



EP13.03: Concurrent Brain Radiotherapy Combined with Tislelizumab and Chemotherapy for Patients with Small-Cell Lung Cancer and Brain Metastases

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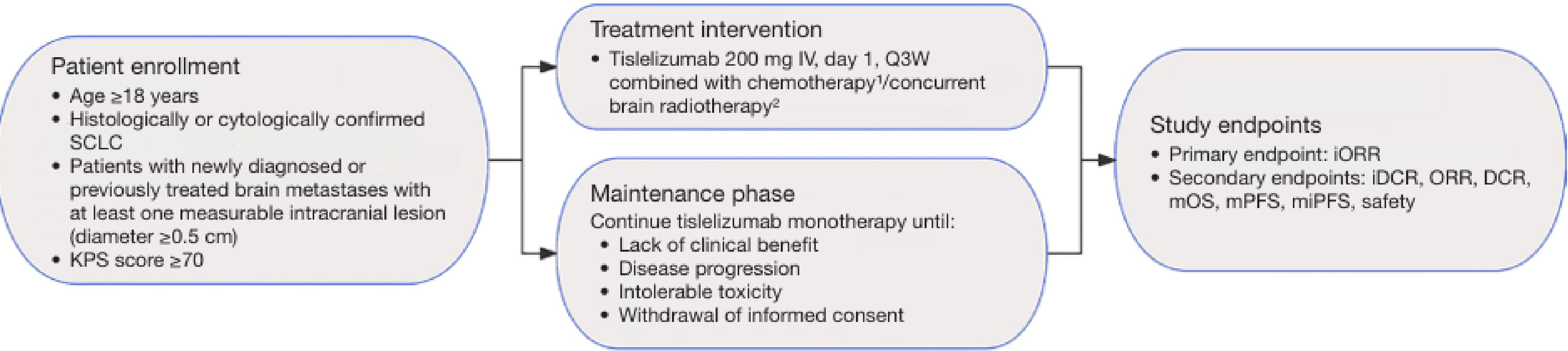
INTRODUCTION

Brain metastases are frequently observed in patients with small-cell lung cancer (SCLC) and are associated with particularly poor clinical outcomes. While chemoimmunotherapy is the current standard of care for extensive-stage SCLC, evidence supporting its efficacy in patients with brain metastases is limited. Brain radiotherapy remains a key component of treatment, yet survival remains unsatisfactory. To address this unmet need, we conducted a prospective phase II study to investigate the efficacy and safety of concurrent brain radiotherapy, tislelizumab, and chemotherapy in patients with SCLC and brain metastases.

METHODS

This prospective, single-center, single-arm phase II study enrolled patients with treatment-naïve or previously treated SCLC and measurable brain metastases. Patients received tislelizumab (200 mg Q3W) plus platinum-based chemotherapy, followed by concurrent brain radiotherapy (WBRT, WBRT-SIB, or SRT) and maintenance tislelizumab. The primary endpoint was intracranial objective response rate (iORR). Secondary endpoints included intracranial disease control rate (iDCR), objective response rate (ORR), progression-free survival (PFS), intracranial progression-free survival (iPFS), overall survival (OS), and safety. Tumor responses were assessed using RANO and RECIST v1.1 criteria

Study Design



Chinese Clinical Trial Registry (ChiCTR2300070273).

Abbreviations: iORR, intracranial objective response rate; iDCR, intracranial disease control rate; iPFS, intracranial progression-free survival; ORR, objective response rate; DCR, disease control rate; PFS, progression-free survival; OS, overall survival.

Assessments and Endpoints

Intracranial response was assessed according to RANO criteria, and systemic response according to RECIST v1.1. The primary endpoint was iORR, while secondary endpoints included iDCR, ORR, DCR, OS, PFS, iPFS, and safety. Treatment-related adverse events were graded using NCI-CTCAE v5.0, and radiation-induced neurotoxicity was assessed using RTOG CNS toxicity criteria. Statistical analyses were performed using a Simon two-stage phase II design and Kaplan-Meier methodology.

RESULTS

1. Patient Characteristics

Twenty-five patients with SCLC and brain metastases were enrolled. The median age was 62 years, and 88.0% were male. All patients received tislelizumab plus chemotherapy and concurrent brain radiotherapy. The median number of chemotherapy and immunotherapy cycles was 3.0, and WBRT was the most commonly used radiotherapy modality (88.0%).

2. Treatment Exposure

All patients received tislelizumab plus chemotherapy and concurrent brain radiotherapy. The median number of chemotherapy cycles was 3 and immunotherapy cycles was 3. WBRT was administered in 88% of patients.

3. Efficacy

With a median follow-up of 23.8 months, the iORR was 76.0% and the iDCR was 100.0%. Systemic ORR and DCR were 56.0% and 80.0%, respectively. Median OS, PFS, and iPFS were 11.1, 5.6, and 7.6 months, respectively.

4. Safety

Treatment-related adverse events were mainly hematologic and manageable. Grade ≥3 TRAEs occurred in 36.0% of patients, primarily neutropenia and thrombocytopenia. No grade 3–4 radiation-induced CNS toxicity was observed.

