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Special article

Spanish implantable cardioverter-defibrillator registry. 19th official report of Heart Rhythm Association of the Spanish Society of Cardiology (2022)

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ABSTRACT

Introduction and objectives: This article presents data on implantable cardioverter-defibrillator implants in Spain in 2022.
Methods: The data were collected from implantation centers, which voluntarily completed a data collection sheet during the implantation process, either manually or through a web page.
Results: In 2022, 170 hospitals participated in the registry. A total of 7693 forms were received compared with the 7970 reported by Eucomed (European Confederation of Medical Suppliers Associations), representing 96.5% of the devices. The total rate of registered implants was 162/million inhabitants (168 according to Eucomed), showing a slight increase compared with previous years. Disparities persisted among autonomous communities and Spain continued to have the lowest implantation rate among countries participating in Eucomed.
Conclusions: The data from the registry for 2022 reflect the complete recovery of activity after the impact of the COVID-19 pandemic in 2020. Despite a slight improvement, there was no significant change in our position in Europe or in the substantial differences among autonomous communities.
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Registro español de desfibrilador automático implantable. XIX informe oficial de la Asociación del Ritmo Cardiaco de la Sociedad Española de Cardiología (2022)

Palabras clave:
Desfibrilador automático implantable
Muerte súbita
Registro nacional

RESUMEN

Introducción y objetivos: Se presentan los datos de implantes de desfibrilador automático implantable en España en el año 2022.
Métodos: Los datos provienen de los centros implantadores, que cumplimentaron voluntariamente una hoja de recogida de datos durante el implante, a mano o a través de una página *web*.
Resultados: Durante 2022, han participado en el registro 170 hospitales. Se han recibido 7.693 formularios, frente a los 7.970 comunicados por la *European Confederation of Medical Suppliers Associations* (Eucomed), lo que representa un 96,5% de los dispositivos. La tasa total de implantes registrados fue 162/millón de habitantes (168 según Eucomed), un ligero incremento respecto a años anteriores. Las diferencias entre las comunidades autónomas persisten, así como nuestra última posición respecto a los países europeos que participan en la Eucomed.
Conclusiones: Los datos del registro de 2022 reflejan la recuperación completa de la actividad tras el impacto de la pandemia de la COVID-19 en 2020. Pese a la leve mejora, se mantiene nuestra posición en Europa y también las grandes diferencias entre nuestras comunidades autónomas.
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INTRODUCTION

Implantable cardioverter-defibrillators (ICDs) are essential for improving the prognosis of patients who have survived or are at risk of cardiac arrest due to a ventricular arrhythmia. Numerous clinical trials have demonstrated the role of these devices in the prevention of sudden cardiac death (SCD) in patients with heart failure and left ventricular systolic dysfunction or severe ventricular arrhythmias.[1,2] When combined with cardiac resynchronization therapy (CRT), ICDs improve functional class and left ventricular contractile function, decrease left ventricular diameters, and reduce hospitalization and mortality among patients with heart failure, severe systolic dysfunction, or intraventricular conduction disorders.[3]

The indications for ICD therapy for patients with or at risk of ventricular arrhythmias are listed in several clinical practice

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Abbreviations

CRT: cardiac resynchronization therapy
EUCOMED: European Confederation of Medical Suppliers Associations
ICD: implantable cardioverter-defibrillator
SCD: sudden cardiac death
SEC: Spanish Society of Cardiology

guidelines and include primary and secondary prevention of SCD.[1–3] SCD is one of the leading causes of death in Western countries, accounting annually for 400 000 deaths in Europe and around 30 000 in Spain. Approximately 40% of deaths occur in people younger than 65 years.[4]

The Heart Rhythm Association of the Spanish Society of Cardiology (SEC) has produced an annual report on the Spanish ICD Registry since 2005.[5–8] In this article, we present the data on ICD implantations performed in Spain submitted to the registry in 2022.

METHODS

The Spanish ICD Registry contains information that is voluntarily submitted by participating hospitals during de novo ICD implantations and replacements. This information is then entered into the registry database by a team comprising a technician, a computer scientist from the SEC, and a member of the Heart Rhythm Association. The data presented in the current report were cleaned by the technician and the first author. All authors analyzed the data and are responsible for this publication. Since 2019, participating hospitals have been able to submit data via an online platform designed by the SEC. In 2022, this platform was used to submit information on 1816 implantations (23.6% of all procedures reported).

Implant rates per million population for Spain and for each autonomous community and province were calculated using population data for the first quarter of 2023 obtained from the Spanish National Institute of Statistics.[9] As in previous years, the registry data were compared with statistics collected by the European Confederation of Medical Suppliers Associations, Ecomed.[10]

The percentages for all variables analyzed were calculated by taking into account the information available for each variable and the total number of implants. When concurrent arrhythmias were reported, the most serious type was selected.

Statistical analysis

Data are expressed as mean ± SD or median [interquartile range] depending on the normality of distribution. Continuous quantitative variables were analyzed using analysis of variance or the Kruskal-Wallis test, while qualitative variables were analyzed using the chi-square test. Linear regression models were used to analyze the number of implants and implanting centers per million population, the total number of implants, and the number of primary prevention implants per hospital.

RESULTS

Spanish hospitals submitted a total of 7693 implantation forms to the Spanish ICD registry in 2022. Considering that Eucomed reported 7970 ICD implants for the same year, this represents a reporting rate of 96.5%.

Implanting centers

A total of 170 hospitals participated in the Spanish ICD registry in 2022. This figure is down from previous years (198 in 2021, 173 in 2020, 172 in 2019, 173 in 2018) due to a reduction in the number of hospitals with low procedure volumes. The data for the 170 hospitals are shown in table 1. Numbers of implanting centers, implants per million population, and implants per autonomous community according to the data submitted are shown in figure 1. Twenty-five hospitals (23 in 2021) implanted ≥ 100 ICDs, and 5 of these implanted > 200. Sixty-seven hospitals (74 in 2021) implanted 11-99 devices and 78 (101 in 2021) implanted ≤ 10. In this last group, 13 (28 in 2021) implanted just 1 device.

The implanting center was specified in 99.9% of cases (table 1). Most procedures (7235, 94%) were performed in a public hospital.

Total number of implants

The total number of ICD implants reported to the registry over the past 10 years and the corresponding Eucomed estimates are shown in figure 2. In 2002, information was submitted for 7693 procedures, including de novo implants and replacements. This is a historic high for the registry and represents an increase of 2.6% compared with 2021 (7499 implants). The 2022 Eucomed estimate for 2022 (7970 implants) is also the highest to be reported since the creation of the Spanish ICD registry and represents a 2.9% increase with respect to 2021 (7743 implants).

