Changes in Diet, Weight, and Serum Lipid Levels Associated With Olestra Consumption

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**Background:** Specially manufactured low-fat and nonfat foods have become increasingly available over the past 2 decades and controversy has surrounded the issue of whether these products have beneficial or adverse effects on the health and nutritional status of Americans.

**Methods:** This study examines the association of olestra consumption with changes in dietary intakes of energy, fat, and cholesterol and changes in weight and serum lipid concentrations. Data are from a cohort of 335 participants in the Olestra Post-Marketing Surveillance Study sentinel site in Marion County (Indianapolis, Ind). Diet, weight, and serum lipid levels were assessed before the market release of olestra and 1 year later, after olestra-containing foods were widely available. Olestra intake at the 1-year follow-up was categorized as none, low (0 to 0.4 g/d), moderate (0.4 to 2.0 g/d), and heavy (>2.0 g/d).

**Results:** Participants in the heavy olestra consumption category significantly reduced dietary intake of percentage of energy from fat (2.7 percentage points, P for trend, .003) and saturated fat (1.1 percentage points, P for trend, .02). Consumers in the highest category of olestra consumption had statistically significantly reduced total serum cholesterol levels of –0.54 mmol/L (–21 mg/dL) compared with –0.14 mmol/L (–5 mg/dL) among olestra nonconsumers (P for trend, .03).

**Conclusions:** These results indicate that introduction of a new fat substitute (olestra) in the US market was associated with healthful changes in dietary fat intake and serum cholesterol concentrations among consumers who chose to consume olestra-containing foods.

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The last 10 to 15 years have seen an unprecedented increase in the availability of specially manufactured low-fat and nonfat foods and a reduction in the percentage of energy obtained from fat in the diets of Americans. This increase in nonfat and low-fat replacements for full-fat foods has also been paralleled by a notable increase in the prevalence of obesity in the United States such that almost 55% of adults are overweight or obese. Although there is clearly no evidence for cause and effect between these 2 events, their coincidence does highlight an important research question for public health nutrition policy regarding the effects of reduced-fat products on the health and nutritional status of Americans. Of particular interest is the effect of newly introduced foods made with the nonenergy fat substitute, olestra. Unlike many other fat-modified foods, which may be highly dense in energy, those made with olestra are substantially lower in energy than their full-fat counterparts.

To understand how olestra-containing foods can affect diet, it is useful to consider the ways olestra can alter dietary intake and the nutritional consequences of each pattern of use. Behaviorally, persons choosing to eat olestra-containing foods could add them to their diet in 1 of 3 nonexclusive ways: (1) by substituting olestra-containing foods for their full-fat counterparts (eg, eating olestra potato chips instead of full-fat chips), (2) by replacing other foods with olestra-containing foods (eg, eating olestra chips instead of fruit), or (3) by adding olestra-containing foods to the diet without making other changes. The nutritional consequences of these changes are primarily as follows: (1) if olestra-containing foods are substituted for the full-fat version, both energy and total fat intakes will decrease; (2) if olestra-containing products replace other foods, changes in energy, fat, and other nutrients will depend upon the foods that are replaced; and (3) if olestra-containing products are added, energy intake will increase but total dietary fat will not.
METHODS

DESIGN

The overall objective of the OPMSS is to assess olestra consumption and its association with serum concentrations of fat-soluble vitamins and carotenoids in population-based samples of US consumers. The OPMSS consists of 4 clinic sites, an operations support unit at Westat Inc (Rockville, Md), and a coordinating center at the Fred Hutchinson Cancer Research Center (Seattle, Wash). This study was approved by all institutional review boards and participant consent was obtained verbally (for telephone interviews) and in writing (for clinic interviews).

The sentinel data collection site was in Indianapolis, Ind, which was the location of the first major market introduction of olestra snacks. The OPMSS has several components, including a random-digit dial telephone survey, clinic cross-sectional samples, and a cohort. Data for this report are from the sentinel site and were collected at baseline, prior to the availability of olestra-containing foods in the local market, and at a second clinic visit approximately 1 year later, after the introduction of olestra-containing savory snacks. The analysis is confined to the cohort sample, which was chosen from the cross-sectional sample (n=1962) interviewed at the clinic in Indianapolis between September 1996 and January 1997. The cohort was selected for higher levels of olestra consumption, based on dietary information collected from telephone interviews that were conducted approximately 3, 6, and 9 months after the baseline clinic visit and after olestra snacks appeared in the marketplace. Specifically, we recruited all adults who reported at least 2 occasions of eating olestra-containing foods, a random sample of 67% of those who reported a single eating occasion, and a random sample of 16% of those adults who did not report eating olestra. Of the 478 adults invited into the cohort, 88% completed the year-1 follow-up clinic visit. The final sample consists of adults with complete dietary and covariate data (n=335) or complete weight, serum lipid, and covariate data (n=326).

