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Effects of postoperative intravenous Cyclosporine treatement on the survival and functional performance status of patients with glioblastoma: A randomized, triple-blinded, placebo-controlled clinical trial

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Abstract

Background: Glioblastoma is associated with low median survival time irrespective of maximal treatment. Previous in vitro studies have revealed tumor inhibitory effect of cyclosporine A. However, whether the addition of cyclosporine could improve survival among patients with glioblastoma is unknown. This study aimed to determine the impact of post-operation treatment with cyclosporine on the survival and performance status.

Methods: In this randomized, triple-blinded, placebo-controlled trial, 118 patients with glioblastoma who underwent surgery were treated with standard chemoradiotherapy regimen. Patients were randomized to receive intravenous cyclosporine for three days postoperatively or placebo during the same period. The primary endpoint was the short-term effect of intravenous cyclosporine on survival and Karnofsky performance scores (KPS). Secondary endpoints were chemoradiotherapy toxicity and neuroimaging features.

Results: The overall survival (OS) in the cyclosporine (17.03±5.8, 95% CI: 11-17.37 months) group was statistically lower than in the placebo (30.53±4.9, 95% CI:8-32.3 months) groups (p= 0.049). However, compared to the placebo group, a statistically higher percentage of patients in the cyclosporine group were alive at 12 months follow-up. Also, progression-free survival (PFS) in the cyclosporine group was significantly prolonged than in the placebo group (6.3±4.07 months vs 3.4±2.98 months, p<0.001). In the multivariate analysis, age <50 years (p=0.022) and gross total resection (GTR)(p=0.03) were significantly associated with overall survival.

Conclusion: Our study results demonstrated that administering post-operative cyclosporine does not improve overall survival and functional performance status. Notably, the survival rate was significantly dependent on the patient age and the extent of glioblastoma resection.

Keywords: Chemoradiation; Cyclosporine; Glioblastoma; Performance status; Survival.