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EFFICACY OF ERYTHROPOIETIN IN THE CORRECTION OF ANEMIA IN ONCOLOGY PATIENTS UNDERGOING CHEMOTHERAPY

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ABSTRACT

Relevance: *Anemia is a common complication in oncology patients, reducing their quality of life and potentially decreasing the effectiveness of antitumor therapy. Its prevalence among patients with solid tumors reaches 40%, and during chemotherapy, it increases to 54%. The deterioration in patients' condition is associated with chemotherapy-induced myelosuppression, making anemia correction a crucial task. The primary pharmacological method for correction is using erythropoietins, which stimulate the proliferation of erythroid progenitor cells.*

The study aimed to *evaluate the effectiveness and safety of erythropoietin in correcting anemia in oncology patients receiving chemotherapy, focusing on improving treatment outcomes by correcting hematological parameters in real clinical practice.*

Methods: *This prospective, non-interventional study included 133 patients from two clinical centers in Kazakhstan. Inclusion criteria: age ≥18 years, histologically confirmed solid tumor, anemia (Hb ≤100 g/L), and ongoing chemotherapy. The sample included 100 (75.2%) women and 33 (24.8%) men, with a median age of 60 years (52.0-67.5). The drug was administered 3 to 5 times in 78.2% of patients and 1 to 2 times in 21.8%. Statistical analysis was performed using the Friedman and Wilcoxon criteria, with a significance level of $p<0.05$.*

Results: *Data from 133 patients were analyzed. An increase in hemoglobin and erythrocyte levels was observed in 65.4-78.2% of patients. In the first and third months, hemoglobin levels increased by 0.6 g/L ($p<0.001$), and erythrocyte levels increased by 0.2-0.3×10¹²/L ($p<0.001$). 33.1% of patients received the drug five or more times. No serious adverse events were recorded.*

Conclusion: *Erythropoietin demonstrated a statistically significant improvement in clinical parameters, confirming its effectiveness and safety in correcting anemia in oncology patients receiving chemotherapy. This contributes to an improved quality of life and better treatment outcomes.*

Keywords: *anemia, oncology, chemotherapy, erythropoietin, erythropoiesis, anemia correction, biosimilar, solid tumors.*

Introduction: Anemia associated with chronic diseases occurs in 40% of cancer patients with solid tumors. The incidence of anemia during chemotherapy reaches 54%, with 30% of cases being mild, 9% moderate, and 1% severe. Anemia is most often observed in lung cancer (71%) and tumors of the female reproductive system (65%) [1, 2].

Chemotherapy may worsen anemia by decreasing hemoglobin levels and worsening the general condition of patients. In this context, the importance of anemia correction cannot be underestimated since it affects patients' quality of life and can also reduce the effectiveness of antitumor therapy [3]. Erythropoietins stimulate the proliferation of the erythroid hematopoietic lineage in the bone marrow. These drugs are actively used to correct anemia in cancer patients. Erythropoietin has been approved for clinical use and has shown its effectiveness in increasing hemoglobin levels and reducing the need for blood transfusions in patients receiving chemotherapy. However, despite its widespread use, questions remain about optimizing the administration regimen, efficacy, and safety profile. In this regard, there was a need to conduct this study in real clinical practice to assess the efficacy and safety of erythropoietin in cancer patients receiving chemotherapy.

The study aimed to evaluate the efficacy and safety of erythropoietin in the correction of anemia in cancer patients receiving chemotherapy, focusing on improving treatment outcomes by correcting hematological parameters in real clinical practice.

Objectives of the study: to analyze the drug's effect on hemoglobin levels, the frequency of blood transfusions, and the general condition of patients, as well as to identify possible side effects when using it in real clinical practice.

Materials and methods: The study was prospective, non-interventional, and conducted in two clinical centers in Kazakhstan. The study included and analyzed data from 133 patients. The main inclusion criteria were age 18 years, verified diagnosis of solid cancer, laboratory-confirmed anemia (hemoglobin level ≤100 g/L), and ongoing chemotherapy. The study patients included individuals of both sexes, with a three-fold predominance of females: 100 women (75.2%) and 33 men (24.8%). The average age of

patients was 60 years (range 52.0-67.5). Most study participants (57.1%) had a normal body mass index. The predominant tumor localizations included gynecological tumors – 40 patients (30.1%), tumors of the gastrointestinal tract – 38 patients (28.6%), breast cancer – 22 patients (16.5%), and other localizations – 33 patients (24.8%) (Table 1).

