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EDITORIAL COMMENT

Mortality Risk of Fidelis Management*

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The Fidelis lead recall is the latest in a series of device recalls that have challenged clinicians with regard to appropriate patient management strategies. Medtronic (Minneapolis, Minnesota) recalled the Sprint Fidelis 6949 implantable cardioverter-defibrillator (ICD) lead in 2007 after 665 lead failures and 5 reported deaths. Prior to the recall, approximately 150,000 patients in the United States received the Fidelis lead among about 268,000 patients worldwide. The implications of these numbers for patient morbidity and mortality that will result from device failure are sobering. The challenge for physicians managing patients with functioning Fidelis leads is to balance risks of prophylactic replacement with or without extraction of the recalled lead versus a conservative strategy of monitoring the lead's electrical performance in the hope that impending lead failure will be predicted before a potentially lethal device malfunction occurs. As a guide to this calculus, any data about mortality risks of lead management strategies are extremely helpful to clinicians. In this issue of the *Journal*, the paper by Morrison et al. (1) provides this valuable guidance.

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In the article, the authors retrospectively assay the impact of a largely conservative management strategy for the Fidelis lead employed at 3 prominent medical centers on all-cause mortality in a cohort of patients who received the recalled Fidelis lead relative to a cohort who received a non-recalled Medtronic Quattro ICD lead manufactured contemporaneously. The 2 large cohorts were generated from 3 institutions, totaling 1,030 in the Fidelis lead group and 1,621 in the comparison group implanted with the Quattro lead. The conservative management strategy observed in most patients involved replacement of a malfunctioning Fidelis lead, with or without extraction, only when lead performance metrics indicated a lead malfunction. Whether the downloadable Lead Integrity Alert software, provided by Medtronic, was used for the majority of patients was not stated but inferred by the comment in the discussion that the lack of increased mortality may have been due in part to the use of this "downloadable algorithm." The conservative management strategy was followed in 94.9% of implanted Fidelis leads, whereas prophylactic removal of a functioning Fidelis lead was done in 5.1% of patients, of which 36% were pacemaker-dependent patients as defined by 100% pacing.

Mortality was measured through a review of medical records as well as the Social Security Death Index. Although the absolute mortality was higher in the Fidelis cohort, the difference was not significant after adjustment for relevant comorbidities. Fidelis lead failures were identified in 85 patients from 1,030 implants, which corresponded to a 48-month lead survival of 87.0% compared with 98.7% of the Quattro leads. None of these lead failures was associated with death. In the Fidelis cohort, 155 patients were pacemaker dependent, and 19 underwent prophylactic lead replacement. Although there was not an increased mortality risk in the pacemaker-dependent patients with the Fidelis lead, 1 patient presented with asystole that required emergency intervention. The authors did not attempt to adjudicate the mechanism of deaths, so the possibility that some fraction of the deaths were associated with a mechanism involving lead failure could not be excluded.

How are we to incorporate this information into our own practices for management of patients with the Fidelis lead? As the authors so aptly state in the paper, "Management of patients with implanted Fidelis leads involves balancing the risk of malfunction, the ability of surveillance to detect malfunction before catastrophic clinical events, and the risk of intervention." Most would agree that patients can be divided into 2 groups for purposes of consideration of prophylactic lead replacement, based upon the perceived risk of a fatal complication resulting from a Fidelis lead malfunction. In light of the data provided by Morrison et al. (1), these 2 groups might be called a "low-risk" group and a "lowest-risk" group. Patients in the lowest-risk group would be those who received their device for primary prevention of sudden death in the absence of pacing indications or serious comorbidities. Patients in the other group who are predictably at higher risk of a lethal complication resulting from lead failure would be patients who are pacemaker dependent or who received their device for secondary prevention of sudden death. Armed with this patient triage scheme, clinicians are guided by the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines that "lead revision or replacement should be considered if the risk of malfunction is likely to lead to patient death or serious harm, and the risk of revision or replacement is believed to be less than the risk of patient harm from the lead malfunction" (2). Of interest in light of this policy

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statement is that only 12% of the pacemaker-dependent patients in the Fidelis cohort were managed with prophylactic lead replacement.

One can infer from the low rate of prophylactic replacement of functioning Fidelis leads observed in this report that the perception among the group of participating physicians was that the risk of morbidity or mortality associated with replacement of the functioning lead, with or without extraction, was high. Published data appear to support that position. The report from the Canadian Heart Rhythm Society Device Advisory Committee summarizing the outcomes observed in a cohort of 469 patients referred for revision or replacement of the Fidelis lead found a complication rate of 19.8% of patients that underwent extraction combined with lead replacement and 8.6% in patients who had the Fidelis lead abandoned associated with placement of a new lead (3). In this report summarizing the outcomes from 25 Canadian Centers, 95% of patients with Fidelis leads received a new ICD lead, with 53% of patients undergoing an associated extraction. Four percent of patients received a new pace/sense lead only. Of the extractions, 61% of patients had the lead removed by traction, 33% of patients underwent laser lead extraction, and 1% of patients with a nonpowered extraction tool. Fifty-one patients had failed traction extraction, with subsequent lead abandonment. Two deaths were associated with lead revision, with 1 patient dying from pneumonia post-operatively after lead extraction, and the second patient dying from sepsis related to an infected hematoma after lead abandonment.

An equally important consideration in the decision to replace the Fidelis lead is patient-specific perceptions, not only about risk of death and morbidity associated with intervention, but also about the risk of inappropriate ICD shocks resulting from Fidelis lead failure. In this report with arguably ideal lead surveillance in place, 38 of the 85 lead failures were associated with inappropriate shocks. This observed rate was slightly higher than the observed rate in a smaller cohort from a single facility described by Kallinen et al. (4) where 4 in 23 patients with failed Fidelis leads experienced inappropriate ICD shocks despite the Lead Integrity Alert software algorithm. Most physicians who follow patients with ICDs have encountered at least 1 patient who has experienced devastating anxiety that is long lasting following a bout of inappropriate ICD shocks. Avoidance of inappropriate ICD shocks will become an increasingly important consideration in the decision to prophylactically replace the Fidelis lead as failure rates increase.

The clinical decision making for management of patients with the Fidelis leads continues to evolve as the lead failure rate mounts. The study by Morrison et al. (1) provides an important snapshot in time of the current mortality considerations of a conservative strategy for managing these leads. The conservative strategy appears justifiable at present provided adequate intensive follow-up is available with routine remote surveillance and implementation of the Lead Integrity Alert software. The price to be paid for this management strategy is inappropriate ICD shocks that occur without warning of impending lead failure through monitoring methods in a significant fraction of failing Fidelis leads. The demonstration provided by Maytin et al. (5) that lead extraction can be done with acceptably low mortality and morbidity at high-volume centers suggests that lead extraction can be considered for selected patients when access to substantial clinical expertise with lead extraction is available. For other centers, lead abandonment, when possible, with placement of a new ICD lead may be the preferred management strategy. ICD lead failure, even among models with good reliability, remains a clinical management challenge with complex risk-benefit considerations.

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