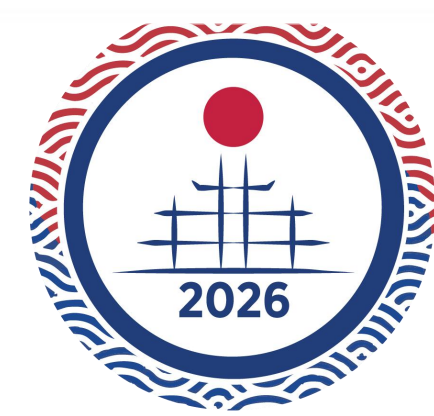




EP11.18: Efficacy and Safety of PD-(L)1 Inhibitors Plus Rh-endostatin for Consolidation Therapy After Chemoradiation in Unresectable NSCLC

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INTRODUCTION

This study is to evaluate the efficacy and safety of recombinant human endostatin (rh-endostatin) combined with immune checkpoint inhibitors (ICIs) as consolidation therapy in driver gene-negative, unresectable stage III or medically inoperable early-stage non-small cell lung cancer (NSCLC) who have completed definitive chemoradiation therapy (CRT). Building on the PACIFIC regimen paradigm of immune consolidation therapy, we hypothesize that dual-pathway strategy which were targeting both angiogenesis suppression and immune checkpoint blockade may enhance outcomes while reduce the adverse events, providing a viable therapeutic alternative for patients.

METHODS

- We conducted a prospective, single-arm, single-center small sample study (Ethics ID: KY-2024-062).
- Eligible patients were 18-75 years old with NSCLC who were driver gene-negative and unresectable stage III or inoperable early-stage after undergoing CRT. Consolidation therapy was initiated within 42 days post-CRT and continued for 2 years or until disease progression.
- Primary endpoints were adverse events (AEs) and progression-free survival (PFS). AEs were graded per CTCAE 5.0. Secondary endpoints included overall survival (OS), survival rates, and disease control rate (DCR).

Key Inclusion/ Exclusion Criteria:
Aged ≥18 years old;
Histopathologically confirmed NSCLC,
clinical unresectable stage III;
Absence of EGFR/ ALK ROS1 mutations;
ECOG PS score 0-1;
Receive either concurrently or
sequentially chemoradiotherapy and
without severe AEs (≥3° AEs) ;

Receive induction ICIs plus rh-endostatin
within 42 days post-CRT for up to 2 years
or until disease progression, death or
toxicity that leads to drug discontinuation.

Primary endpoint: inducense of adverse
progression-free survival (PFS);
secondary endpoints included overall
survival (OS), survival rates, and disease
control rate (DCR). AEs were graded per
CTCAE 5.0.

Abbreviations:
AEs (adverse events);
ICIs (immune checkpoint inhibitors);
TB (tuberculosis).

Fig. 1 CONSORT flow diagram.

DISCUSSION AND CONCLUSION

- Rh-endostatin combined with ICIs as consolidation therapy demonstrated promising efficacy and manageable toxicity in driver gene-negative, unresectable stage III or medically inoperable early-stage NSCLC after CRT. Promising efficacy of 12-months PFS and OS rates exceeded historical immunotherapy consolidation therapy data, and median PFS is comparable to previous clinical trials.
- The absence of severe immunotherapy-related pneumonia supports the manageable toxicity of rh-endostatin combined with ICIs as consolidation therapy strategy. The lower rate of treatment discontinuation due to adverse events compared to previous clinical trials further indicates the feasibility of rh-endostatin combined with ICIs as consolidation therapy.
- Although limited by small sample size, these results provided evidence for combined anti-angiogenic and immunotherapy as consolidation therapy for NSCLC, warranting validation in larger trials.

RESULTS

- 11 Patients were enrolled, receiving rh-endostatin combined ICIs as consolidation therapy every 3 weeks.
- Median PFS was 20.9 months, median OS 36.5 months, 12-month OS rate 100%, 12-month PFS rate 63.6%, and DCR 100%.
- With a median follow-up of 26.4 months, 1 patient (9.1%) had grade 3 dermatitis. Two had grade 2 immune-related pneumonia. Most AEs were grade 1-2, with anemia being the most common. Only 1 patient (9.1%) discontinued therapy due to AEs.

