Effects on Health Outcomes of a Mediterranean Diet With No Restriction on Fat Intake

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**PREDIMED, total mortality, and the dangers of using unspecific definitions of the Mediterranean diet**

TO THE EDITOR: We are concerned by the statements on weak evidence of benefit of the traditional Mediterranean diet in Bloomfield and colleagues’ systematic review (1). Rating the available evidence as limited is unfair. The quality and quantity of scientific evidence supporting the benefits of this diet is impressive and not available for any other dietary pattern.

The PREDIMED (PREvención con DIeta MEDiterránea) trial, a low-risk-of-bias study, was not designed to assess differences in all-cause mortality. The primary end point was cardiovascular disease—including myocardial infarction, stroke, and cardiovascular death, as stated in the protocol (2)—but not all-cause mortality. This is also the case in most cardiovascular trials, which are rarely powered for testing the effect on total mortality. The data and safety monitoring board recommended stopping the PREDIMED trial at 4.8 years for early evidence of benefit, although the planned duration was 6 years. The number of observed deaths was consequently even smaller than if the trial had been completed. Therefore, highlighting that no statistically significant results were observed for all-cause mortality is not fair. Doing so is even worse when these nonsignificant results are interpreted as evidence of equality and are placed as the first sentence in the Data Synthesis section of the abstract to support a conclusion of “no difference in all-cause mortality.” Dozens of adequately powered cohort studies already gave the correct conclusion: A strong inverse association exists between the Mediterranean diet and all-cause mortality (3,4).

Why the authors included only cohort studies for cancer and rheumatoid arthritis but not for other outcomes is unclear; they provided no rationale for this unusual decision. The whole available evidence should have been used. Why cohort studies for all-cause mortality, cardiovascular disease, and type 2 diabetes were discarded is difficult to understand. The conclusion that evidence is weak or limited is highly misleading given the consistent available scientific evidence (3, 4).

More important is the inappropriate and highly nonspecific definition of the Mediterranean diet (2 or more of 7 components) chosen by the authors. Their definition is almost completely useless, because many studies meet at least 2 criteria but assess diets quite different from the traditional Mediterranean one. Some of these dietary patterns are also healthy, but they have little in common with the traditional Mediterranean diet (5). The criteria used for defining a Mediterranean diet in this systematic review are wrong and will only confuse readers. Such a peculiar definition of this diet should be avoided in the future.

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References

1. Bloomfield HE, Koeller E, Greer N, MacDonald R, Kane R, Wilt TJ. Effects on health outcomes of a Mediterranean diet with no restriction on fat intake. A systematic review and meta-analysis. Ann Intern Med. 2016;165:491-500. [PMID: 27428849] doi:10.7326/M16-0361

2. Estruch R, Ros E, Salas-Salvadó J, Covas MI, Corella D, Arós F, et al; PREDIMED Study Investigators. Primary prevention of cardiovascular disease with a Mediterranean diet. N Engl J Med. 2013;368:1279-90. [PMID: 23432189] doi:10.1056/NEJMoa1200303

3. Sofi F, Macchi C, Abbate R, Gensini GF, Casini A. Mediterranean diet and health status: an updated meta-analysis and a proposal for a literature-based adherence score. Public Health Nutr. 2014;17:2769-82. [PMID: 24476641] doi:10.1017/S1368980013003169

4. Martinez-Gonzalez MA, Martin-Calvo N. Mediterranean diet and life expectancy;

beyond olive oil, fruits, and vegetables. Curr Opin Clin Nutr Metab Care. 2016;19:401-7. [PMID: 27552476] doi: 10.1097/MCO.0000000000000316

5. Schwingshackl L, Hoffmann G. Diet quality as assessed by the Healthy Eating Index, the Alternate Healthy Eating Index, the Dietary Approaches to Stop Hypertension score, and health outcomes: a systematic review and meta-analysis of cohort studies. J Acad Nutr Diet. 2015;115:780-800. [PMID: 25680825] doi:10.1016/j.jand.2014.12.009