Optimal Management of Riata Leads with No Known Electrical Abnormalities or Externalization: A Decision Analysis

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Riata Decision Analysis. ***Introduction:*** **Riata and Riata ST implantable cardioverter-defibrillator (ICD) leads (St. Jude Medical, Sylmar, CA, USA) can develop conductor cable externalization and/or electrical failure. Optimal management of these leads remains unknown.**

Methods and Results: **A Markov model compared 4 lead management strategies: (1) routine device interrogation for electrical failure, (2) systematic yearly fluoroscopic screening and routine device interrogation, (3) implantation of new ICD lead with capping of the *in situ* lead, and (4) implantation of new ICD lead with extraction of the *in situ* lead. The base case was a 64-year-old primary prevention ICD patient. Modeling demonstrated average life expectancies as follows: capping with new lead implanted at 134.5 months, extraction with new lead implanted at 134.0 months, fluoroscopy with routine interrogation at 133.9 months, and routine interrogation at 133.5 months. One-way sensitivity analyses identified capping as the preferred strategy with only one parameter having a threshold value: when risk of nonarrhythmic death associated with lead abandonment is greater than 0.05% per year, lead extraction is preferred over capping. A second-order Monte Carlo simulation ($n = 10{,}000$), as a probabilistic sensitivity analysis, found that lead revision was favored with 100% certainty (extraction 76% and capping 24%).**

Conclusions: **Overall there were minimal differences in survival with monitoring versus active lead management approaches. There is no evidence to support fluoroscopic screening for externalization of Riata or Riata ST leads.** *(J Cardiovasc Electrophysiol, Vol. 26, pp. 184-191, February 2015)*

decision analysis, implantable cardioverter-defibrillator, fluoroscopy, lead extraction, primary prevention

Introduction

Lead failure remains a challenging issue in implantable cardioverter-defibrillator (ICD) management. Historically, 56% of lead failures have been due to insulation defects.[1] Riata and Riata ST ICD leads ("Riata leads," St. Jude Medical, Sylmar, CA, USA) have been identified as being at risk for externalization because the electrical conductor wires have a tendency to erode through the silicone insulation.[2] Externalized leads are at increased risk of electrical failure, which can manifest as oversensing, undersensing, or inability to deliver effective tachytherapies.[3-7] The US Food and Drug Administration (FDA) issued a class I advisory for the Riata and Riata ST leads in December 2011.[8] Subsequently in August 2012, the FDA recommended screening with x-ray or other imaging techniques for all patients with Riata or Riata ST leads to evaluate for externalization.[9]

The electrical failure rate of a diverse group of ICD leads has been estimated at 2.5%,[10] while the reported Riata and Riata ST electrical failure rate varies from 3.5% to 10%.[5,6,11] Cinefluoroscopy has high sensitivity (90%) for identifying externalized leads[3]; however, externalization does not appear to be an ideal predictor of Riata lead electrical failure, with reported electrical failure rates in nonexternalized leads ranging from 1% to 9% compared with 4% to 71% in externalized leads.[5,6,12-18] The best management strategy for *in situ* Riata or Riata ST leads remains unclear, even when information about externalization is known.

It is impractical to obtain direct clinical trial evidence on device advisories. Decision analysis provides a method to infer preferred treatment strategies by creating a decision tree of plausible scenarios and assigning probabilities to each scenario.[19] We developed a Markov model to assess the mortality benefits of the various patient care strategies in patients with primary prevention ICDs and Riata or Riata ST leads *in situ* without known electrical failure or evidence of externalization.

Methods

Decision Model

This decision model represents the range and sequence of clinical events experienced by a patient with a Riata or

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Riata ST defibrillator lead *in situ*. The modeled base case is a 64-year-old patient with a primary prevention ICD and a Riata lead *in situ* without known electrical failure or externalization. We used baseline estimates of probabilities and US population life table data to calculate life expectancy under each clinical management strategy.

Figure 1 shows a simplified version of the decision model, representing the events in the first month following patient presentation with a normal functioning Riata ICD lead *in situ*. This structure represents a simulation of a 4-arm clinical trial. There are 2 conservative lead management strategies: routine device interrogation alone[20]; initial fluoroscopy with subsequent imaging every 12 months to evaluate for lead externalization. The remaining arms are strategies in which the patient undergoes lead revision—either by capping or explanting the Riata lead—with insertion of a new right ventricular ICD lead. The square node at the left of the model represents the "decision" node or choice of a clinical management strategy. Points of uncertainty are represented by circular "chance" nodes. Death in the first month is indicated by a triangle ("terminal" node). For individuals surviving the first month, subsequent events are represented by an encircled "M" representing a Markov model.

