Spanish Implantable Cardioverter Defibrillators Registry. Second Official Report of the Spanish Society of Cardiology Working Group on Implantable Cardioverter Defibrillators (2005)

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Introduction and objective. We report the results for the Spanish Registry on Implantable Cardioverter Defibrillators (ICD) (year 2005), developed by the Working Group on ICD of the Spanish Society of Cardiology.

Methods. Data were collected (prospectively in 77% of implants) by single page form questionnaires transmitted after the procedure to the Spanish Society of Cardiology. Participation was voluntary.

Results. The number of implants sent to the Registry was 2050 and this represents 74.4% of the total ICDs implanted. The implantation rate per million was 46.5 and the estimated total implantation rate per million was 62.5. The proportion of first implants was 70.3%. The majority of patients were males, with a median age of 65 years, severe or moderate to severe left ventricular dysfunction and in functional class II or I. Ischemic heart disease was the more frequent underlying heart disease followed by dilated cardiomyopathy. The main reason for ICD indication was secondary prevention related to sustained monomorphic ventricular tachycardia or aborted sudden cardiac death. A significant number of prophylactic indications were done, specially in non ischemic heart disease. The proportion of ICD implanted at the electrophysiology laboratory by cardiac electrophysiologist continues increasing. There was an increase in the number of ICD plus cardiac resynchronization therapy, that represent a 23.6% of the implants. The incidence of complications during the implant was very low.

Conclusions. The National Registry on ICD, with a participation rate greater than in previous years, provides a representative sample of the ICD implants performed at our country.

Key words: *Defibrillator. Registry. Arrhythmia.*

Registro Español de Desfibrilador Automático Implantable. II Informe Oficial del Grupo de Trabajo de Desfibrilador Implantable de la Sociedad Española de Cardiología (2005)

Introducción y objetivo. Se presentan los resultados del Registro Nacional de Desfibrilador Automático Implantable (DAI) en el año 2005 elaborado por el Grupo de Trabajo de DAI de la Sociedad Española de Cardiología (SEC).

Métodos. Se envío a la SEC la hoja de recogida de datos cumplimentada de forma voluntaria por cada equipo implantador. La recogida fue prospectiva en el 77% de los implantes.

Resultados. El número de implantes comunicados fue de 2.050 (el 74,4% del total estimado, de implantes). El número de implantes por millón de habitantes comunicados fue 46,5 y el estimado 62,5. El número de primoimplantes fue del 70,3%. La mayor parte de los DAI se implantaron en varones con una edad mediana de 65 años, con disfunción del ventrículo izquierdo severa o moderada-severa y en clase funcional II o I. La cardiopatía más frecuente fue la isquémica, seguida de la dilatada. Las principales indicaciones fueron por prevención secundaria en pacientes con taquicardia ventricular monomórfica sostenida o muerte súbita abortada. Las indicaciones por prevención primaria fueron muy frecuentes, sobre todo en cardiopatías distintas de la isquémica. Continúa creciendo el número de implantes realizados en el laboratorio de electrofisiología y por electrofisiólogos. Se ha producido un aumento del número de DAI con terapia de resincronización cardiaca implantados, que constituyeron el 23,6%. La incidencia de complicaciones durante el implante fue muy baja.

Conclusiones. Con una participación mayor que la de años previos, el Registro Español de DAI recoge una muestra representativa de los implantes de DAI que se llevan a cabo en nuestro país.

Palabras clave: *Desfibrilador. Registro. Arritmia.*

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ABBREVIATIONS

ICD: implantable cardioverter defibrillator
WGICD: Working Group on Implantable Cardioverter Defibrillators
EAS: Electrophysiology and Arrhythmia Section
SSC: Spanish Society of Cardiology
CRT: Cardiac Resynchronisation Therapy
SMVT: Sustained Monomorphic Ventricular Tachycardia

INTRODUCTION

Health registries are useful in determining the extent to which the outcomes of clinical trials and recommendations in clinical guidelines are actually incorporated into medical practice. Conclusions drawn from information in registries can lead to improved prevention and treatment strategies and enhanced resource-allocation, as well as generating new research questions.

The Electrophysiology and Arrhythmia Section (EAS) of the Spanish Society of Cardiology (SSC) set up the first National Registry of Implantable Cardioverter Defibrillators (ICD) in 1996. The first results were published in 1997.[1] The EAS's Working Group on Implantable Cardioverter Defibrillators (WGICD) was established in 2001, and last year published its first official report of findings from the Spanish Registry of Implantable Cardioverter Defibrillators for the period 2002-2004.[2] The present report provides data on ICD implants collected by the Registry in 2005. Most of the health care centers providing ICD implants in Spain are included in the Registry.

Methodology

Data collection was primarily prospective. Centers used a standard data collection form, which is available on the EAS web-page (www.arritmias.org). ICD implant teams completed this form on a voluntary basis, either during or after the implant, and in collaboration with ICD manufacturers. The completed forms were sent by fax or e-mail to the SCS. In June 2006, sites which had provided prospective data were sent a list of the implants they had reported in 2005. The list included patient initials, the date of the implant, the name of the manufacturer, and the model of implant used. Centers were asked to send retrospective data on any patient who had received an implant but for whom data had not been reported prospectively. Retrospective and prospective data were collected using the same format, and both were communicated by fax or e-mail.

