Lead-related complications in patients undergoing ICD/CRT-D upgrade in real life practice: the DECODE registry experience

Paolo De Filippo
Vincenzo Russo
Francesco Zanon
Maria Lucia Narducci
Enrico Menardi
Massimo Zoni Berisso
Attilio Pierantozzi
Alberto Bandini
Pasquale Notarstefano
Gennaro Miracapillo
Carlo Ferretti
Leonardo Calò
Attilio Del Rosso
Paolo Sabbatani
Valerio Zacà
Giulio Boggian
Valeria Carinci
Giulia Bottoni
Maurizio Malacrida
Paola Ferrari
Cristina Leidi
Mauro Biffi

Introduction: Complications threaten lead addition while upgrading ICD/CRT-Ds, as learnt by the REPLACE registry experience. We aimed at understanding the extent and the mechanism of lead-related adverse events (AEs) in a contemporary cohort of ICD/CRT-D upgrade recipients in a large real-world 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 983 consecutive patients who underwent ICD/CRT-D replacement/upgrade from 2013 to 2015. We prospectively analyzed all clinical and device-related data of these patients at 12-month follow-up. In this work we analyzed the reason for ICD/CRT-D upgrade, the occurrence and mechanism of lead related AEs at 12 months follow-up.

Result: We analyzed 179 consecutive patients who underwent device upgrade (median age 70 years, 78% male, 57% ischemic, 25% CRT-D): 84 (47%) due to lead failure, 85 (47.5%) for clinical reasons, and 10 (5.5%) for clinical reasons plus lead failure. Lead failure was more common in CRT-D recipients (44/460, 9.5%) than in ICD recipients (40/523, 7.6%). In 40 ICD recipients, RV coil failure was the most common cause of lead addition (38/40 patients, 95%), atrial lead failure occurring in 2 (5%). In 44 CRT-D recipients, lead failure was reported for the RV lead in 25/44 (56.8%), LV lead in 20/44 (45%), and atrial lead in 1/44 (2.2%). Loss of RV sensing occurred in 100% of RV lead failures, while loss of LV capture occurred in 90% of LV lead failures. Sensing issues for RA lead were present in 3 cases. The
lead addition procedure was burdened by AEs in 22/179 patients (12.2%), specifically 9/44 (20%) CRT-D and 13/135 (9.6%) ICD. AEs occurred in 12/70 (17%) patients with RV lead failure (12 required repeated surgery), in 13/103 (12.6%) patients with LV lead procedures (8 required repeated surgery), and in none of the 12 patients with atrial lead procedures.

**Conclusion:** RV lead loss of function is the leading cause of ICD/CRT-D upgrade due to lead failure. RV lead addition is associated to repeated surgery after upgrading more commonly than LV addition. Technologic development in ICD/CRT-D should focus on electronic recovery of sensing and detection to minimize repeated surgery, that is associated to infection.