

Health-Related Quality of Life in Outpatients of a Psychosomatic Medicine Clinic: A Pilot Survey in Japan

Tomoaki KIMURA^{*,**} and Junichi NAKAMURA^{***}

^{*}*Department of Psychiatry, Tokai University School of Medicine*
^{**}*MOA Health Science Foundation*
^{***}*MOA Nakamura Clinic*

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The objective of this study is to clarify the difference of health-related quality of life (HRQoL) profiles by disease category with the SF-36 questionnaires, and to examine the possibility of application for a longitudinal study. A number of subjects was 536, specifically 127 men and 409 women. For all of the eight domains, Cronbach's alpha exceeded 0.7. Categories in which all of the domains were approximately equal to the national standard included hypertension, neck and shoulders syndrome, diabetes, hyperlipidemia and cardiac disease. Bodily pain was especially lower in gastrointestinal disorder, spondylopathy and hemopathy. Patients with mental disorder had lower scores in all domains. Categories in which 5-7 of the eight domains had lower scores included arthropathy, asthma, chronic hepatitis, autonomic imbalance, 'ovariopathy and hysteropathy' and chronic rheumatism. No significant change was found between the first and second scores in hypertension as a representative of the high HRQoL categories. In mental disorder as a representative of the low HRQoL categories, however, five of the eight domains increased significantly. We concluded that a target disease should be chosen among subjects with low HRQoL scores before an intervention to assess its effectiveness. Or subjects with high HRQoL scores can be examined to determine whether they keep the same level of HRQoL.

Key words : Quality of life, SF-36 questionnaires, Psychosomatic medicine, Chronic disease

INTRODUCTION

In recent years, health-related quality of life (HRQoL) has received well-deserved attention especially in medical outcome research. The word of HRQoL has been defined as a subset of the overall concept of quality of life [18]. HRQoL is directly associated with patients' subjective health status, daily living functions and severity of disease.

The author has conducted a number of researches related to HRQoL in preventive medicine to reveal the association between lifestyle and HRQoL in healthy subjects [7, 8] and the effectiveness of a health promotion program [9]. These revealed that HRQoL

scores are widely distributed and strongly affected by various factors.

Doctors of psychosomatic medicine treat not only patients with mental problems but also those with chronic diseases, in whom perfect recovery from diseases are hardly observed. If improvements are seen in HRQoL, interventions are meaningful. We could perform a sharp measurement with a disease-specific instrument for an individual disease, but must make assessments with a generic scale for various kinds of diseases. A large number of studies focusing on a specific disease have been conducted all over the world. For example, an epidemiological study of hypertension and HRQoL was carried out in

Sweden [1]. HRQoL in patients with chronic hepatitis C was investigated in Mexico [5]. In Japan, the SF-36 scores in diabetes patients were accumulated for discussion in utility values [13]. Few studies, however, were conducted to compare patients' HRQoL by disease. If HRQoL scores for patients with a specific disease are comparatively high before an intervention, it may be difficult to assess whether further improvement can be achieved through an intervention for the patients.

The objective of this study is to clarify the difference of HRQoL profiles by disease category with a generic instrument and to examine the possibility of application for a longitudinal study.

METHODS

Subjects were outpatients in a psychosomatic medicine clinic at Wakayama, a city south of Osaka, Japan. This clinic has introduced some therapies such as art therapy and dietary intervention, based on a patient-centered strategy.

Data for this study were collected from July 2001 to January 2003. The outpatients were asked to participate in this survey at the reception counter. A total of 557 subjects who agreed to participate completed the SF-36 questionnaires, Japanese version 1.20. When the participants visited the clinic again after more than one month, they completed the SF-36 for a second time to survey changes with time.

A medical doctor (one of the authors) who is a physician and specialist in primary health care classified the subjects into categories of disease such as hypertension, cardiac disease, diabetes and mental disorder.

The SF-36 is not an age or disease specific measure of health status, but generic one, and consists of eight domains: physical functioning (PF); role physical (RP); bodily pain (BP); general health perception (GH); vitality (VT); social functioning (SF); role emotional (RE); and mental health (MH). The SF-36 had been developed by Ware *et al.* in the United States mainly to assess medical outcomes of chronic diseases from the standpoint of patients [21]. It has also been widely used in many countries such as the United Kingdom [2], the Netherlands [6], Switzerland [14], France [10], Spain [16], and China [11, 17]. In Japan, this measure

has been translated, and its validity and reliability have been verified [3]. First, the domain scores were calculated as scale data of 0-100. Second, these data were adjusted to deviation scores of mean 50, based on the Japanese standard scores, according to the SF-36 manual [4]. Moreover, deviation scores were calculated by gender and age group to control these confounding factors.

