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Allergic Reaction to Percutaneously Placed Amplatzer Device for Symptomatic Patent Foramen Ovale

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Abstract

Transcatheter placement of patent foramen ovale occluders is an alternative to open heart surgery for repair of PFO's. We present a case of a 33 years old male with a previously unknown nickel allergy who developed a severe allergic response after placement of a nitinol based cribriform amplatzer device, for closure of symptomatic PFO.

Our patient presented with neurological symptoms consisting of visual field defects and right sided weakness. MRI showed a left hemispheric parieto-occipital. An echocardiogram showed a large PFO. He was discharged eventually with a plan for long term anticoagulation. However he presented again with similar symptoms in a few days. Due to recurrence of symptoms his neurologist recommended PFO closure. This was successfully closed percutaneously using a 25 mm amplatzer cribriform device and no residual shunt was seen. The patient returned two days later with shortness of breath, chest pain and a pruritic rash. All further laboratory testing was negative. Suspecting nickel allergy, testing was performed with a 25 mm cribriform device taped to the patients left arm. He was then referred to cardiothoracic surgery for explantation of the amplatzer device which resulted in resolution of his symptoms.

Nitinol is the material that constitutes amplatzer occluders. Though considered safe for PFO closure, there are reports of allergic responses to it. Here we have an early onset case of an allergic response to the device with a novel way to test for allergies using the device itself, with an emphasis on questioning patients regarding allergies and testing them as well.

Keywords: Nickel allergy; Septal occluder device; Foramen ovale; Patent

Introduction

Transcatheter placement of patent foramen ovale occluders (PFO) is a safe and effective alternative to conventional open heart surgery with surgical repair of patent foramen ovale. Most devices involved in this repair are made up of a nitinol frame and over time there have been sporadic reports of allergic reactions in some patients to these devices, which are a composite of 55% nickel and 45% titanium. These reactions have ranged from cutaneous dermopathies, pericarditis, migraines to device syndromes [1-3].

Most patients who have presented with these symptoms have eventually been diagnosed with a type 4 hypersensitivity reaction to nickel. In spite of this, allergies to nickel containing devices have remained poorly studied.

We present a case of a patient with a previously unknown nickel allergy who developed not just cutaneous symptoms, but also a form of device syndrome within two days of placement of a cribriform Amplatzer device for closure of symptomatic patent foramen ovale.

Case

A 33 years old previously healthy male presented with a complaint of a severe headache as well as visual field deficits, along with left sided paresthesias. An Initial CT scan of the head and spinal tap were unremarkable, as were a CT angiogram and doppler of the carotids. However MRI films showed a left hemispheric parieto-occipital stroke. Further work up included an echocardiogram with bubble study which showed a PFO with a bidirectional shunt. In the hospital he was treated with IV heparin and aspirin and as his symptoms resolved he was discharged with a plan for long term anticoagulation with Coumadin. However within a few days he had a recurrence of similar neurological symptoms and returned to the emergency department. A follow up CT scan did not show any new abnormalities. Since his history of PFO was well known, a paradoxical embolus was suspected and a trans-esophageal echo was performed which showed a large bidirectional PFO. Along with this a lower extremity Doppler was also performed which was negative for any DVT. Given his age, cryptogenic recurrent strokes while on treatment and the large PFO, his neurologist recommended PFO closure.

The PFO was successfully closed percutaneously using a 25 mm amplatzer cribriform device, under intra-cardiac echo guidance. The procedure was uneventful and no residual shunt was seen. The patient was discharged the same day on aspirin 81 mg and clopidogrel 75 mg.

The patient was stable at the time of discharge; however he returned two days later with a complaint of shortness of breath, chest pain and a pruritic rash. He described the dyspnea as markedly restricting his daily activities. Furthermore he described the pain as substernal, non-radiating and squeezing. He denied having any palpitations, syncopal episodes or migraines. Physical examination was unremarkable, and all known labs were within normal limits. Subsequent imaging included a CT angiogram of the chest and cardiac catheterization to assess coronary anatomy, which were normal. Repeat echo demonstrated a well seated device with no residual shunt or erosion. There was no

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pericardial effusion. Multiple chest X-rays, electrocardiograms, upper endoscopy's and even a bone scan did not reveal any abnormality either. A drug reaction was initially suspected, therefore his clopidogrel was held. In spite of this, he had multiple ER visits with the same debilitating symptoms however no obvious etiology could be elucidated. There was a concern that his symptoms were due to an allergic response to the device itself, and he was now started on a 40 mg dose of oral prednisone for one month.

At follow up a week later, the skin rash had visibly resolved, however his cardiopulmonary symptoms did not show much improvement. At this time a dermatology consult was sought and the patient underwent a TRUE patch test for allergy to nickel which was moderately positive (Figure 1).

