OLBI pacing - The Italian experience

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Summary

An extensive study was conducted at 34 Italian implant centers to evaluate the feasibility of pacing the atrial myocardium through a floating dipole using the overlapping biphasic impulse (OLBI). The OLBI stimulation generates 2 simultaneous, monophasic pulses with inverse polarity: each of them is delivered from 1 electrode of the dipole and the pulse generator case serves as an indifferent electrode. A population of 125 patients, all with symptomatic A-V block and without evidence of sinus node dysfunction, were implanted with a single A-V lead VDD/DDD pacing system (Biotronik, Inc. models, DROMOS SL M7 and EIKOS SL), allowing temporary or permanent OLBI atrial stimulation. Results show that short-term OLBI, atrial pacing through a floating atrial dipole is feasible in more than 80% of the patients at a sufficiently low threshold and without parasitic phrenic nerve stimulation.

Key Words

Floating electrode, atrial overlapping stimulation

Introduction

The necessity for minimizing the number of leads used in DDD pacing, to reduce vascular burden and related thrombogenesis, and also to simplify implant procedures, spurred some pacemaker (PM) manufacturers to realize implantable systems capable of atrio-ventricular pacing through a single A-V lead. This concept is supported by the excellent performance shown in recent years by single A-V lead systems [1] for VDD pacing. Reports in the literature cite several experiences with acute and chronic DDD pacing using the single A-V leads currently used for VDD pacing[2-12]. The aim of these studies was to induce atrial depolarization through an electric field generated in the vicinity of the floating dipole electrodes. The field generates an electric current in the muscle fibers, which induces cellular depolarization[13]. Various electric signals are applied to generate the field: unipolar, bipolar and the novel OLBI (overlapping biphasic impulse).

A major aspect of atrial pacing with single A-V leads is the effort to avoid parasitic phrenic nerve stimulation (PNS). PNS occurs when the field outside the atrial wall, where the phrenic nerve is located, is still sufficiently high to induce its stimulation. In OLBI pacing, two single impulses with identical width and amplitude, but with inverse polarity, are simultaneously emitted by the atrial ring electrodes. These electrodes are distal and proximal with respect to the PM case. This method allows the generation of an intense field strength in the proximity of the dipole and inside the atrial wall. External to the heart, the field strength becomes significantly lower due to the opposite electrical sign of the interacting field lines. The field is also oriented on a plane containing the dipole and the PM case. These conditions limit the inordinate broadcast of the field, thus minimizing the induction of PNS[14].

Methods

The study was performed at 34 Italian implant centers.

A population of 125 patients, 75 male and 50 female, with a mean age of 75.0 ± 9.4 years (range: 40 - 103), all with symptomatic A-V block and without evidence of sinus node dysfunction, were implanted with Biotronik PM models: 89 DROMOS SL M7 and 36 EIKOS SLD. Both models are equipped with the same capability to perform OLBI atrial pacing at a maximum programmable amplitude of 4.8 V for each pulse. All PMs were connected to single A-V leads, SL 60 (Biotronik, Inc), with 1.0 cm atrial dipole spacing, passive ventricular fixation, and an iridium fractal coating on the electrode surfaces. An A-V distance of 13 cm was used in 84% of the patients and a 15 cm distance in the remaining 16%.

The implantation of the lead was done following the standard procedure of a single lead VDD system. The atrial lead position was only selected in terms of sensing characteristics. Atrial pacing thresholds (APT) were not measured during implantation. APT and parasitic phrenic nerve stimulation (PNS) threshold were assessed at: 1 day, and at 1, 3 and 6 months (m) after implant. Follow-up data also categorized results according to gender and the orientation of the stimulation vector (i.e., if the PM was implanted in the left or right side of the chest). Data were collected from patients in various body positions (supine, sitting, right and left decubitus). In a large number of these patients, a 24-h, dynamic ECG recording (Holter) was performed at the 3-month follow-up.

Results

The average follow-up time was 3.2 months. Only a limited number of patients (20) had attained implant longevity by the time this paper was submitted for publication. This explains why data at 6 months may differ in trend from that collected at previous follow-ups.

The mean values of APT at 0.5 ms measured in supine position were: 2.49 ± 0.86 V at 1 day (125 patients), 2.54 ± 0.85 V (125 patients) at discharge, 2.68 ± 0.79 V at 1 month (91 patients), 2.70 ± 0.71 V at 3 months (53 patients) and 3.02 ± 0.95 at 6 months (20 patients). The difference between data is not significant using one-way analysis of variance. Only 1 patient showed no atrial capture (APT > 4.8 V) at 1 day and at discharge, but at 1 month, stable atrial capture was achieved with an APT of 3.5 V in this patient. Data are shown in Figure 1.

