Lead Concepts for Fifth Generation ICDs

A. REVISHVILI
A.N. Bakulev Institute of Cardiovascular Surgery, Russian Academy of Medical Sciences, Moscow, Russia

M. SCHALDACH, T. THONG
Department of Biomedical Engineering, University of Erlangen-Nuremberg, Erlangen, Germany

Summary

With the availability of fifth generation dual-chamber implantable cardioverter-defibrillators (ICDs), a new set of ICD leads is necessary to meet the requirements for sensing and providing therapies in the atrium. In this paper we will review the capabilities of existing lead systems, then discuss some new lead concepts for these fifth generation ICDs. Specifically, we will look at the requirement for a single lead system, a dual lead system, and a triple lead system, including a coronary sinus lead for bi-atrial pacing and atrial defibrillation.

Key Words

defibrillation, ICD, dual-chamber defibrillator, atrial fibrillation, AV discrimination, supraventricular tachycardia, SVT, coronary sinus, single lead ICD system, bi-atrial pacing, high rate pacing.

Introduction

Since the first fifth generation ICD was implanted [1], a succession of new dual-chamber ICDs[2-4] have entered the market. The impetus for the development of these dual-chamber ICDs has been the reduction of inappropriate shocks due to atrial tachyarrhythmia, which can occur in as much as 41% of the ICD patient population[5-8]. In addition, dual-chamber ICDs provide improved hemodynamics associated with DDD bradycardia support, as opposed to VVI. Thus the emphasis has been on the discrimination of arrhythmias of ventricular origin from those of supraventricular origins, i.e., AV discrimination[9].

While most of this first wave of fifth generation ICDs do not support atrial therapies for atrial tachyarrhythmia, we expect the next to do so. The atrial tachyarrhythmias to be treated are: atrial flutter and atrial fibrillation. For the first type of arrhythmia, atrial anti-tachycardia pacing (AATP) therapy has been proposed[10]. High-rate pacing[11], bi-atrial pacing[12] and atrial defibrillation[13] therapies are considered for the second type.

Both AATP and high-rate pacing are simply extensions of the atrial-pacing concept. Bi-atrial pacing requires the pacing of both the right and left atrium. Atrial defibrillation is simply R-synchronous cardioversion. Thus, the primary mission continues to be the treatment of all ventricular tachyarrhythmia episodes.

In this paper, we will consider some intravenous lead concepts that can efficiently support the above therapies for terminating atrial tachyarrhythmias in these dual-chamber ICDs. Consequently, these ICDs will always have the capacity to deliver ventricular anti-tachycardia pacing and ventricular shocks. The treatment of atrial tachyarrhythmia is an important secondary mission of these dual chamber ICDs. This feature makes it a different device than the atrial defibrillators[14] which have no ventricular defibrillation capability.

Methods

Atrial defibrillation, which can successfully terminate episodes of atrial fibrillation and atrial flutter, can be delivered with the existing lead system using a 3-shock electrode system[9,15]. The system consists of the ICD "active" housing (HSG) in the left pectoral area, a shock coil in the vena cava superior (VCS)/ right atrium, and a shock coil in the right ventricle (RV) as illustrated in Figure 1.

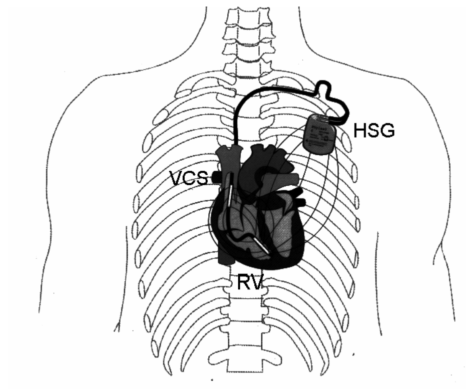

Figure 1. *Present atrial defibrillation electrode configuration.*

While effective, the above electrode configuration results in somewhat of a waste in energy in the path from the RV to the HSG. This path covers most of the left ventricle and only partially covers the left atrium. The ventricular coverage is not needed in atrial defibrillation, whereas any increase in atrial coverage will improve atrial defibrillation efficiency. Furthermore, it is believed that this path is a source of pain as the pectoral muscles contract when a shock is delivered. To reduce both the pain and the atrial defibrillation threshold (ADFT), a coronary sinus (CS) shock coil can be used[13]. In our tests during intra-operative procedures (IOP) for a number of dual chamber Biotronik, Inc. Phylax AV ICD implants, atrial defibrillation was attempted with the lead system depicted in Figure 2. The shock electrodes consist of the ICD housing (not shown), the VCS coil in the vena cava superior/right atrium, and the CS shock coil in the coronary sinus.

