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Impact of Pharmacists' Care in Improving Adherence to Oral Iron Supplementation among Anemic Women

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ABSTRACT

INTRODUCTION: Anemia is one of the major challenging conditions that impair women's health, the most prevalent being iron-deficiency anemia. Intake of oral iron supplementation is associated with various gastrointestinal side effects. This results in reduced adherence to the prescribed medications, leading to worsening of pre-existing symptoms and complications affecting the overall health. Pharmacists are well equipped to educate the patients, thereby help in enhancing their adherence to the medications and hence improve their health. **AIM:** The aim of the study was to determine the impact of pharmacist's care in improving the health among anemic women by enhancing their adherence to oral iron supplementation. **METHODOLOGY:** This is a prospective, interventional study carried out in Obstetrics and Gynecology department, in a tertiary care hospital, India among women prescribed with oral iron supplementation. Participants' symptoms, side effects, medication adherence and causes of non-adherence were recorded and education was given to patients with low adherence. **RESULT:** A total of 250 patients were included, out of which 172 (68.8%) were low adherent. The most frequently complained symptom of anemia was fatigue (58.4%). The main side-effects due to iron supplementation were nausea (31.2%) and black stools (32%). and the main cause of non-adherence was forgetfulness (97.3%). After a period of one month, there was a significant improvement in medication adherence in pharmacist care group (31.52%) when compared to control group (4.86%). **CONCLUSION:** This study concluded that pharmacists' care improved health of anemic women by enhancing their adherence to oral iron supplementation.

INTRODUCTION:

Anemia is defined as a condition wherein the hemoglobin level is less than 13 g/dl in men or less than 12 g/dl in women. According to the WHO, as many as two million people (30% of the world's population) are anemic; and four to five billion people (66%-80% of the world's population) may be iron deficient. [1] The laboratory data from the third National Health and Nutrition Examination Survey reports anemia prevalence is 5.9% in teenage girls, 5.8% in young women, and 4.4% in elderly women. [2]

Anemia can occur in all age groups, gender, and race. However women in the reproducible age group are more prone to anemia, the most pertinent factors being blood loss during menstruation, pregnancies, and loss of iron through breastfeeding. [3] Anemia in Indian women is predicted by both biological and socio-economic factors, i.e., unique confluence of biology (such as sub-optimal gastric acidity for iron absorption), culture (like early marriages leading to early childbearing age and multiple pregnancies), and great variations in relative affluence and education. [4]

The importance of anemia is often overlooked and undertreated. Evidence suggests that anemia is not an innocent bystander; it can affect both length and quality of life. [5] Fatigue is the principle symptom of anemia, but other associated symptoms like headache, dizziness, palpitation and breathlessness can also adversely affect the patients' functional activities. This suggests that even mild anemia (10-12 g/dl) can substantially impair quality of life and thus it needs to be diagnosed early and the treatment should be started as soon as possible.

Among the different types of anemia, Iron Deficiency Anemia (IDA) is the most common type that affects adolescent girls, and women in reproductive age group. IDA is often treated with oral iron supplement followed by intravenous iron in severe conditions. But long-term use of oral iron is limited by gastrointestinal side effects including nausea, vomiting, constipation, diarrhea, abdominal discomforts, black stools, and metallic taste; these side effects are frequent and, although not severe, are often worrisome to patients. The presence of side effects and fear of adverse drug reactions were found to contribute to reduced adherence to oral iron supplementation. [6]

The consequence of non-adherence is waste of medication, disease progression, reduced functional abilities, and a lower quality of life, increased use of medical resources such as nursing homes, hospital visits and admissions resulting in increased health care costs.

