Preparation of a Quality of Life (QOL) Questionnaire for Patients with Type II Diabetes and Prospects for Its Clinical Application

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Original Article

Preparation of a Quality of Life (QOL) Questionnaire for Patients with Type II Diabetes and Prospects for Its Clinical Application

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Abstract Modification of the lifestyle centering on dietary therapy has been proven to be effective for the treatment of diabetes mellitus, which is increasing progressively. However, lifetime treatment for diabetes inevitably puts economic as well as physical and mental burdens on the patients, and many patients drop out by discontinuing or neglecting treatment, promoting exacerbation of the condition. In this study, an original “Quality of life (QOL) questionnaire for patients with type II diabetes” using a visual analogue scale was tentatively prepared. To evaluate the reliability and validity of this questionnaire, 126 patients (64 males and 62 females) being treated as outpatients or inpatients at 8 university or public hospitals in Fukuoka Prefecture were selected at random, and valid answers from 73 patients were analyzed. From the 46 questions, those in which no significant correlation was observed or which were not answered by many patients were excluded. Since the value of sampling adequacy was 0.673 according to the Kaiser–Meyer–Olkin (KMO) measure, the sampling adequacy is considered to have been average. When factor analysis by varimax rotation was performed using the Statistical Package for Social Science, 4 factors consisting of 18 question items were extracted. Eventually, these 4 factors of 18 questions were adopted for the QOL questionnaire for patients with type II diabetes. The alpha values of the 4 factors were high at 0.867, 0.795, 0.706, and 0.756. These results confirmed the internal consistency of the questionnaire and sufficient reliability of this analytical method.

Introduction

Improvements in the lifestyle, particularly the control of the dietary intake and modification of the dietary habit, are important for the treatment of diabetic patients1)–3). However, in chronic diseases such as diabetes mellitus, which require lifetime treatment, patients must bear not only physical and mental but also economic burdens. For this reason, many patients discontinue or neglect treatment with consequent further exacerbation of the condition1)–3). They cannot escape from this vicious cycle and often drop out from treatment.

Improvements in lifestyle are well-known to be a key for successful management of diabetes mellitus. Actually, however, improvements in lifestyle are not attained as expected. For a more rigid compliance to dietary therapy, it is indispensable to sufficiently clarify the background including the state of daily living of individual
patients and to maintain the quality of life (QOL) along with the physical condition as adequate a level as possible. However, a majority of the reports on the QOL of diabetic patients have been from Western countries\(^6\), and no QOL questionnaire of established usefulness that takes the Japanese lifestyle into consideration is presently available. This study was performed to prepare a questionnaire that allows the evaluation of the QOL of patients with type II diabetes and to examine its reliability.

**Materials and Methods**

1. **Preparation of questionnaire**

Internationally applicable QOL questionnaires concerning type II diabetes are in English, and there is no questionnaire with established reliability in Japanese. However, English questionnaires cannot be translated for Japanese subjects because of copyright problems. For these reasons, we prepared our original questionnaire by the following method.

1) Selection and extraction of questions

Words appropriate as key words concerning the QOL of diabetic patients were selected from the records of inquiries and contents of examinations and treatments in the charts, and all of them were extracted without minding duplication of expressions. All duplicated items were adopted for the preparation of questions. Questions that were lacking were supplemented from the literature\(^6\)\(^-\)\(^8\). As a result, we prepared our original “Quality of life (QOL) questionnaire for patients with type II diabetes” consisting of 46 questions (Table 1).

(2) Preparation of the answer sheet and execution of the questionnaire

To increase the precision of assessment of the QOL, a visual analogue scale, which allows continuous rating, was employed rather than a graded scale.

(a) Answering method: The subjects evaluated the degree of fitting of their conditions to the content of each question and expressed them by checking a point on a 10-cm horizontal line in the questionnaire (Fig. 1). The subjects were requested to make judgments intuitively and answer promptly.

