

Special article

Spanish Pacemaker Registry. Eighth Official Report of the Spanish Society of Cardiology Working Group on Cardiac Pacing (2010)

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ABSTRACT

Introduction and objectives: Our aim is to describe the analysis of the pacemaker implants and replacements reported to the Spanish Pacemaker Registry in 2010, with special reference to the selection of pacing modes.

Methods: Data collection was based on the information provided by the European Pacemaker Patient Identification Card, which was processed using a specially designed computer application.

Results: Information was received from 101 hospitals, covering a total of 11 648 cards. An estimated 738 pacemaker generators per million population were placed in 2010. The number of pacemaker implantations is higher and the mean age of the recipients lower among men. Overall, 95.5% of the pacemaker leads used were bipolar, 56% employed an active fixation system, and 60% were placed in atrium. The most common electrocardiographic indication was atrioventricular block, followed by sick sinus syndrome. Twenty-four percent of the patients with atrioventricular block and 25.6% of those with sick sinus syndrome are being paced in VVI/R mode (12% of the patients in each group are aged 80 years or under). Cardiac resynchronization device implantation has reached the level of 47 units per million population, 25.7% of which are not associated with implantable cardioverter defibrillators.

Conclusions: The upward trend in the use of pacemaker generators continues. The pacemaker leads used are predominantly bipolar, and the majority are active fixation leads. Age remains a factor in the choice of the appropriate pacing mode for the different types of heart disease. This choice could be improved in more than 20% of the cases of pacemaker implantation.

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Registro Español de Marcapasos. VIII Informe Oficial de la Sección de Estimulación Cardíaca de la Sociedad Española de Cardiología (2010)

RESUMEN

Introducción y objetivos: En este artículo se describe el análisis de los implantes y recambios de marcapasos remitidos al Registro Español de Marcapasos en 2010, con especial referencia a la selección de los modos de estimulación.

Métodos: La recogida de datos se basa en la información de la tarjeta europea del paciente portador de marcapasos, que se procesa mediante una aplicación informática específica.

Resultados: Se recibió información de 101 centros hospitalarios, con un total de 11.648 tarjetas. Se estima un consumo de 738 generadores por millón de habitantes. Entre los varones hay mayor incidencia de implantes de marcapasos y a una media de edad más baja. El 95,5% de los cables de estimulación utilizados fueron bipolares, el 56% con sistema de fijación activa y el 60% en cavidad auricular. La indicación electrocardiográfica más frecuente es el bloqueo auriculoventricular, seguida de la enfermedad del nódulo sinusal. El 24% de los pacientes con bloqueo auriculoventricular y el 25,6% con enfermedad del nódulo sinusal se estimulan en modo VVI/R (el 12% de unos y otros entre los pacientes de 80 o menos años). Los dispositivos de resincronización cardíaca alcanzan 47 unidades por millón de habitantes; un 25,7% no tiene desfibrilador automático implantable asociado.

Conclusiones: Persiste el aumento del consumo de generadores de marcapasos. Los cables de estimulación que se utilizan son bipolares, y en su mayoría son de fijación activa. La edad sigue

Palabras clave:

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Cables marcapasos

Registro

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siendo un factor influyente en la adecuación del modo de estimulación en las diversas afecciones. La elección del modo de estimulación se puede mejorar en más del 20%.

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Abbreviations

AFib/AF: atrial fibrillation or atrial flutter

AVB: atrioventricular block

BNDM: *Banco Nacional de Datos de Marcapasos* (Spanish Pacemaker Registry)

CRT: cardiac resynchronization therapy

EPPICard: European Pacemaker Patient Identification Card

SSS: sick sinus syndrome

INTRODUCTION

The Spanish Pacemaker Registry, the *Banco Nacional de Datos de Marcapasos*¹ (BNDM), provides information on the major aspects of the use of pacemakers for cardiac pacing in Spain since 1994. Among the objectives of the BNDM is the yearly publication of data on cardiac pacing to examine the situation in clinical practice and changes taking place, as well as the extent to which the use of these devices complies with or adapts to the recommendations of the current clinical guidelines^{2,3}; it also enables us to compare different aspects of pacing with the registries of other countries or with our own activity and thus assess the quality of the pacing carried out and its possible improvement.

The first official report was published in *Revista Española de Cardiología* in 1997⁴ and, since then, it has been issued periodically,^{5–12} maintaining the same structure. The BNDM also submits an annual summary of all the data to the European Pacemaker Registry^{13,14} and to the European Heart Rhythm Association White Book.¹⁵

The current report presents the data corresponding to the activity related to cardiac pacing in 2010 and the major features of the changes observed during the present decade. In some of the items included in the registry, the data is not available for every year, either because these aspects were not taken into account at the time or due to changes and improvements in the database software or in the computer application that have made the data incompatible.

The information for every year since 1999, provided in a series of graphs, is available on the web page of the Working Group on Cardiac Pacing (www.estimulacioncardiaca.org or www.marcapasossec.org).

METHODS

Information on the European Pacemaker Patient Identification Card

Only the data provided for the items on the European Pacemaker Patient Identification Card (EPPICard)⁴ are processed. They include the appropriate codes for symptoms, etiology, electrocardiographic indications, pacing mode, implantation or extraction of leads and/or generator, and file closure; the card does not record data on follow-up, survival, or complications. This card

should be completed in the hospital following implantation, after which a copy is generated to be sent to the registry in accordance with the current Spanish legislation on these implantable devices (RD 1.616/2009 dated 26 October, regulating active implantable health products, chapter IX, article 29), which can be consulted in the *Boletín Oficial del Estado*. The information on the EPPICard can be transmitted by electronic means, provided that the system employed offers the proper guarantees that this information will be used only for the purposes envisaged in the aforementioned article.

The registry processes the information received, by ordinary mail or on disk, as preferred by those responsible for the records in each center, in the form of individual records or from the database pertaining to the center (complying with the data privacy guidelines required by the Data Privacy Law).

The Working Group on Cardiac Pacing allows free access to its own database format⁹ in the attempt to facilitate the uniform collection and processing of the information, but this has not yet had a significant impact on the registry.

The information is processed using a specially designed computer application with the collaboration of the Department of Information Technology of the Spanish Society of Cardiology.

Information Provided by the Distributors of the Devices

The total number of pacemakers placed in Spain during the year and their distribution according to autonomous region is obtained through the collaboration of all the commercial distributors in Spain (information that they generally convey to the European Confederation of Medical Suppliers Associations [EUCOMED] as well), since the registry does not receive 100% of the EPPICards despite the fact that it is obligatory to send information on all the procedures performed to enable monitoring for possible alerts, etc. At the present time, the registry is based on the voluntary activity of professionals and centers.

Report of the Spanish Institute of Statistics

The population-based data for the different calculations related to pacing in a given year, both for the country as a whole and for each autonomous region, were extracted from the latest report issued and updated by the Spanish Institute of Statistics (INE: www.ine.es).

Sample Analyzed

In 2010, the BNDM received data on the activity carried out in 101 hospitals and clinics (Table 1).

The registry processed a total of 11 648 cards, corresponding to implants or replacements of pacemaker generators; this number accounts for 33.5% of all the generators placed, a percentage that is somewhat lower than that of 2009. Participation on the part of the centers has decreased by about 5%.

The following results correspond to the analysis of the available sample, which we consider sufficient to enable us to assess the many different aspects of cardiac pacing in Spain and the progress being made.

