# Cable externalization and electrical failure of the Riata family of implantable cardioverter-defibrillator leads: A systematic review and meta-analysis

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**BACKGROUND** The Riata class of defibrillator leads were placed under US Food and Drug Association (FDA) advisory as of November 2011 because of high rates of cable externalization (CE) and electrical failure (EF). The overall rates of these complications remain unknown.

**OBJECTIVE** The purpose of this study was to systematically search the literature for rates of Riata lead failure and to perform a meta-analysis to estimate failure rates.

**METHODS** We conducted a meta-analysis of observational studies examining the rates of EF, CE, and the interaction of the two. We identified 23 English language manuscripts addressing 1 or more of these questions.

**RESULTS** Across 23 studies, the overall CE rate was 23.1% (95% confidence interval [CI] 19.0%–27.6%). The overall EF rate was 6.3% (95% CI 4.7%–8.2%). The presence of CE was associated with a more than 6-fold increase in the rate of EF compared to no CE (17.3% [95% CI 11.2%–25.9%] vs 2.7% [95% CI 1.4%–5.2%], respectively). The rate of CE was 3-fold higher for 8Fr leads compared to 7Fr leads, but rates of EF were similar (4.6%; 95% CI 3.2–6.6] and 3.9%; 95% CI 2.4–6.1], respectively). Rates of both CE and EF were higher in dual coil vs single coil leads, but confidence intervals overlapped.

**CONCLUSION** In clinical practice, rates of CE in Riata leads are substantial. While CE is associated with a significant increase in the risk of EF, the incidence of EF without externalization is not trivial.

**KEYWORDS** Recall; Advisory; Electrical failure; Cable externalization; Riata

**ABBREVIATIONS** **CE** = cable externalization; **CI** = confidence interval; **EF** = electrical failure; **FDA** = Food and Drug Administration

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In November 2011 the United States Food and Drug Administration (FDA) issued a class I advisory for the Riata and Riata ST ("Riata") implantable cardioverter-defibrillator leads (St. Jude Medical, St Paul, MN).[1] This advisory was due to an "increase in frequency of reported Riata insulation failures." As part of this safety communication, the US FDA recommended imaging via fluoroscopy or 2-view chest X-ray to identify insulation abnormalities.[2] A number of published reports have examined the rate of insulation failures using these recommended imaging techniques, ranging from the experiences of single centers to hospital systems to national reports. Outside of manufacturer-reported data, the overall rates of insulation failures reflected by visible cable externalization (CE) and electrical failure (EF) remain unknown. Moreover, although a correlation between CE and EF may be expected, this specific relationship in the case of Riata leads remains unclear.

In order to address these questions, we conducted a systematic review and descriptive meta-analysis of independent investigator-reported studies of CE and EF of Riata leads to characterize the relationship between these 2 phenomena.

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## Methods

### Study search

The systematic review was conducted according to the PRISMA guidelines for reporting of systematic reviews and meta-analyses as well as the MOOSE guidance for meta-analysis of observational studies.[3,4] We queried PubMed, Cochrane, and the US FDA website using the key word “Riata” to identify all English language reports of CE and/or EF of the advisory Riata and/or Riata ST defibrillator leads. The query was limited to studies involving humans.

### Eligibility and data abstraction

Studies in which patients were systematically screened for CE and/or EF were included. Studies including fewer than 35 patients were excluded. In cases in which the same population was serially monitored, only the manuscript with the most recent reporting of results was included.

Citations were reviewed and each manuscript was abstracted independently by 2 investigators (EPZ and SDP or KZ) using a standardized abstraction form. Forms were compared, and any discrepancies were resolved between reviewers.

Abstracted data included study population demographics, baseline characteristics, study design (including prospective vs retrospective, and single center vs multicenter), and important definitions (including CE, EF, and dwell time). Prespecified outcomes of interest included (1) rate of CE overall; (2) rate of CE by lead size and coil number; (3) rate of EF overall; (4) rate of EF by lead size and coil number; (5) rate of EF in the setting of CE; and (6) EF without CE. Figure 1 shows the study selection process according to PRISMA guidelines.[3]

### Definitions

In all cases, CE was determined by X-ray and/or cinefluoroscopy as reviewed by radiologists and/or electrophysiologists; however, there were inconsistencies in how CE was defined. In some cases, signs of incomplete or early CE were categorized as CE. Whenever possible, for the purposes of this analysis and for the sake of completeness, the definition of CE included early abnormalities. In most cases, the rate of CE was reported as prevalence at 1 point in time rather than incidence rate over a period of screening time. Here we focus on prevalence rates. In many cases, the average lead dwell time was reported. Generally, dwell time was defined as the time from implant to screening.

