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616.ACUTE MYELOID LEUKEMIAS: INVESTIGATIONAL THERAPIES, EXCLUDING TRANSPLANTATION AND CELLULAR IMMUNOTHERAPIES

Venetoclax Combined with Azacitidine and Homoharringtonine in Adults with Secondary Acute Myeloid Leukemia

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Secondary acute myeloid leukemia is an aggressive subset of acute myeloid leukemia (AML) that is, in general, is associated with a very poor prognosis and high mortality. Venetoclax combined with hypomethylating agents have showed relatively successful therapeutic effective in patients with relapse/refractory AML, while efficacy is limited in high-risk subset AML. We hypothesised that Venetoclax combined with Azacitidine and Homoharringtonine could have improved activity in patients with secondary acute myeloid leukemia, particularly in high-risk subgroups.

Methods

This single center, phase 2 trial was done at the first affiliated hospital of Nanjing medical university. The study enrolled adult patients with diagnosed of secondary AML (AML progressed after preexisting myeloid neoplasms or treatment AML arising from prior exposure of leukemogenic therapies). Patients were required to have an Easter Cooperative Oncology Group performance status of 3 or less, and adequate end-organ function. Patients who had received previous BLC2 inhibitor therapy were excluded. Patients received Azacytidine 75mg/m ^{2} and Homoharringtonine 3mg for 7 days with venetoclax 400mg daily. The primary endpoint was overall response rate. The secondary endpoints include safety, overall survival, and duration of response (according to recommendations of European LeukemiaNet 2017 guidelines). The trial was registered on ClinicalTrial.gov (NCT 05513131) and continues to accrue patients.

Results

Since now, we enrolled 11patients; 8(72.7%) patients had secondary AML, 3 (27.3%) patients had treatment related AML, while 2(18.2%) patients had TP53 mutation. The median age was 62 years (48-78 years). At the July 30, 2023 data cutoff, median follow-up time was 36.7 weeks (range 6.57-82.29 weeks). The overall response rate was 81.8% (9 of 11 patients). The most common treatment-emergent adverse events included bone marrow suppression with grades 3 or 4 neutropenia (n=11/11) and febrile neutropenia (n=10/11). The 30-day mortality for all patients was 9.1% (n=1). 2(18.2%) patients were eligible for allogeneic hematopoietic stem cell transplantation. The median overall survival was not achieved.

Conclusion

Venetoclax combined with Azacitidine and Homoharringtonine regimen had a tolerable safety profile and showed encouraging clinical activity characterised by a high response rate. further patients are needed to validate these findings.

Disclosures No relevant conflicts of interest to declare.

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