DEVICE THERAPY

RESEARCH ARTICLE

Single-coil Versus Dual-coil ICD Lead Shock Efficacy in a Large ICD Registry

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ABSTRACT. Single-coil leads account for 5–10% of transvenous implantable cardioverter-defibrillator (ICD) leads. Single-coil leads improve extractability while allowing adequate safety margin for defibrillation in new generation devices (output of 35–41 joules). Limited clinical shock efficacy data exist in patients having single-coil ICD systems. A retrospective analysis was conducted from St. Jude Medical’s ACT ICD registry (St. Paul, MN). Treated arrhythmia episodes were independently adjudicated to confirm true VT/VF (ventricular tachycardia or ventricular fibrillation) events receiving an ICD shock for termination over 2 years of follow-up post implant. Only appropriate shocks delivered for VT/VF were used for comparisons in this study. A total of 5,424 patients (269 single coil, 5,155 dual coil) were enrolled. A total of 618 patients (22 single versus 606 dual) received a total of 1,447 ICD shocks in the registry (38 single versus 1409 dual). Of the 38 shocks delivered in patients with single-coil leads, 20 were delivered appropriately in 12 patients for VT/VF, 17/20 converted with a single shock (85%). Comparison was made with an age- and left ventricular ejection fraction (LVEF)-matched subset of 80 shock episodes from 55 dual-coil lead patients. Single shock conversion for VT/VF was 70/80 (87.3%) in the dual-coil group. No difference was seen in single- versus dual-coil first shock arrhythmia termination of VT/VF (85% single-coil versus 87.5% dual-coil, p = 0.90). Single-coil ICD leads appear equivalent to dual-coil ICD leads in regards to clinical first shock efficacy to rescue VT/VF in modern high-voltage ICD systems followed for 2 years post device implant. Owing to the small single-coil lead sample size, a larger study is necessary to confirm the findings.

KEYWORDS. defibrillation threshold, dual coil, implantable cardioverter-defibrillator, single coil, shock efficacy, transvenous lead, ventricular fibrillation, ventricular tachycardia.

Introduction

Implantable cardioverter-defibrillator (ICD) systems to abort VT/VF (ventricular tachycardia or ventricular fibrillation) arrest have evolved from epicardial patches implanted via thoracotomy to modern transvenous pectoral systems, including leadless ICDs implanted subcutaneously. Transvenous leads are manufactured with true bipolar or integrated bipolar sensing and either a single right ventricular (RV) coil, or dual superior vena cava (SVC) and RV coils, initially favored in “cold-can” devices due to concerns over failure to defibrillate. Early studies on active can defibrillation thresholds (DFTs) at implant demonstrate either a small reduction in DFT energy for dual-coil versus single-coil leads, or no statistical difference depending on the testing method; however, no follow-ups on treatment of VT/VF episodes after implant are available. Current generation defibrillator generators are capable of delivering antitachycardia pacing (ATP) during charging, and maximum

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Methods
Retrospective analysis was conducted from the St. Jude Medical ACT ICD registry (St. Paul, MN) in which patients were followed for a period of 2 years post implant. VT/VF device detection and therapies were programmed independently by each participating investigator at their discretion. All arrhythmia episodes receiving an ICD shock were independently adjudicated by a panel of cardiac electrophysiologists blinded to patient or device data. True VT/VF events receiving an ICD shock for termination were subsequently identified. Only appropriate shocks, those delivered for VT/VF, were used for comparisons in this study. Single-coil ICD lead events in 22 patients were compared with an age and left ventricular ejection fraction (LVEF) matched cohort of 55 patients with dual-coil ICD transvenous leads. Data analysis was performed using standard statistical methods for mean and standard deviation (SPSS, Chicago, IL). A chi-square test was used for comparison between groups with p<0.05 indicating statistical significance. A two-tailed Student’s t-test was used for comparison of continuous variables with 95% CI, and statistical significance at p<0.05.

