Spanish Implantable Cardioverter-Defibrillator Registry. Third Official Report of the Spanish Society of Cardiology Working Group on Implantable Cardioverter-Defibrillators (2006)

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Introduction and objectives. To report the 2006 findings of the Spanish Implantable Cardioverter-Defibrillator (ICD) Registry, established by the Working Group on Implantable Cardioverter-Defibrillators, Electrophysiology and Arrhythmia Section, Spanish Society of Cardiology.

Methods. Each ICD team voluntarily reported data to the Spanish Society of Cardiology by completing a single-page questionnaire. Prospective data were collected on 91.8% of implantations.

Results. In total, 2679 implantations were reported to the registry (86.6% of the estimated total). The reported implantation rate was 60 per million inhabitants, and the estimated rate was 69 per million. The proportion of first implantations was 80%. The majority of ICDs were implanted in males (mean age, 61.5 [14] years) with severe or moderate-to-severe left ventricular dysfunction who were in functional class II or I. Ischemic heart disease was the most frequent etiology, followed by dilated cardiomyopathy. This is the first year that half of first device implantations were carried out for primary prevention, with substantial increases among patients with ischemic heart disease and dilated cardiomyopathy. The number of ICDs incorporating cardiac resynchronization therapy has continued to grow, and now comprises 28.6% of all devices implanted. As in the previous year, around 70% of ICD implantations were performed in an electrophysiology laboratory by a cardiac electrophysiologist. The incidence of complications during device implantation was very low.

Conclusions. The 2006 Spanish Implantable Cardioverter-Defibrillator Registry contains data on more than 86% of all ICD implantations performed in Spain. Half of first device implantations were carried out for the purposes of primary prevention.

Key words: *Defibrillator. Registry. Arrhythmia.*

Registro Español de Desfibrilador Automático Implantable. III Informe Oficial del Grupo de Trabajo de Desfibrilador Automático Implantable de la Sociedad Española de Cardiología (2006)

Introducción y objetivos. Se presentan los resultados del Registro Español de Desfibrilador Automático Implantable del año 2006 elaborado por el Grupo de Trabajo de Desfibrilador Automático Implantable de la Sección de Electrofisiología y Arritmias de la Sociedad Española de Cardiología.

Métodos. Se envió a la Sociedad Española de Cardiología la hoja de recogida de datos cumplimentada de forma voluntaria por cada equipo implantador. La recogida fue prospectiva en el 91,8% de los implantes.

Resultados. El número de implantes comunicados fue de 2.679 (el 86,6% del total de implantes estimado). El número de implantes por millón de habitantes comunicados fue 60 y el estimado, 69. Los primoimplantes fueron el 80%. La mayor parte de los desfibriladores automáticos implantables se implantaron en varones con una media de edad de 61,5 ± 14 años, con disfunción ventricular izquierda severa o moderada a severa y en clase funcional II o I. La cardiopatía más frecuente fue la isquémica, seguida de la dilatada. Por primera vez, las indicaciones por prevención primaria constituyen la mitad de las realizadas en los primoimplantes, con un crecimiento importante en pacientes con cardiopatía isquémica y miocardiopatía dilatada. Ha continuado aumentando el número de desfibriladores automáticos implantables con terapia de resincronización cardiaca implantados, que constituyeron el 28,6% del total. En torno al 70% de los implantes se llevaron a cabo en el laboratorio de electrofisiología y por electrofisiólogos, cifra que se ha mantenido estable desde el pasado año. La incidencia de complicaciones durante el implante fue muy baja.

Conclusiones. El Registro Español de Desfibrilador Automático Implantable del año 2006 recoge información de más del 86% de los implantes totales de desfibrilador automático implantable que se realizan en España. La mitad de los primoimplantes llevados a cabo se indicaron con fines de prevención primaria.

Palabras clave: *Desfibrilador. Registro. Arritmia.*

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ABBREVIATIONS

CRT: cardiac resynchronization therapy
EAS: Electrophysiology and Arrhythmia Section
EUCOMED: European Confederation of Medical Suppliers Associations
ICD: implantable cardioverter-defibrillator
LV: left ventricle
SMVT: sustained monomorphic ventricular tachycardia
SSC: Spanish Society of Cardiology
WGICD: Working Group on Implantable Cardioverter-Defibrillators

INTRODUCTION

The Spanish Implantable Cardioverter-Defibrillator (ICD) Registry was established in 1996 by the Electrophysiology and Arrhythmia Section (EAS) of the Spanish Society of Cardiology (SSC). The first report with the data for 1996 was published in 1997.[1] The Working Group on ICD (WGICD) of the EAS of the SSC, constituted in 2001, provided new impetus to this registry and has published 2 official reports with the data collected over the 3-year period from 2002 to 2004 and those recorded in 2005, respectively.[2,3] The present report gathers the data concerning ICD implantation conveyed to the registry during 2006. It has been prepared by the WGICD, with the collaboration of most of the centers that implant ICD in Spain.

METHODS

The registry data was obtained using a data collection form, which is available on the web page of the EAS of the SSC (www.arritmias.org). This form was completed directly and voluntarily by each implant team, during or after the implantation, with the collaboration of the staff of the manufacturer of the ICD, and was sent to the SSC by fax or by e-mail. Data collection was primarily prospective. However, to improve the representativeness of the registry, in February 2007, a list of the implantations reported by each center in 2006 was sent to all the ICD implant centers that had contributed prospective data so that they could provide retrospective data on those patients for whom prospective data had not been made available to the registry.

Members of the SSC staff introduced the data in the database of the Spanish ICD Registry. The data was cleaned by a SSC computer specialist and a member of the WGICD. Members of the current WGICD executive committee were responsible for data analysis and publication.

The population-based data used to calculate rates per million population, both on the national scale and according to autonomous community and province, were obtained from the estimations reported for the period up to January 1, 2006, by the National Institute of Statistics (http://www.ine.es).

To calculate the representativeness of the registry, we estimated the proportion of all the implants performed in Spain in 2006 that had been reported. To determine the total number of ICD implants and replacements performed in Spain, we used the data reported by the device companies to the European Confederation of Medical Suppliers Associations (EUCOMED).

