Single-Coil Defibrillator Leads Yield Satisfactory Defibrillation Safety Margin in Hypertrophic Cardiomyopathy

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Background: Single-coil defibrillator leads have gained favor because of their potential ease of extraction. However, a high defibrillation threshold remains a concern in patients with hypertrophic cardiomyopathy (HCM), and in many cases, dual-coil leads have been used for this patient group. There is little data on using single-coil leads for HCM patients.

Methods and Results: We evaluated 20 patients with HCM who received an implantable cardioverter-defibrillator (ICD) on the left side in combination with a dual-coil lead. Two sets of defibrillation tests were performed in each patient, one with the superior vena cava (SVC) coil “on” and one with the SVC coil “off”. ICDs were programmed to deliver 25 joules (J) for the first attempt followed by maximum energy (35 J or 40 J). Shock impedance and shock pulse width at 25 J in each setting as well as the results of the shock were analyzed. All 25-J shocks in both settings successfully terminated ventricular fibrillation. However, shock impedance and pulse width increased substantially with the SVC coil programmed “off” compared with “on” (66.4±6.1 ohm and 14.0±1.3 ms “off” vs. 41.9±5.0 ohm and 9.3±0.8 ms “on”, P<0.0001 respectively).


Key Words: Defibrillation threshold; Hypertrophic cardiomyopathy; Implantable cardioverter-defibrillator; Single-coil leads

Dual-coil implantable cardioverter-defibrillator (ICD) leads were developed to minimize the risk of high defibrillation thresholds (DFTs) in patients receiving ICD therapy.1 However, single-coil ICD leads have recently gained favor as they minimize fibrosis in the superior vena cava (SVC), and thereby reduce the risk associated with future lead extraction.2 With the advent of biphasic defibrillation waveforms and high-energy devices, an adequate defibrillation safety margin is present in most patients receiving a single-coil ICD lead.3–5 ICD has been indicated for patients with hypertrophic cardiomyopathy (HCM) who are at high risk of ventricular arrhythmias.6,7 However, a high DFT remains a concern in patients with HCM because of the large left ventricular mass associated with this condition, and dual-coil leads are often used for this patient group.8,9 Studies to determine whether DFTs are higher in HCM than in other conditions have had mixed results, and there are limited data comparing single- and dual-coil ICD systems in HCM.10 We hypothesized that with modern biphasic active can systems, both dual-coil and single-coil leads would effectively terminate ventricular fibrillation (VF). We therefore compared the results of defibrillation testing using dual- and single-coil settings in HCM patients undergoing left-sided ICD implantation.

Patient Population

We studied 20 consecutive patients with HCM undergoing initial left-sided ICD implantation using a high-energy ICD manufactured by St. Jude Medical (St. Paul, MN, USA) in combination with a dual-coil lead at the National Cerebral and Cardiovascular Center (Suita, Osaka, Japan) between July 2011...
and September 2013. ICD models included CD2235-40Q (n=12), CD2277-36 (n=6), CD1235-40Q (n=1) and CD2217-36Q (n=1). Dual-coil ICD leads included 0295 manufactured by Boston Scientific (Marlborough, MA, USA; n=13), 7120Q 36Q (n=1). Dual-coil ICD leads included 0295 manufactured by Medtronic (Dublin, Ireland; n=1). The diagnosis of HCM was established by unexplained increased left ventricular posterior wall thickness at end-diastole. The ICD lead was placed in the apex of the right ventricle in all cases. The defibrillation testing was performed in each patient twice during the procedure: first programming the ICD with the SVC coil “on” and next with the SVC coil “off”. As shown in Figure 2, the total pulse width and shock impedance were significantly greater using the single-coil setting (67.4±6.9 ohm/14.1±1.3 ms with the SVC coil “on” vs. 42.3±5.2 ohm/9.3±0.8 ms with SVC coil “off”, P<0.0001, respectively). The relationship between shock impedance and total shock pulse width is shown in Figure 3. The distribution was clearly separated between the 2 settings.

