



COMPARATIVE EFFECTIVENESS OF MICRODISPERSIBLE FERRIC PYROPHOSPHATE AND FERRIC CARBOXYMALTOSE IN IRON DEFICIENCY ANAEMIA DURING PREGNANCY: A PROSPECTIVE NON-RANDOMISED COHORT STUDY

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ABSTRACT

Introduction: Iron deficiency anaemia (IDA) remains an important complication of pregnancy and may adversely affect maternal well-being, obstetric outcomes and postpartum recovery. Oral iron is widely used but treatment adherence and gastrointestinal intolerance may limit its effectiveness, whereas intravenous ferric carboxymaltose (FCM) permits rapid iron replacement but involves greater direct treatment expenditure. Microdispersible ferric pyrophosphate (MDFP) represents an oral iron formulation intended to improve tolerability and treatment acceptance. **Aim:** To compare the haematological response, iron-store recovery, treatment compliance, patient satisfaction, quality of life and treatment-related cost of MDFP and FCM in pregnant women with IDA. **Methodology:** A prospective, non-randomised, comparative observational cohort study was conducted among pregnant women aged 21–40 years at 28–37 weeks of gestation with IDA. A total of 134 women were enrolled, with 67 receiving MDFP and 67 receiving FCM according to clinical indication and physician judgement. MDFP was administered as 60 mg elemental iron once daily for mild anaemia and 60 mg twice daily for moderate anaemia. FCM was administered according to the Ganzoni formula, with a target haemoglobin of 12 g/dL and a maximum single dose of 1000 mg. Haemoglobin, ferritin, transferrin saturation, compliance, satisfaction, quality of life, adverse events and treatment-related costs were assessed. Follow-up occurred at 32–34 weeks, term and six weeks postpartum. Six-week analyses were based on available complete follow-up data from 61 MDFP and 65 FCM recipients. **Result:** Haemoglobin increased from 9.3 ± 0.8 to 11.3 ± 0.8 g/dL in the MDFP group and from 9.0 ± 1.0 to 12.2 ± 0.6 g/dL in the FCM group at six weeks postpartum, with adjusted between-group differences favouring FCM at all post-treatment assessments ($p < 0.001$). Serum ferritin and transferrin saturation were also higher with FCM. Good oral-pill compliance was observed in 47/61 (77.0%) MDFP recipients, whereas 65/65 (100%) FCM recipients completed the IV course. Additional iron was required in 23.0% versus 1.5%, respectively ($p < 0.001$). Satisfaction and physical and mental quality-of-life scores were higher with FCM, while fatigue severity was lower. Total cost per patient was ₹3,790 ± 985 for MDFP and ₹6,220 ± 1,210 for FCM. **Conclusion:** In this non-randomised cohort, FCM was associated with a faster and greater haematological and iron-store response, complete treatment-course completion and higher patient satisfaction, whereas MDFP had lower overall treatment cost. The findings should be interpreted in view of baseline differences and the observational allocation of treatment.

KEYWORDS

Iron Deficiency Anaemia; Pregnancy; Microdispersible Ferric Pyrophosphate; Ferric Carboxymaltose; Haemoglobin; Ferritin; Compliance; Treatment Cost

INTRODUCTION

Iron deficiency anaemia (IDA) is one of the most frequent nutritional and haematological disorders encountered during pregnancy. Increased maternal iron requirements associated with expansion of maternal red-cell mass, placental development and fetal growth make pregnancy particularly vulnerable to depletion of iron stores. When iron deficiency becomes clinically significant, reduced haemoglobin concentration may contribute to fatigue, impaired physical functioning, reduced quality of life and increased vulnerability to adverse maternal outcomes. Effective treatment therefore requires not only correction of haemoglobin concentration but also restoration of iron stores and adequate treatment completion.^{1,4}

Oral iron remains an established approach for treatment of IDA because of its accessibility, convenience and relatively low cost. However, gastrointestinal adverse effects and the need for sustained daily administration may compromise adherence. Treatment effectiveness in routine clinical practice consequently depends partly on the ability of pregnant women to tolerate and continue oral supplementation. Evidence concerning oral iron formulations has demonstrated variation in tolerability and treatment response, emphasizing the importance of both biological efficacy and patient acceptability.^{5,6}