Although generally defined *a priori* by electrophysiologic parameters, the specific definition of EF was variable (see Appendix). Because the definitions were deemed similar and appropriate for determination of EF, for the purposes of this analysis the designation of EF for each study was accepted.

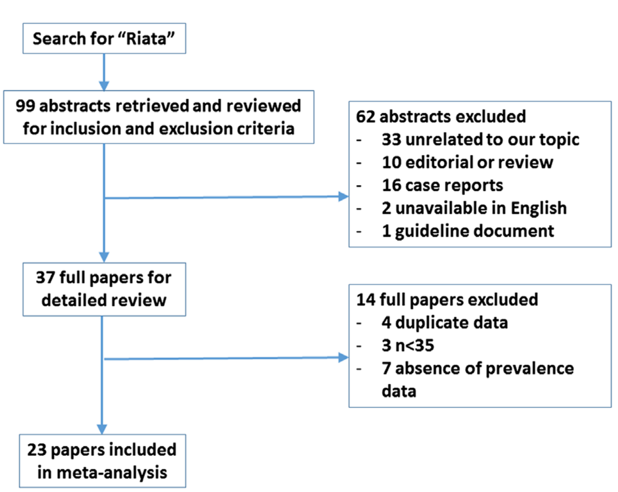



**Figure 1** PRISMA flowchart of studies.

### Statistical analysis

The prevalence of CE and EF (overall and by size and coil number) was estimated using a random effects model. For each study, we calculated the rates of prevalence of each variable of interest. We were not able to report annualized failure rates or adjust for differences in lead dwell time or time to externalization because of a lack of such specific data in the available manuscripts.

The unit of analysis was the patient (or lead). Because prevalence of CE or EF is not assumed to be fixed across study populations, these quantities were estimated with random effects modeling according to the method of DerSimonian and Laird[5] and reported as mean and 95% confidence interval (CI) . Heterogeneity and consistency were assessed using the weighted squared deviations (Q-statistic) and the ratio of true heterogeneity to the overall observed variation (I-squared). Magnitude of heterogeneity was quantified using $\tau^2$. Prespecified subgroup analyses included conditional probabilities of EF contingent on CE status as well as CE and EF rates for 7Fr, 8Fr, single-coil, and dual-coil leads. We used the method of moments for meta-regression to evaluate the impact of mean dwell time, mean age, percentage male, percentage dual coil, and percentage 8Fr leads on overall CE and overall EF.[5] All statistical analyses were conducted using the comprehensive meta-analysis program (Biostat, Englewood, NJ).

## Results

### Search results

A search identified 99 abstracts, which were reviewed for inclusion and exclusion criteria (Figure 1). Among this group of abstracts, 62 were excluded as follows: manuscript unrelated to Riata CE or EF (n = 33), editorial or review paper (n = 10), case report only (n = 16), unavailable for review in English (n = 2), and guidelines (n = 1). The full manuscripts for the remaining 37 studies were retrieved for detailed review. After full manuscript review, an additional 14 studies were excluded as follows: duplicated data in which only the most recent version was included (n = 4), sample size <35 (n = 3), and absence of data sufficient to calculate prevalence (n = 7).

Table 1 summarizes results from the 23 observational studies that examined at least 1 of the following: (1)