Data was entered into the Spanish ICD Registry database by EAS staff and members of the ICD Working Group. An EAS computer specialist and a member of the ICD Working Group cleaned the data, and members of the current ICD Working Group executive committee were responsible for data analysis and publication.

Population data used to calculate rates per million inhabitants, both nationally and by Autonomous Community and province, were retrieved from the January 1, 2005 estimates of the National Institute of Statistics database (http://www.ine.es).

We used information on the total number of ICD implants or replacements performed in Spain provided by ICD vendors to the European Medical Technology Industry Association (EUCOMED) to calculate the proportion of implants reported to the Registry. This in turn allowed us to estimate the representativity of the Registry.

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

Statistical Analysis

Results were expressed as means and standard deviations (SD) in the case of variables with a normal distribution, and as medians and inter-quartile ranges where the distribution was non-normal. Relationships between quantitative variables were analysed using a linear regression model. Qualitative variables were compared using the χ^2 test. *P*-values less than .05 were considered statistically significant. Statistical analysis was conducted using the SPSS Inc. Program, version 12.0, Chicago, Ill, USA.

RESULTS

Response rates for the different fields of the data collection form were high, ranging between 70.6% and 98.8% for the Registry's principal variables.

Participating Centers

A total of 79 centers which performed ICD implants provided data to he Registry (table 1). Most of these (n=64) were public health care centers. Table 2 shows the number of public health care centers which provided data to the Registry per million inhabitants and by Autonomous Region.

Total number of implants 2050 (first implants and replacements) were reported to the Registry in 2005 by 29 centers. Of the total number of implants, 1574 (77%) were reported prospectively and 476 (23%) were reported retrospectively. Comparing this total with the manufacturers' figures on the number of implants fitted in 2005, the Registry's figures represent 74.4% of all implants fitted in Spain that year.

TABLE 1. **Hospitals Which Provided Data to the National Registry on Implantable Cardioverter Defibrillators in 2005, and Number of Implants per Hospital (by Autonomous Community and Province)**

Autonomous Community		No. of Implants
Andalusia		
Cádiz	Hospital Universitario Puerta del Mar	4
Córdoba	Hospital Universitario Reina Sofía	13
Granada	Hospital Universitario Virgen de las Nieves	22
Huelva	Hospital General Juan Ramón Jiménez	30
Málaga	Hospital Universitario Virgen de la Victoria	108
	Clínica Parque San Antonio	3
Seville	Hospital Universitario Virgen del Rocío	51
	Hospital Universitario Virgen Macarena	25
	Hospital Nuestra Señora de Valme	46
	Clínica Sagrado Corazón	2
Aragon		
Zaragoza	Hospital Clínico Universitario Lozano Blesa	34
	Hospital Miguel Servet	55
Asturias		
Oviedo	Hospital Central de Asturias	63
Balearic Islands		
Palma de Mallorca	Hospital Son Dureta	36
	Hospital Son Llàtzer	9
	Clínica Rotger Sanitaria Balear, S.A.	3
Canary Islands		
Las Palmas	Hospital Dr. Negrín	50
	Hospital Insular de Gran Canaria	13
	Clínica San Roque, S.A.	1
Tenerife	Hospital Nuestra Señora de la Candelaria	7
	Hospital Universitario de Canarias	7
Cantabria		
Santander	Hospital Universitario Marqués de Valdecilla	34
Castilla-La Mancha		
Toledo	Hospital Virgen de la Salud	36
Guadalajara	Hospital General Universitario de Guadalajara	9
Albacete	Hospital General de Albacete	8
Castilla y León		
Valladolid	Hospital Clínico Universitario de Valladolid	50
	Hospital del Río Hortega	16
	Sanatorio Virgen de la Salud	3
León	Hospital de León	20
Salamanca	Hospital Universitario de Salamanca	35
Ávila	Hospital Nuestra Señora de Sonsoles	2
Segovia	Hospital Policlínico	1
Burgos	Hospital General Yagüe	3
Soria	Hospital General de Soria	1
Catalonia		
Barcelona	Hospital Clínic	142
	Hospital de la Santa Creu i Sant Pau	56
	Hospital Vall d'Hebron	50
	Hospital de Bellvitge	38
	Hospital German Trias i Pujol	29
	Hospital del Mar	10
	Centre Cardiovascular Sant Jordi, S.A.	6
	Clínica Quirón	4
	Centro Médico Tecknon	2
	Hospital de Barcelona	1
Community of Valencia		
Valencia	Hospital General Universitario de Valencia	27
	Hospital Clínico Universitario de Valencia	20
	Hospital Universitario La Fe	14
	Hospital Doctor Peset	4
	Hospital Lluís Alcanyís	2
Alicante	Hospital General Universitario de Alicante	74
	Clínica Benidorm	11
Castellón	Hospital General de Castelló	8
Extremadura		
Badajoz	Hospital Infanta Cristina	14
Galicia		
La Coruña	Complejo Hospitalario Universidad de Santiago	55
	Hospital Juan Canalejo	45
Pontevedra	Complejo Hospitalario Xeral Cíes	8
Madrid		
Madrid	Hospital Universitario Gregorio Marañón	70
	Hospital Universitario La Paz	58
	Hospital Clínico de San Carlos	56
	Hospital Universitario Ramón y Cajal	50
	Clínica Puerta de Hierro	39
	Hospital Universitario 12 de Octubre	28
	Fundación Jiménez Díaz	11
	Hospital Universitario de Getafe	11
	Fundación Hospital Alcorcón	11
	Hospital Severo Ochoa	8
	Clínica La Luz	6
	Clínica San Camilo	6
	Hospital de Fuenlabrada	4
	Hospital Central de la Defensa	1
	Clínica Nuestra Señora de América	1
	Sanatorio Nuestra Señora del Rosario	1
Murcia		
Murcia	Hospital Universitario Virgen de la Arrixaca	42
Navarre		
Pamplona	Clínica Universitaria de Navarra	20
	Hospital de Navarra	28
Basque Country		
Vitoria	Hospital Txagorritxu	56
Bilbao	Hospital de Basurto	38
Baracaldo	Hospital de Cruces	23
San Sebastián	Hospital Donostia	8

