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Cardiovascular Medical Nutrition Therapy Looking at the DASH Trials

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CARDIOVASCULAR MEDICAL NUTRITION THERAPY LOOKING AT THE DASH TRIALS

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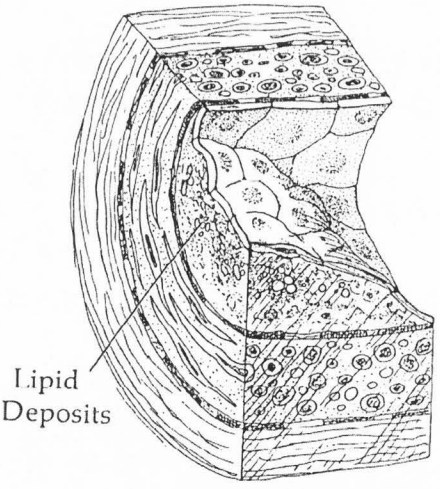

Cardiovascular Medical Nutrition Therapy
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Abstract

OBJECTIVE: To review the recent medical literature on the effects of the DASH diet principles of increased fruits, vegetables, low-fat dairy, and decreased total and saturated fat; focusing on the intent to implement this dietary pattern to reduce hypertension, and thus to reduce cardiovascular disease.

FINDINGS: The combination diet reduced systolic by 5.5 mm Hg, and diastolic by 3.0 mm Hg as compared to the control diet ($P<0.001$ for each) (5, 7, 8). When comparing the two diet variables, the combination diet reduced systolic blood pressure 2.7 mm Hg, and diastolic 1.9 mm Hg more than the fruits-and-vegetables diet, (all with a $P<0.001$)! The results of the DASH-sodium (DASH II), proved also to substantially lower blood pressure when used with the combination diet.

CONCLUSION: Even though the DASH-sodium diet did decrease blood pressure, there is no scientific background to recommend this to all populations, and that instead of focusing attention on reducing sodium, efforts should be placed on increasing sources of micronutrients to reduce blood pressure and cardiovascular disease.

Introduction

Cardiovascular Disease and stroke are the first and third leading causes of death in the United States, according to the Centers for Disease Control (CDC), and in 2004, they accounted for, "more than 40% of all deaths" (1). Examples (but not all) of alarming statistics are the following:

- About 61 million Americans (almost one-fourth of the population) have some form of cardiovascular disease.
- Coronary heart disease is a leading cause of premature, permanent disability among working adults.
- Stroke alone accounts for the disability of more than 1 million Americans.
- Almost 6 million hospitalizations each year are due to cardiovascular disease.

The definition of cardiovascular disease can be broken down further into two categories defining the risks for cardiovascular disease. The first being uncontrollable factors such as age, genetics, and male gender, and the second are controllable factors such as smoking cholesterol, hypertension, physical activity, obesity and diabetes. For years, scientists and health care professionals have tried to lower cardiovascular disease and hypertension by decreasing weight and sodium in the diet, however, the DASH trials intended to look at effects of food only. By keeping sodium and weight constant, researchers evaluated different sources of micronutrients. The DASH diet principles of increased fruits, vegetables, low-fat dairy, decreased total and saturated fat, has effective potential to lower blood pressure and the risk for hypertension and cardiovascular disease.

Prevalence of Hypertension and Risk Factors

Hypertension affects almost 50 million people in the United States, and places them at higher risk for cardiovascular disease (2). Studies have proven that hypertension,

in fact, does lead to chronic heart disease, and in adults ages 40–89, "the risk of death from heart disease and stroke begins to rise at blood pressures as low as 115/75. . . The risk doubles for each increased increment of 20 mmHg in systolic blood pressure, or 10 mm Hg in diastolic blood pressure" (2, 3, 4). Research in the past 30 years, and government statistics, are indicating that health education to encourage healthier lifestyles and increasing early detection and intervention can 1) prevent heart disease and stroke for those who are healthy and 2) improve the health of people who have experienced these conditions (1).