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

For each variable analyzed, unless otherwise stated, percentages were calculated based on the total number of implants, when that information was available.

Statistical Analysis

The numerical results were expressed as means plus or minus the standard deviations (SD). The relationships between quantitative variables were analyzed using a linear regression model. Qualitative variables were compared using the χ^2 test. A P value less than .05 was considered significant. The statistical analysis was carried out using the JMP statistical software program (version 5.0.1).

RESULTS

Response rates for the different fields of the data collection form ranged between 62% and 98.6% for the main variables included in the registry.

Participating Centers

A total of 89 centers that performed ICD implants transmitted data to the registry (Table 1). Sixty-six of them were public health care centers. Table 2 shows the number of public health care centers that sent data to the registry per million population in each autonomous community.

Total Number of Implants

A total of 2679 implants (first-time, or primary implants, and replacements) were reported to the registry in 2006. Of these, 2460 (91.8%) were reported prospectively, whereas 219 (8.2%) were reported retrospectively by 11 centers. Taking into account the fact that, according to the EUCOMED, a total of 3094 implants were carried out in that year, the incidence of reporting to the registry was 86.6%. Figure 1 shows the total number of implants reported to the registry and those estimated by the EUCOMED over the 5-year period between 2002 and 2006.

TABLE 1. **Spanish Hospitals That Provided Data to the National Registry on Implantable Cardioverter Defibrillators in 2006 and Number of Implants Reported by Each Hospital (Grouped According to Autonomous Community and Province)**

Autonomous Community		No. of Implants
Andalusia		
Almería	H. Torrecárdenas	4
Cádiz	H. U. Puerta del Mar	17
Córdoba	H. U. Reina Sofía	28
Granada	H. U. Virgen de las Nieves	54
	H. Clínico Universitario San Cecilio	2
Huelva	H. General Juan Ramón Jiménez	47
Jaén	Complejo Hospitalario Ciudad de Jaén	6
Málaga	H. U. Virgen de la Victoria	192
	Clínica Parque San Antonio	6
	Complejo Hospitalario Carlos Haya	3
Seville	H. Nuestra Señora de Valme	52
	H. U. Virgen Macarena	38
	H. U. Virgen del Rocío	24
	Clínica Sagrado Corazón	1
Aragón		
Zaragoza	H. Miguel Servet	49
	H. Clínico Universitario Lozano Blesa	29
Asturias		
Oviedo	H. Central de Asturias	124
Balearic Islands		
Palma	H. Son Dureta	26
de Mallorca	H. Son Llàtzer	4
	Clínica Rotger Sanitaria Balear, S.A.	2
	Policlínica Miramar	1
Canary Islands		
Las Palmas	Hospital Dr. Negrín	52
	H. Insular de Gran Canaria	35
	Clínica San Roque, S.A.	1
Tenerife	H. U. de Canarias	23
	H. Nuestra Sra. de la Candelaria	20
Cantabria		
Santander	H. U. Marqués de Valdecilla	58
Castile-La Mancha		
Albacete	H. General de Albacete	14
Guadalajara	H. General Universitario de Guadalajara	12
Toledo	H. Virgen de la Salud	62
Castile-León		
Ávila	H. Nuestra Sra. de Sonsoles	8
Burgos	H. General Yagüe	19
León	H. de León	21
Salamanca	H. U. de Salamanca	49
Valladolid	H. Clínico Universitario de Valladolid	49
	H. Del Río Hortega	13
	Sanatorio Virgen de la Salud	2
	H. Campo Grande	1
Catalonia		
Barcelona	H. Clínic	130
	H. de la Santa Creu i de Sant Pau	80
	H. Vall d'Hebron	55
	H. de Bellvitge	37
	H. Germans Trias i Pujol	20
	Centre Cardiovascular Sant Jordi, S.A.	11
	Clínica Quirón	8
	H. del Mar	5
	Centro Médico Teknon	1
	H. de Barcelona	2
Community of Valencia		
Alicante	H. General Universitario de Alicante	64
	Clínica Benidorm	3
Castellón	H. General de Castelló	17
Valencia	H. General Universitario de Valencia	58
	H. U. La Fe	35
	H. Clínico Universitario de Valencia	33
	H. U. Dr. Peset	10
	H. Lluis Alcanyís	2
	Grupo Hospitalario Quirón	2
Extremadura		
Badajoz	H. Infanta Cristina	25
Galicia		
A Coruña	Complejo Hospitalario Univ. de Santiago	54
	H. Juan Canalejo	37
Pontevedra	Complejo Hospitalario Xeral-Cies	22
Madrid		
Madrid	H. U. Gregorio Marañón	95
	Clínica Puerta de Hierro	79
	H. Clínico San Carlos	73
	H. U. La Paz	63
	H. U. Ramón y Cajal	56
	H. U. 12 de Octubre	40
	H. U. de Getafe	23
	Fundación Jiménez Díaz	20
	Fundación Hospital Alcorcón	12
	Clínica La Luz	7
	H. Severo Ochoa	6
	H. Central de la Defensa	6
	H. de Fuenlabrada	5
	H. de Madrid	5
	Clínica Nuestra Señora de América	5
	Sanatorio Nuestra Sra. del Rosario	2
	Clínica Ruber	2
	H. Ruber Internacional	1
	Clínica San Camilo	1
	H. Madrid-Montepríncipe	1
	Clínica Moncloa	1
Murcia	H. U. Virgen de la Arrixaca	68
Navarre		
Pamplona	Clínica Universitaria de Navarra	54
	H. de Navarra	16
Basque Country		
Vitoria	H. Txagorritxu	37
Bilbao	H. de Basurto	40
	H. de Cruces	13
San Sebastián	H. Donostia	13

TABLE 2. **Number of Spanish Public Implant Centers According to Autonomous Community in 2006**

Autonomous Community	No. of Centers (No. per Million Population)
Andalusia	12 (1.5)
Aragón	2 (1.6)
Asturias	1 (0.9)
Balearic Islands	2 (2)
Basque Country	4 (1.9)
Canary Islands	4 (2)
Cantabria	1 (1.8)
Castile-La Mancha	3 (1.6)
Castile-León	6 (2.4)
Catalonia	6 (0.8)
Community of Valencia	7 (1.5)
Extremadura	1 (0.9)
Galicia	3 (1.1)
Madrid	12 (2)
Murcia	1 (0.7)
Navarre	1 (1.7)
Total	66 (1.5)