Medication nonadherence can have negative consequences not only for the patient but also for the provider and the physician. Improving medication adherence helps to avoid higher risk of severe relapses, further complications, and preventable hospitalizations. [7]

In a study conducted to assess the role of pharmacist's interventions in patients with depression, the results show significant positive effect on medication adherence and treatment satisfaction, when compared to patients who received only the routine medical care.[8] A study focused on evaluating the importance of pharmaceutical care among hypertensive patients revealed that pharmacist-initiated educational interventions increase patients' knowledge about their condition that positively modifies their beliefs about medicines leading to improved medication adherence.[9] Studies also indicate that pharmacist-led intervention can improve medication compliance even in patients with relatively high compliance. Hence, individualized pharmaceutical care can improve the medication adherence of patients with a potential improvement in the clinical outcomes. By taking pharmaceutical care focused on the patient and working together with doctors in the process of care, the clinical pharmacists are able to provide better support for the patients with low medication adherence. [10]

Anemia, its symptoms and its complication has been largely studied and is well-documented. Studies focusing on the side effects due to oral iron supplementation and how it affects the adherence among anemic women have also been done. But studies relating to the role of clinical pharmacist in improving the adherence to oral iron supplementations are very few. This study aims at determining the impact of pharmacist's care in enhancing the adherence to oral iron supplementation among anemic women.

METHODOLOGY

Study Setting and Design:

This is a prospective, interventional study, conducted in the Obstetrics and Gynecology department of a tertiary care hospital, in Tamil Nadu, India, for a period of 9 months from December 2016 to August 2017.

Study Tools:

The data source included reviewing patient medical record and direct patient interview. This study used self-prepared, internally validated Anemia Assessment Tool, designed to assess the patient demographic details, past medical and medication history, symptoms of anemia, and side effects experienced due to oral iron supplementation. The Morisky Medication Adherence Scale (MMAS-8) was used to determine the level of adherence to prescribed oral iron supplementation, along with the possible causes leading to non-adherence.

A Patient Information Pamphlet containing information regarding anemia and its causes, symptoms, diagnostic tests, dietary approaches, treatment options, along with various methods to combat the common side effects due to oral iron supplements was prepared and used to educate patients with low medication adherence.

Eligibility Criteria:

This study included women of aged 18 years and above who were prescribed with oral iron supplementation either for the treatment or prophylaxis of IDA for a period of at least one month. Women with diagnosis of sickle cell anemia, thalassemia, psychiatric illness, and those who were not able to provide the required information were excluded from the study.

Randomization:

Once the initial assessment of the participants was completed, those with low medication adherence were divided equally into two groups using simple randomization method. The group that received both routine medical care along with pharmaceutical care was termed as the test group and the group in which the participants received only the routine medical care was termed control group.

Statistical Analysis:

SPSS version 23 was used for statistical analysis. Student t-test was done to analyze the data, pre and post pharmacists' intervention. Results with $P< 0.05$ were considered as statistically significant.

Ethical Considerations:

Ethical clearance and approval for the study was obtained from The Institutional Human Ethics Committee, PSG Institution of Medical Science and Research. The study presents no more than minimal risk of harm to the participants. Written consent was obtained from all the participants after explaining the purpose of the study, risk/benefits, confidentiality of records, right to refuse or terminate the participation in the study at any time.

RESULTS:

A total of 250 women met with the eligibility criteria and were recruited for the study. The average age of the participants was found to be 26.43 years. On the basis of their occupational status, 21.6% of the participants were found to be working and the remaining 78.4% were homemakers.

Table 1: Age wise distribution of participants.

Age Group (Years)	Participants (n= 250)	
	No. of Participants	Percentage (%)
18-22	42	16.8
23-27	130	52
28-32	58	23.2
33-37	20	8
TOTAL	250	100

The various symptoms due to anemia were assessed, majority of participants complained of fatigue (58.4%), followed by headache (33.6%) and dizziness (32.8%). On assessing the various side effects due to iron supplements; most of participants complained of black stool (32%), followed by nausea (31.2%) and vomiting (30.4%)

