Single-Lead DDD Pacing with Two Ring Electrodes in the Right Atrium and One Ring in the Superior Vena Cava

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Summary

Multi-chamber stimulation using floating electrodes of a single lead has become an increasingly studied field in electrotherapy of the heart, with potential applications for bradycardia therapy, as well as for low-energy tachycardia prevention and therapy. The aim of this investigation is to validate the performance of the innovative vena cava atrial stimulation (VECATS) concept. The VECATS single lead provides the usual bipolar sensing combined with atrial pacing provided by a counter electrode in the superior vena cava superior (SVC). Measurements performed at the time of implantation and at 1- and 3-month follow-ups showed consistent P-wave amplitudes, stable atrial capture thresholds (approximately 3.0 V at 0.5 ms), and a high safety margin of at least 142% between the atrial and diaphragmatic thresholds. Our initial results are promising, indicating that this is a feasible mode of single lead DDD pacing.

Key Words

Dual-chamber pacing, single-pass lead, floating electrodes, vena-cava-atrial stimulation (VECATS), proxipolar configuration

Introduction

Dual-chamber (DDD) pacing for maintenance of atrioventricular (AV) synchrony generally requires the implantation of two leads, one in the right atrium and one in the right ventricle. During the early 1990's, the efforts were made to achieve DDD pacing using only one lead [1-3]. The idea was to use the electrical field generated between the floating ring electrodes located in the right atrium to stimulate the atrium and thereby treat bradycardia conditions in a manner that favors safe pacing (reduces the complication rate) and makes the pacemaker implantation easier. Different authors have searched for a suitable mechanism to perform DDD pacing using a single-pass lead; the proposed technical solutions met varying degrees of clinical success [4-13].

Verlato et al. reported on a multicenter study investigating clinical utility of the overlapping biphasic impulses (OLBI) delivered via floating atrial electrodes [14]. Atrial pacing was achieved in all patients in whom the floating electrodes were placed in the superior vena cava (SVC), 77.7% of patients experienced effective pacing with the electrodes floating in the upper atrium, 82.1% with the electrodes placed in the mid-atrium, and 50% of patients were successfully paced with the electrodes floating in the lower atrium. An explanation for these differences may be a lower capture threshold of cardiac cells in the sinoatrial area compared with other myocardial cells.

The knowledge gained in the aforementioned study has incited the development of a single-pass lead with

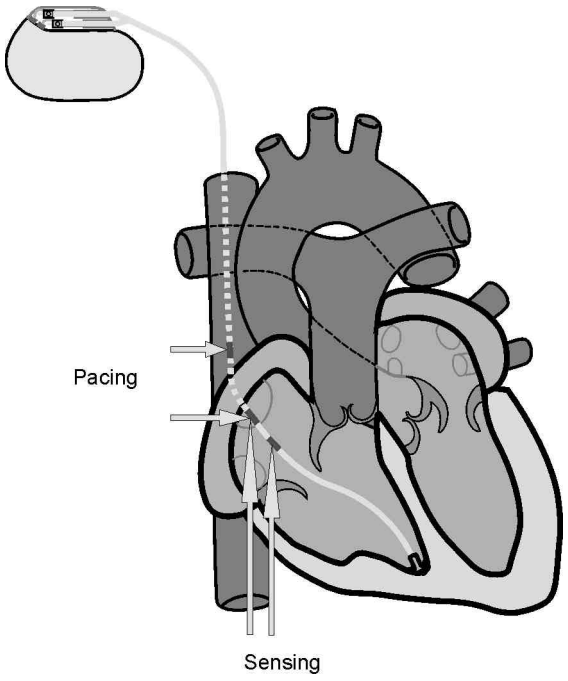

Figure 1. Configuration of the vena cava-atrial stimulation (VECATS) lead. During stimulation in the proxipolar configuration, the proximal ring serves as the referent electrode (anode) and the medial ring as the active electrode (cathode). The intracardiac potential is determined in the bipolar configuration, between the distal and the medial atrial rings.

