Implant Procedure Results from the First-in-Human Chronic Experience of the Substernal Extravascular Implantable Cardioverter Defibrillator

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Introduction: The Extravascular Implantable Cardioverter Defibrillator (EV ICD) is a novel system designed to place an ICD lead outside of the vasculature and in the substernal space (anterior mediastinum). Previously reported proof-of-concept studies demonstrated the acute safety and feasibility of defibrillation using a lead placed in the substernal space. The EV ICD Pilot Study was designed to characterize the safety and efficacy of chronic system implants. This analysis will focus on the EV ICD system implant procedure and training methods used for this first-in-human study.

Methods: The EV ICD Pilot Study is a prospective, non-randomized study conducted in four centers in Australia and New Zealand. Patients with Class I or IIa indications for ICD were enrolled. Cardiologists and Cardiac Surgeons completed a hands-on tunneling training program. For the first 5 implant procedures, surgeons partnered on substernal access through the diaphragmatic attachments and provided emergency support throughout the study. Under fluoroscopic guidance, cardiologists delivered the lead into the substernal tissue using a tunneling tool and sheath. The lead pin was tunneled subcutaneously to the device pocket on the left lateral chest wall for device connection. Fluoroscopy and procedure times were recorded. Implants were assessed using radiographic images and CT scans (Figure), and electrical performance (sensing and pacing) in various postures and exercises. Adverse events were adjudicated by a Clinical Events Committee for relatedness to the system or procedure.

Result: Twenty-six subjects were enrolled and 21 underwent the EV ICD implant procedure. The median (IQR) fluoroscopy time and time from first incision to final lead placement were 4.2(3.4,7.7) minutes and 25(21,35) minutes, respectively. 86% of subjects had the EV pocket posterior of left mid-axillary line. In 67% of procedures tunneling was described as Easy/Extremely Easy. The lead was repositioned during the initial procedure in eight subjects; retunneling was performed in 3 procedures. 17
subjects were discharged with the system. Lead placement was inadequate in a single case. There were no intraprocedural complications with five other system or procedure related adverse events all considered minor and/or resolved without sequelae.

**Conclusion:** The EV ICD implant procedure and training methods demonstrate no intraprocedural complications with a limited number of minor adverse events related to the system or procedure. This first-in-human chronic study supports the procedure and training methods implemented in prior studies and will inform the strategy for a large-scale pivotal study.