Gastrointestinal Symptoms Following Consumption of Olestra or Regular Triglyceride Potato Chips

A Controlled Comparison

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Context.—Olestra, a nonabsorbable, energy-free fat substitute used in snack foods, has been anecdotally reported to cause gastrointestinal (GI) adverse events, although such effects were not expected based on results from randomized trials, in which it was consumed in typical snack patterns.

Objective.—To determine whether ad libitum consumption of potato chips made with the fat substitute olestra results in a different level of GI symptoms than regular chips made with triglyceride (TG).

Design.—Randomized, double-blind, parallel, placebo-controlled trial.

Setting.—A suburban Chicago, Ill, multiplex cinema.

Subjects.—A total of 1123 volunteers aged 13 to 88 years.

Intervention.—Subjects were given a beverage and an unlabeled, white 369-g (13-oz) bag of potato chips made with olestra or TG during a free movie screening.

Main Outcome Measures.—Total and specific GI symptoms reported during a telephone interview conducted from 40 hours to 10 days after ingestion; level of potato chip consumption; and satiety level.

Results.—Of 563 evaluable subjects in the olestra chip group, 89 (15.8%) reported 1 or more GI symptoms, while 93 (17.6%) of the 529 evaluable subjects in the regular TG chip group did so (difference in symptom frequency between olestra and TG, −1.8; 95% confidence interval, −6.2 to 2.7; P = .47). For specific GI symptoms (eg, gas, diarrhea, abdominal cramping), there were no significant differences between olestra and TG chips. Fewer olestra chips were consumed than TG chips (60 vs 77 g [2.1 vs 2.7 oz]; P < .001), with olestra chips receiving lower taste scores (5.6 vs 6.4 on a 9-point scale; P < .001). Consumption levels did not correlate with the rate of symptom reporting in either the olestra or TG group. There was no difference in satiety scores between olestra and TG chips (5.7 vs 5.9 on a 9-point scale; P = .07).

Conclusions.—This study demonstrates that ad libitum consumption of olestra potato chips during 1 sitting is not associated with increased incidence or severity of GI symptoms, nor does the amount consumed predict who will report GI effects after short-term consumption of either olestra or TG potato chips.

A DIET HIGH IN FAT is now well known to be associated with obesity and heart disease. The American Heart Association recommends a diet in which fat contributes 30% or less of total energy. One factor making it difficult for individuals to lower their fat intake is the lack of availability of low-fat foods with taste and aesthetics comparable to the full-fat varieties.

Olestra is a nonabsorbable, energy-free fat substitute approved by the US Food and Drug Administration (FDA) for use in the preparation of snack foods, including potato chips, corn chips, and crackers. Olestra is a mixture of hexa-, hepta-, and octa-esters of sucrose formed from long-chain fatty acids prepared from any edible oil. Because olestra is not hydrolyzed by pancreatic enzymes, it is not absorbed and provides no dietary energy or fat. Extensive studies in laboratory animals and humans were reviewed by the FDA in its determination of the safe use of olestra in foods.

There has been considerable publicity around anecdotal reports of consumers experiencing gastrointestinal (GI) adverse events from olestra. We were interested in conducting a carefully controlled, blinded study that would allow a large number of participants unlimited access to chips in a single sitting (about a 2-hour period).

Participants and Methods

We studied 1123 adult and teenaged individuals who responded to recruitment flyers distributed at a suburban Chicago, Ill, multiplex cinema soliciting participants for a potato chip test at the movies. Potential subjects completed a telephone screening. The only exclusionary criteria were employment at a food or market research firm or participation of more than 2 individuals per household. Participants were scheduled for their choice of 4 first-run movies being shown on the study evenings and were instructed to eat their evening meal 1 to 2 hours prior to arriving at the theater. The theaters were closed to the public during the study.

The study protocol was approved by the local institutional review board. Written informed consent was obtained from all participants, as well as from a parent or guardian for minors. Two free
movie passes were given to each participant as an incentive.

Prior to the movie, participants were assigned to 1 of the 2 test groups via a separate randomization schedule generated for each of 6 sex and age strata (13-17, 18-34, and >34 years) (Figure). Each participant was then given a plain, white, coded 369-g (13-oz) bag of test chips (either regular Frito-Lay Ruffles or Frito-Lay MAX Ruffles made with olestra) by study staff, who were blinded to test group assignment. Participants also received their choice of beverage (various 960-mL [32-oz] soft drinks) and were asked to be seated in the theater at least 1 seat apart from other participants. They were instructed to consume as much or as little of their potato chips and beverage as they liked and not to share with anyone else. The theaters were monitored by several study staff during the movies.

At the conclusion of the movie, participants clipped their bags of potato chips shut; noted the approximate amount of beverage they had consumed; and completed a brief questionnaire regarding product acceptance, subjective satiety, and sensory attributes. Bags of chips were subsequently weighed to determine amounts of consumption.

