

Special article

Spanish pacemaker registry. 21st official report of Heart Rhythm Association of the Spanish Society of Cardiology (2023)

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Article history:

Received 25 June 2024;

Accepted 17 July 2024

Available online 7 September 2024

Keywords:

Pacemaker

Resynchronization

Registry

Remote monitoring

Spain

ABSTRACT

Introduction: Data on implants of cardiac pacing systems in Spain in 2023 are presented.**Methods:** The registry is based on the information provided by centers to the recording platform of the Heart Rhythm Association after device implantations, through Cardiodispositivos, the online platform of the National Registry. Other information sources include: a) data transfers from the manufacturing and marketing industry; b) the European pacemaker patient card; and c) local databases submitted by the implanting centers.**Results:** In 2023, 112 hospitals participated in the registry (30 more than in 2022). A total of 24 343 device implantations were reported (48.1% more than in 2022) compared with 45 120 reported by Eucomed (European Confederation of Medical Suppliers Associations). Of these, 1646 were cardiac resynchronization therapy pacemakers. The devices showing the largest increases were leadless pacemakers, with 963 devices implanted, representing an 18.1% increase over 2022. The most frequent indication was atrioventricular block followed, for the first time, by atrial tachyarrhythmia with slow ventricular response. The number of devices included in remote monitoring also increased (cardiac resynchronization therapy defibrillators, 71%; cardiac resynchronization therapy pacemakers, 63%; and conventional pacemakers, 28%), although more moderately.**Conclusions:** In 2023, there was an increase in the number of institutions participating in the registry. The reporting of device implantations rose by 48.1%, and the implantation of leadless pacemakers grew by 18.1%. Remote monitoring also experienced modest growth compared with previous years.

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Registro español de marcapasos. XXI informe oficial de la Asociación del Ritmo Cardíaco de la Sociedad Española de Cardiología (2023)

RESUMEN

Introducción: Se presentan los datos de implantes de sistemas de estimulación cardíaca en España en el año 2023.**Métodos:** El registro se basa en la información que los centros proporcionan tras el implante de dispositivos a la plataforma de registros de la Asociación del Ritmo Cardíaco de la Sociedad Española de Cardiología, a través de la plataforma *online* del registro nacional, Cardiodispositivos. Otras fuentes de información incluyen: a) la cesión de datos de la industria fabricante y comercializadora; b) la tarjeta europea de paciente portador de marcapasos, y c) las bases de datos locales remitidas desde los centros implantadores.**Resultados:** Han participado en el registro 112 hospitales (30 más que en 2022). Se han comunicado 24.343 unidades (el 48,1% más que en 2022), frente a 45.120 comunicadas por Eucomed (*European Confederation of Medical Suppliers Associations*). De ellas, 1.646 marcapasos resincronizadores. El número de marcapasos sin cables experimentó el mayor incremento, con 963 dispositivos, un 18,1% más que en 2022. La indicación más frecuente fue el bloqueo auriculoventricular, seguido, por primera vez, de la taquiarritmia auricular con respuesta ventricular lenta. Los dispositivos incluidos en monitorización a distancia también crecieron (resincronizadores de alta energía, 71%; marcapasos resincronizadores, 63%; marcapasos convencionales, 28%), aunque más moderadamente.

Palabras clave:

Marcapasos

Resincronizador

Registro

Monitorización a distancia

España

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Conclusiones: En 2023 se ha experimentado un crecimiento en el número de hospitales participantes en el registro, un 48,1% en la comunicación de unidades al registro y un 18,1% en el implante de marcapasos sin cables. La monitorización a distancia también creció discretamente respecto a años previos.

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Abbreviations

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

INTRODUCTION

The current report presents data submitted by Spanish hospitals on cardiac pacing activity for 2023. The report includes demographic data, pacemaker types and numbers, indications, pacing modes, and the characteristics of the material implanted. In addition, we compare the data with that from previous years^{1–8} and with European data provided by Eucomed (European Confederation of Medical Suppliers Association).⁹ Data on remote monitoring are also presented.

METHODS

The registry is based on information voluntarily provided by participating centers and manufacturers after device implantation, covering first implants and replacements. The registry is continuously compiled, updated, and maintained throughout the year by a team comprising full members of the Heart Rhythm Association of the Spanish Society of Cardiology (SEC) and by the technical team and coordinator of the Heart Rhythm Association registries of the SEC. The device manufacturing and marketing industry also collaborate by transferring of relevant data. All members have contributed to data cleaning and analysis and are responsible for this publication.

In addition, in accordance with Spanish legislation SCO/3603/2003,¹⁰ of December 18, and SSI/2443/2014,¹¹ of December 17, 2 partially automated files were created: the “National pacemaker registry” and the “National implantable cardioverter-defibrillator registry”. CardioDispositivos¹² is the online platform of these 2 registries, which are owned by the Spanish Agency for Medicines and Health Products, Ministry of Health, Spanish Government, and have been managed by the SEC since 2016. Article 36 of Royal Decree 192/2023, of March 21,¹³ states that health care centers and professionals are obligated to report specific data on pacemaker and defibrillator implantation (Article 18 of Regulation [EU] 2017/745 of the European Parliament)¹⁴ to the abovementioned registries. In 2023, and up to the date of drafting this report, 15 564 implants have been reported via this route. This figure represents 64% of all implants reported to the recording platform of the Heart Rhythm Association of the SEC. Other information

sources include: a) data transfer from the manufacturing and marketing industry; b) the European Pacemaker Patient Identification Card (EPPIC); and c) local databases submitted by implanting centers. Remote monitoring data are entirely obtained from the manufacturers.

Census data for the calculation of rates per million population, both nationally and by autonomous community and province, were obtained from the Spanish National Institute of Statistics and refer to the first trimester of 2023.¹⁵ For population rates, implantation and remote monitoring data were obtained from the manufacturers' billing data for 2023. As in previous years, the data from the present registry were compared with those provided by Eucomed.⁹ The percentages of each variable analyzed were calculated based on the total number of implants with available information on the parameter.

The present work has been conducted in accordance with international recommendations on clinical research (Declaration of Helsinki of the World Medical Association).

Statistical analysis

Results are expressed as the mean 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, while qualitative variables were analyzed using the chi-square test.

RESULTS

Data submitted to the registry and sample quality

In 2023, 24 343 implants were reported to the recording platform of the Heart Rhythm Association of the SEC (48.1% more than in 2022). This figure includes single-chamber and dual-chamber pacemakers (conventional), pacemakers with cardiac resynchronization therapy, and leadless pacemakers. Of these, 15 564 were reported by direct entry of data into the CardioDispositivos platform,¹² 6153 via EPPICs submitted to the SEC, and the remainder via other information sources (eg, the local databases of implanting centers). In total, 112 hospitals voluntarily participated in the present registry (30 more than in 2022) (table 1).

