Safety and Effectiveness of Single-Lead VDD Pacing

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Introduction and objectives. Single-lead VDD pacing provides the physiological benefits of atrioventricular synchrony with the convenience of a single-lead system. However, concern remains about the method's safety and effectiveness.

Method. In total, 700 patients with single-lead VDD pacemakers were evaluated retrospectively. The following parameters were recorded: age, sex, etiology, the symptoms and electrocardiographic diagnosis that justified pacemaker implantation, the venous access route used for implantation, atrial sensing at implantation, atrial undersensing at follow-up, the occurrence of supraventricular tachyarrhythmias, and final pacing mode.

Results. Third-degree atrioventricular block was the main indication for pacemaker implantation (66.4%). The most commonly used venous access route was via the right cephalic vein (49.1%). At implantation, the mean atrial signal was 1.84 (1.15) mV. During follow-up, significant atrial undersensing occurred in 7.7% of patients; in 1.9%, it could not be corrected by device reprogramming. Uncontrollable supraventricular arrhythmias were observed in 6.4% of patients. Symptomatic sinus node disease was rare. By the end of follow-up, 91.4% of patients were still on VDD pacing, while, in 8.3%, the pacemaker had to be reprogrammed to the VVI mode. Only 0.3% required atrial lead implantation for DDD pacing. Left-side venous access during implantation was a independent predictora of atrial undersensing at follow-up. Low values of atrial detection at implant did not reach statistical signification although it showed a remarkable trend.

Conclusions. Single-lead VDD pacing seems to be safe and effective when appropriately indicated. Our findings are consistent with those of previously published studies.

Key words: VDD pacing. Atrioventricular block. Atrial undersensing. Supraventricular tachyarrhythmias. Sinus node disease.

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Seguridad y eficacia de los sistemas de estimulación VDD monosonda

Introducción y objetivos. La estimulación VDD monosonda proporciona los beneficios fisiológicos de la sincronía auriculoventricular, sumando a ello la comodidad de ser un sistema de cable único. No obstante, la inquietud que generan su seguridad y eficacia parece mantenerse todavía.

Métodos. Estudio retrospectivo en 700 pacientes portadores de marcapasos con estimulación VDD monosonda. Los parámetros analizados fueron: edad, sexo, etiología, síntomas y diagnóstico electrocardiográfico que motivaron el implante, vía venosa de acceso, detección auricular al implante, infradetección auricular durante el seguimiento, episodios de taquiarritmias supraventriculares y modo de estimulación final.

Resultados. La indicación prioritaria de implante fue el bloqueo auriculoventricular de tercer grado (66,4%). La vena cefálica derecha fue la vía de acceso más comúnmente utilizada (49,1%). La detección auricular media al implante fue 1,84 ± 1,15 mV. Durante el seguimiento un 7,7% de los casos presentó infradetección auricular inaceptable, que no se pudo corregir mediante reprogramación en el 1,9%. Se observó aparición de taquiarritmias supraventriculares incontrolables en el 6.4% de los pacientes. La presencia de disfunción sinusal sintomática fue testimonial. Al final del seguimiento, el 91,4% de los pacientes persistían en modo de estimulación VDD, se tuvo que reprogramar en VVI a un 8,3% y sólo un 0,3% precisó el implante de una sonda auricular para estimular en DDD. Las vías venosas de acceso izquierdo fueron un predictor independiente de infradetección auricular. Valores bajos de detección auricular al implante mostraron una clara tendencia, aunque sin llegar a la significación estadística.

Conclusiones. La estimulación VDD monosonda es segura y eficaz cuando la indicación es correcta. Comparando nuestros resultados con los estudios publicados, encontramos correlación en términos de seguridad y eficacia.

Palabras clave: Estimulación VDD. Bloqueo auriculoventricular. Infradetección auricular. Taquiarritmias supraventriculares. Disfunción sinusal.