In subsequent months, patients remain in their current clinical state or transition to another state, as denoted by the Markov state diagram depicted in Figure 2 (a simplified representation of the Markov branches included in our original model). The Markov state diagram depicts the allowable transitions a patient may make over a given time interval, which in this model is 1 month. For example, a patient having undergone surgical lead revision is assumed to remain in the "electrical failure detected and lead revised" state for each month until he or she dies, represented by a transition to the dead state. Moreover, for a patient starting the Markov process in the "Riata not initially externalized" state, the possible sequences of events are represented by arrows to "Riata externalized undetected," "electrical failure undetected," "electrical failure detected and lead revised," and "dead." Death may be due to a perioperative event, arrhythmic death, or nonarrhythmic death. The probabilities of a given transition change from month-to-month to account for time-dependent effects, such as aging and increases in the risk of lead failure.

Model Inputs

Table 1 summarizes the model input parameters used in this analysis. Whenever possible, we obtained estimates and plausible ranges of event probabilities from published articles by PubMed search using the term "Riata." In the base case, the age of the patients at presentation is 64 years, which is the median of the mean ages of participants in the studies listed in Table 1.

The baseline for prevalence of externalization, probability of electrical failure given externalization, and probability of electrical failure in the absence of externalization were derived from the largest published study of routine fluoroscopy with Riata leads.[6] The probability of arrhythmic death given electrical failure is extrapolated from the Manufacturer and User Facility Device Experience (MAUDE) database, a database of adverse events involving medical devices as reported to the FDA by both mandatory and voluntary reporters, and the Canadian Heart Rhythm Society.[4,21] The incidence of arrhythmic death in patients with an ICD from the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) was used for the probability of arrhythmic death in the absence of electrical failure and the probability of arrhythmic death after lead revision.[22] The probability of procedure-related mortality for capping and lead insertion was based on values from the National ICD Registry.[23] The probability of procedure-related death for Riata lead extraction and insertion of a new lead was the average of the procedural mortality from 2 multicenter extraction safety studies.[24,25] Data for rates of nonarrhythmic death were drawn from the 2008 US population life tables,[26] and these rates were increased based on the nonarrhythmic death in SCD-HeFT to adjust for the higher mortality rates in a primary prevention ICD population.[27] The adjusted life table data allow the probability of nonarrhythmic death to increase with age. The excess rate of nonarrhythmic death due to capping is then an additive adjustment to the rate of nonarrhythmic death. The sensitivity of fluoroscopy for detecting externalization was adopted from the Danish screening experience.[3] The range of values of model parameters was based on the literature cited, and when this was not available, the expert opinion of the authors. Annual rates were converted to monthly probabilities for the purposes of the Markov model.

Assumptions and Analysis

Patients diagnosed with electrical failure, who do not die in the interim, undergo lead revision, equally split between capping and explanting. Once a patient undergoes surgical lead revision, no subsequent revision occurs. The probability of dying due to arrhythmia among patients with electrical failure is independent of Riata lead externalization.[28] The cumulative rates of externalization and electrical failure increase over time at a constant rate. The relative risk of nonarrhythmic death is 1.0, indicating that an ICD is not expected to impact nonarrhythmic death. The risk of extraction of a Riata lead, regardless of whether or not it is externalized, is assumed to be the same as the risk of extraction of a non-Riata lead because there is a lack of data to place a numerical increased risk of extraction on an externalized Riata lead. The risk of extraction is age independent.

Sensitivity Analyses

There is inherent variability of probabilities and uncertainty in the literature due to the small studies that are heterogeneous and difficult to compare. Therefore, we conducted multiple one-way sensitivity analyses over a broad range of clinically plausible values to test the robustness of our results.[29,30] These sensitivity analyses included: (a) increasing the rate of externalization over time to as high as doubling it year over year and (b) increasing the excess rate of nonarrhythmic death due to an abandoned lead after capping. Threshold values, which are values within the clinically plausible range at which the preferred strategy changes, were calculated. Key variables were identified by the existence of a threshold value.

