

Influence of focused counseling on hemoglobin status of antenatal women – A non randomized controlled trial

R Arunmozhi^{1*}, T P Jayanthi², Saradha Suresh³

¹Department of Community Medicine, Madras Medical College, Chennai, Tamil Nadu, INDIA.

²Department of Community Medicine, Government Stanley Medical College, Chennai, Tamil Nadu, INDIA.

³Rtd Director and Superintendent, Institute of Child Health, Professor and HOD, Department of Paediatrics, Madras Medical College, Chennai, Tamil Nadu, INDIA.

Email: arunmozhi1960@yahoo.co.in

Abstract

Introduction: Anaemia has major consequences on the health of the mother and the baby. Iron and Folic acid (IFA) tablet supplementation is routinely given to all antenatal women. The consumption of IFA tablets has always been suboptimal. This study was taken up to evaluate the influence of focused counseling on the haemoglobin status of pregnant women. **Materials and Methods:** This was a non randomized controlled trial carried out in Chennai. Focused counseling, defined as holistic counseling guided by each woman's individual situation, was provided to pregnant women on four occasions in the intervention group, in addition to routine care provided by the health centre. The control group of pregnant women received routine care alone. Weight, hemoglobin values and IFA consumption of 145 women in the intervention and 146 women in the control group were compared at the beginning and end of pregnancy. **Results:** There was a statistically significant difference in the weight gain of antenatal women in the intervention group compared to the control group [$t = 3.848$, $df = 289$, $p = <0.001$]. The proportion of women who were anaemic had also declined from 40% to 26.9% in the intervention group. Comparison between the mean hemoglobin values at the beginning and end of antenatal period showed a statistically significant increase at the end of the antenatal period in the intervention group [Mean (SD) = 0.1386 (0.4885), $t = 3.417$, $p = 0.001$]. Antenatal (AN) women in the intervention group were two times as likely to consume more than 90 tab of IFA [Pearson's chi square value = 35.295, p value = <0.001]. **Conclusion:** Focused counseling, leading to improved compliance of IFA consumption and adequate weight gain, can significantly improve the hemoglobin levels of pregnant women.

Keywords: Anaemia, Antenatal, Focused counseling, IFA supplementation, Non randomized controlled trial.

* Address for Correspondence:

Dr. R. Arunmozhi, No.8, I' Block, Anna Nagar East, Chennai – 600102, Tamil Nadu, INDIA.

Email: arunmozhi1960@yahoo.co.in

Received Date: 10/05/2015 Revised Date: 19/05/2015 Accepted Date: 22/05/2015

Access this article online

Quick Response Code:



Website:

www.statperson.com

DOI: 24 May 2015

INTRODUCTION

Iron deficiency anaemia is one of the most common micronutrient deficiencies in the world.¹ A high proportion of women in both industrialized and

developing countries become anemic during pregnancy. Estimates from the World Health Organization report shows that 56% of pregnant women in developing countries, and 18% of women from industrialized countries are anemic. However, many of these women were already anemic at the time of conception, with an estimated prevalence of anemia of 43% in non-pregnant women in developing countries and of 12% in women in wealthier regions.² Anaemia has major consequences on the health of the mother and the baby. Globally anaemia contributes to 115,000 maternal deaths and 591,000 perinatal deaths every year.³ Severe anaemia in pregnancy leads to intrauterine growth retardation, still births, low birth weight and neonatal deaths. Anaemia directly causes 20 per cent of maternal deaths in India and indirectly accounts for another 20 per cent of maternal

deaths.⁴ Anaemia has been a major problem in India, especially among women of reproductive age group. IFA supplementation is given as a routine to all antenatal women, irrespective of their hemoglobin (Hb) status, because the demand for iron increases as pregnancy advances. Women are generally advised on how to take the tablets. But irregular consumption of prescribed iron supplements, due in part to side-effects, has plagued most supplementation programmes.⁵ Chennai, the capital city of Tamil Nadu, is fully urbanized, where almost 30 – 40 % of its population lives in slums. About two-thirds of the pregnant women are anaemic.⁶ Effective counseling involving assessment of individual situation, exchange of information and motivation would increase IFA consumption and improve hemoglobin levels of antenatal women.⁷⁻⁹ The aim of this research was to study the influence of focused counseling on the hemoglobin status of antenatal women, and also compare the values between the intervention groups.

