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Health-Related Quality of Life Using the EuroQol 5D Questionnaire in Korean Patients with Type 2 Diabetes

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We aimed; 1) to determine the validity of the EuroQol 5D (EQ-5D) for the health-related quality of life (HRQOL) of Korean patients with type 2 diabetes, and 2) to identify associated factors of the HRQOL of these patients. Follow-up surveys were conducted for consecutive patients with type 2 diabetes. HRQOL was assessed using the EQ-5D and the Short Form-36 (SF-36). The validity of EQ-5D was assessed with the perspectives of known group, convergent and discriminant validity. Additionally, a linear mixed model using a backward elimination was used for identify associated factors. Of the 1,072 patients included in the first survey, 858 (80.0%) completed the questionnaires in the follow-up. In the known group validity, the problem rates in each EQ-5D dimension were highest among women, elderly people, and less-educated subjects. The Spearman's ρ between the EQ-5D and the SF-36 scales were larger in the comparable dimensions than those in the less comparable dimensions. In the final model, we found that sex, age, education, body mass index, atrial fibrillation, stroke, and retinopathy were statistically significant. Our data suggest that the EQ-5D is a valid tool for Korean patients with type 2 diabetes and that various factors could affect their HRQOL.

Key Words: EQ-5D; Health-Related Quality of Life; Diabetes Mellitus, Type 2

INTRODUCTION

Health policies for non-communicable diseases should include strategies for the management of type 2 diabetes, as this disease has become more common worldwide and remains an important risk factor for cardiovascular diseases. The International Diabetes Federation estimates that 333 million people will have diabetes by 2025 (1). In the USA, the prevalence of diabetes increased from 5.3% to 8.2% between 1980 and 2000 (2). In Korea, the prevalence of diabetes (aged ≥ 30 yr) was estimated to be 9.1% in 2005 (3, 4).

In analyzing the health impact of chronic diseases, health-related quality of life (HRQOL) has been commonly used as an outcome indicator because patient cooperation forms the core of health plans for incurable diseases. The quality-adjusted life years (QALYs) is defined as a measure of a person's length of life weighted by a valuation of their HRQOL and a valuable outcome measure of disease burden. The QALYs can be used in clinical practice, trials, economic evaluation, and health policy formulation.

The EuroQol 5D (EQ-5D), a generic measure of HRQOL, is widely used to determine the utility weight to measure decreases in QALYs due to disease. Some studies have used EQ-5D to estimate the HRQOL of type 2 diabetic patients in Western and Asian countries. Clarke et al. (5) reported that the EQ-$5D_{index}$ is an independent predictor of mortality risk, future vascular events, and other complications in patients with type 2 diabetes. Sakamaki et al. (6) reported HRQOL in Japanese patients with type 2 diabetes using EQ-5D, and Sakthong et al. (7) estimated the EQ-$5D_{index}$ in Thai patients with type 2 diabetes. However, in these studies, the HRQOL has been assessed by cross-sectional design. Because HRQOL is a time-dependent variable, repeated measurements are required to obtain reliable estimates. In addition, the Korean version of EQ-5D has not been validated for use in patients with type 2 diabetes in Korea.

The aim of this study was to assess the validity of the Korean version of EQ-5D to evaluate the HRQOL of Korean patients with type 2 diabetes, and also to identify associated factors to the HRQOL of these patients during follow-up surveys.

MATERIALS AND METHODS

Subjects

Consecutive patients with type 2 diabetes who routinely visited the outpatient clinics of three university hospitals (i.e., Sanggye Paik Hospital and Konkuk University Hospital in Seoul, and Ilsan

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Paik Hospital in Gyeonggi Province) were invited to participate in the first survey (October 2007-January 2008). Participants completed all the questionnaires in the clinic on the day of recruitment to the first survey.

Subjects were included in the study if they were > 20-yr-old and had a confirmed diagnosis and/or received ongoing treatment for type 2 diabetes. The exclusion criteria were type 1 diabetes, a history of not taking relevant treatments, and unwillingness to participate in the study. During subsequent follow-up visits, subjects who participated in the first survey were invited to complete a second survey from December 2007 to April 2008 using same methods. All surveys were conducted by well-trained research nurses.

