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Impact of IM iron therapy in pregnant women with moderate anaemia

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ABSTRACT

In India iron deficiency is the major factor responsible for anaemia. Earlier studies had shown that IM iron sorbitol citric acid injections with 900mg of elemental iron given to pregnant women with Hb levels between 5-7.9g/dL, raised their Hb by about 2 g/dL and did not correct anaemia in all. A study was taken up to assess the impact of 1500mg of IM iron therapy on Hb levels. Apparently healthy pregnant women (n=419) in second trimester, with Hb between 5.0- 7.9 g/dL were enrolled and given ten injections each consisting of iron sorbitol citric acid complex containing 150 mg elemental iron, and 1500 μg folic acid and 150 μg B-12. Impact of the therapy on Hb, course and outcome of pregnancy and birth weight of the offspring was recorded. In a subsample (72 women), the impact of IM iron therapy was assessed on Hb, serum iron and ferritin by comparing the values prior to and 8-12 weeks after IM iron therapy. Eighty-eight per cent of women completed all 10 injections. Following IM therapy there was a significant improvement in mean values of Hb (7.2±0.82 g/dL to 9.2 ±0.86 g/dL, P<0.0001). After IM iron therapy, mean ferritin levels rose from 12.9±12.23 μg/L to 36.2±22.84 μg/L; iron deficiency (ferritin levels < 12 μg/L) decreased from 66.7% to 8.3%. The mean birth weight of infants born to those who received IM iron therapy was 2818±292.9 g. This was significantly higher (P<0.0001) than mean birthweight (2345.4+334.2g) of infants born to women who had Hb less than 8g/dL at delivery. IM iron therapy nearly eliminated iron deficiency, improved Hb levels and birth weight. Women with persistent anaemia after IM iron therapy require investigations to find out factors responsible for anaemia.

1. Introduction

Anaemia had been and continues to be a major public health problem in pregnancy.[1,2] Moderate anaemia (Hb between 5.0-7.9 g /dL) is associated with lower immunity, increase in the risk of maternal infections, low birth weight and higher perinatal loss.[3–5] Studies carried out in the 1960s and 70s had demonstrated that oral iron therapy was ineffective in improving the Hb levels in women with moderate anaemia (Hb levels between 5.0-7.9 g/dL) when treatment was begun in the second trimester of pregnancy,[6,7] IM iron therapy brought about improvement in Hb and reduction in the severity of anaemia.[6–8] Given this, the Tenth Five Year Plan[9] and the National Iron Plus Initiative for control of anaemia[10] recommended universal screening of all pregnant women for anaemia and providing IM iron therapy for pregnant women with moderate anaemia.

Most of the earlier studies with IM iron therapy have been carried out with iron dextran.[6–8] About a week after initiation of iron dextran injections, pregnant women developed side effects such as fever, arthralgia and myalgia; some discontinued the therapy due to these minor but

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troublesome side-effects. IM injection of iron sorbitol citric acid is associated with lower side-effects and, had better acceptance and continuation rates.[11–15] With the injection of 900 mg of elemental iron as iron sorbitol citric acid complex, the rise in mean Hb levels was only about 2 g/dL.[15] This could be due to an inadequate dose of iron because a third of the injected iron sorbitol citric acid complex gets excreted in the urine.[11–14] A study was, therefore, taken up to investigate the impact of IM iron therapy with 1500mg iron as sorbitol citric acid complex on Hb levels of pregnant women and the birth weight of their offspring.

2. Material and Methods

The study was taken up in Defence Colony Maternity Centre (DCMC), New Delhi. The study design is given in Figure 1. Permission to undertake the study was taken from the hospital authorities. The study was approved by the Institutional Ethics Committee.

Haemoglobin estimation was done by the cyanmethaemoglobin method in women in the second trimester of pregnancy who were attending the antenatal clinic for the first time and had not received any iron supplementation earlier. Women with Hb between 5.0 and 7.9. g/dL were given detailed information about the study. Pregnant women who fulfilled the inclusion criteria (Figure 1) and gave informed consent were enrolled for the study.

