

## PB1806 AZACITIDINE + VENETOCLAX IN PATIENTS WITH ACUTE MYELOID LEUKEMIA, POTENTIAL CANDIDATES TO ALLOGENIC HEMATOPOIETIC STEM CELL TRANSPLANT – RESULTS FROM A HOSPITAL CENTER

**Topic:** 04. Acute myeloid leukemia - Clinical

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**Background:** Azacitidine + Venetoclax (Aza/Ven) is indicated for the treatment of Acute Myeloid Leukemia (AML) in patients not fit for intensive regimens. Although this combination is not approved as first line for younger patients, it may be an alternative in situations where chemoresistant disease is predictable.

**Aims:** To evaluate the results of the use of Azacitidine + Venetoclax in patients with Acute Myeloid Leukemia, potential candidates to allogeneic hematopoietic stem cell transplant (alloHSCT) treated at the Centro Hospitalar e Universitário de Coimbra in Portugal, a country where CPX-351 is not available.

**Methods:** We included the patients aged 18-60 years old who were diagnosed with AML, potential candidates to alloHSCT, and treated with Azacitidine + Venetoclax as first line treatment or following relapse post chemotherapy, between 2019 and 2021.

We evaluated the characteristics of the disease at diagnosis, the risk classification according to the ELN 2017 classification, the response to Aza/Ven, the complications of the treatment and how many patients were able to proceed to transplant.

**Results:** 13 patients were included, 61% female, median age 46.2 yo [19-60], 3 secondary AML and 10 de novo including 1 myeloid sarcoma.

At diagnosis 9 patients (69.2%) presented with high risk disease, 2 with intermediate risk and 2 with low risk disease.

9 patients underwent chemotherapy with the 3+7 regimen as first line, with 55.6% (5) being primarily refractory. 2 underwent re-induction with FLAG-IDA remaining unresponsive.

The 5 patients refractory to first/second induction were treated with Aza/ Ven as 2<sup>nd</sup> or 3<sup>rd</sup> line. 3 patients achieved complete response (CR), 2 with negative minimal residual disease (MRD -) and 1 with positive minimal residual disease (MRD +) by Immunophenotyping (IFT). 2 had progressive disease and died. Only 1 patient was able to proceed to alloHSCT.

The remaining 4 had CR to first induction and proceeded to consolidation therapy but relapsed. They were treated with Aza/Ven as 2<sup>nd</sup> line.

4 patients were treated with Aza/Ven as first line treatment, median age 46.25 yo, 3 with high risk and 1 with intermediate risk disease at diagnosis. 3 patients achieved CR, 2 with MRD - by IFT and 1 with MDR + by MB and 2 have received alloHSCT and 1 is waiting for transplant. 1 died with progressive disease.

The most common complication of the treatment with Aza-Ven was febrile neutropenia, 53.8%, with septic shock in 2 patients.

5 patients (38.5%) were able to proceed to alloHSCT: 1 refractory to induction and had a high risk genetic profile (TP53) and is currently one month post transplant, 1 with therapy related AML, 18 months post AlloHSCT and

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asymptomatic, 1 with MRC AML died with post transplant complications and 1 with MRC AML relapsed after transplant and died with progressive disease . 1 patient is currently in CR and waiting for transplant (MPS secondary AML).

The global mortality rate was 61.5% (8), 4 with progressive disease (1 after transplant), 3 with infectious complications and 1 with transplant complications.

**Summary/Conclusion:** This results show that Azacitidin + Venetoclax is a valuable tool for the treatment of young patients with AML allowing the achievement of complete responses in patients with refractory disease to induction, including in patients candidates to CPX-351 or as first line treatment, and their referral to a potentially curative alloHSCT.

We need more data to evaluate Aza/Ven as first line regimen in young patients with predictable chemoresistant disease.

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