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Pharmaceutical Update

Results of a randomized intergroup clinical trial comparing the chemotherapeutic agent fludarabine (Fludara, Berlex Laboratories) with chlorambucil were presented at the American Society of Hematology conference held in Seattle, Wash., in December. Fludarabine performs impressively in previously untreated patients with active chronic lymphocytic leukemia (CLL) when compared with chlorambucil, the drug most commonly used. Fludarabine is effective as second-line therapy in B-cell chronic lymphocytic leukemia and first-line treatment in low-grade non-Hodgkin's lymphoma.

Over a span of three-and-one-half years, more than 450 intermediate-risk and high-risk patients were accrued to compare the efficacy of fludarabine (F) 25 mg/m^2 by half-hour IV infusion daily from days one to five every four weeks versus chlorambucil (C) 40 mg/m^2 by mouth on day one every four weeks. Initially a third randomized arm combined the two drugs (F [20 mg/m^2] and C [20 mg/m^2]) but was closed when an interim analysis showed unacceptably high hematologic toxicity and a response rate no better than that achieved by fludarabine alone. The study, with a primary endpoint of complete remission, was comprised of two phases: patients showing beneficial response received the assigned therapy for a maximum of twelve months, and nonresponding patients and those relapsing within six months were crossed over to the alternate therapy.

Of 233 evaluable patients, those in the fludarabine arm experienced a 36 percent complete remission rate, compared with 9 percent with chlorambucil. Fludarabine achieved a combined complete and partial response rate of 64 percent. It is too early to compare response duration and survival. Overall, both drugs were well tolerated with no significant difference between their toxicity profiles.