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

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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...
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. 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. 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/m² in the first survey and 25.0 kg/m² 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-
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           | 0.8   |
| Men                            | 581 (54.2%)  | 473 (55.1%)   |       |
| 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).

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 (0.0092)     |
| 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.
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 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         |
|                   | P                      |
|                   | -0.462                 |
|                   | < 0.001                |
|                   | -0.362                 |
|                   | < 0.001                |
|                   | -0.422                 |
|                   | < 0.001                |
|                   | -0.276                 |
|                   | < 0.001                |
|                   | -0.321                 |
|                   | < 0.001                |
|                   | -0.258                 |
|                   | < 0.001                |
|                   | -0.216                 |
|                   | < 0.001                |
|                   | -0.201                 |
|                   | < 0.001                |
|                   | -0.484                 |
|                   | < 0.001                |
|                   | -0.158                 |
| Self-care         | Spearman’s rho         |
|                   | P                      |
|                   | -0.340                 |
|                   | < 0.001                |
|                   | -0.292                 |
|                   | < 0.001                |
|                   | -0.290                 |
|                   | < 0.001                |
|                   | -0.191                 |
|                   | < 0.001                |
|                   | -0.227                 |
|                   | < 0.001                |
|                   | -0.266                 |
|                   | < 0.001                |
|                   | -0.170                 |
|                   | < 0.001                |
|                   | -0.153                 |
|                   | < 0.001                |
|                   | -0.338                 |
|                   | < 0.001                |
|                   | -0.138                 |
| Usual activity    | Spearman’s rho         |
|                   | P                      |
|                   | -0.440                 |
|                   | < 0.001                |
|                   | -0.408                 |
|                   | < 0.001                |
|                   | -0.405                 |
|                   | < 0.001                |
|                   | -0.271                 |
|                   | < 0.001                |
|                   | -0.346                 |
|                   | < 0.001                |
|                   | -0.384                 |
|                   | < 0.001                |
|                   | -0.339                 |
|                   | < 0.001                |
|                   | -0.269                 |
|                   | < 0.001                |
|                   | -0.442                 |
|                   | < 0.001                |
|                   | -0.286                 |
| Pain/discomfort   | Spearman’s rho         |
|                   | P                      |
|                   | -0.435                 |
|                   | < 0.001                |
|                   | -0.388                 |
|                   | < 0.001                |
|                   | -0.652                 |
|                   | < 0.001                |
|                   | -0.368                 |
|                   | < 0.001                |
|                   | -0.388                 |
|                   | < 0.001                |
|                   | -0.394                 |
|                   | < 0.001                |
|                   | -0.324                 |
|                   | < 0.001                |
|                   | -0.342                 |
|                   | < 0.001                |
| Anxiety/depression| Spearman’s rho         |
|                   | P                      |
|                   | -0.279                 |
|                   | < 0.001                |
|                   | -0.287                 |
|                   | < 0.001                |
|                   | -0.333                 |
|                   | < 0.001                |
|                   | -0.328                 |
|                   | < 0.001                |
|                   | -0.354                 |
|                   | < 0.001                |
|                   | -0.317                 |
|                   | < 0.001                |
|                   | -0.395                 |
|                   | < 0.001                |
|                   | -0.477                 |
|                   | < 0.001                |
|                   | -0.237                 |
|                   | < 0.001                |
|                   | -0.464                 |

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

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

*P<0.001.
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

| 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          | -0.0229 (0.0077)  | 0.003          |
| Age (yr)  |                 |                  |                   |                |
| < 39      | 0.0690 (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).
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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