**Table 1** Studies included in manuscript by end-point(s) evaluated

| | | | | Distribution of lead types* | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Study (reference) | No. of patients | Average dwell time (y) | Single vs multicenter | 8Fr | 7Fr | SC | DC | CE | EF | EF\|CE | EF without CE |
| Ellis 2009[26] | 104 | NR | Multi | 37 | 67 | 0 | 104 | – | + | – | – |
| Erkapic 2011[8] | 357 | 3.5 | Single | NR | NR | NR | NR | – | + | – | – |
| Kodoth 2012[11] | 165 | 3.98 | Single | 78 | 83 | 92 | 73 | + | + | + | + |
| Parvathaneni 2012[17] | 87 | 5.9 | Multi | 74 | 13 | 0 | 87 | + | + | + | + |
| Shen 2012[20] | 84 | 5.6 | Single | 64 | 19 | 1 | 83 | + | + | + | – |
| Sung 2012[28] | 1403 | NR | Multi | 877 | 526 | NR | NR | – | + | – | – |
| Theuns 2012[22] | 1029 | 5.4 | Multi | 482 | 547 | 440 | 589 | + | + | + | + |
| Van Rees 2012[24] | 195 | 4.4 | Single | 165 | 30 | 30 | 165 | – | + | – | – |
| Abdelhadi 2013[6] | 1081 | 3.89 | Multi | NR | NR | NR | NR | + | + | + | – |
| Cheung 2013[7] | 316 | 4.1 | Single | 254 | 62 | 86 | 230 | – | + | – | + |
| Fazal 2013[9] | 106 | 4.5 | Single | 76 | 30 | 3 | 103 | – | + | – | – |
| Hayes 2013[10] | 776 | 5.93 | Multi | 517 | 259 | NR | NR | + | + | + | + |
| Kubala 2013[12] | 36 | 4.75 | Single | 23 | 13 | 13 | 23 | + | + | + | – |
| Larsen 2014[13] | 298 | 6.2 | Multi | 98 | 200 | 144 | 154 | + | + | – | – |
| Liu 2013[25] | 329 | NR | Multi | NR | NR | NR | NR | + | – | + | – |
| Lorvidhaya 2013[15] | 102 | 5.77 | Single | 95 | 7 | 1 | 101 | + | + | + | + |
| Moorman 2013[16] | 48 | 5.556 | Single | 23 | 25 | 0 | 48 | + | + | – | – |
| Parkash 2013[27] | 4358 | NR | Multi | 2847 | 1412 | NR | NR | – | + | – | – |
| Rordorf 2013[18] | 182 | 3.3 | Single | 141 | 41 | 76 | 106 | – | + | – | – |
| Schmutz 2013[19] | 52 | 5.9 | Single | 38 | 14 | 9 | 43 | + | + | + | + |
| Steinberg 2013[21] | 284 | 6.1 | Single | 204 | 80 | 96 | 188 | + | + | + | + |
| Valk 2013[23] | 374 | 5 | Single | 257 | 0 | 30 | 344 | – | + | – | – |
| Liu 2014[14] | 627 | 3.2 | Multi | NR | NR | NR | NR | – | + | – | – |
| **Totals*** | **12393** | | | **6350** | **3428** | **1021** | **2441** | **14** | **22** | **11** | **8** |

CE = cable externalization; DC = double coil; EF = electrical failure; EF|CE = electrical failure given cable externalization, NR = not reported; SC = single coil.

*Totals do not always equal the overall patient or lead amounts because of various exclusions within individual studies and the possibility of multiple leads per patient.

prevalence of CE, (2) prevalence of EF, (3) prevalence of EF in the presence of CE, and (4) prevalence of EF in the absence of CE. Of the 23 included studies, 10 (43%) were multicenter studies. More than 12,000 leads were represented in the included manuscripts, representing 6350 8Fr leads, 3432 7Fr leads, 1021 single-coil leads, and 2441 dual-coil leads reflecting general patterns of implantation of the Riata family of leads. Overall, 19 studies reported dwell time (mean 4.89 years, range 3.2–6.2 years).[6–24]

## Overall CE and EF

The 13 studies reporting prevalence of CE were of widely varying size and nonuniform methodology. Significant heterogeneity was noted with an $I^2 = 84.999$. Prevalence of CE ranged from 11% to 43% (Figure 2A).[6,10–13,15–17,19–22,25] Based on random effects modeling, the overall rate of CE was 23.1% (95% CI 19.0%–27.6%). In most but not all of these 13 studies, an average lead dwell time was reported (range 3.5–6.2 years). In some cases, a lead dwell time was reported separately for externalized and nonexternalized leads, and these ranges were overlapping (4.4–6.7 years and 3.19–5.9 years, respectively.

The prevalence of EF could be assessed in 22 studies (Table 1) and ranged between 0% and 33% (Figure 2B).[6–24,26–28] Based on random effects modeling, the overall rate of EF was 6.3% (95% CI 4.7%–8.2%). Significant heterogeneity was again observed with $I^2 = 89.507$.

Because of significant heterogeneity identified in the random effects meta-analysis of overall EF and CE, we analyzed the moderating effects of several study characteristics, including mean dwell time, mean age, percentage male, percentage dual coil, and percentage 8Fr. In the case of EF, only percentage male appeared to have a small moderating effect on the result ($R^2 = 21$, $P = .008$; Table 2). When the same moderator variables were examined in CE, both percentage dual coil and percentage 8Fr had a significant impact on the results ($R^2 = 71$, $P < .001$ and $R^2 = 63$, $P < .001$, respectively).

