ORIGINAL ARTICLE

Comparing Compliance and Tolerability of Ferrous Ascorbate versus Ferrous Sulphate in Pregnancy: A Prospective Community-Based Study

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Abstract:

Background: Poor compliance with Iron and Folic Acid (IFA) supplementation, often due to adverse effects from Ferrous Sulphate, severely limits efforts to reduce anaemia prevalence in Indian pregnancy. **Objectives:** To compare the patient compliance rates and tolerability profiles of Ferrous Sulphate and Ferrous Ascorbate formulations in an operational community health setting. **Material & Methods:** This prospective observational study enrolled 110 pregnant women (55 received Ferrous Sulphate; 55 received Ferrous Ascorbate) from the designated field practice areas of medical college in two districts of Madhya Pradesh. Compliance (primary outcome) and adverse effects were collected over follow-up visits spanning 8-10 weeks. Limitations include the non-randomized allocation of groups and the reliance on self-reported compliance. Statistical analysis included the Chi-square test and logistic regression. **Results:** Full compliance was significantly higher with Ferrous Ascorbate (78.2%) than with Ferrous Sulphate (56.4%) (p = 0.014). Adverse drug effects were the dominant reason for partial compliance in in both the Ferrous Sulphate group (87.5%) and the Ferrous Ascorbate group (58.3%). The incidence of nausea/vomiting was notably higher with Ferrous Sulphate (56.4% vs. 34.5%, p=0.027). **Conclusions:** Ferrous Ascorbate is associated with superior tolerability and significantly higher compliance in a community setting compared to standard therapy. Prioritizing a better-tolerated iron formulation is a crucial, modifiable strategy to enhance the effectiveness of national anaemia prevention programs.

Key-words: Iron and Folic Acid; Anaemia in Pregnancy; Patient Compliance; Ferrous Ascorbate; Ferrous Sulphate; Tolerability.

Introduction:

Anaemia during pregnancy remains a significant public health challenge in India, with National Family Health Survey-5 (NFHS-5) data indicating a prevalence exceeding 50% across vulnerable populations, thereby affecting a substantial number of expectant mothers.[1] This condition, primarily driven by iron deficiency, is far from a benign haematological finding. It is robustly associated with a spectrum of adverse maternal and perinatal outcomes that contribute significantly to morbidity and mortality. For the mother, severe anaemia elevates the risk of cardiac failure, postpartum haemorrhage, and sepsis.[2] The consequences for the foetus and neonate are equally grave, with established links to an increased incidence of preterm birth, low birth weight infants, and diminished iron stores in the newborn, which can impair cognitive and motor development.[3,4] The considerable impact of this condition highlights the critical need for effective antenatal interventions aimed not only at treating anaemia but also at ensuring the prophylactic strategies are successfully adopted by the target population.

To address this public health imperative, national health programs in India have established universal supplementation with oral Iron and Folic Acid (IFA) tablets for pregnant women[5]. This cornerstone strategy aims to provide a daily prophylactic dose throughout gestation. Despite the widespread distribution of these supplements, the on-the-ground effectiveness of this intervention is severely hampered by poor patient compliance. Studies consistently report that a

substantial percentage of beneficiaries fail to consume the recommended course of IFA tablets, with adherence rates often falling well below programmatic targets.[6,7] This gap between provision and consumption represents a critical barrier to reducing the burden of maternal anaemia, rendering the intervention less effective than its potential and perpetuating high prevalence rates despite policy implementation.[8]

A significant contributor to this therapeutic gap is the tolerability profile of the conventionally used preparation, Ferrous Sulphate. While effective and inexpensive, this iron salt is frequently associated with a high incidence of adverse gastrointestinal effects, including nausea, epigastric pain, and constipation.[9] These side effects are a well-documented barrier to adherence and often lead to discontinuation of therapy by the patient[10]. In response to this challenge, alternative formulations have been developed. Ferrous Ascorbate, a chelated form of iron, is one such alternative designed to enhance bioavailability and exhibit an improved tolerability profile. By maintaining iron in its more soluble ferrous state, it is proposed to cause fewer gastrointestinal disturbances, thereby offering a potential pathway to improving patient compliance.[11,12]

