cular disease death by virtue of no history of cardiovascular disease and no diabetes, the overall *P* value for differences in treatment effects was .002 for comparison of combination therapy groups, the main focus of our article. That the number of events was small supports our assertion that these findings pertain to patients with hypertension but without other complications who are at lower risk than are those with a history of cardiovascular disease. In the case of the CCB plus ACE inhibitor group, we acknowledge that the number of women using this combination is small and caution is urged in interpretation. However, our main concern was with diuretic combinations.

The hazard ratios and confidence intervals shown provide estimates of the specific, rather than the overall, differences. We did not adjust the confidence intervals for multiple testing, since our comparisons of the 2-class combinations with diuretic plus β-blockers were planned a priori; also, it is a matter of dispute among statisticians and epidemiologists whether such adjustments are warranted. The reader may evaluate the strength of the presented data.

Dr Bursztyn's point that the antihypertensive effect of CCBs in combination with diuretics is not optimal is reflected in our data (Table 3), which show that average systolic blood pressure at baseline for patients receiving a diuretic plus CCB was 138 mm Hg vs 133 mm Hg for those receiving a diuretic plus ACE inhibitor. Indeed, one reason that the diuretic plus CCB group had higher risk than the diuretic plus ACE inhibitor group may be that the latter combination controls blood pressure more effectively. We do not consider this a study flaw, but rather a possible explanation for our observation that diuretics plus CCBs are associated with a higher risk of CVD mortality than diuretics combined with ACE inhibitors or β-blockers. We did not report results for the β-blocker plus ACE inhibitor or the β-blocker plus CCB combinations because these combinations were not widely used at the time of our study baseline and ALLHAT results had not been published until 2002.[1]

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Comparison of Diets for Weight Loss and Heart Disease Risk Reduction

To the Editor: The study by Dr Dansinger and colleagues[1] suggests that all 4 diets (Atkins, Ornish, Weight Watchers, and Zone) are comparable because the changes in risk factors for coronary heart disease (CHD) are similar. I believe that this would not be a proper conclusion because the study did not distinguish between cardiovascular risk factors and direct measures of cardiovascular disease.

In a randomized controlled trial measuring the effects of the Ornish diet,[2] which is a very low-fat diet that predominantly consists of fruits, vegetables, unrefined carbohydrates (ie, whole grains), and legumes, the progression of CHD was reversed as measured by quantitative coronary arteriography, with more regression of CHD after 5 years than after 1 year, and there were 2.5 times fewer cardiac events. These patients lost a mean of 24 lb in year 1 and had kept off more than half that weight 5 years later. Another study[3] showed halting or regression of CHD in the majority of the patients, as measured by cardiac positron emission tomographic scans. A third study[4] showed improvement as measured by radionuclide ventriculography, with a 91% decrease in frequency of angina in the first 3 weeks.

In contrast, no study has shown that an Atkins, Zone, or Weight Watchers diet can stop or reverse the progression of CHD. The only study of the Atkins diet that examined measures of cardiovascular disease rather than risk factors showed that myocardial perfusion worsened with an Atkins diet but improved with a low-fat diet.[5] These findings are consistent with a large amount of data from epidemiological studies, animal research, and randomized controlled trials linking the intake of a diet high in animal fat and protein with the incidence of CHD.[6] Serial coronary arteriographic studies of 30% fat diets that are similar to Weight Watchers and Zone diets, such as the American Heart Association and National Cholesterol Education Program diets, show continued progression of CHD.[6] Finally, patients assigned to the Ornish diet in the study by Dansinger et al had the greatest reductions in weight, body mass index, total cholesterol,

low-density lipoprotein cholesterol, blood glucose, and C-reactive protein after 1 year when compared with the other 3 diets.

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To the Editor: The study by Dr Dansinger and colleagues[1] provides useful insights into the relative appeal of 4 popular diets. However, it fails to provide a meaningful comparison of their efficacy because of high attrition rates and poor adherence, with the possible exception of those participants reporting the highest adherence. A mean weight loss of 7% is reported for those participants in the highest tertile of adherence; it would be helpful if specific results or comparisons for that subgroup could be provided. In addition, because most of the participants did not follow the diet as defined, it would be more appropriate to pool the data to examine the relationships between outcomes of interest and nutrient intake rather than diet type.

A self-reported adherence level of 6 was considered to "delineate a clinically meaningful adherence level," and was maintained by 25% of participants, but this is not well described. Mean adherence was well below this by the second month for each group, indicating very low adherence with a large positive skew. It is unclear whether adherence measures from self-report or dietary records were regressed with weight change.

The lack of correlation between diet type and weight loss is of uncertain meaning because changing diet order may change correlation. A more meaningful comparison would be the analysis of variance or similar test, because the *P* value for trend across diet groups does not test for differences between characteristics or outcomes of the diets. Finally, relationships between outcomes and nutrients should be energy-adjusted. Adjustment for adherence eliminated the association between changes in exercise level and weight loss, indicating that adherence was associated with exercise and suggesting that the effects of exercise may be confounding reported dietary effects.

