

Reliability and Validity of the Audit on Diabetes-Dependent Quality of Life (ADDQoL) and EQ-5D in Elderly Slovenian Diabetes Mellitus Type 2 Patients

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Abstract

Purpose: This study reports the reliability and validity analyses of the Audit on diabetes-dependent quality of life (ADDOoL) and EO-5D in elderly Slovenian diabetic patients. Methods: A crosssectional study of elderly (age ≥ 65 years) non-insulin dependent diabetes mellitus type 2 (DMT2) patients was carried out. The ADDOoL and EO-5D surveys were conducted between January and May, 2012. Statistical analysis was performed using IBM SPSS Statistics software, version 20.0. Results: After exclusion of non-eligible respondents, the final sample for the analysis was 261 cases (51% male), resulting in 52.2% of response rate. The mean age of the patients was 70.3 years (SD \pm 4.1). The Cronbach's alpha was 0.93 for ADDOoL and 0.73 for EO-5D. There was no improvement in the alpha value if any item was deleted in all instruments. Missing value items ranged from 0.8% to 1.5% for EQ-5D, and from 0.8% to 59.1% (working life) in ADDQoL. Spearman's correlation between the EQ-5D VAS score and ADDQoL weighted overall score resulted in weak correlations coefficient (r = 0.294; p < 0.001). Conclusions: The ADDQoL proved reliable and valid for assessing Health Related Quality of Life (HRQoL) among elderly Slovenian DMT2 patients. EQ-5D seemed to be too generic to describe limitations of DMT2 patients in detail. Using disease specific QoL instruments to learn about patient limitations was recommended. Comparison of ADDQoL results between various studies provided significant differences in the impact of diabetes.

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Keywords

DMT2; Elderly; Patient Reported Outcomes; ADDQoL; EQ-5D; Health Related Quality of Life

1. Introduction

Diabetes mellitus type 2 (DMT2) is one of the most common chronic diseases globally. DMT2 is also psychologically demanding. It can significantly impair the patient's health-related quality of life (HRQoL), particularly if the patient has other chronic conditions [1]-[3]. In 2010, there were 285 million people affected by diabetes [4]. The 2010 OECD report [5] stated that diabetes was the main cause of death of more than 100,000 people in EU countries in 2008, and in most developed countries it was in the top five leading causes of death. Hence, diabetes is an important health concern in high income countries.

In Slovenia, the number of diabetic patients is growing and estimated to be approximately 125,000 adults (20 to 79 years) [6]. As a result, reducing the number of diabetic patients has been put higher in the health policy agenda especially because of the rising incidence and prevalence of DMT2 as a result of negative lifestyle developments (e.g. obesity). This is evident in the establishment of The National Diabetes Prevention and Care Development Programme 2010-2020 [7]. This Programme represents the strategic foundation for taking measures in the area of prevention, early detection and treatment of diabetes mellitus, as well as for monitoring, researching and educating. In addition, diabetes makes social care and economic issues more challenging for the society, as it is one of the diseases that are fully reimbursed by the compulsory health insurance. To better inform patient management and medical decision making, a better understanding of the psychosocial burden of diabetes is required.

In the past two decades, HRQoL as a patient reported outcome (PRO) has gained its importance in health care [8]. This is because HRQoL encompasses physical, psychological and social aspects of diabetic patients. There is a growing interest in literature and medical practices to assess chronic diseases (e.g. diabetes) in relation to their impacts on quality of life (QoL) in addition to medical outcomes (e.g. morbidity and mortality) [9]-[11]. Many studies support the use of HRQoL as a measure because subjective health is perceived as a better predictor of survival than objective health [12]. In addition, associations between chronic diseases and lower levels of HRQoL are evident. This is because if a chronic patient is to be better, the patient will need to change his or her lifestyle significantly [13] [14]. Thus, the measurement of HRQoL is an important activity.

There are several questionnaires created to measure HRQoL in diabetic patients, including generic instruments (e.g. EQ-5D) and disease-specific questionnaires (e.g. ADDQoL) [15]-[17]. However, no diabetes specific HRQoL measurements have been validated in Slovenia. It is crucial to validate a questionnaire specifically for Slovenia because lifestyles vary between countries and cultures, and these differences directly affect how a society perceives a high quality life. Another reason is that it is important to re-validate a translated questionnaire.

