

Spanish Pacemaker Registry. Third Official Report of the Spanish Society of Cardiology Working Group on Cardiac Stimulation (2005)

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Introduction. The aims of this article were to summarize data on pacemaker implantation reported to the Spanish Pacemaker Registry for 2005 and to provide an analysis of the various electrocardiographic phenomena that lead to pacemaker implantation.

Methods. Data were collected using the European Pacemaker Identification Card, with each center individually deciding whether to send the card itself or to submit data in an electronic format.

Results. In total, 82 participating centers submitted a total of 9156 cards, which corresponds to 31.9% of pacemakers estimated to have been implanted that year. The average age of patients who received their first implant remained approximately 75 years and, as in previous years, they were more frequently male. In the majority of cases, the indication was atrioventricular block, followed by sick sinus syndrome and then by atrial fibrillation or flutter with atrioventricular block or bradycardia. In 1.35% of the sample analyzed, biventricular stimulation was used for resynchronization. Some 79% of pacemakers were rate-responsive. In practice, all pacemakers used bipolar leads.

Conclusions. It was observed that the pacing modes selected were better suited to the various electrocardiographic abnormalities that resulted in pacemaker implantation, in accordance with cardiac stimulation guidelines. In the absence of persistent atrial arrhythmia, age had the greatest influence on pacing mode selection. The more frequent use of pacemakers in males was almost exclusively due to the higher incidence of conduction disorders.

Key words: *Pacemakers. Pacemaker lead. Registry. Sick sinus syndrome. Atrioventricular block. Intraventricular conduction disturbance.*

Registro Español de Marcapasos. III Informe Oficial de la Sección de Estimulación Cardíaca de la Sociedad Española de Cardiología (2005)

Introducción. Se describen los resultados de los implantes de marcapasos correspondientes al año 2005 que fueron remitidos al Registro Español de Marcapasos y se analizan en las diversas manifestaciones electrocardiográficas que originan el implante.

Métodos. La recogida de los datos se llevó a cabo por medio de la tarjeta europea del paciente portador de marcapasos, tanto directamente por la remisión de ésta o en formato magnético, y se dejó la elección a cada centro.

Resultados. Han participado 82 centros, con un total de 9.156 tarjetas, lo que supone un 31,9% de los marcapasos que se estima que fueron implantados ese año. La edad media del paciente que recibió el primer implante se mantiene en torno a los 75 años, y hay una mayor incidencia en los varones, como en años anteriores. Los bloqueos auriculoventriculares (AV) son la causa del mayor número de las indicaciones, seguidos de la enfermedad del nódulo sinusal y la fibrilación o aleteo auricular, ya con bloqueo AV o bradicardia. La estimulación biventricular para resincronización supone el 1,35% de los implantes de la muestra analizada. El 79% de los generadores asocia un sistema de respuesta en frecuencia. La práctica totalidad de los electrodos utilizados fueron bipolares.

Conclusiones. Se objetiva una mejor adecuación de la selección del modo de estimulación a las diversas alteraciones electrocardiográficas que originan el implante, según la guías al uso de estimulación cardíaca. La edad es el factor que más influyó en la selección del modo de estimulación, cuando no había una arritmia auricular persistente. La mayor incidencia de los implantes en los varones es casi exclusivamente secundaria a una mayor frecuencia de los trastornos de la conducción en ellos.

Palabras clave: *Marcapasos. Electrodo. Registro. Enfermedad del nódulo sinusal. Bloqueo auriculoventricular. Trastorno de la conducción intraventricular.*

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ABBREVIATIONS

SPR: Spanish Pacemaker Registry
AVB: atrioventricular block
SSS: sick sinus syndrome
ICD: intraventricular conduction disturbance

INTRODUCTION

The Spanish Pacemaker Registry (SPR) contains data going back to the 1990.¹ This information has been published or made available in other formats since 1994²⁻⁵: the complete set of data is available on the Web at www.marcapasossec.org in the heart stimulation section. The present work reports the data for the year 2005 and discusses a number of developments that have taken place in recent years.

METHODS

The information presented is the result of computer processing of different information fields on the European Pacemaker Patient Identification Card.² This card is filled out and sent to the Registry when medical personnel implant a pacemaker. This can be done in paper or magnetic format; the provision of these details to the Registry is meant to be obligatory (Spanish Royal Decrees 634/1993 and 414/1996). Eighty-two hospitals turned in their data in 2005 (see Table, in which these hospitals are grouped by Autonomous Region).

The total number of pacemakers purchased in 2005 was obtained from the different businesses operating in this sector in Spain. The data sent by these businesses to Eucomed was also taken into account. A small error might be expected due to the sale of pacemakers that are not actually implanted. The SPR database is based on the Access computer program. A specific routine was developed to gather the information required for the present study.

The data sent to the Registry have also been sent to the European Pacemaker Registry since 1994, the website of which allows comparisons to be made between pacemaker use in Spain and other European countries (www.heart.org.uk/ewgcp).

In the present work, data referring to the structure of the Spanish population were obtained from the latest report for 2005 published by the *Instituto Nacional de Estadística* (INE: The National Institute of Statistics) (www.ine.es).

RESULTS

Number of Pacemakers Implanted and Structure of the Spanish Population

In the 2005, 9165 pacemaker implant or replacement cards were received by the Registry, a figure corresponding to only 31.9% of all pacemakers implanted in Spain according to the sales data provided by the different businesses operating in the sector. These industry figures report the sale of 28724 pacemakers – 653.1 per million inhabitants. Eucomed reports a corresponding figure of 28 168; if this value is used instead, 32.5% of cards were sent to the SPR and the number of inhabitants per million with a pacemaker implantation was 638.7. In addition, nine units per million inhabitants were implanted for the purpose of cardiac resynchronization therapy (interval=8.89-9.23 depending on which of the information sources is used).

