Spanish Implantable Cardioverter-Defibrillator Registry. First Official Report of the Spanish Society of Cardiology Working Group on Implantable Cardioverter-Defibrillators (2002-2004)

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Objective. To report the 2002-2004 findings of the Spanish National Implantable Cardioverter-Defibrillator (ICD) Registry, established by the Spanish Society of Cardiology Working Group on Implantable Cardioverter-Defibrillators.

Material and method. Data were collected prospectively after implantation using a single-page questionnaire returned to the Spanish Society of Cardiology. Participation was voluntary.

Results. The registry received reports on 925, 1,046 and 1414 implants, respectively, in the years 2002, 2003 and 2004. These figures represent 63%, 59%, and 67.5%, respectively, of the total number of ICDs implanted. The reported implantation rates were 22, 24, and 33 per million, respectively, and the estimated total implantation rates were 35, 41, and 49, per million, respectively. The number of device replacements increased from 20% to 30% between 2002 and 2004. The majority of patients were male, their median age was 66 years, they had severe or moderate left ventricular dysfunction, and they were in functional class I or II. The most common underlying heart disease was ischemic heart disease. The main indications for an ICD were sustained monomorphic ventricular tachycardia and aborted sudden cardiac death, though the number of prophylactic indications has increased. Most ICDs were implanted in an electrophysiology laboratory by a cardiac electrophysiologist. The implantation rates of dual-chamber ICDs and ICDs with cardiac resynchronization therapy were approximately 30% and 15%, respectively. Very few complications occurred during implantation.

Conclusions. The Spanish National ICD Registry contains a representative sample of ICD implantations performed in the country. The registry is one of the largest reported.

Key words: *Defibrillator. Registry. Arrhythmia.*

Registro Español de Desfibrilador Automático Implantable. Primer Informe Oficial del Grupo de Trabajo de Desfibrilador Implantable de la Sociedad Española de Cardiología (años 2002-2004)

Objetivo. Se presentan los resultados del Registro Nacional de Desfibrilador Automático Implantable (DAI) en el período 2002-2004 elaborado por el Grupo de Trabajo de Desfibrilador Automático Implantable de la Sociedad Española de Cardiología.

Material y método. Se elaboró una hoja de recogida de datos que fue cumplimentada prospectivamente y de forma voluntaria por cada equipo implantador y enviada a la Sociedad Española de Cardiología.

Resultados. El número de implantes comunicados fue de 925, 1.046 y 1.414 en los años 2002, 2003 y 2004 que representan el 63, el 59 y el 67,5% del total estimado de implantes, respectivamente. El número de implantes por millón de habitantes comunicados fue de 22, 24 y 33 y el estimado de 35, 41 y 49. El número de recambios aumentó del 20 al 30% entre 2002 y 2004. La mayor parte de los DAI se implantó en varones con 66 años de edad mediana, disfunción ventricular izquierda moderada o severa y en clase funcional II o I. La cardiopatía más frecuente fue la isquémica. Las principales indicaciones fueron taquicardia ventricular monomórfica sostenida y muerte súbita abortada, con un número creciente de indicaciones profilácticas. Cada vez se realizan más implantes en el laboratorio de electrofisiología y por electrofisiólogos. La proporción de DAI bicamerales se aproxima al 30% y la de DAI con resincronización al 15%. La incidencia de complicaciones durante el implante fue muy baja.

Conclusiones. El Registro Nacional de DAI recoge una muestra representativa de los implantes de DAI que se llevan a cabo en nuestro país y una de las mayores publicadas.

Palabras clave: *Desfibrilador. Registro. Arritmia.*

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ABBREVIATIONS

LVEF: left ventricular ejection fraction.
GT-DAI: Working Group on Implantable Cardioverter-Defibrillators.
ICD: implantable cardioverter-defibrillator.
SEC: Spanish Society of Cardiology.
SMVT: sustained monomorphic ventricular tachycardia.

INTRODUCTION

Implantable cardioverter-defibrillators (ICDs) have become a well-established therapeutic option for secondary prevention in patients with malignant ventricular arrhythmias. The number of indications in primary prevention in patients at risk of arrhythmias has also increased.[1-10]

Several scientific societies have published recommendations for the indications for these devices and the resources needed for this therapeutic option.[11-14] However, little information is available on the actual use and indications of these devices either in Spain or internationally.[15-23]

Health registries are a valuable source of information for assessing the day-to-day reality of clinical practice and the actual outcomes of applying the findings of large multicenter studies and clinical guidelines.[24,25] In 1996, the first National ICD Registry was set up in Spain, and the findings were published in 1997.[15] In 2001, the Working Group on Implantable Cardioverter-Defibrillators (abbreviated to GT-DAI in Spanish) was set up within the Electrophysiology and Arrhythmias Working Group of the Spanish Society of Cardiology (SEC). One of the main aims was to set up the SEC's National ICD Registry. This publication of the GT-DAI presents the data of ICD implantations reported to the Registry in the 3 years spanning 2002 to 2004 and covers the majority of centers that implant ICDs in Spain.

MATERIALS AND METHOD

Data for the Registry were collected prospectively. A questionnaire was drawn up, and the final version was approved by the members of the Electrophysiology and Arrhythmias Working Group (Annex). The questionnaire, which is available on the web page of this Working Group (www.arritmias.org), was sent to arrhythmia units in Spain, the members of the Working Group, and the companies that market ICDs in Spain.

The questionnaire was filled in directly and voluntarily by each implant team during or after ICD implantation, and sent by fax or e-mail to the SEC.

The SEC collaborated in creating the database and in data entry. Data were checked for consistency by a SEC computer technician and a member of the GT-DAI. Previous and current board members of the GT-DAI were responsible for data analysis and publication of the findings.

Population data for calculation of rates per million inhabitants, for the all of Spain and for Spanish autonomous regions and provinces, were obtained from estimates made for the years 2002, 2003, and 2004 by the National Institute of Statistics (www.ine.es).

The GT-DAI board requested information on the total number of ICDs implanted in 2002, 2003, and 2004 from the companies that market ICDs in Spain in order to determine how many of the ICD implantations done in Spain were reported to the Registry and in turn to give an indication of how representative the Registry is. Thus, the total number of implants and the number of implants reported to the Registry allowed the calculation of a correction factor which was used to estimate the overall numbers of implants by autonomous region and province.

Statistical Analysis

Numerical results were expressed as means±standard deviation for variables with a normal distribution, and as medians and interquartile ranges for variables not normally distributed. Qualitative variables were compared with the χ^2 test and quantitative variables by analysis of variance. The relationship between quantitative variables was analyzed with a linear regression model. Statistical significance was set at $P<.05$.

RESULTS

The proportion of the questionnaire fields were filled out was high, and this proportion remained stable throughout the 3 years, ranging from 83% to 97% for the main variables of the Registry.

Implant Centers

In 2002, 72 centers that performed ICD implantations reported data to the Registry, compared to 78 in 2003, and 80 in 2004 (Table 1). Most centers were in the public health sector (58 in 2002, 61 in 2003, and 68 in 2004). Table 2 shows the number of public hospitals per million inhabitants that performed ICD implantation in each autonomous region.

Total Number of Implantations

The total number of implantation procedures (initial implants and replacements) reported to the Registry

TABLE 1. **Hospitals That Have Returned Questionnaires to the National ICD Registry from 2002 to 2004, by Autonomous Region**

