Permanent DDD Pacing with a Pre-Shaped Single AV Lead

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Summary

The pre-shaped single AV lead ATS, connected to a pulse generator EIKOS SLD allowing permanent OLBI atrial pacing, was submitted for clinical testing. The system was implanted in 18 patients, all with 2nd or 3rd degree AV-block and normal sinus function. At implant, all pacing configurations were tested (unipolar, bipolar and OLBI) and atrial pacing thresholds were measured. OLBI atrial pacing was performed during follow-up at 1 week and at 1, 3, and 6 months. At 3 and 6 months, an exercise test and 24h Holter monitor were performed to verify the stability of atrial capture and mode switch. Phrenic nerve stimulation occurrence was also tested, up to the maximum pacemaker output. Atrial values at implant were: minimum P-wave amplitude 3.0 ± 1.1 mV, atrial pacing thresholds unipolar 2.8 ± 2.3 V; atrial pacing thresholds bipolar 2.5 ± 1.2 V, atrial pacing thresholds OLBI 1.3 ± 0.8 V. At discharge, atrial capture was no longer achievable in 2 patients for dipole displacement. In a third patient, dipole displacement occurred before the 3-month follow-up. At the 6-month follow-up, in the remaining 15/18 patients, the mean atrial values were: minimum P-wave amplitude 1.9 ± 0.7 mV and atrial pacing thresholds OLBI 2.2 ± 1.1V. Atrial pacing thresholds were not influenced by patient postural changes. Phrenic nerve stimulation was never observed in any patient. In all 15 patients, VDD <> DDD mode switch and atrial capture stability were correct. This first clinical experience with DDD pacing using a pre-formed single AV lead showed promising results. Some initial failures were due to the learning phase for the new lead positioning technique. The stability of the atrial lobe during implant maturation should be improved with changes in lead design.

Key Words

Pre-shaped AV leads, OLBI pacing, atrial pacing threshold, phrenic nerve stimulation

Introduction

The first reports concerning AV pacing with a single lead appeared in the 1970s, regarding transvenous atrioventricular pacing with an investigational temporary multipolar lead inserted in the right side of the heart and made to contact the inner atrial wall [1-3]. These approaches were unsuccessful, since atrial pacing could only be performed at high thresholds and caused continual, painful phrenic nerve stimulation (PNS). From the late 1970s through the early 1980s, many interesting ideas were presented in experimental and/or clinical studies, but none developed into standard products for extended clinical use, and all of those depended on contact between the atrial electrode and the atrial wall [4-10]. Thus, new techniques were needed to achieve a reliable AV single lead.

The concept of a single AV lead was based on practical, surgical, and physiologic considerations, supported by the concept that contact between the lead and the atrial wall is unnecessary in patients requiring P-synchronous ventricular pacing only. In the middle of the 1970s, it was observed that electrodes floating in the atrium consistently detected an electrogram suitable for atrial sensing, leading to the idea that P-synchronized ventricular pacing might be feasible with a single bipolar lead with a proximal unipolar electrode floating in the mid- to high right atrium. Today, the single AV lead VDD system is in clinical use and is

included in the ACC/AHA guidelines for pacemaker implantation [11].

The need to expand the use of such a lead for atrial pacing is self-evident, as it would enable the DDD pacing mode to be applied more easily than with the current general practice of using two leads. However, several attempts in that direction have run into problems in pacing the atrium because of side effects such as stimulation of the phrenic nerve and thoracic muscles, despite only intermittent capture of the atrial myocardium [12,13]. Many ideas have been proposed to find a solution to this problem, and some have been tested. DDD pacing with a single AV lead is an attractive option, yet satisfactory solutions have been either elusive or achieve merely promising results that allow one to foresee a potential means of solving the problem. We are looking at some interesting possibilities in the hope of finding what we have long been searching for. This paper reports basic concepts of single lead DDD pacing and the preliminary results obtained in attempting a new technical solution in achieving it.