In 2005 the population of Spain was 44 108,530, with 21.7 million males and 22.3 million females (INE figures for the January 1, 2005; no later figures are available).

First and Replacement Pacemakers

A total of 74.9% of those who received a pacemaker in 2005 were implanted for the first time. Those receiving a replacement made up accounted for 25.1% of registrations. The replacement of electrode cables on their own accounted for 0.4%; in 2% of procedures these were changed at the same time as the generator itself (due to its wearing out, a need to change the pacing mode, or because of a defect).

Age

The mean age of the patients who received a pacemaker in 2005 was 75.67 years; the mean age of those receiving their first pacemaker was 75.69 years, while that of patients receiving a replacement was 75.64 years. The mean age of the male patients involved in these procedures was lower than that of the female patients (74.91 years compared to 76.63 years). These data were prepared from the record cards on which patient age had been included (92%).

The largest number of implantations involved patients in their 70s (39.7% of the total), followed by those in their 80s (34.4%). This shows that, in the majority of cases, the need for an implant is usually associated with a degenerative problem (Figure 1).

Sex

Men made up 56.6% and women 43.4% of the implanted population. Some 56.9% of those receiving their first implant were men, and 43.1% were women. The sex ratio with respect to those receiving a replacement

TABLE 1. List of Hospitals that Provided Registration Data in 2005 (by autonomous Region)**Hospitals Grouped by Autonomous Region***Andalusia*

Clínica el Ángel
Clínica Gálvez
Clínica Parque San Antonio
Complejo Hospitalario Virgen de la Macarena
Hospital Costa Del Sol
Hospital de la Línea
Hospital General de Jerez de la Frontera
Hospital Infanta Elena
Hospital Juan Ramón Jiménez
Hospital Punta de Europa
Hospital San Cecilio

Aragón

Clínica Quirón
Hospital General de Teruel Obispo Polanco
Hospital Miguel Servet
Hospital Militar de Zaragoza

The Canary Islands

Hospital de la Candelaria
Hospital Dr. Negrín
Hospital General de La Palma
Hospital Insular
Hospital Militar de Santa Cruz de Tenerife
Hospital Universitario de Canarias

Castilla y León

Hospital Clínico Universitario de Salamanca
Hospital de León
Hospital del Bierzo
Hospital del Río Hortega
Hospital General del Insalud de Soria
Hospital General Virgen de la Concha
Hospital General Yagüe
Hospital Provincial San Telmo
Hospital San Juan De Dios de León
Hospital Universitario de Valladolid

Castilla-La Mancha

Hospital Alarcos
Hospital General Virgen de la Luz
Hospital Nuestra Señora del Prado

Catalonia

Ciudad Sanitaria Vall d'Hebron
Hospital Clínic i Provincial de Barcelona
Hospital del Mar
Hospital Germans Trias i Pujol
Hospital Joan XXIII de Tarragona
Hospital Mutua de Terrassa
Hospital San Camilo
Hospital San Pau i Santa Tecla

Ceuta

Ingesa

Extremadura

Hospital Universitario Infanta Cristina

Galicia

Centro Médico Povisa
Complejo Hospitalario Arquitecto Marcide
Complejo Hospitalario Juan Canalejo
Complejo Hospitalario Xeral de Lugo-Calde
Complejo Hospitalario Xeral-Cies
Hospital do Meixoeiro

The Balearic Islands

Complejo Asistencial Son Dureta

Madrid

Clínica Moncloa
Clínica Puerta de Hierro
Clínica San Camilo
Fundación Hospital Alcorcón
Hospital 12 de Octubre
Hospital de Fuenlabrada
Hospital de Móstoles
Hospital La Paz
Hospital Príncipe de Asturias
Hospital Universitario de Getafe
Hospital Universitario San Carlos

Murcia

Hospital General Santa María del Rosell
Hospital Morales Meseguer

Navarra

Clínica Universitaria de Navarra
Hospital de Navarra

Basque Country

Clínica Indautxu
Clínica Vicente de San Sebastián
Clínica Virgen Blanca de Bilbao
Hospital de Galdakao
Hospital de Guipúzcoa
Hospital Santiago Apóstol
Hospital Txagorritxu
Policlínica de San José
Policlínica de Guipúzcoa, S.L.

Principado de Asturias

Hospital de Cabueñes

La Rioja

Hospital San Millán

Valencia

Clínica Vista Hermosa
Hospital General de Alicante
Hospital General Universitario de Valencia
Hospital Universitario La Fe
Vega Baja

implant was only very slightly different: men 55.8%, women 44.2%.

For the first time, and covering the period of the last two years, the numerical relationship between men and women was studied with respect to electrocardiographic

findings. The incidence of sick sinus syndrome (SSS) was virtually the same in both sexes (men/women 1.06 in 2004 and 1.09 in 2005). However, the incidence of disturbances in conduction was clearly greater among men in both years. For example, for intraventricular

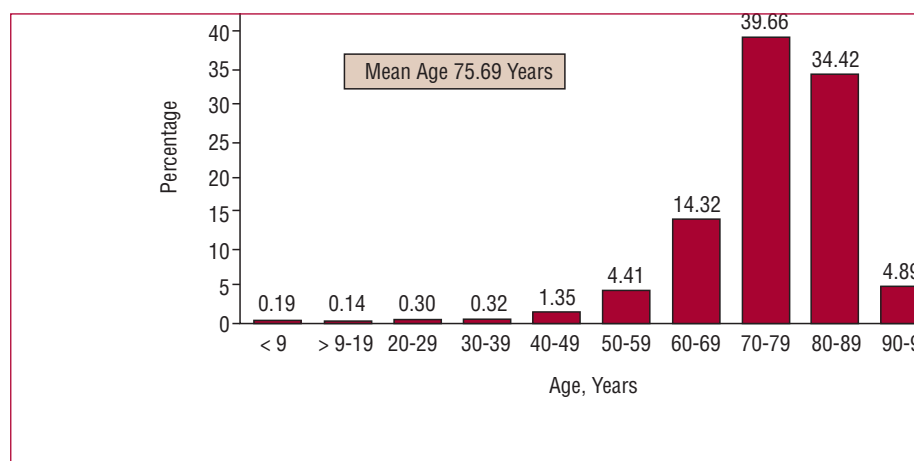


Figure 1. Distribution (in percentages) of implants by patient age and decade of life.