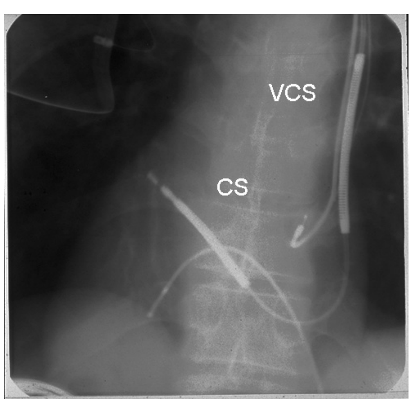

Figure 2. *Coronary sinus shock coil during IOP tests.*

In our IOP tests, since the lead introduced in the coronary sinus is the same lead used in the ventricle, shown in Figure 1, we also have the capability to pace the left atrium using the tip and ring electrodes at the distal end of the lead. When this is combined with atrial pacing, we can achieve bi-atrial pacing. Our pacing location in this case is not optimal since the pacing ring is in the distal CS, whereas it has been reported that the coronary sinus ostium is a better location for bi-atrial pacing[12].

With the lead system considered so far, for dual-chamber defibrillation we need the following leads:

- ventricular defibrillation lead with the vena cava superior/right atrium shock coil, right ventricular shock coil, and the ring and tip electrodes for sensing/pacing in the ventricle,
- atrial sense/pace lead,
- coronary sinus lead: with a proximal pacing ring (in CS ostium) and a distal shock coil.

This is a 3-lead system. Note that if we limit ourselves to 3 independent shock electrodes, then the ICD housing is not used as a shock electrode.

Next we investigated the possibility of reducing the number of leads to 2 as follows:

- ventricular defibrillation lead with the vena cava superior/right atrium shock coil, right ventricular shock coil, and the ring and tip electrodes for sensing/pacing in the ventricle, as previously,
- coronary sinus lead: dual ring for atrial sensing and occasional atrial pacing, coronary shock coil, CS ring for bi-atrial pacing.

This system would be used with patients who are chronotropically competent and thus require mostly VDD bradycardia support and only occasional DDD pacing support. The dual ring will reside in the mid atrium for good sensing and the CS ring will be positioned in the coronary sinus ostium.

The dual ring for atrial sensing would be similar to the atrial sensing electrodes in single lead systems for VDD pacemakers. While sensing during normal sinus activities has been well established, there was some doubt as to whether these rings can sense the atrial signals during atrial flutter and atrial fibrillation. Using a Biotronik, Inc. SL pacemaker lead, we were able to monitor signals during episodes of atrial flutter and expect no problem with atrial fibrillation signals[16].

Next is the issue of atrial pacing. While bipolar pacing[17] can pace from the floating rings, it tends to require much larger voltages. Other methods of atrial pacing[18] would require the development of new pacing circuitry. Using a somewhat similar concept we have experimentally investigated pacing from a ring in the atrium (different electrode) to the vena cava shock coil (indifferent electrode). Preliminary results indicate that this method is feasible with acceptable pacing thresholds.

Next we considered an approach to pacing the left atrium. We were successful in pacing from the coronary sinus ring (different electrode) to the vena cava coil (indifferent electrode). In our tests, the ring was in the far CS, which is not a good location for left atrial pacing. Pacing thresholds were found to be slightly higher.

When atrial shock therapy is not necessary, but where atrial monitoring is required for VDD bradycardia pacing and/or for AV discrimination, the 2-lead system can be reduced to a single lead system with a combined set of electrodes which consists of the following:

- vena cava superior/right atrium shock coil
- 2 atrial rings for sensing
- right ventricular shock coil
- ring and tip for ventricular sensing/pacing

This would require the development of a 6-conductor lead, which may be fairly large. While technically feasible, the large lead diameter affects lead flexibility, which is probably not acceptable to most physicians. If this can be reduced to a 4-conductor lead, then this will definitely become attractive.

Results

During a number of IOP tests, we were able to test the various shock coil configurations for efficacy of atrial defibrillation with biphasic shock pulses. The results, the statistics of which are not meaningful because of the small sample size, are summarized in Table 1.

