

Special article

Spanish Pacemaker Registry. 18th Official Report of the Cardiac Pacing Section of the Spanish Society of Cardiology (2020)

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ABSTRACT

Introduction and objectives: This report describes the cardiac pacing activity performed in Spain in 2020, including the number and type of implanted devices, demographic and clinical factors, and data on remote monitoring.**Methods:** Information consisted of the European Pacemaker Patient Card, data submitted to the cardiadispositivos.es online platform, the databases of participating centers, and supplier-reported data.**Results:** A total of 14 662 procedures were registered from 102 hospitals, representing 39.2% of the estimated activity. The implantation rates of conventional and low-energy resynchronization pacemakers were 759 and 31 units per million population, respectively. In all, 520 leadless pacemakers were implanted, 70 with atrioventricular synchrony. The mean age at implantation was high (78.8 years), and the most frequent electrocardiographic change was atrioventricular block. There was a predominance of dual-chamber pacing mode but VVI/R single-chamber pacing was used in 19% of patients in sinus rhythm, depending on age and sex. Remote monitoring capability was present in 18.5% of implanted conventional pacemakers and 45.6% of low-energy resynchronization pacemakers, although registration in this system increased by 53% in 2020.**Conclusions:** In 2020, in the context of the SARS-CoV-2 pandemic, the number of implanted conventional pacemakers decreased by 8% and cardiac resynchronization therapy by 4.6%. The number of leadless pacemakers increased by 16.5%. Sequential pacing was predominant, influenced by age and sex. Home monitoring played a fundamental role as a mode of follow-up in this SARS-CoV-2 pandemic year.

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Registro Español de Marcapasos. XVIII Informe Oficial de la Sección de Estimulación Cardíaca de la Sociedad Española de Cardiología (2020)

RESUMEN

Palabras clave:

Marcapasos

Registro

Monitorización a distancia

Introducción y objetivos: Se describe la actividad de estimulación cardíaca realizada en España en 2020: cuantía y tipo de dispositivos, factores demográficos y clínicos y datos sobre monitorización a distancia.**Métodos:** Se utilizan como fuentes de información la Tarjeta Europea de paciente portador de Marcapasos, la plataforma *online* cardiadispositivos.es, las bases de datos propias de centros y los datos facilitados por las empresas proveedoras.**Resultados:** Se registran 14.662 procedimientos de 102 hospitales, lo que supone el 39,2% de la actividad estimada. La tasa de marcapasos convencionales y resincronizadores de baja energía es de 759 y 31 unidades/millón respectivamente. Se implantan 520 marcapasos sin cables, 70 con sincronía auriculoventricular. La media de edad al implante es elevada (78,8 años) y el bloqueo auriculoventricular, la alteración electrocardiográfica más frecuente. Predomina el modo de estimulación bicameral, aunque en el 19% de los pacientes en ritmo sinusal se realiza una estimulación monocameral VVI/R, condicionada por edad y sexo. Se incluyen en programa de monitorización a distancia el 18,5% de los marcapasos implantados y el 45,6% de los resincronizadores de baja energía, aunque aumentan en un 53% las altas en este sistema durante 2020.**Conclusiones:** En 2020, en contexto de la pandemia por SARS-CoV-2, disminuye el número de marcapasos convencionales implantados un 8% y el de terapias de resincronización cardíaca, un 4,6%.* Corresponding author: Agencia Pública Empresarial Sanitaria Costa del Sol, Servicio de Cardiología, Autovía A7 Km 187, 29601 Marbella, Málaga, Spain.
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Aumenta el número de marcapasos sin cables un 16,5%. Predomina la estimulación secuencial, influida por edad y sexo. La monitorización domiciliar cobra un papel fundamental como modo de seguimiento en el año de la pandemia por SARS-CoV-2.

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Abbreviations

AF: atrial fibrillation
 AVB: atrioventricular block
 CRT: cardiac resynchronization therapy
 CRT-D: cardiac resynchronization therapy with defibrillator capacity
 CRT-P: low-energy cardiac resynchronization therapy without defibrillator capacity
 CRT-T: total cardiac resynchronization therapy
 SSS: sick sinus syndrome

INTRODUCTION

The present report, drafted by the Cardiac Pacing Section of the Spanish Society of Cardiology (SEC), contains the cardiac pacing activity corresponding to Spain in 2020, previously collected in the Spanish National Pacemaker Data Bank. This document includes overall data on devices implanted and compares the data with those of previous years^{1–9} and those provided by our neighboring countries.¹⁰ Clinical and demographic data are also collected on the individuals receiving these devices.

The health care crisis triggered by the SARS-CoV-2 pandemic has had a major impact on cardiac pacing activity, as on all health care fields, particularly on the device implantation rate and the preferential selection of remote monitoring as follow-up.

METHODS

The information sources used were the European Pacemaker Patient Identification Card (EPPIC), sent to the Spanish National Pacemaker Data Bank, the information submitted to the online platform CardioDispositivos.es,¹¹ and the proprietary databases of some of the centers.

Population statistics were obtained from the Spanish National Institute of Statistics on March 22, 2021, and refer to the population of Spain as of July 1, 2020.¹²

Given that the information provided by the implanting centers is still scarce, the total implantation figures were based on the data provided by the device manufacturers and checked against those provided by the European Confederation of Medical Suppliers Association (Eucomed).¹⁰

RESULTS

Sample quality

In 2020, 14 662 procedures were recorded in 102 hospitals (table 1), 6040 obtained via the CardioDispositivos.es platform and 8622 from the EPPICs or proprietary databases.

Because the EPPICs and the online platform forms are not always fully completed, some data were missing on all parameters

Table 1

Public and private hospitals submitting data to the Spanish Pacemaker Registry in 2020, grouped by autonomous community and with the numbers of interventions performed in each center.