## Prevalence of EF in the presence of externalization

Eleven studies reported the prevalence of EF in the setting of CE.[6,10–12,15,17,19–22,25] In the setting of known CE, the prevalence of EF ranged from 0% to 50.0%. In a random effects analysis, the rate of EF in the presence of CE was 17.3% (95% CI 11.2%–25.9%; Figure 3A). There was evidence of heterogeneity in these included studies with $I^2 = 66.877$.

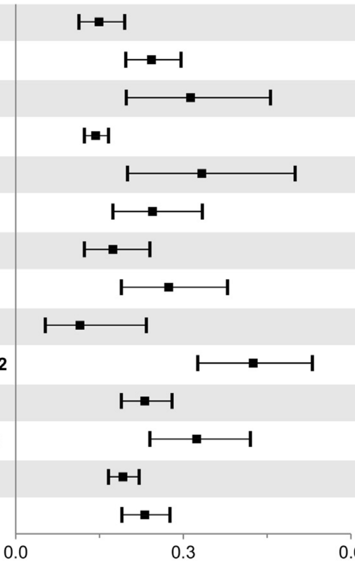
## Prevalence of EF in the absence of externalization

Eight studies reported the rate of EF when CE was absent.[7,10,11,15,17,19,21,22] This rate ranged from 0% to 9.2%. In a random effects analysis, the rate of EF in the absence of externalization was 2.7% (95% CI 1.4%–5.2%; Figure 3B). There was evidence of heterogeneity with $I^2 = 81.327$.

A

**CABLE EXTERNALIZATION**

| Events | Event Rate (%) | 95% CI Lower Limit | 95% CI Upper Limit | |
|---|---|---|---|---|
| 44/295 | 14.9 | 0.113 | 0.195 | **Larsen 2014** |
| 69/284 | 24.3 | 0.197 | 0.296 | **Steinberg 2013** |
| 15/48 | 31.3 | 0.198 | 0.456 | **Moorman 2013** |
| 147/1029 | 14.3 | 0.123 | 0.166 | **Theuns 2012** |
| 12/36 | 33.3 | 0.2 | 0.5 | **Kubala 2013** |
| 27/110 | 24.5 | 0.174 | 0.334 | **Abdelhadi 2013** |
| 28/161 | 17.4 | 0.123 | 0.24 | **Kodoth 2012** |
| 23/84 | 27.4 | 0.189 | 0.379 | **Shen 2012** |
| 6/52 | 11.5 | 0.053 | 0.234 | **Schmutz 2013** |
| 37/87 | 42.5 | 0.326 | 0.531 | **Parvathaneni 2012** |
| 76/329 | 23.1 | 0.189 | 0.28 | **Liu 2013** |
| 33/102 | 32.4 | 0.24 | 0.42 | **Lorvidhaya 2013** |
| 149/776 | 19.2 | 0.166 | 0.221 | **Hayes 2013** |
| | 23.1 | 0.19 | 0.276 | **Overall** |




B

**ELECTRICAL FAILURE**

| Events | Event Rate (%) | 95% CI Lower Limit | 95% CI Upper Limit | |
|---|---|---|---|---|
| 37/298 | 12.7 | 0.091 | 0.167 | **Larsen 2014** |
| 36/284 | 12.7 | 0.093 | 0.171 | **Steinberg 2013** |
| 0/0 | 1.0 | 0.001 | 0.143 | **Moorman 2013** |
| 13/106 | 12.3 | 0.073 | 0.2 | **Fazal 2013** |
| 47/1029 | 4.6 | 0.034 | 0.06 | **Theuns 2012** |
| 20/374 | 5.3 | 0.035 | 0.081 | **Valk 2013** |
| 12/36 | 33.3 | 0.2 | 0.5 | **Kubala 2013** |
| 16/182 | 8.8 | 0.055 | 0.139 | **Rordorf 2013** |
| 201/4358 | 4.6 | 0.04 | 0.053 | **Parkash 2013** |
| 47/1081 | 4.3 | 0.033 | 0.057 | **Abdelhadi 2013** |
| 3/165 | 1.8 | 0.006 | 0.055 | **Kodoth 2012** |
| 1/84 | 1.2 | 0.002 | 0.08 | **Shen 2012** |
| 26/357 | 7.3 | 0.05 | 0.105 | **Erkapic 2011** |
| 7/104 | 6.7 | 0.032 | 0.135 | **Ellis 2009** |
| 0/52 | 0.9 | 0.001 | 0.134 | **Schmutz 2013** |
| 8/195 | 4.1 | 0.021 | 0.08 | **van Rees 2012** |
| 21/316 | 6.6 | 0.044 | 0.1 | **Cheung 2013** |
| 47/1403 | 3.3 | 0.025 | 0.044 | **Sung 2012** |
| 20/87 | 23.0 | 0.153 | 0.33 | **Parvathaneni 2012** |
| 36/627 | 5.7 | 0.042 | 0.079 | **Liu 2014** |
| 5/102 | 4.9 | 0.021 | 0.112 | **Lorvidhaya 2013** |
| 10/776 | 1.3 | 0.007 | 0.024 | **Hayes 2013** |
| | 6.3 | 0.047 | 0.082 | **Overall** |