Research is also showing that improved nutrition and increased physical activity help to lower high blood pressure. The link between improved nutrition and decreased blood pressure was significantly proven in the Dietary Approaches to Stop Hypertension (DASH) intervention trials (1,2). Lifestyle factors and eating patterns either derived from, (or contributing to), our environment can have a large effect on increasing risk for hypertension. This "environment" is carried out through home settings, the work place, schools, and the community in general. One article pointed out that community intervention, "[is] particularly effective in reducing heart disease and stroke throughout the entire community. For example, when a work place adopts a no-smoking policy, all employees benefit whether they smoke or not" (1). Can the idea of adopting better eating policies and increased physical activity policies be incorporated into the work place for the "benefit of all employees" as well? Although a good idea, there are ethical and constitutional rights that still belong to Americans; however the trends in hypertension and obesity could change these views in the future.

What can be done now to improve hypertension that leads to cardiovascular disease? There is in fact, a lack of comprehensive education programs designed specifically to emphasize on food portioning skills, cooking skills, low-fat cooking techniques, increasing fruits, vegetables in the diet and increasing exercise. In designing these educational, community intervention modules, certain tools are recommended such as education of different types of fat and cholesterol, information on what a "healthy diet" is, portion size skills, and current physical activity recommendations. Health care professionals have turned to science and clinical studies to determine what recommendations are appropriate for the population.

DASH Trials and Results of Lowering Blood Pressure

The most effective clinical trial to show the effects of diet on hypertension, is in fact, the Dietary Approaches to Stop Hypertension (DASH) intervention trials which consisted of two parts; the first looking only at diet while keeping weight and sodium intake constant, and the second looking at the effects of diet and sodium keeping weight constant (5). This study was a pioneering study in the sense that it kept the effects of sodium separate and the findings revealed a resounding "yes!" in proving that a diet of increased fruits, vegetables, low-fat dairy, and decreased total and saturated fat could substantially lower blood pressure and thus reduce the risk of cardiovascular disease.

Background to the reasons leading up to the DASH study indicated that it was common knowledge of how obesity, sodium intake, and alcohol consumption influence blood pressure. However researchers on the DASH team wanted to assess the effects of *only* dietary patterns on blood pressure. The objective of the trial, according to one report, was to "determine the effects of diet on plasma lipids, focusing on subgroups by

sex, race, and baseline lipid concentrations" (6). The methods of the first study (DASH I) consisted of specific study subjects, conduct of the trial, three diet variables, and controlled feeding.

The DASH trial began in September 1994 and January 1996, 459 adults who were over the age of 22, had not taken any anti-hypertensive medication and who had systolic blood pressures of less than 160 mm Hg and diastolic blood pressures of 80 to 95 mm Hg, were enrolled in this multi center outpatient feeding control study (5, 6). There were a number of exclusion factors that also determined enrollment, these included diabetes (if poorly controlled), hyperlipidemia, any cardiovascular event in the past six months, chronic diseases that may interfere with ability to participate, >35 body mass index, pregnancy/lactation, and use of any medication that would effect blood pressure. Participants were also excluded if unwilling to stop taking vitamin/mineral supplements or antacids containing calcium and magnesium, or consumed more than 14 alcoholic beverages per week (5, 6).

The particular conduct of the DASH study was unique in the fact that researchers took into consideration the increased occurrence of hypertension in minorities, especially among blacks. This led to one of the goals of the study to have two-thirds of the subjects be members of a racial or ethnic group (5). Then the subjects were recruited and enrolled into two different groups, one started in September 1994, and the other in January 1996.

For both groups the trial was conducted in three phases, which were screening, run-in, and intervention. The screening section, evaluated those items listed above and also measured physical activity and food frequency questionnaires up to a year previous to the study. The run-in phase was a three week time period where all participants were

given the control diet (as described below), and blood pressure was measured four different days, one urine sample was collected and a questionnaire on symptoms was completed. The eight week intervention period randomized participants to consuming the control diet, the fruits and vegetable diet, or the combination diet (as described below).