We performed a second-order Monte Carlo simulation as a probabilistic sensitivity analysis. This simulation consisted of 10,000 iterations of a 4-arm, randomized trial. This analysis used uniform distributions, so that the full range of plausible probabilities for each clinical variable were considered equally likely. Unlike the one-way sensitivity analysis,

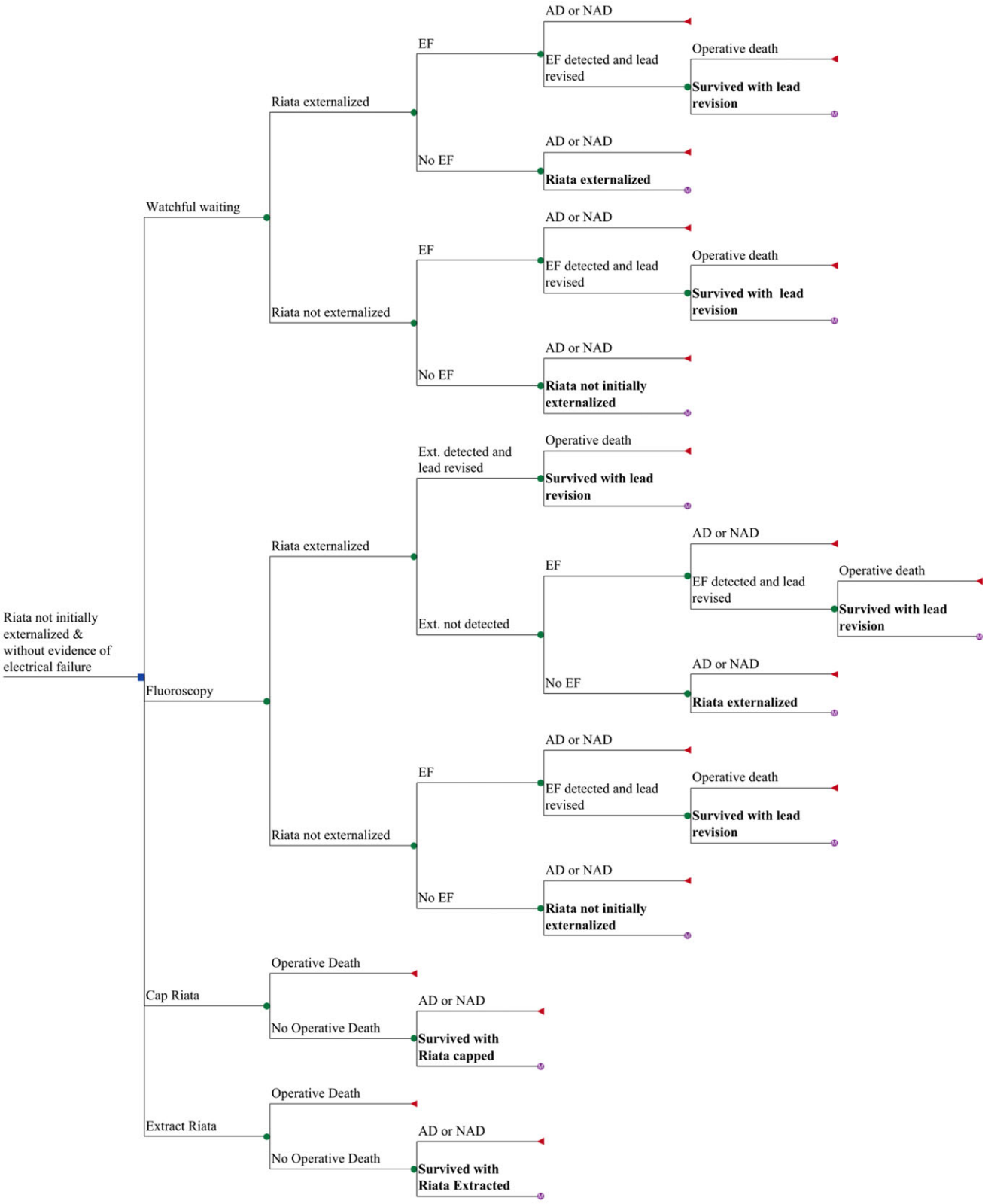

Figure 1. *Simplified diagram of the events in the first month following patient presentation. The square represents the decision node. Circles indicate chance nodes. Bold text denotes the start of different Markov processes. EF = electrical failure; AD = arrhythmic death; NAD = nonarrhythmic death. For a high quality, full color version of this figure, please see Journal of Cardiovascular Electrophysiology's website: www.wileyonlinelibrary.com/journal/jce*

