Gold-coated pacemaker implantation after allergic reactions to pacemaker compounds

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An 86-year-old man underwent pacemaker implantation for symptomatic atrio-ventricular block grade 2 Mobitz II. The patient suffered repeated admissions for iterative sterile wound necrosis, leading to two generator re-implantations. No bacterial infection was detected in the microbiological screening tests. The skin patch testing to titanium was negative. Nevertheless, we decided to remove the pacemaker system and to implant a gold-plated generator with polyurethane leads. Since then, there has been no recurrence of wound complications. Gold-plated generator and polyurethane leads are effective in treating allergic reactions to pacemaker system components in selected cases. Negative skin patch testing to titanium does not exclude allergic reaction to this pacemaker component.

Introduction

Allergic reaction to pacemaker compounds is a rare complication. Initial management of allergic reactions or contact dermatitis is difficult because accurate diagnosis is often delayed. The tendency is to initially suspect a bacterial infection, rather than to quickly rule out an allergy to the pacemaker components. We report on a patient who showed repeated sterile subcutaneous necrosis around the pacemaker implantation site, whereby Prick testing directed at all components of the pacemaker system remained negative. After implanting a gold-plated pacemaker with polyurethane leads, the patient successfully recovered and suffered no further complications.

Case report

An 86-year-old man with symptomatic atrio-ventricular block grade 2 Mobitz II and bradycardia received in June 2007 a DDDR pacemaker system. The generator (Vitatron T70 DR) was implanted subcutaneously in the right chest wall; the leads [St Jude Medical (SJM) Tendril SDX 1688T atrial, SJM Isoflex S 1636T ventricular] were implanted percutaneously via the right subclavian vein. The implantation procedure was uneventful. Eight days later, we observed a pacemaker pocket inflammatory reaction, fluctuation, and tendering. Inflammatory parameters in blood testing were C-reactive protein 13.8 mg/L (<10) and leucocytes (Lc) 8.8 × 10⁹/L (3.6–10.5); the patient had no fever. The system was therefore removed. No bacterial infection had been shown at any time in the microbiological screening of the observed wound material. A new DDDR-System (generator: Vitatron T70 DR; leads: SJM Tendril SDX 1688T atrial, SJM Isoflex S 1636T ventricular) was implanted in the left chest wall after a 2-week system-free interval. One week later, the system was removed again, due to iterative wound dehiscence with fluid excretion and a strong local inflammatory response at the implantation site. Inflammatory parameters in blood testing were C-reactive protein 32.1 mg/L (<10), Lc 7.6 × 10⁹/L (3.6–10.5), and eosinophils 0.4 × 10⁹/L (0.0–0.5). Again, the patient had no fever and no bacterial infection could be detected through the screening of the wound samples. Dermatologic investigations of pacemaker components (titanium can, epoxy head, silicone coating of the electrodes, and suturing material) using the manufacturer’s specified patch test was used. Nevertheless, we suspected a titanium allergic reaction. We decided to implant a gold-plated DDD pacemaker (Medtronic Adapta DR PVV, 24 carat gold, minimal coating thickness 0.45 μm) in the right chest wall, with polyurethane leads (Medtronic 4076/58 BBL atrial and ventricular, lead is polyurethane, and sleeve and connector are silicone) percutaneously via the right subclavian vein. Since then, the wound healing was uneventful and the patient could be discharged in good conditions. A 6-month follow-up revealed no further adverse events related to the pacemaker implantation procedure. All pacemaker system values remained stable within the recommended ranges.

Comment

Allergic reactions to pacemaker compounds are rare, but remain a problem of concern. Few reports were published1–3 since the 1970s. Reported allergens are: titanium,4 nickel, mercury, epoxy resin,5 polyurethane, cadmium, chromate, cobalt, silicone,3 and more. Even a polytetrafluoroethylene (PTFE) allergy cannot completely be ruled out.6

Titanium is widely used in implants because it is generally well tolerated, with little sensitization. Skin testing against titanium is not reliable.7 Like other metallic implants, some dissolution occurs over time.4,8,9 Patch testing does not take this degradation into account.

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and does not recreate the milieu of the pacemaker. Testing titanium with titanium tetrachloride is not valid due to hydrolysis to insoluble titanium dioxide. Yamauchi et al. were able to elicit a positive reaction to intracutaneous testing on the affected patient’s serum incubated with small pieces of titanium for 1 month in a patient who had negative results on patch testing to titanium.

Treatments for pacemaker-induced allergic reactions are described in various case reports. Topical corticosteroids may reduce skin symptoms, but recurrence is the rule. The only valuable treatment is the removal of all the system components, followed by a replacement with hypoallergenic material. One option, as described by Tamenishi et al., is an entire coating of the whole system with 0.2 mm thick PTFE surgical membrane. Alternatively, a gold-plated generator and polyurethane leads can be chosen, as in this case. Using this method, the patient did not experience any recurrence of inflammatory response during the follow-up period of 6 months.

Allergic reaction can occur early or delayed. A cautious follow-up ensures early detection of a change in wound condition and is necessary in helping patients avoid more severe complications such as bacterial infection. In the case of pacemaker pocket inflammation without signs for an infection, we recommend to systematically rule out an allergy to one or more of the pacemaker system components. One has to be aware that a negative reaction to prick testing against titanium does not rule out an allergy to this component.

Conflict of interest: none declared.

References