Basic Concepts

1) A depolarization wave front may be initiated in a neuromuscular fiber by one of the two following approaches:

- by conventional (direct) pacing, using contact electrodes, which directly inject into the excitable myocardium an amount of current that generates the depolarization,
- by indirect pacing, whereby a strong electric field is created between two separate electrodes, neither one in contact with excitable tissue.

2) As the phrenic nerve passes through the mediastinum, in the proximity of the outside of the right atrial wall, it is seldom affected by the direct approach; however, it can be stimulated easily by the indirect one.

The target, DDD pacing with a single AV lead, needs to be reviewed on the basis of the principles involved, with particular attention to:

- the optimal field pattern and pacing pulse morphology according to the floating status of the electrodes in the atrium,
- the lead structure and electrode configuration for optimal atrial pacing.

Pulse Morphology and Field Pattern - Scant information on these subjects is available in the literature other than the following:

- The OLBI (OverLapping Biphasic Impulse) technique uses two single unipolar pulses, with the same amplitude and duration but with opposite polarity. These pulses are simultaneously issued from each of the electrodes of the dipole to the pacemaker case. This way, a high current density is achieved in the neighboring atrial myocardium. This approach, with floating ring electrodes in a straight lead, has been reported to achieve stable atrial capture in more than 80 % of the patients, with few side effects [2-4].
- The BIMOS (BIdirectional MOnophasic Stimulation) technique [5] employs three atrial ring electrodes (distal, medial, and proximal), with 1.0 cm inter-electrode spacing. At present, the literature reports only a few preliminary animal studies regarding this technique.
- The VECATS (VEna Cava-ATrial Stimulation) approach [6]. Similarly to BIMOS, it also employs three atrial rings along the lead: the distal and medial rings float within the atrium, while the proximal ring is positioned in the superior vena cava. The pacing pulse is issued between the medial and proximal rings, while atrial sensing is assigned to the dipole formed by the distal and medial rings. An early clinical study with 21 patients has shown that the threshold for permanent atrial capture obtained with VECATS was comparable with those shown with OLBI, but the threshold for PNS was higher for VECATS than for OLBI [7].

Lead Structure and Configuration - The aim of atrial pacing with floating electrodes has been placing the dipole as close to the atrial wall as possible. Since the field strength decreases with the inverse square of the distance between the electrode and the active tissue, loss of capture or sensing are likely if the dipole is far from the atrial wall. The fractal coating of the electrode surfaces decreases the polarization impedance and the amplitude of the after-potential. This contributes to better sensing and pacing [8]. Despite all these innovative efforts, 100 % success in atrial stimulation has not yet been achieved. PNS and intermittent atrial capture have both remained clinical problems [4], since the "straight" single lead will never be able to assure stable and reliable atrial pacing as long as its dipole remains able to freely float in the atrial blood pool. Nevertheless, whenever at least one of the atrial electrodes was chronically attached to the atrial wall by tissue encapsulation, reliable atrial pacing was feasible at the time of pulse generator replacement [9,10]. In the

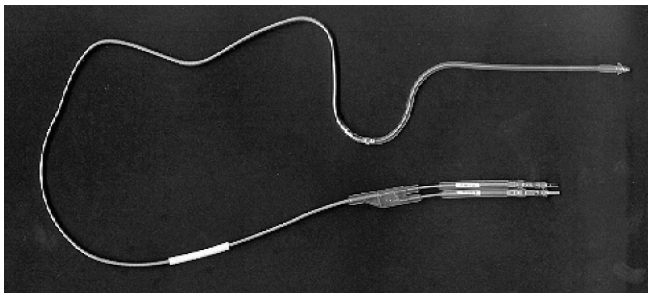

Figure 1. ATS lead (C.C.S., USA).

attempt to improve the contact, new, pre-shaped leads were designed with shaped bends or protrusions in their atrial portion with the intent to force atrial electrodes close to the myocardium. Preliminary clinical results achieved by several investigators seem to be promising [11].

In the implant centers in Ferrara and Viterbo, a joint investigation was performed on a new pre-shaped lead [12,13] combined with an implantable pulse generator with OLBI atrial pacing capability.