The aim of this study was to evaluate the reliability and validity of the Slovenian ADDQoL version in the diabetic population. Due to the lack of other diabetes specific questionnaires, the results of the ADDQol were compared to a generic questionnaire. Specifically, the EuroQol group questionnaire with five dimensions (EQ-5D), which was previously translated and culturally adapted for Slovenian population [18]-[20], was used as a comparison. In addition, a benchmark with other published studies was conducted to identify whether diabetes has a similarly negative impact on the QoL.

2. Methods

2.1. Instruments

The Audit on diabetes-dependent quality of life (ADDQoL) assesses the impact of diabetes on 19 life domains. It consists of two overview items: (1) one measures generic overall quality of life and (2) another one measures the specific impact of diabetes on quality of life.

The 19 life domains can be rated from -3 to +1 (called 'impact ratings') and from 0 to +3 in attributed importance (called 'importance ratings') [3] [8] [21]. Finally, an average weighted impact score (AWI) is calculated for the entire scale, as a multiplier of impact rating and importance rating (range from -9 to 3).

The EQ-5D is a health status instrument that is standardized, validated, generic, preference-based, and has been translated into more than 25 languages including Slovene [18] [22] [23]. It describes the participants' health state on five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each of these dimensions is split into three levels, generating 243 possible health states, each of which is associated with a utility score (range -0.59 to 1) [23] [24].

2.2. Linguistic Validation of ADDQoL

After obtaining the developers' authorization, the ADDQoL was translated from the source English (UK) into Slovenian version using a standardized methodology of forward and back translation. The linguistic validation process is shown in **Figure 1**.

The forward translation (FT) was conducted independently by two Slovene translators, both fluent in English. The initial translation was subject for discussion, and once a consensus was reached among the project manager and translators, the first version of ADDQoL in Slovene was ready. After the FT, two other bilingual translators were recruited to back translate (BT) the ADDQoL into English independently. Following the final reconciliation, a BT report was compiled and sent to the developer. After revision and discussion with the developer, a preliminary ADDQoL was reconciled. This preliminary ADDQoL was subject to clinical and psychological reviews, which were carried out separately, by a medical specialist in diabetology and a public health psychologist, and a report was submitted after their review.

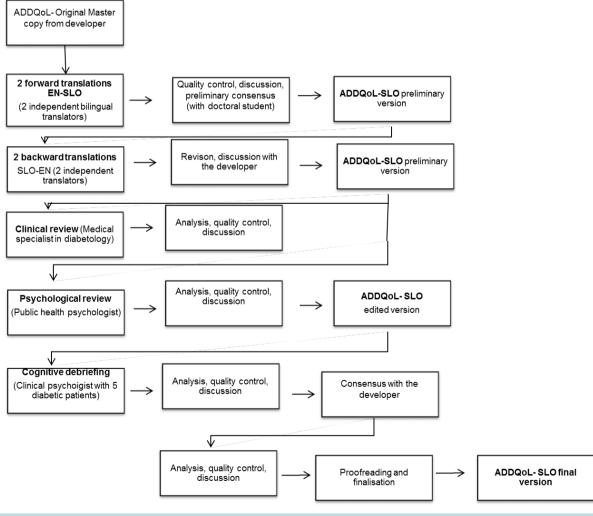


Figure 1. ADDQoL linguistic validation process.

Once the consensus with the developer was reached, cognitive debriefing was conducted. During the interview with a clinical psychologist, five patients (various age, sex, education and type of diabetes) were asked about their view of health and QoL, and relevance of each item to themselves. In addition, the participants were asked about possible difficulties in understanding the items. Results were generated into the cognitive debriefing report. The edited version of the ADDQoL was produced and subjected to reconciliation. After several rounds of reconciliation, the approval was obtained, and the final Slovenian version of the ADDQoL was produced. The Slovenian EQ-5D instrument used for the current study was validated previously [18] [25].