MATERIALS AND METHODS

This is a non randomized controlled trial with one intervention group and one control group. The study was carried out between April 2013 and May 2014. Pregnant women, who registered in the first 12 weeks of gestation and residing in the catchment area of the selected urban health posts of Chennai Corporation and willing to participate in the study, formed the study population. Women with documented pre-existing conditions like heart disease, renal disease, diabetes, hypertension, thyroid disorders, etc were excluded. The calculated sample size was 154 antenatal women in each of the intervention and control arm using a power of 80% and a confidence level of 95%. A design effect of 2 was used to control for the multistage sampling method. The sample size was calculated based on the prevalence of anaemia in India among pregnant women (58.7%) according to NFHS III data.¹⁰ A multistage sampling method was used to select the study area. In the first stage of sampling two zones of Chennai were chosen by simple random sampling, of which one served as the intervention and the other as the control area. In the second stage of sampling one health post was chosen from each of the selected zones by simple random sampling. Consecutive eligible antenatal women were enrolled from April 2013 in both the intervention and control area until the desired sample size was reached. Participants were not randomly selected. The loss of randomness may be accepted because of the homogeneity of characteristics of the pregnant women within one area. To address the loss of randomness, design effect was applied to increase the sample size. In the intervention area 154 antenatal women and in the control area 156 antenatal women were

enrolled in the study. Four women in the intervention and six women in the control group were lost to follow up. One hundred and fifty women in each of the groups were followed till the end of the antenatal period.

Procedure

Women in the intervention area were given focused counseling on four occasions, once in the first 12 weeks, 20-24 weeks, 28-32 weeks and 36-40 weeks, in addition to routine care, given by the health centre during antenatal period. Focused counseling defined as holistic counseling guided by each woman's individual situation, was aimed at reducing iron deficiency anaemia. It involved exchange of information, education and motivation on regular antenatal visits, self care, nutrition, Iron and Folic acid supplementation and identification of danger signs and health seeking behavior (Box1). Antenatal women in the control area received routine care alone. Routine care included provision of maternal and child health services and health education by the health centre. Focused Counseling differs from health education. The difference between focused counseling and health education is explained here with example. Health workers, as part of health education, inform the antenatal woman that Hb estimation should be done on every antenatal visit. Focused counseling involves not only informing the pregnant woman that Hb estimation should be done on every visit, but also explaining its importance. She is informed of her present Hb value and whether it is adequate or not. Focused counseling also involves explaining to the mother the importance of weight gain and the role of nutrition in improving the Hb status: taking greater amount and variety of food and about heme and non heme foods. It includes, verifying if the mother is taking IFA tablets as advised by the health care worker, and discussing reasons or issues pertaining to poor compliance: whether it is abdominal discomfort associated with the intake, or is it some myth like IFA intake will produce a large baby and that would lead to difficult labor, and then helping the mother to understand and reach a suitable solution. The women in both the groups were followed throughout the antenatal period. The weight and hemoglobin values were obtained from the records available at the health centre and also from the records available with the mother.

Ethics

Ethical approval was obtained from the Institution Ethics Committee of Government Kilpauk Medical College, Chennai and permission to carry out the study in the field area was obtained from Chennai Corporation. Individual informed consent was obtained from all the participants. This is part of a bigger study where the mothers were followed up to 6 months following delivery.

GUIDE TO COUNSELING

1. Utilization of Antenatal services:

1.1 Adequate utilization of recommended antenatal visits at: First 12 weeks, 20-24 weeks, 28-32 weeks, 32-36 weeks and 36-40 weeks. *She should take her maternal and child health card on every visit.*

1.2. Examination on every visit should include weight recording.

- The total gain in weight should be around 10-12 kg for the entire period of pregnancy.
- Inadequate weight gain leads to low birth weight babies.
- If the weight of the child is less than 2.5 kg the baby will be more vulnerable to disease and death.
- If the weight gain is inadequate, extra food should be eaten at every meal, and the number of meals should be increased.

1.3 Investigation on every visit should include Hemoglobin estimation. It helps to monitor the hemoglobin status of the pregnant woman. Anaemia during pregnancy can lead to complications for the mother and the baby.

1.4 Antenatal Iron supplementation – 100 tabs of Iron and folic acid during antenatal period. The antenatal mother is advised to take one tablet a day for 100 days from second trimester.

1.5 Tab. Albendazole – A single dose of tab Albendazole given for deworming in the second trimester.

GUIDE TO COUNSELING (CONT)

2. Nutrition:

- Pregnant women should consume more food, more often during the day.
- Should eat greater amount and variety of healthy foods, vegetables, especially dark green leafy veg., milk, cereals, meat and eggs.

