

Observational Study

Riata silicone defibrillation lead with normal electrical measures at routine ambulatory check: The role of high-voltage shock testing

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Abstract

AIM

To describe our experience with shock testing for the evaluation of patients with Riata™ leads.

METHODS

Among 51 patients with normal baseline electrical parameters, 20 died during follow-up. Of the remaining 31 patients, 15 underwent the test: In 10 cases a defibrillation testing with ventricular fibrillation (VF) induction and in 5 cases a R-wave-synchronized shock (> 20 J, without inducing VF). The test was performed under sedation with Midazolam.

RESULTS

Twelve patients (80%) had a normal behavior during shock testing: In 8 cases induced VF was correctly detected and treated; in 4 cases of R-wave-synchronized shock electrical parameters remained stable and normal. Three patients (20%) failed the test. One patient with externalized conductors showed a sudden drop of high-voltage impedance (< 10 Ohm) after a 25 J R-wave-synchronized shock. Two other patients with externalized conductors, undergoing defibrillation testing, showed a short-circuit during shock delivery and the implantable cardioverter defibrillator was unable to interrupt VF.

CONCLUSION

In Riata™ leads the delivery of a low current during

routine measurement of high-voltage impedance may not reveal a small short circuit, that can only be evident by attempting to deliver a true shock, either for spontaneous arrhythmias or in the context of a shock testing.

Key words: Implantable cardioverter defibrillator; Lead failure; Defibrillation testing; Riata™ lead; Externalized conductors

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Core tip: The management of Riata™ defibrillator leads is complex and optimal treatment is often carried out on individual basis. These leads are prone to a unique failure mechanism: The conductors can externalize through the silicone insulation ("inside-out" abrasion) and appear outside the lead body leading to electrical failure. The potential role of high-voltage shock testing for these leads has been poorly studied, only sparse reports being available. In Riata™ leads the delivery of a low current during routine measurement of high-voltage impedance may not reveal a small short circuit, that can only be evident by attempting to deliver a true shock, either for spontaneous arrhythmias or in the context of a shock testing. Defibrillation testing (or alternatively synchronized shock) should be considered an important tool to check Riata™ integrity.

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INTRODUCTION

The Riata™ St. Jude Medical family of implantable cardioverter defibrillator (ICD) silicone leads underwent class I recall by the Food and Drug Administration in December 2011. These leads are prone to a unique failure mechanism: The conductor cables can externalize through the silicone insulation ("inside-out" abrasion) and appear outside the lead body^[1]. The prevalence of externalized conductors (EC) is lower in 7Fr compared to 8Fr leads (9.3% vs 24.2%)^[2]. The rate of electrical failure can be > 6% per year^[3] and it is not always associated with EC^[2,4,5]. However, a meta-analysis of 23 observational studies showed that the presence of EC increased the risk of electrical failure by more than 6-fold^[6].

The management of patients with Riata™ leads is complex and optimal treatment is often carried out on individual basis. The most important factors to consider are: presence of electrical abnormalities; presence and degree of EC; patient's characteristics. When EC is discovered in absence of electrical abnormalities

an "opportunistic" approach is suggested based on patient's risk profile and lead's characteristics^[4,5]. The Food and Drug Administration, the manufacturer and many scientific societies do not recommend preemptive routine replacement/removal of externalized functional leads. Riata lead extraction is difficult (especially with EC) so it is not a first choice when the lead seems to function normally^[5,7]. However essential questions arise: Will the system defibrillate the heart? Can we rely on a lead with normal electrical parameters even when EC is not evident?

In this paper we retrospectively describe our experience with high-voltage (HV) shock testing for the evaluation of Riata™ leads with normal baseline electrical parameters, with and without EC. We also review current scientific evidence and potential role of HV shock testing (full defibrillation testing or commanded R-wave-synchronized shock).

MATERIALS AND METHODS

Overview of Riata leads in our center

From 2003 to 2010 we implanted 60 Riata™ silicone leads: 51 8Fr (85%), 57 dual-coil (95%). Starting from 2012 we initiated a follow-up program according to manufacturer and Italian Arrhythmological Society (AIAC) recommendations, with fluoroscopic evaluation in three orthogonal views (PA: Postero-anterior; LAO/RAO: Left and right anterior oblique - 40°) at least once a year. Externalized conductors were found in 22% of cases (same percentage in 8Fr and 7Fr). Electrical abnormalities were found in 9 patients (15%): Two failed defibrillation testing (DFT) (two patients described afterward), electrical noise by non-physiological signals ($n = 3$), significant increase in pacing threshold ($n = 2$), decrease in R-wave amplitude ($n = 1$), drop of HV impedance after shock ($n = 1$). Notably in 3-out-9 cases electrical dysfunction occurred in absence of externalization (electrical noise in two cases, increase in pacing threshold in the other). Electrical abnormalities without EC occurred all with 8Fr dual-coil leads. All patients with electrical dysfunction were advised to have the lead extracted or replaced. Patients with normal electrical parameters (with or without EC) were evaluated in our ambulatory every 3-6 mo.

