

Back-up Atrial Stimulation in Single Lead VDD Pacing: Experience with 152 Patients Implanted at a Single Center

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Summary

The aim of the clinical study was to evaluate the feasibility of performing back-up atrial pacing using floating electrodes on a single AV lead and the OLBI pacing approach. In 152 patients, all with symptomatic AV block and normal sinus function, a single AV lead VDD/DDD pacing system was implanted. During follow-up examinations performed at the time of discharge and after 1, 3, 6 and 12 months, the atrial pacing threshold, atrial sensing, and incidence of parasitic phrenic nerve stimulation were assessed. The mean follow-up period was 18 ± 5 months. Stable atrial capture ($> 98\%$) was achieved in 84.2% and in 80.9% of patients at discharge and after 1 year, respectively. Mean values of the atrial pacing threshold were: 2.18 V at discharge, and 2.60 V after 1 year. The minimum atrial sensing mean values at discharge and after 1 year ranged from 0.75 mV to 0.82 mV, respectively, without significant fluctuations. Phrenic nerve stimulation (@ pulse amplitude < 4.8 V) occurred in 11.8% of patients at discharge and in 11.2% after 1 year. No patients showed a phrenic nerve stimulation threshold lower than the atrial pacing threshold. Atrial capture was slightly influenced by postural changes (lateral decubitus only) while the phrenic nerve stimulation was not affected. OLBI back-up atrial pacing with floating atrial electrodes is feasible in more than 80% of patients at an acceptable threshold and without side effects. This approach may be helpful in patients implanted with a single lead VDD pacing system who may develop mild or sporadic chronotropic incompetence.

Key Words

OLBI pacing, atrial pacing threshold, phrenic nerve stimulation

Introduction

In conventional DDD pacing, two separate leads are required to sense and pace the atrium and the ventricle. The use of a single AV lead simplifies the implant procedure and could reduce the risk of thrombus formation and other complications. Prior attempts at achieving reliable single lead dual-chamber stimulation, using unipolar pulses, presented high capture thresholds combined with side effects in a large number of patients. OLBI (OverLapping Biphasic Impulse) stimulation was developed for safer and more effective atrial pacing using floating ring electrodes. In OLBI stimulation, two single pulses with the same width and amplitude but opposite polarity are emitted simultaneously by the distal and proximal atrial ring electrodes with respect

to the pacemaker case. The system generates an intense electrical field only in the neighboring area of the floating dipole that depolarizes a large number of myocardial cells. The major side effect of atrial pacing with floating electrodes is the parasitic stimulation of the phrenic nerve (PNS). This occurs when the field outside the atrial wall, where the phrenic nerve is located, is still high enough to induce its stimulation. The OLBI approach generates an intense field strength in the proximity of the dipole and inside the atrial myocardium. Outside the heart, the field strength decreases significantly because of the interaction of field lines with opposite electrical signs, which limit the spread of the field and, consequently, of the PNS.

The aim of this extensive study was to evaluate the reliability of OLBI atrial pacing in a large patient population.

Materials and Methods

A single AV lead VDD/DDD pacing system (EIKOS SLD, Biotronik, Germany) was implanted in 152 patients (91 male, 61 female, mean age 72.6 ± 9.2 years), all with symptomatic AV block and without evidence of sinus node dysfunction. All pacemakers were connected to an SL 60 single AV lead (Biotronik) with an AV distance of 13 cm and 15 cm, respectively, in 94.7 % and 5.3 % of the patients.

Implants were performed in accordance with the standard procedure for a single lead VDD system. The atrial lead position was selected only in terms of sensing characteristics (minimum P-wave amplitude and stability) without performing atrial pacing during implantation procedure. The atrial pacing threshold (APT) and the incidence of PNS were assessed on the first day, at discharge, and after 1, 3, 6 and 12 months (m) following implantation. APT data regarding the patient's sex, the PM implant site, and the atrial position of the dipole were considered. Data were collected in various body positions and a 24-hour ECG recording (Holter) was performed at the 3-month follow-up for a large number of patients.

The mean follow-up period was 18 ± 5 months.

Results and Comments

Atrial sensing remained stable during the entire follow-up period. The mean value of the minimum amplitude of the P-wave ranged from 0.88 ± 0.82 mV at dis-

charge to 0.82 ± 0.70 mV after one year. Figure 1 shows the trend for the minimum amplitude of the P-wave during follow-up.

