Mediterranean diet: Higher fat but lower risk

For patients at high risk for cardiovascular disease, a Mediterranean diet may be the best bet.

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PRACTICE CHANGER

Counsel patients at high risk for cardiovascular disease and stroke to follow a Mediterranean diet, which is associated with a 30% risk reduction.[1]

STRENGTH OF RECOMMENDATION

A: Based on one well-designed randomized controlled trial (RCT).

Estruch R, Ros F, Salas-Salvado J, et al. Primary prevention of cardiovascular disease with a Mediterranean diet. *N Engl J Med.* 2013;368:1279-1290.

ILLUSTRATIVE CASE

A 62-year-old patient with diabetes, obesity, and a family history of early onset coronary artery disease is motivated to make significant lifestyle changes. You recommend moderate aerobic exercise for 30 minutes 5 times a week, but wonder whether a low-fat diet or a Mediterranean diet would be more effective in lowering her risk.

Cardiovascular disease (CVD), including heart disease and stroke, is the leading cause of mortality in the United States. CVD accounts for one in every 3 deaths,[2] and stroke is a leading cause of long-term disability.[2] The direct cost of treating CVD is estimated at $312.6 billion annually.[2]

Many modifiable risk factors contribute to CVD, including smoking, sedentary lifestyle, obesity, alcohol consumption, and poorly controlled chronic disease, as well as an unhealthy diet. A recent report from the American Heart Association suggests that 13% of deaths from CVD can be attributed to poor diet.[2]

Focus counseling on patients at risk

Primary care providers (PCPs) often struggle to effectively counsel patients on behavior change strategies, but face many barriers. Chief among them are the lack of time, training, and confidence in their counseling techniques, as well as a lack of patient motivation and readiness to change.[3] In recognition of these barriers, the US Preventive Services Task Force recently recommended that PCPs focus behavioral counseling efforts on patients at high risk for heart disease.[4]

Large observational studies have found an association between trans fat and an increased risk of CVD, as well as a decreased risk of CVD in patients adhering to a Mediterranean diet.[5-11] This type of diet typically includes a high intake of olive oil, fruit, nuts, vegetables, and cereals; moderate intake of fish and poultry; and low intake of dairy products, red meat, processed meats, and sweets. It also includes wine in moderation, consumed with meals.

Data on the physiologic properties of olive oil, including its antioxidant, vasodilating, and antiplatelet effects—as well as its effects on low-density lipoprotein cholesterol (LDL-C) that may inhibit atherogenesis—support the link between a Mediterranean diet and a decreased risk of CVD found in the observational studies.[12,13] Until recently, however, no RCT had compared the effect of a

Mediterranean diet with that of a low-fat diet for primary prevention of CVD.

STUDY SUMMARY

Mediterranean diet significantly lowers risk

Prevencion con Dieta Mediterranea (PREDIMED) was a large RCT (N=7447) comparing 2 variations of a Mediterranean diet with a low-fat diet for primary prevention of CVD. This Spanish study enrolled men 55 to 80 years of age and women ages 60 to 80 at high risk for developing CVD. The risk was based on either a diagnosis of type 2 diabetes or the presence of ≥3 major risk factors, including smoking, hypertension, elevated LDL-C, low high-density lipoprotein cholesterol, overweight or obese, and a family history of early heart disease.

Participants were randomly assigned to one of 3 dietary groups: One group was assigned to a Mediterranean diet supplemented with ≥4 tablespoons per day of extra virgin olive oil; a second group was put on a Mediterranean diet supplemented by 30 grams (about 1/3 cup) of mixed nuts daily; a third group (the controls) was advised to follow a low-fat diet. The majority of baseline characteristics and medications taken throughout the study were similar among all 3 groups.

Those in both Mediterranean diet groups were followed for a median of 4.8 years, during which time they received quarterly dietary classes and individual and group counseling. The controls received baseline training, plus a leaflet about low-fat diets annually. In year 3, however, the researchers began giving the control group the same level of counseling as those in the Mediterranean diet groups to avoid confounding results.