three floating ring electrodes (VECATS lead, illustrated in Figure 1) [15]. During the implantation, the lead ought to be positioned in the way that the distal and medial rings float in the right atrium and the proximal ring is at the junction between the atrium and the SVC. The bipolar atrial potentials are sensed between the distal ring and the medial ring, whereas atrial pacing pulses are delivered between the proximal ring and the medial ring. The proximal ring, located in the SVC, is expected to generate an electrical field mainly spreading within the sinoatrial portion of the right atrium. Our single-center study investigated clinical performance of the VECATS leads

Materials and Methods

Seventeen patients implanted with the VECATS lead and the Dromos SL M9 pacemaker (Biotronik, Germany) were enrolled in the study. The age of the patients ranged from 13 to 75 years, 57% were female. Fifteen patients had fibrosis of the conduction system and two suffered from hypertrophic cardiomyopathy.

The Dromos SL M9 is a DDDR pacemaker equipped with the header that was specifically designed to accommodate the quadripolar VECATS lead connector. One electrode is aimed at unipolar sensing and pacing in the right ventricle, and the remaining three electrodes are for atrial use in the way described in the introduction. When the proximal electrode was used for pacing or sensing versus the medial atrial ring, the attribute "proxipolar" pacing or sensing was used. Proxipolar pacing and bipolar (between medial and distal ring) sensing is the typical VECATS mode, on which our study focused.

Two different models of VECATS leads are available: VC SL-UP/14, with the 14-cm distance between the midpoint of the distal and medial rings and the distal lead tip, and VC SL-UP/17 with the 17-cm distance between the midpoint of the distal and medial rings and the distal lead tip. The appropriate lead size for each patient was determined to ensure easy access into the right ventricle, with the proximal atrial ring placed in the SVC and the medial and distal rings in the right atrium. The intersection line between the SVC and right atrium was located between the proximal and medial rings. The typical position of the rings is shown in Figure 2.

All intraoperative measurements were made with the ERA 300 pacing threshold analyzer (Biotronik). Data collected during the implantation included the P- and R-wave amplitudes, atrial and ventricular pacing thresholds, lead impedance and diaphragmatic pacing threshold. Ventricular measurements were performed in the unipolar configuration, P-wave acquisition in the bipolar atrial configuration, and atrial threshold measurements in the proxipolar configuration. The intracardiac electrogram (IEGM) was printed to confirm atrial capture during at least eight consecutive events. The appropriate position of the atrial and SVC rings was primarily determined by measuring the bipolar atrial IEGM between the medial ring and the distal ring. The position was considered acceptable if the P-wave amplitude was greater than 0.5 mV.

Following implantation, the atrial output amplitude was programmed to 4.8 V and the pulse width to 0.5 ms in all the patients. The basic rate was set to 70 beats/min. Follow-up measurements were taken at 1 and 3 months after pacemaker implantation, using the PMS 1000 Color programmer (Biotronik). Bipolar P-wave

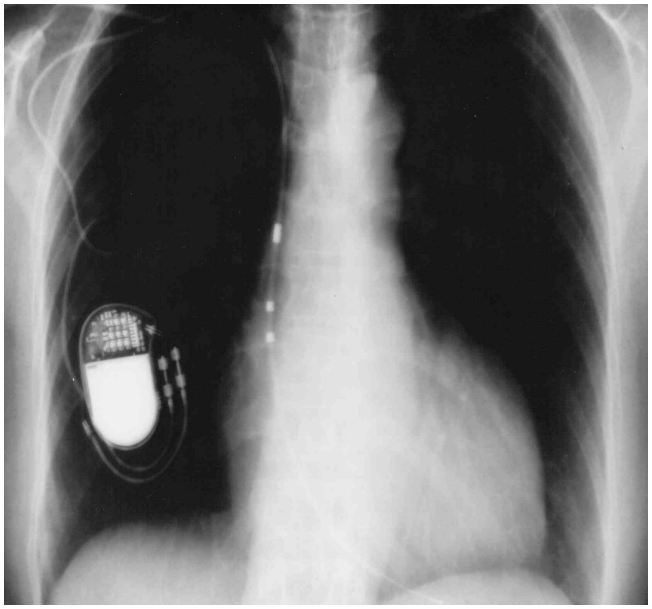

Figure 2. X-ray of typical position of the atrial rings. The function of the rings is described in Figure 1.