TABLE 3. **Number of Implants Reported to the Spanish Registry in 2006 According to Autonomous Community and Number of Implants Reported per Million Population**[a]

Autonomous Community	No. of Implants	No. per Million Population
Andalusia	474	60
Aragón	78	61
Asturias	124	115
Balearic Islands	33	33
Basque Country	103	48
Canary Islands	131	66
Cantabria	58	102
Castile-La Mancha	88	46
Castile-León	162	64
Catalonia	349	49
Community of Valencia	224	47
Extremadura	26	24
Galicia	113	41
Madrid	503	84
Murcia	68	50
Navarre	70	116
Missing data	75	
Total	2679	60

[a]Both primary implants and replacements are included. No defibrillators were implanted in the Autonomous Community of La Rioja or in the autonomous cities of Ceuta and Melilla in 2006.

A total of 60 implants were reported to the registry per million population, whereas the number of ICD implanted per million population according to the EUCOMED was 69. Figure 2 shows the increase in the number of implants per million population reported to the registry and that estimated by the EUCOMED from 2002 to 2006. The number of implants reported to the registry by each implant center appears in Table 1. Table 3 shows the number of implants performed according to autonomous community, as reported to the registry in 2006, and the number of reported implants per million population. The number of implants reported to the registry and the number per million population, according to the provinces and autonomous communities in which the patients resided, are shown in Table 4.

The majority of the reported implants (2522, or 95.5% of the total of 2604 reported to the registry in which the name of the hospital was provided) were carried out in public health care centers.

There was no statistically significant correlation between the number of public implant centers per million population and the number of ICD implanted per million population in each autonomous community.

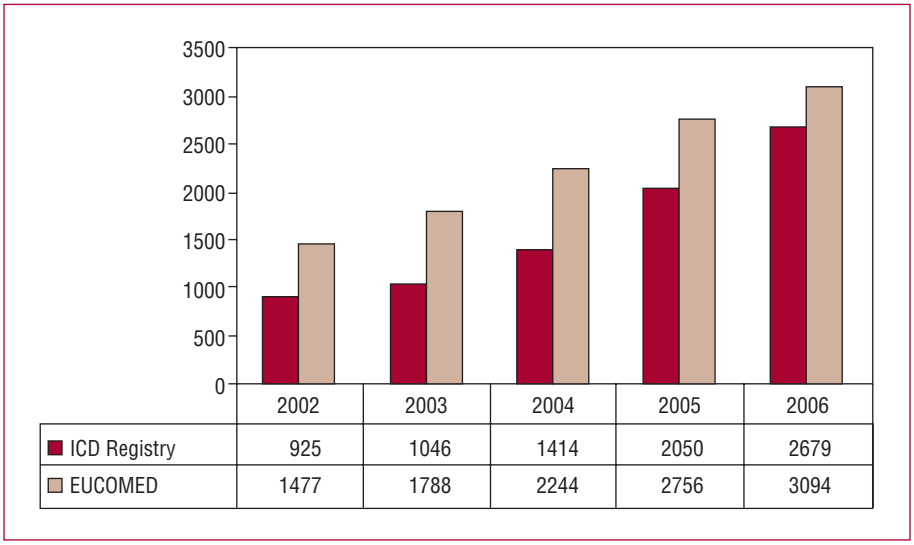

Figure 1. Total number of implants reported to the registry and estimated by the European Confederation of Medical Suppliers Associations (EUCOMED) from 2002 to 2006. ICD indicates implantable cardioverter defibrillator.

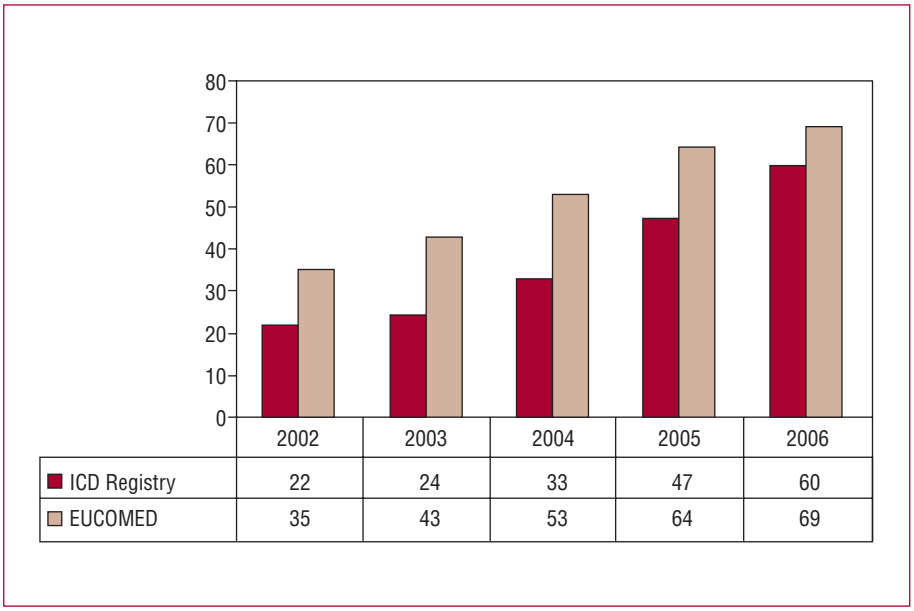

Figure 2. Total number of implants per million population reported to the registry and estimated by the European Confederation of Medical Suppliers Associations (EUCOMED) from 2002 to 2006. ICD indicates implantable cardioverter defibrillator.

