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Comesp - Warder

September 25, 1990

Henry Blackburn, M.D.
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University of Minnesota
1-210 Moos Tower
515 Delaware Street, S.E.
Minneapolis, Minnesota 55455

file corresp.

Re: Diet/Cholesterol

Dear Dr. Blackburn:

I wanted to let you know that I received your fax concerning diet and cholesterol. Your taking the time to prepare a written summary of your views on the appropriateness of various health claims for monounsaturated fats and your willingness to participate in the conference call was truly appreciated.

Please let me know whenever I can be of service to you.

Sincerely,

Nancy Warder

Nancy Warder
Attorney, Division of Advertising
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Corresp - Warder

✓
9/21
9/21/90

TO: Nancy Warder, FTC

FROM: Henry Blackburn *HB*

RE: Attached

I am sorry to learn that the 22 study meta-analysis of monos and lipids from M. Katan's group is not yet published. He may be willing for you to cite some general conclusions if you contact him. You need all his references.

Dr. Martijn Katan
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I believe you will find that the 1989 NAS/NRC report on Diet and Health is still the best general reference, but, of course, is 1+ year outdated.

/nmf
Attachment

bpc: Katan

File: Diet/Cholesterol

Monounsaturates effect on lipoproteins in the blood.

We are all familiar with the early studies of Keys, Anderson and Grande in a careful series of repetitions of isocaloric feedings using natural foods in real diets within the range of human consumption. They found that monounsaturates behaved as carbohydrates. In other words, replacement of fats with either would lower total cholesterol predictably, that there was no basic difference between them across a wide range of diet composition. In the regression of cholesterol change against change in fatty acid composition, monounsaturates contributed nothing to improve the predictions. In comparing the fatty acids, in other words, monos behaved as carbohydrates.

The current flurry of interest in this has derived from Grundy and Mattson's studies using formula diets with large amounts, (35% to 40% of calories) as fats, with different designs in which they found no difference in cholesterol-lowering between oleic acid and linoleic acid in reducing LDL, and a small but significant advantage in avoidance of HDL-lowering, when they replaced saturates.

A recent unpublished meta-analysis of 22 studies from a Dutch group, suggests an edge to polys, that is, a relatively high poly diet was more efficient than high monos in lowering both LDL and HDL, with a slight difference in regard to HDL in that there was more lowering of HDL with linoleic acid.

All this has become of greater interest because of Framingham and a number of other studies that have demonstrated prognostic importance for HDL independent of LDL or total cholesterol, and that this tends to get stronger with age, and that low HDL along with high triglycerides predicts greater excess risk even in individuals having relatively low total cholesterol levels.

The upshot of all this seems to be a generally increased acceptance by the medical community of the idea that removal of saturated fat is the most important recommendation; that there is not a large difference between polys and monos, although there is a slight edge for polys in LDL lowering and for monos in not reducing HDL cholesterol; that partial replacement of saturated fats with monos is almost as effective as replacement with linoleic acid or polyunsaturated vegetable oils and maybe slightly more desirable, at least in a hypercholesterolemic culture, than full replacement with carbohydrate, in terms of preventing a fall in HDL. Health claims based on these issues, it seems to me, however, would be very uncertain.

Ecologic studies are generally favorable for monos. There can exist relatively low coronary disease rates with relatively high monounsaturated fat intake (in the neighborhood of 20% of calories). Ecologic analyses that have to do with fat intake and cancer suggest that saturated and poly unsaturated fats are related to reproductive cancer in women and men, but possibly not monos.

In summary, it would seem that partial but not complete replacement of saturated fat with monounsaturated fat and polys, as well as with carbohydrates, would be advantageous in a hypercholesterolemic society, over replacement with carbohydrate alone.

Monounsaturated fatty acid effects on blood pressure

These are uncertain in normal diets in the normal range of fat intake. This needs more work. The blood pressure fall in the Finnish/Italian reversal diet studies is suggestive of a lowering effect of switching to the Mediterranean diet, but these are not metabolic ward studies or carefully controlled, in the sense of the control in the Keys, Grande studies on this issue. The blood pressure picture is quite uncertain in regard to omega-6. The picture is suggestive in regard to a relatively high intake of omega-3 (from Mark Kestin's Australian studies, who is now at the Fred Hutchinson Cancer Research Center in Seattle). On the other hand, these studies are usually done in normal, slim, young people and the issue in obese, hypertensive, middle-aged people is not clear. Any statement in regard to blood pressure-lowering effects of monos would be doubtful.

Monos and glucose tolerance

The picture is even more confused here. Katan, in a high poly feeding, found no effect on fasting glucose or post-prandial glucose or insulin levels.

The triglyceride effect of modifying diets is still under investigation. The old South African studies of Antonis and Berson suggested that removal of fats from the diet and replacement by carbohydrate caused the triglycerides to rise but they went down after a period of time. This would seem to be confirmed by the relatively low values for triglycerides in a number of carbohydrate-eating adult populations around the world. Questioning the universality of this finding, there are fairly long-term studies, up to three months, in hypercholesteremic middle-aged groups in this country and elsewhere, that indicate triglyceride levels stay up as long as three months. The triglyceride effect is confounded by physically active or underfed populations in which triglycerides are low irrespective of the source of calories. Katan's group recently compared boys in several cultures and found high triglycerides in those cultures eating higher carbohydrate diets. Boys are more similar around the world than adults, so this suggests that triglycerides are somewhat higher. On the other hand, these triglyceride levels in such healthy populations are relatively quite low and thus, hardly relevant to health in the high triglyceride, low HDL findings in obese, sedentary, hypercholesterolemic middle-aged North Americans.

Katan has thought a great deal about the low cholesterol, low LDL picture, as we are doing here, and suggests that we look at genetically low cholesterol people in regard to their susceptibility to disease. The hypobeta and abeta lipidemias have neuromuscular disease which is correctable by Vitamin E, but he cited a study of 100

such cases in which there were no cancers reported. He suggests that Apo E can now be studied in a case-control approach as well as the hypobeta. We should request a list of his publications.

With respect to the potential harmful effect of high poly diets, he indicated that a good comparison would be Israel that takes in 10% polys (related to their breakfast of salad with oil, kosher beef treatment and the fact they eat no pork) in comparison with eastern Europe which has perhaps among the lowest poly intake at this time of any western nations.

He suggests getting away from the cultural differences in 24-hour diet recall by using adipose tissue biopsies and he has demonstrated 3-fold differences in linoleic content of this material from the upper outer quadrant of the buttock, taken with a number 17 needle and a 10 cc vacutainer. He recommends a number 19 needle with a 20 cc vacutainer, which very painlessly gets an adipose tissue specimen that can be frozen and treated at will. He finds this technique better than red blood cells that tend to become oxidized.

"Health Claims" for monos

Public health recommendations that partial substitution of saturated fat calories by monos as well as by polys and carbohydrates are appropriate and physiologic in regard to a wide range of human diets. This is compatible with effective total cholesterol-lowering, LDL-lowering and minimal effects on lowering HDL. The data are still unclear on fat intake and cancer, which seems to relate more strongly to total fat than to composition, but monos may be less associated with malignancy and better associated with longevity than higher carbohydrate or higher poly diets but health claims are not appropriate because the data available are mainly ecologic associations. No health claims in regard to lowering of blood pressure appear to be appropriate at this stage of knowledge, nor are claims in regard to improvement of glucose tolerance or insulin secretion.