Transvenous Implantable Cardioverter-Defibrillator Lead Reliability: Implications for Postmarket Surveillance

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Background—As implantable cardioverter-defibrillator technology evolves, clinicians and patients need reliable performance data on current transvenous implantable cardioverter-defibrillator systems. In addition, real-world reliability data could inform postmarket surveillance strategies directed by regulators and manufacturers.

Methods and Results—We evaluated Medtronic Sprint Quattro, Boston Scientific Endotak, and St Jude Medical Durata and Riata ST Optim leads implanted by participating center physicians between January 1, 2006 and September 1, 2012. Our analytic sample of 2653 patients (median age 65, male 73%) included 445 St Jude, 1819 Medtronic, and 389 Boston Scientific leads. After a median of 3.2 years, lead failure was 0.28% per year (95% CI, 0.19 to 0.43), with no statistically significant difference among manufacturers. Simulations based on these results suggest that detecting performance differences among generally safe leads would require nearly 10 000 patients or very long follow-up.

Conclusions—Currently marketed implantable cardioverter-defibrillator leads rarely fail, which may be reassuring to clinicians advising patients about risks and benefits of transvenous implantable cardioverter-defibrillator systems. Regulators should consider the sample size implications when designing comparative effectiveness studies and evaluating new technology for preventing sudden cardiac death. (J Am Heart Assoc. 2015;4:e001672 doi: 10.1161/JAHA.114.001672)

Key Words: ICD leads • implantable cardioverter-defibrillators • postmarket surveillance

Implantable cardioverter-defibrillator (ICD) lead performance continues to capture the attention of clinicians, patients, and public health advocates. In recent years, analysis and debate have focused on recalled models, whose prior widespread use continues to pose vexing management questions and cast a shadow over ICD technology.1,2 New connector systems and insulation materials and completely new designs such as subcutaneous ICD systems further heighten attention on the performance of transvenous ICD systems.3,4

Questions around lead performance parallel efforts in the European Union and United States to improve postmarket surveillance for medical devices, particularly life-sustaining technology such as ICDs.5,6 For example, the unique device identifier system promises to integrate device data with medical records and streamline adverse event analysis, which is particularly useful for monitoring ICDs.7 However, several technical and policy hurdles plague unique device identifier implantation,8 not least creation of a global unique device identifier website and integration across electronic medical records, insurance claims, and device registries. Thus large, well-powered studies for ICD lead performance will remain an elusive public health goal.

The need for reliable tracking of ICD lead performance gains further momentum as investigators and regulators have focused additional scrutiny on ICD leads with Optim™ insulation. The United States Food and Drug Administration approved Optim™ for the St Jude Medical Riata ST Optim™ leads in 2006 and then Durata leads in 2007.9 Both were approved as “supplements” to a premarket approval application originally approved in 1996.9 Despite favorable early data,10,11 subsequent reports suggest that late insulation abrasions cause Riata ST Optim™ and Durata ICD leads to fail.12–14 Fatal lead failures not attributed to device malfunction pose a particular challenge when comparing marketed leads.15,16 Thus, our primary aim was to compare longevity of
RIATA ST OPTIM™ and Durata leads with established models from Medtronic (Sprint Quattro Secure™) and Boston Scientific (Endotak Endurance/Reliance™). Our secondary aim was to use these data to inform power simulations of postmarket ICD lead surveillance studies.

Methods

Study Design

We identified patients 18 years and older implanted with RIATA ST OPTIM™, Durata, Quattro, and Reliance leads between January 1, 2006 and September 1, 2012 at each study center and followed there. Local data managers and clinicians reviewed medical records for lead failures and patient vital status through February 1, 2014. Data were submitted electronically to the coordinating center at the Minneapolis Heart Institute Foundation. Institutional Review Boards at all participating centers approved this study.

Variables

Study staff at each center abstracted data on device implantation and follow-up for patients implanted there. Lead failures were centrally adjudicated according to prespecified definitions (see Definitions section below). Demographic variables at implant included date of birth, gender, and race/ethnicity (white, African American, Hispanic, Asian, or other/unknown). Cardiac disease features included coronary artery disease, idiopathic/dilated cardiomyopathy, hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, long QT syndrome, and other/unknown. We characterized indication for the ICD as primary or secondary prevention according to history of ventricular fibrillation or sustained ventricular tachycardia, with or without cardiac arrest. We also recorded atrial fibrillation and type (paroxysmal or persistent).

