Psychiatry and Clinical Neurosciences (2007), **61**, 112–119 doi:10.1111/j.1440-1819.2007.01619.x

Regular Article

Reliability and validity of the Japanese version of the World Health Organization-Five Well-Being Index in the context of detecting depression in diabetic patients

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Abstract The present study had two aims. The first was to evaluate the reliability and the validity of the Japanese version of the World Health Organization (WHO)-Five Well-Being Index (WHO-5-J) as a brief well-being scale. The second was to examine the discriminatory validity of this test as a screening tool for current depressive episodes in diabetic patients. A sample of 129 diabetic patients completed the WHO-5-J. Of these, 65 were also interviewed by psychiatrists to assess whether they had any current depressive episodes according to DSM-IV. The internal consistency was evaluated using Cronbach's alpha, the Loevinger coefficient of homogeneity, and factor analysis. The external concurrent validity was evaluated by correlations with the external scales potentially related to subjective well-being. Discriminatory validity was evaluated using receiver operating characteristic (ROC) analysis. Cronbach's alpha and the Loevinger coefficient were estimated to be 0.89 and 0.65, respectively. A factor analysis identified only one factor. The WHO-5-J was significantly correlated with a number of major diabetic complications, depression, anxiety, and subjective quality of life. ROC analysis showed that the WHO-5-J can be used to detect a current depressive episode (area under curve: 0.92; 95% confidence interval: 0.85–0.98). A cut-off of <13 yielded the best sensitivity/specificity trade-off: sensitivity, 100%; specificity, 78%. The WHO-5-J was thus found to have a sufficient reliability and validity, indicating that it is a useful instrument for detecting current depressive episodes in diabetic patients.

Key words depressive episode, diabetes, screening, validity, well-being.

INTRODUCTION

There is a high prevalence of depression among patients with diabetes.[1] Recent studies suggest that depression has a significantly adverse effect on diabetes in terms of decreased glycemic control, a reduction in the quality of life, and an increased health-care expenditure.[2] However, depression frequently goes undetected and it remains untreated.[3] It has been demonstrated that primary care patients with major or minor depressive disorders respond well to psychotherapy and/or treatment with antidepressants.[4,5] Therefore, a brief and rapid instrument for detecting depression in primary care settings may play an important role in the improvement of diabetes care.

One candidate for such an instrument is the World Health Organization (WHO)-Five Well-Being Index (WHO-5). It is a short version of the WHO Well-Being Scale, which was initially developed to evaluate the quality of care for diabetic patients.[6,7] The WHO-5 is a self-administered five-item scale. Each item assesses

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Received 16 June 2006; revised 1 September 2006; accepted 9 September 2006.

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the degree of positive well-being during the past 2 weeks on a six-point Likert scale graded from 0 (at no time) to 5 (all of the time), and the total score ranges from 0 to 25, with high scores thereby indicating an increased sense of well-being. The scale has been translated into various languages (http://www.who-5.org/) and, in the West, validation data have been published in the context of various health conditions, including depressive disorders,[8–11] anxiety disorders,[8] cognitive impairment and dementia,[12] and psychiatric disorders,[12] in addition to the health-related quality of life.[13] Discriminatory validity as a screening tool for depressive disorders has also been examined.[9–11] However, no validation data have yet been published in the East, including Japan.

The present study had two aims: to evaluate the reliability and validity of the Japanese version of the WHO-5 (WHO-5-J) as a brief well-being scale, and to examine its discriminatory validity as a screening tool for a current depressive episodes in diabetic patients.

METHODS

Adaptation of the WHO-5 for use in Japan

Using a state-of-the-art procedure for test translation,[14] the original English version of the WHO-5 was adapted to Japanese in collaboration with the European WHO office as follows: two independent forward- and two independent back-translations, linguistic panels, pilot testing, and formal assessment of the reliability and validity of the index.

The WHO-5 was translated into Japanese by two bilingual translators who worked independently to produce two different Japanese versions. These versions were then back-translated and discussed by a panel of experts until agreement was reached on the most suitable items to be included in the final version. The final version was tested in a pilot study, which confirmed a high level of item acceptability and comprehension. The data regarding the reliability and validity are shown in the present study. The WHO-5-J can be obtained from the website http://www.who-5.org.

