Medium-long-term mortality and change in functional status in elderly patients with pacemaker

Morbimortalidad cardiovascular y variación del grado funcional en pacientes ancianos portadores de marcapasos

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Abstract

Background: Nowadays, 49% of patients with pacemakers are older than 80 years old. Nevertheless, mortality and change in functional status after pacemaker implantation are not well documented in elderly patients. **Objective:** We designed a prospective study to analyze the cardiovascular mortality and change in functional status of elderly patients, medium-long term after pacemaker implantation. **Methods:** An observational study including pacemaker implants in individual older than 70 years old in a single-center university hospital between 2012 and 2014. Analysis testing for an association between pacemaker system, medium-long-term mortality, and functional status after implantation was undertaken. **Results:** About 60% of patients were older than 80 years old. The third-degree atrioventricular blockage (44.3%) and slow ventricular response atrial fibrillation (16.7%) were the most frequent electrocardiogram abnormalities, while bicameral DDD was the sort of pacing our department used the most (38.6%) (VVI in octogenarian patients, 38.7%). Long-term mortality was significantly higher in ventricular devices, especially in octogenarian patients ($p = 0.001$). Single-chamber VVI pacing acted as independent predictors of all-cause mortality in these individuals ($p = 0.001$). We found no significant improvement in Barthel Index and functional status in this subgroup of patients, 3 years after pacing. **Conclusions:** Long-term mortality in individuals older than 80 years old with pacemaker implantation was significantly higher comparing with general population, especially in ventricular devices. No significant improvement in functional status was detected in this subgroup of patients.

Key words: Pacemaker. Octogenarian. Third-degree atrioventricular block. Functional status. Mortality. Spain.

Resumen

Objetivo: Aproximadamente un 49% de los implantes se efectúan a individuos mayores de 80 años; sin embargo, la evidencia científica sobre mortalidad y cambio en la situación funcional de estos pacientes es muy pobre. Diseñamos un estudio

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prospectivo para analizar la morbimortalidad cardiovascular y la variación de su grado funcional a medio plazo en pacientes ancianos con electroestimulación permanente. **Método:** Estudio observacional prospectivo, que incluye 308 pacientes ancianos sometidos a implante de marcapasos en un hospital terciario entre 2012 y 2014. Como variables principales se evaluaron eventos cardiovasculares, mortalidad y grado funcional, con una media de seguimiento de 3.5 años. **Resultados:** El 60% de los pacientes incluidos en nuestro estudio tenían una edad superior a 80 años, y la indicación más frecuente fue el bloqueo auriculoventricular completo (44.3%), seguido de la fibrilación auricular lenta o bloqueada (16.7%). El modo de estimulación más frecuente fue el DDD (38.6%). En el seguimiento, la mortalidad a largo plazo fue mayor en dispositivos ventriculares, especialmente en octogenarios ($p = 0.001$). El modo de estimulación VVI fue predictor independiente de mortalidad. A largo plazo, no se observó mejoría del grado funcional tras el implante del marcapasos. **Conclusiones:** La morbimortalidad cardiovascular en pacientes octogenarios portadores de marcapasos resulta superior a la de la población general, especialmente en dispositivos monocamerales. La electroestimulación permanente no se asocia con mejoría del grado funcional a medio-largo plazo en estos pacientes.

Palabras clave: Marcapasos. Octogenarios. Bloqueo auriculoventricular completo. Grado funcional. Mortalidad. España.

Introduction

Permanent pacemaker is the treatment of choice for significant bradyarrhythmia, usually caused by degeneration of the excitation-conduction cardiac system associated with old age. The 2013 European Society of Cardiology guidelines on cardiac pacing established symptomatic sinus node dysfunction, symptomatic second-degree Mobitz I and Mobitz II, and the third-degree atrioventricular block (AVB) as fundamental indications for permanent pacemaker implantation¹. The most common indications for permanent pacemaker implantation are third-degree AVB followed by symptomatic sinus node dysfunction, a trend that has remained stable over the past few years. However, due to the progressive increase in life expectancy that has taken place in Spain in recent years, mean age at pacemaker implantation has increased from 77 years in 2012 to 77.8 years in 2016². About 50% of total pacemaker implantations correspond to individuals older than 80 years. Nevertheless, most available scientific evidence is based on studies conducted with middle-aged patients below the age of the population usually served in arrhythmia units, and some of these trials even exclude this subgroup of patients³⁻⁷.

