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Special article

Spanish implantable cardioverter-defibrillator registry. 18th official report of the Heart Rhythm Association of the Spanish Society of Cardiology (2021)

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ABSTRACT

Introduction and objectives: This article presents the data corresponding to implantable cardioverter-defibrillator (ICD) implantations in Spain in 2021.
Methods: The data were drawn from implanting centers, which voluntarily completed a data collection sheet during the procedure.
Results: In 2021, 7496 implant data sheets were received, compared with 7743 reported by Eucomed (European Confederation of Medical Suppliers Associations), indicating that data were collected from 96.8% of the devices implanted in Spain. Data completion ranged from 99.9% for "name of implanting hospital" to 8.9% for "implanting hospital". In 2021, 199 hospitals participated in the registry, exceeding the figures of previous years, with around 170 participating hospitals. The total rate of registered implants was 158/million inhabitants (163 according to Eucomed), making 2021 the year with the highest activity. However, the registry continues to show significant differences among the various autonomous communities and the lowest implantation rate of all the European countries participating in Eucomed.
Conclusions: The Spanish implantable cardioverter-defibrillator registry for 2021 recorded an increase in the number of ICD implantations, reflecting the recovery of hospital activity after the initial impact of the COVID-19 pandemic in 2020. Although the total number of implants has increased in Spain, figures are still much lower than the European Union average, with differences persisting among Spanish autonomous communities.

Registro español de desfibrilador automático implantable. XVIII informe oficial de la Asociación del Ritmo Cardiaco de la Sociedad Española de Cardiología (2021)

Palabras clave:
Desfibrilador automático implantable
Muerte súbita
Registro nacional

RESUMEN

Introducción y objetivos: Se presentan los datos correspondientes a los implantes de desfibrilador automático implantable (DAI) en España en el año 2021.
Métodos: Los datos provienen de los centros implantadores, que cumplimentaron voluntariamente una hoja de recogida de datos durante el implante.
Resultados: En 2021 se recibieron 7.496 formularios de implante, frente a los 7.743 comunicadas por Eucomed *(European Confederation of Medical Suppliers Associations),* lo que implica que se han recogido datos del 96,8% de los dispositivos implantados en España. El cumplimiento osciló entre el 99,9% en el campo «nombre del hospital implantador» y el 8,9% en la variable «hospital de referencia». En 2021, 199 hospitales han participado en el registro, lo cual supera las cifras de los años previos en que el número de participantes osciló alrededor de 170 hospitales. La tasa total de implantes registrados fue 158/millón de habitantes (163 según Eucomed), lo que la sitúa como el año con mayor actividad. Sin embargo, el registro sigue mostrando diferencias importantes entre las comunidades autónomas y la tasa de implante más baja de todos los países europeos participantes en Eucomed.
Conclusiones: El Registro español de desfibrilador automático implantable del año 2021 recoge un incremento en el número de implantes de DAI y refleja la recuperación de la actividad hospitalaria tras el

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impacto inicial de la pandemia por COVID-19 durante 2020. A pesar del incremento en el número total de implantes en España, este sigue siendo muy inferior a la media de la Unión Europea y persisten las diferencias entre las comunidades autónomas españolas.

Abbreviations

CRT: cardiac resynchronization therapy
ICD: implantable cardioverter-defibrillator
Eucomed: European Confederation of Medical Suppliers Associations
SEC: Spanish Society of Cardiology (*Sociedad Española de Cardiología*)

INTRODUCTION

Implantable cardioverter-defibrillators (ICDs) are the treatment of choice for the prevention of sudden cardiac death. Numerous clinical trials have shown that ICDs boost the survival of patients with heart failure and left ventricular systolic dysfunction, as well that of those with severe ventricular arrhythmias.[1,2] In addition, cardiac resynchronization therapy (CRT) combined with an ICD improves functional class, diminishes ventricular diameters, boosts left ventricular contractility, reduces hospitalizations, and decreases mortality in patients with heart failure, severe systolic dysfunction, and intraventricular conduction defect.[1]

Clinical practice guidelines list the indications for ICD therapy with and without CRT in the management of patients with ventricular arrhythmias or at risk of developing them and include both primary and secondary prevention measures for sudden cardiac death.[1–3] Sudden cardiac death is one of the leading causes of death in western countries. It has an incidence in Europe of 400 000 cases per year, approximately 30 000 of which occur in Spain; in addition, about 40% of all cases occur in individuals younger than 65 years old.[4]

The Spanish Implantable Cardioverter-defibrillator Registry, drafted by members of the Heart Rhythm Association of the Spanish Society of Cardiology (SEC), has been published since 2005.[5–8] This report presents the data on ICD implantation in Spain reported to the Spanish Implantable Cardioverter-defibrillator Registry in 2021.

METHODS

The registry is based on information voluntarily collected by the participating centers during device implantation and concerns both first implants and replacements. The information was entered in a database by a team comprising a technician, a SEC computer scientist, and a member of the Heart Rhythm Association of the SEC. Data cleaning was the responsibility of the technician and the first author, and all authors of this article analyzed the data and are responsible for this publication. In addition, it has been possible since 2019 to submit the implantation data via a website designed by the SEC. In 2021, this route was used for 2253 implants, which represents 30% of the total.

The census data for the calculations of rates per million population, both national and by autonomous community and province, were obtained from the data of the Spanish National Institute of Statistics as of January 1, 2022.[9] As in previous years, the data from the present registry were compared with those provided by the European Confederation of Medical Suppliers Associations (Eucomed).[10]

The percentages of each of the variables analyzed were calculated by taking into account the total number of implants with available information on the parameter. Only the most serious condition was included if various types of arrhythmias were recorded.

Statistical analysis

Results are expressed as mean ± standard deviation or median [interquartile range], depending on the distribution of the variable. Continuous quantitative variables were analyzed using analysis of variance or the Kruskal-Wallis test, whereas qualitative variables were analyzed using the chi-square test. Linear regression models were used to analyze the number of implants and devices implanted per million population, the total number of implants, and the number of implants for primary prevention in each center.

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

Andalusia		
Almería	Hospital Torrecárdenas	59
	Hospital Vithas Virgen del Mar	8
Cádiz	Hospital de Jerez	37
	Hospital Jerez Puerta del Sur	1
	Hospital Quirón Campo de Gibraltar	2
	Hospital San Carlos	9
	Hospital Universitario de Puerto Real	29
	Hospital Universitario Puerta del Mar	63
	Hospital Dr. López Cano	4
Córdoba	Hospital Cruz Roja de Córdoba	4
	Hospital Universitario Reina Sofía de Córdoba	87
	Hospital Quirónsalud Córdoba	1
Granada	Clínica Nuestra Señora de la Salud	3
	Hospital Clínico Universitario San Cecilio	56
	Hospital HLA Inmaculada de Granada	4
	Hospital Universitario Virgen de las Nieves	74
	Hospital Vithas Salud de Granada	2
Huelva	Hospital Costa de la Luz	5
	Hospital General Juan Ramón Jiménez	60
	Hospital Infanta Elena de Huelva	7
	Hospital Quirónsalud de Huelva	1
Jaén	Complejo Hospitalario de Jaén	67
Málaga	Clínica El Ángel	9
	Clinica Parque San Antonio	7
	Hospital Internacional Xanit	10
	Hospital Quirón de Málaga	6
	Hospital Quirónsalud Marbella	7
	Hospital Virgen de la Victoria	245

