21P-Sintilimab in combination with anlotinib in non-small-cell lung cancer patients with uncommon EGFR mutations: a phase II, single-arm, prospective study (ID5120)

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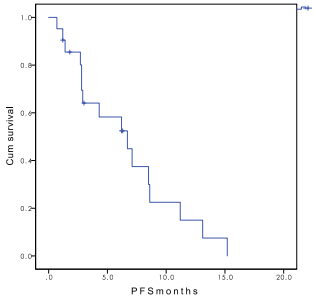
Background

Compared with classic epidermal growth factor receptor (EGFR) mutations, uncommon EGFR alterations showed poorer outcomes in non-small-cell lung cancer (NSCLC) patients. This study aimed to investigate the efficacy and safety of PD-1/PD-L1 blockade and anti-angiogenesis treatments in NSCLC patients with uncommon EGFR mutations.

Methods

Twenty-one patients of NSCLC harboring rare EGFR mutations after previous treatments, including a platinum-based regimen and a targeted treatment (regardless of EGFR Ex20ins), were enrolled. Patients received sintilimab (anti-PD-1) combined with anlotinib (multi-target anti-angiogenesis). The primary endpoint was the objective response rate (ORR).



mPFS : 6.7 months

Results

At the data cut-off time (January 11, 2022), the median follow-up was 10.0 months. Among enrolled patients, twelve cases had EGFR Ex20ins and remaining nine cases had EGFR other mutations such as L861Q, G719A, and G709T. Patients harboring uncommon EGFR mutations exhibited a median progression-free survival of 6.7 months (95% CI, 2.4, 11.0), and the 6-month PFS rate was 52.4%. Moreover, of the nineteen patients evaluable for efficacy, the objective response rate (ORR) was 36.8% (7/19), and the disease control rates (DCR) was 84.2% (16/19). Notably, patients carrying EGFR Ex20ins showed similar ORR/DCR and PFS with other mutation patterns.The most commonly observed grade 3 or greater treatment-related adverse events were hypertension (4.8%,1/21), immune-related pneumonitis (4.8%,1/21) and hand-foot syndrome (9.5%,2/21). Therefore, the use of sintilimab and anlotinib did not result in increased safety concerns.

Conclusions

Combination of sintilimab and anlotinib demonstrated durable efficacy and good tolerability in NSCLC patients with uncommon *EGFR* mutations. And further investigate is warranted to confirm this new chemo-free strategy.

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