MEASURES

Nutrient intakes (dietary energy, fat, saturated fat, and cholesterol) were assessed using a food frequency questionnaire (FFQ) with a supplementary questionnaire on savory snack consumption. Participants were asked about dietary intake in the past month. The supplementary questionnaire assessed the intake of olestra-containing snack foods at year 1. The nutrient database (including olestra) was derived from the University of Minnesota Nutrition Coordinating Center nutrient database (Minneapolis). We excluded FFQs with fewer than 3350 kJ or greater than 20920 kJ for men (n=20) and fewer than 2510 kJ or greater than 16740 kJ for women (n=25) because these energy intakes suggest that participants did not complete the forms in a reliable manner.

Trained staff measured height and weight at the clinic visits and administered questionnaires on demographic characteristics (age, sex, race, education) and health-related behavior, such as physical activity. Fasting blood samples were drawn from all participants. Specimens were stored at −80°C until analysis.

Serum cholesterol and triglycerides were analyzed at Quintiles Laboratories (Atlanta, Ga) using enzymatic methods. Details on blood collection, processing, and analysis are given elsewhere. Precision and bias were less than 3%, as evaluated using packaged reagents, pooled human serum, and control serum.

STATISTICAL ANALYSES

Linear regression was used to model changes in dietary intake and diet-related factors by olestra consumption. We categorized olestra intake (the independent variable) into 4 levels based on mean intake (in grams per day) in the previous month: no intake (0 g/d), low intake (>0 to <0.4 g/d), moderate intake (0.4 to 2.0 g/d), and heavy intake (>2.0 g/d).

The dependent variables were change in dietary intake, change in weight, and change in serum lipid concentrations. All models included age (continuous), sex, race (white and nonwhite), education (≤12, 13-15, >16 years), and baseline body mass index (calculated as weight in kilograms divided by the square of height in meters [kg/m²]). For each model of change in dietary intake, we included the baseline dietary intake being investigated. For example, for the model of change in percentage of energy from fat, baseline percentage energy from fat was included. For all models of change in weight and serum lipids, we also adjusted for change in physical activity. For changes in weight, baseline values of weight, height, and height squared were included. For the model of change in low-density lipoprotein cholesterol, we included change in dietary percentage of energy from saturated fat and change in cholesterol per 4184 kJ. For the model of change in high-density lipoprotein cholesterol, changes in percentage of energy from polyunsaturated fat and alcohol were included. The triglyceride model included change in percentage energy from saturated fat and carbohydrate as well as alcohol. A linear contrast statement was used to test for trends across the ordered categories of olestra consumption.

The effect of adding olestra-containing foods to the diet is complicated by physiologic and cognitive factors. There is considerable controversy about how dietary fat (and therefore fat substitutes) affects hunger, satiety, and the regulation of food intake. This question has been addressed extensively using experimental feeding studies in which the energy density of foods is covertly manipulated (ie, a defined preload is given) to observe subsequent effects on food intake in an ad libitum test meal. Much of this work has focused on olestra and has been previously summarized. Although the data are not entirely consistent, collectively, these studies suggest that consumption of reduced-fat foods is associated with somewhat reduced energy and/or dietary fat intake, which could lead to modest weight loss or prevention of weight gain. However, there are design aspects of experimental studies that limit our ability to draw conclusions about the effects of fat-modified foods on dietary intake in free-living adults. These limitations include the use of an artificial environment, small sample sizes, short study du-
ration, and covert nature of the diet manipulation in most
of these studies, which precludes any increased food con-
sumption that might occur if the test subjects knew they
were eating reduced-fat foods.6

