

at 21% but do not mention that the negative predictive value of the tool is 99%; hence, the tool is highly reliable at excluding LADA and has a sensitivity of 90%, meaning that most LADA patients can be identified with the assistance of this noninvasive and cost-free clinical screening tool.

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Efficacy and Safety of Atorvastatin in the Prevention of Cardiovascular End Points in Subjects With Type 2 Diabetes: The Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in Non-Insulin-Dependent Diabetes Mellitus (ASPEN)

Response to Knopp

We read with interest the results of the Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in Non-Insulin-Dependent Diabetes Mellitus (ASPEN)

(1). The composite primary end point rate (10 mg/day atorvastatin versus placebo) showed a hazard ratio of 0.90 (95% CI 0.73–1.12, $P = 0.34$) after 4 years. Knopp et al. (1) highlight some of the differences between ASPEN and previous atorvastatin trials (Collaborative Atorvastatin Diabetes Study and Anglo-Scandinavian Cardiac Outcomes Trial) also involving diabetic individuals without established coronary heart disease (2,3).

Other differences may also be relevant. In ASPEN, 78.3% of those on atorvastatin and 76.4% of those in the placebo group were included in the analysis. This represents a substantial “drop-out” rate. Furthermore, by the end of the study, medication was taken by 67.5% of those in the atorvastatin group and 57.6% of those in the placebo group. The “drop-in” rate in ASPEN was also high; 26.9% of those on placebo and 15.4% of those in the atorvastatin group took concomitant hypolipidemic agents. Nevertheless, LDL cholesterol was reduced by 29% with atorvastatin relative to placebo. Is it possible that among the patients on atorvastatin, some took a second statin? If so, how many of the placebo-treated patients were taking a statin and for how long?

In the ASPEN study (1), blood pressure was well controlled (mean 133/77 mmHg). The blood pressure in the Collaborative Atorvastatin Diabetes Study and the Anglo-Scandinavian Cardiac Outcomes Trial was ~138/78 and 143/80 mmHg, respectively (2,3). This difference may influence any benefit accruing from lipid lowering in ASPEN. There was also a change in protocol during the ASPEN study. Did this lead to a difference in the duration of follow-up in the primary and secondary prevention groups?

The differences outlined above, together with those mentioned by the ASPEN authors (1), may have contributed to the nonsignificant reduction in events reported in this trial.

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Efficacy and Safety of Atorvastatin in the Prevention of Cardiovascular End Points in Subjects With Type 2 Diabetes: The Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in Non-Insulin-Dependent Diabetes Mellitus (ASPEN)

Response to Gazi and Mikhailidis

We appreciate the interest of Gazi and Mikhailidis (1) in the Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in Non-Insulin-Dependent Diabetes Mellitus (ASPEN) and their proposed reasons for the nonsignificant results (2).

We mention in our article the high rates of treatment “drop in” and “drop