

Overview of olestra: A new fat substitute

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R Hunt, NL Zorich, ABR Thomson. Overview of olestra: A new fat substitute. Can J Gastroenterol 1998;12(3): 193-197. Olestra is a mixture of hexa-, hepta- and octa-esters formed from the reaction of sucrose and long chain fatty acids isolated from edible oils. Olestra has properties similar to those of traditional triglycerides but is not hydrolyzed by pancreatic lipases and, therefore, serves as a noncaloric replacement for fats in the diet. The safety of olestra has been established in over 100 studies in seven different species of animals, with confirmatory safety data coming from approximately 75 human studies; consumption of olestra at levels typical for savoury snacks does not result in reports of gastrointestinal problems in humans. This is consistent with the results of studies of the physiological and morphological effects of olestra in animals and in humans. It is anticipated that olestra will be available in Canada in the near future. Patients will soon be asking their physicians about its use. This article provides an overview of olestra.

Key Words: *Fats, Lipids, Nutrition, Olestra, Savoury snacks*

Survol de l'olestra : un nouveau substitut du gras

RÉSUMÉ : L'olestra est un mélange d'hexa-, d'hepta- et d'octa-esters formés à partir de la réaction de la sucrose et des acides gras en chaînes longues isolés dans les huiles comestibles. L'olestra possède des propriétés semblables à celles des triglycérides classiques, mais n'est pas hydrolysée par les lipases pancréatiques, et de ce fait, peut agir à titre de substitut non calorique des graisses dans l'alimentation. L'innocuité de l'olestra a été confirmée dans plus de 100 études auprès de sept espèces animales différentes, avec données d'innocuité à l'appui provenant d'environ 75 études chez l'être humain. La consommation d'olestra à des taux typiques pour des goûters savoureux n'entraîne aucun problème digestif chez l'être humain. Cela concorde avec les résultats d'études sur les effets physiologiques et morphologiques de l'olestra chez l'animal et chez l'être humain. On prévoit que l'olestra sera offert au Canada dans un proche avenir. Nos patients s'informeront bientôt de son utilisation auprès de leurs médecins. Cet article veut dresser un tableau d'ensemble de l'olestra.

Olestra is a new food ingredient developed by Procter & Gamble to be sold under the brand name Olean. Olestra provides the flavour and desirable texture of fats and oil to foods without adding any fat or calories. Because of its thermal stability, olestra can be used to replace fat in a variety of foods, including baked and fried foods. Currently marketed fat replacers such as carbohydrate-based gums and emulsifiers, and microarticulated proteins are not heat stable. Thus, these replacers have limited use in baked products and cannot be used to prepare fried foods (1).

In January 1996, the United States Food and Drug Ad-

ministration (FDA) approved the use of olestra to replace 100% of the vegetable oil used in the preparation of savoury snacks (2). Savoury snacks include flavoured and unflavoured chips such as potato chips, corn chips and tortilla chips, as well as snacks such as cheese puffs and curls, and crackers (eg, soda crackers). It is anticipated that olestra will be available in Canada in the near future.

Olestra is made from two common food ingredients, sucrose and vegetable oil. Olestra's structure is analogous to that of a triglyceride, with sucrose instead of glycerol as the core, and six to eight fatty acid side chains rather than three.

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The fatty acids can be derived from any vegetable oil. Because of the large size of the olestra molecule it is not absorbed intact nor is it broken down by digestive enzymes. Therefore, it adds no calories, fat or sugar to the diet (1,3).

The physical properties and heat stability of olestra are comparable with those of conventional fats and oils. As with triglycerides, the physical properties of olestra are determined by the properties of the fatty acid side chains. For example, olestra made with predominately polyunsaturated fatty acids is a clear liquid resembling typical vegetable oils. In contrast, olestra made with more saturated fatty acids is an opaque solid, resembling a higher melting point solid fat.

ROLE OF OLESTRA IN THE DIET

An excess of fat in the diet is associated with an increased risk of coronary artery disease, stroke, certain kinds of cancers and obesity. Consistent with these observations, leading health authorities and health professionals recommend that the diet provide no more than about 30% of calories from fat. Despite these recommendations, many North Americans continue to eat more than the recommended level of fat. In addition, the prevalence of obesity is increasing in North America (4). Olestra will not replace the need for balance, moderation and variety in achieving a healthy diet, but it does provide one tool to help people meet the recommended dietary goals.

