**Abstract**—Use of the DASH (Dietary Approaches to Stop Hypertension) diet, which is rich in fruits, vegetables, and low-fat dairy foods, significantly lowers blood pressure. Among the 459 participants in the DASH Trial, 72 had stage 1 isolated systolic hypertension (ISH) (systolic blood pressure, 140 to 159 mm Hg; diastolic blood pressure, <90 mm Hg). We examined the blood pressure response in these 72 participants to determine whether the DASH diet is an effective treatment for stage 1 ISH. After a 3-week run-in period on a typical American (control) diet, participants were randomly assigned for 8 weeks to 1 of 3 diets: a continuation of the control diet (n = 25), a diet rich in fruits and vegetables (n = 24), or the DASH diet (n = 23). Sodium content was the same in the 3 diets, and caloric intake was adjusted during the trial to prevent weight change. Blood pressure was measured at baseline and at the end of the 8-week intervention period with standard sphygmomanometry. Use of the DASH diet significantly lowered systolic blood pressure compared with the control diet (-11.2 mm Hg; 95% confidence interval, -6.1 to -16.2 mm Hg; P < 0.001) and the fruits/vegetables diet (-8.0 mm Hg; 95% confidence interval, -2.5 to -13.4 mm Hg; P < 0.01). Overall, blood pressure in the DASH group fell from 146/85 to 134/82 mm Hg. Similar results were observed with 24-hour ambulatory blood pressure measurements. In the DASH diet group, 18 of 23 participants (78%) reduced their systolic blood pressure to ≤140 mm Hg, compared with 24% and 50% in the control and fruits/vegetables groups, respectively. Our results indicate that the DASH diet, which is rich in fruits, vegetables, and low-fat dairy foods, is effective as first-line therapy in stage 1 ISH. *(Hypertension. 2001;38:155-158.)*

**Key Words:** diet ■ clinical trials ■ hypertension, systolic, isolated ■ blood pressure ■ aging
This subgroup was specified post hoc but before these analyses were performed.

DASH was a multicenter randomized controlled-feeding study. Its design and main results have been reported previously. In brief, participants were 47±22 years old and had an SBP of <160 mm Hg and a DBP between 80 and 95 mm Hg during the screening visits. Exclusion criteria were previously reported.

The study was conducted in 3 phases: screening for eligibility, a 3-week run-in feeding period, and an 8-week intervention feeding period. During the run-in period, all participants ate a “control” diet that was patterned after average US dietary consumption. At the end of the run-in period, the 459 participants were randomized to 1 of 3 diets for an 8-week intervention period: (1) a continuation of the control diet, (2) a diet rich in fruits and vegetables, or (3) the DASH diet. The fruits/vegetables diet provided ~10 servings of fruits and vegetables per day but was otherwise similar to the control diet. The DASH diet emphasized fruits, vegetables, and low-fat dairy products and included fish, poultry, whole grains, and nuts. The DASH diet provided reduced portions of red meats, fats, and sugar-sweetened foods and beverages. It was rich in potassium, magnesium, fiber, calcium, and protein and reduced in saturated fatty acids, total fat, and cholesterol. This was a feeding study. Throughout the 11 weeks of feeding, participants agreed to eat only the foods that were provided. Body weight was kept constant through adjustment of calorie intake, and sodium intake was similar for the 3 diets (3 g/2100 kcal). Alcohol consumption was limited to no more than 2 drinks per day.

Blood pressure was measured with a random-zero sphygmomanometer according to a common protocol. “Baseline” blood pressure was considered the average blood pressure at 3 screening visits and at 4 visits during the last 2 weeks of run-in. The “end-of-intervention” blood pressure was the average measurement obtained on 5 of the last 13 days of the intervention feeding period. Ambulatory blood pressure was measured at the end of the run-in and intervention periods with a Spacelabs monitor (model 90207).