Subjects

The participants were recruited from 197 outpatients with diabetes who received regular treatment at the Diabetes and Metabolism Unit, Tohoku University Hospital. All patients had been diagnosed to have either type 1 or type 2 diabetes mellitus according to the criteria of the American Diabetes Association.[15] Of these patients, a total of 129 were regarded as eligible for the study. These consisted of 71 men and 58 women who gave their written informed consent, had no explicit dementia (Mini-Mental State ≥ 20), and completed the WHO-5-J as well as a set of questionnaires concerning demographic, social, and health-related variables. The most recent clinical data regarding diabetes were collected from the patients' medical records. All data collection was completed in November 2004. Subject characteristics are given in Table 1.

Approval of the research protocol was obtained from the Ethics Committee of Tohoku University Graduate School of Medicine and Tohoku University Hospital.

Table 1. Description of the 129 diabetic patients who completed the WHO-5-J

Variables	Mean ± SD	Range
Age (years)	53.6 ± 10.4	25–73
Sex (Female %)	45.0	
Educational level (years)	19.8 ± 3.2	15–34
Type of diabetes (Type 1%)	16.3	
Use of insulin (%)	55.8	
Duration of diabetes (years)	10.9 ± 10.2	0.1–40
FBS (mg/dL)	149.3 ± 50.5	66.0–503.0
HbA1c (%)	7.0 ± 1.4	4.0–12.0
BMI (g/cm^2)	24.5 ± 4.4	17.0–47.2
Major complication (%)	43.4	
Neuropathy (%)	24.8	
Retinopathy (%)	30.2	
Nephropathy (%)	13.2	
No. complications		
0	56.6	
1	25.6	
2	10.9	
3	7.0	
SDS score	37.6 ± 9.6	22–63
STAI score, state	39.6 ± 10.6	20–67
STAI score, trait	41.5 ± 11.9	21–74
MMSE score	28.2 ± 2.1	20–30
SF-36 subscale		
Physical functioning	82.3 ± 21.2	0–100
Social functioning	83.2 ± 22.9	12.5–100
Role functioning, physical	76.8 ± 37.6	0–100
Role functioning, emotional	78.1 ± 38.4	0–100
Mental health	70.2 ± 21.7	4–100
Vitality	62.9 ± 22.9	5–100
Pain	71.8 ± 25.8	0–100
General health perceptions	49.7 ± 21.0	0–97
WHO-5-J score	15.5 ± 6.1	0–25

BMI, body mass index; FBS, fasting blood sugar; HbA1c, hemoglobin A1c; MMSE, Mini-Mental State Examination; SDS, Zung's Self-Rating Depression Scale; SF-39, Short-Form 36 Health Survey questionnaire; STAI, State–Trait Anxiety Inventory; WHO-5-J, Japanese version of the World Health Organization-Five Well-Being Index.

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Measurements

Sociodemographic variables included sex, age, and educational level. Educational levels were assessed by determining the age when schooling was completed. The assessed clinical variables regarding diabetes included the type of diabetes, the duration of diabetes, fasting blood sugar (FBS), glucosylated hemoglobin (HbA1c), body mass index (BMI), and major diabetic complications (retinopathy, neuropathy, and nephropathy).

Zung's Self-Rating Depression Scale (SDS),[16] the State-Trait Anxiety Inventory (STAI),[17] the Mini-Mental State Examination (MMSE),[18] and the Short-Form 36 Health Survey questionnaire (SF-36)[19] were all used as external scales that were potentially related to subjective well-being.

The SDS is an internationally used 20-item self-administered depression scale. Each item is rated on a four-point Likert scale, with a total score ranging from 20 to 80 and high scores indicating increased depression. The Japanese version was developed by Fukuda and Kobayashi[20] and has been well validated by Kitamura *et al*.[21] The STAI comprises 20-item trait and 20-item state anxiety scales. Each item is rated on the four-point Likert scale, with a total score ranging from 20 to 80 for each scale and high scores indicating increased anxiety. The Japanese version was validated by Nakazato and Mizuguchi.[22] The MMSE is a brief test of several cognitive functions, with a total score ranging from 0 to 30. A score of 23 or less indicates a cognitive disorder and has a high degree of validity and reliability in detecting cognitive impairment.[18] The Japanese version was validated by Mori *et al*.[23] The SF-36 consists of eight subscales for subjective health-related quality of life, with scores on each subscale ranging from 0 to 100 and high scores indicating a high quality of life. The Japanese version was developed and validated by Fukuhara *et al*.[24,25] and is widely used in studies on health-related quality of life among Japanese populations.

