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MAMI registration report 1996–2010

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on behalf of the Cardiologic Intensive Care and Cardiopulmonary Resuscitation Section of the Spanish Society of Intensive Care Medicine, Critical and Coronary Units (GTCICyRCP-SEMICYUC)

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Abstract

Background: *To summarize the results of MAMI registration and compare them to other national and foreign records published.*

Methods: *Observational, prospective and multicenter study based on a wide source of data incoming from 50 Intensive Care Units in Spain during 15 years, from April 1996 to December 2010. Demographic, clinical, etiological and electrocardiographic (ECG) variables were collected before pacemaker implantation. Type of intervention, electrical measurement at implantation, model and serial number of devices and electrodes as well as early complications (before hospital discharge) were also recorded.*

Results: *During this period 31766 interventions have been reported: 24643 first implants (77.6%) and 7123 replacements (22.4). The total number of patients is lower than interventions because some of them were included as first implants and as replacements after years. In first implant the average age, clinical signs, ECG disorders and pacing modes were described. Data collected in device replacement interventions were average age, pacing modes and cause for replacement. 45% of implanted devices were endowed with rate control algorithm. In last 3 years increased to 82.4%. From 1996 to 2010 we have seen a decline in VVI(R) pacing mode in favor to DDD(R) mode. AAI(R) and VDD(R) modes have remained invariable. Finally, we show data on early complications and mortality.*

Conclusions: *MAMI registration is a valid tool for recording the activity of pacemaker implantation. It showed variations and trends of pacing modes and algorithms along the years. Data is recorded separately for men and women so they can be compared.* (Cardiol J 2012; 19, 6: 603–611)

Key words: pacemaker, registration, intensive care unit

Introduction

In Spain, 40% of the pacemaker (PM) implantations are performed by Intensive Care physicians [1]. In 1995, "The Cardiologic Intensive Care and Cardiopulmonary Resuscitation Section of The Spanish Society of Intensive Care, Critical and Coronary Units (GTCICyRCPSEMICYUC)" decided to create a database of all PM implants performed in the Intensive Care Units. This resulted in a pilot study and ended in the MAMI registration (MArcapasos definitivos en Medicina Intensiva) [2, 3]. The data have been presented at the annual meetings of the Cardiologic Intensive Care section and National society. Publication provides data up to December 31, 2010.

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Table 1. Number and type of interventions in MAMI registration.

Type of intervention	Total		Men		Women	
	N	%	N	%	N	%
First implantations	24643	77.6	14127	57.3	10516	42.7
Replacements	7123	22.4	4099	57.5	3024	42.5
Total	31766	100	18226	57.4	13540	42.6

Initially, the data were entered into the database manually. Now, they are entered online with appropriate access codes at the following addresses: http://www.hospitaldonostia.org/mami or http://www.donostiaospitalea.org/mami.

Methods

MAMI registration is an observational, prospective and multicenter study involving up to 50 Intensive Care Units in Spain. Not all of them have been reporting data over the years. Actually, at the moment there are 20 units that send records regularly. Every intervention performed in one of these Units creates a record that is sent to MAMI registration. Data are collected, processed and periodically presented at the annual meeting of the Society.

The variables included in the MAMI registration are: a) demographic and affiliation variables; b) etiology, symptoms, and ECG before implantation; c) type of intervention; d) lead and device location; e) electrical measurements at implant: capture threshold, intracardiac sensing and pacing impedance; f) lead and PM models and serial numbers; g) early complications (before hospital discharge).

The period of time covered by this registration began in April 1996 and patients are still being collected. This study reports data from the last 15 years, until December 31, 2010 and represents about 10% of fist implantations made in Spain.

The study was approved by the local research ethics committee and all patients were asked for written informed consent.

Statistical analysis

Records were collected in an Excel database (Microsoft®) and data were finally processed by SPSS 15.0 for Windows (2006). Results are expressed mainly as percentage or proportions except for the age of patients which are expressed in years as means. One-way analysis of variance (ANOVA) was used to compare A wave measurements. Schaffé post hoc analysis was used to determine the group responsible for ANOVA statistical significance.

