

Superficial femoral artery nitinol stent in a patient with nickel allergy

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We present a case of a patient who developed a systemic allergic reaction following placement of a nitinol stent in the superficial femoral artery for claudication symptoms. Shortly after, he was tested for contact dermatitis and found to have a severe reaction to nickel. His symptoms of severe itch and generalized rash resolved within days following stent explantation and reconstruction with a vein graft. The epidemiology and clinical significance of nickel allergy and the concomitant use of nickel-alloy stents are discussed. (*J Vasc Surg* 2013;■:1-3.)

There has been a rapid rise in the number of endovascular procedures being performed for peripheral vascular disease, and with it, the use of self-expandable nitinol stents in the superficial femoral artery. It is also well documented that worldwide, the most common allergen in patients assessed for contact allergy, is nickel, the predominant component of nitinol.¹ The use of nitinol stents in patients with nickel allergy undergoing superficial femoral artery angioplasty has not been well studied in the literature.

CASE REPORT

An active 55-year-old machinist presented with disabling right calf claudication. After a 6-month trial of risk factor management and exercise, he underwent a subintimal angioplasty of a complete occlusion of the superficial femoral artery and placement of a 7-mm × 15-cm nitinol stent. Clopidogrel therapy was initiated on discharge the same day. Following the procedure, the patient had complete resolution of his claudication in the right leg with an ankle-brachial index of 1.1. The patient had no history of any drug or metal allergies prior to the procedure.

Two weeks following the procedure, he presented to a dermatologist with generalized severe pruritus and an eczematous dermatitis worse on the right leg (Fig 1). Patch testing (according to North American Contact Dermatitis group guidelines²) revealed a severe reaction to nickel sulfate only. A biopsy of the rash revealed spongiotic dermatitis with a moderate superficial perivascular infiltrate consisting of lymphocytes and a few eosinophils. Assuming that the cause of his dermatitis was related to

occupational exposure to nickel, he was put on corticosteroid therapy (topical betamethasone 0.1%, followed by prednisone 40 mg orally, tapered over 6 weeks), and repositioned to a different job location with no potential for metal exposure. Despite this, the patient had persistence of his severe pruritic eczematous dermatitis on his lower extremities, and developed localized pain on deep palpation in his mid-thigh in the area of the superficial femoral artery stent. In addition, the patient complained of shortness of breath and fatigue.

After 8 months, he eventually returned to the vascular surgeon, and the potential for an allergic reaction to the stent was entertained. His blood work was normal, and a computed tomography angiogram revealed a patent stent without any major surrounding inflammatory reaction. After consultation with an expert in contact dermatitis, and with the insistence of the patient, the decision was made to explant the nitinol stent. This was performed in the operating room, through a medial thigh incision and complete mobilization of the distal superficial femoral artery. The segment of artery containing the stent was completely resected (~15 cm). Reconstruction was performed with an interposition reversed saphenous vein graft. We noted dense scar tissue around the artery for the entire length of the stent but no acute inflammatory reaction. On postoperative day 1, the patient had almost complete resolution of his severe itch, and by 1 month he had resolution of his dermatitis and fatigue (Fig 2).

Pathological analysis was performed, with the stented artery formalin fixed and decalcified. The stent was deployed within the arterial wall (subintimal plane) displacing the native lumen and its surrounding media with obliteration of the true lumen. There was severe intimal fibroplasia within the neolumen, with a mild chronic inflammatory response, chiefly plasma cells, macrophages, and lymphocytes. Giant cells and eosinophils were not prominent (Fig 3). X-ray of the specimen revealed a stent fracture. Following the procedure, the patient had complete resolution of his claudication in the right leg with an ankle-brachial index of 1.1. The patient remains asymptomatic with respect to his claudication symptoms and without recurrence of his severe pruritic rash 2 years following stent explantation.

DISCUSSION

Advancements in endovascular techniques have resulted in an increasing use of self-expandable nitinol alloy

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Fig 1. Pruritic and an eczematous dermatitis worse on the right leg 1 month prior to stent explantation.



Fig 2. Resolution of dermatitis 1 month following stent explantation and reconstruction of the superficial femoral artery with an interposition vein graft.

stents in patients with claudication and critical limb ischemia. To our knowledge, despite an increasing incidence of nickel sensitivity in North America,³ this is the first report documenting a reaction to a peripheral nitinol stent as a result of a systemic contact dermatitis from nickel allergy.

