

Role Of Family-Centered Educational Approach In Medication Adherence

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ABSTRACT

Anaemia is defined as haemoglobin (Hb) below two standard deviations of average for age and gender. The common type is iron deficiency Anemia (IDA), which shows microcytic and hypochromic red cells on the peripheral smear. Management includes treating underlying causes and iron supplementation. Iron supplementation is most commonly used in oral form, but rarely requires intravenous iron. Around 25% of people have anaemia globally. Iron deficiency is responsible for 50% of all anaemias. The prevalence of IDA in men under 50 is 1%. In women of childbearing age, the rate is 10% due to losses from menstruation, and one-third of children aged 12 to 36 develop anaemia. Low-income families are particularly at high risk of IDA.1-2

Successful treatment implies 2-g/dL Hb raise in 3-4 weeks. So, taking 70-mg tablet of elemental iron, three times a day, is one of the best ways to treat IDA as per previous studies. Hence, we considered checking for Hb levels after a minimum of 3 weeks of oral iron therapy in the current study. 3-4 Hence, we considered

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INTRODUCTION

Anaemia is defined as haemoglobin (Hb) below two standard deviations of average for age and gender. The common type is iron deficiency Anemia (IDA), which shows microcytic and hypochromic red cells on the peripheral smear. Management includes treating underlying causes and iron supplementation. Iron supplementation is most commonly used in oral form, but rarely requires intravenous iron. Around 25% of people have anaemia globally. Iron deficiency is responsible for 50% of all anaemias. The prevalence of IDA in men under 50 is 1%. In women of childbearing age, the rate is 10% due to losses from menstruation, and one-third of children aged 12 to 36 develop anaemia. Low-income families are particularly at high risk of IDA. Successful treatment implies 2-g/dL Hb raise in 3-4 weeks. So, taking 70-mg tablet of elemental iron, three times a day, is one of the best ways to treat IDA as per previous studies. Hence, we considered checking for Hb levels after a minimum of 3 weeks of oral iron therapy in the current study.

Medication adherence is defined as extent to which a person's behaviour like, taking medication, lifestyle changes, following particular diet, in par with recommendations of a health care provider. Poor adherence to medication regimens was recognized as a substantial roadblock in reaching better outcomes among patients with chronic diseases. Previous data proved that around 50% of the patients do not adhere completely to their prescription advice.⁵

Family-centred care is defined as the "provision of healthcare in a partnership or in recognition that family has a vital role to play in treating persons living with chronic disorders. It is an approach to responding to the values, and cultural needs of the patient and family members. Family-centred health educational approach can reduce non-adherence and can bring better health outcomes in the community. The study done by Palivela et al.⁶ concluded that direct monitoring of intake of iron supplements by family members improved medication adherence among pregnant women. Provision of healthcare in a partnership or in recognition that family has a vital role to play in treating persons living with chronic disorders constitutes family centred approach.

Vital principles of this approach include: 7-9

- 1. Fostering the strengths of patient and family and encouraging partnership between them
- 2. Treating patients with dignity and respect
- 3.Improving communication between patients and families
- 4. Considering family as main source of information about healthcare needs.

IDA is a global problem affecting about 52% of pregnant women¹⁰. Poor compliance or adherence due to gastrointestinal side effects is one of the limitations of iron intake.¹¹ IDA during pregnancy is a serious issue around the world, as per the World

Health Organization (WHO), and prevalence rates ranges from 14% among pregnant women in developed countries to 56% (range 35-75%) in low income or developing countries.¹²

As more than 2 billion people, or above 30% of the global population, are iron deficient, with differing distribution, frequency, and contributing reasons in different areas of world, the number of patients with ID and IDA is staggering. ¹³

In a study bySeck B et al. authors found that iron supplements been shown ineffective due to low compliance and summated importance of usage of iron supplements andbenefits reaped out of the tablets usage in pregnant women. ¹⁴ One study found noncompliance was mainly due to inadequate supporting programs, ineffective service delivery, insufficient supplies and access, reduced motivation by healthcare professionals, misconceptions about instructions, related to side effects, misinformed beliefs of having the big babies and fear of treatment costs. ¹⁵ Another study noted necessity for appropriate counselling and awareness towards anemia and its prevention, treatment. It further showed the need for institutional facilities that help in raising its awareness ¹⁶ Lavanya P et al. ¹⁷ did a study cross-sectional analytical design on 340 pregnant women. and found factors affecting adherence to iron and folic acid supplementation were being primigravida nonanemic in the first trimester and absence of side effects to medications. In view of high burden we would like to see if there is a role of family members and counselling in improving medication adherence.

