Atrial Stimulation Using Floating Electrodes and a Counter Electrode in the Vena Cava Superior

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Summary

Multi-chamber stimulation using floating electrodes of a single-pass lead has become an increasingly explored field in the electrotherapy of the heart, with potential applications for bradycardia, as well as low-energy tachycardia prevention and therapy. The aim of this investigation is to validate the performance of the novel vena cava-atrial stimulation (VECATS) concept. The new VECATS single-pass lead provides usual bipolar sensing combined with atrial pacing with respect to a counter electrode in the vena cava superior (VCS). Measurements, which were performed from the time of implantation to the 2-month follow-up showed consistent P-wave amplitudes, stable atrial capture thresholds around 3.0 V, and a high safety margin of at least 142% between the atrial and the diaphragmatic thresholds. These promising initial results prove that this mode of pacing is a feasible method.

Keywords

Dual-chamber systems, atrial floating electrodes, VECATS concept, vena-cava-atrial stimulation

Introduction

The efforts to develop simplified dual-chamber systems by using a single-pass lead have rapidly increased in the last few years [1-3]. Using the electrical far-field created by floating ring electrodes not only simplifies DDD systems, but also provides the medical professional with new options for antibradycardia and low-energy antitachycardia pacing therapy. Several approaches [4-13] to find a suitable way for single-lead DDD pacing with floating atrial electrodes have been attempted with different levels of success.

The vena cava-atrial stimulation (VECATS) configuration (Figure 1) has been developed as a novel method for effective pacing with floating electrodes. The experience with focused electrical far-fields, gained with the OLBI configuration and atrial defibrillation techniques, has led to the idea of a new single-pass lead providing high current density in the sinoatrial region. The cells in this region are assumed to have lower capture thresholds compared to other myocardial cells [14]. For this purpose, a single-pass lead with three floating ring electrodes in the atrial part was built. Its distal and medial rings provide bipolar sensing, while pacing is accomplished between the medial and the proximal rings. The proximal ring is located in the vena cava superior (VCS), resulting in a current path that is dense in the upper, sinoatrial part of the atrium.

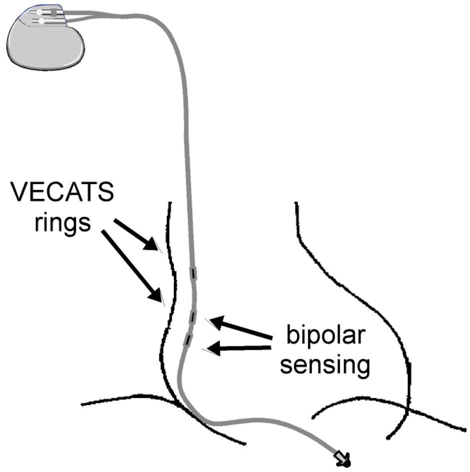

Figure 1. Vena Cava Atrial Stimulation (VECATS): The proximal ring in the VCS serves as counter electrode for atrial stimulation. Sensing is accomplished via distal and medial rings.

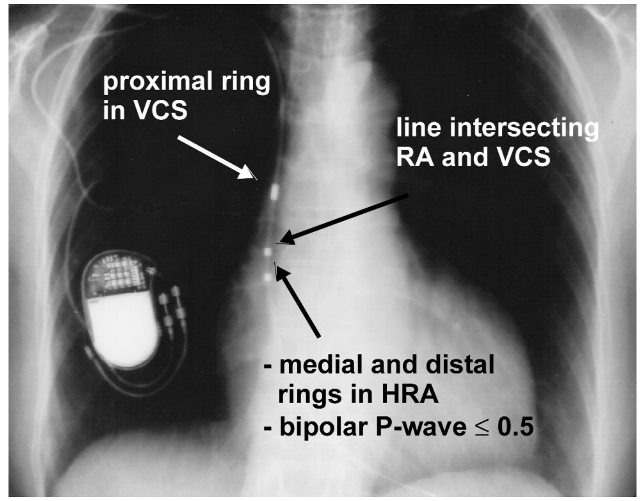

Figure 2. X-ray showing proper positioning of the rings. The proximal ring is located in the VCS and serves as counter electrode, while the other two rings remain in the high right atrium for bipolar sensing. The line intersecting atrium and VCS is located between proximal and medial ring.