We noted lead manufacturer, model name, and number, and characterized additional pacing leads, as well as subsequent (postimplant) lead revisions and whether the patient received shocks or antitachycardia pacing. Each center reviewed medical records to determine whether device therapies were appropriate. Vital status was determined by record review at each center.

Definitions

We considered a lead implanted after the clinician tested it, connected it to the ICD pulse generator, and closed the incision. Co-investigators at each clinical center reviewed lead failures, and coordinating center investigators adjudicated. Our failure definition included (1) abnormal impedance (eg, impedance outside the labeled normal range for that model); (2) electrical noise manifest as nonphysiologic signals on the electrogram or as pulse generator diagnostic data suggesting rapid oversensing (eg, nonphysiologic short intervals and/or recurrent nonsustained ventricular tachycardia with intervals usually <220 ms); (3) increase in pacing threshold or decline in R-wave amplitude necessitating lead replacement; (4) inability to provide effective therapy due to a lead defect; (5) externalized conductor that breached the outer insulation and appeared outside the lead body on fluoroscopy or radiography; and (6) lead dislodgment, except simple dislodgments without an identified fixation mechanism defect. We did not consider functional abnormalities, including exit block and physiologic oversensing in an electrically intact lead, as failures.

Statistical Analysis

We compared the 3 manufacturers’ lead failure times using Kaplan–Meier curves and log-rank (Mantel–Haenszel) tests. In secondary analyses, we adjusted for clinical center, which was the best predictor of lead type. We examined clinical variables for evidence of confounding, but found no clinical or procedural factors that substantially changed our survival model effect estimates. We also studied the sensitivity of our conclusions to treating death as a semicompeting event with lead failure. Finally, we simulated failure, censoring, and death times designed to match our observed data and computed the sample size necessary to detect differences among manufacturers’ failure rates in hypothetical postmarket studies.

Results

Baseline Characteristics

Four clinical centers enrolled 2653 eligible patients; Table 1 displays their demographic, clinical, and device-related characteristics. The cohort’s median age was 65 (25% to 75% interquartile range, 55 to 74) and patients were predominantly male (73%) and white (88%). Nearly half (49%) had coronary artery disease, and a quarter (27%) had idiopathic/dilated cardiomyopathy. Most patients (80%) received ICDs for primary prevention. Implanted leads included 445 from St Jude, 1819 from Medtronic, and 389 from Boston Scientific (Table 2).

Patient and ICD Lead Survival

Table 3 describes the total person-years of follow-up for each manufacturer’s leads. Lead failures were rare, with only 2 failures in St Jude leads, 17 in Medtronic, and 6 in Boston Scientific (Table 3 and Figure 1), for an overall failure rate of
0.28% per year (95% CI, 0.19 to 0.43). Our data did not support any difference between the failure rate of the newer St Jude leads (Durata and Riata ST Optim, 0.15% per year with 95% CI 0.03 to 0.61) and the pooled failure rate of established leads from Metronic and Boston Scientific (0.31% per year with 95% CI 0.20 to 0.47; \( \chi^2 = 0.94 \) on 1 df, \( P = 0.33 \)). Neither could we detect a difference among the 3 manufacturers’ failure rates based on a global test (\( \chi^2 = 1.8 \) on 2 df, \( P = 0.40 \); Figure 2). Sensing problems were common in failed leads (17/25), mostly oversensing (15). Pacing problems were rare (2/25), and only 1 lead failed to defibrillate. Four failed leads displayed conductor fractures.

### Sensitivity Analyses

The test for differences among manufacturers’ failure rates stratified by clinical center remained nonsignificant (\( \chi^2 = 1.1 \) on 2 df, \( P = 0.59 \)). Similarly, semi- and fully parametric models adjusted for clinical center and potential confounders failed to change this result. Finally, to study the potential for deaths to obscure differences in lead failures, we re-analyzed the data with failure defined as lead failure or death from any cause. This analysis posits a worst-case scenario of a same-day lead failure in every patient who died with an intact lead. Again, we

