CASE REPORT

Cardiac Rhythm Device Contact Dermatitis

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We present a series of three cases of patch testing confirmed cardiac rhythm device induced contact dermatitis. In the first two cases, there was complete resolution with device extraction and reimplantation with another device with either an absence of the offending agent or a coating with another resin or metal. These cases illustrate the difficulties in diagnosing pain, tenderness, and dermatological manifestations in patients with cardiac rhythm devices (pacemakers and implantable cardioverter defibrillators)

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An allergy to a cardiac rhythm device (CRD) or its components has been established as a rare but possible complication of CRD (pacemaker and implantable cardioverter defibrillator [ICD]) implantation.¹ An estimate of the actual incidence of this phenomenon is difficult to ascertain but it is an important consideration in the differential diagnosis of patients with device pocket pain and erythema, particularly when a diagnosis of infection cannot be established. The purpose of this case report is to enhance physician awareness of CRD component allergy. An approach to diagnosis and treatment is presented, illustrated by three clinical case examples.

CASE REPORT

Case 1

A 66-year-old female patient was diagnosed as having paroxysms of rapid atrial tachycardia along with recurrent sinus arrest manifested as pauses

over 5 seconds. A permanent dual chamber pacemaker (EnRhythm, Medtronic, Minneapolis, MN, USA) was implanted. Four months later the patient presented to clinic complaining of tenderness and pain over the site of implantation, which extended into the neck and left axilla area. The patient had no history of fever, chills, redness, swelling, or discharge. Physical examination revealed no evidence of infection. Antibiotic treatment was performed with no resolution of symptoms. The possibility of an allergy to one of the components of the pacemaker unit was raised and patch testing was performed revealing an allergy to silicone (she tested positive to Med 4719, MDX-70, ETR-50). Extraction of the pacemaker and both atrial and ventricular leads was performed due to presence of silicone in the outer insulation of the lead. Cultures from the pocket at the time of the extraction showed no evidence of infection. A silicone rubber-free pacing system (Medtronic ADDRL1 Adapta, Medtronic) was implanted (no suture sleeve was

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used) and symptoms resolved and subsequent 44 months follow-up was unremarkable.

Case 2

A 36-year-old male patient with a history of an ostium primum atrial septal defect with repair surgery at the age of five subsequently developed heart block and required permanent pacing. Since then, he had a number of pacemakers and pacemaker revisions, some of which were reportedly due to infection.

He had his first transvenous implant in 1991 on the left side. This system unfortunately was felt to have become infected and was explanted a short time after implantation. Following a few days with a temporary transvenous pacer and the administration of IV antibiotics, a new transvenous permanent system was implanted on the right side. The pacing system worked well until June of 2000 when the pulse generator (PG) reached its end of life and required replacement. A successful PG replacement was performed. Two months later, however, he presented with pain, swelling, and discharge from the site. The pocket discharge was cultured and was positive for *Staphylococcus aureus*. The right-sided system was removed and new transvenous dual chamber pacing system was implanted on the left side (CPI 1270, Guidant, Indianapolis, IN, USA). Approximately 3 years later the patient presented with increased pain in the area of and around his pacemaker site. At the time he reported that the site had become edematous and erythematous. He was admitted for further investigations but no organisms were cultured and neither fever nor leukocytoses were observed. No definite diagnosis was made and the patient was given analgesic medications including carbamazepine, antibiotics, and an empiric course of steroids, all of which offered no improvements in his symptoms. Suspecting the possibility of pacemaker allergy, patch testing was performed and a titanium allergy was demonstrated. He underwent a PG change with a custom manufactured gold-plated pacemaker (Medtronic Kappa KDR 901, Medtronic) (Fig. 1). During PG replacement, pocket cultures were obtained. No evidence of infection was detected (Fig. 2). His symptoms have since completely resolved at 96 months follow-up. Four years later, this pacemaker was upgraded to a gold-plated ICD (Medtronic InSync Sentry, Medtronic) due to severe ventricular dysfunction. Two years ago, he re-

Figure 1. Gold-plated pacemaker.

Figure 2. Direct pocket visualization with no evidence of infection. See text for details.

ceived a gold-plated biventricular ICD (Medtronic Consulta CRT, Medtronic).