**VF Induction and Defibrillation**

ICD implantation was performed under general anesthesia. The ICD lead was placed in the apex of the right ventricle in all cases. The defibrillation testing was performed in each patient twice during the procedure: first programming the device with the SVC coil “on” and next with the SVC coil “off”, with 5 min between tests. ICDs were programmed to 1 zone setting, with a tachycardia cut off of 200 beats/min and a 25 joules (J) shock for the first attempt followed by maximum energy shocks, all with 65% fixed tilt. Figure 1 illustrates the shock waveform. Fixed energy delivery of 25 J with 65% fixed tilt caused a change in the duration of the wave form according to the shock impedance. Higher impedance automatically prolonged the wave duration. VF was induced by direct current or shock on T wave method. An external defibrillator was available for rescue defibrillation. Shock impedance and shock pulse width delivered at 25 J for each coil setting, as well as the success or failure of the shock, were analyzed. Shock pulse width was expressed as the total duration of waveform (ie, the sum of phases 1 and 2). Dual-coil setting was programmed in all cases for follow-up. Written informed consent for the defibrillation testing during the procedure was given by all patients and retrospective data analysis was approved by the National Cerebral and Cardiovascular Center institutional review board (IRB #M25-062-3).

**Statistical Analysis**

Categorical data are expressed as percentages and continuous variables as mean with standard deviation. The values in each setting were compared using paired t-test. P<0.05 was considered statistically significant. Data were analyzed with JMP statistical software (version 1.0.0, SAS, Cary, NC, USA).

**Results**

The clinical characteristics of the 20 study patients are shown in the Table. Left ventricular systolic function was preserved in all patients. Most patients received an ICD for primary prevention of sudden cardiac death (70%); dual-chamber ICDs were used in all but 1 patient. Many of the patients were taking antiarrhythmic drugs, either amiodarone or cibenzoline (Table). VF was successfully terminated by the first 25-J shock in all cases using both settings: SVC coil “on” and “off”. As shown in Figure 2, the total pulse width and shock impedance were significantly greater using the single-coil setting (67.4±6.9 ohm/14.1±1.3 ms with the SVC coil “on” vs. 42.3±5.2 ohm/9.3±0.8 ms with SVC coil “off”, P<0.0001, respectively). The relationship between shock impedance and total shock pulse width is shown in Figure 3. The distribution was clearly separated between the 2 settings.

**Discussion**

In this study, we found that safety margin testing was equally effective with single-coil and dual-coil defibrillation at 25 J in a population of patients with HCM who received a left-sided ICD In addition, we found a considerable difference in shock impedance and pulse width between the 2 settings: SVC coil “on” and SVC coil “off”. These findings suggest that the use of a single-coil lead for patients with HCM in combination...
with left chest placement of a high-energy device delivering at least 35 J provides an adequate defibrillation safety margin. This finding has important implications. Patients with HCM often receive ICDs at a relatively young age, and avoidance of a second coil, and potential future extraction complexity, are therefore important considerations.

**DFT With Single-Coil Lead**

In recent years, single-coil ICD leads have been advocated for left-sided device implantation. Transvenous lead extraction for infection or lead failure carries higher risk in ICD recipients compared with patients with pacemakers, and this excess risk results partly from greater venous adherence caused by vigorous fibrosis around the SVC coil. Other reports indicate that defibrillators implanted on the left side with a single-coil lead have a roughly 5-J higher DFT compared with dual-coil devices. It is important to recognize that the benefit of the SVC coil depends on the location (innominate vein-SVC junction better than SVC-right atrium junction) and the device waveform tilt (higher tilt devices benefit from the waveform duration reductions produced by the lower resistance associated with an SVC coil). Recognizing that current ICDs provide a maximum energy of 35–40 J, it has become rare for patients to lack the conventional 10-J safety margin for defibrillation. As a result, the need for routine DFT testing at implantation has been reconsidered.