Center	Interventions
<i>Andalusia</i>	1677
Complejo Hospitalario de Jaén	78
Hospital Costa del Sol	187
Hospital de la Serranía	30
Hospital Universitario Puerto Real	27
Hospital Universitario San Cecilio	186
Hospital Universitario Virgen del Rocío	349
Hospital del S.A.S. de Jerez de la Frontera	85
Hospital General de Jerez de la Frontera	37
Hospital Punta de Europa	115
Complejo Hospitalario Reina Sofía	1
Hospital Universitario Virgen de Valme	279
Sanatorio Virgen del Mar	1
Hospital Universitario Virgen de las Nieves	293
Hospital Santa Ana de Motril	9
<i>Aragon</i>	573
Hospital General San Jorge	103
Hospital Obispo Polanco	39
Hospital Universitario Miguel Servet	426
Hospital Rojo Villanova	5
<i>Principality of Asturias</i>	173
Fundación Hospital de Jove	56
Hospital Universitario San Agustín	101
Centro Médico Asturias	16
<i>Balearic Islands</i>	384
Grupo Juaneda	19
Hospital de Manacor	74
Hospital Universitario Son Espases	282
Hospital Mateu Orfila	1
Hospital Universitario Son Llàtzer	8
<i>Canary Islands</i>	849
Complejo Hospitalario Universitario de Canarias	194
Hospital Universitario de Gran Canaria Dr. Negrín	349
Hospital Universitario Nuestra Señora de Candelaria	276
Hospital General de la Palma	29
Hospital San Juan de Dios de Tenerife	1
<i>Castile-La Mancha</i>	939
Complejo Hospitalario General de Albacete	366
Hospital General Universitario de Ciudad Real	216
Hospital General Virgen de la Luz	99
Hospital Virgen de la Salud	258
<i>Castile and León</i>	1589
Complejo Asistencial Universitario de Palencia	127
Hospital Clínico Universitario de Salamanca	378
Hospital Nuestra Señora de Sonsoles	4
Hospital Universitario de Burgos	255
Hospital Universitario de Valladolid	153

Table 1 (Continued)

Public and private hospitals submitting data to the Spanish Pacemaker Registry in 2020, grouped by autonomous community and with the numbers of interventions performed in each center.

Center	Interventions
Hospital Virgen de la Concha	147
Hospital de León	356
Hospital Río Hortega	169
<i>Catalonia</i>	1856
Complejo Hospitalario Parc Taulí	144
Hospital de Sant Pau i Santa Tecla	1
Hospital del Mar	174
Hospital Arnau de Vilanova	282
Hospital de Terrassa	72
Hospital del Vendrell	37
Hospital Germans Trias i Pujol	2
Hospital Joan XXIII de Tarragona	135
Hospital Universitario Mútua de Terrassa	103
Parc Sanitari Sant Joan de Déu	55
Hospital de Girona Dr. Josep Trueta	577
Hospital Clínico y Provincial de Barcelona	163
Hospital de Tortosa Verge de la Cinta	111
<i>Extremadura</i>	108
Hospital Virgen del Puerto Plasencia	62
Hospital Comarcal de Zafra	46
<i>Galicia</i>	2079
Complejo Hospitalario Universitario A Coruña	442
Complejo Hospitalario Universitario de Ferrol	87
Hospital Clínico Universitario de Santiago	426
Hospital Álvaro Cunqueiro	402
Hospital Montecelo	232
Hospital Lucus Augusti	368
Complejo Hospitalario Arquitecto Marcide	122
<i>Community of Madrid</i>	1867
Fundación Hospital de Alcorcón	91
Hospital Universitario Fundación Jiménez Díaz	70
Hospital Universitario Puerta de Hierro-Majadahonda	226
Hospital de Fuenlabrada	19
Hospital del Henares	70
Hospital General Gregorio Marañón	445
Hospital Universitario Príncipe de Asturias	106
Hospital Universitario de Getafe	137
Hospital Universitario 12 de Octubre	253
Clínica Virgen del Mar	1
Clínica Universidad de Navarra (Madrid)	9
Hospital Clínico San Carlos	440
<i>Region of Murcia</i>	594
Hospital General Universitario Santa Lucía de Cartagena	90
Hospital Morales Meseguer	178
Hospital General Santa María del Rosell (Santa Lucía)	191
Hospital Dr. Rafael Méndez	135
<i>Chartered Community of Navarre</i>	116
Clínica Universidad de Navarra	113
Complejo Hospitalario de Navarra	3
<i>La Rioja</i>	219
Hospital San Pedro	217
Hospital Viamed Los Manzanos	2
<i>Valencian Community</i>	1238
Clínica Vista Hermosa	24

Table 1 (Continued)

Public and private hospitals submitting data to the Spanish Pacemaker Registry in 2020, grouped by autonomous community and with the numbers of interventions performed in each center.

Center	Interventions
Hospital Arnau de Vilanova de Valencia	105
Hospital General Universitario de Alicante	129
Hospital General Universitari de Castelló	1
Hospital IMED Levante	16
Hospital Universitario de San Juan de Alicante	166
Hospital Universitario del Vinalopó	44
Hospital Universitario y Politécnico La Fe	332
Hospital General Universitario de Elche	123
Hospital IMED de Elche	3
Hospital Perpetuo Socorro	7
Hospital de la Vega Baja	5
Hospital de Manises	101
Hospital IMED Valencia	1
Hospital Clínico Universitario de Valencia	181
<i>Basque Country</i>	401
Hospital Universitario Araba	222
Hospital de Galdakao	179
<i>Total</i>	14 662

analyzed: 7.2% on pacing mode, 14% on lead position, 13.1% on age, 18% on sex, 25.9% on lead polarity, 24% on type of lead fixation, 49.1% on the preimplantation electrocardiogram, 55.2% on symptoms, 67.2% on etiology, 68.9% on reason for generator explantation, and 84.1% on reason for lead explantation. The results reported here were based on the available data, after exclusion of missing information.

Numbers of conventional pacemakers

According to Spanish Pacemaker Registry data, 35 926 conventional pacemakers were implanted in Spain in 2020, representing a rate of 759 units/million population (figure 1). However, according to Eucomed, the pacemaker implantation rate was 766 units/million in Spain in 2020.

Regarding the distribution by autonomous community, Galicia and Cantabria stood out with 1051 and 925 units/million population, respectively, as well as Castile and León and Madrid with 869 units/million (figure 2); the autonomous communities with the lowest rates were the Canary Islands, Extremadura, and Navarre with 609, 563, and 552 units/million, respectively.

Cardiac resynchronization devices

According to the Spanish Pacemaker Registry, 3850 total cardiac resynchronization therapy (CRT-T) devices were implanted in Spain in 2020, comprising 1463 cardiac resynchronization therapy without defibrillation (CRT-P) devices and 2387 cardiac resynchronization therapy with defibrillation (CRT-D) devices. The CRT-T device rate was 81 units/million population, whereas that of CRT-P devices was 31 units/million, which was the same figure as that reported by Eucomed.

