MANAGING CHRONIC MYELOID LEUKEMIA: REAL-WORLD EVIDENCE ON USE OF TYROSINE KINASE INHIBITORS AND RELATED SIDE EFFECTS.

1)Bettiol A. 2)Pirolo R. 3)Bolcato J. 4)Franchin G. 5)Giusti P. 6)Chinellato A.

University of Padua

Introduction

Chronic myeloid leukemia (CML) is a myelodisplastic neoplasia accounting for around 15% of all cases of leukemia in adults. CML treatment is mainly based on tyrosine kinase inhibitors (TKIs). Current TKIs approved as first line treatments are imatinib or second-generation TKIs such as dasatinib and nilotinib. Overall, TKIs have proved great efficacy, accounting for survival rates that are now comparable to those of the general population. As CML has progressively switched from a fatal to a “chronic” pathology, data coming from randomized clinical trials (RCTs) have become insufficient, due to their relative short times of follow-up, as well as to the significant differences in the enrolled cohorts compared to the real-life population. On the brink of the commercialization of generic imatinib, our observational study aimed to take a picture of the management of chronic phase (CP) CML over a decade of local real clinical practice, addressing long-term outcomes such as treatment switches, and occurrence of adverse events

Methods

A retrospective cohort study was performed on CP CML patients followed in the Local Health Authority of Treviso (Veneto, Italy) during the period 2005-2015. Data were captured integrating both administrative databases and physician patient’s diaries.

Results

97 CP-CML patients were examined. Imatinib was the most common first line treatment (73 out of 97 subjects). Among second generation TKIs, only nilotinib was used as first line therapy in 8 patients. No therapeutic switch occurred among patients treated with frontline nilotinib; on the other hand, 38% of imatinib-treated patients switched to a second line therapy, mainly because of severe intolerance. In particular, dermatologic manifestations and osteoarticular pain resulted to be the most common side effects (67% of patients, each), followed by asthenia, diarrhoea, alteration of cardiac rhythm, and epigastric pain. Development of secondary malignancies occurred in 16 patients. No significant difference in the occurrence of adverse events emerged between imatinib and nilotinib.

Conclusion

Although based on a small local cohort, this real-life study showed a central role of imatinib as frontline therapy for CP patients. Adverse events remain a major concern, highlighting the importance of close monitoring of patients in order to avoid the need of therapeutic switches.