Do Patients with CML-CP in MMR still have a hope to receive Nilotinib (Tasigna) while fasting Ramadan ? Unanswered question

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Abstract

The introduction of TKIs have offered much in terms of OS for patients with CML. In ENESTnd, Nilotinib 300 mg BID demonstrated superior efficacy vs imatinib in pts with newly diagnosed CML-CP, including a significantly reduction of progression to AP/BC .

Background

The way of Administration of Nilotinib on empty stomach; without food consumption for at least 2 before the dose and for at least 1 hr after represents a significant obstacle during Ramadan fasting which lasts for about 14 h .

Objective

To assess effect of modification of dosing interval of Nilotinib on MMR during Ramadan fasting .

Materials & Methods

30 patients diagnosed with CML-CP in MMR for at least 2 years were retrospectively assessed after receiving Nilotinib 300 BID as first line treatment with 9 h interval to allow for Ramadan fasting with RT-PCR for BCR-ABL done 2 weeks after ending Ramadan.

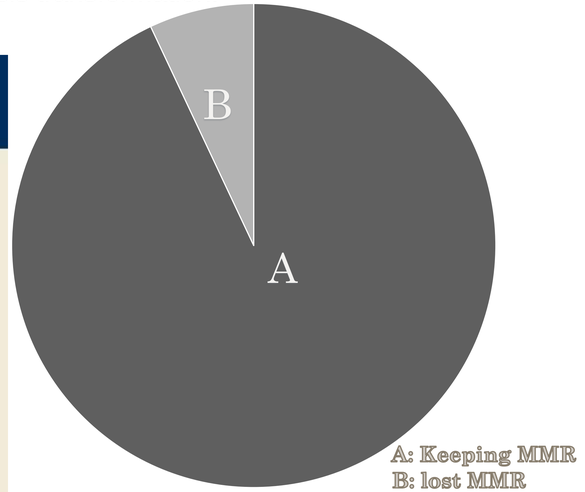
All the patients were 45 y old or less.
No History of accelerated phase or blastic crisis transformation.

Cumulative Incidence of MMR*

Time from randomization	Percent with MMR		
	Nilotinib 300 mg BID (n = 282)	Nilotinib 400 mg BID (n = 281)	Imatinib 400 mg QD (n = 283)
12 months *p*-value	55% <0.0001	51% <0.0001	27% —
24 months *p*-value	71% <0.0001	67% <0.0001	44% —

* ITT population used for all efficacy analyses

Kantarjian HM et al. *Lancet Oncol* 2011;12:841-51.



Summary

28 patients(93.3 %) showed persistence state of MMR while only 2 patients showed one log rise in BCR-ABL expression .

Discussion

Achievement of MMR became a major goal while treating patients with CML-CP. However, Ramadan fasting in Islam represents one of the five pillars of creed and considered as a mandatory religious duty and several attempts were done to allow for Ramadan fasting for such patients.
Our study revealed that modification of dosing interval of Nilotinib did not significantly affect MMR

References

1.Turkina A ,et al. Br J Haematol. 2020.

2.Yassin MA et al.Blood 2019

3. Adel A et al.Blood 2019