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RESULTS OF TREATMENT WITH HYPOMETHYLATING AGENTS VERSUS HYPOMETHYLATING AGENTS/VENETOCLAX IN PATIENTS WITH AML. SINGLE-CENTER EXPERIENCE.

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INTRODUCTION

Acute myeloid leukemia (AML) is prevalent in adults over 65, comprising 55 to 75% of cases. The 3-year survival rate is just 10% due to poor genomic factors, comorbidities, and treatment toxicity. Less intensive hypomethylating agent (HMA) regimens result in lower complete remission (CR) rates and overall survival (OS) under one year. Combining HMA with venetoclax (VEN) enhances CR and OS.

OBJECTIVE

- Compare the overall response (CR and CRi), event-free survival (EFS), and overall survival (OS) in adult patients with AML treated with HMA vs. HMA/VEN.
- Evaluate transfusion support, length of hospitalization, and days of antibiotics within the first 60 days of treatment.

MATERIALS & METHODS

- Retrospective cohort study.
- All patients aged 18 years or older with a diagnosis of previously untreated AML, ineligible for intensive treatment, who received treatment with HMA or HMA/VEN, in the period between January 1, 2010, and June 30, 2023, treated at Hospital Italiano de Buenos Aires, were included.
- Summary measures such as median and interquartile range were reported. OS and EFS were estimated using Kaplan Meier, and subgroup comparison was done using the log-rank test. Categorical comparisons were made using the chi-square test. Cox regression analysis was used for comparative analysis by covariates.

RESULTS

- **96 patients were included**, with a median (Me) follow-up of 9.3 months (IQR 3.5-18.4).The baseline characteristics are presented in Table 1.
- Figure 1 shows the survival curves in relation to the treatment received.
- CR composite was achieved in 78.9% in HMA/VEN group and 26% among those treated with HMA (p<0.001).
- Median EFS was 17.7 months (95% CI 7.7-27.8) in the HMA/VEN group and 6.9 months (95% CI 5-8.9) in the HMA group (HR for relapse/death, 0.44 95% CI 0.21-0.92; p=0.031).

Table 1. Baseline Characteristics

VARIABLES	HMA (n=77)	HMA/VEN (n=19)
Age, Me (IQR)	74.7 (69.9-80.1)	73.3 (68.6-80.3)
Age >75 years, n (%)	38 (49.4)	9 (47.4)
Female sex, n (%)	39 (50.6)	9 (47.4)
ECOG, n(%)		
0	22(28.6)	9 (47.4)
1	17(22.1)	7(36.8)
≥2	38 (49.4)	3(15.8)
Not evaluable	0	0
CCI Charlon, n(%)		
<3	52 (67.5)	12 (63.2)
≥3	25 (32.5)	7 (36.8)
Not evaluable	0	0
Cytogenetic, n(%)		
Favourable	2 (2.6)	2 (10.5)
Intermediate	52 (67.5)	12 (63.2)
Unfavourable	19 (24.7)	4 (21.1)
Not evaluable	4 (5.2)	1(5.3)
Secondary AML, n(%)		
History of MDS or CMML	32 (41.6)	9 (47.4)
Related to treatment	10 (12.9)	3 (15.8)
Other	4 (5.2)	3 (15.8)
Type of HMA, n(%)		
Azacitidine	65 (84.4)	12(63.2)
Decitabine	12 (15.6)	7 (36.8)
Follow-Up, Months, Me (IQR)	8.2 (3.5-18.3)	10.8 (5-18.6)
Transplant, n(%)	8 (10.4)	5 (26.3)

Figure 1. Overall survival

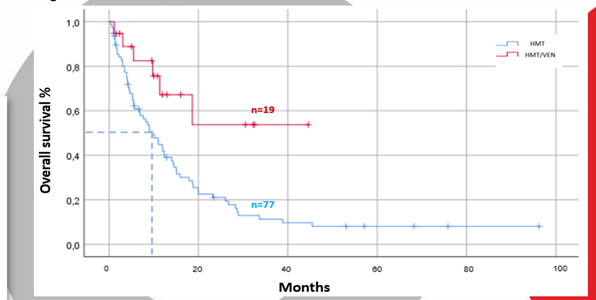


Figure 2. Event-free survival

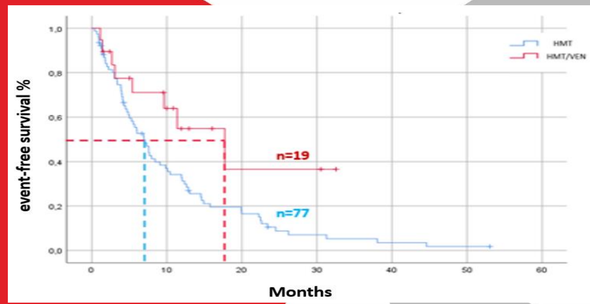
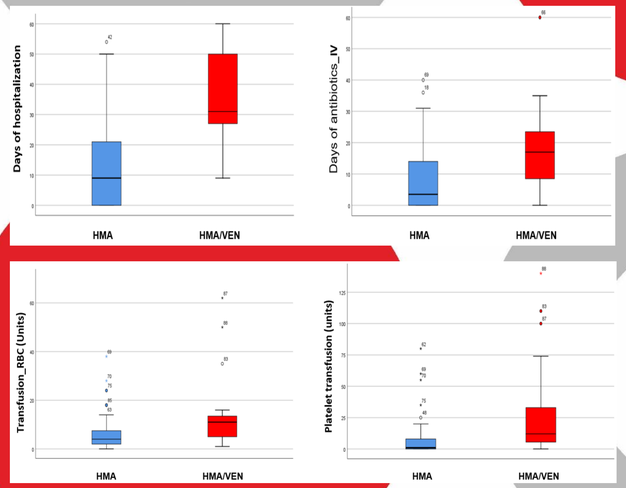


Figure 3 and 4. Hospital Support



- **Median hospital stay** was 9 days for the HMA group and 31 days for the HMA/VEN group (p<0.001).
- **Median duration of antibiotic** treatment was 2 days for HMA compared to 17 days for HMA/VEN (p<0.001).
- **Median RBC transfusion** was 4 units for HMA and 11 units for HMA/VEN, while the **median PLT transfusion** was 1 unit versus 12 units, respectively (p<0.001).

CONCLUSIONS

- In line with published data, in our cohort, the combination of HYPOMETHYLATING AGENT/VENETOCLAX (HMA/VEN) proved to be significantly superior in terms of overall response, OS, and EFS.
- The HMA/VEN combination showed a higher level of support requirements and hospital resource use, increasing treatment costs.
- Individualized approaches will likely be necessary to optimize resources while maximizing the clear therapeutic benefit.

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