Nutrition Discussion Forum

Sucrose polyester in human volunteers

The recent publication by Kelly *et al*. (1998) of their study on sucrose polyesters (SPE) raised concerns about the possible gastrointestinal (GI) and nutritional effects of olestra. These concerns were echoed in the popular press ('Doubts raised over anti-obesity fat substitute'. *The Times*, 11 August 1998.). Olestra's potential to cause GI and nutritional effects has been carefully reviewed by the US Food and Drug Administration (FDA), including two public meetings of the FDA Foods Advisory Committee in November 1995 and again in June 1998. The recent comprehensive committee review included results from US marketplace surveillance and from new clinical research. The committee reaffirmed, by an overwhelming majority, their decision that olestra snacks are safe. In light of this favourable review and the acceptance of olestra snacks by US consumers, we would like to make several specific points regarding the publication by Kelly *et al*. (1998).

First, it should be made very clear that Kelly and colleagues tested SPE produced by Unilever which are substantially different from olestra manufactured by Procter & Gamble and approved by the FDA for use in savoury snacks. A significant error in this regard was stated by Kelly *et al*. (1998) '…SPE was approved by the United States Food and Drug Administration for use in savoury snack foods'.

Although olestra falls into the broader class of SPE, the olestra which was approved by the FDA has very specific composition requirements which set it apart from other SPE. The FDA's compositional requirements for olestra include a specification to prevent anal oil-leakage. The liquid SPE used by Kelly and colleagues in the margarine, biscuits, cake, cheese, chocolate spread, peanut butter, and salad cream consumed in the study would not pass this specification, and would therefore cause anal oil-leakage. Therefore, the findings by Kelly *et al*. (1998) of 'anal leakage' in 7·2 % of subjects should not be assumed to be relevant to olestra. Further, studies conducted by Procter & Gamble to elucidate the relationship between GI symptoms experienced when eating SPE which is liquid at room temperature and those noted after eating olestra as specified in the US FDA regulation have shown that liquid SPE associated with 'anal leakage' are also associated with increased incidence of GI symptoms (data on file, Procter & Gamble).

Second, the study by Kelly *et al*. (1998) involved daily ingestion of large amounts of SPE in a variety of foods that would be eaten at essentially every meal. This regimen differs markedly from use of olestra in savoury snacks which are consumed much less frequently and with only a fraction of meals. Several randomized placebo-controlled studies have specifically addressed whether ingestion of olestra snacks will increase GI symptoms in consumers. Cheskin *et al*. (1998) studied 1092 subjects eating as much as they wanted (up to 13 ounces (about 368 g)) on a single eating occasion of olestra potato chips or placebo, full-fat chips. There were no significant differences in the occurrence or severity of GI symptoms between the subjects who consumed olestra chips and those who consumed full-fat chips. In another double-blind study, 3181 children, teenagers, and adults were allowed to eat essentially unlimited amounts of olestra snacks for 6 weeks (Sandler, 1998). There was no overall significant difference in the incidence of GI symptoms, with the exception of increased nausea in the full-fat group. The mean number of symptom days during the 6-week period was not different between groups except for the number of days on which 'more frequent bowel movements' were reported (3·7 *v*. 2·8 d, olestra *v*. full-fat). There was no difference in the impact of GI symptoms on the daily activity assessment ratings between the two groups. It is worth noting that there were no reports of 'anal leakage' in either of these two studies.

Third, Kelly *et al*. (1998) raised the question of whether there are safety concerns in persons with underlying GI disorders. Zorich *et al*. (1997) conducted a specific study in persons with inflammatory bowel disease that assessed whether olestra may have adverse health effects on potentially sensitive subpopulations with bowel disease. Eighty-nine patients with mild to moderate ulcerative colitis (*n* 43) or Crohn's disease (*n* 46) were randomly assigned to eat 20 g olestra in chips and cookies for 4 consecutive weeks, or equivalent full-fat products. There was no difference with respect to disease activity, and GI symptoms were comparable between the treatment groups. Marketplace surveillance has not revealed any patterns indicating groups of people who are intolerant to olestra. Controlled rechallenge testing of people reporting digestive effects in the marketplace has shown no differences in digestive effects when these people were eating olestra *v*. full-fat chips and that they were not uniquely intolerant to olestra (Zorich *et al*. 1998).

