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Efficacy Of Directly Supervised Oral Iron Supplementation During Pregnancy A Randomized Controlled Trial

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Abstract:
Background: *Anaemia is the most common health issue all around the world. In India, 50 % of pregnant women suffer from anaemia [1]. The study aims to assess the rise in Hb intake of oral iron supplementation during pregnancy, estimate the decrease in prevalence of anaemia and compare the compliance to oral supplements between the directly supervised group and the control group.*
Materials and Methods*: This is a community-based RCT conducted on 200 pregnant women in a rural setting in Tiruvallur, allocated into two groups. In the intervention group, the first dose of IFA intake for every week was supervised by ASHA and given and the remaining tablets for the week were given to the antenatal women. In the control group, the IFA tablet is given to the antenatal women without direct supervision.*
Results: *Oral iron supplements were given for 100 days and there was a 6% increase in Hb level in the directly supervised group compared to the control group. The percentage of compliance in the intervention group was 6.7% higher than the control group.*
Conclusion: *There is an increase in the haemoglobin level in pregnant women in the directly supervised group.*
Keywords: *oral iron supplements, anaemia prevalence, pregnant women, directly observed.*

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I. Introduction

Anaemia is one of the most common health problems, mainly affecting reproductive age women which lead to an increase in maternal morbidity and mortality in the world. In India, most pregnant women suffer from Iron deficiency anaemia. The higher population are from low socio-economic status. Directly observed oral supplements increase compliance which leads to an increase in the haemoglobin level in pregnant women.[1]

Definition [WHO]: Anaemia is a condition in which the number of red blood cells (consequently their oxygen-carrying capacity) is insufficient to meet the body's physiological needs. It varies with person's age, gender, residual elevation above sea level(altitude), smoking behaviour and different stages of pregnancy.[2]

	NORMAL (g/dl)	MILD (g/dl)	MODERATE (g/dl)	SEVERE (g/dl)
Non-pregnant (15 yrs. & above)	>12	11-11.9	8-10.9	<8
Pregnant	>11	10-10.9	7-9.9	<7

II. Materials and Methods

This randomised controlled trial study was conducted in the rural setup in Tiruvallur with 200 antenatal women from 12-28 weeks of pregnancy. Study period: Apr 2023- Nov 2023. It is conducted with proper written and informed consent from the antenatal women.

Study Design: Randomised controlled trial study

Study Location: This study was done in the rural setting of Tiruvallur district, under peripheral health centres affiliated to a tertiary care teaching hospital-based study done in the Department of Obstetrics and Gynaecology, at Indira Medical College and Hospital, Pandur, Tiruvallur.

Study Duration: April 2023- November 2023.

Sample size: 200 patients.

Sample size calculation: The sample size was estimated based on a single proportion design. The study population are selected randomly from PHC affiliated to Indira Medical College and Hospital, Pandur, Tiruvallur. Subjects are divided randomly into a control (100 samples) and an intervention group (100 samples).

Subjects & selection method: The study population was drawn from registered pregnant women aged more than or equal to 15 years, and randomised into control and intervention groups.

Inclusion criteria:
1. Antenatal mothers, who are registered during the first trimester.
2. Aged ≥ 15 years.
3. Women 12- 28 weeks of pregnancy.

Exclusion criteria:
1. Severe anaemia.
2. Patients who already took iron supplements for >1 week in the past 1 month.
3. Pregnant women with comorbid conditions.
4. Aged < 15 years.

Procedure methodology

After obtaining written and informed consent from the subjects, the study population was randomised into control and intervention groups with a sample size of 100 each. Initial Haemoglobin levels were measured on day 0(before oral iron supplements). Each Iron Folic acid (IFA) tablet contains 100mg of elemental iron and 0.5mg of folic acid. Generally, an IFA supplement is prescribed once daily for prophylactic therapy and twice daily for therapeutic therapy [1].

