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Original Research Article

TO COMPARE THE EFFECTIVENESS OF DAILY VERSUS ALTERNATE DAY ORAL IRON THERAPY FOR OBSTETRIC PATIENTS WITH IRON DEFICIENCY ANAEMIA: RANDOMIZED CONTROLLED TRAIL

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ABSTRACT

Background: Iron deficiency anaemia remains a major public health concern among obstetric patients, with significant maternal and fetal consequences. Conventional daily oral iron therapy is often limited by poor compliance due to gastrointestinal side effects. Alternate-day dosing has been proposed to improve iron absorption and tolerability. This study aimed to compare the effectiveness of daily versus alternate-day oral iron therapy in obstetric patients with iron deficiency anaemia.

Materials and Methods: This randomized controlled trial was conducted on 46 obstetric patients with haemoglobin <11 g/dL, allocated into two groups: daily (n=23) and alternate-day (n=23) oral iron therapy (100 mg elemental iron). Patients were followed for 8 weeks. Haemoglobin, haematological indices, serum ferritin, gastrointestinal side effects, and compliance were assessed. Statistical analysis was performed using appropriate tests, with $p < 0.05$ considered significant.

Results: Both groups showed significant improvement in haemoglobin levels from baseline to 8 weeks ($p < 0.001$). At 8 weeks, haemoglobin was higher in the alternate-day group (11.16 ± 1.15 g/dL) compared to the daily group (10.73 ± 1.07 g/dL), though not statistically significant ($p > 0.05$). Serum ferritin improved in both groups without significant intergroup difference. Gastrointestinal side effects, particularly epigastric pain and constipation, were significantly higher in the daily group ($p < 0.05$). Compliance was significantly better in the alternate-day group (85.15% vs 72.49%, $p = 0.0006$).

Conclusion: Alternate-day oral iron therapy is as effective as daily therapy in improving haemoglobin and iron stores, with better tolerability and compliance, making it a suitable alternative in obstetric patients.

Keywords: Iron deficiency anaemia, pregnancy, oral iron therapy, alternate-day dosing, haemoglobin, compliance, randomized controlled trial

INTRODUCTION

Anaemia remains a major global public health concern, particularly among women of reproductive age and during pregnancy. The World Health Organization defines anaemia as a reduction in haemoglobin concentration or red blood cell count below normal levels, leading to impaired oxygen-carrying capacity.[1] In pregnancy, anaemia significantly contributes to maternal and perinatal morbidity and mortality.Globally, approximately 37% of pregnant women were affected by anaemia in 2019, with the highest burden in Africa and South-East Asia.[1] Iron deficiency is the most common cause, with a pooled prevalence of about 19% among pregnant women.[2] It contributes substantially to maternal deaths, accounting for nearly 22% of maternal mortality worldwide.[3] Maternal anaemia is associated with adverse outcomes such as preterm birth, low birth weight, postpartum haemorrhage, and

increased maternal mortality, along with fetal complications including intrauterine growth restriction, impaired neurodevelopment, and perinatal mortality.[4] India carries a particularly high burden of anaemia. According to NFHS-5 (2019–21), 52.2% of pregnant women and 57.0% of women aged 15–49 years are anaemic, showing an increasing trend compared to previous surveys.[5] In north-eastern states such as Assam, prevalence reaches up to 50.1%, indicating a serious public health concern.[6] Oral iron supplementation remains the mainstay of treatment and prevention. The WHO recommends daily iron and folic acid supplementation during pregnancy.[7] However, daily iron therapy is frequently associated with gastrointestinal side effects such as nausea, vomiting, and constipation, leading to poor compliance and suboptimal outcomes.[8]

