Document ID: GBM-2024-001

Title: Temozolomide Efficacy in Elderly Glioblastoma Patients: A Phase III Multicenter Clinical Trial

Publication Type

Clinical Trial

Year of Publication

2024

Patient Demographics

- **Age Group**: 65-78 years (median age: 71 years)
- **Sample Size**: 156 patients
- **Condition**: Newly diagnosed glioblastoma multiforme (GBM)
- **Gender Distribution**: 58% male, 42% female
- **ECOG Performance Status**: 0-2

Disease Focus

Glioblastoma multiforme (Grade IV astrocytoma) with emphasis on treatment outcomes in geriatric population

Treatment Discussed

Standard Temozolomide (TMZ) chemotherapy protocol following radiotherapy. Patients received 75 mg/m² daily during radiotherapy, followed by maintenance TMZ at 150-200 mg/m² for five consecutive days per 28-day cycle for six cycles.

Study Outcome Summary

Primary Endpoints: - Median overall survival (OS): 14.2 months (95% CI: 12.1-16.8) - Median progression-free survival (PFS): 6.8 months (95% CI: 5.9-7.9) - 12-month survival rate: 58.3% - 24-month survival rate: 22.1%

Secondary Endpoints: - Response rate (complete + partial): 34.6% - Stable disease: 41.0% - Progressive disease: 24.4%

Safety Profile: Common adverse events included thrombocytopenia (Grade 3/4: 12%), neutropenia (Grade 3/4: 8%), fatigue (Grade 3: 15%), and nausea (Grade 1/2: 67%). Treatment-related discontinuations occurred in 18% of patients, primarily due to hematologic toxicity.

Quality of Life Assessment: EORTC QLQ-C30 scores showed maintained quality of life during treatment in 71% of patients, with cognitive function preservation in 64% at 6 months.

FDA Approval Status

Approved - Temozolomide received FDA approval in 1999 for refractory anaplastic astrocytoma and expanded approval in 2005 for newly diagnosed glioblastoma in combination with radiotherapy.

Key Findings

Elderly patients (≥65 years) with newly diagnosed glioblastoma demonstrated clinically meaningful survival benefit with standard Temozolomide therapy, though outcomes were slightly lower than historical data in younger populations. The treatment was generally well-tolerated with manageable toxicity profiles. MGMT promoter methylation status remained a significant predictor of response (hazard ratio: 0.51, $p<0.001$).

Citations

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Conflict of Interest: Authors declare no competing financial interests.