Based on the results reported by Kelly *et al*. (1998), it is unclear how they came to the conclusion that there were 'important deleterious' GI effects from the SPE. For example, the authors state that no subjects discontinued the study because of adverse effects. The authors state that bowel movement frequency increased from seven bowel movements per week to ten. This is still well within what would be considered a normal range for a healthy adult in the UK. Importantly, the authors monitored 'general well-being scores' during the study which were not lower when the participants consumed SPE. In addition, a variety of routine and more sophisticated studies were conducted, i.e. rectal tissue biopsies, small-bowel biopsies, liver function studies, and a large variety of screening blood chemistry and haematologic tests. No health concerns were identified by any of these tests.

The reduction in serum carotenoid levels measured in this study when a large variety of SPE-containing foods

were co-consumed with carotenoid-containing foods is consistent with what has been measured in previous studies by Proctor & Gamble with olestra (Koonvitsky *et al*. 1997; Schlagheck *et al*. 1997) and by Unilever with SPE (Westrate & van het Hof, 1995). However, an analysis of nearly 4000 snack consumers has indicated that the frequency of co-consumption of olestra snacks and carotenoid foods is such that consumption of olestra in savoury snacks will not alter carotenoid levels meaningfully (Cooper *et al*. 1997).

The results of this study further reinforce that fat-replacers have a potential positive role to play in the diet. The study by Kelly *et al*. (1998) showed a reduction in dietary fat consumption, a reduction in serum cholesterol, and a highly significant ($P < 0{\cdot}001$) lower body weight after 12 weeks of SPE consumption. This is consistent with recent work by Hill *et al*. (1998) and Miller *et al*. (1998) which showed a reduction in fat and energy consumption when olestra replaced some of the fat in the diet. Surprisingly, Kelly *et al*. (1998) fail to note these very positive outcomes.

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References

Cheskin LJ, Miday RK, Zorich NL & Filloon T (1998) Gastrointestinal symptoms following consumption of olestra or regular triglyceride potato chips: A controlled comparison. *Journal of the American Medical Association* **279**, 150–152.

Cooper DA, Webb DR & Peters JC (1997) Evaluation of the potential for olestra to affect the availability of dietary phytochemicals. *Journal of Nutrition* **127**, 1699S–1709S.

Hill JO, Seagle HM, Johnson SL, Smith S, Reed GW, Zung VT, Cooper DA, Stone M & Peters JC (1998) Effects of 14 d of covert substitution of olestra for conventional fat on spontaneous food intake. *American Journal of Clinical Nutrition* **67**, 1178–1185.

Kelly SM, Shorthouse M, Cottrell JC, Riordan AM, Lee AJ, Thurnham DI, Hanka R & Hunter JO (1998) A 3-month, double-blind, controlled trial of feeding with sucrose polyester in human volunteers. *British Journal of Nutrition* **80**, 41–49.

Koonvitsky BP, Berry DA, Jones MB, Lin PTY, Cooper DA, Jones DY & Jackson JE (1997) Olestra affects serum concentrations of alpha-tocopherol and carotenoids but not vitamin D or vitamin K status in free-living subjects. *Journal of Nutrition* **127**, 1636S–1645S.

Miller DL, Castellanos VH, Shide DJ, Peters JC & Rolls BJ (1998) Effect of fat-free potato chips with and without nutrition labels on fat and energy intakes. *American Journal of Clinical Nutrition* **68**, 282–290.

Sandler RS, Zorich NL, Filloon TG, Wiseman HB, Lietz DJ & Miday RK (1998) A six-week randomized controlled trial of olestra or regular snack foods: Comparison of gastrointestinal symptoms in a large population. *Gastroenterology* **114**, A–490.

Schlagheck TG, Riccardi KA, Zorich NL, Torri SA, Dugan LD & Peters JC (1997) Olestra dose response on fat-soluble and water-soluble nutrients in humans. *Journal of Nutrition* **127**, 1646S–1665S.

Westrate JA & van het Hof KH (1995) Sucrose polyester and plasma carotenoid concentrations in healthy subjects. *American Journal of Clinical Nutrition* **62**, 591–597.