Socio-demographic and obstetric history were recorded in all. Their height (to the nearest mm using a wall-mounted stature meter), weight (to the nearest 100g using a digital balance) and blood pressure were measured; the quality assurance procedures that were put in place during the earlier study to ensure accurate Hb estimation in the OPD[15] were continued during the present study. These women were given IM therapy (ten injections each consisting of iron sorbitol citric acid complex containing 150 mg elemental iron, 1500 μg folic acid, 150 μg hydroxycobalamine acetate - vitamin B_{12}).

The maternity centre staff administered a test dose and after half an hour administered the injection. Pregnant women were advised to rest in the hospital for an hour after the injection and were requested to report if they had nausea or vomiting. Those who had nausea, vomiting or giddiness were given symptomatic treatment and observed for an hour, and then sent home with antiemetic tablets and instructions to take one tablet if they have vomiting. All these women were informed that they could come to the hospital for injections at any time suitable for them; hospital staff administered the subsequent daily injections as and when these women came. Many women tended to skip one or two days between injections but later came back and completed the course of 10 injections (duration between first injection and completion of ten injections ranged between 12 to 22 days).

Pregnant women who had taken IM iron injections were followed up, both through clinic visits and telephonic calls. They were advised to get their Hb levels checked during antenatal follow-up visits and to have hospital delivery; in those who delivered in other hospitals, information on the nature of delivery, and birth weight was obtained telephonically.

In all women attending the antenatal clinics, blood was collected through venepuncture for Hb, blood grouping, and VDRL. In women enrolled for the study in the second year, the study team requested permission to collect additional 2-3 ml of blood for serum iron and ferritin assays. Of the 129 women who agreed to initial blood collection, only 92 women had 10 IM iron injections; follow-up blood samples were collected 8-12 weeks after completion of IM iron therapy in 72 women.

All samples were stored at -20°C after the separation of serum. Frozen serum samples were sent to the National Institute of Nutrition for estimation of serum iron and ferritin. Serum iron was estimated by the bathophenanthroline method.[16] Serum ferritin was estimated by an in-house sandwich ELISA developed using antiserum raised against human liver ferritin in rabbits.[17] Quality of ferritin ELISA was ensured by participation in CDC vital EQA program (CDC, USA).

During the study period, 905 women were delivered in DCMC. Obstetric history, antenatal care and delivery details for all these women were recorded. Their height and weight were taken and Hb estimation was done. The birth weight of their offspring was recorded accurately within 24 hours after delivery. These data were used to assess the impact of maternal anaemia on birth weight, and for comparing the birthweight of the neonates born to women who had received IM therapy.

3. Results

During the study period, 3867 women who attended the antenatal OPD had Hb estimation done during their first visit; only 107 (2.8%) were not anaemic; 2654 (68.6%) were mildly anaemic and 1106 (28.6%) were moderately anaemic. Among those with moderate anaemia, 419 women who fulfilled the inclusion criteria were enrolled for the study.

The demographic profile of the families of the enrolled women is given in Table 1. Over $2/3^{rd}$ lived in nuclear families; over 90% of families had 3 to 8 members. Over 2/3rd of women and 3/4th of their husbands had schooling; 8.2% of the women and 14.3% of men had college education (mostly from evening college or open university). The majority were from low and low middle-income families. There were no differences in the obstetric or nutrition profile of women who fulfilled inclusion criteria, consented and were enrolled and those who were moderately anaemic but

