Western Diet Tied to Colon Cancer Return

BY MARY ANN MOON
Contributing Writer

Colon cancer patients who eat a typical Western diet seem to have triple the risk of recurrence, compared with those who don't follow a Western diet.

After a potentially curative resection of stage III colon cancer and adjuvant chemotherapy, a diet replete with sweets, french fries, refined grains, and red and processed meats "may facilitate a milieu that allows residual microscopic disease to proliferate and spread," Dr. Jeffrey A. Meyerhardt of the Dana-Farber Cancer Institute, Boston, and his associates said.

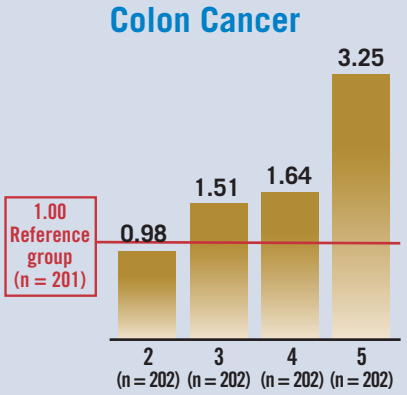
Some studies have examined the influence of diet and other lifestyle factors on the development of colon cancer, but few have addressed diet's influence in patients with established colon cancer. The investigators assessed the effect of two distinct dietary patterns—a typical Western diet versus what the investigators termed a "prudent" diet that included greater intakes of fruits, vegetables, legumes, fish, poultry, and whole grains—in 1,009 adult subjects who were already participating in a National Cancer Institute trial comparing different chemotherapy regimens.

The subjects had undergone complete surgical resection of the primary tumor in 1999-2001, and had regional lymph node metastases but no distant metastases. Their diets were assessed midway through the adjuvant chemotherapy. They were followed for a median of 5 years; a total of 324 developed a recurrence during follow-up.

Greater intake of a Western diet was associated with recurrence and cancer mortality. Patients in the highest quintile of the Western dietary pattern were three times more likely to develop recurrence and die from cancer than those in the lowest quintile of the pattern, the authors said (JAMA 2007;298:754-64). There was no association between the prudent diet and risk of cancer recurrence or mortality.

The deleterious effect of the typical Western diet was not significantly modified by patient age, gender, body mass index, or level of physical activity. ■

Hazard Ratios of Cancer Recurrence or Death In Patients With Colon Cancer



Source: JAMA

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FDA: PPIs Pose No Increased Heart Risks

BY JOHN R. BELL
Associate Editor

New data supplied by AstraZeneca, maker of the prescription proton pump inhibitors Prilosec (omeprazole) and Nexium (esomeprazole), do not suggest that either drug increases cardiovascular event risks in patients with severe gastroesophageal reflux disease, according a preliminary conclusion announced by the Food and Drug Administration.

Physicians and other providers should not change their prescribing practices for either drug, the agency said.

The new information contradicts earlier data from two small, ongoing studies that the company provided to the FDA earlier this year. These data suggested that patients who took either drug were at increased risk for cardiovascular events, including myocardial infarction and heart failure. The agency did not issue a safety warning at that time.

In a teleconference and in the FDA's first-ever "early communication" statement, the agency noted that the increased cardiovascular risk seen in AstraZeneca's two initial trials was likely caused by older patient age and more extensive history of heart problems in patients who received either drug for treatment of GERD, compared with patients who instead underwent surgery for their disease.

Dr. Paul Seligman, associate director for safety policy and communication in the agency's Center for Drug Evaluation

and Research (CDER), said, "The results from the study of Prilosec and analyses from an ongoing study of Nexium raised concerns that long-term use of Prilosec or Nexium may have increased the risk of heart attacks, heart failure, or heart-related sudden death in those patients taking either one of the drugs, compared to patients who received surgery."

The company has since provided the agency with additional follow-up data from the original two studies, as well as data from 14 additional studies, 4 of which were placebo controlled. Despite the agency's earlier concerns, the new data indicate that many patients who had been randomly assigned to undergo surgery dropped out before the planned procedure, leaving a younger, healthier group of patients in the surgery group. "Upon initial examination and review of all available data that we have to date, the FDA has concluded preliminarily that these data do not suggest an increased risk of heart problems in patients treated with either of these products."

The FDA has been in contact with its counterparts in the United Kingdom, Australia, New Zealand, and Canada, where similar reviews are taking place. Data from these independent reviews support the FDA's preliminary findings, he said.

He added that the new announcement will not result in any changes to direct-to-consumer advertising for either drug. As to whether manufacturers of other PPIs would be asked for additional data on their products, the agency is "in the process of accumulating as much data as we can about all of these products," he said.

Dr. Seligman also noted that the communication does not apply to the over-the-counter version of omeprazole, Prilosec OTC, manufactured by Procter & Gamble.

Dr. Julie Beitz, director of CDER's Office of Drug Evaluation III, said that specific information on what conditions were controlled for and what type of statistical analysis was conducted for any of the studies will be available upon completion of the agency's safety review of both drugs. That should occur in early November, Dr. Seligman said.

The early communication statement is available at www.fda.gov/cder/drug/early_comm/omeprazole_esomeprazole-htm. Early-communication statements will not replace the public-health advisories that have been issued periodically beginning 2 years ago or the FDA's health care provider statements, Dr. Seligman said. He said that their introduction at this time did not result from the FDA's recent actions regarding Avandia. ■