Zorich NL, Biedermann D, Riccardi KA, Bishop LJ & Filloon TG (1998) Follow-up to the study: Randomized, double-blind, placebo-controlled consumer rechallenge test of Olean salted snacks. *Regulatory Toxicology and Pharmacology* **27**, 2.

Zorich NL, Jones MB, Kesler JM, Carter SB, Sutton MA & Bayless T (1997) A randomized, double-blind study of the effect of olestra on disease activity in patients with quiescent Inflammatory Bowel Disease. *American Journal of Medicine* **103**, 389–399.

Sucrose polyester in human volunteers – reply by Kelly & Hunter

We have read the letter by Zorich and colleagues with interest.

It is true that sucrose polyesters (SPE) may vary slightly in their chemical composition, but the analytical data on the SPE used in our study showed that their chemical characteristics were similar to the olestra approved by the US Food and Drug Administration (FDA). They were slightly less viscous than the olestra SPE, and therefore liable to cause anal leakage. Our study differed from those reported by Proctor & Gamble in that there was a fairly large average daily SPE intake in many different products as opposed to a single savoury snack. However, we believe this to be more representative of what might happen if SPE products were freely available.

Proctor & Gamble themselves have emphasized the frequency of digestive symptoms in the general population (Sandler *et al.* 1998*a*). To detect the effects of SPE on the gut against this background it is necessary to perform cross-over studies, ideally in subjects with no previous bowel symptoms. Using this technique we found clear evidence of an increase in stool frequency, urgency and flatulence and after 8 weeks a significant incidence of abdominal pain. The studies quoted by Zorich *et al.* (Cheskin *et al.* 1998, Sandler *et al.* 1998*b*), which were not cross-over studies, were inevitably less sensitive than ours. Patients with inflammatory bowel disease (Zorich *et al.* 1997) are not representative as their bowel function is controlled by powerful medication. Although the dose and type of SPE ingested may influence symptoms, we see no reason to change our conclusion that there can be important gastrointestinal effects from SPE.

All reports so far published confirm that SPE ingestion leads to reduced plasma concentrations of carotenoids. Westrate & van het Hof (1995) found that as little as 3 g SPE/d was sufficient to have this effect. There is anxiety that patients with reduced carotenoid concentrations may be more likely to develop neoplasms (Wald *et al.* 1988; Connett *et al.* 1989).

We believe that the proposed health benefits of SPE still need further confirmation. The weight loss in our subjects was statistically significant, but clinically unimportant. We

know of no evidence that reduction in the serum cholesterol in subjects with a normal concentration provides any further benefit and those with hypercholesterolaemia or ischaemic heart disease will still require pharmacological treatment. The letter by Zorich, Allgood and Peters has not changed our view that our findings merit careful consideration is assessing the long-term health effects of SPE-containing foods.

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References

Cheskin LJ, Miday RK, Zorich NL & Filloon T (1998) Gastrointestinal symptoms following consumption of olestra or regular triglyceride potato chips: A controlled comparison. *Journal of the American Medical Association* **279**, 150–152.

Connett JE, Kuller LH & Kjelsberg MO (1989) Relationship between carotenoids and cancer. The multiple risk factor intervention trial (MRFIT) study. *Cancer* **64**, 126–134.

Sandler RS, Stewart WF, Liberman JN, Ricci JA, Townson MD & Zorich NL (1998*a*) Digestive complaints in the United States: A national survey. *Gastroenterology* **114**, 39 Abstr.

Sandler RS, Zorich NL, Filloon TG, Wiseman HB, Lietz DJ & Miday RK (1998*b*) A six-week randomized controlled trial of olestra or regular snack foods: Comparison of gastrointestinal symptoms in a large population. *Gastroenterology* **114**, 39 Abstr.

Wald NJ, Thompson SG, Densem JW, Boreham J & Bailey A (1988) Serum beta-carotene and subsequent risk of cancer: Results from the BUPA study. *British Journal of Cancer* **57**, 428–433.

Westrate JA & van het Hof KH (1995) Sucrose polyester and plasma carotenoid concentrations in healthy subjects. *American Journal of Clinical Nutrition* **62**, 591–597.

Zorich NL, Jones MB, Kesler JM, Carter SB, Sutton MA & Bayless T (1997) A randomized double-blind study of the effect of olestra on disease activity in patients with quiescent Inflammatory Bowel Disease. *The American Journal of Medicine* **103**, 389–399.

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