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Address for Correspondence: Dr. Ahmet Çağrı Aykan,
Ahi Evren Göğüs ve Kalp Damar Cerrahisi
Eğitim ve Araştırma Hastanesi,
Soğuksu Mah., Çamlık Cad.
61040 Trabzon-*Türkiye*
Phone: +90 505 868 94 61
Fax: +90 462 231 04 83
E-mail: ahmetaykan@yahoo.com
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Explantation of an atrial septal occluder device in a patient with nickel hypersensitivity

Emrah Uğuz, Kemal Erdoğan, Erol Şener
Clinic of Cardiovascular Surgery, Atatürk Training and Research Hospital; Ankara-*Turkey*

Introduction

Percutaneous closure of cardiac defects has become increasingly popular among cardiologists. Nitinol containing devices for transcatheter closure of atrial septal defects (ASD) have been used worldwide over the past decade (1, 2). These nitinol devices not only provided excellent results, but also made for safe and easy device implantation (1, 2). Meanwhile, there are certain contraindications and limitations to this relatively popular technique that should be acknowledged. Here, we report a case of nickel hypersensitivity after an ASD device closure requiring device explantation.

Case Report

A 26-year-old woman with a known history of percutaneous closure of ASD, presented with headache, shortness of breath and retrosternal pain and chest compression and her discomfort was exacerbating with inspiration. The secundum ASD had been closed using an Amplatzer Septal Occluder device (AGA Medical, Golden Valley, MN) in another institution a year ago. Within days after deployment, the patient developed symptoms. She also experienced episodes of shortness of breath and palpitations, usually lasting a few minutes. Symptoms progressed in severity and became constant after weeks. During her evaluation, no shunting was documented. She reported a severe metal allergy since childhood, to an extent that wearing any metal jewelry resulted in severe contact dermatitis. Reaction to the device was presumed to be the primary cause of her symptoms after an extensive work up. Since, patch testing is currently the gold standard for evaluating patients with nickel allergy, consultant Dermatology physician recommended to proceed with patch testing. Skin patch testing demonstrated hypersensitivity for nickel. Her symptoms continue to worsen and resulted in multiple hospital admissions. A course of prednisone and clopidogrel was attempted. Her symptoms persisted, requiring visits for control. In this follow up process, the patient was also evaluated at the institution where the device was implanted and they recommended surgical explanation of the device with the diagnosis of nickel hypersensitivity. She subsequently underwent uncomplicated device removal a year after her transcatheter ASD closure (Fig. 1-3) in our institution. Surgery was performed through a standard median sternotomy approach. After removal of the device, the defect in the atrial septum (2.5x2.0 cm) was closed with an autologous pericardial patch. We used polydioxanone sutures for sternal closure after the procedure in order to avoid steel wires. Postoperatively she experienced dramatic improvement of her symptoms. She remains symptom free now at 3 months after her operation.

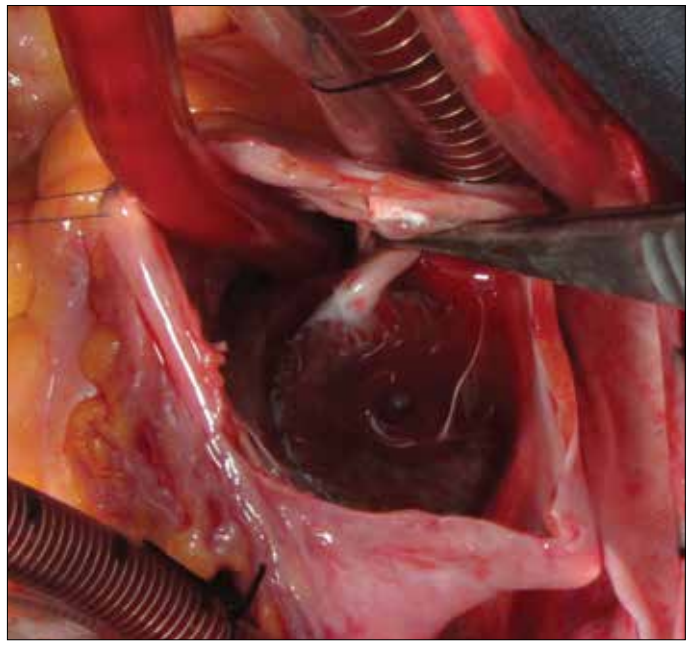

Figure 1. Amplatzer ASD occluder, right atrial surgical view

Discussion

The amplatzer ASD occluder device consists of nitinol which is a metallic alloy composed of 55% nickel and 45% titanium, giving it superior elasticity and shape memory (3). Since 8.6% of the population demonstrates skin sensitivity to nickel (4), the issue of biocompatibility of nitinol implants remains controversial. Patch testing is currently the gold standard for evaluating patients with nickel allergy (4).

