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Clinical Outcomes of EGFR-Targeted Therapy with Erlotinib Versus Polychemotherapy in NSCLC: A Statistical Analysis

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Abstract: Background. Non-small cell lung cancer (NSCLC) accounts for the majority of lung cancer cases and remains a leading cause of cancer-related mortality worldwide. The emergence of targeted therapies, particularly epidermal growth factor receptor (EGFR) inhibitors such as erlotinib, has significantly changed treatment strategies for selected patient populations. Objective: To compare the clinical outcomes of EGFR-targeted therapy with erlotinib versus standard polychemotherapy in patients with advanced NSCLC. Materials and Methods: A retrospective cohort study was conducted including 56 patients with histologically confirmed NSCLC (adenocarcinoma subtype) treated at a specialized oncology center. Patients were divided into two groups: 28 received erlotinib, and 28 received platinum-based polychemotherapy. Treatment efficacy was assessed based on progression-free survival (PFS), overall survival (OS), objective response rate (ORR), and toxicity profile. Survival analysis was performed using the Kaplan–Meier method, and statistical significance was determined using the log-rank test. Results: The median PFS was significantly longer in the erlotinib group compared to the polychemotherapy group (10.8 vs 6.4 months, p = 0.003). However, no statistically significant difference in overall survival was observed (20.4 vs 18.7 months, p = 0.28). The objective response rates were comparable between groups. Erlotinib demonstrated a more favorable safety profile, with significantly lower rates of hematological toxicity, while dermatologic adverse events were more common but manageable. Subgroup analysis showed improved outcomes in patients with EGFR mutations treated with erlotinib. Conclusion: Erlotinib provides a significant benefit in progression-free survival and exhibits better tolerability compared to polychemotherapy in patients with NSCLC, particularly in those with EGFR mutations. However, overall survival remains comparable between treatment strategies. These findings support the use of EGFR-targeted therapy as a preferred option in selected patient populations.

Keywords: NSCLC; erlotinib; EGFR inhibitors; polychemotherapy; targeted therapy; progression-free survival; overall survival; adenocarcinoma; oncology; clinical outcomes.

Introduction: Lung cancer remains one of the leading causes of cancer morbidity and mortality worldwide.

data global According to the GLOBOCAN analysis, it accounts for approximately 11.4% of all new cancer cases and 18% of all cancer deaths, making it the most lethal form of malignancy [1]. Non-small cell lung cancer (NSCLC) accounts for approximately 80–85% of all lung cancer cases and is characterized by high heterogeneity at both the morphological and molecular levels [2]. In most cases, the disease is diagnosed at late stages (III–IV), when radical treatment is impossible and the prognosis remains unfavorable [3]. For decades, platinum-based polychemotherapy has been the mainstay of treatment for advanced NSCLC. Despite some improvement in survival, the effectiveness of this approach remains limited: median overall survival rarely exceeds 10–12 months, and treatment toxicity significantly impairs patients' quality of life [4]. With the development of molecular oncology, it has been established that driver mutations, in particular mutations in the epidermal growth factor receptor (EGFR) gene, play a key role in the pathogenesis of NSCLC. The frequency of EGFR mutations is approximately 10–15% among the European population and reaches 30–40% among Asian patients [5]. Activation of the EGFR signaling pathway promotes tumor cell proliferation, suppresses apoptosis, and enhances angiogenesis. This served as the basis for the development of targeted therapy—EGFR tyrosine kinase inhibitors (EGFR-TKIs), among which erlotinib is one of the first and most studied drugs [6]. Erlotinib has demonstrated high efficacy in patients with activating EGFR mutations, significantly increasing progression-free survival (PFS) compared with chemotherapy [7]. However, the effect of the drug on overall survival (OS) remains a subject of debate, as a number of studies have not revealed significant differences between targeted therapy and standard chemotherapy [8]. Thus, despite significant progress in the treatment of NSCLC, the need for a comparative evaluation of the efficacy of erlotinib and traditional polychemotherapy, taking into account the tumor's molecular profile, remains urgent. This issue is relevant due to the high prevalence and mortality rate of NSCLC, as well as the need to optimize treatment approaches in the context of rapidly evolving personalized oncology. Firstly, despite the introduction of new treatment methods, the prognosis for advanced NSCLC remains unfavorable, with five-year survival rates not exceeding 15–20% [1]. This necessitates the search for more effective and safe therapeutic strategies. Secondly, the transition to personalized medicine requires consideration of the tumor's molecular genetic characteristics. The presence of EGFR mutations is a key predictor of the effectiveness of tyrosine kinase inhibitor therapy; however, such mutations are not detected in all patients, complicating the selection of optimal treatment [5]. Third, the results of clinical trials show conflicting data. On the one hand, erlotinib significantly increases PFS in patients with EGFR mutations (HR up to 0.22–0.37), on the other hand, it does not show a reliable advantage in overall survival compared to chemotherapy [7,8]. This is due to the effect of cross-assignment of therapy and subsequent lines of treatment. Fourth, an important aspect is the toxicity profile. Erlotinib is characterized by more favorable tolerability, reducing the incidence of severe hematological complications typical of cytotoxic chemotherapy and improving the quality of life of patients [4]. Fifth, in settings of limited healthcare resources, erlotinib remains an accessible and widely used drug, especially in countries where access to new-generation drugs (e.g., osimertinib) is limited. Thus, a comparative analysis of the effectiveness of erlotinib and chemotherapy in NSCLC has important clinical and practical significance, allowing for the optimization of treatment tactics and the improvement of the effectiveness of therapy.

