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DISCLOSURE

- Grigorios Rombopoulos is a Novartis Hellas Employee as a Medical Advisor from 2008 till now.
- Magdalini Chatzikou is a Novartis Hellas Employee as a Health Economist
- Dimitra Latsou didn't have any financial disclosure with Novartis Hellas
- Prof. John Yfantopoulos participated in studies of Novartis Hellas as an Investigator and Author

BACKGROUND

- Good glycemic control is a fundamental objective of the management of type 2 diabetes (T2DM) in order to minimize the risk of vascular complications of diabetes.
- The strict glycemic control and intensification of therapy can increase the risk of hypoglycemia, especially for people treated with insulin or sulphonylureas.
- Hypoglycemia results in neuroglycopenia, which causes cognitive impairment and mood change and may progress to behavioral changes, reduced consciousness even seizure and coma.
- Hypoglycemia has negative impact on health care resources and patients' quality of life (QoL).
- During the first decade of the UK Prospective Diabetes Study (UKPDS), mean proportion of patients with any hypoglycemic episode ranged from 1.2% with diet alone, 11-17% with sulphonylureas, to 36.5% with insulin. During the same period, major hypoglycemic episodes ranged between 0.4% - 0.6% for sulphonylureas and 2,3% for insulin*
- On the contrary, in the UK Hypoglycemia group study performed in 1998, a much higher rate of severe hypoglycemic events was reported reaching 7% in T2DM population.

HYPO STUDY OBJECTIVE

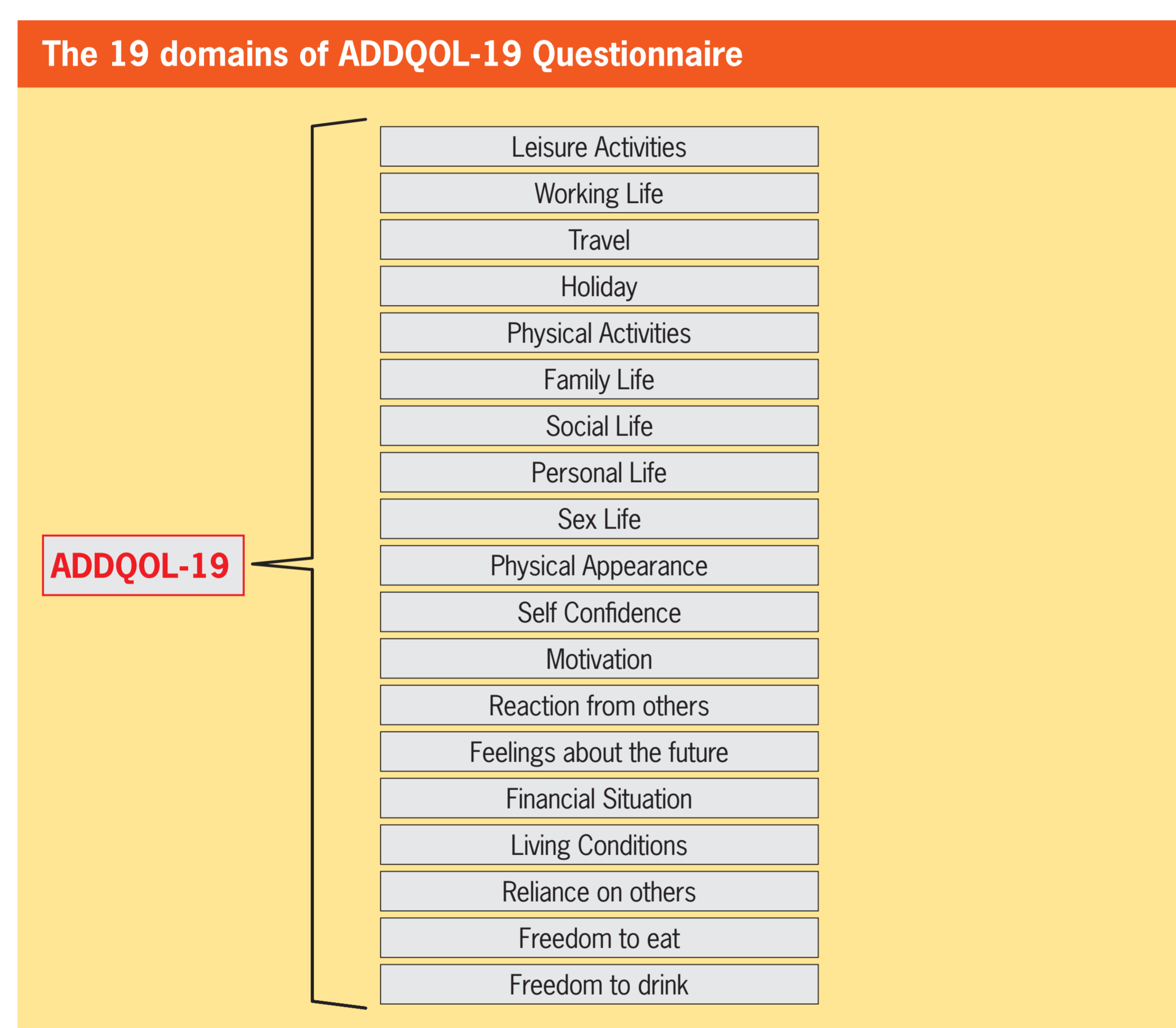
- To estimate the impact of hypoglycaemia on the Quality of Life (QoL) and its prevalence in patients with type 2 diabetes mellitus (T2DM) in Greece.