Defibrillation testing and R-wave-synchronized shock testing

Among 51 patients without baseline electrical dysfunction, 20 died during the follow-up period (3 cases of sudden unexplained death, before 2010, not further investigated). From 2014 we started to consider a HV shock testing in selected cases: At the time of generator replacement, in high risk patients or high risk leads (Table 1). Of the remaining 31 patients with normal baseline electrical parameters, 15 underwent the test: In 10 cases a DFT [ventricular fibrillation (VF) induction with shock-on-T or DC Fibber™] and in 5 cases a R-wave-synchronized shock (> 20 J,

Table 1 Potential role of high-voltage shock testing for the management of Riata™ leads with normal baseline electrical measures

At the time of generator replacement
All cases, with and without externalization, except if contraindications
Independently of generator replacement (case-by-case evaluation)
High risk patient: Recent/prior appropriate ICD shocks; secondary prevention; pacemaker dependency; young age
High risk lead: Externalization, especially if worsening over time; minimal change in electrical parameters not sufficient to define malfunction; 8Fr dual coil leads (?); 1570-1580-1590 families (?)
When to perform: Within 6-12 mo of an effective shock?
How often: Each 6-12 mo?
Contraindication or excessive risk with ventricular fibrillation induction
Commanded synchronized HV shock (preferably > 20 J)

ICD: Implantable cardioverter defibrillator; HV: High-voltage.

without inducing VF). The decision to perform R-wave-synchronized shock instead of classical DFT was based on patient risk profile (high risk of complications from VF induction). The remaining 16 patients were non tested, at the time of manuscript draft, due to different clinical reasons: Patient's refusal (n° 1), low risk patients or low risk leads (n° 6), severe comorbidities/very old age (n° 9). The shock test was performed under sedation with Midazolam in all cases. In patients with atrial fibrillation or flutter the test was performed only if optimal anticoagulation could be confirmed. All patients gave their consent and the study was approved by the Institutional Board of our Department.

RESULTS

Twelve patients (80% of those undergoing the test, 7 with EC) had a normal behavior during the shock: In 8 cases of DFT (5 with EC), with VF induction, the arrhythmia was correctly detected and treated; in 4 cases of R-wave-synchronized shock (2 with EC) electrical parameters (in particular HV impedance) remained normal and stable. At 6 mo follow-up none of these patients died or experienced electrical failure of the lead.

Three patients (20%) failed the test. One patient with EC had a sudden drop of HV impedance (< 10 Ohm) after a 25J R-wave-synchronized shock, so a new defibrillation lead was implanted without complications. Two other patients with EC, undergoing DFT, showed a short-circuit during shock delivery and the ICD was unable to interrupt VF (they were externally defibrillated).

Among the 16 patients who were *not* tested 4 died of non-cardiac causes (cancer), 4 died of end-stage heart failure, 8 continued to have their lead functional (at 6 mo follow-up). The two cases with failed DFT are described in details hereinafter.

Case 1

A 75-year-old man with ischemic dilated cardiomyopathy

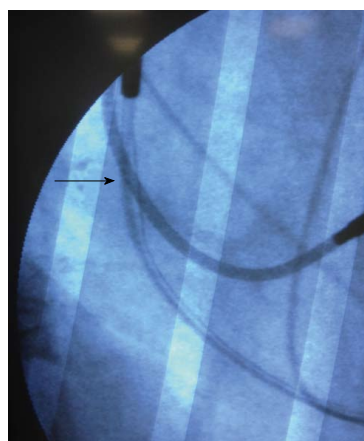


Figure 1 Cable externalization in patient 1.