Intravenous iron has increasingly been used when rapid iron replacement is required, when oral therapy is poorly tolerated or when treatment is initiated relatively late in pregnancy. Ferric carboxymaltose permits administration of a relatively large iron dose over a short period and may therefore reduce the duration of treatment and improve completion. Previous clinical investigations have demonstrated the effectiveness of intravenous iron in pregnancy, including ferric carboxymaltose, although safety, monitoring requirements and treatment cost remain relevant considerations.^{1,3,9,13,15}

The choice between oral and intravenous therapy is therefore multidimensional. Haemoglobin response alone does not fully capture treatment effectiveness. Restoration of iron stores, adherence, additional treatment requirements, adverse effects, patient satisfaction

and quality of life may all influence the practical value of a treatment strategy. Furthermore, the economic consequences extend beyond drug acquisition to include administration, laboratory monitoring, management of adverse effects, travel, lost wages and caregiver time.^{16,20}

Microdispersible ferric pyrophosphate provides an oral alternative intended to facilitate iron supplementation while maintaining the practical advantages of oral administration. FCM, in contrast, provides parenteral iron replacement and may be particularly useful when rapid correction is clinically desirable. Existing literature has predominantly compared intravenous iron with conventional oral iron preparations, while direct evidence comparing MDFP with FCM in pregnancy remains limited. The present study therefore evaluated these two treatment approaches within a prospective clinical cohort.

The present study was designed as a prospective, non-randomised comparative observational cohort. Treatment allocation was determined by clinical indication and physician judgement rather than randomisation. This distinction is important because treatment selection in routine practice may be influenced by disease severity and other clinical factors. In the present cohort, baseline haemoglobin and ferritin were lower in women receiving FCM, reflecting the clinical practice of preferentially using intravenous iron in women with greater treatment requirements. Therefore, adjusted analyses were used to account for baseline haemoglobin and relevant covariates, but the observational design requires cautious interpretation of between-group differences.

The primary clinical focus was comparison of haemoglobin response and restoration of iron stores. Secondary considerations included treatment compliance, need for additional iron, treatment satisfaction, quality of life, adverse events and economic burden. The study was therefore intended to provide a clinically relevant comparison of two different treatment routes while considering both patient-centred and economic outcomes.

Aim

To compare the effectiveness of microdispersible ferric pyrophosphate

and ferric carboxymaltose for the treatment of iron deficiency anaemia during pregnancy.

Objectives

1. To compare haemoglobin and iron-store responses following treatment with MDPF and FCM.
2. To assess and compare treatment compliance and the requirement for additional iron therapy.
3. To compare patient satisfaction, fatigue and quality of life following treatment.
4. To compare the treatment-related direct and indirect costs of MDPF and FCM.

MATERIALS AND METHODS

Study Design and Setting

A prospective, non-randomised, comparative observational cohort study was conducted in the Department of Obstetrics and Gynaecology, The Fatima Hospital, Lucknow. The study was undertaken over a two-year period following institutional ethics committee approval. Written informed consent was obtained from eligible participants before enrolment.

The study included pregnant women between 28 and 37 weeks of gestation with IDA. The eligibility criteria included age 21–40 years, singleton pregnancy, haemoglobin 7.0–10.9 g/dL and laboratory evidence of iron deficiency.

Women with hypersensitivity or serious intolerance to iron preparations, multiple pregnancy, haemoglobinopathy, chronic liver or renal disease, significant infection, bleeding disorders, other causes of anaemia or previous blood transfusion during the current pregnancy were excluded.

Sample Size and Participant Allocation

The calculated sample size was 57 participants per group. Allowing for approximately 15% attrition, 67 women were recruited into each group, giving a total enrolment of 134 participants. Consecutive non-probability convenience sampling was used.

Participants were not randomly allocated. Treatment was selected according to clinical indication and treating-physician judgement. Women receiving MDPF constituted Group A, while those receiving FCM constituted Group B. Consequently, the study was interpreted as a non-randomised observational comparison rather than a randomized controlled trial.