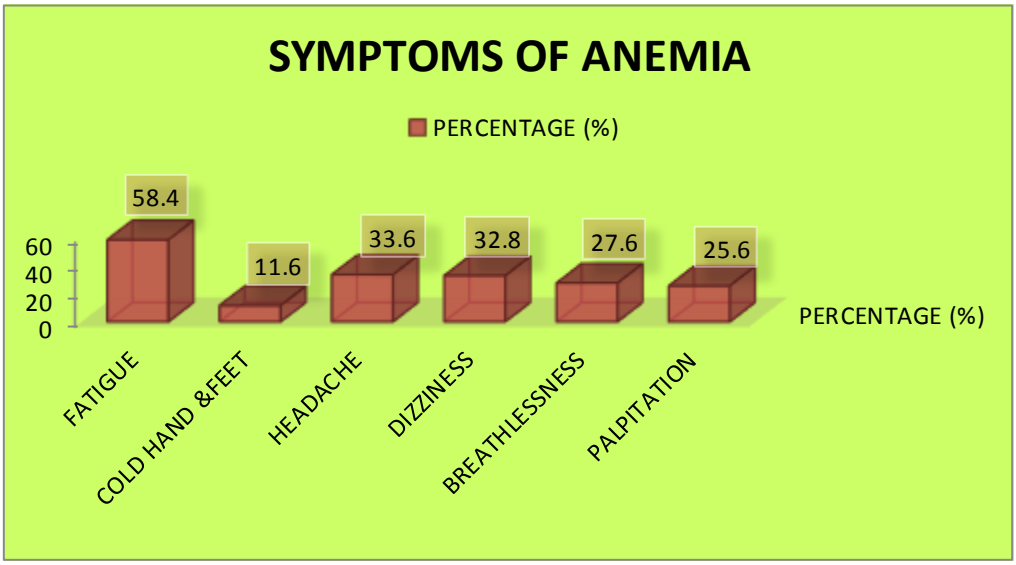

Figure 1: Frequency distribution of commonly experienced symptoms of anemia.

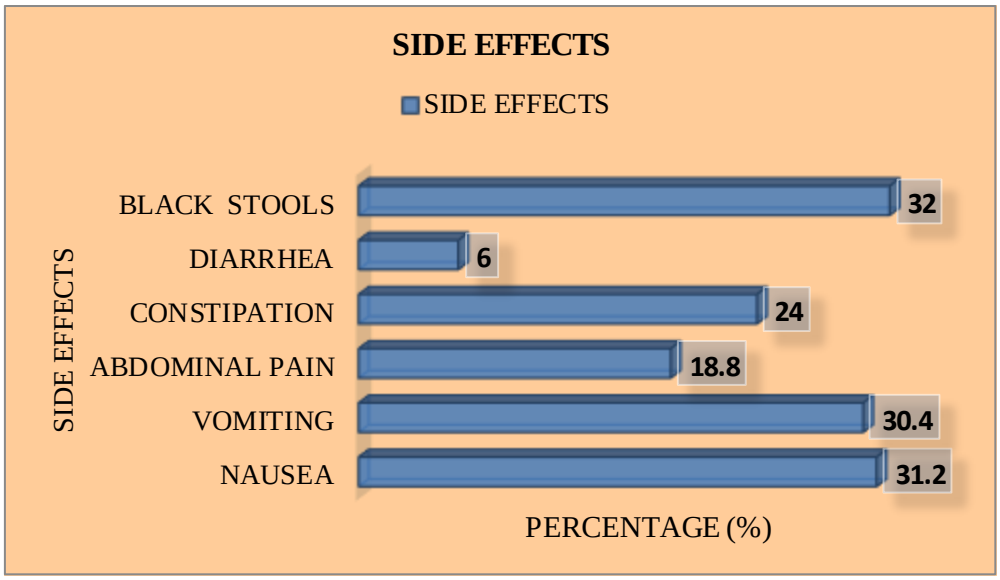

Figure 2: Frequency distribution of side effects of oral iron supplements.

Among the 250, 78 participants (31.2%) were found to have high to medium adherence and the remaining 172 participants (68.8%) had low adherence. The average medication adherence score using MMAS-8 was found to be 3.69. Various causes of non-adherence were assessed and forgetfulness (97.3%) was found to be the main cause of their non-adherence**.** The other causes included busy lifestyle (40%) and side-effects (24%).

