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EVALUATION OF THE EFFICACY OF A LIPOSOMAL IRON PREPARATION FOR THE TREATMENT OF ANEMIC SYNDROME

Suleymanova D. N.
Ulugova Sh. T.
Republican Specialized Scientific Practical Medical
Center of Hematology Doctor of Medical Sciences, Professor

Abstract
Evaluation of the tolerability of the liposomal drug "Liposemi Plus" showed that 100% of patients assessed it as "good", side effects from the gastrointestinal tract typical of conventional oral iron preparations were detected in only 2.2% of patients. For patients with leukemia, it is especially important to protect the gastrointestinal tract from side effects of drugs, since constant chemotherapy already creates a serious negative load on the gastrointestinal tract. Evaluation of the effectiveness of treatment of anemic syndrome in patients with leukemia in remission with liposomal drugs indicates a reliable increase in hemoglobin levels from 84.95±4.4 g/l to 103.6±5.4 g/l, the number of erythrocytes increased from 3.6±0.07 million to 3.9±0.08 million. As a result of treatment, a reliable increase in serum iron levels from 21.2±0.85 μmol/l to 5.21±0.85 μmol/l and a reliable decrease in transferrin levels from 3.52±0.07 g/l to 3.03±0.09 g/l were noted, which indicates the effectiveness of ferrotherapy.

Relevance
Anemic syndrome (AS) is a condition characterized by a decrease in the concentration of hemoglobin and / or red blood cells in the blood, which leads to insufficient oxygen supply to the body, it has general symptoms (weakness, dizziness, fatigue, pallor, etc.) and specific ones with a lack of iron, vitamin B12, folic acid, etc. in the body. Causes of AS can be blood loss, micronutrient deficiency, chronic diseases, hemolysis, hematopoiesis disorders. It is known that anemic syndrome in oncohematological patients in most cases is caused by

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anemia of chronic diseases (ACD) and in 30 - 60% of cases is accompanied by iron deficiency (1,2,4,9,10,11). It is also known that oral salt compounds of iron preparations are not effective in the treatment of ACD, since iron in the gastrointestinal tract is blocked, not absorbed, due to an increase in the content of hepcidin in the blood, which is a marker of inflammatory processes (3). In the treatment of chronic bronchitis accompanied by iron deficiency, an effective pathogenetic method of ferrotherapy is parenteral iron preparations, i.e. their intravenous administration (1,7).

However, in recent years, nanotechnologies have been developed for the use of liposomal preparations, including iron preparations. Liposomes are spherical vesicles characterized by a double layer of lipids with an internal aqueous cavity (1,6).

The structural components of liposomes are phospholipids or synthetic amphiphiles included in the composition of sterols. This phospholipid bilayer is suitable for fundamental cellular functions, such as motility and shape change, and also provides the ability to imitate the biophysical properties of living cells. According to the "Trojan horse" mechanism, the liposome is directly absorbed into the intestinal lumen by microfolded cells (M-cells) of the small intestine, which is part of the lymphatic system. The liposome is then incorporated into macrophages by endocytosis and reaches hepatocytes via the lymphatic system. In hepatocytes, the liposome is opened by lysosomal enzymes, making the iron available for use (1,5,6).

Liposomal protection allows iron to cross the free gastric environment, preventing early degradation of the substance and/or its inactivation, and to be absorbed directly. This mechanism provides greater availability of liposomal iron, reduces gastrointestinal side effects, and prevents iron instability in the gastrointestinal tract, so that it is directly absorbed in the intestine and directly released in the liver (6,8).

Thus, the pathogenetic treatment of iron deficiency by oral therapy in patients with ACD is the use of liposomal iron preparations.

The aim of the study was to evaluate the efficacy of the clinical use of the liposomal drug "Liposemi Plus" and its tolerability in patients with leukemia in remission.

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Materials and Methods

We observed 45 patients with various forms of leukemia in remission, the anemic syndrome is due to concomitant ACD with iron deficiency. All patients were examined before and after for the presence of iron deficiency by 7 diagnostic parameters - hemoglobin, erythrocytes, mean hemoglobin content in erythrocytes, mean hemoglobin concentration in erythrocytes, mean hemoglobin content in erythrocytes, erythrocyte distribution width, transferrin, TIBC.

