Small-Caliber Implantable Cardioverter-Defibrillator Leads Dysfunction: Are Electrical Measurements and Fluoroscopy Images Enough for Early Diagnosis?

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ABSTRACT. Diagnosis of Riata lead dysfunction remains a challenge. A controlled high-voltage shock test may be useful for detecting concealed dysfunction. Our objectives were to determine the prevalence of Riata dysfunction and conductor externalization at our center and to validate the controlled internal shock as a useful test. We prospectively reviewed patients with active Riata or Riata ST leads that had been implanted at our center. We performed an internal R-synchronized shock test in addition to electrical and fluoroscopy analysis. From 2004, 55 Riata leads were implanted at our center. Sixteen patients (29.1%) were dead when the study was launched, three of them due to unexplained sudden death; 15 leads (27.3%) were not active; and three patients (5.4%) did not continue follow-up in our center. Finally, 20 patients (36.4%) were included in the study. Inside-out insulation defects were found in four of them (7.3%), but without electrical abnormalities. In the shock test 19 patients had normal behavior (including the abraded ones). One patient without any abnormality in the revision showed a sudden drop of the impedance after shock, lower than 10 ohms. A controlled R-wave synchronized shock may be a useful test in the diagnosis of concealed failure for defibrillation.

KEYWORDS. defibrillator test, externalization of conductors, inside-out insulation, lead failure, Riata leads.

Introduction

Riata and Riata ST leads (St Jude Medical, St. Paul, MN) were removed from the market in 2010 because of a high incidence of dysfunction. These multilumen silicone leads are prone to inside-out insulation defects caused by movement of conductors,\textsuperscript{1,2} thus resulting in a high incidence of device dysfunction, including inappropriate shocks and deaths.\textsuperscript{3-7} There is a mismatch of fluoroscopic findings of damage insulation and electrical abnormalities. Therefore early diagnosis remains a challenge. On the other hand, reports about acute dysfunctions after appropriate shocks\textsuperscript{3} or the defibrillation threshold test\textsuperscript{8-11} in previously normal leads have been reported.

In this study we propose using a controlled high-voltage shock test in the follow-up of these patients to improve sensitivity in early diagnosis of dysfunctions and to enhance our knowledge of the behavior of leads undergoing shocks.

Objectives

Our aim was to determine the prevalence of Riata and Riata ST dysfunction and conductor externalization at our center. We also wanted to validate controlled internal shock as a useful test in early diagnosis.
Methods

All the records of patients with Riata or Riata ST leads implanted at our center were reviewed. After Ethics Committee approbation, patients with an active lead were studied prospectively. Basal electrical parameters (R-wave detection, threshold and impedance) were checked, and lead integrity was reviewed with high-quality fluoroscopy images in three orthogonal projections (posterior–anterior, 40° left anterior oblique, and 30° right anterior oblique). An internal R-synchronized shock with maximal energy was delivered under sedation with midazolam and etomidate in all of the patients, even if the conductors were externalized. Electrical measurements after shock and fluoroscopic evaluation were performed. Hospital admission was not required if no abnormalities were found. In those patients with atrial fibrillation/flutter, optimal anticoagulation controls were confirmed in the 3 days prior to the test. The patient was admitted to hospital and underwent lead replacement 24 h later. A defibrillator test was performed during the implant that confirmed the normal functioning of the system. The dysfunctional lead, implanted 7 years before the test, was not removed to avoid risks during the extraction procedure.

Analysis

Statistical analysis was performed using IBM SPSS Statistics version 20. Qualitative variables were expressed as percentages and quantitative variables as mean ± standard deviation.

Results

From 2004, 55 Riata leads were implanted at our center: 32 Riata 8F (58.2%) and 23 Riata ST 7F (41.8%). Thirty-nine (70.9%) were single-chamber VR implantable cardioverter-defibrillators (ICD), and 16 (29.1%) were CRT-Ds. The etiology of cardiopathy was 33 (60%) ischemic, 12 (21.8%) dilated, four (7.3%) hypertrophic, four (7.3%) valvular, and two (3.6%) Brugada syndrome. The reason for the implant was primary prevention in 27 patients (49.1%) and secondary prevention in 28 (50.9%). Eighty-nine percent were males; mean age at the date of implant was 61 ± 13 years. The mean time of follow-up period was 6.61 ± 1.27 years. Sixteen patients (29.1%) were dead when the study was launched. The causes of death were advanced heart failure in four patients, terminal cancer in three, ischemic cerebrovascular disease in one patient, and unexplained sudden death in three. Lead failure could not be ruled out in these patients because of insufficient clinical information. In five patients the cause of death was not known. In 16 of the patients who were alive, the Riata leads were not active due to cardiac transplantation (5 patients, 9.1%) or because of lead replacement (11 patients, 20%). The reasons for lead replacement are described in Table 1. In six patients from the last group, the lead was not removed, but none of them presented inside-out insulation in fluoroscopy revision. In the explanted ones, no visible abrasions were found. Of the remaining 23 patients, 20 (36.4%) continued follow-up at our center and were included in the protocol (Figure 1). All of them had normal electrical parameters (Table 2). Inside-out insulation defects were found in four patients (20%). (Figure 2) Manual synchronized internal shock was performed in all patients. Nineteen patients (95%) had normal behavior with the defibrillator test, with stable measurements after the shock. One patient (5%) with an ICD-VR and Riata 8F lead implanted as primary prevention due to ischemic cardiomyopathy, without previous appropriate shocks and without any abnormality in standard testing, presented a sudden drop of impedance after shock, lower than 10 ohms. No new abnormalities were found in fluoroscopy images after that. The patient was admitted to hospital and underwent lead replacement 24 h later. A defibrillator test was performed during the implant that confirmed the normal functioning of the system. The dysfunctional lead, implanted 7 years before the test, was not removed to avoid risks during the extraction procedure.

