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Original Research Article

Intravenous Iron therapy in Obstetrics and Gynaecology Practice

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Abstract: In developing countries, iron deficiency anaemia is a major factor in increasing morbidity of women especially in reproductive age group. Intravenous iron therapy can help tackle the problem and significantly improve the health status of women. The objectives is to assess the efficacy of intravenous iron in the treatment of iron deficiency anaemia observed in obstetrical and gynaecological practice. A prospective cohort study was conducted in the department of obstetrics and gynaecology for a period of 2 years. A total of 108 cases with iron deficiency anaemia were studied. 8 cases were lost to follow up.50 cases were obstetric cases and 50 were gynaecologic cases. On the basis of patient's choice; either Inj. FCM or Inj. Iron sucrose was given to each group and the rise in haemoglobin over a period of 3 weeks was observed. Out of all the cases studied, maximum belonged to the age group of 21 to 30 years and majority cases also had moderate type of anaemia. 60% obstetric cases were given Inj. FCM and rest 40% cases were given Inj. Iron sucrose. Amongst gynaecologic cases, 76% were given Inj. FCM and 24% were given Inj. Iron sucrose. The mean rise of haemoglobin in FCM group was 3 and 3.5 in obstetric and gynaecologic cases respectively. With Inj. Iron sucrose, the mean rise of haemoglobin in obstetric cases was 2.5 and in gynaecologic cases was 2.8. The rise in haemoglobin after 3 weeks amongst both groups was statistically significant. When we tried to compare the rise in haemoglobin in Obstetrics patients with iron sucrose and Inj. FCM, the rise was extremely significant ($p<0.0001$) with Inj. FCM. Again, the same when compared in Gynaecology patients, the rise was again found significantly high ($p< 0.0160$) with Inj. FCM. These p values were calculated with Fisher's Exact test (SPSS 23). Inj. FCM proved to be better than Inj. Iron sucrose in improving the haemoglobin status of women in Obstetrics & Gynecological practice in terms of both compliance and efficacy.
Keywords: anaemia, iron therapy, injection.

INTRODUCTION

Iron deficiency anaemia is a global problem especially affecting women and children in developing countries. About 52% of pregnant women of developing countries are suffering from anaemia. WHO has defined anaemia as level of haemoglobin less than 120 g/l in non-pregnant women of age 15 years and above and less than 110 g/l in pregnant women. Also, severe anaemia in pregnancy is when haemoglobin levels are less than 70 g/l and very severe anaemia is when haemoglobin levels are below 40 g/l [1].

The prevalence of anaemia in women of developing countries (excluding China) was published by WHO in the year 1982. The estimated prevalence of anaemia in women of reproductive age group was 49%. 60% prevalence of anaemia was reported in pregnant women and around 47% prevalence was reported in non-pregnant women [2].

As iron is an important factor for the growth of cells, the mortality as well as morbidity of individuals increases in cases of iron deficiency anaemia [3]. Thus, timely and appropriate treatment is necessary for these patients.

As per WHO [1, 4] anaemia is divided into the following categories on the basis of severity:-
Non-Pregnant women (age>15 years):-
Mild: 110-119 g/l
Moderate: 80 to 109 g/l
Severe: <80 g/l

In pregnant women:-
Mild: 100-109 g/l

Moderate: 70-99 g/l
Severe: <70 g/l

For the evaluation of patients with anaemia, first a thorough history should be taken followed by appropriate investigations. Treating the cause is the initial management followed by iron therapy. A 200mg of iron tablet either in the form of ferrous sulphate or fumarate can be given; three times a day [5]. Vitamin C can be administered alongwith oral iron to increase its absorbtion [6]. Only when oral iron therapy is not tolerated by the patient and we want the rise in haemoglobin faster, injectable iron therapy is considered.

