

DECITABINE IN OLDER PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA (AML)

Abstract No: 7021

Background

Advanced myelodysplasia and AML are age-related diseases with known poor prognosis in patients over age 60. AML is defined by World Health Organization (WHO) criteria as patients with $\geq 20\%$ blasts in the bone marrow. SEER database analysis has indicated that 64% of AML patients over age 65 go untreated, other than with supportive care. Their median survival is 1.7 months. The main reason for this reluctance to treat is perceived toxicity of chemotherapy in this age group. Decitabine is a hypomethylating agent that provides a low-intensity alternative for patients with myeloid malignancies.

Methods

We reviewed patients with $\geq 20\%$ blasts in the bone marrow treated on a randomized

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study of decitabine vs. supportive care in myelodysplastic syndromes, and similar patients enrolled on two consecutive studies of decitabine alone or in combination with valproic acid, conducted at MD Anderson Cancer Center. Response to decitabine was analyzed by International Working Group criteria.

Results

Overall, there were 33 patients with the WHO criteria of AML that were treated with decitabine alone (23 patients) or in combination with valproic acid (10 patients) as first-line therapy. There were 20 men (61%) and their median age was 72, range 39 to 85. Median bone marrow blasts at study entry was 26%, and 14 (42%) had $>30\%$ blasts. There were three different schedules of decitabine IV, which

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gave a total of 100-150 mg/m²/course over 3-10 days. Of the 33 patients treated, there were 8 CRs (24%) and 9 marrow CR/PR/Hematologic improvement (27%) for a total response rate of 17 (52%). Overall mortality at 4 weeks and 8 weeks was 3% and 15%, respectively. At a median follow-up of 20 months, median survival of the entire group was 12.6 months (95% CI: 6.5-23.0), and 2-year survival was 25% (95% CI: 13-48), which compares favorably to reported AML survival in this age group in the United States.

Conclusions

We conclude that decitabine is an effective and less toxic treatment in this AML age group and may prolong survival compared with supportive care. ★

A PHASE II STUDY OF NILOTINIB ADMINISTERED TO PATIENTS WITH IMATINIB RESISTANT OR INTOLERANT CHRONIC MYELOGENOUS LEUKEMIA (CML) IN CHRONIC PHASE (CP), ACCELERATED PHASE (AP) OR BLAST CRISIS (BC) WHO ALSO FAILED DASATINIB

Abstract No: 7038

Background

Nilotinib and dasatinib are two new second generation tyrosine kinase inhibitors used in the treatment of imatinib-resistant/intolerant CML. There is limited data

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regarding the efficacy and safety of these therapies when given sequentially.

Methods

This phase II open-label study was

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designed to evaluate the safety and efficacy of nilotinib at a dose of 400mg BID in CML-CP, -AP, and -BC pts who previously received and either failed or were

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