To characterize postmarketing adverse event reports of myopathy and rhabdomyolysis associated with ticagrelor and atorvastatin or rosuvastatin, we used the SDD to identify prevalent concomitant dispensings of ticagrelor and atorvastatin or rosuvastatin. We identified 45 cases of myopathy (n=7) and rhabdomyolysis (n=38) with concomitant dispensing of ticagrelor and statins. Reports of myopathy and rhabdomyolysis were received in the postmarket setting.

OBJECTIVES

1. To characterize postmarketing adverse event reports of myopathy and rhabdomyolysis associated with concomitant use of ticagrelor and atorvastatin or rosuvastatin, submitted to the US Food and Drug Administration Adverse Event Reporting System (FAERS).
2. To assess the concomitant use of ticagrelor and atorvastatin or rosuvastatin in the Sentinel Distributed Database (SDD).

METHODS

1. We used the Empirica Signal software to analyze disproportionality of reporting of rhabdomyolysis and myopathy associated with concomitant use of ticagrelor and atorvastatin or rosuvastatin from the FAERS data from January 2012 to September 2018 using the Bayesian data mining signal score (INTSS).2
2. We queried FAERS for reports of myopathy/rhabdomyolysis associated with concomitant use of ticagrelor and atorvastatin or rosuvastatin from US approval of ticagrelor to September 2018. Reports were included if both drugs were initiated at the same time or the patient was on a statin prior to ticagrelor initiation. We assessed causality using the Drug Interaction Probability Scale (DIPS).4
3. We used the SDD to identify prevalent concomitant dispensings of ticagrelor and atorvastatin or rosuvastatin using National Drug Codes (NDC) from January 2012 to June 2018. Dispensings of ticagrelor were evaluated for concomitancy of atorvastatin or rosuvastatin in a window 30 days prior to 60 days post dispensing. Dispensings were evaluated by each atorvastatin or rosuvastatin strength.

RESULTS

1. The 3D datamining analyses of ticagrelor and rosuvastatin produced an INTSS >1.0, which was driven by disproportionate reporting in those ≥65 years of age. The combination of ticagrelor and rosuvastatin produced an INTSS < 1.0 across all reports using crude cRR (Table 1). Atorvastatin started ≥65 years More than once or no clinical risk factors or outcome may have been reported per case. Cases may have reported statin or ticagrelor discontinuation or both. Hypothesis defined as being a medication.
2. We identified 45 cases of myopathy (n=7) and rhabdomyolysis (n=38) with concomitant use of ticagrelor and atorvastatin (n=24) or rosuvastatin (n=21), including death cases (n=3). Approximately 50% of the reported cases occurred in patients ≥75 years (Table 1).

REFERENCES


FINANCIAL DISCLOSURES: The authors of this poster declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this poster, including grants, employment, gifts, stock holdings, and honoraria.

ACKNOWLEDGMENT: Many thanks are due to Data Partners who provided Sentinel data used in the analysis.