had received a St Jude Medical biventricular defibrillator in 2009 for primary prevention (Promote™ RF 3213). Defibrillation lead was a 7Fr Riata™ ST 7000, dual-coil, active fixation. At the time of implant, a defibrillation testing had been successfully performed. During routine scheduled device interrogations electrical parameters had always been stable and normal. In accordance with AIAC recommendations we performed a complete fluoroscopic evaluation in three views each 6 mo. In 2013 we discovered an initial, mild conductors' externalization, type 1-2 according to Parvathaneni's fluoroscopic grading score^[8], near the proximal coil. In 2014 the externalization worsened, becoming a type 3 (> 1 cm length extrusion, Figure 1) with extension toward ventricular coil; nevertheless, electrical parameters remained normal and stable. At this point we decided to check system integrity performing a defibrillation testing: Under sedation VF was induced with a shock-on-T; the arrhythmia was correctly sensed and detected but two consecutive internal shocks (20 and 36 J) were unsuccessful (Figures 2 and 3); an external 200J biphasic shock promptly restored sinus rhythm (arrow, Figure 3). Post-shock ICD interrogation revealed very low HV impedance during shock delivery (< 10 Ohms) and warning messages on programmer screen: "Problem with HV electrodes", "High current drainage during HV therapy". Further analysis showed truncated ineffective shocks, likely due to device protection circuitry after recording HV impedance < 10 Ohms. The patient underwent uneventful lead extraction; notably, at visual inspection, there was no sign of abrasion or externalization between the lead and the ICD can. Unfortunately, neither the extracted lead (seriously damaged during the procedure) nor the generator were sent to the manufacturer for further analysis.

Case 2

A 64-year-old man with ischemic dilated cardiomyopathy had received a St Jude Medical single-chamber defibrillator in 2008 for primary prevention (Epic™

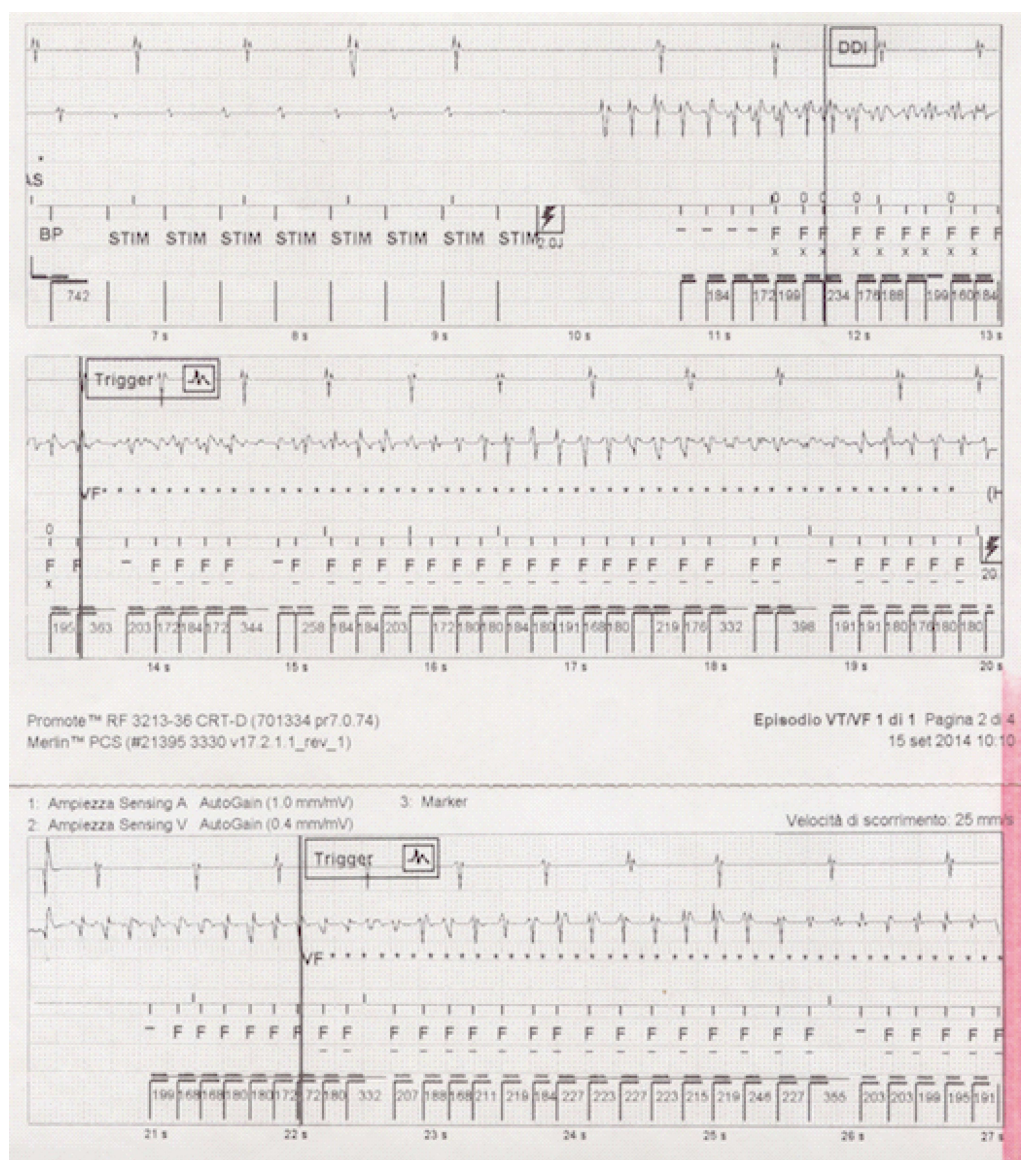


Figure 2 Patient 1: Induction of ventricular fibrillation with shock-on-T and failed defibrillation at 20 J.