Although the ventricular stimulation mode (VVI) is indicated in patients with atrial fibrillation and AVB, it is also used in patients with advanced AVB and high comorbidity or limited life expectancy¹. Physiological devices, such as AAI, VDD, and DDD, which allow a sequential pacing that maintains atrioventricular synchrony, are implanted in individuals with symptomatic sinus node dysfunction or advanced AVB. In Spain, the most widely used stimulation mode is DDD (47.2%) followed by VVI (39.3%) and, far behind, by VDD (10.2%)².

At present, there is controversy about the benefits of physiological cardiac pacing in comparison with ventricular

pacing in terms of morbidity and mortality. Ventricular stimulation has been associated with a higher incidence of atrial fibrillation and heart failure than physiological cardiac pacing, as demonstrated by the DANPACE and MOST trials^{8,9}. However, no study has shown conclusive differences with regard to mortality^{3,10-22}.

On the other hand, the results in quality of life and functional status improvement in elderly patients after pacemaker implantation are contradictory. The PASE trial demonstrated significant improvement in quality of life at 3 months post-pacemaker implantation, regardless of uni- or bicameral pacing²³. However, these findings have not been confirmed in other studies²⁴⁻²⁶.

The main purpose of our study was to analyze cardiovascular and overall mortality in the mid-term in elderly patients with permanent cardiac pacing. The secondary outcomes we looked for were the description of cardiovascular events and the change in functional status after pacemaker insertion.

Materials and methods

A prospective, observational study included 308 consecutive patients older than 70 years undergoing elective permanent pacemaker implantation between January 2012 and December 2014 at the Arrhythmia Unit of the University General Hospital of Ciudad Real. The inclusion criteria were patients older than 70 years with permanent pacemaker indication according to the European Society of Cardiology current guidelines on cardiac pacing¹. Patients younger than 70 years, patients undergoing resynchronizer or defibrillator implantation, patients with left ventricular ejection fraction (LVEF) lower than 35%, and patients undergoing generator replacement were excluded from the study.

Baseline characteristics and follow-up

We analyzed the baseline characteristics, including diabetes mellitus, dyslipidemia, hypertension, chronic obstructive pulmonary disease, atrial fibrillation, LVEF, glomerular filtration (according to the Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI] formula), indications for primary implantation, and the type of pacing (ventricular, in the case of VVI, or physiological, in the case of AAI, VDD or DDD). The recorded peri-procedure complications were atrial/ventricular electrode dislocation, cardiac perforation, pneumothorax, hematoma requiring transfusion, and infection of the pacemaker system. In addition, geriatric functional assessment was performed at admission and at 3 years of the device implantation using the Barthel Functional Index over a score of 100 and the Red Cross Functional (RCF) scale^{27,28}. The primary outcome variable was all-cause mortality. Secondary outcome variables were post-implantation complications, cardiovascular events (defined as acute coronary syndrome, heart failure, and stroke), cardiovascular mortality, and functional and cognitive status modification at end of follow-up.

Statistical analysis

The statistical analysis was carried out with the SPSS program, version 18.0 (SPSS Inc., Chicago, Illinois). The test used to check data normal distribution was the Kolmogorov–Smirnov test. The data are expressed as the mean $\pm$ standard deviation (SD). The age at pacemaker implantation and LVEF variables did not follow a normal distribution (median 82 years – interquartile range 6 and mean 60% – interquartile range 3%, respectively); however, we used centralization and dispersion parameters for their statistical analysis, due to a coefficient of variation of $< 33\%$ and an important sample size. To compare continuous variables between both groups, we used Student's t-test for independent samples (or Mann–Whitney U-test if there was no normal distribution). To compare more than two means, we used the ANOVA test and Tukey's test for *post hoc* analysis. The Chi-square test (or Fisher's test if a subgroup had a representation of < 5 individuals) was used to assess differences between qualitative variables. We analyzed mortality predictors through logistic regression, introducing all-cause mortality at the end of the follow-up period as a dependent variable, and cardiovascular risk factors, valvulopathies, pacing modes, heart failure, and chronic renal failure as independent variables. In addition, we carried out a survival analysis

