VDD pacemaker replacement independently of the implanted lead: a prospective study

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Key words:
Pacemakers; Pacing.

Background. **Single-lead VDD pacing is effective, safe and reliable. The only still open, practical issue is represented by the theoretical need of replacing each device with a similar one compatible with the already implanted lead to guarantee the performance of the system. The aim of our study was to investigate the atrial sensing performance of VDD pacemakers working in combination with non-dedicated chronic leads.**

Methods. **We enrolled 16 consecutive patients (12 males, 4 females, mean age 78 ± 7 years) admitted to our institution for end of life of the battery. Atrial dipoles ranged from 5 to 30 mm. All replacements were done with a VDD(R) Saphir 3 (Vitatron) designed for an atrial dipole of 8.6 mm.**

Results. **All pacemakers were found to be performing well without any complaint by the patients imputable to stimulation defects. The P-wave amplitudes measured by the old and new pacemakers are similar and respectively 0.64 ± 0.40 vs 0.73 ± 0.53 mV (p = NS). So the old and new devices detect similar P waves. The atrial sensing percentage at 1 month of follow-up with the new pacemaker was even better than that of the old one (97 ± 4 vs 95 ± 3% respectively, p = 0.016): this is not imputable to the pacemaker but to the higher programmed atrial sensitivity (0.17 ± 0.06 vs 0.18 ± 0.07 mV respectively, p = NS).**

Conclusions. **Independently of the implanted lead, the replacement of VDD pacemakers with devices designed for a short dipole is feasible, safe and reliable. This possibility overcomes a presumed limitation of this pacing modality.**

(Ital Heart J 2003; 4 (10): 701-705)

Received April 18, 2003; revision received July 30, 2003; accepted August 12, 2003.

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Introduction

Single-lead VDD stimulation is a widely accepted pacing modality representing about 12% of the total implanted units per year in Italy[1]. All manufacturers recommend the use of VDD stimulators with their corresponding leads, since the filters of the atrial channel are designed on the basis of the distance between the floating atrial electrodes[2]. It is easy to respect this rule at the first implant, while at replacement it is difficult to guarantee a pacemaker model similar to the previous one.

Single-lead VDD pacing has been proven to be effective, reliable and safe[3-5]. The only practical, still open issue is the theoretical need of replacing each device with a similar model to guarantee the best performance of the system. Though there are specific technical reasons supporting this concept, to date nobody has quantified the real clinical impact on the sensing function of a pacemaker working with a non-dedicated lead.

The aim of our study was to investigate the atrial sensing performance of VDD pacemakers working in combination with non-dedicated chronic leads. We assumed that the technical differences of atrial filters are not so relevant as to affect the real performance of a VDD system able to provide a wide range of atrial sensitivity down to 0.1 mV.

Methods

We enrolled 16 patients (12 males, 4 females, mean age 78 ± 7 years), who were admitted to our hospital for pacemaker replacement due to a regular end of life of the battery. The first implant was done in March 1993 and first replacement in December 1999. All floating dipoles were positioned in the high right atrium except for those with a distance of 30 mm that were positioned in the low atrium. All replacements were performed using a Saphir 3 (Vitatron) VDDR pacemaker, programmed in VDD mode, which is designed for a floating dipole with a distance of 8.6 mm between the two atrial electrodes. Only in 2 cases did we use a specific adapter to con-

nect the lead Synkel Plus-113S to the new stimulator. The new pacemakers are also equipped with a specific function to collect the P-wave amplitude during the daily activities of the patients. By means of a dedicated histogram, this function allows a reliable and continuous assessment of the sensing performance together with the standard percentage of atrial sensing. All data refer to the total amount of cardiac cycles during the follow-up period[6].

We did not analyze the morphology of the endocavitary signals. The P-wave amplitude was measured at implantation and at replacement by the same pacing sensing analyzer to guarantee values totally independent of the specific implanted devices and so perfectly comparable. Similar measurements were performed also through the old and new devices respectively, before and after replacement. In particular, the P-wave amplitude was assessable through telemetry in 13 out of 16 old devices, and atrioventricular synchronism in 12 out of 16 old pacemakers allowing a direct comparison of these parameters before and after replacement in the respective patients. One month after replacement, all patients underwent a 24-hour Holter recording to verify the atrial sensing function even by means of this standard method. During the same follow-up we collected all data that were automatically stored by the implanted devices. Six months later all patients were submitted to follow-up again.

