

Experience of using modern oral iron formulations for the correction of iron deficiency conditions in women of reproductive age

Valentyna K. Kondratiuk¹, Iryna M. Nikitina², Natalia Y. Horban³, Kateryna O. Kondratiuk⁴, Natalia P. Dzis⁵

¹SHUPYK NATIONAL HEALTHCARE UNIVERSITY OF UKRAINE, KYIV, UKRAINE

²SUMY STATE UNIVERSITY, SUMY, UKRAINE

³STATE INSTITUTION "UKRAINIAN CENTER OF MATERNITY AND CHILDHOOD OF THE NATIONAL ACADEMY OF MEDICAL SCIENCES OF UKRAINE", KYIV, UKRAINE

⁴O.O. BOGOMOLETS NATIONAL MEDICAL UNIVERSITY, KYIV, UKRAINE

⁵NATIONAL PIROGOV MEMORIAL MEDICAL UNIVERSITY, VINNYTSIA, UKRAINE

ABSTRACT

Aim: To scientifically justify the use of the FERRO-EURIKA™ food supplement as a corrective agent for iron deficiency (ID) in women of reproductive age.

Materials and Methods: The study involved 120 women aged 18 to 35 years (median age: 29 years; interquartile range: 24–33 years) with laboratory-confirmed iron deficiency (ID) and iron deficiency anaemia (IDA) related to chronic blood loss (ICD-10 N 92.0 – Excessive and frequent menstruation with regular cycles). In addition to evaluating changes in peripheral blood parameters and iron stores, we analysed the participants' complaints and clinical manifestations of iron deficiency conditions (sideropenic and anaemic syndromes). All subjects were divided into two representative groups of 60 women each. Women of Group 1 (main group, n = 60) received iron bisglycinate 157 mg (equivalent to 30 mg of elemental bivalent iron) in combination with glucosamine salt of (6S)-5-methyltetrahydrofolate – 740 µg (equivalent to 400 µg of folic acid), one capsule twice daily, 30 minutes before meals, for pathogenetically justified correction of ID conditions. Women of Group 2 (comparison group, n = 60) received ferrous sulfate 247.25 mg (equivalent to 80 mg of elemental bivalent iron), one capsule twice daily, 30 minutes before meals. The treatment duration for both groups was 90 days.

Results: We analysed clinical manifestations of iron deficiency conditions and laboratory parameters in women of reproductive age both before the initiation of iron therapy and during correction (on Days 21, 60, and 90 of treatment). Dynamic analysis of clinical symptoms and haematologic indicators in both groups demonstrated a significant decrease in subjective complaints, accompanied by normalization of laboratory parameters, confirming the positive effects of the interventions. Safety and tolerability analyses of the correction of ID conditions were performed to evaluate adherence to long-term iron supplementation among women. An analysis of the causes of treatment discontinuation revealed gastrointestinal adverse effects associated with iron intake: nausea occurred in 5 (8.3%) women of Group 1 and 13 (24.1%) of Group 2; constipation in 2 (3.3%) of Group 1 and 7 (13.0%) of Group 2; and abdominal pain in 2 (3.3%) of Group 1 and 9 (16.7%) of Group 2. These complaints in Group 1 were mild in intensity and resolved by Day 60, allowing all participants in this group to successfully complete the full treatment course. In contrast, gastrointestinal symptoms persisted in Group 2 at Days 60 and 90, resulting in reduced adherence to therapy, with approximately 30% of patients discontinuing further intake of the prescribed iron preparation.

Conclusions: 1. The results of the study indicate that the FERRO-EURIKA™ food supplement may be an effective oral agent for correcting iron deficiency conditions in women of reproductive age. 2. The combination of iron bisglycinate and glucosamine salt of (6S)-5-methyltetrahydrofolate in the composition of FERRO-EURIKA™ contributes to the normalization of haematologic parameters, even at lower doses of iron compared to standard formulations. 3. Women who received the FERRO-EURIKA™ food supplement demonstrated better tolerability and a lower incidence of gastrointestinal adverse effects, leading to higher adherence to therapy and successful completion of the treatment course.

