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A Comprehensive Review on The Effects of Olestra

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Abstract: Olestra is known as a fat substitute or chemically derived as sucrose polyester. It's also known by its brand name Olean. It does not add on calories or cholesterol to the product. It's also used in food preparation such as potato chips. Originally it's been approved by The Food and Drug Admiration [FDA] for the replacement of fats and oil. It is majorly used to condition dough, as one of many ingredients and as flavouring agent in baking and frying or even generally used as dressing for salad. Olestra has zero calories opted for fat replacement in the various preparations of savory snacks. Nowadays, coronary heart diseases [CHD] are commonly known worldwide and research has proven that the type of our diet contributes to the elevation of blood cholesterol depending on the amount and type of fats consumed. Besides CHD, consumption of fats also accords the growth of cancer like breast, colon and prostate. However, Olestra has a few major drawbacks in playing its role in the human system as it is not absorbed into the human digestive system and henceforth not supplying any nutrition nor energy. Besides that, when consumed with other lipophilic dietary supplements, the absorption of Olestra is affected. This review article highlights in detail about olestra.

Keywords: Olestra, fat, oil, Food, Drug

INTRODUCTION

Olestra known as the sucrose polyester is also a mixture of hexa-, heptad and octa-esters formed via the chemical reactions of sucrase and long chains of fatty acids derived from edible oils with potential to be used as alternative harmful fats replacement. In 1996, the U.S. Food and Drug Administration [FDA] approved a new fat substitute, olestra [Olean] initially developed by Procter & Gamble, for use in "savory snacks" [potato, tortilla and corn chips; crackers; and extruded snacks] Federal Register 1996. A series of polyols fully esterified with oleic acids were synthesized accordingly, and the rate of hydrolysis of the hydrolyzed series of polyols were investigated by using pancreatic lipolytic enzymes in vitro [1]

Olestra has physical properties and taste and cooking characteristics similar to regular fats and oils [2]. On the other hand, it does not contribute any energy to the diet because it is not hydrolyzed by gastric lipases and therefore it is not absorbed. Due to its unique properties, olestra can serve a zero-calories replacement for conventional fats and oils [3]. However, due to its high lipophilicity along with the nondigestible and nonabsorbable properties, its major drawback is interference with other lipophilic dietary components as they may combine with Olestra in the gastrointestinal tract and excreted along. The mechanism behind is via the physical interaction of the lipophilic dietary components that occur in the lumen of the gut and thus causing gastrointestinal disturbances like mild stomach ache, diarrhea, nausea, vomiting and awful smelling flatulence problems . Other limitations following Olestra consumption are anal leakage known as "oil loss" or fecal urgency, reduction of vitamins A and E concentration from other foods causing undernourishment to the particular individual eventually and compensate the nutrients as highly recommended by FDA. In addition to that, occurrences such as soft stool, diarrhea, increased bowel movement, loss of carotenoids mainly 60% decrease in beta-carotene which has to be appropriately compensated with supplements. Drug absorption such as coumarin or oral contraceptives are commonly reported with minimal magnitude of effect and inflammatory bowel disease as another consequence due to disturbances in the GI tract.[3]

On the contrary, Olestra does play a role in the reduction of fats and calories without having to affect the original taste. For instance, one bag of common potato chips contains 10-gram fats and 150 calories whilst Olestra potato chips contains no fats and only about 70 calories. Furthermore, Olestra does not affect the bioavailability of macronutrients and micronutrients and reduces the absorption of fat soluble vitamins A, D, E and K when consumed simultaneously. Thus, people who are consuming Olestra derived snacks will also be maintaining daily fat-soluble vitamins recommendations according to the United States. On top of all that, various animal and human studies conducted show that Olestra decreases the absorption and enhances the excretion of cholesterol from the human system . Olestra is mainly effective as it is neither digested or absorbed

