricular severa o moderada a 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 fueron el 55,9% de los primoimplantes y se han reducido con respecto al año previo por primera vez desde el año 2003, y el más importante incremento observado se dio en pacientes con cardiopatía isquémica.

Conclusiones. El Registro Español de DAI de 2009 recoge información de casi el 89% de los implantes de DAI. El número de implantes ha continuado aumentando, aunque sigue alejado de la media europea. Se objetiva una estabilización en el porcentaje de implantes por prevención primaria.

Palabras clave: *Desfibrilador. Registro. Arritmia.*

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ABBREVIATIONS

FC: functional class
ICD: implantable cardioverter-defibrillator
LVEF: left ventricular ejection fraction
WGICD: Working Group on Implantable Cardoverter-Defibrillators
SCD: sudden cardiac death
CRT: cardiac resynchronization therapy
SMVT: sustained monomorphic ventricular tachycardia

INTRODUCTION

Implantable cardioverter-defibrillators (ICD) have proven efficacy in the primary and secondary prevention of sudden cardiac death (SCD). The results of several published studies have enabled the main indications for ICD use to be compiled in the clinical guidelines for the management of patients with ventricular arrhythmias or at risk of SCD.[1,2] However, the increased use of ICD has raised questions concerning their efficacy outside the context of clinical trials, the appropriate selection of patients for ICD implantation, access to treatment, safety, and cost-effectiveness.[3] Health registries may prove very useful in providing information on these issues and the application of the clinical guidelines in nonselected patient populations, given the scarce information in the literature.

The present report brings together data on ICD implantation from the Spanish ICD Registry for 2009. This registry was initiated in 1996 by the Electrophysiology and Arrhythmia Section of the Spanish Society of Cardiology (SEC) and subsequently strengthened following the creation of the Working Group on ICD (WGICD) within this section of the SEC, and which has been publishing the data from this registry every year since 2002.[4-8]

The main objective of the registry is to determine how ICDs are currently used in Spain regarding indications, clinical characteristics of the patients, implantation parameters, types of device and their programming, and procedural complications.

METHODS

The registry data were obtained via a data collection form available at the SEC web page (http://www.secardiologia.es/ images/stories/file/ arritmias/registro-nacional-dai2010.pdf). The form was completed directly and voluntarily by each implantation team in collaboration with staff from the ICD manufacturer, during or after ICD implantation, and was sent by fax or e-mail to the SEC.

The SEC staff input the information into the Spanish ICD Registry database. Data cleaning was performed by a SEC computer specialist and a member of the WGICD. The authors of this article were responsible for data analysis and manuscript preparation.

The population data used to calculate rates per million population for the country as a whole and by autonomous community and province were obtained from the estimates reported for the period up to January 1, 2009 by the Spanish National Institute of Statistics.[9]

To estimate the representativeness of the registry, we calculated the proportion of implantations and replacement procedures reported in relation to the total number of implantations and replacement procedures performed in Spain in 2008. The total number was based on data provided that year by the device manufacturers to the European Medical Technology Industry Association (EUCOMED).[10]

In case different medical conditions or clinical arrhythmias were reported for the same patient, only the most severe condition was included for analysis.

The percentages for every variable analyzed were calculated according to the total number of implantations for which information on that variable was available.

Statistical Analysis

The numerical results are expressed as mean ± standard deviation. Continuous quantitative variables were calculated using ANOVA or the Kruskal-Wallis test. Qualitative variables were compared using the χ^2 test. The relationship between the number of implantations and implantation centers per million population and between the total number of implantations and the number of implantations for primary prevention in each center were assessed using linear regression analysis. The statistical significance of the trend towards use of ICDs in primary versus secondary prevention was assessed using the Mantel-Haenszel χ^2 test. A P value of <.05 was used as a cutoff for statistical significance. The statistical analysis was performed using the SPSS statistical software package, version 18.0.

RESULTS

The response rates for different fields in the data collection form ranged from 54.75% (use in primary or secondary prevention) to 99.46% (name of implantation center), although the response rate was in general higher than 80%.

Implantation Centers

In total, 134 centers performed ICD implantation and provided data to the registry (29 more than in 2008) (Table 1). Of these, 80 were public hospitals (1 more than in 2008). Figure 1 shows the total number of centers and the number of implantations per million population in centers in each autonomous community that provided data to the registry in 2009.

Total Number of Implantations

In total, 4108 implantations (first implantations and replacements) were included in the registry for 2009. Based on a total of 4633 implantations performed that year (according to EUCOMED data), this represents 84.7% of all ICD implantations performed in Spain. Figure 2 shows the total number of implantations reported to the registry and estimated by EUCOMED in the last 7 years.

The total number of implantations per million population reported to the registry was 89. The total number of implantations per million population according to EUCOMED data was 100. Figure 3 shows the increase in the number of implantations per million population reported to the registry and that estimated by the EUCOMED for the last 7 years. Table 1 shows the number of implantations reported to the registry by each implantation center. Figure 4 shows the number of implants performed in each autonomous community and reported to the registry in 2009. Table 2 shows the number of implants reported to the registry by the province and autonomous community in which the patient resided and the number per million population. Most of the implantations reported were performed in public hospitals (3866), which represents 94.0% of the reports included in the registry for which data on the implantation center were available.

First Implantations Versus Replacements

This information was available in 3880 of the forms provided (94.4%). The number of first implantations was 2930, which represents 75.5% of all implantations reported. In total, 63.4 first implantations per million population were reported to the registry. The number of replacements was 950 (24.4%).

Age< and Sex

The mean (standard deviation) (range) age of the patients who underwent first ICD or replacements was 62.19 (13.99) (1-86) years. The mean (SD)

