

Surgical removal of atrial septal defect closure device due to systemic allergic reaction to nickel: A case report

Nikele karşı sistemik alerjik reaksiyon nedeniyle atriyal septal defekt kapatma cihazının cerrahi olarak çıkarılması: Olgu sunumu

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ABSTRACT

Systemic hypersensitivity reaction to nickel-containing medical device is a rare complication after percutaneous atrial septal defect closure. The symptoms regress spontaneously or in response to medical treatment in most cases. Surgical device removal is mandatory and effective in patients whose symptoms persist despite optimal medical therapy. Herein, we report a case of systemic allergic contact dermatitis secondary to nickel allergy after atrial septal defect closure and its successful treatment with surgical removal of the device.

Keywords: Atrial septal defect, closure device, nickel allergy, surgical removal.

Transcatheter atrial septal defect (ASD) closure is the first-line treatment modality in secundum type ASD. With the widespread use of this treatment method, the incidence of periprocedural and late complications has increased in recent years.^[1] Systemic hypersensitivity reaction to nickel-containing medical device is a rare complication after percutaneous ASD or patent foramen ovale (PFO) closure. Herein, we present a case of systemic allergic contact dermatitis secondary to nickel allergy after ASD closure and its successful treatment with surgical removal of the device.

CASE REPORT

A 22-year-old female patient with secundum type ASD and enlargement of the right heart chambers

ÖZ

Nikel içeren tıbbi cihaza karşı sistemik hipersensitivite reaksiyonu, perkütan atriyal septal defekt kapatıldıktan sonra nadir görülen bir komplikasyondur. Semptomlar çoğu olguda kendiliğinden veya tıbbi tedavi ile geriler. Optimal tıbbi tedaviye rağmen semptomları devam eden hastalarda cerrahi olarak cihazın çıkarılması zorunlu ve etkilidir. Bu yazıda, atriyal septal defekt kapatıldıktan sonra nikel alerjisine sekonder sistemik alerjik kontakt dermatit olgusu ve cihazın cerrahi olarak çıkarılması ile başarılı tedavisi sunuldu.

Anahtar sözcükler: Atriyal septal defekt, kapama cihazı, nikel alerjisi, cerrahi olarak çıkarma.

on transthoracic echocardiography was referred to our clinic for percutaneous closure. Her medical history was unremarkable, without any history of allergic disease or reactions. A 22-mm-sized ASD closure device (Amplatzer™ septal occluder, St. Jude Medical Inc., MN, USA) was successfully implanted to the defect whose rims were found to be suitable for percutaneous closure by transesophageal echocardiography. After successful closure, the patient was discharged with acetylsalicylic acid and clopidogrel treatment. About one week after the procedure, widespread itching and diffuse urticarial lesions appeared on her body and extremities (Figure 1). The patient was initially referred to the dermatology clinic and a diagnosis of systemic allergic contact dermatitis was made. A systemic hypersensitivity reaction to

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the implanted occluder device was suspected and epicutaneous patch allergy testing was planned. A strong reaction (3+) to nickel sulfate was observed on the patch test which confirmed definite nickel allergy.

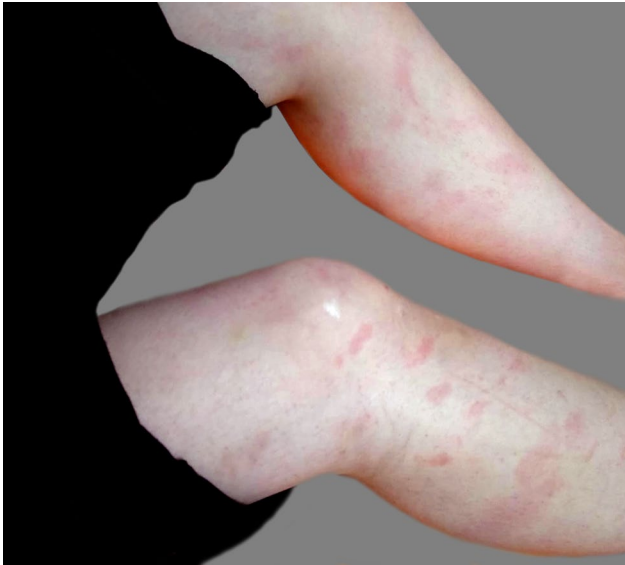


Figure 1. Diffuse urticarial lesions are seen on patient's both legs.



Figure 2. Intraoperative view of Amplatzer™ occluder device in the interatrial septum after right atriotomy.

