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Increased Real-World Biomarker Test Utilization in Patients with Early-Stage Non-Small Cell Lung Cancer in the United States, 2011 to 2021

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Background

- Biomarker testing is increasingly crucial for patients with early-stage non-small cell lung cancer (eNSCLC).
- A growing number of biomarker-based treatments, along with companion diagnostic devices, tailored to patients with eNSCLC are now under development or have been approved by the US Food and Drug Administration.
- However, little is known about how biomarker tests are conducted and used to guide treatments in patients with eNSCLC in the real-world setting.

Objective

- This exploratory study aimed to understand the real-world utilization of biomarker tests and the subsequent treatment among patients newly diagnosed with eNSCLC.

Methods

- This retrospective observational study used COTA's de-identified oncology electronic medical record (EMR) database.
- The study included adult patients ≥18 years old diagnosed with eNSCLC (disease stage 0-IIIA) between January 1, 2011 and December 31, 2021 (See Figure 1 for detailed patient identification).
  - eNSCLC patients were identified using a combination of ICD-9/10-CM diagnosis codes, histology codes, and manual confirmation from medical abstractors.
  - The date of the first eNSCLC diagnosis was the study index date.
- Descriptive statistics were reported for the study.
  - To understand the biomarker test utilization over time, testing rates were reported by the index year for patients who received any biomarker test within 6 months of their eNSCLC diagnosis and by each molecular marker.
  - In a subgroup of patients who received the five most commonly used biomarker tests, we reported the timing of initial diagnosis to biomarker testing, and timing of biomarker testing to first-line systemic treatment initiation.

Conclusions

- This study fills a gap in current knowledge by examining the real-world biomarker test utilization and subsequent treatment over 11 years in a national sample of adult patients with eNSCLC.
- The study suggests a high biomarker testing rate among patients with eNSCLC in the US, with testing rates for various biomarkers increasing over time during the past decade, indicating a continuous trend towards personalization of treatment decisions.
- Future research is needed to understand whether biomarker testing has improved optimal treatment decision making and long-term survival outcomes for patients with eNSCLC.

Results

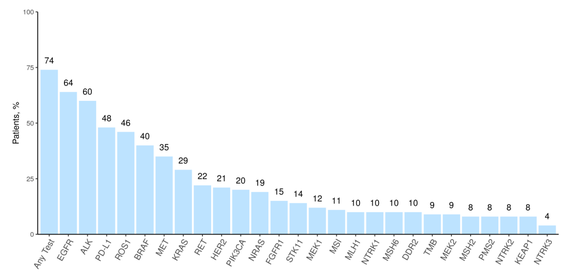
- Of the 1031 eNSCLC patients included in the study (Table), the majority were aged 65 years and older, White (91.8%), and had a history of tobacco use (81.4%).

Table. Attrition table: patient selection

Definition	Patients, *n* (%)
Adult patients ≥18 years old with eNSCLC extracted from COTA	1200 (100)
Patients with eNSCLC diagnosis in or after 2011	1120 (93.3)
Excluding patients with cancer stage unspecified	1119 (93.3)
Patients with biomarker tested on or after initial diagnosis date, excluding patients with biomarker test before initial eNSCLC diagnosis date	1111 (92.6)
Patients had at least one medical activity within 182 days after the initial diagnosis	1103 (91.9)
Excluding patients with no evidence of an interaction with the healthcare system within 90 days of diagnosis or survival less than 30 days after diagnosis date	1043 (86.9)
Patients did not enroll in a clinical trial within 182 days of the initial diagnosis	1031 (85.9)
Analytic sample	**1031 (85.9)**

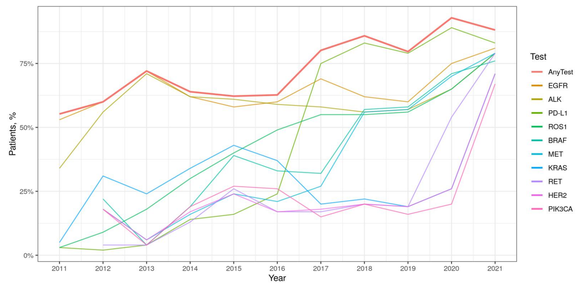
- Most patients (*n* = 764, 74.1%) received at least one biomarker test within 6 months of their eNSCLC diagnosis.
- The 10 most frequently tested biomarkers were epidermal growth factor receptor (*EGFR*) (64%), anaplastic lymphoma tyrosine kinase (*ALK*) (60%), programmed death ligand-1 (PD-L1) (48%), ROS proto-oncogene 1, receptor tyrosine kinase (*ROS1*) (46%), B-Raf proto-oncogene, serine/threonine kinase (*BRAF*) (40%), mesenchymal epithelial transition factor receptor (*MET*) (35%), Kirsten rat sarcoma viral oncogene (*KRAS*) (29%), RET proto-oncogene (*RET*) (22%), human epidermal growth factor receptor 2 (*HER2*) (21%), and phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha (*PIK3CA*) (20%) (Figure 1).

Figure 1. Biomarker tests received within 6 months of diagnosis among the 1031 patients with eNSCLC during the entire study period between 2011–2021



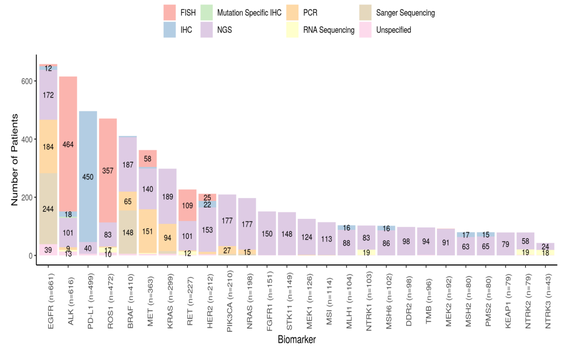
- The proportion of patients undergoing biomarker testing rose from 55.3% in 2011 to 88.1% in 2021 (Figure 2).

Figure 2. Trends in receipt of the top 10 biomarker tests within 6 months of diagnosis over time (2011–2021)



- The most commonly performed testing method was Sanger sequencing for *EGFR* (*n* = 244, 37%), fluorescent in situ hybridization (FISH) for *ALK* (n = 464, 75%) and *ROS1* (n = 357, 76%), immunohistochemistry (IHC) for PD-L1 (n = 450, 90%), and next generation sequencing (NGS) for other biomarkers (Figure 3).

Figure 3. Distribution of biomarker testing methods among 764 patients with eNSCLC who received biomarker tests within 6 months of diagnosis



- The test turnaround time was shortest for IHC testing (median [interquartile range [IQR]]: 9 [7–22] days) and longest for RNA sequencing (median [IQR]: 59 [36–68.8] days).
- Among 763 patients who received the five most commonly used biomarker tests (i.e., *EGFR*, *ALK*, PD-L1, *ROS1*, and *BRAF*), almost all of them received a biomarker test before the initiation of a systemic treatment (Figure 4).

Figure 4. Time from diagnosis to five most commonly used biomarker tests and time from five most commonly biomarker tests to systemic treatment initiation within 1 year of eNSCLC diagnosis