soho2023
ELEVENTH ANNUAL MEETING

AZACITIDINE IN COMBINATION WITH VENETOCLAX FOR MYELODYSPLASTIC SYNDROME (MDS) WITH INCREASED BLASTAS-2 IN CLINICAL PRACTICE SETTING

AML-299

B. Davainiene[1], R. Cepulyte[2], I. Trociukas[3], L. Kevlicius[4], R. Pileckyte[5], L. Griskevicius[6], A. Zucenka [7]

1. HOTC, Vilnius University Santaros Clinics, Lithuania

INTRODUCTION

Azacitidine+venetoclax (AZA+VEN) is currently an investigational therapy for high-risk MDS. We have reviewed our real-life experience with MDS-IB2 patients treated with AZA+VEN.

AIM

To evaluate the efficacy and toxicity of azacidine+venetoclax for myelodysplastic syndrome (MDS) with increased blasts-2.

METHOD

We conducted an observational, retrospective analysis. The data cut-off was on May 15, 2023. All patients provided informed consent for treatment and data collection.

The AZA+VEN regimen consisted of venetoclax 400 mg/d on days 1-14 with azacididine 75 mg/m^2 on days 1-7. The treatment cycles were administered every 28 days or longer intervals. Eligible responders could proceed to allogenic stem cell transplantation (alloSCT).

We evaluated baseline characteristics, IPSS-R, IPSS-M, marrow CR (mCR), CR, CRi rates, overall survival (OS), time to ANC>1x10e9/l, Plt>100x10e9/l recovery, CTCAE v5.0 grade 3-5 non-hematological toxicity, day-30, day-60 mortality rates.

RESULTS

The patients were older than 18 years and had newly diagnosed, previously untreated MDS-IB2, according to 5th edition of the WHO classification.

Overall 17 patients were treated with AZA+VEN.

The median OS was 6.9 months (3.2-22.1).

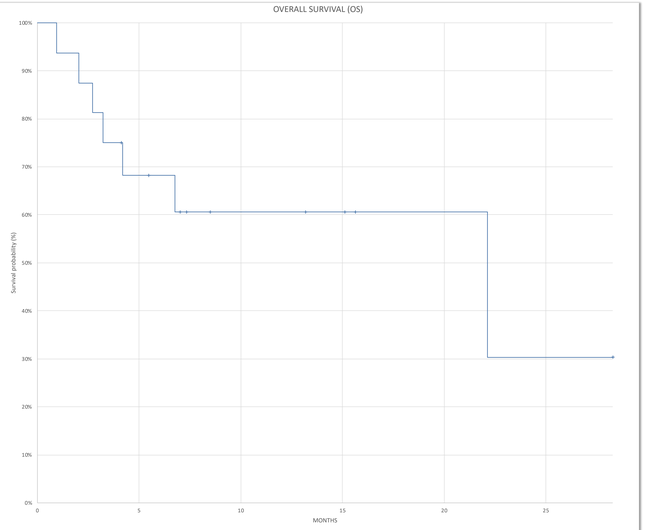
12-month OS was 45%.

Male: female	6:11
Median AGE	63 (38-71)
Median ECOG	1 (0-2)
Median IPSS-R	7,5 (5-10)
Median IPSS-M	2,02 (0,55-4,57)
IPSS-M high risk	59% (10/17)
IPSS-M very high risk	29% (5/17)

Table No. 1

mCR	81% (13/16)
CR+CRi	62% (10/16)
Bridged to alloSCT	47% (8/17)
Median follow-up	13.2 months
Median time ANC>1x10e9/l recovery	44 days (4-165)
Median time Plt recovery	42 days (21-94)
Grade 3-5 non-hematological adverse events occurred	41% (7/17)
Day-30 mortality	12% (2/17)
Day-60 mortality	18% (7/17)

Table No. 2



CONCLUSIONS

AZA+VEN demonstrated promising response rates in this high-risk MDS-IB2 group and allowed a proportion of patients to proceed alloSCT.

Our real-life results should be interpreted with caution due to the small patient numbers and retrospective nature of study.

REFERENCES

Garcia JS, Wei AH, Borate U, et al. Safety, efficacy, and patient-reported outcomes of venetoclax in combination with azacitidine for the treatment of patients with higher-risk myelodysplastic syndrome: A phase 1b study. Abstract #656. Presented at the 2020 ASH Annual Meeting, December 7, 2020.

Bazinet A, Darbaniyan F, Jabbour E, Montalban-Bravo G, Ohanian M, Chien K, Kadia T, Takahashi K, Masarova L, Short N, Alvarado Y, Yilmaz M, Ravandi F, Andreeff M, Kanagal-Shamanna R, Ganan-Gomez I, Colla S, Qiao W, Huang X, McCue D, Mirabella B, Kantarjian H, Garcia-Manero G. Azacitidine plus venetoclax in patients with high-risk myelodysplastic syndromes or chronic myelomonocytic leukaemia: phase 1 results of a single-centre, dose-escalation, dose-expansion, phase 1-2 study. Lancet Haematol. 2022 Oct;9(10):e756-e765. doi: 10.1016/S2352-3026(22)00216-2. Epub 2022 Sep 2. PMID: 36063832.

ACKNOWLEDGEMENTS

Thank you to Dr. Andrius Zucenka and prof. Laimonas Griskevicius for mentoring me throughout this project. Thank you all my colleagues helping me in this study.

CONTACT INFORMATION

https://www.linkedin.com/in/birutė-davainienė-27a1a9280/

birute.pugaciute@santa.lt