Despite the pharmacological rationale for its use, there is a paucity of evidence from programmatic settings that directly compares the compliance rates of women prescribed Ferrous Ascorbate versus those prescribed the standard Ferrous Sulphate. However, there remains a critical programmatic research gap regarding direct, real-world comparisons of adherence rates between Ferrous Ascorbate and standard Ferrous Sulphate in community health settings. Addressing this specific knowledge gap is essential for public health bodies to make evidence-based decisions on which formulation yields better adherence and clinical outcomes. Therefore, the primary objective of the present study was to compare the compliance rates and associated tolerability of Ferrous Sulphate versus Ferrous Ascorbate among pregnant women receiving antenatal care in designated field practice areas of Madhya Pradesh.

Material & Methods:

This study was designed as a community-based, prospective observational investigation to evaluate the compliance of pregnant women to two different oral iron preparations under real-world conditions. The research was conducted within the designated field practice areas of the Department of Community Medicine, Gandhi Medical College, Bhopal. The study settings were strategically selected to encompass two distinct populations: the urban field practice area situated in Bhopal district and the rural field practice area in Raisen district, Madhya Pradesh. This approach allowed for the assessment of compliance across different socio-demographic contexts representative of the region.

The study population comprised pregnant women who registered for antenatal care at Anganwadi centres within the selected study areas. Eligibility for inclusion required participants to be in their first trimester (less than 14 weeks of gestation) at the time of enrolment. Women were excluded if they presented with severe anaemia (baseline haemoglobin level below 7 g/dl) that necessitated intravenous iron therapy or blood transfusion. Additional exclusion criteria included a history of other forms of anaemia, known chronic gastrointestinal illnesses, grand multiparity, or a recent history of receiving parenteral iron or a blood transfusion. Group allocation was determined by the prevailing public health supply chain in each district; participants from the urban Bhopal district received the standard-issue Ferrous Sulphate, while those in the rural Raisen district, designated as a High Priority District, received Ferrous Ascorbate as per local health policy. We acknowledge that this non-randomized, district-based allocation introduces the possibility of selection bias and confounding due to intrinsic habitat differences (urban versus rural). To address this, a one-month supply of the respective pills was dispensed immediately at the conclusion of the enrolment visit, and subsequent statistical analysis incorporated adjustments for observed baseline confounders.

The sample size for this study was established using an a priori power calculation designed to compare two independent proportions, reflecting the primary objective of assessing compliance rates between two different oral iron preparations. Drawing from previous research in similar settings[13], the baseline compliance rate for the standard Ferrous Sulphate group was conservatively estimated at 50%. It was hypothesized that the improved tolerability of Ferrous Ascorbate would lead to a clinically significant absolute increase in compliance of 25%. This 25% increase was established as a targeted programmatic goal for new interventions in this region. To detect this anticipated difference with a statistical power of 80% and a two-sided significance level of $\alpha=0.05$, the required sample size was calculated to be 55 participants per treatment arm

Data were collected using a pre-tested, semi-structured questionnaire administered by the investigator. At the initial visit, information on sociodemographic characteristics and obstetric history was recorded. Subsequent data on compliance, reasons for non-compliance, and any experienced adverse effects were collected during two specific follow-up visits, conducted at 4 to 6 weeks and 8 to 10 weeks post-enrolment. To minimize recall bias, participants were requested to bring their blister packs during follow-up visits to verify self-reported consumption. There was zero loss to follow-up among the enrolled participants over the 10-week observation period.