Recent evidence has highlighted the role of hepcidin, a key regulator of iron absorption. Elevated hepcidin levels following oral iron intake reduce subsequent iron absorption. Moretti et al. demonstrated that doses ≥60 mg increase hepcidin for up to 24 hours, reducing fractional absorption by 35–45%.[9] This has led to interest in alternate-day dosing. Stoffel et al. showed that alternate-day supplementation results in higher iron absorption and lower hepcidin levels compared to daily dosing, along with fewer side effects.[10] However, evidence in pregnant women remains limited, as most studies have been conducted in non-pregnant populations. Pregnancy involves altered iron metabolism with physiologically suppressed hepcidin levels, and thus the clinical benefits of alternate-day therapy in obstetric patients remain uncertain. Given the high burden of anaemia and issues with adherence to daily iron therapy in India, evaluating alternate-day regimens is clinically important. Therefore, the present randomized controlled trial was conducted to compare the effectiveness of daily versus alternate-day oral iron therapy (100 mg elemental iron) in obstetric patients with iron deficiency anaemia, assessing haemoglobin improvement, iron indices, side effects, and compliance.

MATERIALS AND METHODS

This randomized controlled trial compared daily versus alternate-day oral iron supplementation in obstetric patients with iron deficiency anaemia. Randomization was performed using the opaque sealed envelope method, ensuring allocation concealment. Participants were assigned after obtaining informed written consent, and analysis was conducted using the intention-to-treat (ITT) principle.

The study was conducted in the Department of Obstetrics and Gynecology at Oxford Medical College, Hospital and Research Centre, Yadavanhalli, over a period of 18 months after obtaining Institutional Ethics Committee approval. Based on previous studies, with 80% power and 5% level of significance, the calculated sample size was 22 participants per group. Considering a 5% attrition rate, the final sample size was 23 per group (total N = 46).

Randomization and Study Groups

Simple randomization using sealed envelopes was employed. Participants were allocated into:

- **Group 1:** Alternate-day oral iron (100 mg elemental iron)
- **Group 2:** Daily oral iron (100 mg elemental iron)

Treatment was continued until haemoglobin ≥11 g/dL.

Inclusion and Exclusion Criteria

Inclusion

- Pregnant women ≥12 weeks gestation with haemoglobin <11 g/dL
- Postnatal women with haemoglobin <11 g/dL

Exclusion

- Hematological disorders (e.g., megaloblastic anaemia, sickle cell anaemia)
- Severe anaemia (haemoglobin <6 g/dL)

Data Collection

Baseline data included demographic details, clinical and obstetric history, body mass index, socioeconomic status, and gestational age. Participants received iron therapy according to their assigned group.

Laboratory Investigations

Baseline and 4-weekly assessments included haemoglobin, hematocrit, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red cell distribution width (RDW), and serum ferritin. Blood samples were analyzed using automated hematology analyzers and immunoassay techniques.

Monitoring and Compliance

Side effects such as nausea, vomiting, epigastric pain, constipation, and diarrhea were recorded at each follow-up. Compliance was assessed by pill count through returned tablet strips. Patients were instructed to take tablets before lunch.

Treatment Response

- **Positive response:** Increase in haemoglobin ≥1 g/dL
- **Treatment failure:** No rise in haemoglobin after 4 weeks

Non-responders were evaluated for other causes of anaemia.

