Chronic performance and complications of Riata 1580 compared with Endotak 0158 ICD leads: a single centre ten year experience

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Conflicts of interest: none declared

Abstract

Aims

The long term performance of the Riata family of leads has recently come under increasing scrutiny. We aimed to determine the long term performance of the Riata 1580 leads compared with Endotak 0158 leads.

Methods

All patients with Riata 1580 or Endotak 0158 leads implanted from 2003-2008 at the Heart Hospital, UCLH were analysed.

Significant electrical changes were: threshold increase >1V at a set pulse width between pacing checks, persistent R wave fall to < 2mV or reduction in R wave >50%, noise, pacing impedance change to <300Ω or >1500 Ω, HV change to < 20Ω or > 200Ω, HV change ± 15Ω, pacing impedance change > 400Ω over 12 months.

Results

333 Riata and 356 Endotak leads were implanted. Median follow up time + interquartile range, after exclusion of censored events including loss to follow up: Riata 3652 + 655 days, Endotak 3730 + 810 days. A total of 51 (15.9%) Riata leads and 21 (6.3%) Endotak leads were affected.

A greater risk of failure was found for the Riata lead compared with the Endotak lead (p=0.0001). An additional time-dependent effect was found, with the Riata lead 1.9 times

more likely to fail in the first 6 years following lead implantation and 5.3 times more likely to fail after 6 years.

Conclusion

Riata leads have a higher risk of failure compared to Endotak leads over time. The importance of careful ongoing performance surveillance late in the leads' lifetime is reflected in this ten year follow up study.

Keywords

Riata; Endotak; ICD; lead performance; lead failure

Condensed Abstract

We compared the chronic electrical performance of Riata 1580 leads with Endotak 0158 leads. The Riata lead was 1.9 times more likely to fail within 6 years and 5.3 times more likely after 6 years. The importance of ongoing lead surveillance is reflected in this ten year follow up study.

What's New?

● This is a ten year analysis of the Riata 1580 lead electrical performance compared with a non-recalled ICD lead (Endotak 0158)

● There is an apparent time-dependent effect, with the Riata lead 1.9 times more likely to fail in the first 6 years following lead implantation and 5.3 times more likely to fail at any time after 6 years following lead implantation.

Introduction

ICD implantation rates continue to increase, driven by evidence from clinical trials. Despite undergoing rigorous premarket testing, chronic failures of ICD leads are inevitable and described across all manufacturers[1, 2] . Failures may only become apparent after long-term use. The clinical consequences of lead malfunction are serious, often requiring revision procedures and possible extraction, with the consequent risks of severe procedural complications.

A prominent lead advisory in recent years was the Riata lead, manufactured by St Jude Medical. Following FDA Class I recall of Riata and Riata ST leads in December 2011, the long-term performance of the Riata family of leads has been subject to increased scrutiny. Perforations and conductor externalisation were initially described, with concerns later raised about their chronic electrical performance.[3] Limited long term data on the performance of these leads have been available to guide physician management of patients and to date, little data is available on lead function and failure rates over a decade.

Between 2003 and 2008 the Heart Hospital UCLH implanted ICD systems made predominantly by St Jude Medical and Guidant/Boston Scientific. We compared the Riata 1580 leads (St Jude Medical 8Fr dedicated bipolar dual coil active fixation) with the Endotak 0158 leads (Boston Scientific 9Fr integrated bipolar active fixation), implanted over the same time period in large numbers in this single centre.

Methods

All patients who underwent implantation of Riata 1580 or Endotak 0158 leads from 2003-2008 at The Heart Hospital, UCLH were retrospectively analysed from our ICD database. Patient data was anonymised for the purposes of the study.

Demographic information, implantation details and follow up data were obtained from Philips Cardiovascular Information Management System (CVIS), medical notes, pacemaker clinic notes and electronic patient records. Further follow up details were obtained from other hospitals to which patients were transferred for ongoing care within the UK and Ireland and general practice surgeries.

Lead failure was defined by electrical parameters outlined in table I. Where a significant parameter change was transient and resolved or improved without further issue at chronic follow up, it was not included as a failure. Intervention for failure included implantation of a new ICD lead or new pace sense lead (± extraction of the failed lead) or insulation repair.