Treatment Protocol

Women with mild anaemia (haemoglobin 10.0–10.9 g/dL) in the MDPF group received 60 mg elemental iron once daily. Women with moderate anaemia (haemoglobin 7.0–9.9 g/dL) received 120 mg elemental iron daily as 60 mg twice daily.

FCM dosage was calculated using the Ganzoni formula with a target haemoglobin of 12 g/dL. A maximum single dose of 1000 mg was diluted in 150–200 mL of 0.9% saline and administered intravenously over approximately 15–20 minutes.

Follow-up and Outcome Assessment

Participants were assessed at baseline and followed at 32–34 weeks of gestation, at term (≥ 37 weeks) and at six weeks postpartum. Haemoglobin, mean corpuscular volume, serum ferritin, total iron-binding capacity and transferrin saturation were assessed at the relevant follow-up points. Serum phosphate was assessed when clinically indicated in the FCM group.

Compliance with MDPF was assessed using pill count and self-report. Completion of the prescribed IV course was used to assess FCM treatment completion. Patient satisfaction was assessed using a visual analogue scale, and quality of life was evaluated using physical and mental component measures. Fatigue severity was also recorded.

Treatment costs included drug acquisition, administration, laboratory monitoring, management of adverse effects, travel, lost wages and caregiver time. Total cost per patient and cost per 1 g/dL haemoglobin rise were recorded.

Of the 134 women enrolled, 67 were initially included in each treatment group. Six-week postpartum analyses requiring complete follow-up data included 61 women in the MDPF group and 65 in the

FCM group, giving 126 women with relevant completed six-week assessments. The six-week denominators were therefore reported as 61 and 65; no assumption was made regarding outcomes among participants without the relevant follow-up data.

Statistical Analysis

Data were analysed using SPSS version 20. Continuous variables were summarized as mean $\pm$ standard deviation and categorical variables as frequencies and percentages. Between-group comparisons were performed using independent-samples t-test or appropriate non-parametric tests for continuous variables and chi-square or Fisher exact test for categorical variables.

Repeated haemoglobin measurements were evaluated using linear mixed-effects models adjusted for baseline haemoglobin, gestational age, parity and socioeconomic status. Ferritin and other iron indices were analysed using generalized estimating equations, with log transformation used for ferritin where appropriate. Regression analyses were used for relevant continuous and categorical outcomes, with adjustment for baseline haemoglobin, ferritin, gestational age, parity and socioeconomic status. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 134 women were enrolled, comprising 67 in the MDPF group and 67 in the FCM group. Baseline demographic and obstetric characteristics were broadly similar; however, baseline haemoglobin and serum ferritin were lower in the FCM group. Mean baseline haemoglobin was 9.3 ± 0.8 g/dL in the MDPF group and 9.0 ± 1.0 g/dL in the FCM group, while ferritin was 9.2 ± 3.8 and 8.1 ± 3.6 ng/mL, respectively. These baseline differences were considered in adjusted analyses.

Haemoglobin increased progressively in both groups but the adjusted response consistently favoured FCM. At 2–4 weeks, haemoglobin was 10.2 ± 0.9 g/dL with MDPF and 11.6 ± 0.8 g/dL with FCM, with an adjusted difference of 1.35 g/dL (95% CI 1.10–1.60; $p < 0.001$). At term, the corresponding values were 10.9 ± 0.7 and 12.0 ± 0.7 g/dL, with an adjusted difference of 1.08 g/dL (95% CI 0.85–1.31; $p < 0.001$). At six weeks postpartum, haemoglobin was 11.3 ± 0.8 versus 12.2 ± 0.6 g/dL, with an adjusted difference of 0.86 g/dL (95% CI 0.64–1.08; $p < 0.001$).

Iron-store recovery also favoured FCM. Serum ferritin increased from 9.2 ± 3.8 to 32.6 ± 11.5 ng/mL in the MDPF group and from 8.1 ± 3.6 to 48.9 ± 16.8 ng/mL in the FCM group by six weeks postpartum. The six-week transferrin saturation was $20.8 \pm 7.1\%$ with MDPF compared with $31.5 \pm 9.2\%$ with FCM.

