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Delayed systemic allergic dermatitis following Essure insert: A case report

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ABSTRACT

Hypersensitivity reaction to the nickel component of the Essure contraceptive micro-insert (Essure) is extremely rare. We present a case of a 41-year-old woman who reported a delayed systemic allergic reaction to the Essure. This is the fourth such case to be reported in the literature.

Four years after Essure insertion, the patient developed systemic contact dermatitis secondary to the nickel component. The Essure was suspected as the cause after a positive allergy-patch test result for nickel. An initial laparoscopic bilateral salpingectomy did not improve her symptoms (likely due to retained microfilament), but a subsequent hysterectomy resulted in complete resolution of symptoms.

Nickel allergy is a rare but serious complication of the Essure and practitioners should be cognisant of its role in hypersensitivity reactions.

1. Introduction

Allergic reactions to the Essure micro-insert (Essure) are extremely rare. The manufacturer claims that these adverse reactions are estimated to occur in approximately 0.04 cases in 1000 [1]. The Essure is a hysteroscopically inserted device placed in the proximal part of each fallopian tube. It is composed of nitinol, an alloy comprising 54.5% nickel and 45.5% titanium [2].

The possibility of allergic contact dermatitis secondary to the nickel component has been suggested in only three previous case reports worldwide [3–5]. Here, we present the fourth case of systemic contact dermatitis due to the nickel component of the Essure device.

2. Case Presentation

A 34-year-old, gravida 4 para 4, with no significant medical history desired permanent sterilisation using Essure. She underwent an uncomplicated procedure under general anaesthesia.

Four years following this procedure, at the age of 38, she suddenly developed a persistent pruritic, urticarial, maculopapular rash mainly in flexural regions, notably the knees and axilla (Fig. 1). The rash was intermittently present on distant sites such as the face, abdomen and legs. She also experienced angioedema in the face, neck and axilla, to the extent that her usual undergarments did not fit. There was only temporary minimal relief with topical and oral steroids or oral antihistamines.

Initially, no correlation was made between the possibility of hypersensitivity to the Essure and the clinical picture - leading to delayed diagnosis. On further questioning she reported a clinical history of nickel allergy, evident in skin reactions to jewelry, watch straps and belts – but she did not have patch-test confirmation of this.

The patient herself noted similar adverse events reported in the literature and subsequently requested removal of the device. Due to the elapsed time from initial placement of the Essure, the patient was booked for laparoscopic removal of the device with associated bilateral salpingectomy one year after the start of her symptoms.

Laparoscopy confirmed that both inserts where located in the fallopian tubes with no apparent migration or perforation; however, pronounced tenting of the fallopian tubes secondary to the Essure was noted. The left Essure was difficult to remove and frail, and broke in two. Both parts appeared complete. The right Essure was removed without difficulty.

However, the procedure did not relieve her symptoms. At this time, it was thought that microfilaments may have been left in the uterine cornua following traumatic extraction of the micro-insert. This was when she was first seen in our gynaecology clinic, and we advised a total laparoscopic hysterectomy.

Two years after her initial symptoms, at the age of 41, she underwent an uncomplicated total laparoscopic hysterectomy. Two weeks following the procedure she was asymptomatic with complete resolution of rash, angioedema and pruritus. Patch testing was positive

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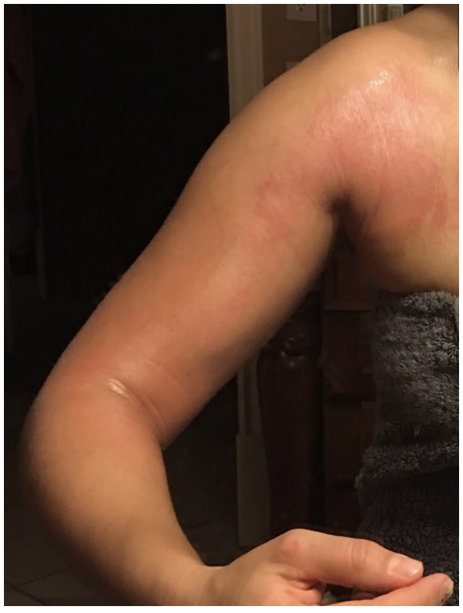

Fig. 1. Persistent rash in the axilla region.

for nickel allergy following the procedure. She remains asymptomatic up to the time of publication.

3. Discussion

Since its introduction, safety of the Essure insert has been the topic of debate. Due to increasing reports of side-effects, the US FDA has made frequent changes in the regulation of the device [6]. Of all adverse events, pain appears to be most frequently reported, followed by delivery catheter malfunction, tubal perforation, post-sterilisation pregnancy with an increased risk of ectopic pregnancy and abnormal uterine bleeding and malposition [7]. The manufacturer recently stated that the Essure permanent birth control device will no longer be sold or distributed after December 31, 2018 due to declining sales [6].

Hypersensitivity reaction to the nickel component of the Essure remains rare and the manufacturer claims this to be 0.004% [1]. Previously, a known nickel allergy was a contraindication for the insertion of the Essure device. However, after a decade of commercial use, no causal relationship between nickel sensitisation and use of the Essure was demonstrated and this contraindication was subsequently removed from the list [2].

To our knowledge we present the fourth, and perhaps most severe, case of systemic contact dermatitis due to the nickel component of the Essure. Importantly, this is the first case that suggests that laparoscopic removal of the Essure and bilateral salpingectomy did not lead to symptom resolution - likely secondary to remaining micro-filaments in the uterine cornua following traumatic removal due to device frailty.

Although the device will soon no longer be available for use, this case illustrates an important and under-recognised adverse effect of the Essure that may present many years after insertion. Timely diagnosis is critical in reducing the morbidity, so practitioners should be cognisant of its role in hypersensitivity reactions.

Contributors

Tanja Baltus, James Brown and Imad Mahmoud were equal and sole contributors.

Conflict of Interest

The authors declare that they have no conflict of interest regarding the publication of this case report.

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Patient Consent

Written informed consent was obtained from the patient for the publication of this case report.

Provenance and Peer Review

This case report was peer reviewed.

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