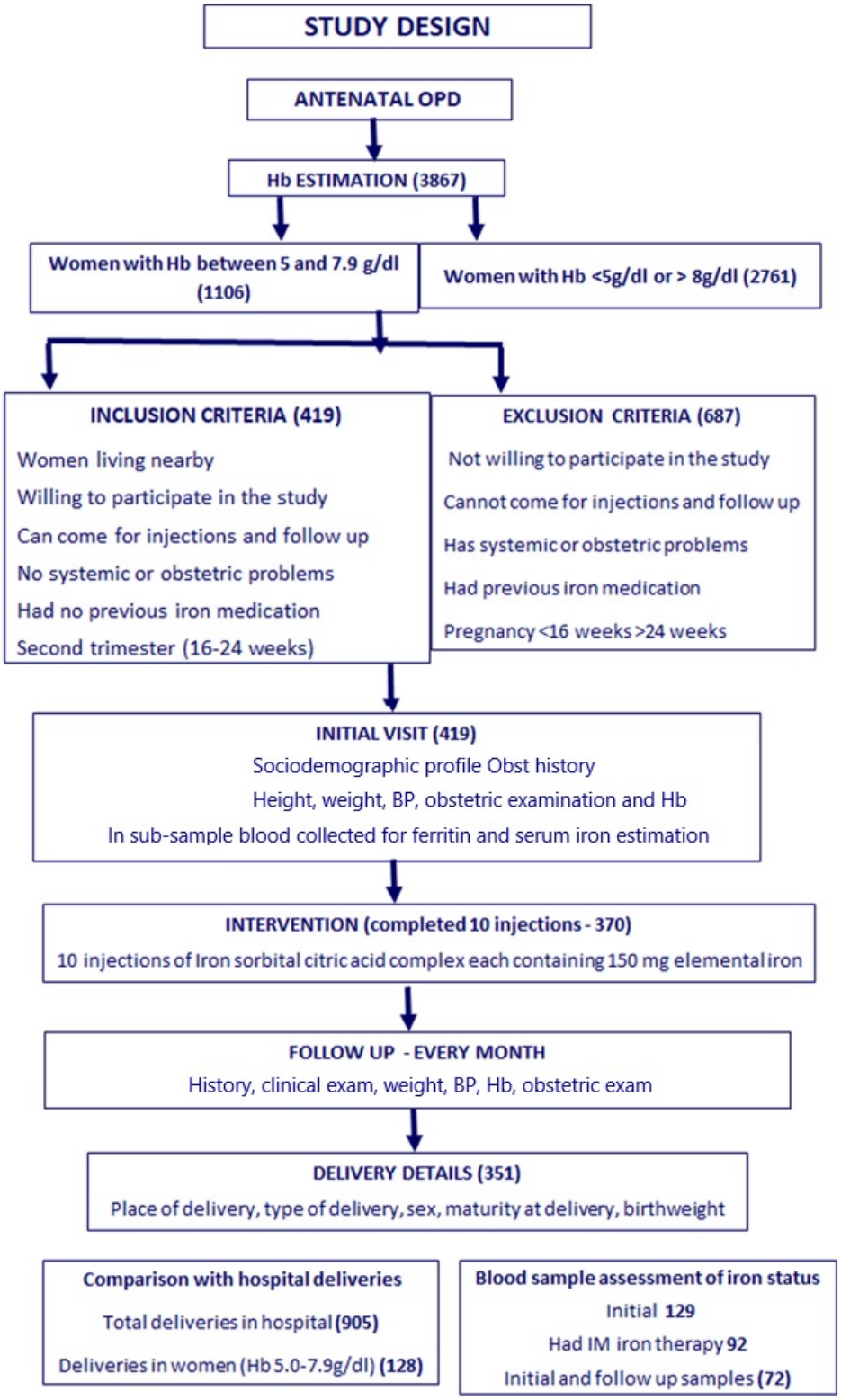

Fig. 1: Study design

were not enrolled. Among the enrolled women, more than $3/4^{th}$ gave their husband's mobile number for contacting them; the remaining gave their landlord or neighbour's mobile or landline number through which they could be contacted. This helped in providing support and reassurance to women who had side effects, reminding them when visits were due and in getting delivery details if they had delivered in other hospitals.

