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EVALUATION OF SAFETY AND EFFICACY OF INTRAVENOUS IRON SUCROSE IN PATIENTS WITH IRON DEFICIENCY ANEMIA

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Abstract:

Background: Iron deficiency is the most common disorder in the world, affecting approximately 25% of the world`s population and the most common cause of anemia.

Objective: to evaluate the safety and efficacy of intravenous iron sucrose in patients with iron deficiency anemia.

Methods: Thirty two adult patients with hemoglobin<8.0 g/dl and <7.63\lng/mlserum ferritin were included. who had intolerance or showed no effect with oral iron therapy, received a weekly dose of 200 mg of intravenous iron sucrose until the hemoglobin level was corrected or until receiving the total dose of intravenous iron calculated for each patient.

Results: The mean hemoglobin and serum ferritin levels were <8.0 g/dl and 7.63ng/ml\l (pretreatment) and 13.1 g/dl and 96.20 ng/ml\l (post-treatment) (p-value < 0.0001), respectively. The average increases in hemoglobin levels were 4.29 g/dL for women and 5.58 g/dl for men; 96% of male and 87% of female patient's responded hemoglobin increased by intravenous iron therapy.

Conclusion: It was concluded that the use of intravenous iron sucrose is a safe and effective in the treatment of adult patients with iron deficiency anemia who lack satisfactory response to oral iron therapy.

Key Words: Iron sucrose, Iron deficiency, Infusion & Iron supplement

Introduction:

Iron deficiency is the most common disorder in the world, affecting approximately 25% of the world`s population, and the most common cause of anemia.[1,2,12] The first choice in the treatment of iron deficiency anemia (IDA) for almost all patients is oral iron replacement because of its effectiveness, safety and low cost. Its efficacy may, however, be limited in many patients because of the side effects related to the drug, particularly gastrointestinal toxicity occurring in 35% to 59% of patients and the long course needed to treat anemia and replenish iron stores.[3,4,11] Non-adherence to a prescribed course of oral iron is common and, even in adherent patients, poor intestinal absorption fails to compensate for iron need in the presence of ongoing blood losses.(3,4) While intravenous (IV) iron has the capability of bypassing all these issues, concerns remain about the acute safety profiles of the available products and the potential for long-term harm from repeated iron administration.[5,6,13]

Parenteral iron preparations available in the past were associated with a high incidence of life-threatening anaphylactic reactions and death, which made physicians reluctant to use them.[13,14] The formulation most frequently responsible for these serious adverse events, observed in 0.6 to 2.3% of the patients, was the high-molecular-weight iron dextran.[7,8,10]

Objective:

To evaluate the safety and efficacy of intravenous iron sucrose in patients with iron deficiency anemia.

Material & Methods:

The prospective observational single centered study was conducted in Department of General Medicine. Study was conducted over a period of three months. Thirty two adult patients attending with both gender, hemoglobin<8.0 g/dl and <7.63\l ng/mlserum ferritin were included after taking a written informed consent. Exclusion criteria included patients with known hypersensitivity to iron preparations and medical disorders (diabetes mellitus, hypertension, hyperthyroidism and hypothyroidism).

Procedure:

Patients received two doses of IV iron sucrose of 200 mg per sitting at interval of 3-5 days. Iron sucrose was given as IV bolus dose over 5 min or with 100ml isotonic saline over 30 min. No test dose was given, and patients were monitored for one hour following first injection. Hemoglobin, reticulocyte count and serum ferritin were estimated at baseline, on day 14 and 28 after treatment. Rise in hemoglobin levels at the end of the therapy was analyzed on coulter cell counter. Clinical safety was evaluated based upon the nature and severity of adverse effects if any, recorded at end of 2 hours and 14 days of treatment. The response and tolerability to therapy was recorded on a global assessment of response to therapy on a 5-point rating scale of "1=Excellent, 2=Good, 3=Average, 4=Poor and 5=Very Poor" at the end of study period. This rating was done

independently by the patients and the physicians with respect to efficacy and tolerability. After completion of the study, hemoglobin deficit of the patients was corrected.