Changes in the number of implants per million population reported by the ICD registry and Eucomed are shown in figure 3. The Eucomed estimate for 2022-168 implants per million population-is higher than in recent years (163 in 2021, 150 in 2020, and 157 in 2019), but still well below the mean for Europe, which was 296 units per million population in 2021, when normal hospital activity had resumed in the wake of the COVID-19 pandemic.[10]

Monthly implantation figures for 2018 to 2022 are shown in figure 4, which reflects variations throughout the year, with a notable drop in April and May 2020 (COVID-19 pandemic) followed by a return to normal levels. ICD implantation activity throughout 2022 can be considered normal. The findings are similar to those observed in 2021 and were minimally impacted by the COVID-19 waves that occurred during the year.

Age and sex

The mean age of patients included in the Spanish ICD registry in 2022 was 62.4 ± 13.9 years (range, 2-92 years). Similar to previous years, de novo ICD recipients were slightly younger (61.6 ± 13.5 years). Also in line with previous findings, the patients were overwhelmingly male (82.4% of patients overall and 83.7% of de novo implant recipients).

Underlying heart disease, left ventricular ejection fraction, functional class, and baseline rhythm

Ischemic heart disease was the most common heart disease in de novo ICD recipients (51.8%), followed by dilated cardiomyopathy (24.9%), hypertrophic cardiomyopathy (8.4%), primary electrical diseases–Brugada syndrome and long QT syndrome– (2.1%), valve disease (2.1%), and arrhythmogenic right ventricular cardiomyopathy (1.5%) (figure 5).

Table 1
Implantation activity by autonomous community, province, and hospital

Autonomous community and province	Hospital	Implants, No.
Andalusia		
Almería	Hospital Mediterráneo	7
	Hospital Universitario Torrecárdenas	69
	Hospital Virgen del Mar	3
Cádiz	Hospital Jerez Puerta del Sur	2
	Hospital Quirónsalud Campo de Gibraltar	2
	Hospital San Carlos de San Fernando	5
	Hospital Universitario Jerez de la Frontera	60
	Hospital Universitario Puerta del Mar	77
	Hospital Universitario Puerto Real	31
Córdoba	Hospital Cruz Roja de Córdoba	2
	Hospital QuirónSalud Córdoba	2
	Hospital Universitario Reina Sofía	88
Granada	Hospital de la Inmaculada Concepción	5
	Hospital Universitario Clínico San Cecilio	54
	Hospital Universitario Virgen de las Nieves	68
	Hospital Vithas Granada	1
Huelva	Hospital Costa de la Luz	2
	Hospital Universitario Juan Ramón Jiménez	55
Jaén	Hospital Universitario de Jaén	69
Málaga	Hospital El Ángel	4
	Hospital QuirónSalud Málaga	2
	Hospital QuirónSalud Marbella	5
	Hospital Universitario Virgen de la Victoria	294
	Hospital Vithas Parque San Antonio	8
	Hospital Vithas Xanit Internacional	8
Seville	Clínica Santa Isabel	6
	Hospital Médico Vithas Sevilla	1
	Hospital QuirónSalud Sagrado Corazón	6
	Hospital Universitario Virgen de Valme	39
	Hospital Universitario Virgen del Rocío	109
	Hospital Universitario Virgen Macarena	97
Aragon		
Zaragoza	Clínica Montpellier, Grupo HLA. S.A.U.	3
	Hospital Clínico Universitario Lozano Blesa	76
	Hospital QuirónSalud Zaragoza	3
	Hospital Royo Villanova	2
	Hospital Universitario Miguel Servet	199
	Hospital Viamed Montecanal	1
Principality of Asturias		
	Hospital Centro Médico de Asturias	2
	Hospital Universitario Central de Asturias	217
	Hospital Universitario de Cabueñes	23
Balearic Islands		
	Clínica Rotger	4
	Grupo Juaneda	4
	Hospital QuirónSalud Palmaplanas	7
	Hospital Son Llátzer	26
	Hospital Universitari Son Espases	117
	Policlínica Nuestra Sra. del Rosario	2
Canary Islands		
	Complejo Hospitalario Universitario Insular Materno Infantil	44
	Hospital Universitario de Gran Canaria Dr. Negrín	100
	Vithas Hospital Santa Catalina	1
	Hospital San Juan de Dios de Tenerife	1

Table 1 *(Continued)*
Implantation activity by autonomous community, province, and hospital

Autonomous community and province	Hospital	Implants, No.
	Hospital Universitario Nuestra Señora de La Candelaria	82
	Hospital Universitario de Canarias	57
Cantabria		
	Clínica Mompía	4
	Hospital Universitario Marqués de Valdecilla	189
Castile and León		
Ávila	Hospital Nuestra Señora de Sonsoles (Complejo Asistencial de Ávila)	7
Burgos	Hospital Universitario de Burgos (Complejo Asistencial Universitario de Burgos)	86
León	Hospital de León (Complejo Asistencial Universitario de León)	70
	Hospital HM San Francisco	1
Salamanca	Hospital Clínico Universitario de Salamanca (Complejo Asistencial Universitario de Salamanca)	67
Valladolid	Hospital Clínico Universitario de Valladolid	104
	Hospital Recoletas Campo Grande	4
	Hospital Universitario Río Hortega	19
Castile-La Mancha		
Albacete	Hospital General Universitario de Albacete	84
Ciudad Real	Hospital General de Ciudad Real	58
Cuenca	Hospital Virgen de La Luz	17
Guadalajara	Hospital Universitario de Guadalajara	30
Toledo	Hospital Universitario de Toledo (HUT)	160
	Hospital Universitario Nuestra Señora del Prado	36
Catalonia		
Barcelona	Centro Médico Teknon, Grupo QuirónSalud	35
	Centre Mèdic Delfos	2
	Clínica Sagrada Família	5
	Hospital Clínic de Barcelona	225
	Hospital De Barcelona	2
	Hospital Del Mar	37
	Hospital El Pilar	1
	Hospital de la Santa Creu i Sant Pau	143
	Hospital QuirónSalud Barcelona	7
	Hospital Universitari de Bellvitge	214
	Hospital Universitari Germans Trias i Pujol	78
	Hospital Universitari General de Cataluña	9
	Hospital Universitari Parc Taulí	33
	Hospital Universitari Vall d'Hebron	153
	Parc Sanitari Sant Joan de Déu	12
Girona	Clínica Girona	6
	Hospital Universitario de Girona Dr. Josep Trueta	98
Lleida	Hospital Universitari Arnau De Vilanova de Lleida	63
	Hospital Vithas Lleida	2
Tarragona	Hospital Universitari Joan XXIII de Tarragona	42
	Hospital Universitari Sant Joan de Reus	7
Valencian Community		
Alicante	Clínica Vistahermosa Grupo HLA	3
	Hospital Clínica Benidorm	1
	Hospital General Universitario Dr. Balmis	199
	Hospital QuirónSalud Torrevieja	2
	Hospital Universitario de San Juan de Alicante	44
	Hospital Universitario del Vinalopó	1
	Vithas Hospital Perpetuo Internacional	1
Castellón	Hospital General Universitario de Castellón	70
	Hospital Rey Don Jaime	4

Table 1 *(Continued)*
Implantation activity by autonomous community, province, and hospital

