



EP11.03: Clinical Efficacy of Immunotherapy in Patients With PD-L1-High Metastatic NSCLC

Real-World Data From a Single Academic Center in Croatia

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INTRODUCTION

The introduction of immune checkpoint inhibitors fulfilled the unmet need for effective treatment in patients with NSCLC and no driver mutations. Treatment with pembrolizumab compared to standard chemotherapy resulted in a higher response rate and significantly longer progression-free survival and overall survival in patients with high PD-L1 expression.

METHODS

This study, conducted at the University Hospital Center Zagreb, Croatia, assessed the real-world efficacy of pembrolizumab in 243 patients with PD-L1-high (PD-L1 expression $\geq 50\%$) metastatic non-small cell lung cancer (NSCLC). Patients were treated between March 2018 and April 2020.

- retrospective cohort analysis
- exclusion criteria: presence of EGFR mutations, ALK rearrangements or ROS1 fusions
- patients received pembrolizumab in the first-line setting (200 mg every 3 weeks; after 6 months they could switch to 400 mg every 6 weeks)
- clinical and diagnostic evaluation of treatment efficacy was performed every 3 months

Artificial Intelligence (AI) Use Disclaimer

The authors declare that no generative AI tools, large language models, or automated image generators were used to create any content, data, or visual materials for this work.

DISCUSSION AND CONCLUSION

- Pembrolizumab therapy compared to standard chemotherapy resulted in significantly longer overall survival and progression-free survival and a higher response rate.
- However, in real-world oncology practice the patient population is heterogeneous.
- Our data showed that pembrolizumab is effective and safe in a real-world setting. Survival and safety outcomes are comparable to those from large clinical trials and provide valuable real-world data from Central and Eastern Europe.

