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POSTER ABSTRACTS

904.OUTCOMES RESEARCH-NON-MALIGNANT CONDITIONS

Efficacy, Safety, and Tolerability of Iron Infusions in Pregnant Women: A Retrospective Chart Review

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Background: Iron deficiency (ID) is the most common nutritional deficiency in pregnancy. Iron deficiency anemia (IDA) is also known to be a common problem among pregnant women, and it has been associated with maternal morbidity, peripartum complications, and impaired infant development. Pregnant women who have ID or IDA may benefit from iron infusions to optimize their iron stores more rapidly prior to delivery, however per the American College of Obstetricians and Gynecologists, oral iron is recommended first-line agent for IDA in pregnancy and treating ID without anemia (IDWA) in pregnancy is not currently recommended. IV iron for IDA is considered a second-line agent in pregnancy for many reasons: lack of data on the experience of iron infusions in U.S. pregnant women, lack of randomized trials in pregnant women, and FDA prescribing information labels for all iron formulations containing warnings about possible adverse effects. Also, there has been reluctance to prescribe newer iron formulations including Ferric Carboxymaltose (FCM), Ferumoxytol (FM), and Ferric Derisomaltose (FDI).

Methods: In this single center case series, pregnant women in their 2nd or 3rd trimesters who had IDWA or IDA received iron infusions in an outpatient infusion center with nurses trained to monitor pregnant patients carefully for infusion reactions. Before the infusions, the women were assessed in a hematology consult for symptoms of ID, including shortness of breath, fatigue, and ice craving/ice chewing, as well as lab testing consistent with ID (ferritin<30 or iron saturation <16%) and anemia (hemoglobin<12).

The iron formulation each woman received was determined by her health plan coverage and, in some cases, by her experience with prior iron infusions. Most women with IDWA were prescribed 400-500mg iron and most women with IDA were prescribed 1000mg iron. Two weeks after the final infusion, follow-up iron and blood counts were measured, and symptoms were re-assessed in a follow-up visit. Safety of iron infusions was determined by reviewing frequency of reactions that occurred during infusions (observed) including complement activation-related pseudoallergy (CARPA) and immune-mediated hypersensitivity reactions, as well as transient discomfort within the first few days after iron infusions (assessed by self-reports or reported during follow-up visits), as well as frequency of discontinuing the infusions.

Results: 1,383 pregnant women with IDWA (n=69) or IDA (n=1,314) received a total of 2,971 iron infusions between June 2021 and June 2023, including Ferric Derisomaltose (FDI) 1000 mg single dose (n=417), two Ferumoxytol (FM) 510 mg doses (n=510), four Iron Sucrose (IS) 200 mg doses (n=1,661) or two IS 400 mg doses (n=383). No routine pre-medications were used. Among these pregnant women who received iron infusions, 94% reported improvement of one or more symptoms (shortness of breath, fatigue, or ice craving/ice chewing). Two weeks after the final infusion, 87% were found to have iron saturation greater than 15%, 83% were found to have ferritin above 30, and 88% were found to have increased hemoglobin compared to their pre-infusion hemoglobin. The average hemoglobin increase was 1.2 g/dL. IDA patients had higher hemoglobin increases than IDWA patients but similar increases in iron saturation and ferritin, regardless of iron formulation received.

Iron infusions were usually well tolerated. The overall incidence of infusion reactions occurring during infusions, including CARPA reactions, was 4.5% (9.8% for FDI, 4.9% for FM, 1.4% for IS 200 mg doses, and 0.5% for IS 400mg doses). Five pregnant women (0.17%) discontinued iron treatments because of infusion reactions. The overall incidence of post-infusion discomfort symptoms was 22.5% (9.5% for FDI, 18.8% for FM, 31.3% for IS 200 mg doses, and 26.7% for IS 400 mg doses), including tiredness, headache, low back pain, leg swelling, or shortness of breath. Two women were evaluated in hospital ER's, one for hypotension during an iron infusion and one for hives after an iron infusion. There were no adverse events that impacted a woman's pregnancy.

Conclusions: Iron infusions in pregnant women are effective, safe, and well-tolerated when administered in an outpatient infusion center that has nurses trained to monitor pregnant patients carefully for infusion reactions. For pregnant women who have IDWA or IDA, the benefits of iron infusions likely outweigh the risks.

Disclosures Fein: *Pharmacosmos:* Speakers Bureau. **Lewkowitz:** *Pharmacosmos Therapeutics, Incorporated:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Shield Therapeutics:* Membership on an entity's Board of Directors or advisory committees.

OffLabel Disclosure: Iron infusions to treat iron deficiency without anemia. Three drugs are mentioned: Iron sucrose (Venofer), Ferumoxytol (Feraheme), and Ferric Derisomaltose (Monoferric)

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