Andalusia	
Almería	Hospital Torrecárdenas
Cadiz	Hospital Universitario Puerta del Mar
Cordoba	Hospital Universitario Reina Sofía
Granada	Hospital Universitario Virgen de las Nieves
Huelva	Hospital General Juan Ramón Jiménez
Jaén	Hospital Universitario Princesa de España
Malaga	Hospital Universitario Virgen de la Victoria
	Clínica Parque San Antonio
	Complejo Hospitalario Carlos Haya
Seville	Hospital Universitario Virgen del Rocío
	Hospital Universitario Virgen Macarena
	Hospital Nuestra Señora de Valme
	Clínica Sagrado Corazón
	Clínica Esperanza de Triana
Aragon	
Zaragoza	Hospital Clínico Universitario Lozano Blesa
	Hospital Miguel Servet
	Clínica Médico-Quirúrgica Montpelier
Asturias	
Oviedo	Hospital Central de Asturias
Balearics	
Palma de Mallorca	Hospital Son Dureta
	Policlínica Miramar
	Clínica Rotger Sanitaria Balear, S.A.
	Hospital Son Llatzer
Canaries	
Las Palmas	Hospital Insular de Gran Canaria
	Hospital Dr. Negrín
	Clínica San Roque, S.A.
Tenerife	Hospital Nuestra Señora de la Candelaria
	Hospital Universitario de Canarias
Cantabria	
Santander	Hospital Universitario Marqués de Valdecilla
Castile-La Mancha	
Toledo	Hospital Virgen de la Salud
Guadalajara	Hospital General Universitario de Guadalajara
Albacete	Hospital General de Albacete
Valladolid	Hospital Clínico Universitario de Valladolid
	Hospital Del Río Hortega
	Hospital Comarcal de Medina del Campo
	Sanatorio Virgen de la Salud
	Hospital Campo Grande
Castile-Leon	
Leon	Hospital de León
Salamanca	Hospital Universitario de Salamanca
Avila	Hospital Nuestra Señora de Sonsoles
Segovia	Hospital Policlínico
Burgos	Hospital General Yagüe
Soria	Hospital General de Soria
Catalonia	
Barcelona	Hospital Clínic
	Hospital Vall d'Hebron
	Hospital de Bellvitge
	Hospital de la Santa Creu i Sant Pau
	Hospital del Mar
	Hospital Germans Trias i Pujol
	Clinica Quirón
	Hospital de Barcelona
	Centro Médico Tecknon
	Centre Cardiovascular Sant Jordi. S.A.
Tarragona	Hospital de Sant Pau i Santa Tecla

TABLA 1. ***(Continued)***

Community of Valencia	
Valencia	Hospital Clínico Universitario de Valencia
	Hospital General Universitario de Valencia
	Hospital Universitario La Fe
	Hospital Doctor Peset
	Hospital Lluís Alcanyís
	Grupo Hospitalario Quirón
Alicante	Hospital General Universitario de Alicante
	Clínica Benidorm
Castellón	Hospital General de Castelló
Extremadura	
Badajoz	Hospital Infanta Cristina
	Hospital de Mérida
	Clideba
Galicia	
La Coruña	Hospital Juan Canalejo
	Complejo Hospitalario Universitario de Santiago
	Hospital Xeral de Galicia
Pontevedra	Complejo Hospitalario Xeral Cies
	Hospital Do Meixoeiro
Lugo	Hospital Xeral de Lugo
Madrid	
Madrid	Hospital Universitario Gregorio Marañón
	Hospital Universitario Ramón y Cajal
	Hospital Universitario 12 de Octubre
	Hospital Universitario La Paz
	Clínica Puerta de Hierro
	Fundación Jiménez Díaz
	Hospital Clínico de San Carlos
	Clínica Moncloa
	Hospital Central de la Defensa
	Hospital Universitario de Getafe
	Fundación Hospital Alcorcón
	Hospital Severo Ochoa
	Clínica Nuestra Señora de América
	Clínica La Luz
	Clínica Ruber, S.A.
	Hospital de Madrid-Montepríncipe
	Hospital Ruber Internacional
	Sanatorio Nuestra Señora del Rosario
	Hospital de Fuenlabrada
	Hospital de La Zarzuela
	Clínica San Camilo
Murcia	
Murcia	Hospital Universitario Virgen de la Arrixaca
	Hospital Los Arcos
Navarre	
Pamplona	Clínica Universitaria de Navarra
	Hospital de Navarra
Basque Country	
Vitoria	Hospital Txagorritxu
Bilbao	Hospital de Basurto
	Hospital de Cruces
San Sebastián	Hospital Donostia

increased progressively over the 3 years. Thus, ICDs were implanted in 925 patients in 2002, 1046 in 2003, and 1414 in 2004. Given that the estimated total number of implants in these years was 1477, 1778, and 2097, respectively, reports reaching the Registry

TABLE 2. **Number of Public Hospitals Implanting Devices (per Million Inhabitants in Parenthesis) by Autonomous Region in 2004**

Autonomous Region	2004
Andalusia	10 (1.3)
Aragon	2 (1.6)
Asturias	1 (0.9)
Balearics	2 (2.1)
Canaries	4 (2.1)
Cantabria	1 (1.8)
Castile-La Mancha	2 (1.1)
Castile-Leon	7 (2.8)
Catalonia	6 (0.9)
Community of Valencia	6 (1.3)
Extremadura	2 (1.9)
Galicia	5 (1.8)
Madrid	12 (2.1)
Murcia	2 (1.5)
Navarre	2 (3.4)
Basque Country	4 (1.9)
Total Spain	68 (1.6)

represented 63%, 59%, and 67.5%, respectively, of the total number of ICDs implanted in Spain.

The total number of implantations per million inhabitants reported to the Registry was 22 in 2002, 24 in 2003, and 33 in 2004. The estimated total number of implants per million inhabitants was 35, 41, and 49, respectively (Tables 3 and 4). There was no significant correlation between the number of hospitals performing ICD implants and the number of ICDs implanted per million inhabitants (r^2=0.21; P=.07).

Most implantations took place in public hospitals, which accounted for 894 procedures in 2002, 1009 in 2003, and 1386 in 2004, corresponding to 96%, 98%, and 98%, respectively, of the total number of procedures reported to the Registry.

Initial Implants Versus Replacements

The number of initial implants was 691 in 2002, 702 in 2003, and 945 in 2004, which represented 80%, 71%, and 70%, respectively, of all procedures reported to the Registry. The number of initial implants per million inhabitants reported to the Registry was 18 in 2002, 17 in 2003, and 23 in 2004, and the estimated number of initial implants in the same years was 28, 29, and 34, respectively. The number of replacements done was 174 in 2002 (20%), 284 in 2003 (29%), and 378 in 2004 (30%).

Age and Sex

The median age of patients receiving an ICD was 66 years (interquartile range, 54-72 years; range, 1-86 years) in 2002, 66 years (interquartile range, 54-73 years; range, 4-85 years) in 2003, and 65 years (interquartile range, 54-66 years; range, 10-85 years) in 2004. The sex of the recipient was predominantly male—87% in 2002, 85% in 2003, and 86% in 2004. Similar age and sex distributions were reported for initial implants.

TABLE 3. **Number of Implantations Done by Autonomous Region and Reported to the Registry and Number of Implantations per Million Inhabitants***

Autonomous Region	2002	No.×10^6	2003	No.×10^6	2004	No.×10^6
Andalusia	129 (204)	17 (27)	109 (185)	14 (24)	226 (335)	29 (44)
Aragon	33 (52)	27 (43)	51 (87)	41 (70)	63 (93)	50 (74)
Asturias	9 (14)	8 (13)	23 (39)	21 (36)	25 (37)	23 (35)
Balearics	5 (8)	5 (8)	30 (51)	32 (54)	27 (40)	28 (42)
Canaries	37 (59)	20 (32)	27 (46)	14 (24)	54 (80)	28 (42)
Cantabria	17 (27)	31 (49)	19 (32)	35 (60)	34 (50)	61 (91)
Castile-La Mancha	18 (28)	10 (16)	31 (53)	17 (29)	31 (56)	17 (25)
Castile-Leon	62 (98)	25 (40)	63 (107)	25 (43)	107 (159)	43 (64)
Catalonia	172 (272)	26 (41)	181 (307)	27 (46)	199 (295)	29 (43)
Community of Valencia	37 (59)	9 (14)	76 (129)	17 (29)	88 (131)	19 (29)
Extremadura	1 (2)	1 (2)	6 (10)	6 (10)	15 (22)	14 (21)
Galicia	53 (84)	19 (30)	55 (94)	20 (34)	88 (131)	32 (47)
Madrid	242 (383)	44 (70)	274 (466)	48 (82)	285 (423)	49 (73)
Murcia	25 (40)	20 (32)	13 (22)	10 (17)	17 (25)	13 (19)
Navarre	10 (16)	18 (28)	17 (29)	29 (49)	28 (42)	48 (71)
Basque Country	43 (68)	20 (32)	47 (80)	22 (37)	98 (145)	46 (69)
Total Spain	925 (1.477)	22 (35)	1046 (1778)	24 (41)	1414 (2097)	33 (49)

*Both initial implants and replacements are included. The proportion of initial implants in 2002, 2003, and 2004 was 80%, 71%, and 70%, respectively. In the Autonomous Region of La Rioja and in the Autonomous Cities of Ceuta and Melilla, no defibrillators were implanted in the 3-year period 2002 to 2004. The total estimated number of implants is shown in parenthesis.

