Pre-induction with Azacitidine and Venetoclax in newly diagnosed patients with Acute Myelogenous Leukemia (AML): three years survival update of a comparative study

Maher Salamoon MD, Al Bairouni university cancer center, Daffodil 88 comprehensive cancer center, Damascus university, Damascus, Syria

INTRODUCTION

The standard upfront treatment for acute myeloid leukemia (AML) among fit patients (pts) has been intensive induction chemotherapy (IC), typically with cytarabine and anthracycline as (7+3) or (5+3) depending on the aggressiveness of disease, age and genetic complexities. However, long-term outcomes remain poor, and IC continues to cause a high percentage of mortality rate especially in the first inductive cycle. azacitidine and venetoclax are a combination that confers a good response rate, elimination a high percentage of leukemic cells without posing an acute serious neutropenia in newly diagnosed AML patients. It can be taken as an outpatient schedule and has shown to improve response rate and event free survival.

AIM

The combination of Azactidine and venetoclax is used in a pre-induction setting to purge bone marrow and decrease the percentage of leukemic cells making it a background for further induction and intensive treatment with serious chemotherapy.

METHOD

30 patients were included with ages between 60 and 72 (66 in median) a male to female ratio of 4:1 diagnosed with AML other than M3. They were treated with a pre-induction phase of two month including Azacitidine at a dose of 75mg/m² for five consecutive days every month for two months accompanied with Venetoclax at a fixed dose of 200 mg daily for two months. Bone marrow aspiration was taken at the end of every month, and the sample was compared with a similar group counting 30 patients treated with the conventional induction treatment. Aspiration thereafter every 3 months until disease progression. The primary endpoint was event free survival (EFS), with events defined as progressive disease, persistent disease prompting therapy change, relapse, hospice, or death. Among secondary endpoints were response rates, OS, toxicity, measurable residual disease (MRD), hospitalization metrics, and quality of life (QOL).

CONCLUSIONS

After three years of follow-up, Azacitidine and Venetoclax showed to improve the event free survival with patients with good quality of life and less toxicity profile compared with patients under treatment with the conventional treatment of AML. Studies to be expanded to gather more patients taking into consideration genetic factors and chromosomal abnormalities and whether the patient is fit or unfit to allogeneic bone marrow transplant.

RESULTS

The event free survival after 3 years was 56% (95% CI: 47.5-61.6), hazard ratio of 72% and p value of .01 compared with 22% in patients treated with the induction arm. an improved quality of life p value .018 and decrease the need to enter the intensive care unit 2 patients in the pre-induction setting compared to 11 in the conventional treatment arm. Grades of grade 3 and 4 hematologic toxicities documented in 4 patients of pre-induction setting compared with 25 in the conventional induction arm. Mortality rate was zero in the first 3 months compared with 5 patients in the induction arm, p value .009. symptom burden and depression were less likely to be documented in the pre-induction patients.

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CONTACT INFORMATION

maher salamoon MD

maher.salamoon@gmail.com

+963933771086

REFERENCES

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Maher Salamoon
Author(s): Maher Salamoon
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