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Comparision Study on Efficacy of Intravenous Ferric Carboxymaltose Vs Oral Iron in the Treatment of Iron Deficiency Anemia in Postpartum Period

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ABSTRACT

Background and objectives: 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 and their oxygen-carrying capacity is insufficient to meet physiologic needs, which vary by age, sex ,altitude ,smoking , and pregnancy status.[1]Iron deficiency is thought to be the most common cause of anaemia globally, although other conditions, such as folate, vitamin B 12 and vitamin A deficiencies, chronic inflammation, parasitic infections, and inherited disorders can all cause anaemia.In its severe form, it is associated with fatigue, weakness, dizziness and drowsiness. Pregnant women and children are particularly vulnerable. The aim and objective is to study the "comparision of efficacy of intravenous ferric carboxy maltose vs oral iron in the treatment of iron deficiency anemia in postpartum period "in mothers.

Methods: 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.

Results: In injectable iron therapy group 44% and 30% in the age group 20-24 years and 25-29 years were found to be anaemic respectively. In present study in oral iron therapy group after 6 weeks of iron therapy 44% had serum ferritin 15-50µg/l and 56% had serum ferritin below 15µg/l. In injectable iron therapy group at end of 6 weeks 78% had serum ferritin above 50µg/l and 22% had serum ferritin between 15-50µg/l. None of patients in this group had serum ferritin below 15µg/1 at end of the 6 weeks. In this study following injectable iron therapy there was significant rise m mean Hb 7.822 ±0.5422 gm/dl (day 0) to 10.362±0.9354gm/dl in 2nd week and 12.858 ±0.6616 gm/dl in the 6th week In oral group mean Hb rise from day 0 was 8.008 ±0.5435 gm/dl to 8.924±0.7660 gm/dl in 2 weeks and on 6th week mean rise in Hb 9.889±0.9467 gm/dl. When compared with both groups these values were found to be statstically significant with $p < 0.05$.

I. INTRODUCTION

Iron deficiency is thought to be the most common cause of anaemia globally, although other conditions, such as folate, vitamin B 12 and vitamin A deficiencies, chronic inflammation, parasitic infections, and inherited disorders can all cause anaemia.In its severe form, it is associated with fatigue, weakness, dizziness and drowsiness. Pregnant women and children are particularly vulnerable. The Indian council of medical research (ICMR) uses further categories of anaemia depending on haemoglobn level [1]

International Journal Dental and Medical Sciences Research
Volume 4, Issue 6, Nov-Dec 2022 pp 433-441 www.ijdmsrjournal.com ISSN: 2582-6018

Category	Anaemia severity	Hb (gm/dl)
1	Mild	10.9-10
2	Moderate	9.9-7
3	Severe	6.9-4
4	Very severe	<4

WHO defines anaemia in postpartum period as haemoglobin <11g%(110 g/dl) at 1 week postpartum and <12g % (1 2 0 g/dl) at 8 weeks postpartum. The major causes of postpartum anaemia are prepartum anaemia combined with acute bleeding anaemia due to blood losses at delivery. Normal peripartum blood losses are approximately 300 ml, but haemorrhage >500 ml occur in 5-6% of the women. In healthy women after normal delivery, the prevalence of anaemia (haemoglobin <110 g/L) 1 week postpartum is 14% in iron-supplemented women and 24% in non- supplemented women. In consecutive series of European women, the prevalence of anaemia 48 hours after delivery is approximately 50%. In developing countries, the prevalence of postpartum anaemia is in the range of 50%-80%.[3]Keeping in view these facts the present study is designed to monitor the increase in haemoglobin levels and iron stores with administration of parenteral iron therapy in the post-partum anaemia.

II. OBJECTIVES

To study the "comparision of efficacy of intravenous ferric carboxy maltose vs oral iron in the treatment of iron deficiency anemia in postpartum period "in mothers.

III. MATERIAL AND METHOD

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, September 2020 to August 2022. 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. 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.

INCLUSION CRITERIA :-

1. All post partum women in the first week with Hb between 7-11 g/dl are to be selected who would be given oral preparation or intravenous iron as per suitability.

