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Research Article

BENEFITS OF THE EFFICACY AND SAFETY OF VITAMIN AND MINERAL COMPLEX "VITRUM PRENATAL FORTE" IN THE PREVENTION OF HYPOVITAMINOSIS AND MINERAL DEFICIENCY IN PREGNANCY

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ABSTRACT

Non-interventional (observational) studies, which are of great medical and social importance, are one of the methods to assess the effectiveness and safety of pharmaceutical products in routine clinical practice, to clarify the risk profile and benefits of certain therapies. The aim of this study was to evaluate the efficacy and safety of vitamin and mineral complex "Vitrum Prenatal Forte" in the prevention of hypovitaminosis and mineral deficiency in pregnancy to improve maternal and perinatal outcomes. One of the important aims of the large-scale study was to evaluate the efficacy of the drug Vitrum Prenatal Forte in the prevention and treatment of anaemia in pregnant women. This article reviews the epidemiology of iron deficiency, features of iron metabolism, etiology and pathogenesis of iron deficiency in pregnant women and maternity women, approaches to the diagnosis of iron deficiency anaemia and iron deficiency, methods of prevention and treatment of iron deficiency states.

KEYWORDS

pregnant women haemoglobin iron deficiency iron deficiency iron deficiency anaemia red blood cell count iron preparations ferritin transferrin, pre-latent iron deficiency latent iron deficiency manifest iron deficiency iron deficiency iron deficiency anaemia.

INTRODUCTION

The need of a woman's organism for vitamins, macro- and microelements during pregnancy increases significantly, and the provision of the pregnant body with micronutrients necessary for normal life activity is the most important factor contributing to the physiological course of pregnancy and normal fetal development [1,7]. Deficiency states cause complicated pregnancy and labour, disturbance of

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placenta formation, increase the risk of perinatal pathology, are one of the causes of prematurity, congenital malformations, disorders of early neonatal adaptation and formation of abnormalities in physical and mental development of children at the stage of postnatal ontogenesis [10]. One of the most common deficiencies is insufficient iron supply, leading to the development of anaemia. In Russia, the number of anaemia cases in women of reproductive age is 30.2% [3]. Anaemia in pregnant women in more than 90% of cases is iron deficiency, and the frequency of iron deficiency anaemia (IDA) depends on the level of socioeconomic development of the region. The incidence of IAA in pregnant women ranges from 25 to 50% worldwide, 35 to 75% in developing countries, and 18-20% in developed countries [2].

Anaemia is a clinical and laboratory syndrome characterized by a decrease in the level of haemoglobin, erythrocytes and haematocrit in a unit of blood volume. The increase in circulating blood volume by 40-45% mainly due to the volume of circulating plasma is accompanied by a gradual decrease in haemoglobin and haematocrit during pregnancy, which is considered physiological anaemia of pregnancy. However, a decrease in Hb less than 110 g/L in the I and III trimesters and less than 105 g/L in the II trimester should be considered pathological, due not only to pregnancy-related haemodilution but also to iron deficiency [5].

Iron deficiency is a hypochromic microcytic anaemia that develops due to an absolute decrease in iron stores in the body. In singleton pregnancy, the iron requirement is about 1000 mg, which significantly exceeds maternal reserves and nutritional intake of iron, so anaemia develops without prophylactic administration of iron preparations. There are three stages of iron deficiency: pre-latent, latent and manifest. Pre-latent deficiency is characterised by a decrease in reserve iron without a decrease in iron consumption for erythropoiesis; latent deficiency is observed when iron stores in the depot are depleted and is accompanied by a deficiency of transport iron, but without signs of anaemia; manifest iron deficiency, or IDD, is manifested by symptoms of anaemia [8].

The complex of factors influencing the development of iron deficiency in pregnant women includes: iron deficiency due to its consumption for fetal and placental growth; low nutritional intake of iron due to the lack of animal protein, raw vegetables and fruits; increased mass of circulating erythrocytes, which increases the need for iron; lack of vitamins necessary for iron absorption and assimilation - polyhypovitaminosis (C, B2, B6, B12, etc.); early toxicosis, which impairs the intake and absorption of iron and other trace elements in the gastrointestinal tract; complications of pregnancy (preeclampsia, cholera, chorepsy, cholumbia, etc.).); early toxicosis that impairs the intake and absorption of iron and other trace elements in the gastrointestinal tract; complications of pregnancy (pre-eclampsia, cholestatic hepatosis) that impair the synthesis of transport proteins and the deposition of ferritin and haemosiderin; a large number of pregnancies and deliveries; short intergenetic intervals; multiple pregnancies; lactation; chronic infectious diseases [4]. High-risk groups for the development of anaemia in pregnancy include patients with a history of anaemia; with a history of menorrhagia; women with multiple births; women with extragenital pathology, chronic infectious diseases; pregnant women with haemoglobin levels in the first trimester < 120 g/l; pregnant women with multiple pregnancies; pregnant women with early toxicosis, pre-eclampsia [3].