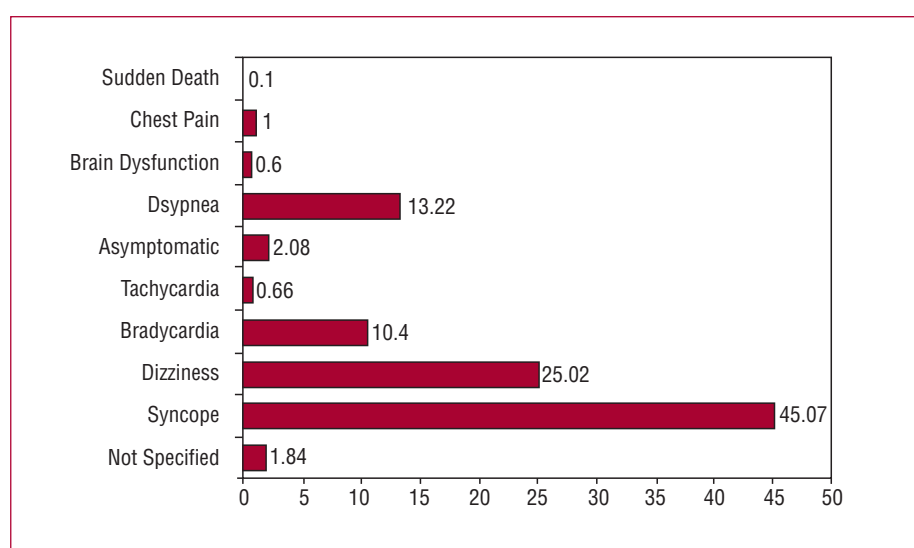


Figure 2. Distribution (in percentages) of the clinical manifestations of patients receiving their first implant.

conduction disturbances (ICD), the men/women ratio was 2.27 in 2004 and 2.35 in 2005, for atrioventricular block (AVB) this ratio was 1.25 in 2004 and 1.3 in 2005, and for atrial flutter or fibrillation it was 1.27 in 2004 and 1.22 in 2005.

Symptoms

Figure 2 shows the distribution of the signs or symptoms associated with the rhythm alterations deemed to indicate the need of a pacemaker. As in previous years, syncope and dizziness were the most often cited problems, followed by dyspnea and bradycardia. Only 2.1% of all implantations involved asymptomatic patients or were performed for preventive reasons.

Etiology

The causes giving rise to the need for a pacemaker were, on most occasions, either unknown, or fibrosis

of the conduction system, followed by ischemia, and cardiomyopathy. Hypertrophic cardiomyopathy was the cause of 0.98% of the total number of implantations, post-ablation was the cause of 0.95%, and neuromediated syndromes were behind 1.04% (among which malignant vasovagal syndromes made up 0.1%) (Figure 3).

Electrocardiographic Abnormalities

Figure 4 shows the preimplant electrocardiographic anomalies recorded and their distribution. Unlike in northern European countries, in which SSS is the most common electrocardiographic abnormality associated with pacemaker implantation, in Spain, AVB was the most common (39.8% of cases; 52.4% if the AVB in atrial fibrillation is taken into account). This was followed by SSS and the group composed of atrial fibrillation or flutter with AVB, or bradycardia. ICD was responsible for 5.9% of cases.

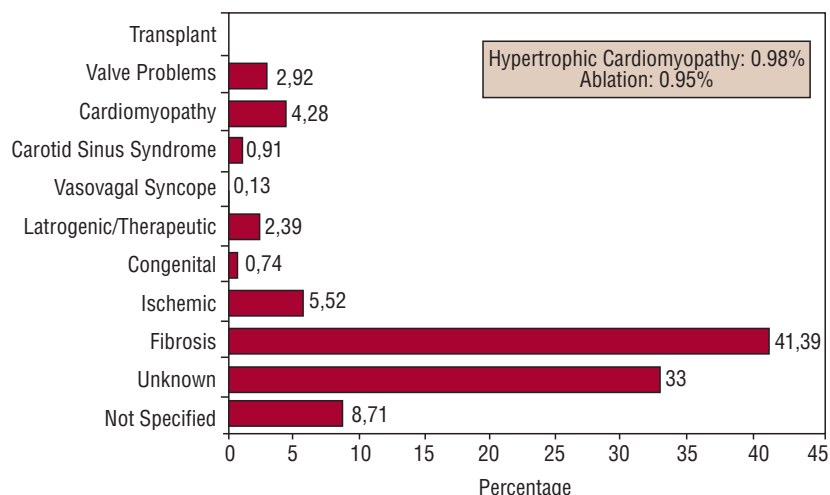


Figure 3. Reason for implantation.

