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

Paolo De Filippo
Endri Menardi
Ernesto Ammendola
Maria Lucia Narducci
Quintino Parisi
Francesco Zanon
Michele Manzo
Giuseppe Stabile
Domenico Potenza
Massimo Zoni Berisso
Fabio Quartieri
Valerio Zacù
Matteo Bertini
Davide Saporito
Fabio Lissoni
Vittorio Calzolari
Gianluca Zingarini
Giulia Bottoni
Maurizio Malacrida
Paola Ferrari
Giovanni Malanchini
Mauro Biffi

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.