TABLE 4. **Autonomous Region and Residence of Recipients of an Implantable Cardioverter-Defibrillator. Number Reported to the Registry (Total Number Estimated)***

Autonomous Region	2002	No.×10⁶	2003	No.×10⁶	2004	No.×10⁶
Andalusia	124 (198)	17(27)	86 (146)	11 (19)	212 (314)	28 (41)
Almería	10 (16)	18 (29)	2 (3)	4 (7)	18 (27)	31 (46)
Cadiz	8 (13)	7 (11)	5 (8)	4 (7)	12 (18)	10 (15)
Cordoba	10 (16)	13 (21)	4 (7)	5 (8)	14 (21)	18 (27)
Granada	13 (21)	16 (26)	8 (14)	10 (17)	42 (62)	50 (74)
Huelva	12 (19)	26 (42)	8 (14)	17 (29)	15 (22)	31 (46)
Jaén	13 (21)	20 (32)	8 (14)	12 (20)	10 (15)	15 (22)
Malaga	20 (32)	15 (24)	26 (44)	19 (32)	49 (73)	35 (52)
Seville	38 (61)	22 (35)	35 (59)	20 (34)	52 (77)	29 (43)
Aragon	31 (50)	25 (40)	43 (73)	35 (59)	45 (67)	36 (53)
Huesca	2 (3)	10 (16)	4 (7)	19 (32)	5 (7)	23 (34)
Teruel	0	0	3 (5)	22 (37)	1 (1)	7 (10)
Zaragoza	29 (46)	33 (53)	36 (61)	41 (70)	39 (58)	43 (64)
Asturias						
Oviedo	9 (14)	8 (13)	22 (37)	20 (34)	14 (21)	13 (19)
Balearics	7 (11)	8 (13)	18 (31)	19 (32)	23 (34)	24 (35)
Canaries	39 (62)	21 (34)	25 (42)	13 (22)	50 (74)	26 (38)
Las Palmas	22 (35)	23 (37)	13 (22)	13 (22)	33 (49)	33 (49)
Tenerife	17 (27)	19 (30)	12 (20)	13 (22)	17 (25)	18 (27)
Cantabria						
Santander	8 (13)	15 (24)	16 (27)	29 (49)	22 (33)	40 (59)
Castile-La Mancha	29 (46)	16 (26)	40 (68)	22 (37)	41 (61)	22 (36)
Albacete	3 (5)	8 (23)	5 (8)	13 (22)	2 (3)	5 (7)
Ciudad Real	8 (13)	17 (27)	13 (22)	27 (46)	21 (31)	43 (64)
Cuenca	4 (6)	20 (32)	2 (3)	10 (17)	0	0
Guadalajara	5 (8)	28 (45)	9 (15)	49 (83)	5 (7)	26 (38)
Toledo	9 (14)	16 (26)	11 (19)	20 (34)	13 (19)	22 (33)
Castile-Leon	63 (101)	25 (40)	61 (104)	25 (42)	101 (149)	40 (59)
Avila	4 (6)	24 (38)	4 (7)	24 (41)	24 (35)	144 (213)
Burgos	7 (11)	20 (32)	3 (5)	8 (14)	8 (12)	22 (36)
Leon	15 (24)	30 (48)	19 (32)	38 (65)	22 (33)	45 (67)
Palencia	3 (5)	17 (27)	5 (8)	29 (49)	3 (4)	17 (25)
Salamanca	7 (11)	20 (32)	7 (12)	20 (34)	15 (22)	43 (64)
Segovia	8 (13)	54 (86)	0	0	2 (3)	13 (19)
Soria	1 (2)	11 (18)	4 (7)	44 (75)	1 (1)	11 (16)
Valladolid	15 (24)	30 (48)	17 (29)	34 (58)	24 (35)	47 (70)
Zamora	3 (5)	15 (24)	2 (3)	10 (17)	2 (3)	10 (15)
Catalonia	157 (251)	24 (38)	130 (221)	19 (32)	120 (178)	18 (27)
Barcelona	126 (201)	26 (42)	115 (195)	23 (39)	112 (166)	22 (33)
Gerona	18 (29)	30 (48)	7 (12)	11 (19)	2 (3)	3 (4)
Lérida	5 (8)	13 (21)	4 (7)	11 (19)	2 (3)	5 (7)
Tarragona	8 (13)	13 (21)	4 (7)	6 (10)	4 (6)	6 (9)
Community of Valencia	38 (61)	9 (14)	66 (112)	15 (25)	88 (130)	19 (28)
Alicante	14 (22)	9 (14)	11 (19)	7 (12)	27 (40)	16 (24)
Castellón	1 (2)	2 (3)	5 (8)	10 (17)	4 (6)	8 (12)
Valencia	23 (37)	10 (16)	50 (85)	22 (37)	57 (84)	24 (35)
Extremadura	29 (46)	27 (43)	19 (32)	18 (31)	22 (33)	20 (30)
Badajoz	17 (27)	26 (42)	13 (22)	20 (34)	17 (25)	26 (38)
Cáceres	12 (19)	29 (46)	6 (10)	15 (25)	5 (7)	12 (18)
Galicia	40 (64)	15 (24)	40 (68)	15 (25)	73 (108)	27 (40)
La Coruña	27 (43)	24 (38)	17 (29)	15 (25)	25 (37)	22 (33)
Lugo	3 (5)	8 (13)	2 (3)	6 (10)	17 (25)	47 (70)
Orense	2 (3)	6 (10)	1 (2)	3 (5)	6 (9)	18 (27)
Pontevedra	8 (13)	9 (14)	20 (34)	22 (37)	25 (37)	27 (40)
La Rioja						
Logroño	2 (3)	7 (11)	5 (8)	17 (29)	2 (3)	7 (10)

TABLE 4. ***(Continued)***

Autonomous Region	2002	No.×10⁶	2003	No.×10⁶	2004	No.×10⁶
Madrid						
Madrid	169 (270)	31 (50)	213 (362)	37 (63)	225 (333)	39 (58)
Murcia						
Murcia	24 (38)	20 (32)	13 (22)	10 (17)	12 (18)	9 (13)
Navarre						
Pamplona	7 (11)	12 (19)	8 (14)	14 (24)	18 (27)	31 (46)
Basque Country	34 (54)	16 (26)	46 (78)	22 (37)	77 (114)	36 (53)
Álava	12 (19)	41 (66)	18 (31)	61(104)	27 (40)	91(135)
Guipúzcoa	8 (13)	12 (19)	10 (17)	15 (25)	15 (22)	22 (33)
Vizcaya	14 (22)	12 (19)	18 (31)	16 (27)	35 (52)	31 (46)
Ceuta/Melilla	0	0	1 (2)	7 (12)	1 (1)	7 (10)

*Both initial implants and replacements are included. The proportion of initial implants in 2002, 2003, and 2004 was 80%, 71%, and 70%, respectively.

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

Figures 1 and 2 and Tables 5 and 6 show the patients heart disease by total number of ICDs implanted and initial implants. The most common underlying condition was ischemic heart disease. The percentages of different heart diseases were similar over the 3 years, and no statistically significant differences in the distribution were observed. Other common conditions were noncompactation cardiomyopathy, peripartum cardiomyopathy, Steinert disease, idiopathic sustained monomorphic ventricular tachycardia (SMVT), Prinzmetal angina, restrictive cardiomyopathy, etc.

Most patients had a left ventricular ejection fraction (LVEF) of less than 30% or between 30% and 40% (Figure 3). The percentage of patients with LVEF above 50% was greater than that of patients with mild dysfunction (LVEF of 40%-49%). A greater percentage of patients with severe left ventricular dysfunction (LVEF<30%) was reported in 2004 compared to 2003 and 2002 (38.3% vs 33.6% and 34.2%, respectively; $P<.01$) whereas a smaller percentage had mild dysfunction (LEVF of 40%-50%) (14% in 2004 vs 17% and 18%, respectively; $P<.01$). On analysis of initial implants only, the percentages of patients in each LVEF range were similar to those for all types of ICD implantation.

The majority of patients were in NYHA functional class II or I. The percentage of patients in functional class III was smaller, and rarely were patients in functional class IV (Figure 4). An increasing and statistically significant trend ($P<.001$) towards larger number of implants in patients in functional class III was observed at the expense of those in functional classes I and II, largely as a result of increased indication of ICD with cardiac resynchronization.