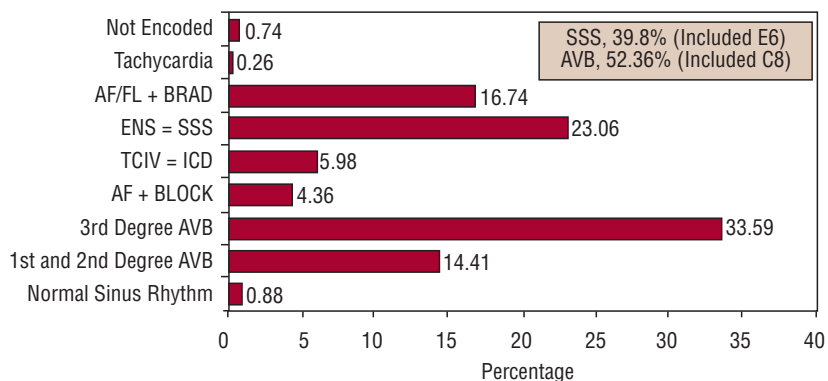


Figure 4. Distribution of electrocardiographic abnormalities before implantation. AF/FL + BRAD: atrial fibrillation/flutter with bradycardia; SSS: sick sinus syndrome; ICD: intraventricular conduction disturbance; AF + BLOCK: atrial fibrillation plus atrioventricular block; AVB: atrioventricular block.

Cables/Electrodes Implanted

Polarity

In 2005, the cables/electrodes implanted were nearly all bipolar (99.3%); these have become established as the most used stimulation system in Spain in recent years (Figure 5). Of the monopolar cables implanted, a significant percentage (15%) were epicardial cables implanted during scheduled heart surgery or during surgery performed specifically for this purpose. Another important percentage was made up of implants put in place via the coronary sinus; the smaller diameter of unipolar electrodes led to their being chosen in such procedures. These were used in 31% of cases (employed in resynchronization therapy or when anatomic difficulties,

or impossibilities presented themselves due to the presence of a tricuspid prosthesis etc).

In the atrial position, bipolarity was even more popular; 99.8% of all cables used in this cavity were bipolar.

Fixation Mechanism

Active fixation was used for an overall 30.9% of cables/electrodes: in the atrium 48.0% were secured in this way, and in the ventricle 23.9%.

Pacing Mode

1.a) Overall, 40.6% of all pacemakers implanted were for single chamber pacing, although only 1% were for atrial pacing. Pacing for maintaining atrioventricular

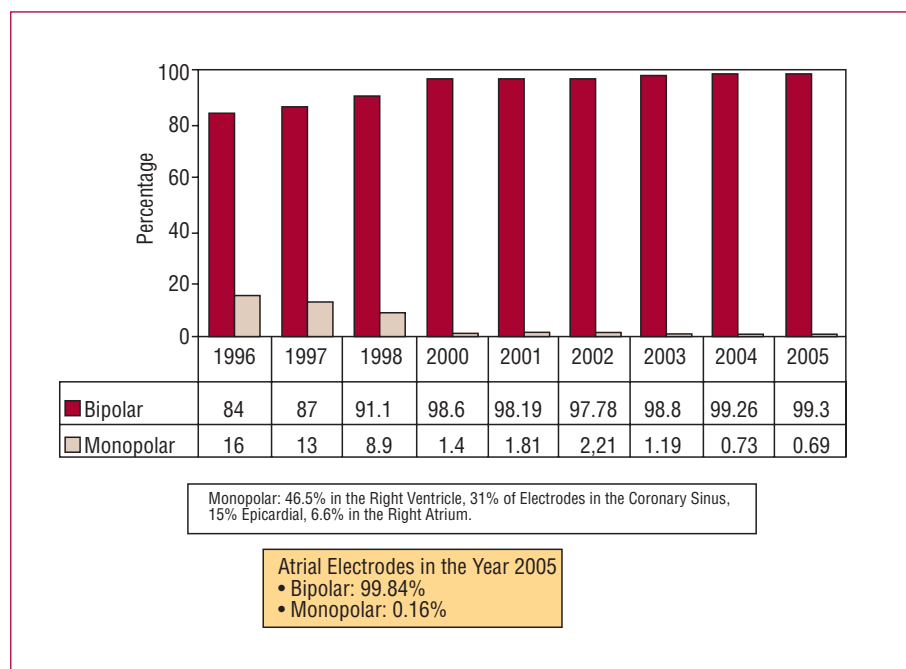


Figure 5. Polarity of electrodes implanted in recent years.

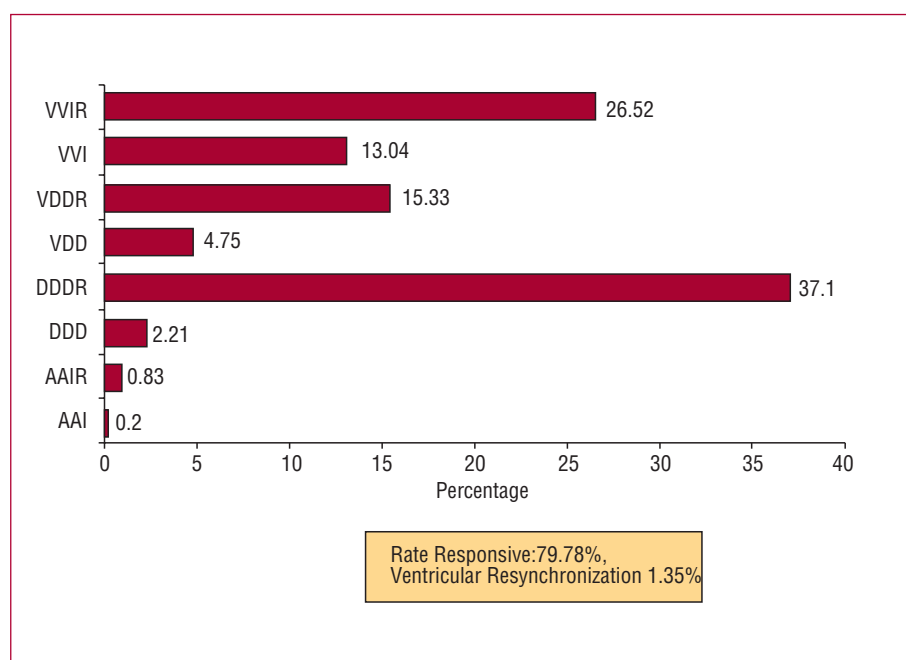


Figure 6. Distribution of stimulation modes in 2005.