Autonomous community and province	Hospital	Implants, No.
Valencia	Hospital Cátolico Casa de Salud	3
	Hospital Clínico Universitario de Valencia	94
	Hospital de Manises	44
	Hospital General Universitario de Valencia	99
	Hospital QuirónSalud Valencia	10
	Hospital Universitario de la Ribera	60
	Hospital Universitario Dr. Peset Aleixandre	35
	Hospital Universitario y Politécnico La Fe	242
	Hospital 9 de Octubre	5
Extremadura		
Badajoz	Hospital de Mérida	3
	Hospital Universitario de Badajoz	171
Cáceres	Clínica Quirúrgica Cacereña San Francisco	5
	Hospital San Pedro de Alcántara	36
	Hospital Universitario de Cáceres	16
Galicia		
A Coruña	Complexo Hospitalario Universitario de A Coruña	152
	Complexo Hospitalario Universitario de Santiago	125
	Hospital HM Modelo-Belén	7
	Hospital Quirónsalud A Coruña	7
	Hospital San Rafael	2
Lugo	Hospital Universitario Lucus Augusti	23
Orense	Complejo Hospitalario Universitario de Ourense	43
Pontevedra	Complejo Hospitalario Universitario de Pontevedra	14
	Grupo QuirónSalud Miguel Domínguez	3
	Hospital Álvaro Cunqueiro	116
	Hospital Povisa	17
	Vithas Hospital Nosa Señora de Fátima	2
Community of Madrid		
	Clínica La Luz, S.L.	21
	Clínica Universidad de Navarra	3
	Clínica Viamed Santa Elena, S.L.	2
	Hospital Central de La Defensa Gómez Ulla	10
	Hospital del Henares	7
	Hospital General de Villalba	8
	Hospital General Universitario Gregorio Marañón	131
	Hospital QuirónSalud Sur	6
	Hospital Ruber Juan Bravo	6
	Hospital San Francisco de Asís	1
	Hospital San Rafael	5
	Hospital Universitario Clínico San Carlos	173
	Hospital Universitario de Fuenlabrada	20
	Hospital Universitario Fundación Alcorcón	29
	Hospital Universitario Fundación Jiménez Díaz	79
	Hospital Universitario de Getafe	21
	Hospital Universitario de Torrejón	12
	Hospital Universitario HM Montepríncipe	9
	Hospital Universitario HM Puerta del Sur	1
	Hospital Universitario Infanta Elena	7
	Hospital Universitario Infanta Leonor	24
	Hospital Universitario La Paz	155
	Hospital Universitario Puerta de Hierro-Majadahonda	124
	Hospital Universitario QuirónSalud Madrid	2
	Hospital Universitario Ramón y Cajal	86
	Hospital Universitario Rey Juan Carlos	25
	Hospital Universitario Severo Ochoa	7

Table 1 *(Continued)*
Implantation activity by autonomous community, province, and hospital

Autonomous community and province	Hospital	Implants, No.
	Hospital Universitario Vithas Madrid Arturo Soria	6
	Hospital Universitario Virgen de la Paloma, S.L.	1
	Hospital Universitario 12 de Octubre	105
Region of Murcia		
	Hospital Clínico Universitario Virgen de La Arrixaca	56
	Hospital General Universitario J.M. Morales Meseguer	27
	Hospital General Universitario Reina Sofía	17
	Hospital General Universitario Santa Lucía	37
	Hospital La Vega Grupo HLA	4
	Hospital Rafael Méndez	24
Chartered Community of Navarre		
	Clínica Arcángel San Miguel-Pamplona	5
	Clínica Universidad de Navarra	17
	Hospital Universitario de Navarra	76
Basque Country		
Álava	Hospital Universitario Araba	64
Guipúzcoa	Hospital Universitario Donostia	133
	Policlínica Guipuzcoa	5
Vizcaya	Clínica IMQ Zorrotzaurre	2
	Hospital de Galdakao-Usansolo	32
	Hospital Universitario de Basurto	58
La Rioja		
	Hospital San Pedro	62

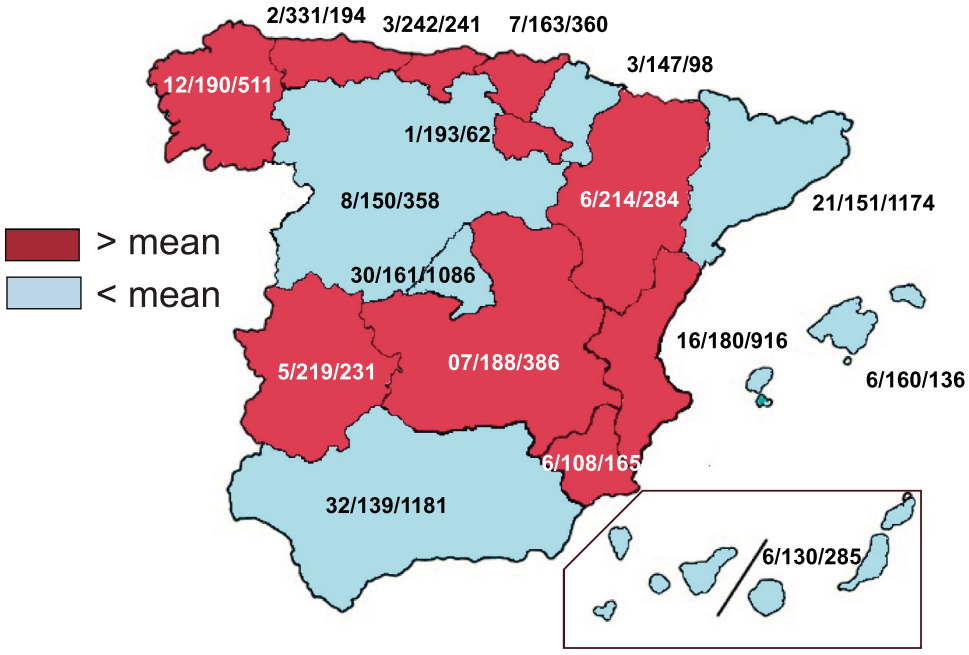
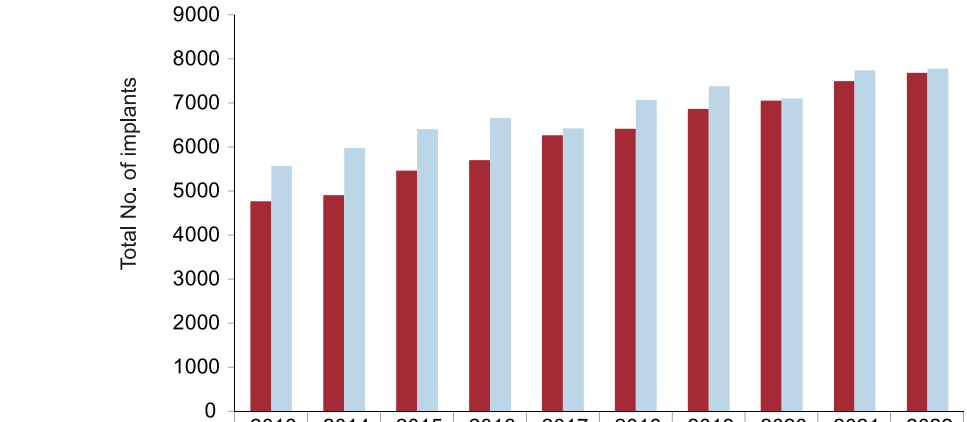


Figure 1. Distribution of implantation activity by autonomous community in 2022: number of implanting centers/rate per million population/total number of implants. Mean rate, 162 implants per million population.