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ABBREVIATIONS

AVB: atrioventricular block. AS: atrial sensing. SSS: sick sinus syndrome. AU: atrial undersensing. PM: pacemaker. SVT: supraventricular tachvarrhythm

SVT: supraventricular tachyarrhythmia.

INTRODUCTION

At present, most cardiologists prefer dual-chamber pacemakers (PM) treating for symptomatic atrioventricular block (AVB) to maintain atrioventricular synchrony.^{1,2} Single-lead VDD pacing provides the physiological benefits of AV synchrony with the convenience of a single-lead system.^{3,4} The low cost of this type of pacing compared to doublelead dual-chamber PM,^{5,6} the low incidence of complications7,8 and reduced implantation time9,10 make this system a suitable mode when appropriately indicated (high degree of AVB with intact sinus function).4,11,12

Several explanations have been offered regarding the skepticism among physicians regarding employing this pacing mode. There are three main objections: the lack of cumulative evidence, concerns regarding atrial sensing (AS) stability¹³⁻¹⁷ and uncertainty surrounding the future appearance of symptomatic sick sinus syndrome (SSS).¹⁰

In recent years, authors have focused on these 3 factors. These concerns motivated the present study, whose main aim is to review this pacing mode in the long term and, specifically, the diagnosis of atrial undersensing (AU), the appearance of uncontrollable supraventricular tachyarrhythmia (SVT), and the development of symptomatic SSS leading to modifying the pacing mode during follow-up.

METHODS

Patient Characteristics

We retrospectively studied those patients fitted with a PM in single-lead VDD pacing mode in our hospital between July 1994 and February 2004. These patients belonged to our center's catchment area, which encompasses 6 of the 9 health area sectors in our region (pop. 893 966). All patients undergoing this pacing mode and who fulfilled the criteria for this type of implantation were included in the study: symptomatic AVB with normal sinus function and without need of negative chronotropic agents.¹¹ If sinus function was unknown, then chronotropic function was assessed when the baseline sinus rate was less than 70 beats/min using the atropine test (a maximum dose of 0.04 mg/kg was given intravenously and sinus node was considered dysfunctional on empirical grounds when an atrial rate of \geq 90 beats/min was not achieved). Patients who could not be completely followed up for different reasons were excluded (no AS record at implantation time, moving outside the refernal area, failing to attend check-ups or other reasons).

The following parameters were analyzed: age, sex, etiology, symptoms, and electrocardiographic diagnosis justifying implantation, venous access route, AS at implantation, AU during follow-up, SVT episodes and final pacing mode.

Pacemaker and Lead Models

The PM models used were as follows: Philos SLR (186), Actros SLR (152), Kappa VDD 700 (93), Unity (76), Dromos SLR (60), Pulsate VDD (47), Thera VDD (39), Virtus VDD (37), Kappa VDD 900 (8), and Phymos ADV (2). The electrodes employed had a dipole to detect atrial activity and bipolar configuration with \leq 1-cm separation between concentric atrial rings. Up to 5 different electrode models were used: Biotronik SL (separation between rings, 1 cm), Biotronik Solos SLX (1 cm), Medtronic Capsure VDD (0.86 cm), Medtronic Capsure VDDZ (0.86 cm), Guidant Selute Picotip VDD (1 cm).

Implantation Technique

A cardiologist verified the suitability of the pacing mode in each case according to classic criteria and actively participated in threshold detection during implantation via the Medtronic 2098 programmable analyzer.

The implantation technique was decided by a cardiac surgeon experienced in this field, choosing the venous access route depending on the individual. After the lead was introduced, the first step was to locate the electrode site in the right ventricular apex, and once the thresholds were measured in the cavity, the atrial dipole was moved to try to obtain a mean AS threshold amplitude of ≥ 1.0 mV which was stable during inspiration and expiration. Once in place, the cable was carefully fixed while avoiding the slightest displacement. If acceptable atrial thresholds were not achieved, the electrode was detached from the ventricle and relocated at a new site, more proximal or distal, until suitable parameters were achieved. When an optimal result could not be achieved, a new active or passive fixation lead was implanted in the atrium and the pacing mode changed to a DDDR generator. All patients underwent chest x-ray before and after implantation.

