CD4/CD8 RATIO AS A HIV-ASSOCIATED FACTOR OF THE LUNG CANCER COURSE AND OUTCOME PROGNOSIS

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Non-AIDS-defining cancers represent one of the leading causes of death among people living with HIV in developed economies due to successful antiretroviral therapy. Malignant neoplasms (MNs) of the lung occupy leading positions in prevalence and mortality, affecting younger people compared to the general population. Despite the fact that the role of HIV in the direct mechanism underlying the lung cancer carcinogenesis has not been proven, the immunodeficiency-mediated effect, including that on the anti-tumor immunity, contributes to the earlier neoplastic process development and to the features of the disease course and anti-tumor treatment. HIV often becomes an exclusion criterion for multiple oncology clinical trials, and this group of patients is overlooked. The study aimed to assess the impact of the CD4/CD8 ratio as one of the key markers of the state of cell-mediated immunity on the lung cancer course prognosis during anti-tumor treatment. The data of 17 HIV patients with MNs of the lung and 31 non-HIV patients of the control group, who underwent treatment in 2018–2023, were analyzed. The analysis determined the threshold CD4/CD8 ratio value (≤ 0.57) and the fact of its decrease by more than 0.01, which reflected a significant overall survival worsening ($p < 0.05$) during lung cancer treatment. Furthermore, comparative analysis of patients of the index and control groups revealed no significant differences in progression-free survival and the number of therapy lines, which suggests comparable treatment outcomes in patients with lung cancer against the background of existing HIV ($p > 0.05$).

Keywords: lung cancer, HIV, non-AIDS-defining cancers, CD4/CD8 ratio

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ИММУНОРЕГУЛЯТОРНЫЙ ИНДЕКС КАК ВИЧ-АССОЦИИРОВАННЫЙ ФАКТОР ПРОГНОЗА ТЕЧЕНИЯ И ИСХОДА РАКА ЛЕГКОГО

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В развитых странах благодаря успешной антиретровирусной терапии ВИЧ-неассоциированные опухоли являются одной из ведущих причин летальных исходов среди людей, живущих с ВИЧ. Злокачественные новообразования (ЗНО) легких занимают лидирующие позиции по частоте встречаемости и смертности, затрагивая лиц более молодого возраста по сравнению с общей популяцией. Несмотря на то что роль ВИЧ-инфекции в прямом механизме онкогенеза рака легкого не доказана, опосредованное через иммунодефицит влияние в том числе и на противоопухолевый иммунитет способствует более раннему развитию опухолевого процесса, вносит особенности в течение заболевания и в противоопухолевое лечение. Зачастую ВИЧ-инфекция является критерием исключения из большего числа клинических исследований в онкологии, и данная группа пациентов остается без внимания. Целью исследования было изучить влияние индекса CD4/CD8 как одного из ключевых маркеров состояния клеточного иммунитета на прогноз течения рака легкого в ходе противоопухолевого лечения. Анализировали данные 17 пациентов с ЗНО легких и ВИЧ-инфекцией и данные 31 пациента контрольной группы без ВИЧ, проходивших лечение с 2018 по 2023 г. В ходе анализа определены пороговый уровень индекса CD4/CD8, составивший ≤ 0,57, и его динамика снижения более чем на 0,01, которые значимо отражали ухудшение общей выживаемости ($p < 0,05$) в ходе лечения рака легкого. Кроме того, в ходе сравнительного анализа основной и контрольной групп пациентов не было выявлено статических значимых различий в выживаемости без прогрессирования и в числе линий терапии, что позволяет сделать предположение о сопоставимых результатах лечения больных раком легкого на фоне имеющейся ВИЧ-инфекции ($p > 0,05$).