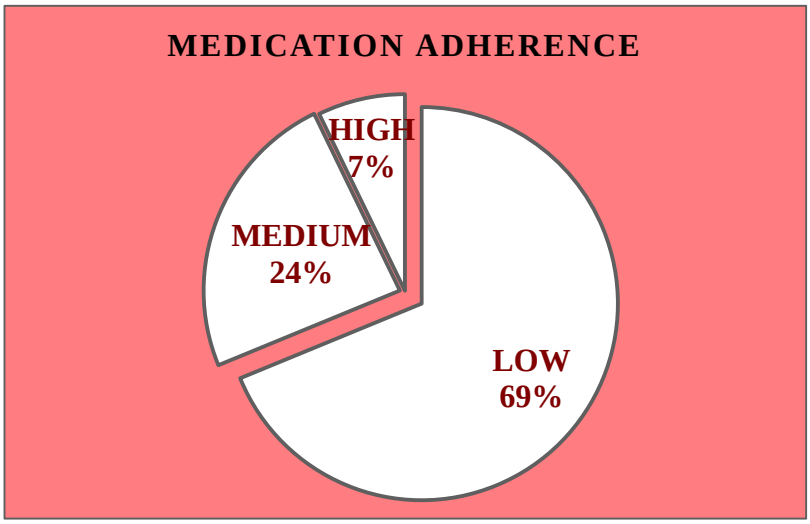

Figure 3: Frequency distribution of medication adherence of participants.

Table 2: Frequency distribution of various causes of non-adherence to oral iron supplementation.

Causes	No. of Patients	Percentage (%)
Forgetfulness	167	97.09
Busy Life Style	40	23.25
Side Effects	24	13.95
Complex Regimen	18	10.46
Poor Physician- Patient Relationship	3	1.74

The average score of symptoms at baseline and at review of the test and control group were compared using Student t-test. A significant improvement was seen for all the symptoms in test group (p-value <0.05); whereas in control group, a significant improvement was seen only for dizziness (p = 0.021). On comparing the average score of side effects at baseline and at review of the test and control group, all improvements in side effects for test group were found to be significant, except for diarrhea (p=0.058); whereas in control group, all improvements were insignificant (p-value >0.05), except for nausea (p=0.000) and vomiting (p=0015).

Table 3: Comparison of symptoms at baseline and at review.

Sl. No	Symptoms	BASELINE Average score		REVIEW Average score		P value	
		Test Mean± SD	Control Mean± SD	Test Mean± SD	Control Mean± SD	Test	Control
1	Fatigue	1.270± 1.123	1.000± 1.040	0.325± 0.518	1.127± 1.049	**0.000**	0.303
2	Cold hands& feet	0.448± 0.909	0.127± 0.454	0.034± 0.185	0.162± 0.481	**0.012**	0.442
3	Headache	0.627± 0.958	0.581± 0.900	0.104± 0.376	0.407± 0.725	**0.000**	0.071
4	Dizziness	0.755± 1.050	0.674± 1.022	0.116± 0.357	0.441± 0.820	**0.000**	**0.021**
5	Breathlessness	0.767± 0.990	0.500± 0.917	0.104± 0.343	0.325± 0.676	**0.000**	0.075
6	Palpitation	0.593± 0.962	0.453± 0.849	0.081± 0.314	0.372± 0.720	**0.000**	0.388

Table 4: Comparison of side effect at baseline and at review.

Sl.No	Side effects	BASELINE Average score		REVIEW Average score		P value	
		Test Mean± SD	Control Mean± SD	Test Mean± SD	Control Mean± SD	Test	Control
1	Nausea	0.593± 0.986	0.523± 0.877	0.116± 0.357	0.209± 0.511	**0.000**	**0.000**
2	Vomiting	0.651± 1.060	0.360± 0.765	0.209± 0.596	0.174± 0.513	**0.000**	**0.015**
3	Abdominal pain	0.523± 0.942	0.209± 0.652	0.127± 0.454	0.162± 0.550	**0.010**	0.550
4	Constipation	0.546± 0.821	0.302± 0.633	0.220± 0.582	0.209± 0.511	**0.000**	0.175
5	Diarrhoea	0.069± 0.256	0.046± 0.303	0.011± 0.107	0.046± 0.261	0.058	1.000
6	Blackcolour stool	0.662± 0.989	0.511± 0.979	0.453± 0.713	0.460± 0.859	**0.002**	0.200

When improvement in medication adherence was assessed, test group participants showed a significant change with average Morisky score at baseline, 5.279 decreasing to 2.127 at review (p value=0.000). Whereas in the case of control group, the average score at baseline 4.718 decreased to 4.232 at review, which was not significant (P value=0.292).

