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**Temozolomide concomitant and adjuvant to radiotherapy in elderly patients with glioblastoma: correlation with MGMT promoter methylation status.**

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**BACKGROUND::** A recent randomized study conducted on newly diagnosed glioblastoma (GBM) patients demonstrated that concomitant and adjuvant temozolomide added to standard radiotherapy had a survival advantage compared with radiotherapy alone. The overall survival benefit of this aggressive treatment, however, was attenuated in older or poor performance status patients. The aim of the present study was to verify the activity and the toxicity of temozolomide administration concurrent and adjuvant to radiotherapy as first-line treatment for elderly GBM patients, and to explore correlations between clinical outcome and O6 methylguanine-DNA methyltransferase (MGMT) promoter methylation status. **METHODS::** Newly diagnosed GBM patients  $\geq 65$  years were considered eligible. Treatment comprised radiotherapy (60 Gy in 30 fractions over 6 weeks) plus continuous daily temozolomide (75 mg/m<sup>2</sup>/day), followed by 12 maintenance temozolomide cycles (150 mg/m<sup>2</sup>) once a day for 5 consecutive days every 28 days if MRI showed no enhancement suggesting a tumor; otherwise, chemotherapy was delivered until complete response or unequivocal progression. **RESULTS::** A total of 58 patients (34 males; median age, 68 years; range, 65-82 years) were enrolled. Sixteen patients (43%) presented MGMT promoter methylated and 21 unmethylated (57%) status. The median progression-free survival and median survival time (MST) were 9.5 months (95% confidence interval [CI], 8.6-10.5) and 13.7 months (95% CI, 10-17.3 months), respectively. Mental status deterioration grade 3-4 was detected in 25% of patients. Leukoencephalopathy was diagnosed in 10% of patients. **CONCLUSIONS::** The overall and progression-free survival of patients given concomitant and adjuvant temozolomide are greater than in those given radiotherapy alone; however, this regimen incurs a greater deterioration in mental status. Further randomized trials should, therefore, be conducted to investigate the efficacy and against the toxicity of this regimen as first-line therapy in patients with GBM. *Cancer* 2009. (c) 2009 American Cancer Society.

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