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An unsual medical management for nickel allergy in patients with amplatzer occlusive device

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Abstract

Medically significant Nickel allergy following an Atrial Septal Defect (ASD) or Patent Foramen Ovale (PFO) closure with an Amplatzer occlusive device is a rare phenomenon with few case reports in the literature. The universally acceptable medical therapy for patients who develop this complication post implantation of the device is poorly defined. We present a case of a Caucasian female with no known Nickel allergy who developed chest tightness, dyspnea and malaise immediately following percutaneous implantation of this occluder in the setting of an ASD. She did however experience complete resolution of her symptoms with dual antiplatelet therapy (Aspirin and Clopidogrel). This case proposes a possible medically feasible therapeutic option for the management of hemodynamically stable patients who developed a Nickel allergy following placement of an Amplatzer device.

Keywords

amplatzer occlusive device; dual antiplatelet; atrial septal defect; patent foramen ovale; noblestitch

Abbreviations

ASD: Atrial Septal Defect; PFO: Patent foramen ovale; CCISC: Congenital cardiovascular interventional study consortium; NSAID: Nonsteroidal anti-inflammatory drugs; TLR4; Toll-like receptor 4

Introduction

Medically significant Nickel allergy following an Atrial Septal Defect (ASD) or Patent Foramen Ovale (PFO) closure with an Amplatzer occlusive device is a rare phenomenon with few case reports in the literature. We present a case of a Caucasian female with no known Nickel allergy who developed chest tightness, dyspnea and malaise immediately following percutaneous implantation of this occluder in the setting of an ASD. This cases proposes a possible therapeutic option in these patients.

Clinical Summary

A 29-year-old female with a history of hypothyroidism, who was diagnosed via a transthoracic echocardiogram with a bidirectional secundum atrial sepal defect and right ventricular dilation seven years after chronic palpitations, shortness of breath, malaise and weakness. She was then referred to the congenital heart disease division of our medical center for percutaneous closure of her ASD with a 24 mm St Jude Amplater occlusive device. Soon after her ASD closure while still in the cardiac catheterization lab,

she developed chest pain and tightness radiating to the neck, shortness of breath, diaphoresis and generalized malaise. Despite these symptoms, she was hemodynamically stable and underwent a thorough work up that was unrevealing and included an EKG, chest x-ray, and echocardiogram. There was concern for a possible nickel allergy given a prior history of contact dermatitis that was successful treated with steroids. She was discharged on indefinite Aspirin therapy and Plavix for a month. A week after being on dual antiplatelet therapy, there was complete resolution of her symptoms with great improvement in her daily functionality compared to her baseline prior to placement of the ASD occlusive device. After a month on dual antiplatelet therapy, she was taken off Plavix and her symptoms of increasing fatigue, chest tightness, dyspnea and malaise returned. A discussion was had with the patient and a decision was made to put her back on Plavix and aspirin. Within a week of resumption of dual antiplatelet therapy, she experienced a complete resolution of symptom again. She is one of three patients at our congenial clinic who have developed similar symptoms after closure of an ASD or PFO with a St Jude Amplatzer occlude device followed by complete resolution of symptoms with dual antiplatelet therapy (Aspirin and Clopidogrel).

Discussion

The Amplatzer occlusion device is made of nitinol alloy, which is composed of 55% nickel and 45% titanium. Nitinol is used in many medical devices for its biocompatibility, radiopacity, elasticity, thermal shape-retaining properties, and resistance to fatigue and corrosion [1]. The use of nitinol is widespread in implantable medical devices such as septal occluding devices, vascular and nonvascular stents, IVC filters, tubal sterilization coils, and orthodontic appliances, among others.

The prevalence of nickel allergy in the general population is estimated to be as high as 10%, with a higher reported prevalence in women than men [2,3]. This poses a potential problem for patients with nickel hypersensitivity who receive a device implant containing this material. The occurrence of nickel allergy following device implantation is a rare, incompletely understood, but a well-established entity.

