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Letter to the Editor: Metal hypersensitivity reactions in the context of Essure™

HIGHLIGHTS

- Allergic systemic contact dermatitis has been reported with the use of Essure™.
- Hypersensitivity may be considered upon exclusion of common pelvic disease etiologies.
- Asymptomatic, functioning implanted devices do not warrant patch testing or removal.

Recently Baltus et al. [1] reported the fourth case of metal hypersensitivity associated with Essure™ coiled contraceptive micro-inserts developed by Conceptus Inc. (California). Since 2002, over 21,000 Essure™ events have been reported to MedWatch, from pelvic pain, heavier menses, headache, and fatigue to patient-device incompatibility due to migration, breakage and possible contraceptive metal hypersensitivity reaction (CMHR).

We endorse the importance of addressing CMHR in the setting of gynecologic, as well as endovascular, dental, and orthopedic implanted devices [2]. In 2016, experts in allergic contact dermatitis published guidelines for the evaluation of and testing options for specific target patients in the pre- and post-implant setting based on current scientific evidence and consensus expert opinions [2]. Based on current evidence, we recommend a risk-stratified approach to patch testing that focuses on the population with self-reported histories of cutaneous dermatologic reactions to metal and/or prior failure of an implant device [2].

Of note, Bayer has made a business decision to discontinue sales of Essure™ after December 31, 2018. In April 2018, the FDA implemented a restriction on sales and distribution of the Essure™ "to ensure women are fully informed of the risks associated with the device" [3]. A strategic plan needs to be implemented to ensure an informed public with access to evidence-based knowledge. Without this there is a risk of unnecessary removal of well-functioning devices with resultant morbidities.

While clinicians and patients should be aware of the possibility of CMHR with Essure™, testing for metal allergy and device removal in patients with asymptomatic, well-functioning devices is not indicated [4]. Given that CMHR symptoms may overlap with more common implant-related adverse events, an appropriate diagnostic work-up is indicated, including patch testing if indicated [5]. And, thus, the decision as to whether to revise or remove an implanted contraceptive device should be weighed on a careful risk-benefit analysis with respect to all available clinical information [4].

Conflict of Interest

The authors declare that they have no conflict of interest in relation to this letter.

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