Results
A total of 5,424 ICD or cardiac resynchronization therapy defibrillator (CRT-D) patients (269 single-coil leads, 5,155 dual-coil leads) were enrolled in the ACT registry. There were 618 patients (22 single-coil versus 606 dual-coil patients) who received a total of 1,447 ICD shocks in the registry (38 single coil versus 1409 dual coil). Patient demographics, ICD lead model number and LVEF are outlined in Table 1. There were no significant differences between the groups in regards age, sex, LVEF, proportion of primary versus secondary prevention devices, or ischemic versus non-ischemic cardiomyopathy. There was a trend towards a higher percentage of female patients in the single-coil group. Left ventricular dimensions, use of amiodarone, right- versus left-sided implants, and clinical syncope episode data were not available from this registry. Of the 38 shocks delivered in patients with single-coil leads, 20 were delivered appropriately for VT/VF, and 17/20 converted with a single shock (85%). Intracardiac electrograms from ICD device interrogation were reviewed; selected episodes for VT-1, VT-2, and VF in single-, and single- or dual-lead devices are included (Figures 1, 2, and 3). Eleven of 12 patients had a successful VT/VF event rescued by a single ICD shock (91.7%). One patient required three consecutive high output (830 V) shocks for VF termination.

Comparison was made with an age- and LVEF-matched subset of 80 shock episodes from 55 dual-coil lead patients. Single ICD shock conversion for VT/VF was 87.5% in the dual-coil lead group (70/80), with 10 patients requiring an additional ICD shock to restore sinus or paced rhythm. Forty-five of 55 patients had conversion from VT/VF with a single shock (81.8%). All patients in both groups were successfully rescued by ICD therapy; no patient deaths from VT/VF occurred. No difference was seen in single- versus dual-coil ICD lead first shock arrhythmia termination of true VT/VF events (85% single-coil versus 87.3% dual-coil first shock success, p=0.90). There was no difference in the proportion of patients rescued by a single ICD shock (11/12 in the single-coil group, 45/55 in the dual-coil group, p=0.27). Only one patient in the single-coil group required multiple shocks to terminate a single episode.

Mean shock strength was 772±99 volts in the single-coil group versus 750±100 volts in the dual-coil group (p=0.43). There was no difference in the proportion of ICD shocks delivered for VT-1/VT-2 zone events (<240 bpm) versus VF episodes (>240 bpm) between groups (p=0.76 for VT-1/VT-2, p=0.27 for VF). The majority of ICD shocks delivered for VT/VF episodes were for sustained VT (<240 bpm) in both groups (90% in single coil, 81.2% in dual coil, p=0.76). Notably a higher percentage of patients received inappropriate ICD shocks in the single-coil ICD lead group (47.3% single versus 24.5% dual, p=0.04), without a difference in single VF only zone detection programming (Table 2). A greater proportion of patients in the single-coil group

<table>
<thead>
<tr>
<th>Group (n)</th>
<th>Single coil (22)</th>
<th>Dual coil (55)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>58±15</td>
<td>61.2±11.4</td>
<td>0.33</td>
</tr>
<tr>
<td>Male (%)</td>
<td>15 (68.2%)</td>
<td>51 (93%)</td>
<td>0.25</td>
</tr>
<tr>
<td>Caucasian (%)</td>
<td>16 (72.7%)</td>
<td>45 (81.8%)</td>
<td>0.59</td>
</tr>
<tr>
<td>LVEF%</td>
<td>29±13.3</td>
<td>28.5±10.8</td>
<td>0.86</td>
</tr>
<tr>
<td>Primary prevention (%)</td>
<td>13 (59.1%)</td>
<td>36 (65.5%)</td>
<td>0.75</td>
</tr>
<tr>
<td>Ischemic cardiomyopathy (%)</td>
<td>15 (68.2%)</td>
<td>39 (70.9%)</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Table 1: Patient demographics and implantable cardioverter-defibrillator lead model numbers

LVEF%: left ventricular ejection fraction; M: Medtronic; S: St. Jude Medical.
had a tuned waveform, suggesting concern regarding DFT at implant (4/20 in single coil, 1/80 in dual-coil group, \( p < 0.02 \)). Maximum output first ICD shock programming was noted in 15 of the 20 single coil and 37 of the 80 dual-coil lead episodes (\( p = 0.11 \)). Although not statistically significant, a trend was noted towards

Figure 1: Implantable cardioverter-defibrillator intracardiac electrogram for treated ventricular tachycardia (310-ms cycle length) episode in a single coil, dual-chamber device.

Figure 2: Intracardiac electrogram for treated fast ventricular tachycardia (290-ms cycle length) episode which failed antitachycardia pacing \( \times 3 \), in a single-coil, dual-lead device.
higher maximum output first shock programming in the single-coil group.

