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Therapeutics results of 2nd generation TKIs in CML Multicentric study West region of Algeria

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Introduction: Historical treatments for chronic myeloid leukemia (CML) were non-specific agents with palliative intent, except for allogeneic hematopoietic stem cell transplantation, which is a treatment with curative intent. Despite the good results obtained by the use of the 1st generation tyrosine kinase inhibitor (TKI) imatinib, some patients with CML have a poor response to this treatment. The availability of 2nd generation TKIs, in this case dasatinib and nilotinib, and their use have made it possible to introduce therapeutic alternatives in patients with Ph+ CML resistant to imatinib. Multicentric

Goals: Our objective is to study the epidemiological and clinico-biological characteristics of CML patients resistant, intolerant or failing imatinib and treated with Dasatinib or Nilotinib in 2nd intention. We will then assess the tolerance and response to these treatments in order to compare our results with those of the literature.

Material and Methods: This is a retrospective, multicenter study concerning 6 hematology centers in western Algeria. Patients over 15 years of age with CML treated with Dasatinib or Nilotinib as 2nd line were included. The analysis of the various prognostic factors and the study of the therapeutic responses: complete hematological response CHR molecular response RMM as well as the failure was done according to the ELN 2013 criteria. The analysis of event-free survival (EFS), progression-free survival (PFS) and overall survival (SG) were calculated according to the Kaplan Meyer method in univariate (log rank test) and multivariate (cox model) analysis.

Results: Between 2007 and 2017 we collected 435 patients with CML, 152 of whom were treated with TKIs2.

Patient Characteristics

• Patients on ITK2 (n=152) Median age 47 years Extremes 16 to 83 years' old

• Sex ratio (M/F) 0.87

• Splenic overflow Average=8 varies between 0 and 22

The distribution of patients according to prognostic scores is as follows:

• For the EUTOS score: S/ITK1 patients: high risk n=64 i.e. 25%, low risk n=184 i.e. 65%, for S/ITK2 patients: high risk n=32 i.e. 20% and low risk n =120 or 80%

• For the sokal score: high S/ITK1 patients n=98 i.e. 35% intermediate n=100 i.e. 35% and low n=85 i.e. 30%, high S/ITK2 patients n=55 i.e. 38% intermediate n=60 i.e. 42% and low n=30 i.e. 20%

Distribution according to the phase of the disease:

• S/ITK1 patients: Myelocyte P n=264 i.e. 93%, accelerated phase n=15 i.e. 5% and Accutization P. n=4 i.e. 1%

• S/ITK2 patients: myelocytic P. n=132 i.e. 86% the accelerated phase n= 13% and the accutation P n=1 i.e. 1%

Indications for Itk2 According To The Phase:

• Accelerated phase: 70%, ITK1 failure: 25%, intolerance: 4%

• High sokal score: 1%

• The use of ITK2: DASA n=75 i.e. 50%, NILO n=44 i.e. 30% and DASA+NILO n=33 i.e. 20%

Therapeutic results of TKIS

Of the 435 patients, only 410 are evaluable

Conclusion: The use of ITK2 IN 2nd intention allowed us to catch up with 62% of intolerant or failed patients after using Imatinib at the cost of cardiac, hepatic and hematological toxicity. Moreover, we did not achieve the expected results knowing that the NILO provides an MMR at 12 months of 44% V/S 22% for IMATIB while the DASA provides an MMR at 12 months of 52% V/S 33% for imatib. The search for the T315I mutation could not be done in our series, which could have guided our therapeutic choices and improved the management of our patients.