REFERENCES & ACKNOWLEDGEMENTS

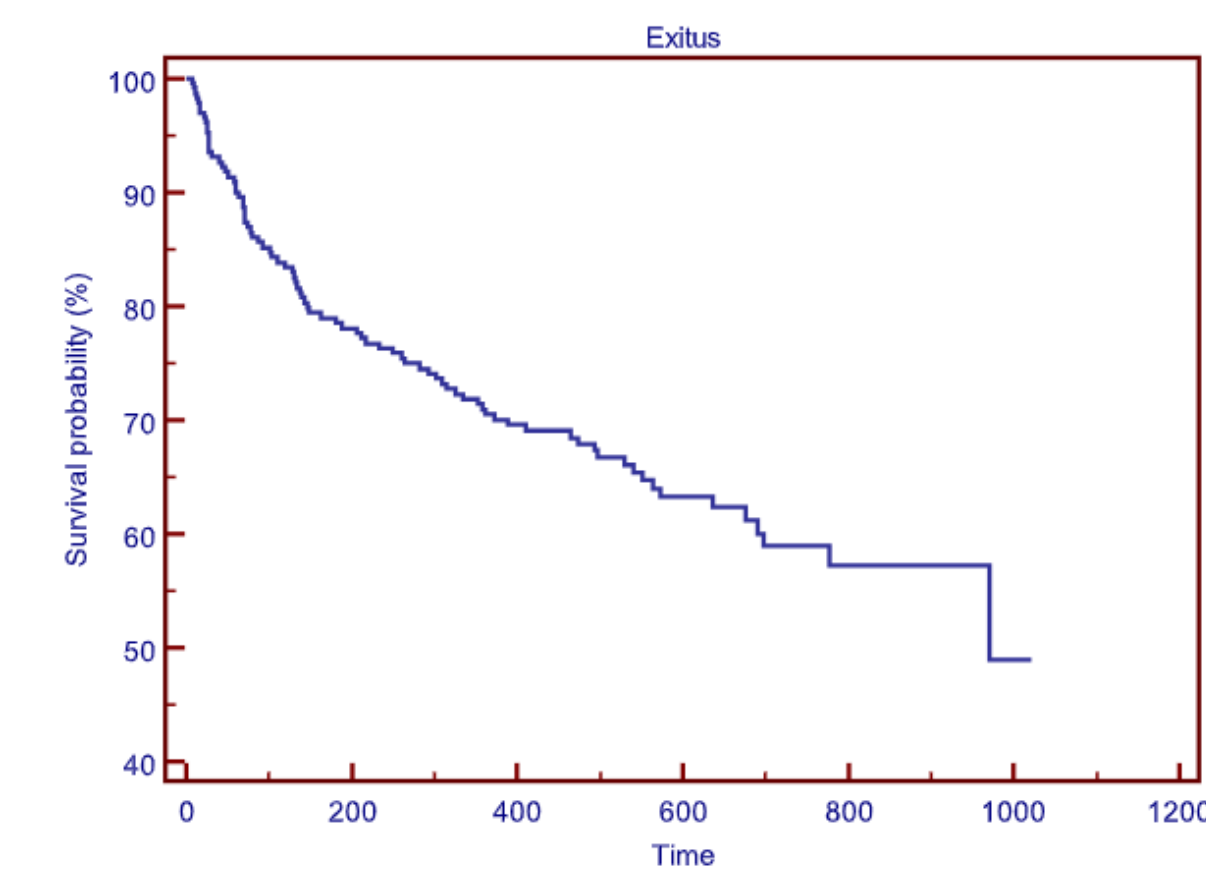
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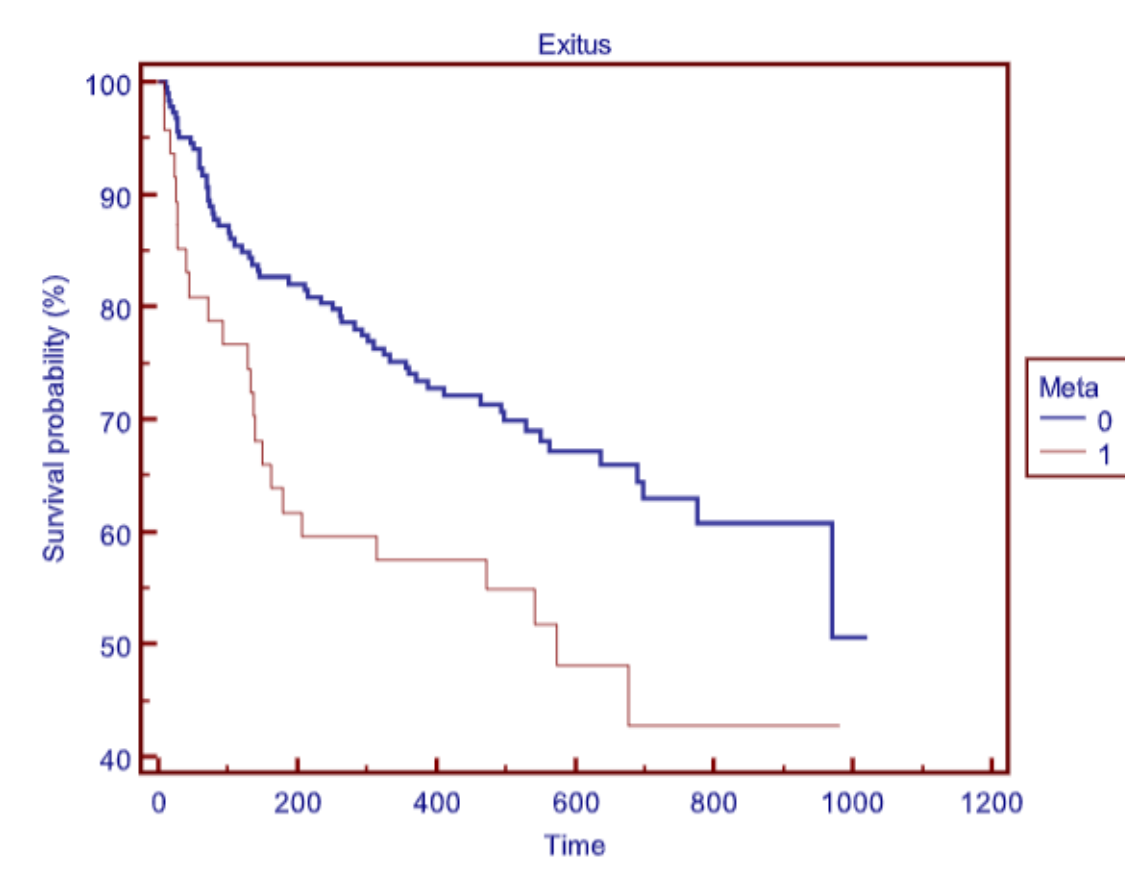
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RESULTS

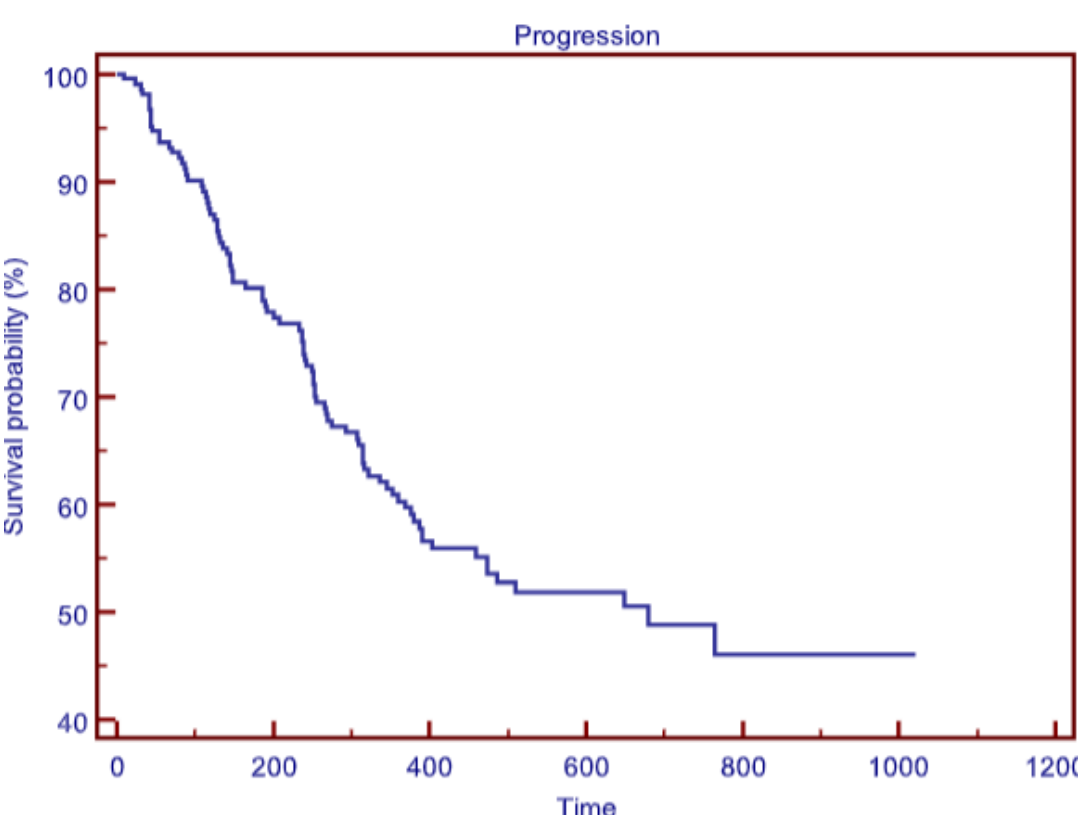
The mean age of patients was 65 years, 69.5% were male and most patients (92.9%) had a history of smoking (52.7% were current smokers, 40.2% were former smokers). The most common histology was adenocarcinoma (67.5%). Brain metastases were present at diagnosis in 21% of patients. Median progression-free survival (PFS) was 22 months and median overall survival (OS) was 32 months. At 12 months, 60.6% of patients were alive without disease progression. The objective response rate (ORR) was 48.1%, with a disease control rate of 75.8%. There was no statistically significant difference in mPFS between different tumor types (adenocarcinoma mPFS not reached vs squamous cell carcinoma mPFS 15.3 months; $p = 0.251$; $HR = 1.31$), smoking status (current smokers mPFS 25.4 months vs never- or former smokers mPFS 16.2 months; $p = 0.48$; $HR = 0.86$), presence of CNS metastases (patients with CNS metastases mPFS 16.2 months vs no CNS metastases 24.8 months; $p = 0.478$; $HR = 1.21$) or PD-L1 status determined by IHC or on a cytology specimen (PD-L1 IHC mPFS 25.4 months vs PD-L1 cytology mPFS 15.7 months; $p = 0.258$; $HR = 1.27$). A statistically significant difference was observed only in mOS, between patients with and without CNS metastases ($p = 0.013$; $HR = 1.80$, 95% CI 1.04–3.15). In 44 patients (18.1%) an adverse event led to treatment discontinuation, and in 7 patients (2.9%) it led to death. Among the events leading to discontinuation, 50% were grade 1 or 2. The most common treatment-related adverse events of any grade causing treatment discontinuation were pneumonitis in 21/44 patients (47.7%) and dermatitis in 9/44 (20.4%). Among serious adverse events (grade 3–5), pneumonitis was the most common, in 6/44 patients (13.6%).



- Figure 1: median overall survival (mOS) 32 months (95% CI 25.9–32.3); estimated percentage of patients alive and without disease progression at 12 months was 60.6%



- Figure 2: median overall survival (mOS) in patients with or without CNS metastases ($p = 0.013$; $HR = 1.80$, 95% CI 1.04–3.15)



- Figure 3: median progression-free survival (mPFS) 22 months (95% CI 13–25)

Treatment related AEs (N=44)		
AEs	Any Grade	Grade 3,4 or 5
Pneumonitis	21 (47.7 %)	6 (13.6 %)
Dermatitis	9 (20.5 %)	5 (11.3 %)
Endocrinological AEs	3 (6.8 %)	2 (4.5 %)
Diarrhea / colitis	3 (6.8 %)	2 (4.5 %)
Hepatitis	3 (6.8 %)	2 (4.5 %)
Neurological /muscular toxicity	2 (4.5 %)	2 (4.5 %)
Nephritis	2 (4.5 %)	2 (4.5 %)

- Table 1: adverse events