TABLE 2. **Number of Public Implant Centres (in Brackets, per Million Inhabitants) by Autonomous Community, 2005**

Autonomous Community	Centres
Andalusia	8 (1)
Aragon	2 (1.6)
Asturias	1 (0.9)
Balearic Islands	2 (2)
Canary Islands	4 (2)
Cantabria	1 (1.8)
Castilla-La Mancha	3 (1.6)
Castilla y León	8 (3.2)
Catalonia	6 (0.9)
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)
Basque Country	4 (1.9)
Total for Spain	64 (1.45)

TABLE 3. **Number of Implants Reported to the Registry in 2005, by Autonomous Community, and Number of Reported Implants per Million Inhabitants**

Autonomous Community	No.	No./10^6 Inhabitants
Andalusia	304	38.7
Aragon	89	70.1
Asturias	63	58.6
Balearic Islands	48	48.9
Canary Islands	78	39.6
Cantabria	34	60.5
Castilla-La Mancha	53	28
Castilla y León	131	52.2
Catalonia	338	48.3
Community of Valencia	152	32.4
Extremadura	14	12.9
Galicia	108	39.1
Madrid	361	60.5
Murcia	42	31.5
Navarre	40	67.5
Basque Country	125	58.9
Missing	70	
Total Spain	2050	46.4

Both first implants and replacements are included. No defibrillators were implanted in the Autonomous Community of La Rioja or the cities of Ceuta and Melilla in 2005.

The total number of implants per million inhabitants was 46.4 as reported to the Registry and 62.5 according to EUCOMED figures. Table 1 shows the number of implants reported to the Registry by implant center. Table 3 shows the number of implants by Autonomous Community, as reported to the Registry in 2005, and the number of implants per million inhabitants. There was a significant correlation between the number of implant centers per million inhabitants and the number of ICDs fitted in each Autonomous Community (r^2=0.59; P=.01).

Table 4 shows the number of implants fitted by province and Autonomous Community, and the figure per million inhabitants.

The majority of implants (1959, or 96% of the implants reported to the Registry) were performed in public health care centers.

First Implants Versus Replacements

There were a total of 1400 first implants (70.3% of all implants fitted) giving a rate of 32 per million. The remaining 593 implants (29.8%) were replacements.

Age and Sex

The mean (SD) age of patients receiving an ICD was 61.8 (14) years (range, 4-90 years). The median (IQR) age was 65 (55-72) years. The figures were very similar for first implants (mean age of 61.6 [13.7] years with the same range). The median age in this group was also the same, with an IQR of 54-72 years. The majority of patients were male (85% of the total and 84.4% of first implants).

Underlying Heart Disease, Left Ventricular Ejection Fraction (LVEF), and Baseline Rhythm

Figure 1 and table 5 show the proportions of different underlying heart disease in patients receiving implants, overall and by first implant. There were no differences in the percentages of underlying heart diseases between first implants and overall. The most frequent underlying condition was ischemic heart disease, followed by dilated cardiomyopathy and hypertrophic cardiomyopathy. An appreciable number of ICDs were performed because of primary electrical disturbances, particularly Brugada syndrome, idiopathic ventricular fibrillation, and long QT syndrome.

The majority of patients had a left ventricle ejection fraction (LVEF) of <30% or 30%-40% (Figure 2). The proportion of patients with an ejection fraction >50% was higher than that of patients with only mild dysfunction (40%-49%). There was a higher proportion of patients with severe left ventricle dysfunction (ejection fraction <30%) in the group of first implants compared to total implants (P<.05).

The majority of patients were in functional class I or II in the New York Heart Association classification. There was a lower proportion of patients in functional class III and very few cases of patients in functional class IV (Figure 3).

TABLE 4. **Residence of ICD Implant Patients and Number per Million Inhabitants As Reported to the Registry, by Autonomous Community and Province (Includes Both First Implants and Replacements)**

