

## Editorial

### The Single-Lead Concept Today

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The single atrioventricular (AV) lead with a floating atrial electrode for P-synchronous ventricular pacing was developed in the 1970s to replace the VVI/VVIR mode and to assure reliable AV synchronization in patients with high-degree AV block and "normal" sinus node and atrial function [1]. Under continuous development since the 1980s, the present variety of single AV lead designs embodies years of research findings, applications, and clinical studies. Included in the 1991 Guidelines for Pacemaker Implantation, single-lead VDD pacing is now widely used in clinical practice [2]. Both early and recent literature has confirmed the overall long-term reliability and stability of the "A" wave characteristics detected by this lead. Under almost all conditions, VDD single-lead systems are practically identical to conventional dual-chamber, dual-lead pacemakers as regards the high percentage of atrial synchronization, the low incidence of atrial tracking loss, and the rate of occurrence and type of complications. Thus, this pacing approach represents not only a "truly hemodynamic" substitute to VVI pacing, but also an interesting alternative to DDD pacing in patients with advanced or complete AV block and normal, or only mildly compromised, chronotropic competence [2-4]. Today, high-quality, sophisticated devices dedicated to single-lead VDD pacing are available, but proper patient selection and a thorough understanding of the principles and complexities of the system are still necessary to ensure appropriate operation and reliability of the system. The benefit of expanding the use of single AV leads to include permanent atrial pacing is self-evident, as this would enable DDD pacing to be applied more easily than with the currently prevalent dual-lead method.

Efforts to pace the atrium using a straight (non-contacting), single AV lead were aimed at depolarizing the

myocardium with the electrical field generated in the area of the floating dipole electrodes. In this approach, electrolytic conduction causes current to flow to the muscle fibers and trigger cellular depolarization. In the past decade, several attempts were made in that direction using single AV leads originally designed for VDD pacing connected to conventional DDD pulse generators. However, problems have arisen with atrial pacing due to side effects, such as phrenic nerve and thoracic muscle stimulation, despite only intermittent capture of the atrial myocardium [5].

Parasitic phrenic nerve stimulation is a major obstacle to successful atrial pacing with single AV leads. This side effect occurs when the electrical field outside the atrial wall – where the phrenic nerve passes – is strong enough to stimulate the latter. Overlapping Biphasic Impulse (OLBI) pacing, (Biotronik, Germany) was developed to reduce the size of the electrical field in order to improve atrial capture and avoid stimulation of non-cardiac tissue. The OLBI pacing concept uses two single unipolar pulses with identical amplitude and duration but opposite polarity, delivered between each ring electrode and the pulse generator case (mirror electrode) respectively. The electrical field strength generated by OLBI pacing is mostly concentrated inside the neighboring myocardium and focused in the direction of the mirror electrode. The first extensive, long-term studies of "back-up" single-lead DDD pacing with OLBI atrial pacing have shown encouraging results. During the one-year follow-up, consistent atrial capture (> 95%) was achieved in about 75% of the observed population (n = 250). The atrial pacing threshold was stable with a mean pulse amplitude of 2.8 V at 0.5 ms pulse width, phrenic nerve stimulation occurred in less than 15% of patients and was strongly

correlated to the body mass index ( $BMI < 25$ ), and thoracic muscle stimulation was never observed [6,7].

Another attempt to reach consistent atrial capture was represented by the VECATS (Vena Cava ATrial Stimulation, Biotronik) approach. The VECATS system uses a straight, single AV lead with a floating tripolar atrial electrode. Conventional bipolar pacing occurs between the median (cathode) and proximal ring electrode located inside the superior vena cava, while sensing occurs between the median and distal ring electrodes, both pacing the right atrium. Current pacing locations are mainly in the high right atrial position, while sensing is still accomplished in the right atrium, possibly enabling pacing and sensing sites to be optimized. The system was tested in 78 patients in Europe and Canada and data are available up to the third month of follow-up. The preliminary results of this study are less promising than those achieved with OLBI pacing. The atrial pacing threshold at implant and at the 3-month follow-up was acceptable for floating pacing (3.3 V and 4.5 V respectively) and tended to increase over time, but consistent atrial pacing without side effects dropped from 93% at implantation to a disappointing 54% at 3 months post-implantation [8].

These studies showed that concentrating on the electrical field alone is not sufficient to achieve optimal results. Additional improvements were made to the lead design and technology in order to shape and orient the atrial portion of the lead and allow the atrial electrodes to stay closer to the atrial wall. This induced depolarization in a greater amount of myocardial cells and maintained electrodes in a more stable position than with non-shaped leads. Two pre-shaped, single AV leads were tested in recent clinical trials: the ATS (Cardiac Control Systems, USA) and the V411 Omega (Biotronik).