Most patients were in sinus rhythm—83% in 2002, 82% in 2003, and 81% in 2004. Atrial fibrillation was

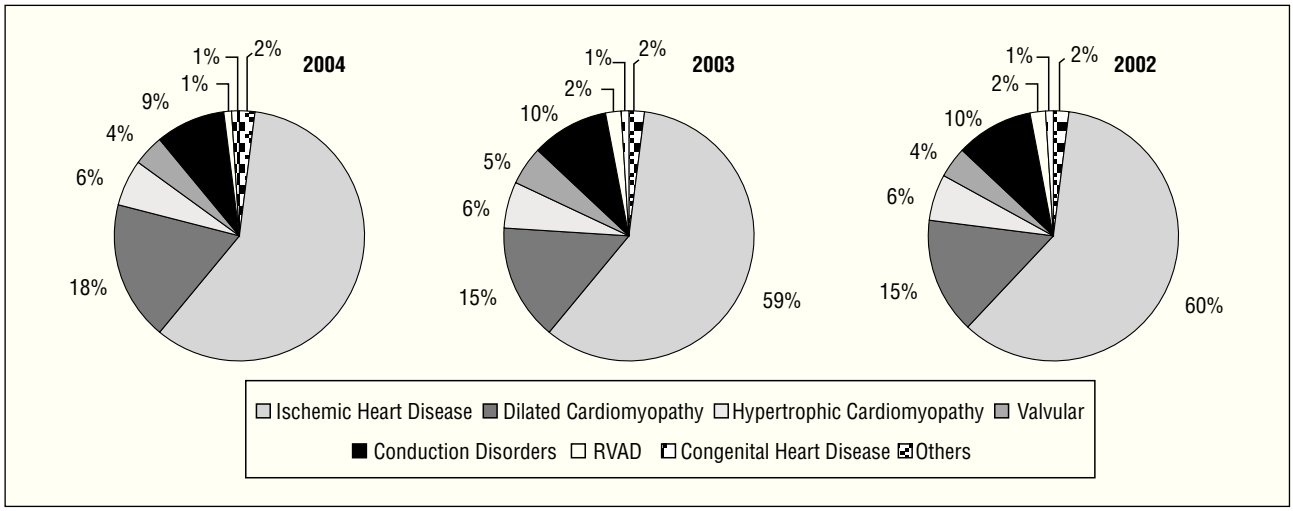

Figure 1. Heart disease in the patients reported to the Registry (initial implants and replacements). RVAD indicates right ventricular arrhythmogenic dysplasia.

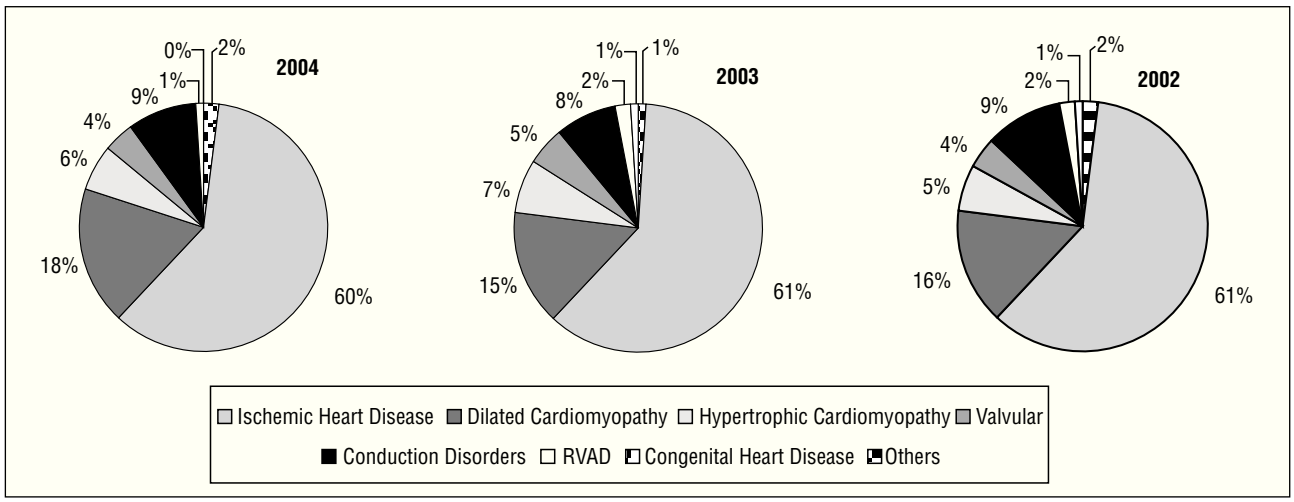

Figure 2. Heart disease in patients reported to the Registry (only initial implants). RVAD indicates right ventricular arrhythmogenic dysplasia.

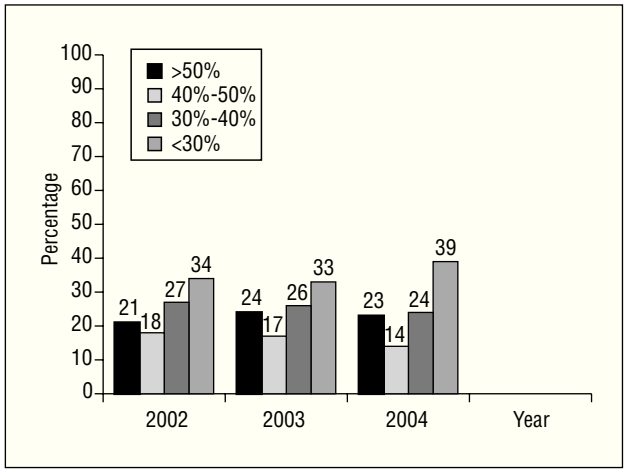

Figure 3. Left ventricular ejection fraction of the patients

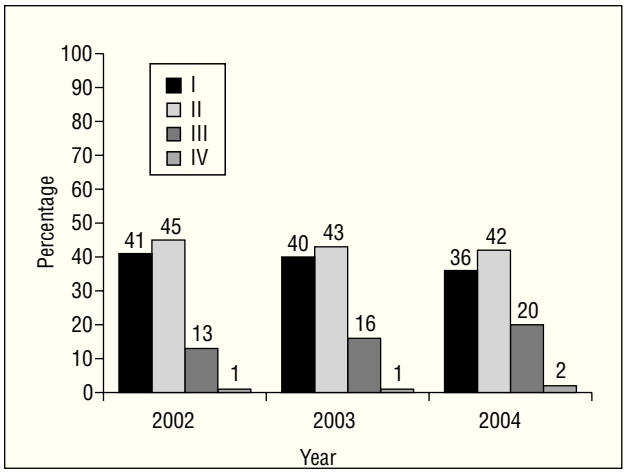

Figure 4. New York Heart Association Functional Class of the Patients in the Registry.

reported in 13% of the patients over the 3 years. Paced rhythm was reported in 3%, 4%, and 5% in 2002, 2003, and 2004, respectively.

Clinical Arrhythmia Leading to Implantation, Form of Presentation, and Induced Arrhythmia in the Laboratory (Figures 5-7)

Implantation was indicated for SMVT in almost half of the cases. The second most common type of clinical arrhythmia was ventricular fibrillation or polymorphic ventricular tachycardia. The remaining devices were implanted as prophylaxis in patients with nonsustained ventricular tachycardia or with no documented clinical arrhythmia. The most common form of presentation was syncope, followed by "other symptoms," and cardiorespiratory arrest.

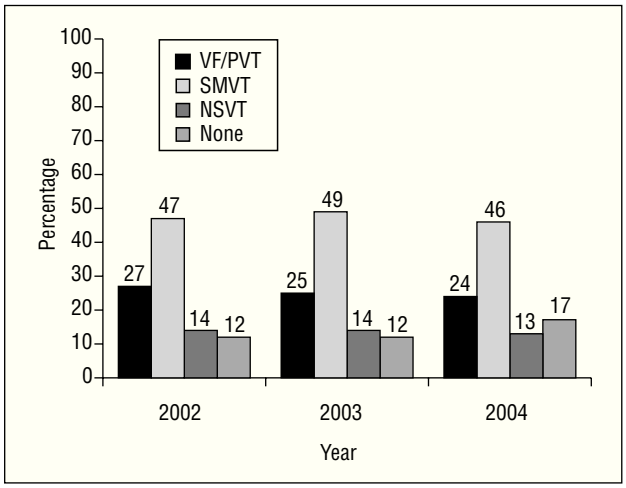

Figure 5. Clinical Arrhythmia of the Patients in the Registry. VF indicates ventricular fibrillation; SMVT, sustained monomorphic ventricular tachycardia; NSVT nonsustained ventricular tachycardia; PVT, polymorphic ventricular tachycardia.