Table 1

Public and Private Hospitals That Submitted Data to the Spanish Pacemaker Registry in 2010, According to Autonomous Region

Andalusia	Complejo Hospitalario Ntra. Sra. de Valme
	Complejo Hospitalario Virgen Macarena
	Hospital Costa del Sol
	Hospital Cruz Roja de Córdoba
	Hospital del Servicio Andaluz de Salud de Jerez de la Frontera
	Hospital Infanta Elena
	Hospital Juan Ramón Jiménez
	Hospital Punta Europa
	Hospital San Cecilio
	Hospital Virgen de la Victoria
Aragon	Clínica Quirón
	Hospital Miguel Servet
	Hospital Militar de Zaragoza
Canary Islands	Clínica La Colina
	Clínica Santa Cruz
	Hospital de La Candelaria
	Hospital Dr. Negrín
	Hospital General de La Palma
	Hospital General de Lanzarote
	Hospital Insular
	Hospital Universitario de Canarias
Castile and León	Hospital Clínico Universitario de Salamanca
	Hospital de León
	Hospital del Bierzo
	Hospital Río Hortega
	Hospital General de Segovia
	Hospital General del Instituto Nacional de la Salud de Soria
	Hospital General Virgen de La Concha
Hospital General Yagüe	
Castile-La Mancha	Hospital Universitario de Valladolid
	Clínica Marazuela
	Hospital Alarcos
	Hospital General Virgen de la Luz
	Hospital Ntra. Sra. del Prado
Catalonia	Hospital Virgen de la Salud
	Complejo Hospitalario Parc Taulí
	Consorcio Sanitario de Mataró
	Hospital Arnau de Vilanova
	Hospital Clínic i Provincial de Barcelona
	Hospital de Tortosa Virgen de la Cinta
	Hospital del Mar
	Hospital del Vendrell
	Hospital Germans Trias i Pujol
	Hospital Joan XXIII de Tarragona
	Hospital de Mataró
Extremadura	Hospital de Terrassa
	Hospital San Camilo
	Hospital de Sant Pau i Santa Tecla
	Hospital Mútua de Terrassa
	Hospital San Pedro Alcántara
Galicia	Hospital Arquitecto Marcide
	Complejo Hospitalario Universitario de A Coruña
	Hospital Xeral de Lugo-Calde
	Hospital do Meixoeiro

Table 1 (continued)

Balearic Islands	Hospital Montecelo
	Complejo Asistencial Son Dureta
	Hospital Mateu Orfila
La Rioja	Hospital de Manacor
	Hospital de San Pedro
Community of Madrid	Clínica La Luz
	Clínica Ntra. Sra. de América
	Clínica Ruber Internacional
	Clínica San Camilo
	Clínica Virgen del Mar
	Fundación Hospital de Alcorcón
	Hospital 12 de Octubre
	Hospital de Fuenlabrada
	Hospital de Móstoles
	Hospital General Gregorio Marañón
	Hospital Infanta Elena
	Hospital La Paz
	Hospital La Moraleja
Region of Murcia	Hospital Príncipe de Asturias
	Hospital Ramón y Cajal
	Hospital Puerta de Hierro
	Hospital San Rafael
	Hospital Universitario Madrid Sanchinarro
	Hospital Severo Ochoa
	Hospital Universitario de Getafe
Chartered Community of Navarre	Hospital General Santa María del Rosell
	Hospital Morales Meseguer
	Hospital Rafael Méndez
Basque Country	Clínica Universitaria de Navarra
	Hospital de Navarra
	Hospital de Cruces
Principality of Asturias	Hospital de Galdakao
	Hospital Txagorritxu
	Fundación Hospital de Jove
	Hospital Central de Asturias
Valencian Community	Hospital de Cabueñes
	Clínica Quirón
	Hospital de Levante
	Hospital de San Jaime
	Hospital de Vinalopó
	Hospital General de Alicante del Servicio Valenciano de Salud
	Hospital Provincial de Castellón
Hospital Universitario La Fe	
Hospital Vega Baja	

RESULTS AND DISCUSSION

Number of Pacemakers Implanted per Million Population

In 2010, between implantations and replacements, a total of 34 706 pacemaker generators were implanted. These included 578 biventricular devices for cardiac resynchronization therapy (CRT) without defibrillation capability, according to the data conveyed to the BNDM by the manufacturers (as on other occasions, these data differ somewhat from those sent to EUCOMED: 35 137, 574 of them biventricular).

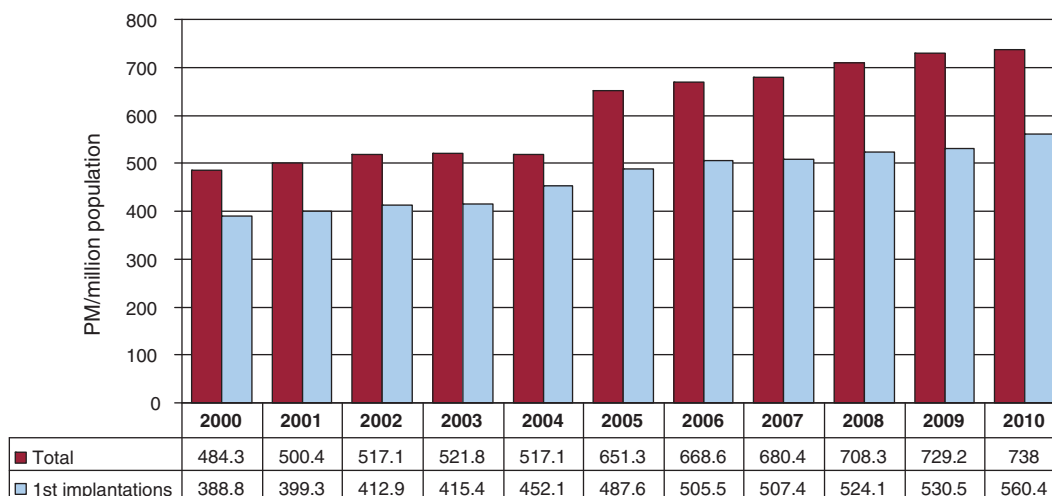


Figure 1. Number of pacemaker generators utilized per million population between 2000 and 2010. PM, pacemakers.

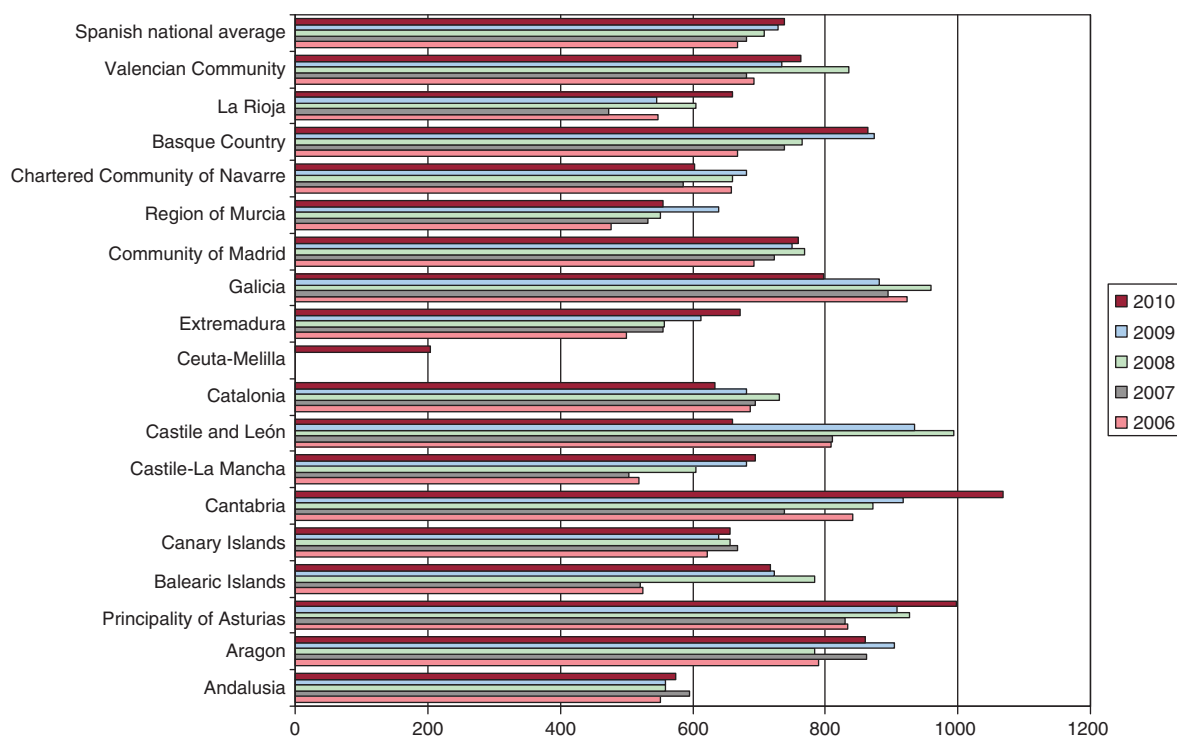


Figure 2. Number of pacemaker generators implanted per million population between 2006 and 2010, according to autonomous region, and the Spanish national average for each of those years.

According to the INE report, based on the census data corresponding to that year, the population of Spain was 47 021 031 inhabitants. Thus, according to BNDM data, a total of 738 pacemaker generators were placed per million population. We note that, aside from the expected increase in the use of generators due to population growth, the upward trend in the number of generators placed per million population continues (Fig. 1).