TABLE 4. **Place of Residence of ICD Implant Patients and Number per Million Population as Reported to the Registry, According to Autonomous Community and Province**[a]

Autonomous Community	No.	No./Million Population	Autonomous Community	No.	No./Million Population
Andalusia	419	52.53	Soria	4	43.96
Almería	9	14.6	Valladolid	35	68.6
Cádiz	46	39.4	Zamora	9	46.2
Córdoba	22	48.3	Catalonia	324	45.4
Granada	45	51.8	Barcelona	298	57.6
Huelva	42	87.3	Girona	11	16.7
Jaén	20	30.8	Lleida	6	15
Málaga	145	100.4	Tarragona	9	12.7
Sevilla	90	50.3	Community of Valencia	208	43.3
Aragón	80	62.6	Alicante	70	40.8
Huesca	2	9.3	Castellón	18	32.2
Teruel	4	28.6	Valencia	120	50.4
Zaragoza	74	82	Extremadura	46	42.3
Asturias	111	104.9	Badajoz	32	48.2
Balearic Islands	32	32.5	Cáceres	14	34.4
Canary Islands	126	63.2	Galicia	107	38.7
Las Palmas	79	78.4	La Coruña	47	42.3
Tenerife	47	49.8	Lugo	6	17.2
Cantabria	29	52	Orense	16	48.3
Castile-La Mancha	93	48.13	Pontevedra	38	41
Albacete	16	41.9	La Rioja	13	43.3
Ciudad Real	24	48.2	Madrid	447	75.3
Cuenca	11	53.1	Murcia	69	51.7
Guadalajara	10	48.5	Navarre	31	52.7
Toledo	32	53.6	Basque Country	97	45.5
Castile-León	156	61.8	Álava	24	66.9
Ávila	11	66.7	Guipúzcoa	21	30.7
Burgos	24	67.2	Vizcaya	52	46
León	21	43.5	Ceuta and Melilla	1	8.3
Palencia	9	52.6	Other countries	10	
Salamanca	39	112.7	Missing data	320	
Segovia	4	26	Total Spain	2679	60

[a]Both primary implants and replacements are included.

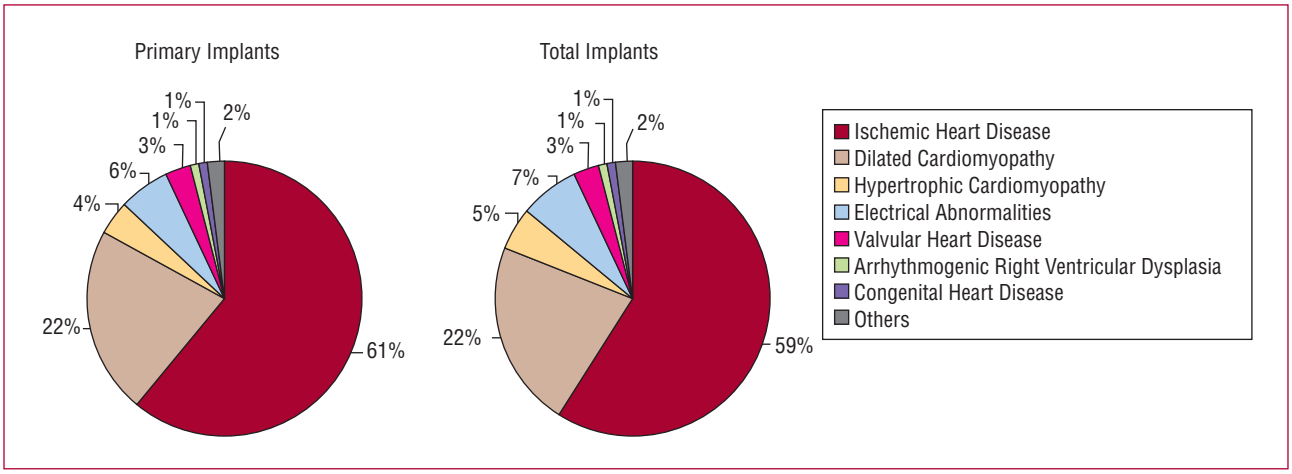

Figure 3. Underlying heart diseases reported to the registry (primary implants and total implants).

Primary Implants Versus Replacements

The number of primary implants was 2105 (80% of all the implants registered), for a rate of 47 per million population. The number of replacements was 535 (20%).

Age and Sex

The mean age of the patients, including both those who underwent primary implantation and those who underwent replacement of an ICD, was 61.5 (14) years (range, 4 to 86 years). These findings were very similar in the case of primary implants: 61.1 (14) years (range, 7 to 84 years). The majority of the patients were men (85.4% of the total and 84.9% in the case of primary implants).

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

The incidences of the different heart diseases were very similar in both the patients who underwent primary implantation and in the group as a whole (Figure 3). The most common condition was ischemic heart disease, followed by dilated cardiomyopathy, hypertrophic cardiomyopathy, and primary electrical abnormalities (Brugada syndrome, idiopathic ventricular fibrillation, long QT syndrome, and short QT syndrome). These were followed by valvular heart disease and arrhythmogenic right ventricular cardiomyopathy.

Approximately half the patients had severe ventricular dysfunction, with a left ventricular (LV) ejection fraction less than 30%. This group was followed in frequency by the patients with an ejection fraction between 30% and 39% and those with LV systolic function greater than 50%. The smallest group was that of patients with mild ventricular dysfunction (Figure 4). Although there was a trend toward a higher proportion of patients with severe LV dysfunction (ejection fraction less than 30%) in the group that underwent primary implantation than in the group as a whole (50.2% vs 47.7%), the difference was not statistically significant (P=.2).

Somewhat over 40% of the patients were in New York Heart Association functional class II. They were followed in number by the group of patients in functional classes I and III, whereas only a very small number of patients were in functional class IV (Figure 5). There were no significant differences between those who underwent implantation for the first time and the group as whole in terms of this variable.

The majority of the patients (80%) were in sinus rhythm, whereas 14.8% had atrial fibrillation, 4.9% had pacemaker rhythm, and the rest exhibited other rhythms (atrial flutter or other atrial arrhythmias). These incidences were similar in both the primary implant patients and the group as a whole.

Clinical Arrhythmia that Led to Implantation, Presentation, and Laboratory-Induced Arrhythmia

The absence of documented clinical arrhythmia was the most common finding among patients who underwent primary implantation. They were followed in number by those with sustained monomorphic ventricular tachycardia (SMVT) and those with ventricular fibrillation. In the group as a whole, the most common findings were SMVT and the absence of clinical arrhythmia. The difference between the proportion of patients without documented clinical arrhythmia in the primary implant group versus the group as a whole (34.2% vs 29.5%) did not reach statistical significance (P=.1) (Figure 6).

