Results from a study testing methylphenidate for cancer-related fatigue

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Cancer-related fatigue is often a major problem for cancer patients, beginning at diagnosis, during treatment and after completing therapy. Researchers at Mayo Clinic and the North Central Cancer Treatment Group (NCCTG) recently completed a study testing methylphenidate in the treatment of cancer-related fatigue and found that, while it did not improve fatigue for a broad group of patients, the data did not rule out a benefit for those with stage III/IV cancer. Results of this NCCTG study, N05C7, will be presented on Sunday, June 6, 2010, at the American Society of Clinical Oncology annual meeting in Chicago.

"Cancer-related fatigue can impact a patient's ability to tolerate therapy and their overall quality of life," says Debra Barton, R.N., Ph.D., associate professor of oncology at Mayo Clinic in Rochester, Minn., and an investigator for the study. "While our study did not demonstrate improvement in fatigue for a broad patient population, our results do not rule out some benefit for patients with advanced cancer and point to the need for further research."

The study included 148 adult patients with cancer-related fatigue. Of these, 74 were randomized to receive long-acting methylphenidate and 74 were randomized to receive a placebo over a four-week period. Patients taking methylphenidate were titrated from 1 to 3 tablets in order to reach the target dose of 54 mg per day. To be part of the study, patients had to report fatigue that was defined as a score of greater than or equal to 4 on an 11-point Brief Fatigue Inventory (BFI) scale.

Methylphenidate is one of a group of psychostimulants that "wake up" or stimulate the central nervous system in the brain, producing chemicals such as dopamine and norepinephrine, which cause a person to be alert. In this study, a long-acting dose was selected to deliver a constant level of medication in the bloodstream throughout the day.

In the study, all participants rated their usual fatigue on the BFI every week for four weeks. Fatigue was rated on a scale of 0 to 10, with 0 being no fatigue and 10 being severe fatigue.

Results indicated no significant difference between the methylphenidate and placebo groups for usual fatigue over the four-week period. "In patients with stage III/IV disease, however, there appeared to be a difference in the fatigue score between the two arms," says Dr. Barton. "In addition, there was a trend for patients receiving methylphenidate to be more satisfied with their treatment compared to those on the placebo arm. Caution should be used in interpreting these results, as this was an exploratory analysis and should only be used to generate hypotheses for future research," Dr. Barton says.

As far as side effects, Dr. Barton adds, "Anxiety and appetite loss were more prominent in patients on the treatment arm. There was no significant difference in the incidence of other potential side effects such as insomnia and dizziness between the two groups, but side effects, in general, were more often observed in the patients receiving the active drug."

"When considering using methylphenidate in the treatment of cancer-related fatigue, patients and their physicians need to consider the benefits and side effects of the medication," says Dr. Barton.

According to Dr. Barton, "Currently, we are developing a new study to test a newer psychostimulant medication for cancer-related fatigue in

patients with advanced cancer. Hopefully, it will be more effective and less toxic."

Provided by Mayo Clinic