Compared with the 2023 billing data from all manufacturers (42 848 implants in Spain), the total number of implants reported to the recording platform of the Heart Rhythm Association of the SEC represented 56.8% of all implant activity in Spain (16 percentage points higher than in 2022).

Missing data for the various variables analyzed were excluded from the statistical analysis. Their distribution was heterogeneous among variables but generally strongly affected the representativeness of the data. In summary, the percentages of missing data for each variable were 8.3% for age, 11.3% for sex, 97% for symptoms, 78% for etiology, 68% for preimplantation electrocardiogram, and 68.5%, 66.2%, and 21.2% for lead position, access route, and lead fixation, respectively. In addition, 76.3% of data were missing for magnetic resonance compatibility and 90% for the reason for generator explantation.

Table 1

Public and private hospitals submitting data to the Spanish Pacemaker Registry in 2023

Autonomous community/center
<i>Andalusia</i>
Área de Gestión Sanitaria Este de Málaga-Axarquía
Hospital Costa del Sol
Hospital HLA Inmaculada de Granada
Hospital de La Serranía
Hospital Universitario de Jaén
Hospital Universitario Juan Ramón Jiménez
Hospital Universitario Punta de Europa
Hospital Universitario Reina Sofía de Córdoba
Hospital Universitario San Cecilio
Hospital Universitario Virgen de las Nieves
Hospital Universitario Virgen del Rocío
Hospital Universitario Virgen de Valme
Hospital Universitario Virgen de la Victoria
Hospital Vithas Granada
Hospital Vithas Virgen del Mar
<i>Aragon</i>
Hospital General San Jorge
Hospital Obispo Polanco
Hospital Universitario Miguel Servet
Hospital Viamed Montecanal
<i>Principality of Asturias</i>
Fundación Hospital de Jove
Hospital Universitario de Cabueñes
Hospital Universitario San Agustín
<i>Balearic Islands</i>
Clínica Juaneda Menorca
Hospital de Manacor
Hospital Universitario Son Espases
<i>Canary Islands</i>
Hospital Universitario de Gran Canaria Dr. Negrín
Hospital Universitario de Canarias
Hospital General de La Palma
Hospital Universitario Nuestra Señora de Candelaria
<i>Cantabria</i>
Hospital Universitario Marqués de Valdecilla
<i>Castile and León</i>
Complejo Asistencial Universitario de León
Complejo Asistencial Universitario de Palencia
Hospital Clínico Universitario de Valladolid
Hospital Nuestra Sra. de Sonsoles
Hospital Universitario de Burgos
Hospital Universitario Río Hortega
Hospital Universitario de Salamanca
Hospital Virgen de La Concha
<i>Castile-La Mancha</i>
Hospital General Universitario de Albacete
Hospital General Universitario de Ciudad Real
Hospital General Virgen de la Luz
Hospital Nuestra Señora del Prado
Hospital Universitario de Toledo
Hospital QuirónSalud de Albacete
<i>Catalonia</i>
Clínica Mi Novaliança
Hospital Clínic de Barcelona

Table 1 (Continued)

Public and private hospitals submitting data to the Spanish Pacemaker Registry in 2023

Autonomous community/center
Hospital del Mar
Hospital de la Santa Creu i Sant Pau
Hospital de Terrassa
Hospital de Tortosa Verge de la Cinta
Hospital del Vendrell
Hospital Universitario Arnau de Vilanova
Hospital Universitario de Bellvitge
Hospital Universitario Germans Trias i Pujol
Hospital Universitario de Girona Dr. Josep Trueta
Hospital Universitario Joan XXIII de Tarragona
Hospital Universitario Mútua de Terrassa
Hospital Universitario Parc Taulí
Hospital Universitari Vall d'Hebron
Parc Sanitari Sant Joan de Déu
<i>Valencian Community</i>
Hospital Arnau de Vilanova de Valencia
Hospital Clínica Benidorm
Hospital Clínico Universitario de Valencia
Hospital Francesc de Borja
Hospital General Universitario Dr. Balmis
Hospital General Universitario de Castelló
Hospital General Universitario de Valencia
Hospital HLA Vistahermosa
Hospital Imed Levante
Hospital de Manises
Hospital Marina Salud de Denia
Hospital Universitario y Politécnico La Fe
Hospital Universitario de San Juan de Alicante
Hospital Universitario del Vinalopó
<i>Extremadura</i>
Hospital Universitario de Badajoz (Infanta Cristina)
Hospital Universitario de Cáceres
Hospital Comarcal de Zafra
<i>Galicia</i>
Hospital Universitario Lucus Augusti
Complejo Hospitalario Universitario A Coruña
Hospital Montecelo
Hospital Álvaro Cunqueiro
<i>Madrid</i>
Clínica Universidad de Navarra Madrid
Hospital Central de La Defensa Gómez Ulla
Hospital General Universitario Gregorio Marañón
Hospital HM Madrid
Hospital HM Montepríncipe
Hospital HM Puerta del Sur Madrid
Hospital HM Sanchinarro
Hospital Universitario Clínico San Carlos
Hospital Universitario 12 de Octubre
Hospital Universitario de Fuenlabrada
Hospital Universitario Fundación Alcorcón
Hospital Universitario de Getafe
Hospital Universitario del Henares
Hospital Universitario Infanta Elena
Hospital Universitario Príncipe De Asturias
Hospital Universitario Puerta de Hierro-Majadahonda

Table 1 (Continued)

Public and private hospitals submitting data to the Spanish Pacemaker Registry in 2023

Autonomous community/center
Hospital Universitario de Torrejón
<i>Region of Murcia</i>
Hospital General Universitario Los Arcos del Mar Menor
Hospital General Universitario J.M. Morales Meseguer
Hospital General Universitario Rafael Méndez
Hospital General Universitario Santa Lucía de Cartagena
Hospital HLA La Vega
<i>Chartered Community of Navarra</i>
Clínica Universidad de Navarra
Complejo Hospitalario de Navarra
<i>La Rioja</i>
Hospital Viamed Los Manzanos
Hospital San Pedro
<i>Basque Country</i>
Hospital de Basurto
Hospital Universitario Araba
Hospital Universitario de Cruces
Hospital Universitario Donostia
Hospital Universitario de Galdakao

Conventional pacemakers

According to the billing data from the manufacturing and marketing industry, 42 848 conventional pacemakers were implanted in Spain in 2023. Because the Spanish population on January 1, 2023, comprised 48 085 361 individuals, according to the National Institute of Statistics,¹⁵ the implantation rate was 891 units/million population (figure 1). In 2023, 4 autonomous communities exceeded 1000 units/million population: Castile and León, Galicia, Madrid, and Asturias (1126, 1124, 1113, and 1100 units/million, respectively). The autonomous cities of Ceuta and Melilla implanted about 100 units/million population while Murcia was the autonomous community with the lowest implantation rate, at 722 units/million population (figure 2).

