SUGGESTED CLINICAL TRIALS OF VITAMIN C AS AN ADJUNCT TO OTHER PROPHYLACTIC AND THERAPEUTIC EFFORTS TO CONTROL AIDS

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It is my opinion, and also that of Dr. Ewan Cameron, Medical Director of the Linus Pauling Institute of Science and Medicine, that vitamin C (ascorbic acid, sodium ascorbate, calcium ascorbate) may have significant value in the prevention and treatment of Acquired Immunosuppressive Disease Syndrome. I list below some suggestions about clinical trials.

First, I point out that there is no need to carry out toxicity studies or dosage studies. It is known from observations on hundreds or thousands of persons that vitamin C has no significant toxicity, at any dosage rate. Hundreds of people have ingested by mouth large amounts of vitamin C, 10 grams per day or more, for long periods of time, with no significant manifestations of toxicity. One cancer patient, a chemist in San Jose, California, ingested 130 grams per day of vitamin C (90% sodium ascorbate, 10% ascorbic acid) for thirteen years. Intravenous infusions of sodium ascorbate solution have been given to patients in amounts of 100 grams per day or more, with no serious side effects. As to dosage, it is likely that the effectiveness increases with increase in amount administered orally or intravenously. The amount given orally is limited by bowel tolerance (laxative effect), but the bowel tolerance level is high for seriously ill persons.

SUGGESTED CLINICAL TRIALS

1. Dr. Ewan Cameron has suggested that a randomized prospective double-blind control trial be carried out with AIDS patients at such a stage that they would be acceptable candidates for AZT treatment. The trial would be continued for one or two years, or whatever period

of time is customary in AZT trials. He suggests that one subgroup of patients receive AZT, a second receive AZT plus 20 grams per day of vitamin C, orally, and a third receive only 20 grams per day of vitamin C. A placebo for vitamin C might be given to the first group, along with the AZT. Dr. Cameron has expressed the opinion that the third group, treated only with vitamin C, might fare better than the other two groups.

One interesting result of this study is that the vitamin C might decrease the amount of toxicity of AZT, as shown by comparison of the second group and the first group.

2. A controlled trial might be carried out with AIDS patients at an earlier stage. All patients would be given vitamin C orally. There might be four groups, receiving respectively 1 gram, 5 grams, 10 grams, and 20 grams per day.

3. In an uncontrolled trial, AIDS patients in a hospital and in serious condition might be given continuous intravenous infusions of sodium ascorbate solution at rate between 50 and 150 grams per day. The physicians in charge could compare the response of the patients to that of similar patients not receiving vitamin C.

4. Ambulatory patients with full-blown AIDS and Kaposi's sarcoma could be given intravenous ascorbate for three hours per day, every day, plus oral ascorbate. The physicians could compare the observed development of the disease in these patients with those who did not receive the ascorbate.

5. Similar ambulatory patients could be given oral vitamin C at the bowel-tolerance level, in an uncontrolled study. The physicians could evaluate the response by comparison with similar patients not receiving ascorbate or the similar patients receiving both intravenous ascorbate and oral ascorbate.

6. A similar study with oral vitamin C could be made with

patients with full-blown AIDS, but without manifestation of Kaposi's sarcoma.

COMMENT ON COST OF TRIALS

The controlled trials would be expensive, costing millions of dollars. The uncontrolled trials would be far less expensive. It is my opinion and that of Dr. Cameron that both the uncontrolled trials and the controlled trials have value.

My associate Dr. Ewan Cameron has discussed with physicians in San Francisco in the AIDS project there the possibility of a clinical trial carried out jointly by him and these physicians in San Francisco, and I have discussed in a preliminary way the possibility of a similar joint project with physicians in the Oregon Health Center, Portland, Oregon.