Letters to the Editor

Study Duration and Validity

Letter to the Editor:

At the NHLBI workshop on sodium and blood pressure held on January 28–29, 1999, to re-examine the US recommendation on sodium intake for healthy people, two meta-analyses addressing this issue were harshly criticized for including randomized clinical trials of less than 2 weeks duration. It was argued that their inclusion invalidated estimates of the blood pressure lowering potential of a sodium-restricted diet. This viewpoint has been expressed before in letters to the editor1 and in editorials.2,3 Yet, Hypertension continues to publish short-term intervention studies such as that by He et al, which compared the effects of a 5-day low sodium diet (10 mmol/d) on the blood pressure of black and white hypertensive subjects.4 For researchers interested in pooling data, these mixed messages from experts in the field create confusion. Should they heed the comments made about the scientific validity of short-term trials1–3 or merely view them as criticisms leveled at meta-analyses with findings that differ substantially from the critics’ own assessment of the evidence?

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Response

We are grateful to Dr Logan for raising the important topic of how to interpret trials of salt restriction. In relation to the short-term acute studies of changes in salt intake, no one is questioning the validity of these studies; it is the way that they are interpreted that is at issue. They are clearly useful to investigate differences in response, in particular because larger changes in salt intake can be achieved and the study can be better controlled. The study1 that we published in Hypertension looking at differences in response to an acute change in salt intake between black and white patients made this absolutely clear. In the conclusion we stated that “with short-term sodium restriction hypertensive blacks have a greater fall in blood pressure compared with whites. . . . . our findings reinforce the accumulating evidence that at least in the short-term (5 days), changes in blood pressure with a reduction in salt intake are largely modulated by reactivity of the renin-angiotensin-aldosterone system.”1

The problem that has occurred with other short-term studies is that they have been included in some meta-analyses to look at the effectiveness of long-term salt restriction on blood pressure.3 Clearly, these short-term studies are not designed to answer this question.

If salt plays an important part in regulating population blood pressure as a large amount of epidemiological, intervention, animal, and genetic evidence suggest,4 then the effect of a high salt intake, which we are all exposed to, is a gradual increase in blood pressure throughout life. The Intersalt Study, in particular, suggested a strong relationship between salt intake and a progressive increase in blood pressure with age, independent of other variables that were measured.5 If this is correct, it is somewhat unlikely that a few days of salt restriction are going to reverse a process that has occurred over many decades. Therefore, to include short-term studies of only a few days’ duration so that the median duration in one meta-analysis was 14 days2 and the other only 8 days3 and to then claim that the small, but still significant fall in blood pressure that was found in normotensives completely negates any recommendation for a reduced salt intake2,3 in the population is, at the very least, ill-judged.

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References


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