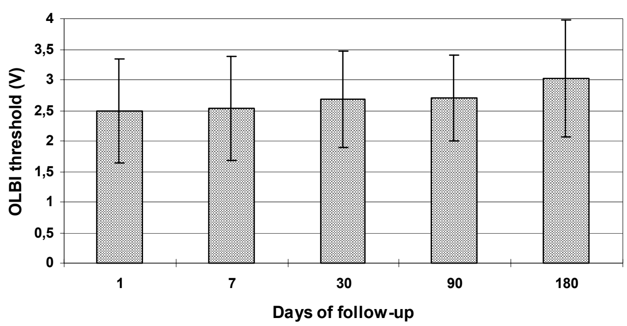

Figure 1. *Mean values of OLBI-APT at 0.5 ms measured for the supine position at the follow-up.*

At pulse amplitudes lower than the highest programmable pulse amplitude, PNS was observed in patients in the supine position in 18.4% cases at 1 day, in 17.6% at discharge, in 20.8% at 1 month, in 13.2 % at 3 months, and in 25% at 6 months. Percentages are shown in Figure 2.

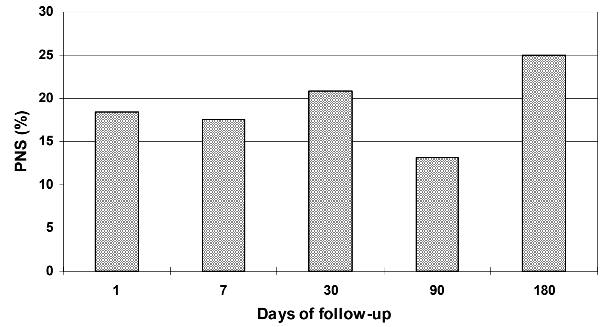

Figure 2. *OLBI-PNS at 0.5 ms detected for the supine position at the follow-up.*

The measured minimum values of atrial sensing were: 0.74 ± 0.72 mV at 1 day, 0.70 ± 0.77 mV at discharge, 0.76 ± 0.93 mV at 1 month, 0.95 ± 1.11 mV at 3 months and 0.92 ± 0.97 mV at 6 months (see Figure 3). The difference between these data is not significant. No P-wave undersensing was detected during the entire follow-up.

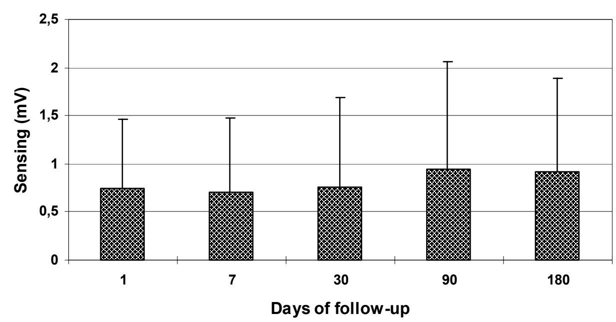

Figure 3. *Mean value of the minimum atrial sensing measured in supine position at the follow-up.*

From this first group of data, a preliminary conclusion can be deduced: the stability of APT and P-wave sensing over time demonstrates an apparently substantial stability of the dipole position inside the atrial chamber.

The pacing constancy was also investigated in relation to changes in posture. During this test, the APT detected for the supine position was increased by 50%; after which the patient was directed to assume various postures. The results are shown in Table 1.

	Constancy of Pacing (% of patients)			
Postural Position	95-100	50-95	< 50	No Pace
Sitting	83	15	2	0
Lying	85	15	0	0
Left Decubitus	58.5	34	7.5	0
Right Decubitus	60.3	35.8	3.9	0

Table 1. *Patient postures vs. constancy of atrial pacing.*

This test was performed at the 3-month follow-up, when the vascular and endocardial formation of endothelium encasing the lead was still in progress. At that point, the dipole was quite free to float inside the atrial chamber, changing its spatial position and consequently its capture function. This occurred essentially during supine decubitus, which is affected by respiration and gravitational force.

