Abstract: P1788

Title: TREATMENT PATTERNS AND OUTCOMES OF VENETOCLAX+HYPOMETHYLATING AGENTS VS HYPOMETHYLATING MONOTHERAPY IN PATIENTS ENROLLED IN MEDICARE ADVANTAGE WITH ACUTE MYELOID LEUKEMIA UNFIT FOR INTENSIVE THERAPY

Abstract Type: e-Poster Presentation

Topic: Acute myeloid leukemia - Clinical

Background:

Acute myeloid leukemia (AML) is a common type of leukemia found in adults and is primarily found among those aged 65 and over. The appropriate treatment for newly diagnosed AML is informed by patient fitness to receive intensive therapy. Among individuals unfit for intensive chemotherapy (IC), venetoclax plus hypomethylating agent (VEN+HMA) regimens have become the standard of care based on data from the phase 3 VIALE-A study. Data on the real-world translation of the clinical benefits of VEN+HMA in the Medicare Advantage (MA) setting continues to be needed.

Aims:

The aim of this study was to examine real-world treatment patterns and survival among individuals in the US enrolled in a MA plan. Individuals newly diagnosed with AML and classified as unfit for IC who received first line treatment (1L Tx) with VEN+HMA or HMA monotherapy (HMA) were identified for this analysis.

Methods:

This was a retrospective analysis including data from November 2018 – June 2022 using administrative claims from the Humana MA population. Humana is the second largest MA insurer in the United States, with more than 5 million members enrolled as of 31 December 2022. Individuals with a new diagnosis of AML and considered unfit for IC were identified based on age \geq 75 years and/or comorbidities per the Ferrara criteria. The index was the date of 1L Tx initiation. Demographic, clinical, and treatment pattern characteristics of the individuals receiving VEN+HMA or HMA as 1L Tx were summarized and compared. Kaplan-Meier methods and a covariate-adjusted Cox proportional hazards model were used to estimate and compare overall survival (OS). For individuals receiving VEN+HMA, bone marrow biopsy (BMB) and azole use during 1L Tx were described, and observed duration of Tx (DOT) was summarized, stratified by whether a BMB was performed during 1L Tx.

Results:

There were 693 patients newly diagnosed with AML and evidence of 1L Tx, and 531 (76.6%) patients were classified as unfit. Among the unfit, 224 initiated VEN+HMA and 98 initiated HMA; the rest received other treatments such as IC or other targeted regimens. Demographic characteristics and comorbidity burden were generally similar between the VEN+HMA and HMA groups (mean age 76.5 \pm 5.9 vs 78.0 \pm 6.2, P=0.045; Charlson score 2.5 \pm 2.2 vs 2.7 \pm 2.1, P=0.529) (see Table 1). Median time to 1L Tx initiation with VEN+HMA was 11 days and 18 days for HMA (log-rank P=0.003). Median follow-up time was 10.2 months for VEN+HMA and 8.4 months for HMA. Median DOT with VEN+HMA was 4.9 months and 4.8 months for HMA. Median OS for VEN+HMA compared to HMA was 14.2 vs 9.4 months (log-rank P=0.009). The covariate adjusted hazard ratio for all-cause mortality with VEN+HMA vs HMA was 0.69 (95% CI: 0.49–0.95; P=0.025). Age was not associated with OS in the adjusted analyses. During 1L VEN+HMA Tx, 75.9% (n=170) of patients had a BMB post treatment initiation, 51.8% (n=88) of whom received a BMB within 42 days of Tx initiation; median DOT was 5.9 among all those with a BMB vs 2.5 months for individuals without a BMB; 57.1% (n=128) received an azole.

Summary/Conclusion:

In this study of individuals classified as unfit for IC, VEN+HMA as 1L Tx was associated with improved OS compared to HMA monotherapy. Age was not associated with poor outcomes in terms of OS. Individuals receiving any BMB assessment during 1L Tx of VEN+HMA were observed to have a longer DOT; however, this may be related to the study design, and further analyses are warranted to better understand the potential association between BMB and DOT.

Table 1. Summary of I	Key Baseline	Characteristics	and Outcomes
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Measures	VEN+HMA (N = 224)	HMA Mono (N = 98)	P-value
Baseline characteristics			
Age (years), mean \pm SD	76.5 ± 5.9	78.0 ± 6.2	0.0447
Female sex, n (%)	106 (47.3%)	39 (39.8%)	0.2254
White race, n (%)	173 (77.2%)	70 (71.4%)	0.4466
Dual eligible/low income subsidy, n (%)	34 (15.2%)	11 (11.2%)	0.3872
Deyo-Charlson score, mean ± SD	2.5 ± 2.2	2.7 ± 2.1	0.5289
Elixhauser condition count, mean ± SD	3.9 ± 2.9	4.5 ± 3.1	0.1007
Outcomes			
Time from AML diagnosis to 1L treatment (days), mediana	11	18	0.0027
Overall survival time (months), mediana	14.2	9.4	0.0085
All-cause mortality, HR (95% CI)b	0.69 (0.49-0.95)	ref	0.0245

^aFrom Kaplan-Meter analysis. P-value is from log-rank test; ^bFrom Cox proportional hazard model including the following covariates: age, sex, race, region, population density, Elixhauser comorbidity count (0, 1-2, 3+), time from diagnosis of AML to initiation of first line treatment

Abbreviations: IL, first line; AML, acute myeloid leukemia; CI, confidence interval; HMA, hypomethylating agent; HR, hazard ratio; SD, standard deviation; VEN, venetoclax

Keywords: AML, Survival, Real world data