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Azacitidine maintenance after intensive chemotherapy in older patients with acute myeloid leukemia – final analysis of the HOVON97 study

Anna Bartus Stephanie Hill | Jan 16, 2019

On 10 January 2018, Gerwin Huls from the Department of Hematology, University Medical Center Groningen, Groningen, the Netherlands, and colleagues published the final analysis of the HOVON97 study in *Blood*. This phase III study evaluated the value of azacitidine as postremission therapy in older patients (≥ 60 years) with acute myeloid leukemia (AML) or myelodysplastic syndrome with refractory anemia with excess blasts (MDS-RAEB) in CR/CRi after receiving at least 2 cycles of intensive chemotherapy.

Patients were randomized 1:1 to receive either azacitidine (n = 56 patients; median age = 69 years [range, 64–81]; maximum of 12 cycles of azacitidine at a dose of 50 mg/m^2 sc) or no further treatment (n = 60; median age = 69 years [range, 60–79]). The primary endpoint of the study was disease-free survival (DFS). The secondary endpoint was overall survival (OS).

Key findings:

- Median follow-up time: 41.4 months
- At least one cycle of azacitidine was administered to 55 patients, four cycles to 46 patients and 12 cycles to 35 patients
- 1-year DFS in the azacitidine maintenance arm and the observation arm: 64% *vs* 42%, *P* = 0.04
- 24-month and 36-month DFS in the azacitidine maintenance arm and the observation arm: 44% and 32% *vs* 20% and 16%
- 1-year OS was not significantly different in the azacitidine maintenance arm and the observation arm: 84% *vs* 70%, *P* = 0.69
- There were differences observed in the use of salvage therapy after relapse between the two cohorts: rescue treatment was administered more frequently in the observation arm (n = 32 patients) than in the azacitidine arm (n = 9 patients)

Taken together, azacitidine maintenance after CR following intensive chemotherapy demonstrated positive clinical activity and showed superior DFS in newly diagnosed, heavily treated older patients with AML. The authors questioned that why the improvement in DFS did not translate into a significant benefit in OS. They stated that “firstly, the trial was not powered to assess differences in OS between treatment groups. Secondly, the markedly greater frequency of the use of salvage treatment at first relapse in the observation arm may have confounded the analysis of OS.”

Reference

1. Huls G. et al. Azacitidine maintenance after intensive chemotherapy improves DFS in older AML patients. Blood. 2019 Jan 10. DOI: 10.1182/blood-2018-10-879866. [Epub ahead of print].