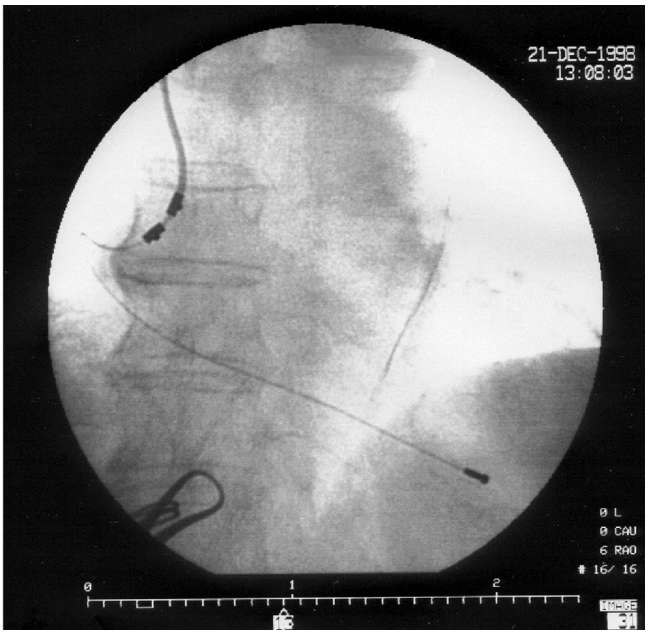

Figure 2. Typical position inside the right atrium achieved by the atrial lobe of the lead in the 15 patients in which the dipole position was found stable during the entire follow-up.

Materials and Methods

The new polyurethane model ATS lead (C.C.S., USA) has several pre-shaped curves (see Figure 1). The first "S" curve is located at the level of the superior vena cava, just before the junction with the right atrium, and serves as a fulcrum for the distal atrial portion of the lead, which has a "lobe" to keep its polished-platinum electrodes in contact with the atrial wall. The electrodes are positioned at the apex of the "lobe" and are half-rings, spaced 7 mm apart, both oriented toward the atrial wall. This approach does not introduce critical changes in the electrode structure and allows stable positioning of the dipole against the anterior wall of the atrium (see Figure 2), far from the phrenic nerve.

The ATS lead was implanted in 18 patients (12 males and 6 females) with mean age 76.8 ± 6.2 years, all with symptomatic AV Block and normal sinus function. The lead was connected to an implantable pulse generator, the EIKOS SLD (Biotronik, Germany), which permits permanent OLBI pacing to be performed in the atrium. At implant, the atrial pacing threshold (APT) was assessed using unipolar, bipolar and OLBI pulse forms. During follow-up, performed at 1, 3, and 6 months, APT (OLBI pulse only) was assessed for various body positions to verify lead stability. DDD pacing was temporarily programmed during follow-up only.

Results and Comments

Table 1 shows the parameters measured at implant (at pulse duration 0.5 ms) with a pacing system analyzer (ERA 300B, Biotronik).

After implant, 2/18 patients exhibited a significant displacement of the atrial dipole, and no atrial capture was detected at the one and three-month follow-up. In one patient, the dipole moved inside the superior vena cava; in the second, the rotation of the atrial "lobe" was about 80° clockwise (detected by X-ray). In both cases, the P-wave amplitude was kept between 0.5 and 0.8 mV assuring a reliable VDD pacing function. Since the two patients were the first two implanted in each center, it seems reasonable to presume that the inconvenience should be attributed to the learning phase for the new implant technique. A third patient showed no atrial capture at the 3- and 6-month follow-up, and the dipole was found in the superior vena cava. P-wave detection was also stable for this patient, with a minimum value of 0.5 mV. The patient reported spending several days performing heavy and stressful agricultural works during the month before the last follow-up. Data collected for the remaining 12/15 patients are reported in Table 2.