In the analysis of the distribution of the units employed per million population in the different autonomous regions, we see that, as in previous years, there are marked differences, with a profile similar to that of other years.^{10–12} Thus, around 1000 per million population are reported for Cantabria and Asturias, followed by the Basque Country and Aragon with 860. In general, a higher number of implantations are recorded in the autonomous

regions of northern Spain (Fig. 2) due to the fact that the population is older, as has been noted on previous occasions, with a higher proportion of inhabitants over the age of 75 years.⁹

Biventricular Pacing

The number of devices employed for CRT continues to increase each year. In 2010, this increase was due to units with or without implantable cardioverter defibrillator but, to a greater extent, to the higher percentage of the latter device. After a slight decrease in the total number of low-energy CRT devices employed in 2009, the rate of use increased again in 2010 to 12.2 per million population, while the total number of CRT devices placed was 47 per million population (Fig. 3).

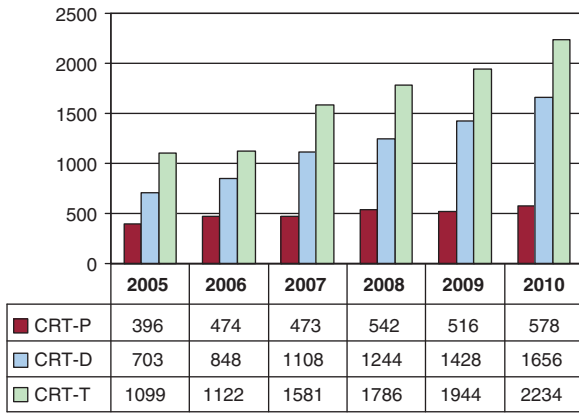


Figure 3. Number of cardiac resynchronization therapy devices implanted during the period from 2005 to 2010. CRT-D, biventricular devices with defibrillation capability; CRT-P, low-energy biventricular devices without defibrillation capability; CRT-T, total number of CRT devices.

Of the interventions reported to the registry, 1.6% of all the generators used were biventricular units, which were placed in 1.3% of first implantations and in 2.1% of replacements (the latter either to upgrade the original generator or simply to replace a depleted battery).

There were marked differences in the use of CRT devices from one autonomous region to another that are not easy to explain. They may be due to disparity in the number of implantation units and/or to the centers' degree of dedication to use of pacing in the treatment of heart failure, as occurs among European countries.¹⁶ The Chartered Community of Navarre was the community with the greatest number of implantations of both types of resynchronization devices, followed by Cantabria, the Valencia Community, the

Basque Country, and Canary Islands. Ceuta and Melilla reported no implantations. The data for the remaining regions are shown in Figure 4.

Patient Age and Sex

The mean age of the patients who underwent implantation of a cardiac pacing system in 2010 was 76.8 years; patients undergoing generator replacement were somewhat older, 77.1 years. The slight increase in the mean age at implantation continued, due to the aging of the population because of longer life expectancy. This circumstance means that there was a higher incidence of degenerative diseases, the reason implantation was indicated in the majority of the cases.

In 2010, once again, there was a sex-related difference in the mean age at implantation (76.1 years in men vs 77.7 years in women), very similar to that observed over the course of the years studied.

The highest rates of both implantation (39%) and replacement (39.2%) was reported in the age interval of 80 to 89 years, followed by the 70- to 79-year-old group (implantations, 37%; replacements, 32.2%) and the 60- to 69-year-old group. There was limited activity in patients aged 100 years and older, 0.2% for replacements and 0.18% for implantations (Fig. 5).

There was a higher incidence of implantations and generator replacements among men, as has been observed since the registry has been collecting this data.⁹⁻¹² Taking into account all the procedures, 57.7% were performed in men, 58.4% of first implantations (Fig. 6) and 56.6% of replacements (despite the fact that the female population is somewhat larger, 23.79 million vs 23.22 million men). According to the proportion of activity reported to the registry, 863.3 and 615.8 generators per million population were placed in men and women, respectively.

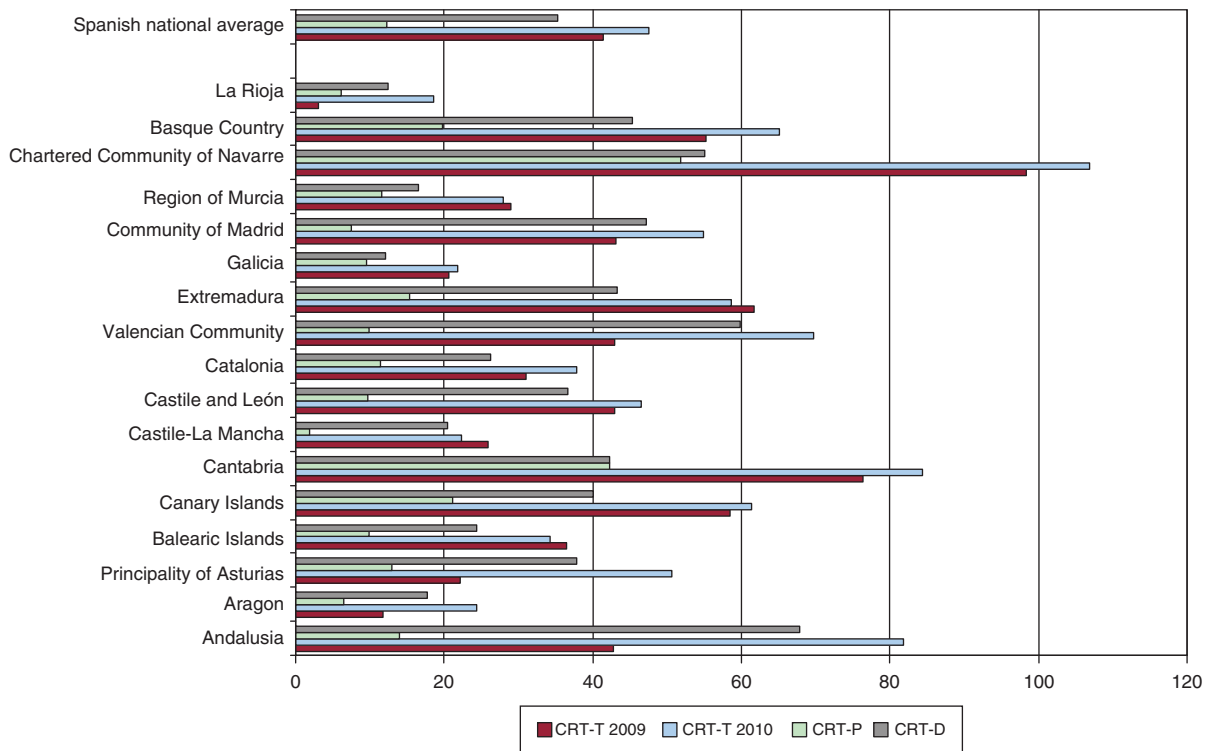


Figure 4. Number of cardiac resynchronization therapy devices implanted per million population, according to autonomous region, and the Spanish national average. CRT-D, biventricular devices with defibrillation capability (2010); CRT-P, low-energy biventricular devices without defibrillation capability (2010); CRT-T, total numbers of CRT devices in 2009 and 2010.

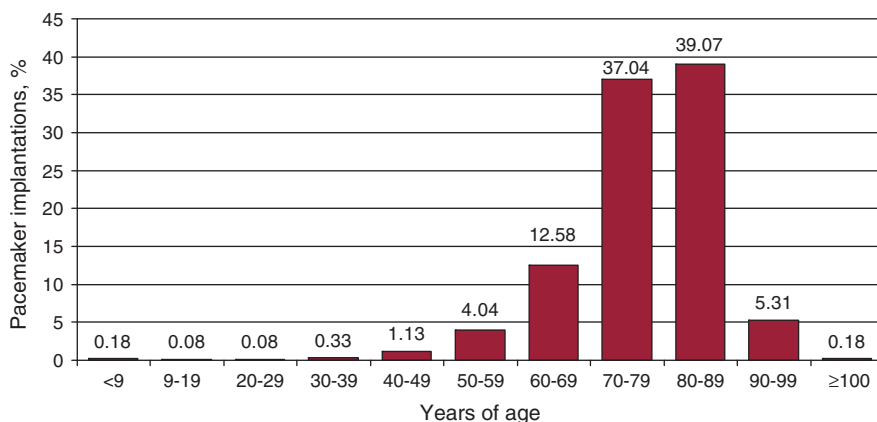


Figure 5. Distribution of the pacemaker implantations performed in 2010 according to age group (10-year intervals).