The most common clinical presentation, both in the group as a whole and among patients who underwent primary implantation, was syncope, followed by "other symptoms" and the absence of symptomatic arrhythmias (Figure 7).

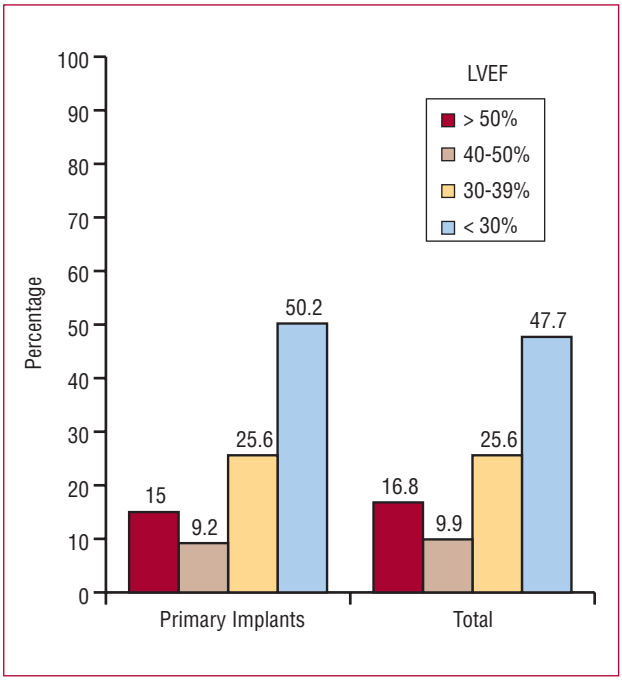

Figure 4. Left ventricular ejection fraction (LVEF) of the patients in the registry (primary implants and total implants).

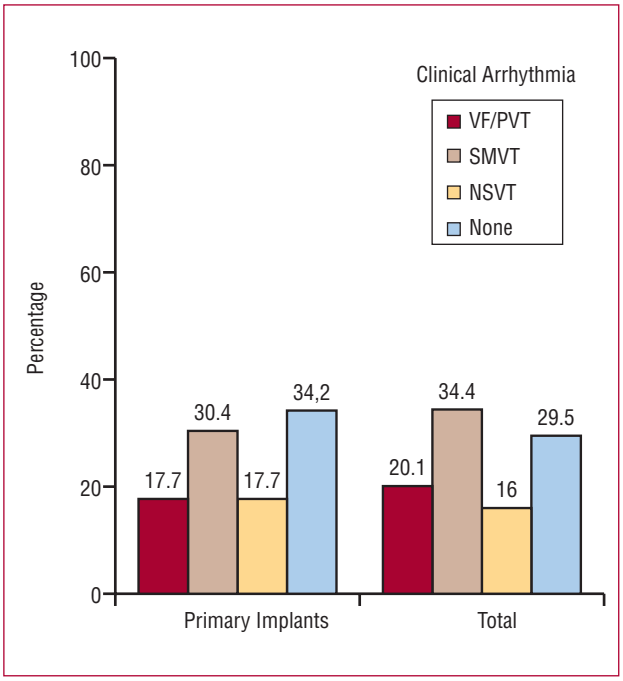

Figure 6. Clinical arrhythmia of the patients in the registry (primary implants and total implants). VF/PVT indicates ventricular fibrillation/paroxysmal ventricular tachycardia; SMVT, sustained monomorphic ventricular tachycardia; NSVT, nonsustained ventricular tachycardia.

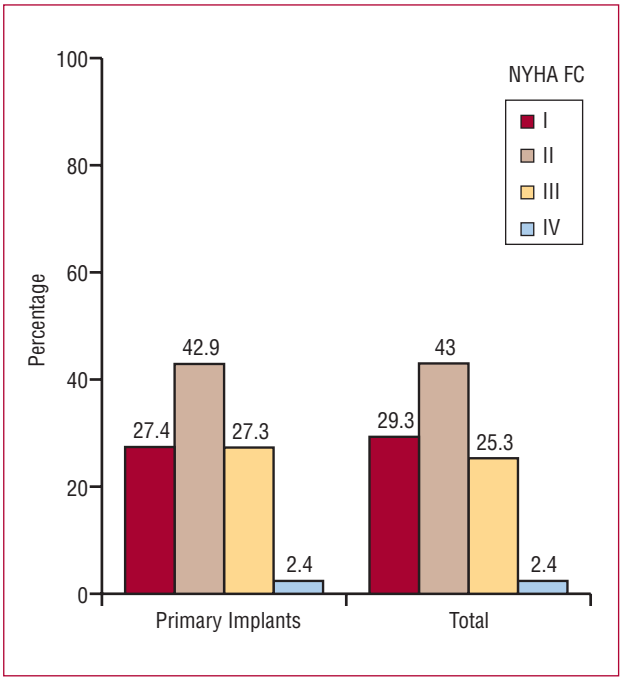

Figure 5. New York Heart Association functional class (NYHA FC) of the patients in the registry (primary implants and total implants).

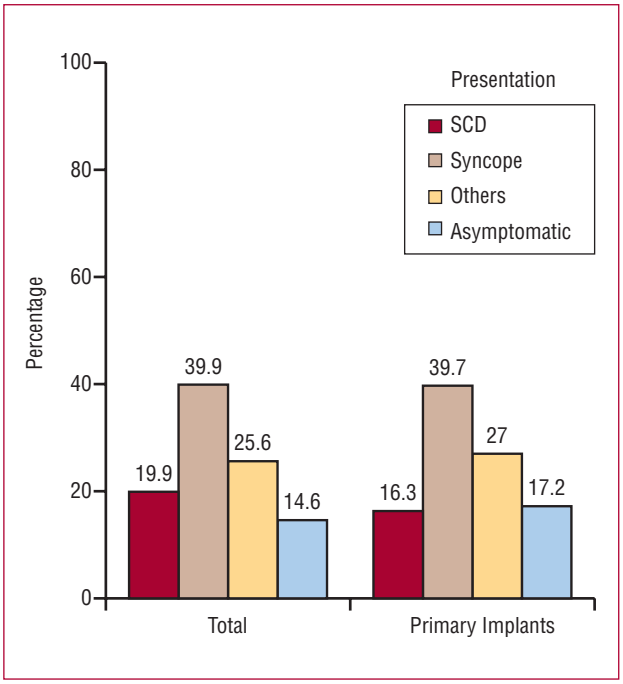

Figure 7. Clinical presentation of arrhythmia in the patients of the registry (primary implants and total implants). SCD indicates sudden cardiac death.