Discussion

We report the first clinical data comparing shock efficacy of ICD treatment for true VT/VF events comparing single- versus dual-coil ICD transvenous leads in a large prospectively followed ICD registry. Patient data include all ICD shock-treated arrhythmia episodes over 2 years following device implant. There was no significant difference in first shock success, or overall treatment success in single- versus dual-coil ICD lead systems; all devices had active cans. Programming for detection and VT/VF therapy was at the discretion of the implanting physicians, with a high rate of inappropriate therapy in the single-coil group. This may be the result of a trend towards routine maximum output, single zone “out of box” settings in the single-coil group due to fears over failure to rescue an event by the implanting physician. Maximum output first shock programming was not statistically higher in the single-coil group, but a trend towards higher first shock output, and VF only zone detection in the single-coil group was evident; a larger study is necessary to confirm this finding. Notably, a significantly higher proportion of patients in the single-coil group had a tuned waveform for defibrillation programmed, suggesting there may have been concern for high DFT by the implanting physician at initial implant. Treated episodes in this study were predominantly for VT (<240 bpm), either as first-line treatment or following attempted antitachycardia pacing.

Early studies on active can DFT demonstrate a small reduction in DFT energy for dual-coil versus single-coil leads. A study of 50 consecutive patients with a dual-coil

Table 2: Implantable cardioverter-defibrillator shock episode data, output, and programming

<table>
<thead>
<tr>
<th></th>
<th>Single coil</th>
<th>Dual coil</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VT/VF episode first shock conversion</td>
<td>17/20 (85%)</td>
<td>70/80 (87.5%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Patients with VT/VF single shock conversion</td>
<td>11/12 (91.7%)</td>
<td>45/55 (81.8%)</td>
<td>0.27</td>
</tr>
<tr>
<td>Mean delivered output (volts)</td>
<td>772 ± 99</td>
<td>750 ± 100</td>
<td>0.43</td>
</tr>
<tr>
<td>First shock programmed at maximum output</td>
<td>15/20 (75%)</td>
<td>37/80 (46.3%)</td>
<td>0.11</td>
</tr>
<tr>
<td>Tuned waveform (n)</td>
<td>4/20 (20%)</td>
<td>1/80 (1.3%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Inappropriate ICD shocks</td>
<td>18/38 (47.3%)</td>
<td>26/106 (24.5%)</td>
<td>0.04</td>
</tr>
<tr>
<td>Shock only VF programming (single VF zone)</td>
<td>6/22 (27.3%)</td>
<td>11/55 (20%)</td>
<td>0.57</td>
</tr>
<tr>
<td>Shock delivered for VT</td>
<td>18/20 (90%)</td>
<td>65/80 (81.2%)</td>
<td>0.76</td>
</tr>
<tr>
<td>Shock delivered for VF</td>
<td>2/20 (10%)</td>
<td>15/80 (18.8%)</td>
<td>0.27</td>
</tr>
</tbody>
</table>

ICD: implantable cardioverter-defibrillator; VT: ventricular tachycardia; VF: ventricular fibrillation.

Figure 3: Intracardiac electrogram for treated ventricular fibrillation (<200-ms cycle length) episode in a single-coil, single-lead device.

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ICD lead and active can, underwent formal DFT testing at implant with the SVC coil programmed on or off in random order (mean DFT 8.7 joules ± 4.0 in dual-coil configuration, versus 10.1 joules ± 5.0 in the single coil configuration). A randomized study in 76 patients from 2003 demonstrated no significant difference in DFT with single- or dual-coil leads (DFT 10.2 ± 5.2 joules in dual-coil group n=38, 10.3 ± 4.1 joules in single-coil group n=38). Our study provides the first true outcomes data over 2 years of follow-up, confirming that any difference in DFT at ICD implant between single- and dual-coil leads (likely minor) does not appreciably affect first shock success for VT/VF conversion. This finding is important as implanting physicians in the United States have opted for dual-coil leads in >90% of patient implants, despite no data to support superiority of dual-over single-coil leads.

An elevated defibrillation threshold may be encountered at implant regardless of the choice of transvenous ICD lead type. Clinical predictors of high DFT (>20 joules in a study by K Khalighi et al,5 including dilated LV chamber (left ventricular end diastolic diameter (LVEDD) >6.7 cm ± 1.4)), body size (body surface area (BSA) >2 m²), chronic amiodarone use and RV coil position. A >1 cm increase in RV coil to RV apex spacing on right anterior oblique radiography was associated with DFT >20 joules, and favors true RV apical lead positioning and integrated bipolar sensing leads. Non-ischemic dilated cardiomyopathy may raise the DFT. In the Optimal Pharmacologic Therapy in Cardioverter Defibrillator Patients study, chronic amiodarone use was associated with a small increase in DFT of 1.3±4.4 joules after 12 weeks on a mean dose of 314±243 mg. Sotalol use resulted in a decrease in mean DFT of 0.9±3.8 joules at 12 weeks on a mean dose of 167±65 mg. All patients maintained adequate safety margins for DFT. Whether these small changes in DFT are clinically relevant in modern ICD systems is not known, but certainly these factors may be additive in a single patient and should be considered in lead selection, although the high output of modern ICD generators often renders these factors irrelevant to successful VT/VF therapy.