Beginning 40 hours after the movie, trained telephone interviewers (Elrick & Lavidge, Chicago) began collecting information on any adverse events experienced since the movie. A telephone follow-up was conducted 5 and 10 days after the movie. The percentage of individuals with any GI complaints in those receiving olestra was no greater than that of TG subjects, with 2.6% vs 0%; P = .99. We found no increased incidence or severity of GI symptoms with olestra or TG group compared to those eating more than 113 g (4 oz) of chips (mean, 1.5 vs 1.3; P = .49). The percentage of individuals with any GI symptom and with each of the specific symptoms (gas, diarrhea, abdominal pain, upset stomach, abdominal cramping, and loose stool) was compared between olestra and TG groups across 4 chip-consumption levels (0-57, 57-113, 113-170, and 170-369 g [2-2.4, 4.6, and 6-13 oz]). There was no indication of increasing symptom incidence with greater consumption in either the olestra or TG group. Also, there were no significant differences between the 2 groups in incidence within 7 symptom and consumption categories (28 comparisons), except for 2 isolated findings of increased incidence of any GI symptom for the TG group in individuals eating more than 113 g of chips (2-4 oz) compared to olestra. In such cases, the percentage of individuals with any GI symptom and with each of the specific symptoms (gas, diarrhea, abdominal pain, upset stomach, abdominal cramping, and loose stool) was compared between olestra and TG groups across 4 chip-consumption levels (0-57, 57-113, 113-170, and 170-369 g [2-2.4, 4.6, and 6-13 oz]). There was no indication of increasing symptom incidence with greater consumption in either the olestra or TG group. Also, there were no significant differences between the 2 groups in incidence within 7 symptom and consumption categories (28 comparisons), except for 2 isolated findings of increased incidence of any GI symptom for the TG group in individuals eating more than 113 g of chips (2-4 oz) compared to olestra. In such cases, the percentage of individuals with any GI symptom and with each of the specific symptoms (gas, diarrhea, abdominal pain, upset stomach, abdominal cramping, and loose stool) was compared between olestra and TG groups across 4 chip-consumption levels (0-57, 57-113, 113-170, and 170-369 g [2-2.4, 4.6, and 6-13 oz]). There was no indication of increasing symptom incidence with greater consumption in either the olestra or TG group. Also, there were no significant differences between the 2 groups in incidence within 7 symptom and consumption categories (28 comparisons), except for 2 isolated findings of increased incidence of any GI symptom for the TG group in individuals eating more than 113 g of chips (2-4 oz) compared to olestra.
large group of subjects consuming olestra chips ad libitum during 1 sitting in a movie theater. While this setting may be unique for a clinical trial, the study was structured to meet rigorous controlled clinical trial standards under conditions typical for the use of the snack foods.

Overall preference for olestra potato chips was slightly lower, and this is probably reflected in the 22% lower chip consumption in the olestra group. Despite lower consumption, the olestra group reported being no less satiated than the TG chip group. This suggests a previously reported1 possibility that olestra use will reduce energy and fat intake, aiding weight control in those who consume potato chips. While the median consumption of olestra chips was less than TG chips, it was more than 57 g (2 oz), which is more than a typical single-serving snack-sized bag of chips, and there were 155 subjects who consumed more than 113 g (4 oz) of olestra chips (>33 g of olestra). Thus, the consumption levels were adequate to ensure that enough olestra was consumed to evaluate potential GI effects. However, even in the participants consuming more than 113 g (4 oz) of olestra chips (>33 g of olestra), there were no differences observed in the frequency or severity of reported GI symptoms between groups, nor was there any indication of a dose-response relationship of increasing symptoms with higher consumption levels in either test group. The 2 statistically significant findings (increased upset stomach in the 0- to 57-g [0- to 2-oz] olestra group and increased incidence of any symptom in the 57- to 113-g [2- to 4-oz] TG group) appear likely to be due to random variation.

The information label on olestra products states that “olestra may cause loose stools and abdominal cramping.” The current study findings do not support this statement. The label primarily reflects the results from 2 clinical studies in which subjects were required to consume olestra at every meal for 56 consecutive days. In those studies there were statistically significant increases (19%-42%) in mild to moderate GI symptoms in persons eating 20 or 32 g of olestra per day in foods (equivalent to 68-111 g [2.4-3.9 oz] of chips relative to the current study) compared with placebo subjects.8,9 However, in other studies conducted under ad libitum home-use conditions that included more than 3500 participants, no differences were found in the reporting of GI symptoms compared with TG snack control groups.10 The manufacturer of olestra is currently conducting postmarketing surveillance via toll-free telephone numbers on packages of olestra-containing snack products. Reporting frequency has been related to news media coverage on the controversy about potential GI effects. While the current study was designed to evaluate symptom occurrence under conditions at 1 sitting, this type of consumption constitutes the majority of consumer complaints to the manufacturer to date (81%). These same individuals report a median consumption of 48 g (1.7 oz) of chips.11 Thus, these reports would not appear to be supported by the findings in the present study.

What, then, are alternative explanations for the symptoms experienced by these consumers and by the participants in the present study? It has been demonstrated in a large-scale survey that functional GI symptoms are quite common in the general population, with up to 69% of individuals reporting 1 or more symptoms during a 3-month period.12 Food intolerances are also commonly reported in the population.13 Of note, however, are our findings that increased symptom rates were not observed in individuals consuming more chips and that there was a lack of association between reported history of GI problems and symptoms in the present study. Finally, because possible GI symptoms were mentioned in the informed consent, a potential “nocebo,” or negative placebo effect, may be increasing the rate of reporting. For example, in 1 published study, a 6-fold increase in the number of patients withdrawing from a trial because of minor GI symptoms was found when a statement outlining these possible adverse effects was included in the informed consent.14

Regardless of the potential explanations for the high rate of GI symptoms reported, we were unable to demonstrate any increase in the frequency of GI symptoms when participants ate as many olestra potato chips as they cared to at 1 time. Previous and ongoing studies address GI symptom incidence under a variety of other consumption settings. The present findings provide practical information on the effects of olestra consumed in a typical fashion.

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References

9. Schlagheck TG, Kessler JM, Jones MB, et al. Olestra’s effect on vitamins D and E in humans can be offset by increasing dietary levels of these vitamins. J Nutr. 1997;127(suppl 8):1666S-1685S.