The primary outcome of the study was patient compliance, which was categorized as either 'Fully Compliant' or 'Partially Compliant'. A "dose" was strictly defined as the consumption of one prescribed tablet per day. Partial compliance was operationally defined as missing two or more consecutive doses of the prescribed oral iron supplement during the follow-up period, including individuals who completely ceased taking the medication after initial doses. Secondary outcomes included the specific reasons cited for discontinuation and the incidence of self-reported adverse effects. The terminology "adverse effects" is used consistently throughout to describe these events.

Statistical analysis was performed using Epi-Info 7 software. Proportional differences in compliance rates and reasons for discontinuation between the two groups were assessed using

the Chi-square test. A p-value of less than 0.05 was considered statistically significant. To evaluate factors potentially associated with compliance and to isolate the independent effect of the iron formulation by minimizing the influence of baseline differences (such as habitat, religion, and family type), binomial logistic regression was employed. The dependent variable for the regression was specified as Full Compliance versus Partial/Non-Compliance. The study protocol received clearance from the Institutional Ethical Committee of Gandhi Medical College, Bhopal, and written informed consent was obtained from all participants prior to their enrolment in the study.

Results:

A total of 110 pregnant women who met the inclusion criteria were enrolled in the study, with 55 participants in each of the Ferrous Sulphate and Ferrous Ascorbate groups. The mean age of the study population was 24.56 ± 4.48 years. The mean gestational age at enrolment was comparable between the Ferrous Sulphate (10.4 ± 1.8 weeks) and Ferrous Ascorbate (10.6 ± 1.6 weeks) groups. As detailed in Table 1, while there were no significant differences in age, educational level, or gravida status, baseline sociodemographic differences were observed regarding religion, family type, and occupation ($p < 0.05$). These differences align with the respective urban and rural habitats of the two designated field practice areas and were subsequently accounted for in the multivariate analysis.

Table 1: Socio-demographic Profile of the Study Participants

Variable	Ferrous Sulphate Group (N=55)	Ferrous Ascorbate Group (N=55)	Total (N=110)	χ^2 value	p-value
Age at present pregnancy (Years)					
<21	13 (23.6)	19 (34.5)	32 (29.1)	4.77	0.312
22-25	21 (38.2)	18 (32.7)	39 (35.5)		
26-29	9 (16.4)	13 (23.6)	22 (20.0)		
30-33	8 (14.5)	3 (5.5)	11 (10.0)		
>33	4 (7.3)	2 (3.6)	6 (5.5)		
Gestational Age at Enrollment (Weeks)					
Mean ± SD	10.4 ± 1.8	10.6 ± 1.6	10.5 ± 1.7	-	0.540*
Educational Qualification					
Illiterate	1 (1.8)	6 (10.9)	7 (6.4)	10.51	0.062
Primary	1 (1.8)	3 (5.5)	4 (3.6)		
Middle School	11 (20.0)	16 (29.1)	27 (24.5)		
High School	15 (27.3)	6 (10.9)	21 (19.1)		
Intermediate	11 (20.0)	9 (16.4)	20 (18.2)		
Graduate	15 (27.3)	15 (27.3)	30 (27.3)		
Professional	1 (1.8)	0 (0.0)	1 (0.9)		

Religion					
Hindu	25 (45.5)	47 (85.5)	72 (65.5)	13.56	<0.001
Muslim	30 (54.5)	8 (14.5)	38 (34.5)		
Occupation				-	
Housewife	51 (92.7)	55 (100.0)	106 (96.4)		
Employed/Other	4 (7.3)	0 (0.0)	4 (3.6)		
Type of Family					
Nuclear	26 (47.3)	6 (10.9)	32 (29.1)	12.75	<0.001
Joint	29 (52.7)	49 (89.1)	78 (70.9)		
Gravida Status					
Primigravida	29 (52.7)	33 (60.0)	62 (56.4)	0.72	0.395
Multigravida	26 (47.3)	22 (40.0)	48 (43.6)		

*p-value calculated using Fisher's Exact Test due to a cell count of zero.