The leads and the corresponding dipole size are reported in table I. The range of atrial dipole sizes goes from 5 to 30 mm, covering all the possible cases that one may encounter in clinical practice[7].

Table I. The implanted leads and the size of their floating dipoles.

Leads	Dipole (mm)	No. patients
3 VR Pacesetter	8	4
830S MEDICO	30	2
Synkel Plus-113S LEM	7	2
Unipass 425-04 Interm	5	8

Results

All pacemakers were found to be performing well without any complaint by the patients imputable to stimulation defects. Detailed data regarding the acute measurements at implantation and replacement by the pacing sensing analyzer, and the data collected through the old and new pacemakers at replacement and at 1 month of follow-up are reported in table II.

The P-wave amplitudes measured by the old and new stimulators were similar and respectively 0.64 ± 0.40 vs 0.73 ± 0.53 mV (p = NS, two-tailed paired Student's t-test). Clearly the old and new devices detect similar P waves.

The atrial sensing percentage at 1 month of follow-up with the new pacemaker was similar to that of the old one, but there still were statistically significant differences as they respectively measured 97 ± 4 vs 95 ± 3% (p = 0.016, two-tailed paired Student's t-test). The improved atrial sensing percentage with the new device was probably not imputable to the pacemaker but to the higher programmed atrial sensitivity. In some patients

Table II. Data collected at implantation and at replacement by the pacing sensing analyzer (PSA) and data collected by the old and new pacemakers (PM).

Patient	Age (years)	A dipole (mm)	P wave (mV)				AS (%)		A sensitivity (mV)	
			PSA 1st implant	PSA replacement	Replacement old PM	Replacement new PM	Old PM	New PM	Old PM	New PM
1	77	8	1.4	0.2	0.2	0.4	92	99	0.1	0.1
2	78	8	1.2	0.4	0.2	0.2	89	96	0.1	0.1
3	85	8	1.6	1.2	0.8	0.5	95	97	0.2	0.1
4	77	30	1	1	–	1.4	–	99	0.15	0.17
5	76	7	3	2.2	0.7	0.7	–	86	0.2	0.17
6	78	5	3	1	1.6	2.2	91	99	0.3	0.25
7	71	30	1.7	0.6	–	0.6	–	99	0.25	0.25
8	69	5	1.6	0.6	0.6	0.6	99	99	0.2	0.17
9	79	5	1.8	0.6	0.65	0.6	99	99	0.1	0.17
10	64	5	1.5	0.4	0.4	0.5	99	100	0.1	0.1
11	80	7	1.4	0.8	–	1.3	–	100	0.3	0.25
12	76	5	1.1	0.3	0.4	0.1	92	96	0.1	0.1
13	90	8	0.9	0.4	0.3	0.3	95	94	0.2	0.1
14	82	5	1	1	0.7	0.7	95	96	0.2	0.25
15	77	5	3.2	1	1.2	1	96	96	0.25	0.25
16	89	5	3	0.4	0.6	0.5	92	94	0.2	0.17
Average	78		1.78	0.76	0.64	0.73	95	97	0.18	0.17
SD	7		0.80	0.49	0.40	0.53	3	4	0.07	0.06
p			0.00005		NS (0.953)		0.016		NS (0.193)	

Empty cells correspond to data not available from the old pacemakers. A = atrial; AS = atrial sensing.

the atrial sensitivity was programmed higher than before, as appropriate (Table II). Besides, it was not always possible to program a sensitivity of 0.1 mV with the old devices. Therefore the old and new programmed sensitivities did not differ significantly (0.18 ± 0.07 vs 0.17 ± 0.06 mV, p = NS, two-tailed paired Student's t-test).

The acute measurements of the P wave at implantation and at replacement were significantly different being respectively 1.78 ± 0.80 vs 0.76 ± 0.49 mV (p = 0.00005, two-tailed paired Student's t-test). This could be the consequence of the lead stabilization process during the first months after implantation, leading to a more stable but slightly different position of the dipole in the atrium.

Figures 1 to 3 show the P-wave amplitude histograms of leads with three atrial dipole sizes (5, 8 and 30 mm respectively). These histograms clearly show reliable P-wave amplitudes during the daily activities of the patients. The analysis of all P-wave histograms at 1 and 6 months of follow-up indicates a constantly reliable amplitude associated with the high atrial sensing percentage reported in table II.

