The Activity and Safety of Anlotinib for Patients with recurrent malignant glioma: A single-center, retrospective study

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Background

- **According to the NCCN guidelines, bevacizumab is recommended drug for recurrent malignant glioma (rMG).**
- **Anlotinib is a multitarget tyrosine kinase inhibitor that can inhibit tumor angiogenesis and tumor cell growth. We report results from this retrospective study to determine the efficacy and tolerability of Anlotinib as a treatment for rMG.**

Trial Design

- A total of 18 eligible patients who relapsed from the standard chemoradiotherapy regimen (TMZ and radiotherapy) after surgery because of tumor located in the eloquent brain areas were enrolled in this study between May 2020 and June 2022.
- Patients were subjected to a concurrent treatment of Anlotinib (12mg qd) until disease progression or intolerable toxicity.

Key Inclusion & Exclusion Criteria

1. Grade III to IV recurrent high-grade gliomas
2. Patients have undergone surgery and relapsed after receiving standard radiotherapy and chemotherapy;
3. Patients with previous cerebral hemorrhage and thrombosis history were excluded

Result

Patients' baseline characteristics were listed in Table 1.

Table 1. Patient Baseline Characteristics (N=18)

Characteristics	Number of patients, n (%)
Gender	
Male	6 (33.3)
Female	12 (66.7)
Age	
≥42 year	8 (44.4)
<42 years	10 (55.6)
ECOG PS	
1	14 (77.8)
2	4 (22.2)
Grade of histology	
IV	7 (38.9)
III	7 (38.9)
Other	4 (22.2)
Tumor location	
Multifocal/dissemination	6 (33.3)
Focal	12 (66.7)
Previous anti-angiogenic agents	
Yes	7 (38.9)
No	11 (61.1)
Previous operation	
Yes	17 (94.4)
No	1 (5.6)

Efficacy

- **Efficacy was evaluated using Response Assessment in Neuro-Oncology criteria for high-grade glioma.Survival was estimated with the Kaplan-Meier curve and log-rank test.**
- **The disease control rate was 88.9% (16/18) and the objective response rate was 38.9% (7/18).(Table 2)**
- **The 6-month PFS rates were 66.7% and the mPFS was Not reached.**

Table 2. Summary of clinical activities (N=18)

Progression-free Suvival	
Median,month(95% CI)	Not reached
6-month PFS	66.7%
Response， n (%)	
Complete response	1 (5.6)
Partial response	6 (33.3)
Stable disease	9 (50.0)
Progressive disease	2 (11.1)
ORR,%(n/N)	38.9% (7/18)
DCR,%(n/N)	88.9% (16/18)

Safety

- **Safety was assessed using NCI-CTCAE 5.0.**
- **Almost all treatment-related adverse events were grade 1 or 2 (Table 3)**
- **The most common treatment-related adverse events were hand-foot syndrome (44.4%), Gastrointestinal reactions(33.3%), hypertension (27.8%) .**
- **Six patient had a dose reduction of anlotinib because of hypertension, nausea, and fatigue.**

Table 3. Overview of Treatment-Emergent Adverse Events (TEAEs) (n=18)

	Grade 1-2 TRAEs	Grade 3-4 TRAEs
All TEAEs,*n*(%)	17(94.4)	1 (5.6)
Hypertension, *n*(%)	5 (27.8)	0
Hand–foot reaction, *n*(%)	8 (44.4)	0
Gastrointestinal reactions, *n*(%)	6 (33.3)	0
Weakness, *n*(%)	6 (33.3)	0
Oral mucositis, *n*(%)	4 (22.2)	0
Hypothyroidism, *n*(%)	2(11.1)	0
Thrombocytopenia, *n*(%)	0	1 (5.6)
Bleeding, *n*(%)	1 (5.6)	0

Conclusion

- **Anlotinib was effective in terms of ORR, and DCR, and was well tolerated.**
- **Further randomized controlled clinical studies are needed to confirm the efficacy of Anlotinib for the treatment of rMG.**