Pacemaker Programming and Follow-Up

Before hospital discharge, all patients underwent an initial check-up to ensure correct operation of the system, based on several stable AS values both in supine decubitus position and under provocation maneuvers (forced inspiration, coughing, sitting and standing positions and right and left lateral decubitus positions). An adjustment to the nominal parameters of the generator was programmed, basically regarding the lower limit and nocturnal rate, as well as atrial sensitivity, and a new check-up done at 3 months; from this time onward an annual check-up was instituted, provided no problems occurred requiring preferential/emergency consultation. In all cases AS was assessed in supine decubitus position and after forced inspiration. Atrial undersensing was considered unacceptable when there was frequent AS instability at check-up (>10% loss of AS of paced beats) and/or >10% AV asynchronism when reviewing histograms.¹⁷ All the implanted pacemakers underwent Holter monitoring facilitating the diagnosis of asymptomatic AU, as well as paroxysmal SVT episodes not perceived by the patient.

The nominal parameters of the generator were programmed according to our protocols: lower limit/baseline rate, 50 beats/min, upper limit rate estimated by individual submaximal rate (80% of the maximal rate, calculated as 220 – age) and nocturnal rate, 40 beats/min. The mode change algorithm was not initially programmed, with the aim of rapidly detecting the appearance of atrial tachyarrhythmias and was only done in this case. The system's response to the onset of these episodes differed according to two possibilities: a second-degree AVB when the upper limit rate was reached or to implement the mode change if this algorithm had been activated previously.

Statistical Analysis

The statistical analysis was carried out with SPSS software version 10.0 for Windows. A general descriptive analysis was carried out. The results are presented with their absolute rates and percentages for qualitative variables and through the arithmetic mean \pm standard deviation (SD) for quantitative ones. Comparisons between qualitative variables were done via χ^2 test and between quantitative variables via Student *t* test or Mann-Whitney U test if required. A multivariate logistic regression analysis was done previously, which included the variables that were significant in the univariate analysis and the sensing failure variable as the dependent variable. A *P*-value <.05 was considered statistically significant.

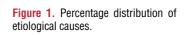
RESULTS

Finally, 700 patients were included in the study, which represents approximately 11.47% of the total PM implanted during this period in our hospital (6098). Thirty-two patients were excluded because they did not fulfill the criteria. Some 57.8% (405) of the patients were male. The mean age of our patients was 69.5±4.53 years (interval, 21-90 years). The mean follow-up time was 33 months (interval, 3-120 months).

The most prevalent etiologies were valvular heart disease (7.4%), and ischemic heart disease (5.2%). Nevertheless, it was impossible to determine this in a high percentage of patients (Figure 1). Syncope was the most common motivation for implantation (39.5%) compared to any other signs and symptoms. Asymptomatic bradycardia (22.1%) and dyspnea (20.1%) were also common manifestations when this was indicated. "Prophylactic" implantation was done in 1.5% (Figure 2). The main electrocardiographic indications for implantation were third-degree AVB (66.4%), Mobitz II second-degree AVB (19.3%), and Mobitz I second-degree AVB (8.5%). A miscellaneous group of electrocardiographic patterns determined the remaining indications (5.8%), among which were biphasic or triphasic block, as well as symptomatic first-degree AVB (Figure 3).

As mentioned, the choice of venous access route was made by the cardiac surgeon. The most widely used route in our hospital was the right cephalic vein (49.1%), followed by the right subclavian (35.4%). Contrary to other centers, access via the left veins was less often used: left subclavian (9.6%) and left cephalic (5.8%). Access via the jugular route was extremely rare (a single case) (Figure 4).