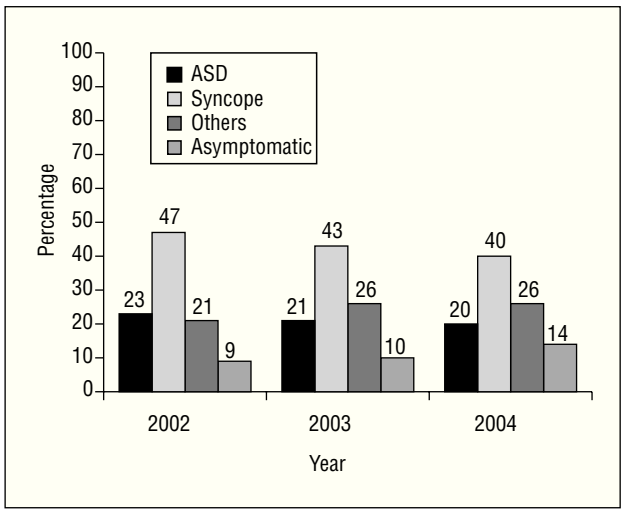

Figure 6. Form of clinical presentation of the arrhythmia in patients in the Registry.
ASD indicates aborted sudden death.

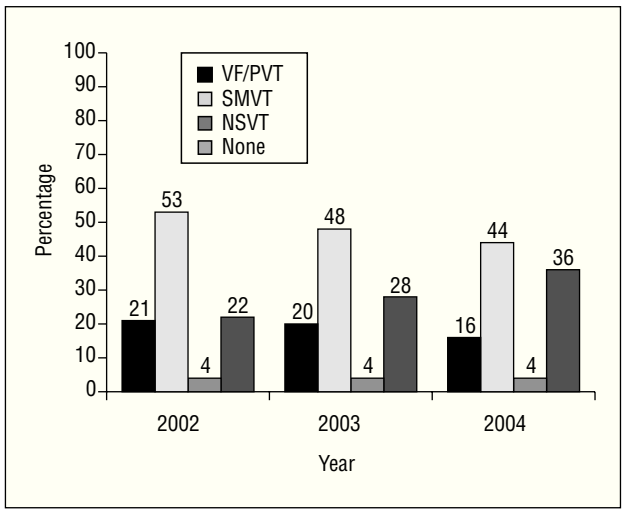

Figure 7. Arrhythmia indicated in the laboratory in patients who underwent electrophysiological study. VF indicates ventricular fibrillation; SMVT sustained monomorphic ventricular tachycardia; NSVT, nonsustained ventricular tachycardia; PVT, polymorphic ventricular tachycardia.

Indications (Tables 5 and 6)

The most common indication for ICD implantation was secondary prevention in patients with ischemic heart disease, mainly with SMVT and aborted sudden death. In 2003 and 2004, there was a statistically significant decrease in the number of implantations due to aborted sudden death in patients with this type of heart disease (19.5% in 2002 vs 13.4% and 13.2%, respectively; *P*<.01). There was also a decrease in the percentage of indications for SMVT with syncope (16.3% in 2004 vs 20.9% in 2003 and 25.9% in 2002) and an increase in the indications in patients with SMVT episodes without syncope from 19.5% in 2002 to 27.5% in 2004 (*P*=.001). Indications corresponding to those in the MADIT I or MUSST[5,6] remained stable over the years. In contrast, other prophylactic indications increased progressively and statistically significantly between 2002 and 2004, representing just 10% in 2002 compared to 21.5% in 2004 (*P*<.001).

For patients with dilated cardiomyopathy, the most common indication was also SMVT, with fewer indications for SMVT with syncope in 2004 compared to previous years (7.7% in 2004, 27.3% in 2003, and 22.8% in 2002; *P*<.01). The next most common indication was aborted sudden death, which followed a progressive nonsignificant trend downwards over the 3 years. Prophylactic indications increased significantly in the last year (24.4% vs 14% and 16.5% in the previous years; *P*=.01).

Implantation Site and Specialist Who Did the Operation Implantation

An increasing number of implantations were done in the electrophysiology laboratory (48.6% of the procedures in 2002, 51% in 2003, and 58% in 2004; *P*<.001). In the remaining cases, implantation was done in the operating room.

Over the 3 study years, the number of implantations done by electrophysiologists increased (accounting for 48.3% of the procedures in 2002, 53% in 2003, and 59.4% in 2004; *P*<.001) at the expense of the proportion of implants done by heart surgeons (48.4%, 44%, and 35.6%, respectively). Implantation was done by other types of specialist in 3.3% of the cases in 2002, 3% of the cases in 2003, and 5% of the cases in 2004.

Generator Site

Subcutaneous pectoral implantation was the most common site for the generator, with the proportion of devices implanted in this site increasing over the 3 years (69% in 2002, 73% in 2003, and 81% in 2004; *P*<.001). The submuscular pectoral site was used in 29%, 25%, and 17% of the implanted patients in 2002, 2003, and 2004, respectively. In each study year, 2% of all implantation sites were abdominal, these procedures being replacements in all but one, corresponding to an implantation in a child.

Device Type

A single-chamber device accounted for 65% of implants in 2002, 69% in 2003, and 57% in 2004. Dual-chamber devices were implanted in 28%, 24%, and 29% of the recipients, respectively. Implantation of ICDs with cardiac resynchronization was done in 6%, 7%, and 14% of the cases in 2002, 2003, and 2004, respectively, with an increase in 2004 with respect to the previous years (*P*<.01).

TABLE 5. **Number of Devices Implanted (Initial implants and Replacements) by Type of Heart Disease, Clinical Arrhythmia, and Form of Presentation***

	2002	2003	2004
Ischemic heart disease			
Aborted sudden death	102 (20)	101 (16)	142 (17)
SMVT with syncope	153 (29)	140 (23)	149 (18)
SMVT without syncope	99 (19)	163 (26)	222 (27)
Syncope+PVT	27 (5)	24 (4)	29 (4)
Syncope+inducible VT	32 (4)	28 (5)	33 (4)
Syncope+noninducible VT+LV dysfunction	28 (5)	38 (6)	45 (5)
MADIT I and MUSST	24 (5)	24 (4)	28 (4)
MADIT II and other prophylactic indications	44 (8) (1 Rs)	78 (13) (19 Rs)	141 (17) (48 Rs)
Not reported	12 (2)	21 (3)	35 (4)
Total	521 (58.7)	617 (62)	824 (62)
Dilated cardiomyopathy			
Aborted sudden death	14 (11)	29 (19)	47 (18)
SMVT with syncope	36 (28)	36 (25)	64 (25)
SMVT without syncope	25 (19)	37 (25)	27 (11)
Syncope+PVT	12 (9)	4 (3)	8 (3)
Syncope+inducible VT	12 (9)	15 (10)	23 (9)
Syncope+noninducible VT+LV dysfunction	11 (9)	6 (4)	21 (8)
Prophylactic indication	17 (13) (4 Rs)	17 (11) (6 Rs)	50 (20) (37 Rs)
Not reported	3 (2)	5 (3)	15 (6)
Total	130 (14.6)	149 (15)	205 (15.4)
Valve diseases			
Aborted sudden death	15 (44)	20 (37)	13 (28)
SMVT with syncope	8 (24)	12 (22)	12 (24)
SMVT without syncope	9 (26)	11 (20)	10 (20)
Syncope+inducible VT	1 (3)	2 (4)	3 (6)
Syncope+noninducible VT+LV dysfunction	0	1 (2)	1 (2)
Prophylactic indication in LV dysfunction	0	7 (13) (1 Rs)	6 (12) (3 Rs)
Not reported	1 (3)	1 (2)	4 (8)
Total	34 (3.8)	54 (5.4)	49 (3.7)
Hypertrophic Cardiomyopathy			
Aborted sudden death	13 (25)	12 (20)	19 (29)
Prophylactic implantation	33 (65)	46 (78)	43 (65)
Not reported	5 (10)	1 (2)	4 (6)
Total	51 (5.7)	59 (5.9)	66 (5)
Brugada syndrome			
Aborted sudden death	5 (11)	5 (11)	8 (13)
Prophylactic implantation with syncope	19 (41)	12 (27)	11 (17)
Prophylactic implantation without syncope	18 (39)	25 (56)	41 (65)
Not reported	4 (9)	3 (6)	3 (5)
Total	46 (5.2)	45 (4.5)	63 (4.7)
RV arrhythmogenic cardiomyopathy			
Aborted sudden death	1 (5)	2 (12)	2 (13)
SMVT	14 (74) (5 with syncope)	11 (69) (4 with syncope)	11 (73) (5 with syncope)
Prophylactic	4 (21)	3 (19)	1 (7)
Not reported	0	0	1 (7)
Total	19 (2.1)	16 (1.6)	15 (1.1)
Congenital heart disease			
Aborted sudden death	4 (36)	1 (17)	1 (14)
SMVT	5 (45)	3 (50)	4 (57)
Prophylactic implantation	2 (19)	2 (33)	2 (29)
Prolonged QT syndrome			
Aborted sudden death	2 (25)	7 (54)	9 (47)
Prophylactic implantation	6 (75)	6 (46)	10 (53)
Idiopathic ventricular fibrillation			
Aborted sudden death	31 (100)	41 (100)	35 (100)