Statistical Analysis

Data were analyzed using SPSS version 26. Continuous variables were expressed as mean ± standard deviation or median (interquartile range) and compared using independent sample t-test or Mann-Whitney U test. Categorical variables were expressed as frequencies and percentages and analyzed using Chi-square test or Fisher's exact test. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 46 obstetric patients with iron deficiency anaemia were enrolled in the study and randomized into two groups: daily oral iron therapy (n = 23) and alternate-day oral iron therapy (n = 23). All participants completed the study and were included in the final analysis. The baseline demographic and clinical characteristics of the study participants are summarized in Table 1. The mean age of participants in the daily group was 24.65 ± 3.88 years, while in the alternate-day group it was 24.48 ± 3.23 years. This difference was not statistically significant (p = 0.87), indicating that both groups were comparable in terms of age distribution. The majority of participants in both groups belonged to the 20–25 years age category. With respect to obstetric status, most participants were antenatal in both groups (78.3% in the daily group and 87.0% in the alternate-day group), and this difference was not statistically significant (p = 0.697). Similarly, gravidity and parity were comparable between the groups. The mean gravidity was 2.26 ± 1.21 in the daily group and 2.57 ± 1.20 in the alternate-day group (p = 0.397). The proportion of nulliparous and multiparous women was identical in both groups (47.8% and 52.2%, respectively), with no statistically significant difference (p = 1.0). Body mass index (BMI) showed a borderline statistically significant difference, with a higher mean BMI observed in the daily group (24.11 ± 3.21 kg/m²) compared to the alternate-day group (22.27 ± 2.89 kg/m²) (p = 0.047). Among antenatal participants, the mean gestational age was 25.72 ± 7.69 weeks in the daily group and 24.35 ± 6.52 weeks in the alternate-day group, with no significant difference (p = 0.556). Overall, the two groups were comparable at baseline, ensuring appropriate randomization. The comparison of haemoglobin levels and iron parameters over time is presented in Table 2. At baseline, haemoglobin levels were similar between the two groups (8.59 ± 0.97 g/dL in the daily group vs 9.04 ± 1.11 g/dL in the alternate-day group; p = 0.149). Both groups demonstrated a significant increase in haemoglobin levels over time. In the daily group, haemoglobin increased to 9.76 ± 0.95 g/dL at 4 weeks and 10.73 ± 1.07 g/dL at 8 weeks. In the alternate-day group, haemoglobin increased to 10.07 ± 1.10 g/dL at 4 weeks and 11.16 ± 1.15 g/dL at 8 weeks. Although the alternate-day group showed higher mean haemoglobin values at both 4 and 8 weeks, the intergroup differences were not statistically significant (p = 0.299 and p = 0.199, respectively). The mean rise in haemoglobin at 4 weeks was 1.17 ± 0.36 g/dL in the daily group and 1.03 ± 0.36 g/dL in the alternate-day group (p = 0.212). At 8 weeks, the increase was 2.14 ± 0.54 g/dL and 2.12 ± 0.48 g/dL, respectively (p = 0.863), indicating comparable haemoglobin improvement between the two regimens. Serum ferritin levels also improved in both groups. At baseline, ferritin levels were comparable (10.46 ± 3.76 µg/L vs 10.32 ± 5.16 µg/L; p = 0.917). At 4 weeks, the alternate-day group had higher ferritin levels (23.01 ± 7.05 µg/L) compared to the daily group (19.84 ± 5.14 µg/L), although this difference was not statistically significant (p = 0.088). At 8 weeks, ferritin levels remained higher in the alternate-day group (34.37 ± 8.04 µg/L vs 30.70 ± 8.46 µg/L), with no statistically significant difference (p = 0.138).

Clinical outcomes, gastrointestinal side effects, and compliance are summarized in Table 3. Gastrointestinal side effects were more frequent in the daily group compared to the alternate-day group. Epigastric pain (30.4% vs 4.3%, p = 0.047) and constipation (43.5% vs 13.0%, p = 0.047) were significantly higher in the daily group. Although nausea (60.9% vs 43.5%), vomiting (21.7% vs 4.3%), and loose stools (21.7% vs 13.0%) were also more common in the daily group, these differences were not statistically significant. The overall incidence of any gastrointestinal side effect was higher in the daily group (87.0%) compared to the alternate-day group (60.9%). Compliance with therapy was significantly better in the alternate-day group. The mean compliance rate was 85.15 ± 11.05% in the alternate-day group compared to 72.49 ± 12.06% in the daily group (p = 0.0006). A significantly higher proportion of participants in the alternate-daygroup demonstrated good compliance (≥80%) (69.6% vs 26.1%, p = 0.011). With respect to treatment outcomes, all participants in both groups showed a positive response, with no cases of treatment failure. The mean duration to achieve target haemoglobin (≥11 g/dL) was shorter in the alternate-day group (9.57 ± 4.13 weeks) compared to the daily group (10.78 ± 4.34 weeks), although this difference was not statistically significant (p = 0.335). At 8 weeks, a higher proportion of participants in the alternate-day group achieved the target haemoglobin (56.5% vs 39.1%), but this difference was also not statistically significant (p = 0.376).

