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Quality of Life in Patients with Type 2 Diabetes in Poland – Comparison with the General Population Using the EQ-5D Questionnaire

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of article; G – other

Abstract

Background. Complications of type 2 diabetes (T2D) lead to increased mortality and reduced quality of life (QOL). **Objectives.** The aim of the study was to compare health-related quality of life (HRQoL) in Polish patients with type 2 diabetes (T2D) and in a matched sample from the general population.

Material and Methods. Data on HRQoL came from two non-interventional studies: a prospective study of patients with T2D and an EQ-5D study of Polish general population norms. The HRQoL analysis was conducted in four separate age groups: 32–44, 45–54, 55–64 and over 65 years old. We analyzed both subjective and objective assessment of HRQoL (EQ VAS and EQ-5D index) and the presence of restrictions within five dimensions of the EQ-5D descriptive part.

Results. A total of 274 patients with T2D and 214 representatives from the study of population norms were included. EQ VAS was systematically lower in diabetic patients as compared to the general population and decreased with age (68.2 vs 83.9, 62.4 vs 79.2; 54.9 vs 78.1, 50.2 vs 69.8 in consecutive age groups). A similar relationship was observed with the EQ-5D index. The largest mean differences were observed among subjects aged 55–64 years (EQ VAS: 23.2, EQ-5D index: 0.085). In three domains, i.e. self-care, usual activities and anxiety/depression, patients with diabetes who were over 45 years of age reported significantly more problems than respondents from the general population.

Conclusions. Both subjective and objective HRQoL in patients with T2D was lower than in respondents similar in age from the general population. Compared with type 2 diabetic populations from other countries, Polish patients are characterized by relatively high HRQoL objective assessment and very low subjective assessment (*Adv Clin Exp Med* 2015, 24, 1, 139–146).

Key words: diabetes mellitus, type 2, quality of life, health surveys, population surveillance.

Complications of type 2 diabetes (T2D) lead to increased mortality and reduced quality of life (QoL) [1]. Measuring the quality of life in diabetic patients broadens the clinical perspective and is particularly relevant considering the prevalence of the disease and its civilizational nature. Improving the quality of life of patients with diabetes was one of the main objectives of the National Program of Support for People with Diabetes, an initiative of

the Polish Association of Diabetes and of the National Consultant on Diabetology [1].

Research studies on various aspects of the impact of T2D on HRQoL have been conducted in Poland since 1997 [2]. Most of these studies have involved subpopulations of patients with diabetes and with coronary artery disease, hypertension, asthma, andropause, hemodialysis, microangiopathy or diabetic foot [3–5]. Another group of

studies assessed the impact of selected therapeutic strategies: fast-acting insulin analogs, educational activities, amputations or health resort treatment [6–8]. Most of the studies were based on non-validated questionnaires with authorship rights or disease-specific questionnaires, such as the Audit of Diabetes-Dependent Quality of Life (ADDQOL) or the Diabetes Treatment Satisfaction Questionnaire (DTSQ) [9–11]. Among the generic instruments, the most popular was the Short Form 36 (SF-36) [12]. In individual cases other instruments were also used, e.g. WHO-QOL-100, WHOQOL-BREF or EQ-5D [3, 9].

Cases where there are population-based norms for the generic QoL questionnaire make it possible to compare a population of specific patients with a matched sample from the general population. Generic QoL questionnaires do not provide a detailed assessment of health problems resulting from the disease and are characterized by limited sensitivity. Instead, they allow looking at the determined population of patients from a distant perspective, i.e. taking into account the health of the general population and the main determinants of QoL – physical, mental and social factors.

EQ-5D is a generic questionnaire assessing QoL and utility of the health state (QoL expressed as a single number as opposed to the classical domain-based approach). It is successfully used in population health surveys, clinical trials, quality of health care assessment and pharmaco-economic analyses [13], and was also used in a UKPDS study [14]. In 2010 the results of a study on EQ-5D norms in the Polish population were published [15]. Until today this normative data has not been used in comparisons of Polish patients with type 2 diabetes.

The aim of the present study was to evaluate HRQoL of patients with type 2 diabetes as compared to the general population by taking into account the age of the respondents. In both populations, QoL was measured with the EQ-5D questionnaire.

