Chronic Retrievability with a Leadless Pacemaker: A Worldwide Nanostim™ Experience

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Introduction: After 1,423 Nanostim™ leadless pacemakers (LPs) were implanted during worldwide clinical trials, enrollments were halted in October 2016 due to premature battery malfunctions and remained paused in November 2017 due to a docking button detachment vulnerability. A common therapeutic option has been to retrieve the LPs which have provided valuable clinical experience to inform system revision strategies as patients continue ongoing follow-up.

Methods: Patients implanted with a right ventricular active-fixation Nanostim LP were enrolled in multicenter clinical trials in the United States, Canada, Europe, Japan, and Australia. Data was collected by investigative sites during each retrieval attempt. Serious Adverse Device Effects (SADEs) were documented per the International Standard Organization definition and adjudicated by a clinical events committee comprised of independent physicians.

Result: As of May 30th 2019, a total of 87% (146/168) of retrieval attempts for chronic Nanostim LPs have been successful. Among the 168 retrieval attempts, 37 (22%) were associated with a reported battery malfunction. The mean time from implant to attempted retrieval was 2.3 ± 1.4 years (range 0 days to 6.1 years). The mean time from implant to successful retrieval was also 2.3 ± 1.4 years (range 0 days to 6.1 years). Retrieval success rate remained at least 79% regardless of implant duration (See Figure). There were 22 unsuccessful retrieval attempts, primarily due to inaccessibility of the proximal portion of the LP. Among the 168 retrieval attempts, 5 Serious Adverse Device Effects (SADEs) were related to the device and/or procedure. These events are comprised of one cardiac tamponade, one AV fistula, one access site bleeding event, one complication related to valve damage, and one docking button detachment.

Conclusion: A high retrieval success rate over a large volume of retrieval procedures, accompanied by low procedural complication rates, demonstrates that chronic retrieval of the Nanostim LP can be safely performed through 6 years post-implant. Regardless of implant duration, retrieval success rates were high.