We excluded from analysis early displacements, electrical failures before the first outpatient pacing check (within 6-8 weeks post implant) and all leads in which the pace-sense component of the ICD lead was not used.

Variables of patient gender, age, lead position (apical or septal), number of leads at time of implant of the index lead, aetiology of heart disease, approach (venous access method), position of generator pocket (pre-pectoral or sub-pectoral) were recorded.

When an electrical failure occurred, lead survival was calculated from date of implantation to the date of defect detection. In patients without electrical failure, the follow up period was calculated from the time of implant to the last recorded pacing check. Serious clinical events of death, cardiac transplantation, device/lead removal for infection or deactivation/ extraction at patient or physician request were also recorded.

Statistics

The Kaplan-Meier method was used to estimate the time of lead event-free survival/failure for each independent variable (lead type, gender, age, lead position, number of leads at time of implant of the index lead, aetiology of heart disease, lead insertion approach and type of generator pocket) and Log-rank tests were used to compare the risk of failure across the subcategories of each independent variable.

The data were analysed using a Cox proportional-hazards regression model, to compare the risk of failure between lead types, whilst accounting for the potential effects of the other independent variables.

A separate analysis was performed using the same statistical methods to further explore the effects of the independent variables on the risk of failure of the Riata lead only.

Results

Between 2003 and 2008, 333 Riata 1580 leads and 356 Endotak 0158 leads were implanted at the Heart Hospital, UCLH. Of those, 12 Riata leads and 21 Endotak leads were excluded from

further analysis due to removal from service before the first follow up after implant (at 6-8 weeks) or where a separate pace-sense lead was in use.

The demographic details for both groups of patients are summarised in table II. Censored events for each lead over the follow up period are shown in table III.

Of the Riata leads, 29 were not assessed within the year prior to termination of the study. Of the Endotak leads, 33 were not assessed within the year prior to termination of the study. Median days of follow up for all Riata leads were 2195 days (range 1-4389). Median days of follow up for all Endotak leads were 2271 days (range 1- 4530). Using the reverse Kaplan Meier method, the estimated median potential follow up time was 2,540 days for all leads combined. Where left and right censored events are excluded for Riata and Endotak leads, the median + IQR days follow up period for both leads are 3652 + 655 and 3730 + 810 respectively.

Of 656 leads, 72 (11.0%) failed during the follow up period. There were 51/321 (15.9%) Riata leads and 21/335 (6.3%) Endotak leads fulfilling criteria for failure (table IV).

Threshold rise was the most common electrical failure recorded in the Riata lead group, occurring in 21/51 (41.2%) cases of lead failure and in 6.5% of all Riata leads over the follow up period. Noise was the second most common electrical failure, occurring in 17/51(33%) cases of lead failure (5.3% of Riata leads).

Of the 51 failed Riata leads, 47 underwent intervention for failure. Interventions included a replacement lead or introduction of a new pace sense lead.

Of the remaining four cases, one patient underwent cardiac transplantation and required no further action; two Riata leads were deactivated without invasive intervention due to advanced age and frailty, and one Riata lead was deactivated in a young man who had not required any therapy since the device had been implanted.

Noise was the most common electrical failure recorded in the Endotak lead group, occurring in 19/21 (90.5%) cases and 5.7% of all Endotak leads. It was not possible to retrieve detailed data for the characteristics of the noise in every case, but available data indicates noise consistent with myopotentials in 9/21 failed Endotak leads. All 21 failed Endotak leads underwent intervention for failure, of which 16 leads were extracted. In 5 cases an additional pace-sense lead was used.

Electrical failure resulted in inappropriate shock therapy in 6 Riata leads and 3 Endotak leads. There were no known deaths associated with electrical failure.

Conductor externalisation was documented in a number of Riata leads during the period of follow up. No correlation between electrical failure and fluoroscopic evidence of conductor externalisation was identified.

