

Leukemia & Lymphoma >

Volume 49, 2008 - [Issue 11](#)

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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

Sucha Nand , John Godwin, Scott Smith, Kevin Barton, Laura Michaelis, Serhan Alkan, ... [show all](#)

Pages 2141-2147 | Received 16 Jun 2008, Accepted 27 Aug 2008, Published online: 01 Jul 2009

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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/ $\mu\text{L}$ , followed by azacitidine 75  $\text{mg}/\text{m}^2$  subcutaneously for 7 days and GO 3  $\text{mg}/\text{m}^2$  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, azacitidine 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

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