To evaluate an ctDNA Negative ALK fusion detection of ALK and ROS1 fusions and resistance mutations is poorly described. However, the applicability for the detection of ALK and ROS1 fusions and resistance mutations is poorly described.

OBJECTIVE

To evaluate an amplicon-based ctDNA assay for detecting ALK and ROS1 fusions and mutual in a cohort of ALK/ROS1+ NSCLC patients.

METHODS AND PATIENTS

- ALK and ROS1 rearranged NSCLC patients were prospectively enrolled from Dec. 2016 to Dec. 2017 in our institution.
- The analysis of ALK & ROS1 mutations, EML4-ALK (variant 1,2,3) and ROS1 fusions (with partner genes CD74, SLC34A2, SDC4 and E2R) in ctDNA were performed using InVisionFirst Lung®.

RESULTS

- ctDNA fusion detection at different time points:
  - Treatment-naïve (n=7)
  - On treatment (n=92)
  - At progressive disease (PD) (n=23), particularly at PD to next gen TKI (n=1)

- Sensitivity for ALK was 83% and 90% for ROS1 in treatment-naive patients.

- In treatment-naive patients, ALK & ROS1 ctDNA fusions were detected in 85% of patients (22/26 ALK fusion; 1/3 ROS1 fusion).

- Sensitivity for ALK was 83% and 90% for ROS1, in treatment-naive patients.

- Emulsion PCR (mut):
  - ALK
  - ROS1

- Invariant 12%

- ALK mut + other

- ALK mut

- ROS1 gen partner

- ALK + ROS1 gen fusion

- Other concurrent mutations

- PD to crizotinib, n=6

- PD to next-gen TKI, n=1

- Circulating tumor DNA (ctDNA) is a surrogate material for somatic mutation (mut.) detection, such as EGFR in NSCLC patients.

- The analysis of 35% of all patients presented other resistance mechanisms (%).

- Higher incidence of resistance mechanisms (%).

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