The analysis of the 24-hour Holter recording at 1 month of follow-up and the data collected through the devices at 6 months of follow-up confirm the data of atrial sensing percentage reported in table II.

The patients did not complain of any adverse event related to stimulation. After implantation we observed some atrial oversensing due to a far-field ventricular

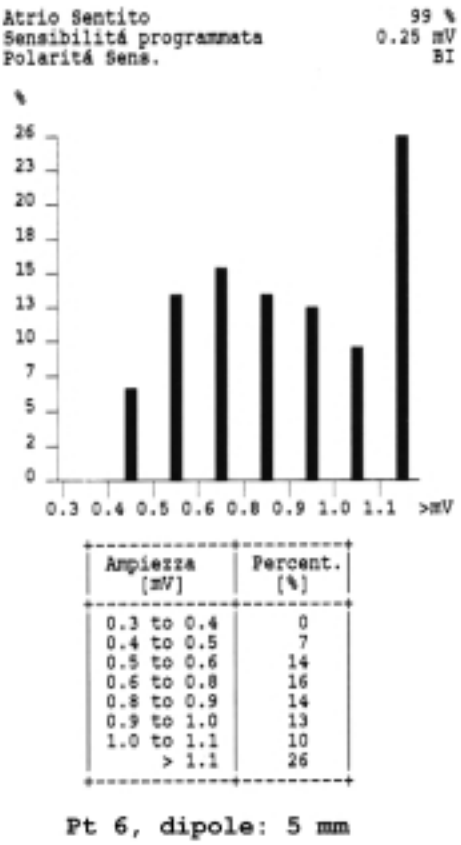

Figure 1. *Histogram of the P-wave amplitude collected in patient no. 6 one month after replacement with the new pacemaker.*

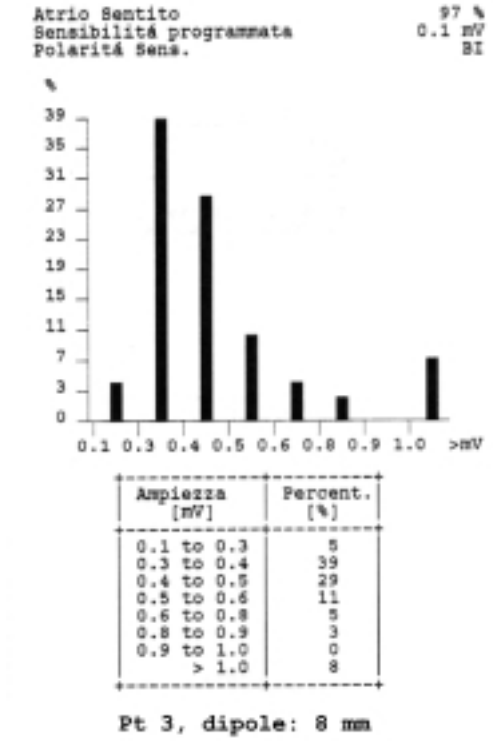

Figure 2. *Histogram of the P-wave amplitude collected in patient no. 3 one month after replacement with the new pacemaker.*

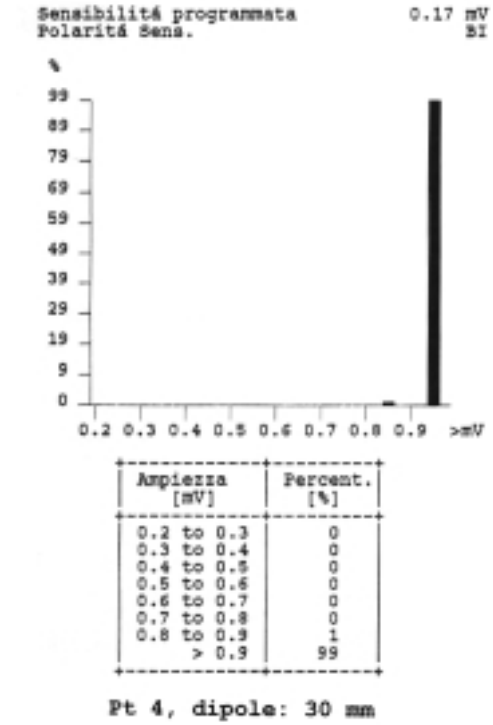

Figure 3. *Histogram of the P-wave amplitude collected in patient no. 4 one month after replacement with the new pacemaker.*

electrogram in patients with a large atrial dipole of 30 mm. We avoided this artifact by programming a longer atrial blanking interval (200 ms instead of 150 ms).

