Predictors of major Adverse Events over 12 months after ICD/CRT-D replacement/upgrade in a contemporary large world population: insight to the DECODE registry

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Introduction: Cardiac Implantable Electronic Device (CIED) surgery is threatened by serious complications both during the procedure and during follow-up. The factors associated to attenuated clinical benefit over long term follow-up are poorly understood. To evaluate type and extent of Adverse Events (AEs) and potential predictors of major AEs over 12 months after ICD/CRT-D replacement/upgrade in a contemporary Italian population.

Methods: Detect long-term complications after ICD replacement (DECODE) was a prospective, single-arm, multicenter cohort study aimed at estimating medium- to long-term complications in a large population of patients (pts) who underwent ICD/CRT-D replacement/upgrade from 2013 to 2015. The endpoint for this analysis is death from any cause, procedure-related infection, and surgical actions/hospitalizations necessary to treat the AEs.

Result: We included 983 consecutive pts (median age 71 years, 76% male, 55% ischemic, 47% CRT-D). During a mean follow-up duration of 353±49 days, 7% of the pts died. A total of 104 AEs occurred in 70 (7.1%) pts. 43 (4.4%) pts needed at least one surgical action to treat the AEs. A total of 23 (2.3%) pts had infective AEs (CIED related in 12 pts, due to other causes in 11). Mortality was unrelated to the occurrence of overall AEs, or of CIED-related AEs, or of surgical actions/hospitalizations needed to correct AEs. The endpoint was reached by 109 (11%) pts over 12-month follow-up (97 pts had a single event, and 12 pts had two events). The median time to the endpoint was 137 [50 – 254] days. On multivariate Cox regression analysis adjusted for baseline confounders, ischemic cardiomyopathy (HR =
1.86, 95% CI: 1.18 to 2.91; p = 0.0076), hospitalization prior to the procedure (2.34, 1.35 to 4.05; 0.0025) and anticoagulation (1.91, 1.25 to 2.92; 0.0032) were associated with the endpoint during follow-up.

**Conclusion**: Evaluation of the patient's profile may assist in predicting vulnerability and should prompt reconsideration of the procedure by deferring at a more stable clinical status, and carefully individualized in the setting of upgrades and anticoagulation management.