In the polyurethane ATS lead, which is no longer available on the market, the atrial segment was "lobe-shaped," with an additional soft "S" bending in the proximal segment (vena cava), which acted as a stabilizer and axial thrust-absorber. The two atrial, half-ring electrodes protruded on the exterior apex of the lobe. This lead was tested in 18 patients. When the ATS lead was positioned using proper surgical techniques in 16 of 18 patients, the atrial dipole remained stable during implant maturation and consistent atrial capture was achieved using the OLBI pacing configuration in

those 16 patients. The atrial pacing threshold showed the same course as observed usually with contact electrodes, increasing during the first 4 – 6 weeks after implantation and then becoming stable. Changes in body position affected the threshold slightly (mean value 2.1 V at 6 months), i.e., the shaped structure correctly absorbed all thrusts generated by movements of the cardiac mass. During exercise tests, atrial pacing and sensing were stable, and two-way mode conversion occurred appropriately without atrial undersensing. Phrenic nerve stimulation was never observed [9]. A similar clinical study is still in progress using the pre-shaped V411 OMEGA lead. This lead has a body made entirely of silicone, the electrode tip and the complete atrial ring are fractal coated (with iridium), and an atrial segment is shaped in the form of a question mark. The substantial change in lead stiffness of the area surrounding the pre-shaped atrial segment acts as an absorber for thrusts generated by cardiac contraction. Currently, no data are available regarding the chronic phase of OMEGA lead implants, but the lead investigator informed this author that the preliminary results of the first 8 implants show data that are largely comparable to results achieved with the ATS lead.

The preliminary clinical studies on DDD pacing with pre-shaped, single AV leads seem to show more promising results than conventional leads. There were some initial failures during the learning phase of lead insertion technique, which is quite different from that used to implant straight leads. The relatively high values of atrial pacing thresholds exhibited by both leads can be reasonably attributed to the sliding movements of the dipole against the atrial wall during implant maturation, which induces a larger growth of fibrotic tissues at the electrode-myocardium interface.

Single-lead DDD pacing is an appealing option, though some room for improvement still exists. Some additional improvements in lead design are required to achieve greater stability of the atrial lobe, especially during the first implant maturation period, and to reduce the waste of pacing current at the blood-electrode interface. Nevertheless, we should not think that the application of a single lead is limited to the right portion of the heart and to bradycardia pacing.

The high incidence of inappropriate shock delivery is the major limitation of using single-chamber implantable cardioverter-defibrillators (ICDs) with

discrimination algorithms based on ventricular rate in combination with sudden onset and stability criteria, in patients with a history of atrial fibrillation (AF). In these systems and under these conditions, the specificity seldom exceeds 80%. Single-lead solutions are now available in ICD therapy. A pentapolar single defibrillation lead (Kainox VDD, Biotronik) with a floating atrial dipole design allows a single-chamber ICD to discriminate atrial rhythm for a more proper delivery of shock therapy [10]. A dedicated single-chamber device (Deikos A+, Biotronik) equipped with a high-sensitivity atrial channel connected to such a lead can detect atrial rhythms with an A-wave amplitude as low as 0.2 mV, which includes most fibrillation waves, and increases the specificity of the system up to 95%. The benefits of this approach are evident: the implantation procedure remains simple, and the patient's safety and quality of life improve.

Another significant step toward the application of the single-lead concept is its extension to the left side of the heart. Recent literature clearly demonstrates that a large percentage of congestive heart failure (CHF) patients with left bundle-branch block experienced a dramatically improved quality of life after treatment with left ventricular resynchronization therapy. On the other hand, it is also known that  $\geq 30\%$  of these patients have developed or will develop a history of paroxysmal AF. The vascular burden caused by the three leads (right atrial, right ventricular, and left ventricular) necessary to perform the basic resynchronization therapy will not allow these patients to benefit from additional biatrial pacing, which may be effective in preventing AF episodes. In this case, a single AV lead approach of the left side of the heart through the coronary sinus may be the optimal solution. Using updated technologies, a tri- or quadripolar lead can be manufactured in a very small French size. The proximal electrode array positioned in the distal portion of the coronary sinus permits left atrial pacing. Due to the stiffer structure of the proximal segment of the lead (from connector to atrial dipole), its distal (thinner) end, which is inserted into the cardiovascular system, becomes more stable, and its maneuverability during insertion improves. The long-term reliability of such a lead is not a concern. The thrust and bending stress on a lead while inside blood vessels are substantially lower than those of freely floating leads in the right chambers of the heart.

The combination of various electrical therapies and delivery sites with appropriate single leads will determine that, at the dawn of the third millennium, the expected "all-in-one device" will become a reality. The more accelerated and vigorous the interaction between medicine, science, and technology becomes, the sooner we will see our hopes realized.

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