AIM & OBJECTIVES

Aim:

To know the role of a family-centred health education approach in improving medication adherence to iron supplements among pregnant women.

Objectives:

1.To see adherence levels before and after the introduction of the approach.

2.To check improvement in Hemoglobin(Hb) levels before and after the approach.

MATERIAL AND METHODS

Study site and duration:

The study was carried out at a tertiary care center for one and half months from September to October 2023. 15 days for patient recruitment. 30 days for observation of the effectiveness of the approach.

Sample size: 200 patients were included.

Study type: Interventional study.

Sample size calculation: As per the study done by Bentley et al. 18 the prevalence of anemia in India was 52%.

Using the sample size formula $N=Z^2PQ/E^2$

Error: 5%, Confidence levels: 80%

The minimum sample size came to 164. So, we included 200 patients, considering few lost to follow-ups.

Inclusion criteria:

□Pregnant women aged above 18 years.	
□ Pregnant women with IDA- IDA was diagnosed as per Hb levels (Below 10g/dl).	
□Women who provided informed consent	
□ Pregnant women with Hb levels varying from 8 to 10 g/dl.	
□Patients coming to the OPD with their family members (minimum 1 family member)	
Exclusion criteria:	
□Women with twin pregnancy	

□Women who came alone or along with their friends or other members apart from their family members.

□ Pregnant women with known diabetes, hypertension, epilepsy, HIV, tuberculosis and thyroid abnormalities.

Randomization and allocation concealment

Participants were randomly assigned into two groups (Group A and Group B) using acomputer-generated simple random sequence created in Microsoft Excel. Allocation was performed in a 1:1 ratio. To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes (SNOSE) were used. Each envelope contained the group assignment, and envelopes were opened only after obtaining informed consent and enrolling the participant. Because the intervention involved counselling, blinding of participants and investigators was not feasible; however, outcome assessment (Hb measurement) was carried out by laboratory personnel who were unaware of group allocation.

Group A patients received the counselling plus standard care 100 patients.

Group B patients did not receive counselling-100 patients but standard care.

Medication adherence was assessed using self designed questionnaire: Score varies from 0 to 30. Medication adherence questionnaire was shown in Table 1.

Table 1 Showing self designed questionnaire:

Item				Highest Score
Q1. Taken recommended medication dose (last 10 days)		0–5	0	5
Q2. Taken recommended number of medications (last 10 days)	Scale 0–5	0–5	0	5
Q3. Taken medications at prescribed time	Scale 0–5	0–5	0	5
	J -	0–2	0	2
Q5. Times ran out of medicines in last week(Negative qns- reverse coded)		0–5	5	0
Q6. Checked right composition/dose/time for family member	Scale 0–5	0–5	0	5
Q7. Hb levels	Post Hb -Pre Hb difference: below 1: Score 1, difference 1-2: Score: 2, Difference above 2: Score 3 No improvement score: 0	0–3	0	3

Table 1: Self Designed Questionnaire for assessing medication adherence

- •Q1–Q3: Higher scores indicate better adherence. Each item is scored Likert scale. 0 representing *no adherence* and 5 representing *full adherence* over the last 10 days.
- ··Q4:Scores range from 0 (Never) to 2 (Always), reflecting increasing adherence-supportive behaviour.
- •Q5 (Reverse-coded item): More frequent running out indicates poorer adherence.

Reverse scoring is applied: 0 times = Score 5; >4 times = Score 0, ensuring alignment with adherence direction.

•**Q6:** Scored 0–5, with higher scores indicating greater involvement and adherence.

Q7: Higher scores reflect better biochemical response related to adherence.

Validation of the questionnaire

Self-designed seven-item questionnaire was used to assess medication adherence. Content validity was established through expert review by two faculty members from the Department of Obstetrics, who evaluated each item for relevance, clarity, and appropriateness. The questionnaire was piloted on 20 pregnant women with iron deficiency anaemia who were not included in the final study sample. Minor modifications in wording and response options were made based on feedback.

Internal consistency reliability was assessed using Cronbach's alpha, which showed good reliability for the overall scale (**Cronbach's** $\alpha = 0.81$). Item-total correlations ranged between 0.42 and 0.67, indicating acceptable inter-item coherence. This tool was therefore considered suitable for evaluating medication adherence in the present study population.

Study Flow

364 pregnant women were screened for eligibility. Of these, 156 were excluded (12 did not meet inclusion criteria. The remaining 208 participants were enrolled and randomized into Group A (n=106) and Group B (n=102). At 30-day follow-up, 100 participants in Group A and 100 in Group B completed outcome assessment. CONSORT flow diagram was given.