The predominant component of the nitinol is nickel (54.5%-57% by weight).⁴ Nickel allergy is one of the most common allergies and causes of dermatitis in the world, with a reported incidence of 8% to 15% in the general population.^{3,5} History often suggests previous pruritic rashes or dermatitis in the area of contact with metal jewelry, or previous occupational exposure.⁶⁻⁸ The “nickel itch” is an early symptom and is often severe and continuous as long as the allergen is present.^{1,6,8} Nickel dermatitis is classified into primary (an eczematous reaction

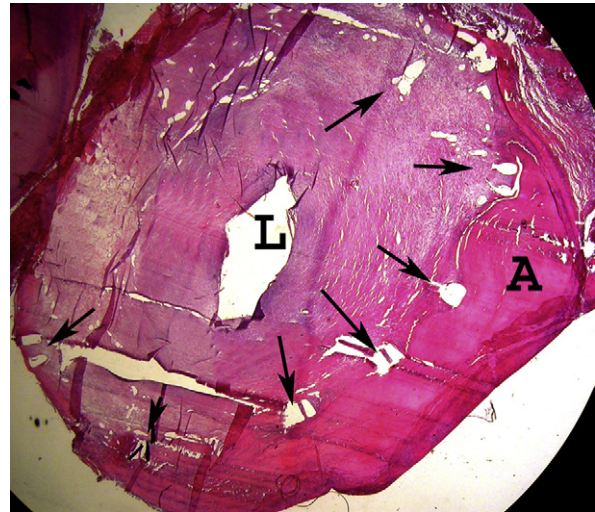


Fig 3. Low power microscopy with hematoxylin and eosin (H&E) stain of cross-section of explanted arterial segment of superficial femoral artery. A, Native artery compressed; L, neo-lumen with intimal hyperplasia inside of subintimally-deployed stent. Arrows are pointing to the stent struts.

in the area of skin that is in contact with nickel) and secondary (a more widespread dermatitis as a result of exposures such as ingestion, transfusion, inhalation, and implantation of metal medical devices). Secondary eruptions are considered as systemic contact dermatitis and are typically widespread and symmetrically distributed.

Despite the incidence of nickel allergy in the general population, a literature review of the PubMed, Medline, Embase, and Cochrane databases did not identify any previous studies or reports of reactions during the use of superficial femoral artery nitinol stents in patients with nickel allergy. We postulate that this may be a result of a few factors including: (1) the amount of free nickel allergen from nitinol stents may be too low in most individuals to surmount a clinically significant reaction; (2) the intravascular location of the nickel exposure may dilute the severity of the reaction compared with a localized dermal exposure; and (3) patients who develop systemic contact dermatitis reactions post-nitinol stenting are possibly unrecognized.

Gimenez-Arnau et al⁹ reported generalized pruritic dermatitis in a patient after endovascular repair of an abdominal aortic aneurysm with an early aortic stent graft made of nitinol in 1999. The patient complained of persistent pruritus and eczema with excoriated papules approximately 3 weeks post aortic stent insertion. The graft was not removed, and her symptoms were managed with anti-histamine medications and topical steroids.

Khan et al¹⁰ reported the occlusion of a biliary stent place for biliary stricture attributed to nickel allergy. The patient had a previous diagnosis of nickel dermatitis clinically but not confirmed by patch testing. After the diagnosis of recurrent biliary obstruction, the stent was

removed surgically. Histological evaluation revealed eosinophils and lymphocytes in an inflammatory infiltrate.

Several reports have hypothesized that the delayed type IV hypersensitivity reaction in nickel-allergic patients may be a triggering or exacerbating factor to the inflammatory process involved in coronary in-stent restenosis, and some have contrarily suggested no clinical significance of nickel allergy in this setting.¹¹⁻¹⁹ A definitive association between in-stent restenosis and nickel allergy has yet to be confirmed. Coronary stents are smaller stainless steel or cobalt chromium alloy stents, and thus the proportion of nickel and the overall nickel burden is significantly lower when compared with the self-expandable nitinol stents used in peripheral vascular disease (5%-10% vs 55%, respectively).¹²⁻¹⁴

Although our patient had a definitive diagnosis of nickel allergy, we did not have any objective radiological, laboratory, or pathologic findings of a systemic reaction to the nitinol stent. As he continued to worsen, despite steroid therapy and removal of occupational exposure, we assumed he had continued exposure to nickel from his stent. Removal of the stent and reconstruction with a vein graft led to an immediate improvement in his symptoms of itch and rash, which was appreciated on postoperative day 1. We suspect the stent fracture also contributed to the systemic nickel contact dermatitis reaction in our patient. The histological evaluation of the stent and surrounding artery showed a significant fibro proliferative reaction, and, although there was no significant eosinophilia, the histological sections illustrated a marked activation of inflammatory cells. Having said that, although there may be eosinophils in the dermal infiltrate, this is often not present in the chronic phase.

This case report illustrates the potential of a systemic reaction in the setting of nickel allergy following placement of these large nitinol stents used in peripheral vascular disease. The clinical significance of known nickel allergy in patients requiring peripheral vascular stents is unknown but likely dependent on the degree of severity of the previous allergic reaction.²⁰ The affect of nickel allergy on stent patency is also unknown and may be dependent on bioavailability of nickel, potentially increased in the setting of metal wear-and-tear and stent fracture. Further studies are required to test these hypotheses. Although, there is little literature on reactions to nitinol stents, one should consider alternatives to the use of nitinol stents in patients with a history of severe reaction to nickel-containing products.

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