The Effect of Olestra on Gastrointestinal Symptoms

Sandler RS, Zorich NL, Filloon TG, Wiseman HB, Lietz DJ, Brock MH, et al. Gastrointestinal symptoms in 3181 volunteers ingesting snack foods containing olestra or triglycerides. A 6-week randomized, placebo-controlled trial. Ann Intern Med 1999;130(4 Pt 1):253–61.

Study Overview

Objective. To evaluate the frequency and impact of gastrointestinal symptoms in adults and children who consume snacks containing olestra, a nonabsorbable, energy-free fat substitute.

Design. Randomized, parallel, placebo-controlled trial.

Setting and participants. 3181 volunteers aged 2 to 89 years from households in Phoenix, AZ, and St. Petersburg, FL. Households received identical packages labeled as containing olestra corn or potato chips. These packages contained either olestra or regular chips.

Main outcome measures. Gastrointestinal symptoms and their impact on daily activities, as reported by the participant or a household adult in a daily record. Gastrointestinal symptoms monitored were heartburn or indigestion, nausea or queasiness, vomiting, gas, bloating, abdominal cramping or pain, more frequent bowel movements, or looser stool or other digestive symptoms. The impact of symptoms on the participants' daily activities was ranked using 4 categories: (1) noticed symptoms but did not affect activities, (2) symptoms slightly affected activities, (3) missed some time at activities, and (4) missed an entire day of activities. Symptoms were monitored for 6 weeks.

Main results. Of the participants who consumed the most snacks, members of the olestra group reported more frequent bowel movements than the control group (27.9% versus 11.7%; difference, 16.2 percentage points [95% confidence interval (CI), 5.0 to 27.4 percentage points]; $P = 0.005$) and looser stools (30.3% versus 16.8%; difference, 13.5 percentage points [CI, 2.1 to 25.1 percentage points]; $P = 0.02$). Overall, at least 1 gastrointestinal symptom was reported by 619 of 1620 (38.2%) participants in the olestra group and 576 of 1561 (36.9%) participants in the control group (difference, 1.3 percentage points [95% CI, –3.6 to 6.2 percentage points]; $P = 0.60$). Although the groups did not differ significantly in the proportion of participants who reported individual gastrointestinal symptoms, more controls reported nausea (8.4% compared with 5.7%; difference, –2.7 percentage points [CI, –4.9 to –0.4 percentage points]; $P = 0.02$). There was one difference between groups for the mean numbers of days on which symptoms were reported: participants in the olestra group had 1 more symptom-day of more frequent bowel movements than did controls (3.7 symptom-days versus 2.8 symptom-days; difference, 0.9 symptom-days [CI, 0.1 to 1.8 symptom-days]; $P = 0.04$). The impact of symptoms on daily activities did not differ between the 2 groups.

Conclusion

Frequent, in-home consumption of snacks containing olestra is not associated with clinically meaningful or bothersome gastrointestinal effects.

Commentary

Anecdotal accounts of severe gastrointestinal distress associated with consumption of olestra [1] have not been substantiated by extensive controlled testing [2,3]. These authors examined the issue by obtaining data from a large sample that freely consumed olestra snacks in a home setting over a period of several weeks. It is notable that a remarkably high proportion of individuals in each study group reported at least 1 gastrointestinal symptom, albeit with low levels of symptom severity.

While it is important to note overall effects, results of analysis of the "high consuming" participants are of particular interest. Within that cohort, the olestra group had significantly higher rates of more frequent bowel movements and looser stools. Although the producers of olestra and marketers of olestra products might object, "everything in moderation" seems to be the best advice this study provides.

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"Outcomes Research in Review" is edited by Chris L. Pashos, PhD, Executive Director of Pharmacoeconomics and Outcomes Research, Abt Associates Clinical Trials, Cambridge, MA, and Associate Editor, Health Policy, Journal of Clinical Outcomes Management. *Dr. Pashos selects, summarizes, and provides the commentary on the studies that appear in this section.*