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Iron deficiency, especially in combination with deficiency of other vitamins and trace elements, leads to haemodynamic, metabolic, immune and hormonal disorders, contributes to the complicated course of pregnancy and childbirth, impaired placenta formation, perinatal pathology, may be one of the causes of pregnancy failure, fetal growth retardation syndrome, impaired early neonatal adaptation [9]. Anaemia affects the vascularisation of the placenta, impairing angiogenesis in early pregnancy, which may contribute to premature placental detachment, bleeding in the postpartum and early postpartum periods [2]. The levels of ferritin, transport iron, and transferrin saturation coefficient are significantly reduced in newborns born to mothers with iron deficiency, which may be accompanied by the development of such complications as growth retardation syndrome, prolonged physiological jaundice, excess physiological weight loss of more than 10%, and neonatal infections. Severe anaemia in mothers may lead to iron deficiency and anaemia in their newborns, as well as psychomotor retardation in the first years of life [8]. Diagnosis of ALD is based on clinical and haematological signs and includes determination of Hb, Ht levels, red blood indices, careful examination of peripheral blood smear; determination of serum iron and ferritin levels. Depending on the level of Hb, anaemia is subdivided into severe, moderate and mild anaemia. In mild anaemia, the haemoglobin concentration is below normal, but more than 90 g/l; in moderate anaemia, the haemoglobin content is less than 90 g/l, but more than 70 g/l; in severe anaemia, the haemoglobin concentration is less than 70 g/l. Clinical signs of anaemia severity do not always correspond to the severity of anaemia according to laboratory criteria.

According to WHO recommendations, drug prophylaxis of GID during pregnancy consists in the prescription of a standardised complex consisting of iron (60 mg of elemental iron per day) and folic acid no later than the beginning of the second trimester (within 6 months) [2,5]. The diet of the pregnant woman should contain iron (meat products), ascorbic acid, which promotes iron absorption; it is also necessary to enrich with iron, folate and ascorbic acid some foods for pregnant women . Routine prophylaxis is mandatory in developing countries with low socioeconomic levels, where the prevalence of iron deficiency may be as high as 80%. In developed countries, selective prophylaxis based on early (before 12 weeks of gestation) determination of serum ferritin is possible [3]. However, routine use of iron may also be recommended in developed countries: for example, in the USA, the Centre for Disease Control and Prevention and the American Dietetic Association recommend 30-60 mg of elemental iron per day for all pregnant women from the first presentation [9].

Both monotherapy with iron preparations (divalent and trivalent) and the prescription of vitamin and mineral complexes containing not only iron but also its synergists (vitamin C, folic acid, copper, zinc, calcium, manganese) may be recommended for the prevention and treatment of iron deficiency in pregnant women, which determines the advantages of their prescription over monotherapy [3]. The total amount of iron in the human body is 2-6 g. Of this amount, 65% is haemoglobin iron, 20% is deposited iron (ferritin), 10% is present in myo-globin, 5% is in enzymes, and 0.1% is transferrin (transport iron) [1, 2].

Iron deficiency states (IDS) are caused by disorders of iron metabolism due to iron deficiency in the body and are characterised by clinical and laboratory signs, the severity of which depends on the degree of iron deficiency. Currently, iron deficiency states are divided into pre-latent iron deficiency (PID), latent iron

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deficiency (LID), and manifest iron deficiency or iron deficiency anaemia (IDA). Pre-latent and latent iron deficiency is characterised by a decrease in deposited and transported iron while its erythrocytic pool is preserved [3, 4]. In the presence of pre-latent iron deficiency, clinical and biochemical signs of iron deficiency are absent. In most cases, PID develops by the end of the third trimester of pregnancy. This form is characterised by a decrease in the indices of all the funds of iron metabolism within normal values. Determine the presence of PJD can test the absorption of Fe3+. In 60% of cases of PJD there is an increase in iron absorption above 50%, while the normal value of this indicator is 10-15% [7].

Latent iron deficiency is characterised by iron deficiency in tissues in the absence of clinical signs, a significant decrease in both iron stores in the depot and erythropoietin (EPO) to a level that maintains haematological parameters within the lower limit of normal values. It most often occurs at 19-24 weeks of pregnancy. The absence of iron therapy in LGE leads to the development of iron deficiency anaemia in 65% of pregnant women and, consequently, to an increased incidence of complicated pregnancy [2, 7, 8].

