REAL-WORLD COMPARATIVE OUTCOMES OF VENETOCLAX PLUS AZACITIDINE VS CYTARABINE-ANTHRACYCLINE INDUCTION IN ACUTE MYELOID LEUKEMIA: A PROPENSITY-MATCHED ANALYSIS OF THE TRINETX GLOBAL COLLABORATIVE NETWORK

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Background

- **Acute myeloid leukemia (AML)** is an aggressive hematologic malignancy with high mortality, particularly in older or medically unfit patients.
- **Venetoclax + azacitidine (Ven+Aza)** has emerged as standard-of-care for AML patients unfit for intensive chemotherapy, following landmark trial results.
- **Cytarabine-anthracycline (Cyta+Anthra)** induction remains standard for fit patients but carries significant toxicity and treatment-related mortality.
- **Real-world comparative data** between these regimens remain limited; most evidence derives from clinical trials with strict eligibility criteria.
- **Objective:** To compare all-cause mortality and remission rates between Ven+Aza and Cyta+Anthra using the **TriNetX Global Collaborative Network** with propensity score matching.

Methods

- **Database:** TriNetX Global Collaborative Network — federated network of **173 healthcare organizations** with real-time EHR data access.
- **Population:** Adults (≥18 years) with myeloid leukemia (**ICD-10: C92.0–C92.5**) diagnosed on or after July 1, 2025.
- **Cohort 1 (Purple):** Venetoclax + Azacitidine | **Cohort 2 (Green):** Cytarabine + Idarubicin or Daunorubicin
- **Propensity Score Matching (PSM):** 1,742 patients identified → 1,629 PSM-eligible → **335 matched pairs (1:1)** on age, sex, race, and comorbidities.
- **Outcomes:** Primary: all-cause mortality; Secondary: remission (ICD-10 C92.41)
- **Statistics:** Risk ratios (RR), 95% CI, Kaplan-Meier, log-rank test, Cox regression.
- **Limitation:** Broad ICD-10 codes may include non-AML subtypes; remission via APL-specific code (C92.41).

Summary

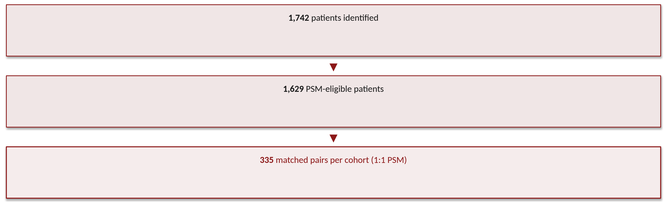
- **Venetoclax + azacitidine** demonstrated **survival equivalent** to intensive cytarabine-anthracycline induction in this real-world propensity-matched analysis.
- **All-cause mortality** was comparable (15.8% vs 15.2%; P = 0.831), with overlapping KM curves through 300 days.
- **Lower remission coding in Ven+Aza arm** (5.1% vs 9.6%; P = 0.026) likely reflects administrative coding differences, not inferior clinical response.
- **Excellent cohort balance achieved** after PSM (SMD < 0.1 for all covariates).

Take-Home Messages

- **Ven+Aza is non-inferior to intensive chemotherapy** in overall survival in a real-world AML population.
- **Remission coding disparities** highlight the critical need for standardized AML response documentation in administrative databases.
- **TriNetX propensity matching** enables robust real-world comparisons across large multi-site networks.
- **Prospective studies with standardized response criteria** are needed to guide treatment selection in diverse AML populations.

Results

- **Cohort Balance:** Mean age 55.8 years; SMD < 0.1 for all covariates post-PSM.
- **All-Cause Mortality:** No significant difference (**15.8% vs 15.2%**; RR 1.04; 95% CI 0.73–1.48; P = 0.831).
- **Overall Survival (KM):** Overlapping curves throughout 300 days (**HR 1.09; P = 0.679**). Day-300 survival: 72.3% vs 72.4%.
- **Remission Coding:** Lower in Ven+Aza (**5.1% vs 9.6%**; RR 0.53; P = 0.026; HR 0.55; log-rank P = 0.040).
- **PSM Distribution:** Post-match score distributions overlap, confirming cohort balance (Fig 1).