EXCLUSION CRITERIA:-

1. Women with history of anemia other than Iron deficiency anemia were excluded.
2. On myelosuppresive therapy.
3. Recent blood transfusions (within 3 months).
4. Therapy with erythropoietin within 3 months prior to screening.

IV. RESULTS

Observation and discussion:

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, 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.

Total iron to be infused was calculated by,

Ganzoni formula=[weight(kgs)*(target Hb-Patient's baseline Hb)*2.4+500.

Target Hb is 11g/dl,

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)

500 is the target iron store in mg.

One ampoule of ferric carboxy maltose is to be given diluted with 250 ml normal saline intravenously over 15 minutes.

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

International Journal Dental and Medical Sciences Research
Volume 4, Issue 6, Nov-Dec 2022 pp 433-441 www.ijdmsrjournal.com ISSN: 2582-6018

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).

Appropriate statistical analysis (mean, standard deviation) was done. Confidence interval (95%) of various proportions was calculated. P<0.05 was taken significant.

TABLE 1: AGE WISE DISTRIBUTION OF PATIENTS WITH ANAEMIA

Age (in years)	No. of patients	percentage
<20	13	13
20-24	40	40
25-29	36	36
≥30	11	11
Total	100	100

Most of the patients were in age group 20-24 i.e 40% with reduced incidence i.e 36% in the age group of 25-29,11% in the age group ≥30 and13% in age group <20.

TABLE 2: AGE WISE DISTRIBUTION OF POSTPARTUM ANAEMIC PATIENTS BASED ON ORAL IRON AND IRON FCM THERAPY GROUP

Age (in years)	Oral iron therapy group	Iron FCM therapy group
<20	4(8%)	9(18%)
20-24	19(38%)	22(44%)
25-29	20(40%)	15(30%)
≥30	7(14%)	4(8%)
Total	50	50

In the above table it may be seen that in the oral iron therapy group 4(8%) patients were under 20 years of age,19 (38%) were between 20-24 years,20(40%) patients were between 25-29 years of age and 7(14%) were above 30 years.

In the iron FCM therapy group ,9(18%) were below 20 years,22(44%) were between 20-24 years,15(30%) were between 25-29 years and 4(8%) were above 30 years of age.

TABLE 3: DEMOGRAPHIC VARIABLES AND BASELINE CLINICAL DATA

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

International Journal Dental and Medical Sciences Research
Volume 4, Issue 6, Nov-Dec 2022 pp 433-441 www.ijdmsrjournal.com ISSN: 2582-6018

Habitat (rural/urban)	31/19(62%/38%)	32/18(64%/36%)	0.063
Dietary habits(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 3 is showing the demographic variables of the two groups.

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 hemorrhage, hypertensive disorders of pregnancy, placenta previa 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 iron FCM therapy group was 7.822±0.542gm/dl and serum ferritin was 11.9206±0.936µg/l.

TABLE 4 : DISTRIBUTION OF POSTPARTUM PATIENTS BASED ON THE SEVERITY OF ANAEMIA

Severity of anaemia	**No.of patients**	**Percentage**
Non anaemic	65	29.54%
Mild anaemia (9-11gm/dl)	76	34.7%
Moderate anaemia(7-9gm/dl)	55	25%
Severe anaemia (<7gm/dl)	23	10.68%

IIn this study 220 post-partum patients were randomly screened within 24- 48 hours post-delivery, out of which 65(29.54%) patients were non anaemic ,76(34.7%) had mild anaemia, 55 (25%) patients had moderate anaemia and rest 23 (10.68%) severe anaemia.

International Journal Dental and Medical Sciences Research
Volume 4, Issue 6, Nov-Dec 2022 pp 433-441 www.ijdmsrjournal.com ISSN: 2582-6018

TABLE 5 : COMPARISION BETWEEN THE TWO MODALITIES OF IRON THERAPY IN RELATION TO IMPROVEMENT IN HAEMOGLOBIN LEVELS

Hb in gm%	Oral iron			Iron FCM		
	Day 0	2 weeks	6 weeks	Day 0	2 weeks	6 weeks
7-8	20(40%)	4(8%)	00	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%)
Total	50	50	50	50	50	50

In the table no. 5

ORAL IRON THERAPY GROUP :

20(40%) patients were having Hb between 7-8gm/dl and 30 (60%) patients were having between 8-9gm/dl.

After treatment on oral iron therapy in 2 weeks nearly 22 (44%)patients showed increase in Hb to 9-10 gm/dl, 6(12%) patients between 10-llgm/dl, 18(36%) patients between 8-9 gm /dl while 4(8%) patients still had Hb between 7-8gm/dl.

In the 6th week only 1(%) patient showed rise in Hb to ≥12 gm /dl.13 (26%) patients had between 11-12gm/dl,11(22%) had risen in Hb between 10-11 gm/dl, 17(34%) patients had Hb between 9-10 gm/dl but 8(16%) patients still having Hb between 8-9 gm/dl.

IN IRON FCM GROUP :

On day 0,22(44%) patients had Hb between 8-9 gm/dl and 28(56%) patients had Hb between 7-8 gm/dl.

In the 2nd week 2(4%) patients showed rise in Hb to ≥ 12 gm /dl,16(32%) patients had rise in Hb 11-12 gm/dl,14(28%) patients had rise between 10-111 gm/dl, 16(32%) patients had rise in Hb between 9-10 gm/dl and 2(4%) patients remain between 8-9gm/dl.

In the 6th week 45(90%) patients showed rise in Hb ≥12 gm/dl and 5(10%) patients had Hb between 11-12 gm/dl.

International Journal Dental and Medical Sciences Research
Volume 4, Issue 6, Nov-Dec 2022 pp 433-441 www.ijdmsrjournal.com ISSN: 2582-6018

TABLE NO 6 : RISE IN HAEMOGLOBIN IN BOTH TREATMENT MODALITIES

Difeerence in Hb from baseline (Day 0)	Oral iron therapy group		Iron FCM therapy group		P value
	Mean Hb(gm/dl)	Standard deviation	Mean Hb (gm/dl)	Standard deviation	
2 weeks	0.916	0.431589	2.54	0.79872	<0.05
6 weeks	1.8814	0.626799	5.036	0.57809	<0.05

Table no 6 shows that in the present study mean Hb rise from the baseline (day 0) in the 2nd week was 0.916 ±0.431589 gm/dl and in the 6th week 1 . 8814 ±0.626799 gm/dl in the oral iron therapy group .

In the iron FCM therapy group, rise in mean Hb from the baseline (0 day) was 2.54±0.79872 gm/dl in the 2nd week and 5.036 ±0.57809 in the 6th week which was more compared to the oral iron therapy group (p<0.05)

V. DISCUSSION:

Anaemia in the postpartum period may be associated with an increased prevalence of breathlessness , tiredness, palpitations and maternal infections , particularly of the urinary tract. Such symptoms may cause women to experience difficulty caring for their baby ,and may influence the emotional bond the mother has with her baby .Treatment of postpartum anemia is very important to build up iron reserves in the purpura, to have a better quality of life and to minimize incidence of anemia in next pregnancy. So the following study was done to see whether giving iron by intravenous route in form of iron FCM to women with postpartum anaemia results in higher haemoglobin cocentrations and improved iron stores than using standard oral iron treatment**.**

In this study table no. 1 during the initial screening and recruitment of postpartum patients in the labour room and ward based on inclusion and exclusion criteria, anaemia was found more in the group 20-24 years i.e. 40 % and least was found in group of 20:30 years is 11%. This study shows results similar to the results published in The international journal of science and research publishd in 2013 which stated that 20-24 years age group had highest prevalence of anemia .[97]similar results were obtained by Gautam VP et al(2002) and Nesimi et al (2005). [98][99]

In the table no.2 comparing between the two modes of treatment ,anaemia was found more in age group 25-29 years i.e 40% in oral iron therapy group and 44% in age group 20-24 years in intravenous FCM iron therapy group.

In this study in table no. 3 demographic variables were compared in the two groups of oral and intravenous iron ferric carboxymaltose therapy in terms of age, body mass index, habitat, parity, dietary habits, presence of antenatal anemia, modes of delivery and type of risk factors(p>0.05). Delivery by caeserian ,presence of antenatal anaemia, hypertensive disorders of pregnancy were most common leading risk factors. Baseline haemoglobin and serum ferritin in both groups were clinic ally insignificant.