Case 3

A 46-year-old female with a history of repaired atrial septal defect presented with symptomatic sick sinus syndrome and a dual chamber pacemaker was inserted (Medtronic ADDR1 Adapta, Medtronic). About 14 months after implant, the patient developed a rash, pruritis, and tenderness in the pocket region along with enlarged left axillary lymph nodes and left arm pain. No evidence of infection was found; blood cultures were negative. There were no systemic symptoms. Pacemaker contact dermatitis was suspected and 72-hour patch testing (MED 494719) confirmed allergy to polysulfone (Fig. 3A), polyurethane

Table 1. Device (Offending Agent), Clinical Manifestations, Testing, and Management

Case	Device	Offending Agent	Clinical Manifestation	Testing	Management
Case #1	DDD PPM	Silicone	Pain, tenderness	Positive	Leads and device extraction, reimplant with silicone-free materials
Case #2	DDD PPM	Titanium	Edema, erythema	Positive	PG extraction, gold-plated PM implant
Case #3	DDD PPM	Polysulfone, polyurethane, titanium, silicon rubber	Rush, pruritis, tenderness	Positive	Not decided yet. Possible PG + leads extraction, gold-plated PM implant

DDD PPM = dual chamber pacemaker; PG = pulse generator; PM = pacemaker.

Figure 3. (A) Patch test result 48 hours after removal of polysulfone beige, applied for 72 hours, showing a 3+ reaction-erythema, edema, papules, and vesicles. (B) Patch test result 30 minutes after removal of Polyurethane, applied for 72 hours, showing a 2+ reaction-erythema, edema, and papules.

(Fig. 3B), titanium, and silicon rubber. Allergies to the latter two can be managed by replacing the PG with one that is gold-coated (as in Case 2) and/or replacing the leads. However, given the novel allergies noted in this case, a treatment solution to the reported allergies to polysulfone and polyurethane had yet to be determined at the time of the writing of this paper. Polyurethane can be found in the outer insulation, as well as in the header of the device.

DISCUSSION

CRD contact dermatitis has been well established with the first documented case being reported by Raque and Goldschmidt in 1970.¹ This patient developed eczematous dermatitis in the area overlying the pacemaker 3 weeks postimplantation secondary to exposure of untreated silicone. Since this report, other occurrences

of pacemaker allergies including cobalt,² epoxy resin,³ mercury,⁴ nickel,² paraxylene,⁵ and titanium⁶ have been reported. These reported cases have also illustrated the variability of dermatological reactions that may develop: localized swelling and circumscribed eczematous skin lesions are the most common manifestations, but dermatitis at distant sites and generalized dermatitis may occur.⁶ The time from implant to onset of symptoms is also variable ranging from a few days to 17 months.⁶

The differential diagnosis of skin lesions overlying pacemakers should include possible device extrusion or impending erosion, infection, contact dermatitis, and reticular telangiectatic erythema^{7,8} (Table 1). Device extrusion presents with pain that is exacerbated with motion.⁸ The presentation of infection is variable but may present with warmth, fever, tenderness, chills, an elevated erythrocyte sedimentation rate, and leukocytosis. The presence of positive blood or tissue cultures and

response to antibiotic treatment is also characteristic of infection. Some clinical pacemaker infections may present with mild symptoms or may be culture negative.⁹ In such situations CT imaging may be useful in establishing the soft tissue inflammation and thereby infection.⁸ The absence of these symptoms, signs, and diagnostic findings suggests the possibility of an allergy and should be further investigated with skin patch testing to all the components of the pacemaker system.

The diagnosis of CRD contact dermatitis is confirmed by positive skin patch testing to any of the components of the pacemaker device together with an absence of proof of infection. The patch testing series can be obtained by the corresponding device manufacturer. Existing protocols for the testing and diagnosis of contact dermatitis recommend for the removal of test samples after 48 hours of exposure. However, positive patch testing to components of a CRD system may require a prolonged exposure time of 120 hours.⁵ Thus, traditional patch testing may be insufficient for the diagnosis of CRD allergies. In our case series, patch testing samples were applied for 72 hours and the patch testing sites were followed closely for another 72 hours postremoval of the patches. There is also a potential problem with existing protocols with skin patch testing, particularly with that for titanium.¹⁰ The concern is that the internal milieu characteristic of a device pocket is not recreated in patch testing. In our case series, the patch testing samples were treated with normal saline before application, as per the manufacturer's instructions. However, the literature review demonstrated that titanium tetrachloride is often used in patch testing and is administered with sterile water.⁵