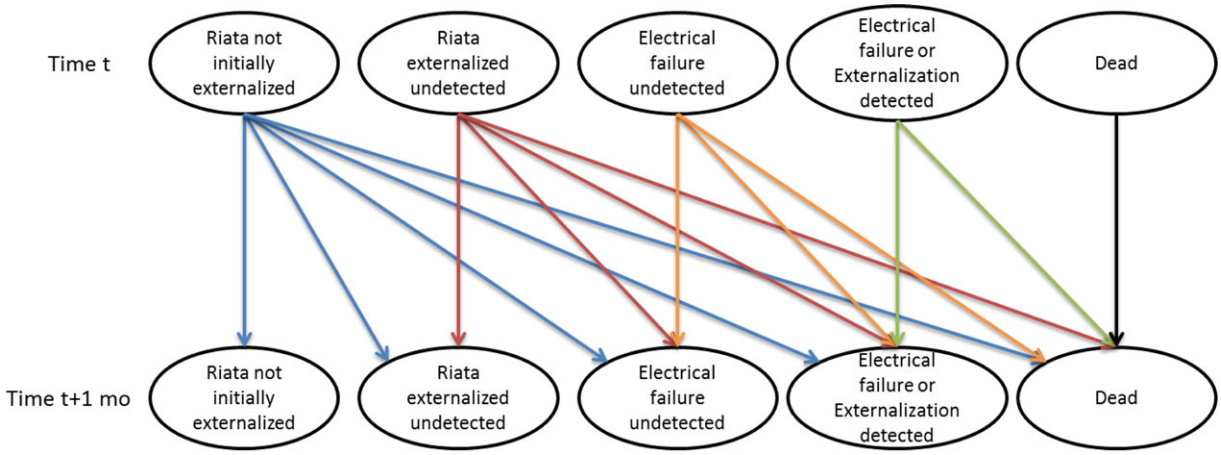

Figure 2. *Markov state diagram, illustrating the plausible transitions a patient could undergo during an interval of 1 month. (From left to right) the first 3 states represent the possible statuses of patients with Riata leads who have not undergone lead revision; the electrical failure state captures the events that trigger lead revision. All patients in immediate lead revision cohorts would start the Markov model with their lead revised. For a high quality, full color version of this figure, please see Journal of Cardiovascular Electrophysiology's website: www.wileyonlinelibrary.com/journal/jce*

TABLE 1

Model Input Parameters and Probabilities

Description	Baseline	Range	Distribution
Natural history of Riata			
Prevalence of externalization (%)	14.30[6]	5.30–53.10[3,15,31,37]	Uniform
Incidence of externalization (% per year)	2.64[6]	1.10–10.60[3,15,32,37]	Uniform
Increase rate of incidence of externalization (% per year)[a]	0	0–100	Uniform
Probability of electrical failure given externalization (% per year)	2.10[6]	0.10–17.40[14-16,37]	Uniform
Probability of electrical failure in the absence of externalization (% per year)	0.66[6]	0.00–5.00[11,14,18,33]	Uniform
Probability of arrhythmic death given electrical failure (% per year)	40.30[21]	13.70–100.00	Uniform
Probability of arrhythmic death in the absence of electrical failure (% per year)	1.20[22]	1.20–2.30[34]	Uniform
Procedure characteristics			
Probability of procedure-related death for capping (%)[a]	0.02[23]	0.005–0.2	Uniform
Probability of procedure-related death for extraction (%)	0.46[24,25]	0.17–0.65[35,36,38]	Uniform
Probability of arrhythmic death postprocedure (% per year)	1.20[22]	1.20–2.30[34]	Uniform
Excess rate of nonarrhythmic death due to capping (% per year)[a]	0	0–0.20	Uniform
Testing characteristics			
Sensitivity of fluoroscopy in detecting externalization (%)	90.00[3]	27.90–100.00[12,15]	Uniform
Interval between fluoroscopies (month)[a]	12.00	6.00–60.00	Uniform
Interval between interrogations (month)	3.00		
Patient characteristics			
Patient age at point of decision making[a]	64.00	57.00–71.00	Uniform

[a]Authors chose a range that was felt to be clinically relevant based on the baseline value from the literature.

all ranges of variables were randomly tested at the same time, accounting for the impact of combined uncertainty of model imputs.