<u>All leads combined dataset</u>

A statistically significant difference was observed in the survival distributions of the two lead types ($p=0.0001$), with a greater risk of failure for the Riata 1580 lead compared with the Endotak 0158 lead. No statistically significant differences were observed for any other independent factors in the Log-rank tests at the 5% significance level. However, there was a

trend towards greater risk of lead failure seen for a sub-pectoral generator pocket compared with a pre-pectoral pocket (p=0.0893).

The estimated survival probabilities by lead type are shown in table V. The survival probabilities by year for both leads, from 1-11 years, are estimated using stepped interpolation. The estimates are based on the closest Kaplan -Meier survival probabilities available, which are drawn from the latest failure event prior to the year end.

A statistically significant effect of age on the risk of failure is found when a univariate Cox-proportional hazards regression model is applied with age as a discrete variable, rather than a categorical independent variable, and as the only independent variable (Wald p=0.0053). The risk of failure is estimated to decrease by approximately 2.0% for each year increase in age at implant (HR=0.98; 95% CI= 0.97, 0.99) under the univariate model, suggesting younger patients are at greater risk of lead failure.

A backward stepwise regression algorithm was applied to the full Cox proportional-hazards regression model including all independent variables. The model fit was determined using Akaike's Information Criterion, ensuring only variables with a substantial effect on the performance of the model were included. The final model from the stepwise regression analysis includes the variables of lead type, age at implant and pocket type. The coefficient values for the variables lead type, age at implant and pocket type under the final model are shown in table VI. Under this model, the regression coefficient for pocket suggests a greater risk of failure where the generator is placed in the subpectoral position, but does not reach significance at the 5% level (Wald p=0.0592). Under this model, the regression coefficient for

age at implant suggests that older patients have a lower risk of lead failure although, again, the effect is not observed at the 5% level (Wald p=0.0670).

Evidence was found to contradict the proportional hazards assumption for lead type only, indicating that the effect of lead type on the risk of failure is not constant over time. A time dependent coefficient for lead type was included by stratifying the time since implantation into distinct periods and calculating the effect of lead type separately in each period. A range of time period cut-offs were explored, with stratification in to ≤6 years and >6 years providing the best fit by Akaike's Information Criterion.

The regression coefficients for lead type, stratified by time since implant of ≤6 years and > 6 years, suggest that the risk of failure is greater for the Riata lead in both time periods (Wald p=0.0505 and 0.0008 respectively), although the coefficient for ≤ 6 years did not reach significance at the 5% level. The estimated hazard ratios and confidence intervals for each time period are1.86 (95%CI 1.00, 3.45) and 5.3 (95%CI 1.99, 14.10), respectively. This is reflected in the survival distributions of the leads shown in the Kaplan-Meier curve (figure I and table VII), with a greater separation in the survival distributions occurring after several years.

Riata lead only dataset

A separate statistical analysis was performed, exploring the effects of the independent variables on the risk of failure of the Riata lead only.

The results of the Log-rank tests for the Riata lead showed a statistically significant difference in the survival distribution for pocket position, with a greater risk for the sub-pectoral pocket compared with the pre-pectoral pocket (p=0.0394). There was further evidence found for a difference in survival distributions by aetiology of cardiac condition (p=0.0393). The observed and expected lead failure events suggests a lower risk of failure in the ischaemic patient group and a higher risk in the hypertrophic cardiomyopathy and dilated cardiomyopathy groups. There were no other statistically significant differences at the 5% level in the Log rank analysis of the other independent factors in the Riata lead group.

Performing a univariate Cox-proportional hazards regression model with age at implant as a discrete rather than a grouped categorical variable, we found a statistically significant effect of age on the risk of failure for the Riata lead (Wald p=0.0120). The risk of failure is estimated to decrease by approximately 2.1% for each year older a patient is at the time of implant (HR = 0.98; 95% CI = (0.96, 0.995)), indicating a greater risk of lead failure in younger patients.

A Cox Proportional hazards model was applied to the Riata lead dataset (with lead type variable redundant). The final model from the stepwise regression analysis includes the variables age at implant and pocket. The risk of Riata lead failure is estimated to decrease by approximately 1.9% for each year older a patient is at the time of implant. There is weak evidence of an effect of generator position, with the risk of failure estimated to be 1.6 times higher where the generator is placed in the sub-pectoral position compared with the pre-pectoral position.