Six-week treatment-compliance analyses included 61 MDPF and 65 FCM recipients. Good pill compliance ($\geq 80\%$) was observed in 47/61 women (77.0%), whereas 65/65 FCM recipients (100%) completed the IV course. Additional iron was required in 14 women (23.0%) receiving MDPF compared with one woman (1.5%) receiving FCM ($p < 0.001$). Satisfaction, physical and mental quality-of-life scores were higher with FCM, while fatigue severity was lower.

Total treatment cost per patient was $\text{₹}3,790 \pm 985$ for MDPF and $\text{₹}6,220 \pm 1,210$ for FCM, representing a mean difference of $\text{₹}2,430$. MDPF had lower drug and administration costs, whereas FCM had lower travel, lost-wage and caregiver costs. The thesis-derived cost per 1 g/dL haemoglobin rise was $\text{₹}1,580 \pm 420$ for MDPF and $\text{₹}2,020 \pm 510$ for FCM. This metric was retained as reported in the thesis and was treated as an individual-patient-derived economic measure rather than recalculated from aggregate mean costs and aggregate mean haemoglobin changes.

Table 1. Baseline Demographic and Clinical Characteristics

Characteristic	MDPF Group (n=67)	FCM Group (n=67)	Standardized Difference
Age (years)	27.3 ± 4.5	28.1 ± 4.2	0.18
Gestational age at enrollment (weeks)	30.5 ± 2.4	29.8 ± 2.6	0.28
Primigravida	28 (41.8%)	25 (37.3%)	0.09
Multigravida	39 (58.2%)	42 (62.7%)	0.09
Baseline Hb (g/dL)	9.3 ± 0.8	9.0 ± 1.0	0.33
Baseline serum ferritin (ng/mL)	9.2 ± 3.8	8.1 ± 3.6	0.29

BMI (kg/m ²)	23.8 ± 3.2	24.5 ± 3.5	0.21
Upper-middle socioeconomic status	12 (17.9%)	15 (22.4%)	0.11
Lower-middle socioeconomic status	38 (56.7%)	35 (52.2%)	0.09
Upper-lower socioeconomic status	17 (25.4%)	17 (25.4%)	0.00

Note: Standardized difference >0.2 indicated potential imbalance. Baseline haemoglobin and ferritin were lower in the FCM group, consistent with clinical practice of reserving IV iron for women with greater treatment requirements.

Table 2. Haemoglobin Response Over Time

Time point	MDFP Group (Mean ± SD)	FCM Group (Mean ± SD)	Adjusted Difference (95% CI)	p-value
Baseline	9.3 ± 0.8	9.0 ± 1.0	–	–
2–4 weeks post-treatment	10.2 ± 0.9	11.6 ± 0.8	1.35 (1.10, 1.60)	<0.001
At term (≥37 weeks)	10.9 ± 0.7	12.0 ± 0.7	1.08 (0.85, 1.31)	<0.001
6 weeks postpartum	11.3 ± 0.8	12.2 ± 0.6	0.86 (0.64, 1.08)	<0.001

Statistical analysis: linear mixed-effects model adjusted for baseline haemoglobin, gestational age, parity and socioeconomic status.

Table 3. Iron-Storage Parameters Over Time

Parameter and time	MDFP Group	FCM Group	Adjusted Difference (95% CI)	p-value
Serum ferritin – baseline (ng/mL)	9.2 ± 3.8	8.1 ± 3.6	–	–
Serum ferritin – 2–4 weeks (ng/mL)	20.5 ± 7.3	112.4 ± 32.6	91.2 (84.5, 97.9)	<0.001
Serum ferritin – term (ng/mL)	25.8 ± 9.1	89.7 ± 28.4	62.8 (55.3, 70.3)	<0.001
Serum ferritin – 6 weeks postpartum (ng/mL)	32.6 ± 11.5	48.9 ± 16.8	15.6 (10.2, 21.0)	<0.001
TSAT – baseline (%)	14.2 ± 5.3	13.5 ± 5.8	–	–
TSAT – 6 weeks postpartum (%)	20.8 ± 7.1	31.5 ± 9.2	10.4 (7.8, 13.0)	<0.001

Statistical analysis: generalized estimating equations; log transformation was used for ferritin.