According to a survey of member of the Congenital Cardiovascular Interventional Study Consortium (CCISC), nickel allergy incidence was 2.1% after closure of congenital heart defects with nitinol-containing devices [4]. There have been a handful of prior case reports in adults describing nickel hypersensitivity reactions following septal occluder placement. Additionally, nickel allergies have also been described in reaction to vascular and nonvascular stents [5], Essure tubal sterilization coils [6], IVC filters [7], and orthodontic appliances [8].

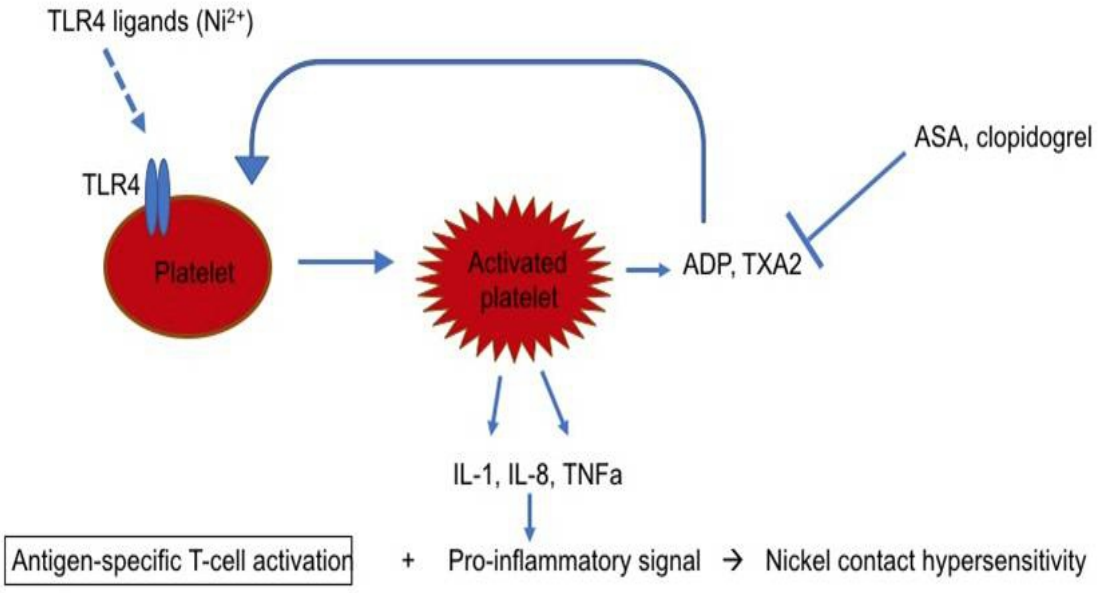
Prior cases reported a similar clinical presentation to ours, with substernal chest pain, radiation to the scapula and arm. Previous reports of systemic allergic reactions to nickel containing occlusion devices also included clinical presentations of fever, dyspnea, palpitations, headache and pruritic rash. Prior studies have demonstrated a rise in serum nickel levels following device implantation with a peak at 1 month and a return to near normal at 12 months following implantation [9]. Time to symptomatic presentation following device implantation ranges from hours to months.

Regarding other cases of septal occluder devices, one proved successfully medically managed with steroids, while others ultimately required device explantation [10]. Thus far, medical management has proved limited to steroids and NSAIDs for pain relief for these symptoms. Cases refractory to this

medical management proceeded to device explantation. As with the other nickel-containing medical implants, with explantation of the Essure coils, removal of IVC filter, and with utilization of titanium instead of nickel dental braces, patients experienced resolution of their symptoms.

Our case report is novel in that it proposes an additional possibility for medical management to trial prior to surgical device explantation. In this case and two others at our institution, symptomatic resolution was observed with daily dual antiplatelet (clopidogrel and aspirin therapy). Regarding the mechanism, nickel contact allergy is an allergic contact dermatitis, mediated through a contact hypersensitivity reaction. Initial exposure triggers antigen presentation by dendritic cells to T lymphocytes. Subsequent exposure results in activation of the antigen-specific T cells, plus an inflammatory response that results in the release of pro inflammatory cytokines and chemokines. Prior work has shown that in humans, nickel contact allergy is largely mediated through TLR4 receptors [11]. Downstream signaling from TLR4 receptors results in the release of pro inflammatory cytokines such as IL-1, IL-8, and TNFa [12].