(b) Measurement method: The distance from the left end of the line (dissatisfied) to the point of the check was measured, and the percentage of the distance relative to the entire length of the line was regarded as

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**Fig. 1** Quality of life questionnaire for patients with type II diabetes and answering method.

Each patient checks the above 10-cm horizontal line at the point representing his/her present state. In this example, the distance from the left end of the line to the location of the check is 3.25 cm, and the degree of satisfaction with sleep is judged to be 32.5%. The patients were asked to make intuitive judgments and promptly answer each questions.
the degree of satisfaction.

2. Execution of the questionnaire

The questionnaire was performed in inpatients and outpatients with type II diabetes by cooperating nutritionists at 8 university or public hospitals in Fukuoka Prefecture.

(1) Investigation period and subjects

This questionnaire was performed over a period of about 3.5 months from August 20 to November 30, 2003 in 126 patients (64 males and 62 females) with type II diabetes treated as inpatients or outpatients at 8 university or public hospitals in Fukuoka Prefecture. The subjects were collected with a selection criterion of “patients with type II diabetes who had few opportunities of education or guidance”, and the answers of 73 patients (39 males and 34 females; their mean age, 55.7±11.1) who answered
all questions were analyzed. All the enrolled subjects gave written informed consent to verify their voluntary participation in the study in accordance with the second Helsinki Declaration. In addition, they were indicated to insert their answered QOL questionnaire into an envelope to protect their individual information from its leakage. None of them was requested to fulfill the questionnaire again after they sent the envelop to nutritionists because the response to the questionnaire was kept reliable. The patients were considered to have complications if they had any diabetic microangiopathy or macroangiopathy, together with serum data including HbA1c, insulin and lipids.

(2) Basic information of patients and the methods to answer the questionnaire

The nutritionists at the 8 universities or public hospitals in Fukuoka Prefecture took background profiles of fixed items from the subjects themselves. The items were as follows: date of the profile compiled, gender, age, height, weight, body mass index, presence of complications, choice of 3 major therapies presently given, i.e., dietary therapy alone, oral hypoglycemic medications, insulin injection.

3. Statistical analysis

The questionnaire fulfilled was extracted from the answers by the following methods.

(1) Factor analysis

Before factor analysis, the correlation coefficient between [the score of each item] and [the sum of the scores of all items - the score of each item] was calculated to examine the internal consistency of each question. The sampling adequacy was examined by calculating the Kaiser-Meyer-Olkin (KMO) value. The KMO value is an index for the comparison between the observed correlation coefficient and partial correlation coefficient. The KMO value was calculated as ∑Σr_{ij}/(∑Σr_{ij}+∑Σa_{ij}) (r_{ij} is the simple correlation coefficient between the variables i and j, and a_{ij} is the partial correlation coefficient between the variables i and j). The sampling adequacy was evaluated using the KMO value. The sampling adequacy is evaluate to be excellent when the KMO value is ≥0.90, good when 0.90 > KMO value ≥ 0.80, moderate when 0.80 > KMO value ≥ 0.70, average when 0.70 > KMO value ≥ 0.60, poor when 0.60 > KMO value ≥ 0.50, and unacceptable when the KMO value is < 0.50.

To extract factors from the questionnaire used in this study, factor analysis was performed using the maximum likelihood method and varimax rotation. To determine the number of factors, a scree plot of the intrinsic values along the vertical axis and factor numbers along the horizontal axis was prepared (Fig. 2). Factors were adopted serially from the first factor to the one before the factor that showed a scree.

(2) Confirmation of the reliability of each factor

Cronbach's alpha was calculated to analyze the reliability of each factor. Alpha was calculated as K × r/(1+(K−1)×r) (K is the number of variables contained in the factor ; r is the mean correlation coefficient among the variables).