Autonomous Community	No	No/10^6 Inhabitants	Autonomous Community	No	No/10^6 Inhabitants
Andalusia	275	35	Soria	6	65.3
Almería	5	8.2	Valladolid	54	104.9
Cádiz	22	18.6	Zamora	7	35.4
Córdoba	11	14	Catalonia	310	44.3
Granada	17	19.7	Barcelona	290	55.5
Huelva	26	53.7	Gerona	8	12.1
Jaén	14	21.2	Lérida	4	10.1
Málaga	84	57.8	Tarragona	8	11.4
Sevilla	96	52.3	*Community of Valencia*	147	31.4
Aragon	87	68.6	Alicante	85	49.1
Huesca	6	27.8	Castellón	11	20.3
Teruel	5	35.5	Valencia	52	21.5
Zaragoza	76	83.3	*Extremadura*	38	35.1
*Asturias:*Oviedo	60	55.8	Badajoz	23	38.8
Baleares	36	36.6	Cáceres	15	36.4
Canarias	70	35.6	*Galicia*	100	36.2
Las Palmas	54	53.4	La Coruña	50	44.4
Tenerife	16	19.9	Lugo	15	42
Cantabria: Santander	21	37.4	Orense	8	23.6
Castilla-La Mancha	54	28.5	Pontevedra	27	28.8
Albacete	8	20.8	*La Rioja:* Logroño	5	16.6
Ciudad Real	11	22	*Madrid:* Madrid	275	46.1
Cuenca	10	48.1	*Murcia:* Murcia	41	30.7
Guadalajara	5	24.5	*Navarre:* Pamplona	40	67.4
Toledo	20	33.5	*Basco country*	115	54.1
Castilla y León	139	55.4	Álava	39	130
Avila3	10		Guipúzcoa	15	21.8
Burgos	14	38.8	Vizcaya	61	53.4
León22	44.4		*Ceuta/Melilla*	1	7
Palencia	1	5.8	Other countries	12	
Salamanca	27	76.7	Missing	234	
Segovia	5	32.3			

Includes both first implants and replacements.

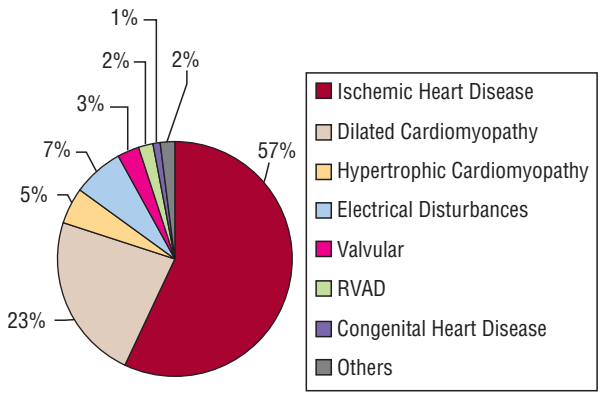

Figure 1. Underlying heart disease as reported to the Registry.

The majority of patients (82.3%) presented a sinus rhythm, whereas 12.8% had atrial fibrillation, 4.8% had a pacemaker rhythm, and 8 patients presented other rhythms (atrial flutter or other atrial arrhythmias).

Reason for Implant (Clinical Arrhythmia), Presentation, and Laboratory-Induced Arrhythmia

The leading cause for implant was sustained monomorphic ventricular tachycardia (SMVT), with syncope being the main clinical symptom. The second most frequent cause for implant was non-sustained ventricular tachycardia or ventricular tachycardia without documented clinical arrhythmia. In patients with ventricular tachycardia, ICD was indicated as a preventive measure. The most frequent form of clinical presentation was syncope, followed by "other symptoms," and cardiac

TABLE 5. **Number of Implants (Totals and First Implants) by Type of Heart Disease, Clinical Arrhythmia, and Presentation**

Type of Heart Disease and Indication	Total	First Implants
Ischemic heart disease		
Aborted sudden death	138 (12.7)	82 (10.7)
Syncopal SMVT	185 (17)	123 (16.2)
Non-syncopal SMVT	258 (23.7)	168 (22)
Syncope without documented arrhythmia	144 (13.1)	109 (14.3)
Prophylactic indication	283 (26) 88 CRT	238 (31.2) 80 CRT
Missing/unclassifiable	82 (7.5)	44 (5.6)
Total	1090	764
Dilated cardiomyopathy		
Aborted sudden death	37 (8.4)	16 (5.1)
Syncopal SMVT	76 (17.2)	47 (15)
Non-syncopal SMVT	63 (14.3)	33 (10.5)
Syncope without documented arrhythmia	51 (11.6)	37 (11.9)
Prophylactic indication	164 (37.2) 103 CRT	136 (43.5) 9 1 CRT
Missing/unclassifiable	50 (11.3)	44 (14)
Total	441	313
Valvular heart disease		
Aborted sudden death	11 (16.9)	6 (13.6)
Syncopal SMVT	28 (43.1) 13 S	20 (45.5) 10 S
Syncope without documented arrhythmia	9 (13.8)	6 (13.6)
Prophylactic indication for LV dysfunction	15 (23.1) 15 CRT	10 (22.7)
Missing/unclassifiable	2 (3.1)	2 (4.6)
Total	65	44
Hypertrophic Cardiomyopathy		
Aborted sudden death	17 (17)	10 (14.3)
Arrhythmogenic RV cardiomyopathy	78 (78)	58 (82.3)
Missing/unclassifiable	5 (5)	2 (3.4)
Total	100	70
Brugada Syndrome		
Aborted sudden death	16 (18.6)	10 (21.7)
Prophylactic implant, syncope	23 (26.8)	18 (39.1)
Prophylactic implant, no syncope	34 (39.5)	16 (34.8)
Missing/unclassifiable	13 (15.1)	2 (4.4)
Total	86	46
Arrhythmogenic RV cardiomyopathy		
Aborted sudden death	2 (5.9)	1 (4)
SMVT	21 (61.8) 15 S	15 (60) 12 S
Prophylactic indication	10 (29.4)	3 (12)
Missing/unclassifiable	1 (2.9)	6 (24)
Total	34	25
Congenital heart disease		
Aborted sudden death	3 (20)	1 (14.2)
SMVT	5 (33)	3 (42.9)
Prophylactic implant	5 (33)	2 (28.6)
Long QT syndrome		
Aborted sudden death	7 (30)	5 (28)
Prophylactic implant	16 (70)	13 (72)

LV: left ventricle; RV: right ventricle; SMVT: Sustained Monomorphic Ventricular Tachycardia; CRT: cardiac resynchronization therapy; S: syncopal. The figures in parentheses are percentages for each type of heart disease.

