Supportive care

Olanzapine for the Treatment of Advanced Cancer-Related Chronic Nausea and/or Vomiting: A Randomised Pilot Trial.

Navari RM, Pywell CM, Le-Rademacher JG, White P, Dodge AB, Albany C, Loprinzi CL.

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IMPORTANCE:

Nausea and vomiting, unrelated to chemotherapy, can be substantial symptoms in patients with advanced cancer.

OBJECTIVE:

To evaluate the utility of olanzapine for treating chronic nausea/vomiting, unrelated to chemotherapy, in patients with advanced cancer.

DESIGN, SETTING, AND PARTICIPANTS:

This study is a double-line, placebo-controlled, randomised clinical trial conducted from July 2017 to April 2019, with analysis conducted in 2019. Eligible participants were outpatients with advanced cancer who had persistent nausea/vomiting without having had chemotherapy or radiotherapy in the prior 14 days. Chronic nausea was present for at least one week (worst daily nausea numeric rating scores needed to be greater than 3 on a 0-10 scale).

INTERVENTIONS:

Patients received olanzapine (5 mg) or a placebo, orally, daily for seven days.

MAIN OUTCOMES AND MEASURES:

Patient-reported outcomes were used for study end points. Data were collected at baseline and daily for seven more days. The primary study end point (the change in nausea numeric rating scores from baseline to the last treatment day) and the study hypothesis were both identified prior to data collection.

RESULTS:

A total of 30 patients (15 per arm) were enrolled; these included 16 women and 14 men who had a mean (range) age of 63 (39-79) years. Baseline median nausea scores, in all patients, were 9 out of 10 (range, 8-10). After one day and one week, the median nausea scores in the placebo arm were 9 out of 10 (range, 8-10) on both days, compared with the olanzapine arm scores of 2 out of 10 (range, 2-3) after day one and 1 out of 10 (range, 0-3) after one week. After one week of treatment, the reduction in nausea scores in the olanzapine arm was 8 points (95% CI, 7-8) higher than that of the placebo arm. The primary two-sided end point P value was <0.001. Correspondingly, patients in the olanzapine arm reported less emesis, less use of other antiemetic drugs, better appetite, less sedation, less fatigue, and better well-being. One patient, on the placebo, stopped treatment early owing to lack of perceived benefit. No patients receiving olanzapine reported excess sedation or any other adverse event.

CONCLUSIONS AND RELEVANCE:

Olanzapine, at 5 mg/d, appeared to be effective in controlling nausea and emesis and in improving other symptoms and quality-of-life parameters in the study population.