For CRT-T devices, Cantabria stood out with 176 units/million population, followed at quite a distance by Asturias and the Community of Madrid with 105 and 104 units/million, respectively. Regarding CRT-P devices, Cantabria was once again top of the

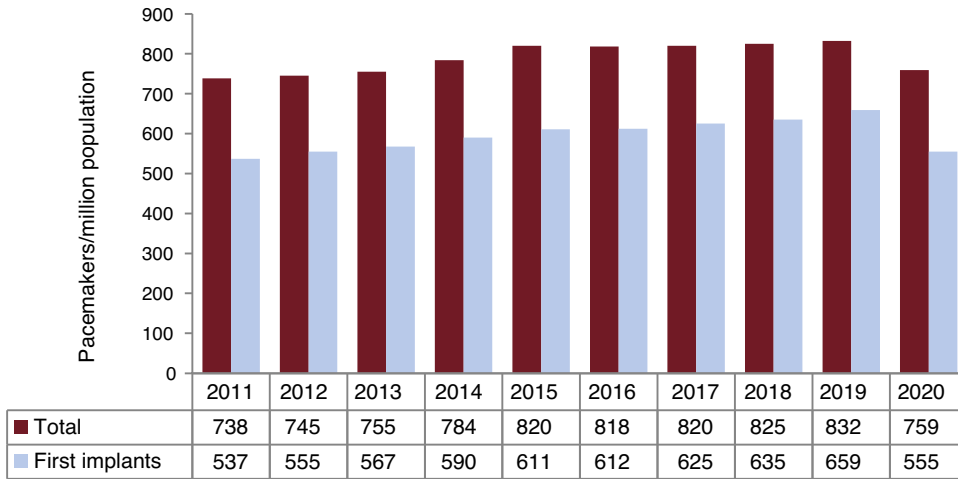


Figure 1. Total number of pacemaker generators and first implants per million population from 2011 to 2020.

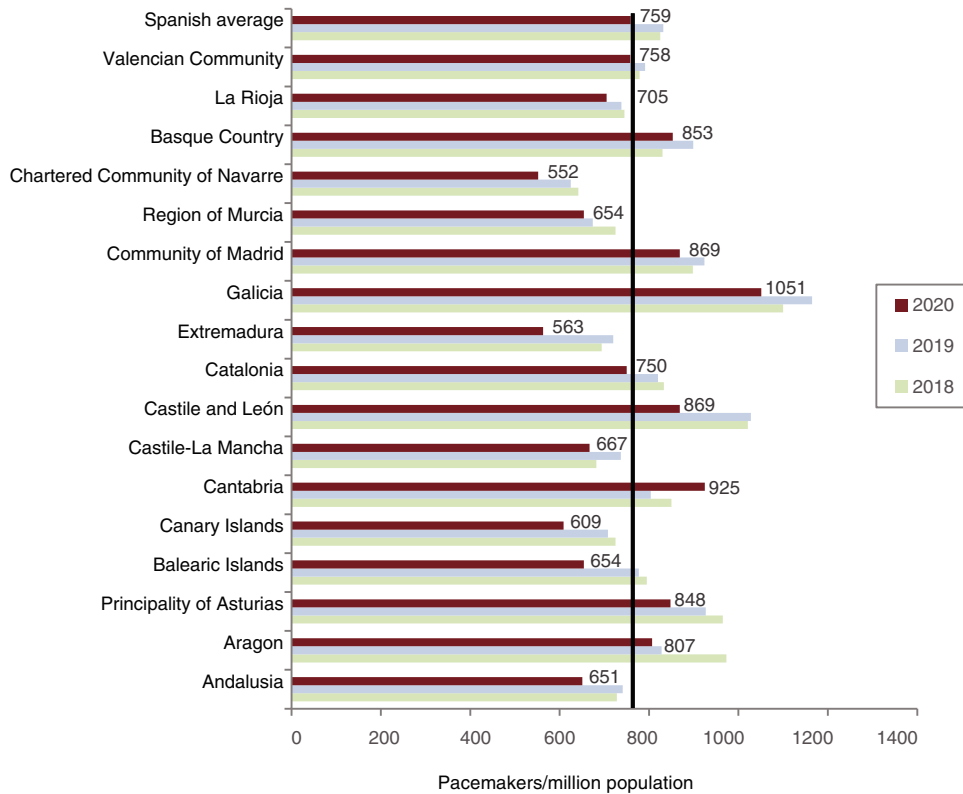


Figure 2. Pacemaker use per million population (national average and by autonomous community) from 2018 to 2020.

list with 94 units/million population, followed by the Community of Madrid and Navarre with 46 units/million. La Rioja had the lowest number of CRT-T devices with 19 units/million population, whereas Aragon implanted 0 CRT-P devices (figure 3).

Leadless pacemakers

In 2020, 520 Micra (Medtronic, United States) model leadless pacemakers were implanted, 70 with the ability to maintain atrioventricular (AV) synchrony. Catalonia and Madrid continued

to be the autonomous communities with the highest number of such implants (115 and 113 units), followed by Galicia with 93; these 3 provinces represented 61.7% of leadless pacemakers implanted. Aragon, Cantabria, Extremadura, and La Rioja did not implant any pacemakers of this type (figure 4).

Age and sex

Pacemaker implantation was much more frequent in men (59.3% of devices vs 40.7% in women), both for first implants (60.1% vs 39.9%) and replacements (57.2% vs 42.7%).