All meals and snacks were provided by the clinical centers, where there was strict protocol to prepare the standardized menus in a special research kitchen (5, 6). It was also noted that "Energy intakes were adjusted as needed to keep body weight constant. Participants attended the clinic each weekday to be weighed, to consume one meal on-site (lunch or dinner), and to pick up the balance of their meals and snacks. The participants picked up their weekend meals and snacks on Fridays", and, "Participants were requested not to change their habitual levels of physical activity for the duration of the study" (6). Again these parameters demonstrated that this study was very careful to look at every angle possible and account for numerous variables.

In accordance to determine the effects of the varied diets, all participants followed the control diet for three weeks which, "reflected the consumption of macronutrients, fruit, vegetables, and dairy products typical of what many Americans eat", or in other words, decreased fruit, vegetables, fiber and potassium magnesium and calcium levels close to the 25th percentile. The fat content was also typical of the average diet in the United States, keeping sodium at a 3 gram per day level and keeping weight constant. After the three week run-in period, the study subjects were asked to provide a twelve hour fasting blood sample to check levels before entering into the intervention period.

The participants were then randomly assigned to receive for eight weeks the control diet, or one of the two variable diets. The fruit and vegetable diet provided fewer snacks and sweet, high amounts of fiber, and, potassium/magnesium levels close the 75th percentile of U.S. consumption (5). The combination diet went one step further to provide a diet rich in fruits, vegetables, and low-fat dairy foods while decreasing total and saturated fat and cholesterol. This also provided high fiber, and potassium, magnesium, and calcium levels close to the 75th percentile of U.S. consumption. Sodium was held constant at 3 grams per day and weight was held stable (5, 6).

The study parameters carefully validated the seven day cycle menu for consistency among the clinics, and chemically analyzed each meal before the start of the intervention period and also during the study. "During the entire 11 wk of feeding, participants were instructed to keep a daily diary that was reviewed by study staff to keep track of the allowed beverages and diet deviations as well as consumption of standardized muffins and cookies (unit foods) that were provided as needed to maintain body weight" (6). This is yet another example of the thoroughness of the DASH intervention trials.

To further expand on the statistical tools used to be successful study, The DASH trial was, "designed to test the alternative hypothesis: that the change in blood pressure would differ between the combination and control diets, that the change in blood pressure would differ between the fruits-and-vegetables and the control diets; and that the change in blood pressure would differ between the combination and fruits-and-vegetable diets" (5). The statistical power for the sample size of 456 was estimated to be 85 percent, to detect a mean diet difference of 2 mm Hg in diastolic blood pressure. A

"between-diet difference" was considered statistically significant at P<.025, or in other words a 97.5 percent confidence interval. This appears to be very confident!

According to two different reports of the original research, the results were categorized into lipid changes of each diet, blood pressure, and other effects (5, 6). Lipid changes with the DASH or "combined" diet, showed a significantly lower mean (95% CI), and net reductions of 7.3%, 9.0%, and 7.5% in concentrations of total, LDL, and HDL cholesterol. The reduced values were larger in men than in women, which can indicate that they started out with a lower baseline lipid level. Compared to control diet, there were no changes in total, LDL, or HDL cholesterol for those participants that consumed the fruits-and vegetables diet (6).

When measuring actual blood pressure, the combination diet reduced systolic by 5.5 mm Hg, and diastolic by 3.0 mm Hg as compared to the control diet (P<0.001 for each) (5, 7, 8). Systolic and diastolic blood pressures were reduced only 2.8 mm Hg, and 1.1 mm Hg as compared to the control diet. When comparing the two diet variables, the combination diet reduced systolic blood pressure 2.7 mm Hg, and diastolic 1.9 mm Hg more than the fruits-and-vegetables diet, (all with a P<0.001)! Other effects that showed up were complaints of severe constipation (10.1, 5.4, and 4.0 percent of the subjects eating the control, fruits-and-vegetable, and combined diet)

Further background into what researchers found was that, "nutrients in dietary supplements may not reduce blood pressure to the same extent as nutrients in food, because of interactions with other dietary components or because of altered bioavailability" (5).

DASH-Sodium (DASH II) Trial

Researchers were so astonished by the findings of the first study, that they organized a subgroup to look at the effects on decreasing hypertension with the new DASH diet (combination diet) and different sodium level intakes. Objectives of the second study were to answer questions such as, "Does reducing the level of sodium from the average intake in the United States (approximately 150 mmol per day, which is equivalent to 3.5 g of sodium,) to below the currently recommended upper limit of 100 mmol per day lower blood pressure more than reducing the sodium level only to the recommended limit?", and "Does the DASH diet lower the blood pressure beyond the level achievable by simply reducing sodium intake?" (2).

The design was also a multi-center, randomized study that compared blood pressures of three different levels of sodium intake, and allowed for 412 adults with blood pressures exceeding 120/80 to enter, (including those with stage one hypertension (systolic 140 to 159 mm Hg over diastolic 90 to 95 mm Hg) (1, 2). The criteria for eligibility was similar to the first study, however they desired to enroll 50 percent blacks and 50 percent women. This time, the run-in period was two weeks of all participants consuming a high sodium control diet, then randomly assigned to either the control diet or DASH diet with one of three sodium levels for 30 consecutive days (2).

The combined effect of the DASH diet and reduced sodium intake, demonstrated that with reduction in the three levels of sodium intake systolic and diastolic blood pressures were also lowered. According to the DASH-Sodium research group, "The level of dietary sodium had approximately twice as great an effect on blood pressure with the

control diet as it did with the DASH diet ($P<0.001$ for the interaction)" and, "In the control diet, a reduction in the sodium intake of about 40 mmol per day from the intermediate sodium level lowered blood pressure more than a similar reduction in the sodium intake from the high level ($P=0.03$ for systolic blood pressure, $P=0.045$ for diastolic blood pressure)" (2, 8). In other words, when eating the typical American diet, they concluded that any reduction even if it's small, will lower blood pressure.

Two other critical findings pointed out that the newly proved DASH diet, compared to the control diet, resulted in a significantly lower systolic blood pressure at every sodium level and especially lower diastolic blood pressure at the high and intermediate sodium levels. The report went on to state that, "It had a larger effect on both systolic and diastolic blood pressure at high sodium levels than it did at low ones ($P<0.001$ for the interaction). . . As compared with the high-sodium control diet, the low-sodium DASH diet produced greater reductions in systolic and diastolic blood pressure than either the DASH diet alone or a reduction in sodium alone" (2, 8).

A subgroup analysis of the DASH sodium trial stated that even though there are some experts who, "question the universality of the findings" and oppose public health recommendations to decrease sodium intake in the general population, the DASH trial had many components that, "substantially decreased blood pressure compared with a more typical U.S. diet", and in fact should be recommended to the general public (9). They also found an increase in salt sensitivity over the age of 45 years old, and that there was no evidence of different salt sensitivity in relation to body mass index (7, 9). It is important to note the population used in the DASH-Sodium trial. Most participants were hypertensive and increased age, while half of participants were black. There is not

substantial scientific background that supports the recommendation to lower sodium intake in all populations.

Current studies that have re-visited the DASH principal, looked at specifically Stage 1 Isolated Systolic Hypertension, and also reported on a follow-up study to DASH-Sodium intervention (10, 11). Upon going back and evaluating whether the DASH diet would be effective at combating stage one hypertension, Moore and the research team at Boston University determined 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" (10).

A brief summary of the follow-up study showed that after a 12 month follow-up for 56 of the 113 participants at the Duke medical center, "The DASH participants significantly increased their intakes of fruits or juices and vegetables at 12 months", and went on to state that, "After the feeding intervention, DASH diet participants ate more fruits/vegetables and had sustained reductions in BP despite increased sodium intake" (11). To summarize the proposed recommended eating pattern and serving sizes for each food group a table provided by the U.S. Department of Health and Human Services, NIH, and NHLBI, can be viewed in appendix A.

