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HOW FEAR OF HYPOGLYCEMIA INFLUENCES HEALTH-RELATED QUALITY OF LIFE IN TYPE 2 DIABETES MELLITUS PATIENTS IN SPAIN?

HIPOQOL-II STUDY

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BACKGROUND

• Hypoglycemia is the most frequent complication in diabetic patients\textsuperscript{1}.

• Hypoglycemia and the fear of suffering it in diabetic patients can limit the effectiveness of current treatments to reach and maintain an optimal glycemic control\textsuperscript{2}.

• Hypoglycaemia is an important factor in the glycemic control in terms of adherence and satisfaction with treatments\textsuperscript{3}.

• The Health-Related Quality of Life (HRQoL) of patients with hypoglycemia can be diminished by the fear it produces, reducing productivity and increasing healthcare costs\textsuperscript{4}.

OBJECTIVES

Primary objective

• To explore the impact of fear of hypoglycemia in HRQoL in type 2 diabetes mellitus patients in Spain.

Secondary objectives

• To evaluate HRQoL in T2DM patients using the disease specific questionnaire ADDQOL.
• To evaluate the fear of hypoglycemia in T2DM patients using the HFS-II worry subscale.
• To describe the impact of hypoglycemia on HRQoL of T2DM patients.
MATERIALS AND METHODS

Study design:

• Observational, cross-sectional, multicentre design.

Sample selection:

• T2DM patients diagnosed at least 1 year before inclusion in the study, 18 years of age or older, attended in public healthcare centres in Spain, were consecutively recruited.

Research tools:

• Audit of Diabetes-Dependent Quality of Life (ADDQoL)\(^1\).
• Worry Subscale of the Hypoglycaemic Fear Survey-II (HFS-II)\(^2\).
• Visual Analogue Scales (VAS).

2. Diabetes Care 1987;10:617-621
RESULTS: population

- **3,812 patients** participated in the study (661 health care centres: 77.77% primary care centres; 17 Spanish regions):
  - 53.57% were men, mean age (SD) was 63.70 (11.37) years, mean (SD) time from T2DM diagnosis was 9.67 (6.91) years.
  - **44.88% referred at least one episode of hypoglycemia in the previous 6 months** that were more frequent (40.50%) and severe (43.37%) in the morning.
  - **Mean time from T2DM diagnosis** (p<0.0001), **frequency of microvascular** (p<0.0001) and **macrovascular complications** (p=0.0002) and **family history of T2DM** (<0.0001) were significantly higher in patients with hypoglycemia compared to those without episodes.
RESULTS: ADDQoL scores

- The mean score of present QoL of patients (ADDQoL overview item-I) falls between “neither good nor bad” and “good”:

<table>
<thead>
<tr>
<th></th>
<th>excellent</th>
<th>very good</th>
<th>good</th>
<th>neither good nor bad</th>
<th>bad</th>
<th>very bad</th>
<th>extremely bad</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. In general, my present quality of life is:</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>-1</td>
<td>-2</td>
<td>-3</td>
</tr>
</tbody>
</table>

Mean scores:
- Global: 0.39
- Hypoglycemias: 0.37
- No hypoglycemias: 0.40

p=0.28
RESULTS: ADDQoL scores

- The mean score of QoL of patients “if they did not have diabetes” (ADDQoL overview item-II) falls between “a little better” and “much better”:

<table>
<thead>
<tr>
<th>II. If I did not have diabetes, my quality of life would be:</th>
<th>very much better</th>
<th>much better</th>
<th>a little better</th>
<th>the same</th>
<th>worse</th>
<th>very much better</th>
<th>much better</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-3</td>
<td>-2</td>
<td>-1</td>
<td>0</td>
<td>1</td>
<td>-3</td>
<td>-2</td>
</tr>
</tbody>
</table>

Mean scores

Global: -1.38
Hypoglycemias: -1.41
No hypogligemias: -1.36

p=0.11
RESULTS: ADDQoL scores

- The mean score of each individual ADDQoL domain was significantly more negative in T2DM patients with hypoglycemia than in those without previous episodes.

- “freedom to eat” and “freedom to drink” were the most affected domains.
RESULTS: ADDQoL scores

- **Average Weighted Impact Score** (mean of scores for all domains) showed that T2DM had a greater significant negative impact on QoL in patients with hypoglycemia than in those without previous episodes:

<table>
<thead>
<tr>
<th>Population</th>
<th>Average Weighted Impact Score, mean (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global</td>
<td>-2.01 (1.54)</td>
<td>-</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>-2.48 (1.61)</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>No hypoglycemia</td>
<td>-1.64 (1.36)</td>
<td></td>
</tr>
</tbody>
</table>
**RESULTS: HFS-II worry subscale scores**

- Mean (SD) **HFS-II worry subscale score** was higher in patients who reported hypoglycaemic episodes during the previous 6 months compared to those who did not.

<table>
<thead>
<tr>
<th>Population</th>
<th>HFS-II worry subscale score, mean (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global</td>
<td>24.41 (17.05)</td>
<td>-</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>31.32 (15.71)</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>No hypoglycemia</td>
<td>18.85 (16.03)</td>
<td></td>
</tr>
</tbody>
</table>
RESULTS: VAS scores

- Patients with hypoglycemia scored significantly higher the **impact and fear of hypoglycemia** on daily life, on daily activities and in relation to other health problems, compared to patients without previous hypoglycemia episodes.

<table>
<thead>
<tr>
<th></th>
<th>No hypoglycemia</th>
<th>Hypoglycemia</th>
<th>Global</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact of hypoglycemia on daily life</td>
<td>1,73</td>
<td>3,29</td>
<td>5,19</td>
</tr>
<tr>
<td>Fear of hypoglycemia on daily life activities</td>
<td>2,89</td>
<td>4,28</td>
<td>5,89</td>
</tr>
<tr>
<td>Fear of hypoglycemia in relation to other health problems</td>
<td>2,73</td>
<td>3,98</td>
<td>5,50</td>
</tr>
</tbody>
</table>

p<0,0001

![Mean VAS scores graph](image-url)
**RESULTS**

- **Average Weighted Impact Score** (mean of ADDQoL scores of individual domains) negatively correlated with HFS-II worry subscale scores.

<table>
<thead>
<tr>
<th>Correlation coefficient</th>
<th>Independence test</th>
</tr>
</thead>
<tbody>
<tr>
<td>-0.441</td>
<td>p&lt;0.0001</td>
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</tbody>
</table>
CONCLUSIONS

• T2DM negatively influences patients’ HRQoL, especially when they suffered hypoglycemia.

• The fear of hypoglycemia affects HRQoL and daily-life activities of patients with T2DM.

• These results illustrate the impact of fear of hypoglycaemia in T2DM patients’ HRQoL.

• Results of this nature should aid therapeutic decision making.