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

Sevilla	Clínica HLA Santa Isabel	9
	Hospital de Fátima	3
	Hospital Infanta Luisa	4
	Hospital Nisa Aljarafe	4
	Hospital Nuestra Señora de Valme	50
	Hospital Quirónsalud Sagrado Corazón	5
	Hospital Virgen del Rocío	109
	Hospital Virgen Macarena	85
	Hospital Vithas Sevilla	1
Aragon		
Zaragoza	Clínica Montpelier	1
	Hospital Clínico Universitario Lozano Blesa	32
	Hospital Quirónsalud Zaragoza	8
	Hospital General Royo Villanova	3
	Hospital Universitario Miguel Servet	174
Principality of Asturias		
	Hospital de Cabueñes	28
	Hospital Universitario Central de Asturias	201
	Centro Médico de Asturias	6
Balearic Islands		
	Clínica Juaneda	1
	Clinica Quirón Palmaplanas	8
	Clínica Rotger Sanitaria Balear, S.A.	1
	Hospital Son Llàtzer	19
	Hospital Universitari Son Espases	110
	Policlínica Miramar (Ameba S.A.)	1
Canary Islands		
Las Palmas	Clínica Santa Catalina, S.A.	3
	Hospital Dr. Negrín	80
	Hospital Insular de Gran Canaria	59
	Hospital Nuestra Señora del Perpetuo Socorro	1
	Hospital Dr. José Molina Orosa	2
Tenerife	Hospital Nuestra Señora de la Candelaria	68
	Hospital Parque Tenerife	1
	Hospital San Juan de Dios (Tenerife)	4
	Hospital Universitario de Canarias	54
Cantabria		
	Clínica Mompía	4
	Hospital Universitario Marqués de Valdecilla	221
Castile and León		
Ávila	Hospital Nuestra Señora de Sonsoles	8
Burgos	Hospital Universitario de Burgos (Hubu)	65
León	Clínica San Francisco de León	1
	Hospital de León	53
Salamanca	Complejo Hospitalario de Salamanca	75
Valladolid	Hospital Campo Grande	9
	Hospital Clínico Universitario de Valladolid	103
	Hospital Universitario Río Hortega	23
	Sanatorio Virgen de la Salud	1
Castile-La Mancha		
Albacete	Hospital General Universitario de Albacete	75
	Hospital Quirónsalud Albacete	1
	Sanatorio Santa Cristina	2
Ciudad Real	Hospital General de Ciudad Real	38
	Quirón Ciudad Real	1
Cuenca	Hospital Virgen de la Luz	16

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

Guadalajara	Hospital General y Universitario de Guadalajara	55
Toledo	Hospital Nuestra Señora del Prado	39
	Hospital Universitario de Toledo	128
Catalonia		
Barcelona	Centro Médico Teknon	47
	Clínica Corachan	1
	Clínica Delfos	3
	Clínica Quirónsalud Barcelona	2
	Clínica Sagrada Família	5
	Hospital Clínico de Barcelona	241
	Hospital de Barcelona	9
	Hospital de Bellvitge	161
	Hospital de la Santa Creu i Sant Pau	164
	Hospital de Sabadell Parc Taulí	38
	Hospital del Mar	34
	Hospital El Pilar-Quirónsalud	2
	Hospital Universitari General de Catalunya	7
	Hospital Germans Trias i Pujol	93
	Hospital Universitari Dexeus	3
	Hospital Universitari Sant Joan de Reus	15
	Hospital Vall d'Hebron	150
	Parc Sanitari Sant Joan de Déu	12
Girona	Hospital Universitario de Girona Dr. Josep Trueta	89
Lleida	Hospital Universitario Arnau de Vilanova de Lleida	52
Tarragona	Hospital de Sant Pau i Santa Tecla	2
	Hospital Universitario de Tarragona Joan XXIII	44
Valencian Community		
Alicante	Clínica Glorieta	1
	Clinica Vistahermosa	8
	Hospital del Vinalopó	40
	Hospital General Universitario de Elche	1
	Hospital General Universitario de Alicante	194
	Hospital IMED de Levante	1
	Hospital Mediterráneo	3
	Hospital Quirón de Torrevieja	3
	Hospital Universitari Sant Joan d'Alacant	73
	Policlínica San Carlos S.L.	1
	Sanatorio del Perpetuo Socorro	1
Castellón	Hospital General Universitari de Castelló	63
Valencia	Hospital Arnau de Vilanova de Valencia	1
	Hospital Casa de Salud	2
	Hospital Clínico Universitario de Valencia	96
	Hospital de Manises	48
	Hospital General Universitario de Valencia	84
	Hospital Nisa 9 de Octubre	1
	Hospital Quirónsalud Valencia	4
	Hospital Universitari de La Ribera	42
	Hospital Universitario Dr. Peset	39
	Hospital Universitario La Fe	202
Extremadura		
Badajoz	Hospital de Mérida	2
	Hospital Quirónsalud Clideba Badajoz	2
	Hospital Universitario de Badajoz	143
Cáceres	Clínica San Francisco de Cáceres	10
	Complejo Hospitalario de Cáceres	37

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

Galicia		
A Coruña	Complejo Hospitalario Universitario de A Coruña	126
	Complejo Hospitalario Universitario de Santiago	113
	Hospital Modelo	8
	Hospital Quirónsalud A Coruña	1
Lugo	Hospital Universitario Lucus Agusti	55
Orense	Centro Médico El Carmen	2
	Complejo Hospitalario de Ourense	29
Pontevedra	Complejo Hospitalario de Pontevedra	3
	Hospital Álvaro Cunqueiro	104
	Hospital Miguel Domínguez	3
	Hospital Montecelo	6
	Hospital Nuestra Señora de Fátima	3
	Hospital Povisa	12
	Hospital Provincial de Pontevedra	2
La Rioja		
	Hospital San Pedro	63
	Hospital Viamed Los Manzanos	2
Community of Madrid		
	Clínica La Luz	15
	Clínica La Milagrosa	2
	Clínica Moncloa Asisas	1
	Clínica Ruber, S.A.	1
	Clínica Universidad de Navarra Madrid	5
	Fundación Hospital Alcorcón	30
	Fundación Jiménez Díaz-Clínica Ntra. Sra. de la Concepción	65
	HM Hospitales Madrid	16
	Hospital 12 de Octubre	140
	Hospital Central de la Defensa Gómez Ulla	11
	Hospital Clínico San Carlos	111
	Hospital de Fuenlabrada	21
	Hospital de Torrejón	12
	Hospital del Henares	12
	Hospital General de Villalba	8
	Hospital General Universitario Gregorio Marañón	179
	Hospital Infanta Leonor	30
	Hospital La Zarzuela	1
	Hospital Los Madroños	1
	Hospital Quirón San Camilo	9
	Hospital Quirónsalud Sur Alcorcón	3
	Hospital Ramón y Cajal	81
	Hospital Rey Juan Carlos	13
	Hospital Ruber Internacional	3
	Hospital San Rafael	6
	Hospital Severo Ochoa	10
	Hospital Universitario de Getafe	19
	Hospital Universitario Infanta Elena	11
	Hospital Universitario La Paz	107
	Hospital Universitario Puerta de Hierro-Majadahonda	151
	Hospital Universitario Quirónsalud Madrid	4
	Hospital Virgen de la Paloma	7
	Hospital Virgen del Mar	6
	Hospital Vithas Nuestra Señora de América	5
	Sanatorio San Francisco de Asís	2
Region of Murcia		
	Hospital General Universitario Morales Meseguer	31
	Hospital General Universitario Reina Sofía Murcia	32
	Hospital General Universitario Santa Lucía	76
	Hospital La Vega - HLA	6
	Hospital Rafael Méndez	28
	Hospital Universitario Virgen de La Arrixaca	71
Chartered Community of Navarre		
	Clínica San Miguel IMQ	2
	Clínica Universidad de Navarra	30
	Hospital de Navarra	81
Basque Country		
Álava	Hospital Universitario Araba	68
	Hospital de San José	2
Guipúzcoa	Hospital Universitario de Donostia	64
	Policlínica Gipuzkoa-Quirónsalud	5
Vizcaya	Hospital de Basurto	50
	Hospital de Cruces	77
	Hospital de Galdakao-Usansolo	33
	Imq Zorrotzaurre	4
	Hospital Quirónsalud Bizkaia	1
Not defined*		9