### Table 1. Demographic and Clinical Characteristics of the Study Population

| Characteristics                      | N (%)     |
|--------------------------------------|-----------|
| Study site                           |           |
| Beth Israel Deaconess Medical Center | 290 (11)  |
| Minneapolis Heart Institute Foundation | 1332 (50) |
| Summa Cardiovascular Institute       | 575 (21)  |
| Vanderbilt Heart and Vascular Institute | 456 (17)  |
| Demographics                         |           |
| Age at implant, median (IQR)         | 65 (55 to 74) |
| Male                                 | 1943 (73) |
| Race                                 |           |
| White                                | 2345 (88) |
| African American                     | 154 (6)   |
| Hispanic                             | 17 (<1)   |
| Asian                                | 16 (<1)   |
| Other/unknown                        | 118 (4)   |
| Alive at last follow-up              | 2462 (93) |
| Cardiac history                      |           |
| Ischemic cardiomyopathy              | 1304 (49) |
| Dilated cardiomyopathy               | 707 (27)  |
| Hypertrophic cardiomyopathy          | 136 (5)   |
| Channelopathy                        | 46 (2)    |
| Arrhythmogenic right ventricular dysplasia (ARVD) | 44 (2) |
| Long QT                              | 1 (<1)    |
| Other/unknown/mixed                  | 415 (16)  |
| Indication                           |           |
| Primary prevention                   | 2117 (80) |
| Secondary prevention                 | 440 (17)  |
| VT/VF with arrest                     | 52 (2)    |
| VT/VF without arrest                  | 31 (1)    |
| Atrial fibrillation                  |           |
| Yes (unspecified)                    | 446 (17)  |
| Yes (persistent)                     | 127 (5)   |
| Yes (paroxysmal)                     | 198 (7)   |
| No                                   | 1853 (70) |
| Unknown                              | 29 (1)    |
| LVEF                                 |           |
| <20                                  | 286 (11)  |
| 20 to 34                             | 1131 (42) |
| 35 to 49                             | 550 (21)  |
| ≥50                                  | 507 (19)  |
| Unknown                              | 179 (7)   |

LVEF indicates left ventricular ejection fraction; VT/VF, ventricular tachycardia/defibrillation.

### Table 2. Characteristics of Implantable Cardioverter-Defibrillator Leads

| Characteristic                           | N (%) |
|------------------------------------------|-------|
| Lead manufacturer                        |       |
| Boston Scientific (Endotak Reliance)     | 389 (15) |
| Medtronic (Quattro Secure)               | 1819 (69) |
| St Jude (Durata, Riata ST Optim)         | 445 (17) |
| DF4 connector                            | 251 (9) |
| Additional intracardiac leads            |       |
| None                                     | 624 (24) |
| 1                                        | 986 (37) |
| 2                                        | 868 (33) |
| 3 or more                                | 175 (7) |
| Subsequently revised                     | 46 (2) |
| Inappropriate shock/anti-tachycardia pacing | 117 (4) |
| Lead status at last follow-up            |       |
| Active and functioning                   | 2289 (86) |
| Patient died                             | 236 (9) |
| Failed                                   | 25 (<1) |
| Elective removal/abandonment             | 36 (1) |
| Infected                                 | 22 (<1) |
| Other/unknown                            | 44 (2) |

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found insufficient evidence to describe a difference among manufacturers ($\chi^2=3.7$ on 2 df, $P=0.15$).

**Power Simulations for Postmarket Surveillance**

We compared the sample size requirements for postmarket safety surveillance and comparative-effectiveness studies of lead failure. In all scenarios, we reproduced 2 features of our observed data: unbalanced manufacturer shares (0.15, 0.25, and 0.60) and a censoring distribution similar to our observed data. We considered follow-up times of 3 years, as in our study, and 5 years, similar to the requirements for new leads in the United States. We described the results in terms of the failure rate ratio between the manufacturer with the smallest share of leads (0.15) versus the largest (0.60). We fixed the failure rate in the remaining manufacturer (share=0.25) at 0.3% per year. Rate ratios <1 indicate the dominant manufacturer has the highest failure rate, and >1 that the smallest manufacturer has the highest failure rate. In our comparative effectiveness scenarios, we used rate ratios of 0.5 and 2, corresponding to the 0.4% and 0.2% failure rates in our real data. In our safety surveillance scenarios, we used rate ratios between 0.07 and 13, corresponding to elevated failure rates from 0.8% to 2.6%.