VR197). Defibrillation lead was an 8Fr Riata™ 1571, dual-coil, passive fixation. At the time of implant, a defibrillation testing had been successfully performed. During routine device interrogations, electrical parameters of the lead had always been stable and normal. Notably in Epic™ family HV impedance cannot be measured automatically with a painless sub-threshold test, but requires a true shock at 12 Volts (< 0.1 J) synchronized with the QRS complex. In 2014 the patient was hospitalized for elective pulse generator change. At this time fluoroscopy showed conductors externalization, type 2 according to Parvathaneni *et al.*^[8]'s grading score, near the ventricular coil (Figure 4). For this reason, we decided to perform a defibrillation testing before the generator replacement, even if we could expect a prolonged charging time (battery charge time about 20"). Under sedation VF was induced with DC Fiber™, that delivers a single, direct current pulse through HV electrodes. A very "bad" VF was induced (Figure

5) with very low and fragmented QRS complexes; however the arrhythmia was correctly sensed and detected. After a long charge time (> 28 ") a 30J shock was delivered but it did not interrupt VF. So an external 200J biphasic shock was promptly delivered, with resumption of sinus rhythm only after the third attempt. Post-shock ICD interrogation revealed no detectable HV impedance during shock delivery and warning messages on programmer screen: "HV impedance not detectable", "High current drainage during HV therapy", "Charge time limit reached", "Delivered shock truncated at 12 ms". As impedance was not detectable during the defibrillation testing, we decided to check it with a "routine" HV lead impedance (HVLI) test, the same test performed during routine ambulatory interrogation. Figure 6 shows what happened: Soon after the delivery of 12 V (arrow, Figure 6) VF restarted and again we promptly delivered external 200 J biphasic shock, and again sinus rhythm was restored