Information on the performance of an electrophysiological study was available for 62% of the primary implant patients. It was carried out in 496 (37.8%) of the 1312 patients who underwent implantation for the first time and for whom this information was reported. In most cases, it was performed in the context of secondary prevention in patients who had had a previous infarction or with dilated cardiomyopathy and SMVT, and SMVT was the arrhythmia most frequently induced.

TABLE 5. **Number of Primary Implants in 2005 and 2006, According to Type of Heart Disease, Clinical Arrhythmia, and Presentation. The Percentages With Respect to Each Type of Heart Disease Appear in Parentheses**

Type of Heart Disease and Indication	2005	2006
Ischemic heart disease		
Aborted sudden cardiac death	82 (10.7)	105 (8.6)
Syncopal SMVT	123 (16.2)	158 (12.9)
Non-syncopal SMVT	168 (22)	197 (16)
Syncope without documented arrhythmia	109 (14.3)	165 (13.5)
Prophylactic indication	238 (31.2); 80 CRT	520 (42.4); 200 CRT
Missing/unclassifiable	44 (5.6)	81 (6.6)
Total	764	1226
Dilated cardiomyopathy		
Aborted sudden cardiac death	16 (5.1)	21 (4.6)
Syncopal SMVT	47 (15)	46 (9.9)
Non-syncopal SMVT	33 (10.5)	55 (11.9)
Syncope without documented arrhythmia	37 (11.9)	62 (13.5)
Prophylactic indication	136 (43.5); 91 CRT	228 (49.5); 133 CRT
Missing/unclassifiable	44 (14)	49 (10.6)
Total	313	461
Valvular heart disease		
Aborted sudden cardiac death	6 (13.6)	9 (14)
SMVT	20 (45.5); 10 S	20 (31.3); 11 S
Syncope without documented arrhythmia	6 (13.6)	10 (15.6)
Prophylactic indication for left ventricular dysfunction	10 (22.7)	19 (29.7)
Missing/unclassifiable	2 (4.6)	6 (9.4)
Total	44	64
Hypertrophic cardiomyopathy		
Aborted sudden cardiac death	10 (14.3)	16 (17.8)
Prophylactic implant	58 (82.3)	67 (74.4)
Missing/unclassifiable	2 (3.4)	7 (7.8)
Total	70	90
Brugada syndrome		
Aborted sudden cardiac death	10 (21.7)	6 (9.5)
Prophylactic implant, syncope	18 (39.1)	25 (39.7)
Prophylactic implant, no syncope	16 (34.8)	20 (31.7)
Missing/unclassifiable	2 (4.4)	12 (19.1)
Total	46	63
Arrhythmogenic right ventricular cardiomyopathy		
Aborted sudden cardiac death	1 (4)	5 (23.8)
SMVT	15 (60); 12 S	8 (38.1); 1 S
Prophylactic indication	3 (12)	6 (28.6)
Missing/unclassifiable	6 (24)	2 (9.5)
Total	25	21
Congenital heart disease		
Aborted sudden cardiac death	1 (14.2)	3 (20)
SMVT	3 (43)	3 (20)
Prophylactic implant	2 (28.6)	7 (46.7)
Missing/unclassifiable	1 (14.2)	2 (13.3)
Total		15
Long QT syndrome		
Aborted sudden cardiac death	5 (28)	6 (25)
Prophylactic implant	13 (72)	15 (62.5)
Missing/unclassifiable		3 (12.5)
Total	18	24

CRT indicates cardiac resynchronization therapy; S, syncopal; SMVT, sustained monomorphic ventricular tachycardia.

Indications

In contrast to previous years, only the indications observed in the primary implant patients are reflected since, as they represent the majority of the group as a whole (80%), the differences in the indications for primary implants and total implants are not significant.

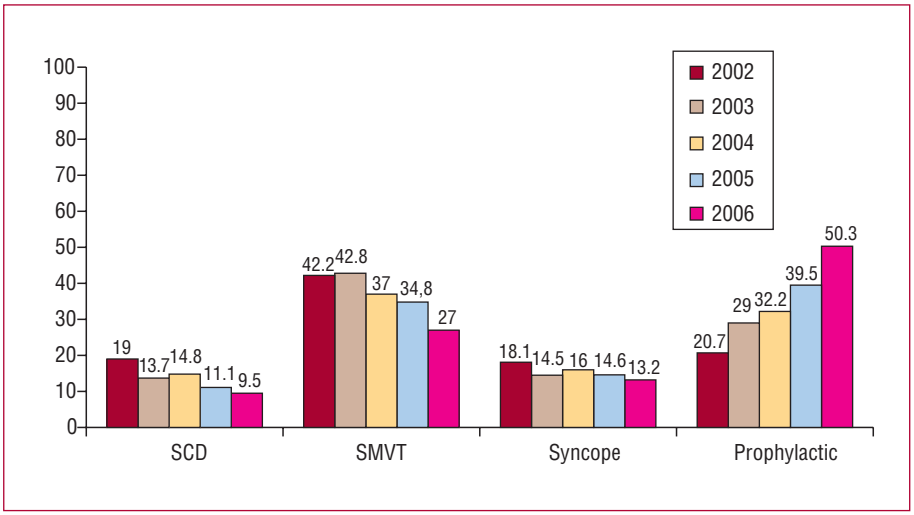

Figure 8. Changes in the major indications for implantable cardioverter defibrillators (primary implants) between 2002 and 2006. SCD indicates aborted sudden cardiac death; SMVT, sustained monomorphic ventricular tachycardia; Syncope, syncope without documented electrocardiographic evidence of arrhythmia.

