

Letter to the Editor

Letter: European Medicines Agency recommendations for allergic reactions to intravenous iron-containing medicines

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SIRS, Previously, we published our results from a RAND appropriateness method on the management of iron deficiency in patients with inflammatory bowel disease (IBD), revealing high agreement on a more often application of high-dose intravenous (IV) iron.¹

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has

more recently published its review of intravenous iron-containing medicines used to treat iron deficiency, and iron deficiency anaemia. The authors concluded that the benefits of these medicines are greater than their risks, provided that adequate measures are taken to minimise the risk of allergic reactions (www.ema.europa.eu/.../IV_iron.../WC500150771.p).

Although we agree that caution should guide all medical actions, the interpretation of reported data concerning the safety of IV iron preparations is difficult. First, the different preparations should be considered individually, as their side effect profiles vary substantially. A considerable amount of data suggest that a) serious reactions are very rare,² and b) different preparations have different side effect profiles both in experimental³ and in clinical studies.⁴

Furthermore, a part of the problem could be historical, because serious side effects were rather more common with older preparations.⁵ It is important to remember that chemical stability of these products is very important, and not all IV iron products are created equal.⁶

We think that there are three important recommendation lines of working that should guide us in the further use of IV iron in IBD patients:

- (i) To use intravenous iron following international guidelines⁷ and EMA recommendations.
- (ii) To report all serious side effects to pharmacovigilance authorities, stating exactly the nature of the product (brand identification needed).
- (iii) To conduct independent prospective studies on clinical tolerance of IV iron products in IBD patients in the long-term.

With these considerations in mind, it is our view that intravenous iron is a very good strategy for improving the quality of life of our IBD patients, and that currently available evidence supports not only the guideline recommendations,⁷ but also the tool we are proposing in our original article.¹

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