Comparative Outcomes

Endpoint	Ven+Aza (n=335)	Cyta+Anthra (n=335)
All-cause mortality	15.8%	15.2%
Risk Ratio (95% CI)	1.04 (0.73–1.48)	Reference
P-value (mortality)	P = 0.831	—
Hazard Ratio (95% CI)	1.09 (0.74–1.59)	Reference
Log-rank P (survival)	P = 0.679	—
Survival at day 300	72.3%	72.4%
Remission coding (C92.41)	5.1%	9.6%
RR – Remission (95% CI)	0.53 (0.30–0.94)	Reference
P-value (remission)	**P = 0.026**	—
HR – Remission (95% CI)	0.55 (0.30–0.98)	Reference
Log-rank P (remission)	**P = 0.040**	—

Table 1. Primary and secondary outcomes after 1:1 PSM. Bold = statistically significant (P<0.05). Ven+Aza = Venetoclax+Azacitidine; Cyta+Anthra = Cytarabine+Anthracycline.

Propensity Score Distribution

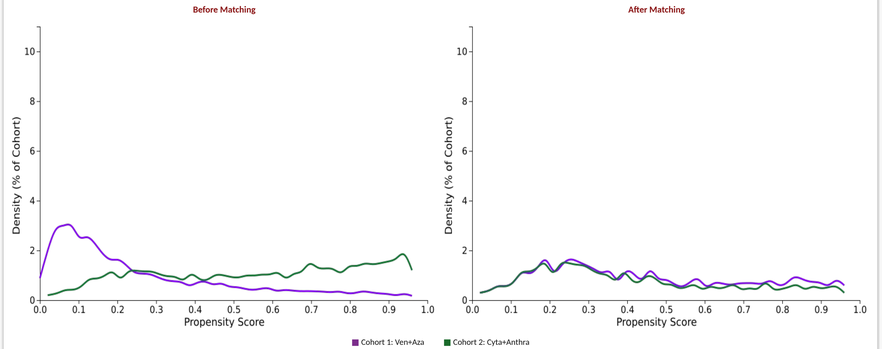


Fig 1. Propensity score density before (left) and after (right) 1:1 matching. Overlapping post-match curves confirm cohort balance.

Outcomes: Mortality & Remission

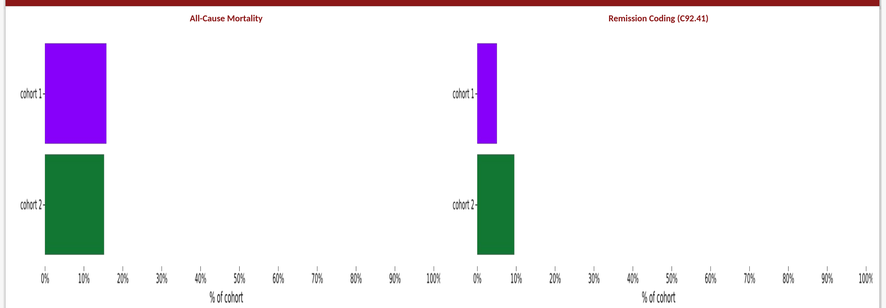


*Fig 2. Bar charts: all-cause mortality (left) and remission coding (right) by cohort. Purple = Ven+Aza; Green = Cyta+Anthra. * = P<0.05.*

Kaplan-Meier Survival Analysis

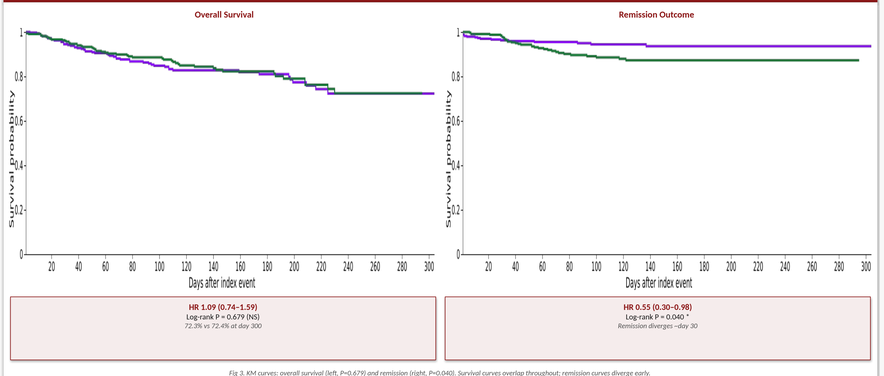


Fig 3. KM curves: overall survival (left, P=0.679) and remission (right, P=0.040). Survival curves overlap throughout; remission curves diverge early.

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