

Comment on Atorvastatin Safety in Kawasaki Disease Patients with Coronary Artery Aneurysms

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To the Editor,

I read with great interest the article by Niedra et al. [1] entitled “Atorvastatin Safety in Kawasaki Disease Patients with Coronary Artery Aneurysms,” which addresses an important gap in current knowledge. The study describes the use of atorvastatin in children with aneurysms after Kawasaki disease (KD) and provides data regarding safety and adverse effects of this drug in this patient population. Because there is currently no standard therapy for children with coronary artery abnormalities after KD, this report provides welcome new information. However, the investigators did not provide clinical details that would help readers to fully evaluate the safety of this approach. Specifically, they should explain the relationship, if any, between per-kilo dose and adverse effects experienced by their patient population. In addition, it would be helpful to know the range of doses (in mg/kg) for these patients as well as the ages of the youngest patients. In the United States, we

have launched a phase I/IIa clinical trial of atorvastatin in children with coronary artery abnormalities during the acute phase of KD (clinicaltrials.gov NCT01431105). In the Canadian study, it appears that infants were also treated with atorvastatin. Due to the lack of juvenile toxicity data, we have been limited by the United States Food and Drug Administration to enrollment of children ≥ 2 years of age. We would like to know what regulatory process was used in Canada to allow treatment of these younger patients. We look forward to your responses.

Reference

1. Niedra E, Chahal N, Manlhiot C, Yeung RS, McCrindle BW (2013) Atorvastatin safety in Kawasaki disease patients with coronary artery aneurysms. *Pediatr Cardiol*. doi:10.1007/s00246-013-0746-9

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