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In Reply: Dr Ornish correctly points out that no study has ever shown that an Atkins, Zone, or Weight Watchers diet can stop or reverse the progression of CHD. Our trial found that adherence level rather than diet type was the primary predictor of weight loss and CHD risk factor reduction, and one can reasonably hypothesize that strict adherence to each dietary approach would decrease CHD in properly designed clinical trials. As discussed in our article, the reduction in low-density lipoprotein/high-density lipoprotein cholesterol ratios observed for each diet is suggestive but not conclusive of net beneficial effects on lipids, and we called for longer-term studies with cardiovascular outcomes. Without well-designed randomized trials that evaluate CHD event rates, it is premature to purport that the Atkins diet affects CHD outcomes differently than other diets do.

Regrettably, existing data regarding the effect of standard vs alternative diets on CHD outcomes are very limited and difficult to compare across studies. For example, the 5-year findings by Ornish et al[1] are limited to 20 individuals in the experimental group and 15 individuals in the control group (71% and 75% completion, respectively). Although the treatment effects on CHD event rates, myocardial perfusion, and coronary stenosis were impressive, it is difficult to disentangle the confounding effects of more exercise, meditation, and dietary adherence level in the experimental group. Furthermore, it is especially difficult to compare these results with those from other trials. For example, the Lyon Diet Heart Study[2] found that advice to follow a Mediterranean diet was associated with reduced CHD event recurrence compared with a standard dietary approach. The various results of these and other studies are difficult to compare not only because the patient populations vary but also because the dietary adherence levels and other factors that impact the treatment effect were undoubtedly substantially different across studies. More trials that compare multiple diets simultaneously would be useful in this regard.

Dr Kelly's requests for additional analyses are very appropriate and raise questions about issues that we were unable to fully address in our article. For example, results for the most highly adherent subgroup as well as predictors of high adherence levels and weight loss were beyond the scope of the principal article, although subsequent manuscripts are in preparation. We also intend to publish data relating individual clinical outcomes to changes in nutrient intake

(with and without adjustment for energy intake) that address many of Dr Kelly's other valid points.

Our finding that weight loss was related to dietary adherence level ($r=0.60$, $P<.001$), but not diet type ($r=0.07$, $P=.40$), is robust to various methods of analysis. Analysis of variance testing supports the lack of relationship between weight loss and diet type ($F=0.37$, $P=.78$), and the strong relationship between self-reported dietary adherence and weight loss persists when adherence is based on diet record results.

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Resurrecting Treatment Histories of Dead Patients

To the Editor: In their Special Communication, Dr Bach and colleagues raise important limitations in the use of the retrospective approach to studying end-of-life care.[1] However, we believe that research that uses multiple methods is needed to examine a complex phenomenon such as dying. Given the uncertainties of prognostication, retrospective assessment of decedents remains an important methodology to examine the quality of end-of-life care.

Like any study design, the retrospective (mortality follow-back) approach has strengths and limitations. A key advantage of this approach is that the selection of cases is not dependent on inaccurate physician prognostication of survival, important when the decedent is enrolled in hospice or other services predicated on a terminal prognosis. The time frames in relationship to death are known, and researchers can compare experiences in the last week across sites of care. If the research goal is to examine the quality of care in the last month of life, respondent burden is an important concern of the prospective cohort approach. Many dying persons are unable to be interviewed in the last month of life. A retrospective approach is more efficient in both case finding and maximizing rate of follow-up.

Incomplete enrollment of patients is an important potential limitation of prospective cohort studies. For example, in the Study to Understand Prognosis and Preferences for Outcomes and Risks of Treatments (SUPPORT), a prospective cohort study, Wenger et al reported that 40% of seriously ill hospitalized patients could not be interviewed regarding their end-of-life care preferences due to illness severity.[2] Those unable to be interviewed were the sickest patients, often closest to death. If the SUPPORT study had required consent from seriously ill patients or their families prior to reviewing the medical record, a substantial number of patients would have been excluded from the study, many of whom died. Exclusion of these patients would have lead to substantial bias.

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To the Editor: In their Special Communication,[1] Dr Bach and colleagues argue that "look-back" studies of decedents produce biased inferences regarding treatment patterns and quality of care because patients who have their initial diagnosis of fatal illness during their last year are not a random sample of those with a disease and thus have systematically different durations of exposure to end-of-life costs and utilization.

However, additional considerations may make these retrospective study designs appropriate. Most Americans with serious, eventually fatal, chronic illnesses such as heart failure and chronic obstructive pulmonary disease live for several years before dying.[2] In many cases, the timing of death is quite unpredictable even very close to death, because the events that precipitate dying may be sudden.[3] One-year look-back studies of these decedents would not raise substantial problems of prediagnosis bias. Similarly, retrospective studies with appropriately shortened time frames could also mitigate that bias. Furthermore, if patients with certain kinds of cancer have predictably high expenses in their first few months of diagnosis and their last few months of life and relatively stable expenses in the middle months, retrospective studies could be adjusted for different survival spans that mainly differ in the length of the middle period.

Retrospective studies are generally more efficient, inexpensive, and inclusive than prospective cohort studies. Prospective studies enrolling patients at the onset of particular conditions would need a very long follow-up period since a few patients will live for many years, and all methods of truncation of follow-up incur biases as well. Retrospective studies have the advantage of ensuring that all included cases had similarly serious illness, since they all did die.

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