An Indo-Mediterranean diet was more effective than a control diet in primary and secondary coronary artery disease prevention


QUESTION: In patients with, or at high risk for, coronary artery disease (CAD), is an Indo-Mediterranean diet more effective than the conventional step 1 National Cholesterol Education Program (NCEP) prudent diet?

Design
Randomised (unclear allocation concealment*), blinded |clinicians, data collectors, and outcome assessors†,§ controlled trial with 2 years of follow up.

Setting
Moralabad, India.

Patients
1000 patients > 25 years of age (mean age 48.5 y, 90% men) with angina pectoris, myocardial infarction, or ≥ 1 major risk factor for CAD, recruited through advertising. Exclusion criteria included cancer, long term diarrhoea or dysentery, blood urea nitrogen concentrations > 6.6 mmol/l, and arthritis. Follow up was 98%.

Intervention
Participants were allocated to an Indo-Mediterranean diet (n=499) or a control diet similar to the step 1 NCEP prudent diet (n=501). Patients in both groups were advised to walk briskly ≥ 3–4 km/day or jog intermittently for ≥ 10–15 minutes/d.

Main outcome measures
Fatal or nonfatal myocardial infarction (MI), sudden cardiac death, and total cardiac endpoints (combined total of MI and sudden cardiac death).

Main results
Analysis was by intention to treat. At 2 years, patients who were on the Indo-Mediterranean diet consumed more fruits, vegetables, nuts, and legumes (mean ≥ 1.8 v 0.78 g/d, p < 0.001), and had lower serum cholesterol concentrations (mean 5.04 v 5.59 mmol/l, p < 0.001) than did patients on the control diet. The Indo-Mediterranean diet group had lower rates of all endpoints except fatal MI (table).

Conclusion
In patients with, or at high risk for, coronary artery disease (CAD), an Indo-Mediterranean diet was more effective in primary and secondary prevention of CAD than the conventional step 1 National Cholesterol Education Program prudent diet.

*See glossary.†Information provided by author.

COMMENTARY
The study by Singh et al shows that an Indo-Mediterranean diet combined with intensive nutritional counselling is clinically beneficial in high risk patients. The results add to the Lyon Diet Heart Study, which used a Mediterranean diet, showing that non-pharmacological intervention can lead to reductions in cardiovascular endpoints. The Indo-Mediterranean diet differs from the Mediterranean diet because fish, rapeseed, and olive oils are replaced by mustard or soybean oils, green leafy vegetables, certain nuts, and whole grains. Although this study is well done, a few caveats should be noted. Firstly, the treatment group differed from the control group in both diet and intensity of nutritional counselling. It is unclear which of these factors accounted for the difference in outcomes. Secondly, the step I diet has been phased out of the 2001 National Cholesterol Education Program (NCEP); Adult Treatment Panel III’s recommendations favour a more stringent step 2 diet, now called therapeutic lifestyle changes (TLC). The Indo-Mediterranean diet was not compared with the TLC diet. Thirdly, the study patient group was a homogenous population of urban Indians, therefore generalisation to North Americans or Europeans is questionable. The population studied was considered high risk. The beneficial effects may be less dramatic in lower risk populations. Also, this was a single blind trial and bias may have occurred among participants and treating physicians. Finally, compliance with this diet may be difficult in a nonvegetarian population. This study may provide another diet choice to reduce cardiac risk. In defining future practice, it would be important to compare the Indo-Mediterranean diet to the TLC diet with equal counselling in each group.


Outcomes at 2 years Indo-Medit Control Adjusted RRR (95% CI)§ Unadjusted NNT (CI)
Nonfatal MI 4.2% 8.6% 53% (21 to 72) 23 (13 to 73)
Fatal MI 2.4% 3.4% 33% (42 to 69) Not significant
Sudden cardiac death 1.2% 3.2% 67% (14 to 87) 50 (25 to 533)
Total cardiac endpoints 7.8% 15.2% 52% (29 to 67) 14 (9 to 29)

Outcomes of Indo-Medit (Indo-Medit diet) vs control diet for coronary artery disease: