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Comaparative Study of Intravenous Iron Ferric Carboxymaltose Vs Oral Iron in the Treatment of Iron Deficiency Anaemia in Post Partum Period

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ABSTRACT

BACKGROUND

Anaemia is a serious nutrition problem affecting millions in developing countries and remains a major challenge for human health and social and economic development Iron deficiency is thought to be the most common cause of anaemia globally.

MATERIALS AND METHODS

It was a Prospective tertiary care hospital based study involving women with postpartum iron deficiency anaemia(IDA). Improvements of those who were treated with intravenous iron ferric carboxymaltose were compared with those who were treated with oral iron.

RESULTS

The demographic variables like age, BMI, habitat, dietary habits, parity, antenatal presence of anaemia, modes of delivery and type of risk factors were comparable. In oral iron therapy group mean Hb on day 0 was 8.008 ±0.5435 gm/dl. On 2nd week it rises in mean Hb 8.924±0.7660 gm/dl and on 6th week mean rise in Hb 9.889 ±0.9467 gm/dl. In iron ferric carboxymaltose therapy group mean Hb on day 0 was 7.822 ±0.5422 gm/dl, in the 2nd week mean rise in Hb 10.362 ±0.9354gm/dl and in 6th week Hb rise was 12.858 ±0.6616 gm/dl.

CONCLUSION

Intravenous iron FCM therapy administration increases the hemoglobin level & iron store more rapidly than oral iron intake of in women with iron deficiency anemia in the postpartum period. It can be used as safe and effective alternative to blood transfusion and oral iron therapy in the treatment of iron deficiency anemia in the postpartum women. If cost is not a limiting factor limited dosage schedule of iron ferric carboxymaltose as prescribed in the study is a safe and effective alternative to daily oral iron taken in treatment of postpartum anaemia. Multiple child birth, poor socioeconomic status, dietary habits, type of habitat and education status of mother also contributed to the incidence of postpartum anaemia.

KEYWORDS : IronDeficiencyAnemia,Serum Iron,Serum Ferritin,Postpartum,Ferric carboxymaltose (FCM)

I. BACKGROUND

Anaemia is a serious nutrition problem affecting millions in developing countries and remains a major challenge for human health and social and economic development. Anaemia is a condition in which the number of red blood cells or their oxygen-carrying capacity is insufficient to meet physiologic needs, which vary by age, sex, altitude, smoking, and pregnancy status. Anaemia in pregnancy is defined by WHO as Haemoglobin below 11gm /dl.[1]According to WHO postpartum anaemia is defined by haemoglobin concentration <11 g/dl at 1 week postpartum and <12 g/dl at 8 weeks postpartum. The major causes of postpartum anaemia are prepartum anaemia combined with acute bleeding anaemia due blood losses at delivery[2].In consecutive European women, the prevalence of anaemia 48hrs after delivery is approximately 50%.In developing countries ,the prevalence of postpartum anaemia is in the range of 50-80%[3]There are various possible forms of treatment for post-partum iron deficiency anaemia.

Iron can be given orally, by intramuscular route or intravenous method. Oral iron therapy can be used for mild anaemia while intravenous and intramuscular iron therapy can be given in patients with severe anaemia.[1] There are cases where parenteral iron is preferable over oral iron. These are cases where oral iron is not tolerated, where the haemoglobinneeds to be increased quickly, where there is an underlying inflammatory condition or renal patients, the benefits of parenteral iron far outweigh the risks.[4]Intravenous(IV) iron therapy can also be considered as an effective and safe method to treat postpartum iron deficiency anemia in repetitive doses as well as total dose infusion(TDI).Out of many Iron IV formulations the 1st generation products include low molecular

International Journal Dental and Medical Sciences Research
Volume 3, Issue 6, Nov-Dec 2021 pp 305-314 www.ijdmsrjournal.com ISSN: 2582-6018

weight iron dextran and iron sorbitol citrate. These compounds can be given in higher doses but are associated with anaphylactic reactions. 2nd generation compounds like iron sucrose require multiple injections to supplement 1000 mg of iron.[4]Thus, a new parenteral iron molecule with the advantages of both the parenteral preparations was needed. A recent IV iron preparation, Ferric Carboxy Maltose (FCM), has been newly developed. It provides quick replenishment of iron stores and can be given up to a maximum single dose of 1000 mg in a duration of less than 15 minutes and one ampoule of ferric carboxy maltose is given diluted with 250 ml normal saline intravenously.[10]

So, we have chosen here iron ferric carboxymaltose to see the results mainly in respect of time taken for the increase in haemoglobin and serum ferritin.

II. AIMS AND OBJECTIVES

The Primary aim is to compare the efficacy of intravenous (ferric carboxymaltose) iron vs oral iron therapy in the treatment of iron deficiency anemia (IDA) in postpartum period. The Secondary aimis tothe effect of use of intravenous iron ferric carboxymaltose complex in improvement of hemoglobin levels and serum ferritin & to study the adverse effect of these therapies in both groups.

III. MATERIALS AND METHODS

It was a tertiary care hospital based prospective study conducted in the dept. of Obstetrics & Gynaecology, Hitech medical college and hospital , Bhubaneswar for the durations of 2 years, September2019 to August 2021. Ethical committee clearance was obtained before commencing the study. All patients were enrolled after duely signed informed consent. After careful history taking, clinical examination and minimal investigations other causes of anemia were ruled out. The initial iron status of the woman was assessed by the clinical and laboratory examinations (complete blood picture and serum ferritin levels). Total 100 postpartum women who had developed postpartum IDA (Having Hb levels between 7-9 gm/dl and serum ferritin level less than 15 µg/ml at 24-48 hours post-delivery) were included in the study based on inclusion and exclusion criteria. All 100 women were allotted serial number of 1-100, those having odd numbers were recruited in group A and those having even numbers were recruited in group B each group having 50 members.

Group A (Intravenous Iron FCM Therapy Group)

50 Patients included in this group received divided dose of intravenous iron ferric carboxymaltose calculated according to body weight and Hb deficit

Dose Calculated(According to Ganzoni formula)

In post-partum anaemia = 2.4 x w x D + 500.

W= weight of patient in kg.

D= target Hb- patient's baseline Hb.

Target haemoglobin in post-partum anaemia =11gm/dl.

500mg for target body iron stores in lactation 2.4-from blood volume which is 7% of body weight and iron content of Hb which is 0.34%.0.07x0.0034x100=2.4(Conversion constant from g/dl to mg).

Iron Ferric carboxymaltose is given by IV injection according to iron deficit calculated and rounded up to nearest multiple of 100 for each individual.one ampoule of ferric carboxymaltose is given dilutedwith 250 ml normal salineintravenously.[10]given as slow IV over 15 minutes

in the study and was repeated on alternate days when necessary. Treatment was stopped after administration of the calculated dose. Patients during the treatment were monitored for any signs and symptoms of reactions.

Group B (Oral Ferrous Sulphate Group)

50 patients included in this group were advised to take 200mg of ferrous sulphate twice daily for 6 weeks. Women were advised to document treatment compliance and symptoms.

Blood samples of patients were taken at the day of recruitment into the study (day 0) and the rest of the samples were taken in 2 weeks and 6 weeks after the start of the treatment to detect any difference in the speed of restoration of Haemoglobin and serum ferritin. Improvement of mean haemoglobin, mean serum ferritin level, adverse reactions tolerability of group A (injectable iron FCM) compared with group B (oral ferrous sulphate iron).

Statistical analysis (mean, standard deviation, unpaired t-test) was done by SPSS inc.USA. Confidence interval (95%) of various proportions was calculated. $P<0.05$ was taken significant.

Inclusion Criteria

The study population consisted of all women in first week of postpartum IDA (defined as Hb of between 7 to 9 gm/dl and serum ferritin of <15 microgram/l at 24–48 hours post-delivery) who would be given oral and intravenous iron as per suitabitlity.

Exclusion Criteria

The women with Previous iron therapy

International Journal Dental and Medical Sciences Research
Volume 3, Issue 6, Nov-Dec 2021 pp 305-314 www.ijdmsrjournal.com ISSN: 2582-6018

during pregnancy, Intolerance to iron derivatives, Peripartum blood transfusion or a History of asthma, thromboembolism, seizures, alcohol or drug abuse,myelosuppressive therapy. Women with signs of infection or evidence of renal or hepatic dysfunction Patients with sickle cell anaemia, thalassemia, megaloblastic anaemia with recent (within 3 months) blood transfusion and other types of anaemia except iron deficiency anaemia.

IV. RESULTS

Parameters	Oral Iron	Iron FCM	P
Mean age(in years)	25.34 ±3.836	23.7 ± 3.775	0.832
BMI	21.2774± 2.328	21.1632±1.471	0.640
Habitat (rural/urban)	31/19(62%/39%)	32/18(64%/36%)	0.063
Dietary habbits (non veg/veg)	37/13(74%/26%)	38/12(76%/24%	0.879
Parity (primi/multi)	23/27(46%/54%)	18/32(36%/64%)	1.033
Antenatal anemia	31(62%)	34(68%)	0.523
Delivery(LSCS/VD)	28/22(56%/44%)	38/12(76%/24%)	0.03
Type of risk factor			
PPH	16(32%)	13(26%)	0.5777
Hypertensive disorder	19(38%)	17(34%)	0.7388
Placenta previa	4(8%)	7(14%)	0.365
Multiple pregnancy	4(8%)	5(10%)	0.738
Exclusive breast feeding/non exclusive	17/33(34%/66%)	16/34(32%/68%)	0.831
Baseline Hb(gm/dl)	8.008±0.543	7.822±0.542	0.7
Baseline ferritin (µg/dl)	11.5796±0.680	11.9206±0.936	0.05

Table 1. Demographic variables and baseline clinical data

The demographic variables like age, BMI, habitat, dietary habits, parity, antenatal presence of anaemia, modes of delivery and type of risk factors were comparable.($p > 0.05$).

Delivery by caesarean section, post partum haemorrhage, hypertensive disorders of pregnancy, placenta praevia and multiple gestation were among the leading risk factors.

Baseline Hb in oral iron therapy group was 8.008±0.543 gm/dl and serum ferritin was 11.5796±0.680µg/l.

Baseline Hb in injectable iron therapy group was 7.822±0.542gm/dl and serum ferritin was 11.9206±0.936µg/l.

Distribution of Patients according to Habitat

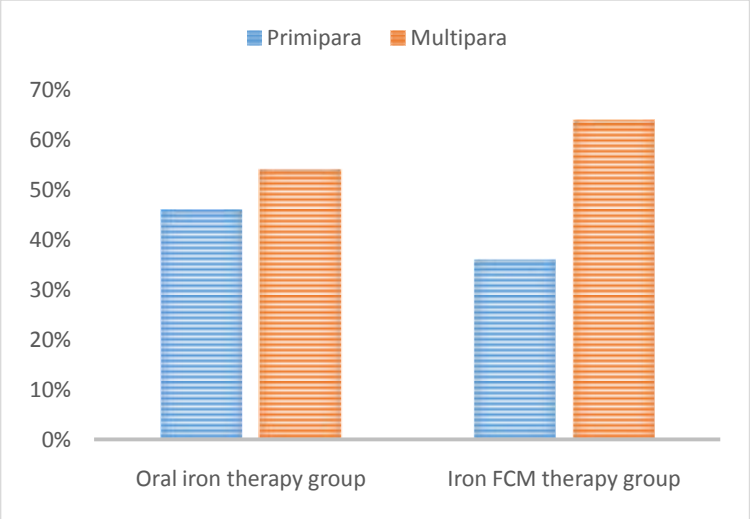
Among the patients with post partum anaemia in my study group, 63% belongs to rural area and rest 37% belongs to urban area.[5]

Parity	Oral iron Therapy Group	Iron FCM Therapy Group	Total
Primiparous	23(46%)	18(36%)	41
Multiparous	27(54%)	32(64%)	59

Table 2. Distribution of patients according to parity

Above table shows most of the patients were multigravida 59% and rest 41% were primigravida. In oral group, 46% were primiparous and 54% were multiparous.In injectable group, 36% were primiparous and 64% were multiparous[6]

International Journal Dental and Medical Sciences Research
Volume 3, Issue 6, Nov-Dec 2021 pp 305-314 www.ijdmsrjournal.com ISSN: 2582-6018



Graph 1. Distribution of patients according to parity

Age Wise Distribution of Postpartum Anaemic Patients Based On Oral and Intravenous Iron FCM Therapy Group

Oral iron therapy group 8% patients were under 20years of age. 38% were between 20-24 years, 40% patients were between 25-29 years of age and 7 were above 30.

In Iron FCM group of iron therapy, 18% were below 20 years of age, 44% were between20-24, 30% were between25-29 and 8% were above 30 years of age.[7]

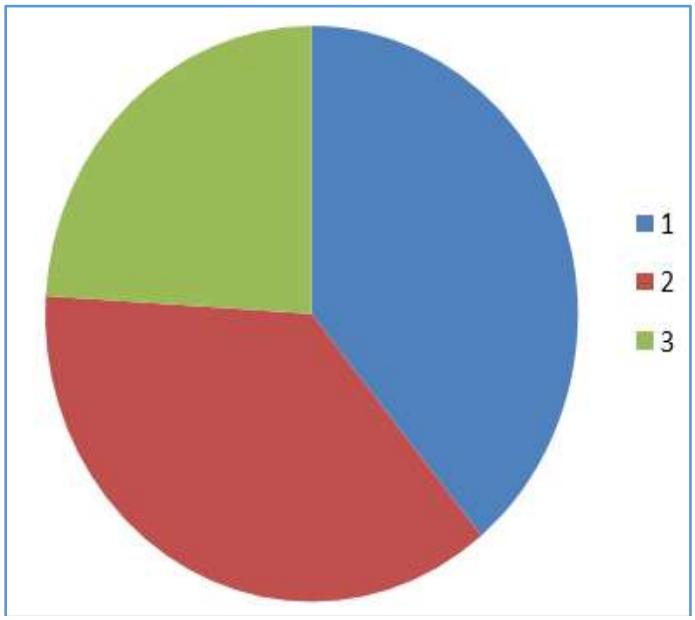
Education Status Distribution of Post-Partum Anaemic Patients Based On Oral and Iron FCM Therapy Group

Oral iron therapy group 34% were illiterate, 22% had primary education, 28% had secondary education and 16% were graduated. In iron FCM therapy group, 22% were illiterate, 38% had primary education, 30% had secondary education and 10% were graduated[8]

Socioecomic Status	No. of Patients	Percentage
1	39	39
2	37	37
3	24	24

Table 3. Distribution of patients according to socio-economic status

International Journal Dental and Medical Sciences Research
Volume 3, Issue 6, Nov-Dec 2021 pp 305-314 www.ijdmsrjournal.com ISSN: 2582-6018



Graph 2: Distribution of Patients

According to Socio Economic Status

1-<Rs. 10000/month,2- Rs. 10000-20000/mont,3->Rs. 20000/month.

Most of the patients belong to group 1(39%), group 2(37%) and 24% patients belong to group 3.

Socioeconomic Status (Group)	**Oral Iron Therapy Group**	**Iron FCMTherapy Group**	**Total**
1	19(38%)	20(40%)	**39**
2	18(36%)	19(38%	**37**
3	13((26%)	11(22%)	**24**
Total	50	50	**100**

Table 4. Socioeconomic distribution of post patum anaemic patients based on oral and iron FCMtherapy group

In the oral group, 38% are in group 1, 36% in group 2 and 26% in group 3. In the iron FCM therapy group, 40% in group 1, 38% in group 2 and 22% in group 3.[9]

Hb gm%	**Oral Iron**			**Iron Ferric carboxymatose**		
	Day 0	**2 Weeks**	**6 Weeks**	**Day 0**	**2 Weeks**	**6 Weeks**
7-8	20(40%)	4(8%)	0	28(56%)	00	00
8-9	30(60%)	18((36%)	8(16%)	22(44%)	2(4%)	00
9-10	00	22(44%)	17(34%)	00	16(32%)	00
10-11	00	6(12%)	11(22%)	00	14(28%)	00
11-12	00	00	13(26%)	00	16(32%)	5(10%)
≥12	00	00	1(2%)	00	2(4%)	45(90%)

International Journal Dental and Medical Sciences Research
Volume 3, Issue 6, Nov-Dec 2021 pp 305-314 www.ijdmsrjournal.com ISSN: 2582-6018

Total	**50**	**50**	**50**	**50**	**50**	**50**

Table 5. Comparison between the two modalities of iron therapy in relation to improvement in haemoglobin levels

In the Oral Iron Therapy Group 40% patients were having Hb between 7-8gm/dl and 60% patients were having between 8-9gm/dl.

After treatment on oral iron therapy in 2 weeks nearly 44% patients showed increase in Hb to 9-10 gm/dl, 12% patients between 10-11gm/dl, 36% patients between 8-9 gm /dl while 4% patients still had Hb between 7-8gm/dl.