The most common indication for ICD was ischemic heart disease and previous infarction and, although secondary prevention continues to be indicated more frequently than primary prevention in these patients, the latter now accounts for 42.2% of the indications. After these, the most common indications, which are similar to each other in terms of incidence, are those for secondary and primary prevention in patients with dilated cardiomyopathy. Among the cases of primary prevention, 58% of the implanted devices provided cardiac resynchronization therapy (CRT). In patients with hypertrophic cardiomyopathy and Brugada syndrome, the majority of the indications were for primary prevention.

Table 5 details the changes in the incidences of the indications for the most prevalent heart diseases between 2005 and 2006 (years with the greatest representativeness in the registry) and Figure 8 presents the changes in these indications, grouped together, over the 5-year period from 2002 to 2006.

Setting and Personnel

These data were available in 94% of the cases (primary implants and replacements) reported to the registry. Implantation was carried out in the electrophysiology laboratory in over two thirds of the cases (67.9%) and in the operating room in 32%. There were isolated cases of implantations performed in other settings.

The implantations were carried out by electrophysiologists in 72.4% of the cases, by heart surgeons in 24.4% of the patients and by other specialists in 3.2%.

Positioning of the Generator

In the majority of cases, the generator was implanted in a subcutaneous pectoral position (87% of all the implants and 89.3% of the primary implants). The submuscular pectoral position was employed in 12.4% of the implants in the group as a whole and in 10.7% of the primary implants. Abdominal implantation was not performed in any of the cases of primary implant reported to the registry that included this information. This approach was employed in 0.5% of the replacements.

Device Type

When all the implants (primary implants and replacements) were analyzed, the percentages of single-chamber ICD, dual-chamber ICD, and CRT devices were 53.4%, 19.9%, and 26.7%, respectively. When only primary implants were evaluated, these proportions were 52.2%, 19.2%, and 28.6%, respectively. According to the data provided by the EUCOMED, in 2006, 1580 single-chamber ICD (51%), 666 dual-chamber ICD (21.5%), and 848 CRT devices (27.5%) were implanted.

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

Of the reported replacements, information on the reason for replacement was available in 70% of the cases. Of these, 83.3% were due to battery depletion and 16.7% were due to complications. Among the replacements due to complications (n=62), 16 took place within the first 6 months after implantation, and 46 occurred during the following 6 months.

Information on the functioning of the original electrodes was available in 89% of the cases. The proportion of nonfunctioning electrodes (55 cases) was 11.6%. The nonfunctioning electrodes were explanted in 37 cases.

Programming the ICD

Antibradycardia pacing was primarily in VVI mode (50.6%), with VVIR mode being used in 11.3% of the

cases, DDD in 21.6%, DDDR in 12.6%, and other pacing modes in 3.9% of the cases (mainly modes selected to reduce the percentage of ventricular pacing in dual-chamber devices).

The device was programmed for ventricular antitachycardia pacing in 87% of the cases, with a combination of ventricular and atrial pacing in 1.9%. Antitachycardia pacing was not programmed during implantation in 11.1% of the cases.

Both ventricular and atrial defibrillation or cardioversion therapies were programmed in 1.4% of the cases.

Complications

Four cases of death during implantation (1.5 per thousand procedures) and 2 cases of pneumothorax were reported. There were no reports of cardiac tamponade during implantation. Other unspecified complications occurred in five cases.

DISCUSSION

For the first time, the 2006 Spanish ICD Registry has achieved a representativeness of more than 85% of the implantations performed in Spain, and can be considered a reference for routine clinical practice in terms of the clinical and epidemiological characteristics and indications associated with ICD implantation in Spain. This achievement has been made possible through the efforts of many professionals who, from the implantation of the ICD to the maintenance of the ICD database, have enabled the consolidation and progressive improvement, year after year, of the registry, which has gone from a representativeness of around 60% between 2002 and 2004 to 86.6% in 2006. Moreover, the majority of the reports concerning the implants were prospective.

Comparison With Previous Years

With respect to previous years, the number of implant centers has increased slightly, mainly due to the greater number of private centers that have begun to report their implants. The total number of implants reported to the registry has continued to increase and, thus, the number of implants per million population. This increase is due as much to the increase in the total number of implantations performed as to the increase in the number of implantations that are reported to the registry. The proportion of primary implants now represents 80% of all those reported, versus 70.3% during the preceding year. There have been no significant changes in the epidemiological characteristics of the patients, which are similar in terms of mean age, the marked predominance of the male sex, the type of heart disease presented by the patient and the baseline cardiac rhythm. Patients with severe or moderate to severe ventricular dysfunction continue to be in the majority, with a gradual increase in their proportion year after year, a trend that is also observed for functional classes II and III.

With respect to the types of indications, in 2006, the trend detected in 2002 to 2005 (more marked in the latter year) toward a significant increase in the proportion of prophylactic implants was even more marked. Considering all heart diseases, for the first time, prophylactic indications accounted for half of the indications in primary implantations. In ischemic heart disease, primary prevention was employed in over 40% of the cases, which represented a significant increase with respect to the preceding year. In the case of dilated cardiomyopathy, as in 2005, primary prevention was the main indication for primary implantation, accounting for nearly 50% of the indications. The main reason for the increase in prophylactic indications is probably the greater diffusion of the major clinical trials involving primary prevention and the clinical practice guidelines published in recent years.[4-7]

Concerning the type of device, as in 2005, the use of CRT plus ICD has become increasingly widespread, especially in primary prevention, the main indication for devices of this type. In contrast, the proportion of single-chamber ICD has decreased slightly. There have been no evident changes with respect to programming of antitachycardia pacing or the antibradycardia pacing mode.

Finally, the trend toward a higher proportion of ICD implantation in electrophysiology laboratories by electrophysiologists, who continue to carry out more than two thirds of these procedures, observed in preceding years, has become established. The performance of subcutaneous pectoral implantation also continues to be the most widespread approach, in a proportion similar to that of the preceding year.

Comparison With Registries in Other Countries

Comparisons are difficult since, at the present time, there are no registries that contain all the clinical information available in the Spanish Registry and whose data is published after a 1-year delay.

