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CML patients on imatinib have similar mortality rates to general population

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Patients taking imatinib (Gleevec) for CML, or chronic myelogenous leukemia, and in remission after two years of treatment, have a mortality rate similar to that of the general population according to a study published online [date] in the *Journal of the National Cancer Institute.*

The article offers the first evidence that a disseminated cancer, not amenable to surgery, can be controlled to the point of giving patients a normal life expectancy.

Many patients in this study, known as the Long-Term Imatinib Effects (ILTE) study, reported side effects, but survival rates remained high even after eight years of taking the drug. Imatinib was the first drug to produce complete and lasting responses in CML patients and is now widely used as first-line treatment. But most information on the long-term effects of the oral, targeted agent has come from industry-sponsored trials at selected centers.

To learn about outcomes in patients taking imatinib under normal circumstances, outside of trials, Carlo Gambacorti-Passerini, M.D. of the University of Milano Bicocca/San Gerardo Hospital in Monza, Italy and colleagues collected data on patients from 27 centers in Europe, North and South America, Africa, the Middle East, and Asia.

The ILTE study enrolled 832 patients who were in complete remission after two years of taking the drug. Twenty deaths occurred during the follow-up period, for a mortality rate of 4.8%--similar to what would be

expected in a comparable group of people in the general population. Only six of these deaths were related to CML. Serious adverse events, such as cardiovascular and digestive system problems, were reported in 139 patients, but were considered related to imatinib in only 27 cases, or 19%.

Other adverse events, less serious but judged by treating physicians to substantially affect quality of life, occurred in more than half of patients and were frequently linked to imatinib use. The most frequent were muscle cramps, asthenia (weakness), edema, skin fragility, diarrhea, and tendon or ligament lesions. Nineteen patients (or 2.3%) stopped taking imatinib because of side effects; at least half of these switched to one of the other targeted drugs for CML, dasatinib or nilotinib, which became available in 2006.

The authors conclude that patients on imatinib "frequently suffer from side effects that are non-serious but can nonetheless reduce their quality of life." They note that the findings highlight the "importance of a good relationship between health care providers and patients, where side effects are easily communicated and addressed to reduce/avoid non-compliance."

In an accompanying editorial, B. Douglas Smith, M.D., of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, writes that the study adds "real-life, long-term" data on the efficacy and side effects of imatinib. "Remarkably, survival rates and the incidence of secondary malignancies in this patient cohort did not differ statistically significantly from the general population, which speaks to… the astounding effect [imatinib] has had on the clinical course of this disease," he writes.

Smith notes that some questions remain: many patients in the study had been treated first with interferon, which may have been a factor in their

remissions, and so a careful analysis of the two groups--patients who had taken interferon and those who had not—would be valuable. Smith also calls for research on ways to completely eliminate the small amount of residual disease after treatment with imatinib. "It is now time for clinical and laboratory investigators to build on this platform and work to turn good and great responses into cures."

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