Table 1: Socio-demographic profile at the time of enrolment (419 women)

Type of family	%
Joint	34.9
Nuclear	65.1
Family size	
≤ 3	51.4
4-8	44.2
>8	4.4
Education of women	
Illiterate, read & write	23.2
Had schooling	68.6
College	8.2
Education of husband	
Illiterate, read & write	9.8
Had schooling	75.9
College	14.3

The obstetric and nutrition profile of women is given in Table 2. Nearly 90% of women were between 20-29 years of age; 45.7.% were primigravida and 33.2% were pregnant for the second time. The mean inter-pregnancy interval in those who had one or more previous pregnancies was 30 months. All were in the second trimester of pregnancy; the mean gestational age at enrollment was 20.3 weeks (range 16-24 weeks). Their mean height was 151.1cm and their mean weight at enrolment was 50 kg.

Table 2: Obstetric and nutritional profile at recruitment (419 women)

Parameters	**Mean±SD**
Age (yr)	24.0±3.41
Gravida (no.)	2.1±1.09
IPI (months)	29.9±19.84
Height (cm)	151.1±4.73
Weight (Kg)	50.0±8.09

Of the 419 pregnant women who received the 10 IM injections, 176 (42%) had nausea after the initial or subsequent injections; and 34 (8.1%) had vomiting sometime during the course of injections. All of them received symptomatic therapy with anti-emetic. Two hundred and four women (48.7%) complained of pain at the injection site for one or more days during the injections. They were treated with paracetamol. These side-effects were relatively mild and responded to the symptomatic treatment.

There was a progressive increase in mean Hb with increasing duration and the maximum increase was noted ≥9 weeks after completion of the IM therapy (Table 3). The mean increase in the Hb levels was about 2 g/dL (Table 3). There were 41 women (9.7%) in whom Hb levels continued to remain below 8g/dL even after 4-5 weeks after completion of the IM therapy. They were referred to the tertiary care centres for further investigations and management of anaemia.

Table 3: Pre and post treatment Hb levels

Weeks after completion of 10 injections	**Number**	**Mean Hb g/dL**	
		Initial	**Final**
4-5	222	7.4 ±0.81	8.9±0.65
≥ 9	394	7.5±0.78	9.4±0.67

Pre vs post treatment Hb statistical significance tested by single tailed paired t test. Pr(T->)<0.00001

During the second year, serum iron and ferritin levels were measured in 129 women with Hb levels between 5-7.9g/ dL. In these women, the mean Hb was 7.0± 0.61g/dL; serum iron 116.6 ±120.24 μg/dL and ferritin was 15.4± 13.6μg/L. Of these 129 women, 92 received 10 IM iron injections. Initial and follow up samples taken 8-10 weeks after completion of 10 injections were available in 72 women. Mean Hb, serum iron and ferritin levels before initiation of therapy and 8-10 weeks after completion of 10 injections in 72 women is shown in Table 5. Iron deficiency was seen in 66.7% of the women before initiation of treatment. Following 10 injections, ferritin levels showed a substantial increase (from 12.8 to 36.1 μg/L) and iron deficiency was nearly eliminated (8.3% at 8-10 weeks after therapy) (Table 4).

During the study period, there were 905 deliveries in the DCMC with the mean birth weight of 2797g. There was a gradient in mean birth weight in relation to maternal Hb at delivery; the mean birth weight of infants born to women with Hb between 5.0 and 7.9g/dL (2345 g) was significantly lower as compared to the birth weight of infants born to non-anaemic women (Table 5).

Of 370 pregnant women, who had taken 10 injections, data on the outcome of pregnancy and birth weight of the offspring could be obtained in 351. The mean birth weight of their offspring was 2818±292.9 g. The mean birth weight in women who had 10 injections of IM iron was comparable to the mean birth weight of infants born to non-anaemic women and was significantly higher as compared to the birth weight of the infants born to women with Hb below 8g/dL (Table 5).

