

Health-related quality of life in insulin-treated Type 2 diabetes is influenced by the level of glycemic control — the HYPO2 study

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Introduction

- Type 2 diabetes mellitus (T2DM) is a progressive condition, and the therapy is intensified with disease progression [1]. Most patients with T2DM are able to cope with their condition through diet and physical activity, however many will eventually require insulin therapy to regulate their glucose levels [2].
- T2DM often induces significant physical and psychosocial morbidity. Health-related quality of life (HRQoL) is also significantly impaired as all aspects of life can be affected, including physical, mental and social functioning [3].

Objective

- To evaluate the impact of level of glycemic control on HRQoL of insulin-treated T2DM patients in Greece.

Methods

Study design

- In a prospective, non-interventional, epidemiological study, 938 subjects were recruited from one hospital center and 57 private practice investigators from various geographical areas of Greece.
- Inclusion criteria: 1) ≥ 18 years, 2) T2DM receiving any type of insulin, 3) mentally capable to respond to HRQoL questionnaire, not participating in any similar epidemiological study within the next one year, 4) necessary laboratory tests in the past and at least two self-glucose measurements daily, 5) written consent.
- Exclusion criteria: 1) under 18, 2) type 1 diabetes, 3) participation in a similar epidemiological study within the previous year.

Data

- Data were collected from medical records and via interviews in two scheduled visits within ~3-months, namely patient demographics, medical history, comorbidities/complications, medical examinations (glycosylated hemoglobin [HbA1c]), T2DM treatment drugs, comorbidities and adverse events.
- At the first visit, subjects self-completed the EQ-5D-5L questionnaire, which is a preference based generic measure of HRQoL. It consists of the EQ-5D-5L descriptive system, with five dimensions of health, and the EQ VAS. Each dimension is measured across a five level scale, with higher level reflecting more problems. A single utility score can be obtained ranging from -0.594 to 1.0, with higher scores representing better overall health status. The EQ VAS records the respondent's self-rated health on a 0-100 (worst to best imaginable health) visual analogue scale [4].

Statistical analysis

- Descriptive statistics. P-values were estimated with Kruskal-Wallis for continuous variables, and χ^2 tests for proportions.
- Logistic regressions to estimate the unadjusted Odds Ratios (ORs) with 95% CIs for the prevalence of problems (levels 2-5) for each health dimension, with glycemic control (3 categories) as independent variable. Corresponding adjusted ORs were computed after controlling for age, sex, BMI, duration of T2DM, duration of insulin treatment (in years), treatment class at baseline and total daily insulin units, and the presence of main comorbidities/complications.
- Regression analyses to estimate the coefficients of glycemic control categories on EQ-5D-5L index and VAS, after controlling for age, sex, BMI, duration of T2DM, duration of insulin treatment (in years), treatment class at baseline and total daily insulin units, and the presence of main comorbidities/complications.
- Statistical significance level was set at $\alpha=0.05$.

Results

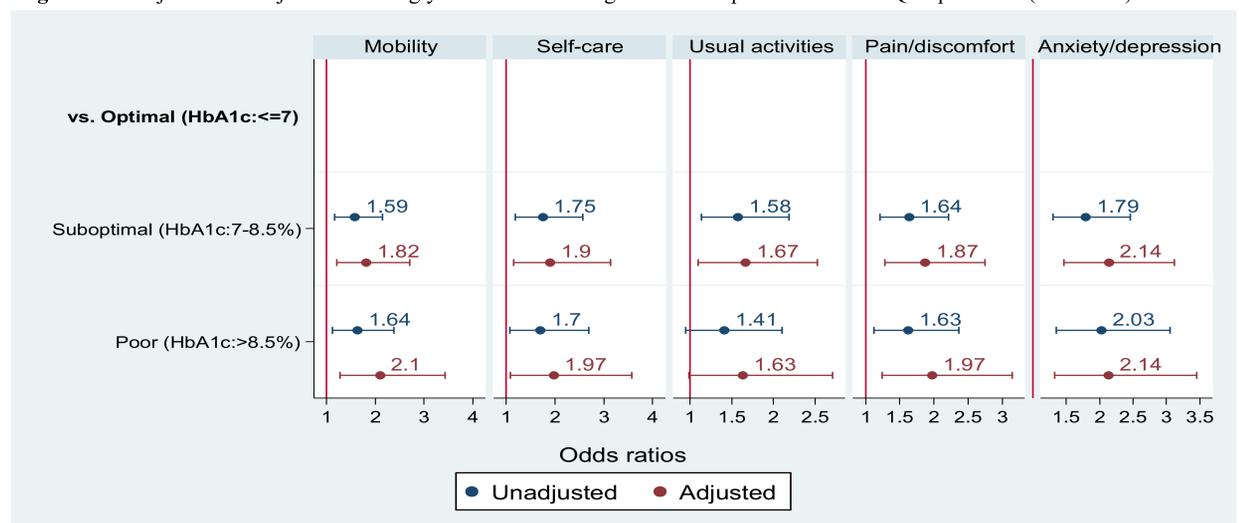
- The mean age of the sample was 67 years (± 10.7), with 52.2% females and 15.1 years mean duration of T2DM
- 28.5% of the patients had controlled T2DM (HbA1c $\leq 7\%$).
- The mean EQ-5D-5L index was 0.71 (± 0.24) and VAS 67.7 (± 18.4).
- The prevalence of HRQoL problems increases in uncontrolled patients in all dimensions (all $p < 0.05$).
- Both EQ-5D-5L index and VAS decrease with uncontrolled T2DM.