In 32 patients, a 24-h Holter monitoring was performed at the 3-month follow-up. Before the test, the PMs in all patients were permanently programmed to the DDD mode at a rate 15 to 20% higher than the patient sinus rate at rest. After application of the recorder, patients were free to return home and to participate in normal daily activities. The system showed good performance with a constant atrial pacing (over 85-95%) at rest and during moderate exercise in 27 of the 32 patients. Regular inhibition by spontaneous atrial activity was observed when patient chronotropic competence exceeded the PM basic rate. In 5 patients, the average atrial capture during the 24-h test period was 50-60%. In 2 of these patients, losses of capture were associated with the standing or seated position (32-40% capture), while the capture rate was good during the night (> 85%). In 3 patients, the capture was very good (85-100%) during the day and during exercise, but poor (40-55%) during the night.

Male and female patients were then considered and compared as separate groups. The mean values of ATP, male vs. female, were respectively: 2.61 ± 0.94 V (75 patients) vs. 2.28 ± 0.69 V (50 patients) at 1 day, 2.65 ± 0.92 (75 patients) vs. 2.47 ± 0.84 (50 patients) at discharge, 2.57 ± 0.83 V (56 patients) vs. 2.74 ± 0.76 V (35 patients) at 1 month, 2.65 ± 0.81 V (32 patients) vs. 2.77 ± 0.54 V (21 patients) at 3 months, and 2.82 ± 0.92 V (12 patients) vs. 3.32 ± 0.99 V (8 patients) at 6 months. Data are shown in Figure 4. Statistical differences in APT data were not significant. A substantial stability in APT values was detected in both groups.

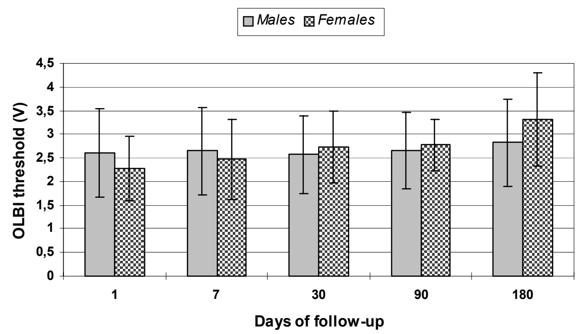

Figure 4. *Male vs. female: mean value of OLBI-APT at 0.5 ms measured in supine position at the follow-up.*

Substantial differences between the two groups were observed in PNS sensitivity. Male patients vs. female patients showed the following PNS values (for the supine positions and at pulse amplitudes lower than 4.8 V/0.5 ms) respectively: 5.6% vs. 38% at 1 day, 13.8% vs. 23.4% at discharge, 14.2% vs. 31.4% at 1 month, 6.2% vs. 23.8% at 3 months and 16.6% vs. 37.5% at 6 months (see Figure 5). In this study, females have an apparently more excitable phrenic nerve, perhaps due to anatomic or physiologic reasons.

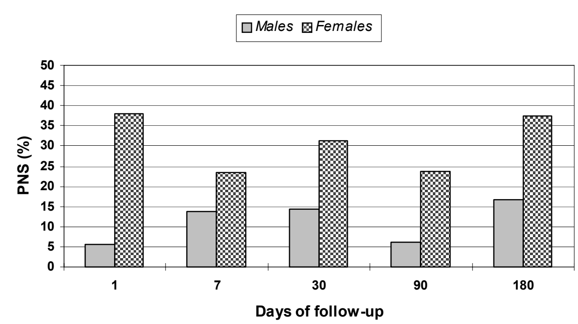

Figure 5. *Male vs. female: OLBI-PNS at 0.5 ms detected for the supine position at the follow-up.*

The minimum values of atrial sensing shown by the two groups were male vs. female respectively: 0.72 ± 0.77 mV vs. 0.80 ± 0.64 mV at 1 day, 0.73 ± 0.90 mV vs. 0.67 ± 0.53 mV at discharge, 0.71 ± 1.0 mV vs. 0.84 ± 0.81 mV at 1 month, 1.02 ± 1.26 mV vs. 0.85 ± 0.86 mV at 3 months and 0.79 ± 1.03 mV vs. 1.12 ± 0.90 mV at 6 months. Data are shown in Figure 6. Also in this case, values were stable and no statistically significant difference between the two groups was observed.

