

Late-Breaking Clinical Trials LB-456087: Late-Breaking Clinical Trials and Science - CIED

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LB-456087-1

FIRST RESULTS OF THE RANDOMIZED PRAETORIAN-DFT TRIAL: PROSPECTIVE VALIDATION OF THE PRAETORIAN SCORE FOR PREDICTION OF DEFIBRILLATION TEST SUCCESS AFTER SUBCUTANEOUS ICD IMPLANT



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Introduction: The PRAETORIAN score was developed to predict the defibrillation success of the subcutaneous ICD (S-ICD), based on anatomical device position on a chest X-ray, as an alternative to defibrillation testing (DFT). Although only retrospectively validated, the score is currently being used in both research and clinical practice. The prospective randomized PRAETORIAN-DFT trial investigates whether the PRAETORIAN score is non-inferior to the DFT in regard to predicting first shock efficacy. The current analysis is the first prospective validation of the PRAETORIAN score for defibrillation success in induced ventricular arrhythmias.

Methods: The PRAETORIAN-DFT trial (clinicaltrials.gov number NCT03495297) included 965 patients undergoing a de novo S-ICD implantation in 37 centers in Europe, the USA and Israel. Patients were randomized 1:1 to DFT or no DFT with calculation of the PRAETORIAN score. A successful DFT was defined as a successful conversion by a 65J shock within two inductions. Chest X-rays of the device position during DFT were collected. PRAETORIAN scores were calculated by a core lab of 3 experienced physicians, based on consensus. Chest X-rays which were considered ineligible for calculation of the PRAETORIAN score were excluded. End point of this predefined analysis is the predictive value of the PRAETORIAN score for defibrillation success in induced events.

Results: From May 2018 through December 2022, patients were randomized to the DFT arm (n=482) or the no-DFT arm (n=483). In the DFT arm, the median age was 55 (IQR 44 -63) years, 24.3 % was female and median BMI was 26.8 (IQR 23.6 – 30.8) kg/m². In this arm, a DFT was performed in 466 patients whereas in 16 patients no DFT was performed due to failed induction, spontaneous conversions, physician discretion or extraction before execution of DFT. DFT outcomes and predictive values of the PRAETORIAN scores will be presented in the Late Breaking Clinical Trial session.

Application: The PRAETORIAN score is increasingly being used in clinical practice. This predefined analysis of the PRAETORIAN-DFT trial is the first prospective validation of the PRAETORIAN score and will give new insights in the predictive value of the PRAETORIAN score as an alternative for DFT.

Next Steps/Future: Patients in the PRAETORIAN-DFT trial are followed for a median of 40 months to investigate whether S-ICD implant without DFT but with a PRAETORIAN score as an alternative is non-inferior to S-ICD implant with DFT with regard to first shock efficacy in spontaneous events.

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CHRONIC SAFETY AND PERFORMANCE OF THE EXTRAVASCULAR ICD: RESULTS FROM THE GLOBAL EV ICD PIVOTAL STUDY



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Introduction: ICDs prevent SCD in patients at high risk for ventricular arrhythmias, but conventional systems carry a risk of transvenous (TV) lead-related complications. The novel extravascular ICD (EV ICD) may reduce some of these complications, while offering ATP, pause prevention pacing, and a device of similar size and projected battery longevity as a TV ICD, by placing a lead sub-ternally. The EV ICD Pivotal study demonstrated EV ICD safety and performance for termination of ventricular arrhythmias at 6 months. Longer-term performance is unknown.

Methods: The EV ICD Pivotal study was a prospective, international, single-arm, premarket clinical study. Patients with a class I or IIa indication for a single-chamber ICD per ESC or ACC/AHA/HRS guidelines were enrolled. Freedom from major system- and/or procedure-related complications at 18 mo was evaluated, as well as conversion of arrhythmias by ATP or shock through all available follow up. Rates of ATP success were evaluated using the generalized estimating equation (GEE) and simple proportions.

Results: Implantation was attempted in 316 patients: 74.7% male, age 53.8±13.1 years, 82% primary prevention, LVEF of 38.9%±15.4%, and NYHA Class I (23.4%) or II/III (65.5%).

Of 299 implanted patients (average follow up 16.2±7.2 mo), 19 experienced 80 spontaneous, appropriately treated arrhythmic episodes: 37 treated by ATP, 15 by ATP and shock, and 28 by shock alone with a Kaplan-Meier (KM) estimated 6.8% of patients experiencing appropriate therapy by 18 mo (**Figure**). Of discrete episodes treated with shock, 21/21 (100%) were successfully terminated. ATP was delivered in 12 patients, successfully treating 35/52 episodes (67.3%;