In the 6th week only 2% patient showed rise in Hb to ≥12gm /dl. 26% patients had Hb between 11-12gm/dl, 22% had risen in Hb between 10-11 gm/dl, and 34% patients had Hb between 9-10 gm/dl but 16% patients still having Hb between 8-9gm/dl.

In Injectable Iron FCM Therapy Group

On day 0, 44% patients had Hb between 8-9gm/dl and 56% patients had Hb between 7- 8gm/dl.

In the 2nd week 4% patients showed rise in Hb to ≥12gm/dl, 32% patients had rise in Hb 11-12gm/dl, 28% patients had rise between 10-11 gm/dl, 32% patients had rise in Hb between 9-10 gm/dl and 4% patients remain between 8-9 gm/dl.

In the 6th week 90% patients showed rise in Hb ≥12gm/dl and 10% patients had Hb between 11-12gm/dl.

Serum Ferritin (µG/L)	**Oral Iron**			**Iron FCM**		
	Day 0	**2 Weeks**	**6 Weeks**	**Day 0**	**2Weeks**	**6 Weeks**
<15	50	46(92%)	28(56%)	50	00	00
15-50	00	4(8%)	22(44%)	00	42(84%)	11(22%)
>50	00	00	00	00	8(16%)	39(78%)
	50	**50**	**50**	**50**	**50**	**50**

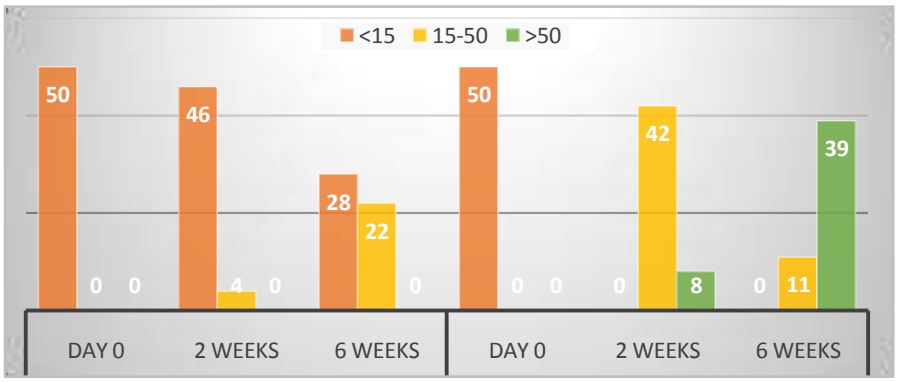
Table 6. Comparison between two modalities of iron therapy in relation to improvement in serum ferritin level

Oral Iron Therapy Group

After treatment in 2nd week 46 (92%) patients had serum ferritin below 15µg/l and 4 (8%) patients had serum ferritin between 15-50 µg/l. In the 6th week 22(44%) patients had serum ferritin between 15-50µg/l and 28 (56%) still had serum ferritin below 15µg/l

Injectable Iron FCM Therapy Group

In the 2nd week nearly 16% patients showed rise in serum ferritin >50µg/l and 84% patients had serum ferritin between 15-50 µg/l. In the 6th week 78% patients had risen in serum ferritin > 50µg/l and 22% patients had serum ferritin between 15-50 µg/l.



Graph 3. Comparison between two modalities of iron therapy in relation to improvement in serum ferritin level

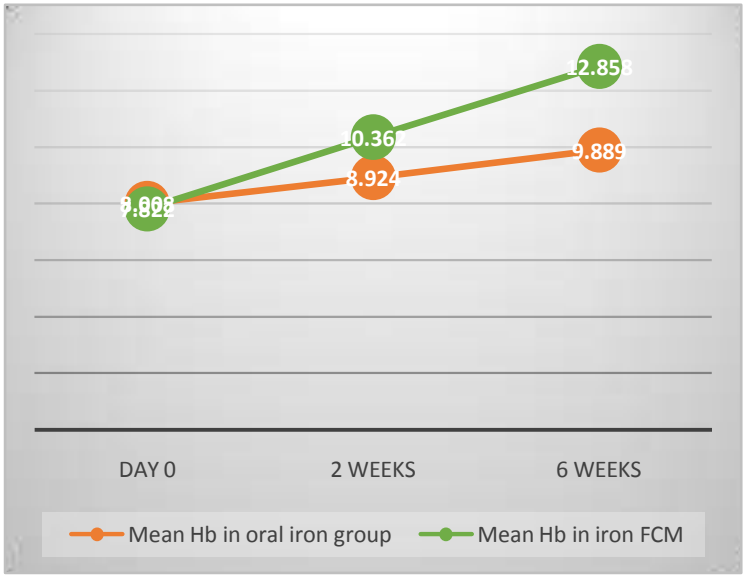
International Journal Dental and Medical Sciences Research
Volume 3, Issue 6, Nov-Dec 2021 pp 305-314 www.ijdmsrjournal.com ISSN: 2582-6018