Subjects with SDS scores ≥40 were selected to undergo an interview with psychiatrists, who were blind to the results of the questionnaires, in order to diagnose any current major or minor depressive episodes using the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I).[26] The Japanese version of SCID-I was developed by Takahashi.[27] Minor depressive episodes were defined as clinically relevant depressive syndromes, not fulfilling the rigorous diagnostic criteria for major depressive episode, but containing two–four symptoms of DSM-IV-defined major depressive episode, one of which must be either a depressed mood or anhedonia (loss of interest or pleasure). Almost the same number of subjects who scored <40 on the SDS were recruited to undergo the same interview.

Statistics

For the evaluation of internal consistency, Cronbach's alpha, the Loevinger coefficient, and a factor analysis were used. Cronbach's alpha is a measure of how well the subsets of the items can be substituted for each other. A high alpha (>0.9) may suggest a high level of item redundancy; therefore, alpha should fall within the range 0.7–0.9. The Loevinger coefficient of homogeneity was used as part of the Mokken analysis.[28] The Loevinger coefficient is an analysis of unidimensionality that tests the extent to which an extra item fits into the structure established by the other items of a scale. According to the Mokken analysis, homogeneity and unidimensionality are acceptable at a Loevinger coefficient of ≥0.40, while a coefficient of 0.30–0.39 is considered to be barely acceptable.[28]

The Loevinger coefficient is thought to be a better indicator of internal consistency than Cronbach's alpha because, in contrast to Cronbach's alpha, it is independent of the number of items in the scale.[7,29] A factor analysis was performed as a standard principal component analysis with orthogonal varimax rotation of the components. If a substantial shift between the first and the second eigenvalues could be observed, then unidimensionality is indicated.[30]

To evaluate the external concurrent validity, the Spearman correlation coefficient was used to correlate the WHO-5-J with health-related variables potentially related to subjective well-being. For the evaluation of discriminatory validity as a screening tool for current depressive episodes, the area under the curve (AUC), sensitivity, and specificity were calculated using a receiver operating characteristic (ROC) analysis. To evaluate the post-test probability, the positive predictive value (PPV) and negative predictive value (NPV) were calculated using a 2×2 contingency table. For group comparisons, Student's *t*-test, the Wilcoxon *U*-test, or χ^2 test were used where applicable. All statistical analyses were performed using SPSS version 11.5 (SPSS, Chicago, IL, USA) and the SAS system, version 9.1.3 (SAS Institute, Cary, NC, USA). Statistical significance was established at $P = 0.05$.

RESULTS

Internal consistency

Cronbach's alpha was found to be 0.89 and the Loevinger coefficient of homogeneity was 0.65. A factor

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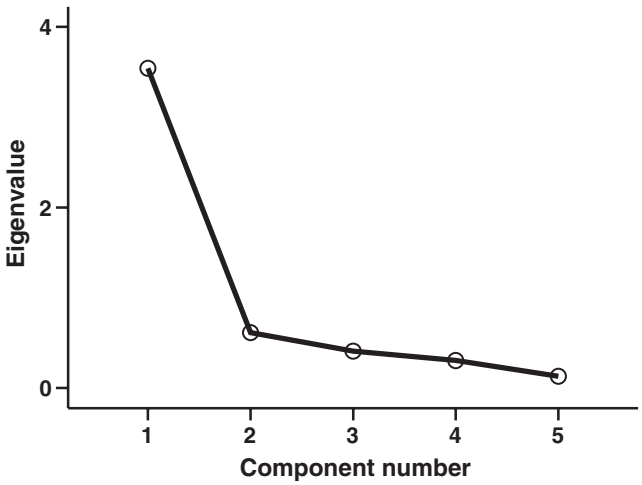

Figure 1. Scree plot for the components of the Japanese version of the World Health Organization-Five Well-Being Index.

Table 2. Factor matrix of the Japanese version of the WHO-5

Item		Factor
Item 1	I have felt cheerful and in good spirits	0.91
Item 2	I have felt calm and relaxed	0.91
Item 3	I have felt active and vigorous	0.83
Item 4	I woke up feeling fresh and rested	0.80
Item 5	My daily life has been filled with things that interest me	0.74

WHO, World Health Organization.
Principle component analysis was used.

analysis identified only one factor when considering eigenvalues >1.0 (Fig. 1, Table 2). The first factor explained 70.8% of the variance. These findings thus indicate that the WHO-5-J has an adequate internal consistency and that the total score has a sufficient degree of statistical validity.

External concurrent validity

No significant differences in the WHO-5-J total scores were observed between the male and female subjects (male *vs* female [mean ± SD], 15.8 ± 6.0 *vs* 15.1 ± 6.3, $t = 0.59$, $P = 0.57$). Neither type of diabetes (type 1 *vs* type 2, 13.9 ± 5.1 *vs* 15.8 ± 6.3, $t = 0.46$, $P = 0.14$) nor status of insulin use (use *vs* no use, 15.9 ± 6.0 *vs* 15.1 ± 6.2, $t = 0.73$, $P = 0.47$) made differences in the WHO-5-J. Table 3 shows correlations between the WHO-5-J and the demographic and health-related variables potentially related to subjective well-being.

Table 3. Correlations between the WHO-5-J and external scales related to subjective well-being

	Spearman correlation coefficients	*P*
Age	0.23	0.01
Education level	0.03	0.77
Duration of diabetes	0.10	0.24
FBS	–0.01	0.88
HbA1c	0.03	0.78
BMI	–0.10	0.25
Number of major complications	–0.21	0.02
SDS score	–0.68	0.00
STAI score, state	–0.73	0.00
STAI score, trait	–0.74	0.00
MMS score	0.11	0.21
SF-36 subscale		
Physical functioning	0.43	0.00
Social functioning	0.40	0.00
Role functioning, physical	0.43	0.00
Role functioning, emotional	0.51	0.00
Mental health	0.70	0.00
Vitality	0.72	0.00
Pain	0.39	0.00
General health perceptions	0.43	0.00

BMI, body mass index; FBS, fasting blood sugar; HbA1c, hemoglobin A1c; MMSE, Mini-Mental State Examination; SDS, Zung's Self-Rating Depression Scale; SF-36, Short-Form 36 Health Survey questionnaire; STAI, State–Trait Anxiety Inventory; WHO-5-J, Japanese version of the WHO-Five Well-Being Index.

The WHO-5-J total score was significantly correlated with age, the number of major complications, and the total scores on the SDS, the STAI, both the state and trait scales, and each subscale of the SF-36. No significant correlations were found between the WHO-5-J total score and educational level, duration of diabetes, FBS, HbA1c, BMI, or the total score on the MMSE.

External discriminatory validity

Table 4 shows the characteristics of the 65 diabetic patients who were interviewed by psychiatrists in order to assess whether they had a current major or minor depressive episode according to the DSM-IV criteria. Seven patients were diagnosed to have a current major depressive episode, while three patients were diagnosed to have a current minor depressive episode. In accordance with our expectations, the patients with current major or minor depressive episodes had a lower mean score on the WHO-5-J as well as higher mean scores on the SDS and the STAI (both the state

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Table 4. Description of the 65 diabetic patients who were interviewed for psychiatric diagnosis of a major depressive episode

	DE (–)	DE (+)	*P*
n	55	10	
Age (years)	53.9 ± 10.4	49.7 ± 14.0	0.39
Sex (Female, %)	47.3	60.0	0.51
Educational level (years)	19.8 ± 3.2	18.9 ± 2.2	0.29
Type of diabetes (Type 1%)	16.4	20.0	0.67
Use of insulin	50.9	50.0	1.00
Duration of diabetes (years)	9.9 ± 10.0	5.8 ± 7.5	0.15
FBS (mg/dL)	146.1 ± 38.5	179.0 ± 118.3	0.10
HbA1c (%)	6.8 ± 1.2	6.8 ± 2.1	0.95
BMI (g/cm^2)	23.4 ± 3.5	24.6 ± 4.3	0.40
Major complication	34.6	50.0	0.48
SDS score	37.8 ± 9.3	51.2 ± 6.1	0.00
STAI, state	37.1 ± 9.9	48.9 ± 6.2	0.00
STAI, trait	39.5 ± 10.6	57.4 ± 9.3	0.00
MMSE	28.2 ± 2.0	28.7 ± 1.5	0.41
SF-36 subscale			
Physical functioning	82.0 ± 21.4	71.5 ± 24.5	0.23
Social functioning	84.7 ± 21.9	56.9 ± 24.3	0.01
Role functioning, physical	79.7 ± 35.0	47.2 ± 47.5	0.08
Role functioning, emotional	83.7 ± 33.7	33.3 ± 44.1	0.01
Mental health	76.0 ± 19.2	39.6 ± 17.7	0.00
Vitality	63.4 ± 24.3	35.0 ± 13.0	0.00
Pain	74.6 ± 25.3	56.3 ± 26.4	0.08
General health perceptions	50.8 ± 21.3	34.6 ± 21.5	0.06
WHO-5-J score	16.7 ± 5.8	6.9 ± 3.5	0.00

BMI, body mass index; DE, major or minor depressive episode; FBS, fasting blood sugar; HbA1c, hemoglobin A1c; MMSE, Mini-Mental State Examination; SDS, Zung's Self-Rating Depression Scale; SF-39, Short-Form 36 Health Survey questionnaire; STAI, State–Trait Anxiety Inventory; WHO-5-J, Japanese version of the World Health Organization-Five Well-Being Index.

Statistical analyses were performed using Student's *t*-test, Wilcoxon *U*-test, or χ^2 test.

and trait scales) and lower mean scores on several subscales of the SF-36 (social functioning, emotional role functioning, mental health, and vitality), than patients without a current depressive episode.

Figure 2 shows the ROC curve for the detection of a current major or minor depressive episode according to the WHO-5-J total score. The AUC was estimated to be 0.92 (95% confidence interval [95%CI], 0.85–0.98), which was significantly different from 0.5 ($P < 0.001$). A cut-off of <13 yielded the best sensitivity/specificity trade-off: sensitivity, 100%; specificity, 78.2%; PPV, 45.5%; and NPV, 100%. When associated with a current major depressive episode alone, similar results were obtained: AUC, 0.90; 95%CI, 0.81–0.98; $P < 0.001$; sensitivity, 100%; specificity, 74.1%; PPV, 31.8%; and NPV, 100%.

DISCUSSION

The present report is the first study to evaluate the reliability and validity of the WHO-5 in an Asian region. Similar to the original version, evaluated in Europe,[8–10,12,13] the WHO-5-J was found to have adequate reliability and validity for Japanese diabetic patients.

In line with the findings of previous studies,[12,13] the scale showed a significant correlation with different indicators of health-related variables including depression (SDS), anxiety (STAI), and subjective quality of life (SF-36). It should also be noted that the WHO-5-J score significantly decreased as the number of major complications increased. Recent studies have indicated that depression has an adverse effect on glycemic control, thus increasing the risk of major diabetic complications, and thereby leading to further reductions in the quality of life among diabetic patients.[2,31] We have reported elsewhere that the presence or absence of major diabetic complications, particularly those of neuropathy, is significantly associated with depression after controlling for potential confounding factors (S. Yoshida *et. al.*, unpub. data). Therefore, the WHO-5-J might be sensitive to decreased subjective well-being in