- Reassurance that the mother can eat any normal foods.
- Pregnant women require extra food to meet the demands of the growing baby and provide for changes in her body.
- Taking extra food helps in gaining adequate weight during pregnancy and contributes to increasing the weight of the baby.
- She should take plenty of water,
- She should not observe fast during pregnancy.
- Should avoid alcohol and tobacco use.
- Identification of Food taboos and counseling of mother on right practices.

3. Iron and Folic acid supplementation:

- IFA tablets to be taken as advised by the health worker.
- One tablet a day of IFA must be taken at least for 100 days in the AN period.
- It increases the weight of the fetus.
- Tablets to be taken after food preferably at night.
- It prevents anaemia in the mother. Symptoms of anaemia are general fatigue, breathlessness on routine and somewhat strenuous work, palpitation, loss of appetite, giddiness and diminishing vision and headache, paleness of eyes, nails and insides of eyelids.
- Anaemia can lead to premature delivery, still birth and low birth weight babies.
- It can also lead to severe bleeding and severe anaemia may endanger the life of the mother also.
- Intake of IFA tablets may cause the stools to become black. This should not be a cause for worry.
- Advice and counseling to ensure compliance of IFA consumption.

Source^{11,12}

OBSERVATIONS AND RESULTS

The mean (SD) ages of the women were 25.4yrs (3.6yrs) and 25.2yrs (3.9yrs) in the intervention and control groups. The characteristics of the study participants are presented in Table 1.

Table 1: Characteristics of Study Participants

	Intervention Group		Control Group		
	n =150	%	n = 150	%	p value
Age of the AN Women					
<=20 yrs	11	7.3	17	11.3	p = 0.503
21 - 25 yrs	68	45.4	72	48.0	
26 - 30 yrs	57	38.0	48	32.0	
30+ yrs	14	9.3	13	8.7	
Education of AN Women					
No formal school education	3	2.0	2	1.3	p = 0.322
Primary	8	5.3	8	5.3	
Middle School	23	15.3	38	25.4	

High School	56	37.4	56	37.4	
Higher Secondary	25	16.7	20	13.3	
Graduate and Above	35	23.3	26	17.3	
Occupation of AN Women					
Housewife	142	94.7	148	98.7	p = 0.103
Employed	8	5.3	2	1.3	
Education of Husband					
No formal school education	2	1.3	0	0.0	p = 0.232
Primary	5	3.3	8	5.3	
Middle School	25	16.7	30	20.0	
High School	58	38.7	52	34.7	
Higher Secondary	18	12.0	28	18.7	
Graduate and Above	42	28.0	32	21.3	
Occupation of Husband					
Casual Laborers	19	12.7	42	28.0	p = < 0.001*
Employed (Pvt / Govt)	96	64.0	93	62.0	
Self Employed	35	23.3	15	10.0	

	Intervention Group		Control Group		
	n =150	%	n = 150	%	p value
Religion					
Hindu	133	88.7	127	84.6	p = < 0.001*
Christian	10	6.7	1	0.7	
Muslim	7	4.7	22	14.7	
Type of family					
Nuclear	97	64.7	85	56.7	p = 0.156
Joint	53	35.3	65	43.3	
No. of Members in the family					
1 - 3 Members	101	67.3	84	56.0	p = 0.102
4 – 6 Members	40	26.7	59	39.3	
7 – 9 Members	6	4.0	6	4.0	
10 – 14 Members	3	2.0	1	0.7	
Parity					
0	71	47.3	83	55.3	p = 0.387
1	79	52.7	64	42.7	
2 and ab	0	0.0	3	2.0	
Last Child Birth (yrs)					
	n = 79		n = 67		
< 2	10	12.6	5	7.5	p = 0.371
2 - 3	24	30.4	27	40.3	
3 and ab	45	57.0	35	52.2	

Among the husbands there were more self employed men in the intervention group and more casual laborers in the control group. There were more Christians in the intervention group and more Muslims in the control group. Fifty three percent of antenatal women in the intervention group and 43% of antenatal women in the control group belonged to first parity. The mean birth interval was 3.5 yrs in the intervention group and 3.3 yrs in the control group. The differences in the obstetric profile were not statistically significant. Hence, the participants in the two groups had similar characteristics except for differences in the occupation of the husband and religion. Five women in the intervention area and four women in the control area had abortions. One hundred and forty five women in the intervention group and one hundred and forty six women in the control group had live births.