We found that comparative effectiveness studies designed to detect differences among low failure rates as in currently marketed leads would require very large sample sizes or long follow-up. One would need to follow $\approx 14,000$ leads for 3 years or 8000 leads for 5 years to detect differences among failure rates like those in our real data.

| Manufacturer          | Follow-up time per person, years | Total person-years of follow-up* | Raw failure rate (per person-year) | Failures | Censored by death | Censored by end of follow-up | Censored by other† |
|-----------------------|----------------------------------|----------------------------------|-------------------------------------|----------|-------------------|---------------------------|-------------------|
| Boston Scientific     | Median 3.4 (IQR 2.0 to 5.2)      | 1407                             | 0.43% CI: 0.17% to 0.98%            | 6 (2%)   | 44 (11%)          | 325 (84%)                 | 14 (4%)           |
| Medtronic             | Median 3.3 (IQR 2.0 to 4.6)      | 6079                             | 0.28% CI: 0.17% to 0.46%            | 17 (1%)  | 166 (9%)          | 1567 (86%)               | 68 (4%)           |
| St Jude               | Median 2.9 (IQR 1.8 to 4.0)      | 1311                             | 0.15% CI: 0.03% to 0.61%            | 2 (<1%)  | 26 (6%)           | 397 (89%)                | 20 (4%)           |

*Taking last follow-up date as censoring/failure time regardless of ordering (person vs lead follow-up).
†Infection, elective removal, etc.

**Figure 1.** Raw failure rate of leads per 100 person-years of follow-up.

**Figure 2.** Unadjusted Kaplan–Meier survival curves of implantable cardioverter-defibrillator leads by manufacturer. Number of leads at risk each year is shown along the x axis.
over 30 years of clinical development.\textsuperscript{18} Advancement beyond initial coaxial lead designs have been associated with improvements in lead durability, but prior reports still suggested lead survival rates as low as 85% at 5 years.\textsuperscript{19} However, other data suggest much lower rates of failure,\textsuperscript{20,21} muddying the picture of ICD lead performance even before the widely reported recalls of popular lead models.\textsuperscript{22} These recalled models, with failure rates as high as 16.8% at 5 years for the Medtronic Sprint Fidelis lead,\textsuperscript{23} generated more urgency for evaluating the engineering, regulation, and clinical evaluation of ICD leads.\textsuperscript{24} Recalls also created understandable skepticism regarding ongoing advances such as novel connector systems\textsuperscript{3} and lead coating materials.\textsuperscript{12} Viewed against this backdrop of concern, our findings may provide further reassurance regarding current lead performance. In particular, the low rate of failure in our study for the St Jude Durata and Riata ST Optim leads accords with a prior report from Canada describing annual failure rates of 0.24% and 0.27%, respectively,\textsuperscript{25} and both our study and the Canadian report had lower rates than the annual Riata ST failure rate noted in a Veteran’s Affairs database (0.82%).\textsuperscript{21} These differences may reflect differences in the study population, particularly in contrasting our study to the Veteran’s Affairs database, in which remote monitoring of a much larger sample (>24 000 in total) coordinated through a national surveillance center may have identified more failures than our passive methodology. Our rates for the Boston Scientific Endotak and Medtronic Sprint Quattro models are lower than that described in a single-center European study (1.14%), but comparable to data gleaned from the Veteran’s Affairs Database\textsuperscript{21} and a prior comparison of Fidelis to Quattro leads identifying a 0.43%/year failure rate in the latter.\textsuperscript{2}

Nevertheless, premarket evaluation of ICD leads, particularly via the premarket approval supplement pathway, relies heavily on engineering and bench testing to identify problematic lead design, and is unlikely to identify clinical lead failures. Incorporating our findings into a parametric model demonstrates that current approaches to postmarket surveillance for ICD leads may be markedly underpowered. Manufacturers in the United States may be required to collect information on up to 1000 recipients of a new ICD lead as a condition of approval.\textsuperscript{26} However, even with relatively long follow-up and careful adjudication of possible failures, our results suggest that this approach is unlikely to detect anything more subtle than a marked deviation in lead performance.

Indeed, while the National Cardiovascular Data Registry—ICD Registry adds in excess of 10 000 cases each month, clinical follow-up and in particular adjudication of deaths or lead-related complications is not currently incorporated into its analytic framework, despite recommendations from the Heart Rhythm Society in 2004 to do so.\textsuperscript{27} For example, few prior studies have described the performance of ICD leads...
with DF-4 connectors. Though our overall failure rate was too low to identify significant differences between DF-1 and DF-4 leads, this will remain an open question with important implications for device design and patient management, and not clearly answerable by any current approach. Our findings also have implications for evaluating subcutaneous ICD systems, whose long-term reliability is largely unknown, and now must be compared with an increasingly solid long-term performance for modern transvenous systems. Thus, we argue for further support for the ICD Registry to take a leadership role in lead surveillance, particularly given the Registry’s demonstrated ability to link individual records to Medicare claims and, potentially, remote monitoring. Integrating unique device identifiers into this registry would potentially leverage these existing linkages to great effect.