Information

The following information was recorded during interviews and by reviewing the medical charts: general characteristics of the subjects, including sex, age, education, marital status, drinking and smoking status; and clinical factors such as weight, height, treatment modality, comorbidities (e.g., hypertension, hyperlipidemia, atrial fibrillation [AF], and cataracts); macrovascular complications such as acute myocardial infarction, angina pectoris, acute stroke, and transient ischemic attack (TIA); and microvascular complications such as retinopathy and nephropathy. The subjects' HRQOL was assessed using the EQ-5D. In the first survey, the Short Form (SF)-36 was used to validate the EQ-5D. $EQ\text{-}5D_{index}$ was calculated using Korean valuation set (8).

Validity of the EQ-5D for evaluation of Korean patients with type 2 diabetes

The known group construct, convergent, and discriminant validities of the EQ-5D were examined. The known group construct validity was determined by comparing the rates of reported problem pertaining to each EQ-5D dimension among different groups based on sex, age, and education. We expected the rates to be higher among women, older individuals, and less-educated patients. To evaluate the convergent and discriminant validity, we examined the correlation coefficients between the EQ-5D and the eight scale scores and two summary scores of the SF-36. Our hypothesis was a greater correlation between the SF-36 scales and the EQ-5D dimensions that represent similar characteristics (e.g., the mobility dimension of EQ-5D and the physical functioning [PF] scale of SF-36) than between less comparable scales and dimensions, such as the mobility of EQ-5D and the mental health (MH) scale of SF-36.

Statistical analysis

Student's t-tests or ANOVA and chi-square tests were performed to compare the characteristics of study participants of the first and second surveys and HRQOL on general characteristics. In addition, Student's t-test was used to examine the mean difference in SF-36 scale scores with regards to EQ-5D dimensions. Spearman's correlation coefficients were calculated between the EQ-5D and the SF-36. The agreement of problems in the EQ-5D dimension was analyzed by Cohen's kappa value. We examined the effect of each general and clinical characteristic on the HRQOL of patients with type 2 diabetes using a linear mixed model and backward eliminations were used for variable selections. Analyses were performed with PASW statistical software 18.0 (SPSS Inc., Chicago, IL, USA) with a P value < 0.05 considered statistically significant.

Ethics statement

The study protocol was approved by the institutional review board of each participating hospital (IRB No. #07-35 in the Sanggye Paik Hospital; KUH 1010058 in the Konkuk University Hospital; and IB-0709-056 in the Ilsan Paik Hospital). And informed consent was obtained from all patients.

RESULTS

General and clinical characteristics of the study participants

The characteristics of the subjects are shown in Table 1. Of the 1,072 patients with type 2 diabetes who completed the first survey, 581 (54.2%) were men. Of the 858 patients who completed the second survey 473 (55.1%) were men. The follow-up rate was 80.0%. The mean ages of the patients who completed the first and second surveys were 57.5 and 57.7 yr, respectively. Education was classified as follows (percentages in the parentheses correspond with the first and second surveys, respectively): "elementary school or below" (25.2% and 25.7%), "middle or high school" (49.6% and 49.7%), and "university or above" (25.1% and 24.6%). The mean BMI was 24.9 kg/m^2 in the first survey and 25.0 kg/m^2 in the second survey. A total of 431 (40.2%, first survey) and 338 (39.4%, second survey) patients were treated with diet therapy; 864 (80.7%) and 693 (80.8%), with oral hypoglycemic agents; and 282 (26.3%) and 234 (27.3%), with insulin therapy (including patients receiving both insulin and oral hypoglycemic agents). No significant differences in general characteristics were observed between the two groups.

Hypertension (55.3% and 55.8%) and hyperlipidemia (53.5% and 54.1%) were the most frequent comorbidities. Angina pectoris (8.3% and 8.9%) and ischemic stroke (5.6% and 6.1%) were frequent macrovascular complications. Furthermore, 23.6% and 24.4% of the patients had retinopathy and 4.6% and 7.2% of the patients had nephropathy in the first and second surveys, respectively. No significant differences were noted in the proportion of complications between the first and second surveys.

