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Hydroxyurea, azacitidine and gemtuzumab ozogamicin therapy in patients with previously untreated non-M3 acute myeloid leukemia and high-risk myelodysplastic syndromes in the elderly: results from a pilot trial

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Abstract

Elderly patients with acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS) have a poor prognosis due to low response rates (26–46%) to standard chemotherapy and high treatment-related mortality (11–31%). In this Phase II study, we used a combination of hydroxyurea (HU), azacitidine and low dose gemtuzumab ozogamicin (GO) to assess its efficacy and toxicity in this group of

patients. Twenty patients with non-M3 AML and MDS were treated with this regimen. The treatment was begun with HU 1500 mg orally twice daily to lower white blood cell count below 10,000/μL, followed by azacitidine 75 mg/m^2 subcutaneously for 7 days and GO 3 mg/m^2 on day 8. Patients who achieved complete remission (CR) received a consolidation course. The median age of patients was 76 years. Eleven patients (55%) were treated in the outpatient setting. Fourteen (70%) achieved a CR, three of which were incomplete (CRi). The median duration of remission was 8 months and median survival was 10 months. Performance status of 0–1 was associated with high complete response rate. Overall toxicity was acceptable with only one (5%) early death due to disease progression. The combination of HU, azacitdine and GO appears to be a safe and effective regimen in the treatment of AML and high risk MDS in the elderly. These results need to be confirmed in a larger cohort of patients.

Keywords:

Acute myeloid leukemia | azacitidine | gemtuzumab ozogamicin