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Evaluation of efficacy, safety and cost effectiveness of iron sucrose versus ferric carboxy maltose in puerperal iron deficiency Anemia

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Abstract
Anaemia is the most common nutritional deficiency disorder in the world. World Health Organization (WHO) has estimated that prevalence of anaemia in developed and developing countries in pregnant women is 14% and 51%. Its alarming to know that the prevalence in India is as high as 65 to 75%. The search for an ideal parentral iron preparation has led to the introduction of ferric carboxy maltose. It comprises a macromolecular iron-hydoxide complex of polynuclear iron hydroxide tightly bound to a carbohydrate shell. This new complex has a molecular weight of 150,000 Daltons. This design allows for a control leddelivery of iron within the cells of reticulo-endothelial system and hence subsequent delivery to the iron binding proteins, with low risk of release of large amounts of ionic iron in the serum. This iron preparation can be used intravenously in high doses with up to 1000 mg infused within 5 min with minimal risk of side effects.

Objectives
The objectives of the present study were;
Primary
- To compare the efficacy of intravenous ferric carboxy maltose with intravenous iron sucrose in treating iron deficiency anaemia in postnatal women.
- The mean rise in haemoglobin at the end of one week is an important parameter to evaluate the efficacy of the therapy.

Secondary
- To investigate the safety in terms of local and systemic reactions and tolerability of ferric carboxy maltose compared with iron sucrose.
- To compare the cost effectiveness of intravenous iron sucrose and FCM

Methodology
Type of Study
- Randomised Control Study

Period of Study
- January 2018-August 2018

Conclusion
- Based on the results of this study it is concluded that, the intravenous.
- Ferric carboxy maltose is more convenient cost effective in the treatment of puerperal iron deficiency anaemia.
- Compared to intravenous iron sucrose. Further it is well. tolerated as side effects are less comparable to that of iron sucrose.

Keywords: Iron sucrose ferric, carboxy maltose iron deficiency anemia

Introduction
Anaemia is the most common nutritional deficiency disorder in the world. World Health Organization (WHO) has estimated that prevalence of anaemia in developed and developing countries in pregnant women is 14% and 51%. It's alarming to know that the prevalence in India is as high as 65 to 75%. Prevalence of anaemia in South Asian countries is highest compared to the countries. WHO estimates that even among the South Asian countries, India has the highest prevalence of anaemia. What is even more important is the fact that almost 50 % of the global maternal deaths due to anaemia occur in South Asian countries.

It is apparent that India's contribution to the prevalence of anaemia inpregnancy and maternal deaths due to anaemia is higher than warranted by the size of its population.3 On hand estimates also suggest that the magnitude of reduction in the prevalence of anaemia during nineties in India is lower than that in neighboring South East Asian countries. In view of the high prevalence of anaemia in the country, five major surveys National Family Health Survey (NFHS) 2 and 3, 6, 7 District Level Household Survey 2 (DLHS), 8 Indian Council of Medical Research (ICMR) Micronutrient Survey9 and Micronutrient Survey conducted by National Nutrition Monitoring Bureau (NNMB) 10 were undertaken to find the prevalence of anaemia in the country. The results of these surveys showed that over 70% of pregnant women and adolescent girls in the country were anaemic.

Iron deficiency anemia is the most common cause of anaemia in the postpartum period, with rates as high as 37% reported in the first postpartum week. Postpartum anaemia is caused primarily by inadequate iron intake before and during pregnancy and by peripartum blood loss. Patients with postpartum anemia have a longer duration of hospital stay, are more likely to receive a blood transfusion, and incur higher hospitalization costs. Eighteen percent of women hospitalized with anemia and postpartum bleeding receive a blood transfusion.

Postpartum anemia is associated with an increased prevalence of tiredness, breathlessness, and palpitations may lead to puerperal sepsis. There is a strong negative correlation between iron status and depression, stress, cognitive function in mothers during the postnatal period. Severe anemia in postpartum period can increase maternal morbidity, increase the length of hospital stay, cause difficulty in breastfeeding and sometimes also result in severe cardiovascular dysfunction. Hence, puerperal IDA requires prompt intervention and high-quality care.

