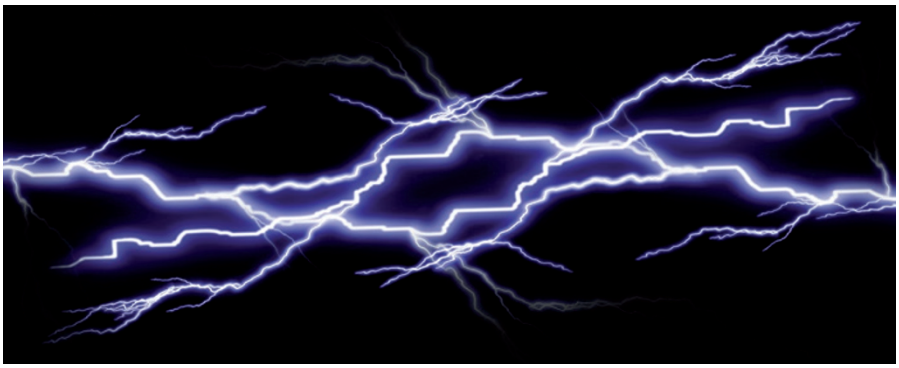
Nature Reviews Cardiology **12**, 193 (2015); published online 3 March 2015; doi:10.1038/nrcardio.2015.25

DEVICE THERAPY

High-zone programming of ICDs reduces inappropriate shocks

Implantable cardioverter–defibrillator (ICD) therapy is indicated for high-risk patients with heart failure, according to current European and US guidelines. However, a substantial number of these patients receive inappropriate shocks, which can impair their quality of life, and result in increased mortality. Investigators of the RISSY-ICD study aimed to investigate whether raising the ICD detection zones could reduce inappropriate therapies while continuing to provide appropriate therapy.



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Patients in the RISSY-ICD trial were randomly assigned to receive conventional ICD programming or an ICD programme with high detection zones. Both the conventional and high-zone programmes included a slower detection zone for ventricular tachycardia (VT_1 zone) and two faster detection zones for fast ventricular tachycardia (VT_2 zone) and ventricular fibrillation (VF zone). The VT_1, VT_2, and VF zones were set to 167–182 bpm, 182–200 bpm, and >200 bpm, respectively, for the conventional group, and were programmed to 171–200 bpm, 200–230 bpm, and >230 bpm, respectively, for the high-zone group. The primary end point of the study was the first episode of appropriate or inappropriate therapy with either antitachycardia pacing or shock.

Overall, 201 patients with heart failure, who received an ICD for primary prevention, were included in the study and followed up after 12 months. A first episode of appropriate therapy was experienced by more of the high-zone group than the conventional group (22% versus 10%; HR 2.18, 95% CI 1.09–4.36, $P = 0.028$). Furthermore, a first episode of inappropriate therapy was experienced by fewer of the high-zone group than the conventional group (5% versus 28%; HR 0.18, 95% CI 0.07–0.44, $P < 0.001$). High-zone programming also resulted in a higher incidence of appropriate therapy. All-cause mortality was not different between the groups; however, more of the conventional group were hospitalized for heart failure compared with the high-zone group (13% versus 4%; HR 0.28, 95% CI 0.09–0.88, $P = 0.021$).

The RISSY-ICD investigators claim that this trial was the first prospective study to show a benefit of both single-chamber and dual-chamber ICDs programmed with high-zone settings in reducing inappropriate therapies, and conclude that "the results of the RISSY-ICD study may have [an] impact on the device programming and selection in the future".

In addition to inappropriate shocks, recipients of ICDs are also at risk of complications arising from defibrillation testing performed at the time of implantation. In a separate study published in *The Lancet*, Healey and colleagues sought to determine whether ICD implantation without defibrillation testing was noninferior to implantation with defibrillation testing. The SIMPLE trial was a single-blind, randomized, multicentre, noninferiority trial, in which patients undergoing initial implantation of an ICD were randomly assigned to receive or not to receive defibrillation testing. The primary outcome was a composite of arrhythmic death or failed appropriate shock, defined as shock delivered for spontaneous ventricular tachycardia or fibrillation that did not result in arrhythmia termination.

Altogether, 2,500 patients were included in the analysis, and followed up for a mean of 3.1 years. The primary outcome was observed in 90 patients (7%) in the no-testing group versus 104 patients (8%) in the testing group (HR 0.86, 95% CI 0.65–1.14, $P < 0.0001$ for noninferiority). Occurrence of neither the primary safety outcome nor the secondary safety outcome (which included only adverse events directly caused by testing) was significantly different between the no-testing and testing groups (5.6% versus 6.5%, and 3.2% versus 4.5%, respectively).

These findings demonstrate that implantation of an ICD without defibrillation testing does not reduce the long-term efficacy of the ICD. The investigators of the study conclude that "clinical application of these findings will simplify routine ICD implantation, by elimination of the need for routine ventricular fibrillation induction to test shock effectiveness".

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Original articles Cay, S. *et al.* Programming implantable cardioverter-defibrillator therapy zones to high ranges to prevent delivery of inappropriate device therapies in primary prevention patients: Results from the RISSY-ICD (Reduction of Inappropriate ShockS bY InCreaseD zones) trial. *Am. Heart J.* doi:10.1016/j.amjcard.2015.01.558 | Healey, J. S. *et al.* Cardioverter defibrillator implantation without induction of ventricular fibrillation: a single-blind, non-inferiority, randomised controlled trial (SIMPLE). *Lancet* doi:10.1016/S0140-6736(14)61903-6