The mean value of APT measured during follow-up was 2.18 ± 0.91 V at discharge, 2.32 ± 0.84 V at 1 month, 2.51 ± 0.90 V at 3 months, 2.62 ± 0.80 V at 6 months, and 2.60 ± 0.77 V at 12 months.

Figure 2 shows the APT trend for all patients during the entire follow-up. Figures 3, 4, and 5 discriminate APT trends by implant site, dipole position, and the patients' gender, respectively.

The data summarized in Figures 1 to 5 allows for some preliminary comments:

- The high values of standard deviation in mean values of atrial sensing and APT, still persistent at the 1-year follow-up, demonstrate the significant absence of the lead encapsulation process; in addition, the floating status of the atrial portion of the lead is still evident a year after implantation.
- Left-side implants show a lower APT than those on the right side, but the difference between groups is not statistically significant. This may suggest that the left surgical approach positions the atrial dipole closer to the myocardium than the right one.
- Dipoles positioned in the upper portion of atrium show the best APT either at discharge or at the 3-month follow-up. The APT progressively degrades when the dipole is moved in the direction of the atrial base, and the difference is statistically significant ($p < 0.05$).
- Myocardial excitability does not differ between the sexes, even though the females show mean APT values slightly lower than males. (There was no significant statistical difference between the groups).

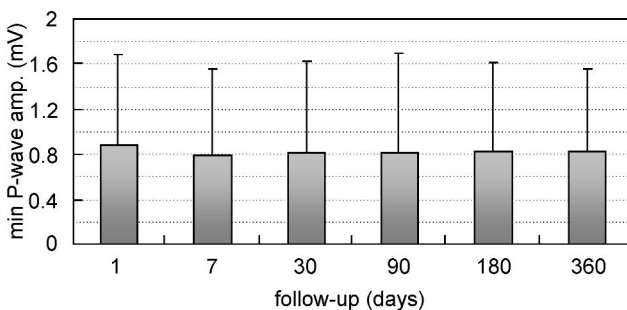


Figure 1. Trend for the minimum amplitude of the P-wave during follow-up.

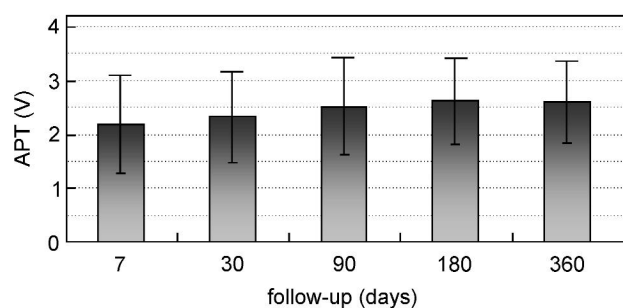


Figure 2. APT trend.

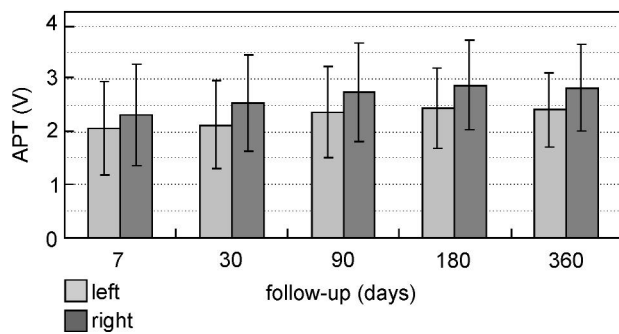


Figure 3. APT trend discriminated by implant site.

The data reported in Table 1 depict the percentage of patients that showed an atrial capture stability that was higher than the 95 % in different body positions during follow-up.

In 92 patients (not in all cases a holter could be performed), a 24-hour Holter monitoring during normal daily life was performed at the 3-month follow-up. (In the DDD mode, the lower rate was 15 to 20 % higher than the patient's intrinsic rate at rest, and the amplitude of OLBI pulses was 1.5 times the APT in supine). The system showed good performance with stable atrial capture at rest and during moderate exercise in 87/92 (94.5 %) of patients. Regular inhibition by spontaneous atrial activity was observed when chronotropic competence exceeded the PM basic rate. In 1 patient, losses of capture were associated with the standing or sitting, while the capture rate was good during the night. In the remaining 4 patients, the capture was very good during the day and when exercising, but it was unsatisfactory during the night probably because the patient remained in a lateral decubitus position for a