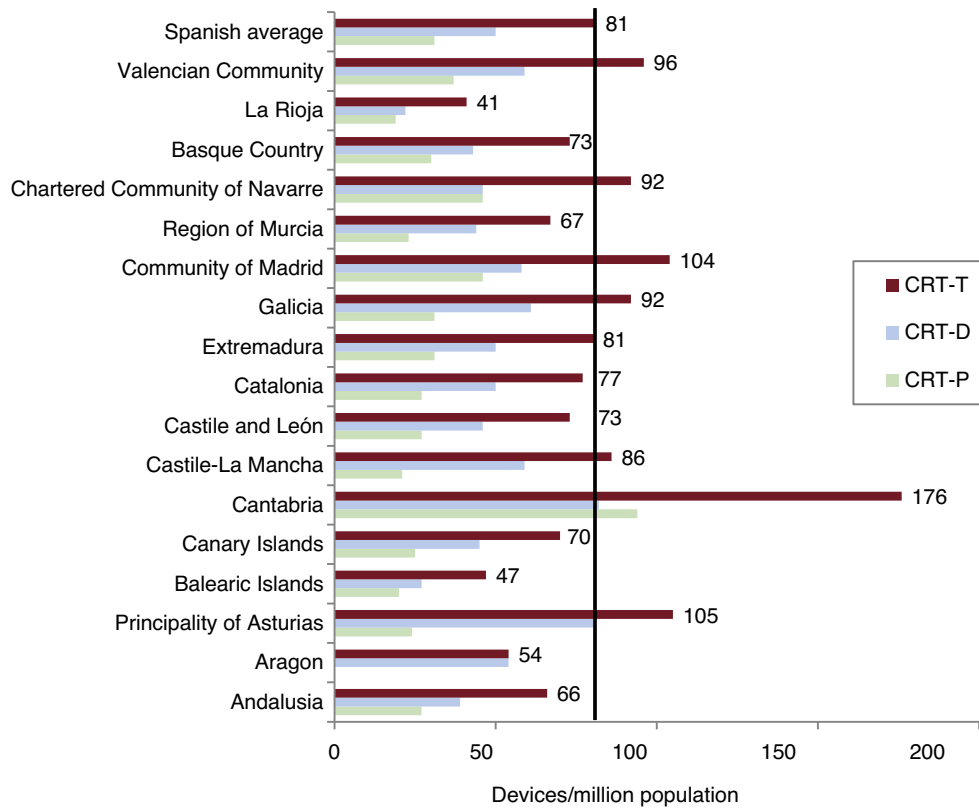


Figure 3. Cardiac resynchronization therapy devices per million population in 2020 (national average and by autonomous community). CRT-D, cardiac resynchronization therapy with defibrillation; CRT-P, cardiac resynchronization therapy without defibrillation; CRT-T, total cardiac resynchronization therapy.

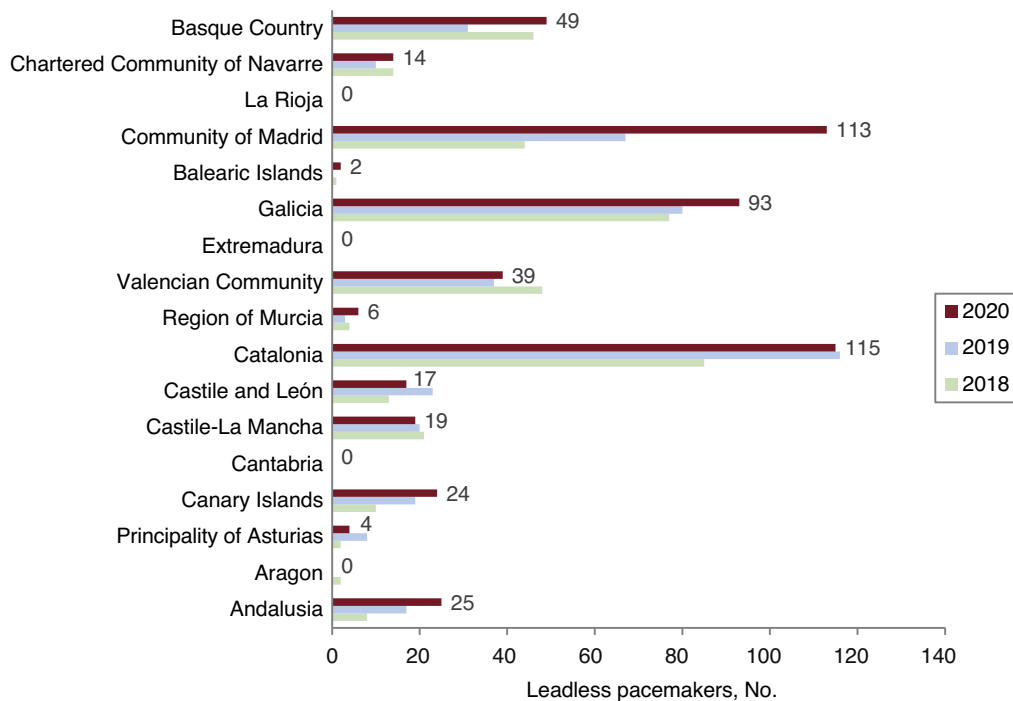


Figure 4. Leadless pacemakers implanted by autonomous community from 2018 to 2020.

The average age of pacemaker recipients was 78.8 years. It was slightly higher in women than in men (80.2 vs 77.8 years) and for replacements vs first implants (80.7 vs 78.2 years). Just 1.7% of devices were implanted in individuals younger than 50 years, as well as 2.8% in those 50 to 59 years, 10.7% in those 60 to 69 years, 30.6% in those 70 to 79 years, 42.5% in those 80 to 89 years, 11.6% in those 90 to 99 years, and 0.1% in those older than 100 years.

Etiology and symptoms prompting implantation

Conduction system fibrosis continued to be the predominant etiology (85.4% of implants). The other etiologies were infrequent: ischemia (2.9%), infarction (0.6%), iatrogenic due to surgery (3.5%), ablation (0.9%), TAVI (1.1%), carotid sinus syndrome (0.4%), vasovagal syncope (0.4%), congenital heart disease (0.7%), unspecified cardiomyopathy (0.6%), hypertrophic cardiomyopathy (0.5%), dilated cardiomyopathy (1%), endocarditis/myocarditis (0.1%), heart transplant (0.1%), and valvular heart disease (1.8%).

Syncope was the symptom most frequently prompting implantation (41.8% of cases), followed by dizziness (25.1%) and heart failure (14.6%).

Preimplantation electrocardiogram

Atrioventricular block (AVB) was the most frequent preimplantation electrocardiographic abnormality (62.7% of cases). Third-degree AVB predominated (40.1%), followed by second-degree (14.7%) and first-degree (1.3%). Atrial fibrillation (AF) with complete heart block was seen in 6.6% of preimplantation electrocardiograms. AVB was followed by sick sinus syndrome (SSS) (28.3% of cases). Sinus bradycardia/sinus pauses prompted 6.2% of implants, followed by bradycardia-tachycardia syndrome (5.9%) and, with lower frequency, sinoatrial block/pause (1.9%). Other abnormalities such as chronotropic incompetence and interatrial block represented less than 1% of implants. The SSS subtype was unspecified in 1.8% of implants. Slow AF was present in 12.2% of preimplantation electrocardiograms and an intraventricular conduction defect was found in 6.1% (figure 5).

Regarding the distribution by sex, AVB was more frequent in men than in women (57.5% vs 53.8%, excluding blocked AF), whereas SSS was more frequent in women (21.9% vs 9.7%,

excluding slow AF). Slow or blocked AF prompted 19.2% of implants in men and 16.4% of those in women. Intraventricular conduction defect was practically twice as common in men as in women (8.0% vs 4.2%).