Statistical analysis

Subjects less than 16 years of age or with acute symptoms were deleted from the sample. Means of the SF-36 scores in the whole group of subjects were calculated and compared with the Japanese standard. To examine internal consistency, Cronbach's alpha coefficients were calculated by domain. Correlations between the domains also were measured with Pearson's coefficients. Using the scores controlled for gender and age group, the SF-36 profiles were compared among the categories of disease which consisted of more than 10 cases. Changes between the first time and the second time in the SF-36 scores were non-parametrically analyzed with the Wilcoxon T-test. The category of hypertension was selected as a representative of the high HRQoL categories. And the category of 'mental disorder' was selected as a representative of the low HRQoL categories. Statistical analyses were conducted using SPSS for Windows, version 11.0 [19]. Statistical significance was set at $p < 0.05$.

RESULTS

The number of subjects was 536, including 127 men and 409 women, and the mean age was 55.95 (± 16.15 SD, range 16-87). Table 1 shows the distribution of age groups by gender. The majority of the participants were women over 50 years of age. Means of the SF-36 scores in the whole group of subjects were shown in Fig. 1. All of the scores were less than 50 (range: 42.5-46.2), which means that the HRQoL of the subjects were worse than the national standard. For all of the eight domains, Cronbach's alpha exceeded 0.7 (range 0.71-0.89). Pearson's correlation coefficients between domains were distributed broadly from 0.29 to 0.77 (Table 2).

The SF-36 profiles by disease category were shown in Fig. 2a (more than 20 cases) and 2b (more than 10 cases). Categories in

Table 1 Number of the subjects by age group and gender.

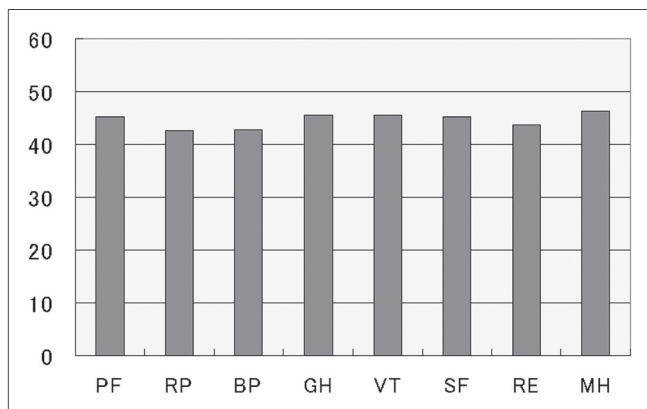
Age group	< 30	< 40	< 50	< 60	< 70	70 =<	Total
All subjects	41	59	66	124	125	121	536
Male	13	23	14	29	27	21	127
Female	28	36	52	95	98	100	409

Table 2 Internal consistency of the domains of SF-36 and correlation between the domains.

	Internal consistency ^a	Correlation for T-score ^b						
		PF	RP	BP	GH	VT	SF	RE
PF	0.89							
RP	0.87	0.52						
BP	0.74	0.43	0.49					
GH	0.81	0.29	0.38	0.33				
VT	0.79	0.33	0.52	0.44	0.63			
SF	0.71	0.34	0.49	0.38	0.42	0.53		
RE	0.87	0.42	0.73	0.40	0.41	0.55	0.52	
MH	0.83	0.29	0.46	0.37	0.57	0.77	0.56	0.56

^a Internal consistency is shown by Cronbach's alpha.

^b Correlation is shown by Pearson's correlation coefficient.

**Fig. 1** Means of the domains of SF-36 in all subjects.

which all of the subscales were approximately equal to the national standard included 'gastrointestinal disorder,' hypertension, 'neck and shoulders syndrome,' diabetes, hyperlipidemia and 'cardiac disease.' PF and BP were lower than the national standard in spondylopathy. In arthropathy, lower scores were noted, especially PF and BP. Patients with 'mental disorder' had lower scores in

all subscales. Categories in which 6-7 of the 8 domains had lower scores included asthma, 'chronic hepatitis,' 'autonomic imbalance,' 'ovariopathy and hysteropathy,' 'chronic rheumatism' and thyroopathy.