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into the body and henceforth no calories or fats are added to the diet. Generally, large size Olestra compared to the size of the fat molecules causing it to be unable to hydrolyze, or break down the sucrose structures. Hence, the Olestra will be able to pass through the body and the number of fatty acids connected to the central structure determines its ability to be broken down by the human digestive system. Fat on the other hand is able to be absorbed because it has a glycerol core, which is capable of holding three fatty acids, while the sucrose core in olestra can hold up to eight fatty acids. Studies on Olestra on how much it influences the bile acid physiology or the pancreatic response to the food to assess the essence of Olestra whereby there are investigations of the effect of olestra on the colon to determine how much it affects the microflora which is speculated not to change by the presence of olestra in the gut under anaerobic conditions which does not facilitate nor metabolize olestra. Furthermore, the choice of Olestra provides more consumer choices. Research shows that Americans are continually searching for good-tasting, low-calorie, reduced-fat choices to consume as part of an overall healthy lifestyle. The availability of a variety of low-calorie ingredients, including olestra without affecting the taste, tasting almost similar to the conventional fats and oils allows food manufacturers to choose the most appropriate ingredient, or combination of ingredients, for a given product or sometimes even the multiple ingredient approach whereby more ingredients mean more consumer choices .[4]

The American Dietetic Association commented that "Fat replacers make it possible for Americans to eat a wide variety of foods without increasing their fat intake, which may already be too high. These products can help consumers achieve a lower-fat diet while still enjoying their favorite food. Fat replacers like olestra are one of the many acceptable ways to help reduce the amount of fat and calories in your diet". This statement is also supported by The Institute of Food Science and Technology where it was quoted that "It [olestra] is intended as a fat substitute in foods and in processing since it is not digested or absorbed and passes through the body unchanged. It thus has the potential to reduce the intake of dietary fats as is recommended by various health authorities. It also has a small effect on reducing blood levels of cholesterol and possibly some limited potential in reducing energy intake. Finally, the American Medical Association promised that "The FDA continues to monitor approved products on an ongoing basis to provide added assurance of safety. The American Medical Association] AMA supports the FDA evaluation and approval process and advocates a balanced diet that is healthful and low in total fat for all Americans." These comments from the scientific community have proven to be in support of Olestra and to encourage the public on its safety and benefits to our health [5–7].

Previously our university had conducted numerous clinical trials[8–10] and in-vitro studies[11,12] and case reports[13,14] and systemic review[15–20] and surveys[21,22] over the past 5 years. Now we are focussing on literature review. Therefore the current article was to review the effects of olestra.

U.S FOOD AND DRUG ADMINISTRATION HISTORY

In 1996, the U.S Food and drug Administration [FDA] approved a new fat substitute called olestra or also known as Olean [1]. Olestra is the first FDA-approved ingredient or alternative for fats that is heat-stable at high temperatures, allowing snacks made with olestra to have great taste almost similar to the conventional fats and oils. Procter & Gamble [P&G] exceeded FDA guidelines and requirements for assessing the safety of a food ingredient in order to be approved. The Food Advisory Committee assessed the olestra data and concluded that olestra is safe for use in savory snacks in controlled amounts with constant monitoring as the benefits are more than disadvantages according to the saying "Benefits outweighs Risks". In fact, former FDA Commissioner claimed that olestra is "one of the most widely and extensively studied food substances to today's date." An American Diabetes Association further added that combined with exercise and a reduced calorie diet, fatmodified food can be a crucial part of a healthy and balanced diet eating plan. In addition, P&G provided more than 20,000 pages of research data on olestra, as requested by interested parties. Over the years, hundreds of clinical tests have validated the safety of olestra. The research program establishing the safety of olestra substantially exceeded testing generally required for regulatory approval. Approximately 100 animal studies and 40 human studies were reviewed by the FDA and its Food Advisory Committee. The scientific evidence includes more than 40 tightly controlled clinical studies in more than 5,000 men, women and children and an additional 55 sensory or preference studies in more than 20,000 people. FDA recently reaffirmed that there are "no significant adverse health consequences" associated with olestra consumption.

Despite its potential public health benefits as an energy fat substitute, there is controversy concerning the effect of olestra. Experimental studies in both humans and animals find that olestra can sequester fat-soluble nutrients in the gut and thereby reduce their absorption. This made the FDA in the addition of vitamin A, D, E and K. In approving olestra, the FDA made assumptions about the level of its consumption and its effect on serum micronutrients concentration. As a condition for approval, the FDA mandated a program of active post marketing. The Olestra Post- Marketing Surveillance Study [OPMSS] was designed to investigate whether consumption of olestra containing food as part of self-selected diets [23,24].