Materials and Methods

For the first clinical mid-term validation of the novel VECATS concept 10 patients (4 female / 6 male) with severe AV conduction blocks were included in the study. Bipolar P-wave amplitudes, atrial and diaphragmatic capture thresholds for the VECATS configuration were determined at implantation, discharge, and the 2-month follow-up, performing changes in posture (sitting and supine position) and Valsalva maneuver.

After 2-months we have done the Holter 24 hours recording, programming all patients with 4.8 V of atrial amplitude and 85 bpm as heart rate. With this procedure, we were able to analyze the bipolar atrial sensibility and the percentage of atrial capture.

Implant Procedure

The VECATS lead is available in two size configurations with respect to the distance between the lead tip and the distal ring. The appropriate lead size for the patient was determined, such that with the lead tip positioned in the right ventricular apex, the proximal ring electrode could be positioned in the VCS and the medial and distal ring in the high right atrium. The line intersecting VCS and the right atrium was located between the proximal (VCS) ring and the medial ring. The typical position of the rings is seen in Figure 2. The adequacy of atrial electrode position was primarily guided by measurement of the atrial intracardiac electrogram (IEGM) amplitude between medial and distal ring electrodes. Atrial electrode position was regarded as acceptable if the atrial IEGM amplitude was > 0.5 mV.

Results

The obtained P-wave values for implantation, discharge, and 6-week follow-up were 1.4 ± 0.6 mV, 1.3 ± 0.5 mV, and 1.1 ± 0.8 mV, respectively (Figure 3), showing no problems of sensing in the high right atrium.

In 67% of the cases, atrial capture thresholds below 3 V at 0.5 ms pulse width were measured intraoperatively, while threshold values lower than 4 V at 0.5 ms were obtained in 100% of the patients.

The mean atrial threshold was 3.0 ± 0.6 V during implantation. The course of atrial thresholds from implantation to the 6-week follow-up with VECATS can be observed in Figure 4. The margin between atrial and diaphragmatic thresholds was at least 142%. As there are no threshold changes due to electrode ingrowth to be taken into consideration with ring electrodes, the stable course of the atrial threshold was previously expected

With respect to the effect of position changes, the atri-

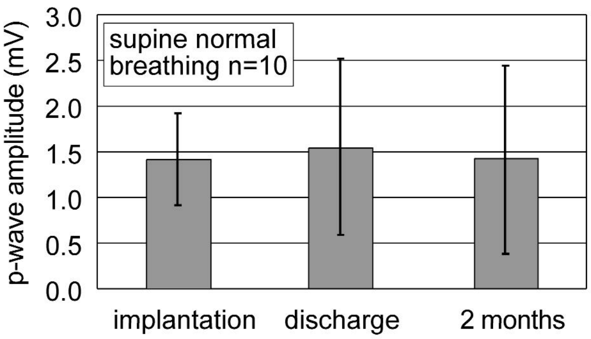

Figure 3. Obtained P-wave values during implant and two follow-ups in supine position for 10 patients.

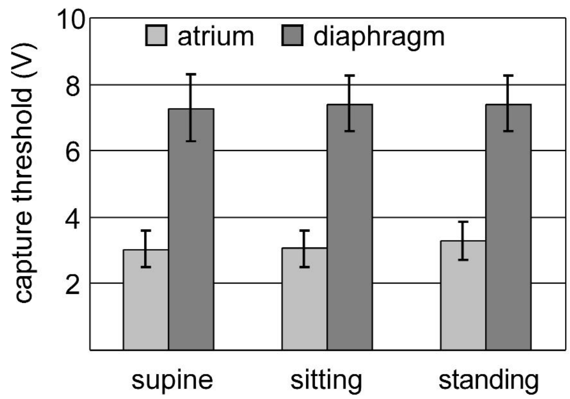

Figure 5. Atrial and diaphragmatic capture thresholds (pulse width: 0.5 ms) obtained with VECATS at supine, sitting, and standing positions with normal respiration during discharge follow-up.

al and diaphragmatic capture thresholds in supine, sitting, and standing position obtained during discharge and 6-week follow-up are summarized in Figure 5. During discharge, the atrial thresholds were 3.0 ± 0.5 V, 3.1 ± 0.5 V and 3.3 ± 0.6 V for supine, sitting, and standing positions, respectively. The measurements during the 6-week follow-up showed no significant changes. Consequently, the effect of changes in posture can be neglected with VECATS since there are no significant variations in the atrial threshold.

Furthermore, the effect of the Valsalva maneuver on threshold stability and safety with respect to diaphragmatic stimulation was observed. Mean atrial thresholds of 3.3 ± 0.6 V during normal breathing and of 3.6 ± 0.6 V during Valsalva maneuver were obtained at the discharge follow-up in standing position. Again, a high safety margin and no significant changes were also observed after 6 weeks (Figure 6).

Analyzing the 24 hours Holter recording we observed approximately 74% of atrial capture during daily activities.

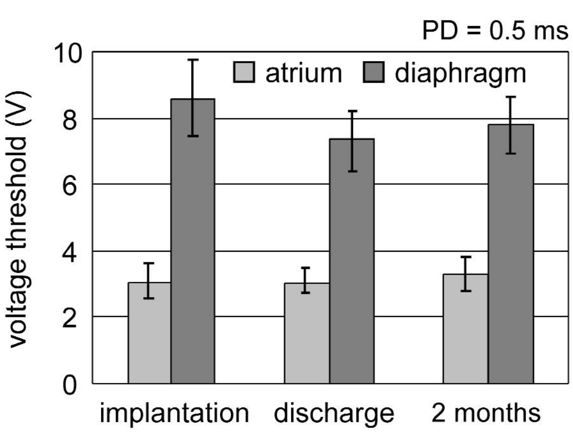

Figure 4. Atrial and diaphragmatic pacing threshold at supine position and with normal respiration during implantation to the 2-months follow-up.

Discussion

At our center, atrial thresholds in the range of 3.0 V and a high safety margin of at least 142% with respect to diaphragmatic stimulation have been observed. These similarly low and consistent threshold values obtained during several follow-ups prove the VECATS configuration to be a feasible and reliable configuration for pacing with floating electrodes, while maintaining the reliable bipolar sensing properties of VDD single-lead systems. The atrial capture thresholds remain stable and within a high safety margin towards diaphragmatic stimulation. Since the ring electrodes do not contact the atrial walls, effects like high acute thresholds due to fibrosis or ischemia are eliminated. In consequence, no rise of atrial thresholds is observed. Furthermore, as a result of pacing via floating electrodes, the stimulation becomes independent from the point of fixation.

A major concern in the design of single-pass is the facilitation of the implant procedure. The clear implant procedure of the VECATS lead provides short implantation times yielding all the expected benefits of a simplified and practical dual-chamber system.

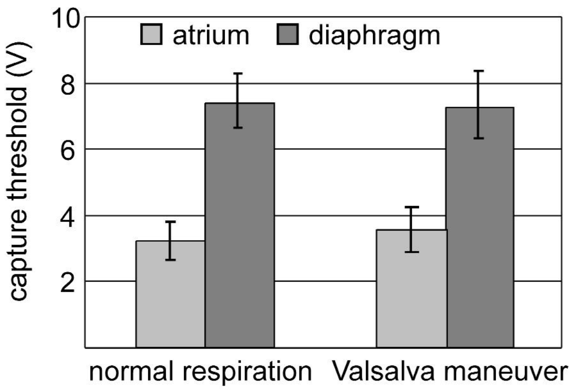

Figure 6. Atrial and diaphragmatic capture threshold with normal respiration and Valsalva maneuver (pulse width: 0.5 ms; n = 10).

Conclusion

With the VECATS configuration, stimulation of a large number of cardiac cells in the sinoatrial region becomes possible, providing reliable and physiologic pacing with floating ring electrodes of a single-pass lead. Further investigations have to be performed in order to assess information regarding system performance in the long term and during daily-life activities.

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