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Safety and Efficacy of Anlotinib Hydrochloride Plus Temozolomide in Patients with Recurrent Glioblastoma

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Abstract

Background: Glioblastoma (GBM) is a highly vascularized tumor with few treatment options after disease recurrence. Here, we report the efficacy and safety of anlotinib hydrochloride plus temozolomide in patients with recurrent GBM.

Methods: Patients with first definite postsurgical progression of histologically confirmed GBM preceded by standard radiotherapy and temozolomide chemotherapy were eligible for inclusion. All patients received temozolomide (150-200mg/m2, orally, QD, d1-5/4wks) and anlotinib (10mg, orally, QD, d1-14/3wks) until disease progression or unacceptable toxicity. The primary endpoint was investigator-assessed 6-month PFS rate by RANO criteria.

Result: Twenty-one patients were enrolled between May 2020 and July 2021, with a median age of 55 (range 27-68) years old. According to the RANO criteria, tumor response occurred in 17 patients, of which 9 patients had a complete response, and the objective response rate was 81.0% (95% CI 62.6-99.3). The disease control rate was 95.2% (95% CI 76.2-99.9), with three additional patients achieving a stable disease without tumor progression. The median PFS was 7.3 months (95% CI 4.9-9.7), and the 6-month PFS rate was 61.9% (95% CI 39.3-84.6). The median overall OS was 16.9 months (95% CI 7.8-26.0). The most common adverse events were leukocytopenia (66.7%), thrombocytopenia (38.1%), and hypertriglyceridemia (38.1%). Five patients had nine grade 3 adverse events, with a 23.8% incidence rate. Two patients discontinued therapy due to ischemic stroke (grade 3) and wound dehiscence (grade 1) respectively. No grade 4 or treatment-related deaths occurred in this study.

Conclusions: Anlotinib combined with temozolomide is efficacious and tolerated in recurrent GBM patients.