# Survival and Toxicity Outcomes With Hypomethylating Agent Plus Venetoclax Versus HMA Alone in Higher-Risk Myelodysplastic Syndrome: A Propensity-Matched Retrospective Cohort Study

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## INTRODUCTION

Venetoclax combined with a hypomethylating agent (HMA) has demonstrated activity in myeloid malignancies, but its role in higher-risk myelodysplastic syndrome (HR-MDS) remains uncertain.

The phase 3 VERONA trial did not meet its primary overall-survival endpoint. Comparative observational data may help define outcomes in routine practice, but remain vulnerable to treatment-selection bias.

## AIM

To compare all-cause mortality, infectious and myelosuppressive toxicity, coded AML diagnosis, and major adverse cardiovascular/cerebrovascular events (MACCE) after HMA plus venetoclax versus HMA monotherapy at 6, 12, and 18 months.

## METHOD

Design: Retrospective cohort study with propensity score matching (PSM).

Setting: TriNetX US Collaborative Network (67 HCOs).

Population: Adults with HR-MDS receiving azacitidine, decitabine, or decitabine-cedazuridine.

Cohorts: Venetoclax within +/-14 days of HMA initiation versus no venetoclax within +/-90 days.

Matching: 371 patients per cohort.

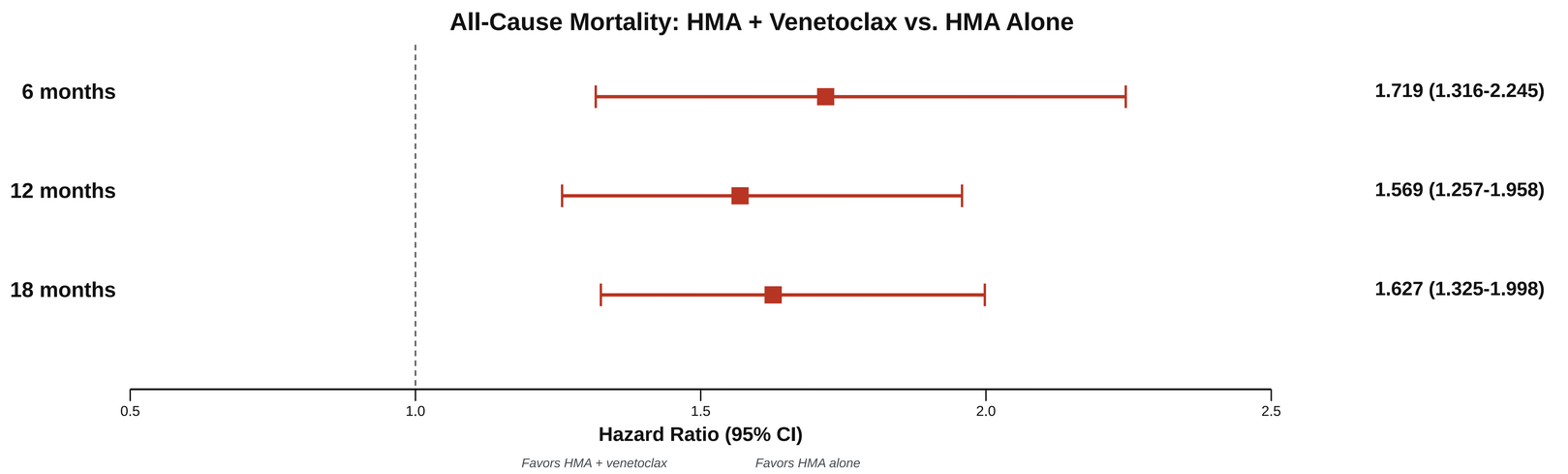
Outcomes: Mortality, sepsis, neutropenia, fever, coded AML diagnosis, and MACCE through 6, 12, or 18 months.

## RESULTS

6 months: Mortality 38.0% vs. 23.5%; HR 1.719 (95% CI 1.316-2.245).

12 months: Mortality 50.9% vs. 36.1%; HR 1.569 (1.257-1.958). Neutropenia 67.9% vs. 54.4%; fever 59.3% vs. 38.5%; sepsis 31.8% vs. 26.4%; MACCE 14.8% vs. 14.6%.

18 months: Mortality 59.3% vs. 42.0%; HR 1.627 (1.325-1.998). Coded AML diagnosis remained more frequent but requires cautious interpretation because blast burden, disease-risk scores, and transformation timing were unavailable.




## CONCLUSIONS

1. HMA plus venetoclax was not associated with improved survival at 6, 12, or 18 months.

2. Mortality remained higher with combination therapy across all three horizons.

3. Neutropenia and fever were consistently more frequent; sepsis was higher at 6 months but not significantly different at 12 or 18 months.

4. The large difference in coded AML diagnosis likely reflects disease severity, diagnostic timing, and residual confounding, not necessarily treatment-caused transformation.

5. These findings support careful patient selection and prospective validation before broader adoption in HR-MDS.

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