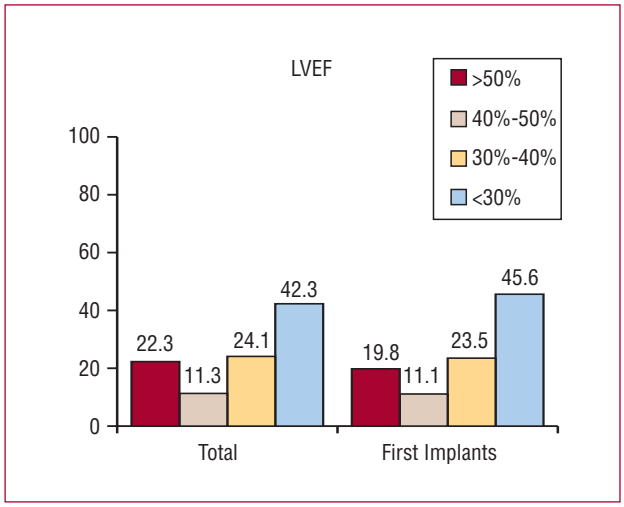

Figure 2. Left ventricular ejection fraction (LVEF) of patients in the Registry, by total and first implants.

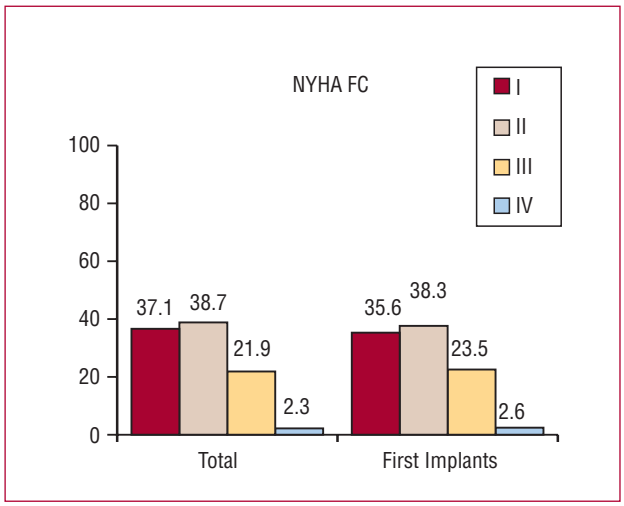

Figure 3. Functional class (FC) of patients in the Registry, by total and first implants.

arrest. In electrophysiological analysis, SMVT was the most frequently induced arrhythmia in both groups. The proportion of patients without clinical arrhythmia or with non-sustained, asymptomatic ventricular tachycardia was higher in first-implant patients than in the overall group. The proportion of patients in whom no electrophysiological analysis was conducted, or who did not have induced ventricular arrhythmias was also higher among first-implant patients ($P<.05$ in the 3 comparisons).

Indications (Table 5 and Figure 7)

The most frequent indication for ICD was secondary prevention in patients with ischemic heart disease, principally SMVT. The next most frequent indication

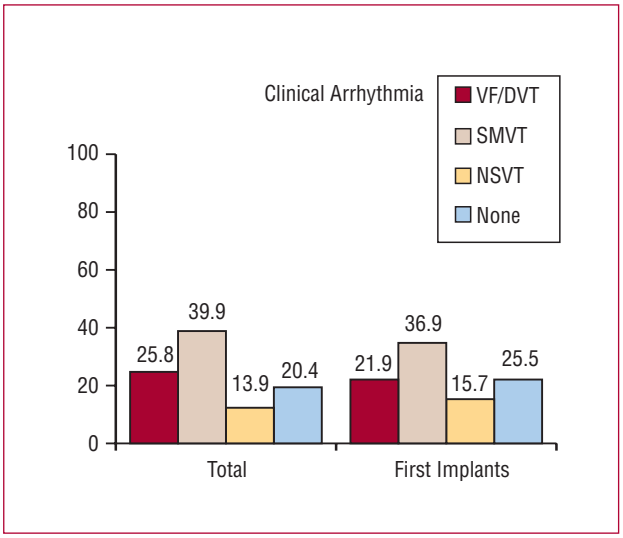

Figure 4. Clinical arrhythmia of patients in the Registry, by total and first implants. VF/DVT: ventricular fibrillation/deep venous thrombosis; SMVT: sustained monomorphic ventricular tachycardia; SNVT: non-sustained ventricular tachycardia.

