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## Abstract

### Phase I/II trial of twice-daily temozolomide and celecoxib for treatment of relapsed malignant glioma: Final data

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**Background:** Anaplastic astrocytoma (AA) and Glioblastoma multiforme (GBM) overexpress COX-2 enzyme. COX-2 inhibitors demonstrate preclinical efficacy in glioma models and have non-overlapping toxicity with chemotherapy, prompting a phase I/II trial for patients with recurrent/progressive AA or GBM utilizing a regimen of combined temozolomide (TMZ) and celecoxib (CEL). Final survival data is presented. **Methods:** For phase I, TMZ was given as a fixed loading dose of 200 mg/m<sup>2</sup> followed by 9 doses of 90 mg/m<sup>2</sup> BID for 5 days. CEL was given in 5 dose levels starting at 60 mg/m<sup>2</sup> BID, escalating to 240 mg/m<sup>2</sup> BID (maximum 400 mg BID) for 10 days. Cycles were repeated every 28 days until disease progression or toxicity occurred. **Results:** 46 patients (28 M, 18 F) received 247 cycles of therapy. 37 patients had GBM, 9 AA. Prior treatment was radiation (N=46) and chemotherapy (N=12). No patient received prior TMZ. Median age was 54 years (range 34–74). No dose-limiting toxicity was observed. Hematologic toxicity was mild with Grade 3/4 neutropenia occurring in 3/235 cycles and Grade 3 thrombocytopenia in 3/235 and did not recur following TMZ dose reduction. Grade 1/2 constipation was common, occurring in 28% of patients. No thrombotic events occurred. Overall response rate after 6 cycles was 72%, with 1/18 (5.6%) CR, 7/18 (38.9%) PR, 5/18 (27.8%) SD, and 5/18 (27.8%) PD. Average duration of response was 6 months (range 2–15). Median survival (MS) from time of trial entry for recurrent disease was 8 months (8 months for GBM, 10 months for AA). MS from initial tumor diagnosis was 15 months (15 months GBM, 23 months AA). **Conclusion:** A regimen of twice-daily TMZ and CEL is safe and potentially effective for the treatment of recurrent/progressive GBM and AA. This combination warrants further study, especially in patients newly diagnosed, given the current use of TMZ in newly diagnosed GBM and the possible value of COX-2 inhibitors in the upfront setting.

#### Author Disclosure

Employment or Leadership	Consultant or Advisory Role	Stock Ownership	Honoraria	Research Funding	Expert Testimony	Other Remuneration
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