* Data were received on 9 devices without information on the implanting hospital.

RESULTS

In total, 7496 implantation forms were received, although 7743 procedures were reported by Eucomed (96.8% of all devices implanted in Spain). Completion ranged from 99.9% for the field *name of implanting hospital* to 8.9% for the variable *referral hospital*.

Implanting centers

In 2021, 198 hospitals participated in this registry. This is the highest number of participating hospitals since the registry began and easily exceeds that of the previous years (173 in 2020, 172 in 2019, 173 in 2018, and 181 in 2017; the latter was the previous peak). The data of the 198 hospitals are visible in table 1. Figure 1 shows the total number of implanting centers, the rate per million population, and the total number of implants per autonomous community according to the data submitted to the registry. In 2021, 23 centers implanted $\geq$ 100 devices (5 hospitals exceeded 200 implanted units), 74 centers implanted between 11 and 99, and 101 centers implanted 10 or less, of which 28 implanted only 1.

The name of the hospital performing the procedure was recorded in 99.9% of forms (table 1). Most procedures (6749, 90%) were performed in publicly-funded health centers.

Total number of implants

The total number of implants reported to the registry and those estimated by Eucomed in the last 10 years are shown in figure 2. In 2021, 7496 implants were recorded (both first implants and replacements). This figure represents a historic high for the registry and a 6.3% increase vs the previous year (7056 units recorded in 2020). In addition, the data provided by Eucomed

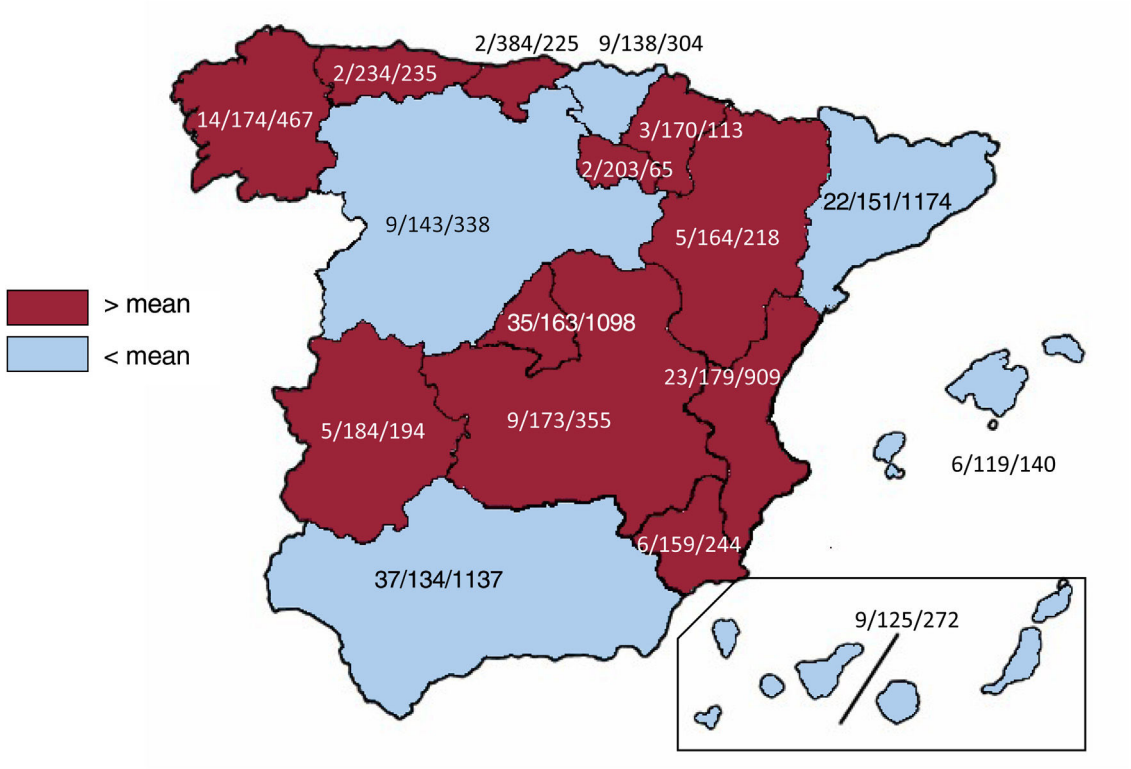
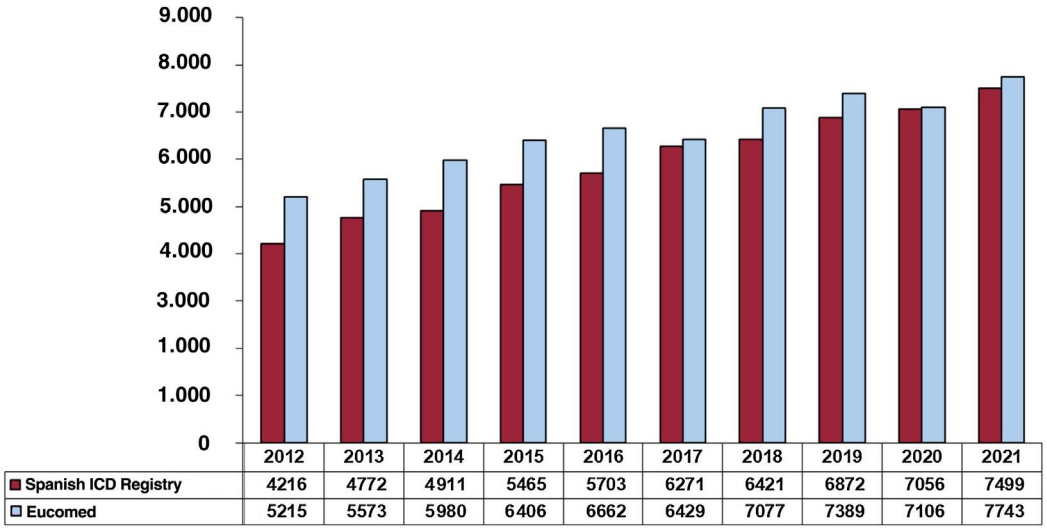


Figure 1. Distribution of implantation activity by autonomous community in 2021: number of implantation centers/rate per million population/total number of implants. Mean rate = 158 implants/million population.

