The incidence of Riata defibrillator lead failure: A single-center experience

Hye Bin Gwag, Jin Kyung Hwang, Kyoung-Min Park, Young Keun On, Seung-Jung Park, and June Soo Kim
Division of Cardiology, Department of Internal Medicine, Heart Vascular Stroke Institute, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea
Implantable cardioverter defibrillators (ICDs) are indicated in patients at high risk of sudden cardiac death and in those who have survived sudden cardiac death due to fatal ventricular arrhythmia.

Different companies have developed various lead designs for their devices, some of which have been reported to have higher lead failure rates than others. Liu J et al. Circ Arrhythm Electrophysiol 2012;5:809-14.; Larsen JM et al. Heart Rhythm 2014;11:2141-7.
The Riata defibrillator leads (St. Paul, MN, USA)

– Class I recall by the Food and Drug Administration in December 2011 due to substantial rates of lead failure and insulation defect

– Silicone-only insulation design contributing to conductor externalization

– The association between externalized conductor (EC) and electrical dysfunction (ED) has not been previously established, and prior studies have suggested that the recalled Riata defibrillator leads might be more difficult to extract than others. Richardson TD et al. J Cardiovasc Electrophysiol 2014;25:36-42.; Bongiorni MG et al. Heart Rhythm 2015;12:580-7
Purpose

• Approximately 500 Riata leads were implanted between 2003 and 2011 in South Korea. However, there is a paucity of data regarding Riata lead failure.

• Therefore, we investigated the incidence of Riata defibrillator lead failure in patients who underwent ICD or CRT implantation at Samsung Medical Center.
Methods

Patient enrollment
- consecutive patients who received ICD or cardiac resynchronization therapy with Riata® or Riata® ST silicone defibrillation leads at our center between January 2003 and December 2010

Device Follow-up
- Chest X-ray: in the posterior-anterior and lateral views on the first visit day after lead implantation, follow-up performed at the physicians’ discretion
- Device interrogation: measurement of the R wave amplitude, pacing and shock impedances, pacing threshold of lead, and episodes of events
Definitions

- **Externalized conductor (EC):** visibly displaced conductor from the lead body on X-ray
Externalization localization

Single coil

Dual coil
Definitions

- **Electrical dysfunction (ED):** when any of the following criteria was met

  1. Non-physiologic signals on intracardiac electrogram (noise sensing)
  2. R wave <3.0mV or 50% reduction
  3. Pacing impedance <200 or >2000 Ω or high-voltage impedance <25 or >200 Ω
  4. Pacing threshold >5 V or >100% increase

* Concurrent episodes associated with lead failure: inappropriate or no shock therapy.
Incidence of EC and ED, and clinical outcomes during follow-up

• Incidence of EC: evaluated using the time at risk at <3 years, 3-5 years, and >5 years after lead implantation

• Incidence of ED: evaluated every year after lead implantation

• Clinical outcomes: lead replacement or extraction, procedural success, and procedure complications
Results
Study population

Patients with Riata defibrillator lead
(n = 49)

- No follow-up (n = 2)
- No chest X-ray (n = 3)

Eligible patients
(n = 44)

Externalized conductor (+)
(n = 12)
- Electrical dysfunction (+) (n = 4)
- Electrical dysfunction (-) (n = 8)

Externalized conductor (-)
(n = 32)
- Electrical dysfunction (+) (n = 6)
- Electrical dysfunction (-) (n = 26)
## Clinical characteristics according to the presence of EC

|                | Total (n = 44) | EC (+) (n = 12) | EC (-) (n = 32) | p value |
|----------------|---------------|-----------------|-----------------|---------|
| **Age (years)**| 53 (40.5 - 64.5) | 47.5 (25.5 - 52.5) | 58.5 (47 - 70) | 0.012   |
| **Male**       | 38 (86.4) | 12 (100) | 26 (81.3) | 0.167   |
| **Cardiomyopathy** | 13 (29.5) | 7 (58.3) | 6 (18.8) | 0.023   |
| **Ischemic**   | 14 (45.2) | 2 (40.0) | 12 (46.2) | >0.999  |
| **Non-ischemic** | 17 (54.8) | 3 (60.0) | 14 (53.8) |         |
| **LVEF (%)**   | 44.0 (29.8 - 60.0) | 59.0 (52.8 - 69.5) | 35.0 (26.0 - 55.0) | 0.002   |