Discussion

As demonstrated by Antonioli[2,8] an atrial dipole size ranging from 5 to 10 mm seems to be optimal for the best signal/noise ratio. The noise does not only signify myopotentials or electromagnetic interference, but mainly reflects the far-field of the ventricular electrogram. For this reason the combination of a short atrial dipole and a high right atrial position may guarantee the best selectivity of the sensed signals. On this basis the large majority of commercially available leads have a dipole size in the range of 5 to 12 mm. Overall, the range of dipole sizes for commercially available VDD leads goes from 5 to 30 mm[7]. We chose a VDD pacemaker designed for a dipole of 8.6 mm as we expected that this pacemaker would at least fit with the majority of leads, the differences in the dipole sizes not being so relevant.

Many factors may influence the beat-to-beat amplitude of a P wave detected through a floating lead: posture, breathing and exercise[9,10]. For this reason we decided to assess the long-term reliability of P-wave detection not only by means of 24-hour Holter monitoring, but also by means of the specific diagnostic functions of the devices we used in our study. In particular, the distribution of the P-wave amplitude during the daily activities of the patients allows us to evaluate the performance of the atrial sensing function during the overall follow-up period in every patient[6]. On the other hand, the 24-hour recordings confirmed the reliability of the automatic diagnostic functions of the devices.

At the beginning we did not expect higher values of atrial sensing percentage with respect to the pre-replacement period. This result seems related to the fact that new generation devices allow a maximum sensitivity level of 0.1 mV that was not always provided by previous models. So the main factor influencing the good pacemaker performance after replacement is probably the wide range of programmable atrial sensitivities rather than the electronic differences of P-wave filters[11]. Following this observation, at the end of the study all patients were programmed with an atrial sensitivity of 0.1 mV independently of the P-wave amplitude, and all patients showed an atrial sensing > 94% at follow-up. If we compare the sensitivity values set in the old devices with a new value of 0.1 mV, even this parameter shows a statistically significant difference ($p < 0.001$) confirming that the sensitivity value itself is probably responsible for the increased atrial sensing percentage associated with the new devices. In addition, it is very rare to observe atrial oversensing with a short dipole, and this allows us to always set the maximum sensitivity level without any adverse effect[12]. In case of a large dipole, the extension of atrial blanking or the use of a standard post-ventricular atrial refractory period would always avoid the potential problems arising from far-field oversensing.

In our study, all leads with a short or large dipole showed similar or better performances with the new devices. Figure 3 shows an excellent histogram of the P-wave amplitude of a lead with a dipole of 30 mm, and all patients with a large dipole had 99% atrial sensing, confirmed by the relative 24-hour Holter recordings. So, even with a very large atrial floating dipole, the sensing function of a stimulator designed for a short dipole is reliable.

We did not investigate the opposite condition by implanting a device designed for a large dipole with a short dipole lead. So we cannot establish whether it is possible to connect every VDD pacemaker to every implanted lead. We only tested the condition of a stimulator designed for a short dipole connected to every type of commercially available leads. The opposite condition should be investigated, as our study does not answer this specific question.

It was not the aim of our study to compare the performance of the different leads with different dipoles. This would imply not only the analysis of the P-wave amplitude, but also the analysis of the morphology and the signal/noise ratio, meaning the ratio between the P-wave amplitude and the ventricular far-field detected by the floating dipole.

It could be argued that to date the technical literature has supported the theory that every specific dipole fits with the relative electronic filter. This is true especially if we are looking for the “best fitting” between the stimulator and the relative lead, but this concept is not investigated by our study. We started from the perception that the real differences between the filters of different devices are not so large as to make the performance of pacemakers working with non-dedicated leads “unacceptable”, and this has been demonstrated by our study. A large body of scientific literature[2,13-15] reports the frequency content of the endocavitary floating signals, showing the bandwidth for the best compromise between P-wave amplitude and signal/noise ratio: every specific atrial filter should lie at least in the range of 30-100 Hz. For this reason, the different pacemaker filters work on frequency bands which at least in part overlap[2], justifying our data.

The results of our study overcome a presumed limitation of VDD pacing, offering the chance of replacing the devices independently of the implanted lead more freely, without compromising the efficiency of the system.

In conclusion, independently of the implanted lead, the replacement of VDD pacemakers with devices designed for a short dipole is feasible, safe and reliable. This possibility overcomes a presumed limitation of this pacing modality.

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