Atrial Rhythm	Shock Electrodes	ADFT
AFib	VCS →CS	< 1 J
AFib	VCS →HSG	< 3J
Aflutter	VCS →CS	< 1 J
Aflutter	RV → VCS, CS	> 3 J
Aflutter	VCS →HSG	< 3J

Table 1. *ADFT as a function of shock electrode configuration.*

Our general experience indicates that the best configuration for atrial defibrillation is VCS → CS. Thus, from a systems viewpoint, the implementation of a dual-chamber defibrillator will require that we use three independently programmable shock electrodes: RV, VCS, CS. During atrial defibrillation, the RV electrode is switched out. During ventricular defibrillation, the CS is switched out since larger energy is normally used, which should not be discharged within the fairly fragile coronary sinus.

The atrial and ventricular IEGMs for a successful atrial defibrillation using the CS →VCS shock coils is illustrated in Figure 3. This was recorded in the internal memory of a Biotronik, Inc. Phylax AV. This is a Type B (shock not immediately effective) successful defibrillation[19] indicating that the shock energy is probably just sufficient for effective defibrillation.

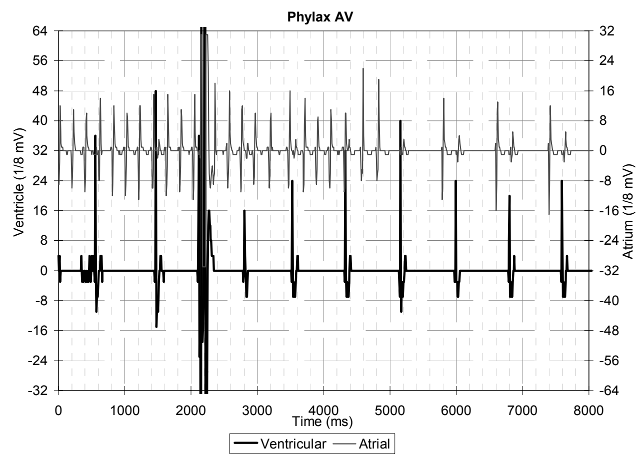

Figure 3. *Successful 1 J atrial defibrillation using CS->VCS shock electrodes.*

The sensing of atrial flutter signals with floating rings was tested using a Biotronik, Inc. SL pacemaker lead. Signals in the range of 0.125 mV to 0.5 mV were recorded in the IEGM storage of a Biotronik, Inc. Phylax AV during induced atrial flutter episodes. The signal amplitude increased to 0.75 mV during atrial flutter.

Atrial pacing threshold measurements are summarized in Table 2 for 0.5 ms pulses.

Configuration	Bipolar	distal atrial ring to VCS	CS ring to VCS
Threshold	2.7 V	1.2 V	3.1 V

Table 2. *Pacing thresholds with a pacemaker single lead system with floating atrial rings and with a coronary sinus ring.*

The atrial pacing threshold is slightly larger than the regular pacing threshold using bipolar electrodes in the atrial appendage. It is definitely better than that of the bipolar pacing with just the floating rings. Since the above value for the left atrial pacing results from using a ring in the distal CS, the non-desirable position, it is expected that the pacing threshold for a ring in the coronary sinus ostium will be much smaller.

Discussion

From our IOP tests with a number of patients, the CS and right atrium/vena cava configuration of shock electrodes appears to require from 2 to 3 times less energy for successful atrial defibrillation than any of the other configurations. Thus, the need arises to develop a small CS lead with both a coil and a pacing ring to achieve the low defibrillation energy, and consequently a low level of pain[20] in response to these non-life-threatening tachyarrhythmias. Fixation of this CS lead is another area of research interest.

While a 3-lead system is required for patients with moderate to high atrial pacing requirements, a dual chamber ICD 2-lead system appears to be possible. Of course, higher sensitivity would be required in the atrial circuit with sensing from rings floating in the atrium than would be needed in the case of a tip-ring atrial sensing, but there appears to be no problem in sensing the fast atrial tachyarrhythmic signals.

Conclusion

In this report, we have described a proposed set of lead requirements for the expected second wave of dual chamber ICDs that will be offering effective AV discrimination, and true dual-chamber therapy.

A 3-lead system is expected to be the bulk of the leads to be implanted to support these dual chamber ICDs. A 2-lead system appears possible for a subset of this patient population.

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