Table 1. Descriptive analysis of baseline characteristics

Age at pacemaker implantation (years)	82.1 $\pm$ 5.1
Gender	
– Female	146 (47.4%)
– Male	162 (52.6%)
Diabetes Mellitus	106 (34.4%)
Dyslipidemia	115 (37.3%)
Hypertension	270 (87.7%)
Chronic obstructive pulmonary disease	40 (13%)
Moderate-severe mitral stenosis	4 (1.3%)
Moderate-severe mitral regurgitation	26 (8.4%)
Moderate-severe aortic stenosis	9 (2.9%)
Moderate-severe aortic regurgitation	12 (3.9%)
Moderate-severe tricuspid regurgitation	18 (5.9%)
Moderate-severe pulmonary hypertension	22 (7.2%)
Paroxysmal/persistent atrial fibrillation	61 (19.8%)
Permanent (chronic) atrial fibrillation	46 (14.9%)
Ischemic heart disease	50 (16.2%)
Chronic heart failure	22 (7.2%)
Moderate-severe CKD (GFR $\leq$ 45 mL/min)	74 (24%)

using the Kaplan–Meier method with comparative survival analysis using the log-rank test. Statistical significance was considered with $p = 0.05$.

Results

Baseline characteristics

Among the entire study population, the mean age at pacemaker implantation was 82.1 ± 5.1 years (52.6% of males), and it was significantly higher in the ventricular pacing group (84.4 ± 5.3 vs. 81 ± 4.7 ; $p < 0.001$). The most common indication for pacemaker implantation was complete heart block (44.3%) followed by slow or blocked atrial fibrillation (16.7%) and symptomatic second degree AVB (13.8%). Single-chamber pacemakers were implanted in 35.1% of patients, while 64.6% received a dual-chamber device. The most commonly used pacing mode was DDD (38.6%) followed by VVI (32.1%) and, very closely, by VDD (27.6%) (Tables 1 and 2).

The subgroup of octogenarian patients with pacemaker primary implantation was composed of 186 patients,

Table 2. Comparative analysis of baseline characteristics

	Ventricular pacemaker	Physiological pacemaker	p
Age at pacemaker implantation (years)	84.24 ± 5.32	81.07 ± 4.71	< 0.001
Gender			0.228
– Female	42 (42.4%)	104 (49.8%)	
– Male	57 (57.6%)	105 (50.2%)	
Diabetes Mellitus	33 (33.3%)	73 (34.9%)	0.783
Dyslipidemia	32 (32.3%)	83 (39.7%)	0.211
Hypertension	88 (88.9%)	182 (87.1%)	0.652
Chronic obstructive pulmonary disease	18 (18.2%)	22 (10.6%)	0.064
Moderate-severe mitral stenosis	3 (3%)	1 (0.5%)	0.099
Moderate-severe mitral regurgitation	15 (15.2%)	11 (5.3%)	0.004
Moderate-severe aortic stenosis	4 (4%)	5 (2.4%)	0.477
Moderate-severe aortic regurgitation	3 (3%)	9 (4.3%)	0.757
Moderate-severe tricuspid regurgitation	13 (13.1%)	5 (2.4%)	< 0.001
Moderate-severe pulmonary hypertension	13 (13.1%)	9 (4.3%)	0.005
Paroxysmal/persistent atrial fibrillation	20 (20.2%)	41 (19.6%)	0.904
Permanent (chronic) atrial fibrillation	45 (45.5%)	1 (0.5%)	< 0.001
Ischemic heart disease	13 (13.1%)	37 (17.7%)	0.310
Chronic heart failure	12 (12.1%)	10 (4.8%)	0.021
Moderate-severe CKD (GFR ≤ 45 mL/min)	28 (28.3)	46 (22%)	0.229