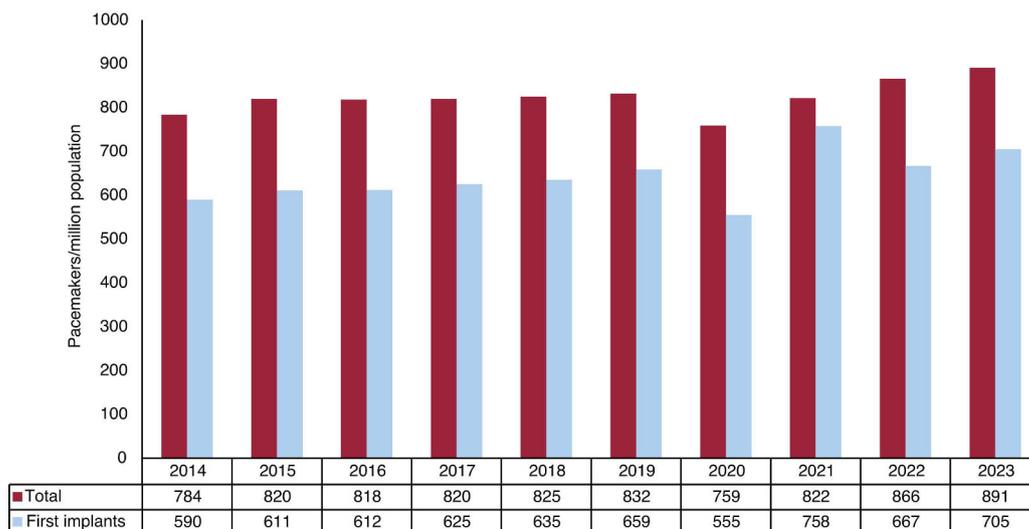


Figure 1. Total number of pacemaker generators and first implants per million population from 2014 to 2023.

Cardiac resynchronization devices

In 2023, 4669 cardiac resynchronization therapy devices were implanted, comprising 3023 CRT with defibrillation (CRT-D) devices and 1646 CRT without defibrillation (CRT-P) devices. The rates of total resynchronization (CRT-T), CRT-D, and CRT-P devices were 97, 63, and 34 units/million population, respectively. Regarding the distribution by autonomous community, the implantation rates of cardiac resynchronization devices were highest in Cantabria, at 199 units/million population, followed by Asturias and Extremadura, at 137 and 133, respectively. The Balearic Islands and Murcia, at 62 and 69 units/million population, had the lowest rates of cardiac resynchronization device implants. For CRT-P devices, Cantabria once again headed the list, at 90 units/million population, followed by Extremadura and Asturias, at 52 and 50 units/million, respectively. Aragon had the lowest number of CRT-P implants, at 16 units/million population (figure 3).

Leadless pacemakers

In 2023, 963 leadless pacemakers were implanted in Spain; 27% of these were capable of maintaining atrioventricular (AV) synchrony (figure 1 of the supplementary data). Since September 2023, some autonomous communities have been able to implant single-chamber devices from a second manufacturer. In absolute numbers, Catalonia had the highest number of such implants (233 units), followed by Madrid and the Basque Country. With 168 and 134 units, respectively (figure 4). However, after adjustment for population, the communities with the highest implantation rates per million population were the Basque Country and Galicia (figure 2 of the supplementary data). Aragon and Extremadura did not implant any devices of this type.

Demographic and clinical data

The mean age of the patients at implantation was 77.8 years. The mean age was slightly higher for women than for men (79 vs 77 years) and for replacements vs first implants (80 vs 77.5 years). Men predominated in pacemaker implantation (60%), both for first implants (61.2% vs 38.8%) and replacements (57.2% vs 42.8%). The main reason for pacemaker implantation was syncope (40%), followed by dizziness (22%) and heart failure (16%). Less common

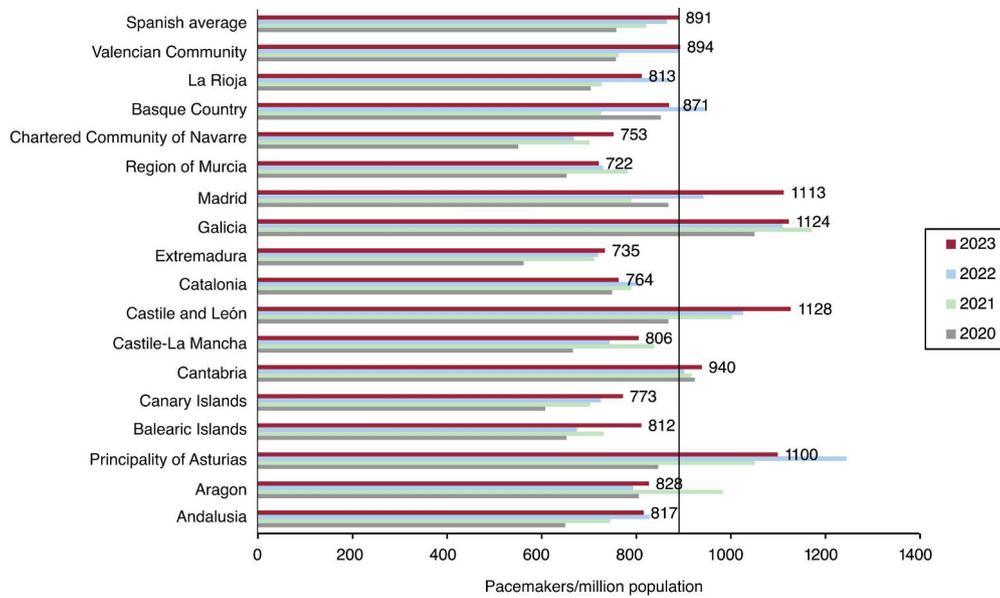


Figure 2. Pacemaker use per million population (national average and by autonomous community) from 2020 to 2023.

reasons were prophylactic implantation (8.4%) and asthenia (5%). The most common cause of a conduction disorder was conduction system fibrosis related to advanced age (80%), followed by iatrogenic causes (5%, surgery; 2%, transcatheter aortic valve implantation; 1%, ablation).

The most frequent preimplantation electrocardiographic abnormality was AV block (AVB) (55.3%). Of these, third-degree AVB predominated, accounting for 41% of procedures, followed by second-degree AVB, at 15.9%. Atrial fibrillation (AF) with complete heart block was reported in 5.5% of implants while sick sinus syndrome (SSS) represented 14%. AF with slow ventricular response accounted for 19.2% of implants. Intraventricular conduction defect was reported in 10% of cases (figure 5).

Type of procedure

Similar to 2022, 76.6% of reported procedures were first implants and 23.4% were replacements. Of the replacements, 95.9% involved the implantation of a new generator. The most frequently used access route continued to be the subclavian vein (50.5%), closely followed by axillary access (46.5%).

