Permanent CIED malfunctions after oncologic radiotherapy: a multi-centre, randomized, in vitro evaluation

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Background: Direct photon exposure of pacemakers (PMs) or implantable cardioverter-defibrillators (ICDs) during oncologic radiotherapy may transiently or permanently affect normal device function. To evaluate potential malfunctions by direct exposure to doses up to 10 Gy in 6-MV oncologic radiotherapy, commonly considered unsafe or even not recommended, 145 PMs and 65 ICDs were observed in three different centres.

Methods: All devices had a baseline interrogation and reprogramming to VVI/40 or to DDD/40 mode, depending on type and model. Rate-adaptive function was disabled in all the devices, whereas in ICDs, even antitachycardia therapies were disabled with the ventricular tachycardia/fibrillation (VT/VF) windows left enabled. To build the corresponding treatment plan, a centring computed tomography was performed with different Treatment Plan Systems among the centres. The devices were blinded randomized to receive either 2-, 5- or 10-Gy direct exposure by a 6-MV linear accelerator (different among the three centres) in a water phantom (600 MU/min). The effective dose received was assessed by a random in-vivo dosimetry. All devices had a telemetry interrogation immediately after exposure and once monthly during a six-month follow-up.

Results: Immediately after photon exposure, no changes in device parameters or software errors were observed in 209 devices (99.5%). A non-reprogrammable reset to emergency back-up mode (VVI/65) occurred in a PM (0.5% overall; 0.7% among PMs). Seven PMs reached the Elective Replacement Indicator immediately after exposure (3.3% overall; 4.8% among PMs). Sixteen ICDs (7.6% overall; 24.6% among ICDs) had multiple VT/VF detections stored in the device memory. Two PMs (1% overall; 1.4% among PMs) reported atrial fibrillation detections.

During a six-month follow-up, a non-reprogrammable software reset (back-up to VVI/65 mode) was reported in one PM three months after a single exposure of 2 Gy (0.5% overall; 0.7% among PMs). Abnormal battery drain was observed in thirteen PMs (6.2% overall; 9% among PMs), and in one ICD (0.5% overall; 1.5% among ICDs). All events presented regardless of exposure dose of either 2, 5, or 10 Gy.

Conclusions: Last-generation devices, both PMs and ICDs, withstood direct 6-MV photon exposure up to 10 Gy, commonly considered not recommended or even unsafe by manufacturer statements and clinical guidelines. The most common failures were referred to battery issues. Malfunctions occurred solely in less recent devices, regardless of photon dose.