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EFFECT OF FREQUENT GENERIC IMATINIB SWITCHING ON TREATMENT RESPONSE IN PATIENTS WITH CHRONIC MYELOID LEUKEMIA

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Objective: The aim of this study was to evaluate the effect of switching one or more generic imatinibs during treatment on outcomes in patients with chronic phase chronic myeloid leukemia.. **Case Report:** Chronic myeloid leukemia (CML) is a myeloproliferative neoplasm associated with the Philadelphia chromosome t(9;22)(q34;q11) and the BCR::ABL1 fusion gene, which produces a constitutively active BCR::ABL1 tyrosine kinase.CML accounts for approximately 15 to %20 of adult leukemia. It has an annual incidence of 1 to 2 cases per 100,000, with a slight male predominance.The median age at presentation is approximately 50 years, and the prevalence of CML is steadily increasing in the Western world because of the dramatic effect of ABL1 kinase inhibitors on survival. Imatinib was the first commercially available TKI to approved by the U.S Food and Drug Administration (FDA) and the European Medicines Administration (EMA) for the initial treatment of CML. The high cost of new cancer drugs, including those developed for CML, is a major concern for healthcare payers, especially in countries with limited resources. Reimbursement policies around the world therefore encourage the use of generics to reduce prices.The European LeukemiaNet 2020 recommendation for the use of generic imatinib is as follows : "As long as a generic medicine meets the national standards of the country concerned in terms of quality of production, bioavailability and efficacy, it is an acceptable alternative to the branded product. *It is recommended that the patients continue to use the same generic brand whenever possible to avoid potential side effects due to changes in drug structure, bioavailability and excipients.*" In the NCCN guidelines, the recommendation for generic drugs is as follows: "Innovator and generic drugs approved by regulatory authorities on the basis of pharmacokinetic equivalence can be used interchangeably" and "*In countries where more than one generic drug is available, switching from one generic drug to another is not recommended*". **Methodology:** We retrospectively analyzed data from patients diagnosed with CML-CP treated with imatinib from 2010 - 2024. Patients with chronic phase chronic myeloid leukemia who were over 18 years of age and who started treatment with original or generic imatinib and switched to generic imatinib at any time during treatment were included. Patients who were diagnosed before the age of 18, patients whose treatment was interrupted during pregnancy, patients who did not use generic imatinib or patients who used only one brand of generic imatinib permanently were excluded from the study.The characteristics of the patients and the follow-up periods were collected retrospectively from the patients' electronic files.The efficacy of treatment was evaluated via standard hematological and molecular assessments to determine the rates of complete hematological response (CHR), molecular response (MR), and treatment failure, which was defined as a bcr-abl level of 1 % or higher on two occasions with an interval of one month. **Results:** A total of 46 patients, 26 (56.5%) male and 20 (43.5%) female (male/female ratio, 1.3), were included in the study. The median age was 45 years (range, 20-77 years). Forty-one (89.1%) of the patients were under 65 years of age, and 5 (10.9%) were over 65 years of age.The starting dose of imatinib was 400 mg/d in all patients. Treatment was started with Gleevec in 11 patients and generic imatinib in 35 patients. All patients were switched to two or more generic imatinibs during treatment.During the treatment process, 12 patients 2, 13 patients 3, 12 patients 4, 7 patients 5 and 1 patient 6 used different types of generic imatinib.Loss of response occurred in 8 of 46 (17.3%) patients. The earliest loss of response occurred at month 6, and the latest loss occured at year 9. One patient lost response at month 6, 1 patient at year 1, 2 patients at year 2, 1 patient at year 3, 2 patients at year 7, and 1 patient at year 9.All patients who experienced a loss of response responded to second-generation tyrosine kinase inhibitors, and none developed an accelerated or blastic phase. No dose increases or switches back to the original product in patients with loss of response. No patients had their dose changed or discontinued due to adverse events.When evaluated according to age, sex and number of generic imatinib switches, none of these variables were found to have any effect on response loss. **Conclusion:** Following the introduction of generic imatinib, several studies have shown that there is no loss of efficacy in patients who are switched from Glivec to generic imatinib. Although the ELN and NCCN CML guidelines do not discourage the use of generic imatinib, switching between generic imatinibs is not recommended. A review of both guidelines and the literature revealed no information on the development of adverse outcomes related to treatment response in patients switching between generic imatinibs.In the abovementioned retrospective studies, data on the responses obtained from patients receiving more than one type of generic imatinib were not shared.In our study, the response loss in patients who received more than one generic imatinib was 17.3%, which is comparable to the response losses observed in other studies of patients who received the original imatinib or generic imatinib.The findings of our study indicate that switching between generic imatinibs does not have a detrimental effect on treatment response.

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ONE CASE OF CHRONIC MYELOID LEUKEMIA IN PEDIATRIC GROUP

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Objective: Chronic myeloid leukemia (CML) is a myeloproliferative syndrome caused by monoclonal myeloid proliferation with the passage of immature granular elements into the peripheral blood. It is a rare disease in children and adolescents,