Abstract: P2220

Title: FREQUENCY OF FUNGAL INFECTIONS IN NEWLY DIAGNOSED AML PATIENTS TREATED WITH VENETOCLAX PLUS AZACITIDINE WITH OR WITHOUT ANTIFUNGAL PROPHYLAXIS

Abstract Type: e-Poster Presentation

Topic: Infections in hematology (incl. supportive care/therapy)

Background:

The combination of venetoclax and azacitidine (VEN+AZA) is an effective treatment option that prolongs survival in unfit patients with acute myeloid leukemia (AML). However, the risk of infections, including mycoses, is rather high and there is a growing debate on the value of antifungal prophylaxis (AFP) in these patients.

Aims:

We explored the usefulness of AFP in AML patients treated with VEN+AZA.

Methods:

Our study included newly diagnosed AML patients receiving 1st-line VEN+AZA in Czech, Austrian, and Slovakian hematology centers between November 2018 and November 2023. A decision to apply AFP was reached based on local center guidelines and the overall risk-profile in each case. Fungal infections were divided into non-invasive and invasive infections. Fisher exact and Mann-Whitney tests were used for statistical analyses.

Results:

A total of 206 patients with de novo (62%), secondary (27%) or therapy-related (11%) AML were included. The median number of VEN+AZA cycles administered was 3. A total of 105 patients (51%) received concomitant AFP including posaconazole (52%), fluconazole (31%), voriconazole (9%), or other antifungals (9%); whereas 101 patients (49%) received no AFP. The median duration of AFP after the initiation of VEN+AZA was 89 days (range 1-705 days).

Fungal infections occurred in 6 patients (3%) and were classified as invasive (n=1; 0.5%) and noninvasive infections (n=5; 2.5%). The median time between starting VEN+AZA and the diagnosis of a fungal infection was 18 days (range: 5-20 days). Only one invasive fungal infection (IFI) was found (0.5%). This patient suffered from a probable invasive candidiasis caused by *Malassezia sympodialis* with lung and conjunctivae involvement. Three cases with oral and two cases with esophageal candidiasis were diagnosed – these cases were classified as noninvasive mycoses. Fungal infection developed in 1/105 patients (1%) with prophylaxis and 5/101 (5%) patients without prophylaxis (p=0.114). IFI occurred in 0/105 (0%) patients with prophylaxis and 1/101 patients (1%) without prophylaxis (p=0.490). The median number of neutropenic days (neutrophils<0.5x10E9/L) after starting VEN+AZA to mycosis diagnosis was 9.

From the start of VEN+AZA, the median follow-up was 152 days. Overall, 83 patients (40%) have died: of these 83 patients, 38 (46%) had AFP and 45 (54%) received no AFP (p=0.256). Two of the deceased patients developed mycoses, but death was not attributable to a fungal infection in these cases. The median time from starting VEN+AZA to death in patients with and without AFP was 79 days and 134 days, respectively (p=0.139). The median follow-up was 132 versus 168 days in patients with and without AFP (p=0.124).

Summary/Conclusion:

In newly diagnosed AML patients treated with VEN+AZA, we found fungal infections in 1% in the AFP prophylaxis group and 5% in the control group (n.s.). However, most infections were not severe, and these

infections had no influence on the patients' survival. Therefore, we are of the opinion that AFP use may not be required in all AML patients treated with VEN+AZA, but may only be considered in specific groups, including those with high IFI risk and on the basis of the overall situation in each case. If considered in newly diagnosed AML patients with high risk of IFI, AFP may be sufficient when only given in the first treatment course.

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Keywords: Fungal infection, Prophylaxis, Venetoclax, Acute myeloid leukemia