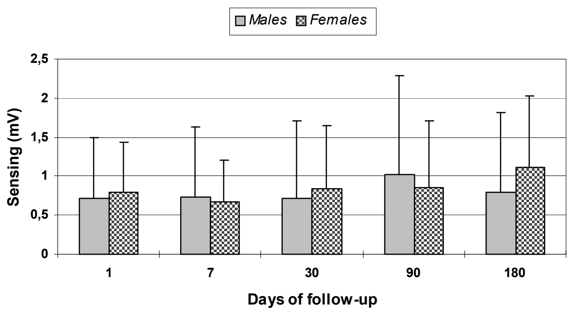

Figure 6. *Male vs. female: mean value of minimum atrial sensing measured for the supine position at the follow-up.*

The position of the PM case implanted in either the left or right side of the chest, will drastically change the anatomical area influenced by the field vector on a deductive basis. When the PM is implanted in the right pectoral area, the field strength will affect more the tissues of the right, free wall of the atrium. Whereas when the PM is implanted in the left pectoral area, the vector interacts more with tissues of the septal wall between the atria. Theoretically, the values measured under the 2 conditions described above must be different.

In the patient population under study, 62 PMs were implanted in the left and 63 in the right pectoral position. The measured mean APTs (at 0.5 ms pulse duration), left vs. right implant, were respectively: 2.66 ± 0.85 V vs. 2.31 ± 0.83 V at 1 day, 2.68 ± 0.70 V vs. 2.40 ± 0.84 V at discharge, 2.73 ± 0.86 V vs. 2.58 ± 0.80 V at 1 month, 2.95 ± 0.70 V vs. 2.48 ± 0.65 V at 3 months and 3.28 ± 1.04 V vs. 2.62 ± 1.16 V at 6 months. The differences were statistically significant at 1 day ($p<0.02$) and at 3 months ($p<0.02$). These data are depicted in Figure 7. The constant discrepancy between APT values of the 2 groups showed that the atrial thresholds of right implants were lower than those achieved by the left.

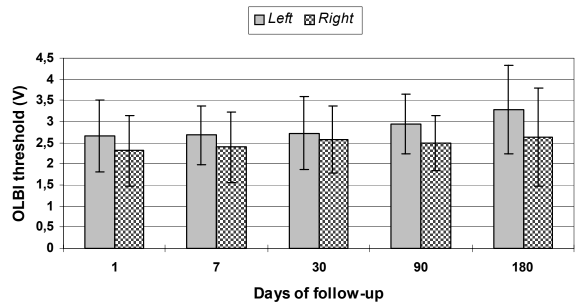

Figure 7. *Left vs. right implants: mean value of OLBI-APT at 0.5 ms measured for the supine position at the follow-up*

The same behavior, except at 1 day, was shown by PNS. Left vs. right implants showed a PNS sensitivity (for the supine position and pulse amplitudes lower than 4.8 V) respectively, of: 16.1% vs. 20.6% at 1 day, 18.3% vs. 16.9% at discharge, 26.0% vs. 15.5% at 1 month, 18.5% vs. 7.7% at 3 months and 36.3% vs. 11.1% at 6 months (see Figure 8). These data indicate that the dipole of the leads implanted through the right access take a position inside the atrial chamber farther from the phrenic nerve, than that taken by a dipole of a lead inserted through the left access.

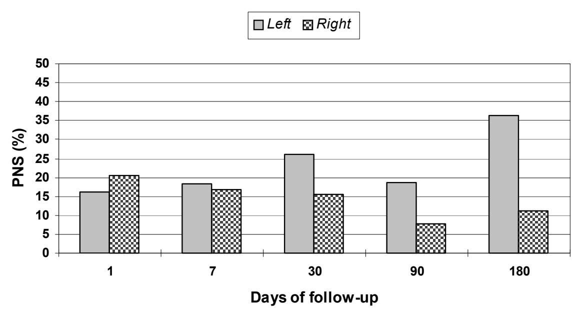

Figure 8. *Left vs. right implants: OLBI-PNS at 0.5 ms detected in supine position at the follow-up.*

Atrial sensing was constant in both groups and did not show any statistically significant difference between the two access conditions.

One last consideration was necessary to test with dipole positioning. The position of the floating dipole inside the atrial chamber, assessed at 1 day and 3 months by X-ray fluoroscopy, was as follows: very high (at the exit of vena cava) in 4.0%, mid-high in 42.5%, mid in 39.2%, and mid-low in 14.3% of the cases. The position was stable without significant changes for deep breathing maneuvers and during the entire follow-up.