Results

During this period 31766 interventions were collected: 24643 (77.6%) first implants and 7123 (22.4%) replacements (Table 1). Replacements were distributed as follows: battery 6094, battery and lead/s 665, and lead/s 248 (Table 2).

Gender distribution is: 18226 (57.4%) men and 13540 (42.6%) women (Table 1). The average age at first implant is 78.03 years and at replacement 78.55 years. The distribution of pacing mode is shown in Figure 1.

In men average age at first implant is 77.29 years: VVI(R) 78.12, DDD(R) 76.58, VDD(R) 76.51 and AAI(R) 77.49 years. In women average age at first implant is 79.02 years: VVI(R) 79.77, DDD(R) 78.17, VDD(R) 78.62 and AAI(R) 78.16 years (Fig. 2).

Figure 3 shows the age distribution of patients.

Most frequent symptoms at first implant are: syncope (39.3%), dizziness (27.5%) and heart failure (14.8%) (Table 3). Indication for replacement is mostly made by battery depletion (73.8%) (Table 4).

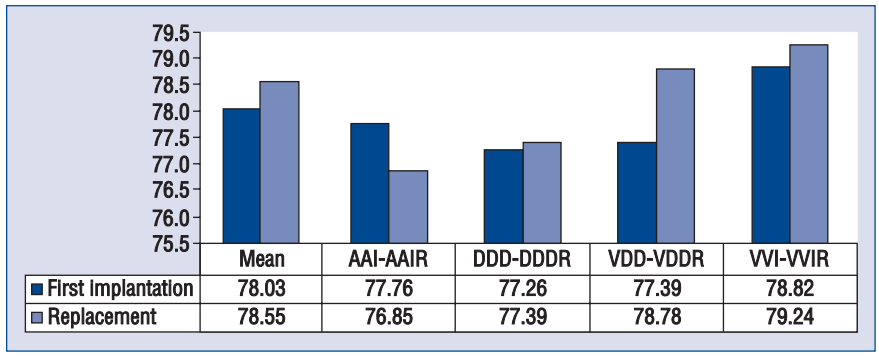
Electrical disorders at first implant were: atrio-ventricular block (AVB) 48.1%, atrial fibrillation (AF) 22.1%, sinus node disease (SND) 21% and bundle branch block (BBB) 4.2%. Table 5 shows complete information and gender distribution.

The most prevalent etiology registered is "conduction system fibrosis" (51.4%) (Table 6).

The technique most commonly used for implantation of ventricular and atrial leads is puncture of the left subclavian vein. Subsequently, PM is usually located over the left pectoral muscle (80%) followed by the right pectoral muscle (17%).

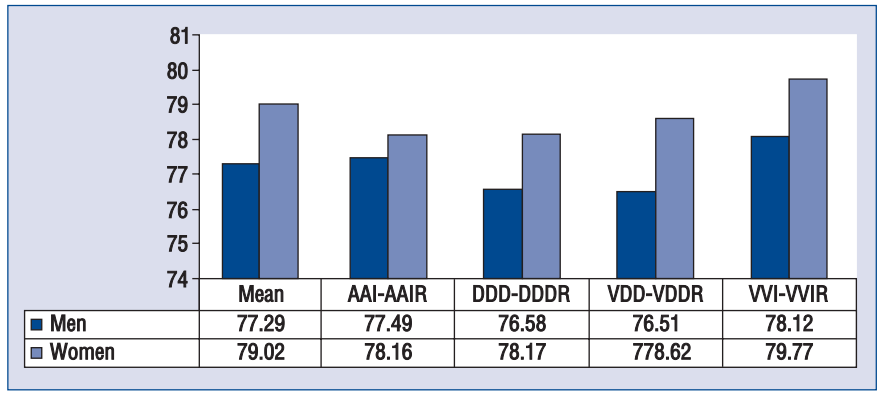
Table 2. Type of intervention in replacement.