Another potential effect of adding olestra-
containing foods to the diet is that consumption of these
nonfat foods could lead to unrestrained eating. One study
of 95 males and females classified as unrestrained or re-
strained eaters specifically compared overt and covert sub-
stitution of full-fat chips with olestra-containing chips.
When participants were unaware of whether they were
consuming regular or fat-free olestra-containing potato
chips, there was no evidence for a compensatory in-
crease in energy or fat consumption during a 10-day pe-
riod.7 However, when information on the fat and energy
content of chips was provided, restrained eaters ate about
15% more fat-free chips than regular chips, although this
increase in consumption did not eliminate the reduc-
tions in fat and energy intake associated with the fat-
free chips. This study provides some evidence that Amer-
cans may use fat-modified foods as license to eat more
of the same, or other, foods.5,8

None of the research to date addresses what hap-
penes to energy and fat intake among free-living adults
who choose to consume fat-modified foods as part of a
mixed diet. In this article we present results from the first
year of the Olestra Post-Marketing Surveillance Study
(OPMSS). Specifically, we examined changes in dietary
intake and a variety of objective diet-related indicators
(weight and serum lipids) among a cohort of adults as-
essed prior to the market introduction of olestra-
containing savory snacks and about 1 year after these
snacks were available to consumers.

### RESULTS

The mean (SD) age of cohort study participants was 41.2
(14.0) years, 62.8% were female, 85.9% were white, 38.1%
had a college education, and 28.0% were obese, defined
as having a body mass index exceeding 30.13

**Table 1** gives associations of olestra intake with di-
etary change from baseline to the year-1 follow-up. In
the cohort as a whole, there was a decrease in total en-
ergy, an increase in dietary cholesterol, and only mini-
mal changes in percentage energy from total and satu-
rated fat. Olestra consumption was associated with a
statistically significant decrease in percentage energy from
total and saturated fat. In the highest olestra intake cat-
egory, percentage energy from fat decreased 2.7 percent-
age points, and there was a significant dose-response trend
for larger decreases in percentage energy from fat with
increasing olestra consumption. There was also a signifi-
cant trend for decreased percentage energy from satu-
rated fat with olestra consumption. There was no evi-
dence for changes in total energy or cholesterol intake
associated with olestra intake.

*Table 2* gives associations of olestra intake with
changes in body weight and serum lipid concentrations
from baseline to the year-1 follow-up. In the entire co-
hort, there were small decreases in weight and serum to-
tal and low-density lipoprotein cholesterol and triglyc-
erides, with an increase in HDL cholesterol. There was a
statistically significant decrease in total serum choles-
terol associated with olestra intake. In the highest oles-
tra intake category, total serum cholesterol decreased by
0.54 mmol/L (21 mg/dL) (a 10.2% reduction compared
with baseline), and there was a significant dose-
response trend for larger decreases in total serum cho-
lesterol with increased olestra intake. Although not sta-

tistically significant, there was some evidence that olestra
intake was associated with weight loss. In the two high-
est olestra intake categories there was a mean 0.55-kg
weight loss, compared with no weight change in nonusers
of olestra. Trends in changes in LDL cholesterol paral-
leled those for total cholesterol but were not statistically
significant. There were no associations of changes in
HDL cholesterol or triglycerides with olestra con-
sumption.

### COMMENT

This report provides the first evidence from a popula-
tion-based sample of adults that consumption of a fat-
modified food (eg, olestra-containing savory snacks) is
associated with decreases in fat intake and total serum
cholesterol levels. We know of no other studies exam-
in ing the nutritional effects of new fat-modified foods in
the US food supply. This study does indicate that the fa-

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*Table 1. Changes in Dietary Intake Over 1 Year (1996-1997 to 1997-1998) Associated With Consumption of Olestra-Containing Savory Snacks in a Cohort of Adults*

