Adverse effects of statins

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Re: Adverse effects of statins

Dear Editor,

Our study, "Discontinuation of Statins in Routine Care Settings"[1], has been cited in several recent publications and subsequent correspondence and editorials in the BMJ regarding the issue of statin intolerance[2-4]. We are writing to underscore the aims and conclusions of the study, which appear to have been misinterpreted in some of these reports.

Our study's central objective was to investigate the 'real world' experience of patients who developed symptoms that they, or their healthcare providers, believed might have been caused by statins. The main finding of our study, which used natural language processing to analyze records of over 100,000 patients, was that when patients discontinue a statin after a presumed statin-related event, and are then rechallenged with the same or another statin, in most cases (over 90%), such patients are able to continue taking a statin long-term. These observations led us to conclude "that many of the statin-related events MAY HAVE OTHER CAUSES, are tolerable, or may be specific to individual statins rather than the entire drug class". Of note, our findings have been subsequently confirmed in another large study from a different institution[5]. Taken together, we stand by our report and the presentation of our data, including our noting of the study's limitations.

The goal of our study was never to establish the rate of adverse reactions caused by statins, which would be impossible using the tools we employed. Indeed, our paper never uses the term "adverse reactions to statins", referring instead to "statin-related events", which were defined as "clinical events or symptoms BELIEVED to have been caused by statins". Implicit in this definition is the recognition that the actual etiological relationship of each identified event to statin use could not be established.

Both randomized clinical trials and observational studies are limited in their ability to estimate the rate of true adverse reactions to statins in actual patient care. Accurate identification of adverse reactions to statins will likely require a better understanding of the mechanisms involved, thus allowing development of more sensitive and specific tests. In the meanwhile, careful interpretation of all available data can help guide prudent clinical management, including avoiding the dangerous prospect that patients with significant cardiovascular risk never undergo statin re-challenge when in fact they may have been able to tolerate the medication.

Sincerely,

Huabing Zhang, MD Jorge Plutzky, MD

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Alexander Turchin, MD, MS

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Competing interests: No competing interests

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