2.3. Study Design and Data Collection

A cross-sectional research design was applied using a structured questionnaire. The study was conducted between January and May 2012. After obtaining the ethics approval from the National Medical Ethics Committee of the Republic of Slovenia, outpatient diabetic centers were asked to recruit patients for the study. For recruitment we used the largest outpatient center in each region of Slovenia; thus providing 12 outpatient diabetic centers for the study. Each outpatient center recruited 20 to 80 patients depending on the region size and prevalence [26]. Patients were eligible to participate in the study if they had been diagnosed DMT2, without insulin therapy, and had been aged 65 years or older. Patients with Type 1 diabetes, secondary diabetes or gestational diabetes were excluded from the study. After obtaining the informed consent, participants were handed out the questionnaire. Because the participants were elderly people, assistance in filling in the questionnaire was provided by medical students who were specially trained for the ADDQoL questionnaire prior to the data collection.

2.4. Sample Breakdown

Five hundred elderly people were asked to participate in the study, in which 78.2% (n = 391) agreed. Considering participants' age and possible life development tasks, the ADDQoL items "working life" and "sex life" were omitted from the analysis. There were some cases excluded from analysis because the following ADDQoL items received a very low response rate: 107 (21.4%) cases of the item "holidays", 28 (4.6%) cases of the item "personal relationship", and the item "financial situation" (0.2%). Although all items from ADDQoL and EQ-5D had at least one missing value, there was no need to exclude further cases because missing values were the combination of two items: a) "holidays" or b) "personal relationship". The final sample for the analysis was 261 cases (52.2% of response rate).

2.5. Data Analysis

The sample data were expressed as frequencies and percentages for categorical variables or by mean values and standard deviations (M \pm SD) for continuous variables. Factor analysis (PAF–principal axis factoring) was calculated with Varimax rotation and eigenvalues > 1. An international comparison was made using one-way ANOVA. Statistical analysis was performed with the IBM SPSS 20.0 software (IBM Corp., Armonk, NY). P < 0.05 was considered as statistically significant.

3. Results

3.1. Patient Characteristics

A total of 261 elderly DMT2 patients responded to the questionnaire, in which 51% were male. The mean age of the patients was 70.3 years (SD \pm 4.1). The patient characteristics are presented in **Table 1**.

EQ-5D results are presented in **Table 2**. Approximately 50% of participants reported some health problems in mobility and pain/discomfort. EQ-5D VAS score was calculated at 0.66 ± 0.12 (range: 0.05 - 0.77).

ADDQoL results are presented in **Table 3**. Participants omitted "sex life" and "working life" domains. The lowest mean weighted impact score (major concern) was calculated in "freedom to eat" (-3.2, SD 2.9) and the highest mean weighted impact score (minorconcern) was calculated in "people's reaction" domain (-0.8, SD 1.6).

3.2. Reliability and Feasibility

For EQ-5D instrument Cronbach's alpha was 0.73, and there was no improvement in alpha value if any item

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	n = 261	%
Gender		
Male	133	51.0
Female	128	49.0
Education		
Primary education	77	29.5
Secondary education	154	59.0
College or higher	30	11.5
Marital status		
Married, in partnership	176	67.4
Widowed	64	24.5
Divorced	10	3.8
Single	11	4.2
Residence		1.2
Own house	159	60.9
Own Apartment	83	31.8
Renting	9	3.4
Relatives	7	2.7
Nursing home	3	1.1
Monthly income in EUR		
365 or less	32	12.3
366 to 730	151	57.9
731 to 1100	53	20.3
1101 or above	25	9.6
Region		
$\leq 200 \text{ per km}^2 \text{ (rural)}$	39	14.9
$> 200 \text{ per km}^2 \text{ (urban)}$	222	85.1
Age in years $(M \pm SD, range)$	70.3 ± 4.1	65 - 84

M: mean, SD: standard deviation.

Table 2. Self evaluated health status in EQ-5D (n = 261).

	Mean score (M \pm SD)	Proportion of at least some health problems (%)	Proportion with severe health problems (%)		
EQ-5D					
Mobility	1.53 ± 0.51	51.5	0.7		
Self-care	1.16 ± 0.41	12.4	1.7		
Usual activities	1.30 ± 0.49	27.8	1.3		
Pain/discomfort	1.57 ± 0.57	49.2	4.0		
Anxiety/depression	1.40 ± 0.57	30.9	4.4		

Table 3. Distribution of ADDQoL responses by impact and importance rating together with the weighted impact score, ranks and zero importance ratings.

