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Midostaurin Plus Intensive Chemotherapy In FLT3 Mutated AML. "Real Life" Data Versus The Ratify Study.

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INTRODUCTION

FLT3 mutation is associated with adverse prognosis in AML (ELN2017, Dohner et al, Blood 2017) and Intensive chemotherapy (IC) has been the standard of treatment for FLT3 mutated AML for decades. Midostaurin (Midos) has been approved in combination with IC for FLT3-mutated AML based on an improvement in overall survival noted in the RATIFY phase 3 trial (Stone et al, N Engl J Med 2017) .

AIMS

The aims of this study are to analyze safety and effectiveness of Midos plus IC in FLT3 AML, to validate RATIFY results in a "real-world" setting and to identify risk factors.

METHODS

Methods: We carried out a retrospective multicenter study (MDA-AML-2018-06) in 27 Spanish centers.

Inclusion criteria:
Age >18 years,
FLT3-mutated AML diagnosis according to WHO criteria.
Start of treatment with midostaurin in combination with IC between June 2016 and June 2021.

Treatment regimen
-Induction: cytarabine 200mg/m2/day x 7 days + Idarubicine 12 mg/m2/day x 3 days.
- Consolidation: HIDAC or Intermediate dose ARAC.

We evaluated the response according to 2017 ELN criteria, toxicity according to CTCAE v4.0 and overall survival (OS) by Kaplan-Meier. Statistical analysis was performed using SPSS program version 20.0.

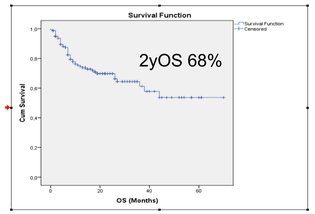
RESULTS

A total of 175 previously untreated AML FLT3 positive patients were included (93 female). Baseline Characteristics Table 1.

1st Line in FLT3 Mutated AML. Midos Plus Intensive Chemo versus Intensive Chemo

Characteristics	N Total 175
Female	93
Age madian	53 (18-76)
60 years and above	111
ECOG<2	110
ELN Low/Int/High	53 / 72 / 26
WBC count median	44.500 (0.4-395.000)/microL
FLT3-ITD / ratio ≥0.5	133 / 74

Overall Survival All Patients

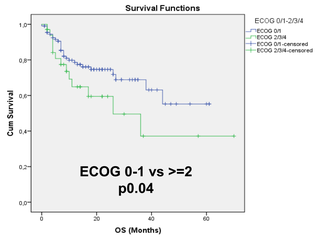


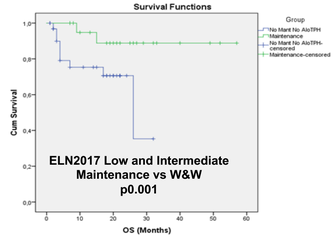
Midos + Intensive Chemotherapy 1st Line FLT3 mutated AML

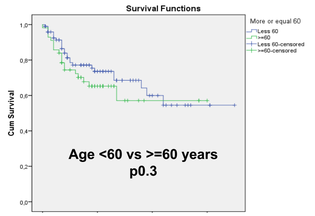
CR rate 81.4%

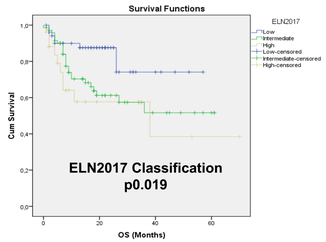
OS median not reached

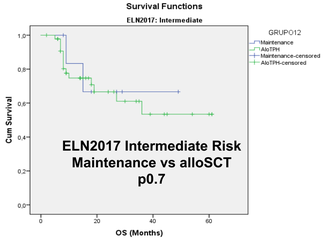
2yOS 68%











CONCLUSIONS

Our experience confirms safety and effectiveness of Midos plus IC as first line in FLT3 AML patients with similar 2 year OS as the previous reported in the RATIFY trial. Interesting that in our experience age 60 and above resulted in no differences for OS.

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