Real-world practice with generic venetoclax and generic Azacitidine in Acute Myelogenous Leukemia (AML) with different risk groups

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INTRODUCTION

AML is treated traditionally by induction chemotherapy (7+3) or (5+2) regimens demonstrating a high percentage of mortality rates especially with those with high-risk presentation. The emergence of Venetoclax and Hypomethylated agents has improved the tolerance of treatment and improved outcome in different risk groups, however; there are still patients showing poor compliance to treatment, further, the best Venetoclax dosing has not been reached yet.

AIM

Syria is a developing country with limited medical resources. The market of generic new drugs is growing overtime. In our study, we used generic sources for both Venetoclax and Hypomethylated agents (Azacitidine) given with the standard doses until disease progression in different risk groups of newly diagnosed AML patients. Our cohort was not eligible for intensive induction chemotherapy.

METHOD

We have included 30 newly diagnosed patients with AML, given Azacitidine at a dose of 75mg/m² for 5 days every 28 days and Venetoclax at a dose ranging between 100-400mg per day in continuous according to patients' tolerance accompanied with azole antifungal therapy as prophylaxis. Those with high white blood cells received subcutaneous Cytarabine for cytoreduction before starting our treatment. Bone marrow aspiration performed after each cycle and flowcytometry was employed whenever needed to evaluate residual disease. treatment continued until disease progression.

CONCLUSIONS

In our study, we have shown that generic new drugs can be employed in newly diagnosed AML patients with evident response and survival advantage in low-income countries. The study results are comparable to other studies using the brands or original versions. However, we need extra time to correlate between response rate and other factors such as genetic abnormalities, sex and karyotype status.

RESULTS

We have recruited newly diagnosed 30 patients with ages ranging between 18-66 years (46 in median) and a male to female ratio of 1.8:1. Documented genetic abnormalities are FLT-3 in 12%, NPM1 in 8% and AML1: ETO in 5%. 8% presented with complex Karyotype. Mean baseline total leucocyte count, platelet, & hemoglobin was 34.300/L, 36000/L. After the first month, 10 patients (33.3%) demonstrated complete morphologic remission and a residual disease of less than 5% by flowcytometry. After the second cycle, 13 patients (43/3%) demonstrated complete response on both morphology and flowcytometry. After the 4th cycle, 15 patients are in complete remission (50%) while 12 patients (40%) switched ti intensive chemotherapy. We lost 5 patients (16.6%) after the first cycle due to infections related to profound neutropenia. The percentage of febrile neutropenia was 86.6% after the 1st cycle and 26.6% after the 2nd one. Toxicities were acute renal failure, tumor lysis syndrome, pulmonary and urinary infections.
After a median follow-up of 14 months the overall survival documented and censored in 18 patients (60%).

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