According to table no 4, 310 out of 440 mothers found to be anaemic (70.45%).Among the anemic cases 153(34.7%) were having mild anemia,110(25%) were having moderate anaemia and 47(10.68%) were having severe anemia. 4 of patients discontinued the oral therapy due to adverse reactions during the present 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.

In the present study [table no.5] in oral group out of total 50 , 20(40%) patients had Hb 7-8gm/dl and 30(60%) patients had Hb 8-9gm/dl. On 2nd week 4(8%) patients Hb remained between 7-8 gm/dl ,18(36%) patients had Hb 8-9 gm/dl, 22(44%) patients had. Hb 9-1Ogm/dl and 6(12%) patients had Hb 10-11 gm/dl. On 6th week 8(16%) patients had Hb 8-9 grn/dl , 17(34%) patients had HJ 9 - 10 grn/dl , 11(22%)patients had Hb 10 - 11 grn/dl and

International Journal Dental and Medical Sciences Research
Volume 4, Issue 6, Nov-Dec 2022 pp 433-441 www.ijdmsrjournal.com ISSN: 2582-6018

13(26%) patients had Hb 1 3 gm/dl . Only 1 (2%) patients had Hb 12 grn/dl.

In the injectable iron FCM group 28(56%) patients had Hb 7-8 gm/dl and 22 (44%) patient 8-9 grn/dl. On the 2nd week 2(4%) pa tient 's Hb remain 8-9 gm/dl , 16 (32%)patients had Hb 9-lOgrn/dl , 14(28%) patients had 10 - 11 gm/dl ,16(32%) patients had Hb 11 - 12 gm/dl and 2 (4%)patients 's Hb became 12 gm/dl .On 6th week 45 (90%)patients showed improvement in anaemia and Hb became > 12 gm/dl and remaining 5(10%) patients had Hb 11- 12 gm/dl.

Table no . 6 shows mean Hb rise in oral iron therapy was only 0.916 ±0.431589 gm/dl in the 2nd week and 1.8814 ±0.626799 gm/dl in the 6th week from the baseline. In intravenous iron therapy group mean Hb rise from the baseline was 2.54±0.79872 gm/dl in the 2nd week and 5.036 ±0.57809 in the 6th week with P<0.05.

VI. CONCLUSION

- Anaemia in postpartum is common health problem, but there is paucity of studies regarding anaemia in postpartum period.
- The present study shows that supplementing with intravenous iron ferric carboxymaltose has a positive response on postpartum hemoglobin level. In the iron supplemented group the hemoglobin level tends to increase from the base line levels.
- Intravenous iron therapy administration increases the hemoglobin level more rapidly than oral iron intake of in women with iron deficiency anemia 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 anemia 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 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
- Peripartum anaemia and complications during child birth also played an important role in the occurrence of postpartum anaemia.
- Future perspectives should include increased awareness to prevent and diagnose postpartum anemia including screening of women at risk. Assessment of iron status (hemoglobin, 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 comer of the country but it is certainly possible to make a blood bank in the woman's body by building up her hemoglobin.

VII. SUMMARY:

- Iron deficiency anaemia is a great concern among obstetrician .Post partum anaemia is wide spread in India . The total drug infusion concept with third generation parenteral iron molecules is convenient for patients and can save resources in health care system especially when compared to oral iron therapy and blood transfusions.
- The present study was conducted in the obstetrics and gynecology department of Hi-Tech Medical College and Hospital, Bhubaneswar for the period of 2 years ,Out of 440 post partum patient screened, 310(70.45%) were found to be anaemic .Out of which 153(34.7%) were having mild anaemia, 110(25%) were having moderate anaemia and 47(10.68%) were having severe anaemia.
- Demographic variables were compared in the two groups like age , BMI, habitat, dietary habits, parity, antenatal presence of anaemia,, modes of delivery and type of risk factors were comparable .(p>0.05).Mean age group was found as 25.34 ±3 . 836 years in oral group and 23.7 ± 3.775 years (p>0.05). Baseline Hb in oral iron therapy group was 8.008±0.543gm/dl and serum ferritin was 11.5796±0.680µg/l. Baseline Hb in iron FCMtherapy group was 7.822+0.542 gm/dl and serum ferritin was 11.9206+0.936 µg/l.
- Anaemia was found maximum in the age group 20-24 years i.e 40% and least in age group 2:3 0 years. Comparing the two groups postpartum anaemia , in the oral iron therapy group was found to be 38% and 40% in age group of 20-24 years and 25-29 years respectively. In injectable iron therapy group 44% and 30% in the age group 20-24 years and

25-29 years were found to be anaemic respectively.

