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Evaluating the risk of rhabdomyolysis and myopathy associated with concomitant use of dronedarone and statins using real-world data

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Background: Dronedarone may interact with statins in that it inhibits Cytochrome P450 3A4, the P-glycoprotein, and organic anion-transporting polypeptide.

Purpose: To evaluate the risk of rhabdomyolysis and myopathy in concomitant users of dronedarone and statins compared to statin-alone users.

Methods: In a retrospective cohort study, the Clinformatics database was used to identify statin users who were at least 18 years old, had a diagnosis of atrial fibrillation or flutter, and had a dispensing of statin between July 2009 and March 2016. Among these statin users who also had indicated condition for dronedarone, concomitant use of dronedarone was identified. The cohort entry date of a patient was defined as the first date when a concomitant user was exposed to both drugs or the date of the first dispensing of statin in the study period for a statin-alone user. Patients who were not continuously enrolled for medical and prescription drug benefits, or had a diagnosis of rhabdomyolysis or myopathy in the 180-day baseline period prior to the cohort entry date were excluded from the analysis. Rhabdomyolysis and myopathy during follow-up was ascertained using a published algorithm that is applicable to claims data. Incidence rate of rhabdomyolysis and myopathy was calculated for each patient cohort.

Results: A total of 1,443 concomitant users and 103,020 statin alone users were identified. The concomitant users had more medical encounters listing atrial fibrillation or flutter as a diagnosis, were more likely to have hypertension, but were less likely to have diabetes, stroke, congestive heart failure, and myocardial infarction, and were less likely to use major medications with potent interactions with statins in the baseline period. There were no cases of rhabdomyolysis or myopathy in the concomitant users who had a total exposure of 848 person-years. In the statin-alone users, 318 cases of rhabdomyolysis and myopathy were observed during a total exposure of 112,279 person-years; and the incidence rate was 2.83 cases per 1,000 person-years (95% confidence interval: 2.52 - 3.14).

Conclusions: There was no evidence in this study supporting that concomitant use of dronedarone and statins is associated with an increased risk of rhabdomyolysis and myopathy.