Weight gain and Hemoglobin Status

The weight gain and hemoglobin values of 145 women and 146 women in the intervention and control groups were analyzed. Women who had abortions were excluded as they did not receive all the counseling sessions. Women with hemoglobin values below 11.0 g/dl were considered as anaemic. The mean weight gain in the intervention (8.70 Kg) and control groups (7.23 Kg) is presented in the table below. An independent sample t test was carried out to examine whether there was a significant difference between intervention groups in relation to weight gain during pregnancy. The test showed a statistically significant difference in the weight gain between the groups. [t = 3.848, df = 289, p = <0.001] (Table 2)

Table 2: Comparison of Mean weight gain between Intervention groups

Independent sample t test		Weight Gain			
Intervention Category	Mean (Kg)	Mean Difference	p Value	95% CI of the Difference	
Intervention Group (N = 145)	8.70	1.471	<0.001*	0.716	2.225
Control Group (N = 146)	7.23				

The proportion of anaemic women (40% and 41.1%) in the two groups at the beginning of the antenatal period did not show any statistically significant difference (Pearson's chi square value = 0.036, p value = 0.849). At the end of the AN period, the proportion of women who were anaemic declined from 40% to 26.9% in the intervention group. The percentage of anaemic women in the control group continued to be high at 44.5%.

Pearson's chi square test carried out to examine the relationship between intervention groups and hemoglobin status at the end of the AN period showed that there was a statistically significant relationship between belonging to a particular intervention group and the hemoglobin status [Pearson's chi square value = 9.839, p value = 0.002] (Table 3)

Table 3: Comparison of Haemoglobin status between Intervention groups

Hb status	Intervention	Control	p value
	No. of AN women n (%)	No. of AN women n (%)	
Beginning of AN period	n = 145	n = 146	0.849
Anaemic	58 (40.0)	60 (41.1)	
Not Anaemic	87 (60.0)	86 (58.9)	
End of AN period	n = 145	n = 146	0.002*
Anaemic	39 (26.9)	65 (44.5)	
Not Anaemic	106 (73.1)	81 (55.5)	

The hemoglobin status at the beginning and end of the antenatal period was compared within the groups. In the intervention group, 53.4% of women, who were anaemic at the start of the study became non anaemic at the end of the antenatal period compared to 45% in the control group, showing that 8% more women had become non anaemic in the intervention group compared to the control group. Among women who were not anaemic at the start of the study, the proportion of women who continued to remain not anaemic was 86.2% in the intervention group as compared to 62.8% in the control group. This shows that 23% more women continued to remain not anaemic

in the intervention group compared to the control group at the end of the antenatal period (Table 4). The haemoglobin status at the beginning and end of the antenatal period was compared using the McNemar test. It showed a statistically significant change in the proportion of anaemic and non anaemic women in the intervention group (p value = 0.005). The McNemar test done to compare the haemoglobin status in the control group, did not show any statistically significant change between the beginning and end of antenatal period (p value = 0.603).

Table 4: Association of Hemoglobin status at the Beginning and End of AN period

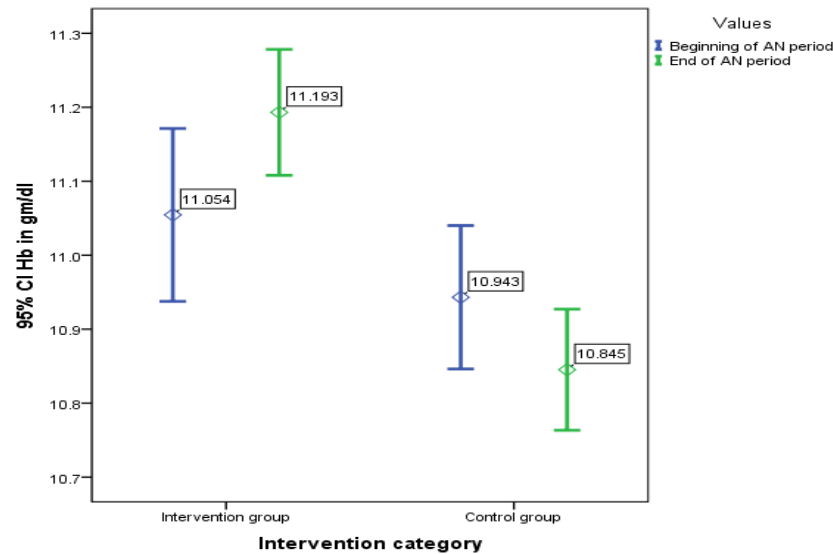
	Beginning of AN period	End of AN period		Total	p value
		Anaemic n (%)	Not Anaemic n (%)		
Intervention n = 145	Anaemic	27 (46.6)	31 (53.4)	58	0.005*
	Not Anaemic	12 (13.8)	75 (86.2)	87	
	Total	39	106	145	
Control n = 146	Anaemic	33 (55.0)	27 (45.0)	60	0.603
	Not Anaemic	32 (37.2)	54 (62.8)	86	
	Total	65	81	146	

The mean hemoglobin values at the beginning and end of the antenatal period were analyzed for the two groups using paired sample t test. There was a statistically significant increase in the mean hemoglobin value at the end of the antenatal period in the intervention group (p value = 0.001), where counseling was given in addition to

routine care. The control group of women who received only routine care, showed a statistically significant decrease in the mean hemoglobin value at the end of the antenatal period (p value = 0.034). The same is depicted in Table 5 and Figure 1.