This study has several limitations. Selection of leads utilized in each case was at the discretion of the operator, and thus unmeasured confounders may have influenced both lead choice as well as lead failure and patient survival. However, we accounted for clinical variables and study center and did not identify important predictors of lead choice that would be expected to confound our findings. Our multicenter consortium consists of academic referral centers, and thus the results may not necessarily extend to community practice. Though we adjudicated suspected lead failures both locally and centrally, both levels of review depended heavily on medical records for content and context of lead revisions, and we relied on passive reporting without mandated fluoroscopy or radiographs. Some underreporting of patient deaths may have occurred, and whether deaths were related to catastrophic lead failure remains unknown. In addition, though longitudinal follow-up at 1 of the study centers was a criterion for inclusion, it is possible that patients hospitalized elsewhere for lead-related complications may not have been subsequently reported as such to their original study center. Last, while we have characterized our identified lead failure rate as reassuringly low, in concert with findings of other investigators, little consensus exists around what actually constitutes an acceptable performance standard for ICD leads or generators.

In sum, 3 models of transvenous ICD leads currently in clinical practice experience very low failure rates. The clinical community, regulators, and manufacturers should take this into account in evaluating new and competing technology as well as in the design of postmarket surveillance systems.

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Disclosures

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References

1. Abdelhadi RH, Saba SF, Ellis CR, Mason PK, Kramer DB, Friedman PA, Gura MT, DiMarco JP, Mugglin AS, Reynolds MR, Bazaz RR, Retel LK, Hayes DL, Hauser RG. Independent multicenter study of Riata and Riata ST implantable cardioverter-defibrillator leads. Heart Rhythm. 2013;10:361–365.

2. Hauser RG, Maisel WH, Friedman PA, Kallinen LM, Mugglin AS, Kumar K, Dodge DO, Morrison TB, Hayes DL. Longevity of Sprint Fidelis implantable cardioverter-defibrillator leads and risk factors for failure: implications for patient management. Circulation. 2011;123:358–363.

3. Hauser RG. Please leave the reliable ICD leads alone. Heart Rhythm. 2013;10:562–563.

4. Sicherling C, Burri H. Introduction of new industry standards for cardiac implantable electronic devices: balancing benefits and unexpected risks. Europace. 2012;14:1081–1086.

5. Blake K. Postmarket surveillance of medical devices: current capabilities and future opportunities. J Interv Card Electrophysiol. 2013;36:119–127.

6. Kramer DB, Tan YT, Sato C, Kesselheim AS. Postmarket surveillance of medical devices: a comparison of strategies in the US, EU, Japan, and China. PLoS Med. 2013;10:e1001519.

7. Rising J, Moscovich B. The Food and Drug Administration’s unique device identification system: better postmarket data on the safety and effectiveness of medical devices. JAMA Intern Med. 2014;174:1719–1720.

8. Campion TR Jr, Johnson SB, Paxton EW, Mushlin AI, Sedrakyan A. Implementing unique device identification in electronic health record systems: organizational, workflow, and technological challenges. Med Care. 2014;52:26–31.

9. Rome BN, Kramer DB, Kesselheim AS. FDA approval of cardiac implantable electronic devices via original and supplement premarket approval pathways, 1979–2012. JAMA. 2014;311:385–391.

10. Epstein AE, Baker JH II, Beul SL, Deering TF, Greenberg SM, Goldman DS. Performance of the St. Jude Medical Riata leads. Heart Rhythm. 2009;6:204–209.

11. Porterfield JG, Porterfield LM, Kuck KH, Corbissiero R, Greenberg SM, Hindricks G, Wazni O, Beul SL, Herre JM. Clinical performance of the St. Jude Medical Riata defibrillation lead in a large patient population. J Cardiovasc Electrophysiol. 2010;21:551–556.

12. Hauser RG, Abdelhadi RH, McGriff DM, Kallinen Retel L. Failure of a novel silicone-polyurethane copolymer (Optim) to prevent implantable cardioverter-defibrillator lead insulation abrasions. Europace. 2013;15:278–283.

13. Hauser RG, McGriff D, Retel LK. Riata implantable cardioverter-defibrillator lead failure: analysis of explanted leads with a unique insulation defect. Heart Rhythm. 2012;9:742–749.

