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MD Anderson Cancer Center Madrid • España

Midostaurin Maintenance Versus AlloSCT Versus W&W in FLT3-Mutated AML: A "Real-Life" Multicenter Study

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Introduction

Introduction: FLT3 mutation is associated with adverse prognosis in AML (ELN2017, Dohner et al, Blood 2017). During the last decades intensive chemotherapy and SCT has been the standard of treatment for FLT3 mutated AML. Based on the results of the prospective, randomized phase3 trial RATIFY Midostaurin (Midos) has been approved in combination with intensive chemotherapy (IC) for FLT3-mutated AML, midostaurin maintenance was part of the treatment schedule in the RATIFY trial but not randomly explored (Stone et al, N Engl J Med 2017).

Aims

The aims of this study are to analyze safety and effectiveness of midostaurin maintenance in FLT3 AML in a “real-world” setting and to evaluate maintenance versus alloSC versus W&W and the impact of risk factors.

Patients and Methods

We carried out a 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 December 2020.
We evaluated the responses according to 2017 ELN criteria
Toxicity according to CTCAE v4.0
Overall survival (OS) by Kaplan-Meier
Statistical analysis was performed using SPSS program version 20.0.
This study has been approved by the Spanish Medicines Agency AEMPS code MDA-AML-2018-06.

Results

A total of 175 previously untreated AML FLT3 positive patients from 27 sites were analyzed.were included (93 female). Baseline Characteristics Table 1

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

Intensive Chemo Regimens

7+3
Citarabine 200 mg/m2/dya x 7 days + Idarubicine 12 mg/m2/day x 3 dias

Consolidation HiDAC or Intermediate doce AraC

+ Midostaurin Days 8 to 21

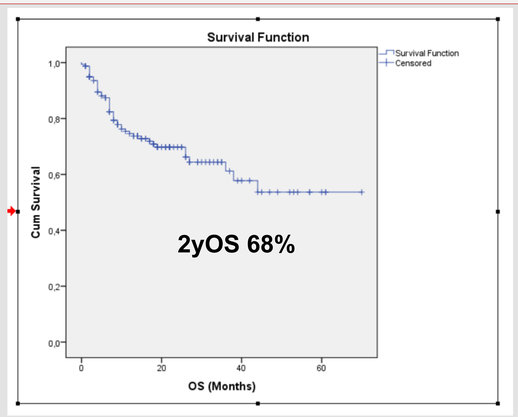


Midos + Intensive Chemotherapy

1st Line FLT3 mutated AML

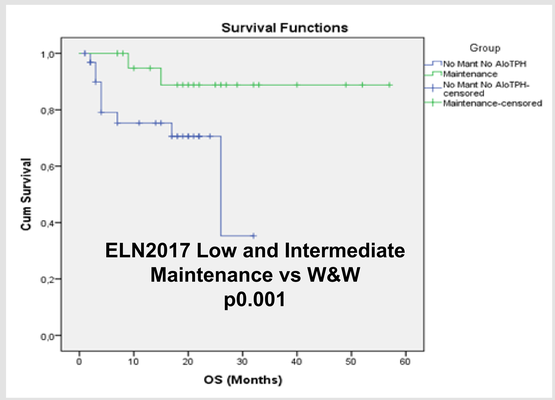
CR rate 81.4%

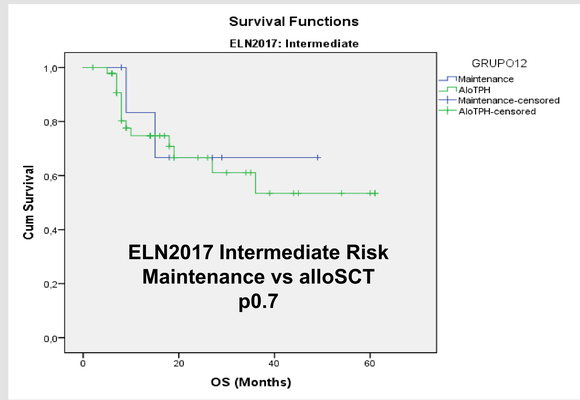
OS median not reached and 2yOS 68%



Patients who achieved CR after Induction1 and/or Induction2. Total n 144 (81.4%)

Total 144 Lost 3	Maintenance	alloSCT	W&W
Patients	24	76	41
Age madian	61 (31-73)	51 (18-69)	56 (23-76)
ELN2017 Low	16	11	21
ELN2017 Int	7	45	16
ELN2017 High	0	16	3
ELN2017 Lost	1	4	1





Safety: AE during maintenance were one case of QT prolongation which required Midos discontinuation.
No cases of febrile neutropenia and no cases of deaths related to Midos maintenance.

Conclusions

Our experience confirms safety of maintenance therapy in AML FLT3 patients after intensive chemotherapy. We also observed a benefit for maintenance versus W&W in Low and Intermediate risk population and no differences in OS when we compere maintenance versus alloSCT in the Intermediate Risk group

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