CLINICAL CHARACTERISTICS, INFECTIOUS COMPLICATIONS AND OUTCOME OF PATIENTS TREATED WITH VENETOCLAX + HYPOMETHYLATING AGENTS (VEN-HMA)

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Introduction

- The use of VEN-HMA is a recognized treatment for patients (pts) who are unfit or elderly with acute myeloid leukemia (AML).
- Real-world studies have documented the complications and outcomes of pts treated with venetoclax; however, there are no such studies conducted in Brazil

Objectives

To describe the clinical characteristics, infectious complications and outcome of pts with AML or MDS treated with VEN-HMA in Brazil

Methods

- This is a multicenter retrospective study conducted in 12 Brazilian centers.
- We included pts with AML or MDS who were treated with VEN-HMA either as first-line or salvage therapy.
- We collected data on demographic and clinical characteristics, antimicrobial prophylaxis practices, documentation of infection during neutropenia, and outcomes

Results

Clinical characteristics of 114 patients treated with venetoclax-based regimen

Characteristic	Total N= 114	VEN+HM 1st line (n=69)	VEN+HM 2nd line (n=24)	VEN+Other* (n=18)
Age (years), median (range)	66 (19 – 95)	70 (37 – 89)	56 (19-74)	44 (19 -95)
Gender (male/female)	71 / 43	48 / 21	13 / 11	7 / 11
ECOG score (data available for 108 patients)				
0 -1	61%	60%	71%	47%
2 – 4	39%	40%	29%	53%
Underlying disease				
Acute myeloid leukemia	90%	94%	87%	94%
Myelodysplasia / other	10%	6%	13%	6%
Quinolone prophylaxis	13 (11%)	8 (12%)	4 (17%)	1 (5%)
Antifungal prophylaxis	48 (42%)	22 (32%)	11 (46%)	15 (83%)
Micafungin	28 / 48 (58%)	16	5	7
Mold-active azole	12 / 48 (25%)	4	2	6
Amphotericin B	1 / 48(2%)		1	
Fluconazole	7 / 48 (15%)	2	3	2
Antiviral prophylaxis	63 (61.1)	38 (60.3)	17 (70.8)	8 (47.0)
Response to treatment (available for 89 patients)				
CR + CRi	52 / 89 (58%)	35 / 51 (69%)	9 / 21 (43%)	8 / 14 (57%)
PR	12 / 89 (13%)	3 / 51 (6%)	3 / 21 (14%)	6 / 14 (43%)
No response	22 / 89 (25%)	13 / 51 (25%)	9 / 21 (43%)	-
Death	9 (8%)	6 (9%)	1 (4%)	2 (11%)

*VEN+ Other: Venetoclax monotherapy (1), venetoclax + cytarabine (5), venetoclax + intensive chemotherapy (12) ; CR = complete remission; CRi = complete remission with incomplete hematologic recivery; PR = partial response

Results

Duration of neutropenia and infectious complications during first cycle of 114 patients treated with venetoclax-based regimen

Characteristic	Total N=114	VEN+HM 1st line (n=69)	VEN+HM 2nd line (n=24)	VEN+Other (n=18)
Neutropenia during 1st cycle	94%	63 (91%)	0	17 (94%)
Neutrophil recovery after 1st cycle	74 / 105 (70%)	47 / 63 (75%)	16 / 24 (67%)	11 / 18 (61%)
GCSF use	41 (35.7)	20 (46.5)	7 (29.2)	12 (70.6)
Febrile neutropenia (n=52)	67%	63%	78%	75%
Bacteremia	11%	6%	22%	25%
Use of non-prophylactic antifungal agente	13%	14%	11%	12%
Invasive fungal disease	5 (10%)	3 (8%)	1 (11%)	1 (12%)
Aspergillosis		2		
Fusariosis		1		1
Kodamaea ohmeri + Trichosporon asahii			1	

* Among patients who obtained complete remission or complete remission with incomplete hematologic recovery

Discussion

- **Our findings indicate that:**
- **Antibacterial and antimold prophylaxis may not be necessary for pts treated with VEN-HMA, given the low incidence of bacteremia and IFD.**
- **The 69% rate of CR + CRi after the initial treatment cycle for frontline VEN-HMA pts aligns with rates observed in randomized clinical trials.**