(AV) synchrony (including two chamber DDD and VDD pacing) was used in 60.4% of cases (Figure 6). However, if it is taken into account that pacing for permanent atrial fibrillation or flutter with AVB or bradycardia (card codes C8 and E6) made up 21.1% of cases, the number of patients requiring sequential pacing must be much higher. In fact nearly 18.5% of cases, pacing was performed without maintaining the atrioventricular synchrony that could have — or indeed should have — been maintained

according to the cardiac pacing guides of Spanish, American, or European cardiology societies.^{6,7} Age was probably the factor that most influenced the decision to proceed in this non-optimum way (although other reasons, such as technical problems, cannot be ruled out). Until the year 2000, the increased use of pacing modes that maintain AV synchrony was owed to the growing popularity of both DDD and VDD modes. However, after 2000, only the use of DDD has increased; the use of VDD

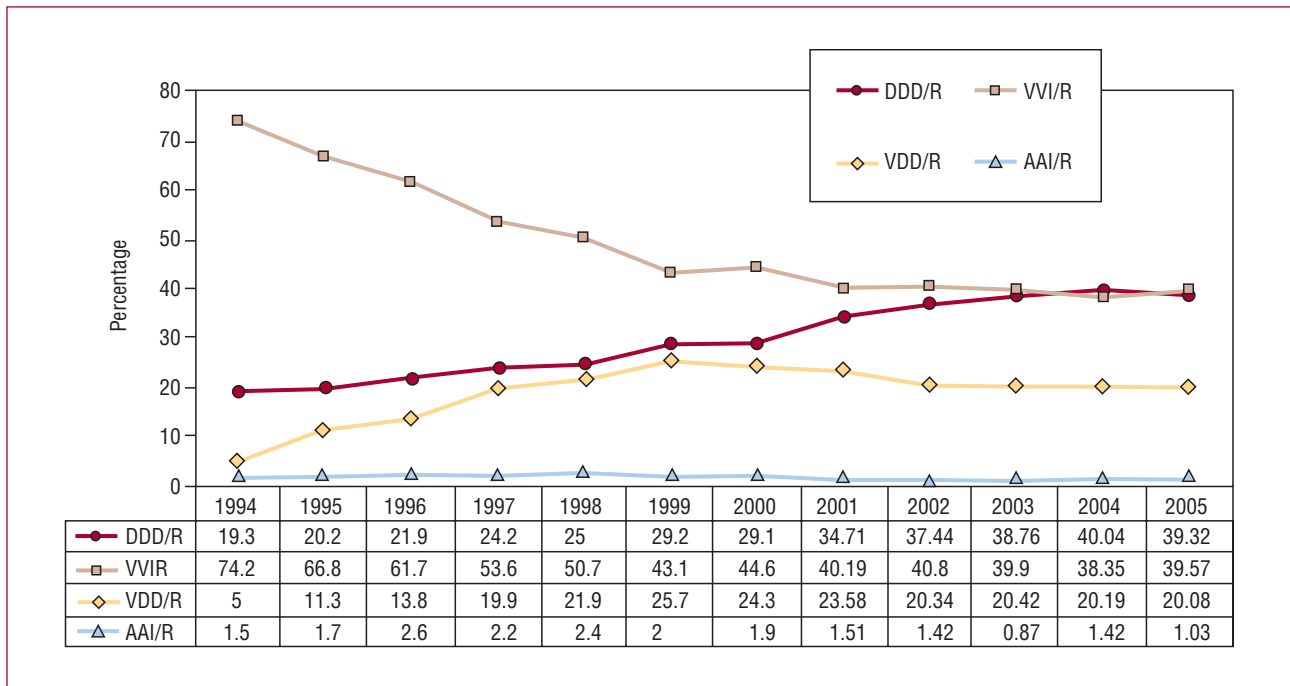


Figure 7. Change in stimulation mode between 1994 and 2005.

