***Side Effects of Iron sucrose in patients with Iron Deficiency Anemia (IDA)***

This study was submitted in partial fulfillment of the requirement for the M.B.Ch.B

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 *In the name of Allah, the first who deserves all thanks and appreciation for our creator and that made all the change, get to what is new and helping patients through his creatures themselves for pervade peace and cooperation among people .*

 *To those who taught us letters of gold and words of jewel of the utmost and sweetest sentences in the whole knowledge. Who reworded to us their knowledge simply and from their thoughts made a lighthouse guides us through the knowledge and success path, To our honoured teachers and especially to my supervisor Dr. Aamer Shareef.*

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  **:Introduction**

Iron deficiency is the most common disorder in the world, affecting approximately of the world`s population, and the most common cause of anemia.(1,2)

Iron deficiency anemia develops when body stores of iron drop too low to support normal red blood cell production. Inadequate dietary iron, impaired iron absorption, bleeding, or loss of body iron in the urine may be the cause. Iron equilibrium in the body normally is regulated carefully to ensure that sufficient iron is absorbed in order to compensate for body losses of iron.

 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.

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)

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.

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.

However, the availability of new preparations (iron sucrose, ferric gluconate, low-molecular weight iron dextran, and, more recently, ferric carboxymaltose, iron isomaltoside and ferumoxytol) with much better safety profiles, is changing the pattern of the use of IV iron in a number of clinical settings.

Parenteral iron is used in two ways: one is to administer the total dose of iron required to correct the hemoglobin deficit and provide the patient with at least 500 mg of iron stores; the second is to give repeated small doses of parenteral iron over a protracted period. The latter approach is common in dialysis centers, where it is not unusual for 100 mg of elemental iron to be given weekly for 10 weeks to augment the response to recombinant EPO therapy. The amount of iron needed by an individual patient is calculated by the following formula:

Body weight (kg) × 2.3 × (15 – patient’s hemoglobin, g/dL) + 500 or 1000 mg (for stores) (7))

**Objectives**

The objectives of this study were to determine the safety and tolerability of( IV) iron sucrose using in patients with (IDA)

**Methodology** **:**

A cross sectional study was undertaken among patients with Iron deficiency anemia (IDA) who received iron sucrose attending AL-Hussein Teaching Hospital, between December 2018 and April 2019 .

The study subjects consisted of 60 patients (M:F=24:36) eligible patients were aged 16 years or older with IDA. All patients had been unresponsive or had poor responses to oral iron therapy or had been unable to tolerate oral iron therapy because of gastrointestinal side effects. Patients with evidence of iron overload, anemia not caused by iron deficiency, acute or chronic bacterial infections were excluded from participating in this study.

**Result :**

An iron sucrose was administered and generally well tolerated. There were no deaths during the study and no moderate or serious adverse effects were recorded (no episodes of anaphylaxis). Treatment was not discontinued in any patient due to drug-related adverse effects. The most frequent drug-related adverse effects were transient and mild as shown in the table below :

*Table 1: Adverse Effects felt by particepants*

|  |  |  |  |
| --- | --- | --- | --- |
| **%** | **N** | **Adverse Effects** |  |
| 28.33 | 17 | Headache | **1** |
| 18.33 | 11 | Dyspnea | **2** |
| 16.66 | 10 | Nausea | **3** |
| 16.66 | 10 | Arthralgia | **4** |
| 16.66 | 10 | Dizziness | **5** |
| 15 | 9 | Back Pain | **6** |
| 15 | 9 | Fatigue | **7** |
| 13.33 | 8 | Muscle Spasm | **8** |
| 13.33 | 8 | Cough | **9** |
| 13.33 | 8 | Epigastric Pain | **10** |
| 5 | 3 | Constipation | **11** |
| 3.33 | 2 | Diarrhea | **12** |
| 3.33 | 2 | P.Edema | **13** |
| 3.33 | 2 | Hypotension | **14** |
| 1.66 | 1 | Pruritus | **15** |

It should be noted that half of the patients included in this study did not show any side effects from Iron Sucrose as show below :

*Table 2: In general, effects of Iron Sucrose on patients with (IDA)*

|  |  |  |
| --- | --- | --- |
| **Side Effects** | **Number** | **Percentage** |
| Negative | 31 | 51.6% |
| Positive | 29 | 48.4% |
| Total | 60 |  |

Figure 1: Effects of Iron Sucrose in patients with (IDA)

By the way, during our study of these patients, we found that some patients with chronic diseases such as (DM, HT, IHD, CKD) they have more side effects if we compare them with the rest of the patients.

