

Single Lead DDD Pacing Using OLBI Atrial Stimulation - Conclusive Results of the Italian Extensive Clinical Trial

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Summary

An extensive clinical trial was performed in 40 Italian implant centers between July 1996 and November 1998 in order to evaluate the feasibility to pace right atrium with the novel OLBI stimulation approach using floating electrodes. In OLBI pacing two simultaneous unipolar pulses, with opposite polarity, are generated in reference to pulse generator (PG) case. A single lead VDD/DDD pacing system (Biotronik mod. DROMOS SL M7 nad mod. EIKOS SLD) allowing OLBI atrial stimulation was implanted in 250 patients (pts), 150 males and 100 females, with mean age of 75.14 ± 9.13 years, all with symptomatic AV block and without sinus node dysfunction. According to study protocol atrial OLBI pacing threshold (APT), atrial sensing (AS) and occurrence of side effects were assessed at discharge and 1, 3, 6 and 12 months (m). 24 h Holter monitoring and atrial capture stability was also assessed during follow-up. Stable atrial capture was achieved in 80.4% of the pts at discharge with negligible fluctuations during follow-up (80.9% at 1 year). Mean minimum AS values ranged from $0.75 \text{ mV} \pm 0.77 \text{ mV}$ at discharge to $0.78 \text{ mV} \pm 0.74 \text{ mV}$ at 1 year without significative fluctuation. Mean APT values ranged from $2.60 \text{ V} \pm 1.01 \text{ V}$ at discharge to $2.80 \text{ V} \pm 1.15 \text{ V}$ at 1 year. Differences between values were not statistically significative. The sole side effect monitored during follow-up was the phrenic nerve stimulation (PNS), which occurrence (@ pulse amplitude < 4.8 V) slightly decreased from 15.2% at discharge to 14.4% at 1 year. No pts showed PNS threshold lower than APT. In 135 pts a 24 h Holter monitoring, performed during daily life, showed in 118/135 pts a stable atrial capture without symptomatic PNS. Discrimination of data depicts that AS and APT are slightly affected by dipole position, implant site and pt sex, while PNS strongly depends from body mass index (BMI) of the pt (no PNS for $\text{BMI} > 25$). OLBI atrial stimulation through floating dipole electrodes is feasible in about 81% of pts at reasonable APT and without side effects. This clinical trial demonstrates that OLBI approach may give a reliable back-up atrial pacing in pts with complete or advanced AV block and exposed to sporadic chronotropic incompetence.

Key Words

OLBI stimulation, single lead DDD pacing, phrenic nerve stimulation

Introduction

Conventional DDD pacing needs two separate leads to sense and pace both atrium and ventricle. A single AV lead, besides simplifying the procedure, could reduce risks of thrombus formation and other complications, as well as overstressing the circulatory system. Prior attempts toward a reliable single lead dual chamber stimulation, using unipolar pulses, presented high capture thresholds combined with unpleasant side effects in most of the patients [1,2].

The OLBI (OverLapping Biphasic Impulse) stimula-

tion, was developed for a safe and more effective atrial stimulation using floating ring electrodes inside the atrial blood pool. This new pacing approach has been evaluated in several experimental and acute clinical studies [3,4], and in some clinical trials as well [5]. 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. This system, which acts in a tripolar configuration, depolar-

Discriminated group	N. pts	Dis.	Day 30	Day 90	Day 180	Day 360
Whole	250	2.60 (1.01)	2.89 (.94)	2.79 (1.04)	2.87 (1.01)	2.80 (1.15)
Males (1)	155	2.66 (1.02)	2.73 (1.01)	2.90 (1.06)	3.03 (1.03)	2.80 (1.12)
Females (1)	100	2.49 (.095)	2.79 (.94)	2.64 (1.01)	2.62 (.96)	2.78 (1.21)
Left implants (2)	132	2.39 (.98)*	2.63 (1.03)**	2.54 (.92)*	2.76 (.99)#	2.58 (1.11)#
Right implants (2)	118	2.89 (.98)*	2.89 (.94)**	3.02 (1.11)*	2.93 (1.03)#	2.97 (.84)#
Dipole position SVC (1)	8	n.a.	n.a.	3.00 (.34)	n.a.	2.00 (.70)
Dipole position HA (1)	95	n.a.	n.a.	2.94 (1.17)	n.a.	2.87 (1.28)
Dipole position MA (1)	112	n.a.	n.a.	2.64 (.95)	n.a.	2.86 (.91)
Dipole position LA (1)	35	n.a.	n.a.	2.88 (1.07)	n.a.	2.92 (1.32)

Table 1. Atrial Pacing Thresholds (OLBI pacing @ 0.5 ms PW) (+ SD).

Notes: SVC exit of superior vena cava, HA high atrium, MA mid atrium, LA lower atrium (floor), n.a. not available.

(1) Statistical difference between groups: not significative; (2) Statistical difference between left and right implants: *highly significative ($<.001$), **significative ($p < 0.05$) and not significative.

izes 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) [6]. This occurs when the field outside the atrial wall, where the phrenic nerve is located, still has strength enough to induce its stimulation. The field strength generated by OLBI pulse configuration is intense in the proximity of the dipole and inside the atrial myocardium, while, outside the heart, it decreases significantly because of the interaction of field lines having opposite electrical signs. That limits the spread of the field and, consequently, the occurrence of PNS.

Methods

Aim of this extensive study was to evaluate the long term reliability of OLBI atrial pacing in a large patient population [7-9].

The study was performed in 40 Italian implant centers. In 250 patients (pts), 150 male and 100 female, with a mean age of 75.14 ± 9.13 years (range: 40 - 103), all with symptomatic AV block and without evidence of

sinus node dysfunction, 95 Biotronik mod. DROMOS SL M7 and 155 Biotronik mod. EIKOS SLD pulse generators (PGs) were implanted. These were connected to a Biotronik mod. SL 60 single A-V leads with an A-V distance of 13 and 15 cm, in 86.4% and 13.6% of the pts respectively.

Implants were performed in accordance with the standard implant procedure for single lead VDD systems. The atrial lead position was selected only in terms of sensing characteristics (minimum P-wave amplitude and stability), without performing any atrial pacing during implantation. Atrial pacing threshold (APT) and occurrence of PNS were assessed at: discharge, 1, 3, 6 and 12 months (m) after implantation. Follow-up data regarding pt sex, the PG implant site and the atrial position of the dipole were also considered separately. Data were collected in various body positions and a 24 h ECG recording (Holter) was performed at the 3rd month follow-up in 135 pts. The mean values APT values (+ SD), measured in Volts, are shown in Table 1. Data summarized in Table 1 can be commented as follows:

Body position	Dis.	Day 30	Day 90	Day 180	Day 360
Supine	80.4	86.5	80.6	80.2	80.9
Left Decubitus	74.0	78.3	69.6	71.3	73.1
Right Decubitus	72.8	75.7	71.5	71.8	74.3
Sitting	78.4	82.9	80.6	80.4	80.6
Lying	80.0	82.9	79.9	80.8	80.6

Table 2. Constancy of Atrial Capture (> 95% capture).

- APT remains stable during implant maturation with a flat course.
- Myocardial excitability does not differ between sexes (no significant statistical difference between the groups).
- Left side implants show a constantly lower APT (the difference between groups is statistically significant during first three follow-ups) than the right ones. This may suggest that left surgical approach locates the atrial dipole closer to the atrial wall facing the mediastinum than the right one. This condition improves ATP but may also increase the probability of PNS (see next paragraph).
- All dipole position inside the atrium shows stable APT during time and no significant statistical difference between positions was found.
- High values of standard deviation persist during entire follow-up demonstrating that the lead encapsulation process is almost absent and, therefore, the atrial portion of the lead is still floating even at one year after implantation.

This last observation is also confirmed by data concerning the constancy of atrial capture (CAC) at different body positions. CAC is defined as atrial pacing giving 95-100% constant and consecutive capture during the entire period of observation. Data are reported in Table 2 and are expressed as percent of pts showing

CAC in the specified body positions during follow-up. Some additional comments on atrial capture can be made examining the data reported in Table 1 and 2:

- The free floating status of the atrial dipole, which persists one year after implant, is the first and major responsible of intermittent lack of atrial capture.
- CAC is not achievable in all pts, even using OLBI stimulation.

The minimum P wave amplitude, measured in the least favourable condition was 0.75 ± 0.77 mV at discharge vs 0.78 ± 0.74 mV at 12 months, the difference between data not being statistically significant, remained substantially stable all the time (Figure 1). No P-wave undersensing was detected in any patient during the entire follow-up.

In 135 pts a 24 h ECG Holter monitoring during normal daily life was performed at the 3 months follow-up (@ DDD mode, lower rate 15 to 20% higher than patient sinus rate at rest, amplitude of OLBI pulses 1.5 times the APT). The system showed good performance with CAC at rest and during moderate exercise in 118/135 pts (87.4%). Regular inhibition by spontaneous atrial activity was observed when chronotropic competence exceeded the PG basic rate. In 6/17 pts (4.5%) loss of capture was associated with the standing or seated positions (56-72% of atrial capture) while the capture rate was good during the night. In 11/135 (8.1%) the capture was very good during daytime and exercise, but poor (47-65%) during night, when the pt may stay in lateral decubitus for a long time period. However, all the 17 patients did not report any PNS symptoms or sensations of changes in the pacing modality during the entire Holter survey.

PNS is the major side effect encountered in single lead DDD pacing. Occurrence of PNS was monitored in supine position during each follow-up programming OLBI pulse amplitudes at its highest value (4.8 ± 4.8 V / 0.5 ms). Figure 2 and 3 depict PNS occurrence, expressed in percent of pts showing this effect, in sex groups and by implant site respectively.

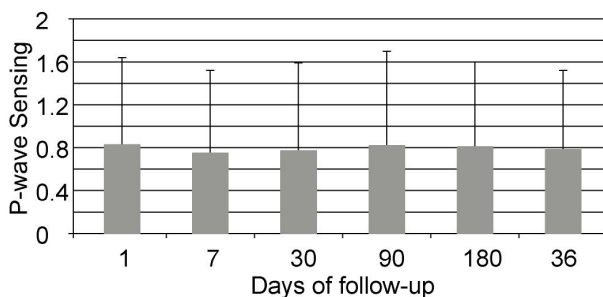


Figure 1. Mean minimum value of sensed P-wave during 1 year follow-up.

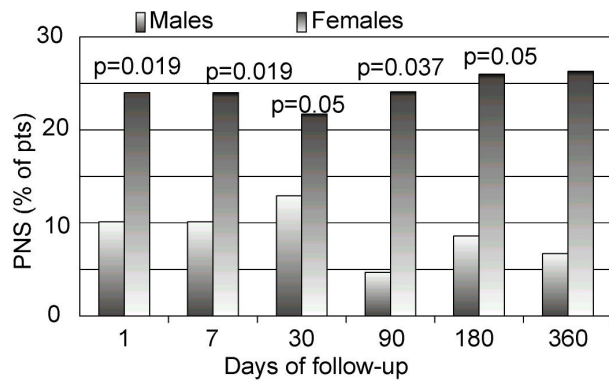


Figure 2. Occurrence of phrenic nerve stimulation in male and female pts during follow-up.

Since there are no anatomic or physiologic reasons to justify the excessive difference in PNS occurrence between male and female groups, data were correlated to the body mass index (BMI) of the pt, expressed as weight / height², which anatomically differs between sexes. The results of this analysis in patients with and without evident PNS evidenced two clear and separate gaussian distributions. All patients presenting PNS had a low BMI, which upper limit was 25 for males and 23 for females, while in those with a BMI over this limit, PNS never occurred.

Thoracic muscle contraction was never observed in any pt during the entire follow-up.

Conclusion

The encouraging results achieved in this extensive clinical trial show that OLBI atrial pacing allows reliable DDD pacing, at acceptable pulse amplitudes and without side effects, in about 81% of patients during their daily activities and exercise. Loss of atrial capture occurs more frequently during night, when pts are supine and in lateral decubitus.

Leads implanted by a left access show lower APTs than those implanted by a right access. There is no correlation between the minimal amplitude of the sensed P-wave and OLBI threshold values. For long term stability of both pacing and sensing parameters, the mid atrium seem to be the best dipole location. PNS is mainly correlated to the patient BMI, with a border limit of 25 for males and 23 for females, besides a slight dependence on the implant site and the dipole position.

Data collected in this trial demonstrate that single lead OLBI system may be considered as sufficiently reli-

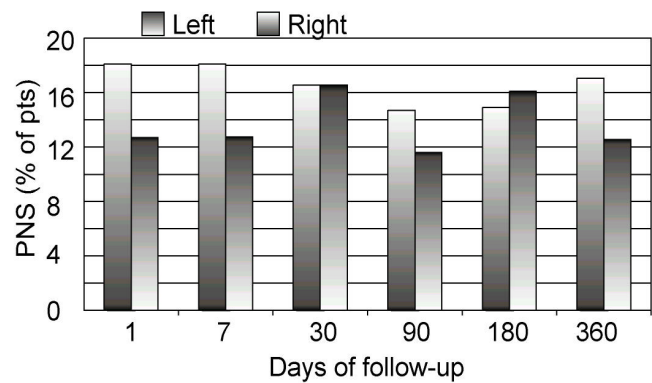


Figure 3. Occurrence of phrenic nerve stimulation in left vs. right implants during follow-up.

able alternative to conventional, dual lead, DDD systems for atrial back-up pacing in patients with complete or advanced A-V block and sporadic chronotropic incompetence.

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