Table 1: Baseline Characteristics of Study Participants

Parameter	Daily (n=23)	Alternate-day (n=23)	p-value
Age (years, Mean ± SD)	24.65 ± 3.88	24.48 ± 3.23	0.87
Antenatal (%)	18 (78.3%)	20 (87.0%)	0.697
Postnatal (%)	5 (21.7%)	3 (13.0%)	
Gravidity (Mean ± SD)	2.26 ± 1.21	2.57 ± 1.20	0.397
Nulliparous (%)	11 (47.8%)	11 (47.8%)	1.00
Multiparous (%)	12 (52.2%)	12 (52.2%)	
BMI (kg/m², Mean ± SD)	24.11 ± 3.21	22.27 ± 2.89	0.047
Gestational Age (weeks, Mean ± SD)	25.72 ± 7.69	24.35 ± 6.52	0.556

Among antenatal participants

Table 2: Comparison of Haematological and Iron Parameters

Parameter	Daily (n=23)	Alternate-day (n=23)	p-value
Haemoglobin (g/dL)			
Baseline	8.59 ± 0.97	9.04 ± 1.11	0.149
4 Weeks	9.76 ± 0.95	10.07 ± 1.10	0.299
8 Weeks	10.73 ± 1.07	11.16 ± 1.15	0.199
Mean Hb Rise (g/dL)			
4 Weeks	1.17 ± 0.36	1.03 ± 0.36	0.212
8 Weeks	2.14 ± 0.54	2.12 ± 0.48	0.863
Serum Ferritin (µg/L)			
Baseline	10.46 ± 3.76	10.32 ± 5.16	0.917
4 Weeks	19.84 ± 5.14	23.01 ± 7.05	0.088
8 Weeks	30.70 ± 8.46	34.37 ± 8.04	0.138

Table 3: Clinical Outcomes, Side Effects, and Compliance

Parameter	Daily (n=23)	Alternate-day (n=23)	p-value
Gastrointestinal Side Effects			
Nausea	14 (60.9%)	10 (43.5%)	0.376
Vomiting	5 (21.7%)	1 (4.3%)	0.187
Epigastric Pain	7 (30.4%)	1 (4.3%)	0.047
Constipation	10 (43.5%)	3 (13.0%)	0.047
Any GI Side Effect	20 (87.0%)	14 (60.9%)	0.091
Compliance (%) Mean ± SD	72.49 ± 12.06	85.15 ± 11.05	0.0006
Good Compliance (≥80%)	6 (26.1%)	16 (69.6%)	0.011
Treatment Outcome			
Positive Response	23 (100%)	23 (100%)	—
Duration to Target Hb (weeks)	10.78 ± 4.34	9.57 ± 4.13	0.335
Target Hb achieved at 8 weeks	9 (39.1%)	13 (56.5%)	0.376