with a mean age of 85 ± 4 years (51.1% of males). The most common electrocardiographic abnormality that drove to implantation continued to be advanced AVB, while the most commonly employed device was VVI (38.7%) followed by VDD (38.2%) and by DDD (21.5%). In the octogenarians with complete heart block, VDD mode was the most widely used (56.4%) followed by VVI (25.5%) and DDD (18.1%) (Fig. 1). Of note, a proportion of tricuspid regurgitation and upper pulmonary hypertension was also observed in the VVI devices (12.5 vs. 0.9% and 15.3 vs. 3.5%, respectively). There were no significant differences in the Barthel Index score or the RCF scale before pacemaker implantation (median 95 ± 76.2 ; $p = 0.669$ and median 2 ± 4 ; $p = 0.749$, respectively).

Follow-up

Overall mortality rate in the entire sample was 21.1% (with a mean follow-up time of 3.5 years), which corresponds approximately to the double that is expected in

individuals of similar age and gender in the general population, according to data from the National Institute of Statistics (overall mortality in patients with pacemaker implantation in Ciudad Real, 20-25% [mortality in individuals of similar age and gender in the general population, 9-10%]) (INEbase, mortality tables of the population of Spain by year, gender, age, and functions). Only 18 patients (5.8%) had complications during the immediate or early post-operative period, of which 10 (56%), 6 (33%) and 2 (11%) corresponded to patients undergoing DDD, VDD, and VVI pacing modes, respectively. There were no differences in the overall statistical analysis in terms of complications or cardiovascular events according to the pacing mode. Although we detected a higher rate of atrial fibrillation episodes in physiological devices, most of these episodes were detected in the pacemaker electrogram analysis and, therefore, comparisons are not valid due to the absence of atrial activity detection by VVI devices. Cardiovascular and all-cause mortality at the end of the follow-up period was higher with ventricular than with physiological

Figure 1. Cardiac pacing modes in octogenarian patients with pacemakers.

devices (33.3 vs. 15.3%; odds ratio [OR]: 0.4; 95% confidence interval [CI]: 0.2-0.6; $p < 0.001$) (Table 3).

In octogenarian individuals, we did not detect significant differences in the rate of post-implantation complications, atrial fibrillation, acute coronary syndrome, or heart failure (4.2 vs. 8.6%; OR: 2.2; 95% CI: 0.2-19; $p = 0.674$; 0 vs. 7.1%; OR: 0.7; 95% CI: 0.6-0.8; $p = 0.324$; 4.2 vs. 1.4%; OR: 0.3; 95% CI: 0.02-5.5; $p = 0.249$, and 20.8 vs. 12.9%; OR: 0.6; 95% CI: 0.2-1.9; $p = 0.415$, respectively). However, the rate of all-cause mortality at 2 and 3 years and at end of the follow-up period was higher with ventricular versus physiological devices (50 vs. 14.3%; OR: 0.2; 95% CI: 0.06-0.5; $p = 0.001$; 63.6 vs. 20%; OR: 0.1; 95% CI: 0.04-0.6; $p = 0.007$, and 54.2 vs. 18.6%; OR: 0.2; 95% CI: 0.07-0.5; $p = 0.001$, respectively). These results were maintained when patients with severe valvulopathies were excluded since the start of the analysis. In the octogenarian patients with advanced AVB, the results were similar: we did not detect any significant difference in the rate of readmissions for acute coronary syndrome ($p = 0.249$) and heart failure ($p = 0.415$) in association with the stimulation mode (VVI vs. VDD vs. DDD), although we found higher

overall mortality at 2 years post-implantation ($p = 0.001$), 3 years post-implantation ($p = 0.004$), and at the end of the follow-up period ($p = 0.001$) with ventricular devices with regard to the VDD and DDD devices (Fig. 2).

An age-adjusted subgroup analysis, where we compared individuals with advanced block and pacing with VVI mode with those who received VDD pacing, did not show significant differences in the rate of readmissions for heart failure or cardiovascular events, although, as in the overall analysis, patients showed higher overall mortality at the end of the follow-up period.

