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TWIN CITIES

*COMES - STAMLER*

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February 1, 1982

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Dear Jerry:

I seem to recall a period in your life when you were marked at many levels of the medical community with the label of "zealot" and "data selector" and so forth. Your continued sound work and judgment has eliminated most of those voices. I seem to be going through such a stage at the hands of Carl Seltzer, George Mann and others. I am not replying to them but would like your advice on whether there should be a reply. George Mann continues to cite my work on the excess of electrocardiographic abnormalities in sedentary occupations of the Seven Countries Study. He obviously does not understand that we cannot, should not, and have not implied causation from such cross-sectional relationships with what we know about concentration of sick people in sedentary classifications and what we have found on longitudinal studies. He continues with his self-delusion that his study among the Masai sounds the death knell to the diet-heart relationship. He continues over the decades to write ugly things as in the enclosed and people continue, to my utter amazement, to publish them. I will not reply to this but wonder if you have any advice about whether there should be a reply to his fallacious arguments and inaccuracies. His personal attacks speak for themselves and should not be responded to. What do you think?

Cordially,

Henry Blackburn, M.D.  
Professor and Director

HB/jml

Enclosure

## Letters to the Editors

### THE DIET-HEART CONTROVERSY

Blackburn's rejoinder to Neurath (*Cardiovasc Rev Rep* 2:503, 1981) in the discussion of diet and lipidemia is a classic example of self-deception. His arguments will be useful in showing schoolboys one of the perils of science.

Chamberlain, advocating the method of multiple hypotheses in 1897,<sup>1</sup> made this penetrating comment about scientific procedure:

The moment one has offered an original explanation for a phenomenon which seems satisfactory, that moment affection for his intellectual child springs into existence, and as the explanation grows into a definite theory, his parental affections cluster about his offspring and it grows more and more dear to him. . . . There springs up also unwittingly a pressing of the theory to make it fit the facts and a pressing of the facts to make them fit the theory.

The Seven Countries Study<sup>2</sup> that Blackburn so admires is in fact a collection of clinical impressions recorded by scores of clinicians in widely separated places and with divergent medical skills and backgrounds. There was no autopsy verification and no measurement of observer bias or of secular drift of observation. Keys, like Bellman, supposes that if he thrice says a thing is true, it is true.

Blackburn is an inveterate data selector. If one admits only data that support a proposition and rejects as fallacious all observations that deny it, a wrong hypothesis will survive interminably. Psychiatrists call this delusion, the selective emphasis of sensory input to construct an imaginary world. The process is as dangerous to science as it is to individuals. The Maasai data, which are by now considerable,<sup>3</sup> have great relevance to the diet-heart issue but have been studiously avoided by the enthusiasts. There are 175,000 Maasai people living in an area three times the size of Minnesota. We have examined 500 of those people<sup>4</sup> and autopsied 55 of them.<sup>5</sup> We know they eat twice the amount of

dairy fat, meat, and cholesterol that US adults consume, yet the Maasai have average levels of cholesterol below 150 mg/100 ml and rarely, if ever, develop coronary heart disease. The diet-heart dogmatists cannot explain this fatal blow to the hypothesis, therefore they try to ignore it. That is data selection.

The early publications of the Seven Countries Study<sup>6</sup> showed a striking relationship between the objective electrocardiographic evidence of coronary heart disease and exertion of occupation. It is significant that those data that offered a nondietary explanation for the observed national differences were not included in the final report of the study. That is data selection.

The influence of cholesterol consumption on cholesteremia is at last resolved.<sup>7</sup> Usual amounts of dietary cholesterol are not important in the regulation of cholesteremia. The significant fact is that no dietary regimen of low cholesterol and low saturated fat has reduced cholesteremia more than about 10%, and that is a trivial effect.<sup>8</sup>

Blackburn scolds Neurath for not joining the "rickshaw rounds" of the 1950s that were used to conclude that coronary disease is rare in many Oriental places. Of course, Neurath and other clinicians know that CHD is not diagnosed from a rickshaw.

Prof. Barry Lewis has lately coined an aphorism: "Good hypotheses die young."<sup>9</sup> That is a profound criticism of the 30-year existence of the diet-heart hypothesis and its funereal advocates who insist that it still looks "quite lifelike." Diet-heart is dead. Now let's get on to something useful.

A redeeming feature of science is that it always moves toward truth. Episodes of error are sometimes injected, honest mistakes are made that cause diversions, but always the truth comes, the error goes.

The most costly errors result from the self-assured, messianic roles played by scientists. These pseudoleaders hope to use a scientific hypothesis to effect social change. That is the tragedy of diet-heart. It has taken an entire generation down the

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**Description:** K-Lyte DS and K-Lyte are oral potassium supplements. Each K-Lyte DS tablet in solution provides 50 mEq potassium as supplied by 2.5 gm potassium bicarbonate and 2.7 gm potassium citrate with 2.1 gm citric acid, saccharin, artificial flavor and color. Each K-Lyte tablet in solution provides 25 mEq potassium as supplied by 2.5 gm potassium bicarbonate and 2.1 gm citric acid, saccharin, artificial flavor and color.

**Indications and Usage:** All K-Lyte® products are used for therapy or prophylaxis of potassium deficiency. They are useful when thiazide diuretics, corticosteroids, or diarrhea cause excessive potassium loss; and when dietary potassium is low. These products may also be useful when potassium therapy is indicated in digitalis intoxication.