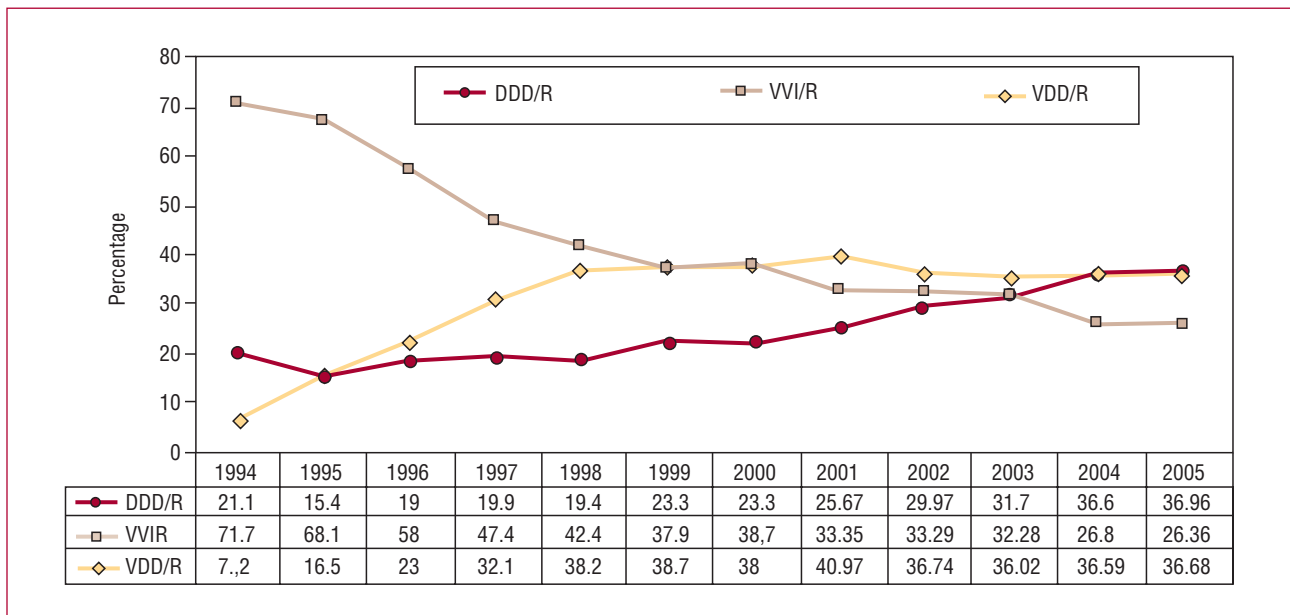


Figure 8. Change in stimulation mode in atrioventricular block (from first to third degree cases [card codes C1-C7], excluding patients with permanent atrial fibrillation [code C8]) between 1994 and 2005.

has remained stable or has slightly dropped away (Figure 7).

b) Rate responsive pacing (using some form of sensor) made up 79.8% of all the pacemakers used.

c) Stimulation for cardiac resynchronization therapy, in the case of heart failure with ICD, accounted for 1.35% of all pacemaker implants according to SPR data (1.37%

according to industry data: 396 units communicated to the Registry; 407 according to Eucomed data). The Registry data reflect no increase with respect to 2004 (1.37%). A movement towards the use of units that provide defibrillation therapy was noted: in 2004 these made up some 473 units according to data obtained from industry and communicated to Eucomed, and 703 in 2005.

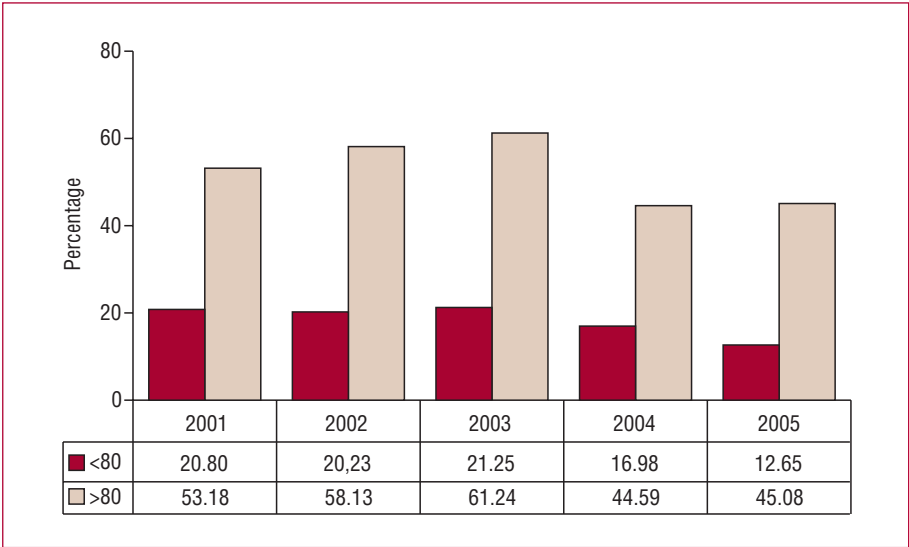


Figure 9. Change in use of VVI/R stimulation in atrioventricular block in patients grouped by age between 2001 and 2005 (excluding patients with permanent atrial fibrillation)

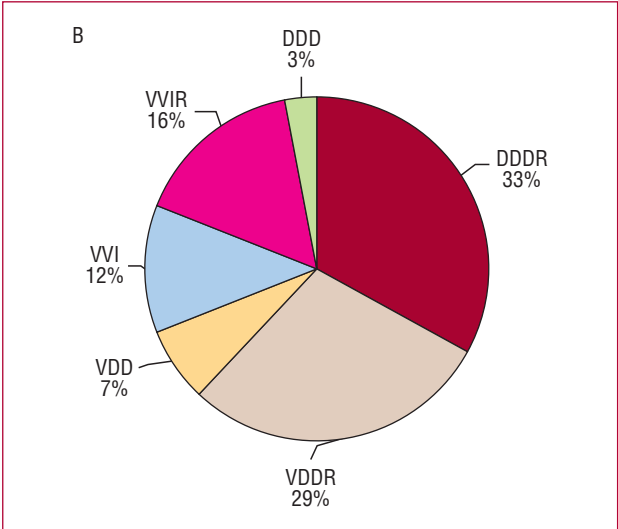
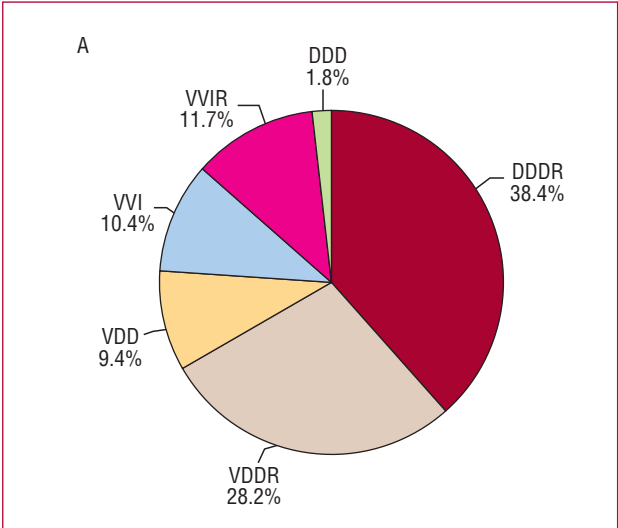


Figure 10. A and B: stimulation modes used in 2005 in first and second (card codes C1-C4), and in third (card codes C5-C7) degree atrioventricular block.