Table 4. Compliance, Satisfaction And Quality Of Life At Six Weeks

Measure	MDFP n=61	FCM n=65	p-value
Good compliance (≥80% pills taken)	47/61 (77.0%)	NA	–
Completed full IV course	NA	65/65 (100%)	–
Additional iron required	14 (23.0%)	1 (1.5%)	<0.001
Satisfaction VAS	6.5 ± 1.8	8.9 ± 1.2	<0.001
Would choose same treatment again	45 (73.8%)	62 (95.4%)	0.001
Physical Component Score	42.3 ± 6.8	46.8 ± 5.2	<0.001
Mental Component Score	44.5 ± 7.2	47.1 ± 6.5	0.032
Fatigue Severity	4.2 ± 1.1	3.1 ± 0.9	<0.001

Compliance was assessed by pill count/self-report for MDFP and completion of the prescribed IV course for FCM. Independent t-test or chi-square test was used as appropriate.

Table 5. Cost Analysis

Cost component	MDFP (Mean ± SD), ₹	FCM (Mean ± SD), ₹	Mean Difference (95% CI), ₹
Drug cost	480 ± 85	3,250 ± 450	2,770 (2,640, 2,900)
Administration/procedure	150 ± 30	750 ± 120	600 (560, 640)
Monitoring tests	1,200 ± 250	1,050 ± 220	–150 (–245, –55)
Management of side effects	280 ± 180	420 ± 310	140 (40, 240)
Travel	450 ± 220	280 ± 150	–170 (–240, –100)

Lost wages	850 ± 420	320 ± 210	–530 (–660, –400)
Caregiver time	380 ± 190	150 ± 100	–230 (–290, –170)
Total cost/patient	3,790 ± 985	6,220 ± 1,210	2,430 (2,080, 2,780)
Cost per 1 g/dL Hb rise	1,580 ± 420	2,020 ± 510	440 (270, 610)

Costs were recorded in Indian rupees from hospital billing and patient interviews. The reported cost per 1 g/dL haemoglobin rise was retained from the thesis and represents an individual-patient-derived economic measure summarized by treatment group; it was not recalculated from aggregate mean total cost divided by aggregate mean haemoglobin change.

DISCUSSION

The present prospective non-randomised cohort demonstrated that both MDFP and FCM were associated with improvement in haemoglobin during pregnancy and the postpartum period, but the magnitude and speed of response were greater with FCM. The FCM group also demonstrated greater recovery of iron stores, complete completion of the prescribed intravenous course, lower need for additional iron, higher treatment satisfaction and better quality-of-life measures. MDFP, however, retained a substantial economic advantage in terms of total treatment expenditure. These findings should be interpreted as associations observed in a clinically allocated cohort rather than as definitive causal evidence of treatment superiority.

The baseline characteristics provide an important context for interpretation. Age, gestational age at enrolment, parity, BMI and socioeconomic distribution were broadly similar between groups. However, baseline haemoglobin and ferritin were lower among women receiving FCM. This pattern is clinically plausible because intravenous iron was preferentially used in women requiring more intensive or rapid correction. Jose et al. demonstrated the clinical value of intravenous ferric carboxymaltose in pregnancy, while Pavord et al. emphasized the role of intravenous iron when oral therapy is unsuitable or when rapid replacement is clinically required.^{1,9} The present findings are therefore consistent with the rationale for intravenous treatment, although the baseline imbalance means that adjusted analyses rather than crude comparisons should guide interpretation.

The haemoglobin response in Table 2 represents the principal efficacy finding. The present cohort showed a substantially greater early haemoglobin increase with FCM, with an adjusted difference of 1.35 g/dL at 2–4 weeks. This was maintained at term and six weeks postpartum, although the absolute between-group difference narrowed over time. The pattern is consistent with the pharmacological advantage of delivering a large quantity of bioavailable iron intravenously without dependence on intestinal absorption. Jose et al. reported clinically meaningful haemoglobin improvement following ferric carboxymaltose treatment during pregnancy, supporting the observation that intravenous iron can provide efficient correction when treatment is initiated during later gestation.¹ Chawla et al. also reported improvement following iron treatment in pregnant women, although treatment regimens and populations differed from those in the present cohort.²

