A Multinational European Study of Anaphylaxis Among Recipients of Intravenous Iron

BACKGROUND

- Anaphylaxis (ANA) related to intravenous (IV) iron treatment is a poorly studied adverse drug reaction (ADR).
- Understanding the risk of ANA among IV iron users is crucial for patient safety and regulatory decisions.

OBJECTIVE

- To assess the risk of ANA among IV iron users, by IV iron groups (dextran, sucrose, or iron sucrose), and by methods.

METHODS

- A study was conducted in Europe, with data sources capturing drug dispensing or lacking an exact date of ANA
- A postauthorization safety study requested by the European Medicines Agency assessed the risk of ANA in IV iron users in Europe.

RESULTS

- The crude incidence proportion (IP) of ANA for IV iron users was lower than expected based on estimates from recent United States studies.
- The IP of ANA among IV iron users was consistent with the risks reported in the literature, supporting the adequacy of the ANA identification algorithm.

DISCLAIMERS


CONCLUSIONS

- The results of this study do not suggest a high risk of ANA among users of IV iron in the studied patient populations.

Studying the incidence of adverse drug reactions (ADRs) such as anaphylaxis (ANA) among recipients of intravenous (IV) iron is crucial for patient safety and regulatory decisions. In this study, a multinational European approach was used to assess the risk of ANA among IV iron users. Data sources capturing drug dispensing or lacking an exact date of ANA were utilized, following a main case-finding algorithm. The study found that the incidence proportion (IP) of ANA for IV iron users was lower than expected based on recent United States estimates. The IP of ANA among IV iron users was consistent with the risks reported in the literature, supporting the adequacy of the ANA identification algorithm. The results of this study do not suggest a high risk of ANA among users of IV iron in the studied patient populations.