The most frequent reasons for generator explantation were end-of-life battery depletion (84%) and infections (2.2%). In addition, 2% of replacements were due to device dysfunction. The most frequent reasons for lead explantation were infection (44.7%), followed by displacement (17.4%) and dysfunction (10.4%).

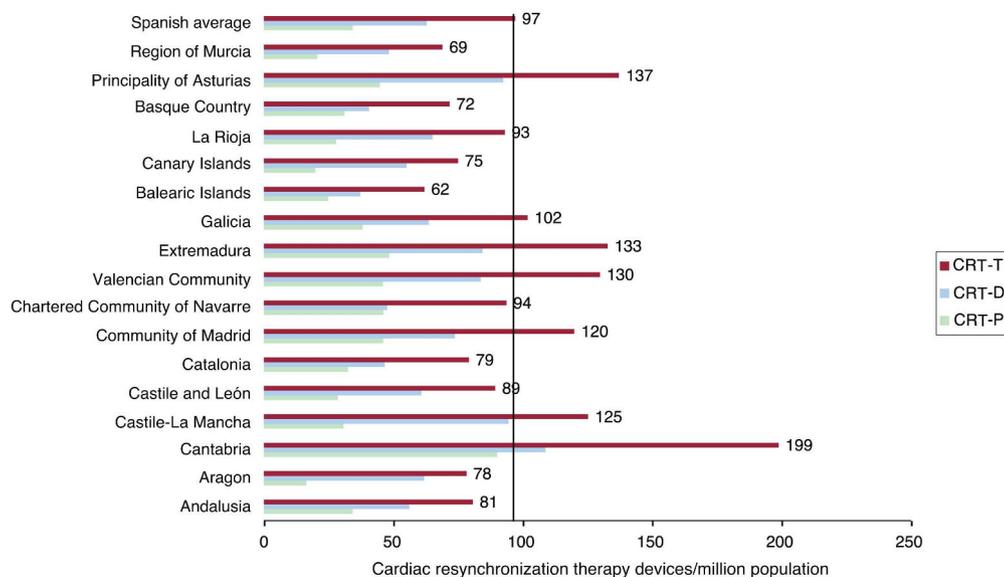


Figure 3. Cardiac resynchronization therapy devices per million population in 2023, national average and by autonomous community. CRT-D, cardiac resynchronization therapy with defibrillation; CRT-P, cardiac resynchronization therapy without defibrillation; CRT-T, total cardiac resynchronization therapy.

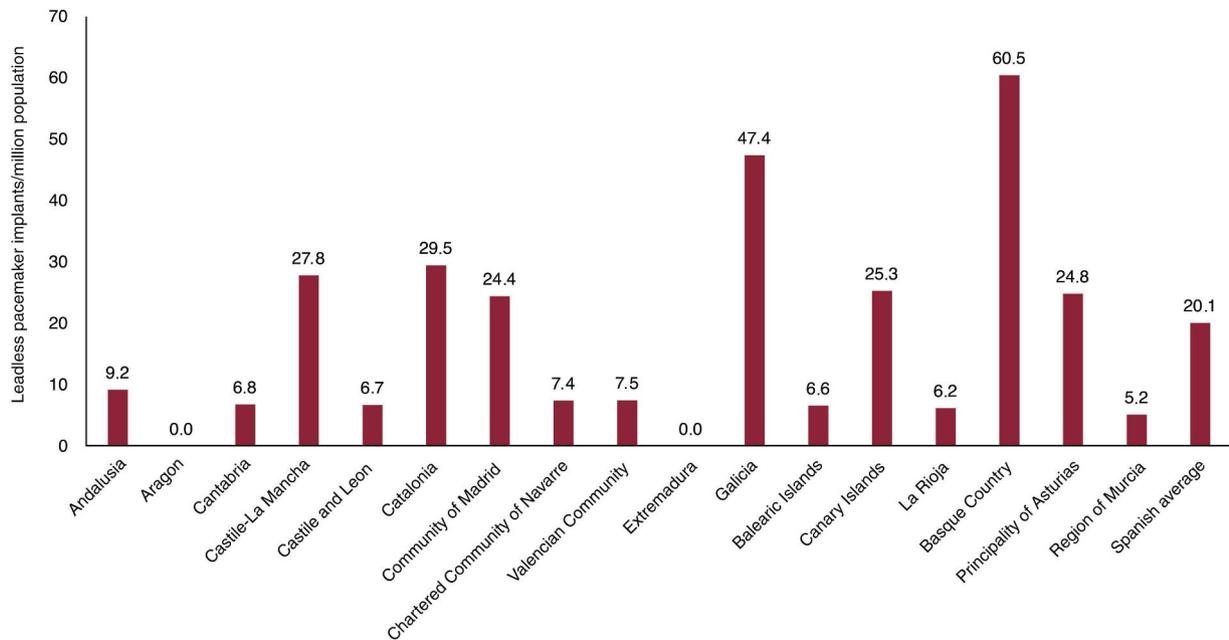


Figure 4. Leadless pacemaker implantation rates by million population by autonomous community and compared with the national average.

Lead type

Most leads used, both in the atrium and the ventricle, were bipolar (98.3% in the atrium and 97.7% in the ventricle) and had active fixation (94.7% and 91.2%, respectively). Active-fixation leads (64.7%) and bipolar leads (50.5%) predominated in the tributary veins of the coronary sinus, followed closely by quadripolar leads (46.4%). No differences by sex were found in the choice of lead type but there was significantly greater use of passive fixation in patients older than 80% years (6.8% vs 4.5% in the atrium [$P = .002$] and 12% vs 5.4% in the ventricles [$P < .001$]).

A lead was implanted in the right atrium (preferentially in the atrial appendage; other locations were rare or not specified) in 47.7% of procedures, in the right ventricle in 74.5%, and in the left ventricle in 5.1%. Epicardial implants were rare in the atrium (0.3%) and right ventricle (0.6%) but were more frequent in the left ventricle (11.4%). The most frequent location in the right ventricle

was once again the apex (49.1%), followed by conduction system pacing (CSP), which continued its increase (19.3%). There was a corresponding significant decrease in implants in the outflow tract/septum, which fell to 17.5% in 2023 (from 27.8% in 2022).

Most of the implanted leads were compatible with magnetic resonance (99% of atrial leads, 98.4% of right ventricular leads, and 95.4% of left ventricular leads), while 96% of generators were magnetic resonance-compatible. However, the use of such leads was significantly lower in patients older than 80 years (94.7% vs 97.7%; $P < .001$).