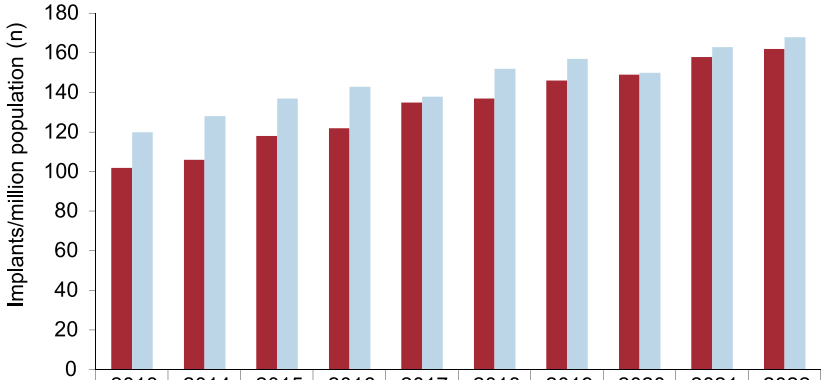
Left ventricular systolic function was reported in 41% of cases. Left ventricular ejection fraction (LVEF) was > 50% in 16.7% of patients, 50% to 41% in 8.5%, 40% to 36% in 9.8%, 35% to 31% in 19.9%, and ≤ 30% in 45.1% (figure 6). The values were similar among patients receiving their first implant and those undergoing replacement.

New York Heart Association (NYHA) functional class was specified in 22.6% of registry forms. Most patients were in class II



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Spanish ICD Registry	4772	4911	5465	5703	6271	6421	6872	7056	7499	7693
Eucomed	5573	5980	6406	6662	6429	7077	7389	7106	7743	7790

Figure 2. Total number of implants and Eucomed estimates for 2013 to 2023. Eucomed, European Confederation of Medical Suppliers Associations; ICD, implantable cardioverter-defibrillator.



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Spanish ICD Registry	102	106	118	122	135	137	146	149	158	162
Eucomed	120	128	137	143	138	152	157	150	163	168

Figure 3. Number of implants per million population and Eucomed estimates for 2013 to 2023. Eucomed, European Confederation of Medical Suppliers Associations; ICD, implantable cardioverter-defibrillator.

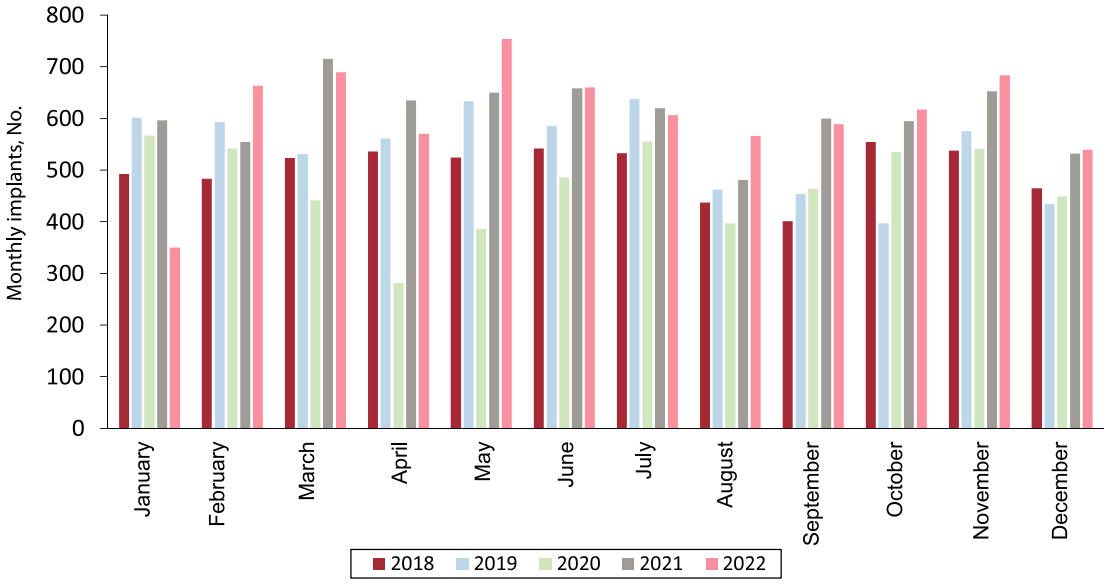


Figure 4. Number of implants per month from 2018 to 2022.

(64.9%); 21.9% were in class II, 11.9% in class I, and 1.2% in class IV. Again, the distribution was similar on analyzing de novo recipients and those undergoing replacement.

Baseline rhythm was reported for 41.3% of cases. At the time of implantation, 78.4% of patients were in sinus rhythm, 17.3% had atrial fibrillation, and 3.5% had a pacemaker rhythm. The remaining patients had atrial flutter or other arrhythmias.

Clinical arrhythmias leading to ICD implantation, clinical presentation, and arrhythmias induced in the electrophysiology laboratory

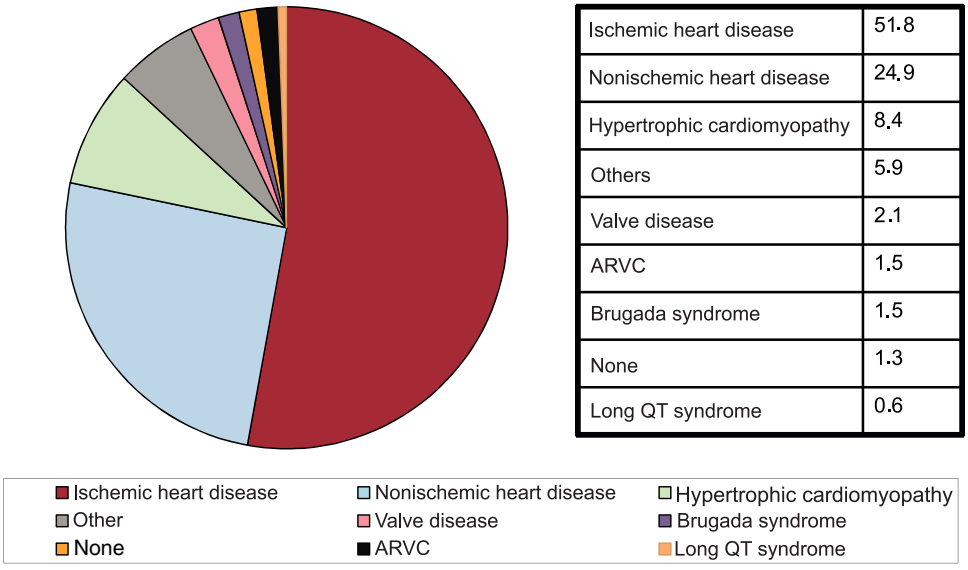
Clinical arrhythmias leading to ICD implantation were specified in 44.3% of forms and are shown in figure 7. Most de novo implant recipients (69.9%) did not have documented clinical arrhythmias, 12.8% had sustained monomorphic ventricular tachycardia, 9% had ventricular fibrillation, and 6.9% had nonsustained ventricular tachycardia.