Table 5: Comparison of Hemoglobin values Estimated at the Beginning and End of Antenatal period

Paired sample t test	Estimated Hb values	Mean (g/dl)	Mean Difference	p Value	95% CI of the Difference	
					Lower	Upper
Intervention n = 145	Beginning of AN pd	11.054	0.1386	0.001*	0.0584	0.2188
	End of AN period	11.193				
Control n = 146	Beginning of AN pd	10.943	- 0.0979	0.034*	- 0.1886	- 0.0073
	End of AN period	10.845				

**Figure 1:** Comparison of Error plot for Hemoglobin values

IFA consumption was assessed between the intervention groups. Antenatal women in the intervention group were two times as likely to consume more than 90 tablets of IFA. Pearson's chi square test showed a statistically significant relationship between interventional category

and consumption of IFA tablets (Pearson's chi square value = 35.295, p value = <0.001). Women in the intervention group (62.8%) were significantly likely to consume more than 90 tab of IFA compared to the control group (28.1%) (Table6)

Table 6: IFA supplementation

IFA supplementation			
Consumption of IFA tab	Intervention (n = 145)	Control (n = 146)	p value
Less than or equal to 90 tab	54 (37.2)	105 (71.9)	< 0.001*
More than 90 tab	91 (62.8)	41 (28.1)	

DISCUSSION

IFA supplementation plays a major role in prevention and treatment of iron deficiency anaemia. The strongest level of evidence about effect of IFA is obtained if individuals' iron status is measured before and after supplementation (e.g., early and late in pregnancy), and the change in status is linked to degree of iron supplement usage.¹ In this study, the mean hemoglobin values were compared at the beginning and end of pregnancy. The intervention group showed an increase in the mean hemoglobin value, which was statistically significant. Prenatal supplementation with daily iron is effective to prevent maternal anaemia and iron deficiency in pregnancy.¹³ Following intervention, the proportion of women who were anaemic had declined from 40% to 26.9% in the

intervention group in the present study. Iron supplements given during pregnancy, have been reported to increase hemoglobin, even in women who enter pregnancy with adequate iron stores.¹⁴ The proportion of women in the present study who were not anaemic to start with and continued to remain not anaemic at the end of the antenatal period was higher in the intervention group (86.2%) compared to the control group (62.8%). Non compliance (non adherence) of medical advice is assumed to reflect patient's lack of knowledge, inability to retain medical instructions, or other behavioral factors.¹⁵ It is evident from the study that when women were given counseling, with the opportunity to discuss and clear their doubts, there was a behavior change leading to better adherence. An eight country study (which included India

also) by Galloway *et al* indicated that when women were counseled on the positive health benefits of Iron and Folic Acid tablets on themselves and their infants, it helped to improve their compliance.¹⁶ The present study also showed that the women in the intervention group who were counseled on the need and benefits of IFA supplementation were more likely to consume IFA tablets. Increase in the population mean hemoglobin of pregnant women even by 1 g/dL is significant as it has shown to reduce maternal mortality by 25%.³ The difference in the hemoglobin level in the intervention group (0.2365 g/dl) was marginal. But sustained counseling on nutrition and IFA supplementation, leading to improved compliance of IFA consumption and adequate weight gain, can improve the population hemoglobin levels of pregnant women and thereby reduce maternal mortality.

CONCLUSION

Anemia has continued to be a major problem even in a developed state like Tamil Nadu. Lack of knowledge on the benefits of IFA tablets and misconceptions about its side effects has led to poor compliance. Lack of information on the various sources of iron rich foods and its importance are other factors contributing to low hemoglobin levels in women. Iron absorption is particularly efficient during pregnancy and there is a great opportunity to provide, encourage, and monitor the use of supplements during pregnancy.³ The health system, in addition to provision of IFA supplementation, should focus on providing regular counseling services in health facilities to enable pregnant women to understand the importance of adequate nutrition and strict adherence to IFA supplementation. In addition other measures like sanitation, literacy status, etc. should also be addressed to combat anaemia.

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Source of Support: None Declared
Conflict of Interest: None Declared