Preparations of iron that are used intravenously are made up of nanoparticles of spheroid iron and carbohydrate. They are all colloids. The main central portion of these particles is made up of a oxyhydroxide gel containing iron and is surrounded by a carbohydrate shell. The chemistry of the carbohydrate shell and the centre core determine the dose of the injectable iron that can be tolerated and also at what rate the preparation should be given [7].

The first usage of injection iron sucrose was seen in Europe in the year 1949 [8]. Its dose varies from 200mg IV over 2 to 5 min to 500mg IV over 2 to 4 hours.

Inj. Ferric Carboxymaltose on the other hand can be given over a period of 15 min with a maximum dose of 1000mg [9].

AIMS AND OBJECTIVES

To assess the efficacy of intravenous iron in the treatment of iron deficiency anaemia observed in obstetrical and gynaecological practice.

METHODS OF STUDY

A prospective cohort study was conducted in the Department of Obstetrics and Gynaecology for a period of 2 years. All women admitted in the Obstetrics and Gynaecology ward with anaemia were classified on the basis of severity as per the WHO guidelines into the following groups:-

1. Mild anaemia
2. Moderate anaemia
3. Severe anaemia

Required iron doses were calculated on the basis of the formula:

Iron requirement (in mg) = Body weight (Kg) * (Target Hb in gm% - Actual Hb in gm %) * 2.4

Extra 500 mg was added for all patients.

Inclusion criteria:-

1. All women admitted in OBG ward during the study period with anaemia.

Exclusion criteria:-

1. All women who refused the treatment.
2. Pregnancy.
3. Haemoglobin less than 6 gm%.
4. Cases lost to follow-up.
5. Any patient with medical or surgical complication.

The rise in haemoglobin after iron infusion was then statistically analyzed. Simple descriptive statistics was used for the same. Haemoglobin for all patients was measured after a 3 weeks period. The results obtained were then compared with various studies.

RESULTS AND OBSERVATIONS

A total of 108 cases were taken in the 2 year period. 51 were gynaecological cases and 57 were obstetric cases and all of the 57 obstetric cases were puerperium cases (either LSCS or normal). Out of the 108 cases, 8 were lost to follow-up and thus were excluded from the study. 7 of theses 8 cases belonged to the obstetric group and 1 belonged to the gynaecological group. All the 8 cases opted for Injection iron sucrose and took only half the dose of the total iron recommended. All the cases had iron deficiency anaemia, which was confirmed by peripheral blood smear and blood cell indices.

As described in the table-1, amongst the obstetric cases, most common age group to present with anaemia was 21 to 30 years that was 68% of the obstetric cases followed by 31 to 40 years age group that was 24% of the obstetric cases.

For gynaecological cases, 56% of the cases belonged to 21 to 30 years age group and about 20% cases belonged to 31 to 40 years age group (Table-2).

In obstetric cases group, the most common type of anaemia was moderate type that was seen in 76% of the cases followed by severe type that was seen in 20% of the cases(Table-3).

In gynaecological cases group, 84% cases presented with moderate type of anaemia and 14% of the cases with severe type and only 2% cases with mild type of anaemia(Table-4).

Amongst the obstetric cases, 60% cases belonged to the Inj. FCM group and 40% cases were given iron sucrose injections. This distribution was

made only on the basis of acceptance by the patients(Table-5).

Amongst the gynaecological cases, 76% were given Inj. FCM and 24% were given iron sucrose injection(Table-6).

The average increase of haemoglobin in the FCM group in obstetric and gynaecological cases was 3 and 3.5 respectively. Whereas, in the iron sucrose group, the average increase in haemoglobin after 3 weeks of completion of therapy in obstetric and gynaecological cases was 2.5 and 2.8 respectively (Table-7).

In the FCM group, 73.3% cases were able to achieve a haemoglobin of 12 and above after 3 weeks in obstetric cases and 60.5% cases showed a haemoglobin of 12 and above in gynaecological cases. On the other hand, in the iron sucrose group; 40% cases had a haemoglobin level of 12 and above amongst obstetric cases and 41.6% cases amongst gynaecological cases(Table-8).