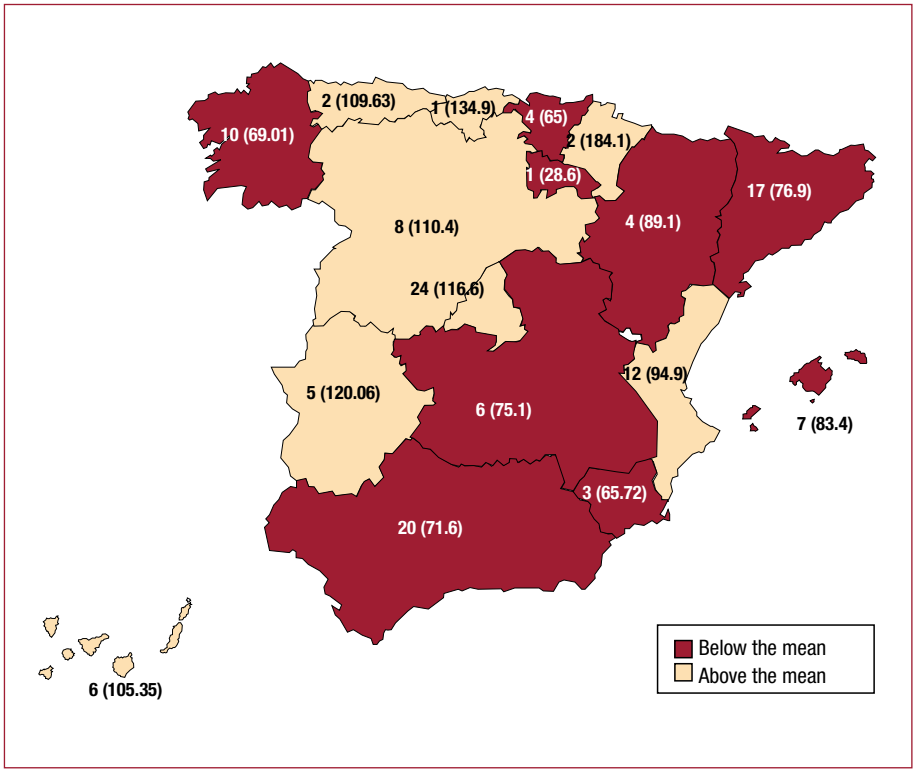

Figure 1. Number of implantation centers (rate per million population) by autonomous community in 2009.

TABLA 1. **Hospitals That Reported Data to the Spanish Implantable Cardioverter-Defibrillator Registry in 2009 and the Number of Implantations Reported per Hospital (Grouped by Autonomous Community and Province)**

Andalusia		
Almeria	Hospital Torrecárdenas	12
Cadiz	Hospital Universitario Puerta del Mar	29
Cordoba	Hospital Reina Sofía	37
	Hospital Cruz Roja	2
Granada	Hospital San Cecilio	4
	Hospital Virgen de las Nieves	77
Huelva	Hospital Blanca Paloma	1
	Hospital Juan Ramón Jiménez	64
Malaga	Clínica El Ángel	1
	Parque San Antonio	16
	Clínica Santa Elena	1
	USP Marbella	5
	Hospital Carlos Haya	5
	Hospital Xanit	1
	Hospital Virgen de la Victoria	181
Seville	Clínica Santa Isabel	2
	Hospital Infanta Luisa	3
	Hospital de Valme	44
	Hospital San Agustín	1
	Hospital Virgen del Rocío	60
	Hospital Virgen Macarena	60
Aragon		
Zaragoza	Clínica Montpellier	1
	Hospital Universitario Lozano Blesa	29
	Hospital Miguel Servet	84
	Hospital Quirón	3
Asturias		
Oviedo	Hospital Central de Asturias	115
	Hospital Begoña de Gijón	1
Balearic Islands		
Ibiza	Can Misses	1
Palma de Mallorca	Hospital Son Dureta	53
	Hospital Son Llàtzer	20
	Policlínica Miramar	5
	Clínica Rotger	5
	Clínica Palmaplanas	3
	Clínica Juaneda	3
Canary Islands		
Las Palmas	Hospital Santa Catalina	1
	Hospital Dr. Negrín	47
	Hospital Insular de Gran Canaria	40
Tenerife	Clínica Santa Cruz	4
	Hospital de La Candelaria	50
	Hospital Universitario de Canarias	78
Cantabria		
Santander	Hospital Universitario Marqués de Valdecilla	78
Castile-La Mancha		
Albacete	Hospital General de Albacete	24
Ciudad Real	Hospital General de Ciudad Real	17
Toledo	Complejo Hospitalario de Toledo	3
	Hospital Ntra. Sra. del Prado	11
	Hospital Virgen de la Salud	76
Castile and Leon		
Avila	Hospital Ntra. Sra. de Sonsoles	28
Burgos	Hospital General Yagüe	45
Leon	Hospital de León (Ed. Princesa Sofía)	45
Salamanca	Hospital Clínico	52
	Hospital Virgen de la Vega	2
Segovia	Hospital Policlínico de Segovia	3
Valladolid	Hospital Campo Grande	5
	Hospital Clínico Universitario de Valladolid	71
	Hospital del Río Hortega	25
Catalonia		
Barcelona	Centre Cardiovascular St. Jordi	5
	Centro Médico Teknon	2
	Centro Delfos	2
	Clínica Dexeus	2
	Clínica Quirón	10
	Clínica Sagrada Família	1
	Fundació de G.S.H. de la Santa Creu i Sant Pau	111
	Hospital Clínic de Barcelona	181
	Hospital de Barcelona	4
	Hospital de Bellvitge	70
	Hospital del Mar	18
	Hospital German Trias i Pujol	41
	Hospital Sant Joan de Déu	2
	Hospital Vall d'Hebron	77
Lleida	Hospital U. Arnau de Vilanova	22
Tarragona	Hospital de Sant Pau i Santa Tecla	2
	Hospital U. de Tarragona Joan XXIII	12
Valencian Community		
Alicante	Clínica Benidorm	2
	Hospital Clínico de San Juan	7
	Hospital General Universitario de Alicante	175
	Sanatorio Perpetuo Socorro	3
Castellon	Hospital de la Plana	3
	Hospital General de Castelló	25
Valencia	Grupo Hospitalario Quirón	4
	Hospital Clínico Universitario de Valencia	94
	Hospital General Universitario de Valencia	42
	Hospital Lluís Alcanyís	10
	Hospital Universitario Dr. Pesset	23
	Hospital Universitario La Fe	86
Extremadura		
Badajoz	Clideba	2
	Hospital de Mérida	5
	Hospital Infanta Cristina	105
Caceres	Hospital San Francisco	3
	Hospital San Pedro de Alcántara	15
Galicia		
A Coruña	Clínica La Rosaleda	1
	Complejo Hospitalario Universitario de Santiago	79
	Hospital Juan Canalejo	72
	Hospital Santa Teresa	1
Lugo	Hospital Xeral de Lugo	1
Ourense	Centro Médico El Carmen	1
Pontevedra	Complejo Hospitalario Xeral Cíes	24
	Hospital do Meixoeiro	7
	Hospital Miguel Domínguez	2
	Hospital Nuestra Sra. de Fátima	1
Madrid Community	Clínica de S. Camilo	3
	Clínica La Luz	5
	Clínica La Milagrosa	2

(continued on the next page)

