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Evaluation of Safety and Acceptability of Injection Ferric Carboxymaltose and Iron Sucrose in Anaemia in Pregnancy

Kavita Arya¹, Alka Batar², Kishna Ram³, Nupur Hooja ^{4*}, Shimla Meena⁵, Bhavini Tuli ⁶

^{1,3,5,6} M.B.B.S., Postgraduate Resident, ²Asst.Professor M.B.B.S., M.S, ⁴Sr.Professor M.B.B.S., M.S. Department of Obstetrics and Gynaecology, S.M.S. Medical College, Jaipur 302004

*Corresponding Author: Dr.Nupur Hooja

A-29,Lal Bahadur Nagar,Girdhar Marg,Malviya Nagar, Jaipur-302017,Rajasthan,India

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ABSTRACT

Background Parenteral iron therapy is an option in women with moderate anaemia who are intolerant to oral iron or have poor compliance to oral iron or malabsorbtion syndrome. The choice of preparation depends on side effects besides the efficacy of the preparation. The objective of the study was to compare the side effects and acceptability of the newer drug, inravenous ferric carboxymaltose (FCM with intravenous iron sucrose .

Method Group A were given injection FCM and group B were given injection iron sucrose.FCM was given in one or two sittings depending on iron requirement and iron sucrose was given in divided doses.Change in haemoglobin,side effects and reasons for acceptability were evaluated.All the observations were tabulated and analysed.

Results The mean rise in hemoglobin values from baseline in the FCM group was 2.03 ± 0.47 at 3 weeks, compared to iron sucrose group, which was 1.51 ± 0.39 at 3 weeks, which was statistically significant. Mild adverse effects like headache, vertigo, arthralgia, pain at injection site were observed in 16% women in FCM group and 36% in iron sucrose group. Being given in lesser number of doses, the infusions were less,the time was shorter and number of visits also were less,hence it was more convenient and acceptable to the women.

Conclusion Women in the FCM group achieved significantly higher hemoglobin level It had fewer side effects and was given in fewer sittings, hence was more convenient and acceptable to the women than iron sucrose.

Keywords: acceptability, ferric carboxymaltose, iron sucrose complex, side effects. **INTRODUCTION**

In pregnant Indian women, 58-89.6% prevalence of anaemia has been observed.¹

Parenteral iron therapy is an option in women with moderate anaemia who are intolerant to oral iron or have poor compliance to oral iron or malabsorbtion syndrome.² With introduction of new intravenous iron preparations, there is now options to choose from. This depends on their efficacy, the side effects and the acceptabilility to the patient due to number of infusions, number of visits and the duration of therapy.

Many intravenous iron preprations are available. Intravenous iron sucrose complex (IVIS) is given in multiple doses which require women to come repeatedly. Newer drug, inravenous ferric carboxymaltose (FCM), can be given in one or two doses.³The objective was to compare the side effects acceptability of intravenous and ferric carboxymaltose and intravenous iron sucrose complex in pregnant women with anaemia.

METHOD

Women with,24-26 wks gestation single live pregnacy,with Hb level between 7-10 g/dL and

ferritin level <50micromg were included in the study. Women with prior parental iron treatment or blood transfusion, intolerance to iron derivatives, medical disorders or women with transport difficulties were excluded from the study. Informed consent was taken from all women in the study.

There were 50 women in each group .Group A were given injection FCM and group B were given injection iron sucrose.FCM was given in one or two sittings depending on iron requirement and iron sucrose was given in divided doses. Change in haemoglobin,side effects and reasons for acceptability for both were evaluated All the observations were tabulated and analysed

RESULTS AND DISCUSSION

Comparing the effectiveness of the two iron therapies, after 3 weeks, mean haemoglobin was higher ($10.53 \pm 0.69 \text{ g/dl}$) in FCM group as compared to iron sucrose group($10.15 \pm 0.95 \text{ g/dl}$). This difference was statistically significant(p=0.02). Mean rise in haemoglobin was significantly more in FCM group as compared to iron sucrose group (2.03 g/dl vs. 1.51 g/dl) (p =0.003) .(Table 1)

Most women tolerated the injections well. There were no major side effects and no allergic or anaphylactic reaction. Mild adverse effects were observed in 16% women in FCM group and 36% in iron sucrose group. Table 2

It was observed that headache or vertigo was noted in 8% women during and one hour after infusion of iron sucrose and 4% in FCM group. Diarrhea 12 hours after infusion occurred in 6% women in iron sucrose and 2% women in FCM group.

Pain at local injection site was more, 6% in iron sucrose than with FCM 4%. Few women complained of arthralgia 2-3 hours after infusion in iron sucrose group and FCM group, 4% & 2% respectively. 6% women had pain abdomen after iron sucrose therapy but nil with FCM None of the women develop fever, urticaria, hypotension or tachycardia in both the groups as reported in other studies.

