Special article

Spanish Pacemaker Registry. Eleventh Official Report of the Spanish Society of Cardiology Working Group on Cardiac Pacing (2013)



Raúl Coma Samartín, a,b,* Óscar Cano Pérez, a,c and Marta Pombo Jiménez a,d

- ^a Sección de Estimulación Cardiaca, Sociedad Española de Cardiología, Madrid, Spain
- ^b Unidad de Cuidados Críticos Cardiológicos, Hospital Universitario 12 de Octubre, Madrid, Spain
- ^c Unidad de Electrofisiología y Arritmias, Hospital Universitari i Politècnic La Fe, Valencia, Spain
- d Unidad de Estimulación Cardiaca, Hospital Costal de Sol, Marbella, Málaga, Spain

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ABSTRACT

Introduction and objectives: The present report summarizes the analysis of pacemaker implantation and replacement data sent to the Spanish Pacemaker Registry in 2013, with specific discussion of pacing mode selection.

Methods: This study was based on information obtained from the European Pacemaker Patient Identification Card.

Results: Information was received on 118 hospital centers, with a total of 12 831 cards, or 35% of the estimated activity. There were 755 and 58.1 conventional and resynchronization devices per million population, respectively. The mean age of patients receiving an implant was 77.4 years. Men received 59.5% of first implantations and 56.6% of replacements. Most implantations and generator replacements were performed in patients older than 80 years. Almost all endocardial leads used were bipolar, and 78.7% of leads had an active fixation mechanism. Despite being in sinus rhythm, 24% of patients with sick sinus syndrome and 25% of those with atrioventricular block were paced in VVIR mode.

Conclusions: The use of pacemaker generators and resynchronization devices per million population continues to increase in Spain. Active fixation mechanisms predominate for leads but just 20% of leads are compatible with magnetic resonance imaging. The factors influencing the correct selection of pacing mode were age and, to a lesser extent, the type of atrioventricular block, and sex. Implementation of home monitoring of pacemakers remains low.

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Registro Español de Marcapasos. XI Informe Oficial de la Sección de Estimulación Cardiaca de la Sociedad Española de Cardiología (2013)

RESUMEN

Introducción y objetivos: Se describe el resultado del análisis de los implantes y recambios de marcapasos remitidos al Registro Español de Marcapasos en 2013, con especial referencia a selección de los modos de estimulación.

Métodos: Se basa en el procesado de la información que aporta la Tarjeta Europea del Paciente Portador de Marcapasos.

Resultados: Se recibió información de 118 centros hospitalarios, con un total de 12.831 tarjetas, el 35% de la actividad estimada. El consumo de generadores convencionales y dispositivos de resincronización fue de 755 y 58,1 unidades por millón de habitantes respectivamente. La media de edad de los pacientes que recibieron un implante era 77,4 años. El 59,5% de los implantes y el 56,6% de los recambios se realizaron en varones. La mayoría de los implantes y recambios de generadores se produjeron en la franja de los 80 años. Los cables endocavitarios utilizados son bipolares, el 78,7% con sistema de fijación activa. Se estimula en modo VVI/R pese a estar en ritmo sinusal al 24% de los pacientes con enfermedad del nódulo sinusal y el 25% de aquellos con bloqueo auriculoventricular.

Conclusiones: Persiste la tendencia a aumentar del consumo de generadores marcapasos y dispositivos de resincronización por millón de habitantes. El sistema de fijación activa de los cables es mayoritario y un 20%, específico de protección de resonancia magnética. La edad y, en menor grado, el tipo de bloqueo

^{*} Corresponding author: Arturo Soria 184, 28043 Madrid, Spain. E-mail address: coma@vitanet.nu (R. Coma Samartín).

auriculoventricular y el sexo son los factores que influyen en la adecuación del modo de estimulación. La monitorización domiciliaria de marcapasos aún dista mucho de generalizarse.