Analysis of the primary outcome demonstrated that the proportion of women fully compliant with the prescribed therapy was 78.2% (43 of 55) in the Ferrous Ascorbate group, compared to 56.4% (31 of 55) in the Ferrous Sulphate group (p = 0.014; Figure 1).

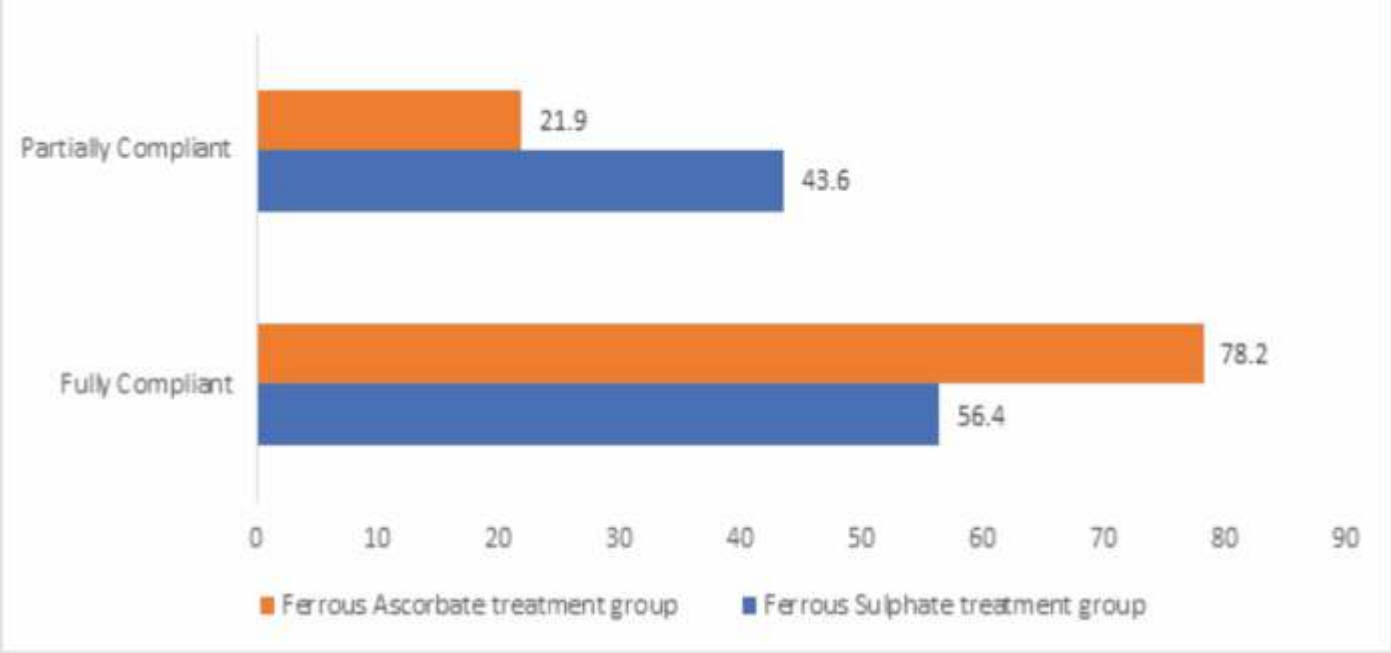

Figure 1: Comparison of Full Compliance Rates Between Treatment Groups

Further assessment of the 36 partially compliant participants indicated that adverse drug effects were the most frequently reported reason for discontinuation. Proportionally, 87.5% (21 of 24) of the partially compliant individuals in the Ferrous Sulphate group cited side effects, compared to 58.3% (7 of 12) in the Ferrous Ascorbate group (Table 2).