The overall dose required was 1200-1400 mgs. As far as the acceptability was concerned, FCM was more acceptable to the patients. The FCM infusion was given in one or two doses, one week apart (maximum 1000 mg in one infusion), as compared to 5 to 7 doses with iron sucrose(200mg per infusion, alternate day, maximum thrice in a week) depending on the requirement.Table 3

The drug was supplied free to the patients under the Janani Shishu Swasthya Karyakram⁶,hence the cost was not an issue in the study.

DISCUSSION

In our study, mean rise in haemoglobin was significantly more in FCM group as compared to iron sucrose group .Most women tolerated the injections well. There were no major side effects and no allergic or anaphylactic reaction. Mild adverse effects were observed in lesser after FCM than after iron sucrose .

Aakanksha Mahajan et al³ also reported mild adverse reactions in 30% patients in FCM Group, while in iron sucrose Group it was observed in 48% patients. No major side effect was noted, making both the drugs safe in pregnancy.

In the study by Dr.Beena Mahaur ⁴, 28% women in iron sucrose group and in FCM group 16% women had mild adverse reactions. Shabina Khan, et al⁵ also found no serious adverse drug reactions in both the groups. Mild adverse effects like nausea, vomiting, diarrhoea, constipation etc were observed in 52% women in iron sucrose group and 34% women in FCM group.

Not only the number of infusions were less, the number of visits to the hospital also decreased. The duration of FCM therapy was shorter, even one day to 8 days(if two doses required) as compared to Iron sucrose ,10 to 14 days. Hence, not only the travel cost was cut down, days of absence from her work was less for the patient on FCM therapy, so was more acceptable to the patients.

CONCLUSION

FCM was more effective and it's tolerance seemed to be excellent in the study with few adverse effect and better acceptability to the patient.

REFERENCES

1. National Health Policy 2017. New Delhi: Ministry of Health and Family Welfare, Government of India; 2017 (http://cdsco.nic.in/writereaddata/ National-Health-Policy.pdf, accessed 15 January 2018).

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- Ambily Jose, Reeta Mahey, Jai Bhagwan Sharma, Neerja Bhatla, Renu Saxena, Mani Kalaivani and Alka Kriplani. BMC Pregnancy and Childbirth (2019) 19:54 https://doi.org/10.1186/s12884-019-2200-3
- 3. Aakanksha Mahajan, Bawa R. Bhagat, Shashi Gupta, Bhanu Mahajan, Manvi Verma International Journal of Reproduction, Contraception, Obstetrics and Gynecology 2018 May;7(5):1938-1942
- 4. Dr.Beena Mahaur, Dr.Satwant Kaur, Dr.Sharda Mahaur. Comparative study of iron sucrose versus ferric Carboxymaltose

in the management of iron deficiency Anaemia in pregnancy. Int J Clin Obstet Gynaecol 2020;4(3):148-152. DOI: 10.33545/gynae. 2020.v4.i3c.595

5. Shabina Khan, Shivika Gupta. A comparative study of injection ferric carboxymaltose and anaemia complicating iron sucrose in Journal International pregnancy. of Contemporary Medical Research 2019;6(8):H6-H9. DOI: http://dx.doi.org/10.21276/ijcmr.2019.6.8.20 .http://www.sihfwrajasthan.com/ppts/full/JSS Y.pdf

		FCM Group (n = 50)	Iron sucrose Group (n = 50)	Pvalue
Baseline	Mean Hb <mark>±</mark> SD	8.53±0.75	8.63±0.98	P=0.568 NS
At 3weeks	Mean Hb <mark>±</mark> SD	10.53±0.69	10.15±0.95	p=0.02,Sig
Rise after 3 weeks	Rise Mean Hb ± SD	2.03±0.47	1.51±0.39	p=0.003,Sig

Table – 1.Correction of Anaemia with the two iron therapies

Table 2. Analysis Of The Side-Effects Of Both Iron Therapies

Side-Effects	FCM group	Iron Sucrose group		
Side-Effects	r Cwi group	%		%
Headache	2	4	4	8
Vertigo	2	4	4	8
Diarrhoea	1	2	3	6
Pain at Injection Site	2	4	3	6
Arthralgia	1	2	2	4
Pain Abdomen	-	-	2	4
Febrile Reaction	-	-	-	-
Urticaria	-	-	-	-
Hypotension	-	-	-	-
Tachycardia	-	-	-	
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FCM groupIron Sucrose groupNo. of infusions1-26-7No of visits1-26-7,alternate dayDuration (in days)1-8Side effectslesserMore

Table 3.Acceptability Of Both Iron Therapies

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