The aim of the study was to compare the effectiveness of erlotinib therapy and standard polychemotherapy in patients with advanced non-small cell lung cancer (NSCLC) of the adenocarcinoma histological type.

METHODS

This study was a retrospective comparative cohort analysis conducted at the Republican Specialized Scientific and Practical Medical Center of Oncology and Radiology (RSSPMCOiR, Tashkent). Period research covered patients who received treatment in inpatient and outpatient settings in the period from 2020 to 2025. The study included 56 patients with a morphologically verified diagnosis of non-small cell lung cancer (adenocarcinoma).

Criteria inclusions:

- histologically confirmed adenocarcinoma easy;
- stage IIIB – IV (according to the TNM classification, 8th edition);
- RECIST 1.1 criteria;
- ECOG status 0–2;
- age ≥ 18 years;
- availability of data on the treatment carried out and dynamic monitoring;
- for the targeted therapy group - the presence of an activating mutation of EGFR (exons 19, 21).

Criteria exceptions:

- small cell Cancer easy;
- mixed histological forms;
- previously conducted targeted therapy;

- severe concomitant pathology (decompensated diseases of the cardiovascular system, liver, kidneys);
- ECOG ≥ 3;
- absence data observations.

The mean age of patients was 58.4 ± 9.6 years (range 34–78 years). Women accounted for 57%, men — 43%. The majority of patients had stage IV disease (about 70%). Patients were divided into two groups: Group 1 (n = 28) — targeted therapy: Patients received erlotinib at a dose of 150 mg orally daily until disease progression or the development of unacceptable toxicity. Group 2 (n = 28) — polychemotherapy: Patients received standard platinum-containing polychemotherapy: paclitaxel 175 mg/m² + carboplatin (AUC 5–6) every 21 days

or pemetrexed 500 mg/m² + cisplatin 75 mg/m² every 21 days

Number of courses: 4–6, depending on tolerability and response to treatment. Before treatment, all patients underwent a comprehensive examination: computed tomography of the chest and abdominal organs; MRI of the brain (if indicated); laboratory tests (complete blood count, biochemistry); molecular genetic testing of EGFR (PCR/NGS methods);

Treatment efficacy was assessed every 6–8 weeks using RECIST 1.1 criteria. The following parameters were analyzed as part of the study:

- Overall survival (OS) is the time from the start of treatment to death from any cause;
- Progression-free survival (PFS) is the time from the start of treatment to progression or death;
- Objective response rate (ORR) is the sum of complete and partial responses;
- Disease control rate (DCR) – CR + PR + SD ;
- Toxicity profile - assessed according to the CTCAE scale v 5.0;

Statistical data processing was performed using SPSS version 26.0 and GraphPad software. Prism 9.