Pacing modes

The use of generators with built-in activity sensors is now widespread. Sequential dual-chamber DDD/R pacing continued its upward trend from previous years, increasing by almost

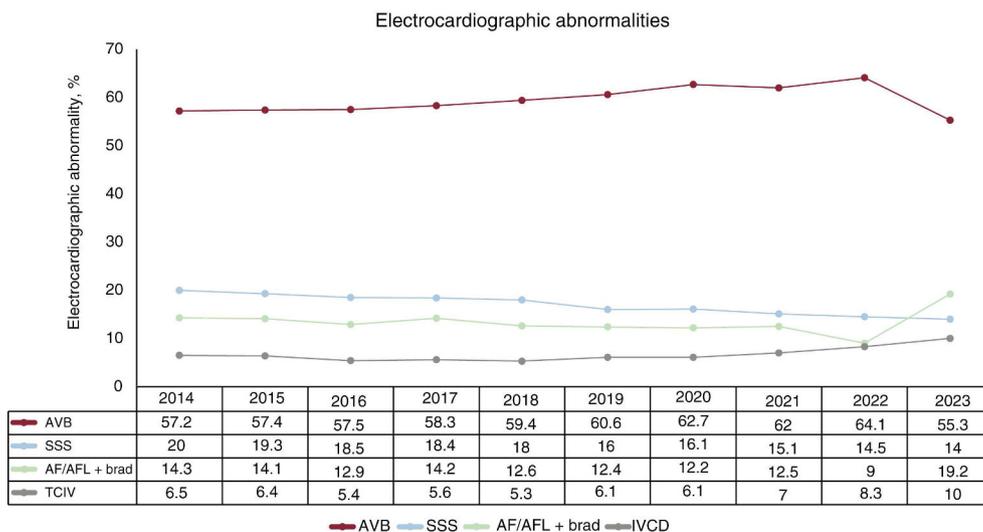


Figure 5. Trends in electrocardiographic abnormalities from 2014 to 2023. AF/AFL + brad, atrial fibrillation or atrial flutter with bradycardia; AVB, atrioventricular block; IVCD, intraventricular conduction defect; SSS, sick sinus syndrome.

7 percentage points (62.1% vs 55.6% in 2022), at the expense of both VDD pacing and single-chamber ventricular pacing. Indeed, this pacing mode represented 63% of first implants and 58.8% of replacements. The use of VDD/R systems continued to be uncommon, particularly for first implants. These systems represented just 4.2% of all pacemakers, similar to 2022 (5.7%) due to replacements (10.7%). Single-chamber ventricular pacing also continued the marked decline in recent years, with an almost 5 percentage point reduction (37.1% in 2021, 36.4% in 2022, and 31.9% in 2023). Isolated atrial pacing (AAI/R) continued to be rare (9 first implants and 24 replacements). Figure 6 shows the trends in pacing modes.

Differences by sex persisted, with DDD pacing used in 64.4% of men vs 59.1% of women. This difference lessened in patients older than 80 years (50% of men vs 48.4% of women) and was more marked in younger patients (77.4% vs 73.8%, $P < .001$).

Pacing mode selection

In this section, we review the selection of different pacing modes and the degree of adherence to the recommendations in current clinical practice guidelines.¹⁶ We also analyze the influence of various demographic factors on the selection. As in previous registries, and to maintain the uniformity of the data and better evaluate adherence in pacing mode selection, we must make some clarifications:

- Patients with AVB and permanent atrial tachyarrhythmia (EPPIC code C8) have been excluded from the AVB subsection.
- The intraventricular conduction defect subsection includes highly variable indications (ranging from complete block of the different branches to alternating bundle branch block).
- For SSS, we have differentiated between patients in AF or permanent atrial tachyarrhythmia with associated bradycardia and those in sinus rhythm.

Atrioventricular block

With the aim of maintaining AV synchrony, the use of sequential pacing has increased (69.3% vs 74.7%). VDD/R mode remained stable (5.1%). Overall, the use of modes maintaining AV synchrony reached 79.9%.

The influence of demographic factors such as age and sex on the selection of pacing modes capable of maintaining AV synchrony is well-known. AV synchrony was maintained in 92% of patients younger than 80 years vs 66.6% of older patients. This figure represents an increase from previous years (57.7% in 2022 and 64.3% in 2021). The use of VDD/R devices was stable (3.1% in patients younger than 80 years vs 7.3% in octogenarians). Figure 7 shows the distribution of pacing modes by clinical indication and age.

Although differences between men and women were also detected (AV synchrony maintenance was attempted in 82.3% of men vs 75% of women), this disparity was even more pronounced at advanced ages. For example, DDD/R pacing was used in 63.2% of men older than 80 years vs only 54.6% of women. VDD/R pacing was similar in both sexes among patients younger than 80 years of age (3%) but was 6.3% in male octogenarians and 8.4% in female octogenarians.

Analysis of pacing mode by the degree of AVB revealed that sequential dual-chamber pacing was used in 87.3% of patients with first-degree AVB, in 84.6% of those with second-degree AVB, and in 76.5% of those with complete AVB. VDD pacing was very similar among the different AVB degrees (ranging between 5.3% and 6.3%). In 2022, the use of VVI/R devices in AV conduction disorders fell to 20.1%, although their use increased in female octogenarians to 37%.

Intraventricular conduction defects

For intraventricular conduction defects, devices capable of maintaining AV synchrony exhibited a notable increase (81.4% overall). DDD/R pacing increased from 66.3% in 2022 to 79.6% in 2023. This pacing mode was slightly less commonly used in men (77.9% vs 82.4%). In octogenarians, DDD/R pacing was also the most commonly used pacing mode but its use dropped from 89.2% in patients younger than 80 years to 68.4% in older patients. All VDD/R devices were implanted in patients older than 80 years, although the percentage was small (3.8%). CRT-P devices represented 14.5% of implants for this indication, with no differences by age (12.7% in octogenarians and 13% in patients younger than 80) but were slightly more commonly used in women than in men (16% vs 13.3%).

Sick sinus syndrome

In SSS patients with permanent atrial tachyarrhythmia, VVI/R was the preferred pacing mode (86.2%). We assume that the use of

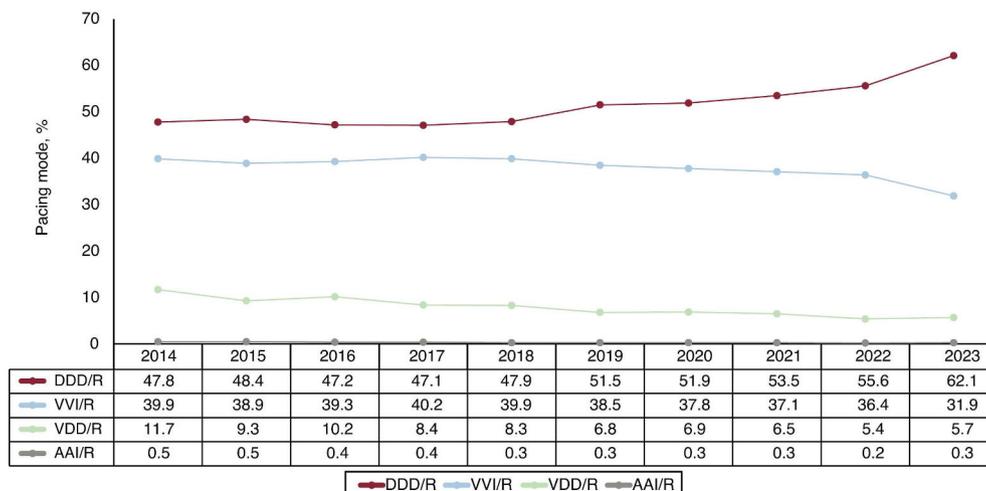


Figure 6. Trends in pacing modes.