Almost 44% of patients were asymptomatic. Less common clinical presentations were syncope, aborted SCD), and other symptoms (figure 8).

The electrophysiology study section of the form was completed in 40.6% of cases. This study was performed before ICD placement in 196 patients (6.2% of patients for whom information was provided). It was performed more often in those with ischemic heart disease, dilated cardiomyopathy, and Brugada syndrome (41.8% of patients for whom these diagnoses were specified). The most common arrhythmia induced electrophysiologically was sustained monomorphic ventricular tachycardia (67.3%), followed by ventricular fibrillation (24.3%), nonsustained ventricular tachycardia (6.5%) and other arrhythmias (1.9%). No arrhythmias were induced in 20.2% of cases.

Indications

The main indications for ICD implantation between 2018 and 2022 are shown in table 2. This information was submitted for



Ischemic heart disease	51.8
Nonischemic heart disease	24.9
Hypertrophic cardiomyopathy	8.4
Others	5.9
Valve disease	2.1
ARVC	1.5
Brugada syndrome	1.5
None	1.3
Long QT syndrome	0.6

Figure 5. Underlying heart disease in de novo ICD recipients. ARVC, arrhythmogenic right ventricular cardiomyopathy; ICD, implantable cardioverter-defibrillator; Other, patients with more than 1 diagnosis.

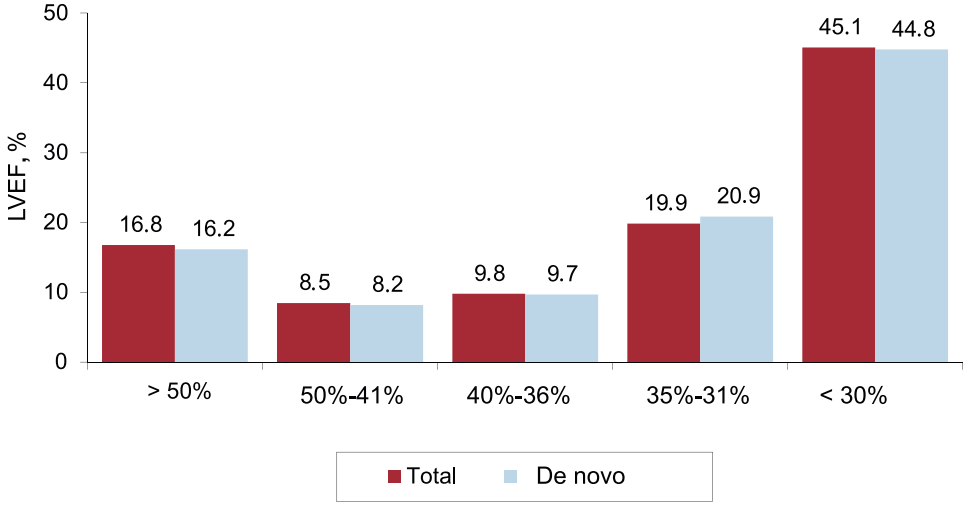


Figure 6. LVEF values among patients in the registry (total and de novo ICD recipients). ICD, implantable cardioverter-defibrillator; LVEF, left ventricular ejection fraction.

54.5% of cases in 2022. Ischemic heart disease is the most common indication in Spain, and in 2022, it accounted for 51.8% of all de novo indications. Primary prevention was the most common indication for ICD therapy in patients with ischemic heart disease (64.7%). The second most common indication overall was dilated cardiomyopathy (24.9% of all de novo implant recipients had this diagnosis). In total, 696 patients with dilated cardiomyopathy underwent ICD implantation in 2022, confirming the downward trend observed in 2021 with respect to previous years (619 in 2021, 1214 in 2020, 925 in 2019, and 803 in 2018). Most ICDs implanted in patients with less common heart diseases were for primary prevention.

ICD indications were specified in 54.4% of forms. The most common indication reported for de novo implant recipients was primary prevention of SCD (75.6% of cases). Although this rate is lower than in 2021 (86.4%), it supports the upward trend observed in recent years, with values of close of 80% (table 3).

Implantation setting and treating specialist

Data on implantation settings and treating specialists were provided in 51.5% and 49.9% of forms, respectively. Overall, 86.5% of procedures were performed in the electrophysiology laboratory and 12.8% in the operating room. The devices were implanted by an electrophysiologist in 90.2% of cases, a surgeon in 1.9%, an intensive care specialist in 1.7%, a cardiologist in 1.3%, and a combination of specialists in 0.6%.

Generator placement site

Generator placement site was specified in 51.4% of forms submitted to the registry. Placement was subcutaneous in 97.2% of cases and subpectoral in 2.9%.

Device type

The ICD devices used by Spanish hospitals in 2022 are shown in table 4. This information was reported for 98.8% of cases and shows an even larger decrease in the use of subcutaneous devices for first-time implants than in previous years. The year 2022 also saw a reduction in CRT-ICD implantations, with the lowest rate observed since 2013. The use of single-chamber ICDs remained stable, at around 51%.

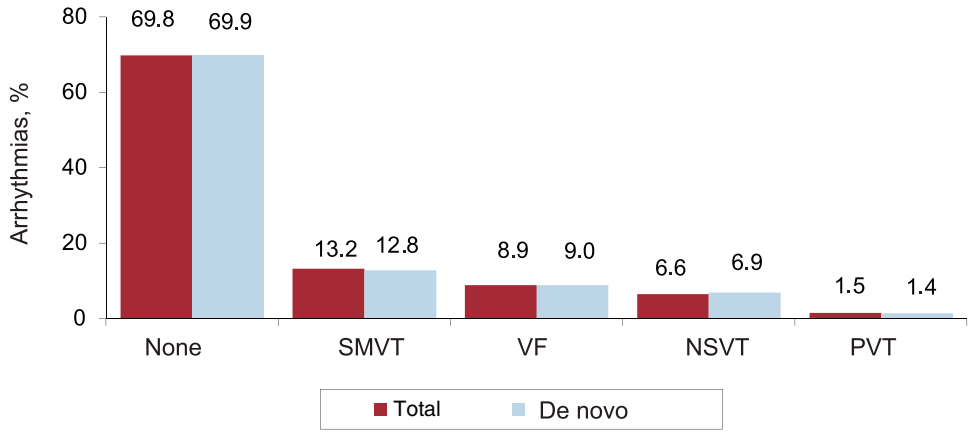


Figure 7. Arrhythmias leading to ICD implantation among patients in the registry (total and de novo recipients). NSVT, nonsustained ventricular tachycardia; PVT, polymorphic ventricular tachycardia; SMVT, sustained monomorphic ventricular tachycardia; VF, ventricular fibrillation.