Haemoglobin	Mean Hb in Oral Iron Group	Standard Deviation	Mean Hb in Iron FCMGroup	Standard Deviation	P value
Day 0	8.008	0.5435	7.822	0.5422	0.7
2 weeks	8.924	0.7660	10.362	0.9354	0.001
6 weeks	9.889	0.9467	12.858	0.6616	0.0001*

Table 7. Comparision of mean and standard deviation in hemoglobin level in both treatment modalities

In oral iron therapy group mean Hb on day 0 was 8.008 ±0.5435 gm/dl. On 2nd week it rise in mean Hb 8.924±0.7660 gm/dl and on 6th week mean rise in Hb 9.889 ±0.9467 gm/dl.

In injectable iron FCM therapy group mean Hb on day 0 was 7.822 ±0.5422 gm/dl, in the 2nd week mean rise in Hb 10.362 ±0.9354gm/dl and in 6th week Hb rise was 12.858 ±0.6616 gm/dl. these values were found to be statically significant with p value <0.05 and <0.0001 for 2nd and 6th week respectively.



Graph 4. Comparision of mean and standard deviation in hemoglobin level in both treatment modalities

Serum Ferritin	Mean Serum Ferritin in Oral Iron Group	StandardDeviation	Mean Serum Ferritin in Iron FCM Group	Standard Deviation	P value
Day 0	11.579	0.6809	11.920	0.9369	0.05
2 weeks	13.057	1.033	48.907	1.542	0.001
6 weeks	15.063	1.089	53.885	5.111	0.00001*

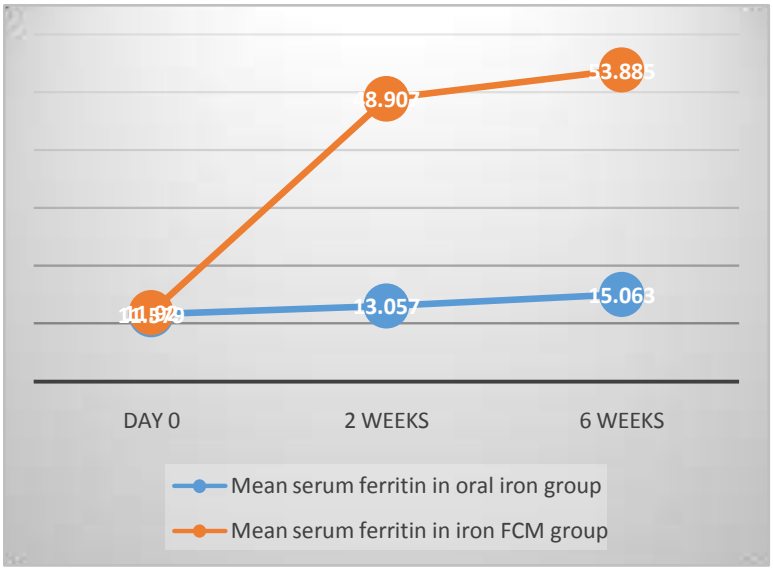
Table 8. Mean and standard deviation of serum ferritin in both treatment modalities

In oral group of iron therapy mean serum ferritin was 11.579±0.6809 µg/l in day 0, which showed rise in mean serum ferritin to 13.057±1.033 µg/l in 2nd week and in 6th week it had increased to 15.063±1.089µg/l.

