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INTRODUCTION

SCLC remains aggressive with poor prognosis: 5-year survival ~10% for stage III and <3% for stage IV. Immunotherapy consolidation improves outcomes in LS-SCLC (ADRIATIC) and ES-SCLC (CASPIAN), yet rapid progression persists. Anti-angiogenic agents (e.g., anlotinib) may reprogram the tumor microenvironment and augment immunotherapy.

This phase II study evaluates benmelstobart + chemotherapy induction followed by benmelstobart + anlotinib maintenance in stage III/IV SCLC.

METHODS

In this prospective phase II trial, patients with ES-SCLC or stage III LS-SCLC and an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0-2, who had not progressed after 3–6 cycles of induction therapy (benmelstobart plus platinum-based chemotherapy), received benmelstobart (1200 mg; every 3 weeks [Q3W]) and anlotinib (8, 10, 12 mg; administered on days 1–14 of each 3-week cycle) as maintenance therapy. The primary endpoint was progression-free survival (PFS) from induction therapy; secondary endpoints included PFS from maintenance therapy, overall survival (OS), objective response rate (ORR), and safety profile.

Key eligibility criteria

- Untreated ES-SCLC or stage III LS-SCLC patients
- ECOG PS 0-2
- Age ≥18 years

induction therapy

Benmelstobart 1200 mg, D1
+ platinum-based chemotherapy
Q3W, 3-6 cycles

non-PD

maintenance therapy

Benmelstobart 1200 mg, D1, Q3W
+ Anlotinib (8/10/12 mg, 1-14 days,
Q3W)

until progression or
unacceptable toxicity

Primary endpoint:

PFS from induction therapy

Secondary endpoints:

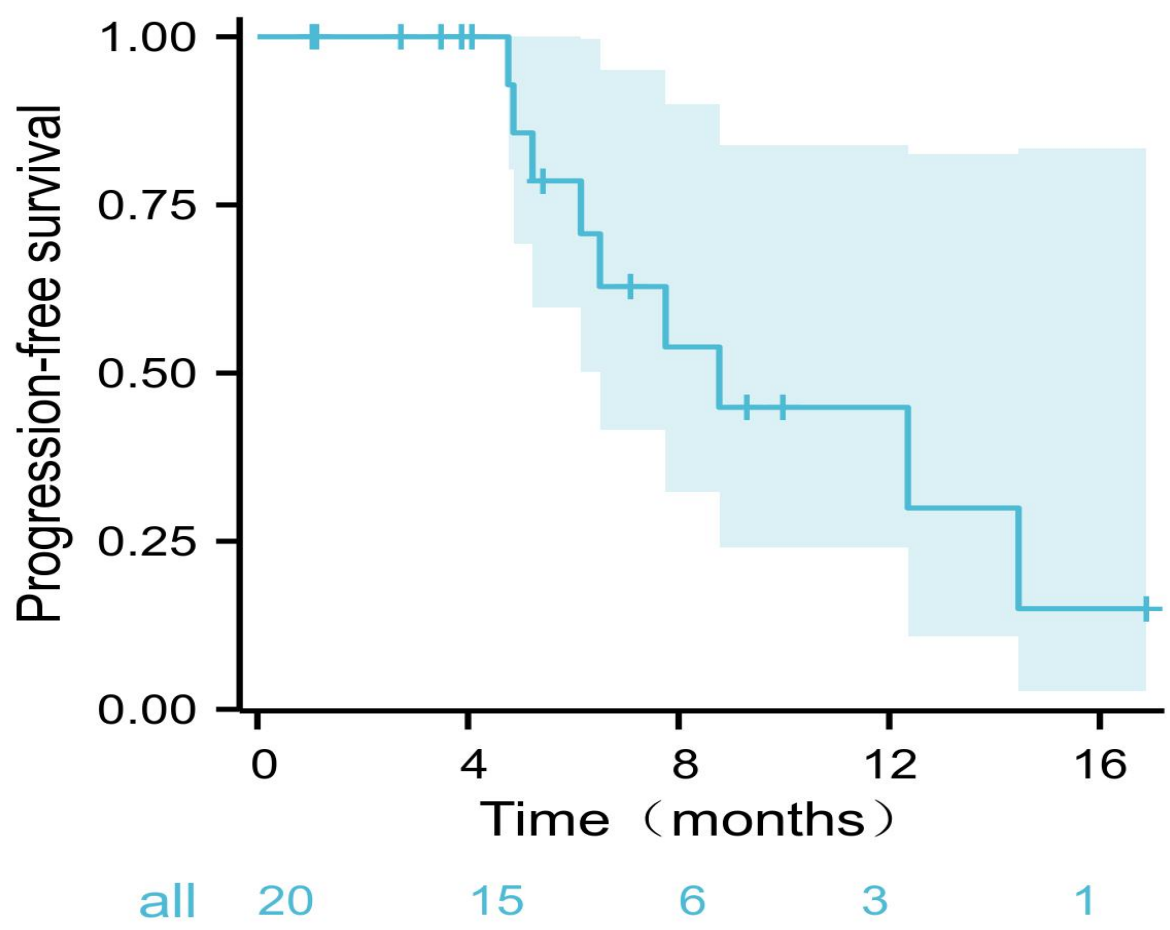
PFS from maintenance therapy,
ORR, DCR, OS and safety