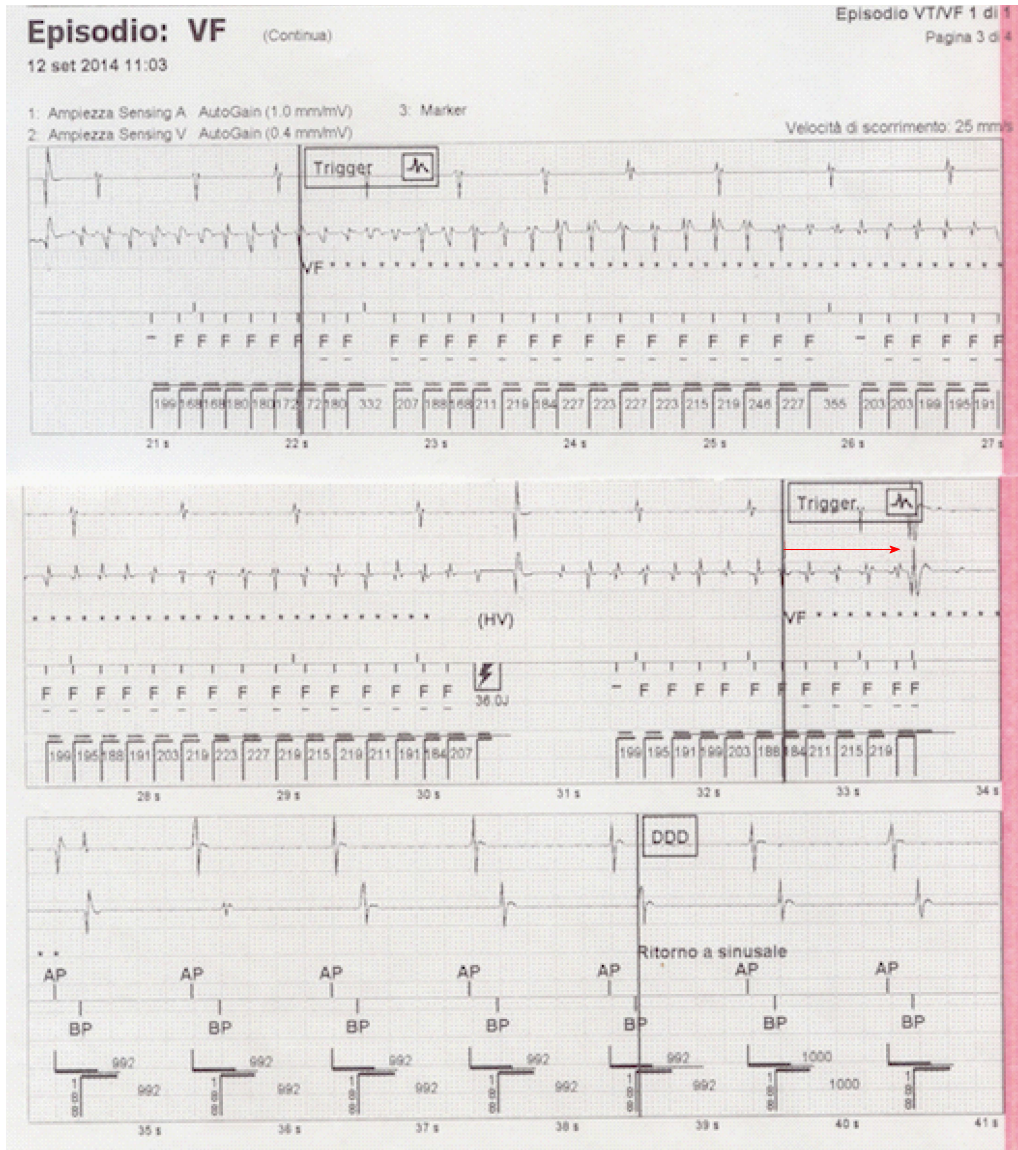


Figure 3 Patient 1: Failed defibrillation at 36 J; external 200 J biphasic shock promptly restored sinus rhythm (arrow).

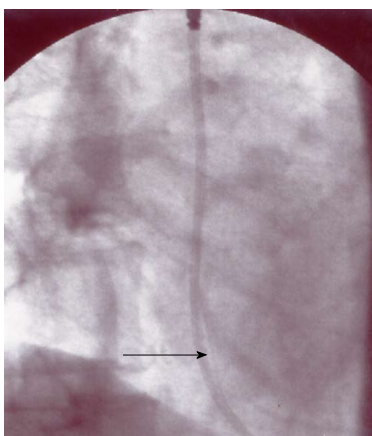


Figure 4 Cable externalization in patient 2.

only after the third attempt. During manual external defibrillation the ICD tried to deliver its own shock at 30 J that was ineffective: Post-shock interrogation showed

a truncated shock with HV impedance < 10 Ohms. Luckily the patient recovered well after this “arrhythmic storm” and he subsequently underwent an uneventful lead extraction. At visual inspection there was no sign of abrasion or externalization between the lead and the ICD can. Unfortunately, also in this case, neither the extracted lead nor the generator were sent to the manufacturer.

DISCUSSION

Structural and electrical failure in Riata™ leads

Riata™ and Riata ST™ leads have a multilumen construction that includes paired HV and pace-sense cables (anode-ring) covered with 1.5 mL of ethylenetetrafluoroethylene (ETFE) and strung through individual lumens that run the length of the silicone body; the central pace-sense coil (cathode-tip), with stylet lumen encased, is further wrapped in a tube of polytetrafluoroethylene. The body of lead is insulated



Figure 5 Patient 2: Induction of ventricular fibrillation with DC Fibber™ and failed defibrillation at 30 J.

with pure silicone rubber that has an increased risk of abrasion^[1,6]. The anatomy of these leads accounts for the mechanism of externalization caused by the movement of the redundant cables within their lumen ("inside-out" abrasion). 8Fr single-coil leads are more prone to externalization: This can be explained by the design with two lumens directly opposed to one another, whereas dual-coil and ST models have three lumens equally spaced around the central coil, which reduces tension^[9]. Importantly, in about 25% of cases (especially dual-coil), externalization is not evident on fluoroscopy because "inside-out" abrasion occurs underneath the shocking coils.

The risk for the patients is mainly linked to electrical failure^[1,6] ranging from 1.3%^[2] to 17.3%^[10]. In our experience electrical abnormalities were found in 15% of patients, the majority with 8Fr leads. Increased

pacing threshold appears earlier, while impedance changes occur later; overall noise and sensing issues are the most common electrical dysfunctions^[1,5]. Short circuits and failure to defibrillate are rare but potentially lethal complications: It is disturbing that such shorts can occur without any other previous electrical abnormality, sometimes being the first and only sign of failure, also in absence of externalization^[1,5-7].