*Rs indicates resynchronization; VT, ventricular tachycardia; SMVT, sustained monomorphic ventricular tachycardia; PVT, polymorphic ventricular tachycardia; LV, left ventricular. Percentages of each type of heart disease given in parenthesis, except total percentages, which refer to total number of heart disease.

TABLE 6. **Number of Initial implants by Type of Heart Disease, Clinical Arrhythmia, and Form of Presentation***

	2002	2003	2004
Ischemic heart disease			
Aborted sudden death	85 (20)	59 (13)	73 (13)
SMVT with syncope	113 (26)	92 (21)	90 (16)
SMVT without syncope	85 (20)	111 (25)	141 (27)
Syncope+FV/PVT	15 (3)	16 (4)	18 (3)
Syncope+inducible VT	30 (7)	22 (5)	27 (4)
Syncope+noninducible VT+LV dysfunction	28 (6)	28 (6)	37 (6)
MADIT I and MUSST	24 (5)	21 (5)	23 (4)
MADIT II and other prophylactic indications	44 (10) (1 Rs)	77 (18) (18Rs)	119(23) (39Rs)
Not reported	12 (3)	13 (3)	24 (4)
Total	436 (63)	439 (62.2)	552 (58.4)
Dilated cardiomyopathy			
Aborted sudden death	14 (12)	12 (11)	16 (10)
SMVT with syncope	26 (23)	29 (27)	13 (8)
SMVT without syncope	25 (22)	24 (23)	45 (27)
Syncope+PVT	8 (7)	1 (1)	5 (2)
Syncope+inducible VT	12 (10)	9 (8)	17 (10)
Syncope+noninducible VT+LV dysfunction	10 (9)	9 (8)	20 (12)
Prophylactic indication	16 (14) (4 Rs)	17(16) (5 Rs)	41(24) (27 Rs)
Not reported	3 (3)	5 (5)	11 (7)
Total	114 (16.4)	106 (15)	168 (17.8)
Valve diseases			
Aborted sudden death	8 (31)	6 (17)	7 (20)
SMVT with syncope	6 (23)	10 (28)	8 (23)
SMVT without syncope	10 (38)	7 (19)	5 (15)
Syncope+inducible VT	1 (4)	2 (5)	1 (3)
Syncope+noninducible VT+LV dysfunction	0	1 (3)	2 (6)
Prophylactic indication with LV dysfunction	0	10 (28)	9 (27) (3 Rs)
Not reported	1 (4)	0 (2)	2 (6)
Total	26 (3.7)	36 (5.1)	34 (3.6)
Hypertrophic cardiomyopathy			
Aborted sudden death	8 (25)	7 (14)	14 (25)
Prophylactic implantation	23 (72)	42 (84)	38 (68)
Not reported	1 (3)	1 (2)	4 (7)
Total	32 (7.3)	50 (7.1)	56 (5.9)
Brugada syndrome			
Aborted sudden death	4 (11)	3 (11)	5 (11)
Prophylactic implantation with syncope	14 (40)	9 (35)	7 (15)
Prophylactic implantation without syncope	17 (49)	13 (50)	31 (67)
Not reported	0	1 (4)	3 (7)
Total	35 (5)	26 (3.7)	46 (4.86)
RV arrhythmogenic cardiomyopathy			
Aborted sudden death	0	0	1 (11)
SMVT	7 (58) (4 syncopes)	9 (69) (3 syncopes)	7 (78) (4 syncopes)
Prophylactic	5 (42)	4 (31)	1 (11)
Not reported	0	0	1 (11)
Total	12 (1.7)	13 (1.8)	9 (1.2)
Congenital heart disease			
Aborted sudden death	3 (33)	1 (14)	1 (25)
SMVT	5 (56)	3 (43)	2 (50)
Prophylactic implantation	1 (11)	3 (43)	1 (25)
Prolonged QT syndrome			
Aborted sudden death	2 (29)	3 (33)	7 (47)
Prophylactic implantation	5 (71)	6 (67)	8 (53)
Idiopathic ventricular fibrillation			
Aborted sudden death	18 (100)	25 (100)	19 (100)

*Rs indicates resynchronization; VT, ventricular tachycardia; SMVT, sustained monomorphic ventricular tachycardia; PVT, polymorphic ventricular tachycardia; LV, left ventricular. Percentages given in parenthesis.

Reasons for Device Replacement: Need for New Electrodes When Replacing the Generator and Use of Additional Electrodes

In 2002, 90% of the replacements reported were done because of battery failure and the remaining 10% because of complications, 88% of which occurred at least 6 months after implantation. In 2003, 88% were due to battery failure and 12% to complications (79% more than 6 months after implantation). In 2004, the percentage of replacements due to battery failure was 90%, and 61% of the complications documented were late complications. In 2002, 6% of electrodes were replaced because of malfunction, compared to 8% in 2003, and 9% in 2004. In 13%, 63%, and 87% of the cases, respectively, electrodes were removed because of malfunction. Additional defibrillation electrodes or sensing electrodes were only rarely used (9 times in 2002, 10 in 2003, and 8 in 2004).

Minimum Defibrillation Energy

In 2002, the mean±standard deviation minimum defibrillation energy was less than 16.9±4.9 J, compared to less than 17.6±4 J in 2003 and less than 17.8±4.2 J in 2004. The limits of minimum effective defibrillation energy over the 3 years ranged from 6 J to 36 J.

Programming the Implantable Cardioverter-Defibrillator

Antibradycardia pacing was used mainly in VVI mode (55% in 2002, 57% in 2003, and 51% in 2004). Overall, VVIR mode was used in 13% in 2002, 14% in 2003, and 13% in 2004, whereas DDD mode was programmed in 11%, 9%, and 12%, respectively, and DDDR mode in 11%, 9%, and 12%, respectively.

Antitachycardia pacing was programmed in 83%, 85%, and 86% in the respective study years for ventricular arrhythmias. Such pacing was programmed for both the ventricle and atrium in 3%, 1%, and 3%, respectively. In 14%, 14%, and 13% of the cases, respectively, no antitachycardia programming was done.

Complications

No deaths were associated with implantation procedures in 2002, whereas 1 death was reported in 2003 and 3 in 2004, corresponding to a mortality rate of 1.2 per thousand and 2.4 per thousand implants, respectively. No cases of tamponade were reported during the procedure in any of the 3 years. Pneumothorax was reported in 3 patients in 2002, 1 in 2003, and none in 2004. Minor unspecified complications were reported with 17 implantations in 2002, 9 in 2003, and a further 9 in 2004.

DISCUSSION

Usefulness of the Spanish Implantable Cardioverter-Defibrillator Registry

The Electrophysiology and Arrhythmias Working Group of the SEC publishes an annual report on the findings of the National Catheter Ablation Registry in the field of arrhythmias.[26] For ICDs, the Working Group itself started the National ICD Registry in 1996, and the results were published in 1997.[15] One of the main aims for 2001 of the recently established GT-DAI was to set up the Spanish ICD Registry. The results from the period 2002 to 2004 are published in this article.

This Registry serves as a good reference for arrhythmia units throughout Spain who wish to assess their own activity, given that registries are usually more representative of the day-to-day reality in a country than data from multicenter clinical trials. On the other hand, data obtained from a large number of procedures over a limited period provide a better indication of possible influences of different multicenter studies published in the literature and the effects of technological innovations on the indications of ICDs, the type of devices implanted, and their programming. In addition, the information of the ICD Registry highlights geographic differences in resources, indications, and number of ICD implants within Spain and should help health managers adapt health planning in this field.