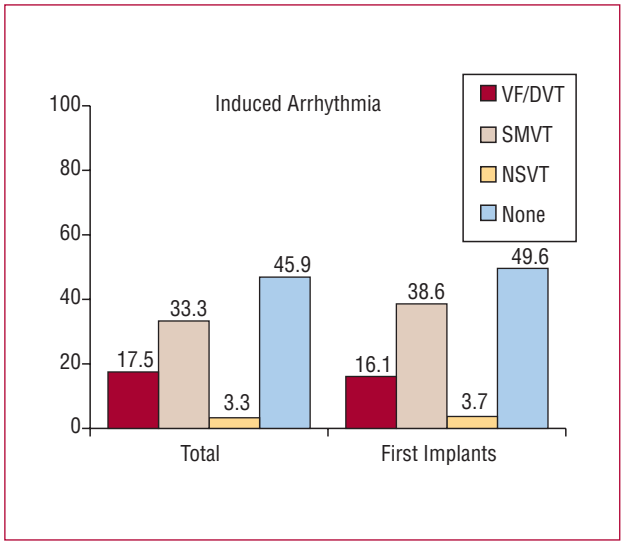

Figure 6. Induced arrhythmia in patients in the Registry (first implants and total implants). Cases where no analysis was conducted or where no ventricular arrhythmia was induced are not included. VF/DVT: ventricular fibrillation/deep venous thrombosis; SMVT: sustained monomorphic ventricular tachycardia; SNVT: non-sustained ventricular tachycardia.

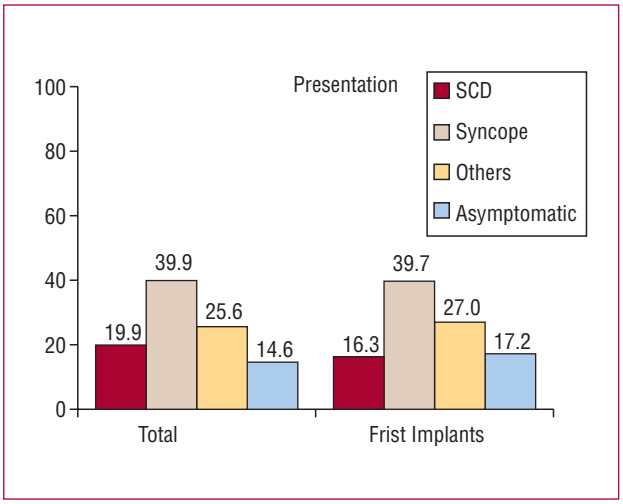

Figure 5. Clinical symptoms of arrhythmia presented by patients in the Registry (first implants and total implants). SCD: sudden cardiac death.

was prophylactic use in patients with ischemic heart disease. This was most commonly of the MADIT II and COMPANION types.

In patients with dilated cardiomyopathy, the most frequent indication was primary prevention, particularly of the COMPANION type, and to a lesser extent SCD-Heft. These were followed by secondary prevention of SMVT and syncope without documented clinical arrhythmia.

Setting and Personnel

Data on the setting for the operation and the personnel involved was available for 2014 patients. In almost two-thirds of cases, the implant was performed in the electrophysiology laboratory (64.9%), and in 34.9% of cases on the surgical ward. There were isolated cases of implants fitted in other settings.

Implants were primarily performed by electrophysiologists, who carried out 66.4% of the implants. In 26.1% of cases, the device was fitted by a heart surgeon, and in 3.4% of cases the operation was performed jointly by a surgeon and an electrophysiologist. The latter mostly involved fitting of heart resynchronisation devices. Other specialists performed the remaining 4.1% of implants.

Positioning of the Generator

In the great majority of cases, the generator was implanted in a subcutaneous pectoral position (86.3% of total implants and 90.7% of first implants). A sub-muscular pectoral position was used in 12.9% of implants overall and in 9.2% of first implants. Abdominal implants constituted only 0.7% of all implants, and almost all of these were replacements. There was only one case, of an adolescent female, where a first implant was fitted abdominally.

Device Type

55.8% of the devices fitted were single-chamber ICDs, 20.6% were double-chamber ICDs and 23.6% were cardiac resynchronisation therapy (CRT) devices. Double-chamber ICDs represented 27% of the implants without CRT. In the case of first implants, percentages of single-chamber ICDs, double-chamber ICDs and