Table 1 – Clinical and demographic characteristics of patients

Indicator	n (%)
Floor	
Men	33 (24.8%)
Women	100 (75.2%)
Age (Median (Q_1-Q_3))	60 (52.0-67.5)
Body mass index	
16-18.5	2 (1.5%)
18.5-25	76 (57.1%)
25-30	41 (30.8%)
30-35	11 (8.3%)
35-40	3 (2.3%)
Tumor localization	
Hematological	3 (2.3%)
Gynecological	40 (30.1%)
Heads and necks	7 (5.3%)
Gastrointestinal tract	38 (28.6%)
Leather	2 (1.5%)
Lungs	8 (6.0%)
Breast	22 (16.5%)
Urogenital system	9 (6.8%)
The locomotor system	4 (3.0%)
Total	133 (100%)

Patients received erythropoietin 40,000 IU/ml for 6 months before inclusion in the study. The total number of drug administrations ranged from 3 to 5 in 78.2% of patients. The most common chemotherapeutic agents were Cisplatin, Carboplatin, and Paclitaxel. These drugs were used for chemotherapy in 74-90 patients (55.6-67.6%).

The study analyzed changes in hemoglobin levels, red blood cell (RBC) count, and the data on side effects. The drug's efficacy was assessed based on changes in hemoglobin levels and RBC count, and safety was assessed based on monitoring adverse events.

Statistical analysis used the Friedman and Wilcoxon criteria to compare laboratory data before and after drug administration. The Kruskal-Wallis criterion was used to compare the blood parameters, considering the number of erythropoietin administrations and chemotherapy courses. The results were considered statistically significant at $p<0.05$.

Results: Data from 133 patients with solid tumors who received erythropoietin for 6 months were analyzed. According to the study results, 33.1% of included patients received erythropoietin five times or more, corresponding to the study's primary endpoint. It is also worth noting that 66.2% of participants underwent 3 courses of chemotherapy before the start of the drug administration, which emphasizes the relevance of using erythropoietin in treating anemia caused by cytostatic therapy. Twenty-five participants (18.8%) received 2 courses of chemotherapy, and in 3 patients, chemotherapy was administered once (2.3%). The proportion of patients who received chemotherapy 4 to 7 times was 11.4%.

Red blood cell and hemoglobin values were assessed each visit before and after erythropoietin administration. No statistically significant changes were found between visits between RBC count and hemoglobin levels (Table 2).

Table 2 – Dynamics of RBC count and hemoglobin levels before erythropoietin administration

Indicator	Month 1	Month 2	Month 3	r*
Erythrocytes	3.2 (3.0-3.5)	3.1 (2.9-3.5)	3.2 (2.9-3.6)	0.221
Hemoglobin	93.0 (87.0-96.0)	92.0 (85.0-95.0)	92.0 (86.0-96.0)	0.125

*Note: *Friedman criterion*

With the introduction of erythropoietin, positive dynamics of erythrocyte and hemoglobin indices were demonstrated in each observation period. During the 1st and 2nd months of observation, with the introduction of the drug, erythrocyte indices increased by 0.2 10^{12}/L ($p<0.001$) and by 0.3 10^{12}/L ($p<0.001$) in the 3rd month. Positive dynamics of hemoglobin indices gave a difference of 0.6 g/l ($p<0.001$) in the 1st and 3rd months of observation and by 0.4 g/l in the 2nd month ($p<0.001$). Taking into account that the clinical course of malignant neoplasms in most cases is accompanied by the development of anemia both as a result of treatment (chemotherapy) and as a result of impaired erythropoietin response, the above dynamics of indices shows excellent results of using the drug [4]. Table 3 shows the data on the effect of erythropoietin administration on blood parameters (hemoglobin, erythrocytes) during the observation period. Statistically significant differences in blood parameters before and after administration of the drug were found for all months of observation.

Table 3 – Effect of erythropoietin administration on blood parameters (hemoglobin, erythrocytes) according to 1-3 months of observation

Indicators	Month of observation					
	1	p*	2	p*	3	p*
Erythrocytes, before the introduction of EZ	3.2 (3.0-3.5)	<0.001	3.1 (2.9-3.5)	<0.001	3.2 (2.9-3.6)	<0.001
Erythrocytes after administration of EZ	3.4 (3.1-3.9)		3.3 (3.0-3.7)		3.5 (3.2-3.8)	
Hemoglobin, before the introduction of EZ	93.0 (87.0-96.0)	<0.001	92.0 (85.0-95.0)	<0.001	92.0 (86.0-96.0)	<0.001
Hemoglobin after administration of EZ	99.0 (91.5-102.5)		96.0 (92.0-101.0)		98.0 (91.0-104.0)	

*Note: *Wilcoxon test*

No statistically significant differences were found when studying the effect of the number of chemotherapy courses on RBC count and hemoglobin levels (Table 4).

Table 4 – Effect of the number of chemotherapies on blood parameters before the introduction of erythropoietin according to visit data

Indicators	Number of chemotherapy treatments			r*
	1-2	3	4 or more	
Erythrocytes	3.2 (2.8-3.9)	3.2 (3.0-3.4)	3.3 (3.1-3.8)	0.592
Hemoglobin	89.0 (83.0-96.5)	93.0 (88.0-96.5)	94.0 (90.0-97.0)	0.234

*Note: *Kruskal-Wallis test, no statistically significant differences found*

Table 5 shows the data on the effect of the number of erythropoietin administrations on hemoglobin and erythrocyte indices. A positive increase in RBC counts and hemoglobin levels was noted after chemotherapy with the administration of erythropoietin in the 1st month of observation. Despite the administration of chemotherapeutic drugs, the differences in the median values of the difference in both the number of erythrocytes and the hemoglobin level are statistically significant. The increase was more pronounced with two and three intakes of the drug. A higher hemoglobin difference was noted with three or more administrations - 10.0 (6.0; 16.0), and erythrocytes with two administrations - 0.23 (-0.02; 0.48). In the second and third months of observation, increases in erythrocyte and hemoglobin indices were recorded in all groups after administering the drug. The greatest increase was noted with three or more administrations of the drug, but these differences are not statistically significant.

Table 6 shows the direction of changes in RBC count and hemoglobin levels by months of observation.

Table 5 – Effect of the number of erythropoietin administrations on the difference in blood parameter values according to 1-3 months of observations

Indicators	Number of erythropoietin injections			r*
	1	2	3 or more	
After 1 month (n=128)				
Median difference in RBC counts before and after chemotherapy	0.10 (-0.03; 0.25)	0.23 (-0.02; 0.48)	0.20 (0.13; 0.40)	0.043
Median difference in hemoglobin levels before and after chemotherapy	3.0 (1.0; 8.0)	7.0 (2.0; 13.0)	10.0 (6.0; 16.0)	0,001
After 2 months (n=122)				
Median difference in RBC counts before and after chemotherapy	0.18 (0.03; 0.35)	0.19 (0.01; 0.40)	0.43 (0.28; 0.55)	0.198
Median difference in hemoglobin levels before and after chemotherapy	4.0 (2.0; 9.0)	5.0 (1.0; 7.0)	15.0 (9.5; 19.0)	0.062
After 3 months (n=109)				
Median difference in RBC counts before and after chemotherapy	0.21 (0.04; 0.46)	0.28 (0.07; 0.51)	0.16 (0.10; 0.36)	0.976
Median difference in hemoglobin levels before and after chemotherapy	5.0 (2.0; 10.0)	8.5 (4.0; 15.0)	4.0 (3.5; 11.0)	0.296

*Note: *Kruskal-Wallis test*

Table 6 – Direction of changes in blood parameters by month against the background of erythropoietin intake (n=133)

Indicator	Month 1	Month 2	Month 3
Erythrocytes			
Decrease	3 4 (25.6%)	23 (17.3%)	18 (13.5%)
No changes	4 (3.0%)	2 (1.5%)	4 (3.0%)
Increase	90 (67.7 %)	97 (72.9%)	87 (65.4%)
No data	5 (3.8%)	11 (8.3%)	24 (18.0%)
Hemoglobin			
Decrease	21 (15.8%)	13 (9.8%)	14 (10.5%)
No changes	3 (2.3%)	5 (3.8%)	1 (0.8%)
Increase	104 (78.2%)	104 (78.2%)	94 (70.7%)
No data	5 (3.8%)	11 (8.3%)	24 (18.0%)

During the study, no serious or serious events or deaths were recorded in patients, confirming the good tolerability of erythropoietin.