Fat and calorie reduction: Snack intake continues to rise despite consumer awareness of fat reduction guidelines. Because snacks are typically high in fat and calories, they present a logical target for efforts to reduce fat intake. Sensory studies have shown that olestra can reduce the fat content of snack foods without affecting taste. The reduction in fat intake accomplished by the substitution of olestra snacks for full-fat snacks can be a positive step towards a person's improved health and weight control. For example, a 1 oz (30 g) bag of potato chips made with vegetable oil contains about 10 g fat and 150 calories. This same bag of potato chips made with olestra contains no fat and only about 70 calories. A reduction in fat intake of 10 g per day, which could be accomplished by substituting one bag of potato chips made with olestra for regular potato chips per day, would save the same number of calories over a year as those in 3.6 kg of fat.

Numerous studies have confirmed that olestra can help people reduce the percentage of calories from fat in their diets, even among individuals who do not need to reduce total caloric intake. For example, studies of the impact of olestra on the diets of lean men and children have shown that, while total caloric intake is unchanged when olestra is substituted for fat in the diet, the percentage of calories that come from fat is decreased and the percentage derived from carbohydrate is increased. In two studies, lean male subjects ate a test breakfast in which olestra replaced 0, 20 or 36 g of fat and were then allowed to eat whatever they wanted over the next 24 h. The results from the two studies were essentially the same – olestra substitution significantly reduced the percentage of calories from fat (41% to 35%) and increased the percentage of calories from carbohydrates (40%

to 45%). Thus, there does not appear to be a 'fat specific' appetite that might render fat replacement ineffective in reducing fat intake. Total daily energy intake was not changed – an indication that caloric regulation was not affected by olestra (5).

In a study of similar design in two- to five-year-old children, 13.7 g of fat in the first three meals of the day was replaced with olestra, and the food intake of the children was monitored for two days. Olestra substitution significantly reduced the percentage of calories from fat (38.7% to 36.4%) and increased the percentage of calories from carbohydrate (51.5% to 53.3%). Importantly, olestra did not reduce total caloric intake nor did it put the children at risk of insufficient intake of essential nutrients. These findings show that substituting olestra for fat in the diets of individuals who do not need to reduce their energy intake provides a fat reduction benefit (6).

Three longer term studies showed a reduction in the intake of both fat and calories following the consumption of olestra. A 14-day study in obese and nonobese men and women, and a 14-day study in young males, showed that fat intake and caloric intake were reduced (7). An 18-day study in obese dieters also showed a reduction in both caloric and fat intake, indicating that olestra may have a role to play in weight reduction (8).

In another study, people who normally eat potato chips as part of their diet consumed chips made with either olestra or vegetable oil as a midafternoon snack in addition to their usual foods (9). The study population included males, females, obese and normal-weight individuals, some people who self-restrained their food intake and some who did not. In one phase of the study the subjects knew when they were eating olestra chips and when they were eating full-fat chips. In another phase, they were not aware of the kind of potato chips they were eating. Most subjects ate the same amount of potato chips, regardless of whether they knew they were eating full-fat or olestra potato chips. One group, the self-restrained eaters, ate an average of 10 g more olestra potato chips when they knew what they were eating than when they did not. All groups consumed fewer calories from fat when they ate olestra potato chips, even those individuals who ate more olestra potato chips.

These studies show that olestra can help people take small steps towards improving their diets by expanding their options for good tasting, lower fat foods. These findings also provide encouraging evidence that olestra can help people move towards the dietary goal of reducing their fat intake.

Effect of olestra on dietary components: The potential effects of olestra consumption on the absorption of essential fat soluble and water soluble dietary components have been investigated extensively in animals and humans. Olestra does not affect the availability of water soluble micronutrients or the absorption and utilization of macronutrients. Olestra can reduce the absorption of fat soluble vitamins A, D, E and K when snacks containing olestra are consumed at the same time as these nutrients. Although the overall effect of eating snacks with olestra is nutritionally insignificant, because

consumers are unlikely to consume olestra snacks with all meals on a daily basis, any potential effect has been offset by adding each of the four fat soluble vitamins to olestra foods on a per-gram basis. Thus, the person eating snacks made with olestra will maintain the United States recommended daily intake for each of the fat soluble vitamins. The amounts required to achieve this offset are small. For example, the amount of vitamin A added to one serving of potato chips made with olestra is roughly the amount found in one-third of a serving of fortified breakfast cereal. The nutritional effects of olestra have been assessed extensively, and the results were published recently in the *Journal of Nutrition* (10).