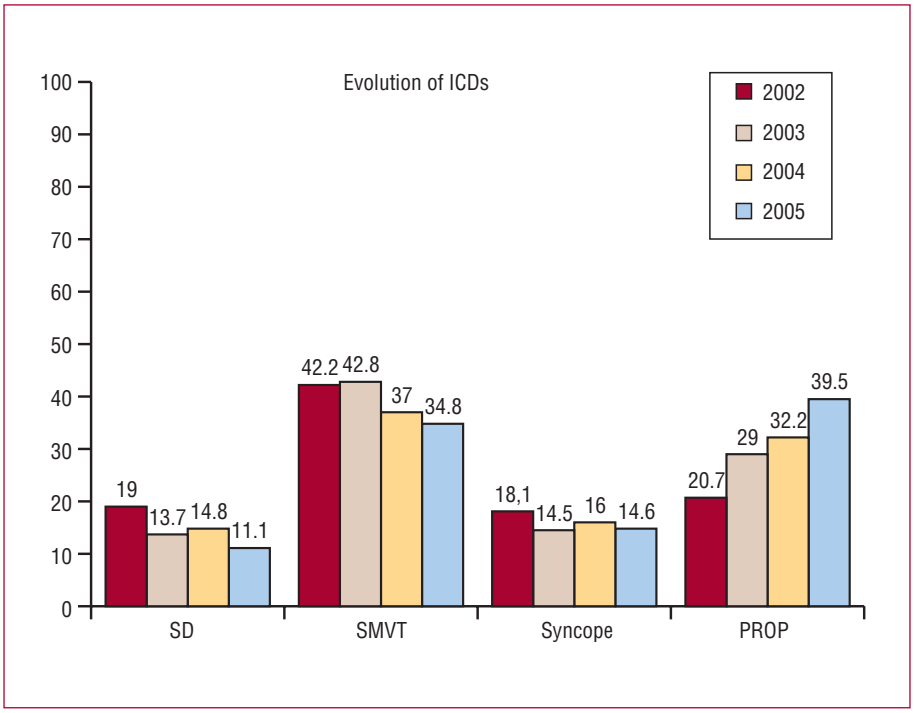

Figure 7. Changes in the principal indications for ICD (first implants) 2002 - 2005. SD: Aborted suden death; PROP: prophylactic indication; SMVT: sustained monomorphic ventricular tachycardia; Syncope: syncope without documented electrocardiographic evidence of arrhythmia.

those with CRT were 56%, 20.6% and 23.4%, respectively. Double-chamber ICDs constituted 26.8% of ICDs without CRT. Finally, for replacement ICDs the percentages were 52.5%, 20% and 22.5% respectively. Double-chamber ICDs represented 25.8% of replacements without CRT. It is likely that the majority of the CRT devices recorded in the registry as replacements were updates of previous ICDs in which this function was lacking. According to the 2005 EUCOMED figures, 1495 single-chamber ICDs were fitted (54%), 558 double-chamber ones (20.4%), and 703 with CRT (25.5%).

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

In 52.7% of cases, replacements were performed due to battery depletion, and 14.9% were required because of complications. Of a total of 198 cases (33.45%) for which no information was provided, 58 were ICDs with CRT. The majority of these were likely to be updates of earlier ICDS which lacked this function. Among the replacements stemming from complications (n=88), 8 occurred in the 6 months after implant and 65 in the following 6 months. In 15 cases, information was not available. Among the replacements stemming from complications, 9 were prompted by possible device failure, 4 by broken electrodes, 2 because of positioning, and 1 because of endocarditis.

In 80% of cases (n=472), information was available on the prior functioning of the electrodes. 10.8% (n=52) of electrodes were non-functioning. In 41 cases of non-functioning electrodes (79%), the device was removed, though it was maintained in the other 11 cases. Additional defibrillation electrodes were used in 5 cases and sensory electrodes in 3 cases.

Programming of ICDs

Antibradycardia pacing was primarily in VVI mode (54%), with VVIR mode being used in 10.8% of cases, DDD in 20.4%, DDDR in 13.1%, and other pacing methods in 1.7% of cases.

The device was programmed for antitachycardia pacing in 90% of cases, with a combination of ventricular and atrial pacing in 3% of cases. Antitachycardia pacing was not programmed in 7% of cases.

Both ventricular and atrial defibrillation or cardioversion therapies were programmed in 1.8% of cases.

Complications

There were no deaths or cases of cardiac tamponade during the implant operation. Five cases of pneumothorax were reported. Complications arose in 14 implants: these included high defibrillation thresholds (n=2), haematoma or haemorrhage (n=2), acute pulmonary oedema (n=1), electrical storm (n=2), problems of capture (n=1), and coronary sinus dissection (n=1). The remaining complications were not specified.

DISCUSSION

The ICD Working Group within the SCS's Electrophysiology and Arrhythmia Section (EAS) continues to consolidate and improve the Spanish ICD Registry. In 2005, the percentage of information sent prospectively was slightly lower than the previous year, probably because of the initiative to allow centers to send information retrospectively using the same forms as those used to provide information prospectively. Nevertheless, although there was a relative reduction in the amount of information received prospectively, the Registry's representativity improved from 57% to 74.4% which is the highest percentage achieved to date.

Comparison With Previous Years

The number of centers performing implants remained unchanged from the previous year, although the total number of implants reported increased from 1414 to 2050. The number of implants reported per million inhabitants, including both first implants and replacements, increased from 33 to 46.4. The increase was mainly due to the increased number of implants performed. According to EUCOMED data, the number of implants per million inhabitants increased from 52 in 2004 to 62.5 in 2005. The introduction of retrospective reporting of implants which was introduced in 2005, as well as increasing the Registry's representativity, may also have contributed to a smaller degree to the increase in implants reported in 2005.

In terms of indications, the period 2002-2004 saw a significant increase in the total number and proportion of prophylactic implants, due to the publication of several studies which demonstrated the usefulness of ICDs as a preventive measure.[3-6] This trend increased in 2005, a year in which the prophylactic use of implants became even better established. Indeed, prophylactic indications were the primary cause of first implants in patients with dilated cardiomyopathy and one of the main causes in patients with ischemic heart disease. The increase in the number of ICDs with CRT is particularly significant.

Lastly, there was a continuation of the trend towards higher proportions of subcutaneous implants and the fitting of ICDs in electrophysiology laboratories by electrophysiologists.

Comparisons With Registries in Other Countries

Information in the scientific literature about ICD implants in other countries remains scarce. The most recent data on the Danish ICD registry (www.pacemaker.dk) is from 2004. In that year, a total of 414 implants and 142 replacements were performed (81 first implants per million inhabitants). The most frequent type of heart disease was ischemia (50%) followed by dilation (25.1%). The most frequent arrhythmias prompting implants were SMVT (55.3% of cases) and ventricular fibrillation (25.1%). Data on the number and type of prophylactic implants was not available. Double-chamber ICDs were used in 34.8% of cases, and ICD in combination with CRT in 17%, indicating a clear increase from 2003. A similar increase was also observed in Spain.