Chemistry

Olestra is derived from a mixture of hexa-, heptad-, and octa-esters of sucrose formed from long-chain fatty acids extracted and isolated from edible oils and as of triglycerides, the energy yielding dietary fats consists of three fatty acids bonded to a glycerol. Because olestra is synthesized from sucrose analogous to triglyceride, it can bond with six, seven or eight fatty acids. The physicochemical properties are influenced by the properties of fatty acid side chains whereby at room temperature, Olestra derived from polyunsaturated fatty acid side chains is a clear liquid whilst if derived from much saturated fatty acids, is an opaque solid. The taste and cooking characteristics is however similar to the conventional cooking oils unaccommodating nutrients necessary for the diet as it is unhydrolyzed by gastric lipases causing poor absorption from gastrointestinal tract [25,26].

Effect on Gi Tract

According to the review article by Thomson and colleagues, histological evaluations of the gastrointestinal tract, including the large intestine, in a 20-month feeding study in dogs and in 2-year feeding studies in mice and rats have shown no indications that olestra causes injury to the gastrointestinal mucosa. In all of these studies, olestra was fed at up to 9 to10% of diet w/w, twice the level required by the FDA [up to 5%]. In its original formulation, olestra was produced as a thin oil and when consumed, this thin olestra structure sometimes separated from food in the gastrointestinal tract, resulting in "anal leakage". However, the manufacturer slightly changed the formulation of olestra by making it thicker so that it no longer has this tendency to separate from food. However, if Olestra is eaten in large enough amounts, it can have temporary gastrointestinal effects. In other words, high consumption can lead to softer, loose stools, diarrhea and flatulence among sensitive individuals. However, in a study conducted for the period of 20-weeks study, over 3,000 people who ate either full fat or olestra-containing snacks, found that only a very small proportion of each group reported any gastrointestinal effects. In fact, the percentage of those reporting such symptoms was virtually identical in the two groups with approximate percentage alleged reporting of 2.5 percent or less. However, these cases are monitored thoroughly by FDA to prevent any severe adverse occurrences that may be lethal in rare cases especially among hypersensitive individuals .[26]

When olestra and a fat-soluble nutrient comes in contact in the GI tract, a portion of the nutrient partitions into olestra . The portion is then unavailable to the mixed intestinal micelles and is removed from the body with the non absorbed olestra. Key factor controlling the partitioning mechanism include following:

- 1. The lipophilicity of the nutrient,
- 2. The relative amount of olestra and nutrient in the GI tract,
- 3. The time between consumption of olestra and nutrient

According to Peter and colleagues who have studied the effects of Olestra on pig and humans whereby the effects were triggered by eating patterns [i.e., eating frequency and Olestra intake] as Olestra has to be present with other lipophilic dietary components to affect the absorption rate of these components. The results were consistent in both humans and pigs whereby the primary contributing factor is the interference of the lipophilic dietary components by physical interaction in the lumen of the intestinal gut by manipulating the eating pattern whether by Olestra consumed simultaneously together with other food or vice versa . Zorich and colleagues conducted a randomized, double blind study to investigate the effect of Olestra in patients with inflammatory bowel disease [IBD] whereby it was concluded that daily consumption of 20 gram of Olestra for 30 days did not affects the general health nor exaggerate the already existing inflammatory bowel disease [IBD] is further proven via the evaluation of laboratory findings . [26,27]

Chemical Composition of Olestra

It is formerly called sucrose polyester, is the generic name of nonabsorbable, synthetic hexa hepta and octa esters of sucrose and fatty acids, with the physical properties of conventional dietary fats. The fatty acids are of chain length C12 and C24, derived from edible oils, such as soybean, corn or cottonseed. Olestra is not hydrolyzed by pancreatic lipase or colonic bacteria and it cannot be absorbed. Being nonabsorbable but with the physical properties of triglycerides ostras are potential; a caloric substitute for dietary fat.[27]

Vitamins Effects and Absorption

Clinical research shows a modest reduction in serum cholesterol and vitamin E levels. The effect on vitamin E absorption can be offset by supplementation of olestra with vitamin E. The status of vitamin D and K and absorption of lipophilic drugs are not altered by daily consumption of 18g olestra. Although serum retinol levels are not reduced, additional research is focusing on the effect of olestra on hepatic stores of vitamin A to assess the appropriateness of supplement. Using olestra to reduce the amount of fat in high fat foods, without affecting other nutrients, should contribute to a diet lower in energy from fat and higher in energy from carbohydrate . Olestra did not affects the absorption, digestion and utilization of macronutrients such as water-soluble nutrients like Vitamin B, C and folate which is proven by the studies conducted by Peters and Colleagues whereby the Olestra did not affect the growth or digestible energy intake of the pigs studies upon . On the contrary, Olestra is

capable of affecting the absorption of fat-soluble nutrients and carotenoids via the partitioning mechanism. For example, study by Peters further proves that the concentration of vitamin A, D, E and K is reduced. Hence, snacks composed with Olestra will have added fat-soluble vitamins to compensate for the loss caused by the Olestra. Studies by Peters by evaluating marker nutrients from major nutrient groups shows that vitamin A, D, E and K are nutrients that are greatly affected by olestra whilst water- soluble nutrients are affected [28].