14. Parvathaneni SV, Ellis CR, Rottman JN. High prevalence of insulation failure with externalized cables in St. Jude Medical Riata family ICD leads: fluoroscopic grading scale and correlation to extracted leads. Heart Rhythm. 2012;9:1218–1224.

15. Hauser RG, Abdelhadi R, McGriff D, Retel LK. Deaths caused by the failure of Riata and Riata ST implantable cardioverter-defibrillator leads. Heart Rhythm. 2012;9:1227–1235.

16. Maisel WH. Semper fidelis—consumer protection for patients with implanted medical devices. N Engl J Med. 2008;358:985–987.

17. Hauser RG, Mugglin AS, Friedman PA, Kramer DB, Kallinen L, McGriff D, Hayes DL. Early detection of an underperforming implantable cardiovascular device.
using an automated safety surveillance tool. Circ Cardiovasc Qual Outcomes. 2012;5:189–196.
18. Maisel WH. Transvenous implantable cardioverter-defibrillator leads: the weakest link. Circulation. 2007;115:2461–2463.
19. Kleemann T, Becker T, Doenges K, Vater M, Senges J, Schneider S, Saggau W, Weisse U, Seidl K. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. Circulation. 2007;115:2474–2480.
20. Eckstein J, Koller MT, Zabel M, Kalusche D, Schaer BA, Osswald S, Sticherling C. Necessity for surgical revision of defibrillator leads implanted long-term: causes and management. Circulation. 2008;117:2727–2733.
21. Sung RK, Massie BM, Varosy PD, Moore H, Rumsfeld J, Lee BK, Keung E. Long-term electrical survival analysis of Riata and Riata ST silicone leads: National Veterans Affairs experience. Heart Rhythm. 2012;9:1954–1961.
22. Maisel WH, Kramer DB. Implantable cardioverter-defibrillator lead performance. Circulation. 2008;117:2721–2723.
23. Birnie DH, Parkash R, Exner DV, Essebag V, Healey JS, Verma A, Couto B, Kus T, Mangat I, Ayala-Paredes F, Nery P, Wells G, Krahn AD. Clinical predictors of Fidelis lead failure: report from the Canadian Heart Rhythm Society Device Committee. Circulation. 2012;125:1217–1225.
24. Maisel WH, Hauser RG. Proceedings of the ICD lead performance conference. Heart Rhythm. 2008;5:1331–1338.
25. Bennett MT, Ha AG, Exner DV, Tung SK, Parkash R, Connors S, Couto B, Crystal E, Champagne J, Philippon F, Yee R, Stephenson EA, Nery PB, Essebag V, Sanatani S, Redfearn D, Krahn AD, Healey JS. The Canadian experience with Durata and Riata ST Optim defibrillator leads: a report from the Canadian Heart Rhythm Society Device Committee. Heart Rhythm. 2013;10:1478–1481.
26. Rome BN, Kramer DB, Kesselheim AS. Approval of high-risk medical devices in the US: implications for clinical cardiology. Curr Cardiol Rep. 2014;16:489.
27. Maisel WH, Hauser RG, Hammill SC, Hauser RG, Ellenbogen KA, Epstein AE, Hayes DL, Alpert JS, Berger RD, Curtis AB, Dubin AM, Estes NA III, Gura MT, Krahn AD, Lampert R, Lindsay BD, Wilkoff BL; Heart Rhythm Society Task Force on Lead Performance P, Guidelines, American College of C, American Heart A. Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines: developed in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA). Heart Rhythm. 2009;6:869–885.
28. Prutkin JM, Reynolds MR, Bao H, Curtis JP, Al-Khatib SM, Aggarwal S, Uslan DZ. Rates of and factors associated with infection in 200 909 Medicare implantable cardioverter-defibrillator implants: results from the National Cardiovascular Data Registry. Circulation. 2014;130:1037–1043.
29. Akar JS, Bao H, Jones P, Wang Y, Chaudhry SI, Varosy P, Masoudi FA, Stein K, Saxon LA, Curtis JP. Use of remote monitoring of newly implanted cardioverter-defibrillators: insights from the patient related determinants of ICD remote monitoring (PREDICT RM) study. Circulation. 2013;128:2372–2383.
30. Maisel WH. Physician management of pacemaker and implantable cardioverter defibrillator advisories. Pacing Clin Electrophysiol. 2004;27:437–442.