(7743 implants in 2021) also show the highest number of implants in registry history, with a 9% increase in units implanted in 2021 and a 5% increase vs the last 2 years (2020 and 2021).

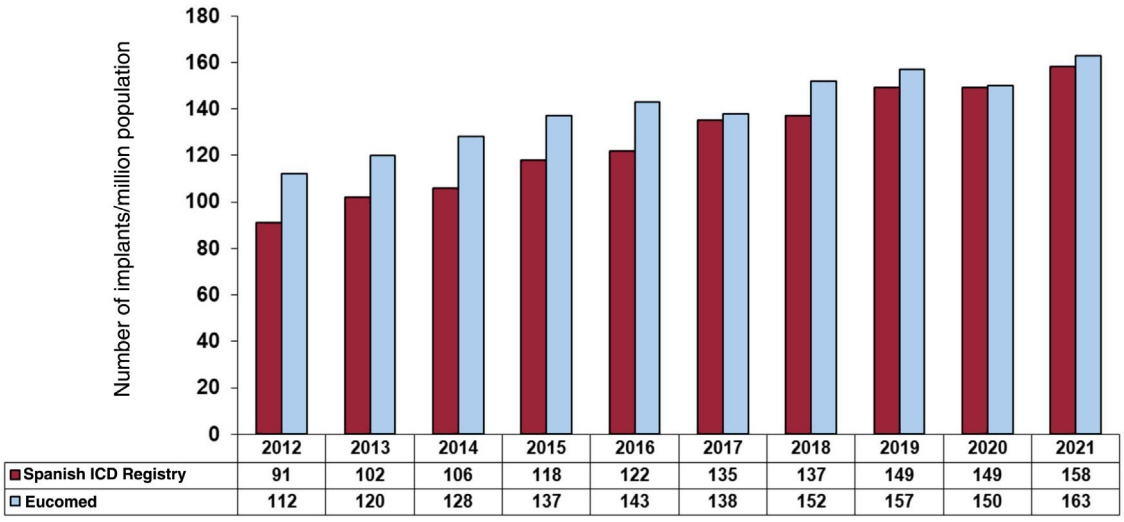
Changes in the implantation rate per million population in the last 10 years according to registry and Eucomed data are shown in figure 3. According to the data from Eucomed, the total implantation rates were 163 implants/million population in 2021, 150 in 2020, and 157 in 2019. Despite the increase detected in the ICD implantation rate per million population in Spain, this number is still much lower than the average ICD implantation rate in Europe. For example, in Europe in 2020 (a year with reduced hospital activity due to the COVID-19 pandemic), the mean implantation rate was 285 units/million population.[10]

Figure 4 shows the number of ICD implants by month between 2018 and 2021. The figure illustrates the implantation dynamic during the year and reveals the recovery in the number of units implanted in March after the end of the peak COVID-19 incidence observed in the winter of 2021. The impact of the other COVID-19 waves in 2021 was lower and activity remained above that of previous years in the rest of the year.



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Spanish ICD Registry	4216	4772	4911	5465	5703	6271	6421	6872	7056	7499
Eucomed	5215	5573	5980	6406	6662	6429	7077	7389	7106	7743

Figure 2. Total number of implants recorded and those estimated by the European Medical Technology Industry Association from 2012 to 2021. ICD, implantable cardioverter-defibrillator.



	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Spanish ICD Registry	91	102	106	118	122	135	137	149	149	158
Eucomed	112	120	128	137	143	138	152	157	150	163

Figure 3. Total number of implants notified per million population and number estimated by Eucomed from 2012 to 2021. Eucomed: European Confederation of Medical Suppliers Associations; ICD, implantable cardioverter-defibrillator.

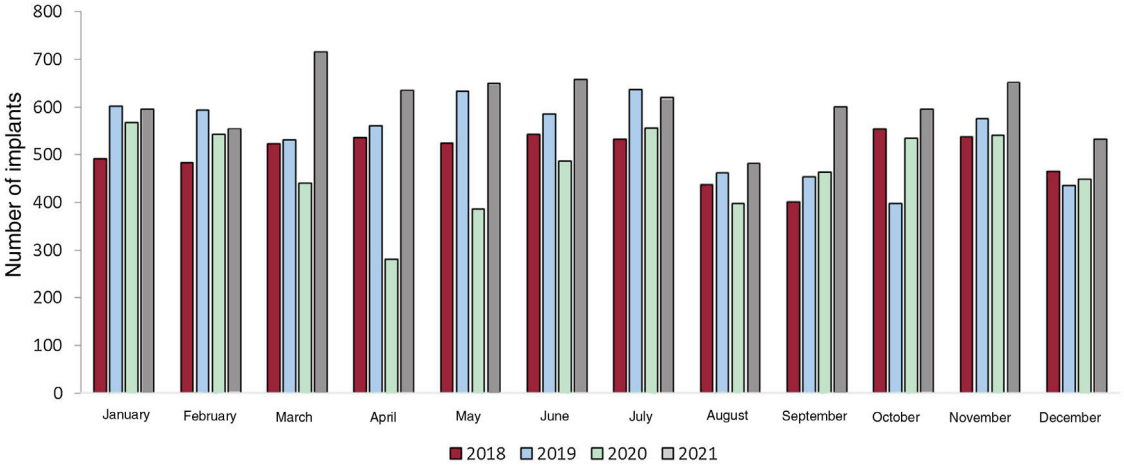
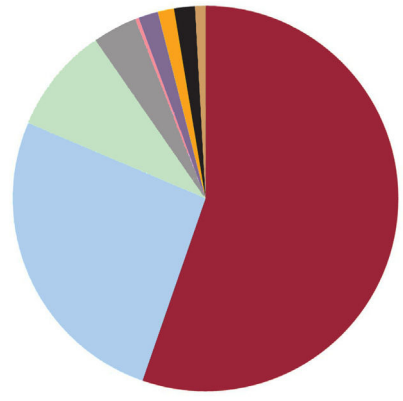


Figure 4. Number of implants per month from 2018 to 2021.



Ischemic heart disease	56.8
Dilated cardiomyopathy	26.8
Hypertrophic cardiomyopathy	9.2
Others	3.8
None	0.3
Brugada syndrome	1.7
Valve disease	1.4
ARVC	1.8
Long QT syndrome	0.9

Figure 5. Type of heart disease prompting implantation (first implants). ARVD, arrhythmogenic right ventricular dysplasia; Others, patients with more than 1 diagnosis.

