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Dealing with a Device Failure- Any Hope for Success?

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Background: In May 2009 Medtronic (MDT) issued an advisory warning of certain subsets of Pacemakers (PM) due to "separation of wires that connect the electronic circuit to other pacemaker components".
Objective: To describe the management of this advisory in a single institution.
Methods: Retrospective analysis and review of charts.
Results: Eighty six pts were identified with the affected PMs. (45 women). The indications for PM were: heart block (53), sinus node dysfunction (21), slow atrial fibrillation (7) and others in 5 . Thirty seven pts died prior to the issuing of this recall.
Forty two pts were PM dependent. Of them, 19 had died before the advisory, 6 had their PM replaced before the advisor, 13 had their PM replaced in response to the advisory, 3 refused to come and have their PM checked in response to the recall and 1 was lost to follow-up. Of the 44 non dependent pts – Five were scheduled for PM replacement.
Two patients experienced adverse events. One patient with complete AV block was admitted with syncope(one week prior to a scheduled generator change- in response to the PM recall) and with an escape rhythm of 20/minute. A temporary PM was inserted and he later had his PM changed with no further complications. A second pt had her PM changed in response to the recall and was readmitted a week later with syncope and bradycardia. During a lead revision a break was found on the insulation and a new electrode was implanted in the right ventricle.
Conclusions : Of the 86 pts from the relevant series- 2 pts(2.3%) were adversely affected by the recall. One with a malfunction of electrode and one with a complication of PM change. Eighteen of the 86 (21%) had (or were planned to have) their PM changed.