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Post-market Risk Assessment based on Malfunction Reports of Implantable Arrhythmia Devices in Japan

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Summary

Post-market risk assessment is important, but information released about malfunction reports is ravely investigated systematically in Japanese papers. The objective of this study is to assess the post-market risk of implantable arrhythmia devices in Japan based on malfunction reports and to analyze the causes and severity of malfunctions, and the implications for risk assessment. We investigated information released in malfunction reports and recall outlines of implantable arrhythmia devices without formally requesting disclosure, and analyzed the frequency and severity of malfunctions between fiscal year 2006 and 2010. Among 2,071 reported malfunctions in implantable arrhythmia devices by industries between fiscal year 2006 and 2010, 1,586 (76.6%) were related to leads. Among 485 malfunction reports on generators, 340 (70.1%) were associated with pacemakers. The estimated frequency of malfunction based on the number of annual implants was higher for implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy with defibrillators (CRT-D) than for pacemakers. We could not calculate the estimated frequency for leads. The severity of malfunction were expected to be more severe for ICD and CRT-D than for pacemakers. We found that the information released was not sufficient to identify the causes of malfunctions. Also, information publicly released about malfunctions was of limited value for risk assessment. For accurate post-market risk assessment, it is necessary to share information about malfunctions appropriately. So, it is important for information regarding the frequency of malfunctions to be released by industry or by a government body and to establish standard evaluation criteria for assessing the severity of malfunctions.

Key words

Risk assessment, Implantable arrhythmia device, Malfunction, Recall