

Low-Salt Diet Controls Hypertension in Older Patients

Appel LJ, Espeland MA, Easter L, et al. Effects of reduced sodium intake on hypertension control in older individuals. Results from the Trial of Nonpharmacologic Interventions in the Elderly (TONE). *Arch Intern Med* 2001;161:685-93.

Study Overview

Objective. To determine the effects of reduced sodium intake in older patients with hypertension.

Design. Subgroup analysis based on the Trial of Non-pharmacologic Interventions in the Elderly (TONE) [1], a randomized controlled trial. Analyses were by intention to treat.

Setting and participants. 681 healthy patients aged 60 to 80 years who had a systolic blood pressure (SBP) of less than 145 mm Hg and a diastolic blood pressure (DBP) of less than 85 mm Hg while taking 1 type of antihypertensive medication. Individuals receiving 2 antihypertensive drugs were also eligible if they could be weaned off of 1 agent during the screening phase. Major exclusion criteria were use of antihypertensive medication for conditions other than hypertension (eg, coronary artery disease), myocardial infarction or stroke in the previous 6 months, angina pectoris, congestive heart failure, elevated serum creatinine level, blood glucose level of more than 260 mg/dL, and excessive alcohol use. The study was conducted in 4 clinical centers, where subjects were recruited through media advertisements, brochure mailings, blood pressure screenings, and enrollments from previous studies.

Intervention. In the TONE study, overweight patients were randomized to 1 of 4 study groups: combined weight loss and reduced sodium intake, reduced sodium alone, weight loss alone, or "usual lifestyle" (control group). Normoweight patients were assigned to reduced sodium alone or control group. (The article presents data only from normoweight patients and overweight patients in the reduced sodium alone or control groups.) The goal for reduced-sodium groups was to achieve and maintain a daily dietary sodium intake of 80 mmol/L or less, as measured by 24-hour urine collection. To achieve these goals, investigators used techniques aimed at changing behavior, including group and individual sessions with an interventionist (typically a registered dietitian) who provided information on ways to adapt to a reduced-sodium diet and motivated participants to sustain long-term lifestyle changes. Interventions consisted of a

4-month intensive phase with weekly meetings, a 3-month phase with biweekly meetings, and a maintenance phase. Antihypertensive drug withdrawal began 90 days after the first group intervention session and at a comparable time in the control groups. During medication tapering and after discontinuation, patients were closely followed to ensure that SBP remained less than 150 mm Hg and DBP remained less than 90 mm Hg. Median duration of follow-up was 29 months.

Main outcome measures. The primary outcome variable was a composite endpoint defined by the need for, or actual resumption of, antihypertensive drug therapy. Trial endpoints were high blood pressure (an average SBP > 150 mm Hg or an average DBP > 90 mm Hg), resumption of antihypertensive medication, or the occurrence of a cardiovascular event.

Main results. Mean baseline age was 65.8 years. 47% of subjects were women, 23% were African American, 34% were college graduates, and 43% were overweight. Participants had had hypertension for an average of 13 years and at baseline were taking a diuretic (32%), calcium channel blocker (27%), angiotensin-converting enzyme inhibitor (22%), β blocker (11%), or another antihypertensive agent (8%). Mean SBP and DBP were 128.0 mm Hg and 71.3 mm Hg, respectively.

In the reduced sodium group, baseline mean urine sodium excretion was 161 mmol/day in men and 126 mmol/day in women. At 9, 18, and 30 months, more than 40% of reduced-sodium patients showed an absolute reduction in urinary sodium excretion of 80 mmol/day or less, compared with fewer than 15% of usual lifestyle patients ($P < 0.001$). Overall, urinary sodium excretion was reduced by 40 mmol/day in reduced-sodium group versus controls ($P < 0.001$). Men experienced greater sodium reduction than women (53 mmol/day versus 27 mmol/day, respectively; $P < 0.001$), while reductions were similar in the 2 age-groups examined (60 to 69 years and 70 to 80 years) and in African Americans and non-African Americans. Sodium reduction tended to be greater in overweight persons than in nonoverweight persons; however, these results were not statistically significant. Compared with controls, the reduced-sodium group lost an

average of 1.1 kg during follow-up ($P < 0.001$) and experienced a mean reduction in SBP of 4.3 mm Hg ($P < 0.001$) and in DBP of 2.0 mm Hg ($P = 0.001$). During follow-up, a trial endpoint occurred in 59% of reduced-sodium patients and 73% of controls (relative hazard ratio, 0.68). The corresponding hazard ratio among African Americans was 0.56 (95% confidence interval, 0.37 to 0.84). In dose-response analyses, endpoints were progressively less frequent with greater sodium reduction (P for trend, 0.002).

Conclusion. Reduced sodium intake can lower blood pressure and control hypertension in older individuals.

Commentary

Multiple studies have shown that a low-sodium diet may reduce blood pressure in hypertensive or normotensive patients. TONE, the first long-term randomized controlled trial to focus on elderly patients, demonstrated that reduced sodium intake, alone or combined with a weight-loss program, can safely and effectively control blood pressure. Notably, the TONE investigators could not show a significant reduction in cardiovascular events among patients assigned to the reduced-sodium and weight-loss groups. The recent DASH-Sodium study [2] found that a low-sodium diet could effectively reduce SBP by up to 8.9 mm Hg and DBP by up to 4.5 mm Hg; however, this study lasted less than 5 weeks and did not include many patients older than 60 years (average age of subjects, 47 years). A meta-analysis that examined randomized controlled trials of sodium restriction indicated that older hypertensive patients receiving this intervention may achieve greater blood pressure reductions compared with normotensive individuals [3].

This study by Appell et al has several strengths: it was a randomized controlled trial that used an intention-to-treat analysis and lost few patients to follow-up. Patient characteristics at baseline were similar in all study groups except for average blood pressure among patients aged 70 to 80 years, which was 18 mm Hg lower in the control group.

The authors did not provide any explanation for such a large difference. The lack of the intervention's effect on cardiovascular events can probably be explained by the relatively small patient population. Also, throughout the study, a declining number of patients remained free of hypertension; however, this number was still significant at 30 months, given that 16% of the reduced-sodium group still had not resumed medication. Further research should be conducted to determine whether a low-sodium diet can reduce risks for cardiovascular events or overall mortality. Also, sodium restriction should be studied in patients with more severe hypertension, as they are usually more difficult to treat.

Applications for Clinical Practice

Appell and colleagues' study confirms the benefits of a low-sodium diet; however, applying such dietary restrictions to a real-world population may be difficult. For example, Medicare does not cover nutrition services, and it is doubtful that the majority of patients could follow a strict low-sodium diet over the long term. However, even a moderate reduction in salt intake may be beneficial, and physicians should counsel their hypertensive patients to reduce sodium intake. Also, the food industry should be encouraged to reduce the sodium content of their products.

References

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