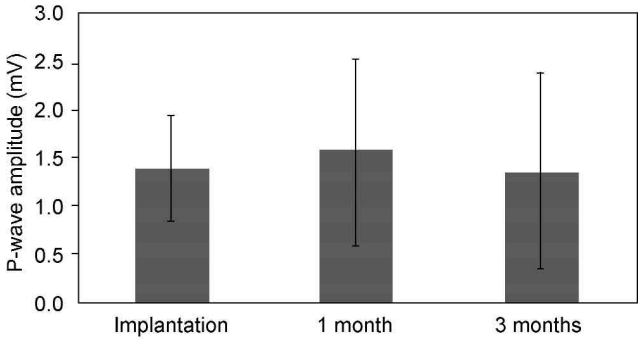

Figure 3. Bipolar P-wave measurements at implantation and 1 and 3 months after implantation.

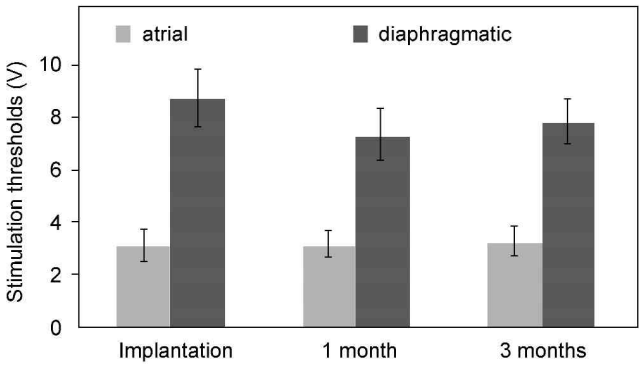

Figure 4. Diaphragmatic and proxipolar atrial stimulation thresholds at 0.5 ms in the normally breathing supine patients.

amplitudes and the diaphragmatic and atrial (proxipolar) pacing thresholds were taken in the supine, sitting and standing positions and during the Valsalva maneuver. Percentage of atrial pacing during 24 hours was taken using the pacemaker's statistical functions (internal 24-hour Holter).

Results

The implantations were carried out without any difficulty. Only 14 cm (VC SL-UP/14) leads were used. The mean acute electrophysiologic values in the ventricle were: R-wave: 12.3 ± 5.8 mV, the pacing threshold at 0.5 ms: 0.6 ± 0.2 V, and the lead impedance: 780 ± 158 Ω.

P-wave values obtained acutely and at 1 month and 3 months after pacemaker implantation were: 1.4 ± 0.5 mV, 1.6 ± 0.8 mV, and 1.4 ± 0.9 mV, respectively (Figure 3). No atrial sensing problems were observed during the study.

The acute atrial pacing threshold was lower than 2.0 V at 0.5 ms in 75% of the patients, with the overall mean value of 3.1 ± 0.6 V. The Figure 4 shows trend of atrial pacing threshold after implantation. The mean safety margin between the pacing and diaphragmatic threshold was greater than 142% at any follow-up point. Figure 5 illustrates variations in the diaphragmatic and atrial pacing thresholds caused by change in patient posture. As seen, the variations were minimal: 3.0 ± 0.5 V (supine), 3.1 ± 0.5 V (sitting), and 3.3 ± 0.6 V (standing). Measurements during the 3-month follow-up did not show any significant change.

The effect of the Valsalva maneuver on the stability of the diaphragmatic and atrial pacing thresholds as well as on the safety margin for diaphragmatic pacing was negligible (Figure 6). Three months after implantation, the average pacing threshold was 3.3 ± 0.6 V during normal breathing and 3.6 ± 0.9 V during the Valsalva maneuver.

The analysis of the pacemaker statistics (internal 24 h-Holter) revealed about 83% of atrial pacing during patients' everyday activities.