Comparison With the 1996 Registry

In 1996, two thirds of the implantation procedures were reported to the Registry.[15] Comparison of the present results with those from 1996 reveals a marked increase in the number of implantations and the number of centers performing implantations. The total number of implantations reported to the Registry in 1996 was 306, compared to 1414 in 2004. The number of implantations per million inhabitants, including both initial implants and replacements, was 9 in 1996 compared to 49 in 2004. Thirty-six centers performed implantations in 1996 compared to 80 in 2004. There was also a notable change in the type of indications. In the 1996 Registry, most implantations were done in patients who had been resuscitated after aborted sudden death or who had presented with SMVT, usually with syncope, whereas prophylactic implants were not reported. In contrast, the proportion of prophylactic implantations has increased significantly in recent years, as reflected by studies published in the literature.[5-10] The site of ICD implantation has also changed substantially (subcutaneous pectoral implantation accounted for 19% of the procedures in 1996 compared to 80% at present). Important changes have also occurred in the place where the implantation is done (15% in the electrophysiology laboratory in

1996 vs 58% in 2004) and in the person who performs the procedure (17% done by the electrophysiologist in 1996 vs 59.4% in 2004).

Comparison With Registries Outside Spain

Information on ICD implants from other countries is limited.[16-23] Few countries in the European Community (Denmark, Sweden, Italy, and the United Kingdom) run national registries, and most do not publish their results. The Danish ICD Registry collects information on all implantations done in Denmark since 1989[16] and publishes a report every year on the web site www.pacemaker.dk. In 2003, 350 initial devices and 153 replacements were implanted (68 initial implants per million inhabitants). The proportion of initial implants to replacements is similar to Spain. The most common cardiomyopathy was ischemia (52%), followed by dilated cardiomyopathy (21.4%). The arrhythmias that most often led to implantation were SMVT, reported in 53.4% of the cases, and ventricular fibrillation, reported in 33.1%. Dual-chamber ICDs were implanted in 36.3% of the cases and resynchronization devices with ICDs in 6%.

The German ICD Registry, EURID, is a project that was launched in 1998 by the Arrhythmias Working Group of the German Society of Cardiology.[17] Participation was voluntary, and initially 62 centers took part, although this number had decreased to 34 by 2000. Between January 1998 and October 2000, information was collected on 3344 ICD implantations. The mean age of the implant recipient was 61 (12) years, and 80.2% were done in men. The most common heart disease, as in Spain, was ischemic heart disease, reported in 64% of the patients and dilated cardiomyopathy, reported in 18.9%. Overall, 54% of the patients were in functional class II and 47% had an ejection fraction of 20% to 50%. Most devices were implanted in patients who had suffered cardiac arrest (44%) or SMVT with syncope (24.7%). Dual-chamber ICDs were implanted in 21.6% of the patients.

The European Cardiac Pacing Registry also collects information on defibrillators implanted in Europe, and results are available at the web site www.heart.org.uk/ewgcp. The most recent data were published in 2001 and correspond to 1997, although these data were retrospective and not very representative of the actual numbers of ICDs implanted.[19]

At present, the United States has no national registry on defibrillators. However, the Bilitch Registry, which was created in 1974 to collect information on pacemaker implantation, later also gathered data on ICDs.[18] The registry disappeared in 1993 due to lack of funding.[20] The most recent data published in the literature on implantation in the United States date from 1997, and were collected by members of NASPE and ICD manufacturers. In total, 35 630 ICD devices were implanted in 817 hospitals (107 initial implants per million inhabitants).

Overall Number of Implantations, Indications, and Trend

The number of procedures reported to the Registry and the total estimated number have increased each year. This increase is due, above all, to an increased number of indications, particularly of the prophylactic type, probably because a number of studies have demonstrated the usefulness of ICDs in primary prevention.[7-10] The increased number of centers that carry out implantations and perhaps a better management of patients with malignant ventricular arrhythmias may also have contributed to the increased number of implants.

Ischemic heart disease is the most common underlying condition leading to ICD implantation. Among patients with this underlying condition, those with SMVT and aborted sudden death occurred most frequently. The number of prophylactic implantations has increased significantly in recent years, probably because of the publication of the findings of the MADIT II study and the presentation of the SCD-HeF study.[7,10] The proportion of patients with implantations due to aborted sudden death has decreased in the last year. The number of implantations for SMVT has remained relatively stable, although in the last 2 years, the proportion of implantations for SMVT without syncope was greater than that of patients with syncope during tachycardia, reversing the trend of the first year. This is partly due to the greater number of prophylactic implantations and a trend towards implanting ICDs in patients with severe ventricular dysfunction, even though they tolerate tachycardia.

Prophylactic indications have also increased in cases of dilated cardiomyopathy, probably in association with the publication of the results of the COMPANION and SCD-HeF studies, and to a lesser extent, those of the DEFI-NITE study.[8-10] The number of resynchronization ICDs has increased significantly in such patients and also in those with ischemic heart disease.

Geographic Distribution: Regional Differences

The estimates of implants per million inhabitants based on the Registry showed marked variations from one Spanish autonomous region to another and within provinces of the same autonomous region. While considering the limitation that only two thirds of the implants are reported to the Registry, these variations implantation rates among and within autonomous regions cannot be readily explained by differences in the incidence of heart disease in Spain and so must be attributed to other reasons. One possibility is that, in some autonomous regions, hospitals performing

implantations tend to concentrate in the capitals of those regions. Another possible explanation is that some hospitals have a weaker "arrhythmia culture" or, in contrast, ICD implantation is done by some services that do not have other therapeutic options available. In particular, catheter ablation might sometimes be preferable to ICD implantation. On the other hand, variations in the availability of centers performing implantations among autonomous regions is probably not a decisive factor, as there is no clear correlation between the number of centers performing implantations and the number of implantations per million inhabitants.

Complications

The incidence of complications associated with implantations is very low, although it should be remembered that the data collected by the Registry refer exclusively to complications during the implantation procedure itself.

Limitations

The main limitation of the Registry is that participation ranged from 59% to 67.5%, and so cannot be truly representative. Nevertheless, the level of participation is acceptable considering that this is a prospective registry that included a large number of ICD implantations. Moreover, the increase in the number of implants reported to the Registry in 2004 highlights the commitment of the professionals who participate in ICD implantation procedures to consolidate it.

National registries of different hospital care activities are descriptive and the consistency of information may vary widely according to autonomous region and hospital. This limitation should be remembered when assessing the reliability of subpopulation data from different autonomous regions and provinces.[25]

Future Prospects

The usefulness of the Spanish ICD Registry is beyond doubt and all professionals involved in the treatment of arrhythmias should be congratulated for contributing to one of the few national ICD registries kept anywhere in the world. These benefits should act as encouragement to ensure the continuity of the project and to improve quality of the data, especially by increasing the number of implantations that are reported to the Registry and extending the patient data collected and improving the control and verification procedures. Some fields are to be changed and some new fields will appear in the questionnaire in order to bring it into line with the recommendations of the CARDS project.[27]

Legislation SCO/3603/2003, dated December 18, published in the Official Gazette of the Spanish State, no. 309, dated December 26, 2003, provided for the creation of several national implantation registries, among them, 1 for cardiac implantations, run by the Spanish Medicines and Healthcare Products Agency. In accordance with this piece of legislation, a collaboration agreement was signed by the SEC and the Agency which should increase the importance of the National ICD Registry.

Aside from these legal aspects, our main motivation should be to obtain real data from Spain to help improve health care, establish epidemiological or clinical lines of investigation that draw on information from the Registry, and ensure that technical and human resources are more efficiently managed by the pertinent bodies.

CONCLUSIONS

The Spanish ICD Registry for 2002 to 2004 is one of the largest samples of ICD implantation procedures published in the international literature and can be considered representative of this activity and the outcomes of the procedure in Spain. The number of implantations has grown in Spain, and was estimated to be 49 per million inhabitants in 2004 (34 per million inhabitants for initial implants). Large regional and provincial variations are observed in the number of ICD implants per million inhabitants. The most common underlying reasons for implantation were SMTV and aborted sudden death, particularly in patients with ischemic heart disease or dilated cardiomyopathy. An increasing number of implants are done in the electrophysiology laboratory and by electrophysiologists. The incidence of complications during implantations is very low.

