ICD Lead Malfunction Due to Failure at the Device-Tissue Interface

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ABSTRACT

Background: ICD lead malfunction (MAL) may result in morbidity and surgical revision. While MAL due to conductor and insulation defects are well known, there are little data for MAL caused by failure at the device-tissue interface. Accordingly we assessed MAL for contemporary ICD leads at our center and compared MAL caused by conductor and insulation defects (ELEC) to MAL due to device-tissue interface failure (DTF).
Methods: This is a retrospective single center observational study that includes all Sprint Quattro (SQ), Endotak Reliance (ER), and Durata (DU) leads followed in our clinic. ELEC were MAL in the presence of electrical failure, mainly impedance and/or noise; DTF were high threshold/exit block and/or undersensing/low R-wave in the presence of electrically intact leads and absence of radiographic lead dislodgement. Kaplan-Meier estimates were calculated to assess lead survivals (SURV).
Results: Of 2,268 ICD leads, 29 MAL were due to ELEC and 31 MAL were caused by DTF; the overall mean implant time was 3.8±3.0 SD yrs. The SURV for ELEC vs DTF are shown in the graph (log rank p=0.90). No significant differences in ELEC or DTF MAL were found for SQ (n=1706), ER (n=363) or DU (n=199). Mean time to failure was significantly shorter for DTF (1.9±2.1 SD yrs) than ELEC (4.9±2.6 SD yrs; p<0.001).
Conclusions: DTF MAL is as common as ELEC MAL in contemporary ICD leads and they occur much earlier. This observation should encourage leadless ICD development and efforts to improve electrodes, fixation mechanisms, and implant techniques.

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OBJECTIVE

- Compare high-voltage ICD lead malfunctions caused by electrical defects (conductor and insulation) to malfunctions due to failure at the device-tissue interface (threshold, sensing).

METHODS

- This is a retrospective single center observational study.
- Included all Medtronic Sprint Quattro, Boston Scientific Endotak Reliance, and St. Jude Medical Durata leads that were followed by the Minneapolis Heart Institute pacemaker and ICD clinic from 2003-2015.
- Kaplan-Meier estimates were calculated to assess lead survivals.

DEFINITIONS

- Electrical failure was an insulation or conductor defect manifested by abnormal impedance or non-physiologic noise.
- Device-tissue interface failure was high threshold/exit block and/or undersensing/low R-wave in the presence of an electrically intact lead and absence of radiographic lead dislodgement.

RESULTS

- 2,268 leads were followed for a mean implant time of 3.3± years (range:<1 to 14 years)
- Including: 1,706 Sprint Quattro
  - 363 Endotak Reliance
  - 199 Durata
- 29 malfunctions were due to electrical defects
  31 malfunctions were due to device-tissue failure
- Mean times to malfunction were shorter for device-tissue (1.9±2.1 SD yrs) than electrical defects (4.9±2.6 SD yrs) (p<0.001)

FIGURES

Figure 1. Freedom from Electrical Failure Stratified by Lead

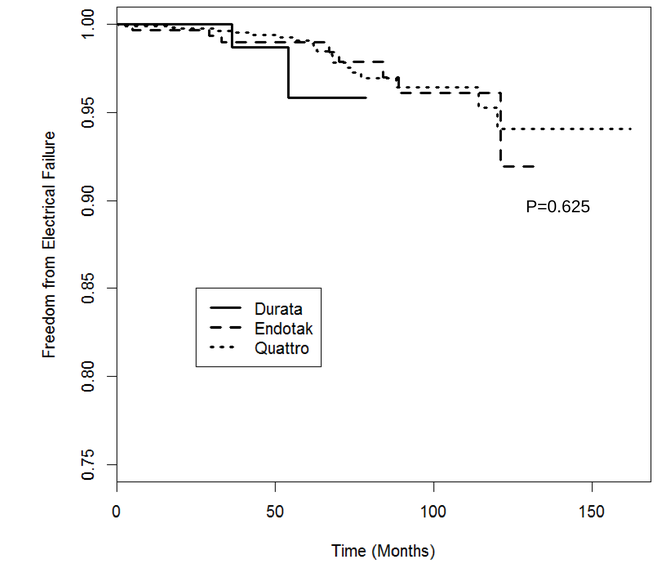
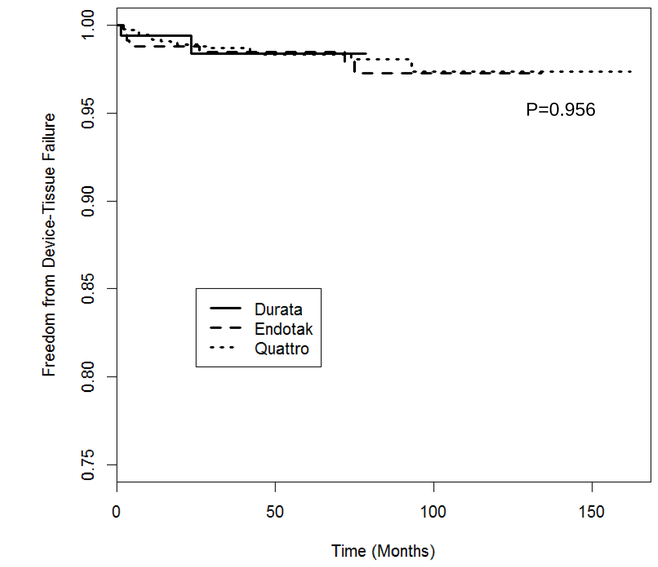
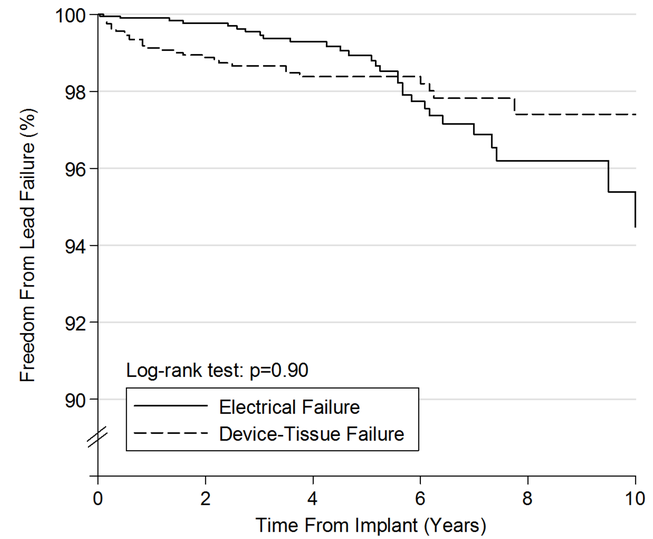


Figure 2. Freedom from Device-Tissue Failure Stratified by Lead



FIGURES

Figure 3. Freedom from Lead Failure Stratified by Failure Type



CONCLUSIONS

- Contemporary ICD lead malfunctions due to failure at the device-tissue interface are as common as malfunctions caused by insulation or conductor defects, and they occur much earlier.
- There are no differences in the nature of these malfunctions between manufacturers.
- This observation should encourage leadless ICD development, and efforts to improve electrodes, fixation mechanisms, and implant techniques.

DISCLOSURES

- The authors have no disclosures to report