The multivariate analysis defined chronic heart failure and VVI pacemaker as independent mortality predictors in octogenarian patients with pacemaker indication ($p = 0.034$, $p = 0.024$, and $p = 0.001$, respectively). Median time to all-cause death was 0.9 years, with no differences between ventricular (1.01 ± 0.5 years [median $\pm$ interquartile range]) and physiological pacing modes (0.9 ± 1.6 years [median $\pm$ interquartile range]) ($p = 0.608$).

In addition, we carried out an age-adjusted sub-analysis excluding those patients with serious valvulopathies to study the rate of hospitalizations for heart failure and long-term cardiovascular and overall mortality. This

Table 3. Overall cardiovascular morbidity and mortality

	Ventricular pacemaker	Physiological pacemaker	OR	p
1-year all-cause mortality	16 (16.2%)	13 (6.2%)	0.344 (0.158-0.747)	0.005
1-year cardiovascular mortality	5 (5.1%)	6 (2.9%)	0.556 (0.165-1.867)	0.336
2-year all-cause mortality	28 (28.3%)	23 (11%)	0.314 (0.169-0.580)	< 0.001
2-year cardiovascular mortality	9 (9.1%)	6 (2.9%)	0.296 (0.102-0.855)	0.018
3-year all-cause mortality	6 (13%)	5 (3.7%)	0.447 (0.209-0.954)	0.035
3-year cardiovascular mortality	6 (13%)	5 (3.7%)	0.256 (0.074-0.885)	0.022
End of follow-up all-cause mortality	33 (33.3%)	32 (15.3%)	0.362 (0.206-0.635)	< 0.001
End of follow-up cardiovascular mortality	11 (11.1%)	8 (3.8%)	0.318 (0.124-0.819)	0.013
Post-pacemaker implantation complications	2 (2%)	15 (7.2%)	4.021 (0.906-17.842)	0.140
Atrial fibrillation “ <i>de novo</i> ” episodes	0 (0%)	17 (8.1%)	0.660 (0.608-0.717)	0.004
Acute coronary syndrome	1 (1%)	3 (1.4%)	1.413 (0.145-13.756)	0.765
Acute heart failure	21 (21.2%)	25 (12%)	0.507 (0.268-0.960)	0.035
Stroke	6 (6.1%)	6 (2.9%)	0.458 (0.144-1.458)	0.177

Figure 2. Cardiovascular and all-cause mortality in octogenarian patients with primary pacemaker implantation.

substudy revealed differences in the latter parameter in favor of patients with physiological versus ventricular pacing, as it was observed in the overall analysis.

As for the relationship of cardiac pacing with functional status modification, we analyzed 82 elderly patients in whom we were able to quantify their Barthel

Figure 3. Functional status variation in octogenarian patients with pacemaker primary implant.

Index and RCF scale at the time of implantation and 3 years later, with a mean age of 84.6 ± 2.9 years (43.9% were male and 56.1% of females). We did not detect significant differences in the variation on the Barthel Index and RCF scale in octogenarian patients with sinus node dysfunction, second-degree symptomatic AVB, intraventricular conduction disorder, and atrial fibrillation. In fact, individuals older than 80 years with complete heart block had a mean variation in the Barthel Index of -17.7 ± 27.1 ($p < 0.001$) and a mean variation in the RCF scale of 0.9 ± 1.3 ($p < 0.001$) (Fig. 3).

Discussion

The progressive increase in age at pacemaker implantation entails an increase in comorbidity, morbidity, and mortality, a finding that we have confirmed with the presented results. Mean age in most observational and experimental studies related to permanent cardiac pacing does not exceed 78 years, and in almost all these trials, the subgroup of octogenarian patients is absolutely underrepresented³⁻⁶. However, in our sample, the mean age was higher and probably better reflects the real situation of pacemaker implantation at present.