Iron is an essential element for the functioning of all types of cells in the body. It plays a vital role in cell cycle regulation, electron transport in the respiratorychain, DNA synthesis and other metabolic reaction. The function of haemoglobin largely depends on the availability of iron. The detection of anaemia and its effective management is available, affordable and it is possible to effectively implement the seven in the rural setting. There are various forms of treatment for iron deficiency anaemia. Oral iron is the most preferred route of administration for mild anaemia. Treatment with iron preparations is used routinely in pregnancy. However, oral iron supplementation often leads to adverse side effects, such as constipation, abdominal pain and other gastrointestinal symptoms. Because of the segastro intestinal effects the compliance to iron treatment is highly variable. Intravenous iron preparations show good potential, especially in cases of severe anaemia. They provide a greater and more rapid iron supply than oral iron therapy without the gastrointestinal side effects of oral preparations and make it possible to avoid blood transfusion which is associated with risks. Iron sucrose has been used for years for intravenous treatment of iron deficiency anemia. However, its use is limited by the low maximum dosage due to local and systemic side effects in higher doses. In order to avoid these adverse effects the drug has to be administered in multiple infusions of lower doses less than 200 mg per day. Hence it increases the number of days of admission in the hospital and it becomes an extra burden on the hospital resources.

The search for an ideal parentral iron preparation has led to the introduction of ferric carboxy maltose. It comprises a macromolecular iron-hydoxide complex of polynu clear iron hydroxide tightly bound to a carbohydrate shell. This new complex has a molecular weight of 150,000 Daltons. This design allows for a controlled delivery of iron within the cells of reticulo-endothelial system and hence subsequent delivery to the iron binding proteins, with low risk of release of large amounts of ionic iron in the serum. This iron preparation can be used intravenously in high doses with up to 1000 mg infused within 5 min with minimal risk of side effects.

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- To compare the cost effectiveness of intravenous iron sucrose and FCM

Methodology

Type of study

- Randomised control study

Period of study

- January 2018-August 2018

Place of study

- LSCS ward, post natal ward, labour ward
- Department of Obstetrics & Gynaecology, Govt. Kilpauk Medical College & Hospital, Chennai

Inclusion criteria

- Postpartum patients with haemogbin 7- 9 gm%
- Age 20-35 years

Exclusion criteria

- History of fever or any chronic illness
- Medical disorder like tuberculosis, diabetes, renal and hepatic disorder
- Patients with hemoglobin less than 7 gm% or more than 9 gm%
- A history of anemia other than iron deficiency anemia
- History of known allergy to parentral iron transfusion

Results

The data was analysed final results and observation was tabulated as follows

Fig 1: Age group * group crosstab

			Group		
			FCM	**Iron sucrose**	**Total**
Age group	Up to 20 years	Count	3	5	8
		% within group	6.0%	10.0%	8.0%
	21-30 years	Count	36	42	78
		% within group	72.0%	84.0%	78.0%
	31 years & above	Count	11	3	14
		% within group	22.0%	6.0%	14.0%
	Total	Count	50	50	100
		% within group	100.0%	100.0%	100.0%