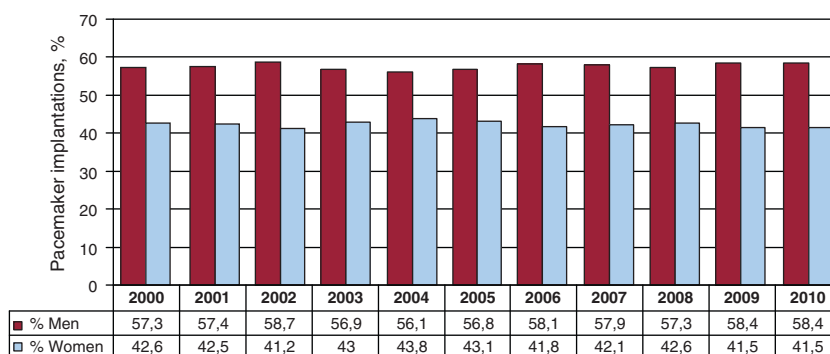


Figure 6. Percentages of pacemaker implantations according to sex, 2000 to 2010.

Type of Procedure

Implantations

Of all the generators used, 75.9% corresponded to first implantations, that is, 560 implantations per million population.

Generator Replacements

Generator replacements accounted for 24% of the devices utilized. In 2010, the slight but continuous upward trend in the

proportion of replacements among all the procedures carried out was interrupted, returning to figures similar to those of 2006 (Fig. 7).

The causes for generator substitution or replacement, in order of frequency, were as follows: battery depletion near the end of its useful life (94.9% of the cases), infection or erosion of the generator pocket (1.9%), elective (1.1%), a change in the system to achieve a hemodynamic improvement (0.9%), a major or minor generator defect (0.2%), and premature battery depletion (0.2%).

Generator replacements that, in addition, included a new pacing lead during the same procedure accounted for 1.1% of the reported activity.

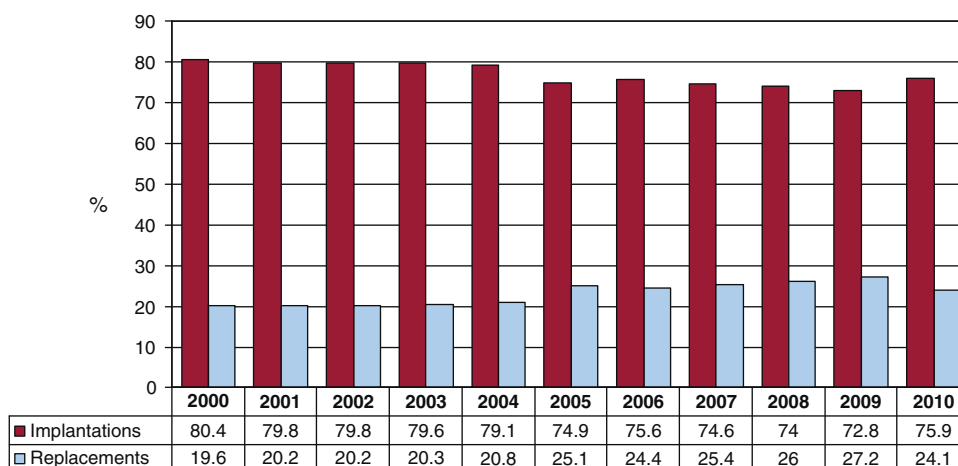


Figure 7. Percentages of pacemaker implantations and replacements, 2000 to 2010.

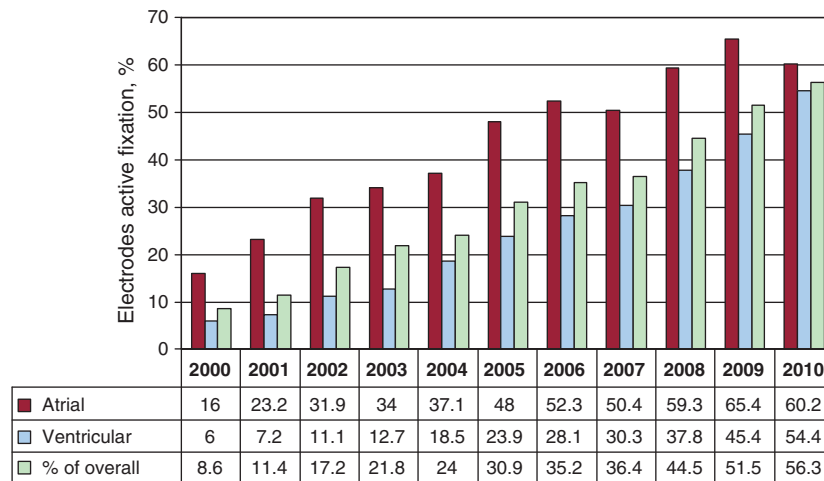


Figure 8. Percentages of overall, atrial, and ventricular active fixation leads, 2000 to 2010.

Pacing Leads

Polarity

Nearly all the leads (99.6%) used for pacing are bipolar. In all, 99.9% of those implanted into atrium are leads of this type, as are 99.7% of those placed in right ventricle and 59% of those utilized for left ventricular pacing with passage of the lead through the coronary sinus.

The small proportion of monopolar leads that remains (0.4%) is distributed as follows: coronary sinus (42.8%); right ventricle (36.5%); epicardium, in various cardiac surgical procedures (15.8%), and right atrium (4.7%). The choice of monopolar leads is generally due to the slenderness of the wire, a feature that could be important in the presence of multiple previous electrodes, venous stenosis, or on occasions for pacing via coronary sinus because of the size or the tortuous anatomy of the coronary veins; moreover, bipolarity is still not widely accepted in the case of epicardial leads implanted during cardiac surgery.

Fixation or Anchorage System

There was an increase in the use of active fixation (extendable and retractile corkscrew-like system to penetrate the myocardium), which was employed in 56.3% of all the leads implanted in 2010 (60.2% in atrium and 54.6% in ventricle) (Fig. 8).

The change in this choice is due especially to the fact that passive fixation (using flexible tabs or tines) requires specific areas of the endocardium that are limited to the highly trabeculated regions (ventricular apex or the atrial appendage), and cannot be used for pacing in other alternative regions, such as the increasingly widely employed pacing of the right ventricular outflow tract, upper or lower atrial septum, or less frequently, due to the complexity, the His bundle. Pacing in these areas, in comparison with the conventional areas, can offer advantages in certain situations. Moreover, active fixation makes it possible to stabilize the lead in adverse situations (as in the case of severe tricuspid insufficiency and marked cardiac dilation); the thresholds of the currently employed leads and the complications with the two systems are comparable. The isodiametric form of the active fixation leads facilitates their future extraction, were it to be necessary, although the retrieval system is frequently found to be broken at that time.

We have attempted to determine whether age is a factor in the choice of lead fixation system by studying two age groups with the cutoff point at 80 years; no noteworthy differences were found.

Active fixation was used in 54.6% of all the leads placed in patients over the age of 80 years and in 58.1% of all those placed in patients aged 80 years or under; this difference is exclusively due to the somewhat more frequent use of this type of fixation for ventricular leads in the younger age group (53.1% vs 57.8% in the older age group), whereas in atrium, it is used in approximately 60% of the leads placed in both groups.

Extraction of Electrode Leads

The most common causes for the extraction of pacing leads reported to the registry were, in descending order: skin infection or ulceration (42.8%), displacement or exit block (9.5%), insulation failure (9%), and conductor breakage (4.7%).

Isolated replacement of a cardiac lead (due to changes in its electrical function) accounted for 0.1% of all the interventions carried out, and implantation with generator replacement (whether to improve the pacing system or because of unacceptable thresholds, or damage to the lead prior to or during the replacement procedure), 1.1%.

Symptoms, Etiology, and Electrocardiographic Findings Leading to Implantation

Symptoms

The clinical signs that indicated the need for pacemaker implantation were, in descending order: syncope (44.2% of the cases), dizziness (25.3%), dyspnea or signs of heart failure (14.8%), and bradycardia (10.2%). Other less frequent symptoms or signs were chest pain (1%), tachycardia (0.9%), brain dysfunction (0.5%), and risk of sudden death after return to bradyarrhythmia (0.1%), whereas 2.7% corresponded to asymptomatic patients or those who underwent prophylactic implantation.

The distribution of these preimplantation symptoms and signs was similar over the course of all the years analyzed.