In our two patients the cause of the short circuits cannot be explained with certainty, as the leads were not sent to manufacturer for further analysis. It is possible that the short took place in correspondence to the externalized cables, but "inside-out" abrasion underneath a shocking coil could not be excluded. An insulation break under a shocking coil can cause friction and abrasion of ETFE, with bare cables coming in contact with the HV conductors: The shock can

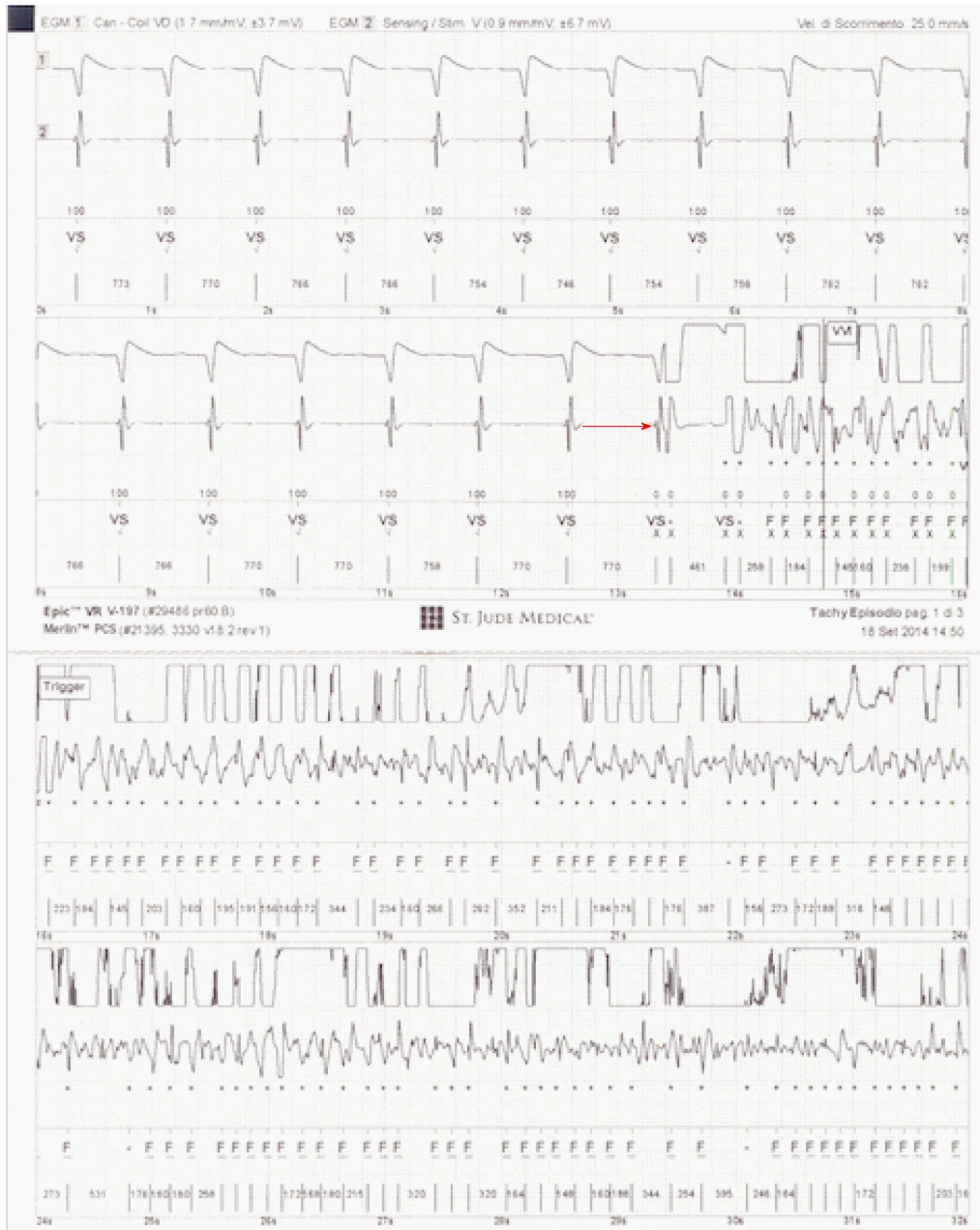


Figure 6 Patient 2: Ventricular fibrillation unintentionally re-induced after high-voltage impedance test with a synchronized 12 V shock (arrow).

be shorted, melting the cable and the coil, and fails to defibrillate^[7]. In more than 65% of cases multiple insulation defects are present on each single lead^[1]. Moreover, in 15%-22% of electrical failures the abrasion occurs between the lead and the can in the pocket or as a consequence of "outside-in" abrasion (contact with another lead or anatomic structures)^[1,5]. In our patients "lead-to-can" abrasion could be reasonably excluded as there was no sign of abrasion/externalization between the lead and the can at a careful visual inspection.

"Lead-to-can", "outside-in" abrasion and ETFE disruption underneath shocking coils are the mechanisms that explain electrical failures and shorts in leads without visible externalization.