TABLE 1. **Hospitals That Reported Data to the Spanish Implantable Cardioverter-Defibrillator Registry in 2009 and the Number of Implantations Reported per Hospital (Grouped by Autonomous Community and Province** *(continued)*

	Clínica Ntra. Sra. de América	10		Hospital Severo Ochoa	11
	Clínica Puerta de Hierro	172		Hospital Universitario de Getafe	12
	Clínica Ruber	2		Hospital Universitario La Paz	74
	Clínica Virgen del Mar	1		Hospital Virgen de la Paloma	2
	Fundación H. de Alcorcón	7	**Murcia**	Hospital Los Arcos	1
	Fundación Jiménez Díaz	59		Hospital Rafael Méndez	4
	Hospital 12 de Octubre	82		Hospital Virgen de la Arrixaca	91
	Hospital General de la Defensa	7	**Navarra**	Clínica Universitaria de Navarra	77
	Hospital Clínico San Carlos	83		Hospital de Navarra	37
	Hospital de Fuenlabrada	6	**La Rioja**		
	Hospital Madrid-Montepríncipe	5	Logroño	Hospital San Pedro	9
	Hospital General Universitario Gregorio Marañón	127			
	Hospital Los Madroños	1	**Basque Country**		
	Hospital Madrid Norte San Chinarro	2	Alava	Hospital Txagorritxu	63
	Hospital Ramón y Cajal	64	Guipuzcoa	Hospital de Donostia	1
	Hospital Ruber Internacional	1	Vizcaya	Hospital de Basurto	43
	Hospital San Rafael	1		Hospital de Cruces	32

The implantation center was not identified in 22 reports.

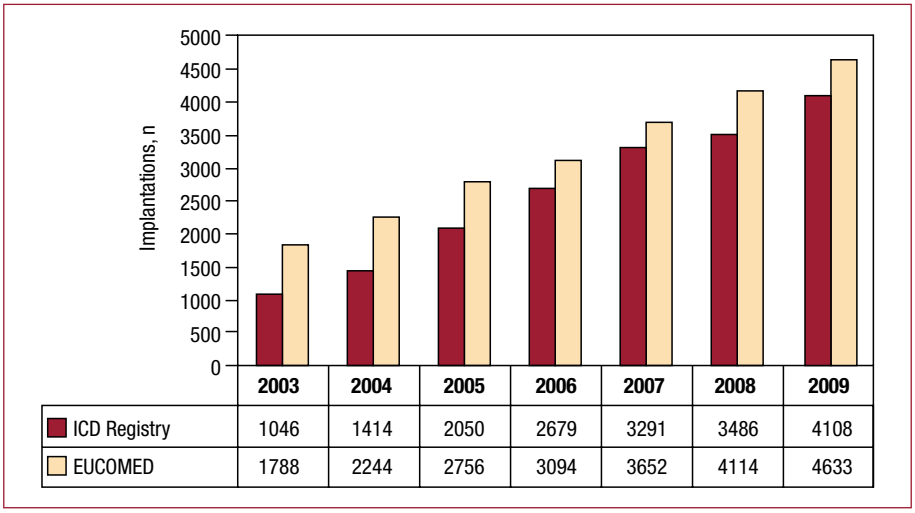

Figure 2. Total number of implantations reported to the registry and estimated by the European Medical Technology Industry Association (EUCOMED) from 2003 to 2009. ICD, implantable cardioverter-defibrillator.

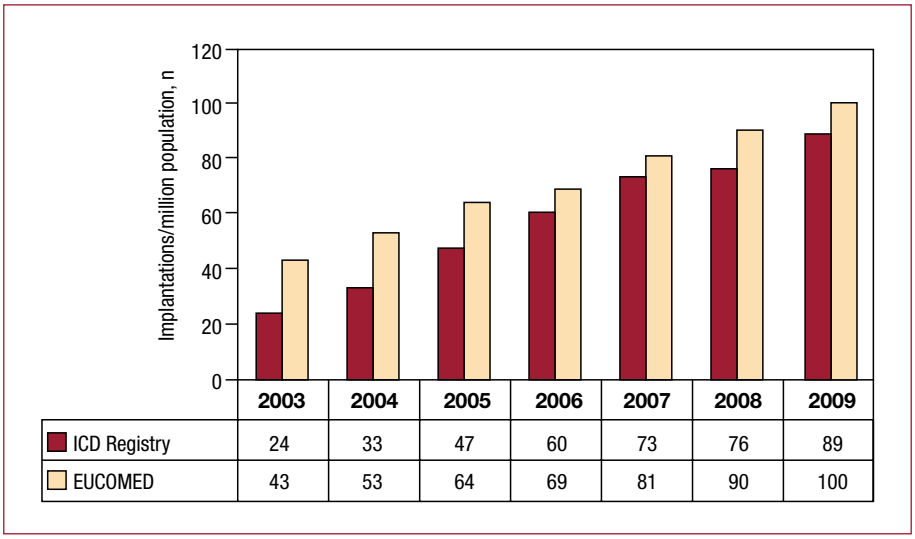

Figure 3. Total number of implantations per million population reported to the registry and estimated by the European Medical Technology Industry Association (EUCOMED) from 2003 to 2009. ICD indicates implantable cardioverter-defibrillator.

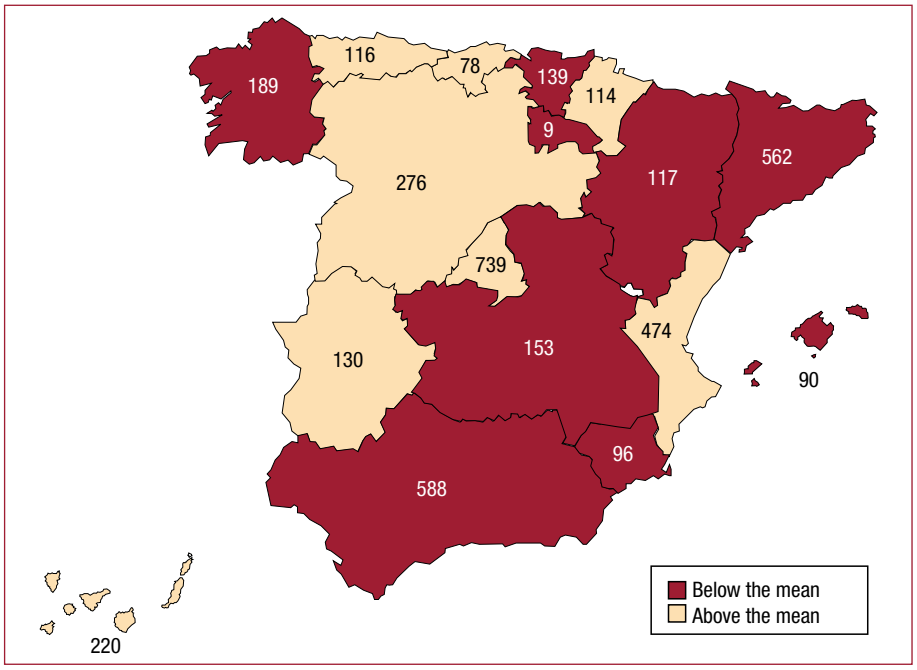

Figure 4. Implantations reported to the registry in 2009 by autonomous community.