Laboratory testing showed a significant increase in immunoglobulin E (IgE) levels (3,110 IU/mL, reference range: 0 to 100 IU/mL) with a normal complete blood count and erythrocyte sedimentation rate. Although the patient was followed with a low nickel diet, allergen avoidance strategies, steroids, and antihistaminic drugs, her symptoms and urticaria worsened. Despite the discontinuation of acetylsalicylic acid and clopidogrel as a possible potential cause of urticaria, the patient's complaints did not regress. Then, the patient was evaluated by the Heart Team, including cardiologists and cardiovascular surgeons for the surgical removal of the closure device, and it was planned to surgically remove the device by taking the patient's opinion based on a joint decision. Eight months after percutaneous closure, the device was surgically removed by right-sided thoracotomy (Figure 2) and the defect was repaired with an autologous pericardial patch. The removed closure device is seen in Figure 3. The patient experienced an uneventful postoperative period, and her urticarial lesions and complaints completely resolved during follow-up.

DISCUSSION

Most of the devices used in interventional cardiac procedures contain different metals and their alloys. Nickel is one of the most commonly used metals in these devices. Nitinol is an alloy composed of nickel and titanium. Nitinol is frequently used in medical products owing to its good radiopacity, superelasticity, corrosion resistance, and shape memory quality.^[2] The prevalence of nickel hypersensitivity is seen in approximately 10% of the adult population.^[3] Despite the high nickel content in approved ASD or PFO closure devices, allergic reactions after implantation of these devices are uncommon. The occluder devices are usually coated with titanium oxide to minimize nitinol release. Hypersensitivity reactions can be seen in patients allergic to nickel; however, it does not



Figure 3. The explanted Amplatzer™ occluder device.

constitute a definite contraindication for percutaneous closure.^[4] If percutaneous closure is planned in patients with a known nickel allergy, devices with less nitinol content such as GORE® HELEX® Septal Occluder (W. L. Gore and Associates, Inc., Flagstaff, AZ, USA), CardioSEAL™ (NMT Medical, Inc., Boston, MA, USA) and Atriasept™ (Cardia, Inc., Eagan, MN, USA) can be used alternatively. However, it should be noted that all current approved ASD and PFO closure devices contain nitinol.

In our case, the diagnosis of allergic contact dermatitis secondary to the device was supported by the onset of allergic reactions one week after implantation, confirmation of contact allergy to nickel present in the device, and rapid resolution after explantation. Additionally, increased IgE levels in laboratory testing supported the diagnosis of a hypersensitivity reaction. The current report presents aggressive and required surgical treatment of an allergic reaction to closure device which is unresponsive to medical therapy.

Percutaneous closure of secundum ASD is a safe and effective procedure with low mortality and morbidity rates.^[1] However, the worldwide use of closure devices has brought some late and rare complications to light. Nickel allergy is one of the main delayed complications of ASD closure procedure.^[5,6] These patients are usually treated conservatively, and most patients respond well to medical treatment. Hypersensitivity to nickel may cause localized and systemic reactions. Localized cutaneous lesions can be seen as dermatitis and urticaria, while systemic nickel hypersensitivity reactions can vary. The most common symptoms of direct exposure to nickel in these patients include chest pain, dyspnea, palpitations, and migraine headache.^[7,8] The systemic allergic reaction can occur within 24 h or up to six weeks after the device is implanted.^[7] Rarely, in some cases, allergic reactions may persist despite medical treatment, and the device may need to be removed. In a multi-center study of 13,736 patients who underwent percutaneous PFO closure, removing the closure devices was required in only 38 patients.^[9] Chest pain was the most common reason for device removal. Although nickel allergy was not listed as the primary cause of removal in any cases, among the 14 patients who required device removal for chest pain, seven of them had a positive patch test for nickel. Other reasons for device removal were residual shunt, thrombus, effusion, and perforation.^[9] In three large-scale studies on PFO closure, more than 2,000 patients had PFO closure, and only one device-related allergic reaction was reported among these

patients.^[10-12] In addition, successful transcatheter ASD or PFO closure in patients with a known nickel allergy has been also described in the literature.^[4,13]

Nickel allergy is quite common in the adult population. Hypersensitivity to nickel may lead to localized or systemic reactions. The immunological mechanism underlying nickel allergy is type IV or cell-mediated hypersensitivity reaction.^[14] Ries et al.^[15] examined serum nickel concentrations in 67 patients who underwent closure with the Amplatzer™ device, and the mean serum nickel levels peaked in the first month and decreased to baseline levels at 12 months. In another study by Burian et al.,^[16] the serum nickel level increased five-fold in 24 patients and decreased to baseline levels at six months. The prognosis of nickel hypersensitivity after ASD or PFO closure often has a good course. Most of the allergic reactions resolve within months after appropriate medical treatment, but rarely in some cases, symptoms do not resolve in response to medical therapy. Device explantation is an effective treatment modality in terminating symptoms of these patients. The usefulness of routine patch testing prior to device implantation is still controversial.

In conclusion, although nickel hypersensitivity is quite common in the adult population, systemic hypersensitivity due to nickel-containing atrial septal defect closure devices is a rare condition. Symptoms resolve spontaneously in most cases; however, removing the device is a mandatory and effective treatment option, if the medical management fails.

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