Table 2: Reasons for Partial Compliance by Treatment Group

Reason for Discontinuation	Ferrous Sulphate Group (n=24)	Ferrous Ascorbate Group (n=12)	Total (N=36)	p-value
Adverse drug effects, n (%)	21 (87.5)	7 (58.3)	28 (77.8)	**0.048**
Forgetfulness, n (%)	2 (8.3)	2 (16.7)	4 (11.1)	
Long course of therapy, n (%)	1 (4.2)	3 (25.0)	4 (11.1)	

Regarding the overall incidence of adverse effects, nausea or vomiting was the most common symptom, reported by 56.4% of participants in the Ferrous Sulphate group versus 34.5% in the Ferrous Ascorbate group (p = 0.027). Based on overlapping patient descriptions, reports of abdominal pain and gastric irritation were merged into a single category of gastrointestinal pain/irritation (Table 3).

Table 3: Overall Incidence of Self-Reported Adverse Effects by Treatment Group

Adverse Effect	Ferrous Sulphate Group (N=55)	Ferrous Ascorbate Group (N=55)	p-value
Nausea/Vomiting, n (%)	31 (56.4)	19 (34.5)	**0.027**
Abdominal Pain, n (%)	2 (3.6)	1 (1.8)	1.000*
Constipation, n (%)	2 (3.6)	1 (1.8)	1.000*
Gastric Irritation, n (%)	2 (3.6)	0 (0.0)	0.495*
Metallic taste, n (%)	1 (1.8)	0 (0.0)	1.000*

To evaluate the independent effect of the iron formulation on the primary outcome, a binomial logistic regression model was utilized (Table 4). The dependent variable was specified as Full Compliance versus Partial Compliance. The model incorporated treatment group, habitat, and baseline sociodemographic variables to adjust for potential confounders. After adjustment, the Ferrous Ascorbate treatment group remained a statistically significant predictor of full compliance, validating the primary observation.

Table 4: Logistic Regression Analysis of Factors Associated with Full Compliance (Dependent Variable)

Correlates of Compliance	**Unadjusted Odds Ratio (95% CI)**	**Adjusted Odds Ratio (95% CI)**	**p-value (Adjusted)**
Treatment Group			
Ferrous Sulphate	1.00 (Reference)	1.00 (Reference)	
Ferrous Ascorbate	2.774 (1.218 - 6.320)	2.512 (1.092 - 5.776)	0.030

Habitat			
Urban (Bhopal)	1.00 (Reference)	1.00 (Reference)	
Rural (Raisen)	1.250 (0.580 - 2.695)	1.105 (0.412 - 2.964)	0.842
Religion			
Hindu	1.00 (Reference)	1.00 (Reference)	
Muslim	0.779 (0.318 - 1.906)	0.812 (0.301 - 2.189)	0.684
Occupation			
Home maker	1.00 (Reference)	1.00 (Reference)	
Employed	0.477 (0.064 - 3.546)	0.521 (0.061 - 4.451)	0.550
Education			
High School & below	1.00 (Reference)	1.00 (Reference)	
Intermediate & above	0.636 (0.275 - 1.471)	1.197 (0.213 - 6.732)	0.838
Socioeconomic Class			
Upper Class	1.00 (Reference)	1.00 (Reference)	
Lower Class	1.025 (0.436 - 2.407)	0.457 (0.054 - 3.866)	0.472
Type of Family			
Nuclear	1.00 (Reference)	1.00 (Reference)	
Joint	0.256 (0.103 - 0.637) *	0.318 (0.048 - 2.103)	0.243
Gravida			
Primigravida	1.00 (Reference)	1.00 (Reference)	
Multigravida	1.574 (0.680 - 3.643)	1.411 (0.552 - 3.608)	0.471

Discussion:

The findings of this prospective, community-based study provide clear evidence that the choice of oral iron preparation significantly influences patient compliance during pregnancy. The principal result demonstrates that Ferrous Ascorbate is associated with a markedly and statistically significant higher rate of full compliance when compared to the standard Ferrous Sulphate regimen administered in a real-world, programmatic setting. This observation addresses a practical operational question in the management of maternal anaemia, suggesting that the formulation of the iron supplement is a key determinant of adherence.