Statistical Analysis:

Data was compiled in excel sheet and statistical analyze the data, to prepare table, graph with the help of SPSS 22.0. The level of significance was 5%.

Results:

A total of 32adult patients with both gender were screened between December 2019 and February 2020 and 86 were enrolled according to inclusion exclusion criteria.

Demographic Details of All Patients:

(n=32) are summarized in table no. 1. The study population consisted of 14 (43.75%) males and 18 (56.25%) females. Frequency of patients falls under age group 21-40 year.

Table 1

	Frequency (%)
Gender	
Male	14 (43.75)
Female	18 (56.25)
Age Group	
<20	04 (12.5)
21-40	16 (50.0)
41-60	12 (37.5)

Frequency Distribution of Anemia in Patients:

(n=32) are summarized in table no.2. Frequencyof severe anemia was more (68.75%) with both genders as compare to other classes of anemia.

Table 2

	Frequency (%)
Mild Anemia (11-12.9 g/dl)	
Male	0 (0)
Female	1 (3.12)
Moderate Anemia (8-10.9 g/dl)	
Male	6 (18.75)
Female	7 (21.87)
Severe Anemia (<8 g/dl)	
Male	12 (37.5)
Female	10 (31.25)

Efficacy Assessment of IV Iron Sucrose in Patients with Anemia:

The mean hemoglobin and serum ferritin levels were <8.0 g/dl and 7.63ng/ml\l (pretreatment) and 13.1 g/dl and 96.20 ng/ml\l (post-treatment) (p-value < 0.0001), respectively. The average increases in hemoglobin levels were 4.29 g/dl for women and 5.58 g/dl for men; 96% of male and 87% of female patient's responded hemoglobin increased by intravenous iron therapy.

Table 3

	Mean	**p-value**
Pre Treatment		
Hemoglobin	<8.0 g/dl	
Serum Ferritin	7.63ng/ml\l	
Post Treatment		
Hemoglobin	13.1 g/dl	< 0.0001
Serum Ferritin	96.20 ng/ml\l	

Safety Assessment of IV Iron Sucrose in Patients:

Majority of the patients were free of side effects (87.56%). Minor side effects were noted in few cases (12.44%; pain at injection site- one, metallic taste- three, headache- one, warm tingling sensation-two cases). The response and tolerability to therapy were recorded on 5-point rating scale. Majority of the patients were satisfied with the treatment.

Table 4

Tolerability Global Rating Scale	**Frequency**
Excellent	35.4%
Good	47.2%
Average	12.6%
Poor	4.7%

Discussion:

Iron is an essential component of haem and accounts for 70% of hemoglobin. Iron balance in the body depends solely on gastrointestinal absorption and Fe bioavailability in food. Iron deficiency state is characterized by decrease in iron stores in body as reflected by serum ferritin levels, with decrease transferring saturation and serum iron levels.[1,2,3] If this continues, erythropoiesis is affected and results in microcytic hypochromic anemia.[4]

Efficacy of oral iron therapy depends upon gastrointestinal absorption and patient's compliance. Iron sucrose injection is safe, efficacious and ensures compliance to therapy and irrefutable data is available on it. The rise in hemoglobin levels occurs after 2-3weeks of treatment. Serum ferritin levels rise only after hemoglobin levels normalize.[5,6,7]

Early response to therapy is an increase reticulocyte count and reticulocyte hemoglobin concentration.[9,10] Majority of the patients were free of side effects (87.56%). Minor side effects were noted in few cases (12.44%; pain at injection site- one, metallic taste- three, headache- one, warm tingling sensation-two cases).[11,12] The response and tolerability to therapy were recorded on 5-point rating scale. Majority of the patients were satisfied with the treatment. In this study, IV iron sucrose was generally well tolerated and treatment was not discontinued in any patient.[13,14]

Conclusion:

It was concluded that the use of intravenous iron sucrose is a safe and effective in the treatment of adult patients with iron deficiency anemia who lack satisfactory response to oral iron therapy.

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