KEY WORDS: iron deficiency; iron deficiency anaemia; prevention; treatment; iron bisglycinate; glucosamine salt of (6S)-5-methyltetrahydrofolate

INTRODUCTION

Iron deficiency (ID) is the most prevalent micronutrient deficiency and a leading cause of iron deficiency anaemia (IDA). This condition remains a significant public health issue, contributing to the global burden of disease [1–3].

Iron plays a fundamental role in oxygen transport, mitochondrial function, DNA synthesis, and aerobic cellular metabolism.

The role of iron in maintaining physiological female hormonal homeostasis is indirect but critically important. Although iron does not directly participate in the

synthesis of oestrogens or progesterone, it indirectly affects hormonal balance, acting as a cofactor for many enzymes required for hydroxylation and transformation of hormonal precursors. Iron is essential for the synthesis of neurotransmitters such as dopamine and serotonin, which influence the secretion of gonadotropin-releasing hormone (GnRH), a key regulator of sex hormone production. As a cofactor, iron is involved in steroidogenesis, the process through which sex hormones (oestrogens, progesterone, testosterone) are synthesized from cholesterol. Consequently, ID and IDA indirectly affect the function of the hypothalamic-pituitary-ovarian axis, leading to clinical manifestations such as ovulatory disorders, abnormal uterine bleeding (AUB), infertility, and tumour-like lesions of the pelvic organs [4,5].

Metabolic disturbances caused by iron deficiency also impact endometrial tissue. In particular, free radical and lipid peroxidation reactions become activated, leading to destabilization of cell membranes and disruption of excitability and functional activity of the endometrium [6].

Among women of reproductive age, AUB is a common cause of ID and IDA, adversely affecting health, quality of life, and healthcare costs. AUB is defined as any deviation from the normal menstrual cycle, manifested by changes in duration, amount of blood loss, or frequency of menstruation. It represents a common gynaecological disorder in women of reproductive age, with a reported prevalence ranging from 10% to 30% in different populations [4–6].

Programs aimed at preventing and treating ID and IDA should focus on eliminating underlying causes, promoting rational nutrition, providing exogenous iron supplementation, and implementing preventive measures to avoid recurrence of the condition. Primary prevention of IDA in women with heavy and prolonged menstruation can be achieved through the monthly administration of 30–40 mg of elemental iron for 7–10 days following menstruation, or through two preventive courses per year, each lasting 6 weeks with daily administrations of 30–40 mg of iron. When selecting an iron compound, it is important to consider the clinical features of ID/IDA, any concomitant diseases, and other individual factors [10,11].

Modern criteria for evaluating the effectiveness of iron compounds include minimal adverse effects, ease of administration, optimal iron content, the presence of components that enhance iron absorption and stimulate haematopoiesis, and a favourable efficacy-to-cost ratio. When prescribing iron therapy, it is essential to consider age, sex, comorbidities, pharmacokinetic properties of the formulation, its pharmacodynamic profile, and potential adverse effects [10,11].

Iron bisglycinate is an amino acid chelate of iron, formed as a result of the reaction between divalent iron and two molecules of the amino acid glycine, covalently bonded during the chelation process. The two glycine molecules bind to iron, protecting it from hydrolysis. As the only form of divalent iron that does not undergo hydrolysis in the stomach, iron bisglycinate is absorbed intact through two types of receptors: DMT-1 (located on duodenal villi) and PEPT-1 (present throughout the gastrointestinal tract). As a result, it demonstrates a bioavailability of 91%. Due to its high bioavailability, a lower dose of iron bisglycinate is sufficient to achieve therapeutic effects compared to other forms of iron, which is particularly beneficial for long-term administration [12–15].

Another important feature of iron bisglycinate is its favourable safety profile. Unfortunately, about half of all outpatients fail to complete their iron therapy due to poor tolerability of conventional iron salts. In contrast, iron bisglycinate is associated with higher patient adherence due to its improved tolerability. Unlike traditional iron salts, iron bisglycinate does not hydrolyse in the stomach, reducing the likelihood of gastrointestinal adverse events [16–19].

There is a relationship between iron absorption and folate levels in the body, both of which are essential for DNA synthesis, the formation of new cells, and normal nervous system function [20,21]. It is recommended that women take daily oral iron and folic acid during preconception preparation and pregnancy to minimize risks of complications for both the mother and the newborn. Experts in gynaecology and nutrition emphasize the importance of exogenous intake of folic acid and iron preparations in women of reproductive age [22].