4. Discussion

Indian obstetricians had recognised that anaemia and associated adverse consequences were major public health

Table 4: Hb, serum iron, vitamin B12 in pregnant women before and after IM therapy (paired values in 72 women)

Hb		Hb g/dl	Serum Iron μg/dL	Ferritin μg/L
Pre	Range	5.4-8.3	28-421	1.8-55.1
	Mean	7.2±0.82	122.6 ±114.77	12.9±12.3
Post	Range	7.5-12.0	41-279	6.8-95.4
	Mean	9.3±0.87**	120.2±44.5*	36.1±22.8**
Difference	Mean	2.07±1.05	- 2.42±119.25	23.31±23.08

Values are means and SD
Values of iron and ferritin, were log-transformed before paired t test was applied.
Statistical significance tested by single tailed paired t test.
**Pr(T>t) < 0.00001, * Pr (T>t) 0.57 NS

Table 5: Effect of Hb levels at delivery and IM iron treatment on birthweight

Group	Hb g/dL	Number	Birth Weight (g)
1	<8	128	2345.4±334.2*
2	8.0-10.9	723	2846.9±351.2
3	≥11	54	3216.7±440.3
Total	Total	905	2797.6±408.5
4	Women who received IM iron therapy	351	2818.0±292.9*

Values are Mean±SD
Statistical significance 1 vs 4 tested by student t test *P<0.001

problems in India. They were at the forefront of research studies documenting the prevalence, causes, consequences of anaemia in pregnancy and evolving appropriate methods of diagnosis and management of anaemia.[1–8] India was the first developing country to have a national programme for prophylaxis and later control of anaemia in pregnancy.[18] However, oral iron therapy was not effective in management of moderate anaemia, especially, when anaemia was detected in late second trimester of pregnancy. Therefore, Indian obstetricians working in medical colleges who had abundant case load of moderate anaemia, conducted what were at that time the world's largest series of studies exploring feasibility, safety and efficacy of intramuscular and intravenous iron therapy using mainly two preparation iron dextran and iron sorbitol citric acid complex.[6,8,19–24] Within a decade, the intravenous administration was given up because of the rare anaphylactic reaction to IV iron preparations which proved to be fatal in some cases, in spite, of intensive resuscitative efforts in medical college settings.[23,24] In the last three decades several newer iron compounds for IV use have been developed and mainly used in renal dialysis patients with chronic anaemia. In India there had been small scale studies in pregnant women on use of these newer compounds as single or multiple IV injections and fatalities though rare had been reported.[25] In view of this IM iron injections remain the safe option for management of moderate anaemia in India.

Indian studies in the sixties and seventies established the safety and efficacy of IM iron therapy[6–8]. Based on these experiences, national policy[9] and programme guidelines[10] and obstetric text books,[23,24] emphasised the need for:

1. Screening all pregnant women for anaemia;
2. Providing one tablet of iron (100mg elemental iron) and folic acid (500μg) daily to prevent any fall in Hb levels in non-anaemic pregnant women;
3. Iron folic acid oral medication at the maximum tolerable dose from second trimester throughout pregnancy for women with Hb between 8-10.9g/dL;
4. IM iron therapy for women with Hb between 5 and 7.9 g/dL, if they do not have any obstetric or systemic complications.

However, IM iron therapy was still not used in all medical colleges and its use in district hospital is very limited. In primary health care settings, neither diagnosis of anaemia by accurate Hb estimation nor treatment of moderate anaemia by IM iron therapy is practised. One of the reasons for reluctance of physicians to use and women's low acceptance of IM iron therapy is mild but troublesome side effects such as myalgia and arthralgia in about a third of subjects who had iron dextran injections.[6,8] These side effects usually appear after a week and once they experience these, women are unwilling to come back to the hospital the remaining injections. It is well recognised that iron sorbitol citric acid complex is associated with far fewer side-effects.[11,14,15] Troublesome arthralgia is rare and therefore, the acceptance and continuation rates are higher with iron sorbitol citric acid complex.