Table 1: Age distribution of 50 obstetric cases of anaemia

Age Group	Obstetric Cases	Percentage (%)
<20 Years	4	8
21-30 Years	34	68
31-40 Years	12	24
41-50 Years	0	0
50 Years And Above	0	0
Total	50	100

Table 2: Age distribution of 50 gynaecological cases of anaemia

Age Group	Gynaecological Cases	Percentage (%)
<20 Years	1	2
21-30 Years	28	56
31-40 Years	10	20
41-50 Years	8	16
50 Years And Above	3	6
Total	50	100

Table 3: Distribution of 50 obstetric cases on the basis of severity of anaemia

Severity Of Anaemia	Obstetric Cases	Percentage (%)
Mild	2	4
Moderate	38	76
Severe	10	20
Total	50	100

Table 4: Distribution of 50 gynecological cases on the basis of severity of anaemia

Severity Of Anaemia	Gynaecological Cases	Percentage (%)
Mild	1	2
Moderate	42	84
Severe	7	14
Total	50	100

Table 5: Type of Injectable Iron given to 50 obstetric cases of anaemia

Type Of Injectable Iron	Obstetric Cases	Percentage (%)
Inj. Orofer Fcm	30	60
Inj. Iron Sucrose	20	40
Total	50	100

Table 6: Type of Injectable Iron given to 50 gynaecological cases of anaemia

Type Of Injectable Iron	Gynaecological Cases	Percentage (%)
Inj. Orofer Fcm	38	76
Inj. Iron Sucrose	12	24
Total	50	100

Table 7: Average increase in haemoglobin of 100 cases of anaemia after 3 weeks follow up

Type Of Injectable Iron	Average Increase In Haemoglobin (After 3 Weeks Period)	
	Obstetric Cases	Gynaecological Cases
Inj. Orofer Fcm	3	3.5
Inj. Iron Sucrose	2.5	2.8

Table 8: No. of cases who achieved haemoglobin above 12gm%

Type Of Injectable Iron	No. Of Cases With Haemoglobin More Than 12gm% After Treatment With Intravenous Iron Therapy After 3 Weeks Period.			
	Obstetric Cases	Percentage (%)	Gynaecological Cases	Percentage (%)
Inj. Orofer Fcm	22	73.3	23	60.5
Inj. Iron Sucrose	8	40	5	41.6

The p value was calculated on the basis of rise of haemoglobin above 12 after 3 weeks. For the FCM group, the p value in obstetric cases was 0.04 and for gynaecologic cases was 0.01. Both the values were significant as they were less than 0.05. Even for the iron sucrose group, the p value for obstetric and gynaecologic cases was 0.004 and 0.008 respectively. Both of them were also significant. Now, when we tried to compare the rise in haemoglobin in Obstetrics patients with iron sucrose and Inj. FCM, the rise was extremely significant ($p<0.0001$) with Inj. FCM. Again, the same when compared in Gynaecology patients, the rise was again found significantly high ($p< 0.0160$) with Inj. FCM. These p values were calculated with Fisher's Exact test (SPSS 23).

No adverse events were noted during the course of the therapy in any of the treatment modalities.

DISCUSSION

In our study, the most common age group to be affected with iron deficiency anaemia was 21 to 30 years age group in both obstetric and gynaecological cases. This is comparable to the WHO data that was published in 2001 [1].

In our study, moderate anaemia was found to be more common amongst both obstetric and gynaecological cases. This can be attributed to the fact that injectable iron therapy is considered more often in patients with moderate to severe than mild to moderate anaemia.

In our study, we compared injection ferric carboxymaltose with injection iron sucrose in terms of efficacy. The average increase of haemoglobin after 3 weeks of follow up was seen to be more in the ferric carboxymaltose group in both obstetric and gynaecological cases with a rapid increase in haemoglobin in the FCM group. Also, patient compliance was better with the FCM group as there were no cases lost to follow up. In the iron sucrose group, about 8 cases were lost to follow up due to poor compliance of the patient. The rise in haemoglobin in both the groups was significant.