Basic Characteristics

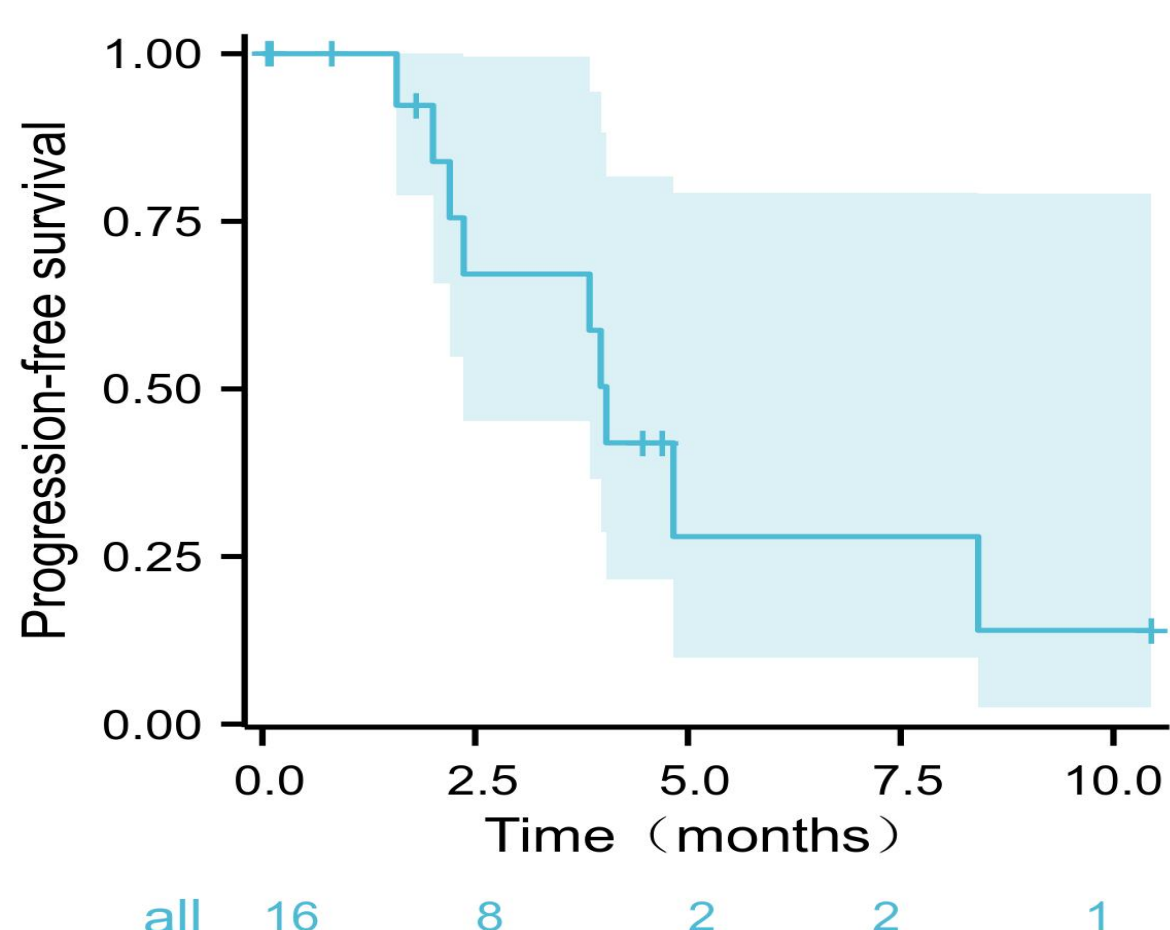
Baseline	N=20
Age, median (IQR), y	67.5(60.5-72.5)
Sex, n (%)	
Male	17(85.0)
Female	3(15.0)
ECOG performance status, n (%)	
0	14(70.0)
1	4(20.0)
2	2(10.0)
Smoking status, n (%)	
Never	12(60.0)
Former	4(20.0)
Current	4(20.0)
Disease stage, n (%)	
Stage III	7(35.0)
Stage IV	13(65.0)
Brain metastases, n (%)	3(15.0)
Liver metastases, n (%)	3(15.0)
Bone metastases, n (%)	6(30.0)