**DFT in HCM**

There is limited literature regarding DFTs in HCM, specifically compared with other groups of patients receiving an ICD. Some reports suggest higher DFTs, which may correlate with the extent of increased LV wall thickness. However, there

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**Figure 2.** Difference of pulse width (Left) and shock impedance (Right) between the 2 settings: SVC coil “on” (dual-coil setting) and SVC coil “off” (single-coil setting). With the single-coil setting, both values increased in all 20 cases. Values are expressed as mean±standard deviation. Ω, ohms; SVC, superior vena cava.

**Figure 3.** Relationship between shock impedance and shock pulse width. Red dots are the data from the SVC coil “on” (dual-coil setting) and blue dots are the data from SVC coil “off” (single-coil setting). The distribution is clearly separated but VF was successfully terminated in all cases using both settings. Ω, ohms; SVC, superior vena cava; VF, ventricular fibrillation.
are no reports comparing DFTs using single- vs. dual-coil leads in HCM patients. In the SIMPLE trial,24 dual-coil leads were used in more than half of the enrolled patients, but patients with HCM represented only 3.8% of the study population. Therefore, in many hospitals, dual-coil leads are favored in patients with HCM.36 Our study showed the efficacy of a 25-J shock with the SVC coil “off”, representing at least a 10-J safety margin for defibrillation.

Effect of Antiarrhythmic Drugs on DFT
Antiarrhythmic drugs are well known to influence the DFT. Amiodarone in particular increases the DFT, albeit modestly.35-37 Cibenzoline is also widely prescribed in Japan to attenuate dynamic left ventricular obstruction. In this study, the majority of patients were receiving treatment with either amiodarone (n=6) or cibenzoline (n=7), or both (n=1). Despite the frequent use of these drugs, all 25-J shocks successfully terminated VF.

Appropriate Shock Pulse Width
This study demonstrated the effect of a single-coil ICD lead on the shock pulse width. Observed shock pulse width in the single-coil lead setting was 14.1±1.3 ms, which was longer than the anticipated ideal shock pulse width when considering the time constant of human myocardial cells. Kroll et al. explained the efficacy of biphasic shock pulse on defibrillation using a charge burping theory and the optimal pulse duration was typically (depending on the shock time constant) 4 ms for the first phase and approximately 3 ms for the second phase, taking into account the time constant of the cell membrane.36-37 Delivering more energy by increasing waveform duration could paradoxically reduce defibrillation efficacy. Our results indicate that the efficacy of 25-J shocks was sufficient to overwhelm the potentially adverse effect of an excessively long shock pulse width. In some ICDs, programmable shock duration or tilt adjustment may permit lowering the DFT when using a single-coil lead.33 Importantly, however, in none of the 20 patients was there a need to optimize shocks despite the use of a single-coil lead, suggesting this practice is safe in HCM.

Study Limitations
Our results are best understood in the context of their limitations. First, the number of patients studied was limited. However, this is commonly the situation in studies of HCM, given that the disease prevalence is limited. Additionally, defibrillation at 25J was tested only once for each setting: SVC coil “on” and SVC coil “off”. However, successful defibrillation by a 25-J shock in all 20 patients with HCM strongly supports the feasibility of using a single-coil lead for these patients. Lastly, left ventricular wall thickness of the studied patients was mildly increased, not extremely hypertrophic. Further study including patients with more severely increased left ventricular wall thickness is warranted to confirm the efficacy of single-coil ICD leads for patients with HCM.

The results of this study only apply to left-sided ICD implantation. Right-sided generator implantation is associated with higher DFTs, and the lack of an SVC coil may have greater implications for successful defibrillation.38-40

Conclusions
The use of a single-coil ICD lead in conjunction with left-sided device implantation provides an acceptable defibrillation safety margin in patients with HCM. It seems appropriate to provide the long-term advantages of single-coil leads to this subset of ICD recipients.

Disclosures
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References
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