Generator replacement	6094 (85.6%)
Replacement of lead/s	248 (3.5%)
System replacement	665 (9.3%)
Unknown	110 (1.5%)
Sum	7123 (100%)



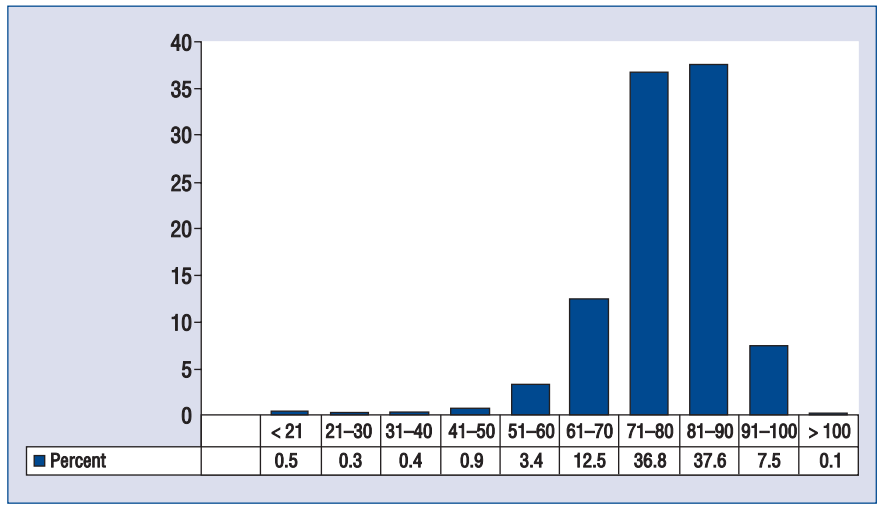
	Mean	AAI-AAIR	DDD-DDDR	VDD-VDDR	VVI-VVIR
First implantation	78.03	77.76	77.26	77.39	78.82
Replacement	78.55	76.85	77.39	78.78	79.24

Figure 1. Mean age at first implantation and replacement by pacing mode



	Mean	AAI-AAIR	DDD-DDDR	VDD-VDDR	VVI-VVIR
Men	77.29	77.49	76.58	76.51	78.12
Women	79.02	78.16	78.17	778.62	79.77

Figure 2. Mean age at first implantation by sex and pacing mode.



	< 21	21–30	31–40	41–50	51–60	61–70	71–80	81–90	91–100	> 100
Percent	0.5	0.3	0.4	0.9	3.4	12.5	36.8	37.6	7.5	0.1

Figure 3. Age distribution of patients at first implantation by decades.

Distribution of pacing modes at first implant are: VVI(R) 47.2%, DDD(R) 31.3%, VDD(R) 20.1% and AAI(R) 1.1%. In replacement is similar: VVI(R) 49.2%, DDD(R) 31%, VDD(R) 18.4% and AAI(R) 1.2%. VDD pacing mode refers to single lead implantation pacemakers with floating sensors for A wave. No differences were registered by sex (Tables 7, 8).

The most prevalent pacing modes in patients with AVB and SND were VVI(R) followed by

Table 3. Symptoms and sex in first implantation.

Symptoms in first implantation	Total		Men		Women	
	N	%	N	%	N	%
Dizziness	6763	27.5	3799	26.9	2964	28.2
Syncope	9683	39.3	5772	40.9	3911	37.2
Heart failure/low mental and physical performance	3642	14.8	1833	13.0	1809	17.2
Brady/brady-tachy	3088	12.5	1801	12.7	1287	12.2
Prophylactic	531	2.1	364	2.6	167	1.6
Unknown	936	3.8	558	3.9	378	3.6
Sum	24643	100	14127	100	10516	100

Table 4. Reason for replacement.