Manifest iron deficiency or iron deficiency anaemia is a haematological syndrome characterised by impaired haemoglobin synthesis due to iron deficiency, as well as the development of organ and tissue disorders. In MWA there are disorders in all funds of iron metabolism - functional, transport, reserve, iron-regulatory in combination with clinical signs of iron deficiency, which leads to an increased incidence of obstetric complications [9, 10].

According to WHO, iron deficiency states are currently the most common pathology in the world after respiratory viral infections. Globally, the incidence of PJD and LJD reaches 92%, and the incidence of WDD in pregnant women is 25-50%. In developed countries, the incidence of GID is 18-20%, in developing countries 35-75%, and in Russia 34.7% [2].

Pregnancy is a physiological condition that increases the need for iron in the body of the future mother in the first trimester by 16%, in the second trimester by 59% and in the third trimester by 67%. During pregnancy and after childbirth, approximately 1,400 mg of iron is consumed:

- 500 mg to enhance erythropoiesis,
- 300 mg for the development of the foetoplacental system (the foetus needs 280-290 mg, the placenta 25-100 mg),
- 190 mg - current iron consumption,

230 mg for losses during labour and delivery,

- 400 mg per lactation in labouring women.

The clinic of WDD in pregnant women is, on the one hand, due to the presence of anaemic syndrome and, on the other hand, due to hyposiderosis (iron deficiency in the body) [7].

Anaemic syndrome is characterised by non-specific symptoms: patients are bothered by weakness, dizziness, tinnitus, rapid fatigue, drowsiness, hypotension, orthostatic hypotension, lipotemia, tachycardia, and dyspnoea on physical exertion.

Clinical manifestations of hyposiderosis are caused by tissue iron deficiency. Decreased activity of iron-

iron-containing tissue enzymes, in particular cytochromes, leads to changes in epithelial tissues (mucous membranes, skin, etc.). Pallor and dryness of the skin, brittleness and disordered structure of nails, perversion of taste, difficulty in swallowing hard and/or

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dry food (sideropenic dysphagia) are characteristic. Muscle weakness occurs in connection with iron deficiency due to deficiency of iron-containing enzymes.

The presence of iron deficiency anaemia in a pregnant woman leads to the following obstetric complications:

■ failure to conceive - 15-42 per cent,

■ development of premature labour 11-42%,

■ arterial hypotension 40%,

■ hypogalactia 39%,

■ fetal hypoxia 35%,

■ placental detachment 25-35%,

■ development of pre-eclampsia 29%,

■ fetal hypotrophy 25%,

■ deterioration of uterine motor function (weakness of labour, hypotonia) 10-15%,

■ purulent-septic complications after labour 12%,

■ haemorrhage in the third and early postpartum period 10%.

In multicentre studies, it has been proven that 70% of haemoglobin in children under 2 years of age is of maternal origin. This fact explains that in the presence of WDD in pregnant women, iron deficiency anaemia may also occur or progress in 68% of children under 1 year of age. The presence of iron deficiency anaemia leads to reduced mental, motor and speech development, impaired metabolism of cellular structures, impaired haemoglobin formation, impaired immune status and resistance to infections in children in the first years of life [2, 6].

To diagnose the presence of iron deficiency anaemia in pregnant women, it is advisable to use haematological and ferrokinetic indicators [2, 16]. Haematological indicators include:

■ HGB (Hb) - haemoglobin content,

■ RBC - red blood cell count,

■ H (NST) - haematocrit (proportion of erythrocytes in the total blood volume),

■ CP - colour index (relative Hb content in the erythrocyte, in WDD <0.85),

■ MO - mean erythrocyte volume (normal 80-95 fl, decreases in ALD). ■ MSN - mean erythrocyte volume (normal 80-95 fl, decreases in ALD),

■ MSN - average Hb content in erythrocyte (normal 27-31 pg, in ALD < 24 pg). ■ MSNS - average Hb concentration in erythrocyte (normal 27-31 pg, in ALD < 24 pg),

■ MSNS - average Hb concentration in erythrocyte (normal 30-38 g/dl, in ALD < 33 g/dl),

■ RDW - erythrocyte anisocytosis (normal 11.5-14.5%, increases in ALD).

Ferrokinetic parameters include:

■ Serum ferritin (SF) is a protein complex that acts as the main intracellular iron depot (15-20% of the total). In pregnancy, normal values in the first trimester are 56-90 μg/l; in the second trimester, normal values are 25-74 μg/l; in the third trimester

normal is 10-15 μg/L. 1 μg/L of SF corresponds to 8 mg of reserve iron.