Type of procedure

Of procedures, 73.1% were first implants and 25.3% were exclusively generator replacements. Generator and lead replacements represented 2.1% of cases, whereas lead replacement alone comprised 0.5%. The most frequent reason for generator replacement continued to be end-of-life battery depletion (73.9%), followed by elective replacement (18.4%), pacemaker syndrome (1.5%), infection/erosion (2.7%), premature depletion (1%), dysfunction (0.7%), advisories (0.7%), and other unspecified causes.

In the case of lead explantation, the most frequent cause was infection/ulceration (45.9%), followed by displacement (19.7%), insulation failure or conduit rupture (18.1%), dysfunction (6.5%), perforation (1.6%), and other unspecified causes (8.2%).

Electrode type

Active-fixation leads represented 89.6% of leads, with similar rates for the right atrium and ventricle (90.4% and 90.9%, respectively), as well as 22.1% of coronary sinus leads. Most leads were bipolar (98.5%; 99.6% in the right atrium and 99.3% in the right ventricle). In addition, 65.4% of coronary sinus leads were tetrapolar, according to CardioDispositivos.es data.¹¹

Magnetic resonance imaging-compatible leads comprised 82.1% of leads, with a slightly higher rate for patients \leq 80 years than in those $>$ 80 years (83.2% vs 80.3%) and in the right atrium than in the right ventricle (85.5% vs 81.4%), according to data submitted to the CardioDispositivos.es platform, the most reliable information source for this parameter.¹¹

Pacing modes

Sequential dual-chamber pacing with 2 leads (DDD/R) continued to be the most commonly used pacing mode in 2020 (51.9% of all procedures, 55% of first implants, and 43.4% of pacemaker replacements), in line with the upward trend of recent years. In

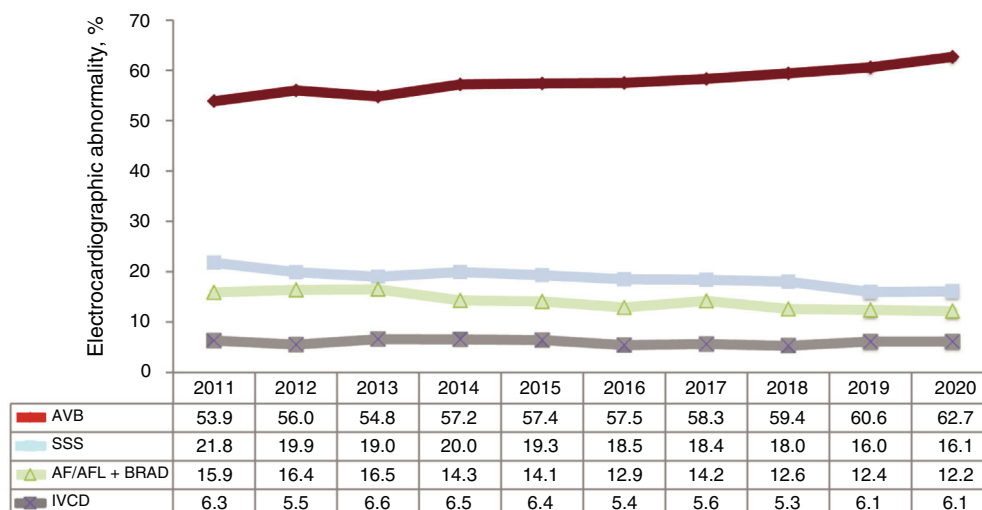


Figure 5. Trends in electrocardiographic abnormalities from 2011 to 2020. AF/AFL + BRAD, atrial fibrillation or atrial flutter with bradycardia; AVB, atrioventricular block; IVCD, intraventricular conduction defect; SSS, sick sinus syndrome.

contrast, the use of VDD pacemakers broke the previously recorded downtrend trend and stabilized at 6.9% of procedures (4.3% of first implants and 14% of replacements).

Single-chamber pacing was used in 37.8% of all procedures, vs 38.5% in 2019, largely due to single-chamber ventricular pacing (VVI/R) (37.5% of all interventions). Single-chamber atrial pacing (AAI/R) continued to be negligible in Spain, with 36 reported procedures (0.3%); just 18 were first implants (figure 6).

Still underused, although becoming more common, biventricular CRT-P pacing represented 3.1% of all implants (2.7% with atrial leads vs 0.4% with biventricular pacing alone).

Compared with men, women received more single-chamber VVI/R pacing (39.7% vs 36.5% of procedures) and VDD pacing (8.5% vs 6.4% of procedures reported) but less dual-chamber pacing DDD/R pacing (49.8% vs 53.3%).

Pacing mode selection

Atrioventricular block

This section excludes patients with AVB and permanent atrial tachyarrhythmia (EPPIC code C8) to properly assess the degree of adherence to the most recommended pacing modes in the clinical practice guidelines. Factors possibly influencing this selection were analyzed, such as patients' age and sex and the degree of AVB.

Pacing capable of maintaining AV synchrony increased again, accounting for 76.5% of cases, and DDD/R mode was the most commonly used mode (66.9% of implants); VDD/R mode comprised 8.4%. A notable finding was the negligible use of CRT-P therapy with atrial pacing for this conduction disorder, at 1.2% of implants (figure 7).

Age and sex continued to determine whether AV synchrony will be maintained. In patients ≤ 80 years, pacemakers capable of maintaining AV synchrony were used in 89.8% of cases, vs 60.5% of cases in patients > 80 . VDD implantation continued to fall in patients ≤ 80 years and represented 3.9% of cases in 2020 vs 5.3% in 2019; however, it was still frequent in those > 80 years (13.4%). Regarding sex, the differences seen in previous years decreased, although men were more likely to benefit from sequential pacing, which maintains AV synchrony. Thus, 78.6% of men received this

pacing mode, with DDD/R mode documented in 69.9% of EPPICs reported. In women, pacing capable of maintaining AV synchrony represented 72.1% of cases and VDD pacing was more common than in men (11.3% vs 7.1%). Nonetheless, this difference was magnified by the disparity in reported procedures because there were more men ≤ 80 years. When these differences were analyzed by age, men ≤ 80 years used sequential AV pacing (DDD/R, VDD/R, or CRT-P) in 90.7% of cases vs 88.8% in women. For those > 80 years, these pacing types were used in 61.7% of men and in 60.4% of women (table 2).

Regarding pacing mode, no major changes were seen vs previous years, with pacemakers capable of maintaining AV synchrony implanted in 81.5% of patients with first- or second-degree AVB and in 74.4% of patients with complete AVB. By age, this pacing mode was much less frequent in patients > 80 years. This was particularly evident for those with complete AVB, with rates of 59.1% in men and 59.6% in women. It was used in 15.9% of women and 12.7% of men in this age group and with this indication (complete AVB), which is considered more amenable to VDD pacing.