An exercise test (treadmill, CAEP protocol) was performed at each follow-up in 15/18 patients. The test

Parameters (± SD)	Implantation	Discharge
P-wave amplitude (mV)	3.0 (1.1)	2.1 (1.7)
APT unipolar (V)	2.8 (2.3)	n.a.
APT bipolar (V)	2.5 (1.2)	n.a.
APT OLBI (V)	1.3 (0.8)	1.3 (0.6)
Ventr. threshold (V)	0.5 (0.2)	1.2 (0.3)

Table 1. Parameters measured at implant (± SD).

verified the atrial capture (pacemaker temporarily programmed at: OLBI atrial pacing, BR 10-15 bpm > patient intrinsic rate at rest, OLBI PA 0.5V higher than threshold value at supine). In all 15 patients, atrial pacing and sensing were 100 % stable and the two-way mode conversion between DDD and VDD occurred properly without atrial undersensing (Figure 3).

An occurrence of PNS or thoracic muscle contractions was never observed in any of the 18 patients, even when the OLBI pulse amplitude was programmed at its maximum value.

The preliminary data summarized in Tables 1 and 2 can be commented on as follows:

- When the pre-shaped lead is positioned using a proper surgical technique, the atrial dipole remains stable during implant maturation.
- APT shows the same time-course as contact electrodes, i.e., increasing during the first 4-6 weeks from implant and then decreasing to stable chronic values.
- Changes in body position slightly influence APT at discharge follow-up only, demonstrating that the shaped structure of the lead will correctly absorb all impacts generated by movements of the cardiac mass.
- The relatively high values of APT during follow-up should be attributed to the quite old technology used for the atrial electrodes (polished platinum), and to the sliding movements of the dipole against the atrial wall during the cardiac cycle. These induce a larger growth of fibrotic tissue at the electrode-myocardium interface. The use of new manufacturing techniques (e.g., fractal coating) will substantially improve the pacing efficacy of the electrodes.

Also, lead encapsulation seems to take place in a reasonably short time. One of the two patients who lost capture during the first month after implantation (the one with 80° "lobe" rotation), reacquired atrial capture at the third month with a reasonable threshold (3.2 V in supine and 2.9 V in standing position). Since no evidence of additional movements of the atrial "lobe" were found at the X-ray fluoroscopy performed during the follow-up, the recover of atrial capture may only be attributed to the lead encapsulation that kept the atrial electrodes close to the myocardium.

Parameters (± SD)	Follow-up 1-month	3-month	6-month
Minimum P-wave amplitude (mV)	2.4 (1.4)	1.7 (0.9)	1.9 (0.7)
APT supine - inspiration (V)	3.3 (1.3)	2.5 (1.5)	2.1 (1.0)
APT supine - expiration (V)	3.1 (1.3)	2.4 (1.4)	2.2 (1.1)
APT supine - left decubitus (V)	3.4 (1.4)	2.4 (1.4)	2.1 (1.0)
APT supine - right decubitus (V)	3.3 (1.3)	2.5 (1.4)	2.2 (1.1)
APT sitting (V)	3.3 (1.2)	2.5 (1.4)	2.1 (1.2)
APT standing (V)	3.1 (1.1)	2.4 (1.4)	2.1 (1.1)
Ventr. threshold (V)	1.9 (0.6)	1.5 (0.2)	1.5 (0.2)

Table 2. Parameters measured during follow-up (± SD) (at atrial OLBI and ventricular pulse duration 0.5 ms).

Conclusions

Pacing is quite a different challenge from sensing, as it involves more problems concerning lead technology and other factors in relation to pacemaker electronics

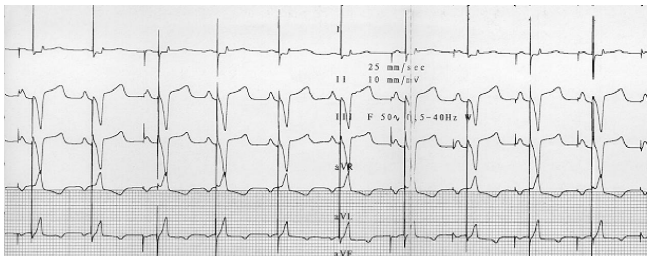

Figure 3. Surface ECG showing proper atrial inhibition (mode conversion from DDD to VDD) when P-waves are detected.