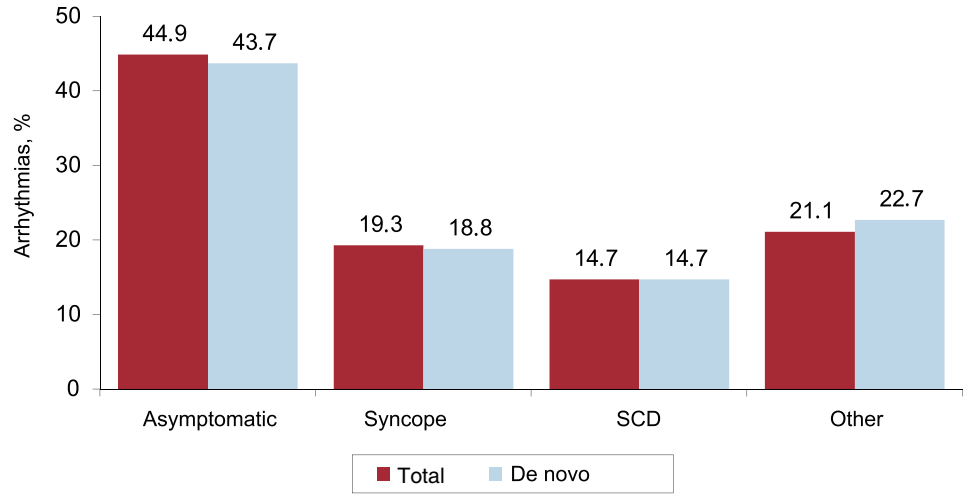


Figure 8. Clinical presentation of arrythmias among patients in the registry (total and de novo ICD recipients). ICD, implantable cardioverter-defibrillator; SCD, sudden cardiac death.

Table 2
Number of de novo implants by type of heart disease, clinical arrhythmia, and clinical presentation from 2018 to 2022

Heart disease	2018	2019	2020	2021	2022
Ischemic heart disease					
Aborted SCD	165 (10.6)	202 (11.2)	183 (8.7)	46 (6)	119 (8.4)
SMVT with syncope	92 (5.9)	132 (7.3)	105 (5.2)	48 (6.3)	64 (4.5)
SMVT without syncope	231 (14.9)	232 (12.9)	204 (9.7)	71 (9.3)	124 (8.7)
Syncope without arrhythmia	62 (3.9)	62 (3.4)	128 (6.1)	20 (2.6)	66 (4.7)
Prophylactic indication	793 (50.8)	988 (54.9)	1.173 (56.1)	445 (56.2)	916 (64.7)
Missing/unclassifiable	217 (13.9)	181 (10.7)	299 (14.3)	135 (17.6)	127 (8.9)
Subtotal	1.560	1.797	2.092	765	1.416
Dilated cardiomyopathy					
Aborted SCD	47 (5.6)	42 (4.5)	74 (5.9)	16 (1.1)	46 (6.6)
SMVT with syncope	39 (4.8)	45 (4.9)	51 (4.1)	19 (1.2)	28 (4.0)
SMVT without syncope	53 (6.6)	121 (13.0)	88 (7.1)	19 (2.3)	11 (1.6)
Syncope without arrhythmia	26 (3.3)	34 (3.7)	59 (4.7)	9 (1.1)	29 (4.2)
Prophylactic indication	355 (44.2)	547 (59.1)	766 (61.7)	278 (33.2)	238 (34.2)
Missing/unclassifiable	283 (35.2)	136 (14.7)	204 (16.4)	278 (57.8)	344 (49.4)
Subtotal	803	925	1.242	619	696
Valve disease					
Aborted SCD	9 (9.8)	12 (12.4)	12 (10.8)	6 (6.3)	13 (14.3)
SMVT	24 (26.1)	28 (28.7)	21 (18.9)	7 (7.4)	8 (8.8)
Syncope without arrhythmia	5 (5.4)	2 (2.1)	7 (6.3)	2 (2.1)	3 (3.3)
Prophylactic indication	37 (40.2)	45 (46.4)	52 (46.8)	23 (24.2)	20 (24.2)
Missing/unclassifiable	17 (18.5)	10 (10.3)	18 (17.1)	57 (60.0)	47 (51.6)
Subtotal	92	97	110	95	91
Hypertrophic cardiomyopathy					
Secondary prevention	48 (19.2)	45 (14.2)	80 (20.4)	82 (20.5)	31 (12.7)
Prophylactic indication	198 (79.2)	207 (65.3)	288 (73.5)	325 (79.8)	200 (82)
Missing/unclassifiable	4 (1.6)	65 (20.5)	24 (6.1)	12 (2.8)	13 (5.3)
Subtotal	250	317	392	419	244
Brugada syndrome					
Aborted SCD	14 (18.9)	10 (12.0)	10 (9.5)	9 (8.0)	3 (7)
Prophylactic implantation for syncope	14 (18.9)	23 (27.7)	18 (17.1)	7 (6.2)	10 (23.2)
Prophylactic implantation without syncope	14 (18.9)	40 (48.2)	56 (53.3)	22 (19.6)	9 (20.9)
Missing/unclassifiable	17 (23.0)	10 (12.0)	21 (20.0)	74 (66.0)	21 (48.8)
Subtotal	74	83	105	112	43
ARVC					
Aborted SCD	4 (10.3)	4 (8.2)	5 (8.9)	3 (4.1)	5 (11.9)
SMVT	16 (41.0)	14 (28.6)	6 (10.7)	8 (11.0)	9 (21.4)
Prophylactic implantation	14 (35.9)	22 (44.9)	29 (51.8)	36 (49.3)	13 (30.9)
Missing/unclassifiable	5 (12.8)	9 (18.4)	16 (28.5)	26 (35.6)	15 (35.7)
Subtotal	39	49	56	73	42
Congenital heart disease					
Aborted SCD	7 (15.2)	6 (14.6)	3 (7.0)	2 (2.4)	4 (6.5)
SMVT	14 (30.4)	11 (26.8)	6 (13.9)	3 (3.6)	1 (1.6)
Prophylactic implantation	21 (45.6)	20 (48.8)	27 (62.8)	58 (69.8)	24 (39.3)
Missing/unclassifiable	4 (8.7)	4 (9.7)	7 (16.3)	20 (24.0)	32 (52.5)
Subtotal	46	41	43	83	61
Long QT syndrome					
Aborted SCD	9 (24.3)	15 (40.5)	9 (21)	2 (7.2)	5 (23.8)
Prophylactic implantation	18 (48.6)	15 (40.5)	23 (53.6)	11 (39.9)	7 (33.3)
Missing/unclassifiable	10 (27.3)	7 (18.9)	11 (25.6)	15 (53.6)	9 (42.9)
Subtotal	37	37	43	28	21