Conclusion

The DASH intervention trial has been a pioneer study, having proven to be one of the most successful controlled feeding studies performed. Subgroups and different research teams have re-visited the methods and performed more studies similar to the original and have come across the resounding effects. Surprisingly there were not as many who dropped out of the study due to non-palatable taste of lower sodium diet. In fact, the DASH diet and the low sodium level were well tolerated, with no increase in

symptoms or dropouts (2). The article also stated that long-term benefits of DASH with low sodium intake will depend on the, "ability of people to make long-lasting dietary changes, including the consistent choice of lower-sodium foods" (2). It would be most beneficial to place educational and financial efforts toward increasing the sources of micronutrients that have proven in this study, to lower blood pressure, rather than focus on decreasing sodium in the diet.

As mentioned before, risk factors for cardiovascular disease have been studied extensively due to the high prevalence of this disease. Hypertension is considered as the main culprit and encouraging the populations at risk, and also the healthy populations, to make small significant changes through improved nutrition and overall lifestyle habits is a very worthwhile goal.

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Food Group	Daily Servings (except as noted)	Serving Sizes	Examples and Notes	Significance of Each Food Group to the DASH Eating Plan
Grains and grain products	7–8	1 slice bread 1 oz dry cereal* 1/2 cup cooked rice, pasta, or cereal	Whole wheat bread, English muffin, pita bread, bagel, cereals, grits, oatmeal, crackers, unsalted pretzels and popcorn	Major sources of energy and fiber
Vegetables	4–5	1 cup raw leafy vegetable 1/2 cup cooked vegetable 6 oz vegetable juice	Tomatoes, potatoes, carrots, green peas, squash, broccoli, turnip greens, collards, kale, spinach, artichokes, green beans, lima beans, sweet potatoes	Rich sources of potassium, magnesium, and fiber
Fruits	4–5	6 oz fruit juice 1 medium fruit 1/4 cup dried fruit 1/2 cup fresh, frozen, or canned fruit	Apricots, bananas, dates, grapes, oranges, orange juice, grapefruit, grapefruit juice, mangoes, melons, peaches, pineapples, prunes, raisins, strawberries, tangerines	Important sources of potassium, magnesium, and fiber
Lowfat or fat free dairy foods	2–3	8 oz milk 1 cup yogurt 1 1/2 oz cheese	Fat free (skim) or lowfat (1%) milk, fat free or lowfat buttermilk, fat free or lowfat regular or frozen yogurt, lowfat and fat free cheese	Major sources of calcium and protein
Meats, poultry, and fish	2 or less	3 oz cooked meats, poultry, or fish	Select only lean; trim away visible fats; broil, roast, or boil, instead of frying; remove skin from poultry	Rich sources of protein and magnesium
Nuts, seeds, and dry beans	4–5 per week	1/3 cup or 1 1/2 oz nuts 2 Tbsp or 1/2 oz seeds 1/2 cup cooked dry beans peas	Almonds, filberts, mixed nuts, peanuts, walnuts, sunflower seeds, kidney beans, lentils,	Rich sources of energy, magnesium, potassium, protein, and fiber
Fats and oils†	2–3	1 tsp soft margarine 1 Tbsp lowfat mayonnaise 2 Tbsp light salad dressing 1 tsp vegetable oil	Soft margarine, lowfat mayonnaise, light salad dressing, vegetable oil (such as olive, corn, canola, or safflower)	DASH has 27 percent of calories as fat, including fat in or added to foods
Sweets	5 per week	1 Tbsp sugar 1 Tbsp jelly or jam 1/2 oz jelly beans 8 oz lemonade	Maple syrup, sugar, jelly, jam, fruit-flavored gelatin, jelly beans, hard candy, fruit punch, sorbet, ices	Sweets should be low in fat