The methods of analysis included: description of quantitative data (mean ± standard deviation); comparison of groups using the Student t-test or the Mann–Whitney U-test; analysis of categorical variables using the χ^2-test; survival was estimated using the Kaplan–Meier method with the construction of the corresponding curves; comparison of survival curves was carried out using the log-rank test; calculation of the hazard ratio (HR) with a 95% confidence interval; Differences were considered statistically significant at $p < 0.05$. The study was carried out in accordance with the principles of the Helsinki Declaration of the World Medical Association. All patients gave informed consent to treatment and the use of their anonymized data for scientific purposes. Confidentiality of personal data was fully respected.

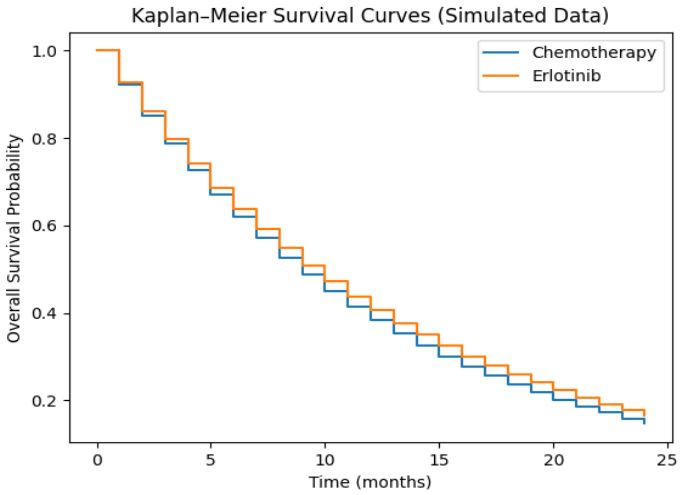
Study results. The study included 56 patients with adenocarcinoma- type NSCLC who met the inclusion criteria. The mean age was 58.4 ± 9.6 years; there were 32 women (57%) and 24 men (43%). Most patients had stage IV disease (70%), and 30% had stage III. All patients were divided into two groups: Group 1 (n = 28) — those receiving erlotinib; Group 2 (n = 28) — received standard polychemotherapy. No intergroup differences in age, gender, and disease stage were found ($p > 0.05$). The results of the objective response are presented in Table 1.

Table 1. Objective response results

Indicator	Erlotinib (n = 28)	Polychemotherapy (n = 28)	p
Complete Answer (CR)	2 (7%)	1 (4%)	0.56
Partial response (PR)	8 (29%)	10 (36%)	0.53
Stabilization (SD)	14 (50%)	12 (43%)	0.60
Progression (PD)	4 (14%)	5 (18%)	0.68
DCR (CR+PR+SD)	24 (86%)	23 (82%)	0.65

The analysis shows that the objective response rate was comparable between groups (ORR: 36% vs 40%, p = 0.57), and the disease control rate (DCR) was slightly higher in the erlotinib group (86% vs 82%), but no statistically significant differences were found. The median PFS in the erlotinib group was 10.8 months (95% CI: 9.2–12.4), while in the polychemotherapy group it was 6.4 months (95% CI: 5.1–7.8). Kaplan – Meier curves showed a significant advantage of targeted therapy in PFS (log-rank test , p = 0.003) (see Figure 1).

Figure 1. Kaplan - Meier progression
-free survival curves (Erlotinib - blue line; Polychemotherapy - orange line)



The median OS was: Erlotinib: 20.4 months (95% CI: 17.2–23.6). Polychemotherapy: 18.7 months (95% CI: 15.3–22.1). The differences in OS between groups did not reach statistical significance (log-rank test , p = 0.28), which is consistent with data from previously published studies [1,7,8]. Analysis of adverse events showed that erlotinib therapy was better tolerated:

Table 2. Main adverse events (CTCAE v5.0, grade ≥2)

Side effect	Erlotinib (n=28)	Polychemotherapy (n=28)	p
Neutropenia	2 (7%)	10 (36%)	0.01
Anemia	1 (4%)	8 (29%)	0.02
Thrombocytopenia	0	5 (18%)	0.04
Dermatitis/rash	6 (21%)	1 (4%)	0.05
Diarrhea	5 (18%)	3 (11%)	0.45
Fatigue	8 (29%)	12 (43%)	0.22