<table>
<thead>
<tr>
<th>No. of Subjects</th>
<th>Energy, kJ</th>
<th>Fat, % Energy</th>
<th>Saturated Fat, % Energy</th>
<th>Cholesterol, mg/1000 kJ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted mean (SD) intake at baseline*</td>
<td>335</td>
<td>7150 (2837)</td>
<td>34.6 (7.9)</td>
<td>11.9 (4.1)</td>
</tr>
<tr>
<td>Unadjusted mean change</td>
<td>335</td>
<td>-873</td>
<td>-0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Adjusted mean change by olestra consumption level†</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonconsumers (0 g/d)</td>
<td>214</td>
<td>-1063</td>
<td>1.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Light consumers (&gt;0 to &lt;0.4 g/d)</td>
<td>60</td>
<td>-1314</td>
<td>0.8</td>
<td>0.3</td>
</tr>
<tr>
<td>Moderate consumers (&gt;0.4 to 2.0 g/d)</td>
<td>43</td>
<td>-569</td>
<td>-0.8</td>
<td>-0.2</td>
</tr>
<tr>
<td>Heavy consumers (≥2.0 g/d)</td>
<td>18</td>
<td>-1335</td>
<td>-2.7</td>
<td>-1.1</td>
</tr>
<tr>
<td>P for trend</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Geometric means.
†All change models were adjusted for age, sex, ethnicity, education, and body mass index; change in energy was adjusted for baseline energy intake; change in percentage energy from fat was adjusted for baseline percentage energy from fat; change in percentage energy from saturated fat was adjusted for baseline percentage energy from saturated fat; and change in cholesterol was adjusted for baseline cholesterol level.
Olestra may also be a marker for healthful lifestyle choices. This hypothesis is supported by another report by the OP MSS in which we found that early adopters of olestra-containing savory snacks had strong beliefs in a connection between diet and health.\textsuperscript{16} For example, consumers reported 2 g/d or more of olestra, and it is plausible that olestra-containing chips are routinely consumed with significant sources of dietary cholesterol, such as hamburgers, which could reduce absorption of a substantial amount of cholesterol.

Regardless of the mechanisms, the association of olestra consumption and serum cholesterol concentrations has several potential, and not mutually exclusive, explanations. Olestra can reduce serum cholesterol concentrations (1) by the inhibition of dietary cholesterol absorption,\textsuperscript{14} (2) by the replacement of dietary saturated fat, and (3) by the reduction of energy intake. In controlled feeding studies, as little as 3 g/d of olestra could reduce serum concentrations of other lipophilic dietary compounds (eg, serum carotenoids) by over 20%.\textsuperscript{15} In this report, the heaviest consumers reported 2 g/d or more of olestra, and it is plausible that olestra-containing chips are routinely consumed with significant sources of dietary cholesterol, such as hamburgers, which could reduce absorption of a substantial amount of cholesterol.

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Olestra may also be a marker for healthful lifestyle choices. This hypothesis is supported by another report by the OP MSS in which we found that early adopters of olestra-containing savory snacks had strong beliefs in a connection between diet and health.\textsuperscript{16} For example, compared with individuals who did not consume olestra, consumers were statistically significantly more likely to believe in the importance of eating a low-fat diet and to think about health when selecting foods. These health beliefs influence disease risk by modifying behaviors such as diet and exercise.\textsuperscript{17} Although we attempted to control for changes in other healthful behaviors (eg, dietary fat intake, physical activity) that might influence serum cholesterol levels, the absence of residual confounding cannot be as sure.

Regardless of the mechanisms, the association of olestra consumption and serum cholesterol concentrations warrants further study, particularly since the magnitude of the effects was similar to that seen for dietary fiber\textsuperscript{18} and even pharmacologic agents.\textsuperscript{19} For example, in a meta-analysis, Brown et al\textsuperscript{18} reported that 10 g of soluble fiber per day was associated with a decrease in total cholesterol of −0.45 mmol/L (17 mg/dL), which is comparable to the decrease of −0.40 mmol/L (15 mg/dL) among heavy olestra consumers compared with nonconsumers observed in the present report.

The major limitation of this study is that dietary data, including consumption of olestra-containing savory snacks, are self-reported and therefore likely to contain significant measurement error.\textsuperscript{20} The FFQ used in this study is the same questionnaire developed for the Women's Health Initiative, a multicenter clinical trial and observational study of approximately 164,500 women.\textsuperscript{21} In a validity study comparing nutrient estimates from this FFQ with 8 days of food records and recalls,\textsuperscript{22} correlation coefficients for the nutrients examined in this study were 0.37 for energy, 0.62 for percentage energy from fat, 0.56 for saturated fat, and 0.49 for cholesterol. The reliability of this instrument was good, with intraclass correlation coefficients ranging from 0.69 to 0.73 for these same nutrients. The analyses performed here focus on changes in dietary intake, and therefore systematic bias (eg, underreporting associated with obesity) should not affect our findings. Nonetheless, results based on self-reported dietary intake should be interpreted with caution. In particular, energy intakes from FFQs are not precise.