[14]. The evolution of the single AV lead, initially hindered by more than just a simple skepticism, favored the emergence of a new pacing system and has served as a springboard for success. The cumulative clinical results achieved using straight AV leads and OLBI stimulation, assure reliable DDD back-up pacing in more than 80 % of treated patients [4]. Additionally, the preliminary, but promising, results of the investigations using pre-shaped leads, as reported in this paper and also by other authors, allow one to foresee that primary DDD pacing with a single lead may not be so far in the future.

A potential and logical role of the single-lead concept can be expected to be easily integrated into new pacing techniques such as biatrial pacing for prevention of AF or biventricular and four-chamber pacing in cases of dilated cardiomyopathy and congestive heart failure. In the first case, a single pre-shaped lead may keep an electrode close to the Bachmann's bundle and drive other electrodes inside the CS for left-atrial sensing and pacing. In the second case, two single leads, instead of the four presently in use, may assure pacing in the right and left portion of the heart, thus reducing vascular burden and simplifying implant procedures.

As the interaction between various technologies accelerates, our hopes and expectations should be realized. At the dawn of the third millennium, these leads may light the way for the "all-in-one device" that we have been striving to achieve for so long.

References

[1] Antonioli GE. Single lead atrial synchronous ventricular pacing: A dream come true. PACE. 1994; 17: 1531.

[2] Hartung WM, Hidden-Lucet F, Mc Teague K, et al. Overlapping biphasic stimulation: A novel pacing mode with low capture thresholds. Circulation. 1994; 90: 365(abstract).

[3] Taskiran M, Weiss I, Urbaszek A et al. Pacing with floating electrodes and various pulse morphologies. Biom. Technik 1996; 41(2): 41.

[4] Sassara M, Arlotti M, Giudice G del, et al. Single lead DDD OLBI pacing. In: E Adornato (ed.): Rhythm control from cardiac evaluation to treatment. Pozzi, Rome, Italy, 1998: 323.

[5] Hartung WM, Hartung D, Klein HU. A novel pacing configuration using a conventional monophasic impulse for atrial floating pacing. Arch. Coer et Vaisseaux. 1998; 91: 158(abstr).

[6] Brofman PRS, Menezes AS, Mateos JCP, et al. First clinical results with the VECATS Single-Lead System. Prog Biom Res. 1998; 3(3): 168.

[7] Brofman PRS, Ramos C, Taskiran M, et al. Threshold comparison of various floating electrode combinations for atrial stimulation. Arch. Coer et Vaisseaux. 1998; 91: 170(abstr.).

[8] Res JCJ, Reilsoo FJ, Woersem RJ van, et al. P wave recognition and atrial stimulation with fractally iridium coated VDD single pass leads. PACE. 1994; 17: 1883.

[9] Papouchado M, Barnes E, Pitts Crick JC. Encapsulation of the atrial dipole of chronically implanted VDD leads: A means of single-pass lead DDD pacing? PACE. 1997; 20: 1211.

[10] Papouchado M, Barnes E, Pitts Crick JC. Encapsulation of atrial dipole in floating single A-V lead. In: GE Antonioli (Ed): Pacemaker Leads 1997, Monduzzi, Bologna, Italy, 1997: 183.

[11] Kruse IM. Evolution of a single pass DDD lead. Arch. Coer et Vaisseaux. 1998; 91: 326(abstr.).

[12] Brownlee RR, Swindle MM, Bertolet R, et al. Toward optimizing a preshaped catheter and system parameters to achieve Single Lead DDD pacing. PACE. 1997; 20(I): 1354.

[13] Lee J, Bertolet R, Brownlee R. Dual atrial contacting electrodes and atrial stimulation. In: GE Antonioli (ed.): Pacemaker Leads 1997. Monduzzi, Bologna. Italy 1997: 137.

[14] Antonioli GE, Audoglio R. Single Lead pacing. Do we have the right lead? In: GE Antonioli (ed.): Pacemaker Leads 1997. Monduzzi, Bologna, Italy,1997: 151.