

THE RESULTS OF TREATMENT WITH IMATINIB MESYLATE IN PATIENTS WITH CHRONIC MYELOID LEUKEMIA. RETROSPECTIVE STUDY.

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Background. Imatinib Mesylate, a Tyrosine Kinase inhibitor, is one of the drug of choice for chronic myeloid leukemia (CML) in chronic phase (CP). During therapy, a few patients develop myelosuppression. Adverse side-effects of the drug could be: edema, nausea, vomiting, diarrhea, cramps and cutaneous reactions. Adverse hematologic side-effects could include anemia, neutropenia, and thrombocytopenia.

Aims. The aim of this study was to evaluate the results of treatment and the safety of imatinib as first line therapy in patients with newly diagnosed CML-CP.

Methods. Between January 2008 and January 2015, 92 patients with Ph+CML-CP were included in the study. They were diagnosed in Department of Hematology, County Hospital Timisoara, Romania. Eligibility criteria included age 18 years and older, ECOG performance status of 0 to 2, adequate hepatic and renal functions, no prior imatinib therapy, non-pregnant patients. CML-CP was defined as less than 10% blasts and less than 20% basophils in the peripheral blood and bone marrow and a platelet count between $100 \times 10^9/L$ and $< 1000 \times 10^9/L$. Therapy was initiated with imatinib 400 mg orally daily and patients were monitored for any adverse effects.

Results. Out of 92 cases with CML-CP included in the study, male: female ratio was 0.8:1.3 with median age 45 (ranged from 18-70). After starting Imatinib a CHR was achieved at 3 month by 89.5% patients. The CyR achieved was major in 65% (with 58% CCR) no CyR in 18 patients. The molecular response was complete in 29% and major in 32% patients. The doses were increased in 23 patients and improved response was achieved in 14 patients. Six patients were switched to Dasatinib and four to Nilotinib. The median follow-up was 62 month (range 22-80) and under Imatinib was 49 months. The twelfth patients died, seven of blastic transformation. The study showed that the commonest hematological side effects were grade 2 anemia (13%), followed by leucopenia 11%, and thrombocytopenia 7%. The most common non-hematological adverse effects were superficial edema and weight gain 30%, followed by musculoskeletal pain 29%, then gastrointestinal (vomiting, diarrhea) 9%.

Conclusions. Data indicated that imatinib mesylate remains effective for the most of the patients is a well tolerated drug, and all adverse effects could be managed for patients with CML-CP. The most common hematological side effect was anemia, while the non-hematological side effect was fluid retention.