Single-chamber ventricular pacemaker implantation (VVI/R) for the treatment of AVB in patients with preserved sinus rhythm fell again, representing 23.5% of procedures. The use of this pacing mode continued to be prominent in patients > 80 years (39.5% of cases, a slight drop vs the 40.2% of cases in 2019).

Intraventricular conduction defects

Pacemakers capable of maintaining AV synchrony continued to be the most commonly used device (75.7% of procedures), largely due to DDD/R (61.6%); 11.4% were triple-chamber CRT-P pacemakers. VDD and single-chamber VVI/R pacing fell again to 2.2% and 23.9% of cases, respectively.

The most commonly used mode continued to be DDD/R in both individuals ≤ 80 years (69.9%) and those > 80 years (49.4%). In patients > 80 years, 38.3% of patients received a VVI/R pacemaker vs 15.5% of those ≤ 80 years, breaking the downward trend of recent years. In addition, the fall in VDD pacemaker implants continued (2.2% of all pacemakers), with 4.3% in patients > 80 years vs 0.9% in patients ≤ 80 (table 2).

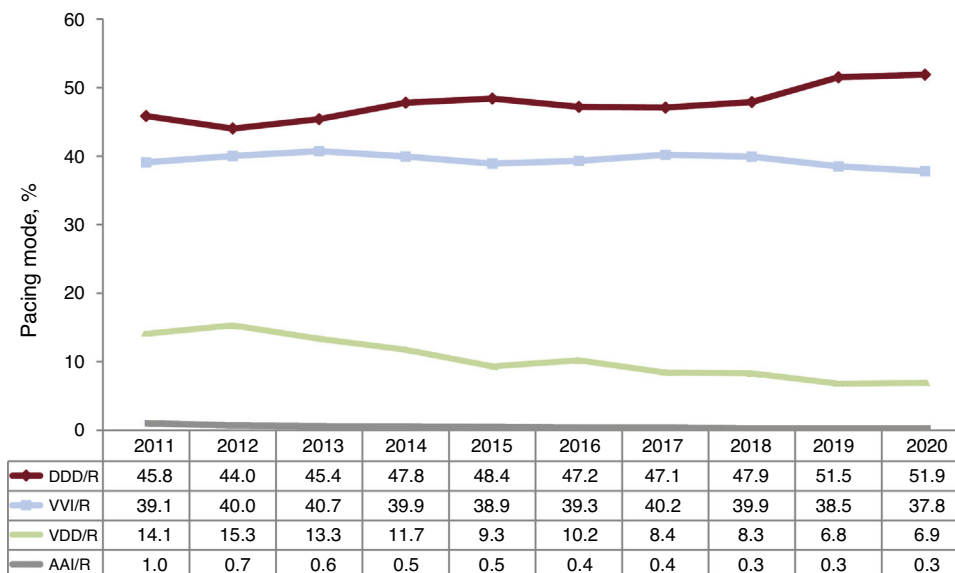


Figure 6. Trends in pacing modes from 2011 to 2020. AAI/R, single-chamber atrial pacing; DDD/R, sequential pacing with 2 leads; VDD/R, single-lead sequential pacing; VVI/R, single-chamber ventricular pacing.

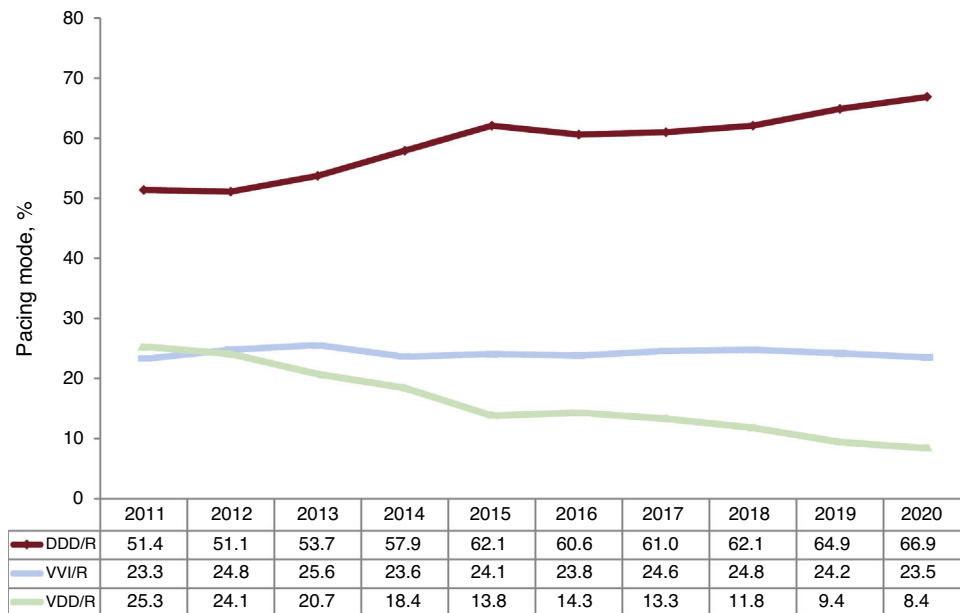


Figure 7. Trends in pacing modes in atrioventricular block from 2011 to 2020. DDD/R, sequential pacing with 2 leads; VDD/R, single-lead sequential pacing; VVI/R, single-chamber ventricular pacing.

Regarding CRT-P devices, there was a decrease from previous years, with 12.3% of implants vs 15.7% in 2019; 8% were in patients > 80 years vs 13.8% in those ≤ 80 years.

Sick sinus syndrome

As usual, patients with SSS were divided between those who theoretically were in permanent AF or atrial flutter and had bradycardia and those who were in sinus rhythm. In this way, the aim was to evaluate the adherence of the pacing modes to the current recommendations in the clinical practice guidelines.^{13,14}

1. Sick sinus syndrome in permanent atrial tachyarrhythmia. VVI/R pacing predominated (92.2% of all implants). A DDD/R system was used in 6.23% and biventricular pacing in 1.4%; the implantation of other pacing types was negligible. There were no major differences by age, except in the use of DDD/R pacemakers, which were used in 4.4% of patients > 80 years and in 9.1% of those ≤ 80 years. We assume that this pacing mode was used because an at least partial return to sinus rhythm was expected in many of the patients.

Table 2

Distribution (%) of pacing modes by electrocardiographic abnormality and age group in 2020.