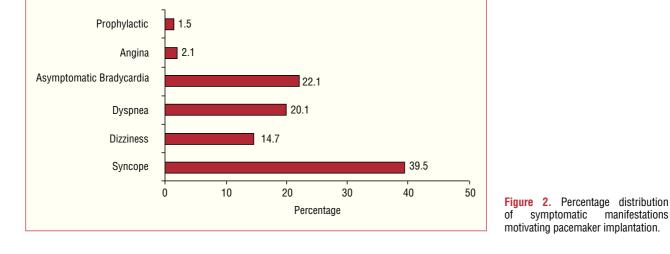
Mean AS at implantation was 1.84±1.15 mV (interval, 0.3-8.2 mV). Up to 15.7% of the patients (110 cases) presented atrial signal amplitude values below 1 mV at check-up prior to discharge. During this check-up electrocatheter relocation was required in 14 patients in the operating theatre due to demonstrated, and frequent, AS instability (>10% loss of atrial sensing of paced beats). Regarding AU during follow-up, 5.8% (41) of the implanted pacemakers presented occasional and transitory loss of sensing which was corrected through adjusting atrial sensitivity; only in 1.9% (13) of cases could this not be corrected with reprogramming. The presence of SVT episodes was detected in 52 (7.4%)patients during follow-up. Of these, 45 (6.4%) finally needed a change in pacing mode to VVI due to uncontrollable tachyarrhythmias. Finally, 16 (2.3%) of our patients presented some SSS data, although it was only necessary to add an atrial pacing electrode in 2 (0.3%) cases due to symptoms related to this dysfunction.

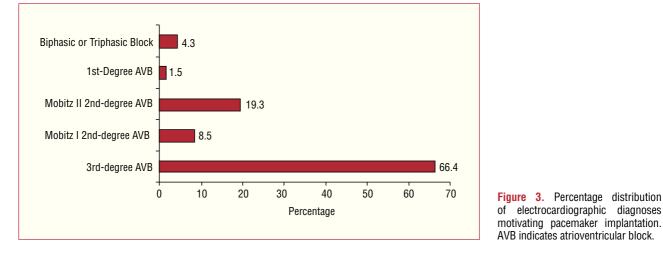


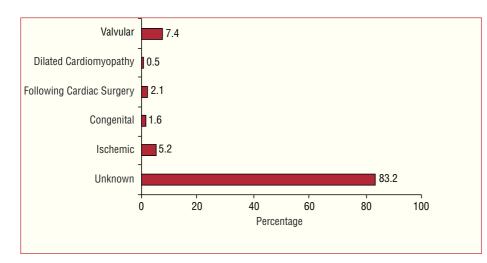
symptomatic

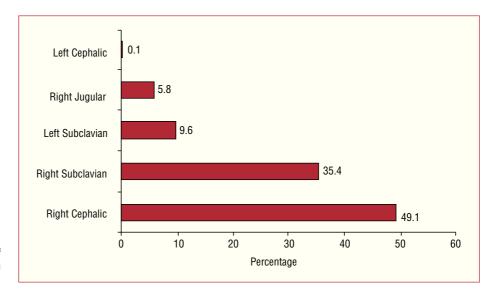
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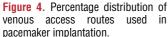
The most relevant data from the univariate analysis relating to the AU study are summarized in Table 1. A comparative analysis was done of the AS values at implantation in relation to loss of sensing. Mean sensitivity at implantation was 1.91 mV in the patients with normal sensing and 1.45 mV in those presenting AU during follow-up (P=.064, close to statistical significance). Failures in AS relating to the access route were more frequent when left venous routes were used compared to right venous routes (12.1 vs 5.7%; P=.047).











Regarding the final aim of the study, that is, to investigate the pacing mode at the end of follow-up, 91.4% (640) of PM stayed in VDD pacing mode, whereas 8.3% (58) had to be reprogrammed to VVI at some time during follow-up, mainly due to uncontrollable SVT or unacceptable AU not corrected through reprogramming, and just 0.3% (2) required the implantation of an atrial pacing lead to modify the pacing mode due to SSS (Figure 5).

