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PRELIMINARY RESULTS OF FLAG VENETOCLAX INDUCTION IN NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA: A SINGLE CENTRE STUDY

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INTRODUCTION

In LMICs like India, the common '3+7' induction regimen has shown poor tolerance with a higher incidence of morbidity and induction mortality in AML patients among all age groups. FLAG (fludarabine, cytarabine, and GCSF), along with Venetoclax, has been an impressive anthracycline-free alternative backbone.

AIM

This study aims to evaluate the safety and efficacy of FLAG-Venetoclax induction in newly diagnosed, treatment-naïve AML patients eligible for intensive therapy. **Endpoints:**

- To assess the rate of CR at the end of one induction cycle.
- Flowcytometry-based MRD negativity at the end of induction.

METHOD

- Single-center retrospective analysis of newly diagnosed AML patients (18–60 years) treated from Jan 2023 to Mar 2025.
- All patients received 4-day FLAG induction with Venetoclax (400 mg daily) for 7–10 days.
- Addition of Midostaurin for 2 weeks during induction was done for patients with FLT3 mutation.

RESULTS

28 patients were included in this study (median age 37 years).

- ELN 2022 risk stratification:

- Favorable-risk: n=8
- Intermediate-risk: n=6
- Adverse-risk: n=14

- Response to Induction Therapy:

- CR rate of 89.2% (25/28) at the end of 1st cycle of induction.

- CR rates by risk group:

- Favorable-risk: 100%
- Intermediate-risk: 100%
- Adverse-risk: 78.5%.

MRD negative rates by risk group:

- Favorable-risk: 87.5%
- Intermediate-risk: 83.3%
- Adverse-risk: 57.1%.

- TP53 mutation is associated with a poor response to FLAG-Ven induction.
- Allogeneic hematopoietic stem cell transplantation was performed in 15 patients.
- No induction-related mortality occurred within the first 28 days of treatment.

Table 1. Baseline characteristics of 28 AML patients

Characteristic	N (%)
Total number of patients	28
Median age, years (range)	37 (19–59)
Gender	
Male	15 (53.5%)
Female	13 (46.5%)
ECOG	
• 0-1	10
• 2	16
• 3	02

Table 2. Outcomes during induction

Haematological adverse events, Grade ≥ 3	
Grade 3 Neutropenia	100% (28/28)
Median duration for cytopenia	
ANC<1000/uL	16 days
Platelets<20000/uL	17.5 days
Median duration of GCSF support	12 days
Induction mortality	
At 2 weeks	Nil
At 4 weeks	Nil

CONCLUSIONS

FLAG-Venetoclax induction is a promising anthracycline-free regimen showing impressive induction outcomes in AML patients in all three risk groups. The study warrants further evaluation in large prospective trial setting.

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