Battery end of life	5259 (73.8%)
Device failure (unspecified)	471 (6.6%)
Skin necrosis	135 (1.9%)
Device or lead infection	220 (3.1%)
Elective lead	137 (1.9%)
Lead-connection failure	26 (0.4%)
Lead-isolation failure	74 (1.0%)
Lead-conduction failure	79 (1.1%)
Pacemaker syndrome	19 (0.3%)
Extra cardiac stimulation	7 (0.1%)
Unknown	696 (9.8%)
Sum	7123 (100%)

Table 6. Etiology at first implantation.

Unknown	6900 (28%)
Conduction system fibrosis	12660 (51.4%)
Cardiomyopathy	1765 (7.2%)
Ablation	138 (0.6%)
Ischemic-post acute myocardial infarction	1648 (6.7%)
Post cardiac surgery	99 (0.4%)
Congenital	81 (0.3%)
Carotid sinus syndrome	332 (1.3%)
Malignant vasovagal syndrome	18 (0.1%)
Unknown	1002 (4.1%)
Sum	24643 (100%)

DDD(R). Data on sex distribution, pacing modes and ECG disorders are shown in Figures 4 and 5.

In Figure 6 temporal evolution of pacing modes from 1996 to 2010 is displayed divided by trienniums. VVI(R) shows a steady decrease from 52.2% to 44.6% and VDD(R) and DDD(R) a slight increase from 18.8% to 20.1% and 27.7% to 33.3%, respectively. AAI(R) is stable around 1.2%. There are no differences between men and women.

Rate control algorithm is present in 45% of implanted devices. Muscular activity sensor is the most commonly used. See Table 9 for detailed information.

Electrical measures at first implant such as lead impedance, pacing threshold and intrinsic activity sensing are displayed in Table 10. When atrial lead is implanted (AAI and DDD) the value of the sensed A wave is higher. With one way

Table 5. Electrocardiogram (ECG) at first implantation.

First implantation ECG	Total		Men		Women	
	N	%	N	%	N	%
3rd degree AVB	8562	34.7	4852	34.3	3710	35.3
2nd degree AVB	3292	13.4	1925	13.6	1367	13.0
Sinus node disease	5165	21.0	2675	18.9	2490	23.7
Flutter/atrial fibrillation	5436	22.1	3225	22.8	2211	21.0
Trifascicular block	901	3.6	669	4.7	232	2.2
Bifascicular block	142	0.6	104	0.7	38	0.4
Unknown	1145	4.6	677	4.8	468	4.5
Sum	24643	100	14127	100	10516	100

AVB — atrio-ventricular block

Table 7. Pacing mode at first implantation.

Pacing mode	Total		Men		Women	
	N	%	N	%	N	%
AAI-AAIR	271	1.1	158	1.1	113	1.1
VVI-VVIR	11643	47.2	6673	47.2	4970	47.3
VDD-VDDR	4945	20.1	2863	20.3	2082	19.8
DDD-DDDR	7703	31.3	4386	31.0	3317	31.5
Unknown	81	0.3	47	0.3	34	0.3
Sum	24643	100	14127	100	10516	100

Table 8. Pacing mode at replacement.

Pacing mode at replacement	Total		Men		Women	
	N	%	N	%	N	%
AAI-AAIR	82	1.2	51	1.2	31	1.0
VVI-VVIR	3501	49.2	2001	48,8	1500	49.6
VDD-VDDR	1314	18.4	766	18.7	548	18.1
DDD-DDDR	2206	31	1271	31.0	935	30.9
Unknown	20	0.2	10	0.2	10	0.3
Sum	7123	100	4099	100	3024	100

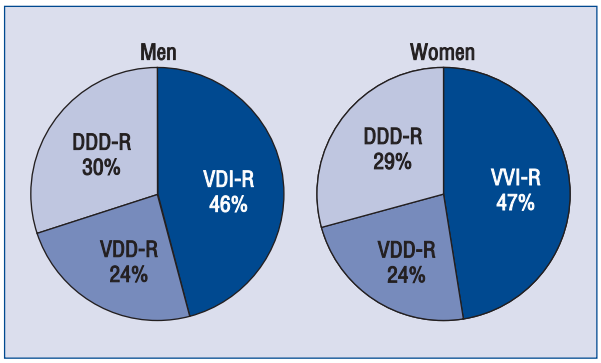


Figure 4. Pacing mode in atrioventricular block at first implantation.

