Chronic exposure to statin drugs and melanoma: A report from the RADAR (Research on Adverse Drug events And Reports) project

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Abstract

Melanoma (MM) after chronic exposure to a commonly prescribed class of drugs, the statins, warrants further exploration, given that none describe a risk of MM in the Full Prescribing Information. We conducted a cohort study of a large urban patient population to further evaluate this association, and found a significant association between MM and statin exposure (aOR: 1.11; 95% CI 1.02-1.22; p = 0.02). Data for the age group subject to statin recommendations of 40-75 years old, also showed a highly significant association between chronic statin exposure and subsequent MM (aOR: 1.19; 95% CI 1.08-1.31; p = 0.0003). Findings in this large U.S. patient population show a significant association between chronic statin exposure and incident MM that points to the need for enhanced surveillance strategies by both patients and physicians, especially for those with preexisting risk factors for MM.

Materials and Methods

A large Midwestern U.S. patient population database (> 5 million) – the Northwestern Enterprise Data Warehouse (EDW) – yielded data from adults (18-89 years) with at least 5 years of in-clinic follow-up. The NMEDW includes prospective patient records for more than 5 million individuals, including those of patients seen in a National Cancer Institute (NCI)-designated Comprehensive Cancer Center and an NCI-designated Chemoprevention Center.

The statin-exposed population consisted of all patients exposed to a statin (atorvastatin, cerivastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, or simvastatin) for ≥ 12 consecutive months while the control population consisted of non-statin-exposed patients. The outcome was MM occurring ≥ 12 months after first exposure (exposed index date) or first in-clinic date (non-exposed index date). Patients with prior history of MM or statin exposure before the index date were excluded.

A multivariate logistic regression model was created to determine the association between incident cutaneous MM and prior exposure to a statin drug. The adjusted model included the identified potential confounders of age, gender, and race. Specifically, there is a documented relatively higher incidence of MM in the elderly, in males, and in the White race.

Results

Of 454,201 patients meeting inclusion criteria, 56,089 had chronic exposure to a statin, of whom 661 (1.2%) were diagnosed with MM, yielding a significant association between MM and chronic statin exposure (aOR: 1.11; 95% CI 1.02-1.22; p = 0.02).

Importantly, data for the age group subject to statin recommendations (40-75 years), showed a highly significant association between chronic statin exposure and subsequent MM (aOR: 1.19; 95% CI 1.08-1.31; p = 0.0003).

Discussion

Notably, these findings are contrary to those of another study in which it was found that statin use was not associated with risk of MM (Hazard Ratio: 1.04; 95% CI 0.78-1.38) in a large cohort of nurses and other health professionals over a follow-up period of 10 years. That study, however, did report limitations specifically in regards to MM analyses, particularly related to a relatively low number of MM diagnoses in the study cohort.

Conclusions

In this study, a significant association was discovered for MM after exposure to statin drugs in both the total study population as well as the 40-75 years of age cohort. Although conflicting evidence exists in the literature, this study is one of the first cohort studies with large prospective data for MM. The potential wide-ranging impact of these results point to the need for enhanced surveillance strategies for this condition by both patients and physicians, especially for those with preexisting risk factors for MM.

References: