Reliability of Single Lead Permanent DDD Pacing with Atrial OLBI Stimulation - One Year Follow-up

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Summary

OLBI stimulation is the most promising approach to perform atrial back-up pacing in primary single lead VDD therapy. Patients (pts) with symptomatic AV block and sporadic mild chronotropic incompetence may take benefit from this new pacing system that avoid some well known problems related to implantation of two leads. In 25 pts, all affected by symptomatic II. or III. degree AV block with or without a mild dysfunction of the sinus node. A pacing system allowing permanent atrial OLBI stimulation (Biotronik mod. EIKOS SLD) was implanted. Follow-up was performed at discharge, 1, 3, 6 and 12 months (m). Atrial pacing threshold (APT) was quite stable during follow-up ranging from 2.47 V at discharge to 2.31 V at 12 m. Phrenic nerve stimulation (PNS) was detected in 4/25 pts at pulse amplitudes > APT and < 4.8 V. The same 4 pts showed inconstant atrial capture (AC) (range 50-95% capture) starting from 1m follow-up. 24 h Holter monitoring performed after implant confirmed the trend of AC detected during ambulatory tests. After 3m from implant, the 21/25 pts, in which AC was always detected, were left with the pulse generator (pg) permanently programmed in DDD mode. The basic rate was programmed in the range of 50-60 bpm and OLBI pulse amplitude 1.5 times the APT. A 24 h ECG Holter monitoring was performed monthly in each of these pts in order to evaluate the stability of AC and occurrence of PNS during daily life. Holter records demonstrated full DDD performance in all 21 pts with only sporadic loss of AC limited to few (1 to 3) consecutive beats. This preliminary experience, limited by the number of pts, demonstrates that atrial OLBI stimulation is a reliable and side effect free method to perform back-up DDD pacing with a single AV lead in about 84% of pts with complete or advanced AV block and sporadic mild chronotropic incompetence. Additional improvements are necessary to achieve effectiveness of the system in the remaining 16% of pts.

Key Words

OLBI

Introduction

The OLBI (OverLapping Biphasic Impulse) stimulation, integrated into a single AV lead VDD pacing system, was developed to supply atrial back-up stimulation in patients (pts) with advanced AV block which after implant may develop a moderate or intermittent chronotropic incompetence.

The OLBI stimulation technique is based on the simultaneous emission of two single, unipolar pulses, with the same width and amplitude, but opposite polarity, by the distal and proximal atrial ring electrodes in respect to the pacemaker case [1]. The positive pulse is issued by the distal electrode and the negative pulse by the proximal electrode. In this way, a strong field is induced in the atrial myocardium in the vicinity of the dipole, sufficient to depolarize it with 2-3 V pulses per phase at about 0.5 ms pulse duration. In the outer atrial wall the interaction of opposing isopotential lines minimize the field strength and reduce the likelihood

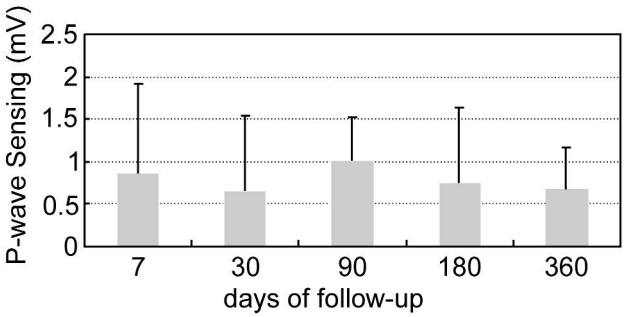

Figure 1. Trend of atrial sensing during follow-up.

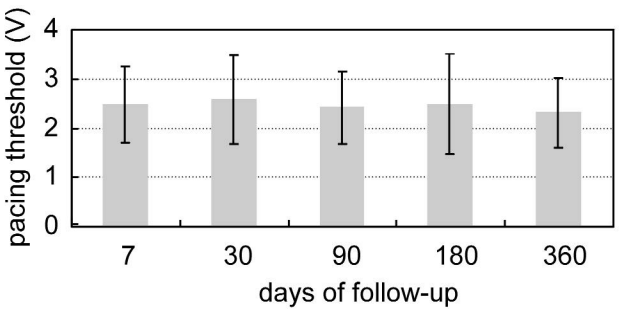

Figure 2. Trend of OLBI atrial pacing threshold during follow-up.

of phrenic nerve stimulation. In effect, high current density is achieved in the atrial myocardium in the plane of the dipole and the pacemaker.

The OLBI approach, using conventional floating atrial ring electrodes, has been evaluated in several experimental and clinical studies [2-6], and it was reported to produce steady atrial capture in more than 80% of the patients with only few side effects [7,8].

Aim of this study was to evaluate, if OLBI atrial stimulation may give, when permanently programmed, a reliable "on-demand" DDD pacing during patient's (pt) daily life.

Methods

In 25 pts, 17 male and 8 female, with a mean age of 69.9 ± 9.6 years (range: 46 - 85), all with complete or intermittent A-V block and without sinus node dysfunction or moderate sinus bradycardia, the pulse generator (PG) mod. EIKOS SLD (Biotronik, Germany) equipped with the capability to perform permanent OLBI atrial pacing was implanted. The PG was connected to a straight single A-V lead (mod. SL 60 (Biotronik) with 1.0 cm atrial dipole electrode spacing, passive fixation and an Iridium fractal coating on the surface of all electrodes. An A-V distance of 13 cm was used in the 21 pts (84%) of the pts and a 15 cm distance in the remaining 4 pts (16%).

The position of the atrial dipole electrode was selected in terms of the best detectable P-wave, in terms of amplitude and stability. During the first three months after implant atrial pacing was only performed during follow-up (at discharge, 1 and 3 months) and during the 24 h ECG Holter monitoring. The 21/24 pts, in which a constant atrial capture (AC) and no phrenic nerve stimulation (PNS) was detected during all follow-ups, the PG was permanently programmed in DDD mode with OLBI atrial pacing. A 24 h ECG Holter monitoring was performed monthly in each of these pts in order to evaluate the stability of AC and the occurrence of PNS during daily life. Atrial pacing threshold (APT) and PNS occurrence were assessed at discharge and at 1, 3, 6 and 12 months (m) follow-up in all pts.

Results

Implants were performed by right access in 22 pts and by left access in 2 pts. At discharge, the position of the electrode dipole inside the atrium, assessed by X-ray fluoroscopy, was: high in 5 pts (20%), mid in 10 pts (40%) and low in 10 pts (40%). After one year the position of the atrial dipole, was: high in 7 pts (28%), mid in 12 pts (48%) and low in 6 pts (24%).

Figure 1 shows the trend of minimum atrial sensing during follow-up. The values were quite stable and no loss of sensing occurred in any pt during the whole period. No significant statistical difference between values was found. The large standard deviation (SD) evidenced at each follow-up demonstrates that the atrial portion of the lead is still floating after one year from implant.

The mean value of OLBI APT (± SD) at 0.5ms pulse duration and measured in supine position were: 2.47 ± 0.89 V at discharge and 2.31 ± 0.63 V at 12 months. Figure 2 depicts the trend of APT during follow-up. The stability over time of APT demonstrates that the atrial dipole constantly floats close to active myocardium and that there is no tissue reactions around the electrodes.

The PNS occurred in 1 male and 3 female pts at OLBI pulse amplitudes lower than 4.8 V and it was constant-

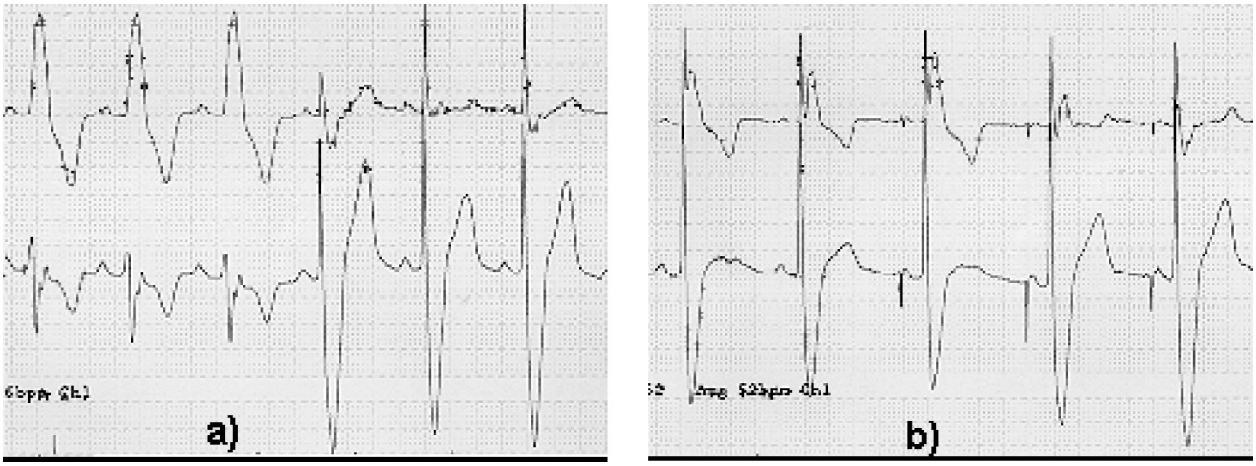

Figure 3. ECG Holter recording in a pt with intermittent AV block and mild sinus bradycardia. a) rate conversion from spontaneous A-V conduction to VDD pacing; b) pacing mode switching from VDD to DDD.

ly detected during the entire follow-up. In all four pts, the calculated body mass index was lower than 25, which is the limits reported literature [5] of occurrence of PNS in pts paced with single lead OLBI approach. In all four pts, PNS threshold voltage was higher than APT.

Later than one month post implant, the same 4 pts showed an inconstant AC (range 50-95%) condition that did not recover during chronic evolution. A 24 h ECG Holter monitoring performed two months after implant confirmed the trend of AC detected during the ambulatory test.

In the remaining 21 pts, the stability of AC was found higher than 95% in all postural positions: supine, lateral decubitus, sitting and standing.

After the third month from implant, the PG was permanently programmed to DDD mode in these 21 pts. The basic rate was programmed in each pt at a value about 10% higher than the intrinsic sinus rate at rest (range 50-60 bpm) and OLBI pulse amplitude was settled at 1.5 times the APT.

A 24 h ECG Holter monitoring was performed monthly in order to evaluate the AC stability and PNS occurrence during pt's daily life. All Holter records demonstrated a full DDD performance at rest condition with only sporadic losses of AC limited to few (1 to 3) con-

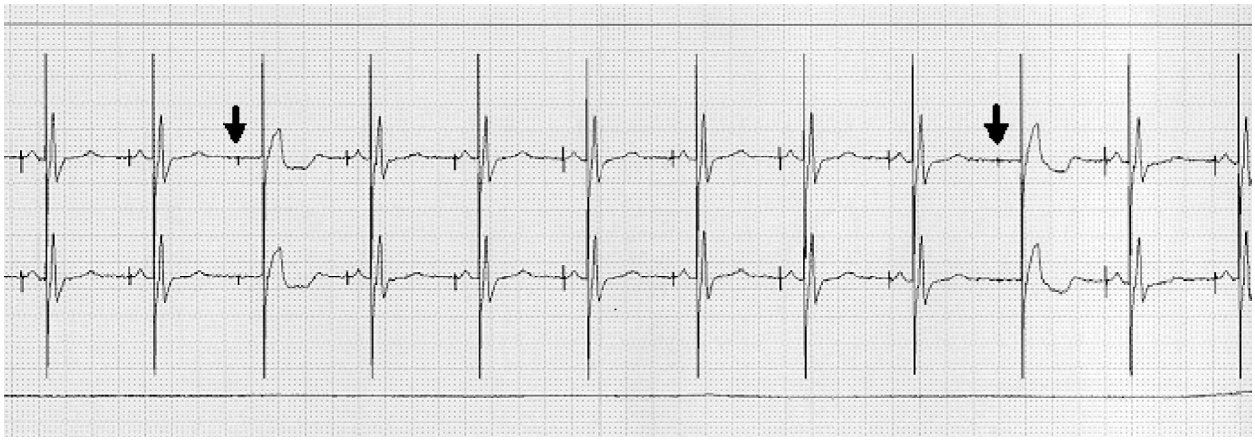

Figure 4. Intracardial EGM recorded by PG telemetry showing sporadic loss of atrial capture (arrows) during ambulatory follow-up of a pt in supine position (lateral decubitus).

secutive beats. Regular inhibition by spontaneous atrial activity was observed, when the pt's intrinsic rate exceeded the PG's basic rate. Moreover, no PNS was reported by pts during the whole follow-up.

Figure 3 shows two rate sequences of an ECG Holter recording in a 72 year old pt with intermittent AV block and mild sinus bradycardia. In 3a) the spontaneous A-V conduction is followed by VDD pacing when AV block occurs; in 3b) the pacing mode switches from VDD to DDD when sinus rate drops below the PG's basic rate.

Relevance of data collected in this preliminary evaluation is limited by the small population of collected pts. Anyhow, OLBI stimulation demonstrates to be an effective and reliable method to perform atrial stimulation through floating electrodes. All pts permanently programmed to DDD pacing, using this atrial stimulation approach, do not report of any side effects or symptoms through lack of A-V synchronization during their daily life. Loss of atrial capture occurred during night for a few consecutive beats only, when pt's posture most likely is supine in lateral decubitus.

On the base of this experience, the 84% of pts suffering of symptomatic AV block with intermittent failure of chronotropic competence may take benefit by single lead VDD pacing with atrial back-up stimulation supplied by OLBI stimulation.

The 16% of pts still suffering from intermittent atrial non-capture and PNS demonstrates, that this new pacing approach needs to be improved either with a more careful patient selection and implant procedure or by a change in the single lead design by limiting the free floating range of the atrial electrode dipole.

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