Ключевые слова: рак легкого, ВИЧ-инфекция, ВИЧ-неассоцированные ЗНО, иммунорегуляторный индекс

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There were major changes in the structure of mortality and the increase in life expectancy among people with HIV due to the state strategy of countering the spread of HIV in the Russian Federation (RF), extensive coverage and availability of advanced antiretroviral therapy (ART). The share of malignant neoplasms (MNs) in the structure of morbidity and mortality of this population increases with increasing overall survival and age of HIV-infected people. Today, in industrialized countries, non-AIDS-defining cancers result in the larger number of deaths, than AIDS-defining ones, hepatitis C, or cardiovascular disorders. It is the second (after AIDS) most common cause of death among HIV-infected patients [1, 2].

In the RF and Russian literature, it is common to allocate AIDS-defining cancers (ADCs) that include Kaposi's sarcoma, primary central nervous system lymphoma, non-Hodgkin lymphomas, invasive cervical cancer. Detection of those suggests AIDS stage in a HIV patient. Furthermore, non-AIDS-defining cancers (NADCs) are distinguished that are most common in early-stage HIV (hepatocellular carcinoma, lung cancer, squamous cell carcinoma of the head and neck, anal canal cancer, Hodgkin lymphoma) [3–5].

The most common NADCs were reported in one of the largest studies of HIV-infected population in the USA, Europe, and Australia D:A:D 3 (176,775 HIV patients, among them 880 cases of NADCs in 2004–2010): lung cancer (0.79/1000 people/year), Hodgkin lymphoma (0.63/1000 people/year), and anal canal cancer (0.45/1000 people/year) [6]. The nationwide Japanese study conducted in 2024 (Longitudinal Annual Survey of HIV/AIDS Referral Hospitals in Japan From 1999 to 2021: Trend in Non-AIDS-defining Cancers Among Individuals Infected With HIV-1) showed an upward trend of NADC incidence in 1999–2021, and lung cancer was the most prevalent MN form (14%) [7].

In HIV-infected patients, lung cancer is diagnosed on average ten years earlier. Even in the group of nonsmokers, HIV was associated with the 4-fold increased risk of death from lung cancer relative to the general population. According to the data of the same Japanese study, lung cancer was second only to pancreatic cancer in mortality rate [8].

Despite the decrease in the rate of HIV incidence from 43.29 to 40.04 per 100,000 population in 2023 (by 7.5% compared to the year 2022), the number of new cases exceeds the number of deaths, and the total number of people living with HIV in Russia is still growing [9]. The relevance of treatment of this group of patients is growing every year. However, HIV is an exclusion criterion for the majority of multicenter randomized clinical trials of cancer treatment. And, therefore, the prevalence and nature of cancer in HIV-infected patients are poorly understood, including lung cancer, its clinical and morphological features against the background of HIV-mediated factors. The prognosis, that was extremely bad in the era when there was no antiretroviral therapy, can currently be almost the same as the prognosis of people having no HIV with the multidisciplinary approach, patient's adherence to treatment, and timely prevention.

The study published in the Journal of Thoracic Oncology in July 2025 involved comparative analysis of immunogenomic characteristics of non-small-cell lung cancer (NSCLC) in people living with HIV (PLWHIV) and immunocompetent patients. HIV severely impairs both systemic and local antitumor immunity, despite similar molecular profiles of the tumor, through severe persistent impairment of the interaction between the CD4 and CD8 T cells. This can contribute to worse prognosis of NSCLC in PLWHIV, even in cases of virological control [10]. One HIV-mediated factor is the CD4/CD8 ratio that has shown its significance as a biomarker for lung cancer screening and a factor of poor prognosis in a number of studies [11–13].

Thus, the study aimed to assess the impact of HIV-associated immunological factors on the lung cancer course prognosis during antitumor treatment, as well as to analyze progression-free survival relative to the control group.

METHODS

Inclusion criteria: malignant neoplasm of the lung; registered diagnosis of HIV infection. Exclusion criteria: patient's blood levels of CD4 lymphocytes < 200 cells/mL; exacerbation of chronic infectious disease.