DISCUSSION

Outstanding developments in cardiac pacing in the last 20 years have generally led to the replacement of single-chamber devices by dual-chamber devices. Although more than 20 years have passed since the appearance of this type of pacing, currently, the proportion of single-lead VDD systems implanted continues to be low, which contrasts with the increased experience with other pacing modes.^{14,18,19} If there has been a weak positive trend in implantation rates (7%) in Europe, this has not been the case in the United States, where the proportion of VDD implantations has remained extremely low (3%).²⁰ Reviewing the most recent series, up to 50% of patients with AVB receive dual-chamber pacing systems, and it is estimated that 30%-50% of them have normal sinus function.²¹ The implantation rates in Spain for 2003 were published approximately 1 year ago, which confirmed a growing trend in single-lead VDD implantation rates (19%).²² During this period, 25% of implantations were of this type in our hospital.

The high percentage of cases of unknown etiology in our study is striking. It is possible that the underlying cause in most of these was fibrosis of the excitatory conduction system,²² but this is only a suspicion as reliable diagnosis remains anatomicalpathological.

TABLE 1. Statistical Analysis of Atrial Undersensing at Follow-Up*

	Undersensing	Normal Sensing	Р
Mean atrial sensing			
at implantation, mV	1.45	1.91	.064
Final VDD pacing, %	75	93.3	.001
Sex, %			
Males	52.3	57.8	NS
Females	47.7	42.2	
Venous access routes, %			
Left	27.3	16.2	.047
Right	72.7	83.8	
Follow-up time, mean±SD,			
months	37±35	32±34	NS

*SD indicates standard deviation; NS, nonsignificant.

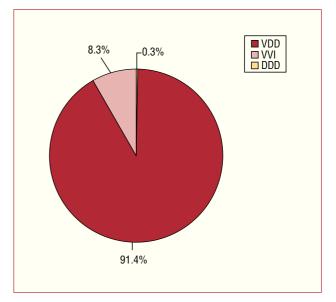


Figure 5. Pacing mode at end of follow-up.

	DDD†	VDD†	VDD‡
Patients, n	80	112	700
Mean age, years±SD	63±16	70±13	69.5±4.53
Males, %	70	59	58
Follow-up time, months±SD	24.9±15.7	17.7±10.0	33±34
Mean AS at implantation, mV	4.0±1.7	2.91±1.48	1.84±1.15
Complications arising from implantation, %	6	3	NC
Early reintervention related to lead dysfunction, %	2.5	0.90	2
Unacceptable AU during follow-up, %	1.25	8.03	7.7
AU uncorrected via reprogramming, %	1.25	1.78	1.9
Reprogramming to VVI due to SVT, %	4	2	6.4
Symptomatic SSS, %	_	0.8	0.3

AD indicates atrial detection; SD, standard deviation; SSS, sick sinus syndrome; AU, atrial undersensing; NC, not collected; SVT, supraventricular tachyarrhythmia. †Data from Huang et al. ‡Our results.

Stability in AS, a subject of special concern to physicians, has been recently studied.²³⁻²⁵ These have shown that the detection of a minimum range of atrial signals should be optimized at implantation (between 1 and 2 mV), avoiding strong fluctuations (<0.5 mV),^{5,26,27} in addition to using autosensing algorithms to adjust sensitivity during activity and postural changes. In our analysis of the results we have highlighted the importance of obtaining an appropriate atrial signal at implantation. Similar to other published works,^{5,28} we found a significant reduction in the amplitude of the atrial signal using telemetry the day after implantation compared to the data obtained in the operating theatre with the Medtronic 2098 programmable analyzer. The explanation for this early fall in AS seems to lie in the different amplifiers, filters and blocking methods used by one device or another to measure atrial electric activity. This fact could explain the high percentage of patients with atrial signal amplitude values below 1 mV (15.7%) in the check-up prior to discharge, as well as the need to relocate the catheter early due to unacceptable AU (2%) in some of them.