Platelets have been shown to express Toll like receptors, including TLR4 [13-15]. Platelet TLR4 has been implicated in the pathogenesis of a number of inflammatory conditions [16-18], and it is thought that TLRs may represent an alternative platelet activation pathway [17]. The inflammatory role of platelets is currently an expanding area of study. From review of prior literature, we propose that nickel may activate platelet TLR4 receptors, and stimulate activation and downstream inflammatory signaling. We propose that with dual anti-platelet therapy, the pro-inflammatory signal and downstream release of inflammatory cytokines is blunted preventing further platelet activation thus providing relief in our nickel allergy patients.



Though many septal occluder devices contain nickel, some newer generation devices are being manufactured such that the nickel containing elements are coated with other materials such as platinum, titanium and ceramic [19]. Patch testing is currently the gold standard in evaluating patients with nickel allergy, and has proved successful in guiding device selection prior to implantation [20]. These may prove better options for patients with known nickel hypersensitivity, and highlight the importance of evaluating patients for nickel allergy prior to device placement.

As with previous reports, we propose that nickel allergy following nitinol-containing implants and devices is likely underestimated and underreported. There are many medical devices and implants that contain nickel, and nickel and metal allergies are not commonly elicited in standard history taking. In the CCISC survey, only 44% of physician respondents routinely inquired about nickel allergy prior to device implantation and no responders performed skin testing prior to device closure [4]. We propose that the prevalence of nickel hypersensitivity is likely to increase as awareness increases, and with increased utilization of these devices.

Though this manuscript provides proved successfully medically management of nickel allergy following placement of an Amplatzer occlusion device, it is worthwhile to mention that newer techniques that might usher a movement away from device implantation are on the rise. One of these newer techniques that has proven successful is the Nobles stitch procedure which uses a percutaneous cardiovascular suturing and PFO/ASD closure system. Though there is little in the literature on the success stories of Noblestitch in American hospitals, there has been report of successful clinical cases in Germany, Sweden, Italy and Kazakhstan. This 30-minuteprocedure seems to have advantages which are not limited to the following; no device implantation, no requirement for antiplatelet or other medical therapy, no risk of dislocation, atrial fibrillation, erosion or thrombosis, allows for future trans-septal procedures and no concern for possible nickel allergy post procedure. A comprehensive report on closure of PFO/ASD utilizing the Noble Stitch™ EL suture based closure system compared to other occluder devices was presented at the 2017 CSI UCSF Congress in Italy. Using the same criteria listed in the RESPECT and CLOSE trial, data for closure rate and adverse events demonstrated a superior closure rate to both the Gore Helix and AGA Amplatzer with a zero-residual shunt rate at 12 months follow up. Furthermore, it was found that the Noble stitch had no complications compared to 4.2 % complication rate in the RESPECT and 12.8% in the CLOSE trial. This newer technique though invasive has the potential to become the standard of care as it eliminates the possible complication of occlusive device and the need to be on lifelong medical therapy.

Prevention and diagnosis going forward should include routine history taking regarding metal allergies, reactions to jewelry, metal buttons on clothing, piercings etc., and definitive diagnosis of a patient with vague complaints and systemic symptoms following implantation of a medical device containing nickel should include nickel skin patch testing. Prior to considering device explantation, we provide a case report with evidence for a medical trial of dual antiplatelet (Clopidogrel and Aspirin) for relief of chest pain associated with nickel allergy from septal occluders. This antiplatelet therapy may interrupt platelet TLR4 downstream signaling, one of the mediators of the nickel hypersensitivity reaction and pro inflammatory reaction. Anti-platelet therapy for nickel hypersensitivity was a successful medical management in these case and two others. This therapy was steroid-sparing and invasive surgical explantation of the device was avoided.

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