The glucosamine salt of (6S)-5-methyltetrahydrofolate, a biologically active form of vitamin B9, provides more efficient folate delivery compared to conventional folic acid, particularly for individuals with genetic mutations affecting folate metabolism. The use of glucosamine salt of (6S)-5-methyltetrahydrofolate eliminates this limitation, ensuring effective utilization of folic acid in the body and maintaining adequate red blood cell levels. [20,21].

AIM

To scientifically justify the use of the FERRO-EURIKA™ food supplement as a corrective agent for iron deficiency (ID) in women of reproductive age.

MATERIALS AND METHODS

To achieve the aim of the study, which was to identify differences in the outcomes of correction of ID con-

Table 1. Dynamics of patients' complaints during treatment (absolute number, %)

Parameter	Day of assessment											
	0			21			60			90		
	Group 1 (n=60)	Group 2 (n=60)	P	Group 1 (n=60)	Group 2 (n=54)	P	Group 1 (n=60)	Group 2 (n=47)	P	Group 1 (n=60)	Group 2 (n=42)	P
Fatigue	60 (100.0)	60 (100.0)	>0.999	23 (38.3)	28 (51.9)	0.187	9 (15.0)	15 (31.9)	<u>0.060</u>	1 (2.2)	6 (14.3)	0.019
Headache	18 (30.0)	19 (31.7)	>0.999	10 (16.7)	13 (24.1)	0.358	5 (8.3)	8 (17.0)	0.235	0 (0)	3 (7.1)	<u>0.067</u>
Reduced work capacity	39 (65.0)	38 (63.3)	>0.999	11 (18.3)	21 (38.9)	0.021	2 (3.3)	6 (10.6)	0.134	0 (0)	2 (4.8)	0.167
Lack of concentration	33 (55.0)	31 (51.7)	>0.999	2 (3.3)	11 (20.4)	0.006	0 (0)	0 (0)	>0.999	0 (0)	0 (0)	>0.999
Memory impairment	30 (50.0)	29 (48.3)	>0.999	9 (15.0)	14 (25.9)	0.167	0 (0)	6 (10.6)	0.006	0 (0)	2 (4.8)	0.167
Dizziness	8 (13.3)	9 (15.0)	>0.999	0 (0)	3 (5.6)	0.103	0 (0)	0 (0)	>0.999	0 (0)	0 (0)	>0.999
Tachycardia	6 (10.0)	6 (10.0)	>0.999	1 (1.7)	3 (5.6)	0.344	0 (0)	0 (0)	>0.999	0 (0)	0 (0)	>0.999
Brittle and splitting nails	7 (11.7)	14 (23.3)	0.148	5 (8.3)	7 (13.0)	0.545	0 (0)	5 (10.6)	0.014	0 (0)	3 (6.4)	<u>0.067</u>
Dry skin	14 (23.3)	13 (21.7)	>0.999	12 (20.0)	11 (20.4)	>0.999	8 (13.3)	9 (19.1)	0.436	0 (0)	3 (4.3)	<u>0.067</u>

Note: Fisher's exact test was used

Source: compiled by the authors of this study

Table 2. Dynamics of haematological parameters during treatment (absolute number, %)

Parameter	Day of assessment											
	0			21			60			90		
	Group 1 (n=60)	Group 2 (n=60)	P	Group 1 (n=60)	Group 2 (n=54)	P	Group 1 (n=60)	Group 2 (n=47)	P	Group 1 (n=60)	Group 2 (n=42)	P
RBC count <3.7×10 ¹² /L	28 (46.7)	29 (48.3)	>0.999	15 (25.0)	22 (40.7)	0.108	0 (0)	8 (17.0)	<0.001	0 (0)	3 (6.7)	<u>0.067</u>
Haematocrit < 32%	16 (26.7)	13 (21.7)	>0.999	4 (6.7)	8 (14.8)	0.223	0 (0)	5 (10.6)	0.014	0 (0)	2 (4.8)	0.177
MCV < 76 fl	16 (26.7)	15 (25.0)	>0.999	4 (6.7)	10 (18.5)	0.085	0 (0)	6 (12.8)	0.006	0 (0)	3 (6.7)	<u>0.067</u>
MCH < 27 pg	23 (38.3)	25 (41.7)	>0.999	12 (20.0)	19 (35.2)	0.092	1 (1.7)	7 (14.9)	0.020	0 (0)	2 (4.8)	0.177
MCHC < 32 g/dL	15 (25.0)	14 (23.3)	>0.999	5 (8.3)	11 (20.4)	0.103	4 (6.7)	6 (12.8)	0.329	0 (0)	1 (2.4)	0.412
Ferritin < 15 ng/mL	60 (100)	60 (100)	>0.999	27 (45.0)	32 (59.6)	0.138	12 (20)	21 (44.6)	0.011	2 (4.3)	5 (11.9)	0.121

