

The PANORAMA pan-European Survey: impact of severe and non-severe hypoglycaemia on quality of life and other patient reported outcomes in patients with type 2 diabetes

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Abstract:

**Background and aims:** Hypoglycaemia is a side effect of glucose-lowering treatment that can cause distress and injury, and may damage quality of life (QoL) in patients with type 2 diabetes (T2D). PANORAMA is a large pan-European cross-sectional survey (NCT00916513) aimed at assessing patient reported outcomes in patients with T2D treated with glucose-lowering therapies. The present analysis compares data on QoL, treatment satisfaction and fear of hypoglycaemia in patients with T2D in relation to their experience of hypoglycaemia.

**Materials and methods:** Patients with T2D were randomly or consecutively selected from physician practices (mainly in primary care) in 8 countries (Belgium, Germany, Greece, Italy, the Netherlands, Spain, Turkey, and the UK). Eligible patients were ≥40 years of age, with a diagnosis of T2D for >1 year prior to study entry and an available medical record at the clinic of >1 year. All patients received dietary and exercise advice. Most patients were also being treated with either oral hypoglycaemic agents (OHAs) or injectables (Insulin and GLP-1 receptor analogues) with or without OHAs. Treatment type was unchanged in the previous 3 months. Patients completed the Audit of Diabetes-Dependent Quality of Life (ADDQoL), Diabetes Treatment Satisfaction Questionnaire (DTSQ) and the worry subscale of the Hypoglycaemic Fear Survey-II (HFS-II). Data on history of severe and non-severe hypoglycaemic episodes were collected.

**Results:** 5,156 patients were included in the study between June and November 2009: 47.8% women; mean age 65.9 years (SD 10.3). Mean time since diagnosis was 9.0 years (SD 7.4). Patients who had experienced at least one episode of severe hypoglycaemia in the past 12 months showed significantly more negative impact of diabetes on QoL (ADDQoL, p<0.001), less satisfaction with treatment (DTSQ, p=0.004) and greater fear of hypoglycaemia (HFS-II, p=0.001) than patients who had not experienced severe hypoglycaemia.

Similar differences were found on all three measures for a comparison of patients who experienced more than one episode of non-severe hypoglycaemia per month with those who experienced one or fewer episodes per month (all p<0.001).

**Conclusion:** The occurrence of both severe and non-severe hypoglycaemia in T2D is associated with greater negative impact of diabetes on QoL, less treatment satisfaction, and greater fear of hypoglycaemia, and may be an important barrier to optimal glycaemic control in some patients.

<table>
<thead>
<tr>
<th>Episodes of hypoglycaemia in past 12 months</th>
<th>n</th>
<th>Mean (SD) score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ADDQoL $^5$</td>
</tr>
<tr>
<td>≥1 severe</td>
<td>313</td>
<td>-1.0 (0.8)</td>
</tr>
<tr>
<td>0 severe</td>
<td>4,831</td>
<td>-0.6 (0.5)</td>
</tr>
<tr>
<td>Difference¹</td>
<td>-0.22**</td>
<td>-1.14*</td>
</tr>
<tr>
<td>-------------</td>
<td>---------</td>
<td>--------</td>
</tr>
<tr>
<td>&gt;1 non-severe/month</td>
<td>869</td>
<td>-0.8 (0.6)</td>
</tr>
<tr>
<td>≤1 non-severe/month</td>
<td>4,258</td>
<td>-0.6 (0.5)</td>
</tr>
<tr>
<td>Difference²</td>
<td>-0.18**</td>
<td>-1.07**</td>
</tr>
</tbody>
</table>

¹Average weighted impact score: range -9 (most negative impact) to +3 (most positive impact of diabetes on QoL); ²range 0-7 (very fearful) to 0 (least fearful); ³Patients with ≥1 episode of severe hypoglycaemia - patients with 0 episodes of severe hypoglycaemia. ⁴Patients with >1 non-severe hypoglycaemic episode/month - patients with ≤1 non-severe hypoglycaemic episode/month.

Differences were calculated with mixed-effects regression models adjusting for centre.

*p<0.004; **p<0.001

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Human studies: True

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