Levels of 24-hour urinary excretion of sodium, potassium, and creatinine were determined at the end of the run-in and intervention periods. Urinary sodium and potassium levels are reported per gram of creatinine to adjust for variations in collection period and body size.

The protocol was reviewed by the human studies committee of each institution, and each participant provided informed consent.

Statistical Analysis
In the DASH trial, a change in DBP from the run-in period to the end of intervention was the primary outcome variable. For this report, we used the change in SBP during intervention feeding in the 72 participants with stage 1 ISH as the primary outcome variable and DBP as a secondary end point. The primary hypothesis was that the DASH diet or the fruits/vegetables diet, or both, would lower blood pressure significantly more than the control diet. All analyses were made on an intention-to-treat basis. For primary analyses, between-diet differences in the change in blood pressure were tested with an intention-to-treat basis. For primary analyses, between-diet differences in the change in blood pressure were tested with ANOVA and Bonferroni’s adjustment for multiple comparisons. The significance of a within-diet change in blood pressure (baseline versus end of intervention) was tested with a paired t test if data were normally distributed or with the signed rank test if data were not normally distributed. Because there were unequal numbers of men and women in our diet groups, we performed 2-way ANOVA to assess possible diet/gender interactions. The abilities of the diets to lower SBP to <140 mm Hg were compared with the χ² test. Unless noted otherwise, values are given as mean±SD. Differences were considered significant at P<0.05 (2-tailed). All trialwide data were compiled and verified by the DASH Coordinating Center. The authors performed all data analyses for this report.

Results
The Table displays the baseline characteristics of the ISH participants assigned to the 3 diet groups. There were fewer women in the DASH diet group, but the groups were otherwise similar in age, ethnicity, body mass index, and baseline blood pressure levels.

There were no significant changes in body weight in any diet group during the intervention feeding period. There were no significant differences in urinary sodium per gram of creatinine among the diet groups at the end of the intervention period. However, as expected, urinary potassium per gram of creatinine was significantly greater in the fruits/vegetables and DASH groups than in the control group (57 and 55 versus 27 mmol/l creatinine, respectively) because of greater fruit and vegetable consumption.

In the DASH diet group, SBP fell 11.8±9.3 mm Hg (P=0.001) (Figure 1). The DBP change also was significant (−3.5±6.3 mm Hg, P<0.01, signed rank test). There were no significant blood pressure changes in either the control or the fruits/vegetables group (−0.6±1.0 and −3.8±1.3 mm Hg, respectively). For between-diet comparisons, the DASH diet reduced SBP more than did the control diet (−11.2 mm Hg; 95% confidence interval [CI], −6.1 to −16.2 mm Hg;
in age, gender, or body mass index among the 18 participants who responded to the DASH diet versus the 5 who did not. There was a tendency for more blacks to respond (60%:40%), but this was not statistically significant.

There was no correlation between baseline SBP and the systolic response to the DASH diet ($r=0.12$).

The 24-hour ambulatory blood pressure changes closely paralleled the random-zero measurements. There were significant reductions in SBP in the DASH group (−9.4 mm Hg) but not in the control or fruits/vegetables groups (−0.6 and −4.1 mm Hg, respectively). The 24-hour DBP did not change significantly in any diet group. Use of the DASH diet lowered SBP during both waking and sleeping hours: the change was $-9.1\pm11.8$ mm Hg during waking hours and $-10.5\pm14.5$ during sleeping hours (both $P<0.05$ versus the control diet group).

**Discussion**

Our results demonstrate that, compared with the control diet, use of the DASH diet lowered SBP by 11.2 mm Hg in participants with stage 1 ISH. This was sufficient to control SBP to $<140$ mm Hg in 18 of 23 participants in the DASH diet group. This treatment effect size is comparable to the blood pressure reduction seen with a typical antihypertensive drug. For example, if we adjust for changes in the control diet group, the DASH diet effect was $-11.2/-4.5$ mm Hg, which is similar to the net-of-placebo treatment effect seen in the trials of drug therapy in stage 2 and stage 3 ISH (SHEP [Systolic Hypertension in the Elderly Program], $-11.1/-3.4$ mm Hg; Syst-Eur [Systolic Hypertension in Europe], $-10.1/-4.5$ mm Hg). Ambulatory blood pressure monitoring confirmed that blood pressure was lowered during both waking and sleeping hours.

