

# PHARMACOVIGILANCE ANALYSIS OF STATIN-ASSOCIATED MUSCLE SYMPTOMS

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## INTRODUCTION

Muscle symptoms are clinically-relevant side-effects of statin therapy. Incidence of statin-associated muscle symptoms (SAMS), including myalgia, myopathy and rhabdomyolysis, varies with the different statins.<sup>1</sup>

## AIM

To analyse adverse drug reaction (ADR) reports of SAMS with different statins (simvastatin, atorvastatin, rosuvastatin)

## METHOD

ADR reports retrieved from EudraVigilance Data Analysis System (EVDAS)

2014-2018 ADR reports of myalgia, myopathy and rhabdomyolysis with simvastatin, atorvastatin and rosuvastatin from 28 European Union countries

Analysis of ADR reports according to SAMS, gender and statin dose

## RESULTS

- The 4,164 ADR reports analysed were distributed as: Myalgia (78%, n=3,260 - atorvastatin 47%, simvastatin 32%, rosuvastatin 21%), Rhabdomyolysis (15%, n=643 - atorvastatin 48%, simvastatin 37%, rosuvastatin 14.5%) and Myopathy (6%, n=261 - atorvastatin 47.5%, simvastatin 34%, rosuvastatin 19%).
- Reports for all SAMS were significantly higher for atorvastatin compared to simvastatin and rosuvastatin (p=0.007).
- Incidence of rhabdomyolysis was significantly higher in males for atorvastatin (p<0.001) and simvastatin (p=0.003) and comparable between genders for rosuvastatin (p=0.103).
- The statin doses associated with SAMS were: Myalgia (simvastatin 20mg-49%, rosuvastatin 10mg-38%, atorvastatin 20mg-36%), Myopathy (simvastatin 40mg-39%, rosuvastatin 5mg, 10mg-33%, atorvastatin 10mg-30%), rhabdomyolysis (simvastatin 40mg-53%, atorvastatin 80mg-40%, rosuvastatin 20mg-38%).

Table 1: Analysis of ADR reports of myalgia, myopathy and rhabdomyolysis according to statin and dose (N=4,164)

ADR / Statin and Dose	Simvastatin (n=1380)				Atorvastatin (n=1963)				Rosuvastatin (n=812)			
	10mg	20mg	40mg	80mg	10mg	20mg	40mg	80mg	5mg	10mg	20mg	40mg
Myalgia (n=3,260)	130	516	381	24	461	556	378	140	230	255	150	36
Myopathy (n=261)	14	29	34	11	37	31	35	21	16	16	10	7
Rhabdomyolysis (n=643)	26	71	127	17	44	57	85	122	13	19	36	26

European Medicines Agency (EMA). EudraVigilance Data Analysis System (EVDAS); January 2019.

## CONCLUSION

Myalgia was the most common statin-associated muscle symptom reported for the three statins. A higher number of ADR reports of myalgia with atorvastatin compared to simvastatin and rosuvastatin were observed.

## REFERENCES

- Morival C, Westerlynck R, Bouzille G, Cuggia M, Le Corre P. Prevalence and nature of statin drug-drug interactions in a university hospital by electronic health record mining. Eur J Clin Pharmacol. 2018;74(4):525-34.