SAFETY AND PERFORMANCE OF NOVEL VENTRICULAR SENSING DISCRIMINATION FEATURES IN IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

ACC Poster Contributions
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Background: Implantable Cardioverter Defibrillator (ICD) shock therapy improves survival of patients at risk for sudden cardiac death. However, previous studies have shown that approximately 30% of all shocks fired by the ICD are inappropriate. The main causes of inappropriate shocks are right ventricular (RV) lead noise, T-wave oversensing (TWOS) and detection of supraventricular tachyarrhythmia’s (SVT). To prevent inappropriate shocks from occurring, new algorithms have been developed to specifically address the primary causes of inappropriate shocks without delaying the detection of true ventricular tachyarrhythmias (VT/VF). The purpose of this study is to determine if new algorithms in a new ICD cause delay in detection of VT/VF.

Methods: A prospective, multi-center, non-randomized clinical study including ICD and CRT-D devices was conducted in 40 centers in Europe, Middle East and Africa. In total, 236 patients were successfully implanted (111 ICD and 125 CRT-D). Detection delay was assessed with the new algorithms ON vs. OFF during VF inductions in patients undergoing implantation of the PROTECTA XT ICD or CRT-D (Medtronic, Minneapolis). A detection delay of more than 2 seconds was defined as being clinically significant.

Results: The patient population consisted mainly of primary prevention patients (75%) and the majority of patients (43%) had NYHA Class III. Eighty-nine patients had a history of atrial fibrillation (AF) either paroxysmal, permanent or persistent. Of the 196 induced VF episodes that were analyzed, detection was not delayed with the Protecta discrimination algorithms ON vs. OFF (p<0.0001). The episode duration in the ON and in the OFF group was 3211 ms (ICD 3250 ms, CRT 3168 ms). No unanticipated serious adverse device effects were reported.

Conclusions: These results show that new Protecta ICD algorithms designed to prevent inappropriate shocks due to lead fracture, T-wave oversensing or SVT can be safely applied without delaying true VT/VF detection.