Need for real-world data on management of the (potentially) failing lead

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This editorial refers to ‘Management of recalled implantable cardioverter-defibrillator leads at generator replacement: a decision analysis model for Fidelis leads’ by H. Burri and C. Combescure, on page 1210.

Pacemaker and implantable cardioverter-defibrillator (ICD) therapy have had many successful years with extended indications, lower costs, and prolonged patient survival leading to a continuously growing population of patients with a cardiovascular implantable electronic device (CIED). Despite the fact that the device may present random and systematic failures, the lead connecting the CIED with the heart has turned out to be the ‘weakest link’ in CIED systems.1 The history has shown a series of mistakes in design and engineering giving rise to smaller enclaves of affected patients, e.g. the J-shaped Teletronics Accufix atrial lead.

However, it is the combination of the surge in using ICDs for primary prophylaxis in heart failure and the quest for smaller diameter ICD leads that has created a problem of sizable dimensions as a large series of the requested new thinner ICD leads have shown poor long-term performance.2–4 Healthcare authorities and the device industry have learned important lessons regarding both short-term testing and long-term surveillance5 as well as the inferiority of product performance reports based on returned product analysis. Lead-related problems with new products will hopefully decrease in the future. Nevertheless we currently have a large population of patients with either a Medtronic Sprint Fidelis lead with a potential defect, in whom we are only beginning to learn the extent and mechanisms of failure.

Although the problematic leads have been identified and errors have been corrected in new models (or older models have been rebranded), there is still a very large population who has been implanted with leads that have a high probability of failure. Algorithms developed to detect first signs of malfunctioning6 as well as remote follow-up have provided means of early warning of impending lead failure. A new lead can be implanted with or without extraction of the old lead. ‘Problem solved!’

A much more difficult situation arises when a patient approaches device replacement due to the device end of life or need for an upgrade, e.g. to cardiac resynchronization therapy (CRT). What to do with a lead at a high risk of failure yet still functioning? Should the lead be left in place and active service, with a ‘wait-and-see’ strategy? Or should the lead be replaced with a new lead, and should the old lead be extracted or abandoned?

The answers to these challenging questions depend upon a multitude of factors. In favour of a conservative strategy are factors such as short-lifetime expectancy and high risk of complications during lead revision and extraction.7 On the other hand, rapidly developing lead failure can pose a risk of inappropriate ICD therapy or inability to treat ventricular arrhythmias, whereas unscheduled lead-related surgery increases risk of infection. Moreover, patients may develop psychological distress knowing that their lead is potentially failing,8 although the reports varied.9 The decision to extract the old lead depends on the age of the patient and on the anticipated risk of complications associated with lead extraction in this patient. Timing is also crucial, as leads are more difficult to extract with longer dwell time. Therefore, it may be reasonable to extract the lead instead of abandoning it, as it may only become harder over time.

Despite the fact that leads with a poor performance have been identified through large-scale observational studies, there is a remarkable lack of studies on the management of patients with potentially or actually failing leads. This is especially true for the 7F diameter Medtronic Sprint Fidelis ICD lead. Several studies, including data from remote follow-up provided by the manufacturer, have documented the poor performance due to conductor fracture leading to inappropriate shocks and failure to deliver therapy. The absence of studies focusing on the management of patients who have Fidelis leads leaves the physician without any qualified guidance except of making their own choice.10

In this issue of the Journal, Burri and Combescure11 report their proposal on how to address the tough question whether to revise the potentially failing Fidelis lead in the setting of ICD replacement due to battery depletion, using decision analysis. This methodology estimates the probability of specific outcomes in different scenarios.
given certain assumptions on the risk associated with the chosen scenarios. The authors examines four different ‘lead revision strategies’: (i) generator replacement only, (ii) adding a new pacing lead, (c) adding a new ICD lead without extracting the Fidelis lead and (d) extracting and replacing the Fidelis lead with an other ICD lead. These are the same scenarios as listed in the Medtronic Fidelis Physician letter. The outcome of these scenarios is based on assumptions derived from previous reported studies, and the outcome measures are mortality, inappropriate shock therapy, re-intervention on a lead and serious complications.

Not surprisingly, the model simulation suggests that if you do not revise the lead, it may cause problems later due to inappropriate therapy. Furthermore, life-threatening complications due to lead extraction occur more often if you chose to extract the lead. These results are expected, based on the assumptions that are fed into the decision analysis model.

Concerning mortality, the perioperative mortality related to lead extraction is not negligible in all patients. However, the current analysis assumes an annual mortality of 9.4% in all patients, and this assumption ‘overrides’ any additional risk–benefit consideration. For example, lead extraction is not the same in a 42-year-old male patient with Brugada syndrome and a second prevention ICD and in a 78-year-old female patient with ischemic heart failure, on anticoagulation for paroxysmal atrial fibrillation who has a primary prevention CRT-D. Furthermore, the centre and operator experience is important. The assumption of a general annual mortality in all patients may hamper the analysis. The individualized approach is briefly discussed, but the current model does not take these considerations (different risk profiles, number of leads, etc.) into account.

Despite these weak points and generalizations, this contribution is appreciated in the continuous discussion how to manage patients with (potentially) lead-related problems. Trying to put some weight and surrogate evidence behind the different strategies in lead management seems to be difficult, but the authors have introduced a systematic approach to this problem and deserve credit for their effort.

The methodology and results of this study and the fact that one has to turn to such indirect ways of generating evidence in the management of leads underlines the paucity of prospective real-world data. Despite both the industry and the medical community have improved premarket testing and post-market surveillance of leads, single center and large scale registries have not been tracking the management of patients with either the risk for or an apparent lead problem. In some way, this is a mystery since there are thousands of leads still in service and equally many patients that must have undergone elective device replacement with many more to come.

A small step forward is the European Heart Rhythm Association (EHRA) sponsored prospective, multicenter, European Controlled Registry (ECR) of consecutive patients undergoing transvenous lead extraction, which provides detailed real-world data on lead extraction. This registry may be able to shed some light on one of the key parameters in lead management, namely the performance of lead extraction. The same structure of data collection could form the basis for a more specific survey on lead management. Furthermore, established national or regional device registries should contain detailed follow-up data on lead management including lead extraction. Such real-world data are urgently needed in order to help physicians and their patients to make the right decision on lead management as many patients with a potentially failing lead are approaching generator replacement.

It would be inexcusable if 8 years after it has been shown that unconsidered ICD replacement was the wrong strategy in device advisories, we continued advanced lead management without a guidance based on solid data. It is even more inexcusable because we know that this issue affects a large group of patients. The results and limitations of the reported decision analysis model should be used as an inspiration for all of us to start collecting data and reporting on lead management.

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**References**