PHARMACOVIGILANCE ANALYSIS OF STATIN-ASSOCIATED MUSCLE SYMPTOMS

Judith Cerdá Iñesta 1, 2, Francesca Wirth 1, Anthony Serracino-Inglott 1, 2
1Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta
2Malta Medicines Authority, Malta Life Sciences Park, San Gwann, Malta
e-mail: judith.cerda.16@um.edu.mt

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