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Phase II Trial of Irinotecan in Children With Refractory Solid Tumors: A Children's Oncology Group Study

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Purpose: A phase II study was performed to determine the efficacy of irinotecan (IRN) in children with refractory solid tumors. Secondary objectives were to evaluate toxicity, pharmacokinetics, pharmacodynamics, and *UGT1A1* genotype.

Patients and Methods: A total of 181 patients were enrolled, of whom 171 were eligible. Patients received IRN 50 mg/m²/d for 5 days repeated every 3 weeks. Pharmacokinetic studies and *UGT1A1* genotyping were performed.

Results: Of 161 patients assessable for response, one patient with hepatoblastoma had a complete response, with partial responses observed in patients with medulloblastoma (n = 4), rhabdomyosarcoma (n = 1), neuroblastoma (n = 1), and germinoma (n = 1), for an overall response rate of 5%. Grade 4 neutropenia and grade 3 to 4 diarrhea occurred in less than 7% of the courses administered. Pharmacokinetic studies were available for 79 patients. The mean ± standard deviation IRN plasma clearance was 374 ± 148 mL/min/m², with median relative extent of conversion and relative extent of glucuronidation of 0.05 (range, 0.01 to 0.25) and 2.24 (range, 0.39 to 9.6), respectively. No association between *UGT1A1* genotype (n = 61) and toxicity or pharmacokinetic parameters was observed.

Conclusion: IRN 50 mg/m²/d for 5 days every 21 days is well tolerated, but was not effective as a single agent in a spectrum of solid tumors, with the possible exception of patients with medulloblastoma (16% response rate). There was no association between *UGT1A1**28 genotype and toxicity or pharmacokinetic parameters.

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Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

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