For both groups, IFA supplementation was started at the 12th week of gestation. In the intervention group, the first dose of every week is given by the ASHA. In the control group, tablets for one month are given to the antenatal women. After 100 days of completion, again Hb% for both groups are done and the values will be estimated and compared.

Compliance rate of the subjects is calculated and expressed as a percentage. It is calculated by,

Compliance rate = No. of tablets consumed / No. of tablets prescribed

III. Result

After 7 months of the study trial, out of the 200 antenatal women who were randomly selected, 2 women had an abortion from the intervention group during the trial and two lost follow-up from control group. So, a total of 196 samples completed the study.

Table 1 shows the distribution of subjects concerning demographic characteristics.

Table no 1: Distribution by demographic characteristics

VARIABLES		CONTROL n (%)	INTERVENTION n (%)
AGE	18-27 yrs.	95 (95%)	97 (97%)
	>28 yrs.	5 (5%)	3 (3%)
PARITY	< 3	90(90%)	85(85%)
	>3	10 (10%)	15 (15%)
BIRTH INTERVAL	<1	23(23%)	25(25%)
	1-2	62(62%)	57(57%)
	>3	15(15%)	18(18%)
RESIDENCE	Urban	15 (15%)	18(18%)
	Rural	85(85%)	82(82%)
	Illiterate	10(10%)	9(9%)
	Primary	10(10%)	10(10%)

EDUCATION			
	Middle	45(45%)	47(47%)
	High school	16(16%)	15 (15%)
	Intermediate	4(4%)	4(4%)
	Graduate & above	15(15%)	15(15%)

Table 2 depicts the baseline haemoglobin values of subjects.

Table no 2: Baseline Haemoglobin values taken on Day 0 *(before oral iron supplements)

Baseline haemoglobin	**Control group** (n=98)	**Interventional group** (n =98)
Mild (10-10.9)	55	53
Moderate (7-9.9)	35	39
No anaemia (>11)	8	6
Baseline prevalence of anaemia	98(91.8%)	98(93.9%)

Table 3 depicts the endline haemoglobin values of subjects.

Table no 3: Endline Haemoglobin values taken on Day-100 *(after oral iron supplements)

Endline Haemoglobin	**Control group** (n=98)	**Interventional group** (n =98)
Mild (10-10.9)	52	45
Moderate (7-9.9)	32	35
No anaemia (>11)	14	18
Baseline prevalence of anaemia	98(87.8%)	98(81.6%)

Compliance rate is calculated as follows,
In the control group= 70.1% and in the intervention group = 63.4%.
Forgetfulness (39.6%) and side effects (30%) were present. Oral iron supplementation was given despite side effects.

IV. Discussion

According to WHO, in India 10- 15% of maternal deaths are due to anaemia. The prevalence of anaemia before therapy was 91.8% in the control group and 93.9% in the intervention group. There is a 6% reduction the intervention group when compared to the control group. The efficacy of oral iron supplements is mainly due to poor compliance. Thus, under direct supervision in the intervention group, the compliance rate has been increased. But 87.7% and 81.6% were still anaemic in the control and intervention groups respectively.

In pregnancy, women need an extra 1000mg of iron to meet the extra requirement for 3-6 months [1]. Oral supplements for 100 days are sufficient enough to increase the haemoglobin level and prevent further fall in anaemia.

The dropouts from the study were 4%. This doesn't affect the study in any manner. Forgetfulness (39.6%) and side-effects (30%) were low in the intervention group. Direct supervision in IFA supplementation reduces forgetfulness and thus improves compliance with tablets. Earlier studies had reported the positive role of directly observed IFA supplementation in improving compliance with IFA tablets [6]. Studies have found side effects from IFA supplementation as an important contributor to non-compliance [7][8].

V. Conclusion

Anaemia in pregnancy can be prevented by direct supervision or by proper counselling and motivation during the antenatal period. Direct supervision improves compliance to IFA supplementation in the reduction of anaemia prevalence in comparison to the control group.

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