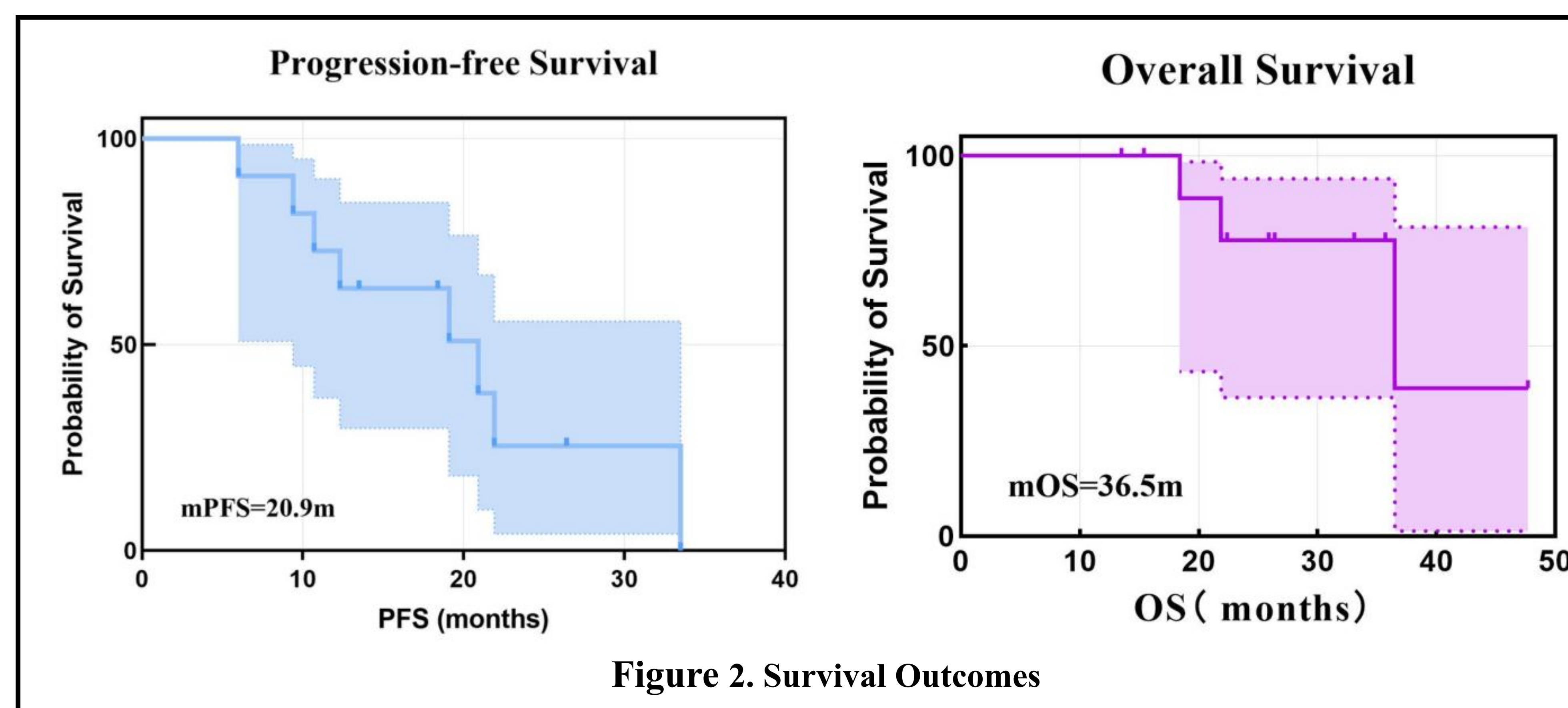


Table 1. Drug-related adverse events

Factors	All Grades	≥3 Grades
Thyroid dysfuction	1	0
Pneumonia	2	0
Anemia	7	0
Myositis	0	0
Myocarditis	0	0
Hepatitis	1	0
Nephritis	0	0
Dermatitis	1	1