All analyses were performed with TreeAge software (TreeAge Pro 2013, TreeAge Software Incorporated, Williamstown, MA, USA), which is designed for medical decision analyses.

TABLE 2

Life Expectancy of a Patient with a Riata Lead Based on Different Management Strategies

Capping	Extraction	Fluoroscopy	Routine Interrogation
134.5 months (11.2 years)	134.0 months (11.2 years)	133.9 months (11.2 years)	133.5 months (11.1 years)

Results

Applying baseline variables and parameters from Table 1,[3,6,11,12,14-18,21,22,24,25,31-38] the model indicated that, with respect to average life expectancy, lead revision with insertion of a new lead was preferred. The average life expectancy for patients that have a new lead implanted with capping of the Riata lead *in situ* was 134.5 months (Table 2). The life expectancy was improved by 0.5 months by capping the Riata lead compared with extracting it (134.5 months vs. 134.0 months, respectively). Using fluoroscopy to screen for externalized leads and using routine device interrogation without fluoroscopy produced life expectancies of 133.9 and 133.5 months, respectively. The net difference between the

highest (capping) and lowest (routine interrogation) life expectancies was 1.0 month.

Sensitivity Analyses

The results of the one-way sensitivity analyses (Table 3) demonstrate that the model is sensitive to one parameter: excess rate of nonarrhythmic death due to an abandoned lead from capping. Lead revision is favored over conservative management (fluoroscopy or routine interrogation) for all values within the sensitivity analyses.

Excess Risk of Nonarrhythmic Death Due to Retained Lead

The type of lead revision that is preferred changes from lead capping to extraction with higher risk of nonarrhythmic death due to retained leads. The procedural risk of extraction remains constant in this analysis. The threshold is an increased risk of nonarrhythmic death of 0.05% per year, above which extraction is favorable and below which capping is preferred. This means that the model recommends extracting the lead instead of capping it if the risk of nonarrhythmic death for a patient is predicted to increase by more than 0.05% per year due to lead abandonment.

Frequency of Fluoroscopy

The frequencies of fluoroscopy to evaluate for externalization or device interrogation to monitor electrical lead characteristics had no impact on the preferred strategy. Lead revision is the preferred management strategy for Riata leads regardless of the frequency of fluoroscopic screening. There is also no threshold for the sensitivity of fluoroscopy, so capping is the preferred strategy regardless of sensitivity of fluoroscopic screening for lead externalization.

Rate of Externalization

A time-dependent sensitivity analysis was performed for the rate of externalization. Increasing the rate of externalization over time did not change the preferred strategy. There was minimal impact on life expectancy of a fluoroscopy strategy (133.9 months) instead of a routine interrogation strategy (133.0 months) even with an assumption of an exponential increase in externalization by doubling the rate year over year.

Monte Carlo Simulation

A second-order Monte Carlo simulation was performed for 10,000 simulated patients. Lead revision, composed of lead extraction and lead capping, was associated with the highest survival for 100% of simulated patients (denoted 100% certainty). There was 76% certainty that lead extraction was the optimal strategy, while capping was the best strategy with 24% certainty (Fig. 3). An additional sensitivity analysis found that the probability of procedure related death with extraction would have to be 1.85% in order for capping to be the preferred strategy with 100% certainty. A procedure related death with extraction of 0.90% would result in 50% certainty that capping was the optimal strategy and 50% certainty that extraction was the optimal strategy.

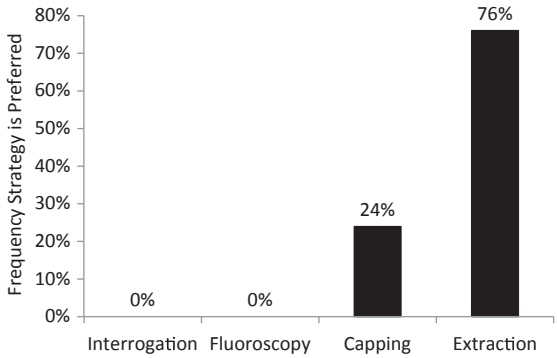

Figure 3. *Preferred management strategies demonstrated by a second-order Monte Carlo simulation of 10,000 iterations.*

Validation of Decision Model

To assess the validity of our model, we compared the mortality rates of the routine interrogation strategy in our decision model to those seen in SCD-HeFT.[27] Our model and SCD-HeFT both have an approximately 6% mortality rate at 1 year. Our model has mortality rates of 18% and 29% at 3 and 5 years, respectively. These rates are similar to the SCD-HeFT 3- and 5-year mortality rates of approximately 15% and 28%, respectively.