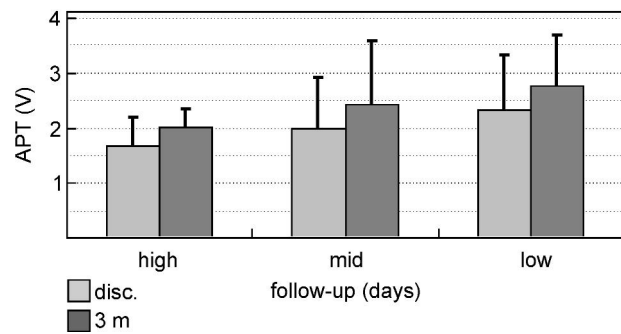


Figure 4. APT trend discriminated by dipole position.

long period of time. However, none of the 5 patients reported symptoms of PNS or of changes in pacing modality during the entire Holter recording.

The occurrence of PNS was tested at all follow-up examinations up to the maximum OLBI pulse amplitude (4.8 + 4.8 V). The percentage of patients that exhibited this effect in the supine position, with OLBI pulse amplitudes < 4.8 V/0.5 ms, are shown in Figure 6.

PNS never occurred at OLBI pulse amplitudes lower than or equal to the APT.

Thoracic muscle contraction was never reported during the entire follow-up. Therefore, this additional side effect is completely avoided during OLBI stimulation. Some additional comments on atrial capture can be made concerning the data reported in Table 1, Holter monitoring, and Figure 6:

- The floating status of the atrial dipole, which persists one year after implantation, is primarily responsible for the intermittent lack of atrial capture.
- Stable atrial capture is not achievable in all patients, even when using OLBI stimulation, with floating

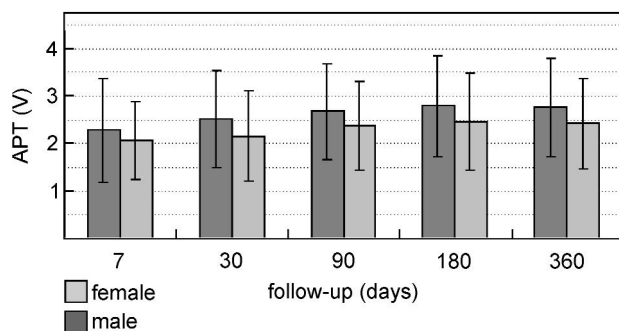


Figure 5. APT trend discriminated by the patients' gender.

Body position	Disc.	6 m	12 m
Supine	84.2	81.6	80.9
Left decubitus	75.6	76.9	76.3
Right decubitus	76.3	75.36	76.3
Sitting	82.9	80.9	80.9
Standing	82.9	80.9	80.9

Table 1. Percentage of patients with atrial capture 95 % [3].

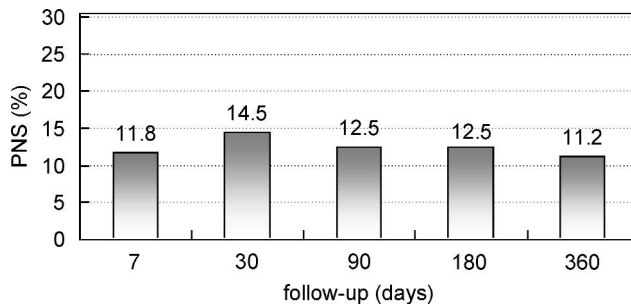


Figure 6. Percentage of patients that exhibited PNS in the supine position.

electrodes.

- PNS occurred more frequently in the female than in the male patients (12 f vs. 5 m). These results, which are limited by the number of cases observed, seem to agree with the data found by others [11] that correlates the occurrence of PNS with the Body Mass Index of the patient.
- This experience demonstrates that the pacemaker implantation site and the atrial dipole position apparently don't play a role in the occurrence of PNS.

Conclusion

The results achieved in this extensive and homogeneous clinical study show that OLBI pacing allows reliable atrial pacing, without side effects, at acceptable pulse amplitudes in more than 80 % of patients during their daily activities and exercise. Loss of atrial capture occurs more frequently during the night when patients are supine and in the lateral decubitus position. Leads implanted with a left access show lower APTs than those implanted with a right access. The upper portion of the atrium is the best position to place the floating dipole in terms of both low APT and long-term stability.

PNS occurred in 17/152 patients and seems to be mainly correlated to the Body Mass Index of the individual

patient.

This experience shows that OLBI pacing capability integrated into a single AV lead VDD system may provide sufficiently reliable atrial back-up pacing in patients who exhibit complete or advanced AV block and who will develop a mild or sporadic chronotropic incompetence after implantation.

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