Cholesterol lowering effects: Studies in animals and humans have shown that olestra decreases the absorption and enhances the excretion of cholesterol. At normal levels of intake, olestra has a modest beneficial effect on lowering total cholesterol and low density lipoprotein cholesterol, while causing no untoward effect on triglycerides, high density lipoprotein cholesterol or apolipoproteins A-I, A-II and B (11,12). Olestra's primary beneficial effect on serum cholesterol, however, comes from reducing the intake of saturated fat.

CONSUMPTION OF OLESTRA FROM SAVOURY SNACKS

An integral part of assessing the safety of a new food ingredient is knowing how much of the product people will eat. Unlike traditional food additives, which are consumed in very small quantities (usually in the order of a few milligrams per day), a macronutrient additive such as olestra may be consumed in gram quantities each day. Procter & Gamble has used a method originally developed by the National Academy of Sciences and accepted by the FDA to estimate the likely consumption of olestra from savoury snacks (13). This procedure involved a 14-day menu survey, in which all foods and beverages consumed by 2000 households and 5000 individuals were tracked. The households were nationally representative of geography, size and income, and the survey was run throughout the year to capture seasonal variation in food availability and intake. Portion sizes of food items were determined from the United States Department of Agriculture Nationwide Food Consumption Survey, and the olestra content of typical savoury snacks was measured analytically.

For the general American population, the estimated mean and 90th percentile single-day (acute) intakes of olestra are about 10 g/day and 18 g/day, respectively (a 28.4 g bag of potato chips contains about 8.4 g of olestra, corn chips have about 5.5 g of olestra). The estimated mean and 90th percentile chronic intakes are about 3 g/day and 7 g/day, respectively. For children (ages six to 12) and teenagers (ages 13 to 17) the 90th percentile chronic intakes of olestra are about 7 g/day and 10 g/day, respectively. Menu census data were also used to estimate the frequency of snack consumption and the frequency with which they are eaten with meals. The average consumer eats snacks about five times in 14 days; the 90th percentile consumer eats them about 10 times in two weeks. Average and 90th percentile eaters consume snacks with 8% and 18% of meals, respectively (13).

OLESTRA SAFETY PROGRAM

Olestra is not absorbed from the gastrointestinal tract. This fact was established in a comprehensive program involving several kinds of testing. First, to determine its disposition and fate if it were to be absorbed, rats were injected intravenously with radiolabelled olestra. The systematically available olestra accumulated in the liver, specifically in the Kupffer cells and later in the parenchymal cells, and was excreted slowly intact in the bile. With the target organ identified, the potential for olestra to be absorbed when dosed orally was determined. A series of studies using highly purified radiolabelled olestra samples was conducted in rats. In addition, the potential effect on absorption of heating under conditions representative of those encountered when olestra is used to prepare savoury snacks was investigated. These studies showed that the maximum absorption of olestra was at the detection limit of the sensitive radiolabel detection method, which was no more than 0.0001% of the administered dose (14,15).

Small variations in composition of olestra (within the FDA approved specifications, including heating) had no effect on its absorption. Using the same methodology, it was also established that olestra was essentially not absorbed in weanling minipigs (this provides a model of the gastrointestinal tract of young children), or in guinea-pigs in which the integrity of the gastrointestinal tract was compromised (a model that simulates the gastrointestinal tract in people with inflammatory bowel disease). Lifetime rodent feeding studies confirmed that olestra did not accumulate in any tissue, including the liver.