Discussion

The mean proxipolar atrial pacing threshold in our study was about 3.0 V, allowing a safety margin of at least 142% in relation to the diaphragmatic threshold. The pacing threshold remained stable with postural

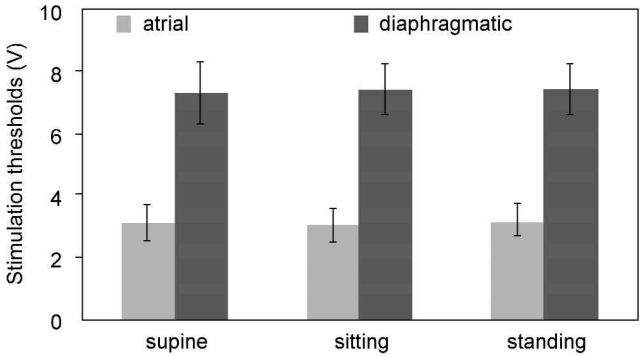

Figure 5. Diaphragmatic and proxipolar atrial stimulation thresholds at 0.5 ms in the normally breathing supine, sitting, and standing patients. The measurements were taken 1 month after pacemaker implantation.

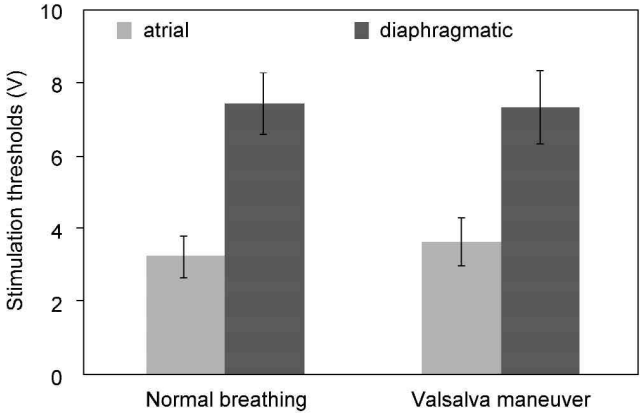

Figure 6. Diaphragmatic and proxipolar atrial stimulation thresholds at 0.5 ms during normal breathing and Valsalva maneuver, determined at 3 months after pacemaker implantation.

changes and with the implantation time. Because the atrial rings are not in contact with the atrial wall, the possibility of threshold increase due to tissue fibrosis around the electrode attached to the myocardium or local ischemia have been eliminated. In the same time, sensing properties of the VDD systems using a single lead have been maintained.

There is a discrepancy between our findings and recently published results of a multicentric study conducted in Europe and Canada in 78 patients with VDD indications [16]. In that study, the VECATS leads were also implanted without any difficulty, but the atrial pacing threshold increased from 3.3 ± 1.1 V during implantation to 4.3 ± 0.5 V at 3 months (European centers). Simultaneously, the diaphragmatic threshold increased from 7.2 ± 2.2 V acutely to 7.9 ± 1.1 V at 3 months. In the Canadian group, the atrial threshold increased and diaphragmatic threshold decreased during the follow-up, leaving a safety margin at the very last follow-up of just 1 V. Vena cava atrial stimulation was found to be safe and initially feasible in the majority of patients, although diaphragmatic stimulation became more prevalent in the Canadian group. Consequently, the results of the two studies have to be compared critically with a focus placed on the implantation techniques used in different centers. Differences in the methods for placing the lead tip and the ring electrodes will effect their position and consequently the value of the proxipolar atrial threshold.

Conclusion

The VECATS lead configuration provides pacing in the sinoatrial region, while the standard bipolar P-wave sensing feature remains unchanged compared with conventional single-pass leads. The VECATS concept is therefore a safe, feasible, and physiologic method optimizing single lead DDD pacing. It maintains atrial pacing with a good margin of safety without diaphragmatic pacing. In order to achieve good performance in view of high diaphragmatic and low atrial thresholds, it is fundamental to adequately position the atrial and SVC rings. The clear definition of the required locations for the three atrial rings brings an advantage over standard single-pass AV pacing leads, where it is still unclear where the atrial dipole has to be located within the right atrium. The additional flexibility provided by the programmable combinations of atrial rings enables to modify the pacing location or to adapt it to the current needs of the patient throughout the course of therapy. In other words, in case the lead is moving up or down after implantation, it is possible to select another ring combination for pacing and/or for sensing and hence optimize the performance of the system without surgical re-interventions.

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