Discussion

In our cohort of 55 patients, 7.3% of conductor externalization and 18.2% of electrical abnormalities were found, but none of the patients presented both. The inside-out insulation defects had been proposed as the cause for the high incidence of Riata lead dysfunction. However, several authors have found dysfunction without visible externalization. In their analysis of the MAUDE database, Hauser et al. found 22 deaths related to Riata leads but none of these deaths could be attributed to externalized conductors. They proposed that masked insulation defects under shocking coils can result in short-circuiting between two or more high-voltage components, and this can occur abruptly during shock delivery. Conventional screening may not detect these defects, and failure to defibrillate may be the first sign of lead dysfunction. On the other hand, if the lead is only partially abraded, the first shock may defibrillate but in the process of delivering high energy, the remaining cover could break down, and the following shock might be ineffective. They described this behavior in one patient who died suddenly 1 day after appropriate shock.

| Table 1: Reasons for replacement. In the right-hand column the number of patients and percentage of total of replacements are shown |
|-----------------|------------------|
| Reasons for replacement | 9 (81.8%) |
| Electrical abnormalities | 4 (36.4%) |
| Noise | 2 (18.2%) |
| Oversensing | 1 (9%) |
| Impedance alterations | 1 (9%) |
| Increased threshold | 1 (9%) |
| Lead dislodgement | 1 (9%) |
| System infection | 1 (9%) |

In six patients from the last group, the lead was not removed, but none of them presented inside-out insulation in fluoroscopy revision. In the explanted ones, no visible abrasions were found.
Other authors have found acute lead dysfunction during the defibrillation threshold test with previous normal function, questioning the usefulness of the non-invasive measurements to guarantee the integrity of the lead.\textsuperscript{8-10} Shah et al\textsuperscript{11} reported a case of acute Riata lead malfunction with an appropriate shock delivery truncated by the device protection circuitry after recording a high-voltage lead impedance of <10 ohms; however, non-invasive measurements were normal before and after the shock. Our findings suggest, as do previous reports, that conventional screening, including electrical measurements and fluoroscopic review, is insufficient for early diagnosis and does not predict which leads may have acute dysfunction. In addition to the current recommendations on standard impedance monitoring and fluoroscopy analysis, controlled shock testing can enhance the ability to identify dysfunctional leads, as occurred in our patient. In our sample, the test was safe with no acute complications. Synchronized shock with R wave reduces the inherent risk of ventricular arrhythmia induction, such as cardiopulmonary resuscitation (0.14%) or even death (0.016%).\textsuperscript{13} Only one patient needed hospitalization 3 weeks after the test; a delayed proarrhythmic effect of the controlled shock in this patient seems unlikely because of

**Figure 1:** Twenty patients were eventually included in the study. Thirty-five were excluded for the reasons that are specified on the right-hand side of the figure.

**Table 2:** Basal electrical parameters measured before the test

<table>
<thead>
<tr>
<th>Pre-shock parameters</th>
<th>Mean ± standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R wave (mV)</td>
<td>11.30 ± 1.52</td>
</tr>
<tr>
<td>Threshold (V)</td>
<td>1.05 ± 1.05</td>
</tr>
<tr>
<td>Pace impedance (ohm)</td>
<td>509.75 ± 121.43</td>
</tr>
<tr>
<td>Shock impedance (ohm)</td>
<td>51.80 ± 10.30</td>
</tr>
<tr>
<td>Shock energy (J)</td>
<td>36.95 ± 3.61</td>
</tr>
<tr>
<td>Time of charge (s)</td>
<td>12.79 ± 1.78</td>
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</tbody>
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the distance in time between both events, but it cannot be ruled out.
A limitation of our study is the small size of the sample; only 20 patients completed the protocol. A significant percentage of patients was lost before the study was launched, and a potential role of dysfunctioning leads as a cause in some of them—such as those having suffered sudden cardiac death—cannot be ruled out. Our data cannot estimate incidence and type of Riata lead dysfunction. On the other hand, this is a highly selected population of leads with normal behavior on electrical analysis, since dysfunctional leads had been replaced. The only pathological response with a potential devastating effect in a cohort with a theoretical low probability of dysfunction supports the utility of the test. The prognosis of a normal defibrillator test and how often this test should be performed has still to be answered.

Conclusion
Electrical measurements and radioscopic assessment may not be enough for detection of Riata lead dysfunction. A controlled R-wave synchronized shock in addition to conventional examinations may be a useful and safe test in the diagnosis of concealed failure for defibrillation.

References

Figure 2: Four patients presented inside-out insulation visible in fluoroscopic revision. The arrow marks a typical image of externalized conductors between the two shocking coils.