We note that overall energy intakes estimated from the FFQ decreased by almost 9% from the baseline assessment to year 1, although energy-controlled measures (eg, percentage of energy from fat) were generally stable. Neither the FFQ nor the data collection procedures were significantly changed from baseline to year 1; therefore, we can only speculate that there may have been a cohort effect resulting in poorer completion of the questionnaire (eg, a fatigue effect). We also note that the sample size for olestra consumers, particularly those in the highest category of consumption, is small. Finally, although our response rates were good for a clinic-based study, these results may not be generalized to other populations.

### Table 2. Changes in Weight and Serum Cholesterol and Triglyceride (TG) Levels Over 1 Year (1996-1997 to 1997-1998) Associated With Consumption of Olestra-Containing Savory Snacks in a Cohort of Adults\textsuperscript{*}

<table>
<thead>
<tr>
<th>Unadjusted mean (SD) concentration at baseline†</th>
<th>No. of Subjects</th>
<th>Weight, kg</th>
<th>Serum Cholesterol, mmol/L (mg/dL)</th>
<th>LDL Cholesterol, mmol/L (mg/dL)</th>
<th>HDL Cholesterol, mmol/L (mg/dL)</th>
<th>TG, mmol/L (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonconsumers (0 g/d)</td>
<td>210</td>
<td>0.01</td>
<td>−0.14 [−5]</td>
<td>−0.32 [−13]</td>
<td>0.15 [6]</td>
<td>0.03 [2]</td>
</tr>
<tr>
<td>Light consumers (&gt;0 to &lt;0.4 g/d)</td>
<td>59</td>
<td>−0.26</td>
<td>−0.29 [−8]</td>
<td>−0.43 [−17]</td>
<td>0.18 [7]</td>
<td>0.05 [5]</td>
</tr>
<tr>
<td>Moderate consumers (≥0.4 to 2.0 g/d)</td>
<td>43</td>
<td>−0.56</td>
<td>−0.29 [−11]</td>
<td>−0.43 [−17]</td>
<td>0.13 [5]</td>
<td>0.04 [3]</td>
</tr>
<tr>
<td>Heavy consumers (≥2.0 g/d)</td>
<td>14</td>
<td>−0.55</td>
<td>−0.54 [−21]</td>
<td>−0.59 [−23]</td>
<td>0.13 [5]</td>
<td>−0.22 [−20]</td>
</tr>
</tbody>
</table>

\textsuperscript{*} LDL indicates low-density lipoprotein; HDL, high-density lipoprotein.

\textsuperscript{†} Geometric means.

\textsuperscript{‡} All change models were adjusted for age, sex, ethnicity, education, and body mass index; change in weight was adjusted for baseline weight, height, height squared, and change in physical activity; changes in total and LDL cholesterol were adjusted for baseline body mass index and changes in dietary fat, cholesterol, and physical activity; change in HDL cholesterol was adjusted for baseline body mass index and changes in dietary saturated fat, polyunsaturated fat, alcohol intake, and physical activity; and change in TG was adjusted for baseline body mass index and changes in dietary saturated fat, carbohydrate, alcohol intake, and physical activity.
Our results indicate that olestra is associated with healthful changes in dietary fat intake and serum cholesterol concentrations in a population-based sample of American consumers. This finding counters suggestions in the literature that consumption of fat-reduced foods results in increased consumption of other, possibly less desirable foods. There has been considerable concern that olestra consumption will result in reduced concentrations of serum fat-soluble vitamins and carotenoids and may cause gastrointestinal cramping and/or diarrhea. In a separate investigation of this same population, we observed no statistically significant trends in reductions in serum concentrations of vitamins A, D, E, or K or carotenoids associated with olestra consumption.23 While controversy continues regarding whether olestra causes serious gastrointestinal effects, a recent double-blind feeding among 563 free-living adults found no evidence that consumption of olestra-containing potato chips was associated with more gastrointestinal symptoms of any type than regular, triglyceride-containing chips.23 Additional follow-up of the full-scale OPMSS will provide larger samples and therefore additional power for more detailed investigations of changes in eating patterns and other health indicators, particularly in different sex, race/ethnicity, and socioeconomic groups.

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