After taking informed consent from the patients, study patients along with family members were given a questionnaire before implementing the "Family-centred Health Education Approach" during their 1st visit to the hospital (Starting visit as per the study). Haemoglobin levels were measured. Counselling was given on-site for around 30 minutes to patients and their family members regarding medication adherence. Patients were asked to come to the hospital again at the end of 30 days. Hb levels were measured at the end of 30 days and the same questionnaire was administered to all patients. Pre- and post-approach scores were compared.

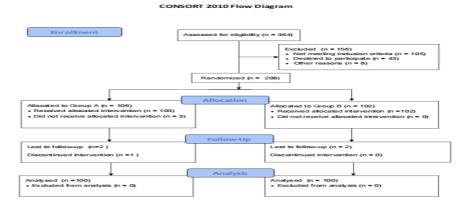


Figure 1: Consort flow diagram

Standard care:

Supplements: Supplement used was ferrous ascorbate 100mg and folic acid daily twice a day(total 2 tablets one hour before food) for all patients for 1 month.

Mean medication adherence score was compared before and after the approach for both groups.

Implications: Patients' non-adherence is a major issue, especially for iron supplements globally. Using compliance aids, proper motivation & support from family also proved to increase medication adherence. Physicians should consider our approach with a few modifications as part of their management plan, leading to the prevention of early complications. Ethical considerations: Permission was taken from the Institutional ethical committee attached to the tertiary care center for conducting the study. Informed consent was taken from every participant.

Statistical analysis: The data were entered in MS Excel 2023 and analysis was carried out using statistical software called Epi info. version 7.2.5 free version. Frequencies and percentages were used. Comparison between mean pre-test and post-test scores was done using the paired student's T-test. Comparison of post test scores between A and B groups was done using unpaired students T test. Comparison between categorical parameters between A and B groups was done using Chi square test.P value less than 0.05 is considered significant.

RESULTS

The current study included 200 pregnant women visiting our tertiary care center.

They were divided into 2 groups (A and B).

Most of the patients belonged to the age group 21 to 30 years in the current study.

There is no significant difference in the mean age of patients of both groups. (P=0.3). This implies that there is no age-related bias in between two groups. Mean age was 22.93 years in Group A and 23.4 years in Group B.

Most of the women belonged to 3rd trimester. There is no significant difference in trimester of pregnant women of two groups. (p=0.06)

Most of the pregnant women were multigravida. There is no significant variation in the parity status between two groups. Most of the patients followed mixed diet. There is no significant difference in diet pattern between two groups. This implies that both groups are comparable at baseline with no variations in demographic variables. It was given in Table 2.

% Variable Category / Group Frequency Statistical Test Mean age (years) Group A Mean = 22.93 ± 3.80 t = -1.04, p = 0.3014Mean = 23.49 ± 3.83 (No significant difference) Group B 20 10.0 1st trimester Trimester 2nd trimester 36 18.0 $72.0 \ \chi^2 = 5.56, p = 0.062$ 144 3rd trimester 200 100 Total (No significant difference) 108 54.0 Parity Multigravida $46.0 \quad \chi^2 = 3.95, p = 0.047$ 92 Primigravida Total 200 100 Diet pattern Mixed diet 135 67.5 Vegetarian 65 $||32.5||\gamma^2 = 0.0228, p = 0.88$ Total 200 **100** (No significant difference)

Table 2: Baseline Demographic Characteristics of the Participants (N = 200)

Mean age was analysed using an independent samples t-test, categorical variables were compared using the Chi-square test. No statistically significant differences were seen in age group, trimester, or diet pattern between the two groups, indicating that the groups were comparable at baseline.

Change in hemoglobin levels:

The mean overall baseline Hemoglobin levels were 9.1 ± 0.6 gm/dl. There is no significant difference in the baseline Hb levels between two groups. There is a significant difference in the mean Hb levels after 1 month in between two groups. Mean Hb levels were more in group A patients (who were given family centered approach- counselling) compared to group B patients. Mean Hb levels in Group A after a month: 9.51 ± 0.6 . It was 9.20 ± 0.67 g/dl in Group B. P=0.0007. Visual deptiction was shown in Figure 2.

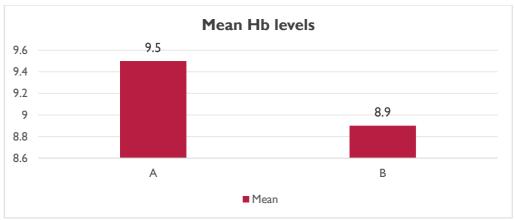


Figure 2: Hemoglobin levels after one month in both groups.