In the Multicenter Riata Evaluation Study^[2], in

Hauser's experience^[5] and in another work^[10] the prevalence of electrical dysfunction was not associated with EC. In our Center 37% of electrical failures occurred without EC, all in 8Fr dual-coil leads.

Some other studies have shown that leads with EC were more prone to electrical dysfunction, in particular lower R waves^[4,6,11]. A recent prospective observational study showed^[12] that the incidence of new electrical dysfunction was 6.4% at 12 mo and was associated with EC. Also in Danish experience EC was associated with a higher risk of electrical abnormalities^[13]. Finally, Zeitler *et al*^[6] in a recent meta-analysis of 23 observational studies, showed that the presence of EC was associated with a more than 6-fold increase in the rate of electrical failure compared to no EC.

Role of defibrillation or HV shock testing

When EC is evident, or when other mechanisms expose the cables, the lead may still function normally because HV and pace-sense ring cables are covered with ETFE, which serves as a second insulation. However, if ETFE abrades, electrical short circuits can occur during shock delivery with potential catastrophic consequences^[1,5]. The delivery of a low current during routine measurement of HV impedance may not reveal a small short circuit, that can only be evident by attempting to deliver a true shock for spontaneous arrhythmias or in the context of a HV defibrillation testing^[1,2]. Moreover HVLI test, during routine ambulatory evaluation, is not without risk: In our patient n° 2 VF was unintentionally re-induced during HV impedance test with a synchronized 12 Volts shock. This disturbing phenomenon had already been described by Hauser *et al*^[5]: A patient, with an 8Fr dual-coil 1581 model, died from VF induced by HVLI test and not terminated by the ICD.

Given this very complex background the clinical decision regarding patients with Riata™ leads is troubling, particularly when managing “apparently” functional leads. Routine follow up (including home monitoring, programming additional far-field and noise reversion electrograms, tightening HV lead impedance limits) may be insufficient to detect such failure^[5].

The potential role of defibrillation testing in the management of Riata™ is currently unclear and has been poorly studied; only sparse reports are available in literature^[14-19]. Some authors advocate it at time of pulse generator change^[1,4,6,7] but patients at high risk could benefit from the test even before that time.

Leong *et al*^[14] was the first to describe a case of failure to deliver an appropriate shock by a 8Fr dual-coil 1570 Riata™ (implanted 8 years before) during a DFT performed after generator replacement; lead measurements were normal and stable, in absence of EC. The lead was not extracted but product analysis report of the generator indicated structural damage by a short circuit in the lead, while lead connection with the header box appeared normal.

Subsequently, Doshi *et al*^[15] described an 8Fr dual-coil 1580 Riata™, with known externalization but no prior electrical abnormality, which was unable to deliver HV shock to interrupt VF at DFT after ICD replacement. After the failed shock HV impedance dropped to < 10 Ohms. The lead was extracted and its analysis revealed that the short in the HV circuit occurred underneath the caval coil.

In the report by Webber *et al*^[16] another failure to defibrillate induced VF was described, again at the time of battery depletion. The lead was an 8Fr dual-coil 1580 Riata™, implanted 8 years before, without signs of malfunction (no externalization) but with decreasing R wave amplitude over time. Induced VF was correctly sensed and detected, the device charged 36 J but delivered 0.6 J first and 0 J at second attempt; post-shock impedance was < 20 Ohms. The lead

was not extracted and the generator not analyzed by the manufacturer, but the normal appearance of the insulation in the lead segment looped beneath the generator suggested a short circuit within the intravascular/intracardiac body of the lead.

Shah *et al*^[17] presented a case of failure to deliver effective shock during DFT by an 8Fr dual-coil 1581 lead, implanted 8 years before, with moderate EC and prior normal electrical parameters. This failure was discovered incidentally while the device was attempting to deliver an inappropriate shock for a supraventricular tachycardia; shock delivery was truncated and HV impedance dropped to < 10 Ohms. The subsequent DFT failed to interrupt VF. The patient refused extraction and a new lead was implanted; careful visual inspection of the proximal part of the lead did not reveal any insulation defect in the pocket.

Lakshmanadoss *et al*^[18] described two cases of failed DFT at time of generator replacement: Both leads were 1581 models, a dual-coil and a single-coil (implanted 5 years before). The two leads displayed normal baseline electrical parameters in absence of externalization. In both cases delivery of shock was aborted due to loss of HV impedance and short circuit. The leads were explanted and the first was analyzed by the manufacturer: Superior vena cava coil and HV cable-to-ventricular coil were melted, confirming a short circuit due to an internal insulation defect not apparent on fluoroscopy.

