Severe Allergic Dermatitis After Closure of Foramen Ovale With Amplatzer Occluder

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Allergic reaction to nitinol is rarely reported, and its incidence, symptoms, and course have not been clearly defined. We report an occurrence of severe progressive generalized exanthema 3 days after the implantation of an Amplatzer occluder for a patent foramen ovale, with symptoms disappearing immediately after surgical removal of the device 3 months later. The risks and possible prevention of allergic reaction to nickel and especially to titanium are discussed.

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a hypersensitive reaction to a wide range of metals, the strongest response being to inorganic mercury (stimulation index of 58.3), titanium trichloride (30.9), titanium dioxide (11.2), and nickel (3.5); a positive reaction is considered to be above 2.0. At that time, removal of the occluder had to be considered because of the patient’s worsening skin problems, fatigue, and stress associated with the debilitating symptoms. The patient also started to report sensitivity (contact dermatitis) to titanium earrings and described having burning sensations in the oral cavity after consumption of certain foods (probably resulting from nickel or titanium contained therein). Owing to the progressive nature of the patient’s problems, the operation was performed in January 2011, and the Amplatz occluder was successfully removed without any complications. Three days after the removal, the patient’s skin lesions resolved completely without any relapse. She remained completely asymptomatic more than 1 year after explantation of the occluder.

Comment

With respect to the straightforward relationship between the rash development and nitinol occluder insertion and resolution of all symptoms after the occluder removal, we conclude that the patient’s problems were most likely attributable to an allergic reaction to nitinol. As per our results, the patient was simultaneously hypersensitive to nickel and titanium. Analogous results with positive Melisa test reactions to titanium have been observed in patients with hypersensitive reactions to titanium pacemaker coating or titanium joint replacements. After titanium removal, Melisa test results can normalize (6). The case described here, of a confirmed allergy to titanium in relation to the Amplatz occluder, is the first case described in the literature as far as we know.

Although the manufacturer of the Amplatz occluder claims that it is safe to use in patients with allergies to metals, experimental studies have confirmed that nickel serum levels rise with maximum values reached approximately within 1 month after implantation, and during the following 2 months they gradually drop again [9]. Therefore, the safety of the occluder in sensitive patients remains questionable. Moreover, the implanted material inevitably undergoes a breakdown, leading to increased exposure to released metal ions, as demonstrated by an electron microscope imaging of the removed occluder in our case (Fig 2).

Owing to the severity of the allergic reaction in the case described here, it was necessary to remove the nitinol occluder through an open-heart procedure with extracorporeal circulation, a procedure with considerable risks. This raises the question of how to prevent similar cases. Allergy to metals is currently being assessed in some patients before the implantation of teeth in dentistry and before joint replacement in and orthopedics. Nevertheless, the patient in our case had no history of contact allergy to metals. Sensitization of the patient to nickel, titanium, or both could occur after previous encounters with food or environmental aggressors. Therefore, an allergic reaction might have been activated after the insertion of the nitinol occluder in the bloodstream. Unfortunately, it is not possible to resolve whether testing for allergies before insertion of the occluder could have detected the risk of subsequent allergic reaction.

Addendum

The case had been presented as an oral abstract at the 2011 meeting of the Czech Society of Allergy and Clinical Immunology and reported in Czech language with an English abstract [10].

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References