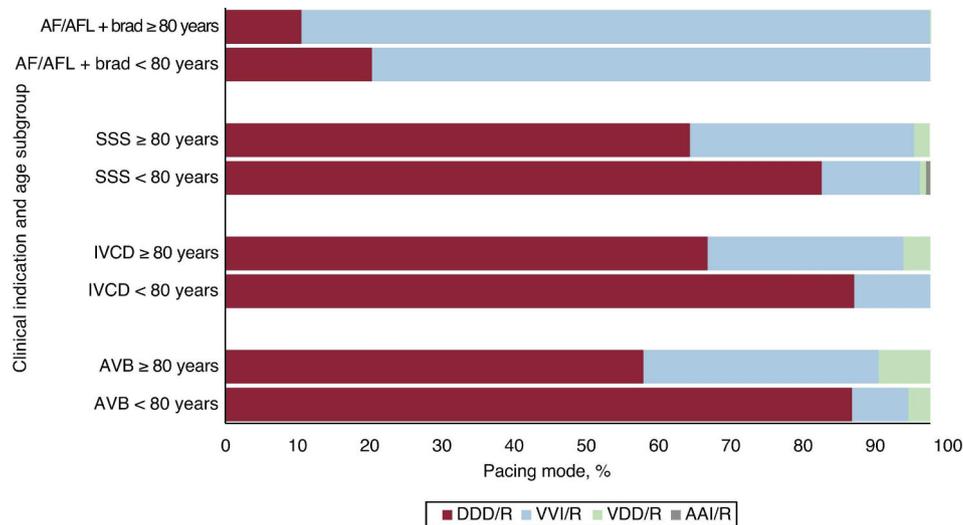


Figure 7. Pacing mode distribution by clinical condition, clinical indication, and age. AF/AFL + brad, atrial fibrillation or atrial flutter with bradycardia; AVB, atrioventricular block; IVCD, intraventricular conduction defect; SSS, sick sinus syndrome.

this type of system is due to doubts about whether to classify AF as permanent or persistent (and, thus, whether AF is amenable to sinus rhythm reversion). For pacing patients in sinus rhythm, there was a slight increase in the use of modes capable of maintaining AV synchrony (77.9%). DDD/R pacing was used in 75.9% while AAI/R mode was rarely used, as mentioned previously. Single-chamber ventricular pacing was maintained at 22.1%. As in previous years, the choice of pacing mode was influenced by the type of SSS, with a 3-fold higher rate of VVI implantation in EPPIC subgroup E2 (bradycardia-tachycardia syndrome): 39.4% vs the 11% to 13% seen in the other subgroups. Once again, these differences were accentuated with age, with the rate of VVI/R pacing reaching 44.8% in octogenarians with bradycardia-tachycardia syndrome.

There were no significant differences by sex in young patients with DDD/R pacing, which was about 90% in both men and women. However, among octogenarians in the other SSS subgroups, DDD/R pacing was used in 30% of women but in 21% of men.

Remote monitoring

In 2023, remote monitoring was included in 28% of conventional pacemakers, 63% of CRT-P devices, and 71% of CRT-D devices, continuing its upward trend. For the first time in the national registry, monitoring data were available for leadless pacemakers, which represented 25% (figure 8). Regional differences were stark. The autonomous communities with the highest percentages of devices equipped with remote monitoring were La Rioja, the Canary Islands, Asturias, and Navarre, which all exceeded 70%. In contrast, less than 20% of devices implanted in Castile-La Mancha had remote monitoring capability. Specifically for conventional pacemakers, La Rioja was once again at the top of the list, with 60% of devices included in a remote monitoring program, while this type of program was practically unused in Cantabria and the Balearic Islands (figure 3 of the supplementary data).

DISCUSSION

In 2023, 24 343 cardiac pacing device implants were reported to the recording platform of the Heart Rhythm Association of the SEC. This figure represents a highly significant increase vs previous years. In addition, the number of hospitals reporting implants

increased by 30 vs 2022. Equally, the number of records included in CardioDispositivos increased by 16 percentage points more than in 2022, a highly positive finding that encourages us to continue raising awareness of the need for centers to report all implants. These data must be reported, not only to support a quantitative national registry, but also for the pharmacovigilance of implanted material. The recording platform of the Heart Rhythm Association of the SEC encourages the direct inclusion of implantation activity in CardioDispositivos or via gateways from compatible platforms that facilitate their integration via automated methods. Of all the devices implanted in Spain reported by Eucomed (45 120 devices), 54% were registered via CardioDispositivos (exceeding the 37.7% recorded in 2022), reflecting of the intense efforts of those responsible in the registry and the collaboration with Spanish hospitals.

By autonomous community, Castile and León, Galicia, Madrid, and Asturias were once again at the top of the list for implants per million population. They are also the most communities with the oldest populations (with the exception of Madrid). Compared with other European countries, Spain is at the bottom of the list with 891 units/million population according to Eucomed⁹ (2022 data; data from 2023 were not available at the time of article preparation). This figure is well below the average (1001) and particularly behind countries such as Germany (1206), Italy (1207), and Sweden (1063).

Leadless pacemakers were the devices showing the greatest increase vs the previous year (18.1%). Part of this increase might be due to the easing of approvals and administrative processes required in some autonomous communities. Catalonia and Madrid were the communities with the highest numbers of implants, but Andalusia and the Basque Country exhibited the greatest growth vs 2022. A notable development is the release of a new active-fixation device from another distributor. Overall, leadless devices represented 2.2% of all pacemakers, which, given the expansion of current indications,¹⁷ is likely an underprescription. The underuse of this therapy may have several explanations, such as the difference in price with conventional pacemakers, the inability to perform CSP, and the lower experience of centers with these devices.