Validity

As expected in the known group construct, the HRQOL significantly differed with sex, age, and education (P < 0.01). In addi-

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tion, the EQ-5D$_{index}$ was lower in women than in men, and scores were higher in younger than in older subjects. Patients in the elementary school or below group had lower EQ-5D$_{index}$ scores than those in the middle/high school and university or above groups (Table 2).

Table 1. Characteristics of the study population

Parameters	First survey	Second survey	*P*
Number of patients	1,072	858	
Men	581 (54.2%)	473 (55.1%)	0.8
Age (yr)			
Mean ± SD	57.5 ± 12.1	57.7 ± 12.0	0.7
Minimum, maximum	23, 86	23, 86	
Education			0.9
Elementary school or below	270 (25.2%)	220 (25.7%)	
Middle or high school	531 (49.6%)	426 (49.7%)	
University or above	269 (25.1%)	211 (24.6%)	
BMI (kg/m^2)			
Mean ± SD	24.9 ± 3.5	25.0 ± 3.5	0.8
< 18.5	26 (2.4%)	21 (2.4%)	
18.5-24.9	565 (52.7%)	448 (52.2%)	
25.0-29.9	401 (37.4%)	325 (37.9%)	
≥ 30	80 (7.5%)	64 (7.5%)	1.0
Alcohol drinking	380 (35.4%)	299 (34.8%)	0.9
Current smoking	248 (23.2%)	198 (23.1%)	0.8
Treatment			
Diet	431 (40.2%)	338 (39.4%)	0.7
Oral hypoglycemic agents	864 (80.7%)	693 (80.8%)	0.9
Insulin	282 (26.3%)	234 (27.3%)	0.6
Oral hypoglycemic agents + Insulin	139 (13.0%)	117 (13.7%)	0.6
Complementary & alternative medicine	56 (5.2%)	40 (4.7%)	0.6
Clinical factors			
Hypertension	582 (55.3%)	469 (55.8%)	0.8
Hyperlipidemia	564 (53.5%)	455 (54.1%)	0.9
Myocardial infarction	50 (4.7%)	42 (5.0%)	0.7
Angina pectoris	87 (8.3%)	75 (8.9%)	0.6
Congestive heart failure	46 (4.4%)	36 (4.3%)	0.9
Atrial fibrillation	21 (2.0%)	15 (1.8%)	0.7
Ischemic stroke	60 (5.6%)	52 (6.1%)	0.7
Transient ischemic attack	18 (1.7%)	15 (1.8%)	0.9
Retinopathy	253 (23.6%)	209 (24.4%)	0.2
Cataract	253 (21.6%)	184 (21.5%)	1.0
Nephropathy	39 (4.6%)	32 (7.2%)	0.7

As results from convergent and discriminant validity analysis, most mean differences of SF-36 scale scores were statistically significant according to problem reporting of each EQ-5D dimension (Fig. 1). The difference of PF scale score in patients on mobility problem reporting (32.2), as determined using EQ-5D, was larger than the difference of MH scale scores (14.2). In addition, the difference of MH scale scores of patients on anxiety/depression of EQ-5D was 25.5, while the difference of PF scale score on problem reporting in anxiety/depression was 14.9. Table 3 showed the spearman's correlation coefficients between the EQ-5D and the SF-36. The coefficients were larger between related dimensions (e.g., -0.462 between mobility in EQ-5D and physical functioning [PF] in SF-36 and -0.652 between pain/discomfort in EQ-5D and bodily pain [BP] in SF-36) than unrelated dimensions (e.g. -0.201 between mobility in EQ-5D and mental health [MH] in SF-36).

Differences of problem rates in each EQ-5D dimension between the surveys

Some differences were found in the rates of problems, as assessed according to the EQ-5D dimensions between two surveys (Table 4). We found that 7.0% of the subjects reported a change in the self-care dimension, and 19.2% of people reported a change in the pain/discomfort dimension.