Etiology

The most common etiology underlying the indication for implantation was possible fibrosis of the conduction system (42.1%), closely followed by unknown etiology (42%)—we would group these two together because the former is considered after the exclusion of other causes; they were followed by ischemic

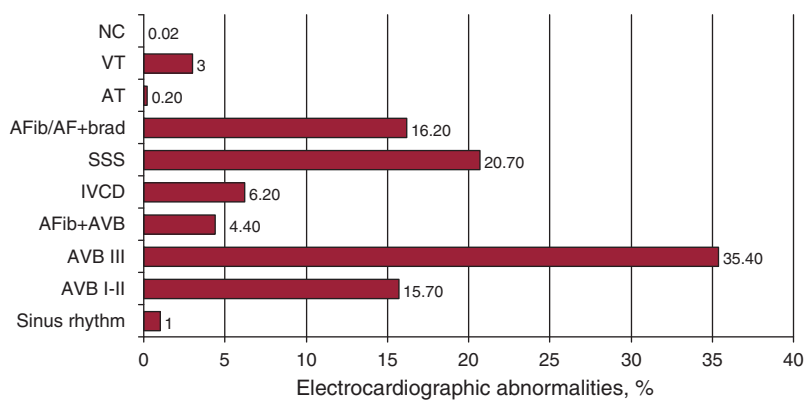


Figure 9. Distribution of electrocardiographic abnormalities prior to implantation in 2010. AFib/AF+brad, atrial fibrillation or atrial flutter with slow ventricular response; AFib+AVB, atrial fibrillation with atrioventricular block; AT, atrial tachycardia; AVB, atrioventricular block; IVCD, intraventricular conduction disturbance; NC, not codified; SSS, sick sinus syndrome; VT, ventricular tachycardia.

etiology (6.3%)—0.4% of which correspond to the postinfarction subgroup—and the cardiomyopathies (2.7%; 0.7% of them hypertrophic.) The group of iatrogenic-therapeutic etiologies represented 2.1% and of these, 0.6% were secondary to atrioventricular (AV) node ablation, intentional or unintentional, a proportion that has been decreasing for the past 2 years,^{9,10} possibly because of the new ablation therapies for the treatment of atrial fibrillation or atrial flutter (AFib/AF). Among the etiologies of the generator replacements in 2010 (that is, years after the first implantation), the iatrogenic-therapeutic group was most frequently reported (4%), with ablation accounting for 1.8%, which confirms the trend.

Neurally mediated causes accounted for 0.8% of the cases, again less than 1% like the year before¹⁰; they corresponded to vasovagal syncope (0.3%) and carotid sinus syndrome (0.5%), which continued to decrease, as in recent years, and accounted for 2.5% of all the generator replacements. The etiology was congenital in 0.4% of the cases and the cause was heart transplantation in 0.05%.

Abnormal Electrocardiographic Findings

The most common electrocardiographic abnormalities prior to implantation were AV conduction disturbances (55.6%)—among them, third-degree AV block (AVB) (35.4%) (excluding AF with AVB), sick sinus syndrome (SSS) in its different forms (sinoatrial arrest, sinus bradycardia, bradycardia-tachycardia syndrome, chronotropic incompetence, etc.) accounted for 20.7%, although

the incidence reaches 36.5% if the AFib/AF patients with bradycardia are also included (code E6 of the EPPICard); intraventricular conduction disturbances represented 6.2% of all the electrocardiographic abnormalities reported.

No significant changes are observed with respect to the electrocardiographic abnormalities reported in recent years, despite the theoretical increase in indications, including those corresponding to CRT.¹⁷

With regard to sex, as in previous years there was a greater incidence of conduction disturbances, both AVB and those involving intraventricular conduction, among men, a sign of the more marked degeneration of their conduction system,^{9–12} whereas the rate of SSS continued to be similar in both sexes; this explains the higher number of implantations in men. The details of the subgroups mentioned and of the changes over the course of recent years can be seen in Figures 9 and 10.

Pacing Modes

General

Of all the generators implanted in 2010, single-chamber pacing was employed in 43.1%, more often in first implantations (44%) than in replacements (40.3%). Among these procedures, isolated, single-chamber atrial pacing (AAI/R) was the mode used in 1.3% of the units placed; these percentages were low, but very similar when implantations (1.2%) and replacements (1.4%) were

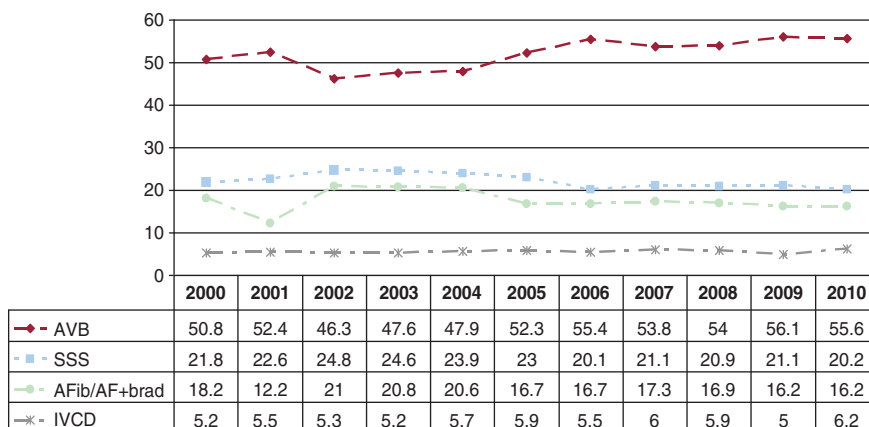


Figure 10. Changes in incidences of electrocardiographic abnormalities prior to implantation, 2000 to 2010. AFib/AF+brad, atrial fibrillation or atrial flutter with slow ventricular response; AVB, atrioventricular block; IVCD, intraventricular conduction disturbance; SSS, sick sinus syndrome.

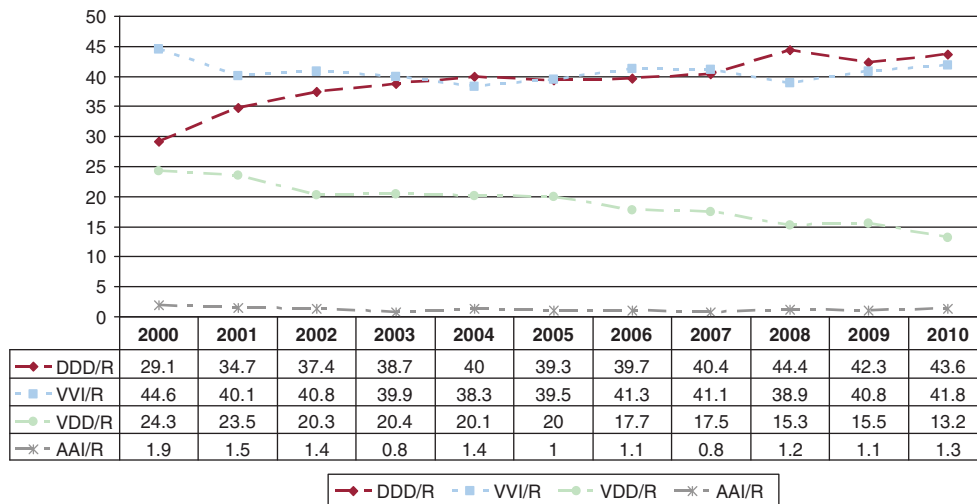


Figure 11. Overall changes in all pacing modes from 2000 to 2010.

compared. At the present time, the use of the AAI/R mode is very limited even in the countries, such as Denmark¹⁸ or Sweden, in which it was most widely employed. This may be due to the use of more sophisticated units, with algorithms having the capability of changing from AAI/R to DDD/R mode or involving the AV interval, which facilitate intrinsic AV conduction and avoid the need to add a new ventricular lead in the uncommon case of future AVB.

Single-chamber ventricular (VVI/R) pacing units were chosen in 41.8% of the cases; we also noted a slight variation between first implantations (42.7%) and replacements (39%). Given that in the preimplantation electrocardiographic abnormalities reported to the BNDM, the patients with atrial tachycardia (the sum of the patients with AFib/AF plus bradycardia and AFib plus block) account for 20% of all those for whom stimulation of this type is indicated, there is a group of patients who are in sinus rhythm and undergoing VVI/R pacing (somewhat over 20%), in whom the quality of pacing could be improved by using modes in synchrony with the atrium, a question that will be studied in the following sections.

Dual-chamber pacing, either with one or two leads, was employed in 56.9% of the cases (55.9% and 59.6% of the first implantations and replacements, respectively). In all, 13.2% of these units involved single-lead sequential pacing (VDD/R), a percentage that indicates a decrease with respect to 2009¹⁰ and a downward trend in recent years, and is the lowest reached

over the past decade; one has to go back to 1996 to find a similar figure. There was also a marked difference in its use in first implantations (11.8%) as compared with replacements (17.6%) due to the fact that this mode was employed more frequently in previous years. Despite this reduction, an estimated 4600 VDD/R units were implanted in 2010 (Fig. 11).

