15TH EUROPEAN CONGRESS OF THE INTERNATIONAL SOCIETY OF PHARMACOECONOMICS AND OUTCOMES RESEARCH. Berlin, 3-7 November, 2012

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

Authors: Beatriu Font¹, Raquel Lahoz¹, Cecilia Roldán¹, Esteban Jódar Gimeno², Fernando Álvarez Guisasola³, Luis Ávila Lachica⁴, Rafael Palomares⁵, Luis Lizán⁶

¹Novartis Farmacéutica, Barcelona, Spain; ²Servicio de Endocrinología y Nutrición, Hospital Universitario Quirón, Madrid; ³Centro de Salud la Calzada II, Gijón, Spain; ⁴Consultorio Local Almachar, Málaga, Spain; ⁵Hospital Reina Sofía, Córdoba, Spain; ⁶Outcomes'10, Castellón, Spain.



BACKGROUND

- Hypoglycemia is the most frequent complication in diabetic patients¹.
- Hypoglycemia and the fear of suffering it in diabetic patients can limit the effectiveness of current treatments to reach and maintain an optimal glycemic control².
- Hypoglycaemia is an important factor in the glycemic control in terms of adherence and satisfaction with treatments³.
- The Health-Related Quality of Life (HRQoL) of patients with hypoglycemia can be diminished by the fear it produces, reducing productivity and increasing healthcare costs⁴.

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).

RESULTS: population

- **3,812 patients** participated in the study (661 health care centres: 77,77% primary care centres; 17 Spanish regions):
- 53.57 % were man, 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.

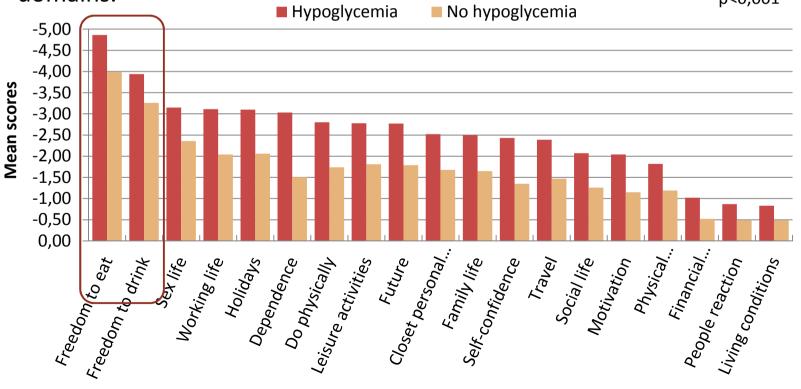
• The mean score of **present QoL** of patients (ADDQoL overview item-I) falls between "neither good nor bad" and "good":

I. In general, my present quality of life is:							
excellent	very good	good	neither goo nor bad	bd b	ad	very bad	extremely bad
3	2	1	0		1	-2	-3
1,00 0,90 0,80 0,70 0,60 0,50 0,40 0,30 0,20 0,10 0,00		0,39	0,37	0,40		 Global Hypoglycer No hypoglic 	
I. In general, my present quality of life is p=0.28					p=0.28		

 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":

II. If I did not have diabetes, my quality of life would be:						
very much better	much better	a little better	the same	worse	very much better	much better
-3	-2	-1	0	1	-3	-2
1,00 0,50 Sequestion -0,50 -1,00						al glycemias ypoglicemias
-1,50	-1	,38	-1,41	-1,36		
-2,00	II. If I did	not have diabe	tes, my quality	of life would be	2	n-0 11

- 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.
 Hypoglycemia
 No hypoglycemia



• 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:

Population	Average Weighted Impact Score, mean (SD)	p-value	
Global	-2.01 (1.54)	-	
Hypoglycemia	-2.48 (1.61)		
No hypoglycemia	-1.64 (1.36)	p<0.0001	

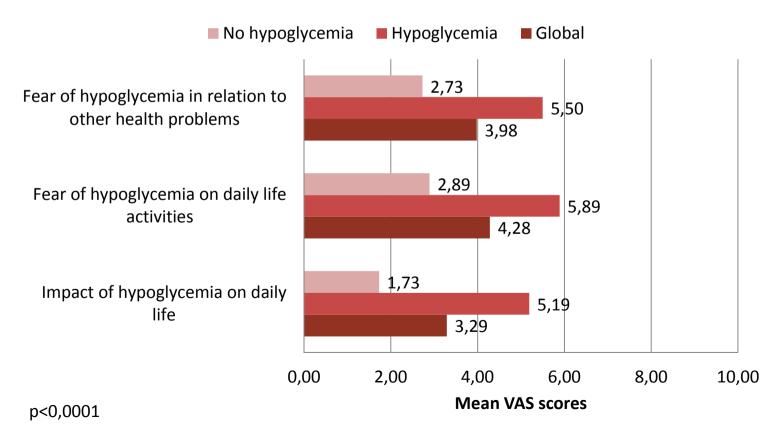
RESULTS: HFS-II worry subscale scores

 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.

Population	HFS-II worry subscale score, mean (SD)	p-value	
Global	24.41 (17.05)	-	
Hypoglycemia	31.32 (15.71)	n <0,0001	
No hypoglycemia	18.85 (16.03)	p<0.0001	

RESULTS: VAS scores

 Patients with hypoglycemias 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.



RESULTS

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

Correlation coefficient	Independence test
-0,441	p<0,0001

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.

THANK YOU