In the injectable iron FCM group in day 0 mean serum ferritin was 11.920±0.9369µg/l, in 2nd week mean serum ferritin was 48.907±1.542 µg/l and mean serum ferritin 53.885±5.111µg/l in 6th week.[10]

Above values were found to be statistically significant with p value<0.05 and <0.00001 in 2nd and 6th week respectively.[11]

International Journal Dental and Medical Sciences Research
Volume 3, Issue 6, Nov-Dec 2021 pp 305-314 www.ijdmsrjournal.com ISSN: 2582-6018



Graph 5. Mean and standard deviation of serum ferritin in both treatment modalities

Adverse Effects of Oral Iron	No. of Patients	%	Adverse Effects of Iron FCM	No. of Patients	%
Heart burn	02	4%	Anaphylaxis	00	
Constipation	04	8%	Hypotension	00	
Vomiting	00		Headache	00	
Nausea	03	6%	Nausea	00	
Metallic taste	03	6%	Utricaria	00	
Epigastric pain	00		Flushing	03	6%
Diarrhoea	01	2%	Metallic taste	01	2%
Total	**13**	**26%**	**Total**	**04**	**8%**

Table 9. Adverse reactions to intravenous iron FCM and oral iron therapy

In oral iron therapy group, out of total 50 patients, 13(26%) patients had adverse reaction while taking oral iron.2 (4%) patients had heart burn, 4(8%) of them had constipation, 3 (6%)had nausea, 3(6%) had metallic taste and 1 had diarrhoea.[12]
In intravenous iron F therapy group out of 50 patients only 4(8%) patients reported to have adverse reactions. 3 (6%)reported to have flushing and 1(2%) had metallic taste.[13]

V. DISCUSSION

Treatment of Post-partum anaemia is very important to build up iron reserves in the puerperal, to have a better quality of life and to minimize incidence of anaemia in next pregnancy. So the following study was done to see whether giving iron by Intravenous route in form of iron sucrose to women with postpartum anaemia results in higher haemoglobin concentrations and improved iron stores than using standard treatment with oral iron.[13][14]

In this study [table no. 1] during the initially screening and recruitment of post-partum patients in the labour room and ward based on inclusion and exclusion criteria,310 out of 440 mothers were found to be anaemic(70.45%).Among the anaemic cases 153(34.7%)were having mild anaemia,110 (25%) were having moderate anaemia and47(10.68% %)were having severe anaemia. Three of patients did not give consent for participating in the study and other 6 patients refused for follow up. Thus 100 patients were selected randomly based on Haemoglobin 7-9gm/dl and serum ferritin <15µg/l.[15][16]

In this study, demographic variables were compared in the two groups of oral and intravenous iron therapy in terms of age, body mass index, habitat, parity, dietary habits, presence of antenatal anaemia,modes of delivery and type of risk factors ($p>0.05$).Delivery by caesarean,presence of antenatal anaemia, hypertensive disorders of pregnancy were most common leading risk factors.

Baseline Haemoglobin and serum ferritin in both groups were clinically insignificant.[17][18]

VI. CONCLUSION

The present study focused on prevalence of anaemia in postpartum women and its effective management with rapid and safe modes of treatment The present study shows that supplementing with intravenous iron FCM has a positive response on postpartum haemoglobin level. In the iron supplemented group the haemoglobin level tends to increase from the base line levels. Intravenous iron FCM therapy administration increases the haemoglobin level more rapidly than oral iron intake of in women with iron deficiency anaemia in the postnatal period. Intravenous iron therapy also replenishes iron stores more rapidly than oral iron.It can be used as safe and effective alternative to blood transfusion and oral iron therapy in the treatment of iron deficiency anaemia in the postpartum period. Compliance can be ensured with the injectable iron group, however the cost of injectable iron is more compared to iron tablets. If cost is not a limiting factor limited dosage schedule of iron sucrose as prescribed in the study is a safe and effective alternative to daily oral iron taken in treatment of postpartum anaemia. Multiple child birth, poor socioeconomic status, dietary habits,type of habitat and education status of mother also contributed to the incidence of postpartum anaemia. Peripartum anaemia and complications during child birth also played an important role in the occurrence of postpartum anaemia Present study found that postpartum anaemia had affected the practice of breast feeding.This also affects the mother and child bonding.Post partum anemia is associated with impaired quality of life, reduced cognitive abilities, emotional instability and depression as well as puerperal sepsis, poor lactation, poor LSCS wound healing.[23]Future perspectives should include increased awareness to prevent and diagnose postpartum anaemia including screening ofwomenat risk. Assessment of iron status (haemoglobin, ferritin) prior to delivery will help to define women at risk for PostPartum iron deficiency and anemia. Measurement of hemoglobin 24-48 hours after delivery will delineate women with anemia who are in need of treatment with iron.It may not be possible to setup the blood bank in every remote corner of the country but it is certainly possible to make a blood bank in the woman's body by building up her hemoglobin.

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