Discussion

Management of patients with Riata leads is a challenging but important problem.[8] This decision analysis found similar patient survival regardless of the management strategy, but there was a demonstrable advantage with lead revision. Fluoroscopy did not change survival even if performed multiple times a year with a sensitivity of 100%. Lead revision was favored across all one-way and probabilistic sensitivity analyses, demonstrating the robustness of capping and extraction within the model. Capping had the greatest survival advantage in the primary analysis of the model, but extraction was preferred based on the probabilistic sensitivity analysis.

The slightly higher rates of mortality in our model compared to SCD-HeFT are consistent with the known risks of Riata leads. The differences in life expectancy between any pair of management strategies was modest. Although the 1-month improvement in longevity per patient with capping or extraction represents a meaningful impact on survival at the population level, at the individual level, this may be seen as an uncertain conclusion—a result which might lead one to view the strategies as effectively equivalent, often denoted as a "toss-up."[39] Patient-level issues not accounted for in the model and patient preferences become especially important. The optimal timing of conversations with primary prevention ICD patients may be at the time of a generator change, given that there is a risk of infection whenever a pocket is opened.

The quantitative risk of capping a lead is difficult to determine,[40] so patient preferences are important for this decision making. In order to understand how long-term risks of a retained lead, such as venous occlusion, impact the model, we performed a sensitivity analysis on the additional risk of capping a lead. We found that capping would be favored in

TABLE 3
Results of One-Way Sensitivity Analyses

Variable	Baseline Value	Threshold Value	Range of Predicted Survival (Year)	Preferred Strategy
Natural history of Riata				
Prevalence of externalization (%)	14.30	None	11.21	Capping
Incidence of externalization (% per year)	2.64	None	11.21	Capping
Increase rate of incidence of externalization (% per year)	0	None	11.21	Capping
Probability of electrical failure given externalization (% per year)	2.10	None	11.21	Capping
Probability of electrical failure in the absence of externalization (% per year)	0.66	None	11.21	Capping
Probability of arrhythmic death given electrical failure (% per year)	40.30	None	11.21	Capping
Probability of arrhythmic death in the absence of electrical failure (% per year)	1.20	None	10.20–11.16	Capping
Procedure characteristics				
Probability of procedure-related death for capping (%)	0.02	None	11.21	Capping
Probability of procedure-related death for extraction (%)	0.46	None	11.21	Capping
Probability of arrhythmic death postprocedure (% per year)	1.20	None	10.20–11.16	Capping
Excess rate of nonarrhythmic death due to capping (% per year)	0	0.05	11.16–11.21	Capping (0-0.05) Extraction (0.05-0.20)
Testing characteristics				
Sensitivity of fluoroscopy in detecting externalization (%)	90.00	None	11.21	Capping
Interval between fluoroscopies (month)	12	None	11.21	Capping
Patient characteristics				
Patient age at point of decision making	64	None	9.20–11.21	Capping

place of extraction in patients with a risk of death attributable to a retained lead of less than 0.05% per year. There are also procedural complications associated with capping a lead, as reported in the REPLACE registry; however, there were no periprocedural deaths reported in single ICD lead upgrades in REPLACE.[41] The focus of this analysis is on mortality and not morbidity, which is why these event rates were not modeled.

Modeling lead management strategies can help avoid unintended consequences. The Telectronics Accufix pacing lead is an example in which extraction increased mortality.[42] The periprocedural mortality with Teletronics Accufix extraction was 0.4%, less than the 0.46% incorporated in our model. However, sensitivity analysis showed no change in the preferred strategy despite increasing the procedure-related mortality to 0.65% (1.5 × Teletronics Accufix). Furthermore, at high-volume centers lead extraction safety has improved over time.[25] The data from our model do not suggest that lead revision with Riata leads will result in net patient harm.

The second-order Monte Carlo simulation is an important analysis, as many of the probabilities in the model are uncertain. The simulation accounts for the aggregate effect of uncertainty by randomly drawing probabilities from their plausible range. By repeating this exercise for 10,000 simulated patients, we obtain an estimate of the certainty that a particular strategy results in the best outcomes. The certainty is the percentage of the 10,000 patients for which a specific lead management strategy provides the longest survival. This analysis does not quantify the difference in survival between strategies. The second-order Monte Carlo simulation shows that the findings of the model are very robust because of the 100% certainty that lead revision has the best survival. Due to the small absolute differences in survivals, this sensitivity analysis is important because it shows that the lead revision does not have a worse outcome than fluoroscopy or routine interrogations. Capping and extraction are similar statistically and clinically in terms of survival, but the second-order Monte Carlo favored extraction over capping 3–1 (76% vs. 24%). The model suggests that extraction has greater certainty of being preferred over capping, as long as an institution's periprocedural extraction mortality from Riata extraction is less than 0.90%.

The one-way sensitivity analyses show that lead revision is always the favored management strategy, and these findings were independent of age, rates of lead externalization, rates of lead electrical failure, procedural complication rates, or patient risk of arrhythmic death. The rate of arrhythmic death in the ICD arm of SCD-HeFT was 1.19% per year,[22] and 2.28% per year in the ICD arm of the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II).[34] Based on our model, the average primary prevention ICD patient in SCD-HeFT and MADIT-II would have benefited from lead revision had those patients had a Riata lead *in situ*. In patients with a higher risk of arrhythmic death, such as a secondary prevention ICD patient, the Markov model underestimates the benefit of lead revision, making this strategy even more attractive.

The current FDA recommendations support fluoroscopic screening for externalization. Based on the sensitivity analyses from this Markov model, frequent fluoroscopic lead

evaluations compared to no fluoroscopic evaluation did not impact the preferred management strategy, nor did improved sensitivity of fluoroscopy. The reason these parameters did not influence the value of fluoroscopy (as well as the relative unimportance of rate of externalization) is that externalization is an imperfect predictor of lead failure. These findings bring into question the value of fluoroscopic screening for externalization in patients with Riata or Riata ST leads.

Limitations

There are several limitations to this analysis. Although the probabilities are derived from the literature, most are based on retrospective studies. Accordingly, several assumptions were required. It is thought that the rate of complication with Riata leads increases over time, but the kinetics of this increasing risk are not well described. If externalization increases faster than exponentially doubling year over year, as modeled in the probabilistic sensitivity analysis, or if lead failure increases at higher rates over time than a linear assumption suggests, our model could underestimate the benefit of lead revision. There was no differentiation between 7 French and 8 French Riata leads because the available data remain limited. In order to keep the model tractable, we did not include the time to generator change-out, but waiting for a generator change-out and then revising the lead would be a hybrid of watchful waiting and lead revision, so the survival would be somewhere between the survival of routine interrogation and capping.

Another assumption was that the probability of nonarrhythmic death was the same for externalized and nonexternalized Riata leads. There have been case reports of thrombi forming on externalized leads[43,44] without evidence of clinical sequelae. The thrombi are usually small, so the risk of a fatal thromboembolus is low; however, patients could theoretically experience chronic thromboembolic events or paradoxical emboli, which could have significant morbidity or even mortality effects. Additionally, there are theoretical concerns that a capped and retained externalized Riata lead could lead to ineffective defibrillation with a new lead due to current arcing from the active lead to the capped lead. The risks associated with retaining a Riata lead and needing an extraction in the future were also not included in the model for simplicity, although longer duration *in situ* and increased externalization over time may increase the risk of a future extraction, and including these considerations would further favor immediate extraction. The decision to extract must be individualized because factors such as age, an institution's extraction volume, and clinical characteristics such as renal insufficiency, diabetes, and low body weight are associated with procedural complications.[25]

Conclusion

The FDA placed Riata leads under advisory and recommended fluoroscopic screening due to higher than expected rates of externalization and electrical failure. This Markov decision model suggests no evidence to support fluoroscopic screening for externalization of Riata or Riata ST leads. Lead revision, including extraction, is a reasonable strategy for these patients, with a high likelihood of modestly improved life expectancy. The decision making needs to be guided by patient preferences, attitudes toward risk, and the possible distress of having an advisory lead *in situ*.

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Supporting Information

Additional supporting information may be found in the online version of this article at the publisher's website:

Table S1. Predicted Survival at Low and High Range of Each Variable.

Figure S1. Full version of decision analysis mode.

Figure S2. Calculations for probability of arrhythmic death in the absence of electrical failure.