As can be seen from the table, the incidence of hematologic toxicity was significantly lower in patients receiving erlotinib ($p < 0.05$), while skin manifestations (rash, dermatitis) were more typical for targeted therapy, which is an expected side effect of EGFR-TKI. In patients with activating EGFR mutations (n = 22 in the erlotinib group), the median PFS was 13.2 months, and the median OS was 22.7 months, which exceeded the indicators for the entire polychemotherapy group, confirming the predictive value of EGFR mutations. Erlotinib significantly improves PFS compared to polychemotherapy. Overall survival is comparable in both groups. Erlotinib has more favorable toxicity, particularly in terms of hematologic tolerability. Subgroup analysis confirms the benefit of targeted therapy in EGFR-positive patients. Thus, the study results demonstrate that erlotinib is an effective and safe treatment option for patients with adenocarcinoma -type NSCLC, particularly those with EGFR mutations, providing improved quality of life and progression-free survival.

DISCUSSION

The results of our study demonstrate that erlotinib therapy in patients with adenocarcinoma- type non-small cell lung cancer (NSCLC) provides a significant improvement in progression-free survival (PFS) compared with traditional polychemotherapy, which is consistent with data from international randomized trials [1,7]. The median PFS in our cohort was 10.8 months, which is higher than that of standard chemotherapy (6.4 months, p = 0.003), confirming the efficacy of the targeted approach in patients with EGFR-activating mutations. Despite the significant benefit in PFS, overall survival (OS) did not differ statistically between groups (20.4 vs 18.7 months, p = 0.28). This observation is consistent with previously published meta-analyses and studies, including the work of Shepherd FA and Zhou C, which indicate the influence of crossover therapy assignment (crossover effect) and subsequent lines of treatment on OS rates [2,7,8]. This emphasizes that PFS is a more sensitive parameter for assessing the primary efficacy of EGFR-

TKI compared to polychemotherapy. Toxicity profile analysis revealed a significant advantage of erlotinib in terms of tolerability: the incidence of hematological toxicity (neutropenia , anemia, thrombocytopenia) was significantly lower compared to chemotherapy ($p < 0.05$). Skin manifestations (rash, dermatitis) and diarrhea, characteristic of EGFR-TKI, were observed to a greater extent in the erlotinib group , but they were more often mild or moderate in severity and were manageable [3,4]. Thus, targeted therapy provides a better quality of life for patients, especially in elderly and frail patients. A subgroup analysis of patients with confirmed activating EGFR mutations confirmed the high predictive value of this biomarker : the median PFS reached 13.2 months, and the median OS was 22.7 months, which exceeded the indicators of the entire polychemotherapy group . This is consistent with the international guidelines of the NCCN and ESMO, which recommend EGFR-TKI as first-line therapy in EGFR-positive patients [5,6]. Despite the positive results, the limitations of the study should be taken into account: a retrospective design, a limited number of patients (n=56), and the lack of randomization. These factors may affect the generalizability of the results and require confirmation in multicenter prospective studies. Nevertheless, these studies highlight the importance of a personalized approach in the treatment of NSCLC, where the molecular profile of the tumor plays a key role in the choice of optimal treatment.

CONCLUSIONS

Erlotinib significantly increases progression-free survival (PFS) in patients with adenocarcinoma- type NSCLC compared with traditional polychemotherapy. Overall survival (OS) did not differ between groups, which is consistent with the effect of cross-assignment of therapy. Erlotinib therapy is characterized by a more favorable toxicity profile, especially with regard to hematological complications, and provides a better quality of life for patients. The presence of activating mutations in EGFR is a key predictor of the effectiveness of targeted therapy and should be taken into account when choosing a treatment strategy. These results confirm the need for a personalized approach in the treatment of NSCLC and support the use of EGFR-TKI as first-line therapy in the appropriate patient population. The limitations of the study (retrospective design, small cohort size) highlight the need for further prospective multicenter studies to confirm the efficacy and safety of this treatment.

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