DEVICE THERAPY

COMPLEX CASE STUDY

Implantable Loop Recorder Hypersensitivity

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ABSTRACT. Allergic responses to cardiac rhythm defibrillators have been documented as rare but important complications. Despite this, no allergic reactions to implantable loop recorders have as of yet been reported. In this manuscript we report the first two documented hypersensitivity reactions to implantable loop recorders.

KEYWORDS. allergic contact dermatitis, ambulatory electrocardiography, hypersensitivity reaction, implantable cardioverter-defibrillator, implantable loop recorder.

Introduction

Implantable loop recorders (ILRs) have become an increasingly important tool for extended ambulatory electrocardiographic monitoring.1 Although a simple procedure, ILR implantation is not devoid of complications. Both pocket-site infection and device allergy are recognized rare complications of cardiac device implantation.2,3 While infection is regarded by the literature as a rare complication of ILR implantation, to date no cases of ILR allergy have been described.4,5 In this manuscript, we present the first two documented cases of ILR-induced allergy.

Case presentations

Our first case involves a 43-year-old woman with severe obstructive sleep apnea who was referred to us for evaluation of paroxysmal atrial fibrillation. The patient was implanted in the left parasternal region with an ILR (Reveal XT 9529, Medtronic Inc., St. Paul, MN). Twenty-four hours after the implant the patient began to complain of localized chest pain and tenderness. At this time the skin looked healthy, with no evidence of infection. She was recommended acetaminophen and regular follow-up. Over the ensuing weeks pain worsened and a decision to extract the device was made. There were no clinical signs to suggest pocket infection at this time (Figure 1). The device was explanted without complication and cultures showed no infection. Following complete resolution of pain several days after the explant a suspicion of device allergy arose and an allergist was consulted for patch testing.

Patch testing was conducted using an implantable cardioverter-defibrillator (ICD) Patch Test Kit (Medtronic Inc., St. Paul, MN). Patch testing samples were prepared according to the test kit protocol. Testing sites were evaluated 30 min after removing the patch test samples and monitored daily for 72 h. Patch test results were scored as negative “0” and as positive “1–3+”. Positive reactions were rated as follows: “1+”, erythema and edema; “2+”, erythema, edema, and papules; and “3+”, erythema, edema, papules, and vesicles. On assessment the patient was found to have an allergic reaction to silicone rubber MDX70 (1+), silicone rubber ETR50 (2+), silicone rubber MED4719 (1+), and barium sulfate filled silicone rubber (1+); patch testing was negative for all other ILR components (Figure 2).

In our second case a 41-year-old man with a history of recurrent palpitations was referred to us for ILR implantation. The patient was promptly implanted in the left parasternal region with an ILR (Reveal XT 9529, Medtronic Inc., St. Paul, MN). One month later, the patient returned to the clinic complaining of remarkable pocket-site tenderness. The patient agreed to a trial of analgesia to
manage the discomfort. When analgesia proved inadequate the patient was scheduled for pocket-site revision, which did not reveal infection. The patient continued to have difficulties with the implanted device and was ultimately sent to an allergist to exclude device allergy prior to repositioning.

The patient had no previous drug allergies, and denied a history of allergic rhinitis, bronchial asthma, or food allergies. Patch testing was conducted using an ICD Patch Test Kit (Medtronic Inc., St. Paul, MN) according to the previously mentioned protocol. On assessment 72 h after patch test application, the patient was found to have an allergic reaction to silicone rubber MDX70 (1+), silicone rubber ETR50 (1+), silicone rubber adhesive (1+), silicone rubber MED4719 (1+), polysulfone (amber) (1+), and polysulfone (beige) (1+). All other patch tests were negative. Following ILR explant the patient’s symptoms resolved.

Discussion

The aforementioned cases illustrate positive patch testing results to substances externally located on ILRs and substances that ILRs were likely to have come in contact with during manufacture. These novel allergies to ILRs represent instances that without further investigation may have been mistaken for infection or improper device placement and consequently led to needless laboratory and surgical investigation.6 It is particularly noteworthy that our second case identifies this unique allergy in a patient with no prior history of atopy. Based on this unique presentation, we would encourage clinicians to consider allergy as an etiology to ILR pocket irritation with a low threshold of suspicion if the presentation fits, even without prior history of hypersensitivity reactions. Specifically, absence of fever and leukocytosis with negative cultures should lead one to strongly suspect allergy, especially if framed in the context of an atopic history.

Drawing on the existing literature for ICD allergies, a number of compounds have been implicated in type IV hypersensitivity reactions, such as titanium, nickel, cobalt, chromium, mercury, polyurethane, parylene, polysulfone, thiuram mix, silicone, and silicone adhesives.2,7,8 As several of these substances are found in ILRs, we urge clinicians to be aware of the components of their devices, in particular those in direct contact with the tissues of the device pocket.

When assessing a patient for putative cardiac device allergy, it is important to be aware of the limitations of patch testing. Both the sensitivity and specificity of patch testing have been found to be approximately 70%, with this value varying based on patient demographics and as a function of allergen prevalence.9,10 Thus, while positive patch tests are indicative of type IV hypersensitivity, negative patch testing does not exclude it. Similarly, positive patch testing results are not to be accepted without context.6,11 This inherent test limitation emphasizes that, although a useful test, patch testing should only be used when there is clinical suspicion of allergy; it is an inappropriate screening test.

Allergy to an ILR poses a problem to the clinician. While removal of the offending agent is the gold standard of managing any contact dermatitis, this implies reducing the ability to establish symptom–rhythm correlation.3 A possible solution to this problem as pertains to ILRs may be found by adopting a similar approach to that used in patients with allergy to cardiac rhythm devices: complete coating with a non-allergenic substance such as gold or use of a device devoid of components to which the patient is allergic.2,7 These cases serve as the first documentation of ILR hypersensitivity reactions. Until a greater body of literature exists highlighting the incidence and prevalence of

Figure 1: Presentation of the patient’s pectoral tissue during implantable loop recorder explant.

Figure 2: Patch-testing from our first case presentation. Implantable loop recorder samples were patched on the patient’s back for 96 h and read 30 min after removal; the results illustrate an allergy to silicone rubber MDX70 (1+), silicone rubber ETR50 (2+), silicone rubber MED4719 (1+), and barium sulfate filled silicone rubber (1+) located at sites 3, 4, 11, and 12 respectively. All other patch tests were negative.
ILR allergies, clinicians should be aware of this possible complication and the similarity of its presentation to that of an infection.

References