Drug Absorption

Studies were conducted in rats and humans which show that it did not affect absorption of lipophilic drugs. The drug tested included pranolol and the oral contraceptives norethindrone and ethinyl estradiol, which are the lipid soluble. Diazepam was also tested due to its wide use. In humans, the drug was tested in a milkshake made with 16g olestra or 16g corn oil water. It shows no difference in amount absorbed. According to Christophe, studies carried out to investigate the influence of Olestra on the absorption of oral drugs proves that it does not affect the drug bioavailability. Miller and colleagues conducted a crossover study on the influence of Olestra on the absorption of lipophilic hormones and analysis of blood samples collected were evaluated and analysed shows that there were no significant differences and therefore safe to be used accordingly. Generally, Olestra does not affect the absorption of carbohydrates, proteins, water-soluble vitamins, or minerals but since Olestra is not absorbed and passes through the gastrointestinal tract unchanged, it can complete with the luminal bile salt micelles for the uptake of highly lipophilic dietary components or molecules that are present in the intestine whereby when sequestered in the Olestra phase, they become unavailable to the micelle-mediated transport and delivery system, and thus are excreted in the faeces with the Olestra instead of being absorbed into the digestive system.[29,30]

Mineral Absorption

In addition to the major components of nutrients, our bodies require other functional molecules even in a small amount to regulate and maintain proper function. Likewise, Magnesium and Zinc are essential to enable the enzymes to function, catalyzing various biochemical reactions. Minerals like sodium, potassium, calcium and chloride helps to regulate and maintain the correct proportion of electrical and water balance in the body enabling the transmission of nerve impulses, stimulation of muscle contraction whilst minerals like calcium and phosphorus are vital to react and form the compound hydroxyapatite for the growth and restructuring of bones. Olestra would not be expected to affect mineral absorption since minerals are not lipid soluble and it does not saponify in the gastrointestinal tract. Animal studies proves that there are no effects on minerals as well as fecal calcium or magnesium, or serum calcium or phosphate[31].

Cholesterol Absorption

According to the review article by Bergholz and colleagues, the absorption of cholesterol is decreased when olestra is included in the diet. The effect has been observed when the source of intestinal cholesterol is either exogenous or endogenous. Low density lipoprotein [LDL] levels have been reduced without a significant reduction in High-Density Lipoprotein [HDL] levels which is important to taken note as it may not be due to the presence of Olestra in our daily diet but speculated by Miller and colleagues that it is merely the consequence of lower saturated fat consumption into daily diet. Another study on the effect of Olestra is where equal weight of Olestra was substituted with another type fat which Olestra consumption has no effect on plasma triglyceride levels but on the contrary, serum triglycerides are decreased after a meal containing olestra as compared with a meal containing triglyceride of equal amount of different type of fats. Moreover, the coronary blood flow was observed to be greater after olestra consumption[31].

CONCLUSION

It's been proven that olestra does not harm our human body unless it's been over consumed in a short period of time. 18g/day of olestra decreases the serum vitamin E levels to within normal range. The risk of over consumption can lead to cardiovascular disease, hypertension, obesity and diabetes. It is crucial for consumers to be aware of the pros and cons of Olestra especially when it has potential to produce GI uneasiness and medical treatment. Therefore, according to the Federal Register, all Olestra derived products will be labelled with potential GI effects that may take place after consumption. Post marketing surveillance whereby reporting of any adverse effects are monitored closely besides keeping track of both the intake and frequency of consumption and also method of consumption whether taken together with other food or vice versa is necessary on any introduction of an ingredient.

FDA continues to monitor approved products to assure customers as well as to assure safety of users whilst the American Medical Association [AMA] supports the evaluation and approval throughout the process besides motivating the public to consume a balanced diet with low in total fat and nourished with extra nutrients to accommodate a healthy lifestyle.

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CONFLICT OF INTEREST

The authors declare that there was no conflict of interest.

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