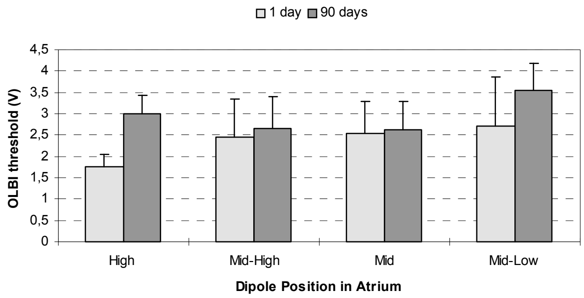

Figure 9. *OLBI atrial pacing trend at 1 day and 3 months with different dipole positions in the atrial chamber.*

Figure 9 shows the mean values of ATP collected at various dipole positions at the 1-day and 3-month follow-up. Differences between groups of values are not significant. In the acute phase, the lower threshold exists at the "high" section of the atrium. However, for chronic evolution, "mid-high" and "mid" atrium seem to have lower and more stable thresholds.

Figure 10 compares the PNS values detected at the different dipole positions. Data at 3 months for the high- and mid-lower atrium are not sufficient to give a complete picture of the PNS trend in these locations.

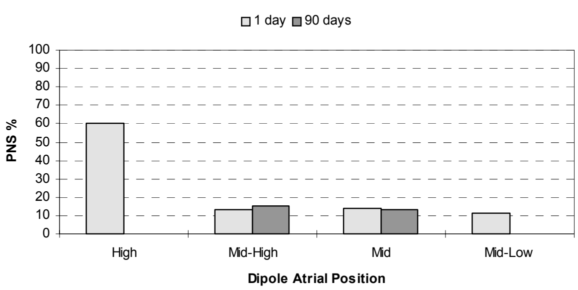

Figure 10. *PNS trend at 1 day and 3 months with different dipole positions in the atrial chamber.*

Figure 11 depicts the mean minimum value of P-wave sensing in the same positions. At 1 day, the high atrium shows the highest amplitude. However at 3 months, the best values are detected in the mid-high and mid atrium. This is in spite of the fact that these last two positions show the highest signal variability (larger standard deviations), because the dipoles in these positions are freer to migrate farther from the myocardium.

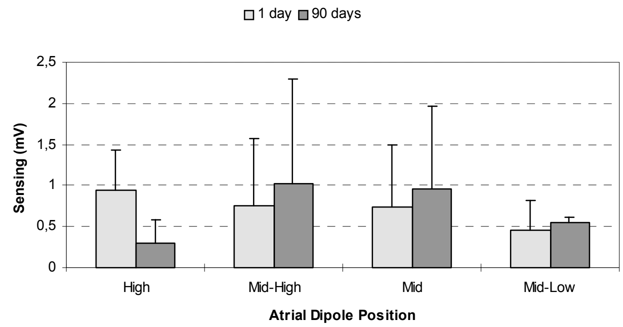

Figure 11. *Minimum P-wave amplitude trend at 1 day and 3 months with different dipole positions in the atrial chamber.*

Since OLBI pacing simultaneously emits 2 unipolar pulses, it is tempting to suppose that it is more energy consuming than other conventional pacing approaches. But, this is not a valid assumption.

In some patients, intraoperative measurements regarding the charge delivered to the ring electrodes at several pulse configurations for floating electrode pacing were performed. For these, a charge measurement setup and an ERA 20B (Biotronik, Inc.) external pulse generator were used. Using this direct information, a comparative analysis regarding battery longevity with unipolar, bipolar, and OLBI stimulation was performed, showing that OLBI (69%) and bipolar (86%) configurations are more efficient than unipolar pacing (100%) at 4.8 V pulse amplitude and 0.5 ms pulse width. Given the low thresholds obtained with OLBI stimulation, the longevity is expected to be higher than with other conventional waveforms.

Discussion

The data collected in this extensive study have provided encouraging results. OLBI pacing allows reliable DDD pacing at acceptable pacing pulse amplitudes, without PNS, during daily activity and exercise in more than 85% of the patients. Losses of atrial capture occur more frequently when the patient is supine in lateral decubitus and during the night.

The phrenic nerve seems to be less excitable in male than in female patients, for reasons that are still unknown. Leads implanted by a right access immediately show lower APT than those implanted by left access.

There is no correlation between the minimum amplitude of the sensed P-wave and OLBI threshold. For long-term stability of both pacing and sensing values, the mid-high and mid atrium seem to be the most favorable sections for dipole positioning.

In this short-term study, the single lead OLBI system demonstrates its reliability, giving a sufficiently reliable, back-up atrial pacing in patients with complete or advanced A-V block and sporadic chronotropic incompetence.

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