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Green tea extract appears to keep cancer in check in majority of CLL patients

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An extract of green tea appears to have clinical activity with low toxicity in chronic lymphocytic leukemia (CLL) patients who used it in a phase II clinical trial, say researchers at Mayo Clinic.

The findings, to be presented Monday, June 7, during the annual meeting of the American Society of Clinical Oncology (ASCO), are the latest in a series of Mayo studies to show promise for use of the chemical epigallocatechin gallate (EGCG) -- the major component of green tea -- in reducing the number of leukemia cells in patients with CLL. Mayo first tested EGCG in a variety of laboratory assays about eight years ago, and it was found to reduce the survival of CLL leukemic cells. This laboratory finding was followed by a successful phase I clinical trial -- the first time green tea extract had been studied in CLL patients.

"Although only a comparative phase III trial can determine whether EGCG can delay progression of CLL, the benefits we have seen in most CLL patients who use the chemical suggest that it has modest clinical activity and may be useful for stabilizing this form of leukemia, potentially slowing it down," says Tait Shanafelt, M.D., a Mayo Clinic hematologist and lead author of the study.

"These studies advance the notion that a nutraceutical like EGCG can and should be studied as cancer preventives," says Neil Kay, M.D., a hematology researcher whose laboratory first tested the green tea extract in leukemic blood cells from CLL patients. "Using nontoxic chemicals to push back cancer growth to delay the need for toxic therapies is a worthy

goal in oncology research -- particularly for forms of cancer initially managed by observation such as CLL."

Drs. Shanafelt and Kay caution that EGCG is not a substitute for chemotherapy. All of the patients Mayo tested with EGCG were early stage, asymptomatic CLL patients who would not otherwise be treated until their disease progressed. The extract was supplied by the National Cancer Institute (NCI) and Polyphenon E International for these initial clinical trials.

CLL is a blood cancer that is a hybrid between leukemia and lymphoma. Progression of the disease is measured by the quantity of leukemia cells in the blood and bone marrow as well as enlargement of lymph nodes due to infiltration by the leukemia cells. In the phase I study, published in May 2009 in the Journal of Clinical Oncology, researchers found that the blood lymphocyte (leukemia cell) count was reduced in one-third of participants, and that the majority of patients who entered the study with enlarged lymph nodes due to involvement by CLL saw a 50 percent or greater reduction in their lymph node size.

Using the highest dose tested in the phase I study, the researchers launched their phase II clinical trial in an additional 36 patients. The results presented at the ASCO meeting evaluate the effects in these 36 patients as well as the six patients from the phase I trial treated at the same dose (total 42 patients). Results from 41 patients who have completed the study show that 31 percent of patients had a 20 percent or greater sustained reduction in blood leukemia count, and 69 percent of patients with enlarged lymph nodes saw a reduction of node size of 50 percent or greater.

In all, 69 percent of CLL patients had a biological response to EGCG as evidenced by a 20 percent or greater sustained reduction in blood lymphocyte count and/or a 50 percent or greater reduction in lymph

node size, the researchers say.

Because EGCG was being studied in patients who did not otherwise need treatment, the researchers took a rigorous approach toward studying side effects. Most clinical trials of therapeutic agents only report grade 3 and higher side effects, but the researchers looked at and reported grade 1 and grade 2 as well. While a number of patients had transient grade 1 or 2 side effects, only three of 42 experienced a grade 3 side effect during their six months of treatment.

"All in all, the treatment was well tolerated with very mild side effects in most patients," Dr. Shanafelt says.

The researchers say that the prior publications on the effects of EGCG on CLL leukemia cells in the laboratory and the data from the published phase I study have been widely disseminated via the Internet by patient advocacy groups. Based on information from patients and colleagues throughout the country, the Mayo researchers have become aware that many CLL patients nationwide have started to use EGCG supplements, which are readily available over the counter.

"Without a phase III clinical trial, we cannot make a recommendation that EGCG be used by CLL patients, but those who want to take supplements should consult with their oncologists and need to receive appropriate monitoring using laboratory tests," Dr. Kay says.

Provided by Mayo Clinic