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## Adjuvant Immunotherapy with Whole-Cell Lysate Dendritic Cells Vaccine for Glioblastoma Multiforme: A Phase II Clinical Trial.

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### Abstract

**BACKGROUND:** This study sought to evaluate effectiveness of autologous dendritic cell vaccine (immunotherapy) for glioblastoma multiforme (GBM).

**METHODS:** Patients 14 to 70 years of age with newly diagnosed GBM and Karnofsky Performance Scale (KPS) score >70 who were receiving initial treatment with were enrolled and were randomized into 2 groups during the 5-year study period. Eighteen patients underwent conventional treatment (surgery, radiotherapy, and chemotherapy) and received adjuvant autologous dendritic cell vaccine, and 16 patients (control group) underwent conventional treatment only. Administration of the vaccine was begun within 1 to 2 months postoperatively, with 10 inoculations given over 6 months. Outcome measures were overall survival (OS); progression-free survival (PFS); 1-, 2-, and 3-year survival rates, and quality of life (QoL).

**RESULTS:** Follow-up time ranged from 14 to 56 months (median, 33 months). The 1-, 2-, and 3-year survival rates were 88.9%, 44.4%, and 16.7% for the vaccine group, respectively, and 75.0%, 18.8%, and 0%, respectively, for the control group, ( $P = 0.299, 0.0035, 0.0014$ , respectively). The median OS for the vaccine group was 31.9 months and for the control group was 15.0 months ( $P < 0.002$ ). The median (PFS) for the vaccine group was 8.5 months, and 8.0 months for the control group ( $P = 0.075$ ). The surviving fraction was significantly higher in the vaccine group based on Kaplan-Meier analysis.

**CONCLUSIONS:** Adjuvant immunotherapy with whole-cell lysate dendritic cell vaccine may improve short-term survival. It seems to be safe, and its long-term effectiveness is worthy of further investigation.

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