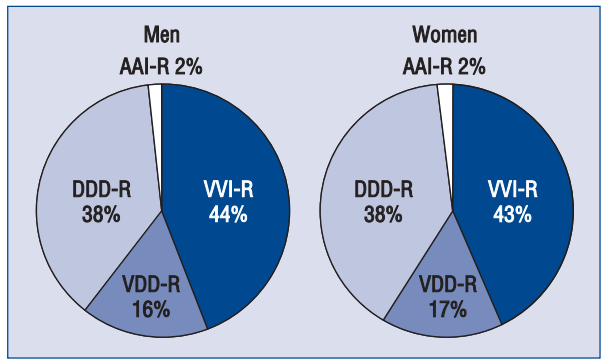


Figure 5. Pacing mode in sinus node disease at first implantation.

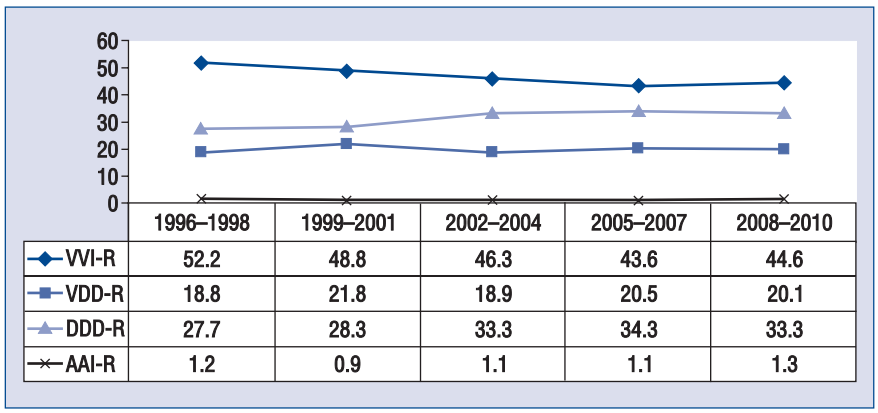


Figure 6. Evolution of pacing mode at first implantation by trienniums.

Table 9. Rate control implanted pacemakers and type of sensor.

Total devices	31766 (100%)
No rate sensor devices	17484 (55%)
Rate sensor devices	14282 (45%)
Type of sensor	
Muscle activity	8930 (62,5%)
Minute ventilation	4514 (31,6%)
QT	216 (1.5%)
Double sensor	622 (4.4%)
Sum	14282 (100%)

ANOVA test (SPSS 15.0 for Windows 2006) we compared the A wave measures obtained with AAI-DDD and VDD leads. Statistical significance difference was found depending on pacing modes. Post hoc analysis (Schaffé) demonstrates bigger A wave value with contact atrial leads (AAI-DDD) than A wave measures obtained with atrial floating leads (VDD) ($p < 0.0001$). No difference was found between AAI and DDD modes.

Early complications (5.1%), appeared before hospital discharge. Death rate is very low at first implant (0.1%) (Table 11) as well as at replacement (0.1%). Complications arising from venous puncture, lead implant and pocket are shown in Table 12.

Table 11. Deaths at first implantation and replacement.

Deaths	N	No		Yes	
		N	%	N	%
First implantation	24643	24618	99.99	25	0.1
Replacement	7123	7118	99.99	5	0.1
Sum	31766	31736	99.99	30	0.1

Table 10. Electrical measures at first implantation.

	N	Mean	Median	Standard deviation
A threshold	3506	0.88	0.80	0.52
Right ventricular threshold	6556	0.79	0.50	0.78
Left ventricular threshold	217	0.60	0.50	0.39
P wave (DDD-AAI)	4245	2.50	2	1.23
P wave (VDD)	2.302	2.09	2	1.17
R wave (right ventricle)	21882	12.38	12	5.46
A impedance	3506	636	587	193
Right ventricular impedance	21882	783	744	215

Table 12. Type of complications at first implantation and replacement.

