Adverse Events of Subcutaneous Loop Recorders: Insights from the MAUDE Database

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Abstract

Background: Complications using internal cardiac monitors are have been reported at a low rate. Targeted analyses of complications have not been well described. Objective: To investigate and describe complications associated with internal cardiac monitor (ICM) events reported to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. Methods: Our team reviewed all reported events for the Reveal LINQ loop recorder submitted to the MAUDE database over seven years (1/1/2013-12/31/2019). A 5% random selection of reports was audited by two researchers to ensure report validity. Two cardiologists manually reviewed death and incongruent events for final interpretation. Results: 12,652 records were obtained during the observed time period. A total of 15,587 device complications were reported. Of this, under-sensing (n = 4509, 28.93%), premature discharge of battery (n = 3262, 20.93%), over-sensing (n = 2788, 17.89%), and other sensing issues (n = 1532, 9.83%) were most commonly reported. Patient adverse events were reported 1,030 times. Pain or discomfort (n = 275, 26.70%), site infection (n = 213, 20.68%), erosion (n = 138, 13.40%), and impaired healing (n = 49, 4.76%) were most commonly reported to affect patients. Death was reported four times; after expert review, no reports justified the device or procedure as a reasonable cause. Verification of events reported 99.53% accuracy of reporting. Conclusion: Several non-life-threatening ICM complications were commonly noted from the analysis. This study supports the safe use of ICMs. A better understanding of the complication profile will help providers select patients, provide informed consent, and expected management.

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