

TOXICITY IN PATIENTS TREATED WITH VENETOCLAX. A SAFETY STUDY IN REAL-WORLD PRACTICE

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Background and Importance

Venetoclax acts as an inhibitor of the anti-apoptotic protein Bcl-2, which is increased in Chronic Lymphocytic Leukemia (CLL) and Acute Myeloid Leukemia (AML). It is described the frequent occurrence of hematological toxicity, among other adverse events (AE).

Aim and Objectives

- 1) To evaluate the hematological toxicity of venetoclax during dose escalation
- 2) To describe AE associated with venetoclax during treatment



Material and Methods

Multicenter, observational, retrospective study in patients who initiated venetoclax until 01/06/2022 with a treatment period ≥ 3 months.

Variables collected: sex, age, diagnosis, treatment schedule, hemoglobin, neutrophil and platelet levels at baseline and after dose escalation and; AE developed according to CTCAE v. 5.0.

Hematologic toxicity during escalation was analyzed using Student's t-test (SPSS Statistics 25.0).

Results

N = 33 patients

Hemoglobin baseline (g/dL)	Hemoglobin after escalation (g/dL)	p
10,6 \pm 1,9	10,8 \pm 2,1	0,282
Neutrophils baseline/ μ L	Neutrophils after escalation / μ L	p
1.667,6 \pm 1.064,9	1.237,3 \pm 1.011,5	0,001
Platelets baseline/ mm^3	Platelets after escalation / mm^3	p
120.060,0 \pm 77.662,3	116.121,0 \pm 77.012,0	0,697

Discontinuations: 15 (restarts: 7)

Dose reduction: 5

Parameters	Result
Male	63,6%
Age	68,7 \pm 9,7y
Diagnosis	CLL: 20; AML: 10; MDS: 3
Schedule	Monotherapy: 2 Bithery (RTX: 16; AZA: 14; DEC: 1; OBI: 1)
Dose adjustment	POS: 2; VOR: 2; FLU: 1

AE	G1	G2	G3	G4
Anemia	-	3	4	-
Neutropenia	1	6	6	4
Thrombocytopenia	-	1	4	-
Asthenia	2	-	1	-
Bradycardia	-	2	-	-
Diarrhea	1	-	-	-
Fever	1	-	-	-
Hypertransaminemia	-	1	-	-
Mucositis	1	-	-	-
Pneumonia	-	2	3	-
Tumor Lysis Syndrome	-	-	2	-

Conclusion and relevance

The main hematological toxicity of venetoclax was neutropenia. This adverse effect also occurred more frequently during maintenance treatment. We consider it relevant to carry out serial haematological controls.