Comparisons between the first time and the second time were shown in Fig. 3 (hypertension) and Fig. 4 (mental disorder). Hypertension was chosen as a representative

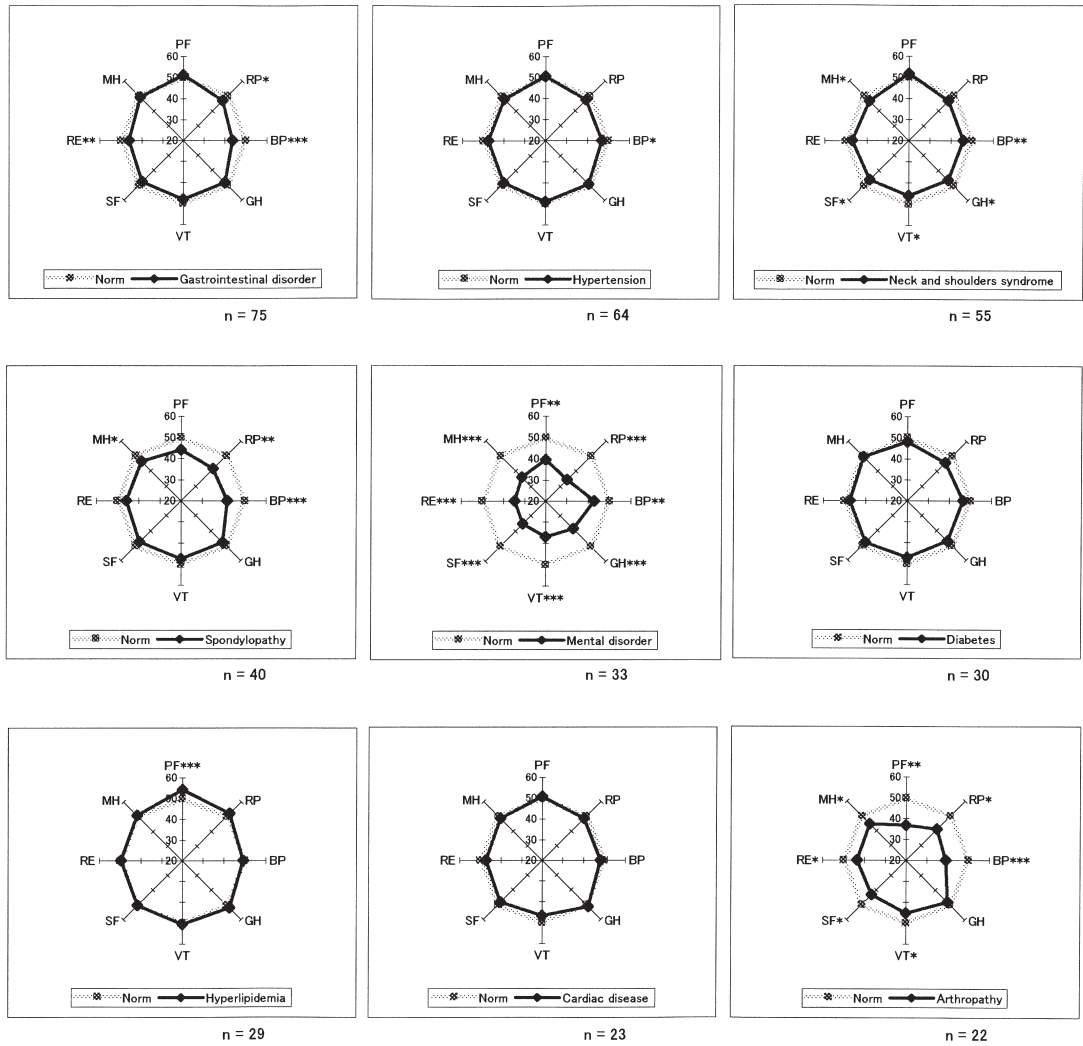


Fig. 2a The SF-36 profiles by disease category (more than 20 cases).
 *** $p < 0.001$; ** $p < 0.01$; * $p < 0.05$