The difference in the rate of VDD pacemaker utilization between our study population and the general population can be explained by the exclusion of individuals younger than 70 years and the tendency toward trying to maintain atrioventricular synchrony in elderly patients with high comorbidity and advanced block in our unit.

There is controversy on whether the VDD mode offers advantages over VVI in this context with regard to the preservation of atrioventricular synchrony. Some studies suggest a certain benefit with the use of the VDD pacing mode in patients with a preserved sinus node function and AVB, although there is an increased risk of atrial sensing loss overtime²⁹. On the other hand, there are no clear morbidity and mortality differences either between VDD and DDD¹¹⁻¹⁴. In our study, we did not detect differences in the rate of post-implantation complications or cardiovascular events (acute coronary syndrome and/or hospitalization for heart failure) in octogenarian individuals with advanced block dependent on the pacing mode (VVI, VDD, and DDD) ($n = 94$), although we observed a higher mortality rate in the mid-long-term with ventricular versus physiological devices. The multivariate analysis defined the VVI pacing mode as an independent mortality predictor in this

subgroup of patients. The limitation that entails having a relatively small sample size of octogenarian patients with complete heart block (94) forces us to be cautious for drawing firm conclusions, although this allows us formulating the hypothesis that the VDD pacemaker can be a valid and useful alternative in elderly patients with pacemaker indication for advanced block and high comorbidity.

In our analysis, we did not detect a significant improvement in the functional or cognitive status of patients in the mid-long term, and even in some patients, such as patients with advanced block, functional status was significantly poorer after the pacemaker implantation. We suggest that, in old and very old patients, actions should be guided within the field of bradyarrhythmias depending on what the cardiac pacing guidelines indicate. However, probably, we should consider other variables such as the probability of modifying the degree of both physical and psychological dependence. Perhaps, a mean of 3.5 years of follow-up is too long for the analysis of this functional degree in a sample with such an elevated mean age. This could partly explain such discouraging results in this context and would be the basis for future prospective studies, with shorter follow-up periods (1 month, 6 months, 1 year, etc.). In view of these findings, we must be cautious in octogenarian patients and not give false expectations since finding a significant improvement in functional and cognitive ability does not seem foreseeable, at least in the medium term. We must assume that functional impairment will depend on other factors, and not only on intrinsic properties of the cardiac excitation-conduction system.

Limitations

The ventricular device implantation indication (beyond slow or blocked atrial fibrillation) was established by the operator in question based on patient comorbidity and risk of complications, but in the absence of objective parameters that quantified both, which can induce selection bias. In addition, mean age at pacemaker implantation was significantly higher for ventricular than for physiological devices, which can introduce important artifacts in the morbidity and mortality results, especially considering that we are dealing with a population with important comorbidities. Finally, the relative sample size that we obtained when analyzing octogenarian patients with block ($n = 94$) and those in whom we could perform previous and post-pacemaker implantation geriatric assessment ($n = 82$) (of the initial

sample of 308 and 186 octogenarians), does not allow us drawing firm conclusions, but to formulate new hypotheses that should be corroborated in future studies.

Conclusions

Cardiovascular morbidity and mortality in patients older than 80 years who are pacemaker carriers are high and far superior to that of the general population of equal age. With the results of our study, the use of dual-chamber devices, such as VDD, could be considered to guarantee a certain degree of atrioventricular synchrony in octogenarian patients with persistent AVB and preserved sinus node function, without thereby increasing cardiovascular morbidity and mortality.

Long-term improvement of physical or cognitive functional status is non-existent, just as we have demonstrated. So much so that there are even subgroups of patients in whom this parameter is significantly worse 3 years after implantation. In our working group's opinion, we believe that prospective studies are needed where short-term functional status variation is analyzed in the elderly and very elderly patients (comparing, for example, the Barthel Index immediately before the implantation, with the score recorded 1 month, 3 months, or 6 months post-implantation) since the elevated half-life of our patients (with their consequent comorbidities and limitations) can introduce artifacts in long-term results.

Conflicts of interest

None.

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Ethical disclosures

Protection of people and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained written informed consent of the patients and/or subjects mentioned in the article. The corresponding author is in possession of this document.

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