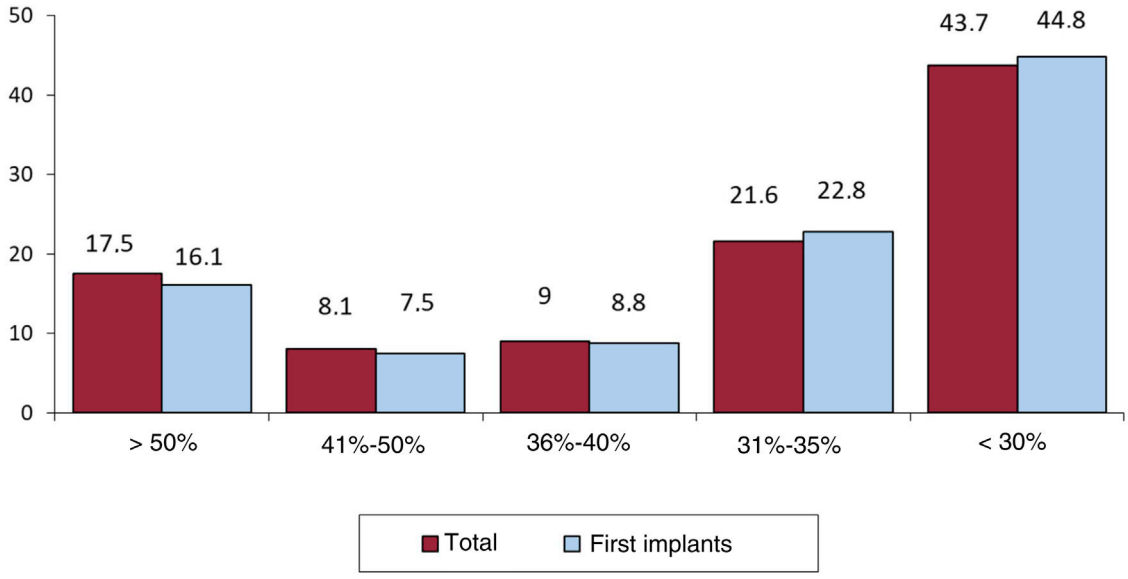


Figure 6. Left ventricular ejection fraction of patients in the registry (total and first implants).

First implants vs replacements

This information was available in 6067 forms (81% of devices included in the registry). First implants represented 4268, or 70.3% of the total. The rate of first implants per million population was 110.

Age and sex

The mean age of all of the patients included in the registry was 63.5 ± 13.5 (3-94) years in 2021, which is higher than the average age in 2020 (62.2 ± 13.4 [5-95] years). The mean age at first implantation was 63.2 ± 13.5 years (61.0 ± 13.1 years in 2020). Once again, and as in previous years, patients were overwhelming male: they represented 81.2% of all patients and 82% of first implants.

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

The most frequent underlying cardiac condition in first implant patients was ischemic heart disease (56.8%), followed by dilated cardiomyopathy (26.8%), hypertrophic cardiomyopathy (9.2%), primary conduction abnormalities (Brugada syndrome and long QT syndrome; 2.6%), arrhythmogenic right ventricular cardiomyopathy (1.8%), and valve diseases (1.4%) (figure 5).

figure 6 shows the left ventricular systolic function data (available in 43.7% of submitted forms). Left ventricular ejection fraction was > 50% in 17.5% of patients, from 41% to 50% in 8.1%, from 36% to 40% in 9%, from 31% to 35% in 21.6%, and ≤ 30% in 43.7%. These values were similar when patients were grouped by first implants and replacements.

New York Heart Association (NYHA) functional class was reported in 29% of submitted forms. Most patients were in NYHA

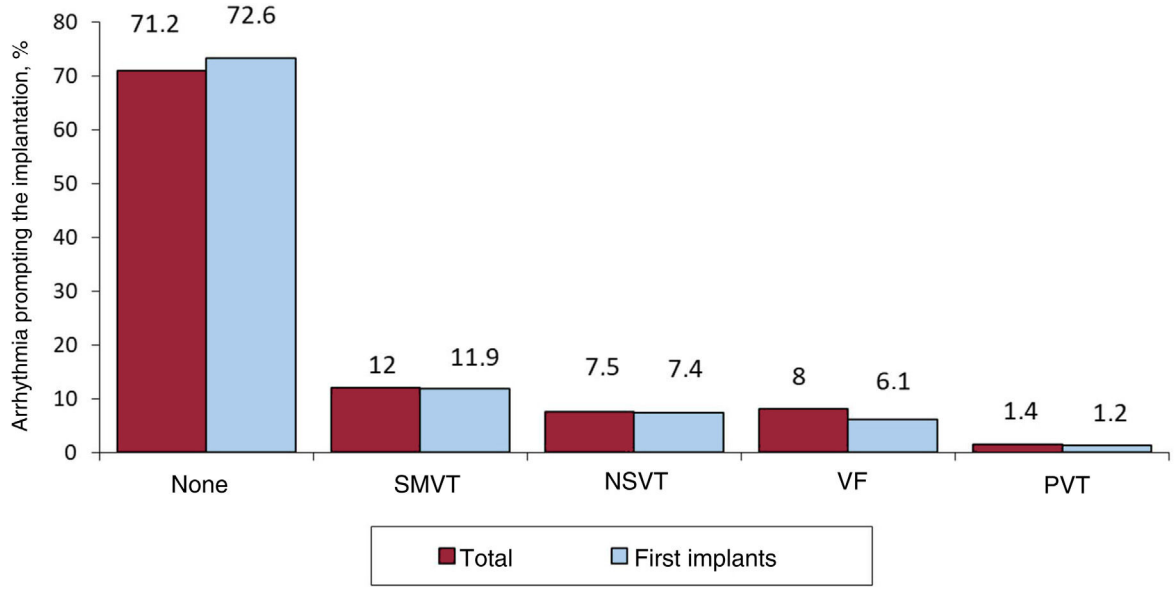


Figure 7. Distribution of arrhythmias prompting implantation (total and first implants). NSVT, nonsustained ventricular tachycardia; PVT, polymorphic ventricular tachycardia; SMVT, sustained monomorphic ventricular tachycardia; VF, ventricular fibrillation.

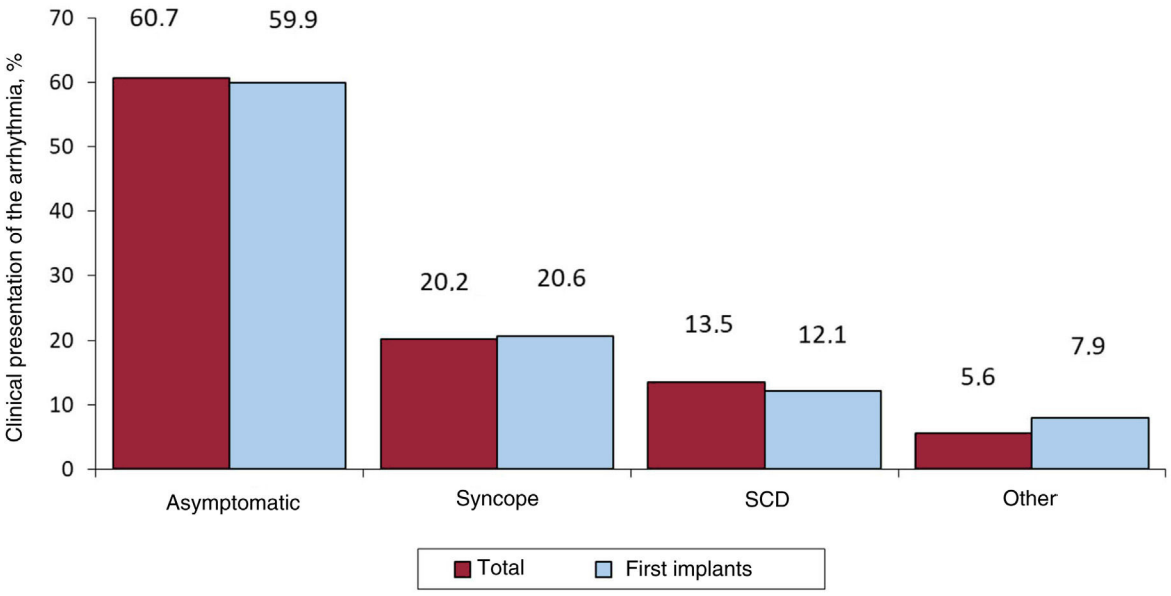


Figure 8. Clinical presentation of the arrhythmia in the registry patients (first implants and total). SCD, sudden cardiac death.