Complications	First implantation		Replacement	
	N	%	N	%
Venous access complications	**264**	**1**	**22**	**0.3**
Thrombosis	12		0	
Pneumothorax	134		14	
Arterial puncture	108		8	
Others: air embolism, subcutaneous emphysema, brachial plexus damage	10		0	
Electric complications	**609**	**2.5**	**90**	**1.2**
Lead dislodgement	429		81	
Ventricular arrhythmias	30		0	
Supraventricular arrhythmias	65		9	
Others: perforation-tamponade, lead fracture, phrenic or diaphragmatic stimulation	85		0	
Pocket complications	**487**	**2**	**94**	**1.2**
Hematoma	412		74	
Infection	32		18	
Pain	24		2	
Others: pocket stimulation, protrusion, seroma	19		0	

Pneumothorax, lead dislodgment and pocket hematoma were the most frequent complications.

MAMI records mortality rate but not its cause.

Discussion

Pacemaker implantation is a continuously growing activity. In Spain in 1994 the rate of implantation was 270 U/10^6 inhabitants but in 2010 the rate has increased until 700 U/10^6 inhabitants (information source from manufacturers). Nevertheless rates of implants in Spain are far from those of Germany, France or USA which are about 1000 U/10^6 inhabitants. Part of this activity is carried out by intensive care physicians specialized in the management of these patients.

MAMI has proved effective showing data on PM implantation with the perspective of time. Analysis of the results will lead us to draw conclusions and raise new hypotheses [4, 5]. We now have data of 31766 interventions. MAMI is the largest registration ever published and only the National Danish Registration is comparable [6].

Although some Units do not continuously send data, registration size and the wide geographical distribution of implanting units validate the results as representative of pacemaker implantation in Intensive Care Units in Spain.

Comparing MAMI data with international registrations no differences were found in first implant-replacement ratio neither in age, gender, complications and clinical situation leading to first implant [7, 8].

However some differences should be highlighted: ECG prior to first implant in MAMI registration shows AVB in 48% of patients, AF 22%, SND 21% and BBB 4%. In Danish registration AVB is reported in 43% of patients, SND 35% and AF 15.4%. Differences in mode of pacing will be determined by these unequal proportions of ECG disorders.

In MAMI the most frequent etiological cause for the electrical disorder leading to PM implant is fibrosis of conduction system and automatism (51%). The unknown etiology is recorded in 28% of patients. In other registrations published the unknown etiology was prevalent. This difference can be explained by the consensus adopted in MAMI registration stating "fibrosis" to unknown etiology for ECG disorders in patients older than 75 years.

Nevertheless, the major difference among data lies on the distinct pacing modes selected for similar electrical disorders. Obviously in patients with AF VVI is the common election, but this consensus is not repeated any more with other electrical disorders [9]. This way, in Spain DDD(R) pacemakers are implanted in 38% of patients showing SND and AAI pacemakers just in 2%. In Denmark however [10] AAI pacing mode is programmed in 10% of patients, in Sweden 3.5%, Russia 8%, Lithuania 20%, Slovakia 4% [10, 11]. This is probably due to the low rate of progression to AVB in these countries which contrasts with the experience in others [12].