When analyzing AU during follow-up, Kuzniec et al^{24} found some degree of AU in 5% of their patients after a follow-up of 33 ± 22 months. Similarly, in a recently published study, Eberhardt et al⁷ detected a nonsignificant percentage of symptomatic AU (0.5%) in patients with an implanted VDD PM after 5 or more years of follow-up. All studies agree on the importance of obtaining stable AS at implantation between 1 mV and 2 mV, with fluctuations less than 0.5 mV. Our results are similar to those of these studies (5.8% transitory AU correctable via programming and 1.9% unacceptable undersensing requiring changes in pacing mode), with the advantage that the sample was bigger than in the majority of these studies.

On the other hand, several works have shown a nonsignificant percentage (2%-5%) of patients who

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require reprogramming to VVI mode due to SVT when appropriately indicated.²⁹ Follow-up time and possible bias regarding indications for this pacing mode are variables that could explain the slightly better result in our study (6.4% vs 2-5%).

Regarding the potential appearance of symptomatic SSS in the long term, several authors have agreed that this is insignificant (<1%),^{7,10,29} which is in high agreement with the data obtained in our study (0.3%).

In recent years, several studies have been published showing the advantages of single-lead VDD pacing compared to VVI and/or DDD pacing.^{5,7,9,21} All agree that this pacing mode involves a lower rate of complications both in the short-and long-term compared to the DDD system, as well as lower costs and shorter implantation time, and some authors have claimed a lower incidence of failure in permanent atrial fibrillation.^{30,31} They generally demonstrate a high degree of long-term safety when correctly indicated. This controversy is now reflected in the influence that one or another pacing mode could have on the efficacy of the new resynchronization systems. Studies have begun to appear that demonstrate the deleterious effects of pacing versus atrial sensing regarding intraventricular asynchronism parameters and ventricular filling times.32

Table 2 shows our results and compares them with those of Huang et al's⁵ study. In their comparative analysis of single-lead VDD pacing, they show higher mean AS at implantation (probably related to the use of different analyzers and the increasing improvements in implantation techniques). There was also significantly less reprogramming to VVI mode, probably due to the much longer follow-up time in our study (most of the patients in the treatment group were at higher risk of SVT due to age). In addition, when analyzing their results, the rate of early complications and reprogramming to VVI mode were significantly higher in the group of patients with DDD pacing. Mean AS at implantation, although significantly greater in the DDD group, remained stable in both groups.

When reviewing the literature we only found one recently published article that, in line with our results, found a significant mid-to long-term difference in AS in the mid-to long-term depending on the venous access route chosen for implantation (left or right routes).²⁸ The hypothesis that our working group puts forward is based on the presence of a sharp curve the electrode makes when passing through the superior vena cava in implantations via right venous access routes, which allows the atrial dipole to be positioned closer to the lateral wall of the right atrium. This would enable broader and more stable AS. Given the enormous implications that this conclusion could have in the future when selecting the implantation access route for this pacing mode, and although data are beginning to appear that seem to endorse our hypothesis, we recommend caution when interpreting this relationship, as new studies are required to confirm the theory.

Study Limitations

The main limitation of our study is its retrospective design, and thus bias cannot be ruled out when establishing the indication for single-lead VDD mode. As this study was based on implantations in a single center with broad experience in this type of pacing it may be difficult to extrapolate the conclusions.

Furthermore, its descriptive character suggests caution when assessing the results, since, given there was no control group, the conclusions could be overstated. However, we find quite similar results when comparing our data with other large series in the medical literature, which tends to support our conclusions.

Finally, it would have been of interest to have more details regarding the possible presence of structural heart disease, and specifically, right atrial dilatation, in order to observe its effect on AS.

CONCLUSIONS

Single-lead VDD pacing is safe and effective when correctly indicated, the implantation technique meticulous and satisfactory and postimplantation programming accurate. We found a low incidence of AU in our series, which is more frequent when left venous access routes are used and in patients with low AS at implantation, a modest rate of uncontrollable SVT and a nominal percentage of SSS.

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