Shen *et al*^[19] described their experience with externalized leads and normal baseline electrical measures. Fifteen-out-23 patients with EC received a recent HV shock: 2 patients for spontaneous ventricular arrhythmias, 5 during scheduled defibrillation testing, 8 during an elective synchronized HV shock. Only one patient (6%) demonstrated post-shock electrical failure. An important finding from this study is that system integrity was checked with a commanded HV synchronized shock, without inducing VF, in 8-out-15 patients.

It is intriguing that, in these reports, the leads were all (except one) dual-coil models 1570-1580-1581. Moreover, in four cases there was no sign of externalization on fluoroscopy^[14,16,18]. Our two patients had a 1571-8Fr and a 7000ST-7Fr, both dual-coil, both with EC. Are dual-coil leads more prone to short circuits and electrical failure in general? Numbers are small so we have no definitive answers, but the hypothesis is plausible given the failure mechanisms described above. Also in Hauser's experience^[1,5] the vast majority of shorts occurred in dual-coil models, independently of EC. In the meta-analysis by Zeitler *et al*^[6] rates of both EC and electrical failure were higher in dual-coil vs single-coil leads. However, Valk *et al*^[20] found that electrical failure of single-coil was 17%, compared to 7% for dual-coil models, but they did not address short circuit in particular.

Externalized conductors are only the “tip of the iceberg” of the “Riata history”. The association between

EC and electrical failure is still controversial but it is clear that these leads have a proclivity to failure. When an overt electrical dysfunction is present the lead has to be replaced or removed, independently of EC. When the lead seems to function normally (routine ambulatory check) management should be individualized and the factors to consider are: Presence/absence of externalization; lead's characteristics (model, implant duration, degree of externalization and its worsening over time); patient's high risk profile (secondary prevention, pacemaker dependency, recent/prior ICD intervention, young age, long life expectancy). Due to the failure mechanisms and the possibility of a short circuit, defibrillation testing should be considered as an important tool to check Riata™ integrity. Based on our experience and literature review, we believe that all patients with an electrically intact Riata™ lead should undergo such test at least at the time of generator replacement. If induction of VF is contraindicated, or too risky for the patient, an alternative "stress test" for the lead could be a commanded synchronized HV shock (preferably > 20 J) with a lower risk of inducing VF^[21,22]. Some patients at high risk should be advised to undergo a HV shock testing even before the time of generator change. For example, if a patient has received a recent/prior effective shock for spontaneous arrhythmias a DFT should be considered within 6-12 mo: The reason is that when the ETFE is only partially abraded, a first shock may defibrillate but subsequent shocks may fail if the remaining ETFE breaks thereafter. HV shock testing should be advised also for "high risk leads": Presence of externalization (especially if worsening over time); minimal changes in electrical parameters (impedance changes < 25%, intermittent non-sustained noise from non-physiological signals); some models (8Fr, dual coil, 1570-1580-1590 families). Many questions remain unanswered: Are dual-coil leads more prone to shorts and electrical dysfunction? When and how often to perform a HV shock test? Is long-term outcome of patients undergoing the test better than non-tested patients? Future studies are needed to define the best strategy for the management of Riata™ leads with normal baseline electrical parameters, with and without EC^[23]. Table 1 summarizes potential indications for HV shock testing in this setting.

The main limitations of our study are the small sample size, the retrospective nature, the empirical selection of patients for HV shock test. Moreover, neither the extracted leads nor the generators were sent to the manufacturer for further analysis.

COMMENTS

Background

The management of the recalled Riata™ defibrillator leads is complex and optimal treatment is often carried out on individual basis.

Research frontiers

The potential role of high-voltage shock testing for management of Riata™

defibrillator leads has been poorly studied, only sparse reports being available in literature. The research hotspot is to evaluate how shock testing can impact on patient outcome.

Innovations and breakthroughs

In Riata™ leads the delivery of a low current during routine measurement of high-voltage impedance may not reveal a small short circuit, that can only be evident by attempting to deliver a true shock, either for spontaneous arrhythmias or in the context of a shock testing.

Applications

Defibrillation testing (or alternatively synchronized shock) should be considered an important tool to check Riata™ integrity.

Terminology

Riata™ defibrillator leads are prone to a unique failure mechanism: The conductors can externalize through the silicone insulation ("inside-out" abrasion) and appear outside the lead body leading to electrical failure. Routine electrical measures may miss small short circuits. Defibrillation testing consists in inducing ventricular fibrillation (VF) and waiting for the implantable cardioverter defibrillator to defibrillate it. R-wave-synchronized shock is a less invasive testing that delivers a high-voltage shock to check the system, but does not induce VF.

Peer-review

This interesting article is a comprehensive discussion about management of Riata defibrillator lead. It is a very important study, about an important issue for which there is much heterogeneity in management.

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