### Indication for device implantation

| Indication for device implantation | Total (n = 44) | EC (+) (n = 12) | EC (-) (n = 32) |
|------------------------------------|---------------|-----------------|-----------------|
| Secondary prevention               | 26 (59.1) | 6 (50.0) | 20 (62.5) |
| Primary prevention                 | 18 (40.9) | 6 (50.0) | 12 (37.5) |
| **Type of device**                 | >0.999       |                 |                 |
| Single chamber ICD                 | 30 (93.8) | 12 (100) | 30 (93.8) |
| CRT                                | 2 (6.3) | 0 (0) | 2 (6.3) |
| **Dwell time (months)**            | 80.0 (55.6 - 109.5) | 94.1 (75.8 - 110.8) | 75.3 (48.2 - 107.5) | 0.216 |
| Venous entrance                    | >0.999       |                 |                 |
| Right subclavian                   | 3 (6.8) | 1 (8.3) | 2 (6.3) |
| Left subclavian                    | 41 (93.2) | 11 (91.7) | 30 (93.8) |
| **Number of shock coils**          | >0.999       |                 |                 |
| Single                             | 2 (4.5) | 0 (0) | 2 (6.3) |
| Dual                               | 42 (95.5) | 12 (100) | 30 (93.8) |

EC = externalized conductor
## Clinical characteristics according to the presence of ED

|                      | Total (n = 44) | ED (+) (n = 10) | ED (-) (n = 34) | p value |
|----------------------|----------------|-----------------|-----------------|---------|
| **Age (years)**      | 53 (40.5 - 64.5) | 46.5 (23 - 52) | 56.5 (47 - 70) | 0.018   |
| **Male**             | 38 (86.4)       | 9 (90.0)        | 29 (85.3)       | >0.999  |
| **Cardiomyopathy**   | 13 (29.5)       | 6 (60.0)        | 7 (20.6)        | 0.043   |
| **Ischemic**         | 14 (45.2)       | 3 (75.0)        | 11 (40.7)       | 0.304   |
| **Non-ischemic**     | 17 (54.8)       | 1 (25.0)        | 16 (59.3)       |         |
| **LVEF (%)**         | 44.0 (29.8 - 60.0) | 56.5 (44.0 - 66.0) | 38.5 (26.0 - 56.0) | 0.055   |
| **Indication for device implantation** |         |                 |                 | 0.489   |
| Secondary prevention | 26 (59.1)       | 7 (70.0)        | 19 (55.9)       |         |
| Primary prevention   | 18 (40.9)       | 3 (30.0)        | 15 (44.1)       |         |
| **Type of device**   |                |                 |                 | >0.999  |
| Single chamber ICD   | 30 (93.8)       | 10 (100)        | 32 (94.1)       |         |
| CRT                  | 2 (6.3)         | 0 (0)           | 2 (5.9)         |         |
| **Dwell time (months)** | 80.0 (55.6 - 109.5) | 74.8 (55.8 - 110.9) | 83.5 (53.3 - 108.3) | 0.885   |
| **Venous entrance**  |                |                 |                 | 0.125   |
| Right subclavian     | 3 (6.8)         | 2 (20.0)        | 1 (2.9)         |         |
| Left subclavian      | 41 (93.2)       | 8 (80.0)        | 33 (97.1)       |         |
| **Number of shock coils** |            |                 |                 | >0.999  |
| Single               | 2 (4.5)         | 0 (0)           | 2 (5.9)         |         |
| Dual                 | 42 (95.5)       | 10 (100)        | 32 (94.1)       |         |

ED = electrical dysfunction
Incidence of externalized conductor during follow-up

- <3 years: 18.2% (n=2)
- 3 to 5 years: 44.4% (n=4)
- >5 years: 25.0% (n=6)

**p-values**:
- p = 0.336 (<3 years vs. 3-5 years)
- p = 0.400 (3-5 years vs. >5 years)
- p > 0.999 (<3 years vs. >5 years)
Localization of externalized conductor