Discussion: The results of our study confirm the high efficiency and safety of erythropoietin in the correction of anemia in cancer patients receiving chemotherapy. Positive dynamics of hemoglobin levels in 78.2% and erythrocytes in 65.4% of patients indicate a significant effect of the drug on improving hematological parameters.

Anemia associated with cancer and its treatment is a serious problem affecting the quality of life of patients and the effectiveness of antitumor therapy [5]. As shown by the results of our study, the hemoglobin level increased by 0.6 g/L ($p<0.001$) during the first month and by 0.4 g/L ($p<0.001$) in the second month, which confirms the relevance of using erythropoietin as a means for correcting anemia.

Using erythropoietin in clinical practice can significantly reduce the need for blood transfusions [6], which is especially important in resource-limited settings and the increasing number of patients with anemia. Reducing the frequency of red blood cell transfusions helps to reduce the risks associated with this procedure, such as complications and transmission of infections through donor blood components. No serious adverse events were reported in our study, which underlines the safety profile of erythropoietin.

Our study data are consistent with the results of other clinical trials that have reported erythropoietin's efficacy in treating anemia in cancer patients [7]. For example, the ORHEO post-marketing study demonstrated that 81.6% of patients responded to erythropoietin therapy within three months, confirming its reliability as a tool for correcting anemia [8].

Conclusion: The main objectives and purpose of the study were achieved. The study included a planned sample according to the protocol. Data on using erythropoietin in real clinical practice for anemia caused by cytostatic therapy in patients with verified solid cancer of any localization were collected and described. The clinical and demographic characteristics of the patients were described. The data obtained indicate a significant predominance of women among patients with anemia, which may be associated with the high incidence of breast cancer and gynecological tumors, as well as the peculiarities of the pathogenesis of anemia in this group. The average age of patients (60 years) and normal body mass index in most participants indicate the need for an individualized approach to correcting anemia, taking into account age and risk factors. A high proportion of patients with gastrointestinal tumors emphasizes the importance of timely detection and treatment of anemia in this category of patients since absorption disorders and blood loss can aggravate the course of the disease.

The drug's efficacy in patients with verified solid cancer has been demonstrated, and positive dynamics of RBC count and hemoglobin levels have been noted in each of the observed periods. Considering that the clinical course of malignant neoplasms in most cases is accompanied by the development of anemia both as a result of treatment (chemotherapy) and as a result of impaired erythropoietin response [4, 9], the above dynamics of indices demonstrate excellent results of drug use.

The high frequency of erythropoietin administration and the absence of reported adverse reactions confirm its favorable safety profile and good tolerability in cancer patients with anemia. These studies demonstrate that five or more times the drug is administered contributes to a stable increase in hemoglobin levels, which allows us to recommend this treatment regimen for effective correction of anemia in real clinical practice.

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АҢДАТПА

ЭРИТРОПОЭТИННІҢ ХИМИОТЕРАПИЯ АЛАТЫН ОНКОЛОГИЯЛЫҚ НАУҚАСТАРДАҒЫ АНЕМИЯНЫ ТҮЗЕТУДЕГІ ТИІМДІЛІГІ

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Өзектілігі: *Анемия – онкологиялық пациенттерде жиі кездесетін асқыну, ол өмір сүру сапасын төмендетіп, ісікке қарсы терапияның тиімділігін нашарлатуы мүмкін. Солидті ісіктері бар пациенттер арасында оның жиілігі 40%-ға, ал химиотерапия кезінде 54%-ға дейін жетеді. Пациенттердің жағдайының нашарлауы химиотерапиямен индуцирленген миелосупрессиямен байланысты, бұл анемияны түзетуді маңызды міндетке айналдырады. Дәрілік түзетудің негізгі әдісі – қан түзілу жүйесінің эритроидты өсуін ынталандыратын эритропоэтиндерді қолдану.*

Мақсаты: *Химиотерапия алатын онкологиялық пациенттерде анемияны түзетуде эритропоэтиннің тиімділігі мен қауіпсіздігін бағалау, нақты клиникалық практикада гематологиялық көрсеткіштерді түзету арқылы емдеу нәтижелерін жақсартуға баса назар аудару.*

