Real-World Data on Clinical Outcomes of Newly Diagnosed Acute Myeloid Leukemia (AML) Patients Treated with Hypomethylating Agents (HMA) plus Shorter Duration of Venetoclax (VEN) At A General Hospital

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Background

- AML is an aggressive myeloid neoplasm often seen in the sixth decade of life.
- The outcomes of older AML patients tend to be poor, given intolerance to standard induction chemotherapy.
- In the phase III VIALE-A study, azacytidine (7 days) in combination with venetoclax (28 days) showed a higher remission rate and overall survival (OS) in older/unfit patients with untreated AML.
- However, the recommended 28-day course of VEN remains a major challenge due to prolonged cytopenia and toxicity.

Objective

- To determine the real-world outcomes of older/unfit AML patients treated with HMA and attenuated duration of VEN therapy in the community setting.

Materials & Methods

- We evaluated the outcomes of newly diagnosed AML patients ≥18 years old treated with HMA plus VEN.
- This was a single-center of AML patients treated at Memorial Hermann Hospital Texas Medical Center from January 1, 2017, to December 31, 2021.
- Clinical outcomes and patient characteristics were extracted from chart review.

Results

Table 1: Baseline Characteristics of AML patients treated with HMA + VEN

Characteristic	N= 18 (%)
Age (years)	Median 72 (range 52-88)
Sex	
Male	11 (61%)
Female	7 (39%)
Race	
White	9 (50%)
African American	5 (28%)
Asian	1 (6%)
ECOG PS	
0	4 (22%)
1	5 (28%)
2	5 (28%)
3	1 (6%)
4	3 (17%)
ELN 2022 Risk Stratification	
Favorable	5 (28%)
Intermediate	2 (11%)
Adverse	11 (61%)
Molecular Characteristics	
NPM1 mutation	3 (17%)
FLT3-ITD mutation	3 (17%)
Induction Regimen	
Decitabine based	17 (94%)
Azacitidine based	1 (6%)

- ECOG PS= Eastern Cooperative Oncology Group Performance Status
- ELN= European LeukemiaNet

Results

Table 2: Response of AML patients treated with HMA + VEN

Response	N= 18 (%)	Composite CR = (CR + CRi)	CR	CRi
Induction Chemotherapy				
HMA + VEN	18	11 (61%)	5 (28%)	6 (33%)
Early Mortality				
<30 days	0			

- CR= Complete response
- CRi= Complete response with incomplete hematologic recovery
- HMA= Hypomethylating agent
- VEN= Venetoclax

- HMA regimens included: decitabine 20 mg/m^2 for 10 days (n=14), decitabine for 5 days (n=3), and azacitidine 75 mg/m^2 for 7 days (n=1).
- Median duration of VEN administration was 7 (range, 4–14) days.
- VEN doses ranged from 100 to 400 mg daily.
- Among 18 response-evaluable patients, 11 (61%) achieved CCR after one cycle of induction chemotherapy (CR, n=5; CRi, n=6).
- Key adverse events included sepsis (28%), respiratory failure (11%), and acute kidney injury (6%).
- There were no deaths within 30 days of induction.
- No patients received allogenic stem cell transplants for consolidation.
- The median OS was 12.5 months.

Discussion

- The use of HMA in combination with a shorter duration of VEN is well tolerated with no induction mortality.
- The response rate and survival outcomes were comparable to the 28-day VEN regimen.
- Our data supports a shorter duration of VEN in combination with HMA.
- Further studies are required to optimize the duration of VEN within the context of this regimen.

Conclusion

- The use of hypomethylating agents as induction therapy in older frail AML patients diagnosed in the frontline setting has demonstrated favorable results in phase 3 randomized studies. The real-world response rates of these regimens at a general hospital have demonstrated consistent findings.

References

- DiNardo CD, et al. Azacitidine and Venetoclax in Previously Untreated Acute Myeloid Leukemia. N Engl J Med. 2020 Aug 13;383(7):617-629.

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