class II (61.7%), followed by NYHA III (26.2%), NYHA I (10.9%), and NYHA IV (1.2%). Once again, the distribution of this variable was similar in the overall and first implantation groups.

With data from 52.1% of forms, the baseline cardiac rhythm was primarily sinus (79.2%), followed by atrial fibrillation (17.1%) and pacemaker rhythm (3.6%). The remaining patients had other rhythms (eg, atrial flutter and other arrhythmias).

Clinical arrhythmia prompting implantation, its form of presentation, and the arrhythmia induced in the electrophysiological study

Figure 7 shows the clinical arrhythmia prompting ICD implantation (recorded in 25.9% of forms submitted to the registry). For first implants, most patients had no documented clinical arrhythmias (72.6%), whereas 11.9% had sustained monomorphic ventricular tachycardia, 7.4% had nonsustained ventricular tachycardia, and 6.1% had ventricular fibrillation.

The most frequent clinical presentation in patients with ICD implantation was asymptomatic (in about 60% of patients), followed by syncope, sudden cardiac death, and other symptoms (figure 8).

Information on the electrophysiological studies performed before ICD implantation was provided in 52.7% of forms. These studies were performed in 296 patients (7.5%), mainly those with ischemic heart disease or dilated cardiomyopathy and in 31.8% of patients with Brugada syndrome. Sustained monomorphic ventricular tachycardia was the most common induced arrhythmia (49.5%), followed by ventricular fibrillation (14.7%), nonsustained ventricular tachycardia (7.5%), and, to a lesser extent, other arrhythmias (3.6%). No arrhythmia was induced in 24.5% of the electrophysiological studies.

Clinical history

Data on patients' clinical history were available in 17.8% of submitted forms. Regarding cardiovascular risk factors and the most relevant medical history of the patients undergoing ICD implantation, the most important findings were as follows: hypertension, 67.9%; hypercholesterolemia, 12.8%; smoking, 4.5%; diabetes mellitus, 43.3%; history of atrial fibrillation, 40%; kidney failure, 18.8%; history of sudden cardiac death, 12.6%; and history of stroke, 9.6%.

The QRS duration interval was reported for 29.8% of first implant patients (mean, 126.5 ms). Of these, it was $>$ 140 ms in 32.9% of the patients, and 78.8% of these patients had a resynchronization-defibrillator device (ICD-CRT).

Indications

Device indications and their changes over time are shown in table 2. These data were provided in 59.4% of forms in 2021. Ischemic heart disease was the most frequent reason for ICD implantation in Spain, accounting for 51.4% of first implants in 2021. Among ischemic heart disease patients, the most common indication was primary prevention (69.4%). The second most common reason for ICD implantation was dilated cardiomyopathy (27.1% of all first implants) and, as can be seen in table 2, the absolute number of first implants reduced in 2021 vs previous years (619 in 2021 vs 1242 in 2020, 925 in 2019, 803 in 2018, and 830 in 2017). In the less common heart diseases, the most frequent indication was primary prevention.

The implantation indication was reported in 66.2% of the forms. Primary prevention of sudden cardiac death was the main indication for first implants in most patients (86.4%) and its number greatly exceeded that recorded in previous years (72.7% in 2020, 65.1% in 2019, 65.7% in 2018, and 62% in 2017 and 2016) (table 3).

Implantation setting and treating specialist

The implantation setting and specialist performing the procedure were recorded in 60% of forms; 85.9% of procedures were performed in electrophysiology laboratories and 13.2% in operating rooms. Cardiac electrophysiologists performed 83.5% of implants, surgeons performed 6.6%, and both together performed

Table 2
Number of first implants by type of heart disease, type of clinical arrhythmia, and form of presentation from 2017 to 2021

	2017	2018	2019	2020	2021
Ischemic heart disease					
Aborted SCD	101 (6.5%)	165 (10.6)	202 (11.2)	183 (8.7)	46 (6)
SMVT with syncope	135 (8.7)	92 (5.9)	132 (7.3)	105 (5.2)	48 (6.3)
SMVT without syncope	212 (13.7)	231 (14.9)	232 (12.9)	204 (9.7)	71 (9.3)
Syncope without arrhythmia	61 (3.9)	62 (3.9)	62 (3.4)	128 (6.1)	20 (2.6)
Prophylactic implantation	603 (39.0)	793 (50.8)	988 (54.9)	1173 (56.1)	445 (56.2)
Missing/unclassifiable	434 (28.0)	217 (13.9)	181 (10.7)	299 (14.3)	135 (17.6)
Subtotal	1546	1560	1797	2092	765
Dilated cardiomyopathy					
Aborted SCD	61 (7.3)	47 (5.6)	42 (4.5)	74 (5.9)	16 (1.1)
SMVT with syncope	65 (7.8)	39 (4.8)	45 (4.9)	51 (4.1)	19 (1.2)
SMVT without syncope	100 (12.0)	53 (6.6)	121 (13.0)	88 (7.1)	19 (2.3)
Syncope without arrhythmia	30 (3.6)	26 (3.3)	34 (3.7)	59 (4.7)	9 (1.1)
Prophylactic implantation	341 (41.0)	355 (44.2)	547 (59.1)	766 (61.7)	278 (33.2)
Missing/unclassifiable	233 (28.7)	283 (35.2)	136 (14.7)	204 (16.4)	278 (57.8)
Subtotal	830	803	925	1242	619
Valve disease					
Aborted SCD	5 (5.3)	9 (9.8)	12 (12.4)	12 (10.8)	6 (6.3)
SMVT	22 (23.2)	24 (26.1)	28 (28.7)	21 (18.9)	7 (7.4)
Syncope without arrhythmia	5 (5.3)	5 (5.4)	2 (2.1)	7 (6.3)	2 (2.1)
Prophylactic implantation	46 (48.4)	37 (40.2)	45 (46.4)	52 (46.8)	23 (24.2)
Missing/unclassifiable	17 (17.9)	17 (18.5)	10 (10.3)	18 (17.1)	57 (60.0)
Subtotal	95	92	97	110	95
Hypertrophic cardiomyopathy					
Secondary prevention	49 (21.5)	48 (19.2)	45 (14.2)	80 (20.4)	82 (20.5)
Prophylactic implantation	166 (72.8)	198 (79.2)	207 (65.3)	288 (73.5)	325 (79.8)
Missing/unclassifiable	13 (5.7)	4 (1.6)	65 (20.5)	24 (6.1)	12 (2.8)
Subtotal	228	250	317	392	419
Brugada syndrome					
Aborted SCD	11 (15.5)	14 (18.9)	10 (12.0)	10 (9.5)	9 (8.0)
Prophylactic implantation in syncope	16 (22.5)	14 (18.9)	23 (27.7)	18 (17.1)	7 (6.2)
Prophylactic implantation without syncope	38 (53.5)	14 (18.9)	40 (48.2)	56 (53.3)	22 (19.6)
Missing/unclassifiable	6 (8.4)	17 (23.0)	10 (12.0)	21 (20.0)	74 (66)
Subtotal	71	74	83	105	112
ARVC					
Aborted SCD	3 (12.5)	4 (10.3)	4 (8.2)	5 (8.9)	3 (4.1)
SMVT	7 (29.1)	16 (41.0)	14 (28.6)	6 (10.7)	8 (11.0)
Prophylactic implantation	10 (41.6)	14 (35.9)	22 (44.9)	29 (51.8)	36 (49.3)
Missing/unclassifiable	4 (16.6)	5 (12.8)	9 (18.4)	16 (28.5)	26 (35.6)
Subtotal	24	39	49	56	73
Congenital heart disease					
Aborted SCD	6 (12.0)	7 (15.2)	6 (14.6)	3 (7.0)	2 (2.4)
SMVT	10 (20.0)	14 (30.4)	11 (26.8)	6 (13.9)	3 (3.6)
Prophylactic implantation	29 (58.0)	21 (45.6)	20 (48.8)	27 (62.8)	58 (69.8)
Missing/unclassifiable	5 (10.0)	4 (8.7)	4 (9.7)	7 (16.3)	20 (24.0)
Subtotal	50	46	41	43	83
Long QT syndrome					
Aborted SCD	15 (48.4)	9 (24.3)	15 (40.5)	9 (21)	2 (7.2)
Prophylactic implantation	12 (38.7)	18 (48.6)	15 (40.5)	23 (53.6)	11 (39.9)
Missing/unclassifiable	4 (12.9)	10 (27.3)	7 (18.9)	11 (25.6)	15 (53.6)
Subtotal	31	37	37	43	28

