A Case of Gold-coated Pacemaker for Pacemaker Allergy

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ABSTRACT. A 65-year-old man underwent pacemaker implantation for symptomatic chronotropic incompetence. Owing to non-healing of primary surgical scar, the patient required reiterative surgical wound evaluation leading to complete explantation. Both the microbiological screening and the standard St. Jude Medical (St. Paul, MN) skin patch testing were negative. A gold-plated pulse generator with polyurethane leads was reimplemented, with normal procedure and good outcome. Highlighting this rare case of pacemaker allergy reminds perioperative and postoperative cardiac rhythm management providers that negative skin testing does not exclude the diagnosis of allergy.

KEYWORDS. gold coated pacemaker, pacemaker allergy, pacemaker allergy testing.

Introduction

Allergic reaction to pacemaker components is a rare complication of pacemaker implantation. Diagnosis is challenging, and can be delayed, because of unfamiliarity with this condition, because skin testing is inconclusive, and because diagnosis is made only after excluding infection. The diagnosis of pacemaker allergy is ideally characterized by the clinical presentation of a non-healing incision site with positive allergy testing to pacemaker components. The purpose of this case report is to raise awareness of the rare occurrence of pacemaker allergy with negative skin testing, managed by implantation of gold-plated pacemaker with polyurethane leads resulting in successful normal recovery.

Case report

A 65-year-old Caucasian male presented with a history of coronary artery disease status post single vessel coronary artery bypass graft via mini-lateral thoracotomy, symptomatic bradycardia and chronotropic incompetency, precluding use of β-blocker therapy. He underwent elective dual-chamber permanent pacemaker implantation (Accent DR, St. Jude Medical, St. Paul, MN) over the first rib extrathoracic axillary vein access. St. Jude Medical silicon leads (Tendril SDX 1688T) were implanted. At the time of pacemaker implantation his medications included aspirin, lisinopril, and simvastatin. He was non-diabetic with no history of corticosteroid use. Despite standard wound care, his post-procedure course was complicated due to a non-healing incision. He was afebrile. The complete blood count (CBC) with differential count was within normal range, highsensitivity C-reactive protein level was 9.5 mg/l (0–2.99), and the erythrocyte sedimentation rate by the Westergren method was 19 mm/h (0–15). The wound culture and blood culture were negative. Except for the incisional erythema there was no sign of infection (Figure 1). The pacemaker was explanted 4 weeks later. A gold-plated pacemaker (Gold Adapta, Medtronic Inc., St. Paul, MN) with polyurethane pacemaker leads (Medtronic 4076) was reimplemented, with normal post-procedure and good recovery (Figure 2). Owing to a history of persistent left superior vena cava, reimplantation was performed over the right pectoral region. A different plane was used to accommodate the gold-plated pacemaker generator, and the extrathoracic...
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Figure 1: Inflamed, Non-Healing Surgical Incision.

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Figure 2: Re-implanted Gold Plated pacemaker with normal recovery.
axillary vein over the second rib was accessed for lead placement.

**Discussion**

Allergic reaction to pacemaker is an uncommon complication to pacemaker components. The wide variety of materials in pacing systems, combined with the limitation of patch tests, can create false negatives in the diagnosis of allergic reaction. Allergic reaction diagnosis is made after excluding infection, because the incidence of pacemaker infection has been reported from 0.13% to 19.9%,\(^1\) whereas the true incidence of pacemaker allergy has not been reported.

Raque et al\(^2\) first reported pacemaker dermatitis in 1970, since then, some reports have described allergy to various components of pacemaker,\(^3,4\) including positive patch test to titanium,\(^5\) nickel, mercury, epoxy resin,\(^6\) polyurethane, cadmium, chromate, mercury, nickel, cobalt, silicone, and polychloroparaffylene (parylene).

Titanium is a commonly reported allergen. Jean-Pierre Déry et al\(^7\) suggest that titanium testing may be unreliable because this test is performed using titanium tetrachloride, which is hydrolyzed to insoluble titanium dioxide after high dilution, resulting in patch test false negatives. We therefore cannot with certainty rule out titanium allergy due to pacemaker generator exposure. In some reports, the exact cause has not been found by patch tests because of negative reaction.\(^8\) Importantly, a negative reaction does not rule out pacemaker system allergy.\(^8\) Additionally, corticosteroid use can result in a false-negative patch test.

Treatments of pacemaker component allergy have been described in various case reports. Rikke et al\(^6\) reported that topical corticosteroid can reduce skin symptoms (erythema, plaques, vesicles, swelling), but recurrence is common. The only complete treatment is removal of all the allergens, which is achieved by complete removal of the pacemaker despite continued symptoms. While the research for the ideal synthetic materials continues, one strategy is to coat the pacemaker system with non-allergic materials prior to reimplantation. Tamenishi et al\(^9\) reported that coating leads with 0.2 mm thick polytetrafluoroethylene (PTFE) sheets is effective, with no reported recurrences during follow-up. Although PTFE is safe and provides definite advantages during the reoperations, there are a limited number of papers in the literature against the usage of PTFE.\(^9,10\) A gold-plated generator and polyurethane leads provides an additional alternative.

Gold plays an important role in medical implants for patients at risk of infection or with an allergic reaction to implants because of gold’s biocompatibility, anti-inflammatory properties, and high degree of resistance to bacterial colonization. In the present case study, a gold-plated pulse generator with polyurethane leads was implanted into a patient who previously demonstrated allergic reaction to a pacemaker. The patient experienced no recurrence of inflammatory response during the follow-up period of 12 months, supporting the efficacy of gold as the material of choice when encountering pacemaker allergy.

Pacemaker allergy masquerades as infection. A cautious follow-up enables early identification of a change in wound condition, and helps avoid more severe complications such as bacterial infection. In the case of sterile infection, we recommend allergy testing to rule out one or more of the pacemaker system components. Since there is presently no definitive diagnostic test for titanium allergy, further work will be required to reliably identify contact sensitivity to titanium. Intracutaneous lymphocyte stimulation testing\(^11\) appears to be more reliable than patch testing but was not investigated in this patient. This case illustrates an important observation: a negative reaction to patch testing does not rule out an allergy to pacemaker components.

**References**