A comparative study of changes in haemoglobin with high and low dose iron preparations in pregnant women

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Summary: A total of 100 pregnant women between gestational age of 20 and 34 weeks who attended the clinic at The Bandra Holy Family Hospital, Bandra, Mumbai were selected. They were randomly assigned to either of the two groups. The Trial group was given a haematinic with the low dose iron preparation (30 mg elemental iron). The Control group was given a haematinic with the high dose iron preparation (116 mg elemental iron). Comparative study of the two groups was carried out with respect to the elevation of haemoglobin levels, the maternal weight gain, baby's weight, side effects, complications, and patient compliance.

Maternal weight gain more than 10 kgs was noted in 14.89% of the trial group as compared to 8.33% in the control group. In patients with an initial haemoglobin level less than 10gm%, a rise of more than 39% was found in 7 out of 11 patients in the trial group as compared to 4 out of 13 patients in the control group; 24% of the control group had gastrointestinal side effects as compared to only 4% in the trial group.

It was hence concluded that 30mg of elemental iron is sufficient to maintain the pregnancy requirements and also leads to better tolerance and improved patient compliance.

Introduction:

Anaemia is the commonest haematological disorder that occurs in pregnancy. (Williams, 1993). Depending upon the criteria used for the diagnosis and the socio-economic class of women studied, the incidence varies widely from 40% to 80% if 10gm% haemoglobin level is adopted as the lower limit. During pregnancy there is a disproportionate 40% increase in the plasma volume as compared to RBC volume and the haemoglobin mass, which increases by 20%. This causes relative haemodilution.

The demand for iron supplementation is maximum during the 2nd and 3rd trimester. The daily requirements at these times become almost 6mg/day. An adequate balanced diet contains not more than 18-20mg of iron. Since only 20% are absorbed, the demand is hardly fulfilled. Hence the need for supplementation of iron during pregnancy and lactation.

Aims:

To compare the haemoglobin levels in pregnant women in two groups. The trial group containing 30 mg elemental iron + essential minerals and vitamins. The control group containing over 100 mg of elemental iron + folic acid + zinc + vitamin C. The study aimed to compare the overall pregnancy outcome with respect to changes in the haemoglobin level, maternal weight gain and baby weight. It also studied the side effects and patient compliance.

Material and Method:

The study was conducted on 100 pregnant women attending the antenatal clinic at The Bandra Holy Family Hospital, Bandra, Mumbai. Patients in the gestational age between 20 and 34 weeks were randomly selected. Fifty of these were given haematinics containing 30 mg of elemental iron (Trial group) and the other 50 were given haematinic containing 116 mg of elemental iron (Control Group). Patients with a haemoglobin level less than 7gm% were not included in the study. On entry into the study, weight, blood pressure, and haemoglobin were noted and on subsequent visits these along with any complications and side-effects were noted.

Results:

Table I shows the maternal weight gained in pregnancy. It was noted that in the control group 70.83% of patients had a weight gain between 0-4.9 kg. However a larger proportion of women in the trial group (14.89% v/s

Table-I:

Showing maternal weight gain in both groups.

Weight gain (in kg)	Trial Group No. of Patients (%)	Control Group No. of patients(%)
0-4.9	19 (40.43%)	34 (70.83%)
5-9.9	21 (44.68%)	10 (20.83%)
10 & above	7 (14.89%)	4 (8.33%)

A large proportion of the patients in the Control group had side-effects mainly those of gastro-intestinal disturbances (24%) as compared to only 6% in the Trial group.

Discussion:

Table – II:

Change in Haemoglobin in Trial & Control Groups

Trial group (N=50)	**Control group (N=50)**
3 Patients discontinued treatment	2 Patients discontinued the treatment
41 Patients showed increased Hb	38 Patients showed increased Hb
5 Patients did not show any change in Hb	2 Patients had no rise in Hb
1 Patient had a decrease in Hb	8 Patients had a decrease in Hb

Summary of change in Hb % in Trial and Control groups.

Basal Haemoglobin in gm %	No. of patients	Increase in Hb in gram %					Hb same as before	Decrease in Hb levels
		0-1	1.1-2	2.1-3	3.1-4	4.1 & above		
Less than 10 g %	T – 11	2	0	2	5	2	0	0
	C-14	4	3	2	3	1	0	0
10-12 g%	T-30	21	4	2	0	0	3	0
	C-30	16	7	1	0	0	1	5
12 g % & above	T-6	2	1	0	0	0	2	1
	C-5	1	0	0	0	0	1	3

8.33%) had the optimum weight gain of 10kg and more. Table II shows the change in the haemoglobin levels in pregnancy on treatment. In the Trial group, 3 patients discontinued treatment, 41 patients showed an increase in the haemoglobin level, 5 patients did not show any change, 1 patient showed a decrease in the level. In the Control group, 2 patients discontinued the treatment, 38 patients showed an increase, 2 patients did not show any change and 8 patients had a decrease in the haemoglobin levels.

Table III shows the baby's weight at birth. It was observed that 27.97% of babies whose mothers were in the Control group were less than 2.5kg. however in the Trial group only 12.76% of the babies weighed less than 2.5kg. In the Trial group 17.02% of the babies weighed more than 3.5kg at birth as compared to only 6.25% of the babies in the Control group.

Table-III:

Birth weight in babies born to mothers in both groups

Birth Weight in kgs	Control Group (%)	Trial Group (%)
2-2.49	13 (27.97)	6 (12.76)
2.5-3	20 (41.66)	20 (42.55)
3.01 – 3.5	12 (25.00)	13 (27.65)
3.51 & above	3 (6.25)	8 (17.02)
Total	48 (100)	47 (100)

It has been stated in pharmacological editions that although iron is needed during pregnancy and lactation, it is to be given in moderation. Goodman & Gilman (1978) have stated that the percentage of iron absorbed decreases as the amount of administered iron increases. In the non-pregnant state the absorption of iron is around 1.4mg/day which increases to 3-4mg/day during pregnancy. Hence any load over 30-40mgs is not desired since there is increased incidence of gastro-intestinal side-effects and decreased patient compliance (WHO

Technical Report, 1989). This is reflected in the decrease in Haemoglobin in the 8 patients in the Control group due to poor compliance to the medicines mainly due to gastritis

In patients with initial haemoglobin level less than 10gm%, both groups showed a 100% rise in the haemoglobin levels. However in the trial group 7 out of 11 patients showed more than 39% rise as compared to only 4 out of 13 patients in the Control group. This could be attributed to more compliance to taking regular iron supplementation due to decreased side effects in the Trial group

It was also observed that fewer babies were born growth retarded in the Trial group and a significant number were born above the average weight of Indian babies. This could be attributed to additional micro-nutrients that were supplemented to the Trial group.

Conclusion:

We conclude that iron is needed in pregnancy but in moderation; 30mg/day averaged over the entire pregnancy for most women. Excess iron supplements in pregnancy are unnecessary and side-effects of iron overload are worse than the effects of deficiency.

References:

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2. WHO Technical Report: Recommended Dietary allowance; 10th Edition 1989. National academy.
3. Williams Obstetrics Edition 20, 1993. Page 26. Publishers Prentice Hall, Conneticut, USA.