ICD lead coil placement at implantation can affect DFT in both single and dual-coil lead systems. A study by Gold et al8 shows the position of the SVC coil at the SVC–innominate junction was optimal for DFT, while intercoil spacing of 17 cm versus 21 cm had no effect. Additionally, in single-coil leads, a shock impedance of >58 ohms was optimal. A simulation study from University of Minnesota suggests that optimal RV coil position for a single coil–active can ICD system is midcavity, and efforts to achieve proper single-coil position should favorably affect DFT at implant.9 Alternatively, consideration for insertion of an azygous coil may reduce DFT at implant.10 Chronic oral dofetilide therapy has also been shown to significantly reduce DFT over a 1–3 month period by 8 ± 3 joules, although use may be challenging in the setting of renal dysfunction or baseline prolonged QT interval.11

Lead extraction for failed or fractured leads, infected devices, or in the setting of chronic venous occlusion is associated with a risk for SVC laceration and death. Expanded polytetrafluoroethylene coating, and silicone backfilled coils facilitate lead extraction, as may the use of single-coil leads, reducing fibrosis at the SVC–RA junction. Leads implanted even <1 year may require use of a laser or mechanical extraction sheath. An additional factor supporting the use of a single-coil lead is a reduction in raw material cost by eliminating the SVC coil, which accounts for up to 60% of the total platinum (typically platinum–iridium), or silver (MP35N) content in dual-coil ICD leads, depending on the manufacturer (actual proprietary information disclosed by St. Jude Medical).

The continuing high utilization of dual-coil leads may stem from early concerns over failed VT/VF rescue in systems using a “cold can.” In the setting of modern ICD generators capable of delivering 35–41 joule outputs, our data suggest that a single-coil lead will perform equivalent to a dual-coil lead, and may be the preferred option. The proportion of right- versus left-sided ICD transvenous lead access was not available from the ACT registry. Previously reported data demonstrated higher DFT with right- versus left-sided ICD systems (mean of 5.7 joules).16 The effect of an SVC coil on DFT is dependent on shock coil impedance. SVC coil turned “on” did not affect DFT in 55% (23/42) of patients in a DFT study of right sided ICD systems. Low shock impedance (<45 ohms) can unfavorably shorten pulse duration (PD). Shortened PD led to increased DFT from a truncated waveform with lower delivered current (7/19 patients had an adverse effect on DFT with dual-coil lead SVC turned “on”).17 Four of the single-coil patients, and one dual-coil patient in our study had a tuned waveform, likely due to high DFT at insertion. A potential factor may have been a right-sided approach in these patients. High DFT may be encountered with right-sided devices regardless of lead choice.

Delivery of antitachycardia pacing therapy for VT or fast VT would not be expected to differ between single- and dual-coil leads, nor for right- versus left-sided devices. Notably in this study, the majority of shocks delivered were in fact for VT, often having failed ATP. Limitations to this study include the non-randomized nature of lead selection at implant, lack of formal DFT test data at implant, and small sample size of episodes treated for VT/VF with a single-coil ICD lead. Additionally, some clinical factors, such as amiodarone use, have not been accounted for. Regardless, this study provides an important starting point for larger formal evaluation. Combined multicenter registry data sets or prospective studies are needed to confirm the non-inferiority of single-coil ICD leads for the treatment of VT/VF; however, sponsorship for these studies has been challenging, and this study provides the best currently available data for comparison.

Conclusions

Single-coil ICD leads are equivalent to dual-coil ICD leads in regards to clinical first shock efficacy to rescue
VT/VF in modern high-voltage ICD systems. Owing to the small single-coil lead sample size, a larger study is necessary to confirm the findings. A single-coil ICD lead may improve extractability, and could reduce cost while maintaining adequate safety margins for defibrillation, particularly with newer generation high-energy devices capable of outputs of 35–41 joules.

References
15. Maytin M, Epstein LM, John RM. Lead implant duration does not always predict ease of extraction: extraction sheath may be required at <1 year. *PACE* 2011; 34:1615–1620.