Domain	NA response (%) n = 391	Impact rating n = 261		Importance rating n = 261		Weighted impact score n = 261		Rank** n = 261	Zero importance ratings n = 261
		M SD		M	SD	M	SD		n (%)
Leisure activities		-1.1	1.0	1.9	0.7	-2.2	2.2	6	47 (18.0%)
Working life*	231 (59.1)								
Journeys		-1.3	1.0	1.8	0.8	-2.5	2.5	2	24 (9.2%)
Holidays	107 (27.4)	-1.1	1.0	1.8	0.8	-2.0	2.2	7	15 (5.7%)
Physical health		-1.2	1.0	1.9	0.7	-2.5	2.4	2	9 (3.4%)
Family life	13 (3.3)	-0.9	0.9	2.4	0.6	-2.4	2.5	5	1 (0.4%)
Friendship and social life		-0.9	1.0	2.0	0.8	-1.9	2.5	11	8 (3.1%)
Personal relationship	81 (20.7)	-0.8	1.0	2.3	0.7	-2.0	2.5	7	5 (1.9%)
Sex life*	144 (36.8)								
Physical appearance		-0.7	0.9	1.5	0.9	-1.4	2.1	16	36 (13.8%)
Self-confidence		-0.8	1.0	2.0	0.7	-1.8	2.4	13	9 (3.4%)
Motivation		-0.9	1.0	1.9 0.7		-1.9	2.5	11	10 (3.8%)
People's reaction		-0.4	0.7	1.5	0.9	-0.8	1.6	18	51 (19.5%)
Feelings about future		-1.1	1.0	1.9	0.7	-2.5	2.5	2	14 (5.4%)
Financial situation	Financial situation		0.9	2.0	0.7	-1.3	2.2	17	9 (3.4%)
Living conditions		-0.9	0.9	2.1	0.7	-2.0	2.5	7	4 (1.5%)
Dependence on others	Dependence on others		0.9	2.5	0.7	-1.5	2.4	15	5 (1.9%)
Freedom to eat		-1.5	1.0	1.8	0.9	-3.2	2.9	1	22 (8.4%)
Freedom to drink		-0.9	1.0	1.2	1.0	-1.6	2.3	14	94 (36.0%)

M: mean, SD: standard deviation, NA: not available. *due to elderly population item was less considered and was omitted from further analysis. **1 being the greatest impact; items with the same mean weighted impact scores have the same rank.

was deleted. Corrected item to total correlation coefficients ranged between 0.39 and 0.53. The mean inter-item correlation coefficients ranged from 0.29 to 0.38, the lowest was 0.25 (usual activities vs. anxiety/depression). The strongest correlation coefficient was 0.58 between self-care and usual activities. Seventy percent of inter-items correlations were between 0.30 and 0.70 (moderate correlation).

For ADDQoL instrument Cronbach's alpha was 0.93, there was no improvement in alpha value if any item was deleted. Corrected item to total correlation coefficients ranged between 0.19 and 0.80. Item "freedom to drink" was the only one that did not meet the correction value of over 0.30. The mean inter-item correlation coefficients ranged from 0.13 to 0.54, the lowest was <0.01 (people's reaction vs. freedom to drink). The strongest correlation coefficient was 0.79 between self-confidence and motivation. Moderate inter-items correlation (0.30 < r < 0.70) coefficients were conducted in 80.9% of cases.

Missing values for EQ-5D items ranged from 0.8% to 1.5%, most for anxiety/depression items. Missing values for ADDQoL ranged from 0.8% to 59.1% (working life). Due to elderly population two items were of less interest: "working life" and "sex life". After exclusion of these two items, missing values were recorded from 0.8% (freedom to drink) to 27.4% (holidays). **Table 4** presents the missing data and reliability coefficients for the two instruments.

3.3. Construct Validity

Construct validity was examined by principal axis factoring. Kaiser-Meyer-Olkin measure of sampling ade-

Table 4. EQ-5D and ADDQoL reliability and feasibility.