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

Table 3
Changes in the main indications for implantable cardioverter-defibrillators (first implants, 2012-2021)

Year	SCD	SMVT	Syncope	Primary prevention
2012	12.5	10.2	19.1	58.1
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

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

4.5%. Other specialists and intensivists were involved in 0.9% and 4.3%, respectively.

Generator placement site

Transvenous ICD generator placement was reported for 66.3% of first implants, with a subcutaneous location in 98.2% of cases and subpectoral in the remaining 1.8%. These figures were 98.2% and 1.7%, respectively, for all devices implanted.

Device type

The type of device implanted is shown in table 4 (information reported in 78.3% of forms submitted to the registry). Among first implants performed in 2021 and in previous years, the data show a reduced percentage of subcutaneous ICD and dual-chamber ICD implants, a similar percentage of CRT-ICD implants, and an increased percentage of single-chamber ICD implants.

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

The most frequent cause of ICD generator replacement was battery depletion (88.5%), with complications prompting 7.3% of replacements. A change in indication prompted 4.1%.

Of the 891 replacements providing this information, 1.6% were performed before 6 months. In addition, 30.2% of forms provided information on the status of leads, which were malfunctioning in 19 patients.

Device programming

With data on 57.0% of implants, the most widely used programming was VVI (47.7%), followed by DDD (24.5%), VVIR (5.0%), DDDR (6.34%), and others (6.3%), which were largely algorithms or modes to prevent ventricular pacing.

At least 1 ventricular fibrillation induction test was conducted in 292 patients (10%). Defibrillation testing was largely performed in patients with subcutaneous ICD implantation and in just 12 patients during transvenous ICD implantation. The mean number of shocks delivered was 1.07. Thus, in the overwhelming majority of cases, correct device functioning was evaluated and not the threshold.

Complications

Complication data were recorded in 31.5% of forms. There were 19 complications: 9 suboptimal positions of the left ventricular lead, 2 pneumothoraces, 2 deaths, 1 coronary sinus dissection, and 5 unspecified complications. As in previous years, the mortality rate was very low, at 0.03%.

DISCUSSION

Of the historic series, 2021 has been the year with the highest number of ICD implants in Spain, reaching an ICD implantation rate of 158 per million population (163 according to Eucomed). However, the data still show major differences in implantation rates among the autonomous communities and rates far below the mean ICD implantation rate in Europe. Nonetheless, the 2021 registry reflects the recovery in hospital activity after the reduction seen in 2020 due to the COVID-19 pandemic.[11–13]

Comparison with registries of previous years

Over the period evaluated, there has been a gradual increase in the number of ICDs implanted vs previous years, with isolated reductions in 2011 to 2012, 2017, and 2020. In 2020, there was a 4% decrease in ICD implants vs 2018 and 2019 (the years with the highest recorded activity before 2021) as a consequence of the reduced hospital activity related to the COVID-19 pandemic. A recovery in ICD implant-related activity was seen in 2021. Nonetheless, somewhat of an impact of the COVID-19 pandemic on ICD implants could still be seen during January and February, with the recovery in March coinciding with the end of the third wave in Spain. Thus, March showed 29% and 20% increases in ICD implants vs February and January, respectively, and was the month with the highest number of implants in all of 2021. In general, 2021 can be considered a year of recovery and a resumption of the activity growth curve seen in 2018 and 2019. Despite this growth, the mean ICD implantation rate per million population in Spain

Table 4
Percent distribution of implanted devices by type

	Total									First implants					
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2016	2017	2018	2019	2020	2021
Subcutaneous				3.6	3.8	4.4	6.2	5.7	8.6	6.4	5.3	6.0	8.3	8.1	7.3
Single-chamber	48.2	48.8	48.6	45.4	45.7	46.6	45.6	45.1	46.7	48.4	49.4	50.1	47.7	50.2	52.6
Dual-chamber	18.9	17.4	14.5	13.7	15.0	15.0	13.8	14.1	10.6	13.0	14.1	13.4	12.6	12.4	10.5
Resynchronization device	32.9	33.7	35.7	37.3	35.7	34.0	34.4	34.7	34.1	32.1	31.5	30.6	31.4	29.3	29.7

(163 implants) is the lowest of all European Union countries and continues to be far from the European average, which was 285 implants per million population in 2020, despite the reduced activity also seen that year in Europe.[14]

ICD implants in Spain continue to be less frequent than expected given the scientific evidence supporting the clinical practice guidelines.[1–3] This situation is not specific to Spain and its consequences were highlighted in a study performed in Sweden[15] that showed that just 10% of patients with a primary prevention indication for an ICD for sudden cardiac death (according to European Society of Cardiology guidelines) between 2000 and 2016 ultimately received the device. ICD implantation was associated with mortality reductions of 27% in the first year of follow-up and 12% at 5 years. Another European registry also showed the benefit of ICDs in the primary prevention of sudden cardiac death in both ischemic and nonischemic patients, with a 27% reduced risk of death during a mean follow-up of 2.5 years.[16] Our registry results also show the clear underuse of ICD therapy in Spain and highlight the importance of the adoption of new measures to increase ICD use in patients who would benefit from the devices.

