

Green tea shows promise as chemoprevention agent for oral cancer, study finds

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Green tea extract has shown promise as cancer prevention agent for oral cancer in patients with a pre-malignant condition known as oral leukoplakia, according to researchers at The University of Texas M. D. Anderson Cancer Center.

The study, published online in *Cancer Prevention Research*, is the first to examine green tea as a chemopreventative agent in this high-risk patient population. The researchers found that more than half of the oral leukoplakia patients who took the extract had a clinical response.

Long investigated in laboratory, epidemiological and clinical settings for several cancer types, green tea is rich in polyphenols, which have been known to inhibit carcinogenesis in preclinical models. Still, clinical results have been mixed.

"While still very early, and not definitive proof that green tea is an effective preventive agent, these results certainly encourage more study for patients at highest risk for oral cancer," said Vassiliki Papadimitrakopoulou, M.D., professor in M. D. Anderson's Department of Thoracic/Head and Neck Medical Oncology, and the study's senior author. "The extract's lack of toxicity is attractive - in prevention trials, it's very important to remember that these are otherwise healthy individuals and we need to ensure that agents studied produce no harm."

In the Phase II dose-finding study, 41 M. D. Anderson oral leukoplakia patients were randomized between August 2002 and March 2008 to



receive either green tea extract or placebo. Participants took the extract, an oral agent, for three months at one of three doses - 500 per meter squared of body mass (mg/m²); 750 mg/m² or 1,000 mg/m² - three times daily. To best assess biomarkers, participants also underwent a baseline and 12-week biopsy, an important component in the design of the study, the researchers say.

"Collecting oral tissue biopsies was essential in that it allowed us to learn that not only did the green tea extract appear to have benefit for some patients, but we pointed to anti-angiogenic effects as a potential mechanism of action," said Anne Tsao, M.D., assistant professor in the Department of Thoracic/Head and Neck Medical Oncology, and the study's first author. "While preliminary because our patient population was so small, this gives us direction for further study."

Of those taking green tea at the two highest doses, 58.8 percent had a clinical response, compared with 36.4 percent in the lowest extract dose and 18.2 percent in the placebo arm. At an extended follow-up with a mean of 27.5 months, 15 participants had developed <u>oral cancer</u>, with a median time to disease development of 46.4 months.

Although not statistically significant, the green tea extract also improved histology and trended towards an improvement in a number of biomarkers that may play a vital role in predicting cancer development.

Another important finding, say the researchers, was that that the extract was well tolerated. Side effects, including insomnia and nervousness, were mostly seen in the high-dose group but produced no significant toxicity.

"While these are encouraging findings, much more research must be done before we can conclude that green tea may prevent oral or any other type of cancer. It's also important to remind people that this trial



enrolled very few participants who, at the highest dose levels took the equivalent of eight cups of green tea three times a day," said Papadimitrakopoulo. "We need to further understand if green tea offers longer-term prevention effects for patients."

Papadimitrakopoulo and Tsao think that future studies with green tea in this high-risk population should focus on participants being exposed to the supplement for a longer time period. The researchers also stressed that the green tea extract studied in this trial was never sold over-the-counter and/or the Internet, both of which are not highly regulated. Rather, the compound was exclusively developed as a pharmaceutical.

According to the American Cancer Society, more than 35,720 are expected to be diagnosed with oral and/or pharynx cancer and the five year survival rate is less than 50 percent.

Source: University of Texas M. D. Anderson <u>Cancer</u> Center (<u>news</u>: <u>web</u>)

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