Discussion

To our knowledge, this ten year period follow-up of Riata lead performance is the longest to date.

Malfunction of chronically implanted ICD leads can result in significant morbidity and mortality. Lead failures once identified, need to be assessed for acute and long term risk management. Although ideally all leads should perform well over many years, some designs are more prone to developing defects over time. ICD leads in particular are more prone to failure due to their complex design compared to pacing leads and manufacturers also make leads differently. Despite rigorous premarket testing, certain leads do not perform as well as others and significant reported failures may take several years to become apparent.

The Riata and Riata ST lead family includes models that differ in a number of ways, including lead diameter, type of fixation and whether dual or single coil. In our study, a single Riata model (1580) was selected for assessment to allow a head-to-head performance comparison with another manufacturer's model (Endotak Reliance 0158) within the same implanting centre. The Riata 1580 lead is an active fixation, dual coil, 8F lead manufactured by St Jude Medical. The Endotak 0158 lead is an active fixation, integrated bipolar, 9F lead manufactured by Boston Scientific.

Comparison of lead performance and survival estimates are hampered by a lack of strict and universally accepted criteria for failure, although there have been attempts to standardise this.[4] The Riata lead is also prone to both structural and electrical failures, with the relationship between the so-called "inside-out" abrasion pattern of structural failure and electrical

abnormalities in this lead remaining unresolved. In our study, lead failure was defined by specific electrical performance criteria. This was to reduce the introduction of bias resulting from change in practice over time in the management of a lead under advisory. There were two Riata leads removed prophylactically for conductor externalisation without associated significant electrical failure in the follow up period.

Some studies have not found an excess of lead-related adverse events in the Riata lead family. Data collected from registries of patients implanted with Riata family leads with a median follow up of 22 months found an incidence of 0.09% conductor and 0.13% insulation damage.[5] A large multicentre study with a mean follow up of 18 months found an incidence of 0.18% conductor fracture and 0.21% insulation damage.[6] The low incidence of adverse events may reflect the relatively short follow up periods.

The need for longer postimplant surveillance periods is reflected in several studies that found survival curves of recalled leads diverge from non-recalled leads some years after implantation. In a study comparing the performance of Riata and Fidelis leads versus non-recalled leads, the survival curves of the recalled leads diverged from the non-recalled leads after 2 years' dwell time.[7] A large single centre retrospective study comparing the failure rates of Riata/ST, Sprint Quattro, Sprint Fidelis and Endotak lead families, found the 5 year survival probability of the Riata/ST leads to be greater than Fidelis leads but less than the Quattro and Endotak groups. The survival curve for the Riata/ST leads was reported to show a significant downward trend in survival at around 48 months.[8]

A non-linear trend of failure in Riata leads has been previously reported, with increased risk of electrical failure several years after implantation. A two-centre retrospective study of

electrical failures of 108 patients with Riata 1581 (n=72) and Riata ST 7001 (n=36) leads, with a mean follow up of 7.0 +/- 1.8 years, found a failure rate of 1.84% per device year. Using conditional survival analysis, electrical failure rate was estimated to be 7% per year in leads surviving beyond 5 years.[9] In a single centre retrospective study of 314 Riata and Riata ST leads with a median follow up of 4.1 years (IQR 1.8-5.7 years) there were 21 electrical failures. The average failure rate was 1.7% per device year. A lead failure rate of 5.2% per year after a dwell time of 4 years was predicted using conditional survival analysis.[10]

It is recognised that a progressively increasing failure rate is unlikely to be unique to recalled leads[2] and instead is likely to reflect those leads with less favourable engineering designs succumbing to a "critical amount of chronic mechanical stress"[10] after a prolonged dwell time.

Factors influencing lead failure

We analysed factors associated with lead failure in both leads and performed a separate analysis of the Riata lead only. Both datasets are consistent in their conclusions, showing weak evidence of an effect of age at implant and pocket position on the risk of lead failure. In the Log rank tests, evidence was also found for a difference in survival distributions of the Riata lead by aetiology.