Computation of the dose of parenteral iron takes into account three factors: type of compound, Hb deficit and body weight. The commonly used formulae for computation of dose for iron dextran was body weight in kg (used as a marker for blood volume) x {target Hb (11g/dL)-current

Hb}x2.4 + 500 mg for iron store replenishment. Using this formula the computed dose for women with mean Hb levels around 7 g/dL and mean body weight of about 45 kg was 1000 mg of elemental iron as iron dextran. This was the dose used in the studies conducted in the eighties.[8] Iron sorbitol citric acid complex has a molecular weight of about 5000; it gets absorbed from the injection site rapidly; about a third of the drug gets excreted in the urine.[12–14] Therefore, it has been recommended that 30% should be added to the dose computed for iron dextran.[15] However, when the study proposal to use 1500mg of iron sorbitol citric acid complex was reviewed by the technical review committee, there were concerns that giving 1500 mg of elemental iron intramuscularly could lead to oxidative stress and its adverse consequences. It was, therefore, recommended that the study at first instance be carried out with 1000 mg of iron sorbitol citric acid complex and Hb response assessed. The study demonstrated that IM injections of 900 mg of elemental iron as iron sorbitol citric acid complex was able to improve Hb only by about 2 g/dL.[11] A study was, therefore, taken up to assess the impact of providing 1500 mg of elemental iron as ten injections; each injection consisted of iron sorbitol citric acid complex containing 150 mg elemental iron, 1500 μg folic acid, 150 μg hydroxycobalamine acetate (vitamin B_{12}).

Over 40% of women reported nausea; about 8% had vomiting on one or more days when injections were given. They were reassured that this was a transient symptom; they responded well to antiemetics. Nearly half the women had pain at the site of injection on one or more days. With paracetamol to provide pain relief and reassurance that the pain will reduce, almost all women continued with the injections. Use of a preparation with fewer and milder side-effects, giving injections at a time convenient to the pregnant women, counselling and support for those who developed side-effects were some of the factors responsible for high compliance rates even with ten injections (370 out of 419 completed the ten injections; therapy completion rate was 88.3%).

The intervention provided in the present study was ten injections each consisting of iron sorbitol citric acid complex containing 150 mg elemental iron, 1500 μg folic acid, 150 μg hydroxycobalamine acetate. Following the injection, the water-soluble folic acid and vitamin B_{12} will peak in the blood and get excreted in the urine. Therefore, it is unlikely that the injection will have any effect on folic acid or vitamin B_{12} status. All women who had received IM iron therapy were advised not to take iron folic acid tablets provided in the antenatal clinic. The hospitals did not have separate folic acid or vitamin B_{12} oral preparations. Therefore, these women did not get folic acid supplementation regularly pregnancy.

Follow up during the first year showed that with 1500mg of elemental iron the improvement in Hb after 9 weeks after completion of the iron injections were similar to those reported with the 900 mg.[15] To find out whether IM iron dose was sufficient to correct the iron deficiency, we undertook ferritin and serum iron estimation before and 8-10 weeks after injection. Prior to the initiation of the IM iron therapy, the mean ferritin levels were below 12 μg/L in over $2/3^{rd}$ of the women suggesting that they were iron deficient. Following ten injections, there was a substantial improvement in mean ferritin levels (12.8 μg/L to 36.2 μg/L). IM injections of 1500 mg of elemental iron as iron sorbitol citric acid complex reduced the prevalence of iron deficiency (ferritin levels below 12 μg/L) from 66.7% to 8.3%. These data suggest that the dosage was sufficient to eliminate iron deficiency in pregnant women with Hb levels between 5.0 to 7.9 g/dL.