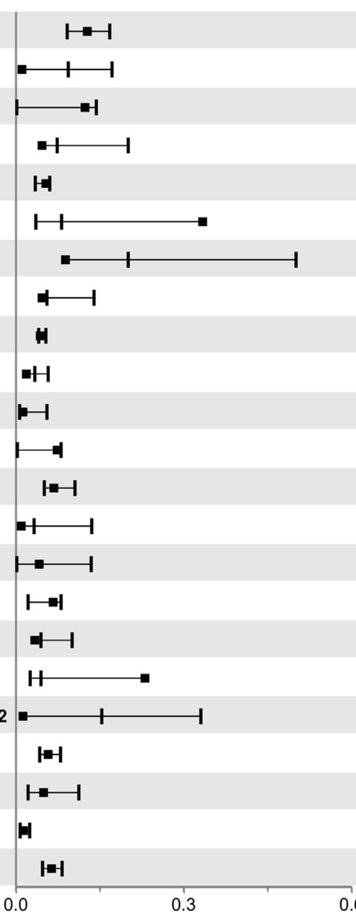



**Figure 2** Random effects modeling of cable externalization and electrical failure. **A:** Cable externalization. **B:** Electrical failure. CI = confidence interval.

**Table 2**   Results of meta-regression for study characteristics of interest

| Moderator variable | No. of studies in analysis | Regression coefficient | 95% Confidence interval | $R^2$ | *P* value |
|---|---|---|---|---|---|
| Cable externalization | | | | | |
| Mean dwell time | 13 | 0.136 | −0.26, 0.27 | 0 | .997 |
| Mean age | 11 | −0.05 | −0.12, 0.027 | 7 | .206 |
| Percent male | 11 | −0.02 | −0.06, 0.015 | 0 | .225 |
| Percent dual coil | 10 | 0.018 | 0.008, 0.030 | 71 | <.001 |
| Percent 8Fr | 11 | 0.019 | 0.008, 0.030 | 63 | <.001 |
| Electrical failure | | | | | |
| Mean dwell time | 19 | 0.18 | −0.31, 0.39 | 0 | .827 |
| Mean age | 17 | 0.02 | −0.1, 0.14 | 0 | .725 |
| Percent male | 17 | 0.12 | 0.03, 0.21 | 21 | .008 |
| Percent dual coil | 15 | 0.00 | −0.02, 0.02 | 0 | .940 |
| Percent 8Fr | 19 | 0.00 | −0.02, 0.02 | 0 | .944 |