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■ Serum iron (SI) is iron bound to the protein transferrin. Normal values in pregnant women are 13.2-30.43 μmol/L.

■ Free transferrin (TF) is transferrin that is not bound to iron. It is the iron-binding glycoprotein of blood plasma, the main carrier of iron to cells.

The indicator reflects the need and reserve of iron in the body, refers to the reverse acute-phase proteins. Normal values in pregnant women are 2.0-4.0 g/l. Synthesis of TF is carried out in the liver and depends on its functional state, on the need for iron and iron reserves in the body. When iron concentration decreases, TF synthesis increases. Transferrin participates in the transport of iron from the place of its absorption (small intestine) to the main places of its use or storage (bone marrow, liver, spleen), preventing the accumulation of toxic iron ions in the blood. When red blood cells are destroyed in the spleen, liver, and bone marrow, TF transports iron released from haem to the bone marrow, where some iron is deposited, incorporated into ferritin and he-mosiderin. One molecule of TF binds two Fe3+ ions, and 1 g of transferrin binds about 1.25 mg of iron, from which it is possible to determine the total amount of iron that can be bound by serum transferrin. This is approximated by the value of total serum iron-binding capacity (TSIC). In diagnosis, a calculated value is used - the percentage of transferrin saturation with iron (the ratio of serum iron concentration to the maximum iron-binding capacity of serum transferrin, expressed as a percentage). In the norm, the percentage of transferrin saturation with iron is about 30%, with insufficient iron intake in the body this indicator decreases.

Latent iron deficiency is characterised by iron deficiency in tissues in the absence of clinical signs, a reliable decrease in both iron stores in the depot and erythropoietin (EPO) to a level that maintains haematological parameters within the lower limit of normal values

Transferrin iron saturation ratio (TIR) is the ratio of serum iron concentration to serum transferrin concentration, expressed as a percentage. CST = [SJ (μg/L)/TP (mg/dl)x1.41]x100%. The normal range is 20-55%.

■ Percentage of hypochromic red blood cells in peripheral blood. Defined as the percentage of cells with reduced Hb concentration in an individual cell. The norm for pregnant women is less than 2.5%. A hypochromic erythrocyte count > 10% indicates functional iron deficiency in the body.

The concentration of protoporphyrins in the erythrocyte. The norm for pregnant women is 0.53 μmol/l (30 μg%), in iron deficiency the value is greater than 1.77 μmol/l (100 μg%). As a result of multicentre randomised studies, it has been proved that the informative significance of various ferrokinetic indices for the detection of iron deficiency in pregnancy is: CF - 70%, KNT - 60%, TF - 50%, CJ - 35% [1, 2, 7].

Differential diagnosis of WDD should first of all be made with physiological dilution of blood, associated with an increase in the volume of circulating blood. Characteristic signs of haemodilution include simultaneous decrease in the number of Hb and erythrocytes, the colour index remains within 1.0-0.85. There is no anisocytosis, poikilocytosis, microcytosis, hypochromia. In peripheral blood, there is neutrophilic leukocytosis, lymphopenia, no eosinophils, and a decrease in the platelet count to 150,000 [2, 3,8].

Due to the fact that iron deficiency in pregnant women leads to a high frequency of obstetric and perinatal complications, the issue of prevention of iron

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deficiency during pregnancy is relevant. According to WHO recommendations for effective prevention of GID in pregnant women, the daily dose of elemental iron is 20-60 mg and 250 µg of folic acid in regions with GID incidence < 20%. In regions with WDD incidence > 20%, the dose of elemental iron should be 100-120 mg. Prophylaxis of GID is also indicated in patients with heavy and prolonged menstruation prior to pregnancy, with an interval between pregnancies of 2 or less years, with multiple pregnancies, and with prolonged lactation after previous births. All pregnant women should be screened for iron deficiency from 5-6 weeks of pregnancy. The use of combined oral iron and folic acid preparations with prolonged iron release is preferable [7, 8].

In order to prevent MWA in pregnant and postpartum women, it is necessary to timely identify PWA in them and prescribe treatment with iron preparations - selective prophylaxis. In LWA, in addition to complex multivitamin preparations with macro- and microelements (1 tablet or capsule per day), oral intake of 50-100 mg of elemental iron per day for 6 weeks is indicated. Fe2+ preparations of 50 mg of elemental iron per day or Fe3+ preparations of 60-100 mg of elemental iron per day are recommended.

