QUOTE GM #24

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Title

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JUST ANOTHER WORRYING SIDE EFFECT FROM STATINS INTAKE!

Amyotrophic Lateral Sclerosis Associated with Statin Use: A Disproportionality Analysis of the FDA's Adverse Event Reporting System.

Golomb BA¹, Verden A², Messner AK³, Koslik HJ³, Hoffman KB².

Author information

- 1 Department of Medicine, University of California, San Diego, 9500 Gilman Drive # 0995, La Jolla, CA, 92093-0995, USA. bgolomb@ucsd.edu.
- 2 Advera Health Analytics, Inc., Santa Rosa, CA, USA.
- 3 Department of Medicine, University of California, San Diego, 9500 Gilman Drive # 0995, La Jolla, CA, 92093-0995, USA.

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INTRODUCTION: Apparent elevations in reporting of amyotrophic lateral sclerosis (ALS)-like conditions associated with statin use have been previously described from data obtained via US and European databases.

OBJECTIVE: The aim of this study was to examine US FDA Adverse Event Reporting System (FAERS) data to compare reporting odds ratios (RORs) of ALS and ALS-like conditions between statins and other drugs, for each statin agent.

METHODS: We assessed for disproportional rates of reported ALS and ALS-related conditions for each statin agent separately by using the ROR formula. FAERS data were analyzed through September 2015.

RESULTS: RORs for ALS were elevated for all statins, with elevations possibly stronger for lipophilic statins. RORs ranged from 9.09 (6.57-12.6) and 16.2 (9.56-27.5) for rosuvastatin and pravastatin (hydrophilic) to 17.0 (14.1-20.4), 23.0 (18.3-29.1), and 107 (68.5-167) for atorvastatin, simvastatin, and lovastatin (lipophilic), respectively. For simvastatin, an ROR of 57.1 (39.5-82.7) was separately present for motor neuron disease.

CONCLUSION: These findings extend previous evidence showing that significantly elevated ALS reporting extends to individual statin agents, and add to concerns about potential elevated occurrence of ALS-like conditions in association with statin usage.

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