All data were expressed as the mean± standard deviation. The Statistical Package for Social Science (SPSS) was used for statistical analyses. The significance level was p<0.05 on two-tailed tests.
Results

1. Therapeutic background factors of the subjects

Of the subjects, 18 (24.7%) received dietary therapy, 39 (53.4%) received oral anti-hyperglycemic medication, and 16 (21.9%) received insulin therapy. Complications were noted in 45 patients (61.6%), being absent in 28 (38.4%). The mean BMI was 24.8±5.0 kg/m², and a low body weight was observed in 5 (7%), normal body weight in 36 (49%), grade 1 obesity in 20 (28%), grade 2 obesity in 9 (12%), and grade 3 obesity in 3 (4%) according to the criteria for obesity disease by Japan Society for the Study of Obesity. Most patients belonged to the categories of normal weight and grade 1 obesity.

2. Analysis of the items of the QOL questionnaire

As a result of evaluation of the internal consistency of the question items, no significant correlation was noted in Q3 and Q31 (Table 1), and the number of respondents was insufficient concerning Q3, Q10, Q25, Q36, Q37, Q38, and Q40, so that these were excluded from the analysis. In the remaining 38 items, a significant correlation (p<0.05) was observed with a correlation coefficient of r = 0.268–0.685, and the internal consistency was confirmed (Table 2). When the KMO value, which is an index of sampling adequacy, was calculated concerning the 38 items, it was 0.673, and the sampling adequacy was judged to be average.

3. Factor analysis and determination of factors for the preparation of the QOL questionnaire

Concerning the 38 items in which the sampling adequacy was confirmed, factor analysis was performed using the maximum likelihood method and varimax rotation. A scree plot was prepared to determine the number of factors. Since the angle of the slope between the 4th and 5th factors was larger than those of the preceding or following interval, the number of factors was determined as 4 (Fig. 2). Factors with an absolute value of factor loading of 0.5 or greater were selected in the order of decreasing factor loading, 5 items each were selected for the 1st and 2nd factors, and 4 items each for the 3rd and 4th factors (Table 3). In consideration of the characteristics of the extracted factors, the 1st to 4th factors were named “degree of apprehension”, “degree of distress”, “degree of satisfaction with life”, and “degree of satisfaction with treatments”, respectively (Table 2).

4. Evaluation of the reliability of each factor

Cronbach’s alpha was calculated to examine the reliability of each factor. It was 0.867 for the 1st factor (degree of apprehension), 0.795 for the 2nd factor (degree of distress), 0.706 for the 3rd factor (degree of
satisfaction with life), and 0.756 for the 4th factor (degree of satisfaction with treatments) (Table 2). Therefore, each factor was found to have high internal consistency and to be reliable.

Discussion

For accurate evaluation of the QOL, which is related to the treatment of diabetic patients, the dietary habit and characteristics of preferences of each patient based on the dietary culture, living environment, and values in living must be sufficiently taken into consideration\textsuperscript{11-31}. To prepare a questionnaire suited for this purpose, we prepared question items by referring to the literature for the methodology\textsuperscript{13}) and reviewing clinical records for responses of patients with type II diabetes to treatments.

In conventional questionnaires, graded scales such as “I always think so”, “I think so”, “I occasionally think so”, and “I do not think so” are commonly used. The greatest problem with this answering method is that the grades are not continuous, and it causes inevitable limitations in the assessment of the patients’ QOL. In this study, a continuous scale was adopted to avoid this problem and to increase the precision of the evaluation of the QQL. By this method, the patients expressed the degree of agreement or disagreement with each question item by checking at an appropriate point on a 10-cm horizontal line, allowing continuous representation of their responses as a percentage.

To prepare a “QOL questionnaire for patients with type II diabetes”, we evaluated each question item as a factor. The KMO value was calculated for factor analysis\textsuperscript{16}). One objective of factor analysis is to determine factors useful for the explanation of the correlation matrix of the variable (scores of the questionnaire). The factors must be interrelated to make the factor model appropriate. If the correlation among the variables is small, the possibility that these variables have a common factor is

<table>
<thead>
<tr>
<th>Name of factor</th>
<th>Question item</th>
<th>Factor loading</th>
<th>Alpha value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st factor (Degree of Apprehension)</td>
<td>Q46 Do you ever worry that others may mind going out with you due to diabetes?</td>
<td>0.785</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q44 Do you ever worry that your body appears different compared with others</td>
<td>0.761</td>
<td></td>
</tr>
<tr>
<td></td>
<td>due to diabetes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q43 Do you ever worry that you may lose consciousness?</td>
<td>0.746</td>
<td>0.867</td>
</tr>
<tr>
<td></td>
<td>Q26 Do you have any problem in driving a car or operating machinery due to</td>
<td>0.712</td>
<td></td>
</tr>
<tr>
<td></td>
<td>diabetes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q27 Do you have any difficulty in exercising due to diabetes?</td>
<td>0.685</td>
<td></td>
</tr>
<tr>
<td>2nd factor (Degree of Distress)</td>
<td>Q29 Do you ever feel anxiety over the future due to diabetes?</td>
<td>0.793</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q45 Do you ever worry about developing complications of diabetes?</td>
<td>0.759</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q30 Is your leisure time or are your pastimes restricted due to diabetes?</td>
<td>0.498</td>
<td>0.795</td>
</tr>
<tr>
<td></td>
<td>Q16 Do you ever feel the treatment for diabetes to be distressing?</td>
<td>0.492</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q19 Do you ever feel you are in poor health?</td>
<td>0.480</td>
<td></td>
</tr>
<tr>
<td>3rd factor (Degree of Satisfaction with life)</td>
<td>Q15 Are you satisfied with your daily life?</td>
<td>0.965</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q14 Are you satisfied with your leisure time and pastimes?</td>
<td>0.758</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q23 Are you satisfied with yourself?</td>
<td>0.650</td>
<td>0.706</td>
</tr>
<tr>
<td></td>
<td>Q11 Are you satisfied with your daily life including work, study, and house</td>
<td>0.676</td>
<td></td>
</tr>
<tr>
<td></td>
<td>work?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4th factor (Degree of Satisfaction with Treatments)</td>
<td>Q4 Are you satisfied with the treatments you are receiving now?</td>
<td>0.804</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q1 Are you dissatisfied with the time needed for the treatment of diabetes?</td>
<td>0.623</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q2 Are you dissatisfied with the time needed to visit the hospital for the</td>
<td>0.574</td>
<td>0.756</td>
</tr>
<tr>
<td></td>
<td>treatment of diabetes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Q5 Are you satisfied with the dietary therapy you are undergoing?</td>
<td>0.520</td>
<td></td>
</tr>
</tbody>
</table>
small. The KMO value is an index of the strength of the relationship among variables and a means to evaluate whether the samples are appropriate for factor analysis. For this reason, we evaluated the sampling adequacy according to the KMO value. The KMO value approaches 1 as the partial correlation coefficient is smaller, i.e., as the variable is more closely related to other variables, and the samples are judged to be adequate when this value is high. Since the KMO value was 0.673 in this study, the sampling adequacy is considered to have been average.

As a result of factor analysis, 4 factors consisting of 18 question items were extracted and classified. The 5 questions included in the 1st factor, “degree of apprehension”, are considered to represent vague mental anxiety or burden, 5 items included in the 2nd factor, “degree of distress”, to represent restrictions of life and discomfort caused by the occurrence of diabetes mellitus, 4 items included in the 3rd factor, “degree of satisfaction with life”, to represent the degree of satisfaction with overall daily living, and 4 items included in the 4th factor, “degree of satisfaction with treatments”, to represent the degree of satisfaction with overall treatment for diabetes.

Since Cronbach’s alpha is interpreted to be a correlation coefficient, its value can be 0–1. The reliability is judged to be higher as the alpha value is closer to 1. The alpha value was 0.7 or higher in all 4 factors. These results established the internal consistency of the factors and reliability of this analytical method. From these results, the QOL perceived by patients during treatment for diabetes mellitus is considered to be represented as the contents (quality) and frequency (quantity) of the dietary habit and preferences and concepts and values of life of each patient, and these 4 factors consisting of 18 questions were confirmed to be useful for precise evaluation of the QOL.