The safety of olestra has been investigated in a large number of short term and long term animal experiments, and has been confirmed in controlled human clinical studies. This program has exceeded the testing typically required for regulatory approval of a food ingredient, both in the number of tests and in the number of species used in the animal toxicology program, as well as by the inclusion of extensive human clinical studies. Safety testing comprised the following six broad areas: absorption of olestra; standard toxicity; olestra's impact on the gastrointestinal tract; olestra's potential effect on nutrient availability; confirmation of olestra's safety in segments of the population with special nutritional needs, such as children, pregnant or lactating women and the elderly; and environmental toxicology. This extended and careful program reflects the fact that macronutrient replacers are consumed in much greater quantities than traditional food additives.

The safety of olestra has been established in over 100 studies in seven different species of animals, with confirmatory safety data coming from approximately 75 human studies. Animal experiments included lifetime studies in rats and mice, and long term studies in dogs. The experiments showed that olestra is not toxic, mutagenic, carcinogenic or teratogenic. It does not affect the animal's growth and development, nor does it affect the morphology and function of the gastrointestinal system, the only organ system that is exposed to olestra. These findings are not surprising, given that

olestra is not metabolized in the gastrointestinal tract and is not absorbed (1,3).

In comparative studies in which individuals consumed olestra or triglyceride foods at every meal for 56 consecutive days, subjects who received higher levels of olestra reported a greater frequency of gastrointestinal symptoms than subjects who received conventional triglyceride at comparable levels (16,17). These findings account for the presence of a product information label for consumers who may be eating substantial amounts of olestra on a daily basis. However, subjects in these same studies who consumed olestra foods at the 90th percentile of expected chronic consumption (13) did not report significantly more gastrointestinal effects than subjects who consumed conventional triglycerides at comparable levels.

Other studies in humans have demonstrated little to no differences in the frequency of reporting of meaningful gastrointestinal symptoms among subjects who consumed olestra chips or triglyceride chips in single eating occasions or in typical snack eating simulations. In a recent double-blind randomized parallel study, 1092 participants ate as much as they wanted of a 369 g bag of olestra or triglyceride potato chips at a single eating occasion (18). There was no difference in the frequency of reporting of gastrointestinal symptoms overall or of any individual gastrointestinal symptoms between subjects who consumed olestra potato chips and those who consumed triglyceride potato chips. In placebo controlled studies, olestra was consumed in various foods at daily consumption levels of about 20 g/day (equivalent to 70.9 g of olestra potato chips) for 16 weeks by 146 normal, healthy subjects (19) or for four weeks by 41 persons with inflammatory bowel disease (20). In both studies, there were no differences between the placebo and olestra groups in the reporting rates of any gastrointestinal symptoms, including diarrhea or abdominal cramping, except for more reports of minor changes in stool frequency or stool character by subjects with inflammatory bowel disease when they ate foods made with olestra. Importantly, these changes were not

characterized as diarrhea by inflammatory bowel disease patients (20).

That consumption of olestra does not result in reports of gastrointestinal symptoms under snack eating conditions is consistent with the results of studies of the physiological and morphological effects of olestra in animals and humans. Such studies have demonstrated that olestra does not injure the gastrointestinal mucosa (21-24) or result in malabsorption of carbohydrates, proteins or fats (3). Further, olestra does not significantly alter fecal bile acid excretion (25), result in significant changes in gastrointestinal transit (26) or lead to significant alterations in stool water content (12,27). Olestra is not metabolized by the colonic microflora (27) and does not cause pathological alteration in the colonic microflora (28,29). Olestra is not recognized as fat by the body and does not signal cholecystokinin release (30). This supports the concept that, although olestra works in food like fat, it does not work in the body like fat. Rather, it passes through the body unchanged adding bulk to the stool and softening the stool. It would not be unexpected for consumers to notice this softening effect, particularly if they consumed foods made with olestra on a regular basis.

CONCLUSIONS

Olestra is a mixture of hexa-, hepta- and octa-esters formed from the reaction of sucrose and long chain fatty acids isolated from edible oils. Olestra has properties similar to those of traditional triglycerides but is not hydrolyzed by pancreatic lipases and, therefore, serves as a noncaloric replacement for dietary fats. The safety of olestra has been established in over 100 studies in seven different species of animals, with confirmatory safety data coming from approximately 75 human studies; consumption of olestra at levels typical for snacks does not result in reports of gastrointestinal symptoms in humans. This is consistent with the results of studies of the physiological and morphological effects of olestra in animals and humans. It is anticipated that olestra will be available in Canada in the near future.

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