An inverse relationship between increasing age at the time of implant and lead failure has also been shown in other studies of lead performance. [2, 10, 11] It has been postulated that this observation is related to the greater physical stresses to which the lead is subjected in a more physically active, younger person.

The degree of stress applied to the lead at the time of implantation and the mode of implantation may also have a bearing on its long term performance. Lead positioning during subpectoral pocket implantation could impose extra stress and abrasion forces by the rib cage on the lead compared with prepectoral pocket implantation. It has also been suggested that the subpectoral position necessitates an acute bend on the lead, which could contribute to stress on the lead and premature failure.[12]

The apparent difference in survival distributions of the Riata lead by aetiology appears to be driven by a lower risk of failure in the ischaemic group and a higher risk in the hypertrophic cardiomyopathy and dilated cardiomyopathy groups. It is notable that the latter groups have a higher proportion of younger, more physically active patients than the former. As this is a univariate analysis, this finding may reflect the association between aetiology and age.

Type of electrical failure

The two leads assessed in this study have important differences in lead design. The Endotak 0158 is an integrated bipolar lead, in which the distal shock coil acts as the ring electrode. The electrode configuration may render it prone to oversensing, which could in part account for the excess lead noise problems. The Riata noise events were predominantly of the 'high amplitude' type, whilst all recorded myopotentials were in the Endotak group. The simpler design of the integrated lead, however, may also confer an advantage with respect to lead failure risks.

A range of electrical failures have been identified in Riata leads. Consistent with our findings, many reports observe predominantly noise [8,10,13,14] and elevated pacing thresholds. [15,16,17]

Limitations

Outcome information was gathered in the same way for both leads, collected from routine pacing check entries. Observation bias could have theoretically arisen in both data entry and analysis, particularly following Riata lead advisory in 2011, due to greater scrutiny of Riata lead performance and more intensive follow up protocols. However, standard measurements were made at the pacing checks for both leads and each recorded failure for both lead types was carefully assessed against the study's failure criteria.

Although the two lead groups' demographics appear overall well-matched, the allocation of subjects to each group is not randomised and choice of lead and generator was down to contracts and choice by operators.

This is a single centre study comparing only two lead models which limits any conclusion when comparing performance to other leads. This does however have an advantage over studies which pool different ICD lead models into a single analysis. [18]

Conclusion

Chronically implanted ICD leads may fail over time. Riata leads have a higher risk of failure compared with Endotak leads. Most Riata lead failures were due to threshold increases and

noise, whilst almost all failure events in Endotak leads were noise-related. Younger age and sub-pectoral generator position are predictors of lead failure in both leads.

There appears to be a time-dependent effect, with the Riata lead 1.9 times more likely to fail at any time in the first 6 years following lead implantation and 5.3 times more likely to fail at any time after 6 years following lead implantation. This ten year study reflects the importance of careful ongoing surveillance of performance late in the leads' lifetime.

Funding

The authors received no specific funding for this work

Consent

Non-identifiable data was obtained from records made in the course of normal clinical care. All patients gave informed consent for the procedure.

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Table I: Classification of significant changes in electrical parameters

Threshold	> 1V increase*
Noise	Oversensing (+/- shock)
R wave	Persistent fall to <2mV Persistent fall of >50%
Pacing impedance	Fall to <300 Ω Rise to >1500 Ω Change +/- 400 Ω**
HV impedance	Fall to <20 Ω Rise to >200 Ω Change +/- 15 Ω

* Threshold increase at fixed pulse width between pacing checks and such that a 2:1 capture safety margin cannot be achieved