The higher compliance observed in the Ferrous Ascorbate group can be attributed to its enhanced tolerability profile. The data indicate that the primary driver of non-adherence, particularly in the Ferrous Sulphate group, was the high incidence of adverse gastrointestinal effects. This is consistent with extensive literature establishing that side effects like nausea and gastric irritation are common barriers to completing a course of conventional oral iron.[14-16] The compliance rate of 56.4% in our Ferrous Sulphate arm aligns with findings from various Indian settings; it is slightly higher than the 48.1% reported by Dutta et al. in an urban slum[13] and comparable to the 64.7% found by Mithra et al. in a similar urban population.[5] Conversely, the 78.2% compliance rate achieved in the Ferrous Ascorbate group approaches the upper range of adherence seen in other interventional studies, such as the 80.5% rate achieved by Godara et al. in a tertiary care setting.[19]

Beyond the pharmacological formulation, evaluating adherence in a public health setting requires attention to operational challenges and sociodemographic confounders. The district-level allocation in this study inherently grouped participants by habitat (urban versus rural). Habitat is a recognized confounder of iron intake, often influencing dietary habits, family structures, and accessibility to healthcare counseling. While our multivariate logistic regression model attempted to adjust for these baseline imbalances to isolate the effect of the iron salt, the intrinsic differences between the Bhopal and Raisen district populations remain a significant contextual factor.

From a public health perspective, these findings carry practical policy implications regarding supplement procurement. While Ferrous Ascorbate may have a higher initial unit cost than Ferrous Sulphate, prioritizing procurement based solely on unit cost may be counterproductive if non-compliance remains high. Improved tolerability and subsequent adherence could potentially reduce the downstream clinical burden of unmanaged maternal anaemia, such as the need for parenteral iron therapy or blood transfusions.[18] While formal economic evaluations are required to establish definitive cost-effectiveness, policymakers should consider patient tolerability as a primary criterion alongside direct procurement costs when selecting oral iron preparations for national initiatives.

Strength and Limitations:

The study's primary strength lies in its prospective, community-based observational design, which allowed for the

longitudinal assessment of compliance in a real-world setting, providing valuable insights into practical adherence challenges.

However, several limitations must be explicitly acknowledged. First, the non-randomized, observational design utilizing district-based allocation introduced significant baseline sociodemographic differences between the groups, most notably regarding habitat (urban versus rural), religion, and family type. While statistical adjustments were made, the potential for unmeasured confounding variables linked to these district-level differences cannot be entirely excluded. Second, compliance was assessed via self-report, which is subject to recall and social desirability biases, although this was partially mitigated by requesting patients to present their blister packs. Finally, while the sample size was adequate to detect the primary outcome, the observational nature of the study precludes establishing strict causality. Larger, randomized controlled trials that eliminate habitat confounding are required to confirm these findings definitively.

Conclusion:

In conclusion, this community-based study indicates that Ferrous Ascorbate is associated with significantly higher compliance rates among pregnant women compared to Ferrous Sulphate. This difference appears closely linked to its superior tolerability and a lower incidence of self-reported adverse gastrointestinal effects. Acknowledging the baseline sociodemographic differences in the study population, these findings contribute practical support for considering Ferrous Ascorbate in public health strategies. Prioritizing a better-tolerated formulation is a highly relevant, modifiable factor that may help improve the overall adoption of anaemia prevention programs in pregnancy.

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Approval of Institutional Ethical Review Board: The study protocol was reviewed and approved by the Institutional Ethical Committee (IEC) of Gandhi Medical College, Bhopal (Letter No - 3872-73/MC/IEC/2018 dated 30/01/2018). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the Helsinki Declaration. Written informed consent was obtained from all participants prior to their enrolment in the study

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