Associated factors to utility of type 2 diabetes patients

In the univariate model, most variables were significantly related with the HRQOL of Korean type 2 diabetes patients except for hyperlipidemia, MI, and nephropathy. The final multivariate model included sex, age, BMI, AF, ischemic stroke, and retinopathy (Table 5). The absolute values of β coefficients on age groups (0.025 to 0.0597) were larger than those values of sex (0.0225) and education (0.017 to 0.0289). In clinical factors, the β coefficient of AF was the largest (-0.0751) and followed by ischemic stroke (-0.0541), BMI group (0.0315 to 0.0448) and retinopathy (-0.021).

Table 2. Problems in each of the EQ-5D dimension and EQ-5D$_{index}$ according to general characteristics

Parameters	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/depression	Mean EQ-5D$_{index}$
Sex						
Male	15.5%	6.0%	13.6%	28.2%	17.9%	0.9365 (0.0046)
Female	24.8%*	10.0%*	21.6%*	42.8%*	32.4%*	0.9023 (0.0052)*
Age (yr)						
≤ 39	8.5%	2.4%	7.3%	20.7%	20.7%	0.9535 (0.0089)
40-49	9.8%	3.4%	11.2%	28.8%	25.4%	0.9349 (0.0096)
50-59	13.6%	7.0%	11.7%	31.1%	26.0%	0.9318 (0.0062)
60-69	22.3%	9.2%	21.1%	37.9%	23.2%	0.9152 (0.0059)
≥ 70	40.5%*	14.1%*	27.6%*	48.1%*	25.4%*	0.8847 (0.0092)*
Education						
Elementary school or below	31.5%	11.9%	26.7%	48.1%	30.4%	0.8913 (0.0074)
Middle or high school	17.1%	7.5%	15.8%	33.1%	24.7%	0.9235 (0.0052)
University or above	13.4%*	4.5%*	10.8%*	25.3%*	18.6%*	0.9463 (0.0051)*

Mean EQ-5D$_{index}$ data are shown as means (standard error). *$P < 0.01$.

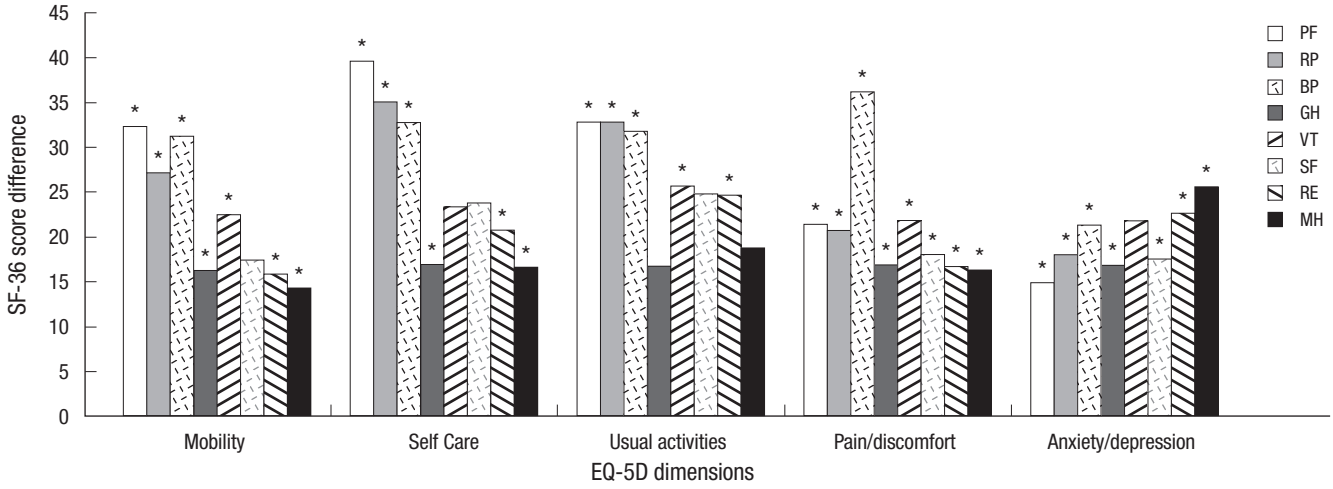

Fig. 1. Differences in eight SF-36 scales with regards to reports of "no problems" and "some or severe problems" in each EQ-5D domain. *$P < 0.05$. PF, physical functioning; RP, role-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health.

