

PubMed

Display Settings: Abstract[Cancer](#). 2005 Jan 15;103(2):329-38.

Phase II trial of irinotecan plus celecoxib in adults with recurrent malignant glioma.

Reardon DA, Quinn JA, Vredenburgh J, Rich JN, Gururangan S, Badruddoja M, Herndon JE 2nd, Dowell JM, Friedman AH, Friedman HS.

Department of Surgery, Duke University Medical Center, Durham, North Carolina 27710, USA. reard003@mc.duke.edu

Abstract

BACKGROUND: In the current study, the authors report a Phase II trial of irinotecan (CPT-11), a topoisomerase I inhibitor active against malignant **glioma** (MG), with **celecoxib**, a selective COX-2 inhibitor, among MG patients with recurrent disease.

METHODS: Patients with MG at any type of recurrence received CPT-11, administered as a 90-minute intravenous infusion on Weeks 1, 2, 4, and 5 of each 6-week cycle plus **celecoxib**, which was administered continuously at a dose of 400 mg twice a day. CPT-11 was given at a dose of 350 mg/m² for patients receiving enzyme-inducing antiepileptic drugs (EIAEDs) and at a dose of 125 mg/m² for those patients not receiving EIAEDs. Assessments were performed after every cycle. The primary endpoint was radiographic response and the secondary endpoints were progression-free survival (PFS), overall survival (OS), and therapeutic safety.

RESULTS: Thirty-four of the 37 patients enrolled in the current study (92%) were diagnosed with recurrent GBM and 3 patients (8%) were diagnosed with recurrent anaplastic astrocytoma (AA). Twenty-one patients were receiving EIAEDs and 16 patients were not. The median follow-up time was 76.9 weeks. Concomitant CPT-11 plus **celecoxib** was found to be well tolerated and safe. Hematologic toxicities of \geq Grade 3 (according the second version of the Common Toxicity Criteria of the National Cancer Institute) reportedly complicated 8.6% of treatment courses. Grade 3 diarrhea, the most commonly reported nonhematologic toxicity, occurred with equal frequency (8%), regardless of whether the patient was receiving EIAED. Six patients (16%), all whom were diagnosed with recurrent GBM, achieved an objective radiographic response whereas an additional 13 patients (35%) achieved stable disease. The median PFS was 11.0 weeks and the 6-month PFS was reported to be 25.1%. The median OS was 31.5 weeks.

CONCLUSIONS: The results of the current study confirm that CPT-11 plus **celecoxib** can be safely administered concurrently at full dose levels, and that this regimen has encouraging activity among heavily pretreated patients with recurrent MG.

(c) 2005 American Cancer Society.

PMID: 15558802 [PubMed - indexed for MEDLINE] [Free full text](#)

[+](#) [Publication Types, MeSH Terms, Substances, Grant Support](#)

[+](#) [LinkOut - more resources](#)