- A1: 16.7% (n=2)
- A2: 75.0% (n=9)
- A3: 8.3% (n=1)
Incidence of electrical dysfunction during follow-up
Inappropriate shock occurred in 3 patients showing noise sensing
No shock therapy event was absent.
Kaplan-Meier curve of cumulative probabilities of electrical dysfunction-free survival according to EC

Electrical dysfunction-free survival rate (%)

*Dp = 0.628

- All patients
- Without externalized conductor
- With externalized conductor

Dwell time (years)
### Predictors of electrical dysfunction

| Predictor                                      | Univariate analysis | Multivariate analysis |
|-----------------------------------------------|---------------------|-----------------------|
|                                               | HR                  | 95% CI                | HR        | 95% CI         | p value |
| Age (years)                                   | 0.976               | 0.942 – 1.012         | 0.187     | 0.664          | 0.143 – 3.088 | 0.601 |
| Cardiomyopathy                                | 0.246               | 0.067 – 0.896         | 0.034     | Cardiomyopathy | 0.664  | 0.143 – 3.088 | 0.601 |
| LVEF (%)                                       | 1.055               | 1.001 – 1.112         | 0.044     | LVEF (%)       | 1.051  | 0.987 – 1.118 | 0.118 |
| Secondary prevention                          | 1.363               | 0.337 – 5.510         | 0.664     |                |        |                |      |
| Dual chamber leads                            | 0.045               | N/A                   | 0.676     |                |        |                |      |
| Left subclavian access                        | 0.144               | 0.028 – 0.739         | 0.020     | Left subclavian access | 0.210 | 0.031 – 0.425 | 0.110 |
| Dual shock coils                              | 22.198              | N/A                   | 0.676     |                |        |                |      |
| Externalized conductor                        | 1.373               | 0.379 – 4.971         | 0.629     |                |        |                |      |
## Lead extraction

| Extraction                        | Total (n = 44) | EC (+) (n=13) | EC (-) (n=32) | p value |
|-----------------------------------|----------------|---------------|---------------|---------|
| Attempted for any cause           | 9 (20.5%)      | 3 (25.0%)     | 6 (18.8%)     | 0.687   |
| for electrical dysfunction        | 8 (18.2%)      | 3 (25.0%)     | 5 (15.6%)     | 0.663   |
| for infection                     | 1 (2.3%)       | 0 (0%)        | 1 (3.1%)      | >0.999  |
| Successful                        | 7 (77.8%)      | 3 (100%)      | 4 (66.7%)     | 0.500   |
| Failed                            | 2 (22.2%)      | 0 (0%)        | 2 (33.3%)     |         |
Summary

(1) The total cumulative incidences of EC and ED were 27.3% and 22.7%, respectively, during a median dwell time of 80 months.

(2) EC were most frequently detected in patients who underwent X-ray analysis 3-5 years after lead implantation, while the incidence of ED demonstrated a bimodal pattern, with peaks at 5 years and 9 years. Interestingly, there was no association between EC and ED.

(3) The success rate of lead extraction was 77.8% without any significant complications.
Conclusions

• Long-term close monitoring is mandatory for patients with Riata defibrillator leads considering the delayed occurrence of electrical dysfunction.

• An individualized approach is required for optimal management of Riata leads according to patient characteristics, potential risk after lead failure, and the experience of lead extraction at each respective center.
Thank you
Mechanism of externalized conductor

- **Structure**
  - Silicone-only insulation
  - Hollow multilumen containing two conductors

- Facilitate movement of internal conductors exerting pressure on the inner luminal surface of the lead, which resulted in inside-out abrasion

Charles D. et al. JACC 2016;67:1358-1368
Location of externalized conductor

• Known mechanisms for lead failure:
  – subclavian crush syndrome
  – abrasion of the lead by the ICD generator
  – abrasion of the lead at the level of lead fixation
  – mechanical stress of tricuspid leaflet (*Duray GZ et al. Heart Rhythm 2008;5:1224-5*)
  – Considering the mechanism of EC, it is likely that tricuspid leaflet attributed further movement of conductors located in A zone.