Instrument	Missing data n = 391 (%)	Internal consistency (Cronbach's α) n = 261	Corrected item-total correlation n = 261	inter-item correlation (lowest, mean) n = 261
EQ-5D		0.73		
Mobility	3 (0.8)	0.67#	0.53	0.27, 0.38
Self-care	3 (0.8)	0.68#	0.53	0.29, 0.39
Usual activities	3 (0.8)	0.68#	0.52	0.25, 0.39
Pain/discomfort	5 (1.3)	0.67#	0.53	0.35, 0.38
Anxiety/depression	6 (1.5)	0.73#	0.39	0.25, 0.29
$ADDQoL^{**}$		0.93		
Leisure activities	9 (2.3)	0.92#	0.62	0.09, 0.43
Working life*	231 (59.1)			
Journeys	9 (2.3)	0.92#	0.64	0.00, 0.45
Holidays	107 (27.4)	0.92#	0.61	0.13, 0.42
Physical health	12 (3.1)	0.92#	0.64	-0.05, 0.44
Family life	13 (3.3)	0.92#	0.69	0.17, 0.47
Friendship and social life	8 (2.0)	0.92#	0.77	0.08, 0.53
Personal relationship	81 (20.7)	0.92#	0.71	0.09, 0.49
Sex life*	144 (36.8)			
Physical appearance	13 (3.3)	0.92#	0.75	0.11, 0.51
Self-confidence	9 (2.3)	0.92#	0.80	0.10, 0.54
Motivation	8 (2.0)	0.92#	0.73	0.22, 0.50
People's reaction	9 (2.3)	0.93#	0.53	0.01, 0.37
Feelings about future	9 (2.3)	0.92#	0.67	0.22, 0.45
Financial situation	11 (2.8)	0.92#	0.64	0.10, 0.44
Living conditions	10 (2.6)	0.92#	0.73	0.16, 0.49
Dependence on others	9 (2.3)	0.92#	0.61	0.05, 0.43
Freedom to eat	7 (1.8)	0.93#	0.49	0.12, 0.33
Freedom to drink	3 (0.8)	0.93#	0.19	-0.05, 0.13

^{*}item was less considered and omitted from analysis. *Cronbach's α if item was deleted. **ADDQoL weighted scores.

quacy for EQ-5D was 0.731 and Bartlett's Test of Sphericity ($X^2 = 328.453$, df = 10, p < 0.001), both indicated that the assumption criterion was met for the factor analysis.

Kaiser-Meyer-Olkin measure of sampling adequacy for ADDQoL was 0.908 and Bartlett's Test of Sphericity ($X^2 = 1378.622$, df = 136, p < 0.001), both indicated that the assumption criterion was met for the factor analysis.

Table 5 shows the factor analysis of the questionnaires. For EQ-5D all items loaded to the same one-factor solution, explaining 49.5% of total variance. For ADDQoL all items loaded above 0.4 to the first factor, but "freedom to drink". Item "freedom to drink" loaded to the second factor and item "leisure activities" loaded to the third factor. A non-rotated three-factor solution explained 64.3% of total variance. In the forced one-factor solution for ADDQoL all items but "freedom to drink" had factor loadings of >0.4. Freedom to drink loaded

Table 5. Factor analysis of EQ-5D and ADDQoL items (n = 261).

Instrument	Factor 1	Factor 2	Factor 3	Total variance explained (%)
EQ-5D				49.5
Mobility	0.727			
Self-care	0.740			
Usual activities	0.745			
Pain/discomfort	0.718			
Anxiety/depression	0.575			
$ADDQoL^{**}$				64.3
Leisure activities	0.673		0.401	
Working life *				
Journeys	0.707			
Holidays	0.656			
Physical health	0.705			
Family life	0.732			
Friendship and social life	0.824			
Personal relationship	0.762			
Sex life *				
Physical appearance	0.798			
Self-confidence	0.843			
Motivation	0.776			
People's reaction	0.598			
Feelings about future	0.701			
Financial situation	0.696			
Living conditions	0.768			
Dependence on others	0.680			
Freedom to eat	0.500			
Freedom to drink		0.806		

^{*}due to elderly population item was less considered and was omitted from further analysis. **ADDQoL weighted scores.

with a value of 0.188 into this factor. The forced one-factor solution explained 48.8% of total variance.