The subclavian approach remains the most popular venous access route (> 50% of procedures), despite evidence showing that this route increases the incidence of pneumothorax and lead fracture during follow-up.¹⁸ Indeed, the recommended access

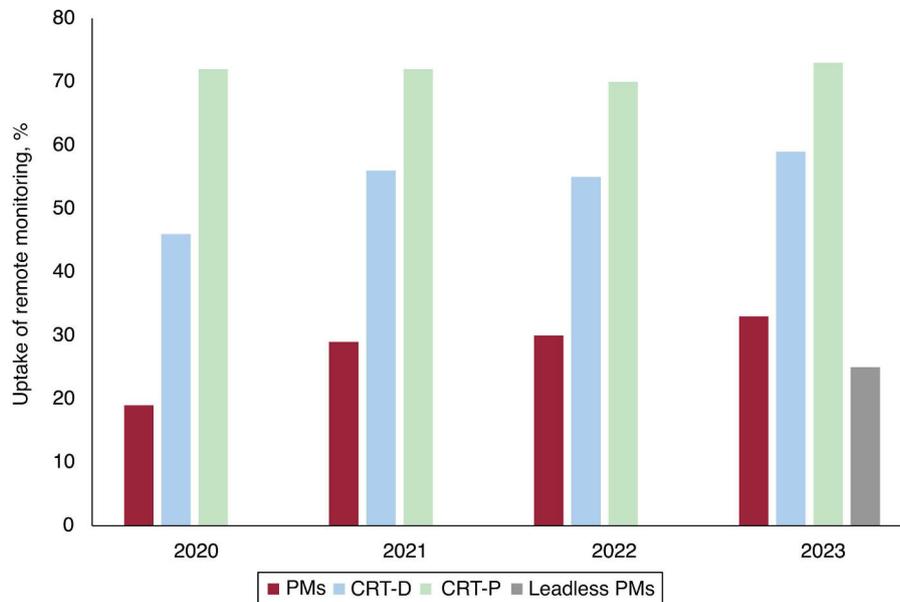


Figure 8. Trends in remote monitoring uptake. CRT-D, cardiac resynchronization therapy with defibrillation; CRT-P, cardiac resynchronization therapy without defibrillation; PM, pacemaker.

route is axillary or cephalic according to the consensus document of the European Heart Rhythm Association endorsed by the Heart Rhythm Society, Asia Pacific Heart Rhythm Society, and Latin-American Heart Rhythm Society.¹⁹ The apex is still the most commonly used lead position for pacing, although CSP is showing rapid growth (almost 20%). This growth is probably due to awareness of the clinical and even prognostic benefits of CSP, as well as the development of new instruments specifically designed to improve outcome reproducibility.²⁰

DDD/R mode is still the most commonly used pacing mode in AVB, even more than in 2022 (62.1%), with limited use of VDD/R mode. Strikingly, modes capable of maintaining AV synchrony increased in elderly patients (> 80 years), undoubtedly due to quality of life improvements and greater use of leadless VDD pacemakers. Differences by sex persisted, with increases directly related to age.

In SSS, the implantation of pacemakers favoring AV synchrony slightly increased from 2022, reaching 75.9%, but fell to 68.1% in octogenarians. This result is likely due to decreased quality of life with age and the fact that most of these patients have permanent AF.

For the first time, AF/atrial flutter with slow or blocked ventricular response was the second most common device indication. There was no increase in AV node ablation in 2023 vs previous years (Spanish Catheter Ablation Registry data, pending publication); in fact, there was a decrease. Thus, the most probable cause is an increased prevalence of this arrhythmia due to population aging.

There was a significant stagnation in the growth of resynchronization devices vs previous years, with a slight increase (1.4%) almost entirely due to CRT-P devices (2.1%). The most plausible explanation could be another sharp increase in CSP due to the consistent clinical evidence published in 2022. Several randomized trials^{21–23} have compared CSP and biventricular pacing in patients indicated for cardiac resynchronization and confirmed the superiority of CSP in terms of functional class and left ventricular ejection fraction.²⁴ The CardioDispositivos platform allows reporting of lead location in the conduction system. Nonetheless, a physiological pacing registry is also available.²⁵ According to Eucomed data, our implantation rate per million population is half that of the European average for both CRT-P devices (69/million) and CRT-D devices (123/million). These differences are very similar

to those of previous years and, even though the use of CSP for cardiac resynchronization is likely higher in Spain than in the rest of Europe,²⁶ there may still be a low indication for this therapy in patients with heart failure symptoms and left bundle branch block.

The use of remote monitoring programs is slowly but continually growing. The programs have a demonstrated prognostic impact in patients implanted with pacemakers and defibrillators and also reduce emergency department visits and face-to-face consultations.²⁷ However, despite current recommendations,²⁸ the widespread use of this technology in all devices remains distant. Notably, La Rioja is the autonomous community with the most devices included in such programs.

Limitations

The main limitation is the heterogeneity of the data reported by hospitals due to the different sources of information. Although the number of centers participating in the registry increased, many implanting centers do not report their data. Because data submission is still incomplete, a certain percentage of data was missing for each variable. This figure was very high in some cases.

CONCLUSIONS

In 2023, the number of units reported to the recording platform of the Heart Rhythm Association increased by 48.1% vs 2022. Of the total number of implanted devices, the greatest growth was seen in CRT-P devices (2.1%), particularly in leadless pacemakers (18.1%). CSP continued its rapid growth and the use of remote monitoring also increased, albeit at a slower rate.

FUNDING

The registry is partly funded through an agreement between the Spanish Agency of Medicines and Medical Devices and the Casa del Corazón Foundation. This agreement channels a registered grant established in the 2023 Spanish budget for the management and maintenance of the national pacemaker and implantable defibrillator registries.

AUTHORS' CONTRIBUTIONS

R. Cózar-León and F.J. García-Fernández performed the data collection, data analysis, and article drafting. M. Molina-Lerma performed the data collection, data analysis, article drafting, and final revision. D. Calvo performed the registry coordination work, data integration, critical revision, and final approval.

CONFLICTS OF INTEREST

R. Cózar-León receives consultancy fees from Medtronic, Abbott, and Boston Scientific; M. Molina-Lerma receives consultancy fees from Abbott, Medtronic, Boston Scientific, and Microport. The other authors have no conflicts of interest to declare.

ACKNOWLEDGMENTS

The authors wish to thank the technical team of the Heart Rhythm Association registries of the SEC, the staff of the Spanish Society of Cardiology (Gonzalo Justes, Miguel Salas, Israel García, and Jesús de la Torre) for their outstanding work in the management and data integration that make this work possible, and the manufacturing and marketing industry for their collaboration.