All patients received the drug "Liposemi Plus" 2 capsules per day for 1 month, which contains 45 mg of liposomal iron, 400 mcg of folic acid, ascorbic acid - 100 mg, B6 - 2 mg, B1 - 1.1 mg, vit B12 2.5 mcg. The following were assessed: tolerability, side effects, dynamics of clinical manifestations of anemic syndrome, dynamics of erythropoiesis indicators and iron metabolism. Clinical research methods - hematological analyzer mindray Bc-5600, in venous blood were determined general blood analysis, including hemoglobin indicators, number of erythrocytes, average concentration of hemoglobin in erythrocyte, average hemoglobin content in erythrocyte, volume of erythrocytes, width of distribution of erythrocytes, hematocrit

Biochemical research methods were carried out on the analyzer Roche Hitachi Cobas C 311, in venous blood were studied indicators of serum iron, ferritin, transferrin, CRP.

Results and Discussion

Table 1. Evaluation of tolerability and side effects of a liposomal drug in patients with leukemia in remission

№	Number of patients	Evaluation criteria	Rating	Number of patients (%)
1	45	Tolerability Side effects	Satisfactory	0
			Good	45 /100%
			Bad	0
			Refusal of treatment	0
2	45	Organoleptic characteristics (color, taste, smell, shape, etc.) Evaluation criteria Tolerability Side effects	Nausea	1(2,2%)
			Diarrhea	0
			Constipation	1(2,2%)
			Black stool	0
			Black staining of teeth	0
			Others	0
3	45	Organoleptic characteristics (color, taste, smell, shape, etc.)	Like	45 / 100%
			Dislike	0

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The assessment of the tolerability of the liposomal preparation showed that 100% of patients rated it as "good". The organoleptic characteristics of the preparation were rated as "liked". Side effects from the gastrointestinal tract typical for all iron preparations were detected in only 1 patient, who noted "nausea", 1 patient noted "constipation", however, it is not a fact that they are associated with the drug, perhaps this is due to nutrition. Refusal of treatment was not noted by 100% of patients.

Particularly noteworthy is the fact that patients did not have black stool after treatment with a liposomal iron preparation, while after taking conventional iron preparations orally, black stool is noted in 100% of cases. This very convincingly confirms the special mechanism of absorption of liposomal iron, when the gastrointestinal tract is not involved in the absorption process. For patients with leukemia, it is very important to protect the gastrointestinal tract from side effects, since constant chemotherapy already creates a serious negative load on the gastrointestinal tract and additional loads on the gastrointestinal tract are extremely undesirable.

Table 2 Clinical manifestations of anemic syndrome in patients with leukemia in remission before and after treatment with liposomal iron preparation

№	Clinical manifestations of anemic syndrome	Before treatment N= 45	After treatment N=45	R
		Абс/%	Абс/%	
1	Weakness	45/100,0	11/24,44	P < 0,001
2	Increased fatigue	45/100	8/17,78	P < 0,001
3	Dizziness	18/ 40,0	7/15,56	P < 0,001
4	Headaches	17/37,78	6/13,33	P < 0,001
5	Pica chlorotica syndrome	12/26,66	4/8,89	P < 0,001
6	Decreased appetite	18/40,0	11/24,44	P < 0,001
7	Pale skin and mucous membranes	19/42,22	12/26,67	P < 0,001
8	Decreased performance	18/40,0	8/17,78	P < 0,001

Evaluation of the dynamics of clinical manifestations of anemic syndrome in patients with leukemia (in remission) as a result of treatment with a liposomal iron preparation indicates that the indicators of all complaints and clinical manifestations of anemic syndrome have been reliably reduced.

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Evaluation of the effectiveness of treatment of anemic syndrome in patients with leukemia in remission with liposomal preparations indicates a reliable increase in hemoglobin from 84.95±4.4 g/l to 103.6±5.4 g/l, the number of erythrocytes from 3.6±0.07 million to 3.9±0.08 million.