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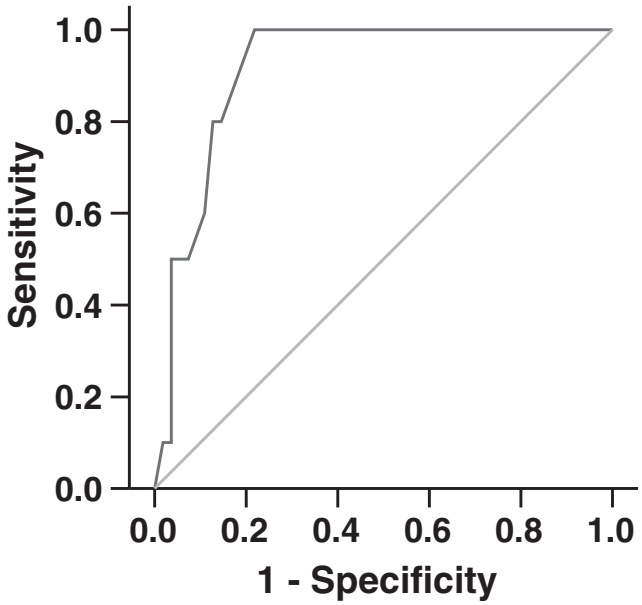

Figure 2. Receiver operating characteristics curve for the Japanese version of the World Health Organization-Five Well–Being Index in association with a current depressive episode as diagnosed according to DSM-IV criteria. The area under the curve was estimated at 0.92 (95% confidential interval: 0.85–0.98), which was significantly different from 0.5 ($P < 0.001$).

patients with major diabetic complications who are prone to develop depression and thus demonstrate a reduction in the quality of life.

However, no significant correlation was observed between the WHO-5-J and cognitive function. The present subjects are comparatively younger and have a higher cognitive functioning than those of a previous study that showed the WHO-5 score to significantly decrease as the MMSE score decreased in a sample of 254 elderly from the general population.[12] This might yield a ceiling effect and conceal the relationship between the cognitive function and subjective well-being. In contrast, the scores on the WHO-5-J significantly decreased as age decreased. In the present study, a decreased age was significantly associated with increases in both state and trait anxiety (state, $r = -0.22$, $P = 0.013$; trait, $r = -0.25$, $P = 0.005$). Younger patients with diabetes might be more likely to feel anxiety regarding an image of his or her future than older patients, and such anxiety might be reflected by the WHO-5-J.

The results of an ROC analysis, in addition to those of comparisons of WHO-5-J scores between the patients with and without a current depressive episode, indicate that the WHO-5-J has a sufficient discriminatory validity as a screening tool for the detection of a current depressive episode. A standard cut-off point of <13 (WHO)[32] had an excellent sensitivity/specificity trade-off. Sensitivity of 100% means that all subjects with depressive episodes were detected by this cut-off criteria (NPV, 100%). However, the specificity of 78% indicates that a considerable number of positive screening subjects had no current depressive episodes (PPV, 45%). Therefore, as Henkel *et al*. suggested,[9,10] this scale might be recommended for use as the first-step screening tool followed by the second-step screening tool such as the Major Depression Inventory to confirm depressive episodes.

The present study had several limitations. First, our sample population may not have been adequately representative of diabetic patients within primary care settings. Because the study population had relatively good glycemic control, the prevalence of depressive episodes in diabetic patients within primary care might have been underestimated. Second, the sample size was relatively small and only 65 patients underwent a diagnostic interview by psychiatrists. To generalize the findings more appropriately, it is necessary to conduct a collaborative multi-institutional study in a larger sample. Third, discriminatory validity for the detection of psychiatric disorders other than depression was not examined in the present study, although it is likely that such psychiatric disorders would influence both the subjective well-being and quality of care of diabetic patients. However, it is evident that depression is highly prevalent and it also has a significantly adverse effect on diabetes. The present study indicates that the WHO-5-J might therefore be a potentially useful screening modality for detecting existing, but unrecognized depression in diabetic patients.

CONCLUSIONS

The WHO-5-J was found to have sufficient reliability and validity as a brief well-being scale. This scale might be a useful instrument for the detection of current major or minor depressive episodes in diabetic patients. A cut-off point of <13 might be recommended for use in the screening of depression.

ACKNOWLEDGMENTS

The authors are grateful to Professor P. Allerup and Mr O. Aaskoven for their valuable advice regarding the statistical analysis, to Professor I. Sora for his close cooperation with research, and to Ms M. Kubota and Ms M. Hino for their valuable assistance. This study was supported, in part, by a Grant-in-Aid for Scientific Research from the Japanese Ministry of Health, Wel-

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fare, and Labor and by a Grant-in-Aid for Scientific Research from the Japan Society for the Promotion of Science (No. 17591194).

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