Note: Fisher's exact test was used.

Source: compiled by the authors of this study

Table 3. Patients' complaints associated with iron supplementation during treatment (absolute number, %)

conditions between two groups, a minimum sample size calculation was performed. This calculation utilized G*Power v.3.1.9.7 software, with a 5% significance level and 80% power, while assuming a 5% risk of treatment failure and a 20% clinically significant effect. As a result, the minimum required sample size was determined to be 55 patients per group [23].

Thus, the study included 120 women aged 18 to 35 years (median age: 29 years, interquartile range: 24–33 years) who had laboratory-confirmed ID or IDA linked to chronic blood loss (ICD-10 N 92.0 — Excessive and frequent menstruation with regular cycles). In addition to assessing changes in peripheral blood indices and iron storage parameters, the study analysed partici-

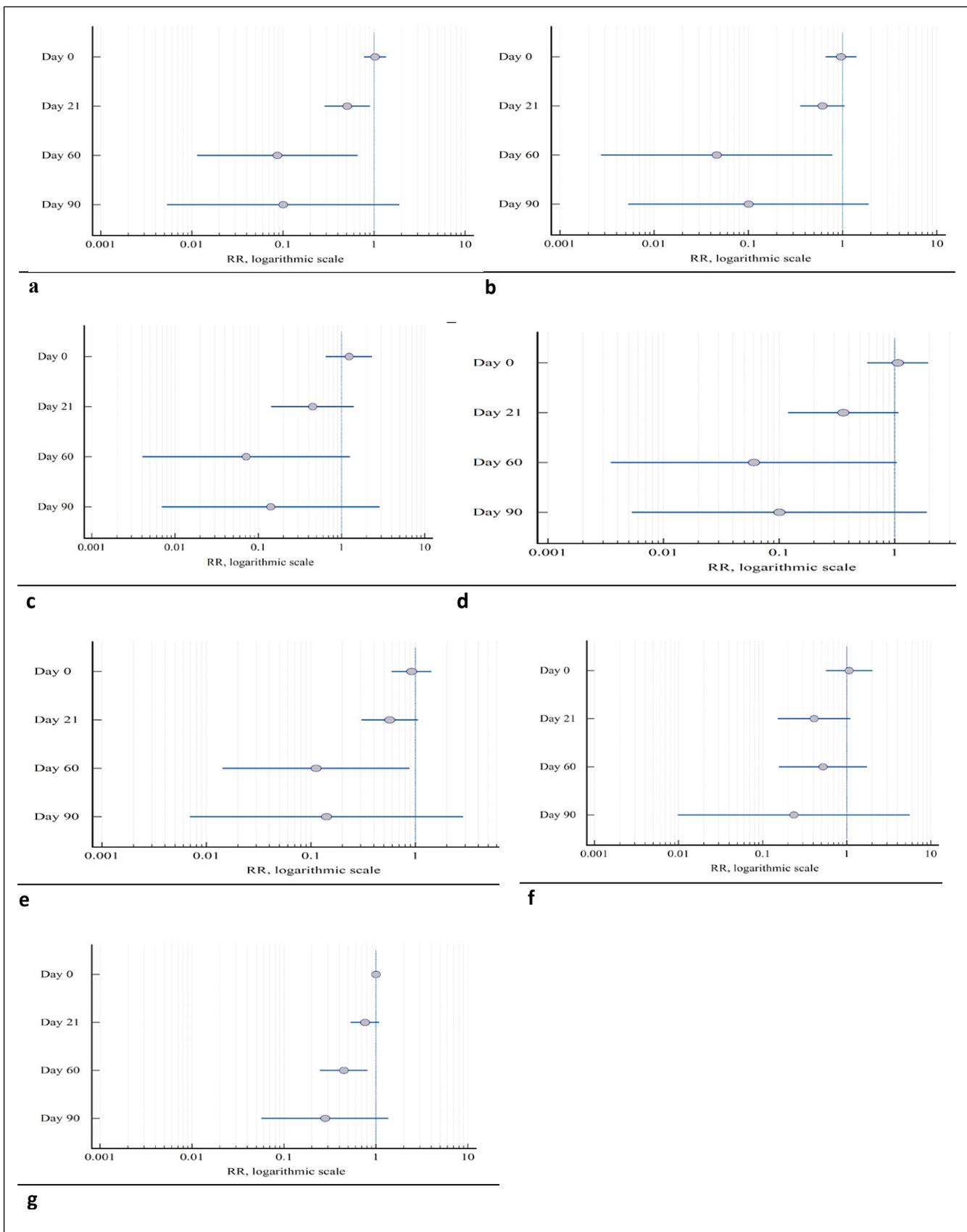


Fig. 1. Dynamics of risk ratio (RR) and 95% confidence intervals (CI) for failure to achieve reference haematological levels between Groups 1 and 2. Legend: (a) Haemoglobin (Hb); (b) Erythrocytes; (c) Haematocrit; (d) Mean corpuscular volume (MCV); (e) Mean corpuscular haemoglobin (MCH); (f) Mean corpuscular haemoglobin concentration (MCHC); (g) Ferritin
 Picture taken by the authors

pants' complaints and clinical manifestations associated with iron deficiency (sideropenic and anaemic syndromes).

All subjects were divided into two representative groups of 60 women each. Women of Group 1 (main group, $n = 60$) received iron bisglycinate 157 mg (equivalent to 30 mg of elemental bivalent iron) in combination with glucosamine salt of (6S)-5-methyltetrahydrofolate – 740 μg (equivalent to 400 μg of folic acid), one capsule twice daily, 30 minutes before meals, for pathogenetically justified correction of ID conditions. Women of Group 2 (comparison group, $n = 60$) received ferrous sulfate 247.25 mg (equivalent to 80 mg of elemental bivalent iron), one capsule twice daily, 30 minutes before meals. The treatment duration for both groups was 90 days.