Markova *et al* [10] published a Cochrane database review in August 2015. They compared various studies for the comparison of treatment modalities used in women with iron deficiency anaemia. They included no treatment, placebo, oral iron and any other modality used for the same. No definitive conclusion could be drawn from the study. A total of 2858 women and 22 randomised controlled trials were taken in account. Though, intravenous iron was found to be better in regards of gastro-intestinal tolerance but more adverse effects were reported with the therapy which was due to injectable iron or some other factor that was not delineated properly.

Bhandal *et al* [11] conducted a study in UK on postpartum anaemia and its treatment with oral iron versus injectable iron. A randomised controlled trial was conducted. The outcome of the study was that intravenous iron was better and a faster treatment modality for treating iron deficiency anaemia in postpartum patients.

Seid MH *et al* [12] also conducted a similar study and compared ferric carboxymaltose injection with oral iron in patients with postpartum anaemia. A total of 291 women were taken under study and it was concluded that Inj. FCM was better as compared to oral iron therapy in improving outcome for patients with postpartum iron deficiency anaemia.

Breymann *et al* [13] also studied the safety and efficacy profile of injection ferric carboxymaltose on patients with postpartum anaemia. The results of this study also proved that injection FCM was better in improving anaemia in patients as compared to oral iron therapy.

Mahey *et al* [14] published their study recently on comparision of intravenous FCM and intravenous iron sucrose injections in patients presenting with

abnormal uterine bleeding. In the one year study period, a total of 60 patients were observed. Initially, Inj FCM showed rapid improvement in haemoglobin levels as compared to Inj Iron sucrose. But, over 12 weeks period the rise in haemoglobin in both the groups was comparable.

Kim YH *et al* [15] compared inj. Iron sucrose with oral iron therapy for management of anaemia in preoperative cases who presented with menorrhagia. Intravenous iron therapy was better and equally safe when compared to oral iron in 67 preoperative patients with anaemia.

Nq O *et al* [16] analyzed 3 randomised controlled trials to determine the role of iron therapy in preoperative patients versus need for blood transfusion. The results of this study did not show any statistically significant reduction in need for blood transfusion. Though, intravenous iron therapy was more efficacious than oral iron therapy.

Auerbach M *et al* [17] studied the safety profile and efficacy of intravenous iron therapy in patients with iron deficiency anaemia. They also stressed on its advantages of better patient compliance.

David B van Wyck *et al* [18] conducted a randomised controlled trial to compare the efficacy of Inj. FCM with oral iron in patients with heavy uterine bleeding. 477 women with anaemia were studied and it was concluded that Inj. FCM was better than oral iron in faster rise of haemoglobin and in improving the quality of life of the patients.

Evstatiev *et al* [19] also compared Inj. FCM with Inj. Iron sucrose in patients with inflammatory bowel disease with iron deficiency anaemia. 485 patients were included in the study. Though both showed comparable rise in haemoglobin levels after a 12 week period, Inj. FCM had a better compliance as well as efficacy.

Onken J E *et al* [20] evaluated 507 patients with iron deficiency anaemia. They divided all the patients into 4 groups. The A group received 2 doses of 750mg Inj. FCM one week apart. B group received oral iron. C group included all the patients who did not respond to oral iron and were later given injectable iron. Group D included those patients who received IV iron from start of their care. The conclusion from the study proved that Inj. FCM is more safe and efficacious in improving the haemoglobin status in patients with iron deficiency anaemia.

CONCLUSION

Inj. Ferric carboxymaltose is more efficacious as compared to Inj. Iron sucrose in correcting iron deficiency anaemia in both obstetric and gynaecological patients. Also, injection FCM has a better patient compliance.

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