**Table. Patient Ratings for Follow-up Questions Regarding Care, Preferences, Prognosis, and Spiritual Care Comparing Usual Care and Intervention Groups**

| Question | Patients, No./Total (%) | | *P* Value |
|---|---|---|---|
| | Usual Care | Intervention | |
| Did a doctor tell you about choices for treatment? (Yes) | 19/40 (48) | 15/40 (38) | .50 |
| Did you have specific wishes or plans about the types of medical treatment that you wanted? (Yes) | 8/40 (20) | 6/40 (15) | .80 |
| Did a doctor talk with you about the chances that you would survive the last hospitalization? (Yes) | 13/40 (33) | 21/41 (51) | .11 |
| Did someone on the health care team talk with you about your religious beliefs? (Yes) | 9/39 (23) | 16/41 (39) | .15 |
| Did someone on the healthcare team suggest seeing a religious leader? (Yes) | 3/38 (8) | 5/40 (13) | .71 |
| Did you feel that anyone at the hospital really understood what you and your family were going through? (Yes) | 33/38 (87) | 31/41 (76) | .26 |
| Did a doctor really listen to you about your hopes, fears, and beliefs as much as you wanted? (Yes) | 17/21 (81) | 20/26 (77) | >.99 |
| Did the nurses really listen to you about your hopes, fears, and beliefs as much as you wanted? (Yes) | 16/18 (89) | 24/27 (89) | >.99 |

ceive palliative care, at earlier stages palliative care may have an impact on different outcomes or require ongoing engagement.[10] Second, a truly interdisciplinary team, as we have now, may have had an impact, whereas the physician-focused PMC did not.

The following limitations temper our results. Findings from 1 institution may not be generalizable, though patients enrolled had common conditions. Although we relied on self-report measures, such reporting is standard and would not account for lack of effect. Prior descriptive and other rigorous studies have demonstrated benefits of PMC. Therefore, the lack of positive findings in our randomized trial should not dissuade clinicians from referring to a palliative care consultation service but highlights the need for further rigorously designed research to demonstrate which approach to palliative care provided to which patients would improve patient outcomes.

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## COMMENTS AND OPINIONS

### Medical Devices and the Approval Processes: United States vs France

Redberg rightly supported the plans for the new approval process from the US Food and Drug Administration (FDA) for medical devices.[1] The FDA has announced it will significantly strengthen its premarket clearance process (which is under review by the Institute of Medicine) and the process for developing and reviewing postmarket data.[1] The FDA also has announced a new transparency initiative requiring that clinical data be publicly available. Indeed, a prudent policy is warranted before approval: high-quality clinical data must show that the benefits outweigh the risks.

Sadly, the ASTRAL (Angioplasty and Stent for Renal Artery Lesions) trial will not be the last one to remind

us that evidence is more important than hope.[2] The practice of dilatating and stenting renal arteries has spread like an epidemic since the 1980s (eg, 45 000 per year in the United States).[3] In 2009, ASTRAL showed no benefit from these vascular procedures vs drug treatment but only serious complications (23 per 400 patients, including 2 deaths and 3 amputations). In the 1980s, FDA standards for medical devices were deficient.[3]

By contrast, the French drug agency (Agence Française de Sécurité Sanitaire des Produits de Santé [AFSSAPS]) has recently developed an opposite concept. The chief executive officer of AFSSAPS has just prefaced a book on medical devices, which is freely offered by Medtronic. One of the authors is Medtronic's director of regulatory affairs, and the other one is the director in charge of medical devices evaluation at AFSSAPS. The chapter on evaluation is a pledge to avoid evaluation: "rapid obsolescene of the products . . . is hardly compatible with the delay necessary for clinical trials, particularly morbidity-mortality data."[4(p57)] The alternative solution recommended is "predictive equivalence"![4] No one seems to know what can be considered "predictive equivalence" but the authors. A two-dozen–lined chapter titled "Predicitive Appearance of Preclinical Evaluation" indicated that clinical evaluation can be limited to the check of the results of the specific test bench. There is no concern for clinical end points such as mortality and morbidity, effectiveness, and the collection of postapproval data.

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## Statins and All-Cause Mortality in High-Risk Primary Prevention of Patients With Cardiovascular Risk Factors

As pointed out in the meta-analysis by Ray et al,[1] as well as by others,[2-5] the effectiveness of a statin is much more dependant on the specific clinical profile of the individual man or woman considered for treatment, and this therefore relates directly to the selection criteria of the study participants in the individual intervention trials. The composition of the components of cardiovascular risk profile—to name just one relevant factor—will have significant bearing on the effectiveness of the drug in a high-risk subject considered for treatment. For instance, an elderly subject at risk because of hypertension will benefit less from a statin than a normotensive middle-aged person with an unfavorable lipid profile.

A matter that Ray et al[1] insufficiently address is the effect of statins on nonfatal cardiovascular events in primary prevention. We, as well as others, have shown that these are considerable. Rates of myocardial infarction, stroke, and revascularizations are all typically reduced by at least 30%.[2,4,5] It is hard to imagine that the reduction in such critical clinical events would have no influence on the final outcome with longer follow-up.

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## Statins and All-Cause Mortality in High-Risk Primary Prevention: A Second Look at the Results

The meta-analysis by Ray et al[1(p1030)] found that statins therapy has "no benefit on all-cause mortality in high-risk primary prevention population." Because of the importance of this study to clinicians and policy makers, its results and interpretation should be carefully examined.

In summarizing the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) study,[2] the authors calculated a risk ratio of 0.98, while the original publication reported a risk ratio of 0.87. This change alone may have biased against finding a statistically significant benefit for statin use.

Moreover, their meta-analysis included 3 studies with major limitations: a significant decrement in low-density lipoprotein cholesterol levels over the study period in the placebo arm (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial [ALLHAT]),[3]