The St Vincent Declaration\textsuperscript{(4)} issued in 1989 mentioned qualitatively and quantitatively ideal lives of diabetic patients as well as prevention of complications as a goal of anti–diabetic treatment. One–way dietary guidance by the therapist is insufficient for the lifetime treatment of diabetes mellitus. This declaration suggests the importance of maintaining the QOL of patients at a comfortable level by sufficiently understanding their daily living and social background as well as the degree of physical disabilities. Attention must be paid to many points for the preparation of a QOL questionnaire, but the appropriateness of the questionnaire depends on measures to carefully reflect background information of individuals. However, a difficult problem, i.e., how to secure the universality, emerges here. As individual information is incorporated into greater detail, the universality of the QOL assessment deteriorates. In fact, we avoided adoption of QOL question items used overseas as much as possible. To solve this contradiction in the preparation of a QOL questionnaire, a large–scale survey must be performed in Japan first by integrating individual background factors (sex, age, occupation, income, etc.) and clinical findings (duration of diabetes, clinical findings, treatment type, severity of complications, etc.) of patients. Moreover, such a survey is indispensable for revising the QOL questionnaire to make it applicable also to foreign countries.

Acknowledgments

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Chief Technician of the Department of Nutrition, Fukuoka University Hospital; Director Suiko Tanaka and Assistant Vice-Director Masako Iwasaki, Department of Nutrition, Kurume University Hospital; Nutritionist Yoshimi Makiyama of Kyushu University Hospital; Keiko Watanabe, Chief of the Department of Nutritional Management, Kyushu Chuo Hospital of the Public School Mutual Aid Association; Taeko Ishii, Director of the Nutritional Section, Saiseikai Fukuoka General Hospital, Keiko Tomioka, Director of the Nutritional Section, Saiseikai Futsukaichi Hospital; and Yoshimi Adachi, Director of the Nutritional Section, and Nutritionist Miho Omura, Chihaya Hospital of the Federation of National Public Servants’ Mutual Aid Associations. Mare Tsukano, Graduate student in Nakamura Gakuen University at the time of this study, cooperated in the preparation of the QOL questionnaire. We express our sincere gratitude to all of them.

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2 型糖尿病を対象にした生活の質 (QOL) 質問表の
作成とその臨床応用への展望

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年々増加の一途を辿っている糖尿病患者の治療は、食事療法を中心とした生活習慣の改善が有効
と実証されている。しかし、生涯にわたる治療は患者の肉体的および精神的苦痛、さらには経済的
負担を余儀なくし、治療中断や放置等のために脱落患者が多発する。その結果として病状悪化が助
長される。本研究では連続表記法を用い独自な「2 型糖尿病のための quality of life (QOL) 質問
表」を試作した。同質問表の信頼性ならびに妥当性を検討する目的で、福岡県内の大学病院および
公的病院 8 ケ所に入院および通院中の 2 型糖尿病患者 126 名（男性 64 名、女性 62 名）を無作為に
抽出し、有効回答が得られた 73 名を対象に解析した。有意相関の認められない、ないし是無回答の
多かった質問項目は 46 質問項目から除外した。標準の妥当性を Kaiser–Meyer–Olkin (KMO) の
適切性基準で検討した結果、測定値 0.673 と算出されたので“並び”の妥当性が得られたと判定
した。統計処理パッケージ Statistical Package for Social Science を用い varimax 回転による因
子分析を行ったところ、18 質問項目からなる 4 因子が抽出された。最終的にはこの 4 因子 18 質問項
目を 2 型糖尿病のための QOL 質問表として採用した。各 4 因子の alpha 係数は 0.867, 0.795, 0.706,
0.756 と高値を占めた、この結果から内部整合性が確認され、本解析法の信頼性は十分に確保
できた。