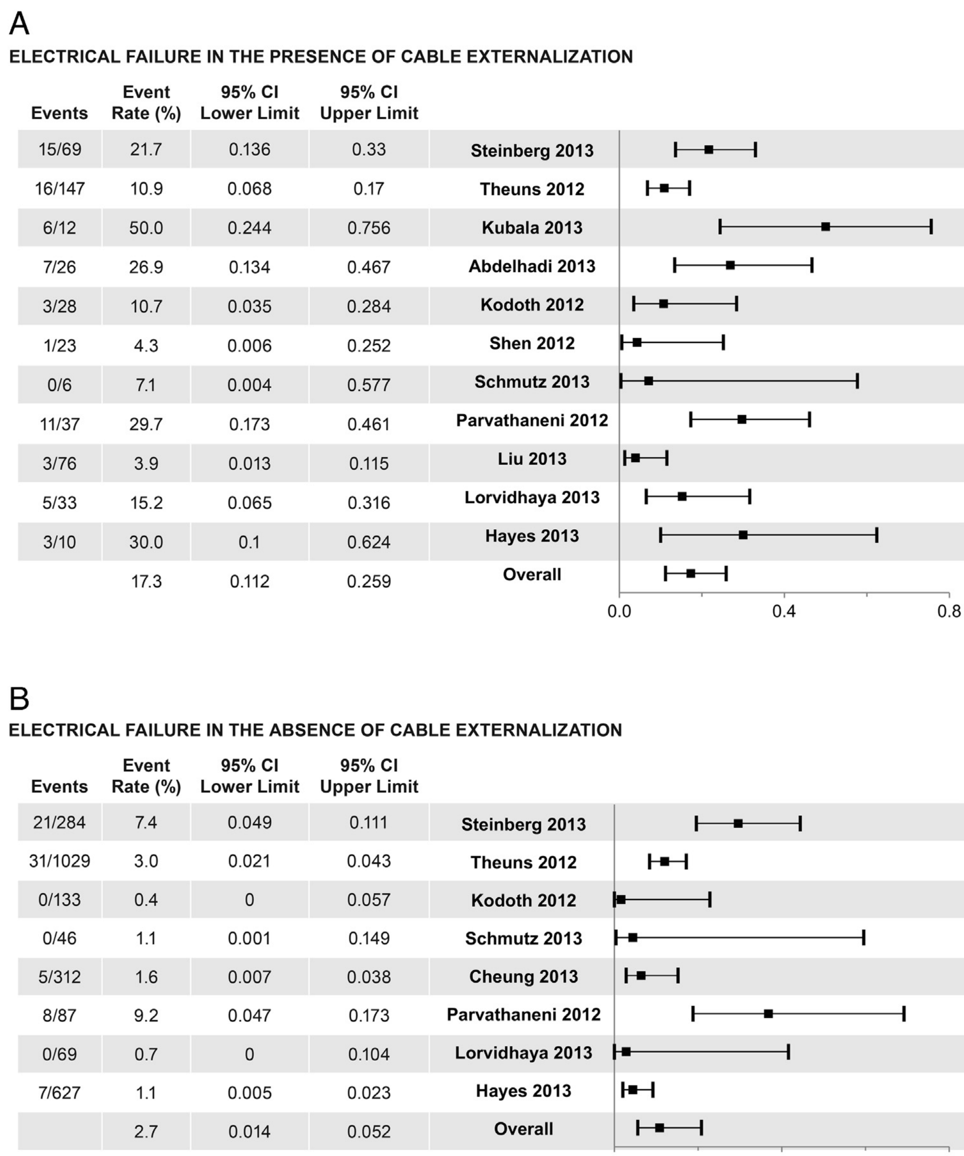



**Figure 3**   Random effects modeling of electrical failure with and without cable externalization. **A:** Electrical failure given cable externalization. **B:** Electrical failure without cable externalization. CI = confidence interval.

**Table 3** Results of meta-analysis of externalization and electrical failure by lead size and number of coils

| Event | Event rate or range | No. of studies in analysis | 95% Confidence interval | Heterogeneity measures $I^2$ | $\tau^2$ |
|---|---|---|---|---|---|
| **Cable externalization** | | | | | |
| Overall | 23.1% | 14 | 19.0%–27.6% | 84.999 | 0.153 |
| 8Fr | 30.5% | 11 | 25.6%–35.8% | 73.757 | 0.107 |
| 7Fr | 9.6% | 11 | 7.0%–13.0% | 34.005 | 0.089 |
| SC | 17.0% | 5 | 13.5%–21.2% | 18.089 | 0.019 |
| DC | 25.0% | 9 | 17.2%–34.8% | 89.293 | 0.433 |
| **Electrical failure** | | | | | |
| Overall | 6.3% | 22 | 4.7%–8.2% | 89.507 | 0.369 |
| 8Fr | 4.6% | 10 | 3.2%–6.6% | 71.412 | 0.194 |
| 7Fr | 3.9% | 9 | 2.4%–6.1% | 55.512 | 0.222 |
| SC | 3.3% | 3 | 1.1%–9.8% | 0.000 | 0.000 |
| DC | 5.2% | 6 | 2.6%–10.4% | 57.874 | 0.412 |

DC = double coil; SC = single coil.