However, since the device was not purely nickel, but a nitinol composite, it needed to be proven unequivocally that the device was indeed causing the symptoms. Therefore cutaneous testing was performed with a 25 mm cribriform device taped to the patients left arm. The results of the skin testing were moderately positive, and since the patient's symptoms persisted, it was decided to refer him to cardiothoracic surgery for explantation of the amplatzer device (Figure 2).

The patient underwent successful removal of the septal occluder with closure of the PFO, and was eventually discharged after resolution of all symptoms. Subsequent follow up has not shown recurrence of his cardiopulmonary symptoms and he has remained stable.

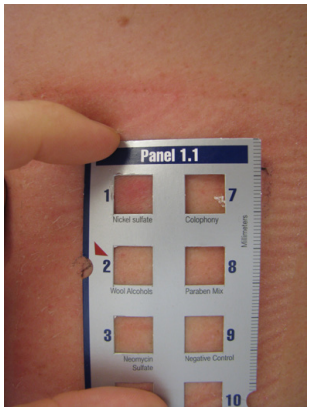

Figure 1: Cutaneous testing for allergy to nickel.

Figure 2: Allergic response to the cutaneous application of the nitinol made amplatzer device.

Discussion

Transcatheter PFO closure has become a reasonable treatment modality due how minimally invasive it is. However, it is pertinent to note that 15% of the general population harbors an allergy to nickel, which makes it important to ascertain whether a patient does have an allergy to this metal or not, before device implantation [4].

Nitinol is the composite material that constitutes this device due to its memory, resistance to corrosion and fatigue, elasticity and thermal properties. However, in spite of this, there are still side effects that have been documented; though rare [1-5]. These side effects have been shown to develop anywhere between 24 hours to up to 6 weeks after device placement [6]. While the mechanism of these side effects which are felt to develop in response to this indwelling device remain unknown, it has been postulated to be related to either the induction of localized inflammation or the slow and steady release of nickel into the systemic circulation from the surface of the PFO occluder [7-11]. This release has been studied by Ries et al. [7] and Burian et al. [8] where they have shown a fivefold increase in nickel levels in the body within 6 weeks of placement of nitinol made PFO implants, and a gradual decline to baseline in 4-6 months as well [7,8]. However, it is this initial increase in nickel levels that is thought to have consequences during the immediate post procedure period for patients who have allergies to nickel containing materials.

Patients with nickel allergies, once implanted with the device usually exhibit symptoms which include dyspnea, chest pain, migraine headaches with or without aura, palpitations, dependent edema and in some cases fever as well [4]. This has been further validated by Rigatelli [9] who have in a prospective study shown the development of symptoms of device syndrome, which included chest pain, dyspnea and asthenia, in 8 out of 9 patients with known nickel allergies who consented to being implanted with nitinol containing amplatzer occluders. Furthermore, similar findings have also been shown by Wertman et al. [3] where a strong association was shown between Amplatzer PFO occluder use and migraine headaches with aura's and chest pain in patients with nickel allergies [3]. A multicenter study has also in 2011 shown the development of symptoms of chest pain in 71% of patients who were implanted with the Amplatzer device with 70% of those patients having tested positive for nickel allergies as well [10].

In our case, since we did not check urine or serum nickel levels in our patient, and histology was not drawn on the Amplatzer device either, we cannot be absolutely sure that this was indeed a hypersensitivity reaction. However correlating the temporal association of the patient's symptoms with the positive patch test and positive cutaneous response to the device that was taped to his skin, along with resolution of symptoms with removal of the device, points towards nickel allergy being the prime cause of his symptoms.

It is important to note that percutaneous closure of PFO's remains a treatment option for recurrent cryptogenic strokes and since most devices used are composites of nitinol, it is useful to know the prevalence of nickel allergies in the population and the implication of placement of a device like this. Device instructions for use regularly stress upon the need to question patients regarding nickel allergies however this is something that is not routinely done in clinical practice. Though such reactions are rare, the consequences can be enormous, and as more devices are being implanted, awareness of potential consequences is of utmost importance. We strongly believe that this is something that needs to be discussed in patient encounters prior to the placement of such devices. While this discussion can be supplemented with TRUE patch

testing, which is a cost effective option, or even radio allergosorbent assays (RAST) for nickel allergy we would also strongly recommend testing directly with the device itself as well, for hypersensitivity prior to placement. Secondly, what can also be considered is testing for titanium induced allergies, which though rare, can also contribute to a systemic allergic response in the same way as nickel, using the MELISA test. In the end, if the clinical suspicion for a hypersensitivity reaction continues to remain high, another option could also be the use of coated devices, such as the platinum coated nitinol device, which has been used in a study by Lertsapcharoen et al., where the use of platinum coated nitinol devices was found to benefit those with nickel allergies [12].

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