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

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.