This latest registry confirms the increase in primary prevention indications detected in recent years, with an 86.4% rate of prophylactic implants (table 3). The rate of prophylactic implantation has increased by 51% in the last 10 years. For the first time, our rate is similar to that of Europe, where primary prevention is the leading indication for ICD implantation, with rates of about 80%.[17,18]

Regarding the types of devices implanted in Spain, there was a stabilization in the percentage of first implants of CRT-ICDs at about 30%, as well as a fall in dual-chamber ICD implants. In addition, the data showed a drop in the percentage of first implants of subcutaneous ICDs (7.3% in 2021), after peaks of 8.3% and 8.1% were reached in 2019 and 2020, respectively. The reduced percentage of subcutaneous ICDs was followed by an increase in single-chamber ICD devices, which were the most frequently implanted type of device in Spain (52.6% of all first implants). Although the publication in 2020 of the Praetorian[19] and Untouched[20] studies, which obtained positive results for subcutaneous ICDs, might have led to a gradual increase in their use, this has not been found in Spain. These figures can probably be explained by factors such as the higher cost per unit or the safety alerts experienced by these devices in recent years.

The most frequent indication in 2020 continued to be ischemic heart disease (56.8%), followed by dilated cardiomyopathy (26.8%). These data consolidate the stabilization observed in 2019 in the percentage of patients with dilated cardiomyopathy as the heart disease prompting the ICD implantation after the reduction seen in previous years. This fall was largely due to lower use of ICD therapy in the primary prevention of sudden cardiac death, which fell drastically in Spain after the publication of the DANISH study.[21] This phenomenon was also seen to a greater or lesser extent in other European countries.[22] Recently, the European Society of Cardiology guidelines for the diagnosis and treatment of heart failure, released in 2021,[23] decreased the level of recommendation for ICD in the primary prevention of sudden cardiac death in patients with nonischemic dilated cardiomyopathy (IIa A), largely due to the results of the DANISH study. However, the same guidelines recognize a possible benefit of ICDs in patients with dilated cardiomyopathy and age < 70 years, who were found, in the same study, to have a 30% reduction in mortality (hazard ratio [HR] = 0.70; 95% confidence interval [95%CI], 0.51-0.96; $P = .03$).[24] In addition, the guidelines consider the results of a meta-analysis including the DANISH trial, in which ICDs were found to reduce all-cause mortality in patients with nonischemic cardiomyopathy.[25] In a recent cost-effectiveness analysis of ICD implantation for the primary prevention of sudden cardiac death in Spain, ICDs were associated with reduced all-cause mortality in both ischemic (HR = 0.70; 95%CI, 0.58-0.85) and nonischemic (HR = 0.79; 95%CI, 0.66-0.96) heart disease. The cost-effectiveness ratio estimated through probabilistic analysis was €19 171 per quality-adjusted life year (QALY) in patients with ischemic heart disease, €31 084 per QALY in patients with nonischemic dilated cardiomyopathy, and €23 230 per QALY in individuals younger than 68 years.[26] These results confirm the efficacy of single-chamber ICDs in Spain in the primary prevention of sudden cardiac death in patients with left ventricular dysfunction of both ischemic and nonischemic origin, particularly in patients younger than 68 years.

Differences among autonomous communities

The 2021 registry continues to show major differences among autonomous communities in the implantation rate per million population. Several autonomous communities showed higher rates than the average: Cantabria (384), Principality of Asturias (234), La Rioja (203), Extremadura (184), the Valencian Community (179), Galicia (174), Castile-La Mancha (173), Chartered Community of Navarre (170), Aragon (164), Community of Madrid (163), and Region of Murcia (159). Below average were Catalonia (151), Castile and León (143), the Basque Country (138), Andalusia (134), the Canary Islands (125), and the Balearic Islands (119). The difference between the communities with the highest and lowest implantation rates has increased to 265 units from 180 in 2020 and 139 in 2019. The disparity in ICD implantation rates among the different autonomous communities continues to be difficult to explain in the context of a supposedly uniform health care system such as that of Spain. These differences are not explained by income level or population density or by the different incidences of ischemic heart disease and heart failure among the autonomous communities. This situation might call into question the equity of our health care system in an area as important as the prevention of sudden cardiac death.

Comparison with other countries

In 2020 (the year with the greatest impact of the COVID-19 pandemic), the implantation rate in the countries participating in Eucomed was 285 per million population (303 in 2019, 302 in 2018, 307 in 2017, and 316 in 2016), including ICDs and ICD-CRTs. The countries with the highest implant numbers were the Czech Republic and Germany (474 and 445 devices per million population, respectively). Despite being compared with a year of reduced hospital activity in Europe, Spain continues to be the country with the lowest number of implants per capita (163 implants/million population in 2021).

There is no simple explanation for these differences. Our neighboring countries have the same regional differences[27] seen in the Spanish registry. One possible explanation is the number of available arrhythmia centers, but that does not explain the relationship, at least in Spain, because communities with the highest number of available centers had lower implantation rates. Income does not seem to be factor because countries with lower incomes than Spain, such as Ireland, the Czech Republic, and Poland, show much higher implantation rates. Nor can this disparity be explained by differences in the prevalences of cardiovascular diseases. Regardless, the low implantation rate in Spain might reflect a lower degree of adherence to clinical practice guidelines, which has been linked to increased mortality in patients with cardiovascular disease. This situation means that we must remain cognizant of the problem and do everything in our power to alleviate it.

Limitations

In 2021, our registry collected data on 96.8% of all implants, which represents the vast majority of all ICDs implanted in Spain. As in previous years, completion of the different fields in the implantation form varied and was lower than desired. In addition, no follow-up data were collected from patients, which would permit more relevant clinical studies. Finally, the unequal completion of the data on ICD implantation-related complications and the absence of follow-up data probably underestimate the true rate of complications.

Future prospects of the Spanish implantable cardioverter-defibrillator registry

This is the 18th official report of the registry, and its extended durability is a credit to all of the participating members of the Heart Rhythm Association of the SEC. The use of the webpage for online completion of the implantation form for both ICDs and pacemakers, whose development involved the collaboration of the SEC and the Spanish Agency for Medicines and Health Products, strengthened in 2021, although its use varies among the different centers participating in the registry. This website enables the real-time recording of both types of implantable heart devices.

CONCLUSIONS

The 2021 Spanish Implantable Cardioverter-defibrillator Registry collected information on 96.8% of all implants performed in Spain, approximating the overwhelming majority of the activity and current indications for this therapy in Spain. In 2021, the total number of implants per million population increased as a result of the recovery in hospital activity after the impact of the COVID-19 pandemic. However, differences in ICD implantation rates persist among the various autonomous communities. In addition, the differences in the implantation rate between Spain and the other European countries are still wide, which indicates our need to improve our ability to identify patients who may benefit from this therapy.

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AUTHORS' CONTRIBUTIONS

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

CONFLICTS OF INTEREST

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

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