Material and Methods

Population

The analysis was conducted in 4 separate age groups: 32–44, 45–54, 55–64 and over 65 years of age. The sample group of diabetic patients came from a non-interventional study conducted in Lublin in the years 2007 and 2008. Patients were recruited in 3 centers: the Department of Endocrinology at the Medical University of Lublin, the Diabetes Outpatient Clinic in Lublin and the District Diabetes Outpatient Clinic in Lublin. The study enrolled patients with T2D: lasting for at

least 6 months, treated with oral hypoglycemic agents (OAD), insulin or during the process of treatment intensification [16, 17].

Age-matched control groups were chosen from the EQ-5D population norms study that had been conducted in 2008 [15]. The respondents ($n = 317$) were guests visiting hospital patients in 8 medical centers located in Warsaw, Skierniewice and Puławy. A random sample was matched to the characteristics of the Polish population in terms of sex and age structure within the 10-year age cohorts. For the purpose of the current study we extracted from the population norms study database records for all respondents matching the age of the patients from the diabetes study (who were at least 32 years old). The selected group constituted 67.5% of the original population.

Analyzed Data

Available data for both populations comprised: data on QoL collected using the EQ-5D questionnaire and general data on age, gender, education, employment, average income per household member, place of residence and marital status. General data questionnaires used in the two studies differed from one another in the format of possible answers (e.g. questions about income and the size of the village). For patients with diabetes, additional data was available about their treatment and control of the diabetes (HbA1c levels). For the general population respondents, there was additional data on their medical history (a directory of 13 selected chronic diseases, previous myocardial infarction, previous stroke).

In both populations, health-related QoL was assessed with a paper-and-pencil version of the generic EQ-5D questionnaire. The EQ-5D consists of two parts: a descriptive system and a visual analog scale (EQ VAS). The descriptive part consists of 5 dimensions: mobility (MO), self-care (SC), usual activities (UA), pain/discomfort (PD) and anxiety/depression (AD). Each dimension has 3 levels: “no problems”, “some problems”, and “severe problems”. The combination of selected levels of implementation for the 5 dimensions defines the health state (there are 243 possible health states in the EQ-5D). The health state, defined by the EQ-5D descriptive system, can be converted into a single index (EQ-5D index) by applying the formula that essentially attaches values (also called weights) to each of the levels in each dimension. In the present study we used the health state value set obtained in the Polish population by using the time trade-off method [18].

The EQ VAS is a standard vertical 20 cm visual analog scale, similar to a thermometer, with a range from 0 to 100. The ends of the scale are

labeled “best imaginable health state” and “worst imaginable health”. The EQ VAS is used for subjective assessment of one’s current state of health.

A comparison of QoL in patients with T2D and in respondents from the general population was carried out in 4 age groups: 32–44, 45–54, 55–64 and over 65 years old. We did not compare the whole diabetic population with the whole general population because the population structures were different, but we did analyze the similarities and differences in the populations’ characteristics, the subjective evaluation of health status (EQ VAS), the objective assessment of health status (EQ-5D index), and the level of restrictions in the 5 dimensions of the EQ-5D descriptive system. According to the authors’ best knowledge, this is the first study in Poland to have been conducted among patients with T2D in comparison with the general population and based on Polish EQ-5D normative data.

Statistical Analysis

Results were considered statistically significant at $p < 0.05$. We used two-sided confidence

intervals. Normal distribution was verified with the Shapiro-Wilk test. Differences between interval variables (the EQ VAS and the EQ-5D index) in 2 independent groups were evaluated using the unpaired t-test. Differences between dichotomous variables (the absence or presence of limitations according to the EQ-5D descriptive system) from 2 independent groups were evaluated using the Fisher exact test. Statistical analysis was performed using StatsDirect 2.7.8 software (StatsDirect Ltd, England).

Results

Populations Studied

A total of 274 patients with T2D and 214 respondents from the EQ-5D study of population norms who were at least 32 years of age were included in the study. Both populations were similar in terms of the proportion of women but were significantly different in terms of distribution of age (Table 1); therefore, quality of life analyses were conducted in subgroups according to age (Table 2 and Table 3). In general, the diabetic

Table 1. Characteristics of the samples: diabetic patients and the general population sample. Due to significant differences in age distribution, quality of life analyses were conducted in subgroups by age (Table 2 and Table 3)

