Rethinking the Role of Conventional Diet Therapy for Coronary Artery Disease

Singh RB, Dubnov G, Niaz MA, et al. Effect of an Indo-Mediterranean diet on progression of coronary artery disease in high risk patients (Indo-Mediterranean Diet Heart Study): a randomised single-blind trial. Lancet 2002;360:1455–61.

Study Overview

Objective. To determine if the Indo-Mediterranean diet has cardioprotective effects for patients at high risk for coronary artery disease (CAD).

Design. Randomized, single-blind clinical trial with an intention-to-treat analysis.

Setting and participants. Participants were recruited from 17 clinical centers around Moradabad, India. Eligibility criteria included one or more major risk factors for CAD (hypertension, diabetes mellitus, hypercholesterolemia), angina pectoris, or a previous myocardial infarction (MI). Exclusion criteria included absence of major risk factors, cancer, chronic diarrhea, a blood urea nitrogen greater than 6.6 mmol/L, arthritis, refusal of laboratory testing, dislike of the intervention diet, and death prior to randomization.

Intervention. Both groups were advised by a physician and a dietitian to follow a National Cholesterol Education Program (NCEP) step I diet. In the intervention group, patients also were advised to consume at least 400 to 500 g of fruits, vegetables, and nuts per day as well as 400 to 500 g of whole grains and legumes per day, plus mustard seed or soybean oil in 3 to 4 servings a day. Compliance with the recommended diets was assessed for weeks 1 to 4, weeks 4, 8, 12, and 24, and then at 12-week intervals for the 2-year study duration. A dietitian assessed food intake through self-reported food diaries and personal interviews.

Main outcome measures. The primary outcomes were fatal or nonfatal MIs, sudden cardiac death, and the combined total of these events. Fatal MIs were determined using medical record review. Sudden cardiac death was diagnosed when CAD had been noted within the medical record and death occurred within 1 hour of onset of symptoms. Nonfatal MIs were determined in inpatients based on electrocardiogram and diagnostic enzyme measurements and in outpatients based on clinical symptoms and electrocardiogram.

Main results. 1650 patients were assessed for eligibility and 1066 agreed to participate. 66 patients were excluded, resulting in 1000 patients being randomized. 499 patients were allocated to the intervention diet, with 3% (15) lost to follow-up, and 501 were allocated to the control (NCEP step I) diet, with 3% (16) lost to follow-up. There were no statistically significant differences in baseline characteristics or dietary factors between the 2 groups. The mean age for the entire study group was 48 years. A high proportion of the patients were men (90%), had a sedentary lifestyle (90%), and were diagnosed with hypercholesterolemia (73%). 47% of the patients smoked cigarettes, and 58% had a diagnosis of CAD. Fewer patients had diabetes (21%) or were overweight (23%).

At the end of 2 years of follow-up, the intervention group consumed a greater percentage of calories from complex carbohydrates, had a higher polyunsaturated to saturated fat ratio, and had a lower energy, total fat, saturated fat, and cholesterol intake than controls ($P < 0.001$ for all comparisons). The intervention group consumed significantly more fruit, vegetables, nuts, and whole grains than the control group ($P < 0.001$). Both the intervention and control groups had significant reductions in total cholesterol, low-density lipoprotein cholesterol, triglycerides, body mass index, blood pressure, smoking, and fasting blood glucose; however, the reduction was significantly greater with in the intervention group ($P < 0.001$). For the primary outcome, the intervention group had a significant reduction in the risk of nonfatal MI (4.2% versus 8.6%), sudden cardiac death (1.2% versus 3.2%), and total cardiac endpoints (7.8% versus 15.2%) when compared with the controls. The adjusted rate ratios of the clinical outcomes in the intervention group compared with the control group were 0.47 (95% confidence interval [CI], 0.28–0.79) for nonfatal MI, 0.33 (95% CI, 0.13–0.86) for sudden cardiac death, and 0.48 (95% CI, 0.33–0.71) for total cardiac endpoints.

Conclusion. The Indo-Mediterranean diet was cardioprotective in patients at high risk for CAD. This diet seemed more effective than the conventional NCEP step I diet.

Commentary

A Mediterranean diet (a diet rich in fish, fruit, vegetables, nuts,

and legumes) seems to influence the progression of cardiovascular disease [1] and is recommended by the American Heart Association and the World Health Organization [1,2]. These recommendations are supported by high-quality evidence [3,4]; however, it is uncertain if people of non-Western cultures would respond to these dietary recommendations. Singh et al have answered this question with a resounding yes. This study is important for several reasons. First, it demonstrated that the Indo-Mediterranean diet was cardioprotective for people of South Asian origin. Second, even though participants in the study group were predominantly vegetarians (two thirds), nonobese, and had normal fasting blood glucose levels, they still had a significant reduction in the number of cardiac outcomes when compared with patients on the conventional NCEP step I diet.

It is unclear from the study how compliant the intervention group was with the study diet. As with most diet intervention studies, food intake is assessed by patient report, which is a potential source of resource bias. The investigators tried to minimize this bias using structured interviews by dietitians. Regardless of these limitations, these impressive results lend further support to the advantages of the Mediterranean diet in cardiovascular disease.

Applications for Clinical Practice

An Indo-Mediterranean diet consisting of whole grains, fruits, vegetables, nuts, and mustard or soybean oil appears cardioprotective for patients at high risk for CAD and may be more effective than the traditional NCEP step I diet.

–Review by Harvey J. Murff, MD, MPH

References

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