Although there were only 72 individuals in this ISH analysis, the results are quite robust. The systolic response to the DASH diet was highly significant and greater than the response in both the control and fruits/vegetables diet groups. The magnitude of the response was also documented with both random-zero and 24-hour ambulatory pressure recordings, which are 2 distinct measurement techniques. The characteristics of the participants assigned to the 3 diets were comparable in all key variables except gender: there were fewer women assigned to the DASH diet group. However, there was no significant diet/gender interaction in this ISH subgroup or in the overall DASH Trial.$^{11,12}$ This study also used a relatively brief treatment duration (8 weeks). We have no data on the durability of the effect of the DASH diet during a longer period. In a previously reported study, however, a combination of weight loss, salt reduction, exercise, and alcohol moderation significantly reduced blood pressure ($-10.6/-8.1$ mm Hg) for 12 months in a hypertensive population.$^{13}$ In addition, in a study group with high-normal pressure, salt reduction, weight loss, or both significantly reduced blood pressure for up to 18 months, but the effect was waning by 36 months, as was adherence to the lifestyle changes.$^{14}$ Long-term testing of the DASH diet combined with other lifestyle modifications is under way.

The renewed focus on the treatment of SBP is being sharpened by a number of factors. The epidemiological
evidence clearly indicates that the level of SBP is a better predictor of complications and death than is the level of DBP.\textsuperscript{2,3} In addition, ISH is the most common “pattern” of hypertension, being present in >65% of individuals older than 60 years.\textsuperscript{4} There is significant risk associated with even stage 1 ISH. In the Framingham Heart Study cohort, after adjustment for other risk factors, those with stage 1 ISH had a 50% excess long-term risk of cardiovascular disease and death compared with nonhypertensive individuals.\textsuperscript{5} This combination of the high prevalence of stage 1 ISH and moderately increased risk results in a significant attributable risk. For example, >40% of the excess deaths in the entire MRFIT (Multiple Risk Factor Intervention Trial) screened cohort could be attributed to stage 1 ISH. Because of this evolving evidence, the Coordinating Committee of the National High Blood Pressure Education Program recently issued an advisory statement calling for a “major paradigm shift” toward making SBP the central criterion for the diagnosis and treatment of hypertension.\textsuperscript{1}

This renewed attention on SBP and ISH will present a major public health challenge. ISH is the most common “type” of untreated hypertension, a particular concern for the healthcare system. Lloyd-Jones et al\textsuperscript{6} examined the SBP and DBP levels of participants in the Framingham Heart Study. After excluding those already on therapy for hypertension, they found that 16% (587 of 3656 participants) had untreated hypertension (SBP >140 mm Hg and/or DBP >90 mm Hg). Among these untreated participants, 83% (486) had stage 1 ISH. Extrapolating this observation to the 20 million untreated hypertensives identified in the NHANES III (Third National Health and Nutrition Examination Survey),\textsuperscript{5} it could be conservatively estimated that there are >10 million Americans with untreated stage 1 ISH.

Hypertension is one of the most common reasons for visits to physicians in the United States. As the millions of persons with ISH are identified and treated, the incremental burden on the healthcare system could be staggering. A nutritional approach to this problem would be especially appealing because it could minimize both the healthcare workload and the dollar cost of therapy. Our observation that use of the DASH diet is effective in ISH makes this dietary approach an attractive and appropriate first-step treatment for stage 1 ISH.

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References

DASH (Dietary Approaches to Stop Hypertension) Diet Is Effective Treatment for Stage 1 Isolated Systolic Hypertension

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