Symptoms, concomitant conditions and cardiac risk in European Hydroxyurea treated Polycythemia Vera patients

Graham A, Manuel L, Milligan G, Taylor-Stokes G
Adelphi Real World, Bollington, Manchester, UK

Introduction/Objectives

- Polycythemia Vera (PV) is associated with an overproduction of blood cells which leads to increased risk of blood clots and associated cardiovascular (CV) complications and may result in increased morbidity and mortality.
- PV is a rare condition, estimates relating to the prevalence of the condition vary. RARECARE estimate that the prevalence to be 5.5 per 100,000 in Europe. Ma et al (2008) estimate the prevalence of PV to be 22 per 100,000 in the US, whilst Ruben et al (2012) analysed two large US claims databases and estimated prevalence to be 48 per 100,000 and 57 per 100,000.
- The management of the condition is mainly through phlebotomy and, where required, through drug treatment in the form of aspirin or cytoreductive therapy: either hydroxyurea (HU), interferon or anagrelide.
- This analysis seeks to evaluate the prevalence of the condition across a number of European markets and to examine the impact of Hydroxyurea (HU) treatment on symptoms, concomitant conditions and cardiac risk.

Methodology

- Data were drawn from the Adelphi PV Disease Specific Programme (DSP), a real world, cross sectional survey of Haematologists and Oncologists managing patients with PV in 8 European countries conducted between March and May 2015. The methodology has been published previously.
- 171 specialists completed a short survey. The survey contained questions relating to the overall patient workload of physicians in terms of PV patients managed.
- Each physician completed a PRF for the last 6 consulting patients diagnosed with PV. In total 969 PRFs were completed capturing information on concomitant conditions, symptoms, treatment history, cardiac and/or thrombosis risk status and control status (both defined by the physician).
- Data for patients currently receiving HU therapy for more than 3 months were included in the analysis.

Results

- Of the 171 physicians completing the survey, 85 (50%) were Haematologists, 80 (47%) were Onco-Haems and 6 (4%) were Oncologists.
- 99 (58%) were hospital based, 51 (30%) hospital/office, 19 (11%) office only and 2 (1%) other
- Physicians estimated that they currently treat an average of 15 PV patients in total. Based on physician population sizes in each country, the number of specialists treating the condition and the adult population numbers in each country we were able to estimate that the prevalence of PV across the European countries is 31.5 per 100,000.
- 499 of the 969 patients (51%) were currently receiving HU for a period of more than 3 months. Highest use was recorded in Portugal (73%) and the lowest in Austria (38%)
- Demographic details are shown in Table 1. Patients had been diagnosed for an average of 39.1 months, had a mean age of 68.5 years, and 58% were male.

Table 1: Patient Demographics

<table>
<thead>
<tr>
<th>Number of Patients</th>
<th>499</th>
<th>158</th>
<th>32</th>
<th>45</th>
<th>32</th>
<th>28</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months since diagnosis (Mean)</td>
<td>39.1</td>
<td>30.3</td>
<td>40.8</td>
<td>38.1</td>
<td>30.4</td>
<td>37.1</td>
</tr>
<tr>
<td>Age (Mean)</td>
<td>68.5</td>
<td>67.9</td>
<td>69.1</td>
<td>70.6</td>
<td>71.9</td>
<td>64.0</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>58%</td>
<td>63%</td>
<td>53%</td>
<td>61%</td>
<td>59%</td>
<td>57%</td>
</tr>
<tr>
<td>Female</td>
<td>42%</td>
<td>37%</td>
<td>47%</td>
<td>39%</td>
<td>41%</td>
<td>43%</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed (including student)</td>
<td>24%</td>
<td>26%</td>
<td>24%</td>
<td>17%</td>
<td>19%</td>
<td>43%</td>
</tr>
<tr>
<td>Unemployed (including retired)</td>
<td>74%</td>
<td>72%</td>
<td>76%</td>
<td>83%</td>
<td>81%</td>
<td>50%</td>
</tr>
<tr>
<td>Unknown</td>
<td>2%</td>
<td>2%</td>
<td>1%</td>
<td>-</td>
<td>7%</td>
<td>2%</td>
</tr>
</tbody>
</table>

- Despite current HU use, 306 (61%) experience concomitant conditions with this ranging from 14 (50%) in Switzerland to 28 (88%) in Greece. Hypertension remained a problem for 186 (37%) patients - Figure 1.

- 49 (10%) patients report moderate splenomegaly on or after HU therapy. A further 2 patients report massive splenomegaly. CV risk remains high for 156 (31%) of patients – Figure 2.

- 216 patients (43%) were reported as symptomatic, ranging from 10 (31%) in Greece to 20 (63%) in Slovakia. 110 patients (51%) experienced fatigue and weakness, 44 (20%) itching and 34 (16%) headache – Figure 3.

Conclusions

- These findings indicate that HU fails to adequately reduce symptoms and cardiac risk in a proportion of PV patients hence need exists for better treatments.

References

3. Ruben et al. 2012 Epidemiology of Myeloproliferative Disorders in the US – a real world analysis

Presented at ISPOR 18th Annual European Congress, Milan, 7th – 11th November 2015, Milan