Score components and comparison between groups:

There is significant difference in behavior pattern in between A and B groups. It was more for Group A patient. Score components were mentioned in Table 3.

Variable	Group	N	Mean	SD	t-value	p-value
Taking recommended medications	A	100	3.45	1.132	11.080	.000
	В	100	1.90	0.823		
Taking recommended dose	A	100	3.47	1.077	18.221	.000
	В	100	0.98	0.841		
Taking medications on time	A	100	2.83	0.995	8.942	.000
	В	100	1.47	1.150		
Carrying medications during travel	A	100	1.46	0.521	10.208	.000
	В	100	0.64	0.612		
Times ran out of medicines	A	100	1.11	0.852	-5.842	.000
	В	100	2.30	1.850		
Checked right for family member	A	100	2.40	1.231	9.892	.000
	В	100	0.94	0.814		
Hb difference score	A	100	0.96	0.585	9.041	.000
	В	100	0.28	0.473		

Table 3: Comparison of score components in both groups

Score improvement in group A:

There is significant improvement in the score from baseline to end of 1 month of counselling in the current study as evident from p value (0.0001). This implies that there is significant improvement in patient's compliance towards iron medications in group B. It was shown in Figure 3.



Figure 3: Score improvement in group A.

DISCUSSION

The current study assessed the effect of family centered health education approach or counselling in medication adherence among pregnant women with anemia.

The study was done for 1 and half month- from September to December 2023.

100 pregnant women of group A received family centered health education approach or counselling and 100 women of group B didn't receive counselling. We found significant improvement in medication adherence in group A patients compared to group B patients.

In the study of Gereklioglu C et al.¹⁹ 96 females in their reproductive age were included. The mean age was found to be 30 years. Age ranged from 18 to 53 years, while in our study, the mean age was 24 years. The mean age was less comparatively in the current study, due to inclusion of only pregnant women aged 19 to 40 years. 6% of patients didn't use the medication regularly or during the recommended duration.

Gorbhani et al.²⁰ did a quasi-experimental study of on 70 women. Questionnaire was used as a research tool. Pre-intervention and post intervention scores were compared similar to the current study. The intervention used was family-centered care program similar to the current study. There is significant difference in scores before and after FCC, similar to the current study. There is significant difference in scores between two groups (cases with anemia and controls) similar to the current study.

In a study by Siddharudha Shivalli et al. effectiveness of FCA (family centered approach) in relation to health issues in urban part of Mangalore in India was understood. Total of 809 families were examined. It took into consideration of various social, ethical and religious issues that in turn effects various morbidities like malaria and maternal, children health care issues. With necessary interventions to develop FCC, patients and people perceptions were improved and there was an increase in service utility. In a study by Alina Gast et al. systematic search for literature in MEDLINE and Embase was done. A total of 21 systematic reviews on 8 conditions for assessing adherence to medications were included. Socioeconomic status and social support found to have a positive impact on adherence and patients with ethnic minority had a negative impact on adherence. Therapy-related factors and disease-related factors (like duration) showed no effect on adherence. Age had a concave relation to adherence, Depression has a negative impact on adherence. ²² In a study done by J M Polinski et al. barriers to adherence of antihypertensive medication were assessed. Authors showed the importance of decision making and supporting interventions that in turn improve the trust between patient and prescriber, enhancing prescribers' credibility for effective approaches to improve adherence by patients. ²³

LIMITATIONS:

The study was conducted at a **single tertiary care centre**, which may limit the generalizability of the findings to wider populations.

The **follow-up duration was restricted to 30 days** because the project had to be completed within the mandated 60-day period. As part of a**funded project**, the study design and timelines were fixed, preventing longer-term assessment of adherence and haemoglobin trends.

Blinding was not feasible due to the nature of the counselling intervention, which may introduce some degree of performance bias.

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CONCLUSION

The current study assessed the effect of family centered health education approach or counselling in improving medication adherence among pregnant women with anemia.

Medication adherence was assessed using a questionnaire at baseline and again after 1 month of counselling. There was significant improvement in total score from baseline to 1 month in counselling group. This implies that there is significant improvement in medication adherence to iron supplements at the end of 1 month in group A patients. While the questionnaire provided good internal consistency, future studies may consider expanding the number of items or incorporating objective adherence measures (such as pill counts or electronic monitoring) to further enhance the tool's robustness and predictive validity.

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