Chi square = 5.533 *p*=0.063 Not significant

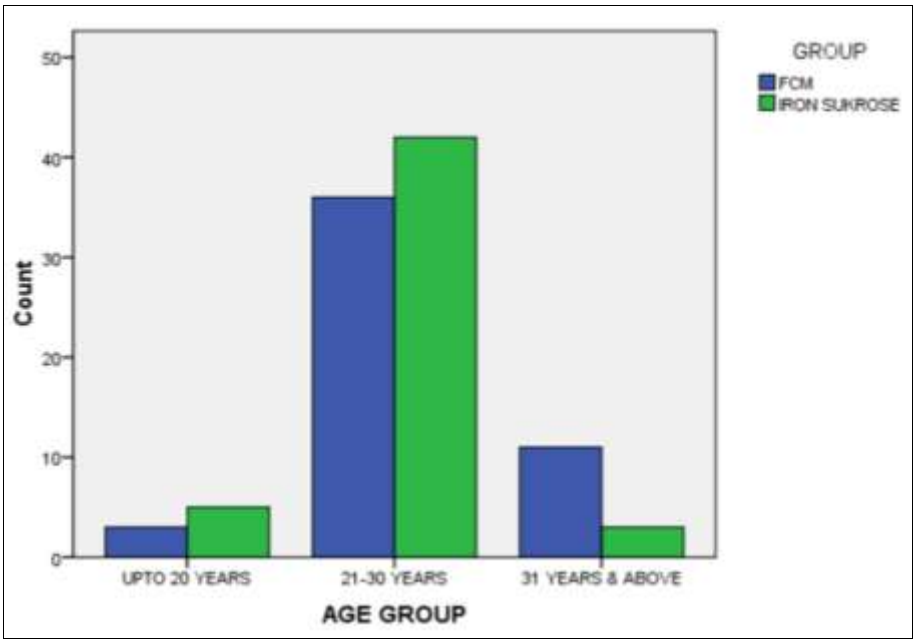

Fig 1: Shows Bar chart

In the present study 72% of women in FCM group and 84% of women in iron sucrose group aged between 21 to 30 years and this difference was not statistically significant

Mode of delivery * group

Table 2: Crosstab

			Group		
			FCM	**Iron sukrose**	**Total**
Mode of delivery	LSCS	Count	31	30	61
		% within group	62.0%	60.0%	61.0%
	NVD	Count	19	20	39
		% within group	38.0%	40.0%	39.0%
	Total	Count	50	50	100
		% within group	100.0%	100.0%	100.0%

Table 3: Chi-square tests

	Value	**df**	**Asymp. Sig. (2-sided)**	**Exact sig. (2-sided)**	**Exact sig. (1-sided)**
Pearson Chi-Square	.042[a]	1	.838		

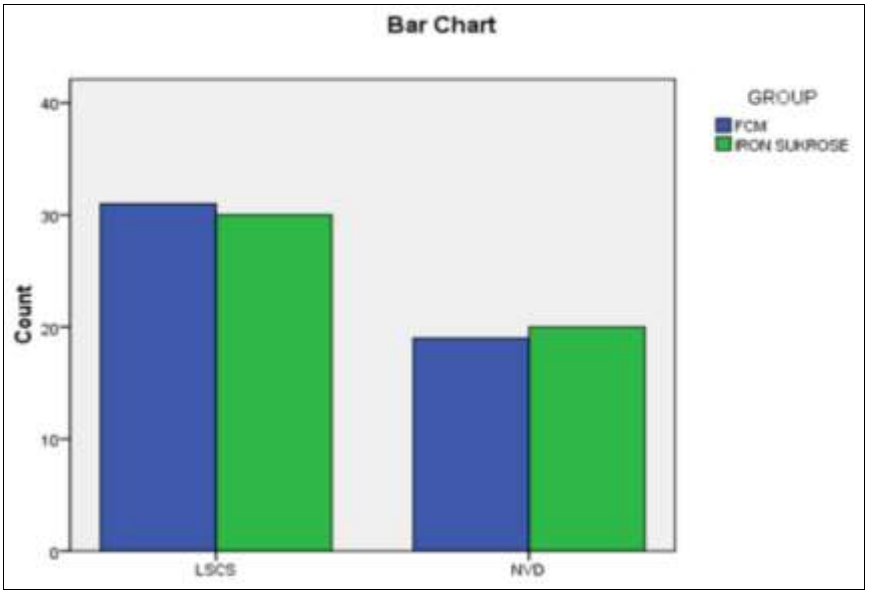

Fig 2: Mode of delivery

In this study 38% in FCM and 40% in iron sucrose delivered vaginally and this difference is statistically insignificant p=0.838.

