Defibrillation Performance with the Substernal Extravascular Implantable Cardioverter Defibrillator: First-in-Human Chronic Experience

Introduction: The Extravascular Implantable Cardioverter Defibrillator (EV ICD) is a novel defibrillator that offers both pacing and defibrillation using a 40J device the size of a Transvenous ICD (TV ICD) with a lead positioned in the substernal space. Previous studies have demonstrated the feasibility of a lead placed in the substernal space (anterior mediastinum) to achieve defibrillation. The EV ICD Pilot study is the first chronic human experience of the safety and efficacy of an implanted EV ICD system. This analysis examines defibrillation performance.

Methods: The EV ICD Pilot Study is a prospective trial conducted in four centers in Australia and New Zealand. A custom defibrillation lead was inserted into the substernal space under fluoroscopic guidance. The device was placed in a left lateral pocket. Defibrillation efficacy was characterized by inducing and converting ventricular fibrillation (VF) episodes. Success was defined as termination of VF with either (1) a single 20J shock or (2) on two consecutive episodes with a 30J shock. Testing at 15J was conducted if conversion was successful at 20J. Chronic defibrillation testing was performed at physician discretion.

Result: A total of 26 subjects were enrolled and 21 underwent the EV ICD implant procedure. The implanted cohort was 85% male with an average age of 55 years and median left ventricular ejection fraction of 33%. Of the 21 subjects, 19 had complete defibrillation testing and 17 (89.5%) met defibrillation success criteria with 15 successful at 20J and 11 also successful at 15J. 2 of 2 subjects tested at 10J also had success. Mean shock impedance at implant was 67 ± 10 Ω (n=19). Of the two subjects who did not complete testing, one subject was due to difficulty inducing VF and in one subject the lead could not be advanced to the desired location. Five instances of chronic defibrillation testing were performed electively. One subject did not have successful testing at 30J and underwent system explant. In these 5 patients, implant and chronic shock impedance was 63 ± 9 Ω vs 78 ± 18 Ω. To date, two spontaneous episodes of monomorphic VT in one subject were successfully terminated with programmed 40J shocks.
Conclusion: Successful defibrillation using energies similar to current TV ICDs can be achieved in a system with a substernal lead. Limited data to date shows variable chronic defibrillation performance. Results support continued clinical evaluation in a large-scale pivotal study to further understand factors influencing defibrillation thresholds in the EV ICD system.