The mode most widely used in all the pacemakers was DDD pacing, both overall (43.6%) and when considering first implantations (44.1%) and replacements (42%). If we compare the modes utilized with those of previous years, DDD/R pacing appears to be stabilized in the 40%-44% range.

One or more biosensors were used in combination with cardiac pacing for the purpose of varying the frequency in 83.4% of the cases.

The use of pacing for CRT, without an implantable cardioverter-defibrillator (low energy), showed a certain upturn in 2010; it rose again, after the slight decrease in the number of units in 2009, increasing both in total units (n=578) and in units per million population (12.2), but maintaining a proportion similar to that of previous years (1.5% of all the generators employed) (Fig. 3). We should point out, however, that the greatest increase in the use of CRT was due to the generators with implantable cardioverter-defibrillator, as was mentioned above, which amounted to 47.5 devices per million population, although this number was still far from the mean in other European countries.¹⁶

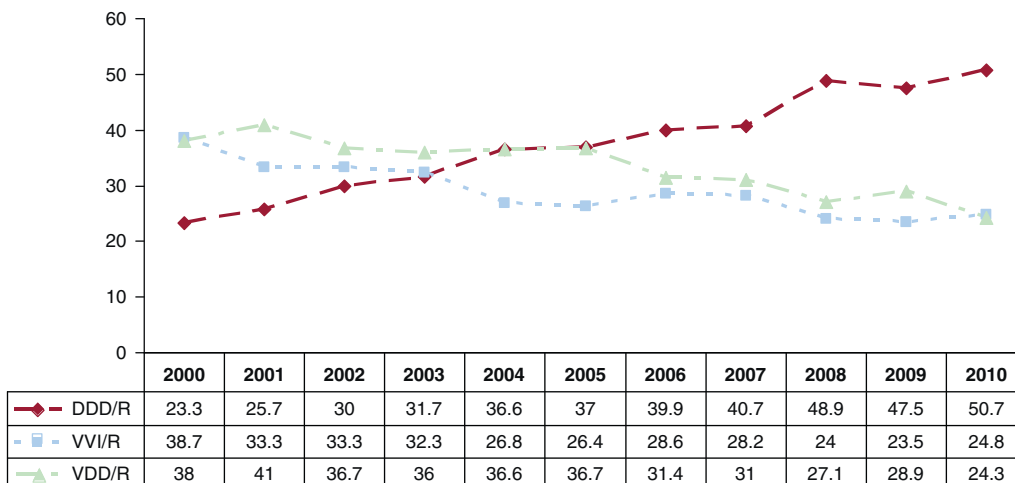


Figure 12. Changes in pacing modes in atrioventricular block, excluding patients with permanent atrial tachyarrhythmia, from 2000 to 2010.

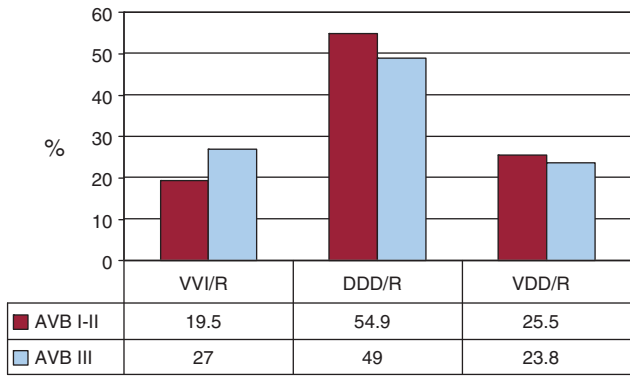


Figure 13. Pacing modes according to the degree of atrioventricular block in 2010. AVB, atrioventricular block.

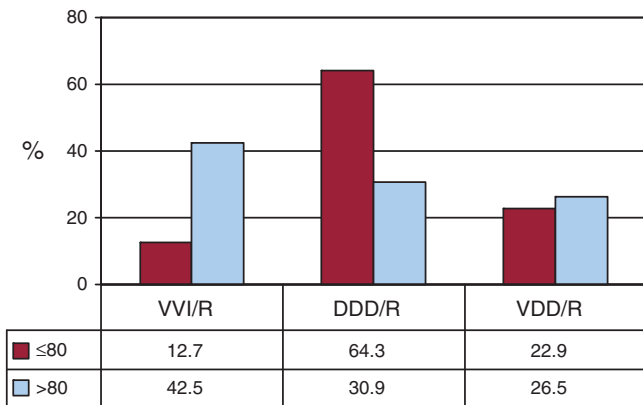


Figure 14. Pacing modes in atrioventricular block according to age group (≤80 years or >80 years of age), excluding patients with atrial tachyarrhythmia, in 2010.

Pacing in Conduction Disturbances

Pacing in atrioventricular block. This analysis was limited to those patients who were in sinus rhythm and excluded the subgroup of patients with atrial tachyarrhythmia in AVB (EPPICard code 8), in order to assess its adjustment to the most highly recommended mode for AVB in the current clinical guidelines.^{2,3}

Ventricular sequential pacing (in synchrony with the atrium) was carried out in 75.1% of the cases: 50.8% in DDD/R mode and 24.3% in VDD/R. The overall percentage was the same as the year

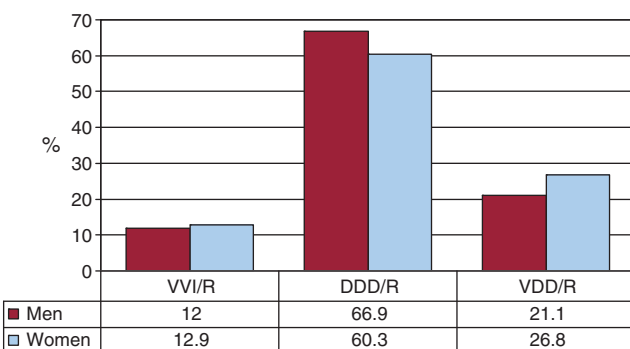


Figure 15. Pacing modes in atrioventricular block in patients aged 80 years or under, according to sex, in 2010.

before,¹² but there was a slight increase in the use of the DDD mode and a decrease in that of VDD (Fig. 12).

When the pacing mode was compared in terms of its distribution according to the degree of block, with first degree and second degree AVB in one group and third degree AVB in another, we observed that, as in 2009, pacing was more often based on atrial synchrony in cases of first and second degree AVB (80.4%) than in those of third degree AVB (72.9%). The variations correspond to a greater use of DDD mode and, to a lesser degree, of VDD mode (Fig. 13).

To determine whether age influenced the selection of the pacing mode, we analyzed, as in previous reports, the distribution of the modes according to two age groups: patients aged 80 years and under and those over 80 years of age. There was a marked difference in the use of modes that maintain AV synchrony, which reached a rate of 87.3% in patients aged 80 years and under, vs 57.4% in older patients. The increase in the utilization of AV synchronous pacing was due to a greater use of DDD/R mode, since VDD/R mode is employed more in the older population, and with percentages close to those of DDD mode in this patient group (Fig. 14). Over the course of time, it can be seen that the VDD mode is that least influenced by patient age.

We also examined, using the EPPICards in which age and sex were provided, whether sex had an influence on pacing mode selection in patients with AVB, and observed that sequential pacing was indicated in similar numbers, but that this was due to a more frequent application of VDD mode in women and less frequent use of DDD; thus, in the group aged 80 years and under, VDD/R pacing was carried out in 26.8% of the women and in 21.1% of the men (Fig. 15), and among the patients over the age of 80 years, these figures were 33.2% and 27.0%, respectively.

There still was a high incidence of single-chamber ventricular (VVI/R) pacing in patients with AVB who preserved sinus rhythm (24.8%) and a slight increase in the use of this mode with respect to 2009 was observed, a circumstance that interrupted the trend of the preceding years toward a better adaptation to more highly recommended modes^{2,3} (Fig. 12).

Age was a determining factor in the selection of VVI/R pacing; 20.8% of the patients in whom this mode was used were aged 80 years or younger vs the 53.1% who were over the age of 80 (Fig. 16). The degree of AVB also had some influence on this choice: 19.5% of the patients undergoing VVI pacing had first- or second-degree blocks, vs 27% with third-degree blocks. There was no notable sex-related difference in the use of this pacing mode in the younger of the two age groups (11% vs 11.7%, respectively, in men and women aged 80 years or under); the incidence of VVI/R pacing was somewhat higher among older women (40.8%) and for the aforementioned groups (35.5%).