Table 3. Spearman's correlation coefficients between EQ-5D and SF-36

EQ-5D		SF-36									
		Physical functioning	Role-physical	Bodily pain	General health	Vitality	Social functioning	Role-emotional	Mental health	Physical component summary	Mental component summary
Mobility	Spearman's rho	-0.462	-0.362	-0.422	-0.276	-0.321	-0.258	-0.216	-0.201	-0.484	-0.158
	P	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Self-care	Spearman's rho	-0.340	-0.292	-0.290	-0.191	-0.227	-0.266	-0.170	-0.153	-0.338	-0.138
	P	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Usual activity	Spearman's rho	-0.440	-0.408	-0.405	-0.271	-0.346	-0.384	-0.339	-0.269	-0.442	-0.286
	P	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Pain/discomfort	Spearman's rho	-0.435	-0.388	-0.652	-0.368	-0.388	-0.394	-0.324	-0.342	-0.528	-0.312
	P	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Anxiety/depression	Spearman's rho	-0.279	-0.287	-0.333	-0.328	-0.354	-0.317	-0.395	-0.477	-0.237	-0.464
	P	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

Table 4. Respondent numbers reporting problems in EQ-5D dimensions on the first and second surveys

The first survey	The second survey		
	No problem, No (%)	Some or severe problems, No (%)	Kappa value
Mobility			
No problem	654 (76.2)	38 (4.4)	0.523*
Some or severe problems	78 (9.1)	88 (10.3)	
Self-care			
No problem	768 (89.5)	26 (3.0)	0.463*
Some or severe problems	34 (4.0)	30 (3.5)	
Usual activities			
No problem	665 (77.5)	45 (5.2)	0.537*
Some or severe problems	63 (7.3)	85 (9.9)	
Pain/discomfort			
No problem	504 (58.7)	61 (7.1)	0.557*
Some or severe problems	104 (12.1)	189 (22.0)	
Anxiety/depression			
No problem	591 (68.9)	73 (8.5)	0.484*
Some or severe problems	80 (9.3)	114 (13.3)	

*$P < 0.001$.

DISCUSSION

Our findings reveal that the EQ-5D is a useful tool measuring the HRQOL of Korean patients with type 2 diabetes. In addition, we found that comorbidities such as obesity and AF and complications such as ischemic stroke and retinopathy significantly affected the HRQOL of these patients. The sex, age and education were also important factors to HRQOL of Korean type 2 diabetes patients.

Previous studies have reported that certain medical conditions hamper the HRQOL of patients with type 2 diabetes. Redekop et al. (9) and Lee et al. (10) reported that obesity significantly reduces the HRQOL of patients with type 2 diabetes, as measured using the EQ-5D. Using the Self-Administered Quality of Well Being index, Coffey et al. (11) reported that the major complications of diabetes are associated with low HRQOL. In addition, Sakamaki et al. (6) found a negative association between the major complications of type 2 diabetes and HRQOL, but this association was statistically insignificant except in the

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Table 5. Univariate and multivariate models

