



Topotecan as a radiosensitizer in the treatment of children with malignant diffuse brainstem gliomas.

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BACKGROUND: The current Phase II study was conducted to evaluate the survival and toxicity observed in children with newly diagnosed brainstem gliomas who were treated with the daily radiotherapy with topotecan used as a radiosensitizer. **METHODS:** Eligible patients were those ages 3-18 years with previously untreated tumors arising in the pons diagnosed within the previous 6 months. Histologic confirmation was not mandatory provided that the clinical and magnetic resonance imaging findings were typical for a diffusely infiltrating brainstem lesion. Treatment was comprised of a 6-week course of topotecan administered intravenously at a dose of 0.4 mg/m²/day over 30 minutes within 1 hour before irradiation. Radiotherapy was comprised of a once-daily treatment of 1.8 grays (Gy) per fraction to a total dose of 54 Gy. **RESULTS:** Thirty-two patients were included in the current study between August 2000 and October 2002. All patients completed the combined treatment in accordance with the treatment design. Only partial responses were observed, occurring in 40% of the patients. The 9-month and 12-month survival rates were 34.4% +/- 8% and 25.5% +/- 8%, respectively. The median duration of survival for these 32 patients was 8.3 months. An intratumoral cystic/necrotic change was observed in five patients, with clinical impairment noted in two patients. One intratumoral hemorrhage occurred during radiotherapy, and was associated with transitory neurologic impairment. **CONCLUSIONS:** The findings of the current study regarding newly diagnosed brainstem glioma patients treated with topotecan given as a radiosensitizing agent did not reproduce the encouraging results obtained in preclinical studies. Therefore, the concomitant combination of topotecan and radiotherapy at this schedule and these doses cannot be recommended for the treatment of patients with brainstem gliomas. Cancer 2005. (c) 2005 American Cancer Society.

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