**Contraindications:** Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: chronic renal impairment, metabolic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns or adrenal insufficiency. Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone or triamterene), since the simultaneous administration of these agents can produce severe hyperkalemia.

**Warnings:** In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and may be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

**Precautions: General precautions**—The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. When interpreting the serum potassium level, the physician should bear in mind that acute alkalosis *per se* can produce hypokalemia in the absence of a deficit in total body potassium, while acute acidosis *per se* can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. Therefore, the treatment of potassium depletion requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the ECG, and the clinical status of the patient.

**Information for patients**—To minimize the possibility of gastrointestinal irritation associated with the oral ingestion of concentrated potassium salt preparations, patients should be carefully directed to dissolve each dose completely in the stated amount of water.

**Laboratory tests**—Frequent clinical evaluation of the patient should include ECG and serum potassium determinations.

**Drug interactions**—The simultaneous administration of potassium supplements and a potassium-sparing diuretic can produce severe hyperkalemia (see Contraindications). Potassium supplements should be used cautiously in patients who are using salt substitutes because most of the latter contain substantial amounts of potassium. Such concomitant use could result in hyperkalemia.

**Usage in pregnancy**—Pregnancy Category C—Animal reproduction studies have not been conducted with any of the K-Lyte products. It is also not known whether these products can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. They should be given to a pregnant woman only if clearly needed.

**Nursing mothers**—Many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from oral potassium supplements, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

**Usage in children**—Safety and effectiveness in children have not been established.

**Adverse Reactions:** The most common adverse reactions to oral potassium supplements are nausea, vomiting, diarrhea and abdominal discomfort. These side effects occur more frequently when the medication is not taken with food or is not diluted properly or dissolved completely.

Hyperkalemia occurs only rarely in patients with normal renal function receiving potassium supplements orally. Signs and symptoms of hyperkalemia are cardiac arrhythmias, mental confusion, unexplained anxiety, numbness or tingling in hands, feet or lips, shortness of breath or difficult breathing, unusual tiredness or weakness and weakness or heaviness of legs (see Contraindications, Warnings and Overdosage).

**Dosage and Administration: Adults**—One (1) K-Lyte DS tablet (50 mEq potassium) completely dissolved in 6 to 8 ounces of cold or ice water, 1 to 2 times daily, depending on the requirements of the patient. One (1) K-Lyte tablet (25 mEq potassium) completely dissolved in 3 to 4 ounces of cold or ice water, 2 to 4 times daily, depending on the requirements of the patient.

**Note:** It is suggested that all K-Lyte products be taken with meals and sipped slowly over a 5 to 10 minute period.

**How Supplied:** K-Lyte® Effervescent Tablets (orange or lime flavors) are available in cartons of 30, 100 and 250. K-Lyte® DS effervescent tablets (orange or lime flavors) are available in cartons of 30 and 100. Each tablet is individually foil wrapped.

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garden path to trivia. Millions die while the false prophets fiddle with saturated fat and cholesterol. Blackburn should sometimes, in the long Minnesota nights, reflect on Ghandi's plaintive remark, "There go my people—and I am their leader."

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## REFERENCES

1. Platt JR: Strong inference, in *The Step to Man*. New York, John Wiley and Sons, 1966, pp 19–36.
2. Keys A: *Seven Countries: A Multivariate Analysis of Death and Coronary Heart Disease*. Cambridge, Harvard University Press, 1980.
3. Mann GV, et al: Cardiovascular disease in the Maasai. *J Atherosclerosis Res* 4:289–312, 1964.
4. Mann GV, et al: Physical fitness and immunity to heart disease in Maasai. *Lancet* 2:1308–1310, 1965.
5. Mann GV, et al: Atherosclerosis in the Maasai. *Am J Epidemiol* 95:26–37, 1972.
6. Keys A: Coronary heart disease in seven countries. *Circulation* 41(suppl 1):211, 1970.
7. Oliver MF: Dietary cholesterol, plasma cholesterol and coronary heart disease. *Br Heart J* 38:214–218, 1976.
8. Mann GV: Diet heart: End of an era. *N Engl J Med* 297:644–650, 1977.
9. Lewis B: Hypothesis into theory: The development of aetiological concepts of ischemic heart disease, a review. *J R Soc Med* 71:809–818, 1978.

The diet-heart controversy will not be settled soon, and certainly not in the Letters section of *CARDIOVASCULAR REVIEWS & REPORTS*. The reader is invited to draw his or her own conclusions. For particularly lucid presentations of the two opposing points of view, see Mann's "Diet Heart: End of an Era" (*N Engl J Med* 297:644–650, 1977) and Blackburn's "Public Health Views of Diet and Mass Hyperlipidemia" (*Cardiovasc Rev Rep* 1:361–369, 433–442, 1980). Other recent studies of interest with bearing on the controversy include the European Cooperative Trial in the Primary Prevention of Ischemic Heart Disease (*Br Heart J* 40:1069–1118, 1978; see also Editors' Critique, *Cardiovasc Rev Rep* 1:64, 1980) and the Western Electric Study relating diet and serum cholesterol to coronary heart disease (*N Engl J Med* 304:65–70, 1981).—The Editors