Rogozińska et al. synthesized evidence concerning iron supplementation and pregnancy outcomes and highlighted the heterogeneity of available evidence, particularly in relation to route, dose and timing of treatment.³ The present findings add a practical comparison between an oral formulation and FCM, but the non-randomised allocation prevents direct attribution of the observed difference entirely to treatment route. Srivastav et al. reported clinical benefits associated with intravenous iron strategies, again supporting the biological plausibility of the faster response observed with FCM.⁴ Laganà et al. discussed the clinical importance of iron replacement and the limitations of oral treatment in settings where treatment tolerance and adherence may affect outcomes.⁵

The iron-storage findings in Table 3 further support the haematological response. Ferritin increased markedly with FCM during the early post-treatment period and remained higher than with MDFP at term and six weeks postpartum. TSAT at six weeks was also higher with FCM. This distinction is clinically important because haemoglobin correction alone does not necessarily indicate complete restoration of iron

reserves. Pavord et al. emphasized the importance of assessing iron deficiency and appropriate iron replacement during pregnancy, while Araujo Costa and de Paula Ayres reviewed the broader evidence regarding intravenous iron and iron repletion.^{9,10} Young et al. described the biological importance of iron availability for maternal and fetal physiology, supporting the relevance of evaluating storage indices in addition to haemoglobin.¹¹

Liu et al. emphasized the relationship between iron status and physiological requirements during pregnancy, while Madendag et al. demonstrated the clinical utility of ferric carboxymaltose for correction of iron deficiency.^{12,13} The magnitude of ferritin elevation observed shortly after FCM in the present study is compatible with the large parenteral iron dose and should be interpreted as evidence of replenishment rather than as a direct measure of long-term functional iron availability. The progressive decline from the early post-treatment ferritin peak to term and postpartum also illustrates the dynamic nature of iron utilization during pregnancy and after delivery.

The compliance and patient-centred findings in Table 4 represent an important distinction between the two strategies. Good oral-pill compliance was achieved by 77.0% of evaluable MDPF participants, while all evaluable FCM recipients completed their prescribed intravenous course. Additional iron was subsequently required in 23.0% of MDPF recipients compared with only 1.5% of FCM recipients. Tolkien et al. demonstrated that oral iron supplementation is commonly limited by gastrointestinal adverse effects and tolerability considerations.¹⁶ Bloor et al. and Culeddu et al. further examined the biological and clinical consequences of oral and intravenous iron exposure, supporting the concept that route of administration can influence treatment experience and adherence.^{17,18}

Kumar et al. emphasized that iron deficiency anaemia management requires attention to both correction of deficiency and practical treatment implementation.¹⁹ The higher satisfaction and greater willingness to choose the same treatment again among FCM recipients in the present study are therefore clinically meaningful. However, this does not imply that intravenous treatment is universally preferable. The convenience of oral therapy, absence of infusion requirements and substantially lower direct treatment cost remain important advantages of MDPF, particularly for women with less severe disease and adequate treatment adherence.

The quality-of-life findings also favoured FCM. Physical and mental component scores were higher, while fatigue severity was lower. These findings may partly reflect the greater haemoglobin response and improved iron availability, but causal attribution is not possible from the observational design. Lo et al. have highlighted the broader clinical consequences of iron deficiency and the relevance of patient-centred outcomes beyond laboratory correction.²⁰ Garzon et al. similarly emphasized the importance of considering the clinical burden associated with iron deficiency and treatment strategies.²¹

The cost analysis demonstrates an important counterbalance to the superior haematological response associated with FCM. Drug cost, administration cost and management of side effects were greater with FCM, resulting in a total mean cost of ₹6,220 compared with ₹3,790 for MDPF. MDPF therefore had a lower overall economic burden in the present cohort. The lower travel, lost-wage and caregiver costs associated with FCM partially offset its greater direct medical expenditure, illustrating why economic evaluation should include both direct and indirect components.

The reported cost per 1 g/dL haemoglobin rise was ₹1,580 ± 420 with MDPF and ₹2,020 ± 510 with FCM. These values have been retained exactly as reported in the thesis. They should not be recalculated using the aggregate mean total cost and aggregate mean haemoglobin values because the reported metric represents an individual-patient-derived economic measure subsequently summarized by treatment group. Thus, the appropriate interpretation is that FCM produced a greater haematological response but at a greater reported economic cost in this cohort. The study should therefore not claim that FCM was “more cost-effective.”

The adverse-event profile also provides important context. The overall frequency of adverse events was 46.3% with MDPF and 35.8% with FCM, but the confidence interval for the overall risk difference did not establish a statistically significant overall difference. Gastrointestinal adverse effects were more frequent with MDPF, particularly nausea,

constipation and epigastric pain. Conversely, IV-related reactions and hypophosphataemia were observed predominantly in the FCM group. These findings illustrate the differing tolerability profiles of oral and intravenous treatment rather than demonstrating universal safety superiority of either formulation.

The severe anaemia subgroup further supports the observation that FCM may provide greater benefit when rapid correction is required. In women with severe anaemia, six-week postpartum haemoglobin was 10.9 ± 0.8 g/dL with MDPF and 12.0 ± 0.7 g/dL with FCM, while the haemoglobin increment was 1.8 ± 0.7 versus 3.2 ± 0.9 g/dL. The need for additional intervention was also greater with MDPF. This finding is clinically relevant because women presenting later in pregnancy with more severe anaemia have less time available for oral correction before delivery.

Nevertheless, the observational design remains the principal limitation in interpreting all comparative findings. Treatment selection was not random and baseline haemoglobin and ferritin were lower in the FCM group. Although the principal analyses adjusted for baseline haemoglobin and selected covariates, residual confounding cannot be excluded. Furthermore, six-week analyses were available for 61 MDPF and 65 FCM participants rather than the complete initial cohort of 134. The reasons for unavailable follow-up data should not be inferred beyond what was documented in the thesis.

The present findings also have to be interpreted within the context of the evidence base. Existing studies have generally compared intravenous iron with conventional oral iron preparations, whereas the present study specifically evaluated MDPF against FCM. Therefore, direct extrapolation from studies involving other oral formulations should be undertaken cautiously. The study nevertheless provides clinically relevant evidence that treatment route is associated not only with haemoglobin response but also with adherence, treatment satisfaction and economic burden.

Overall, the findings suggest that FCM may be particularly useful when rapid correction, restoration of iron stores and assured treatment completion are priorities, whereas MDPF remains attractive where lower treatment cost and oral administration are important considerations. The appropriate choice should therefore be individualized according to severity of anaemia, gestational age, tolerance, treatment adherence, clinical urgency, availability of intravenous therapy and economic circumstances. Confirmation through adequately powered randomized comparative studies would be valuable.

CONCLUSION

In this prospective non-randomised cohort of pregnant women with iron deficiency anaemia, FCM was associated with faster and greater improvement in haemoglobin and iron stores, complete treatment-course completion, lower need for additional iron and higher treatment satisfaction than MDPF. MDPF was associated with substantially lower overall treatment cost. These findings support FCM as an effective option when rapid correction is clinically required, while the observational allocation, baseline differences and incomplete six-week follow-up warrant cautious interpretation and confirmation in randomized studies.

Limitations

The study was non-randomised, and treatment allocation was based on clinical judgement, introducing potential selection and residual confounding. Baseline haemoglobin and ferritin were lower in the FCM group. Six-week analyses were based on 61 MDPF and 65 FCM participants. The study was conducted at a single centre, limiting generalisability, and the reported economic metric was derived at the individual-patient level.

Recommendations

FCM may be considered when rapid correction, greater iron-store repletion or assured treatment completion is clinically important, particularly in later gestation or more severe anaemia. MDPF remains a lower-cost oral option for appropriately selected women. Treatment choice should incorporate severity, gestational age, tolerance, adherence, clinical urgency and affordability. Larger multicentre randomized studies with complete follow-up and prospective economic evaluation are recommended.

Declarations Ethics Approval

The study was conducted after institutional ethics committee approval and in accordance with the approved study protocol.

Informed Consent

Written informed consent was obtained from participating women before enrolment.

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Conflict of Interest

No conflict of interest

The data generated and/or analyzed during the present study are available from the corresponding author on reasonable request. The data are not publicly available due to institutional and participant confidentiality considerations.

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