Statistical data processing was performed using Microsoft Excel 2016 and Statistica 10.0 (StatSoft Inc.). Additional statistical analysis was carried out using EZR v.1.68 (a graphical interface for R statistical software v.4.3.1, R Foundation for Statistical Computing, Vienna, Austria). Fisher's exact test was applied to determine differences in nominal data. Cochran's Q test assessed significant differences in proportions of binary outcomes among more than two related groups, reflecting treatment dynamics. Risk ratios (RR) and corresponding 95% confidence intervals (95% CI) were calculated to evaluate differences in event risk within the case-control setting. The significance threshold was set at $p < 0.05$ [24].

ETHICS

During the study, the general principles of the Declaration of Helsinki "Recommendations for physicians involved in biomedical research with human subjects" (1964), the Council of Europe Convention on Human Rights and Biomedicine (04.04.1997), and the World Medical Association's ethical principles for medical research involving human subjects (1964–2000) were strictly followed, taking into account the requirements of Directive 2001/20/EC of the European Parliament and of the Council, ICH GCP guidelines, and Order No. 690 of the Ministry of Health of Ukraine dated September 23, 2009. Each participant was informed about the purpose and procedures of the study, and inclusion of the obtained data in the scientific research was carried out only after receiving written informed consent to participate in the clinical study. The informed consent form and the patient examination chart were approved by the Bioethics Committee for Experimental and Clinical Research of the Medical Institute of Sumy State University.

RESULTS

We analysed clinical manifestations of iron deficiency conditions and laboratory parameters in women of reproductive age both before the initiation of iron therapy and during correction (on Days 21, 60, and 90 of treatment).

