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DISCONTINUATION OF TYROSINE KINASE INHIBITOR THERAPY IN CHRONIC MYELOID LEUKEMIA IN FIRST OR SECOND LINE

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INTRODUCTION

Data on treatment discontinuation of Tyrosine Kinase Inhibitors (TKIs) in routine clinical practice are limited. It would be interesting to develop discontinuation studies in this context to assess whether discontinuing treatment is safe and effective in real-world settings

OBJECTIVE

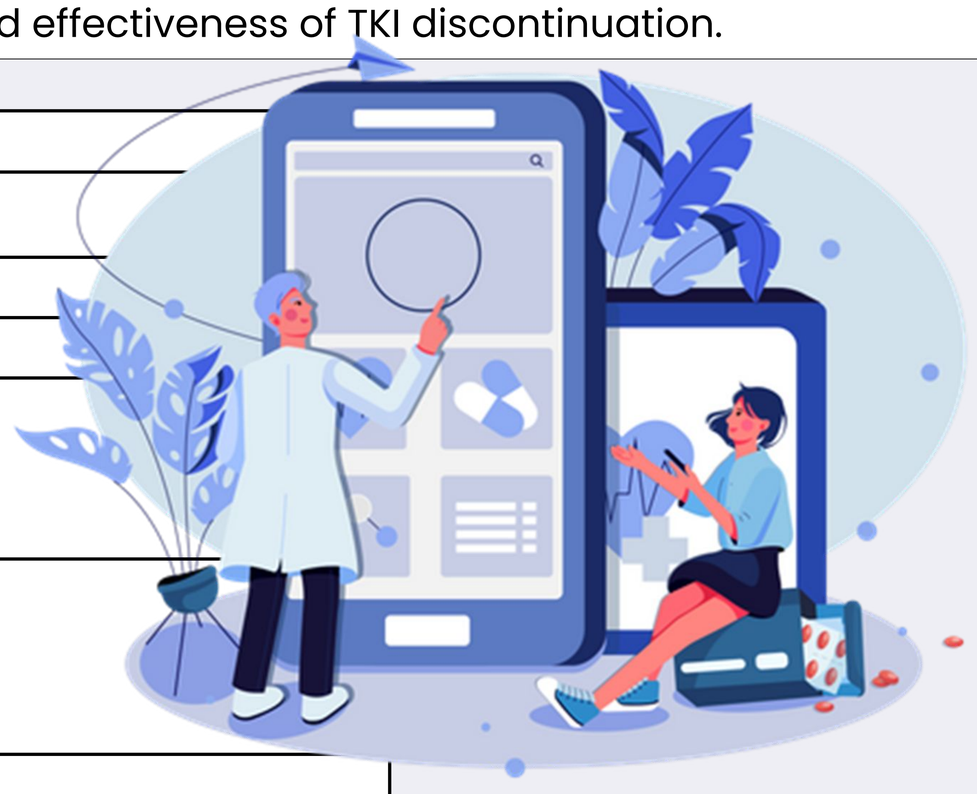
To analyze the Rates of Molecular Relapse Free Survival (MRFS) and Treatment Free Remission (TFR) during discontinuation of TKIs in first- or second-line CML.

METHODOLOGY

Observational, multicenter, prospective follow-up study

- **Eligibility Criteria**: Patients treated with Imatinib, Nilotinib, or Dasatinib at any dose (first or second line). Achieved and maintained Molecular Response (MR) ≥ 4.5 log for at least 36 months. Minimum TKI treatment time of 5 years. No resistance to any previous TKI. No diagnosis of accelerated phase or blast crisis.
- **Ethical Approval:** Authorization obtained from the Andalusian Biomedical Research Ethics Coordinating Committee (CCEIBA).
- **Study Protocol:** Monthly molecular monitoring BCR-ABL level using PCR-RT with GeneXpert® during the first year. Every 2 months in the second year. Every 3 months from the third year onward.
- **Timeline:** 6 months of MR ≥ 4.5 log required before discontinuation. Follow-up Period: Year 1: Monthly. Year 2: Bi-monthly. Year 3 and beyond: Quarterly.
- **Data Collection and Analysis** Regular monitoring of molecular markers. Evaluation of safety and effectiveness of TKI discontinuation.

Category	Details
Number of patients recluted	90
Median age at diagnosis	48 years
Median age at discontinuation	59 years
Number of patients with TKI discontinuations	Imatinib: 60 Dasatinib: 10 Nilotinib: 20
Median time to discontinuation	30 months
Molecular Relapse-Free Survival (MRFS) Rate	74%
Treatment-Free Remission (TFR) Rate	62%
Relapse Cases	25 patients lost Major Molecular Response (MMR)
Patients who achieved MMR after reintroduction of TKI at the same dose	100%
Progression	0
Adverse Events	Withdrawal syndrome reported in 15% of patients



CONCLUSION

The MRFS and RFT of our study is concordant with those reported in several real-life series. In selected patients, with a considerable exposure time to TKI treatment, and in deep and maintained MR, a successful RFT can be expected, which translates into effective and safe discontinuation of TKIs in clinical practice.