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A Phase II feasibility study of oral etoposide given concurrently with radiotherapy followed by dose intensive adjuvant chemotherapy for children with newly diagnosed high-risk medulloblastoma (protocol POG 9631): A report from the Children's Oncology Group.

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Abstract

BACKGROUND: Children with high-risk medulloblastoma historically have had a poor prognosis. The Children's Oncology Group completed a Phase II study using oral etoposide given with radiotherapy followed by intensive chemotherapy.

PROCEDURE: Patients enrolled in the study had high-risk disease defined as ≥ 1.5 cm² of residual disease postsurgery or definite evidence of central nervous metastasis. All patients underwent surgery followed by radiotherapy. During radiation, the patients received oral etoposide (21 days on, 7 off) at an initial dose of 50 mg/m² per day (treatment 1), which was reduced to 35 mg/m² per day (treatment 2) due to toxicity. After radiotherapy, the patients received chemotherapy with three cycles of cisplatin and oral etoposide, followed by eight courses of cyclophosphamide and vincristine.

RESULTS: Between November 1998 and October 2002, 53 patients were accrued; 15 received treatment 1 and 38 treatment 2. Forty-seven patients (89%) were eligible. Response to radiation was excellent, with 19 (40.4%) showing complete response, 24 (51.1%) partial response, and four (8.5%) no recorded response. The overall 2- and 5-year progression-free survival (PFS) was $76.6 \pm 6\%$ and $70.2 \pm 7\%$, respectively. The 2- and 5-year overall survival (OS) was $80.9 \pm 6\%$ and $76.6 \pm 6\%$, respectively. Clinical response postradiation and PFS/OS were not significantly different between the treatment groups. There was a trend toward a difference in 5-year PFS between those without and with metastatic disease ($P = 0.072$).

CONCLUSIONS: Oral etoposide was tolerable at 35 mg/m² (21 days on and 7 days off) when given during full-dose irradiation in patients with high-risk medulloblastoma with encouraging survival data.

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KEYWORDS: high-risk medulloblastoma; irradiation; oral etoposide; pediatric neuro-oncology

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