TABLE 2. **Place of Residence of Implantable Cardioverter-Defibrillator Recipients and Number per Million Population as Reported to the Registry, According to Autonomous Community and Province**

Autonomous Community and Province	No.[a]	Rate per Million Population
Andalucia	588	71.6
Almeria	12	
Cadiz	29	
Cordoba	39	
Granada	81	
Huelva	65	
Jaen	0	
Malaga	210	
Sevilla	170	
Aragon	117	89.1
Huesca	0	
Teruel	0	
Zaragoza	117	
Asturias	116	109.6
Balearic Islands	90	83.4
Canary Islands	220	105.3
La Palma	88	
Santa Cruz	132	
Cantabria	78	134.9
Castile-La Mancha	153	75.17
Albacete	24	
Ciudad Real	17	
Cuenca	0	
Guadalajara	22	
Toledo	90	
Castile and Leon	276	110.4
Avila	28	
Burgos	45	
Leon	45	
Palencia	0	
Salamanca	54	
Segovia	3	
Soria	0	
Valladolid	101	
Zamora	0	
Catalonia	562	76.9
Barcelona	526	
Girona	0	
Lleida	22	
Tarragona	14	
Valencian Community	474	94.9
Alicante	184	
Castellon	28	
Valencia	259	
Extremadura	130	120
Badajoz	112	
Caceres	18	
Galicia	189	69
A Coruña	153	
Lugo	1	
Ourense	1	
Pontevedra	34	
La Rioja	9	28.6
Madrid	739	116.6
Murcia	96	65.7
Navarra	114	184.1
Basque Country	139	65
Alava	63	
Guipuzcoa	1	
Vizcaya	75	
Ceuta and Melilla	0	0
Not reported	18	
Total Spain	4.108	88.6

[a]Both first implantations and replacements are included.

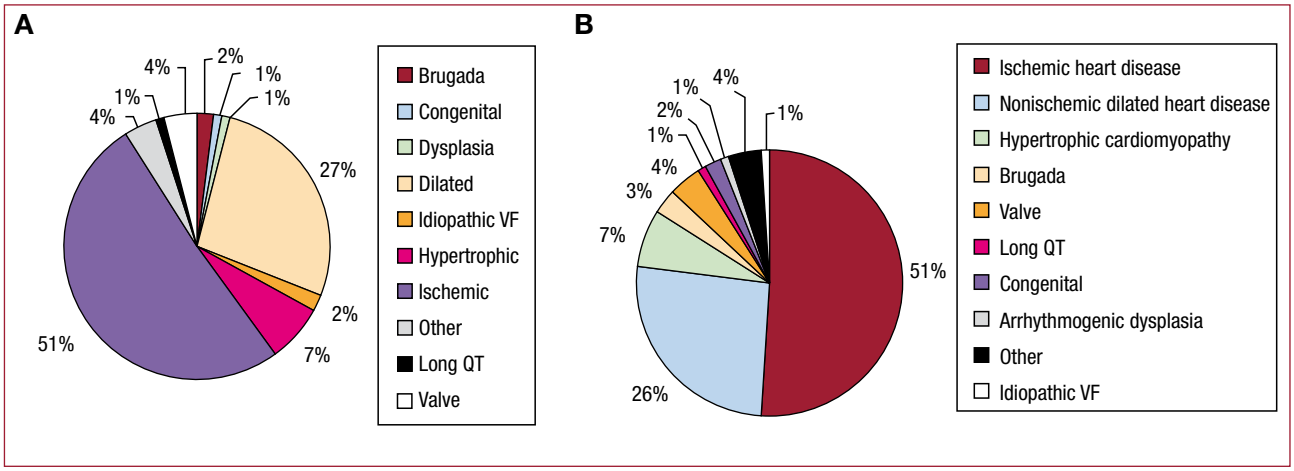

Figure 5. Heart disease reported to the registry. A, first implantations. B, total implantations. VF, ventricular fibrillation.

was 61.66 (13.57) years at first implantation. Most implantations were performed in men, who accounted for 81.7% of all implantations and 81.8% of first implantations.

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

The percentages of patients with different underlying heart diseases were very similar in patients who underwent first implantations and in the group as a whole (Figure 5B). The most common condition was ischemic heart disease, followed by dilated cardiomyopathy, hypertrophic cardiomyopathy, and primary conduction abnormalities (Brugada syndrome, idiopathic ventricular fibrillation, and long QT syndrome). These were followed in frequency by valvular heart disease and arrhythmogenic right ventricular cardiomyopathy.

Regarding ventricular systolic function, 46.22% of patients who received a first ICD had a left ventricular ejection fraction (LVEF) <30%. In total, 29.08% had an LVEF between 30% and 39%. The smallest group of patients was formed by those with mild dysfunction, with an LVEF between 40% and 49%. Similar proportions were found for the total number of implantations (Figure 6).

Regarding New York Heart Association functional class (FC), most patients were in FC II (38.7%). These were followed by the groups of patients in FC III and I (28.5% and 30.7%, respectively), whereas there were very few patients in FC IV (Figure 7).

Regarding baseline rhythm, data on 765 patients was not available. The majority of patients for whom data were available were in sinus rhythm (76.67%), 16.27% had atrial fibrillation, 4.3% had pacemaker rhythm, and the remainder presented other rhythms (atrial flutter or other atrial arrhythmias).

Clinical Arrhythmia Requiring ICD Implantation, Form of Presentation, and Laboratory-Induced Arrhythmia

This information was available in 74.4% of the forms provided. The most common group among patients undergoing first implantation was that of patients without documented clinical arrhythmia (47.6%). These were followed in frequency by those with sustained monomorphic ventricular tachycardia (SMVT) and nonsustained ventricular tachycardia (23.4% and 16.8%, respectively). In the overall implantation group, 41.4% of patients had no documented arrhythmia, whereas the proportion of patients with sustained arrhythmias was greater. The differences in the type of clinical arrhythmia in the first implantation group compared to the overall group were statistically significant (P<.001) (Figure 8).

