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.1

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)

<table>
<thead>
<tr>
<th>ADR / Statin and Dose</th>
<th>Simvastatin (n=1380)</th>
<th>Atorvastatin (n=1963)</th>
<th>Rosuvastatin (n=812)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10mg</td>
<td>20mg</td>
<td>40mg</td>
</tr>
<tr>
<td>Myalgia (n=3,260)</td>
<td>130</td>
<td>516</td>
<td>381</td>
</tr>
<tr>
<td>Myopathy (n=261)</td>
<td>14</td>
<td>29</td>
<td>34</td>
</tr>
<tr>
<td>Rhabdomyolysis (n=643)</td>
<td>26</td>
<td>71</td>
<td>127</td>
</tr>
</tbody>
</table>

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