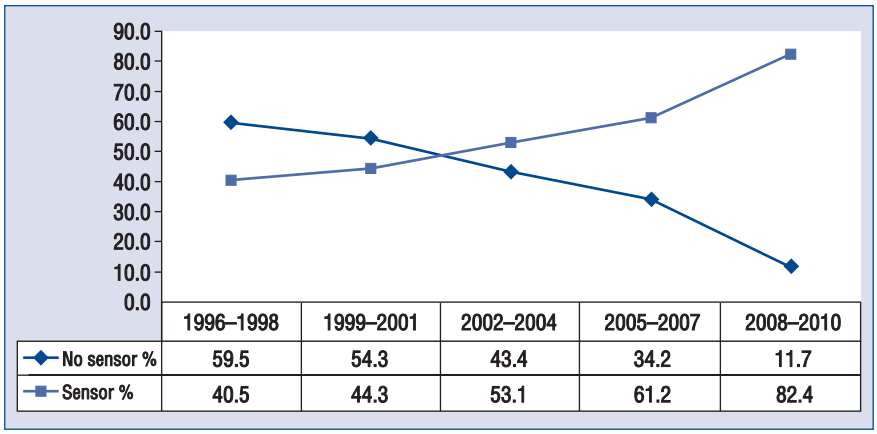
In Spain, 24% of patients showing AVB are implanted with VDD devices and 38% with DDD whereas in Denmark these patients are almost exclusively DDD implanted. Reasons for these differences are not clear.

As we highlighted above MAMI registration is a good tool for chronological analysis of variables like age at first implant, pacing mode and ECG disorders. From 1996 to 2010 (Fig. 6) a decrease in VVI pacing mode from 52.2% to 44.6% has been recorded. On the other side we observed an increase in pacing modes that preserve AV synchrony from 48.8% to 54.7%. AAI maintains in 1.3%. These trends are equal for men and women. Unfortunately MAMI registration never included items for resynchronization pacing. We believe resynchronization therapy is a radical change in heart pacing for patients with low ejection fraction and wide QRS although probably the lion's share of the technique is reserved for implantable defibrillators.

Figure 7 shows the evolution of rate control algorithm PM along the years. In Spain at present 82.4% of devices have this function. In Denmark 93% of devices are equipped with this function.

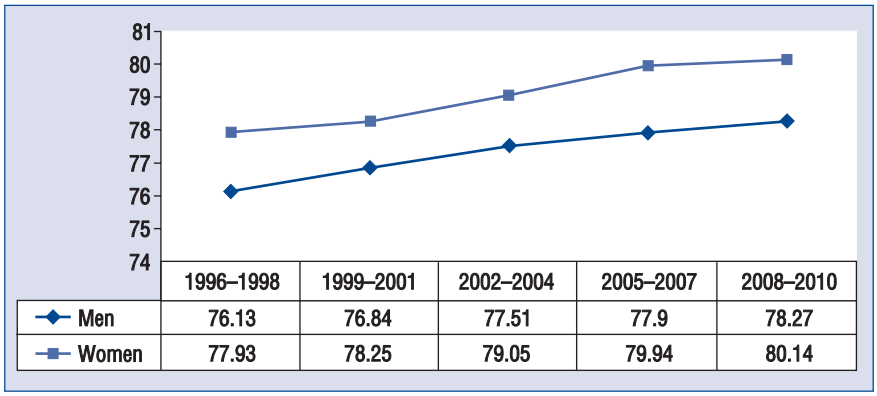
A sustained increase in the average age at first implant is registered in men as well as in women (76.13 to 78.27 in men; 77.93 to 80.14 in women) (Fig. 8). Third grade AVB has shown a decrementing proportion as a main diagnosis for PM implantation. Second degree AVB, AF with low ventricular rate and SND have increased.

And finally, MAMI is to our knowledge the only registration that shows data of the electrical measures at implantation. Hence, we know that capture thresholds for ventricle and atrium are 0.5 and 0.8 V respectively with 0.5 ms impulse wide; V and P measures of 12 and 2 mV; pacing impedance 744 and 587 Ohms for ventricle and atrium. It is worthy to highlight that atrial sensing in VDD mode is clearly inferior to the measures obtained in AAI and DDD modes; this difference although predictable by the fact that in VDD mode there is no electrode directly implanted in atrial tissue (the electrode is floating in the atrium) had never been pointed out before in any registration. Anyway atrial sensing in VDD mode is most of the times good enough for a correct synchronous AV pacing.



