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A STUDY EXAMINING THE SAFETY AND EFFICACY OF FERRIC CARBOXYMALTOSE IN A LARGE PEDIATRIC COHORT

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A STUDY EXAMINING THE SAFETY AND EFFICACY OF FERRIC CARBOXYMALTOSE IN A LARGE PEDIATRIC COHORT

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Janelle Noel-Macdonnell, PhD

IRB Number: STUDY00000987

Describe role of Submitting/Presenting Trainee in this project (limit 150 words):

I along with David Simon performed chart review on eligible study patients and input this data into REDcap. Following chart review, Dr. Noel-Macdonnell performed statistical analysis. I then wrote the following abstract with the aid of Dr. Sharma, Dr. Simon, and Dr. Noel-Macdonnell.

Background, Objectives/Goal, Methods/Design, Results, Conclusions limited to 500 words

Background:

Iron deficiency anemia (IDA) is common in the pediatric population with varying high-risk factors. Intravenous (IV) iron supplementation has become more desirable in patients with moderate to severe anemia and in patients who are either unresponsive to or have adverse side-effects secondary to oral iron. Iron sucrose and Iron dextran have been traditionally used in pediatrics while ferric carboxymaltose (FCM) has only been FDA approved in adults. One of the major advantages of FCM is the ease of dosing and efficacy. Though FCM was approved for adults in 2013 and there have been no safety concerns, it is not yet been FDA approved for pediatric patients despite a few pediatric studies demonstrating its safety and efficacy.

Objectives/Goal:

To examine the utilization of different IV iron formulations in a large pediatric hospital and evaluate the safety and efficacy of FCM compared to other IV iron formulations.

Methods/Design:

This is a retrospective chart review study of patients who met inclusion criteria in a large pediatric hospital who received Iron dextran, Iron sucrose, and/or FCM between 4/1/2016 through 6/30/2020. Anonymized data from eligible patients was entered into a secure electronic database. We reviewed charts individually and collected data including patient demographics, details about each IV iron administration, and pre- and post-iron infusion lab values.

Results:

The overall usage of IV iron has increased in the last 4 years and the utilization of different IV iron formulations has also changed in this time frame. In 2016, iron dextran comprised 35.7% of all IV iron administered while iron sucrose consisted of 64.3%. As the years progressed the usage of iron dextran has decreased while FCM has increased. In the first half of 2020, no patient received iron dextran and 53.4% of IV iron doses administered were FCM. Of the 164 FCM infusions analyzed, there were 7 documented adverse events. Of the 610 iron sucrose infusions analyzed, there were 10 documented adverse events. Approximately 88% of patients who received FCM required 1 to 2 doses to achieve goal hemoglobin and/or ferritin. However, 49% of patients who received iron sucrose required more than 2 doses to achieve goal hemoglobin and/or ferritin with multiple patients requiring up to 8 doses.

Conclusions:

IV iron is being utilized more to treat IDA in certain patient populations. At our institution, the usage of FCM has considerably increased. Our data shows that less doses of FCM are required to treat IDA and is overall well tolerated.