	VVI/R	DDD/R	VDD/R
AVB	23.5	66.9	8.4
≤ 80 y	10.1	84.3	3.9
> 80 y	39.2	46.5	13.4
SSS	26.2	71.1	1
≤ 80 y	16.1	81.1	0.9
> 80 y	38.8	57.9	1.4
IVCD	23.9	61.6	2.2
≤ 80 y	15.5	69.9	0.8
> 80 y	38.3	49.4	4.3

AVB, atrioventricular block; DDD/R, sequential pacing with 2 leads; IVCD, intraventricular conduction defect; SSS, sick sinus syndrome; VDD/R, single-lead sequential pacing; VVI/R, single-chamber ventricular pacing.

2. Sick sinus syndrome in sinus rhythm. Adherence to clinical practice guideline recommendations is gradually improving, with increases in the pacing modes permitting atrial pacing and AV synchrony maintenance. Accordingly, DDD/R pacemakers were implanted in 71.1% of cases and VVI/R in 26.2%. The reported data showed the low uptake of AAI/R pacing, with only 13 patients (1.2% of the total with this indication); the other pacing modes—biventricular and VDD/R—were rare (figure 8).

The electrocardiographic manifestation is key when the device is being chosen in SSS patients. Thus, VVI/R pacemaker implantation may be inflated by the erroneous inclusion of patients with AF or permanent atrial tachyarrhythmia in subgroup E2 of the EPPIC (bradycardia-tachycardia syndrome). Moreover, 59.3% of single-chamber pacemakers implanted in SSS were indicated for bradycardia-tachycardia syndrome.

Analysis of the SSS data in patients in sinus rhythm by age and sex revealed the presence of differences in the devices used, with a higher frequency of dual-chamber pacing in younger patients and in men. In patients ≤ 80 years, DDD/R pacing comprised 81.6%; AAI/R comprised 0.7% and VVI/R mode just 16.1%. In patients > 80 years, VVI/R pacing represented 38.8% of cases, although 56.8% of these had bradycardia-tachycardia syndrome (table 2). Women more commonly received single-chamber VVI/R pacing than men (28.5% vs 23.2%), particularly those ≤ 80 years, in whom VVI/R pacing comprised 18.7% of cases in women vs 14.3% of those in men.

Remote monitoring

In 2020, 6637 conventional pacemakers were included in a remote monitoring program, as well as 1854 CRT-D devices and 668 CRT-P devices (18.5%, 77.7%, and 45.7% of all devices implanted). By autonomous community, La Rioja stood out with 68.2% of all devices included, followed by Aragon, Murcia, the Canary Islands, Navarre, and the Basque Country, with figures around 50%. Notable for their low implementation were Cantabria and the Balearic Islands (2.9% and 4.1% of devices included).

In addition, in this pandemic year, remote monitoring systems were provided to individuals with devices implanted in previous

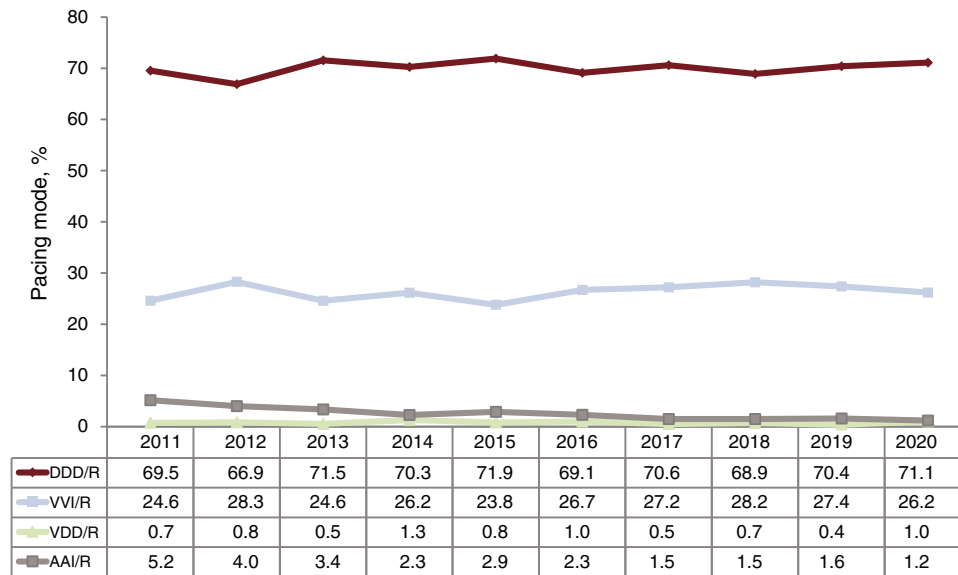


Figure 8. Trends in pacing modes in sick sinus syndrome from 2011 to 2020 (excluding E6). AAI/R, single-chamber atrial pacing; DDD/R, sequential pacing with 2 leads; VDD/R, single-lead sequential pacing; VVI/R, single-chamber ventricular pacing.

years that were subject to face-to-face follow-up, specifically to 3174 patients with conventional pacemakers, 170 with CRT-D devices, and 93 with CRT-P devices. This represents a 53% increase, with a total of 12 596 devices included vs 8241 in 2019.

DISCUSSION

The sample obtained in 2020 represented 39% of the activity reported by the device manufacturers, similar to previous years. Notably, more data were submitted through CardioDispositivos.es,¹¹ with 6040 procedures included (41% of all procedures reported) and a 35% increase vs 2019. Once again, we must stress the importance of data submission via this platform¹¹ as a way to obtain high-quality information, as well as its value as an optimal monitoring system for medical devices in the cardiac pacing field.

The SARS-CoV-2 pandemic of 2020 led to major changes in social, economic, and particularly health care circumstances worldwide, which necessitated major alterations to the activity conducted in both hospitals and primary care centers. During the first wave, hospitals were forced to limit all nonessential medical acts and to maintain emergency procedures alone, which also affected cardiac pacing activity. Salgado-Aranda et al.¹⁵ described this activity reduction, specifically a drop of 35.2% in the number of urgent/preferential pacemakers in the period from March 15 to May 15, 2020, vs the same period in 2019. This reduction was particularly due to a lower frequency of implants vs the previous year in asymptomatic patients or those with mild symptoms and with AVB as the most frequent cause of implants based on proportion. Factors possibly contributing to this fall in nonurgent activity included competing risk, with higher COVID-19-related impact and mortality in the candidate population for pacemaker implantation, lower physical activity during lockdown, with a lower frequency of symptoms, lower probability of early diagnosis due to the closure of nonessential activity, and patients' fear of being infected in the hospital setting.¹⁵

In this context, the number of conventional pacemakers implanted in 2020 decreased by 8% vs 2019, which broke the upward trend and led to the lowest rate of the last 5 years, with 766 units/million population according to the data provided by

Eucomed. This figure is lower than the European average (899 units/million population), which also suffered a major decrease vs 2019 (963 units/million), probably also due to the pandemic. Germany and Finland stand out regarding implantation rates, as well as Denmark, which also exceeded 1000 units/million population in 2020.