At baseline, all women in both groups reported fatigue (100.0%). Complaints of decreased work capacity, headache, lack of concentration, and memory impairment were noted by 39 (65.0%), 18 (30.0%), 33 (55.0%), and 30 (50.0%) women in Group 1, and by 39 (63.3%), 19 (31.7%), 31 (51.7%), and 29 (48.3%) women in Group 2, respectively. Periodic dizziness was reported by 8 (13.3%) patients in Group 1 and 9 (15.0%) in Group 2; concurrently, 6 (10.0%) women in each group experienced tachycardia, which could occur even with minor physical exertion. Brittle and splitting nails as well as dry skin were observed in 7 (11.7%) and 14 (33.3%) participants of Group 1, and in 14 (23.3%) and 13 (21.7%) of Group 2, respectively (Table 1).

Laboratory test results confirmed ID in 22 (36.7%), mild IDA in 14 (23.3%), and moderate IDA in 24 (40.0%) patients in Group 1, and correspondingly ID in 23 (38.3%), mild IDA in 13 (21.6%), and moderate IDA in 24 (40.0%) patients in Group 2. According to laboratory evaluation, all women in both groups demonstrated reduced ferritin levels. Both groups also showed decreases in haemoglobin, erythrocyte count, haematocrit, mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), and mean corpuscular haemoglobin concentration (MCHC), among other indices (Table 2).

Analysis of the dynamics of clinical manifestations of ID and IDA on Days 21, 60, and 90 of supplementation revealed a downward trend in both groups regarding the frequency of complaints and the proportion of patients presenting any symptom (Table 1).

Throughout the treatment course, normalization of all evaluated hematologic parameters was recorded in both groups. The risk of not achieving therapeutic success on Days 21 and 60 was lower among patients in Group 1 compared to those in Group 2 (Table 2, Fig. 1).

An analysis of reasons for discontinuing iron intake revealed that gastrointestinal complaints were prevalent. During treatment (on Days 21, 60, and 90), nausea was reported by 5 (8.3%) women in Group 1 and 13 (24.1%) in Group 2; constipation by 2 (3.3%) women in Group 1 and 7 (13.0%) in Group 2; and abdominal pain by 2 (3.3%) women in Group 1 and 9 (16.7%) women in Group 2 (Table 3).

All patients linked these adverse events directly to iron intake. However, in Group 1, the symptoms were mild and by Day 60 were absent in all participants,

Parameter	Day of assessment											
	0			21			60			90		
	Group 1 (n=60)	Group 2 (n=60)	p	Group 1 (n=60)	Group 2 (n=54)	p	Group 1 (n=60)	Group 2 (n=47)	p	Group 1 (n=60)	Group 2 (n=42)	p
Nausea	0 (0)	0 (0)	>0.999	5 (8.3)	13 (24.1)	0.545	0 (0)	12 (25.5)	<0.001	0 (0)	7 (16.7)	<0.001
Constipation	0 (0)	0 (0)	>0.999	2 (3.3)	7 (13.0)	0.082	0 (0)	5 (10.6)	0.014	0 (0)	4 (9.5)	0.026
Abdominal pain	0 (0)	0 (0)	>0.999	2 (3.3)	9 (16.7)	0.024	0 (0)	3 (6.4)	0.082	0 (0)	2 (4.8)	0.177

Note: Fisher's exact test was used.

Source: compiled by the authors of this study

Table 4. Dynamics of patient withdrawal from the study during treatment (absolute number, %)

	Day of assessment				
	0	21	60	90	
Group 1 (n=60)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Group 2 (n=60)	0 (0%)	6 (10%)	13 (21.7%)	18 (30%)	
p	p>0.999	0.027	<0.001	<0.001	

Note: Fisher's exact test was used.

Source: compiled by the authors of this study

allowing all 60 women in this group to complete the entire prescribed course of supplementation (Table 4).

In contrast, the above gastrointestinal symptoms in Group 2 persisted on Days 60 and 90 of the study. Specifically, on Day 60 of therapy, nausea was reported in 12 (25.5%) cases, constipation in 5 (10.6%), and periodic abdominal pain in 3 (6.4%) cases. By Day 90, the incidence of nausea decreased to 7 women (16.7%), constipation to 4 women (9.5%), and periodic abdominal pain to 2 women (4.8%). These adverse events led some patients to discontinue their iron intake (see Table 4).

It is important to note that all women in Group 1 showed good tolerability to long-term iron bisglycinate supplementation, allowing them to successfully complete the recommended treatment course.