Adherence to the diets was determined by a self-reported 14-item dietary screening questionnaire, plus urinary hydroxytyrosol and serum alpha-linoleic acid levels to assess for olive oil and mixed nut compliance. Self-reporting[5] and biometric data indicated good compliance with the Mediterranean diets, and there was no difference found in levels of exercise among the groups.

After 5 years, those in the Mediterranean diet groups had consumed significantly more olive oil, nuts, vegetables, fruits, wine, legumes, fish, seafood, and sofrito sauce (a popular tomato-based sauce) than the control group. Participants in the low-fat diet group had decreased their fat intake by 2%, while those in the Mediterranean groups had increased fat intake (by 2.03% for the olive oil group and 2.1% for the nut group). Overall, 37% of energy intake by those in the low-fat diet group came from fat (exceeding the <30% of calories derived from fat intake that defines a low-fat diet) vs 39% fat intake for those in both Mediterranean diet groups.

The primary outcome was a composite of myocardial infarction (MI), stroke, and death from cardiovascular causes, and there were clinically meaningful and statistically significant differences between the Mediterranean diet groups and the controls. The primary outcome rate for the supplemental olive oil group was 3.8%; 3.4% for the extra nuts group; and 4.4% for the controls. This represents a 30% reduction in risk for combined stroke, MI, and death due to cardiovascular causes for the Mediterranean diet groups (hazard ratio [HR]=0.7; 95% confidence interval [CI], 0.53-0.91; *P*=.009; number needed to treat [NNT]=148 for the olive oil group and HR=0.7; 95% CI, 0.53-0.94; *P*=.02; NNT=100 for the group consuming extra nuts). Similar benefits were found in the multivariable adjusted analyses. The results correspond to 3 fewer events (stroke, MI, or cardiovascular death) per 1000 person-years for this high-risk population.

The only individual outcome that showed a significant decrease was stroke, with an NNT of 125 in both Mediterranean diet groups. Outcomes for the controls were similar before and after they began receiving quarterly counseling.

A Mediterranean diet, with increased intake of either olive oil or mixed nuts, is more protective against CVD than a recommended low-fat diet.

WHAT'S NEW?

Mediterranean diet is better than a lower-fat regimen

This study indicates that a Mediterranean diet, with increased intake of either olive oil or mixed nuts, is more protective against CVD than a recommended low-fat diet. It also shows that advising patients at high risk to follow a Mediterranean diet, providing di-

etary counseling, and monitoring them for adherence, rather than simply recommending a low-fat diet, can significantly decrease the risk of stroke.

Rates of CVD are higher in the United States than in Spain, so implementing a Mediterranean diet on a large scale in this country has the potential to produce a greater response than that seen in this study.

CAVEATS

Would a true low-fat diet be a better comparison?

Although the control group's diet was meant to be low fat, the participants did not achieve this, possibly due to the relatively low level of dietary education and personalized counseling at the start of the study. Their inability to reach the <30% fat target could also reflect the difficulty patients have, in general, in decreasing fat content in their diet, which may mean the diet they maintained was a more realistic comparison.

This study used one brand of olive oil and a particular mixture of nuts (walnuts, hazelnuts, and almonds); it is possible that variations on either of these could affect the benefits of the diet.

CHALLENGES TO IMPLEMENTATION

Fitting a Mediterranean diet into an American lifestyle

The typical US diet is significantly different from that of most Spaniards. Americans may find it difficult to add either ≥4 tablespoons of olive oil or 30 g (1/3 cup) of nuts daily, for example, due to both cost and availability. Limited access to both individual and group counseling could be a barrier, as well.

On the other hand, this practice changer has the potential to simplify dietary counseling by allowing clinicians to focus on just one type of diet, for which there are many resources available both online and in print. We believe it makes sense to recommend a Mediterranean diet, while continuing to recommend increased exercise, smoking cessation, and improved control of chronic disease to lower patients' risk of poor outcomes from CVD. JFP

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The PURLs Surveillance System was supported in part by Grant Number UL1RR024999 from the National Center for Research Resources, a Clinical Translational Science Award to the University of Chicago. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Research Resources or the National Institutes of Health.

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