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ELEVENTH ANNUAL MEETING

REAL-WORLD EFFICACY AND HEMATOLOGIC TOXICITY OF AZACYTIDINE AND VENETOCLAX IN A COHORT OF ELDERLY PATIENTS WITH NEWLY-DIAGNOSED ACUTE MYELOID LEUKEMIA UNFIT FOR INTENSIVE CHEMOTHERAPY

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INTRODUCTION

Treatment with venetoclax (VEN) and azacytidine (AZA) changed the treatment paradigm of acute myeloid leukemia (AML) in elderly patients unfit for intensive chemotherapy (IC).

Treatment with AZA/VEN is reimbursed by the Polish public healthcare system since September 2022.

AIM

Determination of real-world efficacy of AZA/VEN in patients unfit for IC and the frequency of serious hematologic toxicities related to this treatment regimen.

PATIENTS AND METHOD

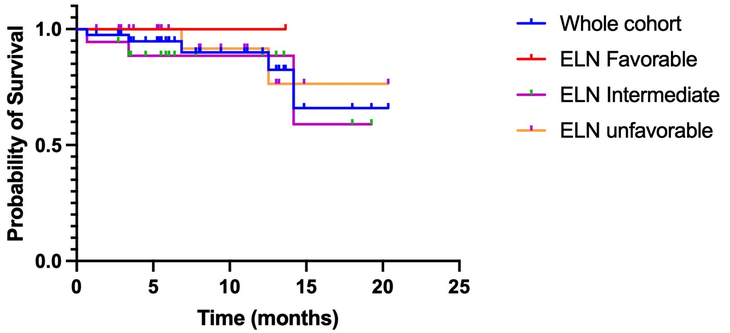
- Retrospective assessment of CR/CRi, ORR, EFS, OS and frequency of grade 3 and 4 hematologic toxicities in elderly patients with newly diagnosed AML treated with AZA/VEN as first line therapy.
- Overall, 40 patients received AZA/VEN as first-line treatment for AML.
- 24 patients were female, 16 were male.
- 1 patient was ELN favorable risk, 18 patients were intermediate risk and 21 were unfavorable risk.
- The median age was 72 years (age range: 57-82).
- In the unfavorable group, nine patients had a complex karyotype and two patients had *TP53* mutations.
- **The median observation time was 6.63 months** (range: 0.68-19.25 months).

RESULTS

- Detailed results for each risk group in the cohort are shown in Table 1.
- In total, 26 patients achieved CR/CRi (65%) including 11 patients with unfavorable risk disease and 14 patients with intermediate risk disease.
- The ORR was 70% and OS was 90%.
- Median EFS and OS were not yet reached.
- Both patients with *TP53* mutations were primary refractory to treatment.
- 36 patients (90%) suffered of at least one grade 3 or 4 hematologic toxicity.
- In total, four deaths occurred, two in the intermediate-risk group, and two in the unfavorable risk group. This accounts for the shape of the probability of survival curve shown in Graph 1.

	CR/CRi (%)	ORR (%)	EFS (%)	OS (%)
Favorable-risk ELN (n=1)	100	100	100	100
ELN intermediate risk (n=18)	78	83	67	89
ELN unfavorable risk (n=21)	52	62	57	90
Whole cohort (n=40)	65	70	63	90

Table 1. CR/CRi, ORR, EFS and OS data for each patient subgroup and the whole cohort.



Graph 1. Probability of survival in the patient cohort

LIMITATIONS

- Relatively short observation time – data will be more accurate when updated and reviewed in a few months.
- Small patient cohort and few patients in the ELN favorable risk category.
- Difficulty with obtaining information on MRD status – impossible to include in this publication.

CONCLUSIONS

- Real-world responses to AZA/VEN treatment are high and similar to those in clinical studies.
- Treatment efficacy is encouraging.
- Response rates and remission rates are related to the disease risk group and patients in the unfavorable risk group.
- Grade 3 and 4 toxicities occur almost always, warranting dose modifications, careful observation and prompt interventions.

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