Table 5: Comparison of medication adherence at baseline and at review

Medication Adherence	BASELINE Average score		REVIEW Average score		P value	
	Test Mean± SD	Control Mean± SD	Test Mean± SD	Control Mean± SD	Test	Control
	5.294± 1.617	4.418± 1.475	2.141± 1.760	4.232± 2.236	0.000	0.292

Table 6: Improvement in total average score from baseline to review in control and test group.

Parameters assessed	Group	Baseline	Review	Improvement
		Total average score		
Side effects	Control	1.93	1.23	0.70
	Test	3.02	1.16	1.86
Symptoms	Control	3.32	2.81	0.51
	Test	4.41	0.84	3.57
Medication adherence	Control	4.71	4.23	0.48
	Test	5.27	2.12	3.15

The total average scores from baseline to review of the test and control groups were compared. The overall improvement was noticeably high for the test group when compared to the control group. The results proved that pharmacist's care have led to improvement of symptoms, tolerability towards side effects and medication adherence in the test group**.**

DISCUSSION:

In a developing country like India, prevalence of anemia is very high among women. Anemia in general and IDA in particular is multi-factorial. Likely answer is some combination of biology and culture, i.e., dietary iron and micronutrient deficiencies, and cultural practices such as early marriages, tendency of less educated women, lower incomes.

The average age group (25-29 years) in our study reflects on the traditional age of marriage in the study area. A similar result was obtained in a study conducted in Ethiopia by Sisay Shewasinad et.al (2013); where most participants belonged to the age group of 25-29 years (33.8%).[11]Better education of Indian girls would help delay their marriage age and would help them make better, more empowered decisions regarding childbirth age, spacing between

children, and increasing iron intake during pregnancy. Housewives were found to be more anemic (78.4%) which can be due to the busy lifestyle and inadequate nutritional intake. The result of this study is consistent with that of study conducted by Devi Sakthi et al. (2017), in Pondicherry, India, where anemic housewives were about 85.6%.[12] Promoting awareness among housewives will be helpful in overcoming this hurdle. Strategies such as food fortification and utilization of easily available and affordable iron rich diet, forming kitchen garden, cooking in cast iron utensils can improve the iron intake in housewives. [13]

Fatigue is a common complaint of patients with anemia. At the clinical level, the relationship between anemia and fatigue is universally accepted. In this study, fatigue (58.4%) is found to be the principle symptom of anemia but other associated symptoms such as headache, dizziness, palpitation, breathlessness adversely affect patients' quality of life as well. This observation is similar to that of the short review published by Salma Al Dallal (2016)regarding Iron deficiency.[14] Most of the studies concluded that fatigue is found to be the most experienced symptom associated with anemia.

A whooping majority of the participants had complained of black colored stools (32%) and nausea (31.2%) as the major side effects. Black colored stool is an indication of the excretion of unabsorbed iron from the body and is often witnessed by patients consuming oral Iron supplements. The result of this study is consistent with those of studies conducted in Iran, by Bondarianzadeh D, et.al (2008) to assess the compliance to Iron Supplementation program during pregnancy where nausea and vomiting were the most prominent side effects (10.8%) [15] and in randomized double blind study in Iran (2015) by Esmat Jafarbegloo, et.al, who concluded that nausea was the most commonly raised complaint among the study subjects.[16] The discrepancy exists because nausea could not be clearly distinguished from pre-existing pregnancy complaints like morning sickness by the participants. to the results of our study was seen in a clinical trial in Brazil conducted by Ariana Impieri Desouza, et.al, involving 150 women taking Iron supplementation, reported that diarrhea, constipation and epigastric pain were the side effects attributed to Iron supplements. The fact that the researcher and participant were not blinded may have induced and influenced the report of side effects. Nevertheless, un-blinding was important to investigate adherence with greater veracity, since the complexity of the treatment regimen administered could influence its correct use.[17]

