(PS1541) OUTCOMES OF PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA TREATED WITH VENETOCLAX AND AZACITIDINE IN REAL-WORLD BELGIAN CLINICAL PRACTICE

Topic: 04. Acute myeloid leukemia - Clinical

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Background

In Belgium, venetoclax with azacitidine (VEN+AZA) is approved for the treatment of adult patients (pts) with newly-diagnosed (ND) acute myeloid leukemia (AML) who are ineligible for intensive chemotherapy. This study is part of the AML Real world evidenCe (ARC) Initiative, an international chart review study.

Aims

To assess real-world outcomes of Belgian pts with ND AML receiving VEN+AZA and evaluate the impact of disease characteristics and antifungal (AF) use on these outcomes.

Methods

The Belgian cohort of the ARC Initiative comprised adult pts with ND AML treated with VEN+AZA unfit for intensive treatment on or after 1 January 2022. Patient and disease characteristics included age, sex, type of AML (de novo vs secondary), European LeukemiaNet (ELN) 2017 risk classification, Eastern Cooperative Oncology Group (ECOG) performance status, and genetic mutations. Outcomes included physician-reported composite complete remission (CRc; i.e., best response of complete remission, complete remission with partial haematologic recovery, or complete remission with incomplete marrow recovery), overall survival (OS), event-free survival (EFS), and transfusion independence (TI). Duration of CRc (DoR), OS, and EFS were analysed using Kaplan-Meier analyses. Subgroup analyses were performed based on disease characteristics, namely ELN risk classification (intermediate vs adverse) and type of AML.

Results

In total, 92 Belgian pts were included in this study (median age: 75.9 years; 33.7% female; 46.7% de novo AML; 53.3% secondary AML). Most pts had ELN adverse risk (59.8%), and 28.3% were intermediate risk. Among pts with ECOG performance status reported (n=69), 30.4% had a performance status of ≥2. Of pts with mutational testing reported (n=84), 26.2% had mutations in *TP53*, 13.1% in *NPM1*, and 9.5% had $FLT3^{ITD}$. Median follow-up duration was 6.7 months (range: 0.1–28.4 months), median observed treatment duration was 5.4 months (range: 0.1–28.2 months). Strong/moderate CYP3A4 inhibitor AFs were used by 39.1% of pts in cycle 1. Overall, 57.1% of pts achieved TI during VEN+AZA treatment. Median OS was 11.9 months (95% confidence interval [CI]: 8.0; 17.3) and median EFS was 10.3 months (95% CI: 6.7; 13.3). Most pts (62.0%) achieved CRc, with a median DoR of 16.2 months (95% CI: 7.6; not reached [NR]). Median time to CRc was 1.1 months (range: 0.5-9.3 months). DoR was similar between pts with prophylactic AF (16.6 months [95% CI: 3.7; NR]) vs no AF (16.2 months [95% CI: 5.8; NR]) in cycle 1. While pts with ELN adverse risk had

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numerically higher rates of achieving CRc, median OS and EFS were numerically higher among pts with intermediate risk (**Table 1**). Median OS and EFS were numerically higher among pts with de novo vs secondary AML; regardless, rates of CRc and DoR were similar (**Table 1**). Sample size was limited in some subgroups.

Table 1. Outcomes by disease characteristics

		Type of AML		ELN 2017 risk classification	
	Overall N = 92	De novo AML N = 43	Secondary AML N = 49	Intermediate risk N = 26	Adverse risk N = 55
Patients achieving CRc[1], N (%)	**57 (62.0%)**	**26 (60.5%)**	**31 (63.3%)**	**13 (50.0%)**	**35 (63.6%)**
CR	30 (32.6%)	14 (32.6%)	16 (32.7%)	8 (30.8%)	16 (29.1%)
CRi	16 (17.4%)	9 (20.9%)	7 (14.3%)	2 (7.7%)	11 (20.0%)
CRh	11 (12.0%)	3 (7.0%)	8 (16.3%)	3 (11.5%)	8 (14.5%)
Duration of CRc[1] (months), median (95% CI)	16.2 (7.6; NR)	16.2 (6.3; NR)	15.0 (6.9; NR)	NR (9.1; NR)	15.0 (3.9; 19.6)
Time to CRc[1] (months), mean ± SD [median]	2.0 ± 2.0 [1.1]	2.1 ± 1.9 [1.6]	1.9 ± 2.1 [1.0]	2.2 ± 2.1 [1.2]	1.9 ± 2.1 [0.9]
OS (months), median (95% CI)	**11.9 (8.0; 17.3)**	**17.7 (9.0; NR)**	**9.4 (5.7; 16.2)**	**16.2 (6.7; NR)**	**9.0 (5.3; 17.3)**
EFS (months), median (95% CI)	**10.3 (6.7; 13.3)**	**11.0 (6.7; 20.4)**	**8.0 (4.1; 13.3)**	**13.3 (6.7; NR)**	**6.7 (3.9; 10.6)**

Abbreviations: *AML: acute myeloid leukaemia; CI: confidence interval; CR: complete remission; CRc: composite complete remission; CRh: complete remission with partial haematologic recovery; CRi: complete remission with incomplete marrow recovery; EFS: event-free survival; ELN: European LeukemiaNet; NR: not reached; OS: overall survival; SD: standard deviation.*

Note:
[1] CRc was defined as a best response of CR, CRh, or CRi.

Summary/Conclusion

These findings highlight the real-world effectiveness of VEN+AZA in treating ND AML pts in Belgium. Most pts achieved a response quickly. AFs were frequently used in cycle 1 and did not appear to impact DoR; ELN 2017 did not appear to be consistently associated with outcomes, although this was limited by sample size. Finally, most pts treated with VEN+AZA achieved TI, which may contribute to improved quality of life.