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

Table 3
Changes in the main indications for implantable cardioverter-defibrillator implantation in de novo recipients from 2013 to 2022

Year	SCD	SMVT	Syncope	Primary prevention
2013	13.5	11.1	22.4	53.0*
2014	13.2	17.9	10.2	58.5*
2015	11.2	13.6	16.9	58.2
2016	11.8	17.0	9.9	62.0*
2017	12.5	15.7	9.8	62.0
2018	13.3	13.5	7.4	65.7
2019	13.3	10.1	11.5	65.1
2020	9.5	8.2	11.9	72.7
2021	3.6	5.4	4.6	86.4
2022	9.5	4.6	10.3	75.6

SCD, sudden cardiac death; SMVT, sustained monomorphic ventricular tachycardia.
* Significantly different ($P < .02$) vs previous year.

Reasons for device replacement, need for lead replacement, and use of additional leads

The main reason for ICD generator replacement was battery depletion (73.2%), followed by upgrading (17.7%), device dysfunction (5%), device infections (1.4%), and other reasons (2.7%).

Lead condition was described in 58.5% of forms, and was defective in 27 cases.

Device programing

Device programing details were provided in 47.4% of forms. The most widely used pacing mode was VVI (50.4%), followed by DDD (21.6%), VVIR (5.9%), DDDR (5.21%), and resynchronization (9.2%). Other modes, which mostly included algorithms or modes to prevent ventricular stimulation, accounted for 9.2% of cases.

Postimplantation induction of ventricular fibrillation was performed at least once in 311 patients (8.6% of those for whom this information was reported). The defibrillation test was mainly performed in patients with a subcutaneous ICD. Just 36 patients with a transvenous ICD underwent ventricular fibrillation induction. The mean number of shocks delivered was 1.06. Accordingly, correct device functioning rather than thresholds was checked in most cases.

Complications

Information on complications was reported in 46.8% of forms. There were 50 complications: 13 coronary sinus dissections, 9 suboptimal left ventricular electrode positions, 4 cases of pneumothorax, 1 tamponade, and 23 unspecified complications. No procedure-related deaths were reported in 2022.

DISCUSSION

A record number of ICD implantations were performed in Spain in 2022, with a total of 162 implants per million population according to registry data and 168 per million population according to Eucomed. Differences, however, remain significant among autonomous communities and overall rates are still well below the 2021 European mean of 296 implants per million population. The data reported to the Spanish ICD Registry in 2022 also confirm that hospital activity has fully returned to pre-COVID-19 levels.[11–14]

Comparison with recent years

Although more ICD devices than ever were implanted in Spain in 2022, the number of implanting centers decreased with respect to previous years, essentially because of a reduction in the number of hospitals with low volumes of procedures (< 100 and in particular < 10).

With some exceptions (2011-2012, 2017, and 2020), implantation activity in Spain has increased progressively over the years since the launch of the national ICD registry. There was a 4% reduction in the number of procedures performed in 2020 relative to 2018 and 2019 (the years with the most activity up to 2021), but this was attributable to a general reduction in hospital activity due to the COVID-19 pandemic. Implantation rates returned to normal in 2021, when hospitals resumed normal operation. Although the effects of the pandemic were still somewhat evident in January and February, 2021, they were offset by the increase in procedures over the rest of the year, which ended with a record high. This increase continued into 2022, which set a new record in the number of procedures performed. Nonetheless, and in line with findings from previous years, Spain, with 168 implants per million population, has the lowest implantation rate in all the European Union and is still well behind the European mean of 296 implants per million population reported for 2021.

As evidenced by the above figures, Spain still has a long way to go before it attains a level of activity that would be expected in light of the scientific evidence underlying current clinical practice guidelines.[1–3] This situation, however, is not specific to Spain, and its ramifications can be observed in a Swedish study that found that just 10% of patients with an ICD indication for the primary prevention of SCD (according to the European Society of Cardiology [ESC] guidelines) between 2000 and 2016 received a device.[15] The same study found that ICD use was associated with a 27% 1-year and a 12% 5-year reduction in mortality. Data from the European EU-CERT-ICD registry have also shown a survival benefit among patients with and without ischemic heart disease

Table 4
Percent distribution of implanted devices by type

	Total									De novo implants						
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2016	2017	2018	2019	2020	2021	2022
Subcutaneous			3.6	3.8	4.4	6.2	5.7	8.6	6.1	6.4	5.3	6.0	8.3	8.1	7.3	6.5
Single-chamber	48.8	48.6	45.4	45.7	46.6	45.6	45.1	46.7	46.1	48.4	49.4	50.1	47.7	50.2	52.6	51.1
Dual-chamber	17.4	14.5	13.7	15.0	15.0	13.8	14.1	10.6	14.5	13.0	14.1	13.4	12.6	12.4	10.5	14.4
Resynchronization device	33.7	35.7	37.3	35.7	34.0	34.4	34.7	34.1	33.2	32.1	31.5	30.6	31.4	29.3	29.7	27.9

who received an ICD for the primary prevention of SCD, with an overall 27% reduction in mortality over a mean follow-up of 2.5 years.[16] The Spanish ICD Registry shows that ICD therapy is clearly underused in Spain. The reasons are difficult to pinpoint, but the figures highlight the need to implement measures ensuring that all patients who could benefit from ICD therapy receive a device.

Most (75.6%) of the ICDs implanted in Spain in 2022 were for primary prevention, confirming the upward trend observed in recent years (table 3). Prophylactic ICD therapy has increased by more than 50% in the past 10 years, positioning Spain at a similar level to other European countries, where approximately 80% of implants are for primary prevention.[17,18]

The percentage of de novo CRT-ICD implants had remained stable, at around 30% in recent years, but in 2022, it was well below this level. There was also an increase in the use of dual chamber ICDs and a stabilization in the use of single-chamber devices. Finally, the data confirmed a downward trend in the use of subcutaneous ICDs among de novo recipients. The rate in 2022 was 6.5%, down from the peaks of 8.3% in 2019 and 8.1% in 2020. Although the favorable results reported for subcutaneous ICDs in 2020 by the PRAETORIAN (Prospective, Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy)[19] and UNTOUCHED (Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction)[20] clinical trials indicated that subcutaneous ICD use would gain traction, this has not been the case in Spain. Possible reasons include higher costs per unit and recent safety alerts. Nonetheless, 2 recent subanalyses of data from the PRAETORIAN trial showed that subcutaneous ICDs were effective in the treatment of ventricular arrhythmias[21] and associated with fewer device-related complications than transvenous ICDs.[22] A new extravascular ICD recently authorized for use in the European Union has a ventricular stimulation feature that provides pause-prevention and antitachycardia pacing.[23] The impact of this novel device and emerging evidence on the use of subcutaneous ICDs will become clearer in the years to come.