	Diabetes sample	General population sample	P-value
n	274	214	
Women, n (%)	154 (56.2)	113 (52.8)	ns.
Age, mean (SD)	62.2 (9.83)	50.9 (11.8)	< 0.0001
Range	32 to 87	32 to 86	
Education			< 0.0001*
low	55 (20.1)	10 (4.7)	
middle	176 (64.2)	111 (51.9)	
high	43 (15.7)	93 (43.5)	
works	49 (17.9)	148 (69.1)	
Income			
< 500 PLN	36 (13.1)	47 (22.1)	
500 to 1000 PLN	159 (58.0)		
1000 to 1500 PLN	46 (16.8)	167 (78.0)	
≥ 1500	33 (12.0)		
Place of living			
country	77 (28.1)	35 (16.4)	
city < 100 000 inhabitants	57 (20.8)	179 (83.6)	
city > 100 000 inhabitants	140 (51.1)		
Marital status			0.0003*
single	13 (4.7)	27 (12.6)	
married	204 (74.5)	158 (73.8)	
divorced	12 (4.4)	14 (6.5)	
widowed	45 (16.4)	15 (7.0)	

*Chi-square test (2 by k).

Table 2. Comparison of characteristics of diabetic patients and respondents from the general population, in subgroups by age

Age group (years)	32-44			45-54			55-64			65+		
	diabetes gr. n	control gr. n (%)	p-value	diabetes gr. n	control gr. n (%)	p-value	diabetes gr. n	control gr. n (%)	p-value	diabetes gr. n	control gr. n (%)	p-value
n	11	71		47	62		105	53		111	28	
Female, n (%)	3 (27.3)	34 (47.9)	ns.	19 (40.4)	33 (53.2)	ns.	64 (61.0)	29 (54.7)	ns.	68 (61.3)	17 (60.7)	ns.
Age, mean (SD)	39.6 (4.5)	37.9 (3.6)	ns.	51.0 (2.5)	49.8 (2.7)	0.02	59.7 (3.0)	59.1 (2.9)	ns.	71.5 (5.4)	71.1 (5.0)	ns.

Table 3. Numbers and percentages of subjects reporting any problems (moderate or severe) in different dimensions of the EQ-5D, according to age

Age group (years)	32-44			45-54			55-64			65+		
	diabetes gr. n (%)	control gr. n (%)	p-value	diabetes gr. n (%)	control gr. n (%)	p-value	diabetes gr. n (%)	control gr. n (%)	p-value	diabetes gr. n (%)	control gr. n (%)	p-value
Mobility	2 (18.2)	5 (7.0)	ns.	20 (17.0)	13 (21.0)	0.0205	76 (72.4)	11 (20.8)	< 0.0001	94 (84.7)	19 (67.9)	ns.
Self-care	1 (9.1)	1 (1.4)	ns.	8 (17.0)	0 (0)	0.0008	25 (23.8)	2 (3.8)	0.0013	59 (53.2)	6 (21.4)	0.0138
Usual Activities	2 (18.2)	6 (8.45)	ns.	17 (36.1)	10 (16.1)	0.0244	55 (52.4)	4 (7.5)	< 0.0001	90 (81.1)	14 (50.0)	0.0294
Pain/Discomfort	5 (45.5)	23 (32.4)	ns.	25 (53.2)	33 (53.2)	ns.	63 (60.0)	28 (52.8)	ns.	90 (81.1)	20 (71.4)	ns.
Anxiety/Depression	6 (54.5)	22 (31.0)	ns.	33 (70.2)	25 (40.3)	0.0022	76 (72.4)	23 (65.7)	0.0005	91 (82.0)	13 (46.4)	0.0064

patients were less educated, more often unemployed and had a lower income (Table 1).

The numbers of patients with T2D and respondents from the general population, respectively, increased and decreased in the 4 consecutive age groups, which resembles the general prevalence of T2D and increased mortality with advancing age (Table 2). In the youngest and oldest age group there was a significant imbalance as to the number of respondents. The subgroups were similar in terms of the proportion of women and average age (except for the 45–54 years age group; mean 51.0 vs 49.8; $p = 0.02$).

Patients with T2D were enrolled in the study during hospitalization ($n = 175$, 63.9%) or during an outpatient visit ($n = 99$, 36.1%). The average time period since the diagnosis of diabetes for inclusion in the study was 10.4 years ($SD = 7.1$). Most of the patients were treated with OAD ($n = 111$, 40.5%), then insulin ($n = 95$, 34.7%), or were in the treatment intensification phase. The average level of HbA1c was 7.51% ($SD = 1.52\%$).

