Background

- Antiangiogenic therapy combined with PD-1/PD-L1 inhibitors has shown excellent efficacy in advanced NSCLC pts.
- The ALTER 0303 trial showed that anlotinib improved both PFS and OS in later-line treatment for advanced NSCLC.
- The purpose of this study is to investigate the efficacy and safety of anlotinib in combination with PD-1/PD-L1 inhibitors as first-line or second-line treatment in advanced non-small cell lung cancer in the real-world setting.

Study Design

- This is a prospective, single-arm, multicenter real-world study (ChiCTR 2100049975).

Key Eligibility Criteria

- Histopathologically or cytologically confirmed NSCLC
- No prior systemic therapy or Progressed after one line therapy
- ≥ 18 years old;
- ECOG PS 0-2

N=300

Primary endpoint: Progression-free survival (PFS)
Secondary endpoint 1 Overall survival (OS), Objective response rate (ORR), Disease Control Rate (DCR), safety

Results

- From Aug 2021 to Apr 2022, 69 patients were enrolled in fifteen centers and 23 of them have undergone at least one tumor assessment. Patients’ baseline characteristics were listed in Table 1.

Patient Baseline Characteristic

<table>
<thead>
<tr>
<th>Age, years, median(range)</th>
<th>66 (39-79)</th>
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</thead>
<tbody>
<tr>
<td>Gender-male, n (%)</td>
<td>18 (78.3%)</td>
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<tr>
<td>female, n (%)</td>
<td>5 (21.7%)</td>
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<tr>
<td>ECOG PS, n (%)</td>
<td>0 1 (4.3%), 1 21 (91.3%), 2 1 (4.3%)</td>
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<tr>
<td>Previous systemic therapy, n (%)</td>
<td>Never 10 (43.5%), First-line therapy 13 (56.5%)</td>
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<tr>
<td>Smoking history, n (%)</td>
<td>Never 8 (34.8%), Current/Former 15 (65.2%)</td>
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<tr>
<td>Metastasis, n (%)</td>
<td>Brain 1 (4.3%), Bone 3 (13.0%)</td>
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<td>Stage (TNM), n (%)</td>
<td>III 16 (69.6%), IV 4 (17.4%), unknown 3 (13.0%)</td>
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<tr>
<td>Pathologic types, n (%)</td>
<td>Squamous 5 (21.7%), Adenocarcinoma 13 (56.5%), Other 5 (21.7%)</td>
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</table>

Efficacy

- Among all patients, Median PFS was 7.70 months (95%CI: 4.49, 10.91) and median OS was not reached. (Figure 1)
- Among all patients, 6 patients were partial response (PR), 15 patients were stable disease (SD), illustrating ORR of 26.1% and DCR of 91.3%, as shown in Table 2.
- In the first-line, ORR was 20%, DCR was 90%.
- In the second-line, ORR was 30.8%, DCR was ≥ 92.3.

Safety

- 73.9% (17/23) patients had at least one treatment-emergent adverse events (TEAEs). The most common adverse events were hypothyroidism (26.1%), hyperlipidemia (21.7%), hypertension (8.7%). Grade 3 or higher TRAEs occurred in 5 patients (21.7%). The most frequently reported grade 3 or higher TEAEs included Neutropenia (8.7%), Leukopenia (4.3%), Thrombocytopenia (4.8%), Hand foot syndrome (4.3%). (Table 3).

Conclusion

- This real-world study finds that anlotinib combined with PD-1/PD-L1 inhibitors shows good efficacy and safety in NSCLC patients.
- The treatment effects are similar to the outcomes in comparable clinical trials, which support the further recommendation of anlotinib combined with PD-1 inhibitors in the treatment of NSCLC.

Conflict of interest disclosure: The authors have declared no conflicts of interest.

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