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Biomarker-Guided Treatment in Non-Small Cell Lung Cancer (NSCLC): Adherence to NCCN Guidelines, and Outcomes in a US-Based Population

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OBJECTIVES

To describe testing rates and test-positivity rate of NSCLC biomarkers prior to first-line initiation; to describe adherence to precision medicine according to the NCCN guidelines among patients who tested positive; to compare outcomes such as real-world overall survival (rwOS) and time to next treatment or death (rwTTNT-D) between patients adherent and non-adherent to NCCN guidelines

CONCLUSIONS

Overall, receipt of biomarker-guided therapy was high and associated with improved clinical outcomes in EGFR+ patients. These findings highlight the benefit of adhering to NCCN recommended biomarker guided therapies in NSCLC

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INTRODUCTION

- Real-world data on the frequency of biomarker testing, its influence on treatment decision making, and subsequent clinical outcomes in NSCLC is limited. This study aims to describe treatment patterns and clinical outcomes among patients who tested positive and received biomarker-guided therapy according to NCCN guidelines

METHODS

- This retrospective cohort study included patients with advanced/metastatic non-squamous (NSQ) NSCLC from ConcertAI structured EHR database (RWD360) between January 1, 2017 and December 31, 2020. ConcertAI RWD360 consists of de-identified, structured EHR data from predominantly community oncology practices across the US
- Patients were required to have at least 30 days of activity in the database, and at least 1 line of therapy
- Multiple biomarkers were assessed prior to first-line initiation including EGFR, ALK, and PD-L1. Patients were classified as NCCN guideline-adherent if, upon a positive test result, they received biomarker-guided therapy as specified by the NCCN guidelines
- Log rank test and multivariable Cox proportional hazard models were employed to compare median overall survival (rwOS) and time to next treatment or death (rwTTNT-D) between guideline-adherent and nonadherent patients. Only EGFR+ and PDL1+ patients were considered due to sufficient sample size in these subpopulations
- Stratified Cox regression models were used to address nonproportional hazards. Piecewise Cox models using the median time-at-risk per event as a cutoff were also conducted as sensitivity analyses
- Adjusted hazard ratios (HR) and their corresponding 95% confidence intervals (CI) were calculated and reported. All analyses were conducted using SAS 9.4

RESULTS

- 2428 eligible patients were identified during the study period with a median follow-up of 11.2 months and average age (SD) at diagnosis of 66.2 (+10.6) years **(Table 1)**
- Testing rates as reported in this structured EHR database prior to first-line treatment were 31.9%, 31.2%, and 27.3% for PD-L1, EGFR, and ALK, respectively **(Table 2)**
- Among tested patients, positivity rate was 52.7%, 23.1%, and 4.5%, respectively **(Table 2)**
- Majority of biomarker-positive patients received biomarker-guided therapy in first line according to NCCN guidelines: EGFR (75.5%), ALK (81.8%), and PD-L1 (67%) guideline-adherent, EGFR-positive patients had reduced risk of TTNT-D and mortality compared to nonadherent patients {mTTNT-D 10.7 vs 2.8 months, *P* <.0001; HR (95% CI) 0.3 (0.19, 0.47) and mOS 22.3 vs 17 months, *P* = .19; HR (95% CI) 0.65 (0.39, 1.1)} **(Figure 1)**
- Median rwOS and rwTTNT-D for guideline-adherent PDL1+ patients was 16.4 and 3.5 months, respectively. The risk of TTNT-D among guideline-adherent patients was substantially lower beyond the time point of 3.5 months compared to nonadherent patients **(Figure 1B)**

Table 1. Sociodemographic Characteristics of Non-Squamous NSCLC Patients

Subject Characteristics	Non-Squamous, N (%) (n = 2428)
Age at Index, Mean (SD)	66.2 (10.6)
Race, n (%)	
Asian	158 (6.5)
Black	290 (11.9)
White	1752 (72.2)
Others	228 (9.4)
Gender, n (%)	
Female	1236 (50.9)
Male	1192 (49.1)
Ethnicity, n (%)	
Hispanic or Latino	92 (3.8)
Not Hispanic or Latino	2122 (87.4)
Unknown	214 (8.8)
Treatment setting, n (%)	
Academic	718 (29.6)
Community	1710 (70.4)
Region, n (%)	
Missing	10 (0.4)
Midwest	959 (39.5)
Northeast	163 (6.7)
South	788 (32.5)
West	508 (20.9)
Insurance, n (%)*	
Missing	402 (16.6)
Self-pay	44 (1.8)
Commercial	690 (28.4)
Medicaid	99 (4.1)
Medicare	618 (25.5)
Medicare and others	575 (23.7)

*Patients aged >65 with missing insurance information were classified as having Medicare.

Table 2. Testing and Test-positivity Rates among NSQ NSCLC Patients in ConcertAI, 2017–2020

Subject Characteristics	Among all NSQ NSCLC treated patients (%) (n = 2428)	Among patients with at least 1 test (%) (n = 1052)	Test-positivity rates among tested patients[‡]
EGFR	31.2	72.1	23.1
ALK	27.3	63.0	4.5
PDL1	31.9	73.6	52.7
ROS1	21.4	49.4	2.3
BRAF	12.2	28.1	7.4
NTRK	0.5	1.1	NA
MET	4.7	10.8	14.9
RET	4.4	10.2	7.5

‡Denominator includes all tested patients with positive, negative, or indeterminate results.

Figure 1. Clinical Outcomes of Patients That Were Classified as Adherent to NCCN Guidelines Compared to Patients That Were Not Classified as Adherent to NCCN Guidelines

	Adhered to NCCN Guidelines			Did not Adhere to NCCN Guidelines				Log rank
Biomarker	Events/N	Median	1-year KM estimate	Events/N	Median	1-year KM estimate	HR (95% CI)	*P*-value
rwOS								
EGFR	61/126	22.3 (16.7–NE)	68.5% (60.5–77.5)	23/41	17 (7.8–NE)	57.8% (44–76.1)	0.65 (0.39, 1.1)	.19
PDL1	123/221	16.4 (12.2–25)	56.9% (50.5–64)	71/109	15.8 (11.6–21.6)	57.8% (48.9–68.2)	0.85 (0.6, 1.2)	.49[‡]
rwTTNT-D								
EGFR	92/126	10.7 (8.6–13.5)	42.7% (34.5–52.7)	36/41	2.8 (2.3–4.2)	8.5% (2.9–24.8)	0.3 (0.19, 0.47)	<.0001
PDL1	184/221	3.5 (3.1–4.5)	23% (17.9–29.5)	99/109	3.7 (3.4–4.6)	13.4 (8.2–21.9)	0.93 (0.69, 1.3)	.28[‡]

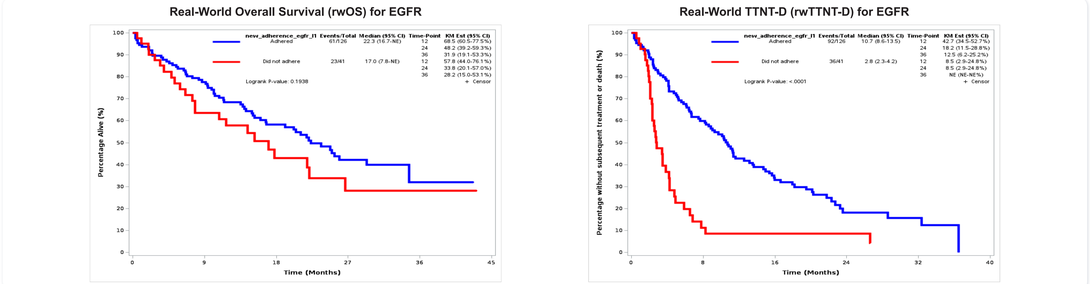
NE, non-estimable; KM, Kaplan-Meier; rwOS, real-world overall survival; rwTNNT-D, real-world time to next treatment or death.
[‡]Stratified Cox regression was used.
Excludes patients with overlapping mutations. Adjusted for age, race, sex, and brain metastases for EFGR. Numbr of distant metastases, insurance status, stage of diagnosis for PDL-1. Adhered to NCCN guidelines means patients tested positive and received biomarker-guided therapy. Only biomarkers with >10 patients per cohort were included.

Figure 1B. Sensitivity Analysis Showing Clinical Outcomes of PDL1+ Patients That Were Classified as Adherent to NCCN Guidelines Compared to PDL1+ Patients That Were Not Classified as Adherent to NCCN Guidelines

	Adhered to NCCN Guidelines	Did not adhere to NCCN guidelines		
PDL-1	Events/N	Events/N	HR (95% CI)	*P*-value[‡]
rwOS				
*11.4 months**	79/193	35/91	1.31 (0.85, 2.02)	.22
>11.4 months	30/97	23/45	0.65 (0.36, 1.15)	.14
rwTTNT-D				
*3.5 months**	94/193	43/91	1.08 (0.74, 1.58)	.68
>3.5 months	68/92	41/46	0.57 (0.37, 0.86)	.01

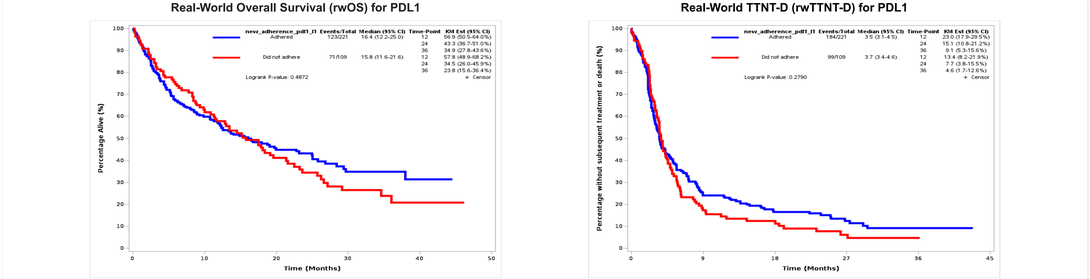
rwOS, real-world overall survival; rwTTNT-D, real-world time to next treatment or death
*Median event time was chosen as the cutoff. [‡]P-value from Wald Chi-square test.
Excludes patients with overlapping mutations. Adjusted for age, race, sex, insurance status, stage of diagnosis for PDL1, brain metastases, and number of distant metastases. Adherence to NCCN guidelines means patients tested positive and received biomarker-guided therapy.

Figure 2. Real-world Overall Survival (rwOS) and Time to Next Treatment or Death (rwTTNT-D) between EGFR+ Patients That Were Classified as Adherent to NCCN Guidelines Compared to EGFR+ Patients That Were Not Classified as Adherent to NCCN Guidelines



Note: Patients were classified as "adherent to NCCN guidelines" if they tested positive for a biomarker and received biomarker-guided therapy.

Figure 3. Real-world Overall Survival (rwOS) and Time to Next Treatment or Death (rwTTNT-D) between PDL1+ Patients That Were Classified as Adherent to NCCN Guidelines Compared to PDL1+ Patients That Were Not Classified as Adherent to NCCN Guidelines



Note: Patients were classified as "adherent to NCCN guidelines" if they tested positive for a biomarker and received biomarker-guided therapy.

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