Table 3. Evaluation of the dynamics of erythropoiesis indices in patients with leukemia in remission before and after liposomal iron

№	Evaluation criteria	Control group n=24	Main group n = 45			
			Indicators before pherotherapy M±m	Indicators after ferrotherapy M ±m	P1	P2
1	Hemoglobin	144,5±2,4	84,95±4,4	103,6±5,4	P < 0,01	P < 0,01
2	Red blood cells	5,09±0,09	3,6±0,07	3,9±0,08	P < 0,01	P < 0,01
3	Mean blood cell hemoglobin content	29,5±0,22	26,2±0,32	29,1±0,42	P < 0,01	P < 0,01
4	Mean blood cell hemoglobin concentration	344,5±7,6	301,7± 8,6	317,5±7,0	P < 0,01	P < 0,01
5	Red blood cell distribution width	13,6±0,17	18,6±0,19	14,1±0,17	P < 0,01	P < 0,01

Note P1 – reliability with indicators before and after treatment
P2 – reliability between the control group and indicators after treatment
Evaluation of the dynamics of iron metabolism indicators in patients with leukemia in remission was carried out in 45 patients 1 month after the start of ferrotherapy with liposomal drugs. A significant increase in serum iron indicators and a significant decrease in transferrin indicators were noted, which indicates the effectiveness of ferrotherapy. However, in comparison with the indicators of the control group, the transferrin indicators 1 month after treatment did not reach normal values, which is the rationale for continuing ferrotherapy.

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Table. 4. Evaluation of iron metabolism parameters in patients with leukemia in remission before and after treatment with liposomal iron

		Control group n=24 M ±m	Main group n = 45		
№	Iron metabolism criteria		Before treatment n =45 M ±m	After treatment n =45 M ±m	R reliability
1	Serum iron µmol/l	26,42±0,89	21,2±0,85	25,21±0,85	P < 0,01
2	Ferritin µg/l	75,92±8,5	1192,5±60,4	1290,4±57, 7	P ≥0,5
3	Transferrin g/l	2,4± 0,18	3,03±0,09	3,52±0,07	P < 0,05

Note – P reliability of indicators before and after treatment

Before the start of treatment with liposomal preparations, severe anemia was detected in 10% of patients with leukemia in remission, moderate anemia in 65%, and mild anemia in 25%. In the dynamics, 1 month after ferrotherapy, severe anemia was not detected in any case, moderate anemia was detected in 1 patient (5%), and mild anemia in 95% of patients.

As a result of ferrotherapy with liposomal iron preparations, the number of patients with mild anemia increased from 25% to 95%, and the number of moderate and severe anemia decreased from 75% to 5%, which allows us to consider liposomal iron preparations effective in the treatment of iron deficiency in patients with leukemia. Thus, the treatment of anemic syndrome (accompanied by iron deficiency) with liposomal iron preparations in patients with leukemia in remission allows us to conclude that the drug is well tolerated, there are virtually no side effects, and no refusals from treatment have been noted.

CONCLUSIONS

1. Evaluation of the tolerability of the liposomal drug "Liposemi Plus" showed that 100% of patients rated it as "good", side effects from the gastrointestinal tract typical of conventional oral iron preparations were detected in only 2.2% of patients. For patients with leukemia, it is especially important to protect the gastrointestinal tract from the side effects of drugs, since constant chemotherapy already creates a serious negative burden on the gastrointestinal tract.

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2. Evaluation of the effectiveness of treatment of anemic syndrome in patients with leukemia in the remission stage with liposomal preparations indicates a reliable increase in hemoglobin levels from 84.95±4.4 g/l to 103.6±5.4 g/l, the number of erythrocytes from 3.6±0.07 million to 3.9±0.08 million.
3. As a result of treatment, a reliable increase in serum iron levels from 21.2±0.85 μmol/l to 25.21±0.85 μmol/l and a reliable decrease in transferrin levels from 3.52±0.07 g/l to 3.03±0.09 g/l were noted, which indicates the effectiveness of ferrotherapy..

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