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REFERENCES

1. The Antiarrhythmic versus Implantable Defibrillators (AVID) Investigators. A comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. N Engl J Med. 1997;337:1576-83.
2. Connolly SJ, Gent M, Roberts RS, Dorian P, Roy D, Sheldon RS, et al. Canadian Implantable Defibrillator Study (CIDS): a rando-

mized trial of the implantable cardioverter defibrillator against amiodarone. Circulation. 2000;101:1297-302.
3. Kuck KH, Cappato R, Siebels J, Ruppel R. Ramdomized comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resucitated from cardiac arrest: the Cardiac Arrest Study Hamburg (CASH). Circulation. 2000;102:748-54.
4. Connolly SJ, Hallstrom AP, Cappato R, Schron EB, Kuck KH, Zipes DP, et al. Metaanalysis of the implantable cardioverter defibrillator secondary prevention trials: AVID, CASH and CIDS. Eur Heart J. 2000;21:2071-8.
5. Moss AJ, Hall WJ, Cannom DS, Daubert JP, Higgins SL, Klein H, et al. Improved survival with an implantable defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. N Engl J Med. 1996;335:1933-40.
6. Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G. A randomized study of the prevention of suden death in patients with coronary artery disease. N Engl J Med. 1999;341: 1882-90.
7. Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med. 2002;346:877-83.
8. Bristow MR, Saxon LA, Boehmer J, Krueger S, Kass DA, De Marco T, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med. 2004;350:2140-50.
9. Kadish A, Dyer A, Daubert JP, Quigg R, Estes NA, Anderson KP, et al. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. N Engl J Med. 2004;350: 2151-8.
10. Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med. 2005;352:225-37.
11. Gregoratos G, Abrams J, Epstein AE, Freedman RA, Hayes DL, Hlatky MA, et al; American College of Cardiology/American Heart Association Task Force on Practice Guidelines/North American Society for Pacing and Electrophysiology Committee to Update the 1998 Pacemaker Guidelines. ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines). Circulation. 2002;106:2145-61.
12. Priori SG, Aliot E, Blomstrom-Lundqvist C, Bossaert L, Breithardt G, Brugada P, et al. Task Force on Sudden Cardiac Death of the European Society of Cardiology. Eur Heart J. 2001;22: 1374-450.
13. Pérez-Villacastin J, Carmona Salinas JR, Hernández Madrid A, Marin Huerta E, Merino Llorens JL, Ormaetxe Merodio J, et al. Guías de práctica clínica de la Sociedad Española de Cardiología sobre el desfibrilador automático implantable. Rev Esp Cardiol. 1999;52:1083-104.
14. Brugada J, Alzueta FJ, Asso A, Farre J, Jose Olalla J, Tercedor L. Guías de práctica clínica de la Sociedad Española de Cardiología sobre requerimientos y equipamiento en electrofisiología. Rev Esp Cardiol. 2001;54:887-91.
15. Madrid AH, Cinca J, Moro C. Registro Nacional de Desfibriladores Automáticos Implantables en 1996. Rev Esp Cardiol. 1998; 51:349-55.
16. Moller M. Arnsbro P. Danish Pacemaker and ICD Register. Pacing Clin Electrophysiol. 2000;23:S2-92.
17. Gradaus R, Block M, Brachmann J, Breithardt G, Huber HG, Jung W, et al. Mortality, morbidity, and complications in 3,344 patients with implantable cardioverter defibrillators: Results from the German ICD Registry EURID. Pacing Clin Electrophysiol. 2003;26:1511-8.
18. Furman S, Parsonnet V, Song S. The Bilitch Registry. Pacing Clin Electrophysiol. 1993;10:1357.
19. Ector H, Rickards AF, Kappenberger L, Linde C, Vardas P, Oto A, et al. The world survey of cardiac pacing and implantable cardioverter defibrillators: calendar year 1997-Europe. Pacing Clin Electrophysiol. 2001;24:863-8.
20. Song SL. The Bilitch Report: performance of implantable cardiac rhythm management devices. Pacing Clin Electrophysiol. 1994; 17:692-708.
21. Bernstein A, Parsonnet V. Survey of cardiac pacing and implanted defibrillator practice patterns in the United States in 1997. Pacing Clin Electrophysiol. 2001;24:842-55.
22. Tsai CT, Huang SK, Lin JL, Lai LP. Taiwan ICD Registry Investigators. Distinct clinical features in the recipients of the implantable cardioverter defibrillator in Taiwan. Pacing Clin Electrophysiol. 2003;26:2083-90.
23. Greenberg D, Katz A, Epstein M, Golovchiner G, Ilia R, Caspi A. Implantable cardioverter defibrillators in Israel: utilization and implantation trends. Int J Cardiol. 2002;82:17-23.
24. Fernández C, Sevilla F. Los registros en cardiología. Instrumento esencial en la planificación sanitaria. Rev Esp Cardiol. 1993:46: 718-20.
25. de los Reyes M, Banegas JR, Villar F. Información epidemiológica actual sobre las enfermedades cardiovasculares en España. Utilidad de los Registros Nacionales en Cardiología. Rev Esp Cardiol. 1994;47:648-57.
26. Rodríguez E, Alvarez M. Registro Español de Ablación con Catéter. III informe oficial de la Sección de Electrofisiología y Arritmias de la Sociedad Española de Cardiología (2003). Rev Esp Cardiol. 2004;57:1066-75.
27. Flynn MR, Barrett C, Cosio FG, Gitt AK, Wallentin L, Kearney P, et al. The Cardiology Audit and Registration Data Standars (CARDS), European data standards for clinical cardiology practice. Eur Heart J. 2005;26:308-13.

ANNEX. **Spanish Society of Cardiology. Electrophysiology and Arrhythmias Working Group. ICD Working Group. National ICD Registry. Questionnaire (Translation from Spanish)**

SPANISH SOCIETY OF CARDIOLOGY
Arrhythmias and Electrophysiology Working Group. ICD Working Group National ICD Registry

Questionnaire

1. Patient

Initials: ☐☐☐
Sex: ☐ Male ☐ Female
Date of Birth:

Implant Hospital:
Province of Birth:
Town of Residence:

2. Underlying Heart Disease

A. Etiology: ☐ ischemic ☐ prior coronary surgery: ☐ Yes ☐ No
☐ dilated nonischemic ☐ hypertrophic ☐ RVAD
☐ valvular ☐ congenital ☐ Brugada
☐ prolonged QT ☐ idiopathic VF ☐ Other:
B. Ejection fraction: ☐ >50% ☐ 40%-49% ☐ 30%-39% ☐ <30% Specify:
C. NYHA functional class ☐ I ☐ II ☐ III ☐ IV
D. Initial rhythm ☐ Sinus ☐ A Fibrillation ☐ Pacemaker ☐ Other:

3. Arrhythmia or Condition Leading to Implantation

A. Clinical arrhythmia: ☐ VF/PVT ☐ SMVT ☐ non-SMVT ☐ None
B. Clinical presentation ☐ Sudden death ☐ Syncope ☐ Other symptoms ☐ Asymptomatic
C. Induced arrhythmia: ☐ FV/PVT ☐ SMVT ☐ non-SMVT ☐ None

4. Implantation

Date: Place of implantation: ☐ Operating theatre ☐ Electrophysiology laboratory
Implanter: ☐ Surgeon ☐ Electrophysiologist ☐ Other
A. Generator: ☐ Initial implant
☐ Replacement: ☐ Battery failure ☐ Because of complications: ☐ <6 months ☐ >6 months
Device implanted: Manufacturer: Model:
Site: ☐ Subcutaneous ☐ Subpectoral ☐ Abdominal
B. Electrodes of current system:
☐ RA ☐ RV ☐ LV
☐ Additional electrode: ☐ Sensing ☐ Defibrillation
C. Previous Electrodes:
☐ Operational
☐ Malfunctioning: ☐ Removed ☐ Not removed
D. Minimum defibrillation energy:

5. Intraoperative Complications

☐ None ☐ Death ☐ Cardiac tamponade
☐ Pneumothorax ☐ Others (specify)

6. Functions

A. Antibradycardia pacing: ☐ VVI ☐ VVIR ☐ DDD ☐ DDDR ☐ Others
B. Antitachycardia pacing: ☐ Ventricle ☐ Atrium ☐ Both ☐ Not programmed
C. CV/Defibrillation: ☐ Ventricle ☐ Atrium ☐ Both
D. Resynchronization: ☐ No ☐ Yes

7. Observations

Send to the SEC at Fax: 917 242 371, E-mail: sec@secardiologia.es or Industria