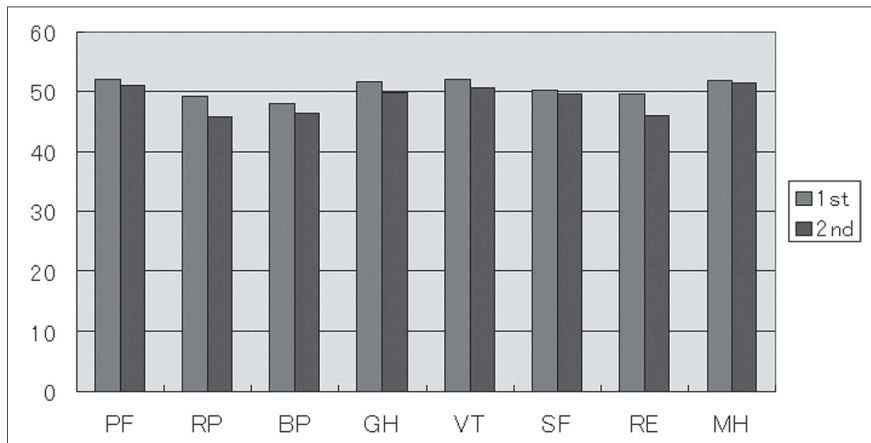


Fig. 3 Change of the SF-36 profiles between 1st time and 2nd time for the subjects with hypertension (n=32, mean interval: 6.0 months).

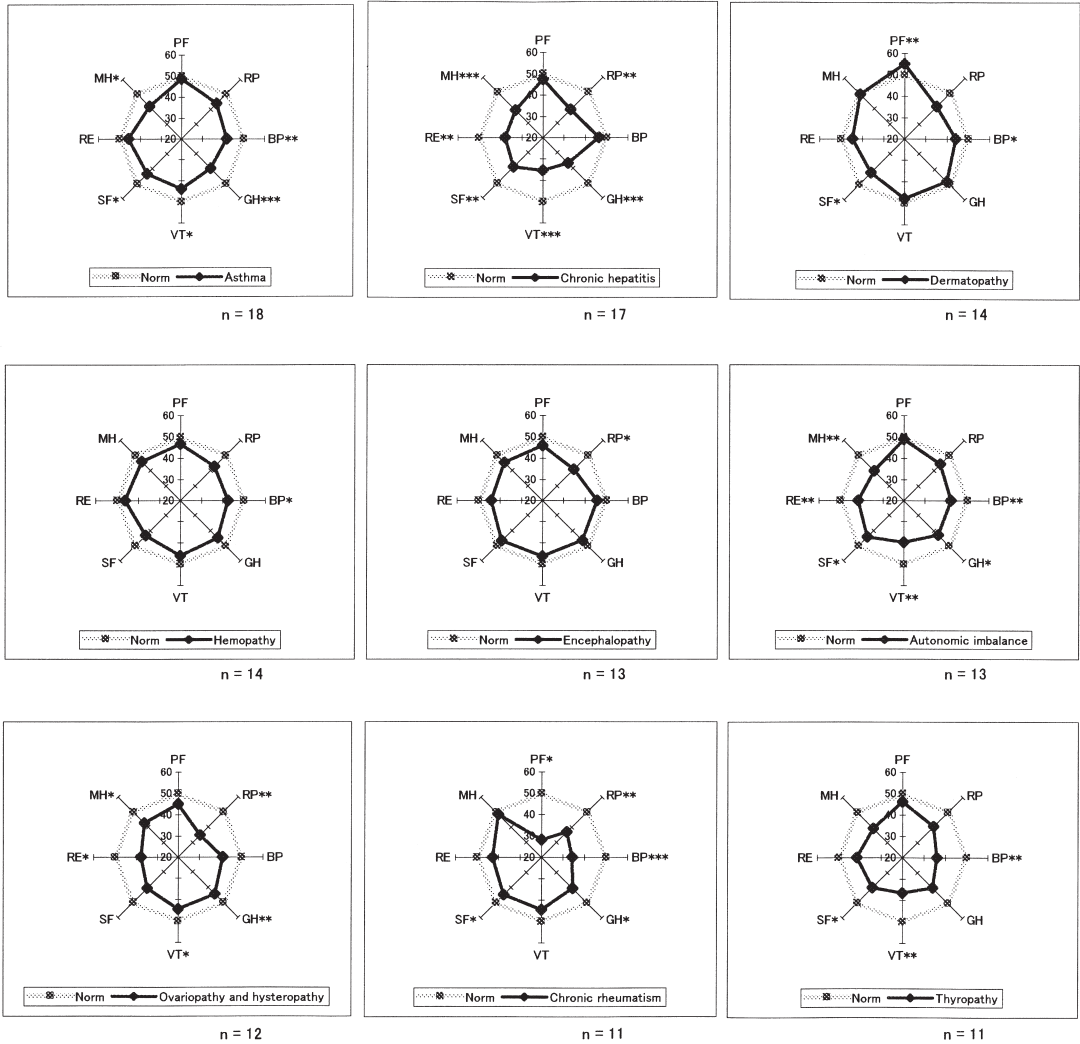


Fig. 2b The SF-36 profiles by disease category (less than 20 cases and more than 10 cases).
 *** $p < 0.001$; ** $p < 0.01$; * $p < 0.05$