MATERIALS & METHODS

- Cross sectional epidemiological study with 6631 T2DM patients
- QoL was assessed with Audit of Diabetes Dependent QoL Questionnaire (ADDQoL-19) patient self-administration.
- The psychometric properties of ADDQoL-19 were assessed for reliability and internal validity.
- Patients' categorized according to hypoglycaemia experience and diabetes control.
- Controlled patients were considered as having Hb1Ac ≤ 7%(53mmol/mol)
- Hypoglycemic episodes were defined as laboratory-confirmed clinical symptomatic events (<70mg/dL or 3,88mmol/L)

The 19 domains of ADDQOL-19 Questionnaire

Audit of Diabetes Dependent QoL 19 Domains:



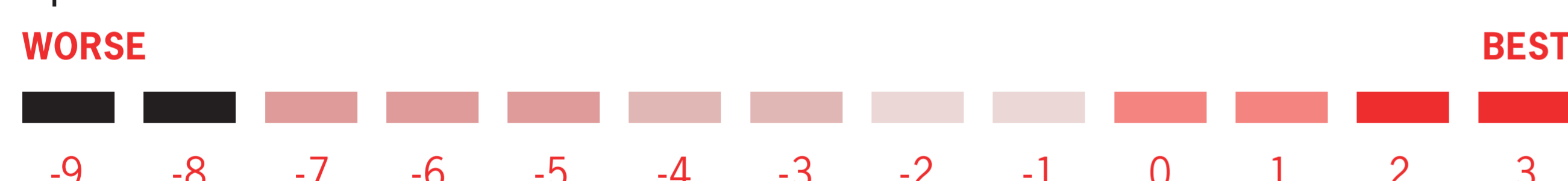
Questionnaire

Quality of Life Questionnaire:

Audit of Diabetes Dependent QoL 19 (ADDQoL 19 in Greek)

The instrument measures the impact of diabetes and its treatment on QoL (1), (2).

Weighted Impact Score: -9 represented the maximum negative impact of DM on QoL and +3 the maximum positive.