We conducted a prospective study of diagnostic value of the CD4/CD8 ratio as a HIV-mediated predictor of fatal lung cancer outcome. The index group included 17 patients with stage I–IV lung cancer and HIV infection, the control group included 31 individuals with lung cancer having no HIV, who had been treated in 2018–2023 at the St. Petersburg City Clinical Oncology Dispensary.

All 17 patients included in the study underwent anti-retroviral therapy in accordance with the current clinical guidelines on NIV treatment issued in appropriate year with assessment of viral load and cell-mediated immunity state after each even-numbered drug therapy cycle or a month after surgical treatment. Together with the infectious disease physician we assessed the need to adjust antiretroviral (ARV) drugs in order to reduce overlapping toxicity in accordance with antitumor drug treatment regimen. The patients included in the index and control groups were comparable based on the main clinical and demographic characteristics (Tables 1, 2).

R ver. 4.1.1 statistical environment (R Core Team, 2020) [14] and MedCalc (ver. 23.1.1) software were used for statistical analysis.

Significance level was set as $p < 0.05$. *P*-values are presented in the report with two decimal places, if exceed 0.05, and with three decimal places at $p < 0.05$.

The qualitative characteristic description is provided as absolute number of observations (*n*), percentage (%), and 95% confidence interval (CI) for shares.

Survival analysis was performed using the Kaplan–Meier estimator; comparison of survival curves between patients in the groups was performed using the log-rank test.

Sensitivity and specificity of significant models were tested using ROC curves. The cut-off value for the model was determined by maximization of the sum of sensitivity and specificity or by determining the sensitivity and specificity balance and the Youden's index.

Based on the predictor analysis results in univariate models, all the predictors identified were integrated into a multivariate model for analysis of the relationship between indicators combined with the fatal outcome probability. The multivariate logistic regression model was considered significant at $p < 0.05$ for all independent traits.

RESULTS

The CD4/CD8 ratio varied between 0.13 and 1.11 in patients of the index group, the median value was 0.79.

ROC analysis was used to assess the impact of baseline CD4/CD8 ratio values and dynamic CD4/CD8 changes during antitumor treatment on the overall survival (OS) of patients of the index group. Optimal threshold values of the indicators considered were determined. The univariate analysis conducted revealed a significant impact of the CD4/CD8 ratio

Table 1. Characteristics of the group of HIV patients and the control group

Groups based on the age of cancer detection (WHO classification)		
Group	Parameter	Rate (share)
HIV patients	Young age (18–44 years)	5/17 (29.5%)
	Middle age (45–59 years)	8/17 (47%)
	Advanced age (60–74 years)	4/17 (23.5%)
Non-HIV patients	Young age (18–44 years)	0/32 (0%)
	Middle age (45–59 years)	15/32 (46.9%)
	Advanced age (60–74 years)	17/32 (53.1%)
Patient distribution by gender		
Group	Parameter	Rate (share)
HIV patients	Male	12/17 (70.6%)
	Female	5/17 (29.4%)
Non-HIV patients	Male	19/32 (61.3%)
	Female	12/32 (38.7%)
Stage I–IV cancer		
Group	Parameter	Rate (share)
HIV patients	IA	2/17 (11.8%)
	IB	0/17 (0%)
	IIA	1/17 (5.9%)
	IIB	2/17 (11.8%)
	IIIA	2/17 (11.8%)
	IIIB	1/17 (5.9%)
	IV	7/17 (41.2%)
	IVA	1/17 (5.9%)
	IVB	1/17 (5.9%)
Non-HIV patients	IA	4/32 (12.9%)
	IB	1/32 (3.2%)
	IIA	0/32 (0%)
	IIB	3/32 (9.7%)
	IIIA	6/32 (19.4%)
	IIIB	7/32 (22.6%) 10.3–41.5%
	IV	7/32 (22.6%)
	IVA	3/32 (9.7%)
	IVB	0/32 (0%)
Histologic type: Adenocarcinoma among HIV and non-HIV patients		
Group	Rate (share)	
HIV patients	7/17 (41.2%)	
Non-HIV patients	19/31 (61.3%)	
Histologic type: Squamous cell carcinoma among HIV and non-HIV patients		
Group	Частота (доля)	
HIV patients	5/17 (29.4%)	
Non-HIV patients	8/31 (25.8%)	
HIV patients	4/17 (23.5%)	
Non-HIV patients	3/31 (9.7%)	
Histologic type: Atypical carcinoid among HIV and non-HIV patients		
Group	Rate (share)	
HIV patients	1/17 (5.9%)	
Non-HIV patients	0/31 (0%)	
Patient distribution by gender		
Parameter	Rate (share)	
Male	12/17 (70.6%) 44–88.6%	
Female	5/17 (29.4%) 11.4–56%	

