Real World ALK Testing Compliance to NCCN Guideline and Factors of Underutilization in US community clinics

Eric H. Bernicker, MD1, Yan Xiao, PhD2, Anup Abraham, MPH3, Stella Redpath, PhD4, Julia Engstrom-Melnyk, PhD5, Denise Croix, PhD6, Baiyu Yang, PhD2, Roma Shah, MPH2, Jaya Madala, MS5, Timothy Craig Allen, MD, JD6

1Houston Methodist Hospital, Houston, TX, 2Data Sciences and Services, Diagnostics Information Solution, Roche Diagnostics, Belmont, CA, 3Genesis Research, Hoboken, NJ, 4Roche Diagnostics, Indianapolis, IN, 5Astra-Zeneca, Gaithersburg, MD, 6University of Mississippi Medical Center, Jackson, MS

Over the last 10 years, guideline recommendations for testing advanced non-small cell lung carcinomas (aNSCLC) have rapidly evolved with the identification of driver mutations and associated therapies. A retrospective study of the testing rates (negative category = not tested/unknown testing status) for ALK utilizing the nationwide Flatiron Health electronic record-derived de-identified database was initiated to understand real world adherence to guidelines. Patients with an aNSCLC diagnosis (Stage IIIB-IV) were initially included (41,728 patients from Jan 2012 to May 2019) to describe the trend of ALK testing in community setting. An increase in ALK testing was seen from 59.5% to 84.1% of NCCN guideline eligible patients from 2012-2019. There was also an increase in the number of ineligible patients (smokers with squamous histology) tested (15.6% in 2012 to 50.8% in 2019). This 2012-2019 patient population was then limited to diagnosis from Jan 2015 to May 2019 to assess factors related to test utilization. In 26,617 aNSCLC patients, 75% were ALK testing eligible (by NCCN guidelines) with one quarter ineligible. Multivariable logistic regression analysis was used to assess clinical and demographic factors for impact on testing rates. Both histology type and smoking status played an important role impacting ALK testing rate. Compared to non-squamous non-smokers (9.3% ALK-positive, 87.9% testing rate), non-smokers with squamous cell histology had a relatively high rate of ALK mutation (3.3%) but a low testing rate (55.03%) (Odds ratio (OR) 7.6, 95% CI 5.6-10.4). Other histology type and smoking status also had lower testing rate, including smoker with NSCLC non-specific type (OR 3.4, 95% CI 2.8-4.2), Non-smoker with NSCLC non-specific type (OR 1.8, 95% CI 1.1-3.2), and smoker with non-squamous type (OR 1.5, 95% CI 1.3-1.7). Additional clinical factors related to test underutilization were patients with poorer ECOG scores and earlier stage at initial diagnosis. Demographic characteristics that also played a role in underutilization were older age (> 50 yrs), non-commercial insurance type, male, and patients diagnosed before 2017. This analysis of real world data shows that test utilization has increased but there remains room for improvement. While testing ineligible patients is an inefficient use of resources (smokers with squamous histology), smokers with a small biopsy should be tested as they might be harboring an actionable driver mutation. Conversely, eligible patients still remain untested and potentially missing therapeutic options.