Variables	Univariate model		Multivariate model	
	β (standard error)	*P*	β (standard error)	*P*
Intercept	-	-	0.8445 (0.0196)	< 0.001
Male sex	-0.0355 (0.0062)	< 0.001	-0.0225 (0.0077)	0.003
Age (yr)				
≤ 39	0.0680 (0.0133)	< 0.001	0.0597 (0.0159)	< 0.001
40-49	0.0558 (0.0102)	< 0.001	0.0375 (0.0120)	0.002
50-59	0.0472 (0.0096)	< 0.001	0.0405 (0.0111)	< 0.001
60-69	0.0261 (0.0093)	0.005	0.0250 (0.0105)	0.018
> 70	-	-	-	-
Education				
Elementary school or below	-0.0571 (0.0087)	< 0.001	-0.0289 (0.0112)	0.010
Middle or high school	-0.0220 (0.0075)	0.004	-0.0170 (0.0088)	0.053
University or above	-	-	-	-
BMI				
< 18.5	0.0271 (0.0114)	0.241	0.0416 (0.0267)	0.120
18.5-24.9	0.0309 (0.0122)	0.012	0.0448 (0.0141)	0.002
25.0-29.9	0.0229 (0.0125)	0.068	0.0315 (0.0144)	0.029
≥ 30	-	-	-	-
Hypertension	-0.0203 (0.0063)	0.001	-	-
Hyperlipidemia	-0.0107 (0.0063)	0.088	-	-
Myocardial infarction	-0.0073 (0.0148)	0.624	-	-
Angina pectoris	-0.0266 (0.0114)	0.020	-	-
Congestive heart failure	-0.0505 (0.0154)	0.001	-	-
Atrial fibrillation	-0.0757 (0.0227)	0.001	-0.0751 (0.0247)	0.002
Ischemic stroke	-0.0761 (0.0133)	< 0.001	-0.0541 (0.0149)	< 0.001
Transient ischemic attack	-0.0684 (0.0242)	0.005	-	-
Cataract	-0.0162 (0.0076)	0.034	-	-
Retinopathy	-0.0217 (0.0093)	0.019	-0.0210 (0.0090)	0.020
Nephropathy	-0.0044 (0.0167)	0.794	-	-

Data are shown as β coefficients (SEM).

case of certain subjective symptoms. The authors proposed that this finding resulted from the exclusion of patients with severe disease. Consistent with this suggestion, our patients were also recruited from outpatient clinics; hence, the impacts of comorbidities and complications on EQ-5D$_{index}$ were relatively low.

Validity was assessed in terms of three aspects, and was found to match our expectations. With regards to convergent validity, there were considerable differences in the PF, RP, BP, and SF scale scores on the SF-36 compared with subjects' scores on the EQ-5D dimensions of mobility, self-care, routine activity (i.e., all three are related to physical ability). Furthermore, there were notable correlation between BP scores of the SF-36 and pain/discomfort scores of the EQ-5D, as well as between the RE scale scores on the SF-36 and the anxiety/depression dimension of the EQ-5D. Therefore, we could conclude that the convergent validity of the EQ-5D is acceptable. The age and sex distributions of the EQ-5D$_{index}$ were also similar to expected values. Most items received lower scores in women and elderly subjects. Therefore, our data suggest that the EQ-5D could be a valid and acceptable method of evaluating the HRQOL of Korean patients with type 2 diabetes.

In this study, there were some differences in the HRQOLs of Korean patients with type 2 diabetes between the surveys. These findings show that the HRQOL is a time-dependent variable, and should be repeatedly measured in type 2 diabetic patients to ensure reliable estimations. In addition, because changes in HRQOL may have caused patients to discontinue follow-up, the actual change in HRQOL may have been greater than estimated in the current study.

There are three valuation sets for the Korean version of the EQ-5D. We used the valuation set reported by Jo et al. (8) because this set was calculated from general populations in Seoul and Gyeonggi province. Although we did not represent the results using the other valuation sets (12-14) in this paper, the coefficients in the models differ according to the valuation sets. These findings indicate that valuation sets could affect the results of utility studies; so sensitivity analyses should be conducted using data from other Korean studies.

This study has limitation in terms of the representativeness of the study population because we did not randomly recruit study participants. However, our study population was derived from three institutes in diverse regions. Also, the mean age and sex distributions of our patients were similar to those in previous population-oriented utilization studies of patients with diabetes in Korea (15).

In conclusion, our findings suggest that EQ-5D is a valid tool

for measuring the HRQOL of Korean patients with type 2 diabetes. In the final model for utility-weight prediction, BMI, hypertension, angina pectoris, CHF, AF, stroke, TIA, and retinopathy negatively affected the HRQOL of Korean patients with type 2 diabetes.

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