Bradley et al. 1999
 Bradley & Speight, 2002

Questionnaire Examples

Audit of Diabetes Dependent QoL 19

I. In general, my present quality of life:

7 different answers from "Excellent" to "extremely bad"

II. If I did not have diabetes, my quality of life would be:

5 different answers from "Very much better" to "worse"

RESULTS

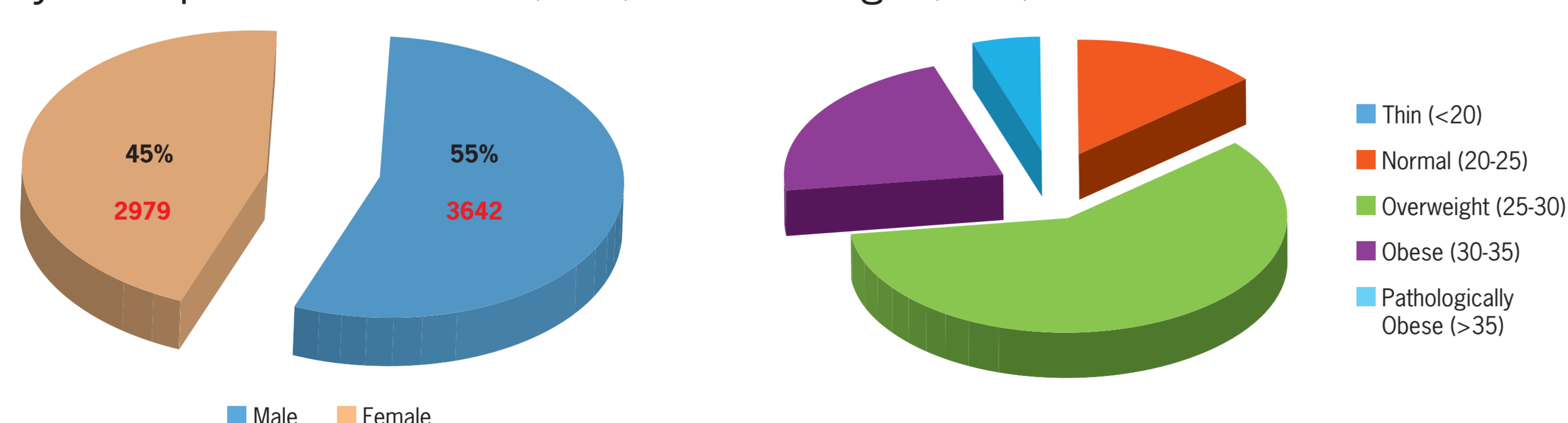
Characteristics of the sample

- The age groups ranged from 19 to more than 90 years old.
- The mean age was 60 years
- 35.1% of the patients were 61-70 and 30% were in the age group of 51-60.

Age Group	Number	Percentage
19-30	18	0.3
31-40	154	2.3
41-50	844	12.7
51-60	1984	30.0
61-70	2326	35.1
71-80	1130	17.1
90+	8	0.1

Demographics

The majority of the patients were male (55%) and overweight (59%)