Table 2. Characteristics of the group of HIV patients

HIV infection stages	
Parameter	Rate (share)
3	1/17 (5.9%)
3 remission	1/17 (5.9%)
4A remission	3/17 (17.6%)
4B remission	5/17 (29.4%)
4C progression	5/17 (29.4%)
4C remission	2/17 (11.8%)
Viral load at the time of cancer detection (copies/mL)	
N	17
M	35106.41
SD	89540.49
95% CI	–7457.65; 77670.47
Min	20
Max	364467
Me	1052
IQR	40; 14696
CD4 cells at the time of cancer detection (cells/mL)	
N	17
M	370.94
SD	120.99
95% CI	313.43; 428.45
Min	252
Max	631
Me	317
IQR	277; 445
CD4/CD8 index at the time of cancer detection	
N	17
M	0.7
SD	0.31
95% CI	0.55; 0.85
Min	0.13
Max	1.11
Me	0.79
IQR	0.48; 0.92

on the overall survival of patients with MNs of the lung and concomitant HIV infection ($p < 0.005$) (Table 3, Fig. 1, 2).

Multivariate analysis was performed using the Cox proportional hazards model, which included the CD4/CD8 ratio and the CD4/CD8 ratio dynamic changes during antitumor treatment that had an effect on survival when applying univariate ROC analysis. The multivariate analysis results showed the following: the baseline CD4/CD8 ratio value (before treatment) and the CD4/CD8 ratio dynamic changes during the ongoing therapy turned out to be independent prognostic factors having a significant effect on the OS of patients with MNs of the lung and HIV (overall significance of the model: $p < 0.0001$, AUC = 0.920 (95% CI 0.851– 0.989)) (Table 4).

With the threshold CD4/CD8 ratio value of 0.57, the median OS of the patients with the ratio values above the threshold value at the time of data set acquisition had not been achieved and was significantly different from the median OS of the patients with the threshold or lower CD4/CD8 ratio values, in whom it was 3 months ($p = 0.0117$) (Fig. 3).

The median OS of the patients, in whom the CD4/CD8 ratio decreased by more than 0.01, was 4 months. It was significantly lower, than that of the patients, in whom the CD4/CD8 ratio did not decrease to the threshold level ($p = 0.0220$) (Fig. 4).

Furthermore, prediction of fatal outcomes revealed a positive correlation with male sex in HIV-infected patients with lung cancer. The likelihood of fatal outcome in males is 5.27 times higher, than in females ($p < 0.05$) (Fig. 5).

Lung cancer in HIV-infected patients of the index group was treated in accordance with the clinical guidelines of appropriate year. Five patients (16.1%) underwent surgical treatment, 14 (45.2%) received combination treatment, eight patients (47.2%) received drug therapy in the therapeutic regimen. Sixteen patients out of 17 were prescribed antitumor drug treatment, and only one patient (5.8%) with small-cell lung cancer died before the beginning of chemotherapy. In this sample of patients, radiotherapy was not prescribed as a method to treat the locally advanced form of lung cancer.

Comparative analysis revealed no significant differences in the number of therapy lines and progression-free survival between HIV and non-HIV patients (Table 5).