** Over a 12 month period

Table II: Demographics

	Riata 1580 N=321	Endotak 0158 N=335
Gender		
Male	223 (69.5%)	237 (70.7%)
Female	98 (30.5%)	98 (29.3%)
Age		
Median	56	64
Range	(16-84)	(18-90)
Lead position		
Apex	283 (88.2%)	300 (89.5%)
Septum	32 (9.9%)	29 (8.7%)
Unknown	6 (1.9%)	6 (1.8%)
Pocket		
Prepectoral	229 (71.3%)	233 (69.6%)
Subpectoral	89 (27.7%)	101 (30.1%)
Unknown	3 (0.9%)	1 (0.3%)
Approach at lead implant		
Cephalic	160 (49.8%)	172 (51.3%)
Subclavian/axillary	144 (44.9%)	141 (42.1%)
Unknown	17 (5.3%)	22 (6.6%)
Number of leads		
1	87 (27.1%)	95 (28.4%)
2	149 (46.4%)	127 (37.9%)
3	71 (22.1%)	101 (30.1%)
4+	14 (4.4%)	11 (3.3%)
Unknown	0 (0.0%)	1 (0.3%)
Aetiology of heart disease		
Ischaemic	95 (29.6%)	125 (37.3%)
DCM	81 (25.2%)	106 (31.6%)
HCM	90 (28.0%)	63 (18.8%)
GUCH	8 (2.5%)	4 (1.2%)
Other	45 (14.0%)	35 (10.4%)
Unknown	2 (0.6%)	2 (0.6%)

Table III: Censored events for the Riata and Endotak leads

	Riata (321)	Endotak (335)
Death	109 (34.0%)	143 (42.7%)
Days: median and range	902 (1-3652)	1247 (1-3915)
Removal or deactivation of lead	38 (11.8%)	24 (7.2%)
Infection	25	14
Transplant	5	5
Disabled at patient or physician request	8	5
Total	147 (45.8%)	167 (49.9%)

Table IV: Comparison of electrical failures

Electrical failure	Riata (n=321)	Endotak (n=335)
Number of leads affected	51 (15.9%)	21 (6.3%)
Threshold increase	21 (6.5%)	0 (0.0%)
Noise With shock Without shock	17 (5.3%) 6 (1.9%) 11 (3.4%)	19 (5.7%) 3 (0.9%) 16 (4.8%)
R wave fall Pacing impedance change HV change	7 (2.2%) 12 (3.7%) 6 (1.9%)	2 (0.6%) 6 (1.8%) 1 (0.3%)

Table V: Table of the yearly estimated survival probabilities by lead type, up to 11 years

All data combined

Year	Endotak 0158			Riata 1580		
	Survival probability	SE	95% CI	Survival probability	SE	95% CI
1	0.987	0.007	0.974, 1	0.982	0.008	0.967, 0.998
2	0.987	0.007	0.974, 1	0.974	0.01	0.956, 0.993
3	0.971	0.01	0.951, 0.991	0.961	0.012	0.938, 0.985
4	0.966	0.011	0.945, 0.988	0.947	0.014	0.919, 0.976
5	0.939	0.016	0.909, 0.969	0.913	0.019	0.877, 0.951
6	0.933	0.016	0.902, 0.966	0.866	0.023	0.822, 0.913
7	0.922	0.018	0.888, 0.958	0.804	0.028	0.75, 0.861
8	0.916	0.019	0.88, 0.954	0.791	0.029	0.736, 0.851
9	0.908	0.02	0.869, 0.949	0.774	0.031	0.715, 0.837
10	0.908	0.02	0.869, 0.949	0.731	0.036	0.664, 0.806
11	0.884	0.031	0.825, 0.947	0.693	0.044	0.612, 0.784

Table VI: Table of the coefficients and hazard ratios for all leads under the final model.

Variable	Factor comparison	Coefficient	SE	HR	HR 95% CI	z-statistic	p-value
Pocket	Sub versus pre	0.4645	0.246	1.5912	(0.982,2.578)	1.89	0.0592
Age at implant	Per year increase	-0.0132	0.007	0.9869	(0.973,1.001)	-1.83	0.0670
Lead type: Time period	R versus E, ≤6 years following implant	0.6182	0.316	1.8556	(0.999,3.448)	1.96	0.0505
	R versus E, >6 years following implant	1.6671	0.499	5.297	(1.991,14.089)	3.34	0.0008

SE = Standard Error, HR = Hazard Ratio, CI = Confidence Interval.

Table VII: Log-rank test of the survival distribution for the leads by lead type.

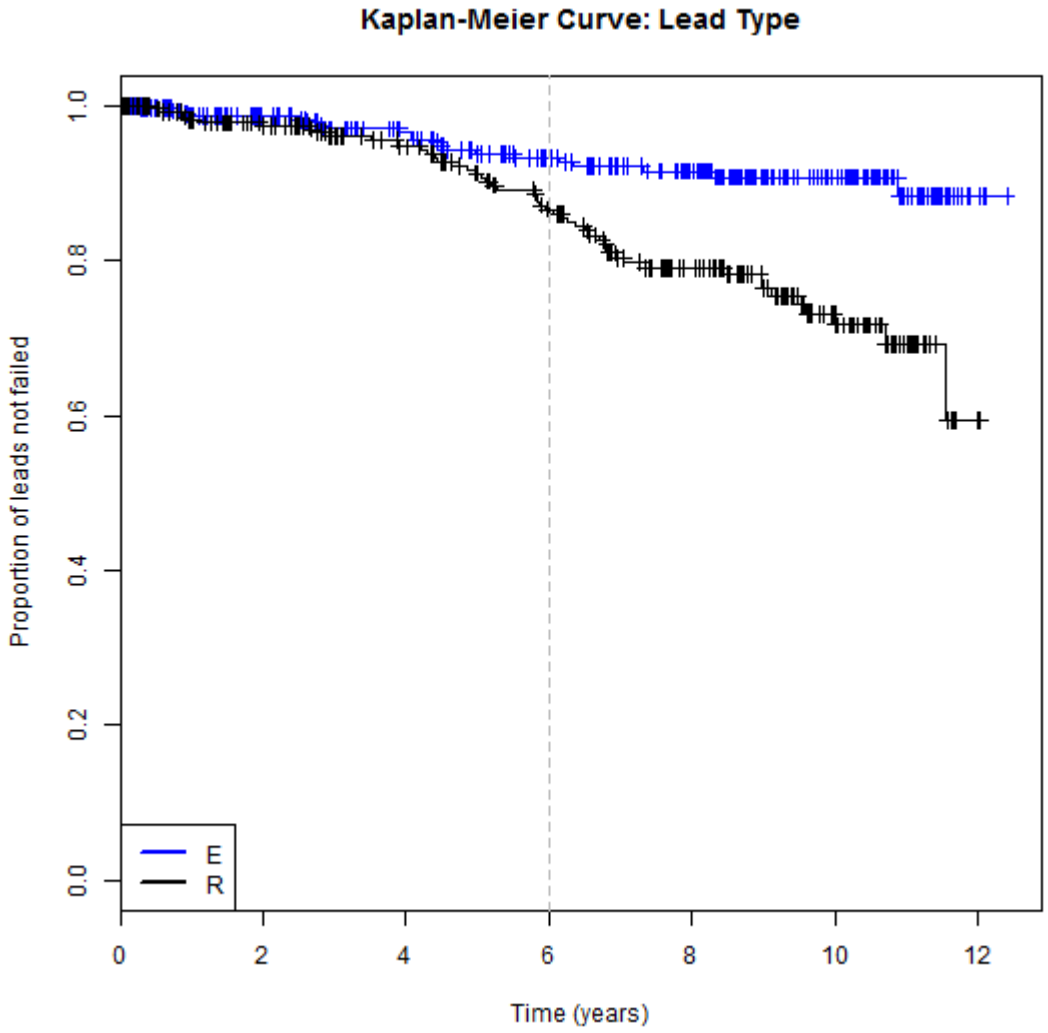
Lead type	N	Observed	Expected	Test statistic	P value
Endotak	335	21	37.9	15.866	0.0001
Riata	321	51	34.1		

N=Number of leads per group.

Observed is the observed number of lead failures.

Expected is the expected number of lead failures under the assumption that the survival distributions are the same.

Figure I: Kaplan-Meier curve showing the estimated survival function for the leads by lead type.



Vertical tick-marks indicate where a lead's failure time has been right-censored. The vertical, dashed line shows the cut-off time of 6 years to be used for stratifying the effect of lead type by time period following implantation.