**Discussion :**

The first choice treatment of IDA is oral iron replacement because of its effectiveness, safety and low cost. Oral iron supplementation is adequate in most clinical conditions and in the absence of inflammation or significant ongoing blood loss, can correct the anemia.(5,6,8)

However, many clinical studies have demonstrated the high incidence of side effects related to this type of therapy, particularly with ferrous sulphate compounds, causing lack of compliance and suboptimal results.(3,4)

Intravenous iron therapy has been indicated in situations such as intolerance of or contraindications to oral iron, in cases of severe anemia especially if accompanied by significant ongoing bleeding, inflammatory diseases and in patients with IDA scheduled for elective surgery.(8,9)

IV iron sucrose has been reported to be safe with an excellent profile in clinical use; it can be administered without a test dose. The incidence of serious life-threatening anaphylaxis with iron sucrose is 0.002% versus 0.6-2.3% and 0.04% with high-molecular-weight iron dextran and ferric gluconate, respectively. Moreover, fatal hypersensitivity reactions and death have not been reported with iron sucrose.(10,11)

**Conclusion :**

Our data confirm that the use of (IV) iron sucrose is a safe and effective option in the treatment of patients with (IDA) who don’t tolerate or lack satisfactory response to oral iron therapy. (IV) iron sucrose is well tolerated and has a clinically manageable safety profile when using appropriate dosing and monitoring. The availability of (IV) iron sucrose would potentially facilitate improved compliance ,and thereby reduce morbidity from iron deficiency .

**References :**

*1­-World Health Organization. Iron deficiency anemia. Assessment, prevention and control. A guide for programme managers [Internet]. Geneva: WHO; 2001. [cited 2010 Jan 12]. Available from:http:// www.who.int/nutrition/publications/en/ida\_assessment\_prevention\_ control.pdf*

*2-World Health Organization. The World Health Report 2002: Reducing risks, promoting healthy life. Geneva: World Health Organization: 2002.p.1-248*

*3-Alleyne M, Horne MK, Miller JL. Individualized treatment for iron- deficiency anemia in adults. Am J Med. 2008;121(11):943-8*

*4-Cançado RD, Lobo C, Friedrich JR. Tratamento da anemia ferropriva com ferro via oral. Rev Bras Hematol Hemoter. 2010;32 (Supl. 2):114-20*

*5-Auerbach M, Ballard H. Clinical use of intravenous iron: administration, efficacy and safety. Hematology Am Soc Hematol Educ Program. 2010:338-47*

*6-Cançado RD, Lobo C, Friedrich JR. Tratamento da anemia ferropriva com ferro via parenteral. Rev Bras Hematol Hemoter. 2010;32 (Supl. 2):121-8*

*7-Harrison"s Principles of Internal Medicine 20th Edition*

*8-Muñoz M, Breymann C, García-Erce JA, Gómez-Ramírez S, Comin J,Bisbe E. Efficacy and safety on intravenous iron therapy as an alternative/adjunct to allogeneic blood transfusion. Vox Sang. 2008; 94(3): 172-83.*

*9- Lindgren S, Wikman O, Befrits R, Blom H, Eriksson A, Granno C' et al. Intravenous iron sucrose is superior to oral iron sulphate for correcting anaemia and restoring iron stores in IBD patients: A randomized, controlled, evaluator-blind, multicentre study. Scand J Gastroenterol. 2009;44(7):838-45.*

*10- Fishbane S, Kowalski EA. The comparative safety of intravenous iron dextran, iron saccharate, and sodium ferric gluconate. Semin Dial. 2000;13(6):381-4.*

 *11- Danielson BG. Structure, chemistry, and pharmacokinetics of intravenous iron agents. J Am Soc Nephrol 2004;15:(Suppl 2):S93-8.*