REAL LIFE TYROSINE KINASE INHIBITOR DISCONTINUATION IN PATIENTS WITH CHRONIC MYELOID LEUKAEMIA

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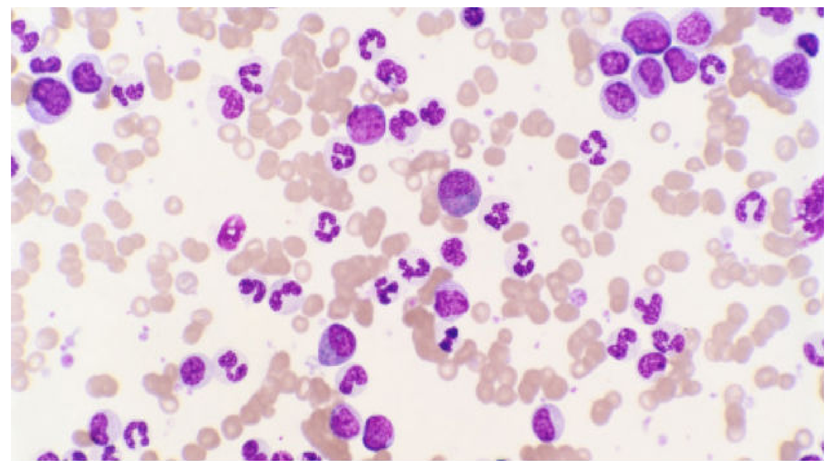
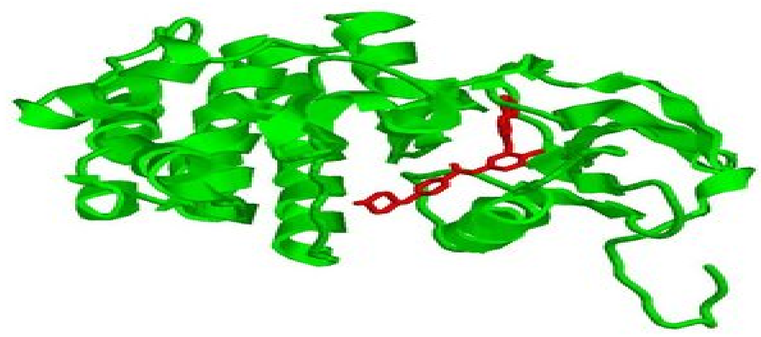




Background and Importance

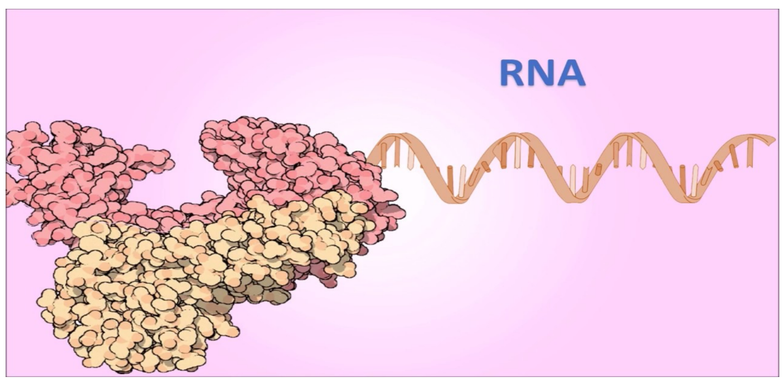
Currently one of the most burning issues regarding the specific treatment of Chronic Myeloid Leukemia (CML) with Interleukin-2-inducible T-cell kinases (ITKs) is whether in a percentage of patients who meet specific requirements treatment interruption could be attempted and maintain molecular relapse-free survival without treatment restarting.

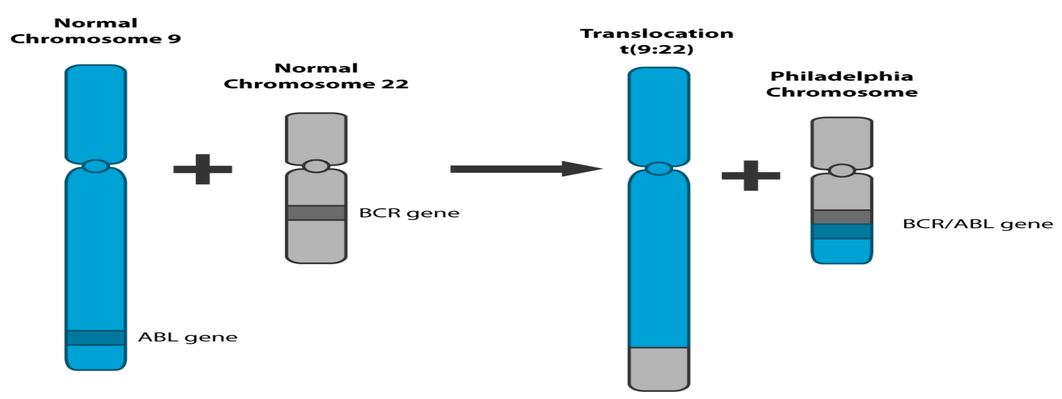
Aim and Objectives

To analyse molecular relapse-free survival after suspension of Imatinib, Nilotinib or Dasatinib, which achieved and maintained a Major Molecular Response (MMR) ≥ 4.5 log for at least 36 months.

Material and Methods

- ❑ Prospective observational study of patients with Chronic Phase Ph+ CML (CP-CML).
- ❑ Inclusion criteria: minimum ITK treatment time of 5 years, no resistance to a previous ITK, no accelerated phase diagnosis or blast crisis and those who have achieved and maintained the MMR ≥ 4.5 log for at least 36 months prior to treatment interruption.
- ❑ Molecular monitoring of bcr-abl oncogene levels was performed using the Real-Time Reverse Polymerase Chain (RT-PCR) technique with the GeneXpert automated system with a sensitivity of 5 log.





Results

- ❑ **30 patients with CP-CML were discontinued.**
- ❑ **13 discontinued Imatinib treatment, 3 discontinued dasatinib treatment and 14 Nilotinib treatment.**
- ❑ **The preliminary rates of Molecular Relapse Free Survival (MRFS) and Treatment Free Remission (TFR) are consistent with those obtained in the different clinical trials, and no progression to advanced stages of the disease has been reported.**
- ❑ **With a median follow-up of 15 months, 78% remain without specific treatment with ITK for not having lost the MMR.**
- ❑ **Relapse occurred before 6 months of discontinued treatment with a median of 4 months. 4 patients lost of MMR, recovering all MMR 4.5 and 5.0 at 3 months after restarting the ITK treatment.**

Conclusion and Relevance

- ➢ **The results contribute to reassure the safety of TKI treatment discontinuation in real-life clinical practice, under close molecular monitoring.**
- ➢ **Resolution of TKI-related toxicity might translate into a clinical benefit for patients with CP-CML and a potential quality of life improvement.**

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