

Study compares risk of anaphylaxis among marketed IV iron products

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Cunlin Wang, M.D., Ph.D., of the U.S. Food and Drug Administration, Silver Spring, Md., and colleagues studied recipients of intravenous (IV) iron (n = 688,183) enrolled in the fee-for-service Medicare program from January 2003 to December 2013. The study appears in the November 17 issue of *JAMA*.

In 2010, anemia affected one third of the global population, and [iron deficiency](#) was the most common cause. Oral iron replacement is the primary treatment strategy for [iron deficiency anemia](#) but may be inadequate for some patients due to intolerance, impaired absorption, significant ongoing bleeding, or nonadherence. For these patients, intravenous iron may be indicated. As of June 2013, there were 5 IV iron products marketed in the United States. While their efficacy is established, the most important safety concern relates to the risk of serious and fatal anaphylaxis (an allergic reaction to a substance), which may occur at both first and subsequent exposures. The comparative safety of each product has not been well established, according to background information in the article.

This study examined administrations of IV iron dextran, gluconate, sucrose, or ferumoxytol. A total of 274 anaphylaxis cases were identified at first exposure, with an additional 170 cases identified during subsequent IV iron administrations. The researchers found that iron dextran was associated with increased anaphylaxis risk compared with nondextran formulations at first administration. Among the nondextran products, the risk of anaphylaxis at first administration was higher with

both iron gluconate and ferumoxytol than with iron sucrose.

Because each IV iron product has a specific recommended dose and schedule of administration, the cumulative risk of anaphylaxis was also calculated based on both the number of administrations and clinically relevant repletion level of iron (1000 mg) achieved within 12 weeks. Both analyses showed iron dextran was associated with the highest cumulative risk of anaphylaxis and iron sucrose with the lowest risk.

The authors note that the mechanism of anaphylactic reaction after IV iron remains unknown.

More information: *JAMA*, [DOI: 10.1001/jama.2015.15572](https://doi.org/10.1001/jama.2015.15572)

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