Portugal maintains a National Registry of Cardiac Electrophysiology which includes data on ICD implants. The most recently published information dates from 2004,[7] when the total number of implants reported was 397 (344 first implants). This represented an increase of 33.8% on the previous year. The figure for implants per million inhabitants also rose from 21.6 in 2003 to 34.4 in 2004. The registry does not contain information on indications. In terms of the type of ICD, single-chamber models constituted 63.6% of the total, double-chamber ICDs 18.1%, and ICD with CRT 20.6%. The latter represented a 16% increase from the previous year.

Last year, the Italian ICD Registry published information on the years 2001-2003.[8] This registry, which was created in 1997 under the auspices of the Italian Society of Arrhythmology and Cardiac Stimulation (SACS) collects information on 85% of the implants carried out in Italy and is based on data from the European Registry of Implantable Defibrillators (EURID). The number of implants in Italy rose from 2400 in 2001 to 5318 in 2003, representing an increase in the number of implants per million inhabitants from 42.1 to 93.3. The number of implant centres increased from 273 in 2001 to 340 in 2003. The figures, although they date from 2003, are significantly higher than those in Spain. The number of prophylactic implants increased three-fold over the 3 years, from 6.4% of implants in 2001 to 18.2% in 2003. Ventricular tachycardia was the underlying cause of implant in 55% of cases, ventricular fibrillation in 18.1%, and both in 6.5%. The percentages of single-chamber ICDs, double-chamber ICDs, and ICD with CRT were 39.2%, 32.4%, and 28.4%, respectively. The figures for ICD with CRT and double-chamber devices, although dating from 2003, were higher than the 2005 Spanish figures.

Data from EUCOMED (the association of the ICD manufacturers) brings together information from Germany, Italy, Ireland, the Netherlands, Denmark, Belgium, Austria, Switzerland, Finland, France, Britain, Spain, Sweden, Portugal, and Norway (Norway did not send data for 2005). In 2005, the mean rate of implants of ICDs with or without CRT in participating countries was slightly over 130 per million. Germany had the highest rate (225) per million, Italy had 190, Ireland and Holland. Denmark, Austria, Belgium, and Switzerland were below the average, but still had over

100 implants per million inhabitants. France had slightly over 80 implants per million. The United Kingdom and Sweden had approximately 70 implants per million, which was slightly more than Spain, and Finland and Portugal had lower rates per million than Spain.

In the United States, the Bilitch registry, which was first established in 1974, included information on ICDs, but it stopped functioning in 1993 because of financial difficulties.[9] In the second half of last year, the American College of Cardiology Foundation and the Heart Rhythm Society set up the National ICD Registry, but it has yet to publish any results. It was considered necessary to set up this Registry after several manufacturers recalled devices due to possible device failure. The Registry is voluntary, is accessed via internet (www.accncdr.com/webncdr/ICD/De-fault.aspx), and to date only includes implants for primary prevention.

Geographic Distribution and Regional Differences

The information in the Spanish ICD Registry highlights geographical differences in the resources available, indications, and the number of ICD implants within Spain and in this sense it should be useful for planning purposes. For instance, there is a significant correlation between the number of centres performing implants in each Autonomous Community and the number of ICDs reported to the Registry.

This conclusion is tentative because the Registry does not receive information on every implant, and regional differences may be in part due to the differences in reporting patterns in the different areas. However, regional differences in the number of implant centers per million inhabitants, combined with the fact that almost all publicly-funded ICD centres in Spain are included in the registry, and the representativity of the Registry (approximately 75%), make it more likely that these regional differences reflect the reality of implant patterns in Spain. This regional imbalance has also been highlighted in the CARDIOFORUM report, which showed an appreciable regional imbalance in the use of cardiovascular technology (including ICDs, cardiac resynchronisation devices, and percutaneous interventions within the National Health System. Source: CARDIOFORUM).

Limitations

Although the number of implants reported to the Registry, and its representativity, are now higher than ever, the principal limitation remains the level of participation, which currently stands at about 75%. It is to be hoped that the commitment and interest of the professionals involved in ICD implants, combined with the possibility to send data retrospectively as well as prospectively, will enable the Registry to continue growing and improving.

CONCLUSION

The National ICD Registry for 2005 contains information on three-quarters of the ICD implants performed in Spain, and the data can be considered representative of the scale and indications for the procedure in Spain. The number of implants reported to the Registry continued to increase in 2005, and reached 46.4 implants per million inhabitants. Nevertheless, there are appreciable differences in the number of implants reported to the Registry by region. Although secondary prevention is the main reason for AID implants, the number of prophylactic implants showed a greater increase than in previous years, and they now represent a significant proportion of all implants. The increase in the number of combined ICD and CRT implants is particularly significant. The number of ICDs fitted in electrophysiology laboratories by electrophysiologists continues to increase.

ACKNOWLEDGEMENTS

We would like to thank all of the health professionals involved in ICD implants in Spain who have voluntarily and disinterestedly sent data on implants to the Registry. To the staff of the different ICD manufacturers (Medtronic, Guidant, St. Jude Medical, Biotronik, and Ela Medical), for their help in data collection and in sending forms for a large number of implants to the SCS. To the SCS for its support in maintaining the Registry, especially to D. Gonzalo Justes, D. José María Naranjo, and D. Miguel Ángel Salas.

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