Ischemic heart disease (51.8%) and dilated cardiomyopathy (24.9%) continue to be the main heart conditions in ICD carriers. Together, they account for more than 75% of all indications for ICD therapy in Spain. The data from 2022, however, show a reduction in the percentage of patients with dilated cardiomyopathy in the registry, which was manifested in a corresponding reduction in the number of prophylactic indications for this disease and probably also explains the reduction in the percentage of CRT-ICD implantations observed. These reductions can be explained by the findings of several recent publications, including the DANISH (Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure) trial[24] and the latest ESC guidelines for the diagnosis and treatment of heart failure[3] and the management of patients with ventricular arrhythmias and the prevention of SCD.[2] Both guidelines, published in 2021 and 2022, respectively, downgraded the recommendation for using ICDs in the primary prevention of SCD in patients with nonischemic dilated cardiomyopathy to a level IIa A recommendation. The use of ICDs in patients with dilated cardiomyopathy, however, remains controversial. The 2021 heart failure guidelines recognize a potential survival benefit in patients younger than 70 years and cite the 30% reduction in mortality (hazard ratio [HR], 0.70; 95% CI, 0.51-0.96; $P = .03$) reported by the DANISH trial.[3] The guidelines also refer to the findings of a meta-analysis (including the DANISH trial) that showed an association between ICD therapy and a reduction in all-cause mortality in patients with nonischemic cardiomyopathy.[25] The ESC guidelines for the management of patients with ventricular arrhythmias recommend genetic testing (eg, to detect *LMNA* mutations, which are associated with a high risk of SCD) and assessment of late gadolinium enhancement on cardiac magnetic resonance imaging to improve SCD risk stratification in patients with dilated cardiomyopathy.[2] This latter recommendation is based on the findings of several studies and meta-analyses showing that late gadolinium enhancement is superior to LVEF as a risk marker for SCD. Finally, a cost-effectiveness analysis of ICD therapy for the primary prevention of SCD in Spain showed this treatment to be associated with a reduction in all-cause mortality in both ischemic (HR, 0.70; 95% CI, 0.58-0.85) and nonischemic heart disease (HR, 0.79; 95% CI, 0.66-0.96).[26] Using probabilistic modeling, the study showed cost-effectiveness ratios of €19 171 per quality-adjusted life year (QALY) for patients with ischemic heart disease, €31 084/QALY for patients with nonischemic dilated cardiomyopathy, and €23 230/QALY for patients younger than 68 years.[26] These results confirm that ICD therapy in Spain is a cost-effective strategy for the primary prevention of SCD in patients with left ventricular dysfunction of ischemic or nonischemic origin, especially in younger populations (< 68 years).

Differences among autonomous communities

Similar to previous years, the 2022 registry showed significant differences in implant numbers per million population among autonomous communities. The rates were higher than average in several regions, namely Principality of Asturias (n = 331), Cantabria (n = 242), Extremadura (n = 219), Aragon (n = 214), La Rioja (n = 193), Galicia (n = 190), Castile-La Mancha (n = 188), the Valencian Community (n = 180), and the Basque Country (n = 163). Below-average rates were observed in Community of Madrid (n = 161), Balearic Islands (n = 160), Catalonia (n = 151), Castile-León (n = 150), Chartered Community of Navarre (n = 147), Andalusia (n = 139), the Canary Islands (n = 130), and Region of Murcia (n = 108). The difference between communities with the highest and lowest rates again exceeded 200 implants per million population (265 in 2021, 180 in 2020, and 139 in 2019). The level of disparities across regions in a supposedly uniform health care system such as that of Spain remains a puzzle and indicates that, despite the available evidence and the work of the SEC, hospitals are not applying the same criteria in this area. The differences cannot be explained by differences in income or population density, or by varying rates of ischemic heart disease and heart failure. They do, however, raise questions on the equity of the Spanish health care system in an area as important as SCD prevention.

Comparison with other countries

On average, 296 devices (ICDs and CRT-ICDs) per million population were implanted in countries covered by Eucomed in 2021. This is higher than the rate of 285 per million population reported for 2020 (the year most affected by the COVID-19 pandemic) and similar to rates from previous years (303 in 2019, 302 in 2018, 307 in 2017, and 316 in 2016). The countries with the highest activity were the Czech Republic, Italy, and Germany, which respectively performed 470, 440, and 436 implantations per million population. Spain again ranked bottom in 2022, with a total of 168 implants per million population, and continues to trail behind other countries with low activity, such as the United Kingdom and Portugal, which respectively performed 197 and 229 implants per million population in 2021.

Limitations

The Spanish ICD registry collected data on 96.5% of all implants performed in Spain in 2022 according to Eucomed data. As in previous years, and despite the creation of the online *CardioDispositivos* platform in 2019 to facilitate reporting,[27] the completeness of the information submitted was inconsistent across hospitals and less than ideal. Just 23.6% of hospitals used the online platform in 2022, down from 30% in 2021. In addition, the registry does not collect important ICD programming data that would help analyze morbidity and mortality. Combined analyses of parameters such as detection times, heart rate thresholds, and intervals at which supraventricular rhythm discriminators operate are helpful for reducing appropriate and inappropriate therapies. The registry also does not collect follow-up data, limiting thus the conduct of more relevant clinical studies. Finally, inconsistent reporting and a lack of follow-up data probably contributed to an underestimation of procedure- and device-related complications.

Future prospects of the Spanish ICD Registry

This is the 19th official report of the Spanish ICD Registry. The continued publication of these annual reports is a credit to all participating members of the SEC Heart Rhythm Association. The online platform, a joint initiative of the SEC and the *Agencia Española de Medicamento y Productos Sanitarios* (AEMPS), has yet to find traction, and its use by hospitals across the country remains inconsistent. To ensure the success of the registry, hospitals need to recognize the importance of the online platform, which facilitates real-time reporting and can serve as a breeding ground for more complex studies.

CONCLUSIONS

The Spanish ICD Registry collected data on 96.5% of all ICD implantations performed in Spain in 2022, thus covering practically all procedures and current uses of this treatment in Spanish hospitals. Although the number of implants per million population reached a record high in 2022, regional disparities persist. In addition, ICD implantation rates remain low compared with other European countries, highlighting the need to improve our ability to identify patients who stand to benefit from ICD therapy.

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AUTHORS' CONTRIBUTIONS

All the authors analyzed the data, wrote and revised the manuscript, and are responsible for this publication. The first author, together with a technician and a computer scientist from the SEC, was responsible for entering and cleaning the data.

CONFLICTS OF INTEREST

I. Fernández Lozano has participated in clinical studies sponsored by Abbott and Biotronik and has received fellowship grants from the SEC and the Foundation for Cardiovascular Research. J. Osca Asensi has participated in clinical studies sponsored by Abbott, Boston, and Biotronik. J. Alzueta Rodríguez has received speakers' fees from Boston and received fellowship grants from the FIMABIS Foundation.

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