Long-term use of oral iron is limited by presence of side effects and fear of ADR, which in turn contribute to reduced adherence to oral iron supplements. Minimal adherence to oral iron supplements can result in reduced quality of life. Most of the participants were poorly adherent (68.8%) which emphasizes that adherence is usually poor when supplements are not supervised. Cigdem Gereklioglu, et.al (2016) conducted a similar study to determine the medication adherence to oral iron therapy in patients with iron deficiency anemia and reported that medication adherence was poor among women, the most important reason being gastro-intestinal side effects.[6] Reduced treatment adherence combined with the negative influence exerted by side effects might help to explain why most treatments fail to control anemia.[17]

Oral iron preparations are commonly prescribed in iron deficiency anemia because of convenience and low cost. Most of the patients well respond to oral preparation, even though minority suffers from side effects which directly relates to reduced adherence. Other causes of non-adherence may include: lack of supplies, access, training, and motivation of healthcare professionals and patient factors such as misunderstanding instructions, side effects, forgetfulness, frustration about the frequency and number of pills taken, personal problems, nausea that accompanies pregnancy.[18] When the various causes of non-adherence were assessed in this study, most participants complained of forgetfulness as the main reason. This observation is similar with that of study conducted by P Mithra et al. (2013), in South India to determine the compliance with Iron-Folic Acid therapy among pregnant women and reported that the main reason for non-compliance to be forgetfulness (48.8%).[19] Providing calendars, diary keeping as reminders can be a means of combating forgetfulness.

This suggests that pharmacist care had played an important role in improving adherence to oral anti-anemic medications. In a single center, prospective, randomized controlled study conducted by Chuanwei Xin, et.al (2015) to determine the effect of pharmaceutical care on medication adherence of patients newly prescribed insulin therapy, the results indicated that individualized pharmaceutical care improved the medication adherence, where the baseline adherence rate improved from 50.8% to 80.7% (p value<0.01) after intervention in the test group and from 52.2% to 58.4% (p =0.596) in the control group.[20]

There was a significant difference in the average score at baseline and at review in the test group for nausea, vomiting, abdominal pain, constipation and black stools and non-significant result for diarrhea. The corresponding results for control showed significant change in nausea

and vomiting only. Since nausea and vomiting are tiresome side effect, participants even in the control group would have tried to compact it by other means. This might be the reason why there is a significant decline in the score for diarrhea in control group, despite lack of pharmacist care. In test group, the average score of symptoms which are fatigue, cold hands and feet, headache, dizziness, breathlessness, palpitation were found to reduce significantly at review. The reduction in symptoms signifies the improved adherence to oral iron supplements which consequently improved the anemic condition. However, in the control group, except for dizziness, all the remaining symptoms did not reduce significantly at review. This may due to no education received by the control group regarding the importance of adherence, which resulted in reduced adherence, thereby no improvement in symptoms of anemia.

Women bear a disproportionate burden from iron deficiency anemia even though the technology exists to address the problem at low cost. Availability of food fortification (wheat flour with iron and folic acid), providing advanced warning about the possibility of side effects, involving the patient in the therapeutic strategy and providing reminders, such as posters and calendars, about taking supplements remains the key to reduce anemia.[18] Thus continuous nutrition education and monitoring programs need to be implemented more efficiently.

Limitations of the study should be emphasized particularly in relation with serum hemoglobin and serum iron, since they are better indicators of iron deficiency anemia, which our budget could not afford.

CONCLUSION

This study concludes that adherence to oral iron supplements is generally poor, the main reasons being forgetfulness, busy lifestyle and side effects. The most frequently complained symptom of anemia is fatigue, followed by breathlessness, palpitation, headache, and dizziness. This study identified consumption of oral iron supplementation resulted in various gastrointestinal side effects, most frequent being nausea and black stools.

Structured education on the various aspects of anemia and methods to compact common side effects of oral iron supplementation resulted in improvement in the symptoms, along with increased tolerability towards side-effects. This ultimately led to improvement in medication

adherence. Thus our study concludes that, the pharmacists' care for anemic women enhanced their adherence to oral iron supplementation.

As this study is purely questionnaire based, the results obtained are wholly from the responses of the participants. No clinical correlation with serum iron levels and hemoglobin prior and post pharmacists' care is done. Hence it is recommended that future studies can be undertaken using clinical findings such measurement of hemoglobin.

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