

GI Drugs Prove to Be Less Effective and More Dangerous



Medscape - A primarily plant-based, Mediterranean-style diet with alkaline water showed significantly greater improvement for laryngopharyngeal reflux (LPR) symptoms than treatment with proton-pump inhibitors (PPIs), according to a retrospective study published September 7 in *JAMA Otolaryngology–Head & Neck Surgery*.

"**This study indicates that**, by supplementing with alkaline water and a Mediterranean-style diet, effective control of symptoms as defined by the RSI [Reflux Symptom Index] may be obtained without PPI use," write Craig H. Zalvan, MD, from New York Medical College in Valhalla, and colleagues. "Other benefits of this diet-based approach include decreased risk for and improved control of cardiovascular disease, diabetes, stroke, and cancer, and avoiding the risks of drug interaction or complication."

The researchers retrospectively analyzed the medical records of two cohorts from different timeframes who received different treatments for LPR. One cohort of 85 patients, from 2010 to 2012 with a median age of 60 years, took esomeprazole twice daily or dexlansoprazole daily. They also followed standard reflux dietary precautions, including avoiding coffee; tea; chocolate; soda; alcohol; and greasy, fried, fatty, and spicy foods.

The other cohort, 99 patients from 2013 to 2015 with a median age of 57 years, received alkaline water and a 90% plant-based Mediterranean-style diet in addition to standard reflux precautions. (The water had a pH above 8.0.) Patients with potentially confounding comorbidities, such as a cough, a history of neuropathic pain, or dysphonia, were excluded.

The researchers compared the change in RSI scores between the two groups after 6 weeks of treatment. Among those taking PPIs, 54.1% of the patients had at least a 6-point reduction in their RSI, the minimum improvement deemed clinically meaningful. The average reduction in RSI across the group was 27.2%.

Meanwhile, 62.6% of those receiving the alkaline water and diet had a meaningful improvement in their RSI (difference between the groups, 8.05; 95% confidence interval [CI], -5.74 to 22.76). This group had a 39.8% average reduction in RSI (difference between groups, 12.1; 95% CI, 1.53 - 22.68).

However, when RSI was treated as a continuous variable there was no significant difference in the mean change in RSI between the two groups (−5.92 vs −7.05; difference in means, 1.12; 95% CI, −1.00 to 3.24)

Patients in both groups had differing symptoms, such as cough, dysphagia, and dysphonia, but too little power existed to analyze statistically significant differences in subgroups. This is a future research goal of the authors.

The authors acknowledge that the lack of a gold standard in LPR diagnostic testing makes it difficult to compare studies' findings. Further, the study design of retrospectively reviewing charts carries multiple potential biases with it, and some patients with dual diagnoses may have slipped through participant criteria and added confounding. The authors also could not link the improvement in symptoms specifically to the alkaline water or diet independently.

"Treatment of LPR is controversial," writes Robert T. Kavitt, MD, MPH, from the University of Chicago, Illinois, in an accompanying editorial. The American Gastroenterological Association advises that patients with the condition who lack typical symptoms avoid PPIs, whereas the American Academy of Otolaryngology-Head and Neck Surgery guidelines suggest that most patients with the condition take PPIs twice a day for at least 6 months.

"Given the conflicting approach of society guidelines, as well as limited data regarding the role of medical therapy in the treatment of LPR, it is important to assess additional options to offer patients," Dr Kavitt writes.

Although PPIs are the most effective current pharmacologic treatment for LPR, adverse effects can be an obstacle to ongoing treatment. The authors cite past research finding that 40% to 80% of people should not receive a PPI prescription.

"Proton pump inhibitors can cause adverse drug effects, such as abdominal pain, nausea, diarrhea and constipation," Dr Zalvan and colleagues write. "In addition, they have been associated with a variety of other adverse events, including fundic gland polyps secondary to hypergastrinemia, hypomagnesemia, hypocalcemia, bone fractures, decreased absorption of vitamin B12, diarrhea, and pneumonia, though evidence for the clinical significance of these relationships is limited."

The authors also note a link identified between PPI use and increased risk for myocardial infarction, dementia, stroke, and cardiovascular mortality. Further, PPIs are known to interact with other medications, and "drug reactions and interactions account for a considerable percentage" of deaths resulting from medical errors, the authors write.

"In this era when patients frequently raise concerns regarding the chronic use of PPIs owing to the potential adverse effect profile, it would be of great benefit to be able to offer additional options beyond acid-suppressive medications to patients with LPR," Dr Kavitt writes. He also identified other limitations to the study that future research could address, such as the lack of data on participants' weights, especially because weight loss from the diet may have influenced the findings.

"Nonetheless, the findings from this study are intriguing and suggest a possible change in future treatment paradigms in the management of LPR should the findings be confirmed," Dr Kavitt concludes.

Dr Zalvan serves on Restech Corporation's scientific advisory board but receives no monetary compensation. The other authors and Dr Kavitt have disclosed no relevant financial relationships.

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