Response to Letters Regarding Article, “Risks Associated With Statin Therapy: A Systematic Overview of Randomized Clinical Trials”

The letters that address our analysis of risks associated with statin therapy1 raise 2 important points: the generalizability of the data and the excess incidence of myalgias observed with atorvastatin therapy. Although inclusion/exclusion criteria required for clinical trials limit generalizability to patients in clinical practice, randomized controlled trials remain the best unbiased source of data to assess adverse effects.2,3 However, there remains a need for additional, large, safety studies in populations previously not studied.

In their letter, Drs Brewster and van Montfrans indicate that some statin trials exclude patients with elevated creatine kinase levels (>1.5 to 6 times the upper limit of normal). We believe that these patients are appropriately excluded, as patients with extreme creatine kinase elevations have an underlying pathology and may represent a population inappropriate for statin therapy.

The issue of excess incidence of myalgia observed with atorvastatin, raised in the letter from Drs Rosenberg and Uretsky, merits further investigation. This observation reached marginal statistical significance (P=0.04) and was based on only 567 patients (19 of 375 patients versus 3 of 192 patients in the treatment and placebo groups, respectively). Accordingly, this finding is worth further pursuit, but should not be considered definitive at this time.

Disclosures

Dr Foody received honoraria from and served as a consultant/advisory board member for Merck, BMS/Sanofi, and Pfizer. The other authors have nothing to disclose.

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_Circulation._ 2007;116:e9
doi: 10.1161/CIRCULATIONAHA.107.697227
_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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