## Lead failure by subgroups

*Cable externalization*

In 11 of 13 studies that reported CE, the prevalence of CE was further classified according to lead caliber (ie, 8Fr vs 7Fr).[6,10–12,15–17,19–22] The prevalence of CE in 8Fr leads ranged from 15.8% to 48%; in 7Fr leads, this range was 0% to 28%. A random effects analysis of externalization revealed higher event rates for 8Fr leads (30.5% [95% CI 25.6%–35.8%]) vs 7Fr leads (9.6% [95% CI 7.0%–13.0%]). Heterogeneity was significant in both of these analyses (Table 3).

Nine studies reported prevalence of CE by the number of high-voltage coils.[11,12,15–17,19–22] In these studies, the number of implanted dual-coil Riata leads (n = 1235) outnumbered the single-coil leads (n = 651). In 4 cases, there were fewer than 3 subjects with single-coil leads.[15–17,20] With these studies removed, the overall rate of externalization of single-coil Riata leads was 17.0% (95% CI 13.5%–21.2%); the overall rate of CE for dual-coil leads was 25.0% (95% CI 17.2%–34.8%; Table 3).

*Electrical failure*

The prevalence of EF of Riata leads was similar across lead size and coil number subgroups. The rates of EF by lead caliber were 4.6% (95% CI 3.2–6.6) and 3.9% (95% CI 2.4–6.1) for 8Fr and 7Fr, leads respectively.[9–11,16,19,23,24,26–28] In those studies reporting EF by coil number, dual-coil leads again far outnumbered single-coil leads (472 vs 105). The overall rates of EF by coil number were 3.3% (95% CI 1.1–9.8) for single coil and 5.2% (95% CI 2.6–10.4) for dual coil (Table 3).[9,11,15,16,19,26]

## Discussion

In this systematic review and meta-analysis of CE and EF of Riata leads in 23 studies including nearly 13,000 leads, there are 4 main findings. First, externalization is apparent in nearly 1 of 4 Riata leads and is 3-fold more common in 8Fr leads compared to 7Fr leads. Second, the overall rate of EF was 6.3% with no significant variation between lead caliber and coil number. Third, the rate of EF was 6 times higher when CE was present compared to leads without externalization (17.3% vs 2.7%). Finally, the risk of EF remained significant, even in leads without evidence of externalization.

In November 2011, the manufacturer-reported overall prevalence of CE was 0.10% based on voluntary reporting and returned product analysis. This estimate contrasts with our estimate of 23.1% based on active screening programs. In addition, 2 reports not included in our meta-analysis due to methodologic differences reported CE rates from longitudinal Riata studies of 21.4% and 22.1%, respectively, both highly consistent with the overall CE rate identified in this analysis.[29,30] This contrast between early reports of Riata externalization and our meta-analyzed findings was consistent within lead caliber subgroups: the rates of CE in November 2011 were 0.14% and 0.03% for 8Fr and 7Fr, respectively, compared to our estimates of 30.5% and 9.6%.[31] These differences are likely due to the well-known limitations of voluntary reporting for device malfunction.[32] In our analysis, we report CE estimates of 25% for dual coil and 17% for single coil and EF estimates of 5.2% for dual coil and 3.3% for single coil; however, the CIs were very wide and largely overlapping. This is in contrast to the Sprint Fidelis (Medtronic, Minneapolis, MN) experience in which single-coil leads had a significantly greater rate of failure.[33,34] However, given the differences in failure mechanism between Fidelis and Riata and patient characteristics that guide lead choice among other things, comparisons of the impact of coil number on mechanical lead failure remain unclear.

The most recent St. Jude Medical product performance report includes a summary of the results from the Cardiac Lead Assessment Study (CLAS), an ongoing postmarket surveillance study required by the US FDA. CLAS is an extension of the Riata Lead Evaluation Study (RLES) started in December 2011.[35] CLAS began enrollment in 2013 with the objective of determining the prevalence and incidence of electrical dysfunction and lead compromise evidenced by imaging.[36] As of August 31, 2014, CLAS included 776 patients (8Fr/7Fr = 66.6%/33.4%) and demonstrated a prevalence of externalized conductors of 9.3% in 7Fr and 24.0% in 8Fr with mean dwell time of 7.1 and 8.8 years, respectively. These findings more closely approximate our estimates than did initial reports based on voluntary reporting and returned product analysis.

Compared with the rates of CE, rates of EF from the literature were more modest but still significant. We found an overall rate of EF of 6.3%. Importantly, rates of EF did not appear to differ between lead subtypes.