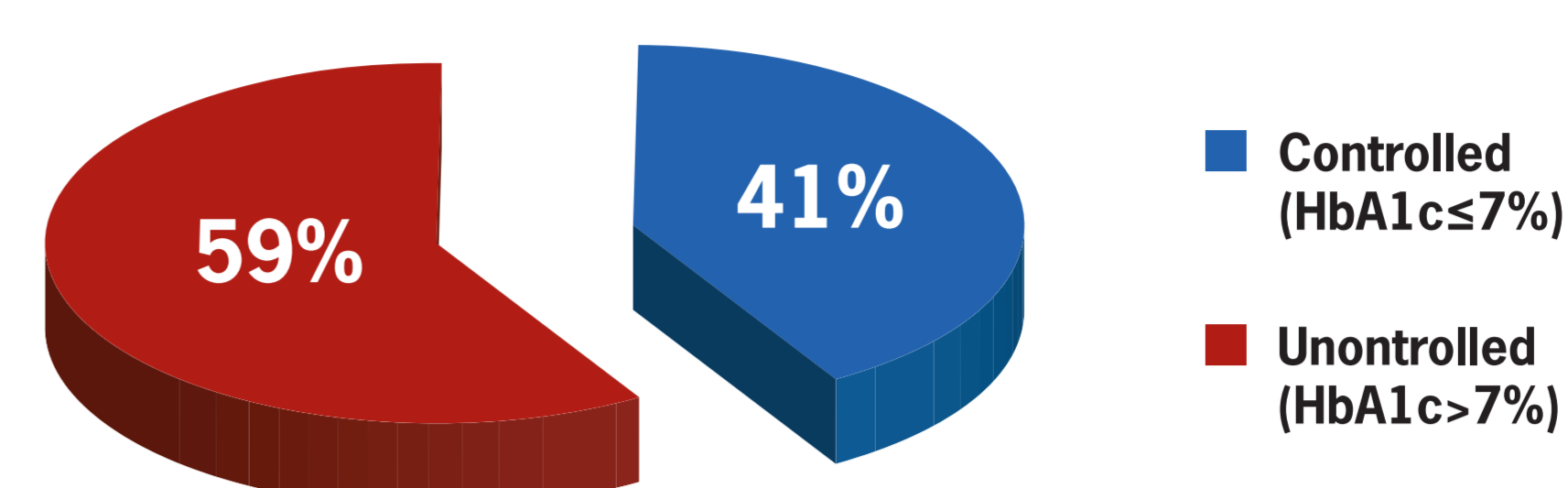
Disease Characteristics

- The majority of the patients (44.4%) with T2DM suffered from the disease over 1 to 5 years and 27.8%, 6 to 10 years.
- The mean T2DM duration was about 10 years.

Years	Frequency	Percentage
1-5 years	2,939	44.4
6-10 years	1,844	27.8
11-15 years	651	9.8
16-20 years	267	4
21-25 years	94	1.4
25-30 years	41	0.6
31-35 years	12	0.2
35-40 years	6	0.1
41+ years	4	0.1

T2DM Control Level

- 59% of the sample had HbA1c >7%.



Hypoglycemia

- 41.9% of patients (n=2779) stated that they had felt hypoglycaemia during the last 3 months, whereas
- Only 20.4% (n=1.354) had laboratory confirmed hypoglycaemia.
- 11.6% (767) of patients had experienced severe hypoglycaemia and were transferred to hospital

Hypoglycemia	Frequency	Percentage
Hypoglycemia	2,779	41.9
Laboratory Confirmed Hypoglycemia	1,354	20.4
Severe Hypoglycemia	767	11.6