Adverse effects * Group

Table 4: Crosstab

			Group		
			FCM	**Iron sukrose**	**Total**
Adverse effects	No	Count	48	42	90
		% within group	96.0%	84.0%	90.0%
	Yes	Count	2	8	10
		% within group	4.0%	16.0%	10.0%
	Total	Count	50	50	100
		% within group	100.0%	100.0%	100.0%

Table 5: Chi-square tests

	Value	df	Asymp. sig. (2-sided)	Exact sig. (2-sided)	Exact sig. (1-sided)
Pearson Chi-Square	4.000[a]	1	.046		

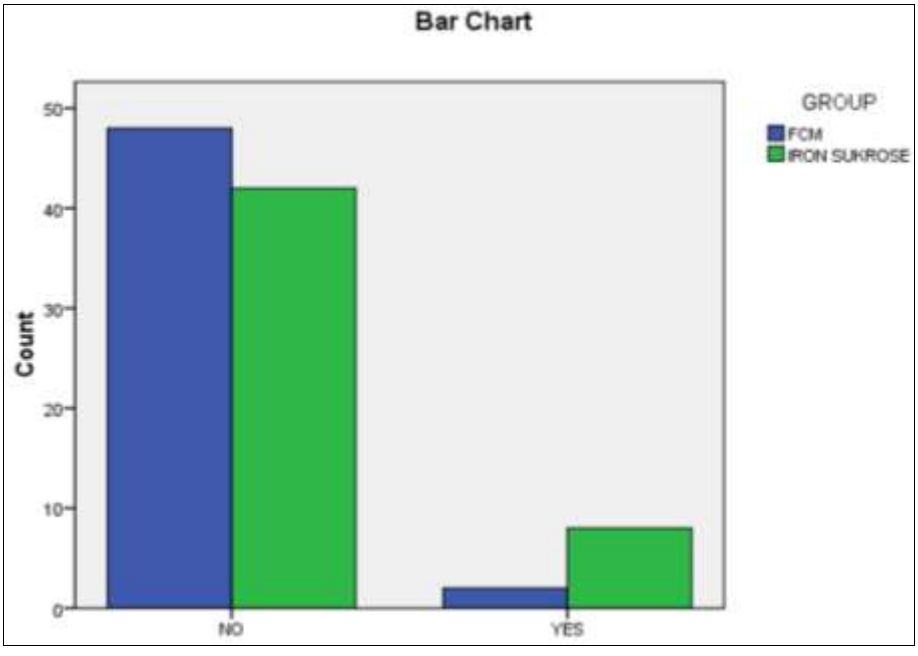

Fig 3: Adverse effects

Table 6: Birth weight group statistics

	Group	N	Mean	Std. deviation	Std. error mean
Birth weight	FCM	50	2.8646	.44516	.06296
	Iron sukrose	50	2.8422	.35685	.05047

Table 7: Independent samples test

t-test for Equality of Means		
Sig. (2-tailed)	Mean Difference	Std. Error Difference

Table 8: Pre and post treatment group statistics

	Group	N	Mean	Std. deviation	Std. error mean
Pre-treatment HB g/dl	FCM	50	7.7980	.50244	.07106
	Iron sukrose	50	8.2440	.50352	.07121
Post treatment HB	FCM	50	9.8640	.49765	.07038
	Iron sukrose	50	8.8100	.39706	.05615

Table 9: Group statistics

	Group	N	Mean	Std. deviation	Std. error mean
% of rise	FCM	50	26.7097	5.52144	.78085
	Iron sukrose	50	7.0553	4.59615	.64999

Fig 10: Independent samples test

t-test for equality of means				
		Sig. (2-tailed)	Mean difference	Std. error difference
% of rise	Equal variances assumed	.000	19.65441	1.01598
	Equal variances not assumed	.000	19.65441	1.01598

Conclusion

Based on the results of this study it is concluded that, the intravenous Ferric carboxy maltose is more convenient cost effective in the treatment of puerperal iron deficiency anaemia compared to intravenous iron sucrose. Further it is well tolerated as side effects are less comparable to that of iron sucrose.

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