The 2006 EUCOMED data (data provided by the ICD industry), which encompass Austria, Belgium, France, Germany, Italy, The Netherlands, Portugal, Spain, Switzerland, and the United Kingdom, report a number of implants of ICD with or without CRT per million population in those countries that ranges between 67 in Portugal and 262 in Germany. In the latter country, Italy and The Netherlands, more than 200 implants per million population had been performed, whereas only the United Kingdom, Spain, and Portugal had carried out less than 100. The increase in the number of implantations with respect to the preceding year was more marked in most of these countries than in Spain. While in this country, the increase was almost 8%, in the remainder, it ranged

between 11% in Germany and 44% in the United Kingdom. However, it was lower in Switzerland (7%), and even decreased from 133 to 118 implants per million population in Belgium.

In the United States, centers are required to participate in the National Implantable Cardioverter Defibrillator Registry, created in 2005 with the collaboration of the American College of Cardiology Foundation and the Heart Rhythm Society, by the Medicare and Medicaid services. This registry records implants indicated for primary prevention. Results have not yet been issued, but its organization and major objectives have been published.[8]

The latest data reported by the Danish ICD registry are from 2006,[9] year in which a total of 600 primary implantations and 157 replacements were performed (117 primary implantations per million population). The number of implants per million population has grown substantially over the past 4 years in that country, going from 68 in 2003 to 117 in 2006. There are only 5 implant centers, a number that has remained constant for years. More than 82% of the implants were carried out in men. The mean age of the patients was 2.8 years. The most common heart condition was ischemic heart disease (51.6%), followed by dilated cardiomyopathy (24.1%). The arrhythmias that most often led to implantation were SMVT (56.9% of the cases) and ventricular fibrillation (25.2%). Although data on the number or type of prophylactic indications are not provided, the fact that the incidences of SMVT and ventricular fibrillation as indications went from 89% to 81.1% suggests an increase, although not very marked, in prophylactic indications. Single-chamber ICD were used in 52.2% of the primary implantations and ICD plus CRT devices in 28.3%, there being a clear and sustained increase in the utilization of the latter over the past 2 years (17% in 2004).

The National Registry on Cardiac Electrophysiology of Portugal includes data on ICD implants. The most recent data published correspond to 2005. The number of implant centers was the same as that of the preceding year (15 centers). However, the number of implants increased by 37.1% with respect to 2004, which, in turn, had increased by 33.8% with respect to 2003, with a total number of reported ICD of 611 (547 primary implants). This represents a rate of 54 implants per million population versus 34.4 per million population in 2004. With respect to the type of ICD, 53.7% were single-chamber implants, 12.6% were dual-chamber implants and 33.6% were ICD plus CRT devices, versus 20.6% in 2004. Data on the indications for implantation are not provided.[10]

Geographic Distribution and Regional Differences

The information in the 2006 ICD registry continues to indicate, as in the preceding year, that geographical differences in terms of the available resources, indications, and numbers of ICD implants in Spain. Thus, while communities like Asturias, Cantabria, Navarra, and Madrid report more than 80 implants per million population to the registry, there are 7 communities that report less than 50 per million population. The differences encountered in the registry data are also discussed by Fitch-Warner et al[11] in a study on the variability among autonomous communities with respect to the use of cardiovascular technologies. This study, like the Spanish Registry of Cardiac Catheterization and Coronary Interventions, found that these differences are also evident in other health care technologies, such as coronary interventional techniques, in which the number of cardiac catheterizations or percutaneous revascularization procedures clearly differs from one autonomous community to another.[12]

These regional disparities are not restricted to Spain. The Italian Implantable Cardioverter-Defibrillator Registry covering 2001 to 2003 reveals an enormous divergence between the northern and southern regions of Italy, and there are up to four-fold differences between the regions in which the minimum and maximum numbers of ICD implantations are performed.[13,14]

The reasons for the variability in clinical practice is a widely debated issue, and the major causes are related to the available health care services, the characteristics of the patients and physicians, the distribution of the disease burden and the quality of the scientific evidence underlying the decision-making process.[15,16] The results of the work of Fitch-Warner et al,[11] based on data from 2003, indicated the lack of a correlation between the number of ICD implantation procedures and the coronary disease burden, but demonstrated the existence of an association between the number of procedures and the number of implant centers and between the number of ICD implants, and the regional wealth. The latter was not associated with the ischemic heart disease burden in each autonomous community. Moreover, colinearity was observed between the number of ICD implant centers and the per capita GDP. In said study, the regional wealth, measured by the per capita GDP, accounted for 40% of the variability in the use of the ICD. Socioeconomic differences have also been included among the major causes of regional differences in other countries, such as the United Kingdom.[14] In contrast, unlike the 2005 ICD registry data, in 2006, no statistically significant correlation was observed between the number of implant centers per million population in each autonomous community and the number of implants per million. The discrepancies between the different clinical practice guidelines, especially with respect to the establishment of indications for implantation for primary prevention, as well as the differences in adherence to them, probably also contribute to the differences among countries and regions.[17]

Limitations

The number of implants reported to the registry do not account for all those performed in Spain, but, given that they constitute more than 85% of the total, it can be considered representative of the situation on a nationwide basis. Nevertheless, the regional differences should be interpreted with caution since, in addition, the effect of the transfer of patients to receive care in other autonomous communities has not been taken into account in the analysis. The information on most of the variables on the data collection form was provided in over 80% of the implants reported to the registry. However, there are some variables, such as whether or not an electrophysiological study had been carried out, in which this percentage was lower and, thus, the validity may be limited.

As in preceding years, the indications for ICD for primary prevention in patients with ischemic heart disease and dilated cardiomyopathy were not quantified in detail in terms of the type of indication (MADIT II, SCD-HeF, etc) due to the fact that not all the information necessary to make that subdivision (ejection fraction ranging between 30% and 39%, QRS width or presence of left bundle branch block) was available.

CONCLUSIONS

The 2006 National ICD Registry records 86.6% of the ICD implants performed in Spain, the highest percentage to date, and can be considered representative of the scale of and indications for this procedure in our country. The number of implants reported to the registry has continued the growth of preceding years, reaching 60 per million population in 2006. This rate is appreciably lower than the mean of the most highly developed countries of the European Union. As occurs with other health care technologies, there are substantial differences from one region to another in terms of the number of implants reported to the registry. The number of ICD implants in the context of primary prevention has continued to grow and, at the present time, they represent half of all ICD implants.

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