REFERENCES

- Pombo Jiménez M, Cano Pérez O, Fidalgo Andrés ML, Lorente Carreño D, Coma Samartín R. Spanish Pacemaker Registry. Thirteenth Official Report of the Spanish Society of Cardiology Working Group on Cardiac Pacing (2015). *Rev Esp Cardiol.* 2016;69:1190–1203.
- Cano Pérez O, Pombo Jiménez M, Fidalgo Andrés ML, Lorente Carreño D, Coma Samartín R. Spanish Pacemaker Registry. 14th Official Report of the Spanish Society of Cardiology Working Group on Cardiac Pacing (2016). *Rev Esp Cardiol.* 2017;70:1083–1097.
- Pombo Jiménez M, Cano Pérez O, Lorente Carreño D, Chimeno García J. Spanish Pacemaker Registry. 15th Official Report of the Spanish Society of Cardiology Working Group on Cardiac Pacing (2017). *Rev Esp Cardiol.* 2018;71:1059–1068.
- Cano Pérez O, Pombo Jiménez M, Lorente Carreño D, Chimeno García J. Spanish Pacemaker Registry. 16th Official Report of the Spanish Society of Cardiology Working Group on Cardiac Pacing (2018). *Rev Esp Cardiol.* 2019;72:944–953.
- Pombo Jiménez M, Cano Pérez O, Chimeno García J, Bertomeu-González V. Spanish Pacemaker Registry. 17th Official Report of the Section on Cardiac Pacing of the Spanish Society of Cardiology (2019). *Rev Esp Cardiol.* 2020;73:1038–1048.
- Pombo Jiménez M, Chimeno García J, Bertomeu-González V, Cano Pérez O. Spanish Pacemaker Registry. 18th Official Report of the Cardiac Pacing Section of the Spanish Society of Cardiology (2020). *Rev Esp Cardiol.* 2021;4:1085–1095.
- Pombo Jiménez M, Chimeno García J, Bertomeu-González V, Cano Pérez O. Spanish pacemaker registry. 19th official report of the Heart Rhythm Association of the Spanish Society of Cardiology (2021). *Rev Esp Cardiol.* 2022;75:949–959.
- Pombo Jiménez M, Chimeno García J, Bertomeu-González V, Cano Pérez O. Spanish pacemaker registry. 20th official report of the Heart Rhythm Association of the Spanish Society of Cardiology (2022). *Rev Esp Cardiol.* 2023;76:1032–1041.
- Eucomed. Medtech Europe. Statistics Cardiac Rhythm Management products 2018–2022. Available at: <https://www.medtecheurope.org/wp-content/uploads/2016/03/statistics-cardiac-rhythm-management-products-2018-2022.pdf>. Consulted 17 Jun 2024.
- España. Orden SCO/3603/2003, de 18 de diciembre, por la que se crean los Registros Nacionales de Implantes, BOE núm. 309, de 26/12/2003. Available at: <https://www.boe.es/eli/es/o/2003/12/18/sco3603>.
- España. Orden SSI/2443/2014, de 17 de diciembre, por la que se modifica la Orden de 21 de julio de 1994, por la que se regulan los ficheros con datos de carácter personal gestionados por el Ministerio de Sanidad y Consumo, BOE núm. 311, de 25/12/2014. Available at: <https://www.boe.es/eli/es/o/2014/12/17/ssi2443>.
- CardioDispositivos. Plataforma de registros nacionales de marcapasos y DAI. Available at: <http://cardiodispositivos.es>. Consulted 16 Jun 2024.
- Real Decreto 192/2023, de 21 de marzo, por el que se regulan los productos sanitarios, BOE núm. 69, de 22/3/2023. Available at: <https://www.boe.es/eli/es/rd/2023/03/21/192>.
- España. Reglamento (UE) 2017/745 del Parlamento Europeo y del Consejo, de 5 de abril de 2017, sobre los productos sanitarios, por el que se modifican la Directiva 2001/83/CE, el Reglamento (CE) n.º 178/2002 y el Reglamento (CE) n.º 1223/2009 y por el que se derogan las Directivas 90/385/CEE y 93/42/CEE del Consejo, DOUE núm. 117, de 5/2/2017. Available at: <http://data.europa.eu/eli/reg/2017/745/oj>.
- Instituto Nacional de Estadística. Censo de Población. 1 de enero de 2023. Primeros resultados [nota de prensa, 13/12/2023]. Available at: https://www.ine.es/prensa/censo_2022_2023.pdf. Consulted 16 Jun 2024.
- Glikson M, Nielsen JC, Kronborg MB, et al. ESC Scientific Document Group. 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: Developed by the Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC) With the special contribution of the European Heart Rhythm Association (EHRA). *Eur Heart J.* 2021;42:3427–3520.
- Boersma V, El-Chami M, Steinwinder C, et al. Practical considerations, indications, and future perspectives for leadless and extravascular cardiac implantable electronic devices. *Europace.* 2022;24:1691–1708.
- Chan NY, Kwong NP, Cheong AP. Venous access and long-term pacemaker lead failure: comparing contrast-guided axillary vein puncture with subclavian puncture and cephalic cutdown. *Europace.* 2017;19:1193–1197.
- Burri H, Starck C, Auricchio A, et al. EHRA expert consensus statement and practical guide on optimal implantation technique for conventional pacemakers and implantable cardioverter-defibrillators: endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), and the Latin American Heart Rhythm Society (LAHRS). *Europace.* 2021;23:983–1008.
- González-Matos CE, Rodríguez-Queralto O, Záraket F, Jiménez J, Casteigt B, Vallès E. Conduction System Stimulation to Avoid Left Ventricle Dysfunction. *Circ Arrhythm Electrophysiol.* 2024;17:e012473.
- Wang Y, Zhu H, Hou X, et al. Randomized Trial of Left Bundle Branch vs Biventricular Pacing for Cardiac Resynchronization Therapy. *J Am Coll Cardiol.* 2022;80:1205–1216.
- Pujol-Lopez M, Jiménez-Arjona R, Garre P, et al. Conduction System Pacing vs Biventricular Pacing in Heart Failure and Wide QRS Patients: LEVEL-AT Trial. *JACC Clin Electrophysiol.* 2022;8:1431–1445.
- Huang W, Wang S, Su L, et al. His-bundle pacing vs biventricular pacing following atrioventricular nodal ablation in patients with atrial fibrillation and reduced ejection fraction: a multicenter, randomized, crossover study—the ALTERNATIVE-AF trial. *Heart Rhythm.* 2022;19:1948–1955.
- Ferreira Felix I, Collini M, Fonseca R, et al. Conduction system pacing versus biventricular pacing in heart failure with reduced ejection fraction: A systematic review and meta-analysis of randomized controlled trials. *Heart Rhythm.* 2024;21:881–889.
- ReseaArch. Available at: <https://app.research.com>. Consulted 17 Jun 2024.
- Kircanski B, Boveda S, Prinzen F, et al. Conduction system pacing in everyday clinical practice: EHRA physician survey. *Europace.* 2023;25:682–687.
- Varma N, Piccini JP, Snell J, Fischer A, Dalal N, Mittal S. The relationship between level of adherence to automatic wireless remote monitoring and survival in pacemaker and defibrillator patients. *J Am Coll Cardiol.* 2015;65:2601–2610.
- Ferrick AM, Raj SR, Deneke T, et al. 2023 HRS/EHRA/APHRS/LAHS expert consensus statement on practical management of the remote device clinic. *Heart Rhythm.* 2023;39:250–230.