

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

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.

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

Randomized (unclear allocation concealment*), blinded {clinicians, data collectors, and outcome assessors}†,* controlled trial with 2-year follow-up.

SETTING

Moradabad, 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 diarrhea or dysentery, blood urea nitrogen levels > 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 to 4 km/d or jog intermittently for ≥ 10 to 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 573 vs 231 g/d, $P < 0.001$), consumed more n-3 fatty acids (mean 1.8 vs 0.78 g/d, $P < 0.001$), and had lower serum cholesterol levels (mean 5.04 vs 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 (Table) except fatal MI.

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.

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*See Glossary.

†Information provided by author.

Indo-Mediterranean (Indo-Medit) diet vs control diet for coronary artery disease‡

Outcomes	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)

‡MI = myocardial infarction; total cardiac endpoints = combined total of nonfatal and fatal MI, and sudden cardiac death. Other abbreviations defined in Glossary; unadjusted NNT and CI calculated from data in article.

§RRRs adjusted for several baseline characteristics.

COMMENTARY

The study by Singh and colleagues shows that an Indo-Mediterranean diet combined with intensive nutritional counseling is clinically beneficial in high-risk patients. The results add to the Lyon Diet Heart study (1), which used a Mediterranean diet and showed that a nonpharmacological 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.

First, the treatment group differed from the control group in both diet and intensity of nutritional counseling. It is unclear which of these factors accounted for the difference in outcomes. Second, the step I diet has been phased out of the 2001 NCEP; Adult Treatment Panel III (2) recommendations favor a more stringent step 2 diet, now called therapeutic lifestyle changes (TLC). The Indo-Mediterranean diet was not compared with the TLC diet. Third, the study patient group was a homogenous population of urban Indians, therefore generalization 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 with the TLC diet with equal counseling in each group.

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References

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