Table 3. Results of univariate analysis of the impact of clinical-morphological and immunological factors considered on the OS of HIV patients

Indicator	Baseline CD4/CD8	CD4/CD8 dynamic changes during treatment
Optimal threshold (cut-off) value	≤ 0.57	Decrease by no more than 0.01 from baseline

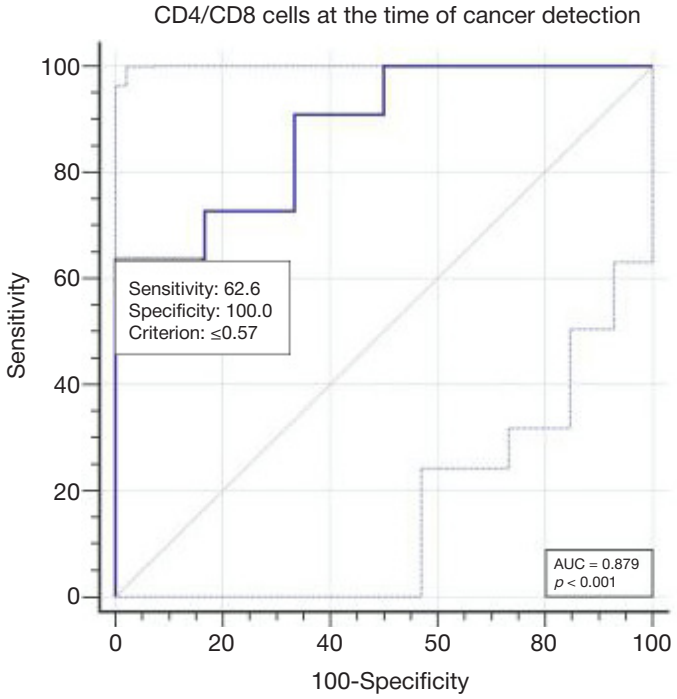

Fig. 1. Results of ROC analysis aimed at determining threshold CD4/CD8 ratio (Youden's index) values at the time of lung cancer detection in HIV-infected patients

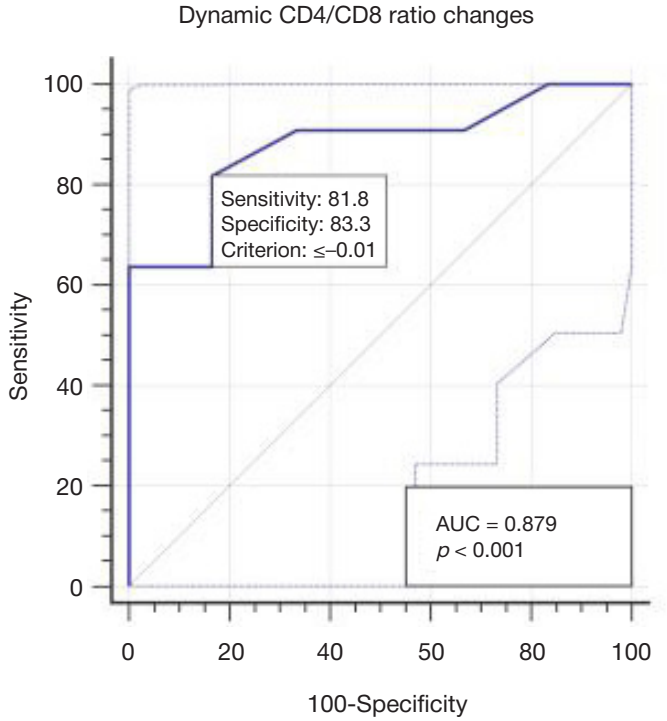

Fig. 2. Results of ROC analysis aimed at determining the dynamic changes in threshold CD4/CD8 ratio (Youden's index) values during antitumor treatment in HIV-infected patients

Table 4. Results of miltivariate analysis of the impact of clinical-morphological and immunological factors considered on the OS of HIV patients ($p < 0.0001$, AUC = 0.920 (95% CI 0.851–0.989))

Indicators included in the model based on the univariate analysis results	OS (95% CI)	*p*-value
Baseline CD4/CD8	0.0006 (0.00–0.19)	0.0117
CD4/CD8 dynamic changes during treatment (relative to baseline)	0.0001 (0.00–0.27)	0.022

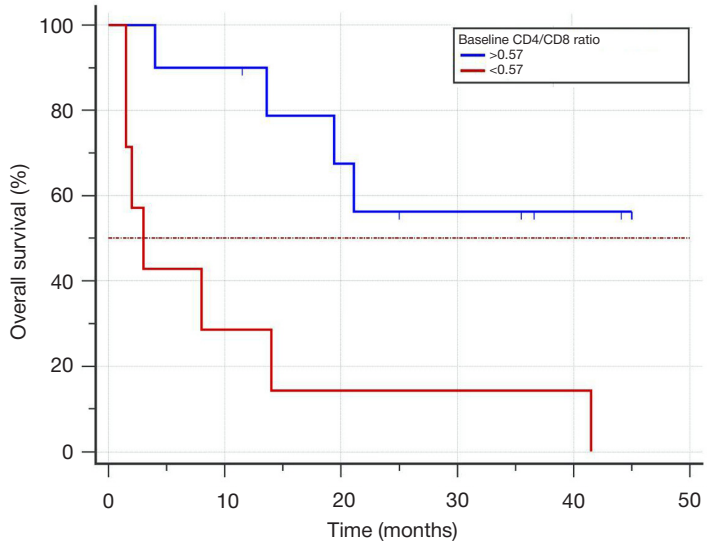

Fig. 3. Miltivariate analysis results: overall survival as a function of baseline CD4/CD8 ratio in HIV-infected patients

DISCUSSION

Low CD4/CD8 ratio value reflects disorganization and dysfunction of the immune system, including antitumor immunity; it is correlated to the degree of lung cancer dissemination and, therefore, indirectly to the neoplastic process severity [15], as well as to potential antitumor therapy efficacy. The threshold CD4/CD8 ratio value of 0.57 and below, as well as the CD4/CD8 ratio decrease by 0.01 during treatment as a HIV-mediated predictor of fatal outcome significantly demonstrates poor prognosis in patients with lung cancer and concomitant HIV infection, which can be used in clinical practice ($p < 0.05$).

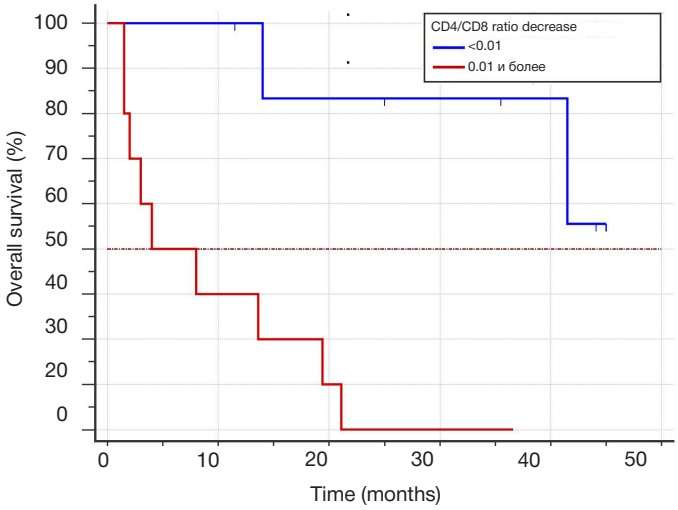

Fig. 4. Miltivariate analysis results: overall survival as a function of the dynamic CD4/CD8 ratio changes during antitumor treatment in HIV-infected patients