Another important aspect of CRD contact allergy is the evaluation of the patch testing response. In our case series, the patch testing was evaluated by direct observation by a qualified allergist. The patch testing sites were evaluated at 30 minutes and 72 hours postremoval of the patches. The patients presented earlier were evaluated based on a grading system, and allergies to silicone, titanium, polyurethane, and polysulfone were identified, using manufacturer-derived skin patch testing. Despite available patch testing kits, prolonged application of pacemaker ingredient patches, and proper allergist evaluation of patch test responses, the sensitivity of patch testing has been reported being poor and a negative patch result has been

obtained in half of reported cases.⁵ Therefore, a positive skin reaction to a component is suggestive of an allergy while a negative result does not exclude the possibility of a pacemaker allergy.¹¹

The gold standard of treatment of any contact dermatitis is the removal of the offending agent.¹⁰ However, this solution is impractical in many CRD allergy cases. Medical treatments such as systemic or topical corticosteroids are not used because of long-term complications¹⁰ as well as the increased possibility of a false negative skin test if administered before patch testing is undertaken.¹⁰ Antihistamines only offer symptomatic relief and are therefore not appropriate on a longer term basis. The only viable options available include the complete coating of the CRD or offending component in a proven nonallergenic substance as shown by skin patch testing¹⁰ such as gold^{12,13} or polytetrafluoroethylene,¹⁴ or the use of a device without any allergenic components that has also been shown to be nonallergenic in the patient. In the case of our first two patients with documented allergies to silicone and titanium, they were treated successfully with a silicone-free system and a gold-plated device, respectively. These changes resulted in complete resolution of symptoms at 44 and 96 months follow-up. Our third case documenting the additional allergies to polyurethane and polysulfone illustrates some ongoing vexing dilemmas in the management of CRD contact dermatitis.

CONCLUSIONS

The three cases presented in this paper highlight the difficulties inherent in the diagnosis and treatment of CRD allergies. The cases illustrate a wide spectrum of possible symptoms ranging from pain and tenderness to dermatological manifestations. The diagnosis is made after the exclusion of infection, impending erosion, and the very rare reticular telangiectatic erythema and is accomplished through skin patch testing. CRD allergy should be considered routinely and appropriate investigations instituted when patients present with CRD pocket pain.

REFERENCES

1. Raque C, Goldschmidt H. Dermatitis associated with an implanted cardiac pacemaker. *Arch Dermatol* 1970;102:646-649.

2. Citerne O, Gomes S, Scanu P, et al. Painful eczema mimicking pocket infection in a patient with an ICD: A rare cause of skin allergy to nickel/cobalt alloy. *Circulation* 2011;123:1241–1242.
3. Anderson KE. Cutaneous reaction to an epoxy-coated pacemaker. *Arch Dermatol* 1979;115:97–98.
4. Brun R, Hunziker N. Pacemaker dermatitis. *Contact Dermatitis* 1980;6:212–213.
5. Iguchi N, Kasanuki H, Matsuda N, et al. Contact sensitivity to polychloroparaxylene coated cardiac pacemaker. *Pacing Clin Electrophysiol* 1997;20:372–373.
6. Peters MS, Schroeter AL, van Hale HM, et al. Pacemaker contact sensitivity. *Contact Dermatitis* 1984;11:214–218.
7. Gerdeen R, Kaiser HW, Friedrich K, et al. Annular erythema caused by impending pacemaker extrusion. *Acta Derm Venereol* 1999;79:385–387.
8. Ferringer T, Mowad C. Telangiectatic erythematous cutaneous reaction to an implantable cardioverter defibrillator. *Dermatitis* 2003;14:37–38.
9. Dy Chua J, Abdul-Karim A, Mawhorter S, et al. The role of swab and tissue culture in the diagnosis of implantable cardiac device infection. *Pacing Clin Electrophysiol* 2005;28:1276–81.
10. Dery JP, Gilbert M, O'Hara G, et al. Pacemaker contact sensitivity: Case report and review of the literature. *Pacing Clin Electrophysiol* 2002;25:863–865.
11. Oprea ML, Schnoring H, Sachweh JS, et al. Allergy to pacemaker silicone compounds: Recognition and surgical management. *Ann Thorac Surg* 2009;87(4):1275–1277.
12. Medtronic Editorial: Looks like a million works like a charm. *Medtronic Pulse* 1985;3:3.
13. Syburra T, Schurr U, Rahn M, et al. Gold-coated pacemaker implantation after allergic reactions to pacemaker compounds. *Europace* 2010;12(5):749–750.
14. Ishhi K, Kodani E, Miyamoto S, et al. Pacemaker contact dermatitis: The effective use of a polytetrafluoroethylene sheet. *Pacing Clin Electrophysiol* 2006;29:1299–1302.