Twelve studies involving ADDQoL were considered for statistical comparisons to Slovenian results. The results were presented in a comparable manner in four studies [27]-[30]. For example, Zhang *et al.* [31] made a comparison between English and Chinese speaking populations, although did not provide results for the entire sample. Chung *et al.* [32] provided median values with interquartile range. While some studies [21] [33] provided only graphical results, others [34] [35] provided only summarised scores which were used for further statistical analyses. Lemon and Rosal [36] and Demirci *et al.* [37] used modified/simplified ADDQoL, therefore some domains were not completely comparable. The international comparison of the relevant studies is presented in **Table 6**.

4. Discussion

Patient reported outcome measurements (PROMs), particularly HRQoL, present an important component in

Table 6. International comparison of ADDQoL domains.

	Present Slov n = 1	enia	y Soon et al. (2010) Singapore n = 88		O) Kong et al. (2011) China n = 697) Wee et al. (2006) China, India n = 152		Holmanova and Ziakova (2008) Slovakia n = 104		p
	M	SD	M	SD	M	SD	M	SD	M	SD	
Leisure activities	-2.2	2.2	-2.4	2.8	-1.9	1.9	-3.5	3.0	-3.1	3.0	< 0.001
Working life*			-3.5	2.9	-1.7	2.4	-4.4	3.0	-3.8	3.2	/
Journeys	-2.5	2.5	-2.6	2.7	-2.1	2.1	-3.3	2.9	-3.3	3.0	< 0.001
Holidays**	-2.0	2.2	-2.5	2.7	-1.7	2.3	-3.5	3.3	-2.9	3.1	< 0.001
Physical health	-2.5	2.4	-2.5	2.6	-2.1	1.9	-4.5	3.0	-3.9	3.0	< 0.001
Family life**	-2.4	2.5	-3.3	2.9	-3.4	2.6	-5.1	3.1	-3.7	3.2	< 0.001
Friendship and social life	-1.9	2.5	-2.4	2.6	-2.5	2.3	-3.6	3.0	-2.6	3.2	< 0.001
Personal relationship**	-2.0	2.5	-2.8	2.9	-2.7	2.6	-4.5	3.0	-2.7	3.1	< 0.001
Sex life*			-2.7	2.8	-1.6	2.4	-3.7	3.1	-2.6	3.0	/
Physical appearance	-1.4	2.1	-2.3	2.7	-2.7	2.2	-3.3	3.1	-2.4	2.9	< 0.001
Self-confidence	-1.8	2.4	-3.3	2.8	-3.4	2.4	-4.2	2.9	-2.8	3.1	< 0.001
Motivation	-1.9	2.5	-3.2	3.0	-3.2	2.3	-3.7	3.2	-3.3	3.1	< 0.001
People's reaction	-0.8	1.6	-1.5	2.2	-1.9	2.2	-2.7	3.0	-1.6	2.5	< 0.001
Feelings about future	-2.5	2.5	-3.7	3.2	-3.0	2.2	-4.9	3.0	-3.9	3.1	< 0.001
Financial situation	-1.3	2.2	-3.6	3.1	-3.6	2.3	-4.1	3.2	-4.2	3.5	< 0.001
Living conditions	-2.0	2.5	-3.8	3.0	-3.2	2.1	-4.2	3.3	-2.5	3.1	< 0.001
Dependence on others	-1.5	2.4	-1.7	2.4	-2.3	2.1	-3.1	3.4	-2.6	3.1	< 0.001
Freedom to eat	-3.2	2.9	-3.9	3.3	-2.9	2.1	-5.5	3.2	-4.3	3.2	< 0.001
Freedom to drink	-1.6	2.3	-3.1	3.2	-2.0	1.9	-3.9	3.0	-3.1	3.2	< 0.001

 $^{^*}p$ was not calculated because NA response was too high(/). ** reduced sample due NA response was considered.

continuous improvement of chronic disease management [38]. A number of instruments for measuring HRQoL have been developed and used across chronic diseases including DMT2. In this study, the diabetes specific questionnaire ADDQoL was translated from the source English (UK) version into Slovene. The aim of the study was to evaluate the ADDQoL and the generic EQ-5D in terms of reliability, validity and feasibility among elderly DMT2 patients in Slovenia.

Similar to other studies [17] [27] [39], our findings show that both instruments seem reliable. Results of factor analysis, the Cronbach's alpha index, showed satisfactory results in multiple aspects of the ADDQoL scale, implying that the items were well translated and culturally adapted for Slovenian population (age 65 years or older).