Fe2+ preparations of 50 mg of elemental iron per day or Fe3+ preparations of 60-100 mg of elemental iron per day. In the absence of laboratory possibilities to determine the level of SF, the decision on the prescription of selective prophylaxis can be made on the basis of haematological criteria (Hb, RBC, No.),

Due to the fact that iron deficiency in pregnant women leads to a high incidence of obstetric and perinatal complications, the issue of prevention of iron deficiency during pregnancy is of topical importance.

corresponding to LJW. The effectiveness of selective prophylaxis is assessed 6 weeks after the start of iron preparations by determining haematological (Hb, No., RBC) and ferrokinetic (NF, SJ, CST) parameters. The efficacy of selective prophylaxis in pregnant women is > 90% [1,9].

Prevention of MWA in parturients includes reduction of blood loss during delivery, measures to replenish blood loss during abdominal delivery, prevention of acute or recurrent chronic infectious-inflammatory diseases in the postpartum period, timely therapy of LWA in the III trimester of pregnancy [3].

In the treatment of iron deficiency anaemia, first of all, it is necessary to confirm the iron deficiency nature of anaemia by determining haematological and ferrokinetic parameters. The use of only a diet consisting of iron-rich foods for the correction of iron deficiency anaemia is not enough. The use of iron preparations and vitamin-mineral complexes is mandatory. Recombinant erythropoietin may be used after 20 weeks of pregnancy in combination with iron preparations in case of moderate and severe HDA. Parenteral administration of iron preparations is required only in special cases [1, 5]. Based on the serum ferritin values of the pregnant women studied, iron preparations are not indicated if the NF value is > 60 µg/litre. If the value of SF < 60 but > 20 µg / l, iron preparations should be prescribed from 20 weeks of pregnancy. If NF < 20 µg/l, iron preparations should be administered from 12 weeks of pregnancy. Blood or erythromass transfusion is not a method of treatment of WDA. It is used only in severe anaemia with haemodynamic disorders and in patients before surgery, or in women before childbirth when haemoglobin level drops below 80 g/l. Therapy with iron preparations should not be stopped after normalisation of haemoglobin level, it should be

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continued for 2-3 months to create iron depot in the body, average daily dose of iron 50-60 mg. Further the question of taking iron preparations is decided individually. It is obligatory to monitor the effectiveness, duration and dosage of the drug: determination of haematological parameters at least once every 2 weeks (more often as indicated), ferrokinetic indicators - at least once a week.

indicators - at least once a month, taking into account diagnostic criteria of different stages of iron deficiency in pregnant women [5, 6].

The choice of iron preparations should be based on the following criteria:

- absence of side effects,
- optimal iron content,
- safety,
- easy administration,
- good organoleptic properties,
- presence of factors affecting iron absorption in the composition,
- the best efficiency/price ratio.

Folates are a genus of substances that have vitamin activity. In food, folate is present in the form of polyglutamate, which must be broken down to monoglutamates for absorption in the intestine. Folic acid is a synthetic form of folate that is present in dietary supplements. Folic acid is a monoglutamate; it does not require enzymatic conversion for absorption. Folic acid (formyltetrahydrofolic acid) is the active metabolite, a natural derivative of folic acid. Folic acid supplements increase serum folate levels much faster than other products, because folinic acid does not need enzyme action for its conversion [8, 22, 23, 25].

Folate deficiency blocks erythropoiesis and haemoglobin production, thereby preventing the physiological use of available iron. Iron deficiency, especially during pregnancy, is known to contribute to the development of secondary folate deficiency. Folic acid in the composition of Furlatum Fol allows to overcome this metabolic problem.

The uniqueness of Ferlatum Fol is that in it Fe3+ is on a protein carrier. The protein fulfils a dual function: transport and protective. In the acidic environment of the stomach, protein precipitation occurs and a dense protein shell is formed around the iron ions. B

CONCLUSIONS

For the prevention of iron deficiency anaemia during pregnancy and lactation, it is recommended to take 1 vial per day (throughout the period). For the treatment of latent or clinically expressed iron deficiency, it is recommended to take 2 vials of Furlatum Fol per day in 2 doses for 60 days. Once normal haematological parameters have been achieved, 1 vial per day for 30 days should be taken as a maintenance dose. Thus, Furlatum Fol fulfils most of the necessary criteria and can be recommended for the treatment and prevention of GDM in pregnant and postpartum women.

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Iron deficiency, especially during pregnancy, is known to contribute to the development of secondary folate deficiency.

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In conclusion, the main properties of LDDs are reversibility and preventability. The reason for the high prevalence of DWA is the underestimation of the importance of diagnosing the early stages of DWA, as well as the lack of a differentiated individual approach to the correction of these stages in order to prevent DWA.

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