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### **Concomitant temozolomide and radiotherapy versus radiotherapy alone for treatment of newly diagnosed glioblastoma multiforme.**

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#### **Abstract**

**PURPOSE:** To study the efficacy and safety of radiotherapy (RT) with concomitant and subsequent temozolomide in comparison to RT alone in the treatment of patients with newly diagnosed glioblastoma multiforme (GBM) after brain surgical intervention.

**METHODS:** Twenty patients received cranial fractionated RT (60 Gy total dose: 2 Gy/day, 5 days/week, for 6 weeks) with concomitant oral temozolomide (75 mg/m<sup>2</sup>/day x 7 days/ week, for 6 weeks) followed by temozolomide monotherapy (200 mg/m<sup>2</sup>/day x 5 days every 28 days for 6 cycles). Another 20 patients received only cranial RT (Co-60 teletherapy, 60 Gy in 30 fractions).

**RESULTS:** At the end of the study the median time to progression free survival (PFS) was 13 months in the temozolomide plus RT treatment group and 5 months in the RT-alone group (p=0.0001). Median overall survival (OS) in the temozolomide plus RT and the RT-alone group was 19 and 11.5 months, respectively (p=0.0264). The main side effect in the temozolomide plus RT group was myelosuppression. Concomitant treatment resulted in grade 3 hematologic toxicity in 6 patients.

**CONCLUSION:** These data show that the combination of temozolomide, concomitant and subsequent to RT seems more effective than RT alone in patients with newly diagnosed GBM and that multimodality treatment is safe and well tolerated.

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