RESULTS

PFS from induction therapy



PFS from maintenance therapy



Safety Summary

	N=20
Any-grade, TRAEs	10(50.0%)
Grade ≥3 TRAEs	1(5.0%)
SAEs	5(25.0%)
TRAEs leading to dose reduction	1(5.0%)
TRAEs leading to discontinuation	5(25.0%)

Counts in the detailed table are events; patients may have had more than one event.

	Any-grade TRAE	Grade ≥3 TRAE	SAE	TRAEs leading to dose reduction	TRAEs leading to discontinuation
Hypothyroidism	4(20%)	0 (0.0)	2(10%)	0 (0.0)	2(10%)
Pneumonitis	4(20%)	0 (0.0)	4(20%)	0 (0.0)	4(20%)
Elevated ALT	1(5%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Elevated AST	2(10%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anemia	1(5%)	1(5%)	0 (0.0)	1(5%)	0 (0.0)
Leukopenia	1(5%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypercholesterolemia	1(5%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Adrenal insufficiency	1(5%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anorexia	1(5%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Between May 2024 and October 2025, 20 patients (7 with stage III LS-SCLC and 13 with ES-SCLC) were enrolled. The median age was 67.5 years (IQR 60.5–72.5); 85% were male. At the data cut-off (February 1, 2026), the median follow-up was 7.8 months (95% CI, 4.8–NR). ORR was 55.0% (95% CI, 31.5–76.9), and the DCR (Disease Control Rate) was 100%. Median PFS was 8.8 months (95% CI, 6.5–NR) from induction therapy start and 4.0 months (95% CI, 2.4–NR) from maintenance therapy start. Median OS was not reached. Any-grade treatment-related adverse events (TRAEs) occurred in 50.0% of patients; and grade ≥3 TRAEs occurred in 5.0% of patients. The serious adverse event (SAE) rate was 25.0% (including 10.0% immune-related pneumonitis in patients with pre-existing lung disease). Hypothyroidism (20.0%) and pneumonitis (20.0%) were the most frequent adverse event (AE). No new safety signals or grade 5 AEs were observed.

DISCUSSION AND CONCLUSION

Induction therapy with benmelstobart plus chemotherapy, followed by maintenance therapy with benmelstobart plus anlotinib, demonstrates promising efficacy and manageable safety among patients with either ES-SCLC or Stage III LS-SCLC. Long-term follow-up is ongoing.