The greatest negative weighted impact observed was consistent with previous studies [3] [27] [30] and the international comparison. The domain "freedom to eat", indicates a strong influence of dietary restrictions on QoL, bearing in mind that overweight is one of the most important factors contributing to the development of DMT2. It was thus not surprising that "freedom to eat" ranked as the first on the list. Domain "freedom to eat" had also the maximum negative unweighted impact score, yet it was not dramatically enhanced by the importance rating. Highest importance rating was reported for "family life", "personal relationship" and "dependence on others". These can be interpreted that Slovenian elderly people highly value family ties and personal relationships, yet

they are afraid to get dependent in activities of daily living and in need to ask loved ones to provide help or to move to nursing home. Other studies [17] [28] [30] provided a similar picture regarding "family life" and "personal relationships" but not regarding "dependence on others". We believe that the latter finding may be connected the fact that our participants were elderly.

Our experience in collecting the data shows that only a few participants reported difficulties in filling in the questionnaire. However, there were still some missing responses. The items "working life" and "sex life" in the ADDQoL had the highest missing data. The missing responses for "working life" is understandable because most of the participants in the study were retired, thus the working life had not been a major concern for them. The missing responses for the item "sex life" may be explained by the fact that most elderly people do not usually discuss sexuality-related topics with their doctors [40] or openly with others. In addition, the study by Robinson and Molzahn [41] shows that elderly people who reported higher satisfaction with personal relationships also reported higher ratings of QoL than those who reported lower satisfaction.

Comparisons of ADDQoL results between various studies provided significant differences in the impact of diabetes. This may lead to the conclusion that it is important to consider the severity of the disease. For example, Holmanova and Ziakova [27] included patients with intensified insulin therapy and results provided a higher negative disease impact. Similarly, Wee *et al.* [42] included DMT1 and DMT2 patients, and found that those who required insulin therapy (35%) reported worsened ADDQoL scores. Soon *et al.* [28] included DMT2 patients, of whom 44% reported using the insulin therapy. Kong *et al.* [17] included DMT2 patients only, without providing the number of patients using the insulin therapy. Slovenian sample included non-insulin DMT2 patients; this study and Kong *et al.* [17] reported lower diabetes impact on QoL when compared to first ones cited [27] [28] [30] in this paragraph. Inconsistency of findings may be related to age differences among various samples, in which the Slovenian sample, with the oldest participants (mean age was above 70 years), reported a lower diabetes impact. Kong *et al.* [17] reported the second largest impact with second largest mean age of 59 years. Studies which reported a higher impact on QoL included younger participants (mean age from 46 to 57 years). This may suggest that an elderly population is less impacted by diabetes. Some studies found that elderly people reported a higher life satisfaction compared to that of middle-aged people [43] [44].

EQ-5D as a generic health score was found to have a weak correlation with the disease specific ADDQoL score, which was similar to the findings in Soon *et al.* [28]. This may conclude that EQ-5D is too generic to describe limitations of DMT2 patients in detail. Using diseases specific QoL instruments to learn about patient limitations is thus recommended.

4.1. Recommendations for Future Research

ADDQoL instrument is frequently used as a diabetes specific QoL instrument internationally. However, results are difficult to compare, because, for example, some studies provided graphical results only, whereas other sonly used interquartile ranges or summarised scores. In addition, some studies have adapted ADDQoL to fit their study populations better and thus it is difficult to make a comparison. If ADDQoL is to be promoted, results should be published as originally suggested, which is by showing the importance rating, impact rating and weighted impact score. In case of unexpected deviations, an explanation should be provided on why some domains were inappropriate for the targeted population. This may lead give a better understanding on how the QoL is influenced by the severity of the disease and age.

4.2. Study Limitations

We recognize that there are limitations in our study. First, the generalizability of our findings to the general population with DMT2 may be limited because of the lack of randomized sampling and the use of a convenience sampling. A larger sample would provide more statistical power to detect significant associations between the study variables and the differences between groups.

5. Conclusion

We have demonstrated that the ADDQoL is culturally appropriate, valid and reliable to measure DMT2 elderly patients in Slovenia. The questionnaire was relatively easy to fill in by elderly patients. An international com-

parison of results however was difficult because results might be influenced by the severity of the disease and age.

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Conflict of Interest

There are no conflicts of interest.

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