Cladribine, Low-Dose Cytarabine (LDAC), and Venetoclax (VEN) in Older/Unfit Acute Myeloid Leukemia (AML) Patients: A Single-Institution Experience

Binoy Yohannan, Hina Khan, Francis Cervoni-Curet, Adan Rios
Division of Hematology/Oncology, McGovern Medical School, The University of Texas Health Science Center at Houston, TX, USA
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Background

- AML is a disease of the elderly, typically affecting patients older than 65, and treatment is dependent on patient's baseline performance status and ability to tolerate therapies.
- Clinical outcomes of older AML patients tend to be poor and there is an unmet need for novel therapies.
- In a phase II study by Kadia et al., a novel lower intensity regimen consisting of cladribine (5mg/m^2 D1-5), LDAC (20mg SC BID D1-10), and Ven (400mg D1-21) in older/unfit treatment-naïve AML patients demonstrated favorable results.

Objective

- To determine the real-world outcomes of older/unfit AML patients treated with the novel lower intensity regimen in the community setting.

Materials & Methods

- We evaluated the outcomes of newly diagnosed AML patients ≥18 years old treated with cladribine, LDAC, plus VEN.
- This was a single-center study of AML patients treated at Memorial Hermann Hospital Texas Medical Center from January 1, 2021, to January 31, 2023
- Clinical outcomes and patient characteristics were extracted from chart review.

Results

Table 1: Baseline characteristics of AML patients treated with cladribine + LDAC + VEN

Characteristic	**N = 12 (%)**
Age (years)	Median 68.5 (range 40-80)
Race	
White	6 (50%)
African American	4 (33%)
Asian	1 (8%)
Unknown	1 (8%)
ECOG PS	
3-4	7 (58%)
ELN 2022 Risk Stratification	
Favorable	0
Intermediate	4 (33%)
Adverse	8 (67%)
AML	
De novo	10 (83%)
Secondary	2 (17%)

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

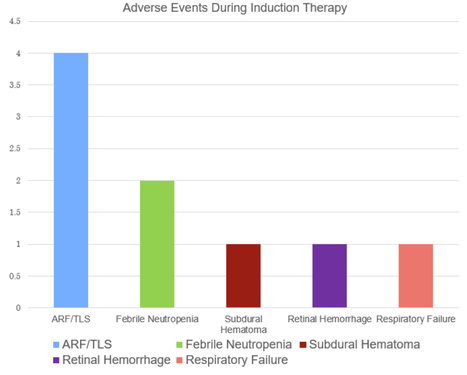
Results

Table 2: Response of AML patients treated with cladribine + LDAC + VEN

Response	**N= 12 (%)**	**Composite CR = (CR + CRi)**	**CR**	**CRi**
Induction Chemotherapy				
Cladribine + LDAC + VEN	12	10 (83%)	6 (50%)	4 (33%)
Early Induction Mortality within 30 days	0			

- CR= Complete response
- CRi= Complete response with incomplete hematologic recovery
- LDAC= Low-dose cytarabine
- VEN= venetoclax

Figure 1: Major adverse events of AML patients treated with cladribine + LDAC + VEN



Results

- The lower intensity regimen consisted of cladribine 5 mg/m^2 on days 1–5 and LDAC 20 mg/m^2 q12h x 10 days.
- The median duration of VEN therapy was 10 days.
- The CR rate was 50% (6/12) and the CCR was 83% (10/12).
- There was no induction mortality.
- No patients received allogenic stem cell transplant (SCT) consolidation.
- The median LFS and OS were 4.5 months and 6.5 months, respectively.

Conclusion

- The cladribine, LDAC, and VEN regimen is well tolerated with high remission rates and low induction mortality in older/unfit AML patients. However, long-term outcomes remain poor in our high-risk AML population, who are ineligible for allogenic SCT.

References

- Kadia TM, et al. Phase II Study of Venetoclax Added to Cladribine Plus Low-Dose Cytarabine Alternating With 5-Azacitidine in Older Patients With Newly Diagnosed Acute Myeloid Leukemia. J Clin Oncol. 2022 Nov 20;40(33):3848-3857.

Contact Information

- Hina.n.khan@uth.tmc.edu

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