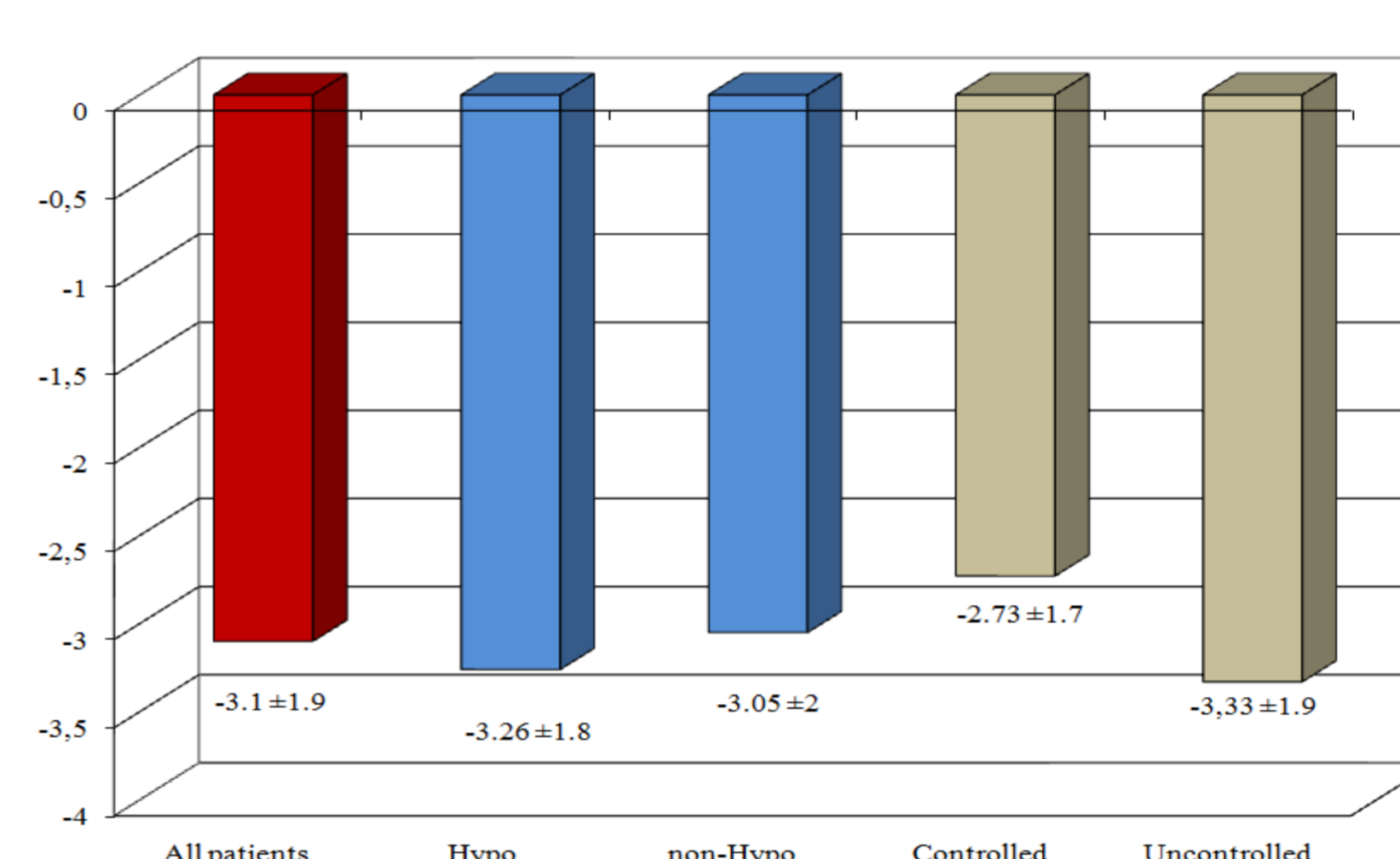
Hypoglycemia among controlled & uncontrolled patients

- Hypoglycaemic and non hypoglycaemic population had statistical significant difference (p<0.001) in HbA1c levels.
- The group of uncontrolled patients had 1.419-fold increased risk of having hypoglycaemic events, in comparison to the controlled patients (CI: 1.610 – 1.971).

HbA1c	Hypoglycaemia			
	NO		YES	
	%	N	%	N
Controlled	82.8%	2,237	17.2%	466
Uncontrolled	77.2%	3000	22.8%	887

Quality of Life Measurements

- Average Weighted QoL Impact Score of the study sample and subgroups



Quality of Life Measurements

Dimensions affected by hypoglycaemia

- According to the logistic regression analysis, the majority of the ADDQoL-19 dimensions (10 out of 19) were significantly affected (p< 0.05) by hypoglycaemia, leisure

- Activities,
- working life,
 - travel,
 - holiday,
 - physical activities,
 - family life,
 - social life,
 - physical appearance,
 - living conditions and
 - reliance on others