DISCUSSION

This study demonstrates that the FERRO-EURIKA™ supplement, containing iron bisglycinate and the glucosamine salt of (6S)-5-methyltetrahydrofolate, is an effective and well-tolerated option for correcting iron deficiency in women of reproductive age. The improvements in hematologic parameters and clinical symptoms are consistent with existing evidence supporting the high bioavailability and favourable safety profile of iron bisglycinate compared with conventional

iron salts. Notably, therapeutic efficacy was achieved even with a lower elemental iron dose, highlighting the value of the chelated formulation [13, 14].

A key finding concerns tolerability. Gastrointestinal adverse events were significantly less frequent and milder in the bisglycinate group, resolving by Day 60 and allowing all participants to complete the 90-day course. In contrast, women receiving ferrous sulfate experienced persistent gastrointestinal discomfort that reduced adherence. These results correspond with prior research showing that traditional iron salts are commonly associated with poor tolerability and treatment discontinuation [21, 23].

The inclusion of an active folate form in FERRO-EURIKA™ may have contributed to the hematologic improvements observed, as folate is essential for erythropoiesis and may enhance the response to iron supplementation. Although folate status was not directly assessed, the combination of iron and active folate may offer additional benefit, particularly for individuals with impaired folate metabolism.

Correction of iron deficiency also led to a reduction in sideropenic symptoms, with faster improvement in Group 1, likely related to better absorption and tolerability. This early symptom relief is clinically meaningful for women who frequently experience reduced quality of life due to chronic menstrual blood loss [20, 22].

The study has several limitations, including the 90-day follow-up period, lack of dietary control, and inclusion of only women with iron deficiency related to heavy menstrual bleeding. Thus, results may not be fully generalizable to other etiologies.

Overall, the findings support FERRO-EURIKA™ as a safe, well-tolerated, and effective strategy for managing iron deficiency. Future research should focus on long-term outcomes, broader populations, and the potential preventive use of the supplement in high-risk groups [23].

PROSPECTS FOR FURTHER RESEARCH

The results obtained provide a basis for further study of the effectiveness and safety of the dietary supplement TM FERRO-EURIKA in wider populations of women of reproductive age with various clinical forms of iron deficiency conditions. A promising direction is to conduct long-term prospective observations to assess the stability of the achieved therapeutic effect, prevent recurrence of iron deficiency, and restore reproductive potential.

Further studies may be aimed at comparative evaluation of the effectiveness of FERRO-EURIKA in women of different ages, with different etiologies of iron deficiency (chronic blood loss, malabsorption, vegetarian diets, etc.), as well as in pregnant women, in whom the need for iron increases significantly.

CONCLUSIONS

1. The results of the study indicate that the FERRO-EURIKA™ food supplement may be an effective oral agent for correcting iron deficiency conditions in women of reproductive age.
2. The combination of iron bisglycinate and glucosamine salt of (6S)-5-methyltetrahydrofolate in the composition of FERRO-EURIKA™ contributes to the normalization of haematologic parameters, even at lower doses of iron compared to standard formulations.
3. Women who received the FERRO-EURIKA™ food supplement demonstrated better tolerability and a lower incidence of gastrointestinal adverse effects, leading to higher adherence to therapy and successful completion of the treatment course.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

CORRESPONDING AUTHOR

Iryna M. Nikitina

Sumy State University

12 R. Korsakov St., 40040 Sumy, Ukraine

e-mail: nikitina1med@gmail.com

ORCID AND CONTRIBUTIONSHIP

Valentyina K. Kondratiuk: 0000-0001-6220-2116 [A](#) [B](#) [C](#) [F](#)

Iryna M. Nikitina: 0000-0001-6595-2502 [B](#) [D](#) [E](#)

Natalia E. Gorban: 0000-0001-8175-6579 [E](#)

Kateryna O. Kondratiuk: 0000-0001-5915-1821 [C](#) [D](#)

Natalia P. Dzis: 0000-0001-8396-171X [E](#)

[A](#) – Work concept and design, [B](#) – Data collection and analysis, [C](#) – Responsibility for statistical analysis, [D](#) – Writing the article, [E](#) – Critical review, [F](#) – Final approval of the article

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