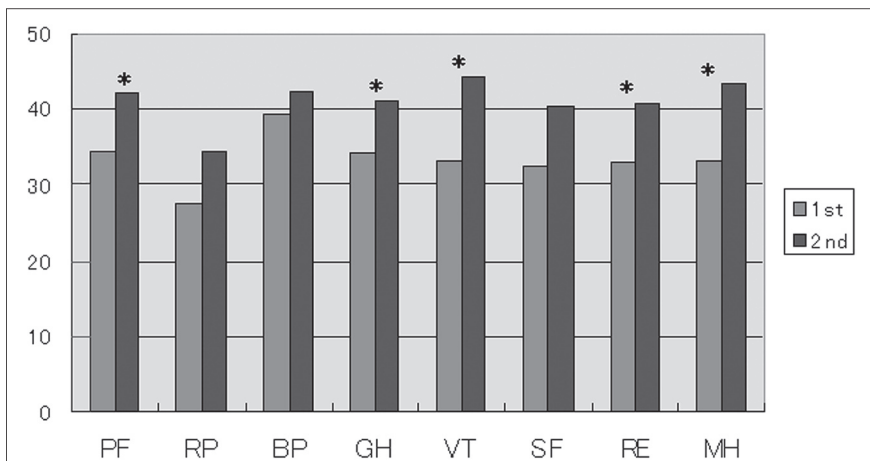


Fig. 4 Change of the SF-36 profiles between 1st time and 2nd time for the subjects with mental disorder ($n=16$, mean interval: 5.0 months).
 * $p < 0.05$

of the categories with better SF-36 scores. For comparison, 'mental disorder' was chosen as a representative of the categories with lower scores. No significant change was found in hypertension at an average interval of six months. In 'mental disorder,' however, 5 of the 8 domains, including PF, GH, VT, RE and MH, increased significantly at an average interval of five months.

DISCUSSION

HRQoL was measured for the outpatients in a psychosomatic medicine clinic and compared among disease categories. This study reveals the followings:

- (1) HRQoL profiles were different among disease categories.
- (2) In those subjects suffering from hypertension, HRQoL scores were maintained approximately equal to the national standard.
- (3) In the subjects of mental disorder markedly lower than the national standard, HRQoL scores were increased.

One of the limitations of this study was that these results were not generic and representative of the population as they were based upon patients in a small clinic. Another limitation was that subjects who made the first or second visit to the clinic were mixed with those who received follow-up treatment. This issue is common with a cross-sectional survey. The third limitation was that effects of interventions in a clinic could not be clearly explained because control subjects did not participate in this study.

Notwithstanding these limitations, knowledge and information obtained by this study were considered beneficial in designing a research setting and protocol. Out patients with some kinds of chronic diseases maintained HRQoL scores equal to the national standard, a result which did not correspond to the manual of SF-36 [20] and previous studies. For example, hypertension patients had lower scores in the SF-36 profiles in the Swedish population [1]. This clear discrepancy partly explains effects of interventions or treatments in the psychosomatic medicine clinic. A randomized control trial must be conducted to prove the effects clearly, although it may be difficult to perform in a research setting like this. Patients with mental disorders had lower scores in all domains of the SF-36 profiles, which corresponded to

the previous study on patients with schizophrenia and those with depression [15]. The subjects in our study were in a mixture of schizophrenia, depression and other mental diseases. It was considered that low HRQoL scores were common among various mental diseases.

These results from the longitudinal survey in subjects with hypertension and mental disorder suggested that the effects of interventions might be assessed through HRQoL measurement. Recently, a response shift has been pointed out, which means that a patient's view point and value in life may change between before and after an intervention [12]. Further researches need to be conducted for discussion about this new essential issue.

A regression effect also must be considered in a longitudinal setting. Usually, it is more possible that higher scores than an average will be reduced and lower scores will be increased. Especially, when subgroups are created through cutting off at a certain score, results from a comparison among the subgroups need to be interpreted carefully and strictly.

CONCLUSIONS

Estimation of HRQoL is beneficial for comparisons among categories and with the national standard, and changes over a certain interval of time. For a longitudinal study, a target disease should be chosen among subjects with low HRQoL scores before an intervention to assess its effectiveness. Or subjects with high HRQoL scores can be examined to determine whether they can maintain the same level of HRQoL.

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