The most common form of clinical presentation, in both the overall group and first implantation group, was a lack of symptoms, followed by syncope and "other symptoms". There were no statistically significant differences (P=.056) in the form of clinical presentation between the first implantation group and the overall group (Figure 9).

Information on electrophysiological studies was available on 2129 patients undergoing first implantation (72.6%). This was performed in 363 patients (17.05% for which this information was reported). In most cases this was performed in patients with previous infarction or dilated cardiomyopathy and SMVT, and in patients with previous infarction and syncope; SMVT was the

TABLE 3. **Number of First Implantations Between 2006 and 2009 According to Type of Heart Disease, Clinical Arrhythmia and Presentation**

Type of Heart Disease and Indication	2006	2007	2008	2009
Ischemic heart disease				
Aborted SD	105 (8.6)	113 (9.3)	93 (7.5)	111 (7.9)
Syncopal SMVT	158 (12.9)	125 (10.3)	126 (10.2)	117 (8.4)
Non-syncopal SMVT	197 (16)	207 (17)	176 (14.3)	201 (14.4)
Syncope without documented arrhythmia	165 (13.5)	172 (14.1)	138 (11.2)	121 (8.7)
Prophylactic indication	520 (42.4) 200R	509 (41.8) 187R	607 (49.3) 198R	637 (45.86%) 155R
Not reported/not classified	81 (6.6)	92 (7.5)	92 (7.5)	202 (14.5)
Subtotal	1.226	1.218	1.231	1.389
Dilated cardiomyopathy				
Aborted SD	21 (4.6)	29 (4.8)	38 (6.6)	53 (5.5)
Syncopal SMVT	46 (9.9)	48 (7.9)	33 (5.7)	61 (6.4)
Non-syncopal SMVT	55 (11.9)	49 (8.1)	43 (7.4)	69 (7.2)
Syncope without documented arrhythmia	62 (13.5)	81 (13.4)	74 (12.8)	102 (10.7)
Prophylactic indication	228 (49.5) 133R	334 (55.2) 193R	337 (58.3) 216R	440 (46.1) 239R
Not reported/not classified	49 (10.6)	64 (10.6)	53 (9.2)	228 (23.9)
Subtotal	461	605	578	953
Valve disease				
Aborted SD	9 (14)	12 (11.8)	11 (12.5)	8 (9.3)
SMVT	20 (31.3) 11S	27 (26.5) 19S	25 (28.4) 12S	27 (31.3)
Syncope without documented arrhythmia	10 (15.6)	11 (10.8)	8 (9.1)	8 (9.3)
Prophylactic indication in LVD	19 (29.7)	49 (48)	39 (44.3)	28 (32.5) 19R
Not reported/not classified	6 (9.4)	3 (2.9)	5 (5.7)	15 (17.4)
Subtotal	64	102	88	86
Hypertrophic cardiomyopathy				
Secondary prevention	16 (17.8)	19 (18.6)	29 (19.9)	24 (14.9)
Prophylactic implantation	67 (74.4)	77 (75.5)	99 (67.8)	97 (60.2)
Not reported/not-classified	7 (7.8)	6 (5.9)	18 (12.3)	40 (24.8)
Subtotal	90	102	146	161
Brugada syndrome				
Aborted SD	6 (9.5)	5 (6.9)	7 (10.4)	11 (8.4)
Prophylactic implantation in syncope	25 (39.7)	20 (27.9)	27 (40.4)	36 (27.6)
Prophylactic implantation without syncope	20 (31.7)	41 (56.9)	28 (41.2)	52 (40)
Not reported/not-classified	12 (19.1)	6 (8.3)	5 (7.8)	31
Subtotal	63	72	67	130 (23.8)
RVAC				
Aborted SD	5 (23.8)	1 (3.7)	2 (6.9)	1 (3.8)
SMVT	8 (38.1) 1S	13 (48.2) 4S	12 (41.4) 7S	16 (61.2)
Prophylactic implantation	6 (28.6)	11 (40.7)	12 (41.4)	5 (19.2)
Not reported/not-classified	2 (9.5)	2 (7.4)	3 (10.3)	4 (15.3)
Subtotal	21	27	29	26
Congenital heart disease				
Aborted SD	3 (20)	2 (16.7)	2 (11.1)	4 (19)
SMVT	3 (20)	2 (16.7)	5 (27.8)	1 (4.7)
Prophylactic implantation	7 (46.7)	4 (33.3)	10 (55.6)	9 (42.8)
Not reported/not classified	2 (13.3)	4 (33.3)	1 (5.5)	7 (33.3)
Subtotal	15	12	18	21
Long QT Syndrome				
Aborted SD	6 (25)	14 (46.7)	3 (15.8)	9 (50)
Prophylactic implantation	15 (62.5)	16 (53.3)	16 (84.2)	3 (16.6)
Not reported/not classified	3 (12.5)	0	0	6 (33.3)
Subtotal	24	30	19	18

Abbreviations: LVD, left ventricular dysfunction; RVAC, right ventricular arrhythmogenic cardiomyopathy; SD, sudden death; R, cardiac resynchronization therapy; S, syncopal; SMVT, sustained monomorphic ventricular tachycardia.

most commonly induced arrhythmia (54.62%). Sustained arrhythmia was not induced in 24.6% of cases.

Indications

In 55.9% of first implantations, the indication for ICD was primary prevention. There has been an