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Abbreviations

AVB: atrioventricular block

CRT: cardiac resynchronization therapy EPPIC: Pacemaker Patient Identification Card

SSS: sick sinus syndrome

INTRODUCTION

The Spanish Pacemaker Registry (SPR, Registro Español de Marcapasos) published its first official report in 1997, ¹ although the first data were actually obtained via a survey in 1989.² Since then, and as one of its objectives, the SPR has annually reported^{3–13} the most relevant characteristics of cardiac pacing in Spain. These reports indicate the degree of compliance with recommendations in current clinical practice guidelines, 14-17 compare pacing in Spain with that reported in the registries of other countries 18-20 or in other Spanish registries, and determine the quality or appropriateness of the pacing performed. The present report summarizes the most relevant data of the cardiac pacing performed with pacemakers in Spain during 2013 and any changes from the results of previous reports. Detailed information on cardiac pacing has been annually published on the website of the Working Group on Cardiac Pacing (Sección de Estimulación Cardiaca) since 1999.²¹ However, the information available is incomplete due to progressive database developments and software improvements.

METHODS

European Pacemaker Patient Identification Card

The information contained in the European Pacemaker Patient Identification Card (EPPIC) was processed, such as age, sex, and codes for symptoms, causes, electrocardiographic indications, pacing modes, and implantations and extractions of leads or generators. An automatically generated copy of the EPPIC is forwarded to the SPR, although this information can also be sent-and is sent-electronically, such as via the databases of each center, with the proper privacy guarantees and with all essential information of the EPPIC. The Working Group on Cardiac Pacing has its own freely accessible database¹⁰ to automate data collection and processing, but this resource has failed to improve the registry and a new website is under development. The data received are refined using specific software by 2 nurses trained in the monitoring of pacing devices.

Information Provided by the Various Manufacturers

Not all EPPICs are relayed to the SPR (despite this practice being required by current Spanish legislation in order to monitor possible

alerts, etc: Royal Decree 1616/2009 dated 26 October, which regulates active implantable medical devices). Accordingly, the total number of pacemakers used and their distribution by autonomous community was obtained through collaboration with pacemaker suppliers in Spain; this information is also regularly forwarded to the European Confederation of Medical Suppliers Associations (EUCOMED).

Report of the Spanish National Institute of Statistics

The population data of Spain as a whole or by autonomous community for the various pacing-related calculations were taken from the latest updated provisional census of the Spanish National Institute of Statistics (*Instituto Nacional de Estadística*) of 2013.²²

Sample Analyzed

The results correspond to the analysis of the activity sent to the SPR from 118 hospital centers (Table), comprising 35% of the generators implanted, which was considered sufficient to evaluate the various aspects of cardiac pacing with pacemakers in Spain. The structure follows that of previous reports.

RESULTS

Number of Pacemakers Implanted per Million Population

According to the data provided by the device manufacturers, a total of 36 042 pacemaker generators were used in 2013 in first implantations and replacements. Of these, 848 were biventricular pacemakers for cardiac resynchronization therapy (CRT) using low-energy electrical impulses or cardiac resynchronization devices without defibrillation capability (CRT-P). As usual, slight discrepancies were seen from the information provided by the companies to the EUCOMED (reporting a total of 36 424 generators, including 854 CRT-P devices). The number of total units increased by 2.6% compared with the previous year.

The latest available census data from the Spanish National Institute of Statistics (provisional results published July 1st 2013) recorded a population of 46 609 000, 22 941 000 men and 23 668 000 women, indicating an estimated decrease of 118 238 people during the first half of 2013. According to the SPR data, 755 pacemaker generators were used per million population (units/million) (781.4 if CRT-P devices are included) (Figure 1); this figure is lower than the mean of those countries sending data to the EUCOMED (933 units/million) but is somewhat higher than those countries such as the Netherlands, Norway, the United Kingdom, and Switzerland.

There were notable regional differences^{9–13} among autonomous communities in the number of units per million population, with clear increases in some regions in northern Spain. Thus, in 2013, there were 1000 units/million in Castile and León, followed by Galicia and the Principality of Asturias with more than 900 units (Figure 2), which, as in previous analyses, are the autonomous communities with the highest mean age.

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