The number of CRT-T devices also fell by 4.6%, with reductions of 3.7% in CRT-P devices and of 5.1% in CRT-D devices. As in 2019, the CRT-D/CRT-P ratio was once again 1.6. CRT-P devices represented 38% of CRT-T devices and Spain continued to have one of the lowest rates in Europe, whose average is 57 units/million population; only Poland and Greece (with 24 and 11 units/million population, respectively¹⁰) have lower rates than Spain (31 units/million).

Leadless pacemaker implantation is gradually increasing year on year, with a 16.5% increase vs 2019. In 2020, data were included on leadless pacemakers capable of maintaining AV synchrony, a device that represents a notable advance in the development of this technology and whose initial results are highly promising.¹⁶ Once again, the data showed a highly heterogeneous distribution in terms of implantation activity by autonomous community: Madrid, Catalonia, and Galicia implanted the highest number of leadless devices, whereas other communities did not implant any devices of this type. A major increase in leadless pacemaker use is likely in the coming years due to the advantages of this device in settings such as a lack of superior venous access routes (due to occlusion or venous system abnormalities), previous device infection, or high infection risk (for various reasons, such as diabetes mellitus, chronic kidney disease, central lines, cardiac prostheses, or immunosuppression), as well as in very old patients,¹⁷ particularly those with dementia at risk of lead displacement. Its low current implementation and irregular distribution among autonomous communities are probably due to economic factors.

In 2020, we also received data specifically submitted through the online platform¹¹ on the magnetic resonance imaging compatibility of the implanted leads (a more reliable source in this aspect), with the results indicating greater use of this type of lead (82.1%). These data are crucial, given the ever growing use of this radiological technique. No reliable data were available on the

physiological pacing carried out in 2020 in Spain because these data are not recorded in the EPPICs, which are still the information source for preparing this report. The Task Force of the Cardiac Pacing Section of the SEC has begun a registry to record this activity, which will prove vital for the present and future development of pacing.¹⁸

Regarding pacing modes, AVB maintained the trend seen in recent years for atrial-based pacing, which comprised 76.5% of cases in 2020 vs 74.3% in 2019; DDD/R mode predominated (66.9% of procedures). In patients > 80 years, single-chamber VVI/R pacing was more widespread, with abandonment of atrial pacing/sensing in up to 39.5% of cases. This result confirmed that age is one of the main factors determining the selection of pacing mode. In this age group and for this conduction disorder, VDD reached its peak implementation (13.4% of patients with these characteristics). Other parameters such as frailty, cognitive decline, or dependency possibly explain the less strict adherence to clinical practice guideline recommendations because, although increased mortality has not been linked to single-chamber pacing vs dual-chamber pacing in AVB, the former pacing mode has been associated with a decreased functional class and the onset of AF or pacemaker syndrome.

Despite the 2020 COVID-19 pandemic, which could have led to a simplification of procedures and greater use of VVI/R or VDD pacemakers, we actually saw increased use of DDD/R pacing, which allows atrial pacing, and a progressive fall in VDD pacemakers, which are now used in less than 5% of first implants for this indication. The coming years may show a stabilization or even an increase in this pacing mode, after the development of atrial-sensing algorithms for leadless pacemakers.

A notable finding in intraventricular conduction defects was the apparent decrease in biventricular pacing, which dropped from 15.7% in 2019 to 12.3% in 2020 (predominantly with atrial lead), and the slight uptick in single-chamber VVI/R pacing, from 21.8% in 2019 to 23.9% in 2020. Although the exact reasons are unknown, it is highly probably that this pattern is related to the increased and widespread use of conduction system pacing techniques, exemplified by bundle of His and left branch pacing, with a shift from biventricular CRT-P pacing devices to conventional DDD/R or VVI/R pacemakers.

In patients with permanent atrial tachyarrhythmia (mainly AF or atrial flutter), as would be expected, single-chamber VVI/R devices continued to dominate (92.1% of patients). Pacemakers capable of stimulating the atrium increased again in patients with SSS. Conventional DDD/R pacing was used in 71.1% of patients, very similar to previous years, and the limited implantation of AAI/R devices, very residual in Spain, comprised more than 1% of interventions. The guidelines recommend DDD/R mode in SSS because of its ability to reduce the incidence of AF, strokes, and pacemaker syndrome. VVI/R mode was used in 26.2% of cases (38.8% in patients > 80 years), and this high percentage is probably because, within SSS, patients with permanent AF are erroneously diagnosed with bradycardia-tachycardia syndrome; the appropriate pacing mode for such patients is VVI/R.

In this pandemic year, remote monitoring gained importance as a crucial follow-up mode for devices, due to its particular ability to avoid or reduce face-to-face visits at times of high infection risk without compromising safety.¹⁹ Discharges with home-based monitoring systems increased by 53% in 2020, which is particularly noteworthy because the use of such systems not only increased for devices implanted in 2020, but also for those implanted in previous years. This increment was largely due to the 69% jump in inclusions of conventional pacemakers in remote monitoring programs, a striking figure given that this type of follow-up has always been less common in this type of device than in CRT-D and CRT-P devices. The use of this follow-up system was mainly driven by the

need for a restructuring of health care activity during the pandemic. We hope that this trend continues due to the clinical advantages and safety of this approach. As noted in the de-escalation document published after the first wave of the pandemic, the Cardiac Pacing Section of the SEC is opting for device follow-up largely based on an organized and well-structured remote monitoring program.²⁰

CONCLUSIONS

In 2020, in the context of the SARS-CoV-2 pandemic, falls were recorded of 8% in the implantation rate of conventional pacemakers and of 4.6% in that of cardiac resynchronization devices, whereas the inclusion significantly increased of devices in remote monitoring programs. The number of leadless pacemakers jumped, including that of the new device with AV synchrony capability. Atrial-based pacing predominated, particularly in the younger population. Greater use of the CardioDispositivos.es platform will boost data quality.

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AUTHORS' CONTRIBUTIONS

J. Chimento drafted the section on pacing modes; V. Bertomeu prepared the section on remote monitoring; Ó. Cano reported the information related to the conventional pacemaker and cardiac resynchronization therapy data; and M. Pombo prepared the clinical and demographic data and coordinated the work.

CONFLICTS OF INTEREST

None.

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