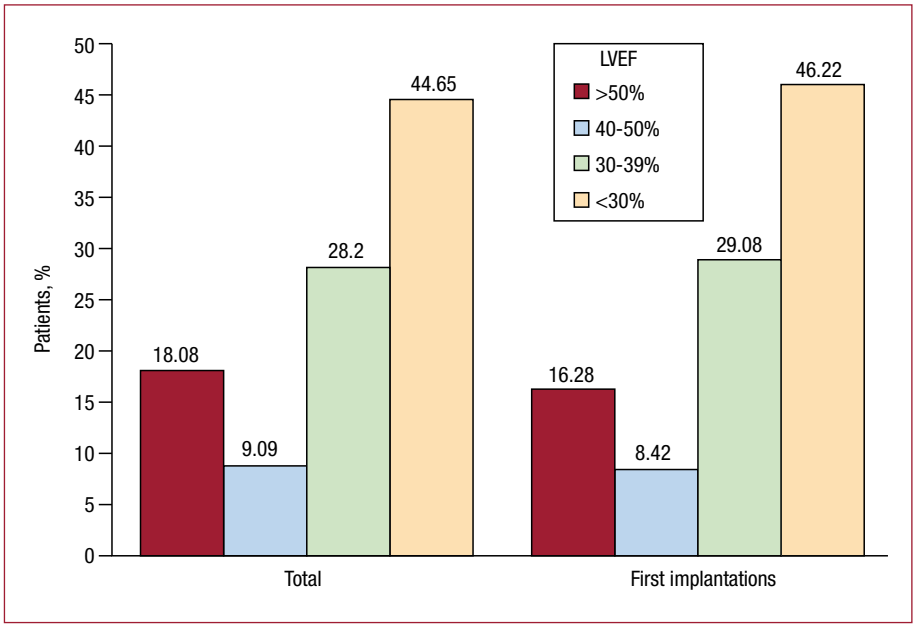

Figure 6. Left ventricular ejection fraction (LVEF) of the patients in the registry (first implantations and total implantations).

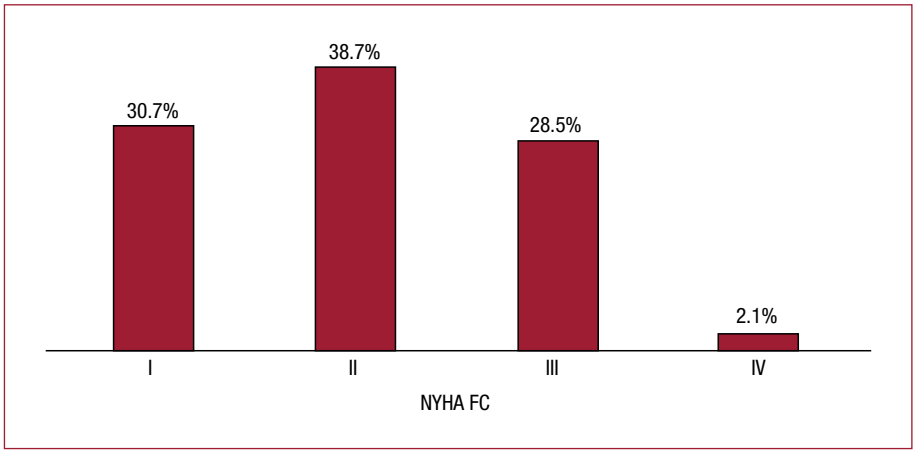

Figure 7. New York Heart Association functional class (NYHA FC) of the patients in the registry.

increasing trend in ICD implantation for primary prevention since the beginning of the second phase of the registry, increasing from 20.7% of the indications reported to the registry in 2003 to 55.9% in 2009. The steady increase in their use for primary prevention and the gradual decrease in their use for secondary prevention between 2003 and 2009 was statistically significant (P<.001) (Table 4). However, between 2008 and 2009 there was a slight decrease that was not statistically significant when the results were compared individually (from 57% to 55.9%; P=.08).

The largest group was formed by patients with ischemic heart disease. In this group, primary prevention accounted for almost half of all indications (49.3%), which was a clear increase compared to the previous year (49.3%). In 31.77% of implantations for primary prevention, ICD implantation involved a device with CRT capability (ICD-CRT).

The next most frequent indication was for primary prevention in patients with dilated cardiomyopathy (69.4% of implantations in patients with this type of heart disease were for primary prevention, which was also more than in 2008 [58.3%]). Of these, 56.2% of the cases involved ICD-CRT implantation.

In patients with hypertrophic cardiomyopathy, Brugada syndrome, long QT syndrome or congenital heart disease, more than 50% of implantations were for primary prevention. On the other hand, in patients with valve disease and arrhythmogenic right ventricular cardiomyopathy, ICD implantation was more commonly performed for secondary prevention.

There was a statistically significant correlation between the total number of first implantations in a center and those performed for primary prevention (r^2=0.72; P<.001).

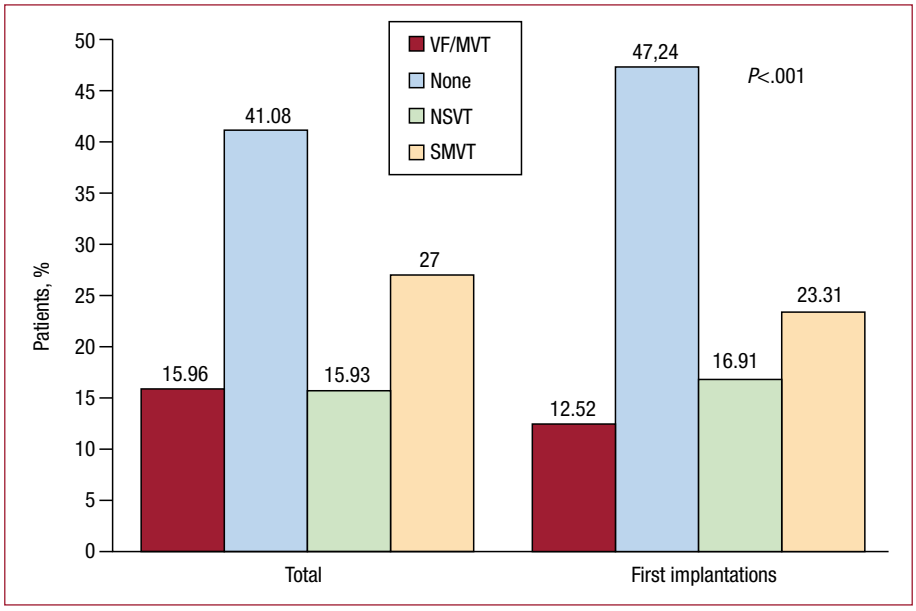

Figure 8. Clinical arrhythmia in patients in the registry (first implantations and total implantations). Abbreviations: VF/MVT, ventricular fibrillation/monomorphic ventricular tachycardia; SMVT, sustained monomorphic ventricular tachycardia; NSVT, nonsustained ventricular tachycardia.