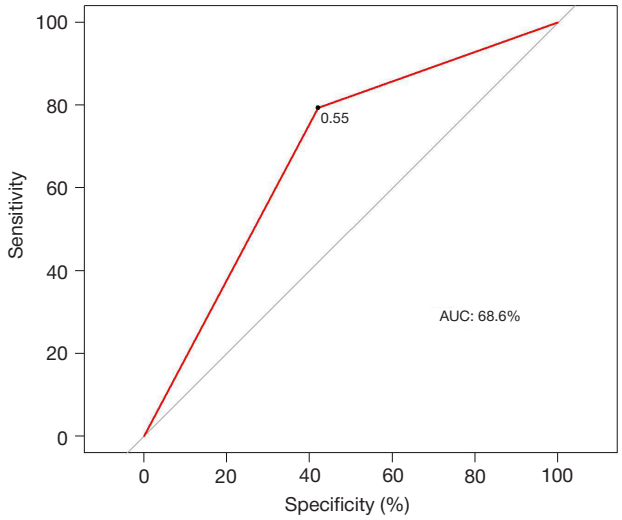

Fig. 5. Fatal outcome likelihood as a function of the “male sex” trait in HIV-infected patients

Table 5. Progression-free survival by therapy lines in the index group of HIV-infected patients and the control group

Group	Parameter	Number of therapy lines	PFS 1st line therapy, months	PFS 2nd line therapy, months	PFS 3rd line therapy, months	PFS 4th line therapy, months
HIV patients	N	17	16	6	2	1
	M	1.47	15.24	7.43	2.99	0.54
	SD	0.94	16.49	5.64	3.75	–
	95% CI	1.02; 1.92	7.4; 23.08	4.75; 10.11	1.21; 4.77	–
	Min	0	0.92	1.61	0.34	0.54
	Max	4	44.75	14.17	5.64	0.54
	Me	1	9.3	6.47	2.99	0.54
	IQR	1; 2	1.52; 28.9	2.64; 12.48	1.67; 4.31	0.54; 0.54
Non-HIV patients	N	31	31	16	7	2
	M	1.81	13.96	6.98	4.86	1.83
	Me	2	9.61	6.51	3.58	1.83
	IQR	1; 2	5.37; 24.78	3.16; 8.71	2.76; 6.8	1.41; 2.26
Test		Mann–Whitney test	Mann–Whitney test	Student's *t*-test	Mann–Whitney test	Mann–Whitney test
p-value for intergroup differences		0.21	0.7	0.87	0.67	0.67

Note: standard deviation and 95% CI for the average time to progression during 4th line therapy in the group of HIV patients could not be calculated, since this value was available for only one patient in this group (marked with "–").

The analysis of antitumor treatment efficacy relative to the control group of non-HIV patients revealed no significant differences in the number of therapy lines and progression-free survival between patients, which showed current options for simultaneous lung cancer treatment and HIV infection control with the multidisciplinary approach involving regular evaluation of the cell-mediated immunity indicators.

The fact of the relationship between high mortality rate and male sex suggests the direct effect of HIV on the lung cancer carcinogenesis, along with smoking, since people living with HIV, both males and females, are historically more likely to smoke tobacco.

CONCLUSIONS

When predicting probability of the lung cancer fatal outcome based the HIV-associated predictors, the baseline CD4/CD8 ratio value and the dynamic CD4/CD8 ratio changes during antitumor treatment had a significant effect on the OS ($p < 0.05$). Identification of such predictors makes it possible to determine the group at high risk of death from lung cancer among HIV-infected patients, requiring more intense therapy and additional discussion of treatment tactics for the patient with the infectious disease physician for potential ART adjustment. Such stratification can either be an extra argument not to reduce the dose of chemotherapy drugs against the background of hematological and other toxic complications or in patients with borderline functional status, or provide the basis for the antiretroviral drug prescription revision. Regular laboratory assessment of the cell-mediated immunity state represents an inevitable part of the comprehensive approach to treatment of this group of patients. If algorithms for management of patients with concomitant HIV infection are developed and introduced into clinical practice, the results of antitumor treatment for lung cancer can be comparable with that in the general population.

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