Data on ferritin levels prior to IM iron therapy showed that $2/3^{rd}$ of the women had ferritin level below 12μg/L suggestive of iron deficiency. Anaemia in the remaining one third were not due to iron deficiency and therefore, unlikely to respond to parenteral iron injections. Data from the study showed that in about 10% of the pregnant women, the Hb levels continued to remain below 8g/dL even after 4-5 weeks after completion of IM therapy. These women might be suffering from anaemia due to other factors which may include folate and vitamin B_{12} deficiency, infections such as malaria, and hook worm infestations as well as haemoglobinopathies. It is essential to undertake repeat Hb estimation after one month after completion of the IM iron therapy. Those who have not shown any increase in Hb will have to be identified and referred to centres where they could be investigated and the factors responsible for the non-response identified and appropriate treatment provided.

5. Strengths of the Study

Carefully conducted hospital-based intervention study on management of anaemia with IM iron sorbitol citric acid complex. Impact was assessed by Hb, birthweight of the off-spring and ferritin levels.

6. Limitations

Study was carried out in one centre. In view of the known differences in contribution of the factors other than iron deficiency in different regions, multi-centre studies are needed to confirm the findings.

7. Policy and Programme implications

IM iron therapy is the safe option for management of moderate anaemia in pregnant women in the second trimester who may have problems with high dose oral iron therapy. IM iron therapy improves Hb levels and ensures repletion of the iron stores in women who have iron deficiency anaemia.

Women receiving IM iron therapy have to be monitored for improvement in Hb levels. Those who do not show improvement in Hb within a month after IM therapy will have to be identified and referred to centres where they could be investigated. Factors responsible for the non-response to IM iron therapy have to be identified and appropriate treatment has to be provided.

8. Summary and Conclusions

Pregnant women in second trimester of pregnancy without any systemic or obstetric problems with Hb levels between 5.0-7.9 g /dL received 10 IM injections each consisting of iron sorbitol citric acid complex containing 150 mg elemental iron, and 1500 μg folic acid and 150 μg B_{12}. About a third of these women had side effects like nausea and pain in the site of injections; they were given symptomatic treatment. With reassurance and symptomatic relief, 88% of women completed all 10 injections.

Two thirds of the pregnant women with Hb levels between 5.0 and 7.9 g/dl had iron deficiency (ferritin levels below 12 μg/L). Repeat Hb estimation 8-10 weeks after getting ten injections showed that the mean Hb improved by about 2.0 g/dL. In about 10% of women Hb levels remained below 8 g/dL, 4-5 weeks after IM injections. Women with persistent anaemia were referred to tertiary care centres for further investigations to find out factors responsible for anaemia and appropriate treatment.

After IM iron therapy, mean ferritin levels rose from 12.9±12.23 μg/L to 36.2±22.84 μg/L; iron deficiency (ferritin levels < 12 μg/L) decreased from 66.7% to 8.3%. The mean birth weight of infants born to those who received IM iron therapy (1500 mg of elemental iron) was 2818±292.9 g which significantly higher (P<0.0001) than mean birthweight (2345.4+334.2g) of infants born to women who had Hb less than 8g/dL at delivery. IM iron therapy which results in substantial improvement in both Hb level of the mother and birth weight of the offsprings, remains one of the treatment modalities for pregnant women with Hb levels between 5 and 7.9g/dL.[26,27]

8.1. Data availability

Data is available with Nutrition Foundation of India and could be accessed.

8.2. Author contributions

PR conceptualisation, study design, writing the paper.

AS Implementation of the intervention in the hospital and monitoring

MN undertook serum iron and ferritin estimations.

SG Implementation of the intervention in the hospital, and monitoring.

All authors: review of literature, methodology, tabulation plan and drafting of the manuscript.

9. Funding Source

Indian Council of Medical Research.

10. Conflict of Interest

The authors declare no conflict of interest.

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