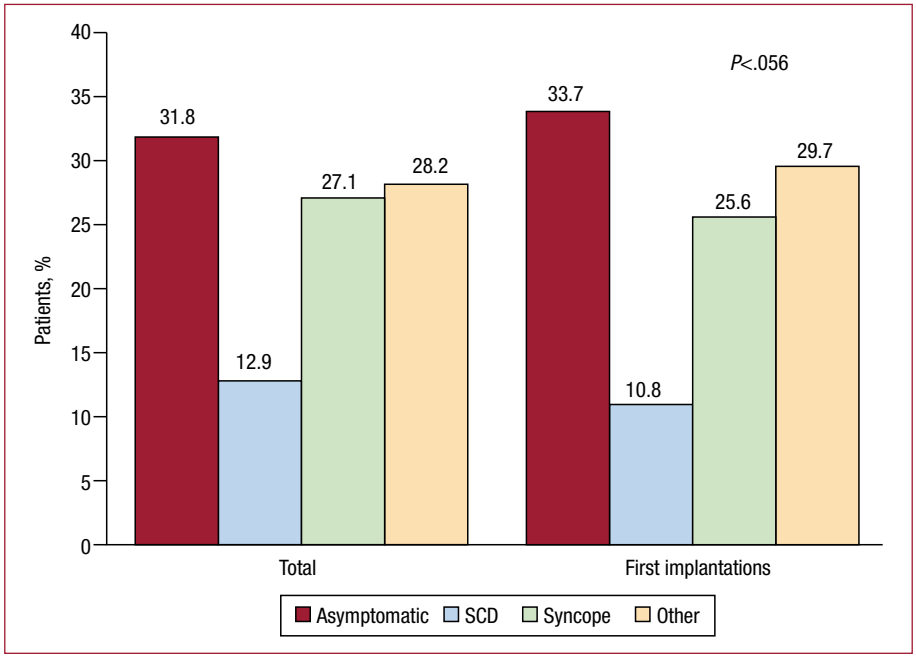

Figure 9. Clinical presentation of arrhythmia in patients in the registry (first implantations and total implantations). SCD, sudden cardiac death.

Table 3 shows the changes in indications related to the principal heart diseases during the last 4 years (those with the greatest representation in the registry).

Implantation Center and Specialists

Data on the center and specialist were available for 95.12% and 92.3%, respectively, of the implantations reported to the registry. In total, 67% of implantations were performed in a electrophysiology laboratory and 33% in the operating theater. No implantations were performed elsewhere.

The intervention was performed by electrophysiologists in 72.7% of the cases, by a heart

TABLE 4. **Changes in the Major Indications for Implantable Cardioverter-Defibrillators (First Implants) Between 2002 and 2009**

Year	ASD	SMVT	Syncope	Prophylactic
2003	13.7	42.8	14	29[a]
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[b]
2009	9.4	20.8	13.9	55.9[a,b]

Abbreviations: ASD, aborted sudden death; syncope, syncope without electrocardiographic documentation of arrhythmia; SMVT, sustained monomorphic ventricular tachycardia.
[a] $P<.001$.
[b] $P=.08$.

surgeon in 19.57%, and by another specialist in 7.6%.

Generator Position

In most cases, the generator was implanted in a subcutaneous pectoral position (91.2% of all implants and 88.3% of first implants). Submuscular pectoral placement was used in 8.3% of all implants and in 5.6% of first implants. Abdominal placement was used in 3 first implants and 13 replacements (0.1% of first implants and 0.4% of all implants).

Device Type

When all the implants (first implants and replacements) were analyzed, the percentages of single-chamber ICDs, dual-chamber ICDs, and ICD-CRT devices were 52.1%, 21.34%, and 26.52%, respectively. When only primary implants were evaluated, these percentages were 55.6%, 19.1% and 25.2%, respectively. According to the data provided by the EUCOMED, in 2009, the percentages of single-chamber or dual-chamber devices and ICD-CRT devices implanted were 69.5% and 30.2%, respectively.

Reasons for Replacements. Substitution of Electrodes in Replacement Generators and Use of Additional Electrodes

Of the reported replacements, information on the reason for replacement was available in 80% of cases. Of these, 85% were due to battery depletion and the remainder were due to complications. In total, 14.6% of the 114 replacements due to complications were performed within the first 6 months following implantation.

In total, 14.1% of the original electrodes were nonfunctioning. Of these, 55.75% were explanted.

Implantable Cardioverter-Defibrillator Programming

The most commonly employed antibradycardia pacing was VVI mode (52.7%). The VVIR mode was used in 9.7% of the cases, DDD mode in 25.16%, DDDR mode in 8.4% and other pacing modes in 3.9% (generally modes aimed at reducing the percentage of ventricular pacing in dual-chamber devices).

The device was programmed for ventricular antitachycardia pacing in 86% of cases and for a combination of ventricular and atrial pacing in 4.4%. Antitachycardia pacing was not programmed in 9.2%.

Both ventricular and atrial defibrillation or cardioversion therapies were programmed in 6.4% of cases.

Complications

Five deaths during implantation were reported (0.12%). In total, 18 complications during implantation were reported: 1 case of tamponade, 4 of pneumothorax and 13 unspecified.

DISCUSSION

The 2009 ICD registry continues to maintain acceptable representativeness (the number of implantations reported increased to 88.6%, compared to the 84% obtained in the previous 4 years). The data provide a good reflection of the current situation regarding the number of implantations, indications, clinical characteristics of the patients, types of device used, programming, and complications, and are a good indicator of daily clinical practice in Spain.

Comparison With Previous Years

When compared to the 2008 registry, a standstill was observed in the number of ICD implantations for primary prevention but without statistically significance differences between the 2 years. Compared to other years, the increase in ICD for primary prevention was maintained. Ischemic heart disease was the most frequent condition, with 56.4% of implantations, followed by dilated cardiomyopathy, which increased from 58.3% in 2008 to 69.4% in 2009, representing more than half of the ICD+TRC implantations for this substrate.

Significant quantitative jumps in primary prevention have occurred in the last 8 years. The first occurred between 2002 and 2003 and was probably related to the publication in 2002 of the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II).[11] The second occurred in 2005 and 2006, mainly related to the results of the Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure (COMPANION)[12] and Sudden Cardiac Death in Heart Failure Trial (SCDHeFT) studies.[13] The third occurred in 2008, but is not related to the publication of a new trial. Although the results of the Multicenter Automatic Defibrillator Implantation Trial-Cardiac Resynchronization Therapy (MADIT-CRT)[14] were known in 2009, we doubt that these would have influenced the increase in the use of cardiac resynchronization, whose effect will probably be more evident in 2010. The total number of implantations in absolute terms and per million population has continued to increase due to the increased number of total implantations. The number of implantations reported increased to 88.6%, whereas this was 84.7% in 2008, in contrast to 90% in 2007 according to EUCOMED data.

The number of centers has continued to increase, with 17 new centers in 2009. However, in 48 centers, the majority of them private, the number of implantations per year was less than 5 and only 47 centers implanted more than 25 defibrillators per year. Their use for primary prevention was more common in centers performing more implantations.