DISCUSSION

The present randomized controlled trial compared daily versus alternate-day oral iron therapy (100 mg elemental iron) in obstetric patients with iron deficiency anaemia. A total of 46 participants were evaluated over 8 weeks for haemoglobin response, iron parameters, side effects, and compliance. The findings support alternate-day iron supplementation as an effective and better-tolerated strategy. Baseline characteristics were comparable between the two groups (Table 1), with no significant differences in age, obstetric status, gravidity, parity, BMI, gestational age, or baseline haematological parameters (all $p > 0.05$). This confirms effective randomization. Similar baseline comparability was reported by Mukhopadhyay et al,[11] and Chu Lam et al,[12] where no significant differences were observed between intervention groups. Both groups demonstrated significant improvement in haemoglobin from baseline to 8 weeks ($p < 0.001$), consistent with the established efficacy of oral iron therapy as reported by Peña-Rosas et al.[13] Although the alternate-day group showed higher mean haemoglobin at 8 weeks (Table 2), the intergroup difference was not statistically significant. The observed trend toward better haemoglobin response with alternate-day dosing is supported by the hepcidin-mediated absorption mechanism. Moretti et al,[9] reported that oral iron doses ≥60 mg increase hepcidin levels for up to 24 hours, reducing subsequent iron absorption by 35–45%. Stoffel et al,[10] demonstrated that alternate-day dosing resulted in higher fractional iron absorption (21.8% vs 16.3%, $p = 0.0013$), and in anaemic women, 40–50% greater absorption compared to daily dosing.[14] These findings explain the improved absorption kinetics with alternate-day therapy. In contrast, Chu Lam et al,[12] reported no significant difference in haemoglobin change at 6 weeks, possibly due to shorter follow-up and lower iron dosing. Similarly, Banerjee et al,[15] found that while daily dosing may slightly increase haemoglobin levels, intermittent regimens achieve adequate correction with fewer adverse events. Serum ferritin improved in both groups, indicating restoration of iron stores (Table 2). Although higher levels were observed in the alternate-day group at 4 and 8 weeks, differences were not statistically significant. Stoffel et al,[16] reported comparable ferritin levels between dosing regimens (43.8 vs 44.8 µg/L, $p = 0.98$), while also demonstrating lower iron deficiency prevalence in the alternate-day group at 6 months (3.0% vs 11.4%, $p = 0.049$). Okam et al,[17] noted that haemoglobin improvement precedes ferritin recovery, which was consistent with the gradual ferritin rise observed in the present study. All red cell indices improved in both groups, reflecting correction of microcytic hypochromic anaemia. No significant intergroup differences were observed at 8 weeks (Table 2). Similar findings were reported by Goone wardene and Senadheera,[18] who observed comparable improvements in haematological parameters across different supplementation regimens.

Gastrointestinal side effects were significantly more frequent in the daily group (Table 3), particularly epigastric pain and constipation ($p < 0.05$). Other symptoms such as nausea and vomiting were also more common, though not statistically significant. These findings are supported by Tolkien et al,[8] who reported increased gastrointestinal adverse effects with oral iron (OR 2.32). Stoffel et al,[16] observed a

higher prevalence of side effects in the daily dosing group (LPR 1.56, $p < 0.0001$). Cancelo-Hidalgo et al,[19] similarly identified gastrointestinal intolerance as a major barrier to therapy. The reduced side effects with alternate-day dosing can be explained by lower unabsorbed iron in the gut. Kortman et al,[20] demonstrated that excess luminal iron promotes inflammation and microbial imbalance, while alternate-day dosing improves absorption efficiency and reduces gastrointestinal irritation.[21] Compliance was significantly higher in the alternate-day group (Table 3), likely due to reduced side effects. Similar findings were reported by Stanworth et al,[22] where adherence was lower in daily dosing (47%) compared to alternate-day (62%) regimens. Siddiqui et al,[23] also reported that gastrointestinal side effects were a major cause of non-compliance, affecting up to 40% of pregnant women. All participants showed a positive response, with no treatment failures. A higher proportion of patients in the alternate-day group achieved target haemoglobin at 8 weeks, although not statistically significant (Table 3). The time to achieve target haemoglobin was also shorter in this group. Mukhopadhyay et al,[11] similarly reported comparable outcomes between dosing regimens, supporting the clinical effectiveness of alternate-day therapy.

CONCLUSION

Both daily and alternate-day oral iron therapy effectively improved haemoglobin and iron stores in obstetric patients with iron deficiency anaemia. Alternate-day dosing showed comparable efficacy with significantly fewer gastrointestinal side effects and better compliance. It also demonstrated a trend toward faster achievement of target haemoglobin levels. Thus, alternate-day therapy may be a more tolerable and practical alternative to daily iron supplementation.

Limitations of the Study

The present study had a relatively small sample size, which may limit the generalizability of the findings. Being a single-center study, the results may not be applicable to broader populations. The open-label design could introduce reporting bias, particularly for subjective outcomes such as gastrointestinal side effects. Additionally, the short follow-up duration of 8 weeks did not allow assessment of long-term outcomes, including sustained iron stores, pregnancy outcomes, and neonatal parameters.

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