Әдістері: *Бұл проспективті интервенциялық емес зерттеуге Қазақстанның екі клиникалық орталығынан 133 пациент қатысты. Қатысу критерийлері: жас ≥18 жыл, верификацияланған солидті ісік, анемия (Hb ≤100 г/л) және жүргізілетін химиотерапия. Зерттеуге 100 (75,2%) әйел және 33 (24,8%) ер адам кірді. Орташа жас – 60 жыл (52,0-67,5). Препарат 78,2% пациентке 3-тен 5 ретке дейін және 21,8% пациентке 1-2 рет енгізілді. Статистикалық талдау Фридман және Вилкоксон критерийлерін пайдалана отырып жүргізілді, маңыздылық деңгейі $p<0,05$.*

Нәтижелері: *133 пациенттің деректері талданды. 65,4-78,2% пациентте гемоглобин мен эритроциттер деңгейінің жоғарылауы байқалды. Бірінші және үшінші айларда гемоглобин деңгейі 0,6 г/л-ге ($p<0,001$), эритроциттер деңгейі 0,2-0,3×10^{12}/л-ге ($p<0,001$) артты. 33,1% пациент препаратты бес және одан да көп рет қабылдады. Елеулі жағымсыз құбылыстар тіркелген жоқ.*

Қорытынды: *Эритропоэтин клиникалық көрсеткіштердің статистикалық тұрғыдан елеулі жақсарғанын көрсетті, бұл оның химиотерапия алатын онкологиялық пациенттерде анемияны түзетудегі тиімділігі мен қауіпсіздігін растайды. Бұл өмір сүру сапасын арттыруға және емдеу нәтижелерін жақсартуға ықпал етеді.*

Түйінді сөздер: *анемия, онкологиялық аурулар, химиотерапия, эритропоэтин, эритропоэз, анемияны түзету, биосимиляр, солидті ісіктер.*

АННОТАЦИЯ

ЭФФЕКТИВНОСТЬ ЭРИТРОПОЭТИНА В КОРРЕКЦИИ АНЕМИИ У ОНКОЛОГИЧЕСКИХ ПАЦИЕНТОВ, ПОЛУЧАЮЩИХ ХИМИОТЕРАПИЮ

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Актуальность: *Анемия – частое осложнение у онкологических пациентов, которое снижает качество жизни и может ухудшать эффективность противоопухолевой терапии. Ее частота среди пациентов с солидными новообразованиями достигает 40%, а во время химиотерапии – 54%. Ухудшение состояния пациентов связано с миелосупрессией, вызванной химиотерапией, что делает коррекцию анемии важной задачей. Основным методом медикаментозной коррекции является применение эритропоэтинов, стимулирующих пролиферацию эритроидного ростка кроветворения.*

Цель исследования *– оценка эффективности и безопасности эритропоэтина в коррекции анемии у онкологических пациентов, получающих химиотерапию, с акцентом на улучшение результатов лечения путем коррекции гематологических показателей в реальной клинической практике.*

Методы: *В данном проспективном неинтервенционном исследовании участвовали 133 пациента из двух клинических центров Казахстана. Критерии включения: возраст ≥18 лет, верифицированный солидный рак, анемия (Hb≤100 г/л) и проводимая химиотерапия. Выборку составили 100 – (75,2%) женщин и 33 (24,8%) мужчины. Средний возраст – 60 лет (52,0-67,5). Препарат вводили от 3 до 5 раз у 78,2% пациентов и от 1 до 2 раз – у 21,8% пациентов. Статистический анализ проведен с использованием критериев Фридмана и Вилкоксона, уровень значимости $p<0,05$.*

Результаты: *Проанализированы данные 133 пациентов. У 65,4-78,2% пациентов наблюдалось увеличение уровня гемоглобина и эритроцитов. В первом и третьем месяцах уровень гемоглобина повысился на 0,6 г/л ($p<0,001$), уровень*

эритроцитов – на 0,2-0,3×10¹²/л (p<0,001). 33,1% пациентов получали препарат пятикратно и более. Серьезных нежелательных явлений не зарегистрировано.

Заключение: *Эритропоэтин продемонстрировал статистически значимое улучшение клинических показателей, подтверждая его эффективность и безопасность в коррекции анемии у онкологических пациентов, что способствует повышению качества жизни и улучшению результатов лечения.*

Ключевые слова: *анемия, онкологические заболевания, химиотерапия, эритропоэтин, эритропоэз, коррекция анемии, биосимиляр, солидные опухоли.*

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