There have been no significant changes in the epidemiological characteristics of the patients, which remained similar regarding age and the predominance of men. Neither were there changes regarding the type heart disease motivating ICD implantation. Patients with severe ventricular dysfunction and FC II-III remained in the majority, although there was a slight increase in FC I compared to 2008.

Regarding the type of device, the proportion of single-chamber ICD, dual-chamber ICD or ICD+TRC remained similar compared to 2008. There was no notable change in programmed pacing mode and antitachycardia pacing functions.

There were no changes in the implantation setting or the percentage of implantations performed by electrophysiologists compared to 2008.

Comparison With Other Countries

EUCOMED data for 2009 include ICD implantations for Austria, Belgium+Luxembourg, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom. The mean number of ICD and ICD+TRC implantations per million population was 234, ranging from 102 in Spain and 413 in Germany. In addition to Germany, above average rates were found for Italy (329), the Netherlands (316), Denmark (269), the Czech Republic (237) and Austria (235). Below average rates were found for Spain (102), Portugal (115), Greece (132) Norway (132), Finland (133), the United Kingdom (139), Sweden (146), France (154), Switzerland (175), Belgium+Luxembourg (187) and Ireland (192). The mean number of ICD+TRC implantations per million was 85. Countries above this mean were Italy (150), Germany (127), the Czech Republic (108), and the Netherlands (108), whereas those below this mean were Finland (30), Spain (32), Norway (34), and Portugal (41). The mean percentage of ICD+TRC compared to total ICD was 27.5%. In Spain the percentage was 30.5%, and ranged between 45.5% in Italy and 22.5% in Finland.

In September of 2008, the second report of the United States National ICD Registry was published, covering the period from April 2006 to June 2008[15]; the implantation rate for 2009 is also known.[16] Despite the decrease in the implantation rate in 2009, the number of implantations per million in the United States is more than double the European average.

The implantation rate per million in 2009 in Spain is less than half the European average, and among the countries participating in EUCOMED Spain is currently placed last for single-chamber and dual-chamber implantations and second to last for ICD+TRC implantations.

The enormous variations between continents and between countries sharing the same environment cannot be explained only by differences in income between them; other aspects probably have a far greater influence, such as the type of health care structure and the nature of the culture within the health care community. Italy has similar incomes to those in Spain and also shares the same Mediterranean environment; yet it has one of the highest rates of ICD+TRC implantations in Europe, 150 per million, and holds second place for the total number of implantations performed in European countries. The Italian registry results were published in September 2009.[17] The implantation rate for prevention primary was 55.7%, similar to that for Spanish woman. The underlying disease was ischemic heart disease in 37.7%, dilated cardiomyopathy in 35.5%, myocardial hypertrophy in 2.6% and valvular disease in 1.6%. The percentage of patients with ischemic heart disease was lower than in the Spanish and US registries. Regarding pacing mode, there was a greater percentage of ICD+TRC and dual-chamber implantations than in Spain.

Differences Between Autonomous Communities

As in all previous registries, there are large geographical differences in the implantation rate per million in Spain. In 2009, the following communities were above the national average of implantations: Navarre (184), Cantabria (132), Extremadura (120), Madrid (116), Castile and Leon (110), Asturias (109), the Canary Islands (105), and the Community of Valencia (94). The following communities were below the national average: the Region of Murcia (65), the Basque Country (65), Galicia (69), Andalusia (71), Castile-La Mancha (75), Catalonia (76), the Balearic islands (83), and Aragon (89). These large differences are also found in relation to the use of other cardiovascular technologies.[18] The Spanish Cardiac Catheterization Hemodynamics Registry[19] reports similar variations for coronary intervention.

There are probably many factors involved in these large differences between autonomous communities, not all of which are well understood. One of them is associated with the number of implantation centers. Countries with greater numbers of implantations, such as Italy,[17] have twice as many centers as Spain, and

although most of the centers have low implantation rates, they have around 50 centers with an average of >50 implantations per year. The results of the Spanish registry for 2009 suggest that there is no statistically significant correlation between the number of centers and the implantation rate per million in each autonomous community (r^2=.009; *P*=.721).

The number of arrhythmia units in each autonomous community, access to them, and overload could explain the variations between them. Other possible causes could differences in clinical presentation and the prevalence of cardiovascular diseases,[18] although, against this argument, some communities have a higher than average prevalence of cardiovascular disease that is not associated with higher rates of implantation.

Direct and indirect economic causes could explain the low implantation rate in some communities, although again there is no association with the income level in each community.

The degree of acceptance and adherence to the clinical practice guidelines, especially regarding primary prevention, may explain differences between countries and also between the different Spanish autonomous communities. Data is available on variations between hospitals in ICD implantation in patients with heart failure in the United States.[20] ICDs were implanted in 20% of patients, but there was great variation between hospitals (between tertiles of 1% and 35%). The hospitals with the highest numbers of ICD implantations performed a greater number of percutaneous or surgical coronary revascularization procedures, reported more extensive use of beta blockers, had more hospital beds, and had facilities for heart transplantation.

Limitations

The number of implantations reported to the registry constitutes 88.6% of the implantations performed in Spain, according to data provided by EUCOMED. This figure is higher than that reached in the 2008 registry, although it can be considered representative of the true situation in Spain.

The data collection form was not fully completed, and some information, such as the use of ICD for primary or secondary prevention, was only reported in little more than half of the forms received, which may limit the validity of the results.

The low rate of complications referred to above is due to the fact that this information is provided at the time of the implantation procedure, thus underestimating the number of complications, the great majority of which occur subsequently, such as pneumothorax, electrode displacement, heart failure, infection, etc.

Future Prospects for the Spanish ICD Registry

The correct completion of the forms and prospective reporting are a future aim that can be achieved via the Web. In addition, the design should be changed, as well as the questions, to better reflect the true situation.

The Ontario registry,[21] and to a lesser extent those of the United States and the United Kingdom,[22] include basic information on patient follow-up. Although including basic questions on follow-up (such as mortality or the number of treatments), would involve extra effort, nevertheless such information could prove very useful.

CONCLUSIONS

The 2009 Spanish ICD Registry recorded 88.6% of the ICD implantations performed and the registry is representative of the situation in Spain. The number of implantations continues to increase and is currently 89 per million. The number of implantations for primary prevention has not increased compared to 2008, although there was an increase compared to other years. The implantation rate in Spain continues to be below the mean of countries within the European Union and the difference seems to be increasing. There continue to be striking differences in the implantation rate between the different autonomous communities.

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