Although device closure of an ASD has been reported to be safe, it has been associated with serious complications that required surgical

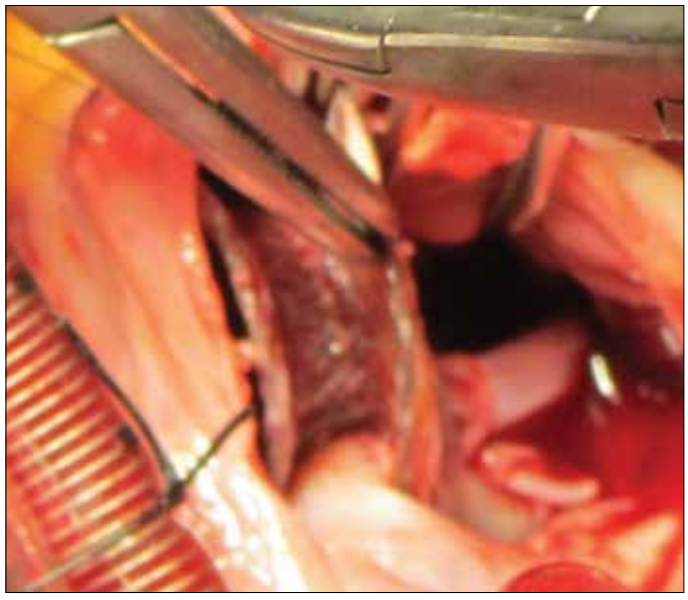

Figure 2. Surgical explanation of Amplatzer ASD occluder

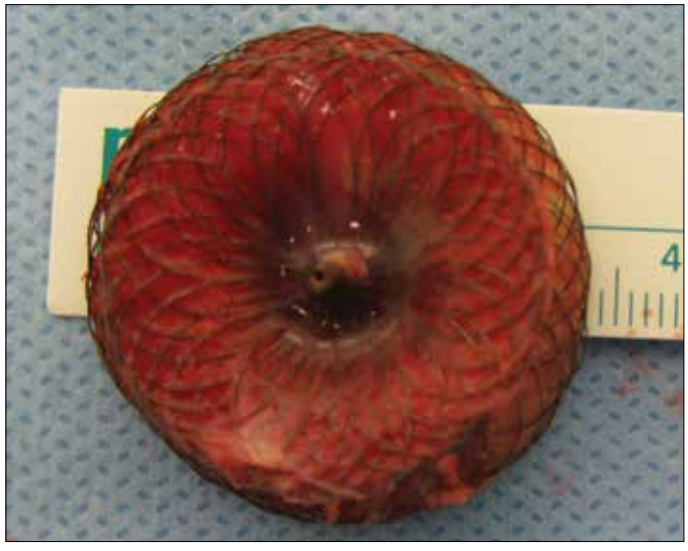

Figure 3. Explanted Amplatzer ASD occluder

intervention. Malposition, migration, arrhythmias, residual shunts, cardiac perforation, valve regurgitation, infectious endocarditis, thrombus formation, and sudden death have all been reported (5, 6). A metal allergy severe enough to require device removal is a rare complication of the device. Although high blood nickel levels may not be a concern in most patients receiving the device, patients with a metal allergy may present with an allergic reaction. This reaction to the device has been documented as dermatitis, bronchospasm or pericardial effusion (7-9). The clinical significance of nickel release after device implantation in patients without metal allergy is unclear and is subject to further studies. Endothelization may prevent systemic exposure to nickel. If the occluder is eventually surrounded by fibrous tissue and not exposed to inflammatory cells, then the hypersensitivity reaction may eventually cease. If symptoms persist and hypersensitivity reactions are unresponsive to medical therapy, surgical explanation of the device should be considered as in our case. In a cardiac operation, any permanent nickel containing material like sternal wires should also be avoided and nickel-free sternal fixation systems (like polyetheretherketone) or polymer sutures (polydioxanone in our case) should be preferred. Temporary epicardial pacing wires are usually removed in days so we think they are not contraindicated.

Conclusion

We present a case of an allergic reaction to a nitinol device in a patient with prior history of a metal allergy. Patients with similar symptoms who have undergone a nitinol device implantation should be tested for possible nickel hypersensitivity. Although the risk of a significant allergic reaction to nickel in these devices is exceptionally low, this case underlines the potential risks associated with inserting a permanent cardiac device. Awareness of this condition might increase the reports of this problem so that patients and physicians might have an improved understanding of the risk associated with implantation of these devices in patients who are sensitive to nickel. It is reasonable to consider nickel hypersensitivity allergy as a contraindication to percutaneous closure of an ASD with devices containing nitinol and take alternative devices or even surgery into account in this circumstance.

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Address for Correspondence: Dr. Emrah Uğuz,
Atatürk Eğitim ve Araştırma Hastanesi,
Kalp ve Damar Cerrahisi Kliniği, Alacaatlı Mah. 3278 Sok Park Sera Sitesi No: 5 Yaşamkent, Ankara-*Türkiye*
Phone: +90 312 291 25 25-4376
E-mail: emrahuguz@hotmail.com

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