Intraventricular conduction disturbances. In this group of electrocardiographic abnormalities, the selected pacing mode was capable of maintaining AV synchrony in 70.5% of the cases, with minimal variations over recent years, and with nearly the same percentage of VDD/R pacing (roughly 13%). The most frequently employed mode was DDD/R (57.5% of the cases), followed by VVI/R (29.5%) (Fig. 17).

As in the AV conduction disturbances, there was a notable difference in mode selection depending on patient age. In the two age groups analyzed in this report (cutoff point at 80 years), VVI/R pacing was found to be more widely used (51.6%) among the older patients, whereas it was employed in only 15.8% of the patients in the younger age group, and somewhat less in men (12.9%) than in women (19.6%). The DDD/R mode was that most frequently chosen among the patients aged 80 years or under (71.9%). The VDD/R mode continued to be that least influenced by age, with a very close rate of application in both age groups (12.1% in patients aged 80 years or under vs 13.5% in those over 80 years of age) (Fig. 18). This

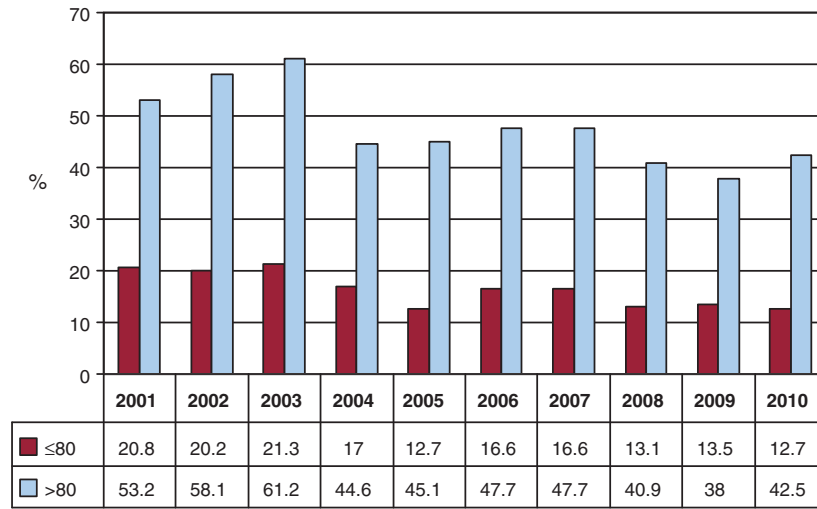


Figure 16. Changes in use of VVI/R pacing mode in atrioventricular block in patients in two age groups (≤80 years and >80 years of age), from 2001 to 2010.

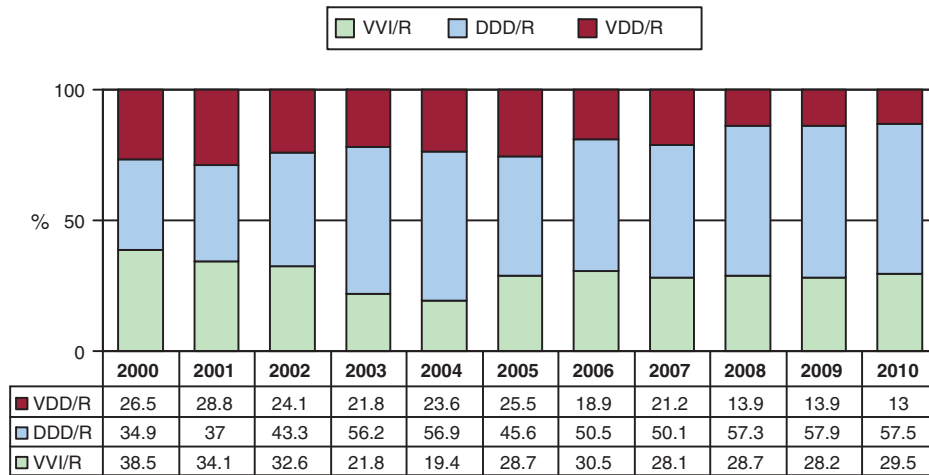


Figure 17. Pacing modes in intraventricular conduction disturbances from 2000 to 2010.

group of electrocardiographic abnormalities was associated with the most unvarying pacing modes of recent years.

The number of devices employed for low-energy CRT in the treatment of heart failure in cases of dilated cardiomyopathy accounted for as many as 10.2% of all the units implanted in this

group and, as occurred with the conventional generators, there were marked differences depending on age (14% among patients aged 80 years or younger and 3.22% among older individuals).

Pacing in Sick Sinus Syndrome

In accordance with our standard practice for the assessment of pacing modes applied in SSS and the degree of adaptation to the modes recommended in the latest clinical guidelines,^{2,3} we divided our study into 2 parts, separating the patients who theoretically are in permanent AFib/AF with bradycardia (code E6 of the EPPICard) from the rest, who are supposedly in sinus rhythm (codes from E1 to E5, plus E7 and E8).

Sick sinus syndrome with permanent atrial tachyarrhythmia. In these patients with AFib/AF, the predominant pacing mode was VVI/R (95.7%), although we could expect it to be 100%. As in previous analyses, the DDD/R mode was employed in 3.6% of the cases; it is our understanding that they corresponded to patients in whom the purpose was to achieve reversion to sinus rhythm. As in preceding years, the use of VDD/R was minimal (0.5%) and can only be justified in a patient with this condition as a response to technical problems.

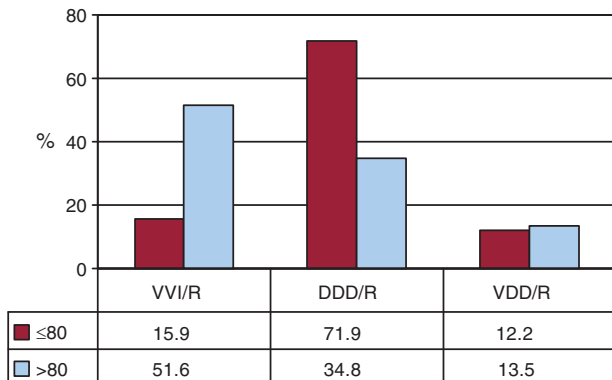


Figure 18. Pacing modes in intraventricular conduction disturbances in two age groups (≤80 years and >80 years of age), in 2010.

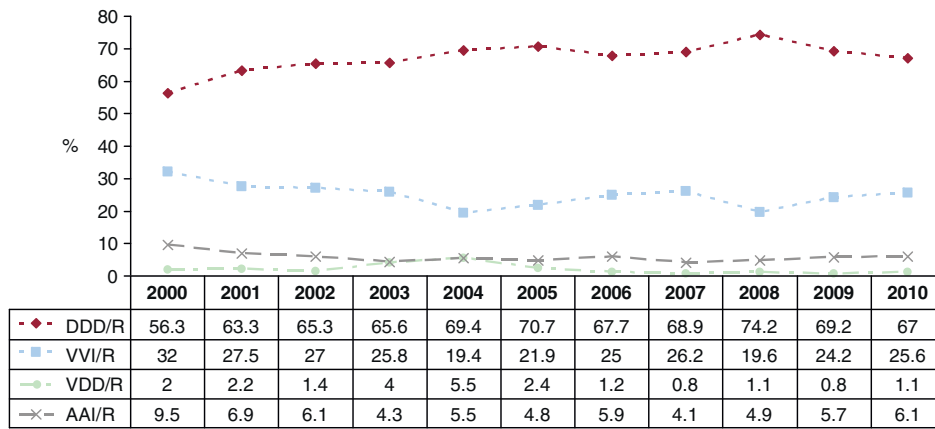


Figure 19. Pacing modes in sick sinus syndrome, excluding patients with permanent atrial tachyarrhythmia, from 2000 to 2010.

Sick sinus syndrome in sinus rhythm. This section includes the remaining electrocardiographic abnormalities associated with SSS, in which the atrial rhythm is supposedly stable, or at least partially so. In most cases (67.1%), DDD/R pacing was employed. The use of isolated atrial pacing increased somewhat (6.1%, the highest percentage in recent years). Atrial-based pacing modes are those most widely recommended for SSS^{2,3} (with atrial pacing and sensing capabilities), and together these two modes (DDD/R and AAI/R) represent an overall utilization of atrial-based pacing of 73.2%, somewhat reduced with respect to 2009; as then, there was a mild setback in the “quality of pacing” with respect to 2008.¹⁰ Single-chamber ventricular pacing was used in 25.6% of the cases and VDD, although difficult to justify, in 1.19%; these two modes are those least recommended in an electrocardiographic abnormality of this type, given the higher risk of atrial tachyarrhythmias, possible clinical symptoms due to pacemaker syndrome, etc. (Fig. 19).