• Consistent with previous study (*Demirel F et al. Europace 2014;16:1787-94*): 75.7% in A zone near the tricuspid valve
Higher incidence of externalized conductor

- Previous studies reporting time-dependency of EC
  - 26% at ≥5 years after lead implantation (Liu J et al. Circ Arrhythm Electrophysiol 2012;5:809-14.)
  - 11% at 5.1 years; 21% for 8Fr (6.4 yrs) and 6% for 7Fr (4.5yrs) (Larsen JM et al. Heart Rhythm 2014;11:2141-7)

- Higher incidence than previous reports and highest incidence at 3-5 years (44%); maybe due to 8 Fr leads

- Incidence of ED was comparable with previous studies.
  - 17.3% during mean follow-up period 5.6 years (Liu J et al. Circ Arrhythm Electrophysiol 2012;5:809-14.)
  - 35.5% at 5-year (Larsen JM et al. Heart Rhythm 2014;11:2141-7)
Extraction

• Challenging due to externalized conductor and absence of backfill
• Prophylactic extraction has been discouraged due to the risk of complications, and routine replacement is not recommended regardless of the presence of EC, unless there is evidence of ED.

• However, several large-volume centers have reported a high success rate and low complication rate of Riata lead extraction.
  – 102 pts., high volume centers in US, procedural success 96.1%, 2 complications (SVC junction injury, pneumothorax) (El-Chami MF et al. Heart Rhythm 2015;12:1216-20)
  – 424 pts. With Riata and Fidelis leads, Cleveland clinic, success rate 98.6%, no difference in complications compared to non-recalled leads (Brunner MP et al. Heart Rhythm 2013;10:1444-50)
Association between EC and ED (1)

• No correlation between EC and ED
  – Retrospective, 273 leads, Netherlands (Demirel F et al. Europace 2014;16:1787-94)
  – Retrospective, 299 pts., Denmark (Larsen JM et al. Heart Rhythm 2013;10:821-7)
  – Possible survival bias resulting from their retrospective and cross-sectional study designs

• Possible relationship between EC and ED
  – Adjusted incidence rate ratio of 4.4 by prospective study in Denmark (Larsen JM et al. Heart Rhythm 2014;11:2141-7)
  – 1029 pts. in Netherlands (Theuns DA et al. Circ Arrhythm Electrophysiol 2012;5:1059-63), 552 leads in Canada (Steinberg C et al. Europace 2013;15:402-8)
  – Serious electrical dysfunctions were more likely to be present in leads with EC (Heart Rhythm. 2012 Aug;9(8):1218-24)
Association between EC and ED (2)

• ED without EC
  – EC is just one type of mechanical disintegration of leads detected by X-ray = possible existence of other types of disintegration caused by conductor movement like conductor fracture
  – possibility of too subtle EC to be detected by X-ray

• EC without ED
  – externalization of non-functional conductor of Riata leads or intact coating prohibiting ED of externalized functional conductor
Prognostic factors of lead failure

• This study underpowered to perform multivariate analysis for the predictors of ED because of the small patient number.

• EC
  – Non-ischemic cardiomyopathy and impaired LVEF: Demirel F et al. Europace 2014;16:1787-94
  – NICM, lower LVEF, multiple or single coil leads, high RV pacing%, lower LVEF, lower age, apical lead position, and 8Fr leads

• ED
  – EC: Larsen JM et al. Heart Rhythm 2014;11:2141-7
Limitations

- A retrospective, single-center study with a small number of patients

- A chance of underestimation of the incidence of EC due to detection by on simple radiography rather than fluoroscopy and definition of EC (only a clear separation of conductor cable from the lead body)

- Follow-up of chest X-ray left to the physicians’ discretion without standardized protocol

- Only 8 Fr Riata lead; 7 Fr leads were not imported in South Korea
| Replacement                           | Total (n = 44) | EC (+) (n=13) | EC (-) (n=32) | p value |
|--------------------------------------|----------------|---------------|---------------|---------|
| Any cause                            | 13 (29.5)      | 6 (50.0)      | 7 (21.9)      | 0.135   |
| Electrical dysfunction               | 10 (22.7)      | 4 (33.3)      | 6 (18.8)      | 0.422   |
| Elective replacement indicator       | 2 (4.5)        | 2 (4.5)       | 0 (0)         | 0.476   |
| Infection                            | 1 (2.3)        | 0 (0)         | 1 (3.1)       | >0.999  |