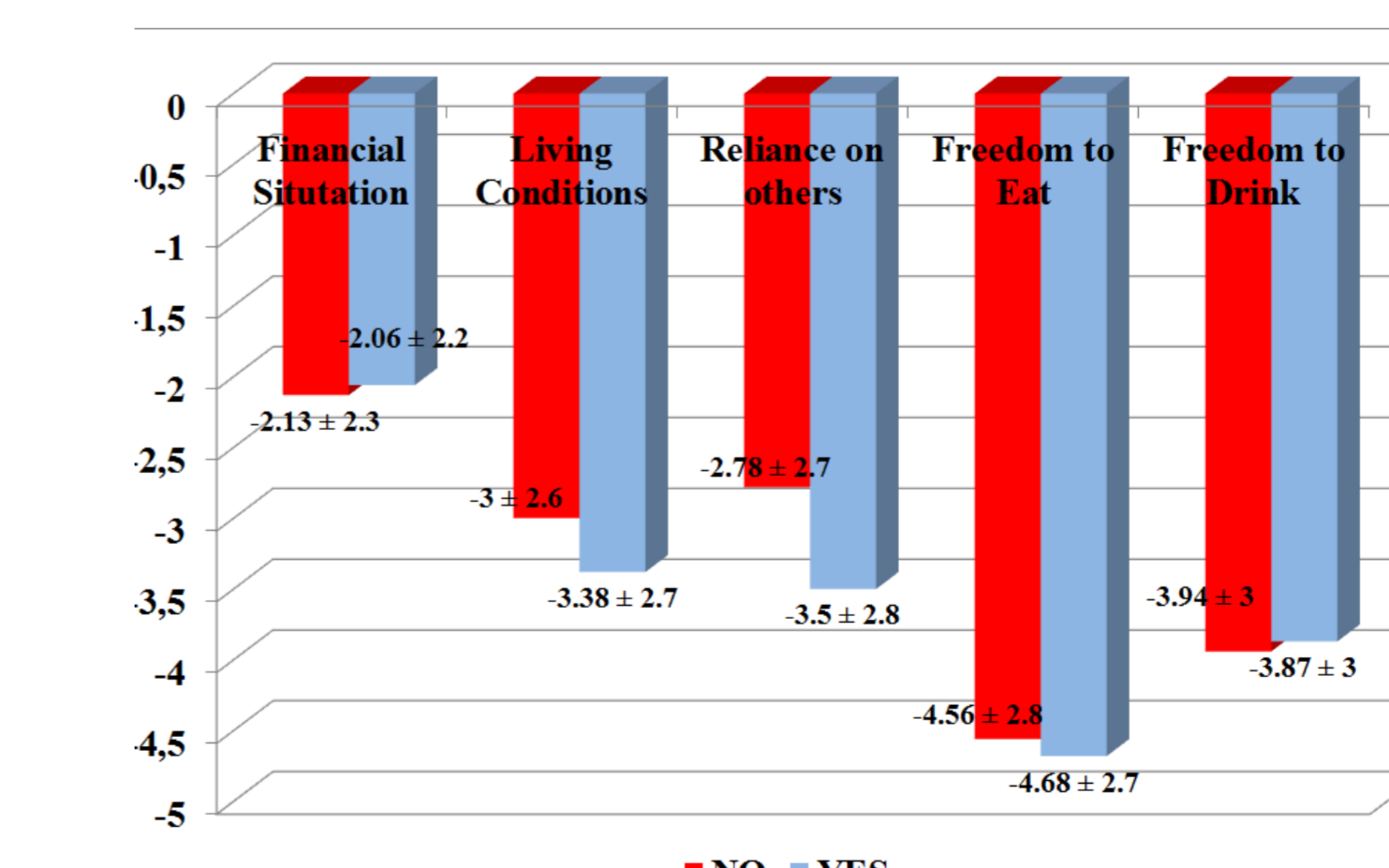
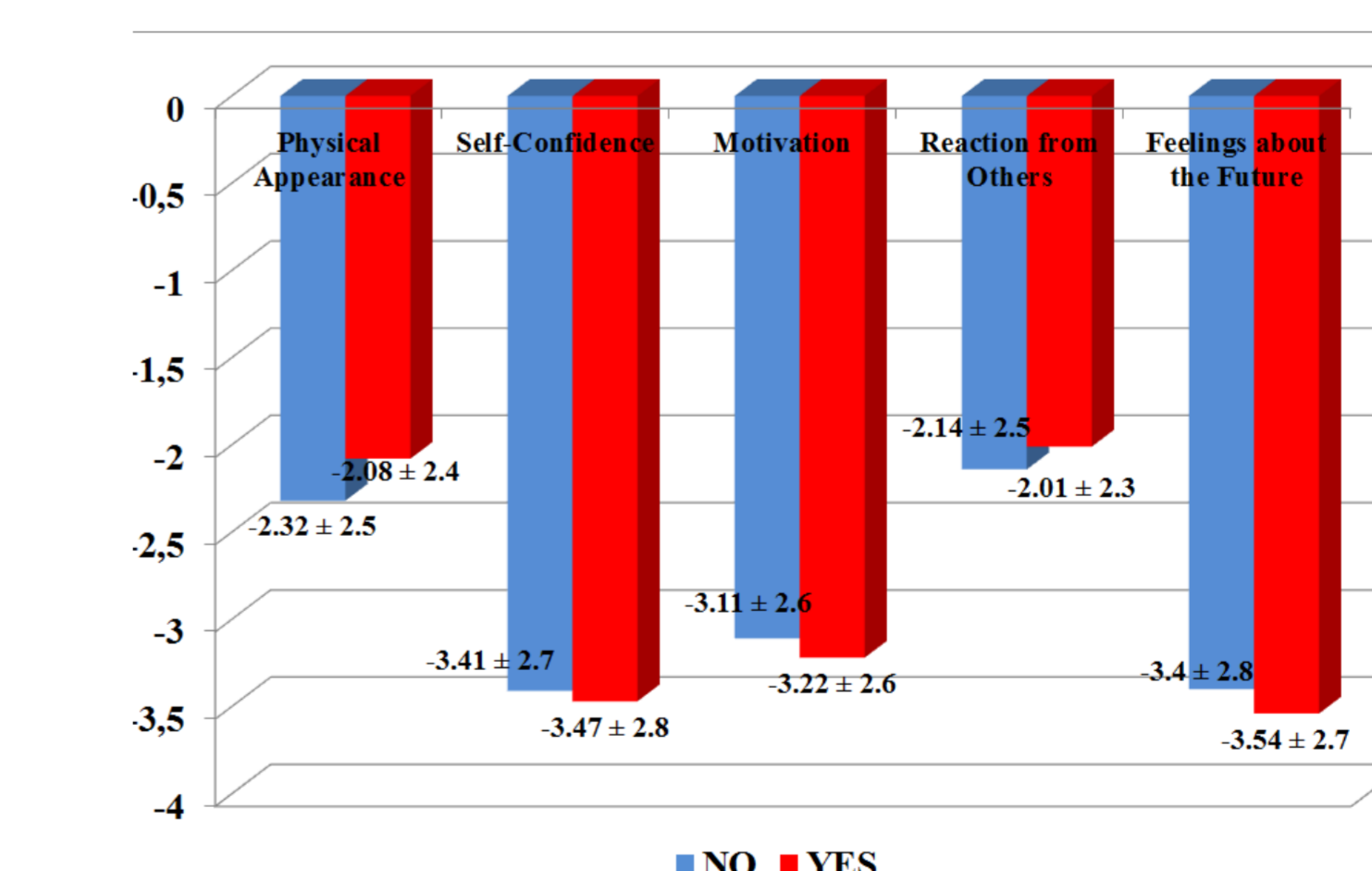
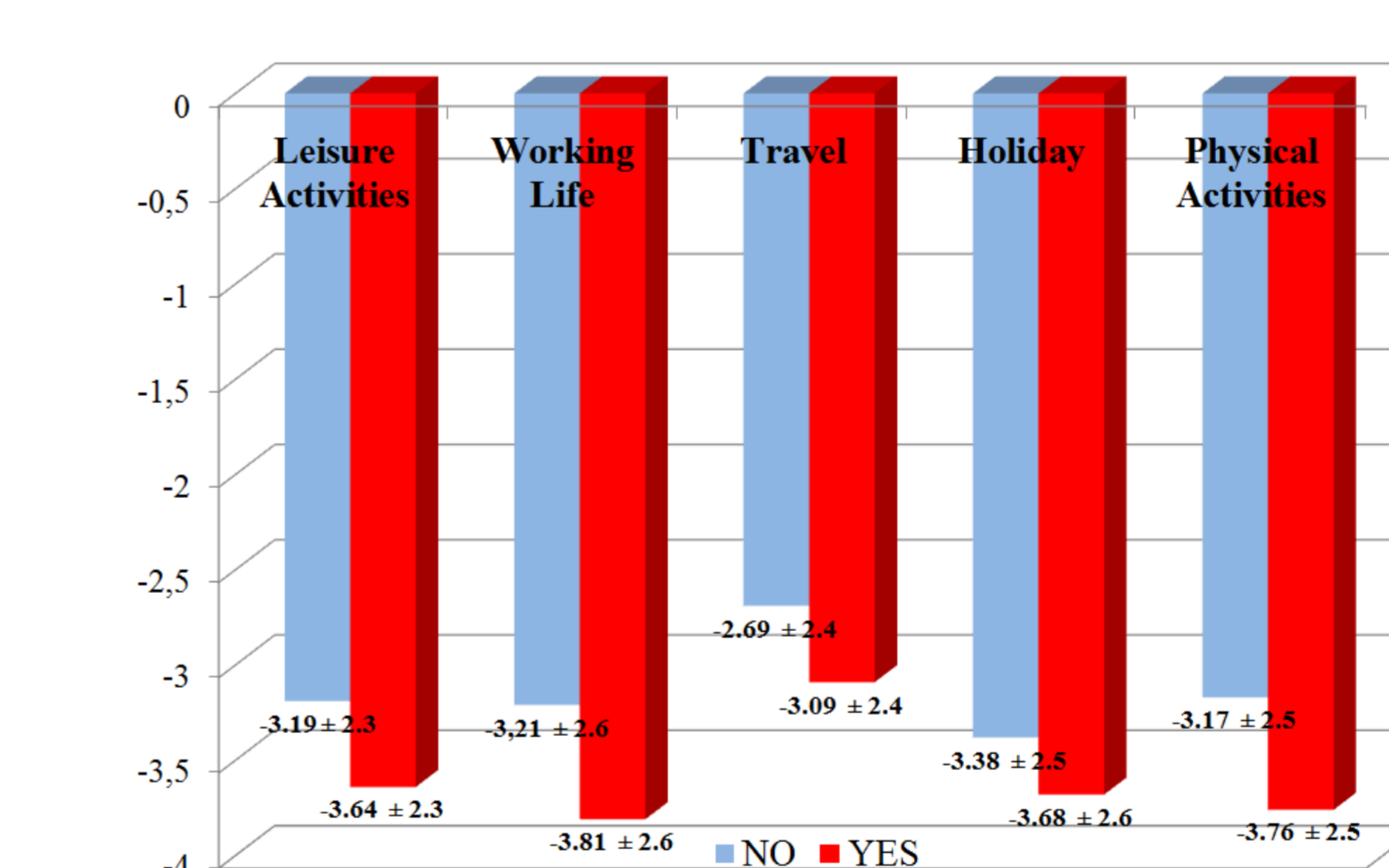
Quality of Life Measurements

Dimensions affected by HbA1c

- Similar results found in uncontrolled patients vs. controlled (patients with HbA1c levels >7%)
- Uncontrolled diabetic patients had a relatively higher probability to confront problems in:

- leisure activities
 - holidays
 - family life
 - sexual life
 - others reaction
 - reliance on others
 - freedom to drink
- However, **hypoglycaemic and uncontrolled patients' QoL** were more affected compared to **the non-hypoglycaemic and controlled**.

ADDQoL dimensions per hypo and non-hypo patients



CONCLUSIONS

- QoL of T2DM patients is significantly affected by **hypoglycemic events** and the **control level of the disease (HbA1c)**.
- In diabetes treatment the ultimate goal should be the **good glycemic control by avoiding hypoglycemic episodes**, which compromise **patients' QoL**.