Based on our systematic review and meta-analysis of 8 eligible studies, there appears to be a 6-fold increased risk of EF in the presence of CE. In all included studies, the rate of EF was higher in the presence of CE. Although not included in our meta-analysis due to methodologic differences in reporting, Larsen et al[13] found a similar relationship among a large Danish population in which electrical abnormalities were present in 19.2% of leads with externalization vs 4.9% without. Based on our data it is not possible to determine the typical sequence of these complications, but the 2 failure mechanisms appear to be associated. Simply put, the data suggest that a lead with visible structural abnormalities is more likely to have EF than one that appears normal. However, the absence of externalization should not be considered reassuring, as the risk of EF remained significant in these leads (2.7% vs the overall EF rate of 5.9%). In contrast to these findings, CLAS has not demonstrated any difference in the rate of EF with and without conductor externalization (4.7% vs 2.5% respectively) compared to our estimates of 17.3% and 2.7%.[36]

## Study limitations

Our analyses provide estimates of CE, EF, and the interaction of these 2 complications using the aggregate published data from independent investigators. However, as with most observational meta-analyses that reflect a broad range of clinical practices and settings, there was evidence of significant heterogeneity.[37,38] This heterogeneity is partially explained by percent male subjects in the case of EF and by the proportion of 8Fr and dual-coil leads in the case of CE. Remaining heterogeneity likely results from a large number of single-center studies with widely varying sample size, screening techniques, definitions of externalization, and reporting styles. Dwell time was similar across studies, which may explain the lack of a significant moderating effect on CE or EF. Despite the presence of heterogeneity, these results incorporate data from multiple sources and practice environments and likely are a more generalizable estimate than those from any single study. Across the studies, there was variability in how patients were screened for CE and EF, and some approaches may have been more comprehensive or sensitive than others. Some reports indicate a strong relationship between time and lead failure,[30] but we included only cross-sectional reports, so this relationship remains unclear and warrants further study.

## Clinical implications

Despite intensified study regarding the incidence of these problems, the true safety implications of both EF and CE are incompletely known. In the 23 studies included in this meta-analysis, 10 deaths are reported.[6,9,11,12,16,20,21,23,24,27] However, only in the case of Parkash et al[27] was a death attributed to lead malfunction. In all other cases, deaths were either due to unknown causes or unrelated to the implanted device.

The risks associated with CE are not fully understood and may include increased thrombogenicity.[39] Our analysis suggests that CE may be associated with increased risk of EF, and this complication has known associated risks, including serious harm or even death. In a 2012 analysis of the Manufacturers and User Facility Device Experience (MAUDE) database, Hauser et al[40] identified 71 deaths involving Riata leads in which 31% were lead related, but none of these could be attributed to conductor externalization.[40] This highlights the fact that although the absolute risk of EF appears to be lower in leads without externalization, it is not zero. Based on the estimated absolute risk, approximately 1 in 33 patients without externalization will experience EF. Thus, a normal-appearing Riata lead is not without risk.

A recent decision analysis comparing management strategies demonstrated only minimal differences in survival between monitoring and active management strategies for indwelling Riata leads.[41] This parallels the variable clinical practice related to Riata leads. Our analyses provide additional information for providers who continue to manage patients with indwelling Riata leads by further clarifying the risks of lead failure with or without evidence of CE.

## Conclusion

In this meta-analysis of independent studies of Riata lead failure, we found that nearly 1 in 4 leads has evidence of externalization and 1 in 20 has evidence of EF. CE occurred with much higher frequency in 8Fr leads compared to 7Fr leads, but EF did not vary significantly by lead size or coil number. EF was much more frequent in the presence of CE than when externalization was absent. Additional studies to clarify the optimal management of at-risk Riata leads are warranted.

## Appendix

### Supplementary data

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.hrthm.2015.03.005.

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## CLINICAL PERSPECTIVES

In this meta-analysis of 23 independent reports, the prevalence of Riata lead failures is presented. Nearly 1 in 4 Riata leads will develop cable externalization (CE). These analyses demonstrate that the risk of electrical failure is about 1 in 20 for all Riata leads and substantially more in patients with CE. These failure rates represent the combined experience of a variety of care settings, geographic locations, and surveillance strategies. Clinicians can adapt these findings to their practice to aid in communicating with patients who have indwelling Riata leads about the risks of lead failure. A better appreciation of failure rates may improve patients' understanding of warning signs (eg, device tones) and lead to more productive conversations between patients and providers regarding treatment strategies.