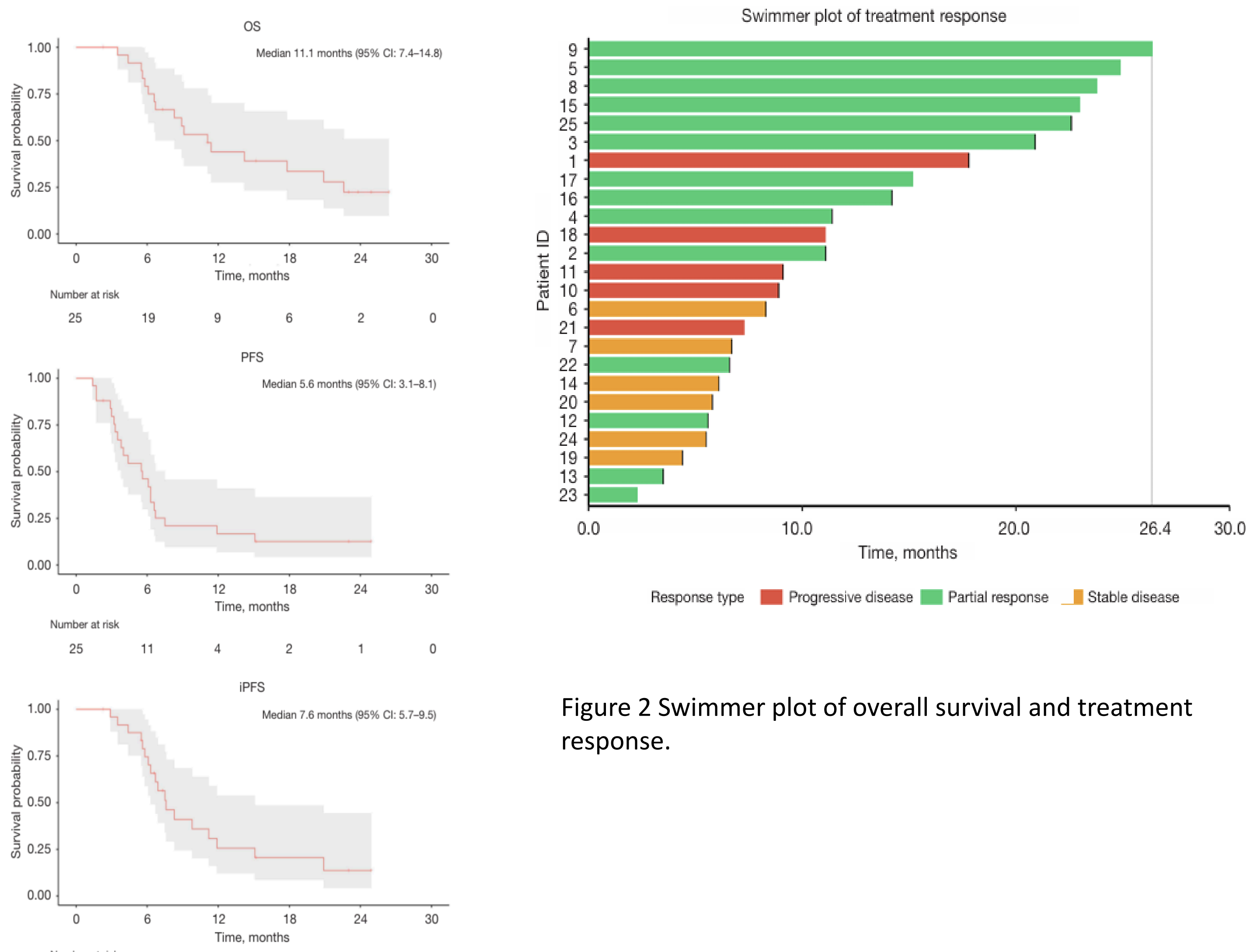


Figure 2 Swimmer plot of overall survival and treatment response.

Adverse Event	Any Grade n (%)	Grade ≥3 n (%)
Hematologic toxicity	22 (88.0)	8 (32.0)
Anemia	21 (84.0)	2 (8.0)
Leukopenia	15 (60.0)	4 (16.0)
Neutropenia	14 (56.0)	5 (20.0)
Thrombocytopenia	11 (44.0)	5 (20.0)
Hypoalbuminemia	14 (56.0)	—
Hepatic toxicity	13 (52.0)	—
Increased γ-GT	9 (36.0)	—
Increased ALT	5 (20.0)	—
Increased AST	4 (16.0)	—
Thyroid dysfunction	12 (48.0)	—
Fatigue	7 (28.0)	—
Nausea and vomiting	4 (16.0)	—
Rash	4 (16.0)	1 (4.0)
Cardiac enzyme abnormalities	3 (12.0)	—
Increased troponin	2 (8.0)	—
Elevated creatine kinase	1 (4.0)	—
Constipation	3 (12.0)	—
Hematuria and proteinuria	3 (12.0)	—
Overall Grade ≥3 TRAEs	9 (36.0)	—
Grade 4 TRAEs	3 (12.0)	—
RTOG score ≥2	4 (16.0)	—

Table 1. Treatment-Related Adverse Events

Conclusions

Concurrent brain radiotherapy combined with tislelizumab and chemotherapy demonstrated promising intracranial efficacy and manageable safety in patients with SCLC and brain metastases. The combination achieved an iORR of 76.0% and an iDCR of 100.0%, supporting the potential role of integrating immunotherapy with radiotherapy in patients with SCLC and brain metastases. Further validation in larger prospective studies is warranted.