For the second time, as in 2009,¹² the authors analyzed the type of pacing applied in the management of each of the electrocardiographic signs of SSS to determine whether any of them could be at the root of the high percentage of VVI/R pacing, whether because of a problem with the classification or a possible code-related confusion (as can occur with tachycardia-bradycardia syndrome [EPPICard code E5], which corresponds to episodes of tachyarrhythmia and sinus bradycardia, and in which there is a risk of the

erroneous inclusion of patients with episodes of permanent AFib with alternating phases of fast-slow ventricular response, which should be included under the aforementioned code E6). A high incidence of VVI/R pacing can be observed for codes E1 to E8 (ranging from a minimum of 18.4% to a maximum of 30%, the latter corresponding to tachycardia-bradycardia syndrome) (Fig. 20). Like the year before, subgroups E7 and E8 were not studied because of their negligible contribution to the cases of SSS reported in the BNDM (0.6% for interatrial block and 0.4% for chronotropic incompetence). Thus, there is still a significant degree of inappropriate pacing mode selection in all the electrocardiographic signs of SSS, a situation that we should make an effort to improve.

In the study of age as a factor in the choice of pacing mode, according to the two age groups defined by a cutoff point at 80 years, as is customary in the BNDM, there was a marked difference in the use of DDD and VVI modes. Pacing was performed in DDD mode in 75% of the patients aged 80 years or under and in 55.5% of those over the age of 80, whereas VVI mode was employed in 17.6% and 38% of the cases, respectively. In 2010, the use of AAI mode was slightly greater in the younger age group; there was also a small percentage of cases in which VDD was utilized in both age groups (Fig. 21). Age continues to be a determining factor in mode selection over the course of the years (Fig. 22).

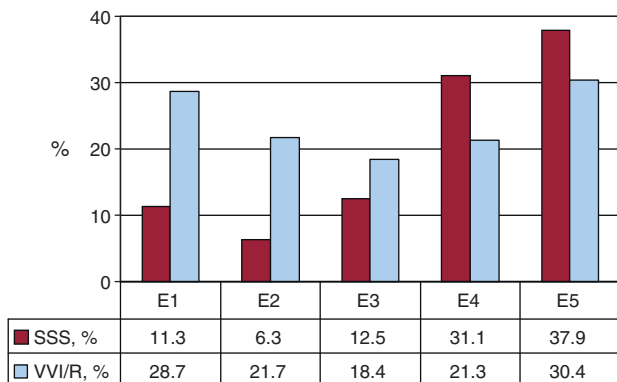


Figure 20. Distribution of the incidence of the use of VVI/R pacing in 2010, according to the electrocardiographic code indicated for sick sinus syndrome on the European Pacemaker Patient Identification Card. E1, not specified; E2, exit block; E3, sinoatrial arrest; E4, bradycardia; E5, bradycardia-tachycardia; SSS, sick sinus syndrome.

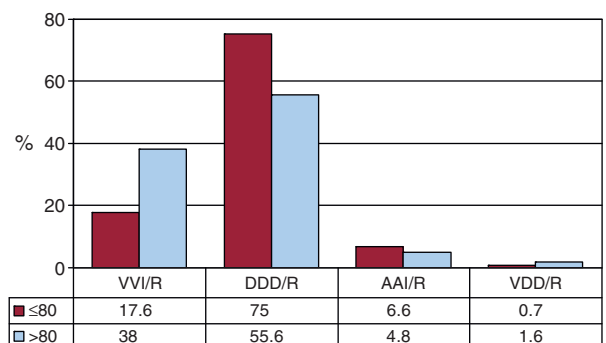


Figure 21. Pacing modes in sick sinus syndrome for the two age groups (≤80 years and >80 years of age) in 2010.

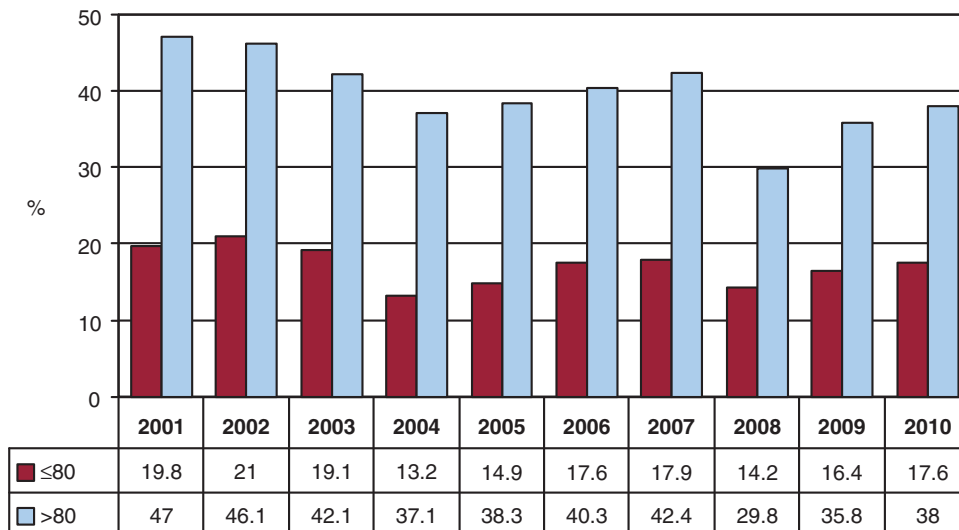


Figure 22. Use of VVI/R pacing in sick sinus syndrome in the two age groups (≤ 80 years and >80 years of age) from 2001 to 2010.

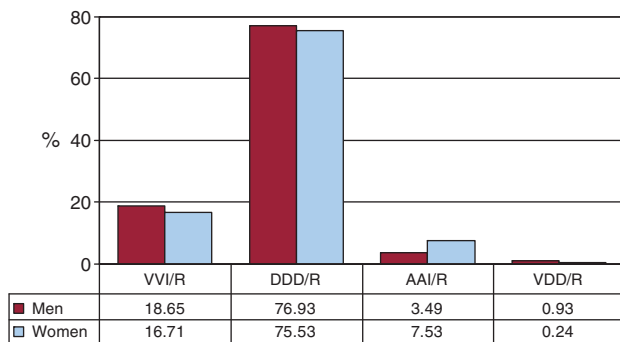


Figure 23. Pacing modes in sick sinus syndrome in patients aged 80 years or under, according to sex, in 2010.

When sex was analyzed as a factor in the appropriate choice of pacing mode in SSS and after adjustment for the two age groups mentioned above, only slight variations were observed; VVI/R pacing was carried out in 18.6% of the men and in 16.7% of the women aged 80 years or under; the use of AAI mode was notably greater among women (3.5% vs 7.5%) (Fig. 23).

The study of the changes taking place over the present decade shows that the utilization of VVI/R pacing has increased during the last 2 years, a circumstance that indicates a certain setback in the selection of appropriate pacing modes in SSS (Fig. 19).

CONCLUSIONS

A total of 34 706 pacemaker generators (738 per million population) were used in Spain in 2010, with a marked disparity in the distribution of conventional units among the autonomous regions due to differences in the aging of their populations.

Generator replacements accounted for 24% of the activity, thus interrupting the yearly upward trend in the percentage of the overall number of procedures performed.

More implantations and replacements were carried out in octogenarians than in other age groups.

Men undergo more implantations than women and at an earlier age.

Nearly all the pacemaker leads utilized were bipolar; the majority of the monopolar leads were employed in epicardial pacing, between cardiac surgery and resynchronization procedures. The active fixation system was more widely used in both cardiac chambers, especially in atrium.

The most common (55.7%) electrocardiographic abnormality prior to implantation was AVB, primarily of the third degree.

Age, but not sex, was found to be a determining factor in the choice of pacing mode for the different electrocardiographic abnormalities.

There has been a slight decrease in the use of AV sequential pacing.

Overall, VVI/R pacing was employed in 24.8% of the patients with AVB and 25.6% of those with SSS in sinus rhythm.

The use of single-lead VDD/R units decreased once again, with an estimated 4600 being implanted in 2010.

There was an increase in the number of devices for biventricular pacing implanted in Spain, reaching a high of 47.5 units per million population, with a marked disparity between autonomous regions.

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CONFLICT OF INTERESTS

None declared.

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