The general population sample was characterized by the presence of different diseases. Those that were most frequently indicated on the list of 15 current or previous health problems were: hypertension (33.6%), osteoarthritis (18.2%), gastric or duodenal ulcer (15.9%), liver disease (15.4%), rhinitis (15%), or headache (14.5%). Less frequently indicated were: coronary heart disease (9.3%), depression (8.4%), heart failure (7.5%), diabetes (7.0%), asthma (6.1%), previous heart attack (4.7%), renal failure (3.7%), cancer (1.9%) or previous stroke (1.4%). A total of 30.8% and 57.0% of the respondents reported current or previous smoking, respectively.

EQ VAS

In both of the studied populations, subjective assessment of HRQoL decreased with age, but only among the T2D patients was the decrease steadily dynamic (Fig. 1). In all 4 age groups, patients with T2D were characterized by significantly lower VAS assessment as compared to the respondents from the general population. The differences were smallest in the youngest age group ($MD = 15.7$ pts., $p = 0.0004$) and highest in the group of 55–64-year-olds ($MD = 23.2$ pts., $p < 0.0001$).

EQ-5D Index

Similarly, objective assessment of HRQoL, measured by the EQ-5D index, decreased with age in both study populations (Fig. 2). Patients with T2D were characterized by a lower EQ-5D index as compared to respondents from the general population, but only in age groups 45–54 and 55–64-year-olds the differences were significant ($MD = 0.045$,

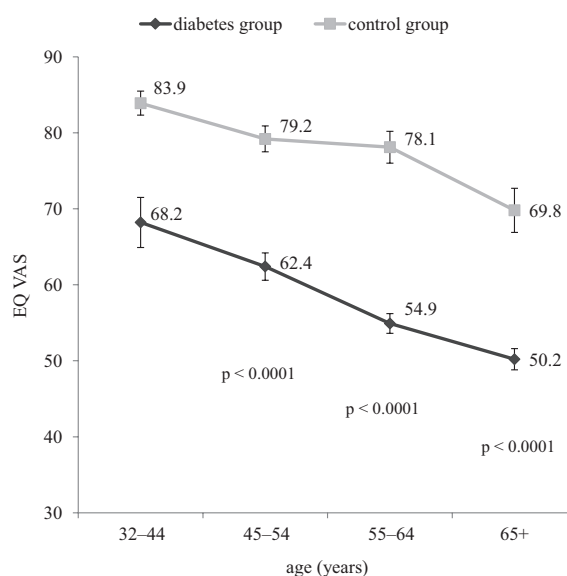


Fig. 1. Subjective assessment of health: results of visual analogue scale (EQ VAS)

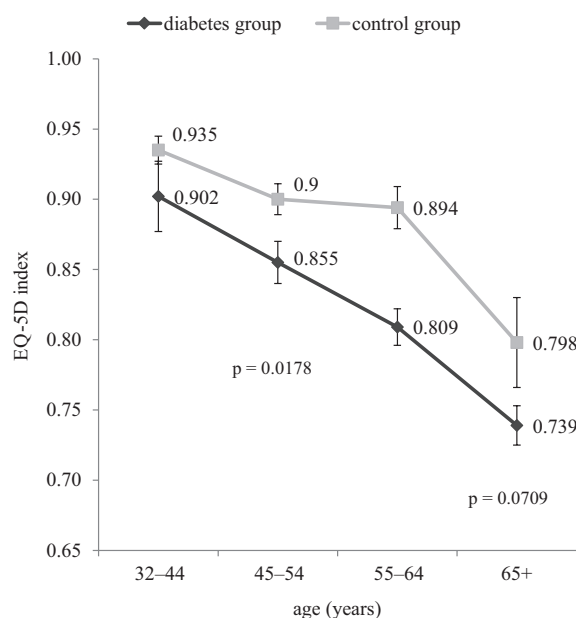


Fig. 2. Objective assessment of health: results of EQ-5D index

$p = 0.0178$ and $MD = 0.085$, $p = 0.0001$), and in the oldest age group they were close to statistical significance ($MD = 0.059$, $p = 0.0709$).

EQ-5D Descriptive Part

The incidence of restrictions in EQ-5D dimensions is presented in Table 3. In the youngest age group (32–44 years old) the number of respondents was too small and the observed differences did not reach statistical significance. The only dimension with a consistently reported lack of differences between type 2 diabetic patients and respondents from the general population was pain/discomfort. In 3 domains, i.e. self-care, usual

activities and anxiety/depression, patients with diabetes, starting at 45 years of age, reported significantly more problems than respondents from the general population. The case was similar for mobility in age groups 55–64 and over 65.