	1996–1998	1999–2001	2002–2004	2005–2007	2008–2010
No sensor %	59.5	54.3	43.4	34.2	11.7
Sensor %	40.5	44.3	53.1	61.2	82.4

Figure 7. Evolution of rate control devices by trienniums.



	1996–1998	1999–2001	2002–2004	2005–2007	2008–2010
Men	76.13	76.84	77.51	77.9	78.27
Women	77.93	78.25	79.05	79.94	80.14

Figure 8. Age evolution at first implantation by sex and trienniums.

Conclusions

We can conclude that MAMI allows us to analyze chronologically the changes in PM implantation practice over the years. The evaluation of data collected in MAMI is very useful to understand the evolution of our practice and compare with registrations published by other groups and countries.

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Conflict of interest: none declared

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Remittent physicians	Hospital	City	N
Dr. Antón Tomás	Hospital de la Ribera	Alcira	420
Dr. Ricardo Navarro	Hospital Virgen de los Lirios	Alcoy	286
Dr. Cobo Castellano	Hospital Punta Europa	Algeciras	1.101
Dra. De la Fuente O'connor	Hospital Príncipe de Asturias	Alcalá de Henares	680
Dr. García-Arroyo	Hospital San Pedro de Alcántara	Cáceres	176
Dr. Jiménez Pagan	Hospital Santa María Rosell	Cartagena	2.595
Dr. Monferrer Guardiola	Hospital Gran Vía	Castellón de la Plana	385
Dr. Gutiérrez Cortés	Hospital Arquitecto Marcide	El Ferrol	361
Dr. Rueda Cuenca; Dr. Santos Calle	Hospital General	Elche	89
Dr. Lapuerta Irigoyen	Hospital de Cabueñes	Gijón	1.787
Dr. Márquez Florez; Dr. Alonso	Hospital Infanta Elena	Huelva	23
Dr. Manzano Alonso; Dr. Bolaños Guerra	Hospital Dr. Negrín	Las Palmas de Gran Canarias	3.373
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Dr. Garrido Valenzuela	Hospital Santa María Madre	Orense	269
Dr. Montilla Jurado	Hospital Vega Baja	Orihuela	105
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Dr. González Martín; Dr. Cabello Casados	Hospital Virgen del Puerto	Plasencia	50
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Dr. García Moreno; Dr. Gutiérrez Martínez	Hospital Naval San Carlos	San Fernando	42
Dra. Azcarate Ayerdi; Dr. Porres Aracama, Dr. Urbistondo Ayestaran	Hospital Donostia	San Sebastián	4.663
Dr. Ancillo García; Dra. López Cambra	Hospital General de Segovia	Segovia	1.381
Dr. Leal del Ojo	Hospital Valme	Sevilla	29
Dr. Medina Santaolalla; Dr. Quintana Díaz	Hospital del Insalud	Soria	125
Dr. Contreras Rosino	Clínica Marazuela	Talavera de la Reina	118
Dra. Merlo González	Hospital N. S. del Prado	Talavera de la Reina	155
Dr. Valdés Puig; Dr. Trenchs Verdaguer	Hospital de Terrassa	Terrassa	1.093
Dr. Rodríguez Alonso	Hospital Virgen de la Salud	Toledo	336
Dr. Oscar Luque Lezcano	Clínica La Asunción	Tolosa	89
Dr. Castro Pareja; Dr. Ruano Marco	Hospital La Fe	Valencia	4.027
Dr. Muñoz San José	Hospital del Río Hortega	Valladolid	1.762
Dr. Castillo Guerrero; Dr. Pascual de la Parte	Hospital de la Axarquia	Vélez-Málaga	25
Dr. Sieres Pérez; Dr. Mosquera Pérez	Centro Médico POVISA	Vigo	69
Others	Hospital de la Victoria	Malaga	14
	Hospital General	Gandia	16
	Hospital General	Guadalajara	14
	Hospital General	Sagunto	14
	Hospital San Roque	Las Palmas de Gran Canarias	4

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