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Outpatient-Based Low-Intensity Induction With Sorafenib In *FLT3-ITD*-Mutated Newly Diagnosed Acute Myeloid Leukemia (AML)

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INTRODUCTION

- *FLT3-ITD*-mutated AML is reported in 25%–30% of patients and it is associated with inferior outcomes and early relapse.[1]
- Although transplant remains the treatment of choice, *FLT3* inhibition in addition to induction chemotherapy has shown to have effect on survival outcomes.
- Overall induction mortality was reported to range from 7% to 40 % from various centers across India. [2]

AIM

In this retrospective study we explored the effect of low-intensity triplet therapy as an induction regimen in *FLT3-ITD*-mutated AML.

METHOD

- Study period: June 2022 to April 2023.
- **Regimen used:** Patients have received a cumulative dosage of azacytidine 75 mg/m^2 subcutaneously daily for 7 days and dosed at 100 mg daily. Venetoclax and sorafenib were also given for the similar duration of azacytidine with venetoclax at the dose of 50 mg per day with azole and sorafenib at the dose of 200 mg per day.
- Patients were started on induction after adequate cytoreduction. Cycles were repeated at monthly intervals.

RESULTS

- Seven patients have received this combination regimen in the given study period and herein report the outcomes of **Cycle 1 induction**.
- Median age was 39 years (33 to 59). Out of 7 patients, 3 had diabetes and 1 had hypertension.
- A next-generation sequencing report was available for 4 patients. Co-mutations detected were *NPM1* in 3, *IDH2R140* in 2 and *EZH2* in 1 patient.
- Median duration of venetoclax and sorafenib was 8 days.
- Out of 7 patients, 6 had febrile neutropenia(FN) and 2 required hospitalization(RN). Median absolute neutrophil count recovery time was 28 days.
- **All 7 patients had complete remission.** Minimal residual disease assessment was available for 6 patients and was negative in 4 of them.

CASE NO	AGE	NGS N=4	AV NO OF DAYS	FN	RN	SORA INDUCED HFS	EOI	MRD
1	39	*NPM1,FLT3ITD, IDH2R140*	8d	Y	N	N	CR	CR
2	37	*FLT3ITD,RUNX1, EZH2*	8d	Y	N	N	CR	CR
3	33	*FLT3ITD (BY PCR)*	9d	Y	Y	N	Cri	Cri
4	59	*FLT3ITD (BY NGS)*	7d	Y	N	N	CR	CR
5	32	*FLT3ITD (BY PCR)*	7d	N	N	N	CR	CR
6	50	*NPM1 FLT3ITD (BY PCR)*	8d	Y	Y	**G 2**	CR	CR
7	55	*NPM1,FLT3ITD, IDH2R140*	7d	Y	N	**G1**	CR	CR

CONCLUSIONS

Triple therapy with azacytidine and venetoclax with sorafenib for limited duration causes ***adequate myelosuppression and remains a feasible induction option*** in FLT3-ITD-mutated AML as a bridge to transplant.

REFERENCES

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2.Kayal S, Sengar M, Jain H, Bonda A, George B, Kulkarni UP, Balasubramanian P, Bhurani D, Ahmed R, Biswajit D, Jayachandran PK. Induction related mortality in acute myeloid leukemia: multivariate model of predictive score from the Indian Acute Leukemia Research Database (INwARD) of the Hematology Cancer Consortium (HCC). Blood. 2019 Nov 13;134:2615..

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