Discussion

In this study, the quality of life in patients with T2D, expressed as a single indicator, decreased in consecutive age groups. These changes were similar to those seen in the general population, although patients with diabetes consistently rated their health as worse. The difference in how health was perceived was greater in subjective assessment (EQ VAS) than in objective assessment, taking into account the preferences of Polish society (EQ-5D index). The most significant differences in the HRQoL of the surveyed populations were recorded in the age group of 55–64 years. In the general population this evaluation was slightly lower than in the younger age group, and among patients with diabetes it decreased rapidly. In terms of the EQ-5D descriptive part, patients with T2D were characterized by a greater number of restrictions in dimensions of usual activities, anxiety/depression, and self-care.

The main limitation of our study was the disproportionate number of respondents in the analyzed age groups (i.e. a growing number of patients with T2D and a parallelly decreasing number of respondents from the general population with advancing age). This described disparity stems from the way the data was collected. The diabetic patients' data was obtained in a prospective observational study and reflects the increasing prevalence of T2D with age. The data of the control group was obtained from a survey in which a selection of the respondents was based on age and gender quota resembling the structure of the Polish population. As a result, a decreasing number of individuals in subsequent age groups can be seen. Both studies were carried out at the same time but in slightly different populations. The main demographic differences relate to geographic origin, education, economic activity and average income per household member. In both studies the number of patients was too small for us to perform a reliable statistical adjustment, e.g. one based on the propensity score method.

The main advantage of our study was that a well-known generic quality of life questionnaire, the EQ-5D, was used. Such a tool, although not as responsive as disease-specific questionnaires, allows us to carry out comparisons with other, sometimes distinct, populations, i.e. diabetic populations from other countries and populations with different diseases. Second, it allows us to use the results in

pharmacoeconomic analyses of anti-diabetic drugs in order to estimate quality adjusted life years (QALYs) and the incremental cost-utility ratio (ICUR).

In 2011, a systematic review of studies, in which the EQ-5D was used in adults with T2D, was published by Jansen et al. [19]. The analysis confirmed the questionnaire's usefulness in measuring the impact of diabetes and the entire spectrum of its complications on HRQoL in different patient subpopulations. Sixteen studies were conducted in general populations of patients with T2D. The average objective HRQoL assessment (EQ-5D index) differed significantly between the populations: from about 0.61 in Greece and 0.67 in the UK, Italy, Canada and Finland, to around 0.80 in the United States and 0.84 in Spain. The largest studies, with probably the most reliable measurements, indicated a level of 0.69 (5 countries in the European Union, $n = 4641$) to about 0.77 (United Kingdom, $n = 3192$) and 0.78 (United States, $n = 3849$) [20–22]. These observed differences can be explained by several different factors, e.g. specific inclusion criteria, use of different utility norms, and, finally, real differences in the states of health of the studied populations. The average objective assessment of HRQoL of patients from the Lublin region was relatively high, i.e. 0.792, and second only to evaluations from Spain and the United States. A similar type of diversity can be noticed in the subjective evaluation of HRQoL using the EQ VAS scale: from about 56 in the UK, to 59 in Italy, 60 in Greece, to around 76 in another study in the UK and 78 in Australia and New Zealand. Measurements in the largest studies were more scattered than the EQ-5D index: from 62 (5 countries in the EU, $n = 4641$), through 74 (UK, $n = 3192$), to the aforementioned maximum recorded value, i.e. 78 (Australia and New Zealand, $n = 7348$). Subjective assessment of patients from the Lublin region, about 55 points on the VAS scale, turned out to be the lowest recorded rating. In our study both objective and subjective HRQoL assessment decreased steadily with age. In studies carried out in the UK and the Netherlands, a consequent change was not recorded [23, 24]. At the same time, a prospective study in a sample of Canadian diabetic patients pointed to the fact that each year objective assessment of HRQoL is consistently declining [25].

Our study has at least 2 practical aspects. First, we show how EQ-5D population norms can be used to assess patients in clinical practice. This is the first study in T2D using EQ-5D population norms. Second, our results indicate a subpopulation of patients aged 55–64 years old as a group with apparently reduced QoL in comparison to the general population, and, therefore, requiring special attention from clinicians.

In conclusion, both subjective and objective assessment of HRQoL in patients with type 2 diabetes is lower than observed in the matching general population. Particular differences were recorded in the age group of 55–64 years. In comparison with

T2D populations from other countries, Polish patients are characterized by relatively high average objective assessment of health status and very low subjective assessment.

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