Table 1. Demographics, clinical characteristics, HRQoL per level of glycemic control, n (%) or mean \pm SD

	Whole sample	Glycemic control (HbA1c)			p-value
		Optimal ($\leq 7\%$)	Suboptimal (7-8.5%)	Poor ($>8.5\%$)	
n	938	267 (28.5)	475 (50.6)	196 (20.9)	
Females	490 (52.2)	130 (48.7)	243 (51.2)	117 (59.7)	0.051
Age (years)	67 \pm 10.7	66.3 \pm 10.7	67.9 \pm 10.2	65.85 \pm 11.6	0.062
Body Mass Index (kg/m ²)	30 \pm 5.2	29.8 \pm 5.6	29.8 \pm 4.7	30.8 \pm 5.8	0.083
Duration of diagnosed T2DM	15.1 \pm 8.2	15.3 \pm 8.4	15.5 \pm 8.1	14.0 \pm 8.1	0.110
HbA1c (%)	7.8 \pm 1.2	6.6 \pm 0.4	7.7 \pm 0.4	9.6 \pm 1.1	<0.001
Duration of insulin treatment	4.9 \pm 5.3	5.0 \pm 5.3	5.3 \pm 5.7	4.2 \pm 4.6	0.069
Prevalence of problems					
Mobility	453 (48.4)	107 (40.1)	244 (51.5)	102 (52.3)	0.006
Self-care	214 (22.9)	44 (16.5)	121 (25.7)	49 (25.1)	0.012
Usual activities	322 (34.5)	74 (27.9)	179 (37.9)	69 (35.4)	0.023
Pain/discomfort	490 (52.5)	116 (43.8)	265 (56.0)	109 (55.9)	0.003
Anxiety/depression	653 (69.8)	160 (60.2)	346 (73.0)	147 (75.4)	<0.001
EQ-5D-5L index	0.71 \pm 0.24	0.77 \pm 0.22	0.70 \pm 0.24	0.68 \pm 0.25	<0.001
VAS	67.7 \pm 18.4	71.1 \pm 18.7	66.9 \pm 17.0	65.2 \pm 20.5	<0.001

- Both suboptimal (HbA1c: 7-8.5%) and poor (HbA1c: $>8.5\%$) glycemic controlled patients exhibited significant higher odds of having problems in all HRQoL domains compared with controlled subjects (HbA1c: $\leq 7\%$).

Figure 1. Unadjusted and adjusted ORs of glycemic control categories for the prevalence of HRQoL problems (levels 2-5)



- Suboptimal glycemic control (HbA1c: 7-8.5%) reduces significantly both EQ-5D-5L index and VAS (both $p < 0.001$), compared with controlled glycemic control.
- Poor glycemic control (HbA1c: $>8.5\%$) has even higher detrimental impact on both EQ-5D-5L index ($p=0.005$) and VAS ($p < 0.001$).

Table 2. Regression coefficients of glycemic control on EQ-5D index and VAS, after controlling for plausible predictors

	Coefficient	95% CI		p-value	Partial Eta ²	Model		
		Lower	Upper			F-statistic	p-value	Adj-R ²
EQ-5D-5L index						F(23, 721)=8.83	<0.001	0.195
Glycemic control								
Suboptimal (7-8.5%)	-0.076	-0.112	-0.039	<0.001	0.022			
Poor ($>8.5\%$)	-0.093	-0.138	-0.048	<0.001	0.022			
VAS						F(23, 728)=5.92	<0.001	0.131
Glycemic control								
Suboptimal (7-8.5%)	-4.304	-7.281	-1.328	0.005	0.011			
Poor ($>8.5\%$)	-6.698	-10.348	-3.048	<0.001	0.018			

Conclusions

- Insulin-treated T2DM frequently report HRQoL problems, in anxiety/depression, pain/discomfort and mobility domains in particular.
- Uncontrolled patients were associated with poorer HRQoL, even after controlling for various factors. Consequently, improved glycemic control is essential for curtailing the negative impact of T2DM.

References

- [1] Fonseca V. Defining and characterising progression of type 2 diabetes. Br J Diab Vasc Dis. 2008;8:S3. [2] Nathan DM et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. Diabetes Care. 2009;32:193-203. [3] Holmes J, McGill S, Kind P, Bottomley J, Gillam S, Murphy M. Health-related Quality of Life in Type 2 Diabetes (T2ARDIS-2). Value in Health. 2000;3:47-51. [4] Tadros A et al. Psoriasis: is it the tip of the iceberg for the quality of life of patients and their families? J Eur Acad Dermatol Venereol. 2011;25:1282-7.

Disclosure of conflict of interest