2. *Pacing in AVB.* When the patients with ABV and sinus rhythm were analyzed, similar percentages were seen in terms of the use of VDD and DDD modes (36% each). The increase in the percentage use of pacing modes that maintain the atrioventricular synchrony in this group of patients has been due to the progressive increase in the use of DDD pacing in recent years, and the non-significant change in the use of VDD (Figure 8). Some 26.4% of these AVB patients received VVI/R pacing in 2005, although this percentage has fallen year after year and is clearly used more among older patients. This can easily be seen from the analysis of patients below and above 80 years of age; this type of pacing was used in 45.1% and 12.71% of cases respectively. A significant difference was recorded for the last two years of analysis (Figure 9).

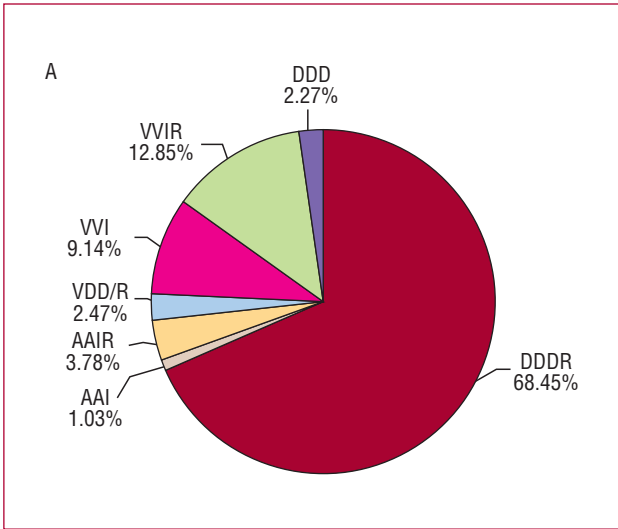


Figure 11. A and B: stimulation modes used in sick sinus syndrome in 2005, and the change seen between 1994 and 2005

Figure 10 shows the modes used in the first/second and third degree AVB subgroups of patients.

3. *Pacing in SSS.* The DDD/R mode is still the most used (employed in just over 70% of cases). The use of the AAI/R mode (4.8%) has not increased, nor has the use of the VDD/R mode (2.5%) (Figure 11). As Figure 11 shows, although there has been a notable improvement in pacing in SSS,^{6,7} the maintenance of the use of the VDD/R mode is noteworthy. In recent years its use has in fact matched or surpassed that of AAI, even though it is clearly not indicated for this type of electrocardiographic anomaly. Neither is the VVI/R mode very justifiable when sinus rhythm persists, although it was used on 22% of occasions. It has, however, shown a clear trend towards a reduction in usage over the years which the Registry has been in operation (with the exception of a small upturn in 2005). The use of the VDD mode has also decreased. The choice of the VVI/R mode seems to be importantly influenced by patient age (used in 38.7% of cases in patients over 80 years of age, but only in 14.9% in those younger; see Figure 12)

4. *Pacing in intraventricular disturbances.* In ICD, the most commonly used mode was DDD/R (45.7% of patients), followed by VVIR (28.8%). The remainder (25.6%) received VDD/R pacing. Among these patients, age was also the factor that most influenced the choice of pacing mode; 49.6% of those over 80 years of age received VVI/R pacing, while only 18.1% of younger patients were treated with this mode.

Pacemakers for cardiac resynchronization therapy made up 1.35% of all implants (19% of those <80 years of age in the ICD subgroup, and 0.8% of those >80).

Data Quality

Only the data supplied – which corresponded to 31.9% of all the pacemakers implanted in Spain in 2005 (32.5% if industry or Eucomed data are taken into account) – were analyzed.

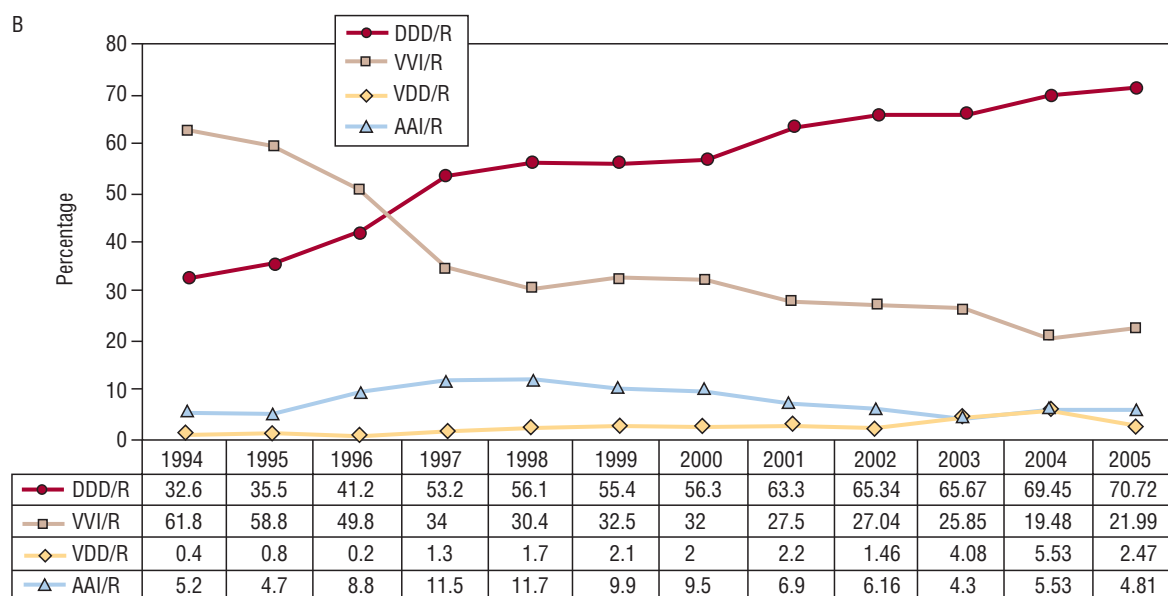
Data were missing on some of the cards received:

- Age on 8.0%
- Sex on 11.1%
- The symptoms experienced on 22.4%
- Etiology on 37.3%
- ECG results on 22.2%

The sample was large enough for conclusions to be drawn on the quality of pacing provided in Spain, but not for this to be broken down by Autonomous Region (great disparities were seen because of the wide variation in the participation of the hospitals in these regions, which varies from 0%-100%).

SUMMARY AND COMMENTS

The greater frequency of pacemaker implantation in men compared to women was maintained in 2005, mainly because of the greater incidence of conduction



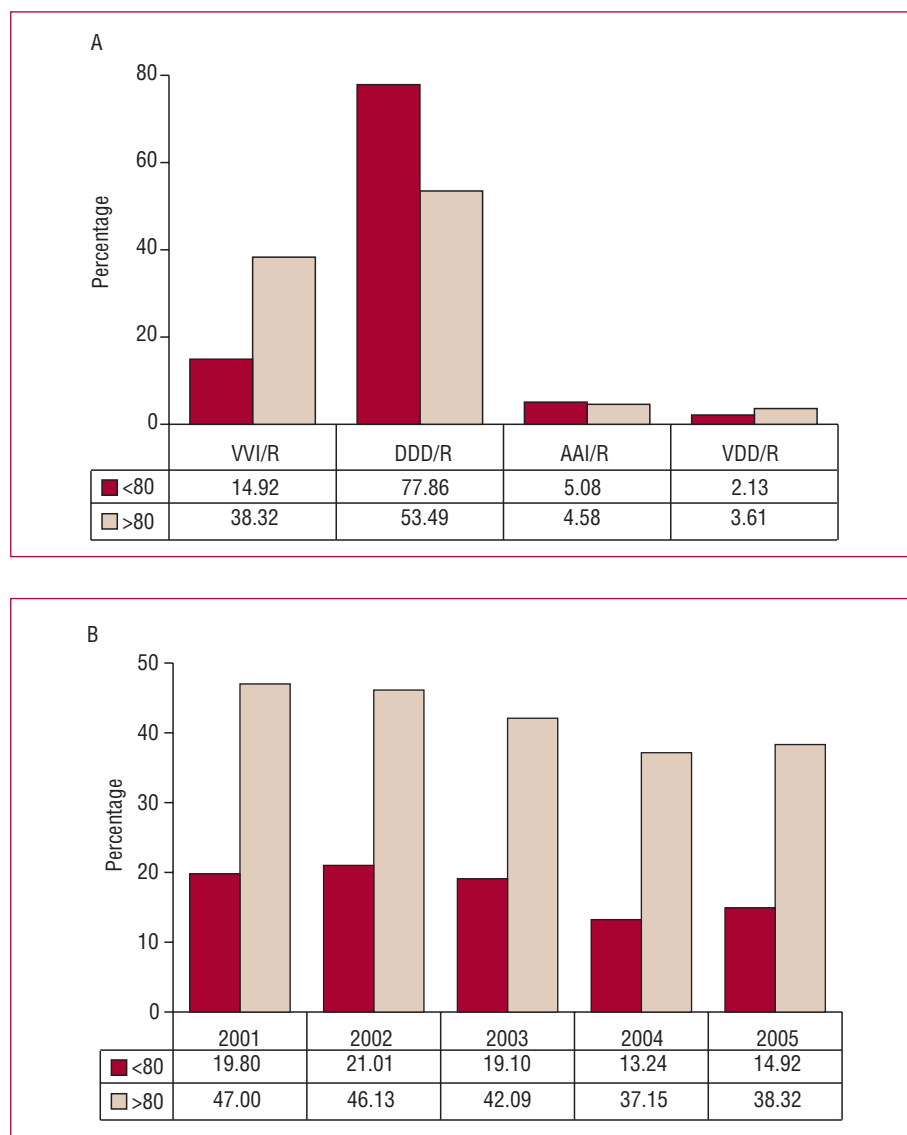


Figure 12. A and B: Influence of age on stimulation modes employed in sick sinus syndrome, and the change in the use of VVI/R stimulation between 2001 and 2005 (patients with permanent atrial fibrillation were excluded [card code E6]).

abnormalities among men (both atrioventricular and intraventricular, although the incidence of SSS was the same for both sexes). In men, the mean age of implantation was somewhat older than in women. Most patients received pacemakers when in their 70s or, to a lesser extent, in their 80s.

The cable/electrode selected was nearly always bipolar in both chambers; only a few monopolar cables/electrodes were used in special circumstances (such as in epicardial emplacements). The number of cables that employ active fixation continued to increase notably, especially in atrial implants where they now account for almost 50%.

The pacing modes used to maintain AV synchrony has improved significantly in recent years, although this has tended to stabilize over the last two years. These improvements have largely due been to an increase in the use of DDD double chamber pacing, while the use of VDD and single chamber atrial pacing has remained stable.

Resynchronization therapy accounted for 1.35% of the pacemakers implanted. This figure is no different to that of previous years, owing to the notable use of units that afford the possibility of defibrillation.

Although more cards have been received, the overall percentage of implantations recorded has not improved. Neither has there been any improvement in the quality of the data the Registry receives.

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