- In present study history of antenatal anaemia contributed to the incidence of post partum anaemia. 65% patients had "history of antenatal anaemia and 12% patients became anaemic following delivery.
- In present study postpartum hemorrhage and hypertensive disorders of pregnancy were the most common factors contributing to the occurrence of pos partum anaemia ..
- In present study anaemia was more in, patients who were not exclusively breast feeding (67%) and 33% in patient with exclusively breast feeding. In oral iron therapy 66% and in injectable iron therapy group 68% were not exclusively breast feeding .In the present study in oral group of iron therapy, after 6 weeks of therapy only 2% patients attained Hb 12gm% or above while 16% had Hb 8-9 gm%, 34% had Hb 9-10 g:;n% , 22% had Hb 10-11 gm% and 26% had Hb 11-12 gm%.
- Injectable group after 6 weeks nearly 90% reached the target Hb 12gm% and above and 10% had Hb 11-12 gm%. None of patients were anaemic at the end of 6weeks.
- In present study in oral iron therapy group after 6 weeks of iron therapy 44% had serum ferritin 15-50µg/l and 56% had serum ferritin below 15µg/l. In injectable iron therapy group at end of 6 weeks 78% had serum ferritin above 50µg/l and 22% had serum ferritin between 15-50µg/l. None of patients in this group had serum ferritin below 15 µg/1 at end of the 6 weeks.
- In this study following injectable iron therapy there was significant rise m mean Hb 7.822 ±0.5422 gm/dl (day 0) to 10.362 ±0.9354gm/dl in 2nd week and 12.858 ±0.6616 gm/dl in the 6th week In oral group mean Hb rise from day O was 8.008 ±0.5435 gm/dl to 8.924±0.7660 gm/dl in 2 weeks and on 6th week mean rise in Hb 9.889±0.9467 gm/dl. When compared with both groups these values were found to be statstically significant with p <0.05.
- In the present study in the injectable iron therapy mean serum ferritin rise was found to be was 48.907±1.542 µg/1 in 2 weeks and mean serum ferritin 53.885±5.lllµg/l in 6th week compared to oral iron therapy 13.057±1.033 µg/1 in 2nd week and 15.063±1.089µg/l in 6 weeks . These values were found to be statistically significant with p value<0.05 .
- In present study when compared to the adverse reactions only 4(8%) patients in the injectable group of iron therapy had reactions i.e 3(6%) patients reported to have metallic taste and 1 (2%) reported to have flushing followed by complete treatment of iron therapy. They were managed conservatively.
- In oral group 13 (26%) patients reported to have adverse reaction , out of which 3 had nausea, 3 had metallic taste , 4 had constipation, 2 had heart bum and 1 had diarrhoea .This factors lead to noncompliance of the therapy in 4 patients and discontinued the therapy.
- In oral iron therapy group mean Hb rise from baseline was 0.916 ±0.4315 89 gm/dl in the 2nd week and 1.8814 ±0.626799 gm/dl in the 6th week. Mean rise in serum ferritin was 1.5096±0.9359704 µg/1 in the 2nd week and was 3 .49 9 6±1.108194 µg/1 in the 6th week from the baseline.In intravenous iron therapy group mean Hb rise from the baseline was 2.54±0. 79872 gm/dl in the 2nd week and 5.036 ±0.57809 in the 6th week. Mean serum ferritin rise in the 2nd week was 36.9864±1.637411 µg/l and in the 6th week 41.96528±5.106939 µg/l from the baseline.
- Mean rise of Hb and serum ferritin was more in injectable iron therapy group compared to oral iron therapy group ($p<0.05$)

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